Inclusive health: Medtech innovations for the early detection of cancer in India

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Abstract

This interdisciplinary study focuses on understanding the advances in conceptualising inclusive health innovations in low-resource healthcare settings. To this end, this research responds to two main gaps. First, an empirical gap exists to conceptualise inclusiveness in high-technology health innovations in low-resource healthcare settings. Second, no theoretical framework enables studying technical change in the health sector by linking unmet needs with industrial and health systems. In this research, I propose a novel Inclusive Health Innovation (IHI) framework, integrating and extending the sectoral system of innovation approach (Malerba & Mani, 2009) and the qualitative heuristics of the institutional triad of healthcare (Srinivas, 2012). This research employs the IHI framework to conceptualise inclusive innovations using cases of Medtech innovations for the early detection of cancer offered by startups in India. It identifies and investigates the actors and factors influencing various stages of the innovation process, including development, diffusion, and adoption. This research uses qualitative methods, comprising both primary and secondary data, for a landscape study and four case studies of point-of-care MedTech innovations for early detection of breast, oral, and cervical cancer in India. The research finds that MedTech innovations are driving inclusiveness in the early detection of cancer, both in process and outcomes, in low-resource healthcare settings. The analysis reveals a strong alignment of STI policy with industrial and health policies in the form of a robust MedTech ecosystem to support the development of these innovations. As regards diffusion, this thesis pinpoints that startup firms choose various business models, partnerships, and stakeholder interactions to create new markets and generate demand for the early detection of cancer. These are 'pocket wins' in increasing the availability of locally relevant solutions for cancer screening and early diagnosis. The last-mile adoption of these innovations in the healthcare delivery system hinges upon stronger policy alignment and regulatory changes in the health and industrial sector. The thesis contributes a novel theoretical framework and original analysis of rich empirical case studies. The thesis further contributes to observable characteristics of inclusive health innovations in the early detection of cancer in India. The research findings are relevant for designing targeted policy instruments for (i) cancer screening and early diagnosis using high-technology solutions in low-resource healthcare settings, (ii) digital infrastructure and regulations to support the adoption of innovations in the public healthcare system and (iii) data privacy and security for Medtech based on AI and ML.

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As I pen acknowledgement of the unwavering support I have received, I take a moment to reflect on my PhD journey. In addition to being an intellectually stimulating process, PhD in the pandemic has been emotional and self-reflecting. They say, 'it takes a village to raise a child', this thesis is as special for me, so are the numerous people I am grateful towards – it is difficult to name everyone, but I will try. First, I would like to express my gratitude to my supervisors and mentors. I am grateful to Professor Dinar Kale and Dr Aravinda Guntupalli for their guidance and patience in helping me navigate through various phases of research and writing. Their consistent and unconditional support in research and beyond has been essential in driving my motivations. Special thanks to Emeritus Professor David Wield for profound inspiration, and his generous time and patience in mentorship and guidance. I am truly grateful to you all for your valuable inputs and feedback in several drafts, making it possible to finalise this thesis. I am grateful to Professor Smita Srinivas for encouraging me to pursue this PhD, and all our discussions that gave me the confidence of thinking out of the box in research. I thank Dr Geraint Morgan for our discussions on emerging technologies for cancer care.

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List of abbreviations

AB	Ayushman Bharat
ADMI	Association of Diagnostic Manufacturers in India
AI	Artificial Intelligence
AiMED	Association of Indian Medical Device Industry
ASHA	Accredited Social Health Activists
BIS	Bureau of Indian Standards
BRI	Below the Radar Innovation
BoP	Bottom of the pyramid
CDSCO	Central Drugs Standard Control Organisation
CT	Computed Tomography
DBT	Department of Biotechnology
DCA	Drugs and Cosmetics Act
DCR	Drugs and Cosmetics Rules
DL	Deep Learning
DST	Department of Science and Technology
GoI	Government of India
HBCRs	Hospital-based cancer registries
HWCs	Health and Wellness Centres
ICMR	Indian Council of Medical Research
ICRC	Indian Cancer Research Center
IHI	Inclusive Health Innovation
IS	Innovation systems or systems of innovation
ISO	International Organization for Standardization
IVD	In-vitro diagnostics
LIPS	Local Innovation and Production Systems
LMICs	Low- and middle-income countries
MDR	Medical Device Regulations
Medtech	Medical Technology
MeitY	Ministry of Electronics and Information Technology
MoHFW	Ministry of Health and Family Welfare
MRI	Magnetic Resonance Imaging
ML	Machine Learning

NCC	National Cancer Grid
NCCP	National Cancer Control Programme
NCD	Non-communicable diseases
NCRP	National Cancer Registry Programme
NHM	National Health Mission
NHP	National Health Policy
NIS	National Innovation Systems
NPCDCS	National Program for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke
NPPA	National Pharmaceutical Pricing Authority
PBCR	Population-based cancer registries
PMJAY	Pradhan Mantri Jan Arogya Yojana
RIS	Regional Innovation Systems
RSBY	Rashtriya Swasthya Bima Yojana
OECD	Organisation for Economic Co-operation and Development
SDGs	Sustainable Development Goals
SII	Scarcity Induced Innovation
SSI	Sectoral Systems of Innovation
STI	Science, Technology, and Innovation
STIP	Science, Technology, and Innovation policy
TMH	Tata Memorial Hospital
TIS	Technology Innovation Systems
TPS	Technology Policy Statement
UK	United Kingdom
UKRI	UK Research and Innovation
USA	United States of America
WHO	World Health Organization

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Chapter 1: Introduction

1.1. Research focus

In this thesis, I examine advances in the conceptualisation of inclusive Medtech innovations for early detection of cancer. Specifically, I study how policies can be used as an effective tool to influence the development, diffusion, and adoption of innovations for the early detection of cancer in low-resource settings. In resource-constrained settings, the value of innovation derives from technological advance and how it resolves the health sector's challenges vis-a-vis existing health technologies. To this end, this thesis defines inclusive innovations as problem-solving innovations that address the unmet needs in the early detection of breast, cervical, and oral cancer in India and the critical gaps in the healthcare delivery system.

This introductory chapter has five sections. In Section 1.2, I provide the contextual background and rationale of this thesis. In the next section, I elaborate on the gaps in the literature and theory and present the research questions. In Section 1.4, I outline the novel Inclusive Health Innovation framework proposed in this thesis. I also explain the concomitant research methodology adopted in this study. Using qualitative research methods, and both primary and secondary data, I present a comprehensive landscape study of early detection modalities of breast, cervical, and oral cancer in India and in-depth cases of point-of-care (PoC) MedTech innovations for the early detection of breast, cervical, and oral cancer emerging in the Indian context. In Section 1.5, I present the key findings. In the last section, I present the thesis structure along with a research question-wise navigation of the chapters.

1.2. Setting the context

In recent years, the rising burden of non-communicable diseases (NCDs) has resulted in tremendous loss of life and raised critical concerns for the sustainability of global health systems. To give some perspective, in 2019, 42 million people died from NCDs, which is 74.37 per cent of global mortality (56.5 million) (GBD, 2019). What is of even more concern is the increasing premature mortality (i.e., deaths between ages 30 and 70 years) from cardiovascular diseases, cancer, diabetes, and chronic respiratory diseases. Notably, while the overall burden of NCDs has increased, cancer has emerged as one of the leading causes of death and premature mortality in high-income and low-and middle-income countries (LMICs) (GBD 2019, IARC 2020). As per recent data, 3 out of 10 premature deaths due to NCDs are attributed to cancer (Bray et a., 2021; IARC, 2020). The focus

on premature mortality due to NCDs has gained more traction in recent years because the Sustainable Development Goal 3.4 suggests reducing it by one-third by 2030. While it's a global concern, LMICs bear a disproportionately higher burden, as 85 per cent of premature mortality due to NCDs occur in these countries. Moreover, despite a lower cancer incidence, LMICs have a much higher mortality rate than high-income countries (Globocan, 2020; GBD, 2019). This 'cancer paradox' is attributed to resource constraints present in LMICs that hinder the early detection of cancers. As a result, around 70 per cent of cancer patients are diagnosed at advanced stages when treatment is either too expensive to continue or ineffective (IARC 2020).

This research focuses on India. India presents a challenging and paradoxical landscape in which a strong healthcare industry co-exists, with a large section of the population bearing a triple burden of diseases and inadequate access to affordable healthcare.

In terms of cancer, in a population of over 1.3 billion people, India has the second highest mortality due to cancer (851,678) and the third highest estimated new cancer cases (1.32 million) in the world (IARC, 2022). While 'India' is one country, there are substantial inter-state variations within India (see figure 1.1). In fact, mortality figures in some Indian states are comparable with those of some entire countries. Each Indian state is in a different stage of epidemiological transition. There is substantial heterogeneity in the state-level incidence rate and health loss due to different types of cancers (see Appendix A.1 – A.3).

Moreover, 'Health' is a state-subject in India as per the Constitution of India. This means that whilst national policies provide an overarching framework for the country, states have their own health policies and the prerogative of implementing health-related schemes including cancer control programmes and regulatory oversight. For this reason, there are differences in healthcare service and delivery across the states which impact health outcomes. This is why the published data could be the tip of the iceberg, underrepresenting the real situation due to poor diagnoses of poor people, especially those living in rural areas with a lack of access to health care.

Figure 1.1: Age-standardised death rates (per 100,000) of cancer in India, 2019
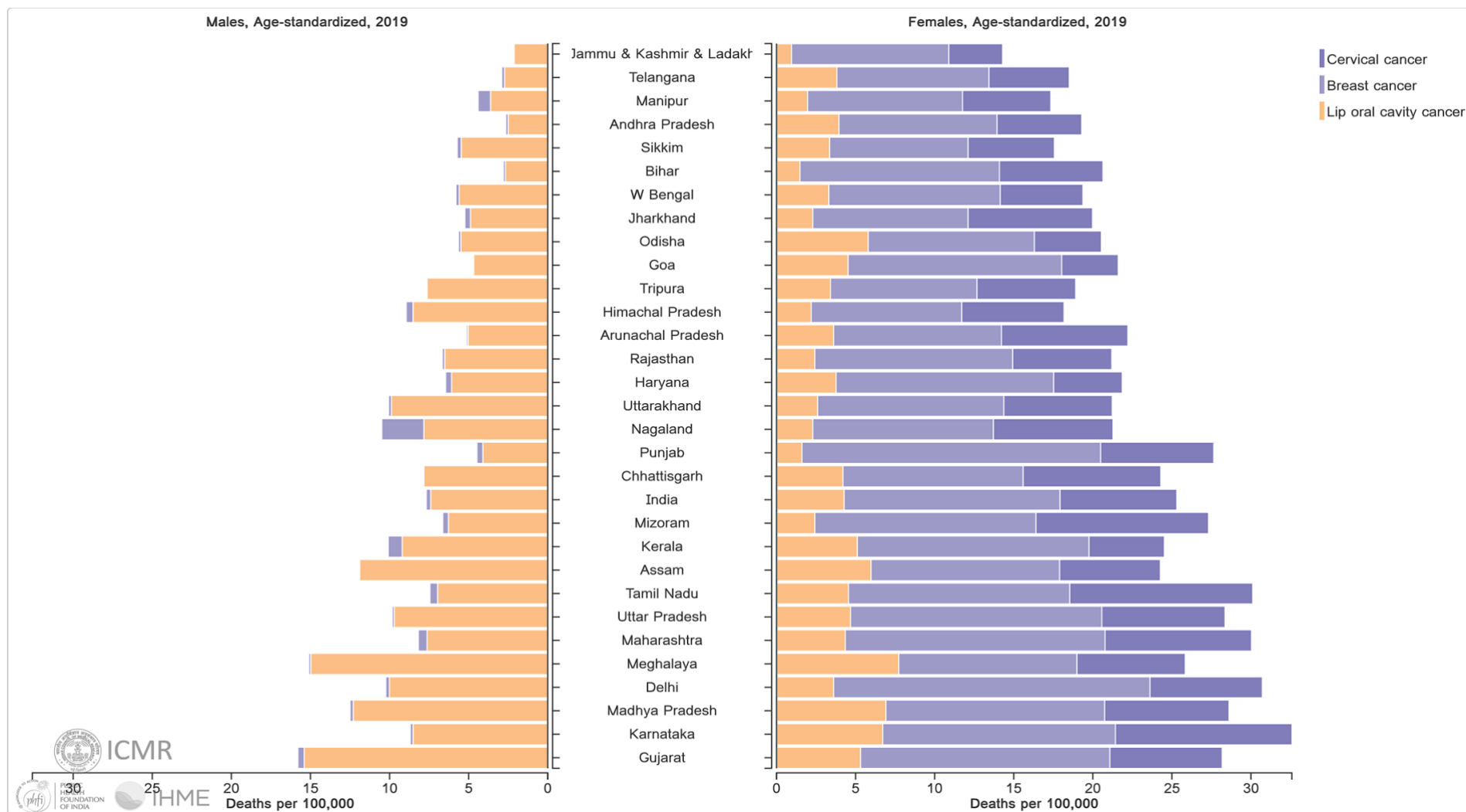
Source: GBD Compare India, 2019, IHME

Breast, cervical and oral cancers constitute the leading causes of incidence and mortality in India between 1990 and 2019 (GBD India Compare, 2019). The broad trends at the country level present a compelling need for early detection measures:

(1) Breast cancer: The age-standardised incidence rate of breast cancer in India has increased between 1990 to 2019 (Mehrotra & Yadav, 2022). A huge cause of concern is a low 5-survival rate of only 66 per cent compared to over 90 per cent in high-income countries. Evidence suggests that high mortality trends could be because 60-70 per cent of breast cancer cases are reported at an advanced stage of illness when prognosis and survival rate significantly worsen (Singh et al., 2015). While the evidence suggests that screening in asymptomatic women and early diagnosis in symptomatic women can potentially reduce the burden of breast malignancies, the ground-level reality is far from ideal in the Indian states. Recent data from the National Family Health Survey of India (NFHS-5) reflect alarmingly low levels of breast screenings throughout the country (Subba, 2021).

(2) Cervical cancer: The age-standardised incidence rate for cervical cancer declined in India between 1990 to 2019, with varying levels in different states. Albeit it remains the most common and the leading cause of mortality in women (GBD, 2019). Evidence suggests that early detection can result in a better prognosis and survival rate. For instance, a recent study estimated the 5-year survival rates of cervical cancer patients in India and reported survival rates as 83.5 per cent (for Stage I), 80.6 per cent (Stage II), 66 per cent (Stage III), and 37.1 per cent (for Stage IV) (Balasubramaniam et al., 2021). The later the stage, the higher the chance of involvement of either node/site, or poorer the survival rates (ibid). The data suggest that very few women have undergone cervical cancer screening in India (Subba, 2021). Despite several national and global awareness campaigns, there is a general lack of awareness among women to go for pap smears and regular screening (Dahiya et al., 2019). Moreover, Human papillomavirus (HPV) infection is one of the major risk factors for cervical cancer in India (ibid). However, there is a general lack of awareness that human papillomavirus can infect anybody, not only through sexual contact but also by other means. Recently, some strides in prevention have been expected with the development of the first local quadrivalent HPV vaccine in India (PIB, 2022).

(3) Oral Cancer: As regards oral cancer, the age-standardised incidence rate of lip and oral cavity cancer has shown an increasing trend in India from 1990 to 2018. It is the leading cause of mortality in males (GBD, 2019; Bray et al., 2018; Mathur et al., 2020). The 5-year survival

rate varies across Indian states,[1] depending upon the location, exposure to the risk factors, stage of cancer, awareness, and access to health care (Lohia et al., 2019; Thavarool et al., 2019; Mohan et al., 2020). Late and delayed diagnosis is one of the primary causes of high health (high morbidity and mortality) as well as economic costs to several patients. In India, 60-80 percent of oral cancer cases are diagnosed at stages III and IV, in contrast to around 40 percent in most developed countries which have better healthcare access (Coelho, 2012; Mohan et al., 2020).

Several studies also confirm timely availability and access to affordable early detection modalities can prevent premature deaths and triage access to treatment (see for instance, WHO, 2017; IARC, 2020). With a goal of reducing cancer incidence and mortality, cancer control policies consist of primary and secondary prophylaxes, which means prevention of disease and control of its spread. Primary prophylaxis includes avoiding exposure to known carcinogenic agents and enhancement of host-defensive mechanisms, for instance, through vaccination, modifying lifestyle and chemoprevention (Kato and Asaka, 2012). Secondary prophylaxis consists of screening and treatment for an early stage of cancer (ibid). In planning cancer control strategies, the WHO suggests that policymakers can focus on either one of two pathways for early detection, namely, pre-cancer screening and early diagnosis of cancer (see figure 1.2). While through screening, asymptomatic cancers or pre-cancerous lesions can be identified in the target population without symptoms, early diagnosis identifies symptomatic cancer cases at the initial stages (WHO, 2017).

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[1] Indian states including Meghalaya, Gujarat, Madhya Pradesh, and Assam have the highest Disability Adjusted Life Years rate due to lip and oral cavity cancer in India (GBD 2019).

Figure 1.2: Understanding early detection (screening and early diagnosis)
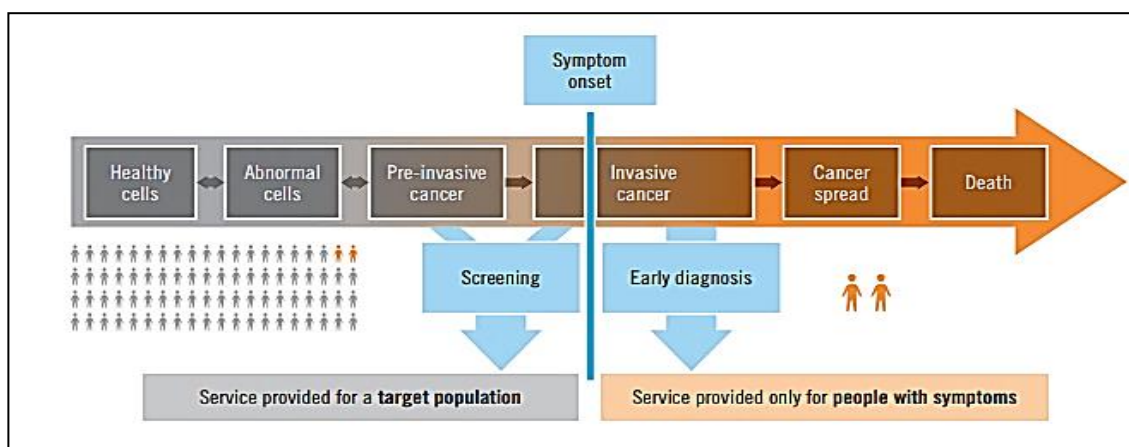
Source: World Health Organization (2017).

In countries with robust health systems, survival rates of several cancers are improving due to accessible early detection and quality tertiary treatment (ibid). However, as highlighted above, 5-year survival rates are poor as the resources for cancer prevention, diagnosis, and treatment are severely limited in India. Prolonged institutional gaps and non-aligned health and industrial policies pose a significant barrier to accessing health technologies for cancer (Srinivas, 2012; Mackintosh et al., 2018; Ganju et al., 2020). Such gaps are detrimental to coherent public health needs and the concomitant development of early detection modalities, making cancer a 'wicked problem' for health and industrial systems (for instance, Chaudhuri, 2007; Srinivas, 2012).

Therefore, merely stating early detection as a tool for reducing incidences and averting cancer deaths can be a simplistic view of cancer prevention. It requires further analysis of complex issues. For instance, the need for early detection modalities to be responsive to the socioeconomic construct and the implications it has for health inequities. I next elaborate on the health-industry conundrums of cancer because of the lack of health and industrial policies linkages:

(1) Complex aetiology of cancer brings a policymaking enigma.

Cancer presents a complex aetiology, presenting a combination of infectious, behavioural, and metabolic risk factors. Thus, it is often emphasised that cancer is not one disease but a spectrum of several diseases. For instance, even though cancer is an NCD, it could be caused by infections, e.g., Human papillomavirus (HPV) is one of the primary causes of cervical cancers, and H pylori bacterial infection is one the major causes of stomach cancer. This means policy prescriptions focusing on cancer prevention involve multifactorial concerns. On the one hand,

the focus is containing exposure to identified carcinogens or risk factors and strengthening early detection methods. On the other hand, continuous research is carried out to understand several unknown unknowns. For instance, it is hard to comprehend why different types of tumours (cancers) are prevalent in some populations and not others. Why inequalities in risk factor exposure exist? How may technologies identify information on individual susceptibility and novel methods of early diagnosis? (IARC, 2020). In practice, targeted screening and early diagnosis are not antitheses and are used as complementary measures in cancer control strategies. Scholars of health policies suggest that 'only' focussing on screening and early diagnosis methods may not be a pragmatic approach as it assumes two things (a) undiagnosed cancer to be the underlying cause of mortality and (b) the availability of tertiary health care facilities to manage the potential cases (Shah et al., 2019). Therefore, differential access to screening and early diagnosis in different populations needs to be considered. Thus, unknown unknowns and complexity increase as cancers are multifactorial, both in terms of their aetiologies and risk factors. Due to such complexities, early detection remains a policy enigma in the Indian context.

(2) High cost of medicines and treatment

India has gained tremendous specialisation in low-cost generic pharmaceutical manufacturing and is considered the pharmacy of the global south. However, access to cancer medicines remains a challenge. For instance, an analysis by Goldstein et al. (2017) highlights that a 4-weekly dose (mg) of Trastuzumab (a drug used to treat stomach and breast cancer) costs USD 2,761 in India and USD 6,849 in the US. However, Goldstein et al. (2017) used Purchasing Power Parity to convert drug prices to USD and found the cost of the same drug to be USD 12,228 in India, raising serious affordability concerns. Moreover, recent data suggest that only patients in the United States of America, Germany and the United Kingdom have access to more than 40 of the 54 new cancer medicines launched between 2014 and 2018 globally (IQVIA, 2019). In other countries, there are several challenges, including originators not filing for regulatory approval, delays or denials of approval, and manufacturers awaiting the results of reimbursement negotiations prior to launching the drug in the country (ibid).

There is also a lack of affordable access to broader treatment which involves surgery, radiotherapy, or chemotherapy. The treatment and care are usually available to those who can afford huge Out of Pocket (OOP) expenditures (Dhankhar et al., 2021). Public hospitals offer subsidised treatment, but there are long waiting lines, which are detrimental to the prognosis

of cancer. Due to this, a large proportion of the population seeks treatment from private hospitals where the average medical expenditure for one episode is catastrophic in the absence of adequate health insurance coverage (see Figure 1.3). In large parts of India, treatment and care are usually available only to those who can afford huge OOP expenditures, which raises questions on the equality in access to essential and life-saving care.

Figure 1.3: Average medical expenditures for treatment in hospital, per hospitalisation case, cancer vis-a-vis other ailments
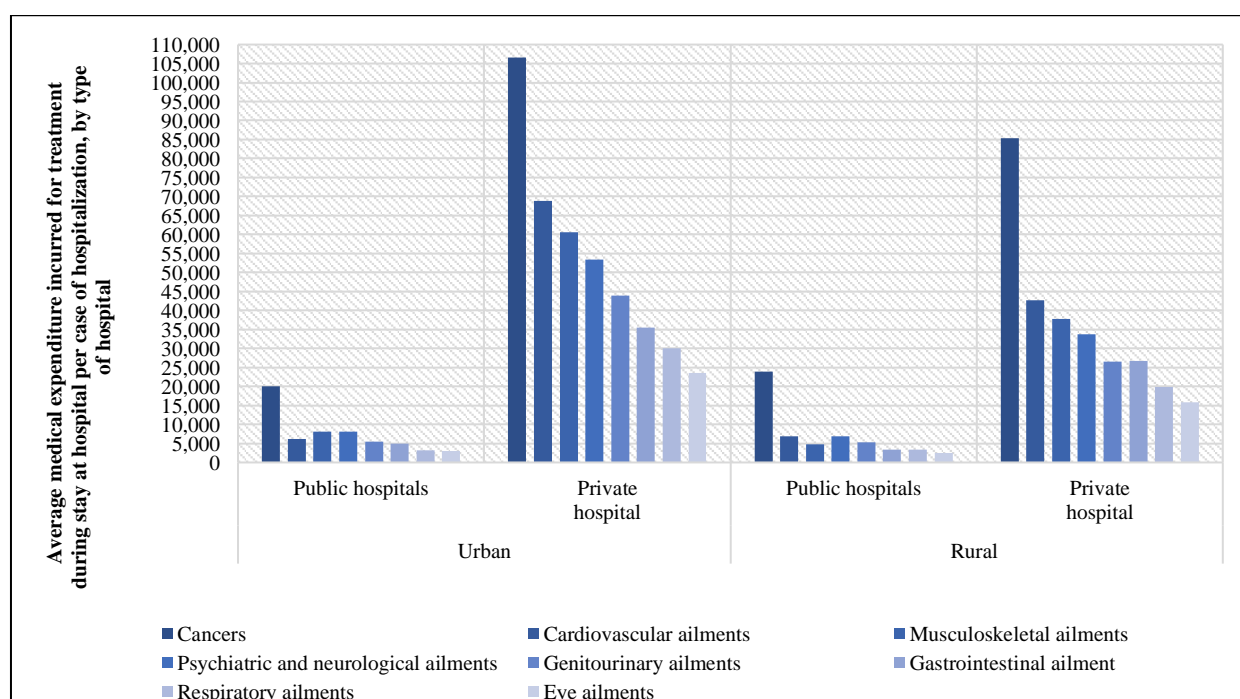
Source: 75th National Sample Survey (Health), June 2017 – July 2018

The increasing cost of cancer treatment has garnered attention because of 'financial toxicity' and emotional distress caused by the catastrophic[2] nature of treatment expenditures borne by patients (Zafar et al., 2013; Tran and Zafar, 2018). These impediments due to low public health spending raise questions about the equality in access to essential and life-saving care. It also depicts how battling cancer for many is between the extremes of life or death, with no middle ground.

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[2] Catastrophic health spending is defined as OOP expenditures exceeding 10% of household total consumption or income. It corresponds to SDG indicator 3.8.2, which states the proportion of population with large household expenditures on health as a share of total household expenditure or income.

(3) Lack of availability of context-specific and efficient early detection modalities

The importance of appropriate medical devices and diagnostics for early detection is paramount in LMICs. As highlighted above, there are several barriers to access to cancer treatment in LMICs resulting in a dual burden of poor diagnosis and low survival rates. Access to appropriate medical devices is crucial in ensuring disease prevention through screening, diagnosis, treatment, and rehabilitation. Even the WHO's Global Action Plan for the Prevention and Control of NCDs stresses ensuring 80 percent availability of the affordable basic technologies which are required to treat major NCDs at both public and private health facilities.

At present, the gold standard early detection modalities for early detection of breast, oral and cervical cancers in India are not conducive to low-resource healthcare settings. These include mammography, pap smear tests, HPV DNA test, etc. These are mostly invasive, not affordable to a large section of the population, and not conducive for low-resource healthcare settings. The gold standard modalities are primarily designed for use in high-income countries with sufficient resources and infrastructure (see Chapter 5 and 6).

Studies suggest that even when modalities are cost-effective, they may not be efficient in low-resource healthcare settings due to factors other than affordability. For example, clinical breast examinations are a widely accepted low-cost modality for screening in Indian settings. However, the effectiveness of successful screening depends upon the expertise of the clinician and healthcare worker (Mehrotra & Yadav, 2022).

Several scholars have recently emphasised the importance of locally available and affordable innovations to balance the global agenda of improving cancer outcomes. Reflecting upon an analogy describing the range of innovations available for cancer, the following quote from Sullivan, Pramesh, and Booth (2017, p328) states:

> 'Cancer 'moonshots' may improve individual outcomes in high-income countries with strong governance, but they will not solve the rising economic and social burden of cancer globally. What we need are 'earthshots' that focus on building infrastructure and delivering affordable, equitable and effective care.'

The discussion on cancer 'moonshots' began in 2016, when the 21st Century Cures Act was signed into law in the USA, authorising a budget of USD 1.8 billion to fund the 'Cancer

Moonshot' over a seven-year period to accelerate cancer research focussing on the discovery, increasing collaboration, and expanding data sharing among the research community.[3] The initiative sparked several debates in the clinical and public health community. Researchers found the 'moonshots' to be technocentric, focusing on high-cost research with 'huge funding and little transnational coordinated planning', excluding crucial dimensions of global cancer control that pose a risk of widening global health inequities (Gyawali et al., 2018). Proposing an alternative 'cancer earthshot', public health researchers in LMICs underscored that 'cancer patients need better care, not just more technology' and 'a technological earthshot that significantly increases adoption of guideline-based care is the first step towards cancer moonshots' (Sullivan et al., 2017; Pramesh et al., 2020).

1.3. Defining policy, and its role in shaping innovation in health

The evolutionary and institutional approach to economic analysis suggests that policies are essential for building an effective innovation system (for instance, Nelson and Winter (1982). Scholars in the field of innovation studies acknowledge the prominent role of institutions and capacities in supporting dynamic health innovation systems that can address local health needs (Srinivas 2012; Chataway et al., 2009; Sutz and Srinivas, 2008). Karo and Kattel (2018, p. 10) emphasize the key role of policies and policy processes in creating the capacity to innovate for complex societal challenges:

> "...from an evolutionary perspective, policy capacities – especially for innovation and other complex public-policy goals where uncertainty is the prevalent condition – a) are located, nurtured, and routinized within organizations; b) are often dispersed into a variety of organizations within a system of organizations (policy domain); and c) evolve through organizational search and selection in the context of specific punctuated feedback environments of these organizations. In terms of Nelson's The Moon and the Ghetto [Nelson, 1977] terminology, policy capacities capture varying ways in which knowledge (expertise, skills, know-how, learning) is operationalized within policy making. Organizational and policy-domain specific differences in one or several of these elements lead to differences in policy capacities between organizations (even in the same policy domain) and policy domains (even in the same country)."

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[3] https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/about (last accessed on 31 March 2023).

Improvement of innovation capacity to develop context specific and problem-solving innovation does not happen in isolation but is a result of a combination of investment for advancement in science and technology, and consistent policy measures that drive industrial and health goals.

In the context of this thesis, policy is defined as institutional bundles in science, technology, and innovation (STI), health and industrial policy that support (or not) sectoral capacity to develop and adopt innovation that respond to unmet needs of early detection of cancer in low resource healthcare settings. The institutional bundles comprise rules and regulations, standards, etc. (Malerba, 2002) as well as various types of public and non-public actors/organisations that co-evolve to shape industrial production, capture unmet needs and demand, and health care delivery system (as also discussed in Srinivas, 2012; Wield et al., 2017). This broader approach to view policy measures influence problem framing and solving which are critical part of policy processes in innovation system.

Previously, several scholars have studied health and industrial policy linkages for pharmaceuticals. These studies suggest that the demand patterns and investment incentives caused by health care and health policies provide an 'implicit' industrial policy for manufacturers of pharmaceuticals and medical products (Mackintosh et al., 2016). For instance, in the case of Japan, Reich (1990) highlights that the success of the pharmaceutical industry was propelled primarily by government regulation and funding of the health sector and manipulation of pharmaceutical pricing. Similarly, for Brazil, studies by Shadlen & Fonseca (2013) elaborate two pathways – demand-driven and regulation-induced – that promoted positive synergies between health and industrial policies in the case of Brazil. They suggest that government interventions in the health sector promote industrial development in the pharmaceutical sector, making health policies more effective.[4] In addition, there is a recent focus on reorienting science, technology, and innovation (STI) policies and their role in shaping innovation efforts that are relevant to health needs (for instance, Walsh et al., 2020). Extensive scholarship has broadened our understanding on policies linkages and technical change that influences industrial structure. A range of studies brings in 'systems approach' linking innovation systems with historical approaches through co-evolution between industry, knowledge organisations and national policy (for instance, Nelson & Winter, 1982; Lundvall, 1992, 2016). These suggest that a conducive environment for innovations evolves not only as a self-organised process between industry and knowledge organisation but

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[4]In the case of Brazil, the weakness in the local pharmaceutical industry that highlighted vulnerabilities in flagship health policies triggered new industrial policy responses. Albeit the existing challenges of Brazilian pharmaceutical industry what has been noteworthy is the backward linkages from health policy to industrial policy.

also due to public policy (Sæther, 2010). This direction is useful in guiding the nature of projects that have the potential to be technologically successful, along with enabling an understanding of user needs for better value creation (Nelson, 1994).

The discord between health and industrial policies results in a paucity of medical devices specifically designed to be sufficiently robust and affordable for use in low-resource settings (WHO, 2010). In the Indian case, such a health-industrial complex of cancer reflects a 'mismatch' between the available early detection modalities and realities of low resource healthcare settings. This thesis shows how the goals of STI, and industrial policy have largely remained disjointed with health policy and local health needs (Chapter 2). The discord between health and industrial policies results in a paucity of devices specifically designed to be sufficiently robust and affordable for use in low-resource settings (WHO, 2010). This mismatch presents serious policy dilemmas as it not only has implications for poverty, inequalities, and social justice but also fiscal implications. Some immediate questions that come to mind include - Does policy focus on building technical capabilities in the medical device sector, making it more export-oriented than catering to domestic health mandates? How can policy instruments be directed so that the capabilities of the medical device sector do not alienate the need for the early detection of cancer?

Historically, scholars suggested that technologies which emerge after time, experimentation, and competition become a 'dominant design' (for instance, insights of Abernathy and Utterback, 1978, based on the automobile industry). In such product innovations, radical innovations follow incremental improvements. However, while it provided a rich understanding of the selection process, there were several debates on the generalisability of empirical evidence, the applicability of 'dominant design' in all industries, and whether it is the best technology. These questions mainly concern sectors and industries where competing technologies are cumulative and needs are diverse in nature. For instance, after one technology gets an early advantage due to both systemic and stochastic factors, the subsequent technologies may not have the resources to advance in the race (Nelson, 1995). The majority of empirical evidence collected to trace this technological evolution was informed by North American, European, and Japanese firms, and underline firms and industrial structure as central to analysis, and in bringing technological innovations (Krugman, 1991; Klepper, 1996). Such empirical evidence explains why R&D process and knowledge production are institutionalised in the industrial processes of industrialised countries. This necessitates an explicit conceptual understanding of science and technology

investments in economic development and concomitant learning and innovation in industrialising countries (Srinivas, 2021).

Over the years, the increasing number of research institutions and universities have led to an array of institutions co-evolving with and shaping Medtech modalities in India. This change broadened the role of other actors, not just private firms, in the co-evolution of technology or industry-specific institutions. There is a need to capture the interactions among actors and institutions at the national, regional, and sectoral levels to inform institutional aspects of planning and policy (ibid). This will also address ways to scale up emerging technological skills in entrepreneurs and small and medium enterprises in India for more locally relevant technologies (Kale et al., 2013, Bianchi et al., 2017).

In recent years, some signs of policy convergence have led to coherent emergence of knowledge and technologies, actors, and networks (see Chapter 2). This capacity has led to development of context specific innovation development that aim to address unmet needs. Such signs of inclusiveness are seen in the emerging trajectory of innovation in the medical technology (MedTech) sector in India. There is an increase in MedTech innovations by Indian start-up firms for the early detection of cancer. These innovations lie between *cancer moonshot*s and *earthshots* by mainstreaming signs of inclusiveness using high technology. In particular, the application of advanced computing technologies, artificial intelligence (AI), and machine learning (ML), to develop MedTech innovation for the early detection of cancer in low resource healthcare settings. This provides an excellent opportunity to understand (a) what institutional bundles led to this development? (b) evolving meaning of inclusiveness in these MedTech innovations.

Several scholars in innovation studies highlight that inclusive innovation may be one way of engaging with complex questions and challenges like early detection of cancer (for instance, Mazumdar-Shaw 2018, Gras et al., 2019). One view is that 'inclusive' element of health innovation focuses on fostering the development and implementation of new ideas. These ideas aspire to create opportunities that enhance the socioeconomic well-being of all, particularly for the poor and marginalised section of society (George et al., 2012). There are several conceptualisations in the literature. For instance, bottom of pyramid innovations (e.g., Prahalad, 2005), pro-poor innovations (e.g., Ramani et al., 2017), below the radar innovations (e.g., Chataway et al., 2007, Chataway et al., 2014), frugal innovations, scarcity induced innovations (e.g., Srinivas & Sutz, 2008), inclusive innovations (e.g., Foster & Heeks, 2013), social innovations (e.g. Kale et al., 2013). However, each typology has its assumptions. The thesis also

delves into the inclusiveness typologies that fit closest to emerging MedTech innovations for the early detection of cancer in India.

1.4. Stating the gaps and research questions

I found two sets of gaps in the literature. First, there is an empirical gap to conceptualise inclusiveness in high-technology health innovations in and for low-resource settings. The existing literature lacks evidence on the application of knowledge and technologies to develop context-specific high technology innovation that are designed to address local health challenges of low-resource health settings. Second, there is a lack of theoretical frameworks that enable studying technical change in the health sector with a lens of inclusiveness. Primarily understanding the role of institutional bundles guiding this change.

In this regard, I investigate the main research question: To what extent have STI, health, and industrial policies aligned to facilitate the development and adoption of inclusive innovations for the early detection of cancer care in India? and the following sub-research questions:

(i)   How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings of India?

(ii)   What are the key actors and factors that influence the development, diffusion, and adoption of MedTech conducive to the local health system, and in what way do they interact with each other to address the early detection of cancer in India?

(iii) How do these factors influence the development of inclusive MedTech innovations for the early detection of cancer in India?

(iv)   How are such inclusive MedTech innovations mainstreamed into health systems for their 'last mile' diffusion in India?

1.5. Theoretical framework and research methodology

This section provides an overview of the theoretical and methodological underpinnings of this research.

1.5.1. Theoretical framework

I propose a novel theoretical framework, the 2X3 Inclusive Health Innovation (IHI) framework, which combines and extends two evolutionary theoretical frameworks. First, the sectoral system of innovation (SSI) and production for developing countries (Malerba and Mani, 2009). The broad pillars of the SSI approach link knowledge and technologies, actors and networks, and a set of institutions. I found these broad pillars of the SSI framework to be useful in understanding the technical change in the MedTech sector in India. However, it is not sufficient to understand the variety of institutions in the real-world required for technological capabilities to innovate, mainly in an Indian context (elaborated in Chapter 3). To bridge this gap, I combined SSI with qualitative heuristic of the institutional triad of healthcare (Srinivas, 2012). I use heuristics because they go beyond the traditional boundaries of conceptual frameworks and offer a dynamic approach to study complex problems. The IHI framework exemplifies the role of institutional bundles in driving (1) the creation of new markets through industrial production addressing unmet needs; (2) compatibility of these innovations with healthcare delivery systems, and (3) the role of demand generation. It provides a bottom-up approach to link unmet needs with the industrial production of innovations for early detection of cancer in low-resource health care settings (see Chapter 3 and 4 for further details).

1.5.2. Research methodology

In terms of research design, this study uses a multiple case study research design which is the preferred research strategy when researching an under-researched topic (Yin, 2017). It comprises a qualitative data collection methodology for an in-depth investigation of inclusive MedTech innovations for the early detection of cancer within its real-world context. This study uses qualitative research methods comprising archival and policy document reviews, online-structured research interviews, and a range of secondary data sources.

The data collection plan of the study was impacted by a change in original project focus from breath analysers[5] for stomach cancer to identifying case studies for oral, breast, and cervical cancer. The breath analyser case study could not be included because of delays and challenges in the funding to roll out the project. The challenges further exacerbated due to COVID-19.

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[5]See
https://www.open.ac.uk/about/employment/sites/www.open.ac.about.employment/files/Job%20Related%20Information%2011756.pdf (last accessed on 21 January 2023).

Secondly, face to face data collection was not possible because of safety and travel restrictions during the pandemic in both UK and India. The directive from UKRI and the university advised researchers to revise the projects' scope to mitigate COVID related challenges. Therefore, after additional literature review towards the end of the first year of the research project, I expanded the research focus to innovations for the early detection of breast, cervical, and oral cancers.

In phase one of data collection, I reviewed archival data and documents, and conducted online semi-structured interviews with various interest stakeholders, including policymakers, heads of key industry associations, venture capitalists, and incubators. This facilitated deeper insights into the landscape of MedTech innovations for cancer in India. I further corroborated the data using non-traditional secondary sources, including podcasts, Twitter space, Instagram live, online conferences and webinar participation. These data in the first phase helped identify four cases of MedTech innovations offered by start-up firms, for the early detection of cancer in India: Thermalytix, OralScan, CerviScan, and CervAstra (see figure 1.4). The cases present similarities and differences in the innovation process in the same selection environment. I identified these cases based on the following broad criteria. First, all cases offer diversity in early detection modalities of three cancer types, with one on breast cancer, one on oral cancer, and two on cervical cancer. There are two cases of cervical cancer, however, they approach separate challenges in the prevailing cervical cancer screening in India. Second, all cases are the point of care and non-invasive modalities for early detection of cancer. Third, all cases identify unmet needs of the early detection of cancer in low-resource healthcare settings. Fourth, all cases apply advanced computing technologies such as artificial intelligence and machine learning to address unmet needs and gaps in the health care delivery system (details are discussed in Chapter 5).

The second phase of primary data collection involved online semi-structured interviews with the lead innovators of case studies through online semi-structured interviews, online conferences, and workshops. The data from innovators were triangulated by interviews with clinical research scientists, biomedical engineers, and incubators.

Figure 1.4: Four cases of PoC MedTech innovations for early detection of breast, cervical, and oral cancer
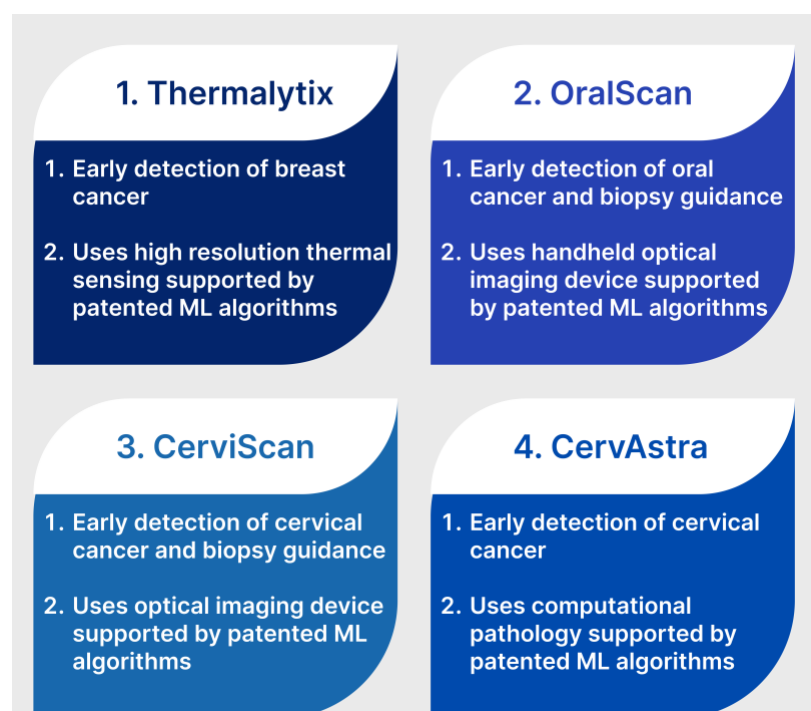
Source: Author's depiction of case studies.

In a departure from firm-level analysis, this thesis uses PoC Medtech innovations for early cancer detection as the unit of analysis. The primary aim in doing so is to capture the various nuances of understanding unmet needs and inclusions by understanding their development, diffusion, and adoption process. Further, analytical techniques, including thematic codes based on the IHI framework, are used for analysing empirical evidence. Both pattern matching and coding strategies were used to understand the role of health, science and technology, industrial policies, and related institutions in shaping inclusive innovations for early cancer detection in the Indian MedTech sector.

1.6. Key findings

This research conceptualises inclusiveness in both process and outcomes of MedTech innovations, building on the ladder of inclusiveness from Heeks (2014), for the early detection of cancer in low-resource settings. Employing the novel IHI framework and 4 empirical case studies, the thesis finds that the primary influence driving the development, diffusion, and adoption of these innovations is the alignment of STI, industrial, and health policies. The analysis shows that

the degree of this alignment varies in the innovation process. It is stronger for the development vis-à-vis diffusion and adoption of such inclusive innovations. Specifically, institutions guiding STI policies have incorporated both health and industrial goals to channel innovations addressing the India-specific challenges of the early detection of cancer. For instance, policies and schemes from the Ministry of Science and Technology support early-stage funding and incubation and support innovation ideas that aim to address unmet medical need. However, the last-mile adoption of these innovations is a slower process. A major reason for this variation in alignment is the slower evolution of demand generating institutions than the supply-side institutions in the health system which is demonstrated using the institutional triad of the IHI framework. The efforts of start-up firms in the form of innovative business models, partnerships with government and non-government partners, and stakeholder engagement has been instrumental in generating new markets and demand.

Using both primary and secondary data sources, this research bridges the existing gaps in linking unmet needs with industrial and health systems and contributes original theoretical and empirical insights.

1.7.Structure of the thesis

The thesis structure, as presented in Table 1.1, provides a snapshot of how the thesis unfolds around each research question. It also reflects the inter-connected nature of the chapters.

Table 1.1: Structure of the thesis according to research questions

	Sub-research questions	Chapters
1	How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings?	Chapters 3, 5, 6, and 7
2	What are the key actors and factors that influence the development, diffusion, and adoption of MedTech conducive to a local health system, and in what way do they interact with each other to address the early detection of cancer?	Chapters 2, 5, 6, 7
3	How do these factors influence the development of inclusive MedTech innovations for the early detection of cancer in India?	Chapters 6 and 7

	Sub-research questions	Chapters
4	How are such inclusive MedTech innovations mainstreamed into health systems for their 'last mile' diffusion in India?	Chapters 6 and 7
	Bringing together the insights on the research questions, thesis contributions, limitations, and future research	Chapter 8

Chapter 2 traces the evolution of cancer control policies for early detection of cancer in India. In parallel, it analyses the evolution of the MedTech sector that has emerged as a significant part of the larger medical device sector and health care delivery system in India in recent years. It then compares two timelines to understand linkages between STI, health, and industrial policies with the availability of (or not) locally relevant modalities for the early detection of cancer in India.

Chapter 3 situates the thesis in literature in two main parts. Part A reviews various conceptualisations of inclusiveness in the literature and their assumptions. Part B reviews the frameworks that enable understanding of actors and factors in the development, diffusion, and adoption of health innovations. The chapter identifies key gaps in Part A and B and sets the research questions.

Chapter 4 proposes the novel IHI framework and presents the research methodology that operationalises the research aims and objectives by explaining the research design, and data collection sources and methods.

Chapter 5 engages with RQs 1 and 2, with an extensive landscape of modalities of early detection for oral, breast and cercal cancer in India, using a 2x2 matrix.

Chapter 6 provides answers to RQs 3 and 4 with four in-depth cases of PoC MedTech innovations facilitating early detection of breast, cervical, and oral cancer.

Chapter 7 presents case analysis by focussing on the 'how' questions RQs 3 and 4. It has 3 main parts. Part A analyses the conceptualisation of inclusiveness in cases of PoC MedTech innovations for the early detection of cancer in low-resource settings. Part B analyses key actors and factors influencing the development of these innovations. Part C analyses actors and factors influencing the diffusion and adoption of these innovations.

Chapter 8 is the conclusion chapter of the thesis, bringing together the research questions, research methods, findings, originality, and contributions. In doing so, it shows that inclusiveness in innovation is integral to addressing challenges of the early detection of cancer in low-resource settings.

Chapter 2 - Evolution of policies for early detection of cancer health care delivery in India

2.1. Introduction

In this chapter, I present the background of the thesis by tracing over 75 years of co-evolution of policy environment shaping (a) the early detection of cancer in India (b) the concomitant MedTech sector in India. The extant literature on the early detection of cancer focuses on epidemiological or health policy perspective, not industrial development (Rajaraman et al., 2015). On the other hand, studies on the medical device sector in India seldom discuss health challenges and broader health system perspectives: for instance, trade trends and diffusion of medical devices and diagnostics (Mahal & Karan, 2009; Mahal et al., 2006), enablers and barriers to the development of medical devices (Rane & Kirkire, 2016; Jarosławski & Saberwal, 2013), medical device regulations and their impact (Manu & Anand, 2022; Gomez et. al, 2020; Kale, 2019) and analysing weak development of local medical device sector vis-à-vis the evolutionary trajectories of other sub-sectors of the health sector (Srinivas & Kale, 2022; Kale & Wield, 2018). To understand the crucial role of policy over time and access to inclusive medical innovations for the early detection of cancer, it is pertinent to thoroughly review both the literature and policy strands.

I present the co-evolution in three sections. In Section 2.2, I discuss four phases of cancer control policies for the early detection of cancer and India's health care delivery system. It highlights different phases; mapping how early detection became a part of cancer control policies in India. In Section 2.3, I analyse the role of STI, health and industrial policy in shaping the evolution of the Medtech sector in India within the larger medical device sector. It focuses on the co-evolution of unmet clinical needs, industrial production of innovative medical devices and diagnostics, and healthcare delivery in the Indian context. In Section 2.4, I bring together the first two sections pointing to the disconnects (and signs of convergence) in phases shaping the policies for early cancer detection and the availability of the medical device in health care delivery. In doing so, it presents the first research question of the thesis.

2.2. Evolution of early detection in cancer policies

This section charts the evolution of policies for the early detection of cancer and health care delivery in India. Table 2.1 shows a four-fold periodisation characterised by key milestones in policies for the early detection of cancer in India. The first phase was shaped by the formation of Tata Memorial Hospitals in 1941, it became the anchor point of cancer control policies in India.

In the second phase, a more structured focus on early detection emerged with the formation of dedicated institutions, starting with Cancer Control Programme in 1975. The third phase is characterised by the launch of the National Program for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) by the government in 2010. NPCDCS provided an impetus to policy implementation of the early detection programmes of oral, breast, and cervical cancer in India. The fourth phase characterises increased multistakeholder collaboration in cancer control with the release of Choosing Wisely India list. In the aftermath of COVID-19 pandemic, marks an increased focus on strengthening early detection using emerging modalities and a new digital ecosystem for healthcare delivery infrastructure.

Table 2.1: Key phases in the evolution of cancer policies for early detection

	Phases	**Key developments**
I	1940s-1974	o Establishment of Tata Memorial Hospital (1941) and the Indian Cancer Research Center (1952). o Some early signs of focus on early detection in five-year developmental plans of the country
II	1975 -2010	o Pap smear (or cervical cytology) was used as a standard of care for testing for cervical cancer in India (the 1970s) o National Cancer Registry Programme (NCRP) was launched under the Indian Council of Medical Research (1982) o Reformed National Cancer Control Programme (NCCP) (1985) o Formation of NRHM (2005) and later NUHM (2013), which institutionalised public health care delivery
III	2010-2017	o National Program for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2010 o Pap smear screenings at the district level o First population-wide screening program for breast, cervical, and oral cancer, but low coverage and demand. (2016)

	Phases	Key developments
IV	2017- present	o National Health Policy (2017), Choosing Wisely India (2017)
		o The emergence of PoC MedTech innovations for early detection
		o Delays in cancer screening and early detection due to pandemic
		o Cancer insurance coverage by Ayushman Bharat and National Cancer Grid for screening
		o New digital ecosystem for cancer screening

Source: Author's periodisation of cancer policies in India

Phase 1: 1940s-1974 – Understanding the cancer burden, establishing key institutions.

The first phase is characterised by the efforts to understand cancer epidemiology in the country and the establishment of key medical and health research institutions that play a critical role in cancer care in India even today.

Establishment of Tata Memorial Hospital and understanding cancer epidemiology

The first tertiary cancer hospital in India, Tata Memorial Hospital (TMH), Bombay (Mumbai), was established in 1941 by the philanthropic Tata Trust. TMH has led to pioneering work on cancer epidemiology and control in India. TMH was then the only dedicated institution to study the diagnosis and treatment of cancer. Vasant Ramji Khanolkar, the first pathologist in India and the director of laboratories in TMH, studied the epidemiology of the disease and highlighted that cancer was common in India even in the 1940s (Pai, 2002). In the initial years, TMH research established the aetiology of common cancers in India, including links between tobacco chewing and oral cancer, and lung cancer and smoking (Badwe & Goel, 2022). The government's attempt to comprehend the cancer burden was aided by the Health Survey and Development Committee, formed in 1946. The Bhore Committee, led by Joseph William Bhore, was the driving force behind the committee and had the support of five advisory committees (GoI, 1946). The Bhore Committee provided extensive recommendations for overhauling healthcare services in India, including insights into cancer, medical devices, and regulatory structures. The report noted that cancer research was underway to determine its relative position amongst the causes of mortality in India. At the same time, Western data showed that cancer required significant public health

intervention (ibid). In 1948, the Indian government recommended transforming the pathology department of TMH into the Indian Cancer Research Center (ICRC) to support cancer research and develop effective cancer control policies under the mentorship of V.R. Khanolkar (Pai, 2002). The following year, the Indian Council of Medical Research (ICMR) was reformed to support cancer research initiatives. The ICRC merged with the Tata Memorial Hospital (TMH) in 1952 to form the Tata Memorial Centre (TMC), India's first comprehensive cancer centre. TMC has played a pivotal role in shaping cancer control policies in India and continues to work towards reducing the cancer burden in the country through research, education, and advocacy.

Some signs of focus on the early detection of cancer and the establishment of critical institutions

Given some initial data on the burden of cancer, cancer control policies gained traction in the five-year plans. The initial plan (1951-1956) stressed the importance of cancer awareness and increased funding for cancer education and research for fundamental research in the laboratories and applied or clinical research in the clinics (GoI, 1951). The second plan focussed more on creating more treatment centres (GoI, 1956).

The initial recognition of the importance of early detection was brought forth by a second Health Survey and Planning Committee. In 1959, the Indian government set up a committee under the chairmanship of Dr A. Lakshamanaswami Mudaliar, Vice Chancellor of Madras University, to review and formulate medical relief and public health. The report (1961) identified inadequate cancer care facilities in India, recognising the 'early signs' of disease in a person and recommended 'a considerable extension of diagnostic facilities will be necessary' and 'cancer in laboratories at secondary health centres and teaching hospitals' (GoI, 1961a; p25). The third five-year plan also reflected the commitment to building facilities for the early diagnosis of cancer and further research in this field (GoI, 1961). This resulted in a better understanding of cancer epidemiology in India. In 1963, the first population-based cancer registry (PBCR) in India was established with funding from the Indian Cancer Society and the National Cancer Institute of the United States. It was a fundamental step to facilitate the continuous availability of data on cancer incidence, it was followed by three satellite registries Pune (1973), Aurangabad (1978), and Ahmedabad and Nagpur (1980) (Sahoo et al., 2018).

In summary, this period marked the establishment of Tata Memorial Hospital, which has played a lasting role in understanding cancer epidemiology and shaping cancer control policies. There were some early signs of the emergence of early detection in cancer control policies.

Phase 2: 1975 – 2010: National Cancer Control Programme, Cancer Registry, and introduction of pap smear in the testing of cervical cancer

In the second phase, the cancer control polices gained momentum with the establishment of key institutional bodies dedicated for cancer control policies, including the National Cancer Control Programme and the National Cancer Registry Programme. However, the first national health policy pointed out inadequate focus on local health needs and challenges in implementing early detection in practice. In terms of healthcare delivery, there were efforts to integrate policy into practice by decentralising health care delivery.

Launch of National Cancer Control programme

The government channelled its focus on tertiary care and launched a Cancer Control Programme (CCP) with focus on building premier cancer hospitals/health care institutes in India in 1975. Under the program, financial assistance (INR 250,000) was provided by the central government to each cancer institution to buy cobalt machines for radiotherapy. In terms of screening, while in terms of clinical practice, a pap smear (or cytology) was available as a standard of care for testing for cervical cancer in India since the 1970s, as such, it was not part of any screening protocol for cervical cancer under a government programme (Srinivasan et al., 2018).

Launch of National Cancer registry programme

In 1982, the National Cancer Registry Programme (NCRP) was launched under the Indian Council of Medical Research (ICMR), to collect data on cancer by undertaking epidemiological studies. It started with establishing three PBCRs at Bangalore, Chennai, and Mumbai and three hospital-based cancer registries (HBCRs) at Chandigarh, Dibrugarh, and Thiruvananthapuram.

While cancer care policies and institutions were focussing on early detection in this phase, early detection in practice was still challenging. The importance of correct diagnosis was highlighted in a retrospective analysis performed on the protocols of 1,000 consecutive adult patients who had autopsies performed between June 1983 and December 1988, and the results were compared with clinical diagnosis (Sarode et al., 1993). The scholars found that cancer was incorrectly diagnosed

in 25.8 percent of cases (ibid). As the incidences and mortality, there was no equipment developed in India for the early detection of cancer (Rajya Sabha, question no. 1504). This lack of connection between policy and practice was captured in first national health policy.

First national health policy highlighting an inadequate focus on local health needs.

In 1983, the first national health policy (NHP) strikingly reflected on the conundrum of how the planning process was not adequately addressing the local health needs and priorities, and socioeconomic conditions:

> 'the existing [health care] situation has been largely engendered by almost wholesale adoption of health manpower development policies and the establishment of curative centres based on the Western models, which are inappropriate and irrelevant to the real needs of our people and the socio-economic conditions obtaining in the country. The hospital-based disease and cure-oriented approach has been at the cost of providing comprehensive primary care services to the entire population.' (MoHFW 1983; pp3)

While after the NHP 1983, there were some positive developments in health outcomes, there were still large gaps in establishing more public health institutions at a decentralised level to address unmet needs of public health services, including cancer. One of the big changes was the transformation of caner control program to include early detection policies and activities.

Revision of Cancer Control Programme to National Cancer Control Programme (NCCP)

The Cancer Control Programme of 1975 was transformed into the NCCP in 1985 to plan, monitor, and evaluate cancer control activities. The NCCP aimed to prevent tobacco-related cancer, address cervical cancer, and enhance treatment facilities on a national level (MoHFW, n.d.). Between 1990-91 and 2000-01, the NCCP was decentralised further to District Cancer Control Programme in selected districts near the medical college hospitals (ibid).

Efforts to enhance decentralised healthcare delivery to strengthen last mile access.

In line with the above decentralisation of cancer control, the National Health Policy of 2002 aimed to improve healthcare accessibility by expanding health financing and restructuring national public health initiatives. These measures focused on decentralised healthcare service delivery, financing, and equity. The policy emphasised upgrading existing healthcare infrastructure, establishing new facilities, and implementing tailor-made government schemes for vulnerable and

socio-economically under-served populations. The policy recognized the importance of private and non-governmental sectors as partners in healthcare delivery. The NHP 2002 also aimed to increase health sector expenditure to 6 percent of GDP, with 2 percent of GDP allocated to public health investment by 2010, to address the underfunded health sector and its adverse impacts. The state governments were also expected to increase their financial commitment to the health sector. NHP 2002 explicitly started equity to be the main measure of its success.

To some extent, post-NHP 2002, the government of India implemented some fundamental institutional changes to improve public health infrastructure and provide accessible, affordable, and high-quality healthcare to rural areas. A primary result was the launch of the National Rural Health Mission (NRHM) in 2005, which decentralised health care delivery in the Indian states with weak public health indicators and infrastructure and was later extended to cover the entire country (MoHFW, 2005). To increase health care affordability, Rashtriya Swasthya Bima Yojana (RSBY), a health insurance scheme by the Union Ministry of Labour with a cover of INR 30000 per family per year, was introduced to ease out-of-pocket expenditures on health. This policy mainly focussed on the poor and marginalised population. Financial assistance was also made available to cancer patients through the Rashtriya Arogya Nidhi (RAN) and the Health Minister's Cancer Patient Fund.

In summary, during this period, some concerted efforts of early detection efforts came in with the launch of the National Cancer Control Programme Launch and the National Cancer registry programme. Additionally, the government introduced several efforts to enhance decentralised healthcare delivery by the government.

Phase 3: 2010-2017 – Formation of NPCDCS, National Cancer Grid, and population-based screening programmes

The third phase is characterised by formation of institutions to strengthen policy implementation of early detection measures, including the National Program for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) and the National Cancer Grid.

Cancer control to be a part of a NPCDCS.

With a focus on controlling breast, cervical, and oral cancers in India, the Government of India (GoI) initiated the National Program for Prevention and Control of Cancers, Diabetes,

Cardiovascular Diseases and Stroke (NPCDCS) was launched in 2010 in 100 districts across 21 states. This programme aims to prevent and control these diseases via education, behavioural and lifestyle changes using multistakeholder participation, and early detection of people with high risk factors. The programme manages these chronic noncommunicable diseases through early detection, treatment, and follow-up by establishing NCD clinics across Indian states. The programme includes provisions for free diagnostic services and drugs for NCD patients attending NCD clinics at the sub-national levels for decentralised care. The GoI approved the 'Tertiary Care for Cancer Scheme' under NPCDCS in the year 2013-14 to establish State Cancer Institutes and Tertiary Care Cancer Centres in different parts of the country.

Formation of National Cancer Grid to ensure uniformity of care.

Despite several cancer control policies, there have been disparities in the implementation of cancer policies across India. Primarily, the National Cancer Grid (NCG) was established in 2012. NCG, funded by the Department of Atomic Energy, Government of India, was established to create uniform standards of cancer care across India and has undertaken several steps, including the development and implementation of evidence-based guidelines (Chopra et al., 2018).

First population-based screening programme

GoI introduced an operational plan for a population-based screening in 2016 and rolled it out in 2017-2018 to control breast, cervical and oral cancer (see Table 2.2) of a target population of age 30-65 years, under the National Health Mission (NHM), as a part of comprehensive primary healthcare.

Table 2.2: Once in 5-years screening for a population between the age of 30-65 years

Type of cancer	Method of screening	Referral (if positive)
Oral	Oral, visual examination	Referred to surgeon/dentist/ENT/specialist/Medical officer at community health centre/district hospital for confirmation and biopsy
Cervical	Visual inspection with acetic acid	Referred to the primary health centre/community health centre/district hospital for further evaluation

Type of cancer	Method of screening	Referral (if positive)
		of pre-cancerous conditions, where a gynaecologist /trained lady medical officer is available.
Breast	Clinical breast examination	Referred to a surgeon at community health centre/district hospital for confirmation using a breast ultrasound followed by a biopsy.

Source: Ministry of Health and Family Welfare, MOHFW (2016), p7.

Under the initiative, frontline health workers, such as Accredited Social Health Activists (ASHA) and Auxiliary Nurse Midwives, are leveraged to carry out screening and generate awareness about NCD risk factors among the population. The key components of the screening include community-based risk assessment, screening, referral, and follow ups.

Low coverage of government screening programme

In 2019, about 215 districts (out of 766 districts in India) have been covered for screening for oral, breast and cervical cancer across the country.[6] However, even though the screening methods are cost-effective, they have limited coverage and depend upon the level of capacity building and training provided to grassroots workers (Mishra et al., 2021). Only 1.2 percent of the population is covered in a population-based cancer screening programme, suggesting the inability of the NCD Clinics as first-line screening for cancer patients (Department-Related Parliamentary Standing Committee On Health And Family Welfare, 2022). The sparse coverage across Indian states is corroborated by a low percentage of people ever undergone screening, which indicates a lack of both demand generation of government screening initiatives and awareness in the population.

In summary, this period was characterised by strengthening the early detection efforts with the formation of NPCDCS, the National Cancer Grid, and population-based screening programmes.

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[6] http://164.100.24.220/loksabhaquestions/annex/171/AU1160.pdf (last accessed on 3 April 2020).

Phase 4: (2017 to present) NHP 2017, Choosing Wisely and focus emerging early detection technologies to detect cancer.

