Master Thesis

Success factors for implementation of novel decentralized diagnostics: How publicly funded multidisciplinary innovation networks can disrupt German Healthcare

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Title: Success factors for implementation of novel decentralized diagnostics: How publicly funded multidisciplinary innovation networks can disrupt German Healthcare

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“Instead of working to preserve the existing system, health care regulators need to ask how they can enable disruptive innovations to emerge”

Clayton M. Christensen, Richard Bohmer, and John Kenagy

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Abstract

Mobile diagnostics – or mobile health in general – is highly appealing, not only for clinicians, but also for patients. It implies empowerment, in particular of those who are really in need, such as inhabitants of less developed regions within the world who have limited access to healthcare. It also implies simplification: Easy data management – a continuous flow of information.

Therefore, development of miniaturized and highly integrated diagnostic systems allowing near patient “instant” diagnostics gain a lot of momentum since more than a decade. However, system integration requires time and a significant amount of investment. In addition, there is strong competition on resources from other emergent technologies, such as next generation sequencing which made the collection of e.g. human genome data less expensive and much faster. A more severe challenge is that mobile diagnostics require a change in healthcare management, e.g. towards integrated practice units. This, in turn, requires implementation of adequate reimbursement, standards of interoperability, training of staff, quality control.

In 2010, Germany’s Federal Ministry of Education and Research (BMBF) launched the grant initiative *Mobile Diagnostic Systems* (MD, 2011–2015) as part of its high-tech strategy. MD aimed at generating knowledge on how microsystem technologies fit into German healthcare environments. On the basis of interviews with multidisciplinary MD actors, this thesis evaluated retrospectively how the publicly funded innovation network managed to overcome pre-defined external barriers of diffusion, including technology, regulatory affairs and market access.

Retrospectives reveal internal barriers involving knowledge and technology transfer, negatively influencing generation of innovation. In particular, financing still represents a high hurdle for biotech innovators in Germany: Larger firms look predominately for market-ready or in-market technologies rather than prototypes and venture capitalists are rare or extremely risk-averse. Another important finding was, that actors involved were highly focused on individual work packages. This risks of not seeing the whole environment embedding MD. Consequently, potential opportunities may be missed, e.g. synergies with relatively close (DIALOC) or more distant initiatives (Global Health Delivery Project-based discussion

rounds). This could be partly due to the fact that publicly funded networking activities provide less freedom-to-operate because of pre-defined milestones. In addition, further development of actors with respect to role playing (e.g. boundary spanning or innovation selling) is often not included in such “innovation packages”, but can help to maneuver change.

Internal barriers need to be addressed first before targeting the major remaining external hurdle: Reimbursement. Although the latter was covered within MD, standardization of technology evaluation is still an unmet need which strongly influences the willingness-to-implement novel mobile diagnostics. Thus, the value added is to be demonstrated to justify adequate reimbursement.

Achieving this goal can be successful, when innovation networking finds its path towards a common vision, e.g. towards value-based integrated healthcare. Pathfinding and visioning can be facilitated by process promoter with excellent network management capabilities. In addition, such a promoter could help to further develop engagement, openness and commitment of collaborators. Therefore, transfer of MD activities to established “top” networks or clusters is recommended for securing valuable knowledge generated. In this environment, an important next step – globalization of MD for ensuring future return on investment – could be triggered as well.

Since MD innovation was found to involve both product and service innovation, maneuvering change is particularly challenging for small and medium sized enterprises. These could benefit from engagement in innovation networking. Findings of this case study can help all direct and indirect actors in the field of MD innovation or in other high complex environments to reconsider pathfinding as well as role playing in networking.

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Abbreviations

AS-SU-R-E-D	Affordable, Sensitive, Specific, User-friendly, Rapid & Robust, Equipment-free, Deliverable
AD	Adopter
AMR	Antimicrobial Resistance
APAC	Asia Pacific
BCG	Boston Consulting Group
BMBF	Bundesministerium für Bildung und Forschung
CAGR	Compound Annual Growth Rate
CH	Switzerland
CoIN	Collaborative Innovation Network
DARPA	Defense Advanced Research Projects Agency
EMEA	Europe, Middle East, Africa
EP	Expert Promoter
EU	European Union
GBS	Global Business Service
GDH	Global Health Delivery
GDP	Gross Domestic Product
GK	Gatekeeper
HIC	High Income Countries
HOI	House of Innovation
HTA	Health Technology Assessment
IPU	Integrated Practice Unit
IVD	In Vitro Diagnostics
KM	Knowledge Management
KW	Knowledge Worker
Lab	Laboratory
LCM	Life-cycle Management
LIMIC	Low and Middle Income Countries
LOC	Lab-on-a-Chip
M&A	Mergers and Acquisitions
MD	Mobile Diagnostics
MP	Market Promoter
NPO	Non-profit Organization
OECD	Organization for Economic Cooperation & Development
PO	Physician office
POC	Point-of-Care
PO	Power Promoter
QALY	Quality-adjusted Life Year
QDA	Qualitative Data Analysis
PP	Process Promoter
PPP	Public Private Partnership
R&D	Research and Development
ROI	Return on Investment
SFM	Stanford Foresight Model
SME	Small and Medium Enterprises
TP	Technology Promoter
UK	United Kingdom
USA	United States of America
VBH	Value-based Healthcare
VC	Venture Capitalist
VDE	Association for Electrical, Electronic & Information Technologies
VOC	Voice-of-Customer
VDGH	German Diagnostics Industry Association
WHO	World Health Organization
XT	External

1 Introduction

Many countries, including Germany, are facing the challenge of a significantly increasing proportion of elderly inhabitants who generally cause more healthcare costs. In 2012, the USA launched a program defined as “choosing wisely”. In 2016, Germany followed this approach. The initiative aims at reducing under- and over-treatment of patients. A significant number of medical doctors do not readily accept this approach as they fear that patients will be managed inefficiently due to ever decreasing resources. In addition to limited resources, there is a lack of adequate technology that supports clinical decision making and management in certain disease areas like infections caused by drug-resistant bacteria.

Antimicrobial resistance (AMR) represents a severe health problem. According to a recent review AMR leads to about 700,000 deaths every year, and this number is expected to grow to 10 million deaths in 2050 – if there are no adequate reactions (O'Neill, 2016). In May 2015, the WHO[1] launched the global action plan. Objectives for combatting AMR globally include the development of the “economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions”. Canada, Germany, Netherlands, Sweden, and UK are leading the action package *AMR* of the Global Health Security Agenda, which ensures that objectives of the Global action plan are followed. In May 2016, the task force around Jim O`Neill came up with the final report on AMR and ten main action items. One action item is the promotion of “new, rapid diagnostics to cut unnecessary use of antibiotics”.

Innovative rapid diagnostics that can be used close to the patient in remote settings cannot only positively influence the management of AMR associated infections – they are also highly needed in outbreak situations, such as the latest Ebola and Zika virus outbreaks in 2014 and 2015, respectively: Patients diagnosed earlier can be managed immediately and their prompt isolation can circumvent infection of further persons. From a global perspective, decentralized testing is of highest importance for rapid identification of infectious agents. In industrialized countries, there is also a strong trend that shifts healthcare to a more patient-

[1] World Health Organization

centric value-based approach. Consequently, near-patient testing is also attractive for personalized management of non-communicable diseases, including cancer, diabetes, and neurological disorders. Notably, oncological and specific chronical diseases like rheumatoid arthritis are more present in elderly persons (>65 years old) who will represent the highest percentage of the global population by 2030. This demographic change is expected to further increase healthcare costs without countermeasures. Thus, in theory, innovative near patient diagnostics using intelligent algorithms for result analysis, interpretation, and telehealth guided reporting could serve as cost-effective platforms that address unmet needs in various scenarios.

In 2004, the *ASSURED* criteria were defined for rapid diagnostics allowing decentralized testing of sexually transmitted infections (Kettler, White and Hawkes, 2004). Test specifications are associated with each single letter:

A *Affordable*
S *Sensitive* ─ avoid false-negative results
S *Specific* ─ avoid false-positive results
U *User-friendly* ─ simple-to-perform and based on non-invasive specimens
R *Robust* and *Rapid*
E *Equipment-free*
D *Delivered* ─ accessible to end-users.

In short, an automated laboratory test with excellent accuracy needs to be brought into a miniaturized low cost *lab-on-a-chip* (LOC) or *sample-in-answer-out* format. Often the *Star Trek* term “tricorder” is used for such highly wanted test systems in order to highlight the technological challenge.

So far, there is no rapid mobile diagnostic system that is disruptive, i.e. easy-to-use, robust, in-expensive and shows lab-test-like accuracy for most important test parameter. However, there are promising technologies in the pipeline. Even though these pipeline technologies receive high funding rates since several years, the tipping point cannot be predicted easily. Therefore, it is important to better understand the barriers that hold back mobile diagnostics from market implementation.

1.1 Purpose and Rationale of the Study

In the Global Innovation Index 2016 Switzerland ranked highest, followed by Sweden, UK, the USA and Finland (Dutta, Lanvin and Wunsch-Vincent, 2016). Germany was “only” ranked in 10th position. The impact of innovation is most evident in healthcare, where innovation could be measured as gain in QALY, i.e. quality adjusted life year. Since several decades, QALY is predominantly used in for economic evaluations and represents health outcome based on a combination of duration as well as quality of life.

In 2010, Germany’s Federal Ministry of Education and Research (BMBF) launched the grant initiative *Mobile Diagnostic Systems* (MD) as part of its high-tech strategy. MD aimed at generating knowledge on how microsystem technologies (lab-on-a-chips) fit into healthcare environments: Potential barriers for innovation were to be identified to define measures supporting efficient implementation. In total, eleven grant projects were financed by BMBF. All projects focused on development of microsystems allowing decentralized testing. All projects were composed of interdisciplinary teams with members from both industry and private and/or public institutes. All collaborators were embedded in an innovation network as set up by BMBF in parallel.

This case study takes a retrospective look at MD from the biotech industry perspective. The study discusses social economic factors triggering an innovation friendly environment for new high technological healthcare solutions in general. Specifically, it evaluates the impact of the MD innovation network on supporting implementation of near patient testing in German healthcare settings.

1.1.1 Significance of the Phenomena of Interest

From the industry perspective, regulatory compliant mobile diagnostics development is expected to require investment of up to 50 million US dollars ($US) and about 5 years (Morel et al., 2016). Next to relatively high investment, there is a significant risk of project failure because development involves multiple disciplines working closely together (*technology promoters*). It is further assumed that for some marketers (*market promoters*) internal positioning of new near patient technologies within a portfolio of products for centralized laboratory testing may represent another hurdle: Industrial decision makers could behave protective by

downsizing market opportunity for mobile diagnostics, followed by business case rejection. Conflicts of interest may also exist in laboratory decision makers (*adopters*) who could tend to protect their centralized organization against change such as potential reduction of lab personal. For users beyond hospital settings (e.g. physician offices) limitations in reimbursement for near patient testing as well as regulatory hurdles may result in non-acceptance. Consequently, top-management (*power promoters*) of shareholder-driven biotech companies do not easily execute development of mobile diagnostics.

Catalyst financing at governmental or union level can allow overcoming potential internal barriers, thereby increasing willingness-to-innovate. Next to financing, the use of a network based-approach is expected to be very powerful for overcoming external barriers. In case of MD, eleven projects received in total 15 million Euro[1] over a period of about 3 years[2]. With respect to the above estimate of up to $US 50 million needed for launch, this funding is assumed to allow prototype development only. Therefore, it is highly important to evaluate whether funded teams manage technology transfer efficiently within the project to ensure that the flow does not stop.

1.1.2 Research Question

The initiative MD was launched as innovation package, providing a starting point for various research questions. The package was reduced to the following themes: knowledge management, diffusion of innovation, and innovation network. This thesis will particularly address a single master question accompanied by sub-questions listed below.

Did network *Mobile Diagnostics* have a sustainable impact on healthcare innovation in Germany?

a. Which socioeconomic factors represent main barriers for implementation of lab-on-a-chip (LOC) technologies in German healthcare settings?

[1] Three projects were below and eight above 2 million €, including ~50% contribution

[2] Some projects were extended after official termination

b. How was the *Mobile Diagnostics* innovation network used to overcome potential barriers of technology innovation?

c. What are the key insights / lessons learnt and how can these be used to further empower network-driven healthcare innovation as from different perspectives

- Technology promoters (system integrators)
- Gatekeeper (project coordinators)
- Expert Promoter (knowledge manager)
- Adopter (future user)
- Market promoters (voice of the market)
- Power promoter (sponsor)
- External innovators
- Process promoter (innovation manager)

1.2 Study Design

The BMBF initiative *Mobile Diagnostic Systems* included eleven projects funded in-between 2011 and 2015. Germany's "new" high-tech strategy includes five strategic pillars (BMBF, 2014). With respect to Mobile Diagnostics, the "priority challenge" (Figure 1, item 1) was miniaturization and mobilization of diagnostics for allowing rapid near patient testing. Targeted solutions were to "enhance competitiveness and increase prosperity". This case study will particularly evaluate qualitatively how "networking and transfer" (Figure 1, item 2) was managed to "strengthen cooperation" and to "support implementation".

Figure 1 Case study *Mobile Diagnostics* (MD), with focus on networking and transfer
*duration of accompanying research is indicated (networking)

Out of the eleven projects in-depth evaluation is performed for a selected project with a high number of interdisciplinary collaborators. To discuss potential generalization of findings, coordinators from other projects will be interviewed as well. In addition, external perspectives were collected from selected individuals who did not participate in MD, but were connected to the network shortly or over a longer period.

2 Theoretical Framework

2.1 Innovation Management

Not surprisingly, priority challenges of Germany's high-tech strategy are selected with respect to the ability to increase competitiveness as well as prosperity (→1.2). Since more than three decades Michael E. Porter significantly influences individuals' and organizations' behavior towards competitiveness (Porter, 1984). More recently, he highlighted two strategies for gaining competitive advantage[1]: Get the best *versus* get unique. The latter cannot be reached by imitation, but innovation. Accordingly, sustainable competitiveness requires innovation – if not radical innovation. This would be an easy task, if innovation would not be a moving target.

What is innovation at all? Innovation has been defined in manifold ways by various leaders. Therefore, it is difficult to find a term that is commonly well accepted. In general, innovation can be understood as maneuvered change that has a positive impact on efficiency. In the *EU Innovation Union pocket guide* innovations are defined as "new or significantly improved i) product, ii) marketing approach, iii) process or iv) organization" that adds "value to markets, governments, and society" (2013). The degree of value added is strongly dependent on how the evolution of new solutions – the innovation – is managed.

2.1.1 House of Innovation

Schumpeter intensively studied the efficiency of entrepreneurs – the innovators. He described early in the twentieth century that creating something new requires a specific behavior which is present in a limited number of individuals only (Schumpeter, 1912): A high level of energy, willingness-to-change, coupled with a strong need for obtaining wealth and power. In his perspective, effective entrepreneurial activity results in "creative destruction", i.e. successful market uptake of the new creation, followed by elimination of outdated solutions. This phenomenon occurs relatively automatically, whereby the innovator resembles a catalyst. Contemporary perspectives on innovation consider efficient management of the

[1] Michael E. Porter: Shared Value and Strategy; Shared Value Leadership Summit New York, NY May 12th, 2015

whole innovation process – from idea generation to successful market implementation. Important tasks within the innovation process, as identified by Roberts and Fusfeld involve I) *idea generating*, II) *entrepreneuring and championing*, III) *project leading*, IV) *gatekeeping*, V) *sponsoring or coaching* (Roberts and Fusfeld, 1980). These critical functions are generally driven by a minority of the team and are embedded in non-innovative routine problem solving ideally driven by all team members. A.T. Kearney embedded this process within the *House of Innovation* (HOI; →Figure 2; Engel, Diedrichs and Brunswicker, 2010). Coming back to Porter and his advice "get unique" for achieving sustainable competitiveness: It is reasonable to assume that all rooms within the HOI need to managed continuously for generating an innovation-friendly environment. Without this holistic approach, it may be difficult to stay ahead of competition and to ensure profitable growth. Here, the HOI is used as an example framework of innovation management, demonstrating that commitment of multiple stakeholders with diverse social economic behaviors is required and all individuals involved are to be set into the innovation context.

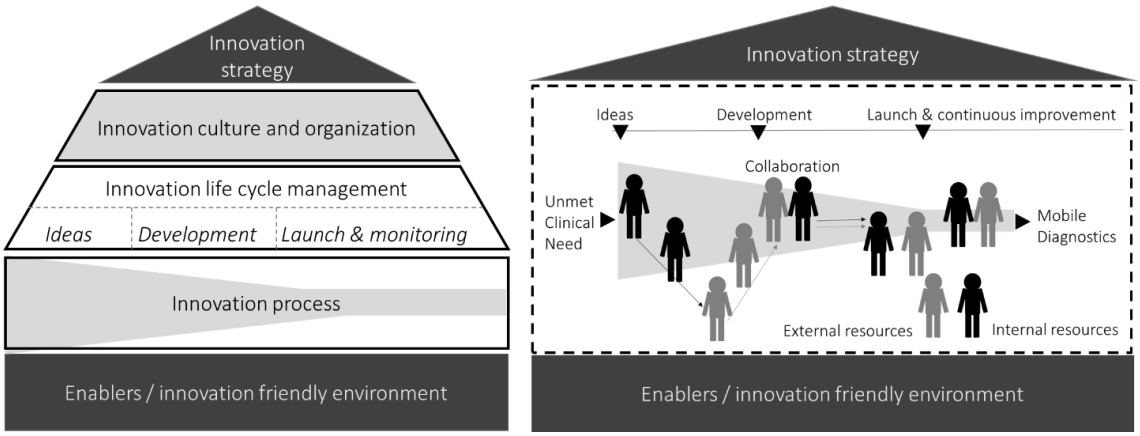

Figure 2 The *House of Innovation* as closed (left panel) and open (right panel) version. Adapted from: A.T. Kearney (Engel, Diedrichs and Brunswicker, 2010)

2.1.1.1 Innovation Strategy

At the top of the roof, new attractive opportunities are defined. These are not restricted to new products, but could also be innovative service solutions or new business models. Ideally, the envisaged solution is aligned with the business strategy. The latter defines the degree of innovativeness, which can be incremental (routine innovation) or even radical. In the latter case, a new technological

solution is used (in biotech e.g. rapid laser-based amplification of nucleic acids instead of thermal cycling: new to the world), whereas the incremental approach uses existing technology as basis which is “tuned” (Table 1). Various further types of innovation have been described, including architectural or disruptive innovation.

Table 1 Types of innovation. Adapted from: Pisano, 2015 & Henderson and Clark, 1990, p. 12

	Technology Core	
System / Linkages	*Reinforced*	*Overturned*
Unchanged	Incremental / Routine *(multiplex testing)*	Disruptive *(Lab-on-a-chip)*
Changed	Architectural *(direct-to-consumer testing)*	Radical *(Lab-on-a-chip)*

Inhabitants of the house need to be informed intensively on the vision created at the top (2.1.3). A continuous monitoring of the environment embedding the targeted innovation is mandatory to allow in time adjustments.

2.1.1.2 Life-Cycle Management & Enablers of Innovation

Life-cycle management (LCM) of an innovation initiates with generation of ideas at the *fuzzy front end*. Selected ideas enter the development process which often involves opening of boundaries of the firm for collaboration with external partners (Figure 2, right panel). The development phase is followed by launch and monitoring of the innovation within its specific environment. A competitive advantage can be achieved, if time-to-market is as short as possible.

This can be only achieved if enabling factors are integrated into the LCM. If more complex solutions are envisaged, experts with different knowledge background need to be brought together. Interdisciplinary team work requires smooth and reliable flow of information. Ideally innovators collaborate closely together under one single roof or even in one single room of the house. If this is not possible due to regional barriers channels need to be establishes for efficient communication. A gatekeeper can help to strengthen collaboration, oversee / allocate resources, improve knowledge management (→2.1.2) and monitor achievements which could be triggered by supervisory encouragement. Further tools enabling an innovation-friendly environment are described under *diffusion of innovation* (→2.1.3).

