Master's Thesis – master Innovation Sciences

UK Digital Health Platform Market Formation Barriers and Policy Trade-offs

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Abstract

Healthcare in the UK is becoming more expensive and less efficient. The from origin public National Health Service has started to invite companies into the system to try and tackle these problems, for example by providing digital health solutions. This privatisation is often viewed by the public as a threat to free healthcare, but also brings significant opportunities. Digital health is suggested to streamline healthcare processes, lower the pressure on healthcare professionals, and provide easy access for healthcare consumers. In its development, the digital health market is facing challenges that need to be overcome to serve its part in healthcare. Taking the case of digital health primary care platforms in Greater Manchester, this research focused on what barriers market actors experience while forming the market and proposes policy trade-offs to tackle these.

Frameworks of Boon et al. (2022) and Flanagan et al. (2022) were used to specify the digital health market formation processes and regional industrial policy trade-offs. A Historical Event Analysis (HEA) and interviews were used to gather and analyse data. The HEA clarified the context of the research by connecting events from 2012 to 2022 to market formation indicators and aimed to show an either inhibiting or facilitating function to the process. Interviews were conducted with an interview guide derived from the HEA narrative and aimed to validate and add to the narrative while also exploring the factors that influence developments in the digital health market in relation to the isolated events.

The HEA and interview outcomes led to the following barriers: *SME and multinational market entry inhibition by strict and changing regulation, expensive and time-consuming evidence gathering value proposition for gaining legitimacy, healthcare digitalisation causes health inequalities to worsen, lack of integration into GPs' workflow and IT systems as a barrier of adoption, healthcare digitalisation causes health inequalities to worsen, and data usage by companies is ambiguous to the consumer.* As of the upcoming implementation of Integrated Care Systems, local actors will increasingly gain legitimacy to exert influence on their region through decision-making in healthcare. This research suggests shifting the attention in policy to a narrower framing of the problem, a more diverse network and customization of the institutions to the actors in digital healthcare.

Preface

To carry out the research in the context of the case, the author of this report travelled to Manchester throughout February – July for data collection and analysis. In Manchester, the author was geographically close to interviewees and the local digital health market, and the author got to learn from the expertise of the Manchester Institute on Innovation Research institute while incorporating parts of it in this research. It also provided the opportunity to experience the functioning of the primary care market firsthand, which further clarified the need for this research.

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Acronym	Full name
A&E	Ambulance & Emergency
BM	Business Model
CCG	Clinical Commissioning Group
COVID-19	Coronavirus 2019
EPR	Electronic Patient Record
GM	Greater Manchester
GMCA	Greater Manchester Combined Authority
GMDA	Greater Manchester Devolution Agreement
GMHSC	Greater Manchester Health and Social Care
GP	General Practitioner
HaSCA	Health and Social Care Act
HEA	Historical Event Analysis
HInM	Healthcare Innovation Manchester
HSMoU	Health and Social care Memorandum of Understanding
ICS	Integrated Care System
ICT	Information and Communication Technologies
IT	Information Technologies
MFT	Manchester University NHS Foundation Trust
MHCC	Manchester Health and Care Commissioning
MHRA	Medicines & Healthcare products Regulatory Agency
NHS	National Health Service

NICE	National Institute for Health and Care Excellence
SME	Small to Medium Enterprise
UK	United Kingdom
WHO	World Health Organisation

1. Introduction

In 1948, the National Health Service (NHS) was founded in the United Kingdom (UK) to provide affordable and accessible healthcare to all inhabitants (Maynard, 2005). Although in the beginning, the population of the UK was somewhat hesitant to shift from private practices to a publicly funded system, nowadays, the NHS cannot be dissociated from British culture anymore. Even though in 2019, 60% of surveyed UK inhabitants indicated to be satisfied with the quality of the system, they also expressed worries about its future (Appleby et al., 2020). 42% of surveyed inhabitants mention that they expect the standard of care will get worse in the years 2020-2024, and 80% mention that the NHS is facing a significant funding problem. This funding concern is grounded since the percentage of the Gross Domestic Product spent on healthcare has risen from 3.5% in 1948 to 7.2% in 2019, and it is expected to grow even more (Charlesworth et al., 2021). At the base of these rising costs of the healthcare system is a rising demand for healthcare that can be attributed not only to a growing population but also to changing demographics of the inhabitants, as they are getting older and unhealthier (Papanicolas et al., 2019). Efforts to improve cost efficiency by predominantly staff freezes have led to a higher working pressure for care staff and longer waiting times for general practitioners and hospital appointments.

One of the rising innovations that has gained high expectations for tackling the funding and work pressure issues in healthcare is digital health, defined by the World Health Organization (2021) as *"the cost-effective and secure use of information and communications technologies (ICT) in support of health and health-related fields".* By improving the cost efficiency of healthcare while not compromising its quality, these ICT solutions have the potential to slow down the rising healthcare costs in the UK (Vanagas et al., 2018). An example of such a digital health solution is remote consultation platforms, which can be regarded as online information mediators between multiple user groups, for example, a medical specialist and a person seeking health advice (Benedict et al., 2018). Solutions such as these can decrease the work pressure experienced by the healthcare professional as the information exchange is more time efficient than in regular healthcare (Talboom-Kamp et al., 2016). Not only is the accessibility to medical information relatively high and quick, so that people choose this option above seeing a general practitioner face-to-face, but also mobility and geographical factors are reasons for users to engage in these platforms.

Digital solutions are often developed by companies and are thus not inherent to the NHS (Benjamin & Potts, 2018). As it has proved difficult to innovate within the big organisation of NHS, it looks at the market to bring forward fitting solutions to their problems. Despite its great potential, the digital health market in the UK remains relatively small and fragmented, with Small to Medium Enterprises (SMEs) and start-ups making up the most significant part (Oderanti & Li, 2018). Although these smaller companies are often a source of innovation, the integrated approach needed to address, among others, telecommunication, hardware, and healthcare services requires numerous resources that SMEs usually do not have at their disposal (Barlow et al., 2012). When no solution is brought forward to either support these SMEs or attract larger companies to the digital health market, barriers could remain to exist in the market formation. This would severely diminish the potential of the UK digital health market to tackle healthcare problems.

Recent research has started to acknowledge the potential of the UK digital health market and its barriers but focuses on either isolated businesses or is not context specific to the UK healthcare system. Oderanti et al. (2021; 2018) have focussed on what barriers exist in the UK digital health market and how to overcome them in their research. They consider business model components and user uptake processes in their inductive approach, focusing on the company level of the UK digital health market. However, it leaves mechanisms related to the broader market, such as establishing a market-wide dominant product (category) and the influence of policy, out of the equation. As the healthcare system is heavily regulated and relies on policy to steer it in the desired direction, these overarching market processes should not be neglected when researching the digital health market (Maier et al., 2021). Other research focuses on the influence of broader market mechanisms but only

considers non-UK markets (e.g. German, Danish, Swedish) or does not define a geographical context in the research (Dewald & Truffer, 2012; Ekeland & Linstad, 2020; Hellberg & Johansson, 2017; Kierkegaard, 2015). Context-specific research, such as the formation of markets, is often not generalizable, as a region's system embeds innovation systems, regulations, and institutions that might differ from other systems (Cheng et al., 2016). While non-context-specific research on market formation processes within digital health can give rise to knowledge for uncovering these processes in the UK market, context-specific mechanisms such as the institutionalized NHS should also be considered to pinpoint the barriers in the system. Combining the inclusive market perspective with context-specific research gives rise to knowledge on what barriers exist in the digital health market in the UK and what solutions should be focused on.

As healthcare systems are typically heavily regulated, policy can be used to steer them in the desired direction. Policy interventions are often mentioned in existing literature as a powerful tool to influence markets and tackle barriers (Dewald & Truffer, 2012; Ekeland & Linstad, 2020; Kierkegaard, 2015). Policy structures and the availability of policy instruments are often context-specific and cannot be generalized or applied to every context. With the barriers to the UK digital health market formation not clearly defined, the possible policy interventions to overcome these also remain ambiguous to this point. Flanagan et al. (2022) describe regional industrial policy trade-offs revolving around problem framing, network assembly and institutional change to solve local problems concerning market formation. Viewing digital health markets as demarcated on the regional level will further specify the solutions that come up throughout this research.

The aim of this research is twofold, both to research the barriers to the digital health market in the UK and to provide policy intervention trade-offs, resulting in the following research question:

"What are the barriers to the digital health market formation in the UK, and how can these be addressed using policy trade-offs?"

A framework on market formation processes is used to distinguish the processes deemed necessary while forming the digital health market in the UK. Before, market formation was approached from isolated strands of literature (e.g. economical, technological, social), nowadays, researchers are starting to define the process dimension and integrate these into one framework. Boon et al. (2022) distinguish five processes in market formation: demand articulation and empowerment, formation of new user practices and experimentation, formation of institutions and institutional entrepreneurship, defining legitimate market boundaries and establishing dominant product categories, and formation of dominant product or service design. This research not only aims to elaborate on the state of these processes in the light of possible barriers but also to specify the framework for the digital health market and add to or change the processes. A Historical Event Analysis (HEA) is performed to understand the context of the market and events that have led up to the current state while linking them to the development of the processes. Using the literature on market formation processes and the distinguished events as a backbone, representatives of companies operating in the digital health platform market and policymakers are interviewed to derive the state of the market formation processes and barriers to the market formation. Based on the barriers derived from interviews, literature research is performed to deduct policy intervention trade-offs in regional industrial policy. A case study in the UK environment is selected to make the research more empirically grounded and provide the interviewees with an example to make market formation more tangible.

The market formation framework and regional industrial policy trade-offs are relatively new developments in literature and will be further developed by applying them to the digital health market case. Focussing on the market formation specifically will give rise to knowledge on what processes exist in the UK digital health market and how companies navigate the highly institutionalised landscape. Boon et al. (2022) propose the framework in the light of transformative policy, by linking it to the policy trade-offs of Flanagan et al. (2022), this connection is made between processes within

the market formation and policy trade-offs to overcome barriers related to these. From a societal perspective, this research gives rise to knowledge on what barriers exist on a regional level and how national and local governments can stimulate the market formation of digital health, thereby mitigating the high pressure on the current healthcare system.

In **section 2** of this report, a definition of digital health is provided, followed by the theoretical framework in **section 3**, and the used methodology in **section 4**. The results are divided into **sections 5 to 7**, where subsequently the context of the market, the barriers, and policy trade-offs are sketched. In **sections 8 and 9**, the conclusion and discussion are made up.

2. Digital health definition

Digital health is at the intersection of digital technologies and healthcare and exists under many different names such as eHealth, mHealth and telehealth (Fatehi et al., 2020). As this new gathering of two disciplines creates new dynamics in the field of healthcare, academia and industry have not yet formulated a largely accepted definition of digital health. Some of the existing definitions focus more on Information and Communication Technology (ICT) innovations, while others focus more on healthcare integration. The digital health market is still finding its place in the healthcare market while developing itself. Although there are some developments directed toward private healthcare practices, this research focuses on companies trying to integrate with the existing public healthcare structures and institutions.

In 1995, the concept of digital health was first introduced by Galvin et al. (1995) as 'the Virtual Hospital.' In this virtual hospital, ICTs were used to store medical information by image, text, and audio. Since 1995, the field of digital health has evolved and next to storing data, many other sub-disciplines have joined the overarching definition. In 2018, the WHO (2018) classified the different digital health interventions and their applications for problem-solving into taxonomy for the field. This taxonomy includes, among others, data management and exchange, personal health tracking, coordination structures, and communication between the healthcare professional and the client. Digital practices in this last category can be used in having online GP/ specialist appointments or repeating prescription medication. This communication takes place in an environment that both the healthcare professional and client can use and is trusted and reliable. Often a platform is created for the purpose. The NHS, for example, has an app in which you can seek health information, order repeat prescriptions, view your health record, book appointments for vaccinations, and get direct written advice from your GP (NHS, 2022d).

Lennon et al. (2017) split the healthcare market into three levels (macro, meso, and micro) and apply these to digital health. The macro level entails the structures of the market and the influence of policy on these structures. In digital health, the readiness of the regulatory landscape determines the development of digital health into the healthcare system with, for example, policy on the collection and storage of patient data by third parties. The meso level is focused on the processes of companies and organisations operating in the healthcare market. These processes entail the competition and collaboration between different actors in healthcare, but also the infrastructure readiness of healthcare to include digital practices and the resource availability for digital health companies to develop their products. On the micro level, the focus is more on the interaction at the point of care and the individuals/ groups that are involved in this. Here, the trust of the users of digital health solutions, as well as the means to engage with them comes forward. For patients, digital literacy and access to the internet are needed to engage with digital health, while for doctors, this is often more focussed on having enough time on hands to experiment with it.

Although all three levels are relevant in market formation, the meso level is chosen as a focus of this research. The healthcare company and local healthcare organisations are particularly relevant to research, as the public healthcare ecosystem has just started to invite companies in, and the perception of companies to this change is vital to form a market. The effects of the macro and micro level processes are taken along as an effect on these companies while entering the healthcare system.

3. Theoretical framework

The theoretical framework of this research uses literature on market formation processes and regional industrial policy to research the existing barriers to the UK digital health market and explore possible policy interventions. To answer the research question, the desired market formation processes for healthcare are used to create a framework that the healthcare market can be placed against to determine what processes are contributing to barriers. A framework on regional industrial policy trade-offs is researched to create a theoretical base that can be used to apply to the barriers to find a solution to these barriers.

3.1. Market formation processes

The processes necessary for a successful market formation are defined in the context of the digital health market. Two strands of literature are used to do so: literature on market formation in general and literature on digital health market formation. Together, these strands form the framework used to derive the barriers.

3.1.1. General market formation processes

Recently, Boon et al. (2022) created a framework for market formation processes that distinguishes five processes in market formation: (1) Demand articulation and empowerment, (2) Formation of new user practices and experimentation, (3) Formation of institutions and institutional entrepreneurship, (4) Defining legitimate market boundaries and establishing dominant product categories, and (5) Formation of dominant product or service design. These processes were derived from different strands of literature (evolutionary economics of innovation, sociology of markets, marketing studies and transition studies), and focus on technology-based innovations in a socio-technical environment at the centre of such processes. Digital health qualifies as such an innovation, as it finds its origin in emerging technological capabilities of creating and maintaining platforms with substantial data flows and artificial intelligence. The socio-technical application comes into play when considering the acceptance and adoption of this technology in society's geographical, demographical, and sectoral context. Using literature on digital health, the processes are specified to what they entail in the digital health market formation. Consequently, it is elaborated on what effect the absence of process activities could have on market formation.

3.1.1.1. Demand articulation and empowerment

The demand articulation and empowerment of technologies is the process that establishes a communication channel between the need or wish of the consumer and the technological development and applications (Boon et al., 2022). Digital health initiatives can target a broad range of user groups as of their broad applicability and sales market. Companies can influence the demand by engaging in marketing activities or defining product categories. The demand for a specific innovation is not always apparent in healthcare systems. With the NHS providing free or reimbursed health care, paid services might have difficulty defining the demand for their product as the need might be there, but the willingness to pay not (van Gorp, 2018). When individual consumers do not consistently articulate this demand, companies often collaborate with healthcare suppliers such as NHS institutes to create this bridge between supply and demand. In this case, the NHS institutes act as an intermediary organisation between the patient and the industry and sometimes engage in the developmental process or provide financial resources (Boon et al., 2008, 2011). The demand is not only defined by companies' activities; also (potential) users can define it by expressing trust in the safety and efficiency of the innovation, lobbying or (co-)creating the desired innovation themselves. Users such as medical professionals feel underserved, or a problem occurs in their work that the healthcare sector does not provide a solution to; these users may start to innovate themselves, fuelled by their experience.

When there is a lack of demand-defining activities on either the producer or user side, this could lead to a mismatch between these parties, thereby increasing the risk of creating a product or service that is not according to the needs and wishes of the user (Boon et al., 2011). The service not being

to the users' needs could lead to a lower social acceptance of the service, and a lower adoption rate of the digital health service, which affects not only the product itself but might also form a barrier to the market formation.

3.1.1.2. Formation of new user practices and experimentation

The formation of new user practices and experimentation entails how users familiarise themselves with the product or service and how it is integrated into their daily life (Boon et al., 2022). Companies can promote the formation by piloting their product and receiving feedback. Not only the adoption of a product itself but also the way of engaging with the product or service can encourage the co-creation of user practices. Users of a product can define the use of the product by incorporating it into their routines in different ways. Digital technology is already starting to take a more prominent place in people's everyday practice, and Ramtohul (2015) describes that digital health user practices touch upon how people are used to interacting and communicating through technologies but differ from these because of the healthcare aspect. When communicating through a digital platform, users might question if the quality of care is the same as they are used to in an offline solution. The success of integrating the digital health platform in the clinical workflow of a medical professional or search for medical advice by healthcare consumers depends on the accessibility of these platforms (Lennon et al., 2017).

When the accessibility to a product is low, for example, digital literacy or a bad internet connection, this can form a barrier to the market formation (Lennon et al., 2017). The incorporation of the digital health service in the users' daily routines remains low, and the users do not have the capabilities to create new user practices. When this happens, the information exchange between user and producer will stay low with little feedback, thus hampering the product category and market development.

3.1.1.3. Formation of institutions and institutional entrepreneurship

The formation of institutions and institutional entrepreneurship shows the importance of the context in which technological innovation is developed (Boon et al., 2022). Stimulating regulation and standardisation of practices can steer society to accept a new product or service by changing the dominant institutions. Creating institutions around a healthcare innovation can lead to a better embedding into the context, while an institutionalised environment favouring traditional healthcare practices might hamper it (Ahangama & Poo, 2012). The existing institutions often find their origin in or are influenced by medical standards, guidelines, and protocols. If a company's vision does not align with the existing institutions, institutional entrepreneurship is needed to change these. Institutional entrepreneurs in healthcare, for example, facilitate the digital health market by changing the societal assumption that seeing a doctor in real life is necessary to receive an adequate diagnosis. In healthcare, research shows that subject positions with less structural legitimacy are more willing to change the system, while those with more structural legitimacy are less willing to promote system change (Lockett et al., 2012a). For digital health, this could translate to medical professionals and users wanting a digital change, while NHS governing bodies are reluctant to it.

