

Commercialising Digital Health in Australia

FY2023 Industry Sentiment Survey

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.

Acknowledgements

ANDHealth appreciates the support of its partners, supporters and program participants in supporting its vision for an integrated ecosystem for the development, commercialisation and implementation of evidence-based digital health in Australia.

We acknowledge their enormous contribution towards our ability to fulfil our core purpose of accelerating the commercialisation of Australian digital health companies.

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Foreword

ANDHealth's industry sentiment survey offers us a unique look into the challenges faced by companies in our fast-growing sector.

Comparing key trends across the past three financial years, *Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey* is based on responses from 101 industry participants out of the 698 active digital health SMEs in ANDHealth's pipeline.

This report represents a comprehensive industry snapshot, providing invaluable insights into the drivers and barriers for the future growth of the digital health sector and a deeper understanding of the commercialisation landscape as it stands in FY2023.

Despite challenges faced throughout the COVID-19 pandemic, the number of companies supported by ANDHealth has increased from 300 to almost 700, signifying a growing and vibrant industry that is progressively more resilient. According to the latest PitchBook data, the healthtech sector is proving to be more durable on a deal value basis than many other verticals tracked, such as SaaS, FinTech, AI and machine learning.¹

In 2023, rising interest rates and inflation, however, are of renewed concern to economists and digital health SMEs are now navigating tricky post-pandemic economic conditions and seeking out new revenue sources, such as grants and angel investors.

Around half of digital health SMEs report that the current economic situation has negatively impacted their ability to raise capital, representing an increase from one third in FY2022. However, in positive news, after four quarters of decline, global digital health funding levels have now flattened for the first time in a year, during the December 2022 quarter.²

As we learn to live with COVID-19, digital health SMEs report the main opportunities eventuating from the pandemic are increased acceptance by the medical community and patients, a potentially larger market for digital health technologies, increased awareness among investors and the potential for increased government funding.

Notwithstanding the hazy macro-economic outlook, there are many reasons to be optimistic about the Australian digital health industry and its future commercialisation opportunities.

An increasing number of SMEs are looking to raise funding despite the current state of the economy, with 84% planning to do so in the future, compared with 80% in FY2022.

Confidence in working with local investors has also doubled - albeit off a low base - and digital health companies have demonstrated improved maturity, including a better understanding of regulatory pathways, with FY2023 data also showing strong intent from SMEs in Australia to expand staffing levels.

Positively, the benefits and prominence of digital health solutions are gaining traction and becoming more apparent to a wider group of stakeholders, including media, consumers and policymakers.

Globally, the digital therapeutics (DTx) industry has seen a strong uplift in mentions across international media.³ DTx solutions are emerging across specialities such as diabetes, migraines, GI and others due to key drivers like the ability for 24/7 treatment, enhanced real-time patient information and treatment possibilities with AI and VR.³

There has also been a renewed investment by the Australian Government into Medicare-subsidised

telehealth appointments in the federal budget. While investment into and understanding of digital health must go beyond electronic medical records and data sharing, the government's recent \$950 million re-investment into digital infrastructure, the establishment of the \$15 billion National Reconstruction Fund and a new \$392 million Industry Growth Program for SMEs and startups announced in June, are important opportunities for our industry to make the case for greater investment in digital health commercialisation.

Drawing upon our proud traditions in technological innovation, digital health policy is now an area ripe for reform and investment. Building upon Australia's deep roots in traditional health and medical research capability, digital health companies can deliver significant economic and health outcomes for Australians, through globally enabled and immensely scalable technologies.

The prospect, as the digital health industry grows, of creating a world class centre for digitally enabled medical devices, digital medicines and digital therapeutics right here in Australia, is not a pipedream. If we invest smartly, Australian companies and patients alike could enjoy the benefits collectively, leading to the creation of a whole new sector of economic activity.

Bronwyn Le Grice
CEO and Managing Director,
ANDHealth



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):

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.

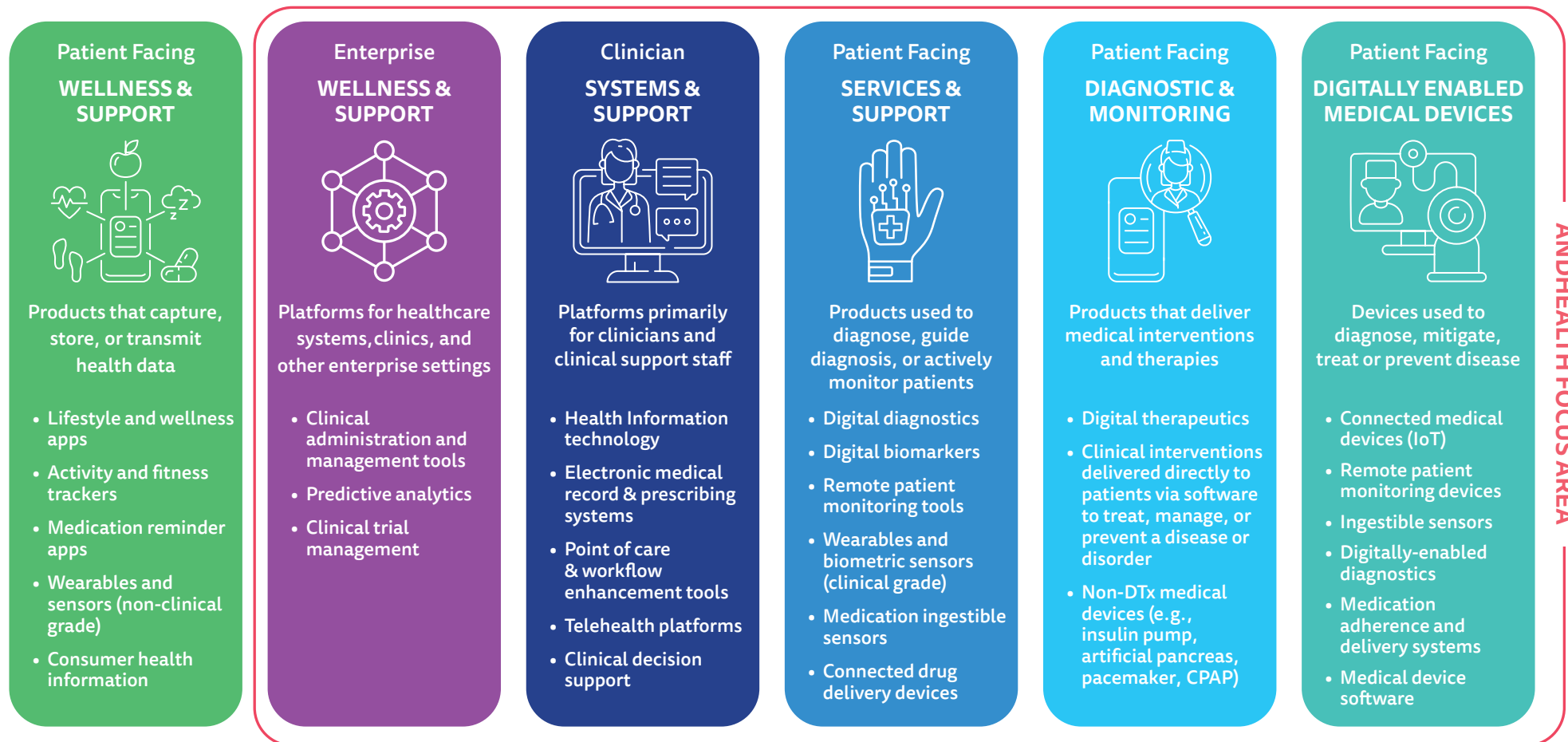
The use of technologies, such as smart phones, social networks, and internet applications, is not only changing the way we communicate, but also providing innovative ways for us to monitor our health and well-being and giving us greater access to information. Together, these advancements are leading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



US Food and Drug Administration (FDA) Digital Health Definition.⁴

Breaking Down the Digital Health Sector

Categorisations of the digital health technology ecosystem will continue to evolve.



