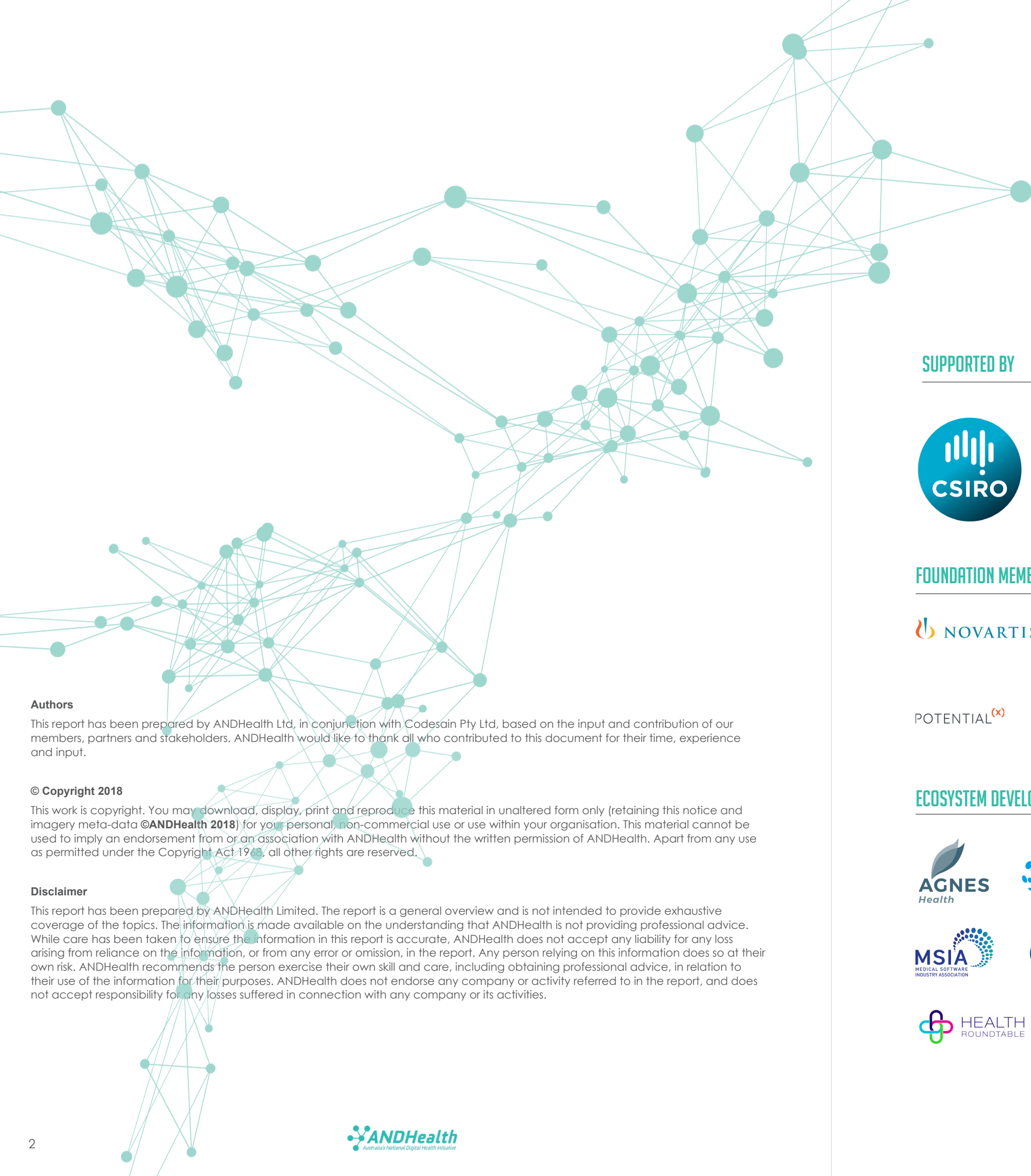# DIGITAL HEALTH: CREATING A NEW GROWTH INDUSTRY FOR AUSTRALIA

Strengths, Opportunities, Constraints and Barriers to the Commercialisation of Evidence Based Digital Health Technologies in Australia

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[FOREWORD]

Bronwyn Le Grice
CEO | ANDHealth

ANDHealth is a not-for-profit company that was established in 2017 by a consortium of industry partners. The goal of ANDHealth is to develop a more effective ecosystem to support Australian digital health companies as they navigate the commercialisation pathway to institutional investment and international market entry. The formation of the organisation was catalysed by the incorporation of and first funding rounds of the Federal Government's Industry Growth Centres program, specifically MTPConnect.

The organisation's vision is to leverage Australia's existing strengths in health and medical research, medical technology and healthcare delivery into the creation of a world-leading, national, integrated ecosystem for the development, commercialisation and implementation of evidence-based digital health technologies in Australia.

ANDHealth achieves its vision by bringing together participants from the medtech and pharmaceutical sectors with a broader stakeholder group drawn from a wide range of sectors involved in the evolution of digital health technologies, and by putting in place the key elements required to create a cohesive and collaborative digital health industry.

Such an industry will allow Australian healthcare consumers to benefit from world-leading technologies in the treatment and management of acute and chronic conditions, increased healthcare system efficiencies, and better health outcomes, alongside the economic development benefits of an increasingly efficient and connected healthcare system, creation of high value skills and employment opportunities, and the development of a new sector, based in innovation and commercialisation, to take Australia forward into the future.

There are many players within the digital health ecosystem that include industry associations, scientific and technical associations, universities, medical research institutes, healthcare providers, industry participants and state and federal government agencies all actively involved. Since its inception, ANDHealth has pro actively sought to work alongside these organisations to bring a coordinated approach to supporting Australia's digital health innovators and nascent digital health companies navigate the commercialisation pathway both within Australia and in key overseas markets.

This whitepaper represents the views of a diverse group of senior executives from across the Australian healthcare industry who were brought together in a series of roundtable consultations conducted in late 2017. These meetings were held to discuss the strengths, opportunities, constraints and barriers in Australia with respect to creating an integrated ecosystem for the development, commercialisation and implementation of digital health technologies, as the foundation of a thriving, international digital health industry.

Four roundtables were convened to explore interrelated but diverse areas relevant to creating an ecosystem within which both digital health innovation and commercialisation can prosper.

The four key areas explored were:

· Technology development · Regulation
· Investment · Market entry / Implementation

Following the roundtables, interviews were conducted through the first half of 2018 with thought leaders from a variety of industry subsectors, from organisations both large and small including venture capital, life sciences, pharmaceuticals, health IT, software, technology, legal, government, policy and regulation.

Across each theme outlined above, this whitepaper seeks to explore the opportunities and constraints which Australia faces, should it wish to pursue the creation of a digital health sector for Australia, and poses recommendations intended to represent tangible activities for both government and industry to partner on to accelerate the growth of the sector in Australia. More than anything, this paper is intended to reflect the perceptions and views of the participants of the roundtables in such a way as to facilitate a dialogue around the importance of digital health to Australia and Australians, and the economic opportunity posed by this rapidly emerging area of healthcare innovation.

I wish to thank the generous contribution of our lead partners in delivering this whitepaper, CSIRO and MTPConnect, and also the support of the Australian Digital Health Agency. In addition, I would like to thank the Foundation Members of ANDHealth: Novartis Pharmaceuticals, Murdoch Children's Research Institute, Curve Tomorrow, Planet Innovation, Allens, GP2U, AusBiotech, HPM Executive, Potential (x) and HealthXL, and our Ecosystem Development Partners, Melbourne Health Accelerator, BioMelbourne Network, NWR Communications, Health Horizon, Agnes Health, Informa, the Medical Software Industry Association and the Medical Technology Association of Australia for their support and contribution to the project.

Sincerely yours,

Bronwyn Le Grice
Managing Director | CEO | Co-Founder ANDHealth

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[INTRODUCTION]

The rapid changes driven by the Fourth Industrial Revolution (Industry 4.0)[1] that are transforming many industries including healthcare presents both valuable opportunities and complex challenges for Australia.

The delivery of healthcare is inherently complex. In Australia our healthcare systems involves a matrix of public and private sector entities, and a highly regulated, risk-aware environment, all focused on delivering world class care at every point in the healthcare journey.

Such a complex system slows the uptake of new technologies and innovation and their transfer to the front lines of healthcare. These challenges are not unique to Australia, however with maintenance of our world-class healthcare system becoming increasingly expensive[2], embracing new types of digital healthcare management and treatment tools will be key in the future wellbeing of our population.

Australia is considered a global leader in health and medical research, our citizens are early adopters of new technology, and we have an abundance of innovative ideas, yet we must continue to ensure that we have the optimal environment required to create, build and nurture commercially viable and resilient fast-growth companies in emerging sectors.

There has been significant investment to date by all levels of government in developing core components of the national health and health technology infrastructure, including supply chain interoperability, terminology standards, health identifiers and data repositories, such as the My Health Record system. In addition to fit for purpose regulation, reimbursement and procurement practices and supportive public policies, this infrastructure will contribute to a viable platform for digital health technology commercialisation and implementation.

Thus, Australia now has the opportunity to develop an internationally competitive digital health industry sector, which would complement and leverage our traditionally strong biopharmaceutical and medical device sectors.

The existing infrastructure and ongoing innovation will create opportunities to deliver improved health outcomes for all Australians.

Leveraging new technologies will be instrumental in improving healthcare access and affordability for taxpayers. Australia has the opportunity to build and strengthen a thriving and successful industry.

However, in order to succeed, there needs to be widespread understanding that the digital health sector goes beyond health information technology and infrastructure, and that digital health is not a subset of the medical devices sector. Evidence-based digital health products face a significantly different commercialisation pathway, an evolving regulatory landscape and limited reimbursement potential. In addition, these digital health products require novel commercial models to penetrate risk-averse and budget constrained procurement systems.

In order to fully realise our potential as a global digital health leader we need to build an integrated ecosystem that supports the growth and establishment of this nascent industry. We have experience and capability in doing this as proven by our biopharmaceutical and medical devices industries.

To achieve this ANDHealth recommends Australia:

Recognise that digital health is a sector, which sits alongside traditional biopharmaceutical/ life sciences and medical devices, and is a key driver of both health and economic outcomes for Australia in the future.

Leverage investment in national infrastructure and facilitate access to this infrastructure for innovators, technology developers and growth companies, in a structured way.

Support and incentivise industry-led innovation support programs to provide innovators with access to professionals and advisors with demonstrable track records of success throughout the commercialisation pathway.

Act to implement necessary changes to the broader healthcare environment, specifically with respect to regulation, reimbursement and procurement.

Address challenges relating to access to capital to retain equity and foster company growth within Australia until later in the company lifecycle.

Recognise the need for specialised expertise to support digital health companies to develop their international commercialisation plans and identify and support programs that provide this.

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WHAT IS DIGITAL HEALTH

Healthcare is always evolving, often in giant leaps, as we embrace new technology to find innovative ways to improve the way we deliver health and care. For example, over the past century the development of new pharmaceuticals, biologics and medical devices have enabled us to treat more conditions more effectively, transforming healthcare and human longevity.

Digital health differs as it represents a technological change that cuts across every aspect of the healthcare paradigm, spanning prevention, diagnosis, management and treatment, but also transforming the way frontline healthcare services are created, delivered and measured.

Also, digital health puts the patient at the centre of health and care, creating a new focus on "healthcare consumers" and "the empowered patient" as a driver of improved health and healthcare outcomes.

The term "digital health" means different things to different stakeholders. For a significant length of time, the Australian government's focus on digital health was centered on the concept of digitalising medical records. Terms such as "e-Health", "m-Health", "HealthIT", and "health informatics" were all concepts which contribute to the digital health sector, but which do not represent the entirety of the sector.

Roundtable participants suggested that an evolution in the definition of digital health has been occurring as we have moved from "eHealth"(primarily focused on patient records, systems and solutions to manage the health data) to a broader scope of digital health as outlined in the US Food and Drug Administration's (FDA) definition of digital health.

The convergence of the digital and genomic revolutions with health, healthcare, living, and society — is empowering us to better track, manage, and improve our own and our family's health, live better, more productive lives, and improve society. It's also helping to reduce inefficiencies in healthcare delivery, improve access, reduce costs, increase quality, and make medicine more personalised and precise.

Paul Sonnier, The Fourth Wave: Digital Health

FDA DIGITAL HEALTH DEFINITION

The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

Patients and consumers can use digital health to better manage and track their health and wellness related activities. The use of technologies such as smart phones, social networks and internet applications is not only changing the way we communicate, but is also providing innovative ways for us to monitor our health and well-being and giving us greater access to information. Together these advancements are leading to a convergence of people, information, technology and connectivity to improve healthcare and health outcomes.[3]

Providers and other stakeholders are using digital health in their efforts to:

| REDUCE INEFFICIENCIES | IMPROVE ACCESS | REDUCE COSTS | INCREASE QUALITY | MAKE MEDICINE MORE PERSONALISED |
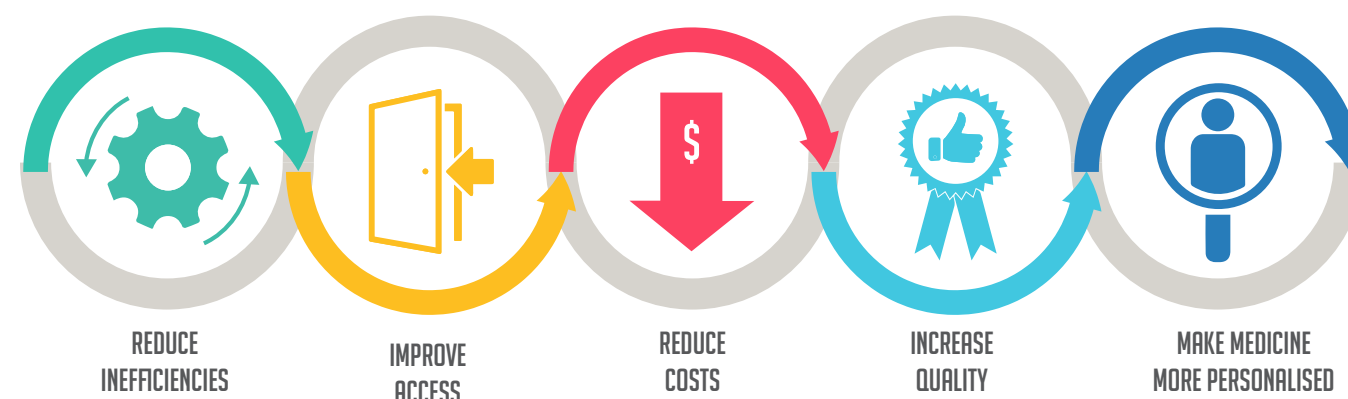
This definition shows that our understanding of digital health has shifted from the systems, services and infrastructure that support the frontline delivery of healthcare, to a system which recognises that, in addition to systems, services, and infrastructure, a complete digital health ecosystem includes the development of innovative evidence-based products and services that change the clinical outcome for healthcare consumers, and in doing so change the efficiency and effectiveness of the healthcare system as a whole.

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PREVENTION

Sensors
Virtual gym
Fitness tracking
Alerts & Notifications
Wearables
Virtual health coaches
Genetic screening
Remote monitoring
Personalised nutrition

Sports
Population health campaigns
Early childhood programs
Wellness
Community Outreach
Vaccination
Nutrition

AWARENESS

Social Media
Online booking service
Search engines
National health services directory
Patient generated data, e.g. Blogs
Ratings & reviews
Targeted digital advertising

Yellow Pages
Word of mouth
Community centres
Print/Radio/Outdoor
Communications

MANAGEMENT

Outpatient telehealth
Virtual health coach
Online peer support
Health portals
Polypharmacy support services
Virtual mental health solutions
CBT medication adherence
Chronic disease medication & adherence

Care plan
Clinical care team
Pharmaceutical
Community support service
Medical device

CONSULTATION

Telehealth
Preconsult triage
Virtual health assistant/chatbot
EHR
EMR
Electronic prescription

Pharmacy
Paper records
Clinical point of care
(physical location)

TREATMENT

Bioprinting
Virtual reality
Remote monitoring
Virtual clinical trials
Adherence technologies
In-home treatment solutions
Online rehab programs
Hospital in the home
Digital therapeutics

Clinical care treatment plan
Medical devices
Implantables
Surgery
Pharmaceutical
Physical therapy

DIAGNOSIS

Genomics
Surgical simulations
Wearable sensors
Telehealth
Ingestible sensors
Connected remote diagnostic kits
Wearable digital diagnostics

Pathology
Radiology
Government screening programs
Clinical assessment

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THE DIGITAL HEALTH OPPORTUNITY

