



# DIGITAL HEALTH

THE SLEEPING GIANT OF AUSTRALIA'S HEALTH TECHNOLOGY INDUSTRY



# Acknowledgements

ANDHealth is Australia's only organisation dedicated to providing programs designed specifically to address the unique commercialisation challenges faced by digital health companies.

ANDHealth was incorporated to address an identified gap in the Australian innovation landscape: to provide programs and support to digital health companies specific to the challenges of commercialising in this new and emerging sector.

Our unique non-profit, industry-led model supports Australian digital health companies to navigate the commercialisation pathway to institutional investment and international market entry.

Created by a consortium of partners led by the Murdoch Children's Research Institute in 2017, ANDHealth's Members

comprise Murdoch Children's Research Institute, Novartis Pharmaceuticals, RMIT University, Planet Innovation, Curve Tomorrow, Allens, Potential(x), HealthXL, AusBiotech and HPM Executive.

This Member network represents a unique multi-sectoral, multi-disciplinary group which works collaboratively across ANDHealth's operations to support and deliver our programs and services.

Alongside our Corporate Members, we also recognise and appreciate the support of our Program Partners, MTPConnect, Amazon Web Services, LaunchVic, Planet Innovation, Telethon Kids Institute, New Industries Fund from the Western Australian Government, Department of Jobs, Tourism, Science and Innovation, Cicada Innovations and NSW Health. In addition to our members and program partners we thank our national network of ecosystem development partners for their ongoing support.

## MEMBERS



## PROGRAM PARTNERS



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# Foreword

**T**he tumultuous times in which we live have thrown spotlights on many aspects of our lives. One of the brightest is the one which illuminates the way in which we seek and receive healthcare.

After ongoing debate for years on whether or not to roll out and reimburse telehealth on a broad scale, policymakers and care providers have now embraced virtual consultations as a way to protect both health providers and citizens from infection during COVID-19.

But when we consider our ideal post-COVID reality telehealth is only the tip of the iceberg in a vibrant, world class, technology-enabled healthcare system.

We need to manifest a post-pandemic future in which care shifts from the clinic to the home, with digital health solutions delivering disease prevention, diagnosis, management and treatment – at the same time improving the efficiency of our healthcare system, and the ability of all Australians to access it.

The recent appetite for telehealth in Australia does not mean that everyone now understands the ultimate potential of digital health in an international context. In Australia, our understanding and promotion of digital health has predominantly been firmly and deeply focused on the digitalisation of existing health data systems, implementation of critical connectivity and infrastructure such as MyHealthRecord and implementation of health informatics and health software systems (e-health or health IT).

In the international landscape, digital health incorporates health IT, but extends far beyond it, and includes mobile health, connected devices and wearables, telehealth and telemedicine, and personalised and precision medicine. “Digital medicine” and “digital therapeutics” are also concepts increasingly gaining traction on the global stage.



**This report outlines data from more than 300 emerging high growth potential digital health companies across Australia.**

COVID-19 has challenged us to reimagine our healthcare systems, and to rapidly adopt best-in-class technologies which leverage our connectivity and significant historical investment in already available funded digital health infrastructure.

A recent global survey of digital health and adjacent companies found that many are optimistic that the COVID-19 pandemic will lead to greater adoption of digital health services, more favourable regulatory and reimbursement environments, increased digital health acceptance among patients, and positive changes to the regulatory and reimbursement environments.<sup>1</sup>

This optimism is encouraging. But access to capital remains a significant issue for Australian companies seeking to commercialise in this space.

In the next two to three years accessing capital will be difficult, particularly when there are no specialised investors focused on the industry and companies attracting foreign investment will need to navigate the changed foreign investment review thresholds whilst they remain in place. Capital restraints are likely to exacerbate cash-flow issues for pre-revenue companies developing medical grade products and services, as will the likely reality of a global recession.

Many companies will also need additional and highly specialised support to enter international markets, especially while barriers to international travel remain in place. The extent of which deals can be done via Zoom will be tested by companies and investors alike throughout 2020 and 2021.

But among the doom and gloom there is overwhelming opportunity, primarily in the destruction of the institutionalised inertia that has been a hallmark of healthcare systems to date. Health policymakers have embraced rapid reform during the COVID-19 crises, enabling them to adjust reimbursement and regulatory levers to rapidly change the way healthcare resources are deployed. Simultaneously, clinicians and patients have been forced by circumstance to put aside their misgivings around virtual care and “give it a go”, resulting in significant changes to adoption rates.

In a global sense, Australia's highly successful management of the COVID-19 pandemic has given us an unprecedented



opportunity to position ourselves as a COVID-safe “cleanroom” destination for medical research and education, including in digital health, leveraging the significant need for industry players to be able to continue to undertake clinical trials and real-world evidence gathering in settings in which COVID is not an overwhelming factor.

This report outlines data from more than 300 emerging high growth potential digital health companies across Australia. It clearly shows we have a pipeline of world-class innovation and technology, navigating the novel pathway to commercial success in digital health. Each of these companies has been supported in some way by ANDHealth since 2017, and we are constantly finding new ways to partner with both government and industry to continue to provide this highly specialised domain expertise to our emerging digital health sector.

What it also illustrates is that digital health is the sleeping giant of the Australian health technology sector, which, if awakened, will achieve the triple aim of economic growth through high-value STEM-based job creation, increased advanced manufacturing and clinical trials activity, and sovereign health system capability and resilience. It is evident that alongside our traditional investment and competitiveness in the medical devices and biopharmaceutical sectors, investment into our nascent digital health sector is also critical for the health and wealth of all Australians.

**Bronwyn Le Grice**  
Founder and CEO, ANDHealth

# Executive Summary

**A**ustralia's decades-long policy of supporting innovation, significant investment into digital health capabilities and infrastructure, and now our highly successful management of the COVID-19 pandemic has given us an unprecedented opportunity to build a world-leading digital health industry.

Globally, the digital health market is predicted to reach US\$505.4 billion by 2025, up from US\$86.4 billion in 2018. This report demonstrates that the Australian digital health industry is well positioned to capitalise on this growth and drive Australia's economy and healthcare system into the future.

However, the industry is hampered by key commercialisation challenges: access to capital, access to customers, and access to expertise necessary to commercialise (regulation, reimbursement and overseas markets) in this nascent and evolving space.

The COVID-19 pandemic has been a catalyst for swift, wholesale change to the way we view healthcare in the modern world. In the first half of 2020 we have seen significant reform to reimbursement for telehealth and virtual care services, increased acceptance of digital health technologies by the medical community and patients, and a widespread recognition of the need to embrace digital health, in all its forms, to create a resilient, pandemic-proof healthcare system.

Since mid-2017, ANDHealth has engaged with more than 300 companies, demonstrating a huge pipeline of high potential growth companies in the digital health sector. These companies work across a diverse set of clinical indications, technologies and end user settings:

- 37% are developing technologies aimed for home use (remote patient monitoring), and a further 27% are seeking to deliver technology in a GP or allied health setting;
- 29% are focused on self-management and patient behaviour change (harnessing the shift to empowered healthcare consumers);

- 25% are developing data analytics and systems, 22% are developing mHealth technologies; and
- 25% are focused on diabetes and lifestyle conditions, with a further 17% focused on mental health.

However, the industry is hampered by some key challenges, particularly those related to capital. Asked to identify key impacts of COVID-19 on the sector, digital health companies noted that COVID-19 had had a negative impact on:

- their ability to access customers (71%)
- their ability to raise capital (63%); and
- their ability to access government funding (46%)

Companies also noted that, in a post-COVID world, commercialisation of their technologies would remain hindered by:

- a lack of digital health specific grant programs (59%);
- a paucity of digital health dedicated investors (47%); and
- access to capital (47%).

Despite this, 84% of respondents to our survey of Australian digital health companies said that they intended to raise capital in the year ahead, reflecting the optimism and energy of the industry at large.

This report is the first report to thoroughly demonstrate the vibrancy and diversity of Australia's emerging digital health industry, and showcases the potential of this sector to drive Australia's economy and healthcare system into the future, if supported appropriately.

Publicly funded infrastructure and capabilities such as the Australian Digital Health Agency's MyHealthRecord, the Digital Health CRC and substantial State-led initiatives have created the necessary infrastructure upon which digital medicine and digital therapeutics companies can begin to build patient facing interventions to substantially improve patient care and outcomes. Targeted commercialisation programs, such as those developed and delivered by ANDHealth, have proven their ability to accelerate the commercialisation and growth of these companies.

The pipeline of companies and technologies outlined in this report demonstrates the potential to position Australia as a global destination for digital health development, commercialisation, clinical trials and implementation, delivering against the triple aim for post-COVID recovery investment:

- 1.** Economic growth through high value, STEM-based companies headquartered in Australia, delivering globally;
- 2.** A resilient, agile, scalable and personalised healthcare system, focused on preventing, diagnosing, managing and treating illness using cutting edge technologies; and
- 3.** Expanded high-value manufacturing capabilities, through sensors, wearables, connected devices and regulated software products.



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# Introduction

**In 2017, ANDHealth was formed to provide specific support to high potential growth companies innovating within the broader digital health sector, with a specific focus on technologies designed to have a positive impact on patients and transform clinical outcomes (digital medicine and digital therapeutics).**

ANDHealth's initial objective was to support mid-stage companies to navigate systemic barriers to commercialisation and accelerate their ability to access institutional investment and global markets. The initial two-year pilot was designed to test a number of hypotheses:

1. There existed a significant pipeline of high potential growth companies in digital health that were not fulfilling their potential due to a lack of specific domain expertise and support;
2. That a novel, multi-sector, industry-led model would have the greatest impact in supporting these companies to scale; and
3. That ANDHealth's program could significantly accelerate these companies to investment and export success.

Since 2017, ANDHealth has now validated all three of these hypotheses:

1. We have engaged with more than 300 high potential growth companies within three years, and have gathered data on these companies, provided in aggregated form in this report, which spans a broad range of aspects of

their focus, technology and business approach;

2. The ANDHealth model has been proven to have significant impact across all our programs, with overwhelmingly positive feedback from innovators, entrepreneurs and broader industry professionals who have attended our programs; and
3. Our flagship program has delivered clear and measurable impacts for the 10 companies who participated in our two-year, globally unique ANDHealth+ program, resulting in clear commercial outcomes, creation of new jobs and growth and investment into the industry.

The data presented in this report paints a picture of a vibrant, diverse digital health sector that is growing in size and confidence. Yet in many ways these companies remain almost invisible within Australia. They don't meet criteria for grant programs and they don't fall within the prevailing e-health, informatics and health IT view of digital health within Australia. Many of our digital health companies achieve commercial outcomes overseas before they get traction here at home.

The purpose of this report is to shine a light on these companies, their diversity in technology, in clinical focus and in business model, and the potential of this sector to drive Australia's economy and healthcare system into the future.



The ANDHealth+ program has been a key source of advice and assistance in CancerAid's commercialisation. The industry insight of the panel members has helped us translate our digital health research into patient use, and mature our business model to reach life insurers with a sustainable business model which allows us to further support patients closely in their cancer care throughout Australia. From our experience, ANDHealth's commercialisation support will be essential for the growth of Australia's emergent digital health industry.

*Dr Raghav Murali Ganesh,  
Co-Founder & President, CancerAid*

Digital health is a true sleeping giant within the Australian economy. Given the right investment, it could provide the economy with a much-needed boost in a post-COVID world, and achieve a triple aim:



## 1. ECONOMIC GROWTH

- Fast-growth companies hiring STEM-trained professionals
- Global companies, headquartered in Australia
- Attraction of inward investment and clinical trials



## 2. ADVANCED MANUFACTURING

- Sensors, wearables and connected devices
- Evidence-based, high-value software products
- Environmental monitoring, prevention, diagnosis, management and treatment technologies



## 3. HEALTH SYSTEM RESILIENCE

- Direct patient impact
- Ability to respond with sovereign capability and domestic supply chain resilience to future opportunities as well as threats

# What is Digital Health?

“Digital health” is a term which has been in broad use across the health sector for decades, evolving from earlier terminology such as e-health and health IT. Although the sector has its roots in the health software industry, today’s digital health sector spans much more than e-health, health IT or the implementation of electronic medical records and connected healthcare infrastructure.

The US Food and Drug Administration (FDA), which has taken a leading position in encouraging the adoption of digital health technologies, defines digital health as follows:

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.

These technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings.

From mobile medical apps and software that support the clinical decisions doctors make every day

to artificial intelligence and machine learning, digital technology has been driving a revolution in health care. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease and to enhance the delivery of health care for the individual. Digital tools are giving providers a more holistic view of patient health through access to data and giving patients more control over their health. Digital health offers real opportunities to improve medical outcomes and enhance efficiency.<sup>2</sup>

Working from the FDA’s definition, it is clear that the digital health sector, when viewed holistically, comprises proven, evidence-based healthcare systems and interventions that are driven by digital technologies – technology-based products and services that treat, diagnose, cure, mitigate, and/or prevent disease.

A recent report published by HealthXL, the intelligence platform and community for digital health, and Node Health expanded upon the sector definition to provide further clarity over certain types of products within the broader digital health remit, providing a view as to how different types of digital health technologies require different levels of evidence and attract different levels of regulatory oversight:<sup>3</sup>

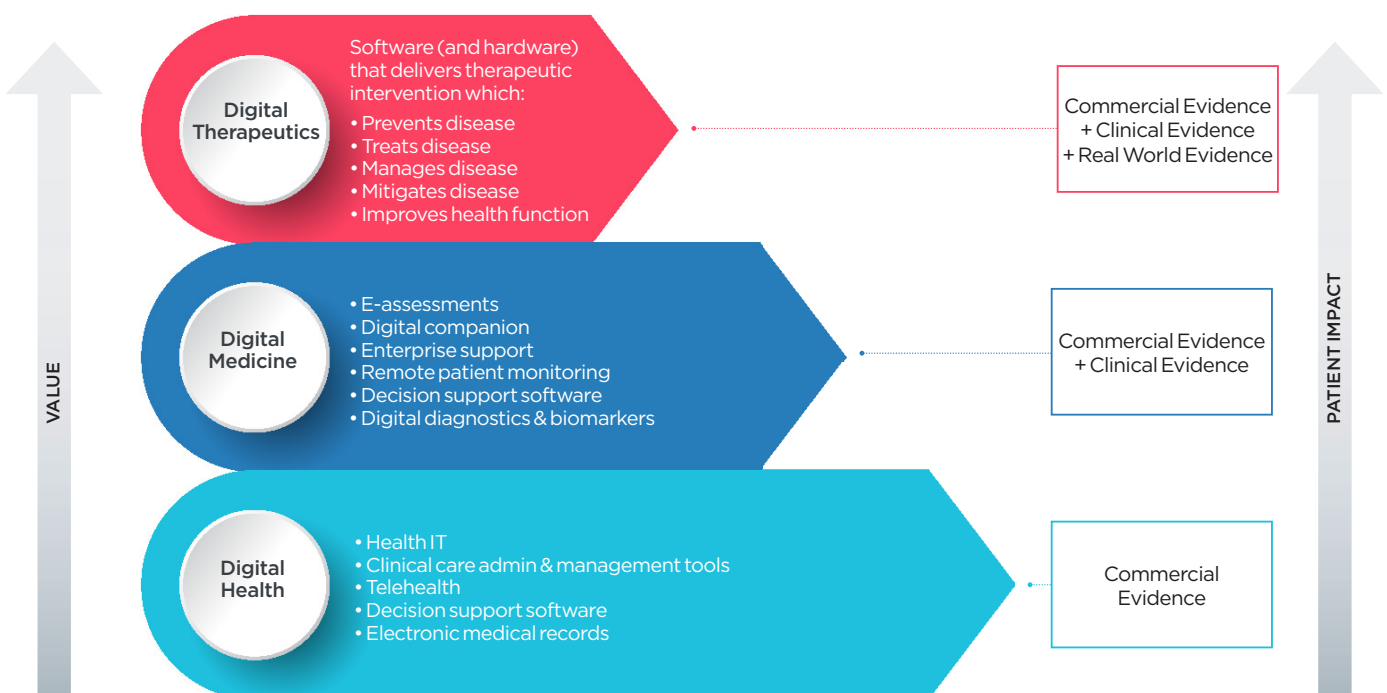
• **Digital health** includes technologies, platforms and systems that engage consumers for lifestyle, wellness and health-related purposes, capture and store health data, or support operations. They do not typically require clinical evidence or regulatory oversight.

• **Digital medicine** includes evidence-based software and/or hardware products that measure and/or intervene in human health. They all require clinical evidence and are likely to require regulatory approval.

• **Digital therapeutics** deliver evidence-based therapeutic interventions to prevent, manage or treat a medical condition. They all require clinical evidence and real-world outcomes data and must be cleared by regulatory bodies to support their claims of safety, efficacy and intended use.

This approach is useful as it clearly illustrates how certain technologies attract greater development risk, have higher evidence requirements and attract different levels of regulatory oversight. The following graphic – adapted from HealthXL to reflect what we have observed in the market – illustrates the different levels of risk and impact within the digital health sector.