In this phase, NHP 2017 played a critical role in coordinating health and industrial policy goals. Secondly, Choosing Wisely India task force was convened by the National Cancer Grid of India in 2017 to identify and reduce harmful cancer services in India. Thirdly, there is a renewed focus on scaling up cancer screening using new technologies and under Health and Wellness Centres of Ayushman Bharat scheme.

Choosing Wisely India

The healthcare delivery system in India has evolved in fragmented and unregulated manner (Pramesh et al., 2019). To provide more value to cancer care, Choosing Wisely India lists low-value or potentially harmful practices that are often undertaken in cancer care in the Indian context. Such steps, although very recent, offer some semblance to measures that can be used by policymakers in this complex policy domain. It is inspired by the Choosing Wisely initiatives in the USA and Canada. Choosing Wisely India promotes active communication and collaboration among physicians, patients, policymakers, and patient advocacy groups to improve the quality and efficiency of healthcare in India. Two recommendations in the list that are particularly important from the perspective of early detection are (ibid, e220):

> 'Do not deliver care in a high-cost setting when it could be delivered just as effectively in a lower-cost setting'.

> 'Do not order tests to detect recurrent cancer in asymptomatic patients if there is not a realistic expectation that early detection of recurrence can improve survival or quality of life'.

As this list is developed by a multistakeholder and consensus-based manner and is driven by NCG, it has the potential to create alternative models of early detection and care in low-resource health settings. For instance, the 'Choosing Wisely 2022' conference focussed on ways to select more cost-effective and high-value interventions and minimise financial toxicity in LMICs (Akhade et al., 2022). These multistakeholder collaborations have been effective in changing how early detection is being implemented in practice as well.

Two key examples include:

(i) **Making cancer screening a part of the Ayushman Bharat Scheme**

The Ayushman Bharat (AB) scheme was launched in 2018 in response to rising demand for healthcare delivery and out-of-pocket expenditure. It has two main components (a) Health and Wellness Centres (b) Pradhan Mantri Jan Arogya Yojana. The government has now integrated screening for the three common cancers, i.e., oral, breast and cervical, for people over 30 years under Health and Wellness Centres (PIB, 2023). To ensure more people have access to screening, AB-PMJAY, a scheme that provides for secondary and tertiary healthcare financial cover to poor and vulnerable families, has partnered with the National Cancer Grid to provide cancer insurance (NHA, 2021).

(ii) **Emerging digital ecosystem for downstaging cancer**

Two key developments support the new ecosystem for the early detection of cancer. To facilitate evidence-based treatment options for cancer patients throughout India, Tata Memorial Centre (TMC) has developed an AI-based online solution called Navya. Navya offers expert opinions to patients, removing the need to travel long distances to access an expert opinion. In addition, TMC is conducting research studies finding applications of AI and ML in radiology and pathology for scaling up and increasing coverage. These advances depict the increasing role of technology in the early detection and treatment of cancer. A recent initiative of NCG's formation of the Koita Centre for Digital Oncology focuses on integrating digital technologies and tools to improve cancer care. In the words of the director of the TMC:

> 'The Koita Centre for Digital Oncology is a very timely initiative. It will help create an innovation ecosystem across hospitals, healthcare technology companies, academic institutions, and research organizations to address challenges in cancer care. The positive impact of this ecosystem can extend beyond cancer care'. (Press Information Bureau, India)[7]

In this section, I mapped policies for the early detection of cancer in four phases. The first two phases focussed on establishing key institutions for cancer research, treatment, and building an

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[7] https://pib.gov.in/PressReleasePage.aspx?PRID=1854682 (last accessed 31 August 2022).

epidemiology understanding of cancer in India. From the third phase, the early detection of cancer gained some momentum in policymaking. However, policy implementation remained slow. Moreover, there was no focus on developing locally relevant technologies for the early detection of cancer. In the last phase, there are signs of coherence in policy and practice of early detection of cancer. This phase showed convergences in health and industrial goals. The convergence is reflected in (a) policy focus on the implementation of screening programmes, (b) increased development of new modalities for early detection of cancer, (c) creation of a digital ecosystem. In the next section, I analyse the parallel policies and institutional trajectories mapping the evolution of MedTech.

2.3. Evolution of MedTech sub-sector within the Indian medical device sector

This section is divided into five phases characterised by the key policy developments for the medical device sector that led to MedTech innovation. The first phase reflected a phase of no regulation, patchy local manufacturing, and piecemeal policy efforts to promote locally relevant innovations. In phase 2, after the structural changes of the 1990s, there was an increase in imports of high-technology medical devices, but the concomitant absorptive capacity of the healthcare system was inadequate. It also shows that policy and regulation disconnect persisted as in phase 1. Phase 3 was then characterised by some efforts to streamline policies and regulations to shape the medical device sector. Two key changes characterise phase 4, first, the development of a MedTech innovation ecosystem by the Ministry of Science and Technology, Ministry of Chemicals and Fertilizers, Ministry of Commerce and Industry, and Ministry of Electronics and Information Technology channelling an innovation ecosystem to address local challenges. Second, the introduction of medical device regulations. This phase thus shaped the rise of the MedTech sector and innovation by start-up firms. The last phase is characterised as the post-

pandemic phase. In the aftermath of supply chain disruptions due to COVID-19, this phase further highlighted the importance of local manufacturing and local innovation efforts.

Table 2.3: Key phases in evolution of Medtech evolution in India

	Phases	**Key developments**
I	1940s-1990	• Regulations for drugs, not devices. • Local manufacturing remained patchy, unorganised, and lacked long-term planning. • Individual innovation efforts with a lack of policy support • Separate science and technology policy, some alignment in technology and health policy, but no links with industrial policies.
II	1990-2003	• High imports of high-technology medical devices but poor geographic distribution across the country. • The regulation was limited to a few low-technology appliances; policy disconnects.
III	2003-2012	• Science Technology Policy 2003 aligned both science and technology policy. • Mashelkar Committee Report envisaged a complete overhaul in the regulatory domain. • Bombay High Court ordered stronger regulations for medical devices after public health concerns over the usage of unapproved drug-eluting stents at JJ Hospital • Some regulations with complex governance and uncertainty.
IV	2012-2022	• Emerging signs of academic – industry-government collaborations • NHP 2017, for the first-time connected health needs with appropriate medical device. • Introduction of medical device regulations

	Phases	Key developments
		• Swift policies to mitigate the supply chain disruptions and promote local manufacturing, for instance, PLI scheme, MedTech Parks, etc.
V	2022-	• Developments during the COVID-19 pandemic reinstated the need for locally relevant technologies. • Increased awareness of medical devices and diagnostics during the pandemic

Source: Author's periodisation of the medical device sector and MedTech sub-sector in India

Phase 1: 1940s-1990s: The phase of policy disconnects for local health needs, some signs of micro-entrepreneurship.

Early development in the regulatory framework

The decade of the 1940s was important from the perspective of regulatory underpinnings for the import and manufacture, sale, and distribution of drugs in India. The Drugs Act and the rules came into force in 1940 and 1945 respectively. This legislation later became the legal bases for regulating medical devices in India in 2005 (to be discussed in the next phases).

Initial government reports on sluggish local manufacturing

The Bhore committee report (1946) signalled the first mention of local medical device manufacturing in India (GoI, 1946). The report pointed out the development of a 'surgical instruments industry', which was dependent on imported raw materials. In terms of the nature of production, a range of 'medical appliances' were emerging at the time, e.g., surgical dressings, plaster of Paris, artificial limbs, and dental cotton. The Mudaliar Committee Report (1961) made some striking observations on the sluggish manufacturing of medical devices and the lack of local standards (GoI, 1961). This report was one of the first official policy documents to record that the growth in local manufacturing of pharmaceuticals was not observed in the then medical devices:

> 'some progress has been made by the Pharmaceutical industry in many directions, the same is unfortunately not true in the case of the indigenous manufacture of instruments, hospital appliances, laboratory equipment, etc.' (GoI, 1961; p 431)

During this phase, 'medical device' as a nomenclature did not come to the fore. The medical devices were broadly referred to as 'instrument and appliances' comprising instruments, hospital appliances, laboratory equipment, etc. (ibid). The local firms included private firms clustered in Jullundur (Punjab), Bombay, Calcutta, Madras, Lucknow, and Masulipatnam and limited manufacturing and repairing of instruments and appliances by the central and state government of West Bengal and Punjab. However, these signs of manufacturing 'instruments and appliances' were patchy and unorganised and lacked long-term planning and objectives (ibid). The locally manufactured instruments had low acceptance by users in hospitals and laboratories because of a lack of defined specifications, standards, and technical knowledge:

> 'there are no standards, and the products are generally of a quality which compares very poorly with the imported materials and does not find acceptance with the users in the hospitals and laboratories.' (GoI, 1961; p 432)

Therefore, the overall quality of medical devices was poor compared with the imported counterparts. In particular, the absence of standards and specifications was a huge challenge in producing quality equipment and instruments. The Indian Standards Institution had listed specifications for limited items, including glass ampoules, rubber tubing, lint, gauze, bandages, hot water bags, and plaster of Paris. The Technical Development Unit of the Defence Ministry (Kanpur) was the only organisation that had laid down specifications for a broad range of items, including surgical, anaesthesia, dental laboratory and X-ray, appliances, and instruments. Additionally, it had a comprehensive testing and inspecting protocol to check the output from industries located in the region. However, these were for the requirements of medical services in the defence forces and not for civilian needs (GoI, 1961a; p 433). The efforts to collaborate on organising a countrywide set-up were supposed to be initiated between the Ministry of Commerce and Industry, Ministry of Defence and Ministry of Health, but could not find much success. The broad protectionist policies with import restrictions did provide some protection to local manufacturing. The Mudaliar Committee Report also called for a need for India to be 'self-sufficient' in manufacturing surgical instruments, mainly electronic and optical instruments, and appliances.

Individual effort to build locally relevant innovations, albeit lack of policy support

In parallel, some keen interest in building a robust scientific environment was witnessed post-independence, albeit policy efforts were sporadic thereafter. For instance, envisioning to build a

welfare state, the Science Policy Resolution of 1958 laid down the Government of India's commitment to invest in science. As a result of SPR 1958, some large-scale investments were made in several scientific organisations and national laboratories (Udgaonkar, 1970). However, there was much to be done to intertwine such grand scientific policy objectives with the health and clinical needs of the population.

There were some signs of indigenous innovation at the micro level in this phase. One of the first innovations of using technology to address local health needs developed in the late 1960s. Dr Pramod Karan Sethi, an orthopaedic surgeon at Sawai Man Singh Hospital in Jaipur (Rajasthan, India) collaborated with Ram Chandra, a craftsman who taught handicrafts to design foot prosthetics to leprosy patients (Oransky, 2008). This local innovation was ground-breaking as it served the rural population, mainly as the western limbs were expensive, and rigid, and did not allow people the mobility they wanted. After several iterations, the duo developed a more flexible, hinged wooden ankle supported by a vulcanised rubber foot prosthetic that is now popularly known as the Jaipur foot. They also developed a business model leveraging funding from donations, government, and self-earned income and joined *Bhagwan Mahaveer Viklang Sahayata Samiti* (ibid). They then offered free prosthetics and artificial limbs in India and later even globally. However, this remained an individually driven innovation with minimal state support, and other therapy areas like cancer did not witness such design translations to capture unmet clinical needs.

In 1976, in another part of India, the Sree Chitra Tirunal Medical Center was inaugurated, wherein the hospital also had a biomedical department to support medical device development. Due to the combination of medical sciences and technology within a single institutional framework, the center became an 'Institute of National Importance under the Department of Science and Technology by an act of Parliament in 1980. It was renamed Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala. The institute contributed to successful technologies, for instance, they developed low-cost technology for heart valves and transferred it to a local Indian firm to scale up its production. However, such ground-breaking local innovations, interdisciplinary knowledge collaborations between clinicians and technologists/engineers, and further development of supporting institutions addressing local health needs mainly hinged on individual efforts and motivation (Kale and Wield, 2018). The larger policy architecture remained detached from local realities.

First signs of linkage between technology and health policy

In 1983, the Technology Policy Statement stressed the role of technology, mainly the development and absorption of local technology and the adaptation of imported technology to address the national priorities and local needs of citizens (TPS, 1983). In the same year, the first national health policy also concurred with the need for local manufacturing to make affordable medical devices to cope with high cost imported biomedical equipment (NHP, 1983). The NHP 1983 highlighted the extensive use of costly and sophisticated biomedical equipment by practitioners of the western medical system to facilitate diagnosis. Interestingly, even in 1983, the national health policy planned to put an effective mechanism in place to identify essential equipment extensively used at health centres and pathways to promote local manufacturing to make such devices available at affordable prices (NHP 1983).

Despite the critical articulation of the health system challenges and ambitious plans, TPS 1983 and NHP 1983 could not make significant changes in the health sector, which remained underfunded and prone to selective healthcare delivery (Rao, 2017). The majority of the Indian population had limited access to medical devices due to the absence of a robust local industry, and imports of medical devices were subjected to high tariffs, from 40 to 60 per cent (Mahal et al, 2009; James & Jaiswal, 2020). Only life-saving medical devices could be imported duty-free imports.

Absence of adequate regulations and lack of standards for medical devices

In this phase, the Drugs and Cosmetics Act (1945) (DCA) and Drugs and Cosmetics Rules (DCR) only had provisions to regulate pharmaceuticals and not medical devices. Although in 1989, disposable syringes, needles and perfusion sets became the first set of medical devices to be regulated under the DCA, there was a complete regulatory vacuum because of no pre-market approvals. Instead, some provisions existed to prove quality via optional certification in the form of the Indian Standards Institution marking developed by the Bureau of Indian Standards (BIS) under the Ministry of Consumer Affairs, Food and Public Distribution. This option was available for manufacturers of low-tech devices, including medical equipment, thermometers, and weighing instruments. However, the proof of quality was inadequate for high-technology devices because of the limited scope and depth of these standards and procedures, as only two thermometers and x-rays required mandatory certification (Kale, 2019).

In summary, the first phase reflected the laggard growth of the medical device sector. The availability of appropriate and affordable medical devices remained limited due to challenges at a systemic level, including a lack of supportive institutions and regulations. This lack of institutional support impacted the sustainability of sprouts of innovation that emerged briefly, resulting in increased reliance on imports following the structural transformation policies in the next phase. The science and technology policies were separate and not aligned. Nevertheless, there were some signs of coherence in technology policy and health policy in 1983, but no significant results in practice.

Phase 2: 1990-2003: A period of high import of high technology diagnostics, and underutilisation, policy disconnects, and regulatory vacuum.

Tremendous increase in imports post liberalisation

The 1990 economic liberalisation led to changes in the broader policy architecture of India. In the decades following liberalisation, India, and most LMICs, remained largely import-dependent. Most LMICs thus find their presence in global value chains as an end market rather than a production location of medical devices (Horner, 2021).

Studies suggest that imports of diagnostic and therapeutic medical devices continued to increase in the mid-1990s due to increased income, liberalisation, progress in modern medicine, and lack of local production capabilities (Mahal & Kothari, 2009). Several factors, including lack of a regulatory system, inverted duty structure favouring import of finished goods than raw materials or components, availability of low-cost labour, attracted multinational companies (MNCs) to enter and dominate the Indian markets with imported products (Markan and Verma, 2016). On the one hand, economic liberalisation resulted in the lowering of import tariffs; on the other hand, domestic manufacturers were subjected to customs duties on imported raw materials (Kale and Wield, 2019). Therefore, medical device imports were de-licensed, and import tariffs were lowered to 15–30 per cent (Mahal et al., 2009). This meant that finished imported products were cheaper than importing raw materials to produce locally. Therefore, the domestic medical device sector continued manufacturing low-tech devices and basic instrumentation. The demand for high-tech instruments thus was met with imports. The imports primarily comprised MRI, CT scans, ultrasound apparatus, x-ray machines, full-body scanners, and parts and accessories of larger diagnostics (ibid). The import of medical devices such as computed tomography (CT) and magnetic resonance imaging (MRI) apparatus in India increased by 1300 per cent between 1988

and 2008, reflecting the extent of import dependency during this time and the slow growth of exports (ibid). However, this steep increase in imports of medical devices were not in line with domestic health needs. This gap to some extent, was attributed to a lack of local biomedical engineering industry, lack of industry associations, and a collaborative network of research institutes. The absence of such networks, particularly the lack of a dedicated industry association, resulted in lop-sided growth of the medical device sector, that indirectly tilted towards imports.

Lack of uniformity in geographical distribution and utilisation of medical devices

A significant study by Mahal and colleagues (2006) highlights the challenges of uneven geographical distribution and utilisation of this imported medical device resulting in inefficient use and inequality in access. They reported that 63 per cent of MRI facilities were clustered in Bengaluru, Chennai, Delhi, Hyderabad, and Mumbai (ibid), further contributing to the country's health inequalities. They also highlighted challenges due to inefficiencies in public facilities due to the unavailability of trained health professionals to operate diagnostics, poor coordination of procurement and installation processes, and a lack of accountability. First, public facilities faced acute shortages of essential equipment. These scholars studied 150 public hospitals in Andhra Pradesh and observed severe shortfalls of basic equipment. Second, in most facilities across the country, there were serious concerns over the time taken for installation and repairs. Several diagnostics were not fully functional and classified as 'non-useable, idle, or with low utilisation rate' (ibid). Significant time lags were reported between receiving medical diagnostic equipment and actual installation in public health facilities.

Further, upon comparing private and public MRI facilities in Delhi, these authors found that a stand-alone private MRI facility operational for 360 days a year conducted 7,500 scans. In contrast, the public-sector MRI unit in a big public hospital was operational for 300 days per year and only performed 740 scans. This issue of underutilisation has been a grave concern as public hospitals were often the only affordable facilities for the public to access advanced technological devices, mainly for the poor in India (ibid). For instance, the household surveys from 1986–1987 to 1995–1996 reveal a decline in the share of free diagnostic services accessed by outpatients from 25 per cent to 10 per cent (unpublished data Mahal 2005 as cited in Mahal et al., 2006). Private diagnostic facilities could provide the services without delays and cumbersome administrative issues in the public sector. Albeit in the absence of adequate regulatory oversight, a large part of the private sector was prone to unethical practices in producing counterfeit devices and high-cost healthcare delivery.

Hence, while imports increased with liberalisation and globalisation, a prolonged lack of regulatory environment resulted in a significant gap in industrial, and science, and technology policy toward priority health needs. These direct and indirect tools allow governments to stimulate and drive innovation and create a level playing field for local manufacturers, mainly as the sector is prone to information asymmetry. In the absence of adequate institutional support and acute shortage of even the most basic equipment, the absorption, and capabilities to utilise the imports of high-end diagnostics were limited.

Some inclusive innovation efforts lack an ecosystem.

Kale (2013) studied cases of three Indian firms that developed innovations which significantly altered healthcare costs. These include Sree Chitra Tirunal Institute for Medical Sciences and Technology and TTK Healthcare (heart valves), Shushrut-Adler (devices facilitating treatment and rehabilitation in the case of extremity fractures), and Medived (pacemaker). These case studies revealed that, much like the previous phase, innovations were sporadic in the Indian context due to a lack of effective regulation. The focus of domestic production and trade was on relatively less technology-intensive segments like disposables and, only to some extent, on technologically advanced radio diagnostics (Datta et al., 2013). Further, studies also suggest that there was an increase in low-quality device/counterfeits in the absence of regulation, which posed serious public health concerns, tainted the overall reputation of medical devices produced in India, and affected the export competitiveness of genuine Indian manufacturers (Kale et al., 2015). Given constrained government health budgets in India in the 1990s – as public health investment as a percentage of GDP declined from 1.3 per cent in 1990 to 0.9 per cent in 1999 – the burgeoning and unregulated private sector drove the diffusion of medical technology (MoHFW, 2002). To some extent, the private sector increased medical device availability. However, that came with a higher cost, and severely under-resourced public health facilities raised several equity concerns in the country.

In summary, the second phase is characterised by a major increase in imports of high-technology medical devices. However, these imported devices were not uniformly distributed and utilised across the country. There were individual-level efforts for inclusive innovation to some extent, but they were not sustainable because of the lack of an ecosystem.

Phase 3: 2003-2012: Shaping of regulations, institutionalisation of public health care delivery, and emergence of actors and networks to build the ecosystem for Medtech.

Integrated policy focus on science and technology.

For the first time in Indian history, the Science and Technology Policy (STP, 2003) presented a unified approach to strengthen science and technology and cope with the changes in the post-liberalised country. In words of the then President APJ Abdul Kalam in STP 2003 (p1),

> 'we [India] have come a long way since our independence, from mere buyers of technology to those who have made science and technology an important contributor to national development and societal transformation. In a world where the powers are determined by their share of the world's knowledge, reflected by patents, papers and so on, the WTO starts to play a crucial role in economic development. It is important for India to put all her acts together to become a continuous innovator and creator of science and technology intensive products.'

STP 2003 provided a particular emphasis on building national science and technological capabilities and strong international science diplomacy, mainly global south cooperation. It envisaged promoting research and innovation in areas of relevance for the economy and society by productive interaction between private and public science and technology institutions, with priority to sectors including agriculture, water, health, education, industry, energy including renewable energy, communication, and transportation. STP 2003 also pointed out the instrumental role of leveraging technologies such as information technology, biotechnology and materials science and technology to strengthen technology development, evaluation, absorption, and upgradation from concept to utilisation. However, from the standpoint of health research in health policy, the focus was entirely on post-TRIPs (Trade Related aspects of Intellectual Property Rights) availability and affordable access to drugs and vaccines and not on medical devices and diagnostics (NHP, 2002). The discussion of medical devices and diagnostics in the health policy was confined to the discussion on highlighting need for regulating their delivery in the private clinical establishment, ensuring adequate standards by diagnostic centres / medical institutions, and proper conduct of clinical practice and delivery of medical services (ibid).

Despite the enhanced policy focus on developing locally relevant innovations in STP, lack of supportive developments in the regulatory space meant that only high technology devices approved by the country of origin or by the USFDA were allowed to be marketed in India, and there was no defined regulatory process to check the certification or product quality (Kale, 2019).

The lack of domestic regulations made local manufacturers reliant on international regulations and approvals, which increased the cost of product development due to its impact on project completion, and the product launch timelines (ibid).

Health and safety concerns led the initial steps to define regulatory process.

This phase is particularly important because of key changes in regulatory policies. In 2003, a landmark parliamentary committee report, Mashelkar Committee Report, underscored a complete overhaul in the regulatory domain of medicine, vaccine, and medical devices (MoHFW, 2003). The report highlighted that the regulatory infrastructure at both the centre and states level was inadequate to carry the regulatory functions in an effective and efficient manner. It strongly recommended strengthening the existing infrastructure to support an independent and professionally managed Central Drugs Standard Control Organisation (CDSCO) that could be given the status of Central Drug Administration (CDA) under the MoHFW (ibid). Under this framework, medical devices should be clearly defined under section 3 of the DCA, DCR, and in the guidelines for effective, clear, and uniform implementation of regulations. The report acknowledged that 'a device [unlike a drug] does not achieve its principal intended purpose by pharmacological, chemical, immunological, or metabolic means although it may be assisted in its function by such means' (p.63). It therefore recommended strengthening institutional support for implementing regulatory processes for medical devices through a separate Medical Devices Division in the proposed restructured CDA for proper management of approval, certification, quality, and post-marketing surveillance of imported as well as locally made medical devices.

The regulatory uncertainty became crucial when the loophole in regulations posed a severe threat to health and safety. In 2004, the cardiologists at Jamshedjee Jeejeebhoy (JJ) Hospital in Mumbai (Maharashtra) used unapproved drug-eluting stents on 60 high-risk cardiac patients (Marpakwar, 2005). These stents, manufactured by a Netherland-based company, were not approved for use in either market. Although there were no regulations for premarket approvals or registrations of stents at that time, it was necessary for such a device to be either approved by the country of origin or the US FDA. After this incident, the Mumbai High Court ordered the government to set comprehensive rules and standards for the medical device sector (Singh, 2012; Kale, 2019). Finally, in October 2005, the MoHFW declared ten devices to be considered drugs under Section 3 (b) (iv) of the DCA, including cardiac stents, drug eluting stents, catheters, intra-ocular lenses, cannulae, bone cement, heart valves, scalp vein set, orthopaedic implants, and internal prosthetic

replacements. There was some level of regulatory oversight with these ten medical devices (subsequently four more) under the purview of the DCA.

Lack of clarity as drugs and devices are regulated under the same legal bases.

Historically, as the regulation of medical devices has evolved with the precedence of medicine regulations, interlinkages of definitions of drugs and medical devices have been a part of legislative trajectories of many jurisdictions like the United States (for instance, Merrill, 1994). However, regulations were revised to define drugs and devices distinctively in other jurisdictions with the expanding universe of medical devices (ibid). In the case of India, as the drugs and devices are umbilically attached, in some instances, it has led to the imposition of blanket clauses for drugs and devices alike. The devices being treated under the same law as drugs had strong ramifications for the safety and efficacy of medical devices. Moreover, in the absence of supporting guidelines, there was a lack of clarity among stakeholders. To address this issue, in March 2006, MoHFW introduced guidelines for licensing of import and manufacture of these medical devices in the country (CDSCO, 2006). There were still no separate regulations supporting the implementation of pre-market approval, registration, certification, and post-marketing surveillance from the regulatory agency. This concern is exacerbated by inadequate health technology assessments (HTA) and regulatory measures that ensure such products' safety, efficacy, and relevance (Kale, 2019).

To deal with this issue, two government ministries/departments, the Department of Science and Technology (DST) and MoHFW, shared two independent proposals for a comprehensive regulatory framework for medical devices. On the one hand, DST shared the draft Medical Devices Regulation Bill, 2006, to consolidate all legislation concerning medical devices. On the other hand, MoHFW proposed the Drugs and Cosmetics (Amendment) Bill, 2007, in response to Mashelkar Committee Report and called for establishing a CDA covering all regulated healthcare technology products. Rather than remedying the confusion, these two drafts deeply reflected the siloed governance within the health sector.

Due to a lack of clarity for a prolonged period, the medical devices manufactured and imported in India continued to be monitored and regulated in a confusing regulatory structure (Kale, 2019). These bills were referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare for examination and report to address the differences. In its 30th report, the committee made several recommendations, including creating a separate chapter for regulating

medical devices in DCA and expanding the provisions of clinical trials regulations and exports in the bill. Moreover, there was firm opposition from the state governments to the centralised licensing of drugs. The issue was revisited to evolve a mechanism acceptable to all stakeholders (Parliamentary Committee Report, 2013). It was decided that the states would continue to share the responsibility of licensing for the majority of drugs, AYUSH drugs and all cosmetics. Since it required multiple amendments, the legislative department of the Ministry of Law and Justice decided to withdraw the bill and suggested presenting a revised one (ibid).

Impact of regulatory uncertainty on domestic manufacturing and innovation efforts

In terms of local innovation efforts, there were some developments on a micro-scale. However, there were several challenges across product development to scaling up (Frew et al., 2007; Dang & Sharma, 2019). Jarosławski and Saberwal (2013) presented evidence on critical challenges using case studies of six innovative medical device firms that developed products appropriate for use in low-resource settings. Such cases highlight the patchy development of local technical capabilities to absorb, synthesise, and adapt medical devices relevant to the local context (Sampath, 2010). Jarosławski and Saberwal highlighted that each firm took two to three years to develop the products from concept to validation. In product development and diffusion, they reported that the key challenges these firms faced included a lack of funding, relevant human resources to access the market with finished products, and the absence of guidance from regulators and healthcare payers on certain product classes (ibid). To mitigate these challenges, firms independently assessed the needs of healthcare providers in local settings and developed product profiles based on their market- and consumer research. Regarding access to advanced technological knowledge, the firms relied on their links with global academic and industry communities. However, these innovation efforts were difficult to sustain in the Indian market because of a lack of ecosystem support, an underfunded public health system, and a poorly regulated for-profit private market.

Lack of an ecosystem continues to be a challenge.

Historically, in India, and LMICs in general, industrial policies did not make access to medical devices a concern, so firms did not prioritise it. At the same time, at the collective level, it was hard to enforce accountability (WHO, 2011a). In this regard, the rapid diffusion of technology to the local health system went with the development of local production that is not aligned with health priorities. As a result, the medical device sector remained prone to inefficiencies resulting

in inequitable and inappropriate use of medical devices in India, which can be closely associated with high medical expenditure (Mahal & Karan, 2009). Due to these challenges, domestic firms gained specialisation in producing low-cost, high-volume medical devices, mainly in the disposals and consumables segment like syringes and surgicals. They exported more than 60 per cent of their output (WHO, 2017).

Kale and Wield (2019) analysed the challenges of the slow development of the medical device sector in India. They found that the medical device sector lacked 'collaborative actions', which are 'reflective public policy activities to support capability development between myriads of different public and private institutions and organisations along with a wide public to private spectrum' (ibid). These collaborative actions were missing because of a range of factors. First, there were numerous disincentives for local firms and entrepreneurs, given the complex nature of technologies. In particular, there was a lack of a conducive research ecosystem. Dedicated R&D collaborations with research institutes, hospitals, and universities were required to build knowledge gaps and basic technological capabilities to assist in developing an ecosystem. Such an ecosystem was needed to support local Indian firms struggling to access diverse knowledge and product base to manufacture relevant devices for local use. Second, healthcare objectives and industrial and technology policies have remained disjointed with inadequate regulations. Moreover, a lack of clear communication between the firms in the Indian medical device sector and policymakers, and among different key stakeholders, can be seen in the piecemeal policy efforts and lack of establishment of appropriate supportive institutions. The inability of regulators and policymakers to grasp and respond to complex technologies further adds to the disconnect. At the level of firms, the lack of linkages between manufacturers and clinicians and the complexity of knowledge associated with the development of medical devices has remained a significant bottleneck towards developing this sector. In the absence of adequate regulations, it was challenging to find acceptance of their products (ibid).

Some signs of collaborative actions with emergence of industry associations

The role of effective government-industry relations is instrumental in innovation and has been a significant contributor to the shaping of regulations in the pharmaceutical sector in India and across the world (Watkins et al., 2015). While larger industry associations like the Confederation of Indian Industry and Federation of Indian Chambers of Commerce and Industry represented industry in the formation of an adequate regulatory structure and larger industrial policy, there was a strong need for dedicated sector-specific industry associations to represent the medical

device industry's concerns to the government as the regulatory changes were shaping up (Kale et al., 2015).

Several studies support that intermediary, such as industry associations, are a useful tool to inform policies for sectoral development (Watkins et al., 2015). This is because they provide insights on how countries engage and react to the new technologies and industries, external flows of knowledge and investment. Two key industry associations emerged in this phase. In 2002, the Association of Diagnostic Manufacturers in India (ADMI) was formed for knowledge dissemination on intellectual property rights and good manufacturing practices and liaison with the government on the challenges and issues facing the medical device sector, mainly around uniform VAT tariff (Kale et al., 2015). The formation of the Association of Indian Medical Device Industry (AiMED) fulfilled the need for a standalone industry association representing Indian medical device manufacturer. Due to the efforts of these industry associations with government, the Indian Medical Device Regulatory Review Group was formed in 2009. This group was an informal forum comprising regulators, industry representatives, consumer groups, and the conformity assessment quality system auditing bodies.

The MNCs that operated in India only as distributors also established subsidiaries and joint ventures. For instance, liberalisation facilitated entry of multinational companies of high-end medical devices, including Siemens, Philips, and Medtronic, and joint ventures, for instance, between Wipro India and General Electric Healthcare, to produce diagnostics, including ultrasound and CT scanners in India. The huge presence of subsidiaries of multinational firms meant that domestic production represents a reassembly operation of imported parts with little value added to make it commensurate to local environment. The resulting inadequate supply of appropriate medical devices and poorly working devices poses a great challenge in Indian health systems as it contributes to widening disparities in household access to affordable medical care (WHO, 2012).

In summary, this phase witnessed an integrated policy focus on science and technology for the first time. Second, the initial steps of strengthening the regulatory framework for medical devices were triggered by adverse public health events. However, there was confusion as drugs and devices were regulated under the same legislation. The muddled regulatory framework also impacted domestic manufacturing and innovation efforts. Moreover, a lack of a conducive ecosystem was also a challenge. Nevertheless, in the years of this phase, some signs of

collaborative actions were instilled in the medical device sector, with the formation of industry associations.

Phase 4: 2012-2022 – Signs of policy coherence and the emergence of the MedTech ecosystem

This phase is critical in context of this thesis because it shows the emergence of medical technology (MedTech) ecosystem in India. I explain it in two parts. First, showing the early signs of coherence in STI, health, and industrial policies to drive the Medtech ecosystem. Second, the development of medical device regulations. Table 2.4 presents the broad governance mechanism that shaped MedTech ecosystem in this phase.

Table 2.4: Medical device and diagnostics governance in India

Department / Ministry	Role in defining medical device and diagnostics policy framework
o Ministry of Health and Family Welfare and State department of health	o National and state health policy
o Central Drugs Standard Control Organisation and State Drug Controller	o Medical Device Rules
o Department of pharmaceuticals, Ministry of Chemical and Fertilisers	o Medical device policy, Production linked incentives, o Promotion of medical device parks, public procurement policy
o National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical and Fertilisers	o Price controls
o Department of promotion of industry and internal trade, Ministry of Commerce, and Industry	o Make in India initiative. o Foreign direct investment

o Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology, Ministry of Science and Technology	o Academia-Industry collaborative mission for accelerating discovery research to early development for medicines, medical devices and diagnostics, vaccines, biologics, etc.
o NITI Aayog	o Atal Innovation Mission to align innovation policies between central, state, and sectoral innovation schemes and promote an ecosystem of innovation and entrepreneurship at various levels. o AI for all
o Ministry of Electronics and Information Technology	o Policies for Emerging Technologies o National AI Strategy with NITI Aayog

Source: Authors' collation from data.

Ministry of Science and Technologies focus on fostering medical technology ecosystems

In this phase, the policy paradigm shifted to building technical capabilities to reduce reliance on imports and foster innovative ideas in the medical technology ecosystem (BIRAC, 2012).[8] Some emerging signs of academic – industry – government collaborations also emerged during the end of this phase. For instance, the Department of Biotechnology (DBT) and the Department of Science and Technology collaborated with several funders and introduced schemes to support innovations. DBT set up Biotechnology Industry Research Assistance Council (BIRAC) as an interface agency to support the emerging biotech and Medtech enterprises undertaking strategic research and innovation by translating knowledge into technology-led affordable and globally competent product development, addressing unmet needs.

In this regard, BIRAC acknowledged the key bottlenecks to health innovation, including long gestation periods and complex regulatory pathways. BIRAC provided access to strategic partnerships network of national and global stakeholders and access to risk capital through targeted funding, technology transfer, IP management to help individual entrepreneurs and start-ups to network, scale up, and commercialise their innovation. The Affordable Healthcare in India

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[8] https://www.birac.nic.in/grandchallengesindia/program.php?pid=11 (last accessed on 21 February 2023).

initiative, funded by The Wellcome Trust, also promoted the development of innovative and affordable healthcare solutions to enhance access.[9] Stanford India-Bio design, a medical technology program funded by DBT, Stanford University, IIT Delhi, in collaboration with All India Institute of Medical Sciences (AIIMS) and Indo US Science Technology Forum, promoted entrepreneurship in locally relevant medical devices and diagnostics (ibid). Private sector collaborations with the government also paved some way for affordable diffusion of available medical technologies. For instance, GE Healthcare, Government of Madhya Pradesh, and Sanya Hospitals and Diagnostic Centre set up a diagnostic centre facilitating affordable diagnostics at Netaji Subash Chandra Bose Medical College Hospital at Jabalpur (a town in Madhya Pradesh) (ibid).

STP 2013: Linking science and technology policy with innovation policy.

Science, Technology, and Innovation Policy (2013) laid down integral linkages between innovation and science and technology as drivers of sustainable and inclusive growth. The focus of STIP was on the creating a new ecosystem to develop solutions for societal problems. It did so by focusing on both demand and supply side policies for stimulating private sector investments in R&D. However, this led to a substantial focus of policy on innovation as a product of R&D, without highlighting the growing importance of knowledge exchange, training of scientists and biomedical engineers, transfers of intellectual property (Mani, 2013). Studies also suggest that the policy was far from the contemporary reality of the political economy of health innovations at that time. For instance, while the policy was ambitious, it did not connect with the larger debates around lack of regulatory oversight. Also, it reflected grandeur with ambitious statements but did not clarify important key terms, including 'National Innovation Systems', and 'innovation' for the 'local context' (Sheikh, 2014). The lack of depth of key terms made the policy based on the western formal innovation systems that did not support informal ways of knowledge production in India. Even in the formal system, STIP 2013 also did not highlight the role of industrial and trade policies in stimulating demand for innovation (ibid). Nonetheless, the STIP did change the larger narrative around the role of knowledge-intensive entrepreneurship and innovations, and the role of STIP in wider economic growth and development.

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[9] https://www.birac.nic.in/grandchallengesindia/program.php?pid=11(last accessed on 21 February 2023).

First linkages between industrial and health goals in public policies

In this period, industrial and health goals showed some signs of convergence in public policy. The government of India acknowledged the rising importance of medical devices in the health sector and the importance of strengthening local production special schemes under the Make-in-India initiative. In 2014, the government of India permitted up to 100 per cent FDI under automatic route in greenfield and brownfield projects in the medical device sector. The segments of equipment and instruments, consumables and implants attracted the most FDI from major source countries, including the USA, Europe, and Japan (DIPP, 2017). Moreover, the sector also consolidated and organised with several mergers and acquisition transactions, and private equity investments, mainly in the equipment and instruments and consumables segments. Between 2012 and 2016, imports remained high and increased by 16.8 per cent. In contrast to the previous periods, exports also increased by 25.7 per cent (DIPP, 2017). Despite this, even by 2016, 70 per cent of total imports constituted high-end diagnostics, including imaging (CT scan, X-Ray, MRI, USG, X-ray tubes etc.), in vitro diagnostics, and other medical devices (including ECG, heart-lung machine, etc.) (ibid). The policies in support of FDI received a mixed reaction from the industry associations, with AiMED arguing this to be detrimental to Indian medical device manufacturers. To reflect the interests of local manufacturers, the Department of Pharmaceuticals issued the first draft 'Medical device policy' in 2015, with the objective of strengthening the medical device sector under the Make in India initiative. An evaluation of factors including import dependency, manufacturing capabilities, and share of the segments in the overall medical device market in India suggested that diagnostic imaging, IV diagnostics, orthopaedic and prosthetics, and consumables had high potential for investments for medical device manufacturing in India (DIPP, 2017). There were some initial strides in small and medium-scale enterprises with some clusters of medical devices in Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, and Tamil Nadu (ibid).

Meanwhile, industrial policy continued shaping to promote local production. For instance, in 2016, the government of Andhra Pradesh introduced the first Medtech park, Andhra Pradesh MedTech Zone Limited (AMTZ) with specialised laboratories, warehousing, and testing centers for medical device manufacturing, to reduce the cost of manufacturing and the import dependency. There were some signs of connecting local manufacturing with locally relevant devices and addressing the unmet health and clinical needs by the government. For instance, BIRAC continued supporting numerous projects and proof of concept studies addressing strategic

research and innovation in areas of healthcare importance in India. Startups and SMEs further got some impetus with the introduction of the 'Startup India' program in 2016 by the government, which focussed on building a strong ecosystem for innovation and startups.[10] However, because of the fragmented and complex governance, there was no coherence in the various medical device and Medtech sector policy initiatives.

NHP 2017 acknowledges a need for a coherent policy ecosystem for medical devices.

In the previous phases, there was no clear policy focus on medical devices and diagnostics in the national health policies. As highlighted in section 2.2, in 2017, National Health Policy (NHP) redefined the state's role in making a coherent policy ecosystem for medical devices. NHP highlighted the importance of aligning the growth of the private healthcare sector with public health goals by introducing measures, such as 'strategic purchasing', to create demand for the private healthcare sector and serve public health goals (NHP 2017). At a larger level, the health policy aims to use several instruments such as effective regulatory provisions, aligning public health goals with the private sector's growth, a well-developed public procurement system, and supportive policies to increase the effectiveness of regulations and industry development. Further, NHP highlights facilitating local manufacturers by incentivising and enhancing their manufacturing capabilities to develop customised indigenous medical devices and diagnostics for the Indian population in the long run. These objectives also align with the national agenda of 'Make in India' and '*AtmaNirbhar Bharat* mission (self-sufficient India), under which the goal regarding medical devices and diagnostics is to create forward and backward linkages in indigenous production. One such step is creating med-tech parks to mitigate the capital-intensive nature of medical device manufacturing, particularly for individual manufacturers. Under the scheme, financial and technical assistance is provided to create a robust ecosystem for medical device manufacturing in the country, including common testing and laboratory facilities in one place to reduce manufacturing costs. The scheme is valid for five years, from 2020-21 to 2024-25, wherein the Medtech park project is implemented by a dedicated state implementation agency.

Government schemes and focus of STI policy to bolster locally relevant innovation.

Several government schemes are introduced to support local manufacturers of medical device. These policies are supporting local manufacturers with cost of manufacturing, infrastructure,

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[10] https://www.startupindia.gov.in/content/dam/invest-india/Templates/public/5_years_Achievement_report%20_%20final%20(1).pdf (last accessed on 31 January 2023).

supply chain and logistics, cost of finance, design capabilities and investments on R&D and skill development. For instance, the government has approved a 'Production Linked Incentive Scheme' in March 2020 and has also offered a 15-year income tax exemption for locally created medical technology products (IBEF, 2021).[11] Moreover, in addition to BIRAC, a range of national and international private equity investors, incubators and accelerators provide significant handholding to start-ups and new ideas in healthcare. In this phase, the government also recognised the application of artificial intelligence and machine learning as a driver of healthcare innovations in the fourth industrial revolution in National Strategy for AI, 2018 (NSAI, 2018). The COVID-19 pandemic also worked as a major push in the general awareness and policy changes for medical devices and diagnostics. Mainly there is an increased focus on innovations for prevention, early detection and creating the continuum of care in the health system.

Some semblances of this focus were reflected in the release of the draft Science, Technology, and Innovation Policy (STIP) in 2020. For a sustainable development pathway, STIP underscored promoting traditional knowledge systems, developing indigenous technologies, and encouraging grassroots innovations to foster economic development, social inclusion, and environmental sustainability.

Road to medical device regulations and related complexities

Since 2013, some key changes happened in the regulatory system. To begin with, the mission statement of CDSCO was revised from 'meet the aspirations.... demands and requirements of the pharmaceutical industry' to 'to safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.' The regulations were shaping up, albeit there was no real progress. In 2013, the Drugs and Cosmetics (Amendment) Bill, 2013, a new bill that included parliamentary recommendations from 2007, was drafted and introduced in the Rajya Sabha (the upper house of the Parliament) to amend the DCA. This bill proposed to add a separate chapter containing regulatory provisions for medical devices to separate them from being defined as drugs. In fact, in 2015, the draft Drugs and Cosmetics (Amendment) Bill, 2015 were also released. However, the proposed bills were withdrawn again in 2016 with the objective of comprehensively reviewing the law that facilitates ease of doing business and enhances the quality and efficacy of Indian products (PIB, 2016). Consequently, MoHFW was recommended to prepare separate rules under the DCA for regulating medical devices and draft separate

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[11] https://pib.gov.in/PressReleasePage.aspx?PRID=1779693

legislations for regulating medical devices, and drugs and cosmetics. After extensive stakeholder discussions, the draft rules for regulating medical devices were prepared the work on drafting the new legislation also commenced.[12]

Introduction of Medical Device Regulations (MDR)

The government drafted and notified medical device regulations (MDR) under DCA in January 2018. MDR lays down the legal bases to regulate medical devices in India by stating the pre-and post-marketing requirements, including the grant of licence to manufacture, import, clinical performance, sale, and distribution of medical devices. MDR spells out the pre-and post-marketing requirements, including granting licences to manufacture, import, clinical performance, sale, and distribution of medical devices (ibid). The introduction of MDR is a step that helps to build trust in the safety and quality of medical devices and diagnostics manufactured in India. MDR has followed Global Harmonization Task Force (GHTF) definitions and classified medical devices based on the intended use, whether used standalone or in combination with some other device/software, other parameters including risk, invasiveness / non-invasiveness, etc. Accordingly, medical devices (other than in-vitro diagnostics medical devices (IVD)) are classified based on parameters in the following risk categories: Class A - low risk, Class B - low, moderate risk, Class C - moderate-high risk, and Class D - high risk. This has been a major development from a safety and appropriateness perspective. To assuage the concerns raised in different forums regarding the safety, quality, and performance of various medical devices, including emerging diagnostic kits manufactured/imported into the country, MOHFW constituted a committee for the inclusion of all non-notified medical devices. After deliberations with industry stakeholders and concerned departments, the committee recommended a phase-wise expansion in the scope. Consequently, the government notified all medical devices as drugs under the DCA from April 2020. For the ease of doing business and period to comply with the MDR, CDSCO has notified that licensing of Class A and B medical devices shall be effective from 1 October 2022 and licensing of Class C and D medical devices shall be effective from 1 October 2023 (DoP, 2022).[13] Post this period, all medical devices will be required to be licensed under the MDR as amended by Medical Devices (Amendment) Rules, 2020, except 37 categories of medical devices.

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[12] https://pib.gov.in/newsite/PrintRelease.aspx?relid=146413 (last accessed on 22 January 2023).
[13] https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice%20and%20Approch%20paper%20on%20draft%20NMDP%202022.pdf (last accessed 17 January 2023).

Due to India's quasi-federal governance structure, the MDR is implemented and enforced by the central licencing authority (DCGI, CDSCO) and the state licencing authorities (see Figure 2). The central licencing authority (CLA) is the competent authority for enforcement in matters relating to the import of all classes of medical devices, manufacture of Class C and Class D medical devices, clinical investigation and approval of investigational medical devices, clinical performance evaluation and approval of new IVDs, and coordination with state licensing authorities. CLA is also responsible for periodically classifying the medical devices based on rules two and sub-rule 3 of MDR and publishing a class-wise list on the website of the CDSCO. On the other hand, state licensing authorities oversee the manufacturer for sale or distribution of Class A and Class B medical devices and sale, stock, exhibit or offer for sale or distribution of medical devices of all classes. Furthermore, notified bodies (registered with CLA) are responsible for the oversight of the quality management system (QMS) for Class A and Class B devices. QMS for Class C and D devices would be under the purview of CLA due to the safety concern associated with high-risk products. To streamline the implementation process, the New Medical Device Online portal is available to upload the applications for import license and manufacturing licenses of medical devices and IV diagnostics, for post-approval changes, registration of medical devices testing laboratories, clinical investigation etc.

The regulatory enforcement structure for devices is the same as for drugs. The implementation of harmonised drug regulatory standards throughout the country has been challenging because of the lack of uniformity in both the legal interpretations of the DCA and the regulatory decision-making between CDSCO and state regulatory agencies (for instance, Chowdhury et al., 2015; Department-Related Parliamentary Standing Committee on Health and Family Welfare (2012)). Such challenges have repercussions on the timely availability and access to drugs and could impact devices as well.

Figure 2.1: Enforcement of MDR in India
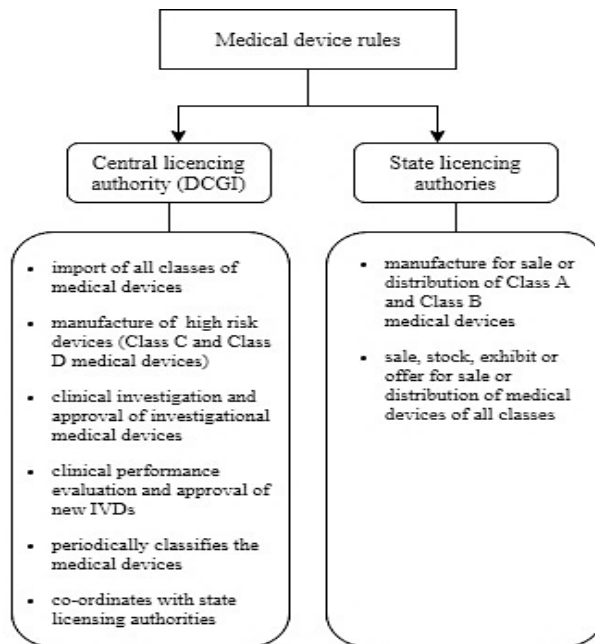
Source: Authors' diagrammatic representation of the information available on the website of CDSCO

Secondly, MDR has brought in some regulatory certainty by defining devices as previously drugs were subsumed as devices under the scope of the DCR. Defining medical devices help in (a) establishing procedures to regulate medical devices, (b) differentiating medical devices from other health technologies like vaccines and medicines (c) deciding if there are medical products that are not medical devices but could be subject to the regulations because of similarity of design, quality, safety, and other characteristics (WHO, 2016; pp 33). The MDR clarifies to be having an overriding effect in case of inconsistency with Drugs and Cosmetic Rules. However, despite clarity in the definitions and rules for medical devices under MDR, the medical device continues to have the original reference to the sub-clauses of clause (b) of section 3 of the DCA. This original reference to devices as drugs in DCA may continue to complicate the regulatory processes. For instance, due to this reference, medical devices are also brought under regulations meant for drugs. For instance, devices also came under the purview of the Drug Price Control Order (2013) of the National Pharmaceutical Pricing Authority (NPPA), the price control authority of pharmaceuticals in India. The NPPA capped prices for cardiac stents (in 2015) and knee implants (in 2017). The ad-hoc price control raised further confusion in the sector. Furthermore, after the release of MDR, the NPPA directed the manufacturers, importers, marketers, and associations to submit price data to monitor the price movements of 19 medical devices (out of the 23 medical devices notified as drugs under DCA). While aimed at improving the affordability of medical

devices, GoI's approach towards pricing medical devices has been more reactive and indirect rather than based on a targeted approach based. Its rationale was to treat devices as drugs. On the other hand, in some cases, the government has taken active steps in delinking devices and drugs. For instance, to expand the scope of the definition and garner more FDI in the medical device sector, GoI's approved an amendment to the definition of 'medical devices' by dropping the reference to DCA from FDI policy in 2018 (Dang and Sharma, 2019). These contrasting examples highlight the further need for streamlining regulatory approaches towards medical devices in strengthening health systems and fostering industrial development.

Mechanisms to adopt rules with the evolving health technologies.

MDR also directs manufacturers to follow essential principles for manufacturing medical devices after taking cognisance of contemporary scientific and technological knowledge and developments. Further, the product standards for medical devices should conform to the standards laid down by the BIS established as notified by MOHFW. If relevant standards have not been defined, then such devices should conform to the standards of the International Organisation for Standardisation, International Electro-Technical Commission, or any other pharmacopeial standards or validated manufacturer's standards. Such provisions are expected to play a dual role in ensuring patient safety and providing some uniformity and level-playing field for the otherwise heterogeneous market.

In summary, in this phase, Medtech, within the larger medical device industry, developed as an industry of significance. This was mainly due to two key developments. First, a MedTech ecosystem by the government of India. Secondly, the introduction of medical device regulations has provided some regulatory certainty, however, it requires more catching up with the evolving technologies.

Phase 5: 2022 – present: Post-pandemic phase.

The pandemic provided a compelling opportunity to increase interaction and collaboration in R&D institutions, academia, and industry to work on disruptive and impactful technologies. Mainly, increased awareness of medical devices and diagnostics during the pandemic reinstated the need for local manufacturing and innovation efforts. As a result, DoP is converging medical device policy to facilitate availability and access to affordable innovations in medical devices and medical technologies and has shared an approach paper with all the stakeholders to have a more

robust, holistic, and responsive industrial policy.[14] This development is also supported by a strategic price control strategy by the government to increase affordability, as the NPPA has made interventions to regulate essential medical devices and cap margins on retail prices, such as stents, oxygen concentrators and some point-of-care devices (ibid). Additionally, recognising the healthcare gaps during the pandemic, this phase started with leveraging analytics AI and ML for targeted public health interventions in low-resource healthcare settings. These MedTech innovations included the early detection of major therapy areas, including cancer and cardiovascular conditions (Nair & Sethumadhavan, 2022). In the next chapters, this thesis elaborates on the role of the above policy and institutional changes in developing problem-solving innovations for early cancer detection.

2.4. Connecting the two separate trajectories for unmet need for early detection of cancer: Is the evolving Medtech system the bridge?

This chapter provides 75 years of evolutionary journey describing the non-linear and co-evolving policies and institutions, actors, and networks, and the health care delivery system from the perspective of the early detection of cancer and the emergence of transformative MedTech as a key sub-sector of medical device sector in India. The focus on early detection of cancer in cancer control policies evolved gradually in the Indian context. The initial phases focussed on building key research organisations and tertiary care support. The policy support for early detection gained momentum post-1975. However, there was no dedicated population-level programme for screening and early diagnosis of cancer until 2016. In the last two phases, there were some signs of policy into practice by rolling out of cancer screening via HWCs and adopting of technology to scale cancer screening.

In the initial phases, the medical device sector suffered from lack of regulation and weak convergence among the science and technology policies, health policies, and industrial policies. The local manufacturing was limited to low-technology equipment and appliances and was not aligned with the clinical needs per se. A primary reason for unorganised efforts in medical device manufacturing could be attributed to the complex governance involving multiple ministries, disjointed policies of the medical device sector, and regulatory uncertainty in India. In the third and the fourth phase, there were some convergences and forward and backward linkages of health

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[14]https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice%20and%20Approch%20paper%20on%20draft%20NMDP%202022.pdf (last accessed on 31 January 2023).

and industrial policy in the national health policy of 2017 and regulations. A dedicated ecosystem connected various actors and R&D networks, including government, industry and industry associations, academia, and hospitals. There is some semblance of policy convergence in the larger medical device, mainly the Medtech segment in India, which historically has been a poorly institutionalised sector. The emerging MedTech sector with burgeoning startups shows some signs of increasing linkages of unmet clinical needs, industrial development, and health care system in key therapy areas. These interlinkages in MedTech provide a crucial means to study the massively underemphasised relationship between STI, industrial, and health policies, and the character of inclusive innovations for the early detection of cancer in India. This thesis explores these linkages with the main research question – to what extent have STI, health, and industrial policies aligned to facilitate development and adoption of inclusive innovations for the early detection of cancer care in India?

Chapter 3: Situating the thesis: Inclusiveness in the MedTech innovation process.

3.1. Introduction

In recent years, there has been an increase in inclusive MedTech innovations in India, enabling early detection of cancer in low-resource settings. In this chapter, I review existing literature to understand what inclusive means in this new trajectory of innovations. I found three main themes in the literature on inclusive health innovations for industrialising countries (a) identification of unmet needs, (b) industrial production of health innovations, (c) absorption in health care delivery system (see figure 3.1).

Figure 3.1: Highlighting inclusive elements in the health innovations
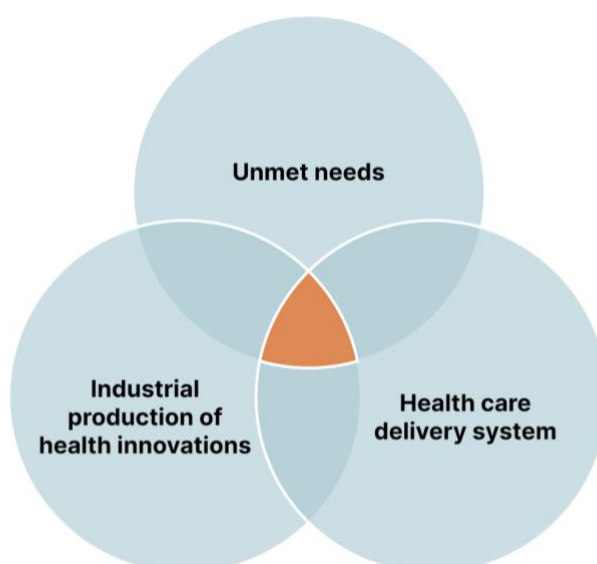
Source: Author's representation of literature

I present these themes in two parts in this chapter. Part A reviews the scholarly work on the conceptualisation of inclusiveness in innovations. It does so mainly from the perspective of the diverse terminologies of 'inclusive innovations', 'bottom-of-the pyramid innovations', 'social innovations', 'frugal innovations', and 'below the radar' innovations. Broadly, the literature focuses on inclusiveness in innovation either as a process (for instance, community-driven, mobilising local knowledge and resources, driven by policies focussed on societal change) (for instance, Papaioannou, 2014) or outcome (for instance, pro-poor and serving the needs of the marginalised) (for instance, Ramani et al. 2012) or a combination of both (Foster & Heeks, 2013).

In these different conceptualisations, there are different framings of the needs and demands of people in varying contexts. I then draw these insights for the concept of inclusion in health innovations, with Medtech for early detection of cancer as a case in point, where doctors and clinical professionals decide and administer the device or diagnostic on the patients. I find that one way to understand inclusiveness is by studying the cycle of innovation. In doing so, it is important to draw lessons about the influences of technical change in the health sector by studying health innovations as an evolutionary process. This helps in capturing the actors and factors that influence the selection environment of health innovations within its broader context.

Part B of this chapter delves deeper into evolutionary frameworks to study the influence of technical change in MedTech sector. This part is crucial in laying the research frameworks that allow the identification of actors and factors that influence the process of development, diffusion, and adoption in healthcare delivery system.

The chapter ends by highlighting the gaps in the literature, suggesting a need for further theoretical and empirical work on integrating technological change and industrial development in the health sector with the unmet needs. It lays down research questions concerning the need to understand how inclusiveness is conceptualised in the innovations for the early detection of cancer in India, what the actor and factors are, and how they influence the development, diffusion, and adoption of such innovations in India.

3.2. Conceptualising inclusiveness in innovations

To begin with, it is crucial to refer to the evolving meaning of innovation to set the discussion of this chapter. Innovation is traditionally referred to as (the use of) a new idea or method. Over the years, scholars of innovation studies have proposed a broader view of innovations (for instance, Freeman, 1987; Lundvall 2004). They define innovation as a continuous cumulative process comprising both radical and incremental innovation, and the interactive learning in diffusion, absorption, and use of innovation highlights the major source of innovation is not necessarily science. Therefore, a broader understanding of innovation calls for deeper insights into inclusiveness at various levels – at the level of the innovation process and outcomes it impacts.

In this section, to understand how 'inclusiveness' is captured in the literature in the context of innovation in general and the health sector in specific, I pose some questions: what are inclusive innovations and for whom? Why are they highlighted in the developmental challenges? Engaging with these questions as I review the literature seems pertinent because the role, meaning, and

process of innovations have an instrumental role in the early detection of cancer, mainly due to its complex relationship with inequality and poverty.

I start with understanding exclusion to understand inclusiveness.

3.2.1. Exclusion to understand inclusion.

The literature linking 'innovation' and 'development' highlights two contrasting impacts of innovation - exclusionary and inclusive. First, many studies have captured the exclusionary effects of dominant, large-scale, and capital-intensive innovations that exacerbate poverty and inequality in the LMICs (for instance, Cozzens & Kaplinsky, 2009; Chataway et al., 2014). Innovation, thus, is predominantly seen as a phenomenon of industrialised countries influenced by 'mainstream science, technology and innovation' reflecting 'market–based' framings (Pansera and Owen, 2018, p 25). The nature and trajectory of technological progress in these innovations are determined by three significant factors (Ruttan, 2001 as cited in Kaplinsky, 2011), including the nature of demand, factor prices and the quality; nature and price of infrastructure; and path-dependencies of innovating firms. Thus, exclusive technological innovations focus on meeting the needs of higher-income consumers of the industrialising economies, making the value chain standards-intensive (Kaplinsky, 2011), thereby placing barriers to entry on small-scale, informal producers. This model of innovations also assumes that innovations and changes in socio-technical systems influence the 'Global North' or the so-called developed countries, and the rest 'need to catch up with those innovations' (Schot & Steinmueller, 2016; p 21).

This dominant trajectory becomes concerning when the health needs of high-income countries drive innovations in the health sector. For instance, as highlighted in Chapters 1 and 2, for years, medical devices and diagnostics in India largely involved reassembling imported parts with little value added to make it commensurate to the local environment. This is also captured by a WHO report based on the Priority Medical Device project (WHO, 2010; p2):

> 'Medical research priorities in most high-resource countries are based primarily on scientific and technological preferences, with little explicit regard for public health needs. In consequence, information about medical conditions and diseases does not translate into effective management of local health systems, nor does it translate into efforts to build the capability of low-resource countries to conduct and use research and to become technology innovators themselves.'

The resulting inadequate supply of poorly working medical devices poses a significant challenge to Indian health systems. First, due to the challenges of integrating imported device and diagnostics into local health systems, particularly at the primary level of care, because of the skill requirements for sophisticated operations (ibid). Second, there are impediments due to low public health spending, ill-defined procurement, varying implementation of regulations, and the absence of health technology assessment. It contributes to widening disparities due to the lack of availability and access to affordable and locally appropriate medical care (WHO, 2012). In the case of cancer, the lack of access to appropriate early detection modalities in India has been raised as a critical public health challenge. For instance, routine mammography screening, which is widely accepted in western countries, is not a favourable option for India's low resource healthcare setting (Mehrotra & Yadav, 2022) (also see Chapter 2 and 5).

The co-existence of dominant or so-called mainstream innovation and perennial health challenges echoes Richard Nelson's reflection on the USA of 1970s in his work, *The Moon and* the *Ghetto* (Nelson, 1977, 2011). He questioned how nations have capacities for missions to the moon amid unaddressed social ghettos. This reflection also connects with the policy debates on cancer moonshots and earthshots in Chapter 1. The frameworks for *moonshots,* including defining the problem, and supporting it with funds and technical expertise to solve it in a given timeframe, is somehow difficult when applied to more complex or wicked problems (Nature 571, 145 (2019). Scholars, including Mazzucato (2017) recommend that policymakers adopt a participative and inclusive approach to support moonshot-style grand challenges or 'missions'. Mazzucato explains that doing this requires defining problems, implementing solutions and dynamic progress monitoring, as opposed to the market failure framework of static 'before and after' cost-benefit analyses (ibid). Mission modes are tested to be a successful approach in advanced economies as they make innovation efforts goal oriented within well-defined systems of innovations. However, how feasible are they for complex issues like access to early detection technologies for cancer in India? Historically, having 'missions' to resolve Indian healthcare challenges have resulted in the creation of several 'siloed' disease verticals (for instance, Kandasamy and Sharma 2022). Also, in under resourced health systems, how can the state do dynamic progress monitoring? What about the local health needs? The next section attempts to engage with some of these questions, by reviewing how inclusiveness in innovations has been approached in general and in low-resource settings.

3.2.2. Different conceptualisations to decipher inclusive innovations – lost in terminologies?

To fathom innovations' inclusiveness, scholars highlight innovation and technological change, resulting from the growing global diffusion of technological capabilities and entrepreneurship in the rapidly rising late industrialising economies (Chataway et al., 2014). Given stark global disparities, the scholars linking innovations and development highlight such innovations as 'inclusive' and a critical ingredient of development (Kaplinsky, 2011). In this sense, the 'narrative of innovation' has a central role within this broader policy discourse wherein innovation is framed as a critical ingredient of development. LMICs are seen as a significant driver of global innovation in the 21st century (Kaplinsky, 2011). Particularly by way of their contribution to growth, use of factors of production, the social relations associated with production, and mainly the characteristics of the products they produce (ibid). Such innovations that aim to foster the development and implementation of new ideas, aspiring creation of opportunities that enhance the socio-economic well-being of all, particularly for the poor and marginalised section of society, have been broadly termed as 'inclusive'. In innovation and development literature, scholars have highlighted such emerging inclusive innovations with a range of terminologies, including 'jugad innovation' ', frugal innovation', 'BoP (bottom-of-the-pyramid) innovation', 'below-the-radar innovation', 'scarcity induced innovations', 'social technologies' (Prahalad, 2005; Srinivas & Sutz, 2008; Chataway et al., 2007; Altenburg, 2009; Foster & Heeks, 2013; Kale et al., 2013; Chataway et al., 2014; Gras et al., 2019). This section delves deeper into each of these conceptualisations. In particular, it builds on the ladder of inclusiveness by Heeks et al. (2013) and Heeks et al. (2014) that conceptualise different levels of inclusiveness in innovation in process and outcomes. Heeks et al. (2014) provided a broader conception of inclusiveness by engaging in questions to identify who should be included and aspects of whether they be included in innovation outputs or innovation processes innovations. In their framework, Level 1 to Level 6 highlight the varied levels of inclusion based on needs, consumption (demand), adoption, and involvement of marginalised or excluded group (ibid):

Level 1: Intention – address the needs of the excluded group.

