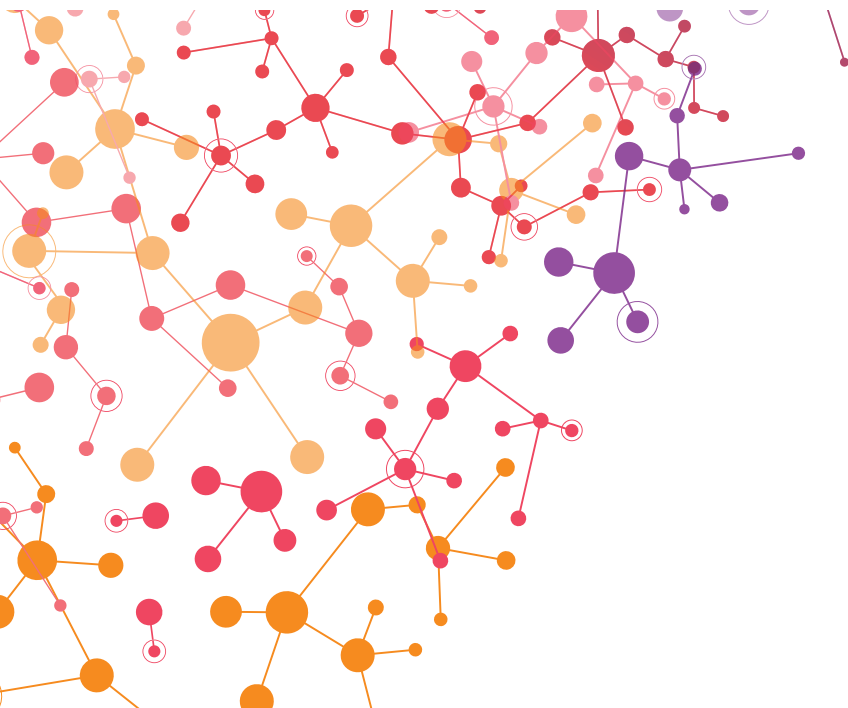




THE AWAKENING GIANT

The Rise of Australia's *Evidence-Based*
Digital Health Sector



Acknowledgement of Country

In the spirit of reconciliation, ANDHealth acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community. We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples.

About ANDHealth

ANDHealth is Australia's only organisation dedicated to accelerating the commercialisation of evidence-based digital health technologies.

ANDHealth is one of Australia's leading health technology commercialisation organisations with proven outcomes across a program suite which supports innovators from idea to exit. Our unique non-profit, industry-led model provides a non-profit, non-equity-taking solution to support Australian companies navigating the commercialisation pathway to institutional investment and international market entry and growth.

With over \$30M of committed funding, ANDHealth leverages specialised technology selection, assessment and commercialisation

support capabilities to drive measurable impact and improvement across technology, clinical and business outcomes.

ANDHealth is supported by the Australian Government Department of Health Medical Research Future Fund. ANDHealth's partner network represents a unique multi-sectoral, multi-disciplinary group which works collaboratively across ANDHealth's operations to support and deliver our programs and services.

We acknowledge and thank the support of our Core Partners, Program Partners, International Partners and Ecosystem Partners for their enormous contribution to our core purpose of accelerating the commercialisation of digital health technologies in Australia.

ANDHealth is supported by the Australian Government Department of Health under the Medical Research Future Fund Early Stage Translation and Commercialisation Support Program



Australian Government
Department of Health

Medical Research
Future Fund

CORE PARTNERS



PROGRAM PARTNERS



INTERNATIONAL PARTNERS





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Foreword

Digital Health: Leading the Post Pandemic Future

Australia has long been recognised as an international leader in health and medical research. From the Cochlear implant to one of the world's largest connected health companies, ResMed, Australia has a long and continuing reputation as an originator of ground-breaking medical technologies.

With the increasing impact of technology on our lives, it is no surprise that the types of medical technologies sought, and the role of software in those medical technologies, are rapidly evolving. Digital and digitally enabled medical technologies are gaining increasing importance on the global stage, and Australia is uniquely positioned to capitalise on this fast growing digital and connected health sector.

Our deep capabilities in health and medical research are augmented by rapidly expanding capabilities in technology and increasing early to mid-stage investment capacity. It is the perfect location to capitalise on the commercialisation of evidence-based digital and digitally enabled medical technologies.

A robust digital health industry will put Australia in a strong position to develop a world class, future-proofed healthcare system in which digital health solutions can prevent, diagnose, manage and treat disease and disability, whilst shifting care out of physical sites like hospitals and

empowering all Australians to live healthier lives. A connected, digitally enabled and patient-centric healthcare system allows us to improve both the affordability and the accessibility of healthcare for all Australians whilst building an enviable fast growth export industry.

As we look forward, our learnings from the COVID-19 pandemic tell us that sovereign capabilities across the medical research, development, commercialisation and manufacturing landscape are critical as we look to diversify and strengthen our economic and health system resilience in advance of future shocks.

By leveraging investment into digital health commercialisation and into ANDHealth, we are creating a robust evidence-based digital health industry which will support the Government's goals of increasing employment and boosting innovation and local capability, leading to a healthier and more prosperous Australia.

Gavin Fox-Smith
Chair, ANDHealth





From CEO and Managing Director Bronwyn Le Grice

The Awakening Giant: The Rise of Australia's Evidence-Based Digital Health Sector provides unique and detailed insights into Australia's emerging digital health industry. Based on the broadest and deepest database of high-growth potential digital health companies in Australia, *The Awakening Giant* tells the story of a fast growing, emerging, innovation-driven sector providing a prime opportunity to position Australia as a global destination for digital health, digital medicine and digital therapeutics research, development and commercialisation.

In 2020, ANDHealth published *Digital Health: The Sleeping Giant of Australia's Health Technology Industry* which showcased the potential of the emerging, evidence-based digital health sector to drive our economy and healthcare system into the future. Since then the number of companies supported by ANDHealth has increased from 300 to more than 600.

In 2020, the COVID-19 pandemic was in its early stages, and no one knew what lay ahead. The pandemic has now impacted the lives of people and challenged health, economic and social systems around the globe. We emerge from the pandemic, with a new government, a renewed focus on health and medical research, medical manufacturing, and adoption of new and innovative ways to deliver healthcare in Australia and globally.

The pandemic has accelerated the already fast-growing digital health sector. Shifts in government policy in response to the pandemic drove widespread reimbursement and adoption of telehealth, and necessity created a new focus on technologies which enabled remote patient management and monitoring to shift care from the clinic to

the home or workplace.

Globally, the digital health market has reached record levels and is predicted to reach US\$660 billion by 2025, up from US\$175 billion in 2019.¹ We have also seen increasing policy shifts as international governments take steps to modernise their reimbursement policies to incentivise the use of clinically proven, evidence-backed digital medicines and digital therapeutics.

ANDHealth is Australia's only organisation that focuses specifically on the commercialisation of evidence-based digital health technologies that go beyond electronic medical records, system connectivity and health system infrastructure to technologies that are clinically proven, evidence-backed (and often regulated as therapeutic goods) and have a direct, measurable, and safe impact on patient outcomes.

ANDHealth's work spans the entirety of the US Food and Drug Administration's definition of digital health: personalised and precision medicine, sensors and wearable devices, m-health technologies, digital diagnostics, digital therapeutics and health IT. These technologies have been proven to deliver significant healthcare outcomes, improve the affordability and effectiveness of the healthcare system, reduce emergency presentations, and provide actionable insights in real time to both clinicians and consumers.

With the right investment, support, regulation and reimbursement frameworks, this critical part of our economy has the potential to improve health and economic outcomes, including job creation, high value local manufacturing, export opportunities and future healthcare system resilience.

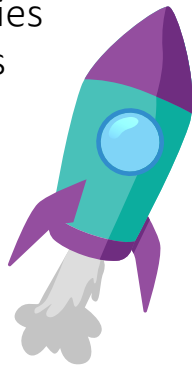
Bronwyn Le Grice
CEO and Managing
Director, ANDHealth



Highlights from *The Awakening Giant*

Since 2020, the number of digital health companies in ANDHealth's pipeline has increased by

74%



Companies who disclose their financing outcomes have raised a total of

A\$524.8M

(dilutive and non-dilutive)



85%

of companies plan to expand their team in the next 12 months



85%

of companies plan to raise capital in the next 12 months



38%

of companies have a female founder, CEO or managing director



41%

of companies identified patients/consumers as their primary end user

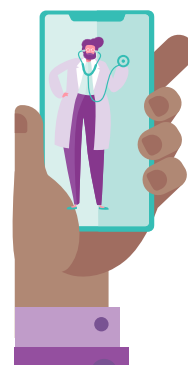
47%

of companies are creating solutions to be used in the home



39%

of companies identified health practitioners as their primary end user



Mobile health is the primary technology for

17%

of companies

26.5%

of companies listed mental health as their primary, secondary or tertiary clinical indication



42.6%

of companies listed clinical decision support as their primary, secondary or tertiary primary purpose



50%

of companies identified health providers (27%) and paying patients/consumers (24%) as primary payers





What is Digital Health?

At ANDHealth, and in this report, we are guided by the broad definition of digital health provided by the US Food and Drug Administration (FDA) (Figure 1.1).

‘Digital health’ encompasses more than e-health, health IT or the implementation of electronic medical records and connectivity, albeit these are critical infrastructure that underpins the health system.

Our international partners, Digital Therapeutics Alliance and Health XL, have suggested useful representations of the broad, diverse range of digital health technologies as those with a specific purpose (Figure 1.2) and those requiring different levels of commercial and clinical evidence (Figure 1.3). It is important to note that categorisations of the digital health technology ecosystem will continue to evolve as the industry evolves and grows.

The FDA Definition of Digital Health

‘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.

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 health technologies use computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products.

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.

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 health care settings. Providers and other stakeholders are using digital health technologies in their efforts to:

- Reduce inefficiencies,
- Improve access,
- Reduce costs,
- Increase quality, and
- Make medicine more personalized for patients.

Patients and consumers can use digital health technologies to better manage and track their health and wellness-related activities.

The use of technologies, such as smart phones, social networks, and internet applications, is not only changing the way we communicate, but also providing innovative ways for us to monitor our health and well-being and giving us greater access to information. Together, these advancements are leading to a convergence of people, information, technology, and connectivity to improve health care and health outcomes.’

Figure 1.1: US Food and Drug Administration (FDA) Digital Health Definition.²

Breaking Down the Digital Health Sector | International Perspectives

Categorisations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.

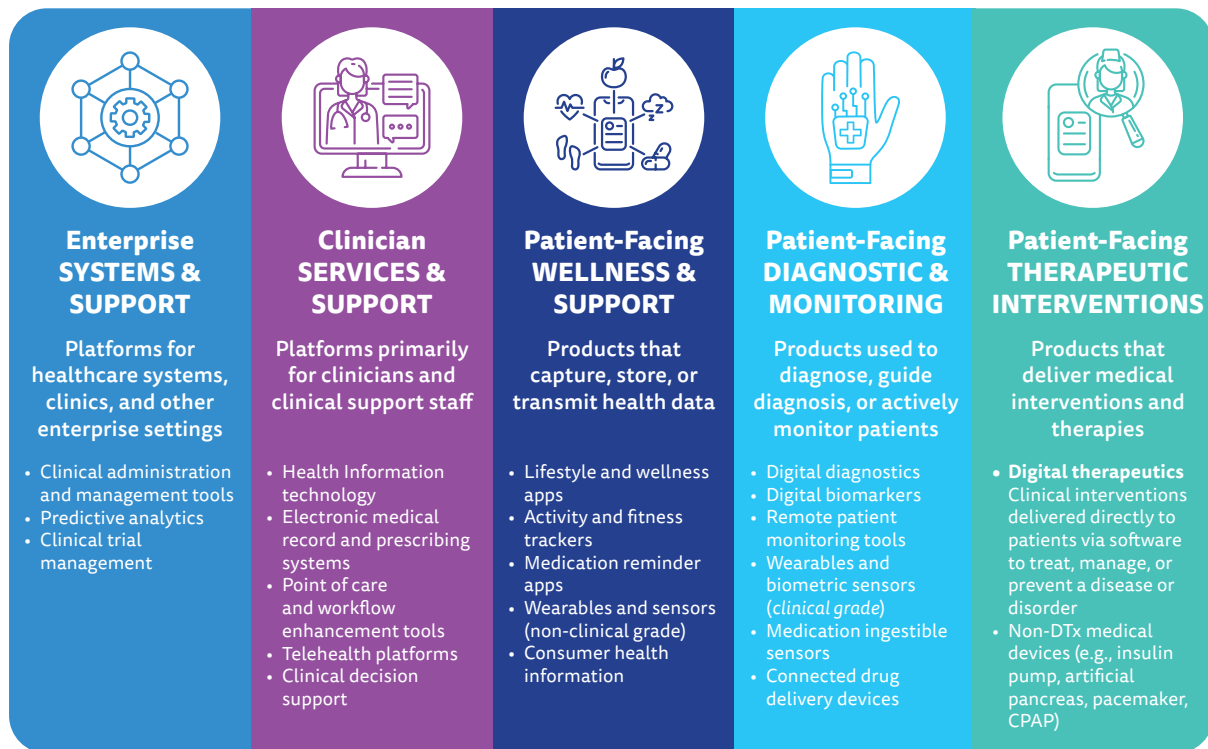


Figure 1.2: Digital Health Technologies. Adapted from Digital Therapeutics Alliance DTx Value Assessment & Integration Guide.³