Institutional entrepreneurs are subject to the medical standards, guidelines and protocols that are dominant in the healthcare industry, as well as the technology industry when influencing institutions concerning digital health. If these intra-industrial standards facilitate digital health practices to be adopted in the clinical flow, the institutions are more likely to be affected and changed. If the standards do not comply with the digital health market, this might form a barrier to market formation.

3.1.1.4. Defining legitimate market boundaries and establishing dominant product categories

The 'Defining legitimate market boundaries and establishing dominant product categories' market formation process entails establishing new markets in the institutional environment and defining the boundaries of this market (Boon et al., 2022). Kierkegaard (2015) argues that policies and processes that influence technology dissemination affect the adoption rate of digital health into the system. In

the formation of the digital health market, the question is raised whether it will be a market on its own or whether it should integrate with the traditional healthcare market or the digital technology market (Lennon et al., 2017). Within the integration, especially data acquisition and storage-related issues such as storing privacy-sensitive information online can be a subject of legitimization, as this is pushing the current boundaries of the regular healthcare market. Whether the digital health market develops as integrated with or detached from the current healthcare system, it must define the boundaries to come to a common understanding of the definition and eventually legitimization of the existence of the market. Market boundaries are closely connected to product categories, defined as socially demarcated partitions (Suarez et al., 2015). When a dominant product category emerges, this accelerates the market formation. It creates space for different market actors to compete to fulfil consumer needs that arise with development and convergence.

When the actors' vision on the place of digital health in healthcare does not align, this could cause the market to lose vision of what part it will take in healthcare. Less directed innovation will occur when this placement remains ambiguous, and the market fragmented.

3.1.1.5. Formation of dominant product or service design
The formation of a dominant product or service design is the convergence process to a dominant design of a product or service (Boon et al., 2022). With the convergence, the use of the product or service category is better understood and accepted by society, thereby establishing a widely spread definition and design. Reaching a dominant design in platforms coordinates users in their use of the application, as the understanding of what these platforms entail and their use is established (Eklund & Bestek, 2019). As digital health has a broad definition, the subcategories must be defined on their own before a dominant design can emerge. The accepted definition can be achieved by companies making their intellectual property available for other companies to use (Lennon et al., 2017). Gaining expertise in the healthcare field might incentivise companies focused on digital solutions to enter the digital health market when a dominant design is emerging and help co-designing it. Next to co-design, also competition drives a dominant design. When more actors of various natures enter the market, this promotes the development of knowledge and competition for fulfilling the limited demand in the market. This stimulates the specificities of the design to be developed to the needs of the market to proliferate in it, eventually setting a design standard.

When a dominant design is absent, the consensus on the healthcare solution is missing. The consumers and potential producers that step in engage less with the market segment (Suarez et al., 2015). Especially in a market that relies on trust and accessibility, such as the digital health market, establishing a dominant design is vital for further development as this trust needs to be gathered based on understanding and experience with the design.

3.1.2. Digital health market formation processes
In researching the market formation processes for digital health, next to the general market formation processes also another process comes forward. Adding specified market theory to the general market formation processes brings context to this research by which a clear picture of the presence/ absence of required processes can be formed.

3.1.2.1. Business model (innovation)
In digital health literature, next to the processes in the framework of Boon et al. (2022), also the existence of a Business Model (BM) for healthcare is viewed to be a critical process in market formation (Hwang & Christensen, 2008; Marcos-Pablos et al., 2019; Oderanti & Li, 2018). The framework of market formation processes considers the market's micro, meso, and macro levels. However, the active role of the company to promote market formation through the valuation of their product remains underexposed in the framework. Whether innovations are adopted from a technology-push or needs-pull model, the value proposition still needs to align with societal needs, and often the company is central in forming this value proposition and corresponding BM.

According to Oderanti et al. (2018; 2021), for commercial companies to emerge and proliferate in the digital health ecosystem, a sustainable BM needs to be adopted to become competitive with regular healthcare practices. One of the building blocks of a BM is the value proposition, which seeks to solve customer problems and satisfy customer needs (Osterwalder & Pigneur, 2010). Especially in digital healthcare initiatives, where healthcare and digital technologies come together, a new value proposition is needed to connect the markets (Marcos-Pablos et al., 2019; Steinberg et al., 2015). In the health market, where the product is a public good instead of a good of transactional nature, the advantages of digital health (e.g. accessibility, mobility and efficiency) over regular healthcare are the key to adoption. Pruthi et al. (2013) found that digital health services looking to operate in the public healthcare system need to contain two values in their value proposition, namely, satisfy the patients that use them and create a positive financial impact on the healthcare system.

Van Limburg et al. (2015) argue that the creation of value propositions and innovation of BMs is not only a company's responsibility but an essential part of the developmental process of digital health for all stakeholders to engage. Not only can the definition of technological ecosystems create value, but also the actors and the system's network and the way they communicate stimulate innovation (Marcos-Pablos et al., 2019). Integrating a product or service into the system can be a consequence of the BM complying with the system's (unfulfilled) needs, either by developing capabilities that suit existing BMs, creating collaborations with traditional actors or technology companies, or innovating BMs (van Velthoven et al., 2019). Traditional BMs in (offline) healthcare rely on heavily invested actors in the healthcare market, such as hospitals, medical specialists, and pharmaceutical companies (Maier et al., 2021). Digital health providers could use these BMs, change them to fit their characteristics or create new BMs.

3.2. Problem-oriented policy interventions

When the market formation processes framework is used to distinguish barriers to market formation, this is when the formation of policy interventions comes in to propose a solution to solve these barriers and promote market formation in the digital health market. Literature on problem-oriented policy interventions is used to find possible pathways to policy solutions.

3.2.1. Policy in healthcare

When there is a pressing problem such as healthcare becoming more expensive, this affects not only the individual but society at large. These societal problems involve many stakeholders such as healthcare institutes, the state, inhabitants, and companies. With this many stakes involved, finding an optimal solution for all parties is not evident, and a guiding hand is needed to steer the system in another direction. This is where policy comes in. Within the field of technological innovations, policy often focuses on transformative change: reaching solutions to multidisciplinary problems through the alignment of innovation objectives and adjacent environmental and social dimensions (Schot & Steinmueller, 2018).

Looking through a problem-oriented lens, Innovation Systems, whether technological, national, regional or mission-oriented, are affected by societal problems and are directed towards providing solutions for these (Flanagan et al., 2022). When a societal need develops, this stimulates a potential market demand through creating agency, institutions, and a network. Flanagan et al. (2022) argue that as most societal problems have a place-based origin, the solution to these societal problems should also be focused on the region. In past years, this focus on a place-based solution for healthcare has increased; however, the geographical dependency of the problem has not been acknowledged as much in the literature (Flanagan et al., 2022). An active role in the place-based problem is needed in forming policy interventions to understand the problem and create a solution.

Kierkegaard (2015) explains the dependency of digital health on governance systems and how the (de)centralisation of these systems can lead to (un)favourable legislation for the digital health

market. Focussing on national legislation provides consensus on the wide adoption of the technology while focusing on the region leads to contextual needs being considered. In both cases, a prominent role for policy is cut out to change the existing healthcare regime, not only to follow the trend of digital health development but actively steer the market formation.

3.2.2. Regional industrial policy

Local and national policy interventions can be approached by identifying trade-offs in the industrial strategy of a region. Flanagan et al. (2022) propose a framework of trade-offs in market formation based on problem framing and legitimacy creation, agency and network building, and institutional change. These trade-offs are based on complex societal challenges within the market formation, thus focussing on the problem itself to base policy solutions on. They recognize the regional aspect of societal challenges to fully understand the problem and argue that innovations are inherently activities of problem-solving. This connects to this research on the market formation of digital health by seeing the problems in healthcare as societal challenges that can be unpacked in regional specifications. The barriers from the framework of Boon et al. (2022), in this case, can be seen as problems that need to be solved with policy focussing on the regional aspect.

The trade-offs in problem framing and legitimacy creation focus on keeping the problem's frame narrow or broad, and the geographical replication of the problem. Whereas a narrow frame can create a specific solution to a specific problem, a broader frame can create legitimacy through bridging frames and gaining social traction as more stakes are involved. Diversity, openness, geographical boundaries, and transparency in communication are considered for agency and network building. While a smaller, less diverse, or more homogenous network is more likely to embed actors' trust and understanding, an open and diverse network can create opportunities to express different perspectives and embed new knowledge. This embedding of new knowledge happens differently based on the orientation of the network to create new knowledge itself or internalize it from knowledgeable actors outside of the region. The transparency in communication can also lead to more or fewer actors entering the regional healthcare system. The last trade-off category of market formation, institutional change, is about whether the institutions form around the problem or the problem is framed around the institutions. Adapting institutions could lead to a higher specification in the solution while framing the problem reduced uncertainty of solution providers as a norm. For the other institutional factor, valuation metrics, the same applies as a narrower valuation process can stimulate a better reflection of needs. In comparison, for a broader valuation process, the standard gives space for various innovations.

4. Methodology

In the methodology section, the theoretical framework proposed in **section 3** is operationalised to find the barriers to the UK digital health market formation and to come to policy trade-offs.

4.1. Research design

A qualitative research approach was taken to answer the research question, as this research aims to create a deeper understanding of the market formation processes. The digital health market formation is researched cross-sectional as of time constraints but also includes the longitudinal aspect by including an analysis of the processes over time.

4.1.1. Context and scope

The UK context is appealing to research on the subject of digital health market formation, as the highly institutionalized and tax-funded NHS is starting to show its weaknesses, yet a clear plan toward a more efficient and cheaper healthcare system has not been developed successfully. With digital health being a possible solution to the problems NHS is facing, researching the market formation processes can clarify the potential and current barriers that need to be addressed by NHS and industry.

The NHS region of Greater Manchester is chosen to research to further narrow the research and include region-specific health problems. This region was chosen as of the generally poorer health than the UK average, with deaths related to cancer and heart disease being more common (GMHSC, n.d.). This poorer health came to the light in COVID-19 times, where mortality rates in GM were 25% higher than the national average (Butler, 2021). These health problems translate into higher pressure on healthcare and a rise in association costs (Institute of Health Equity, n.d.). These pressure and costs are expected to increase over time as of the ageing population and increasing health inequalities in the region. In 2015, 37 local authorities signed a landmark agreement to take charge of the region's health and social care spending and decisions. In the 'Taking charge of our health and social care in Greater Manchester plan', the following statement is taken along (Greater Manchester Combined Authority, 2015):

> *"A fundamental change in the way people and our communities take charge of – and responsibility for – managing their own health and wellbeing, whether they are well or ill. This will include exploring the development of new relationships between NHS and social care staff and the public who use services; finding the thousands of people who are currently living with life changing health issues and do not even know about them and investing far more in preventing ill health. We want people to start well, live well and age well."*

Not only is the problem of poor health regional, but the solution might also be. The innovative character of the universities and the centrality of the region in the 'Northern Powerhouse' network create opportunities for GM to attract and maintain skilled people while developing its innovation profile in both healthcare and digital technologies (Institute of Health Equity, n.d.). The combination of expertise in healthcare and digital technologies resulted in the Northwest having the highest MedTech company concentration in the UK, with the potential to roll out digital health solutions applicable to GM problems (Mahon, n.d.). Therefore, the unit of analysis used in this research is the digital health market in GM.

4.1.2. Digital primary care

As digital health is a broad topic that includes different subsections, a case selection is made within the GM digital health market. Pressure on primary care structure is rising. General Practitioners (GPs) experience a high workload, and Ambulance & Emergency (A&E) services have waiting times of several hours in the region (Gibson et al., 2014). Digital health platforms are suggested to make primary care more efficient. These platforms connect healthcare practitioners and consumers through an online tool where patients can see the GP through video consultation. Inserting digital

health platforms into the clinical workflow of GPs could reduce the time of consultations and streamline the process of seeing patients. Also, as patients can see a doctor remotely, they are more flexible in making appointments. The hurdle of physically going to the doctor can be lowered when this appointment can be carried out in break time at work or just from home, thereby saving waiting times.

Nationally and locally, many parties are involved in this digital transformation of consultations. The NHS first set out the 'Digital-first primary care' plan in 2019, stating that every patient has the right to choose for a video consultation from 2023 (NHS, 2019). Following this plan, the local NHS organisation, the Greater Manchester Health and Social Care Partnership, set out to also implement this strategy in GM and researched the system's needs to make the change. As the industry is entering the ecosystem through different entrance mechanisms, the question is how these commercial parties, together with the incumbent system, will form the digital health platform market in GM. In this market, activities related to the processes have occurred, but the market formation is not completed. The adjacent markets of private healthcare practices and non-medical devices pose dynamics to the market formation that actors can resort to when the market formation of the public digital health market is stalled.

4.1.3. Research steps
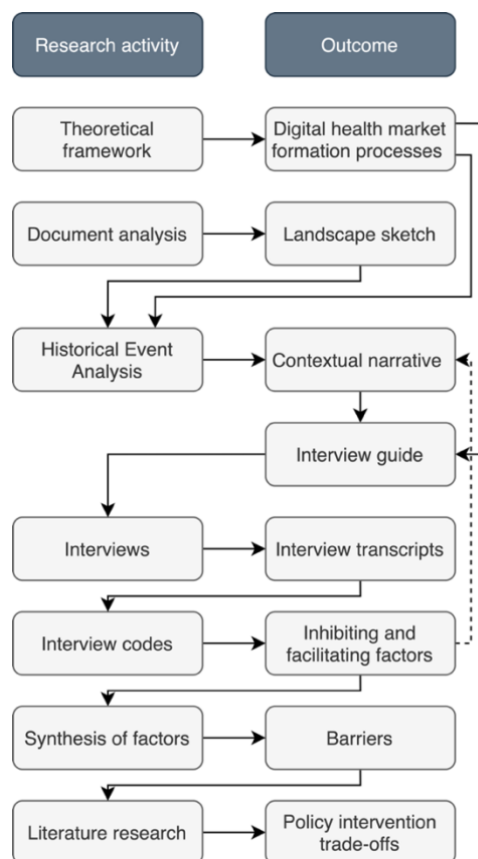
Figure 1: Structure of the research process

The research steps have carefully been thought out to find the barriers to GM's digital health market formation (see **figure 1)**. After the theoretical framework uncovered the digital health market formation processes, the first step in the research process is to visualize the healthcare actor landscape relevant to GM's digital health platform market. The market formation processes are converted into ± 4 indicators for each process using the theoretical framework. The indicators and actor landscape sketch are then used to perform the Historical Event Analysis (HEA). The HEA method is a process-based approach that can be used to map the dynamics of a process such as market formation. This approach was developed by Van de Ven et al. (2008) with the idea in mind that innovation is a nonlinear dynamic system. It was operationalized by Negro et al. (2008) to technology-centred analysis, using not only scientific publications but also news articles and websites. This analysis forms a narrative of the development of the processes over time.

The HEA narrative contributes to the backbone of the interview guide by adding event-specific questions and establishing the connection between the events and the current situation. The interview guide is used to conduct interviews with local actors in the digital health platform market. Businesses embedded in the local business ecosystem, governmental organizations such as the NHS and local policymakers related to the case were interviewed to form a well-rounded view of the digital health market. The interviews are analysed and coded to obtain information on the market's events and current state. The outcome of the coding process is input to the HEA, which is validated and added to by an iteration of literature research, and the information on the current state is transformed into barriers. Consequently, the barriers are connected to trade-offs in regional industrial policy interventions within the GM context using the framework of Flanagan et al. (2022).

4.2. Data collection

Qualitative data were used as input for this research. As some of the process developments were expressed more explicit in literature, while others are embedded in actors, data collection from both sources is necessary to create a well-rounded view of the digital health market formation processes. Literature research was performed to gather information from publications, newspapers, and web pages, while interviews were performed to collect data from actors within the GM healthcare ecosystem.

4.2.1. Literature research

The goal of the document analysis was threefold: to create a better understanding of the GM health ecosystem, to identify the effect of events on the GM digital health market formation processes, and to identify policy intervention trade-offs specific to these barriers. The scientific literature was derived from Google Scholar and Scopus, where different newsletter articles on events were derived from Google Scholar and Nexis Uni. Actor-specific documents such as policy and vision documents were derived from the website of the actors that were established as active in the digital health network.

4.2.2. Semi-structured interviews

Using the narrative derived from the HEA, semi-structured interviews were used to validate and elaborate on the past events and further research on how they affect the current state of the UK digital health market formation processes. The focus is on mechanisms of the (digital) healthcare market that are not explicitly researched or stated in publications. To create insights on the meso level of the market and the functioning of the digital health market, different stakeholders involved in the case were interviewed on their views on the case and market. By encouraging interviewees to talk about what barriers exist, not only knowledge on these barriers was created, but also possible solutions to these barriers came forward.

4.2.2.1. Sampling method

Interviewees were initially selected based on convenience sampling. After this initial sampling and interview round, snowball sampling was performed by asking the interviewees who they think should be interviewed next. Different contacts in academics and the business ecosystem in Manchester served as a network providers. The actors were selected based on their involvement in GM's (digital) healthcare system. The landscape is further researched by interviewing actors involved in advancing health start-ups/ SMEs and local policymakers. In total, 11 actors were interviewed for at least an hour.

4.3. Operationalization

Using the theoretical background, indicators were derived for each market formation process that could indicate a facilitating factor or an inhibiting factor to this process. In **appendix I**, the table of the market formation process indicators is added. In the event research on HEA, events were identified that influence the digital health market in GM by doing a broad search on the GM digital health timeline. Publications, news articles and web pages about these events were consequently searched in databases containing a mention of the facilitating or inhibiting state of the indicator, thereby indicating the effect on the process. In the narrative, the abbreviations expressed in **table 1** and **2** are used to indicate the process and the effect on the process.

