The Road to Commercialisation: Expanding Digital Health Therapeutics Across International Markets

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Abstract

In recent years, a substantial number of digital health ventures have commercialised in several international markets from inception. The phenomenon of rapidly internationalising digital therapeutics firms and the findings of previous studies suggest that there is an overlap between the commercialisation and internationalisation processes. In addition, concurrent commercialisation and internationalisation by digital therapeutic start-ups are not well understood.

Currently, commercialisation and internationalisation are addressed as two distinct processes in literature. The rapid internationalisation of small firms is explained by the 'international new ventures' and 'entrepreneurial internationalisation' theory (Oviatt & McDougall, 1994). On the other hand, commercialisation strategies for digital health are not well established; however, Gbadegeshin (2019) proposes a model to explain the process. In addition, generalisable commercialisation models like the 'Entrepreneurial Strategy Compass' (Gans et al., 2018) provide an interesting framework to explore the commercialisation of digital health.

Given the current uncertainties, this study aims to understand how these elements overlap, particularly in the digital therapeutics industry. As part of the explorative qualitative study, semi-structured interviews with an inductive approach were used to address the research aim. Three aggregate dimensions were then extracted from the qualitative data: new product development, strategic market entry, and commercialisation environment. These dimensions were then broken down into specific internationalisation and commercialisation activities that contributed to understanding the overlap between these two processes.

The findings of this study contribute to the digital health commercialisation literature and the understanding of the firm-level process of bringing a digital health product to market. The study finds that activities undertaken by digital therapeutics firms contribute to both commercialisation and internationalisation simultaneously, thus suggesting internationalisation elements should be considered further in commercialisation frameworks. Additionally, the study contributes to entrepreneurial internationalisation literature by showing internationalisation is a process in which new ventures achieve through different activities over time to achieve rapid internationalisation. A future research area could be to understand the behaviour and activities that drive these internationalisation processes.

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List of Abbreviations

BG – Born-global

CPT – Current procedural terminology

DVG – Digital Health Care Act

FDA – Food and Drug Administration

ICT – Information and communications technology

IE – International entrepreneur

INV - International new ventures

IP – Intellectual property

IT – Information technology

LoF – Liability of Foreignness

mHealth - mobile health

MNC – Multinational corporation

PBM – Pharmacy benefit manager

PMPM – per-member-per-month

SaaS – software as a service

SaMD – software as a medical device

WIPO – World Intellectual Property Organisation

USA – United States of America

UK – United Kingdom

Chapter 1 Introduction

Digital health firms have commercialised into several international markets from inception. During the COVID-19 pandemic, digital technologies have become an essential route for accessing healthcare services. Government lockdowns and mandatory social distancing swept nations resulting in surging international demand for virtual care applications and remote healthcare tools. With few regions left untouched, the increased global need for digital health interventions has resulted in ventures pursuing internationalisation earlier, some even since their inception. However, despite the increasing numbers of international digital health start-ups, the internationalisation and commercialisation of digital therapeutics is not well understood.

Digital health has been shown to be beneficial in promoting value-driven, more cost-effective, and more comprehensive personalised care (Deloitte Centre for Health Solutions, 2015). In particular, digital health therapeutics have been receiving increased attention for their potential to improve patient care. 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.), digital therapeutics is a subgroup of digital health that is rapidly emerging as a tool to provide care to unmet medical needs. However, despite the increased demand, digital therapeutics firms face issues with user adoption, clinical validation, and sustainable commercialisation.

The phenomenon of the rapid internationalisation of small firms is known as ‘international new ventures’ (Oviatt & McDougall, 1994). Today, the global market has evolved dramatically, with firms seeking to gain value and competitive advantage through scientific, technological, and design innovations (Bracio & Szarucki, 2019; Cavusgil & Knight, 2015). The emergence of the internet and other information and communications technology offers a low-cost avenue for firms to overcome costs associated with internationalisation (Wentrup, 2016), resulting in increased competition from new ventures against established firms in the market. Vadana et al. (2019) terms rapidly internationalising digital firms as “born-digital” which are defined as “services or manufacturing companies in which most of the inward and outward value chains are digitalised soon after inception” (p.200). Cahen (2019) suggests that high technology start-ups identify internationalisation as a natural step of their commercialisation. Thus, the internationalisation of Born-Digitals, such as digital therapeutics firms, could be perceived as a part of the commercialisation process.

Additionally, as the digital health industry is still emerging, there is no evidence of a gold standard or established commercialisation strategy (Henze et al., 2021). The proliferation of digital health applications demonstrates the need for start-ups to develop a commercialisation strategy that enables sustainable advantage and scalability of the product in an increasingly saturated market (Henze et al., 2021). Generalisable commercialisation models such as the 'Entrepreneurial Strategy Compass' created by Gans et al. 2018 can be used to explore the commercialisation strategies of digital therapeutics start-ups. Gbadegeshin (2019) also suggests a commercialisation framework for digital health specifically. However, despite the proliferation of international digital health start-ups, the internationalisation and commercialisation of digital therapeutics is not well defined. This may be due to the infancy of the digital health space and the broader life sciences industry differing from other technology industries, given its reliance on evidence or science-based knowledge (Pistorius, 2017).

Previous research indicates there is a potential overlap between commercialisation and internationalisation. Pellikka and Virtanen (2009) found that firms were finding opportunities to enter overseas markets during their commercialisation process. All study participants stated that internationalisation was a key issue during the commercialisation process. Additionally, Gbadegeshin (2019) highlights internationalisation as a key activity in the diffusion and marketisation phase of digital health commercialisation. Bracio and Szarucki (2019) suggest that commercialisation of innovation occurs through internationalisation. There are two relationships between innovation and internationalisation; firstly, innovation and the firm's previous innovative activities can drive internationalisation. Secondly, internationalisation stimulates innovative activities through exposure to new knowledge and challenges which force firms to be more innovative (Bracio & Szarucki, 2019).

The phenomenon of quickly internationalising digital therapeutics firms and the findings of previous studies suggest there is an overlap between the commercialisation and internationalisation processes. Thus, there is an opportunity in research to further explore how new ventures conduct internationalisation and commercialisation simultaneously and the key challenges behind this process.

1.1 Research Purpose and Questions

The present exploratory study aims to better understand the motivations and strategies of new ventures who seek to commercialise internationally. To investigate the phenomenon of international commercialisation, the following research question was developed:

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

1.2 Methodology

A qualitative approach was used to address the above research question, with primary data collected through semi-structured interviews. The interview participants were management team members from digital therapeutics organisations who were selected through purposive sampling. After sampling, eight interviews were conducted over Zoom with interview transcripts uploaded and coded on NVivo, a qualitative analysis software. The themes identified across the interviews were then used to inform the findings and discussion of the research.

1.3 Contribution

This research will be relevant to both academics and the healthcare industry. On the academic side, this thesis will contribute to the digital health commercialisation literature by providing a better understanding of the firm-level process of bringing a digital health product to market. It will also contribute to the understanding of overlaps between internationalisation activities and the commercialisation processes, as well as the internationalisation elements that should be considered further in commercialisation frameworks. This thesis will also contribute to the entrepreneurial internationalisation literature to suggest that internationalisation is a process in which new ventures achieve through different activities over time to achieve rapid internationalisation.

On the industry side, this study provides an in-depth understanding of how commercialisation and internationalisation activities are conducted in parallel by new digital health ventures. This topic will provide useful insights for digital health industry members as they develop and review strategies for overseas expansion, particularly with the increasing globalisation of economic markets. In recent years, particularly with the COVID-19 pandemic, many new ventures creating digital therapeutics have sought to explore various markets concurrently. This research will also help firms understand how firms seek to capitalise on opportunities internationally and the key challenges that are encountered in this process. Identifying these challenges will support industry members in understanding how to mitigate their risks during global expansion in the digital health industry.

1.4 Thesis Structure

The thesis is structured as follows. Chapter Two introduces the empirical context for the research and identifies the overall purpose and objectives of the study. Chapter Three comprises the 'Literature Review' where the relevant literature on commercialisation theories and internationalisation theories is reviewed. Chapter Four describes the qualitative semi-structured interview and analysis methodology undertaken to study the empirical context. Chapter Five outlines the research findings. Chapter Six provides a comprehensive discussion of the results referencing empirical data, theoretical frameworks, and the research questions. Chapter Seven summarises the research findings, highlights research implications, identifies limitations and proposes recommendations for future research.

Chapter 2 Digital Health

The digital health industry was used as the empirical context focussing on digital health therapeutics. For example, a digital product that supports health behaviour change, chronic disease management, or offers effective virtual treatment.

The chapter comprises of two sections. Firstly, the introduction to the digital health industry will describe the current market trends, the definition of digital health, how COVID-19 has impacted how the market operates, and the commercial models that digital health interventions are utilising to remain sustainable. Secondly, the definition of digital therapeutics, followed by an explanation of how regulation affects the commercialisation of these products and how reimbursement is a critical revenue stream for digital therapeutics. The chapter ends with discussions on the current barriers to digital therapeutics adoption.

2.1 Definition

As the digital health industry is in its infancy, digital health has accumulated different definitions from authors and relevant organisations. Robinson et al. (2015) state that digital health currently “lacks theoretical definition” (p.105) but also suggests that digital health could be defined as the “use of digital media to transform the way healthcare provision is conceived and delivered” (p.105). Robinson et al. (2015) suggest that digital health facilitates the healthcare transformation in by providing easily accessible information, personalised care, and improving access to healthcare.

The Healthcare Information and Management Systems Society (HIMSS) definition describes digital health as a tool to promote equitable access to health which “connects and empowers people and populations to manage health and wellness” (HIMSS, 2020). The HIMSS definition emphasises how digital health supports healthcare professionals through providing “flexible, integrated, interoperable and digitally-enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery” (HIMSS, 2020).

Regulatory bodies like the Food and Drug Administration in the USA (FDA) have also contributed to defining digital health as technologies that “… span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products” (FDA, 2020). The FDA definition

also outlines several technologies that come under the definition of digital health, including: “mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine…computing platforms, connectivity, software, and sensors for health care and related uses” (FDA, 2020).

For the purposes of this study, digital health will be defined as the “use of digital media to empower people and populations to manage health and wellness”. This study will focus specifically on digital therapeutics which is a subset of digital health that “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.).

2.2 Industry Overview

Modern digital lifestyles have drastically changed the nature of consumerism and have opened up new opportunities for digital health to be used in the general consumer market. The swift development of digital health innovations provides significant opportunities for addressing the current challenges faced in healthcare (Deloitte Centre for Health Solutions, 2015). Despite the widespread use of technology and digital software, large-scale adoption of digital health solutions is scarcely implemented in most countries (Oderanti & Li, 2018). As a result, the development of the digital health market has been slow and fragmented (Oderanti et al., 2021). The implementation and use of digital health tools are complicated and underused by patients, caregivers and other members of the healthcare journey as there is a lack of understanding of how digital health tools fit into patient care (Oderanti & Li, 2018).

Digital health has been identified as a viable option to create more sustainable healthcare systems and promote better, more cost-effective, and comprehensive patient care (Deloitte Centre for Health Solutions, 2015). However, the lack of user-centric design has resulted in high non-adherence rates of digital health tools (Ammenwerth & Rigby, 2016). To succeed, product creators must consider human, social, and organisational factors that promote sustainable market development of digital health tools (Mosconi et al., 2019). Thus, businesses must design their products with the end-user during development to resolve design issues early on (Greenhalgh et al., 2017).

The geographical, cultural, and regulatory challenges of the COVID-19 pandemic have driven the emergence and adoption of new technologies in the health ecosystem (Petracca

et al., 2020). Prior to the pandemic, despite the recognised benefits of digital health to increasing efficiency of care and improving health outcomes, many stakeholders, including hospitals and doctors, were not willing to make the initial investment to integrate digital health into their practice or pay for the transactions (Herzlinger, 2006).

However, with mandatory social distancing and postponement of elective procedures, healthcare providers have been forced to use digital health products to deliver virtual consultations and remote monitoring of patients (Greenhalgh et al., 2020). The socially distanced nature of the pandemic has also grown the dependence on digital media for sources of medical information (IQVIA, 2021). As a result, this has also driven the use of applications and wearables to help individuals maintain their health and exercise (IQVIA, 2021). Thus, the pandemic has grown the need for remote care provision beyond traditional healthcare settings. Examples include patient self-monitoring using various Bluetooth and medical devices and digital therapeutics that can deliver interventions via digital media (IQVIA, 2021).

Funding and investment in digital health ventures have also seen significant growth over the past four years. 2021 was described as a breakthrough year for digital health funding, with $29.1 billion invested across 729 deals in the USA market, doubling the investment compared to 2020 (Krasniansky et al., 2022). The level of funding for digital health research and development has also grown exponentially since the COVID-19 pandemic, with $5.8 billion invested in 2021 (Figure 1) (Krasniansky et al., 2022). The critical stimulus has been the adoption of real-world evidence and decentralised trials that allow a more flexible approach to collecting clinical data regardless of the physical location (Krasniansky et al., 2022).

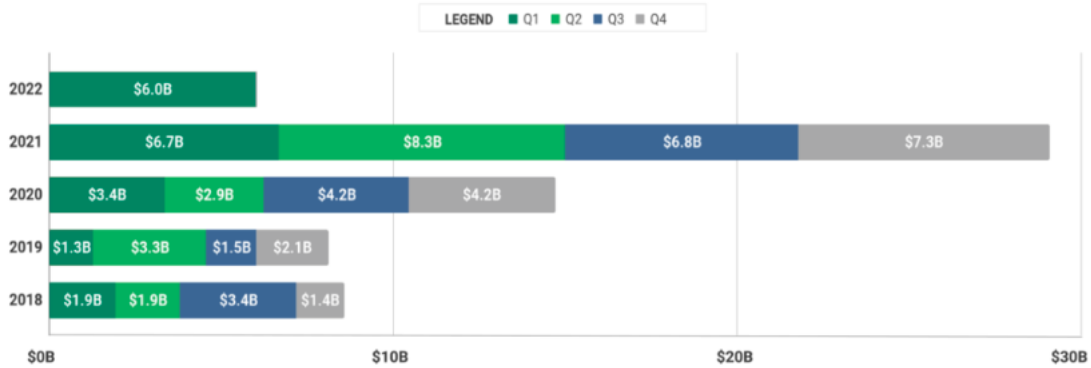

Figure 1: Annual Digital Health Funding from 2018-2022

Digital mental healthcare remains the most highly funded clinical indication with $5.1 billion raised in 2021, which is $3.3 billion more than any other medical condition (Figure 2). The integration of mental health care into existing platforms and the increase in digital options for cognitive care has driven the drastic increase in cognitive care investment (Krasniansky et al., 2022). There was also a significant increase in funding for diabetes and musculoskeletal care, which are conditions that can be managed virtually (Figure 2).

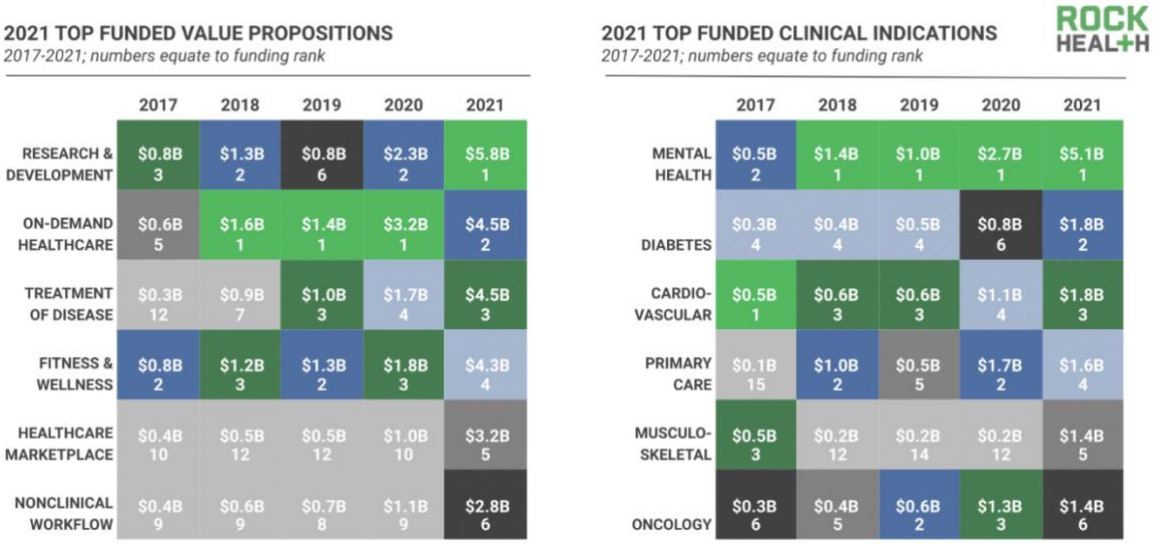

Figure 2: Funding into Value Propositions and Clinical Indications

Clinical validation is essential in showing that a digital intervention is generally safe and effective for its intended purpose in a healthcare context. The increasing amount and usage of applications have sparked growth in the body of literature on digital application efficacy. In total, there have been more than 2000 studies published in the last 14 years, but 1500 of these were published in the last five years as seen in Figure 3 (IQVIA, 2021). There is also an emergence of guidelines and white papers from both clinical and government agencies worldwide providing advice on how to implement digital health tools into traditional healthcare and remote settings (IQVIA, 2021). The growing body of literature and white papers demonstrates different stakeholders' growing interest in digital health.

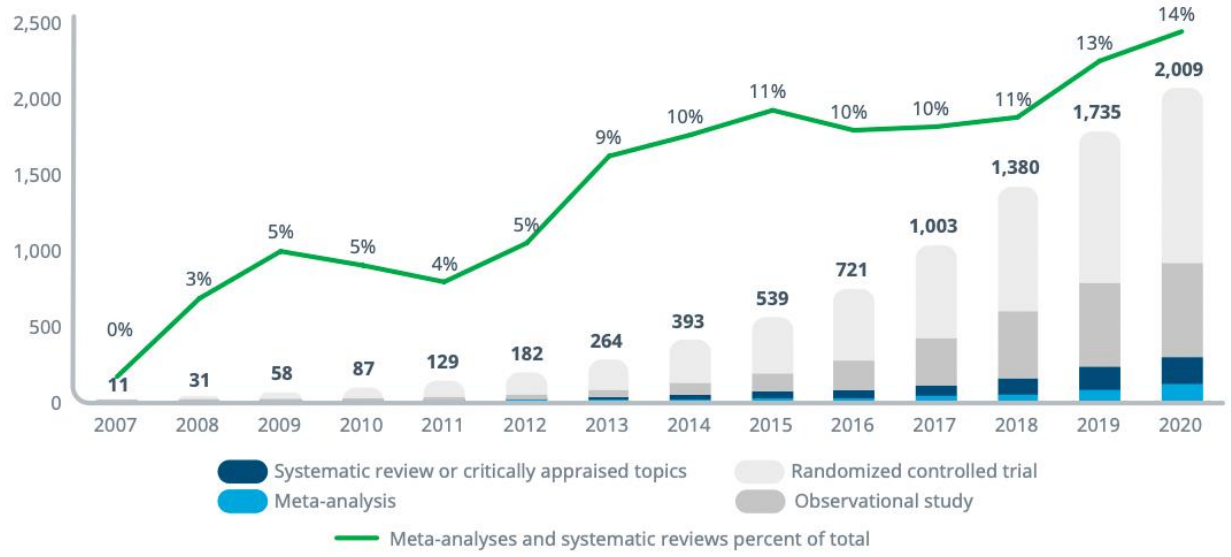

Figure 3: Number of efficacy studies on digital health efficacy

Overall, digital health innovations are currently solving the long term problem of reducing costs while improving health outcomes concurrently. The usage of digital health tools is predicted to grow as the world starts to navigate the new “normal”.

2.3 Digital Therapeutics

Digital therapeutics is a subgroup of digital health that is rapidly emerging as a tool to prevent, manage, or treat medical conditions. Digital therapeutics “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.). Digital therapeutics are a type of clinical intervention that is driven by clinically validated software (Digital Therapeutics Alliance, n.d.). Examples of digital therapeutics include virtual reality and digital cognitive behavioural therapy (Goldsack et al., 2019). These tools can replace existing pharmacological interventions or be used together with other medical devices, medications, or treatments to improve patient and health outcomes (Digital Therapeutics Alliance, n.d.). Adjunctive therapy with digital therapeutics enhances the efficacy and adherence of prescribed medication and demonstrates benefits in hypertension, obesity, and diabetes (Deloitte, 2021). To implement the use of digital therapeutics in clinical use, it is imperative for clinical evidence and real-world outcomes (i.e. data generated outside of clinical research) to be available to prove its efficacy and safety for patient use (Deloitte, 2021).