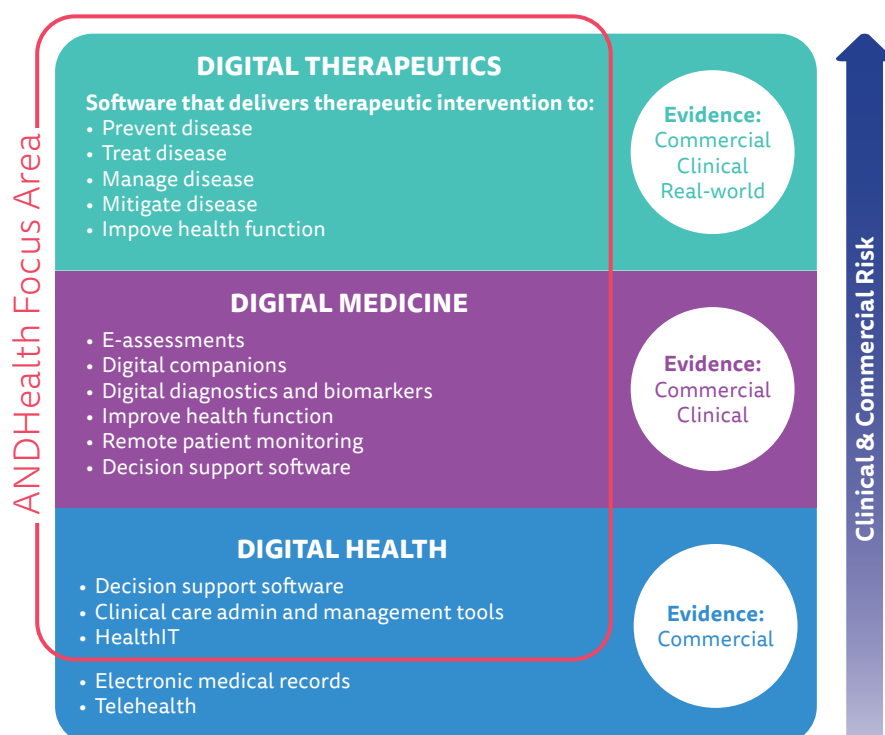


Figure 1.3: Digital Health Categories. Adapted from HealthXL's Framework.⁴



Historic Shift in Global Healthcare

The COVID-19 pandemic accelerated the transformation of healthcare globally and in timeframes not thought possible in the past.

Out of necessity, traditional healthcare delivery models changed, supported by improved technologies such as remote patient management solutions, virtual hospital beds and 'hospitals in the home', along with greater acceptance of telehealth consultations by health professionals and consumers. This significant transformation was supported by fundamental changes to the payment and reimbursement landscape for these technologies.

Whilst governments and regulators had previously recognised that appropriate regulatory frameworks for evidence-based digital products were essential to safeguard

patients, during the pandemic they also implemented policies which substantially changed the economic and social imperative to utilise new, technology-based solutions.

What we are yet to fully understand is the degree to which, as global economies return to 'normality', these policy changes will revert to pre-pandemic baselines.

In some countries, we are seeing new policies and/or policies implemented to support the reimbursement of novel digital health interventions whilst in other areas some regulations have 'snapped back' to a pre-pandemic status quo. Overall though, it is widely accepted that a lack of reimbursement is a key barrier to uptake of these cutting-edge solutions to some of our largest health challenges.

The Australian Story

Since 2020, the industry has developed substantially, both through systemic changes caused by the pandemic and through significant shifts in the policy and funding environment.

1

Government commitment to strengthen commercialisation of the industry

ANDHealth was awarded \$19.75 million from the Medical Research Future Fund (MRFF) Early-Stage Translation and Commercialisation Support program to fund expansion of Australia's only digital health commercialisation program ANDHealth+.

2

Universal telehealth for all Australians

The reimbursement of telehealth for all Australians marks a significant shift to delivering healthcare in the home.

3

Clarification of the regulatory environment for Software as a Medical Device

Australia's regulator, the Therapeutic Goods Administration (TGA) implemented welcome reforms and guidance to the regulation framework for Software as a Medical Device (SaMD).

4

National Digital Health Strategy 2022 – 2027

After extensive consultation, the Australian Digital Health Agency will launch the national strategy in 2022.

5

Lack of reimbursement remains a significant challenge

Australia lags behind other parts of the world in defining clear reimbursement frameworks for digital health technologies, a barrier to sector commercialisation and uptake by health professionals and consumers.



Government Commitment to Strengthen Commercialisation of the Industry

In late 2020, the Medical Research Future Fund (MRFF) acknowledged the role of digital health in preventing, diagnosing, treating, managing and mitigating disease and other health conditions by including a dedicated digital health stream in the Early-Stage Translation and Commercialisation Support program. This competitive funding spanned four independent but interconnected funding streams for health and medical research commercialisation including:

1. preclinical medical research or medical innovation projects with commercial potential
2. early clinical development of novel drugs, or novel uses for existing drugs, with commercial potential
3. early clinical development of medical devices with commercial potential
4. early-stage development of digital health technologies with commercial potential.

Three organisations were awarded the four streams of funding, with streams 1 and 2 being awarded to Brandon Capital, the third stream to Industry Growth Centre, MTPConnect, and the fourth stream, for digital health, to ANDHealth. This funding has been deployed to support 25 SMEs to participate in the ANDHealth+ program, with \$3.75M of direct investment deployed from the ANDHealth Digital Health Accelerator Fund each year. Comprising over \$22M in total commitments, plus substantial in-kind support and ongoing industry development and growth activities, this represents the largest single investment into digital health commercialisation by the Australian Government.

Universal Telehealth for all Australians

In line with other developed nations, since 2020 Australia has experienced dramatic changes to the delivery of health and care services. After years of ongoing debate on the validity of telehealth and connected health platforms, telehealth is now funded by Medicare (with some limitations) for all Australians. Whilst the pandemic overcame many of the barriers to technology-based communication between clinicians and their patients, there is still some way to go before we see telehealth truly enabled by technology, with more than 90% of telehealth consultations undertaken by Australian doctors between March to

December 2020 utilising telephone rather than video technology.⁵

However, the pandemic-driven focus on the need to shift patients out of physical clinical sites, unless totally necessary, has provided a foundation for a more agile and responsive healthcare system, with the potential to deliver health and care to Australians when they need it, wherever they may be. This change will require ongoing investment into the development and implementation of new technologies, supported by a willing, committed and coordinated cohort of policy makers.



Telehealth Use Between March 2020 and February 2022

- 16.8 million patients and 91,087 practitioners used 95.9 million telehealth services.⁶
- \$4.4 billion in Medicare benefits paid.⁷
- >83% of people who had a telehealth consultation reported they would use a telehealth consultation again if offered (ABS, 2021).⁸

“For telehealth to be used routinely within primary care settings, evidence that supports the delivery of higher quality care to patients through telehealth and sustainable funding models will be required.”

– De Guzman et al. GP perceptions of telehealth services in Australia: a qualitative study. BJGP Open; 2022.

Case Study

Coviu, the virtual care engagement solution spun out of CSIRO, was in its infancy at the start of 2020 with 400 telehealth consults facilitated per day. Prior to the pandemic, Coviu had entered an agreement with the federal government (Healthdirect) with a goal to make healthcare accessible for everyone. Prompted by the lockdowns in early 2020, Healthdirect made available Coviu's platform free of charge to all Australian GPs. This catalysed widespread industry adoption of Coviu's solution as an effective alternative to traditional brick and mortar clinics.

Coviu hired 10 new staff within the first week following the first lockdown bringing its team to 17. In a very short period, Coviu scaled from 400 to 30,000 consults per day. Two years on (September 2022), Coviu has grown beyond 6,250% since the pandemic commenced. The company's platform is now used by over 90,000 clinicians globally and is now averaging 13,000 calls per day. Over 7 million consults have been facilitated on its platform and its workforce includes 50 FTE. Coviu raised A\$6 million in a series A allowing it to launch in the US.⁹

Clarification of the Regulatory Environment for Software as a Medical Device

In 2021 after ongoing consultation with industry and global regulators, the Therapeutic Goods Administration (TGA) issued draft guidance for Software as a Medical Device (SaMD) manufacturers, providing clarity on existing regulatory requirements and introducing new requirements for software-based medical devices.¹⁰

Software-based medical devices are software products that typically diagnose,

monitor, specify or recommend treatment to consumers or health professionals and must be included in the Australian Register of Therapeutic Goods (ARTG) before being legally supplied in Australia. The reforms set out to clarify the boundary of regulation for these devices, reduce or remove unnecessary regulatory burden, and align more closely with international frameworks. The regulatory framework is technology agnostic, meaning that the software may be in the cloud, an app, a web app, or a website.

“If you're commercialising novel digital health technologies, the stronger your regulatory position, the more competitive your product will be. Your technology is worth more when you have the evidence to back up your claims and the approval of an independent regulator – it triggers higher-value innovation and creates a more defensible competitive position.”

– Bronwyn Le Grice, CEO and Managing Director, ANDHealth



ANDHealth welcomed the new guidance as it provided much needed certainty within the sector, both for Australian manufacturers of SaMD products and international manufacturers looking to support the Australian patient population.

The new guidance is aligned to similar requirements in international markets and ensures a level of rigour and clinical evidence in the development of software-based

medical devices, as well as safeguarding the public from products making unsubstantiated health claims.

A strong regulatory environment for digital health products not only provides access to safe, evidence-based digital health products, but also improves the commercial viability of new digital health technologies and supports Australia's credibility as an internationally competitive digital health destination.

National Digital Health Strategy 2022 – 2027¹¹

After broad-reaching consultation spanning consumers, the healthcare sector, and industry participants, the Australian Digital Health Agency will launch Australia's National Digital Health Strategy in 2022. Designed to set strategic priorities for the healthcare sector, preliminary consultation results include:

- 91% of industry bodies agreed that digital health technology will transform and improve health outcomes for Australians.
- Health professionals identified primary prevention and maximising well-being, quality use of medicines and medicine safety, and mental ill-health as the top three areas in which digital technologies will have significant impact.
- 69% of health professionals said lack of integration with existing systems and processes is a barrier to using digital health in day-to-day activities.
- The general public identified health tools and technologies as the second reason they used digital health services and technologies in the past 12 months, following administration for bookings and payments.

The consultation also identified inadequate funding models as one of the biggest challenges to the uptake of digital health technologies, including the following:

- 52% of healthcare providers thought that cost/funding model is a barrier to using digital health in day-to-day activities, second to lack of integration with existing systems and processes (69%).
- Industry bodies identified business and funding models as one of the most important three areas requiring change to improve digital health in Australia, along with technical infrastructure and standards, and increased use of data, intelligence and analytics.
- Cost/funding models were also identified by industry bodies as one of the highest barriers to preventing the increased use of digital health in Australia, along with integration of existing systems and processes, insufficient infrastructure and support, and privacy and security.

Lack of Reimbursement Remains a Significant Challenge

Broader reimbursement of telehealth as a model of care and a clear regulatory landscape for SaMD products are a major step forward for the growth of a domestic digital health industry. However, the sector includes many other types of solutions that currently have no defined or well understood reimbursement pathway. Current non-specific healthcare reimbursement policies are consistently identified by industry as a substantial barrier to commercialisation and implementation of digital health technologies, specifically in the areas of digital medicine and digital therapeutics.

In global markets, significant progress is being made in putting in place direct reimbursement policies for remote patient management activities and digital therapeutic technologies. For example, in the United States, Current Procedural Terminology (CPT) codes have made the review of remote patient data generated by Remote Patient Monitoring technologies a directly billable activity for clinicians, driving a substantial increase in the uptake and deployment of such technologies across the US.¹²

In Europe, Germany has pioneered how the EU regulates market access and reimbursement of digital health applications through the implementation of the Digital Healthcare Act (DVG) by the German Parliament (Bundestag). This pivotal

legislation came into effect in January 2020 and established the DiGA framework which involves a 'Fast Track' reimbursement pathway for digital health applications.¹³ The framework allows digital health applications to preliminarily obtain DiGA listing for 12 months and thus go to market with Germany's statutory health insurers as contractual payers before positive clinical evidence is formally validated.¹⁴ Other EU countries Belgium and France are also leading the DTx reimbursement charge. Belgium's mHealth Pyramid is in place, having reimbursed its first application in May 2022, while France's DiGA replica will be launched later this year.^{15, 16}

In ANDHealth's annual industry sentiment survey in 2021,¹⁷ 79% of respondents agreed or strongly agreed that access to reimbursement will accelerate growth. Without reimbursement, Australian patients and clinicians lack direct incentives to take up high impact digital medicine, and digital therapeutics technologies and companies face enormous hurdles in creating long-term sustainable businesses.

A clearer reimbursement policy will create a stronger environment for commercialisation through incentivising implementation, and improve the health of Australians by making world-class digital health products accessible to all Australians.



Clearer pathways to reimbursement will create a stronger environment for commercialisation and improve the health of more Australians by making world-class digital health products accessible."