In order to realise value we need to create an environment in which innovators flourish and growth companies can thrive. This in turn will transform both our healthcare system and our economy.
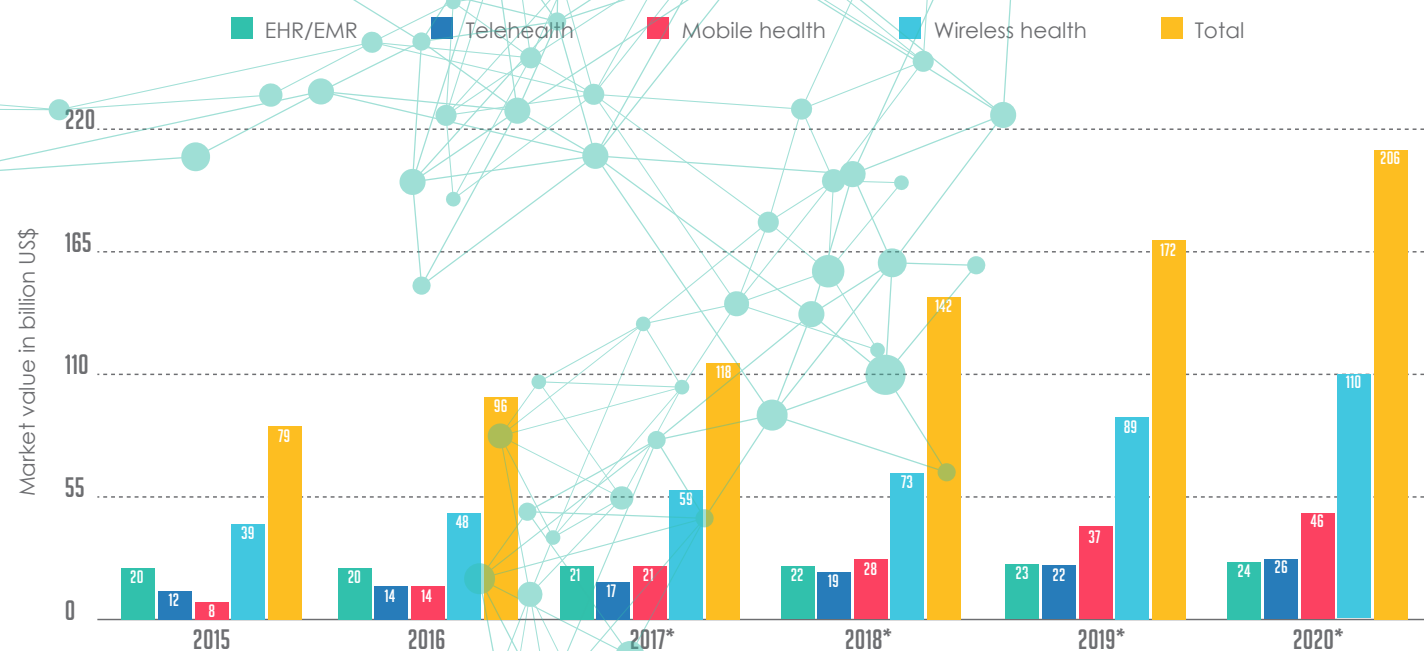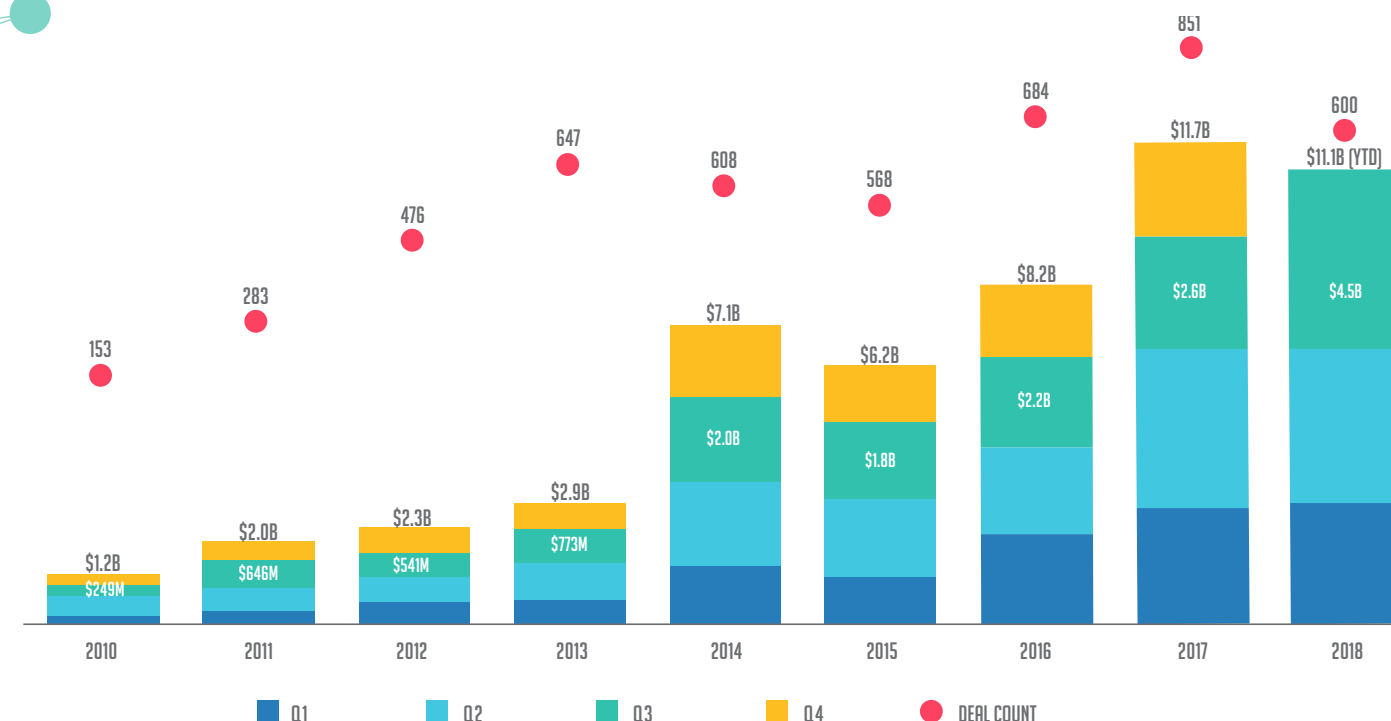
The digital health market is expected to reach US$206 billion by 2020, driven particularly by the mobile and wireless health market. Statista also note that the Asia-Pacific region is expected to be a key region in the future.

Global digital health market from 2015 to 2020, by major segment (in billion U.S. dollars)

Legend: EHR/EMR — Telehealth — Mobile health — Wireless health — Total

Market value in billion US$

Segment	2015	2016	2017*	2018*	2019*	2020*
EHR/EMR	20	20	21	22	23	24
Telehealth	12	14	17	19	22	26
Mobile health	8	14	21	28	37	46
Wireless health	39	48	59	73	89	110
Total	79	96	118	142	172	206

Roland Berger. Global digital health market from 2015 to 2020, by major segment (in billion U.S. dollars).[4]

In addition, investment into digital health companies is growing rapidly, both in total funds invested and in the maturity of the deals being done.

Year	Total	Q4	Q3	Q2	Q1	Deal Count
2010	$1.2B		$249M			153
2011	$2.0B		$646M			283
2012	$2.3B		$541M			476
2013	$2.9B		$773M			647
2014	$7.1B		$2.0B			608
2015	$6.2B		$1.8B			568
2016	$8.2B		$2.2B			684
2017	$11.7B		$2.6B			851
2018	$11.1B (YTD)		$4.5B			600

Legend: Q1 — Q2 — Q3 — Q4 — Deal Count

Source: StartUp Health Insights / startuphealth.com/insights Note: Report based on public data through 9/30/18 on seed (incl. accelerator), venture, corporate venture and private equity funding only. © 2018 StartUp Health Holdings, Inc.

"Q3 of 2018 saw more digital health funding than any previous quarter on record. Funding topped $4.5B USD for the quarter and over $11B USD YTD (compared with $1.2B in 2010, the year Start up Health began tracking) with investors already beating their annual totals from 2017. Investors are making deals across all stages, and in new territories, with no signs of slowing down"
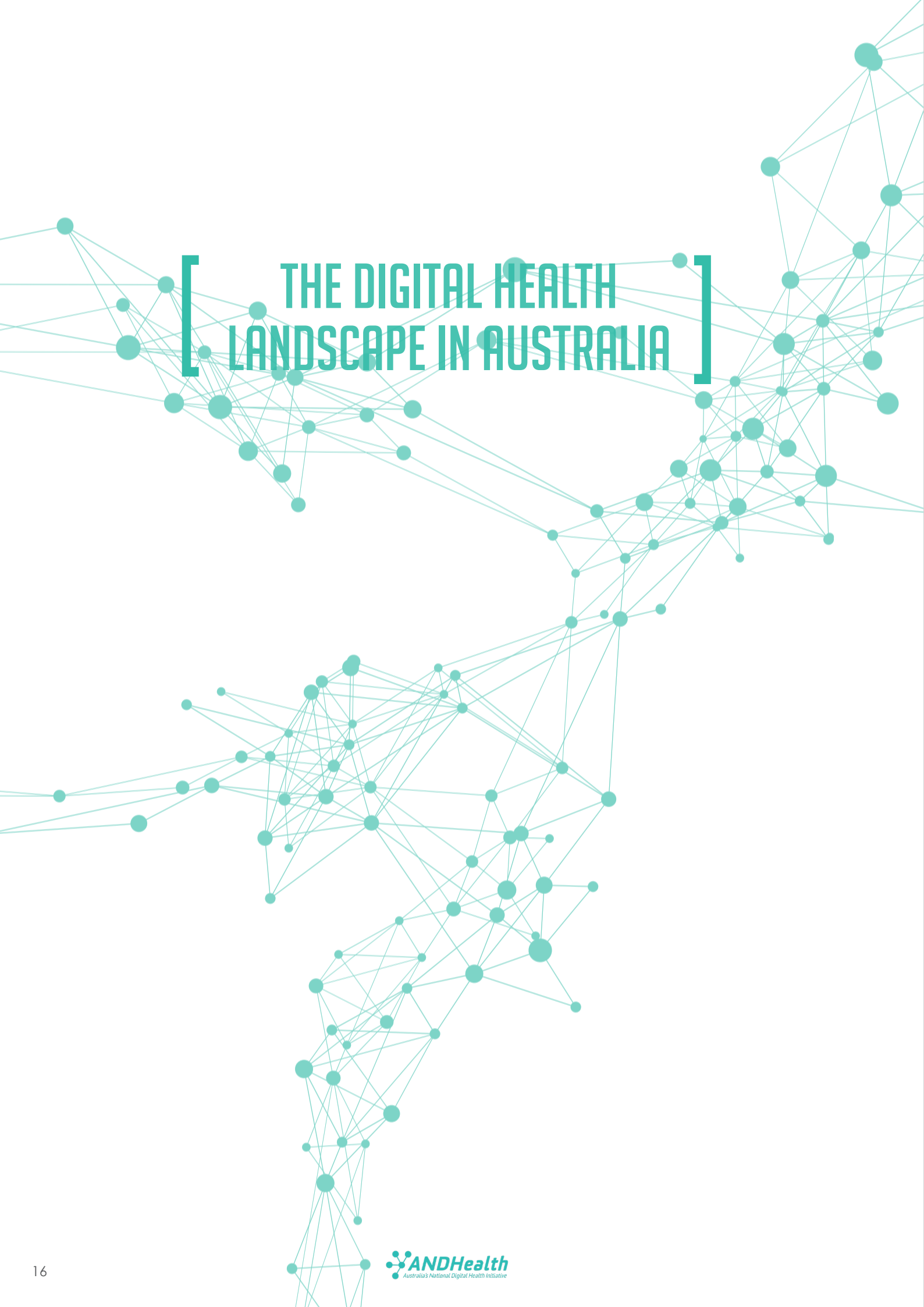*Startup Health Insights Global Digital Health Funding report, 2018 Q3 insights report[5]*

The opportunity for Australia to capture significant investment, become a destination for inbound digital health research and development (e.g. CSIRO's ability to run randomised controlled trials for digital health products), alongside becoming a world-leading exporter of digital health products, is significant.

In order to capture the benefits of one of the world's fastest growing areas of innovation and high growth investment, Australia can seek to undertake the following activities.

- Leverage the lessons learnt from the development and growth of the medtech, biotech and medical software industries.

- Facilitate access between industry and frontline healthcare providers so that they can understand, develop and deliver meaningful digital health products and services that have a clear pathway to market.

- Provide a supportive business environment where companies can validate and commercialise new products for local and international markets.

- Support the development of investment groups with specific skill sets in investing in and supporting digital health companies, similar to the Biomedical Translation Fund model deployed for life sciences and medical devices focused venture capital.

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THE DIGITAL HEALTH LANDSCAPE IN AUSTRALIA

There are an increasing number of players within the digital health ecosystem across Australia, such as biotechnology, pharmaceutical and medical technology companies, looking to digital health technologies such as connected devices and wearables, digital outcomes monitoring, patient and clinician facing apps and AI and machine learning to improve their own product pipelines.[6]

Health IT companies that provide back-end systems, informatics and medical software solutions are also looking to incorporate new innovations such as:

1. clinical decision support

2. cloud solutions

3. telehealth; and

4. voice interfaces

to provide a competitive edge and improve usability and user engagement.

Consumer technology companies, such as the global heavyweights FAAMG (Facebook, Amazon, Apple, Microsoft, Google) are also looking to capitalise on the significant global opportunity in the healthcare vertical.[7]

In addition;

- frontline healthcare providers in hospitals, aged care and disability services and allied health are all seeking to improve their access to innovative solutions

- health insurers are looking to utilise technology to increase efficiencies and improve their clients' outcomes

- telehealth and telemedicine are playing an increasing role in the delivery of treatment to rural populations; and

- healthcare consumers are increasingly looking online for solutions to their health queries and in some cases, are using technology to take control of their health

Underpinning this is a rapidly evolving need for robust and reliable technical infrastructure and information systems for the safe and secure transfer of data.

Australia continues to be a world leader with a deep history in health and medical research[8] with world-class scientific and academic institutions pursuing innovation in technology such as artificial intelligence, immersive simulation, big data and the Internet of Things (IoT).[9]

This combination of research excellence, workforce capability and industry expertise provides a unique opportunity for Australia to transform the health sector by delivering products, services and systems that:

- improve outcomes for healthcare consumers

- improve population health

- reduce healthcare system costs

- support improvements in effectiveness and efficiency for clinicians; and

- develop a new growth industry for the Australian economy

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GLOBAL TRENDS IN DIGITAL HEALTH

"the drug of the future will be an empowered patient"

Anand Iyer, Co-Founder and Chief Strategy Officer, WellDoc, a health care technology company that develops solutions to transform the management of chronic disease

OVERVIEW

The United Nations has predicted that the global population will grow from 7.6 billion to 9.7 billion by 2050, and the number of people over the age of 60 will reach approximately 2 billion.[10] The world is currently ill-equipped to respond to both the growth and changing distribution of its population, requiring major transformation of the global health system in order to provide an environment in which people live healthier, happier and longer lives.

Digital health solutions across the healthcare spectrum from prevention to care delivery, can add value to the system by unlocking opportunities and drawing investment to disease prevention and health promotion.[11]

Many countries agree that digital health provides enormous opportunities to generate efficiencies that lead to benefits and measurable outcomes for the economy and better clinical experiences and improved health outcomes for patients.[12]
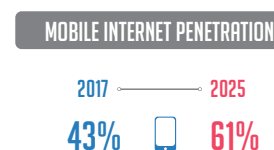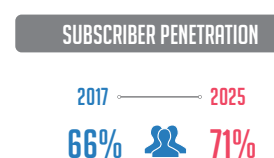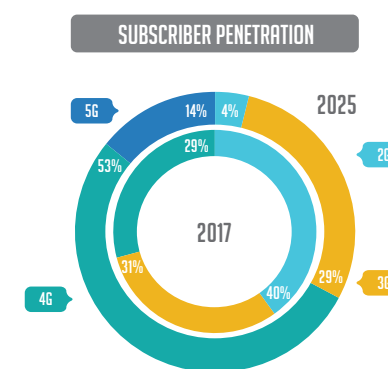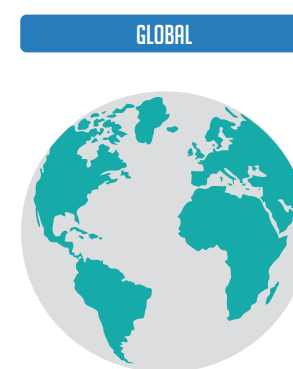
"If we were looking to the future, I think we will see less bricks and mortar, I think we will see more technology. We will see a greater focus on the patient, a greater way that we can manage people at home, we will see more consumer directed care – how do we as consumers want to be treated as opposed to how the system is (set up to) treat us"

Martin Bowles, CEO of Calvary Health Care and former Secretary of Health. Skynews business – Interview with Bernard Salt 2018

Globally, there are a number of technology-driven changes that are driving transformation:

Internet access becoming normalised

Internet access through either fixed or mobile devices has become almost ubiquitous in many areas of the world. According to the GSMA Mobile economy 2018 report, there were 3.3 billion internet connected mobile devices in 2017, and this number is expected to grow to 5 billion in 2025.[13]

GLOBAL

SUBSCRIBER PENETRATION

2025 | 14% | 4% | 2G
5G | 29% |
53% | 2017 |
4G | 31% | 40% | 29% | 3G

SUBSCRIBER PENETRATION

2017 ——— 2025
66% 71%

MOBILE INTERNET PENETRATION

2017 ——— 2025
43% 61%

Connectivity built-in

Increasingly, a broad range of devices are coming with connectivity as standard, from cars with built-in GPS and virtual assistant concierge services, to wearables, and smart home devices such as voice-activated assistants, appliances, energy monitors and entertainment.

Statista sources predict that there will be over 75 billion connected devices worldwide by 2025.[14]

Integration of diverse data sets for broader insights

This new data-rich environment – merging traditional data sets with Real-World Data (RWD) or Real-World Evidence (RWE) – also creates opportunities to gain better and faster insights to understand both population health drivers and impacts to policy initiatives. This can lead to a more agile approach to health reforms and be a useful extension in clinical research and clinical trials.

From fee-for-service to value-based care delivery models

With this new ability to better understand outcomes through data insights, increasingly governments are looking to shift from a fee-for-service to a value-based care model focused on outcomes.

Many countries, including Australia with its Health Care Homes program[15], are trialling this new approach. This potential shift in the commercial model of how government will pay providers, based on health outcomes rather than traditional fee-for-service unit-based pricing, is currently in its infancy but is expected to drive innovation as organisations shift to operate within this new model of care.

Increasingly complex and large data sets becoming available

These devices generate a substantial amount of data which can be utilised by a broad range of organisations in a safe, secure, and ethical way to provide significant insights and information to drive a more personalised service for the patient, putting their specific needs at the heart of their care.

Consumer empowerment

Consumer expectations are changing, as they are provided with more access, information, tools and services on how to manage that information. Ultimately, they are taking more control over their decisions and needs.

Travel, finance, entertainment, retail and even public-sector service delivery have all shifted a considerable amount of operations and administrative tasks to the customer through self-service offerings. 60% of Salesforce customers expect to implement a self-service portal within the next 12-18 months[16]. This is not only generating efficiencies but also improving the experience and convenience for their end-users.

Healthcare has been relatively slow to embrace this shift, but changes are starting to be made. This is driven by increased awareness, accessibility and affordability of products and services such as wearables and other personalised health devices.

Behavioural economics

New digital tools provide healthcare consumers with the ability to take more control over their health and wellbeing and provide the basis for an objective, data-based healthcare conversation that uses behavioural economics to support improved outcomes such as medication adherence and lifestyle changes.

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[GLOBAL TRENDS IN DIGITAL HEALTH]

[THE OPPORTUNITY FOR AUSTRALIA]

Australian inventions are many; having delivered world firsts such as the black box flight recorder, polymer bank notes, the electric drill and Triton WorkCentre, as well as permaculture, the technology behind Google maps (created by an Australian company before being purchased by Google) and, most famous of all, Wi-Fi technology which was created by CSIRO.

Our organisations and researchers have also delivered a range of world-leading innovations in the health space, with the first electronic pacemaker, ultrasound scanner, spray on skin, penicillin for civilian use, extended-wear contact lens, on-demand 3D printed titanium products, the cochlear implant and cervical cancer vaccine. We have translated this research into significant commercial successes with companies like Resmed, Cochlear, Sirtex, Fibrotech, Elastagen and others, demonstrating our abilities to build health technologies and businesses that are in demand in a global environment.

