New-Normal Market Entry Mode for Pharmaceuticals: An Internet of Things (IoT) Market Entry Framework Stemming from COVID-19 Priporas, C.V. and Vellore-Nagarajan, D.

Abstract

Purpose: To determine new-normal uncertainty considerations stemming from the covid-19 pandemic to consider within transaction-cost analysis for pharmaceuticals. To propose new-normal market entry strategies to address the uncertainty as a result of covid-19's implications and provide for lack of knowledge and information in an uncertain business environment by way of Internet of Things (IoT) ecosystem for pharmaceutical market entry.

Methodology: In this paper, we focus on the uncertainty facet within transaction-cost analysis consideration and utilise a descriptive three-case study approach taking in Johnson and Johnson (J&J), GlaxoSmithKline (GSK) and Novartis to present an ADO (Antecedent-Decisions-Outcomes) understanding of their usual market entry approach, the approach undertaken during the pandemic and the outcomes thereafter facilitating new-normal uncertainty considerations to factor in. Further with this insight, we develop a conceptual framework addressing the transaction-cost analysis implications of uncertainties toward lack of knowledge and information for new-normal market entry approach and operating strategy for pharmaceuticals applicable due to IoT (Internet of Things).

Findings: Uncertainty (external and internal) is different now in the new-normal business environment for pharmaceuticals and boils down to acute shortage of knowledge and information impact to make an appropriately informed decision. Therefore, considering the changed factors to consider, pharmaceuticals need to be able to undertake market entry with vaccines and medicines by way of IoT thereby enabling, the filling of the gap via real-time data access and sharing including enhancing predictive analysis for sustenance.

Originality: It is the first study to our knowledge that throws light on transaction-cost analysis theory's uncertainty facet for pharmaceuticals. It is also the first study that provides new-normal market entry strategy for pharmaceutical companies built on interoperability of real-time IoT.

Keywords: New-normal Market Uncertainties, Pharmaceutical Market Entry Processes, COVID-19, IoT (Internet of Things) Pharmaceutical Framework, Transaction-Cost Analysis Theory, Lack of Knowledge, and Information Impact.

Introduction

Literature indicates that when operating domestically firms face uncertainties related to supply of product (such as quality, quantity, and performance of the product) or changes in technology, consumer preference and so on (Pore, 2018), whereas in international operations firms face additional uncertainties related to host country environment and the ability to enforce contracts (Bylund, 2021; Li et al., 2021; Spiller, 2010; Tan and Zhao, 2019). Firms are better off selecting non-equity or low-investment mode in countries with high environmental uncertainty (Anderson and Gatignon, 1986; Buckley and Casson, 1998, 2019), as this gives them flexibility to change partners or exit the market, if needed (Pore, 2018). However, certain environmental factors are beyond any organisation's control retracting them to employ usual methods or catching them off-guard such that improvisation is key (Verbeke and Faribozi, 2019). One such event is the covid-19 pandemic. Particularly, pharmaceuticals whilst being centre stage in fighting the pandemic, also have increased pressures on how to operate, what to factor in, what to provide for, and how best to capture the first advantage whilst ensuring quality control and patient compliance. So far, although transaction-cost analysis as a market entry theory has seen coverage in literature, it has not been adequately covered within the pharmaceutical industry. There is a dearth of studies factoring in transaction cost analysis (TCA) within the pharmaceutical industry (Araja and Sumilo, 2020; Experfy, 2021; Javalgi and Wright, 2003; Zhao et al., 2020; Smarta, 2008).

Moreover, the uncertainty facet of transaction-cost analysis theory has also not been adequately covered from a pandemic and new-normal factors' perspective, given the changing times. Specifically, the facet of lack of knowledge and lack of information impact to inform market entry mode – approach, requirements, firm types, and final success orientation which will be the focus of this paper. According to Madhok (1996), TCA is a static approach and does not consider issues pertinent to firm capabilities. According to Porter (1980), entry mode decision must go beyond the analysis of costs and investment requirements and must consider the broader strategic issues of integration versus use of market transactions (Hennart, 2019). Contemporary literature also suggests that there is a dearth of the dynamism of changing factors in the theory and most importantly the uncertainties' implications to market-entry decision-making (Buckley and Casson, 2019; Cuypers *et al.*, 2021; Li and Fang, 2022; Hara, 2020; Tzempelikos and Kooli, 2018; You *et al.*, 2021). According to TCA, external factors drive a firm's structure; Murray and Kotabe (1999) argue that external environment would influence

the mode of sourcing of services/collaboration. If this is the case, then how should pharmaceuticals operate in a pandemic new-normal context?

In this regard, digitalisation within which specifically the IoT (Internet of Things) in recent times has been seen to enable low-barrier market entry in a variety of technology intensive sectors such as nanotechnology, mobile phones and slowly starting off in healthcare (Asefi, 2020; Businesswire, 2021; Broring, 2020; Gong and Ribiere, 2021; Hennart, 2019; Narula et al., 2019; Park, 2020). Interoperability ecosystems wholly built on IoT for the sectors have been set up, enhancing how products and services have entered markets. For example, "interoperability lets developers/providers create applications by combining data from multiple platforms (for example, parking information from various smart-city platforms). Also, platforms enabled via IoT sensors from multiple domains can then be combined—for example, a wearables platform with a smart-home platform or RFID tags and growing evolving environment in relation to the medicines. The interoperating ecosystem will thus combine multiple sensors' data and work on top of a smart-city platform in Berlin, Barcelona, and London whilst at work with few changes in BRIC countries, enabling one time product and service entry" (Broring, 2020). The storage of data in the cloud, the pace of constant patient interaction (for pharmaceuticals) and immediate constant real-time changes as development happens, has the ability to enhance-quality control, patient compliance, faster specific winning drug development and release and easy one-time market entry into multiple market segments (Aggarwal, 2019; Cheng et al., 2017).

The insights above, and the understanding arrived at as a result of searching for contemporary models of pharmaceutical market-entry which led to not being able to retrieve more recent pharmaceutical market entry modes' literature highlight that market entry within pharmaceuticals has not been studied from the changing angle in the recent past. These factors including the understanding of how the pandemic has affected pharmaceuticals (Grangeia *et al.*, 2020) warrant further the premise of this paper.

