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The road to commercialisation: expanding digital therapeutics across international markets

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Abstract: In recent years, numerous digital therapeutics firms have rapidly commercialised and expanded internationally, yet, the intersection between these processes needs to be better understood. Existing literature treats commercialisation and internationalisation as largely separate processes, with theories like 'international new ventures' explaining rapid internationalisation but providing limited insights into born-digital therapeutics firms' commercialisation strategies. This study explores the overlap between commercialisation and internationalisation, focusing on the digital therapeutics industry. Three aggregate dimensions – new product development, strategic market entry, and commercialisation environment – are identified through semi-structured interviews. These dimensions reveal that born-digital therapeutics firms simultaneously pursue both commercialisation and internationalisation. The study advocates for integrating internationalisation elements into commercialisation frameworks, contributing to the understanding of bringing digital therapeutics products to market and entrepreneurial internationalisation literature.

Keywords: commercialisation; internationalisation; digital therapeutics; born-digital; process.

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1 Introduction

The rapid internationalisation of small firms, termed international new ventures (INVs) or born globals (BGs) (Oviatt and McDougall, 1994), is a phenomenon driven by a changing global market emphasising value and competitive advantage through innovation (Bracio and Szarucki, 2019; Cavusgil and Knight, 2015; Dana et al., 2022). Leveraging the internet, information and communication technology minimises internationalisation costs for firms (Yordanova et al., 2024), intensifying competition between new and established players (Wentrup, 2016). Vadana et al. (2019) term rapidly internationalising digital firms 'born-digital'. Defined as "services or manufacturing companies in which most of the inward and outward value chains are digitalised soon after inception" [Vadana et al., (2019), p.200]. Digital firms often operate internationally (Tajpour et al., 2022), and internationalisation is a natural facet of commercialisation for these firms (Cahen, 2019). Consequently, for born-digital firms, internationalisation can be perceived as an integral part of their commercialisation activities. However, despite sustained attention paid to the process of internationalisation (Hurmerinta et al., 2016; Schweizer and Vahlne, 2022; Welch and Paavilainen-Mäntymäki, 2014) and our growing understanding that digital technologies are an important driver for small firms' internationalisation (Yordanova et al., 2024), the blurring of the lines between commercialisation and internationalisation has not received sufficient attention.

The rising global demand for virtual care and remote healthcare, accentuated during the COVID-19 pandemic, has led firms to internationalise early, some from inception. Digital health – defined as a method to "deliver medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of diseases and disorders" (Digital Therapeutics Alliance, n.d.) – is beneficial in promoting value-driven, cost-effective, and comprehensive personalised care (Deloitte Centre for Health Solutions, 2015). Digital therapeutics is a digital health subgroup that has received increased attention for its potential to provide care to unmet medical needs.

An established commercialisation strategy is absent in the evolving digital therapeutics industry (Henze et al., 2021). Born-digital therapeutics firms must craft strategies for sustainable advantage and scalability in a saturated market of digital therapeutics applications (Henze et al., 2021). Generalisable models, like the 'entrepreneurial strategy compass' by Gans et al. (2018) and the framework proposed by Gbadegeshin (2019), offer insights into born-digital therapeutics firms' commercialisation strategies. However, the combination of internationalisation and commercialisation of digital therapeutics remains ambiguous amid the nascent digital health space (Pistorius, 2017). Moreover, previous research, including Pellikka and Virtanen (2009), indicates that commercialisation and internationalisation overlap, with

firms exploring overseas markets during commercialisation and that commercialisation, like internationalisation, can follow a processes model (Pellikka and Pellikka, 2011). Gbadegeshin (2019) also emphasises internationalisation in digital health commercialisation, while Bracio and Szarucki (2019) connect innovation and internationalisation. The swift internationalisation of digital therapeutics firms suggests a convergence of commercialisation and internationalisation processes. This study explores how new ventures simultaneously engage in internationalisation and commercialisation by asking the following research question:

- How do born-digital therapeutics firms enter different international markets with their digital therapeutics, and what are the key challenges associated with this?

This research contributes to both academic literature and practice in the healthcare industry. It contributes to digital health commercialisation literature (Gbadegeshin, 2019; Henze et al., 2021) by offering insights into the firm-level process of bringing digital therapeutics products to market. In doing so, it sheds light on the intersections between internationalisation and commercialisation processes, emphasising that internationalisation should be incorporated into commercialisation frameworks (e.g., Gans et al., 2018; Gbadegeshin, 2019). Additionally, it contributes to entrepreneurial internationalisation literature (Bracio and Szarucki, 2019; Cavusgil and Knight, 2015; Vadana et al., 2021) by portraying internationalisation as an evolving process (Hurmerinta et al., 2016; Schweizer and Vahlne, 2022; Welch and Paavilainen-Mäntymäki, 2014) of finding commercial opportunities for new ventures. For healthcare industry practitioners, the study provides a detailed understanding of simultaneous commercialisation and internationalisation activities in digital therapeutics firms, aiding in refining strategies for global expansion amid increasing market globalisation.

The paper is structured as follows: Section 2 reviews relevant literature on commercialisation and internationalisation and introduces the empirical context. Section 3 details the research design and methodology. Section 4 presents research findings, while Section 5 discusses the findings. Section 6 concludes the study.

2 Theoretical basis and empirical context

2.1 Theoretical basis

Various theories aim to explain internationalisation. Transaction cost analysis, for instance, explains vertical integration decisions based on asset specificity and transaction costs (Whitelock, 2002). The resource-based view posits that a firm's knowledge and capabilities form the basis for internationalisation (Teece and Pisano, 1994). The eclectic paradigm suggests that firms seek the most cost-effective strategy by evaluating ownership, location, and internalisation advantages (Dunning, 2001). Internationalisation process theory emphasises experiential knowledge for international growth, incrementally reducing the liability of foreignness and investment risks (Hurmerinta et al., 2016; Johanson and Vahlne, 1977; Schweizer and Vahlne, 2022; Welch and Paavilainen-Mäntymäki, 2014). Similarly, INVs collaborate to access resources, overcome constraints, and gain foreign market knowledge (Coviello and Munro, 1997; Knight and Cavusgil, 2004; Oviatt amd McDougall, 1994).

Despite resource constraints, INVs or BGs leverage innovation, deviating from the gradual internationalisation pattern observed in some multinational corporations (MNCs) (Knight and Cavusgil, 2004; Luostarinen and Gabrielsson, 2004; Oviatt and McDougall, 1994). BG/INV, interchangeably used, denotes a business with a global vision, targeting a global niche, achieving 25% of sales in international markets within two to three years (Knight and Cavusgil, 2004; Oviatt and McDougall, 2005). INVs create globally viable products, operate in high-risk conditions, and often stem from small, open economies (Arenius et al., 2005; Efrat and Shoham, 2012; Luostarinen and Gabrielsson, 2004).

