



# DIGITAL HEALTH INSIGHTS

A REPORT ON THE DIGITAL HEALTH SECTOR IN IRELAND





## **Digital Health Insights**

A report on the Digital Health sector  
in Ireland

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This report has been prepared for IMSTA by **Athena Life Sciences Consultancy Ltd**, in association with IMSTA's Digital Health Steering Group  
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<sup>1</sup> There are several terminologies used to describe Digital Health such as eHealth, Connected Health, Internet of Medical Things (IoMT) etc. However, for the purpose of this report the term 'Digital Health' will be used throughout the majority of this document and does not intend to omit or offend relevant stakeholders.

<sup>2</sup> Disclaimer: The information contained in this report was sourced from stakeholder interviews and secondary market reports, the contents of which cannot be held liable in respect of any business losses, opportunities or goodwill.

# 1. Executive Summary

The growing Digital Health sector is a global phenomenon with a record number of investments during 2016 of **\$8 billion in 500 Digital Health companies** alone<sup>(12)</sup>. The estimated rise in health care spend from **\$7.1 trillion in 2015 to \$8.7 trillion in 2020**<sup>(1)</sup> coupled with available technological innovations are driving the sectors growth. The Digital Health market is now expected to grow from **\$41bn in 2017 to \$158bn in 2022** in the quest to find digital solutions to address global health care challenges such as ageing populations and chronic illnesses<sup>(1)</sup>.

Ireland is seen as having an ideal eco-system to capitalize on the Digital Health emerging market due to its strong base in Medical Technologies, ICT, Pharmaceuticals/Biopharmaceuticals and Financial Services. As with the rest of the world, the number of indigenous Digital Health SMEs is steadily increasing with approximately 65 identifiable Digital Health SMEs by 2018. It is somewhat difficult to estimate the total number of Digital Health companies in Ireland due to the sector diversity, company origins and lack of industry representation, however for the purpose of this report it has been estimated that there is at least 130 Digital Health companies in Ireland.

While it is generally accepted that Digital Health can help respond to the many global healthcare challenges, it is also recognised that Digital Health companies cannot address these issues alone and need to partner closely with healthcare providers to transform patient pathways and address cultural and other issues. There are many other challenges including clinician and patient adoption, leadership, talent and skill acquisition, and industry regulation. In Ireland, budgetary issues are also at play as Ireland's national healthcare ICT spend is typically 0.85% of the total healthcare budget relative to the EU range of 2-3%<sup>(2)</sup>. However, the Government plans to increase the 2019 Health Budget from €15.2bn to €17.2bn with €1.2 billion earmarked for healthcare ICT<sup>(24)</sup>.

The Digital Health sector in Ireland today does not believe they have a dedicated industry group who can provide the sector with one voice when communicating with stakeholders. While there are a large amount of Digital Health events throughout the year, the sector does not appear to be strategically networked and can struggle to identify sector Key Opinion Leaders (KOLs), leading academics and regulatory connections.

The majority of people (88%) interviewed for this report expressed an interest in participating in an IMSTA Digital Health group to help lead, shape and influence the development of policy to facilitate and enhance the adoption of technology-enabled solutions in the Irish health service.

## 2. **Introduction**

This report was commissioned by the Irish Medical and Surgical Trade Association (IMSTA), the representative organisation for medical technology manufacturers, importers and distributors, to undertake an evaluation of Digital Health health companies wishing to lead, shape and influence the development of policy to facilitate and enhance the adoption of technology-enabled solutions in the Irish health service.

The key objectives were:

- To assess whether or not Digital Health companies in Ireland had an interest and/ or need to help shape and influence National health/ enterprise policy
- To identify, if any, the collective industry needs of the Digital Health sector
- To ascertain if the Digital Health sector would be interested in collaborating as part of an IMSTA Digital Health industry group

The evaluation drew evidence from meetings with 18 Organisations including 16 Digital Health Companies, 6 MNCs and 10 SMES as well as Government Agencies.



## 3. Background

### 3.1. IMSTA

Established in 1982 and now with over 100 member companies, IMSTA is the representative body for medical technology and healthcare suppliers in Ireland. IMSTA's membership include the full spectrum of medical technology supply and service companies from SMEs to MNCs, many of whom have R&D and/or manufacturing facilities in Ireland.

Due to the changing healthcare landscape, and growing and diverse Digital Health Sector, IMSTA is now broadening its scope to also represent health ICT companies wishing to shape and influence the development of policy to facilitate and enhance the adoption of technology-enabled solutions in the Irish health service.

IMSTA's current membership has a key role to play in the advancement of connected health by aligning IT solutions with existing medical technologies, ultimately helping health care organisations achieve better patient outcomes, lower health care costs, improved efficiency and new ways of engaging and empowering patients<sup>(1)</sup>.

IMSTA is also recognised as a reputable and trustworthy voice for the medical technology providers it represents and the stakeholders it works with. IMSTA's expertise in advocacy, government affairs, public relations and lobbying have enabled the organisation to effectively develop and propose health policies which benefit patients, the health service, industry and the economy.

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### 3.2. Healthcare & Digital Health

Digital Health is the integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. This includes patients and their records, caregivers and their systems, monitoring devices and sensors, management and administrative functions. It is a fully integrated digital 'supply chain' and involves high levels of automation and information sharing <sup>(2)</sup>.

It is now accepted that Digital Health is a critical enabler of best-practice health systems and optimum healthcare delivery. Embedded in the management of delivery processes, Digital Health is essential to ensure significant continuous improvements in efficiency, effectiveness, quality and safety of patient services and underpins organisational transformation and development. The availability of high quality, accurate and timely information is fundamental to enhanced provider-patient relationships with the resultant improvements in outcomes <sup>(2)</sup>.