– Bronwyn Le Grice, CEO and Managing Director, ANDHealth

Global Investment in Digital Health

At a Glance

1 | The global digital health market has been predicted to reach **US\$660 billion** by 2025, up from **US\$175 billion** in 2019, with an expected compound annual growth rate of almost **25%** from 2019 to 2025.¹

2 | Digital health in the APAC region, including Australia, is estimated to increase in value from **US\$37 billion** in 2020 to **US\$100 billion** by 2025.¹⁸

Investment Landscape

Global investment in digital health hit an all-time high of US\$57.2 billion in 2021, a 79% increase on the US\$32 billion raised in 2020, with record levels in all geographies.¹⁹ In the last 10 years, investment in the sector has increased 20-fold, shifting our expectations for the future of healthcare.²⁰

This accelerated growth in 2020-2021 is not surprising given that the global pandemic

accelerated the transformation of the healthcare sector providing opportunities for innovation in delivery, models of care, digital health products and technologies. More than 63% of Australian healthcare technology companies said they 'felt the benefits of increased innovation from the impact of the pandemic' according to a survey conducted by the Economist Impact across Asia Pacific's Healthcare Technologies ecosystem.²¹

Global Digital Health Investment Funding

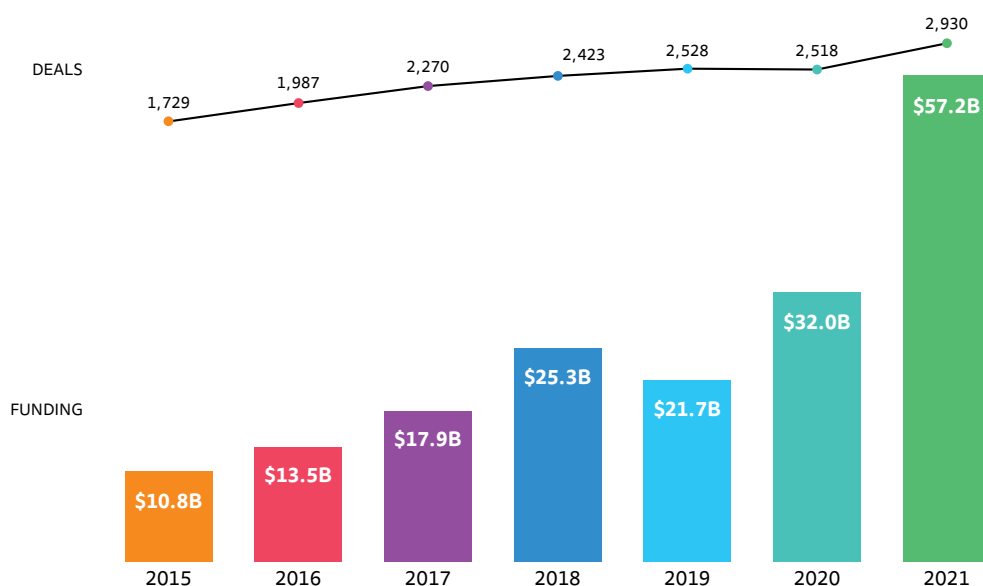


Figure 3.1: Global Digital Health Investment funding (In USD). Adapted from CB Insights 2021 State of Digital Health Report.¹⁹

2022...

State of the Sector

2022 has seen global digital health funding slow down, in line with the state of the macroeconomic environment. For the first half of 2021, US\$29.4 billion of digital health funding was deployed globally, whereas the first half of 2022 saw only US\$17.6 billion invested into the sector.²²

While this decline in investors deploying capital is significant, it is in line with the idea that digital health company valuations are undergoing a worldwide reset. As discussed above, there was substantial growth globally in digital health funding in 2021, nearly double the funding seen in 2020. It is therefore not surprising that the amount of funding deployed so far in 2022 is more aligned with 2020 rather than 2021's unprecedented year. The lower funding

observed in 2022 also remains on track to surpass 2020's total of US\$32 billion.¹⁹ 2022 should therefore be viewed as a healthy correction and an opportunity for investors to deploy capital as valuations are recalibrated.

In the public markets, digital health company IPO and SPAC activity has largely come to a halt in 2022. After 23 US digital health public market exits in 2021, none have occurred in the first half of 2022. Macroeconomic forces including inflation, risk of recession and supply chain disruption are causing companies to think twice about going public, at least until the public markets stabilise. According to Rock Health, four digital health companies have put on hold their plans to go public until, at earliest, 2023.²³

Digital Health Public Exit Activity

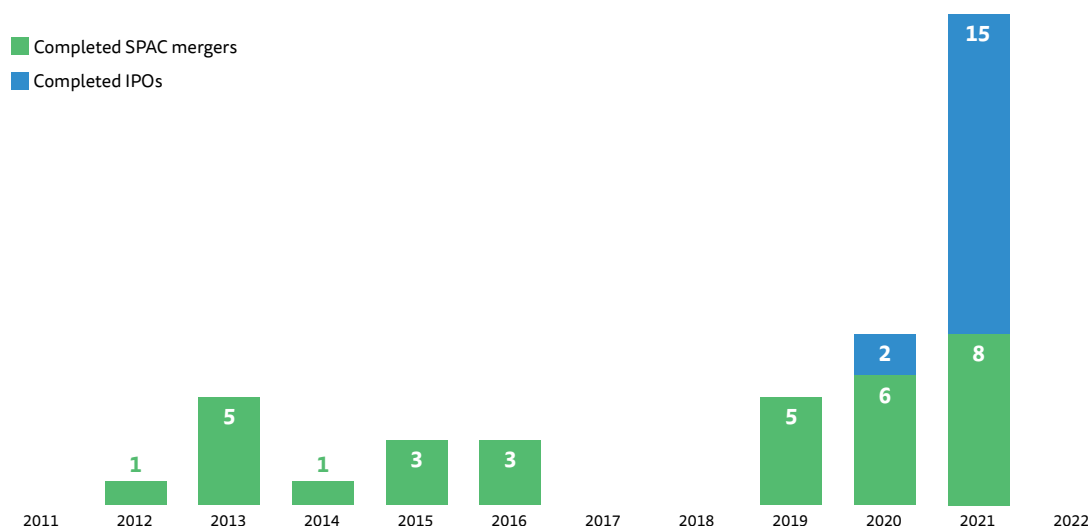


Figure 3.2: Global Digital Health Public Company Index. Adapted from Rock Health 2022.²³



Investment Success

Despite funding slowing down, companies that have secured significant investment this year include:

- 1 | **Biofourmis** raised \$300M at a \$1.3B valuation
- 2 | **Reify Health** raised \$220M at a \$4.8B valuation
- 3 | **Alan** raised \$193M at a 2.8B valuation
- 4 | **Clarify Health** raised \$150M at a \$1.4B valuation

In Australia:

- 1 | Breakthrough Victoria's recent investment into **Seer Medical** in July 2022 emphasises that investment into the sector is still occurring in Australia
- 2 | **Harrison AI** raised \$129M in December 2021
- 3 | **Atmo Biosciences** secured \$9.6M in an oversubscribed capital raise in late 2021

Investment Sentiment and Outlook

While the prospect of funding drying up and valuations crashing may sound alarming, many experienced investors and experts in the sector believe that a correction to company valuations is healthy and that a tougher funding environment will foster stronger long-term growth.

StartUp Health reports that many digital health investors are welcoming the valuation correction and the return to sustainable growth in the digital health sector. While fundraising has undoubtedly tightened in 2022, some founders surveyed by StartUp Health said that investors are looking for 'profitable businesses, rather than growth'.²⁴

“I think now there's going to be more scrutiny and focus – which is a good thing – on sound fundamentals, on the quality of revenue (not just top line growth) and on the importance of healthy margins... a lot of things that perhaps were overlooked or maybe dusted under the rug, and the funding environment in the last few years.”

– Deena Shakir, Partner at Lux Capital (US digital health venture capitalist)²⁵

and beyond



Investment Key Drivers

While the COVID-19 pandemic has been a significant catalyst for the current transformation in healthcare systems, other major factors promoting market growth include increasing cases of obesity, high prevalence of chronic diseases, such as diabetes, cardiovascular disorders, the growing need for remote patient monitoring services, and increasing patient engagement and connectivity due to the high adoption of digital health technology.

Globally, record levels of funding have been reported across the following sub-sectors, with potential growth anticipated in future years¹⁹:

- Mental health funding increased 139% YoY in 2021, driven by the need to develop digital solutions for the mental health crisis precipitated by the pandemic; 68% of deals were early stage, indicating further growth in this sector.²⁶
- Digital therapeutic (DTx) funding reached a record breaking \$3.4 billion across 122 deals in 2021, up 133% from 2020; the average deal size was 65% greater than in 2020.²⁶ Investor interest in the technology's future is being driven by the demonstration of improved patient outcomes in clinical trials and their potential to enable the treatment of chronic conditions at scale.
- Global funding for clinical trials technologies increased 53% YoY to \$US2.7 billion despite a drop in the number of deals.²⁶
- Global funding for telehealth was up 68% over 2021, hitting a new high of US\$17.6 billion, as telehealth services expanded to meet the need to control infection and manage health service delivery created by COVID-19.²⁶



Australia's Awakening Giant

With the right support and investment, Australia's emerging digital health sector can become a global powerhouse, leveraging our traditional international leadership in health and medical research, combined with our increasing prowess in technology. Such a sector would attract inward investment, create high value jobs, generate substantial exports and improve the health and wealth of Australians.

Conditions are ripe for growth. A sound digital health infrastructure is in place with a central agency, Australia's Digital Health Agency (ADHA), coordinating a nationwide digital health strategy that includes My Health Record. As at March 2022, more than 23 million Australians had a personal health record, with 96% of records populated with data.²⁷

The newly elected Labor Government has reaffirmed its commitment to innovation with the National Reconstruction Fund and Jobs and Skills Summit being key platforms in transforming Australia's future economy.

In addition, various parts of the sector are supported by a strong industry advocacy network that includes the Australian Institute of Digital Health (AIDH), Medical Technology Association of Australia (MTAA), The Medical Software Industry Association (MSIA), AusBiotech, BioMelbourne Network and others.

With growing investment into digital health solutions from Australian and global governments, pharmaceutical companies and healthcare providers, regulators are increasingly focusing on the clinical claims made by these innovations and requiring that appropriate evidence is available to substantiate those claims. There has been positive progress for Australia's digital health regulatory environment since the TGA regulation of SaMD came into effect in February 2021, establishing a clear regulatory path for evidence-based digital health products.

Australian consumers are highly connected, enabling them to manage their health through digital technologies when they choose to do so. Estimates for 2021 are that 23.6 million Australians use a smart phone, and there are nearly 31.9 million mobile connections including using mobiles for voice calls and for accessing the internet²⁸. In 2021, 99% of adults had access to the internet, and 91% had a home internet connection. Among older Australians aged 55+, the greatest users of the health system, 98% used the internet.²⁶

“If I want to have the best possible pipeline in the future, then I've got to grow the best possible ecosystem around me. For a successful industry, you've got to have talent, capital, customers and policymakers. We need to work collaboratively, promote each other's activities, grow this market and make it a globally leading industry sector, together. Otherwise, we are just competing for crumbs.”

– Bronwyn Le Grice, CEO and Managing Director, ANDHealth in Asia Pacific's Healthcare Technologies Ecosystem: Enhancing start-up and SME success White Paper Report²¹



Realising Value From the Awakening Giant

Despite this positive environment, digital companies face unique challenges as they move along the path towards commercialisation. To fully realise the potential of this awakening giant, action needs to be taken to:

- 1** | Recognise digital health as its own industry with unique needs / requirements and a commercialisation pathway that is fundamentally different to that of medical devices or biopharmaceutical products.
- 2** | Address the significant challenges digital health companies face in accessing capital and build appropriately focused funding structures here at home.
- 3** | Align reimbursement models to incentivise the use of clinically proven, evidence-backed digital health products and technologies.
- 4** | Build a resilient, agile, scalable and personalised healthcare system, focused on preventing, diagnosing, managing and treating illness using cutting edge technologies.
- 5** | Expand high-value manufacturing capabilities, through sensors, wearables, connected devices and regulated software products.
- 6** | Provide specialised support and access to executives and industry leaders who have 'done it before' (there's no substitute for real world experience).
- 7** | Review existing systems and structures to accommodate new technologies. An important step in this direction, implemented earlier this year, was the changes to regulations around software as a medical device.
- 8** | Include clinically proven, evidence-backed digital health solutions into clinical guidelines to support clinicians who wish to utilise cutting edge digital interventions.

Insights from Australia's Digital Health Pipeline

The magic of successful programs is not in the surface-level structures and processes; what makes them successful is the “investability DNA” that is ingrained in the way that they started, and how they have evolved to function today.²⁹

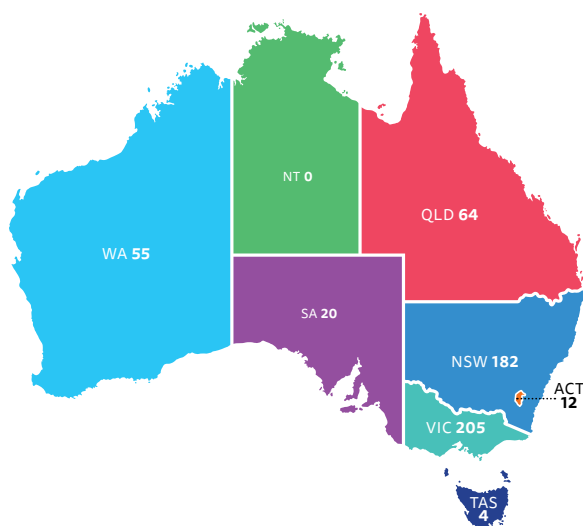
Between July 2017 and March 2022, ANDHealth supported 569 high-growth-potential digital health companies across Australia. In keeping with our data collection and privacy policy, the data encompassed in this report has been collected and aggregated across key metrics, providing an unrivalled view into one of Australia's most exciting growth industries. This allows ANDHealth to identify trends, opportunities, challenges, and gain insights into the state of the industry as a whole. In collating this data, we have looked across a broad variety of criteria to assess the types and focus of our innovative Australian digital health companies, and to highlight the diversity and potential within the sector.

Data is reported by companies at the time of engagement with ANDHealth and collated and aggregated at 31st March 2022. Of the 569 companies we have supported, 552 remain active while, 17 companies are no longer operational.³⁰

In contrast to the 2020 report, this year the data includes primary, secondary and tertiary focus areas in the following key categories: company purpose, end users, paying customers, end user setting, clinical indication and technology. Where data has been consistently collected across several years, trend data has been collected. In future reports, these trends will become increasingly important to understand how the industry can be best supported.