Figure 1: Emerging High Impact Areas of Digital Medicine & Digital Therapeutics



Source: ANDHealth, adapted from HealthXL

## Growth and Investment in the Digital Health Sector

The global digital health market has been predicted to reach US\$505.4 billion by 2025, up from US\$86.4 billion in 2018.<sup>4</sup>

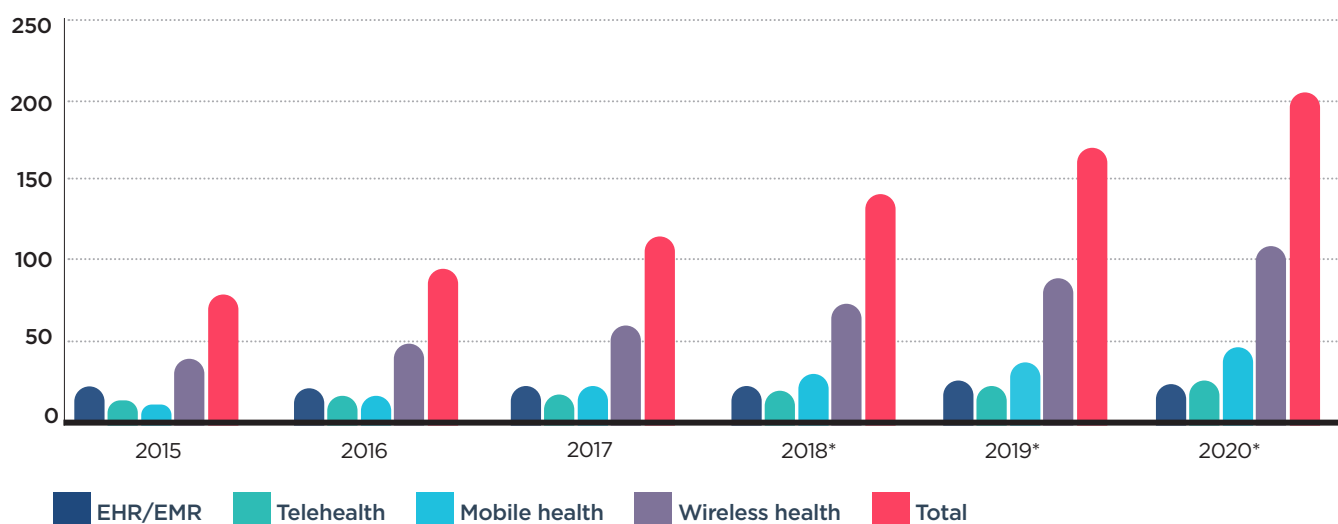
In 2020 the digital health market was forecast to reach US\$206 billion, with over half of this (US\$110 billion) being attributable to wireless health technologies, US\$46 billion to m-health technologies, US\$26 billion to telehealth and US\$24 billion to EMR technologies. The COVID-19 pandemic may impact the size of these markets in 2020 and beyond, but it is still worth noting that telehealth and EMR technologies comprise only about 25% of the total market.<sup>5</sup>

Prior to the outbreak of COVID-19 investment in digital health was largely growing year on year. According to StartUp Health, from 2010 to 2019 US\$69.9 billion was invested into the sector, representing an average annual CAGR of 27.57%. In 2019, US\$13.7B was invested into digital health globally, and 2020 was on track to be a record year with US\$4.5 billion invested in the first quarter.

Following the first reported coronavirus death in China in January 2020, weekly investment into the sector dropped off dramatically.

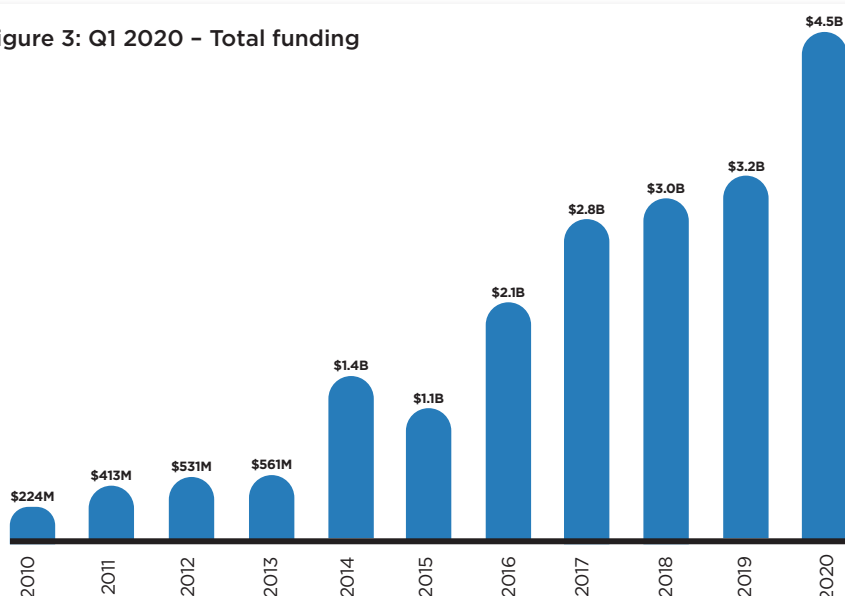
The economic challenges presented by COVID-19 necessitated that investors focus significantly on portfolio company survival over new investments, leading to uncertainty as to whether or not they will deploy the levels of capital which they may have anticipated prior to the pandemic. In addition, US investors indicate a tougher capital environment for digital health companies, with 67% of investors agreeing that companies will have a harder time raising funds this year.<sup>6</sup>

Figure 2: Global digital health market, 2015-2020, by major segment (US\$B)



Source: Statista

Figure 3: Q1 2020 - Total funding



Source: StartUp Health Insights: 2020 Q1 Special Pandemic Response Report



Following the first reported coronavirus death in China in January 2020, weekly investment into the sector dropped off dramatically.

Although this data is from the US, there is no reason to think that Australian companies will have an easier time. With a lack of dedicated digital health funds, or domain experience within existing funds, digital health investment in Australia was already much more sporadic and financing was tougher to access than in more mature markets such as the US. In a post-COVID environment we expect access to capital to remain a substantial hurdle for Australian digital health companies, especially as changes to our foreign investment framework increase challenges for those seeking to attract offshore investment.

Looking forward to areas of positive growth, international reports point to significant drivers of digital health in

a post-pandemic world. In the UK, for example, continued growth is expected in:

- The diabetes market, with the advent of continuous glucose monitors;

- Treating mental health and addiction (digital healthcare is a key tenet of the UK NHS five-year strategy to treat mental health);

- Telemedicine, as developments produce greater productivity for healthcare professionals; and

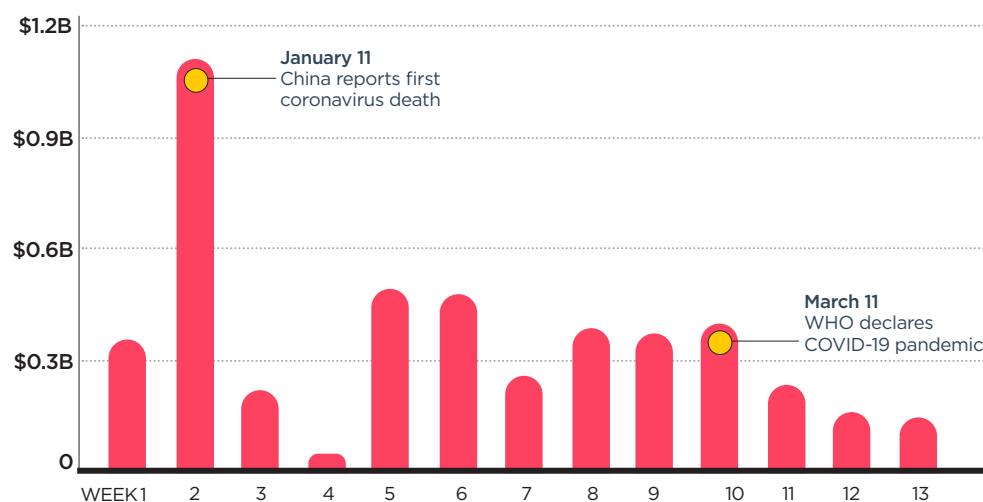
- Digital therapeutic treatments in oncology and neurology, which are increasingly found to be effective as therapies for rehabilitation and prevention of such diseases.<sup>7</sup>

US digital health investment group Rock Health points to greater growth in telemedicine and remote monitoring,

alongside symptom checking and triage tools, digital therapeutics, tools which expedite drug discovery and clinical trials, and clinical decision support technologies than would have been expected prior to COVID-19.<sup>8</sup>

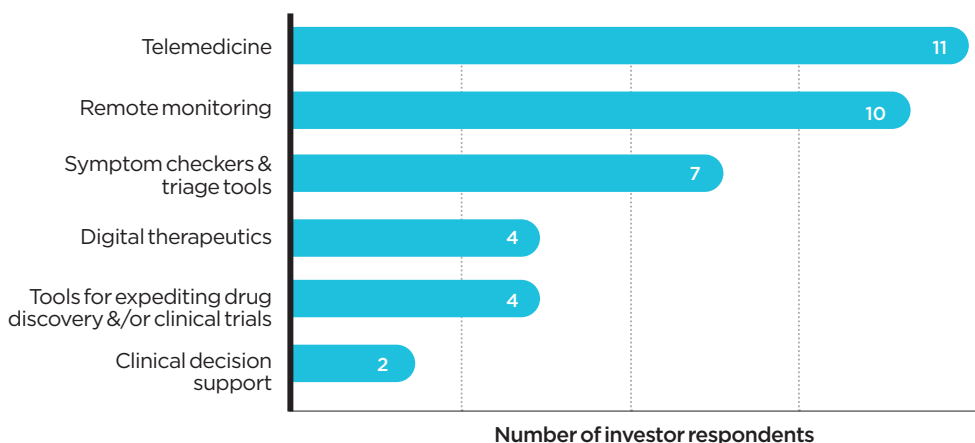
Here in Australia we are seeing increasing green shoots in key areas which will support the ability of our companies to develop and commercialise domestically, specifically with respect to programs that improve connectivity within and between hospitals, uptake of MyHealthRecord and e-prescribing capabilities, and willingness of Government to consider changing reimbursement and procurement frameworks.

**Figure 4: Total health innovation funding – a breakdown of the first 13 weeks of 2020**



Source: StartUp Health Insights, 2020 Q1 Special Pandemic Response Report

**Figure 5: Which areas within digital health are positioned for greater growth in 2020 than originally anticipated because of the COVID-19 pandemic?**



Source: Rock Health Investor Survey Q1 2020

# Digital Health in Australia

Australia has a world-class health and medical research sector, an advanced healthcare system, and an entrepreneurial and successful technology sector. With a decades long policy at State and Federal level of supporting innovation, Australia is in an enviable position to leverage these areas of competitiveness into a thriving digital health sector.

Australia has invested significant resources into building both the capabilities and infrastructure to underpin a world-class platform for the delivery of connected and digital healthcare. This creates a critical platform upon which the industry can now begin to grow and thrive.

The Australian Digital Health Agency, established in 2016, has delivered the MyHealthRecord project and continues to expand upon the critical infrastructure essential to a fully connected healthcare system, including e-prescriptions. Australia has also developed significant capabilities in data analytics, machine learning and health informatics. Industry groups have formed to support these capabilities, including the Medical Software Industry Association and the Australasian Institute for Digital Health (formerly HISA) creating a collective effort around these technical capabilities



**There's no longer any doubt that digital health is at the heart of the modern healthcare landscape.**

and industry players within the broader digital health sector.

In 2018, the Digital Health Cooperative Research Centre (DHCRC) was established, bringing key capabilities developed within the Capital Markets CRC, together with a large cohort of more than 60 university and industry partners to accelerate the use of data and data analytics in improving healthcare across a number of key research streams, including chronic disease, clinical practice, decision support, remote care, rehabilitation and aged care.

This significant investment by the Federal Government, and substantial State-led initiatives such as e-Health NSW, Victoria's Connecting Care Electronic Medical Record (EMR) program, E-Health QLD and the Centre for Digital Transformation of Health, the Commission on Excellence and Innovation in Health (South Australia) and others, have created the necessary infrastructure upon which digital medicine and digital therapeutics companies can begin to build patient facing interventions to substantially improve patient care and outcomes.

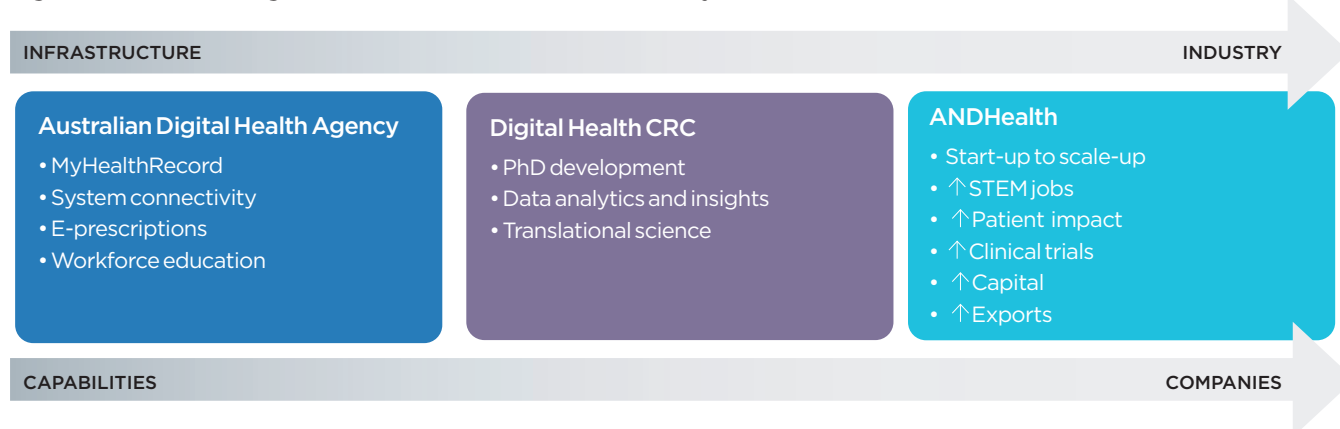
ANDHealth was formed to leverage this significant investment, by supporting innovative digital health companies to commercialise successfully, creating health-system-ready products and services that can be "plugged into" the infrastructure created by decades of government investment, thereby creating a growth industry of the future with the potential to become a globally recognised leader alongside our medical devices and biopharmaceutical sectors.



There's no longer any doubt that digital health is at the heart of the modern healthcare landscape. The technologies around data standardisation, artificial intelligence and machine learning are transforming healthcare services, with digital enablement and integration providing opportunities for continuous healthcare improvement that we couldn't have imagined just a few years ago. Most excitingly, the possibilities for future innovation are profound. MTPConnect is proud to support ANDHealth, Australia's only organisation focused specifically on supporting digital health companies prepare for investment and international market entry. Together, we're building an increasingly vibrant, evidence-based digital health industry in Australia, creating sought-after products for the world market.

*Sue MacLeman, Chair, MTPConnect*

**Figure 6: Australian digital health infrastructure and industry**



Source: ANDHealth

# The Australian Digital Health Landscape

Since July 2017, the ANDHealth team has engaged with and supported more than 300 high growth potential digital health companies across Australia. In doing so, we have collected and aggregated high-level data across key metrics which provide an unprecedented view into a growth industry which has, until now, flown largely under the radar.

In collating this data, we have looked across a broad variety of criteria to assess the types and focus of our innovative early and mid-stage digital health companies, and to highlight the diversity and potential within the sector to transform all areas of the healthcare system and improve the health of all Australians. We explore the purpose and type of technologies, the clinical focus, where technologies are intended to be used and by whom, and, importantly, who will pay for them. Where possible we have assessed where companies might sit along the commercialisation pathway and, where companies were willing to disclose, we have explored financing and funding circumstances and projections.

In future reports and summary insights reports we will begin to explore trends

in this data, but for the purposes of this report we present the data as reported by companies at the time that they engaged with ANDHealth, available as at 10 June 2020.

## Company Purpose

When assessing digital health companies, it is useful to contemplate the purpose for which they believe their technology will be used. The rise of the “empowered patient” or “empowered healthcare consumer” is a key macro trend which is driving agile and digital health solutions globally.

This is reflected in the fact that the vast majority of companies are looking to processes and behaviours at the clinical and patient level. Very few companies (7%) are focused on EMR technologies.

More than a quarter (26%) of companies in our database are seeking to address challenges in workflow (both clinical and non-clinical). They include precision dosing platform DoseMe (now acquired by NASDAQ-listed Tabula Rasa), AI-driven pathology disruptor LBT Innovations, and practice management and practice patient engagement platforms Halaxy and HotDoc.

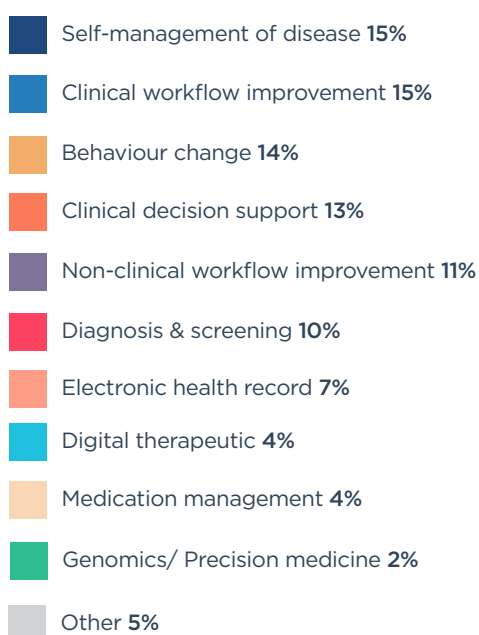
A further 10% of companies are focused on clinical-grade diagnosis and screening tools (such as Atmo, Life Whisperer and ResApp), and 13% are looking to provide technology-based clinical decision support tools, without necessarily looking to reach the evidence level of a regulated diagnostic.

With respect to involving patients themselves in their own healthcare, 33% of companies are deploying technologies in self-management of disease, patient behaviour change and medication management. These companies are at the forefront of shifting care into the hands of empowered patients and reducing healthcare system costs. Sub-optimal medication use alone costs health systems US\$564 billion annually<sup>10</sup>. As Leonard Kish, a health IT consultant, has said, “If patient engagement were a drug, it would be the blockbuster drug of the century and malpractice not to use it.”<sup>11</sup>

“  
The single most unused person in healthcare is the patient.

David M. Cutler<sup>9</sup>

Figure 7: Company purpose



Source: ANDHealth company data

## End Users

In all types of technology development, a deep understanding of how your end-user will engage with your technology is critical. Understanding the key drivers behind your users and their engagement will have a material impact upon your success. In a connected world, 76% of people expect pharmaceutical companies and healthcare providers to provide services which help them manage their health and an equivalent proportion of people expect those providers to understand their individual needs.

Human-centric healthcare is the way of the future, and if our healthcare systems do not deliver it, patients will be drawn to those that do.