2.1.1.3 Innovation Culture

As stated above, innovation begins with generating ideas. This process requires creativity. In a componential theory by Amabile (2013), creativity can be traced back to a combination of knowledge (domain-relevant skills), creative thinking, and motivation (excitement) as intrinsic factors as well as the social working environment as external influencer (Amabile, 2013). The environment is expected to have direct impact on individuals' intrinsic motivation: examples for negative impact on creativity include harsh critic of new ideas, politically charged business environment, risk-averseness in top managers, and too tight project deadlines; examples for positive influencers are interesting challenges, high level of collaboration, diversity in skills, strong focus on selected ideas, visionary top managers, and effective knowledge sharing. These factors strongly depend on the organizational culture.

"The way we do things around here" is a term often used to describe culture: A group of individuals sharing core values and beliefs – often subconsciously (Lundy and Cowling, 1996). Ability-to-innovate and organizational culture have long been linked in various studies. Organizational culture could also be considered as mortar, fixing the *house on innovation*. A model of (Martins and Terblanche, 2003) highlights eight building blocks influencing innovativeness of a culture: (i) *mission and vision*, (ii) *external environment*, (iii) *means to achieve objectives*, (iv) *image of the company*, (v) *management processes*, (vi) *employee needs and objectives*, (vii) *interpersonal relationship*, and (viii) *leadership.*

Extensively discussed examples for highly innovative cultures are global players that were very successful over a long period and still manage to generate sustainable innovations: 3M, WL Gore, IKEA, and LEGO (two based in the US and Sweden, respectively). These examples have in common that the organizational culture itself provides a competitive advantage that grew over many years – or even decades – and cannot be copied easily.

Particularly small enterprises are often not able to provide all resources internally. Thus, many innovation processes are becoming more and more interactive, requiring simultaneous networking across multiple "communities of practice" (e.g. functional groups, business units, IT suppliers) sometimes on a global scale. Knowledge needed for innovation is therefore increasingly distributed both within

organizations (e.g. across functions and geographically dislocated business units) and across organizations (e.g. across IT suppliers, consultants and user firms). This poses new challenges for innovating firms in terms of creating, sharing and managing knowledge and expertise. In these situations, knowledge has to be continuously negotiated through interactive social networking processes. (Swan et al., 1999) That is, the communication of knowledge is only possible between people who, to some extent at least, share a system of meaning (Trompenaars, 1995).

Adequate addressing of the innovation strategy may require external collaborators. In addition, an increasing number of enterprises involves lead users in the innovation process, ensuring that the solution fulfills user needs and allows successful uptake. Accordingly, the innovating organization must be permeable, i.e. able to integrate external knowledge easily. A shared understanding and excitement regarding the envisaged innovation is important. This can be a challenge, because the two or more parties involved present with different behaviors. These are getting particularly evident within specific situations, e.g. if mistakes occur or if decisions need to be made on contradicting data. Innovation can benefit from tensions, if they lead to constructive change. However, if these tensions cannot be resolved due to unwillingness-to-change / -collaborate, the innovation process stops. It can be helpful to start the journey with a teambuilding, where collaborators can learn about the other culture in a friendly environment. Takeuchi and Nonaka (1995) described such an environment or place as “ba” – a mandatory basis for efficient knowledge creation.

2.1.2 Knowledge Management

Knowledge can be regarded as accelerator for innovation – if it is generated, used and transferred efficiently. This has been confirmed e.g. by Pawlowsky and Schmid (2012) based on data of the German industry. Particularly, sharing of knowledge has a strong impact on innovation and depends on the behavior of each *knowledge worker* (KW) – a term which has been brought in by Peter F. Drucker. He equated KW as capital assets and stated that an increase in their productivity “requires changes in attitude not only on the part of the individual KW, but on the part of the whole organization” (Drucker, 1999, p. 92). These changes could be best triggered when initiated in a small group of KW who were identified

to be more open minded, curious and communicative as compared to the remaining work force. Next to a high level of receptiveness, knowledge on knowledge management (KM) is an advantage.

More recently there have been efforts to standardize KM: It has been explicitly included into ISO 9001:2015. This norm includes standards for quality management and will be effective for all ISO 9001 certified organizations in 2018. The embedding of KM in this norm emphasizes on its importance for organizations. Four requirements are highlighted in the updated ISO norm: I) definition of knowledge mandatory for preservation of the normal business operations, II) its regular updating and expansion, III) its effective sharing within the organization, and IV) acquisition of new knowledge to react up on external conditions and trends.

For this purpose, it is helpful to find a common understanding with respect to what exactly knowledge is. This can be a highly complex task already as knowledge is always on the go and therefore hard to tackle. One attempt is the *DIKW* model: data -> information -> knowledge -> wisdom, with an increase in hierarchy from right to left or from bottom to the top as it is usually presented in form of a pyramid (reviewed by Rowley, 2007, pp. 32–37). Here, *knowledge* (know how) derives from *information* (know that) and could further be transferred to *wisdom* (know why) that may even be followed by *enlightenment* (socially accepted and sanctioned acting; Zeleny, 1987). A more detailed approach is exemplified by the knowledge latter (Figure 3).

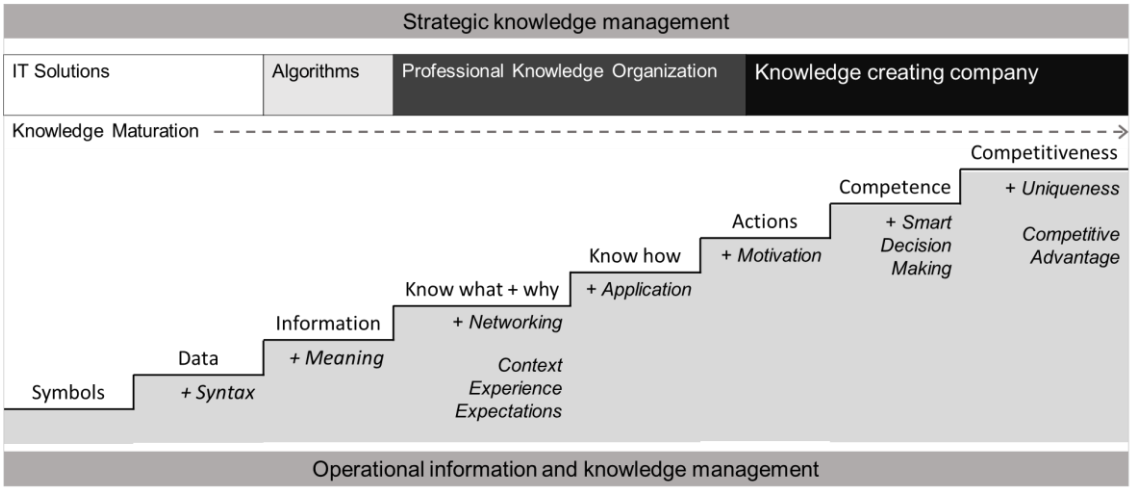

Figure 3 Knowledge ladder. Source: Adapted from North and Kumta, 2014, pp. 32–37.

Here, it is evident that information can only be turned into knowledge when set into context. Turning data into useful or actionable information (knowledge) requires analytical, interpretative as well as collaborative skills. The ultimate goal of this knowledge generating process is to act strategically towards gaining competitive advantage. This can only be achieved by going upstairs in high speed, i.e. by agile KM. Notably, KM does not mean that the direction is upstairs only – it is rather needed to go up and down easily. In addition, it requires juggling of both explicit and tacit knowledge, which are often discussed as two major types of knowledge. Characteristics of knowledge types are listed in Table 2.

Table 2 Characteristics of types of knowledge. Source: Alavi and Leidner, 2001, p. 113

Types of knowledge	Definition	Examples
Tacit	Rooted in actions, experience, and involvement in specific context via mental models (cognitive tacit) or know how applicable to specific word (technical tacit)	Best means of dealing with specific customer
Explicit	Articulated, generalized knowledge	Knowledge of major customers in a region
Individual	Created by and inherent in the individual	Insights gained from completed project
Social	Created by and inherent in collective actions of a group	Norms for inter-group communication
Conscious	Explicit knowledge of an individual	Syntax of a programming language
Automatic	Individual's tacit, subconscious knowledge	Riding a bike
Objectified	Codified knowledge of a social system	An operating manual
Collective	Tacit knowledge of a social system	Organization culture
Declarative	Know-about	What drug is appropriate for an illness
Procedural	Know-how	How to administer a particular drug
Causal	Know-why	Understanding how the drug works
Conditional	Know-when	Understanding when to prescribe the drug
Relational	Know-with	Understanding how the drug interacts with other drugs
Pragmatic	Useful knowledge for an organization	Best practices, business frameworks, project experiences, engineering drawings, market reports

For moving stairs up and down quickly, types of knowledge must be differentiated reliably. It facilitates implementation of the right management support tools that

serve as a kind of banister. With respect to the last upper stairs (Figure 3, highlighted in black), tacit knowledge plays an important role. Knowledge researcher Polanyi had a strong focus on tacit knowledge, which is also known as implicit or silent knowledge. For him, (scientific) breakthroughs were impossible by using explicit knowledge only (Polanyi and Sen, 2010). Nonaka and Takeuchi grounded their work on Polanyi's tacit dimension. However, in contrast to Polanyi they believe that tacit knowledge can be made explicit, namely by an interplay termed SECI (Figure 4; Nonaka and Takeuchi, 1995).

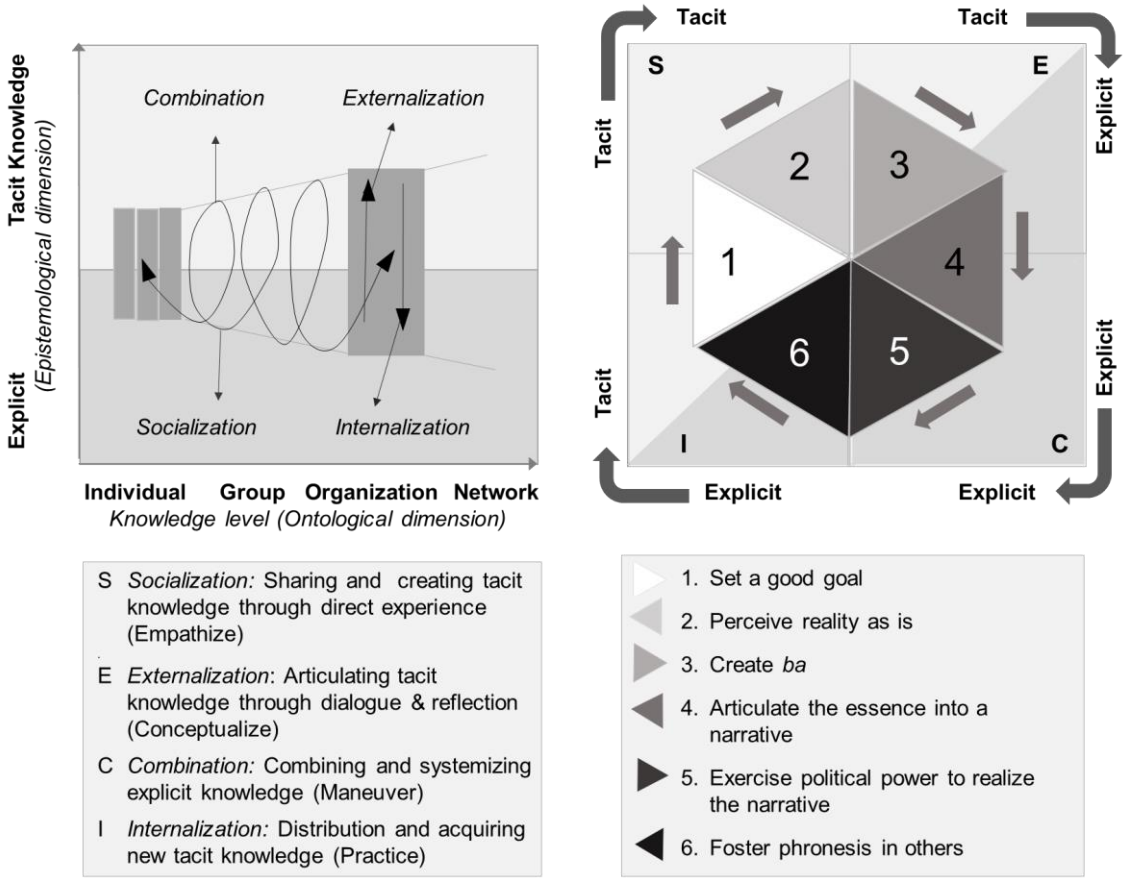

Figure 4 Spiral creation of organizational knowledge (SECIng, left panels), exemplified by creation of phronesis (right panels). Adapted from: Kawamura, 2014 Nonaka and Takeuchi, 1995

SECI translates / converts tacit into explicit knowledge by intensive collaboration. Analogy or metaphors (cross-imagination / conceptualization, Figure 4, "E") are used for overcoming Polanyi's "ineffability" of tacit and highly personal knowledge (Nonaka et al., 2000). This translation requires a certain overlap of redundant information which is mandatory for establishing cross-imagination, i.e. to ensure

that specific metaphors can be taken up and modified (Figure 4, step 3). There is a metaphor for this overlap: "*ba"* – "shared context for emerging relationships, which provide a platform for advancing individual and collective knowledge" (Nonaka et al., 2014, p. 369). Organizations knowing how to live SECI are suggested to achieve a higher level of innovativeness: Valuable knowledge evolves through dynamic and empathic interactions (sharing, creating, and acquiring of knowledge) in a continuous, spiral manner. Published examples for successful SECIng included the Japanese firm Honda with its innovative city car (Nonaka and Takeuchi, 1995). More recently, examples from the finally adopting "western world", e.g. Cisco, were added (Kawamura, 2014).

This suggests that the organizational culture which is significantly shaped by tacit knowledge can play an important role for knowledge generation as facilitator of innovation. As mentioned in chapter 2.1.1.3, culture has a significant impact on whether KM is efficient and has a positive impact on innovation. For using differences in cultural behavior as an advantage that fuels creativity, it needs to be understood that knowledge is only valuable when in continuous flow and not in steady state. This culture also influences dealing with mistakes. If these are not accepted and if lessons learned (Figure 4, left panel: Externalization) are not integrated well in the corporate learning process, new patterns of thinking cannot be generated. Consequently, implementation of change is blocked and the innovation process stops.

Not only usage of tacit knowledge, i.e. the upper black stairs of the knowledge ladder, can represent a challenge for the organization: In the past years, there was an ever-increasing flood of data (Figure 3, left stairs). For processing of these big data, (machine learning) algorithms are regarded as very promising tools which help to deliver "good" information – or better: Valuable or actionable insights in time (→Figure 17). However, even well-established flight autopilots which are used in every day transportation can make wrong decisions when, e.g. connected sensors deliver signals that are automatically set into a wrong context. Confidence on data means that at least as many data (and ideally not more) are collected and analyzed as needed for obtaining timely and accurate information (set of data set into context), providing a valid basis for decision making.

Risk cannot be eliminated completely, particularly within innovation processes associated with relatively high uncertainties. Balancing risk is strongly depending on the knowledge management within an organization and defines the level of entrepreneurial power. Thus, information dominates the innovation process because it has direct impact on risk management. In the future, a main challenge for organizations will be noise reduction and to cope with the ever-increasing flow of innovation in an agile manner, i.e. to break it down into manageable packages.

2.1.3 Diffusion of Innovation

Before focusing on diffusion and the last phases within the innovation process, it is helpful to return to zero milestone. John Kao (2007, p. 17) defined innovation as “the ability of individuals, companies and entire nations to continuously create their desired future”. His view implies that a strong visionary leadership is of importance, guiding the innovation process. In addition, it also suggests that political affairs can strongly influence whether the desired future can be created or turns out as an illusion. A desired future often relates to a specific socioecological environment and compares the situation today with those in, e.g. year 2020: Year 2020 as desired (with maneuvered change) and year 2020 as not desired (without maneuvered change). For better envisioning of year 2020, a technique described as *foresight* may be a good starting point: “What you foresee is what you get” (principle #1: Carleton et al. 2013, p. 14). For some this may sound spiritual or remind of Nonaka’s phronetic visionary leadership (→2.1.2; Figure 4, right panel). However, at least one point of the Stanford foresight method (SFM) sounds obvious: “You can’t cheat at innovation” (Carleton et al. 2013, 32, item 10). SFM is based on the following five phases:

I) perspective — using lessons learned to predict the future

II) opportunity — identifying upcoming changes in customer needs

III) solution — identifying answers to industry-related questions

IV) team — selecting team members regarding needed talent and leadership profiles

V) vision — driving towards the desired future by engagement of the whole team

Table 3 Tools supporting the Stanford foresight method. Adapted from: Carleton et al., 2013, pp. 18–20

Phase & Tool	Related techniques	Our unique benefit
I) Context Maps 	• Brain Storming • Mind Mapping	Retains complexity of topic, while beginning to converge on priority areas
I) Progression Curves	• S-curve (technology adoption) • Historical timelines	Connects multiple related events and highlights precedents
I) Janus Cones 	• Cones of uncertainty • Milieu studies	Uncovers indirect influencers and events within an era
II) Generational Arcs 	• Population analytics (demographics) • Generational research	Identifiers relevant population group and shared values
II) Future User 	• User personas • "VoC"* exercises • Need-finding	Describes future user needs without extrapolating biases from today's users
II) Future-Telling 	• Storytelling • Experimental design • Use cases • Role playing	Conveys nonverbal and contextual details about a future use case
III) White Spots 	• Growth-share (BCG) matrix • Blue ocean strategy	Determines future focus of opportunity through iterative filters
III) Paper Mock-ups 	• Prototyping (low fidelity) • Scale models (maquettes)	Produces system models that display the interactions and related components
III) Dark Horse	• Out-of-box thinking	Resets idea back to essential core innovation
III) Change Path 	• Backcasting • Strategic inflection points	Prioritizes top decisions based on direct path to desired future
IV) Buddy Checks 	• Start-up speed dating • Role playing	Let you quickly filter promising innovation partners and teammates
IV) Voice Stars 	• T-shaped people • Career planning tests • Creative leadership profile	Describes the mix of traits needed for radical innovation leadership
IV) Crowd Clovers 	• Social network mapping • Weak ties • CoIN	Identifies types of relationships required for fostering a culture of innovation
V) Vision Statement 	• Start-up elevator pitches • Mission statements	Provides a simple formula to tell a future vision
V) DARPA Hard Test 	• Technology readiness scales	Evaluates future vision in terms of its breakthrough potential
V) Pathfinders 	• Wayfinding • Diffusion of innovation • Knowledge activists	Charts the most efficient success path for an innovation idea through an organization

Abbreviations: BCG, Boston Consulting Group; CoIN, Collaborative innovation network; VOC, voice of the customer

In principle, the method could be integrated under the roof of the house of innovation as basement (innovation friendly environment; →2.1.1.2). Two elements of the tool box are *DARPA Hard Test* and *Pathfinder* (Table 3, Carleton et al., 2013, p. 20). These are useful for evaluating breakthrough-ability of technologies and for diffusing innovation, respectively. According to Rogers (2002, p. 2), “diffusion is the process through which (1) an innovation (2) is communicated through certain channels (3) over time (4) among the members of a social system”. Some individuals adopt immediately, whereas the majority (>90%) lags. The degree of lagging behind can be slightly (early adopters: 13.5%), moderately (early and late majority: both 34%) or high (laggards: 16%; Rogers, 1983, p. 247). Innovation characteristics affecting diffusion include (Rogers, 1983, pp. 14–15):

- *Relative advantage* — the innovation is superior as current solutions
- *Compatibility* — the innovation fits unmet user needs
- *Complexity* — the innovation has a high ease-of-use
- *Trialability* — the innovation can be tested first prior to potential adoption
- *Observability* — impact of innovation can be traced

2.2 Innovation Networks

As indicated in the *House of Innovation*, the product development process must not take place within the boundaries of the firm. More than two decades ago, more and more high tech companies, including biomedtech firms, started to incorporate external knowledge within some or even all steps of innovation. This is because generating a unique solution often involves more than one discipline: e.g. sensor technologies may need to be connected for sending data securely to a specific data base. In addition, globalization increases competition and it can be observed that life-cycles of products decrease. Mergers and acquisitions (M&A) can provide access to needed know-how or help to reduce time-to-market. However, one hand M&A often fail (e.g. potential loss of incorporated knowledge) and on the other hand an SME may not have the legal, financial, and administrative background needed to execute an M&A. Therefore, formation of R&D partnerships can be a superior solution, where resources, costs and risks could be shared. Other examples for collaborations are joint ventures, strategic alliances,

or distribution agreements. In addition, partnerships between private and/or public partners (PPP) have been triggered significantly by research grants favoring interdisciplinary team work. In parallel, match making opportunities were supported publicly by network or cluster initiatives. The latter is a specified network linked to a specific region and technology in focus (e.g. Silicon Valley in the USA or microTEC Südwest in Germany).

