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Digital Health Roadmap

A Guide for innovators
developing digital
health products

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Contents

List of Resources

www.healthandwealthoxford.org   2

1. Foreword

Digital innovation has transformed our lives in ways which were unimaginable even 20-years ago. Digital health products now act as enablers and interfaces for most of our financial transactions and are indispensable in many of our daily activities. In this context, the impact of digital technology in healthcare delivery remains surprisingly limited, perhaps due to inherent conservatism and caution in many parts of the health care system about the risks of change and the failure of some high visibility national digital initiatives.

The opportunity for digital technology to transform care pathways is clear. If we are to move more care and assessment closer to the patient's home, then digital innovation will be a key part of supporting appropriate decision making by the patient and their health care professionals.

However, taking an idea for digital innovation through to a product that can be used widely across the NHS and other health care systems is challenging and most innovators or aspiring digital health entrepreneurs need support with the regulatory, technical and logistical issues that need to be addressed.

The idea for this guide arose from my own experience of being involved in the development of a digital technology to support decision-making by patients and stroke specialists for thrombolysis in acute stroke.

We hope this guide will act as a resource and provide guidance to innovators seeking to develop the digital health products that will improve and transform health care for future patients.

Professor Gary Ford CBE, FMedSci

Chief Executive Officer of Oxford Academic Health Science Network

2. Executive Summary

Digital technology is an important enabler in the delivery of high quality services, improving patient outcomes and increasing efficiency and productivity in health and social care systems. Health and social care systems across the world are undergoing significant change and restructuring to manage demand, maximise self-management and to keep people healthy and out of hospital. Digital health is increasingly recognised as having the potential to play a leading role in this transformation, as well as to support healthcare solutions in remote or impoverished regions.

However, the rapidly developing global market for digital health products poses numerous challenges for both innovators and payors. Whilst the supply side of the market is developing at pace, innovators face many challenges in developing digital health products, that will be adopted by the health and social care systems, and in particular the NHS.

There is currently no clearly defined pathway to support innovators in navigating their way through the development, commercialisation, and commissioning of digital health products. Drawing upon its deep knowledge and understanding of the pathway from concept through to adoption into the NHS or private and global healthcare markets, Oxford Academic Health Science Network (Oxford AHSN) has developed the Digital Health Roadmap (**Figure 3**) and a guide for innovators developing digital health products.

The Guide for Innovators focuses in more depth on key issues that innovators will need to consider as early as possible during the development of their digital health products, in order to maximise the chance of success and is available to SMEs working with Oxford AHSN. Alongside the "Guide for Innovators", Oxford AHSN offers a range of services to support innovators to navigate through this complex environment and progress through the various stages of the Digital Health Roadmap. Further details can be found on the Oxford AHSN website (http://www.healthandwealthoxford.org/[1]).

2.1. Oxford AHSN

In 2013, the UK government established 15 Academic Health Science Networks (AHSNs) with the aim of improving health and generating economic growth through the adoption of new innovations at pace and scale within the NHS. AHSNs bring together researchers in universities, industry and entrepreneurs from global companies and small and medium sized enterprises (SMEs), as well as clinicians and managers from the local NHS and social care systems with the aim of translating research into practice and providing rapid evaluation and early adoption of new innovations in healthcare[2]. Each of the 15 AHSNs is empowered to exploit the strengths and innovations from their local areas.

- The Oxford AHSN region (Oxfordshire, Berkshire, Buckinghamshire, Milton Keynes, and Bedfordshire) represents a strong digital health cluster, and recently published a regional digital health report surveying the strengths surrounding digital health within the region[3].

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[1] http://www.healthandwealthoxford.org/
[2] http://www.ahsnnetwork.com/
[3] http://www.healthandwealthoxford.org/wp-content/uploads/2016/11/Digital-Health-in-Oxford-Wider-Region.pdf

www.healthandwealthoxford.org   4

- There is significant academic expertise in digital health at the University of Oxford, University of Reading, Oxford Brookes University, University of Buckingham, Cranfield University and Open University.

- There are over 150 global and digital SMEs across the Oxford AHSN region.

- Within the 2013-2018 five-year license, Oxford AHSN has demonstrated a return on investment (ROI) of 2.5 times and within 2017/18 this has increased to a ROI of 5 times[4].