Digital therapeutics are currently being developed for many diseases where current clinical therapies do not meet patient needs and health behaviour change is integral for end-to-end management of the condition (Makin, 2019). Digital therapeutics can deliver clinical therapies and patient education, facilitate patient behaviour change, and remote monitoring to produce better long term health outcomes (Dang et al., 2020). Some key advantages of delivering care through digital therapeutics include:

- Digital delivery of therapeutic exercises enables physiotherapy in the community or the comfort of the patient's home (Dang et al., 2020).
- Patients can access therapeutic content in the privacy of their personal space and at a time that suits their schedule (Dang et al., 2020).
- Digital therapeutics can personalise therapy based on the individual's observed outcomes, progress, or other measures (Dang et al., 2020).
- Clinicians can use data collected via digital therapeutics to personalise patient care and improve treatment success rates (Dang et al., 2020).
- Digital delivery of therapeutic interventions ensures consistent quality of therapeutic delivery (Dang et al., 2020).

In addition to the advantages of digital therapeutics, there are several opportunities identified by Sverdlov et al. (2018), including:

- More streamlined release of interventions from their conception
- Safer, cost-effective, and accessible treatment (provided relevant regulatory bodies approve the therapy)
- Potential for use in paediatric populations
- Integration of gamification into therapies

2.4 Regulation

The health sector is a highly regulated industry unsuited for rapid developments in technology and change. A key determinant of the future success of digital therapeutics is the readiness for global regulators to adapt and create approval pathways for digital therapeutic products to be used in the market. Current regulations define most digital therapeutics as Software as a Medical Device (SaMD); however, not all digital therapeutics are compliant, nor are all digital therapeutics intended to be a SaMD (Deloitte, 2021).

There have, however been recent examples of regulators enabling changes that will help to encourage the adoption of digital therapeutics (Deloitte, 2021):

United States of America (USA)

The FDA defines a mobile application as “a software application that can be executed (run) on a mobile platform…or a web-based software application that is tailored to a mobile platform but is executed on a server” (FDA, 2019, p.4). The intended use of the application will determine whether it meets the definition of a “device”. Approximately 35 to 40 digital therapeutics have been approved by the FDA since 2017, however, the organisation does not have a clear definition for the products (Galvin, 2021). Some examples of FDA approved digital therapeutics can be found in Figure 4 below:

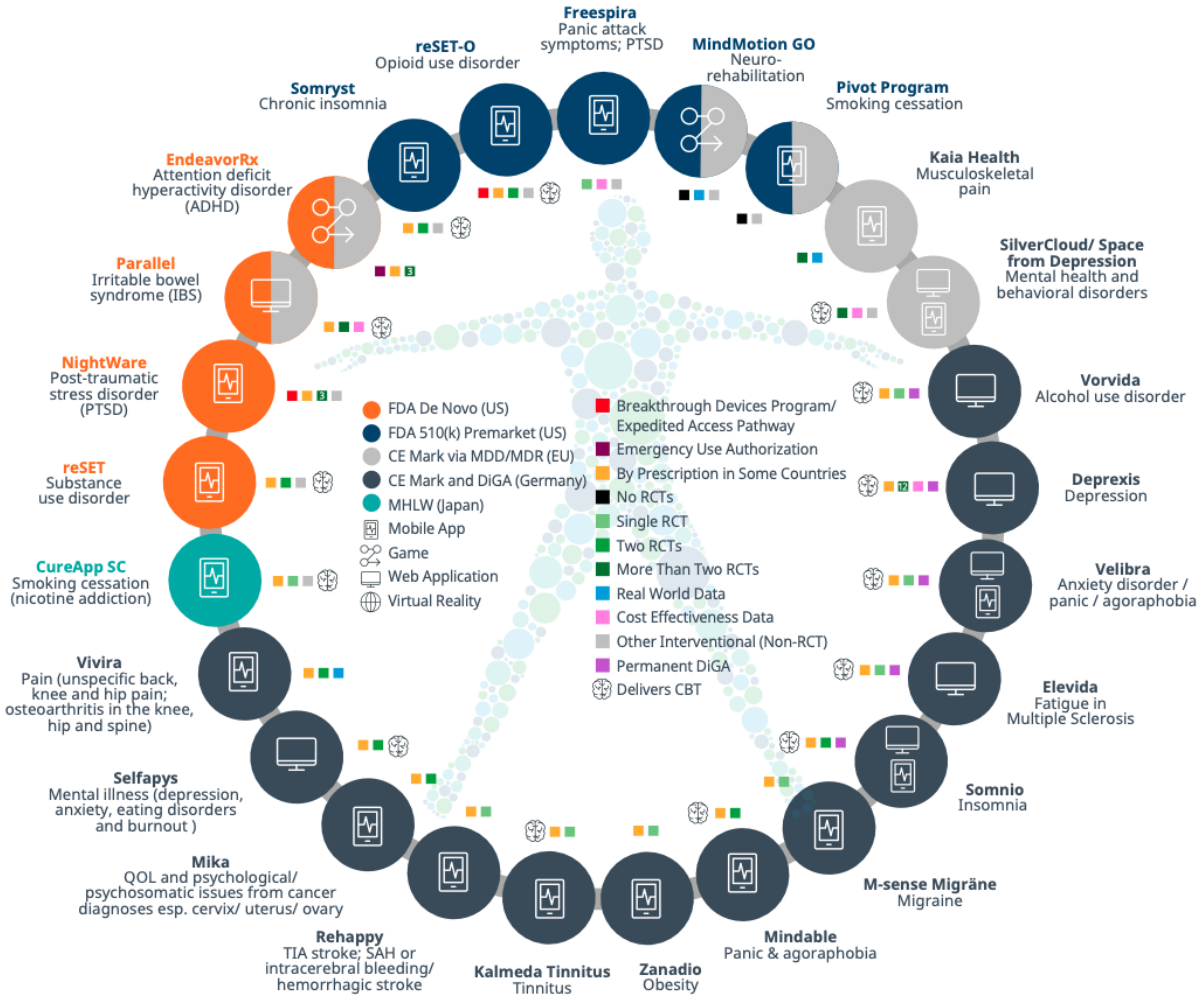

Figure 4: Examples of regulatory approved digital therapeutics

The latest development in the approval of digital therapeutics by the FDA is the Digital Health Software Precertification (Pre-Cert) Program (FDA, 2021). The outcomes of this program will be used to inform the structure of future regulatory models to provide a streamlined avenue for SaMD product approval (FDA, 2021). A unique aspect of this

program is that the FDA can approve the developer of the digital health product rather than a specific software product, therefore, expediting the development, approval, and release of the product (FDA, 2021).

Germany

The Digital Health Care Act (DVG) was introduced in 2019 to provide a streamlined regulatory framework for digital therapeutics (Stern et al., 2020). The DVG accelerates the German healthcare system's digitalisation and formalises the prescription of health apps such as software, software as a service (SaaS), and mobile or browser applications (Stern et al., 2020). The DVG provides an expedited regulatory pathway, called the Fast-Track process, for digital health organisations to take their product to market (Stern et al., 2020). Once approved, the app is added to a central registry of reimbursable apps that healthcare professionals can prescribe. These therapeutics can be reimbursed by every statutory German health insurance provider that insures approximately 90% of the population (Stern et al., 2020). There are at least 50 applications in the Fast-Track process and many more applications are expected in the coming years (Stern et al., 2020).

Belgium

In 2021, the National Institute for Health and Disability Insurance in Belgium established a reimbursement system for medical applications, including digital therapeutics (GlobalData Healthcare, 2021). Medical applications must meet the criteria for the M3 classification, which requires the highest level of clinical validation (GlobalData Healthcare, 2021), which includes:

- Evidence of clinical and socio-economic value to users (GlobalData Healthcare, 2021)
- Approval as a CE marked device and fulfilment of General Data Protection Regulation (GDPR) requirements (GlobalData Healthcare, 2021)
- Interoperability and connectivity tests (GlobalData Healthcare, 2021)

2.5 Reimbursement Models

The purchasing decision for health products, such as digital health tools, is usually not undertaken by patients or consumers but by healthcare professionals and third parties like insurance companies who pay for the products (Brinkmann-Sass et al., 2020). Thus, for digital therapeutics to succeed, firms must consider reimbursement models or payment models of the health system or market that the firm is targeting (Brinkmann-Sass et al., 2020). There are more than 350,000 digital health applications on the market, with more

being developed mainly through technology firms and start-ups entering the market for the first time as opposed to MNEs (IQVIA, 2021). Generally, start-ups and technology firms target opportunities with high returns. However, many of these firms quickly find it difficult to generate returns and secure payment for their innovative solution in the complex health sector (IQVIA, 2021). The path to reimbursement is a complex process that requires stakeholder engagement and approval by governing bodies (Brinkmann-Sass et al., 2020). This often means a much slower route to market for start-ups and technology firms who traditionally follow the direct-to-consumer models via digital application stores (Brinkmann-Sass et al., 2020).

There are early signs of reimbursement of digital therapeutics which contribute to four emerging commercialisation pathways to create a return on investment, namely:

Direct-to-consumer

In this commercial model, the applications are generally unregulated and distributed through an online application store (IQVIA, 2021). A patient can download the application to help manage their health for a monthly or annual subscription fee (IQVIA, 2021).

Value-based contracting

The application developer will enter a contract with an employer, health system, or payer and the payments are determined by the improved outcomes or reduced costs (IQVIA, 2021). The fee is either paid on a per-member-per-month (PMPM) basis where milestones must be met around improved outcomes, reduced costs or performance outcomes or the fee will be based on the amount of user engagement (IQVIA, 2021). This requires evidence of improved outcomes or reduced costs through randomised controlled trials or pilot studies (IQVIA, 2021).

SaMD *reimbursement*

SaMD is medical software intended for one or more medical purposes without being part of a hardware medical device (IQIVIA, p. 13, 2021). The SaMD fee is included in an insurance health plan or partially covered by a patient when prescribed by a clinician (IQVIA, 2021). Medicare may reimburse the app developer and the clinician's time on remote monitoring via digital therapeutics under existing CPT codes, as shown in Table 1 below (ChronicCareIQ, 2022). The application developer must negotiate a PMPM amount for each patient, so the reimbursement is based on the number of patients treated (IQVIA, 2021).

Table 1: Relevant CPT Codes for the reimbursement of digital therapeutics

Code	Reimbursement	Service
CPT 99091	$59/month	Remote Patient Monitoring
CPT 99453	$21	Remote Monitoring of Physiologic Parameters – Initial set-up and patient education
CPT 99454	$69/month	Remote Monitoring of Physiologic Parameters – Collection, transmission, and report/summary services
CPT 99457	$54/month	Remote Monitoring of Physiologic Monitoring – Interpretation and management
CPT 99458	$43/month	Additional Remote Physiologic Monitoring
CPT 99490	$42/month	Chronic Care Management
CPT 99487	$93/month	Complex Chronic Care Management
CPT 99489	$47/month	Additional Complex Chronic Care Management
HCPCS G0506	$64	Chronic Care Management Initiating Visit in addition to primary face-to-face visit service
HCPCS G2065	$12	Remote Evaluation - Recorded video and/or images
HCPCS G2065	$40/month	Principal Care Management
HCPCS G2058	$38/month	Additional Chronic Care Management

Software as a drug reimbursement

The application developer can be paid through the pharmacy benefit of an insurance policy or may form a part of its digital formulary (IQVIA, 2021). Some application developers may be reimbursed through a national drug code (NDC) (IQVIA, 2021). In 2019, the two largest pharmacy benefit managers (PBMs) in the United States, CVS and ExpressScripts, launched a platform that helps payers select digital therapeutics suitable for the treatment scope and patient base (LaRock, 2019).

These emerging commercialisation pathways are summarised in Figure 5 below:

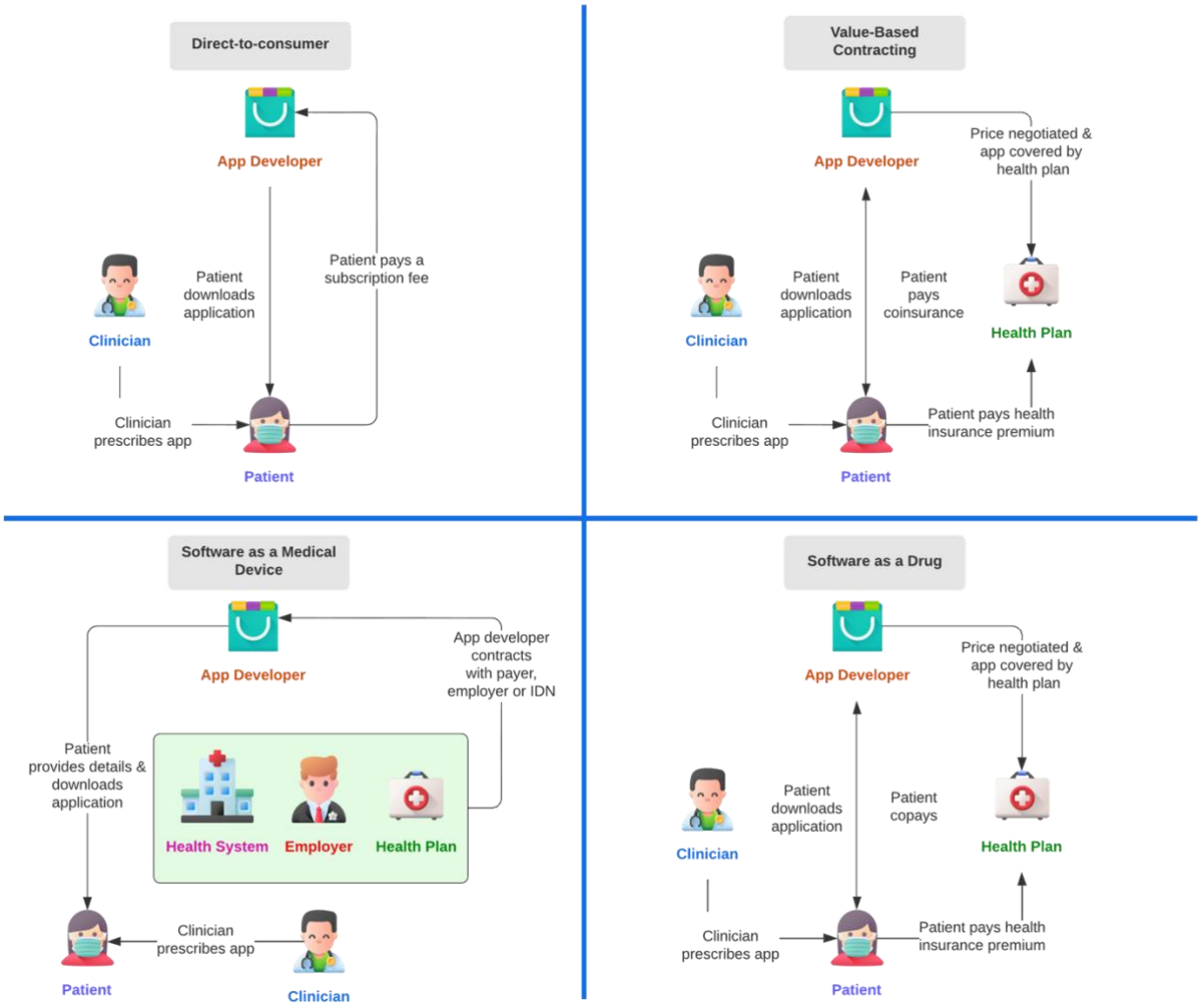

Figure 5: Digital Application Commercialisation Pathways

2.6 Barriers

The expansion of the digital therapeutics industry is primarily influenced by market and technological uncertainties. The adoption of digital therapeutics is complicated as it involves several stakeholders across different sectors, complex decision-making processes, and multiple value judgement (Sverdlov et al., 2018). Several factors have hindered the adoption of digital therapeutics, which include:

Sparse Evidence Base

Clinical data from clinical trials and real-world evidence are pivotal to persuading decision-makers to adopt digital therapeutics. (Gräfe et al., 2020). However, with digital therapeutics companies still working on building their evidence base to demonstrate improvement in measurable clinical outcomes, sparse evidence make adoption difficult. Healthcare

professionals are also unlikely to support the use of their innovation without randomised controlled trials in peer-reviewed journals (Gräfe et al., 2020).

Complex Trial Design

Clinical trial designs for digital therapeutics can often be complex. For example, evaluating the technical aspects of digital therapeutics can be difficult as the manufacturers may update the software or device during the trial. Therefore, the evaluation becomes redundant as the evaluated technology has been updated to a newer version with different functions and features (Sverdlov et al., 2018). Blinding of digital therapeutics trials can also be problematic as ethical issues may arise with the control group (Sverdlov et al., 2018). Another concern for trial design is privacy, where participants are asked to provide consent remotely and may not be fully informed. Poor participation rates can also cause inconclusive results (Sverdlov et al., 2018).

Poor Regulatory Infrastructure

Currently, there is little focus on the regulatory aspects of medical applications by governing bodies despite there being long term concerns around efficacy, reliability and validity of medical applications available to the public (Holfelder et al., 2021). Unlike other digital health tools, the software behind digital therapeutics is regularly updated to align with clinical guidelines or for adaptive algorithms to improve the software with collected data (Miao et al., 2022). Thus, the use and predictability of outcomes from using digital therapeutics is more complex and calls for regulation in this field (Miao et al., 2022).

Rapid Technological Developments

The continuous emergence and advancement of digital technologies creates an ever-evolving competitive environment for digital therapeutics (Sverdlov et al., 2018). Having new and improved technology constantly appearing in the market can make the market more saturated and difficult for users to identify and adopt the technology they require. New entrants may also overcome current market players resulting in increased competition for uptake (Sverdlov et al., 2018).

Data Compliance Costs

Several challenging policies and regulations could apply to mobile health applications, including clinical governance, information governance, and other digital care organisations (Oderanti & Li, 2018). Adhering to standards set out by governing organisations could introduce considerable overhead costs to the commercialisation process, thus disincentivising the adoption of digital therapeutics.

Stakeholder Adoption

The lack of quality assurance currently within the industry makes it difficult for stakeholders to understand which application is suitable for their needs. Healthcare professionals also have difficulty determining which health applications are evidence-based therapeutic value, particularly with many health and wellness applications. Medical applications should have a specific industry standard or validation process with the exact requirements to make comparison easier (Holfelder et al., 2021). In addition, new digital health tools require changes in care provider workflows, increasing clinicians' burden with notification fatigue, data overload, and clinical interpretation (Dang et al., 2020).

The digital health industry has shown significant growth as a billion dollar industry in the last four years which has been largely driven by the COVID-19 pandemic. Previously, digital health tools had poor adoption rates however mandatory social distancing have enforced a new normal of remote patient care. Digital health tools have demonstrated evidence of cutting healthcare costs while simultaneously improving health outcomes. As a result of the pandemic, flexibility in traditional reimbursement and regulatory processes have been observed however, for digital interventions such as digital therapeutics, this is still poorly defined. Digital therapeutics are a new and upcoming area of digital health that is receiving attention however, user adoption, demonstrated evidence, and sustainable commercialisation models are issues still faced by digital therapeutic companies.

Chapter 3: Literature Review

3.1 Commercialisation

This section will provide an overview of how the literature defines a ‘commercialisation strategy’ and the previous work on commercialisation strategies for the life science and digital health sector.

3.1.1 Commercialisation strategy

Commercialisation is a crucial component of innovation that enables new technology, products, or services to be brought to the market (Bandarian, 2007). It is described as “the series of activities undertaken by firms to transform knowledge and technology into new products, processes, or services, in response to market opportunities” (Rosa & Rose, 2007, p.9). This series of activities is divided into phases, starting from the introduction of the innovation to the production, marketing, distribution, sales, and customer support (Rosa & Rose, 2007). As commercialisation is affected by political, social, commercial, institutional, and historical factors, firms must determine the commercial potential of an innovation to best define the commercialisation strategy (Bandarian, 2007). For example, Pisano (2006a) explains that the lack of profitability in the biotechnology sector is due to structural issues in the institutional environment. The unique characteristics of science-based businesses are not accommodated by the institutional structure or ‘anatomy’ of the sector, therefore, hindering the full potential of the industry.