Networks usually evolve by loose relationship building between independent actors who share specific goals (Johannisson, 1987). This relationship can get stronger as time goes by. Bonding is positively influenced by open communication, trust and success stories in-between networkers, such as knowledge generation. The stronger the bonding, the smoother the flow of information. Negative influencers include conflicts of interests resulting in power distances between actors. In this case, knowledge sharing is rather difficult if not impossible. Thus, the dynamics and interaction patterns within a network strongly depend on behaviors of actors involved. Consequently, each network has its own footprint which makes its classification difficult.

According to OECD (2014, p. 221), “the main rationale for public policies to promote clusters, through infrastructure and knowledge-based investments, networking activities and training, is an increase in knowledge spillovers among actors in clusters and thus the generation of a collective pool of knowledge that results in higher productivity, more innovation and increased competitiveness”. Networks can help to complement codified knowledge (as presented e.g. in reports) by tacit knowledge. This can facilitate decision making. Thus, networks can provide the place, which Nonaka and Takeuchi termed “*ba*” (→2.1.2): A place for accessing and sharing various information outside the own organization which may be hierarchical, cumbersome or characterized by silos of departments.

Innovations are associated with a high degree of uncertainty, such as technological uncertainty. In addition, markets can present with a lack of transparency, with inconsistent voices of future customers and key opinion leaders. In an innovation network, reduction of uncertainty could be obtained by interorganizational collaboration of interdisciplinary actors is suggested to increase the power to disrupt established technology. “Innovation depends on harvesting knowledge from a range of disciplines besides science and technology, among them design, social

science, and the arts" (Kao, 2007, p. 19). Network-based innovation approaches can facilitate what Schumpeter termed "gales of creative destruction" (Powell et al., 1996). Thus, an informal and voluntary combination of network resources (e.g. technological with market expertise) may increase willingness-to-innovate, whereas standalone enterprises may not overcome their risk averseness (De-Bresson and Amesse, 1991).

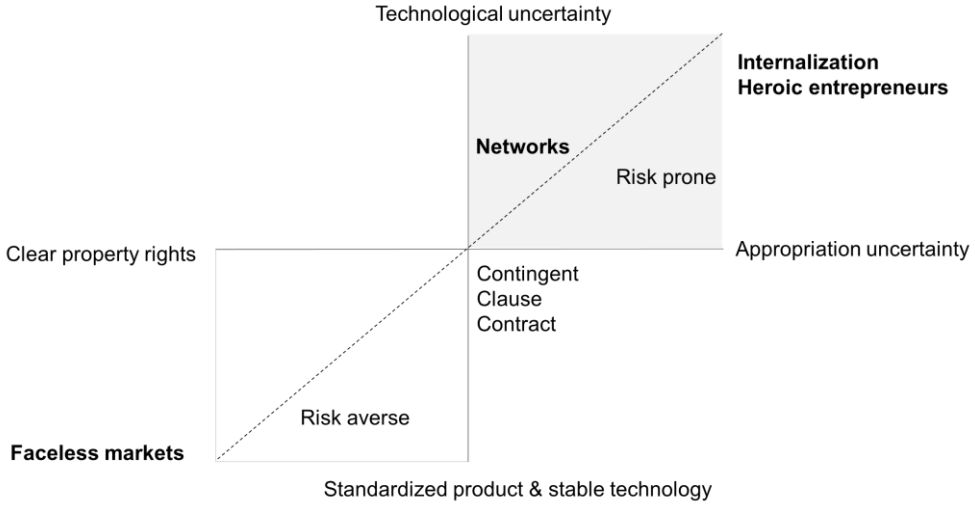

Figure 5 Typology of transaction. Adapted from: DeBresson and Amesse, 1991, p. 365

This advantage inherent to innovation networks also bears a disadvantage: Collaborating innovators may not easily find a consensus because of differences between innovation culture of each single partner (→2.1.1.3). In addition, networking individuals may come into a hazardous competing situation which makes it difficult for them to differentiate between friends and foes. An anticipated barrier-free communication as well as relinquishing control may become an illusion. With respect to potential risks on return of investment (ROI), Powell and colleagues (1996, p. 117) compared the decision whether to collaborate or not as "variant of the make-or-buy decision, framed largely in terms of transaction cost economics". Dhanaraj and Parkhe (2006, p. 660) proposed a framework for influencing ROI actively within innovation networks: Orchestrating of "knowledge mobility, innovation appropriability, and network stability" rather than passive behavior is at least for key actors a superior strategy.

2.3 Innovations in Healthcare

As for other segments, innovations in healthcare can be differentiated in continuous and discontinuous innovations. The latter results in a new technological paradigm. This process can be influenced by various factors, e.g. scientific breakthroughs, economic benefits, institutional circumstances as well as limitations of existing technological solutions (Dosi, 1982). Theories discussing drivers of innovation are generally directing towards either a “demand-pull” or “technology-push” approach. Demand-pull approaches focus on unmet or insufficient met clinical needs. An example would be a medical surgery device that allows in situ identification and labeling of tumor tissue, followed by a precise and guided resection. A technology-push approach would argue that a new technological solution like digital printing allows creation of innovative products like on demand production of patient-specific implants. These “black or white” considerations have their limitations as an innovation process may evolve in the “grey zone”, i.e. a user-centric approach that uses a specific technological approach which seems to be most appropriate to fulfill unmet needs identified. From health perspective, an innovation improves the outcome of a patient significantly: patients have a benefit that is measurable in a real-world scenario.

2.3.1 Drivers

Over the past two decades, healthcare expenditures increased only slightly in Germany (Figure 6). Highest expenditures can be assigned to the USA (17.1% of GDP in 2013). In Germany, healthcare spending amounted to 11.2% of GDP in 2013, which is significantly lower. However, with respect to the demographic changes, i.e. a significant increase of individuals older than 60 years, it is important to install countermeasures. These include the *choosing wisely* program which was initially launched in the USA in 2012[1]. As one can assume, this initiative aims at reducing diagnostic and therapeutic measures in a “wise” manner. Diagnostic procedures such as MRI (magnetic resonance imaging) provide one example: In 2013, there were e.g. 107 MRI performed in 1,000 inhabitants of the USA, whereas the OECD median was roughly half of it (Squires and Anderson, 2015). Here, the question may evolve whether less is more. The higher use of

[1] http://www.choosingwisely.org/ (accessed on February 25, 2017)

health technology in the USA may also suggest that technology adoption shifts more to the left on a time scale, i.e. percentage of innovators and early adopters is higher compared to other countries (→ 2.1.3). Therefore, healthcare cost cannot only be evaluated with respect to actual cost, but also need to balance innovativeness of a certain industry, e.g. biomedtech industry with companies such as GE healthcare. Another example is genetic sequencing that has been pushed by billions of US dollars in the nineties. More than two decades later return on investment can be observed.

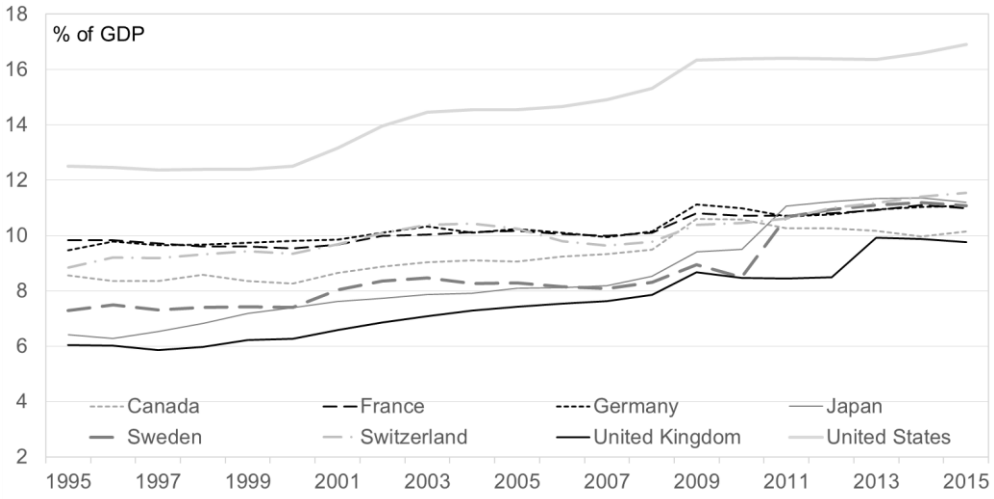

Figure 6 Healthcare spending (% of GDP[1], 1995–2014; OECD Health Data, October 2016)

Another important driver are the patients themselves. Workers shifted more and more from blue collar to knowledge worker over the past decades. This shift went along with an increase in life expectancy, particularly in high income countries. In case of an illness, individuals have more time to focus on disease management. Since digitalization has facilitated access to information, they are also able to identify latest breakthroughs in healthcare. This allows patients to influence disease management.

2.3.2 Moves

The term “mobile” within *Mobile Diagnostics* implies that innovations restricted to a technological solution are not fulfilling the needs of all users in healthcare anymore. By contrast, technological solutions allow higher implementation rates, when embedded into service solutions. In 2014, consulting firm Deloitte provided

[1] GDP, gross domestic product

a 2020 outlook for healthcare and Life Sciences including the following 10 predictions (Taylor et al., 2014, p. 3):

1. Empowered patients
2. Digitalization of patient management
3. **Monitoring of clinical parameter and "quality of life" by mHealth solutions**
4. Big data supported clinical decision making
5. Convergence of technology and science
6. Network-based interdisciplinary R&D approaches
7. **Towards value-based healthcare**
8. End-to-end process governance by GBS (Global Business Services)
9. New business models for emerging markets
10. Recovery of corporate reputation by generating trust

The first five predictions are external moves, whereas the remaining focus on the industrial environment. In the following, two items (3. & 7.) will be highlighted.

Towards Value-Based Healthcare

One move – particularly shaped by Michael E. Porter – is towards a value-based healthcare (VBH) system (Porter and Guth, 2012; Porter, 2010). Notably, value of care has ever been in focus. However, the VBH approach aims at standardizing assessment of value added (→Figure 7).

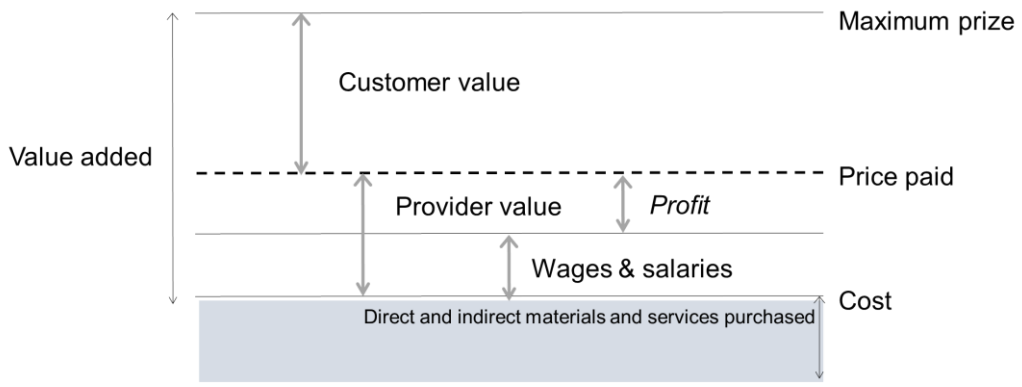

Figure 7 Added value. Adapted from: Zeleny, 2006, p. 9

This approach can help to identify whether management is efficient or needs to be adjusted. Added value refers not only to a specific step within patient management, but intents to consider the whole patient management cycle (→Figure 8). This process can be termed health technology assessment (HTA), if the value is added by a specific technology.

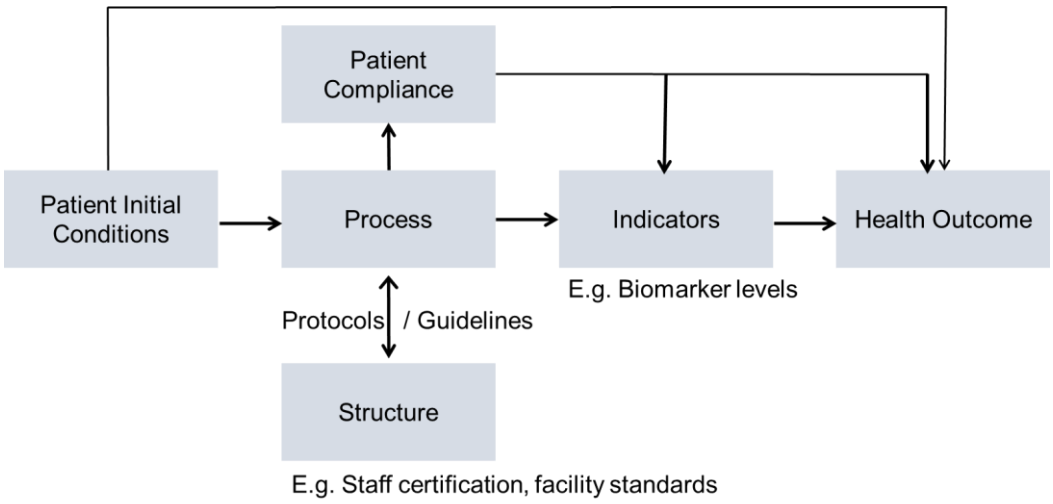

Figure 8 Assessment of value added in healthcare. Adapted from: Porter and Guth, 2012, p. 37

Towards Patient-Centered Decentralization

A further move, aligning with the VBH approach, is to use more patient-centered management procedures in specialized setting such as integrated practice units (IPU). According to Kodner and Spreewenberg (2002, p. 3), “Integration is a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors.” Within IPU, teams of medical experts take care of patients in a multidisciplinary manner, with the goal to obtain best outcomes as possible.

Individuals can differ significantly and thus, information should be set into the specific (e.g. genetic) context of each patient. Personalized medicine is an attempt to design a individual patient management. For this purpose, additional information obtained by e.g. biomarker analysis can be helpful for determining adequate treatment options or to monitor outcome (→Figure 8). Ideally, this information can be obtained near to the patient and in time to achieve immediate

impact on patient management. Even test-and-treat algorithms can be performed: Biomarker levels are measured onsite and then the physician decide whether e.g. antibiotics are useful or not. Thus, novel near patient diagnostics can support VBH within IPU.

2.3.3 Barriers

Innovations are embedded into uncertain environments. Sometimes the environment is even unfriendly due to hurdles, such as those included in the EU Innovation Union guide (2013, p. 8):

- *weaknesses in public education and innovation systems*
- *poor availability of finance*
- *costly patenting*
- *outdated regulations and procedures*
- *slow standard-setting*
- *failure to use public procurement strategically*
- *fragmented efforts among member countries and regions*

In healthcare, environments can be extremely unfriendly, if not frosty. Implementing new solutions can be unpredictable and time consuming. Potential barriers or influencers of innovations in the field of mobile diagnostics have been addressed within the initiative *Mobile Diagnostics* (MD; see next chapter). These include technology, quality and regulatory affairs as well as market-related barriers – components of the *PESTEL* analysis. PESTEL aims at generating a reliable picture of a country-specific, macroeconomic situation, namely political, economic, social, technological, environmental and legal.

External factors can have a significant impact on a company's innovation strategy. Therefore, it is important to include only information which is relevant for the target innovation. In addition, information needs to be handled carefully as misleading group think can occur, i.e. a swan turns black although it is white and vice versa.

2.4 Innovation Package *Mobile Diagnostics*

The initiative *Mobile Diagnostic Systems* (*Mobile Diagnostics*, MD) was launched in 2010 by BMBF[1] as part of the country's high-tech strategy. Historically, BMBF grants have a strict focus on R&D. In this case, integrated microsystem (lab-on-a-chip) technologies for biotechnological applications was the target. The target is reasonable with respect to future demographical changes and an expected increase in healthcare expenditures (→2.3.1): A promising outlook to cost-efficient diagnostic decentralized testing, particularly in rural areas with time consuming transportation of patient samples to more distant laboratories.

In total, eleven collaborative R&D projects were supported in parallel, resulting in a competitive set-up. The majority of projects consisted of multidisciplinary teams: Academic researchers, industrial partners and clinicians who represented the voice-of-the-customer in user-centric system integration approaches. Industry partners were predominately SME (small and medium enterprises). System integration was accompanied by an interdisciplinary team of knowledge manager who addressed selected barriers or influencers listed above (→2.3.3). Their mission was to support funded system integrators and to generate a better understanding for the innovation environment embedding lab-on-a-chip technologies. For this purpose, the whole value chain was considered by including specific needs of integrators. Accompanying actors had also the goal to create awareness for mobile diagnostics within the German health sector and beyond: Science marketing and community building were performed under the umbrella "Mobile Diagnostics" as innovation pitch. Notably, MD innovation networking was meant to be sustainable, i.e. after termination of MD successful transfer to established networks was envisaged.

In this thesis accompanying actors are defined as *promoters* referring to the model of Eberhard Witte (1973). This model describes two types of promoters – *expert promoters* (EP) and *power promoters* who are responsible for knowledge creating and ensuring resources, respectively. More recent studies added *process promoters* (or *champions*; Chakrabarti and Hauschildt, 1989), *relationship promoters* (Gemünden, Salomo and Hölzle, 2007). The latter study could show

[1] Germany's Federal Ministry of Education and Research

that specialized promoters have a positive impact on success of innovation. Further, the authors assigned relationship promoters an important role as “boundary spanners”.

Table 4 Key actors within *Mobile Diagnostics* Innovation Network

Key Actor	Official Description	Role
GK, Gatekeeper	Project coordinator	Cross-organizational flow of knowledge
EP, Expert Promoter	Knowledge manager	Knowledge generation and transfer

In this thesis, relationship promoters are designated as *gatekeepers* (GK) to differentiate them from promoters (Table 4). GK function as sensors and transmitters: They identify and capture useful information as well as potential collaboration partners. “The technological gatekeeper mediates between his organizational colleagues and the world outside, and he effectively couples the organization to scientific and technological activity in the world at large” (Allen, 1970). Thus, a GK is interactive and requires excellent networking skills.

Within MD, GK were represented by coordinators of each R&D project. They interacted predominantly with collaboration partners within project boundaries. However, GK were also responsible for external interaction with GK from other projects and knowledge managers, i.e. EP. EP were responsible for knowledge generation and diffusion. Because of their profound analytical expertise, an EP can deal with high uncertainty and ambiguity inherent to innovation. Furthermore, EP identify and analyze potential barriers of innovation efficiently.