Level 2: Consumption – adopted by the excluded group.

Level 3: Impact – a positive impact on the livelihoods of the excluded group

Level 4: Process – involvement of the excluded group in the development of the innovation

Level 5: Structure – created within a structure that is itself inclusive.

Level 6: Post-structure – created within a frame of knowledge and discourse that is itself inclusive.

These six levels enable an instrumental tool to delve into inclusiveness both from the process and outcomes. Albeit very few studies have compared the conceptualisation of inclusiveness in different innovation typologies (for instance, Papaioannou, 2014; Pansera and Owen, 2018; Onsongo and Knorringa, 2020). Such a comparative perspective is important because these diverse conceptualisations of innovations cannot be used synonymously due to their different assumptions about innovations and production's relationships to demand and inclusion. Therefore, I elaborate on the differences in various conceptualisations to understand 'inclusiveness' in innovation (see Table 3.1).

Bottom of the Pyramid (BoP) innovations (Prahalad, 2005), below-the-radar innovation (Clark et al., 2009), pro-poor innovations (Benyacar et al., 2008), and social technologies (Kale et al., 2013) bring out the role, characteristics of markets, and final beneficiaries of the innovations as the poor and marginalised populations. However, these frameworks approach inclusiveness very differently. To start with, Bottom of the Pyramid (BoP) innovations (Prahalad, 2005) is a popular strand in the business management and innovation studies literature. It takes a business perspective to inclusion by bringing out the poorest socioeconomic group, earning less than USD 2 a day, as a potential market with a new class of consumers. The approach suggests that the BoP population is a market opportunity. Thus is a win-win for both innovation providers and potential end-user. Thus, BoP approach identifies MNCs as primary providers for low-income consumers, as opposed to SMEs and locally owned firms suggested by studies on appropriate technology (Schumacher, 1975) and informal sector (Cozzens and Sutz, 2014). It does highlight the inclusion of the poor population as a promising untapped market. However, the concept has very weak linkages to the needs of the BoP population as its primary objective is to capture the market for profit expansion. The specific needs and demand of BoP population, and how these can be translated into demand for poverty alleviation and reduction of inequalities is not captured adequately in this approach. Moreover, in such discussions, the focus of inequality is often on vertical inequality (taking the population as a whole) and not so much on horizontal inequality (within sub-groups, like gender, ethnicities, etc.) (Cozzens & Kaplinsky, 2009). The focus on both vertical and horizontal inequalities is important in the context of this thesis because of a myriad of barriers to access screening and early diagnosis. For instance, Negi & Nambiar (2021) examine inequalities in education, place of residence, religion, caste and tribal status, education, age,

employment status and marital status in self-reported breast examination among different wealth groups in India. They reported a concentration of breast screening among wealthier quintiles (ibid). Another study highlighted that in addition to economic status, healthcare coverage, marital status, area of residence and caste are important indicators determining the uptake of cervical and breast screening (Monica & Mishra, 2020).

Therefore, a top-down approach of targeting BoP populations may work for consumer goods such as mobile handsets but not so much capture the complex need and demand for early detection of cancer. For instance, the Indian pharmaceutical industry has earned the moniker of 'pharmacy of the global south' and benefitted several countries through its low-cost generics. However, access to medicines is still a challenge in many states in India because of the complexity of various institutions, actors and networks, health finance mechanisms, and health care delivery systems. Some of the missing linkages of developmental indicators in BoP approach (as discussed by Prahalad, 2005) were covered in further concepts that provided more character to the 'needs' and demands of the BoP population and the concomitant nature of inclusiveness of innovations.

The scholars introducing the BRI approach emphasized building a deeper understanding of the underlying dynamics of technology developments taking place in the 'Asian Drivers', where 'new patterns of institutional change and capacity building are evolving under the radar' (Clark et al, 2009). Inclusiveness at this level meant the inclusion of LMICs or late industrialising economies as a contributor of innovative products or services by challenging some deep assumptions about the structure and functioning of established knowledge systems. Some empirical studies have further elaborated on the distinct nature of innovations in resource-constraint settings. Presenting the experience of eco-toilets in India, Ramani et al (2012) emphasise that vis-à-vis the mainstream innovations, the creation and diffusion of pro-poor innovations have not received much attention by economists and management science experts. They highlight pro-poor BoP innovations emerge from the identification of a 'need'. The identification of the need of the BoP population as an important indicator of innovation is a significant development in conceptualising inclusiveness. This is a departure from previous discussions of BoP innovations (Prahalad, 2005), where BoP was seen as a mere market (end user) in the global value chain.

'Frugal, jugad, grassroot innovations' emerged as a bottom-up approach of innovations focussed on social inclusion, highlighting stages of the innovation process and channelling of knowledge production towards social relevance, which is crucial in engaging with local challenges in low-resource settings (Gupta, 2010; Arocena & Sutz, 2012; Bhatti, 2013; Chataway et al., 2014;

Cozzens & Thakur, 2014; Papaioannou, 2014; Arocena, Göransson, & Sutz 2019). The purpose of innovation in low-resource settings is driven by the capabilities of communities to create value by addressing the basic needs in low-resource settings. The 'inclusiveness' of innovations is contingent upon generation and diffusion to the poor and their generation based on a bottom-up process and political process of equitable and participatory mode of identification and satisfying of 'need' (Papaioannou, 2014). However, as inclusiveness is a complex concept, scholars also suggest that frugal innovations in the form of low-technology solutions may not be the best way to address the larger needs of education and health care of the poor population. In these sectors, safety and quality considerations are highly important and should be carefully evaluated from public policy perspectives (Papaioannou, 2016). In this case, grassroots innovations and BRI innovations depart from being mere frugal innovations, as they are driven not just by demand for low cost of products / services but also a participative process (ibid). Some examples from India include the Jaipur foot (discussed in Chapter 2) and the Honeybee Network. The Honeybee Network, founded by Anil Gupta in 1988, is a multimedia database that democratises a larger pool of practical knowledge with high ethical standards, respecting the dignity and value of its contributors. It was a departure from reaching out to the government, private sector, and NGOs for solutions in the local context by connecting ingenious ideas of people for their innovative approaches for their problems. Such grassroots-level networks challenged the notion that innovations are resource intensive and pointed out that scarcity of resources does not stop people from finding creative solutions. HBN provides grassroots outreach to local communities to share the solutions,[15] encouraging sharing ideas and knowledge that publish in a newsletter in 8 languages and distributes to 75 countries. In this process, it also developed a new model for scalability and sustainability where the innovations on the database are funded to support the inventors and their communities. Attributing innovations to the original inventor and thus treating innovations as 'by the poor, for the poor' (ibid), grassroots innovations conceptualise the intricate relation between 'need' and translating the need to demand in the innovation process. It thus brings out communities in low-resource settings as both producers and users of the innovation.

Some reflections on users being central to the innovation processes are also reflected in the work of Eric von Hippel (for instance, von Hippel, 2005). He suggests that in the traditional manufacturer-centric model, products and services are developed by manufacturers in a 'closed way' (protected by patents, copyrights, etc.). The user's role is limited to having 'needs', that

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[15]See: http://honeybee.org/seeking_solution.php (last accessed on 22 December 2022).

manufacturers identify and fill by designing and producing new products, with the traditional pattern of concentrating innovation-support resources on a few individuals is hugely inefficient. While there has been a tremendous increase in the value and success of user development innovations, he cautions that it is difficult to identify and allocate high-cost resources for innovation to 'the right people with the right information' before such users develop an innovation that turns out to have general value (von Hippel, 2009). The allocation issue becomes less problematic as the cost of high-quality resources for design and prototyping declines, making it possible for resources to be widely diffused (ibid). This plays an instrumental role in '*democratisation*' of product and service innovation in the form of knowledge and innovation as open source. It differs in the way HBN referred to a democratisation of innovation. It does this by channelling the knowledge across communities yet attributing it to the original innovator (via patents) rather than keeping it open-source innovation.

In the case of health innovation, it is essential to bear in mind different assumptions of need and demand in the different frameworks of inclusive innovations discussed above. In terms of health care, the concepts of need and demand are very complex. Srinivas (2014) describes needs and demands in healthcare into three categories,

(1) 'need that is not recognised as a need' - needs that are invisible due to inequalities and poor political representation, and lack of recognition of needs in STI and health policies (top-down policies). Since policies play a critical signalling mechanism, such unrecognised needs are not picked by even the private sector due to a lack of incentives.

(2) 'need recognised as a need but not as a demand' – needs which are recognised in the policies yet remain unaddressed due to the absence of market demand, for instance, innovations that remain in research labs and are never commercialised. In this regard, national and sub-national priority settings for certain innovations can play an instrumental role in shaping industrial and social investments.

(3) 'recognised, but unfulfilled demand' – cases when need and demand is recognised but remain unfulfilled.

Having a more nuanced perspective of needs, scholars suggest that in settings where innovation and poverty co-exist, focusing on mere technology-led economic policies is unlikely to meet most people's needs (Srinivas & Sutz, 2008; Arocena & Sutz, 2012). The specific needs and

idiosyncratic paths motivate innovations that can solve urgent and otherwise unsolved problems in resource-scarce conditions (ibid). These scarcity-induced innovations (SII) and problem-solving innovations are adapted to developmental processes embedded in scarcities that are not widely present in industrialised societies, lead to different technology incorporation and production (Srinivas & Sutz, 2008). This approach again does not focus alone on a low income or cheap products but on problem-framing for local contexts through which new and diverse set of consumers may emerge (Srinivas, 2017). It focuses on specific needs, using a problem-solving approach, and aims at innovation for a wider user base. This thesis is inspired from conceptions of SII and uses an adaptation of SII matrix to situate various early detection modalities for breast, oral, and cervical cancer in India (in Chapter 5).

Based on the insights from Chapter 2 and above discussion, it is pertinent to understand how unmet needs and demands are captured in innovations for the early detection of breast, cervical, oral cancer. Historically, despite the increasing burden of these cancers (see Chapter 1) there have been lack of availability of technologies that are relevant to the local context. The emerging MedTech for the early detection of innovations provides an opportunity for MedTech to understand the unmet needs and demand for cancer detection as a means of inclusiveness.

Table 3.1. briefly summarises different conceptualisations of inclusive innovations, along with their strengths and limitations.

Table 3.1: Summarising various conceptualisations of inclusive innovations

Concepts of inclusive innovations	Process of innovation development	Outcomes of the innovation	Strengths	Limitations
Bottom of the Pyramid	o Innovation is a learning process: how to innovate effectively in and for BOP markets?	o Creating new markets and ecosystems to acquire new consumers at the BoP population	o A shift in focus on the BoP population as an important market	o A top-down approach, suitable for consumer goods but not medical devices. o A narrow understanding of the needs of the BoP population focuses on

Concepts of inclusive innovations	Process of innovation development	Outcomes of the innovation	Strengths	Limitations
				only the vertical inequalities
Pro-poor innovations	o Identification and fulfilment of the need of the BoP population	o Creating new markets based on the needs of the BoP population	o Solutions to address needs of poor and focussed demand creation.	o Scalability could be a challenge
Below the radar	o Evolution of new patterns of institutional change and capacity building under the radar	o Innovations developed by small teams or individual innovators in economies to create new products with low resources.	o Aim to address previously unmet needs, challenging assumptions of knowledge use in industrialising countries.	o It may be challenging to gain traction as the innovation happen 'below the radar' of mainstream markets. o Regulatory and legal constraints.
Social innovations	o Socially driven by the ethos of social inclusion.	o Innovations addressing social needs	o The flexibility of scale based on the context.	o Weak conceptualisations on need and demand
Frugal innovations	o Low-technology variants of high technology	o Simplification of sophisticated technology	o Bottom-up approach	o Quality concerns in areas like health. o Regulatory and legal constraints.
Grassroot innovations	o Channelling knowledge production towards social relevance by a participative process of innovation	o Communities in low-resource settings are both producers and users of the innovation.	o Participative approach to identification of needs, demand generation	o Scalability of innovations beyond communities.

Concepts of inclusive innovations	Process of innovation development	Outcomes of the innovation	Strengths	Limitations
User-driven innovation	o Involving users in the innovation process	o Focuses on keeping innovation open source.	o Democratisation' of product and service innovation	o Difficult to find the right people with the right knowledge at the right time.
Scarcity-induced innovations	o Specific needs and idiosyncratic paths motivate innovations	o Solutions for urgent and otherwise unsolved problems in resource-scarce conditions	o Articulation of needs of a wide range of consumers, not just poor	o Differences in various institutional bundles of innovations may be difficult to segregate.

Source: Author's review of literature on inclusive innovations.

I explore the inclusiveness of emerging AI and ML based PoC MedTech innovations in the Indian context by understanding – how inclusiveness is conceptualised in the emerging MedTech innovations in the Indian context. Scholars, including Chataway et al. (2014) argue the need to understand inclusive innovation in the 'context of a holistic conception of the innovation cycle' focusing on the various process and product innovations. In particular, understanding the roles played by the people in industrialising countries as both producers and consumers. It is thus pertinent to understand some questions that emerged from the literature: who are the producers and users of these innovations? Who are the innovators that are taking an interest in developing problem-solving innovations? It is pertinent to ask this question from an inclusion (and exclusion perspective) because of the dominant neglect of women as bottom-up innovators in the innovation literature (Cozzens & Sutz, 2014). Engaging with these questions would fathom understanding of factors that influence the development, diffusion, and adoption of the problem-solving role of innovations that aim to address unmet clinical needs, demand, and critical gaps in the healthcare delivery system in an affordable manner. These questions drove the purpose of my fieldwork.

In studies of health systems and health economics, the dominance of neoclassical economics and market failure approaches have led to a static understanding of health innovation: in terms of technologies and products as input components of health systems and apparent market failures. To go beyond this static approach, studying concepts of inclusiveness from an evolutionary perspective is particularly valuable in the context of health innovations. In case of MedTech innovations, there has been a recent technical change in industrial structure that is catalysing these innovations. As a first step, the literature draws attention towards evolutionary frameworks. In this part, I review different frameworks studying influence of technical change in industrial structure using insights from evolutionary economics.

3.3. Evolutionary perspective to study innovation process

The pioneering work of Nelson and Winter (1982) enabled how to study the influence of technical change on industrial structure. They introduced an evolutionary theory of economic growth that integrates appreciative (like historical accounts) and formal theorising of economic growth. They characterise technical advance as an evolutionary process, within which new technologies compete not only with one another but also the existing technologies in practice, considering two critical aspects (ibid):

(i)   Ex-ante uncertainty on which technology will prevail, highlighting the elements of uncertainty in technological evolution – which variety of technology will succeed?

(ii)   Ex-post selection determines which technology prevails and which does not in a given selection environment facilitated by many market environments.

Both the focussed market selection environment and systematic selection provide direction to technical advance, which works on both sides. Importantly, such evolutionary focus enables a dynamic analysis because industrial structures, technologies, the nature of competition, and key public policy issues change over time. The screening, selection, and implementation of new technologies is a time-consuming process. The selection mechanisms may involve new markets but may also involve non-market character, i.e., through institutions like firms/innovator strategies, government regulations, and STI policies. Therefore, evolutionary models of

technological change provide a realistic way of understanding innovations vis-a-vis the neoclassical models that treated technology as exogenous (Edquist, 1997).

Evolutionary models enable a wider approach to the study of health innovation by integrating local characteristics that shape technological needs and national policies to facilitate (or restrict) innovation (Bianchi et al., 2015). For instance, WHO defines *health innovation* as a multidimensional concept – not merely a product/process innovation – which encapsulates the development of 'new or improved health policies, systems, products and technologies, and services and delivery methods to 'improve people's health', with a 'special focus on the needs of vulnerable populations.'[16] Many studies, for instance, Abrol et al. (2016), have highlighted health innovations as a complex interplay among political, administrative, technological, institutional, and legal issues. However, the structure and dynamics of health innovations are often assumed and studied in silos (Consoli and Mina, 2008). As a result, they are defined narrowly as new drugs, devices, and vaccines. Their development process is either studied in isolation from the broader socioeconomic framework of systems or disconnected from the health care delivery system (ibid; Srinivas, 2012). Innovation is the consequences of the particularities of specific countries or regions (Cozzens and Kaplinsky, 2009). Therefore, it is crucial to understand innovations in a specific social, political, and economic context shaped by different institutions. The research on health innovation and health equity is poorly integrated (Sutz, 2015). The analyses of gaps in the availability and access to health innovations are often attributed to market failure, leaving few alternatives for informed policymaking. Therefore, a critical step to understand the nature and character of inclusiveness is to underscore several characteristics of health innovations that are unique and allow us to study them as an evolutionary process (Gelijns et al., 2001):

(1) presence of a high degree of uncertainty regarding the eventual usage of health technology continues resulting in a heavy reliance on clinical practice, mainly due to the complexities associated with the human body and heterogeneity of populations,

(2) findings generated because of complex interactions between understanding the technology and its actual practice influence translational, further biomedical, and technological research. This closely relates to our understanding that technical change is path-dependent and evolves from earlier technological development,

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[16] https://www.who.int/teams/digital-health-and-innovation/health-innovation-for-impact (last accessed on 15 July 2023).

(3) more importantly, the complex selection environment determines the health technologies that survive the development process. The decision-making process of physicians, the main agents that select the technologies for the primary users (patients), is influenced by other actors, including regulatory agencies, policies, health financing mechanisms, patients, etc.

Thus, moving beyond ceterus paribus, evolutionary perspectives (Consoli and Mina, 2009; Srinivas, 2012, 2020) place dynamics, processes, and transformation at the heart of the analysis of inclusion and process of the health systems, facilitating close to real-world analysis.

3.4. Finding appropriate theoretical framework to study inclusive MedTech innovations.

I reviewed various frameworks to assess the feasibility of studying technical change in the Medtech sector and inclusive innovations for the early detection of cancer. In addition to Nelson and Winter (1982), a range of other neo-Schumpeterian work in the 1980s, notably Freeman (1982, 1987), Nelson (1993), Lundvall (1992, 2007) paved the way for analytical frameworks that allowed building a richer understanding of innovation as a dynamic process. Mainly in analysing the instrumental role of innovation and learning in economic growth and development (Lundvall, 2007). This includes extensive work within the 'systems of innovations' (IS) approach belonging to the family of models forming evolutionary economics brought a departure from the linear view of technological progress. It defines *innovation* as an interactive process among a wide variety of actors. These include firm and non-firm actors (such as universities, government agencies etc.) and their actions shaped by institutions (Lundvall, 1992). IS approach highlights historical perspectives and learning as the key determinant of innovation (Edquist, 1997). Different boundaries of systems of innovations are explored in the literature, depending upon the level of aggregation.

The first notion was articulated in the form of national systems of innovation or NSI (Freeman, 1987; Lundvall, 1992; Nelson, 1993). The primary conception of the NSI approach focussed on national boundaries, in which technological change and innovations are driven by a complex set of relationships among actors producing, distributing, and applying various kinds of knowledge (OECD, 1997). The actors mainly include organisations (private enterprises, universities, public research institutes, governments) and individuals (ibid). The regional systems of innovation approach focus on regional boundaries of innovation systems. This approach combines innovation research and regional science systems to explain the locational distribution and policy impact of

regional innovation processes (Cooke et al., 1997; Asheim & Isaksen, 1997). While these frameworks are well accepted in global policymaking, there are concerns about their applicability in industrialising economics (discussed later in the chapter). Some efforts have been made to benefit from the spatial dimensions of the above frameworks, in developing more localised systems, for instance, the Local Production and Innovation Systems (LIPS) approach (Cassiolato et al., 2008). LIPS was developed by RedeSist, a Brazilian research network, with a broad approach of NSI to study local processes of production, innovation, and knowledge accumulation and how to mobilise them in the Brazilian context (Cassiolato & Lastres, 2020). Going beyond the geographical boundaries, the framework of technological systems focuses on specific technologies and participation and interaction of dynamic agents to drive economic growth (Carlsson and Stankiewicz, 1991). However, while all the frameworks focussed on the development and diffusion of new technologies, none of these provides a lens to study inclusiveness.

Due to the study's strong component of sectoral innovations, I reviewed the sectoral systems of innovation approach, SSI (Malerba, 2005; Malerba and Mani, 2009). The SSI approach enabled development of the initial framework to undertake an in-depth study of inclusive innovation in India's Medtech sector. Inspired by evolutionary theory and IS approach, the SSI approach (see figure 3.2) focuses on the rate and type of innovations and innovative activities in sectors (Malerba, 2005), with 'learning' as a critical determinant of innovation. SSI consists of the knowledge base, technologies, inputs and potential or existing 'demand. 'Knowledge base, technologies and inputs' define the nature of sectoral boundaries and influence the behaviour and organisation of firms (ibid). The 'actors and 'networks' are characterised by specific learning processes, competencies, organisational structures, beliefs, etc. They comprise individuals (consumers, doctors, scientists, etc.) and organisations at numerous levels of aggregation, such as firms (users, producers, suppliers) and non-firms (universities, regulatory agencies, trade associations) (ibid).

Figure 3.2: Three main building blocks of SSI
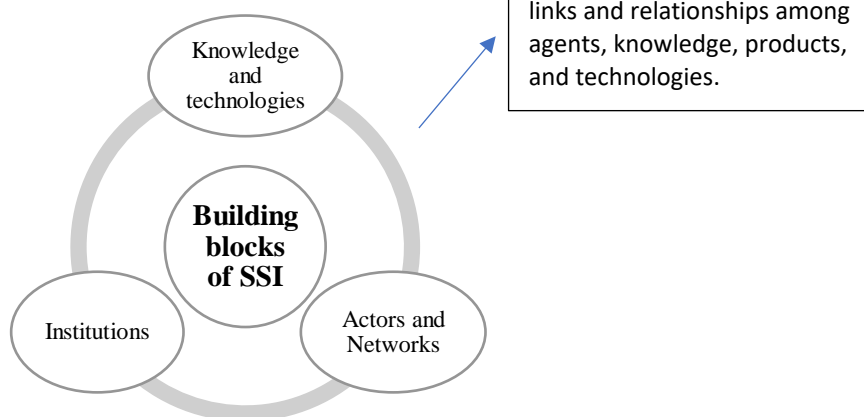
Source: Malerba, 2005

Further, SSI focuses on supply and demand, wherein demand is not merely an aggregation of a set of similar buyers but composed of heterogeneous agents whose institutions shape interactions with producers. These agents are connected through various market and non-market relationships and interact -– 'through 'sector-specific processes' of 'communication, exchange, cooperation and' command'- to create, develop and diffusion new sectoral products (ibid; Malerba and Mani 2009). Moreover, institutions that shape interactions include rules, standards, regulations, established practices, etc., some are specific to the sector, and others are national institutions bearing different impacts on innovation in different sectors and countries. This aspect of SSI allows us to study institutions relevant to the sector, even in assessing the roles that local, national, and global institutions play in the innovation process of a particular sector. Hence, the process of change and transformation in the sectoral system involves the co-evolution of several elements involved. In this sense, SSI departs from NSI, as NSI facilitates the study of innovation systems at a national level. SSI helps build an in-depth understanding of sectors with the boundaries of the innovation process in local, national, and global dimensions - which often co-exist in a sector. SSI also allows for flexibility while selecting the unit of analysis and variables depending on the level of detail of the study. SSI approach facilitates descriptive analyses of the innovations, dynamics of the Indian MedTech sector, and the nature of innovations that emerge through interactions among knowledge, actors, and institutions. It provides a systemic perspective on science, technology, and innovation in health.

However, it is not a complete framework to study of inclusive health innovations in India (and LMICs) for the following reasons:

(1) There are concerns with the 'ex-post' conceptions associated with the systems approach, i.e., the systems approach is mostly built on empirical findings of the global north or the industrialised countries. On the contrary, it is an 'ex-ante' concept in the global south as socioeconomic behaviour concerning innovation is not always systematised (Arocena and Sutz, 2002). Moreover, innovation system frameworks highlight selective policy instruments that benefit a small group of firms and do not have a nationwide impact (Altenburg, 2011). Applications of SSI in sectors of LMICs, including the Indian pharmaceuticals sector, have been explored by some scholars (such as Chaturvedi, 2007; Malerba and Mani, 2009). However, there is a need to delve deeper into the complex linkages of local health needs and demand and institutional framework in influencing sectoral innovations. Such linkages are crucial to understand new-age health innovations in India.

(2) Studies suggest that to channel government interventions towards the production of innovations in specific areas, it is imperative to have a deeper understanding of demand and supply influences that motivate innovation process at the level of industry and firms (Mowery and Rosenberg, 1979; p 103). Further, IS approaches do not allow for an evolutionary understanding of demand in resource-constraint settings of LMICs, which is important for developing and introducing need-based innovations (Heeks et al., 2014). While the focus of policies based on systems of innovation approach is often to boost supply-side institutions, the significance of collective demand facilitating the diffusion of health technologies as the buyers are a mix of individuals (individuals, doctors, and organisations like government, hospitals, clinics) is often undermined (Andersen and Johnson, 2015; Srinivas, 2012). The IS literature does not comprehensively discuss the market varieties that shape the diffusion of health innovations in LMICs (Altenburg, 2009). In health innovations, mapping demand remains particularly important because a range of actors, co-evolving institutions, politics, and policies play an instrumental role instead of solely relying on price signals and market dependence (as in traditional economics). This is true for industrialising economies like India, where technological advances are built rapidly on the supply side to 'catch up', while demand remains vaguely defined due to its heterogeneous and complex nature. There is a need to adequately study the concept and influence of demand in innovation generation in innovation studies, whilst existing literature mainly highlights sectoral advances and technological investments

created by supply-side institutions (Srinivas, 2014). This is particularly true in our case in point – health innovations.

The concept and influence of demand in innovation generation have not been adequately studied in the innovation studies; much of the literature – including NSI and Schumpeterian and neo-Schumpeterian frameworks – mainly highlights sectoral advances and technological investments created by supply-side institutions (Srinivas, 2014). In health innovations, mapping demand remains particularly challenging because, beyond the price signal and market dependence fixation of traditional economics, it is influenced by a web of actors, including institutions, politics, policies, and evolutionary processes. It is interesting to note that in the absence of a defined innovation policy, strategic demand-led policies and national welfare regimes play an immense role in determining the nature and rate of innovations. The policies have the potential to transform needs into demand to create new markets (Srinivas, 2012).

The state faces significant challenges associated with the sustainability of the health care system, particularly while fulfilling the health goals and maintaining the viability of the industry. In this process, the state engages with several stakeholders with conflicting interests to match demand into several supply-side institutions. Boon et al. (2011) highlight that 'intermediary user organisations' can be critical in demand articulation and influence emerging technologies. They suggest that targeting the governing process to heterogeneous actor groups with coordinated roles and strategies influence more demand-oriented policy push for innovations for businesses and users. Public procurement has been suggested to enhance markets for new and existing technologies by shaping the demand environment (Chataway, 2016; p245). Several scholars have offered intermediation of demand and supply through public procurement of innovation (Edler and Georghiou, 2007; Uyarra and Flanagan, 2009; Kattel and Lember, 2010; Edler and Yeow, 2016). These studies have shown how public procurement differs according to the nature of the innovative product and disruptions caused by different types of innovations in the practices of buying organisations. Instrumentalising demand can be a very important source to instil 'access' to innovations. These concepts are not adequately dealt with in the systems approach.

(3) Institutional variety in India (and LMICs) is much broader than rules, laws, standards, regulations, and established practices and comprises a mix of formal and informal

institutions at the national and state levels. The selection agents of innovations, particularly in the health sector in LMICs, are influenced by a range of complex institutions and are not abstracted from ethical norms and moral and political values (Papaioannou and Srinivas, 2019). Moreover, in the absence of a defined innovation policy, the strategic demand-led policies, national welfare regimes and the political economy around the health sector play an immense role in determining the nature and rate of innovations and have the potential to transform needs into demand to create new markets (Srinivas, 2012).

(4) The innovation systems literature does not allow the incorporation of complexities of delivery mechanisms in LMICs. Scholars like Ramani et al. (2012) highlight that the role of various actors in the effective diffusion of innovation hinges upon a complex network of actors (including funding agencies, facilitators, service providers, and field staff) that closely interact with the target population. Specifically, in terms of health innovation, Angeli and Jaiswal (2016) highlight that sustainable business models for health care delivery in India is an under studied domain. They emphasise that sustainable business models involve 'co-creation of patient needs, community engagement, continuous involvement of customers, focus on human resources for health, strategic partnerships, economies of scale, and cross-subsidization' (ibid; p 498).

Some of these limitations are addressed in the framework introduced in the qualitative institutional heuristic to study health care by Srinivas (2012). Srinivas (2021) explains that heuristics are handy dynamic 'thought experiments' to study complex problems. The heuristic involves a co-evolving institutional triad of health care, which comprises (1) industrial production of health innovations, (2) provision of health care delivery, and (3) consumption (demand) of health care through individual or collective buying systems. One can picture these three vertices (see figure 3.3) as constantly evolving, and countries require consistent efforts on all three institutional fronts. The variability of the three domains of the triad helps in analysing institutional and organisational variety assisting health systems. This serves as a broad guide to how policies can guide the production of context-specific and inclusive innovations. It suggests that countries that are assumed to be at similar developmental stages or industrial features may exhibit different interactions between the three evolutionary domains of the triad (ibid).

Figure 3.3: Institutional triad of healthcare
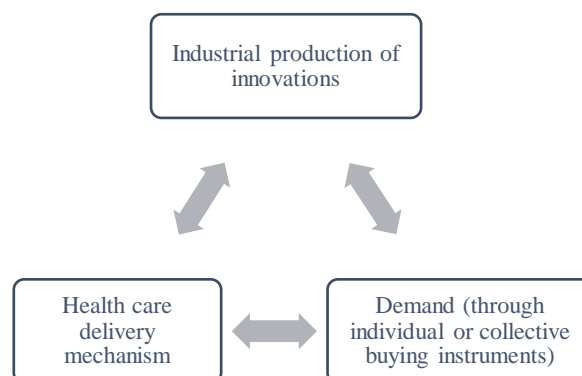
Source: Srinivas (2012).

The heuristic goes beyond the traditional health economics concepts of market failure in public goods. It does so by offering a richer approach to studying technological advances in the health sector and the complex process of planning, institutional change and historical characteristics of knowledge and theories of change (Srinivas, 2020). The qualitative heuristic of the institutional triad has been used for inter-country comparisons for markets for medicines, vaccines and, more recently, COVID-19 test kits (Srinivas et al., 2020). However, the difficulty of separating delivery from consumption in healthcare industries is one of the key areas where the application of heuristic calls for caution.

3.5. Directions and gaps in the literature

Reviewing the literature in Parts A and B, I found three directions and gaps. First, there are several ways in which inclusiveness has been conceptualised in the literature, stating the various assumptions of inclusiveness. These are based on the different lenses of needs and demand, based on who produces and who consumes. The emerging MedTech innovations for the early detection of cancer show signs of inclusiveness that resemble BRI and SII approaches (see Chapter 5, 7 and 8). The literature directs to the study of the cycle of innovations (mainly development, diffusion, and adoption) and focuses on both producers and consumers of innovations in LMICs for an in-depth perspective on inclusiveness.

Second, there is extensive scholarship on policy influencing technological changes in the development, diffusion, and adoption of health innovations in LMICs (Srinivas, 2020; Natera et al., 2019; Gras et al., 2019; Chataway et al., 2009; Consoli and Mina, 2008; Hwang et al., 2008;

Chaudhuri, 2007; Chataway et al., 2007; Kale and Little, 2007). However, some of these focus on inclusive health innovations from STI policy and industrial development perspective, and some have focussed on health equity and access dimensions. There is a dearth of empirical studies integrating unmet needs, industrial development, and effective delivery mechanisms for inclusive innovations in India (and in general). There are no such comprehensive studies in the case of the early detection of cancer in India. This raises an empirical gap in understanding the actors, networks, and knowledge exchange and technologies to create, diffuse, and sustainably adopt medical devices in India and LMICs.

Third, as the emerging Medtech innovations are a result of technical change in the Medtech sector, I reviewed the literature for the impact of technical change in industrial structure. It suggested an evolutionary perspective to study the innovation process. I reviewed a range of frameworks to have a theoretical lens to study MedTech innovations for the early detection of cancer in India. I found SSI to be instrumental in shaping the theoretical underpinnings. It helps in understanding the actors and factors, knowledge and technologies driving innovations in the MedTech sector. However, it is not a complete framework to study inclusiveness in MedTech innovations for the early detection of cancer in the Indian scenario. The key limitations involve missing complexities of unmet needs and demand variations and the political economy of healthcare in the Indian context. I found heuristic by Srinivas (2012) mitigating these limitations.

Given these directions and gaps, I investigate the following sub-research questions in the thesis:

(1) How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings?

(2) What are the key actors and factors that influence the development, diffusion, and adoption of MedTech conducive to a local health system, and in what way do they interact with each other to address the early detection of cancer?

(3) How do these factors influence the development of inclusive MedTech innovations for the early detection of cancer in India?

(4) How can such inclusive MedTech innovations be mainstreamed into health systems for their 'last mile' diffusion in India?

Focussing on phase 4 of both section 2.2 and 2.3 highlighted in Chapter 2, and based on the theoretical and empirical gaps, the next chapter proposes a novel theoretical framework which combines the elements of SSI and the qualitative heuristic of the institutional triad of healthcare. In doing so, it presents a framework to study emerging MedTech innovations that are showing signs of mainstreaming of inclusiveness in MedTech in India. It also presents research methodology of this thesis.

Chapter 4: Inclusive Health Innovation framework and research methodology

4.1. Introduction

In this chapter, I propose the Inclusive Health Innovation (IHI) framework, a novel theoretical framework and present the research methodology adopted to test the framework. I present the chapter in six sections.

In Section 4.2, I explain the IHI framework, which combines elements of SSI and qualitative heuristics of health care. It provides an inclusive lens to study the technical change in the MedTech sector. It does so by offering an evolutionary approach to understand the development, diffusion, and adoption of MedTech innovation for the early detection of cancer in India. I highlight that the combination of two frameworks allows two key advances. First, a deeper understanding of a wide range of factors that influence the development, diffusion, and effective adoption of innovative products in emerging Medtech. Second, providing ex-ante tools for public policy by bringing a better understanding of 'inclusiveness' in the innovation process and outcomes in low-resource healthcare settings.

In Section 4.3, I connect the IHI framework with research questions.

In Section 4.4, I present the policy implications that the IHI framework enables for the early detection of cancer in India.

In Section 4.5 of this chapter, I present the research plan and methodology adopted to collect and analyse data to test the framework in the real-world context. I use an exploratory landscape study of the early detection modalities for cancer in India. For an in-depth understanding of the innovation process, I use multiple case study research design to study 4 cases of point-of-care Medtech innovation for the early detection of cancer. I use online semi-structured interviews for primary data collection and a range of secondary data sources to triangulate the evidence for both landscape studies and case studies. The data collection was scheduled in two phases for landscape and then for in-depth case studies to answer all research questions. I faced several challenges in the data collection process as it was scheduled during the peak of the COVID-19 pandemic. I explain the challenges and the mitigation strategies I adopted to continue the study. I then present the approach to analyse the empirical data. In Section 4.6, I summarise the chapter bringing together the IHI framework and research methods.

4.2. Introducing the novel theoretical framework

The IHI framework incorporates insights from the periodisation analysis of Chapter 2 and theoretical gaps in Chapter 3. The framework facilitates an understanding of the development, diffusion, and adoption of MedTech innovation for the early detection of cancer in the Indian context (see Figure 4.1).

Figure 4.1: Inclusive Healthcare Innovation framework
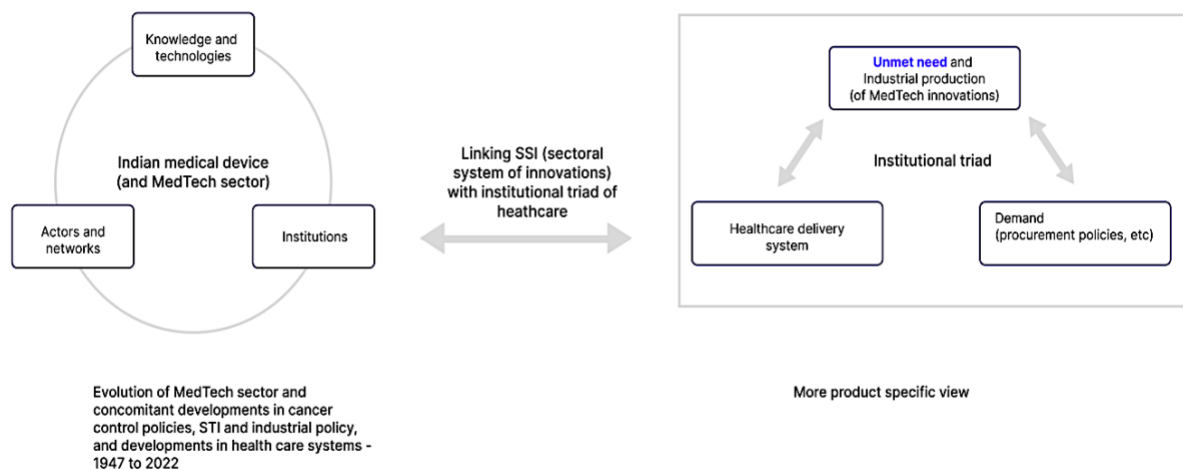
Source:Authors' adaptation of SSI and triad to contextualise industrial production of health innvoations and its adoption.

It does so by, first, using SSI for a deeper understanding of all components of the sectoral ecosystem, which goes beyond any product or innovation. To outline briefly, the SSI approach is valuable in understanding sectoral developments due to its foundations in

(1) evolutionary theory, which places dynamics, process, and transformation at the centre of the analysis, and

(2) the innovation systems approach, which considers innovation as an interactive process among a wide variety of actors (Malerba, 2005). It suggests that various factors influence innovation and production in a sector (Malerba & Mani, 2009), including:

(a) firm-specific variables, which are learning and capabilities, R&D, production investments, strategies, and organisational structure, and

(b) broader knowledge and technologies that categorise a sector, links with other sectors, the role of actors (competitors, suppliers, users, universities, financial organisations, public agencies, and government), and demand characteristics and types of institutions.

Thus, it enables conceptualising inclusiveness in the MedTech sector in India, which is rapidly gaining technological capabilities. These technological capabilities are driven by advanced computing technologies, including artificial intelligence (AI) and machine learning (ML).

On the other hand, the institutional triad of three domains – industrial production, demand, and healthcare delivery – help in defining the linkages between health and industrial policies. They show these linkages by pointing out the strong role of these domains in the development of health sector performance and industrial growth. However, the cumulative interactions between these three domains are often neglected in health system research and industrial policy analysis. The co-evolutionary triad domains facilitate understanding the role of technological advances and problem-solving innovation in bridging the gap between industrial concentrations and health deprivation (Srinivas, 2012, 2016, 2020). They reconceptualise the roles of health planning and developmental state to take cognisance of technical advances rather than merely taking them as given. This element guides policies, institutions, and market varieties to showcase the compatibility (or not) of MedTech innovation for early detection of cancer with the health care delivery system to address prevailing needs. To capture these needs in the framework, I have introduced a new element of 'unmet need', which is crucial to study on inclusive innovation. Table 4.1. provides a visual representation of how analysis using IHI framework can be presented.

Table 4.1. Using IHI framework to analyse cases of MedTech innovations

Triad institutional domain / Sectoral systems of innovation	Unmet need and industrial production (1)	Healthcare delivery (2)	Demand (3)
Knowledge and technologies			
Actors and networks			
Institutions	According to SSI, institutions include rules, laws, standards, regulations, established practices, etc. To extend SSI, different domains of institutional triad emphasize the variety and bundles of institutions for healthcare system in India. Therefore, for IHI framework I highlight 'institutional bundles' in green in Table 7.12		

Source: Author's representation of IHI framework.

In Chapter 7, I summarise the analysis using the template from Table 4.1 (see table 7.12). I next explain how each element of the IHI framework enables the study of inclusiveness in innovation for the early detection of cancer driven by the technical change in MedTech sector.

4.2.1. Knowledge and technologies

SSI approaches suggest that knowledge base, technologies and inputs define the nature of sectoral boundaries and influence the behaviour and organisation of firms (Malerba, 2005). Sectoral boundaries are not fixed and change over time, specifically for sectors like MedTech, where innovation is rapid. These boundaries are shaped with several links and complementarities, either static or dynamic. Dynamic complementarities are significant sources of transformation and drive innovation and change because they consider interdependencies and feedback at the level of demand and production (ibid). Literature on innovation systems considers the firm as the key unit of analysis and suggests that knowledge transfers and exchange within and between firms influence a firm's capability to innovate. The IS approach puts 'learning' as a key determinant of

innovation. It reflects innovation as an interactive process in which firms interact with other firms as well as non-firm organisations (including universities, research institutes, government agencies, etc.), and their actions are shaped by institutions (Malerba, 2005).

I am using innovation for the early detection of cancer as the unit of analysis to analyse different case studies. I describe the rationale for using this unit of analysis in the next section on research methodology. This change helped in studying knowledge in the broader context of the health sector in India. In particular, how the trajectories of knowledge and technologies have shaped innovation in MedTech in India. More specifically, the choice of this unit of analysis is crucial in the context of this thesis as it allows the identification and analysis of the various actors and factors that influence the development of inclusive innovation (see 4.2.2). In previous chapters, I discussed emergence MedTech innovation focussed on addressing local health needs and filling gaps in the health care delivery system. However, who is innovating in this space? What is the nature of knowledge and technology? Since mere knowledge does not result in innovative solutions but rather creative applications, how are knowledge production and transfer happening? Literature suggests that the studies on knowledge creation and transfer theory in business management and administration are mechanistically compared to neurobiological and psychological perspectives (Philipson, 2020). Therefore, while firm-specific learning is pertinent to reflect on, the human experience is also essential. In this regard, this thesis also explores the professional and personal motivations of innovators and the team in conceptualising innovation and developing technologies (Chapter 6). It showcases that human experience is diverse and differs from one individual to another (ibid). The role of tacit knowledge is instrumental in depicting such experience.

The seminal work of Polanyi (1966) posits that knowledge is either tacit or rooted in tacit knowledge and cannot be entirely explicit. Examples in day-to-day life are the activities we do without realising how they are done, making unconscious efforts to utilise tacit knowledge. Polanyi (1966) highlights things we know and cannot tell, like riding bikes (knowledge). How do we balance? How do we recognise faces? He describes that tacit knowledge can be possessed by itself, but explicit knowledge must rely on being tacitly understood and applied. Thus, tacit knowledge and explicit knowledge are interlinked. The knowledge applied in science and technological efforts consciously utilises tacit knowledge (Senker, 1995). This perspective helps understand the knowledge exchange of different people associated with technological development pre-incubation of the start-up and post it.

Koskinen and Vanharanta (2002) suggest that tacit knowledge can play an instrumental role in small technology companies' innovation processes, particularly at the beginning of the innovation process, like product development. Small technology firms have an advantage in utilising tacit knowledge over MNCs, primarily due to their non-bureaucratic organisational structure through informal interaction among people, leadership style, and interactive learning by engaging with their customers. Since a range of innovative MedTech is introduced in the start-up space, the framework also highlights the differences in knowledge utilisation both at the level of individuals and the firm (viz. MNCs vis-à-vis small companies) and in the global supply chain. So, while modified elements of SSI help in understanding the nature of knowledge and technologies, the qualitative heuristic helps in understanding how institutional and market varieties help in generating (viz. R&D, open-source innovation) and utilising (viz. product development, intellectual property) the knowledge and technologies. It also elaborates on co-evolution of vertices of the triad – unmet clinical needs, industrial production, collective demand, and health care delivery system.

4.2.2. Actors and networks

The systems of innovation dimension in the SSI approach considers innovation as an interactive process among various actors. Actors are the heterogeneous agents that are characterised by specific learning processes, competencies, beliefs, objectives, organisational structures, and behaviours, comprising (Malerba, 2005),

    (i) organisations

        a. firms (e.g., users, producers, and input suppliers)

        b. non-firm organisations (e.g., universities, funding organisations, government agencies, multilateral organisations, technical associations)

        c. subunits of larger organisations (e.g., R&D or production departments)

        d. groups of organisations (e.g., industry associations)

    (ii) individuals (e.g., consumers, entrepreneurs, scientists)

These actors interact through processes of communication, exchange, cooperation, competition, and command and are connected in various ways through the market and non-market relationships that are broader than the market for technological licensing and knowledge, inter-firm alliances, and formal networks of firms (Malerba, 2002, 2005). The types and structures of relationships and networks differ in every sector based on knowledge, learning processes, basic technologies, demand characteristics, key links, and dynamic complementarities. For this reason, innovation and production involve systematic interactions among various actors for generating and exchanging knowledge relevant to innovation and its commercialisation. 'Boundedly rationality' of different agents makes them act, learn, and search in uncertain and changing environments (Malerba, 2002).

The evolutionary theory emphasises how previous learning and experience and the environment in which agents act relate to cognitive aspects such as beliefs, objectives, and expectations (ibid). Thus learning, knowledge and behaviour entail agents' heterogeneity in experience, competencies and organisation and their persistent differential performance. Hence, the systems dimension of the sectoral perspective underscores the non-linear view of innovation, suggesting that innovation does not happen in isolation. Instead, they interact with other organisations to generate, acquire, and develop the knowledge used to develop and deploy new products and technologies. Understanding the actors also gives a more refined understanding of who is innovating? and for whom? And who channels the adoption? (Heek et. al, 2013; Mazumdar et al 2022)

4.2.3. Institutional variety

The SSI approach suggests that the institutions shape the actions and interactions of the actors (Malerba, 2005). These institutions include rules, regulations, routines, habits, established practices, laws, and standards. A variety of institutions are described as binding or enforcing on agents, ranging from more binding to less binding and formal and informal. Some institutions are sector specific (for instance, regulations, STI, health and industrial policies), while there are also various interconnections between national and sectoral institutions (for instance, national institutions such as the patent system, property rights or antitrust regulations that have different effects on innovation in the sectors). However, as discussed in Chapter 3, institutional variety is missing in most innovation studies' frameworks, including SSI. The innovation systems literature misses fully capturing the role of government that can be politically motivated, mainly in complex governance structures. For instance, MedTech and, broadly health sector is not divided under traditional ministries and agencies but is spread over different ministries targeting different

segments of the same sector (Chapters 2 and 5). Moreover, as stated on several occasions in the thesis, the state governments implement health policies, which may have agendas that may or may not match long-term health priorities. An example can be seen in policies that are biased towards instruments that often have a high cost per beneficiary and thus limited outreach, viz. technological clusters, technology transfer centres, science parks, and incubators, instead of more extensive market solutions like streamlining doing business (Alternburg, 2011). Therefore, more emphasis is required to be shed on analysing the political economy of the health sector.

The institutional triad helps engage in the development complexities of the health sector due to the co-evolution of three institutional domains, underscoring a combinatorial notion of how multiple institutional effects can occur at once and change as well (Srinivas, 2020):

(1) Unmet needs and industrial production of health innovations: This element of the triad entails development of industrial capacity and production elements using knowledge exchange, technological learning, testing, prototyping of technological solutions (Srinivas, 2012). To add an inclusiveness dimension, I added capabilities to frame and solve unmet needs by explicitly defining it for local context. Adding 'unmet needs' along with industrial production in institutional triad emphasizes a specific kind of capacity to develop innovation and production capability that are relevant for both industrial development and health services. This element of the triad engages with STI and industrial policy by Ministry of Science and Technology, Ministry of Commerce and Industry, Ministry of Chemicals and Fertilizers, AI related policies, impact capabilities to develop AI and ML based PoC Medtech innovation, supporting development of context specific solutions for early detection of cancer for low resource healthcare settings.

(2) Provision of health care delivery: This domain of triad involves health policy instruments that channel actors through which innovation can be adopted in the healthcare system, including primary and community health centres, private and public hospitals, clinics, diagnostics provider.

(3) Demand of health care: This triad domain focuses demand through individual or collective buying systems, including procurement policies (also see discussion demand in Chapter 3). Another critical aspect is an evolutionary understanding of the emergence and transformation of demand which plays a significant role in the dynamics and evolution of healthcare innovation, as it includes individual consumers, firms, and public agencies, each characterised by knowledge, learning processes, competencies and goals and affected by social factors and institutions.

Co-evolution of these three triad domains emphasises the interdependency between STI, industrial, and health policy in the shaping of sectoral developments and in innovation, production, and adoption.

4.3. Connecting the framework with research questions

My framework facilitates a bottom-up approach to investigate the research questions by engaging with the research questions. It does so by allowing us to study and theorise the Medtech sector in India, which is building industrial capabilities with a range of complementary developments within and in other sectors. This includes crucially the growing integration of advanced computing in devices with the rise of AI. At the same time, understanding such technological advances can bridge the gap between policies and the health sector to overcome the contrasts of industrial concentrations amid health deprivation (ibid). Such peculiar features are observed in some industrialising countries, like India, which have developed supply facilities, including many hospitals, diagnostics labs, firms, and universities coexisting with a lack of health access. Qualitative heuristics take cognisance of technical advances rather than merely taking them as given. Elements of SSI and the qualitative heuristic facilitate study of the 'problem-solving' aspect of innovation. They help in finding the type of state capacity required to reconcile industrial and health goals, not as a consequence but as an essential part of development plans (Srinivas, 2016).

4.4. Public policy implications

Several countries have implicitly used health policies to guide industrial policies, which have helped achieve better health outcomes (Mackintosh et al., 2016). However, in the Indian case, particularly in the case of pharmaceuticals, technological advances instilled economic and industrial growth, but health outcomes have not improved in line with innovation. The primary task facing the state is the alignment of health and industrial goals in the developmental agenda. Thus, the conundrum of a robust pharmaceutical industry and a large population lacking access to medicines provide the precedent to calibrate a more conducive policy ecosystem for India's broader medical device sector, mainly MedTech, which is showing some signs of policy convergence and inclusiveness (Chapter 2 and 3). This is particularly important as the sector has witnessed an increase in MedTech innovation that mainstream inclusiveness in recent years. A one-size-fits-all approach may fail to capture the nuances of studying such inclusive innovation. Therefore, my framework helps understand the larger MedTech ecosystem and who is innovating

and for whom? What is available in the market, and how are these innovations addressing the unmet clinical and health needs? On the one hand it provides a better understanding of an evolving sector; on the other hand, the framework helps in providing public policy considerations for the diverse setting of India. India faces substantial epidemiological and institutional heterogeneity across states, allowing for studying various scenarios across Indian states, such as medical technology innovation clusters in Bengaluru (Karnataka, India). The framework allows the factoring-in of nuances of state-specific institutions in the Indian context, including:

1. 'health' is a state subject in India as per the Constitution of India, i.e., whilst national policies provide an overarching framework, the states have the prerogative of implementing health-related matters,

2. each Indian state is in a different epidemiological transition stage and has different health care delivery and finance mechanisms amid a lack of a unified health financing scheme.

Using the triad heuristic, the thesis elaborates on the signs of inclusion by delving into the role of states in operationalising the reconciliation of these two goals in the case of MedTech innovation for the early detection of cancer. Using the institutional triad to complement SSI, the combined framework facilitates a more profound understanding of how India has and can sustainably operationalise the reconciliation of these two goals to calibrate a conducive policy ecosystem for the MedTech sector in India.

IHI, combining elements of SSI and institutional triad by capturing focus of innovation production on unmet needs, allows exploration of the role of policy instruments and institutional framework in operationalising:

(1) Understanding of the needs and gaps in and from the prevailing early detection modalities

(2) Building of technological and industrial capabilities to address these gaps.

(3) Translation of health needs into demand for innovative solutions, and finally,

(4) Ensure emerging inclusive innovation fit the delivery and consumption profile for generating demand and integrating health care delivery mechanisms.

The IHI framework facilitates understanding of the seriously deficient industrial and health system linkages in developing and adopting emerging inclusive innovation in LMICs. It does this by providing an alternative approach to understanding the factors influencing industrial production and the effective diffusion and adoption of inclusive innovation in India that aim to fulfil unmet health needs and focus on improving quality of life. Building this understanding requires targeted engagement with the perennial dilemma of policymakers. The dilemma is to ensure policy instruments directed at developing local industrial capabilities do not set against the needs of the local population and health system. It is an evolving approach to studying inclusive health innovation at large and a step in searching for alternatives by focussing on local context and health needs. The aim is to nudge interest groups and policymaking institutions to harness the potential of innovative solutions in MedTech to facilitate inclusion. Moreover, inclusive innovation may, in turn, become a new goal for innovation efforts (as introduced by Arocena and Sutz, 2016).

In summary, the IHI framework underscores a bottom-up approach and a co-evolutionary perspective, highlighting the non-linear and iterative process of development of innovation shaped by institutions and knowledge exchange that creates new markets by transforming unmet clinical needs to demand. It allows analytical investigation of the role of sectoral systems in shaping innovation that mainstream inclusiveness, importantly aligning health and industrial goals in the developmental agenda. At the same time, it enables an understanding of the state capacity required to reconcile industrial and health goals, which are an essential part of development plans (Srinivas, 2016). Thus, the originality of this framework stems from the fact it highlights the need to extend SSI approach to study both early detection of cancer and the concomitant MedTech innovation and allows extension through focus on healthcare systems, which is also a more gendered area of study.

The next section of this chapter elaborates on the research methodology adopted to gather empirical evidence to test this framework.

4.5. Research design, methodology, and analysis

In this section, I present the research approach of the study, including the broad assumptions, methods of data collection, analysis, and interpretation. I first discuss the research philosophy that guides my research methods. I then explain using multiple case study research design to investigate 'inclusiveness' in the MedTech innovation in the Indian context. I present the research setting, criteria of selecting case studies. I then present data collection methods corresponding to each research question and data analysis strategy.

4.5.1. Research philosophy and strategy

The main research question of the study uses policy as a tool to influence inclusive innovation – to what extent can STI, health, and industrial policies be aligned to facilitate the development and adoption of inclusive innovation for the early detection of cancer care in India? The aim of the research is to answer the following sub-research question that informs the overarching question at the centre of this study:

(1) How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings?

(2) What are the key actors and factors that influence the development, diffusion, and adoption of MedTech conducive to a local health system, and in what way do they interact with each other to address the early detection of cancer?

(3) How do these factors influence the development of inclusive MedTech innovations for the early detection of cancer in India?

(4) How inclusive MedTech innovations are mainstreaming into health systems for their 'last mile' diffusion in India?

Given the above research questions, the underlying research strategy is based on understanding inclusiveness in Medtech innovations for the early detection of cancer using the IHI framework. This comprises two main aspects (a) technical change in the Medtech sector by knowledge and technologies, actors, and networks, and (b) the institutional variety that enables it. Therefore, it requires a theory-driven research philosophy.

Research philosophy provides a framework to guide the research based on ideas about reality and the nature of knowledge. It provides an essential guide for designing the study and data collection process. It shapes by different ways of knowing (ontology) and how we explain and share our understandings (epistemology). This research aligns with critical realism (Bhaskar 1975). It offers a theory-driven approach to understanding the mechanisms of what works, in what circumstances and how structures work (or not) in their contextual setting (Pawson & Tilley, 1997), rather than simply measuring outcomes. Critical realism has been used in numerous research studies involving qualitative methods in the health sector. One such example is the functional, structural problems in the Indian context, like trust in large biometric infrastructure (Masiero, 2018). A key strength of critical realism is that it enables a researcher to explore different aspects of reality which may not be apparent from a single perspective (Bhaskar et al., 2008). This characteristic enables more comprehensive results and nuanced insights and patterns by combining objectivity with subjectivity compared with a single perspective. Additionally, critical realism encourages researchers to acknowledge the power dynamics at play in any given context, facilitating meaningful and equitable interpretations of data when used in understanding technical changes in the MedTech sector in India.

In the thesis, an exploratory landscape study of early detection modalities and comparative case study design uses both quantitative and qualitative research methods. Studies suggest that case study research design is one of the best approaches to be used in critical realism philosophy (for instance, Easton 2010). This is because case study research design enables a deeper insight into complex social phenomena by the interaction of structure, events, and actions, allowing multiple perspectives and identifying any underlying causal relationships. Next, I explain the relevance of the case study research design in this study. I mainly focus on its applicability in understanding social phenomena by examining the underlying structures, processes, and mechanisms of a particular context.

4.5.2. Case study research design

In this research, I use multiple case study research designs using four cases of point-of-care innovations for the early detection of cancer embedded in the landscape discussed in Chapter 5. Table 4.2 sets out potential research methods to answer specific research questions.

Table 4.2: Relevant Situations for Different Research Methods

Method	Form of RQ (a)	Requires control of researcher over behavioural events. (b)	Focuses on contemporary events (as opposed to historical events)? I
Experiment	**How,** Why?	Yes	**Yes**
Survey	Who, **What,** Where, How many, How much?	**No**	**Yes**
Archival Analysis	Who, **What,** Where, How many, How much? To what extent?	**No**	**Yes**/no
History	**How,** why?	No	No
Case study	**How,** why**?**	**No**	**Yes**

Source: Table from Figure 1.2. Relevant Situations for Different Research Methods, Yin (2018).

Based on the table, survey methods, archival analysis, and case study methods are the most appropriate to answer the form of RQ raised in this thesis. The 'what' questions are more exploratory. To answer the questions of 'what' and 'to what extent' I used archival analysis and document review, as they also satisfy (b) and (c). Experiments, history, and case studies are appropriate methods to answer the 'how' question. While experiment allows study of 'how' questions, it requires the researcher to control actual behavioural events, which is inappropriate in this study. A historical account does not require (b) but focuses on a historical event and does not focus on contemporary events. For the purpose of this study, the most suitable method was a case study as it facilitates the study of contemporary events (emerging Medtech innovation) and does not require the researcher to have control of behavioural events.

Case study research design is an empirical method that facilitates an in-depth investigation of a contemporary phenomenon in its real-world context, where the phenomenon and context are not distinctly evident (Yin, 2018). The strength of this approach lies in its ability to provide comprehensive data on the specific context through a single case or multiple cases, mainly those that are difficult to measure quantitatively (Reichert et al., 2016). It allows researchers to identify patterns, relationships and causal links that would otherwise remain hidden using more general methods such as surveys or interviews (Yin, 2009). In addition to Yin's approach, this thesis is inspired by Extended Case Study Method by Burawoy (1998), which applies reflexive science to ethnography to extract the general from unique, move from micro to macro, and connect the present to the past in anticipation of the future, all by building on pre-existing theory.' Burawoy described reflexive science as a model of science developed based on 'dwelling in' theory that adopts engagement, and not detachment, to knowledge. This model is premised on the self-participation of the world and uses multiple dialogues to engage with empirical phenomena. However, while the thesis inspires from the essence of 'dwelling in', in practice, an ethnographic study to understand various actors and networks and making observations by being directly in the field context was not possible due to travel limitations during the COVID-19 pandemic.

The empirical data collected from the cases enables identification of patterns and relationships the development and testing of theories and hypotheses in larger studies. These characteristics of case study research designs allow researchers to develop deep insights into a particular phenomenon, and critical realism provides a valuable framework for understanding the underlying mechanisms that drive this phenomenon. For example, using cases of PoC MedTech innovation in the Indian context, critical realism facilitates exploring factors that influence the development, diffusion, and adoption of these innovations in India. This highlights the strengths of case study research, including its ability to provide rich, contextualized data to understand existing phenomenon and generate hypotheses that can be tested in future research (Yin, 2014).

However, one needs to exercise caution when using a case study research design. If the focus is on one single or few cases or phenomena there is a potential lack of generalisability and difficulty in replicating results (Yin, 2014). In terms of the generalisability of case research, Yin (2017) suggests that case studies are an opportunity to shed empirical light on theoretical concepts or principles instead of merely a sample. Nonetheless, multiple cases are selected to reduce any prospective bias. Further, the theoretical framework which aids the initial design of the case

studies presents an opportunity to test empirically enhanced by the case study's findings in the Indian context and can potentially form the groundwork for analytic generalisation for LMICs.

In this study, I focus on conceptualising inclusiveness in the emerging MedTech innovations for early cancer detection in India. I do so by studying the actors and factors that influence the development, diffusion, and adoption of these innovations in the Indian context. This area is very under researched. First, inclusiveness is in danger of being a catchall phrase despite gaining momentum in public policy. Also, the medical device sector is a multi-product sector. Therefore, a consolidated view of the sector in terms of the size of the market in value or volume does not reflect the nuances of each sector segment. There is a dearth of studies and databases that provide comprehensive empirical insights into various segments of medical devices, particularly for LMICs. Such data or information is available primarily in high-income countries and is expensive and difficult to access. There is a lack of empirical studies emphasising the inclusive role of innovation by understanding the factors that influence their development, diffusion, and adoption. Particularly to what extent the role of policies reconciles the unmet needs with the industrial production of innovation and their sustainable last-mile diffusion in the health systems. Therefore, the focus of this thesis is specific, to provide an in-depth perspective on the MedTech segment, with a particular focus on the early detection of cancer, in the Indian context. I define a case as development, diffusion, and adoption of PoC MedTech innovation for early detection of innovation offered by for-profit start-ups. The selection criteria of case studies are described later in chapter. In Figure 4.2, I present the visual representation of the research design adopted in this study.

Figure 4.2: Visual representation of the research design
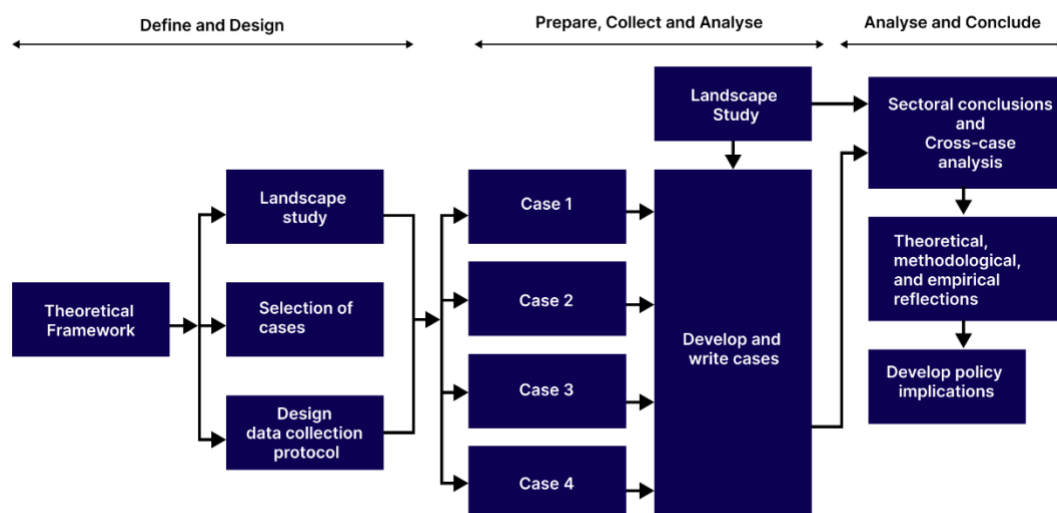
Source: Author's representation of the research design.