The immense opportunity created by these developments is driving significant investment into the digital health sector. Over US$11.5 billion was invested into the digital health sector in 2017, across ten subsectors including: Patient/ Consumer Experience; Personalised Health; Big Data and Analytics; Connected Devices; Wellness; Workflow; Research; Education and Training; Population Health; and, Electronic Healthcare Records and Systems.

Funding data from StartUp Health Insights™ is one of the datasets commonly used internationally to reflect the digital health funding landscape. Information, data and figures represent only publicly available data.

Australia has a history as a nation of innovators; we ranked 19th out of 128 countries in the 2016 Global Innovation index, have produced 15 Nobel Prize winners, and rank 8th out of 140 economies for the quality of our science and research institutions.

The 2016 Scientific American Worldview, which is an assessment of innovation potential in biotechnology around the world and analyses large collections of data from over 54 countries, ranked Australia 5th in the world behind the US, Singapore, Denmark and New Zealand respectively.

Australia has a global reputation as a great place to start a business, ranking 8th out of 38 OECD countries when it comes to starting new businesses. However, this has not translated into strength in growing these businesses to their full potential, ranking last for start-up growth out of 27 OECD countries[19].

Digital health is a sector where key interventions could create an immediate opportunity to become a global destination for the commercialisation of evidence-based digital health technologies. Through the combination of infrastructure, streamlined regulatory frameworks, commercialisation support programs, investment facilitation and changes to procurement/ incentives for implementation, we can develop and attract the next generation of healthcare companies to Australia, and retain their core operations here.

Supporting the development and growth of a digital health industry for Australia creates four key opportunities.

- **Healthier Australians**
  New technology is critical to our ability to maintain and improve the standard of healthcare available to all Australians.

- **A more cost-effective, value-based healthcare system**
  Digital technologies provide opportunities to: engage healthcare consumers in preventative health; improve the efficiency of the delivery of healthcare services; and improve efficiency and effectiveness of existing treatments.

- **Leverage existing capabilities and strengths**
  Developing a robust and resilient digital health sector is critical to ensure our traditional strengths in health and medical research remain internationally competitive and relevant to a rapidly changing world.

THE TOP 10 MOST ACTIVE SECTORS OF 2017

Contrary to what the average deal size may show, median deal sizes are hovering between $4-6M. The biggest surprises are workflow and research, with median deal sizes of $3M and $10M, respectively.

	Subsector	Total Raised	Deal Count	Avg. Deal Size	Median Deal Size
1	Patient / Consumer Experience	$1.64B	191	$9.3M	$4.0M
2	Personalized Health	$1.59B	71	$25.7M	$4.0M
3	Big Data / Analytics	$1.39B	56	$26.7M	$5.7M
4	Medical Device	$1.37B	72	$20.2M	$6.4M
5	Wellness	$1.12B	77	$16.5M	$3.8M
6	Workflow	$1.07B	161	$7.5M	$3.1M
7	Research	$933M	38	$24.6M	$10.0M
8	Education / Training	$730M	17	$48.7M	$5.2M
9	Population Health	$696M	56	$13.4M	$6.2M
10	EHR	$404M	12	$33.6M	$7.9M

Source: StartUp Health Insights | startuphealth.com/insights Note: Report based on public data through 12/31/17 on seed (incl. accelerator), venture, corporate venture and private equity funding only. © 2018 StartUp Health LLC

THE 10 LARGEST DEALS OF 2018 (YTD)

Diversification continues to trend as 2018's largest deals covered seven out of ten digital health functions in Q3. Oscar makes the list twice with a total of $540M in funding this year, however, their investments are still $10M less than Peloton's $550M injection into the wellness sector.

	Company	Round Total	Function
1	PELOTON	$550M	Wellness
2	Oscar	$375M	Insurance
3	grail	$300M	Biometric Data Acquisition
4	23andMe	$300M	Personalized Health
5	American Well	$290M	Patient Empowerment
6	BUTTERFLY Network, Inc.	$250M	Biometric Data Acquisition
7	HeartFlow	$240M	Clinical Workflow
8	Helix	$200M	Biometric Data Acquisition
9	Oscar	$165M	Insurance
10	LinkDoc	$149M	Population Health

Source: StartUp Health Insights | startuphealth.com/insights Note: Report based on public data through 9/30/18 on seed (incl. accelerator), venture, corporate venture, and private equity funding only. © 2018 StartUp Health Holdings, Inc.

The figure above shows the subsectors by level of investment in 2017[17].

The figure above illustrates the trend moving away from Electronic Medical Records[18].

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SUMMARY OF KEY MESSAGES

TECHNOLOGY DEVELOPMENT

- Australia has traditional strengths in health and medical research and significant public funds have been invested in building and supporting biotechnology/ life sciences and medical technology sectors.

- Academic leadership in technology fields of artificial intelligence, natural language processing and data science provide a solid foundation to develop innovative evidence-based digital health solutions.

- These skills, and others, establish a solid capability upon which Australia can build a new growth industry in evidence-based, patient-centric digital health technologies, leveraging past public investment and current strengths.

- Creating and preserving a broader positive business environment for innovation is essential, including maintenance of R&D Tax Incentives, supporting industry development programs aimed at fulfilling unmet market needs, and a tax and operating environment supportive of small businesses.

- Ensuring new technology developments are supported with access, information skills and experienced mentors to encourage more innovation and reduce roadblocks to commercialisation is key to building a digital health sector.

- In order to develop this new growth industry we need to encourage engagement and adoption from current industry leaders, frontline healthcare providers, government and its agencies (Australian Digital Health Agency, Department of Human Services, Department of Industry, Innovation and Science, the Therapeutic Goods Administration, State Governments, etc.), and innovators to work together to create an ecosystem which provides a clear, trusted pathway for the development, delivery and scalability of innovation and new technologies.

REGULATION

- Companies seeking to scale internationally must consider medical regulatory frameworks, quality management requirements (ISO), data security and privacy requirements (HIPAA, GDPR, SOC, etc.) and reimbursement requirements.

- Approvals in some jurisdictions can ease the regulatory and compliance pathway in other jurisdictions, so the sequencing of approvals is an important factor.

- Clarity and consistency within regulation and expert guidance are required to support understanding of the regulatory framework to minimise risk for product development, commercialisation and investment.

- In order to fully realise the health and economic benefits inherent in evidence-based digital health, new models/ evolution of regulation and reimbursement frameworks need to be considered in Australia.

- New methods of regulation such as Secondary Use of Data (Finland) and Pre-cert programs (US FDA) that have been developed in other jurisdictions can be used to inform new/evolving frameworks for Australia to accommodate new products such as digital therapeutics.

- Digital health innovators should be encouraged to view regulation as a competitive advantage, as it can smooth the adoption and customer acquisition process by indicating a product is safe and efficacious as verified by an independent body, the regulator.

- The regulatory framework around access to health data needs to enable innovation while protecting consumer interest and engendering consumer trust.

- Most therapeutic and medical device regulatory and reimbursement frameworks were developed prior to widespread adoption of connected technology solutions such as smartphones and the internet. Across many sectors, including healthcare, existing regulation often fails to keep pace with new technologies, leading to regulatory grey areas and limiting the rate at which the digital health sector can deliver transformative solutions.

INVESTMENT

- Australia's investment levels into digital health are comparatively much lower than global counterparts.

- Digital health companies face specific challenges and have unique attributes which mean that they often don't comfortably fit into the investment frameworks for either technology-focused or healthcare-focused venture funds.

- Digital health companies that have successfully raised capital often sit outside the medical technology regulatory pathway or they include a regulated medical device component, which fits within a traditional healthcare venture investment framework.

- Many digital health start-ups are departing Australia and moving directly into investment readiness programs in major markets due to the perceived lack of capital for digital health companies.

- As a nascent industry with a commercialisation and regulatory pathway that is still emerging, there is a need to educate investors from both technology and healthcare backgrounds as to what makes a successful digital health company from an investment perspective.

- Increasing the confidence of our domestic investment industry and increasing access to capital for digital health companies will enable these companies to stay in Australia for much longer, and be much further developed in the value chain, before they substantively move offshore.

- Investor returns are compromised by lack of C-Suite resources that are capable, experienced and available. Existing staff should be upskilled by encouraging experienced and successful digital health professionals to share their knowledge through executive in residence programs and targeted investor education programs.

- Generating an ecosystem where industry leaders with demonstrable track records in digital health and technology commercialisation can share their knowledge, skills and experience through industry-led company support programs and via targeted education, can significantly improve the availability of skilled digital health professionals.

IMPLEMENTATION

- Healthcare costs are increasing at an unsustainable rate globally, generating a focus on value-based care. While this shift will generate new ways to think about how to deliver care and in turn, drive innovative new models, without a change in procurement practices, value-based care could drive a decrease in innovation as commercial and investment returns in healthcare are squeezed.

- Innovation in procurement and the facilitation of frontline healthcare implementation will drive better and more affordable health outcomes for healthcare consumers, providers and payers, as well as support strong investment and commercial cases for entrepreneurs.

- While the majority of major implementations and purchasing decisions will continue to be driven by Business2Business (B2B) and Business2Government (B2G) models, healthcare consumers will play an increasingly important role and Business2Business2Consumer (B2B2C) and Business2Consumer (B2C) models will open up new avenues for implementation and commercialisation of evidence-based digital health products and services.

- B2C models must be protected and strengthened by clear regulations, strong clinical evidence and adaptive reimbursement models.

- Providing a clear pathway to market and defined implementation channels may also encourage more investment and development of new solutions as customer acquisition of new solutions becomes more viable.

- Truly successful commercialisation of digital health solutions means that they are implemented at scale, requiring a procurement pathway for products/ services to be easily purchased and implemented by a range of end-users so that they are providing value to users and improving health outcomes.

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TECHNOLOGY DEVELOPMENT

"As pressure on our healthcare system increases, costs escalate, and healthy choices compete with busier lives, a new approach is needed to ensure the health and wellbeing of Australians,"

CSIRO Director of Health & Biosecurity Dr Rob Grenfel

KEY MESSAGES

- Australia has traditional strengths in health and medical research and significant public funds have been invested in building and supporting biotechnology/ life sciences and medical technology sectors.

- Academic leadership in technology fields of artificial intelligence, natural language processing and data science provide a solid foundation to develop innovative evidence-based digital health solutions.

- These skills, and others, establish a solid capability upon which Australia can build a new growth industry in evidence-based, patient-centric digital health technologies, leveraging past public investment and current strengths.

- Creating and preserving a broader positive business environment for innovation is essential, including maintenance of R&D Tax Incentives, supporting industry development programs aimed at fulfilling unmet market needs, and a tax and operating environment supportive of small businesses.

- Ensuring new technology developments are supported with access, information skills and experienced mentors to encourage more innovation and reduce roadblocks to commercialisation is key to building a digital health sector.

- In order to develop this new growth industry we need to encourage engagement and adoption from current industry leaders, frontline healthcare providers, government and its agencies (ADHA, DHHS, DIS, State Governments, TGA, PBAC/MBS etc.), and innovators to work together to create an ecosystem which provides a clear, trusted pathway for the development, delivery and scalability of innovation and new technologies.

BACKGROUND

Globally, digital health is an attractive market for developing new products and services, with the digital health market anticipated to rise at a CAGR of 13.4% between 2017 and 2025, reaching $536.6 billion by the end of 2025[20].

Organisations and innovators across a number of sectors are contributing to the growth of this industry – including information technology, medical software, informatics, records and practice management, medical devices, life sciences, biotechnology, consumer technology, and increasingly from frontline healthcare service delivery.

This convergence of activity from different sectors across the economy can be difficult for innovators to navigate.

Digital health products need to demonstrate clinical efficacy, meet stringent quality and regulatory standards and, in addition, need a consumer-tech-like focus on UX/UI and end-user engagement. Beyond the development of the product, digital health companies also need commercial evidence, that can point to real-world validation that the product enhances both clinical outcomes for end-users, but also meets key economic requirements to support a long-term procurement engagement (which differs substantially across jurisdictions). No other sector faces such a complex array of requirements to become a truly global, scalable solution.

DIGITAL HEALTH COMMERCIALISATION ROADMAP
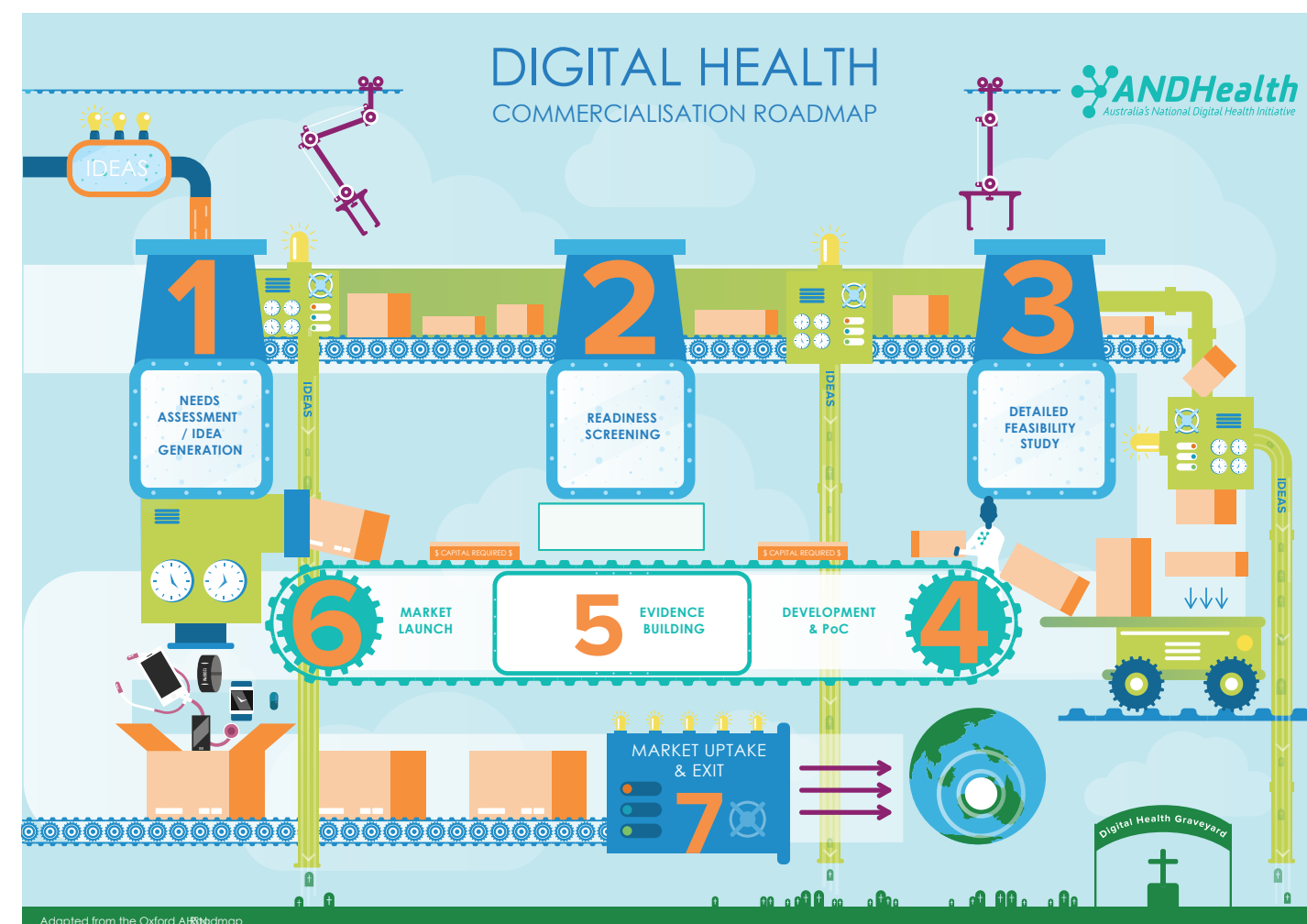
Adapted from the Oxford AHSN Roadmap

[TECHNOLOGY DEVELOPMENT]

KEY MESSAGES

The commercialisation pathway for digital health is still evolving, and is often poorly understood, with digital health companies often being encouraged to pursue a technology company approach (fast scalable revenues direct to consumer) or, in the case of connected devices, to pursue a slower, more traditional medical device pathway that puts clinical trials and regulatory approvals before voice of customer studies and time to market.

What is lacking is a clear framework for these innovators to access the key information, critical tasks and industry expertise they need to build a successful digital health business.

Challenges faced by Australian digital health innovators include:

- Limited examples of successful business models and insufficient commercial evidence to support an enterprise-scale purchasing decision.

- Lack of clinical evidence to drive uptake in a market focused on both improved healthcare outcomes and cost reduction simultaneously.

- Beyond solid clinical and technical evidence, products have to deliver world-class usability and design functionality to both customers and end-users.

- Difficulty in accessing frontline healthcare providers to identify problems (unmet market needs) and test early concepts for digital health solutions.

- Lack of awareness and understanding of the regulatory (quality system, medical technology, data security and privacy etc.) obligations they need to meet in order to sell to healthcare consumers.

- Lack of understanding of customer (purchaser) requirements and procurement processes (not to be confused with end-user requirements).

- No clear path to reimbursement locally and challenging reimbursement models overseas.

STRENGTHS

Australia has traditional strengths in health and medical research and has invested significantly in the underpinning of its life sciences and medical devices/ medical technology (MedTech) sectors in the past. Our citizens are early adopters and high users of connected services and technology[21]. They are connected, responsive and not afraid to adopt the new technologies that can quickly impact their lives for the better.

Australia has a diverse, innovative, skilled workforce across both technology and health, with a commitment by public and private sector organisations to support improved workforce education in digital health.

These skills, and others, leverage the activity to date in the development of the medical technology and medical software industry, and establish a solid capability upon which Australia can compete on a global stage. Providing an opportunity to create a new growth industry in evidence-based, patient-centric digital health technologies, leveraging past public investment and current strengths.

The investment in the development and scaling of the national infrastructure, alongside increased funding for research and early stage innovation, in addition to promised public policy, that rewards innovation through tax regimes, regulation changes, procurement/ reimbursement reform, and increased education for both entrepreneurs as well as investors in this nascent industry.

Australia has the building blocks to encourage a broad range of ideas to utilise new technology to solve some of the challenges and unmet needs within the system, generating value through measurable improvements that transform the lives of patients and providers.