This paper essentially provides the following contributions and thus fills the following gaps. First, we provide a conceptualisation that brings in market entry considerations, factors undertaken by conglomerates in one study and in one specific context – i.e., the pandemic. Thus we fill the gap of delineating how transaction-cost analysis' uncertainty considerations for pharmaceuticals have changed due to pandemic effects, resulting in differential market-entry modes consideration in relation to TCA's uncertainty factors of growth for pharmaceuticals. Particularly, we exemplify via a three-case approach of leading

pharmaceutical conglomerates, an ADO (Antecedents-Decisions-Outcomes) insight which highlights the shortcomings in terms of market entry models of pharmaceuticals for both developed and emerging economies as a result of COVID-19. Thus, providing insight of the variability of factors, and what uncertainty factors hereafter have to be considered for a new-normal business environment for pharmaceuticals within TCA. Second, we provide a conceptual framework developed by way of Internet of Things (IoT) on how companies can tackle the new-normal considerations which otherwise cause lack of knowledge and information and can be empowered to enter a market fully informed, and with ample ability to adapt. Till now, there has been a dearth of pharmaceutical market-entry frameworks, utilising the digitalisation (Narula *et al.*, 2019) specificity of IoT due to its complexity and we thus fill this gap of literature.

Contextual Overview

International Pharmaceutical Industry

Specifically for the pharmaceutical industry, there is increasing competition at the global scale and with the growing impact of AI (Artificial Intelligence) and IoT (Internet of Things), that drives understanding of medicines, there is an increased pressure to improve market entry models to combat with the new changes specifically that has been brought in by the pandemic (Grangeia *et al.*, 2020). Extant literature indicates that these afore-mentioned areas have implications for quality and operational performance of products (Khoberle and Schiemenz, 2017; Ohage *et al.*, 2016; Narula *et al.*, 2019; Rantanen and Khisnat, 2015) and thereby pharmaceutical companies' expansion. Furthermore, the 'time to market', 'product quality', 'regulatory compliance', 'cost reduction' and 'international product life cycle time' are all concerns that must be re-thought and addressed to benefit the industry and be in line with the requirement of times and consumer behavioural changes (Grangeia *et al.*, 2020; Yu and Kopcha, 2017).

The pharmaceutical industry, therefore, is undergoing an accelerated forced structural and operational change not only driven by the above-mentioned technology and societal changes, sudden pandemic changes (Grangeia *et al.*, 2020), but also due to being pushed by the regulatory authorities to accept novel approaches that can secure higher quality and safety standards whilst enabling dominance and international acceptance of medicines across borders (Yu and Kopcha, 2017).

Market Entry Models for Pharmaceuticals

Market entry models in pharmaceuticals have mainly been studied as cases of ownership models (Newham et al., 2019), cases explained by way of utilising internationalisation theory (Frank et al., 2021; Anderson and Gattignon, 1986; Teramae et al., 2020), transaction and cost theory (Brouthers and Brouthers, 2003; Meyer, 2001), resourcebased theories and organisational capability theories (Meyer and Estrin, 2001; Wrona and Traczinski, 2012). However, there is a dearth of studies that match the same context, the same influential factors and that propose to understand the various entry models undertaken in one given context by pharmaceutical conglomerates and the issues faced therein (Araja and Sumilo, 2020; Experfy, 2021; Javalgi and Wright, 2003; Smarta, 2008). Specifically, also a pandemic context. This paper will then essentially be the first to fill this gap. Furthermore, with shift to niche busters as drug treatments (Tannoury and Attieh, 2017; Teramae et al., 2020), the necessity to better understand the changing dynamics, resulting in a shift in factors to be considered and where they have fallen short via real-life case examples of market entries undertaken by pharmaceutical conglomerates in this pandemic, will provide for better understanding of how market entry models for pharmaceuticals ought to change and operate in a new-normal context.

COVID-19's Impact on Pharmaceuticals

In the case of covid-19 and pharmaceuticals, there has been so far to our knowledge a paucity of studies that explicate the impact of covid-19 on market entry models for pharmaceuticals. However, market entry models are bound to change in such a time of uncertainty, shortage, changing need and rapid dynamism. As per the Airfinity data set, as of February 2021, for therapeutics there are around 60 production and joint venture transactions. For instance, the following organisations below:

• Eli Lilly and Company (Lilly) and the Bill and Melinda Gates Foundation have gone into an agreement to work with admittance to future Lilly restorative antibodies being worked on for the prediction and treatment of COVID-19, to help low-income countries (Lilly, 2021).

• Gilead Sciences has gone into a partnership with 9 generic medicines producers to additionally extend supply of Remdesivir to 127 nations that address virtually all low-income countries. Additionally, Gilead has extended its worldwide organisation and manufacturing

locations, by collaborating with multiple industry leaders, including Pfizer to make and supply Remdesivir (Gilead Sciences, 2021).

• Merck KGaA, IAVI, and Serum Institute of India (SSI) are working together to create and produce a monoclonal immunizer (mAbs) co-produced by IAVI and Scripps Research as predictive analysis to address the covid-19 pandemic (Pharmatimes, 2021). The reasoning behind these tie-ups boils down also to market entry and penetration (Cuypers *et al.*, 2021; Hennart, 2019). However, how has covid-19 changed the considerations to be accounted for in terms of market-entry models for pharmaceuticals and how can better modes of entry be proposed. Specifically:

- (i) Uncertainty factors to be considered
- (ii) Changes of entry modes to sustain entry and ensure growth

The reason for asking these questions, is this will then present us with adequate understanding, to develop and propose new-normal market entry model for pharmaceuticals in developed and emerging countries, now that with covid-19 the gap doesn't seem to be too prevalent.

Digitalisation Via IoT and Pharmaceutical Market Entry Possibilities

According to Gong and Ribiere, "A fundamental change process, enabled by the innovative use of digital technologies accompanied by the strategic leverage of key resources and capabilities, aiming to radically improve an entity and redefine its value proposition for its stakeholders" (Gong and Ribiere, 2021, p. 32). Eden (2016) emphasises that digitalisation has changed the way market entry has been undertaken over the years. Research has long highlighted how information technology is modifying the internationalisation process, emphasising such distinct advantages as reduced transaction costs, user network economies, speed, and scalability (Brouthers *et al.*, 2016; Kotha *et al.*, 2001; Singh and Kundu, 2002; Surdu and Mellahi, 2016). However, there is a growing awareness that digitalisation not only alters the information costs of cross-border transfers of firm-specific advantages (FSAs), but also modifies the very nature of FSAs (Strange and Zucchella, 2017).

Extant literature demonstrates that digitalisation is the process of transforming the essence of an organisation's products, services, and processes into internet-compatible data packages that can be created, stored, and transferred in bits and bytes, along with the information associated with them, for marketing, sales, and distribution (Benito *et al.*, 2019;

Chen *et al.*, 2019; Sambamurthy *et al.*, 2003). Mobile devices, big data analytics, cloud, social media, 3D printing, additive manufacturing, artificial intelligence (AI), and machine learning are examples of technologies that are driving digitalisation (Benito *et al.*, 2019; Narula *et al.*, 2019).