As in case of MD, more than one EP can be involved in innovation processes. This is depending on project size, complexity and degree of innovativeness (e.g. routine versus radical innovation). In MD, one or more EP were related to each potential barrier identified. With respect to Nonaka’s model of knowledge management (→ 2.1.2; Figure 4), experienced EP may facilitate creation of *ba*: They may promote collaboration or networking between different stakeholders for initiating complex learning. In MD, compiling of information was intended to be timely, agile and actionable. For knowledge transfer, different formats were used, included face-to-face meetings with integrators. These meetings were also foreseen to connect actors with each other for promoting community building as mentioned above.

3 Methodology

This thesis is a case study on the initiative *Mobile Diagnostic Systems* (MD) launched by BMBF in 2010. Details are given in Table 5.

Table 5 Overview: Initiative *Mobile Diagnostic Systems*

Where	Germany, nation-wide
When	2011 to 2015
Who	Participants from public and private organizations
What	Development of microsystem technology-based mobile diagnostics (lab-on-a-chip, LOC) for biotechnological application in healthcare settings (hospitals and physician offices / integrated practice units)
How	Interdisciplinary and user-centric system integration, accompanied by knowledge workers who supported the innovation process over the whole value chain
Why	To gain knowledge on how targeted technologies fit into the environment and to reduce the level of uncertainty associated with these new technologies
Driver	Need to re-define healthcare due to significant healthcare costs and demographic changes leading to a significant increase in individuals older than 65 years over the next decades
Volume	11 funded projects

Since initiative MD ended in 2015[1], this thesis takes a retrospective look at it. Focus is on key activities within the MD-related innovation network and socioeconomic factors influencing the complex undertaking of innovating German healthcare. Qualitative analysis was performed to understand maneuvering of change needed to introduce novel lab-on-a-chip technologies into healthcare setting. In this context, interviews were performed with 19 MD innovators as internal perspectives.

In addition, four external perspectives were included by interviewing individuals who came in contact with the MD network. Finally, one interview with a network and cluster expert was added, resulting in a total of 23 interviews. This retrospective is intended for teams targeting innovations in healthcare. It highlights activities in MD that went well and those that may need to be improved for addressing potential barriers of diffusion more efficiently (Figure 9). Finally, it provides an outlook on how activities of the MD innovation could be continued for further driving decentralization.

[1] Project end refers to the companion research

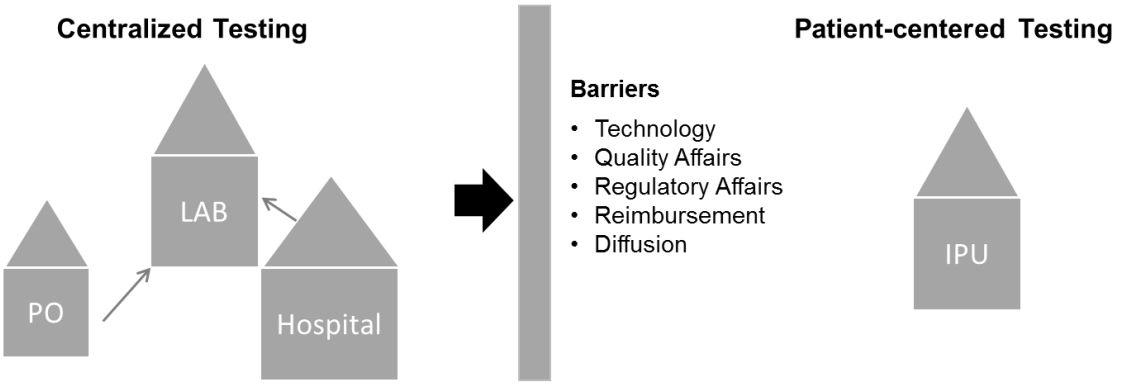

Figure 9 *Mobile Diagnostics*: Innovation networking towards decentralization (Abbreviations: PO, physician office; LAB, laboratory; IPU, integrated practice unit)

3.1 Data Collection

Data were collected based on interviews. Interview partners were selected in a way that different perspectives were covered for one of the biggest interdisciplinary MD projects: Gatekeeper, adopter, power promoter, technology promoter and market promoter. These actors were from public as well as private organizations. Both executive and managerial level were presented by the interviewees. In addition, gatekeeper perspectives of five further MD projects were collected. These perspectives were complemented by those of individuals who conducted MD knowledge management (i.e. expert promoters).

Prior to each interview, participants were provided orally with background information concerning the researcher and the research object, i.e. case MD. In addition, they received information on the interview procedure itself, including planned time-frame. All participants were informed that data is handled anonymously and participation is voluntary.

The majority of interviews were scheduled as telephone interviews, only two participants were interviewed face-to-face. All participants were asked whether they agree that the interview is being audio-recorded. Before starting the interview, there was time to answer open questions of participants. Written informed consents are available in German language for all participants, including agreements upon audio-recording (an example form is attached).

Interviews were on average about 40 min in duration (range: 24–96 min). All interviews were audio-recorded and only a limited number of notes was made. This allowed high concentration on the interview partner. Interviews were performed

in German and in a semi-structured manner using predominately open questions. A standardized part related to potential barriers of innovation in the field of mobile diagnostics – the work package addressed by expert promoter of the companion research team:

- Technology
- Standardization
- Regulatory Affairs
- Market Access / Reimbursement
- Diffusion

3.2 Description of Actors

An overview of interview participants interacting directly or indirectly with initiative MD is given in Table 6. Actors were categorized with respect to eight different perspectives on the innovation network. These are described below. In addition to their perspectives, roles and hierarchies are indicated. Of the 23 participants, all are Germans, and 6 (26%) are female. Three interviewees shifted their focus significantly beyond near-patient testing since termination of initiative MD (Table 6: AD-II, GK-V, GK-VI). Categorization of actors' perspective is based – with some adaptations – on the promoter model that has been further developed since its introduction by Witte (1973). Promoters can be understood as actors who support the innovation process intensively by overcoming resistance. In this thesis, perspectives are related to specific barriers that need to be overcome. It is important to note that roles of actors can overlap significantly. Actors who were more in-directly involved within the MD innovation network are highlighted in gray in Table 6.

Table 6 Characteristics of interview partners

#	Perspective		Role in mobile diagnostics (focus today)	Gender (age range)
	Technology Promoter			
1	TP-I		Director of R&D, non-profit organization (MD)	M (35-44)
2	TP-II		Senior Scientist R&D, industry partner (MD	M (35-44)
3	TP-III		Group leader R&D, public institution (MD)	M (40-49)
	Gatekeeper			
4	GK-I		Entrepreneur, industry partner (MD)	F (40-49)
5	GK-II		Director of Finance, industry partner (MD)	M (40-49)
6	GK-III		General Manager, NPO (MD)	M (50-59)
7	GK-IV		Manager in R&D, Industry partner (MD)	F (40-49)
8	GK-V		Manager in R&D, Industry partner (biotech)	F (40-49)
9	GK-VI		Director of R&D, Industry partner (medtech)	M (45-55)
	Expert Promoter			
10	EP-I		Knowledge Manager, NPO (standardization)	M (45-55)
11	EP-II		Scientist R&D, NPO (rapid diagnostics)	M (45-55)
12	EP-III		Knowledge Manager, NPO (healthcare innovation)	F (35-44)
13	EP-IV		Knowledge Manager, NPO (healthcare innovation)	M (30-39)
	Adopter			
14	AD-I		Specialist Lab Medicine, hospital lab (IT & eHealth)	M (35-44)
15	AD-II		Specialist Lab Medicine, private lab (business)	M (40-49)
	Market Promoter			
16	MP-I		Director of Marketing, NPO (science marketing)	M (30-39)
17	MP-II		Market Access Expert, NPO (reimbursement)	F (40-49)
	Power Promoter			
18	PO-I		Top manager, biotech industry (business)	M (45-54)
19	PO-II		Top manager, biotech industry (marketing)	M (45-54)
	Externals			
20	XT-I	(XT-EP)	Knowledge Manager, public institution (social science)	M (45-55)
21	XT-II	(XT-MP)	Application Expert, SME (marketing)	F (30-39)
22	XT-III	(XT-PO)	Entrepreneur, start-up (business)	M (40-49)
	Process Promoter			
23	PP		Expert in Technology Cooperation, NPO	M (45-54)

Abbreviations: Lab, laboratory; MD, *Mobile Diagnostics*; NPO, non-profit organization

Technology Promoter Perspective

Technology promoters (TP, n=3) are motors of the organizations' R&D, holding the technology related knowledge. Here, three different R&D organizations are represented: public institution, non-profit organization, industrial partner. All SI collaborated in one of the biggest MD system integration projects. One integrator (TP-I) was involved in more than one project. TP are experts in a specific (bio-) technological field in which they worked for at least 5 years. Represented disciplines are: Physics, biochemistry, engineering. Included SI cover the whole system integration process: Instrument with optics, microfluidic cartridge, and test technologies (immunological and molecular detection of specific parameter).

Gatekeeper Perspective

Gatekeepers (GK, n=6) are sensor and transmitter of information. Their role can also be defined as *boundary spanner* or *relationship promoter* who is usually strong in identifying and connecting to partners (Gemünden et al., 2007). Depending on GK's background (e.g. technology, finance or marketing), these partners can be R&D collaborators, suppliers, key opinion leaders or customers. Originally the term *gatekeeper* was shaped by Allen (1970) who considered GK more in the context of closed organizational boundaries, where information was predominately brought in by GK. Relationships and the *quid pro quo* custom may not have been as important as today. However, GK's role in MD is multidirectional exchange of knowledge, which can also include exploitation in terms of licensing-out or technology transfer, i.e. knowledge export. Therefore, their relation management skills play an important role.

Expert Promoter Perspective

Expert promoters (EP, n=4) are representatives of the MD companion research who are knowledge manager. Their role is to gain a better understanding of the innovation system around MD and to share this knowledge in an agile manner predominantly with GK who then have the role to further spread this information.

Adopter Perspective

Adopter (AD, n=2) allow user-centric system development and contribute highly valuable information. Therefore, they are closely related to TP and MP to influence usability and diffusion of innovation, respectively.

Market Promoter Perspective

Market promoters (MP, n=2) could be also described as *market-related relationship promoters* as introduced by Gemünden and co-workers (2007). Usually, they have good relationships to adaptors of innovation, but also to power promoters. Their role is to identify and address barriers of implementing new solutions.

Power Promoter Perspective

Power promoters (PO, n=2) have “necessary hierarchical power to drive the project, to provide needed resources, and to help to overcome any obstacles that might arise during the course of the project” (Gemünden et al., 2007). Thus, PO are usually in top-management position within an organization. In general, PO are expected to help innovations gaining “momentum”. This includes also protection of innovations from hazardous environments.

External Perspective

Externals (XT, n=3) include individuals who came in contact with MD at least once via different channels. All of them are active in the field of near-patient testing. XT-I is a knowledge manager from an academic institute (social science) and could also be designated as external *expert promoter*. The focus of XT-I is on mobile health and on implementation of near-patient diagnostics in rural settings of Germany. XT-II is from an SME and could be also designated as external *market promoter.* XT-III is from a start-up and could be also designated as external *power promoter*.

Process Promoter Perspective

The so-called *process promoter* (PP, n=1) was introduced by Hauschildt and Kirchmann (2001) as an actor with “diplomatic skills” who “knows how to approach and win over different types of people”. PP allows bridging between technology and power promoter and functions as technology transferor. PP knows how to establish houses of innovation and how to connect these with the external environment. In this thesis, PP represents an expert of technology cooperation with excellence in clustering and networking whose aim is to foster innovation-friendly environments. PP was not directly involved in MD and was included as external innovation expert.

Role of the researcher

The researcher could be described as market promoter and has been working for a biotech firm that was partner in one of the biggest MD project. In October 2012, the researcher came in contact with MD and was involved in several activities driven by expert promoters even after official termination of initiative MD, e.g. a work group on requirements for near patient testing. During a period of about four years within the environment of MD, the researcher made acquaintance with all externals as well as technology, market, power, and expert promoters. Four of the six gatekeepers as well as the process promoter were not known to the researcher.

3.3 Qualitative Data Analysis

Data analysis was performed as framework approach in analogy to Gale and colleagues (Gale et al., 2013). However, analysis was done by a single researcher (MH) and manually only – not software-assisted. Audio-recordings from semi-structured interviews (n=23) were listened before transcription, which allows a better immersion with the content. In parallel, emerging thoughts during listening were noted down by the researcher. Afterwards recordings were transcribed verbatim, except that word replications as well as specific German filling words were removed (“also”, “eben”, “ja”, “halt”, and “so”). In addition, sequences not related to MD, were cut. All persons, organizations, and locations directly related to MD were blinded (i.e. person A, B, C). In total, more than 100 pages of textual data were obtained in German language. These are presented in a supplementary printed booklet. On request, this can be reviewed by contacting the researcher.

Textual data were reviewed regarding key themes: Themes related to actors’ experiences of innovating within the network-based approach. Remarkable text sequences were highlighted and coded. Codes and related sequences were extracted from the text and transferred to an Excel Spreadsheet. Extracted sequences were translated into English language. This was performed for each actor (perspective). Then, codes were cross-reviewed. Some codes were merged together and those which did not make sense after iterative reviewing (3 cycles) were excluded. In a next stage, a matrix of key themes was prepared by linking different perspectives (→Table 7). Themes included potential barriers in implementing decentralized diagnostics as addressed by MD expert promoters as well

as emergent themes. Themes were analyzed with respect to differences or concordances between perspectives of MD actors. Subsequently, interpretation of findings was embedded into the theoretical framework.

Table 7 Framework of qualitative data analysis

#	Theme	Target / Focus
1	Barriers of Innovation	• Technological barriers • Regulatory barriers • Organizational barriers (silos) • Financial barriers (valley of death)
2	Innovation Management	• Uncertainty and Foresight • Visionary leadership
3	Networking & Collaboration	• Knowledge management (socialization, knowledge transfer and sharing) • Interdisciplinary team work
4	Diffusion / Implementation	• Market Access • Technology push versus market pull • Innovation selling (creating awareness)
5	Innovation-friendly environment	• Willingness-to-innovate

3.4 Quality of Data

This study is intended to provide an objective case analysis of the network-based innovation approach started within the initiative MD. Therefore, different perspectives were included in the interviews to get a valid basis for data interpretation. Moreover, data were collected from actors in private and public institutions as well as industry. At least two interview partner were selected for each perspective to reduce subjectivity. However, risk of bias cannot be elucidated because not all participants of initiative MD were included: E.g. only six coordinators – gatekeepers – were interviewed, although 11 projects were funded. Thus, perspectives of about half of the gatekeepers are not available.

Another source of bias is represented by the researcher itself due to involvement in MD as knowledge worker of one industry partner. Notably, the researcher is not an experienced qualitative researcher, such as MD expert promoters. Therefore, interviews could be influenced by non-professional manner of questioning. In addition, categorization of data was performed by one researcher only (MH).

Thus, there was no cross reviewing by further researchers or verification by applying software-assisted qualitative data analysis (QDA).

Finally, it has to be noted that QDA as non-standardized research method cannot eliminate subjective elements completely. This is due to the specific fingerprint of the researcher and storyteller who looks at the specific case from its own perspective.

4 Results

Within initiative *Mobile Diagnostics* (MD), problem and one potential solution were pre-defined as high priority challenge by BMBF[1]. Problem is the demographic change associated with an increasing number of the elderly (>65 years). This is expected to result in higher healthcare expenditure as well as shortage in care in rural areas of Germany. Notably, this is not only problematic for Germany, but can be considered as global challenge. One potential sub-solution represents mobile diagnostics for near patient testing and monitoring.

Decentralized diagnostics can also be considered as important component of patient-centered value-based healthcare (VBH; →Figure 10). BMBF initiative MD supported the move towards this direction. Aim of MD was to generate knowledge in this emerging field: Factors positively and negatively influencing the innovation process were to be identified by a multidisciplinary team of knowledge workers (expert promoters).

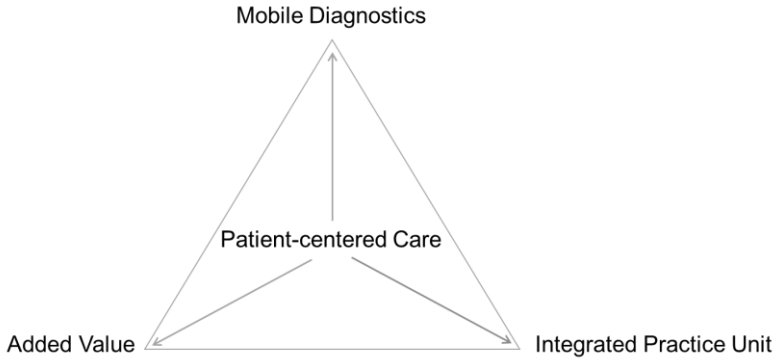

Figure 10 Towards patient-centered healthcare

MD started in 2011 and was terminated in 2015. Often it is recommended to not look back, but into the future. This thesis breaks with it and looks behind. Theoretical background information included a foresight model of the Stanford University (SFM, →2.1.3). SFM proposes to start an innovation process with perspectives on lessons learnt. These are crucial for potentially adjusting strategy and to develop a long and clear view into the future – foresight. Thus, the new strategy is grounded on insights of the past. Perspectives on the case MD were obtained

[1] BMBF, German Federal Ministry of Education and Research

by interviewing a sub-set of actors involved (→Table 8). In case of citations, English translations are used, whereas original sequences in German are included as footnotes. The following table helps to get engaged with different actor perspectives (see also Table 4):

Table 8 Actors with roles

Actor	Abbr.	Role
Technology promoter	**TP**	System integration: R&D engine of the organization
Gatekeeper	**GK**	Project coordinators: Bridging & knowledge transfer
Expert promoter	**EP**	Generation and transfer of knowledge
Market promoter	**MP**	Market insider and voice of the customer
Adopter	**AD**	Future user: Implementation of innovation
Power promoter	**PO**	Top-Management: Sponsoring / financing of innovation
Externals	**XT**	External innovators in the field of mobile diagnostics
Process Promoter	**PP**	Expert in innovation management and networking

Results presentation refers to selected phases of SFM (→Figure 12: Perspectives and Vision), intertwined with the thesis' theoretical framework. Starting point will be perspectives on barriers of innovation in the field of decentralized diagnostics in German healthcare (→4.1). The first part covers external "hard" factors (→4.1.1): Technology and user needs as well as standardization and market access. The second part focuses on more internal "soft" influencers of innovation environments (→4.1.2). Here, perspectives derive predominantly from individuals who were close to the initiative MD (TP, EP, GK, AD), as demonstrated in the following figure:

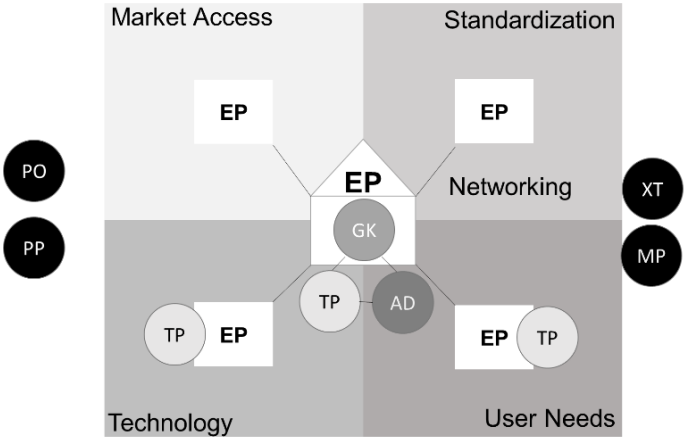

Figure 11 Set-up of innovation network *Mobile Diagnostics*

The last chapter refers to the final phase of SFM (→4.2). It uses insights on perspectives — *aha*-moments — for vision creating. Vision shaping is predominately based on external perspectives (PO, XT, MP, and PP, presented in black in Figure 11). This vision is meant to help maneuvering the change strategically towards healthcare innovation in Germany. Focus will be particularly on innovation networking and how this can positively influence innovation-friendliness for MD. In this context, one perspective – those of the process promoter (PP) – is of particular importance. Thus, retrospectives (lessons learnt, part I) are used to shape the future more actively by networking and by help of external perspectives (strategic impact, part II).