- Oxford AHSN supports over 150 projects, 30 partnerships with industry, and at the time of the 2016/17 annual report had attracted £18m inward investment funding.

- Three NHS Trusts in the region have been designated as Global Digital Exemplar (GDE) sites (Oxford University Hospitals NHS Foundation Trust (OUHFT), Oxford Health NHS Foundation Trust and Berkshire Healthcare NHS Foundation Trust).

- Oxford AHSN is a strategic partner in two new Innovation Centres in the region: *The Hill*, a digital accelerator at Oxford University Hospitals NHS Foundation Trust, and *The Buckinghamshire Life Sciences Innovation Centre*, with locations at Buckinghamshire New University in High Wycombe and Buckinghamshire Healthcare NHS Trust in Stoke Mandeville Hospital.

- Oxford AHSN led the digital health theme in the Oxfordshire Transformative Technologies Alliance Science and Innovation Audit, coordinating a high level of activity across a range of sectors, including space-led data applications, autonomous vehicles and quantum computing.

- Harwell campus is home to a thriving ecosystem of innovative companies across a broad spectrum of emerging pharmaceutical/biotech, medtech, diagnostic, digital health and other areas of healthtech. Advances in all areas of healthcare are increasingly dependent on the cross fertilisation of ideas across different fields. An exciting advance is the new Harwell HealthTec Cluster, which is rapidly developing into a leading healthcare innovation hub founded on multidisciplinary collaboration between physical and life sciences focusing on preventative medicine practices and improving medical diagnosis and treatment through enhanced digital, e-health and remote healthcare capabilities.

2.2. Oxford University Innovation

Recently named Technology Transfer Office (TTO) of the year for the second time, Oxford University Innovation (OUI) is the technology transfer company of the University of Oxford. Over the last year it has spun-out 26 new companies, raising a combined seed investment of over £52.6M.

OUI recognises the opportunity for digital health innovations to transform patients, clinicians, and payors and has supported a number of new initiatives to stimulate innovation in the sector. OUI has run regular Digital Health Showcase events designed to highlight the most innovative technologies being developed in Oxford to industry and investors, OUI offer support and advice to Digital Health Oxford's idea and innovation lab, *The Hill*, and to the Oxford Biodesign programme being run by the Institute of Biomedical Engineering. OUI also works closely with other local healthcare organisations, such as the Oxford University Hospital's NHS Foundation Trust, Oxford Health NHS

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[4] Source: "Oxford AHSN Year 4 Annual Report for year ending 31 March 2017", Oxford AHSN (March 2017)

Trust, the Oxford AHSN and is involved in various regional initiatives such as Bicester's NHS Healthy New Towns project.

To support Digital Health innovators, OUI has a dedicated digital health team with expertise in informatics, software development, the regulatory environment and in bringing healthcare products to market through licensing, partnering and new ventures. The team are presently working with over 200 innovation teams and OUI has spun out over 20 companies in the digital health space.