As digitalisation includes utilising IoT, this brings the power of the internet, data processing and analytics to the real world of physical objects. For consumers, this means interacting with the global information network without the intermediary of a keyboard and screen; many of their everyday objects and appliances can take instructions from that network with minimal human intervention (Aggarwal, 2019; Nolin and Olson, 2016; Park, 2020). For firms, IoT can bring the same efficiencies to physical manufacturing and distribution and market entry that the internet has long delivered for data functioning. Millions if not billions of embedded internet-enabled sensors worldwide are providing an incredibly rich set of data that companies can use to gather data about the safety of their operations, track assets and reduce manual processes (Fruhlinger, 2020; Hui, 2014).

However, no collaborative IoT ecosystem exists yet because the entry barriers are high, and the potential gain is low for a single stakeholder (Asefi, 2020; Narula *et al.*, 2019). Providers of platforms, things, and services require a simple, established way to sell access to their assets (Broring, 2020). Marketplaces letting providers monetise such access are not yet available within pharma care (Kim, 2019). However, literature indicates that once these marketplaces are established, developers will be able to easily create IoT services and applications and build their products around them. Revenue streams can then be shared across all contributing entities (service, platform, and product providers) (Alamanos *et al.*, 2018; Bizer, 2009; Broring, 2011; Hui, 2014; Lolloudes *et al.*, 2015). A key task of a marketplace is to provide extended functionalities to enable the advertising, dynamic discovery, automated orchestration, and negotiation of services to facilitate their use. BIG IoT (Bridging the Interoperability Gap of the IoT) enables the emergence of cross-platform, cross-standard, and cross-domain IoT services and applications toward building IoT ecosystems. These ecosystems will connect product providers, service providers, and users (Alamanos *et al.*, 2018; Broring, 2020).

Within pharmaceuticals, several reports and literature have been seen stemming from covid-19's implications of the need to establish IoT ecosystems for faster drug discovery, marketing, and market entry globally (Aggarwal, 2019; Benito *et al.*, 2019; Park, 2020). However, little application has been seen within academic literature. Taking literature from

other fields and correlating it with pharmaceutical market entry modes, we can understand that through the BIG IoT API, services and products can be composed into more complex or added-value requirements.

Furthermore, providers can advertise their resources in the marketplace so that consumers can discover those resources and access the desired providers. So, we can foresee multiple pharmaceutical market entry places (Turber *et al.*, 2014). They could each cover a different application domain (for example, vaccines, medicines, medical service) (Livari *et al.*, 2016). Or different organisations could set up marketplaces all related to one domain – for example vaccine production and can further foster an IoT pharmaceutical ecosystem enabling easy market entry and success (Agarawal, 2019; Broring, 2020; Lee *et al.*, 2017; Lolloudes *et al.*, 2015).

Literature Review

Definition of Market Entry Theories

Before we enter into specific market entry theories, we have to first understand the definition of market entry as market entry theories have been well researched within international business. Hennart (2019) and Terpstra and Sarathy (1994) accept that the determination of market entry technique includes long-term corporate targets identified with the entire marketing plan and that difficulties come with the course of how to arrive at these global markets. Anderson and Gatignon (1986) proposed the market entry model of entering global markets as the most ideal decision of an undertaking when a company is attempting to grow its overseas market share. All in all, market entry models/theories can be viewed as the institutional game plan to enter global markets – developed for some, emerging for others (Buckley and Casson, 1998). Anderson (1997) upheld the view that the market entry model is an institutional course of action of an endeavour while dealing with the overseas markets, including legally contractual agreements, joint ventures (Rodgers *et al.*, 2018), and other methods (Nippa and Reuer, 2019).

Further literature (Dunning, 1992; Glowik, 2010; Hennart, 2019; Pan and Tse, 2000; Vrontis *et al.*, 2006) indicates that the types of market entry theories and models, is determined by these four following motivations:

(i) Resource seeking – a strategy in which the main aim of the company is that of acquiring in foreign markets particular types of resources that are not available in the home country, or that are available abroad at a lower cost (Hansson, 2007).

- (ii) Market seeking a strategy in which companies invest to exploit the possibilities granted by foreign markets (Hansson, 2007).
- (iii) Efficiency seeking a strategy to exploit specific location advantages for specific activities and design a production network that rationalises the production processes (Morschett *et al.*, 2015)
- (iv) Strategic assets or capability seeking a strategy to enhance the capabilities of a firm technologically, organisationally via changes and/or selling acquired firms' products or services (Meyers, 2015).

Transaction-Cost Analysis as a Market Entry Consideration

Within market-entry theories, the most dominant is TCA. Specifically, for TCA, scholars (Anderson and Gatignon, 1986; Cuypers *et al.*, 2021; Vrontis *et al.*, 2006), support the theory that the function of the trade-off from control and the cost of course commitment is the most suitable entry mode. In order to reach the long-term efficiency, four constructs are used to determine the optimal degree of control:

- (i) transaction-specific assets refers to the extent to which investments made to support a particular transaction or relationship have a higher value to that transaction or relationship than they would have if deployed for any other purpose (Christiansen, 2015)
- (ii) external uncertainty refers to anything externally in the environment that affects the transaction, unknown and unexpected (Cuypers *et al.*, 2021)
- (iii) internal uncertainty refers to entrant's inability to determine its agents' performance by observing output measures (Cuypers *et al.*, 2021)
- (iv) free-riding potential agents agents' ability to receive benefits without bearing the associated costs (Christiansen, 2015)

While transaction cost theory as a consideration is the dominant approach used in the entry mode literature in recent decades (Brouthers and Hennart, 2007; Cuypers *et al.*, 2021; Jell-Ojobor *et al.*, 2022) we have seen a dearth of this being addressed by the pharmaceutical market-entry literature (Araja and Sumilo, 2020; Experfy, 2021; Javalgi and Wright, 2003; Smarta, 2008; Zhao *et al.*, 2020). According to the theory consideration, firms can figure out market entry via (no joint ventures or externalisation) keep them inside the organisation, or by some other mode reflecting a certain coordination (pleasant acquisition) (Papanastassiou *et al.*, 2020).

In this regard, exchange cost within TCA is affected by different factors like bounded rationality, benefits, resource explicitness, uncertainty, information impact and small numbers dealing (Buckley and Casson, 2019; Jones and Hill, 1988). Any of these six factors alone or in combination might prompt market setback and the organisations might pick chain of command over market (Jones and Hill, 1988). Notwithstanding these six factors, exchange recurrence moreover impacts exchange cost. From a pharmaceutical market entry perspective, each of these factors with regard to covid-19's dynamism and firms' approaching market entry as seen in the context indicate that transaction-cost-analysis consideration of uncertainty (internal and external) is main factor. Therefore, considering covid-19 as an external uncertainty that has internal uncertainty implications, what are the influential uncertainty factors within an evolving pandemic context, for new-normal market entry to be considered by pharmaceuticals to ensure appropriate foothold, advantages, and profits? What do the factors lead to or boil down to?