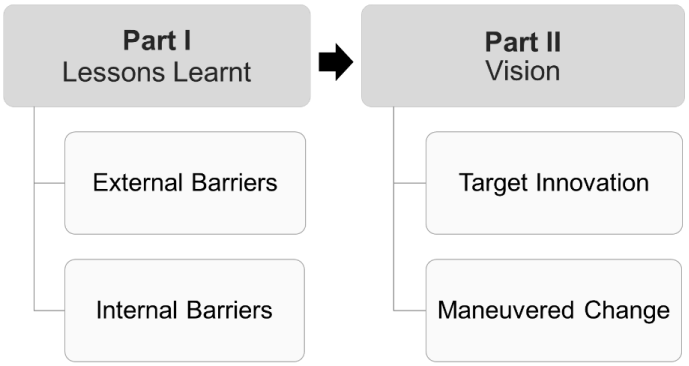

Figure 12 Structure of results presentation

4.1 Perspectives: Lessons Learnt

In agile management procedures, retrospectives are starting point for the next sprint. These are meant not meant to be for the project, but for the team – to allow improvement of collaboration. Within MD retrospectives based on separately conducted interviews, the researcher tried to identify such insights for which the term *“aha”-effect* or *aha-moment* was used. Lessons learnt require a dialogue between all actors involved. In the following, a dialogue is started artificially by collaging interviews with participants of initiative MD.

4.1.1 External Barriers of Innovation

Development of *in vitro* diagnostics is embedded in a complex environment of technical standards and regulatory requirements which ensure a high standard of quality and safety. For novel decentralized diagnostic systems, there was a

lack of requirements and standards (e.g. IT connectivity) prior to initiative MD. Gaps were addressed within MD by including users and other important stakeholders into knowledge generation.

Technology Push Versus Market Pull

Decentralized diagnostics are not new, but in use for decades. Established near-patient tests are using mainly a technology termed as *lateral flow*. Pregnancy home tests are using this technology which allows easy and fast results generation. However, there are limitations in test performance, at least for some parameter, such as infectious agents or small amounts of cancer-specific biomarkers. Molecular technologies can result in higher detection rates (sensitivity) and thus, can be more adequate to diagnose specific diseases reliably. In this thesis, next generation mobile diagnostics using integrated molecular detection technologies are in focus.

Expert promoters within MD found that more than a hundred R&D teams develop next generation mobile diagnostics world-wide. Hot-spot is in the USA. One major reference platform – already in market in 2012 – was *GeneXpert* of US company Cepheid[1]. This reference system is not portable (mobile) and time-to-result is about 60 min which may not be fast enough for generating actionable results.

What is fast? The answer is technology-driven. During MD, there were two remarkable events in 2014: Launch of a molecular system termed *Alere i* (Alere, USA)[2] and acquisition of US company Iquum by F. Hoffmann-La Roche (Roche, CH)[3]. Both (to be-) acquired technologies reduced time-to-result of molecular applications significantly, namely from about 60 min to less than 30 min.

In addition, both systems are available in relatively small formats – not yet mobile, but they allow near patient testing, e.g. in physician office labs. Therefore, these technologies made an important move from hospital to more decentralized settings, including envisioned integrated practice units (Figure 10). The lower left end of the triangle – added value with respect to cost-efficiently – remains a hurdle: Integrated test reagents are still about three times more expensive compared

[1] Acquired by US group Danaher for 4 billion US dollars in 2016

[2] US company Abbott initiated acquisition of Alere in 2016, but the case is still open

[3] Transfer costs amounted to 450 million US dollars, including upfront and milestone payments

to centralized testing. This is where innovators can have a significant impact (→4.2.1.).

Since initiative MD is not insulated, these moves need to be observed carefully to adapt innovation strategies proactively: If innovators come up with a system requiring more than 30 min, competitiveness must be visible somewhere else. For time-critical parameters within a test-and-treat patient management, a relatively low speed could be the game out. TP who are responsible for system integration risk to get insulated. GK have the important function to set TP back to reality.

Reality is not the hundreds of MD innovators, but the five that could hurt a lot. Therefore, the technology landscape prepared by MD expert promoters was very helpful for all coordinators of collaborative development projects, namely GK. With respect to the highly dynamic and changing environment one GK suggested:

"[…] such a status quo prepared there [in MD] is certainly good and useful, but I think that it should be continued or updated."[1]

In parallel to MD, companies like Iquum and Alere demonstrated that further decentralization of molecular testing is possible. Actors of MD had different perspectives on the challenge of system integration and project outcome. One GK emphasized that a final product was clearly envisioned:

"Sure – this was to 100% my motivation to start the whole thing."[2]

One TP, by contrast, considered the approach more as demonstration of technical feasibility, with a running prototype as output:

"There are two types of companies that participate in such funded projects: Those that […] use the resources to support their strategic development […] and those that believe that at the end there will be a product and that they will supply one component of this blockbuster, which is a classical erroneous assumption."[3]

---

[1] „[…] so ein Status Quo, der da [in MD] erarbeitet wurde, [ist] sicher gut und auch sinnvoll, aber ich denke, man müsste das natürlich auch weitermachen oder aktualisieren."

[2] „Na klar, das war 100% meine Motivation, das ganze Ding zu starten."

[3] „[…] es gibt zwei Arten von Firmen, die an solchen Förderprojekten teilnehmen: Die einen, […] die Mittel einfach nutzen, um ihre strategische Entwicklung abzufedern […] die andere Art von

Regulatory and Quality Affairs: Much Ado

In the last phase of MD, it was obvious that a new EU regulatory guideline for *in vitro* diagnostics (IVD) will be launched. Particularly regulation of near patient testing will change significantly, i.e. regulatory hurdles will be higher in the future. Consequently, expert promoter activities addressing gaps in the regulatory environments were of high and for some GK of highest interest. Standardization activities of EP did not only influence MD innovators. Accordingly, quality compliant development has also highest priority for the start-up of an XT:

"*First we introduce 13485 compliant quality management step by step as basis for subsequent CE IVD marking*".[1]

One adopter observed in industrial partners an extreme focus on legal affairs:

"*It was surprising for me how penetrated it was that everywhere were seen liability risks and such things. Not in all, but in many [firms]*."[2]

4.1.2 Internal Barriers of Innovation

Innovation Management

Solid *Houses of Innovations* — strategically integrated and actively lived innovation management — could not be identified. This was independent from size (S, M and L) of organizations included. Innovations are rather maneuvered through a process which has been established somehow over time. One industrial TP mentioned that innovation comes as a "*package*", in this case package MD transferred to consortium Z by BMBF.

For larger publicly listed firms, a challenge of establishing innovation management represent quarterly reports, with financial data directly linked to share value. Although shareholder value thinking is expected to shift towards a mid-term or even long-term strategy for sustainable growth, a PO pointed out that:

Firmen, die gehen halt fest davon aus, dass da am Schluss ein Produkt steht und sie eine Komponente zu diesem Blockbuster liefern. Und das ist halt eine klassische Fehlannahme."

[1] „Wir wollen / oder sind langsam dabei, erst mal ein Qualitätsmanagement nach 13485 bei uns peu à peu einzuführen, um da eine Basis zu haben, um nachher ein CE IVD Kennzeichnung anzubringen"

[2] „Das hat mich gewundert, wie das schon durchgedrungen ist, dass überall Haftungsrisiken gesehen werden und ja solche Sachen. Nicht bei allen, aber bei vielen [Firmen].

"[…] there are internal resistances, which are always the same: "I am already occupied. Do I really need that?" *And this is a perspective which is just quarterly-driven [...] and, of course, this makes innovation management requiring money and time — time in form of resources — difficult."*[1]

Therefore, SME and start-ups are regarded as engine of innovation – at least from the perspective of the PO. These engines can be incorporated by larger players, if the moment in time is right and if the target is in market already (see next chapter). This is demonstrated by the acquisitions mentioned above.

With respect to some smaller MD innovators, one adopter had the impression that…

"[…] there was absolutely no desire for bringing the product to market, instead, to follow the strategy to get bought by one of the really big player that in turn brings it to market."[2]

Both behaviors – wait-and-buy and wait-and-get-bought – are negatively interfering with innovation management.

Technology Transfer: Gimme 5

Although financial affairs were not included in the work package of EP, it represented one of the highest hurdles for innovators. One important task of actors was to present a plan for technology transfer at the end of MD. If this step is successful and in time, it can help to overcome the "valley of death" (→Figure 13). Technology transfer was a challenge for most actors, independent from their background (small or medium private or public organizations). One option is to transfer the prototype to a (larger) company. This is difficult according to a GK who made the experience that:

[1] „Es ist eher, dass die internen Widerstände da sind, die immer die gleichen sind: Ich bin schon beschäftigt; brauche ich das wirklich? Und das ist eine Sichtweise, die einfach Quartals-getrieben ist, oder sagen wir mal, die short-term ist […] Und das macht natürlich Innovationsmanagement, wenn es Geld und Zeit kostet — und Zeit eben auch in Form von Ressourcen —, schwierig."

[2] „[…] es geht überhaupt nicht darum, das Produkt jetzt wirklich selber bis zum in den Markt zu bringen, sondern die Strategie irgendwann sich aufkaufen zu lassen von einem sehr ganz Großen und dann würden sie das dann in den Markt bringen."

"[…] most [companies] looking for it [mobile diagnostics] want something practically marketable."[1]

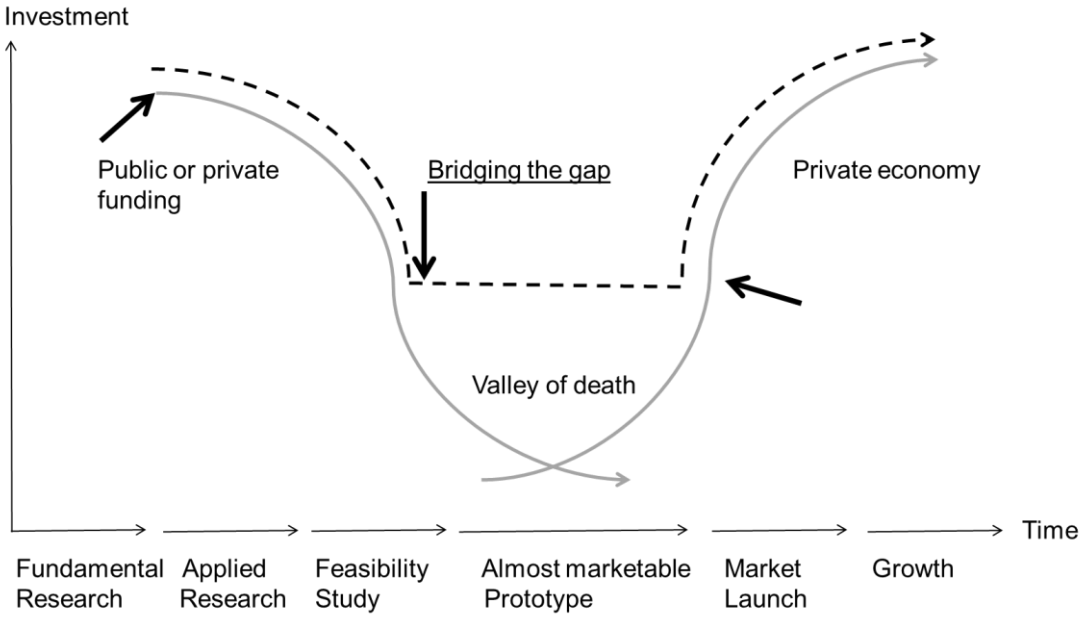

Figure 13 Overcoming the valley of death. Adapted from: Künzel, Meier zu Köcker and Köhler, 2016

This is also reflected by above mentioned acquisitions of biggest players in the field of near patient testing, namely Abbott, Danaher, and Roche: All acquisition targets were in market and generated significant revenue already. Acquirers did not want to take the risk of microsystem integration and wait until market readiness. In contrast to private firms, listed companies strongly depend on the behavior of their shareholders who want return of investment – the sooner, the better. Share values are a promise for the future and for some GK a prisoner's dilemma, where from PO perspective…

"[…] publicly listed firms tend to buy rather than build, if this firm [target] is able to come up with revenue immediately, because it is already in market or two years ahead with technology compared to a potential internal one"[2]

[1] „[…] dass die meisten [Firmen], die zwar danach [Mobile Diagnostik] gucken, was haben wollen, was praktisch schon marktreif ist."

[2] „[…] wo bei Public gelisteten Firmen die Nadel eher in Richtung *buy* geht als *build*, wenn denn diese Firma [Target] in der Lage ist, sofort dann entsprechend auch mit Umsatz aufzuwarten, weil sie vielleicht auch schon im Markt drin ist, oder weil sie bei der Technologie zwei Jahre weiter ist als eine mögliche interne Entwicklung."

Consequently, technologies not meeting these criteria risk to be rejected or put on standby, i.e. wait-buy-eventually mode. Very recently, in December 2016, German Start-up Carpegen sold[1] its mobile molecular diagnostics technology[2] to Curetis (not yet publicly listed firm located in Germany). The running prototype was in parts developed within MD. Thus, transfer was successful in this case, with the technology being made market-ready within the next years.

Technology readiness is, of course, not the only determinant for make-or-buy decision-making. It depends on the market segment as well. If the market targeted is relatively unknown to the firm[3], then PO's anticipation is as follows:

"*Before building it internally including know-how – which is with respect to technology not incremental –, publicly listed firms would rather move towards M&A*"[4]

Thus, MD innovators should start a dialogue with as many firms as possible, including not publicly listed firms, like those of the German Mittelstand. However, the network should go beyond Germany. This insight is not new. However, the impact could be improved. The example shows that implementation of tacit knowledge – in this case experience in finding the right partner – can be challenging. Like in private life, there is risk to get blinded by beauty or in this case: Power. Notably, PO are in general very smart and it may not be easy to look behind the curtain as they usually like to ploy. Nevertheless, there are few questions which can be posed and which may provide a hint, whether further engagement is worth, as also recommended by the PO:

"In general, an interested party [transferor] should use questioning, probing to figure out what one really needs. If they don't do it – I am now very open and direct –, then it is their own fault."[5]

[1] Upfront payment was 5 million Euro

[2] Human diagnostics-related applications

[3] In case of mobile diagnostics e.g. not laboratory professionals in centralized settings, but general practitioner in physician offices

[4] Bevor ich das intern aufbaue inklusive Know-how – und das ist sozusagen nicht etwas, was von der Technologie her eine Fortentwicklung dessen ist, was man kennt – dann geht die Nadel eher bei Public gelisteten Firmen in Richtung M&A.

[5] In der Regel sollte ein Interessent [Transferor] versuchen, über Fragen über Probing herauszufinden, was man wirklich braucht. Wenn die es nicht tun – da bin ich jetzt mal ganz offen und direkt – sind sie selber schuld.

In private life, one question may be: “Do you like cats?”. With respect to a potential professional partner and in context to its specific build-buy-borrow strategy, questions related to sales channels can be useful. If the potential partner is more marketing driven (pull) rather than R&D driven (push), the focus of probing may not be on technology. Companies can be pull-push in-balanced. Therefore, the drive can be relatively dynamic. For fast and efficient screening of potential innovation partners SFM proposes the tool “Buddy Check”. As presented in Figure 14, promoters of innovation can bring new solution to the next level, if innovators know how to play the game. *Buddy Checks* can help to identify new team members, complementing skills needed for innovation. Moreover, they can help to better cope with real-world situations in which an emergent solution can be confronted e.g. with PO or opponents of innovation. This confrontation can be as simple as the question: Do I really need it? Thus, the transferor should not only a good seller but ideally also a good buyer to strategically project the other party. One additional remark of the PO regarding *probing* (Buddy Check) is:

“It is, of course, fact that we do not disclose everything which is strategically important to us. It is like purchasing: If there is one interested party that absolutely wants to achieve something, then this party is, of course, always a little bit more open compared to the other, asking itself: Do I really need it?”[1]

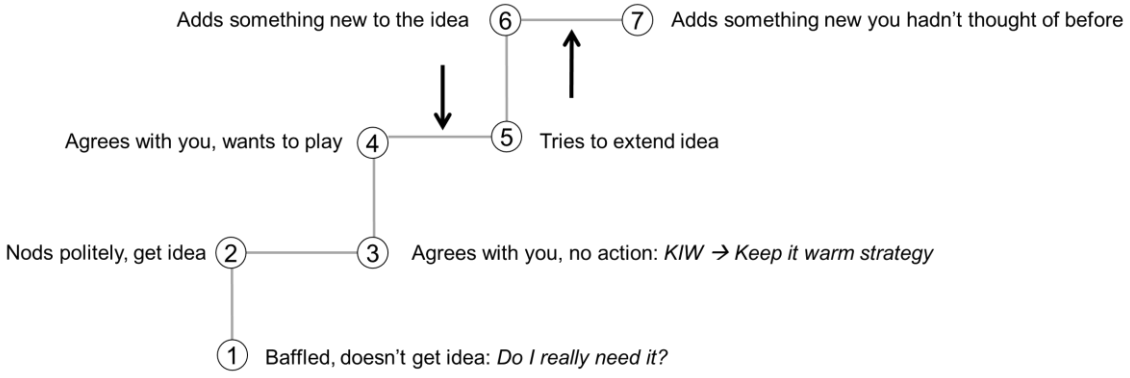

Figure 14 Buddy Checks: Getting to the next level with promoters of innovation. Adapted from Carleton et al., 2013

[1] „Dass wir natürlich nicht alles preisgeben, was strategisch für uns wichtig, ist natürlich auch ein Fakt. Das ist wie beim Kauf: Wenn es einen Interessenten gibt, der unbedingt etwas erreichen möchte, dann ist der natürlich immer etwas offener als derjenige, der sich fragt: Brauche ich das eigentlich?

Another fact is that industries have a specific pace of innovation. This pace can lack considerably behind those of smaller organizations, such as start-ups. In this case the transferor will face difficulties in selling a solution or in creating demand for it. It may be observed that a potential transferee starts to play for some level, but slows down after a while. From PO perspective (Figure 14, level 3)…

"*that's the keep-it-warm philosophy. These are the interesting ones [technologies] which cannot be promoted within the organization at that moment in time, but of which one is personally convinced that they would be beneficial for the company*."[1]

Consequently, transferors need to be patient when dealing with companies presenting with a slow pace of innovation. An alternative to "get bought" or "buy" is "make". As stated in the introduction, voices of the industry estimate about five years and an investment of about 50 million US dollars required for financing of regulatory compliant mobile diagnostics system integration (Morel et al., 2016). For one TP, even a tenth of this amount could bridge the gap, but:

„[…] somebody coming along and saying, 'I give you 5 million and you do product development including documentation for conformity declaration', *did simply not happen. The barrier is certainly more a financial one […]".*[2]

This was confirmed by a GK: "*In general, we have this financing issue here. Germany is not such a liquid market compared to the American one."*[3]

The factor of 10 in-between 5 and 50 is in this case not a moon shot, but a financing gap: Prototype versus product launch. In this context, an experienced GK stressed:

[1] „Das ist die Keep-it-warm-Philosophie. Das sind so die Interessanten [Technologien], die aber momentan irgendwie in der Organisation schlecht zu vertreten sind, von den man persönlich überzeugt ist, dass sie der Firma guttun würden"

[2] „[…] dass jemand kommt und sagt, „Ich gebe euch jetzt 5 Millionen und ihr macht eine Produktentwicklung drauf mit der Dokumentation, die man dann für die Konformitätserklärung benötigt", das ist einfach nicht passiert. Die Hürde ist mit Sicherheit eher eine finanzielle […]"

[3] „Wir [haben] generell dieses Finanzierungs-Problem hier. Deutschland ist nicht so ein liquider Markt wie der amerikanische zum Beispiel."