4.5.3. Research setting

I focus on India as the research setting for several reasons. First, oral, breast, and cervical cancer are among the leading causes of death, and, at present, the coverage of public screening is low. While the treatment of cancer is expensive, there are huge concerns over the availability and access to affordable and appropriate medical devices and diagnostics that could substantially reduce the cost of the treatment. Second, according to the Constitution of India, 'health' is a State subject in India, i.e., whilst national policies provide an overarching framework, states have the prerogative of implementing health-related matters, including cancer. Therefore, the one-size-fits-all approach does not work for the Indian health system and allows for studying various comparable scenarios across states. Third, in recent years, there has been a surge in MedTech innovations that mainstream inclusiveness. This gives an opportunity to study the institutional bundle that channelled this inclusiveness. This is important because historically coherent STI and industrial policy have been missing or neglected health goals.

4.5.4. Data collection methods

(i)   Original project and data collection plan – pre-pandemic

The data collection plan of the study was originally designed employing a mixed methods approach (survey and semi-structured interviews) for the case study of breath analysis tool developed by Oxford Micromedical Ltd.[17] The tool is a non-invasively test for H pylori bacteria for stomach cancer screening and was expected to roll out in India in partnership with Tech Mahindra in 2020. Accordingly, I planned to employ using three methods document review, questionnaires for landscape study, and face to face semi-structured interview. The document review was planned to design questionnaires for landscape study, identify stakeholders, and design semi-structured interviews. Then, a questionnaire was designed to gather a uniform and comparable set of answers for the landscape study of cancer diagnostics availability in India. Lastly, semi-structured interviews were planned. However, the project plan needed revisions due to two major reasons. First, funding to roll out the above test did not come through even by end of first year of research. The delays exacerbated due to COVID-19 disruptions. Given these challenges, further literature review and India's policy focus, I expanded the scope from stomach cancer screening to other breast, cervical and oral cancers. Without a structured database for early detection modalities, I planned to conduct a detailed landscape of the different early detection modalities available in India. I planned two phases of data collection: Phase 1 (July 2020 – September 2020), a questionnaire component to support the landscape study of the Medtech sector and face-to-face semi-structured interviews from July to December 2020 and Phase 2 (April 2021 to June 2021). However, these plans were disrupted due to COVID related uncertainties explained below.

(ii)   Impact of the COVID-19 pandemic in planning data collection

It is pertinent to mention that the COVID-19 pandemic impacted the research methods and data collection strategy of this research, originally planned to start in August 2020. There were several uncertainties in data collection due to evolving situation of the COVID-19 pandemic, constant

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[17]The link for advert is provided for more information on the original project: https://www.open.ac.uk/about/employment/sites/www.open.ac.uk.about.employment/files/Job%20Related%20Information%2011756.pdf (last accessed on 21 January 2023).

lockdowns, and travel restrictions in the UK and India through 2020-2021. The face-to-face fieldwork in India got postponed, delayed, and eventually cancelled to minimise the risk of COVID-19 to both the respondents and me as a researcher. After completing my upgrade exam in May 2020, I continuously updated my data collection plan and eventually to switch to online research methods completely. Moreover, the guidance provided by the UKRI strongly advised all funded students to speak to adjust their projects to complete a doctoral-level qualification within their funded period.[18] I finally started collecting data in October 2020 after obtaining a favourable opinion from the Human Research Ethics Committee (HREC) of the Open University. I amended the original plan of face-to-face data collection to remote data collection methods per the HREC guidelines relating to the COVID-19 pandemic. Accordingly, an integral component of primary data collection involved online questionnaires by Qualtrics and online semi-structured interviews with various stakeholders and interest groups. I piloted online questionnaires by Qualtrics by sharing an online set of questions with some firms developing early detection technologies for cancer, but there were no or limited responses. Given the limitations, and paucity of time and resources, I decided to only use online semi-structured questionnaires and a wide range of secondary data sources. Thus, given several uncertainties of lockdowns, evolving understanding of the COVID policies related to travel in the UK and India, and feasibility issues, the data collection methods were revised for landscape study and identification of case studies to mitigate COVID-19-related disruptions.

(iii)   Revised data collection methods and sampling

Table 4.3 presents the final data collection methods adopted in this study for each research question.

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[18] https://www.ukri.org/news/doctoral-students-advised-to-adjust-projects-for-covid-19/

Table 4.3: Research question-wise data collection methods

Research Questions	Data collection methods		
	Archival data and document review	**Online semi-structured interviews**	**Webinars, Online conferences, Podcasts, and social media**
RQ1	Review of policy documents National STI, industrial and health policy documents Department-related Parliamentary committee reports Rajya Sabha and Lok Sabha questions Regulatory reports and committees	Phase 1: Policymakers, diagnostic companies, industry experts, researchers, representatives of industry associations Phase 2: Innovators, biomedical engineers, venture capitalists, clinical research scientists, incubators	**Key online conferences and webinars:** APACMed Medtech Forum 2021 – Conference Global Healthcare Conclave Oncology TechSparks 2021–- Technology, innovation, and leadership summit in India Webinar Global changes affecting Medical Devices Intelligent Healthcare: AI Today & Beyond Roundtable Discussion: Rising Need for Gender Lens Investing to Solve India's Complex Healthcare Challenges Interactive Meeting with Regulator, Licensing Authorities on medical device regulations WHO Compendium of Innovative Health Technologies for Low-resource Settings **Podcasts episodes:** ICCA India Podcast; Forbes India: The daily tech conversation; The Healthtech Podcast; The Healthtech narrative podcast; Yourstory; Inside India **Social media:** Verified social media accounts (Twitter, Instagram, and LinkedIn) of innovators and start-up firms of selected case studies
RQ2 and RQ3	Clinical research data on early detection of oral, breast, and cervical cancer, including what kind of research, who is conducting research, funding agencies, and types: Cancer Trial Registry of India Comparing cancer control policies and MedTech policies		
RQ4	Policy documents on procurement, health care delivery system, and population-based and hospital-based cancer registries in India		

Source: Author's presentation of data collection methods

I collected data in two phases. First, I conducted an exploratory landscape study of MedTech for the early detection of cancer to understand the nature and varieties of emerging technologies in

the Indian context (RQ 1, 2 and 3). Second. for in-depth insight, using a case study research design, I selected 4 case studies of PoC MedTech innovation for the early detection of oral, breast and cervical cancer (RQ 1, 2, 3).

Phase 1: Landscape study

The data for the landscape study of MedTech for early detection of cancer was collected using archival data and documents review followed by online multistakeholder semi-structured interviews. I conducted a thorough policy analysis of STI, health and industrial policy, regulations, and health care delivery system-related documents for 75 years (1947-2022) to study a broad medical device and in specific MedTech evolution, and parallel cancer policies in India (Chapter 2). The document review of institution-specific documents, regulatory data, nature and scale of innovation, their market entry strategies, etc., helped identify specific knowledge and technologies, actors and networks and institutions in MedTech for early cancer detection. I collated a list of innovators (including MNCs, small and medium-sized companies, start-ups, research institutes, and independent researchers) developing and commercialising innovative technologies for early detection of cancer from a range of secondary resources. It also helped me in identifying potential respondents to contact for online semi-structured interviews for the landscape study. The semi-structured interviews facilitated deeper insights into the landscape of MedTech innovation for cancer in India.

The study used a purposive sampling method, selecting study participants because of qualities/characteristics they possess, followed by snowballing in selecting the respondents and other relevant stakeholders. Purposive sampling was used because it is a niche sector with key opinion leaders, mainly in the supply side institutions, including policy institutions, regulators, industry associations, etc. The key opinion leaders provided an overview of the MedTech sector in general and prevailing challenges of cancer detection and screenings in India, both from the perspective of the providers (for instance, government screening programmes, hospitals, and diagnostics firms) and patients (as reported by clinical researchers), emerging technologies (as highlighted in government funding schemes, incubators, clinical researchers). I asked questions on the emerging MedTech innovation in India, including the actors, the nature of innovation, and how innovation evolved in the cancer segment from industry representatives and representatives of industry associations and sector experts (see Appendix B). To the policymakers and regulators, the questions aimed at understanding the measures for early cancer detection and the evolution of medical device regulations. Broadly, the interactions also reflected the approach to understanding

the role of regulation and policy in influencing development, and as demand generators, in the form of signalling mechanisms of the government to reconcile health needs with innovation. Further, to ensure a better response rate, representatives of large and small and medium-sized firms will be contacted through various mediums, including emails, professional social networks (LinkedIn) and industry associations. Combining archival data and document review with the first round of multistakeholder interviews helped facilitate a nuanced understanding of innovative MedTech modalities for early cancer detection and opportunities and challenges in the sector.

COVID disruptions during online data collection

COVID brought challenges associated with the online data collection process, particularly as data collection was timed at the peak of the COVID-19 pandemic. First, there were challenges in recruiting the study participants:

(1) A periodic rise in COVID cases resulted in delays in recruiting study participants. The respondents were also facing physical disruptions in the usual work environment and mental well-being considerations due to uncertainties of the COVID-19 pandemic. The delays were also pressing because the potential key respondents for this study were healthcare professionals, hospitals, policymakers, and medical device innovators who were deeply involved in managing the local COVID situation.

(2) Online modality is not a favourable mode for all the stakeholders. For instance, some key policymakers and regulatory agencies have not been keen on online semi-structured interviews due to security protocols.

(3) Inadequate access to online modes of communication due to internet bandwidth issues at respondents' locations.

(4) The pandemic also witnessed a surge in online communication platforms like Zoom, Google Meet, Microsoft Teams, Skype for Business team calls, etc. The data collection process raised concerns about multiple online modalities requiring respondents to use multiple communication applications. For instance, people prefer using Zoom (which reported some security issues at the beginning of the pandemic) and Google Meet, not Microsoft Teams, which became the preferred mode for encrypted calling in phase 2.

(5) The time difference between India and the UK also affected the number of interviews.

Secondly, there were challenges with online engagement with respondents:

(1) Especially in cases where the respondents did not switch on their videos or were not comfortable switching on their videos, it was difficult observing their responses. It is easier to make the human connection face-to-face by establishing trust and observing the respondents' responses.

(2) A range of respondents, mainly innovators, were very keen on showing their labs and prototypes to understand the look and feel, which was impossible in the online modality.

Phase 2: Data collection of case studies

From the landscape study, I identified 4 case studies of POC MedTech innovation for early detection of oral, breast and cervical cancer in India to study the development, diffusion and adoption process and map inclusiveness from various dimensions. The following case studies were selected from the landscape:

(1) OralScan: a novel technology providing a radiation free, non-invasive, and handheld PoC device for the early detection of malignant lesions of the oral cavity.

(2) CerviScan: a novel technological handheld PoC device innovation for non-invasive and enhanced accuracy of early detection and grading of cervical cancer.

(3) Thermalytix: a novel technology which enhances privacy-aware screening of breast cancer lesions for women of all ages.

(4) CervAstra: a novel technology for faster computing of pap smear samples.

The insights derived during landscape study on various early detection modalities exemplified these cases and the diversity they offer despite being in the same selection environment. Three case studies offer an opportunity to study female technology (femtech) for early detection of breast and cervical cancer. And one is for oral cancer, which is affects both males and females, but predominantly men in India (see Appendix A1 to A3). These cases of PoC MedTech innovation were selected based on a multiprong selection approach:

(1) These cases reflect innovation to fulfil unmet needs of the screening and early diagnosis of breast, cervical and oral cancer, which are not met by existing technologies. All the case studies offer solutions that are conducive for the India healthcare system settings.

(2) These cases are driven by the personal motivation of lead innovators and their strong problem-framing and solving skills to respond to challenges of early detection of oral, breast, and cervical cancer in low-resource healthcare settings of India.

(3) All the cases have a ML and AI based component along with a hardware component, reflecting a change of trajectory of innovation in a sub-sector of import dependent medical device sector.

(4) These cases offered studying real-time progress of innovation, mainly CerviScan, which is yet to launch.

(5) Lastly, an element of convenience was involved because data was available from multiple sources for these cases, which was crucial in the data collection during the pandemic. Out of the 4 case studies, CerviScan is yet to launch in the market, which is why the data is available only for development process.

Two rounds of semi-structured interviews were conducted with the lead innovators, wherever possible, to elicit information on research questions. These included questions such as how factors impact their decision and ability to innovate, how past and prevailing policy ecosystems have impacted and shaped markets, what instruments supported their market strategies, the cost and timeframe of developing and commercialising innovation, and various business models. To triangulate the response, semi-structured interviews were also conducted with others associated with technological development and product innovation, including biomedical engineers, clinical research scientists, etc. In cases where interactions with lead innovators were not possible, I utilised publicly available interviews and podcasts, clarifying with follow-up questions in online workshops and webinars where they were a participant. I also utilised secondary materials and contacted with other key members associated with the innovation (for instance, incubators, biomedical engineers, clinical research scientist, etc.).

Learning from the challenges of Phase 1, I adopted a multipronged approach to mitigate the COVID-related disruptions for phase 2 of semi-structured interviews. I used diverse sources of

secondary data to bridge gaps in primary data collection. For instance, industry and government-organised webinars on MedTech regulations and policy; Twitter Spaces (live webinar) on early detection of cancers; verified account Twitter updates, Instagram live of innovators and clinical professionals, and podcasts. These secondary sources also enabled triangulation of the responses of semi-structured interviews. For instance, if the lead innovator was unavailable for a semi-structured interview, I collected data from diverse sources. These included participating in live discussions in webinars and online conferences, publicly available podcasts, and interviews, and verified social media accounts (Instagram, Twitter, and LinkedIn) associated with the case studies. I also triangulated data for case studies by conducting online semi-structured interviews with more people associated in the innovation process. For instance, clinical research scientist, biomedical engineers, incubators, investors, and clinicians, and even through secondary sources like podcasts, public interviews, and articles. Therefore, a multipronged approach comprising traditional and non-traditional research instruments played an instrumental role in the data collection during the pandemic. As I have been a policy researcher in Indian context, triangulating empirical data using this approach also enabled me to include multiple perspectives. In this manner, acknowledging my positionality, I emphasised on the reflexivity to present ethical and robust empirical evidence.

In total, 16 respondents voluntarily consented to semi-structured interviews in phase 1 and phase 2 (see Appendix C). I had follow-up interviews or email exchanges with respondents, who agreed to be contacted again in case further clarification was required. In addition to this, I interacted with several stakeholders in webinars and online conferences. I corroborated the insights using podcasts, publicly available interviews, and grey literature.

4.5.5. Ethical considerations and data protection

I ensured the potential respondents were not personally or professionally familiar with me to avoid any prospective bias and conflict of interest. Some participants might be familiar due to attendance in previous conferences and seminars, or they are experts and key informants of the sector. However, I do not know them on a personal basis. Moreover, to be objective and avoid any risk of bias, I referred to relevant literature (viz., positionality, issues of validity and reliability in qualitative research, etc.) to plan interviews and write this chapter on methodology. There was no compensation for participation in the study, and participation was on a voluntary basis. Instead, a periodic update on the study was given to those who opted for the study's progress. Given that the study includes cases of innovative technologies, I highlight that no business sensitive information on organisations or information that can be linked with a participant or risks

confidentiality of sensitive information is included in the thesis. All the online semi-structured interviews were conducted after obtaining informed consent from participants and anonymised in transcription. This research files of this study are stored in encrypted files in the cloud.

4.5.6. Data Analysis

(1) Unit of analysis

The unit of analysis to be used in this research is Medtech innovation for the early detection of cancer in India, while the evolution is analysed at the level of the MedTech sector and the nation-state policies to define the holistic context of the Indian health sector. The choice of unit of analysis reflects the nature of the research questions (Carlsson et al., 2002). I detail the choice of unit of analysis here because several reviews of innovation studies highlight that many studies of innovation do not mention the unit of analysis, which results in vague or convenient interpretations (Crossan & Apaydin 2010; Damanpour 2014; Silva & Di Serio, 2021).

As discussed last chapter and earlier in this chapter, this thesis presents a departure of the unit of analysis from 'firms' as in the case of most innovation studies. Even the SSI approach suggests the most appropriate units of analysis in specific sectoral systems are not necessarily firms, but individuals, firms' sub-units (such as the R&D or the production department), groups of firms (such as industry consortia) (Malerba, 2002). For instance, in sectoral systems such as MedTech, the key actors driving innovations could also lie outside the firm, for instance inventors, scientists, engineers, university department or a research laboratory. This is an important factor in determining unit of analysis to study innovation process. Studies have acknowledged the need for going beyond 'firm' as a unit of analysis to understand wider dynamics of innovation in which firms are a part of the innovation process but not central to it (for instance, Altenburg 2011). Some creative examples include Hill & Birkinshaw (2010) presented 'idea sets' as a new unit of analysis facilitating a better understanding of the antecedents, processes, and outcomes of entrepreneurial opportunity. Kornberger (2017) proposed shifting the unit of analysis of organisation design from the individual firms to networks of actors to study how to design organises distributed innovation systems.

The reason to focus on the innovation as a unit of analysis is to interact with all the research questions and facilitate framing the advances in the conceptualisation of inclusiveness in a sector that has been institutionally weak. This unit of analysis in a multi-case study research design

presents diverse aspects of emerging MedTech innovation, including knowledge sources and learnings, technology, identification of needs, institutional and market varieties shaping conceptualisation of demand, the process of development, diffusion, and adoption of innovation. Since multistakeholder semi-structured interviews was a key method of data collection, triangulated by several data source for validity, having a common lens helps in presenting a coherent narrative. However, presenting a coherent narrative does not mean that the study simplifies the complexities, albeit aims for an anchor to narrate the complexities of MedTech innovation for the early detection of cancer in India. Chapter 5 presents the landscape study at the level of the sector, keeping the evolutionary phases of Chapter 2 in consideration, and maps the emerging knowledge and technologies, actors, institutional and market varieties. Given this broad landscape, Chapter 6 presents the in-depth case studies of four innovation and depict how the broad actors utilise knowledge and technologies to address unmet clinical needs and transform the need to demand.

(2) Methods of analysis

The content analysis facilitated a review of key policy documents, including STI, health, and industry policies, cancer policies, and the health care delivery system from 1947 to 2022. This allowed analysis of evolution both at the level of the MedTech sector, and at the level of the nation- state policies.

I analysed the empirical evidence gathered from both phases using various analytical techniques. First, I transcribed all the online semi-structured interviews. I used manual coding by highlighting broad themes emerging from the data. I then used NVivo 12 software for detailed coding and comparing thematic content. This twofold process helped going beyond the linear process of coding using NVivo. I utilised analytical generalisations from theoretical frameworks and pattern-matching (Yin, 1994, 2017). Pattern-matching is a popular analytical technique used to analyse in case study research. It facilitates comparison between two patterns that emerged from theory to the empirical data to determine similarity similarities or differences for theory-testing. In case empirical and predicted patterns are the same, it provides a case study to strengthen its internal validity (Yin, 2017). It is a relevant method to analyse 'how' questions on conceptualising inclusiveness and understanding the influence of actors and factors.

Triangulation of data using publicly available podcasts and interviews and verified social media accounts (Instagram, Twitter, and LinkedIn) helped in a threefold manner:

(1) map the key actors and networks, knowledge and technologies and institutions from sectoral perspectives.

(2) understand the role of STI, health and industrial policies, and related institutions in signs of inclusiveness and the development of MedTech as a major subsector of the medical device sector.

(3) studying MedTech innovations as they were evolving real-time, for instance, interviews of founders in the public domain and podcasts at various points in time enabled triangulation of perspectives.

4.5.7. Chapter Summary

This chapter introduced an IHI framework and methodology to study the potential of MedTech innovation to facilitate inclusiveness. The IHI framework proposed integrates two evolutionary theoretical frameworks, the SSI approach, and the qualitative heuristic of the institutional triad. Based on the insights from Chapter 3, I have introduced a new element of 'unmet need' in the institutional triad. Unmet need is a crucial ingredient in studying inclusive health innovations. Thus, the focus on inclusion is a normative approach to studying innovation which aims to fulfil unmet health and clinical needs and focus on improving quality of life.

In terms of research methods, this study uses qualitative research methods to investigate research questions. Using a multiple case study research design embedded in a landscape of the early detection modalities of cancer, I examine two broad dimensions. First, conceptualising inclusiveness in point of care MedTech innovations for the early detection of oral, breast, and cervical cancers. Second, identify and analyse the influence of the key actors and factors in these innovation development, diffusion, and adoption. The data is collected and presented at two levels. In phase 1, an exploratory study was conducted to understand the landscape of MedTech innovation for early cancer detection in India. The landscape study was an essential first step to mitigate the unavailability of a database that provides comprehensive information on the nature and characteristics of this segment. Landscape study helped identify specific case studies, the preferred research strategy for an in-depth study of an under-researched topic. Therefore, in this study, I use data from multiple sources to examine the relationships, complex links and working procedures to enable continuous interaction between the research questions and the collected data (Yin, 2013). In phase 2, I selected four case studies of MedTech innovations for the early detection

of cancer embedded in the landscape using a multiprong criteria. I used online semi structured interviews with lead innovators (founders of startup), wherever available, and other core team members associated with the case study. I also used a wide range of non-traditional data sources to mitigate the challenges of reaching out to respondents during the pandemic. These included participation in webinars and online conference interactions with key people associated with a case study, publicly available interviews, and podcasts, and verified social media (Instagram, LinkedIn, Twitter Spaces). Using a wide range of sources enabled completing different shortcomings of case studies and triangulation to evidence increasing validity of arguments.

In the next chapter, I present the empirical evidence from India based on the research methods described in this chapter. Chapter 5 presents the landscape of the existing early detection innovation for cancer in India and provides a broad overview of MedTech's various actors and networks, knowledge and technologies, and institutional triad.

Chapter 5: The landscape: Situating the knowledge, actors and networks, and institutional variety of PoC MedTech innovations for oral, breast, and cervical cancer in India.

5.1. Introduction

In this chapter, I present an analytical landscape of the early detection modalities for breast, oral, and cervical cancer in the Indian context. I extend the discussion of Chapter 2, by identifying the institutional bundle that led to the emergence of the PoC MedTech innovations. I present this chapter in three parts, which are a function of the following research questions of this thesis:

1. How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings? (RQ1)

2. Who are the key actors, and what are factors that influence the development, diffusion, and adoption of MedTech conducive for a local health system, and in what way do they interact with each other to address early detection of cancer? (RQ2)

I analyse both primary and secondary data for this chapter. The primary data includes online semi-structured interviews with policymakers, representatives of key industry associations, incubators, senior management of diagnostic firms and firms offering various screening modalities of cancer. The secondary data includes publications of government multilateral organisations, relevant podcast and interviews, and insights gathered from online seminars and conferences (comprehensive details on methods is available in Chapter 4).

I use the IHI framework and an adaptation of the 2x2 scarcity-induced innovations (SII) matrix presented in Srinivas and Sutz (2008) to analyse the landscape of the early detection of cancer in the Indian context. The rationale for using this matrix is situates early detection modalities in their industrial context. The main assumption is that institutional bundles are a key explanatory variable for emergence of distinct technologies in industrialising LMICs (Srinivas, 2021). I next explain how to navigate the landscape using the matrix's four categorisation of early detection modalities in India. It is followed by discussions the early detection modalities presented in each quadrant.

5.2. Navigating the landscape using IHI framework and 2x2 matrix

I use Table 5.1 to illustrate the matrix and how each quadrant of it represents various institutional bundles available for different sets of early detection modalities. I segregate early detection

modalities using the IHI framework, presenting knowledge and technologies, actors, networks, and institutional variety from the co-evolution of three domains (tried element 1) unmet needs and industrial production of existing technologies / Medtech innovations for the early detection of cancer, (triad element 2) health care delivery, (triad element 3) demand. In doing so, each quadrant of the matrix represents how different technologies result due to specific combinations of institutional bundles comprising actors, knowledge, networks, and organisations. In doing this, different early detection modalities are represented in the following categories A, B, C, and D according to the types of cancer.

Section 5.3 presents Category A early detection modalities for cancer in the top left quadrant. These modalities are imported from industrially advanced countries, and the corresponding locally relevant technologies also exist in India. For instance,' gold standard' technologies including mammography (breast cancer), cytology screening using pap smear and HPV test (cervical screening).

Section 5.4 presents Category B early detection modalities for cancer in the top right quadrant. These are innovations not imported from industrialised countries but rather developed in India, solving problems for which no solution has been developed in industrially advanced countries. These include AI and ML based PoC MedTech innovations developed focussing on the local health context and unmet needs. In this case, technological learning in the local industrial environment has found solutions for the unmet needs of low resource healthcare settings that are not being developed in industrially developed countries. In-depth case studies of 4 such PoC MedTech innovations are discussed in Chapter 6.

Section 5.5 presents Category C early detection modalities for cancer in the bottom left quadrant. These are high technology innovations developed in industrially advanced countries but with no local infrastructure to absorb them in India. Such innovations include highly specialised proprietary tests that are not compatible to the healthcare infrastructure and resources of India.

Section 5.6 presents Category D early detection modalities for cancer in the bottom right quadrant. This category represents problems for which no innovation either in industrially advanced countries or in India (bottom right quadrant).

These sections are analysed by cancer type, identifying the knowledge and technologies, actors and networks, and the institutional variety that shapes these innovations.

Table 5.1: Situating existing modalities and emerging PoC MedTech innovations for the early detection of cancer using SII and IHI in the Indian context.

	Early detection modalities imported from industrially advanced countries.	Early detection modalities are not imported from industrially advanced countries.
Locally relevant early detection modality exists in India.	**Unmet need and industrial production (1):** Problem framing and solving of needs of early detection of cancer in advanced industrialised countries. Import driven. **Knowledge and technologies**: Specialised knowledge and capabilities through reverse engineering and technology transfers from MNCs for gold standard early detection modalities, Low local R&D, high capex and opex technologies. Breast cancer (mammography, ultrasound), Cervical cancer (HPV testing and pap smear), and Oral Cancer (only adjunct modalities) **Actors**: Policy and regulatory actors, MNCs, Indian firms, hospitals, universities and research institutes, primary users, health insurance, importers, and distributors. **Networks**: Intermediary organisations like industry associations (AiMED, APACMed, FICCI, CII) **Healthcare delivery (2):** Available at the private health facilities (hospitals and large clinics, diagnostic centres) and public hospitals but high OOP expenditure. **Demand (3):** Procurement rules favouring MNCs but lack of coverage under health insurance plan.	**Unmet need and industrial production (1):** Problem framing and solving of unmet needs of underserved population in early detection of cancer in low resource healthcare settings India. Local assembling and production of final product. **Knowledge and technologies**: Local knowledge and resource for low tech solutions for early detection of cancer. Increased AI and ML infrastructure and knowledge sources due to increase in AI and ML engineers, and scientists. High technological PoC MedTech innovations for breast, cervical, and oral cancer for low resource health settings. **Actors:** Policy and regulatory actors, universities**,** researchers and scientists, healthcare providers, start-up firms, incubators, accelerators, private funders, primary and end users, NGOs **Networks**: Networks like INDIAai (The National AI Portal of India), BIRAC, public centre of excellence viz KTech, etc. **Demand (3):** Procurement policies not yet conducive to PoC MedTech innovation, start-up firms are generating demand using PPP and stakeholder engagements. Government is using public awareness methods to generate demand for public screening modalities. **Healthcare delivery (2):** Start-up firms creating new markets using business models and partnerships with public health settings to cater to low resource healthcare settings.
Locally relevant detection modality does not exist in India	**Unmet need and industrial production (1):** Need of niche population, import driven. **Knowledge and technologies:** High-cost technologies, proprietary tests requiring specialised laboratory (like gene test Mamaprint, Oncotype) **Actors:** Indian healthcare as end user (limitedly) in the global value chains. **Networks:** No intermediary networks, direct engagement with end user due to limited scope of market **Demand (3):** Corporate hospital in metro cities, big diagnostic chains, high income population. **Healthcare delivery (2):** Technology difficult to scale and integrate in health system due to high cost.	No solution exists: In relation to cancer, apart from cervical cancer, there are no vaccine or intervention available to prevent* cancer. *Risk factor modification is considered to have some benefits in reducing risk to cancer

Source: Author's adaption of the matrix from Srinivas and Sutz (2008)

<center>**Category A**</center>

5.3. Early detection modalities are imported from industrially advanced countries and locally relevant technologies for India exist.

These screening modalities include the gold standard tests for early detection of breast, cervical and oral cancer in India.

5.3.1. Breast cancer: Mammography, breast MRI, and ultrasound

In terms of their placement in the matrix in table 5.1, mammography, CT scans, breast MRI, and ultrasound as techniques lie in the upper-left quadrant. These modalities are developed in advanced industrialised or developed countries and continue to dominate production.

Mammography, low-energy x-ray imaging, is the gold standard in the early detection of cancer. The selection process of mammography in clinical settings greatly illustrates how cultural, ideological, and political factors that reflect the interests of various actors influence the diffusion and adoption of medical technologies into clinical practice (Lerner, 2003). To provide some perspective, I refer to the historical developments that helped in understanding why breast screening modalities have developed the way they are at present (see Appendix D) – who are the main actors in the development, diffusion, and adoption, and aspects of 'inclusiveness' in this process.

Three types of mammography have emerged - analogue (film-based), digital, and breast tomosynthesis (3-dimensional digital mammography). Radiologists dominated the initial developments of mammography as a technique, and subsequently, North American, and European firms took an active role in commercialising and scaling it up (ibid). It also showcased the role of large-scale clinical trials and regulatory interventions in shaping demand and protecting the end users by ensuring safety and efficacy in the USA, and European context (Bhidé et al., 2021). This historical trajectory presents that firms from the USA and European companies became the first movers, standard-setting dominant actors in the global value chain (Gold, 1993; Picard, 1998; Bhidé et al., 2021). They continued to be market leaders in the industrial production of resource-intensive mammography and related X-ray-based technologies like CT scans (and adjunct technologies like ultrasound and MRI).

<center>126</center>

They continue to dominate with MNCs as the major providers in India. In India, mammography equipment was available more widely from the second phase (post-1990s), with marked increases in imports of high technology devices, and later when MNCs entered through establishing Indian subsidiaries or joint ventures:

(1) Phillips:[19] IntelliSpace Breast integrates mammography, ultrasound, and MRI, MicroDose SI offers digital low-dose spectral mammography, and products like SmartExam Breast and DynaCAD Breast, provide advanced visualization for breast MRI analysis.

(2) GE Healthcare (via Wipro GE Healthcare):[20] 3D Senographe Pristina

(3) Siemens:[21] MAMMOMAT Revelation, MAMMOMAT Inspiration, MAMMOMAT Fusion, along with reading solutions for screening and diagnostics.

(4) Fujifilm India:[22] Amulet Innovality

Referring to parallel developments in India from Chapter 2, some local manufacturing capabilities were developed in India via technology and knowledge transfers, acquisitions, and changes in policies over the years (partial **triad element 1** due to no capture of need of low resource healthcare settings). For instance, Trivitron Healthcare Private Limited[23] acquired imaging manufacturer Kiran Medical Systems, and Imaging Products (India) Pvt Ltd, provides Kiran Felicia, a digital mammography system. Allengers Medical Systems Ltd. also produces mammography equipment in India.[24] Both Trivitron Healthcare and Allengers Medical Systems have an international presence, especially in the global south. Therefore, the upper left-hand side quadrant in Table 5.1 reflects the actors that have emerged due to a distinct set of institutions and policies, technology, and knowledge transfers in the global value chain. These include specific FDI policies, standard settings for high technology products, development of regulations which are conducive for MNCs, and changes in procurement rules with preference to 'make in India' devices (DoP, 2018).

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[19] https://www.philips.co.in/healthcare/product/HCNOCTN143/intellispace-breast-breast-imaging-workstation
[20] https://www.gehealthcare.in/products/mammography;
https://www.gehealthcare.in/products/mammography/mammography
[21] https://www.siemens-healthineers.com/en-in/mammography
[22] https://www.biospectrumindia.com/news/75/8123/fujifilm-nm-medical-launches-3d-mammography-machine-.html
[23] https://www.trivitron.com/specialty/mammography
[24] https://www.allengers.com/our_products/mammography

Currently, mammography, MRI, ultrasounds, and CT scans are available in both public, including district hospitals and tertiary teaching hospitals, and private healthcare settings **(triad element 2)** in India. However, due to cost considerations and concerns for overdiagnosis, mammography (and adjunct technologies) as a population-based measure for early cancer detection is discouraged for India and LMICs in general (Badwe and Gupta, 2013). While mammography is the most utilised mode of early diagnosis in tertiary care hospitals (for instance, AIIMS Twitter Space, 2022), the key challenges with mammography and CT scans that raise concerns for inclusiveness in the local context (weak development of demand in **triad element 3**):

(1) *Not ideal for women of all ages:* Mammography is not ideal for women of all ages as its sensitivity varies with women with dense breast tissue, i.e., more fibro glandular and supportive tissue than fatty tissue. It is important to note that while several studies in the western population have found mammography screening to have a sensitivity of 77 to 95 percent and a specificity of 94 to 97 percent, it varies with the density of the breast. For this reason, mammography is more effective for women over 45 years old and relatively less effective for younger women who are likely to have dense breasts. Some studies suggest that the role of supplemental breast ultrasounds can be explored in women with dense breast. However, it is not easily accessible and affordable to a large proportion of the population (for instance, Nothacker et al., 2009). These challenges leave very limited screening options for women below 45 years of age.

(2) *Geographical disparities, infrastructural and cost issues:* These imaging technologies involve infrastructural and logistical issues, resulting in both high capital expenditure (capex) and high operating expenditure (opex) due to the cost of setting up machines including the space and sterilisation, repair, and maintenance, availability of radiologists and trained technicians. These costs pose a considerable burden on hospitals and medical centres in India, particularly in rural areas. In the absence of coverage under population screening and lack of availability at public hospitals, a large proportion of women are posed with the option to go for private diagnostics and clinics in urban settings. In these healthcare settings, each scan costs an average of INR 1000 - 4000 depending upon the location, type of facility, and whether the scan is for one breast or both breasts (Naidu, 2022). On the other hand, it is available in public hospitals (like All India Institute of Medical Science) at INR 300 (outpatient or general ward) and INR 350 (in the private ward). In May 2022, AIIMS further announced the

removal of user charges for all investigations or laboratory charges costing up to INR 300 in its Delhi-based and other centres (Dutt, 2022).[25] However, due to the long wait list, it is difficult to access it. In the absence of health insurance coverage to cover private health care expenses, mammography is unaffordable to a large section of women. There are geographical disparities in access to these diagnostics, which is also highlighted in Chapter 2. For these reasons, while accepted as a gold standard in clinical practice, mammography is not advocated to be a population-based screening modality. The Tata Memorial Hospital, which has a prominent role in shaping cancer control policies (see Chapter 2), asserts mammography is not conducive for mass screening in low-resource healthcare settings:

> 'The use of mammography for screening for breast cancer requires expensive machinery, highly trained radiologists and radiographers and a high level of quality control. In India, a digital mammography machine costs approximately INR 3 crores, and each examination costs around INR 2000. Clearly, India cannot afford mass screening by mammography for all its women.' (Press Note, Tata Memorial Hospital, Mumbai (25.02.21)

(3) *Exposure to radiation*: Mammography includes radiation exposure because it is X-ray based. Studies point out that such exposure to radiation may be harmful mainly in women who are in the high-risk category, for instance, due to abnormal DNA damage (Pauwels et al., 2015). However, there is a divide in the opinion of radiologists and clinicians on whether radiation exposure is significant enough to be feared carcinogenic. In the words of an AIIMS Delhi representative in a panel on breast cancer awareness:

> 'people should not be afraid of mammography. It is a modality involving radiation, but the radiation exposure is minimal, the benefits outweigh the risks, and it is not a very painful procedure. One mammogram at the age of 40 and then an annual screening mammogram after age 50. And ultrasound is a non-radiation modality. So, a combination of ultrasound and mammography as a diagnostic tool has to be used mammography as a screening tool.' (AIIMS Delhi Twitter Space, 2022)

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[25] https://www.aiims.edu/aiims/hosp-serv/revised-rate-list.htm#_Toc471767111 (last accessed on 15 February 2023).

Nonetheless, due to the cost and infrastructural challenges highlighted above, it fails to address unmet needs and demand for affordable and accessible screening modalities available to both urban and rural populations in India. Breast MRIs (Magnetic Resonance Imagining) and ultrasound provide a radiation-free alternative; however, both share the same infrastructural and cost challenges.

(4) *Emotional and socioeconomic barriers to women:* Some respondents and the literature (for instance, Mahalakshmi and Suresh, 2020) also highlight the fear of cancer detection, shyness, and issues of privacy to be huge concerns among females when it concerns going for screening. It is particularly prohibitive if male technicians or clinicians perform the screening.

5.3.2. Cervical cancer: Cytology and HPV DNA Testing

In the case of cervical cancer, conventional and liquid-based cervical cytology (pap smear) and HPV DNA testing are two modalities that lie in the upper-left quadrant.

Conventional and liquid-based cervical cytology (pap smear)

At present, conventional cytology through pap smear test is the gold standard for cervical cancer screening. In pap smear cells are obtained from the cervix and examined for any cellular and nuclear abnormality. George Nicholas Papanicolaou, with a doctorate in Zoology from the University of Munich, was the first to publish (1917) on the physiology and cytologic characteristics of the female reproductive system. He proposed that individual cells from the cervix possess morphological features which can help in diagnosing carcinoma while working at the Cornell Medical College, USA (Shaw, 2000). His work was further developed by Aurel A. Babes, a Roman pathologist, who extended the theory that invasive carcinoma is preceded by a pre-invasive stage. He made a case for cervix cytology in the early diagnosis of cervical cancer (ibid). In 1940s, George Papanicolaou worked on developing a new cancer test in collaboration with gynaecologist and pathologist, Herbert F. Traut, and gynaecologist, Andrew Marchetti, in developing exfoliative cytology (Pap. smear test) as a screening and early diagnosis tool for cervical cancer detection (Diamantis and Magiorkinis, 2014).

In the Indian case, as mentioned in Chapter 2, conventional pap smears started being used to screen cervical cancer from the 1970s, but the test was not available universally under a government programme (Srinivasan et al, 2018). As seen in Table 5.2, cervical cytology is

available at private (hospitals, gynaecology clinics, diagnostic labs) and public health settings. It requires laboratory infrastructure, microscopes, specialised healthcare professionals including smear collectors, cytotechnicians, and pathologists, consumables including slides, fixative, pap stain containing dyes, solutions which are resource intensive (Bobdey et al., 2016). However, there are challenges in cervical cytology in Indian settings. A respondent shared the cumbersome nature of screening, from sample collection to processing of results, and the lack of availability of screening facilities in primary health settings (triad element 1 with no capture of need, triad elements 2 and 3 are only evolving for urban settings with low infrastructural challenges such as public and private hospitals and diagnostic chains):

> 'women do not like the way the samples are collected. It requires specialised nursing staff and doctors to collect those samples. So, one issue is collecting the sample. Then the second thing is putting them through the right kind of media and then bringing them to one centralised diagnostic centre for reporting and presenting. Now in India, general health care is given by primary health centres. You will be surprised that the screening facilities are not even there in many of the health centres, especially in primary health centres. It has to come back to a district health centre. One report of pap smear sometimes even takes 3-4 weeks to reach up to cytologist because it is transported across - they're simply overloaded. Even in District Hospitals there are very few cytologists who would be actually willing to report. The technology is there, all the expertise is still limited in those areas.'

> Director of an Indian pathology and diagnostic firm, Author's interview (2021)

In addition to infrastructural bottlenecks, another challenge relates to the accuracy of the sample collection depends on the expertise of the cytologist:

> 'Accuracy of a pap smear depends upon the sample and the expertise of the pathologist or cytologist who reads the specimen, which is subjective. If the smear is taken wrongly from a wrong area, it could be negative.'

> CEO of a MedTech start-up, Author's interview (2021)

The PAP smear is also performed using liquid-based cytology (LBC). Unlike conventional cervical cytology, in which the smear is tested by putting on a glass slide which is dipped in the Koplin jar containing 95 per cent ethyl alcohol, cells are transferred to a liquid preservative solution which is transported to a laboratory in case of LBC (Rajaram and Gupta, 2021). It is

becoming increasingly available in big hospitals and private diagnostics; however, challenges of infrastructural constraints remain.

HPV DNA-PCR testing

HPV DNA test is a laboratory test for which cells are scraped from the cervix to examine if the DNA of human papillomaviruses (HPV) exists. Guidelines by organisations like WHO also play a significant role in the selection of the technologies, for instance, a recent guideline published:

> 'When compared with VIA or cytology as a primary screening test, greater benefits are also more likely with HPV DNA testing. HPV DNA testing is acceptable to women and providers, is feasible and is not likely to lead to inequities. In some settings, HPV DNA testing is not yet available, though, and there will be a period when existing quality-assured programmes will need to remain until HPV DNA testing becomes operational.' (WHO, 2021; p34)

The guideline of WHO also suggest moving toward a more objective screening modality (discussed further in chapters 6 and 7). However, while objective than other screening modalities, HPV DNA testing is a resource intensive technique requiring more time and ancillary infrastructure, including sophisticated laboratories (Sankaranarayanan, et al., 2009; Srivastava et al., 2018). Even study respondents suggested HPV DNA test may be used as an opportunistic screening, catering to those who can pay for it and not as part of the government's population based early detection programmes:

> 'An HPV DNA test, with the cost of the equipment, the collection of samples etc is almost going to be an INR 1000. Now if you have around 300 million women in India between ages of 25 and 65 and an INR 1000 test – we are talking about INR 300 billion – which is impossible! It has no meaning right, and it's screening for cancer so there's no direct political or statistical mileage which the government or the bureaucracy can have – wherein they can say - we save 5000 women from dying, else they would have come in stage 1 or stage 2. So, the challenge is how to find technology that works for a country like India. The flip side is a lot of companies and institutes have started working on such technologies, but we in India do not spend enough financial resources or time validating the sensitivity or specificity of our tests. So, what ends up happening is a lot of technologies come out locally, but after some time people find that it is not working as it should.'
>
> Managing Director of an Indian firm providing blood screening technologies for cancer, Author's interview (2021)

The above quote from the respondent shed light on how finding the right technology for screening is often driven by both political and logistical concerns (triad element 1 with no capture of need, triad elements 2 and 3 are disjointed due to lack of scalability of HPV as a mass screening modality).

5.3.3. Oral cancer

In case of oral cancer, there are only adjunct technologies and no screening modality in upper-left quadrant that is developed in industrialised country that is also locally manufactured or available in the Indian context. Some use of adjunctive technologies used as a screening tool include (NCG, 2019): vital tissue staining (toluidine blue, Methylene blue), visualisation adjuncts developed by North American firms (for instance, ViziLite Plus with TBlue, ViziLite by DenMat; Microlux DL by AdDent Incorporated, Orascoptic DK, VELscope). However, there is a lack of evidence that support they reduce oral cancer mortality (ibid).

Category B

5.4. Early detection modalities are not imported from industrially advanced countries, but locally relevant technologies for India exist.

Category B, which is the upper-right quadrant of the matrix in Table 5.1, magnifies on two sets of modalities. One of the low-cost modalities used in government screening programmes of India. Second, the new trajectory of MedTech innovations for the early detection of cancer (discussed in Chapter 2). These innovations are a result of technical change in the MedTech sector due to the affordable availability of high computing technology, artificial intelligence and its subsets, machine learning and deep learning. Figure 5.1 shows how AI, and its subsets use data to identify complex patterns that humans find difficult to comprehend and notice.

Figure 5.1: Illustration depicting the role of AI and its subsets.
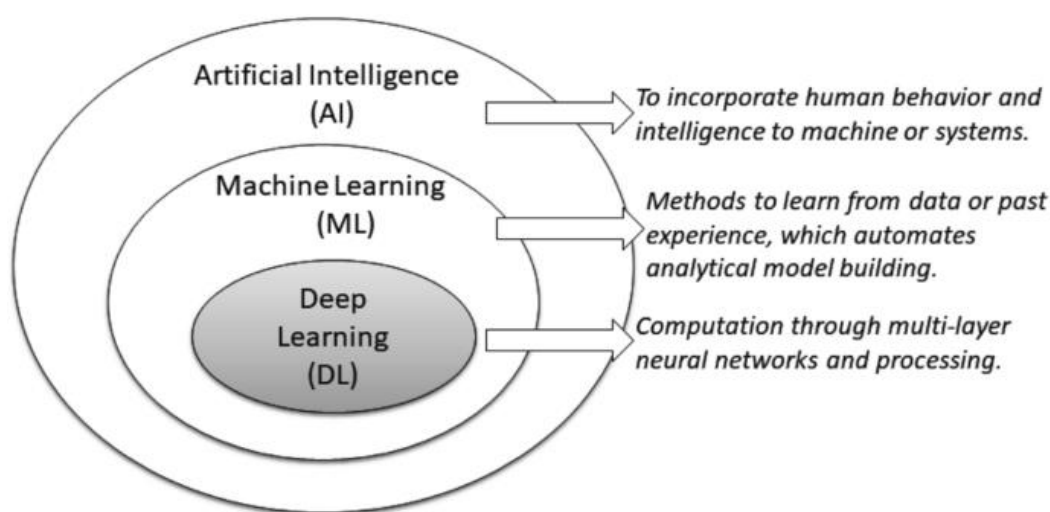
The integration of AI in part of a larger health system change. For instance, Indian Council of Medical Research has drafted ethical guidelines for application of artificial intelligence in biomedical research and healthcare (ICMR, 2022). The report acknowledges the role of AI in screening and diagnostics (ibid, p7):

> 'AI-based tools have the potential of enhancing known methods of screening and diagnosis of disease, improving diagnostic accuracy, and guiding evidence-based treatment algorithms, predicting outcomes, identifying health system gaps, with an overall impact human health and wellness.'

In Indian health, AI applications have been used in electronic health and medical records, MedTech diagnostics, healthcare analytics, health financial services, and wellness platforms (STPI, 2022).

In the next sub-sections, I elaborate on two sets of modalities in this category, one low-tech modality and second, early detection MedTech modalities for cancer using applications of AI. Both these sets of modalities are offering context-specific solutions for low-resource healthcare settings.

5.4.1. Breast cancer

Clinical Breast Examinations

The clinical breast examination (CBE) is a screening modality used in a government screening programme. It connects (triad element 2) health care delivery and (triad element 3) demand of the intuitional triad for health by mitigating some of the challenges of the gold standard modality. The results from a large-scale clinical study conducted by Tata Memorial Hospital indicate that CBE every two years by primary health workers significantly downstages breast cancer at diagnosis, leading to the overall reduction in breast cancer mortality (Mittra et al., 2021). CBE is considered one of the low-cost methods of breast screening, particularly in resource resource-constrained settings where more precise tools are either unavailable or unaffordable. CBE as an intervention is not actively used as a screening option in advanced industrialised countries, where mammography and ultrasound is a screening modality (Ngan et al, 2020). In this case, the inadequate triad domain (1) created the conditions to develop an alternative strategy, clinically testing the application of practical knowledge into medical practice.

At present, CBE is adopted by the GoI's population-based breast screening programme for women of 30 years and above (triad element 2). The screening is available at health and wellness centres, primary health centres, and community health centres and performed by trained health workers, female physicians, staff nurses or auxiliary nurse midwives (village-level female health workers), who have received training for conducting CBE. It is a bottom-up effort for screening by community mobilisation, depicting inclusive characteristics of 'grassroot' innovations, as discussed in the previous chapter. CBE falls under the low-cost and low-technology solutions for higher coverage in the upper right-hand side column of Table 5.1 The low-cost and high coverage potential of this screening modality has received acceptance in clinical practice and government in the Indian context.

However, as stated earlier, the screening uptake of the government screening programme is very low. The studies also suggest that while CBE is better in scenarios of no screening, its subjective nature and dependency on the clinician's / health workers' experience have raised several debates about its overall effectiveness in early detection (for instance, Menes et al.,

2021). Recent innovators have raised concerns for CBE has the potential to miss smaller lesions for early detection as it can detect palpable lumps more than 2 cm in size.[26]

Femtech: Recent PoC MedTech innovations

In response to the lack of affordable and locally relevant technologies, there has been a surge of 'femtech' in India. Femtech are the technologies (products or services) specifically designed to cater to female health. From an inclusiveness perspective, 'femtech' has prioritised the representation of women's health concerns in the health and medical technology domain and legitimacy to female health technology markets (Kemble et al., 2022). These innovations are showing early signs of bridging (1), (2), and (3) domains of the triad. There is a surge in PoC MedTech innovations for breast cancer for both early detection and treatment management.

Table 5.2 shows Clinical Trial Registry of India (CTRI) data on clinical research on breast cancer screening in public and private healthcare settings. The data shows an increase in clinical studies using novel screening modalities for the Indian context. This trend points to institutional capacities in the form of hospitals and university research, carrying out Indian-specific clinical research. The clinical research highlighted in blue is conducted by Medtech startups to validate the novel early detection modalities in clinical settings.

Most of these new technologies aim to remove subjectivity from primary screening modalities to facilitate effective triage. Albeit, just like the initial challenges of acceptance faced by prevailing gold standards, they face challenges of scaling up and garnering larger acceptance in the clinical practice. These innovations show characteristics of scarcity-induced problem-solving innovations that utilise design thinking to identify and frame the 'need' and then create new markets (capturing collective demand). Some of the MedTech innovations for the early detection for breast cancer that have been introduced in India in the recent years include, Thermalytix by Niramai Health Analytix (Bengaluru), and Oncostem (Bengaluru).

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[26]https://www.biospectrumindia.com/views/69/20747/addressing-breast-cancer-burden-with-innovation-and-technology.html (last accessed on 15 March 2022).

Table 5.2: Increasing clinical research using novel screening and early diagnosis modalities for breast cancer in India (2017-2022)

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2017	Screening	Blood test for screening of breast cancer using novel screening device, Pandora CDx MammoAlertTM	Amrita Institute of Medical Sciences and Research Centre, Kerala. Basvatarakam Indo American Cancer Hospital and Research Institute, Andhra Pradesh. HCG Multispecialty Hospital HCG Cancer Center, Gujarat; KIMS Hospitals, Andhra Pradesh. Manipal Hospital, Karnataka. Maulana Azad Medical College University of Delhi & Associated Lok Nayak Hospital, Delhi. Tata Medical Center, West Bengal	POC Medical Systems Inc	Pharmaceutical industry-Global
2017	Medical Device, Screening	Evaluation of Mammographic Rotational Infrared Tomography (MAMRIT) as a breast imaging device	Rajiv Gandhi Government General hospital, Tamil Nadu	Cura Healthcare Pvt. Ltd, Chennai	Private company

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2017	Medical Device, Screening	Non-invasive Breast Cancer Screening Solution	HCG Cancer Hospital, Karnataka Mazumdar Shaw Medical Center, Karnataka	NIRAMAI Health Analytix Pvt Ltd, Bengaluru	Medtech company
2018	Screening	Screening and early detection in Cachar, Assam	Cachar Cancer Hospital and Research Centre, Assam	Indian Council of Medical Research, New Delhi	Government funding
2019	Cross-Sectional Study	A study to understand the level of knowledge on Breast cancer, and the practice of breast cancer prevention strategies like screening among women in the Udupi district	Udupi, Kaup and Karkala taluks of Udupi district, Karnataka	Dr Kunjaru Sneha	Self-sponsored
2019	Questionnaire-based	Evaluation of acceptance of cancer screening among members of the community in Uttar Pradesh	National Institute of Cancer Prevention and Research, Uttar Pradesh	National Institute of Cancer Prevention and Research	Research institution
2019	Cross-Sectional Study	Evaluation of a new tool for early detection of breast	National Institute of Cancer Prevention and Research, Uttar Pradesh	National Institute of Cancer Prevention and Research	Research institution

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
		cancer - Thermalytix screening			
2020	Medical Device, Screening	Breast cancer screening by clinical breast examination and a new instrument named iBreastExam	Prayas, Maharashtra	Prayas, Amrita Clinic, Pune	Non-profit organization
2020	Cross-Sectional Study	A study of a safe and non-invasive method for preventive screening for breast cancer and monitoring of breast cancer patients.	Regional Cancer Centre (RCC), Trivandrum, Kerala	NIRAMAI Health Analytix Pvt Ltd, Bangalore	Medtech company
2020	Preventive, Screening	Linking cancer cases of Puducherry to their Primary Health Centres through Community Health Workers	All Primary Health Centres (PHC) of Puducherry	Dr Swaroop Kumar Sahu, IPMER (Jawaharlal Institute of Post-Graduate Medical Education and Research) Puducherry	Self-sponsored
2022	Screening	Motivational intervention for regular breast cancer screening	PGIMER Outpatient department, Chandigarh	New OPD PGIMER Chandigarh	Research institution and hospital

Source: Author's data extraction from Clinical Trial Registry of India

5.4.2. Cervical cancer

Visual inspection using 5 percent acetic acid (VIA)

VIA involves the examination of the cervix after the application of acetic acid. The health worker looks for acetowhite areas to check for potential malignancies. This test has been advocated in low-resource health settings, showing some signs of connecting domains (2) and (3) of the intuitional triad for health. It is a part of the national screening program. However, it requires trained healthcare workers for correct interpretations. Hence, there exists an unmet clinical need for novel diagnostics to support clinicians in the early detection of cervical cancer and which are implementable in resource-constraint settings. While several clinical studies have supported VIA as the best modality of screening in low-resource settings, there are numerous challenges in conducting it. For instance, frontline healthcare workers have reported challenges in screening delivery, including training to interpret the screening outcomes and technical challenges (like a slow tablet):

> 'Even after breast or cervical screening of a woman is done, she is not told if there is something abnormal or even what symptoms to look out for. We ourselves do not know; how will we tell her?' (ASHA interview, Yadavar (2022))

There is also a state-wise disparity in screening practice because of a small number of trained health workers post-pandemic, mainly as the grassroots workers ANM and ASHA are tasked with multiple other responsibilities (ibid).

Femtech: Recent MedTech innovations

The innovations developed for the early detection of cervical cancer are a part of the femtech innovations mentioned earlier. These innovations are engaging with challenges of resource constraint healthcare settings posed by the gold standard, and subjectivity involved with VIA. Table 5.3 shows the Clinical Trial Registry data of India, showing a substantial increase in clinical research studies testing MedTech innovations for cervical screening from 2013 to 2022. The studies include cross-sectional, screening, interventional, case-control, observational, and preventive studies for cancer screening and early diagnosis.

Table 5.3: Increasing clinical research using novel screening and early diagnosis modalities for cervical cancer in India (2013-2022)

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2013	Cross-Sectional Study	Pilot study to know whether menstrual pad/cloth can be a cervical cancer screening tool	Rural Cancer Registry Barshi, Maharashtra	Department of Biotechnology, Ministry of Science and Technology	Government funding agency
2017	Screening	Pilot study to evaluate a smartphone based cervical imaging device in cervical cancer screening program	Apollo FirstMed Hospitals, Tamil Nadu; Apollo Health City, Andhra Pradesh; Apollo Hospitals, Karnataka; Apollo Speciality Hospital, Tamil Nadu; Apollo Tondiarpet Hospital, Tamil Nadu; Apollo Total Health, Andhra Pradesh	Mobile Optical Detection Technologies, International Finance Corporation (Tech Merge Program, New Delhi)	Pharmaceutical industry-Global
2017	Cross-Sectional Study	A study to evaluate Enhanced Visual Assessment System in detecting cervical cancer	Dr L H Hiranandani Hospital, Maharashtra	Mobile ODT Mobile Optical Detection Technologies	Private Company (ISO Certified)
2017	Interventional	Cancer of the mouth of the uterus-Prevention is possible by screening and treatment of precancers	Chittaranjan National Cancer Institute, West Bengal	Ministry of Health and Family Welfare Govt of India; Hybrid Capture 2 test kits provided by Qiagen India	Government funding agency

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2017	Medical Device Screening	Inspection Device For Cervical Cancer Screening	Agada Hospital, Tamil Nadu	Chemical Engineering Department, Indian Institute of Technology Bombay, Mumbai	University [Internal Grant]
2017	Case Control Study	New Cervical Cancer Screening Tool	Kasturba Hospital, Karnataka	Department of Science and Technology, Ministry of Science and Technology, India; KH KMC Manipal	Private medical college
2018	Cross Sectional Study	Visual Inspection after Application of Acetic Acid versus Pap smear in Cervical cancer screening	Tata Motors Hospital, Jharkhand	Department of Obstetrics and Gynaecology, Tata Motors Hospital, Jharkhand	Private hospital/clinic
2018	Screening	comparison of performance of portable colposcopes with standard colposcope in cervical cancer screening	All India Institute of Medical Sciences, New Delhi	Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences New Delhi	Government medical college
2018	Cross Sectional Study	A study to Understand the reasons for Cervical Cancer screening uptake among Indian women	NPCDCS Programme Managers	Jyoshma Preema Dsouza, Institute of Psychological Sciences Research, Universite Catholique de Lou-vain, Louvain la neuve	Self-sponsored

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2019	Drug, Ayurveda, Preventive Screening	Cervical cancer early detection and Prevention	OPD 16, SDM College of Ayurveda and Hospital, Karnataka	Rajiv Gandhi Universuty Health Sciences, Bangaluru	University
2019	Screening	Development of a new low-cost computer assisted visual Cervical Cancer Screening method	Homi Bhabha Cancer Hospital (HBCH), Punjab; Mahamana Pandit Madanmohan Malviya Cancer Centre, Uttar Pradesh	Clinton Health Access Initiative (CHAI), USA to Tata Memorial Center TMC	Research institution and hospital
2019	Screening	Comparison of two methods of cervical cancer screening i.e., cell-based method (papsmear) and naked eye examination after VIA	Kempegowda Institute of Medical Sciences, Karnataka	Dalrada Health Products Inc; Westchester Knowledgeworks Pvt Ltd.	Private company (Non-India based MNC)
2020	Medical Device	A Comparative Study Of Truescreen vs Pap Smear For Cervical Cancer Screening In General Screening Population	All India Institute of Medical Sciences, Delhi	Khandelwal Laboratories Ltd, Mumbai	Pharmaceutical industry-Indian
2020	Cross Sectional Study	Factors influencing cervical cancer screening uptake	Karnataka	Universite Catholique de Louvain	Research institution
2020	Medical Device Screening	Use of a novel device to ease the routine gynaecological examination as compared to the conventional gynaecological examination	Kasturba Hospital, Karnataka	Biotechnology Industry Research Assistance Council (BIRAC), New Delhi	Government funding

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2020	Screening	Cervical cancer screening using HPV self-sampling method	National Institute of Cancer Prevention and Research, Uttar Pradesh, and State NCD cell, Sikkim	Indian Council of Medical Research	Government funding
2021	Observational	Cervical cancer screening using two methods, Pap smear and visual inspection with acetic acid in a tertiary medical college	M K C G Medical College Hospital, Orissa	VIA Test Kit, Dalrada Health, Escondido, San Diego, USA; Department of Obstetrics and Gynecology, M K C G Medical College; Westchester KnowledgeWorks	Government medical college
2021	Cross Sectional Study	Accuracy of incorporating Artificial Intelligence into a transvaginal digital screening device for detecting pre-cancerous conditions in the cervix	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Safdarjung Hospital, New Delhi; Periwinkle Technologies Private Ltd Pune	Government funding and MedTech firm
2021	Preventive, Screening, Behavioural	Preventing Cervical Cancer through HPV self-sampling	Tata Memorial Hospital, Maharashtra	Fund for Innovation and Transformation, Program of the Inter-Council Network of Provincial and Regional Councils (ICN), Global Affairs Canada.	International funding

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2021	Screening	Community Based Study of Cervical Cancer Prevention through self-testing and health education in India	Tata Memorial Centre, Maharashtra	Canadian Institutes of Health Research (CIHR); Indian Council of Medical Research ICMR	International funding and Government funding
2022	Medical Device	Performance of CERVICHECKTM Kit, an HPV self-sampling kit for screening of cervical cancer or pre-cancerous lesions	Prayas, Maharashtra Sir Sayajirao General Hospital and Medical College, Gujarat	BIRAC Seed Fund, Pragmatech Healthcare Solutions Pvt Ltd	Government funding and MedTech firm
2022	Preventive, Screening	Prevention and Screening Innovation Project Towards Elimination of Cervical Cancer	Chittaranjan National Cancer Institute Kolkata, West Bengal; Manipal Academy of Higher Education Manipal, Karnataka; Sikkim Manipal University Sikkim, Sikkim; Sri Dharmasthala Manjunatheshwara College and Hospital of Ayurveda Udupi, Karnataka; St Johns National Academy of Health Sciences SJNAHS Bengaluru, Karnataka; Tata Medical Center Kolkata, West Bengal; Tata Memorial Hospital TMH Mumbai, Maharashtra	Department of Biotechnology Government of India as part of H2020-DBT grant; Sikkim Manipal University Sikkim; Chittaranjan National Cancer Institute Kolkata	Government funding and University
2022	Diagnostic Accuracy Study	PredAID-CERVIA: AI based Cervical Cancer Screening	NKPSIMS & Lata Mangeshkar Hospital, Maharashtra	BlockAPpsAI PVt. Ltd.	MedTech firm

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2022	Screening	Finding ways to improve cervical cancer screening programs for women (SHE-CAN study).	Christian Medical College Vellore, Tamil Nadu; National Health Mission Mizoram, Mizoram; Tribal Health Initiative hospital (THI), Tamil Nadu	National Health and Medical Research Council, Australia, and GA–D - Global Alliance for Chronic Diseases	International not-for-profit
2022	Diagnostic Accuracy Study	PredAID-CERVIA: AI based Cervical Cancer Screening in female sex workers	SRM Medical College Hospital and Research Center, Tamil Nadu	BlockAPpsAI pvt. Ltd	MedTech firm
2022	Diagnostic, Preventive, Screening	Improving the quality of screening using Smart Scope	ICMR National Institute of cancer prevention and Research, Uttar Pradesh	ICMR National institute of cancer prevention and Research; Periwinkle Technologies Pvt Ltd	Research institution
2022	Case Control Study	Cervical Cancer Screening in Rural Areas	Karunya Hospitals, Tamil Nadu	Dr Kumudha Raimond, Department of Science and Technology DST-BDTD Technology Bhavan, New Delhi	Principal Investigator of DST BDTD Project
2022	Cross Sectional Study	Sexual Health in school employees of Vijayapura District, Karnataka India.	District Hospital Vijayapura, Karnataka	BLDEDU Shri BM Patil Medical College Hospital and Research Center, Vijayapura, Karnataka	Private medical college

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2022	Preventive, Screening	Prevention of Cervical Cancer (PRECERCA 1)	Chittaranjan National Cancer Institute, West Bengal	Cepheid India Private Limited, Gurugram, Haryana; Manisha Nandi Foundation	Pharmaceutical industry-Global
2022	Cross Sectional Study	Smartphone based application for screening of cervical cancer	National Cancer Institute, Jhajjar, AIIMS, New Delhi, Haryana	National Cancer Institute, Jhajjar, AIIMS, New Delhi	Self-sponsored
2022	Medical Device, Preventive Screening, Process of Care Changes	Cervical cancer screening using Smart Scope in primary health centres	ICMR National Institute of cancer prevention and Research, Uttar Pradesh NPCDCS Directorate of health Services, Chhattisgarh	ACT Grant, Periwinkle Technologies Pvt Ltd, Pune, Maharashtra	Government funding and MedTech firm

Source: Author's data extraction from Clinical Trial Registry of India.

The study sites include major hospitals, medical colleges, and cancer registries located in different states of India. Further, the sponsors for these studies include government funding agencies, pharmaceutical industries, private companies, research institutions, and international funding agencies. There are three focus areas of these studies (a) developing new cervical cancer screening tools, including smart-phone-based imaging devices, inspection devices, and low-cost computer-assisted visual screening methods, (b) comparing different screening methods such as pap smear, naked eye examination, and visual inspection with acetic acid, (c) understanding the factors that influence cervical cancer screening uptake among women in India. The innovations (highlighted in blue) are by MedTech startup firms to provide a low-cost solution showing early signs of bringing together (1), (2), and (3) of the institutional triad of health care.