## a. Struggling Health Care Systems

The rise of digital care comes at a time when health care is becoming increasingly expensive with global spending expected to grow 4.2% per year, from \$7.1 trillion in 2015 to \$8.7 trillion by 2020. This increase can be attributed to ageing populations, people living longer with multiple comorbidities and an increase in chronic diseases across age groups <sup>(1)</sup>.

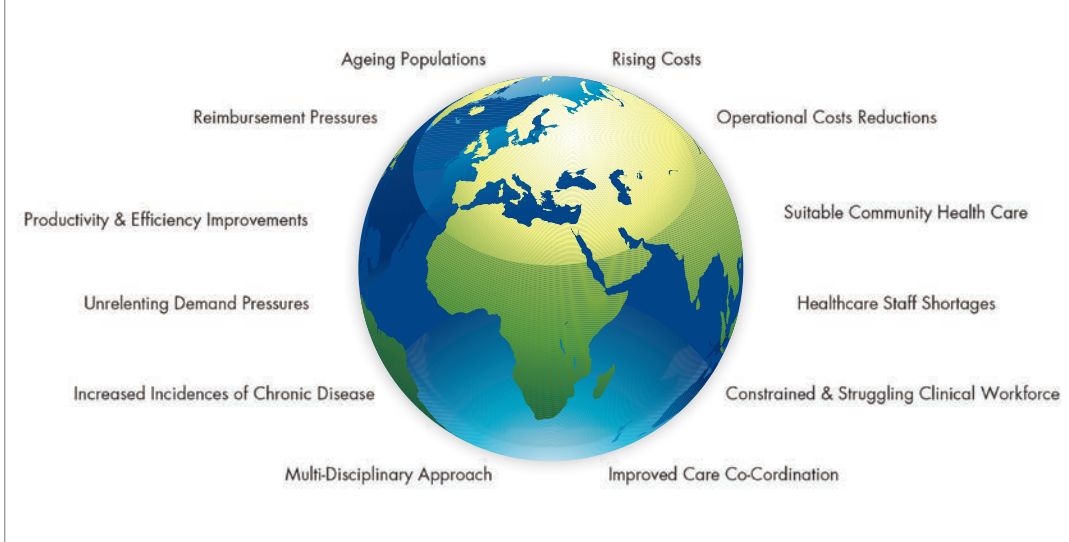
Chronic diseases such as Diabetes Mellitus Type 2, Heart Failure and Chronic Pulmonary Obstructive Disorder (COPD) are on the rise globally with Diabetes Type 2 being branded an ‘epidemic’ by all major global health organisations. A major contributor to the rise of chronic diseases is the problem of obesity across developed countries <sup>(2)</sup>.

In addition, seasonal related illnesses such as the 2017 -2018 flu was the worst in several years. Hospitalisations, mortality and prevalence were up considerably thereby increasing care utilization and driving up medical costs <sup>(3)</sup>.

Cost, staffing and demographics challenges, combined with an exponential rate of technology change and advances in medical science are forcing a shift in the conventional model of health care provision towards value-based care <sup>(1)</sup>.

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**FIGURE 1: GLOBAL HEALTH CARE CHALLENGES**



3.

## Background continued

3.2.

## Healthcare & Digital Health continued

In common with healthcare systems globally, the Irish healthcare delivery system faces significant challenges in continuing to efficiently and equitably deliver high standards of health outcomes while also facilitating the fundamental healthcare reorganisation to which Ireland has committed. Globally these challenges can be seen by the increasing amounts of national GDP being allocated to healthcare spending <sup>(2)</sup>.

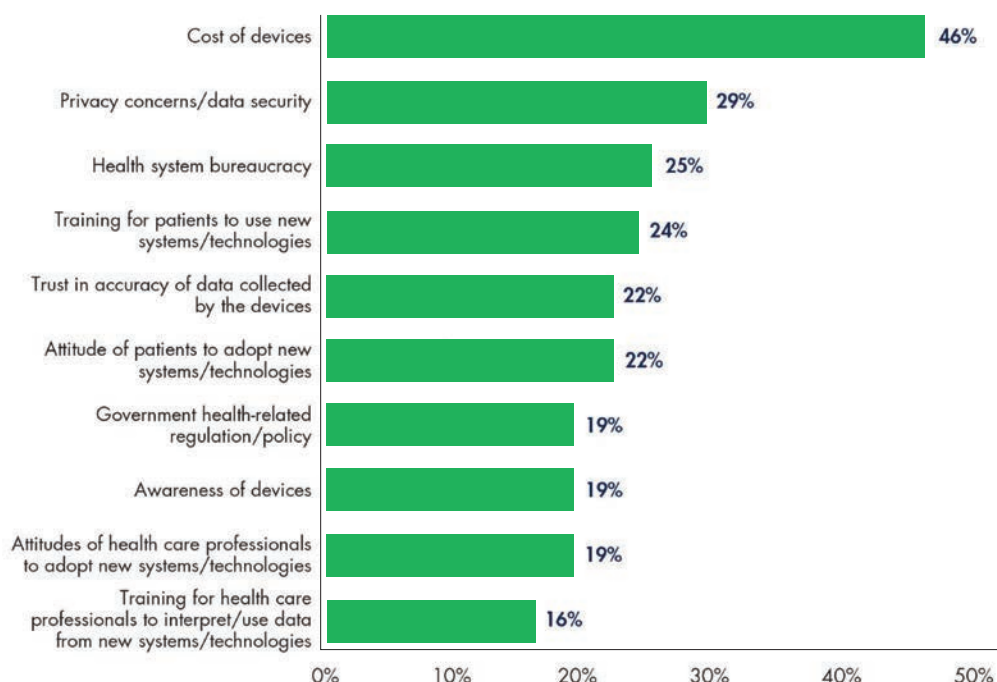
The healthcare sector globally has traditionally lagged behind other industry domains where powerful information-based systems have been embedded for well over 30 years or more. Reasons for this include failure to adapt and change, operational and management processes, lack of technical standards and reimbursement solutions among others (see Figure 2). However it is generally acknowledged that the integration of health systems and processes via information technology will be a critical enabler in the transformation of healthcare service delivery, the promotion of population health and wellbeing, and the creation of significant economic development potential <sup>(2)</sup>.