2.3. Acknowledgements

This document was prepared by the Oxford AHSN and Oxford University Innovation, with advice and guidance from various stakeholders. In particular, valuable input was provided by Beverley Scott, Clare Sanderson and Dominic McKenny.
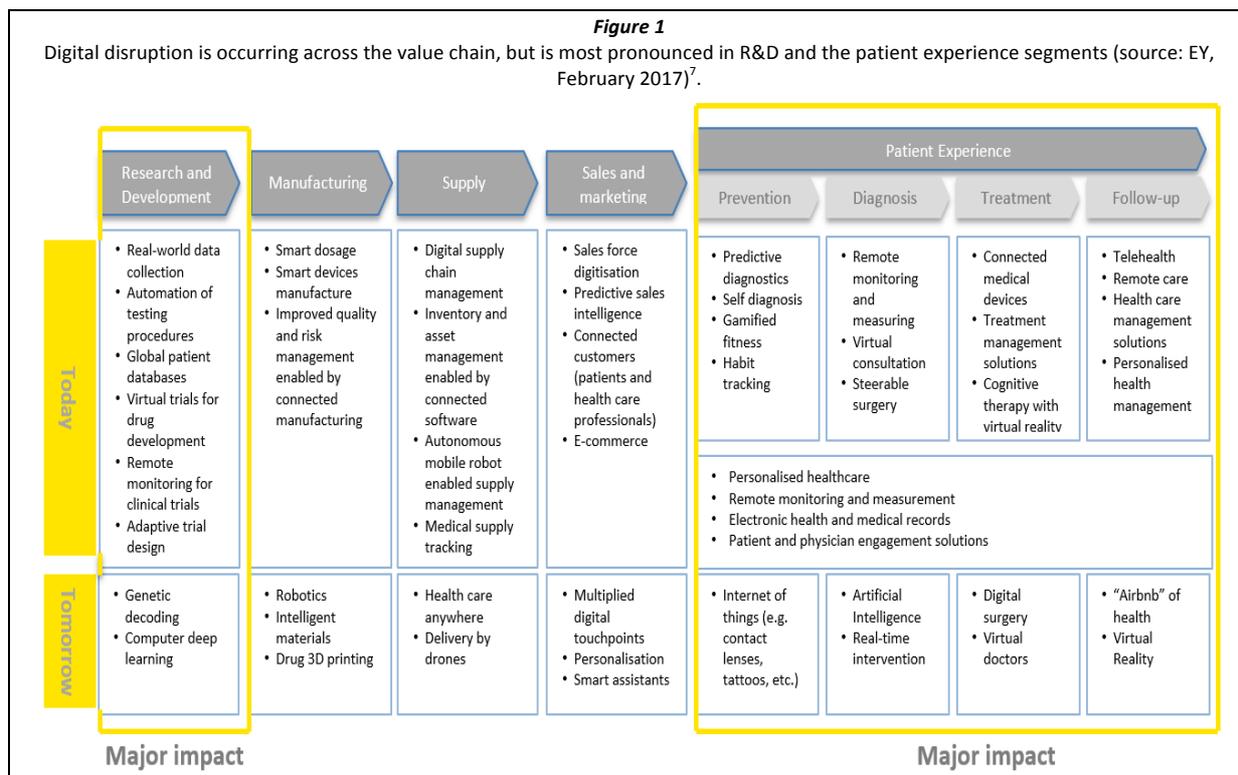
This work was also supported by an NIHR Senior Investigator Award received by Professor Gary Ford.

3. Introduction

3.1. A Growing Demand for Digital Health

Digital technology is an important enabler in healthcare systems with the potential to increase efficiency and accessibility to patients and users, reduce costs, and improve health outcomes and well-being. Digital health can be defined as "the use of digital technologies to improve human health"[5]. Digital health can be applied to all aspects of healthcare commissioning and delivery, and has the potential to transform the way in which healthcare is delivered across the whole patient pathway from prevention, through diagnosis and intervention, to on-going monitoring (**Figure 1**).

Digital health is increasingly recognised as having the potential to shape the future of healthcare services in the UK and around the world. The demand for digital health products is growing rapidly. In 2014, the global market for digital health was worth £23 billion and was expected to almost double to £43 billion by 2018, at a Compound Annual Growth Rate (CAGR) of around 18%. In 2014, the UK market size was £2 billion (**Figure 2**) and with the right support was expected to grow to £2.9 billion by 2018 with a CAGR of 11%, driven predominantly by high growth in markets such as mHealth apps (35% CAGR) and health analytics (24% CAGR). Therefore, in 2014 the UK market represented approximately 9% share of the global market share, which was predicted to fall to approximately 7% by 2018 due to stronger growth in other markets[6].

Figure 1
Digital disruption is occurring across the value chain, but is most pronounced in R&D and the patient experience segments (source: EY, February 2017)[7].

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[5] Source: "Digital Health in Oxford and the wider Thames Valley region", Oxford AHSN, Oxford University & OUI, October 2016
[6] Source: Monitor Deloitte. Digital Health in the UK. An industry study for the Office of Life Sciences (September 2015)
[7] Source: EY. Digital deals: spotlight on life sciences. (February 2017).