5.4.3. Oral cancer

Oral visual inspection

At present, conventional oral visual inspection (OVI) of the oral cavity using incandescent light is the standard method for oral cancer screening, with an overall high sensitivity and specificity (NCG, 2019). It is adopted in general clinical practice as well as in the population screening programme of GoI. It shows some signs of (2) and (3) of the intuitional triad for health. Early detection of oral cancer has the potential for better prognosis as tumour stage and grade are strongly related to the survival rate (Yeole et al., 2003; Lohia et al. 2019). It is because oral cancer is responsive to treatment when detected early or at the level of oral potentially malignant disorders (precursor lesions that may result in oral cancer due to malignant transformations) (Mohan et al, 2020; Wetzel and Wollenberg, 2020). However, oral cancer is a heterogeneous group of cancers that involve different parts of the oral cavity, with different predisposing factors, prevalence, and treatment outcomes. In addition to this, changing demographics and aetiology associated with oral cancer add to the diagnostic challenges faced by clinicians (Sujir et al, 2019). As a result, despite the general accessibility of the oral cavity during physical examination, it is difficult to locate malignancies. Particularly, with OVI there is a potential of overdiagnosis since it cannot differentiate between potentially premalignant lesions and non-progressive lesions, which poses a concern as only a small percentage of leucoplakias are progressive or become malignant (NCG, 2019). Another challenge is lack of regular dental check-up when patients may only visit health practitioner in case of concern.

Recent MedTech innovations

There are several diagnostic challenges because oral cancer is a heterogeneous group of cancer. A range of MedTech innovations, both product and service, has emerged in the Indian context showing early signs of bringing together (1), (2), and (3) of the institutional triad of health care. Table 5.4 presents a quick overview of clinical research studies in oral cancer screening and early diagnosis in India between 2017 and 2021. These include cross-sectional studies, follow-up studies, and observational studies, conducted at various institutions and hospitals across India. The sponsors for these studies include research institutions, hospitals, government funding agencies, pharmaceutical industries, and public trusts. The clinical research highlighted in blue is clinical research studies conducted by Medtech start-ups. For instance, OralScan, a handheld and non-invasive device by Sascan Meditech Private Limited (one of the cases discussed in the next chapter) is a novel breakthrough multimodal technology for screening and early diagnosis and for biopsy guidance as well. This is one case of the application of photonics in biomedical instrumentation by miniaturisation of instrument design. On the other hand, Erlysign, a Nagpur based start-up has developed a test kit to screen for oral cancer through a saliva sample (Kashyaap, 2021). In addition to these devices and tests, there are a few app-based services, including Berry Care (a collaboration between Atom360 and AIIMS Delhi and Bhubaneswar) and DentalDost (app by a dentist and digital entrepreneur) to identify and detect suspicious lesions in the mouth.

Table 5.4: Overview of clinical research studies in oral cancer screening and early diagnosis in India

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2017	Case Control Study	Using saliva and oral smears for early detection of oral cancer	Manipal College of Dental Sciences, Karnataka	Deepika Rathna M, Department of Oral Pathology, Manipal College of Dental Sciences, Manipal	Self-sponsored
2017	Cross Sectional Study	A study to evaluate the role of Telediagnosis in the early diagnosis of oral cancer	Coorg Institute of Dental Sciences, Karnataka	Dr Veena S Narayanan, Coorg Institute of Dental Sciences, Kanjithanda Kushalappa Campus, Karnataka	Research institution and hospital
2017	Case Control Study	Screening and detection of oral cancer	Bangalore Baptist Hospital, Karnataka HCG Bangalore Institute of Oncology, Karnataka	Karnataka Startup Cell, KBITS, Department of IT and BT, Bangalore and Sascan Meditech Pvt Ltd	Government funding and Medtech firm

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2018	Follow Up Study	Oral Cancer Early Detection Project, a population-based study.	MNJ Institute of Oncology and Regional Cancer Centre, Andhra Pradesh	Pain Relief and Palliative Care Society and Government resources; MNJ Institute of Oncology and Regional Cancer Centre; Government Dental College	Research institution and hospital
2018	Screening	Cancer Screening and Early Detection Program at Tata Tea gardens Dibrugarh	ICMR Regional Medical Research Centre, Assam	Indian Council of Medical Research	Government funding agency
2019	Cross Sectional Study	Developing an efficient and cost-effective method for screening of oral cancer in India	Dr. B. Borooah Cancer Institute, Assam	Medical Research Council (MRC), London and Tata Trusts, Mumbai	Public Trust

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
2019	Screening	Oral cancer screening study	National Institute of Cancer Prevention and Research, Uttar Pradesh	Global Challenges Research Fund (GCRF) University of Warwick Coventry	International research institution
2019	Cross Sectional Study	Mobile Oral Cancer Screening In Limited Resource Setting	Christian Institute of Health Sciences and Research, Nagaland KLE Society's Institute of Dental Sciences, Karnataka Mazumdar Shaw Medical Center, Karnataka	National Institute of Health	International-government funding agency
2021	Cross Sectional Study	To compare the efficacy of Oral cancer screening by mHealth application Vs Conventional screening by	Homi Bhabha Cancer Hospital, Varanasi, Uttar Pradesh Mahamana Pandit Madan Mohan	Biocon Foundation	Pharmaceutical industry-Indian

Year of registration	Type of Study	Clinical study	Study site	Sponsors	Type of sponsor
		healthcare workers in rural Varanasi.	Malaviya Cancer Centre, Uttar Pradesh		
2021	Observational	Screening of oral cancer	Manipal College of Dental Sciences, Karnataka	Department of Science and Technology	Government funding agency

Source: Author's data extraction from Clinical Trial Registry of India.

Category C

5.5. Early detection modalities are imported from industrially advanced countries, and there are no locally relevant technologies for India (category C of Table 5.1)

In this category, the innovations are mainly resource-intensive and technocratic technologies for which the Indian market, if at all, is seen as a mere end user in the global value chains. Because even the test samples are sent out of the country to specialised laboratories for analysis and reports. Some of the primary examples of such technologies include proprietary gene test include,

Mammaprint and BluePrint: These tests, provided by Agendia, a global molecular diagnostic firm, are a genomic prognostic test for women of all ages that analyse the activity of certain genes in early-stage breast cancer for prognosis and prediction of appropriate treatment. Such tests are increasingly used for personalised and precision treatment of cancer in resource-intensive settings. The tests are available in India via iLife Discoveries, which has acquired the technology-transfer for India.[27]

Oncotype DX test by Genomic Health Inc (now a part of Exact Science Corporation) predicts the likelihood of breast cancer spreading in the body within ten years of diagnosis in people who will be taking hormone therapy for at least five years. One test of Oncotype DX Breast Recurrence Score test costs INR 320,000 (approximately USD 3900), therefore, while it is used by some of private hospitals in India, it is unaffordable for majority of the population (Ghosh, 2018).[28]

Such technologies are being increasingly used in the US and other advanced countries for early diagnosis, but they are difficult to integrate into the larger health system in India, with no connections with domains (1) and (3) because they are expensive for Indian patients with a long turnaround time (3 weeks).

In recent years, even in this category, there have been some strides in the Indian context (triad element 1). OncoStem Diagnostics is one of the first start-ups focussing on innovative

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[27] https://www.biospectrumindia.com/features/73/7130/indian-diagnostics-stuck-with-traditional-testing-methods.html (last accessed 31 January 2023).
[28] https://www.medilinksinc.com/patient-info/add_patient.html#:~:text=Cost%20of%20the%20Oncotype%20DX,to%20Genomic%20Health%20Inc%20USA (last accessed 31 January 2023).

'multimarker prognostic and predictive tests' to support personalised treatment and reduce the overtreatment of patients in India. It was founded in 2011 by Dr Manjiri Bakre, an expert in cell biology and cell signalling with over three decades of experience in research and technology in India, the USA, and Singapore – to develop and deliver innovative, cost-effective, and reliable tests for personalised cancer treatment. Dr Bakre's motivation was to address the problem of overdiagnosis or overtreatment of breast cancer with a prognostic test. OncoStem developed CanAssist Breast (CAB) in 2018, an AI-based prognostic test that provides information on the risk of recurrence of early-stage, hormone receptor-positive breast cancer in patients by analysing critical biomarkers in the tumour. As large studies have shown that many early-stage patients are over-treated, the test was developed with the objective of assisting the treatment plan following early detection. The website of OncoStem states that if a patient is diagnosed with early-stage, invasive breast cancer, it is likely that they may not benefit from chemotherapy. If the doctor prescribes CAB post the completion of surgery, proceeding the cancer treatment, CAB examines the tumour using a proteomics-based method and proprietary machine learning-based algorithm to analyse a patented combination of 5 protein biomarkers and three clinicopathological parameters from the patient's tumour to predict the risk of cancer returning post-surgery. Hence, the test integrates tumour biology with clinicopathological parameters to provide a risk score that classifies patients as 'low risk' or 'high-risk' for breast cancer recurrence over five years to personalise treatment plans. The accuracy of AI/ML-based methods is dependent on the quality of data on which they are developed, hence care must be taken to use the best data (Bakre, 2021). In comparison to the above tests (Oncotype and Mammprint), CAB costs approximately INR 60,000, and the report takes 8-10 days as it is processed in a reference laboratory at Bengaluru, accredited by the College of American Pathologists (CAP) and NABL and participates in various External Quality Assessment Schemes (EQAS). Moreover, CAB is CE marked, ISO 13485 certified, and has been validated in a retrospective multi-centric clinical study in India, USA, and Europe (Austria, Italy, Germany, Spain) on close to 2000 patients inclusive of both pre-menopausal and post-menopausal patients. Several tests in personalised genomics are also being offered by mapmygenome, a molecular diagnostic firm in India.[29] Mapmygenome has partnered with

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[29] https://mapmygenome.in/diagnostic/cancers/

a diagnostics firm, Lucid Diagnostics, to provide such personalised genomics as a part of comprehensive cancer screening tests.[30]

Category D

5.6. Early detection modalities are neither developed in industrially advanced countries nor in India (category D of Table 5.1)

The bottom right quadrant particularly represents the unavailability of appropriate population-level early detection modalities for cancers which are prevalent in some Indian states, for instance, stomach cancer, lung cancer, and prostate cancer. The senior officer of National Centre for Disease Informatics, ICMR explains the heterogeneity of cancer burden and the concomitant need for diagnostics:

> 'India is not one country so one size fits all do not work – there is a huge requirement of customising and tailoring interventions depending on the cancer epidemiology. Since 2003, cervical cancer rates are on decline – but there are regions where still find higher rates. So, using same kind of resources for high and low burden areas is not cost effective – this is one example. Then there are some cancers which are prevalent in somewhere in higher proportions – for instance if you look at oral cancer, you will find it more in central part of India, north-east and some part of west – however, oral cancer is not much of a problem in Punjab, Haryana, Jammu Kashmir. But these states have their own problems, like Punjab has higher proportion of prostate cancer – so we need programmes to screen prostate cancer. Similarly, we [India] requires methods and tools for early detection of (a) stomach cancer in north-east, north-eastern states have a very peculiar distribution of cancer – for instance nasopharyngeal carcinoma which is most prevalent in Nagaland. Then, (b) Thyroid cancer is prevalent in coastal belt of Kerala, pockets of Arunachal Pradesh and Mizoram. Similarly, you don't see a lot of cervical cancer cases in Jammu Kashmir area. So, there is a lot of heterogeneity in cancer distribution – so newer cancer screening tools should come up particularly for stomach cancer. The focus should be on early diagnosis in oesophageal, GI, liver cancers, colorectal cancer, prostate cancer, thyroid cancer. It is because screening for all these cancers will not be cost-effective in India.'

Health policy, Author's interview (2021)

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[30] https://www.biospectrumindia.com/news/78/12894/lucid-diagnostics-mapmygenome-partner-for-cancer-screening.html (last accessed 31 January 2023).

5.7. Chapter summary

In this chapter, I presented the co-evolutionary journey of the existing early detection measures of breast, cervical, and oral cancer, and the emergence of the recent PoC Medtech innovations in India.

The chapter utilised the lens of a theoretical framework to understand the actors and networks, and technologies and how each technology is channelled by the institutional triad differently and vice versa. In India, health care delivery infrastructure, health finance, and human resources vary from state to state due to the quasi-federal nature of governance in India, a complex set of interactions shapes early detection modalities for cancer. By dividing early detection modalities into four A, B, C, and D categories (Table 5.1), the chapter presented the landscape of technologies and selection environment through the lens of a theoretical framework of this thesis.

In category A, I highlighted early detection modalities for cancer imported from industrially advanced countries, and locally relevant technologies for India exist (top left quadrant). These screening modalities include the gold standard tests and devices for early detection of breast, cervical and oral cancer in India. The knowledge and technology transfers from MNCs for 'gold-standards', particularly imaging technologies, for early detection of breast cancer (mammography and CT scans), and cervical cancer (HPV testing and pap smear) and no modality for oral cancer. There are minimum local R&D, and key producers include North American and European MNCs, with some of the Indian firms locally manufacturing to lower the cost of production (triad element 1). In terms of networks connecting various actors, there are multiple industry associations driving collaborative actions and networks of these actors. In mammography and related imaging, the development and diffusion are predominantly MNCs firm driven. Technologies are available at private health facilities (hospitals and large clinics, diagnostic centres) and public hospitals (Triad element 2), but high OOP expenditure reflects low health insurance schemes covering diagnostics. Regulatory processes are challenging both MNCs and Indian firms, and procurement rules have been based on firm size, favouring MNCs. Albeit recent changes in PLI schemes and recent changes in procurement highlighting purchase preference to suppliers with a stipulated percentage of local content (no capture of need and weak development of demand in Triad element 3).

In category B, early detection modalities for cancer are not imported from industrially advanced countries, but locally relevant technologies for India exist (top right quadrant of the matrix). This category presents two sets of diametrically opposite modalities. First, low-cost technologies are adopted in public health screening programmes. Second, a new trajectory of AI and ML-based innovations is emerging in the Medtech sector. Therefore, regarding knowledge and technologies, this category includes low and high-technological solutions. While the first set of modalities, including CBE, VIA, and visual inspection of the oral cavity are cost-effective, there are weak linkages in terms of generating demand both through the health system and at individual levels. As regards the new trajectory of MedTech innovations, there are some signs of linkages among three co-evolutionary vertices of triads (1), (2), (3). A wide range of starts and academic research links are primary contributors to innovation activity. A range of multidisciplinary networks across ministries, academia, and industry provides important networks for actors in these innovations. There has been a major change in actors and knowledge sources as innovations emerged in the Indian MedTech. For instance, there is a surge in researchers/technologists / management professionals turned entrepreneurs in the landscape of cancer detection innovations. This not only signifies role of industrialising countries as a producer of innovations but also prompts us to understand the nature of the innovations. These new trajectories of innovations aim to mitigate the existing unmet needs and gaps in the early detection methods by expanding affordable access utilising advanced computing solutions (like machine learning and artificial intelligence-based solutions) and sustainable business models.

In Category C, early detection modalities are imported from industrially advanced countries but with no locally relevant technologies for India (bottom left quadrant of the matrix). In terms of knowledge and technologies, these are primarily high-cost technological tests that are proprietary in nature, requiring specialised laboratories for breast cancer (like gene test Mamaprint, Oncotype). For these innovations, the Indian market is seen as merely as end user, that too in a limited manner, in the global value chains. The technology used in these early detection modalities is available from advanced industrialised countries but difficult (and not viable) to integrate in the larger health system in India due to high cost and (weak connections triad element 2), with no connections with (triad element 1) and (triad element 3). Albeit there are some strides in this domain in the Indian context, for instance, innovations like OncoStem and Mapmygenome.

In the last category D, no solutions and innovations are available in industrially advanced countries or India (bottom right quadrant of the matrix). This category represents an opportunity to tailormade an approach to policy and research in screening and early diagnosis modalities for cancers which are prevalent in some Indian states, for instance, stomach cancer, lung cancer, and prostate cancer.

Given these reflections on the selection environment and evolutionary framework highlighted in this chapter and the earlier chapter, and the MedTech innovations discussed in the chapter, it is important to study MedTech innovations in more detail. In the next chapter, I analyse in-depth study of 4 cases of PoC MedTech innovations focussing on identifying inclusiveness, the process of development, diffusion, and adoption of early detection innovations emerging for breast, cervical, and oral cancers. Case 1 is a novel radiation-free and privacy-aware breast screening technology targeting women of all ages, Thermalytix and SMILE 100, developed by NIRAMAI, founded by female technologist and management. Case 2 is OralScan, a novel handheld screening device for oral cancer screening. Case 3 is CerviScan a novel technology for faster computing of pap smear. Case 4 is CervAstra, point of care computational pathology for cervical cancer detection.

Chapter 6: Case studies for four point of care MedTech innovations

6.1. Introduction

In the previous chapter, I provided an analytical overview of landscape of the early detection methods. This chapter describes in-depth cases of four PoC MedTech innovations for the early detection of breast, cervical and oral cancer developed in the Indian context (see Table 6.1). This chapter engages with all the research questions of the thesis.

Table 6.1: Brief case description

Early detection of cancer (type)	Innovation	Market introduction	Start-up firm
Breast cancer	Thermalytix	2017	Niramai Health Analytix Private Limited
Oral cancer	OralScan	2020	Sascan Meditech Private Limited
Cervical cancer	CerviScan	Yet to be launched	
Cervical cancer	CervAstra	2020-21	Aindra Systems

Source: Author's presentation of case studies.

These cases reflect data collected from online semi-structured interviews with a range of stakeholders including innovators, biomedical engineer, clinical research scientist, private diagnostics provider, incubators, and private equity investors. I also corroborated the data with insights from podcast interviews and online conference interactions with health care professionals, and regulators. Within the ambit of the research questions, these cases are developed to provide an in-depth insight on emerging innovations, unmet needs and their innate

embeddedness of local context, and how same selection environment works differently for different cases. From Section 6.2 to Section 6.6, I present these four in-depth case studies.

6.2. Thermalytix: Novel breast screening technology

This is the case study of MedTech innovation to screen and detect breast cancer. The screening solution, Thermalytix, is offered by Niramai Health Analytix Private Limited (Niramai), a start-up based in Bengaluru, Karnataka, India. The ethos behind application of AI and ML is based on mission of NIRAMAI, which is an acronym for 'Non-Invasive Risk Assessment with Machine Intelligence'. It transliterates to 'being free from illness' in *Sanskrit*.

The novel solution uses a high-resolution thermal sensing device and a patented cloud hosted analytics solution driven by AI for analysing the thermal images. It is a portable, non-invasive, radiation-free, and no-contact solution that measures the temperature distribution on the chest to detect early-stage breast cancer accurately.[31] This case presents an opportunity to understand the inclusive elements of this innovation, and the factors that influenced the development and adoption of Thermalytix in the Indian health care system.

6.2.1. Who is the lead innovator and what motivated them to develop the technology?

The lead innovator and founder of Niramai, Dr Geetha Manjunath, is a computer scientist with extensive research leadership experience of over 25 years with major multinational IT companies.

Her training as an engineer (1984-89) and experience in a research-oriented environment at the Indian Institute of Science, Bangalore (India) – where she got her master's degree in computer science (1989-91) – nurtured her innovative thinking and problem-solving skills:[32]

> 'IISc gave me a lot of fundamental thinking about research, how to do something that not many people have done before. I decided to have career in research' (TEDx Talks, 2022).

These skills further developed while working with C-DAC between the years 1991-1997, where she worked with the team that developed the first commercial supercomputer of India. She continued working on innovative solutions in her research leadership positions in large IT

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[31] https://www.niramai.com/technology/ (last accessed on 21 March 2022)
[32] https://in.linkedin.com/in/geetha-manjunath-82b8058 (last accessed on 21 March 2022)

multinational companies. She has experience of working with international IT firm like Hewlett-Packard Laboratories (1997-2009) in Bengaluru (India) and Xerox Research Centre India (2013-2016). During this time, she worked with global teams on business and research ideas and prototypes of technology solutions. This experience played an instrumental role in furthering her interest in making a real impact through research. She mentored machine learning and analytics researchers and academics trying to develop innovative solutions in healthcare, transportation, education, and customer care. Alongside, she pursued her doctoral degree in artificial intelligence from the IISc and management degree in innovation leadership from Kellogg School of Management of Northwestern University, Illinois (USA).

Dr Manjunath was motivated to research the challenges of early detection of breast cancer after close family members were detected with late-stage breast cancer.[33] Therefore, she delved into understanding the gaps and challenges with the prevailing methods of sensing early detection of breast cancer. During her research, she found there is no appropriate early detection solutions exist for women under 45 years of age. With the help of a colleague, she found thermal imaging to be adjunct modality, but not being used due to subjectivity and interpretation challenges. Several studies have found challenges and opportunities on the role of thermography in breast cancer screening (Kennedy et al. 2009, Borchartt et al., 2013, Kandlikar et al., 2017). During her initial research on early detection of breast cancer, Dr Manjunath and her team learned that some doctors use thermal imaging to detect early-stage breast cancer. The thermal images measure the temperature variations on the skin. The thermography clinics provide a report based on visual analysis of thermal images, but these are very complex and capture around 400,000 temperature points shown as a 'colour pixels', wherein each pixel can be any of 2000 colours. However, there are myriad of challenges associated with the visual interpretation of complex thermal images. For instance, visual interpretation of these thermal images constitutes a huge cognitive burden even for an experienced thermographer.[34] Thermography thus has not been widely used in medical practice as manual diagnosis can be subjective and prone to errors. Therefore, as a part of an exploratory project in Xerox, Dr Manjunath and colleagues worked on the initial ideas of using machine learning to automate the process to facilitate high accuracy of interpretation of thermal images:

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[33]InvestIndia interview with Dr Geetha Manjunath: https://www.investindia.gov.in/team-india-blogs/interview-geetha-manjunath-niramai-health-analytix (last accessed on 1 October 2022).
[34] https://www.niramai.com/faqs/ (last accessed on 20 October 2022).

'we though why not use a non-radiation based thermal imaging for breast cancer screening. But if you google you will find a lot of negative opinions about it. I thought as technologist and AI scientist lets improves accuracy of this'. (TEDx Talks, 2022)

There were several considerations in developing the solutions, including factoring in for an increase in temperature due to several factors – how to ensure accuracy in identifying the malignant site and reduce false positives? This question was quite pertinent in the development of the solution because it can impact critical clinical decision-making for cancer. The interest increased as the research yielded early results of using machine learning on thermal images. The founder explains,[35]

'The results of just thermal imaging were not great at start. For instance, even if there are no abnormalities, they turn up as red spots in a screening. Not all red spots are cancerous. So, we had to do a lot of research in machine learning algorithms, and we now see promising results. In fact, I decided to quit my corporate job in January 2017 to focus on it completely.' (Natarajan, 2019).

To pursue this full-time, Dr Manjunath, along with her colleagues started NIRAMAI, which incubated as a start-up under Tata Elxsi (further details are discussed in the later sections).

6.2.2. What is the novel technology?

The main novelty of technology is facilitating detection of breast cancer for women of all age group by ensuring that AI-based computer-aided diagnostic engine that demonstrates high levels of accuracies.

The first technical solution developed by the team facilitated identification of the location of tumour in a cancer patient and detection of even very small lesions without any side-effects. This prompted the idea of developing the solution as a screening tool for women of all ages as a preventive measure (Natarajan, 2019).[36] The key elements of the novel breast screening tool by Niramai mitigates several challenges in the prevailing methods of the early detection of

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[35] https://www.healthcareexecutive.in/blog/niramai-a-non-invasivelow-cost-portable-device-curbing-breast-cancer#:~:text=How%20cost%2Deffective%20are%20the,it%20for%20under%2010%20lakh last accessed on 20 March 2022).

[36] https://yourstory.com/2020/05/product-roadmap-healthtech-startup-niramai-breast-cancer-river-blindness/amp (last accessed on 20 March 2022).

breast cancer and has received 26 granted international patents.[37] Some of the key features of Thermalytix (see Figure 6.1) include:

(1) The thermal sensor or infrared camera is used to capture thermal images and provide temperature distribution on the chest. Due to the increased metabolic activity of cancer cells, the affected region exhibits temperature elevations, which can be detected as an abnormality on thermographic imaging. The high-resolution thermal images and heat maps are uploaded into SaaS based software and analysed using patented machine learning algorithms (Thermalytix) along with the demographic information of the woman.

Figure 6.1: An image of Thermalytix solution offered by Niramai.
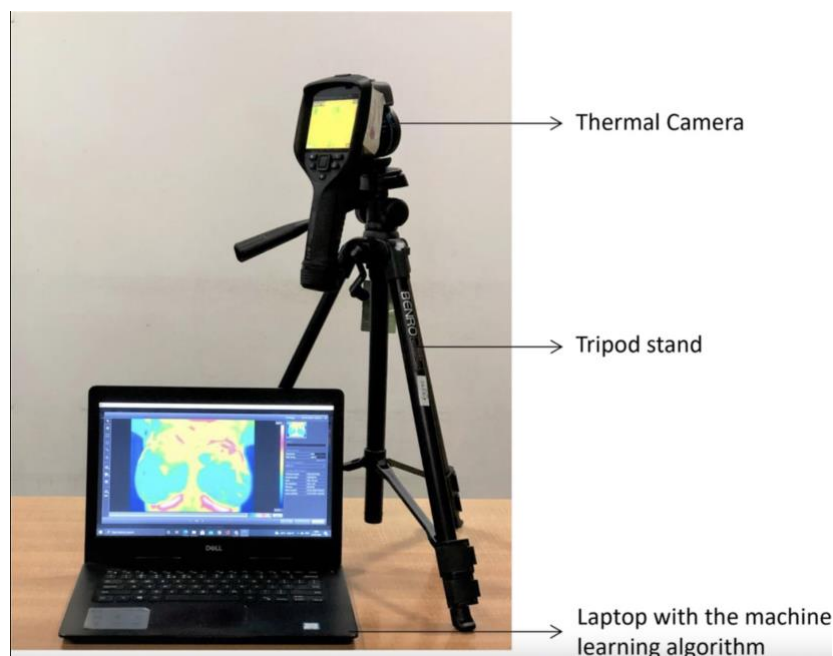
Source: Image from Singh at al. (2021).

(2) AI-enabled software and machine learning model facilitate objective assessment of the thermal analysis, of all the 400,000 colour points both in imaging domain as well as temperature domain. Unlike thermography, in which two different shades of a colour are hard to distinguish, Thermalytix can distinguish even a difference of even 0.02 degree Celsius, providing a sensitive analysis.

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[37] https://www.niramai.com/niramai-bags-us-fda-clearance-for-their-medical-device-us-markets-now-open-for-the-innovative-indian-startup-niramai/

(3) The machine learning models are calibrated with historical data labelled with current standard of care. The models are trained based on labels learnt from mammography and sono-mammography and biopsy, and not using reports of thermographers.

(4) It can localise breast cancer lesions, as small as 4 mm, in women. It analyses the thermal images for every screening and provides a quantitative report.

(5) The auto-generated report identifies and locates any abnormalities in the breast, and the probability of it to be cancerous, which can be reviewed by radiologist or doctors. It is thus able to detect abnormal thermal signatures at the tissue level by examining the irregular metabolic activity via increase in focal asymmetric temperatures and provide consistent and accurate results without any human bias or interpretation. Several clinical studies have demonstrated that Thermalytix can be used as a novel method for early detection for breast cancer (Manjunath et al 2019; Kakileti et al, 2020; Singh et al 2021).

Additionally, Niramai has developed a patented technology that automates the checks and balances for accurate imaging so that users do not make mistakes when capturing images. This is done through a web interface called SMILE (Software with Machine Intelligence for Life Enhancement), which allows Niramai-certified technicians to upload patient demographic data and their thermal images (see figure 6.2). Image processing is then done using Thermalytix, which analyses the health of the patient's breast and produces a report with scores indicating the likelihood of malignant tumours or other abnormalities. This is specifically to ensure that aspects that affect the accuracy of the screening are in place. These include the position of the woman in front of the thermal sensing device, the time taken to prepare the woman being screened for cooling and ensuring that the correct type of images is taken. The SMILE -100 system has also received US FDA 510(k) approval for use as a breast thermography device to assist healthcare professionals in reviewing and analysing thermally significant indications in the breast region.

Figure 6.2: Graphic representation of the SMILE-100 System by Niramai
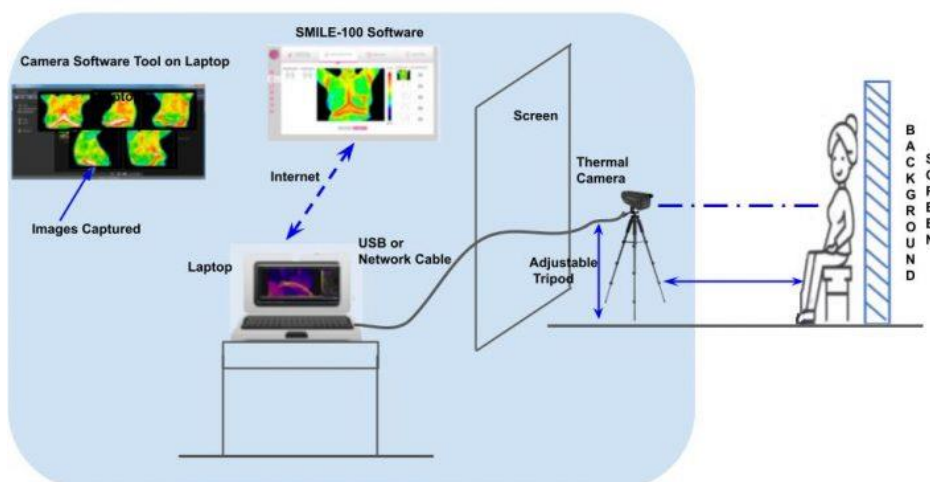
Source: Niramai's website

6.2.3. What are the inclusive elements of Thermalytix?

Thermalytix is a femtech for breast screening that identifies and targets unmet needs that arise due to existing modalities by offering a simple screening test for women of all age groups. The innovators suggest that the use of thermal imaging supported by machine learning algorithms have multiple advantages: (a) no-contact, non-invasive, painless as it does not involve breast compression, radiation-free, and privacy aware method that works for women of all ages without any side effects,

(b) it does not depend on the breast density of the user which increases the acceptability by the women users,

(c) the solution is low-cost and is designed to be used in low-resource healthcare settings,

(d) it conclusively identifies women who need further testing.

It has also been used for large-scale population screening in rural areas or as a part of regular health check-ups in hospitals and diagnostic centres, particularly in tier-2 and tier-3 cities (non-metropolitan). The women-lead innovator has taken cognisance of sociocultural aspects and sensitivities related to breast cancer screening. These are reflected in the fact that the screening

protects the privacy and does not require touching. It also relieves the women of the psychological burden of voluntarily opting for screening as a preventive measure.[38]

In terms of usage in low-resource healthcare settings, the novel screening solution is portable, easy to use, and can be used with minimal training. The founder explains the portability of the device,

> 'it is almost the size of your cabin baggage. The reason is that a small cooler goes with it, the device itself is vert portable and can even be put in a bag pack'. Forbes India – Tech Conversation (2022)[39]

Niramai has also leveraged technology to mitigate the challenges associated with the lack of availability of clinicians and trained human resources, as well as subjectivity and human bias in reviewing and analysing reports. Because the technology is automated, it can be used by users who are not doctors or medically trained. During field implementation, the team of Niramai found that the software needed to be smarter to enable successful screening at scale, especially in remote and rural areas where end users may not be very tech-savvy. The technology is leveraged to develop a user-friendly innovation that can be used even by less skilled people in the shorter time frame with limited training (100xExntreprenuer, 2020). The automation offered by AI and its subsets also enable scalability for the doctors. The whole process of screening using Thermalytix takes about 15-20 minutes. Out of this time, 10-15 minutes needed for the patient's body temperature to normalise to room temperature and the actual screening taking less than 5 minutes.[40]

6.2.4. Factors that influenced development of the breast screening solution

(1) Interdisciplinary knowledge exchange and tacit learning

The diverse skill set of the team members at Niramai has been instrumental in the development and diffusion of innovation. For instance, the co-founder, Nidhi Mathur has experience of working with multinational IT companies and a master's degree in business administration from the Indian Institute of Management Bangalore (India) with a specialisation in marketing

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[38] https://www.prlog.org/12629317-tata-elxsis-incubte-mentors-ai-healthcare-startup-niramai.html (last accessed on 12 March 2023)

[39] https://www.forbesindia.com/audio/forbes-india-daily-tech-conver-sation/geetha-manjunath-founder-and-ceo-of-niramai-on-cancer-detection-using-smartphones-and-ai/74291 (last accessed on 12 March 2023).

[40] https://www.niramai.com/faqs/ (last accessed on 12 March 2023)

and strategy[41]. This management experience and education helped in finding a product-market fit for technologies, particularly validating new technologies through incubation, launching innovative products and scaling in large enterprises and start-ups by identification of viable business models.[42]

The team has been working on developing the technology since 2013 and utilised their deep competence in the field of artificial intelligence and worked with regular feedback and insights from radiologists and oncologists to enhance the accuracy levels at par with the standard of care.[43] These interactions helped Niramai to bridge knowledge gaps in the early detection methods for breast cancer screening in an affordable manner.

(2) Continuous funding provides impetus to mitigate supply chain disruptions.

Niramai has received funding and incubation support through various stages of product development and raised around USD 14 million (STPI, 2022). Table 6.2 provides details on funding and incubation support received by Niramai. To start with, Niramai got incubation support from Tata El'si's Incub@TE. Tata Elxsi is a provider of design and technology services across industries, under which the Incub@TE program supports start-ups and entrepreneurs to understand the product-market fit and develop ideas into commercially viable products or services. Building on this, Niramai partnered with Pi Ventures, an AI-focused fund, to lead the seed round of funding, with co-investments from Axilor Ventures, Ankur Capital, and Binny Bansal (TeamInc42, 2019). This funding helped mitigate some initial challenges to purchasing high-resolution thermal sensors for experiments. The Niramai team imported its thermal hardware from Sweden and Korea. Successful clinical studies of the product further helped to find both Indian and international investors, and a next series A funding of USD 6 million in 2019.[44]

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[41] https://www.analyticsinsight.net/niramai-a-revolutionary-breast-cancer-screening-solution-powered-by-ai/ (last accessed on 1 March 2022).
and https://www.niramai.com/ (last accessed on 1 March 2022).
[42] https://www.niramai.com/team/nidhi-mathur/ (last accessed on 1 March 2022).

[43] https://www.indiainfoline.com/article/editorial-interviews-leader-speak/nidhi-mathur-coo-and-co-founder-niramai-118082700167_1.html (last accessed on 13 March 2022).
[44] http://timesofindia.indiatimes.com/articleshow/68156748.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (last accessed on 5 March 2022).

Table 6.2: Different funding and accelerator avenues for novel breast screening tool of Niramai

Year	Source of training / funding	Type of funder
2016	Tata Elxsi's Incub@TE	Incubator
	K-tech Innovation Hub at Nasscom10K, Phillips Health Works	Virtually Incubated
2017	Pi Ventures, Bengaluru, India	Early-stage venture fund
	Axilor Ventures, Bengaluru, India	Venture capitalist
	Ankur Capital, Mumbai, India	Venture capitalist
	Binny Bansal, Bengaluru, India	Angel investor
	500 Start-up, USA	Venture capitalist
2017	Google Launchpad Accelerator	Equity free support program for growth-stage start-ups
2018	BIRAC Women in Entrepreneurial Research Award	Accelerator
2019	Dream Incubator, Japan	Venture capitalist
	BEENEXT, Singapore	Venture capitalist
	Axilor Ventures, Bengaluru, India	Venture capitalist
	Binny Bansal, Bengaluru, India	Angel investor

Source: Authors' compilation from secondary sources.

The team has experienced a difference in the approach of Indian and international funders (Arakali, 2022). Some non-government investors expect very high revenues that are in line with finance or e-commerce companies. Such expectations on the revenue growth are mainly from investors which are based in India. One the other hand, the experience of Niramai suggest that international funders are somewhat more understanding of the challenges of health care technology markets, for instance, those based in US-based and Singapore (ibid).

(3) Timely identification of sites for clinical studies and support for regulatory process

As a planned strategy for clinical validation at an international level, Niramai conducted a blinded multicentric study in two reputed hospitals that are known for ethics and quality of care, Mazumdar Shaw Medical Center, Narayana Hrudayalaya and HCG Cancer Hospital (Singh et. al, 2021). The regulatory clearance was obtained in India before the start of commercial deployment. On the international front, Thermalytix has also received CE mark approval, which enable it to be marketed in any part of the European Economic Area. Further certifications including ISO 13485 and MDSAP (Medical Device Single Audit Programme) International Certifications provide validation for international medical device quality standards and regulatory requirements compliance. The recent US FDA 510(k)[45] for SMILE - 100 system has further strengthened the applications of technology not only in India but in the USA market.

6.2.5. Understanding the process of adoption of the innovations in the health system

As a new screening modality, Thermalytix faced market entry challenges. Initially, during business discussions with big hospitals, there was hesitancy in adopting the technology. According to AIIMS Delhi Twitter Space discussion on breast cancer awareness, there is less acceptability of emerging technologies vis-à-vis gold standard, mammography. The radiologist of AIIMS suggested that the benefit of early detection outweighs the risk of radiation exposure in mammography. On the other hand, some doctors agreed with the radiation-free aspect of the technology but were sceptical of its larger accuracy and validity in regular clinical practice. In an interview, the founder highlighted that the doctors would often say:

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[45] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212965 (last accessed on 20 October 2022).

'doctors have questions li–e - it's a new test, how do we believe that this actually works, even though it is radiation free, and you have some publications as well. So, the first and the foremost learnings for us was that our studies should be world-class in terms of results and the way study is conducted.' (Arakali, 2022)

In addition to the clinical studies to assuage the concerns of doctors, Niramai has adopted the following routes for effective scaling-up and diffusion:

(1) Multiple business models for effective and affordable diffusion

At present, Niramai provides its solution using various business models that aim at minimising both capex (capital expenditures) and opex (operating expenditures). First is the paper use model i.e., a subscription-based model which highlights the key value proposition of providing automated interpretation of thermal images and generation of reports. Under this model, Niramai provides solution for diagnostics centers and hospitals, and works on a revenue sharing basis under which Niramai receives payments each time Thermalytix is used for breast cancer screening. Many hospitals prefer to buy the hardware as well to have unlimited screenings and benefit from the lower per screening cost. Hospitals including Apollo Clinics, HCG Hospital, HealthSpring Diagnostics, Dr. Ambadi's Calicut Centre for Surgery (CCS) located at Metromed Hospital, etc. are using Thermalytix (eHealth Network, 2020; eHealth Network, 2020a; IndianWeb2, 2020).

Secondly, they are utilising an outreach business model through the screening camps, for instance, team Niramai or their partner institution organise a screening camp for corporate employees, or organise screening camps with NGOs, and cancer societies. Under this model, Niramai charges a 'per day' fees (daily rental) for unlimited screenings (maximum of 50-60 screenings). Thirdly, Niramai has also developed an even lower cost model that can be used for triaging only, i.e., to determine if the screening is abnormal or normal. This is an annual unlimited screening model, with annual payment and AMC. This model is more suitable for settings that need high volume-based support including primary or community health centres, or private clinics wherein gynaecologist can use this test instead of clinical breast exam for more definitive detection and if need be, refer the patient for more detailed tests.

Several studies highlighted the potential increase in cancer mortality and morbidity as an impact of lack of timely access to early detection measures during the COVID-19 pandemic. In this regard, responding to the barriers to access to early detection measures during COVID,

Niramai further launched home screening for breast cancer in Bengaluru, Bharampur, Bhopal, Bhubaneshwar, Hyderabad, Mumbai, Delhi NCR, Chennai, Pune, etc. which allows anyone to book a regular screening by registering in the Niramai's website (see Figure 6.3).[46]

Figure 6.3: Process of home breast screening facility by Niramai
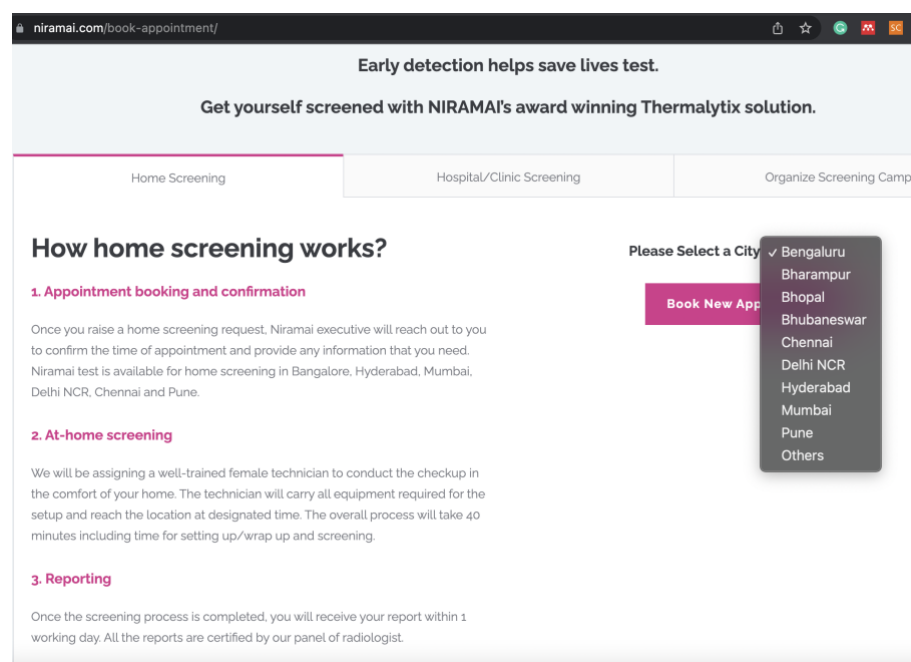
Source: Screenshot from Niramai's website

(2) Participating accelerator programmes to scale up.

Niramai also participated in accelerator programmes to scale up the technology. For instance, Google Launchpad Accelerator programme, provided Niramai opportunity to get guidance from 100 highly skilled mentors from different countries and different industries, who provided the technical and business assistance to address different challenges. Some examples from mentorship gained in Accelerator programme (Google Launchpad Accelerator, 2017):

(i)   Change in business thinking about end users and beneficiaries: An entrepreneur helped Niramai to reorient the business thinking about customers after understanding their business models that involved selling end-to-end managed solution to hospitals and diagnostic centers. He helped in understanding that hospitals could be considered as simple distribution channels, and there could be more places through which Niramai

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[46] https://www.niramai.com/book-appointment/ (last accessed on 10 March 2022).

could reach their actual beneficiaries. This idea motivated them to add new channel partners like shopping malls to cater to women who are shy and scared of visiting a screening facility (see figure 6.4).

Figure 6.4: A new article on Thermalytix screening available at less than USD 2.

(ii)   Making the product interface more user friendly: One of the mentors provided guidance to modify the interface to the product to make it more intuitive and user friendly for the primary end users (technicians, clinicians, and nurses).

(iii)   Scaling-up by cloud infrastructure: Mentors in Launchpad also advised team Niramai to transform its original monolithic web services architecture into microservices to have smaller pieces that could parallelly scale in a seamless manner. The accelerator programme also helped understanding the application of the Google based cloud infrastructure in ways that are scalable by design (ibid). Further, the launchpad also enabled mobile based software integration to enable doctors to view and certify images on mobile devices. Thus, using infrastructure of Google Cloud Platform scaling, Niramai has made more installations in India with two products to maximise coverage in rural and urban areas: a real-time triaging report for women in rural screening camps, and a detailed report for women taking the test in diagnostic centers and hospitals in urban areas.

(3) Steps undertaken to garner acceptance of the technology among clinical community.

The founder stresses that the clinical efficacy and regulatory clearance plays an instrumental role in the deep tech adoption of a health technology at a commercial level (Arakali, 2022). As highlighted before, conducting the multicentric blinded clinical study in Mazumdar Shaw Medical Center, Narayana Hrudayalaya (Bengaluru, India) and HCG Cancer Hospital (Bengaluru, India) with an external clinical research organisation and publishing it in reputed peer reviewed journal helped gaining validation and acceptance in clinical community. For instance, this reduced the time taken for pilot deployment at the hospitals from 6-8 months (before the multicentric study) to up to 6 weeks. However, even with the international publications demonstrating the use and concept of the technology, the doctors want a trial before usage. The adoption in Indian hospitals has picked up after the test received CE approval. The innovation has also received accolades, including BIRAC's Women in Entrepreneurial Research Award 2019, World Bank Group, and the Consumer Technology Association's Global Women's Health Tech Awards, which also helped in building credibility in national and international markets (DBT, 2022).

In summary, Thermalytix is a case of inclusive femtech which addresses challenges of breast screening in a low resource healthcare system using machine learning.

6.3. OralScan

OralScan is a point-of-care and non-invasive handheld device for early detection of oral cancer (see figure 6.5). It is offered by Sascan Meditech Private Limited, a start-up based in Kerala (India). The innovation enables the early identification of oral lesions. In addition, it assists the dental surgeon in performing a biopsy on the most appropriate site to confirm the diagnosis of malignancy.

Figure 6.5: Prototype of OralScan

Source: Sascan website.

6.3.1. Who is the innovator, and what motivated them to develop the technology?

The founder, Dr Subhash Narayanan is a physicist who completed his doctoral degree in laser technology from Cochin University of Science and Technology. Dr Narayanan started his scientific career in 1980 at the National Centre for Earth Science Studies (NCESS), Trivandrum, India. He established a laboratory for Biophotonics at the Atmospheric Sciences Division at NCESS and initial research included the development of multispectral imaging systems to study stress in corals and plants.

In the years between 1993-1998, Dr Narayanan got several opportunities to engage with international scholars, including, Marie Curie fellowship in the Institute of Quantum Electronics-CNR, Italy (now Nello Carrara Institute of Applied Physics) and later DAAD (German Academic Exchange Service) fellowship in Institute of Botany, University of Karlsruhe, Germany. These scholarships facilitated his investigations of ultraviolet stress-induced changes in salvia splendens plants using laser-induced fluorescence and senescence in tobacco plants from chlorophyll fluorescence. During these years, he interacted with scientists at Malmo University, Sweden, who were using remote sensing in health care by working on human tissues for cancer diagnostics. These interlinkages motivated Dr Narayanan to investigate the application of remote sensing of vegetation and corals in the field of medicine.

He shares,

> 'some scientists in Sweden were working in both the remote sensing as well as on human tissues or cancer diagnostics, so I had an opportunity to visit them in 1998. I got really fascinated by their work and I thought it would be much more worthwhile for me to work on that area than on remote sensing – because I can create an impact to the society.'

> Founder, Sascan, Author's interview (2021)

6.3.2. What is novel about this technology?

Currently, to detect early-stage cancers of the oral cavity, visual inspection of oral cavity is done by clinicians using torchlight. If the clinician suspects malignancy, it is followed by biopsy guided histopathological analysis. However, visual inspection can be subjective, and biopsies are invasive and painful procedures. Particularly in cases where several biopsies of oral tissues are taken to assess precancerous lesions and suspected malignant sites.

OralScan is a non-invasive handheld device for the early detection of oral cancer. It is the first to integrate a camera into a screening device for oral cancer. The camera used in OralScan uses fluorescence to locate the area of abnormality and diffuse reflectance to map the changes in oxyhaemoglobin in the tissue for cancer detection in that area. Hence, OralScan provides a clear picture of the developments inside the tissue through the technique of fluorescence and absorption of biomolecules inside the tissue to identify the most malignant site. Some existing point of care devices, through mobile phone photography, can take a photograph using autofluorescence imaging and white light imaging on a smartphone platform (for instance, Uthoff, et al, 2019). However, the development team of Sascan suggests that although these facilitate assessment of surface level changes, there are many tissue fluorophores that change with cancer transformation. Consequently, the signal from such pictures is a combination of emissions from different protocols. Even if one wavelength is used, it can be absorbed by various fluorophores and cannot facilitate a conclusive decision.

OralScan is thus being launched as a technological breakthrough which aims to objectively detect malignancy (and premalignancy) and correlate the pathological findings with the absolute changes in the intensity of emission.

The device is doing this by integrating handheld screening device with quantitative algorithm-based software. OralScan uses a twofold mechanism of an optical system which comes with a multispectral imaging technology based hand-held device and tablet which facilitates tissue analysis via customised software and algorithms (see Image 1). Therefore, first, the device comprises light emitting diodes (LEDs) which uses tissue fluorescence and diffuse reflectance at four different wavelengths and a monochrome camera for recording of the light emitted from the oral cavity at specific wavelengths. Second, the device includes a portable Windows tablet which has an intuitive proprietary software, which controls capturing of images synchronously with LED triggers, and further with machine learning algorithm processes image in real-time to detect early cancer lesions. The device also marks lesion boundaries and identifies the most malignant site for tissue biopsy, thereby avoiding subjectivity, misdiagnosis, and unnecessary treatments.

The diagnostic advantages of using OralScan include its non-invasive nature, facilitate a wide-field imaging of oral cavity, and utilises a cloud-based machine learning algorithm for real-time feedback on tissue status and application of oxygenated haemoglobin (HbO2) absorption maps for biopsy guidance.

6.3.3. What are the inclusive elements of OralScan?

The innovation mitigates the unmet needs due to the challenges of existing screening modalities. The device has both software and hardware component, which have been integrated and work in a way that it can capture the images in real-time to give real-time feedback to the user.

OralScan is designed particularly to expand the availability of cancer detection methods to the rural population in India, which has limited access to health care.

> 'There are a lot of companies in this domain working in US and Europe. But I find some of those devices to be expensive, and you cannot put to practice that kind of screening in the Indian context. That is why I thought we could develop something which can be suitable for the Indian context with minimal consumables and minimal screening cost. So that is why we went into this kind of technology based on optical imaging.'

> Founder, Sascan, Author's interview (2021)

It is developed with design thinking principles, considering the needs at low resource healthcare settings. The design team included electronic hardware engineers as the product is basically an electrical optic mechanism. The founder, being a physicist, also added electronic optics and contributed to the initial designing. The team also includes hardware engineers for the PCB design, testing of the device, and the actual configuration of the device. The software engineers are responsible for program coding. Users have access to all the data, and a copy of the data is stored in Amazon cloud for algorithm development through machine learning. In this regard, while the devices can be used without an internet connection, to have the recent update on algorithms the user may have to connect to the cloud. Initially, the team also included social scientists with public health and global health background to understand how the device can be placed to satisfy the larger screening needs. The design specialists worked on the user-interface design which is very critical from the clinicians' point of view and focused on the following aspects during the initial designing:

(i) What design of device would be easy to handle for the clinicians in the clinic i.e., user friendliness and human-centric philosophy of the device design?

(ii) How can it go inside the oral cavity and look for operability?

(iii) How can technical points like uniformity, the speed of image capture, the movement of the patient during screening be ensured in the design prototype?

(iv) How steady clinician can capture an image and fast the image needs to be captured to get good quality images?

After multiple iterations of biomedical instrumentations, unlike conventional techniques used for cancer detection, the design of OralScan uses an optical system with custom-built software and algorithms for tissue analysis.

Due to its user-centric and intuitive design elements, health workers across the country can be easily trained to operate the instrument, collect patient data, and share the screening report with clinicians for follow-up. The device is simple to use, and the total time taken for this procedure is 5 minutes per patient. To start with, the clinician or health care worker is required to enter the patient details and parameters in the software and mark the areas of suspicion that were located upon visual examination, if any. For optimal results, the device is required to be used

in a dark room. The clinician is required to calibrate and control the device for correct light conditions and camera opening times. This is a necessary requirement because there are multiple wavelengths, and each LED has different intensity, the aperture of the camera is required to be calibrated by the software such that all the images are equally illuminated and exposed on the three wavelengths. Once the clinician has calibrated for a particular light level, it does not need to be re-calibrated for the next patient. Then the clinician can take pictures of the oral cavity through the handheld device, and these be seen in the tablet in real-time (see Figure 6.6), which processes the image with an algorithm and provides a number which can be correlated with pathological result to suggest if the picture is normal or abnormal, and in case of abnormality what is suspected degree of malignancy. In case the tissue status warrants a biopsy, the proprietary software processes the captured multispectral images and assists the clinician in locating the most optimal site for biopsy, avoiding unwanted and repeated biopsies in conventional settings.

Figure 6.6: Images of oral cavity on the tablet
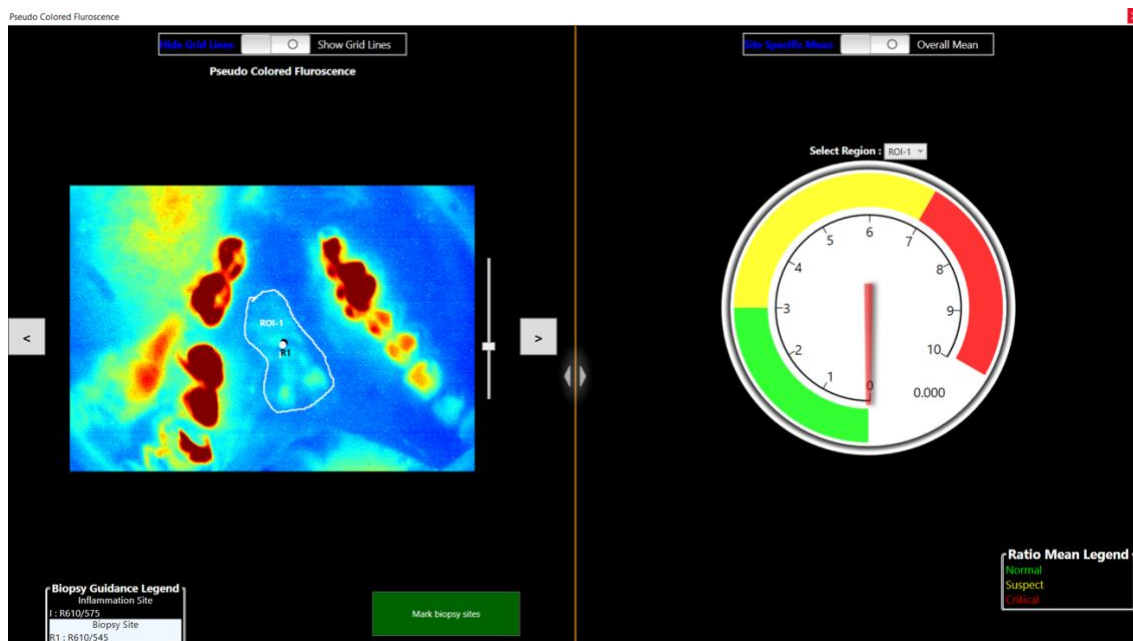
Right hand panel: Upon selecting a region on the left-hand panel image, right hand panel depicts a ratio suggesting Normal, Suspect, and Critical is displayed to guide clinician.

6.3.4. Factors that influenced development of OralScan

(1) Knowledge transfer and interdisciplinary collaborations between actors

The development of technology of OralScan was a result of several years of scientific research, multidisciplinary collaborations among physicists, medical practitioners, management professionals, and tacit learning of various actors. These collaborations spanned several disciplines, including laser technology, optoelectronics, atmospheric sciences, biophotonics, remote sensing and biomedicine, integrating the interaction of light with matter for developing non-invasive detection of vegetation / coral stress, disease diagnostics, and therapeutics, facilitated the development of devices based on combination of physics, spectroscopy, and electronics. The founder of Sascan explains the importance of prior research experience and collaborations in building credibility in MedTech space:

> 'The interactions are a great learning process, I have been in this domain for more than 20 years and the interaction with other scientists and doctors are helpful even today because such connections are always helpful, particularly if one wants to be an entrepreneur and develop device like these, for instance, I can access the doctors for clinical studies who are familiar with my work over the last 15-20 years. Having such connections is helpful as unless one has an extensive background the doctors or clinics find it hard to accept the devices. Like I had a range of publications to my credit, so it was easier for me to understand the challenges and needs of the doctor, and even interacting with them about the devices. Now suppose, someone comes up with an idea but does not have a strong background in Medtech domain, or interconnections with clinicians and scientists, it will be difficult to even raise initial funding.'

> Founder, Sascan, Author's interview (2021)

To progress his interdisciplinary motivations, Dr Narayanan collaborated with his colleagues at the Centre for Earth Science Studies, doctors at Chithra Dental Speciality Centre, Trivandrum India, and the Regional Cancer Center (RCC) (Trivandrum, Kerala, India). The investigated clinical applicability of optical techniques to discriminate different stages of dental caries on a project funded by the Department of Science and Technology (DST), Government of India. They compared the role of laser-induced fluorescence emission and reflectance spectroscopy in the detection of tooth caries lesions (Narayanan et al, 2005). In this study, laser-induced fluorescence and reflectance measurements were carried out on each sample using a laser-induced fluorescence reflectance spectroscopy (LIFRS) system developed in their

laboratory for screening of oral cancer, which was approved for clinical trials by the Ethical Committee of the Regional Cancer Centre, Trivandrum (ibid). They concluded that nitrogen laser-excited fluorescence spectral studies are found to be more suited for detection of caries lesions and have the potential to screen varying levels of tooth decay in a clinical setting.

As a result, the funding from DST facilitated several co-investigated projects on developing a point monitoring system to monitor abnormalities in the oral cavities. Dr Narayanan collaborated with PhD students in physics, and doctors to support the clinical studies, recruit patients, and collect the pathology samples to conduct analysis. Pathological analysis was compared with the spectral data to derive statistical significance to validate the study. The multidisciplinary knowledge exchange was beneficial was all the project participants, the PhD students who initially had physics background gained extensive knowledge on tissue characteristics, whereas the doctors got exposure to biomedical instrumentation. They developed a portable system (see figure 6.7) to use in clinical environment based on diffuse reflectance spectral signatures which had the potential of translating into a low-cost, fast, and non-invasive method for early diagnosis of malignant lesions of oral cancer (Narayanan et al 2006). The development of appropriate technology for OralScan gained impetus through these collaborations.

Figure 6.7: Experimental setup of diffuse reflectance spectral measurements from intact tissues
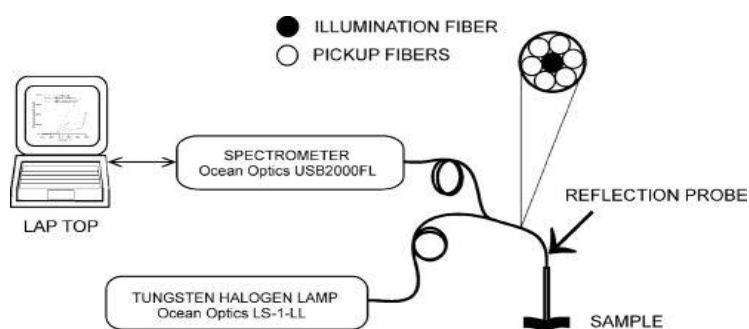
Source: Image from Narayanan et al (2006).

Their technology focussed on of diffuse reflectance i.e., probing the developments inside the tissue with diffusely reflected light and map the changes in the oxygenated haemoglobin to locate the malignant sites much more accurately than other techniques. The founder of Sascan Meditech explains the core technology,

'The science is simple, to be healthy, you need oxygen, the cells get enriched with oxygen through the oxygenated haemoglobin. If the oxyhaemoglobin level is high that suggests (among other things) a tissue and the immune system is strong. In cancer affected tissue, the heme cycle is disturbed. There is an enzyme called ferrochelatase which is low in cancer cells because heme production is low. So, oxyhaemoglobin levels are inherently low in cancer cells, which we are mapping to detect cancer. Even the Yogic principles suggest breathing techniques that facilitate more oxygen absorption in tissues. In this way, it matches and blends with the Indian school of thoughts as well.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

Tumours or cancerous tissues exhibit increased microvasculature involving elevated blood content and have abnormally low haemoglobin (Hb) oxygenation owing to the disturbed metabolism (ibid).

The clinical studies in Government Dental College, Thiruvananthapuram validated established high accuracy in the use of diffuse reflectance spectra technique in the early detection of malignant changes in the oral cavity gives with very low misclassification rate and recommended it as a tool for screening of oral cancer in wider clinical settings (Jayanthi et al, 2011). The same principle was used and became the basis of developing a hand-held probe for oral cancer. In addition to cancer detection, the researchers also successfully probed on alternate application of the technology for benign conditions viz. inflammation mapping, for instance, gingival inflammation mapping.

The initial focus was using the technology for early detection of oral cancer because (a) it is a huge public health concern in India, (b) it affects the epithelial tissues of oral cavity which is the surface of the tissue (about 2-3 mm deep), which makes it the right modality for probing, (c) technique cannot penetrate deeper tissues so it is difficult to use this technology for breast cancer or other internal organ cancer unless there are some interstitial probes. The point monitoring imaging system was used with big imaging cameras to capture the images of oral cavity.

These interdisciplinary collaborations resulted in learning transfers through which the founder enhanced the understanding of nuances of cancer detection and diagnosis. These unique trajectories of knowledge systems helped the founder in translating his scientific expertise to biomedical instrumentation. For his contributions to the field of cancer detection, Dr

Narayanan was conferred the Novartis Oration Award 2010 by the Indian Council for Medical Research (ICMR), Government of India.

(2) Management and sectoral entrepreneurial skills

To strengthen understanding of the Medtech space, Dr Narayanan shifted to Bangalore after his superannuation, where he worked as a consultant in Forus Health Pvt. Ltd, a start-up for diagnostics for pre-screening eye diseases. He explains,

> 'I was a consultant in developing the device. I could understand how the startups work and how they raise the funding. So that environment helped me a lot in thinking of starting a company.'

Founder, Sascan, Author's interview (2021)

This brought an opportunity which helped in making the transition from scientist to entrepreneur. A senior management official in Forus Health mentored Dr Narayanan to apply for Biotechnology Industry Research Assistance Council (BIRAC)'s call for proposals which was specifically looking for the researchers with innovative ideas but without substantial industrial background. This funding scheme from BIRAC has been quite instrumental in supporting the start-up ecosystem in biomedical research in India as it involves generous funding up to INR 5 million (approximately USD 68,400) to an innovator or institute with an innovative idea to develop products and mentoring support embedded in systems to ensure that the funding is utilised properly.

(3) Funding and incubation sources

Table 6.3 shows different funding and incubation sources that supported development of OralScan.

Table 6.3: Different funding sources for OralScan

Year	Source of funding	Type of funder
Prior to 2015	Various government grants for technology development and clinical studies	Government

Year	Source of funding	Type of funder
2015	BIRAC	Government
2017	Karnataka Biotechnology and Information Technology Services, Government of Karnataka	Government
2018	Villgro Innovation Foundation	Venture Capitalist
2018	KIIT-Technology Business Incubator, Kalinga Institute of Industrial Technology, Bhubaneswar	Initiative by support of Department of Science & Technology (DST)
2018	Sree Chitra Tirunal Institute for Medical Science and Technology	Government
2020	Unicorn India Ventures	Venture Capitalist

Source: Authors' compilation from interview transcripts and secondary sources

An initial funding of INR 5 million (USD 68,400) from BIRAC for an 18-month project helped to design the prototype of OralScan and conduct clinical studies in a limited number of patients. Subsequently, OralScan was incubated at the Centre for Innovation in Medical Electronics (CIME) of BMS College of Engineering, Bangalore, India [47] by Dr Narayanan (who worked as a full-time researcher) and his colleagues from Forus Health, who worked part-time. Hence, in the year 2015, Sascan Meditech Private Ltd incubated as a start-up with the objective of developing affordable screening devices suitable for the Indian context with minimal consumables and minimal screening cost. Team Sascan developed the prototype of OralScan at this stage and performed clinical studies in HCG Cancer Hospital, Bengaluru. In 2017, they received follow-on funding from Government of Karnataka as a part of Karnataka Start-up Mission which facilitated refinement in the product design and multicentric clinical trials in 5 centres.