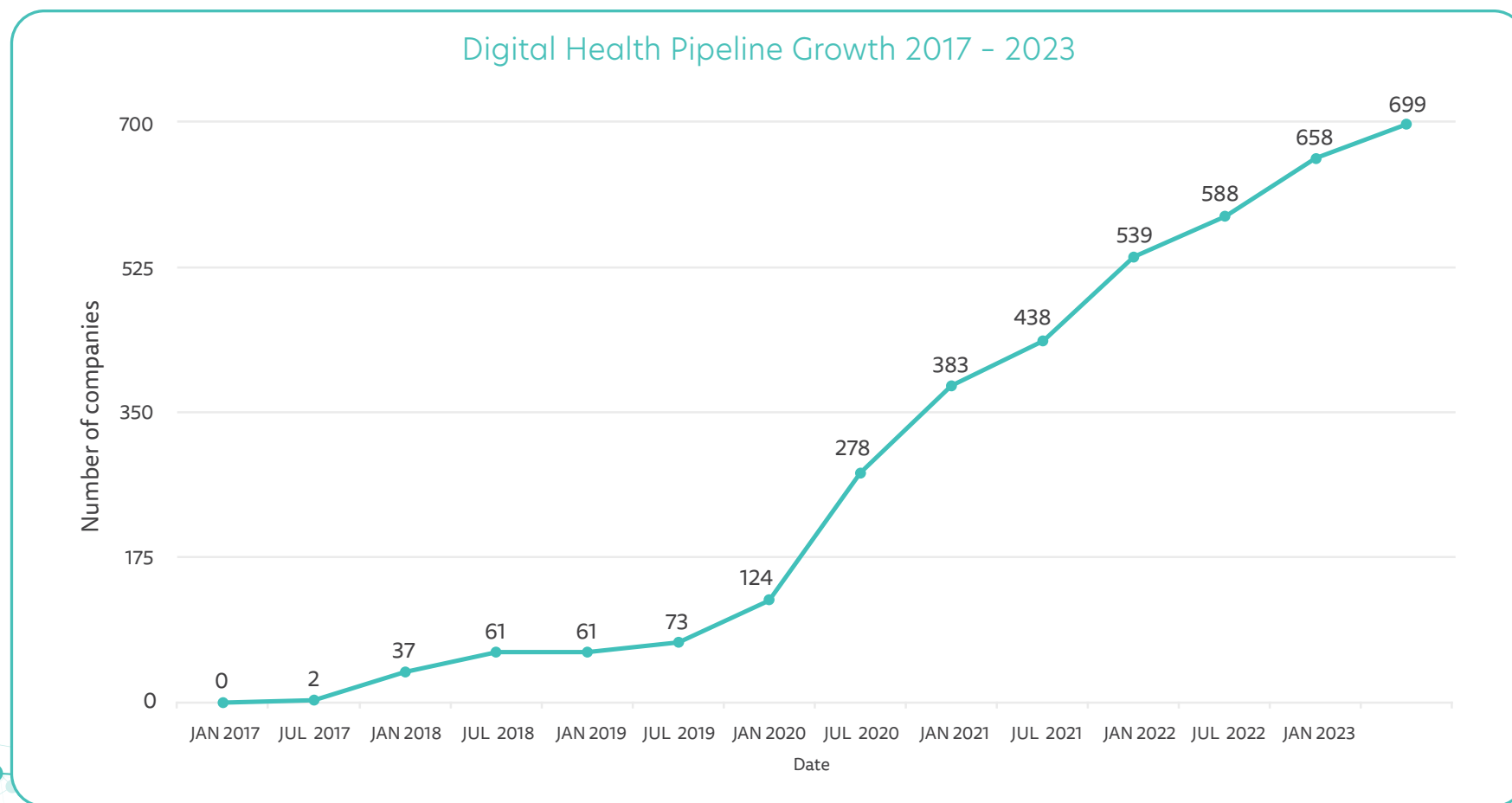
Digital Health Technologies. Adapted from Digital Therapeutics Alliance DTX Value Assessment & Integration Guide.⁵

Industry Growth

The number of companies in the ANDHealth Australian digital health pipeline has now reached around 700 companies, demonstrating the rapid growth in digital health in this country.

Since June 2017, the Australian digital health pipeline has grown at an astounding rate of 178% each year.

This reflects growth in regional and global markets with digital health in the Asia-Pacific region, including Australia, estimated to increase in value from US\$37 billion in 2020 to US\$100 billion by 2025.⁶



Australian Digital Health companies & technologies screened by ANDHealth | July 2017- Jan 2023

Survey Demographics

ANDHealth's *Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey* includes responses from 101 participants from across Australia's digital and connected health sector. This report builds upon our previous surveys conducted in FY2021 (n=60) and FY2022 (n=53) and reveals a growing digital health sector with an increasing number of companies maturing in relation to their commercialisation journey.

By the Numbers

101 respondents completed the survey

88% represented digital health companies

60% of respondents were CEOs or Founders; same representation as 2021

61% of companies were founded in the last **5 years**

70% of the companies have **10 or less** full time employees

Gender Diversity



54%

of companies have one or more female founders, up **7% from FY2022 (47%)**



75%

of companies have appointed at least 1 female on their board/advisory board, **up from 65% in FY2022**



38%

of companies have a female CEO or managing director, up **5% from FY2022 (33%)**



78%

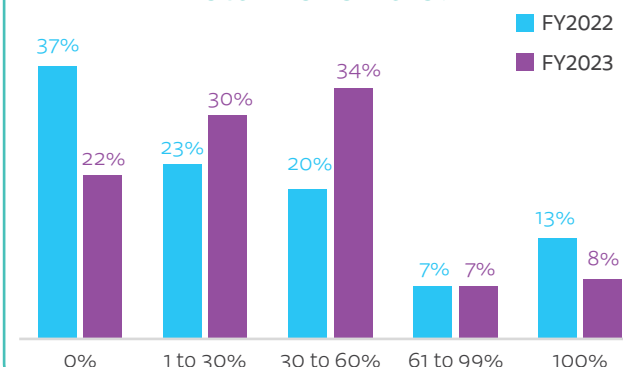
of companies have at least 1 female appointed to the executive level, **up from 63% in FY2022**



22%

of companies reported an absence of female executive staff, substantially **less than in FY2022 (37%)**

What percentage of your executive staff is female?



Female executive staff | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

Company Locations

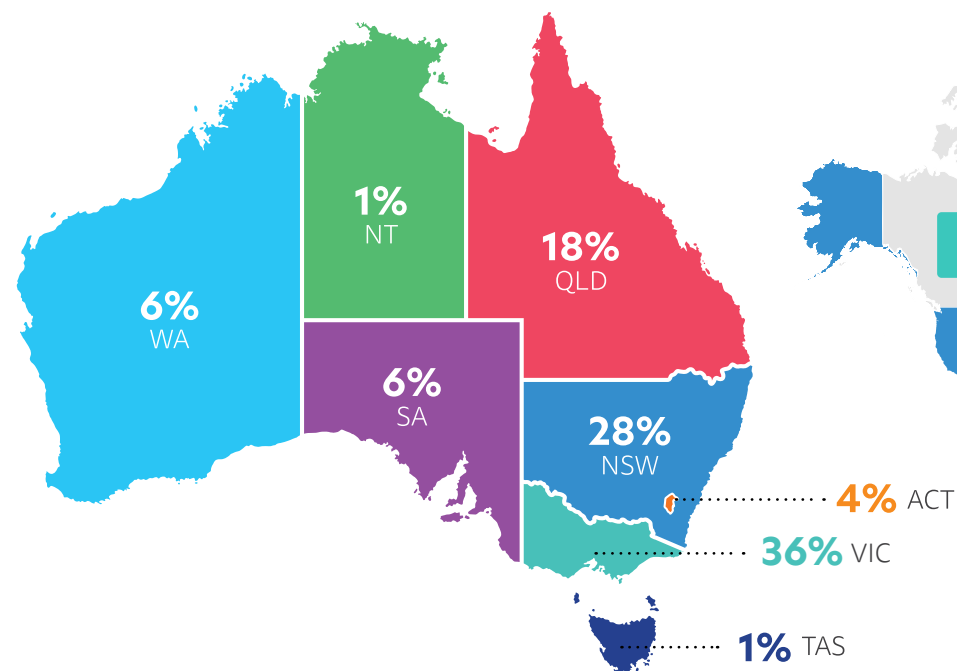
Companies could select more than one response.