"Most founders are naïve and underestimate the effort which follows. What they also underestimate is the conservatism of the market. It is not that all people are waiting for point of care [mobile diagnostics]."[1]

With respect to potential financing issues mentioned above, it is important to note that out-of-the-box corporate venture capitalists (VC) emerge: VC having a weak or non-biomedtech background, but considering healthcare as new sector. With respect to out-of-the-box VC one XT who benefited from this move explained that…

"*they invest as corporate investors to get familiar with new sectors via these start-ups*."[2]

Prioritization: Baby Steps

Among MD actors, GK played the most important role in terms of networking: Because of their function as project coordinators they were first contacts of knowledge worker (EP).

Knowledge generation and networking was acknowledged by all GK, whereas active engagement was restricted to a sub-set of actors. One EP had expected more activity in terms of networking:

"*We offer it [knowledge generation] and if people don't react, then we continue with those who are engaged. That's it. After all, it was voluntary."*[3]

Potential reasons for relatively low engagement can be diverse. For GK, highest priority is on financing, followed by technology (Figure 15): First deficits, then growth. This can result in a dilemma, at least from EP perspective:

„*I believe that regarding barriers of innovation there is simply a certain naivety, I have to say, in one or the other […]: It is taken care of financiers, offices […],*

[1] Die meisten Gründer sind naiv und unterschätzen den Aufwand, der dann kommt. Und was sie auch unterschätzen, ist der Konservativismus im Markt. Es ist ja nicht so das die Leute jetzt alle auf Point of Care warten [mobile Diagnostik].

[2] […] dass sie als Corporate Investor investieren, um über diese Start-ups etwas über neue Branchen kennen zu lernen.

[3] „Klar, wir bieten das an, und wenn die Leute nicht darauf reagieren, dann machen Sie mit denen weiter, die sich engagieren. Das ist ganz klar. Das ist ja auch freiwillig gewesen."

while they often forget that in a regulated market one has to address, e.g. regulation."[1]

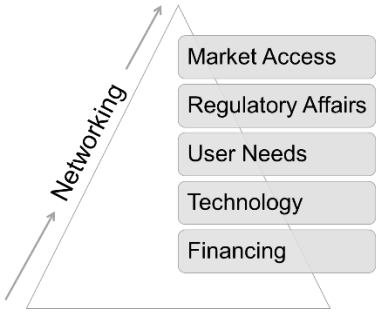

Figure 15 Activities within Mobile Diagnostics in relation to Maslow (1943)

Networking was meant to be established in a sustainable manner, with continuing activities after termination of MD in 2015. Until today, there are indeed activities in the network set up within MD. Post-MD, activities were restricted to a small subset of actors. One GK explained:

„Apart from regulatory affairs / registration, where one colleague is involved […] we are actually more passive with respect to the network and take care of the follow-up project."[2]

Moving on is here the maxim. Thus, some left the MD community due to shifting of priorities, while others joined.

Major networking platform set-up within MD is an (bi-) annual event termed "Mobile Diagnostics at Point of Care" (MD-POC). MD-POC is generally highly frequented and planned to be continued, according to EP. In addition, there were several different workshops in MD, where particularly one that addresses real world laboratory medicine will also be continued, because return on investment has been demonstrated. Both formats went beyond MD, inviting explicitly externals as well. One external who joined the MD community in 2015 (late phase) via

[1] „Ich glaube, dass, was die Innovationshürden angeht, schlichtweg einfach da eine gewisse Naivität, muss ich mal sagen, auch bei dem einem oder anderen […] vorhanden ist: D.h. da wird sich um Geldgeber gekümmert, um Büroräume […] nur sie vergessen dann häufig, dass in einem regulierten Markt, man sich eben mit den Regularien, zum Beispiel, auseinandersetzen muss."

[2] „Regulatory Affairs / Zulassung, da wirkt an der einen oder anderen Stelle unser Kollege mal noch mit […] ansonsten sind wir da, was jetzt dieses Netzwerk angeht, tatsächlich eher passiv unterwegs und kümmern uns um das Nachfolgeprojekt."

MD-POC was included in the interview. From this external perspective, motivation to join was not only to share knowledge and to make contacts, but:

"[…] of course, to be able to influence a little bit or to have the possibility to influence as small and medium enterprise"[1]

Another motivation as strong driver for network engagement was curiosity in case of one AD:

"I was personally interested in getting familiar with the industry perspective".[2]

Thus, it seems that both individuals (AD and XT) have a clear intrinsic motivation. Moreover, it seems that these individuals – innovators – who are not predominately occupied with financial affairs are more open regarding networking in comparison to GK.

4.2 Vision: Towards Value-based Healthcare

"Without a vision, groups can survive, but they can't expect to achieve greatness." This could be another remark of one PO, but it cites SFM playbook (Carleton et al., 2013). Important actors in MD like PO do not want to see good, but great ideas. If one is lucky, good ideas may be handled as *KIW* — keep it warm —, but often it is put on hold or closed, together with about 90% of other good ideas. Game over. Thus, innovation management needs a strategy, including a vision statement. The willingness-to-innovate can be influenced positively by a strong vision. In this context, one GK reflected:

"*Maybe that was what was missing: Simply the target and market associated. That we were unaware what we can achieve, when we make it [MD innovation]. What the potential revenues really are. […] We knew that it is a sensible move we make, but we did not really have a business case*."[3]

[1] „[…] dass man natürlich da als kleines mittelständisches Unternehmen auch ein bisschen Einflussnahme hat oder die Möglichkeit zur Einflussnahme."

[2] „Für mich ging's vor allen Dingen darum, aus persönlichem Interesse, die Hersteller-Seite kennen zu lernen".

[3] "Vielleicht hat uns auch das gefehlt: Einfach das Ziel und den Markt hinten dran. Das uns einfach nicht bewusst war, was wir schaffen können, wenn wir das [MD Innovation] schaffen, was das wirklich für ein Umsatz ist. […] Wir wussten, das ist eine sinnvolle Geschichte, die wir da entwickeln, aber wir hatten nicht wirklich einen Business Case."

PO can easily list characteristics of good visions: Ambitious, wise – to include Nonaka – idealistic, credible, realistic, tangible, etc. With respect to *tangible*, a bad, but real example of a vision is as follows: “We will be market leader in 5 years”. This is indeed ambitious, however: How? Where to put energy? This example does not include a direction for activities. It is correct that a vision should be simple, but in an idealistic or wise manner.

An example vision statement goes beyond Germany to UK: Start-up QuantuMDx founded in 2008. Focus is also on development of mobile molecular diagnostics using a radical innovation approach. It could collect a significant amount of money, demonstrating that obviously, the team *sold* its technology effectively by communicating a vision. The latter was accessed from the company’s homepage, February 15, 2017, and is as follows:

“QuantuMDx is dedicated to improving and democratising global health by providing transformative diagnostic tools to overburdened healthcare systems.”

Even though creating of a vision sounds simple, it is not. Tools such as SFM can help to create a vision that can be diffused easily and within a minute. A vision may not only be important for single organizations, but can positively influence the power of a network (→4.2.2).

A vision is of importance and helps to market a great idea successfully, thereby turning it into innovation. With respect to science marketing, German biotech start-ups could benefit from a little bit more self-confidence. It seems that some German entrepreneurs feel uncomfortable, if external data drift too far away from the confidential *status quo*. One entrepreneurial XT noted with respect to “over selling”:

“*There must be somehow still a healthy balance: At the one end of the spectrum, serving as negative example, is Theranos[1]. At the other end are German developers who […] may have super great technologies, but developed for too long in*

[1] A US company that had a very good far reaching idea (paradigm shift in laboratory diagnostic testing), which turned out to be not actionable (see below, DARPA Hard Test I) and IV))

the ivory tower without attracting attention and who then complain about not getting any money."[1]

4.2.1 DARPA Hard Test: Sustainable Competition

The reason why SFM was put into play is not only because it emphasizes on vision, but also because it targets more radical rather than incremental innovation. Foresight targets emergent growth.

Why DARPA? DARPA is the *US Defense and Advance Research Project Agency* and is of interest in the context of MD because some technologies started in military research: For example, former US company Biofire[2] developed its rapid molecular diagnostic system initially for biothreat applications, i.e. the detection of hazardous material such as *Bacillus anthracis*. Notably, one technology developed within MD started in this field as well. DARPA usually works on challenging complex projects like MD, which are defined by DARPA program managers as follows:

I) *Far reaching* — paradigm shift, e.g. healthcare as integrated practice unit, impacting not only a single, but many individuals

II) *Technically challenging* — e.g. integration of microsystem components

III) *Multidisciplinary* — e.g. physicists, software engineers, optoelectronics, mechanical engineers, molecular biologists, clinicians, nurses, etc.

IV) *Actionable* — e.g. vision can be followed not only theoretically, but practically

These four dimensions can help to characterize the innovation targeted. During the dialogue with MD innovators it was found that understanding of innovation differs. Even if radical innovation is not targeted, it is helpful to discriminate it from a radical innovation and to handle it accordingly. This is important, since depend-

[1] Es muss irgendwo trotzdem noch eine gesunde Balance da sein. Am anderen Ende des Spektrums, was als negativ Beispiel dienen kann, ist Theranos. Das andere Ende sind deutsche Entwickler, die […] vielleicht super tolle Technologien haben, haben aber viel zu lange im Elfenbeinturm entwickelt und nicht auf sich aufmerksam gemacht und dann darüber schimpfen, dass sie kein Geld bekommen.

[2] Acquired by French diagnostic firm BioMérieux in 2013 for 450 million US dollars

ing on the innovation targeted, different strategies for diffusion are to be considered. More radical innovation (moon shots, 10x) may require a completely different communication platform. Thus, change is maneuvered differently.

To discriminate radical from incremental, an external innovator and entrepreneur (XT) was interviewed as well. XT's perspective showed that technologies going beyond existing knowledge on technology can suffer from alienation, even in relatively innovation-friendly environments, such as academic institutions:

"*Unfortunately, technology was – why only unfortunately? – it was fairly new, even at university. By using standard university research, it would have been impossible to obtain a high degree of maturity. Therefore, we had to raise a lot of capital*"[1]

This exemplifies that in case of radical technology innovation — doing something not as usual, but out-of-the-box in 5 min instead of 60 min or more (10x) — there is a significant gap between invention (maybe), prototyping (likely) and product development (very likely). Notably, major challenge is to marry this technology with an application that allows demonstration of value added (actionable).

The Challenge: Targeting Value Innovation

Kim and Mauborgne (2004) focus since many years on strategic innovation management and proposed the so-called *Blue Ocean Strategy*. Here, one important discrimination from the "dominant" strategy (*Red Ocean Strategy)* is to break with the value-cost trade-off. This strategy and the DARPA Hard Test help to evaluate innovation activities in MD. For this purpose, a benchmark system is used as pioneer or first mover.

Reliable test results (performance) can be regarded as hygienic factor (must have): Physicians would not accept a technology that does not reliably support clinical decision making. This was confirmed by one external expert promoter (XT) who focuses on implementation of mobile diagnostics and mHealth applications in Germany:

[1] „Leider war die Technologie – was heißt leider? – sie ist so neu gewesen, dass sie auch an der Uni noch recht frisch war. Und dass man nicht durch reine Uniforschung schon zu einem großen Reifegrad hätte gelangen können. Deswegen mussten wir einfach auch sehr viel Kapital aufnehmen."

“[interviewed physicians] would only use such a system, if it generates robust results.”[1]

Thus, if a system has poor sensitivity, then high false negative rates would force to do confirmatory laboratory testing, resulting in higher rather than lower overall costs. This could be observed in Germany and other countries for first generation lateral flow (strip) devices testing for one pathogen that causes sexually transmitted disease, i.e. *Chlamydia trachomatis*. Detection rates were demonstrated to be poor in larger studies (about 40% sensitivity). Although this is about a decade ago, such near patient devices still have a “quick-and-dirty” stigma which is hard to eradicate. Next to sensitivity, specificity is evaluated: If it is poor, then the false positive rate would be inacceptable due to a risk of potential overtreatment. The latter would be contraindicative with respect to treatment with antibiotics.

Back to the benchmark system, marketed as *sensitive, specific, and easy to use*: Selected pioneer is *liat* (lab-in-a-tube; Roche, CH). It follows the value-based pricing strategy: Laboratory-like performance with a pricing 3-4 times higher compared to centralized testing. However, the test can be done onsite in about 20 min. Thus, costs for sample shipment and administration are saved. In addition, the patient does not need to come back, because of a potential test and treat algorithm: Test for dominant respiratory viruses, identify e.g. Influenza A or B virus and decide whether to treat with antiviral agents like e.g. Oseltamivir[2]. Thus, the former “espresso cup” business model (recurring revenues per installed base through test [espresso] cartridges) is in transition: Diagnostic test results are used to support treatment with a specific therapeutic agent. This may ensure future pharma revenues as one-stop-shop-solution, even in case of patent expiry of the agent.

Figure 16 exemplifies the challenge in targeting moon shots or blue oceans. It is a mix of reduced and adapted *DARPA Hard Test* and *Blue Ocean Strategy*. Here, it is used to highlight potential gaps addressed in the following chapter (→4.2.2). One strategy could be to imitate *liat* as fast follower, indicated by the solid arrow termed *Red*. This can be done by decreasing test price and/or speed, whereas

[1] „[Ärzte] würden so ein System nur nutzen, wenn es auch belastbare Ergebnisse liefert“
[2] Therapeutic agent provided by Roche as Tamiflu®

test performance may be the same, slightly lower or varies more between tests performed. A radical (next pioneer) approach, by contrast, is demonstrated by the broken arrow termed *Blue* in Figure 16. This is the extreme – solutions can also be in-between red and blue.

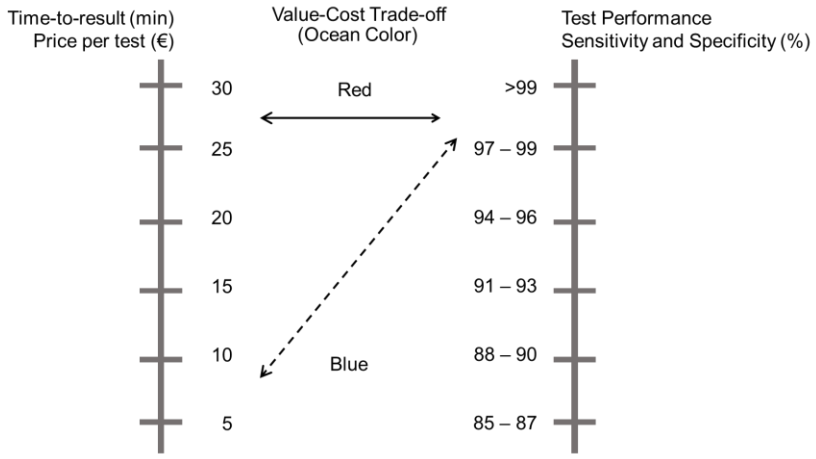

Figure 16 Example for radical MD innovation. In relation to DARPA Hard Test and Blue Ocean Strategy

With respect to diffusion of innovation, a bluer solution that can cut costs is expected to have higher impact and allows a broad distribution of mobile diagnostics, even under the tree as envisaged by the QuantuMDx team. Costs are not only critical in low and middle income countries, but also in Germany, as found by studies involving XT:

“Costs are the main risk factor, followed by a certain skepticism towards technology”.[1]

A solution with value-cost trade-off is envisioned by the Bill and Melinda Gates Foundation, investing significantly in decentralized diagnostics. Funding was granted to bigger publicly listed player and smaller organizations, amongst others Alere (US) and Quidel (US), respectively. However, cutting costs by maintaining performance has not been achieved so far. Costs can be mainly traced back to expensive cartridges containing test reagents. Particularly, quality control in regulated environments can increase costs dramatically. Therefore, not only system

[1] „Kosten ist der Hauptrisikofaktor und dann kommt schon eine gewisse Skepsis bezüglich der Technologie“

development itself is critical, but identification of solutions for cost reduction, e.g. by using reagent integrating 3*D* printing instead of injection molding.

Friend or Foe?

It is evident that complex challenges may be more likely to solve in a multidisciplinary environment. In this context, new out-of-the-box player can help complement value creation. One example is German Group Bosch that is not only strong in 3*D* printing and packaging, but has experience in regulated markets (albeit automotive), connectivity and system integration. Although this group is already active in the field of mobile diagnostics, the market PO does not see severe emergent competition:

"*In the end, they need know-how, meaning a partner with which they can enter [the market].*"[1]

What hurts? More dangerous emergent competition sees the market PO from…

"*firms having today a market leadership role in the field of digitalization. That these enter those fields [mobile health], which they already do*."[2]

This move was also foreseen from an entrepreneurial XT:

"[Other player] that do not belong to the known classical molecular diagnostic firms penetrate or try out this sector, e.g. Google, Samsung, which interestingly also started poaching in other sectors, such as automotive […]. Big classical player like Roche and Qiagen target innovations via acquisitions – very expensive acquisitions."[3]

[1] „Aber am Ende brauchen Sie auch Know-how. Das heißt sie brauchen auch einen Partner, mit dem sie da [in den Markt] reingehen"

[2] „Gefährlicher halte ich da, ehrlich gesagt, Firmen, die im Bereich Digitalisierung heute eine marktführende Rolle haben. Dass die sich in solche Bereiche reinbegeben. Und das tun sie alle schon […]."

[3] „[andere Player], die nicht zu den klassischen bekannten molekularen Diagnostikfirmen gehören, drängen oder schnuppern in diese Branche hinein, beispielsweise auch Google, Samsung, die interessanterweise auch in anderen Branchen anfangen zu wildern, auch zum Beispiel im Bereich Automotive. […]. Die ganz großen klassischen Player wie Roche und Qiagen, die suchen sich Innovationen durch Übernahmen – durch sehr teure Übernahmen."

Thus, mobile diagnostics are more than just instruments delivering results or data points. It requires service innovation as well. The value to be added and demonstrated is an actionable result, as addressed in the following chapter.

4.2.2 Innovation Network Facilitated Diffusion

“Choose your idea’s most efficient network path to success” (Carleton et al., 2013, p. 46). *Pathfinders* is the final tool of SFM. Creation of a sustainable network that help actors to be successful was one major target of initiative MD. This thesis aimed at evaluating the impact of network MD on healthcare innovation in Germany. Main barriers to implementation of mobile diagnostic systems were to be identified. This was based on perspectives of different actors within the innovation network. In this chapter, lessons learnt are used to find a network pathway which can disrupt German Healthcare more successful. A process promoter as well as expert promoter will serve as pathfinders.

Main Barriers of Healthcare Innovation

Within initiative MD expected barriers for implementation of lab-on-a-chip technologies were addressed by a multidisciplinary team of expert promoter. Barriers involved user needs, technology, standardization, regulatory affairs, and market access. Expert promoter created valuable knowledge in the field of mobile diagnostics transferred in meetings, workshops and events or in form of paper, e.g. *German Standardization Roadmap Mobile Diagnostic Systems* available in English as well (DKE - Roadmap, 2015). Knowledge generated in the field of quality and regulatory affairs had highest impact on innovators. It empowered innovators with respect to establishment or adaption of harmonized product development processes. Notably, this impact could also be identified in external innovators who integrated knowledge generated within MD into their organizations. However, more than a year after official termination of MD, there are still barriers as specified by one EP:

“*Everything going towards point-of-care has two hurdles: Reimbursement by the insurer as well as sensitivity and specificity. The latter are somehow valued artificially as bad by diverse people. On the other hand, there are indeed examples*

in the field of point-of-care testing, especially devices for blood glucose measurements, where significant differences [in test accuracy] occurred. "[1]

In theory, solutions for overcoming remaining barriers of healthcare innovation in Germany are expected to exist in the network. However, there are hints that innovation networking itself represents a hurdle itself which needs to be overcome first.