Table 1: Abbreviations of the processes

Abbreviation	Process
DemandArt	Demand articulation and empowerment
NewUse	Formation of new user practices and experimentation
InstiTrans	Formation of institutions and institutional entrepreneurship
MrktBndry	Defining legitimate market boundaries and establishing product categories
DomDesign	Formation of dominant product or service design
BMInno	Business Model Innovation

Table 2: Abbreviations of the effects on the processes

Abbreviation	Effect on process
FF	Facilitating factor
IF	Inhibiting factor

The identified market formation processes and the barriers that arise in the HEA were converted into interview questions to make up the interview guide (see **appendix II**). First, the interviewee was asked general questions about the critical market formation processes and current barriers. Hereafter, the interviewees were introduced to the market formation processes and state of the processes derived from literature and asked about their views on them.

4.4. Data analysis

After the data was gathered for HEA, the narrative was written using the events and their effects on the market formation processes. The interviews were conducted, and the transcripts were analysed using a coding process in NVivo. This analysis process contained a mixed inductive and deductive approach, following the steps:

- *Open coding*: passages from the interviews where statements were made concerning landscape factors were coded (inductive step)
- *Axial coding*: the open codes were taken together in subjects (inductive step)
- *Selective coding*: the subjects were linked to the indicators belonging to the market formation processes and it was determined whether they were a facilitating factor or inhibiting factor (deductive step)

When subjects arise within a market formation process that cannot be directly linked to an indicator but are believed to be essential to the research and market formation process, these were added to the framework. In **appendix I**, these are shown in bold. The coding process resulted in a coding tree (see **appendix V**) and has the following structure:

- 6 level-3 codes: the core processes as described in theory
- 12 level-2 codes: a division in the core processes of developments/ facilitating factors and inhibiting factors
- 39 level-1 codes: the subjects found after the open coding process, linked to the market formation process indicators
- 181 level-0 codes: references to what is mentioned in the interviews related to theoretical activities

Based on the coding outcomes, the HEA narrative was revised and connections between the different facilitating and inhibiting factors were established by looking into interviewees' expressions of causal links. These assemblies led to the barriers to the digital health market formation.

5. Context of the market

The context of the market is researched to create an understanding of the mechanisms present in the market and how it has developed over time. In this section, first, an overview of the actors in Greater Manchester is provided to understand the actors involved and their place in the health ecosystem. Second, the Historical Event Analysis is drawn from document analysis and interview outcomes to provide the history of the market.

5.1. Greater Manchester Actors and Network

The healthcare ecosystem in the GM region has reformed itself in the last ten years, as the industry entered the healthcare market. Actors have come in and moved out, and regulatory and overseeing bodies have changed. Where more power has been vested in local authorities instead of national authorities, local actors and organisations are joining forces to improve healthcare and stimulate innovations in this sector. An overview of the actors involved on the meso level of the digital health market is included below.

5.1.1. General Practitioners

General practitioners are often the first point of medical contact for people looking for care. They write prescriptions for medication, give health advice, refer patients to secondary care, and give out sick notes (NHS, 2022a). Next to having medical knowledge, GPs are also often required to be able to work with current systems in practices such as Electronic Patient Records. This importance in digital literacy can be found on the NHS careers site, where the must-have skill of 'good IT skills' is stated when applying for a GP position. Other than in secondary care, GPs are not always employed by NHS itself but instead contracted as individual practices.

5.1.1.1. Primary Care Network

The GPs are united in 14 Primary Care Networks (PCNs) across Manchester since 2019. These PCNs have geographical boundaries and thus cover districts within the city (Baird & Beech, 2020). Through PCNs, primary care activities that reach beyond GPs' activities are tackled within districts. These activities include connecting health and care, medication reviews, and personalised and preventative care.

5.1.2. National Health Service

The National Health Service exists out of many different departments, both national and local. GM is embedded in NHS England, but other departments such as NHS Digital have a say in what decisions are made concerning primary care in Manchester. On the local level, the NHS Foundation Trusts and the Clinical Commissioning Groups make healthcare decisions.

5.1.2.1. NHS Digital

NHS Digital is the department of NHS that deals with digital services and digitalisation problems within the healthcare system (NHS, 2022b). Among other tasks, NHS Digital manages the NHS App, which nowadays is not only used for gathering health advice but also shows patient records, has options for contacting a GP and integrates digital primary care services with the NHS.

5.1.2.2. Manchester University NHS Foundation Trust

Next to the national NHS, there are also local NHS organisations that have a say in healthcare. The NHS trusts are overarching organisations that set a vision and employ the staff for the regional hospitals. One of these trusts is the Manchester University NHS Foundation Trust (MFT) which oversees the ten hospitals in Manchester. Based on the needs of their employees, they have the option to translate these problems and seek industrial solutions through procurement.

5.1.2.3. Manchester Health and Care Commissioning

Combining three local Clinical Commissioning Groups (CCGs) in 2017, the Manchester Health and Care Commissioning (MHCC) CCG takes commissioning and procurement decisions on primary care and community health services in GM (MHCC, 2020). It unites the 14 PCNs across Manchester and thereby represents the GPs in the region. As the board and decision-making body exist out of GPs, GPs' needs are taken in high regard. At the same time, these groups decide what (industry) partners are appointed to solve regional problems, such as rising pressure on GPs.

5.1.3. Healthcare alliances

At the centre of the GM health ecosystem, two alliances closely work together: the Greater Manchester Health and Social Care (GMHSC) partnership and the Health Innovation Manchester (HInM). The function of these alliances is to create a connection between different actors of the (digital) healthcare system in GM such as healthcare professionals, research institutes, and policy organs.

5.1.3.1. Greater Manchester Health and Social Care Partnership

The GMHSC Partnership exists out of local authorities/ city councils, commissioning groups, and NHS (foundation) trusts (Greater Manchester Combined Authority, 2015). In the GM region, two-thirds of deaths are related to external factors such as smoking, diet, alcohol and air pollution. The main pillars are more healthy lives, joined-up health and social care, innovative thinking and strong partnerships. The integration of the NHS departments and city councils, as well as the integration of healthcare and social care is stated to make the system more efficient and streamlined in dealing with the regions' issues concerning healthcare.

5.1.3.2. Health Innovation Manchester

By fusing the Greater Manchester Academic Health Science Network and Manchester Academic Health Science Centre in 2017, the Health Innovation Manchester was set up. The HInM was designated to connect the academic health sciences and the life sciences industry to create a pipeline of health solutions and innovations in the healthcare ecosystem (HInM, 2021). It encourages knowledge sharing between universities/ research institutes, industry, and NHS care institutes, targeted through collaboration with the MFT. The pillars of the HInM are accelerating innovation at pace and scale, data science, pathway analysis and transformation. They conduct traditional trials, real-world studies, and place-based transformation. The data science pillar mainly focuses on data sharing between patients and care institutes using digitalisation.

5.1.4. Regulatory bodies

In regulating digital technologies in the healthcare ecosystem, some bodies set standards for apps and other digital services used in healthcare.

5.1.4.1. National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) is an independent institute with standards for evidence in digital health (NICE, n.d.). Based on the function a digital health platform wants to fulfil in the healthcare ecosystem, NICE informs and advises them on how to gather this evidence. Next to developers, CCGs can also ask NICE for help in commissioning decisions.

5.1.4.2. Medicines & Healthcare products Regulatory Agency

The Medicines & Healthcare products Regulatory Agency (MHRA) regulates medicines and medical devices (NHS, 2021). They set out product categories and what quality assurances these product categories need to adhere to to be approved for medical use. The MHRA also hands out certificates to companies during the process.

5.1.4.3. Organisation for the Review of Health and Care Apps

Specialising in health and care apps, the Organisation for the Review of Health and Care Apps (ORCHA) advises NICE on what standards to set for digital health apps (ORCHA, 2020). They are also licensed to apply the framework that follows this and assess apps on the standards.

5.1.5. Industry players

Many companies are trying to enter the UK or GM health ecosystem, either from outside or from within. The industry players described are not the only companies operating in the GM health ecosystem but are the players that explicitly engage in activities that shape the market.

5.1.5.1. Babylon Health

Babylon Health is a company that focuses on changing the existing model of healthcare and how people engage with healthcare. Babylon's GP at Hand app connects patients and GPs by providing the platform and the GPs (Ahmed, 2016). Healthcare consumers hand over their Electronic Patient Record (EPR) while changing practice. Most practices are set up in London, with Babylon expanding to Birmingham and trying to enter the Manchester health ecosystem. From the beginning, Babylon has been in the news a lot for the disruptive character of its business model.

5.1.5.2. Kry

The Swedish company Kry owns the platform Livi Connect, that provides the platform but does not employ the GPs as it only provides the remote consultation software (Livi, n.d.). Free of charge during COVID-19, GP practices can use the service to call patients for a remote consultation. Already operating in Surrey, the service extended to other locations in the UK and is currently in talks with the MHCC.

5.1.5.3. Accurx

Accurx started with a free-of-use providing platform where practitioners could message each other before providing GPs and patients with a paid platform for video consultation and triage during COVID-19 (Accurx, n.d.). One of its pillars is integration with Electronic Medical Records, which gives the company a large support base.

5.1.5.4. PushDoctor

PushDoctor is a platform that has provided a remote consultation platform since 2014, connecting patients to self-contracted GPs all over Europe (Begum, 2016). The UK-based service set up business in Manchester and received £6.4 m over three years. In January 2022, PushDoctor merged with Square Health, which partly provides private services (Engberg, 2022).

5.1.5.5. Local SMEs

Parts of the GM health ecosystem are focused on facilitating local SMEs to develop their product further by working on their value proposition, gaining evidence, or raising funding (HInM, n.d.). Innovation in GM mainly focuses on these SMEs that originate from local entrepreneurs or as spinoffs of academics or medical professionals. The Research & Innovation Health Accelerator connects universities with HInM and the local council and aims to help lasting connections between these parties and industry through support activities.

5.2. Historical Event Analysis

The purpose of the Historical Event Analysis is to research the events that have led up to the current state of the digital health market to understand the underlying mechanisms in the market formation. In this HEA, the processes are linked to the events. A table of the HEA, including the events, quotes from articles and interviews and the corresponding process, indicator, and effect on the process can be found in **appendix III**. The abbreviations for the processes and effect on the processes used are stated in **table 1** and **table 2** in **section 4**. The timeline in **figure 2** shows the most significant happenings in the digital health platform market in GM that are explained in the narrative below. Some events can be pinpointed to a specific date, while others continued for some time.
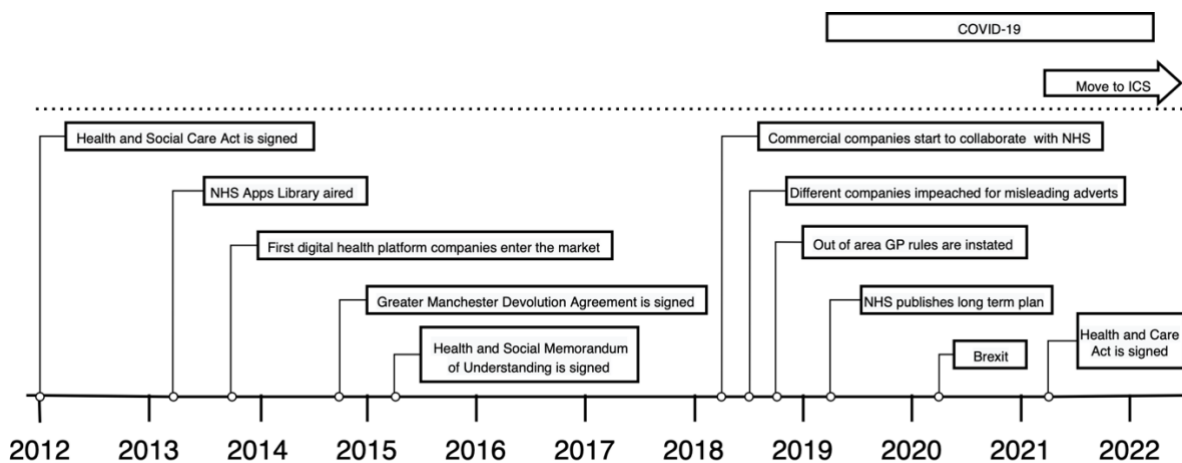
Figure 2: Historical Event Analysis timeline

5.2.1. Health and Social Care Act

The start of the marketisation of the UK healthcare system can be pinpointed in 2012 when the incoming Conservative-Liberal Democrat Coalition introduced the Health and Social Care Act (HaSCA) to reform the primary care-led commissioning (Calovski & Calnan, 2019). New Clinical Commissioning Groups (CCGs) were formed for the different NHS care regions to make decisions over the budget and providers related to primary care. GPs make up the most significant part of these groups, meaning they can make decisions based on their experiences in primary care and implement solutions that fit their wants and needs [*DemandArt FF*]. Another significant reform of the act is that the CCGs can now turn to the market and private companies for procurement and introduce them to the healthcare ecosystem, thereby paving the way for privatisation of the healthcare [*MrktBndry FF*]. As the CCGs search for innovations that are not yet available in the system, digital technologies are well suited to be internalised this way as NHS is only at the beginning of digitalisation. In this model, the funding is provided by the public's tax money that flows into the NHS, and the NHS remains free of charge at the point of care. As the efficiency and costs of the public system have been a subject of conversation for a longer time, healthcare providers jumped in on this and created private healthcare practices that play into these issues.

Whereas first, the public and private healthcare practices were starting to form separate market segments with consumers choosing for a less efficient public system or to pay for their private healthcare, now the act mentions to refute the focus of healthcare commissioners on the integration of health and social care through the formation of partnerships between the NHS, national and local governments, and the industry to move forward together [*BMInno FF*] (NHS, 2012a). By inviting private players to get integrated with the public healthcare market, competition between players (among those also NHS Foundation Trusts) is encouraged; however, to be able to deliver services through the NHS system, the provider needs to adhere to specific standards and be licensed by the NHS [*InstiTrans IF, DomDesign FF*]. In 2017, the MHCC was formed from the North, Central and South CCGs. Interviewee 2 mentioned that even though the formal decision-making process of the

HaSCA has changed, the same people remain to be involved in these decisions. The organization's ambitions have also remained the same throughout this process.

5.2.2. *Greater Manchester Devolution Agreement & Health and Social Care Memorandum of Understanding*

The Greater Manchester Devolution Agreement and Health and Social Care Memorandum of Understanding were signed by the Greater Manchester Combined Authority and NHS England at the end of 2014 and the beginning of 2015 (GMHSC & HInM, 2016). These agreements noted a 'historical deal' as the local government of GM was the first to go through this devolution and receive a £6 billion budget to revolutionise the health and social care in the region. As GM was a largely inhabited area of 2.7 million people, it had a university where healthcare was researched and a network of primary and secondary care providers. GM was thought to be able to make decisions on treating their context-dependent health problems without London's governmental structures. Interviewee 5 mentioned that the North-South divide was a relevant topic and a reason for Manchester to gain a budget to tackle its problems concerning heart disease and cancers related to bad lifestyle choices such as smoking, drinking alcohol and poor diets. The agreements imply a transfer of powers and responsibilities from the central (national) government to local authorities in GM, and state health and social care as a big part of this. Decisions about GM are now to be taken in GM, leaving space for (local) businesses to specify innovations to the context of GM [*MrktBndry FF*]. A key objective was to forge new partnerships between NHS, universities, health and social care institutes, and knowledge industries to promote quick knowledge overflow from research institutes to the industry while working on problems that pressing and accelerate new developments to promote the 'Third Academic Mission' [*InstiTrans FF*]. Following this, in 2016, the Greater Manchester Health and Social Care (GMHSC) Partnership was instated that promotes integrated care on a local level. This partnership includes the NHS CCGs, GM local authorities and GM NHS (foundation) trusts (Greater Manchester Combined Authority, 2015). In 2017, the HInM was formed from two academic health networks to promote the knowledge overflow between academia, care institutes and industry (HInM, 2021).

5.2.3. *Digital health platform industry takes off*

In late 2013, Babylon launched its GP at hand app as one of the first digital health platforms in London in partnership with the NHS as a trial. This app deploys artificial intelligence to answer consumers' healthcare questions and accordingly link them with the proper follow-up steps, such as an online consultation with a GP (Ahmed, 2016). If after the online consultation it turns out that the patient needs to see a GP or specialist offline, they are referred to designated practices. The CCG of Hammersmith & Fulham commissioned Babylon at an early stage after the promising start-up raised $60m (Murgia, 2017). Before the partnership with NHS, consumers paid a monthly subscription fee of £4.99 to be connected to the service, but the service became free of charge for NHS users in designated areas when the partnership was instated [*BMInno FF*]. The NHS compensates Babylon by paying them for every UK-based health consumer signed up to the service, thereby de-enrolling with their 'offline' GP practice. Integrating this online platform with the system, the CCG was hoping to cut costs and improve the efficiency of primary care in UK cities (Winward et al., 2021). Although Babylon brings proof forward for the improvement in quality and efficiency of care, it is argued that this proof is not peer-reviewed and only highlights the positive metrics while leaving the negative behind [*InstiTrans IF*] (Winward et al., 2021). GPs and academics also comment on the business model as cherry-picking as the 'easier' patients might move to Babylon's practice while the 'harder', more complex patients stay with their GPs (Baird, 2019; I2; I3; I10). As NHS funding for both types of patients is the same, this poses the potential threat of limited effect on the workload on GPs and budget improvement [*BMInno IF*].