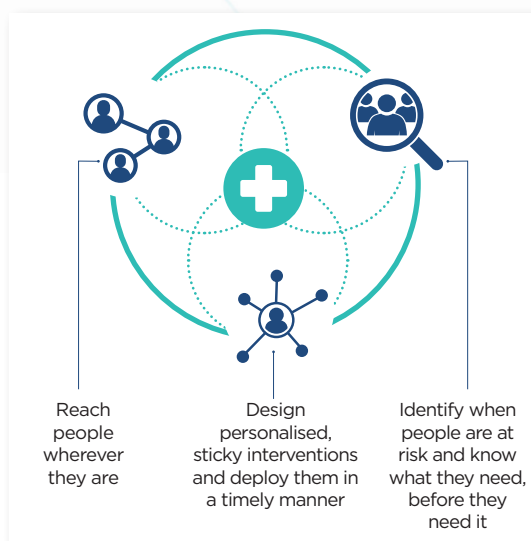
This will be done by reaching people where they are, identifying people at risk and anticipating their needs, and deploying evidence-based interventions in a timely manner. But critically, products need to be personalised and “sticky” in order to sustain long standing uptake and engagement.<sup>13</sup>

However, we also need to be aware that most technologies will need to appeal to multiple end users – the most common combination being patients and their

clinicians, but also laboratory staff, care givers, allied health workers, employees and administrators. These groups will often have multiple, varied requirements, depending on how the technology impacts their care, interactions and workflow.

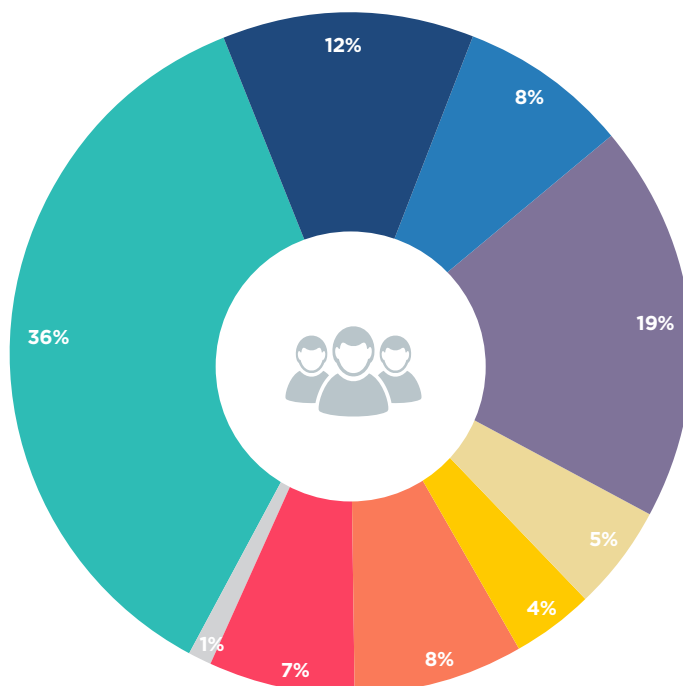
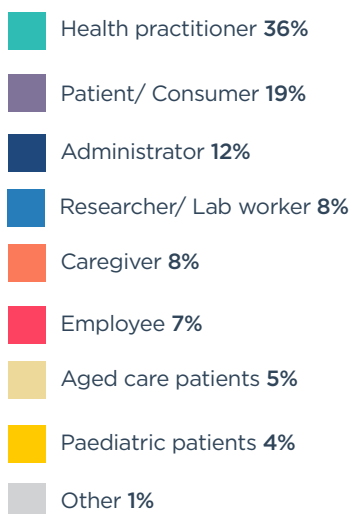
Within our dataset, a predominance of companies (36%) identify health practitioners as their primary end user, 28% of companies identify patients/consumers, aged care patients or paediatric patients as their primary end user, and a further 7% are focused on employees, bringing the total of companies focusing on the individual end user/consumer to 35%. One-fifth (20%) of companies are focused on end users not directly involved in the exchange between clinicians, patients and technology – administration, research and laboratory personnel.

Where digital health starts to become more complex is in assessing the tensions between end users and paying customers. For example, 36% of companies identify health practitioners as their primary end-user but only 8% of companies believe practitioners will be their ultimate paying customer. Which begs the question: who will pay?



**In a connected world, 76% of people expect pharmaceutical companies and healthcare providers to provide services which help them manage their health and an equivalent proportion of people expect those providers to understand their individual needs<sup>12</sup>**

**Figure 9: End users**



Source: ANDHealth company data

## Paying Customers

Following on from the prior section, one of the most difficult challenges in successful commercialisation within the digital health sector is navigating the tension between designing products and services which are effective and appealing for multiple end users (patients, clinicians, carers etc.) and developing a product which has a clear paying customer. Unfortunately, a patient-pays model rarely works – the person using the technology will often not be the person who ultimately pays for it.

Digital health companies need to have a deep understanding of the voice of their paying customers, as well as the voices of their users. Clinical need itself does not necessarily create an incentive for a particular cohort to invest in the technology. Neither does the economic impact of a disease, or the cost of wastage in treating a disease, or the savings to the system if patients were better diagnosed, managed or treated, necessarily relate to an incentive to use and/or pay for the technology.

Our data shows that Australian digital health companies have diverse expectations about who will ultimately pay for their technologies. A high number – 15% – expect that patients themselves will pay. However, experience elsewhere in the world has shown that this may be an unreasonably optimistic belief, especially in government-funded healthcare systems such as Australia's. Consumer-pay models most often work in the unregulated wellness space, but only in narrow segments in the clinical-grade intervention space, and of course rely on users being able to afford the technology in the first place, limiting the total addressable market.

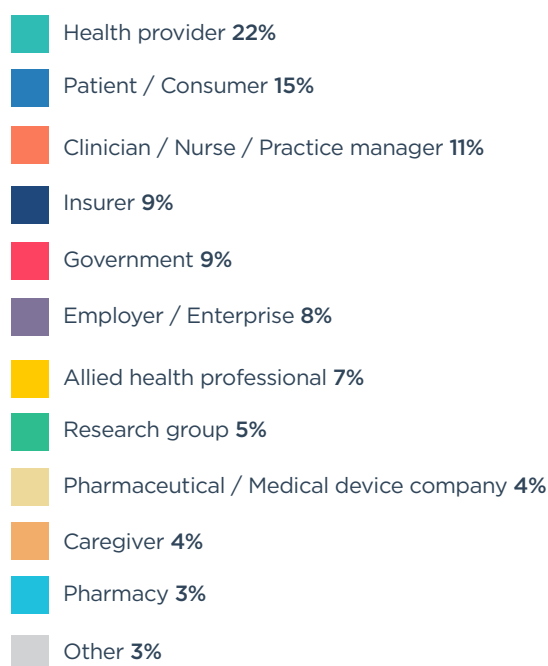
In other jurisdictions, such as the US, companies may have greater success going to market as there are a broader range of reimbursement structures available to digital health companies, especially in the field of remote patient monitoring. In the US, Current Procedural Terminology (CPT) codes covering patient-initiated digital communications provided by physicians or other health

professionals allow companies (assuming they can meet strict criteria) to provide their products in an environment where clinicians are reimbursed – and therefore incentivised – to utilise remote patient monitoring technologies.

Notably, only 9% of companies believe that their ultimate paying customer is government. In a single-payer market such as Australia, it is often believed that government is the ultimate paying customer, but the variety of customers outlined in this data suggests that there is a much greater variety of proposed business and payment models than simply “government should pay”.

“  
Notably, only 9% of companies believe that their ultimate paying customer is government.”

Figure 10: Paying customers



## End-User Setting

In a fully connected healthcare system, we will be able to leverage data and inputs from all aspects of a patient's life, not simply capture the moments when the patient interacts with the system.

In his book *The Patient will See you Now: The Future of Medicine is in Your Hands*, Dr Eric Topol notes that healthcare data is now not just a sum of a patient's medical interactions, scans, tests and clinician notes, but that most healthcare data is today generated and gathered by consumers using their own devices.<sup>14</sup>

Topol observes that the digitalisation and subsequent democratisation of healthcare is likely to disrupt the traditional paternalistic "doctor knows best" and "patients should do as they are told" model of healthcare delivery. The proliferation of "the Internet of Medical Things" will mean that information will flow from the patient upwards to their care teams and the healthcare system,

rather than downwards from the provider to the patient.<sup>15</sup>

Digital technologies provide care, support, actionable insights and interventions, outside of a physical healthcare setting. There is a high expectation among Australian digital health companies that the products they are developing will be used in non-clinical settings – the home and the workplace. This represents a huge potential for homegrown technology to be applied to remote patient monitoring, a market which by at least one forecast is expected to reach US\$1.8 billion by 2026.<sup>16</sup>

Within the Australian digital health sector, 37% of companies are looking to deploy technology into the home, and a further 8% into the workplace. More than one-third (36%) of companies aim to see their products and services used in a community care, aged care, primary

health (GP) or allied health setting with only 19% focusing on in-hospital or surgical settings for implementation.

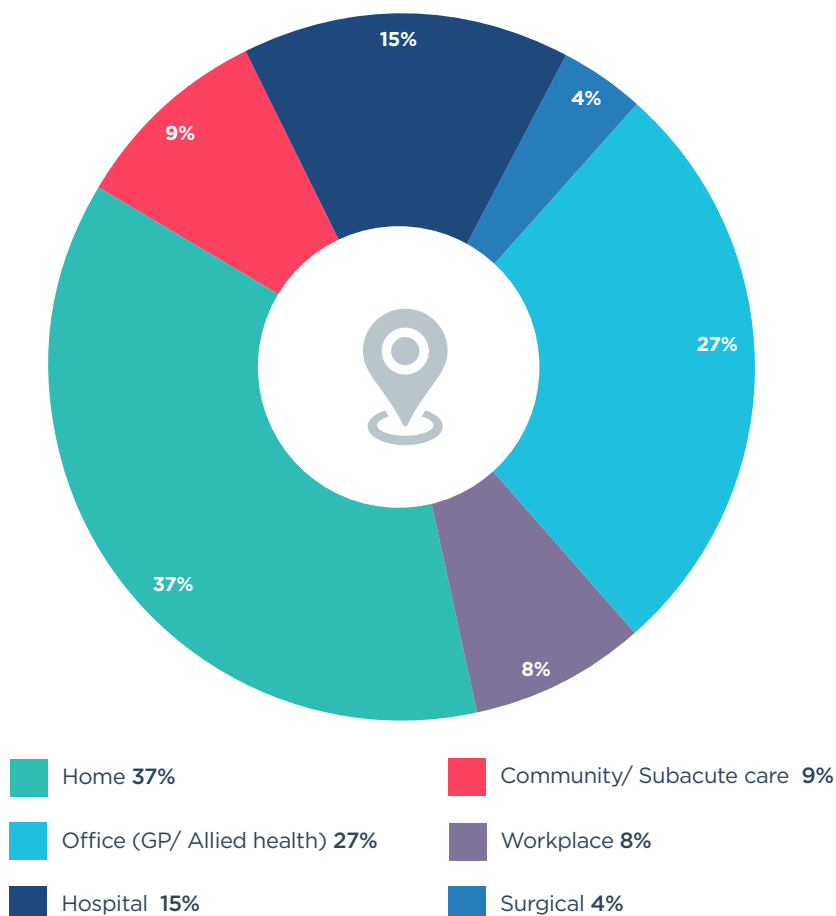
This demonstrates the significant potential, with the right policy frameworks, to grow these companies and improve the quality of care in settings outside the hospital, optimally reducing the need for surgical interventions and unscheduled hospital visits and improving healthcare outcomes.



### CASE STUDY: VITALIC MEDICAL

Vitalic Medical, which is developing a targeted, smart trigger system to help nurses identify early signs of deterioration and potential falls in at-risk patients, significantly matured their product strategy throughout their time in ANDHealth+, greatly reducing the risk for the business. This included a quality improvement trial at Ramsay Hospital. The ANDHealth+ panel commissioned a deep third-party regulatory analysis to inform and support the company in developing the MyCue MVP and its regulatory strategy. Vitalic benefited from a health economics report that informed initial financial/economic modelling and industry engagement supporting its broader value proposition. Vitalic has explored US, UK and EU market opportunities as well as strategic partnerships. ANDHealth has facilitated direct introductions to UK health networks including the NHS and accompanied Vitalic to perform in-market business development and intelligence as a delegate to the Australian British Health Catalyst.

Figure 11: End-user setting



Source: ANDHealth company data

## Primary Clinical Indication

Across Australia companies are pursuing a wide range of primary clinical indications in developing their companies and technologies. This diversity of focus demonstrates the breadth of impact that a fast-growing digital health sector can have on the health of all Australians.

Chronic diseases are well known as areas where digital health technologies are having a direct impact. In our database, 25% of companies are focused on diabetes and other chronic diseases, and 17% are focused on the increasingly important area of mental health. With these two areas tipped to grow — investment in mental health technology alone reached more than US\$740 million in 2019 — we would expect to continue to see a healthy pipeline of innovation in these areas. Musculoskeletal, nervous system and cardiovascular conditions are also key areas of focus.

Overall, though, the diversity of focus reflects the enormous opportunity for digital health to make a difference across the healthcare spectrum and across the nation's population. It also illustrates areas of potential where there is limited domestic competition for new entrants to the market.

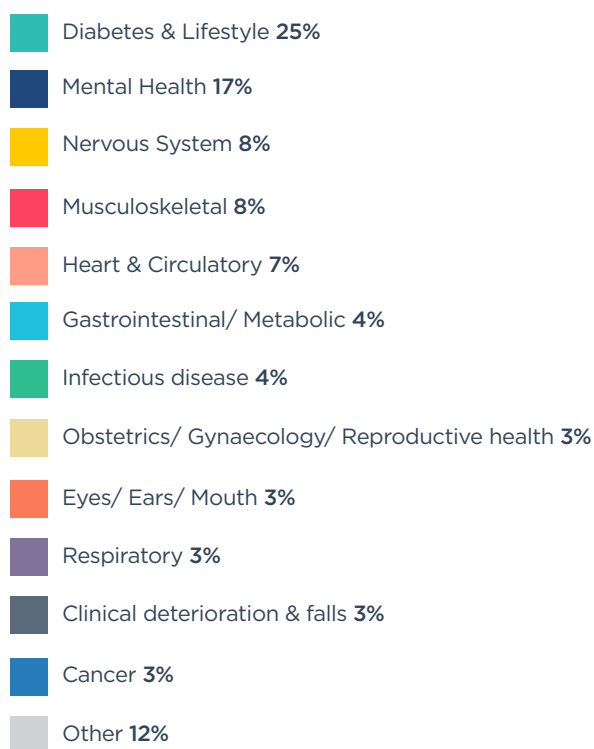


### CASE STUDY: HEALTH DELIVERED

Health Delivered's dietary management platform is designed to tackle the growing rates of obesity, diabetes and other chronic health issues. The initial focus of the platform was to allow dietitians to generate meal plans. But participation in ANDHealth+ helped the company to pivot to alternative business models. Sector-specific mentoring, including workshops with Novartis, and third-party market data allowed the company to improve its business narrative and product market fit and identify additional target markets. ANDHealth+ performed a deep third-party review of the commercial environment and provided the company with recommendations to position itself as a clinical meal plan support tool for corporate wellness programs, later expanding to aged care and health insurance.

Clinical validation is a core value of ANDHealth. Through the program, Health Delivered engaged with CSIRO to conduct a clinical assessment of its algorithms. This allows the company to be informed by data and research, ensuring accountability throughout the development process, as well as supporting a unique market position.

Figure 12: Primary clinical indication



Source: ANDHealth company data

## Technology

The primary technology focus for companies within our data set provides an interesting view into where technical skills are being deployed, and where there may be future demand, within a digital health context.

One-quarter (25%) of companies list data analytics and systems as their primary technology set, with a further 14% leveraging machine learning and artificial intelligence. This is expected to grow significantly – investment into AI in healthcare reached US\$4 billion in 2019, up from US\$2.7 billion in 2018.<sup>17</sup> This could possibly be attributed to US regulatory changes, as well as the push towards and value of remote patient monitoring (this is evident in the user setting graph above – 37% of companies in our database are developing technologies aimed for home use).

More than a fifth (22%) of companies are focusing on m-health as their core technology, which aligns with global trends. The number of consumer health apps has nearly doubled since 2015: more than 300,000 are now available for download on the leading app stores, and about 200 new apps are added daily. Recent research suggested that five million people download a health app every day.<sup>18</sup>

However, in the absence of regulation, it remains challenging for clinicians and patients to identify those applications which are firmly centred in clinical evidence, and those that are simply suggesting health benefit without investing in the necessary research and development to validate their claims.

Regulatory frameworks such as the regulation of Software as a Medical Device (SaMD) by the FDA (and proposed regulation of SaMD in Australia by the TGA) are particularly useful tools to differentiate those apps which have robust evidence in support of their claims, and those that do not. Curated app libraries, such as the one provided by the NHS in the UK, are also valuable tools by which clinicians and patients can assess the utility and applicability of particular health apps.<sup>19</sup> Regardless

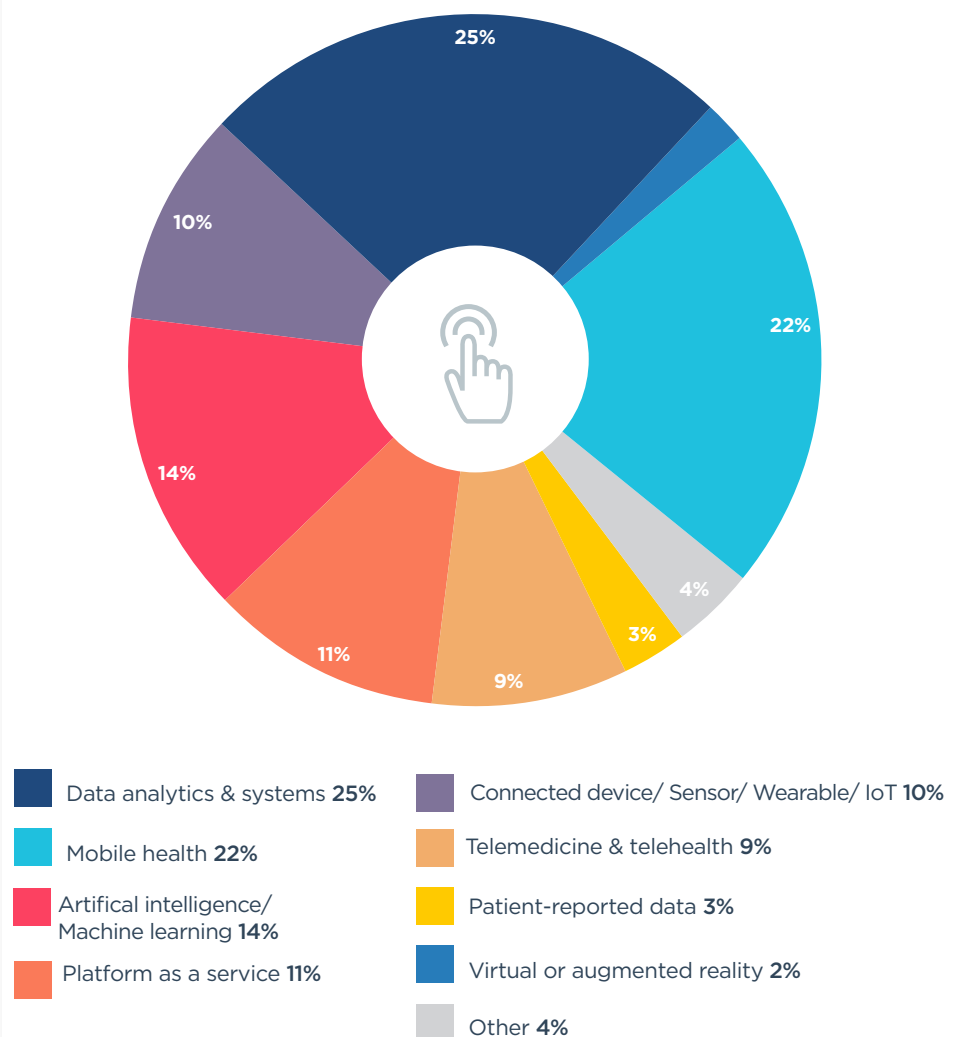
of these challenges, the m-health segment remains a growth area with a forecast CAGR of 41% from 2015 to 2020.<sup>20</sup>

Not surprisingly, given Australia's strength in the medical devices sector and emerging areas of unique competitive advantage in sensor and device development (e.g. RMIT University's development of stretchable sensors and the Atmo Gas Sensing Capsule), 10% of companies are looking at connected devices, wearables and sensors. Due to the overlap with existing medical device support programs in this area, we also

estimate that there is a significant number of these companies with which ANDHealth is yet to engage.