Despite the advances made in understanding internationalisation, the digital revolution challenges traditional internationalisation theories (Tajpour et al., 2022; Yordanova et al., 2024), particularly for born-digital firms offering products globally through online platforms (Shaheer and Li, 2020; Yordanova et al., 2024). These firms leverage the internet, and information and communication technologies to create unique customer value, facilitating multilateral communication and offering innovative digital products (Vadana et al., 2019; Yadav and Varadarajan, 2005; Yordanova et al., 2024). Born-digital firms distinguish themselves by transferring business models and platforms, rather than physical merchandise, to different markets (Brouthers et al., 2016). Born-digital firms face distinct challenges in their internationalisation in various market environments. In markets with no competitors offering similar products, born-digital firms must build relationships with potential users and consider the costs of being a first mover (Eisenmann, 2006). When facing dominant competitors, overcoming switching costs and building relationships with foreign users becomes crucial (McIntyre and Subramaniam, 2009). A late-mover approach can benefit born-digital firms in markets with several competitors but no dominant player, emphasising differentiation and integration into local user networks (Eisenmann, 2006). Born-digital firms are different from other firms because the characteristics of digital goods impact decisions on entry mode, country selection, speed of internationalisation, and post-entry activities (Mahnke and Venzin, 2003; Wentrup, 2016).

High technology industries, particularly in life sciences encompassing medical technology, biotechnology, and pharmaceuticals, are characterised by early internationalisation due to the pursuit of value and competitive advantage through scientific, technological, and design innovations (Cavusgil and Knight, 2015; Laurell et al., 2013; Oviatt and McDougall, 1994). The life sciences sector faces unique challenges in internationalisation, such as stringent regulatory requirements, costly clinical trials, and the need for localisation in each region (Deloitte, 2021; Laurell et al., 2013). The digital transformation of healthcare, specifically through digital therapeutics, poses additional hurdles, including the clash between fast-moving born-digital therapeutics firms and cautious, risk-averse regulatory bodies, concerns about digital literacy, data interoperability, and patient privacy (Lupton, 2014; Mathews et al., 2019; Murray et al., 2016). Successful market entry in the digital health industry requires interdisciplinary collaboration, reconciling differences between disciplines, and managing diverse stakeholders (Lee et al., 2019; Murray et al., 2016).

Commercialisation is a pivotal facet of innovation, focused on introducing new technology, products, or services to the market (Bandarian, 2007). Described as transforming knowledge into market-ready offerings (Rosa and Rose, 2007), it involves all phases from innovation introduction to production, marketing, distribution, sales, and customer support (Yencken, 2008). Influenced by political, social, commercial, institutional, and historical factors, firms assess the commercial potential to devise

effective strategies (Bandarian, 2007). The commercialisation strategy, defined as creating financial returns through the innovation's value chain interaction (Hansen and Birkinshaw, 2007), necessitates choices between collaboration or competition with incumbents, deciding when to enter the market (Gans and Stern, 2003) and which commercialisation process to follow (Pellikka and Pellikka, 2011).

Firms often opt for product-based, intellectual property (IP)-based, or hybrid strategies (Gans and Stern, 2003), with technology-based firms benefiting from broader options like integration or licensing. The increasing exchange of patents, licenses, and IP in the technology market expands options for new ventures (Kasch and Dowling, 2008). Information asymmetry, investment, tacitness of know-how, and appropriability influence success in the market for ideas or IP (Pisano, 2006). The choice of strategy and process thus impacts technology-based firms in particular (Pellikka and Pellikka, 2011), influencing market entry costs, performance, resource dependencies, and liability of foreignness (Onetti et al., 2012).

Despite digital therapeutics' recognised benefits, few studies explore these firms' concept-to-creation journey and go-to-market strategies. This is surprising because this market is known for its complex commercialisation process, which often requires localisation (Oderanti et al., 2021). Nevertheless, Cho et al. (2008) proposed a relevant four-stage commercialisation framework. Building on this, Gbadegeshin (2019) expanded it to five stages, emphasising the critical role of protecting technology/solutions in the digital era. Digitalisation, Gbadegeshin (2019) concludes, has profoundly impacted all stages of digital health product commercialisation.

The study integrates existing commercialisation frameworks (Gans et al., 2018; Gbadegeshin, 2019; Pisano, 2006) and theoretical ideas about born-digitals to analyse how firms execute international commercialisation in digital therapeutics. Gbadegeshin's (2019) digital health commercialisation framework guides the exploration. In this approach, discovery involves tapping into the management team's tacit knowledge and conducting market analysis to understand opportunities and challenges (Gbadegeshin, 2019; Reuber et al., 2017). Exploration focuses on product differentiation, testing in clinical and everyday settings, and creating unique products (Fontes and Coombs, 1997; Gbadegeshin, 2019). Decision-making centres on commercialisation methods, encompassing intellectual property, architectural, value chain, or disruption strategies based on profitability and environmental factors (Gans et al., 2018; Zahra and George, 2017). Protection concerns patenting, trade secrets, and internalisation of transactions for information confidentiality (WIPO, 2016, n.d.). Diffusion and marketisation overlap commercialisation and internationalisation, emphasising early internationalisation during these phases (Gbadegeshin, 2019; Knight and Cavusgil, 2004).

2.2 Empirical context

Robinson et al. (2015, p.105) suggest that the digital health industry is distinguished by the "use of digital media to transform healthcare provision", enhancing accessibility and personalised care. The Healthcare Information and Management Systems Society (HIMSS, 2020) underscores digital health as a tool for equitable health access, connecting and empowering individuals while transforming care delivery through flexible, integrated, and digitally-enabled environments. Regulatory bodies like the FDA (2020) expand the scope of this definition to encompass technologies from general wellness applications to medical devices. This study defines digital health as using digital

media to empower people and populations to manage health and wellness. This study focuses on digital therapeutics, a subset of applications using evidence-based software to deliver medical interventions directly (Digital Therapeutics Alliance, n.d.).

The surge in digital health innovations presents significant opportunities to address healthcare challenges (Deloitte Centre for Health Solutions, 2015). Despite the potential, widespread adoption of digital health solutions remains limited, resulting in a slow and fragmented market development (Oderanti et al., 2021). Challenges persist due to complexities in implementing and utilising digital health tools, partly due to the lack of understanding among stakeholders (Oderanti and Li, 2018). While digital health holds promise for more sustainable healthcare systems (Deloitte Centre for Health Solutions, 2015), non-adherence issues persist due to a lack of user-centric design (Ammenwerth and Rigby, 2016).