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[47] https://bmsce.ac.in/Research/Facilities/cime_-_a_brief_report.pdf (last accessed on 2 February 2023).

Sascan diversified its funding sources, and in addition to the government funding, they periodically connect with venture capitalists and seed funding organisations. In 2018, the firm participated in a contest organised by Villgro, a social incubator that provides funding support as well as mentoring. Villgro connected the Sascan team to Kalinga Institute of Industrial Technology in Bhubaneshwar, which provided the first seed funding to Sascan in 2018. Sascan then moved to TiMED, the technology business incubator for medical devices and biomaterials. TiMED is a department in the Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST) in Thiruvananthapuram, Kerala, India. SCTIMST also provided seed funding of INR 5 million (USD 68,400) as a part of NITI seed-funding scheme, of which Sascan took INR 2.5 million to minimise equity dilation. In 2020, a further funding of INR 20 million (around USD 269,570) from the venture capitalist firm, Unicorn India Ventures, which facilitated introduction of OralScan in the Indian market. By this stage, the design evolved, and quantitative algorithm-based software was supported by machine learning.

According to the management team, Sascan received seed funding from different sources at the right time. The founder explains the importance of making the most of limited resources and being in the right connections:

> 'we didn't face that many issues as far as the funds were concerned, either, because we were bootstrapped, we were not spending lavishly, we were concerned about how much we should spend. The runway was made to the maximum possible length with the available resources. Luckily, we could get connected to the right ecosystems and right funding came at the right time'.

<div align="right">Founder, Sascan, Author's interview (2021)</div>

However, he also pointed out that it is a huge challenge to continuously raise funding to keep the firm functioning for longer durations and making quality products.

The major challenges have been to sustain the firm, market the product post the initial impetus by various funding sources and maintaining salaries of the employees at the end of the months. Sascan management explained that lack of funding is more challenging for the start-ups than mid-sized or large companies, as they have alternative revenue streams or are established companies with tie-ups with other companies or their parent company is able sustain losses. The key subsystems for OralScan are sources from various vendors and final device are

assembled in-house. The founder explained how they procure their critical parts of the device and the challenges:

> 'camera we get from Germany, and earlier camera cables were also from Germany.' 'German supplier was reluctant to give us a cable because they want larger volumes, and it requires a lot of money also to be put into that money was a concern. But now the cables are manufacturing in India. So, developing that manufacturing knowhow was a long-term process, those are intricate things, very high-level skills are needed to manufacture those kinds of cables worldwide. Because these camera connectors are very small and with so many connectors, the manufacturing is very complicated. no vendors are coming forward to do it in India. So that was a major concern. Our vendor had to learn it.'

> <div align="right">Founder, Sascan, Author's interview (2021)</div>

The manufacturing of the OralScan was affected in initial months of COVID-19 because vendors were unable to source essential subsystems as the plants were closed viz. the camera is imported from Germany. For instance, despite OralScan is in the marketing phase, the cable of the device still needs to be injection moulded. This could not be done by the launch date (in October 2020) due to supply chain delays caused due to COVID. However, initial sales of OralScan took some impetus as the minimum viable product was ready to be marketed. In this regard, the Sascan management team shared that the funding from Unicorn Ventures helped them in mitigating such COVID-19 related delays.

(4) Clinical studies and regulatory process

The clinical studies for OralScan were conducted in 6 hospitals (2 in Kerala, 1 in Tamil Nadu, 2 in Karnataka, 1 in Orissa). The team applied for approval of study protocol from the ethics committee of the concerned hospital / institution for the clinical studies. One of the major challenges in conducting clinical studies was recruiting early-stage cancer patients because hospitals usually have patients who have been already diagnosed or at advanced stages of cancer. Another challenge was ensuring successful follow-up with the patients who came for the screening. In this regard, the team found dental colleges to be a better trial site because they have a better system (through routine check-up) to recruit early-stage cancer patients. Therefore, Sascan selected JSS Dental College in Mysore, Karnataka and Sree Balaji Dental

College and Hospital in Chennai, Tamil Nadu for clinical studies. Additionally, a clinical trial coordinator facilitated ethics approval and conducted some clinical studies in Bhubaneshwar, Orissa.

Both for the no objection certificate for clinical studies and for the manufacturing license, an applicant is required to approach the Central Drugs Standard Control Organisation (CDSCO) or the concerned state drug controller office. At the time of prototyping OralScan, the medical device rules were not enforced in India. In consultation with the support in SCTIMST, Sascan completed registration of OralScan and no objection certificate from the Kerala Drug Controller office to do the clinical studies in 2018. Later, manufacturing license for OralScan was four to six months. Additionally, there are norms for ISO standards for medical device development / medical technology products, that is ISO 13485 2016. It is mandatory for the firms to have regulatory mechanisms or quality management systems in place. This includes keeping records of different versions of the design of the device, versions of software, update record keeping, etc. While the CDSCO approval and CE marking is device specific, the ISO certification is for the firm. Sascan applied for CE marking while developing Oralscan. OralScan is a Class 1 device, which means CE marking required based on self-declaration and clinical data. These additional steps enabled building quality and credibility on the innovation.

6.3.5. Understanding the process of adoption of the innovations in the health system

Sascan faced two critical challenges in initial diffusion first, doctor's reluctance to use new technology, and people's reluctance to go for regular dental check in general. One of the key members of the Sascan team shared that oftentimes upon interacting with the doctors who have been involved in the training programs for cancer diagnostics, they were told that some doctors do not feel the need to enhance the technology. In their own words:

'In my experience, no doctor in this world would ever accept that they have taken a wrong biopsy and hence there was a wrong diagnosis of the patient. They may think that it was not detected before and now it is detected so we should do the surgery or radiation therapy or chemotherapy and all. So, the doctors are never questioned enough - they feel that whatever they do is perfect. We also face these challenges, when we go to meet the doctors and tell them that sometimes you could be wrong - they are not happy with that statement. They often say that they have seen so many patients, so they do not need these kinds of devices because they feel that with their expertise, they can be very accurate in the judgements'.

At present, in some cases multiple biopsies are followed for oral cancer and these are painful procedures, which necessitates a need for painless and non-invasive devices. For devices like OralScan to enter the health care practice, willingness of doctors is very important as this could be an important step in bringing down the mortality, particularly by focussing on cases where the cancers can be screened, detected, and prevented. To this end, Sascan is creating awareness among the doctors and community clinicians about the OralScan, the clinical benefits which can be achieved in the quality of detection and diagnosis. In addition to this, Sascan is also to engaging with key opinion leaders by giving them OralScan for free and educating them on how the device can change the way the disease is prevented and detected, and in other cases diagnosed and treated in the country.

Another challenge is to generate demand among people. For instance, despite the several national and global awareness campaigns, miniscule proportion of population go for regular dental check-ups, which also impacts the early detection of oral cancer. Ideally, when an individual observes some abnormality, they should go to the doctor at the earliest stage because the late-stage detection can lead high mortality rates as well as enhanced expenditure on the treatment. While targeted awareness focussed on a clear message for the importance of early detection is of outmost importance, the senior management of Sascan suggested that people could be incentivised for screenings and early detections.

Sascan has adopted the following measures to overcome some of these challenges by adopting business models, policy recognition of technology at various platforms, and participating in screening initiatives.

(1) Business models

Three business models are being followed to market OralScan - direct sales, lease model, and pay-per-use model. The team suggests that the direct sales model is always good from a business perspective because the device could be sold without a reduction in cost and margins. However, to make the device more affordable, they are exploring different kinds of business models. For instance, lease models, wherein health practitioners / institutions can use the device for a monthly rental. Secondly, there is a paper use model in which case one can buy a recharge pack of 100-500 scans (like in case of mobile service providers) for instance, INR 500 (USD 6

-7) per scan. If user does not have enough resources to buy the device at the INR 0.59 million (around USD 7950), they can buy the device maybe at half the cost INR 0.30 million via pay per use model.

Initially, OralScan found it difficult to penetrate the market in public health system. The challenges of complex procedures for health technology assessment and government procurement processes makes it difficult to get into public health system. Therefore, for the distribution and marketing of OralScan, a multipronged strategy has been adopted. Broadly, it is being marketed through 7 channel partners in different Indian states. These channel partners, with the support of team Sascan, demonstrate usage of OralScan in different hospitals of their region, which helps in getting orders for the device.

(2) Partnerships and stakeholder interactions

In addition to this, mass media coverage, and featuring on platforms of BIRAC, DST, and SCTIMST also helped in gaining traction for the device and attracted hospitals and clinicians to opt for OralScan in regular practice. Sascan team share that they are collaborating with different screening initiatives and providing the device at a subsidised price to facilitate enhanced access to device. Some examples include:

o   a dental college in Kerala bought this device with the help of funding from Rotary Club and used it in mobile dental clinics to cover the rural population of a district.

o   a Japanese company involved in a cancer screening project with the public health system of Arunachal Pradesh, has also approached Sascan for 2 devices for OralScan to screen the local population.

In summary, OralScan is a case of inclusive modality for oral cancer screening and early diagnosis by addressing challenges of subjectivity and wrongful biopsies in a low-resource healthcare setting.

6.4. CerviScan

CerviScan is a non-invasive device for the early detection of cervical cancer developed by Sascan. Using similar technological principle as OralScan, CerviScan works by capturing fluorescence and diffuse reflectance images of cervix. Along with this, a proprietary cloud-

based software using machine learning algorithms analyses the image for objective results on whether there is malignancy. The clinician can examine the cervix and assess the grade of cervical intraepithelial neoplasia (CIN) with the help of a machine learning algorithm on illumination with LED light sources centred at the peaks of collagen and oxygenated haemoglobin absorption. This section studies the development of CerviScan.

6.4.1. Who is the lead innovator and what motivated them to develop this technology?

Dr Narayanan, along with his team in Sascan Meditech, have developed the design and prototype of CerviScan.

6.4.2. What is the novel technology?

CerviScan aims to reduce subjectivities in the prevailing techniques of early detection of cervical cancer via multimodal imaging technology and proprietary software developed by machine learning algorithms. The biomedical engineer who designed the prototype of Cerviscan explained that the fundamental principle of the technology is the clinical relevance of reducing haemoglobin production in cancer cells. Therefore, machine learning algorithms on illumination with LED light sources, centre at the peaks of collagen and oxygenated haemoglobin (HbO_2) absorption facilitate the clinicians to examine the inflammation of the cervix. It also enabled assess the grade of cervical intraepithelial neoplasia (CIN) i.e., malignancy in cervix (Damjanov, 2009).

The image clicked using diffuse reflectance uses four colour LEDs - violet (fluorescence image), green, red, and yellow. The proprietary software processes the image and produces the ratios that help identify collagen fluorescence and oxygenated haemoglobin. The ratio of LEDs (6:10 red) red and green marks premalignant or malignant lesions, and the ratio of LEDs red and yellow locates the inflammation in the cervix. In malignancy, the ratio between red and green is high as the 'green' would be low compared to healthy cells. The red will be constant because haemoglobin has a spectrum at 545 (superior absorption of haemoglobin) and is non-absorbing for haemoglobin. The CerviScan enables the clinician to mark the area of suspicion, and the most malignant site in that area is where the red/green value is the highest.

6.4.3. Understanding inclusive elements of CerviScan

CerviScan aims to replace conventional digital cytology and colposcopy, the gold standard for diagnosing or early cervical cancer detection. In case of suspected malignancy, the gynaecologist identifies the site of biopsies. However, these methods and even biopsy site identification are subjective and depend on several factors, including the clinical expertise of the clinician/health care professional. Any mistake in identifying the affected tissue can miss premalignant lesions, result in false negatives, and the smear results may not reflect malignancy. Moreover, in some cases, even with experienced clinician/ health care professionals, it could be hard to identify the cases where the first layer of the tissue is healthy, and the subsequent layers may be affected by cancer. Using CerviScan's optical technologies and machine learning algorithms can help in improving the accuracy and speed of cervical cancer screening by (i) real time detection of changes in tissue architecture, cell morphology and biochemical composition (ii) user friendly nature of the innovation.

The first objective in designing the prototype was ensuring design is conducive to the use of screening women, user-friendly, and has an in-built power supply to enhance portability. The female biomedical engineer developed the prototypes, which improved the design thinking process as it was easier for her to understand the anatomical nuances relevant to design for female patients. The initial two prototypes comprise a hand-held device with a camera, and the clinician/health care professional had to hold a speculum in one hand and a camera on the other to see the cervix. Figure 6.8 provides a prototype of CerviScan.

Figure 6.8: A prototype of CerviScan

Source: Sascan website

The gynaecologists' feedback suggested that involvement of both the hands of the clinician/health care professional in the process was causing difficulties in capturing the image and often resulted in blurred images. Another challenge during the prototype development was to design an appropriate method to integrate the CerviScan camera with the tablet or laptop so that it is convenient for the gynaecologist or health worker to complete the entire process of screening by the image capturing and data sharing to the cloud for follow-up and report generation. Mitigating this was crucial because the pathologically coordinated data enhances the algorithm through the cloud-based system. The basis of the software is on the aetiology of cervical cancer, which aligns with the graphic interface and interpretation. For instance, while in OralScan, the software marks 13 different anatomical sites of the oral cavity, in CerviScan, the software is based on anatomical sites of the cervix and grading of high- and low-grade lesions.[48] The biomedical engineer suggested that integrating the device with the laptop, instead of the tablet, was more user-friendly because the laptop could be secured on the table, whereas the tablet was heavier to handle. This issue motivated the development of a third prototype in which the camera is mounted firmly and can be tilted to give stability and allow refocusing, along with larger display screens. With this design change, the screening process has become more user-friendly. The gynaecologists also provided insights to develop clinical knowhow for the software, including terminologies for staging the cancer, etc.

Second, the device is portable to be used in low resource healthcare settings. It uses 5-volt in-built rechargeable battery that usually requires a recharge once a month, makes the device handy and portable to be used in remote locations or in screening camps.

6.4.4. Factors that influenced development of CerviScan

(1) Interdisciplinary knowledge exchange and tacit learning

As highlighted before, CerviScan applies the same technological principle as OralScan in the case of early detection of cervical cancer. The technology is a result of several years of multidisciplinary collaborations. They developed a portable system to use in clinical environment based on diffuse reflectance spectral signatures which had the potential of translating into a low-cost, fast, and non-invasive method for early diagnosis of malignant lesions of oral cancer (Narayanan et al 2006). This project laid down the foundation of

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[48] https://winfoundations.org/wp-content/uploads/2021/04/WIN-Newsletter-March2021-v2n1.pdf (last accessed on 17 August 2021).

potential low-cost screening, using diffuse reflectance ratio technique for the in-vivo detection of cervical cancer and superficial tumours of internal organs with the help of endoscopes (ibid).

To develop this technology for cervical cancer, the founder collaborated with engineers, scientists, and clinicians from Tata Memorial Hospital, National Centre for Earth Science Studies, and Advanced Centre for Treatment, Research and Education in Cancer to conduct clinical studies. The studies compared the sensitivity and specificity of two in-vivo modalities, diffuse reflectance spectroscopy and Raman spectroscopy, by utilising spectra recorded from the same sites (Pratibha et al., 2015; Shaikh et al., 2017). Both Raman spectroscopy and diffuse reflectance techniques are quantitative and non-invasive and use fibre optic probes. This enables easy access and objective screening of the whole cervix compared to traditional methods such as the Pap smear and colposcopy directed biopsy (Shaikh et al., 2017). However, they found that point monitoring requires a more extensive timeframe to screen a larger area. Nonetheless, both 'see and treat' methods have the potential of benefiting resource constraint settings of LMICs. Raman spectroscopy is ideal for centralised facilities due to its improved diagnostic accuracies, and diffuse reflectance spectroscopy is more suitable for largescale screening modalities among rural communities due to its lower cost and complexity (ibid).

(2) Funding

In 2017, Sascan received follow-on funding from Government of Karnataka as a part of Karnataka Start-up Mission which facilitated refinement in the product design and multicentric clinical trials in 5 centres in India. The funding also helped in prototyping CerviScan; however, it could not be materialised into good product as financial resources was diverted for OralScan and related actives. COVID related disruptions affected funding.

(3) Timely identification of sites for clinical studies and support for regulatory process

As Sascan has implemented ISO regulations and has obtained CE marking for OralScan, the regulatory processes became clearer for CerviScan. For the CerviScan, Sascan conducted the initial clinical studies in Regional Cancer Centre (Kerala). Sascan team has also obtained approval from the ethics committee at Manipal University and Government Medical College, Trivandrum was conducting clinical studies to fine-tune the device at the time of data collection (2021-22). The clinical team suggested that delays in clinical studies were due to COVID, as all the studies stopped as the focus of hospitals was on managing COVID.

6.4.5. Understanding the process of adoption of the innovations in the health system

At present, phase-1 clinical study with CerviScan on 110 patients is completed and the diffusion in the market is delayed because clinical studies were longer than planned due to COVID-19 disruptions. To gain initial traction, Team Sascan plans to utilise different business models including channel partners and marketing consultants, gynaecologists, the hospitals, and the NGOs who are into screening of NCDs.

In summary, CerviScan is a case of inclusive modality for cervical cancer screening and early diagnosis by addressing the challenges of subjectivity and wrongful biopsies in a low-resource healthcare setting.

6.5. CervAstra

CervAstra, is a computational pathology-based point-of-care cervical cancer detection system offered by Aindra System Private Limited, a start-up based in Bengaluru (India). CervAstra analyses pap smear (cells from the cervix) samples using a computational pathology platform to examine and detect normal or abnormal cells within a few hours with minimal human intervention, compared to other devices, which are expensive and take a longer time. The aim of CervAstra is to revolutionise the health care delivery in India and facilitate access to faster and affordable innovation to analyse pap smear samples.

6.5.1. Who is the lead innovator and what motivated them to develop this technology?

The founder is a trained electronic engineer from the Bangalore University and had experience of more than a decade of working with several IT companies like Infosys, Wipro, and Lucent.[49] He undertook a master's degree in business administration from Indian Institute of Management (IIM Bangalore), was also a fellow at the in the Startup Leadership Program in Bangalore. His work experience in IT sector and higher education in business administration inspired him to begin his entrepreneurial journey by leveraging technology to solve complex problems. Whilst working with a pilot program of IIM B's Centre for Public Policy, the founder worked on the challenge of fixing subsidy issues in the State government's midday meal scheme. He highlighted that their team suggested to the government that a touchless modality

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[49] https://in.linkedin.com/in/adarshnatarajan (last accessed on 25 March 2022).

would work better than the fingerprinting solutions to record attendance. Consequently, they designed a biometric scanner that utilises facial recognition to record attendance and machine learning to verify photo IDs against facial images captured (Aijaz, 2015). This project laid foundations for the formation of Aindra Systems by two founders in 2012 which focussed on creating AI solutions for large industries. In 2015, Aindra was split into two entities namely, Aindra Systems for designing AI models and devices for health care and Aindra Labs to developing the technology in the financial space. From 2016, Aindra System, began with using the technology for early detection of cervical cancer which is a huge public health challenge in India (Balaji, 2019). The team aimed to target early detection at the point-of-care, which is targeted to bring a fundamental change the way healthcare functions in India. The founder thus started exploring the possibilities of deep learning to address some of the significant gaps in the healthcare system. He acknowledged that it is helpful to utilise data from large medical image repositories to identify complex interlinkages and patterns to supplement the ability of clinicians to detect any anomalies at an early stage. It motivated them to use computer vision to develop adjacencies and evaluate the impact of such a tech intervention in healthcare to make a meaningful impact. The team decided on computational pathology to detect critical illnesses like cancers at the point of care and improve the accessibility and affordability of healthcare solutions for all (Mundhra, 2021). The founder explains,

> 'Technology like AI and Computer Vision have vast, multiple application areas. That's when I started meeting people from across sectors and domains to talk to them and understand what is happening in their spaces. I met people from the automobile industry, manufacturing, textiles, and then also in healthcare – and healthcare struck a chord with me. There were much more lucrative and easier routes in other segments, but what struck me was that we could democratize technologies like this and make it available for a large population to solve big problems in an economically viable manner. I felt passionate about that.' NextBigWhat (2019)

6.5.2. What is the novel technology?

CervAstra, the innovation, allows this by leveraging AI-based computational pathology using four advanced technologies - Aindra IntelliStain, Aindra VisionX and AIndra Astra (see figure 6.9) (IndiaAI, 2022).

(i) Aindra IntelliStain is an automated slide stainer dyes the sample, supporting all major staining processes like Haematoxylin and Eosin, PAP, Leishman, etc. It is designed using state of the art mechatronics and software to stain biological samples.

(ii) Aindra VisionX is modelled using data assessed by a pathologist and facilitates clear whole slide images (WSI) of the slides and allows for faster turnaround time and enables telepathology.

(iii) Aindra Astra facilitates computational pathology faster and makes an accurate diagnosis.

(iv) Clustr, Aindra's proprietary Telepathology platform, enables pathologists to share the system's preliminary results, wherein they validate the report generated by the CervAstra system.

Initially, Aindra systems planned to create one bespoke application, however due to lack of integrative ecosystems, they build the above multiple components as a single end-to-end product. The initial proof of concept had the AI software component to be tested on small data sets. However, due to lack of enabling ecosystem to capture data there were initial challenges in building the computational pathology system. Good quality data is required to be captured, which is then converted it into a digital format and then AI algorithms are applied to it. To support this process, Aindra systems built enabling systems and hardware for end-to-end ecosystem conducive for Indian settings. The founder explains the importance of building India specific point of care device,

> '[we] built hardware which just wasn't available commonly. The bitter truth hit home that India still imports 75-80 percent of its medical devices from outside and most aren't built for point-of-care but for centralized large centers such as a Vedanta or a Fortis. So, we had to design everything from the ground up to take the bull by the horns in this space and truly create a point-of-care system.' NextBigWhat (2019)

Figure 6.9: CervAstra system components for early detection of cervical cancer
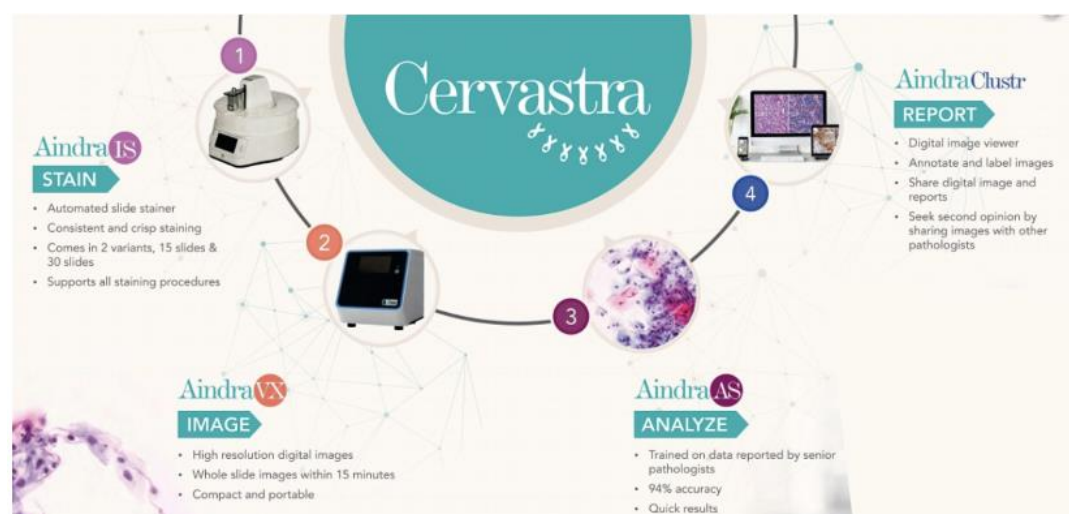
Source: Image from BIRAC[50]

6.5.3. What are the inclusive elements of CervAstra?

The design of CervAstra aims to address infrastructural gaps and structural constraints of the health care delivery system. The edge compact design and portability increase its reach beyond the diagnostic centres, particularly in the rural health care settings.

The founder explains that the to make it more inclusive, they opted not to offer AI algorithms on the cloud (ibid),

> 'This is an edge computing device, where the first level of triaging – whether a sample is normal or abnormal – takes place in real-time. For confirmation, we bring in a pathologist for a report on a non-real time basis. So once the sample is analysed by a pathologist, only then is the confirmation provided. What we're doing is decoupling the need to have a pathologist available all the time for analysis and reporting. From a medico-legal perspective, we still have a pathologist sign off. The easy way would have been to put the solution on the cloud, where it would only work in urban centers with good connectivity but that would not serve the purpose at all.'

Thus, it responds to the challenges due to shortage of pathologists, health facilities, and medical personnel in cervical cancer screening. The founder highlights that the chances of pathologists failing to detect the onset of cervical cancer despite multiple levels of screening are as high as

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[50] https://birac.nic.in/product-detail.php?product=162 (last accessed on 29 October 2022).

60-65 per cent (Shobha, 2018). This is partly due to pathologists looking at physical samples under the microscope, which is equivalent to looking for a needle in a haystack for the early detection of cervical cancer. The algorithms help automate the process of screening pap smear images. [51] Both the autostainer and image magnifier are compact and can fit into any small space, for instance, in a gynaecologist clinic, facilitating patients to submit their samples at the clinic (Balaji, 2019). The autostainer dyes the sample, and VisionX scans the sample and converts it into an enlarged digital image. Finally, the microscopic picture is analysed using algorithms to determine whether the cells are normal or cancerous.

Pap smear process mainly in rural India, is both tedious and expensive. It takes around 4-6 weeks in India and costs approximately INR 2000 (approximately USD 26.54) for the entire process of pap smear sample collection to report delivery depending on the sample collection location (Balaji, 2019). CervAstra simplifies the process by automating the analysis of the pap smear slides, making the entire process less than an hour, with a significantly lower cost of test between INR 200 to INR 400 (USD 2.5 – USD 5.31). This incentivises early detection for two reasons, first, making it convenient to get a test done. secondly, reducing dropout rates (Khan, 2020).

In this regard, medical image processing algorithms built using advanced graphic processing units can be more efficient (ibid). Aindra's AI algorithms continuously learn and evolve from the feedback from pathologists when they regularly report cases through CervAstra.

6.5.4. Factors that influenced development of the cervical screening solution

(1) Interdisciplinary knowledge exchange and tacit learning

The founder stresses healthcare industry requires typically an interdisciplinary approach. Mainly bringing together different expertise, including complex engineering, scientific and medical expertise, is a prerequisite. This is a huge entry barrier but crossing this barrier opens a range of opportunities, like it did for Aindra (Aijaz, 2015).

As the founder is not from a medical background, he collaborated with clinicians to understand the gaps and build the use case of AI based algorithm for cervical cancer screening (Balaji,

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[51] https://www.biospectrumindia.com/news/78/15215/iit-m-aids-aindra-systems-in-developing-cervical-cancer-screening-device.html (last accessed on 25 October 2022).

2019). Aindra Systems Aindra Systems (Bengaluru) collaborated with the research team in the School of Computing and Electrical Engineering, Indian Institute of Technology (Mandi) to analyse microscopy images with high accuracy and develop AI-based algorithms that enable the device to undertake automatic screening for cervical cancer (Biospectrum, 2020). Aindra obtained rigorous approvals and partnered with tertiary oncology centres, including, Kidwai Memorial Institute of Oncology, Bengaluru. This partnership facilitated knowledge exchange between clinical practice by working with pathologists and practical AI applications by using archival data that helped build the product and the algorithm.

In the initial stages of building the technology for cancer detection, the team faced significant challenges involved extracting medical data and drawing valuable information from it. The next crucial component was digitising the data, i.e., turning archived glass slides into a usable data format for training the algorithms and validating the solutions by mid-2019 (nextbigwhat, 2022). The team at IIT Mandi analysed pap smear images by Aindra and segmented them into 'normal' and 'potentially cancerous' and developed a computer program that could differentiate between the two.[52]

(2) Funding and incubation sources

CervAstra has received funding and incubation guidance from both government and non-government sources (see table 6.4). Mainly, initial funding from BIRAC and incubation support from social incubator, Villgro enabled in forming technical partnerships for design and prototype development. Further, initial support from the 'Oracle for Start-ups program, particularly Oracle Cloud Infrastructure, helped the team design improved analytics and model training time.

Table 6.4: Different funding avenues for CervAstra

Year	Source of training / funding	Type of funder/ incubator
2014-15	Villgro	Incubator

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[52] https://www.cxotoday.com/cloud/cloud-digital-tech-helping-health-tech-innovators-to-thrive-during-pandemic/ (last accessed on 1 April 2022).

Year	Source of training / funding	Type of funder/ incubator
2015	Government of Karnataka, and BIRAC	Initial Funding
2015-22	Indo-US Science and Technology Forum	Inter-governmental agreement
	Oracle for start-ups	Private
	Millennium Alliance	Inclusive platform by the Indian government (DST) in collaboration with FICCI, USAID, and the UK government.
	IKP Knowledge Park	Science Park and Incubator in Hyderabad and Bangalore, India
	Forge Factory	Incubator

Source: Authors' compilation from secondary sources

(3) Timely identification of sites for clinical studies and support for regulatory process

As highlighted above, Aindra obtained rigorous approvals and partnered with a tertiary oncology centre, Kidwai Memorial Institute of Oncology, to build the product, algorithm, and enhance consistency of the prototypes.[53] The device prototypes were tested in the clinical studies at Kidwai Memorial Institute (Karnataka), Manipal Hospital (Karnataka) and Raja Rajeswari Medical College and Hospital (Karnataka). Aindra has also received ISO-13485 certification and CE compliant, which has helped in building trust among stakeholders within and outside India (Balaji, 2020).

6.5.5. Understanding the process of adoption of the innovations in the health system

The founder expressed that it was challenging to convince pathologists, hospitals, and doctors that technology could make their jobs more straightforward and effective (Vignesh, 2018).

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[53] https://theindiasaga.com/social-sector/now-a-portable-device-to-screen-for-cervical-cancer/ (last accessed on 31 March 2022).

Initially, pathologists and doctors hesitated in using and providing inputs for software that expedites early detection faster than a pathologist. One of the key concerns were that the software may make the role of pathologist redundant because of automation. However, in one of the public interviews, consulting oncology pathologist highlights that persistence of the founder and familiarity with technology helped bridging the apprehensions:

> 'I could see the point after a while. If machines could take over mundane tasks like reading plates, reading one patient's cervical scan could take up to 25 minutes, doctors could focus their clinical acumen on more important things, like the treatment plan'. Shoba (2018)

Aindra Systems thus adopted the following measures to strengthen the diffusion and generate demand:

(1) Business models for effective and affordable diffusion

The founder underlined the importance of continuous dialogue with government to create a large-scale impact. However, he admits it is challenging because the government procurement system is historically not conducive for a start-up for twofold reasons. First, the inclusion of factors like the number of years of operational history and profitability has been a part of the eligibility criterion (Aijaz, 2015). The product was launched commercially in the fiscal year 2020-21, with an aim to screen more than half a million women across India (Khan, 2020). Multiple business models are planned to make the innovation more accessible and affordable across India, particularly in the rural parts of the country. These include both capex and opex based models targeting hospitals and NGOs. The main models include opex models like direct sale model for higher volume facilities including private and public hospital, and healthcare centres. Second, opex models including price-per-test for pathology labs, in which pathology labs are given an option to pay per test charges. A lease-based model and annual or monthly subscription-based model for health settings with moderate volumes of screening and where the capital expense can be spread over time. (ICMR, 2017).

(2) Strong sales and marketing strategy for scaling up.

In India, the use of AI was not completely democratised when Aindra Systems began operations. This posed a significant initial challenge marketing because of cost of components, computing and return on investment issues for many industries. The technological breakthrough of Aindra Systems has also won the health innovation challenge by the India-

Sweden Healthcare Innovation Centre,[54] which develops an open innovation ecosystem for start-ups and healthcare delivery stakeholders. This ecosystem facilitates clinical validation guidance at AIIMS Jodhpur and deployment of Aindra Systems' innovation at the hospital and mentoring for international expansion. Aindra has also become a part of the A. Catalyst network, an interconnected and dynamic global network of physical and virtual partnerships of AstraZeneca health innovation hubs that catalysis the development of new health care solutions.[55]

In summary, CervAstra offers an inclusive femtech by automating pathological resources for pap smear test and making it conducive for low resource healthcare settings.

6.6. Chapter summary

In this chapter, I presented an in-depth description of four cases of PoC MedTech innovations for oral, breast, and cervical cancer. Table 6.5 provides a summary of the case studies.

Table 6.5: Summarising cases of PoC MedTech innovations

Case	Description	Key characteristics
Thermalytix	High resolution thermal sensing supported by patented AI algorithms to detect abnormal thermal patterns to detect early-stage breast malignancies.	o Clinically validated novel technology o For women of all ages o Radiation free, non-invasive and privacy aware o Scalable to both urban and rural areas of India with basic training to health workers o Aims to make early detection affordable by offering different business models
OralScan	Handheld optical imaging multimodal device, along with cloud-based ML algorithms for real time feedback on	o Clinically validated novel technology o Breakthrough technology as very few precise technologies are available to screen

[54] https://www.coe-iot.com/blog/category/uncategorized/ (last accessed on 31 October 2022).

Case	Description	Key characteristics
	tissue status, and early detection of precancerous lesions of the oral cavity.	and early detect oral cancer, and biopsy guidance. o Eliminates subjectivity in early detection vis-à-vis existing technology. o Non-invasive and radiation free o Scalable to both urban and rural areas of India with basic training to health workers o Aims to make early detection affordable by offering different business models
CerviScan	Handheld multimodal imaging along with ML algorithm to examine the cervix and assess the grade of cervical cancer.	o Clinically validated novel technology o Non-invasive and radiation free o Eliminates subjectivity in early detection vis-à-vis existing technology. o Scalable to both urban and rural areas of India with basic training to health workers o Aims to make early detection affordable by offering different business models.
Cervastra	Computational pathology system improving pap smear cytology	o Clinically validated novel technology to improve existing early detection modality. o Analyses pap smear samples using a computational pathology platform to examine and detect normal or abnormal cells. o Takes a few hours (vis-à-vis conventional analysis of pap smear samples requiring a few days) o Reduces dependence on laboratory infrastructure and requires minimal human intervention.

Case	Description	Key characteristics
		o Scalable to both urban and rural areas of India with basic training to health workers
		o Aims to make early detection affordable by offering different business models.

Source: Author's representation from within cases analysis.

Some key insights connecting the cases with the theoretical framework that I analyse in detail in next chapter:

(1) The ecosystem that I captured in phase 4 of Section 2.3 of Chapter 2 is enabling innovation and entrepreneurship ecosystem in the Medtech segment of larger medical devices sector. These cases demonstrate the burgeoning of new startups in the MedTech sector, which has been a poorly institutionalised sector until recently in the Indian context. These startups focus on developing innovations that aim to address the unmet clinical needs and improve access to affordable health care.

(2) These cases are utilising advanced computing technologies to increase accuracy and scalability of early detection in low resource settings.

(3) These are cases of health system strengthening through a more inclusive form of industrial development by,

   o bridging gaps in the existing methods in a problem solving and disruptive manner, increase the accuracy of early detection of cancer in India, with a vision of scaling up to a global level, and

   o creating models of adoption that create affordable access in both rural and urban areas.

The present phase in MedTech sector reflect coherent emergence of these actors backed by policy measures. This coherence in the sector reflects some signs of mainstreaming inclusiveness with the growing linkages between health needs and industrial development. For the past decades, inclusive innovations have been seen as an alternative, off-shoots, and outside the mainstream innovation trajectories.

These cases thus provide an opportunity to conceptualise inclusiveness by engaging with unmet need of early detection of cancer. These unmet needs were from the diagnostic challenges and lack of responsiveness of existing modalities to the low resource healthcare settings. These innovations are a departure from a historical pattern that India (and industrialising economies) tend to develop low-tech devices (WHO, 2010; p 15). Thus, these innovations alleviate some perpetual challenges of 'mismatch' in the optimal use of available medical devices, and their contextual relevance to address priority health needs (WHO, 2010). It is important to note that these innovations aim to address the challenges in screening and detecting cancer in India in its early stages rather than introducing technological advancements per se. In other words, the inclusion of unmet need is a precursor than retrofitting a predeveloped technology for Indian context. In terms of the elements of IHI framework, the framing of unmet needs to influence industrial production of context specific innovation signals the beginnings of mainstreaming of inclusive innovations in the Indian MedTech sector. The primary actor in these case studies are thus the lead innovators and their motivation to resolve challenges in the early detection of cancer in India affordably. Interdisciplinary knowledge production and exchange by the lead innovator and their teams have played a crucial role in framing the gaps in existing modalities of early detection. In addition, increasing role of tacit knowledge is observed to support entrepreneurial efforts by managerial and financial knowledge from their respective education and work experiences. The involvement of primary users (including radiologist, pathologists, oncologists) in conceptualisation of early detection modality reflects significant effort to capture unmet needs. Additionally, a robust ecosystem of early-stage funding and incubation by government, hospitals for clinical studies, incubators, venture capitalists, angel investors, and private equity investors is found to be crucial in emergence of these POC MedTech innovations for cancer. In these case studies, I analyse these factors that have influenced the development of the innovations and how innovations can be sustainably adopted in the health care delivery system. I do this by analysing various business models and partnerships influencing diffusion and adoption these innovations in the healthcare system.

In the next chapter, given the references in Chapter 3, and data presented in Chapter 5 and 6, I present the conceptualisation in understanding inclusiveness in these MedTech innovations, and the actors and factors that influence their development, diffusion, and effective adoption of inclusive innovations in the Indian context.

Chapter 7: Analysis and discussion

7.1. Introduction

In this chapter, I analyse the development and adoption of inclusive innovations in the Indian context. I present the analysis in three parts, which are a function of the 'how' research questions of this thesis:

1. How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource settings (RQ1)?

2. How do the actors and factors influence the development of inclusive MedTech innovations for the early detection of cancer in India? (RQ3)

3. How are such inclusive MedTech innovations mainstreamed into health systems for their last mile' diffusion in India? (RQ4)

To guide the analysis, I use the IHI framework that facilitates a study of technical change in the MedTech sector using a co-evolutionary triad that links unmet needs and industrial production, demand, and healthcare delivery (see Chapter 4). To increase the accuracy of the analyses and minimise any potential bias, I use a broad range of secondary data for triangulation to supplement multiple case studies (see Chapter 4 for comprehensive discussion data sources and methods).

Section 7.2 focuses on RQ1 (Part A) and captures the conceptualisation of inclusive innovations for early detection of cancer in low resource healthcare settings. It provides analytical and observable, not merely theoretical, characteristics of inclusiveness in the innovation process and outcomes.

Section 7.3 explores RQ2 (Part B) and illustrates the four key actors and corresponding factors in driving development of inclusive innovations in the case studies. First, private actors as innovators, driven by personal motivations, and synthesising knowledge and technologies to create an impact in the early detection of cancer in low-resourced healthcare settings. Second, the active role of government as a policy actor in enabling conducive Medtech ecosystem driving collaborative actions, knowledge exchange, and clinical research to develop locally relevant solutions. Mainly the role of government support in early-stage finance and incubation

for product development. Third, strong presence of government in the ecosystem has also signalled non-government funding and incubation agencies. Fourth, the role of government as regulatory actor has evolved but requires further strengthening (i) to incentivise innovations (ii) to enable effective regulatory provisions for innovations with hardware and software component.

Section 7.4 investigates RQ3 (Part C) and showcases three key actors and factors influencing diffusion and adoption in the case studies. First, creation of new markets using varied business models by start-up firms capturing value through the process of innovation. Second, demand generation using partnerships with government and non-government actors. Third, stakeholder engagement by start-up firms for general awareness on cancer and benefits of using their technologies. These actors and factors are enabling effective diffusion and shaping demand for screening and early diagnosis in resource constraint settings.

Section 7.5 concludes the chapter by summarising key findings.

Part A

7.2. Conceptualising inclusiveness in MedTech innovations for the early detection of cancer in India

The analysis reveals three major signs of inclusiveness, both in the process and outcomes of PoC MedTech innovations vis-à-vis other early detection modalities. First, in terms of process of PoC MedTech innovations for the early detection of cancer, the case studies reveal (i) inclusiveness is achievable in resource-constraint settings due to the affordable applications of high technology; (ii) inclusiveness is incorporated by framing unmet needs of the early detection of cancer in low resource healthcare settings of India; (iii) inclusiveness is incorporated by involving users, clinicians, radiologist, in the design process to address unmet needs. Second, in terms of outcomes of MedTech innovations for the early detection of cancer, the case studies point out inclusiveness by (i) enabling availability and access to point of care, non-invasive, portable, and easy to use early detection modalities of cancer in low resource healthcare settings; (ii) recognising women as innovators in low-resource constraint settings; (iii) making end users (beneficiaries) not just receivers but contributors to improving technology.

7.2.1. Inclusiveness is achievable in resource-constraint settings by affordable application of high technology

The case studies underline application of advanced computing technologies by private actors to resolve challenges of availability and access to early detection modalities of cancer in India. Increased application of AI and ML in healthcare is a result of a wider ecosystem change. In the fourth industrial revolution, increased availability of AI and its subsets, ML and DL, have increased scale of delivery in several sectors, including healthcare, in India. The National Strategy for Artificial Intelligence, India (p 28) stresses on the application of AI in healthcare, mainly cancer screening, in India:

'The increased advances in technology, and interest and activity from innovators, provides opportunity for India to solve some of its long existing challenges in providing appropriate healthcare to a large section of its population.' 'AI solutions can augment the scarce personnel and lab facilities; help overcome the barriers to access and solve the accessibility problem; through early detection, diagnostic, decision making and treatment, cater to a large part of India. Cancer screening and treatment is an area where AI provides tremendous scope for targeted large-scale interventions.'

This change is driven by a spillover effect created by affordable availability of big data, cloud computing, cloud infrastructure, i.e., availability of computing infrastructure that can handle large data sets. A senior management professional of a deep-technology incubator that supported one of the case studies explained reason behind this increased availability of advanced computing technologies,

> 'declining cost of computing resources required for these AI and ML technologies; for instance, cloud infrastructure has drastically decreased in the last five years.'

Senior professional, Private incubator, Author's interview (2022)

Additionally, there is an increase in knowledge sources, e.g., an increase in AI and ML scientists, developers, and data scientists. Table 7.1 shows how each case study utilises hardware and a software component driven by AI and its subsets, ML, and deep learning (DL) for the early detection of cancer in low-resource healthcare settings.

Table 7.1: Applying AI and ML in early detection of cancer in low resource settings.

Innovations	Which existing modality is being improved?	What are its challenges?	What is the novelty in the PoC MedTech innovations?		How high technology invoke inclusiveness?
			Hardware component	**Software component**	
Thermalytix	o Thermography	o Multiple temperature points, difficult to interpret and analyse for human eyes.	o High resolution thermal camera	o Uses cloud-based ML solution to analyse different temperature points pf thermal images	o Making thermal imaging conducive for low resource settings by applying ML to analyse and extract more than 120 features from the image. o Give an objective score to identify whether a person is likely to have breast cancer.
OralScan	o Visual inspection of oral cavity	o Involves subjectivity, no biopsy guidance, and shortage of clinicians.	o Multimodal LED camera	o Uses cloud-based ML solution to analyse images for peaks of collagen and oxygenated haemoglobin absorption.	o Making available an objective early detection modality conducive for low resource healthcare settings by real-time identification potentially malignant sites; and biopsy guidance (if needed)
CerviScan	o Pap smear test o Visual inspection of cervix		o Multimodal LED camera		o Making available an objective early detection modality conducive for low resource healthcare settings. Real time analysis and grade cervical cancer and locate the most malignant site.
CervAstra	o Pap smear test	o Time consuming results because of lack of infrastructure and shortage of pathologists	o 3-part system for staining and digitisation of pap smear samples	o AI platform facilitating computational pathology	o Making pap smear conducive for low resource settings, and screening geography independent, by offering faster and accurate diagnosis at point of care.

Source: Author's data analysis.

Each case study is driving inclusiveness using these high technologies in two primary ways:

- introducing a novel method of screening and early diagnosis.

- making current adjunct and gold standard modalities conducive to Indian settings.

In the case of breast cancer, thermography is an older adjunct technology of using temperature variations on the skin using an infrared camera. However, it has not been adopted in clinical settings due to the low accuracy of visual analysis by clinicians and radiologists. The lead innovator of Thermalytix explains,

'Use of Thermography for breast cancer screening has been tried by some doctors and there are some companies selling pure hardware solution to capture thermal images. However, manual interpretation of thermal images is error-prone and is very complex as the radiologist needs to look at 400,000 colour data points to decide if a subject is malignant or not. Thermalytix generates a quantitative thermal analysis report with health scores that depict the level of abnormality, which can be reviewed by a doctor to quantitatively identify the abnormal condition.' Boynton (2019)

The use of ML in Thermalytix enables objective analysis of thermal images. It segregates hot spots, warm spots, and vascular patterns from the thermal images obtained during screening process. Thus, a pretrained and clinically validated cloud-based ML software generates quantitative scores. These scores along with annotated thermal images provide markings of hot spots indicating the probability of a malignant breast lesion. These quantitative interpretation report with the scores are generated within 5 minutes. In the manner, use of ML enables a point of care femtech for breast screening that is objective, non-invasive and radiation free.

In case of OralScan and CerviScan, the images of oral cavity and cervix, respectively, taken using multimodal imaging devices are analysed using cloud-based ML software. The ML algorithm enables automated analyses of images, analysing oxygenated haemoglobin absorption maps to locate potentially malignant transformations in tissues in oral cavity (DST, 2020) and cervix (Win Foundation, 2021). Thus, the ML algorithm enables a point of care modality that is objective and provide a real time feedback on tissue status supporting both screening and biopsies for oral cancer and femtech for cervical cancer.

In the case of CervAstra, the focus is on using advanced computing to expedite the processing time of reports of pap smear test at the point of care under a few hours. It provides a point-of-care cervical screening solution conducive for low-resource settings. It is doing this by simplifying the logistical requirements of pap smear test by using computational pathology.

Two key insights emerge from this analysis. First, each case study shows inclusiveness through increased scale and scope of early detection of cancer using advanced computing technologies to automate and analyse results at the point of care. Thereby, they depart from the traditional assumptions of application of knowledge and high technology in low resource health care settings. Thus, inclusive innovation in low resource healthcare settings is made possible by applying knowledge to context specific and affordable applications of high technology. Second, the case studies are not sporadic instances of high technology innovations, but a larger mainstreaming of inclusive innovations in MedTech ecosystem using advanced computing technologies (also see Sharma, 2023). This change is reflected in emergence of a coherent Medtech policy ecosystem bringing together different actors and knowledge networks (as also discussed in Chapters 2 and 5).

7.2.2. Inclusiveness by framing unmet needs and involving primary users in design process

The case studies explicitly identify unmet needs in the early detection of cancer in low resource healthcare settings than assuming them. In low resource healthcare settings, innovation efforts that do not correspond to such needs may in turn increase the health care expenditure. For instance, the gold standard modalities of cancer detection pose several challenges to appropriateness and affordable access in the Indian context.

The innovators and their core team involved primary users including clinicians, radiologist, pathologists in the design process to include these unmet needs. Table 7.2 captures how each case study presents inclusiveness in innovations by identifying unmet needs for the early detection of cancer in resource constraint settings, and involvement of users to address them.

Table 7.2: Inclusion of unmet needs and primary users in design process

Innovation	Inclusiveness driven by	
	identification of unmet needs	including users in design process
Thermalytix	o Low sensitivity of mammography, women under the age of 45 years and/or women with dense breast tissue. o Inadequate health infrastructure, and high cost of mammography machine. o Shortage of qualified human resources. o High cost of mammography exam. o Cultural issues associated with touch-based screening methods. o Radiation and pain in mammography.	o Senior radiologist and expert thermographer
OralScan	o Lack of objective modalities for early detection of oral cancer. o Shortage of clinicians. o High cost of adjunct technologies.	o Clinical researchers, Dentists, and PhD researchers
Cerviscan	o Lack of objective modalities, varying accuracy of samples. o Shortage of clinicians and pathologist	o Female biomedical engineer, gynaecologists
CervAstra	o Shortages of pathologists in resource constraint settings. o High cost of pap smear test.	o Pathologist and clinicians

Source: Author's data analysis

(i) Inclusiveness by framing of unmet needs of cancer screening specific to Indian context

In case of breast cancer, NIRAMAI, the startup firm of Thermalytix, underscore structural challenges of health systems and challenges of appropriateness of mammography in terms of technique and cost (see table 7.2). These challenges in technologies exacerbates with geographic disparities of imaging technologies with

only 30 percent of cancer centres have advanced imaging technologies (NITI Aayog, 2021). However, the biggest unmet need identified by Niramai is low sensitivity of prevailing screening modalities especially for women under the age of 45 years and/or women with dense breast tissue. It is difficult to interpret mammograms in dense breast tissue because of challenges to distinguish dense breast tissue and abnormal breast changes.[56] The founder of Niramai explained these challenges with mammography that Thermalytix takes into consideration:

> 'mammogram has limitations. For example, it does not work on women under 45 years of age and women with dense breast tissue, whole breast appears white and is difficult to find a white spot which is likely to be cancer. Now there are also rules which say that people need to know the overall breast density to see whether mammography results can be dependent upon or not. The other aspect is affordability and accessibility which is a big deal for countries like India, where 1000 rupees test cannot be administered for everyone, even a working lady will think twice before paying that much because we are talking about every person going through screening once a year, irrespective of whether she has symptoms or not. And the machine itself is so expensive, the capex is so high that small diagnostic centers are not able to provide this test. This again increases the accessibility issues because women hesitate to go to a cancer hospital for screening'.

> 100xEnterpreneur Health Podcast (2021)

Similarly, the lead innovator of OralScan highlights that firms in the US and Europe are developing screening modalities for oral cancer, but the devices are expensive and cannot be used for screening in the Indian context. The clinical research scientist of OralScan elaborated on the challenges of invasiveness, subjectivity of existing screening modalities in identifying precancerous lesions in the oral cavity, and difficulties of integrating in low resource healthcare settings (also see discussion in Chapters 5 and 6):

> 'existing modalities are not useful in the low resource Indian healthcare settings. For instance, visual inspection of the oral cavity, in which the dentists look in oral cavity with the light identifies the lesion is only if there is a big mark. Even in these cases dentists send the patient for further scanning like CT scans or MRI to confirm

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[56] https://www.cancer.gov/types/breast/breast-changes/dense-breasts#:~:text=Dense%20breasts%20can%20make%20a,tissue%20appears%20as%20dark%20areas (last accessed on 31 January 2023).

malignancy. Other methods including molecular method requires the testing of the tissue to do some molecular study. But taking up the tissue or blood involves some level of invasive process that can be traumatizing for the patient. There are some other techniques that are developed outside India, but these are not basically used by Indian doctors. Two major reasons are their prohibitive costs, and these technologies just show a lesion and do not interpret the data. The clinicians interpret and detect whether the lesion is there by seeing and making the diagnosis which requires expert opinion. There are also some staining methods, but their sensitivity is very less.'

<div align="right">Clinical researcher - Sascan, Author's interview (2022)</div>

In the case of cervical cancer, there are two case studies. Each highlights unmet needs relating to the early detection of cervical cancer at different levels. The biomedical engineer of CerviScan points out the unmet needs due to challenges of subjectivity and the invasive nature of early detection using conventional cervical cytology. The founder of Sascan Meditech further explains,

> 'the accuracy of pap smear depends upon (a) the sample you take and (b) the expertise of the pathologist or cytologist who reads the specimen. If the smear is taken wrongly from a wrong area, it could be negative. And only pap smear positive cases are examined for colposcopes. Colposcopes are done on the positive cases which is again a subjective technique, and highly depends on the expertise of the doctor who is examining the patient. There are chances of lot of unwanted biopsies and false negatives also happen because of inaccurate biopsies.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

Additionally, the infrastructural bottlenecks in pap smear testing. The founder of Aindra Systems explains the prohibitive costs and lack of infrastructure, shortage of pathologists, and doctors are major constraints facing cervical cancer screening, mainly in rural areas. Specifically challenges with manual staining technique for slides, and samples being brought in big batches to the diagnostic centres increases the turnaround time for reports (ibid). Such infrastructural bottlenecks exacerbate delays in processing the pap smear test samples (Deoras, 2018). Even the technologies that are conducive for low resource settings due to low-cost have challenges. Even low-cost methods require trained health workers for effective training:

'the government takes the least cost method, the VIA, WHO is also promoting, and a lot of people suggest it for low-income country – but how should this scale up?'' Even in this case, there needs to be a trained nurse and presence of a gynaecologist'.

CEO blood screening firm for cancer in India, Author's interview (2021)

(ii)   Involvement of users in design process

Analysing the case studies, I found design-thinking principles to be at the heart of development process to address the above unmet needs. Design thinking is an iterative process to problem solving by understanding how the needs of people and healthcare system can be resolved.[57] For instance, Niramai partnered with radiologist for guidance and collaborated with leading hospitals for data acquisition, which is an integral part of AI algorithm development (Mabiyan, 2020). The founder explains collaborating clinicians and radiologist helped in shaping the technology by 'doing clinical studies and receiving authentic screening observations from doctors at the end of the preventative screening' (100x entrepreneur, 2021). Secondly, collaborations with hospitals and doctors also ensure quality of data, in form of images of mammography, ultrasound, and doctor's prognosis are crucial for ML based innovation. Good quality of data is crucial to ML algorithms, mainly to avoid errors and false results so that screening can be performed by health workers and technicians with minimal training (Mabiyan, 2020).

The lead innovator of OralScan explained the importance of collaborating with dentist, as co-investigators, to build the technology helped in translating applications of physics into biomedical engineering.

'being a physicist, who is getting into the medical field - some collaboration in the medical fraternity helped. I collaborated with doctors from Regional Centres for Cancer in Trivandrum, they were co-investigators in our project to develop a point monitoring system – to monitor abnormality in the oral cavity. I learned the nuances of cancer diagnosis and slowly develop some devices based on combination of physics and spectroscopy and electronics. The technology we developed was different from what was existing at that time, others were using a tissue fluorescence, and reflectance. So we went into diffuse reflectance, probing with the light to see what is happening inside the tissue.

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[57] [57]For instance, see here for brief details on design thinking principles
https://www.thinkwithgoogle.com/future-of-marketing/creativity/design-thinking-principles/.

And we were trying to map the changes in the oxygenated haemoglobin to test the tissue. This collaboration helped in bringing out this uniqueness in the whole process of locating the malignant sites much more accurately than the other techniques.' 'we could develop something which could be useful for the screening of oral cancer'.

<div align="right">Founder, Sascan, Author's interview (2021)</div>

In case of CerviScan, the female biomedical engineer and interactions with a gynaecologist helped in prototype developments. For instance, a mounted device prototype is more user friendly for gynaecologists than handheld device for cervical cancer screening.

'the clinician holds the speculum with one hand to see the cervix properly and the device with another. This was a challenge as using both the hands was challenging for the clinician. However, in the third prototype this issue resolves as the device will be mounted in a stand and tablet / laptop will have another stand.'

<div align="right">Biomedical engineer - Sascan, Author's interview (2021)</div>

For CervAstra, Aindra Systems worked with engineers of Indian Institute of Technology (Chennai and Mandi) to test feasibility of optics in the solution, and algorithm development (Villgro, 2014-15). Additionally, Aindra Systems worked with Cytopathologist from Kidwai Memorial Hospital to gain a holistic understanding of the challenges in cervical cancer screening and detection. These initial conversations and collaborations, helped in designing the innovation to address health system needs and its community level adoption (ibid). The start-up also worked with pathologists to validate the algorithms in practice. The lab operations head of Metropolis Healthcare Ltd associated with clinical validation of algorithms of CervAstra explains,

'There is a dire need for a solution that supports population-based screening and CervAstra serves that need by helping pathologists render their services to the masses without geography being a constraint. I have been working with Aindra for the validation of CervAstra and it is great to see the amalgamation of technology and medicine to create accessible and efficient solutions.' (Khan, 2020)

7.2.3. Inclusiveness in outcomes of innovation

In terms of innovation outcomes, there are three key points. Table 7.3 brings out inclusiveness in outcomes of innovations across the case studies.

Table 7.3: Reflecting on inclusiveness in outcomes of innovation.

	Outcomes of innovation process
Innovation	**Addressing needs**
o **Thermalytix**	o Early detection femtech for women (and men) of all ages, and breast type. o Clinical validation studies in Indian population. o Radiation free, pain free, and no touch. o Portable, compact, and point of care modality. o Low hardware cost vis-a-vis mammography machine. o Easy to use with minimal training. o Variety of business models aimed to increase affordable access. For instance, INR 1000 - INR 1500 in hospitals and clinics, and INR 100 – 150 low-cost version for rural settings.
o **OralScan**	o Objective and effective screening and diagnosis using technology. o Clinical validation studies in Indian population. o Portable, compact, and point of care modality. o Easy to use with minimal training. o Lower per patient screening cost o Variety of business models aimed to increase affordable access.
o **Cerviscan**	o Objective and effective early detection femtech for cervical cancer. o Clinical validation studies in Indian population. o Portable, compact, and point of care modality. o Easy to use with minimal training. o Biopsy guidance.

Innovation	Outcomes of innovation process
	Addressing needs
o **CervAstra**	o Early detection femtech using computational pathology provides results within few hours. o Clinical validation studies in Indian population. o Portable, compact, and point of care modality. o Variety of business models aimed to increase affordable access. Price per test is INR 200 – 400.

Source: Author's analysis of data.

First, inclusiveness is demonstrated by availability and access to appropriate MedTech for the early detection of cancer in low resource healthcare settings. All cases offer both novelty and inclusivity by offering a point of care, non-invasive, portable, and easy to use solutions for Indian context. OralScan presents the first handheld and objective modality for both screening and early diagnosis of oral cancer. Thermalytix, CerviScan, and CervAstra are concerted efforts of building femtech for early detection of cancer in low resource settings. For instance, a BBC podcast (2023) shared a patient experience for Thermalytix,

'After the screening, she reported that she was a bit cold due to the air conditioning that was used to get the body temperature conducive for screening, a bit scared, but felt comfortable during the screening, and relived that the report was normal.' 'culturally, it felt more private, with no touch, privacy aware and much less intimidating'.

The focus in all the cases is to make the innovation conducive for the low resource healthcare settings. Even though these are high technology innovations, compact and user centric design, and ease of use with limited training to frontline health workers, enable them to integrate well into Indian health system. These innovations also offer a variety of business models that reduce capital expenditure (capex) and screening logistics in gold standards. The reduction in capex and portability increases the chance of their integration in the rural and community screening drives. In this regard, these innovations particularly engage with gaps in healthcare delivery system of shortages of clinicians, radiologists, and pathologists. Additionally, all the innovations are clinical validated in India, which provides clinical sensitivity of these innovations and representation of Indian population in clinical research.

Second, inclusiveness is observed in women as innovators in resource constraint settings. Thermalytix is a successful case of women entrepreneurship in femtech for early detection of breast cancer. Even in other case studies, CerviScan and CervAstra, presence of women as biomedical engineers, consulting oncologists, and clinical researchers has been crucial to design development. Highlighting this point is critical as there has been a general lack of representation of women as entrepreneurs in low resource healthcare settings (see Chapter 3). The Senior Adviser of Department of Biotechnology and Managing Director, BIRAC concurred the role of government support in strengthening the presence of women entrepreneurs marks women as key producers and users in femtech space.:

> 'there are special funding programmes …to recognise and reward women entrepreneurs in Biotech sector. Till now, BIRAC has supported over 250 women entrepreneurs through its various funding schemes and incubation centres.' (BIRAC, 2022, p7)

Third, in an unintended outcome, inclusiveness is also observed by active role of the end users as contributors to improving technology. As stated earlier, usage of AL and its subsets ML and DL is a strong component of the innovations. ML being a statistical technique for fitting models to data, learns by training models with data (for instance, see Brown, 2021). The ML models are (a) trained on large, supervised data sets comprising historical early detection images to learn and mimic the patterns by a real radiologist, pathologist, and clinicians (b) test its quality in clinical settings vis-à-vis the current standard of care through clinical studies. These algorithms improve in accuracy with more use and input of data. Therefore, the end beneficiary indirectly is involved in the process of improving the technology. This outcome has some policy and regulatory implications, mainly for ensuring that the data is securely stored and managed.

In summary, analysis in Part A points out conceptualisation of inclusiveness in both process and outcome of PoC MedTech innovations for the early detection of cancer in India. The analysis reveals how advanced computing technologies invoke inclusiveness in low resource settings by expanding the scale, scope, and complexity of the technical capabilities of the MedTech sector. Secondly, the analysis shows explicit problem framing of unmet needs of early detection of cancer in low resource settings by innovators and their teams in the case studies and user involvement. These unmet needs reflect the needs of not just the poor or marginalised but a wide range of users and beneficiaries in resource constraint healthcare systems. The analysis also provides evidence of role of women innovators and entrepreneurs

in screening and early diagnosis. Lastly, as an unintended outcome, inclusion of end beneficiaries in improving screening technology in AI and ML based Medtech innovations. In the wake of emerging data privacy and protection rules, the impact of this outcome needs further probing in future research. In the next section, I analyse innovation process in further detail to showcase how conceptualisation of inclusiveness is operationalised across case studies.

Part B

7.3. Key actors and factors influencing the development of inclusive Medtech innovations for the early detection of cancer in India.

This part deep dives into the key actors and the corresponding factors that influenced the development of PoC MedTech innovations, as highlighted in the case studies (see table 7.4).

Table 7.4: Key actors and corresponding factors influencing development process of MedTech innovations.

Actors	Factors	Stage of development
Innovators with multidisciplinary teams	Personal motivation of innovators driven by knowledge	Conceptualisation
Government	Early-stage finance and incubation	Proof of concept, Prototype development
Private, Non-profit	Funding and incubation	Proof of concept, Prototype development, Scaling-up and go-to market strategy
Regulatory	Patent, Clinical studies, Medical device regulatory framework	Clinical validity, safe and quality

Source: Author's analysis of case studies

7.3.1. Personal motivations driven by knowledge and collaborations.

The analysis reveals that a major factor in the development of these PoC MedTech innovations was the personal motivations of lead innovators (founders). These motivations were driven either by lived experience of friends and family with cancer and a drive to use technology for bigger societal impact. Along with motivation, the innovators' extensive technical knowledge and experience, and mentorship helped to innovate in the early detection of cancer, which was evident in all four cases under investigation (see figure 7.1).

Figure 7.1: Personal motivation of individuals driven by knowledge and collaborations.
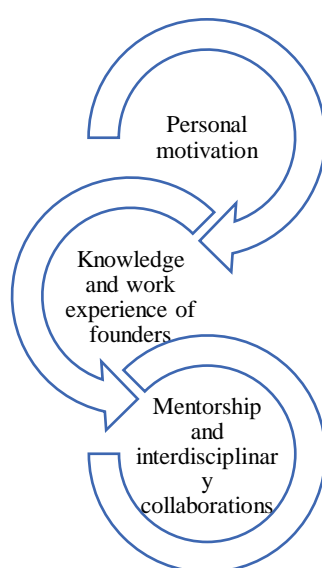
Source: Author's analysis of data.

In the case of breast cancer, the personal motivation of the lead innovator proved to be a crucial driver in working on ideations for a widely available screening solution for breast cancer. The lead innovator of Thermalytix, and founder of NIRAMAI explained how a case of breast cancer in her family motivated her to probe the challenges in the existing early detection modalities:

> 'I was working on some innovative AI projects along with my team in healthcare, smart cities, and customer care. Around that time, two of my close relatives discovered they had breast cancer. I could see how the disease affected the person and their whole family.' 'as a technologist, I said – can we do something about it? So, I started reading about the problems in the breast cancer. I found that there is absolutely no solution to detect breast cancer in women under 45 years and there were more and more cases coming in that age group. So, with that in mind, 'After about a year or so, we started seeing some early results in our efforts of putting AI

to thermal images. Unfortunately, around that time, both my relatives lost their lives. At that stage, I decided to quit my job at Xerox, develop the solution further to take it to all the women to enable early detection of cancer.' (Cisco Blogs, 2019)

Similarly, the lead innovator and founder of Sascan Meditech Private Limited, observed the long-term effects of wrongful diagnosis on health due to unnecessary radiation and strong cancer treatment in the case of his mother.