When combined with increasing knowledge, experience and expertise in digital health commercialisation and dedicated commercialisation support programs, will create a platform that enables innovation and the ability to scale and compete in an increasingly competitive global marketplace.

CASE STUDY - VITALIC

ABOUT: The Vitalic system is a combination of data analytics and wireless patient sensors which assists nurses to prioritise inpatient care. Optimised to detect early clinical deterioration and potential falls, the Vitalic platform prompts nurses to intervene and see their patients at critical moments. With such a clear focus on the hospital market, and on assisting busy nursing staff, it was critical that the product be developed to meet the needs of both the end-user and the customer. Vitalic followed a Collaborative Development approach, including nurses as the user, and the likely purchasing partner, Ramsey Health, in the development from the outset.

KEY LEARNINGS: *"We have to keep checking our assumptions and make sure that the end-user and customer are involved in the identification of problems and then development of the solution. By focusing on solving real challenges in hospital and aged care, our digital solutions fit naturally into the healthcare workflow and aim to support greater quality patient care"*
Sue Dafnius, CEO of Vitalic Medical.

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TECHNOLOGY DEVELOPMENT

OPPORTUNITIES

Early Stage Industry Agnostic Accelerators & Pitch Contests
Ideation|Concept
Creation|Lean Canvas

Health Industry Specific Accelerators
Product Definition|
Early Product Market Fit | MVP

Clinical Validation |
Evidence | Commercial
Validation| Investment/
partnership readiness

Investment, International Commercialisation, Commercial Partnerships
Commercialisation & expansion

*List is not exhaustive

CASE STUDY - ATMO

ABOUT:

Researchers at RMIT, have developed the Atmo Gas Capsule, a world-first patented solution to accurately profile gases within the gut, leading to improved diagnosis and management of gastrointestinal disorders.

Due to the complexity of the gut, many gastroenterologists are unable to differentiate between different disorders. The solution was developed to help the 1 in 5 people who will have a gastrointestinal problem at some point in their life.

CHALLENGES:

Conflicting Timelines -coordinating the timelines and expectations working in the commercial and academic/research space was a challenge.

Operating within a research institute to deliver activities necessary to meet regulatory requirements - such as clinical trials and development of the product's evidence base- was considerably slower than the commercial demands and expectations from investors.

Approvals and review cycles - Universities and research institutions have a longer lead time and review cycle for activities than the commercial sector and concepts that are developed or spun out from a University or research centre can encounter challenges in navigating the necessary academic evaluation and review processes.

Funding limitations – Research funding and grants are often specific to research activities such as, animal or human clinical trials. This can lead to core business activities or design requirements, such as user interface and experience design for end products, or creation of commercial models and core business documents such as value propositions, not being budgeted for.

This can slow an organisations ability to scale and may mean repeating activities due to lack of commercial foresight at the concept development stage.

KEY LEARNINGS:

• Creating a consumer communications strategy to engage with traditional media to drive awareness and engagement not only helps increase awareness and value for investors, it can help to prioritise and accelerate activities required within academic and research institutions.

• Including funds for commercialisation and business development activity as well as customer insights and design work when seeking initial funding will create a stronger product offering and smooth the way to scale in future.

Australia has a large and increasing "start-up" ecosystem, supported by public and private sector investment, which fosters the generation of new ideas and concepts via hackathons, incubators and early-stage accelerators.

Our diverse population, skilled workforce, and globally recognised research excellence provides an opportunity to position Australia as a leading centre for real-world evidence gathering, clinical trials and evaluation of digital health products and services.

In addition, Australia's location, skills, size and time zone provide us with competitive advantages in a global marketplace where virtual services and overnight turnarounds fuelled by rising consumer demand are becoming the norm.

As interest and investment increases in the innovation economy, the number of Australian accelerators and incubators has exploded over the past 5 years.

Leveraging this network of technology-led incubators and early-stage innovation centres with specialised programs that provide access to deep expertise in the specific challenges of developing evidence-based commercially viable digital health solutions will accelerate the creation and growth of an Australian digital health sector.

An increasing number of clinician and patient/carer "lived experience" innovators are also entering the sector, which provides a unique opportunity to bring these innovators

together with those from technology and technology commercialisation backgrounds to develop stronger product offerings.

Similarly, bringing skills, knowledge, expertise and talent from other industries relevant to digital health (medical devices, pharmaceuticals and life sciences, consumer technology etc.) to encourage cross-pollination of ideas to generate new approaches to known problems will also strengthen the pipeline of promising digital health technologies.

As the industry grows, there is a growing cohort of industry professionals in Australia who have taken digital health products and services to market and seen commercial success internationally. An opportunity exists to leverage and incentivise these individuals to contribute to the broader industry by providing their experience, insights and support to address key challenges in building successful global digital health businesses via executive in residence programs, industry-led commercialisation programs and mentor and advisory roles.

There is a strong belief within the sector that, following in the footsteps of Cochlear, Resmed, Atlassian, Canva and others, Australia has the ability to build globally successful and dominant digital health companies.

[TECHNOLOGY DEVELOPMENT]

BARRIERS & CONSTRAINTS

Technology push versus end-user needs

A technology-push approach often results in new products being developed because we can, not because people actually want or need them or because they solve a significant problem. This technology-push approach is often unsuccessful as it creates a situation where health professionals feel that new technology is something that is done to them, not for them.

Cultural barriers

By nature and for good reason, the healthcare industry is highly risk averse. As one doctor said: "The moment we step into medical school, we are trained to identify the most statistically proven method for treating a particular disease, and we are taught to not deviate from that path until a better method has been found and proven." Compounding this issue is the fact that the majority of healthcare workers are increasingly time-pressed today, and so learning and adopting new systems, new methods of care or new devices often take a backseat to day-to-day patient care[22].

Access to frontline healthcare people and scenarios

In order to be successful, clinical workflow and organisational purchasing requirements and reimbursement models must be factored in early in the development of the product. Access to frontline healthcare providers and patients/ healthcare consumers to conduct early problem definition, idea generation and early voice of end-user studies can be challenging; legally, ethically and culturally, for innovators from non-frontline-healthcare roles.

Lack of support programs

There is a limited number of support programs specifically for digital health in Australia. ANDHealth is currently the only industry support program focused on digital health in Australia.

Imported and non-specific programs often don't understand the nuances of the local market, including major market penetration challenges facing offshore companies from a small nation, access to talent, and capital flows and access to funding within an Australian context.

Creating a natural home-base

Globalisation affects every industry, no longer are we simply competing internally across Australia, but reduction in market entry barriers to accessing global markets has presented unprecedented opportunities, particularly in an unregulated environment. We need to ensure that we protect and nurture new ideas and innovations and provide a strong pathway to market so that innovators do not leave to go overseas, or that competitors operating in regions with a faster speed to market are competing on a level playing field.

Workforce

Many technologists view health as difficult because of culture, development effort, quality and regulatory hurdles, and time to market[23]. On the flip side, clinician innovators often don't have the technology skills or commercial skills to fully exploit their ideas that arise from frontline healthcare delivery. In a sector where access to talent is key, this poses a significant challenge.

STEM enrolments in Australia are at their lowest point in 20 years, creating a potentially catastrophic skills shortage, as jobs of the future, in healthcare and beyond, become increasingly STEM dominant. To enable innovation to flourish, Australia must facilitate a workforce that is able to quickly adapt and evolve and be open to new ideas, putting the end-user first, embracing data and encouraging collaboration across different departments and skills.

Access to data and understanding of regulatory obligations

Although patient record systems such as the My Health Record and other data sets such as Medicare transactions and PHiDu (Public Health Information Development Unit) represent an immense asset (when accessed ethically and under appropriate privacy and security protocols), accessing patient and clinical data for research can be difficult and time consuming. The regulatory framework around who can access the data and under what conditions and for what purposes needs to evolve and be framed to enable innovation whilst protecting consumer interest and engendering consumer trust.

Many technology developers lack clarity on obligations for the access, management and storage of health information, particularly in regards to use of cloud-based solutions with offshore hosting. This is compounded by difficulties in accessing trusted, cost-effective advisors who understand the regulatory landscape for digital health in Australia.

Infrastructure

A reliable, accessible and affordable internet system is a prerequisite for the creation of a world-class digital health industry in Australia.

The democratisation of information through the internet has led to a broad range of innovations from many sectors, however, the relative ease of access to software development kits, open source code libraries and developer programs means there is a low barrier to entry for anyone to design, build and launch an application or software, often exacerbated by lack of knowledge of existing standards and certification. This creates an abundance of new products and services, however it can be difficult to determine those that meet clinical quality and safety guidelines and can be considered safe and effective for end-users.

Since last year, 78,000 new health apps have been added to major app stores. The supply side of the market for mobile health apps shows robust growth of 25% year-on-year, with the Google Play store now (2017) home to 158,000 apps categorised as health – a 50% increase compared to last year. However, there is currently no easy way for consumers to assess whether the app they are using has any evidence base to support its effectiveness or substantiate any health claims[24].
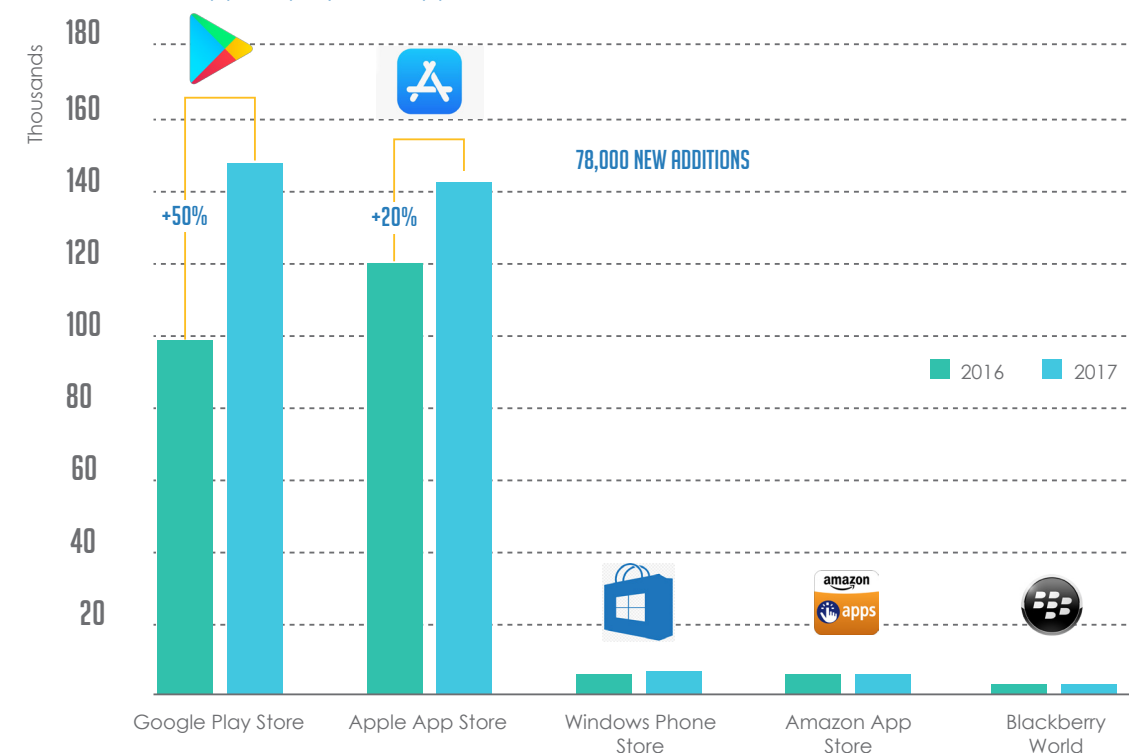
Embracing failure/Innovation culture

According to the Wall Street Journal article, The Venture Capital Secret: 3 out of 4 Start-ups fail (D Gage Sept 20, 2012) anywhere from 75-90% of all start ups "fail", which is to say they don't make it to a trade sale or IPO or are wound up.

It is essential to acknowledge and value failure as a key component of innovation. Leading innovation hubs such as Silicon Valley are known for embracing failure, and in valuing the experience that executives gain from a failed commercialisation attempt. In Australia, we are less likely to value this type of experience, and often err against executives that may have been through a journey with a negative outcome. Changing this culture is difficult, but key, to unlocking our full potential in developing an innovation economy.

325,000 mHealth Apps available - Google Play Store is now number one for healthcare apps, overtaking Apple App Store
Number of mHealth apps displayed in App Stores

78,000 NEW ADDITIONS
+50%   +20%

Legend: 2016   2017

Y-axis (Thousands): 20, 40, 60, 80, 100, 120, 140, 160, 180
X-axis: Google Play Store, Apple App Store, Windows Phone Store, Amazon App Store, Blackberry World

Source: Research2Guidance - mHealth App Developer Economics study - n = 2,400   *©Research2Guidance 2017*

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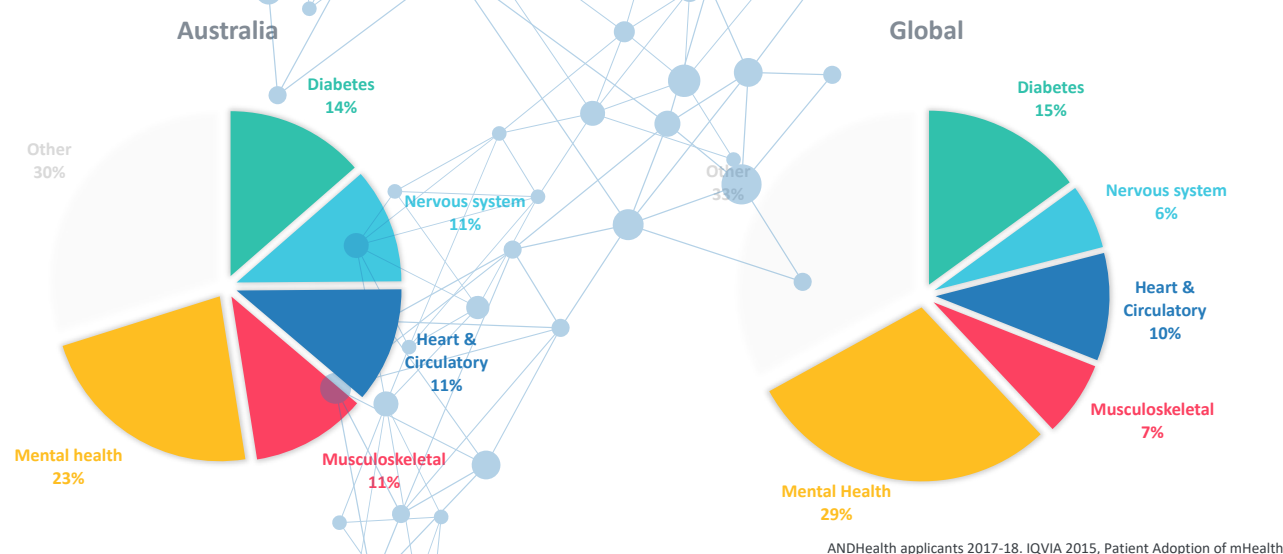Australia's National Digital Health Initiative

[TECHNOLOGY DEVELOPMENT]

RECOMMENDATIONS

In order to create a sector that will put Australia "on the map" in digital health, we first and foremost need to recognise that digital health is a sector in its own right, rather than a subsector of medical technology, or of the general technology sector. It encompasses much more than health software and electronic medical records, and has greater economic impact potential than medical technology alone.

AUSTRALIAN DIGITAL HEALTH ACTIVITY BY INDICATION

Australia

- Other 30%
- Diabetes 14%
- Nervous system 11%
- Heart & Circulatory 11%
- Musculoskeletal 11%
- Mental health 23%

Global

- Other 33%
- Diabetes 15%
- Nervous system 6%
- Heart & Circulatory 10%
- Musculoskeletal 7%
- Mental Health 29%

ANDHealth applicants 2017-18. IQVIA 2015, Patient Adoption of mHealth

When looking at disease-specific digital health innovation, ANDHealth sees similar trends between Australia, based on the ANDHealth applicants, and global trends, from IQVIA.

In addition, roundtable attendees believe action needs to be taken to:

- Acknowledge digital health as a sector in its own right, benchmark development of the sector internationally and set in place dedicated funding programs to support the development of the sector, analogous to the many programs brought around the life sciences/ biotechnology and medical device sectors since the late 1990s.

- Facilitate increased innovation into and out of frontline healthcare providers to understand the impact, and opportunity of new technology in an environment that is part of the system, via adapting proven models such as the MCRI/ Curve Tomorrow partnership or Melbourne Health Accelerator, where living labs provide an environment for innovators to interact directly with clinicians and healthcare consumers to develop and test new ideas.

- In partnership with the Therapeutic Goods Administration (TGA), develop educational resources for innovators that clearly outline regulatory pathways and other challenges to commercialisation so that their product development plan can incorporate necessary frameworks and associated mandatory activities and timelines.

- Address roadblocks in the reimbursement of new health technologies that provide evidence that they improve health outcomes and reduce costs.

- Create a framework for supporting the trialling, purchasing and implementation of these technologies via incentivising pilot and procurement practices or providing incentives to providers that adopt new solutions, which have achieved appropriate regulatory clearances/ approvals, with a Practice incentive Payment (PiP) or MBS rebate item.

- Ensure that Australia's flagship R&D tax incentive program is retained and supports both clinical research and the development of related software.

- Accept and welcome that failures are an expected component of successful innovation and create a supportive environment in which entrepreneurs can fail, and their learnings and talent be redeployed into other innovations/ technologies.

- Identify and support ways to encourage more entrepreneurship and technology development investment in health organisations through partnerships and specialised programs.

- Support the health innovation exchange concept as per Australia's National Digital Health Strategy, to provide an open platform for people to access the data and information about the types of problems that are worth solving, and access to the places to trial new ideas.

- Encourage health and medical students to diversify their studies to include an engineering, design and/or computer science subject and show the applicability for developing future digital health solutions.

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[REGULATION]

"The decades old regulatory paradigm just did not contemplate the challenges that we see with the rapid innovation and iterative nature of software, so the precertification pilot for us was the first step in trying to find a more fit-for-purpose regulatory paradigm,"

Danelle Miller, Vice President of Global Regulatory Policy at Roche[25].

KEY MESSAGES

- Companies seeking to scale internationally must consider medical regulatory frameworks, quality management requirements (ISO), data security and privacy requirements (HIPAA, GDPR, SOC, etc.) and reimbursement requirements.

- Approvals in some jurisdictions can ease the regulatory and compliance pathway in other jurisdictions, so the sequencing of approvals is an important factor.

- Clarity and consistency within regulation and expert guidance are required to support understanding of the regulatory framework to minimise risk for product development, commercialisation and investment.