Babylon is not the only digital platform provider trying to enter the GM healthcare market. As Babylon was a frontrunner in the digital health industry lobbying for market change, Babylon was often mentioned as an example when interviewees were asked about commercial parties that merely want

to generate profit (I2, I3, I7, I8, I10). Other platforms, such as Push Doctor, Accurx and Livi, have slightly different business models and strategies to gain traction [*BMInno FF, InstiTrans FF*]. Most of these platforms set out pilots in designated areas to test their concept and receive consumer input. Livi for example partnered up with GP practices in Surrey to test their service [*NewUse FF*] (Ram, 2018). On this road to establishing themselves in the market, some companies encountered barriers in the regulatory or healthcare system. Babylon and Push Doctor were engaging and investing in marketing activities to grow their business but were reprimanded by the Advertising Standards Authority (ASA) for misleading advertisements [*DemandArt IF*] (Dyer, 2018; Rimmer, 2018). In Push Doctor's case, the advertisements stated that their service was provided by NHS and thus free of use. Only a specific part of their services is commissioned by NHS, and when people would sign up for the private part of the service, they would have to pay a fee of £20 for a consultation. GPs reacted relieved to the decision of the ASA for showing the unvocalized risks of these platforms. For the Babylon adverts, Babylon failed to clarify in their advertisements that healthcare consumers need to deregister from their GP practice to make use of the platform and misled the public by stating that signing up will 'only take them three minutes', while this could take up to a week. Babylon was in the media once again in 2021 when it came out that health secretary Matt Hancock had endorsed Babylon's GP at Hand app multiple times in public in 2018 while the donators of the Conservative overlapped with Babylon's shareholders [*DemandArt IF*] (Lawrence, 2021). This made it seem as though Babylon was receiving special treatment through paid advertisement through a high-placed person, but both Babylon and the health secretary denied the involvement.

Pushed by the concerns of GPs regarding the cherry-picking of commercial parties, in September 2019, out-of-area rules were instated that entailed digital services providers to only have 1000 registered patients that are not in proximity to the associated practice [*InstiTrans IF*] (Downey, 2019a, 2019b). Together with this decision, the decision was made to direct digital providers to set up practice in under-doctored areas, with GM being one of these main areas. At the same time, the Babylon app gained popularity in London because of the new regulation. Babylon and NHS were looking to expand the trial to 9 other locations at the beginning of 2020, including Birmingham and Manchester (CCG Hammersmith & Fulham, 2019). As a reaction to this, at the end of 2019, the MHCC expressed concerns regarding integrating the app into the local primary care system, mainly concerning the safe and efficient data exchange. Accordingly, the Hammersmith & Fulham CCG decided to re-evaluate the trial, allowing for a more gradual change of the primary care system to facilitate a safe data exchange [*MrktBndry IF*] (Downey, 2019c).

5.2.4. Digital health platform quality control

When it comes to assessing digital health apps on their safety, the NHS plays a part in this. In 2013, NHS aired the 'NHS apps library' to gather NHS-approved apps and make them available to the public [*DomDesign FF*] (Meek, 2015). After a study published in 2015 that brought health data collection and storage problems to the light, the NHS apps library was closed, only to return in 2018 with more elaborate clinical standards (Hunt, 2019). Since 2018, the NHS is also advised by the independent organisation National Institute for Health and Care Excellence (NICE) on their evidence standards framework (Nwe et al., 2020). Using this framework, digital health technologies are classified on their desired clinical function based on a set of safety indicators, with apps making up a subsection of digital health technologies [*InstiTrans FF*]. Depending on the classification of the app, the required evidence of its functioning is established. When the app plays a part in the diagnosis, extensive evidence has to be collected before being labelled efficient and save to be included in the library. In 2022, the apps library closed again, leaving it up to commercial parties such as ORCHA to assess digital health apps for NHS trusts (Kleinman, 2021). Interviewed GPs mentioned that even though understanding NHS-approved apps are not bulletproof, the fact that they are approved is sometimes enough for them not to be reliable when recommended (I2, I3).

5.2.5. NHS long-term plan

The NHS came out with a long-term plan in January of 2019, including a section about Digital Primary Care stating that every patient will have access to a digital primary care platform by 2024 (NHS, 2019). The plans are described to be achieved by creating a new framework for digital providers to adhere to NHS standards [*InstiTrans FF*], providing a safe environment for users to operate in [*DomDesign FF*], and reviewing GP regulations to increase participation rates [*InstiTrans FF*]. Following the NHS long-term plan, digital health platform providers such as Livi expressed their trust in the direction of the NHS to include more digital technologies in their practices of healthcare [*InstiTrans FF*] (Crouch, 2019). Because of this long-term plan, NHS followed up with noticing tenders for digital health, including the Digital First, Online Consultation and Video Consultation tender in late 2020 (Crouch, 2021). By noticing this tender, NHS invites companies to apply for the procurement in the digital primary care practices, thus expressing its need for the digital market to form [*MrktBndry FF*]. Also, the NHS app is progressing in 2022 as it focuses on integrating third-party services into the NHS system.

5.2.6. COVID-19
Another event that has accelerated the development of digital primary care while uncovering its shortcomings is the emergence of the COVID-19 pandemic throughout 2020 and 2021. Because physical contact with people other than the household was minimised, healthcare services such as 'seeing' a GP were changed to telecommunication rapidly. Where before, only a small percentage of primary care was carried out through a (video) call or online platform, now this was close to 100% within a matter of weeks (Peek et al., 2020). As the technology was already included in the innovation profile of UK tech companies, one of the main reasons being named for the rapid developments in the healthcare field was the adjustment of regulation in favour of the digital healthcare market [*MrktBndry FF*]. The government now required remote care to be installed where physical interaction was not necessary, thus giving space for companies to enter the market [*InstiTrans FF*]. Concerning data and privacy, the General Data Protection Regulation (GDPR) was adjusted by the UK government because of public interest and (patient) data became available to process by organisations for COVID-19 purposes. In surveys, especially in this state of urgency, the population started to trust clinicians to handle the data, winning over the distrust in pharmaceutical companies [*DemandArt FF*].

The pandemic not only advanced the digital healthcare market but also brought its problems to light. Although the data were now more readily available, the type and format of the data differed strongly between different sources, making it harder to aggregate and turn into a practical platform design [*DomDesign IF*] (Budd et al., 2020). Next to data in different formats, the data availability of minority groups is questioned, with the danger of developed solutions that do not benefit these groups, thereby contributing to health inequalities [*NewUse IF*] (Ibrahim et al., 2021). As public resources could not be mobilised adequately, the private outsourcing of the NHS continued as the knowledge of big tech companies was brought in through procurement to manage the health data [*BMInno FF*] (Wamsley & Chin-Yee, 2021). The HInM' Digital First Primary Care' initiative gathers data in another way, which supports primary care practices in GM by sharing learnings through best practices in a platform blueprint, researching the public's wants and needs, and monitoring activities [*DomDesign FF*] (HInM, 2020).

The pandemic has created momentum that the government has leveraged to enable institutional changes, but the question remains whether the changes that happened during the urgent state of COVID-19 will endure once the crisis has definitively subsided (Peek et al., 2020). Eighteen months into the pandemic, the government launched a Build Back Better plan for healthcare post-COVID, stating it wants to facilitate innovation into the system by integrating better [*MrktBndry FF*] (NHS, 2022c). Also, practitioners that used to be reluctant to introduce digital health platforms into their workflow were forced by COVID to experiment with them and, in some cases, change for the better [*InstiTrans IF*] (I1, I5). Healthcare-related data was aggregated on a national and local level to visualize and act on COVID statistics, simultaneously making these available to companies to enable

them to work on solutions for COVID-driven challenges [*DomDesign FF*] (I6). In GM, the focus was placed on progressing sharing of care records to deliver more efficient care because of the overwhelming demand for healthcare.

There is a doubt on whether the changes are here to stay as priorities shift back away from healthcare and problems concerning digital health have come to light. One of the main reasons for this doubt is that where the NHS, HInM, and GMHSC want to work on reducing health inequalities, the digitalisation of healthcare only seems to be contributing to these inequalities (GMHSC & HInM, 2016; NHS, 2019). Accessibility to and confidence in digital health platforms is linked to different demographics and includes digital literacy and accessibility to the internet or digital technologies technology [*NewUse IF*] (Sounderajah et al., 2021). The groups that deviate are people that are elderly, have lower educational attainment, have a lower social grade, or are part of an ethnic minority.

5.2.7. Brexit

Next to the pandemic, on the 31st of January 2020, the UK left the European Union. Brexit has not only brought change to the way digital health providers can operate in multiple countries, but it also changed the regulation on medical tools. Slowly, regulation is becoming UK based again, with companies operating in the digital healthcare market needing to have their digital platforms approved for medical use at the Medicine and Healthcare products Regulatory Agency (MHRA) since the 1st of January 2021 [*InstiTrans IF*] (UK GOV, 2022). This approval requires gathering UK-based evidence and comes with high costs.

5.2.8. Health and Care Act & move to Integrated Care Systems

At the beginning of 2022, the new Health and Care Act was signed after a call for a revised legislative framework on collaborations and partnerships within NHS (Charles, 2022). In this act, a lot of current challenges of the healthcare system are addressed. However, diving deeper into the proposed interventions, the focus does not seem to be on tackling the most pressing issues at the base, such as growing pressures on healthcare, a shortage in the workforce, and the existing backlog in healthcare needs [NewUse IF] (Alderwick, 2022). Because of this Act, on the 1st of July 2022, the healthcare system of GM statutory moved to an Integrated Care System (ICS). In the ICS, decision-making in FTs does not change drastically, but CCGs will be abolished, with their functions becoming integrated with the ICS, thereby streamlining the procurement process. In April 2021, the UK was divided into 42 ICSs, with the Greater Manchester Health and Social Care Partnership ICS covering GM. One of the pointers of the ICS is the enhancement of place-based partnerships between healthcare and industry, including the local voluntary, community and social enterprise (VCSE) sector [*DomDesign FF*] (Charles, 2022). Giving the VCSE sector a bigger role in digital health could create an understanding of the digital exclusion of groups in healthcare and how to solve this (Stone, 2021). Next to actively including new sectors, the NHS also aims to award longer-term contracts to (industry) partners to roll out innovation [*DomDesign FF*].

6. Barriers
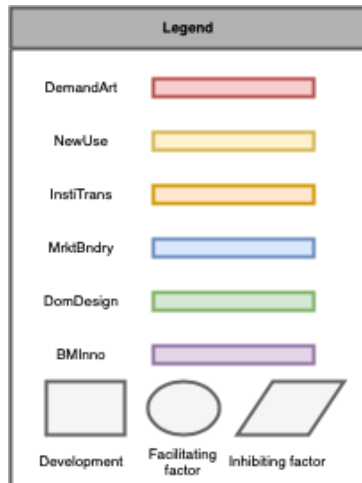
Figure 3: Legend of processes and effects

This section describes how the coding outcomes are aggregated to barriers. The effects on processes are classified as facilitating factors (FF) or inhibiting factors (IF). Often, the inhibiting and facilitating factors are intertwined, or the interviewees expressed what they would see as a focal point of a possible solution. These are taken along in the visualizations. The following six aggregated barriers are deducted from the selected coding step of the interviews; *SME and multinational market entry inhibition by strict and changing regulation, expensive and time-consuming evidence gathering value proposition for gaining legitimacy, Healthcare digitalisation causes health inequalities to worsen, lack of integration into GPs' workflow and IT systems as a barrier of adoption, healthcare digitalisation causes health inequalities to worsen, and data usage by companies is ambiguous to the consumer*. The effect on the process and indicators of the processes can be found in **appendix IV,** and the complete coding tree can be found in **appendix V**.

In the text of the barriers, the related events are pressed in **bold**. The legend used for all visualizations can be found in **figure 3**. The relationships are deducted from connections made by interviewees.

6.1. SME and multinational market entry inhibition by strict and changing regulation
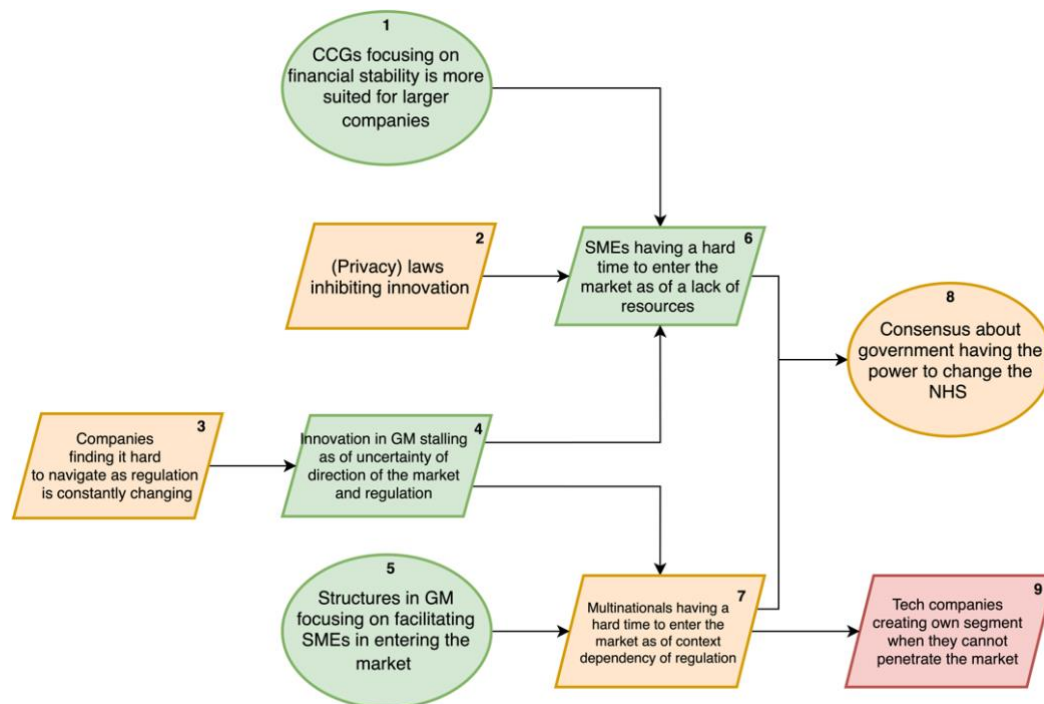
Figure 4: Processes concerning the barrier 'SME and multinational market entry inhibition by strict and changing regulation' and their relationships

As was shown in the HEA, entering digital health companies bring new healthcare solutions to the market that compete to be procured for a partnership with the NHS or GP practices. The first barrier to the market formation of the digital health platform market deducted from the interviews is connected to this entry of companies into the GM health ecosystem, specifically concerning SMEs and multinationals. Various reasons for this barrier to market entry apply to either or both SMEs and multinationals. For SMEs, the data and IP availability within the healthcare sector is a problem [*DomDesign IF 6*]. When requesting data from a health institute, industry players are often let down when they are told that the procedure to access health data could take up to a year (I1, I6). This difficulty in data gathering also links to the more significant problem of needing funding to stay operational and develop healthcare solutions further. In the public healthcare system in the UK, funding is sparse and often comes with many rules SMEs need to adhere to, for example, spending it first and getting reimbursed after or only receiving part of it in advance (I9, I11). As regulation concerning technologies used for medical purposes is strict, especially regarding user privacy and health data storage, navigating the field of digital health can require regulatory knowledge that SMEs do not have readily available (I5, I6, I11) [*InstiTrans IF 2*]. Getting an approved product onto the market can take a while, where little to no income for the company. Working together with a CCG provides companies with a partnership with the NHS and more security of funding and developmental opportunities, but as one of the requirements when getting commissioned is financial stability, SMEs often do not qualify for these partnerships [*DomDesign FF 1*] (I2). A reason brought up for this is that the CCG wants to minimise the risk of commissioning a party that might file for bankruptcy and cannot carry on with their healthcare services when embedded in the system. One interviewee said about the current commissioning system (I2):

"So that the finance team look at, you know, the financial stability. So they look at what information is available to have an understanding of the risk of contracting with the provider. So someone without a track record, without business history, without existing contracts, all these things, you know? … And, you know, to get the sort of accreditation and everything that's needed in terms of getting that level of approval, it just lends itself more to large companies than start-ups. "

When SMEs cannot enter the market and providers stay sparse, co-design and competition are not promoted, so a dominant design stays out as companies aren't pushed to meet the needs of the system and eventually outcompete others with their design. While commissioning is set up more for larger companies rather than SMEs, a problem that both SMEs and multinationals face is the uncertainty of where the market is heading and what boundaries exist to it [*DomDesign IF **4***] (I8). If the boundaries are unclear, companies cannot innovate according to needs and guidelines, leading to no convergence to a design. This is caused by a constant change of policy and regulation in the medical field [*InstiTrans IF **3***] (I1, I6, I9). Currently, the healthcare system in GM is making a change to an **ICS** to deliver better and integrated care within the region, and interviewees asked about it admitted not knowing what it exactly will entail and what it will change for companies trying to position themselves in the market (I1, I2, I8, I9, I10, I11). This uncertainty leaves healthcare institutes and procurement organs undirected and in doubt on how to implement healthcare solutions from companies, staying at a stand-still of innovation. An interviewee explained this using CCGs as an example (I11):

"I've got a lot of companies I work with that have really good health apps, and if I take them to local CCGs and say: "Are you interested in piloting or commissioning this?" The response will be: "Maybe, but at the moment we can't do anything because we don't know what's happening with the ICS." So, it's stalling innovation, which obviously means that patients aren't getting the benefit of them. A lot of CCGs are just sort of like hanging tops now and saying: "We don't want to commit to piloting any single using anything or commissioned anything new because we don't know what's going to change next." So, we'll just hang on, see what happens when the explosion, and then we'll make some decisions."