These markets are areas of significant growth internationally: the global wearable healthcare devices market is projected to reach US\$46.6 billion by 2025 from US\$18.4 billion in 2020, representing a CAGR of 20.5% during that period.<sup>21</sup> This market includes generic consumer devices such as smartwatches, but it still represents a large and growing international market opportunity.

Figure 13: Technologies



Source: ANDHealth company data

Notably, telehealth and telemedicine represent only a small part of this data set. This likely reflects the limited reimbursement for these types of businesses prior to the COVID-19 pandemic. Since the pandemic commenced and universal reimbursement for telehealth for all Australians was put in place, we have observed an increase in the number of telehealth companies approaching ANDHealth for support.

Assuming ongoing reimbursement frameworks for telehealth and, beyond that, potential introduction of reimbursement for remote patient monitoring, we would expect to see significant growth in the numbers and maturity of companies across several sub-segments.



## CASE STUDY: DOSEME

DoseMe has developed the world's first precision dosing platform designed for clinicians at the point of care. Using readily available patient data, it provides real-time dose-related decision support. From just one blood sample, DoseMeRx virtually constructs a model of each patient's individual pharmacokinetics, allowing clinicians to predict the optimal dose of medication – taking away guesswork and manual calculations. Through its participation ANDHealth+, DoseMe successfully expanded its operations in Australia and the US and entered new markets in South Africa, UK, Portugal, Brazil, Slovenia and Italy. The DoseMe team grew significantly, creating seven new jobs.

The DoseMeRx platform was ranked in the top 20 2018 Hot Apps for healthcare providers by Health Data Management.

## Stage of Development

The commercialisation pathway for digital health is distinctly different from medical devices or pharmaceutical drug development. The basic premises of safety and efficacy hold just as true for digital health products as they do for drugs and devices. To get to market, digital health products need to be backed by real-world evidence spanning both clinical and commercial outcomes. Proof of clinical efficacy is not enough – digital health companies must also prove that there is a health economics model that supports a viable and sustainable business model with a relevant paying customer.

We know from many internationally successful digital therapeutics companies, including WellDoc, Omada and Propeller Health, that healthcare utilisation studies are incredibly important, alongside compelling clinical data packages that can show clear improvement in clinical outcomes. These companies also demonstrate that the road to market is long (often more than 10 years), far from straightforward, and requires similar levels of investment to a novel medical device.

What they also show is that the pathway to commercial success in digital health

is varied. Value inflection points often do not necessarily hinge on clinical data, customers require complex commercial validation studies (and even then, they may not purchase), and valuations are not tied to large intellectual property portfolios. In addition, the commercialisation landscape for these types of companies is constantly changing, with new and changing regulatory hurdles, global data governance regulations and a reimbursement environment that offers minimal support for most digital health technologies in many major jurisdictions.

### Pharmaceutical drug development



### Medical device development



### Digital health product development



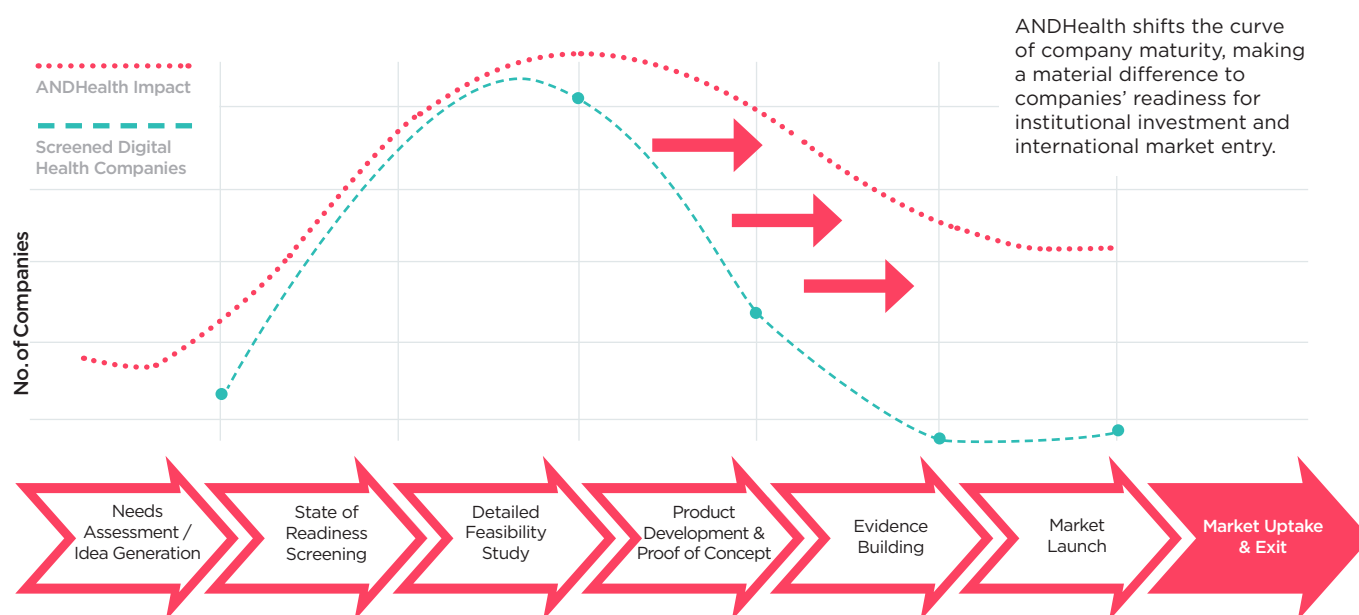
Source: ANDHealth, Scott T. Ham, Oxford AHSN

ANDHealth uses a proprietary stage of development screening methodology to assess the maturity of companies in our pipeline. For the purposes of this report we have mapped a cohort of 146 companies against the Oxford Academic Health Science Network's Digital Health Roadmap to give an indicative

view of emerging sector maturity.<sup>22</sup> Unsurprisingly, given the relative youth of the sector, most companies are in the early development stage, and are completing detailed feasibility studies as they move towards proof-of-concept. A healthy number have progressed to evidence-building in the lead-up

to market launch. Importantly, the ANDHealth program suite is the only offering within Australia with proven ability to both grow the size of this pipeline, and shift the curve to the right, supporting increasing maturity across the sector nationwide, from idea generation to market uptake and exit.

**Figure 15: ANDHealth: building a high impact growth industry**



Source: Australian Digital Health Companies & Technologies screened by ANDHealth | July 2017 - 1 June 2019 (n=139)

## Financing

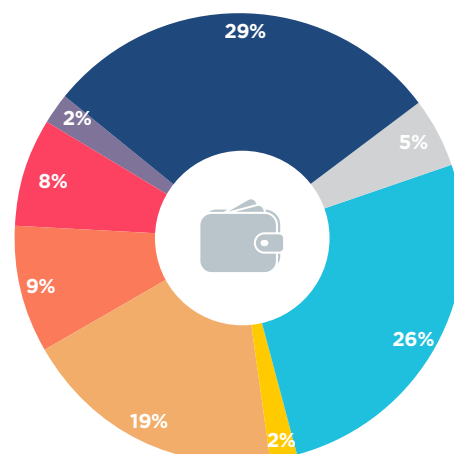
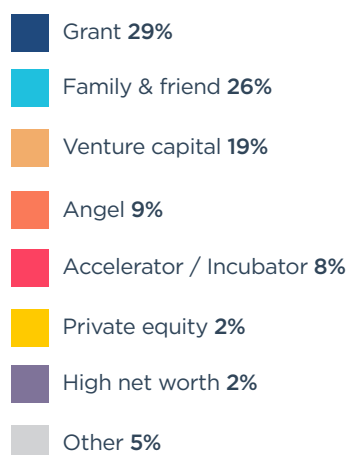
There is a significant gap in investment and support for companies developing evidence-based digital medicine technologies, especially in Australia. Even before the onset of the COVID-19 pandemic, Australian digital health companies found accessing capital to be their biggest challenge. Beyond systemic reasons such as lower levels of venture capital per capita than other jurisdictions, this limited capital market also reflects a relative lack of maturity in the understanding of digital health as a sector, its potential and the pathways to market success. In more mature jurisdictions, it is common to find fund managers and venture capitalists with funds and/or management teams which are specifically focused on digital health, whereas in Australia our funds largely fall into general technology funds or "traditional healthcare" (biopharmaceutical/medical device) funds.

There is no doubt that in the next two to three years, following this year's pandemic, accessing capital will be difficult due to impacts of the pandemic across equity capital

markets. In addition to the shortage of specialised local investors, companies will find it difficult to attract international investment as long as foreign investment frameworks create regulatory hurdles for attracting offshore equity investors to fill the gaps left by a lack of local capital.

International market entry and global expansion will also be difficult while travel restrictions are in place, making global investment roadshows a thing of the recent past. Many pre-revenue digital health companies will have existing cash-flow issues, and there is the overshadowing reality of a global recession.

**Figure 16: Percentage of funding raised from various sources**



Source: ANDHealth company data

Despite these barriers, digital health companies in Australia have so far raised a total of AUD\$441.5 million (dilutive and non-dilutive), bearing in mind that not all the companies on our database have disclosed their financing outcomes. As can be seen, 37% of companies were financed via family, friends, angel investors and high net worth individuals, and 29% of companies have sourced their majority of their capital from grants. Another 8% of companies accessed financing through accelerator and incubator programs. Interestingly, 19% of companies have received venture capital financing, although the data does not differentiate between local and offshore funding sources.

Perhaps indicative of the nascent stage of the industry's development in Australia, 72% of companies have raised less than AUD\$1 million in financing,

reflective of small pre-seed and seed rounds in the Australian environment, and similarly aligned to the majority of funds being sourced from friends, family, angel investors and grants. Another 17% of companies have raised between AUD\$1 million and AUD\$5 million, reinforcing what we observe in late seed/early series A rounds, with 11% of companies going on into later rounds of AUD\$5 million and over. Notably, 6% of companies have raised more than AUD\$10 million, demonstrating the capital intensity of digital health as companies progress down the commercialisation pathway.

Time taken to achieve financing also reflects in many ways where finance has been sourced. More than half (52%) of companies indicated that they accessed finance in less than six months, suggesting smaller, more agile

and personal sources of capital and structured grant programs. Meanwhile, 26% of companies indicated that their financing took between 6-12 months to complete, and 22% of companies stated that their financing took a year or longer. In future data sets, assessing whether the time to raise is influenced by the scale of the raise and the source of the financing would provide added clarity of the function of the financing and capital market for these companies.



## CASE STUDY: ATMO BIOSCIENCES

Atmo Biosciences is developing an ingestible electronic pill-shaped sensor that profiles the gases within the gut. Developed by researchers at RMIT University, the Atmo Gas Capsule has the potential to revolutionise how gut disorders are diagnosed and managed.

Atmo Biosciences significantly matured its product and business strategy through ANDHealth+, greatly reducing the risk for the business and for investors as they seek to raise capital. This included deciding on the initial therapeutic application, identifying potential partners, and developing clinical trial and regulatory strategies. Atmo also established an external clinical advisory board and one of its key studies was published in a prestigious Nature journal which triggered national and international media coverage across print, web and television.

In June 2020, Atmo Biosciences raised \$2.5 million in an oversubscribed funding round, supplementing an initial seed raise in March 2019.

Source: Australian Digital Health Industry Survey by ANDHealth

Source: Australian Digital Health Industry Survey by ANDHealth

Figure 17: Amount of funding raised

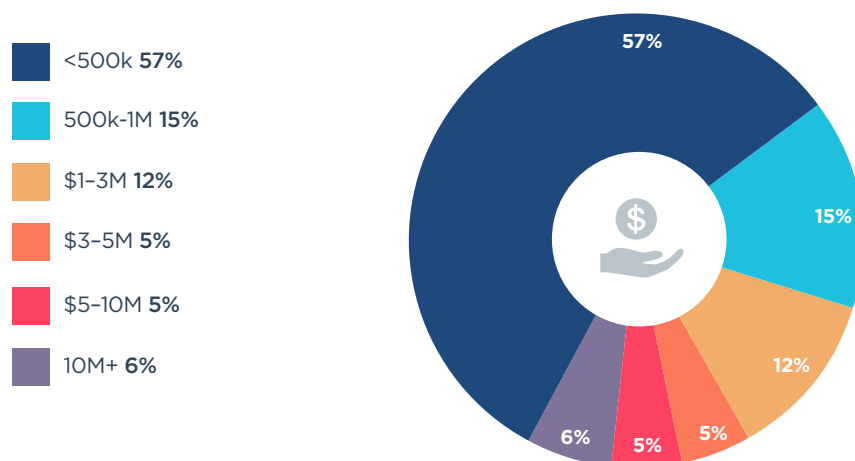
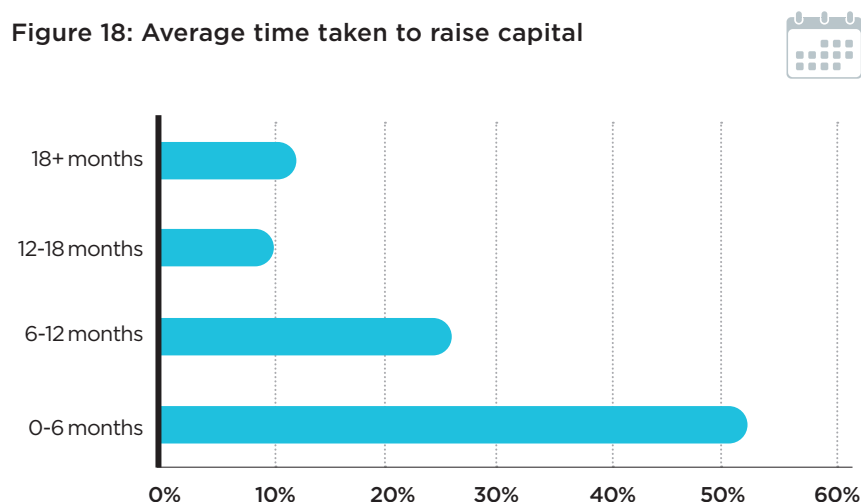


Figure 18: Average time taken to raise capital

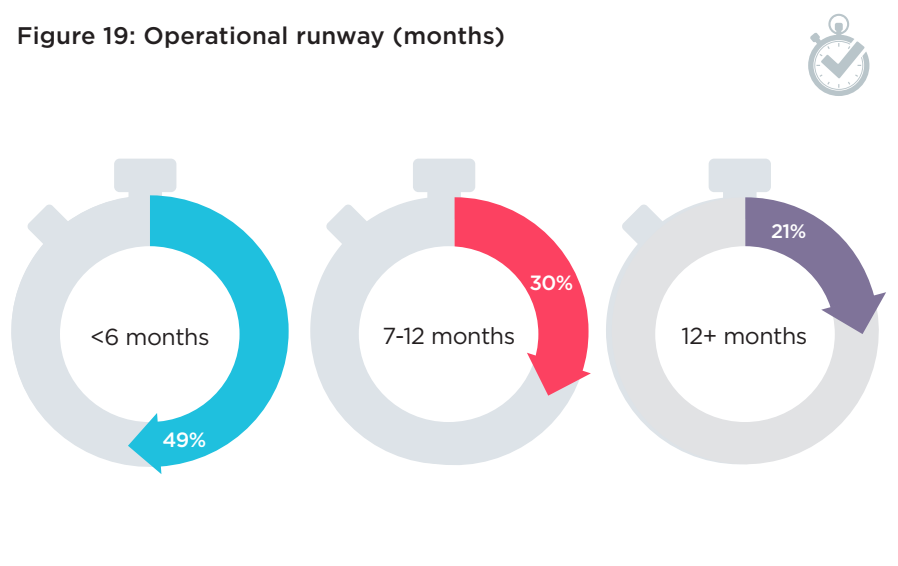


## Operational Runway

It is concerning, but not surprising given the difficulties of raising capital in Australia, that many of the companies in our database are working on noticeably short operational runways. 80% of companies are working under conditions which allow them an operational runway of under 12 months. This may reflect the maturity of companies in some cases, but also points to the stress that this sector is under from limited access to capital.

Short operational runways prevent companies from embarking upon critical clinical and commercial studies and can limit options to engage with larger corporate partners. It is encouraging to see 20% of companies looking at longer term horizons, but continued support of this nascent industry is clearly key to realising its full potential.