- In order to fully realise the health and economic benefits inherent in evidence-based digital health, new models/ evolution of regulation and reimbursement frameworks need to be considered in Australia.

- New methods of regulation such as Secondary use of Data (Finland) and Pre-cert programs (US FDA) which have been developed in major jurisdictions, can be used to inform new/ evolving frameworks for Australia to accommodate new products such as digital therapeutics.

- Digital health innovators should be encouraged to view regulation as a competitive advantage, as it can smooth the adoption and customer acquisition process by indicating a product is safe and efficacious as verified by an independent body, the regulator.

- The regulatory framework around access to health data needs to enable innovation while protecting consumer interest and engendering consumer trust.

- Most therapeutic and medical device regulatory and reimbursement frameworks were developed prior to widespread adoption of connected technology solutions such as smartphones and the internet. Across many sectors, including healthcare, existing regulation often fails to keep pace with new technologies, leading to regulatory grey areas and limiting the rate at which the digital health sector can deliver transformative solutions.

BACKGROUND

The World Health Organization has recognised Australia's expertise in healthcare regulation and facilitates collaboration between Australia and other countries to support strengthening healthcare regulatory systems internationally[26]. In addition, we have a robust regulatory environment for the protection and use of health data. However, the pace of technological change and the rapid emergence of disruptive products and services are creating challenges for regulators on a global scale.

In healthcare, industry recognises that disruptive digital health products and services pose challenges for both regulators and government funded reimbursement programs, but also believes this disruption offers opportunities to transform approaches to regulation (especially in post-market monitoring) and, in some cases, offers a genuine case for reimbursement on a value-based basis.

In addition, clarity and certainty around the regulatory pathway and subsequent reimbursement opportunities are critical to swift and cost-effective commercialisation, which can place regulators and governments under significant pressure to adapt regulatory and reimbursement frameworks, whilst needing to preserve the necessary quality and evidence thresholds with respect to safety, efficacy and value, in both pre and post-market contexts.

It can be difficult for regulators to adapt to changing regimes around the world and to meet industry's expectations of regulation in areas that are constantly evolving. Over the years, the amount of existing legislation, regulation, and the associated administrative formality can become inefficient and burdensome[27].

For Cochlear, an Australian exporter of medical devices, a new product cleared by European regulators took a full 14 months longer to clear safety checks in Australia — during which time it wasn't available to patients in either market.

Barriers to Prosperity: Red Tape and the Regulatory State in Australia[28]

For digital health regulation there are a number of international activities that our regulators can look to for information, inspiration and guidance.

One model which is attracting increasing attention from the global digital health community is the US Food and Drug Administration's (FDA) current pilot of the Digital Health Software Pre-Certification (Pre-Cert) Program,

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Traditional industries are being disrupted and the distinctions between industry sectors are becoming blurred as tech firms move into new areas like banking, retail and healthcare. Our traditional regulatory approaches, which take a sectoral approach, may no longer be appropriate.

Digital Economy Strategy team
Department of Industry, Innovation and Science

which encompasses products categorised as Software as a Medical Device (SaMD)[29]. The premise behind the program is that the FDA certifies the company that creates the product, and following this company-wide certification, new products released by the company are deemed "precertified" and as such benefit from an expedited approval pathway. Once approved, products then go on to meet usual post-market monitoring and reporting requirements.

For the pilot program, the FDA selected nine companies from more than 100 that expressed interest: Apple, FitBit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Verily.

The FDA believes the pilot can be used to inform the development of a new regulatory model that enables the least burdensome regulatory oversight with a tailored, pragmatic approach that does not inhibit access to technology for patients. In addition, the real-world data collection capabilities of SaMD products create a unique opportunity to add value to post-market monitoring and reporting. During the pilot the FDA is working with companies on the best way to collect and interpret real-world data on patient experience, software performance and clinical outcomes to monitor and improve performance, safety, effectiveness and address emerging risk.

Activities such as this, and current consultations being undertaken by the TGA with respect to SaMD regulation and Cybersecurity regulation in Australia, demonstrate the willingness of global regulators to adapt to disruptive technologies and to ensure that regulatory frameworks remain relevant.

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[REGULATION]

STRENGTHS

Australia's Therapeutic Goods Administration (TGA) is a founding member of the International Medical Device Regulators Forum (IMDRF), a group of medical device regulators from around the world who meet regularly to accelerate international medical device regulatory harmonisation and convergence. The IMDRF management committee includes: Australia, Canada, Europe, Japan, Singapore, South Korea, and the United States of America, placing the TGA in an ideal position to maintain international leadership and be a driving force for harmonisation across major markets.

Key examples of this include:

- The TGA is currently undertaking extensive industry consultation and seeking to implement standards aligned with IMDRF documents for Software as a Medical Device (SaMD) - intended to identify commonalities, establish a common vocabulary and develop approaches for appropriate regulatory controls that promote prospective convergence in areas of advanced and innovative technologies[30].

- The TGA is also working with the IMDRF on Personalised Medical Devices to develop guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients[31] such as 3D printed devices.

Australia has a strong legislative framework protecting the use of personal data, data privacy and data security requirements. Whilst data security, protection and use remains a topical issue in the public discourse, in general most parties agree that legislation with respect to personal data is well designed to protect consumers and researchers.

Roundtable participants observed that the TGA has made significant attempts in recent years to improve the regulatory process for SME's, specifically with respect to providing improved pre-submission interactions, and has taken steps to make itself more accessible for industry participants seeking advice and guidance on existing regulatory requirements, therapeutic goods classification and processes for regulatory acceptance. This consultative process supports the view of roundtable participants that the relatively small size of Australia supports greater access and consultation between industry and the regulators.

In general, roundtable participants felt that relevant regulatory clearances and approvals for digital health products and services were a positive aspect of creating an ecosystem that supported development, commercialisation and implementation of such products.

> *Attendees of the ANDHealth Roundtables agree that regulation should be seen as a competitive advantage for digital heath innovators, as it indicates a product can demonstrate clinical outcomes, which have been verified by an independent third party (the regulator).*
>
> *Australia's position globally and our partnership with the international community are essential to ensure that products and services not only meet regulatory requirements within the Australian market but also have the ability to align to international standards and to enable export potential for key markets such as Europe (through the EMA) and the US (through the FDA).*

OPPORTUNITIES

Roundtable participants agreed that there is a significant opportunity to leverage Australia's strengths in innovation, technology and health and medical research within the robust regulatory standards established by the TGA, to develop and commercialise evidence-based digital health technologies which can compete globally, forming the foundation of a new innovation-based growth industry.

Participants were all broadly aware of the FDA SaMD Pre-Certification Pilot program and were supportive of a similar approach being deployed in Australia, and encouraged the TGA to develop a regulatory information kit and education program to support industry awareness and utilisation of new regulatory pathways. Similarly, the consultation pieces being undertaken by the TGA in relation to SaMD and Cybersecurity are viewed as positive steps to clarify the regulatory environment.

The 21st Century Cures Act enables the FDA to use real-world evidence to approve medical devices and drugs using post-market data from health insurance registries, disease registries and other sources that can be used by the FDA to approve new uses of existing drugs. This has received a varied response as some see this as an attempt to replace the need for standard clinical trials, whereas others view it as utilising technology to improve the efficiency of regulation[32]. Australia has the ability to consider the impact of the 21st Century Cures Act as relates to the use of real-world evidence, and select key aspects of this regime that can drive regulatory efficiency.

Combining elements of the pre-certification concept with the use of real-world data and evidence (often patient generated) is the idea of an adaptive open outcomes based regulation (OOBR) regime – an adaptation of industry-led regulation for safety and efficacy based on the model established by the automotive industry. OOBR is a potential alternative review process for qualified medical products in which real-world evidence is used for the determination of long term risks and effectiveness. It leverages the tools of connected health to engage patients and collect data that is unavailable in standard pre-market clinical trials.

OOBR is intended to improve the review of innovative healthcare technologies, reduce the time and cost of pre-market trials and enable the continuous improvement of existing products[33]. Within the context of a review of regulatory systems to address the rapid, iterative development required for software based products (or devices with a significant software component), OOBR offers some ideas which regulators can consider as they look for new ways to regulate disruptive products and services throughout the healthcare system.

Beyond products and into data issues, the European Union's (EU) General Data Protection Regulation (GDPR) became enforceable beginning 25 May 2018, creating a requirement for Australian businesses "to comply with the GDPR if they have an establishment in the European Union (EU), if they offer goods and services in the EU, or if they monitor the behaviours of individuals in the EU."[34] These changes to data privacy and identity management provide an opportunity to assess the impacts (positive and negative) that this new regulation creates, and utilise these learnings to create a similar, aligned framework for Australia.

The Finnish Government's Ministry of Social Affairs and Health proposed a new act on the secondary use of health and social data. Their aim is to ensure flexible and secure use of data by establishing a centralised electronic licence service and a licensing authority for the secondary use of health and social data thereby increasing research and innovation activities relating to public health and wellbeing, disease prevention, and the development of new treatment methods.[35] Again, this provides an example that can be reviewed in the context of informing Australian regulatory frameworks.

For non-SaMD products a common consumer facing initiative is the digital services library that lists evaluated apps, portals, online services and wearables. Note that they are often called app libraries, as apps are the ubiquitous digital service for consumers.

New Zealand, Canada, the UK, and the USA have curated libraries. All libraries have similar objectives and processes for targeting digital services based on health priorities such as mental health and wellbeing. The UK has three libraries: one government and two private libraries that offer services to consumers and developers.

In Australia, there is no national standalone equivalent although there is evidence of curated libraries being utilised:

- VicHealth provides a service as a sub-section of its main Health website called the Healthy Living Apps Guide[36]
- Healthdirect Australia also includes some information about apps related to health topics on its consumer website[37]
- Primary Health Tasmania is currently using a privately developed Digital Health Guide[38]

> *There is a clear opportunity to develop a national consensus on a regulatory approach to evaluating SaMD, SiMD and non-clinical health apps to ensure informed choice for consumers and patients.*

Currently Australian healthcare consumers have no easy way of assessing the applications they use, identifying which have clinical evidence supporting their claims and which are not evidence-based. Such a directory or ratings system would incentivise developers of both medical grade and direct to consumer health products and services to develop a evidence base.

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[REGULATION]

BARRIERS & CONSTRAINTS

A recent CSIRO report found that Governments need to respond to an increasingly complex operating environment and start the process of defragmenting the sector-based approach to regulatory compliance and remove barriers to regulatory process efficiency.[39]

When considering the constraints and barriers in adapting regulatory frameworks it is important to consider that the healthcare sector is being impacted by a 'perfect storm' of significant macro-economic trends:

- healthcare expenditure takes up a significant and increasing proportion of GDP in most developed nations,
- the global population is aging,
- the required skill set for health care workers is changing; and
- delivery of care and development of new treatment modalities are being changed by the introduction of new technology.

A number of important sector-based structural foundations for regulations that have been built over decades to support the traditional healthcare sector are lacking the critical components required to support emerging digital health technologies.

Roundtable participants felt that there was existing uncertainty over the current regulatory regime that can increase perceived risk in these companies on the part of investors. Feedback suggested that it is often unclear whether or not a product should be undertaking a process of regulatory approval, and if it is decided to seek regulatory approval it is also unclear which process should be utilised.

"When viewed from the perspective of 'connected care', the Australian healthcare sector is severely fragmented, something that stems from a series of historical decisions that have left the market with numerous disconnects and 'rail gauge' problems.

[This has led to] numerous policy, administrative and compliance bodies and agencies operating at state, territory and Commonwealth government levels."

Flying Blind: Australian Consumers and Digital Health

Roundtable attendees noted that the TGA is a respected organisation that is generally accessible, open and collaborative, however identified that there are significant resource constraints in the funding model under which it operates. As a cost recovery agency, the Therapeutic Goods Administration (TGA) implements cost recovery activities associated with the registration and listing of medicines and inclusion of medical devices, including in vitro diagnostic (IVD) devices, and biologicals onto the Australian Register of Therapeutic Goods (ARTG) and the ongoing monitoring and surveillance of them.

While some funding is provided to the TGA by the government in the form of an interest equivalency payment against the special account balance (reserves), the vast majority of funding is generated through fees and charges charged under cost recovery arrangements. This leaves limited budget available for activities such as developing educational materials and undertaking industry information and consultation sessions.

The centralisation of regulators has worked while they have been able to maintain expertise and cope with the volume of work for evaluation, oversight and continuous quality review. However, the volume of digital health technology is challenging the capacity and capability of government and regulators to review existing legislation, regulation, and meet operational requirements that are needed to provide timely approval and ensure patient access and positive health outcomes.[40]

While industry and government continue to invest heavily in digital health technology there is a vital lack of experience, knowledge bases and data that can inform:

- organisational readiness,
- the efficacy of digital health interventions,
- outcome measurement,
- best-practice approaches,
- the expertise required for training, integration with existing workflows; and
- access and use of data to improve safety and quality.

Finally, data is the cornerstone on which the success of a digital health ecosystem is built, however currently multiple government departments and agencies regulate what data is collected and how it is codified, stored and shared. This segmented and fragmented approach to regulation creates barriers to the safe and efficient sharing of personal health data.

"Health data is regulated by the Australian Government Department of Health (and its many agencies), state health departments, private and public health insurers and accident compensation insurance schemes. Each stipulates the mandatory minimum data set requirements that health service providers are required to collect and report to them. The reporting mechanisms and details (56) vary between public and private medical and hospital service providers. This diversity combines to weaken the basis upon which funders, policies agencies and compliance agencies make significant decisions related to policy, planning, safety and quality, which in turn directly and indirectly compromises consumers' health."

Flying Blind: Australian Consumers and Digital Health

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[REGULATION]

RECOMMENDATIONS

Regulation provides a critical framework that influences whether evidence-based technologies thrive or die. The overarching view of roundtable participants was that all healthcare focused technologies should have to substantiate their health claims via robust clinical evidence, verified by an independent regulator.

In support of this, the TGA should be financially supported to provide greater industry engagement activities, specifically in relation to improving information materials and undertaking industry consultation and education sessions.

> *Navigating the labyrinth of regulations is a costly challenge for many digital health companies. Industry, government and regulatory professionals should come together to support our future innovators to accelerate the growth of this new sector.*
>
> *Paul L. Clarke, Paul L Clarke and Associates ANZ MedDev Specialists*

Roundtable attendees recommended extending a number of recommendations encompassed in the CSIRO Medical Technologies and Pharmaceuticals roadmap specifically to digital health technologies: [41]

- A nimble regulatory framework that addresses industry concerns and which is clearly and effectively communicated (which may utilise elements of the OOBR regime).
- Regulatory agility including addressing uncertainties regarding reimbursement (extending beyond bionics and bespoke implants to digital therapeutics and other digitally enabled healthcare interventions).
- Regulatory Sandbox – Creation of a Regulatory Sandbox to facilitate development and commercialisation of evidence-based digital health solutions.

Engagement between industry and the TGA could be enhanced with respect to developing a suitable framework for the broad spectrum of digital health technologies via:

- More effective communication between the TGA and industry, especially with respect to works being undertaken in the fields of SaMD and cybersecurity.
- Once new classifications and regulatory frameworks are in place, undertaking extensive industry workshops to inform industry and service providers operating in the space as to the processes, timelines, expectations and costs of regulatory approval with respect to digital health products.
- Creation of a TGA-led, industry advisory committee to bolster the regulator's skills / capacity to take a more proactive role in developing and/or amending regulatory frameworks to support growth in the digital health sector.
- Improved educational and information materials, especially with respect to SaMD and digital health products, incorporating clear outlines of necessary regulatory requirements, processes and approval pathways and associated timelines and costs.

Look to overseas regimes where the digital health sectors are more mature and seek to align regulatory frameworks to reduce costs (including ongoing compliance costs) and increase certainty in commercialisation of new products, such as:

- Monitoring the outcomes of the FDA Pre-Certification Pilot and seek to undertake a similar study here in Australia to illustrate streamlined regulatory pathways for SaMD companies following reclassification activities currently underway.
- Streamlining the regulation of data use, storage and security across the many different departments and agencies across Australia as outlined in the Flying Blind: Australian consumers and digital health report. [42]
- Assess the impacts of the GDPR regime as it is adopted in practice across Europe and consider aligning Australian data privacy and security regulations with it.
- Consider the creation of a curated library of health applications which are supported by clinical evidence, potentially extending this to a "heart tick of approval" style system for consumer facing applications to better inform consumers of the validity of the applications they are purchasing and using in their daily lives.

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[INVESTMENT]

KEY MESSAGES

- While globally we have seen strong growth in venture capital investment in the digital health sector, Australia is proportionately well behind other nations investing in this space.[43]

- Digital health companies face unique challenges in both the clinical and commercial domains, which mean that they often are not a natural fit within the investment frameworks and methodologies for either technology-focused or healthcare-focused venture capital funds.

- Digital health companies that have successfully raised capital often sit outside the regulatory pathway or they include a regulated medical device component and centre their commercial strategies around the known commercialisation pathways for medical devices.

- Many digital health start-ups are departing Australia and moving directly into investment readiness programs in major markets due to the perceived lack of capital for digital health companies.

- As a nascent industry with evolving commercialisation and regulatory pathways, there is a need to educate investors (across the capital spectrum) from both technology and healthcare backgrounds as to what makes a successful digital health company from an investment perspective.

- Increasing the digital health expertise within our domestic investment industry and increasing access to capital for digital health companies will enable promising young companies to stay in Australia for much longer, and be much further developed in the value chain, before they need to raise offshore equity financing.

- Investor returns are compromised by lack of C-Suite resources that are capable, experienced and available. In this context, accessing and securing talent, especially in executive management, with demonstrable track records of success is a significant constraint that limits investment readiness of digital health companies.

- Generating an ecosystem where industry leaders with demonstrable track records in digital health and technology commercialisation can share their knowledge, skills and experience through industry-led company support programs and via targeted education, can significantly improve the availability of skilled digital health professionals.

BACKGROUND

Australia has seen a significant increase in Venture Capital in the past 5 years. Venture fundraising more than doubled from A$568M raised in FY2016 to approximately $1.32B raised in FY2017, this includes (but is not limited to):

- $500m for the Biomedical Translation Fund (managed by Bioscience Managers, Brandon Capital and One Ventures)
- $250m by AirTree Ventures
- $234m by Square Peg Capital
- $100m allocated by the Federal Government to the CSIRO Innovation Fund – now known as Main Sequence Ventures - (with another $100m expected to be raised from private investors)
- $75m by IAG Ventures (a new corporate venture capital fund)

Whilst we can expect these funds to be deployed in the next five to seven years, none of these funds have a specific skill set in digital or connected healthcare nor a specific mandate to deploy funds in this sector.[44]

This recent growth in local venture while significant, has come off a very low base. As AVCAL's research report, The Venture Capital Effect, shows, Australian venture capital sector remains small, both in absolute terms, and relative to its international peers. Australian venture capital investment as a percentage of GDP is 0.023%, less than half the OECD+ average, and less than a tenth of the size of Israeli or US markets.