The COVID-19 pandemic accelerated the adoption of digital health technologies, necessitating remote care provision and driving unprecedented funding growth with $29.1 billion invested across 729 deals in the USA. This represents a doubling of the investment compared to 2020, and funding for digital health research and development is growing exponentially, with $5.8 billion invested in 2021 (Krasniansky et al., 2022). Digital mental healthcare remains the most highly funded clinical indication, with $5.1 billion raised in 2021, $3.3 billion more than any other medical condition (Krasniansky et al., 2022). The increasing body of literature and guidelines further indicate a growing stakeholder interest in integrating digital health tools into traditional healthcare settings, and this has sparked growth in the body of literature on digital application efficacy (IQVIA, 2021). More than 2,000 studies have been published in the last 14 years, but 1500 were published in the last five years. Overall, digital health innovations are expected to continue growing in the evolving global landscape.

Digital therapeutics, a rapidly emerging subset of digital health, delivers evidence-based medical interventions directly to patients, utilising clinically validated software (Digital Therapeutics Alliance, n.d.). Examples encompass virtual reality and digital cognitive behavioural therapy, which has proven effective in treating hypertension, obesity, and diabetes and enhancing medication adherence (Deloitte, 2021). These tools – often developed for conditions with unmet patient needs – facilitate health behaviour change and provide personalised therapy, remote monitoring, and patient education (Dang et al., 2020). Digital therapeutics offer advantages such as flexible, personalised, and consistent therapeutic delivery in various settings (Dang et al., 2020). Sverdlov et al. (2018) identify further opportunities, including streamlined intervention release, safer and cost-effective treatment, potential use in paediatrics, and integration of gamification into therapies.

The decision to purchase health products, including digital therapeutics tools, is often made by healthcare professionals and third parties like insurance companies rather than patients or consumers (Brinkmann-Sass et al., 2020). To succeed, digital therapeutics firms must align with reimbursement or payment models of the targeted healthcare system (Brinkmann-Sass et al., 2020). With over 350,000 digital health applications in the market, born-digital therapeutics firms and other technology firms face challenges generating returns and securing payment in the complex health sector (IQVIA, 2021). Reimbursement pathways for digital therapeutics include direct-to-consumer models, value-based contracting (a per-member-per-month fee or a fee based on user engagement), software as a medical device reimbursement, and software as a drug reimbursement, each with distinct payment structures and requirements (IQVIA, 2021).

These models offer various approaches for digital therapeutics firms to create returns on investment, providing flexibility but requiring evidence of improved outcomes or reduced costs (IQVIA, 2021).

The digital therapeutics industry faces market and technological uncertainties, impacting adoption due to complex stakeholder involvement, intricate decision-making processes, and various value judgments (Sverdlov et al., 2018). Hurdles to adoption include a sparse evidence base, complex trial designs, poor regulatory infrastructure, rapid technological developments, data compliance costs, and stakeholder adoption issues (Holfelder et al., 2021; Oderanti and Li, 2018; Sverdlov et al., 2018).

Nonetheless, the digital therapeutics industry has experienced substantial growth in the past four years, primarily accelerated by the COVID-19 pandemic. Mandated social distancing has led to a surge in remote patient care, showcasing the potential of digital therapeutics tools in reducing healthcare costs and enhancing health outcomes. While the pandemic has brought flexibility to traditional reimbursement and regulatory processes, the landscape for digital interventions like digital therapeutics remains unclear.

3 Research design

A qualitative approach, emphasising in-depth understanding, is instrumental in gaining detailed insights into various phenomena (Dana and Dumez, 2015). Qualitative studies are pivotal for cultivating nuanced perspectives from participants, facilitating a rich exploration of their views (Dana and Dana, 2005; Thomas, 2006). Given the nascent stage of the digital therapeutics industry and the paucity of research on the commercialisation and internationalisation of digital therapeutics, formulating fresh theoretical concepts is crucial (Choi et al., 2019). Employing a qualitative study enables us to develop theoretical ideas on commercialisation and internationalisation rooted in prior literature while using empirical data from the emerging digital health sector (Dana and Dumez, 2015).

Interview questions, presented in a semi-structured format, aimed to extract participants' views (Dana and Dana, 2005). The question flow centred on participants' experiences, addressing digital therapeutics design, market entry strategies, interaction with potential partners for foreign market understanding, and challenges encountered in internationalising and commercialising digital therapeutics.

Interview participants were selected through purposive sampling based on the authors' professional networks. Purposive sampling is the intentional selection of participants due to the qualities or characteristics of the participants (Etikan, 2016), where even a small number of participants can provide interesting, context-specific insights (Dana and Dana, 2005). In our case, we required participants who founded or worked in a digital therapeutics firm and have relevant experience and knowledge (Etikan, 2016) in commercialisation and internationalisation. Specifically, the first selection criterion required participants to work in or have founded firms that offer products or services which support health behaviour change, chronic disease management, or effective virtual treatment. Secondly, the product had to feature some form of multimedia, like gamification or a chatbot function. Criteria two was that the firm must have internationalised within five years since inception and expanded to at least one international market within the same timeframe. Criteria three specified that the product must be digitally purchased and delivered through a digital platform. This resulted in a

pool of eight interviewees from Australia, New Zealand, Singapore, Turkey and the USA who held the positions of founders, directors, chief operating officers and strategist. The results, therefore, need to be interpreted in light of the potential limitations and biases introduced by the small sample, the sampling frameworks and the geographic origins of interviewees.

For primary data analysis, the audio recordings of the interviews were transcribed. To ensure accuracy, participants had an opportunity to review their transcripts and remove any inaccurate sentences or sensitive material. This process helps improve the transcript's accuracy, credibility, and validity (Groenland and Dana, 2019). Once the participants confirmed the transcripts, NVivo was used to organise the data into first-order codes, second-order themes, and aggregate dimensions. Internal credibility assesses result reproducibility within the same sample, setting, and context, while external credibility gauges generalisability across populations (Dana and Dumez, 2015; Groenland and Dana, 2019). The study aimed to explore, not generalise, focusing on descriptive validity (Dana and Dumez, 2015). To ensure credibility, codes were rigorously defined and checked. Trustworthiness relates to participant-provided information accuracy (Elo et al., 2014). This study prioritised credibility and trustworthiness by framing open-ended questions, avoiding interviewer influence, building rapport for honest responses, and ensuring confidentiality.

4 Findings

The interview data underwent analysis, which involved categorisation into first-order codes and subsequent classification into second-order themes. This process facilitated an understanding of born-digital therapeutics firms' concurrent commercialisation and internationalisation activities. The data was categorised based on emergent themes, and results will be presented under three aggregate dimensions:

1 new product development

2 strategic market entry

3 commercialisation environment.