'I knew about the issues of wrong diagnosis and unwanted treatment in cancer since childhood. When I was in school, may be in 8 or 9 standards [12-13 years of age], my mother was wrongfully diagnosed with cancer.' 'I thought we could develop something which can be suitable for the Indian context with minimal consumables and minimal screening cost. So that is why we went into this kind of technology based on optical imaging. I was fascinated because I'm not initially from this field – I am a remote sensing guy, atmospheric remote sensing, and I was working with National Centre for Earth Science Studies for many years [from 1980s]. During the last phase my working years in the institute, I planned to investigate application of my field into medicine and later included ML to it.'

Founder, Sascan, Author's interview (2021)

He observed the larger benefits of translation of his research in physics with biomedical engineering and ML-based software to develop objective modalities for the early detection of oral and cervical cancer. Mainly a larger aim is to make cancer screening quick, accurate, painless, and affordable in both rural and urban India.

In case of CervAstra, after successful application of AI in financial sector, the founder of Aindra Systems realised the transformative ability of AI and ML for cervical screening:

'I realised the immense power and potential of a deep technology like AI and ML. Over a period, I understood that these concepts, if implemented, will have the capacity to transform the Indian healthcare space. One day, I was looking for the statistics and came across a set of dismal numbers regarding the cases of cervical cancer reported in India. I decided to do something to make a difference! (Balaji, 2019)

This drive also reflects in Aindra System's mission to democratise access to affordable healthcare solutions by using deep technology. It uses computational pathology in CervAstra to enable affordable cervical screening solutions for all.

It is pertinent to stress that all the innovators are non-domain actors, i.e., they are not embedded in the healthcare system. However, they could enter the highly technical domain due to their education and previous work experience (see table 7.5). The lead innovators are scientists from disciplines of sciences (like physics and advanced computer science) and engineering and management experts. It is essential to highlight that all innovators turned entrepreneurs gained problem-solving skills from their educational training and subject expertise from well-established research and academic institutions.

Table 7.5: Key knowledge sources of non-domain lead innovators

	Educational background of lead innovators	**Work experience**	**Interdisciplinary collaborations**
Thermalytix	o University of Visvesvaraya College of Engineering, Bengaluru o Indian Institute of Science, Bengaluru	o Research leadership role in Hewlett Packard Limited and Data Analytics Research Laboratory, Xerox Research Centre India	Worked with radiologist and thermographer, clinicians, and hospitals.
OralScan	o Sree Narayana College, Kollam, Kerala o Cochin University of Science and Technology, Kerala	o Centre for Earth Science Studies, Trivandrum, Kerala o Marie Curie and DAAD fellow	Collaborated with dental colleges, researchers, and biomedical engineers to apply physics to oral cancer screening
CerviScan		o Research roles in biomedical startups	Collaborated with clinical researchers, biomedical engineers to apply physics to cervical cancer screening

	Educational background of lead innovators	Work experience	Interdisciplinary collaborations
CervAstra	○ Scientist, Centre for Earth Science Studies, Trivandrum, Kerala ○ Indian Institute of Management, Bengaluru	○ Software engineering roles at Infosys, Lucent Technologies, and Wipro Technologies	Partnered with IIT Mandi, IIT Chennai, for hardware and software, Kidwai Memorial Hospital to understand challenges of cervical cancer screening.

Source: Author's data analysis.

For instance, the founder of Niramai explains,

> 'IISc had an excellent teaching style that stimulates the researcher in you. After my master's program, I was determined to go towards a career in research and innovation. My first job was in C-DAC, as a proud member of the team which built India's first commercial supercomputer. After that great learning experience, I joined Hewlett Packard Labs as it was an opportunity to work with global researchers on 'cutting-edge' technologies and innovate in the global scene along with my Palo Alto colleagues. After about 10 years of very exciting innovative work at HP Labs, upon the advice of my professors, I decided to pursue formal research as a PhD candidate. I was back in IISc as an external registrant, studying parallel to my work. I chose a topic around AI for my research thesis…The PhD made a huge difference in the way I think about problems and prioritize ideas that would create fundamentally novel and technically sound solutions. As a senior manager and Lab Director of a multinational company, I had a great opportunity to mentor my team to develop such deep solutions to problems that matter to business and/or society.' (Boynton, 2019)

They closely build their teams and multidisciplinary collaborations with universities, clinicians, research-based hospitals, and medical institutes for clinical research to conceptualise innovations. Additionally, strong mentorship played a crucial role for all the cases. For instance, in case of CervAstra, the founder of Aindra system explains,

> 'Mentors and industry guidance are key to product development, strategy, go to market and more. Aindra Systems relies on the counsel of pathologist, oncologist, and industry experts from

CAMTECH MGH; RV Metropolis Bengaluru, Kidwai Cancer Institute, HCG Hospitals' (Balaji, 2020).

Combing these knowledge and technical expertise, with mentorship provided problem framing and solving skills required in innovation of Medtech for early detection of cancer in low resource healthcare settings.

7.3.2. Funding, incubation, and accelerators supporting various stages of development process.

The role of government and non-government funding and incubation support is critically important for every stage of innovation development (see figure 7.2 and table 7.6). The analysis points out that mainly government funding and incubation have played a critical role in fostering the early stages of the development of innovation. In particular, OralScan, CerviScan, and CervAstra have benefitted from government funding since the early stages of the product development whereas Thermalytix has primarily relied on private funding. Nonetheless, Thermalytix has also benefitted from BIRAC award and Startup Karnataka's support in technical guidance.

Figure 7.2: Funding received by technology-based startups in Indian health sector, 2021 (USD million)
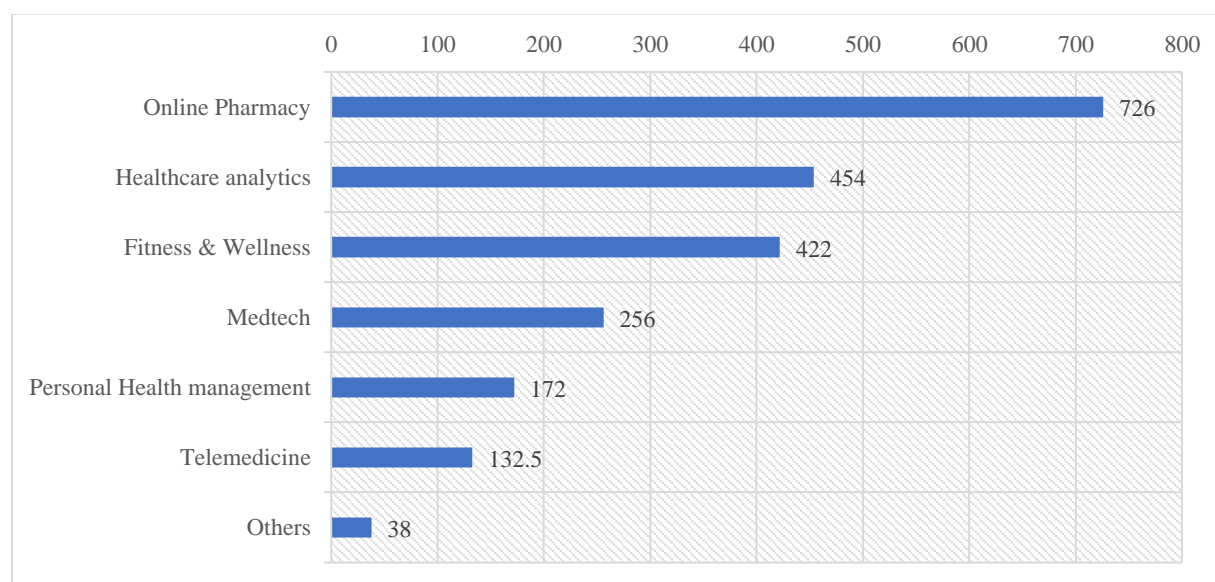
Source: Inc42. In Statista, 2023

In recent years, the government has played an instrumental role in channelling the MedTech ecosystem in India (also see Chapter 2). Several policies and schemes under the Department of

Science and Technology and the Department of Biotechnology under the Ministry of Science and Technology have increased the availability of early-stage finance in recent years (also see Chapter 2).

Table 7.6: Funding and incubation support from government and non-government sources

Case study	Proof of concept	Prototype development	Scaling-up
Thermalytix	o Tata Elxsi, India (Incubator) o Virtually Incubated at K-tech Innovation Hub @ Nasscom10K, Phillips Health Works o Pi Ventures, Bengaluru, India (Early-stage venture fund) o Axilor Ventures, Bengaluru, India (Venture capitalist) o Ankur Capital, Mumbai, India (Venture capitalist) o Binny Bansal, Bengaluru, India (Angel investor) o 500 Start-up, USA (Venture capitalist)		o BIRAC Women in Entrepreneurial Research Award (accelerator support) o Google Launchpad Accelerator o Dream Incubator, Japan o BEENEXT, Singapore o Axilor Ventures, Bengaluru, India o Binny Bansal, Bengaluru, India
OralScan	o Government grants for technology development and clinical studies, Department of Science & Technology	o BIRAC o BMS College of Engineering, Bengaluru o Karnataka Biotechnology and Information Technology Services, Government of Karnataka o Villgro Innovation Foundation (Social incubator)	o TIMed, the Technology Business Incubator of Sree Chitra Tirunal Institute for Medical Sciences & Technology o NIDHI funding scheme, DST o Unicorn India Ventures (private venture capital)

Case study	Proof of concept	Prototype development	Scaling-up
		o KIIT-Technology Business Incubator, Kalinga Institute of Industrial Technology, Bhubaneswar (seed funding)	
CerviScan	o Government of Karnataka as a part of Karnataka Start-up Mission	o TIMed, the Technology Business Incubator of Sree Chitra Tirunal Institute for Medical Sciences & Technology o NIDHI funding scheme	Unicorn India Ventures
CervAstra	o Government of Karnataka o BIRAC o Indo-US Science and Technology Forum	o Villgro Innovation Foundation o Oracle for Start-ups program o IKP Knowledge Park	o Forge Factory (incubator)

Source: Data analysis

Mainly, BIRAC has enabled industry-academia interface and strategic research and innovation addressing nationally relevant product development needs. Figure 7.3 shows the availability of BIRAC funding and incubation support at various stages of innovation, pointing out the policy recognition of the innovators and start-up firms addressing unmet needs. In 2020-21, cancer devices and diagnostics received the highest funding (INR 617.3 million) from BIRAC in medical device and diagnostic segments (BIRAC, 2021).

Figure 7.3: BIRAC schemes along the product development process and funding stages
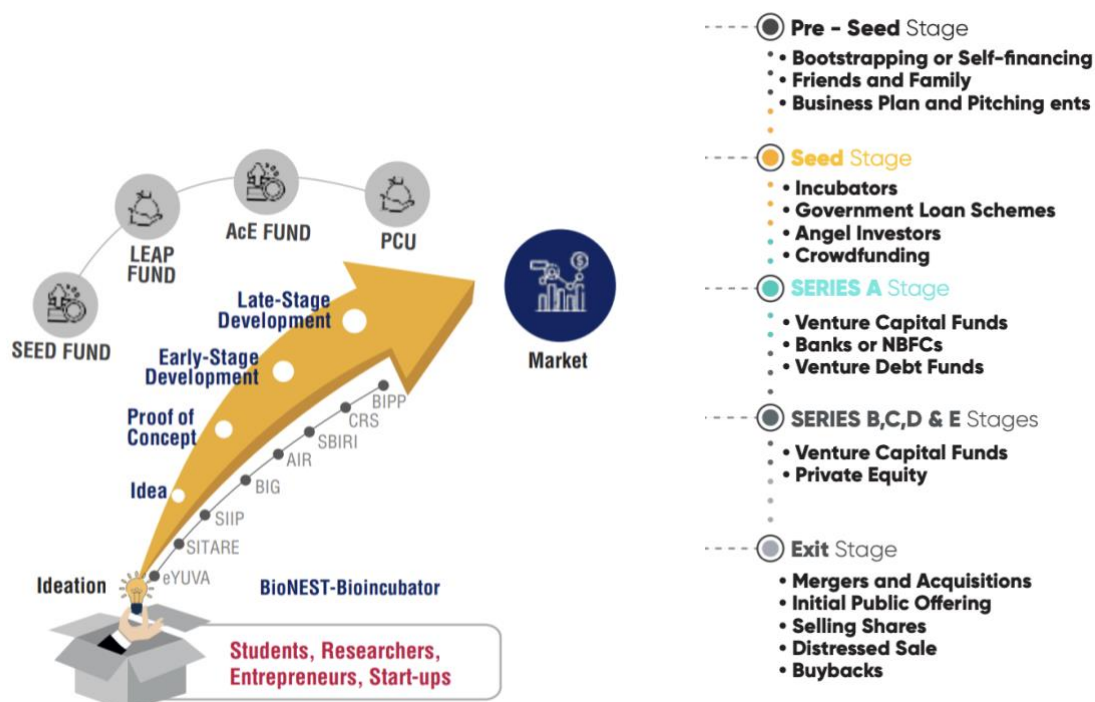
Source: BIRAC's annual report 2021-22 (p42), and corresponding stages of start-up funding (Start-up India, p29)

A senior official heading the Strategy Partnership & Entrepreneurship Development of BIRAC explains the key criteria for funding new ideas and start-up firms,

> 'BIRAC focuses on start-ups that are working to address unmet needs through development of technology-based globally competent and affordable solutions with the potential for commercialisation. A start-up can receive funding support from BIRAC across the value chain from ideation to proof of concept, minimal viable protype to validation and pilot to manufacturing stage. Unmet needs, value proposition, technical feasibility, team strength and commercialisation potential are the key parameters used for competitive evaluation'.
> Roychowdhury (2021)

The role of BIRAC's initial funding and guidance has provided an impetus for OralScan, CerviScan, and CervAstra.

Figure 7.4. shows government funding and incubation support mainly in early stages of stages of product development for OralScan, CerviScan, and CervAstra.

In case of OralScan, the funding from BIRAC helped with initial prototype development. The lead innovator explains how BIRAC funding is instrumental to encourage the non-domain actors with ideas to enter the MedTech innovation space:

> 'BIRAC has been very much instrumental in supporting the startup ecosystem. They give good funding up to INR 50,00,000 to with to a person / institute with a good idea to develop products. They also have mentoring support embedded in systems to ensure that the money is utilised properly. The also organise conferences to create on the new developments. So, a lot of useful guidance is available.' 'there are several opportunities for funding researchers without any background in industry'.

<div align="right">Founder, Sascan, Author's interview (2021)</div>

This initial funding from BIRAC along with funding from follow-on funding from Karnataka Start-up Mission, Government of Karnataka enabled the prototype development of OralScan and CerviScan respectively.

In case of OralScan, once the start-up firm formed the course of funding also changed to both operational cost of running a start-up firm and developing the innovation. Post the early-stage funding, Sascan Meditech participated in various awards and competition and accelerator programmes. The lead innovator and founder shares,

> 'Then we went in to set an acceleration program and all And so I was learning all these things, and I was not familiar with the management, but I had some interest in the stock market, you know. So, I had a little bit familiarity on what the balance sheet and the equity systems and all are. But I had to learn a lot in the process of this kind of training, acceleration programs and other things when interacting with the colleagues and contemporaries in the field. So, I learned a lot.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

Figure 7.4: Role of early-stage government funding and incubation support for OralScan, CerviScan and CervAstra

OralScan

2005-2015	2005-2015	2018	2019	2020
Proof of concept studies using DST funding	First prototype using BIRAC funding and incubation at BMS College of Engineering, Bengaluru	First seed funding from Kalinga Institute of Industrial Technology, Bhubaneswar	Second seed funding, NIDHI Seed Funding DST funding scheme	Commercial launch using funding from Unicorn India Ventures (private funding)
	Karnataka Start-Up Mission	Moved to Kerala, incubated under SCTIMST-TIMed Technology Business Incubator		

CerviScan

2005-2015	2017	2018-2020
Proof of concept using DST funding	Karnataka Start-Up Mission Started developing prototype	Unicorn India Ventures, prototype development under SCTIMST-TIMed Technology Business Incubator Ongoing clinical studies in Kerala (delayed due to COVID)

CervAstra

2015	2015-2020	2020-2021
Aindra was split into two – Aindra Systems (healthcare) and Aindra Labs (finance) BioTech Ignition Grant (BIRAC) Incubated by social enterprise incubator Villgro Building first prototype model Mentorship and guidance BIRAC BIG Grant INR 50,00,000	Indo-US Science and Technology Forum (2016) Funds for prototyping, clinical studies, and pilot Millennium Alliance, an inclusive platform by Indian,USA and UK government Idea2PoC, Government of Karnataka Prototypes of Intellistain developed, Vision X final design phase, fine tuning algorithms	Indo-Sweden Health Challenge (2021) Incubation support from Forge Innovation and Ventures Commercial launch of the product

Source: Author's data analysis

As shown in figure 7.4, after fine-tuning the prototypes of OralScan, Sascan Meditech won seed funding from the government to conduct further clinical studies and develop a prototype of CerviScan and incubate at the specialised centre at SCTIMST-TIMed Technology Business Incubator. The government funding and incubation support fostered the early stages of product development of both OralScan and CerviScan. In case of Aindra systems, the initial BIRAC funding support followed by a comprehensive support from social incubator Villgro that supported development of CervAstra through the entire cycle of the product offering from prototyping to market launch (Villgro Annual Report, 2014-15). It provided seed funding and strategic support and mentorship by helping build business models, identifying and prioritising customer segments, identifying networks for support and pilots. This funding helped to test feasibility of optics in collaboration with IIT-Chennai, algorithm development with IIT Mandi and follow-on funding to support prototype development (ibid).

In contrast, Niramai (Thermalytix) has largely participated in both Indian and international private funding rounds and has secured support at various stages of innovation development. In 6 rounds of funding, Niramai has secured around USD 14 million (STPI, 2022). The founder highlights,

> 'my 'Doctorate' was helpful in initial days. And I am very glad Niramai is an established brand now… my experience helped in securing funding, because investors knew I was serious about it and verified through connections like professors, managers, etc. Me and my team managed to secure USD 1 million in the first month of operation.' (Suriyakumar, 2022).

Along with this, Niramai was incubated at Tata Elsxi that specialises in design and technology services. This level of funding and specialised incubation supported not only the technological development, but also multicentric clinical studies, 27 successful international patents for the various of ML algorithms, regulatory approvals, and scaling up within India and outside India. In terms of government support, Niramai benefitted from K-tech Innovation Hub @ Nasscom10K and awarded an intensive accelerator programme for women in biotech by BIRAC.[58]

Government endorsement and support during all stages development process has signalled confidence in the private sector. This has led to an increase in social and private incubator, equity, and venture capital investment in the MedTech innovations in India (see figure 7.4).

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[58] https://birac.nic.in/desc_new.php?id=414 (last accessed on 21 February 2023).

The analysis highlights differences in the scale and scope of funding in government and private resources. This difference in the scale of funding from private sources is also reflected in the case of Sascan Meditech, which garnered funds from Unicorn India Ventures that helped scale up, sustaining operations through the pandemic, and launching OralScan in October 2020. As shown in figure 7.5, private equity and venture capital funding in the MedTech sector has increased considerably in recent years. To some extent, policy recognition and ecosystem has influenced these actors to enter the Medtech space.

Figure 7.5: Private equity and venture capital investments in the MedTech sector in India in 2015-21 (in USD million)
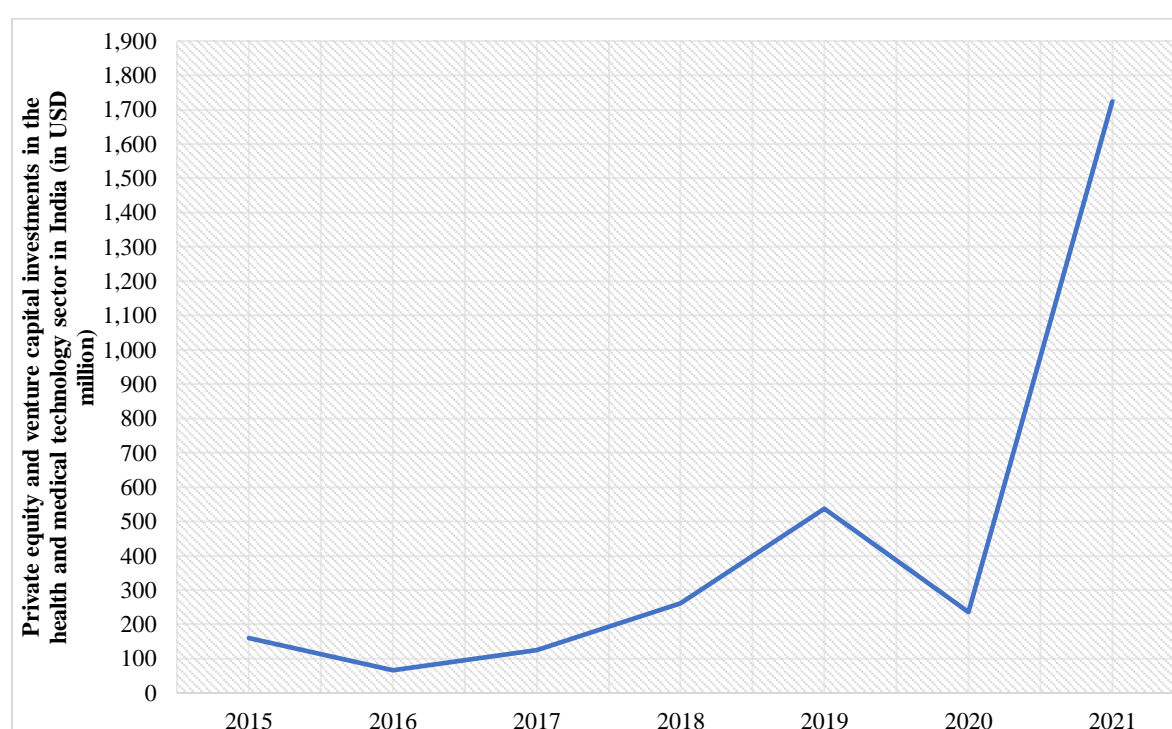
Source: India; EY; Venture Intelligence; Reuters; 2013 to 2021 in Statistica, 2022

However, while the level of funding is higher, sometimes private funding involves different expectations in terms of returns on investment. The founder of Niramai explains that sometimes private investors often anticipate a swifter return on investment from MedTech innovations, like the returns witnessed in fintech (financial technology) and e-commerce platforms:

'there is some kind of expectation that you [MedTech startup] will also have…high revenues like a finance or an e-commerce company. But obviously, we don't have that kind of skyrocketing revenue.

Some people [funders] especially from India are expecting different kinds of growth numbers. Whereas when we talk to a US based or a Singapore based investor, there is more understanding and our expectation matches much, much higher.' (Arakali, 2022).

The experience of Niramai's founder is also acknowledged by respondents of the study. Given the long product development cycle, requiring extensive clinical studies and regulatory approvals, it is hard to be viable for some innovations let alone high revenues. The founder of an organisation that provide 'lab to market' support to ideas that aim to address India specific challenges explains how start-up ecosystem for MedTech innovations is different from other technologies developed by start-ups:

'inclusive innovation requires 'patient capital' 'long time horizon' and 'expertise'. Start-up ecosystem in India cannot be generalised because unlike consumer technologies or fintech, MedTech innovations relies on extensive clinical data for machine learning and clinical judgement. Moreover, each process from proof of concept to go to market strategies are lengthy and time consuming with several clinical studies and regulatory approvals.'

Founder, organisation providing lab to market support to inclusive innovations, Author's interview (2022)

Founder of Sascan also shared that 'it's a challenge to raise the funding and to keep the company going, to make a product of this level and market it.' In India, obtaining funding for MedTech innovations can be challenging, especially during emergencies and disruptions such as the COVID-19 pandemic. A stable funding source is crucial to sustain PoC MedTech innovations, absorb supply chain shocks and delays, and prevent the 'valley of death.'

7.3.3. Evolving regulatory environment

Institutions include rules, laws, standards, regulations, established practices, etc. Some are specific to the sector, and others are national institutions bearing different impacts on innovation in different sectors. The case studies have developed in an evolving regulatory space, subjecting to two types of regulatory processes, clinical validation studies and medical device regulations.

Case studies use applications of AI in the early detection of cancer. They have lengthy product development cycles to fine-tune the machine learning algorithms based on clinical validation studies. Effective clinical studies provide impetus to the development process and build the

credibility of innovation in the clinical community. The clinical validity of the innovation primarily drives the adoption of technological innovation in the health sector in the local context, regulatory environment, and collective buying instruments, including procurement and health finance mechanisms. To do that, the innovators are required to obtain a no-objection certificate from the state drug controller / CDSCO to conduct studies and then take approvals from the institutional ethics committee of the hospital or medical research institute separately. Concerted efforts to streamline medical device regulations have only begun post-2017 with the medical device rules. Therefore, the innovations developed before this phase faced serious challenges and a lack of clarity. For instance, the founder of Sascan shared:

> 'when we went for ethics approval for a project, you know, they ask whether the device is certified. For example, a regional cancer centre, a major hospital in the state and very recognized in the country. We have been refused many times with the question – whether devices are approved by ICMR! And for that matter, ICMR is not a regulatory body. A particular examiner or maybe a member in the ethics committee may question and refuse permission. They would often suggest that you submit a proposal to ICMR and get approval to work. But the fundamental thing is that in those days there was no regulatory body for medical device in the country, only the drug controller was there. And even the drug controller did not have any rules for medical device registration / approvals. In such a scenario it was very difficult.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

Secondly, in the case of OralScan, the founder shared difficulties in recruiting patients and how they mitigated it:

> 'there were different phases, different regulatory issues were involved, we had to get the ethics approval from the concerned hospital and then clinical trial registry - they have to register the trials in the clinical trial registry of India and then doing trials - getting the patient, getting the doctors, etc.' 'getting patients was pretty difficult, we realised that in some of the hospitals, you know, number of patients are very limited. Because in hospitals, you don't get early-stage cancer, you get the cancers that are already diagnosed and who come for surgery. So, we had to go to field to do screenings' 'it's better to get patients from government dental college because patients come there for regular dental check ups'.

<div align="right">Founder, Sascan, Author's interview (2021)</div>

He further elaborates on the challenges associated with the cost of conducting multi-centric clinical studies with limited funding resources.

> 'sometimes we have to pay for the ethics committee cost'.

> 'suppose a company spent so much money, maybe INR 10-15-20 lakhs or maybe INR 1 crore to develop a product and they are not able to sell the device because of the regulatory issues – then this is very challenging. Most of the companies will shut doors. [explains, only the ones with multiple revenue streams and tie ups with other companies for instance parent company is able to sustain such losses]'

> Founder, Sascan, Author's interview (2021)

The regulatory framework supporting emerging Medtech innovations, with both hardware and software components, is evolving. For the newer devices, that came in after the introduction of new rules, it was easier to register the device per se. This is because innovations discussed in the case studies come in the Class A or low-risk category.

> 'could get the required approval faster for Cerviscan and now we are in the clinical validation, and we are obtaining the manufacturing license for the oral scan as well and applied for CerviScan once we get the initial clinical result. The things are much clearer, so we are better positioned for medical device / diagnostic development in the country.'

> Founder, Sascan, Author's interview (2021)

Post the introduction of medical device regulations, lack of clarity remains an issue however they are not identified as a barrier by the innovators. However, nor do the regulations offer any incentive to the new technologies for fulfilling an unmet need. In terms of incentives, in all the case studies securing patents early in the development process enabled technological development. Moreover, to overcome the varying perceptions of the quality of the devices manufactured in India (as discussed in Chapter 2), the case studies highlighted that innovations and start-up firms are re-routing for external approvals as well. For instance, the founder of Aindra systems suggests,

> 'As a startup, we have to contend the questions that customers might have around the brand, the longevity and also the perception that India-made products lack deep technology and

quality. But with the right kind of signals like the ISO certification and the CE certification, we have been able to make inroads' (Balaji, 2020).

This is the experience of all case studies. All the innovations have received CE mark approval, and ISO 13485 at the firm level for the quality management system. The ISO 13485 2016 provides a thorough record of technical standards at the firm level. Sascan's founder explains the process and scope in detail:

> 'there are norms for ISO standards for medical device development / medical technology products, that is ISO 13485 2016, so the company has to be certified. And for that, the company should have regulatory mechanism or quality management systems in place in the company to get those kinds of certification and that is mandatory.' 'ISO certification is usually done by TUV or BSI and similar companies. So, we have to follow different versions of the device, update the record keeping is very important – like where you source the components, which component goes into what product, what serial numbers, all those are controlled by the ISO regulation. So, the quality of the product is much more robust when one follows these regulations. We are following it in our company.' 'ISO certification is for the company, we got it for Oralscan, and it took merely one year. One year for implementing the ISO regulations in the company including the quality management systems, the record keeping, bookkeeping of everything.'

> Founder, Sascan, Author's interview (2021)

Further, CE marking, reflects that the manufacturer has met the EU safety, health, or environmental requirements. The case study respondents shared that it helped them raise credibility in the hospitals and other partners. In case of Thermalytix, a version of it, SMILE 100 has got a USFDA 510 k approval as well. The founder of Niramai, shared the increase in validity due to this approval:

> 'We are super excited to announce the FDA 510(k) clearance of SMILE-100 System…This win further validates the intrinsic power of NIRAMAI team and has given us the confidence that we can build many more such world-class medical devices of high quality and help reduce untimely deaths due to cancer.' (Niramai website)[59]

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[59] https://www.niramai.com/niramai-bags-us-fda-clearance-for-their-medical-device-us-markets-now-open-for-the-innovative-indian-startup-niramai/ (last accessed on 1 February 2023).

In all the cases, the evolving nature of regulations did not help increase the credibility of these technological breakthroughs. As discussed above, every leading doctor requires a clinical study despite published results in internationally acclaimed journals. On the other hand, it is observed that international regulations are still considered to provide credibility to the innovations and help in increase adoption in Indian hospitals. Therefore, in terms of general advances in sectoral systems, having defined regulations helps existing actors, including domestic manufacturers and even MNCs. However, the role of MDRs in the process and outcomes of AI and ML-based MedTech innovations is unclear, mainly regarding applicability and expectations. These considerations also reflect that the role of domestic MDRs needs to update to reflect the new devices fulfilling unmet needs.

Furthermore, the compatibility of the current regulatory framework involves some considerations as the case studies use a combination of AI and hardware components. The data privacy and security provisions are not envisaged in the DCA and MDR. As medical devices continue to be governed as a subset of drugs under the Drugs and Cosmetics Act, 1945 and Medical Device Rules, the primary legislation is not adequately equipped to deal with the rapidly innovating sector. Although not revealed explicitly by respondents involved in case studies, the actors in the larger MedTech ecosystem concur challenges for public health due to non-compatible regulations with AI-based Medtech:

> 'Traditional healthcare regulations cannot be applied for AI-based treatment as it is different from a drug or a vaccine. We are dealing with machine learning, and due to its "learning" capabilities, the algorithm keeps evolving. Consider this, by the time a regulatory approval for an algorithm is granted, the algorithm 'learns' from more added data and thereby evolves and becomes a different algorithm altogether. Another aspect is that AI, especially neural nets, is a black box; while we can program it, we don't really know how it works inside. That poses the problem of explicability. More than the regulatory challenge holding back AI, regulatory authorities are trying to keep pace.' (Raj, 2020)

In summary, analysis in B showcased actors and factors that influenced development of advanced technologies for the early detection of cancer in India. Using the IHI framework, it is found that the coherent emergence of all these actors increased the effectiveness of the factors to develop successful prototypes offering affordable and accurate early detection of cancer. Therefore, despite case studies meeting unmet needs (linking triad element 1 with 3), there need to be stronger linkages between triad element 1 (industrial production) with triad element

2 (health policies and regulatory clarity). Since the regulations for the safety and efficacy of medical devices and diagnostics are the same as pharmaceuticals and vaccines, the requirement of clinical trials also resonates with the burden of proof, mainly for pharmaceuticals and vaccines. There are challenging aspects of the applicability of regulations for emerging innovations for early detection of cancer that still needs clarity and simplification.

<div align="center">**Part C**</div>

7.4. Factors influencing diffusion, and adoption of Medtech innovations for the early detection of cancer.

In this part, I discuss the factors that are helping the effective diffusion and sustainable adoption of PoC MedTech innovations for the early detection of cancer in India. Table 7.7 summarises the actors and the corresponding factor that influence the diffusion and adoption of emerging innovations for the early detection of cancer in India. These actors and factors elaborate how case studies are generating demand and creating new markets for the early detection of cancer in low resource healthcare settings.

Table 7.7: Actors and the corresponding factors influencing diffusion of MedTech innovations.

Actors engaging with Start-up firms	Factors	Innovation process
o **Public and private funders, incubators, and accelerators** o **Hospitals, clinics, and diagnostic partners**	o Innovative business models	o Creating new markets
o **Government and non-government partners**	o Partnerships	o Generating demand
o **Key opinion leaders (clinicians, hospital networks, industry experts)**	o Stakeholder engagements	

Source: Author's analysis of data.

7.4.1. Diverse business models

The investigation of case studies presents distinct modes of diffusion tailored to the institutional variety and idiosyncrasies of the low-resource healthcare system of India. I use and extend the conceptualisation of business models for inclusive health care introduced by Angeli & Jaiswal (2016).

Table 7.8 elaborates on the business models of each case study based on four key dimensions: value discovery, value proposition, value creation, and value appropriation (ibid). In terms of value discovery, the case studies identify and state unmet needs of early detection of cancer in low resource healthcare settings rather than assuming them. Working with the users (clinicians, radiologists, and pathologist) from the start of the design process provides an opportunity to the start-up firms to develop strong value propositions (as discussed in Part A). These value propositions define how innovations respond to needs of user and end user, within the larger healthcare delivery system.

Value creation through the innovation cycle, comprising research and product development, and diffusion and adoption, reflect the ways in which the value proposition is operationalised in the business models. Literature suggests that business models do this by creating and capturing new value by adopting multiple ways of diffusion (Hossain, 2021). Finally, value appropriation, how a share of value that is created benefits the organisation and other stakeholders. Both value creation and value appropriation focus on achieving dual role of providing multiple offerings to the users and beneficiaries (end users) to enable affordable access whilst ensuring sustainability of operations. Table 7.8 provides details of the business models in each of the case study that helps to capture value tailored to low-resource health settings throughout the whole innovation process.

Table 7.8: Innovative business model for scaling-up, diffusion, and adoption in low resource health settings

Innovation (Start-up firm)	Value discovery	Value proposition	Value creation through innovation cycle		Value appropriation
			Research and product development	Diffusion and adoption	
Thermalytix (NIRAMAI Health Analytix)	o Lack of awareness o Lack of qualified human resource o Limitations of previous modalities for younger women / dense breast tissue o Radiation and pain o Lack of affordability	o Portable, automated results, non-invasive modality at point of care. o Easy to use, with limited training. o No-touch, privacy aware. o Radiation free. o Suitable for women and men of all age o Destigmatising breast screening.	o Uses AI on thermal images. o Pure ML innovation simplifying deep learning statistics. o Automated checks and balances to help non-clinical staff to conduct accurate screening. o Partnered with clinicians and hospitals from the start. o Clinical studies on Indian population.	o Direct sales to hospitals and diagnostics chains. o Pay per use model. o Outreach model (per day). o Triage model. o Public private partnerships o Awareness seminars, media coverage, awards on the innovation.	o Agile knowledge production and use of technology. o Multiple offerings o Patents o National and international regulatory approvals.
OralScan (Sascan Meditech Private Limited)	o Lack of a non-invasive and objective oral screening. o Lack of qualified human resource.	o Portable, automated results, non-invasive modality at point of care. o Biopsy guidance to reduce overdiagnosis. o Easy to use, with limited training.	o Miniaturised their lab-based technology to handheld device. o Combining optics, biomedical engineering, and ML based software.	o Direct sales. o Lease model. o Pay per use model. o Screening camps.	o Agile knowledge production and use of technology. o Multiple offerings o Patents o National regulatory approvals

Innovation (Start-up firm)	Value discovery	Value proposition	Value creation through innovation cycle		Value appropriation
			Research and product development	Diffusion and adoption	
CerviScan (Sascan Meditech Private Limited)	o Lack of objective and non-invasive early detection of cervical cancer. o Lack of qualified human resource.	o Non-invasive modality. o Biopsy guidance to reduce overdiagnosis.	o Miniaturised their lab-based technology to handheld device combining, optics, biomedical engineering, and ML based software.	o Launch awaited; progress slowed due to COVID-19	o Agile knowledge production and use of technology. o Patents o Regulatory approvals.
CervAstra (Aindra Systems)	o Lack of lab infrastructure and pathologist to process pap smear samples. o Lengthy processing time.	o Point-of-care and portable computational pathology platform. o Automates analysis of pap smear image. o Easy to use, with limited training in community settings.	o Advances in optics, electronics, and mechanical systems with 4-part solution. o Multidisciplinary collaborations for software and hardware validations.	o Direct sales to hospitals. o Diagnostics chains (price per test). o Awareness seminars, media coverage, and conference participation, TEDx talks.	o Agile knowledge production and use of technology. (eg. CovAstra) o Multiple offerings o Patents o National regulatory approvals

Source: Author's analysis of data.

To choose the most appropriate business model, in each case, incubators and accelerators helped conduct in-depth product-to-market fit research to understand the market, scale up, and identify consumers. A senior professional from the incubator organisation involved in one of the case studies explains:

> 'the lead innovators have a deep understanding of the technology and product prototype development, and they also have clarity on what help they require from us. Mainly the innovators require help in business modelling, finding product-market fit, and building a sales engine. This is because many of them do not have a sales and marketing background, they do have a view and perspective of it, but not experience, so the knowledge of market interface in most cases is missing. Beyond technologies, these are the areas they require help on - how to package product/solutions services and how to do the offering design.'

<div align="right">-   Senior professional, Private incubator, Author's interview (2022)</div>

All the case studies offer a combination of capex (capital expenditure) and opex (operational expenditure) business models for inclusive diffusion of innovations in the low resource healthcare settings. Table 7.9 provides a deep dive into such combinations. In the case of capex models, the hardware and software are offered as a product offering for an upfront purchase. This involves institutional sales either directly or through channel partners, mainly to hospitals and diagnostics centres.

Table 7.9: Creation of new markets for the early detection of cancer in low resource healthcare settings

Case study (Commercial launch)	Business model (Value creation)	Partners	Charges	Creation of new markets for early detection of cancer
Thermalytix (August 2017)	Direct sales	- Hospitals, clinics, and diagnostic centres	- One time charge	- More than 150 hospitals networks and diagnostic centres in in more than 30 cities in India. Apollo Clinics, HCG hospitals, Medall Diagnostics, Rainbow Hospital, Medanta, etc.
	Pay per use		- Per screening charge	
	Triage model	- Niramai team, partner team (like government, CSR teams)	- One time charge	- Suitable for primary health centres, village centres, gynaecologist clinics.
	Home-based screening	- Healthians (diagnostic company), - Apollo Clinics (hospital clinics) - MiyaraWomen (femtech product and services), - ProactiveForHer (digital platform for women)	- Per screening charge	- Home-based screening in numerous cities
OralScan (October 2020)	Direct sales	- Hospitals, dental clinics through channel partners	- One time charge (no additional cost on consumables)	Private and public hospitals and dental centres Including Government Dental College (Thiruvananthapuram), JSS Dental College & Hospital (Mysuru), Institute of Medical Sciences and Sum Hospital (Odisha), Sree Balaji Dental College And Hospital (Chennai), Dayanand Sagar Dental College (Bengaluru)
	Lease model		- Monthly rentals	
	Pay per use		- Price per scan, differentiate it based on scans in the package	

Case study (Commercial launch)	Business model (Value creation)	Partners	Charges	Creation of new markets for early detection of cancer
CervAstra (2020-21)	Price per test	- RV Metropolis, Pathology Consulting Services, Enveda Therapeutics, Kidwai Memorial Hospitals, Mahila (A to Z of Women's Health by Atrimed), Adharstambh Foundation, Chimco	- Pay per test	- Diagnostics centres
	Direct sales (planning)	- Gynaecology clinics, nursing homes, hospitals, NGOs	- One time charge	Ongoing

Source: Author's analysis of data.

They connect with these hospitals and diagnostic centres directly or through a partner organisation. This is being used in all cases. The founder of Sascan explains,

> 'the direct sales model is always good to sell device because of reduction in cost and the margins. The user is important, and that is why we are thinking of different models for someone who does not have enough money to buy the device' 'our perspective is public health driven - we want oral cancer to be detected early.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

The opex models, including pay-per-use, subscription, lease model etc. in which several product offerings are available depending on the scale of operations and nature of the buyer. It brings down the cost by spreading it through per screening, scan, or test. For instance, CervAstra's price per test is INR 200 – 400 (Balaji, 2020). The founder of Aindra System presents the rationale behind the pricing and business model strategies,

> 'What we realised was that as a country, we [as industry] were trying to retrofit systems built for large, centralised healthcare systems to geography that required a point-of-care, lower volume solution'. (Khan, 2020)

Therefore, key consideration in all the case studies is realising value proposition to make early detection for cancer technologies available to maximum population. I also found that the level of diffusion differs depending on the funding and launch time. These innovations are launched recently therefore the business models are still evolving. Thermalytix was launched before OralScan and CervAstra, hence it has a broader reach. The broader variety of business models in Thermalytix also enable reaching out to a wider set of users. For instance, all the cases have a direct sale and pay per use component to provide flexibility in affordable screening and early detection modalities. In case of Thermalytix, Niramai also has a triage model, home-based screening, and even experimented a shopping mall-based screening to destigmatise breast screening. Since COVID pandemic, to make screening accessible in safer home environment, home-based screening was made available in Bengaluru, Bhopal, Chennai, Delhi, Hyderabad, Jaipur, Mumbai, Pune, Vadodara. Furthermore, the triage model offers an annual unlimited screening at a lower cost for triaging only (abnormal / normal) and not detailed reports.

7.4.2. Partnerships - government, private sector, and non-profits

In terms of demand generation, partnerships are found to be vital for all case studies. Table 7.10 shows a range of such partnerships in each case study that are helping to trickle down the innovations.

Table 7.10: Key partnerships to generate demand for innovations.

Partnerships	Details
Thermalytix	
- Memorandum of Understanding (MoU) with Government of Punjab and Roche Pharmaceuticals (2022)	- The Pink Project (Punjab Breast Cancer AI- Digital project) providing screening, diagnostics, and treatment modalities.
- Karnataka Cancer Society and Swasthya Initiative of Abalashrama (2021)	- Free screening camps
- Bengaluru Mahanagara Palike (BBMP) (municipal corporation's) hospitals	- Mayor of Bengaluru announced free screening for underprivileged women using Thermalytix
- Rotary Palmville and Sakra World Hospital (2019)	- The Pink Express in pink-coloured bus of Rural Bangalore, Karnataka, and Tamil Nadu to organise the camps for breast cancer screening
OralScan	
- Government and private dental colleges	- Free of charge (or sponsored) screening camps and demonstrations
- Indira Gandhi Institute of Dental Sciences, Kerala	- Mobile OralScan screening with (support from Rotary club)
CervAstra	
- Indira Clinic & RV Metropolis (2020)	- Screening camps Low cost, Free of charge (or sponsored pilots) in rural and urban areas of Karnataka like Tumakuru, Chikballapur, and Bengaluru.

Source: Author's analysis of data.

Mainly, public private partnerships are a great source of endorsement in the health system and are crucial for last mile diffusion in the public health system. For instance, the Department of Health and Family Welfare, Punjab (DoHFW) has signed an MoU with Niramai and Roche Pharmaceuticals (India) to address the challenges of late diagnosis of breast cancer in Punjab (see Figure 7.6). The Punjab Breast Cancer AI- Digital project in which (i) the DoHFW is the initiator and fund supporter, (ii) Niramai is screening partner using Thermalytix is creating a state-wide screening for early detection of breast cancer connected with digital referral pathways (iii) Roche Pharmaceuticals (India) is the technical partner in planning, implementing, and monitoring the project integrating the digital referral pathways. The epidemiological statistics and GIS mapping thus generated by the digital systems is planned to feedback into cancer control policy under NPCDCS in NHM by mapping nature and spread of breast cancer cases in Punjab (EH News Bureau, 2022).

Figure 7.6: Punjab, the first state to include AI based screening programme in NPCDCS.
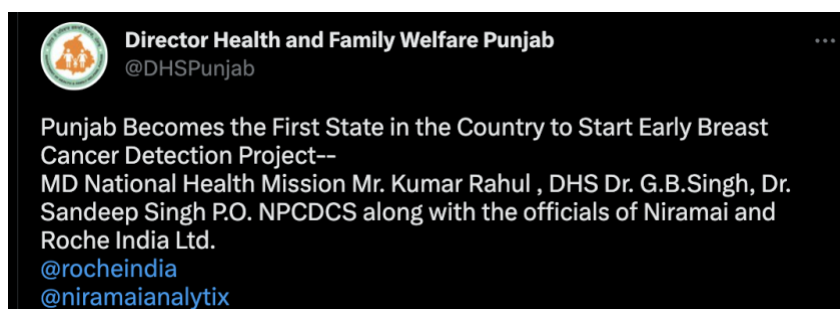
Source: Official Twitter handle of Department of Health and Family Welfare, Punjab

Some other states, like Kerala also envisage such partnerships. For instance, in the launch of OralScan, State Health Minister, Kerala signalled government receptiveness for emerging point of care innovations like OralScan:

 'Kerala government plans to compile a registry of cancer patients in the state as part of efforts to codify its various initiatives against the deadly disease. These kinds of innovations have come forward to brace this change'. (DST, n.d.)

Secondly, Table 7.9 points out that the start-up firms are engaging with government healthcare facilities or partnering with NGOs and private hospitals to organise community screening programmes. Such demand generation by partnering with both government and non-government partners are diversifying pathways for effective adoption of these innovations in the Indian context. This diversification also helps in expanding markets in cases private entities

may not find incentives in promoting a cheaper screening modality as they are well equipped with the gold standards like mammography, pap smear, CT scans, etc.

7.4.3. Stakeholder engagements for awareness and demand generation

The case studies also involve a demand-generating component through awareness generation on cancer and the new technologies. Table 7.11 shows how each start-up firm is engaging both with key opinion leaders in the healthcare industry and general population through various mediums. In addition to this, awards and policy recognition has also been helpful in building trust and awareness on innovation.

Table 7.11: Various mediums identified in case studies for demand creation and awareness.

	Key opinion leaders	Public engagement	Key recognition
Niramai	National and international MedTech conferences and workshop participation Engaging with mentors like Dr Kiran Mazumdar- Shaw Mentors from incubation and acceleration Seminars on Continuing Medical Education	Talks by founder on early detection of breast cancer and Thermalytix on various platforms: TEDx, Instagram Live, Podcasts, Newspaper, and magazine interviews, Social media	Aegis Graham Bell Award (2017 and 2018); Accenture Applied Intelligence AI Award (2019); National Start-up Award (Diagnostics), 2020. PHC Tech Challenges Winner (2021); Global Women's HealthTech Awards by World Bank and Consumer Technology Association (2022)
Sascan Meditech	National and international MedTech conferences and workshop participation Mentors from incubation and acceleration Product release, sales, and distribution launch by Kerala's Health Minister	Talks by founder on early detection of oral and cervical cancer and OralScan and CerviScan on various platforms: Newspaper and magazine interview, Rajya Sabha TV	Start-up India Grand Challenges Winner (2021) Anjali Mashelkar Inclusive Innovation Awards (2021) International Quality Innovation Award (2022)

	Key opinion leaders	Public engagement	Key recognition
		DD News, the public broadcaster of India	
Aindra Systems	National and international MedTech conferences and workshop participation Multidisciplinary advisory board Mentors from incubation and acceleration	Talks by founder on early detection of cervical cancer and CervAstra on various platforms: Harvard Global Health Institute, Washington University's Forum for India, Social media	Bangalore Tech Summit – Best Startup 2018 Research and Innovation Circle of Hyderabad (RICH) Award, Government of Telangana Indo Sweden Health Innovation Challenge 2021

Source: Author's collation of data from primary and secondary sources.

The case studies point out that sometimes the innovation receive scepticism from some doctors in accepting these being new modalities. Highlighting some key challenges in garnering larger acceptance among some doctors and radiologist, the founder of Niramai explains:

> 'small pocket of them is a little sceptical and want to see a couple of thousand screenings to test the validity of the solutions. Doctors are sceptical to technological change and rightly so because they are making an extremely important decision, talking about cancer is a life and death situation. so, we definitely understand why they are sceptic and why those questions are being asked. And the most important thing is that our solution has absolutely no side effects, we are not using X-rays, we are not using radiation, just measuring the temperature…so when we provide these details they say - of course you can do this as another test, and when they see the results they say that this can be plausibly used as the main test - we like this journey from transforming the scepticism to possibility' (100xenterpreneur, 2021)

Even the founder of Sascan highlight that shifting to a new technology is difficult for doctor, and therefore they are involving stakeholders and key opinion leaders to vouch for the new technology:

> 'the essential challenge is to change the views of doctors. So, what we are looking including key opinion leaders, who can vouch for our device, so we will try to catch up with some of the leaders and give them the device free of cost, educate them and make them understand that this can change the way the disease is detected, diagnosed, and treated in the country. We hope that some of them

may agree and may try to experiment with this new technology.' 'Once they are convinced about the quality of the device and its functions and the way it can make their life easy, they may talk about the device in conferences and meetings. In this manner people will come to know that top notch doctors are using it, so they will follow us to it and slowly the change can happen.'

<div align="right">Founder, Sascan, Author's interview (2021)</div>

Some examples of endorsement by key opinion leader are shared in Figure 7.7.

Given the overall demand for cancer screening is poor in India, case studies strongly engage in public engagement, working as extended arm of the government by awareness programmes. The case studies showcase through regular seminars, TEDx talks and reaching out to the end beneficiaries. In all case studies, start-up firms are doing these using talks and webinars through accessible digital mediums like Instagram and YouTube.

In summary, creation of new markets and demand generation for screening and early diagnosis of cancer in resource constraint settings are driven by start-up firms and partnerships. Policy recognition of these innovation is also a is a key factor in building credibility and trust on new technologies. These are 'pocket wins' to mitigate gaps in healthcare delivery through technologies. Integrating new technologies into the healthcare system and matching supply with demand, however, requires a significant policy overhaul that can be a slow and arduous process, particularly in the last mile of implementation.

Figure 7.7: Examples of endorsement from key opinion leaders

(1) OralScan Minister of State for External Affairs & Parliamentary Affairs, Kerala
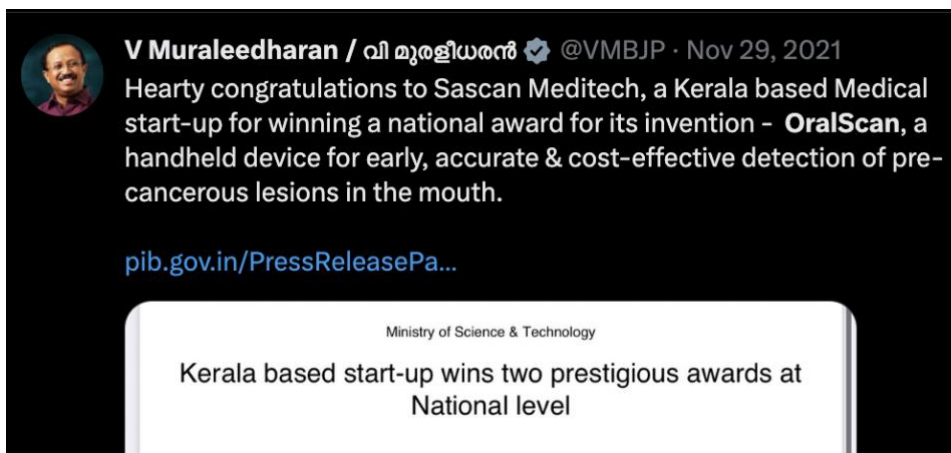
Source: Tweet from official account of the Minister of State for External Affairs & Parliamentary Affairs, Kerala, India

(2) Thermalytix mentioned in 37th Foundation Lecture on 'Driving Future Biotechnology Revolution in Amrit Kaal' by Director of IIM Bengaluru
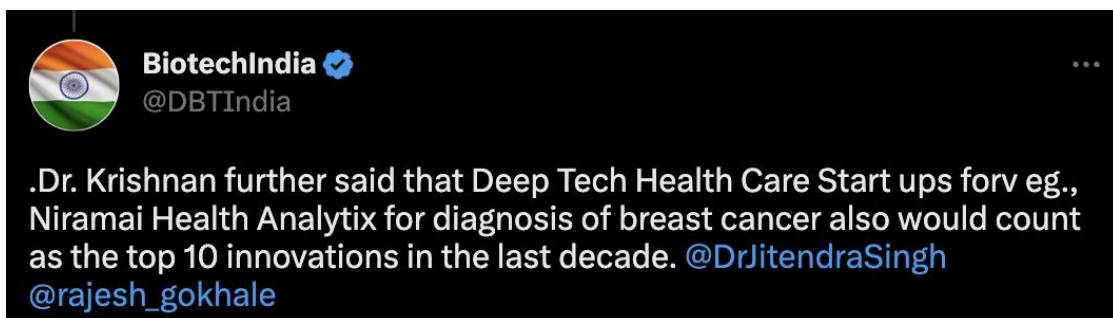
Source: Tweet from official account of Department of Biotechnology, Ministry of Science and Technology, India

(3) Aindra System's CervAstra publicised by INDIAai.
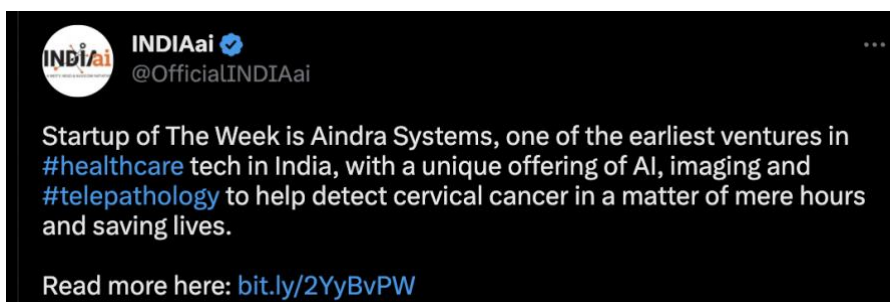
Source: Official account of the National AI Portal of India, a joint venture by MEITY, NEGD and NASSCOM

7.5. Chapter summary

In this chapter, I presented the analysis in three parts: A, B and C. Table 7.12 provides a 2X3 matrix (introduced in Chapter 4) presenting a summary of the analysis using the IHI framework. The table demonstrates the institutional variety that channels the combination of knowledge and technologies, and actors and networks that drive capacity to undertake inclusive innovation. The institutional bundles have led to Medtech innovation that are an alternative trajectory of high technological solutions for the early detection of cancer in resource-constraint settings.

This chapter presented both observable insights on inclusiveness in both process and outcomes, and factors that enable such inclusiveness through the process of innovation. In terms of process of innovation, inclusiveness is found by stating and meeting unmet needs of the early detection of cancer in low resource healthcare settings. To fulfil these needs, users were involved to validate the design process of both hardware and software. This view of inclusion in process of innovations challenges deep assumptions in the literature on technology and knowledge utilisation in the innovation process in low-resource settings. In terms of outcomes, each case study presents point of care modalities that are non-invasive and easy to use. In three cases, there is a concerted effort of building femtech for the early detection of breast and cervical cancers. These cases also highlight the role of women innovators, engineers, and scientists designing solutions for challenges that affect women. As a renewed sign of inclusiveness, the role of end user is also reimagined in ML driven modalities. In terms of actors and factors that influence development of these innovations I found two insights. First, government funding support is crucial in various stages of product development. Second, private actors, including incubators and accelerators, have emerged. It highlights the role of larger ecosystem, mainly specific actors, and factors, coming together coherently to invoke inclusiveness in the process and outcomes of innovations. Lastly, in terms of diffusion and adoption, the analysis revealed that there is a lack of policy instruments to facilitate the absorption of the emerging Medtech innovation. Further, acceptance of the new technologies is a gradual process. It involves trust building by continuous testing of these technologies in larger healthcare system. There are several business models and partnerships that are creating new markets for the early detection of cancer in low-resource settings. In addition to creating new markets, the case studies also point towards crucial ways of demand generation. Albeit proactive policy support is required to absorb the innovations in the healthcare system to improve early detection of cancer along with adequate regulatory framework.

Table 7.12: Summarising overarching analysis using elements of IHI framework

Sectoral systems of innovation \ Triad institutional domain	Unmet need and industrial production (1)	Healthcare delivery (2)	Demand (3)
Knowledge and technologies	• STI (viz. BIRAC, DBT and DST policies) and industrial (viz. Start-up India) policies driving industrial support to channel industry – academia – government links and support early-stage development of AI and ML based MedTech addressing unmet needs in India. (strong integration of health and industrial goals in policies) • Both explicit and tacit knowledge sources driving problem framing and solving of unmet needs in the early detection of cancer. • Learning as key determinant enter the entrepreneurial space of cancer diagnostic (technical guidance, etc.)	• Lack of dedicated health policy instruments to direct knowledge and technology development of innovation for early detection of cancer conducive for low healthcare settings. (2) Evolving regulations but no incentive for utilising knowledge and technologies to innovate and address unmet needs. (weak integration of health and industrial goals in policies) • Specialised knowledge and clinicians / radiologists / pathologist are required to operate and review results from gold standard early detection modalities. The AI and ML based MedTech can operate with limited training to frontline health workers, and in remote and community settings.	• Procurement rules are based on firm size and experience, supporting specialised knowledge and gold standard technologies by large firms and MNCs. Some respite due to recent changes in procurement rules that include some preference to 'made in India' devices. (3) (evolving integration of health and industrial goals in policies) • Lack of policy pathways, viz. health technology assessment, to absorb emerging MedTech innovations into healthcare system, competition with imported medical devices (weak integration of health and industrial goals in policies) • Utilising interdisciplinary knowledge and learning by doing, using, and interacting to generate demand for early detection of cancer by mapping product to market fit, and ways to reach

Triad institutional domain / Sectoral systems of innovation	Unmet need and industrial production (1)	Healthcare delivery (2)	Demand (3)
	• Using applications of advancement in technology - AI and ML - to address existing unmet needs with gold standards in the early detection of breast, oral, and cervical cancer.	• Utilising knowledge to apply advancement in computing technologies (AI and ML) to apply the business models and fill the gaps in healthcare delivery system.	different end user through innovative business models.
Actors and networks	• Emerging Medtech startup ecosystem – combining STI, industrial and health polices by bringing together a range of actors, and funding, incubation, and accelerator support to innovation development (1) • Individuals with personal motivations and knowledge to innovate and startup • Policy actors supporting locally relevant innovations • Regulatory actors • Clinicians, radiologist, pathologist	• State cancer control policies on screening, Cancer screening and diagnosis under Ayushman Bharat Scheme, Choosing Wisely (2) • Policy actors • Private diagnostic chains • Primary and community healthcare, Public and private hospitals, clinics, screening camps by corporates and NGOs	• Public private partnerships and stakeholder engagement to generate demand and awareness for early detection of cancer (3) • Government partners • Non-government partners, including diagnostic partners, and NGOs • Key opinion leaders (clinicians, hospital networks, industry experts)

Triad institutional domain / Sectoral systems of innovation	Unmet need and industrial production (1)	Healthcare delivery (2)	Demand (3)
	• Private incubation and funding agencies • Research hospital networks • End users		
Institutions	According to SSI, institutions include rules, laws, standards, regulations, established practices, etc. However, different domains of institutional triad already emphasize on the variety and bundles of institutions for healthcare system in India. For the IHI framework. I have used green font to highlight the elements of institutional domain.		

Source: Author's summary of analysis using IHI framework.

Chapter 8: Conclusions: Key findings, contributions, policy implications, and future research

8.1. Introduction

This conclusion chapter brings together the research questions, research methods, and findings of this thesis to show that inclusiveness is integral to a sustainable industrial and health system. Specifically, I examined to what extent STI, industrial, and health policies have aligned to facilitate the development, diffusion, and adoption of inclusive PoC MedTech innovations for the early detection of cancer in the Indian context. Inclusiveness is an integral part of a sustainable health system, but what does it mean in the evolving health and industrial sectors? I investigated how inclusiveness is conceptualised in these MedTech innovations, and what actors and factors influence their development, diffusion, and adoption, and how?

In Section 8.2, I summarise the findings, answering each sub-research question. I arrived at these findings using and employing the IHI framework for a twofold analysis. First, I used the landscape study of the early detection modalities to situate the problem-solving PoC Medtech innovations using a 2X2 matrix (adapted version of SII framework) in their current industrial context (see table 5.1). The matrix highlighted how a different mix of institutional combinations enables problem-framing for social change in the emerging PoC MedTech innovations. In Chapter 6, I delved deeper into this category by using multiple case study research design to study the innovation process of 4 PoC MedTech innovations for early detection of breast (Thermalytix), oral (OralScan), and cervical cancer (CerviScan and CervAstra). I used case study research design because it enables rich and in-depth analyses of complex and dynamic phenomena within a specific context. It facilitated capturing the complex and iterative process of innovation and identifying the key actors and factors driving innovations for early detection of cancer in low-resource healthcare settings. In Chapter 7, I analysed the advances in the conceptualisation of inclusiveness in the cases of PoC Medtech innovations for the early detection of cancer. Secondly, I brought together insights from the previous chapters to analyse the impact of actors and factors in developing, diffusing, and adopting innovation in low-resource healthcare settings. I summarise the overarching analysis using the 2X3 IHI matrix (see table 7.12).

I use the key findings to summarise the answer to the main research question, explaining (i) a stronger alignment of policies supporting the development process of Medtech innovations for

the early detection of cancer (ii) a gradual but weaker alignment of policies facilitating the adoption of the PoC Medtech innovations.

In Section 8.3, I present the main contributions and originality of my research. First, I proposed a novel IHI framework. Second, I applied the framework to study advances in conceptualisations of inclusive innovations for the early detection of cancer driven by technological advances in the MedTech sector. Third, empirical evidence on combinations of actors, factors, and institutions that enable problem-framing and solving of unmet needs of early detection of cancer in low-resource health settings. In Section 8.4, I present some reflections on public policy. In Sections 8.5 and 8.6, I present some limitations of findings in my case study research design. I used data from multiple sources for triangulating to mitigate any potential bias and data collection and limitations due to COVID-19. In addition, using the IHI framework to conduct the analysis enabled an iterative data analysis process, increasing the findings' validity. In Section 8.7, I present future research, mainly weaving in findings of the thesis in the upcoming policy changes for screening and early diagnosis in India, data privacy and storage regulations.

8.2. Key findings

This section presents the key findings and answers to each sub-research question.

8.2.1. How is inclusiveness conceptualised in the MedTech innovations for the early detection of cancer in low-resource healthcare settings? (RQ1)

The thesis reports on conceptualisation of inclusiveness present in both process and outcomes of innovations for the early detection of cancer in low resource healthcare settings. In terms of process,

(1) Inclusiveness in innovation is achievable in resource-constraint settings with affordable applications of high technology.

(2) Inclusiveness is incorporated by framing unmet needs for early cancer detection in low-resource healthcare settings.

(3) Inclusiveness involves users, clinicians, and radiologists in the design process to address unmet needs.