Uncertainty Within Transaction-Cost Analysis and Corporate Strategies

Scholars (Buckley and Casson, 1998, 2019; Duncan, 1972; Surdu and Ipsmiller, 2021), identify three components of uncertainty - the lack of information regarding the environmental factors, the lack of knowledge about the organisational consequences of a specific decision, and the lack of ability to assign probabilities as to the effects of a given environmental factor on organisational success or failure. Similarly, Milliken (1987) suggests three types of uncertainty of state, effect, and response uncertainty, which respectively refer to the lack of knowledge about the state of nature, the lack of knowledge about cause-effect relationship, and the lack of knowledge to predict the likely consequences (Freeman *et al.*, 2020; Shin, 2003). With regard to covid-19, we can understand that lack of information and lack of knowledge of consequences of a specific decision is of paramount effect.

TCA recognises two distinct sorts of uncertainty – behavioural and environmental (Gatignon and Anderson, 1988; Tseng and Lee, 2010; Williamson, 1985). Behavioural uncertainty can be depicted as firms "inward vulnerabilities that arrangement with human issues like limited judiciousness and advantage. Environmental uncertainty concerns the outside vulnerabilities a firm faces when entering an unfamiliar market, originating from significant possibilities encompassing a trade which are too erratic to be in any way indicated ex-risk in an agreement" (Geyskens *et al.*, 2006, p. 279). Given an evolving time as is the pandemic, we can understand from literature that the external and behavioural uncertainties

will be different, as there is an acute shortage of ready real-time data available to enhance informed market entry decisions.

Internal Uncertainty - Behavioural vulnerabilities emerge from the powerlessness of an organisation to foresee the conduct of people in an unfamiliar nation because of data imbalance or potentially need of straightforwardness (Brouthers and Nakos, 2004, p. 232). These vulnerabilities may result in crafty conduct of representatives or colleagues in the target country (Williamson, 1985). Moreover, interior vulnerabilities lead to more muddled ex post execution assessments, signifying "vulnerabilities play out regardless of whether the authoritative consistence has occurred" (Geyskens *et al.*, 2006, p. 521). Scholars contend that inner vulnerability ascends with expanding social contrasts among home and host country (Kogut and Singh, 1988), since collectively far off partners' behaviour is more difficult to foresee. Additionally, such social contrasts may prompt correspondence issues. Moreover, interior vulnerabilities can likewise emerge because of an absence of contextual experience (Narula *et al.*, 2019; Zhao *et al.*, 2004, 2020).

External Uncertainty – Ecological or outer vulnerabilities are made by the objective market's climate. Such vulnerabilities are outer and can scarcely be affected by the contributing firm. Instances of outer vulnerabilities contain law and agreement requirement by the host country's legitimate structure, world of politics, property security and other environmental issues (Williamson 1985; Erramilli and Rao, 1993). A few specialists (Anderson and Gatignon, 1986; Erramilli and Rao, 1993; Mayrhofer, 2004; Surdu and Mellahi, 2016) recommend that organisations ought to respond to outer vulnerabilities by remaining as adaptable as conceivable through authoritative or market administration modes (Li and Xiong, 2022; Surdu and Ipsmiller, 2021). This "maintains a strategic distance from asset responsibility as well as liberates participants to change accomplices or rework contract terms and working game plans generally effectively as conditions create and change" (Anderson and Gatignon, 1986, p. 15).

Moreover, Morschett et al. (2010) found in their meta-investigation that ventures are bound to market entry modes with low contribution in nations with high external uncertainty. One reason may be that a local partner with host country market information can lessen the danger engaged with an endeavour. Another explanation could be that by shared control, as in a joint endeavour, the responsibility of the two firms is decreased as far as assets and value (Puck *et al.*, 2009). Thus, to amplify the adaptability (Verbeke and Faribozi, 2019) for changing agreements in a shaky climate, firms are seen to go in for joint types of market entry (Erramilli and Rao, 1993; Mayrhofer, 2004).

However, if production and acceptance of required items, is threatened not only environmentally, but also behaviourally by patients' adoption vis-à-vis the pharmaceutical sector – given a pandemic, how can firms address and deal with it, whilst operating in a situation that affects them geographically as well? As a very important factor of uncertainty, as it is in TCA – is the resulting lack of knowledge and lack of information impact. Therefore, how can new-normal market entry account for new uncertainties and address the implications to the knowledge and information impact? In this regard, we have to first develop an insight into what the new-normal pharmaceutically oriented uncertainties exist from a TCA perspective? Then, see how it brings about lack of knowledge and information impact. Since, the context is new, and TCA as a theory has not been implemented within pharma care, literature of uncertainty within TCA for this is scarce, resulting in us having to take real examples, to find out the uncertainties and shortcomings in the current market entry approaches stemming from uncertainty insight within TCA.

Methodology

As the context of the pandemic in relation to pharmaceuticals is a volatile one, in this paper, we utilise a descriptive case study approach (Yin, 2014; Harrington *et al.*, 2017; Loyd *et al.*, 2014, Nataraja and Peterson, 2019). We take three firms – Johnson and Johnson (J&J), GlaxoSmithKline (GSK) and Novartis to present an ADO (Antecedent-Decisions-Outcomes) understanding based on the descriptive insights of the sudden decisions taken by firms and the outcomes thereafter owing to the antecedent – i.e., the pandemic in terms of Transaction-Cost Analysis theory's uncertainty facet. Our strategy to select these three firms for the descriptive study, was based on the below criteria given the context: -

- (i) Raised concerns about the way of operation and market entry within a pandemic context
- (ii) Has not been studied in a pandemic context thus far
- (iii) Part of the top five firms in pharma care, so that the insights and subsequent proposed framework have further generalisability and applicability for other pharmaceuticals

Once we chose the three firms, we prepared an understanding of the firms' mode of entry, the approach undertaken during the pandemic, and the expected outcomes vis-à-vis outcomes received. This descriptive insight is presented in the form of an ADO understanding with contemporary reports regarding the pandemic and the companies in context. Thereafter, we utilise the insights to identify the key themes (i.e., a common thread among the cases) within context.

The reason for utilising a descriptive three-case study approach can be attributed to a variety of reasons. Firstly, Johanisson and Hiete (2021) refer to a descriptive case study approach as one which enables understanding phenomena within a specific context. Furthermore, Gerring (2007), specifies that a case can be of different sizes depending on the object of the case study – for instance it can be a country, a city, a social group, a business, a family, or a single individual. Yin (2014) elucidates that descriptive case studies describe the phenomenon in context. Given the complexity of the pandemic and its real-world implications (PWC, 2019), a descriptive case study approach will provide for adequate understanding of the implications of the antecedent in question and pharmaceutical companies' decisions and outcomes (Loyd *et al.*, 2014). Further, equipped with this understanding, we can then provide solutions applicable in real-world contexts of how new-normal market entry models need to be formed and applied.