Each subsection will further break down dimensions into second-order themes supported by first-order codes extracted from the interviews.

4.1 Product development

'New product development' refers to the process that unfolds from idea generation to market entry (Rogers et al., 2004; Rosa and Rose, 2007). Interview participants identified new product development activities as a key in international commercialisation to create a product which could be used in several foreign markets. In this process, they focused on user-centric design, product management and product protection. In reference to user-centric design, many interviewees explained how it is essential to co-design the product with potential users and include iterative feedback cycles.

> "You need to think about it from a health angle rather than a tech angle…understanding the health system and what the gaps are. As well as the tech angle, so that it is easy to use and easily adopted or quickly adopted." Participant U1

Iterative feedback cycles enabled the firms to quickly improve their innovation to ensure it fits the target market. Interviewees also highlighted that 'early adopters' are essential in the development process as they provided the initial feedback to improve the user experience. Interviewees emphasised how the feedback from early adopters is essential in identifying problems and improving the product's scalability. Interviewees also highlighted that product managers play a vital role in the development process, as they understand the commercial and technical aspects of the product and bring it all together to create a prototype that meets commercial and technology needs while integrating customer feedback. Iterative product development permits rapid feedback and quick development cycles with limited resources. Interviewees also stressed the importance of protecting their technology through IP protection mechanisms. This enables firms to license their product and the associated IP to other firms safely and profitably. Even though IP protection through patents can be a costly process, interviewees expressed that they were able to gain more bargaining power when negotiating with potential licensees or other buyers.

4.2 Strategic market entry

Strategic market entry for born-digital therapeutics firms focuses on a few key considerations. Participants stressed understanding the market beforehand, though some concurrently learned while immersed in it, refining marketing and sales strategies. Many interviewees highlighted that their core commercialisation strategy revolved around being the first to market. This was rooted in the belief that being first to market would enable them to build their reputation and brand. The interviewees also emphasised the importance of having a product with a clinical safety and efficacy history. Interviewees believed that being the first with strong business acumen and evidence-based products would give them an advantage. Interviewees noted that while founders were specialised, they often lacked business acumen, impacting the born-digital therapeutics firms's commercial success. They also highlighted how founders' clinical or research backgrounds were sometimes a hindrance. Some interviewees described how, as a result of the inexperience of the management team, there was a lack of strategic planning, and impromptu decisions had, in some cases, serious consequences. The main takeaway for interviewees was to plan out decisions and major steps carefully as the consequences are often time and financially demanding.

> "We're still the only ones that have a commercial product. Not to say that there are others trying but we've seen a couple try and fail. Probably one or two have proceeded further down the path, but they're probably 12 to 18 months away from having a commercial product." Participant A1

Interviewees highlighted that accessing unique resources was key in helping digital therapeutics firms commercialise their innovation. To this end, interviewees explained that they formed partnerships to access unique resources. Partnerships were formed through the networks of investors, founders, and board members. These partnerships were critical for entry into foreign markets and supported a number of the key activities for foreign market entry. A fundamental challenge was user adoption, mainly due to the novelty and the many digital applications available to consumers. To resolve this, interview participants accessed specialised assets such as patient and customer bases from their channel partners to increase the rate of user adoption. The channel partners

also provided a sales channel where firms could increase the exposure of their product with the digital therapeutic bundled with a complementary health product. They could combine their products with other products or services through partnerships to address different parts of the patient journey. Participants also stated how established pharmaceutical and medical device companies could act as research and development partners supporting or funding their research projects to prove efficacy for a specific clinical indication. These findings highlight how unique resources through partnerships can be a significant catalyst for growth and product development. Born-digital therapeutics firms can source the needed capabilities and resources without bearing the cost financially.

> "[our partner] have got pockets of money specifically around research and development and help us on a case by case basis, so if we find a problem to solve, they'll throw people and time and money in to help us…we don't do it ourselves." Participant N4

Interviewees suggested that obtaining revenue in the digital therapeutics industry can be complicated. Some possible revenue streams were business-to-consumer (B2C), reimbursement by the government, and business-to-business-to-consumer (B2B2C) through insurance companies and healthcare organisations. Interviewees suggested that with B2C, it was difficult to become profitable for digital therapeutics as consumers were not willing to pay for healthcare themselves. Interviewees identified the reimbursement system as one of their key revenue streams. This was also an important factor in market selection. Interviewees expressed that Germany and the US are some of the world's largest and most established healthcare markets, which was a key motivator for firms to enter these markets. Interview participants expressed that the absence of a proper reimbursement system meant it was nearly impossible to succeed in a market. Interview participants also suggested that a lack of incentives could discourage clinicians from adopting digital therapies. Clinicians were important in the reimbursement process as they often endorsed using the firm's digital therapeutics. An interesting perspective on reimbursement was that even if the digital therapeutic meets the criteria of the reimbursement system or has regulatory approval, it does not equate to success within that market. For example, in the US, connecting with the right people, navigating through the layers of the reimbursement system, and understanding how the product fits into the market can impede success. As such, reimbursement systems were highlighted as both a driver and a barrier to the growth of digital therapeutics.

> "With digital therapeutics like Germany is right now the easiest market just because there is a centralised process." Participant U1

4.3 Commercialisation environment

The health industry has unique characteristics that can affect digital therapeutics product commercialisation. For example, being in a regulated industry adds complexity to born-digital therapeutics firms aiming to enter the market. Interestingly, many interview participants did not undergo regulatory approval because their product or solution was not identified as a medical device or regulated product. Instead, some interview participants identified ways to avoid regulatory approval while being permissible for health-related purposes. The participants who did seek regulatory approval identified this process as challenging. One interviewee suggested that their error of judgment in the

regulatory approval process led to a crucial setback in their plan. Through this setback, they recognised that it is important to have extensive regulatory knowledge and experience. Despite not being formally regulated as a medical device or treatment, interviewees suggested that having supporting evidence on the efficacy of their digital therapeutic tools was critical for their success. A clinical team's decision to adopt a new product heavily depends on clinical data and the quality of data that validates the benefits of introducing the product. Thus, digital therapeutics require substantial data to legitimise their use on patients. Interview participants expressed how comparative studies with current gold standard treatment were important to prove efficacy and safety.

> "Although we are not a regulated medical device, we have taken that route, where we have done as many studies and like stringent randomised control trials, as well as independent studies and internal studies. To essentially validate our technology showing that it works and that physical therapists agree with it." Participant U1

Interview participants leveraged the scientific work of organisations, such as universities and research groups, to endorse their innovative products. This method allowed firms to obtain supporting data without conducting the study themselves. As clinical trials can be costly and lengthy, there was often a delay in the availability of clinical trial data to support their product. Interview participants explained how they needed to use alternative means of evidence to support the use of their product. Clinical data from third-party studies supported the firms' sales efforts to help potential customers make educated decisions about digital therapeutics.