Health care systems can be characterised by their underdeveloped infrastructure which result in acute shortages of resources. Governments worldwide are looking to improve healthcare access and affordability without compromising quality of care.

Patients and consumers are also more discerning around their own health and customer experience. Healthcare providers that fail to adopt to this consumer shift will risk consumers running elsewhere to have health needs met <sup>(3)</sup>.

The healthcare sector globally has traditionally lagged behind other industry domains where powerful information-based systems have been embedded for well over 30 years or more.

**FIGURE 2: TOP TEN PERCEIVED BARRIERS TO ADOPTION OF CONNECTED TECHNOLOGY<sup>3</sup>**



<sup>3</sup>Source: Philips Future Health Index 2016



## b. Benefits of Digital Health

It is now generally accepted that successful reform of healthcare systems and delivery is highly dependent on realising the potential of Digital Health as a change catalyst and enabler in addressing the challenges of new and existing models of healthcare <sup>(2)</sup>. However Digital Health care should not be about the technologies alone but about identifying new ways of solving healthcare problems, creating better experiences for patients and efficiencies for providers. Transformational leadership is also necessary to ensure change is sustainable, measurable and creates positive benefits for both patients and those working to deliver healthcare.

**TABLE A: THE BENEFITS OF DIGITAL HEALTH<sup>4</sup>**

| Benefits to Patients   | Benefits to Care Givers   | Benefits to Health Care Management   | Benefits to the Economy   |
|--|---|--|---|
| Enables personalised, preventative and proactive care throughout the health system and across the lifespan   | Gives access to current, specialised, accredited knowledge for clinical care, research and public health; and to research, publications and databases | Establishes hospitals as a virtual network of providers, connecting all levels of the System   | Investment in eHealth brings new markets & encourages business start-ups & entrepreneurial activities       |
| Patient/Citizen is empowered to manage their own health journey  | Enables better communication between patients and providers regardless of physical distance between them.   | Monitors quality and safety; improves care processes and reduces the possibility of medical errors   | Such eHealth services are imminently exportable once developed  |
| When patients/ citizens interact with the healthcare system, healthcare providers will know who they are and have access to relevant details of their health information | Makes high-quality distance learning for basic and continuing professional education readily available  | Allows transparency of delivery system and enables budget, pricing, billing, claims and resource management systems  | Development & innovation of eHealth services will lead to extensive R&D and product/ services opportunities |
| Will have the ability to access their own health records and maintain a personal health diary  | Allows remote consultations with patients for second opinions and with professional networks  | Assists mobility of citizens and their medical records – providing patient empowerment   |   |
| Will have the ability to better manage their own health through access to reliable and accredited sources of health information  |   | Opens new opportunities in basic and applied research; from health knowledge to policy and actionable information when and where needed  |   |
| Care can be brought to remote rural areas where distance to care may otherwise have been an issue.   |   | Delivers more reliable, responsive and timely reporting on public health; as health becomes increasingly central to economy, security, foreign affairs and international relationships |   |

<sup>4</sup>Source: EHealth Ireland <http://www.ehealthireland.ie>

3.

## Background continued

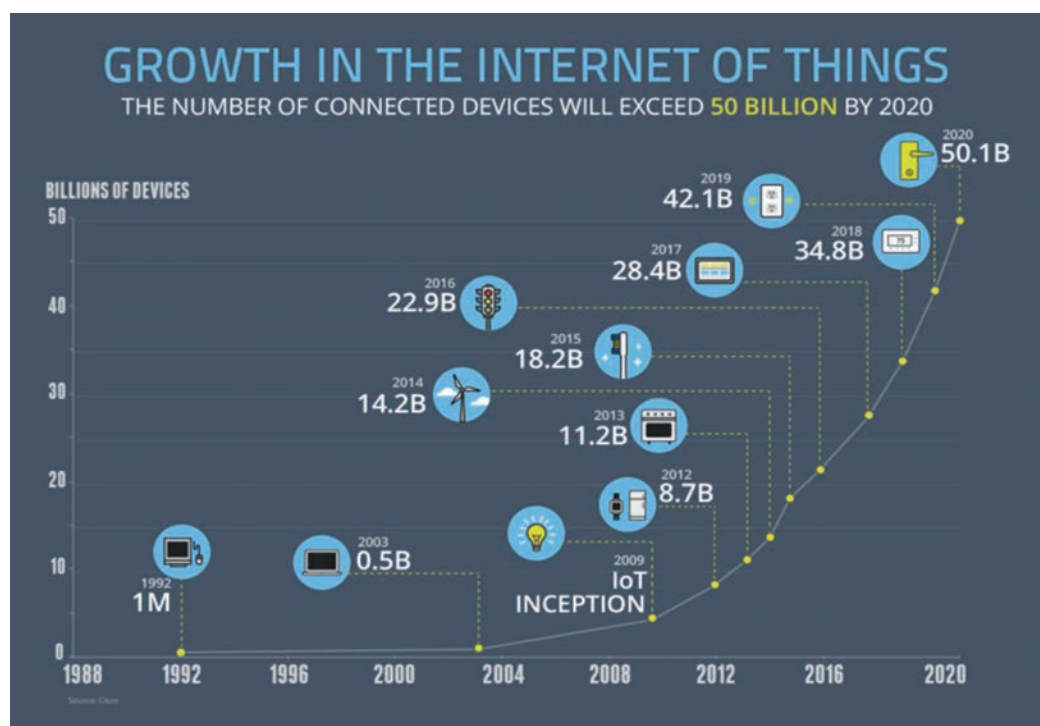
3.2.