For nationwide and multinational companies, often developing their products from a technology-push rather than a problem-pull perspective, there are other problems than SMEs while entering the digital health market. Often, these companies already operate in the tech industry or are trying to move into the UK/ GM health ecosystem from another country or region. However, the solid local context-dependency in regulation while designing healthcare solutions is often an inhibiting factor as there is no 'one size fits all' in healthcare, and every CCG has other specifications they are looking for [*InstiTrans IF **7***]. In GM, the focus is on facilitating patients' needs while reducing health professionals' workload, and solutions should aim to contribute to solving those to have a chance of survival (I5, I11). **As of the devolution of GM 2015**, GM can make its own choices regarding health and social care and whether to support technology for its primary care system financially or in other ways. An interviewee at HInM mentioned that it only supports companies based in Manchester and embedded in the ecosystem when entering the local market(I6) [*DomDesign FF **5***]. When tech companies are scared off by the regulation that comes with public health, they sometimes resort to creating their segment (f.e. non-medical health trackers) in which they can still use their tech expertise but do not need to comply with the medical device regulation [*DemandArt IF **9***] (I5). Interviewee 5 mentioned:

"And so, they start to find out how hard it is to get into the NHS, and they find out how difficult it is to find a champion and often they then think: "Oh actually, well, we need to actually bring that champion in to the company and offer them a directorship in order to get them to really engage with us." But then they quite often then revert back to and say: "Okay, well, if we can't get this registered as, say, medical device, then we'll just offer it to the consumer as a way to when you're running and doing your fitness to just check on your heartbeat or check on your pulse, you know."

When asking the interviewees which actor has the legitimacy to change the current institutions embedded in the healthcare system, the answer is unilateral: the government [*InstiTrans FF **8***] (I1, I3, I5, I6, I7, I9, I11). When asked what the hampering factors are in changing, they mention the political cycle that changes NHS every five years, destabilising the system and making the regulation

less clear for companies to navigate (I3). A transparent, understandable policy that includes a long-term vision of changing the NHS could give companies and commissioning bodies the opportunity to see beyond pilots and short-term connections.

6.2. Expensive and time-consuming evidence gathering value proposition for gaining legitimacy
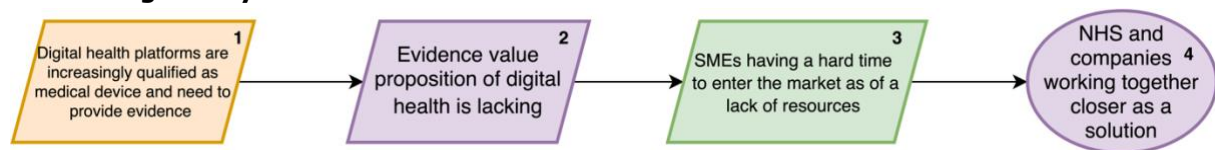

Figure 5: Processes concerning the barrier 'Expensive and time-consuming evidence gathering value proposition for gaining legitimacy' and their relationships

The second barrier builds on SMEs entering the market but focuses on the process of providing evidence for a value proposition. In the market formation of the digital health platform market, having a strong value proposition provides a digital solution with legitimacy to operate in the market and form it accordingly. **Brexit** imposed new regulations on (digital) tools used for healthcare because the UK was no longer dependent on EU regulations. Increasingly, tools using software are also marked as a 'medical device' and need to comply with regulations regarding providing evidence of the efficiency and safety of the product and privacy legislation [*InstiTrans IF 1*] (I3, I5, I11). When a device is produced for a clinical setting, and there is a risk that the malfunctioning of the digital health platform declines the quality of healthcare outcomes, the device needs to be tested in a clinical setting to the **framework of NICE**. In providing this evidence, NHS trusts and CCGs will often not accept evidence of the device tested in anything other than a UK setting. This poses an inhibiting factor as evidence is often cheaper and easier to gain in an international setting (I11). This regulation makes it expensive and time-consuming for SMEs to bring their product to the market [*DomDesign IF 3*]. In this non-medical device market, consumers become confused as they do not know which app to trust or what their data is used for, while for companies this market is more competitive, and margins on consumer goods are generally lower. An interviewee working with SMEs said (I11):

"What we're seeing a shift towards because of Brexit is that any digital software remotely pertaining to health care will be classed as a digital medical device. And that might not sound like such a change, but it is for small companies because it's very expensive to get your device tested and classified as a medical device. And if it is a medical device is a lot more regulations that you have to jump through."

Often there is ambiguity on whether the value proposition the entering company proposes can fill the needs of the healthcare system [*BMInno IF 2*]. Not only does the value proposition need to comply with GP and patient needs, but also the system needs to improve its efficiency while staying low on costs. There is an oversupply of platform suppliers in the healthcare market, so NHS FTs and CCGs have options on what platforms to engage with (I9). Interviewees in these bodies mention that they are sometimes contacted by companies with the same (poor) business case week after week (I6). Interviewee 6 spoke about how this repetition can lead to reluctance in collaboration with hospitals:

"I do find it harder to get people to talk to companies with apps that haven't already engaged with the NHS because you're like, Oh no, another app. I've spoken to five companies that have got an app that says they can do that. None of them are very good, especially if they're linked in with MedTech and wearable devices and things like that. So, I think a lot of the wearable devices that have come on the market haven't been appropriately evaluated it in terms of how well they compare to, you know, what you would get in the hospital."

Most of the data available evidence is supplied by companies or implicit. A healthcare consumer mentioned in an interview that it could take weeks to see a GP online, but that through online options, the GP is often available quicker (I4). During **COVID-19**, there was also proof of evidence gathered while doing the vaccination program [*BMInno FF 4*]. People were sent a link through which they could make an appointment, which is not yet possible for all GP practices now, where one needs to

phone at a specific time of day to make an appointment. It was mentioned often that the technology is there to roll out digital practices on a larger scale, but the evidence gathering and carrying out value propositions still poses a problem. To develop this evidence on value propositions, interviewees propose closer and longer-term partnerships between NHS and industry (I11).

6.3. Companies turning to private healthcare market because of NHS structures
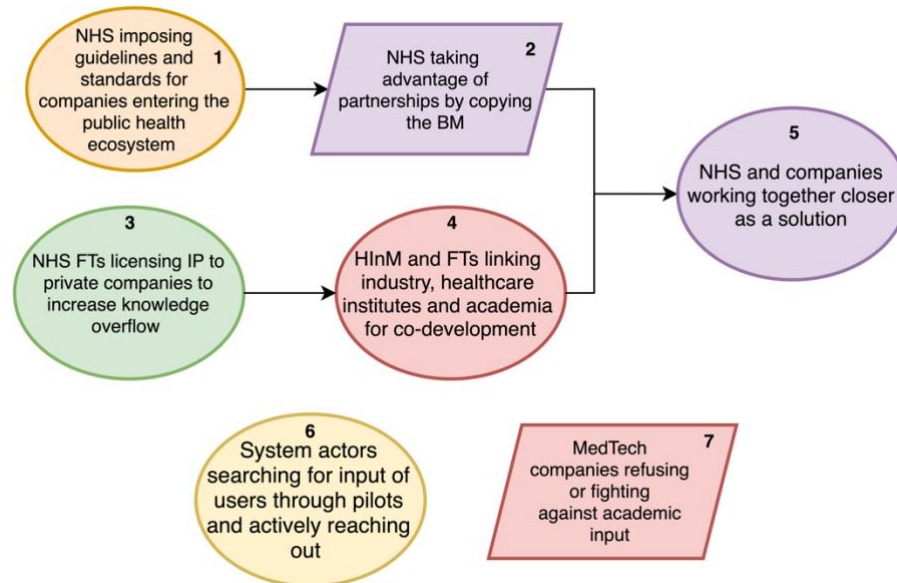

Figure 6: Processes concerning the barrier 'Companies turning to private healthcare market because of NHS structures' and their relationships

As in the healthcare market, traditional healthcare models are still dominant in rolling out healthcare solutions, having traditional actors collaborating with digital health specific actors could stimulate the market to form. Often, these collaborations are formed as partnerships, where the parties work together towards fulfilling the need. The NHS is always present in conversations about the healthcare system in GM, although interviewees' perspective on it differs. As the NHS regulation concerning industry partnerships imposed by the government is both stimulating and de-stimulating for companies to enter the market, finding new BMs in collaboration to provide services to healthcare and form the digital health platform market is essential to market formation. As the NHS imposes standards on commissioning companies, it allows companies to pilot and develop their medical devices [*InstiTrans FF 1*] (I2, I3, I9, I11). Interviewees agree that NHS has the agency to be a gateway for companies to the healthcare market. However, some interviewees also mention that in the process of deciding whether to 'buy or build', NHS sometimes picks an in-between version and cherry picks from companies' solutions to later build and incorporate it themselves [*BMInno IF 2*] (I9):

> *"So, I'll give an example of what we've seen. If a digital health company today adopts a solution that an NHS organisation was actually looking for, for example a management system that was innovative, the NHS may engage with that supplier, understand how the system works and build it themselves. But they would use the pilot and that time, you know, 12-18 months working with an SME in digital health care and understand what they were doing and then use that knowledge to build an NHS system."*

The effort of NHS for the knowledge overflow is increasing by appointing regional **Academic Health Science Networks such as Health Innovation Manchester**, connecting healthcare (needs), academics and industry to search for solutions to healthcare problems. When industry players are profiling themselves to the investment market, they often need an academic and practitioner on board to gain credibility and attract investment (I1, I5, I11). Academics and practitioners are only on board when they believe in the concept and provide input for the solution, enabling co-development of the user and producer [*DemandArt FF 4*]. The FT also actively seeks to connect SMEs to practitioners and academics, and one of their ways to do so is licensing hospital/healthcare professional-owned IP to companies [*DomDesign FF 3*] (I6). SMEs are often perceptive of this as their business idea is still mouldable. However, when academia tries to give input to incumbents on user preferences and developments, companies are not always interested in taking this along in their

process and shut it down (I10). In some cases, they actively go after academics that are critical of their way of working while not letting articles on their effectiveness be peer-reviewed by the scientific community [*DemandArt IF **7***]. Interviewee 10:

"Why are people sceptical about Babylon? Because people have seen the claims they're making and they know that it's not particularly robust. And on top of that, also, as far as I can see, I don't know for sure, but their behaviour is not always really ethical and at some stage they tried to go after academics who are critical and that's not acceptable in the legal department as I could see."

While looking for solutions, local NHS organisations use pilots to test out digital health platforms. This way, the concept is tested out, and input from the users is gathered for further development [*NewUse FF **6***]. Some interviewees mentioned that engaging in pilots has evolved into pilotitis: doing pilot after pilot without committing to one business concept (I9). **The decentralised way of working of NHS** enables districts to make their own decision, but it also results in having a geographically scattered approach to integrating digital tools. A solution for this pilotitis is to engage with companies for a more extended period to ensure the development [*BMInno FF **5***] (I9).

6.4. Lack of integration into GPs' workflow and IT systems as a barrier of adoption
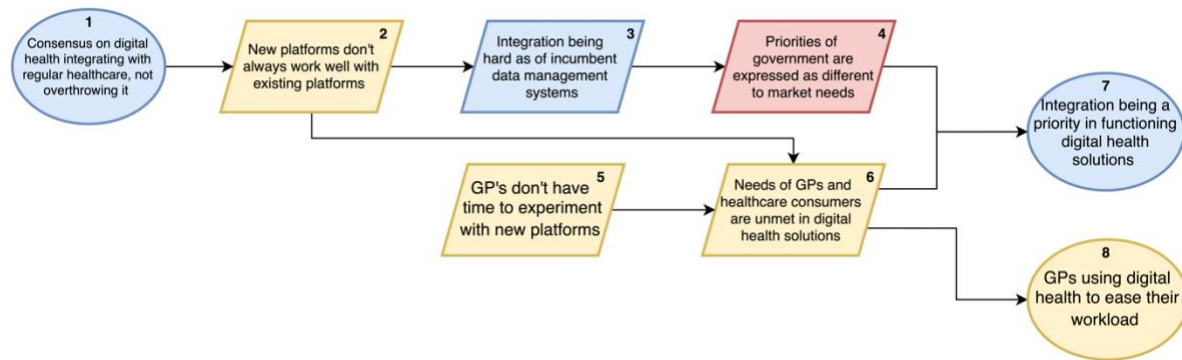

Figure 7: Processes concerning the barrier 'Lack of integration into GPs' workflow and IT systems as a barrier of adoption' and their relationships

The integration of the digital health platform into the workflow of GPs is a factor that is critical for the adoption of digital health into the system. As interviewees agree that the place for digital health is in public healthcare, this integration is essential for the formation of the market, but this is not always put in the first place. The lack of integration into current digital systems and GPs' workflows has formed a barrier because healthcare problems are not always well-defined. While the NHS suggests that digital health can be a solution to the problems it is facing concerning rising costs, efficiency and workload, interviewees mention that often solutions are developed to an ill-defined problem. There are many aspects to the efficiency of a system and proposed solutions sometimes focus on aspects that are merely a consequence of the problem instead of at the base of it. Interviewees agreed on expecting the digital health market to grow in the following years and that digital health will integrate with the regular healthcare market. [*MrktBndry FF 1*] (I1, I5, I11). They mention that digital solutions can work well for the relatively healthy population or 'easy' diagnosis, but that the boundaries of the market should be clear as the traditional healthcare model of seeing a GP will keep existing for those more in need of complex care. As a reason for digital health not overthrowing 'offline' healthcare, some interviewees mentioned the human aspect of healthcare, as lonely people and gut feelings in diagnostics are not tackled in digital health (I3, I5, I11). Interviewee 3 said:

> *"You know, being a GP, there's a lot of subtleties and there's a lot of uncertainty and sometimes we can't really put into words why we're worried about somebody. And often it's sort of the gut feeling which must come from some sort of idea that we've been given that can make the difference between realising that someone's got something quite serious going on and realising that someone you know is okay or they're just overly anxious about something."*

The pressure on GPs is increasing, and **numerous companies are starting to offer solutions** to this. Often companies forget to address in their solutions what the real problem of GPs is: a lack of time [*NewUse IF 6*] (I2, I3). The interviewees mentioned that the needs that come with it are not communicated to companies operating in the market [*DemandArt IF 4*]. Even in solutions with the goal and proof of concept to decrease the GP's workload, the GP often does not have time to scan for them or experiment with them and incorporate them into their workflow [*NewUse IF 5*] (I6). A GP included in the interviews mentioned (I2):

> *"It's just I think been very busy. And so, I used to have more time to go to national events, to user group conferences and things like that. In the last two years or three years the opportunity to horizon scan has been taken away by managing, you know, overwhelming demand."*

Another GP said (I3):

"We did briefly use Doctor Link at the beginning of COVID, and the idea was that we were told quite early on that we had to move to total triage. So rather than a patient come in to the reception and booking an appointment, waiting in the waiting room we moved immediately to, we shut the front doors if anybody wanted to be seen. They either had to go on to Doctor Link or take a telephone call back from the GP. The problem of Doctor Link, an electronic triage system, was that it was very poor at filtering out any of the patient requests. It pretty much told everybody that they had to see a GP. So we stopped using it very, very quickly because it didn't really benefit us any more than just calling the patient immediately ourselves. I can see where the use is for triage. I think one of the problems with opening was it wasn't integrated into the Electronic Record System, so it was done over email. So you've got this strange scenario where people filled in a doctor link questionnaire, they got emailed to the practice, one of the receptionist printed out the email, and then we had to look at the email and then call the patient back"

In interviewing different GPs and people working with GPs, it becomes clear that the different practices adopt digital transformation differently. While in one practice, the appointments are primarily online, in another, the GP mentioned wanting to see the patient in person as of the ability to measure the blood pressure and heart rate and develop a gut feeling about whether and how to treat the patient. This difference is also brought about by **COVID-19**, where the change to digital was rapidly pushed, and GPs were forced to experiment with digital tools (I1, I5). This changed the reluctance of GPs to change or strengthen their institutions of preferring to see a patient offline.

Next to not having time to incorporate new solutions into a GP's workflow, sometimes the platform cannot integrate with existing digital means in the GP's workflow, such as EPR or triage systems [*NewUse IF **2***]. Electronic Patient Records (EPRs) are held by three companies (TPP, Vision and EMIS) that are reluctant about facilitating companies coming into and bridging their software and data gateways as it might pose a threat to their position in the market [*MrktBndry IF **3***] (I6, I8, I9). Talking to the companies involved in supporting the industry to enter the market, they all conclude that integration of digital health into the current healthcare market is a priority to benefit both user groups, for healthcare consumers to receive more effective care and for GPs to lower their work pressure [*MrktBndry FF **7***] (I2, I5, I8, I9).

When asking for examples or opinions on digital health providers and the possibility of integrating these into the healthcare system, Babylon was often named for its provocative approach to shaking up the healthcare system. Instead of integrating into regular healthcare, interviewees mention that Babylon's strategy was rewarded with a partnership with the CCG in London, but that it created resistance in other NHS regions such as Manchester (I7). With their BM being transactional (either you pay, or NHS pays), they found a way to **cherry-pick the younger, more healthy healthcare consumers,** while GPs were left with the more demanding patients (I5, I8). As a GP practice and Babylon receive the same amount of money from NHS for having high and low demanding patients signed up for their practice, the commercial interest of Babylon stands out to interviewees (I1, I2, I8, I10). This was brought up in multiple interviews, with interviewee 10 saying the following:

"Well, Babylon is getting easier patients and I simply do not believe that their platform is usable by frail, elderly, lots of conditions, those who don't speak English very well or have not been trained very well in English. So I think that's why you still need the GP, but that's the model currently that they are using all that same amount of money to get these new patients."

Most of the interviewees do conclude that digital can be used to ease GPs' workload and that GPs are willing to experiment with it when it is offered to them in a format that they can embed in their workflow [*NewUse FF **8***]. Although actors call for a centralised approach when assessing the safety and performance of apps, they also mention that GPs should always be able to make their own decisions on using or not using a digital platform (I1, I2, I3).