A firm’s commercialisation strategy is described as the process of creating a financial return on an innovation through interacting with its value chain (Hansen & Birkinshaw, 2007). Firms must find or create an efficient channel to identify the most appropriate commercialisation method which is influenced by the sector that they are operating in (Gbadegeshin, 2017). In the commercialisation strategy decision, every firm must consider two competitive trade-offs, whether to ‘collaborate or compete’ with incumbents and whether to ‘build a moat or storm a hill’ i.e., how long does the firm want to delay the time to market (Gans & Stern, 2018). Gans and Stern (2003) highlight that extensive analysis of the commercialisation environment is critical to an effective commercialisation strategy. Firms must decide whether creating a value chain or contracting to access an existing value chain is more profitable based on the commercialisation environment (Gans et al,. 2018). Thus, firms may choose a strategy that is either product-based, intellectual property (IP) based or hybrid (both product and IP) (Gans & Stern, 2003; Gans & Stern, 2018). With developments in business process

outsourcing and open innovation, commercialisation strategy options for technology-based start-ups have broadened (Di Gregorio et al., 2009; Marx & Hsu, 2015). Firms can integrate their innovation into their own products and services or license out their IP for integration into services or products of incumbents and other competitors (Gans & Stern, 2003). Firms who use a hybrid strategy can also sell their innovation as a product and license their IP concurrently.

In addition, with the rapid growth in transactions of patents, licenses, and other IP in the technology market (Kasch & Dowling, 2008), new ventures who operate in the market for ideas sell licences, copyrights, and other types of IP to other companies for integration into the buying firm's products or services (Gans & Stern, 2003). Pisano (2006) found that the extent of information asymmetry, amount of investment in specialised assets, and tacitness of know-how, and the degree of appropriability (the extent to which the firm can retain value for its own benefit) of the know-how can impact the success of a commercialisation strategy in the market for ideas or IP. The decision to adopt a IP-based, product-based, or hybrid commercialisation strategy is important for technology-based firms as their commercial success is based on inventing and exploiting IP (Onetti et al., 2012). Firms who pursue an IP-based commercialisation strategy do not compete directly in the product market and therefore, do not necessarily need to acquire or build value chain resources when expanding into foreign markets. Rather, these firms require robust internal research and development capacity and technology insourcing. As a result, different commercialisation strategies may impact the costs of foreign market entry and performance, resource dependencies, and the liability of foreignness faced by the firm.

To better assist with commercialisation, Gans et al. (2018) have created the 'Entrepreneurial Strategy Compass' which is a simple quadrant that guides entrepreneurs on possible commercialisation strategies (see Figure 6). This involves four strategies including the Intellectual Property, Disruption, Value chain, and Architectural Strategy. Gans et al. (2018) express how founding teams often worry that exploration will delay the time to market. Entrepreneurs operating in high uncertainty and competitive markets may choose the first feasible strategy and abandon the planning and evaluation that comes with strategising. However, when firms undergo impromptu experimentation of strategies, they may commit to a commercialisation strategy that is inferior to the other available strategies. Thus, enabling competitors to surpass the firm with a more well-planned and executed commercialisation strategy.

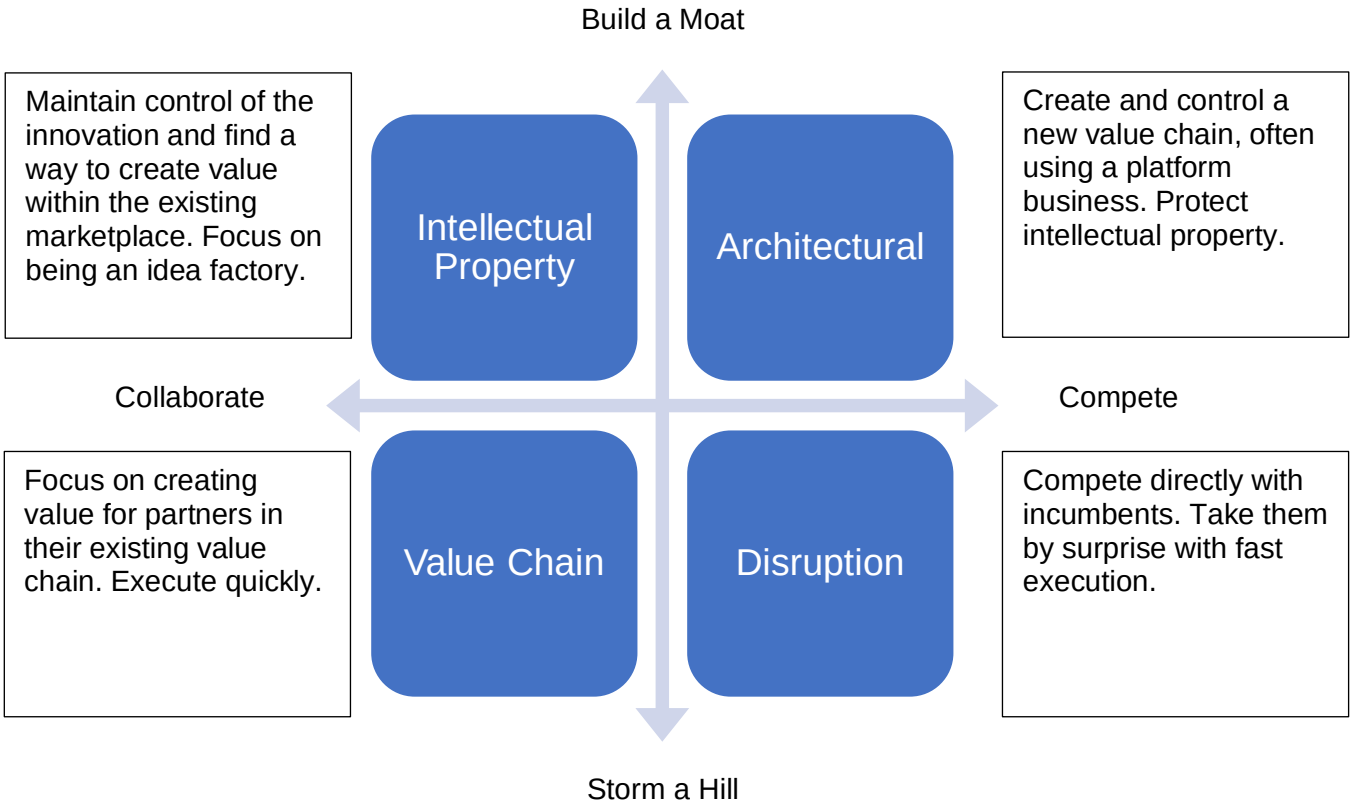

Figure 6: Entrepreneurial Strategy Compass

The 'Entrepreneurial Strategy Compass' involves four strategies:

1. ***The Intellectual Property Strategy***

The new venture maintains control of its innovation and tends to collaborate with incumbents. Often generalisable technology will be developed to ensure compatibility with existing value chains. These start-ups focus their resources on ideation and development and evade downstream customer-facing activities. Thus, intellectual property focussed new ventures can create an influential difference in the industry, however, the start-up will not need to participate in risky experimentation with the new potential technology. The intellectual property must be valuable to end-users and the ideas to be developed are dictated by the partners which the start-up wishes to enter a collaboration with.

2. The Disruption Strategy

Firms compete directly with incumbents. These firms reinvent existing value chains and focus on rapid commercialisation of the innovation and accelerating growth of market share. The aim of the strategy is to benefit from the “first movers’ advantage” where the start-up swiftly builds up the resources, capabilities, and customer base to sustain the competitive advantage gained through early commercialisation to avoid imitators gaining traction. Thus, the target customers are typically in a niche market that is poorly served by incumbents. This gives the opportunity for start-ups to obtain credibility in this segment and test and improve new technologies quickly. Established market players often struggle to keep up with these start-ups as they have existing commitments to established technologies as well as capabilities that are built to support these existing technologies.

3. The Value Chain Strategy

The firm aims to compete in an existing market through developing specialised capabilities and resources for unique value propositions to enhance their partnership opportunities. The innovation must be able to provide a unique differentiation or cost advantage for incumbents. If the innovation does not benefit the existing value chain, then the start-up is only sustainable if other established companies cannot imitate the value that has been created.

4. The Architectural Strategy

Ventures can compete and control their technology by creating a new value chain from pre-existing innovation. Architectural entrepreneurs tend to build platforms as opposed products. These ventures are then able control the market that they have created. However, this strategy is not viable and too high risk for many firms. Facebook and Google are examples of firms that pursue the architectural strategy.

For each compass quadrant, the firm must identify the customer segment to target, which technology to use, the identity to assume, and the competitive landscape. The entrepreneur needs to note down as many strategic options as possible within the quadrants. This process will involve market research, information gathering, and potentially some experimentation. Entrepreneurs should then select the strategy that aligns with the purpose of the venture. The decision to pursue one commercialisation strategy does not prevent the firm from adopt other strategies in the future (Marx & Hsu, 2015). However, the firm must consider whether the chosen strategy enables opportunities to transition from the start-up to scale-up phase.

The commercialisation frameworks described in this section (Gans & Stern, 2003; Pisano 2006; Gans et al., 2018) are not specific to the digital health industry. However, Gans & Stern (2003), Pisano (2006), and Gans et al. (2018) provide understanding of the strategic aspect of commercialisation. Gans et al. (2018) and Gans & Stern (2003) provide relatively generalisable commercialisation frameworks that help new ventures understand the structure and relationships of the industry that can affect their commercialisation. Thus, newer models have addressed digital health specifically.

3.1.2 Digital Health Commercialisation

Despite the recognised benefits of digital health on patient care and the health system, there are few studies on how health innovations go from concept to creation and their go-to-market strategy. For example, the life sciences industry is known to have a convoluted, extensive, and unique commercialisation process which can require localisation (Oderanti et al., 2021). Cho et al. (2008) suggested a commercialisation framework for digital health, in which there are four main stages (as seen in Figure 7):

1. Adoption
2. Implementation
3. Commercialisation
4. Diffusion

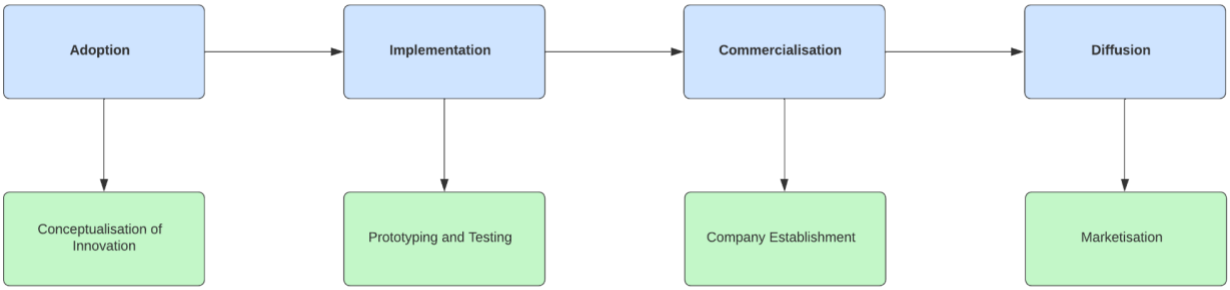

Figure 7: Commercialisation of digital health

Building on the work of Cho et al. (2008), Gbadegeshin (2019) found that current commercialisation frameworks requires further development as traditional commercialisation frameworks are not easily understood by industry members. Gbadegeshin (2019) suggest that there should be five stages of commercialisation (as seen in Figure 8) as opposed to four, which include:

1. Discover of new technology or solution
2. Exploration of the new technology/solution

3. Decision on commercialisation method
4. Protection of the technology/solution
5. Diffusion and marketisation

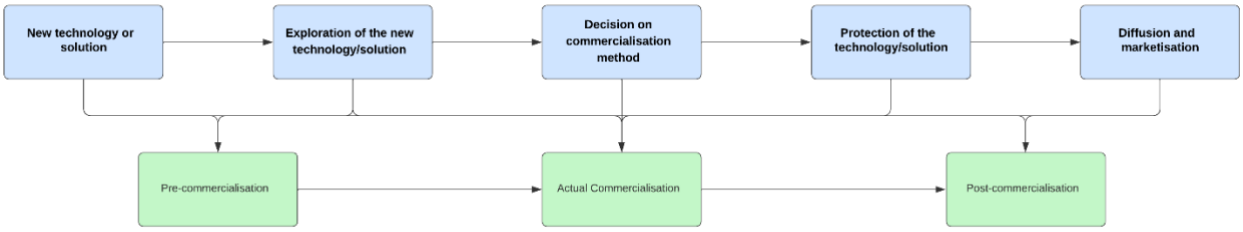

Figure 8: Commercialisation of digital health

The key contrast to the commercialisation framework of Cho et al. (2008) is stage four - protection of the technology/solution. Gbadegeshin (2019) found this to be critical in the digital era given that information is readily available through the internet thus increasing the importance of protecting information and ideas through intellectual property. Gbadegeshin (2019) concluded that digitalisation has affected all stages of the commercialisation process of digital health products. A summary of the digitalised processes can be seen in Table two below:

Table 2: Activities in the Commercialisation Process

Phase	**Activities**
Discovery (New Application or Solution)	• Competitive analysis • Defining novelty (uniqueness) • Forming a development plan for the application • Accessing solution delivery mode • Evaluating market needs • Monitoring market trends • Assessing technical possibilities • Conducting IP scan
Exploitation of new application/solution	• Prototyping • Normal testing • Clinical testing

Decision on final method of commercialization Protection of new application/solution	• Analysing market information • Identifying most promising markets • Evaluating commercialisation methods and their potential outcomes
Protection of new application/solution	• Patent application (if applicable)
Diffusion and marketization	• Reviewing production process • Marketing through digital means • Managing post-sales activities (e.g. feedback) • Collecting big data • Deciding on a and testing business model • Managing stakeholders • Early internationalization

The research question of this thesis is that internationalisation occurs as a part of the commercialisation process as identified in Pellikka & Virtanen (2009)'s study of commercialisation in small technology firms. Internationalisation could be integrated into the commercialisation process rather than being viewed as a separate process for firms that internationalise at an early stage. The concept of internationalisation will be explained in the next section.

3.2 Internationalisation

This section will provide an overview of how the literature explains early internationalisation and how this relates to foundational internationalisation theories. This will be followed by an overview of contextually sensitive theories, firstly the internationalisation pattern of a digital firm and secondly, industry specific factors that affect internationalisation. Lastly, the international entrepreneurship theory will be described to show the importance of context in the internationalisation process.

3.2.1 Definition

Firms that operate internationally shortly after or from inception are emerging in considerable numbers globally. The substantial growth in early internationalising firms across most regions indicate that this is an important phenomenon. The early rapid internationalisation phenomenon of these firms is referred to as 'International New Ventures (INVs)' (Oviatt &

McDougall, 1994) or 'Born Globals (BG)' (Knight & Cavusgil, 2004) which have come to the forefront of international business due to globalisation and advancement of technology (Cavusgil & Knight, 2015). Even with the resource, experience, and market constraints of small businesses, these internationalising firms utilise knowledge and capabilities through innovative avenues to achieve substantial foreign market penetration at an early stage. Thus, INVs are said to deviate from the gradual internationalisation pattern that is observed in multi-national corporations (MNCs) (Luostarinen & Gabrielsson, 2004).

The definition of BG or INV varies across the international business literature where some studies use both definitions in parallel (Johanson & Martín, 2015; Sultan & Wong, 2011) and others suggest that future research should clearly differentiate the different terms (Madsen, 2013). For the purposes of this study, BG and INV will be used interchangeably. The most commonly used definitions of BG/INV is that it is a business that from inception aims to satisfy a global niche (Jones et al., 2011), it has a global vision from inception (Knight and Cavusgil, 2004; Oviatt & McDougall, 1994), it has internationalised into at least two international markets within two to three years of inception from which 25% of its total sales would have these international markets (Oviatt & McDougall, 2005; Knight and Cavusgil, 2004; Andersson & Wictor, 2003) and the firm must be independent i.e. cannot be a spin off from an established firm (Arenius et al., 2005).

INVs have distinct characteristics which distinguish them from MNCs. INVs create products with global potential (Arenius et al., 2005), and are typically high technology firms with innovative products that serve a global niche market (Efrat & Shoham, 2012; Wentrup, 2016), and originate from small and open economies with limited domestic market growth (Chetty & Hunt, 2004; Luostarinen & Gabrielsson, 2004). INV operate in conditions of high risk and uncertainty due to the novelty of their innovation, limited financial capacity, the pressure for growth, and global nature of operations (Neubert, 2017; Arenius et al., 2005).

3.2.2 Theoretical Background

Several theories have been developed to describe the internationalisation process. Transaction cost analysis is used to explain vertical integration decisions in international operations where the transaction costs are a result of asset specificity and transaction costs (Whitelock, 2002). The resource-based view suggests that the knowledge, organisational capabilities, and resources that a firm has access to and makes proper use of forms its competitive advantage (Teece & Pisano, 1994; Barney, 1991) that allow it to internationalise. The eclectic paradigm summarises many of the foundational ideas to explain foreign

expansion and suggests that firms seek the most cost-effective strategy while evaluating the ownerships, location, and internalisation advantages of the strategy (Dunning, 2001). The internationalisation process theory shifted the focus to the process of internationalisation and states that experiential knowledge is an important resource for driving international growth (Johanson & Vahlne, 1977). This theory suggests that ventures internationalise incrementally and gradually acquire foreign market knowledge to reduce liability of foreignness (LoF) and investment risks (Johanson & Vahlne, 1977). However, this behaviour is not observed in INVs that seek to expand abroad from inception (Phillips McDougall et al., 1994; McNaughton, 2003). Instead, the social network theory has been considered as the foundation of how small firms internationalise (Knight & Cavusgil, 2004).

The social network theory to internationalisation originates from the work of Johanson & Mattsson (2015). The underlying assumption is that industrial markets are constructed of a network of relationships between suppliers, competitors, and distributors (Johanson & Mattsson, 2015). In foreign markets, INVs face two types of liabilities, the liability of novelty which is amplified by the LoF. LoF is defined as the additional costs incurred by a foreign firm in international markets which a local firm would not encounter (Zaheer, 1995). LoF can be due to lack of relationships with suppliers and distributors, lack of foreign market and competitive knowledge, as well as resource limitations (Zaheer, 1995). LoF infers that foreign players will be less profitable and sustainable than local firms with all other circumstances equal. This emphasises the importance of collaboration and networking with partners for INVs to overcome resource constraints and gain foreign market knowledge (Coviello & Munro, 1997).

Networks can help firms discover market opportunities, obtain foreign market knowledge from experienced partners, and outsource activities like distribution (Coviello & Munro, 1995; Ellis, 2000; Hadley & Wilson, 2003). Oviatt and McDougall (1994) found that INVs minimised the use of internalisation and took more advantage of alternative governance structures compared to MNEs. Thus, INVs form mutually beneficial relationships with buyers, other companies, research organisations, and trade associations to access unique resources that enable production and trade of their innovation (Oviatt and McDougall, 1994; Zahra et al., 2003). INVs partner with large organisations to take advantage of their pre-existing sales channels, reputation, and brands. INVs also form alliances with MNEs which can incorporate the INV's product into their offerings (Gabrielsson & Manek Kirpalani, 2004). Though these mutually beneficial relationships are beneficial during the entry phase, over-dependency can be problematic for INVs as it causes a loss of autonomy (Chetty & Holm, 2000). Thus, ventures internationalise through their relationships within a network which provide a

platform to overseas markets and reduce the LoF and investment risks (Coviello & Munro, 1997).

3.2.3 Entrepreneurial Internationalisation

Entrepreneurial internationalisation can be described as the process that is distinguished by innovative, dynamic, sustainable, and audacious activities across national borders under situational uncertainty (Nummela et al., 2022; Autio, 2017). Previously, international entrepreneur (IE) was used to describe the rapid internationalisation behaviour of INVs. IE describes the behaviour of organisations, groups, or individuals who undergo discovery, evaluation, and exploitation of opportunities in international markets to create innovative products and services (Oviatt & McDougall, 2005). However, IE poorly defined the rapid internationalisation behaviour and generalised any internationalisation activities as entrepreneurial behaviour despite MNCs simply replicating their existing operations into different markets (Verbeke & Ciravegna, 2018). Alayo et al. (2019) argues that entrepreneurial internationalisation involves identifying and exploiting new opportunities in foreign markets with a high-risk tolerance and skills to innovate. Thus, the switch from IE to entrepreneurial internationalisation to better understand the behaviour of INVs.