Figure 2
The UK Digital Health Markets in 2014 (Source: Monitor Deloitte) [6]
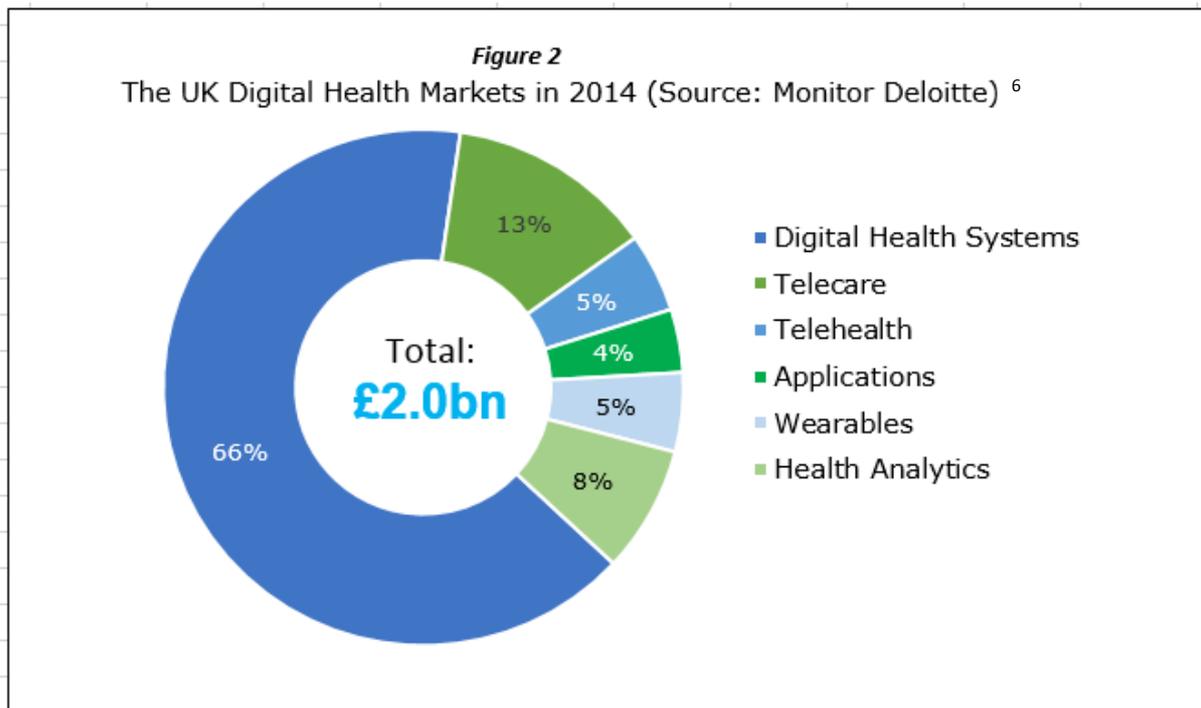
3.2. Context, Market and Current Challenges

As yet, there is no clearly defined pathway for the development, commercialisation and commissioning of digital health products in England. The Accelerated Access Review[8] sets out new recommendations regarding how patients could get quicker access to innovative new diagnostic tools, treatments, and medical technologies including a high-level pathway for digital products, but a number of gaps still remain.

An immature market and a nascent commercialisation pathway for digital health products, coupled with complex regulatory, commissioning and reimbursement models within the NHS, create a challenge for innovators seeking to successfully monetise their digital health products.

Multiple misalignments exist in the current system. The "supply" side (innovation policy-makers, entrepreneurs, investors) and the "demand" side (health policy-makers, regulators, health technology assessment, purchasers) operate under different and conflicting logics. "Value" means different things to different stakeholders and whilst supply-side regulatory checks are designed to assure quality, safety and efficacy. This does not ensure that technologies entering the market are either desirable or cost-effective. Assessment of comparative and cost-effectiveness usually comes too late in the process to shape an innovation's development[9].

An integral part of the challenge going forward will be for innovators to pursue a robust clinical and regulatory framework that can deliver new products and services which are fit-for-purpose within the healthcare system and which demonstrate clear benefits for patients, clinicians, healthcare providers, and commissioners. An additional challenge is understanding the requirements of different healthcare systems within the global market and the associated challenges of implementation and uptake.