6.5. Data usage is ambiguous to the consumer

Figure 8: Processes concerning the barrier 'Data usage is ambiguous to the consumer' and their relationships

For companies to be able to develop their product and attract users, trust in their data management is important. This trust does not only apply to a specific company operating in the digital health market but is also needed to gain as a market. Digital health is inextricably linked to data management, and companies such as Babylon make their users hand over their patient records when starting to engage with the platform. Users often do not understand the implications of sharing their data with commercial companies [*DemandArt FF 2*] (I3, I4, I7, I10). When the commercial company holds this data, these companies, on their part, can engage with third parties and sell 'anonymised' data packages when the user has given permission. The anonymous aspect of the data is not always well regarded, making third parties able to trace back the data to a person. However problematic, interviewees mention that the most significant part of health consumers do not seem to worry too much about it, while a small group is very vocal (I3, I7, I8, I10). An interviewee said the following about societies' concerns about data sharing with commercial companies (I7):

"And I think the bottom line is that while certainly 95% of people, if not more, just couldn't care less, it's just not a thing for them. Um, so in the end you're talking about 5% of people so who have a concern, you know, about what happens to that in general. And then as part of that, they would also be concerned about what happens to their health data. And then from the 5%, you know, does that again, a minority 1% or probably even less than that who are very concerned and very, very, very vocal. So, what happens with we have a candled data and what has happened also in some of these um more recent events, scandals that you mentioned is that, you know, the 1% that is extremely vocal. Make sure that this reaches the news and that, you know, there's that there's a lot of uproar about it."

Data breaches have occurred on platforms such as Babylon and Push Doctor, and the media and vocal groups of healthcare consumers have brought risks to the public [*DemandArt IF 1*] (I2). Interviewees mention that healthcare consumers might ask questions about their data for some time, but the public's concern dies down quickly. The media cannot only bring trust breaches to the people, but companies also use the media and marketing strategies to find the legitimacy of their product through marketing their solutions [*DemandArt FF 3*] (I2, I3). About the solution to gain trust in companies, interviewee 8 suggested that transparency in data usage by companies or organisations is important (I8):

"So I think we have got the basis of trust from the patients and the public with the NHS brand. We need to be absolutely focused on making sure that we maintain that trust with transparency and ensuring, you know, security and control over that data. Because the moment we lose that trust, we lose that. And I think the biggest challenge for me really is dealing with the complexity of the information governance to enable data controllers to be able to share and release some of that data."

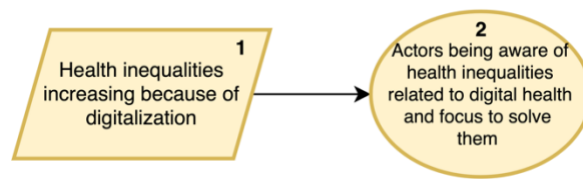### 6.6. Healthcare digitalisation causes health inequalities to worsen

Figure 9: Processes concerning the barrier 'Healthcare digitalisation causes health inequalities to worsen' and their relationships

Access to digital health platforms is essential in creating new user practices. When healthcare consumers do not have access to a GP because of language discrepancy or lack of access to a phone to call for an appointment, these problems are not easily solved by including digital health solutions in the healthcare system. For health inequalities such as immobile people, people that are not sufficient in English, or digital illiterate people, engaging with digital health platforms is not an effective solution to create access to healthcare. Although the NHS named digital health as a tool to lower health inequalities, interviewees still doubted if digital health could function as such. On the one hand, the argument is brought to the table that digital health brings flexibility to the health consumer by not needing to be close to a GP [*NewUse FF 2*] (I9). However, it is also mentioned that the problem concerning health inequalities is focused on specific individuals or groups that currently cannot access healthcare in general, let alone digital health. The minorities that do not have access to healthcare are **typically unrepresented in data** and are not explicitly taken along in pilots and the developmental process of apps [*NewUse IF 1*] (I1). Healthcare professionals often advise healthcare consumers to use a certain app or use a remote consultation app themselves, and if healthcare consumers cannot find their way to a GP, the connection with the app will also not be established (I2, I3)*.* Also, interviewees argue that digital health can increase health inequalities due to the need for digital literacy and access to the internet and energy (I1). Increasingly, this is not the case in the UK, as interviewee 1 mentioned:

"But, you know, with fuel poverty and the energy crisis and I saw that tens of thousands of people have disconnected their homes from electricity. They have self-disconnected because they can't pay for it. And not just that they can't afford the data on their smartphone, nor do they have an internet connection, they can't even power the thing at the moment. How would that person contact the GP? We've now made it impossible to walk in the door and arrange an appointment."

When health inequalities are not tackled with the solution of digital health, the legitimacy for the formation of the market will also decline, therefore stalling it. Focussing on the wrong leverage points of the system might lead to formatting a market and proposing solutions to problems that do not exist or are arbitrary to others. In the direction toward a digital-first primary care system, digital health is proposed as a solution to the declining efficiency of the healthcare system, with access to healthcare becoming a bigger problem. Interviewees mentioned that a decision needs to be made on who benefits from digital health solutions and how these solutions work in the bigger picture of healthcare (I1, I8, I11).

7. Policy trade-offs

With the healthcare system in the middle of changing towards the ICS, national and local policymakers are making choices to implement this healthcare system in the local context and get it up and running. There are some concerns of the public and local healthcare actors concerning this change, as it may require extra workforce, while a shortage in this is part of the problem (Charles, 2022). As GM was already working towards integrated care and proving to be successful, these changes might not affect them as hard as other regions in the UK. Especially in gradual changes, the focus should be on tackling the existing barriers, despite the advanced integrated care approach. In this section, first, the barriers are linked to relevant trade-offs in market formation derived from the framework of Flanagan et al. (2022). Next, the trade-offs are elaborated on in the light of the government, as the government is often the prime mover when it comes to policy, especially when it comes to public services such as NHS.

7.1. Trade-offs in market formation

The framework of Flanagan et al. (2022) is used to connect the barriers found in **section 6** to trade-offs, shown in **table 3**. The trade-offs focus on 1) problem framing and legitimacy creation, 2) agency and network building, and 3) institutional change in the digital health market formation in GM. They bring attention to the problems the digital market is facing instead of overthrowing the current policy instruments in use. The connection between the barrier and policy trade-off is made by connecting the barrier with one or more of the three trade-off categories and the corresponding trade-off(s).

Table 3: Market formation barriers and regional industrial policy trade-offs

Barrier	Trade-off	
SME and multinational market entry inhibition by strict and changing regulation	Tighter, more closed network (e.g. few potential users or suppliers)	More open network (e.g. many potential users or suppliers)
	Geographically localised network	Geographically dispersed network
Expensive and time-consuming evidence gathering value proposition for gaining legitimacy	Narrower valuation metrics (customization)	Broader valuation metrics (standardisation)
Companies turning to private healthcare market because of NHS structures	Homogenous network with low cognitive and value diversity	Cognitive- and value-diverse network
Lack of integration into GPs' workflow and IT systems as a barrier of adoption	Institutional customisation – adapting institutions to the problem (applicability)	Institutional promotion/diffusion/ adoption –adapting the problem to existing institutions (predictability)
	Narrow problem framing (legitimisation through specificity)	Broader problem framing (legitimisation through extension or bridging existing frames)
Healthcare digitalisation causes health inequalities to worsen	Narrow problem framing (legitimisation through specificity)	Broader problem framing (legitimisation through extension or bridging existing frames)
	Problem specific to one place	Problem discourse potentially applicable to many places
Data usage by companies is ambiguous to the consumer	Transparency in communication	Information asymmetries

7.2. Government trade-offs

As the government makes decisions about the structure of the NHS, the trade-offs are framed as policy intervention trade-offs to be considered by the government or governmental organisations in the light of changing to the ICS.

7.2.1. SME and multinational market entry inhibition by strict and changing regulation

With the market entry of SMEs and multinationals forming a barrier to the market formation of the digital health market, the changing healthcare system brings about possibilities to revise the standards and regulations. To address the difficulties concerning market entry, the government needs to balance the advantages and disadvantages of different market concentrations. A tighter network could stimulate long-term partnerships and give suppliers more users and thus more perspective on their operations, while a more open network could diversify the different solutions, which could serve users as they can find a solution fitted to their needs (Flanagan et al., 2022). Through regulation on procurement and partnerships, the government can express this desire by either focussing on engaging in long-term partnerships with the same solution inclusive partner or making the process more open and commissioning different companies with more specific solutions.

Local SMEs and multinational parties serve different needs in the healthcare market and are thus handled differently in NHS procurement and partnerships. Local SMEs often have more knowledge of local problems and how to solve them, while multinationals can provide overarching solutions. While focussing on local actors could lead to regional knowledge development through investing in knowledge generation and skills, focusing on actors outside the region could attract and internalise knowledge through collaboration (Flanagan et al., 2022).

7.2.2. Expensive and time-consuming evidence gathering value proposition for gaining legitimacy

Regarding SMEs lacking resources to provide evidence for their value proposition, the trade-off of the government to make is to either provide SMEs with clear and strict, narrow standards or broader standards to navigate putting their solution up for procurement (Flanagan et al., 2022). Both options have advantages. For a broader valuation process, this gives the SME more space to innovate itself in a direction they deem desirable. For a narrow valuation process, the SME is given a clear direction to innovate and as SMEs are more flexible in their innovation process and adapt easier to context-specific circumstances, which works to their advantage. Disadvantages could be that applicability concerning the implementation of the solution containing many novelties might be low, and there are still many resources needed to innovate in the desired direction. This last disadvantage could guide SMEs to team up with other (local) actors when looking for resources, which is wished for in integrated care.

7.2.3. Companies turning to private healthcare market because of NHS structures

With NHS stimulating collaboratives and partnerships more in ICS, the question arises on how these can be made attractive for companies to engage in and how will these networks assemble. Based on proximity in cognition and value diversity, networks can be heterogeneous or homogeneous. Heterogeneous networks are typically more extensive and take more time to gain trust among actors but could bridge societal issues by bringing together previously unconnected actors. Homogenous networks create trust between the actors in these networks but are also subject to becoming closed and sometimes even corrupt. The public is expressing concerns about the privatisation of the NHS and healthcare getting under the control of a couple of powerful private companies, which could be remedied by keeping the digital health market network diverse and open (Charles, 2022).

7.2.4. Lack of integration into GPs' workflow and IT systems as a barrier of adoption

In the implementation of digital health, the discussion of whether a technology-push of companies or demand-pull of GPs should be at the base of innovation is well visible. Deeper rooted in this discussion is whether institutions should be applied from widely formed norms or tailored around the GP needs (Flanagan et al., 2022). Where broadly set standards can create stability and guide innovation in the desired direction, tailored institutions can stimulate experimentation in the local setting and give the GP the possibility to define the use of the digital health systems him/ herself.

The framing of the problem is essential when trying to find a solution to it (Flanagan et al., 2022). The more specific a problem is framed, generally, the more specific the solution will be suggested. A narrow problem frame has advantages, as the chances of GPs finding a solution that fits their needs and integrates into their workflow are bigger, but also disadvantages concerning creating momentum for it. On the other hand, a broader frame can create more legitimacy in the search for a solution but does perhaps not touch upon the real problem at stake.

7.2.5. Healthcare digitalisation causes health inequalities to worsen

In the framing of the health inequalities, considerations should be made on whether to regard health inequalities as an umbrella term or whether these should be more investigated. Health inequalities of different groups might have different causes. While for some groups, mobility might pose a problem, for others, it is access to healthcare in general because of a language discrepancy or digital literacy. Considering these groups as separate could create an understanding of the nature of the problem but could also make it more difficult to propose a solution.

The trade-off of viewing the issue as place-specific or present in the broader healthcare ecosystem is also applicable to the worsening of health inequalities (Flanagan et al., 2022). Framing the problem as place-specific possibly attracts more local actors to get involved in tackling the issues and would more likely result in a better regional fit of the solution. Framing on a broader or national level, however, might trigger larger companies with more resources to find a solution. Given the fact that health inequalities can differ per region, this would inevitably mean that solutions might be less fit to tackle regional challenges.

7.2.6. Data usage by companies is ambiguous to the consumer

With health data storage and usage by companies with a commercial interest being a subject of discussion, there is a trade-off to be made by the government on how transparent they are concerning data sharing. While ambiguity on data usage can trigger a public debate on the one hand, on the other, so can be open about it (Flanagan et al., 2022). As came forward in the interviews, a small part of healthcare consumers is expressing their concern very vocally, while the largest part either does not realise or care about the risks of sharing their data. More transparency on where the public's data is stored and used, why the ICS made this decision, and the company's place in the system might lead to a broader understanding of fewer concerns.

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8. Conclusion

In this report, the research question "What are the barriers to the digital health market formation in the UK, and how can these be addressed using policy trade-offs?" was researched using a theoretical framework on market formation, literature review, HEA, and actor interviews. The market formation framework of Boon et al. (2022) was operationalised into digital health-specific indicators that served to recognize inhibiting and facilitating effects of events on the development of the process in the HEA This HEA then served as input to the interview guide, which was used to deduct interviews with system actors in the Greater Manchester digital health landscape. Barriers were consequently derived from interview coding aggregates and policy interventions were linked to these using the framework on policy trade-offs by Flanagan et al. (2022).

Six barriers were derived from an assembly of facilitating factors and inhibiting factors of different market formation processes found in the interview analysis. In the barrier '**SME and multinational market entry inhibition by strict and changing regulation,**' the difficulty of companies to reach the market and navigate its whims is expressed. As companies entering the market is essential for the convergence to a dominant design by competition or co-design, limited availability of companies (and thereby solutions) stalls market formation. The barrier '**Expensive and time-consuming evidence gathering value proposition for gaining legitimacy'** also touches upon market entry limitations but is caused by the substantial evidence companies need to gather to be able to be commissioned by NHS. To gain legitimacy in the traditional healthcare sector as a new market entrant, extensive proof of validity and credibility needs to be gathered. This especially forms a barrier to companies with fewer resources, as it is expensive and time-consuming. The barrier '**Companies turning to private healthcare market because of NHS structures**' explains the crucial part NHS plays as the gateway for companies into the UK market through their commissioning process. Because of the strict company requirements on financial stability and short-term partnerships, a public partnership with NHS often affects company growth negatively. The distrust in NHS structures that this creates discourages market entry, which further stalls market formation.

The '**Lack of integration into GPs' workflow and IT systems as a barrier of adoption**' barrier indicates a mismatch between the way the needs of the healthcare system are voiced and the problems that primary care professionals experience at the GP level. When GPs cannot or do not want to use a digital health solution due to this mismatch, the demand for the solution declines, thereby negatively affecting the need for the market to form. The barrier '**Healthcare digitalisation causes health inequalities to worsen**' involves a discrepancy between the intended and created change of the healthcare system resulting from digital health innovation. This discrepancy raises questions from the public on its purpose and thereby decreases societal support. The barrier '**Data usage by companies is ambiguous to the consumer**' explains a distrust from the consumer of the producer and calls for more transparency in the way health data is stored and processed. This distrust, especially when voiced, can lead to a lower adoption rate by the consumer, and thus a stalled market formation.

The policy trade-offs focus on three areas. The first trade-off area identified a discrepancy between the vocalized framing and societally conceived framing of the need for the digital health market. More specifically, framing the need (to tackle health inequalities and decrease the workload of GPs) in a regional or national and broad or narrow context affects the involvement of GPs in the adoption of digital solutions and companies in developing solutions. Moreover, problem framing affects to what extent the company-developed solution will fit the market. To solve the discrepancy between the actual problem and how its vocalized, the government should consider different components of this policy trade-off. First, a narrow framing could more clearly focus solutions on healthcare consumers' needs, while a broad framing could stimulate legitimization of the market and attract more companies to solve the problem. Second, framing the problem as specific to one geographical site or as applicable to many cases should be considered. This directly affects where the capacity of solving it

is built. Health inequalities exist all over the UK, creating a nationwide market formation need, but when these are framed context-specific, solutions that fit regional dynamics are improved.

Second, a trade-off exists for network formation and agency, which also involves several components. This for one includes facilitating homogenous or more diverse network formation. As companies are now turning to the private healthcare market when they cannot get a partnership with NHS easily, the government needs to envision what parties it wants the network to include, and act on this to realize its vision. The government could for example decide to stimulate the creation of a homogenous network by specifying procurement standards for a specific actor or group (e.g. SMEs or multinationals). Also, the trade-off between creating open or closed networks affects market entry. Long-term partnerships with NHS could be used to facilitate the formation of a smaller and more specific network, while a more open network could attract more parties into the digital healthcare system. In addition, the geographical localization of digital health networks is a trade-off between the increased activity of local actors versus the increased availability of larger actors in case of a dispersed geographical focus. Last, a trade-off in high versus low transparency in the communication of the procurement process determines the information available to digital health companies on what they need to adhere to. Higher transparency leads to clearer standards that companies can play into and thus a more specified approach to tackling safety issues in their solutions.

Third, a trade-off in the interplay between the digital health market and institutions focuses on institutional change. The application of broad versus narrow institutional standards to the market affects GPs' ability to tailor digital health products and guidelines to their practice and preference. This is of importance for stimulating GPs to integrate digitalisation in their workstream. It also hampers the generalizability of standards and therefore affects implementation flexibility, which would benefit from more broad institutional standards.

9. Discussion

Some limitations exist to the scope of this research related to the case selected to research the GM digital primary care market. One of these limitations involves the selection of a subset of actors within the digital primary care market due to time constraints. The subset of actors that was interviewed in this study was aimed to represent a diverse reflection of the market and specific perspective differences. This has led to SMEs and policy makers being statistically underrepresented in the data. The perspective is still included by interviewing representatives of collaboratives on the perspective of these parties. Another limitation is the focus of this research on the integration of industry in the public healthcare market, while not addressing the integration of industry in the private healthcare market. As mentioned by Boon et al. (2022), the interplay between adjacent markets needs to be considered, as developments in these adjacent markets might influence the market of focus and actors might move between markets or become involved in both. Further research should be performed to examine the interplay of these markets and what actors' considerations are when choosing to operate in either or both. This would develop further understanding of the effect of the identified market formation barriers on these considerations. Last, despite the strong geographical dependency of market dynamics and the GM focus of this study, the insights presented could be valuable for the broader digital health market. The framework and HEA lend themselves to be replicable to other digital health segments or regions. To add to this, given the continuous policy landscape changes, it would be valuable to use and update the outline of this research over time for the GM area and other areas similarly.