Reuber et al., (2017) suggest that the context and the dynamic nature of new firms are key influential factors of entrepreneurial internationalisation. Firstly, context is intrinsic to internationalisation as it is a process that occurs under situational uncertainty, and therefore, existing theories are contextually sensitive (Welch et al., 2011). Autio et al. (2011, p.13-14) describes situational uncertainty as “the combination of firm-specific context-dependent ambiguity, variability, and complexity of institutional, product, and market conditions where the new venture’s appropriate course of action is not immediately apparent”. Previous research has identified the external environment, organisational factors, and the management team to be antecedents or outcomes of internationalisation behaviour (Zahra & George, 2017).

Firstly, environmental factors such as variation across countries and industry characteristics, can influence the opportunities pursued by a firm (Guler & Guillén, 2010). For example, international opportunities may be affected by the contextual factors such as the availability of local partners or the evolving local government policies (Sarkar et al., 1999). Research also suggests that institutional factors influence the process and type of opportunities that entrepreneurs and their partners pursue (Bowen & De Clercq, 2008). Institutional factors are also believed to be impacted by the activities of entrepreneurial firms which instigate

institutional changes (Alvarez et al., 2015). Furthermore, opportunities can also be influenced by “events” such as changes in leadership, government changes, or a merger and acquisition (Johns, 2006). Entrepreneur internationalisation suggests that environmental and organisational factors influence the context that a firm is operating in and therefore, affect the international behaviour of these firms.

The activities of the entrepreneurial firms are dynamic, and opportunities are not simply just recognised and assessed (Teece, 2014). Instead, the opportunity may need to be created where position-building processes such as learning, trust, and commitment in a foreign market must occur during the entry phase (Santangelo & Meyer, 2011). The result of these dynamic activities is that it can impact on the firm’s processes and their pursuit of future opportunities over time. Firms that take on international opportunities early after inception may avoid organisational inertia and may benefit from learning how to utilise newness rather than suffering from liability of newness (Autio et al., 2000). The fundamental processes of previous successful pursuits are likely to contribute to the firm’s routines. However, this can cause issues if the firm is not adaptive enough to meet the environmental demands of different markets (Hutzschenreuter et al., 2011). This illustrates how the continuously changing activities of a firm can impact its international growth.

Additionally, Verbeke and Ciravegna (2018) suggests that the features of individuals should be considered in international along with environmental and organisational factors in entrepreneurial internationalisation. Coviello (2015) emphasises that motivators the entrepreneur to pursue internationalisation should be considered along with their technical and international knowledge, networks, attitude to risk, international intentions, experience, and education. Chavez (2016) argues that the personality, skillset, and values of the entrepreneur will impact their behaviours and decisions. Thus, the characteristics of the entrepreneur will influence the firm’s strategies, decisions, and processes that promote or lead to internationalisation. The contextual factors that impact entrepreneurial internationalisation are summarised in Table three below:

Table 3: Summary of factors that affect internationalisation

Individual factors	
Variable	**Description**
International orientation	The entrepreneur attitude and perceived value of international activities (Michel & Hambrick, 1992).
Social capital	The entrepreneur's networks e.g. social, business, or personal connections (Chetty & Holm, 2000; Johanson & Vahlne, 2003).
Human capital	The entrepreneur's international orientation, foreign work experience, risk tolerance, education, and innovativeness (Michel & Hambrick, 1992).
Organisational factors	
Variable	**Description**
Structure	The degree of centralisation, formalisation, and process coordination within the firm (Oviatt & McDougall, 1997)
Resources	The firm's tangible, financial, human, organisational resources (unique assets, networks) (Zahra & George, 2017).
Product	Product differentiation (Fontes & Coombs, 1997)
Entrepreneurial orientation	The firm's attitude towards innovativeness, risk acceptance, competitive aggressive, and autonomy (Knight & Cavusgil, 2004).
Environmental factors	
Variable	**Description**
Environmental scanning	Environmental scanning was positive correlated with international collaboration (Autio, 1997)
Market	The market's size, government policies, potential and degree of internationalisation (both domestic and foreign) (Chetty & Hunt, 2004).
Industry	The industry's degree of internationalisation, knowledge intensity and technological intensity (Oviatt & McDougall, 1994).
Environmental	The intensity, hostility, and dynamism of the competitive environment (Shoham, 1999).

3.2.4 INV in a Digital World

Early internationalisation has largely been driven by two changes in the market environment. Firstly, the globalisation of markets in which firms are participating permit cross-border partnerships in additional to international supply chains and marketing (Cavusgil & Knight, 2015). Globalisation is believed to streamline product development and positioning in overseas markets due to customer preferences becoming increasingly similar globally (Levitt, 1983). Secondly, advancement in information and communication technologies (ICT) has reduced transaction and product costs which have driven growth in international trade (Picot et al., 1997). The Internet, email, and other related technologies have provided a feasible and economical alternative for internationalisation (Nambisan, 2017; Wentrup, 2016). Therefore, technological advancements have increased the internationalisation prospects of small firms by removing geographical barriers (Brouthers et al., 2016).

The digital revolution has challenged the foundations of the internationalisation theories as these digital products are globally available from inception through online platforms and therefore, more rapid internationalisation (Shaheer & Li, 2020). Digital technology has stipulated an adaptation of prior internationalisation beliefs (Meléndez-Ortiz & Samans, 2016). Vadana et al. (2019) proposes that ibusiness, technology firms, and online service providers to be termed as “born-digital” which are defined as “services or manufacturing companies in which most of the inward and outward value chains are digitalised soon after inception” (p.200). As the value of digital firms is completely digital and is distributed via electronic networks, the product or platform can be accessed instantly from any location, meaning that the costs of transferring a digital firm’s platform from one region to another is less significant (Brouthers et al., 2016). Cahen (2019) suggests that high technology start-ups operate in knowledge-based industries perceive internationalisation as a natural part of their commercialisation. Cahen (2019) found that technology start-ups acquired digital skills that enabled them to enter markets with limited assets and non-equity investments and thus, no foreign direct investment. Therefore, digital firms hold a certain set of characteristics that impact their internationalisation process. Mahnke and Venzin (2003) have identified the following as key characteristics and challenges that distinguish digital products (see Table four below):

Table 4: Characteristics and challenges of Born-Digitals

Characteristics of Digital Firms	**Challenges**
● Ability to produce valuable data for customer feedback and personalisation ● Product is not perishable and does not require transportation ● Benefits from economies of sale ● Impacted by network effects ● No diminishing returns to scale	● Competitors can imitate products easily ● Liability of novelty ● Liability of foreignness ● Building a foreign user group ● Quality and speed of digital infrastructure ● Virtuality trap (replacing all business activities with virtual alternatives (Yamin & Sinkovics, 2006)) ● Cost, privacy, and security of data

Born-Digitals leverage the internet and other ICT technologies in two ways to create unique value for customers. Firstly, the internet and ICT technologies facilitate multilateral communication between users of the digital product instead of direct interaction with its users (Yadav & Varadarajan, 2005; Varadarajan & Yadav, 2002). The exchange of information and/or products between users generates value for customers (Yadav & Varadarajan, 2005). Secondly, the well-defined and innovative products or services offered by the firm are novel and provide a unique value proposition to the firm's customers (Amit & Zott, 2001). Born-Digitals typically have high novelty as the Internet and ICT technologies are fundamental to their business model, increasing the feasibility into providing efficiency, complementaries, and lock-in effects to customers. Therefore, Born-Digitals are unique due to the fact that they utilise the internet and ICT technologies for value creation benefits to provide an digital product for multilateral communication between users.

The internationalisation of Born-Digitals will differ to industrial firms as the product offered by the digital firm has a unique value proposition due to the distinct and innovative nature of the offering (Brouthers et al., 2016). Born-Digitals do not transfer physical merchandise from one region to another but rather transfer their business models and platforms to different markets (Brouthers et al., 2016). However, Born-Digitals are still affected by LoF as they still face the prejudice of being foreign and are affected the availability of the Internet and the

digitalisation of the foreign market (Arenius et al., 2005). The institutional structure of the government, such as regulations and the tax system, can also impact the value of the born-digital's offering (Brouthers et al., 2016).

There are three possible market environments when Born-Digitals enter a foreign market:

1. ***There are no competitors that offer a similar product***
    a. The born-digital is affected by LoF as there is no distinct set of users and there is a lack of relationships to potential users in the market. The firm needs to build a strategy to increase exposure to potential users and then persuade them to adopt the product (Eisenmann, 2006). The firm can exploit the 'first mover' advantage when developing a user network however, this can be costly and make market entry complex (Eisenmann, 2006). Some risks of this scenario are that there may be no potential users in the market, or the size of potential users may prove to be not profitable (Eisenmann, 2006).
2. ***There is already a dominant competitor in the market***
    a. This can be difficult for the born-digital as the competitor has an established set of users and switching costs may prevent users from transferring to a different provider (McIntyre & Subramaniam, 2009). There are three ways the firm can overcome switching costs. Firstly, offering superior or technology may persuade users to change providers (McIntyre & Subramaniam, 2009). Secondly, there may be groups of users whose needs are not met by any offerings in the market (McIntyre & Subramaniam, 2009). Thirdly, the born digital may have better interoperability where the product can integrate with other software to provide greater functionality (McIntyre & Subramaniam, 2009). In all three of these situations, LoF is still an issue as the firm may still lack relationships with foreign users (Zaheer, 1995).
3. ***There are several competitors but no dominant competitor***
    a. In a developing market, Born-Digitals can benefit from the late-mover approach as there is an existing and growing user network as well as lower switching costs (Eisenmann et al., 2006). Firms must develop a strategy which differentiates and uniquely positions their offerings without directly competing with other firms (Cennamo & Santalo, 2013). Typically, firms will choose to target a specific market segment to minimise rivalry (Cennamo & Santalo, 2013). To be successful, the born-digital must focus on becoming a part of the local user network to entice new and competitor's users (Cennamo & Santalo, 2013). Users in this scenario tend to adopt the product with the

biggest user network as this is perceived as providing better value to their users (Schilling, 2003).

Therefore, the current literature suggests that these qualities of digital goods and the degree of the firm's digitalization of their products will impact decisions on mode of entry, choice of country, speed of internationalisation, and post-entry activities (Mahnke & Venzin, 2003; Wentrup, 2016).

3.2.5 IE in Health

Authors have suggested that INV research should consider industry specific factors that affect the internationalisation process (Fernhaber et al., 2007; Mahnke & Venzin, 2003; Rialp et al., 2005). Moreover, researchers have also highlighted the importance of other influential factors such as product characteristics, product strategies, market strategies, environmental factors, managerial background, strategic and firm factors (Gabrielsson & Pelkonen, 2008; Zahra et al., 2003).

Many studies have honed in on internationalisation in the high technology industry as new ventures from this industry show a tendency to internationalise early on (Oviatt & McDougall, 1994). The life sciences industry, which includes medical technology, biotechnology, and pharmaceuticals, is considered to be a high technology industry (Laurell, Andersson, & Achtenhagen, 2013). Typically, the value and competitive advantage is derived from scientific, technological, and design advancement (Cavusgil & Knight, 2015).The objective of innovation in this space is to improve health outcomes and quality of life (Stremersch & Van Dyck, 2009). The life sciences industry differs from other technology industries due to dependency on clinical evidence or science-based knowledge as well as strict international standards (Stremersch & Van Dyck, 2009; Pellikka & Virtanen, 2009).

In the context of life science new ventures, it is important to consider intellectual property, innovation infrastructure, industrial enterprises, innovative capacity, new products, technology transfer, and multinational corporations during the commercialisation and internationalisation process (Laurell et al., 2013). Different factors such as costly and complex clinical trials, strict regulatory requirements, scaling up marketing and sales, funding the research and development process as well building connections with hospitals and clinicians add to the difficulty of internationalising in the health industry (Stremersch & Van Dyck, 2009; Laurell et al., 2013). Due to the highly regulated nature of the life sciences

industry, international product launch in the life sciences industry can be complex and therefore, requires localisation in each region (Deloitte United States, 2021).

The digital transformation of healthcare through tools such as digital therapeutics presents unique challenges to digital start-ups. The health industry is highly regulated and often evidence is required to prove the benefits and safety of any treatment. A unique aspect of digital health is that the technology can be rapidly iterated, and this causes issues with regulatory standards that cannot be adapted fast enough to the changes in the industry (Mathews et al., 2019). Start-ups are traditionally very fast moving which contrasts greatly with regulatory bodies that are cautious and risk-averse (Mathews et al., 2019). Policymakers tend to undergo gradual and time-consuming processes to evaluate novel treatments to ensure that no harm is done which can impede market entry (Mathews et al., 2019). The application of ICT to health raises concerns around the digital literacy of patients which may lead to unequal access to healthcare (Lupton, 2014). The use of digital therapeutics on smartphones and the data generated raises concerns around regulation, data interoperability, and patient privacy (Murray et al., 2016). The creation of a digital health tool requires a multidisciplinary team involving software or technical experts as well as science or health experts. Murray et al. (2016) found that engineers or computer scientists did not anticipate the importance of RCTs and those with a science background thought there was too much focus on activities other than RCTs. Though RCTs are a crucial part of developing health interventions, it is only one step in the development process. Murray et al. (2016) concluded that scientists could learn from the iterative approach of engineering and computer science. It is important to reconcile differences between different disciplines to ensure efficient product development. Additionally, the health industry is made up of many layers of stakeholders who are incentivised by different factors such as financial or clinical benefits (Mathews et al., 2019). Thus, an effective and efficient process must be built to achieve a success market entry strategy that manages all the key stakeholders and environmental factors of the digital industry (Lee, Park, & Lee, 2019).

3.3 Commercialisation and Internationalisation

A review of the strategic and entrepreneurial literature has only uncovered limited useful frameworks on internationalisation and commercialisation strategies and little to explain the link between the two activities. For example, Pellikka and Virtanen (2009) found that the firms in their study were actively seeking international markets to enter during their commercialisation process. All study participants stated that internationalisation was a key issue during the commercialisation process. The key driver behind internationalising during the commercialisation process was that there was limited potential for technology products in the Finnish market i.e. there was limited domestic growth (Pellikka & Virtanen, 2009).

Some authors describe internationalisation as a driver of commercialisation as "commercialisation of innovations through internationalisation". Bracio and Szarucki (2019) found there two examples of interdependence between innovation and internationalisation. The first relationship is that the impact of innovation on the internationalisation where the internationalisation of the firm is based on its previous innovative activities (Bracio & Szarucki, 2019). The second relationship is where internationalisation promotes innovative activities through access to new knowledge, exposure to new challenges, and therefore, a need to improve the firm's innovativeness (Bracio & Szarucki, 2019). The authors from this study suggest that it would be interesting to see commercialisation of scientific innovations as this type of innovation is typically conducted by entrepreneurs who work in academia or scientists (Bracio & Szarucki, 2019).

Therefore, the theories that are proposed to guide this study involves the overlaps between existing commercialisation frameworks such as Pisano (2006), Gans et al., (2018), Gbadegeshin (2019), INV, and entrepreneurial internationalisation theories which will be used to understand how firms conduct international commercialisation. The overlaps of the different theories are outlined under each step of the digital health commercialisation framework by Gbadegeshin (2019).

1. ***Discovery of a new technology***

The management team is identified as a key organisational factor in entrepreneurial internationalisation and are usually those who hold tacit knowledge, incrementally accumulated specialised knowledge, that provides a competitive advantage to the firm. Management team members with tacit knowledge can leverage this to build innovative products and utilise their unique experiences to streamline the internationalisation process. Market analysis is also a key activity in the discovery phase that enables a firm to

understand the opportunities and challenges of a specific market Gbadegeshin (2019). Reuber et al. (2017) suggests that internationalisation is contextual and thus, the analysis of environmental and organisation factors is important for understanding the context of the markets in which the firm wants to enter.

2. Exploration of the new technology

Firms must prototype and test the product in clinical and normal settings for product development (Gbadegeshin, 2019). An important element in internationalisation is product differentiation and creating unique products with distinct characteristics to address a specific market need (Fontes & Coombs, 1997; Cavusgil et al., 1993).

3. Decision on commercialisation method

According to the Entrepreneurial Strategy Compass, start-ups will typically adopt one of four commercialisation strategies, namely, intellectual property, architectural, value chain, and or disruption strategy (Gans et al., 2018). Gans and Stern (2003) explain that a firm must decide whether competing in the product market or licensing their innovation is more profitable based on the commercialisation environment (Gans et al., 2018). Environmental factors such as domestic growth, international competition, and the institutional structure can impact the firm's choice of commercialisation and market entry method (Zahra & George, 2017). The highly regulated and fragmented nature of the health industry will be a key consideration for the start-ups in this study.

4. Protection of the technology/solution

Firms commonly protect their innovation through patents or trade secrets. Innovations that are covered by patents are guaranteed monopolies of a 20-year period in exchange for comprehensive public disclosure of the invention (WIPO, 2016). Another method is through trade secrets where a strict process is undertaken to keep commercially valuable information confidential (WIPO, n.d.). The lifetime of a trade secret is perpetual however lack the legal protection that patents offer (WIPO, n.d.). In the case of trade secrets, it will require an internalisation of a transaction to reduce costs and also keep the information within the company.

5. Diffusion and marketisation

The diffusion and marketisation of the innovation is perhaps where the largest overlap of commercialisation and internationalisation activities occur. (Gbadegeshin, 2019) suggests that early internationalisation occurs during diffusion and marketisation. Knight and Cavusgil (2004) suggests that smaller and resource-scarce ventures are more likely to pursue

strategies that differentiate themselves from their competitors. INVs have defined marketing strategies which involves branding, networking, intellectual property, and user feedback (Chetty & Hunt, 2004). Thus, Firms can leverage their unique resources through alternative governance structures derived from their social networks (Johanson & Mattsson, 2015).

The management team must consider the environmental factors of the markets which they are planning to enter, which entry strategy to utilise, and how they will build a foreign user community in each of these markets to promote user adoption. The management team are able to utilise internal unique resources such as their previous foreign market experience, networks, and tacit knowledge to improve the success of their market entry strategies.

Information asymmetry is a challenge highlighted in the market for know-how (Pisano, 2006) and is related to LoF and liability of novelty that Born-Digitals encounter. Information asymmetry relates to the gap in knowledge between buyers and sellers of an innovation which could correspond to liability of foreignness where the firm does not completely understand the market they are entering and liability of novelty where their innovation is a completely foreign concept in the new market (Pisano, 2006). As a part of their functional strategy, a firm must conduct marketing to increase exposure of their innovation and educate potential customers (Zahra & George, 2017).

Figure 9 below depicts how the different internationalisation and commercialisation factors align with the commercialisation phases of Gbadegeshin (2019)'s digital health framework and will be used to guide the design of this study.

Figure 9: Overlaps in Commercialisation and Internationalisation

Chapter 4 Methodology

This chapter presents the research design that was employed to address the research objective of understanding how new ventures conduct commercialisation and internationalisation activities concurrently and the associated challenges they face. This chapter will also outline the data collection, interview process, and analysis that was carried out is designed to answer the following research question:

- How do new ventures/start-ups enter different international markets with their digital therapeutics and what are the key challenges associated with this process?

4.1 Ideological view of the study

The commercialisation and internationalisation of digital health therapeutics is an interesting phenomenon in which the understanding of how firms undergo these processes is yet to be developed. Therefore, to gain a deep understanding how digital therapeutics firms perceive the commercialisation and internationalisation process, an interpretivism paradigm will be used for this study. Interpretivism is described as research that "concentrates on the meanings people bring to situations and behaviour, and which they use to make sense of their world; these meanings are essential to understanding behaviour" (Punch, 2014, p.17). The interpretivist approach acknowledges that multiple possibilities or realities exist and this can be due to an individual's perspective. This viewpoint is important in understanding the decision-making process behind internationalisation and commercialisation and what activities new ventures undertake to achieve this.

4.2 Research Design

A qualitative approach allows for an in-depth and interpretive understanding of different phenomena. Qualitative studies are valuable for developing rich and meaningful perspectives from research participants. The inductive approach allows the researcher to uncover new theories (Thomas, 2006). Given the infancy of the digital health industry and the limited research on the commercialisation and internationalisation of digital therapeutics, the generation of new theoretical ideas is essential to developing further commercial understanding in this sector (Choi et al., 2019). Thus, inductive analysis would be appropriate in this study as it allows the establishment of commercialisation and internationalisation theoretical ideas that utilises previous theories and empirical data in the emerging digital health industry.