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[8] Source: Gov.uk Accelerated Access Review
[9] Source: The Bright Elusive Butterfly of Value in Health Technology Development, Comment on "Providing Value to New Health Technology: The Early Contribution of Entrepreneurs, Investors, and Regulatory Agencies". Trisha Greenhalgh*, Nick Fahy, Sara Shaw 2017

Challenges for innovators include understanding:

- the health and social care environments

- which stakeholders to approach to discuss the concept

- the General Data Protection Regulation (GDPR) , information governance requirements, and other data regulations

- the regulatory requirements

- how a product will be paid for and procured within the NHS

- how to test and validate the product and the evidence base required

- the pathway to adoption for the product within the health and social care system within the UK markets

Digital health is a rapidly evolving landscape. There is a need to consolidate key learnings and recommendations in order to facilitate the process of designing, developing, testing and bringing new digital health products to market. Currently, the market is largely driven by high consumer demand for digital health products (in particular mobile health) which do not need to go through such a complex pathway. However, the market for clinically proven digital health products is still evolving and will, with time require a deeper understanding of value, based upon solid clinical evidence and quantifiable economic evidence in healthcare systems (e.g. within primary, secondary, tertiary and social care settings).

Health and social care commissioners and purchasers need assurance that digital health products are of a high quality, clinically safe, evidence-based, and user-friendly. Additionally, it is essential that they deliver value for money and can be maintained and updated so that they continue to deliver benefit to the system in the longer term.

With guidelines set out in the NHS Five Year Forward View, the overarching objective of harnessing the information revolution is to make the NHS paperless by 2020. This vision is encompassed in the National Information Board's Personalised Health and Care 2020 Framework, of which NHS England is a key stakeholder and contributor. The key points are:

- NHS England's vision is to transform the way people experience the NHS, by designing digital health tools and services that connect them to the information and services they need, when they need them. To help with this, two new digital platforms (NHS Digital Tools Library and a Mobile Health space for developers on Developer.nhs.uk) have been launched.

- New digital tools pages on NHS choices (http://www.nhs.uk) showcase a selected number of apps in the 'testing' phase. The vision is for www.nhs.uk to host leading healthcare apps so they are accessible and trusted by the public. Each tool has been through an assessment and is safe to use.

- NHS Digital will oversee the technical categories, whilst The National Institute for Health and Care Excellence (NICE) will preside over the indicators of effectiveness and the Medicines & Healthcare Products Regulatory Agency (MHRA) will oversee the regulatory framework.

- The National Institute for Heath and Care Excellence (NICE) has produced several Health Application Briefings (HABs).

- NHS England has developed the Innovation and Technology Payment (ITP) 2018/19. Building on the Innovation and Technology Tariff (ITT), the ITP aims to support the NHS in adopting innovation by removing financial or procurement barriers to uptake of innovative products or technologies.

- A competitive process to identify cost effective digital and medtech innovations and technologies that will offer the greatest quality and efficiency benefits with wider adoption. The ITP is specifically focussed on low cost innovations which can deliver significant patient outcomes and savings to the NHS and have a wide-reaching impact on patient care. The programme will be delivered in partnership with the Academic Health Science Networks (AHSNs), sponsors, national and international experts[10].

All of these resources will support discussion between Academic Health Science Networks (AHSNs), developers and NHS Commissioners and frontline clinicians regarding the safety, efficacy and impact of available digital health products.

3.3. Oxford AHSN's Digital Health Roadmap and Service Offering

Oxford Academic Health Science Network (Oxford AHSN) is seeking to identify and support digital innovations that address a clear and compelling clinical need and/or have a significant impact on patient outcomes, productivity and efficiency within the health and social care system. There is currently no robust process for innovators to follow in order to test the potential value of their ideas, and no structured approach for evaluating the clinical and economic value of new digital innovations. Accessing the NHS as a market can be challenging and whilst there is a wealth of information available to innovators, it is currently fragmented between various resources, and can be difficult to access.

Oxford AHSN, in collaboration with Oxford University Innovation has developed the Digital Health Roadmap (**Figure 3**) and a "Guide for Innovators" to support SMEs with an interest in developing and commercialising digital health products to navigate the pathway from concept generation through to adoption in the NHS and other healthcare systems. The Roadmap comprises seven stages: from concept through to detailed feasibility screening; development and proof of concept; and evidence building and market launch. These stages will support innovators in testing the potential value of their digital health product.