In this research, the frameworks of Boon et al. (2022) and Flanagan et al. (2022) have been tested and extended by a case study in the technology of digital health. To the framework of Boon et al. (2022), the concept of indicators and facilitating and inhibiting factors of the processes were added. One observation of this study was in contrast with the theoretical framework used. The identified barriers arose from multiple processes and inhibiting or facilitating factors, instead of being isolated in one process. This shows that the processes in market formation are not to be viewed as isolated when distinguishing market-wide barriers, but rather as integrated and dynamic, with barriers overarching multiple processes. Even though Boon et al. (2022) acknowledge that a barrier in the development of one process could lead to a hampered development of another resulting in patterns or even cycles, these barriers are still viewed as a subject of one process. Diving deeper into the origin of market formation research, Dewald & Truffer (2011, 2012) describe that the development of markets is to be viewed as non-linear and inclusive, which underlines the observations in this study. As such, the result presented in this research adds to the conviction that further research should interpret relations between different market processes when determining barriers that affect the development of innovation.

Building forward on the relations between market formation processes, a more integrated approach was added to market formation policy interventions by connecting overarching barriers to policy trade-offs related to the framework of Flanagan et al. (2022). Boon et al. (2022) acknowledge that an interplay of the market formation processes exists in patterns or cycles but gives a set-up to policy interventions specific to the isolated market formation processes. As this research has shown, barriers do not limit themselves to one market formation process. Given the interplay between barriers and policy interventions, this suggests that policy inventions should as well be interpreted in a more relational and less isolated context thus also overarching multiple processes.

Further research in digital health market formation should focus on further exploring the relationship between the market formation processes, barriers to the market formation, and policy trade-offs. Developing this relationship further could lead to a stronger connection between research on the state of the market formation and the possible policy inventions. It could be researched by generalizing the operationalization of the framework used in this study. Next to this, it would be valuable to test the presented framework against other markets to further validate its value in market formation research.

The policy trade-offs that have arisen throughout this research are primarily a concern for the national government, as they currently have the agency to make changes regarding the healthcare system. As came forward in the interviews, local healthcare actors are increasingly calling for the devolution of healthcare decision-making to regional-level politics, as many healthcare-related problems are context specific. The national government also started acknowledging this, as is reflected by the development of the ICSs, which entails a bigger role for local decision-making at its core. Localization of decision-making agencies driven by the ICS structure also shifts the trade-offs towards a regional focus. For example, in ICSs the networks are aimed to be more geographically localized and contain longer-term partnerships with NHS (Charles, 2022). Further, the transparency of the procurement process increases, affecting valuation metrics and gathering input from companies operating in the field. This gives rise for SMEs to develop their solutions alongside other local actors within the safety of NHS.

However, not all the barriers and policy trade-offs are addressed in the ICS plans. Several barriers remain to be tackled in order to successfully develop the digital health market. As this research has shown, the healthcare system in the UK is highly institutionalized and complex. There is a constant interplay between actors on the national and local levels to shape this healthcare system and get it to function cost-efficiently. Only an integrated approach will effectively stimulate market formation, with the great importance of listening to the actors and clear communication on the changes that are going on to system users. The national and, increasingly, local governments will need to display vital leadership in addressing the market formation barriers at their base.

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Appendices

Appendix I: Indicators Market Formation Processes
*****Bold** indicators are added during the interview analysis

Table 4: Market formation process indicators

Process	Indicator in the context of the UK digital healthcare market	Abbreviation
Demand articulation and empowerment [DemandArt]	Producers creating new consumption categories to gain cognitive legitimacy and get valuated by the consumer (Boon et al., 2022)	[CnsmrCat]
	Producers engaging in marketing activities to induce consumers' demand and preferences (Boon et al., 2022)	[MarketAct]
	Users of healthcare service interactions (both consumers and medical professionals) expressing their use preferences by lobbying for innovations at companies, government, or healthcare providers (Boon et al., 2022)	[UseLob]
	Healthcare consumers expressing trust in digital health technologies concerning data storage, data sharing, and sufficient healthcare quality (Lennon et al., 2017)	[CnsmrTrust]
	Users co-creating product with a company, or setting up own company with their healthcare experience to serve the market (Lennon et al., 2017)	[UserInno]
Formation of new user practices and experimentation [NewUse]	NHS, healthcare institutes and/or industry players seeking or receiving input from (possible) consumers to define their use of the product or service (for example through launching a pilot) (Boon et al., 2022)	[CnsmrInput]
	Users engaging with the digital health platform and defining its use in own context (Boon et al., 2022)	[DefCntxt]
	The existence or formation of infrastructure for the health consumers to access digital health platforms (concerning internet connectivity, digital literacy, GP reachability) (Lennon et al., 2017)	[UseAccess]
	Digital health platforms becoming embedded in the 'workflow' of medical professionals in giving care or patients in seeking for health (Lennon et al., 2017)	[EmbWrkflw]
Formation of institutions and institutional entrepreneurship [InstiTrans]	Existence of or change towards enabling medical standards, guidelines, and protocols that comply with digital health practices (Boon et al., 2022)	[MedStand]
	Existence of national or local healthcare and data regulation or policy enabling digital healthcare to develop (Lennon et al., 2017)	[HealthReg]

	Healthcare market diverges as new digital healthcare solutions enter the market that deviate from the initial healthcare system and search fitting institutions (Boon et al., 2022)	[DvrgntMrkt]
	System actor with agency to act as an institutional entrepreneur that exerts influence on the institutions of the primary healthcare system (Lockett et al., 2012b)	[InstiEntr]
	Digital health provider vision aligns with the vision of the local/national government and NHS services/group to change the system and form the digital health market (Lennon et al., 2017)	[VisionAlign]
	Digital health provider actively expresses trust in or lobbies to change the existing institutions (Oliver, 1991)	[PrvdrTrust]
Defining legitimate market boundaries and establishing product categories [MrktBndry]	Government, NHS, healthcare institution or society express the need of the emergence of the digital health market to solve healthcare problems such as increasing costs and decreasing efficiency (Boon et al., 2022; Hwang & Christensen, 2008)	[MrktNeed]
	Producers use their solutions to solve larger societal problems as a narrative and gain legitimization of the market while doing so (Boon et al., 2022)	[GainLegit]
	Common understanding of actors in healthcare what place digital health takes in the health ecosystem (separate market/integrated in health market) (Lennon et al., 2017)	[PlaceMrkt]
	Expression of convergence to dominant product category within digital health with multiple product/service owners involved in category that promote competition (Suarez et al., 2015)	[DomCat]
	Possibility of integration and interoperability of digital health with the existing healthcare IT ecosystem (Frenk, 2009; Goodwin, 2018)	[SysInter]
Formation of dominant product or service design [DomDesign]	A dominant product or service design arises as a standard for the digital health primary care platform market, having similar core characteristics (Boon et al., 2022)	[DomProd]
	Existence of an infrastructure through which companies can enter the market, even when they did not already gained legitimacy in both healthcare and digital practices (Lennon et al., 2017)	[MrktEntry]
	Market actors make intellectual property or data available to other system participants to build forward on and converge to one type of design (Lennon et al., 2017)	[IntelProp]
	Common sense of direction of the healthcare market in actors and clarity how it is set up to develop (Lennon et al., 2017)	[DirectSns]
Business model (innovation) [BMInno]	Value proposition digital health platform design aligns with regular healthcare problems or needs (Oderanti et al., 2021; Oderanti & Li, 2018)	[ValueProp]
	Technology company entering the market through collaboration with traditional healthcare actor(s) for rolling out digital health innovations (Maier et al., 2021; van Velthoven et al., 2019)	[TechEnt]
	Company using a new BM for the delivery of health care or creates a new BM that differs from existing dominant business models (van Velthoven et al., 2019)	[EmrgncBM]

	Company providing evidence of value proposition digital health BM (Lennon et al., 2017; Shaw et al., 2018)	[EvdncVP]

Appendix II: Interview guide

Name interviewee:

…......

Place and time of interview:

…......

Thank you for taking the time to participate in my interview. This interview will serve to gather data for my master dissertation, which aims to research the development of the digital health market in the UK, taking the case of Greater Manchester. The interview will take around an hour, in which I will ask you several questions about the more specific case study of '*Digital primary care'*. This means that unless I specifically state something else in a question, all questions should be understood in the context of this specific project. I will ask you questions related to events that happened throughout the last 10 years, and what their influence was on the digital health market in your view. Next to this, I will dive further into the current state of the digital health market, and what barriers still exist. I'm mainly looking for underlying mechanisms of the healthcare market and developments that have not been described extensively in literature. Also, I'm looking for motivations and strategies to these developments. The interview is conducted to gather data for my research only, in which the data will remain anonymous and undistributed. Furthermore, there are no right or wrong answers, and feel free to elaborate extensively. Do you have any questions before we start?

I will use the data of this interview in my research to code and analyse, if I use any quotes, they will be anonymized. Now that everything is clarified, do I have your consent to start the interview and **record the answers** for later analysis purposes?

- Primary care system
  - General:
    - What role do you/does your organisation take in the primary care system/digital primary care market? And what role do you take in your organisation?
    - What made you as a person/organisation interested in the subject of digital health and when did you start engaging with this subject?
    - What are, in your view, the UK/GM system actors and how are they connected?
- Event timeline
  - General:
    - What do you think are the most significant events that have shaped or influenced the digital primary care market over the last 10 years?
      - Did this event have a stimulating or hampering effect on the market? In what way?
      - What were the preceding events or facilitating factors to this event?
      - What were the consequences to this event? How did it work through in the digital health market?
      - Which parties were involved?
  - Specific (follow up questions or show backbone):
    - Health and Social Care Act
      - What effect do you think the National Health and Care Act has had on the development of digital primary care in the UK/GM?
      - As in some articles it is noted as the start of privatisation of healthcare, how did the market/industry respond to this act?
      - Were there any preceding/succeeding events related to this act?

- ▪ GMDA & HSMoU
  - • How did the decentralisation of power of national to local government work through on the different governmental levels? And what effect did it have on the market?
  - • In what way was the information transformation of knowledge institutes to businesses encouraged?
- ▪ Industry taking off (Babylon's GP at hand, Livi, PushDoctor, askmyGP)
  - • What parties do business or are trying to do business in GM?
  - • What are the facilitating and hampering factors while trying to enter the GM digital health ecosystem?
  - • What does having a partnership with NHS mean for companies when gaining legitimacy? Is it necessary to penetrate the market?
  - • What are the main concerns of consumers of digital health platforms when they use one (privacy, access, data)? And how does that affect the user uptake?
- ▪ COVID-19 (if I have time)
  - • What effect do you think COVID-19 has had on the development of digital primary care?
    - o What role did government play in this?
    - o What role did consumers play in this?
  - • How did COVID-19 affect your organisation and the development of your project?
- ▪ Do you think there are still events missing in the timeline or factors unmentioned?

- Current state
  - o Do you think the digital health market is currently reaching its full potential? Why (not)?
    - ▪ If not: Where do you think change should originate?
  - o What do you think are the main barriers of the (digital) health market?
- Ending
  - o Do you have any additions?
  - o Do you have other contacts that could be interesting for me to interview?
  - o Do you have contacts in organisation …?
  - o Can I contact you if I have further questions or things remain unclear?

Appendix III: Historical Event Analysis Process
*FF stands for facilitating factor, IF for inhibiting factor

Table 5: HEA events, processes, indicators, and effects

Event	Article	Quote	Process	Indicator	Effect
Health and Social Care Act was signed (Calovski & Calnan, 2019)	(Calovski & Calnan, 2019)	*"In summary, the Act put an emphasis on primary care-led commissioning, in the form of GP-led CCGs as the method by which over two-thirds of the NHS budget is delivered. Being responsible for the dispensation of the largest part of the NHS budget, CCGs could decide to commission a large number of private providers. The CCGs were to operate in a framework that included regulators with additional powers in order to promote competition, while simultaneously being obliged to assist CCGs in integrating public, private and third sector providers in one system."*	DemandArt	UseLob	FF
	(Calovski & Calnan, 2019, p. 132)	*"In addition to the creation of these groups, the Health and Social Care Act (UK Legislation 2012) included clauses which suggested an enhanced role for the private sector in the delivery of healthcare, increasing public concern about the issue of privatization."*	MrktBndry	DomCat	FF
	(NHS, 2012b)	*"The Act contains a number of provisions to encourage and enable the NHS, local government and other sectors, to improve patient outcomes through far more effective coordinated working. The Act provides the basis for better collaboration, partnership working and integration across local government and the NHS at all levels."*	BMInno	EmrgncBM	FF
	(NHS, 2012c)	*"Monitor will license providers, so there is no "free-for-all" to deliver NHS services. Through licensing conditions, Monitor would be able to prevent potentially anti-competitive behaviour and identify at an early stage if a provider was at risk of financial distress and, insofar as legislation provided for this, require the provider to take action to address potential problems."*	InstiTrans	DvrgntMrkt	IF
			DomDesign	InfraStruc	FF
The Greater Manchester Devolution Agreement and Health and Social Memorandum	(Anstee et al., n.d., p. 10)	*"The government invites the GMCA and Greater Manchester Clinical Commissioning Groups and acute trusts to develop a business plan for the integration of health and social care across Greater Manchester, making best use of existing budgets and including specific targets for reducing pressure on A&E and avoidable hospital admissions. The government will continue to set out incentives for health and care partners in Greater Manchester to develop this plan. The government will also work with local*	MrktBndry	DomCat	FF

of Understanding was signed (GMHSC & HInM, 2016)		*government and NHS England to give greater certainty about health and care funding settlements. This includes by working towards multi-year allocations at the next Spending Review. HMT is keen to support a Greater Manchester-wide health and social care strategy which fairly and accurately reflects the priorities of the full range of NHS and social care stakeholders, including acute trusts. It would therefore not be appropriate for central government to Mandate any particular approach. Agreement from Greater Manchester Clinical Commissioning Groups will be required to implement any plan for services and budgets which are their responsibility."*			
	(GMHSC & HInM, 2016, p. 5)	*"The system allows us to focus the collective expertise of all partners – our Universities, hospitals, CCGs, primary health care providers, industry, Public Health England and NHS England – on developing the best approaches to addressing the health needs of our Greater Manchester population."*	InstiTrans	InstiEntr	FF
Industry takes off (Al-saffar et al., 2021)	(Makortoff, 2021; "UK Healthcare Technology: Your Robot Doctor Will See You Now," 2016)	*"Babylon, a Chelsea-based firm that launched in 2013, is an app-based service that offers patients unlimited private GP consultations for £149 a year or one-off appointments for £49. Patients can gain instant access to doctors via video-call consultations 24 hours a day, seven days a week, including bank holidays. The firm also offers appointments with therapists and specialists from £39."* *"The company did not disclose its financial performance but said its business model is for customers to pay £4.99 a month. It did not say how much it charges business customers or how much it would charge the NHS."*	BMInno	TechEnt	FF
	(Postelnicu, 2018; Winward et al., 2021)	*"This paper is the first to show that an association between a highly accessible, 24/7, digital-first model of primary care and significantly lower acute hospital costs. … The reduction in hospital care costs observed is likely to be much greater than the additional cost of delivering 24/7,digital-first primary care."* *"Researchers have called into question claims made by health tech company Babylon Health that its diagnostic and triage system performed better than doctors on a subset of the final exam for trainee GPs in the UK."*	InstiTrans	VisionAlign	IF
	(Baird, 2019)	*"The digital-first approaches we've seen to date prioritise access at the expense of the other components. That might work for some patients, some of the time (an evaluation of GP at Hand found that the model seemed to attract younger patients who prioritised convenience). But it isn't clear that the model works for other patients – for example, those*	BMInno	TechEnt	IF

		who need regular physical access to a GP; who are waiting for a diagnosis, for whom continuity of GP/clinician might be really important; who need a GP who knows them, their community and the local services available to them; who need a multidisciplinary practice team who know and trust each other; or who are digitally excluded."			
	(Monitor Deloitte, 2015)	*"The desire to become a platform player in this space has attracted new entrants from various related industries. However, as the high-profile failures of initiatives such as Google Health show, this space requires detailed knowledge and stakeholder buy-in, especially at a platform level."*	BMInno	EmrgncBM	FF
			InstiTrans	DvgrntMrkt	FF
	(Ram, 2018)	*"Swedish doctor app Kry will take on British start-up Babylon in its home market, after striking an agreement with 40 general practices in England. The app, called Livi in the UK, will offer video consultations to National Health Service patients at the 40 surgeries in Surrey, as well as private patients across the country.* *Caroline Baker, chief executive of the NICS, said: "GPs in north-west Surrey, just like GPs all around the country, are struggling with an increased workload from a growing and ageing population, tight budgets and a workforce crisis. "Livi offers a fast, safe and effective alternative for our NHS patients, which will benefit many patients of all ages, whilst helping to support and relieve pressure on our local GP practices.""*	NewUse	CnsmrInput	FF
	(Rimmer, 2018)	*"The UK's advertising watchdog has ruled that GP at Hand cannot longer use adverts that don't make it clear to patients that they must deregister from their current practice to use the service. The ruling from the Advertising Standards Authority (ASA)came after eight complainants, including a GP, challenged whether the adverts were misleading."*	DemandArt	MarketAct	IF
	(Dyer, 2018)	*"Advertisements for the commercial online GP consultation service Push Doctor have been banned by the Advertising Standards Authority (ASA) for implying that the services were provided by the NHS and for not making it clear that patients have to pay to use it. …* *Push Doctor argued that consumers were already sufficiently aware of the brand and knew that it was a private, paid-for service. But the ASA said that most consumers who saw the poster would be unfamiliar with Push Doctor, its position as a private healthcare company, and its links with the NHS."*			
	(The Guardian, 2020)	*"Babylon Health has suffered a data breach involving confidential patient information, with users of its GP video consultation app allowed to see other patients' appointments. The breach emerged when one of its users discovered they had access to video recordings of other patients'*	DemandArt	CnsmrTrust	IF

		consultations. Babylon later said a small number of UK users could see each other's sessions and that the problem was a limited software error and not a "malicious attack"." *"Leeds-based Rory Glover had access to the service via his membership of a private health insurance plan with Bupa, one of Babylon's partners. On Tuesday morning, when he went to check a prescription, he noticed he had about 50 videos in the Consultation Replays section of the app that did not belong to him. … However, Mr Glover said he still had concerns and did not intend to use the service again."*			
	(Lawrence, 2021; I3)	"Matt Hancock has promoted a healthcare startup whose shareholders have made donations to the health secretary and the Conservative party, the Guardian can reveal. The revelations about investors in Babylon Healthcare, a startup that offers smartphone-based NHS GP consultations and symptom-checker services, raise questions about possible conflicts of interest for Hancock. … Hancock has repeatedly endorsed Babylon's products publicly, and said he wants everyone in England to have access to them." *"So Matt Hancock, who was the Health Secretary at the time? I'm fairly convinced, although I couldn't prove it, I would say he's had some sort of commercial interests in Babylon health, which is probably hidden in an offshore account somewhere."*	DemandArt	CnsmrTrust	IF
	(Downey, 2019a, 2019b)	*"GP at Hand will also be required to set up a new alternative provider medical services (APMS) in Manchester after NHS England <u>approved changes to out-of-area patient registration rules</u> meaning digital providers would have their contracts disaggregated once they reach a threshold of 1,000 patients."* *"Mr Waller said the decision to put the threshold at 1,000 was about "balancing the fact that we are trying to return patients to a practices that is based locally".*	InstiTrans	MedStand	IF
	(Downey, 2019c)	*"'Whenever any new provider of health and care services plans to come into Manchester, our priority is to ensure that their services are high quality, meet the needs of local people, and contribute to the financial and clinical sustainability of the health and care system in the city,' a spokesperson for the CCG said.*	MrktBndry	DvrgntMrkt	IF