This leaves Australia ranking 18th out of 30 OECD+ nations.[45]

Digital health is one of the largest and fastest growing classes of investment globally. In 2017, StartUp Health monitored 794 deals, with a value of US$11.5B, surpassing 2016 by almost US$3.5B of investment.[46] In the first half of 2018, deal volume has continued on an upward trend with 414 deals with a value of US$6.1B. 2018 has also seen three of the top ten deals done taking place outside of the US for the first time, showing the globalisation of the sector. US and global data points to a maturing sector, with the number of later stage (Series B, C, D) deals increasing steadily as companies who raised early stage rounds continue to grow.

Globally, investors are on track to nearly double their 2017 investments this year demonstrating their long-term commitment as well as the overall growth potential in the market. Together these trends confirm a heightened confidence in the sector.[47]

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[INVESTMENT]

Technology investors

Typically Invest in

Agile, fast to market companies
In revenue with exponential revenue growth forecasts
Large markets, rapid globalisation
Discounted cash flow or MRR driven valuation
Often B2C business models

Struggle with

Longer development timelines
Complex & evolving regulatory landscape
Limited product iteration
Long sales timelines
Slow revenue growth
Complex business models - who will pay?

Healthcare investors

Typically Invest in

Strong intellectual property position
Strong clinical data
Known development/ regulatory path
Value inflection points driven by milestones
Comparable exit driven valuation
Usually B2B business models
Often no revenues for life of investment

Struggle with

Minimal or partial patent protection
Unclear & shifting regulatory landscape
Lack of clinical data
Understanding of IT based offerings
Lack of significant number of comparable exits for valuation
Identification & validation of a clear business model – who will pay?

Given this global growth and focus, many of it in centres which Australia has previously effectively competed with in traditional sectors of biopharmaceuticals and medical devices, it is concerning that Australia continues to lag significantly in recognising the investment opportunity inherent in digital health.

One of the core challenges in Australia is our comparatively small capital market, which limits our ability to develop investment teams that are highly specialised in specific sectors. All venture investors seek to bring skills and experience to their portfolio companies, over and above the capital that they invest. Therefore, successful investment teams tend to invest in areas where they themselves have deep experience and global networks.

Whereas in other jurisdictions, companies may be able to approach a suite of funds who specialise in digital health,

in Australia our venture investors tend to fall into one of two camps, either focusing on technology companies (B2B or B2C software and applications, SaaS and marketplace companies) or focusing on healthcare, but with a skill set and focus which has been developed investing within the traditional therapeutics and medical devices sectors.

Both types of investors can find digital health companies difficult to assess, and may determine that, due to their own lack of experience in the space or due to an inability to reach a level of comfort with a business and business model that may be, in parts, highly unfamiliar, that their funds are better invested in companies where the investment team has greater knowledge and expertise.
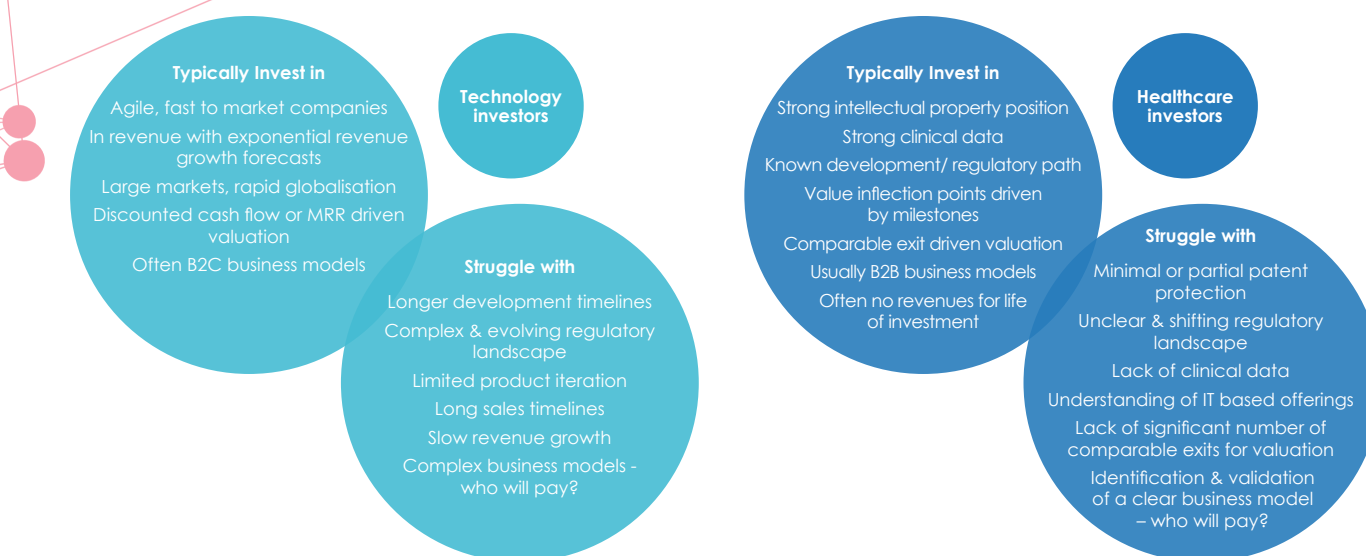
For example, with respect to digital health companies, a "tech VC" may struggle with:

- Inability to generate revenues from a Minimum Viable Product in the absence of clinical data and regulatory clearances/ approvals.

- Long sales timelines and slow revenue growth.

- Complex and changing regulatory landscapes across multiple jurisdictions.

- Clinical trial protocols, ethics approvals and clinician engagement.

- Limited ability to iterate products within regulatory clearance and approval process.

- Complex business models (B2B2C/ Reimbursement/ Government vs Private Payers etc.).

In contrast healthcare investors, with backgrounds in assessing early-mid stage therapeutics, diagnostics and medical devices, are very comfortable in no-revenue or pre-revenue companies which face high regulatory thresholds and require clinical evidence to support market entry.

However, in digital health companies they can struggle with:

- Minimal or partial patent protection.

- Unclear and evolving regulatory requirements.

- Lack of data to verify value inflection points within the commercialisation pathway.

- Complex commercial models and procurement challenges unique to digital health.

- Understanding of the technology underpinning purely digital offerings.

- Lack of significant number of comparable exits for valuation.

These challenges, and the lack of specialised investment capability familiar with digital health commercialisation, are driving the alarmingly low levels of investment into digital health in Australia. This is of concern as access to capital is key to Australia's ability to grow successful global companies, and we are at risk of "missing the boat" with respect to the fastest growing healthcare sector across the globe.

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[INVESTMENT]

STRENGTHS

After a significant period of zero to slow growth, venture capital is increasing in Australia with a rise in the number of venture capital funds and quantum of venture capital investment across the country.

Venture financing in Australia - 2012 - Q4'17

Legend: Capital Invested ($M) — # of deals closed
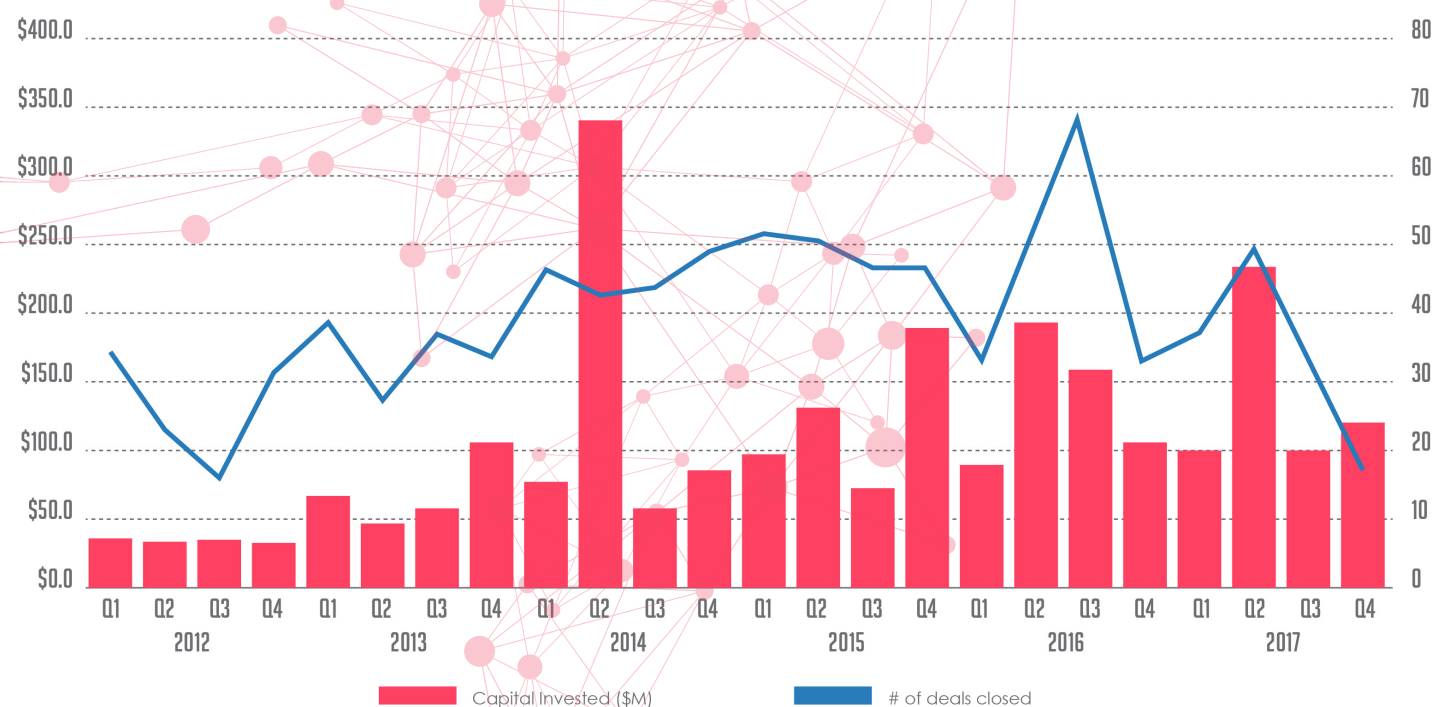
Source: Entrepreneurship at a Glance 2016 OECD

The creation of the Medical Research Future Fund (MRFF)and BioMedical Translation Fund (BTF) are directly supportive of improving our early stage innovation and subsequent venture funding environment for Australian healthcare innovators, although early deals from these funds suggest that the majority of these funds will be invested in therapeutics and medical devices, rather than be directed into digital health.

In addition, Australia continues to demonstrate its ability to develop technologies and companies that are in demand globally with a number of companies achieving impressive exits:

- Spinifex Pharmaceuticals $700m
- Fibrotech $400m ($75 upfront)
- Elastogen $120m
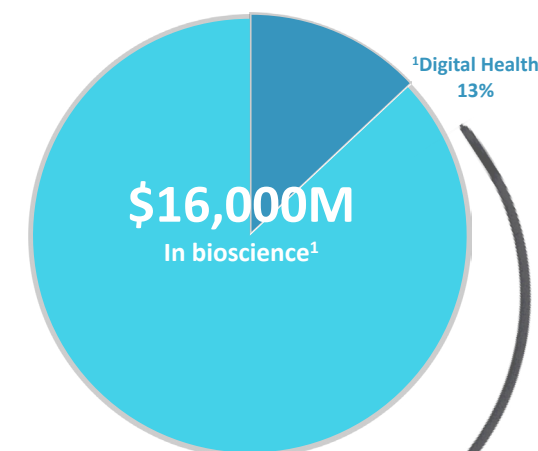- Hatchtech $279m
- Medical Director $155m

We are also seeing a maturing of our healthcare venture capital deal structures with Brandon Capital actively investing in syndicated deals with high profile US corporate and venture investors, and a slight increase in syndication of deals between healthcare venture investors. Australia's technology venture community often co-invest into technology deal flow. However, we are yet to see a partnership/ syndicated deal between Australian technology and healthcare venture investors around a digital health company (based on publicly available data).

Australia

[3]Digital Health 13%

$100M
In bioscience[2]
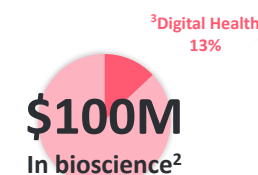
$0.54
Digital health annually invested per capita

USA

[1]Digital Health 13%

$16,000M
In bioscience[1]

$6.38
Digital health annually invested per capita

[1]Statista 2018, Bioscience VC investments
[2]Australian Private Equity and venture Capital Activity Report, 2017
[3]Active dialogue with Australian innovators & investors

In Australia, $100M was invested in bioscience startups in 2017 (2). In the USA in an average of the same period, $16B was invested in bioscience startups, of which 13% was in digital health(1). Assuming that Australia also invested 13% of the bioscience investment in digital health(3), there is still a significant difference in the investment in digital health in Australia, even when considering the smaller population.

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[INVESTMENT]

OPPORTUNITIES

Currently, we have the largest amount of venture capital available in Australia to date, however as a percentage of GDP and compared to other countries it is still low.[44]

Fig.8.1
Venture capital investments as a percentage of GDP
Percentage, 2015, or latest available year

SEED start-up early stage   Later stage venture   Total
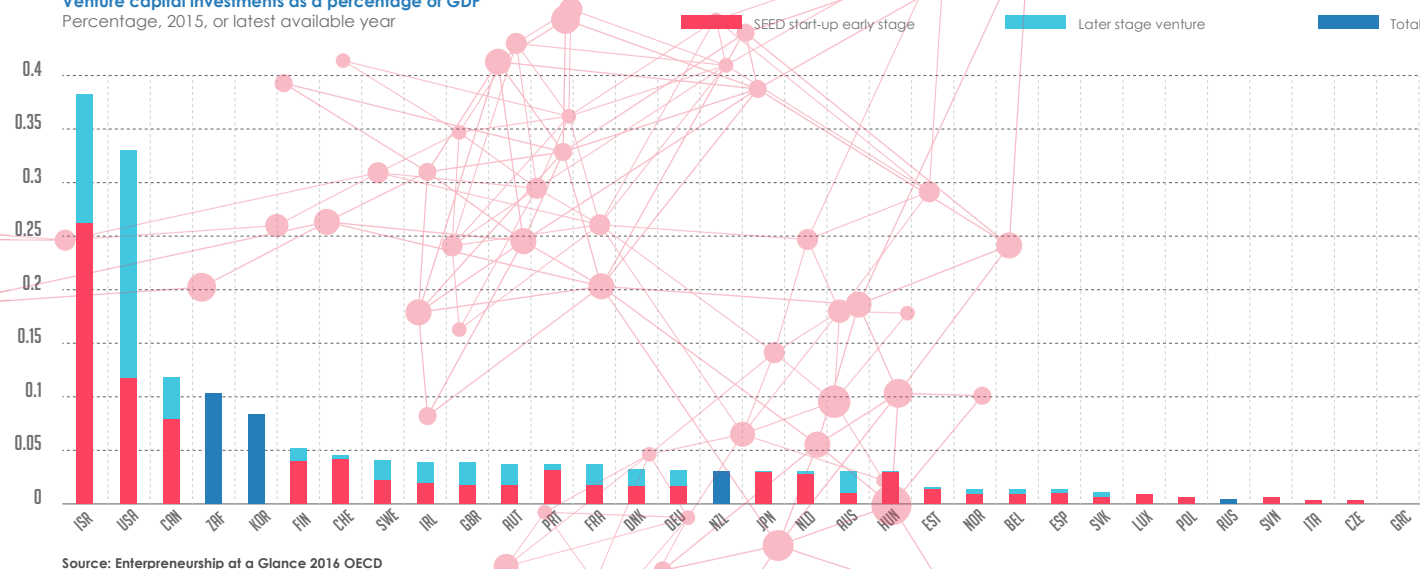
Source: Enterpreneurship at a Glance 2016 OECD

Large amounts of capital available in Australia

Australia has a number of highly successful venture capital firms and a broader capital ecosystem that is showing a willingness to invest in the venture capital asset class. In addition, we have one of the largest pools of superannuation monies in the world, with superannuation funds (including the MRFF) starting to increase their financial involvement in local venture capital.[48]

The global growth in digital health investment and the comparatively low levels of digital health investment in Australia, create an opportunity for us to learn from some of the mistakes and losses of international digital health funds, and develop investment capability in a sector which now has increasing market uptake, increasing M&A activity and increasing deal volume to inform investment decisions.

Established models to encourage specialised investment

The model for encouraging investment into a specialised investment team has already been established via public-private venture models such as the Biomedical Translation Fund (BTF) and the South Australian Venture Capital Fund. These models substantially de-risk the decision to invest into a venture capital fund for large institutions by providing dollar for dollar matching on commercial venture terms by governments. These types of models can be utilised to catalyse investment into key industry sectors where a lack of capital is limiting our economic potential, by making specialised funds easier to raise and allowing specialised managers to attract proven local and international talent.

Alongside equity investment, access to corporate partnerships, corporate investors and enterprise scale customers are also key drivers of value for digital health companies, and often can provide a bridge between early stage investment and venture funding. Stuart Elliott, Co-Founder and Co-CEO of leading Australian medical technology firm, Planet Innovation, states, "The best investor is a customer". Early engagement with enterprise customers generates both revenue and valuable voice of customer (VOC) input into product development at an early stage (e.g. Vitalic Medical). Companies that can point to early uptake by customers are significantly more attractive to investors and attract a higher valuation. As such, testbeds, in-hospital programs and programs which facilitate innovator / industry / healthcare provider interaction can support early commercialisation and lead to better investment outcomes.

Healthcare is ripe for digital disruption

Finally, a significant opportunity lies in the fact that digital disruption allows healthcare to deliver health differently. Just as other well-established industries such as transport and banking have been disrupted by technology companies delivering entirely new models of product and service delivery (e.g. uber), healthcare too is ripe for disruption. The emergence of novel business/ revenue models, adopting the value-based care philosophy, which allows for risk and reward sharing at implementation, the growing cohort of proven digital therapeutics companies transforming health outcomes through smartphone applications, and the increasing impact of the "Internet of Things", telehealth and voice driven communication, alongside all other manner of digital health innovations, all offer increasing opportunities for skilled and savvy investors.