In terms of outcomes,

(1) Inclusiveness showcases availability and access to non-invasive, portable, point-of-care, easy-to-use early detection modalities of cancer in low-resource healthcare settings—for instance, femtech for early detection of cancers affecting women.

(2) Inclusiveness in women as innovators in resource constraint settings.

(3) Inclusiveness of the end users (beneficiaries) not just as receivers but contributors to improving technology.

I now briefly explain the above points of inclusiveness by the process.

The analysis reveals that historically there has been a lack of strong motivation to drive inclusive innovation in the medical device sector. Nevertheless, the AI and ML surge in the fourth industrial revolution has substantially increased the scale and scope of inclusive innovation in the MedTech sector in India. For instance, the case studies of the thesis highlighted how PoC Medtech innovations leverage the spillover effects of these advances in AI and ML to screening and early diagnosis of breast, oral, and cervical cancer in resource constraint settings. They do so mainly in two ways (i) by introducing novel screening modalities minimising subjectivities in the early detection of cancer and (ii) by making existing modalities conducive to low-resource healthcare settings of India. This finding contributes to the under-researched area of conceptualising inclusiveness in high-technology health innovations developed in resource-constraint settings of LMICs.

To some extent, reverse innovation captures the role of LMICs as producers of high-technology innovations (Immelt et al., 2009). However, it is found to be conflating with other terminologies (like frugal innovations) and limiting policy implications due to innate assumptions about the scaling-up and flow of the markets from industrialising to industrialised (for instance, Harris et al., 2016). Traditionally, innovation and development studies have conceptualised the inclusive character of innovations in resource-constraint settings with a focus on frugality (low-technology solutions) or grassroots (being low-cost products/services driven by communities) (also discussed in Chapter 3). Even in the Indian context, recent studies highlight frugality as the essence of innovations (Bhaduri & Bhattacharya, 2021). A recent study also analyses the development of medical devices from innovative manufacturing firms

in South Africa. However, it uses a frugality lens (Chakravarty, 2022). The findings of the thesis align with these studies in so far as highlighting the need for locally relevant solutions is concerned. The results of this thesis mark a departure from the traditional reference to the innovations in resource constraint settings in the literature. Such distinction between frugality and inclusive innovations is also explored by Onsongo and Knorringa (2020).

Secondly, the analysis highlights inclusiveness by identifying and stating unmet needs for early cancer detection in low-resource healthcare settings. The founders (lead innovators) were motivated by lived experiences of the pain and difficulties of cancer in family and friends.

This experience enabled the innovators and their team to state and unravel the following layers of unmet needs of early detection of cancer in low-resource settings, which are otherwise un-spelt.

- *Need for early detection modalities that mitigate limitations of existing screening and early diagnosis modalities.*

- *Need to address more considerable systemic challenges of limited healthcare capacity in the form of scarcity of healthcare staff (doctors, radiologists, and pathologists).*

- *Need for affordable and non-invasive screening modalities due to the lack of financial coverage for expensive gold standard tests, mainly in rural areas in India.*

The analysis points out unmet needs due to challenges both with the gold standard and low-cost screening modalities available for the early detection of breast, cervical, and oral cancer. For instance, in the case of breast cancer, there is no conducive modality for women of all ages and women with dense breasts. Mammography is suitable for women above the age of 45 but not younger age groups and women with dense breast tissue. Ultrasound is for younger women but is not a practical option for screening in resource constraint settings. In the case of oral cancer, there are concerns about the subjectivity of clinicians involved in visual inspections, which increases the chances of wrong biopsies. In the case of cervical cancer, in addition to the subjectivity of screening methods and infrastructural challenges with pap smear screening. All case studies acknowledge the cost concerns shortages of doctors, radiologists, and pathologists, and infrastructural gaps in using gold standard modalities. These healthcare challenges make

low-cost screening techniques used by government screening programmes also prone to subjectivity.

To incorporate these needs into the design of innovations, the analysis showcases the application of design thinking by innovators and their teams. Design thinking is a problem-solving approach that focuses on understanding the needs of the user (for instance, see Oliveira et al., 2022). In all the case studies, this has been done by understanding unmet clinical needs by involving clinicians, pathologists, and radiologists in the prototype development process. The degree of user involvement in customising the process of innovation plays a key role in democratising innovation (as discussed in von Hippel, 2005). In reference to this thesis, democratising means a step to gain broader acceptability in clinical practice.

I now briefly explain how inclusiveness showcases outcomes.

First, by bringing a concerted focus on point-of-care technologies for female health (Femtech), mainly in screening and early cancer detection, which has historically been neglected in the Indian context (for instance, Parez, 2019). Thermalytix provides effective solutions for breast cancer screening for women of all ages, a characteristic missing in the gold standard modality (mammography), which is only suitable for women over 45 years. Moreover, the innovation provides no-touch screening in separate screening rooms. It thus acknowledges the sociocultural sentiments towards touch-based screening in many women in the Indian context. CerviScan is offering a non-invasive screening modality for cervical cancer screening, easing some level of pain and discomfort associated with it. CervAstra has expedited and improved the traditional pap smear cervical cancer screening for low-resource healthcare settings. It does so by using an AI-based computational pathology system, enabling faster results at the point of care. OralScan enables both objective screening and biopsy guidance for oral cancer in low-resource healthcare settings.

In all case studies, the easy-to-use design of innovations leverages technology to trickle down innovations in remote and rural areas in India where there is a lack of clinicians, health care professionals, and infrastructure to conduct screening. These innovations' compact and portable nature increases their reach beyond the diagnostic centres and hospitals in urban settings, facilitating point-of-care access to rural healthcare settings. They do so by eliminating the need for space, capital expenditure, and infrastructure required to maintain and operate large machines and apparatus (required in mammography, MRI, etc). These innovations are designed

to be used with limited training for frontline workers of primary health centres or community health centres in rural and resource constraint settings. Such point-of-care availability offers usefulness in community settings with large-scale screening. Moreover, it also offers reduction in operational time and screening logistics as compared gold standard modalities. All case studies use several business models targeting different populations. These business models consider where the screening is provided, including rural or urban health care settings, public or private hospital or clinics, diagnostics providers, screening camps. This facilitates options of availing the same technology at a lower cost. Therefore, high-technology innovations are meant for not just poor but for a wider range of users. This user base is expanded from just poor or rich to include the 'missing middle' population, which lacks coverage under any kind of health insurance in both rural and urban areas (Sarwal et al., 2021).

Second, the analysis reports the increased role of women in the innovation process in these cases, for instance, lead innovator and entrepreneur (Thermalytix), biomedical engineer (CerviScan), and consulting pathologists and clinicians (CervAstra). These insights are important as previous studies suggest a lack of recognition of women as bottom-up innovators in the literature (for instance, Cozzens and Sutz, 2014). The finding aligns with BRI and SII conceptualisations of inclusiveness in so far as understanding the role of industrialising countries as a producer and users of innovation are concerned.

Third, the analysis of inclusiveness by the involvement of end users in technology development and improvement. It is a unique feature that reimagines technological development in healthcare. These case studies have a software component based on trained and tested ML algorithms that facilitates the screening and early detection results. ML algorithms continue to learn and update their models as new data is collected and processed with more use of these PoC Medtech innovations. Therefore, it is an unintended but prominent inclusion of the beneficiaries in improving technological capabilities of cancer screening and early diagnosis. However, this aspect of inclusiveness needs to be supported by strong regulations on the ethics of data collection, privacy, and storage.

8.2.2. What are the key actors and factors that influence the development of MedTech innovations for a local health system, and in what way do they interact with each other to address the early detection of cancer? (RQ 2)

The analysis revealed a variety of actors and factors and examined their influence on development, diffusion, and adoption of PoC MedTech innovations for the early detection of cancer in India. Primarily, a combination of two actors and factors was critical. First, the growing interest of private actors, driven by personal motivations and knowledge, to resolve unmet needs of early detection of cancer. Second, government as key policy actors by recognising these innovation efforts and supporting them with early-stage finance and incubation.

First, in all case studies, innovations are driven by personal motivations of private actors either due to lived experiences of cancer cases in their family and friends or to create societal impact. In addition to motivation, their prior knowledge and skills enabled them to utilise AI and ML to bring a large-scale effect on cancer screening and early diagnosis. Therefore, in these cases, innovations are not driven by large firms but by individuals with a personal motivation who formed 'start-ups' to make an impact. The role of lead innovators is critical in driving every stage of innovation through their active participation in interdisciplinary knowledge production and exchange in the development process.

Second, the government policies and governance architecture for AI-based innovations targeting challenges of the Indian healthcare system have enabled an ecosystem. The policy efforts include (a) promoting multidisciplinary learning and collaboration (among universities, clinicians, research-based hospitals and medical institutes for clinical research, IT sector) and (b) early state funding and incubation support to these innovations. This role of policy actors has facilitated collaborative linkages in the R&D and development of innovations in MedTech space for the early detection of cancer and health care delivery. These linkages have historically been weak, which hampered the development of local technological capabilities and affordable health care (for instance, in Kale and Wield, 2018). The policy recognition of these innovations also signalled the private funders, incubators and accelerators who played a crucial role in enabling diffusion efforts. The availability of these actors, enabled funding, mentorship, and technical guidance in bridging the journey of ideas to market.

It is important to note that some of these actors are common in other sub-sectors of health sector including pharmaceuticals and vaccines. However, the case studies underscore that application of technological advancement in the early detection of cancer shows signs of convergence in health and industrial policy actors for MedTech. Use of the IHI framework to map different actors and factors illustrates that such convergence is the result of cumulative interactions and synergies from the actions of different actors in co-evolving vertices of the institutional triad. This convergence has enabled a systemic change showcasing that these innovations are not sporadic. This systemic change showcases that the actors and factors have come together in a coherent manner to channel the triad vertices – industrial production – demand – health care delivery - to co-evolve somewhat synchronously. These insights are crucial to understanding the underemphasised issue of health-industry linkages in health system research and industrial policy analysis. This combination of actors and factors within the institutional milieu has enabled (a) availability and access to non-invasive, portable, and easy-to-use innovations for the early detection of cancer, (b) the potential of lowering cost of existing screening modalities by increasing choice and competition.

8.2.3. How do these factors influence the development of inclusive MedTech innovations for the early detection of cancer in India? (RQ3)

Innovation in medical technology is identified with huge entry barriers due to high investment, delayed returns due to long product development and diffusion cycles, and a constant threat of going down the valley of death. The factors first facilitate framing the unmet needs and leveraging technology to develop locally relevant solutions, and secondly, provide institutional support to translate these needs to demand and new markets (discussed in answer to the following question). The IHI framework enabled an understanding of how various factors channel the impact of broader systemic change and selection environment influences for the case studies:

(i) identifying innovators, who are not from health system domain, as essential actors with the intention of developing solutions that mitigate challenges in the early detection of cancer in low-resource healthcare settings. Various policy instruments, including early-stage funding and incubation support, incentivise and instil confidence in non-domain innovators to enter the Medtech sector (innovators with a non-health sector background, mainly from the IT sector, other hard sciences, and management domains). This was a

missing link in innovations in the medical device sector from earlier decades (Chapter 2). Mainly to enter the space of early detection of cancer in India with inclusive solutions where there are no public providers. For instance, the emergence of Femtech by effective problem-framing of the unmet needs and challenges women face when accessing breast and cervical cancer screening. Historically, this space is dominated by two extremes capital intensive and exclusive technologies and low-cost technologies with low uptake. The first category includes large MNCs keeping in mind the needs of people in high-income settings (e.g.: mammography, MRIs) and advanced health systems. The latter category includes very low-cost technologies (e.g., clinical breast examination, visual inspection of oral cavity, and cervix with acetic acid) but has low uptake apart from public screening programmes.

(ii) Since these innovators were not entrepreneurs to begin with, funding and technical and operational guidance from incubators and accelerators has enabled them to understand how to put capital into operation. This involves help with increasing the size business operations, understanding go-to market strategy, and scaling up to a certain.

The analysis also reflects some challenges, mainly in securing continuous funding, and regulatory clarity. First, the continuous flow of funding remains a key challenge for early-stage innovators to sustain operations for longer periods. These innovations depend on dedicated funding for every stage of development, including proof of concept studies, the cost of conducting clinical studies, filing for patents, certifications, and regulatory approvals. The second relates to procedural clarities and delays. For instance, each hospital has a different institutional ethics committee, requiring separate approvals, which can be time-consuming.

Further, as stated earlier, lack of clarity on regulations is a persisting challenge. However, the national medical device regulation per se does not pose a major barrier for Class A or low-risk category innovations including in case studies. However, their influence on these innovations is weak and unclear for two reasons: they still are under the umbrella regulatory architecture for pharmaceuticals, and do not incentivise innovation for fulfilling unmet needs and gaps in the early detection of cancer. Moreover, clarity on regulations would also have bearing on data security and privacy considerations associated with these new innovations. The lens of the IHI framework presents two considerations (1) there are increasing linkages between STI and industrial policy from a MedTech sector perspective, and strong signs of actors and factors

working towards the development of problem-framing innovations for early detection of cancer; (2) the actors and factors are connecting but still weakly linked with health policy.

8.2.4. What are the actors and factors that influence diffusion, and adoption of these innovations? How are such inclusive MedTech innovations mainstreamed into health systems for their last mile' diffusion in India? (RQ4)

The thesis presents a contrasting scenario in the landscape of the early detection of cancer in India. On the one hand, capital intensive screening and early diagnosis modalities (for instance, mammography and pap smear) have limited compatibility with health systems and lack affordable access for a large section of the population. On the other hand, while the low-cost technologies (clinical breast examinations, visual inspections of the oral cavity, and cervix) are advocated for resource constraint settings and are used in public screening programmes for breast, cervical, and oral cancer, the coverage, and uptake are low. Within this landscape, case studies discussed PoC MedTech innovations that frame unmet needs due to these existing modalities in the early detection of breast, cervical and oral cancer in India. These innovations are propelled with the support of transformative public institutions. Such a scenario becomes critical as it highlights policy and innovators' recognition of unmet needs, and concomitant innovation production to fulfil the unmet need through institutional support in the development process of innovations.

However, it is crucial to note that demand-side institutions are not progressing at the same pace as supply-side institutions. This lacuna of slower adoption is captured in the IHI framework through the institutional triad heuristic. The triad showcases this point through the unsynchronised co-evolution of different institutions linking the production of innovation and delivery in the healthcare system to translating unmet need to demand. This finding connects with literature on needs and demand in health care (Srinivas, 2014), stressing interventions wherein needs are recognised, but demand remains unfulfilled in the policies. This reflects in the form of (a) weak public demand for screening in general, (b) a lack of government initiatives to absorb the new technologies in the health system, and (c) a lack of private incentives to choose the new technologies over the more profitable gold standard techniques.

It is essential to highlight that despite these challenges in institutional support, the case studies demonstrate how actors are shaping demand by creating new markets using different business models, stakeholder engagement and public-private partnerships:

(i) Innovative business models targeting different ways in which primary users (business to business) and beneficiaries (business to customer) can access the device (i) health care delivery system using direct sales to hospitals and diagnostic firms, pay per-use model and subscription-based model for health care clinics targeting those who are unable to purchase the whole system. (ii) end beneficiaries through home screening options, outreach model facilitating mass screening camps, simpler version of the product innovation only for triaging purposes to conduct large screening, and conducting seminars, webinars, and startup competition for publicity and advocacy of regular screenings and the value provided by innovations to people. The findings on innovative business models align with and build on previous work by Angeli and Jaiswal (2016) that extended existing business model conceptualisation of value proposition, value creation, and value appropriation by introducing 'value discovery' as a necessary precursor. This thesis shows the role of value discovery by identifying the unmet needs in screening and early diagnosis of breast, cervical and oral cancer at various levels rather than assuming them for the sustainability of business models.

(ii) Stakeholder engagement and public-private partnership (through complementary pilots) collaborating with different state governments in the public health care system is a direction to demonstrate the validity of these innovations beyond clinical studies and in a larger context, for instance in rural settings.

Therefore, in the words of a lead innovator in one of the case studies, these factors enable 'winning in pockets' to shape demand and new markets for these PoC and non-invasive innovations with an aim for affordable access to the early detection of breast, cervical and oral cancer. At the same time, it is important to note that the process of mainstreaming these innovations for a 'last mile' diffusion is a longer process, requiring policy change and endorsement by national and subnational governments. Towards this end, the case studies reflect the need for more flexible institutional designs and planning for health technological assessment, procurement, technical standards, etc.

With answers to the sub-research questions, I revisit the main research question: **To what extent have STI, health, and industrial policies aligned to facilitate the development, diffusion, and adoption of inclusive innovations for the early detection of cancer care in India?**

Cancer screening and early diagnosis are relevant and to low-resource healthcare settings has been a weak area for public and private research and innovation efforts are concerned in India. The timely availability and access to appropriate early detection modalities has been a challenge. The disparity between health needs and the industrial efforts to develop innovations relevant to the local context has been attributed by scholars to a lack of collaborative actions. Chapter 2 delved deeper into this issue by showing different phases of the evolution of STI, health, industrial policies, and the medical device sector. Some signs of convergence in STI, industrial and health policy was observed in phase 4 of section 2.2 and 2.3. These signs of convergence shaped an ecosystem for innovation which was missing for medical devices in India. The sector experienced a technological shift fuelled by the spillover effects of AI and ML, which are the crucial drivers of the fourth industrial revolution. This technological change has led to a new trajectory of innovation by Indian startups in the MedTech sector. These MedTech innovations offer novel modalities that primarily focus on meeting the unmet needs of early detection of cancer in the low-resource healthcare settings of India. This development prompted my overarching research question to understand to what extent integration of STI, health and industrial policy influenced change in a sector that has been a poorly institutionalised until recently in the Indian context. Table 8.1 shows broader sectoral developments and schemes and policies that were relevant in each case studies to point how some policy arenas more conducive than others.

Table 8.1: Summary of policy instruments supporting Medtech sector and case studies

Policy domain	Medtech sector	Thermalytix	OralScan	CerviScan	CervAstra
STI policy	BIRAC, DBT and DST schemes, TiMed under SCTIMST	BIRAC in accelerator, BIRAC Women in Entrepreneurial Research award	BIRAC funding and TiMed under SCTIMST to support incubation, NIDHI scheme of the DST	TiMed under SCTIMST	BIRAC funding
Industrial policy	Make in India, Medical device policy, FDI Policy, State Start-up India policy, Tax exemptions, Medtech parks	Mission Karnataka Start-up, Incubated at K-tech Innovation Hub @ Nasscom10K, Winner of ELEVATE under Elevate 100	Kerala Startup Mission	Kerala Startup Mission	K-tech centre of excellence, Data Science & AI Startups, NASSCOM, and Government of Karnataka; Winner of ELEVATE under Idea2PoC, Mission Karnataka Startup
Health policy	NPCDSC, National health policy, Medical device regulations, ethical guidelines for biomedical research on human subjects and Institutional Review Board, Clinical validation, Health technology assessment, Ayushman Bharat, Choosing Wisely, Public private partnerships.	Novel tool for breast cancer screening, area of focus of NPCDCS Separate approval from IRB of each hospital for clinical studies PPP with Punjab government	Novel tool for oral cancer screening, area of focus of NPCDCS Separate approval from IRB of each hospital for clinical studies Efforts to apply for health technology assessment at the state and national level	Novel tool for cervical cancer screening, area of focus of NPCDCS Separate approval from IRB of each hospital for clinical studies	Novel tool for cervical cancer screening, area of focus of NPCDCS Separate approval from IRB of each hospital for clinical studies

Source: Summary from author's data analysis

Employing a novel theoretical framework, the IHI framework, and using 4 case studies of PoC MedTech innovations for the early detection of breast, cervical, and oral cancer in India, the thesis investigated the massively underemphasised relationship of STI-health-industrial policies for early detection of cancer in India. The primary assumption in the IHI framework is that institutional bundles (varieties) are the key explanatory variable to operationalise knowledge, distinct technological and problem-framing and solving capabilities to address unmet needs. The results of the thesis find varying levels of alignment in STI policy, industrial policy, and health policy in the development, diffusion, and adoption of PoC Medtech innovations for the early detection of cancer in the Indian context. The main findings of this thesis reflect how these levels affect:

(1) the conceptualisation of inclusiveness in the PoC Medtech innovations for the early detection of cancer,

(2) the actors and factors, and their influence in the development, diffusion, and adoption of such inclusive innovations for the early detection of cancer.

To summarise how policy integration has supported MedTech, I present two key points:

(i) **Signs of stronger alignment in STI, health, and industrial policies to drive early-stage development of Medtech innovations for the early detection of cancer in low-resource healthcare settings**

Cancer screening and early diagnosis has been a weak area insofar as strong public and private research and innovation efforts are concerned in India. In Chapter 2, I highlight that the policy developments in phase 4 of section 2.2 and 2.3 build some signs of alignment in STI, health, and industrial policies to drive the development of Medtech innovations for early detection of cancer in low-resource healthcare settings.

At the sectoral level, for the first time, the STIP (2013) focussed on linkages of innovation and science and technology as drivers of sustainable and inclusive growth by creating a new ecosystem to develop solutions for societal problems. While the change in STIP's focus was a critical policy development, it was not sufficient to drive locally relevant innovation in the health sector. There was a significant emphasis on innovation as a product of R&D, but neglect of the growing significance of knowledge exchange, scientist and biomedical engineer training, and intellectual property transfers (Mani, 2013). Moreover, studies indicate that this policy change failed to align with the contemporary reality of the political economy of health innovations during

that period. For example, despite its ambitious nature, the policy did not address the broader discussions surrounding the lack of regulatory oversight. Nonetheless, the STIP did alter the larger narrative around the role of knowledge-intensive entrepreneurship and innovations, and the role of STIP in wider economic growth and development. This was reflected in schemes and policy instruments that focussed on bolstering academic – industry – government collaborations. This gave initial impetus to the building of technical capabilities to reduce reliance on imports and foster innovative ideas in the MedTech ecosystem (BIRAC, 2012). For instance, the Department of Biotechnology and the Department of Science and Technology under the Ministry of Science and Technology collaborated with several funders and introduced schemes to support locally relevant innovations. Some key examples of institutional support in early-stage innovation development include BIRAC and TIMed in Sree Chitra Tirunal Institute for Medical Sciences and Technology, which support individuals and organisations involved in strategic research and innovation addressing the unmet need by translating knowledge into technology-led affordable and global competent product development. Additionally, a range of non-government actors have emerged in this space. For instance, Tata Elsxi, Villgro Foundation, etc., have played an essential role in initial funding, incubation, and development of prototypes of emerging MedTech innovations. There is also the emergence of bridging organisations to support research scientists and academics who do not have the requisite knowledge of entrepreneurial aspects but are keen to scale disruptive innovations. Such organisations play an intermediary role to bridge knowledge gaps by connecting the innovation and investment ecosystems. They do so by linking entrepreneurs seeking financial and operational support with technical expertise and risk capital providers.

Key industrial policies complemented the support of STI policy to support emerging technologies and start-up firms. For instance, the Department of Pharmaceuticals launched a Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Medical Devices ensuring a level playing field for domestic manufacturing and attracting large investment in the sector. The Startup India initiative by the Department for Industrial Policy and Promotion, Ministry of Commerce and Industry was established to support startups by offering state-specific compliance handholding, funding and incentives, incubation support and fostering industry-academia partnerships. These initiatives helped build a strong and inclusive ecosystem for innovation and entrepreneurship. In addition, some key policy developments in other ministries supported the use of AI in healthcare to mitigate challenges of access to healthcare facilities. These included policy support by the AI and Emerging Technologies Division of the Ministry of

Electronics and Information Technology promote the adoption of cutting-edge technologies that have the potential of creating economic and societal impact. Furthermore, the National Strategy for AI by NITI Aayog laid out policy recognition of the ethical application of AI in healthcare, including imaging diagnostic, to mitigate challenges of shortage of qualified healthcare professionals like qualified doctors, nurses, radiologists, pathologists, and health infrastructure. The policies and instruments for industrial development along with the penetration of AI stirred up an ecosystem conducive to domestic Medtech innovation.

Historically, health policy has not been integrated with STI and industrial development. In a change of policy discourse, the NHP 2017 played a critical role in coordinating health and industrial policy goals regarding the availability of locally relevant MedTech innovation. At national level, the NHP focussed on adequate regulatory provisions to align public health goals with the private sector's growth, a well-developed public procurement system, and supportive policies to increase the effectiveness of regulations and industry development. Further, the NHP highlights the facilitation of local manufacturers by incentivising and enhancing their manufacturing capabilities to develop customised indigenous medical devices and diagnostics for the Indian population in the long run. These objectives, in turn, aligned with the national industrial development agenda of 'Make in India' and *'AtmaNirbhar Bharat* mission (self-sufficient India), under which the goal regarding medical devices and diagnostics is to create forward and backward linkages in indigenous production. Even in terms of larger cancer control policies, some key institutions were established to strengthen early detection efforts: NPCDCS, the National Cancer Grid, and population-based screening programmes. Mainly resulting from the COVID-19 pandemic, the need for locally relevant technologies was reinstated for resilient health systems. For example, there was a renewed focus on scaling up cancer screening using new technologies under the Health and Wellness Centres of Ayushman Bharat scheme.

All the case studies reflected the focus on local context by encompassing inclusiveness in both process and outcomes through effective problem-framing of layers of unmet needs. Each spelt out unmet needs in the early detection of cancer in a limited healthcare capacity. The policy support for these layered unmet needs has catalysed innovation efforts that are not sporadic but systemic change driven by technological advances in AI and ML. The analysis reflects health system strengthening through an inclusive form of industrial development that shows signs of linkages in both health and industrial goals.

Specifically, the answers to the sub-research questions highlight signs of policy integration via coherent collaborations among various actors: including policy systems, academic institutions, industry entities, funding bodies within a healthcare system that fosters an environment conducive to drive transformative inclusive innovation within the Medtech domain. The focus on mainstreaming inclusiveness in innovations is essential because, in the past several decades, inclusive innovations have been seen as an 'alternative' and 'off-shoot' outside mainstream innovation trajectories. The thesis evidenced mainstreaming of inclusiveness and growing linkages between health needs and industrial development through in-depth discussion and analysis of empirical case studies of locally relevant PoC innovation for early detection of cancer (in Chapters 6 and 7). The case studies show the iterative process of how innovation develops in the given selection environment. As shown in answers to sub-research questions, policy integration is strong regarding support early-stage development of innovations. However, some of the policy issues concerning late-stage development are yet to be streamlined. These primarily include expanding the role of policy instruments in late-stage development, like scaling up for sustainable diffusion to prevent valuable innovation efforts from drowning into a valley of death. Some of these policy gaps were addressed by the presence of private for profit and non-profit actors through funding, incubation, and accelerator support in go-to market strategies and scaling up, for instance, in the case of Thermalytix and OralScan. In terms of role of regulatory processes, the requirements for Medtech innovations are still tied to pharmaceuticals and do not incentivise locally relevant MedTech innovations for the early detection of cancer.

(ii) Gradual but weaker alignment of policies facilitating the adoption of the PoC Medtech innovations.

At the systemic level, interactions among policy actors and institutions facilitating demand generation and adoption are weaker than support by supply-side institutions facilitating the development process. This is reflected in policy discussion and analysis in Chapters 2, 5, 6 and 7. There are a lack of policy initiatives and schemes facilitating effective integration and absorption of PoC innovations compared the range of policy instruments introduced to promote the development process of MedTech innovation. To elaborate on this point, the analysis showcases that demand side institutions like health insurance schemes, procurement policies, and health technology assessments respond slower to facilitated effective adoption vis-à-vis the pace at which the supply-side institutions have supported development. The literature on inclusive innovation linking health and industrial policy focuses more on building local manufacturing of locally relevant innovations. However, empirical evidence on simultaneous capacity creation and

demand generation is weak. The empirical case studies show the weak signs of linkages in STI, industrial policies and health policies for the early detection of cancer, because policy pathways to integrate emerging innovation into health systems are either absence or are in a nascent stage of development. Nonetheless, the analyses highlight that the policy vacuum in this domain is filled with innovative business models, and stakeholder engagement, and that public-private partnerships are shaping demand and creating new markets for PoC MedTech innovations for early cancer detection in India. This also is reflected using the 'institutional triad' element of the IHI framework as it shows that the co-evolution of institutions linking the production of innovation and delivery into the health care system to translating unmet need to demand can be unsynchronous. Having said that, some recent multidisciplinary and multistakeholder efforts like 'Choosing Wisely' have emerged as key for developing value-based accessible solutions relevant to the early detection of cancer. There is also recommendation to creat more public demand for early detection efforts in the Parliamentary Committee Report. The report recommends integrating new MedTech innovations into a larger decentralised diagnostic plan in both urban and rural areas under PMJAY (the Department-related parliamentary standing committee on Health and Family Welfare, p172).

In summary, table 8.2 shows the integration of STI, health, and industrial policies supporting inclusive innovation processes for the early detection of cancer in low resource healthcare settings.

Table 8.2: Actors and factors that channel development, diffusion, and adoption of inclusive innovation

INNOVATION CYCLE	DETAILS	ACTORS	FACTORS
SIGNS OF STRONGER ALIGNMENT IN STI – INDUSTRIAL – HEALTH POLICIES			
DEVELOPMENT	Conceptualisation	Private innovators with multidisciplinary team in start-up firms	Personal motivation of innovators, driven by knowledge
	Proof of concept and prototype development	Government (DST and DBT schemes, Start-up India schemes), private and social incubators	Early-stage finance and incubation
	Clinical validity, safety, and quality	Research hospitals, primary users, regulatory actors	Access to hospital network, Funding, incubation support to conduct clinical validation, and evolving regulatory framework
	Scaling up and go-to market strategies	Government (DST and DBT schemes, Start-up India schemes), private, non-profit funders, incubators	Patent, clinical studies, medical regulatory framework
SLOW BUT EVOLVING RESPONSE FROM OF DEMAND SIDE INSTITUTIONS: STI – INDUSTRIAL – HEALTH POLICIES			
DIFFUSION AND ADOPTION	Creating new markets	Government (DST and DBT schemes, Start-up India schemes), private, non-profit funders, incubators, and accelerators Hospitals, clinics, and diagnostic partners	Innovative business models
	Generating demand	Government and non-government partners	Partnerships
		Key opinion leaders (clinicians, hospital networks, industry experts)	Stakeholder engagements

Source: Author's summary from analysis.

8.3. Original theoretical and empirical contributions

In this section, I present both theoretical and empirical contributions of the findings and originality of my research.

8.3.1. Advances in the theoretical framework

In this thesis, I proposed a novel 2X3 IHI framework to study technical change in the MedTech sector with a lens of inclusiveness. There are few scholars who study the technical change in the health sector, for instance, Reich, 1990; Gelijns et al, 2001; Kaplan & Laing, 2005; Srinivas, 2012; Shadlen & Fonseca, 2013; Mackintosh & Tibandebage, 2016; Mackintosh et al., 2018. Even fewer scholars, both theoretically and empirically, connect the STI policy (Arocena and Sutz, 2006, 2012; Fressoli et al, 2014; Cozzens, 2021) and the implicit role of health policy in the industrial development of innovations to address complex health care challenges in the Indian context (viz. Chaturverdi & Chataway, 2006; Srinivas 2012, 2021). My novel IHI framework offers a co-evolutionary perspective to study the technical change in the health sector with a lens of inclusiveness. The framework assumes that institutional bundles are the key explanatory variables in driving technical change in health innovations. The IHI framework points out the crucial role of actors, knowledge and technologies, and institutional bundles, in identifying and framing of unmet needs to develop innovations for the early detection of in low resource settings.

The IHI framework thus captures both health and industrial dimensions by facilitating a bottom-up approach to fathom:

(i) How inclusiveness is mainstreaming in the MedTech innovations: Using 2x3 IHI framework, I showcase different domains of institutional triad emphasising the variety and bundles of institutions for healthcare system in India. The 2x3 IHI framework extends the definition of institutions in SSI that include rules, laws, standards, regulations, established practices, etc (see Tables 4.1 and 7.12). Further, to highlight the knowledge, technologies, and actors that influence industrial production of inclusive innovations for the early detection of cancer in a resource constraint environment, I employed IHI framework on an adapted 2X2 SII matrix from Srinivas and Sutz (2008, p132) (see Table 5.1 from Chapter 5). _Different quadrants of this

matrix describe actors, knowledge and technologies, and institutional environment leading to specific categories of innovations for early detection of breast, oral, and cervical cancer in India:

Category A: Early detection modalities imported from industrially advanced countries, and locally relevant technologies for India exist (top left quadrant)

Category B: Early detection modalities are not imported from industrially advanced countries, but locally relevant technologies for India exist (top right quadrant)

Category C: Early detection modalities are imported from industrially advanced countries, but with no locally relevant technologies for India (bottom left quadrant)

Category D: Early detection modalities are neither imported from industrially advanced countries, nor any locally relevant technologies in India (bottom right quadrant)

In Chapter 5, I discussed all the above innovation categories within their industrial context with the key assumption that institutional variety is the primary explanatory variable of distinct technological capabilities.

(ii) How the PoC MedTech innovations fit the delivery and consumption profile and their compatibility with the context for generating demand and integration in health care delivery mechanisms. Using SII along with the IHI framework helps elucidate knowledge and technologies and the actors and networks that drive key institutions that shape selection environment. It also demonstrates the key factors that channel capacity to develop and adopt inclusive innovation in the space of early detection of cancer in low resource healthcare settings.

In this way, the IHI framework builds on key theoretical and analytical frameworks in the academic field of innovation and development and can be used to inform future research and policy instruments towards inclusive innovation and sustainable development.

8.3.2. Advances in conceptualisation of inclusiveness

This thesis brings out a nuanced conceptualisation of inclusiveness by linking unmet needs of the early detection of cancer with industrial production of innovations and health care delivery systems in resource constraint settings. Firstly, it highlights the under-researched aspect of inclusiveness in high technology MedTech innovations for early detection of cancer in low resource settings. Secondly, the findings present who is innovating, why, and how? This aspect helps spelling various assumed unmet needs of early detection of cancer in low resource settings. The case studies operationalise this by offering inclusiveness by-design, in both process and outcomes. Thirdly, the findings highlight the renewed role of user and end user (beneficiaries) in improving the technologies as machine learning algorithms improve with usage. In this manner, indirectly, the end user (beneficiaries) is also included in improving technological capabilities through continuous industrial development.

The findings build on the existing literature on the conceptualisation of inclusive innovations by bringing forth additional dimensions relevant to the inclusive health agenda. For instance, some studies (for instance, Gras et al, 2019) use the ladder of inclusiveness by Heeks et al. (2013) and Heeks et al. (2014) to conceptualise different levels of inclusiveness (as discussed in Chapter 3): namely intension, consumption, impact, process, structure and post-structure. In addition to these levels, the findings of this thesis indicate that the MedTech innovations for early detection of cancer showcase multiple layers at each of the levels. These layers are depicted in the answer to RQ1 in the form of different levels of unmet needs, which go beyond the need of only the excluded or marginalised group. Secondly, the thesis also showcases intricate relations with the user base and inequality impacting level 2 and level 3, emphasising insights for public policy. First, layered problem-framing of unmet needs, and creation of new markets through various business models and partnerships in these innovations enable emergence of new and diverse set of users. The end user base covering rich, middle-income, and poor users of the innovations, goes beyond the needs of just poor and marginalised population articulated in larger inclusive innovation literature. These efforts have the potential of reducing vertical inequalities (Cozzens, 2009; 2021) i.e., income related inequality that can arise from an unequal distribution of Medtech innovations among the population. Second, these innovations also engage with horizontal inequalities (ibid) in accessing a high-technology health innovation, including gender, geographical (rural-urban), culturally defined factors, etc.,

by addressing the barrier to access and design-related challenges in existing screening and early detection modalities, and focusing on different pathways for effective diffusion and adoption.

With respect to Levels 5 and 6, the thesis does not assume any one level and underscores the variety of inclusiveness (RQ1) in case studies which are developed in the same selection environment.

8.3.3. Bridging the gap in the studies for inclusive MedTech innovations for early detection of cancer in low-resource health settings

There is a wide range of scholarship on different aspects of the development and diffusion of health innovations in low-middle-income countries (for instance, Srinivas and Kale, 2022; Arocena and Sutz, 2012; Natera et al., 2019; Gras et al., 2019; Srinivas 2016; Malerba and Mani 2009; Srinivas and Sutz, 2008). However, there is no empirical study focusing on a nuanced view of inclusiveness in innovation cycle of MedTech innovations, in general, and specially for the early detection of cancer in the low resource healthcare settings. This study bridges empirical gap conceptualising both inclusiveness in MedTech innovations for the early detection of cancer. In addition, it also identifies actors and factors influencing the development, diffusion, and adoption of these innovations to test the primary assumption of the IHI framework.

8.4. Policy implications

In terms of applicability of evidence and insights, the policy implications on inclusiveness of innovations are valid for both resource constraint and industrialising LMICs, and industrialised countries. Mainly in the post-pandemic context, the role of inclusiveness has gained prominence in enabling sustainable health and industrial systems. Using the IHI framework, the findings of the thesis connect academic endeavour with policy and practice. They do so by (a) informing the indicators that can strengthen the efforts for better outcomes for cancer care and (b) offering indicators for effective policy instruments for inclusive health agenda, including Sustainable Development Goals 2030. I give some examples to showcase this point:

(1) The thesis highlights the need for further alignment to strengthen national and subnational demand institutions to mainstream diffusion and adoption these innovations in the health care delivery system. In fact, there is some semblance of creating more

public demand (in the Parliamentary Committee Report) by integrating the new MedTech innovations in a larger decentralised diagnostic plan which can systematically decentralise and incentivise the innovations and competition in this space in both urban and rural areas under PMJAY (Department-related parliamentary standing committee on Health and Family Welfare, p172). Additionally, a renewed role of private health insurance was a strong recommendation brought forth during online semi-structured interviews. This can be done by using cancer screening in the pre-health check-up for health insurance, which at present only includes no or limited set of tests and tying it with the premium to incentivise screening.

(2) To reiterate, health is a state subject as per the constitution of India, which means every Indian state has the prerogative to formulate and implement its own policies, in addition to or as a part of overarching national-level policies. Further, every state in India is at different epidemiological trajectory in India, i.e., each state has a varying level of demographic profile and disease burden. In Chapters 1 and 2, I presented these differences in cancer burden and policies across states. However, the key focus of early detection of cancer remains with breast, cervical and oral cancer for all the states (please see Chapters 1, 2 and appendices for state-wise variation). This presents an opportunity to design a more tailored approach to apply this knowledge and technologies to address the screening and early diagnosis needs of various Indian states. The findings underscore the potential of these Medtech innovations in inclusive cancer control policy and data collection, both at the national and subnational level, to tailor to the state level variations in needs. For instance, this is an element in Pink Project, the public private partnership between Government of Punjab, Niramai, and Roche (as discussed in Chapter 6 and 7). This point also raises some important policy considerations (a) what this means for ethics and regulatory processes, mainly in collecting, managing health data security and privacy at an aggregated level; (b) how to make use of this data by integrating it in cancer registries to corroborate data gaps and informing tailored cancer control policy.

(3) The findings also present sustainability lessons beyond cancer care due to agility in the application of knowledge and technologies. This reflects strong opportunities for the government to utilise knowledge and technological capabilities to meet broader healthcare needs by incorporating such centres of excellence in the Medtech parks. For instance, promptly responding to the need for mass testing during the pandemic,

NIRAMAI (the startup firm associated with one of the cases discussed in thesis, Thermalytix), and Aindra Systems (the startup firm associated with one of the cases discussed in thesis, CervAstra) developed locally relevant solutions for COVID detection. These solutions were curated to mitigate the scarcity of testing in the rural healthcare system and given the lack of doctors and radiologists.

8.5. Limitations of the research

This section states the limitations of the research and some measures to mitigate them. Firstly, there are some limitations associated with case study research design, mainly concerning bias and the generalisability of findings. In this regard, this study relied on (a) multiple case designs for compelling and robust views, (b) theoretical propositions to drive the analytical generalisations by corroborating and advancing theoretical concepts that helped in designing cases (Yin, 2018). Such analytical generalisation provides greater insight into 'how' questions (ibid).

The second relates to completeness of case studies due to business-sensitive and confidential discussions on the development, diffusion, and adoption of product innovations in the health sector. This thesis aimed to capture real time developments in the innovation process in the MedTech sector. However, lengthy research and development, product development, and sales and marketing cycles affected time taken in the data collection process. The completeness of the case studies was also affected by pandemic uncertainties and, more importantly, sensitive, and confidential reasons. For instance, some innovators and innovating startups are reluctant to share detailed information. These include extensive discussion on the cost and business models. In addition, the limited availability and willingness of key innovators to participate as respondents impacted the selection of cases. To overcome this limitation, I utilised publicly available resources and approached different team members and actors involved with the innovations to triangulate findings. I also used secondary data for triangulation and capturing innovation progress at various point in time as opposed to capturing one time period in semi-structured interviews.

Third, some of the challenges associated with online semi-structured interviews as a method of data collection impacted the depth of analysis because of reliance on a few key respondents:

(1) The disruptions of pandemic affected the data collection process due to (a) reduced availability of respondents, as some of them were actively participating and supporting Indian response and preparedness for the pandemic. Therefore, the interview duration was restricted to less than 1 hour, with a lower possibility of follow-up interviews. In some cases, despite their willingness for a follow-up interview, the key informants found it challenging to allocate more time because of their busy schedules.

(2) The time difference between UK and India also contributed to limited time slots for the interviews, and increased time taken to identify and contact respondents.

(3) The online modality of semi-structured interviews vis-à-vis face-to-face also limited the range and quality of discussions. First, connectivity issues due to varying availability of internet bandwidth in different locations in India limited contacting some respondents, who were working from home. Second, trust and rapport building with the respondents was impacted in video calls, particularly if the respondents choose not to use their cameras.

(4) Some of the potential respondents were not comfortable discussing business-sensitive (innovators) and policy sensitive issues (policymakers and regulators) online.

Given these limitations in collecting primary data during the pandemic and the sensitive nature of information associated with the process of innovation does present challenges for the depth of the analysis. Nonetheless, as highlighted in Chapter 4, this research triangulated the evidence using multiple sources of data to increase the accuracy of the findings and overcome any potential biases due to the perception of reality as shared by the key respondents, limited availability of some of the key innovators of cases, my reflexivity and positionality.

In summary, despite the above challenges and limitations, this research posits substantial advances in the existing knowledge and understanding of high technology inclusive innovations for the early detection of cancer in low resource settings.

8.6. Future research

In the next 5 to 10 years, rich data is likely to be available on the utilisation and adoption of PoC Medtech innovations for the early detection of cancer, particularly as these innovations innately use data for improving machine learning algorithms. Future research on two key areas can finetune policy instruments for robust STI, health and industrial systems in India and

LMICs. First, there is a dearth of studies on the utilisation of medical devices in the Indian context. Therefore, once such data is available in future, it would be prudent to have a comprehensive study assessing the long-term utilisation of such emerging PoC Medtech innovations for cancer (and other therapeutic domains) to understand,

(1) Impact of these innovations in the health system strengthening and industrial development from a sustainability perspective.

(2) Impact of using such PoC MedTech innovations on clinical practice and early detection of breast, oral, and cervical cancer in India.

(3) Evolution of regulations on data storage and data privacy medical innovations that use advanced computational technologies.

Second, the findings for this research are based on the Indian Medtech innovations and concomitant public health scenario for screening and early diagnosis of breast, oral, and cervical cancer. Further research in additional geographic contexts would be useful.

8.7. Conclusion

The thesis examined opportunities and challenges for inclusive health by investigating cases of MedTech innovations for the early detection of cancer and their integration into the Indian healthcare delivery system. Several countries implicitly use health policies to guide industrial policies to achieve better health outcomes. However, in the Indian case, particularly in the case of pharmaceuticals, technological advances instilled economic and industrial growth with lesser impact on health outcomes. The disconnect between industrial and health goals reflects the piecemeal nature of efforts of the government (policy actor) to address structural barriers to resolving the challenges of access to affordable medicines among large parts of its population. Such a disconnect is a peculiar feature of late industrialising economies focusing on supply-side institutions but weak demand institutions. Thus, the conundrum of a robust pharmaceutical sector with a large population lacking access to medicines provided a precedent to calibrate a more conducive policy ecosystem to sustain signs of inclusiveness in Indian MedTech sector.

My analysis finds a strong alignment of STI and industrial policy with health policy in the form of technological advance in the health sector that supports development of innovations for early

detection of cancer. In comparison, there are weaker linkages between STI and industrial policy on the one hand and health policy on the other with visible lack of institutional support facilitating effective adoption of these innovation. However, despite this, these PoC MedTech innovations are disrupting the affordable health care system with incremental 'pocket size wins'. They do so by addressing a variety of unmet needs and shaping demand through business models, stakeholder engagement, and public private partnerships by aiming for policy change and policy endorsement as a long-term goal.

As the need for a sustainable health system intensifies, mainly as the aftermath of COVID-19 pandemic, this thesis engages with the ongoing debates and dialogues on inclusiveness in the cancer *moonshots* and cancer *earthshots*. It does so by contributing,

i. a novel IHI framework to study health and industrial actor and factors, specifically focussing on MedTech innovations for early detection of breast, cervical and oral cancer in Indian context,

ii. a nuanced conceptualisation of inclusiveness in the process of development, diffusion, and adoption of the Medtech innovation for early detection of cancer in resource constraint settings.

The findings of this research thus make theoretical, empirical and policy contributions to the development and adoption of inclusive health innovations for the early detection of cancer in LMICs.

In summary, I developed a more profound understanding of how India has begun and can sustainably operationalise the reconciliation of health and industrial goals for early detection of cancer. My research thus enables an understanding of the seriously deficient industrial and health system linkages in the development and adoption of emerging inclusive innovations in LMICs. It does so by proposing an alternative approach to conceptualise and study the inclusive health innovations in India that aim to fulfil unmet health needs. It thus invokes targeted engagement with the perennial dilemma of policymakers to direct policy instruments such that local industrial capabilities do not set against the challenges of the domestic health system and the needs of the local population. The overall aim is to nudge interest groups and policymaking institutions to harness the potential of innovative solutions in MedTech by taking a multiprong lens for inclusion. In doing so, inclusive innovations may become a new goal for innovation

efforts in low resource health care settings. Thus, while the novel IHI framework needs testing in more contexts, it is an evolving approach to studying inclusive health innovations.

I wrap the thesis with an optimistic and cautious perspective for the role of technology in the early detection of cancer in low-resource settings. The policymakers can use a mix of institutional bundles at both national and subnational levels to channel problem framing and solving capabilities. Problem framing and solving enable coordination among diverse set of stakeholders which is essential to solve wicked problems, particularly defeating the emperor of all maladies!

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Appendices

Appendix A.1: Country-wise estimated age standardised incidence and death rates, females

Country-wise estimated age standardised incidence rates for leading cancer in females, 2020

Source: Globocan data, International Agency for Research on Cancer, 2022

Country-wise estimated age-standardised death rates for leading cancer in females, 2020

Source: Globocan data, International Agency for Research on Cancer, 2022

Country-wise estimated age standardised incidence rates for leading cancer in males, 2020

Source: Globocan data, International Agency for Research on Cancer, 2022

Country-wise estimated age-standardised death rates for leading cancer in males, 2020

Source: Globocan data, International Agency for Research on Cancer, 2022

Heat map depicting state-wise age-standardised deaths (per 100,000) in females, by types of cancers in India (2019)

Females, Age-standardized, 2019, Deaths per 100,000

Higher rank ▮▮▮▮▮▮ Lower rank

	Andhra Pradesh	Arunachal Pradesh	Assam	Bihar	Chhattisgarh	Delhi	Goa	Gujarat	Haryana	Himachal Pradesh	Jammu & Kashmir & Ladakh	Jharkhand	Karnataka	Kerala	Madhya Pradesh	Maharashtra	Manipur	Meghalaya	Mizoram	Nagaland	Odisha	Punjab	Rajasthan	Sikkim	Tamil Nadu	Telangana	Tripura	Uttar Pradesh	Uttarakhand	W Bengal	India
Breast cancer	2	2	1	1	1	1	1	1	1	1	3	1	1	1	1	1	2	2	3	2	1	1	1	3	1	2	1	1	2	1	1
Colorectal cancer	3	4	4	3	3	4	3	2	3	3	4	4	4	2	4	3	3	4	5	4	2	2	4	5	3	3	2	3	3	2	2
Cervical cancer	4	3	5	2	2	2	9	3	7	4	7	2	2	5	2	2	4	6	4	3	6	3	5	7	2	4	3	4	5	4	3
Stomach cancer	1	1	9	5	4	11	2	10	2	2	1	3	3	10	5	10	6	3	2	1	3	10	3	2	6	1	8	2	1	3	4
Lung cancer	6	5	7	6	10	5	5	5	5	7	2	8	8	4	6	4	1	7	1	6	7	4	7	1	5	5	5	5	4	5	5
Other malignant neoplasms	7	11	11	4	6	7	6	6	6	5	5	5	7	7	9	9	7	11	7	9	4	9	2	11	8	10	10	6	6	6	6
Lip oral cavity cancer	5	10	6	12	7	8	4	4	8	12	15	11	6	3	3	5	11	5	13	12	5	13	11	10	4	6	7	7	12	9	7
Ovarian cancer	9	6	8	8	12	6	7	9	9	9	6	7	10	6	7	6	9	12	10	10	9	5	9	8	7	7	11	10	10	7	8
Gallbladder cancer	10	8	3	7	8	3	11	11	11	11	9	6	11	14	8	13	5	8	9	11	8	8	8	6	15	8	4	8	8	8	9
Pancreatic cancer	12	9	12	9	11	9	10	8	10	10	8	9	12	8	12	8	8	9	8	8	10	7	10	9	9	11	9	11	9	10	10
Esophageal cancer	16	7	2	13	9	10	13	7	12	8	11	15	9	13	10	7	10	1	6	7	12	6	12	4	10	16	6	12	11	11	11
Other pharynx cancer	8	24	10	21	5	18	8	14	4	6	10	10	5	22	11	15	21	10	15	17	11	18	6	13	13	9	12	9	7	14	12
Lymphoma	11	14	13	11	14	12	12	12	13	12	12	12	13	9	13	11	12	13	13	11	13	12	11	12	14	13	13	12	13	12	13
Brain cancer	13	16	14	10	15	14	14	13	14	14	13	13	14	11	14	12	14	14	17	14	14	15	12	13	13	14	14	14	13	14	14
Uterine cancer	14	22	16	14	16	13	15	15	15	14	14	15	12	15	14	24	18	24	19	15	14	15	21	14	14	20	15	16	15	15	15
Chronic lymphoid leukemia	15	23	17	16	18	17	16	16	16	17	16	16	18	16	17	16	17	18	16	16	15	16	18	17	15	15	18	17	17	16	16
Bladder cancer	17	25	21	17	13	15	17	20	17	16	17	18	16	19	18	16	18	19	21	18	17	17	19	25	16	17	18	19	15	18	17
Larynx cancer	18	20	15	15	17	21	20	23	19	21	18	17	19	25	17	23	17	15	22	20	18	20	17	14	25	18	16	17	18	20	18
Thyroid cancer	19	15	19	19	22	19	24	20	19	19	19	18	15	20	20	15	25	23	15	19	23	18	20	19	20	19	20	23	21	22	19
Myeloma	20	17	18	20	21	16	21	18	21	18	20	21	20	16	19	21	19	20	25	21	22	16	21	24	18	19	17	23	21	21	20
Liver cancer hepatitis C	22	12	20	23	29	23	26	25	18	20	22	23	23	20	21	19	20	21	12	22	20	22	23	15	22	24	19	16	19	16	21
Nasopharynx cancer	21	13	25	18	20	31	23	21	22	24	21	20	22	28	22	28	13	16	14	5	21	32	20	16	23	21	24	20	22	26	22
Acute myeloid leukemia	24	27	29	22	23	20	22	19	23	23	24	22	21	17	23	18	23	23	28	24	23	21	22	29	20	22	27	25	24	27	23
Kidney cancer	23	26	22	25	24	19	18	22	24	22	23	24	25	21	25	22	22	26	23	25	19	25	26	21	23	21	28	23	25	24	24
Chronic myeloid leukemia	25	29	23	24	22	24	25	17	26	27	25	25	24	23	24	26	26	24	31	25	26	24	24	31	24	25	22	24	26	28	25

Source: GBD, 2019

Heat map depicting state-wise age-standardised deaths (per 100,000) in males, by types of cancers in India (2019)

Males, Age-standardized, 2019, Deaths per 100,000

Higher rank ▮▮▮▮▮▮ Lower rank

	Andhra Pradesh	Arunachal Pradesh	Assam	Bihar	Chhattisgarh	Delhi	Goa	Gujarat	Haryana	Himachal Pradesh	Jammu & Kashmir & Ladakh	Jharkhand	Karnataka	Kerala	Madhya Pradesh	Maharashtra	Manipur	Meghalaya	Mizoram	Nagaland	Odisha	Punjab	Rajasthan	Sikkim	Tamil Nadu	Telangana	Tripura	Uttar Pradesh	Uttarakhand	W Bengal	India
Lung cancer	1	2	3	1	1	1	2	2	2	1	2	2	2	1	1	1	1	3	2	5	1	1	2	2	1	1	1	1	1	1	1
Prostate cancer	2	4	7	2	5	3	1	3	3	3	3	1	5	4	4	4	2	7	6	7	2	3	5	5	4	2	6	4	5	2	2
Stomach cancer	3	1	5	5	2	10	3	9	4	5	1	4	3	5	6	7	3	4	1	1	3	8	3	1	2	3	7	2	3	3	3
Colorectal cancer	4	5	6	4	4	4	4	4	6	4	5	5	6	3	5	3	4	8	4	6	4	2	4	4	3	4	5	5	6	5	4
Lip oral cavity cancer	9	9	4	7	6	2	6	1	7	6	12	3	4	2	2	2	9	5	7	8	7	5	7	6	5	9	4	6	7	4	5
Other pharynx cancer	6	8	1	11	3	7	5	5	1	2	6	8	1	7	3	8	10	2	5	4	6	11	1	7	7	6	2	3	2	6	6
Other malignant neoplasms	5	10	10	3	10	6	7	7	5	8	4	6	7	6	7	6	6	9	10	11	5	6	6	11	8	5	9	8	4	7	7
Larynx cancer	7	11	8	6	7	5	9	8	9	9	7	7	9	10	8	10	11	6	8	9	8	10	8	8	11	7	8	7	8	8	8
Esophageal cancer	14	3	2	15	11	9	10	6	8	7	8	16	8	9	9	5	5	1	3	2	10	4	9	3	6	14	3	10	9	9	9
Pancreatic cancer	8	12	12	9	8	11	8	10	10	10	9	9	10	11	11	9	8	10	11	10	9	7	11	10	9	8	10	9	10	10	10
Lymphoma	10	15	11	10	12	13	11	11	11	12	10	14	11	8	10	11	12	12	14	13	11	9	10	16	10	10	11	11	11	14	11
Bladder cancer	13	19	13	12	9	8	12	12	13	11	11	11	13	12	13	13	14	15	15	15	13	14	14	15	13	13	16	12	12	12	12
Brain cancer	11	17	14	8	14	14	14	13	12	14	13	13	12	13	14	12	15	14	17	15	12	12	12	17	12	12	13	14	14	15	13
Gallbladder cancer	12	14	9	13	13	12	13	14	14	13	14	15	14	18	12	15	13	13	16	14	14	13	13	14	16	11	12	13	13	16	14
Liver cancer hepatitis B	18	7	15	16	21	18	23	17	22	18	17	10	15	15	17	14	16	16	12	16	15	15	18	12	14	20	14	16	18	11	15
Nasopharynx cancer	15	13	17	14	15	26	16	15	15	15	15	17	17	26	15	21	7	11	9	3	17	27	15	9	21	16	17	15	15	18	16
Liver cancer alcohol	20	6	16	17	24	20	24	19	24	19	18	12	16	16	18	16	17	17	13	18	16	16	21	13	15	23	15	17	21	13	17
Kidney cancer	16	21	19	22	17	15	16	16	16	16	16	22	18	17	21	17	18	20	21	19	20	19	17	21	17	15	18	19	16	17	18
Acute myeloid leukemia	19	23	23	18	19	17	17	18	19	20	19	18	19	19	20	18	21	21	18	20	18	18	19	25	18	17	21	21	19	20	19
Myeloma	21	20	18	19	18	16	18	21	19	21	21	20	21	14	19	19	23	23	25	24	21	17	20	22	19	19	20	20	20	21	20
Chronic myeloid leukemia	17	22	20	20	16	19	19	20	18	17	20	23	20	22	16	20	19	19	26	21	19	20	16	19	20	18	22	18	17	22	21
Other leukemia	22	26	21	21	20	24	25	22	20	23	23	21	22	24	22	26	26	24	20	26	22	21	22	30	23	22	24	22	24	24	22
Skin cancer SCC	23	24	22	23	22	27	20	24	21	22	22	24	25	25	23	24	20	18	24	23	24	23	23	24	22	21	19	23	22	23	23
Liver cancer hepatitis C	27	16	24	25	30	21	30	28	32	27	26	19	23	23	27	23	24	22	19	25	23	22	28	18	25	29	23	24	30	19	24
Thyroid cancer	24	25	26	27	23	25	21	31	23	24	24	28	24	20	25	25	25	25	23	22	25	33	24	20	27	24	29	25	23	27	25

Source: GBD, 2019

Appendix B: Broad questions to understand the landscape

(1) How has the MedTech evolved over the years with the healthcare delivery system in India?

(2) What are the challenges with the existing cancer screening and early detection modalities?

(3) How have modalities for the early detection of cancer evolved in India? Who are key players?

(4) What are the major factors for AI and ML penetration in health sector recently?

(5) How has the changed early detection of cancer?

Appendix C: Primary and secondary data sources for landscape study and case studies

Phases	Primary data respondents (online semi-structured interview)	Secondary data
Landscape study	Senior Indian health policymaker	Interactive Meeting with Regulator, Licensing Authorities on medical device regulations
	Board member of industry association (APAC Med)	
	Director and head, Government affairs and policy at a medical device MNC in India	Clinical Trial Registry of India
	Marketing director, Cancer medical device MNC in India	TechSparks 2021 - Technology, innovation, and leadership summit in India
	Founder, MedTech firm in blood screening of cancer	Webinar on Global changes affecting Medical Devices
	Sector expert	
	Independent oncology innovations and Medtech expert	Intelligent Healthcare: AI Today & Beyond
	Senior Management (Medical affairs) of a leading Indian pharmaceutical company specialising in cancer management	Roundtable Discussion: Rising Need for Gender Lens Investing to Solve India's Complex Healthcare Challenges
	Founder, social organisation supporting lab to market journey of inclusive innovations	WHO Compendium of Innovative Health Technologies for Low-resource Settings
	Founder, Pathology firm in India (oncology pathologist with over 30 years of experience)	Podcasts, and interviews on print media
Thermalytix	Professional, Venture capital	Interview of founder in podcasts, TEDex, and print media; Verified Twitter Spaces, Instagram Live, LinkedIn
	Senior professional, Incubator	
OralScan	Founder of MedTech start-up	Interview of founder in podcasts, and print media; Verified Twitter, LinkedIn
	Clinical Research Scientist	
CerviScan	Founder of MedTech start-up	Awards and recognitions by government.
	Biomedical engineer	
CervAstra	Interviews of founder in podcasts, and print media.	
	Online conference including Tech Sparks with the Founder's participation.	
	Annual reports of incubators and funders.	

Source: Author's compilation of data collection sources

Appendix – D: A brief history of emergence of mammography as the gold standard modality

X-rays, discovered in 1895, played an instrumental role in radiology in detection and diagnosis of critical diseases. However, it was only used to image harder tissues because the images for softer tissues including breast tumours used to come out as blurred and non-conclusive, which made physicians rely on physical exams and biopsies. In 1913, a German surgeon, Albert Salomon, made initial attempts studying distinctive patterns of large tumours in X-ray images of surgically removed breast (Gold et. al, 1990; Picard, 1998; van Steen and van Tiggelen, 2007). Subsequently, there were attempts to improve breast x-rays, for instance via techniques like adjusting x-ray beams, flattening the breast during the X-ray, taking images from multiple angles, using more sensitive film. In particular, the efforts of radiologists in France and USA were instrumental in developing mammography equipment for wider radiology, and commercial use. In terms of larger clinical acceptability, Lerner (2003; pp 303) highlights the dominant role of radiologists in the clinical setting, and initial scepticism of surgeons on mammography.

> 'In the 1940s and 1950s, surgeons had been highly sceptical of mammography, refusing to operate if they could not palpate a lesion detected by x-ray "If I can't feel it on examination," many surgeons opined, "it's not there." But as …growing number of articles claiming that mammography enhanced the detection of small breast cancers, it became more difficult for surgeons to ignore the potential benefits of the new technology as well as the help that radiologists could offer. The power of finding a previously unsuspected cancer on x-ray, and possibly saving a woman's life as a result, was highly dramatic.' (Lerner, 2003; pp303)

After several years of improving the techniques and protocols led to the development of mammography as a screening modality. Some studies have traced the history of mammography, explaining how mammography evolved as a screening modality in the selection environment (Gold, 1993; Picard, 1998; Bhidé et al., 2021):

1950-1980: Development of the protocols, and standardisation of equipment mainly in France and USA, and mammograms emerged as an accepted technology.

o Multiple large scale randomized controlled trials (RCTs) to establish mammography as a screening modality.

o Several private firms started manufacturing mammography equipment predominantly from USA (including Kodak, Xerox, Du Pont, Picker, Fischer, General Electric, Technicare, Xonics), Europe (Compagnie Générale de Radiologie (France), Siemens (Germany), Philips (The Netherlands)), Japan (Toshiba)

o As a clinical practice, as compared to USA, mammography did not gain as much support in Europe and Japan where the relied on physical exams and ultrasounds respectively.

o Regulatory framework shaped in USA with increasing safety concerns on the exposure to radiation in mammography, mainly 1976 Medical Device Regulation Act provided legal basis for the US Food and Drug Administration (US FDA), asking for clinical trials to demonstrate safety and effectiveness for new devices that were not 'substantially equivalent' to existing devices.

1980s: Broadened use and shaping of regulatory processes.

o Private firms from USA remained the dominated producer across the globe, followed by European, Israel, Japan, focussed on developing equipment with controls and filters that reduced radiation exposure.

o New rules and regulations were introduced in USA from 1986 and 1992 to establish quality standards for and required regular inspections of equipment, forcing hospitals to stop adapting general purpose X-ray equipment for mammography.

o US FDA classified new mammographic equipment as substantially equivalent to pre-1976 equipment, making them exempt from clinical trials.

o Successful clinical trials in Netherlands and Sweden demonstrated benefits of mammography, leading to national health insurance funded screening programmes in most European countries, however Japan continued to use physical examination for breast screening.

1990s and post 2000s – Digitisation and opening of emerging markets.

o US FDA again exempted digitized devices, that were developed for minimally invasive biopsies, by taking them as substantially equivalent to earlier analog devices, which helped the rapid adoption of digital diagnostic mammography. However, in 1999, two companies (GE and Trex Medical) did not provide sufficient data to obtain equivalence exemption, consequently US FDA required that all digital equipment developed for mammographic screening to undergo large-scale clinical trials to demonstrate its safety and effectiveness.

o Unlike their American counterparts, the regulators in European regulators did not require trials to demonstrate effectiveness of new medical devices, instead just the safety standards. Consequently, US and Japan based firms introduced their digital diagnostic equipment in Europe and Japan by the mid-1990s and accounted for approximately 90 percent of total diagnostic equipment sales in Japan and Europe.

o Post 2000s, there were rapid changes in the sales of refurbished analog mammography equipment towards developing countries and emerging markets which did not enforce stringent technical standards.