95% of respondents represent Australian-based companies

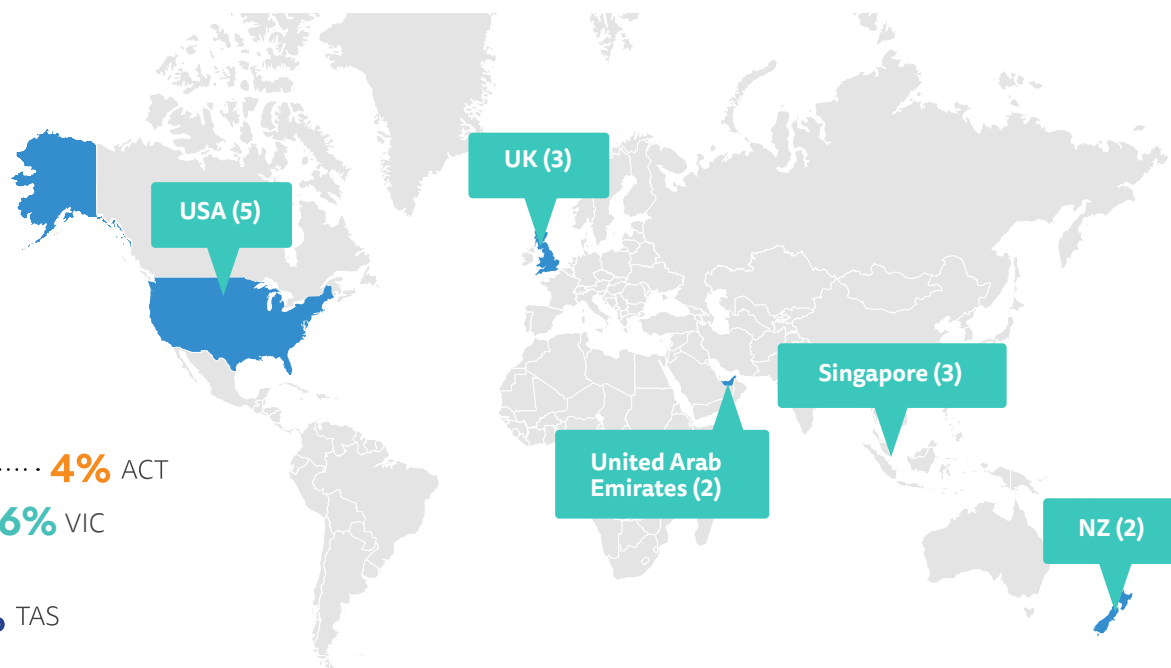
14% of respondents have an international presence

3% of respondents were exclusively international

Australian-based Company locations



Of the 12 companies with an international presence, the locations listed included:



Australian-based company locations. Companies can select more than one response.
State of Digital Health in 2023: Trends and Insights | FY2023 n=97 with 122 responses

Industry Insights FY2023

Despite the challenging capital environment, Australia's digital and connected health sector is growing and maturing.

1. COMPANY GOALS

Increasing revenue remains the primary priority for companies, as seen in FY2022 and FY2021. Raising additional funding also remains a key priority, as does creating new partnerships and hiring new staff.

2. ECONOMIC ENVIRONMENT

The global economic environment is changing, and trends show that company decision-making is beginning to be influenced by the more challenging external economic environment. Almost double the amount compared to the year before are consolidating their position and not looking to actively make changes to their business.

3. COMMERCIALISATION CHALLENGES

The top 5 commercialisation challenges for digital health companies are: limited access to capital and investors; lack of dedicated grant programs; implementation and uptake issues; and difficulty in accessing customers.

4. CLINICAL EVIDENCE

The increasing complexity of the types of evidence required, and how to develop studies which generate meaningful data, is taking its toll with only 28% of companies confident that they have quality clinical evidence. However, clinical trial activity in the sector should remain strong in coming years, with less companies (6% compared to 15% in FY2022) putting clinical trials on hold.

5. REGULATION

Companies have increasing confidence in navigating the Australian regulatory landscape. However, for major international markets (EU, UK, US), company confidence in navigating the regulatory environment is lower than in previous years.

6. REIMBURSEMENT

Health technology assessment and reimbursement frameworks have not been specifically designed or updated to foster the adoption and uptake of digital health technologies in Australia. As a result, 54% of respondents strongly agreed that access to reimbursement would accelerate growth in their business, up 7% from FY2022.

7. FUTURE COMPANY EXPANSION

Recruiting new staff is firmly in the sights of most companies in the digital health sector in FY2023 with 90% of respondents planning to expand their teams in the next 6 months through additional hires, however, plans to expand interstate or overseas have slowed. The US remains the location of choice internationally.

8. FUNDING AND INVESTMENT LANDSCAPE

The median capital raised increased to \$1M, despite around half of companies saying economic conditions had impacted their ability to raise capital. More companies are looking to grants, angel & high net worth individuals and accelerator/incubators for this funding compared to FY2022, while a smaller proportion are looking to venture capital. Data suggests that venture capital is contracting in the current environment, and so companies may be expecting less venture investment to be available.

9. IMPACTS OF COVID

The COVID-19 pandemic has 'shifted the needle' for digital health, with significant transformation in healthcare delivery here to stay. The digital health sector is anticipating significant growth opportunities in remote monitoring (up 28%) and wearable technologies (up 58%), aligned to the trend of shifting care from the clinic to the home.

1. Company Goals

In an environment of decreasing valuations and difficulty in accessing capital, increasing revenue remains the primary priority for companies, as seen in FY2022 and FY2021.

Raising additional funding remains a key priority, as does forging partnerships and hiring new staff. In a change on prior years, clinical trials and studies have assumed increased importance in FY2023.

This reprioritisation of goals could be indicative of company growth and intentions to focus efforts on the generation of evidence through clinical trials or studies.

Top 5 Goals

	#1	#2	#3	#4	#5
FY2021	 Increase revenue	 Commercial customers	 Commercial pilots	 Hire staff	 Partnerships
FY2022	 Increase revenue	 Raise additional funding	 Partnerships	 Commercial customers	 International market launch
FY2023	 Increase revenue	 Raise additional funding	 Partnerships	 Hire staff	 Clinical trials or studies

Company goals for the next 6-12 months ranked from 1st highest down to 5th lowest | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n= 53

2. Economic Environment

The failure of Silicon Valley Bank (SVB), the bankruptcy of digital therapeutics (DTx) pioneer Pear Therapeutics, and the winding up of operations of high-flying digital health company Mindstrong, are clear indicators that the economic environment is changing globally.^{7, 8}

Closer to home, interest rate increases, cost of living pressures and budgetary constraints are a constant in our daily news feeds.

Unsurprisingly, across the data, there are clear trends showing that company decision-making is being influenced negatively by the external economic environment.

There is a clear picture emerging of companies being responsive to the external economic environment and consolidating operations throughout FY2023, without materially reducing current company activity.

Only 6% of companies were placing clinical trials on hold, down 9% from 15% in FY2022, which may relate to the opening up of clinical trial activity after COVID-19 restrictions, and/or the increasing focus on evidence generation within the digital health space.

By the Numbers

31% sought to raise capital, down **2%** from **33% in FY2022**

12% of companies were hiring new staff, down **6%** from **18% in FY2022**

14% looked to enter new markets, down **9%** from **23% in FY2022**

12% of companies reduced staff numbers, up from **10% in FY2022**

9% looked to accelerate expansion, down **11%** from **20% in FY2022**

38% of companies were consolidating their position and not looking to actively make changes to their business, up almost two-fold from **20% in FY2022**

Have you changed any aspect of your business in response to current economic challenges?