Geographic Distribution

Since *Sleeping Giant* was published in 2020, there has been strong evidence of industry growth across Australia. Overall, the number of companies in the pipeline increased by 74%. On a state-wide basis, the number of digital health companies in NSW increased by 112%, Victoria by 45%, Queensland by 121% and WA by 67%.



As a program-driven pipeline, the geographic distribution partly reflects the states in which ANDHealth has been directly funded to deliver localised activity, but it also reflects uptake of our national initiatives. The distribution is expected to further diversify as we increase our state-based activities across Australia.

Figure 5.1: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 March 2022 (n=542 responses from 529 companies), 18 companies were based internationally.

Clinical Indications

As in 2020, companies in 2022 reported a broad range of clinical indications, reinforcing the enormous opportunity for a thriving digital health sector to make a difference across the healthcare spectrum for a diverse range of Australians. It also highlights areas of potential where there is limited local competition for new companies and technologies in development.

In 2022, we offered companies the option of choosing an 'agnostic' solution (not offered in 2020) – solutions that are not specific to a particular clinical indication but may be relevant to a broad range of conditions such as complex medication management, polypharmacy, chronic conditions more broadly or patients with multiple co-morbidities. A notable proportion (23%) of companies indicated 'agnostic' as their primary clinical focus.

Following on from the pandemic, mental health is a significant area of focus with 15% of companies indicating this as their primary indication. Deloitte Global projects that global expenditure on digital mental health applications will reach close to US\$500 million in 2022.³¹

Unsurprisingly, given ANDHealth's stated focus on evidence-based and often regulated technologies, only 7% of companies were focusing on general lifestyle and wellness as their primary clinical indication. However, 40% of companies were focused on highly diverse areas of medicine including: nervous system; musculoskeletal; gastrointestinal and metabolic health; diabetes; cancer; cardiovascular; infectious diseases (only 2% despite the pandemic); paediatrics; obstetrics and gynaecology; eyes, ears and mouth; and deterioration and falls.



As COVID-19 accelerates the demand for digital mental health services, companies will need to separate themselves based on who has high-quality evidence that it works."

– Dr John Torous, Director of the Digital Psychiatry Division at Beth Israel Deaconess Medical Center in Boston³²

Primary Clinical Indication

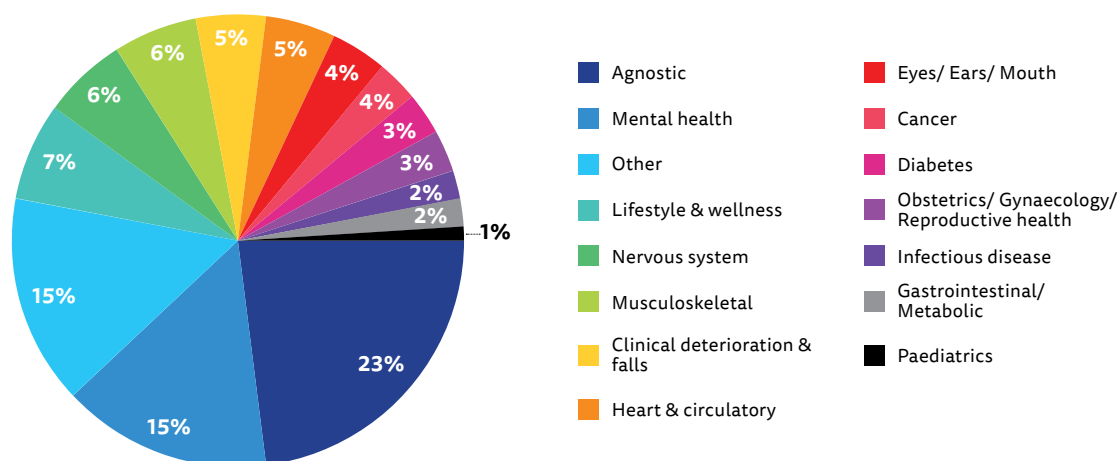


Figure 5.2: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 March 2022 (n=513 companies).
Other: sleep, skin, respiratory, allergy/immunology, renal/urology.
In 2020 Agnostic was not provided as an option.

When we look at the combined data of the top three focus areas for companies in the pipeline, the lifestyle and wellness category increases substantially from 7% to 26% of responses. This could be explained by the role of consumer behaviour change which underpins significant improvements in patients with chronic disease, and the lifestyle changes that can enable profound health improvements. Many digital health

technologies rely on patient engagement and empowerment in taking control of their health to yield significant gains in patient outcomes, often leveraging consumer behaviour techniques and changes to help patients better manage their conditions. Similarly, in the combined data, mental health increases from 15% to 26%, showing the complex interactions which may occur between physical and mental health.

Clinical Indication – Combined Primary, Secondary & Tertiary Selections

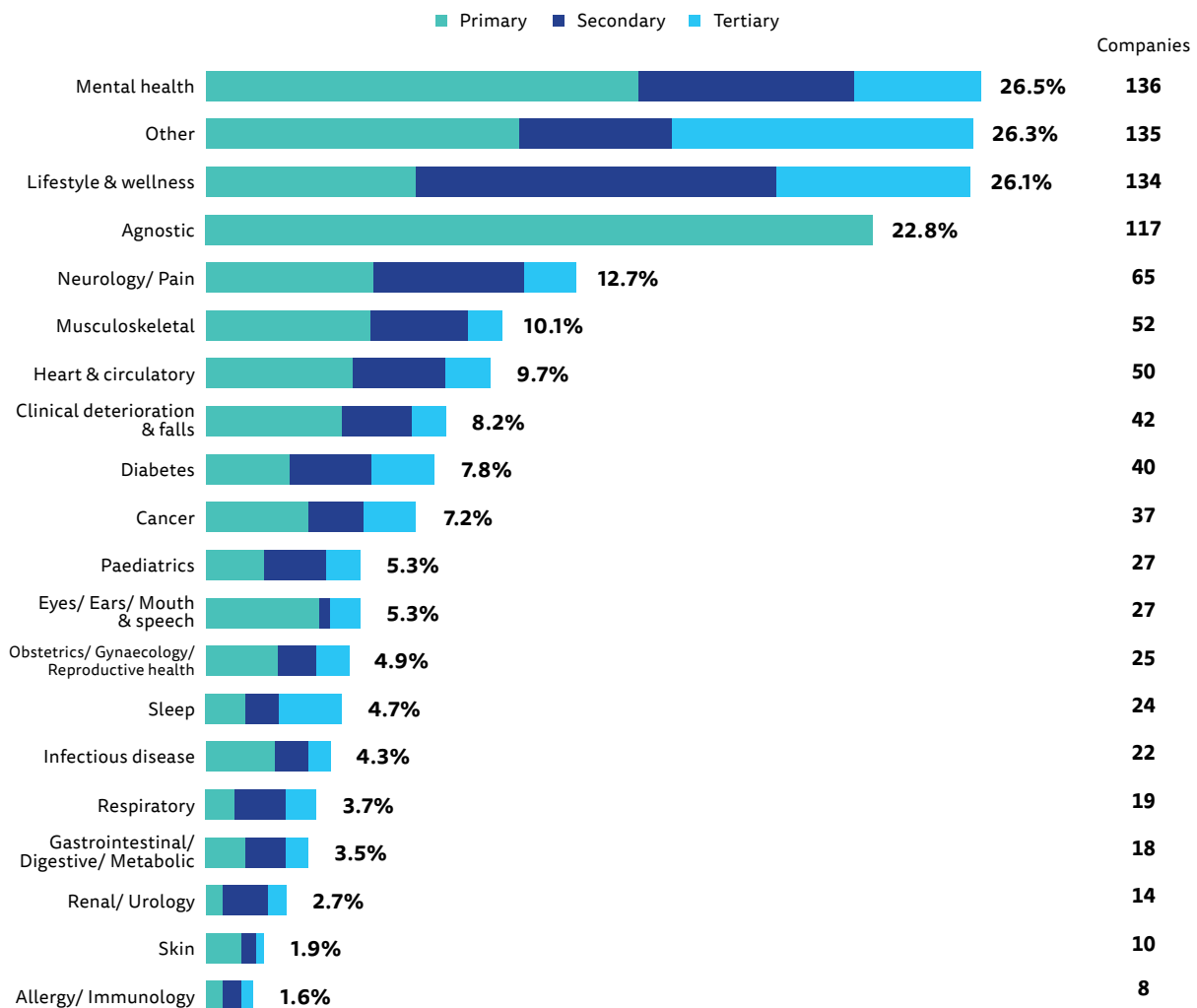


Figure 5.3: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 March 2022 (n=1002 responses from 513 companies).

Company Purpose

Looking across the sector, it is useful to contemplate the purpose for which companies believe their technology will be used. This year's data continues to reflect a key trend observed in 2020 which is driving digital health solutions globally: the rise of the 'empowered patient' or 'empowered healthcare consumer'.

A significant proportion (30%) of companies identified their primary purpose as deploying technologies intended for self-management of disease, behaviour change or medication management. When considering companies' top three focus areas, 69% were found to be focusing on self-management of disease, behaviour change or medication management.

The proportion of companies whose primary purpose is focused on Digital Therapeutics (DTx) increased to 8% of companies in 2022. DTx technologies are one of the fastest

growing segments in digital health with US\$3.4 billion in investment across 122 deals in 2021. The DTx market is projected to continue to grow, hitting US\$13.1 billion by 2026, up from \$3.4 billion in 2021.³³

Similarly, in Australia the number of companies focusing on DTx technologies is expected to grow as regulatory and reimbursement policies around the world (e.g. Germany's DiGA reimbursement framework) allow DTx companies to go to market with contractual national payers.³⁴ However, in the short term, Australian DTx technologies continue to endure regulatory and payer-side hurdles that may slow their adoption.

More than two-thirds of companies are seeking to empower patients through better self-management, consumer behaviour change and medication management.

Primary Purpose

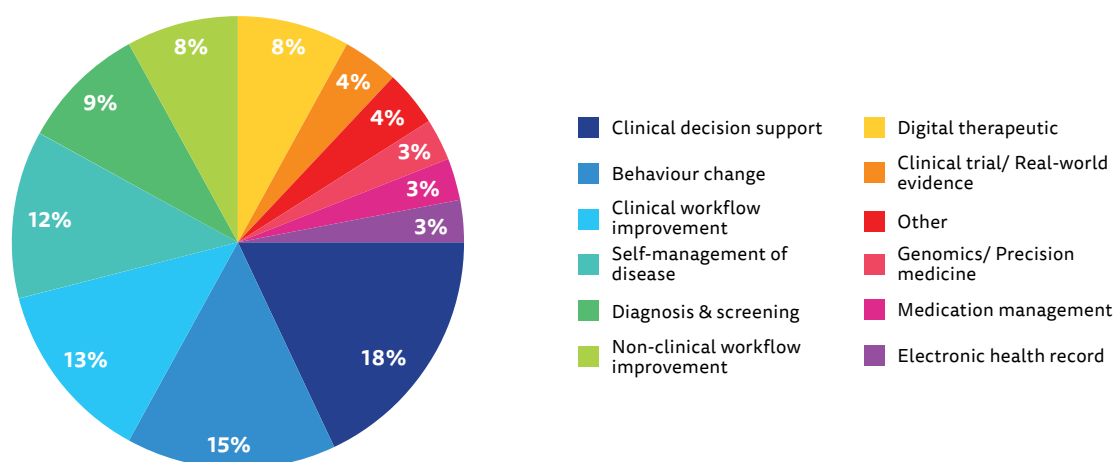


Figure 5.4: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 March 2022 (n=513 companies).
Other: Drug delivery/ dosing/ discovery, practice management software.

In line with the data reported in 2020, a large proportion of companies continue to focus on clinical decision support: 18% cite this as their primary purpose. When companies' top 3 areas are included, it is evident that 42% of companies have solutions that incorporate a level of clinical decision support.

In some cases, clinical decision support tools which are deemed to be low risk, are highly transparent in their provision of information and that meet a predetermined criteria would be conditionally exempt from regulation by the TGA.

Purpose – Combined Primary, Secondary & Tertiary Selections

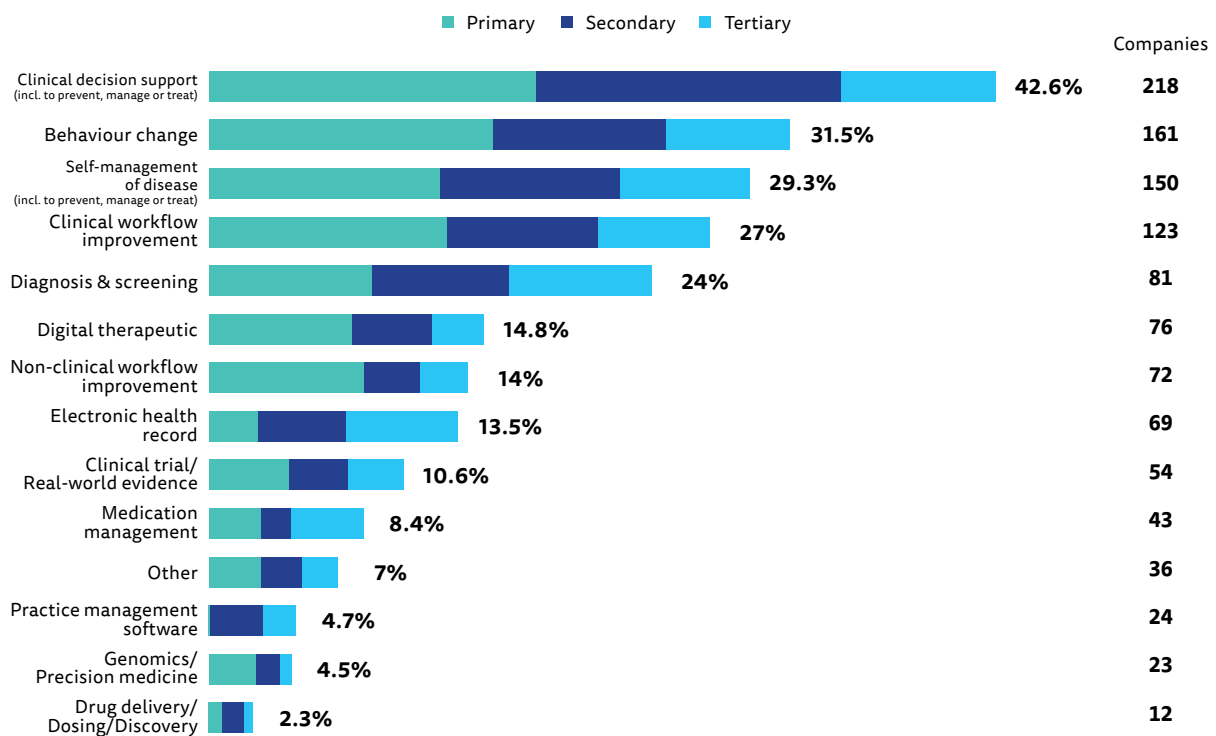


Figure 5.5: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 March 2022 (n=1199 responses from 513 companies).