		'Whilst we believe that new digital approaches have the potential to enhance GP service provision in the city, we are not convinced that Babylon GP at Hand's model of care is sufficiently integrated with other local and national services to ensure safe and effective care for local people. Areas of concern include screening programmes and safeguarding.'"			
Digital health platform quality control	(Meek, 2015)	*"The library, which was set up in March 2013 as a way for the public to access a selection of smartphone and tablet apps reviewed by the NHS, is set to end a "period of testing", according to the updated about page of its website."*	DomDesign	DomProd	FF
	(Nwe et al., 2020)	*"Clinical governance of medical mobile apps is challenging, and there is currently no standard method for assessingthe quality of such apps. In 2018, the National Institute for Health and Care Excellence (NICE) developed a framework forassessing the required level of evidence for digital health technologies (DHTs), as determined by their clinical function. Theframework can potentially be used to assess mobile apps, which are a subset of DHTs. To be used reliably in this context, theframework must allow unambiguous classification of an app's clinical function."*	InstiTrans	MedStand	FF
NHS long term plan (NHS, 2019)	(NHS, 2019, p. 25)	*"First, we will create a new framework for digital suppliers to offer their platforms to primary care networks on standard NHS terms."*	InstiTrans	MedStand	FF
	(NHS, 2019, p. 25)	*"Second, and in parallel, we will ensure that new 'digital first' practices are safe and create benefit to the whole NHS. This means reviewing current out-of-area arrangements and adjusting the GP payment formulae to ensure fair funding without inequitably favouring one type of GP provider over another."*	DomDesign	MrktEntry	FF
	(NHS, 2019, p. 25)	*"Third, we will review GP regulation and terms and conditions to better support the return to practice and increased participation rates by GPs wanting to work in this way."*	InstiTrans	MedStand	FF
	(Crouch, 2019)	*"Luke Buhl-Nielsen, UK Director at LIVI, said: "With the launch of the NHS long term plan, there is increasing recognition that technology will play a pivotal role in the future of healthcare as the system undergoes a digital transformation."*	InstiTrans	PrvdrTrust	FF
	(Crouch, 2021)	*"A tender notice, published on December 15, revealed the NHS is looking for "suitably experienced and qualified" suppliers to join the Digital First, Online Consultation and Video Consultation (DFOCVC) Framework.* *The framework aims to deliver commitments in the NHS Long Term Plan to support online consultation in general practice."*	MrktBndry	MrktNeed	FF
COVID-19	(Peek et al., 2020)	*"In the UK, an exceptional legal basis has been provided for this by the Secretary of State for Health and Social Care activating the Health*	MrktBndry	MrktNeed	FF

	Service (Control of Patient Information) Regulations, which requires affected organisations to 'process confidential patient information... where the confidential patient information to be processed is required for a Covid-19 Purpose and will be processed solely for that COVID-19 Purpose."			
(Peek et al., 2020)	*"Third, change was necessary because governments required that any care that does not require physical interaction must now be provided through remote consultation ."*	InstiTrans	VisionAlign	FF
(Peek et al., 2020)	*"Second, many countries have relaxed privacy and data protection regulations for video and other communications technologies during the crisis; the General Data Protection Regulations, which apply in the UK and the European Union, already include a clause excepting work in the overwhelming public interest."*	DemandArt	CnsmrTrust	FF
(Ibrahim et al., 2021)	*"Data-driven digital health technologies have the power to transform health care. If these tools could be sustainably delivered at scale, they might have the potential to provide everyone, everywhere, with equitable access to expert-level care, narrowing the global health and wellbeing gap. Conversely, it is highly possible that these transformative technologies could exacerbate existing health-care inequalities instead".*	NewUse	UseAccess	IF
(Budd et al., 2020)	*"Some companies are making subsets of aggregated data available. These data are not consistent and are not provided within the same timeframe, and there is no standard format or long-term commitment. Researcher-led international collaborations have aimed to aggregate multiple international data sources of voluntarily reported information."*	DomDesign	IntelProp	IF
(Wamsley & Chin-Yee, 2021)	*"Just as countries have deployed differing public health strategies to address the COVID-19 pandemic with varying degrees of success, there have also been different models for integrating novel technologies in public health. Across the US, UK, Canada, and other liberal Anglophone countries, data-driven approaches throughout the pandemic, consistent with more long-standing trends, have emerged largely from private-sector initiatives, often as substitutes for integrated public health responses … In the UK, private outsourcing within the NHS has continued apace, with contracts offered for PPE procurement and health data management to digital giants such as Capita, Serco, and Palantir."*	BMInno	TechEnt	FF
(HInM, 2020)	*"A digital primary care outcomes framework was also developed, including a set of standards and outcomes which all practices should work towards, regardless of what digital products they have implemented. It was developed through a series of design workshops comprising representatives from across Greater Manchester including public members, GPs, practice managers, health and care managers*	DomDesign	DomProd	FF

		and technical experts. As part of the Greater Manchester Digital First Primary Care programme it will be used to support practices to measure outcomes, set standards, monitor activity and performance and address issues."			
	(NHS, 2022c)	**"***Well coordinated care enabled by single digital health and social care record across primary care, NHS trusts and social care providers, and collaborative working practices, so that the burden of coordinating care falls on ICSs not the user."*	MrktBndry	SysInter	FF
	(I5)	*"Actually, the doctor said it for most things, it's absolutely fine. And he said, But I have to say, we were all so reluctant to do it at first, he said. I was quite keen, but my colleagues didn't want to know, he said. But now they love it and I don't want to go back to it. Now I have to say, can I have an in-person one?"*	InstiTrans	MedStand	IF
	(I6)	*"And so, it provides those in primary care, but also beyond that, better access to more joined up data, although that only really it was spoken about and tried and I would say ultimately failed until COVID came along."*	DomDesign	IntelProp	FF
	(Green, 2020)	*"The NHS partnership with Big Tech has prompted an open letter from a group of campaigners, doctors and academics imploring the US agency to avoid cutting ethical corners and to maintain transparency in areas such as contact tracing."*	DemandArt	CnsmrTrust	IF
	(Sounderajah et al., 2021; I6)	*"Despite increasingly high levels of internet connection and device availability and the pandemic accelerating digital technology adoption, we report a gradient among older, lower social grades and lower education attainment demographic groups interacting with digital public health approaches. The inability to promptly access and under-stand online information and services prevents individuals from taking protective steps against COVID-19. These same groups are also at higher risk from COVID-19, so the observed digital divide effectively compounds health risks. This suggests that digital inequality potentiates vulnerability to the pandemic, thereby further increasing health inequalities. This is in keeping with previous descriptions of digital inclusion as a wider determinant of health."* *"That's so true because and the other thing is ease reluctance on people like GP. There was massive reluctance on then and and and secondary care clinicians to adopt video appointments. They wouldn't do it and absolutely would not do it. And um, and I had a conversation with my own GP about this and when the first started and then I had occasion where I did have to go and see him and I said to him: "How are you getting on with the video appointments?" … Actually, he said it for most things, it's absolutely fine. And he said, But I have to say, we were all so reluctant to do it at first, he said. I was quite keen, but my colleagues didn't want to*	NewUse	UseAccess	IF

		know, he said. But now they love it and I don't want to go back to it. Now I have to say, can I have an in-person one?"			
Brexit	(UK GOV, 2022; I11)	*"And I think the other interesting thing is how it will affect the medical device regulations. So at the moment, if you're a company that has a device or piece of software and you have to go to the MHRA and have your device classified as to whether it's a medical device or whether it isn't. And if it is a medical device, you have to classify it in terms of class one, class two, class three. What has been the case is that it's if you have a product or software, it's not only deemed as a medical device, if it has an interaction with the patient and it changes the patient's journey, if it doesn't affect the patient's journey, it's not a medical device. What we're seeing is a shift towards because of Brexit is that any digital software remotely pertaining to health care will be classed as a digital medical device. And that might not sound like such a change, but it is for small companies because it's very expensive to get your device tested and classified as a medical device. And if it is a medical device is a lot more regulations that you have to jump through."* *"All medical devices, including in vitro diagnostic medical devices (IVDs), custom-made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market."*	InstiTrans	MedStand	IF
Health and Care Act & move to ICS	(Alderwick, 2022)	*"Standing back, the Act helps cement a shift away from competition within the NHS but will do little to tackle the major challenges facing health and care in England – including a massive backlog of unmet need, chronic workforce shortages, and growing pressures on services. Local areas will need to be given the time and resources to implement the changes and minimise potential disruption."*	NewUse	CnsmrInput	IF
	(Charles, 2022)	*"Place-based partnerships operate on a smaller footprint within an ICS, often that of a local authority. They are where much of the heavy lifting of integration will take place through multi-agency partnerships involving the NHS, local authorities, the VCSE sector and local communities themselves."*	DomDesign	MrktEntry	FF
	(Charles, 2022)	*"Concerns were most prominent around the development of the integrated care provider contract (a new contractual form allowing commissioners to award a long-term contract to a single organisation to provide a wide range of health and care services to a defined population), with campaigners arguing that this could lead to health and care services coming under the control of private companies."*	Domdesign	MrtkEntry	FF

Appendix IV: Interview coding outcomes

Table 6: Facilitating and inhibiting factors in interview coding outcomes

Processes	Facilitating factors	Inhibiting factors
DemandArt	Users being unaware of data sharing or prioritise the advantages [CnsmrTrust]	Users and media being vocal about distrusting commercial digital platforms [CnsmrTrust]
	Companies marketing their solution to healthcare consumers [MarketAct]	MedTech companies refusing or fighting against academic input [UserInno]
	HInM and FTs linking industry, healthcare institutes and academia for co-development [UserInno]	Tech companies creating own segment when they cannot penetrate the market [CnsmrCat]
		Priorities of government are expressed as different to market needs [UseLob]
NewUse	System actors searching for input of users through pilots and actively reaching out [CnsmrInput]	New platforms don't always work well with existing platforms [EmbWrkflw]
	GPs using digital health to ease their workload [EmbWrkflw]	Needs of GPs and healthcare consumers are unmet in digital health solutions [CnsmrInput]
	Actors being aware of health inequalities related to digital health and focus to solve them [UseAccess]	Health inequalities increasing because of digitalization [UseAccess]
		GPs don't have time to experiment with new platforms [DefCntxt]
InstiTrans	NHS imposing guidelines and standards for companies entering the public health ecosystem [MedStand]	Companies finding it hard to navigate as regulation is constantly changing [HealthReg]
	Consensus about government having the power to change the NHS [InstiEntr]	Digital health platforms are increasingly qualified as medical device and need to provide evidence [MedStand]
		(Privacy) laws inhibiting innovation [HealthReg]
		Multinationals having a hard time to enter the market as of context dependency of regulation [HealthReg]
MrktBndry	Integration being a priority in functioning digital health solutions [SysInter]	Integration being hard as of incumbent data management systems [SysInter]
	Consensus on digital health integrating with regular healthcare, not overthrowing it [PlaceMrkt]	
DomDesign	Structures in GM focusing on facilitating SMEs in entering the market [MrktEntry]	Innovation in GM stalling as of uncertainty of direction of the market and regulation [DirectSns]
	NHS FTs licensing IP to private companies to increase knowledge overflow [IntelProp]	IP and data not being shared efficiently across the system [IntelProp]

|	CCGs focusing on financial stability is more suited for larger companies [MrktEntry]	SMEs having a hard time to enter the market as of a lack of resources [MrktEntry]
BMInno	NHS and companies working together closer as a solution [TechEnt]	NHS taking advantage of partnerships by copying the BM [TechEnt]
	New BMs proof to have working VPs [EvdncVP]	Evidence value proposition of digital health is lacking [EvdncVP]

Appendix V: Interview coding tree
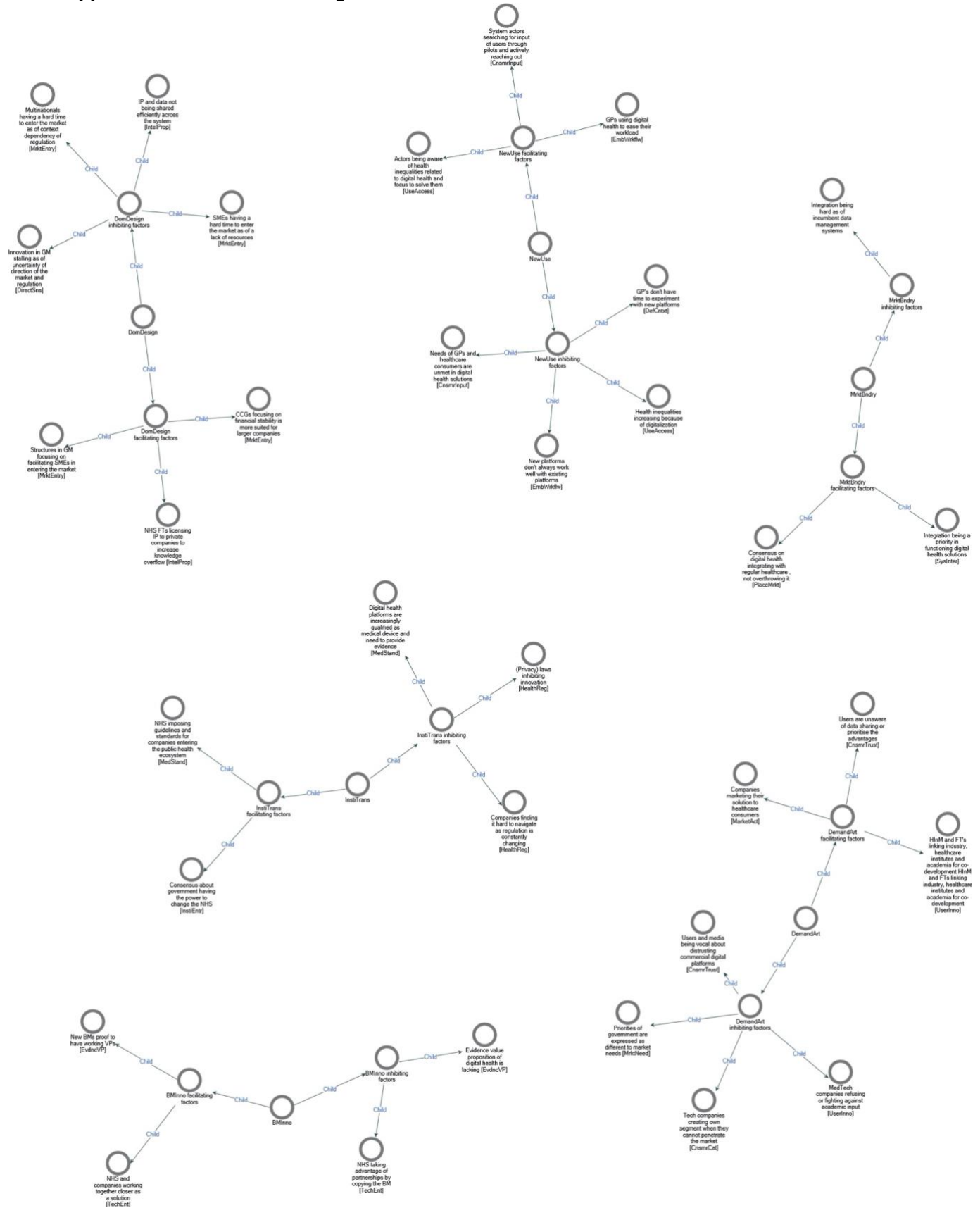
Figure 10: Coding tree interview outcomes