Top 3 Answers FY2023

#1



Haven't made any changes

#2



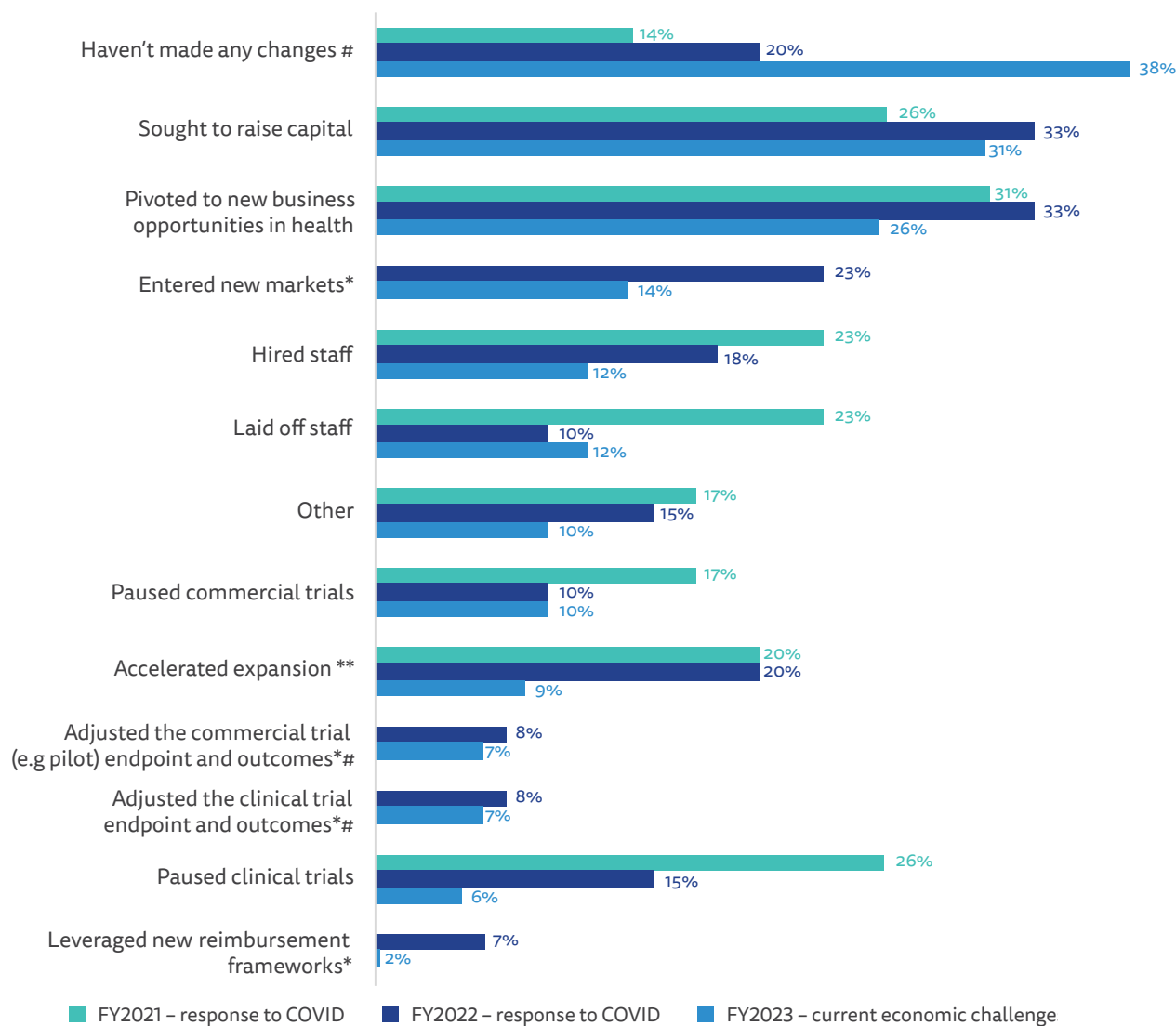
Sought to raise capital

#3



Pivoted to new business opportunities in health

Have you changed any aspect of your business in response to current economic challenges (FY2023)/ COVID (FY2022 & FY2021)?


















Business changes in response to economic challenges. Companies could select more than one response | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=53

3. Commercialisation Challenges

Notwithstanding current economic headwinds, the global digital health sector is predicted to reach a value of US\$809.2 billion by 2030, growing at a CAGR of 18.6% during the forecast period.⁹ Off the back of the pandemic, the digital health sector had initially seen an influx of capital and interest, leading to rapid growth.¹⁰ In Australia, however, there remain systemic challenges to commercialisation.

Limited digital health dedicated investors, access to capital and lack of digital health specific grant programs have been consistently ranked in the top five challenges faced by digital health companies over the last three years. In addition, implementation and uptake challenges and access to customers remain barriers to commercialisation for our most promising new technologies, suggesting that procurement and adoption programs which support local innovation could be an area ripe for reform.

Top 5 Challenges

	#1	#2	#3	#4	#5
FY2021	 Access to capital	 Limited digital health dedicated investors	 Talent and skill attraction and retention	 Implementation and uptake challenges	 Lack of digital health specific grant programs
FY2022	 Access to capital	 Lack of digital health specific grant programs	 Implementation and uptake challenges	 Access to customers	 Limited digital health dedicated investors
FY2023	 Access to capital	 Limited digital health dedicated investors	 Lack of digital health specific grant programs	 Implementation and uptake challenges	 Access to customers

Top 5 commercialisation challenges FY2021 - FY2023 | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=53

4. Clinical Evidence

Clinical evidence does not just have relevance for regulatory approvals but is also incredibly important when digital health companies are presenting themselves to existing and potential customers.¹¹

Clinical evidence has never been more critical for digital health companies, with digital health companies needing to consider “traditional” measures of evidence as well as real-world data and real-world evidence.

The increasing complexity of the types of evidence required, and how to develop studies which generate meaningful data, is taking its toll in FY2023 with only 28% of companies confident that they have quality clinical evidence, a 10% decrease compared to FY2022.

Interestingly, given the increasing focus on evidence in global markets, 18% of companies indicate that clinical evidence is not relevant to their company. Another 25% of companies believe they have preliminary evidence in support of their product claims, 7% are currently undertaking a clinical trial or study and 21% are planning to commence clinical evidence gathering within 12 months, indicating that clinical trial activity in the sector should remain strong in coming years.

Do you have clinical evidence for your product's clinical claims today?

Response	FY2021	FY2022	FY2023
We are confident that we have quality clinical evidence that we can achieve our product claims	24%	38%	28%
We have preliminary evidence that we can achieve our product claims	26%	27%	25%
We are currently undertaking a clinical trial or study	4%	5%	7%
We are planning to begin gathering clinical evidence in the next 12 months	19%	23%	21%
We know what we need but we don't know how to get it	6%	7%	2%
N/A, We don't believe clinical evidence is relevant to our company	21%	-	18%

Clinical evidence for product's claims. Year on year comparison | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=53

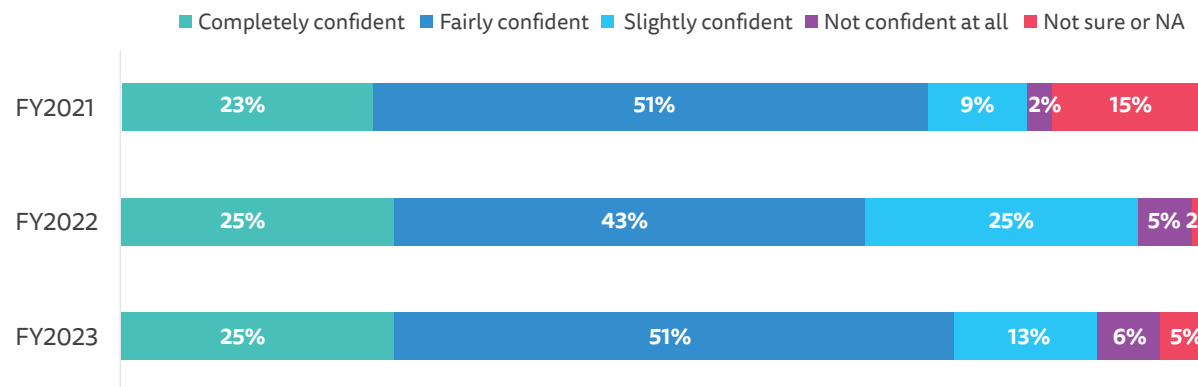
5. Regulation

Australian Regulatory Environment

Following the release of Software as a Medical Device Guidance (SaMD) by the TGA over the past four years, alongside proactive industry outreach and support undertaken by the TGA in partnership with ANDHealth, it is a positive sign that companies have increasing confidence in navigating the Australian regulatory landscape, with 25% of companies completely confident and 51% of companies fairly confident.

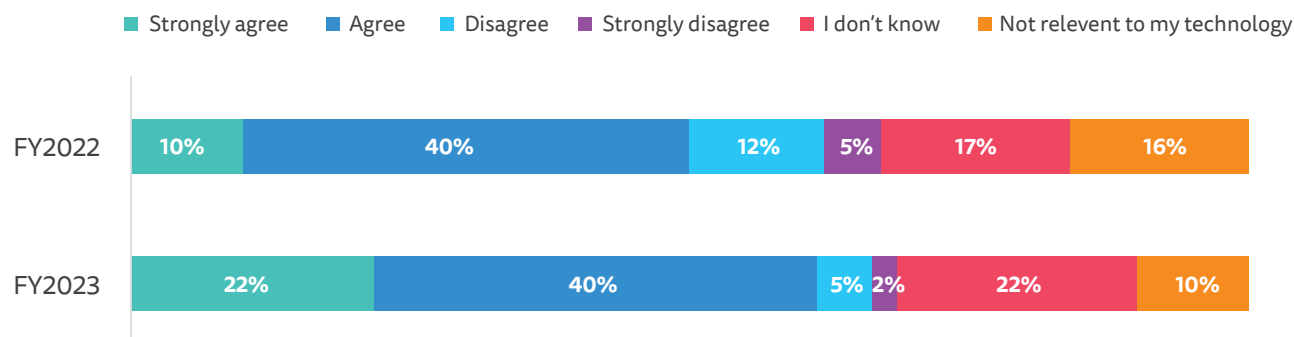
With respect to the TGA's guidance, 62% of companies agreed or strongly agreed that the TGA SaMD regulatory guidance has provided greater certainty of regulatory pathways for their business, up from 50% in FY2022. This highlights the positive impact the TGA guidance has on companies' understanding and confidence in navigating the landscape. It also suggests an increased awareness for meeting these requirements.

How confident is your company with strategically navigating digital health regulation in Australia?



Digital health regulation in Australia | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=53

"I believe the guidance provided by the TGA, with respect to the regulation of software as a medical device, has provided greater certainty of regulatory pathways for my business."