Interview questions were asked in a semi-structured format to elicit deep and rich information from participants. The eight participants were asked questions according to the interview schedule (Appendix 1) based on insights from the literature review and the research questions. Due to the COVID-19 pandemic constraints, all interviews were conducted over video conference. As per the ethics approval, participants were made aware of the recording and had the right to ask for the recording to stop at any time. Furthermore, the researcher informed all participants that their contributions would remain non-identifiable.

To help participants feel more comfortable with answering the interview questions, the researcher built rapport with the participant through an introduction and general conversation prior to the interview questions (Guillemin & Heggen, 2009). The flow of the questions was structured in a way to ensure that participants spoke about their own experiences. The interview schedule was designed to cover the following topics:

- How do participants and their companies design digital health therapeutics and their market entry strategies?
- How do participants interact with potential partners to better understand foreign markets?
- What were some examples of challenges faced in the internationalisation and commercialisation of digital health therapeutics?

4.3 Data Collection

4.3.1 Participant Selection

Primary data was collected via semi-structured interviews. Interview participants were selected through non-random and purposive sampling. Purposive sampling was used for this study as the phenomena and context were only specific to digital therapeutics only rather than digital health generally. Purposive sampling is described as the intentional selection of participants due to the qualities or characteristics of the participant (Etikan, 2016). Subsequently, participants were required to have founded or worked in a firm with specific and relevant experience and knowledge (Etikan, 2016) in the commercialisation and internationalisation of digital therapeutics to provide deep and insightful data. The sampling criteria is outlined in Table five below.

Table 5: Sampling Criteria

Criteria 1: Digital Therapeutics Provider
The product must support health behaviour change, chronic disease management, or offer effective virtual treatment
The product must have some sort of multimedia aspect such as gamification or chatbot function

Criteria 2: International New Venture/Born Global
Firm must have internationalised within 5 years since inception
Firm must have internationalised to at least one international markets within 5 years since inception

Criteria 3: Digital Firm
The product must be purchased digitally
The product must be delivered through a digital platform

Industry connections of the researcher provided guidance and assistance with purposive sampling by bringing insight into the relevant industry members who would best have the right experience and knowledge as well as being able to articulate these experiences in an expressive and reflective manner. Using the advice of the industry connections, eight industry members were selected as the interview participants.

Participants identified through the purposive sampling strategy described were recruited by way of an email explaining the project, along with a participant information sheet (PIS) detailing the purpose of the research and an overview of their rights as a participant. Upon agreeing to participate in the study and understanding all the information in the PIS, participants were provided with a consent form that they were required to sign and return to the researcher.

4.3.2 Data processing and analysis

For primary data analysis, the audio recordings of the interviews were transcribed by the researcher. The process utilised in qualitative research called ‘member checking’ was undertaken to maintain the quality of the data. The transcribed copies of the interviews were provided to each participant approximately one to two weeks after the completion of the interview for accuracy and confidentiality purposes. Participants had an opportunity to review their own transcript and remove any inaccurate sentences or sensitive material. This process helped the researcher in improving accuracy, credibility, and validity of the interview transcript (Harper & Cole, 2012; Bryman & Bell, 2007). Participants had two weeks to return the transcript back to the researcher with any comments or concerns.

Once the transcripts were confirmed by the interview participants, the transcripts were uploaded to NVivo, a qualitative data analysis software, to be processed by the researcher. NVivo was used to organise the qualitative data into first-order codes, second-order themes, and then aggregate dimensions.

The research process is summarised in Figure 10 below:

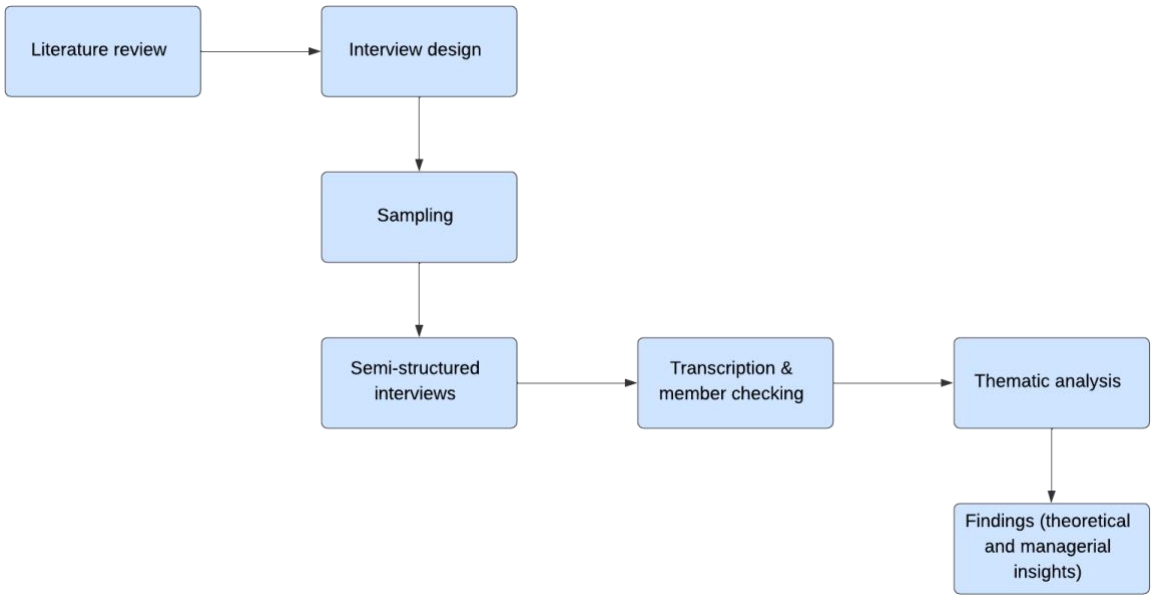

Figure 10: Illustration of the research flow

4.4 Study credibility and trustworthiness

Credibility

The credibility of a particular study describes how accurately the findings reflect the perspectives and insights provided by the interview participants (Glaser & Strauss, 1966). Credibility has two categories, internal and external credibility. Internal credibility refers to the degree that the findings of a study would be reproduced if the study was conducted with the same sample, setting, and context (Onwuegbuzie, 2003). External credibility is defined as the extent to which the results of a study is generalisable across various populations, settings, and contexts (Onwuegbuzie, 2003). It is important to note that the objective of this study was to explore and deepen understanding of the overlap between commercialisation and internationalisation of digital therapeutics but not to generalise. This exploratory study was undertaken to describe and explore current commercialisation and internationalisation theories as opposed to testing statistical significance of previous theories. Descriptive validity is a key concern around the credibility of qualitative research, particularly in research which depend on the researcher to accurately recall the findings from the interviewees. To minimise this risk in this study, the codes were defined and checked several times to ensure they were consistently used during analysis.

Trustworthiness

The trustworthiness of a study is defined as the accuracy of the information that participants provide during the interview (Elo et al., 2014). To increase the credibility and trustworthiness of this study, the interview questions were asked in a way where participants can give open-ended answers and were not influenced by the interviewer. Rapport was built with the participants and they were reassured that interview data would be kept confidential to facilitate a comfortable environment where open and honest answers could be provided.

Chapter 5 Findings

This chapter presents the research findings from the data collected from the semi-structured interviews. The first section provides an overview of the key findings from the analysis. The second section is split into three subsections which describes the findings in detail with quotes from the interviewees. The final section details a summary of the findings and how the different themes and dimensions could be integrated into the international commercialisation process.

5.1 Study Overview

As previously outlined, the focus of this study to understand the interaction between commercialisation and internationalisation activities of new ventures and start-ups. To address the research question:

- How do new ventures/start-ups enter different international markets with their digital therapeutics and what are the key challenges associated with this process?

Interviews were conducted with management teams of digital therapeutics start-ups to understand the firm's approach to commercialisation and internationalisation. The interviews were conducted and recorded digitally, transcribed by the researcher, and then analysed through NVivo software. As described in Chapter 4, the data collected was analysed to form key aggregate dimensions to further understand and answer the research questions. Table six provides details on each of the eight interviews.

Table 6: Interview participants

Participant	Country	Role	Type of Digital Product
A1	Australia	Director	Respiratory disease platform
N1	New Zealand	Founder	Gamified mental health product
N2	New Zealand	Founder	Medication adherence platform
N3	New Zealand	Founder	Digital rehabilitation platform
N4	New Zealand	Director	Artificial intelligence chatbot
S1	Singapore	CEO	Gamified neurodegenerative

Participant	Country	Role	Type of Digital Product
			platform
T1	Turkey	Founder	Gamified neurodegenerative platform
U1	USA	Strategist	AI pain management product

5.2 Thematic analysis

The interview data analysis involved categorising the data into first-order codes then further classified into second-order themes to piece together the three aggregate dimensions to help understand how new ventures undergo concurrent commercialisation and internationalisation activities. The data was categorised according to the themes that emerged during the data analysis. The results will be presented broadly under the following aggregate dimensions:

1. New product development
2. Strategic market entry
3. Commercialisation environment

In each subsection, the dimensions will be broken down into their second-order themes with the provision of first-order codes which were taken from the interviews.

5.2.1 New product development

The term ‘product development’ in innovation accounts for the process of idea generation to market entry (Rosa & Rose, 2007). ‘New product development’ is described as the product design of an innovation (Rogers et al., 2004). Interview participants identified new product development as a key activity of international commercialisation to create a product in which could be used in several foreign markets.

User-Centric Designs

It is important for health products to be user-centric (World Wide Web Consortium, 2008) as the liability of novelty for digital therapeutic tools is high and can significantly reduce user adoption rates. This has also influenced the adoption rates from providers as they lack confidence in the clinical efficacy and safety of digital tools (Holfelder et al., 2021).

Additionally, digital health tools demand changes in existing clinical workflows, adding additional stress on clinicians (Dang et al., 2020).

"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

Participant N3: *"The computer gaming for rehabilitation was unheard of back then. And why would someone like me, not even a clinician was able to create this."*

From a patient's perspective, there are also concerns around the quality and efficacy of these tools. For digital therapeutics firms, it is important to consider patient centred care to improve patient adoption rates. One identified method to support patient centric design is to include patients in the development process.

"We did codesign with 14 young people and we developed a prototype according to their feedback."

- Participant N1

"How do you design the report and the services that come after in a human centred way? How do you motivate people to take action? People were not willing to take a cognitive assessment before because they were worried because there was stigma if you don't fix that problem."

- Participant S1

Many interview participants explained how it was important to co-design the product with potential users and conduct iterative feedback cycles. Iterative feedback cycles enabled the firms to quickly improve their innovation to ensure it fit the target market.

"We take every opportunity to just organically ask people…we just keep taking the user feedback and evolving our product roadmap".

- Participant S1

"We get constant feedback through our app around the customer experience so people can provide that feedback at the consumer level."

- Participant A1

Interview participants highlighted that 'early adopters' were important in the development process as they provided the initial feedback to improve the user experience. Interview participants emphasised how the feedback from early adopters were important in identifying problems with the product and improving the scalability of the product.

"*The first adopters of that gave pretty valuable feedback on our product for the future launch."*

- Participant T1

"In an early stage start up with a new idea, the key is finding your early adopters…clearly, you want to pick an early adopter, in a segment that you want to penetrate. You get the use case, right, you iron out the kinks, you should technically be able to scale."

- Participant S1

The healthcare industry is complex and introducing a new therapy such as digital therapeutics in a fragmented health sector can cause concerns in both provider and patient groups. Start-ups must consider user centric designs and positive experiences to obtain commercially and clinical beneficial use cases of digital therapeutics in patient care.

Product Management

Product management involves planning, creating, commercialising, and managing a product or service (Rogers et al., 2004). An important role in the product development process is a product manager as they are able to understand both the commercial and technical aspects of the product and bring it all together to create a prototypes that meets commercial and technology needs. Additionally, product managers are able to prioritise customer feedback to ensure the most valuable and cost effective features are implemented into the final product.

"We need a product manager, to be a conduit between the commercial team and the technology team… they can sit on some of the calls and feed that information back into the technology team, and we can make those changes and tweaks to the product."

- *Participant A1*

"You need a system that says, these are all the things that were mentioned and how many markets or people have asked for this? And then you got to think will not having this impact the usage or revenues. The key is to have a system to prioritize, and that's really a key role of a good product manager."

- *Participant S1*

Iterative product development permits rapid feedback and development cycles to develop products quickly with limited resources. It also allows new ventures to manage customer expectations around the functionality of the product and internal expectations around what needs to be developed. By employing a continuous feedback loop, firms can address any commercially or clinically sensitive concerns and improve chances of success in the market.

Product Protection

Interview patients highlighted the importance of protecting their technology through intellectual property. This enabled firms to license out their product and the associated IP to other firms safely and profitably. Intellectual property protection such as through patents supported the firm's competitive advantage as they were able to commercially exploit the unique features of their products without direct competition from incumbents. Intellectual property was particularly important for products that were novel and were the 'first' in the market.

So our competitive advantage sits in a in our technology and our people that have developed all the IP around our tech.

- *Participant N4*

"We do have patent protection on our technology, because it is a specific type of AI that is used for a very specific purpose.

- *Participant U1*

Product protection was found to be important for those who competed in the market for ideas i.e. licensed or sold the intellectual property of their innovation (Gans & Stern, 2003). Intellectual property protection through patents can be a costly process in which firms must weigh the benefits and risks of. However, by obtaining a patent, interview participants expressed that they were able to gain more bargaining power when negotiating with potential licensees or acquisitions.

"We had a portfolio of five different patents and we have been able to pass that over to [MNC name omitted]"

- *Participant N3*

5.2.2 Strategic Market Entry

The dimension of strategic market entry emerged from how new ventures need to make the decision on which foreign markets to enter. This helped to outline the different approaches to how a firm would enter a foreign market and the factors that they need to consider. Interview participants highlighted the importance of understanding the market prior to entry. However, for some of the participants, entering and learning about the market occurred simultaneously where the firm learn incrementally about the market while being immersed in it to create the best marketing and sales strategy. Previous literature has highlighted that internationalisation research and subsequently foreign market entry is impacted by several influential factors such as product characteristics, product strategies, market strategies, environmental factors, managerial background, strategic and firm factors.

Management Team Influence

Managerial capabilities have been highlighted in the IE model as a key factor that influences the competitive advantage of a firm (Zahra & George, 2017). An interesting point that interview participants found was that the original founders of the firm were relatively specialised in their area of expertise but lacked the business acumen in key areas. Interviewee participants also discussed how the founders influence the trajectory and the direction of the new venture. Some of the participants found that because the founders of the digital health start-up had either a clinical or research background, they lacked the understanding and experience to build a successful commercial venture. Interview participants expressed how the initial strategic roadmap of the company were often not commercially viable.

"*[the founder] didn't have a whole lot of commercial experience. So it can be really distracting, because you're all over the place…we suffered because we moved very slowly, we didn't fully get product fit in each market."*

- Participant S1

"Sometimes founders just get too caught in detail and theory of how things should look based on legacy or the technology that they have built…most out of 10 haven't got a defined problem statement… they don't actually understand what problem they're solving for so it's very hard to build a proposition around that."

- *Participant A1*

Some interview participants described how their inexperience had an impact on the growth of their start-up. 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. A key challenge that was faced was the impact of rectifying the damage of their poor decisions. The main takeaway from this event was to carefully plan out decisions and major steps as the consequences are often time and financially demanding.

"There were some country markets that we shouldn't have [opened]. We didn't appreciate some of the gravity of the decisions that were casually and the difficulty of undoing that decision."

- *Participant N2*

"We've gone through phases of like being focused, and then being completely expanding it and but yet being too young or not well resourced enough, and therefore then stretching our resources and product without gaining any traction."

- *Participant N3*

IE research also suggests that the management team can influence market selection as previous international experience, global networks, and foreign market knowledge were seen as advantages in entering a foreign market.

"One of our directors worked in the healthcare technology space in the US. So he's helped us understand the marketplace a lot and we got lucky with knowing some good people."

- *Participant N4*

"[in my previous job] I was helping out in America and Germany so that's what I'm familiar with and so I had lots of contacts in those countries"

- *Participant N2*

Accessing Unique Resources

Gaining access to unique resources was a key step in helping digital therapeutic companies to successfully commercialise their innovation. International new ventures are often described as resource deficient and must find ways to overcome this (Gabrielsson & Manek Kirpalani, 2004). Interview participants explained that they formed partnerships to access unique resources to support their internationalisation and commercialisation processes.

Partnerships

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 key challenge was user adoption particularly due to the novelty and large number of digital applications available to consumers. To resolve this, interview participants accessed specialised assets such as patient and customer bases from their channel partnerships to increase the rate of user adoption. The channel partnerships also provided a sales channel where firms could increase exposure of their product with the digital therapeutic bundled together with a complementary health product.

"The channel partnership is just getting your product into more patients hands because that channel partner has a large base of patients and they handle the facilitation and the marketing."

- *Participant U1*

"We have this partner who is producing brain wave devices for consumers, and they are predominantly selling to North America and Europe and they're selling [our product] at the same time."

- *Participant T1*

In contrast, interview participants with an academic background had a technology transfer office who would be responsible for commercialising their innovation. These participants expressed that their IP was often licensed out to other organisations for integration in their organisations or to create a whole new product.

"The TTO had quite a go at commercializing it…we have licensed the source code for use in Japan and there's a firm there that has commercialised it."

- *Participant N1*

"I was not part of the commercialization team…It was licensed out to a group of entrepreneurs".

- *Participant N3*

Product or hybrid partnerships were another unique resource that interview participants utilised to commercialise their product. Through the partnership, new ventures could combine their innovation with another product or service from another organisation to address a different part of the patient journey. This also opened up the clinical indications in which their product would be used for.

"Product partnership which is more about filling gaps in the patient's care by providing complimentary solutions... with musculoskeletal pain, mental health is a huge comorbidity you also see problems with"

- *Participant U1*

"[our partner] used our product for a couple of real world evidence studies and this showed we could measure improvement in the real world. And so now we are commercially bundling with them."

- Participant S1

For digital health tools, it can be important to gain clinical or real world evidence to demonstrate the product's efficacy and safety. Interview participants stated how MNEs such as pharmaceutical companies and medical device companies could act as research and development partners who would provide support or funding for their research projects to prove efficacy for a specific clinical indication.

"We had a pharmaceutical company that would go fund us commercially and for another research project. We have started clinical research to validate against traditional clinical tests."

- *Participant T1*

"[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

These findings highlight how unique resources through partnerships can be a significant catalyst for growth and product development. New ventures are able to source the needed capabilities and resources without bearing the cost financially. Figure 11 below outlines a summary of the different partnerships utilised to access unique resources and specialised assets.

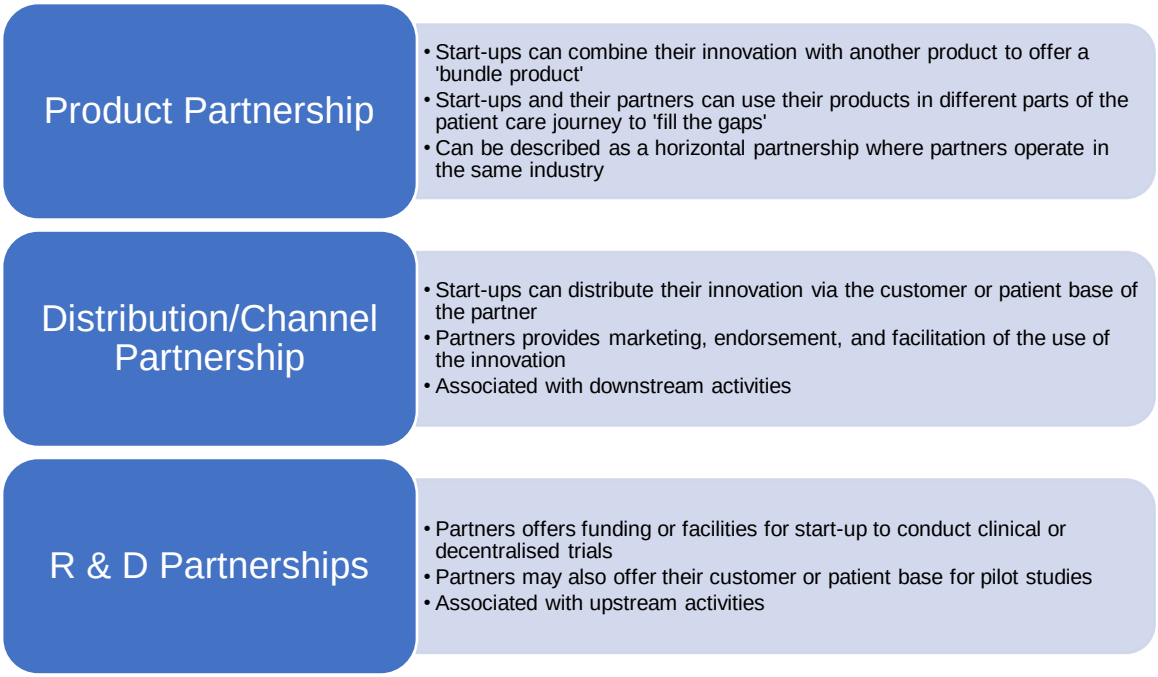

Figure 11: Types of Partnerships

Sourcing Revenue

For any start-up or new venture to be successful, a sustainable revenue stream is required to fund business operations. The approach to obtaining revenue in the digital health industry can be complicated. Some possible revenue streams identified by interview participants were business-to-consumer models (B2C), reimbursement by the government, and business-to-business-to-consumer (B2B2C) models through insurance companies and healthcare organisations. Participants expressed that B2C was not profitable for digital therapeutics as consumers were not willing to pay for healthcare themselves.