Table 1 Summary of codes, themes, and aggregate dimension

First order codes	*Second order themes*	*Aggregate dimensions*
Including user in design process	User-centric design	New product development
Integration into clinical workflows		
Prioritising features to user and commercial needs	Product management	
Intellectual property	Product protection	
First mover	Commercialisation strategy	Strategic market entry
Licensing		
Partnerships	Accessing resources	
Management team influence		
Payer landscape	Revenue streams	
Reimbursement system		
Complying with international and regional regulations	Clinical approval	Commercialisation environment
Obtaining Safety and efficacy data		
Adapting to different cultures and local standards	Localisation	

Institutional factors such as the regulatory and reimbursement system were also identified as key factors. The regulatory and reimbursement landscape were identified as two factors that affected the perceived value and potential of the market. Digital therapeutics differ from other high-technology industries as they are highly regulated and require

localisation in each region. Localising and culturally adapting the product in different regions was identified as a key entry challenge for born-digital therapeutics firms. Localising the technology was time-consuming and costly, requiring significant product development and testing. For example, some interview participants deemed the Southeast Asian market difficult, given the cultural barriers often faced when entering this market. There were also some concerns about the product's efficacy as the interview participants lacked in-house language experts. Interview participants expressed that localising their market entry approach was important to match each region's institutional structure because each region had different regulations and reimbursement models. Thus, the institutional structure around reimbursement and regulations was a key environmental factor influencing a digital therapeutic firm's market entry strategy.

4.4 Internationalisation and commercialisation process

New product development, strategic market entry, and the health market environment were key themes that emerged from the commercialisation and internationalisation activities of digital therapeutics. We also integrated the ideas expressed by participants across cases using a holistic cross-case comparison (Groenland and Dana, 2019). The following flow diagrams are the result of this cross-case comparison. The flow diagrams provide high-level overviews of how the second-order themes and first-order codes can be integrated into the internationalisation and commercialisation process for four commonly entered markets by the interviewees: the UK, Singapore, the USA, and Germany.

4.4.1 The UK

Interview participants suggested that the UK had a decentralised health system where the national health system (NHS) governs the health service provision. Interview participants took these high-level steps to enter the market.

1 To understand the possible revenue streams and market environment, firms researched the market to identify key stakeholders, such as the payers and regulators. In parallel, the firms conducted pilot, research, or product fit studies, for example, in a local hospital.

2 Once sufficient studies have been conducted, it is important to connect with the right people within the health system, such as the head of digital at the NHS and present their products to highlight clinical efficacy, safety, health and economic benefits.

3 If regulators approve, the firm has a high chance of successfully entering the market.

4 no generalised regulatory and reimbursement pathway exists for digital therapeutics.

4.4.2 Singapore

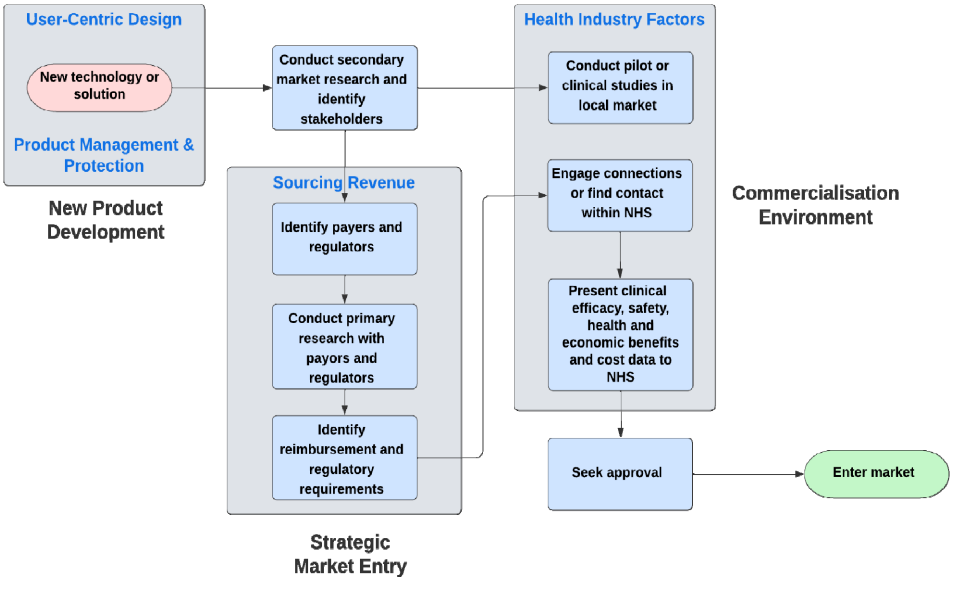
The Singaporean healthcare system is made up of private providers. The Health Sciences Authority (HSA) regulatory guidelines for Software as a Medical Device (SaMD) are applied to regulate the sector. Thus, if the product falls under a regulated category, it must go through regulatory approval. Singapore does not have an established reimbursement model for digital therapeutics. Interview participants expressed that

creativity is required to secure reimbursement. The B2B2C model was identified as the most profitable reimbursement model for their digital therapeutic. Interview participants described two main revenue streams (Figure 2).

1 Private health insurers who may cover the cost of digital therapeutics for private customers.

2 Firms may identify established firms or other born-digital therapeutics firms to bundle their products to sell as a package. Established firms may also integrate the firm's product into their existing health systems or products. Revenue generated through this method will come from royalties or revenue sharing.

Figure 1 International commercialisation process in the UK market (see online version for colours)