End Users

Human-centric healthcare requires reaching end users where they are, identifying those at risk, anticipating their needs, and deploying evidence-based interventions in a timely manner.

Most technologies need to appeal to multiple end users – the most common being patients and clinicians, but also laboratory staff, care givers, allied health workers, employees and administrators. These groups will often have multiple and varied requirements, depending on how the technology impacts their lives, patient care, care team interactions and workflow.

A deep understanding of how end users will engage with a product, including their key drivers, is critical to success. Products need to be personalised and 'sticky' to sustain long standing uptake and engagement, which is particularly important if the technology is to support management of chronic conditions or medications.³⁵

Consumer empowerment is a major trend driving the adoption of digital health technologies, as is the recognised role

that consumer behaviour-change plays in improving health outcomes. On the market-pull side, there is also a clear trend for patients to increasingly take their health into their own hands by adopting digital health solutions.³⁶

The second largest end user segment is health practitioners, with 39% of companies aligning their solutions for practitioners. Fewer companies (6%) are focused on the primary end user segments of administration, research, and laboratory personnel. This change in proportionality demonstrates the increasing focus of Australian companies on being directly engaged in the interplay between clinicians, patients, and technology.

Interestingly, the picture changes markedly when we dive deeper into the secondary end user segments (chart not shown). Only 20% of companies view patients/consumers as their secondary end user, with 29% viewing practitioners as their secondary end user. Meanwhile caregivers are seen as the secondary end user for 12% of companies versus only 2% viewing caregivers as the

Primary End User

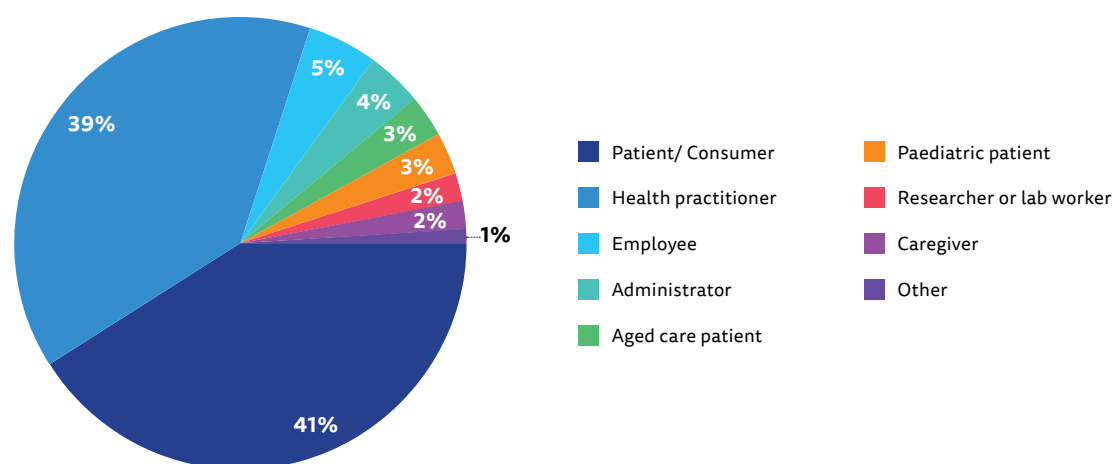


Figure 5.6: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n= 512 companies).

primary end user. This demonstrates the need for companies to think holistically when designing solutions for the complex interactions between consumers, clinicians and care teams.

Similarly, the end user segments of administration, research and laboratory personnel are considered secondary end users for 20% of companies, vs only 6% of companies focusing on these segments as primary end users.

Overall, the diversity of end users increases markedly when we start to dive into secondary end users, indicating that, whilst companies have a very strong idea of who their primary users might be, once we start to unpick other relevant end user segments, designing relevant and sticky products becomes substantially more complicated.

End User – Combined Primary, Secondary & Tertiary Selections

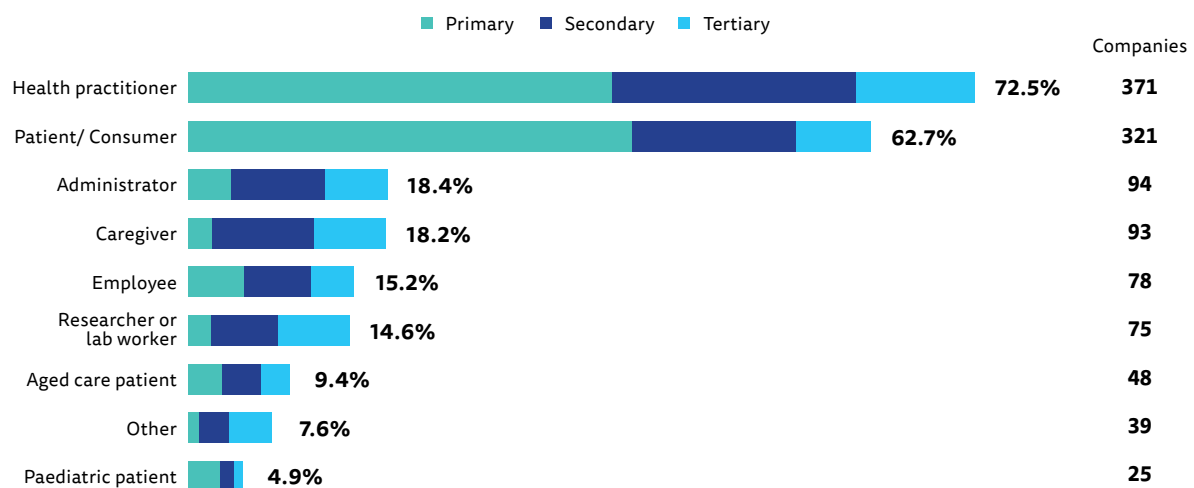


Figure 5.7: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n= 1144 responses from 512 companies).

Paying Customers

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 and developing products which have a clear paying customer. When we look internationally, company failures in the space are often not due to product failure but to the inability to find a scalable, economic business model in an increasingly noisy global market.

Successful digital health companies have a deep understanding of their paying customers, what drives/incentivises them and the complex business models that underpin the healthcare system. Clinical need itself does not necessarily create an incentive for a particular market segment to invest in or purchase new technologies. Also, the economic impact of a disease, the cost of wastage in treating a disease or the savings to the system if patients were better diagnosed, managed or treated do not necessarily relate

to an incentive to use and/or pay for the technology.

This data showcases the diverse approaches companies take to business and revenue models, often differing depending on the jurisdiction in which the company operates. In earlier stage companies, proposed paying customers may change significantly throughout commercialisation, especially in those with non-health experienced founders and CEOs who may not initially appreciate the complexity of the healthcare system and market.

Tension remains evident between end users and paying customers, emphasising the difficulty in designing innovative business models and securing long term, highly scalable revenue streams. While 39% of companies identified health practitioners as their primary end user, a smaller proportion (27%) identified them as their primary paying customer. Similarly, 41% of companies identified individual patients/consumers as their primary end user, while only 24% recognised this group as their ultimate paying customer. This discrepancy begs the question: who will pay?

Based on both data and anecdotal evidence from ANDHealth's engagement with hundreds of SMEs, the prevailing expectation

is that health providers and patients/consumers will be the primary purchasers of digital health technologies. 24% of companies expect that patients/consumers will be their ultimate paying customer. Interestingly, this is contrary to the international experience where, except for certain sub-segments and consumer grade (unregulated) wellness products, consumers are rarely willing to bear the cost of clinical interventions, especially in government-funded healthcare systems like Australia's. 'Consumer pays' models also rely on users being able to afford the technology in the first place, limiting the total addressable market and further exacerbating health equity challenges.

Given the single-payer model in Australia, it is notable that only 10% of companies believe that their primary paying customer is government and an even smaller proportion (4%) believe insurers will pay for their product. Likely reasons for this include lack of awareness of the ultimate paying customer (in the case of public health providers), and the lack of a clearly defined health technology assessment and reimbursement pathway in Australia that is directly relevant and achievable for digital health interventions. In other countries, such as the United States and Germany, companies have the benefit of assessment

Primary Paying Customer

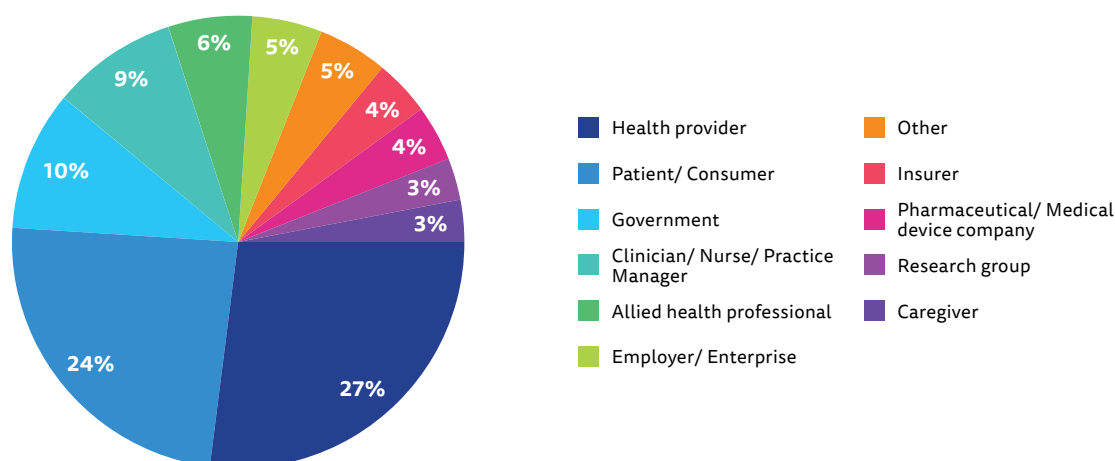


Figure 5.8: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=513 companies). Other: Laboratory (pathology or imaging), pharmacist/ pharmacy/ pharmacy network.

and reimbursement frameworks that allow their solution to be paid for by government and insurers.

In the United States, Remote Patient Monitoring Current Procedural Terminology (CPT) codes were enhanced with five new CPT codes in early 2022 that build on the existing coverage for remote patient monitoring.³⁷ The new codes cover remote therapeutic monitoring and treatment management. This advancement in digital health reimbursement can allow more companies to secure recurring revenue with government (US Medicare) as their paying customer. Similarly, Germany's DiGA framework can allow certain digital therapeutic solutions to obtain a reliable revenue model with statutory health insurers as contractual payers.³⁴

When we look beyond the primary paying customer to the combined top three segments, the view becomes more diversified with less focus on the patient and practitioner. Notably when we look at the

combined data, governments and insurers account of 33% and 26% of customer market segments respectively. Small increases are seen across employers, caregivers, allied health professionals, pharmaceutical/medical device companies and researchers.

The question of who pays remains complicated by regulation and health technology assessment (HTA) and reimbursement policies which have not kept pace with the development of digital health technology. Until a national model for HTA and reimbursement which accommodates the specific needs of digital health technologies is developed in Australia, companies may continue to struggle to achieve meaningful market penetration locally. Without meaningful market access and revenues in Australia, our highest potential companies will be forced to look abroad, often moving overseas before the real economic and health impacts of their technologies and organisational growth can be captured for the health and wealth of Australians.