Figure 19: Operational runway (months)



## Employment and Skills

Across the sector, teams are generally small, reflecting a “lean start-up” philosophy and tech-industry-style agility. However, 36% of companies have 3-10 staff and a further 13% have 10-40+ staff. Although these team sizes may seem small, it is important to recognise the high levels of industry specific skills and expertise that are resident in these companies. These employees will be the future veterans of this sector, and will go on to work with other companies, and potentially create new companies, as the sector matures.

Beyond their current status quo, it is also useful to note that 82% of these companies intend to expand in the future. Following the impact of COVID-19, our May 2020 Industry Sentiment survey found that while 29% of companies had been forced to lay off staff, 21% were hiring even during the pandemic, demonstrating the ability of this sector to create highly skilled, pandemic-proof employment, while also improving the quality of care we are able to deliver to all Australians.

Figure 20: Team size

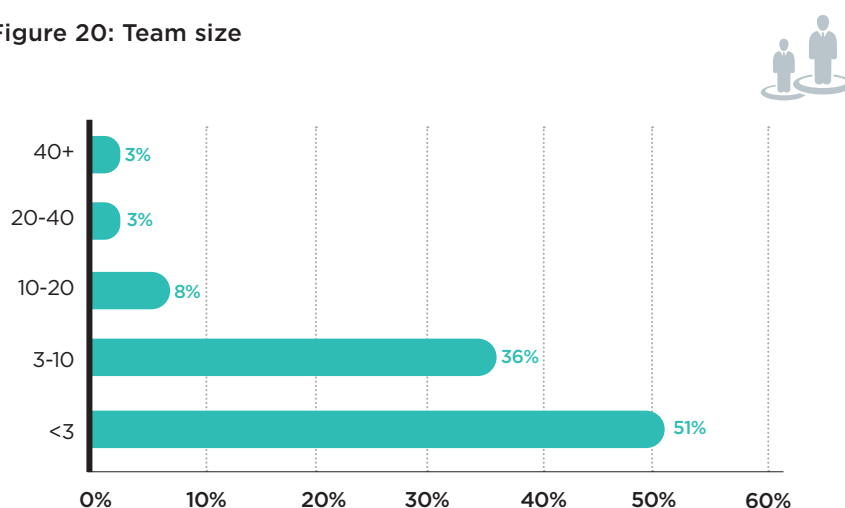
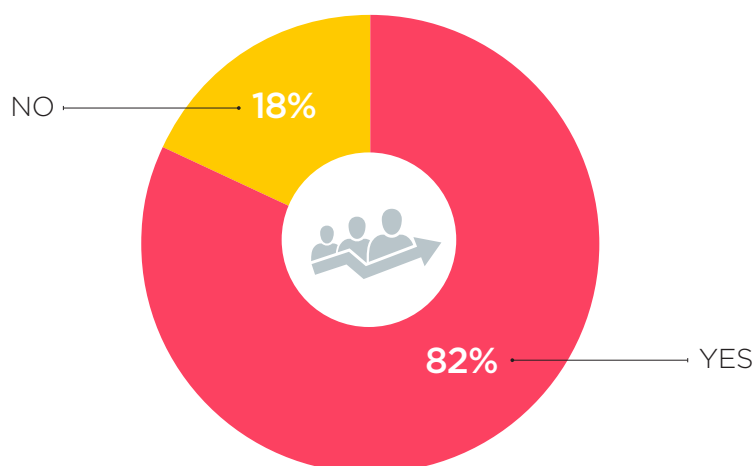


Figure 21: Do you plan to expand your team in the next 12 months?



Across the sector, teams are generally small, reflecting a “lean start-up” philosophy and tech-industry-style agility.



## CASE STUDY: SEER MEDICAL

Parkville-based epilepsy diagnosis company Seer Medical is a clear demonstration of how digital health companies can scale and deliver high-value jobs. Formed in 2017, Seer Medical has deployed technology which enables patients to undergo hospital grade EEG and ECG monitoring for the diagnosis of epilepsy in their own homes. The scale-up of the Seer technology has dramatically reduced patient wait times from years and months to weeks, and has significantly improved access to diagnosis for many patients, who were previously unable to spend seven days in hospital undertaking the necessary monitoring.

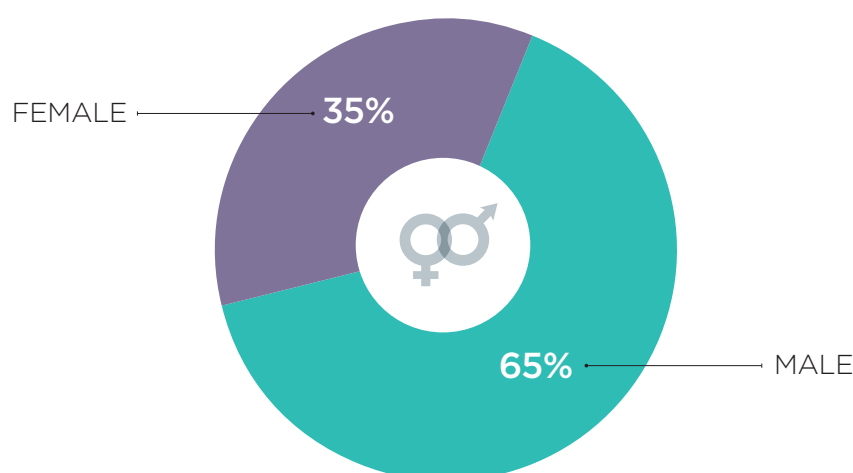
Seer Medical was one of the five companies in ANDHealth's first ANDHealth+ cohort and has become a stand-out performer in the sector. From its incorporation in 2017, Seer now employs 103 highly skilled and specialised staff across the domains of biomedical engineering, user experience and design, hardware engineering, platform development, clinical scientists, data scientists, research and product managers.

## Gender Diversity

As Australia's only female-founded and female-led health technology accelerator organisation, gender diversity is core to the values of ANDHealth. Of the more than 300 companies with which we have worked, 35% are female-founded or led, a better balance than in the Australian start-up ecosystem overall, in which female founders made up just 22.3% of the total in 2018.<sup>23</sup> Gender parity remains a difficult issue throughout the sector, globally. In 2019, just 14% of deals by US digital health start-ups were made by female-lead companies, and just 12.6% of US VCs active in digital health have female partners.<sup>24</sup>

However, we have seen positive shifts in the recognition of the role female founders play in the Australian ecosystem, with the introduction of the Boosting Female Founders Initiative through the Department of Industry, Science and Resources.<sup>25</sup> Unfortunately, in healthcare, the successive rounds of capital required to commercialise have left some female founders ineligible for these grants based on their equity position, but we look forward to seeing continued government support for female founders across all disciplines, including digital health and health technology as a whole.

Figure 22: Gender diversity



Source: ANDHealth company database



We have seen positive shifts in the recognition of the role female founders play in the Australian ecosystem, with the introduction of the Boosting Female Founders Initiative through the Department of Industry, Science and Resources.

## Geographic Distribution

ANDHealth is a national organisation, headquartered in Melbourne, Victoria. In the earliest days of its incorporation, the companies accessing ANDHealth's services were mainly Victorian. Since then, ANDHealth has partnered with several state groups to broaden the reach of its programs and profile.

In June 2020, we see an industry that is spread across the country, demonstrating that this is a national growth industry, supported by a variety of state-level programs and initiatives, but with national significance and global opportunity. Notably we do see significant growth in states where ANDHealth has secured

collaborative partnerships through which it provides programs and services.

In the coming years we would expect to see geographic growth continue to diversify, noting it may be accelerated in particular states and regions where designated funding and support programs are deployed.

Figure 23: Geographic distribution



Source: ANDHealth company database



The advice and recommendations from the ANDHealth+ Program were of high value to SkinView. The non-profit, non-equity taking model allowed ANDHealth to remain free of conflicts of interest and for the industry advisory panel to give impartial business assessment and independent business strategy advice. The third party review of the technology and commercial landscape, both hardware and AI opportunities, provided the company with a suite of recommendations based on this independent information. The feedback that we should not raise capital on the business as it stands today, and that the assets are better suited to a partnering model was incredibly valuable, saving time and focusing the use of existing shareholder funds. ANDHealth+ delivered over \$270,000 of value and saved us time, money and reputation.

*Sarah Richardson, General Manager, GP2U*

# Digital Health Industry Sentiment Surveys: A Pre- and Post-COVID World

## December 2019: the Pre-COVID View

**In late 2019 ANDHealth surveyed the companies in our database to ascertain how they felt about the issues that matter in the Australian digital health sector. Before we had a chance to publish our outcomes, COVID-19 hit and the whole world was upended, so we conducted a second brief survey in May 2020 to see whether the pandemic had changed the industry's viewpoint on key issues.**

The results of the 2019 survey showed us an industry confident in its ability to navigate issues such as regulation – perhaps over-confident, considering the shifting regulatory environment in which they operate.

Within the context of this report, it is important to recognise that the survey responses reflect a much smaller cohort (53 companies) than the industry data gathered by ANDHealth (about 300 companies), and so should be viewed as a small sample of sentiment data only.



COVID-19 has forced healthcare payers and providers to reconsider the way they deliver care and support high-risk chronic disease patients. The first wave of this change may just be transposing face-to-face appointments to telehealth consults. However, as with any other industry, as healthcare begins to adopt a digital-first mindset we will see innovations that don't just replicate traditional healthcare into the digital realm but completely reinvent the way we think about delivering care to patients altogether - from activity-based, episodic interactions to more outcome-based, continuous, integrated management. Perx is already playing a key role in this transformation as we enable our partner organisations and their patients to improve self-management outside the clinical setting, and over the medium-term we expect to use the outcomes we deliver for patients and these organisations to push for more outcomes-based, remote management programs to support high-risk chronic disease patients.

*Scott Taylor, Founder and CEO, Perx Health*

## Regulatory Considerations

Three-quarters (75%) of respondents to our 2019 survey said they were completely or fairly confident about navigating digital health regulation in Australia. Only 6% indicated they were not at all confident. This level of confidence may be due to the fact that many digital health companies in Australia do not currently need to meet regulatory requirements until the introduction of Software as a Medical Device regulations by the TGA in February 2021. It may also be driven by a lack of awareness of the impact that these regulatory changes may have on both new technologies and those already in the market.

Similarly, confidence was high (69%) with respect to navigating regulation in overseas markets. This confidence

level appears to be artificially high and may reflect a naivete among innovators and entrepreneurs who have not previously been exposed to the complexities of international medical device regulation. Alternatively, it may be that entrepreneurs are confident that they can circumvent regulation or that the regulatory burden is not as high as outsiders may perceive.

The sector is less confident in its ability to access qualified service providers and consultants (at home or overseas) to support their regulatory activities. 80% were either only somewhat certain, uncertain or unsure that there are qualified consultants who can help them with their regulatory strategy, while only 18% said they were confident that adequate support was available to them.



**With respect to quality management systems, confidence levels were significantly different with 27% of companies unsure or not confident of meeting quality system requirements.**

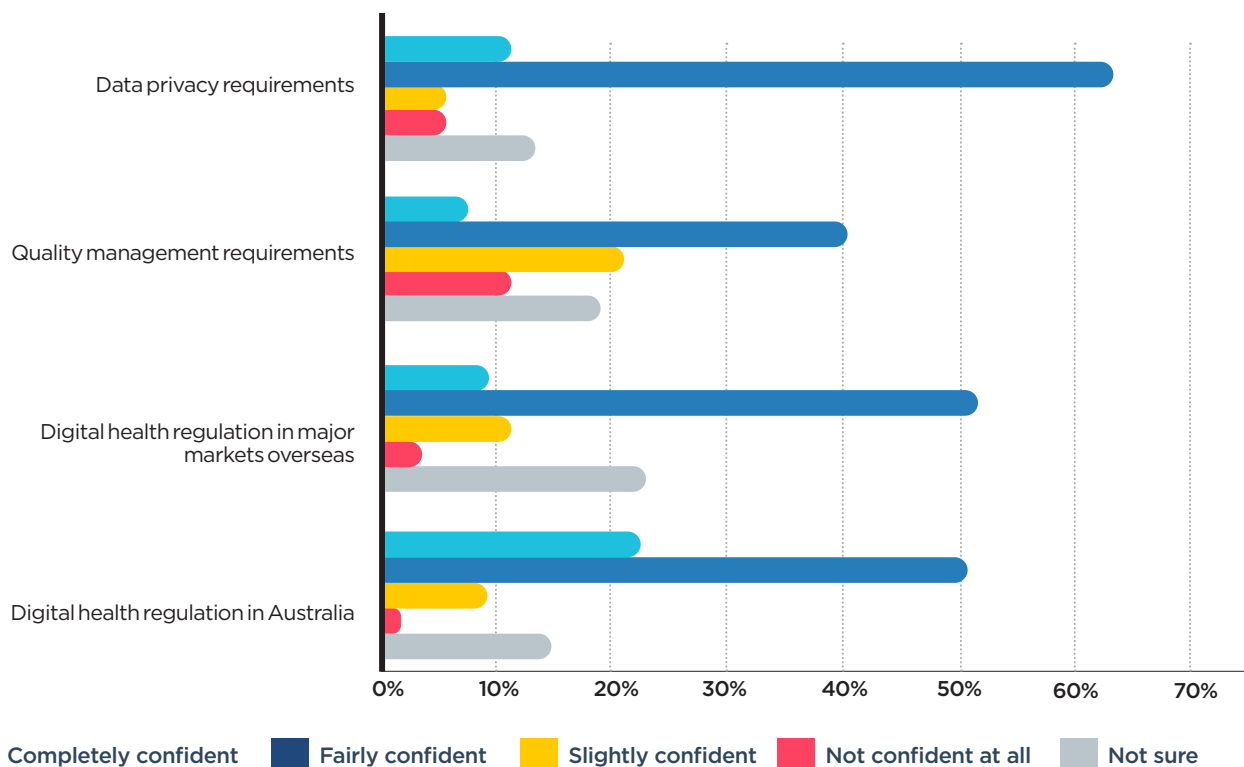
With respect to quality management systems, confidence levels were significantly different with 27% of companies unsure or not confident of meeting quality system requirements. The remaining companies held varying levels of confidence with 62% fairly or completely confident. Interestingly, companies were more confident in

achieving regulatory success overall than they were in implementing quality systems.

One of the key challenges for digital health companies is the management of data: be it security, privacy, cross-jurisdictional regulations or data governance. Again, a large number

of respondents were significantly confident in their ability to meet regulatory requirements around the management of data. Nearly three-quarters (74%) of companies indicated they were completely or fairly confident that they could meet requirements relating to data management and privacy.

**Figure 24: How confident is your company with strategically navigating these requirements?**



Source: Australian Digital Health Industry Survey by ANDHealth



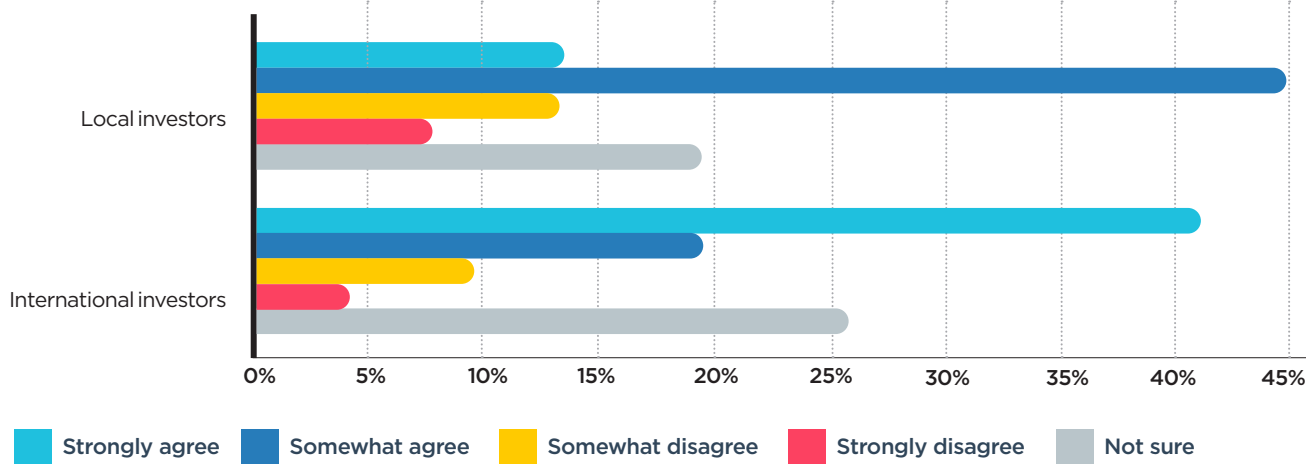
## CASE STUDY: KESEM HEALTH

Kesem Health is a connected health company improving the convenience, accuracy, and validity of data in support of the diagnosis and management of urological conditions. The company's iUFlow is a fully automated bladder monitoring device, implemented on a smartphone platform. Kesem Health's vision is to position iUFlow as the gold standard management tool for urological conditions, through the integration of data analytics & AI. The ANDHealth+ panel worked with Kesem to develop its digital health strategy and business model. A deep third-party review of the EU opportunities for Kesem Health was conducted, which informed Kesem's EU market expansion strategy. ANDHealth member Planet Innovation performed a manufacturing and cost of good review for iUFlow to inform the hardware development strategy in order to gather high-quality data for the digital arm of the business. ANDHealth+ also supported a review by Curve Tomorrow on Kesem Health's accompanying app, providing feedback and recommendations for improving usability and design.

## Investors

As expected from our observations of the industry within the broader data set, confidence ebbed when companies were asked their view on the investment landscape.

**Figure 25: Do you feel that investors (local and international) have the knowledge, skills and ability to adequately support your company?**



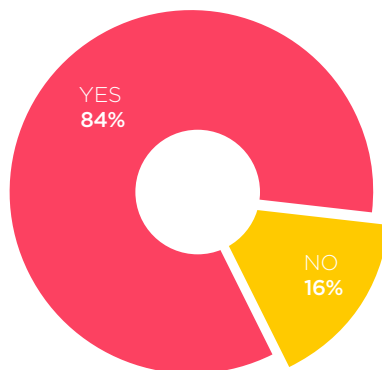
Source: Australian Digital Health Industry Survey by ANDHealth

Respondents were less confident about the knowledge, skills and ability of local investors than they were about international investors. Asked whether local investors have the knowledge, skills and ability to support their companies, 22% say they disagreed with the notion, with 45% somewhat agreeing and just 14% strongly agreeing.