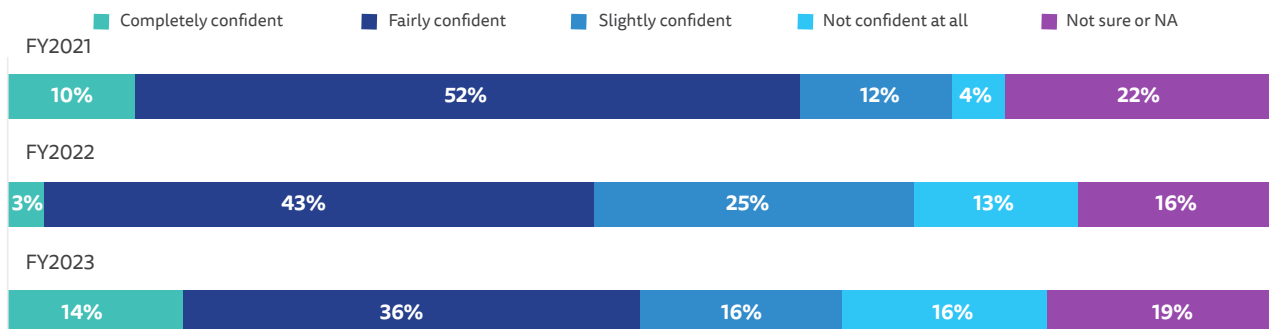


Certainty in the regulatory pathway after TGA guidance. | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

International Regulatory Environment

For major international markets (EU, UK, US), company confidence in navigating the regulatory environment was lower than in previous years. In FY2023, only 66% felt some level of confidence navigating overseas market regulation overall, down 5% from FY2022 and 8% from FY2021. Lower confidence levels may be due to the significant changes occurring in the international regulatory landscape.

How confident is your company with strategically navigating Digital Health regulation in major markets (EU, UK, US) overseas?



Digital health regulation in major markets (EU, UK, US) | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=53

Deep Dive: Medical Device Regulation in Europe & the UK

The implementation of the EU Medical Device Regulation (MDR) meant medical device manufacturers would face potential up-classification of devices (increased classification and oversight), as well as increased levels of clinical evidence and post-market requirements. More detailed technical documentation requirements and recertification by an EU notified body would be needed to allow continued supply before the end of the MDR transition period. The effect was a rising demand from companies requiring certification, creating bottlenecks. As a result, the European Commission recently decided to extend the deadline for transitioning high risk medical devices up until 2028.¹²

These compounding issues came to bear in early 2023, when the European Commission recognised that “[...] many manufacturers are not sufficiently prepared to meet the robust requirements of the Medical Devices Regulation by the end of the current transition period. This threatens the availability of medical devices on the EU market.” In February 2023 the Commission adopted the proposed delay to MDR deadlines, extending the deadline for higher risk class III and class IIb devices to 2027 and lower risk devices to 2028.¹²

Post Brexit, with the Medicines and Healthcare products Regulatory Agency becoming UK's standalone regulator, medical device developers will face challenges navigating the new UK regulatory

environment, together with the changes posed in the EU.

On a positive note, the release of guidance by the FDA on Artificial Intelligence (AI) and Machine Learning (ML) and resources such as Good Machine Learning Practice for Medical Device Development and the UK's guidance on Software and AI as a Medical Device¹³, indicate the increasing responsiveness of regulators to emerging technologies. They are beginning to develop frameworks to provide clarity to companies integrating AI and ML within software enabled medical devices.



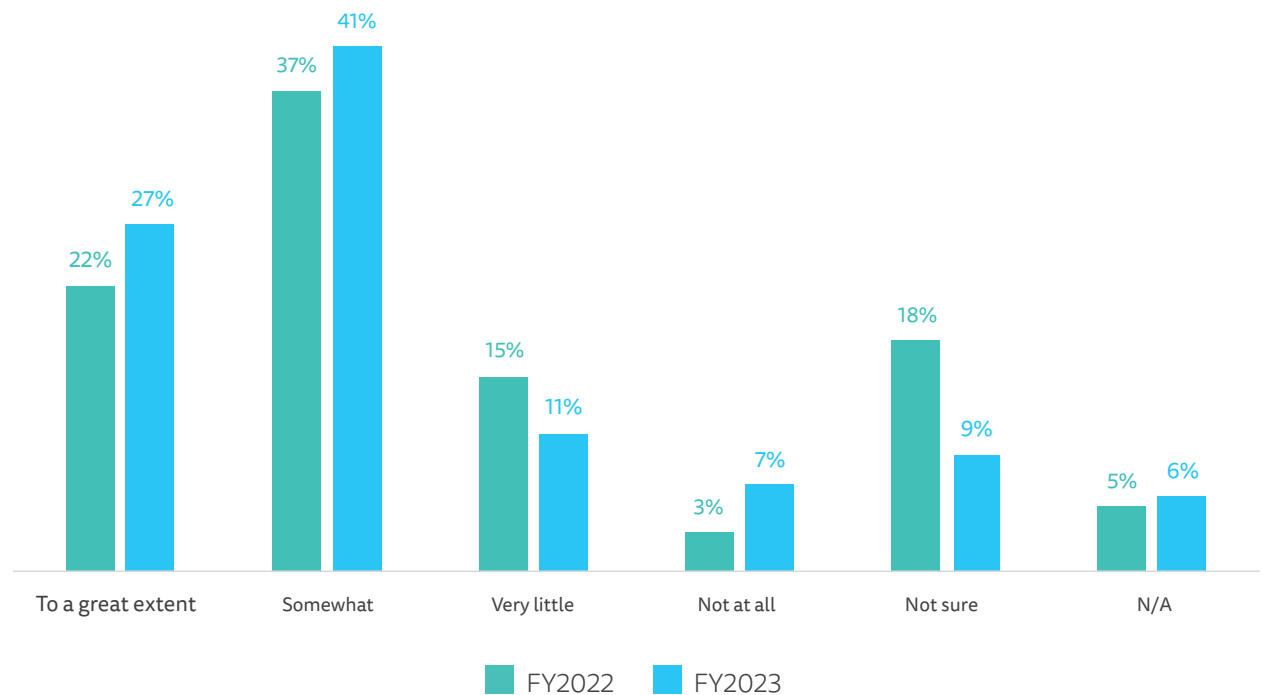
Access to regulatory consultants and advice

As the regulatory landscape evolves and becomes increasingly complex, especially internationally, access to regulatory consultants is becoming increasingly important for digital health companies. Access to experienced service providers can be a critical step for companies as they seek to commercialise and scale globally. In FY2023, 27% of companies reported being able to readily access skilled regulatory advisors to a great extent, up from 22% in FY2022. A further 41% felt somewhat able to access skilled advisors.



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.¹⁴

Are you able to readily access skilled regulatory consultants to assist you with your regulatory strategy?



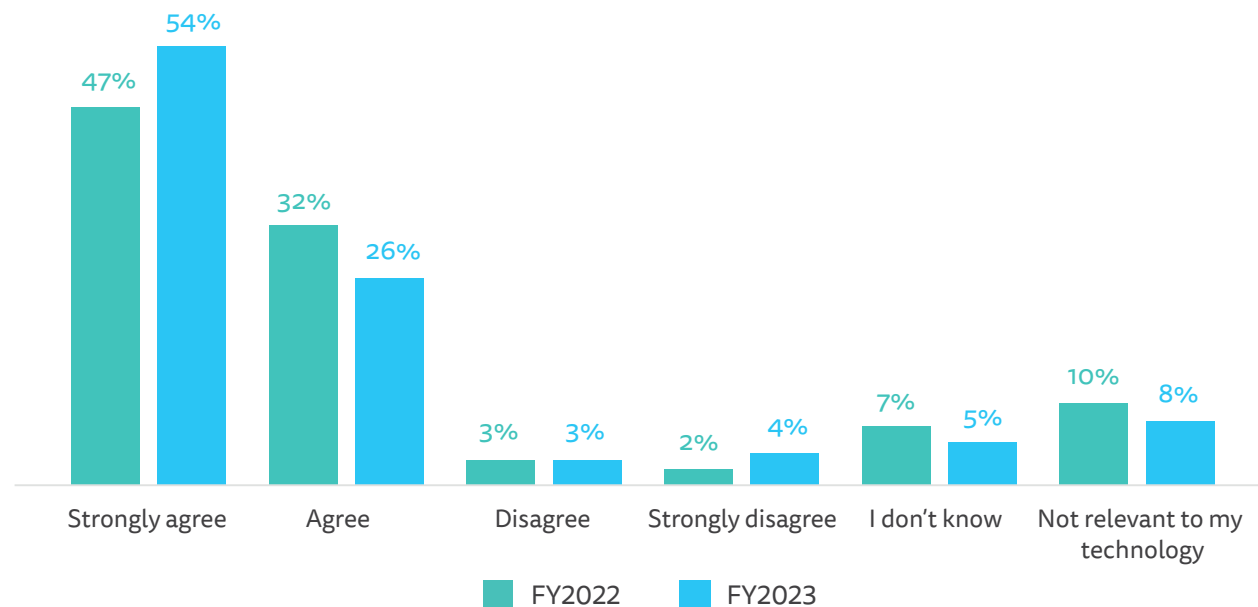
Access to regulatory consultants and advice || Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

6. Reimbursement

One of key challenges to commercialisation identified by survey respondents is uptake of digital health technologies. There is a global trend towards specifically designed, fit-for-purpose reimbursement schemes which are increasingly driving uptake of digital health technologies. Schemes such as the CPT codes for remote patient management in the US market and Germany's DiGA framework for digital therapeutics are encouraging physicians and patients to engage with technology, driving the growth in uptake of digital health technologies.