## Healthcare & Digital Health continued

### c. Digital Health Systems

Digital Health systems have grown organically from the late 1990's as digital communications processing power has evolved in line with Moore's Law<sup>5(2)</sup>. There has been increasing interest in the use of digital technologies within the healthcare field as digital devices have become more powerful, more mobile and cheaper in cost. Cisco has reported that the number of internet connected devices will reach 50 billion by 2020 equating to an average of 6.5 internet connected devices for every person on the planet and by 2022, 1 trillion networked sensors will be embedded in the world around us, with up to 45 trillion in 20 years<sup>(4)</sup>.

**FIGURE 3: GROWTH IN THE INTERNET OF THINGS<sup>6</sup>**



<sup>5</sup> Source: Moore's Law is a computing term which originated around 1970; the simplified version of this law states that processor speeds, or overall processing power for computers will double every two years.

<sup>6</sup> Source: <https://www.ncta.com/whats-new/behind-the-numbers-growth-in-the-internet-of-things-2>

## Digital Health systems categories<sup>7</sup> include:

### i. EHR & ePrescribing

Electronic Records are generally classified using a hierarchical structure. At the top level are **Electronic Health Records (EHRs)**. These are generally associated with an enterprise-wide record system within a hospital or hospital network and are 'hosted' by the institution. Beneath this are Electronic Medical Records (EMRs) and Personal Health Records (PHRs). EMRs generally refer to smaller non-enterprise deployments of record systems, such as standalone hospitals or GP clinics. Personal Health Records (PHRs) such as Microsoft HealthVault are maintained and updated locally by the individual (patient) <sup>(2)</sup>.

Such record systems typically replace classic manual paper-based records to a greater or lesser extent. Key to the deployment of electronic records, in a national health service setting, is the existence of a national health identification number on which the records system is centred <sup>(2)</sup>.

**Recent example:** In October 2018 St. James's Hospital Dublin installed the Cerner Millennium EHR system <sup>(5)</sup>.

**ePrescribing** typically refers to the process of fulfilling medical prescriptions outwards from clinician to patient via pharmacy. Sometimes referred to as Drug Information Systems (DIS), these systems are concerned with the automation of the medication prescribing process including online repeat prescription ordering. The goal of ePrescribing systems is to reduce errors due to manual prescribing and incorrect fulfilment and to speed up access for the consumer to necessary prescriptions. In Ireland medication errors cost the state around €10 - €15 million per annum. International experience has demonstrated that a phased approach to ePrescribing systems with initial efforts concentrating on dispensing medication within the community rather than hospital settings is best <sup>(2)</sup>.

Currently, there is a legal requirement in Ireland to produce a paper prescription for patients to present to their pharmacist, but legislation is being drafted to allow for electronic prescribing, which is currently being piloted to trial available models in discrete locations in Ireland <sup>(6)</sup>.

**Example:** eScript is a pilot prescription notification service being run by Clanwilliam Group that sends a secure notification of the prescription details from the GP's computer to the patient's chosen pharmacy <sup>(6)</sup>.

The goal of ePrescribing systems is to reduce errors due to manual prescribing and incorrect fulfilment and to speed up access for the consumer to necessary prescriptions.

<sup>7</sup> Due to the speed at which ICT technology is moving the range and number of Digital Health systems/ applications is very diverse. It is therefore difficult to fully categorise all Digital Health products and services being offered at any one point in time.

3.

**Background** continued

3.2.

**Healthcare & Digital Health** continued**ii. Telehealthcare & Telemedicine**

The terms telehealthcare and telemedicine are often used interchangeably. However, strictly speaking telemedicine can be viewed as a higher level (parent) category covering many areas of which telehealthcare is one subset.

**Telemedicine** systems include remote radiology (teleradiology) and reporting and teleconsultations between doctor and patient.

**Telehealthcare** (also called eHealth or mHealth) systems are concerned with the remote monitoring and management of personal healthcare usually from a remote location such as the home, with the aim being to proactively manage healthcare and avoid costly hospitalisations<sup>(21)</sup>. Various technology devices such as blood pressure monitors, glucometers, lung capacity monitors and others are deployed to the remote setting (most often the home) and regular measurements are made using the devices deployed. The data is typically transmitted back to a monitoring base (often a hospital) where decision support systems featuring pre-set alarms, alerts and management care flows, assist attendant care personnel. Telehealthcare systems show significant potential for the proactive management of chronic diseases. Many trials and pilots have been implemented over the past ten years and full commercial deployments are now becoming more common.

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The major advances in wireless technology, miniaturisation and computing power is driving innovation in medtech.

The major advances in wireless technology, miniaturisation and computing power is driving innovation in medtech, leading to the development of an increasing number of connected medical devices that are able to generate, collect, analyse and transmit data. The data, along with the medical devices themselves, is creating the Internet of Medical Things (IoMT). The IoMT is rapidly transforming medtechs relationship within health care <sup>(1)</sup>.

**Telemedicine example includes:** NIMIS Enterprise Medical Imaging Solution by Change Healthcare <sup>(7)</sup>. Telehealthcare examples include: AliveCor's Kardia Mobile which can remotely monitor cardiac patients ECGs. Patients can record an ECG and email directly to their physician <sup>(8)</sup>.