Secondly, according to Johanisson and Hiete (2021), "The whole point of a case study is to investigate the links between the case and its context and thereby get a sense of what is common about the case and what is specific about it" (p. 4). Therefore, given that covid-19 is an event and a context in itself, the combination of this context with the understanding of antecedents, decisions, and outcomes (ADO) framework in a descriptive way, equips us to delve deep to understand the implications of the antecedent – covid-19, the decisions taken in thereafter – market entry procedural considerations and the outcomes resulting issues/implications for the pharma companies in this paper (Loyd *et al.*, 2014).

To elaborate, as the whole intent for undertaking a descriptive case study is to understand contextually, the "how" and "why" of a specific phenomenon with the researcher's little control "while allowing investigators to retain holistic and meaningful characteristics of these events" (Yin, 2014), we via the descriptive analysis identify the key themes in context with regard to new-normal considerations of uncertainty within TCA. Specifically, based on the descriptive ADO presentation and insights thereafter, we analysed the themes further to find a common thread among all the uncertainties within the context – which led to one main theme supported by cogent literature. Subsequently, with that understanding, we utilised contemporary reports and literature from IoT and pharma care to address how the main theme

can be addressed for pharmaceutical new-normal market entry if powered by IoT which is similar in methodology to a few other descriptive case studies (Chayer and Lunsford, 2021; Cozmiuc and Petrisor, 2020; Gretzinger *et al.*, 2020; Salabarria *et al.*, 2020; Upright and Forsythe, 2021). In this regard, we developed the proposed conceptual framework applicable to pharmaceuticals in the new-normal.

Additionally, in order to ensure further validity secondary reports, and literature sources were used. For example, reports on drug discovery, literature on BIG IoT adapting to ensure market entry with lower barriers from various interdisciplinary contextual studies have been used. Specifically, we utilise triangulation to validate further the findings from the descriptive case studies. Triangulation refers to the use of multiple methods or data sources in qualitative research to develop a comprehensive understanding of phenomena (Patton, 1999). Triangulation also has been viewed as a research strategy to test validity through the convergence of information from different sources (Hancock *et al.*, 2021). Via the approach of triangulation from various reports and literature as employed in other studies (Adderley, 2021; Chayer and Lunsford, 2021; Gretzinger *et al.*, 2020; Cozmiuc and Petrisor, 2020; Salabarria *et al.*, 2020), we found that our descriptive analysis, identified theme, and its subsequent implications which were found and addressed by the conceptual framework, were all reliable and valid evidenced in other field literature and several reports of 2019-2021.

The Three Cases

In order to answer the above question, as the uncertainty currently being dealt with is context specific, we will look at Johnson & Johnson (J&J), GlaxoSmithKline (GSK) and Novartis. The reason for taking these three companies as descriptive cases to present an antecedents-decisions-outcomes understanding, is because these companies currently operate in multiple levels in a variety of geographic locations. This has given them the opportunity as well as the disadvantage of being confronted by the pandemic, in both developed and emerging economies giving us ample evidence and understanding, of how the pandemic has affected market-entry operations in both economies for pharmaceuticals.

Case 1: Johnson & Johnson: (Janssen)

At the moment of facing up to the pandemic, J&J executives understood their real-time focus has to be the cure for covid-19. However, they also had to keep in mind the growing illnesses being addressed by their products for HIV, Respiratory issues of asthma etc, in order

to maintain their presence in the emerging economies (J&J, 2021). Given the umpteen pressures, J&J, took the approach as in figure 1 to combat the pandemic. However, the outcomes and the results were not as accepted. In the figure, we first depict the usual market entry considerations undertaken by J&J in general. Within figure 1 itself, we delineate what happened during the pandemic, the antecedent – i.e., pandemic of covid-19 and its implications, the decisions and strategies undertaken by J&J in developed and emerging economies, and the outcomes of that.

[FIGURE 1a HERE] [FIGURE 1b HERE]

To explicate the figure 1, above, given the antecedent of covid-19 as a pandemic, J&J was one of the last to conduct phase 3 clinical trials and release its vaccine. In this scenario, therefore, strategically speaking, their collaboration was from a resource angle of immunology considering the partnering firms. However, their limitations concerned not being able to understand the evolving issues of the uncertainty and the resources thereafter being required for every variant of the virus.

[FIGURE 2 HERE]

Extant reports indicate how J&J believed that since they have the financial ability, they can acquire or merge with more companies (J&J, 2021). However, we have seen how companies within the pandemic have not been able to transfer their capability and knowledge in light of an evolving situation (Aeris, 2021; Aggarwal, 2019). This then, hinders understanding and insight of collaborations and choice further, providing secluded approvals and trials which are not global, that can increase market-entry speed (Chandra, 2017) which is critical, as well as access and penetration.

Furthermore, if we delineate, we can understand that the fast mutation of the virus, and thereby the requirement of quick knowledge transfer with patient compliance due to not understanding the situation in a real-time manner further restricted fast drug development, quality control and other issues which made joint ventures and acquisitions difficult as the considerations to be considered, differed highly from their usual process. However, developing an IoT-driven ecosystem would have enabled appropriate decision-making in the future.

Case 2: GlaxoSmithKline (GSK)

GSK on the other hand, have a market-entry process and penetration model which is characterised by a focus in emerging economies. This by default therefore enables easy marketentry access. Furthermore, for the example of covid-19 vaccines, GSK seem to have partnered with two firms both who have competence in R&D for biosimilars and are situated in emerging economies. This resulted in excess production, fast penetration as market-entry process.

[FIGURE 3a HERE] [FIGURE 3b HERE]

To explicate the figure 3 above, GSK via their usual market-entry process have seen to it that, within the new normal, they have stayed afloat as much as possible via strategically joining forces with Sanofi and SK Bioscience to ensure robustness of vaccine and presence in developed and emerging economies. This resulted in multiple global trials, more time taken for approval, instead of just one global trial which could have been accomplished in an IoT-driven pharma care ecosystem.

[FIGURE 4 HERE]

To highlight the extraction and further insights from figure 4, GSK albeit right in their approach, have suffered from the type of vaccine results. Furthermore, they had to enter into multiple agreements with firms, which could have been avoided if the one company that they did partner with was equipped with IoT and the patient base and populations could be equipped with that too. Specifically, GSK, due to being unsure of how the mutation will happen, as well as equipped with limited understanding/information of changing factors including patient compliance due to reviews of every type of vaccine, had to hedge their decisions on multiple companies, of which the second was seen to be more promising than the first. This could have however been avoided if IoT had been applied within pharma care market entry procedures, to hasten the process of drug development, ensure higher patient compliance due to real-time data enhancement sharing and knowledge transfer between parties, and also better-quality control and fast-paced changes for newer versions of the virus.