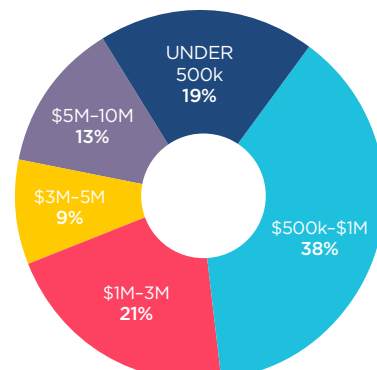
But 41% strongly agreed that international investors have that knowledge, skills and ability, and another 20% somewhat agreed, while just 14% disagreed.

Confidence notwithstanding, 84% of respondents said that they intended to raise capital in the year ahead, with 38% intending to raise a modest AUD\$500,000 to AUD\$1 million.

**Figure 26: Are you planning to raise capital in the next 12 months?**



**Figure 27: How much are you planning to raise?**



Source: ANDHealth company database



### CASE STUDY: MCRI ALLERGYPAL

MCRI AllergyPal, co-developed with the Murdoch Children's Research Institute, is an electronic record of a child's ASCIA allergy plan that helps a non-primary carer to manage a child's food allergy. Created by leading paediatric allergists, AllergyPal aims to minimise the risks associated with childhood food allergies for the 400,000+ Australian families affected by the condition.

MCRI AllergyPal made significant commercial progress throughout its participation in ANDHealth+. It launched its commercial product and consolidated its partnerships with Australasian Society of Clinical Immunology and Allergy (ASCI) and Allergy & Anaphylaxis Australia. MCRI AllergyPal hired an industry CEO, began generating revenue, served thousands of patients and entered new markets both nationally and internationally.

## Reimbursement

In mid-2020 reimbursement is under the spotlight as never before, with the Government stating that it has managed to implement a 10-year reform plan in only 10 days for the universal reimbursement of telehealth for all Australians. This has created an opportunity for us to highlight the importance of reimbursement for creating incentives for implementation, uptake and adoption of digital health technologies throughout the clinical community. However, prior to COVID-19 the views on reimbursement in our December survey were mixed.

In December 2019, only 13% of respondents said reimbursement was critical to their business model in Australia, although 38% said reimbursement in Australia was part of their business model. Reimbursement was not considered part of the business model for 45% of respondents. However, international evidence, specifically from the US, would suggest that the implementation of reimbursement significantly accelerates uptake and improves the growth potential of the digital health sector.

Reimbursement is a complex area, even for seasoned health technology professionals. It is not surprising that

companies were largely not confident about dealing with reimbursement in Australia. Only a third said they were confident to any degree, and just 4% said they were completely confident. Meanwhile, 18% said they were not confident at all, and nearly half were not sure.

When it comes to external support for companies seeking advice on reimbursement, there was a widespread lack of awareness that there is anyone who can help with reimbursement strategies. More than one-fifth (22%) said there were very few or no consultants to help, and 62% said they were not sure.

More than half (53%) of respondents said reimbursement was critical or somewhat important to their business models in international markets. It is possible that this reflects knowledge across the industry that reimbursement is available in other jurisdictions, but not available in Australia, and that companies are shaping their business models accordingly.

However, confidence among respondents was even lower with respect to navigating reimbursement in major overseas markets. More than a

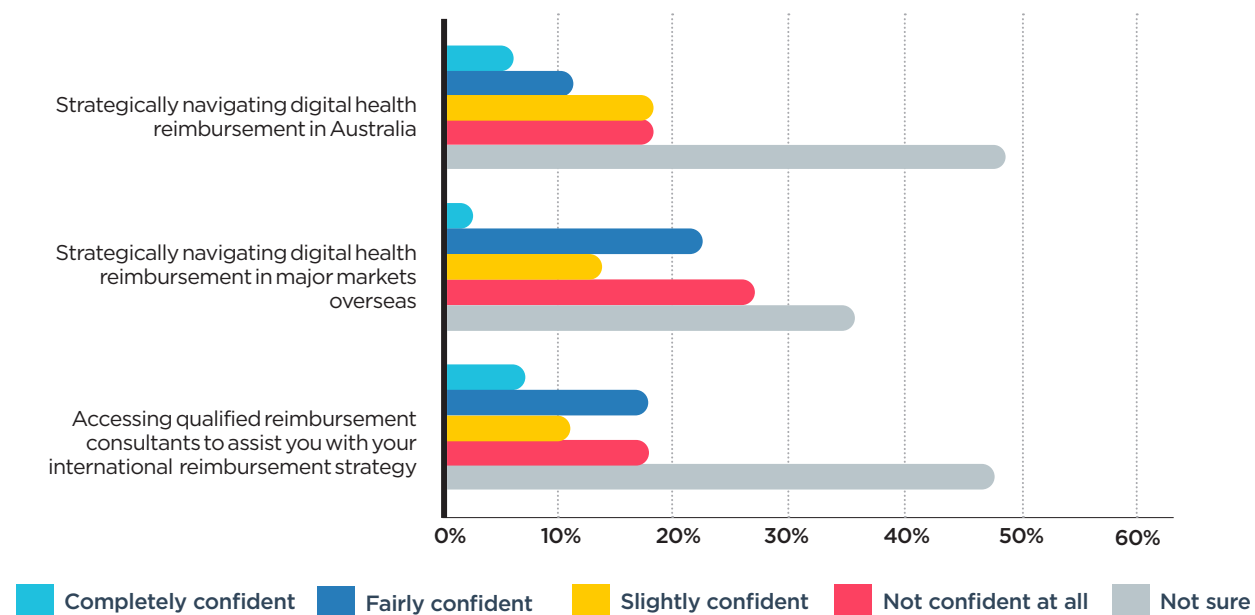
quarter (27%) were not confident at all, and 36% were not sure.

The lack of external support with respect to reimbursement were similarly low when looking to overseas markets with 65% of respondents either not confident at all or not sure that they can get access to a consultant to help them with an international reimbursement strategy.



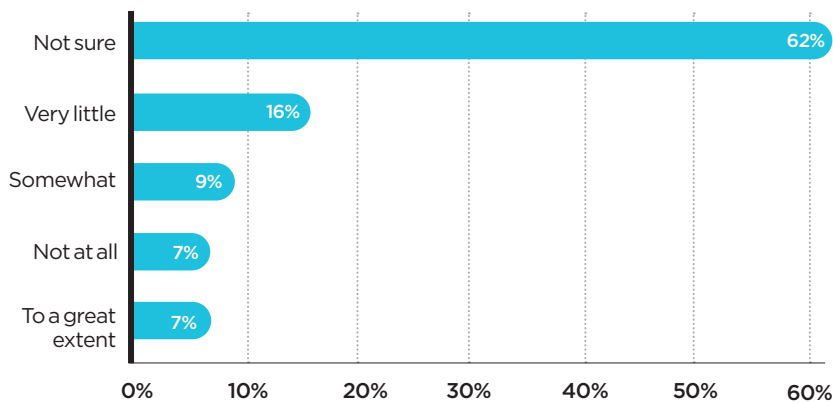
**In December 2019, only 13% of respondents said reimbursement was critical to their business model in Australia.**

**Figure 28: How confident is your company with these aspects of digital health reimbursement in Australia and globally?**



Source: Australian Digital Health Industry Survey by ANDHealth

**Figure 29: Do you feel that there are qualified reimbursement consultants to assist you with your Australian reimbursement strategy?**



Source: Australian Digital Health Industry Survey by ANDHealth

## Clinical Validation

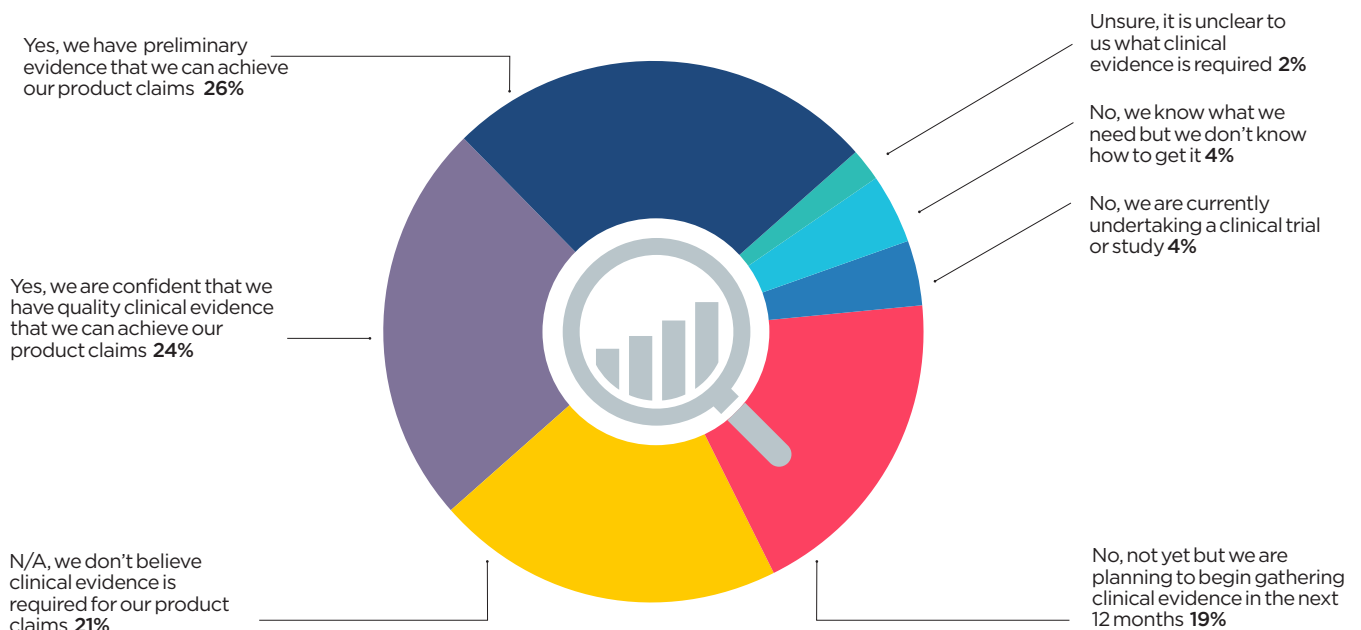
In an evidence-based, regulated digital health environment, clinical evidence is critical. The December survey found that vast majority of respondents are aware of the importance of clinical evidence in supporting the claims they make for their products. Almost one-quarter (24%) said that they already

have quality clinical evidence, 26% have preliminary evidence, 19% are planning to gather clinical evidence this year and 4% are already doing so. However, 21% said that they did not believe clinical evidence was required for their products, and a small number said that they did not know how to gather

the evidence or understand what kind of clinical evidence they need.

With many trials internationally struggling to define appropriate trial design and endpoints, support for digital health clinical trials is a key foundation for continuing to build our digital health sector.

**Figure 30: Do you have clinical evidence for your product's clinical claims?**



Source: Australian Digital Health Industry Survey by ANDHealth

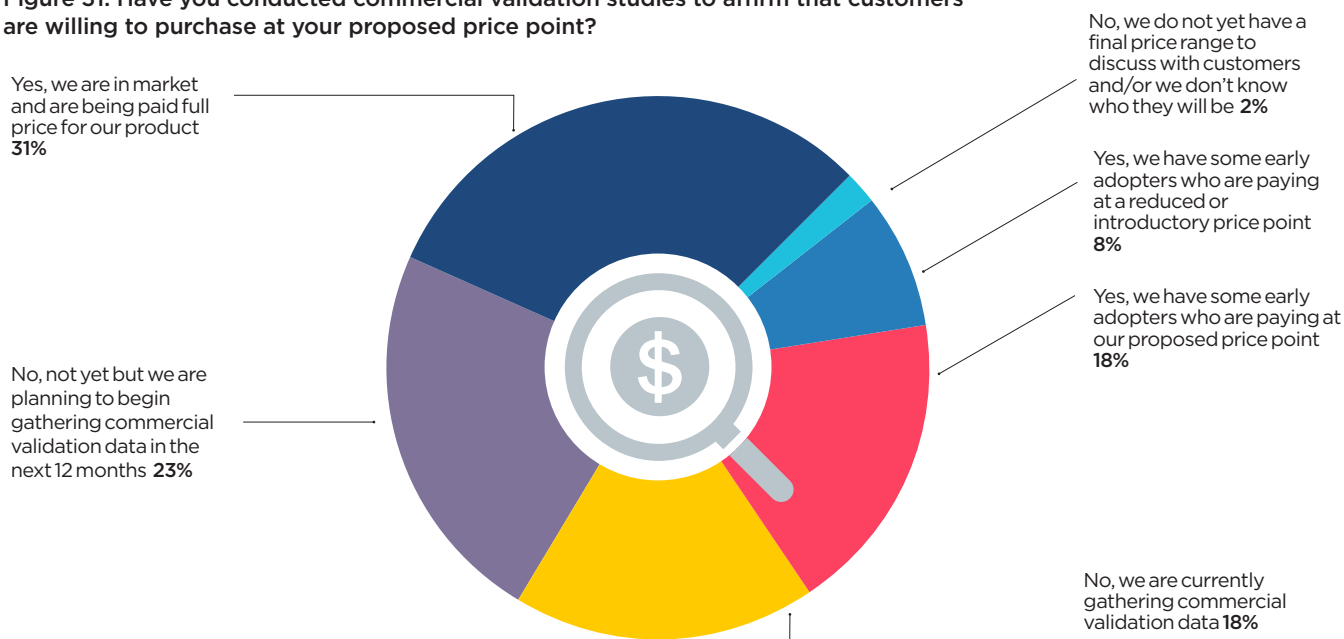
## Commercial Validation

Successful digital health companies have one thing in common: they can demonstrate their commercial need. Health economics, real-world healthcare utilisation data and strong return on investment rationales are key to international expansion.

The importance of this data in commercialisation appears well understood – commercial validation studies were underway or being planned by 41% of respondents, while 26% were working with early adopters of their products on commercial

validation, either at full price point or an introductory rate. Almost one-third (31%) were fully in the market and being paid full price for their products.

**Figure 31: Have you conducted commercial validation studies to affirm that customers are willing to purchase at your proposed price point?**



Source: Australian Digital Health Industry Survey by ANDHealth

## Users vs Paying Customers

As outlined previously in this report, one of the biggest challenges facing digital health companies is designing a product to appeal to users who will ultimately be unlikely to be the paying customers for their product or service.

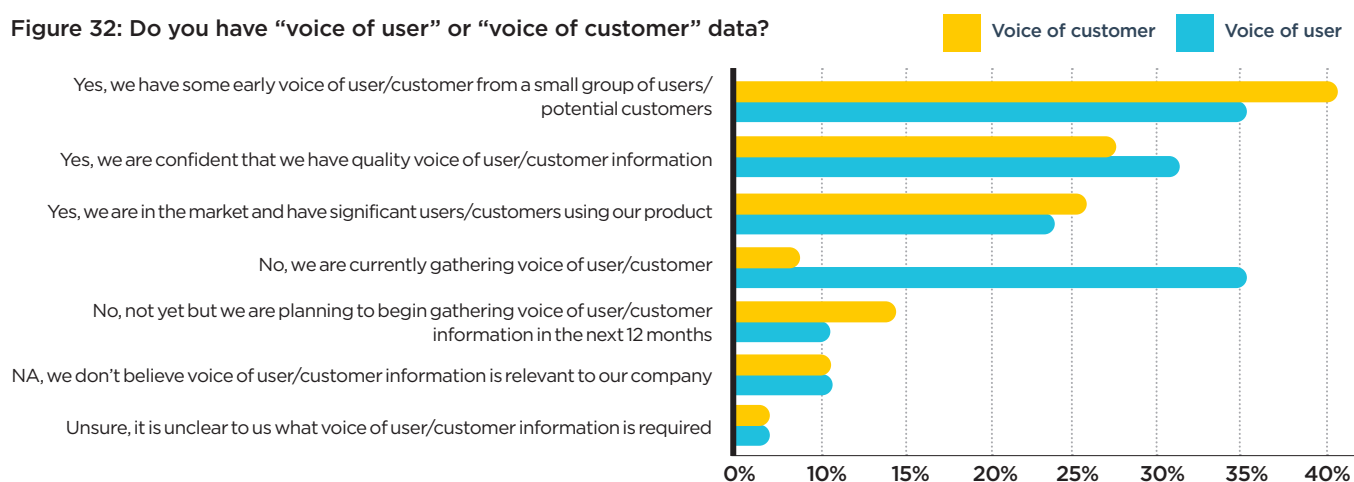
Voice of user data gathering was extremely strong across respondents.

Three quarters of respondents had collected voice of user data with a further 17% currently gathering or planning to gather voice of user feedback regarding their product or service.

Similarly, the majority of respondents were clearly prioritising voice of

customer data with 79% utilising voice of customer data (including 21% of respondents which were in market being paid full price for their product). Meanwhile, 13% were either gathering the data or planning to, and a small number (4%) said that they did not believe it was relevant to them.

**Figure 32: Do you have “voice of user” or “voice of customer” data?**



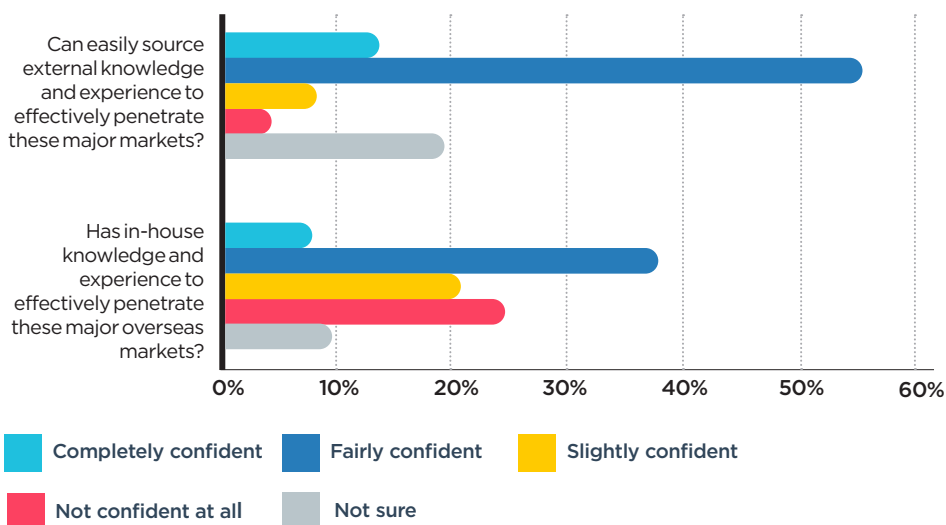
Source: Australian Digital Health Industry Survey by ANDHealth

## International Markets

As a trading nation, and one with a relatively small domestic population, successfully entering international markets is usually key to significant success within health technology industries, and digital health is no exception. However, as an emerging industry, professionals who have “been there and done that” in digital health are in short supply.