**iii. Digital Therapeutics**

A digital therapeutic is an intervention based on software as the key ingredient, which has direct impact on a disease. This is what distinguishes this category from the broader term Digital Health <sup>(9)</sup>. Digital therapeutics are beginning to demonstrate how software can work in conjunction with traditional healthcare and therapeutics to deliver cost savings and better patient outcomes e.g. a sensor placed on an inhaler or pill bottle enables an app to track a person's medication usage or a software package delivering drug and alcohol addiction treatment, teaching new coping skills and reporting progress to a clinician.

The development of these and many other digital therapeutics is leading to major changes in the healthcare landscape that will impact every healthcare player, from pharma and regulators, to payors and providers, and, ultimately, patients. As a result, pharma now has the opportunity to realise the potential of this new force in healthcare and regulatory bodies must ensure digital therapeutics are deployed safely through standards development.<sup>(10)</sup>

**Examples include:** Akili Interactive <sup>(30)</sup> and Pear Therapeutics <sup>(31)</sup>.

#### iv. Consumer Digital Health

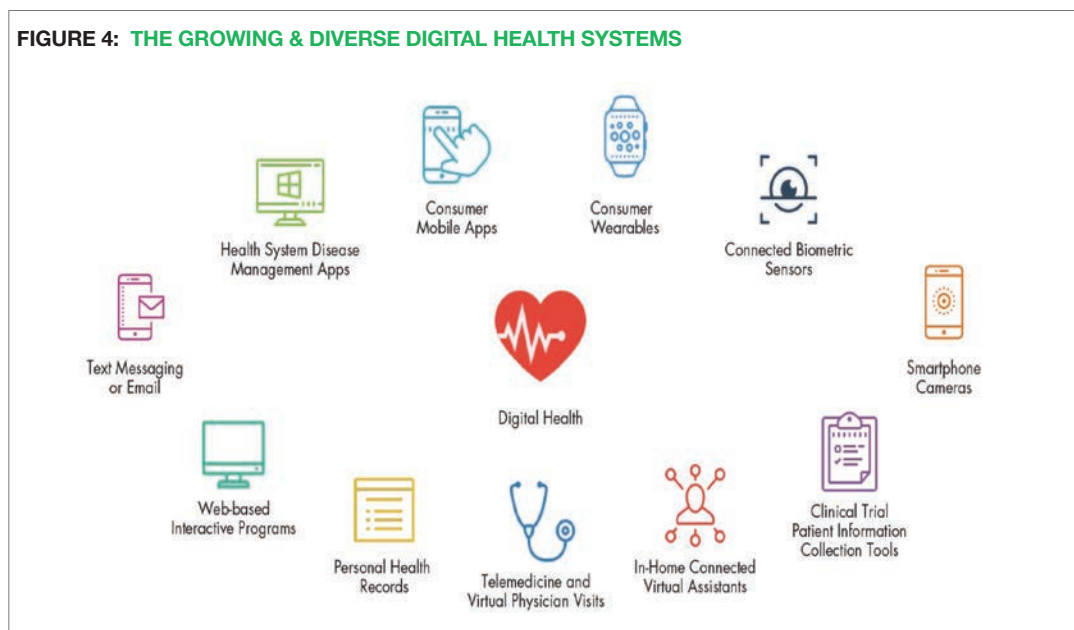
Consumer Digital Health is rapidly becoming a fundamental component of healthcare with €2.8 billion globally invested in 2017. Consumer Digital Health can be split into groups Personal Healthcare Companies and Healthcare Service Platforms.

Personal Healthcare companies such as Patients Like Me <sup>(25)</sup> and Resound <sup>(26)</sup> develop connected devices and provide digital solutions to help consumers or patients.

Healthcare Service platforms on the other hand offer web-based platforms and mobile apps which help patients in avail of healthcare services e.g. Web Doctor <sup>(27)</sup>, One Medical Group <sup>(28)</sup> and 23 & Me <sup>(29)</sup>

Digital therapeutics are beginning to see how software can work in conjunction with traditional healthcare and therapeutics to deliver cost savings and better patient outcomes.