"In consumer health, people are willing to pay out of pocket for things because their governments or employers. So they're used to it. But it's really hard to be profitable through B2C in digital health."

- *Participant S1*

"No one wants to put their hand in their pocket to pay for a test"

- *Participant A1*

Interview participants identified the reimbursement system as one of their key revenue streams as well as a method of commercialisation. This was an important factor in market selection. Interview participants expressed that Germany, and the US were identified as

some of the largest and more established healthcare markets in the world. The history of commercial success of healthcare in these countries was a key motivator for firms to enter these markets.

"In the US, there is very clear reimbursement guidelines and you tend to go with providers, because every time they ask somebody to sponsor, they get reimbursed."

- *Participant S1*

"England and America have completely mature frameworks for health technologies."

- *Participant N2*

"With digital therapeutics like Germany is right now the easiest market just because there is a centralized process, and the US has the biggest market."

- *Participant U1*

"*Germany was way more of a market than England was even though it's 20% bigger because of the insurance model*"

- *Participant N3*

There are few large-scale reimbursement systems globally for the reimbursement of digital health solutions such as digital therapeutics. Interview participants expressed that the absence of a proper reimbursement system meant it was near impossible to succeed in that market. It is not common for consumers to pay for their own healthcare in many developed countries and this supports the importance of being able to utilise the region's reimbursement system for a digital health firm.

"In New Zealand, we don't have procurement models that make any sense. If I turn up to PHARMAC with an intervention that is better than a pill they can't procure me – so who's door do I knock on?"

- *Participant N2*

"In the health system, users generally don't pay. A government will pay or user will pay a portion."

- *Participant N3*

Interview participants expressed that the lack of incentives could discourage clinicians from adopting digital therapies. Clinicians were an important stakeholder in the reimbursement or

sourcing revenue process as often they were the group endorsing the use of the firms digital therapeutics.

“If you get a GP to use another tool, it won’t happen. When is no incentive for change or doing anything differently then you can’t expect those different things to happen?”

- *Participant N2*

An interesting perspective on reimbursement was that even if the digital therapeutic meets the criteria of the reimbursement system or had regulatory approval, it does not equate to success within that market. For example in the US, there is a very distinct reimbursement system, however, connecting with the right people, navigating through the layers of the reimbursement system, and understanding how the product fits into the market can make this process complex and impede success.

“[reimbursement systems] doesn't guarantee you business because you got to really delve into which kind of providers? Is a managed care providers? Is it these primary care? Is it a specialist?”

- *Participant N2*

“Just because you have regulatory approval doesn't mean you have a pathway to revenue.”

- *Participant A1*

Reimbursement systems are both a driver and a barrier to the growth of digital therapeutics. Though it is complex to navigate, if a strategy is put in place, reimbursement can help to make a digital therapeutic product to succeed.

Interview participants emphasised that revenue streams were important in allowing the business to ‘survive’ and continue business operations. Thus, were a key consideration when entering a market. However, due to the lack of defined reimbursement and established revenue models in digital therapeutics, it can be difficult for firms to establish a sustainable revenue stream in a new market.

First Mover Advantage

The digital therapeutics industry is still very much in its infancy (Choi et al., 2019). The “first mover advantage” was a described by interview participants as their avenue into gaining competitive advantage. The first mover advantage is a characteristic of the ‘Disruption’ strategy outlined by Gans et al. (2018) which are normally adopted by firms that target niche

segments such as digital therapeutics. The firm was able to get ahead of its competitors by being the first in the market to bring their type of product to market. This enables firms to build up their reputation and brand in their desired medical area to be accepted by partners.

"[It] literally has been the only computer game for stroke rehabilitation on the market to go beyond a university project."

- *Participant N3*

"*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. There's probably one or two who have proceeded further down the path, but they're probably 12 to 18 months away from having a commercial product.*

- *Participant A1*

Interview participants have built up large datasets to support the use of their product and have used this data to drastically develop their product for an exceptional user experience in addition to being a first mover. Participants expressed that despite the plethora of health apps, analogous studies to prove efficacy of these apps were rare.

"We have about 600,000 people who have actually used our product, so we have all that data feeding into our algorithm that has made it much more precise and personalized versus any technology that's going to come out is going to have a lot of catching up to do."

- *Participant U1*

"The biggest advantage that we have is that we've got a lot of research data and there are no other digital interventions for adolescent depression that I know of that have rolled out nationally so in this part of the world… there's a whole lot of stuff that's coming out commercially but they haven't got they have trials to show that it works."

- *Participant N1*

The interview participants emphasised the importance of having a reputable product with a history of clinical safety and efficacy. Though there are more players entering the digital therapeutics market, being the first mover with strong business acumen and evidence-based products enables sustainable competitive advantage.

5.2.3 Commercialisation Environment

The health industry has unique characteristics which can affect the commercialisation of digital health products. For example, the regulated nature of the health industry adds another layer of complexity to start-ups who are aiming to enter this sector.

Clinical Approval

The health industry is notorious for being highly regulated and requiring comprehensive clinical trials to allow the routine clinical use of therapeutic tools (Stremersch & Van Dyck, 2009). Digital therapeutics is no exception to these health regulations and often this has been a key challenge in the commercialisation process. Interestingly, many of the interview participants did not undergo regulatory approval as their product or solution was not strictly identified as a medical device or regulated health product. Instead, some interview participants identified ways in which they could avoid regulatory approval while still being permissible for health-related purposes.

" We just call it a memory scan test because we don't want to make medical claims because it's an issue with FDA or other governmental bodies, we are trying to pick our words to be ultimately more like a supplementary health application."

- *Participant T1*

"We haven't gone through FDA because we're just like a website on steroids. We're not managing a bunch of data, we're just traversing the data."

- *Participant N4*

For those participants who did seek regulatory approval, they identified this process as often challenging. One interview participant identified their error of judgement in the regulatory approval process as a key setback in their international commercialisation plan. Through this setback, they learnt the importance of having in-house capabilities or outsourcing regulatory activities to those with extensive regulatory knowledge and experience. It is imperative to improve the internal knowledge of regulatory approval.

"We had a false start with the FDA so we went through [the FDA process] for 12 months. We found we failed on our submission, not on technology…we failed in 2019 so we could have been in the US market over the last two years with COVID."

- *Participant A1*

Despite not being formally regulated as a medical device or treatment, interview participants cited that having supporting evidence on the efficacy of their digital therapeutic tools was critical for their commercial success. Interview participants emphasised that their large scale projects have produced a considerable amount of real-world and clinical data to support the efficacy and safety of their platform. The continuous and safe use of their platform instilled confidence in their customers and helped to sustain their competitive advantage in their respective medical areas.

"Two weeks ago, we started a new clinical research which would validate the tracking system of against clinical tests… it's a long process but we will have something that will help us to claim that you're really measuring and diagnosing something."

- *Participant T1*

During the clinical research trials, we found through that the algorithms compared to using a clinician with a stethoscope, we had a higher sensitivity and specificity in diagnosing respiratory conditions so you're improving patient outcomes, as well as bringing new technology into the field.

- *Patient A1*

A clinical team's decision to adopt a new product is heavily dependent on clinical data and the quality of data that validates the benefits of introducing the technology. Thus, technology such as digital therapeutics requires substantial data to legitimise its use on patients. Interview participants expressed how comparative studies with current gold standard treatment was 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 randomized 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*

Interestingly, interview participants have leveraged the scientific work of organisations, such as universities and research groups, to endorse the use of their innovative product. Through this method, the firm was able to have supporting data without conducting the study themselves. As clinical trials can be costly and long, there was often a delay in clinical trial data being available 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 effort to help potential customers make an educated decision on the use of digital therapeutics. Interview participants have utilised external clinical studies that demonstrate the positive health benefits of novel technology such as digital cognitive tracking and artificially intelligent chatbots.

"In the last three years or so there's been a lot of science and papers about published about what you can do to reduce your risk and the programs that have reversed mild cognitive impairment…so no one's fully commercialized it but we've taken the answer.

- *Participant S1*

"There's been some really awesome studies in the US historically around things like chatbots, and digital assistants to help with PTSD and anxiety. So leveraging, those clinical studies has been really useful"

- *Participant N4*

Clinical validation is often required to give credibility to the efficacy and safety of that tool to be used by clinicians to treat their patients. As the digital therapeutics industry is still emerging in clinical care, there is still hesitation in using these tools in patient care. Emerging regulatory approval and clinical studies about the benefits of digital therapeutics however will increase the clinical and commercial recognition of digital therapeutics and therefore increase adoptability in the future.

Institutional factors such as the regulatory and reimbursement system was also identified as a key factor for market selection. The regulatory and reimbursement landscape were identified as two factors that affected the perceived value and potential of the market.

"The first thing we look at is market size…how many patients we'd actually be able to reach is effectively a function of the regulatory and the payment landscape."

- *Participant U1*

"We started to break down those markets on which markets have attractive funds and where do we have regulatory approval?"

- *Participant A1*

Localisation

Digital health differs to other high technology industries as it is highly regulated and requires localisation in each region that the product is released (Deloitte United States, 2021). The

need to localise and culturally adapt the product in different regions was identified as a key entry challenge for start-ups. The process of localising the technology was time and financially heavy as it would require significant product development and testing. For example, the Southeast Asian market was deemed to be difficult by some interview participants given the cultural barriers that were often faced when entering this market. There were also some concerns on the efficacy of the product as the interview participants lacked in-house language experts.

"Asia is a little bit harder because of languages and cultures and the type of solutions that we build are very aligned to culture and language. We've had a lot of success in Singapore. But Singapore is actually really hard. Because there's not a lot of data for Singlish as a technology stack for a computer to understand what you're saying. And it hurts the experience a little bit."

- *Participant N4*

"We are only targeting the English-speaking community…internationalisation of our product is not easy because we have to standardise the instructions in those languages which really affect their test score if the customer interprets it differently."

- *Participant T1*

Interview participants expressed that because each region had different regulations and reimbursement models, it was important to localise their market entry approach to match the institutional structure and mandatory processes of each region. However, one challenge that interview participants faced was the poorly-defined reimbursement and regulatory systems as governing bodies are still trying to decide whether digital therapeutics are acceptable.

"It just depends on how the digital health is being reimbursed and actually provided to patients."

- *Participant U1*

"With digital therapeutics is tough, because a lot of these things are still being Figured out in the markets."

- *Participant N3*

"Healthcare varies by the reimbursement or lack thereof."

- *Participant S1*

"*Regulatory approval processes change per country*"

- *Participant A1*

Thus, the institutional structure, especially around reimbursement and regulations, was a key environmental factor that influenced the market entry strategy and commercial success of a digital therapeutic.

5.2.4 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. The interview participants explained that the process of foreign market entry was important for superior performance. The flow diagrams below will provide a high-level overview of how the second-order themes and first-order codes (as outlined in Table 6) were integrated into the internationalisation and commercialisation process for four commonly entered markets by the interview participants, namely the United Kingdom (UK), Singapore, USA, and Germany.

UK

Interview participants expressed that the UK had a decentralised health system where the health service provision is governed by the NHS. These are the high-level steps that interview participants took to enter the UK market:

- Firstly, the firm must research the market and identify key stakeholders such as the payers and regulators to understand the possible revenue streams and market environment.
- In parallel, the start-up must conduct pilot studies, research studies or product fit studies, for example in a local hospital, to successfully deploy the product into the market.
- Once sufficient studies have been conducted, it is important for the firm to connect with the right people within the health system, in this case it was the Head of Digital at the NHS and present their product to head of digital to highlight clinical efficacy, safety, health and economic benefits, and cost.
- If approved by regulators, the firm has a high chance of successfully entering the market.
- At present, there is no generalised regulatory and reimbursement pathway in the UK for digital health or digital therapeutics.

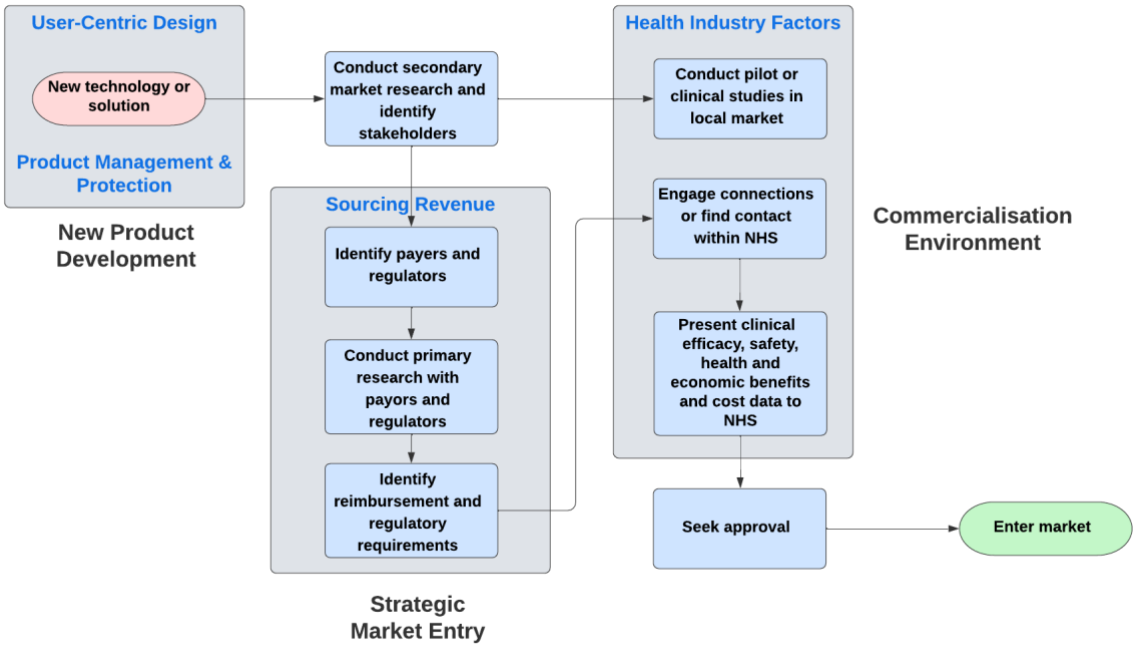

Figure 12: International Commercialisation Process in the UK Market

Singapore

The Singaporean healthcare system is made up of private providers. In Singapore, the Health Sciences Authority (HSA) regulatory Guidelines for SaMD. Thus, if the product falls under a regulated category then they must go through regulatory approval. Singapore does not have an established reimbursement model for digital health. Interview participants expressed creativity is required in securing reimbursement in Singapore. The B2B2C model was identified as the most profitable reimbursement model for their digital therapeutic. Interview participants described two main revenue streams (as seen in Figure 13) in the Singaporean market:

- The payers in Singapore are generally made up of private health insurers who may cover the cost of digital therapeutics for private customers. This achieved through relationship building and partnerships.
- The firm may identify MNCs or other start-ups to bundle their products together to sell as a package. MNCs may also integrate the firm's product into their existing health systems or product. Revenue generated through this method will come from royalties or revenue sharing.

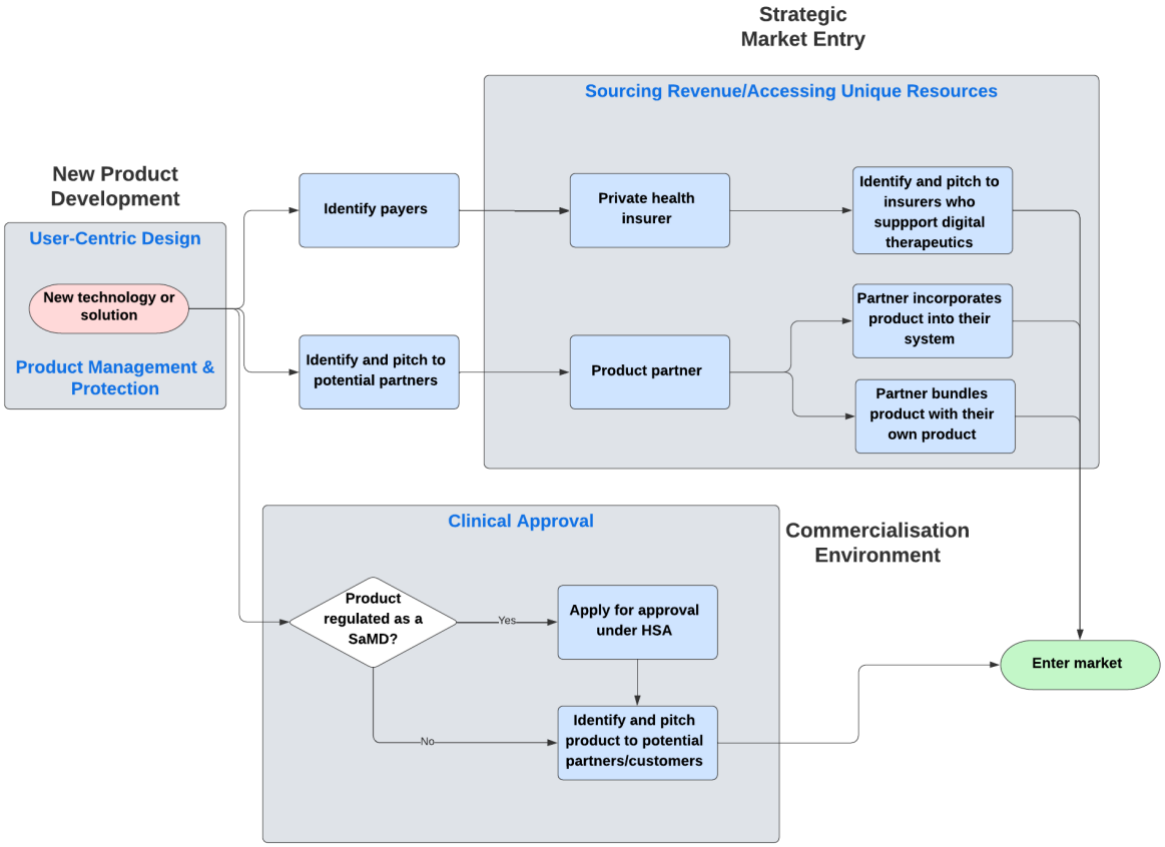

Figure 13: International Commercialisation Process in the Singaporean Market

USA

In comparison, the US health system is also decentralised, however, it is made up of both private and public care. Interview participants typically start with an organisation with brand recognition such as a large hospital system in New York and use this pilot to demonstrate clinical efficacy and safety as well as health and economic benefits to pitch to other players in the US market. There are several reimbursement strategies (as seen in Figure 14) in which a firm can choose from to generate sustainable revenue, including:

- **Direct-to-employer**: Most people in the US will be insured by their employers where their employer will pay for their health plan which provides their care. Thus, the care they can receive under the health plan is managed by the health benefits managers within the human recruitment department of their employers. If a firm pursues this strategy, they will sell to an employer and all their employees will have access to the digital therapeutic.
- **Health Plan**: Firms can choose to sell to a health plan which are distributed by insurance companies. These companies work with thousands of employers and provide insurance for these employers. Insurers have their own internal system for organising benefits and medical care packages for different employers. This strategy

is similar to the direct-to-employer strategy except the firm is able to target multiple employers at once and increasing the scale of use.