Case 3: Novartis: (Sandoz)

Novartis' Sandoz (pharmaceutical division) deploy a strategic market entry process which factors in addressing unmet needs of underserved communities and regions. Furthermore, their focus has been to accelerate access to transformative therapies as maximum impact of their firm's discovery can be realised therein. Their acquired companies or collaboration firms are also ones situated in emerging economies, with focus on immunology and oncology.

[FIGURE 5a HERE] [FIGURE 5b HERE]

To elucidate the figure 5 above, in terms of the pandemic, Novartis collaborated with the right R&D enabled company in terms of expertise – i.e., molecular competence company in terms of vaccines. This resulted in a lot of research already done, from a biosimilar angle for Novartis. However, the cohort restriction being provided to relating to DARPin, was overlooked and thus, resulted in more than one collaboration that had to be sought. Albeit appropriate joint ventures, we have to understand that the outcomes weren't as expected.

[FIGURE 6 HERE]

To detail the figure 6 above, a major restriction for Novartis was the number of people that can be reached via the collaboration – i.e., only DARPin program individuals. Furthermore, given non IoT-based data sharing, transference and the amount of insight for the merging/collaborating company is less, resulting in more need for collaborations and understanding of what will work and what won't. Additionally, joint ventures of this kind during uncertainty have to be strengthened with real-time patient compliance and appropriateness data which was missing as well, to enable quick and more robust drugs and vaccines.

COVID-19's Impact Resulting in New Uncertainty Considerations effecting TCA in the New-Normal for Pharmaceuticals

Via the three cases, we can see that whatever the mode of entry – which is seen mostly as joint ventures in the examples and following the understanding of behavioural and technological uncertainty paving way for joint ventures for increased market entry penetration, the considerations to factor in have significantly changed. The reason being the uncertainty is more when it comes to the pharmaceutical industry's engagement with an ongoing healthcare issue as joint ventures for a pandemic of the magnitude similar to covid-19 shows that vaccine and medicine production is restricted, slow, and causing shortages in many places. Therefore, to only consider the uncertainties in a huge arching banner, is inappropriate. Therefore, the three cases have provided for what the actual uncertainty was for every case.

Furthermore, competence and expertise are unknown in an uncertain evolving situation, thereby even with expertise of R&D, trials and tests need to be performed of top quality, and in this regard whilst joining forces may be appropriate, the outcome is not certain and is a gamble. Thus, from the three cases above, we also saw how they had to form more collaborations and also alter the competence from time to time. Categorizing them, from the extraction in the cases, we can see that for pharmaceuticals – the uncertainty takes on specific categories which have to be considered.

Below, we present the new-normal uncertainties, in other words, considerations, for transaction-cost analysis perspective and how it effects market entry modes for pharmaceuticals.

(i) External Environmental Uncertainty – Unknown Evolution of the Pandemic's Mutating Virus

Reports and literature over the years have indicated how during an unknown epidemic or pandemic, we have the virus mutating at a pace, which we cannot keep track of, until newer cases are detected and seen. For instance, particularly, if we take covid-19, we first had covid-19 (as a virus), then the virus mutated to become what became known as the Delta variant, following which recently, we have the Omicron variant. In such a fast-changing scenario, market entry vis-à-vis drug discovery, development and marketing for pharmaceuticals becomes fraught with flaws (not because of the development issues in the vaccines or drugs, but from the angle of keeping current) which is seen by patients. This then results in companies having to either retract and/or form newer ventures to address the requirements.

This external uncertainty, therefore, causes more spending, more fear, scepticism not only from patients but also firms entering the market, in their decisions to partner or collaborate with other firms. This, therefore, increases non-equity modes of entry resulting in more issues whilst entering existing developed markets and newer emerging markets. Furthermore, given the mutating virus can act differently on different people even whilst entering an emerging market, cogently speaking, the efficacy of the drug and vaccine apart from clinical trials is unknown in a real context. This puts pressures on firms entering markets to conduct global trials with a mixed population thereof. However, data is still constricted as it is not entirely wired-in real-time data. Wired-in real-time data as is available via IoT, will enable firms to assess every few hours what is happening to the patient on trial, resulting in modifications of understanding based on every single person's lifestyle, geographic location and not just a specific demography (race, age) that is currently used.

(ii) Internal Competence Uncertainty – Ability to Develop Quick Approvable and Tested Vaccines and Drugs

Firms have been haggling for success of drugs that work in a pandemic as we are currently seeing. However, the choice of one partnering firm cannot always be the right choice. This pandemic has taught firms, such as the ones in the case and others in the industry that even when joining forces for quick approvable and tested vaccines and drugs for a cause, competence is key. For instance, BioCon is a leading molecular immunology firm which produces vaccines and drugs for unknown novel autoimmune diseases and tropical diseases. However, even that capacity was not enough, steering the partnered firm to look for more partners.

The ability herein, is not only from a production competence angle, but also approvable and appropriate angle. Operating via a joint venture or a collaboration will not increase competence of a firm during a pandemic if the ability, requirements, and competence required is unknown. In fact, reports from the pandemic indicate dilution of production as a result of the uncertainty in capabilities needed for the production and entry to market of drugs and vaccines (EMA, 2021; EMC, 2021; IFPMA, 2020). In this regard, if IoT as a pharma care ecosystem for market entry is setup, capability to fast-track and develop appropriate vaccines and drugs increases due to interoperability of the mechanism.

(iii) Internal and External Competence Uncertainty – Effective Quality Control of Developed Vaccine and Drug

A major factor for market entry by pharmaceuticals into newer markets is their quality control mechanism during vaccine and drug development. Regarding the covid pandemic and market entry that firms undertook via joint ventures, many of the ventures were short lived and required constant changes, not internally within a firm, but changing the firm in itself who would aid in developing the drug and vaccine (ABPI, 2021; Airfinity, 2021; Bump, 2021; Pavlovic, 2020). This results in inefficient market entry, falling short in resource seeking and resulting scepticism toward a particular drug or vaccine produced by that venture.

Resource seeking therefore needs to be more informed from the angle of individual effects on target population, what quality control criteria has to be adapted for the new market being entered into. Further, this will then increase efficiency which is also sought by companies entering the new market.

(iv) External Behavioural Uncertainty – Patient Acceptance and Compliance

Previously, as we understood the issue of mutation of a virus, patient compliance and belief in vaccine and drug development wavers. Recently, there were many reports of how patients in the USA declined taking in Moderna, J&J and Pfizer vaccines out of fear of blood clots in brain and heart and other reported side effects (BBC, 2021; Branswell, 2021). This hampers not only market entry when the end consumer/patient is not willing to adopt a solution, but also production costs, specific kinds of tie-ups and decisions of who to choose over others. Probably this is why joint ventures as a mode of entering have been seen as an adopted mechanism due to the pandemic, as no one firm would like to bear all the cost whilst operating in uncertainty.