**FIGURE 4: THE GROWING & DIVERSE DIGITAL HEALTH SYSTEMS**





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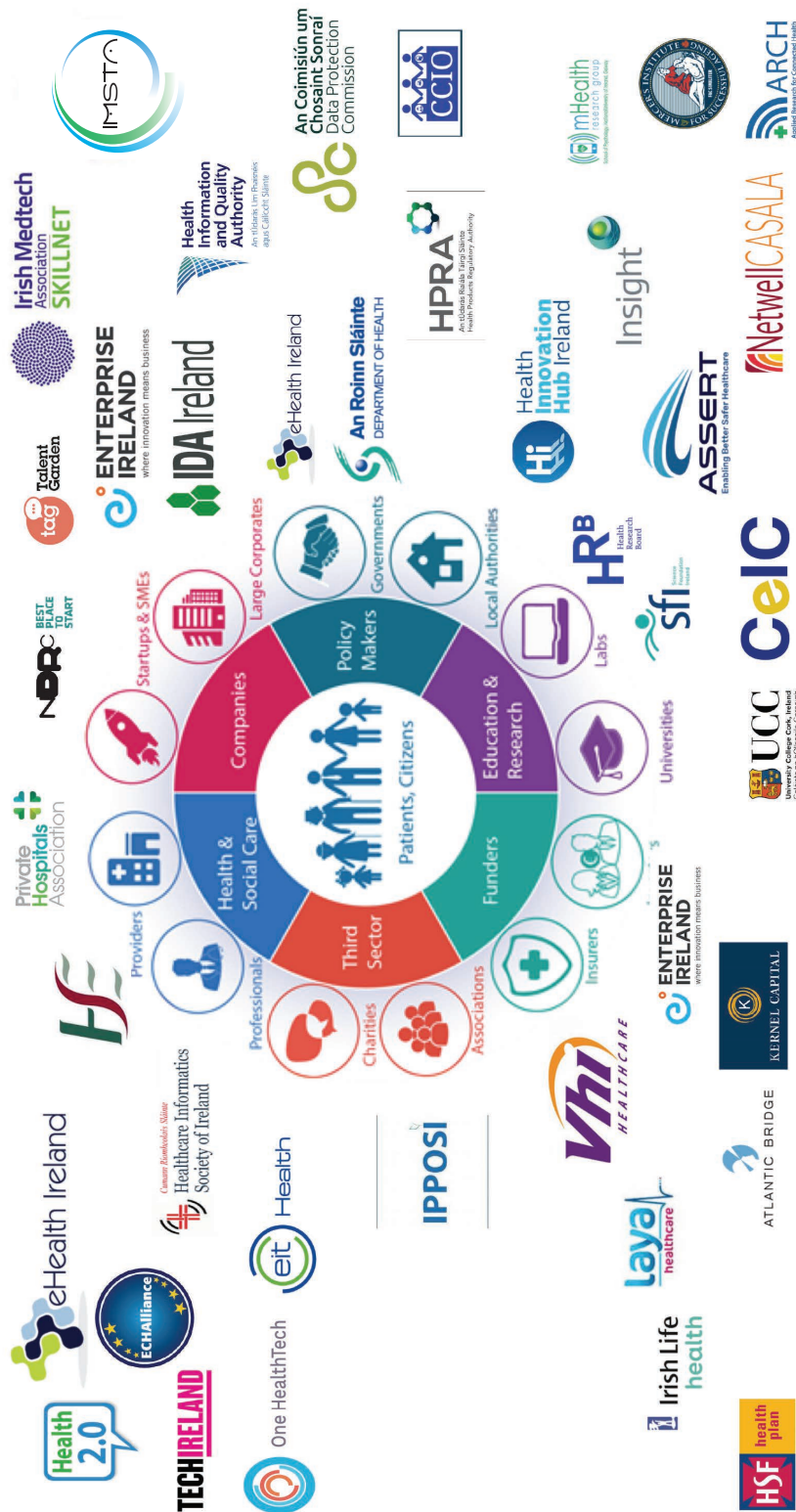
## Background continued

**FIGURE 5: DIGITAL HEALTH LANDSCAPE<sup>8</sup>**



<sup>8</sup> Source: <https://home.kpmg.com/xx/en/home/insights/2016/03/current-digital-healthcare-landscape.html>

**FIGURE 6: DIGITAL HEALTH STAKEHOLDERS<sup>9</sup>**



<sup>9</sup> Source: Diagram amended for IMSTA. Original Core Diagram Source: <https://www.ehealthireland.ie/News-Media/News-Archive/2018/Digital-Strategy-Creation-the-Health-Perspective.html>

3.

**Background** continued

3.3.

**The Digital Health Landscape in Ireland****a. Sector Stakeholders**

Ireland is in an ideal position to capitalise <sup>(10)</sup> on emerging Digital Health markets due to its already-strong base within the key pillar industries of Medical Devices, ICT, Pharma/Bio and Financial Services. An economic impact analysis for Ireland estimates that a properly executed Digital Health strategy, leading to the development of commercial and export-oriented opportunities, can add between 2 and 2.9% to National GDP and contribute a significant number of highly skilled jobs to the economy. Overall, Digital Health needs to be seen as an infrastructural investment in Ireland's future, not only for the transformation of the Irish healthcare sector, but also for the economy as a whole <sup>(2)</sup>.

Investment in Digital Health brings new markets and encourages business start-ups and entrepreneurial activities. Quite aside from the benefits to population wellbeing and improvements to healthcare system delivery, there are significant potential economic benefits associated with investment in Digital Health infrastructure. The creation of new 'Digital Health markets' gives rise to entrepreneurship and start-up opportunities and much of this will be readily exportable <sup>(2)</sup>. Ireland is already seeing this increase in Digital Health starts ups with 65 companies already established, e.g. companies such as Oneview, TickerFit, Beats Medical, Jinga Life and PatientmPower.

The rise in Digital Healthcare companies is a global phenomenon; a record number of global investments took place in the sector in 2016 with over \$8 billion invested in over 500 Digital Health companies alone. This investment has fueled innovation in medicine, infrastructure and consumer-driven health <sup>(12)</sup>.

eHealth Ireland estimated that there are 179 Digital Health companies with over 2300 employees in Ireland. However this estimate includes many of the medtech MNCs such as Boston Scientific, GE and Abbott <sup>(13)</sup>. For the purpose of this report it has been estimated that there are at least 130 Digital Health companies in Ireland.

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<sup>10</sup> Source: Ireland's life sciences sector exports more than €45 billion annually to global healthcare markets and employs over 50,000 people directly (11). Ireland is recognised as a global hub for the manufacture and research of medical technologies with over 300 companies employing 29,000 people and 60% of companies carrying out valuable R&D activities. Indeed, Ireland has the highest number of personnel per capita employed in Medtech in Europe. And as a leading cluster for medical device products globally, exports of medical devices and diagnostic products now represent 8% of Ireland's total merchandise exports (11). As the second largest exporter of Medtech products in Europe, Ireland supplies 95 of the world's top 100 countries (ranked by GDP).

## b. Healthcare Stakeholders

### Department of Health

The Department of Health's recently published Sláintecare provides a vision for a new health service in Ireland. It is the first time there has been political consensus on a health reform plan for the next 10 year years and cross party support on delivering a universal health system in Ireland <sup>(14)</sup>. Over the next ten years, Sláintecare promises to:

- Promote the health of our population to prevent illness
- Provide the majority of care at or closer to home
- Create a system where care is provided on the basis of need not ability to pay
- Move our system from long waiting times to a timely service – especially for those who need it most
- Create an integrated system of care, with healthcare professionals working closely together <sup>(15)</sup>.