Innovators at the start of their journey can use the Digital Health Roadmap and the "Guide for Innovators" to help them determine whether their product concept is viable and has the potential to demonstrate value to the health and social care system. The Guide will also support innovators to understand the path ahead before they begin designing and developing their digital health product. For each of the seven stages of the Digital Health Roadmap, Oxford AHSN offers a range of supplementary services to support innovators with products that demonstrate clear value, to navigate through this complex environment.

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[10] NHS England Innovation and Technology Payment: http://www.innovation.england.nhs.uk/en/itp

Oxford AHSN Service Offering

Oxford AHSN has expertise in a number of key areas within the digital health pathway, from concept generation, clinical pathway mapping and real-world evidence gathering through to service evaluation and adoption of new products or services at scale and pace across the region and beyond.

Specifically, Oxford AHSN can provide support in the following areas:

- support of concept generation and access to clinical thought-leaders, clinicians and patients within the NHS to test and validate an idea

- evaluation of business propositions and support innovators to optimise the digital health products to meet the needs of the NHS market

- support for innovators with clinical pathway mapping for the development of a product or service, and understanding of the pathway to adoption of the technology

- support of the development of evaluation studies that generate robust health economic data through a real-world evidence base, gathering essential data for successful market adoption

- support of the development of a business case to commissioners, that demonstrates value for money and maximises procurement of the product

- support with access to a network of potential funding bodies to bring the new product to market

- providing access to a community of industry leaders who can offer advice, business support and mentoring to innovators

- providing access to Oxford AHSN's network of academic and NHS resources

For more information, please contact Oxford AHSN.

Website: http://www.healthandwealthoxford.org/

3.3.1. *Oxford AHSN's Digital Health Roadmap Stages*

The Digital Health Roadmap (**Figure 3**) comprises seven stages: from concept through to detailed feasibility screening; development and proof of concept; and evidence building and market launch.

The seven stages are conceptual. In reality, the stages are fluid and merge into one another, and there are periods of re-iteration throughout the roadmap.