- **Federal Programme**: Medicare currently covers some FDA approved digital therapeutics products and providers can claim for reimbursement for chronic care management under CPT codes.

These reimbursement strategies described by the interview participants align with the commercialisation strategies outlined by IQVIA (2021) in section 2.4 Regulation.

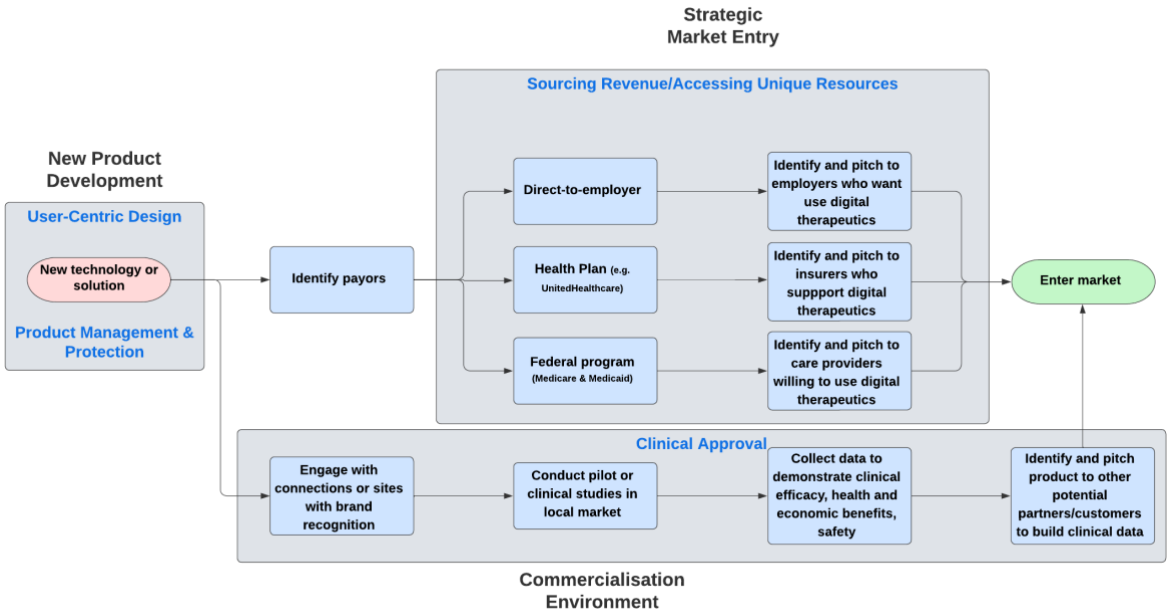

Figure 14: International Commercialisation Process in the USA Market

Germany

Interview participants described Germany as having a more centralised health system and is the first country to have a defined reimbursement and regulatory model. The Digital Healthcare Act (DVG) provides a reimbursement model for digital health (DiGA). There are two application processes (as seen in Figure 15) that a firm can go through:

1. **Fast Track**: If the app is already a certified Class I or IIa 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. BfArM will approve or reject the application within three months. Once approved, the digital health app can be reimbursed by statutory health insurance. The app 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 app. The firm must then submit clinical evidence e.g., a comparative study which shows health benefits, within 9 months.

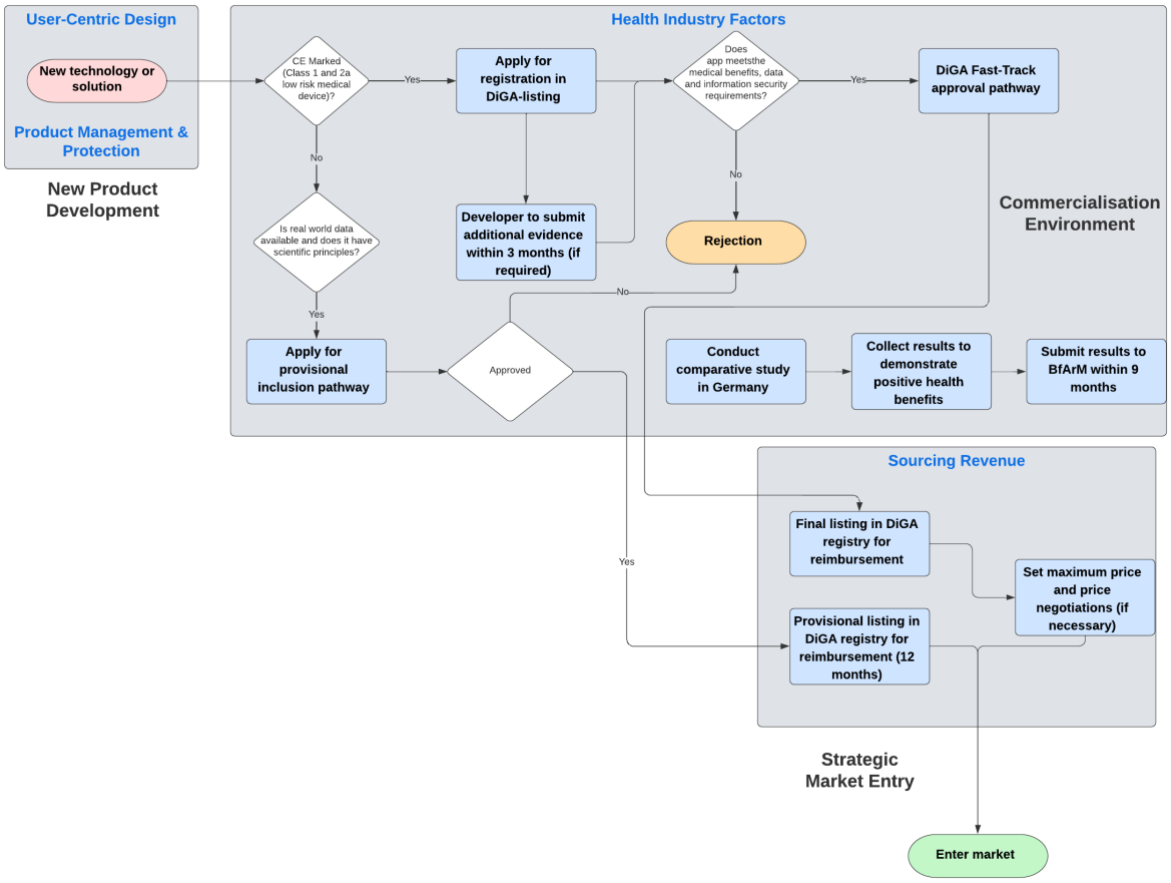

Figure 15: International Commercialisation Process in the German Market

5.3 Results Summary

The interview participants have identified various factors that have supported and challenged the concurrent commercialisation and internationalisation of their innovation. Firstly, product development is a key aspect of commercialisation and interviews revealed that user-centric design was important in health products to promote user adoption. Additionally, product management was key to designing a high value product that is able to offer a unique value proposition to potential users. Interestingly, participants expressed that product protection through intellectual property was considered in the initial stages of product development to ensure they were able to recover the costs of research and development.

In terms of strategic market entry, founders had an impact on the targeted foreign markets which were influenced by their previous experience or connections within those regions. Additionally, the scientific and academic backgrounds proved to be challenging in the commercial side of the venture as they lack business acumen. Reimbursement systems are a unique revenue stream in the health system which proved to be initially difficult for interview participants. Participants expressed that reimbursement models were important in the sustainability of the digital therapeutic in the market and that market research was important in identifying markets that had reimbursement models and institutional structures that would support digital therapeutics. New ventures have built networks and created innovative channels to obtain unique resources and the necessary capabilities to overcome these challenges.

Finally, as the commercialisation environment for the life sciences industry presents a number of complexities that do not exist in other retail or consumer markets, evidence demonstrating safety and effectiveness is often required to promote confidence in clinicians and patients. Thus clinical data is important to commercially exploit the firm's innovation. Interview participants stated that pilot or clinical studies were often conducted within the target market to improve the chance of market entry and foreign user adoption. The process in obtaining evidence is often time-consuming and expensive which new ventures are typically lack. Digital health therapeutics is still a new very foreign concept to the general market and to clinical stakeholders but interview participants have demonstrated successes in their ventures.

Table seven below outlines the codes, second-order themes and aggregate dimensions. The second-order themes were created by combining first-order codes that explain a specific activity or process within the international commercialisation context. The second-order themes were then group together to form the aggregate dimensions.

Table 7: 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 advantage	Commercialisation Strategy	**Strategic Market Entry**
Licensing		
Partnerships	Accessing Unique Resources	
Management team influence		
Payer landscape	Sourcing revenue	
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	

The process undertaken by interview participants is summarised in Figure 16 below. The process begins with new product development where testing, establishment of product management, and product protection occurs. The firm will then conduct market research to identify potential markets, understand what revenue models are possible in that market, and then 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 particular market. The commercialisation environment influences each phase of commercialisation and partners and networks have a role to across all the different phases.

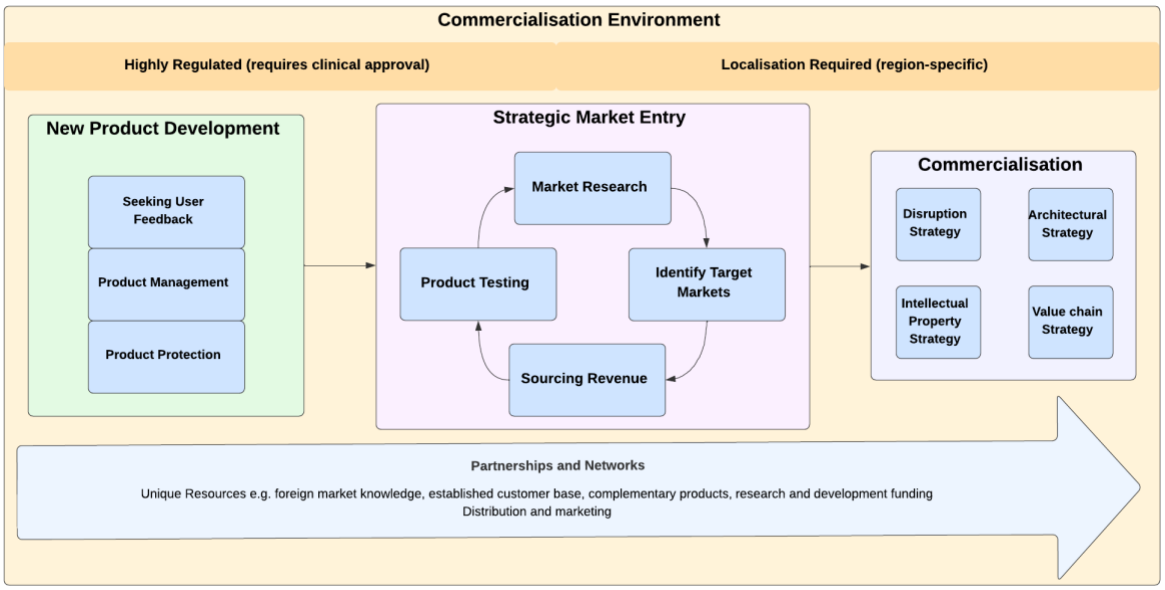

Figure 16: Summary of International Commercialisation Activities

Chapter 6: Discussion

This chapter discusses the empirical findings of this study highlighted in Chapter 5 in the context of the current literature. The discussion is structured according to the commercialisation and internationalisation process.

The discussion addresses the research question of this study which is to understand how new ventures/start-ups enter different international markets with their digital therapeutics and the key challenges associated with this process (as seen below in Figure 17). This chapter evaluates the findings of this study according to existing commercialisation and internationalisation theories.

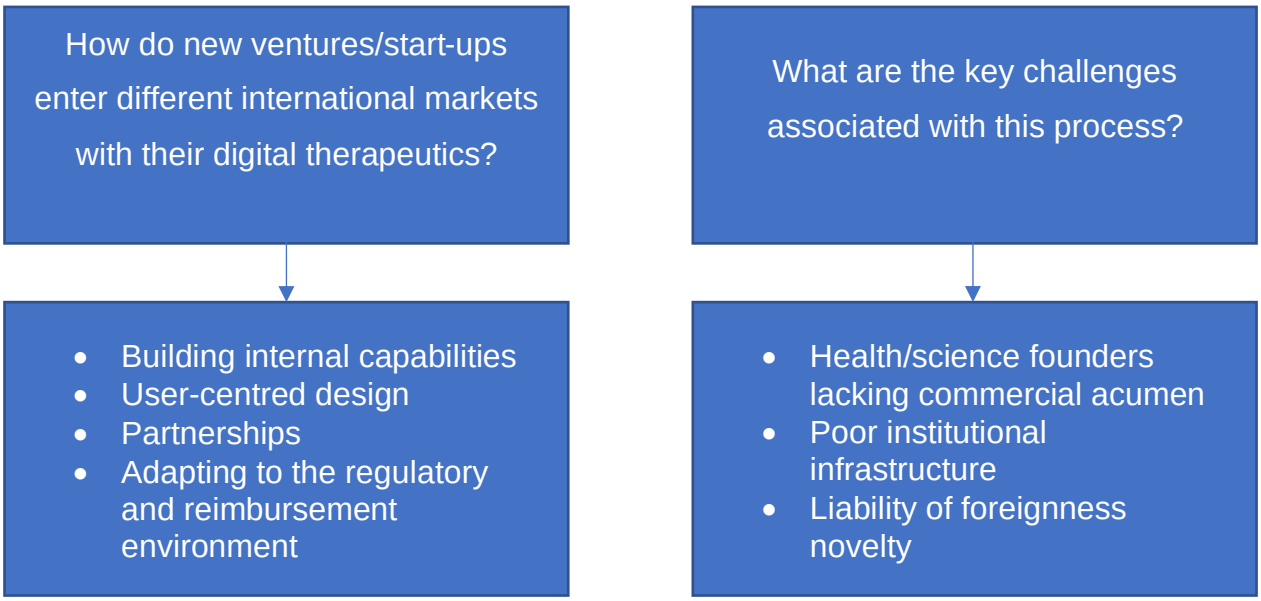

Figure 17: Research Questions and Answers

6.1 Discovery of market opportunities

The study found that founder characteristics such as their background and education impacted the firm strategies and international performance. Digital therapeutics start-ups are commonly founded by scientists, academics, or healthcare professionals. Founders tend to hold tacit knowledge (Pisano, 2006) about their expertise, such as clinical knowledge that supports the original development of an innovative product. However, interview participants expressed that founders had valuable technical and scientific knowledge but often lacked the business skills for successful commercialisation and market entry.

Often, founders chose to enter markets without proper commercial planning, which depleted resources without any benefit and thus, impacted the firm's international performance. Coviello (2015) states that characteristics of the entrepreneur such as knowledge, experience, and education can affect the internationalisation strategies of the firm. Cho et al. (2008) suggest start-ups should consider business-oriented leaders early on in a start-up to ensure complementary skills are available to prepare the product and business model for successful commercialisation and diffusion. The Interview participants agreed with this and emphasised that internal business or strategic capabilities were important in understanding the unique value proposition, understanding product-market fit and thus, determining the markets with the most potential.

In addition, founders were also found to lack the business acumen to create a technology development plan and evaluate market needs despite these being critical steps within the discovery phase in Gbadegeshin (2019)'s commercialisation model of digital health. Lee et al. (2019) suggest that start-ups need to develop their entrepreneurial capacity to conduct market analysis and use the analysis results for marketing their product effectively. In line with existing literature, this study finds that building a team with the right capabilities is critical in facilitating commercial activities such as planning and developing innovative products and discovering market opportunities. Having business expertise is pivotal for building the vital structures and processes to create a viable business. Thus, a lack of business know-how can be a significant barrier to commercial and international growth.

6.2 Exploration and partnerships

Participants expressed the importance of an intuitive design for their digital therapeutics and seamless integration into existing clinical workflows. Digital health tools can increase efficiency and care delivery (Herzlinger, 2006). However, as Dang et al. (2020) explain, new digital health interventions can cause changes in clinical workflows and can increase the burden on clinical teams with data overload and clinical interpretation. In line with this tension, participants in this study agreed that when speaking to clinicians and healthcare organisations, healthcare professionals had concerns around learning different systems and increased activities as digital health tools were yet to become a part of their routine. Participants also emphasised the difficulty of motivating clinicians to adopt digital therapeutics due to the already stressed clinical workforce. The addition of digital therapeutics created more work and lacked defined incentives or rewards. Therefore, digitalisation of care may increase efficiency once implemented (Herzlinger, 2006), yet the increased workload and need to create new workflows and routines can be barriers to their

adoption. This resonates with Gbadegeshin (2019), who expressed exploring the new technology/solution as a critical step in commercialising digital health innovation. This step involves prototyping and testing the technology to understand user preferences and identify areas for improvement. In this study, participants explained that they designed processes to collect user feedback, particularly in the early adopter's group, who provided feedback on the functionality and experience of the product. Interview participants described early adopters as those most likely to implement their technology in the future and thus, were critical in the user-centric design process. As found in this study, the user-centric design was necessary for internationalisation as each region requires localisation to address specific needs in the local market.

Mathews et al. (2019) emphasise the importance of testing with external providers for validation. Interview participants conducted user testing with hospitals and other care providers to demonstrate the clinical efficacy of digital therapeutics in a real healthcare setting and not just in a research environment. The collaboration with external care providers also showed alternative governance structures described by Oviatt and McDougall (1994) who explain how INVs tend to minimise the internalisation of assets and seek to outsource capabilities and resources through networks. Testing across relevant healthcare providers also validates its use across various health settings and integration with current medical technologies. As such to facilitate adoption, a user-centred design is critical in ensuring that the digital therapeutic is intuitive for clinicians and would have minimal disruptions to existing workflows. Thus, this study highlights that one way in which adoption may be facilitated is by working with both clinicians and patients to receive iterative feedback for continuous improvement and to ensure that the design considerations align with the user audience's needs. Developing user-centric technologies is particularly important in healthcare as established medical technologies or treatments are used in routine care (Pistorius, 2017). These mature treatments have the advantage of demonstrated efficacy, existing user bases, distribution channels, and protection through intellectual property rights (Pistorius, 2017). Health providers tend to be cautious when adopting new technologies due to the potential for harm. Thus, this emphasises designing a health product with users to establish a clear and unique value proposition to improve health outcomes.

6.3 Protection of technology

Commercial protection of innovations is important in operating in the digital marketplace to prevent imitation by competitors (Mahnke & Venzin, 2003). The technology-intensive and highly specialised nature of digital therapeutics suggests that protection through intellectual

property rights is important for succeeding in the market, as Pisano (2006) discussed. Bracio and Szarucki (2019) indicate that intellectual property is one of the essential concepts for the commercialisation of innovation through internationalisation. Thus, it is not surprising that interview participants with AI and other novel technology protected their technology to sustain their competitive advantage as a first mover in the global markets. Interview participants highlighted that their strategy for product protection was an early part of their product strategy to ensure the innovation could make a financial return to recover the money invested in research and development. This poses an interesting contrast to Gbadegeshin (2019), who concluded that product protection occurred post-commercialisation. However, this study suggests that product protection occurs before commercialisation to prevent imitation by competitors and preserve the novelty of the product. This was especially important for digital therapeutics as the product can be accessed instantly upon its release and is distributed through digital networks. Thus, the ability of competitors to access and replicate the product is a crucial challenge for Born-Digitals (Brouthers et al., 2016). Chetty and Hunt (2004) describe protecting intellectual property as a marketing strategy for INVs with digital products. With intellectual property protection, firms can market their product openly without the fear of competitors creating a similar and potentially superior product. Interviewees with research backgrounds often compete in the market for ideas by licensing their innovations to both research and commercial organisations globally. Hence, strong IP protection was necessary for the firm to retain control while licensing the invention for profit (Gans & Stern, 2003).

6.4 Commercialisation strategy across borders

The findings of the study show that there may be a relationship between the entry mode and the choice of commercialisation strategy within a specific market. Gans et al. (2018) emphasise that firms must make an informed decision on a commercialisation strategy to bring a product to market successfully. Interview participants expressed that partnerships and MNCs played a crucial role in their commercialisation activities in overseas markets. MNCs usually led the foreign market entry of industry-based interview participants. In partnerships with incumbents, firms adopted a value chain strategy (Gans et al., 2018) where their products would be integrated into their existing offering or bundled to complement their offering. With insurance partnerships, firms would adopt a disruption strategy (Gans et al., 2018) to distribute their product where they would compete directly with incumbents. Interview participants explained that the extensive efficacy and safety data and defined use cases were valuable in the approval process of insurance companies to include their products in their insurance policies.