This is reflected in the survey responses with just under half (46%) being fairly or completely confident they had the skills in-house to enter international markets. Almost a quarter (24%) of companies lacked any confidence that they had the skills to move offshore, clearly indicating a need for domain-specific support programs.

**Figure 33: International markets: How confident are you that your company...**



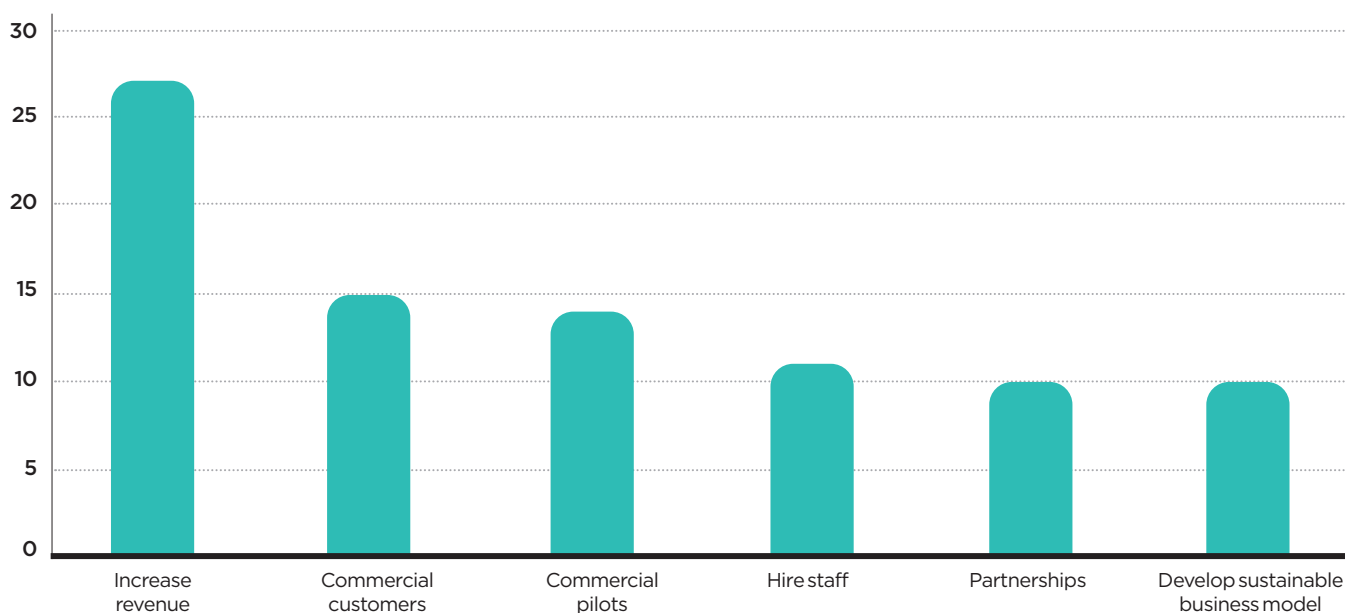
Source: Australian Digital Health Industry Survey by ANDHealth

## Company Goals

Asked to rank their companies' goals for the next 12 months, respondents were presented with a list of about 20 options. The top six priorities were clear; companies want to

- Increase revenue;
- Find commercial customers;
- Launch commercial pilots;
- Hire staff;
- Form partnerships; and,
- Develop a sustainable business model.

**Figure 34: What are your company's goals for the next 12 months?**



Source: Australian Digital Health Industry Survey by ANDHealth

## Skills

In December 2019 the majority of survey respondents indicated that they planned to hire staff in the next 12 months to help them to grow. Their highest priority was capital raising and partnering, followed by grant writing and non-dilutive funding attraction; branding, PR and marketing; and market assessment.

## Challenges

When assessing how the industry is developing and what programs we can deploy to accelerate its growth, it is critical to understand the things that keep entrepreneurs awake at night, or their biggest challenges. Unsurprisingly, access to capital was seen as by far the most significant challenge facing digital health companies in Australia. Other factors holding the sector back, respondents said, were a limited number of specialised investors, attracting and retaining talent, implementation and uptake challenges, and the lack of grant programs specific to digital health.

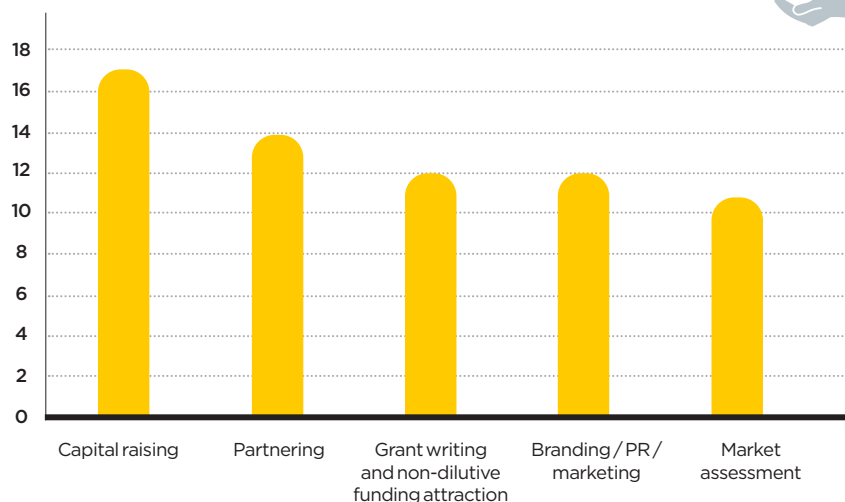
Beyond the top 5, technology development was the area of least challenge with access to appropriately skilled staff also not a major concern, suggesting there is a core of highly skilled people within the sector, a situation which can be leveraged for significant short-term growth.

## Supporting Digital Health

As an organisation which is focused on removing systemic barriers to commercialisation success for Australian digital health companies, it was important for ANDHealth to explore the types of support digital health innovators saw as most important.

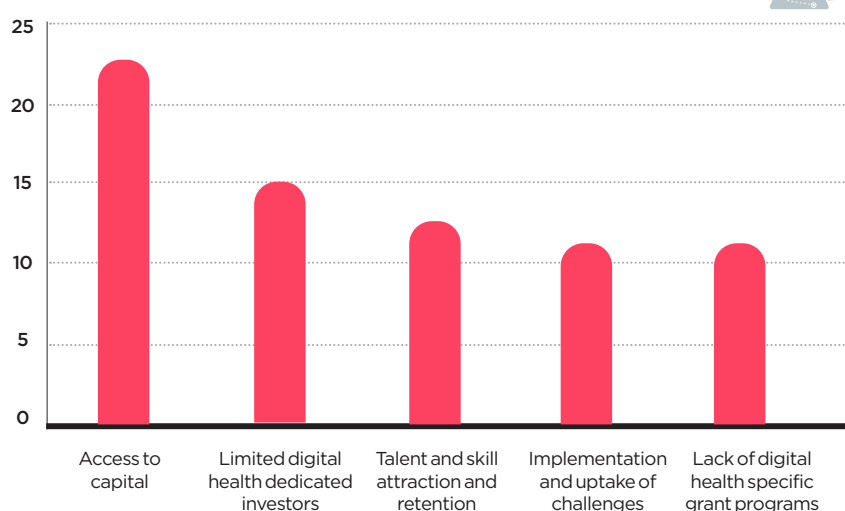
Out of a range of pre-COVID incentives aimed at attracting more investment into digital health, facilitated investor matching ranked highest, followed by one-on-one meetings. Respondents were also keen to see more digital health success stories showcased, delegations to international markets, and international investors touring Australia. Many respondents also wanted to see scale-up firms, rather than start-ups, being prioritised for funding, a sentiment ANDHealth fully supports.

Figure 35: What skills and services does your company need?



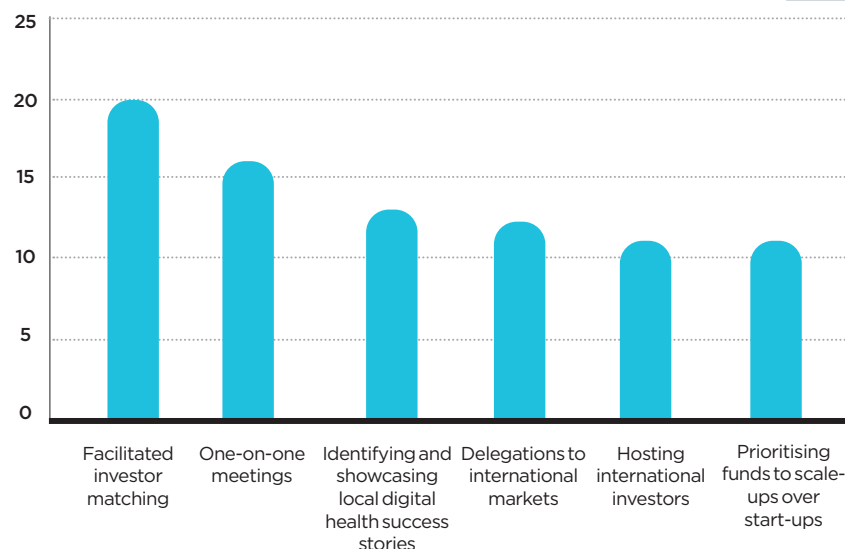
Source: Australian Digital Health Industry Survey by ANDHealth

Figure 36: What do you see as the top five challenges to commercialisation of digital health in Australia?



Source: Australian Digital Health Industry Survey by ANDHealth

Figure 37: What opportunities do you think will assist attracting more investment into Australian digital health technologies?



Source: Australian Digital Health Industry Survey by ANDHealth

# May 2020: The pandemic and beyond

In early 2020 the world as we have all known it changed. As Australians we are global citizens from birth – travel and international commerce are core to the way we live our lives and build our businesses. With widespread border closures and travel shutdowns across the globe from February 2020, health systems forced into emergency measures, and economies racing to stem the pandemic-induced decline in employment and economic stability, COVID-19 turned our normal upside down.

International partnering conferences, delegations and ordinary face-to-face meetings are off the agenda for the foreseeable future, whilst many offices sit empty as staff work from home, and employers become familiar with the “whole humans” in their teams with their household décor and family lives often overlapping with video conferencing calls and the need to balance unprecedented pressures on home life alongside a demanding business and work environment.

Internationally, many see the pandemic as a tipping point for

healthcare, destroying institutionalised inertia and driving clinician and patient adoption of new technologies and new ways of doing things.

With all that in mind, we went back to the industry in May 2020 with a brief survey to obtain views on how COVID-19 has impacted and will impact Australian digital health companies.

## The Impact of COVID-19

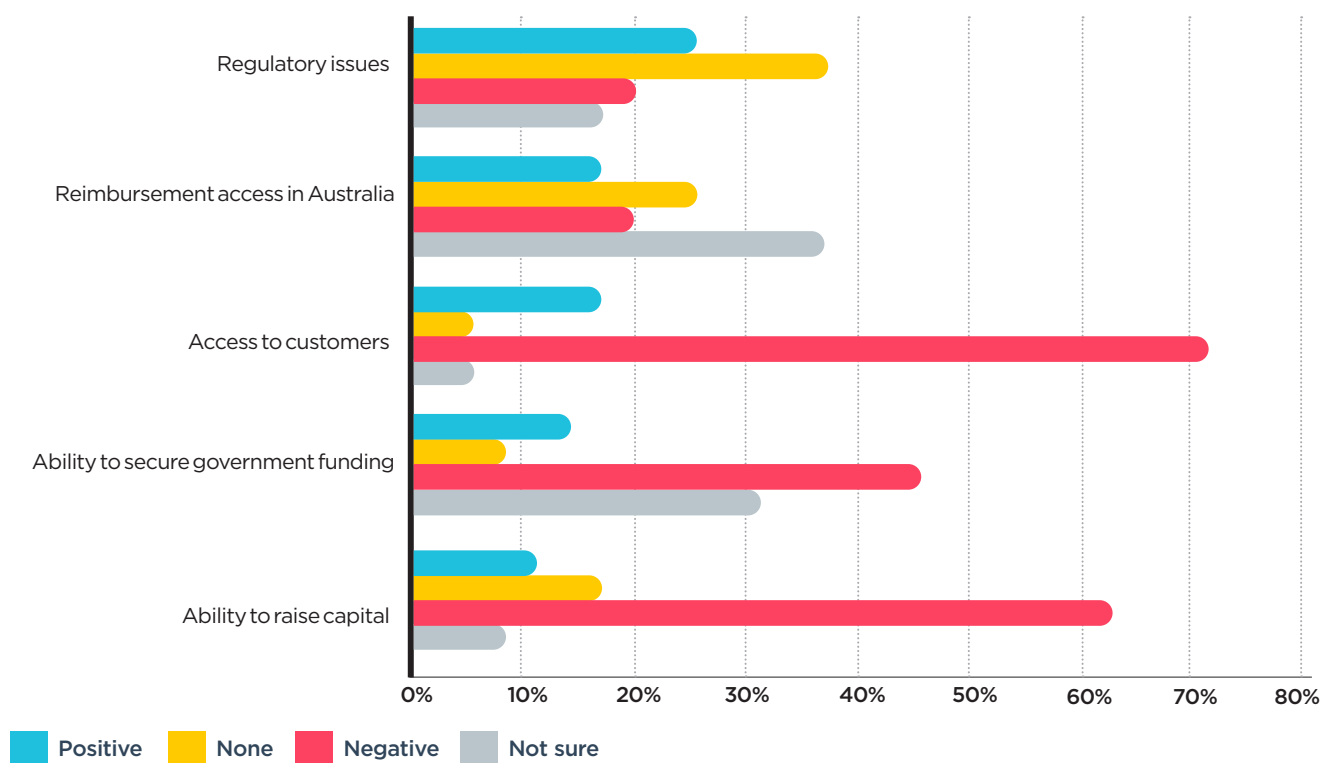
With respect to the impact of COVID-19 on core aspects of their businesses, most respondents were concerned that COVID-19 will have a negative impact on their ability to raise capital and attract government funding. However, most importantly, 70% of respondents identified that COVID-19 would likely have a negative impact on their ability to access their customers. However, respondents felt that the pandemic would have a positive impact on regulatory issues, presumably associated with moves towards healthcare systems’ increased appetite for digital health.

The survey also showed that the number of companies planning to raise capital in the next 12 months was only at 70%. However, regardless of limitations of capital availability post-COVID, short operational runways for many companies, especially those ineligible for Government wage support programs, will force them to test the market and raise capital where they can.

Notably, COVID has not triggered a significant positive response with respect to the potential for digital health reimbursement, nor ability to secure government funding, but sentiment may change as government policy changes are communicated over the coming months.

“  
70% of respondents identified that COVID-19 would likely have a negative impact on their ability to access their customers.”

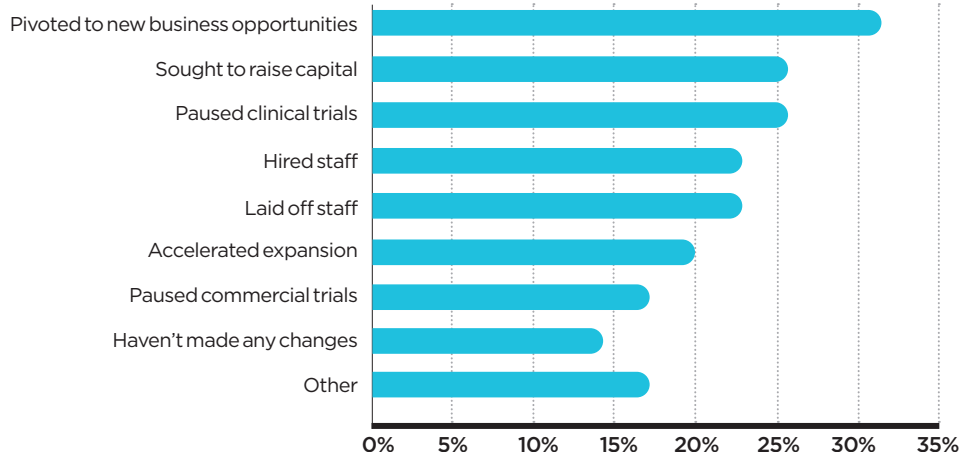
Figure 38: How would you assess the impact of COVID-19 on the following impacts of your business?



## Business Changes in Response to COVID-19

COVID-19 forced Australian digital health companies into making some big shifts. Almost 30% pivoted to new business opportunities, demonstrating their agility. However, 23.5% were forced to pause clinical trials and a further 14.75% paused commercial trials of their products. The number of companies who laid off or hired staff is evenly split (23.5% vs 23.5%) and encouragingly, 20.5% have accelerated their expansion plans. In a difficult market 26.5% have sought to raise capital, but data as to the success of those capital raising efforts is, as yet, unavailable.

**Figure 39: Have you changed any aspect of your business in response to COVID-19?**



Source: Australian Digital Health Industry Survey by ANDHealth

## Top Five Challenges Post-COVID

In the context of COVID-19, the top five challenges identified by respondents shifted in priority. While access to capital remains a core challenge, respondents identified the lack of digital health specific grant funding and programs to be their primary concern. Again, Australia's lack of specialised digital health investors also remains a key challenge.

One of the ironies for the digital health sector is that, although the pandemic has caused disruption and in some cases damage to companies,

in many companies it has provided an unprecedented opportunity.