[INVESTMENT]

BARRIERS & CONSTRAINTS

Digital health not its own sector

Without recognition of digital health as an emerging industry sector in its own right, it is difficult to create and communicate the need for specialised commercialisation support programs and investment teams. The view that digital health is synonymous with e-health, or alternatively is a subsector of medical devices, obfuscates both the opportunity, but also the need to bring specialised skills, knowledge and experience to bear to support the industry from technology development through to global commercialisation.

Lack of digital health specific accelerators, incubators

As the only program offering specific support to digital health companies, in the first 18 months since inception ANDHealth has had contact with over 120 mid-stage Australian digital health companies who are all seeking specialised knowledge and expertise. In many cases these companies have spent time in non-specific accelerator and incubator programs and in some cases they have raised money from investors who view them simply as a technology company active in the health vertical. In most of these cases, these companies have struggled to realise their full potential and have suffered slower growth and slower paths to market as a result. Internationally, programs such as the Texas Medical Centre Accelerator also recognised this issue, creating a specific program for digital health companies, as their original medical device program was not a good 'fit' for these innovators.

Lack of understanding of commercialisation pathways appropriate for digital health

In order to create investment ready opportunities, digital health companies and investors need to understand the commercialisation pathway for digital health, understand how it differs from medical devices and access domestic and international industry leaders who have delivered connected and digital health solutions to global markets. Currently, there is limited opportunity for Australian innovators to access this information or these skills and expertise.

The disruptive nature of some business models in digital health also poses challenges for companies seeking to raise capital. Companies that can point to strong clinical data, often struggle to determine a compelling commercial proposition for their customers. Procurement pathways are complex in every healthcare system, and this creates additional challenges for Australian companies looking to enter markets both domestically and overseas, as each market has a different framework. Getting these commercial models right, and accessing strategic advice to guide international market entry, remains difficult and out of reach for some companies, severely limiting their ability to raise capital.

Limited access to Australian investment funds

On the investor side, many Australian venture capital firms are small, with limited funds under management, which puts pressure on operational budgets and limits funds available for international industry experts and third-party advisors. Following the Global Financial Crisis of 2008, additional scrutiny on management fees placed significant downward pressure on the operating budgets of venture capital fund managers, making it difficult, especially for new funds, to attract and retain an optimally sized, skilled and funded team.

In addition, it is difficult for first time venture capital managers to access public-private funding frameworks such as the BTF or SAVCF, due to the requirement for managers within these programs to point to successful track records.

One of the largest barriers and constraints facing digital health companies seeking to raise capital is the lack of fund managers specialised and experienced in the specific nuances of digital health investing. These factors combine to make the creation of a new digital health venture firm a challenging prospect. In the interim, international digital health funds, such as Qure Ventures, which is domiciled in Israel, are entering the Australian market seeking to capture the latent value in companies that have limited access to capital. Thus, in order to continue to grow the sector for the benefit of Australia and Australians, the establishment of a dedicated and specialised investment team focused on digital health in Australia is key to unlocking the sector's potential.

RECOMMENDATIONS

In recognising that the digital health sector has specific needs across technology development, regulation and implementation, we also need to recognise that it has specific needs with respect to investment.

As the only organisation currently running dedicated digital health commercialisation support programs, ANDHealth provides a critical channel to proven expertise and global networks specific to the digital health sector.

Roundtable attendees believe the following recommendations will significantly improve the investment readiness of our digital health companies, and improve the investment environment for the sector:

- Develop a clear set of unmet needs or challenges within the healthcare system to stimulate innovation in areas of system-wide need (e.g. US cancer moonshot), and provide supporting funding, facilitated implementation and commercialisation support to early stage innovations in these areas.

- Deliver specialised services and support to early-mid-stage digital health innovators and companies to significantly de-risk the investment proposition prior to pitching to growth capital providers.

- Support investors to make smart digital health investment decisions and build their capability via tailored educational programs and resources.

- Access international industry leaders via supporting programs which bring international leaders around promising Australian companies to support them in their commercialisation journey but also to provide specific advice and networks with respect to market entry strategies into major international markets.

- Extend the public-private venture funding model to managers seeking to invest solely in digital health, and support fund management teams which can point to a background in commercialising technology within the digital health sector.

- Identify and showcase (and incentivise) change champions within frontline healthcare environments. Innovation is often driven by frontline users (clinicians, patients, care-givers etc.) who may develop or partner to develop a new innovation but lack the investment or commercial business acumen to commercialise their idea, these individuals should be supported and showcased as industry 'Champions of Change'.

- Encourage cross-sectoral engagement across the venture capital industry. Undertake consultation to identify roadblocks to syndication between technology and healthcare venture firms and seek to address these via supported programs.

- Incentivise corporate and provider interactions with digital health innovators, via matched funding programs and testbed environments, and incentivise the uptake of Australian innovation in frontline healthcare providers.

- Create widespread understanding of Australian "success stories" in the industry by cultivating case studies and promoting our successes.

Most Australians are unaware of some of our biggest success stories in the MedTech and biotech space, by increasing the communication in the mainstream media space about the great products and innovations we have already delivered so that we see these becoming household names and in turn driving both demand from users (patients and providers) increasing confidence in the sector and driving increased investment opportunities.

Roundtable Participant

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[IMPLEMENTATION]

KEY MESSAGES

- Healthcare costs are increasing at an unsustainable rate globally, generating a focus on value-based care. While this shift will generate new ways to think about how to deliver care and in turn drive innovative new models, without a change in procurement practices, value-based care could contribute to a decrease in innovation as commercial and investment returns in healthcare
are squeezed.

- Innovation in procurement and the facilitation of frontline healthcare implementation will drive better and more affordable health outcomes for healthcare consumers, providers, and payers, as well as support strong investment and commercial cases for entrepreneurs.

- While the majority of major implementations and purchasing decisions will continue to be driven by Business2Business (B2B) and Business2Government (B2G) models, healthcare consumers will play an increasingly important role and Business2Business2Consumer (B2B2C) and Business2Consumer (B2C) models will open up new avenues for implementation and commercialisation of evidence-based digital health products and services.

- B2C models must be protected and strengthened by clear regulations, strong clinical evidence and adaptive reimbursement models.

- Providing a clear pathway to market and defined implementation channels may also encourage more investment and development of new solutions as customer acquisition of new solutions becomes more viable.

- Truly successful commercialisation of digital health solutions means that they are implemented at scale, requiring a procurement pathway for products/services to be easily purchased and implemented by a range of end-users so that they are providing value to users and improving health outcomes.

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[IMPLEMENTATION]

SHARE OF EXPENDITURE

- Hospitals
- Primary health care
- Other recurrent

RESPONSIBILITY FOR SERVICES

- Combined private sector & public sector - all levels of government
- State & Territory governments
- Private providers

FUNDING

- Australian government funding share
- State/territory government funding share
- Private funding share

Source: Australian Institute of Health and Welfare, AIHW

BACKGROUND

Healthcare Expenditure

Australia's total health expenditure (recurrent and capital expenditure combined) in 2015-16 was A$170.4B, of which 67.3% was government expenditure (A$114.6B) and 33% was non-government spending. Of this A$55.8B was comprised of individuals, private health insurance and other non-government sources.

Data from the Australian Institute of Health and Welfare shows funding for healthcare from non-government sources – mostly out-of-pocket costs – increased four-and-a-half times faster than government funding in 2014-15. Australian healthcare consumers were responsible for 52.7% of non-government expenditure (17.3% of total expenditure) equating to $29.5 billion. This individual contribution is mainly driven by insurance fees, gap payments for consultations, treatments, diagnostic procedures and therapeutic goods such as prescriptions, over the counter and complementary medicines and services and additional fees for medical devices after subsidies and rebates are applied.[49]

Complex Procurement Ecosystem

For digital health companies seeking to access the healthcare expenditure dollar, navigating the complex maze of procurement organisations and processes at an enterprise level is extraordinarily difficult. Predominantly procurement is managed/ undertaken by government(s), healthcare providers and health insurance companies, but all healthcare procurement is affected by an extremely complicated value chain of who pays (and when) and who gets the value.

Meanwhile, consumers are often not willing to pay significant amounts for digital health technologies, even when there is clear evidence of better health outcomes as a result.

In the public health system, procurement of medical products, equipment and technologies is further complicated by suboptimal, duplicated or repetitive processes that increase costs and delays implementation. Several attempts at reform have been undertaken in the past, but their effectiveness has been undermined by the fractured and complex nature of Australian public health care.[50]

Commercialisation Requirements

Successful implementation of evidenced based digital health products and services requires innovators to develop a product that solves problems and generates positive outcomes for both end users (often patients) and customers (healthcare providers, public and private payers). Alongside navigating the commercialisation pathway, including regulatory clearances and capital raising, companies also need to understand the complex value chain that exists within the health system, the reimbursement models and the procurement rules, particularly for government purchasers or public healthcare entities.[51]

Unlike traditional biotechnology or medical device companies, digital health companies are likely to have to demonstrate actual customer uptake (where the customer is often a frontline healthcare provider) in order to secure growth capital.
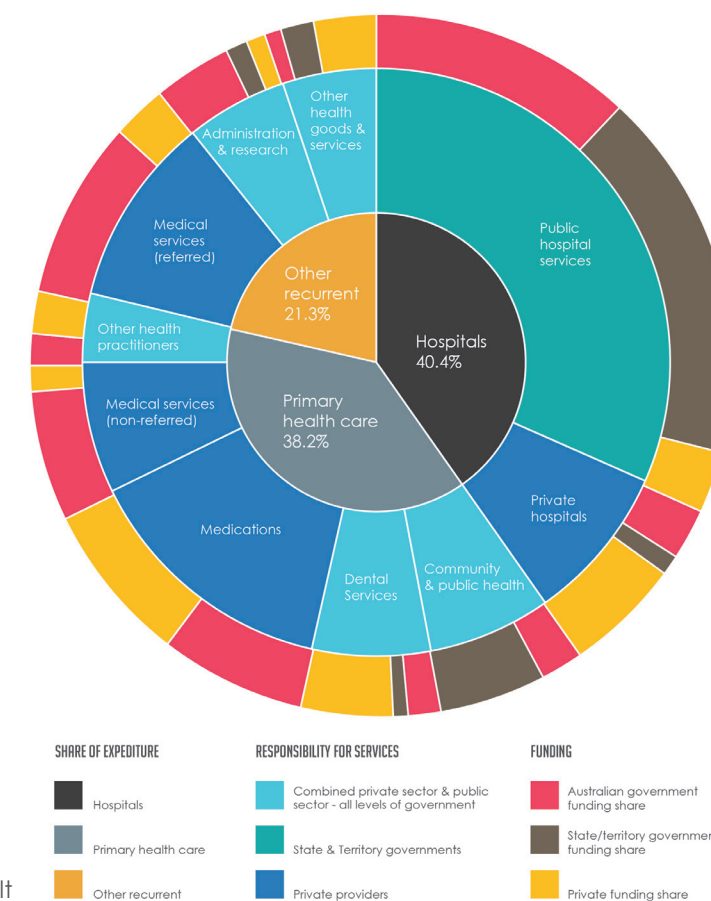
Government has successfully fuelled innovation through early stage innovation funding and programs to support the development of new technologies, however limitations in existing procurement rules, interoperability, reimbursement models and cultural risk appetite can result in evidence-based digital health solutions being unable to secure major customers and thereby grow their business.

Consumer Trends

There is also a growing trend for consumers to access information and manage their own services across all industries. This trend is increasingly having an impact in healthcare with patient expectations driving new models of care targeting convenience, access and choice.

In the USA, where average health spending per person per year in 2016 was $9,892, compared to only $4,708 in Australia[52], consumers expect more and better healthcare as a retail-like experience. However, a recent study found that while funders and providers are focused on consumer engagement, more effort is required to promote adoption.[53]

We expect that the majority of expenditure in health will remain the domain of large enterprise and government, however increased healthcare consumer engagement will play an increasingly important role as both a direct to consumer market, and via consumer choice within the provider, payer and government expenditure areas. This will provide new business models and commercial pathways for digital health companies to access new customer segments and growth opportunities.

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STRENGTHS

Increasing opportunities for collaboration are being developed between healthcare professionals, software developers, clinician entrepreneurs, researchers, data scientists, consumers and government to build on the unique insights and challenges faced at the frontline of healthcare delivery. This enables innovators to identify real world problems and develop solutions that address these challenges whilst still aligning to clinical workflow, which can help facilitate implementation of new solutions due to a greater alignment with end customer and end user requirements.

Test Beds

One such example is the Australian Digital Health Agency digital test bed initiative. This initiative is designed to support the implementation of sustainable and nationally scalable digital models of care. The successful projects will build on areas with a high level of digital maturity, with integrated governance arrangements between consumers, governments, healthcare providers, and entrepreneurs to produce evidence of their positive impact. Importantly, the Agency test bed projects involve new approaches to addressing healthcare challenges, which can point to ability to scale across the national population.[54]

The Australian Centre for Health Innovation's (ACHI) offers a market-focused, medical grade test-bed to provide an integrated suite of end-to-end test solution. Testing outcomes include:

- Complete product lifecycle assessment, from R&D to post launch
- Risk mitigation solutions, reducing financial burdens
- Methods of testing / showing workflow integration without risk to patients or hospital systems
- Improved product / service and process decision making
- Increased uptake due to improved 'fit for purpose'
- End user guided input to product refinement process
- Improved procurement processes due to credible testing and professional sign-off.[55]

Collaboration Models

Other programs, such as the Murdoch Children's Research Institute collaboration with Curve Tomorrow, also facilitate close interaction between technology developers and clinicians. The MCRI program has created a collaboration model that facilitates software and product developers working alongside health researchers and health professionals to develop and implement innovative digital health products.[56] Products such as AllergyPal, HeadCheck and Sleep Well Be Well, are all evidence based digital health tools that have been generated as a result of this approach.

Innovative Government Procurement Strategies

One of the largest challenges faced by many digital health companies when seeking to penetrate the procurement pathway is their small size. As such it is almost certain that the industry would likely benefit from the implementation of updated procurement strategies as defined in the Australian Government report, Prosperity Through Innovation. This report outlines a strategy that includes the use of innovative procurement strategies to grow government procurement from small to medium enterprises to 33% of all government contracts by 2022.[57] The report cites successful examples of similar programs in the UK and USA that support the creation and growth of new firms with a higher likelihood of attracting venture capital funding.

ABOUT: Seer Medical was founded in 2017 by a team with over a decade's experience working together in translational medical research. They identified that there were significant challenges in how Epilepsy is diagnosed. Seer Medical developed a breakthrough monitoring device to improve management of epilepsy and seizure-related conditions.

CHALLENGES: Initially one of the major challenges was creating a device that was robust enough to handle being used in the home by a broad variety of patients and ensure the quality of the data collected met and exceeded current standards for diagnosis. A lot of time, resources and money has been invested to ensure the device meets very high quality controls.

Raising awareness amongst clinicians who would be referring the service to their patients required significant effort and tactical approach to understanding the existing MBS (Medicare benefit scheme) rebates and ensuring alignment to provide a smooth pathway for reimbursement to drive clinical uptake.

Utilising an existing MBS rebate number to ensure that specialists are able to be reimbursed for patients using the device was also critical to their ability to implement their solution into market.

Seer Medical was founded by highly respected clinicians and engineers and was able to leverage the insights and network of their clinical specialists (Neurologists) to gain access and build a customer base for their solution.

While access to Neurologists has been achieved through their network, other specialities such as Cardiologists who may benefit from providing this service to patients have been slower to take up the product and this highlights the siloed nature of many clinical specialities who may be hesitant to trust services from another field.

KEY LEARNINGS:
- Ensure you have a clinical specialist in the field of the customer base you are targeting involved in product design and to champion your product either in your team or medical/clinical advisory board.
- Look to understand and leverage existing MBS and PBS item numbers rather than create something that will require many years to be listed for reimbursement, and can't be actioned for a single product/service or organisation.

CASE STUDY - SLEEPFIT

KEY LEARNINGS: Sleepfit is dedicated to improving the lives of the estimated 7.4million Australians that get inadequate sleep, costing the country more than $26.2 Billion per annum. Sleepfit provides workplace programs that provide targeted online therapies and support for a range of sleep disorders to radically transform lives and improve workplace productivity.

Sleepfit founders took a novel approach to the development and implementation of their service by cocreating their solution with future customers. They identified the growing number of people with sleep issues and the massive impact that was having to the economy and instead of then seeking to create a solution and then take it to potential customers, they identified and validated their was a problem worth solving from conception. By working with a range of organisations to validate the impact, understand the cost and in turn value of solving sleep disorder impacts to workplace productivity, they created not only a fit for purpose usable solution but also created a strong base for implementation and customer acquisition with cocreation companies.

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OPPORTUNITIES

Healthcare is arguably one of the last remaining major industries to be significantly disrupted by advanced technology coupled with novel business models, however it is certain that such disruption will happen at some stage in the future. Australia has an opportunity to not only grow the innovative healthcare businesses of the future, but to benefit by being a destination for new technologies from offshore which have the potential to transform healthcare and health outcomes.

While the procurement model in health focuses on acquiring health organisations or government agencies as primary purchasers, the outcomes are primarily targeted at improving health outcomes for patients. Australia has an attractive potential customer base to target new evidence-based digital health solutions with a diverse range of needs that are open and willing to trial and take up new technology solutions.

To achieve an internationally competitive, digitally enabled healthcare system, Australia needs to:

- Address roadblocks to innovation and commercialisation as outlined in this report.
- Adopt regulatory frameworks which are aligned to those of major markets to reduce costs for offshore companies seeking to bring new technologies to Australia.
- Establish test beds and 'sandboxes' for digital health innovators to generate real-world evidence for their technologies in a frontline healthcare environment.
- Provide programs and incentives for organisations to implement digital health solutions which can point to robust evidence and/or relevant regulatory approvals and clearances.
- Adapt current procurement and reimbursement models to support novel technologies, assessed on their ability to improve outcomes and reduce the cost of care, rather than their classification as either a therapeutic agent or medical device.

Australia has a number of programs active in this space and delivering outcomes in support of creating an Australian digital health industry. We have an opportunity to leverage programs such as the MCRI/ Curve Tomorrow partnership, ANDHealth, Melbourne Health Accelerator, and ADHA testbeds. These programs provide access to specialised resources and support for commercialisation by facilitating innovation into and out of frontline healthcare providers to understand the opportunity of new technology in an environment that is part of the system.

Alongside these existing programs, the funding in 2017 of the Digital Health Co-operative Research Centre (DHCRC) further expands our early-stage research and development capability and brings unprecedented data analytics and visualisation capability to our healthcare system.
In addition, the DHCRC will address significant knowledge and skills requirements as healthcare becomes increasingly digital.