Firms could benefit from the ‘first-mover’ advantage where they would be adopted for reimbursement by insurance companies before other competitors. As these firms were considered the ‘first movers’ of their product category, it is not surprising that they reflected the typical characteristics of INVs, which aim to create an innovative product which has global potential to serve a specific niche as a market leader (Jones et al., 2011). Thus, interview participants had to adapt their commercialisation strategy based on the region and the available local partners. This demonstrates how contextual factors such as the local environment can affect firms' international opportunities (Sarkar et al., 1999). When local partners were available, firms could access unique resources, such as their established customer base and marketing channels, through their insurance and MNC partners to facilitate downstream activities such as distribution.Additionally, firms could mitigate LoF by working together with a local partner who could provide the local market knowledge and connections within the region (Coviello & Munro, 1997). The interplay between commercialisation strategy and partnerships demonstrates how concurrent internationalisation and commercialisation can occur. The local collaboration provides a platform to enter a specific foreign market and simultaneously determines the commercialisation strategy, i.e., how they bring the product into that market. The partner decides how the innovation will fit into their commercial plan.

Interview participants with research backgrounds explained that the technology transfer offices (TTO) at their university were responsible for commercialising their innovation. Research interview participants explained that the TTO would adopt an IP strategy (Gans et al., 2018) and the IP would be licensed out to research and commercial organisations globally. This cooperation with TTOs represents the potential for mutually beneficially relationships where TTOs have the resources to pay for patent fees and the capabilities to enable the commercialisation of the product to generate revenue for both the TTO and researcher. However, the dependency of the TTO to commercialise their innovation means that researcher loses autonomy over the commercial and international direction of the product (Chetty & Holm, 2000). Unlike the industry-based participants, the need for foreign market partners was not emphasised by these research-based participants. Gans and Stern (2003) explain that IP-based firms are further removed from downstream product activities as their IP is integrated into the licensor’s products or services. This resonates with Hsu and Ziedonis (2013) who suggest that start-ups that adopt an IP commercialisation strategy have less need to obtain foreign market knowledge as they face less legitimacy issues from holding intellectual property from a verified agency.

6.5 International Diffusion and Marketisation

Interview participants explained that existing or trusted relationships within a region were an important driver for product adoption. The management team, board members, and investors were important in building an ecosystem of commercial partners and customers. The participants expressed that their firms partnered with MNEs, healthcare organisations, local care providers, and government agencies to support their international commercialisation activities. The use of business partners to gain market knowledge and to grow in overseas markets quickly is characteristic of INVs (Johanson & Mattsson, 2015). Mahnke and Venzin (2003) state that a key challenge for born-digital firms is building a foreign user community which is often difficult due to the foreign discrimination faced by the firm in an overseas market. To mitigate this risk, interview participants explained that their firm partnered with MNEs, such as insurance companies or large care providers, to access the partners' established customer base and to gain enterprise validation to increase confidence in users. These firms were able to break into the local market by using the unique resources and specialised assets of partners, such as local firms' customers and the local firm's reputation, to promote user adoption. These partners were identified as 'distribution partners' who provided a platform for firms to enter new markets. Although Brouthers et al. (2016) suggest that born digitals do not have to deal with suppliers or distributors in the foreign market, interview participants expressed that distributors were critical in the diffusion of their innovation and also provided a consistent revenue stream. Thus, while generally born digitals may be able to bypass distributors, in digital health, distribution is still an important consideration for these firms given the need to gain legitimacy in the market. Thus, firms are able to use their networks to form bridges into new markets as described by the social network theory (Johanson & Mattsson, 2015).

Interview participants expressed that analysis of the market environment was important for successful market entry and commercialisation. Reuber et al. (2017) suggest that the context of internationalisation, such as environmental factors, can have a significant effect on the firm's strategy and commercial activities. The digital health industry is an example of a unique environment which is highly regulated due to the effect that medical treatments can have on humans (Laurell et al., 2013). This study found that the ambiguity of reimbursement and regulatory systems in healthcare systems negatively affected the ability of start-ups to succeed within a market. This aligns with the argument of Pisano (2006) who suggest that the institutional inefficiencies do not accommodate the unique characteristics of science-based businesses and thus, impact the success of these businesses. The findings showed that digital therapeutics firms found it challenging to operate within the constraints of the

different health systems. Due to the regional differences in the reimbursement and regulatory landscape, firms had to localise their commercialisation strategy and business model for each market they want to enter which supports the findings of Bowen and De Clercq (2008) who explain that institutional factors influence how firms pursue opportunities. During the localisation process, the firms had to consider any potential language barriers, the available reimbursement pathways, and the degree of regulation. Four different commercialisation patterns emerged from the four main markets that the firms of interview participants entered. These commercialisation patterns emerged as a result of the regulatory and reimbursement differences of each region, namely the UK, Singapore, USA, and Germany. The findings highlight that the regulative and cultural dimensions, and thus institutional structures, of a market are important to analyse in the health industry across different regions. This demonstrates how firms must be able to adapt their processes in order to enter different markets successfully.

Interview participants have expressed the challenges of the poorly defined regulatory and reimbursement frameworks of foreign markets. Mathews et al. (2019) explains the delay in regulation of digital health is due to the risk-averse and stepwise nature of regulatory bodies in contrast with the fast moving and iterative technology firms. Thus, the development of regulations is considerably slower than the rapid development of new health technology. The emergence of digital health start-ups has impacted the institutional characteristics of some markets for example, in Germany, a provisional listing pathway was revealed recently to allow digital health companies with real world evidence to seek reimbursement for their use as described by interview participants who entered the German market. Another example from this study was the entry strategy into the Singaporean market which is largely made up of private health insurers. Interview participants explained that they had found creative ways of breaking into the market by convincing MNCs to adopt digital therapeutics to result in a collaborative relationship. This is an interesting phenomenon which resonates Teece (2014)'s idea of creating a supportive market ecosystem when the foreign markets do not accommodate the innovative product. Thus, the changes in healthcare systems can occur as a result of the entrepreneurial actions of digital therapeutic start-ups which contribute to institutional changes that support their commercial activities.

The availability of clinical and real-world data was identified by interview participants as a value driver in the diffusion of digital therapeutics. Interview participants expressed that their product and distribution partners requested for clinical data that demonstrated efficacy and safety of the digital therapeutic. The importance of clinical evidence is reinforced considerably by Gräfe et al. (2020) who found that healthcare professionals are unlikely to

support the use of digital therapeutics unless they have randomised clinical trials in peer-reviewed journals that demonstrate improved clinical outcomes. As a result of the COVID-19 pandemic, interview participants explained that collecting real world data or conducting decentralised or virtual trials were a viable option to prove clinical efficacy. Often these were cheaper and simple to design compared to traditional trials (Krasniansky et al., 2022; Agrawal et al., 2021). Interview participants who had accumulated large sets of real world and clinical data emphasised that this provided a competitive advantage as competitors often had a delay in clinical trials and lacked clinical data. Thus, the execution of clinical trials and pilot studies with local healthcare organisations and other companies was a beneficial process in the commercialisation and internationalisation of digital therapeutics.

Interview participants expressed the importance of sourcing revenue to support business operations. Digital health differs from other high technology industries as users are reluctant to pay for healthcare, instead, insurance companies, government agencies, or employers tend to pay for an individual's healthcare (Brinkmann-Sass et al., 2020). As a result, a B2C model is generally not profitable due to the structure of healthcare system in many developed countries. Interview participants expressed how their firms used a B2B2C approach where they seek reimbursement from larger organisations such as MNCs, government agencies, or employers. Interview participants expressed that USA and Germany had the appropriate institutional structure for reimbursement of digital therapeutics and that being a reimbursable product helped to drive uptake by clinicians and sales. This indicates that there is a foreign location advantage (Oviatt & McDougall, 1994) in Germany and USA which have established institutional structures and familiarity with new innovation that enable digital therapeutics to be accepted and reimbursed formally (Stern et al., 2020). Because there is not a defined reimbursement pathway in many regions, start-ups have had to find unique ways of seeking reimbursement or adapt current reimbursement pathways to fit the use of digital therapeutics. Interview participants described MNCs as their gateway into the Asian market due to the opportunities provided by the MNC. Reimbursement in this environment occurred through health insurance claims or co-payments from patients. Sourcing revenue is an activity associated with business models (Oderanti & Li, 2018) and has not been explicitly examined in this study. Gbadegeshin (2019) considers the creation and testing of business models as a key activity in the diffusion and marketing phase of his commercialisation framework. Therefore, there is potential for further research to understand the process of constructing sustainable and financially viable business models of digital therapeutics. Identifying a distinct revenue stream is important for the sustainability of digital therapeutics firms for both commercial and international expansion.

6.6 International Commercialisation Process

The findings of this study discuss how digital therapeutic start-ups adopt various commercialisation strategies, utilise their networks for foreign market expansion, access unique resources for product development, and obtain clinical data to sustain a competitive advantage. Much of the current literature describes commercialisation and internationalisation as two distinct processes. Interview participants, however, described commercialisation and internationalisation as parallel processes. In which activities contribute to overlapping commercialisation and internationalisation outcomes. For example, market analysis and product validation are two key overlapping activities. Current internationalisation and commercialisation theories highlight the success factors and barriers and support understanding the industry's structure and relationships. The findings of this study suggest the importance of the process at the firm-level.

The study findings suggest that internationalisation is a process that involves market analysis, network formation within the market, and identifying the most valuable commercialisation strategy for that market. Several internationalisation theories in the international business literature illustrate different aspects of internationalisation. Transaction cost and resource-based internationalisation theories that focus on the costs, investments, and risks, suggest that market entry decisions are discrete and occur at specific points in time (Andersen 1993; Oviatt & McDougall, 1994). Export development theories have also described the internationalisation process and suggest that internationalisation occurs gradually. However, this theory focuses on the predetermined phases rather than the process (Johanson & Vahlne, 1977). Thus, the transaction-cost, resource-based, and export development theories describe the factors that affect internationalisation rather than the process. The learning, networking activities, and entry into market in this study suggest that internationalisation is a process that occurs over time. This aligns with the network and organisational-learning theories, which describe how the behaviour processes contribute to the internationalisation process (Johanson & Mattsson, 2015). The findings of this study also suggest that environmental, organisational, and founder-related factors influence the process of internationalisation. The INV theory describes the organisational-level behaviour and the development process that must account for contextual factors, such as firm and environmental factors, that create conditions for the internationalisation process (Oviatt & McDougall, 1994). Thus, the findings suggest that the process of entrepreneurial internationalisation is essential to understand how born-digital firms utilise a unique set of resources to capitalise on new opportunities.

The organisational learning and decision-making behaviour for commercialisation also suggest a process in this study. There is evidence of process in the commercialisation literature such as Gbadegeshin (2019)'s for the commercialisation process of digital health. The study has found that the invention of the technology, exploration, decision on commercialisation strategies, and the marketisation and diffusion of the technology occurs as outlined by Gbadegeshin (2019). However, existing models of commercialisation do not account for internationalisation activities. Gbadegeshin (2019) suggests that early internationalisation occurs at the "diffusion and marketing" phase, however, the model does not explicitly examine how internationalisation occur and thus, categorises internationalisation and commercialisation as two distinct processes. While systemic reviews conducted by Bracio and Szarucki (2019) suggested internationalisation is the result of the innovation or that internationalisation increases the innovativeness of the firm. Findings from this study suggest the former, where firms have created a technology-intensive health product that has the potential to succeed in the global markets. The overlap between commercialisation and internationalisation activities found in this study suggest that commercialisation and internationalisation can occur in parallel.

6.7 Summary

The findings with reference to previous commercialisation and internationalisation literature suggest 'simultaneous' activities for commercialisation and internationalisation of new ventures. Founder characteristics impact the commercial success of a firm. As Gans et al. (2018) suggest, when firms adopt the first feasible strategy, they are often disadvantaged compared to competitors. Thus, this highlights the process of developing internal capabilities, especially business capabilities that understand product-market fit. Firms must accommodate the environmental factors that impact both commercialisation and internationalisation activities. For example, the availability of local partners influenced the exploration and commercialisation strategy of new ventures. The digital health industry is unique in that the institutional structure is a key determinant of the firm's success in a market. However, firms have undergone position-building processes that stipulate institutional changes to accommodate the product better. The commercialisation and internationalisation process of interview participants suggests an overlap between the activities. Thus, internationalisation activities should be examined further in future commercialisation frameworks to account for this. Additionally, this supports the idea of rapid internationalisation of new ventures as a process rather than a distinct opportunity or decision at a point in time.

Chapter 7: Conclusion

This chapter summarises empirical findings in relation to the research questions and details implications, recommendations, and research limitations.

7.1 Conclusion

Three main dimensions were outlined in the commercialisation and internationalisation activities of digital therapeutics start-ups – new product development (user-centric design, product management, product protection), strategic market entry (unique and specialised assets, influence of management team, sustainable revenue streams), and the barriers to implementation (clinical evidence, localisation). International new ventures are becoming more prevalent in the digital therapeutics space. Thus, this study aimed to understand how new ventures undergo concurrent commercialisation and internationalisation in the digital therapeutics sector.

In alignment with the social network and entrepreneurial internationalisation literature (Zahra & George, 2017; Johanson & Mattsson, 2015), the social and business networks, environmental, organisational, and management team factors impacted the internationalisation pattern of the firms. Additionally, collaboration with partners provided benefits in the commercialisation of digital therapeutics and the opportunities these partners provided influenced the commercialisation strategy adopted by the firms. The contextual factors, such as the environment and institutional structures, imposed challenges for sustainable market entry. For digital health specifically, the institutional factors seem to be of utmost importance compared to other industries as digital health's success is driven mainly by reimbursement and regulations. Interview participants explained how they had to adapt their internationalisation and commercialisation strategies to overcome the challenges brought by institutional factors. The different activities outlined in this study suggest that examining the process of internationalisation and commercialisation strategies is important. Previous internationalisations indicate that the decision to internationalise is made up of distinct alternatives at a single point in time. The findings suggest that firms go through firm-level learning and networking processes over time to promote the international commercialisation of their digital therapeutics product.

7.2 Academic Implications

The findings of this study suggest that commercialisation and internationalisation activities can occur in parallel. This study contributes to the literature in two ways. Firstly, it makes contributions to the technology commercialisation literature on digital health. This study provides insights into how firms competing in the digital health sector must adapt their commercialisation strategies to accommodate industry specific factors such as institutional structures of different health systems. In line with previous research, internationalisation is a key activity in the diffusion and marketisation of innovation (Gbadegeshin, 2019; Pellikka & Virtanen, 2009). Exhibited by separate commercialisation and internationalisation frameworks, current literature describes these as two discrete processes, however, this study indicates that these two processes are integrated as one process in the industry. The different actions taken by a firm contribute both to the commercialisation and internationalisation of a firm, thus, the internationalisation aspect should be considered further in commercialisation frameworks.

Secondly, the findings contribute to the IE literature and suggest that the process of internationalisation of international born digitals should be investigated further. Previous internalisation, resource-based, and export development internationalisation theories tended to focus on factors rather than the process of internationalisation (Andersen 1993; Oviatt & McDougall, 1994; Johanson & Vahlne, 1977). The networking and learning behaviour over time in digital therapeutic firms suggest there is a process in the internationalisation of Born-Digitals.

7.3 Managerial Implications

Based on the findings of this study, there are several implications for managerial practice. These implications are important considerations for industry members who are involved in the digital therapeutics sector.

Building a team with the right capabilities

It is important for digital therapeutics ventures to build the right capabilities in the company. Business leaders should be employed early on to ensure that the structure and operations of a business are commercially viable (Cho et al., 2008). Founders of digital therapeutics start-ups are also driven by their clinical expertise and typically lack business acumen. The lack of business acumen can result in poor decision-making where founders may act on untested assumptions and adopt the first viable strategy without proper commercial planning.

Design with users

Customisation of products through user-centric design were found to increase user adoption rates and promote business sustainability. For example, products that are easily integrated into the clinician's workflow and are simple to use increased the acceptance of the product. Thus, firms must work collaboratively with potential customers and partners to identify the distinct value propositions of the innovation that meet user needs.

Leveraging networks

The importance of networking in commercialisation and enabling the international expansion of digital therapeutics firms was found to be critical for success. In line with the network theory (Johanson & Mattsson, 2015), it was found that large MNCs, such as health insurance and pharmaceutical companies, and their relationships are of great importance. Networks can provide credibility, access to existing users, and sources of revenue to support firms in the commercialisation and internationalisation process. Though Born-Digitals can normally avoid distributors, in digital health, distribution is important for gaining credibility in a new market. Managers should consider the effect of the partnership on the entry mode, commercialisation strategy, and opportunities available to the firm as this can affect the firm's strategic direction.

The importance of context

Contextual factors such as the institutional structures of different health systems and the environment of the global markets can shape the commercialisation strategy. Gans & Sterns (2003) suggested that firms must assess the commercialisation environment to best determine the most optimal commercialisation strategy. The payer and reimbursement landscape in healthcare is vital for a sustainable health business. Health revenue is generally not market-based, and thus, digital health providers must identify and convince stakeholders to pay for the health product. The regional differences in reimbursement and regulations mean that a business model or commercialisation strategy may not necessarily be transferable from one region to another. Therefore, firms must adapt their approach to the environment.

Understanding the international commercialisation process

Unlike traditional literature, which describes internationalisation and commercialisation as two distinct processes, the study indicates that commercial activities overlap. Industry actors already perceive some of these processes together. Therefore, understanding where these overlaps occur can help firms design more cost-effective and efficient activities, such as

market analysis and product protection, or streamline their activities. Doing so allows international commercialisation more efficiently than undertaking the same activities again for each process.

7.4 Limitations and future research

The undertakings of experiential learning and network building suggest that Born-Digitals undergo a process to achieve internationalisation. Conducting research in this area will enable an improved understanding of the internationalisation process in a digital context, particularly in digital health and can help extend the understanding of the supply-side of digital health and therefore, inform international entrepreneurship research. Current commercialisation and internationalisation frameworks explain the structure of the industry and its relationships. The findings of this study demonstrate the importance of understanding the internationalisation process at the firm-level and how these processes are designed.

It is noted, the results are derived from the digital therapeutics sector, which is a very niche industry that is constantly evolving. Digital therapeutics firms, like other science-based businesses, usually need to cover a wide range of activities from conception to international commercialisation. The COVID-19 pandemic has accelerated the adoption of digital technology across all industries, especially in healthcare. Digital firms allow customers/patients and providers/suppliers to be more connected to enable more effective interactions and better care experiences. Thus, born-digital health firms represent the beginning of a new revolution in which international commercialisation of these firms can occur. Therefore, more studies need to be conducted with digital therapeutics start-ups to fully determine the factors that influence the international commercialisation process.

Several limitations were recognised in carrying out this study. Firstly, due to the limited timeframe to carry out the study, the sample scope was restricted. Data saturation is achieved when participants are continuously introduced into the study, and new data is not found where data starts to become repetitive or redundant (Saunders et al., 2018). Many of the interview participants were based in New Zealand and there was only one participant each from the USA, Singapore, Turkey, and Australia. Future research should conduct a more comprehensive study with a much larger sample size from different countries to achieve sampling and data saturation to ensure the findings are applicable to digital therapeutics start-ups in their respective geography. The purpose of this study was to contribute to theory building rather than generalisability.

Another limitation is that the inclusion criteria for study participants varied from the most common academic definition of IE. Due to the limited timeframe and difficulty in obtaining participants, the time of internationalisation (the point where the firm entered an international market) was extended to five years since inception instead of two to three years of inception as proposed in the literature. Additionally, the number of international markets was reduced to one to broaden the participant pool instead of at least two international markets. These changes in the definition of INV for this study may have affected the findings of the study.

Appendix

Appendix 1: Interview Schedule

For the participant

- Please tell me about your role within the organisation
- What are some of your duties or key responsibilities?

About the digital health organisation

- What is your digital product and what was the design process behind your product?
- What types of expertise were important in the development and commercialisation of your product?
- What was your commercialisation strategy from concept to creation and market entry?
- How would you describe the internationalization of your digital product and the key steps that the company took?
- How did the internationalisation of the digital product affect the commercialisation strategy?
- What strategies did you use to ensure competitive advantage and continuous competitive analysis and how did this help to overcome the challenges you faced?
- What were the main managerial and technological capabilities of the company?
- How were these capabilities incorporated with the commercialisation and internationalisation process?

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