Address both "hard" (e.g. technology, regulatory) and "soft" barriers (e.g. willingness-to-innovate, bridging) for improving innovation networking

Willingness-to-Innovate

In this thesis, actors of the innovation network received special roles based on the promoter model of Witte (1973). In contrast to this first model, here, more key actors were brought into play as a complex multidisciplinary project like MD forces various interfaces. Notably, the network driving MD innovation does not only constitute of key promoter, but a gatekeeper who connects to multidisciplinary project teams. SFM recommends that these teams cover different characters needed for successful innovation management: Pioneer (technology promoter), problem solver, analyst, producer, rebel, and pragmatist.

One important finding is that innovator roles defined by the researcher were not fitting adequately. For example, a PO was initially meant to support innovation processes by providing resources and integration into the house of innovation. It turned out that power regarding internal innovation activities is reduced significantly by quarterly reports. In this case the power shifts from build to hunt. In parallel, the need for building a solid house of innovation is little as long as shareholder expect short-midterm return on investment.

[1] „Alles, was in Richtung Point of Care geht, hat zwei Hürden: Einmal das Reimbursement durch den Versicherungsträger und einmal Sensitivität und Spezifität. Die werden irgendwie von diversen Leuten künstlich als schlecht bewertet. Auf der anderen Seite gibt es auch Beispiele im Point-of-Care Bereich, gerade Blutzuckermessgeräte, wo dann schon eklatante Unterschiede [in der Akkuratesse des Tests] aufgetreten sind."

Another example are gatekeepers whose role was meant to share, generate and transmit knowledge. Some GK fulfilled this role very well. However, there are indications that relevant knowledge has not always reached all members of the team. In addition, creation of new knowledge was limited to a subset of actors only.

Ensure that each actor empathizes with her or his role and that each key character is involved: Rearrange or exchange actors, if necessary.

In general, networks generated spontaneously by incentives like funding risk of staying a plunder community, as pointed out by the PP:

"*Often, there is interest in using these funds and not in following the motto: Where is my problem? What are the solutions? And how can I get started? It is more a top-down approach.*"[1]

The motto is rather: Make the job as described by the funder, take the money and move on. Often, actors move on without doing lessons learnt involving key actors, as described by one EP:

"*There were no reflections. Actually, everyone was happy to deliver papers in time and to be conform with work packages and pre-defined project scope, so that one could say with a clear conscience: It was worth it supporting us with money."*[2]

Thus, a main challenge in networking is to take off the blinkers (pre-defined project scope) put on by funder like BMBF. Blinker are highly efficient for keeping focus on one specific work package – keeping on track, as demonstrated by the successful fulfillment of milestones. Therefore, employees of larger firms tend to use blinker quite frequently, because their incentives are usually related to some

[1] „Da ist oftmals das Interesse, diese Fördermittel zu nutzen und nicht nach dem Motto: Wo liegt mein Problem? Was gibt es für Lösungen? Und wie kann ich da loslegen? Eher ein Top-down Approach."

[2] „Es gab keine Reflektionen. Eigentlich war jeder froh, dass er seine Arbeitspapiere fristgerecht abgeliefert hat, dass man formell den ganzen Arbeitspaketen und dem vordefinierten Projektumfang entsprochen hat. Und dass man mit gutem Gewissen sagen kann: Das Geld war es schon wert, dass Ihr [BMBF] uns unterstützt habt."

selected milestones. However, in innovation networking activities, blinkers are not appropriate: Wearing blinkers does not allow consideration of the whole environment. If the overall goal is to improve friendliness of innovation environments, then not only a part of the environment should be considered, but 360°: It is important to ask what innovators really need, apart from pre-defined work packages. In spontaneous plunder communities, this is difficult, as explained by PP:

"*They [actors] won't do it, because generally they are so much trapped in research that they at first try to fulfill work packages associated with funding*."[1]

Retrospectives of innovators showed e.g. that technology transfer / selling is a significant hurdle. This was also because identification of partners took mainly place in Germany. Technology transfer in and beyond Germany is therefore an unmet need. An EP mentioned that a technical design review or process review could be helpful for some actors. This is difficult since innovators demonstrated to be closed with respect to internal knowledge. Here, network MD faced its border, demonstrating that this activity must be transferred to a trustful environment, such as an exclusive cluster like MicroTEC Südwest, Baden-Württemberg, Germany. Some MD innovators are already in transition.

One further example for negative effects of wearing blinker was a project running nearly in parallel to MD, namely DIA-LOC. DIA-LOC was a multidisciplinary project that focused on the implementation of mobile diagnostics by evaluating socioeconomic factors. Even if these initiatives were strategically meant to run separately, it would have been valuable for MD actors to benefit from knowledge generated in DIA-LOC and *vice versa*. These cross-networking activities can empower innovator.

Remove blinkers and use synergies with other networks for allowing creation of a larger collective intelligence: Find the path via 360°

[1] „Das machen sie [Akteure] nicht, weil sie dann meistens in der Förderung so gefangen sind, dass sie dann erst mal daran arbeiten, die Vorgaben, die mit der Förderung verbunden sind, dann umzusetzen."

Who Cares?

Insights out of MD's dizygotic twin DIA-LOC would have been interesting for MD actors, since market-related hurdles turned out to be highest, as stressed out by an EP:

"*The problem is really reimbursement. Reimbursement is the highest hurdle*."[1]

Within MD, activities in this field were imbalanced when compared to standardization of near patient testing. Best practices for health technology assessments are an unmet need.

Demonstrate value added by mobile diagnostics, thereby overcoming main barriers in healthcare innovation: Market access and performance stigma

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George Harry Heilmeier who was director of (D) ARPA in the seventies proposed a set of questions – known as Heilmeier Catechism – to be answered by the team (Carleton et al., 2013, p. 227). Here, one question is highlighted:

Who cares? If you're successful, what difference will it make?

This answer may be easily answered as follows: Mobile diagnostics in rural settings empower clinicians and nurses and add value to patients by maintaining high standard healthcare in a cost-efficient manner – not only in Germany, but globally.

Although the answer may be convincing, value added needs to be demonstrated. In addition, as proposed by SFM, this vision needs to be communicated to guide future activities, involving long-term collaboration of multidisciplinary teams. Long-term collaboration can e.g. involve merging of DIA-LOC experts with MD EP.

[1] „Das Problem ist wirklich Abrechnung. Die Abrechnung ist die größte Hürde."

Pathfinding by Networking

Implementation of novel mobile diagnostics require intensive change management. Success of diffusion of innovation strongly depends on I) relative advantage, II) compatibility, III) complexity, IV) trialability, and V) observability. Characteristics II to IV can be covered quite easily, whereas I and V cannot be demonstrated easily: How to demonstrate superiority and impact of mobile diagnostics?

Near patient testing is already widely used. However, it is still restricted to a limited set of parameter, including cardiac marker, blood glucose, and blood gas analysis. Emerging lab-on-a-chip technologies broadening the menu of test parameter, by contrast, are associated with higher costs per result as compared to established classical point-of-care parameter mentioned above. Therefore, reimbursement is not an easy pathway — at least in Germany, as pointed out by the market access promoter (MP):

"*Now, an additional hurdle for point-of-care has been set by contractual partners: Now, a point-of-care test has to demonstrate that e.g. a faster turnaround time has an added value as compared to standard laboratory testing*".[1]

[1] „Da wurde jetzt noch mal eine zusätzliche Hürde für Point-of-Care von den Vertragspartnern aufgemacht: Dass jetzt ein Point-of-Care Test nachweisen muss, dass eine schnellere Turnaround Time, zum Beispiel, einen so genannten in Anführungsstrichen Zusatznutzen gegenüber dem normalen Labor Test hat."

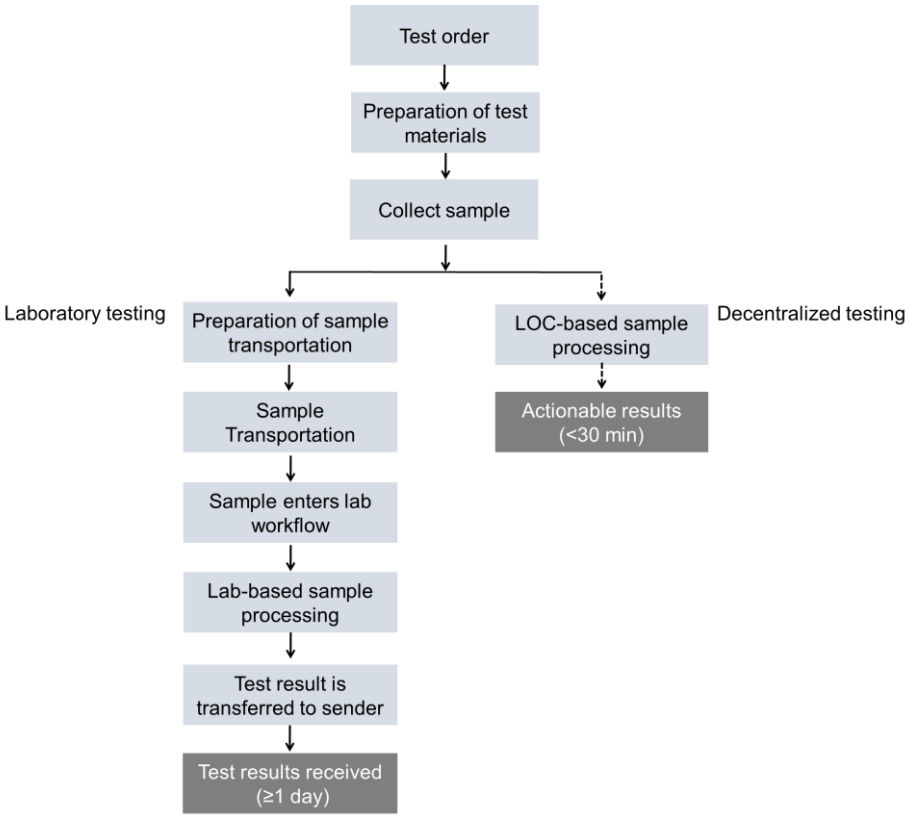

Figure 17 Centralized versus decentralized testing. Adapted from: Larsson, Greig-Pylypczuk and Huisman, 2015, p. 2
Abbreviations: Lab, laboratory; LOC, lab-on-a-chip

If this value added cannot be demonstrated, then the case is rejected. Game over. In this case, return on investment is only possible, if innovators were able to break the value/cost trade-off. As presented in Figure 17, time-to-result can be significantly reduced by a near patient test (right workflow). In case of severe illness like sepsis, every minute counts. However, if results are inactionable, because data generation was not quality controlled and reliable, then these cannot be used to support clinical decision making. Users of next generation mobile diagnostics (e.g. nurses) often do not have a technical background. Even though devices are designed for highest ease-of-use, mistakes in handling can occur. This can also involve sample handling (e.g. loading of sample material onto the cartridge). Thus, next to cost-efficiency, near patient testing must meet quality standards for laboratory testing in healthcare (in Germany defined by *RiliBÄK*), as added by MP:

“In this context, *point-of-care is a little bit difficult at the moment, because point-of-care or mobile diagnostics are relatively under attack from each side, including*

RiliBÄK. […] Supervisory authorities share the opinion that staff [professional users, such as nurses] are not sufficiently educated."[1]

One measure to ensure sufficient education in handling near patient instant diagnostics is to further reduce potential sources of error in handling by superior usability design (e.g. intelligent devices: voice guidance next to visual workflow guidance and more quality checkpoints within the device). A measure initiated my MD innovators is a best practice guide for implementation of MD, including user training. This will be available in 2017 and shows that innovators – in this case a multidisciplinary team consisting of users as well as legal, training, standardization, and industry experts – maneuver change by efficient networking.

Regarding MD reimbursement situation, there is a little light at the end of the tunnel: Some test parameters are expected to have lower reimbursement hurdles, namely fast diagnostics used to combat infections with resistant bacteria. It is assumed that accurate fast diagnostics have a significant impact on patient management. This needs to be demonstrated as well. However, the whole process is expected to be more straight forward, as the legal framework for medical supply in Germany has been renewed very recently. In this context, rapid diagnostics used as companion diagnostics for guiding treatment with antibiotics are included, as empathized by MP:

"*The remarkable point is there that fast diagnostics – they did not explicitly write point-of-care, but fast diagnostics – are included there to combat antibiotic resistances more efficiently*."[2]

In January 2017, one German health insurer *cares* and started a pilot, where impact of established near patient rapid tests in decreasing subscription rates of antibiotics is evaluated as pilot in a selected region.

[1] Von daher ist leider bei Point-of-Care gerade ein bisschen schwierig, weil Point-of-Care oder Mobile Diagnostik gerade von allen Seiten relativ angegangen wird, auch bei der RiliBÄK. […] Die Überwachungsbehörden sind der Meinung, dass das Personal [professionelle Anwender wie Schwestern] nicht gut genug ausgebildet ist.

[2] „Dort ist das Besondere, das schnelle Diagnostik – die haben nicht explizit Point-of-Care geschrieben, aber die Schnelle Labordiagnostik -- wird dort benannt, um Antibiotika Resistenzen wirksamer bekämpfen zu können."

These steps need to be triggered actively, e.g. via the German Association of Diagnostics Industry (VDGH). In case of mobile diagnostics, network-based activities such as those initiated within MD can help to push these technologies forward, e.g. in analogy to *Luftfahrtcluster (Aviation Cluster) Hamburg* as confirmed by the PP:

"*A lot of cluster and networks do lobbying — especially when a critical mass is reached*".[1]

However, requirement would not only be consensus on goals, but active instead of passive networking, as observed for some MD actors.

Networking can help to strengthen the voice of start-ups and SME: If there is no voice, no vision — who cares *at all?*

Michael E. Porter outlined the path towards value based healthcare within integrated practice units (IPU). Within IPU healthcare is proposed to follow specific key attributes (Porter and Guth, 2012, p. 232):

- *Organized around the patient medical condition or set of closely related conditions*
- *Involves a dedicated, multidisciplinary team that devotes a significant portion of its time to the condition*
- *Providers involved are members of or affiliated with a common organizational unit*
- *Provides the full cycle of care for the condition*
- *Encompassing outpatient, inpatient, and rehabilitative care as well as supportive services (e.g. nutrition, social work, behavioral health)*
- *Includes patient education, engagement, and follow-up*
- *Utilizes a single administrative and scheduling structure*
- *Co-located in dedicated facilities*

[1] „Lobby Arbeit machen viele Cluster und Netzwerke – vor allen Dingen, wenn sie eine kritische Masse haben."

- *Led by a physician team captain and a care manager who oversee each patient's care process*
- *Meets formally and informally on a regular basis*
- ***Measures outcomes, costs, and processes for each patient using a common information platform***
- *Accepts joint accountability for outcomes and costs*

To understand and improve value in healthcare, outcome must be measured and readily available in an information platform that can be ideally assessed by both patient and healthcare providers. Mobile diagnostics can help to support measurement of outcome. However, the key attribute highlighted in bold demonstrates that MD does not terminate with the product innovation process, as summarized by an EP:

"*Of course, one can do lobbying or something like that, but to allow establishment of a product innovation like a mobile diagnostic system and to take maximum advantage of it requires system innovation / structural innovation as a next step. Something like really the realization of integrated care, which still does not work in Germany. […] For us, this is one key outcome of this [MD] and of many other projects, where healthcare innovations repeatedly fail in the end: They bounce off the structure of the relatively conservative system*." [1]

[1] „Man kann natürlich über Lobby oder sowas gehen, aber dass dann eigentlich auch im Anschluss damit so eine Produktinnovation wie ein mobiles Diagnostiksystem, damit es sich wirklich etablieren kann und damit es maximal genutzt werden kann, dass man da eigentlich auch im nächsten Schritt Systeminnovationen bräuchte / Strukturinnovationen. So was wie wirklich die Realisierung der integrierten Versorgung, die nach wie vor nicht klappt in Deutschland. […] das ist für uns auch ein zentrales Ergebnis aus diesem [MD] und auch aus vielen anderen Projekten, an dem Gesundheitsinnovationen immer wieder scheitern letztendlich: Sie prallen ein bisschen an den Strukturen des doch relativ starren Systems ab."

5 Discussion and Conclusion

Initiative Mobile Diagnostics (MD) was arranged around pre-selected barriers expected to be relevant in healthcare innovation of mobile diagnostic systems in Germany. It is important to note that mobile diagnostics are not only helpful in supporting immediate clinical decision making in acute care, but can also help to improve management of chronical diseases by superior continuous digital monitoring. This allows a transformation from reactive to proactive management of individuals, as intervention and prevention is expected to merge (Kost et al., 2015). Digitalization is expected to support this move by empowering patients and by generating new business models around health information technologies.

The global *in vitro* diagnostics market is estimated to amount to US$ 48 billion in 2016 (A.T. Kearney, 2013, 7): Near patient (point-of-care) testing represents roughly a forth of it (CAGR[1], 8%); main drivers are the Americas, EMEA[2], and APAC[3] with a split of 50%, 32%, and 18%, respectively. An important emerging market for near patient testing is China (CAGR[1], >10%), with large rural areas in the West of the country. Expected market size and growth opportunities show that MD can represent a significant growth driver for Germany's high-tech industry: Microsystem technology can balance the strong automotive sector. And even firms highly active in the automotive sector may identify mobile diagnostics as new business opportunity, such as Bosch (Germany). In the latter case, it can be a benefit to use synergies within production capabilities or to transfer know-how from system integration, connection and monitoring to this emerging field.

Nevertheless, the multidisciplinary development approach needed for mobile diagnostics is a challenge. The Bill and Melinda Gates foundation (BMGF) took this challenge and sponsored innovators who integrate systems for low and middle income countries. Targeted disease areas involve particularly Malaria, TB, and HIV. In 2013, point-of-care diagnostics firm Alere received roughly each 20 million US dollar grant and low-interest subordinate loan, respectively. The loan was predominantly for upscaling of the production line, allowing reduction of cost of goods sold to a minimum. Although grants from BMGF and other sponsors helped

[1] CAGR: Compound Annual Growth Rate 2010 − 2020
[2] EMEA: Europe, Middle East, and Africa
[3] APAC: Asia Pacific

to narrow the existing gap in technology, affordable and broadly available diagnostics are still an unmet need in resource limited settings and rural areas of more developed regions in the world.

Recently, expert promoters in Global Health presented results from a special online platform used for discussing and solving this unmet need (Engel et al., 2016): Global Health Delivery Project (GHD) at Harvard University[1]. GDH was given birth by a team around Michael E. Porter in 2007. It is meant to support maneuvering change in healthcare by using collective intelligence of global networkers. The discussion on better access to diagnostics involved 12 expert moderators, including Jim Gallarda from BMGF. Aim of the session was to find new paths to better address universal challenges. None of MD expert promoter or gatekeeper participated. Now, one could argue that MD networking is restricted to Germany with an already high standard in healthcare, whereas the discussion on GDH focused and focuses on LIMIC[2]. Nevertheless, findings of the GHD-based session showed that barriers for broader implementation of diagnostics are similar around the world (Engel et al., 2016, p. 1):

"Innovation processes need to also include end-users and service innovations, the local evidence base needs to be expanded, and guidelines and evaluation processes need to be harmonized".

Service innovation involves the need for new business models. Thus, MD can be either disruptive or radical as may be irritating in Table 1: Disruptive MD (lab-on-a-chip) can "just" replace laboratory testing[3], whereas radical MD allow broader distribution by e.g. breaking the value-cost trade-off, being connected, and allowing service remote control. With respect to an envisioned broader distribution, MD innovators should not only focus on a single country: Germany alone would not ensure return on investment, which may be a factor of 10 higher than the about 5 million Euro available for some larger MD projects. This is another reason why it would make sense to engage not only in local networking, but to broader the horizon.