Sláintecare strategic action plan also points to putting in place a modern Digital Health infra-structure and improve data, research and evaluation capabilities (see figure 7).

**FIGURE 7: SLÁINTECARE STRATEGIC GOALS<sup>10</sup>**

| 4 Goals |  | 10 Strategic Actions |   |
|---------|--|----------------------|---|
| Goal 1  | Deliver improved governance and sustain reform through a focus on implementation.      | Strategic Action 1   | Improve governance, performance and accountability across the health service.   |
|         |  | Strategic Action 2   | Put in place an effective implementation and governance structure for Sláintecare and establish a Sláintecare transition fund to support key reforms.             |
| Goal 2  | Provide high quality, accessible and safe care that meets the needs of the population. | Strategic Action 3   | Improve population health-based planning and develop new models of care to deliver more effective and integrated care.  |
|         |  | Strategic Action 4   | Expand community-based care to bring care closer to home.   |
|         |  | Strategic Action 5   | Develop and modernise the acute care system to address current capacity challenges and increase integration between the hospital sector and community-based care. |
|         |  | Strategic Action 6   | Expand eligibility on a phased basis to move towards universal healthcare and support a shift to community-based care.  |
| Goal 3  | Ensure the health system is financially sustainable.                                   | Strategic Action 7   | Reform the funding system to support new models of care and drive value to make better use of resources.  |
|         |  | Strategic Action 8   | Implement measures to address inequities in access to public acute hospital care based on the independent impact assessment.                                      |
| Goal 4  | Enable the system to deliver its goals.  | Strategic Action 9   | Build a sustainable, resilient workforce that is supported and enabled to deliver the Sláintecare vision.   |
|         |  | Strategic Action 10  | Put in place a modern eHealth infrastructure and improve data, research and evaluation capabilities.  |

<sup>10</sup> Source: <https://health.gov.ie/wp-content/uploads/2018/08/Sláintecare-Implementation-Strategy-FINAL.pdf>

3.

**Background** continued

3.3.

**The Digital Health Landscape in Ireland** continued**eHealth Ireland**

eHealth Ireland is the HSE's office of the Chief Information Officer (CIO) which has been tasked with delivering Ireland's eHealth Strategy. The latest eHealth strategy was published in 2013 outlines the importance of recognising eHealth as a national infra-structural investment for Ireland. eHealth Ireland work closely with all key business organisations within the health service in order to drive the eHealth strategy and ensure that key IT systems are implemented on time and to budget.

Seven key strategic eHealth programmes were agreed as a priority for eHealth Ireland which would act as a catalyst for change in how technology can deliver health in Ireland including: Individual Health Identifier (IHI), ePrescribing, eReferral, Telehealthcare (chronic disease) and EHR<sup>(15)</sup>.

**c. Regulatory Bodies**

**Health Products Regulatory Authority (HPRA):** is a State agency that governs and regulates the use of health products in Ireland to ensure their safe use in human and veterinary medicine<sup>(17)</sup>.

The ever-changing regulatory environment is constantly evolving which makes it challenging not only for life science sector but for Ireland's developing Digital Health care sector. While there is a well-recognised regulation pathway for pharmaceuticals and medical technologies products, the regulatory pathway for Digital Health companies has not been so clear.

In 2012 the Poly Implant Prothese (PIP) scandal sparked a global healthcare scare which prompted the EU Commission to seek to strengthen the existing Medical Device Directive (MDD) 93/42/EEC. The new Medical Device Regulation (MDR) will replace the existing Medical Device Directive (MDD) and Active Implantable Medical Devices (AIMD)<sup>(18)</sup> and aims to be fully implemented across Europe by 2020. It applies to all medical device manufacturers who intend to place their products in the European Union which accounts for one-third of the global medtech market.

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The ever-changing regulatory environment is constantly evolving which makes it challenging not only for life science sector but for Ireland's developing Digital Health care sector.



The new regulation will also introduce new rules, including specific requirements addressing the classification of software. The new classifications cover diagnostic, therapeutic, and physiological purposes, with the potential impact on patient safety and treatment determining the classification:

- **Class III** software intended to provide information used to take decisions for diagnostic or therapeutic purposes that has the potential to cause death or an irreversible deterioration in health.
- **Class IIb** software intended to provide information used to take decisions for diagnostic or therapeutic purposes that can cause the serious deterioration of a person's health or a surgical intervention. Also covers software intended to monitor vital physiological parameters that could result in immediate danger to a patient.
- **Class IIa** software intended to provide information used to take decisions for diagnostic or therapeutic purposes or to monitor physiological processes.
- **Class I** all other software.

#### d. Research Groups<sup>11</sup>

**Centre for eIntegrated Care (CeIC) DCU:** is based at DCU's School of Nursing and Human Sciences and led by Dr. Pamela Hussey, the centre aims to apply health and social care research findings to the delivery of connected healthcare in Ireland. Dr. Hussey has over 20 years' experience in nursing and health informatics and has also developed EU health informatics standards.

The CeICs first task is to help design the information architecture in partnership with the HSE to support eHealth Ireland which will involve defining properties of health records to optimise communications.

Secondly, the centre will help cultivate innovation through health ecosystems and communities of practice and provide scholarships, acting as a springboard to assist practitioners, patients and industry in Ireland to assimilate, learn and do <sup>(21)</sup>.