In Australia, health technology assessment and reimbursement frameworks have not been specifically designed or updated to foster the adoption and uptake of digital health technologies. As the world changes around us, and change at home is minimal, 54% of respondents strongly agreed that access to reimbursement would accelerate growth in their business, up 7% from FY2022.

Access to reimbursement will accelerate growth?



Sentiment towards the impact of reimbursement on business growth | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

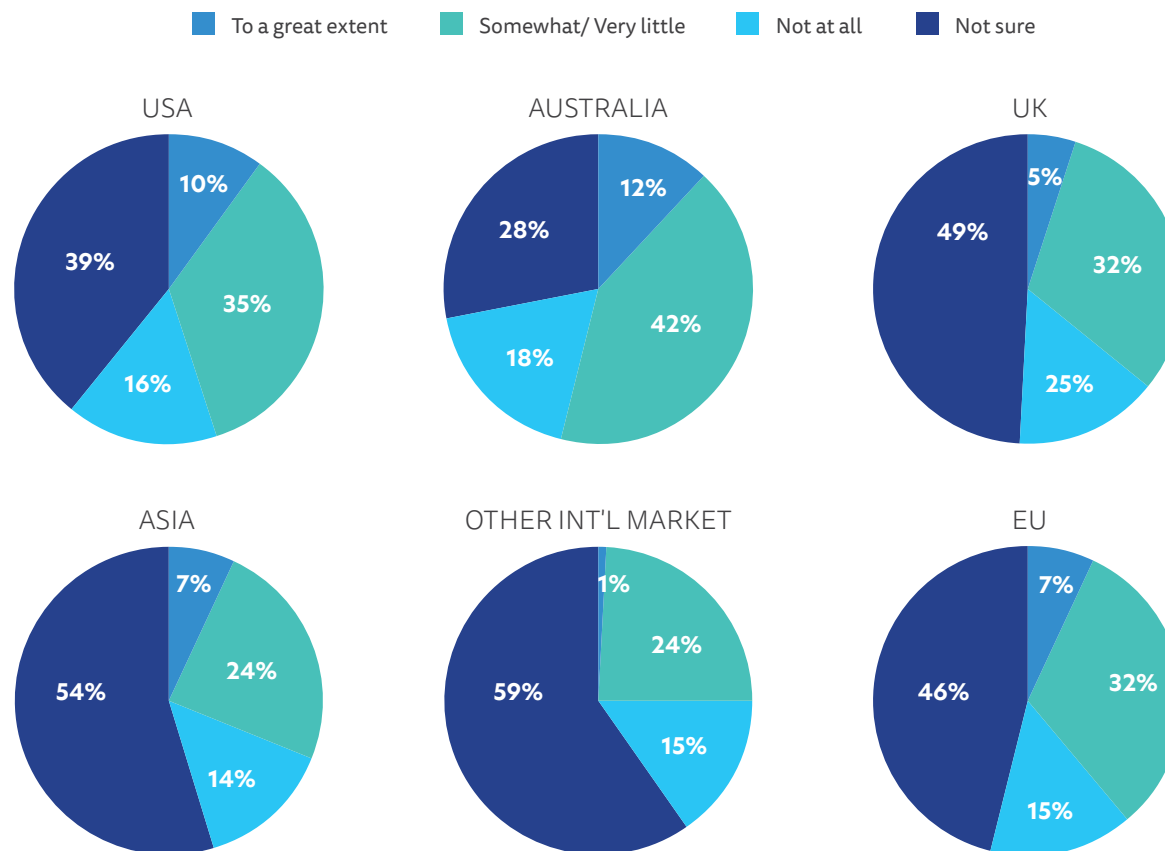
Accessing Reimbursement Advice

In contrast to access to skilled regulatory consultants outlined in the *Regulation* section, less than 12% of companies felt they were able to access skilled reimbursement consultants in all jurisdictions to a great extent.

42% of companies feel somewhat able to access skilled reimbursement consultants in Australia, 35% for US advice and just 31% & 32% in the UK and EU, respectively.

Confidence levels are lower in Asia, and other international markets. This suggests that there may be a shortage of, or lack of awareness of, where and how to identify and engage with advisors who are skilled and experienced in securing reimbursement.

Are you able to readily access skilled reimbursement consultants to assist you with your reimbursement strategy in the following markets?



Ability to access reimbursement advice | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | Australia n=85, USA n=77, UK n=75, EU n=74, Asia n=70, Other International Markets n=71

Confidence in Securing Reimbursement

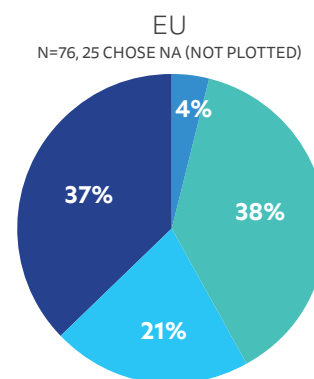
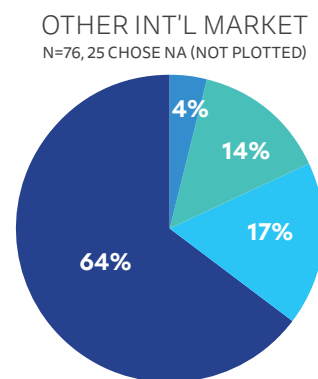
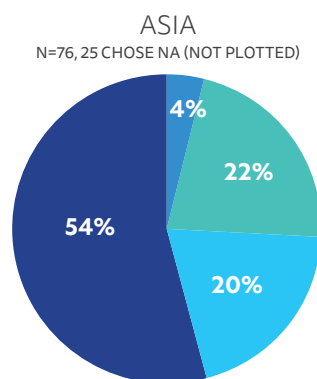
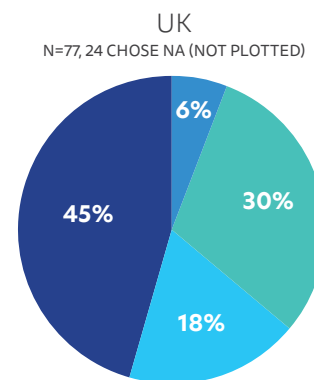
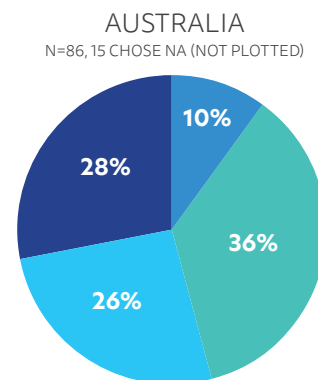
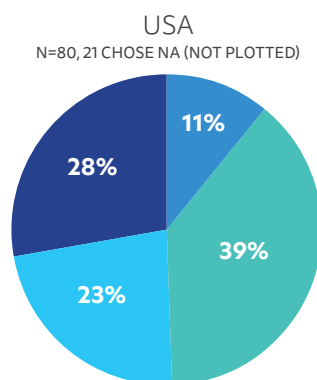
Confidence levels in securing reimbursement in Australia have remained largely stable over the past two years, however, confidence decreased for the UK market (down 3% between FY2022 and FY2023 – data not shown). Small decreases in confidence are also evident in the US and UK markets.

Confidence with respect to securing reimbursement in Europe, however, has increased more significantly, going from 31% of companies fairly or completely confident in FY2022 to 42% in FY2023.

With larger digital health companies in international markets, many of which have multiple regulatory clearances, admitting defeat on whether they can create an economic, sustainable business (e.g. Pear Therapeutics, Mindstrong, Driver, Arivale), reimbursement is likely to become an increasingly important issue if we are to realise the immense health and economic gains of our digital health innovation.

How confident is your company in securing digital health reimbursement in the following markets?