4.4.3 The USA

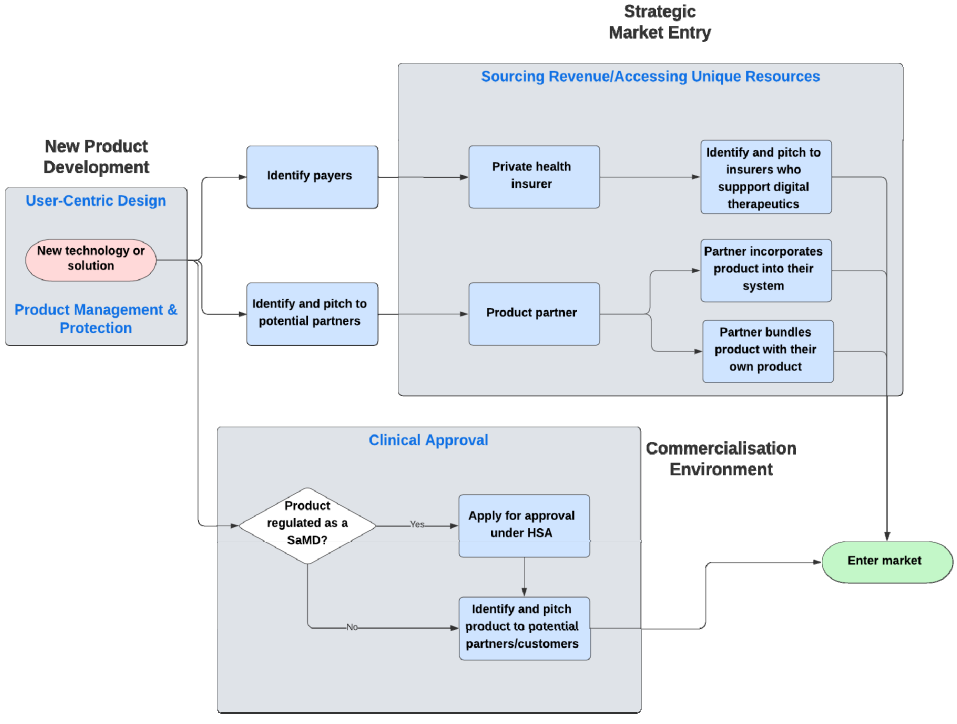
The US health system is decentralised, comprising private and public care. Interview participants typically started with an organisation with brand recognition, such as a large hospital system in New York. They used this pilot to demonstrate clinical efficacy, safety, and health and economic benefits to pitch to other players. There are several reimbursement strategies.

1 Direct-to-employer: Many employees are insured by their employers, and their employer pays for their health plan. If a firm pursues this model, it sells to an employer, and all its employees will have access to digital therapeutics.

2 Health Plan: The firm bundles its products into a health plan, which insurance companies distribute. Insurers have an internal system for organising benefits and medical care packages for different employers. This model is similar to the direct-to-employer model, except the firm can target multiple employers simultaneously.

3 Federal program: Medicare currently covers some Federal Drug Administration approved digital therapeutics products, and providers can claim reimbursement under this system.

Figure 2 International commercialisation process in the Singaporean market (see online version for colours)



4.4.4 Germany

Interview participants described Germany as having a centralised health system and a defined reimbursement and regulatory model. The Digital Healthcare Act provides a reimbursement model for digital therapeutics. There are two application processes.

1 Fast track: If the product is already a certified class I or II medical device under the European Medical Device Regulations and can show a health benefit, such as improving recovery or quality of life, then the product is eligible for fast track. The Federal Institute for Drugs and Medical Devices will approve or reject the application within three months. Once approved, statutory health insurance can reimburse the digital therapeutics product. The product developer can negotiate prices if needed.

2 Provisional inclusion: The firm can apply for provisional inclusion in the registry for 12 months if they can provide real-world evidence and scientific principles to justify the product. The firm must then submit clinical evidence, e.g., a comparative study that shows health benefits, within nine months.

Figure 3 International commercialisation process in the US market (see online version for colours)

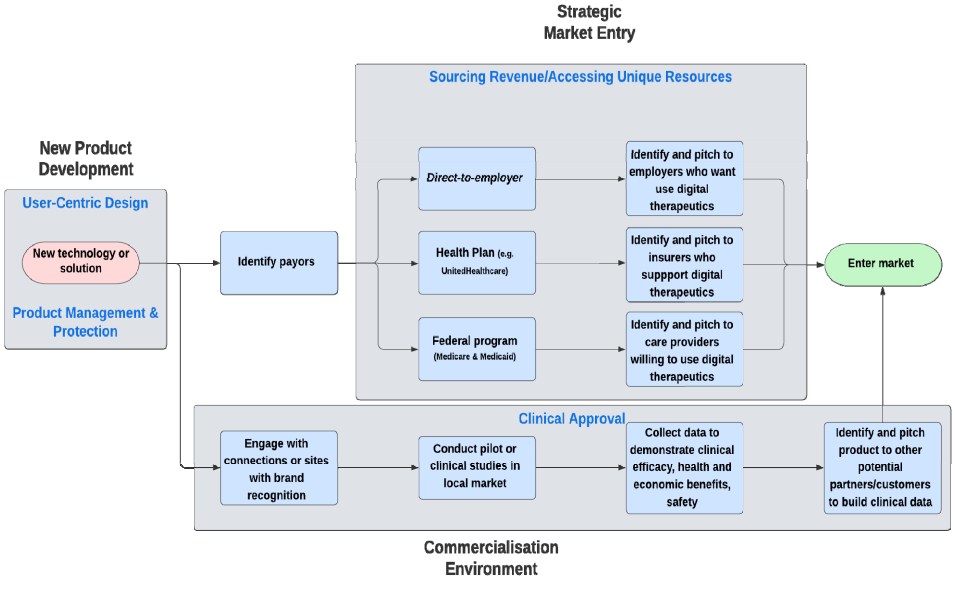


Figure 4 International commercialisation process in the German market (see online version for colours)

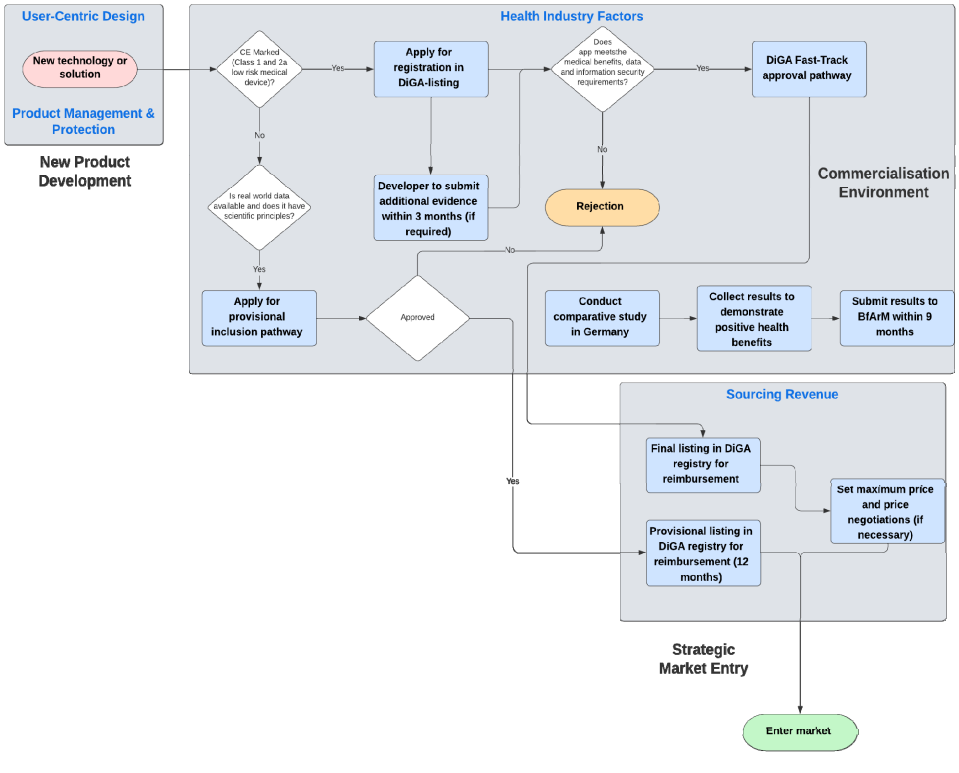


Figure 5 Summary of international commercialisation activities (see online version for colours)