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BARRIERS & CONSTRAINTS

Competing on a global scale

Feedback from Australian digital health entrepreneurs suggests it is easier to access customers and sell their products and services overseas than in Australia, due to perceived regulatory, reimbursement and market implementation barriers. This can result in a focus on overseas markets and investors extremely early in the life cycle of the company.

Globalisation provides a range of opportunities to support growth and expansion for organisations and individuals looking to develop new evidenced based products and services by providing a global marketplace. However, they must be cognisant of the speed to market in other territories and regions that may be faster than Australia to ensure ongoing competitiveness and retention of first mover or early market penetration.

Understanding end-user requirements, integration and workflow

Digital health interventions can deliver significant improvements to health outcomes at scale when they become part of accepted clinical workflow and clinical protocols. This often starts with pilots or trials that are funded through academic research or specific government taskforce or population health programs. Successful pilots can lead to bigger challenges.[58]

Healthcare providers are overrun with legacy IT systems and contracts, preventing new technologies from being able to access necessary workflow infrastructure and limiting the ability of these systems to evolve as technology changes without significant costs. This means that digital health companies face scaling and interoperability

challenges, in addition to the need to align stakeholders and gain budget approval, in order to move beyond the pilot stage, regardless of how successful their pilot was. A change in the way that technology is contracted and implemented to embrace a more agile approach is the only long-term solution.

There is a need for providers to address risk management practices, to allow for risk-mitigated adoption of new technologies. Robust, clear and well-understood regulatory frameworks support this. Healthcare providers should have the capability to adopt novel technologies in a risk mitigated way and feel comfortable in doing so. This requires education and clarification of clear standards and regulatory approvals / certifications, and potentially the concept of approved/ certified suppliers for digital health products.

End-user expectations

Patients are increasingly expecting a similar quality of service, availability and experience from healthcare that they receive from the retail, banking and other sectors, a study by ORC International shows that while funders and providers are focused on consumer engagement, more effort is required to obtain feedback and promote adoption.[59]

Involving patients and providers in the development of new solutions can minimise risk of integration with clinical workflow and identify and address pain points early on in the development lifecycle. However, access to frontline healthcare providers and patients/carers to conduct early problem definition, idea generation and early voice of customer studies can be challenging, both legally and culturally, for innovators from non-frontline-healthcare roles.

The lack of flexibility and bureaucratic resistance to the pace of change means Australia is "stuck with the old and overwhelmed with the new" and it is difficult for developers to create a resilient commercial model in the absence of a clear path to reimbursement, either through MBS/PBS type rebates, or a viable pathway into and through legacy IT procurement systems. There is no clear model for transitioning from current listed treatments and technologies to new more efficient offerings. A series of recommendations from the Deeble Institute included developing dis-investment strategies for low value care.[60] These strategies include simultaneous transitioning out of current (old) technology while promoting the adoption of new technology.

Lack of interoperability across geographic and sector boundaries

Silos between public and private, state and federal, primary and acute care providers can be a challenge in implementing a solution for patients that will cross across these boundaries. Therefore, providing a seamless service or solution across multiple systems and workflows, in addition to ensuring the solution is engaging for the end-user makes implementation difficult and creates confusion as to who will (or should) pay.

Clinical adoption and engagement

Healthcare is one of the oldest and most established industries in the world. It has a strong cultural basis in clinical evidence and risk aversion. From the time a new medical breakthrough reaches global acceptance as best-in-class,

to the time it is the foremost prescribed treatment currently takes 17 years. At the same time technological shifts will have more than likely eclipsed or transformed the solution from its original intention, process or capability.

Clinicians are the primary source of information for patients and trusted by them to provide safe and proven information and recommendations. Gaining support and adoption from the clinical workforce is paramount to the success of any evidenced based digital health product or services.

Healthcare professionals can be resistant to change and adoption of new ways of approaching treatment and healthcare delivery. Time and cost pressures, and a complex operating environment make early adoption of new technologies unviable for most. In addition, there are concerns about legal liability and impact to professional insurance requirements for many clinicians. Facilitating education for clinicians regarding the benefits of innovation and implementation of new methods is key to supporting widespread adoption of new technologies.

In summary, many of the core components of our healthcare system, which have developed to make it safe and effective, are now becoming barriers to the evolution of the system to capitalise on technological change. Whilst value-based care remains the aim, institutionalised practices in procurement and in clinical practice limit our abilities to utilise disruptive technologies to change healthcare on a system-wide scale.

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RECOMMENDATIONS

Innovative digital health companies need to be given the knowledge, skills and access to develop the clinical and commercial evidence to support implementation of their technologies in frontline healthcare organisations. As the industry grows, the benchmarks for this evidence will continue to evolve and the knowledge base on how best to approach such modeling will mature, increasing the ability of small companies to meet required thresholds.

In a world of digital therapeutics that deliver health outcomes in excess of new drug offerings, it is essential that we facilitate the use of these technologies via streamlined regulatory approvals and clearances, reimbursement pathways commensurate with those offered to other treatment modalities and improved procurement processes.

New approaches (both cultural and economic) to procurement are required to ensure that all Australians benefit from the best new healthcare technologies possible. Changes to procurement models will likely be, in a significant part, driven by changes to rebates and reimbursement models, and potentially procurement incentives to encourage more purchasing of innovative rather than standard solutions.

The GAP Taskforce on Government Health Procurement report released in 2016[49] urges a number of specific reforms to improve procurement process and maximise value.

Highlighting the benefits for the growth of the digital health industry by actioning the following specific reforms is recommended.

- A simplification and standardisation of tendering rules and specifications to reduce compliance costs and encourage innovation.
- A relaxation of strict divides between capital and operational expenditure to allow the purchase of service-oriented solutions.
- The use of blank Implementing Technical Standards (ITS) templates to facilitate discussions with vendors regarding desired outcomes, create more relevant tenders and help businesses address them more effectively.
- Agreement regarding commoditised elements that can be standardised, and those regarding a more sophisticated and holistic solution, should be secured within and between state public health purchasers to build a more predictable and uniform approach to purchasing decisions.
- Investment to standardise practices and infrastructure across states and the nation should be funded by both governments and business to allow supply chain processes that are commonly used in other industries to be adopted across the health system.

Market pull for adoption of new, proven technologies could be improved by the following initatives.

- Creating innovation key performance indicators for key senior roles within health service organisations to drive new behaviours and appetite for change.
- Addressing roadblocks in the reimbursement of new health technologies which improve health outcomes and reduce cost.
- Improving the pathway from pilot to commercial agreement and widespread use of innovative products by:
  - » funding commitment to support adoption
  - » programs which support developers to understand their target market and plan for success and how to scale production and distribution[61]; and
  - » reframing of pilot programs as phased implementation projects.
- Develop a directory (or linked directories) of digital health organisations, services or solutions with all relevant details of interoperability and integration capabilities, clinical evidence and commercial validation to support health organisations looking for appropriate solutions for their technology environment as well as provide a pathway for software companies and solution providers to acquire new customers and grow their business.

Health is a major contributor to economic growth, from both a consumption of available capital as well as wages, products and service provisioning.

By embracing the opportunity to transform the way we deliver health and care through implementing innovative new evidence-based technologies we have the ability to transform our healthcare system, improving both cost efficiency and health outcomes.

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[QUOTES]

From my perspective as an advisor to numerous digital health organisations, ANDHealth really stands out as a visionary organisation with unique leadership that understands the need to target real problems in healthcare and address them with innovation and transformation that are grounded in economic sustainability and successful long term outcomes.

Aenor J. Sawyer, MD, Centre for Digital Health Innovation, University of California, San Francisco

The provision of healthcare is largely delivered by government agencies and as such an interoperable national infrastructure or platform including a shared patient record, identifiers, secondary use of data frameworks, is essential. That creates opportunities for investors to feel more comfortable in investing in new innovations that are able to enter the market, scale and deliver real commercial growth through measurable improved outcomes for both patients and clinicians.

Chris Nave, Brandon Capital

The regulations were originally written based on the Act in 1989 and updated in 2002. Since this time there has been significant advances in technology, particularly in areas such as digital health and artificial intelligence, thus its critical that the regulatory landscape is adaptive enough to encourage the innovation of breakthrough technologies without compromising safety and efficacy.

Paul Clark, Paul L. Clark and Associates

If you want to get differentiated thinking, you need to get different ideas and groups around the table, government as the primary funders in health need to address procurement barriers to ensure we can have start ups and mid tier established smaller players compete and help to shape new thinking to deliver transformational change within the sector and help to strengthen and grow our own industry players.

Ben Heap, H2 Ventures

I'm grateful for the pacemaker that keeps me alive, but I'm frustrated with the amount of paper and wasted time with prescriptions, long trips for doctors' visits, accessing simple advice and information. I'm an IT professional and I'm also one of the 60% of Australians who live with a chronic disease, there's an enormous opportunity for digital health to make my life easier and that's something I'm willing to pay for.

Female cardiac patient living in regional NSW

I support the continued need for ANDHealth's activities in the future to build expertise in digital health commercialisation and highlight the digital health sector needs with a view to contributing to the nation's economic prosperity.

Sue Macleman, MTPConnect

Digital health is seen as a key pillar for the Novartis of tomorrow, and a significant, dedicated digital infrastructure is emerging in Australia to support this journey.

Novartis invests in the digital health ecosystem not only to improve the care of one patient, but many patients at a time. Digital health impacts the healthcare system as a whole and every stakeholder in health around the world. By preparing local assets for the global stage, Australia can change lives of many around the world, and become the epicentre for digital medicine globally - Australia can lead the way.

Adam Wardell, Novartis

There is a broken risk capital situation for investors, we need to build a bridge between the health and technology sectors to enable participants to understand each other and collaborate to deliver innovation in the Digital Health space that is able to succeed on a global stage, not just within Australia.

Sam Lanyon, Planet Innovation

Digital health has the potential to improve wellbeing outcomes for many Australians and the clinicians, researchers and industry professionals who care for them. Now is the time to deliver this transformational change by leveraging the use of data across clinical trials, telehealth and telecare, precision medicine and medical devices. In so doing, we'll enable personalised solutions that improve some of the challenges of today such as medication adherence.

Dr Dan Grant, MTPConnect

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[SUMMARY OF RECOMMENDATIONS]

TECHNOLOGY DEVELOPMENT

- Acknowledge digital health as a sector in its own right, benchmark development of the sector internationally and set in place dedicated funding programs to support the development of the sector.
- Facilitate increased innovation into and out of frontline healthcare providers to understand the impact, and opportunity of new technology in an environment that is part of the system, via adapting proven models.
- In partnership with the Therapeutic Goods Administration (TGA), develop educational resources for innovators that clearly outline regulatory pathways and other challenges to commercialisation so that their product development plan can incorporate necessary frameworks and associated mandatory activities and timelines. Support market pull for new technologies by addressing roadblocks in the reimbursement of new health technologies which provide evidence they improve health outcomes and reduce costs.
- Create a framework for supporting the trialing, purchasing and implementation of these technologies via incentivising pilot and procurement practices or providing incentives to providers that use or trial new (safe) solutions.
- Ensure that Australia's flagship R&D tax incentive program supports both clinical research and the development of related software.
- Accept and welcome that failures are an expected component of successful innovation and create a supportive environment in which entrepreneurs can fail, and their learnings and talent be redeployed into other innovations/ technologies.
- Identify and support ways to encourage more entrepreneurship and technology development investment in health organisations through partnerships and specialised programs.
- Provide an open platform for people to access the systems data and information to identify unmet needs.
- Encourage health and medical students to diversify their studies to include an engineering, design and/or computer science subject and show the applicability for developing future digital health solutions.

REGULATION

Regulation provides a critical framework within which an internationally competitive digital health industry which develops and commercialises evidence-based technologies can with thrive or die. The overarching view of roundtable participants was that all healthcare focused technologies should have to substantiate their health claims via robust clinical evidence, verified by an independent regulator.

In support of this, the TGA should be financially supported to provide greater industry engagement activities, specifically in relation to improving information materials and undertaking industry consultation and education sessions.

Roundtable attendees recommended extending a number of recommendations encompassed in the CSIRO Medical Technologies and Pharmaceuticals roadmap specifically to digital health technologies.

- Provide a nimble regulatory framework that addresses industry concerns and which is clearly and effectively communicated (which may utilise elements of the OOBR regime).
- Enable regulatory agility including addressing uncertainties regarding reimbursement (extending beyond bionics and bespoke implants to digital therapeutics and other digitally enabled healthcare interventions).
- Develop a Regulatory Sandbox – Creation of a Regulatory Sandbox to facilitate development and commercialisation of evidence-based digital health solutions.

Engagement between industry and the TGA could be enhanced with respect to developing a suitable framework for the broad spectrum of digital health technologies in the following ways.

- More effective communication between the TGA and industry, especially with respect to works being undertaken in the fields of SaMD and cybersecurity.
- Once new classifications and regulatory frameworks are in place, undertaking extensive industry workshops to inform industry and service providers operating in the space as to the processes, timelines, expectations and costs of regulatory approval with respect to digital health products.
- Creation of a TGA-led, industry advisory committee to bolster the regulator's skills / capacity to take a more proactive role in developing and/or amending regulatory frameworks to support growth in the digital health sector.
- Improved educational and information materials, especially with respect to SaMD and digital health products, incorporating clear outlines of necessary regulatory requirements, processes and approval pathways and associated timelines and costs.

Learn from overseas regimes where the digital health sectors are more mature and seek to align regulatory frameworks to reduce costs (including ongoing compliance costs) and increase certainty in commercialisation of new products.

- Monitoring the outcomes of the FDA Pre-Certification Pilot and seek to undertake a similar study here in Australia to illustrate streamlined regulatory pathways for SaMD companies following reclassification activities currently underway
- Streamlining the regulation of data use, storage and security across the many different departments and agencies across Australia (as outlined in the Flying Blind report).
- Assess the impacts of the GDPR regime as it is adopted in practice across Europe and consider aligning Australian data privacy and security regulations with it.
- Consider the creation of a curated library of health applications that are supported by clinical evidence, potentially extending this to a "heart tick of approval" style system for consumer facing applications to better inform consumers of the validity of the applications they are purchasing and using in their daily lives.

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[SUMMARY OF RECOMMENDATIONS]

IMPLEMENTATION

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INVESTMENT

In recognising that the digital health sector has specific needs across technology development, regulation and implementation, we also need to recognise that it has specific needs with respect to investment.

As the only organisation currently running dedicated digital health commercialisation support programs, ANDHealth provides a critical channel to proven expertise and global networks specific to the digital health sector.

Roundtable attendees believe the following recommendations will significantly improve the investment readiness of our digital health companies, and improve the investment environment for the sector:

- Develop a clear set of unmet needs or challenges within the healthcare system to stimulate innovation in areas of system-wide need (e.g. US cancer moonshot), and provide supporting funding, facilitated implementation and commercialisation support to early stage innovations in these areas.
- Deliver specialised services and support to early-mid-stage digital health innovators and companies to significantly de-risk the investment proposition prior to pitching to growth capital providers.
- Support investors to make smart digital health investment decisions and build their capability via tailored educational programs and resources.
- Access international industry leaders via supporting programs which bring international leaders around promising Australian companies to support them in their commercialisation journey but also to provide specific advice and networks with respect to market entry strategies into major international markets.
- Extend the public-private venture funding model to managers seeking to invest solely in digital health, and support fund management teams which can point to

a background in commercialising technology within the digital health sector.

- Identify and showcase (and incentivise) change champions within frontline healthcare environments. Innovation is often driven by frontline users (clinicians, patients, care-givers etc.) who may develop or partner to develop a new innovation but lack the investment or commercial business acumen to commercialise their idea, these individuals should be supported and showcased as industry 'Champions of Change'.
- Encourage cross-sectoral engagement across the venture capital industry. Undertake consultation to identify roadblocks to syndication between technology and healthcare venture firms and seek to address these via supported programs.
- Incentivise corporate and provider interactions with digital health innovators, via matched funding programs and testbed environments, and incentivise the uptake of Australian innovation in frontline healthcare providers.
- Create widespread understanding of Australian "success stories" in the industry by cultivating case studies and promoting our successes.

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[ROUND TABLE ATTENDEES]

Name	Company (at time of roundtables in November 2017)
Duane Attree	Chappell Dean / Potential (x)
Kyle Berean	RMIT - Human Gas Capsule
Meagan Blackburn	dorsaVi
Tim Blake	Semantic Consulting
Jason Borrie	HPM Executive
Arthur Brandwood	Brandwood Biomedical
Sunil Chandra	icare
Paul Clark	Paul Clark and Associates
Karen Clarke	ANDHealth
Angie Corbo	Roche
Gareth Dando	Lek
Rachel De Sain	Australian Digital Health Agency
Kea Dent	KD&A
Paul Dodson	CSIRO
Denise Eaton	Austrade
Krystal Evans	Bio Melbourne Network
Adam Feddon	Amazon
Cameron Ferris	The IQ Group
Gavin Fox-Smith	Johnson & Johnson
Amanda Gillon	bioscience managers
Michelle Goldsmith	Global Kinetics Corp
Dinah Graham	MIMS
Rob Grenfell	CSIRO
Lusia Guthrie	ANDHealth Board Member
Andrew Hall	Stone Ridge Ventures
David Hansen	CSIRO Health Research Center
Malcolm Hebblewhite	Planet Innovation
Annette Hicks	IBM
Emma Hossack	MSIA
Peter Kambouris	CSIRO
Mohan Karunanithi	CSIRO
Anna Lavelle	ANDHealth Board Member
Bronwyn Le Grice	ANDHealth
Grace Lethlean	ANDHealth
David Lewis	EBOS Group
Sue MacLeman	MTPConnect
Alfredo Martinez-Coll	MTPConnect
Rob McCray	Wireless Life Sciences
Michael McGarry	CSIRO (USA)
Damien Millen	Department of Economic Development, Jobs, Transport and Resources
Chris Nave	Brandon Capital
Judith Ngai	Bupa
Paul Nicolarakis	Lorica Health
Anne O'Neill	NSW Government
Adriana Platona	Australian Government - Therapuetic Goods Association (TGA)
Lisette Pregelj	UQ Business School
Hugo Rourke	Perx Health
Tony Shaw	Allens
Evan Siegel	Ground Zero
Elizabeth Stares	MTPConnect
Gus Taddeo	Cardihab
Scott Taylor	Perx Health
Sandhya Tewari	MTP Connect
Adam Vogel	Redenlab
Adam Wardell	Novartis
Jerome Wielens	MCRI

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