Lack of Required Knowledge: The Culminating Thread of all the Uncertainties

Essentially, if we have to group all these uncertainties into TCA terms, we can map them to lack of knowledge, and lack of information impact as well. This lack as a result of the uncertainties, fuelled having unsure capabilities to decide upon, owing to unsure knowledge. Therefore, the joint ventures seen thus far in the examples warranted having to further make more decisions of collaboration, which was informed after a first venture, not prior. The shortcomings of every venture were therefore not predicted but endured from time to time. This lack of knowledge, and predictive power from an uncertain market entry perspective is required to ensure successful market entry, ventures, and successful strategic operations for pharmaceuticals due to their unique positioning in the face of the pandemic.

Conceptual Framework

From the above descriptive case analysis and further literature insights of IoT, we understood what needs to be developed from start to finish for market entry modes for pharmaceuticals to enable being able to deal with the detailed uncertainties. Below is the conceptual framework from the various insights.

[FIGURE 7 HERE]

Figure 7 explains the process of market entry and below we describe how that is made possible further with extant literature.

IoT's Interoperability Patterns to Deal with Uncertainties and Aid Market Entry

To counter these specific uncertainties whilst entering newer markets in even newer situations, within IoT, interoperability is used. IoT and specifically interoperability cases in McKinsey (2019) and PWC (2021) reports indicate that public health and safety usage of IoT to link digital and physical environment to combat growing illnesses is possible. Furthermore, over 150 cases in other realms suggest how the feature of interoperability is key to enable such an ecosystem of market entry and operation (Metallo *et al.*, 2018; PWC, 2021). The key issue interoperability solves for pharmaceutical market entry and functioning is providing real-time data for quick changes and long-term sustenance. Interoperability in IoT basically refers to "the ability of IoT systems and components to communicate and share information among them. This crucial feature is key to unlock all of the IoT paradigm's potential, including immense technological, economic, and social benefits" (Palau, 2019). In this regard, extant literature indicates IoT and its interoperability offers many advantages, primarily when dealing with development and proliferation of medicines to combat evolving conditions and diseases (Alagarsamy *et al.*, 2019; Dimiter, 2016; Li *et al.*, 2020; Shugalo, 2019).

Reports post-Covid-19 have emphasised that business models of operation need to be developed for pharmaceutical efficiency across borders in terms of vaccine and drug discovery (Aeris, 2021; Cerner, 2021; Colson, 2019; PWC, 2019; Richards, 2021). So how does the IoT-driven framework above help?

Addressing the Lack of Knowledge – Steps 1, 2, and 3

Lack of information of environmental and behavioural uncertainty, coupled with information impact needed to form an informed market-entry is addressed adequately. In this regard, IoT sensors capture in real-time data vis-à-vis external factors as well as internal factors and are constantly updated. This is furthered via IoT predictive analysis which is enabled via Ai within the sensors in actionable IoT used to predict patterns of where the environmental factors are headed – thus addressing the mutations of the virus. Issues are flagged by IoT in real time about readings and insights in such a way that adequate futuristic preparation and insight can be formulated by the top management (Digiteum, 2021; Gong and Ribiere, 2021).

Furthermore, the data also enables us to see what competency is needed to effectively face the uncertainty and aids in detailing inadequacies in competence and further, how that can be rectified via actionable IoT. This aids in understanding the style of collaboration, specific transaction, and exchange costs. Furthermore, it also aids in understanding the kind of resource seeking within immunology and molecular innovation futuristically. Additionally, via the approach of wearable devices to understand consumer effects and behaviours, companies are equipped with first-hand, real-time information on how to approach markets and consumer segments to maximise patient compliance depending on lifestyle and added reactions to the clinical trials.

A One-Time Global Launch Ensuring Competitive Advantage and Pioneering Entry

Via IoT, drug discovery is made faster and more accurate (FDA, 2021). This integrated with actionable IoT, and all the data as detailed in the framework, results in being able to launch for a multitude of segments of population, in one go. The information derived is not only age, race- and geographically oriented, but also individualistic to an extent, thereby enabling more accuracy and appropriate profiling of consumer segments. This enhances resource usage, costs in process and also due to the accuracy provided by the entry system, the ability for success resulting in profits, and increased market share is certain (Asmussen *et al.*, 2009).

Conclusion

Via this paper and all the literature reviewed, we understood the new nature of uncertainties within transaction costs in a pandemic and how it can be dealt with via actionable IoT to ensure effective market entry. Further, we also understood how a closer to fool proof mechanism to inform market entry by the help of IoT can be developed. Companies in the pharma care industry need to deploy an IoT-driven market entry approach in order to sustain in the changing dynamic environment considering the new-normal uncertainties highlighted in this paper via the three cases.

Market entry strategies for the new-normal specifically for pharmaceuticals need to adopt an IoT-driven approach as suggested in this paper, as there is excessive uncertainty in the situation, and IoT provides predictive and descriptive intel in order to operate with certainty in an uncertain environment due to the types of sensors and AI (Zhao and Priporas, 2017). This also provides informed entry by pharmaceuticals into newer and existing markets assured of consumer behaviour understanding, and reactions to solutions, thereby ensuring success and providing more data for making real-time changes. The major contribution of the IoT-driven market entry approach is constant real time data to inform decisions, changes and/or quick fixes to be made – from initial stages till the end of launch.

Implications

Theoretical Implications – First, this paper addresses categorising the new-normal transaction cost uncertainties by way of highlighting three cases in the recent past in dealing with covid-19. Herein, we highlight what approach was adopted, what went wrong and why. With this understanding, we delineate the common thread in the uncertainties – i.e., lack of knowledge and impact of information. Second, the paper entails how IoT can be used to ensure a more robust market entry approach. We detail a four-step approach to deal with uncertainty and also detail the IoT to be used, and how these effect in an informed market-entry process. Third, we enhance the aspect of digitalisation within market entry approaches by way of our IoT understanding and implementation. In this respect, we specifically exemplify the immense contribution of digitalisation in current times.

Practical Implications – This is the first paper to detail IoT-driven market entry for uncertain times. This results in having a prototype for implementation by pharmaceuticals. Furthermore, this paper also details for the first-time uncertainties of transaction costs for pharmaceuticals and fills that gap. Pharmaceuticals equipped with IoT currently for drug discovery can now try to utilise the propositions for market-entry via the actionable IoT approach highlighted herein. Second, via the insights formed by way of this approach, we encourage application of digitalisation to market entry that can aid low-cost, appropriate transparency in light of major uncertainties.