■ Completely confident ■ Fairly/Slightly confident ■ Lacking confidence ■ Not sure



Confidence securing digital health reimbursement | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | Australia n=86, USA n=80, UK n=77, EU n=76, Asia n=76, Other International Markets n=76

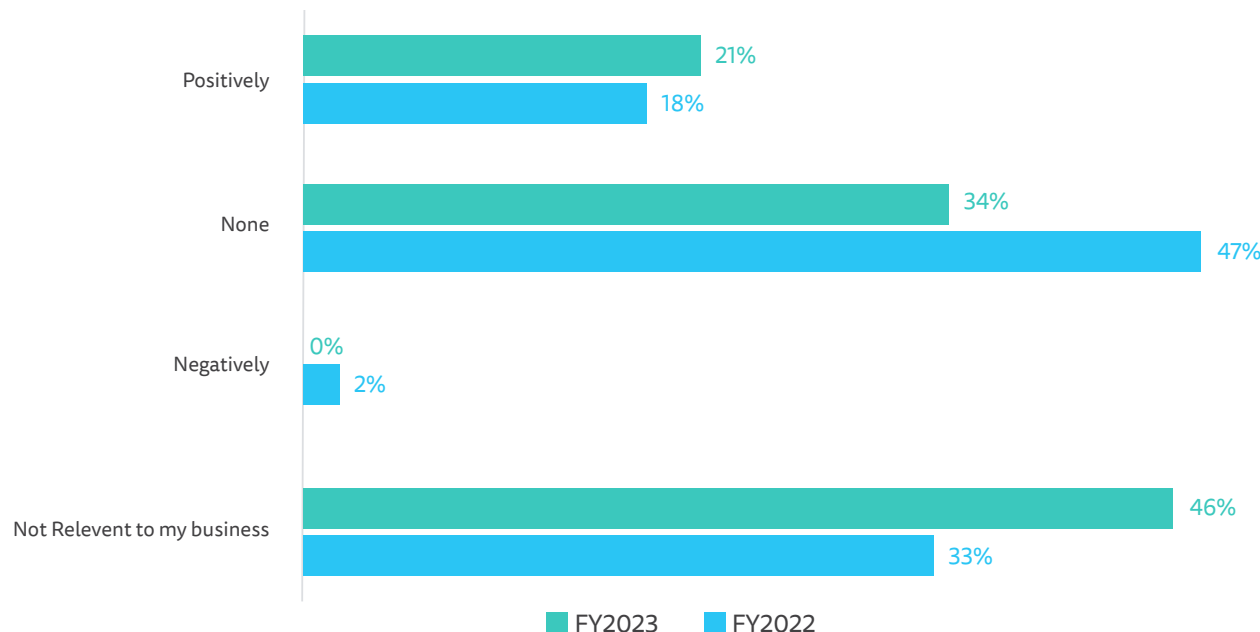
The Impact of Reimbursement of Telehealth

During 2020, as the pandemic took hold, a “ten year in ten day” policy change was undertaken, making universal telehealth a reality for all Australians, funded by Medicare. Largely considered one of the more significant health policy shifts in the past decade, despite some refining of the policy framework in the past 12 months, Medicare funded telehealth remains a component of the healthcare system for many Australians.¹⁵

Despite this, only around 21% of companies in FY2023 indicated that telehealth reimbursement had a positive impact their business. Most companies in the last two years deemed the reimbursement of telehealth to have no impact on their business or not be relevant, suggesting that many digital health technologies have a mechanism of action and impact that sits outside a telehealth framework. It is therefore apparent that

there is a need to explore expanded reimbursement coverage of digital health technologies as a whole, especially as more care moves out of the hospital and into the home.

Has the reimbursement of telehealth materially affected your business?



Impacts of telehealth reimbursement | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

7. Future Company Expansion

Despite the data showing a contraction in the number of companies actively looking to expand various areas of activity in the economic climate of FY2023, when we asked respondents to look forward, the data is more positive, with expansion firmly in the sights of most companies.

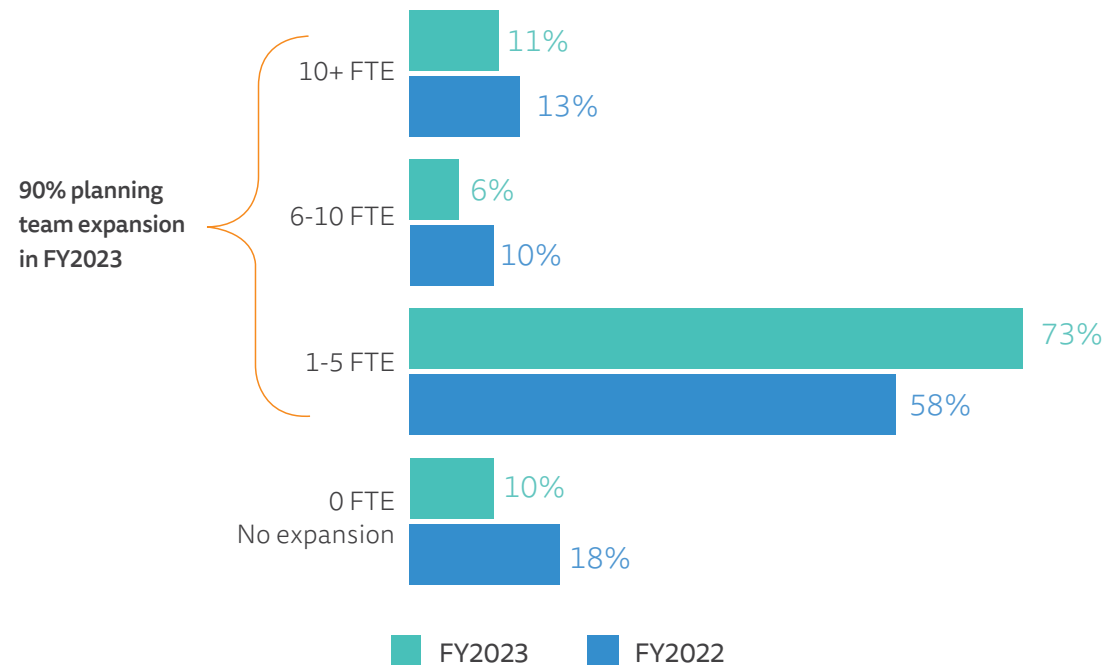
Team Expansion

In positive news for the growth of the sector, 90% of respondents plan to expand their teams in the next 6 months through additional hires.

Similar to the capital raising data, which points to a maturing sector, 73% of companies are seeking to increase their team by 1-5 FTE, up from 58% in FY2022, as we start to see larger, more mature and more resilient companies embed themselves into Australian and international markets.

Also positive is the fact that the percentage of companies not intending to grow their teams in FY2023 has decreased from 18% in FY2022 to only 10% in FY2023, indicating that growth is firmly on the agenda for respondent companies.

How many additional FTE are you planning on recruiting in the next 6 months?



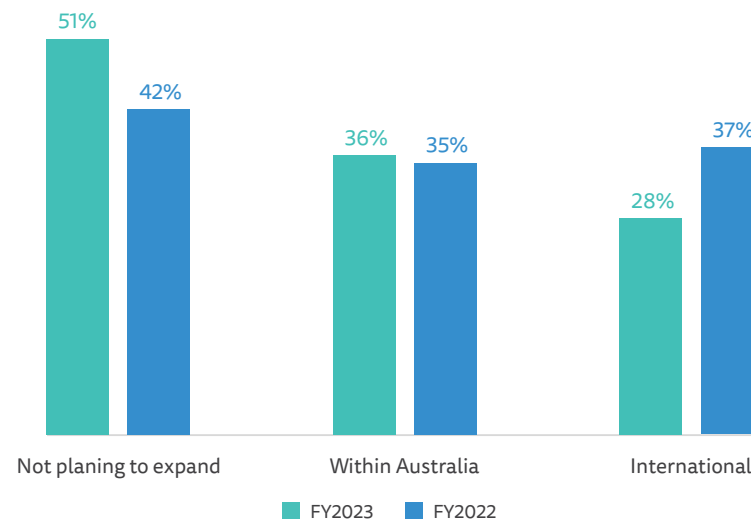
Size of planned team expansion | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

Geographic Expansion

In FY2023, 51% of respondents were not looking to expand geographically, up from 42% in FY2022, which aligns with the data outlined in the *Economic Environment* section, whereby an increasing number of 38% of respondents are not looking to make changes to their business in response to the current external environment. Additionally, the number of companies looking to expand internationally was down 9% to 28% (from 37% in FY2022).

This may reflect a more cautious approach within the industry as the post-pandemic normal sets in and external economic conditions have a greater impact.

Are you planning to expand your team to one of these destinations in the next 12 months?

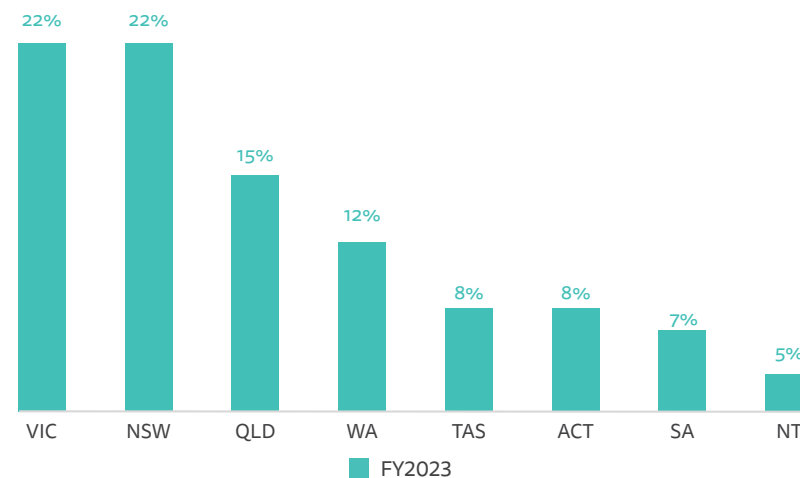


Desired expansion locations | Companies could select more than one response | State of Digital Health in 2023: Trends and Insights | FY2023 n=101, FY2022 n=60

Domestic Expansion

Here at home, 36% of companies are planning to expand within Australia. Leading destinations include Victoria, New South Wales, Queensland and Western Australia.