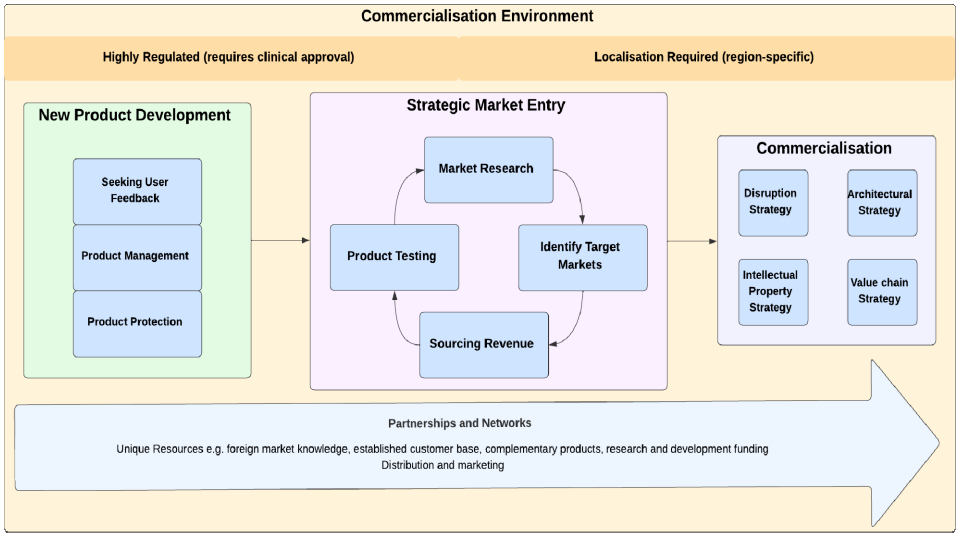


Table 1 Summary of main findings across different markets

Country	*Interview participant market entry strategy*	*Revenue source (payer/reimbursement)*	*Clinical approval/regulator*	*Defined regulatory pathway*	*Defined reimbursement pathway*
UK	Digital therapeutic as a supplement to a clinical trial	• Contingent reimbursement	Medicines and Healthcare products Regulatory Agency	No	No
US	Product partnership	• Direct-to-employer • Health insurance • Federal program (CPT codes)	Food and Drug Administration	No	Yes
Singapore	Product partnership	• B2B2C model • Health insurance • Package with MNC or start-up	Health Services Authority	No	No
Germany	Channel partnership	• Digital Healthcare Act • Fast track • Provisional inclusion	Federal Institute for Drugs and Medical Devices	Yes	Yes

Table 1 summarises the main findings across countries. The process undertaken by interview participants is summarised in Figure 5. The process begins with new product development, where testing, establishment of product management, and product protection occur. The firm will then conduct market research to identify potential markets, understand possible revenue models, and test the product locally, typically with care providers and health organisations. From there, the firm will decide on a commercialisation strategy that best suits that market. The commercialisation environment influences each phase, and partners and networks have a role across all the phases.

5 Discussion

Similar to the observations made in Pisano (2006), the study reveals that founder characteristics, such as background and education, influence firm strategies and international performance, with born-digital therapeutics firms often led by individuals rich in technical knowledge but lacking in business acumen. This deficiency can lead to resource depletion due to premature market entry without proper commercial planning. Coviello (2015) and Cho et al. (2008) emphasise the importance of integrating business-oriented leadership early to complement existing skills, thereby enhancing commercialisation and market diffusion. The present study highlights the critical role of understanding product-market fit and identifying potential markets. This aligns with Gbadegeshin (2019) and Lee et al. (2019), who suggest that building entrepreneurial capacity for market analysis and effective marketing is crucial. This suggests that assembling a team with the right mix of skills is critical to planning, innovation, and discovering market opportunities, underlining that business expertise is essential for creating viable structures and processes for sustained commercial and international growth.

Participants emphasised the critical role of intuitive design and seamless integration of digital therapeutics into clinical workflows, noting that while digital therapeutics tools can enhance efficiency and care delivery (Herzlinger, 2006), they also have the potential to disrupt workflows and increase the burden on clinical teams (Dang et al., 2020). The concern among clinicians about learning new systems and managing additional activities creates resistance to adopting digital therapeutics, stressing an already burdened workforce. Because of these challenges, the importance of prototyping and testing to understand user preferences and improve digital therapeutics innovations was underscored (Gbadegeshin, 2019; Mathews et al., 2019). Participants conducted user testing with hospitals and care providers to demonstrate clinical efficacy in realistic healthcare settings, aligning with the idea of outsourcing capabilities through networks (Oviatt and McDougall, 1994). This ensures integration with existing medical technologies and minimal workflow disruption. Ultimately, a user-centric design incorporating continuous feedback from clinicians and patients is vital for adoption, especially in healthcare, where the cautious adoption of new technologies is prevalent.

Commercial protection of innovations is vital in the digital marketplace to prevent competitor imitation, with the specialised nature of digital therapeutics underscoring the necessity of IP rights for market success (Mahnke and Venzin, 2003; Pisano, 2006). Bracio and Szarucki (2019) highlight IP's essential role in the commercialisation and internationalisation of innovations, a sentiment echoed by interview participants who

protected their IP and novel technologies early to secure a global competitive edge. Contrary to Gbadegeshin's (2019) perspective that product protection follows commercialisation, early IP strategy emerged as crucial for safeguarding financial returns on R&D investments and preserving novelty by preventing imitation, which is a significant challenge for born digitals (Brouthers et al., 2016). Similar to the ideas put forward by Chetty and Hunt (2004), IP protection can be a strategic marketing tool for INVs offering digital products, facilitating open marketing while mitigating the risk of imitation and also allowing firms to maintain control and profit from licensing agreements (Gans and Stern, 2003).