Paying Customer – Combined Primary, Secondary & Tertiary Selections

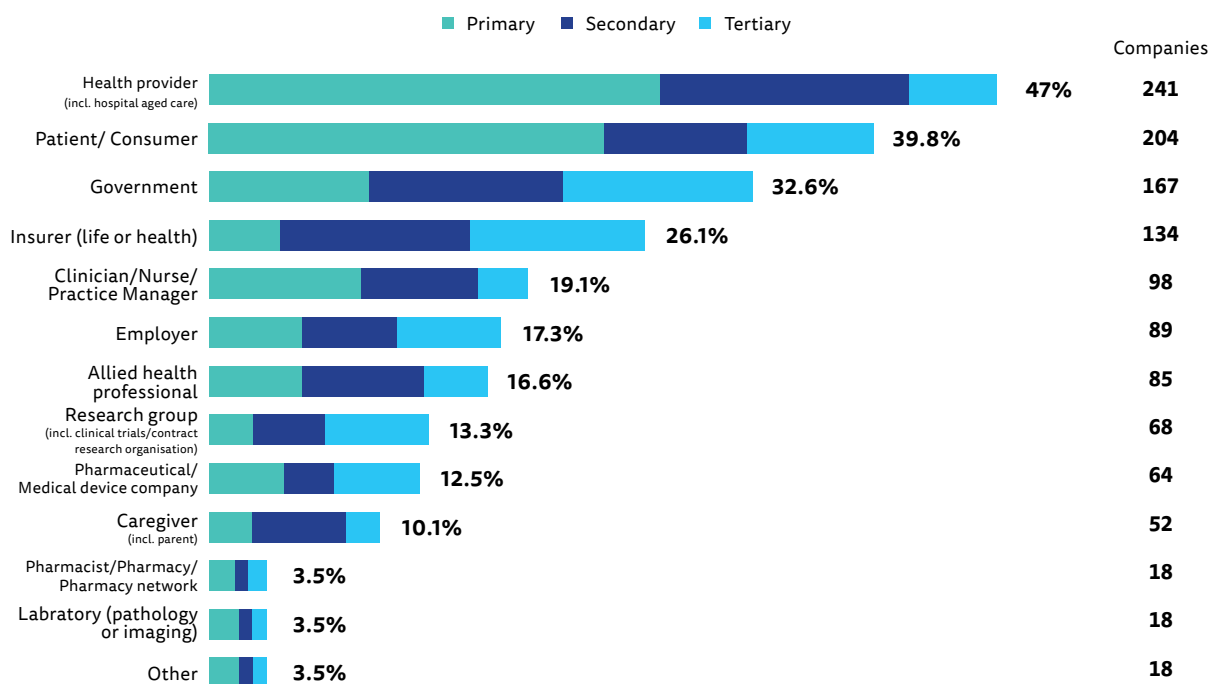


Figure 5.9: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=1256 responses from 513 companies).

End User Setting

Digital health technologies have been proven to have the ability to prevent, diagnose, manage, mitigate and treat health conditions outside of a clinical setting. In a fully connected healthcare system with engaged consumers, health data can be generated, shared and viewed by patients, consumers, caregivers and clinicians and can be leveraged wherever they might be, not only during scheduled (or unscheduled) health system visits.

Health system data is, by its nature, episodic, relying on the patient to interact with the system to gather and generate data to inform ongoing care. In a world of connected sensors in phones, watches, wearables and medical devices, most healthcare data will soon be generated outside the healthcare system, so how healthcare professionals access this high value data set becomes increasingly important.

This is particularly relevant to Australia where access to equitable and timely healthcare in our vast rural and remote areas is challenging. Dr Sonj Hall, Editor-in-Chief, Australian Health Review, notes that *"Telehealth and other digital health services*

*have enabled our health system to look after patients in their own homes during lockdowns, while easing pressure on resources, workforce and reduced unnecessary spread in the community."*³⁸

This change in where and how health system interactions were conducted during the pandemic is reflected in the number of companies seeking to deploy digital health products in non-clinical settings. 47% of companies are looking to deploy their technology into the home. In contrast, the proportion of companies targeting GP/ allied health clinics is 19%.

The hospital environment remains appealing to digital health companies, with 19% of companies indicating they are focusing on this setting. This is a more demanding environment in which to deploy digital technologies than in the patient's home, with a high barrier to entry and stringent requirements for integrating technology and workflow with existing systems.

Again, when we look at the combined primary, secondary and tertiary segment data across proposed end user settings,

Primary User Setting

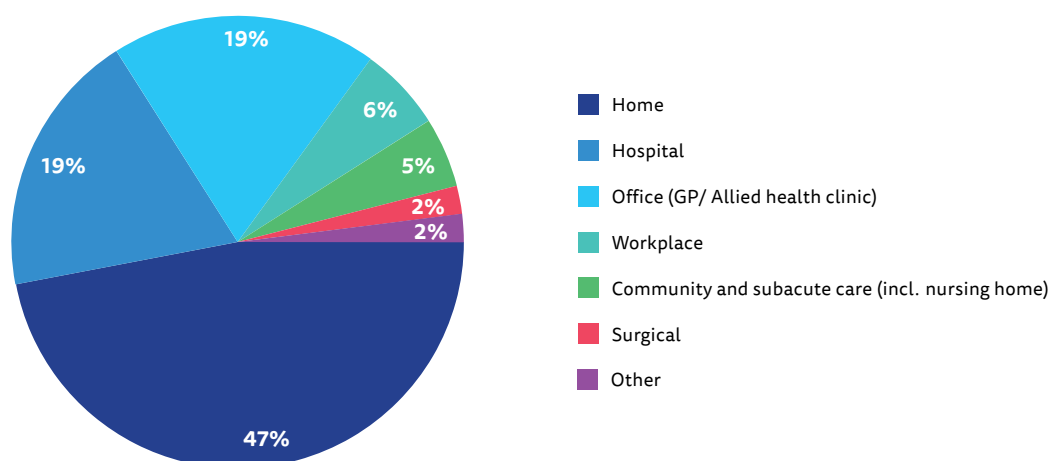


Figure 5.10: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=498 companies).

we see a greater spread across various settings. The home accounts for 66% of total responses, whilst GP and allied health clinics increase to 48% and workplaces to 22%. Community and subacute care also take up a greater proportion of the combined responses at 27%, versus only 5% of primary end user settings.

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 management and monitoring. These technologies have significant potential to improve quality of care in settings outside the ‘clinic’, reducing unscheduled health system access, improving health outcomes and management of chronic conditions and, in some cases, removing the need for surgical interventions. However, as we observed with telehealth, in the absence of policies which put in place appropriate financial and economic incentives, the barriers to uptake for these technologies remain high.

User Setting – Combined Primary, Secondary & Tertiary Selections

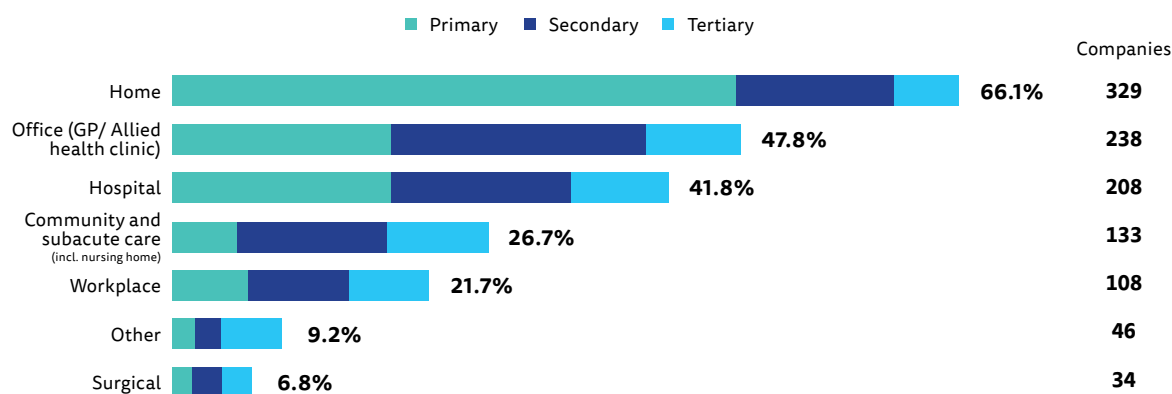


Figure 5.11: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=1096 responses from 498 companies).

“ Remote monitoring technology can facilitate equitable healthcare, in particular for private medical practices in rural and remote areas, yet there are no appropriate funding mechanisms that exist to encourage this. Medical practices can invest in these technologies; however practices struggle to justify this without a means of funding, despite the benefit to the patient.”

– Australian Medical Association, Federal Election Statement 2022³⁹

Technology

The primary technology focus for companies provides insight into the areas where innovators feel there is untapped potential for technology to change the clinical paradigm or patient outcome. It also provides a view of which skills are currently being utilised and which skills may be in demand in the future.

Unsurprisingly, artificial intelligence and machine learning (15%) continues to grow as a primary technology focus area. This closely aligns with international trends: the global AI healthcare market was valued at US\$10.4 billion in 2021 with an expected CAGR of 38.4% from 2022 to 2030.⁴⁰ As investment and adoption of these technologies continues to grow, it is critical that companies ensure their technology solutions can be clinically validated as safe and effective in the same way that we expect pharmaceuticals and medical devices to demonstrate safety and efficacy.

In line with global trends, mobile health is the primary focus of technology for 17% of companies. The number of consumer health apps has doubled since 2015 with more than 350,000 currently available for consumers.⁴¹

However, it should be noted that many mobile health applications have long-term engagement challenges, lacking the sustained uptake and engagement required to make a digital health technology business scalable at a global level. Studies show that digital health applications fail to retain engaged participants, with the median retention across eight studies being just 5.5 days.⁴²

Connected devices, sensors or wearables are incorporated into the products of 12% of companies. Based on anecdotal evidence and interactions with the broader health technology sectors, ANDHealth believes that there is a much larger pool of connected device companies in the Australian innovation ecosystem which are being supported by medical device focused commercialisation programs. As the global trend of the Internet of Things (IoT) in healthcare continues to expand, we expect that connected devices, sensors and wearables will play an increasing role in Australia's digital health sector.

A further 11% of companies are focused on deploying telemedicine and telehealth

Primary Technology

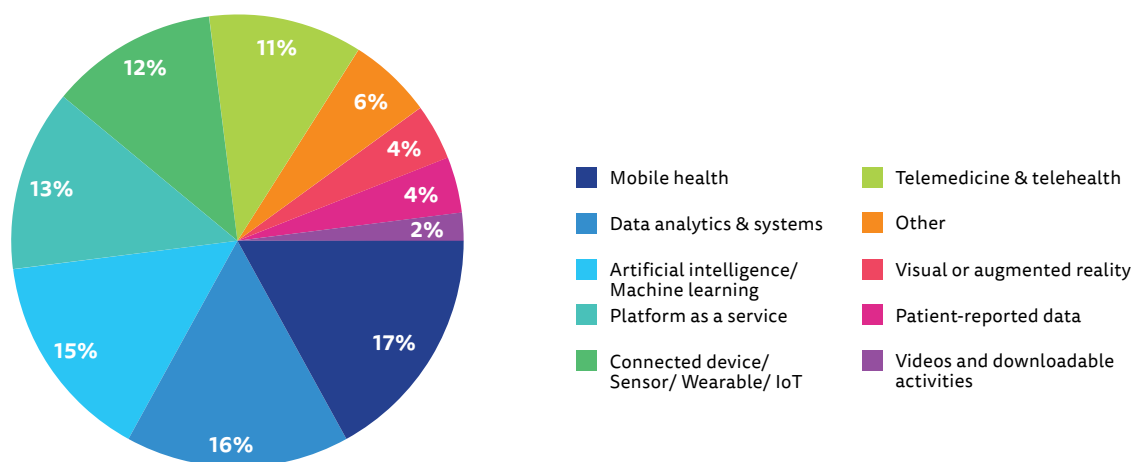


Figure 5.12: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n= 513 companies). Other: 3D modelling or printing, implantable/ ingestible, voice-assisted technology, blockchain.

technologies. There has been an observable increase in the number and size of telehealth-based companies in the Australian market, with global players such as Teladoc establishing Australian teams and local player Covu experiencing substantial growth. This has almost certainly been catalysed by the implementation of reimbursement codes for telehealth for all Australians during the pandemic and beyond.

Going forward, experts are projecting a change in focus to improving specialised care with telehealth and connected device technology. Bill Taranto, founding partner and president of Merck Global Health Innovation Fund, foresees that we should “expect telehealth players to build out their offerings across the chronic care landscape in a meaningful way in 2022.”⁴³

Technology – Combined Primary, Secondary & Tertiary Selections

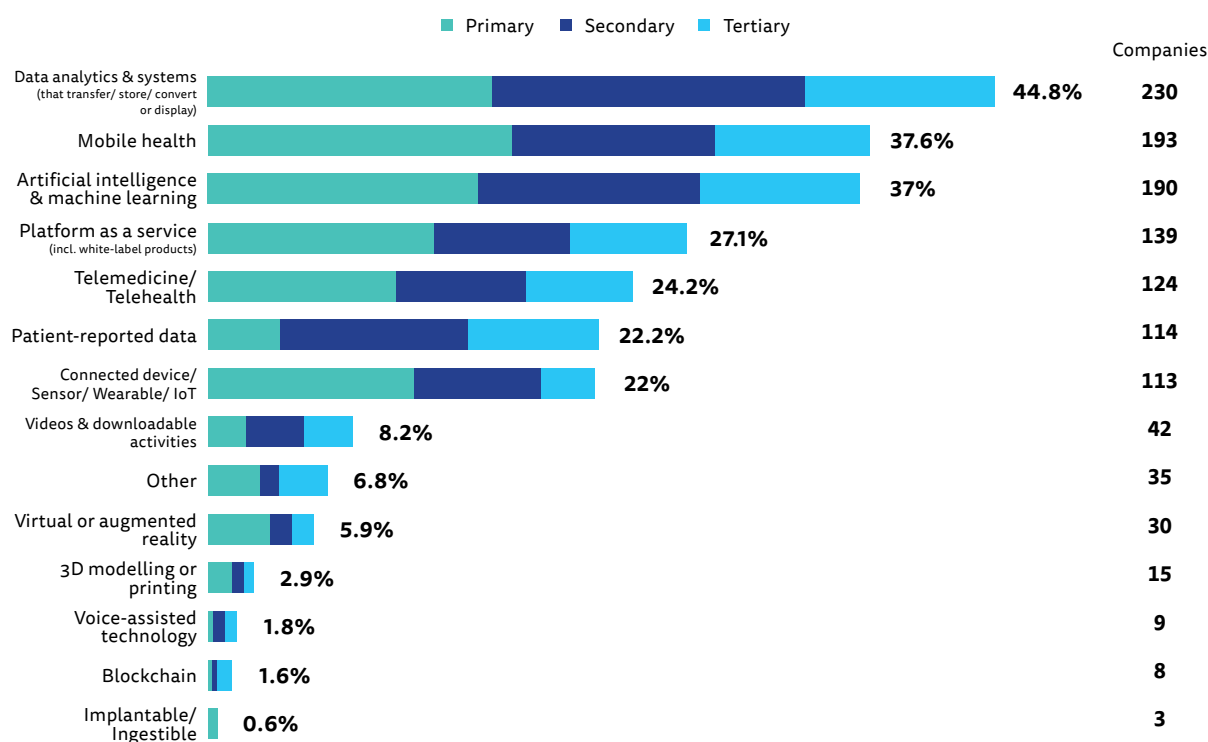


Figure 5.13: Australian digital health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=1245 responses from 513 companies).