[1] http://www.ghdonline.org/ (accessed online on February 22, 2017); >19,000 members from 185 countries

[2] Low and middle income countries

[3] E.g. in the hospital and on weekends, where running a lab test would be too inefficient

From these global perspectives and activities back to Germany and its high-tech strategy: Main question of this thesis was whether network MD had a sustainable impact on healthcare innovation in Germany. This question was answered by the help of retrospectives of MD actors: MD had and still has an impact on healthcare innovation in Germany. However, the work is not done, as pointed out by one GK:

"Innovation management is something that I position long-term. […] That's hard work: Innovation management."[1]

In fact, initiative MD tried to address findings of the GDH-based discussion by integrating end-users from the beginning into the innovation process. However, even though harmonization of MD development and testing was done or is still ongoing, standardization of MD evaluation is still open. In addition, activities were focused on Germany as funding was provided by BMBF. Generated knowledge in form of written paper is only available in German language, except for the Roadmap (2015). Although the latter is termed "German" standardization roadmap for mobile diagnostic systems it may be a basis for a global one, if networking goes beyond Germany. More global networking in case of MD would help to flatten the spikes we are facing in healthcare. It may be helpful as well, if corporate innovators do not only get attractive incentives from the government for reduced carbon dioxide footprints, but also for increased global health footprints. Upscaling of production can help to provide cost-efficient diagnostics in the home country.

As mentioned above, a main remaining external barrier is reimbursement. To justify a potentially higher pricing in case of near patient testing, it is mandatory to demonstrate added value or according to Michael E. Porter (2010, p. 2477): That "health outcomes achieved per dollar spent" are higher compared to standard laboratory testing. Although this may sound intuitive, it is difficult to target, because a lot of tacit knowledge is involved. This tacit knowledge makes health technology assessment debatable and susceptible for destructive opponents.

Thus, cost-benefit analyses often lack of quantity and/or quality of studies, representing a poor basis for decision making. This was exemplified by selected

[1] "Innovationsmanagement, das ist was, was ich langfristig ansetze. […] Das ist harte Arbeit: Innovationsmanagement."

healthcare “innovations” evaluated in a report of Bratan and Wydra (2013, p. 140): In many cases, diffusion of innovation is not in line with its benefit/cost ratio, resulting in e.g. increasing costs, inefficient use or unexploited benefit in healthcare. Consequently, MD innovators have to focus early on applications allowing demonstration of a high benefit/cost ratio.

A current example and unmet need is fast detection of antimicrobial resistances (AMR): High benefit/cost ratio, e.g. by preventing shutting down of operating rooms due to contamination or in the worst case death of a patient. Another benefit beyond hospitals would be control of over-use of antibiotics in physician office labs. If the need is severe enough, then political decision makers seem to be more open towards rapid diagnostics. In this case, a higher willingness-to-innovate has also been observed in health insurer. This is exemplified by a German pilot targeting over-use of antibiotics by rapid test-guided clinical decision making.

In initiative MD, knowledge transfer and generation was used to address limitations in diffusion of innovation, including market access. Notably, not only SME experience difficulties in gaining reimbursement, as confirmed by a market access expert (MP):

“[…] *We recognize that even for larger firms there is always need for this extreme complex reimbursement system that we unfortunately have in Germany – in the first place to be able to find orientation in this jungle*.”[1]

Although larger companies face challenges in market access as well, they have more resources or a broader product portfolio that is used to bundle MD e.g. with therapeutic agents, as mentioned by an external actor (XT):

[1] “[…] Da merken wir, auch bei etwas größeren Firmen, dass da immer Bedarf ist für diese extrem komplexe Vergütungssystematik, die wir in Deutschland ja leider auch haben – überhaupt erst mal diesen Dschungel durchblicken zu können”

"*The example – the mobile diagnostic system just mentioned – is launched against the backdrop that it improves diagnosis of a disease for which the manufacturer provides already, shall we say, the most widely distributed, the most widely used therapeutic agent*."[1]

This shows that larger player are more flexible with respect to value demonstration and business model innovation. Innovation networks can compensate for this disadvantage of smaller firms. For example, integration of expert promoter was highly valuable as most participating firms cannot afford to arrange an advisory panel accompanying the innovation process.

Nevertheless, it was observed that not all MD actors were engaged in the activities driven by expert promoters. For some gatekeepers, networking was even terminated or significantly reduced after official termination of MD. Retrospectively, the advantages of innovation networking seemed to be more evident, as reflected by a GK:

"*Definitely, we should have used knowledge generation by expert promoters more intensively. It was a poor relation. And actually it was an essential part, because some of the conversations and presentations were more innovative, to my mind*."[2]

For better engagement and successful innovation networking, according to the process promoter it is important that...

"[…] *key actors involved from the beginning identify the topics. Here, innovation management can play a role, but it doesn't have to. […] It [product or process innovation] happens most frequently, when networks have been generated bottom-up, when actors came together, saying: We want to do something together, no matter, if there is funding or not*."[3]

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[1] „Das Beispiel dafür – das Mobile Diagnostik System, von dem ich gerade sprach – wird eigentlich vor allem vor dem Hintergrund lanciert, dass es die Diagnostik für eine Erkrankung verbessert, für das der Hersteller das bereits, sagen wir mal, das am weitverbreitetste, meist genutzte Medikament zur Verfügung stellt."

[2] "Begleitforschung definitiv, die hätten wir mehr nutzen müssen. Die war ein Stiefkind. Und eigentlich war es ein essenzieller Teil, weil da, denke ich, manches war innovativer, was da geredet wurde und präsentiert wurde."

[3] "[dass] die Kernakteure, die am Anfang dabei sind, die Themen identifizieren. Da kann Innovation eine Rolle spielen, sie muss nicht. […] Es [Produkt- oder Prozessinnovation] kommt gerade

Thus, future activities have to allow freedom-to-operate and ideas coming bottom-up. Like in case of the GDH-based discussion: Interested people met easily online ─ without the need for traveling ─ and then knowledge generation started as supported by a set of expert moderators. The outcome may be similar to preset barriers in MD, however, its “theirs”, which is a good basis for successful implementation of solutions proposed. In case of MD, some gatekeepers were obviously relatively occupied with administration, financial affairs, and/or technology transfer. In this respect, it is evident that before further addressing above mentioned external barriers, internal “soft” influencers need to be tuned: Strengthen cooperation and transfer (→Figure 1).

It is reasonable to suggest that coordinators of MD may not be the best gatekeepers due to the fact that they often do not have the “leisure” for knowledge generation and transfer. In an ongoing MD networking activity, it was observed by the researcher that one external innovator was highly engaged. This person is not only active in MD-networking, but also frequently attends work-shops and congresses. In addition, this innovator is in close contact with adopters to gather information for product and service improvement. It is a person in-between marketing and R&D, that can easily transfer knowledge from one to the other side of its organization:

“*It is taken up relatively grateful – this knowledge around the market: What is the target? What do we need to consider? What do I need to be aware of? That helped us a lot. It helped us to improve things, to understand things better, to understand the user better. […] A lot of information was collected there [MD network activity], which was not easy accessible before or had a limited context*.”[1]

Obviously this person is embedded in an innovation-friendly organizational culture, which is able to balance technology-push and market-pull. The innovator added further:

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dann häufig vor, wenn Netzwerke sich wirklich von Bottom-up gebildet haben, wenn Akteure sich zusammengetan haben und sagen: Wir wollen etwas zusammen machen, ob es Förderung gibt oder nicht.”

[1] “Es wird eigentlich sehr dankbar aufgenommen, muss ich sagen. Also dieses Wissen um den Markt: woran müssen wir uns halten? Woran muss man denken? Was muss ich beachten? Das hat enorm geholfen hier. Das hat uns geholfen, Sachen zu verbessern, Sachen besser zu verstehen, den Anwender besser zu verstehen. […] Da kam viel Information, an die man vorher nicht so ohne weiteres ran kam, oder dass man so einfach in einem besseren Kontext ran kam.“

"*And what I believe is very important: To be a little bit ahead of the others; to know, what is coming up; to be able to shape; not to be overwhelmed by things*."[1]

Boundary spanning is a key soft skill of gatekeeper. It does not only help to transfer information into or out of the organization, but it also helps to reach out to individuals who serve, e.g. as power promoter. In this thesis, gatekeeper can also be understood as relationship manager. An expert manager noted:

"*That this person has these core competences is from my experience very important for the success of a consortium. And this is what founding bodies do not take care of. It is not covered in the research proposals and then it is a little bit good luck somehow, whether this person can and is willing to play the role or not.*"[2]

SME may not have the resources to train all roles needed for innovation management and for setting up a solid house of innovation. A small tent can already be sufficient in many cases. However, if there is nothing that protects initiated innovation processes against external or internal destructive opponents, then there is high risk of not being able to handle the targeted challenge successfully. Established innovation management has not been described by actors interviewed. Networks and cluster can help to close potential gaps in innovation management capabilities, as pointed out by the process promoter:

"*Regarding network and knowledge transfer, we are especially successful in case of education and training, when employees of firms are to be further developed*."[3]

Initiative MD may offer team checks in order to find out whether role playing is possible or whether actors could benefit from fine tuning, e.g. to be able to do better probing / *Buddy Checks* in case of technology transfer. The latter turned out to be still an internal barrier for several involved organization, although this topic is an "old hat". Nevertheless, data on funding of biotech start-ups are still not convincing in

[1] "Und ich denke, was auch immer ganz wichtig ist, dass man so ein bisschen vor anderen ist; dass man schon weiß, was kommt; dass man mitgestalten kann; dass man nicht so überfallen wird von Sachen."

[2] Dass die Person diese zentralen Kompetenzen hat, das ist aus meiner Erfahrung für den Erfolg von einem Konsortium enorm wichtig. Und da achten die Fördergeber nicht drauf. Das wird in den Anträgen nicht thematisiert, und dann ist es ist letztendlich so ein kleines bisschen ein Glücksfall irgendwie, ob die Person diese Rolle ausführen kann und will oder nicht.

[3] Wo wir besonders erfolgreich sind, im Prinzip, bei dem Thema Netzwerk und Wissenstransfer, ist bei der Aus- und Weiterbildung, wenn es darum geht, Arbeitskräfte, die in Firmen sind, weiter zu entwickeln.

case of Germany. According to BioCentury Online Intelligence (BCIQ), average million US dollar raised by German biotech start-ups per financing round A was seven in 2014[1] (Huggett, 2015). Globally, this result positioned Germany at place ten, with Switzerland at the top of the list[2], followed by UK. The US[3] was at 3rd position. In 2015, average series A funding of German biotech start-up was $13.5 M, but data are based on two start-ups only (Huggett, 2016). US biotech start-ups were again more successful in raising money: $1.5 billion by 67 start-ups (average was $22.1 M). In 2016, it was not surprising to see that China continued to catch up. The US was at the top of the list with 76 academic starts-up collecting in round A (Huggett, 2017). Even though Germany has roughly four times less inhabitants compared to the US, the number of three start-ups in this round is to be improved. So much for competitiveness and prosperity (→Figure 1).

Although this is only a snap shot, it may be a hint that biotech start-ups in Germany still did not gain enough momentum. Retrospectives of MD showed that technology transfer is still not easy in Germany. On the one hand, there is a lack of venture capitalists who are non-risk averse and willing to invest high amounts of money. They rather stay apart from the relatively long lead times related to biotech start-ups. On the other hand, German biotech entrepreneurs may not be very successful in raising funds. According to in-sider Steve Blank, scientific entrepreneurs are often not well prepared, when investors ask for details on customers and revenue models. Steve Blank was responsible for the US National Science Foundation (NSF) and started to further develop biotech entrepreneurs with respect to innovation selling[4] (Rathi, 2015). His main advice for his trainees is to accept that they have nothing but hypotheses that have to be challenged by customers for establishing a commercialization model.

Nearly a decade ago, in 2008, Luong and colleagues concluded (2008, p. 499):

"*The development of ideal biosensors which are fast, easy to use, specific, and inexpensive, doubtlessly, requires the significant upfront investment to support R&D efforts and this is a key challenge in the commercialization of biosensors.*

[1] Calculated on the basis of 5 rounds and a total fund of $34.4 M

[2] 5 A rounds with a total raised funding of $104.1 M

[3] 61 A rounds, resulting in $961.6 M ($17.5 M in average)

[4] Web-based publication by Akshat Rathi, September 16, 2015: Why scientists make bad entrepreneurs—and how to change that: https://qz.com/502143/why-scientists-make-bad-entrepreneurs-and-how-to-change-that/ (accessed on February 24, 2017)

To date, progress in biosensor development is somewhat incremental with low success rates and there is the absence for huge volume markets except for glucose sensors. The future trend includes the integration of biosensor technology with leading-edge integrated circuit, wireless technology and miniaturization."

Today, it is the phase of MD system integration. However, glucose measurement is still this huge volume market for near or in patient testing. It is dominated by two player, namely Abbott and Roche. Notably, it can be observed, that innovation is more radical. MD are so small that these can be implanted as in vivo sensor and the business model is changing significantly: Some insurer started to provide equipment for glucose detection on their website. Of course, physicians are integrated into this process. Reduction of administration is meant to allow more patient centered rather than administration centered approach. This maneuvered change was possible by a certain power which is definitely behind these players. One remark regarding player Abbott: End of 2015, US online publisher *STAT* presented a small device termed "MAP"[1], i.e. *Mobile Analysis Platform*, alias MD. MAP may not have been on the radar of MD innovators. Interestingly, the MAP prototype was developed within a collaboration involving Abbott and DARPA[2]. It seems to follow a more radical innovation process as the target is multiple detection of both immunological and molecular parameter in a cost-efficient manner.

Back to competitiveness: Retrospectives on MD confirmed that small firms have difficulties in finding their niche or their bigger partner or a sponsor. Further support in this field should be intensified in MD networking. However, as assumed by the process promoter: Activities of network MD are expected to continue to go down. An important next step is therefore to support or recover still existing activities and to secure knowledge generated in this field. Transfer of activities to powerful so called "top" cluster and networks would be one measure to circumvent loss of knowledge generated. One AD had the impression that…

[1] https://www.statnews.com/2015/11/24/darpa-biotech-infectious-disease/ (accessed on February 24, 2017)

[2] Defense Advanced Research Projects Agency

"*Everyone was focused on the individual work package. To make this project together successful in the end, someone would have been needed who oversees the whole picture and who takes care of it*."[1]

With respect to the holistic approach needed to drive innovation in this field, it is obvious that this thesis has several limitations. First of all, not all multidisciplinary innovators were included for generating the retrospective: For example only six gatekeepers were involved, which is about the half, since 11 projects participated. A general conclusion is therefore not possible. A major weakness is that interviews were performed about one and a half year after termination of MD. Some interview partners had difficulties in recovering all relevant information. This was most evident in case of power promoter who were more distant actors in MD – maybe too far away from the activities. Consequently, insights directly related to the particular project were limited or even absent in power promoter. Nevertheless, there was evidence that at least in case of gatekeepers, interviews may be helpful to reconsider ongoing or follow-up projects in the field of MD.

Due to the time lag, it is reasonable to assume that only remarkable information was transferred within interviews, whereas nuances were difficult to recover. Retrospectives should be included in all projects immediately in order to adjust maneuvering of change efficiently. This thesis shows that a delayed retrospective may not help to save and transfer all knowledge generated in time. Furthermore, retrospectives are best, when performed by a person not involved in MD. This is not the case for this thesis: The researcher was involved – at least to a certain degree – and brings a bias into qualitative data analyses. Even though the researcher tried to evaluate the case objectively, several subjective elements were introduced.

One example is the choice of the interview partner: It was not randomized and included mainly MD actors who were related to the researcher. Only some partner were not familiar with the interviewer. In this case, another bias may be introduced as semi-structured qualitative analyses are influenced by the level of trust. This is a disadvantage of qualitative studies which are also limited by the fact that

[1] „Jeder hat eigentlich bloß auf seine eigene Aufgabe geschaut, und um das Projekt dann hinterher zusammen erfolgreich zu machen, hätte es jemanden bedurft, der das Ganze sieht und das Ganze in die Hand nimmt."

generalization is difficult or not possible. Although the researcher tried to create a trustful atmosphere, it was observed in case of few specific questions that more distant partners tended to behave not as open as closely related actors. In addition, it has to be noted that nearly all interviews were performed via telephone, where trust may not be installed easily. However, in telephone interviews it can be expected that interviewees more likely forget that conversations are being recorded to ensure quality.

Despite these limitations, this thesis was able to highlight major remaining challenges. Notably, these are not only external barriers as knowledge generated within initiative *Mobile Diagnostics* already had a slight impact on healthcare innovation in Germany. For example, MD helped actors to better address regulatory barriers and standardization of MD development and implementation. Moreover, networking created awareness and onboarded external innovators who continue to drive activities. However, a significant external barrier remains: Reimbursement by standardized technology evaluation. Next to this external barrier, internal hurdles were identified which should be addressed before expanding activities or launching new initiatives. For strengthening of networking and transfer, the following key lessons learnt may be taken into account:

- Address both “hard” (e.g. technology, regulatory) and “soft” barriers (e.g. willingness-to-innovate, bridging)
- Ensure that each actor empathizes with her or his role and that each key character is involved: Rearrange or exchange actors, if necessary.
- Remove blinkers and use synergies with other networks or initiatives for allowing creation of a larger collective intelligence: Find the path via 360°
- Include a “Hard Test” (e.g. the DARPA[1] one) into the innovation process
- Use networking to create a clear vision that makes important stakeholder care, including user and power promoter / financiers

[1] Referring to the Stanford University Foresight Model, SFM (2013).

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Attachment

Template Informed Consent

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Einverständniserklärung zur Erhebung und Verarbeitung von Interviewdaten[1]

Forschungsprojekt (Thesis):	"Mobile diagnostics": A network based approach to innovate German healthcare
Durchführende Organisation:	HFU Hochschule Furtwangen University
Projektleitung:	Prof. Dr. Eva Kirner
Interviewerin:	Dr. Merle Hanke
Interviewdatum:	13.12.2016

Beschreibung des Forschungsprojekts (zutreffendes bitte ankreuzen):

☐ Schriftlich ☐ Mündlich

Mir wurde erklärt, dass meine Interviewaussagen im genannten Forschungsprojekt mit einem Aufnahmegerät aufgezeichnet und von der Interviewerin in Schriftform gebracht werden. Für weitere wissenschaftliche Auswertung des Interviewtextes werden alle Angaben, die zu meiner Identifizierung führen könnten, verändert oder aus dem Text entfernt. Mir wird versichert, dass meine Interviewaussagen in wissenschaftlichen Veröffentlichungen nur in Ausschnitten zitiert werden. Das bedeutet, dass das gesamte Interview nicht veröffentlicht werden darf. Damit soll erreicht werden, dass ich auch durch die Reihenfolge und Kombination meiner erzählten Ereignisse im gesamten Interview nicht für Dritte erkennbar sein werde.

Mir ist bewusst, dass die Teilnahme am Interview freiwillig ist und ich mein Einverständnis dazu jederzeit ohne Begründung und ohne Nachteile zurückziehen kann. Ebenso kann ich einer Speicherung meiner Daten jederzeit widersprechen und deren Löschung verlangen.

Ich bin damit einverstanden, im besprochenen Forschungsprojekt ein Interview zu geben.

☐ Ja ☐ Nein

Vorname, Nachname in Druckschrift	Ort, Datum, Unterschrift

[1] Angepasst nach: Mustervorlage des Projekts Qualiservice, Universität Bremen, August 2016

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Attestation of Authorship

I hereby certify this thesis is my own work and contains no material that has been submitted previously, in whole or in part, in respect of any other academic award or any other degree. To the best of my knowledge all used sources, information and quotations are referenced as such.

Merle Hanke