Figure 3

Oxford AHSN's Digital Health Roadmap
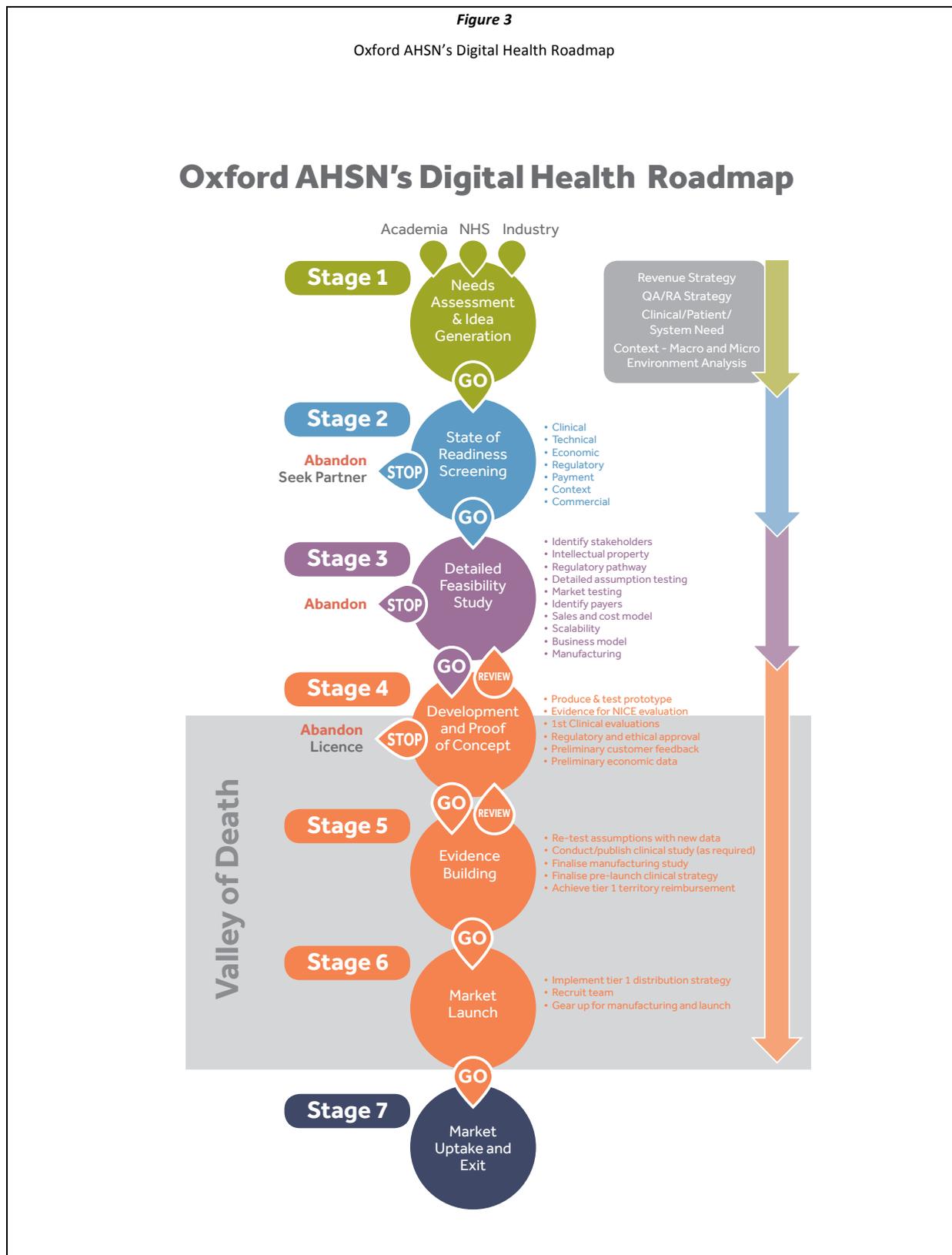
- **Stage 1 – Needs Assessment and Idea Generation**. This first stage involves developing a concept or idea from a robust assessment of the unmet clinical need and clearly articulating the problem or opportunity that the digital health product seeks to address. Oxford AHSN can support these conversations to test and refine the concept.

- **Stage 2 – State of Readiness Screening**. Oxford AHSN has developed a state of readiness checklist for innovators to carry out a self-assessment of their proposed product or service. Covering seven broad domains, this tool will help innovators to focus on the key issues that are essential to the successful development of their product, ideally before they even start to develop it. Oxford AHSN can evaluate business propositions and support innovators to pivot their business model to meet the needs of the NHS market.

- **Stage 3 – Detailed Feasibility Study**. During this stage, an in-depth assessment of the feasibility and viability of the proposed product or service will be undertaken. At this stage, Oxford AHSN will invite dynamic and committed innovators with a suitable early-stage product to participate in a Detailed Feasibility Study, providing them with access to advice, mentoring, and business support. This analysis will support creation of a fundable proposition.

- **Stage 4 – Development and Proof of Concept**. This stage is focused on developing and proving the product service through a series of iterations. Innovators will continue to refine and develop the digital health product, test it, address regulatory requirements in more detail, complete further clinical and usability testing and align the product to the targeted healthcare system. Oxford AHSN can support innovators in building the relationships required to successfully progress through this stage and get ready to build an evidence base.

- **Stage 5 – Evidence Building**. During this stage, Oxford AHSN can support innovators to generate robust evidence of relevant outcomes, such as the usability, safety, clinical and cost effectiveness of their digital health product prior to market launch.

- **Stage 6 – Market Launch**. This penultimate stage marks the launch of the digital health product in the targeted healthcare system.

- **Stage 7 – Market Uptake and Exit**. For many digital health entrepreneurs, the sale of the business at a substantial profit to a larger company ('the exit') is the very definition of success.

3.4. A Guide for Innovators developing Digital Health Products

3.4.1. Purpose of the Guide
During all seven stages of the Digital Health Roadmap, there are a number of key issues and challenges that innovators need to work on iteratively in order to convert their idea into a viable marketable product. The "Guide for Innovators" explores each of these issues in more detail.