Pipeline 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, but the pathway to market and the value inflection points along the way are still evolving rapidly as both the healthcare sector and capital markets adapt to these new types of technologies and interventions.

To get to market, digital health products need to be backed by real-world evidence spanning both clinical and commercial outcomes. Value drivers in development stage companies are often more closely tied to user/ customer traction and revenues than would be common in a medical device or biopharmaceutical product. Similarly, demonstrating a robust, scalable and economic business model is critical, often in the absence of the reimbursement opportunities that are more clearly accessible for other types of health technologies.

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 or specific clinical trial endpoints. 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 currently offers minimal support for most digital health technologies in many major jurisdictions.

ANDHealth uses a proprietary methodology, based on the Oxford Academic Health Science Network's Digital Health Roadmap, and developed through hundreds of hours of engagement with digital health companies,

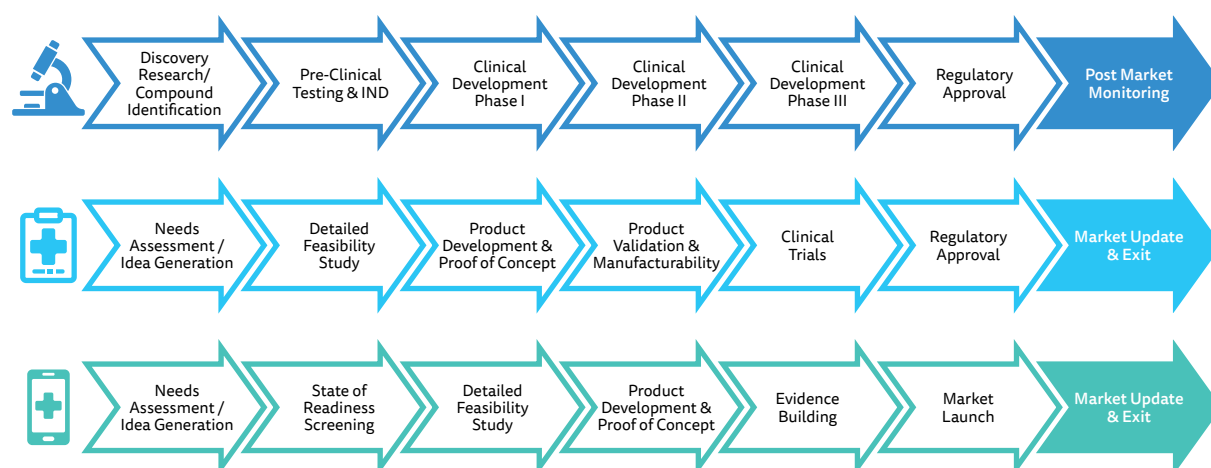


Figure 6.1: Stages of Development: Pharmaceutical drug, Medical device, Digital health product. Source: Oxford AHSN, Scott T. Ham, ANDHealth.⁴⁴

investors and enterprise customers, to assess the maturity or 'stage of development' of the companies in our pipeline.⁴⁴ ANDHealth's pipeline of high-growth potential digital health companies has grown substantially since 2018, averaging 100% growth year on year. Since June 2020, we have used our maturity assessment methodology to map the pipeline, allowing us to track sector maturity over time.

In June 2020, given the nascent nature of the sector, the ANDHealth pipeline was predominantly early development stage companies who were completing detailed feasibility studies as they move towards proof-of-concept. There were also a number of companies who had progressed to evidence-building in the lead-up to market launch. ANDHealth's goal at the time was to both increase the size of the pipeline whilst also maturing the companies within it, making a material difference to companies' readiness for institutional investment and international market entry. Since then, the pipeline has exhibited a notable increase in both the number and maturity of companies.

The combination of an overall increased number of early-stage companies (stages 1-3) and a decrease in their proportion relative to mature stage companies indicates that even though there continues to be a strong influx of new and early-stage companies, a strong shift towards increasing company maturity exists in the pipeline. This trend of progressing a growing pipeline of companies along the commercialisation pathway provides an attractive environment for both government and private sector investment.

It is becoming increasingly clear, following the growth since ANDHealth's incorporation, that investment into this emerging industry will create the foundations of a sector which will drive economic growth, highly skilled jobs and health system resilience for Australia in the future. Importantly, ANDHealth's commercialisation support program suite remains 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.

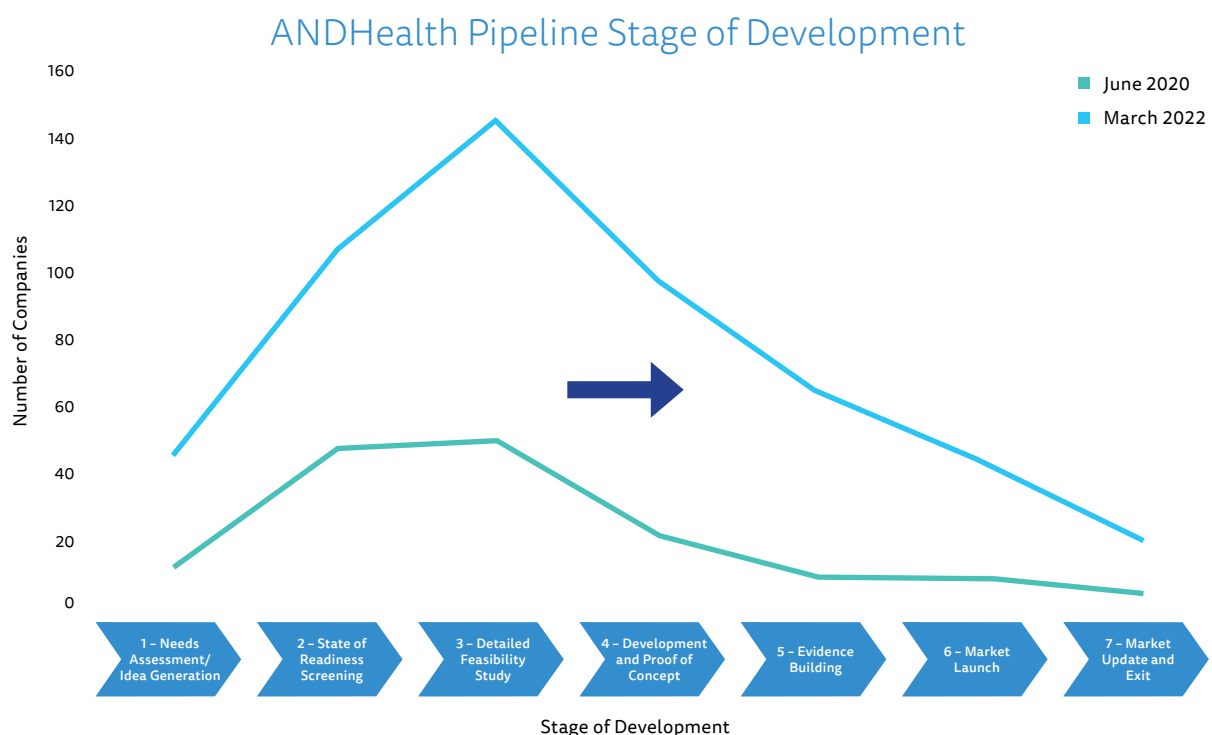


Figure 6.2: Australian Digital Health companies & technologies assessed against ANDHealth's proprietary stage of development matrix | Companies assessed at June 2020 (n=146) and at March 2022 (n=520).



Australian Investment Landscape

Despite the high levels of investment into digital health seen globally throughout 2020 and 2021, a significant gap remains in local investment for Australian digital health companies developing evidence-based technologies.

There are many systemic reasons why accessing capital remains one of the sector's biggest challenges, including:

- lower levels of venture capital per capita than other jurisdictions
- the relative lack of understanding of digital health as a sector
- the sector's potential and pathways to market success
- the lack of investors with specific and deep domain expertise in this space.

In more mature markets such as the United States, it is common to find fund managers and venture capitalists with funds that have a digital health mandate or investment team. In contrast, specific Australian funds largely fall into general technology funds or 'traditional healthcare' (biopharmaceutical/medical device) funds.

It should be noted that funds across both generalist technology and traditional healthcare are increasing their exposure to digital health, however access to patient, informed and expert capital remains a consistently reported gap in the market in the eyes of the CEOs and founders of our most promising digital health companies.

In 2022, we have seen a wholesale correction of valuations across all technology sectors, with healthcare being no exception. Many companies which raised capital at the peak of the market now need to consider raising at lower valuations in order to secure the necessary capital to fund ongoing operations and growth. This may have repercussions for broader market issues which have proven challenging for many companies, including the availability and affordability of talent.

The flip side of low valuations, however, is an increasing interest in deploying capital at more affordable valuations. Many experienced investors note that periods of economic correction and subdued valuations offer fantastic investment opportunities for those with funds to deploy, supported by a market which is more forgiving of longer timelines for due diligence and places less pressure on investors to make investment decisions in highly compressed timelines.

As we look forward, it is clear that companies actively raising capital, who have not adjusted their valuations according to market conditions, will struggle to raise capital for development and growth. Those companies which have adapted to the market conditions and can put a compelling case to investors will likely continue to raise, within the constraints of the Australian capital market as a whole.

Investment Source and Size

Despite these barriers, the 449 digital health companies in the pipeline, who have disclosed their financing outcomes, have raised a total of A\$524.8 million (dilutive and non-dilutive), up from A\$441.5 million in June 2020. Median funding reported by companies has increased to A\$278,500, up from A\$250,000 in June 2020 (an 11.4% increase). Across the data set it can be seen that companies obtain their financing from various sources. The most common funding source is from grants (28%); family, friends, angel investors and high net worth individuals (37%). Only 13% of companies

had accessed venture capital financing which is indicative of the small pool of VC funding flowing into the digital health sector in Australia.

Interestingly, drawing on the technology company experience, 8% of companies were bootstrapping their development, commercialisation and operations. In addition, a small percentage of companies (4%) had secured funds through accelerator and incubator programs.

Investment Source and Size

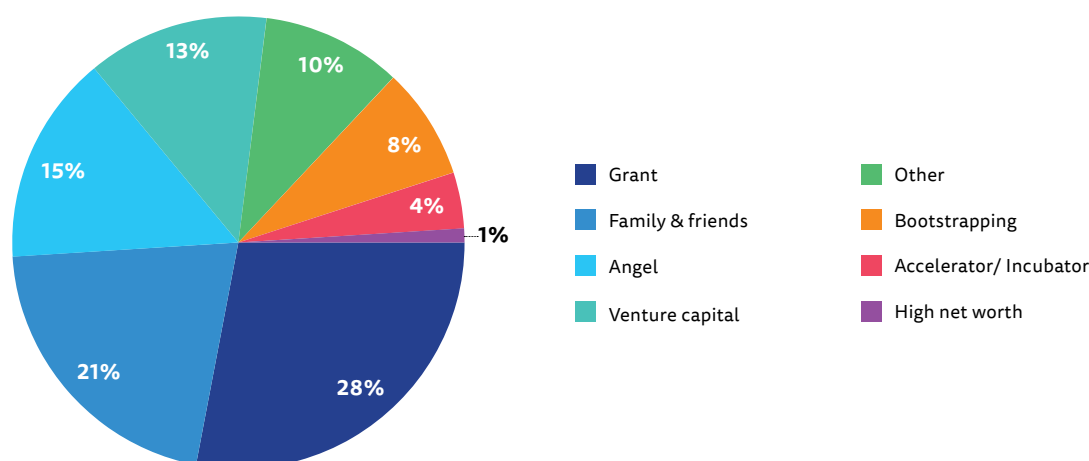


Figure 7.1: Australian Digital Health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=449 funding sources reported). Other: public investment, debt, trade, RTO, self-funding, crowd funding.

Indicative of the nascent nature of the Australian digital health sector, the vast majority of companies reporting financing data (73%) have raised less than A\$1 million. This has not significantly changed since 2020 where 72% had raised under A\$1 million. Similarly, 60% of reporting companies have secured less than A\$500k, a slight increase on the 57% reported in 2020.

Contrary to the increasing product maturity we are seeing across the pipeline, the number of companies securing larger quanta

of funds has remained relatively stagnant: 16% of companies have raised between A\$1 million and A\$5 million and 12% of companies, the same percentage as in 2020, have raised in excess of A\$5 million, mainly from venture capital and angel investors.

Looking forward, 85% of companies are planning to raise capital in the next 12 months and 6 companies (vs zero in 2020) have indicated that they will be seeking to raise in excess of A\$10M, demonstrating that there will be no lessening of demand for capital despite current market conditions.

In fact, it is likely that the shortage of capital available to the sector will grow in the short to medium term, in the absence of new pools of capital with specific mandates and dedicated expertise to invest in digital health.

Median funding is up 11.4% on 2020 but still low at \$278,500.