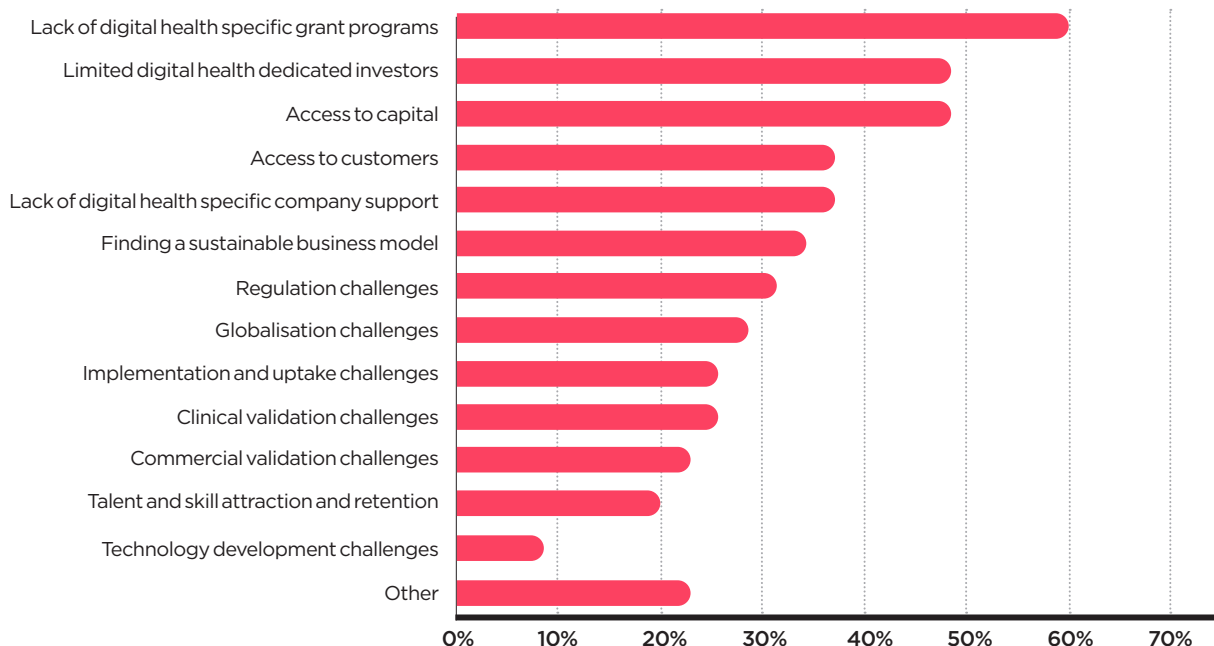
Almost three quarters (73.5%) of respondents to our May 2020 survey indicated that they looked forward to increased acceptance of digital health innovations by the medical community, and 50% to increased acceptance by patients. Almost a quarter (23.5%) were looking forward to more reimbursement for digital health technologies, and 23.5% said that there would be a larger market for their products in the COVID era.

This again illustrates the importance of supporting our emerging digital health sector as we look to invest in key areas to drive a post-COVID economic recovery.



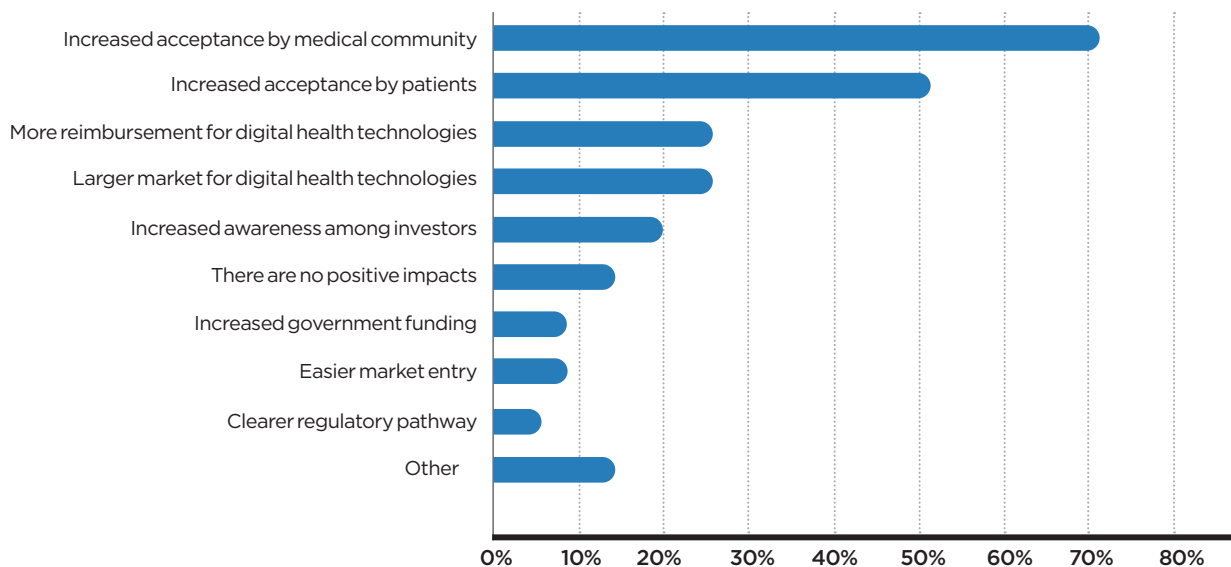
**Australia's lack of specialised digital health investors also remains a key challenge.**

**Figure 40: What do you see as the top five challenges to commercialisation of digital health technologies in Australia, in the context of COVID-19?**



Source: Australian Digital Health Industry Survey by ANDHealth

Figure 41: What do you see as the potential positive impacts of COVID-19 on the Australian digital health industry?



Source: Australian Digital Health Industry Survey by ANDHealth

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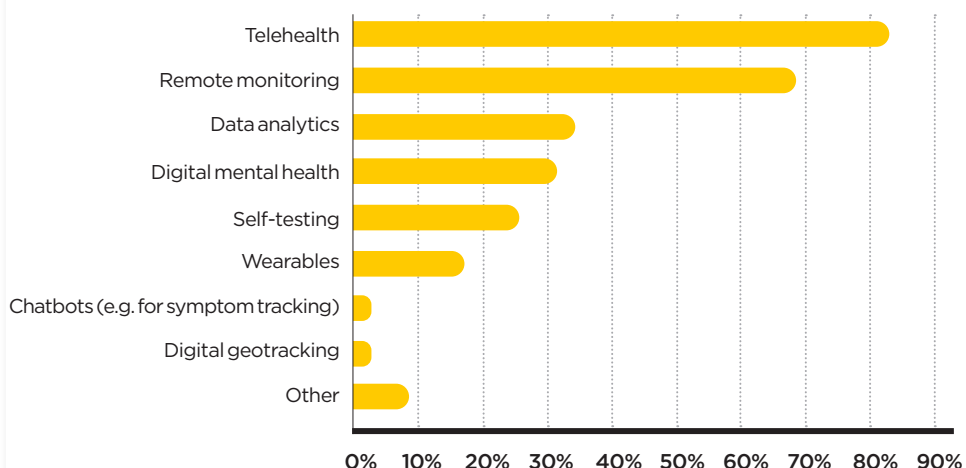
**None of our respondents believe that no aspect of digital health will not benefit from the pandemic.**

Unsurprisingly, respondents to our May 2020 survey believe that telehealth-related digital health technologies will be the biggest beneficiaries of the pandemic (85.3%), followed by remote monitoring (67.6%). However, they are hopeful that data analytics will also benefit (35.3%), along with mental health-related technologies (29.4%) and self-testing (26.5%). None of our respondents believe that no aspect of digital health will not benefit from the pandemic.

Finally, more than half (53%) of our May 2020 respondents are convinced that COVID-19 will leave a permanent imprint on the digital health industry. Another 26.5% believe that it will only make its mark for one or two years.

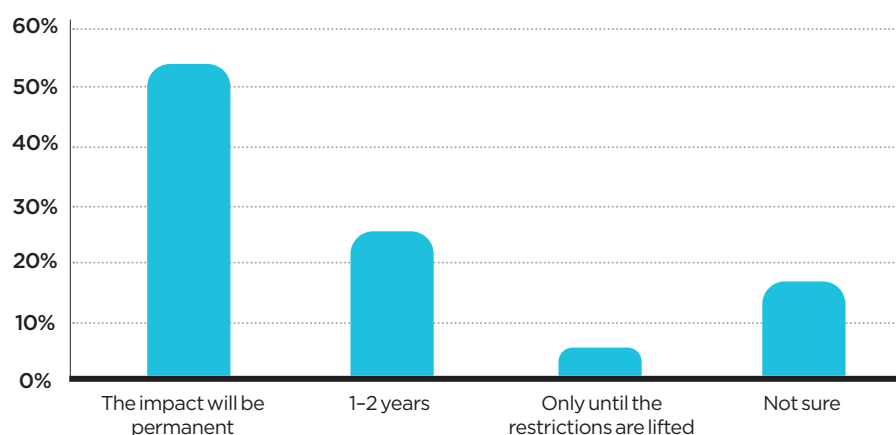
We believe the impact will be long lasting – the pandemic will leave behind it a wave of healthcare policy reform and changed patient and clinician mindsets, that have the potential to make digital healthcare universally accepted and utilised for the health and wellbeing of all Australians.

Figure 42: Which areas of digital health will be most likely to grow as a consequence of COVID-19?



Source: Australian Digital Health Industry Survey by ANDHealth

Figure 43: How long do you think the impact of COVID-19 on the digital healthcare industry will last?



Source: Australian Digital Health Industry Survey by ANDHealth

# Conclusions: The Future of Digital Health in Australia

Australian digital health companies face some unique challenges, not least of which is that as a sector it struggles for recognition and appropriately focused funding structures here at home. That in turn means that there is a paucity of investors with enough knowledge of the sector to be able to make smart investments – which means that digital health companies often have to seek capital from investors who lack the knowledge to adequately support them.

The first step to supporting these companies is to accept that they are facing challenges that do not fall within the broadly understood commercialisation pathway for purely physical medical devices. They face unique challenges, and thus require unique and tailored support.

To address the challenges our digital health entrepreneurs face, we must also continue to build an ecosystem of knowledgeable and skilled professionals with demonstrable hands-on experience in successful digital health commercialisation.

Accessing international networks, reflecting on best-practice models and technologies and implementing appropriate regulatory and reimbursement frameworks, supporting access to dedicated capital, all offer significant benefit for Australia: as we build this world-class digital health ecosystem, we don't only create the best possible environment for Australian innovation to thrive, we also attract international companies seeking partners for development and commercialisation here in Australia.

COVID-19 has been a catalyst for wholesale change in patient and clinician behaviour and in policy reform, and these changes should be embraced, consolidated and built upon with a view to creating the world's best healthcare system, enabled by technology and equitable in access for all Australians.

We also know that with savvy, sustained investment, Australia can create world-leading health technology sectors, as we have done in biopharmaceutical development and medical devices. However, simply assuming these traditional investments will allow us to “keep pace” with other OECD nations across healthcare, without support for emerging and enabling sectors such as digital health, is naïve.

Australia's response to COVID-19 has been world leading, and we now face a once in a lifetime opportunity to position ourselves as a “cleanroom” or COVID-safe destination for health technology development and commercialisation, spanning technology development, clinical trials and advanced manufacturing. The global digital health market remains largely untapped for attracting these inbound opportunities, and we have now become one of the world's most attractive destinations for both talent and investment as we look to the future.

However, to fully realise the potential of this nascent sector, we need to provide support. Proven programs with quantifiable commercial outcomes such as ANDHealth+ and the ANDHealth program suite are invaluable resources for innovators in a sector that lacks availability of specialised service providers and investors, as are the many other non-digital-health specific accelerators and incubators we work with across Australia. Funding

programs which are specifically designed for digital health companies, and highlight milestones relevant to digital health which are often lost in “medtech” programs, are critical, as are interventions to support the investment of private capital into the sector.

Collaboration between academic institutes, clinical sites, industry players and innovators is also key. We also need to acknowledge that, increasingly, innovators and innovations may not originate in the traditional domains of research and academia, but might come from clinicians, patients, caregivers, allied health professionals, and non-health domain professionals with smart ideas for transforming health.

Healthcare remains one of the last remaining sectors to experience wholesale disruption, until now. Digital health will be absolutely essential in delivering equitable, high-value and affordable care in the future. As healthcare costs rise and consumers demand more from health systems around the world, digital interventions which improve our health and wellbeing and save the system critical capital will be key. For our early innovators, such as the companies that this report highlights, this means navigating often uncharted waters, and linking into a growing and dynamic international network of innovators, investors and service providers, to reach their global potential.

“

**As healthcare costs rise and consumers demand more from health systems around the world, digital interventions which improve our health and wellbeing and save the system critical capital will be key.**

# The ANDHealth Approach to Supporting Australia's Digital Health Sector

ANDHealth was formed to address an identified gap in the Australian Innovation landscape: to provide programs and support to digital health companies that was specific to the challenges of commercialising in this new and emerging sector. By forming a multi-sectoral, multidisciplinary membership and working collaboratively across Australia, we bring proven expertise to our innovators and investors.



Companies need to take a global-first approach and understand the global marketplace to ensure that their digital health solutions meet the needs of industry abroad. ANDHealth provides global connectivity to provide context, understanding, and connections needed for companies to expand to the global marketplace in digital health. ANDHealth understand that expanding Australian digital health companies globally drives the value of the local health ecosystem in Australia. They facilitate this growth and global reach to ensure that we develop a sustainable industry in Australia that can stand up world-class technologies across the globe."

*Michelle Perugini, Founder and CEO, Life Whisperer*



Australian medtech companies have a long history in driving improvements in patient outcomes, economic growth and job opportunities in Australia and are at the forefront of our current response to the challenge of COVID-19. Supporting programs like the Medical Device Commercialisation Training Program delivered by Cicada Innovations and ANDHealth's programs in digital health are critical in ensuring we are continuing to develop and nurture our clinicians and researchers in bringing new solutions to market and drive long-term growth of the sector in Australia.

*Sally-Ann Williams, CEO, Cicada Innovations*



Specialised digital health programs are critical to the development of the ecosystem in Australia. Digital health companies often find themselves caught between consumer technology start-ups and deep biotech start-ups, when in reality their product validation approach, growth trajectory and go-to-market strategy can be and often needs to be very different from either. Expert advice on how to commercialise and validate digital health products from people who have travelled the path before is important to ensuring digital health companies don't slip through the cracks when it comes to potential customers, users and investors.

*Scott Taylor, Founder and CEO, Perx Health*



Proven commercialisation programs spanning the commercialisation pathway from ideation to market uptake and exit specific to digital & connected health.

NON-PROFIT, NON-EQUITY TAKING, CO-FUNDED BY INDUSTRY & GOVERNMENT

TARGETED EVENTS



INDUSTRY DATA



ADVOCACY  
& LEADERSHIP



ECOSYSTEM DEVELOPMENT | STATE, NATIONAL & INTERNATIONAL EXPERT NETWORKS | POLICY SUPPORT

## A NOVEL MODEL



### VC Led

Model derived from deep buy-side & corporate development experience, including Australia's largest digital health growth company IPO.



### Working backwards

Programs are designed to address the most common gaps arising when assessing digital health investment opportunities from both VC & enterprise customer perspectives.



### Control of funds

Advisory teams determine where funding should be deployed for maximum effect & commercial impact.



### No-Equity & Non-Profit

No set valuations & no conflict of interest when advising on go/ no-go decisions. No passive commercial gain for industry partners. If members do not participate, they do not benefit.



### Not about "start-ups"

Focus and proven ability to scale and commercialise the existing pipeline and improve the ecosystem to create a better "flow through the funnel".



### Harness the Collective

Cross-sectoral & multi-disciplinary speakers & advisory teams.  
Proven track records:  
Product development, or  
Commercial Agreement at Scale, or  
Significant Capital Raising.

ANDHealth has grown from its initial ambition to run a two-year pilot of its flagship ANDHealth+ program by industry growth centre MTPConnect, to running programs across multiple states, with eight program partners, across all stages of development. We have proven our ability to both increase and mature the pipeline of high growth potential digital health companies in Australia and have facilitated significant international networks via our industry development activities. ANDHealth is the leading resource in Australia for best practice commercialisation support and advice in digital health.

The pilot of our flagship ANDHealth+ program selected 10 companies from more than 150 applications, which were

then screened by our multi-sectoral, C-suite member panel. Those companies then participated in a globally unique deep industry immersion and advisory program which delivered tailored support and advice specific to their needs and business strategy. Unlike other programs, ANDHealth+ is not curriculum-based but involves a tailored, multi-disciplinary, multi-sector panel of C-suite executives advising and supporting the company across all aspects of its business for up to nine months.

The ANDHealth+ program has delivered outcomes which are internationally competitive and which demonstrate extraordinary impact. Our 10 cohort companies have gone on to deliver exceptional commercial outcomes, raising

AUD\$28.7 million in new capital, creating 165 new jobs and generating AUD\$11.9 million in new revenues. They have undertaken 28 clinical studies of their innovative products across the world. And – most importantly – more than 70,000 patients have so far benefited from these Australian digital health technologies, all in less than three years.



**ANDHealth is the leading resource in Australia for best practice commercialisation support and advice in digital health.**

## ANDHEALTH+ COHORT COMPANY REPORTED OUTCOMES

Cohort Company Outcomes Reported to ANDHealth (as at March 31 2020).

FY18 Cohort Onboarded October 2017 | FY19 Cohort onboarded September 2018.

1  
Exit of DoseMe  
(to Tabula Rasa  
NASDAQ: TRHC)



**\$28.7M**

Raised  
(dilutive & non-dilutive)



**\$11.9M**

New revenue



**165**

New jobs (FTEs)



**10**

New CxO Roles



**778**

Commercial pilots  
commenced



**28**

Clinical trials and studies  
commenced



**17**

New international  
market launches



**153**

New commercial  
customers



**70,190**

New patients served



**291**

New operational sites



**165**

New partnerships formed



**92**

New product releases

### THANK YOU

ANDHealth appreciates the support of its members, partners, cohort companies and sponsors in supporting our vision for an integrated ecosystem for the development, commercialisation and implementation of evidence based digital health companies in Australia.

**Contact information:** [info@andhealth.com.au](mailto:info@andhealth.com.au)

### Authors

This report has been prepared by ANDHealth Limited. ANDHealth would like to thank all who contributed to this document for their time, experience and input. The report was designed by Tania Simanowsky.

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