The study finds a link between entry and commercialisation strategies in the digital therapeutics market. Interview participants noted that partnerships and MNCs were crucial for overseas activities. MNCs often led the foreign market entry, with firms adopting a value chain strategy to integrate or complement incumbents' offerings (Gans et al., 2018). Firms sometimes use a disruption strategy in insurance partnerships, competing directly with incumbents. Participants also explained that efficacy and safety data were crucial for gaining insurance approval, securing a first-mover advantage and reimbursement before competitors. These firms, typical of INVs, aimed to innovate globally in niche markets (Jones et al., 2011). They adapted their commercialisation strategy based on regional factors and local partners, echoing the ideas expressed by Pellikka and Virtanen (2009) that commercialisation and internationalisation activities go hand in hand. Local partners provided resources like established customer bases and marketing channels, mitigating liabilities of foreignness (Coviello and Munro, 1997). Local partners also helped determine market entry and commercialisation plans, deciding how innovations fit into their offerings.

Interview participants highlighted that relationships within a region were crucial for product adoption. The management team, board members, and investors were critical in building a network of commercial partners and customers. Firms partnered with multinational enterprises, healthcare organisations, local care providers, and government agencies to support international commercialisation. This use of business partners to gain market knowledge and expand quickly is typical of INVs (Johanson and Mattsson, 2015). Mahnke and Venzin (2003) state that born-digital firms often face foreign discrimination, making building a foreign user base challenging. To mitigate this, firms partnered with multinational enterprises, such as insurance companies and large care providers, to leverage their customer base and gain legitimacy. These partnerships, identified as 'distribution partners,' provided the necessary platform for market entry and user adoption. Despite Brouthers et al. (2016) suggesting that born digitals may bypass distributors, participants found them critical for innovation diffusion and consistent revenue streams in this industry.

The study identified four commercialisation patterns based on regulatory and reimbursement differences in the UK, Singapore, the USA, and Germany. These findings underscore the importance of adapting commercialisation processes (Pellikka and Pellikka, 2009) to succeed in different markets, demonstrating the impact of regulatory and cultural dimensions on market entry. Interview participants highlighted challenges with poorly defined regulatory and reimbursement frameworks in foreign markets. Mathews et al. (2019) explain that regulatory bodies' risk-averse nature contrasts with the fast-paced development of health technology. As noted by participants, born-digital therapeutics firms have influenced institutional changes, such as Germany's provisional listing pathway for digital therapeutics reimbursement. In Singapore, participants

creatively entered the market by convincing MNCs to adopt digital therapeutics, reflecting Teece's (2014) idea of creating a supportive market ecosystem. In this respect, participants identified clinical and real-world data as crucial for the diffusion of digital therapeutics. They noted that partners required clinical data demonstrating efficacy and safety. The COVID-19 pandemic prompted the use of real-world data and virtual trials, which were cost-effective and easier to design than traditional trials (Krasniansky et al., 2022). Participants with extensive clinical data gained a competitive advantage, as competitors often faced delays and lacked such data. Conducting clinical trials and pilot studies with local healthcare organisations and companies was beneficial for commercialising and internationalising digital therapeutics.

Interview participants emphasised the importance of establishing revenue streams in digital therapeutics. Unlike other technology-intensive industries, healthcare users typically do not pay directly; insurance companies, government agencies, or employers cover costs (Brinkmann-Sass et al., 2020). Consequently, a B2C model is often unprofitable. Firms adopt a B2B2C approach, seeking reimbursement from larger organisations. Participants noted that the US and Germany have institutional structures conducive to digital therapeutic reimbursement, which drives clinician uptake and sales, demonstrating a foreign location advantage (Oviatt and McDougall, 1994; Stern et al., 2020). In many regions without defined reimbursement pathways, born-digital therapeutics firms adapt existing pathways or find unique methods for reimbursement. MNCs serve as gateways into the Asian market, offering opportunities through health insurance claims or patient co-payments. Revenue streams are a key aspect of business models (Oderanti and Li, 2018) and are crucial for commercial and international expansion. This study aligns with Gbadegeshin (2019), who highlights business model creation and testing as vital in the diffusion and marketing phase of commercialisation. Nonetheless, further research is needed to understand sustainable and financially viable business models for digital therapeutics.

This study explores how born-digital therapeutics firms adopt commercialisation strategies, leverage networks for foreign market expansion, access unique resources, and obtain clinical data to maintain a competitive edge. While existing literature often treats commercialisation and internationalisation as separate processes, interview participants described them as parallel and overlapping. Key activities such as market analysis and product validation contribute to both processes simultaneously. The findings emphasise the importance of firm-level processes in internationalisation, involving market analysis, network formation, and identifying the most effective commercialisation strategies. Various internationalisation theories highlight different aspects of this process. However, this study's findings align more closely with network and organisational-learning theories, emphasising the ongoing nature of internationalisation through learning and networking activities (Hurmerinta et al., 2016; Johanson and Mattsson, 2015; Schweizer and Vahlne, 2022; Welch and Paavilainen-Mäntymäki, 2014). The study also indicates that environmental, organisational, and founder-related factors significantly influence internationalisation. According to INV theory, these contextual factors shape the conditions necessary for internationalisation (Oviatt and McDougall, 1994). Understanding the process of entrepreneurial internationalisation is crucial for comprehending how born-digital firms use unique resources to seize new opportunities (Yordanova et al., 2024).

This study explores how born-digital therapeutics firms navigate commercialisation and internationalisation as intertwined processes. The findings align with Gbadegeshin's

(2019) commercialisation model, which includes invention, exploration, strategy decisions, marketisation, and diffusion and commercialisation process models (Pellikka and Pellikka, 2011). However, existing models like Gbadegeshin's (2019) do not fully integrate internationalisation, often treating it as a separate process or only focusing on one of the processes in isolation (Pellikka and Pellikka, 2011). This study reveals that commercialisation and internationalisation can co-occur, with activities overlapping. Previous literature, such as Bracio and Szarucki (2019), suggests that internationalisation either results from innovation or enhances a firm's innovativeness. This study supports the former, showing that technology-intensive health products are designed for global markets from the outset. The simultaneous nature of these activities suggests a need for updated frameworks that integrate both processes.

6 Conclusions

This study explores the commercialisation and internationalisation of born-digital therapeutics firms, focusing on new product development, strategic market entry, and barriers to internationalisation. It reveals how these processes can occur concurrently, challenging traditional views and enriching technology commercialisation literature in digital health. Key influences include social and business networks, environmental and organisational factors, and the management team. The research highlights the importance of collaboration, the impact of contextual factors, especially institutional ones, on market entry strategies, and the critical role of reimbursement and regulations. It suggests reevaluating existing frameworks to integrate commercialisation and internationalisation better, emphasising the significance of firm-level learning and networking.

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