Amount of Funding Raised

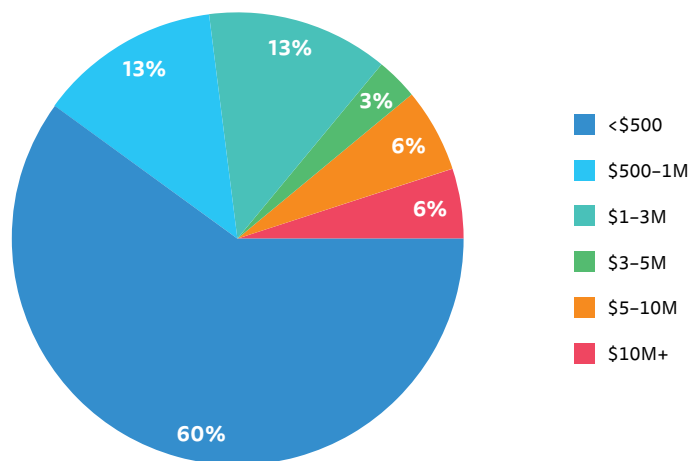


Figure 7.2: Australian Digital Health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=274 companies reporting funding values > \$0).

Operational Runway

Despite access to capital remaining a key challenge, companies in the pipeline in 2022 have greater financial resilience than in 2020. Currently, 41% of companies have the capacity to sustain operations for more than 12 months (up from 21% in 2020) and a further 48% of companies report having 7–12 months of runway. It is positive to see that there are substantially fewer companies (11% vs 49% in 2020) with less than 6 months of funded operations.

This shift towards more companies having longer operating timelines indicates a more resilient pipeline, especially in the face of current market conditions, which should support companies to reach key milestones and greater maturity before returning to the capital and/or grants market.



Operational Runway

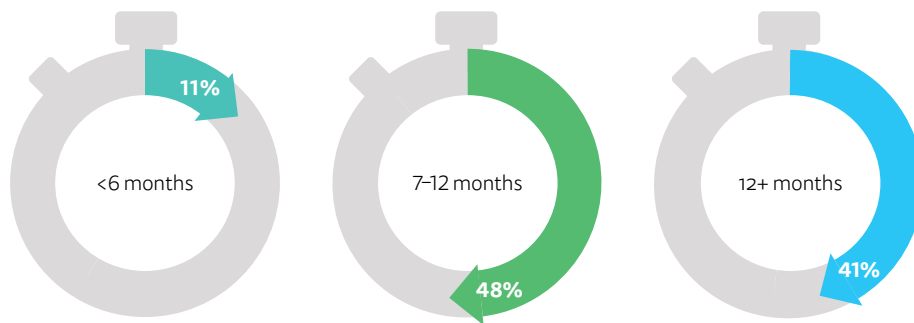


Figure 7.3: Australian Digital Health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=167).

Team Size and Expansion

As expected from an emerging and nascent sector and the very low levels of funds raised by many companies, the majority of companies (59%) have very small teams of three or less people, reflecting a lean start-up philosophy and tech-industry-style agility.

It is therefore not surprising that there are few large teams – 32% have 4–10 staff and a further 8% have 11–40+ 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.

Highlighting the growth that underpins the sector, 85% of companies intend to expand their teams in the next 12 months, slightly up from 82% in 2020, demonstrating an optimistic outlook. Access and affordability of talent however are increasing challenges across Australia.

Team Size

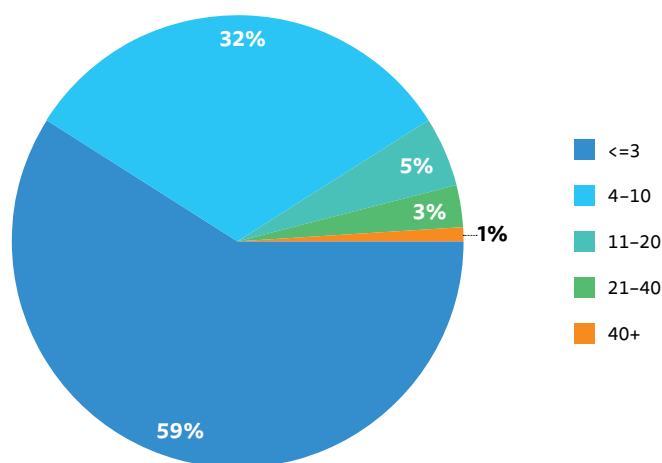


Figure 7.4: Australian Digital Health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022 (n=557).

Gender Diversity

As a female founded and led organisation, the promotion and support of gender diversity across the digital health sector and across STEM industries in general is a core value of ANDHealth. Of the companies which disclose gender outcomes, 38% have a female founder, CEO or Managing Director, up from 35% in 2020.

Gender equity remains a difficult issue throughout the sector globally. In 2019, just 14% of deals by US digital health start-ups were made by female-led companies, and just 12.6% of US VCs active in digital health have female partners.⁴⁵

The ANDHealth pipeline (where gender outcomes are reported) features a higher proportion of female founded or led companies than the start-up sector

generally. Females comprise 16% of founders across all sectors according to the State of Australian Startup Funding 2021 report.⁴⁶

While there has been progress towards improving gender diversity in the start-up landscape, including the establishment of dedicated investment funds such as Scale Investors and LaunchVic's Alice Anderson Fund, there is still a significant gap to be overcome in Australia. According to the State of Australian Startup Funding 2021 report, 82% of female founders across all sectors believe gender has impacted their ability to raise VC funding compared to 15% of male founders surveyed.⁴⁶ This is not surprising since the report also reveals that only 19% of Australian VC deals involved at least one female founder.

“Talking about prioritising gender diversity appears to be at an all-time high but all companies must be committed, as we are at ANDHealth, to taking specific actions with real outcomes that will break the bias and lead to a more equitable world for us and our future generations.”

– Gavin Fox-Smith,
Chair, ANDHealth



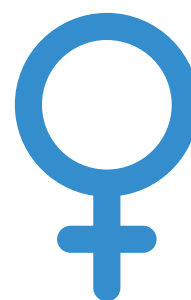
38%

of companies have
a female founder, CEO
or managing director



39%

of companies have
a female founder



35%

of companies have
a female CEO or
managing director

Figure 7.5: Australian Digital Health companies & technologies screened by ANDHealth | July 2017–31 Mar 2022, female founder, CEO or MD (n=498), female founder (n=452), female CEO or MD (n=316).



Conclusion: Supporting the Awakening Giant into the Future

Australia's digital health industry is a future giant of Australia's health and economic well-being that is starting to rise. Since the publication of the *Sleeping Giant* report in 2020, the Australian evidence-based digital health sector has grown significantly, with the number of companies in the pipeline increasing by 74%. The data from these companies demonstrate that the sector is growing in both size and company maturity. This provides attractive investment opportunities for both the government and private sector, with the ability to drive substantial returns for both the economy and the health and wellbeing of all Australians.

To thrive into the future, the sector needs:

- 1 | Savvy, sustained investment and experienced investors
- 2 | Regulation and reimbursement frameworks which incentivise new products
- 3 | Procurement processes which recognise, reward and stimulate Australian innovation
- 4 | Support programs proven to deliver meaningful clinical and commercial outcomes

Savvy, Sustained Investment and Experienced Investors

Savvy, sustained investment in Australia has created world-leading health technology sectors in biopharmaceutical development and medical devices. There is no doubt that investment in the fast-growing, innovation-driven digital health sector will position Australia as a global destination for digital health, digital medicine and digital therapeutics research, development and commercialisation, while at the same time building resilience in and transforming our healthcare system to improve health outcomes.

Despite the extraordinary levels of global investment into digital health seen

throughout 2020 and 2021, a significant gap remains in investment and support for Australian companies developing evidence-based technologies. Given that 85% of Australian digital health companies plan to raise capital in the next 12 months – with six companies looking to raise in excess of A\$10M – without new pools of experienced and patient capital, these companies will either fail to reach critical value inflection points or will look to move offshore early in their value creation journey. As such, creation of dedicated and experienced digital health funds and fund managers will be critical to enable the industry to become a global player at scale.



Regulation and Reimbursement Frameworks Which Incentivise New Products

Recent reforms made by the TGA to the framework for regulation of SaMD have increased certainty for Australian digital health companies and brought the Australian market into alignment with key international jurisdictions. Although regulation is often seen as a cost which may be better avoided by companies (and some investors), approval by an independent regulator often leads to enhanced appeal in the eyes of risk-averse health sector customers and creates a more defensible competitive position for companies.

Alongside the regulatory frameworks, internationally governments and regulators are grappling with aligning reimbursement frameworks to incentivise the deployment of digital health products into the hands of clinicians and consumers. Clear reimbursement pathways for digital health products are a cornerstone of a world class health system, whilst also incentivising deployment of cutting-edge digital health, digital medicine and digital therapeutics

products to clinicians and consumers.

In ANDHealth's 2021 Sentiment Survey, 79% of companies said that access to reimbursement will accelerate growth. In global markets, such as Germany, dedicated reimbursement structures are being implemented to ensure patients can benefit from wide-scale deployment of digital therapeutics, making access to international markets start to appear favourable to the Australian market for some of our leading innovators.

At home, a lack of clear, accessible and easily navigable reimbursement pathways will be a key barrier to the uptake of cutting-edge solutions to some of our largest health challenges, in the absence of a focused effort to modernise the reimbursement landscape around medical technologies with proven clinical outcomes.

Procurement Processes Which Recognise, Reward and Stimulate Australian Innovation

Across the Australian healthcare system, navigating healthcare provider procurement processes which are often state-based, alongside federal regulation and reimbursement challenges, can often prove too complex for highly innovative, technology based SMEs. Such SMEs are often then penalised in international markets as they cannot demonstrate market penetration at home.

Reforming procurement within healthcare systems so that our home-grown innovation is supported and rewarded over and above engagements with large international

companies and/ or a 'build it ourselves' mentality is a key step to driving the success of emerging technology sectors, such as digital health, both here in Australia and on the international stage.

As a nation, we need to back our innovators with our purchasing power. Deploying our substantial healthcare procurement budget, where possible, into internationally competitive Australian-developed technologies will drive exponential growth in the sector and embed the concept of Australia as an 'innovation nation' into the fabric of our large healthcare institutions.

Support Programs Proven to Deliver Meaningful Clinical and Commercial Outcomes

Australian digital health companies face challenges that do not fall within the broadly understood commercialisation pathway for physical medical devices or biopharmaceutical products. In many ways, especially if a regulated product, they also face substantively different challenges to more traditional health IT and health software firms. These highly innovative, breakthrough companies face unique challenges, and thus require unique and tailored support.

Since 2017, ANDHealth has invested heavily in building a national and international network of knowledgeable and skilled professionals, with demonstrable hands-on experience in successful digital health commercialisation. Through a suite of programs, supported by our Core Partners, and Federal and State Government partners, ANDHealth supports digital health innovators from idea through the entire commercialisation pathway to global scale, market uptake and exit. As at 30 September 2022, more than 630 emerging digital health companies have engaged with ANDHealth, with more than 2,100 hours of programming delivered to 1,330 program participants.

As governments across Australia grapple with challenging economic conditions, falling productivity and the need to diversify and strengthen the Australian economy, it is critical that our investment into innovation is directed into programs which can demonstrate that they make a measurable difference to the sectors in which they work. Australia is fortunate to have a highly committed network of industry development and growth focused organisations across the country, but fragmentation of funding and lack of future certainty around ongoing investment limits the ability of these organisations to think big for Australia's future.

ANDHealth has proven that sector-specific, industry-led collaborative commercialisation models can have immense impact on an industry. We encourage all policy makers to look to innovative, locally led solutions to provide the critical support which will fast-track Australian innovation onto the global stage.



The ANDHealth Approach to Supporting Australia's Digital Health Sector

ANDHealth's purpose is to accelerate the commercialisation of Australian digital health technologies, creating a world leading digital health sector, centred in health and medical research and leveraging technology to create companies with global scale, reach and patient impact.

Currently ANDHealth is delivering on over \$30M of programs funded by state and federal governments and industry. This funding for our world-class programs reflects ANDHealth's proven capability and documented outcomes in supporting evidence-based Australian SMEs to accelerate

their technology commercialisation and scale their businesses.

Proven programs with quantifiable clinical and 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. Companies participating in our flagship programs Masterclass: ACCELERATE and ANDHealth+ have reported impressive outcomes as shown below.

Proven Outcomes

MTPConnect Funded Pilot ANDHealth+ Cohort Companies Reported:



MTPConnect Funded Pilot Program – FY2018 – FY2019. 9 companies continuing & reporting. One company advised to pursue alternative path. Cohort company outcomes reported to ANDHealth (as at December 2021) | FY18 Cohort onboarded Oct 2017 | FY19 Cohort onboarded Sept 2018.

Masterclass: ACCELERATE 2020 and 2021 Cohort Companies Reported:



\$23.2M
Raised
(dilutive & non-dilutive)



365,000+
New patients served




80
New jobs (FTEs)



20
Research projects,
pilots or clinical trials
commenced



70%
Experienced
growth in their
team following
completion of the
program



98%
Intend to grow
their team in the six
months following
the reporting period

MTPConnect REDI Funded Masterclass: ACCELERATE Program = 36 Respondents | Company outcomes reported to ANDHealth 6 months following each of Masterclass 2020 and Masterclass 2021.

ANDHealth plans to continue to be a leader in collaboration, not competition, and to continue to expedite private sector investment into research, development and commercialisation of digital and digitally enabled medical technologies. We are committed to working with government and industry to create a globally competitive digital health industry, underpinning better health outcomes and significant export opportunities for Australians.

Proven commercialisation programs spanning the commercialisation pathway from ideation to market uptake and exit specific to digital and 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 and corporate development experience, with a focus on creating companies that are truly and readily "investable."



Harness the Collective

Cross-sectoral and multi-disciplinary members, mentors and advisors with proven track records:

- Product development, or
- Commercial Agreement at Scale, or
- Significant Capital Raising.



Working Backwards

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



No-Equity and Non-Profit

No set valuations and 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.



Focus on Scale Ups

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



Thank you

ANDHealth appreciates the support of its 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.

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