3.4.2. Key Issues and Themes
The "Guide for Innovators" will address the following key issues and themes:

- **Starting the Journey.** Before development can begin, it is important that innovators understand what their digital health product will be, what need it will address and the key

issues they will need to navigate over the course of their journey. These issues include identifying key stakeholders, understanding the context or environment they are operating in, developing a business case, sourcing appropriate funds, and performing the state of readiness screening checklist.

- **Design and development.** Innovators will be responsible for developing a suitable initial version of their digital health product and updating it continuously throughout the development pathway. The product or service will eventually be tested in the clinical environment or directly with patients during the clinical data gathering stage, and there are varieties of topics that need to be considered both before and during software design and development.

- **Interoperability**. Innovators will need to consider how their digital health product or service will communicate, exchange data and use the information that has been exchanged. Interoperability is a crucial issue in digital health and its benefits are clear, but there is large variability regarding its implementation across the UK.

- **Information governance and data management**. The types of data controls that need to be in place will depend on the purpose of the digital health product or service. Innovators need to consider what information is processed and stored, who the users are, where the data is sourced from and who the data will be shared with. It is crucial that innovators address these information governance and data considerations early on in the development process.

- **Regulatory**. Innovators will need to address the regulatory requirements concerning the safety (patient, public and environmental) of their digital health product. This involves identifying when a digital health product qualifies as a medical device and navigating the evolving European Union (EU) and US Food & Drug Administration (FDA) regulatory landscape for medical devices. It is critical that innovators understand the current and future digital health regulatory landscape, since it will dictate the overall route to market and potentially the entire business case.

- **Clinical testing**. Throughout the Digital Health Roadmap, innovators will need to generate and collate evidence to demonstrate the value of their digital health product. The clinical trial methodology for digital health products is evolving. Oxford AHSN can support SMEs to develop data collection studies such as real-world evidence studies or health economic evaluations appropriate to the evidence required for their digital health product, in order to support adoption within the NHS and other healthcare systems.

- **Development of a commercial model and the NHS commissioning pathway**. Throughout the Digital Health Roadmap, innovators need to consider a variety of factors, in order to define the appropriate business model and go-to-market strategy for their products. The most appropriate approaches will be heavily influenced by who the payor is (which may or may not be the end-user). The Oxford AHSN team can support entrepreneurs seeking to navigate the commercialisation pathway.

Resources and Tools 1 – Existing Resources and Guidance for Digital Health Innovators

- Oxford AHSN
- http://www.oxfordahsn.org/our-work/
- Oxford and Wider Thames Valley Digital Health Report
- Oxfordshire Transformative Technologies Alliance Science and Innovation Audit: Digital Health theme led by Oxford AHSN
- OLS Guide to navigating the innovation pathway in England May 2016
- Oxfordshire Innovation Engine Update Report
- The Accelerated Access Review, including Annex C (Digital Health)
- AAR / Office of Life Sciences How To Guide - provides advice and resources on key stages of the digital innovation pathway
- Monitor Deloitte Digital Health in the UK: Industry Study for the Office of Life Sciences
- Office for Life Sciences: Industrial Strategy
- Industrial Strategy: Building a Britain for the Future
- Imperial College Health Partners (ICHP)'s pathway
- MHRA guidance on medical stand-alone software, including apps and IVDMDs
- Care Quality Commission: Clarification of regulatory methodology: PMS digital healthcare providers
- The Community Equipment Code of Practice Scheme – Assistive Technology Hub
- NHS England Five Year Forward View on the remodelling of care pathways (https://www.england.nhs.uk/five-year-forward-view/)
- NHS England Five Year Forward View Innovation into Action
- NHS England Innovation and Technology Payment
- Public Health England digital health strategy
- DHACA's pathway and report on Medical Apps Processes
- The King's Fund report on Digital Health
- The King's Fund Alternative Guide to the new NHS in England
- The World Health Organization's Monitoring and Evaluating Digital Health Interventions
- NHS Developer Site and https://apps.beta.nhs.uk/
- NHS Digital Supplier Information Exchange – Information on how NHS Digital can support route to market
- Code4Health – Initiative supported by NHS England & NHS Digital to enable best use of digital tools & technology
- https://www.england.nhs.uk/blog/apps-library-is-advance-for-a-digital-nhs/
- NHS Digital
- NICE

www.healthandwealthoxford.org   15