Limitations and Suggestions for Future Research

This paper exemplifies how IoT can help in market entry for pharmaceuticals by way of a literature-backed conceptualisation. However, such mechanisms/frameworks have to be tested for efficacy quantitatively and qualitatively. Specifically, research to aid companies to understand imperative factors that enable and enhance such an approach must be undertaken. Lastly, more research can also be undertaken on specific IoT mechanisms within pharmaceutical research for every market entry mode within contemporary literature as there is limited studies in this context.

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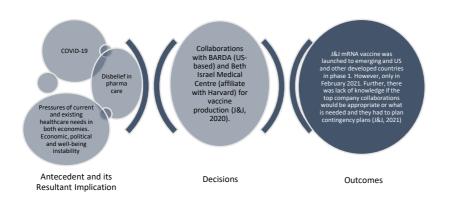
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Figure 1a: The usual market-entry approach undertaken by J&J by taking a recent 2020 example

	Johnson & Johnson		
Maximizing company potential to deliver the mediccines pipeline promised.	Collaboration/N	/&A Company Outcome Received	N)
Forging new relations to get new populations, new discovery, development and delivery of the company's transformational medicines. Investment of cutting-edge innovation (J&J, 2021)	firm addressing new drug discovery not tapped by J&J Merging of forces to innovate technology to address unmet needs similar to competitor moves like Biosmilars produced by Sanofi, Pfizer (J&J, 2021).	Acquistion with Momenta Pharmaceuticals to adress novel autoimmune illnesses and also releasing the pipeline of Momenta's drugs, and biosimilars not performable by J&J Ability to produce biosimilars launchable immediately in developed and emerging economies (J&J, 2020)	

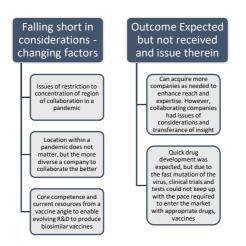
Source: The current authors

Figure 1b: The way J&J responded to the pandemic with decisions and outcomes.



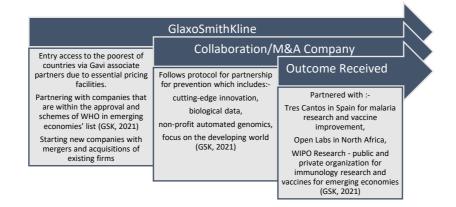
Source: The current authors.

Figure 2: Mismatch for J&J of consideration of evolving factors, and expectations and outcomes received



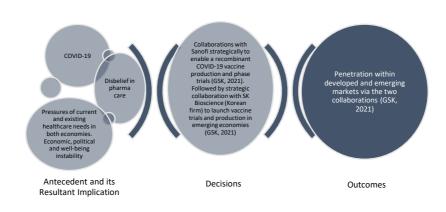
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Figure 3a: The usual market-entry approach undertaken by GSK by taking a recent 2020 example



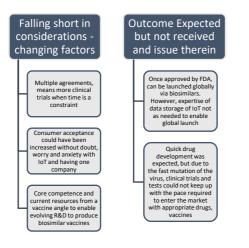
Source: The current authors

Figure 3b: The way GSK responded to the pandemic with decisions and outcomes.



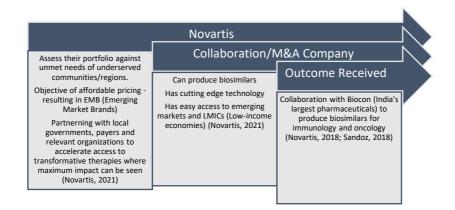
Source: The current authors.

Figure 4: Mismatch for GSK of consideration of evolving factors, and expectations and outcomes received



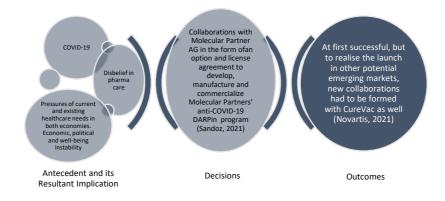
Source: The current authors.

Figure 5a: The usual market-entry approach undertaken by Novartis by taking a recent 2018 example



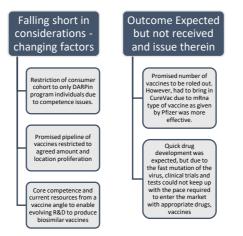
Source: The current authors.

Figure 5b: The way Novartis responded to the pandemic with decisions and outcomes.



Source: The current authors.

Figure 6: Mismatch for Novartis of consideration of evolving factors, and expectations and outcomes received



Source: The current authors.

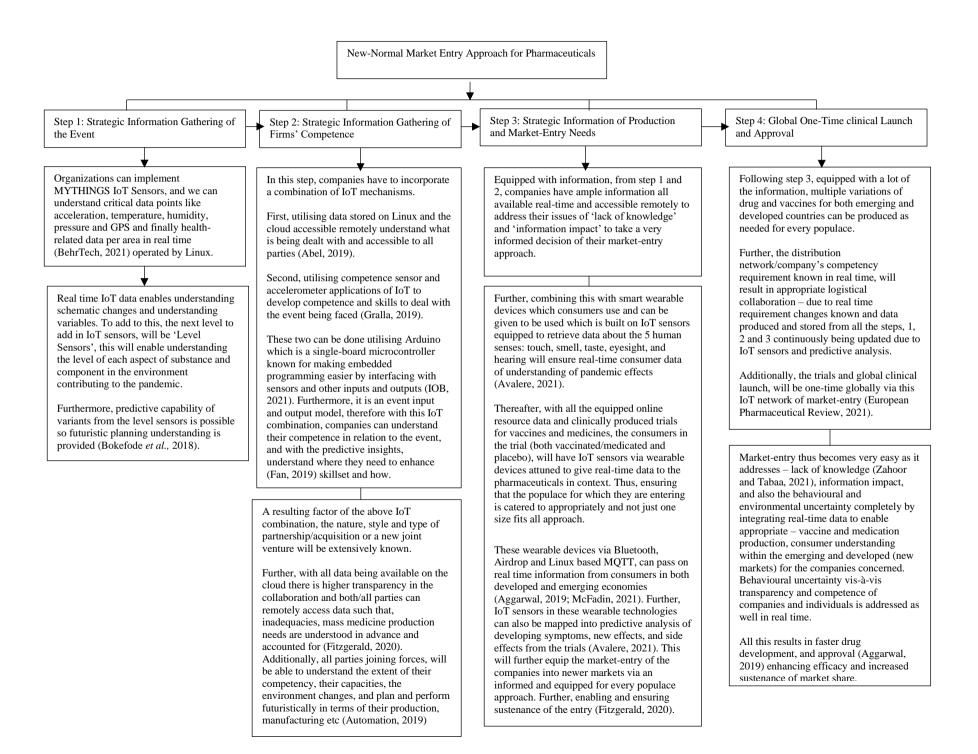


Figure 7: The Conceptual Framework of IoT-driven Market Entry Mode for Pharmaceuticals