**The Innovation Value Institute (IVI):** was established in 2006 as a not-for-profit multi-disciplinary research and education institute within Maynooth University, Ireland. It was co-founded by Intel Corporation and the University with the objective of creating an international consortium of companies and public sector organisations to build on work already carried out in Intel and create an international standard for the management of information technology. Enterprise Ireland and IDA Ireland, through the Technology Centre programme, support IVI's research agenda to focus on the creation and accumulation of knowledge and best available practices in the management of IT <sup>(22)</sup>.

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<sup>11</sup> Source: <https://www.idaireland.com/doing-business-here/industry-sectors/medical-technology>. Accessed September 2018.

3.

## Background continued

3.3.

## The Digital Health Landscape in Ireland continued

**Insight – Centre for Data Analytics:** is a SFI funded research centre and one of Europe's largest data analytics research organisations, with 400+ researchers, more than 80 industry partners and over €100 million of funding.

Insight is made up of four main centres in DCU, NUI Galway, UCC and UCD. Insight's research aims to find solutions for the areas of connected health and the discovery economy. The centre is currently conducting research projects whose outcomes are expected to benefit Chronic Disease Management & Rehabilitation, Novel Personal Sensing, Connecting Health & Life Sciences, Smart Enterprise and Discovery Analytics <sup>(23)</sup>.

**Health Innovation Hub Ireland (HIHI):** works across the health sector with Irish businesses to creatively solve problems and improve patient care through development of new healthcare technologies, products, and services. HIHI is funded by Enterprise Ireland and supported by the Department of Health & Department of Business, Enterprise & Innovation.

HIHI is head quartered in UCC and has offices in Dublin (St. James CRF) and Galway (Galway CRF). The HIHI works to help forge relationships between SMEs and healthcare professionals /clinical networks. HIHI works with connected healthcare companies that need to access the clinical system for development reasons. To date HIHI has assisted with over 100 healthcare projects. HIHI also reaches out to healthcare professionals looking to develop an innovative idea through open or targeted research calls <sup>(16)</sup>.

### Other related research centres:

Cloud Computing Technology Centre  
(EI/ IDA Funded)

<http://www.ic4.ie>

Data Analytics Technology Centre  
(EI/ IDA Funded)

<http://www.ceadar.ie>

Connect – Centre for Future Networks  
& Communications (SFI Funded)

<https://connectcentre.ie>

CURAM – “Smart” Medical Devices & Implants  
(SFI Funded)

<http://www.curamdevices.ie>

INFANT – Dedicated Perinatal Research  
Centre (SFI Funded)

<http://www.infantcentre.ie>

TRIL – Supporting Independent Living (UCD)

<https://www.cs.ucd.ie/tril-supporting-independent-living>

Assert UCC – Enabling Safer Healthcare

<https://assert.ucc.ie>

## 4. **IMSTA Digital Health Report Findings**

### **a. Stakeholder Findings**

Eighteen individuals were interviewed from 16 leading Digital Healthcare companies and 2 Government Agencies. Stakeholders were consulted with to establish their interest in participating and/ or supporting a Digital Health Trade Association within IMSTA and to also identify current key industry challenges. Another 13 Digital Health companies were also briefly consulted with at the HISI 2018 Conference in Croke Park.

Based on stakeholder company interviews the following was concluded:

- There is an interest in industry coming together to help support the Digital Health sector under the auspices of IMSTA.
- Stakeholders are very supportive about the Implementation of Sláintecare. They wish to ensure that the environment is in place for its success and support the health systems ability to implement the change needed to support a Shift Left strategy i.e. moving from acute care to community settings to home settings while ensuring that the quality of care is enhanced, leveraging innovation and information to bring new approaches to address unmet needs.

Key Industry challenges include:

- The National roll out of successful Digital Health programmes. Unfortunately many Digital Health projects do not make it past pilot stage.
- Open EHR systems (interoperable with other systems) are important to help foster healthcare innovation, however questions around data security & regulation remain.
- There appears to be a lack of value outcomes experience within Digital Healthcare due to lack of skills and data management.
- SMEs are concerned that Ireland's health system is unable/ unwilling to procure innovative Digital Health solutions from SMEs who are encouraged and often funded by other government agencies to develop and grow young innovative businesses.
- Real collaboration between SMEs and customers or larger companies is a challenge but the benefits of these collaborations may be exponential for the health service.
- On-going integration challenges (software integration i.e. that products work as one solution. Instead of passing information between the two systems over a bridge, the systems share the same code and database).
- Brexit will be challenging regarding information flow and regulation.
- The continuously changing regulatory environment across the sector.

## 5 Conclusion

The magnitude of the challenge facing health care is considerable. Its implications are far reaching for all aspects of society and the economy. Finding a sustainable solution to enable better health care delivery is no longer the sole responsibility of the public sector but a collective responsibility across the public and private sectors to redefine traditional health care business models to find new pathways to sustainability.

Innovative Digital Health companies are empowering health care providers with new solutions and forcing the entire industry to rethink the way it does business. With patients becoming more discerning around their own health, customer experience has become a key motivator for many providers.

The Digital Health sector in Ireland today does not have a dedicated industry group who can provide the sector with one voice when communicating with stakeholders. While there are a large amount of Digital Health events throughout the year, the sector does not appear to be strategically networked and can struggle to identify sector KOLs, leading academics and regulatory connections.

In response, IMSTA launched it's Digital Health Transformation Group on 2nd April 2019 with the appointment of a senior C/level executive and a leading industry expert to Chair the group. The group will be very focused and add real value in addressing industry concerns regarding the health systems capability to implement change, the changing regulatory landscape, open vs. closed IT systems, lack of value outcomes experience and little to no access for SMEs to the health system.

The group will lead, shape and influence National Health and Enterprise Policies by coming together under the auspices of IMSTA to address the poor collaboration across the sector and to give industry a single trustworthy voice to engage with government.

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