Are you planning to expand your team to one of these Australian destinations in the next 12 months?



Desired expansion locations within Australia | % of companies intending to target these states, where more than one response could be selected | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=36 that plan to expand within Australia with 85 responses

International Expansion

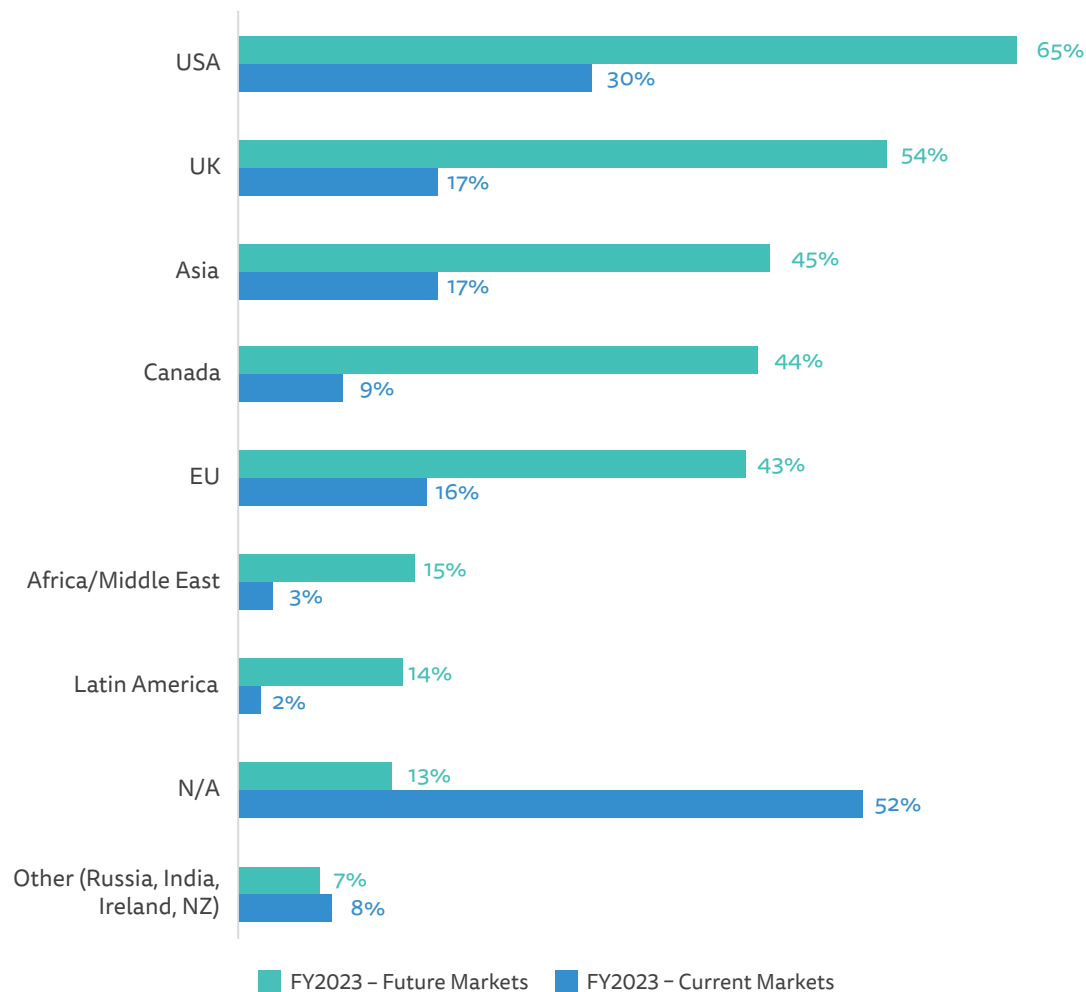
The USA remains the priority international market for both current activity (30%) and short-term international expansion (65%). The USA is one of the world's most complex and difficult to enter healthcare markets, but also a market which, anecdotally, companies tell us that investors most want to see traction in, which supports the significant weighting towards the US as a desired location for international expansion.

The UK is similarly positioned as a key international market, albeit with lower levels of current activity (17% vs 30%), but substantial interest (54%) in the UK as a market for short-term international expansion.

Asia has a similar level of current activity with 45% of respondents flagging it for future expansion. A similar number of responses indicate that Canada and the EU are also key markets of interest.

There is mild interest in Africa, the Middle East and Latin America, but it is definitely the major markets of North America, Europe and the UK which are front of mind for most companies.

International market(s) in which companies are active and future international target markets



Current activity vs future markets | Companies could provide more than one response | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | Current Market FY2023 n=101 with 155 responses, Future Market FY2023 n=101 with 302 responses

8. Funding and Investment Landscape

Throughout FY2023, the global digital health funding environment slowed significantly as macroeconomic forces took hold.⁶

However, within the respondent group in Australia, the median capital raised increased to \$1M, up 18% from the median reported in FY2022 (\$850k). This may represent a lag effect in Australia compared to the US market or alternatively represent the increasing level of maturity and viability of the companies in the survey group.

It is also worth noting that while this respondent group have reported median financing outcomes of \$1M, the ANDHealth industry database, which includes data collected since 2017 from over 340 companies which have raised funding, suggests much lower median financing levels across the industry of \$368k as of 31 March 2023. The increasing proportion of companies raising larger amounts of finance is reflective of a maturing sector.

Funding Trends

65%

of companies reported having raised capital, up by 4% since FY2022 (61%)

35%

of companies have not yet raised capital

15%

of companies have raised over \$5M, down by 1% since FY2022 (16%)

19%

of companies have raised between \$1M - \$5M, up by 6% since FY2022 (13%)

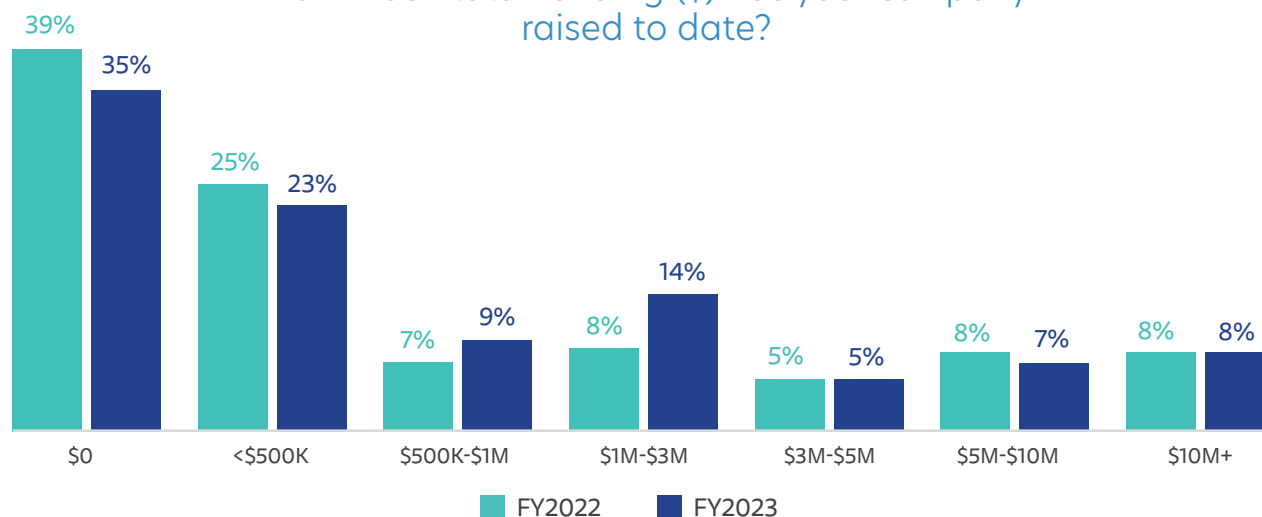
\$1M

Despite the tough capital environment, the median funding raised has increased to \$1M, up 18% on FY2022

51%

indicated the current economic situation negatively impacted their ability to raise capital, an increase from 32% in FY2022

How much total funding (\$) has your company raised to date?



Total funding raised to date | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60

Capital Raising Timeframe

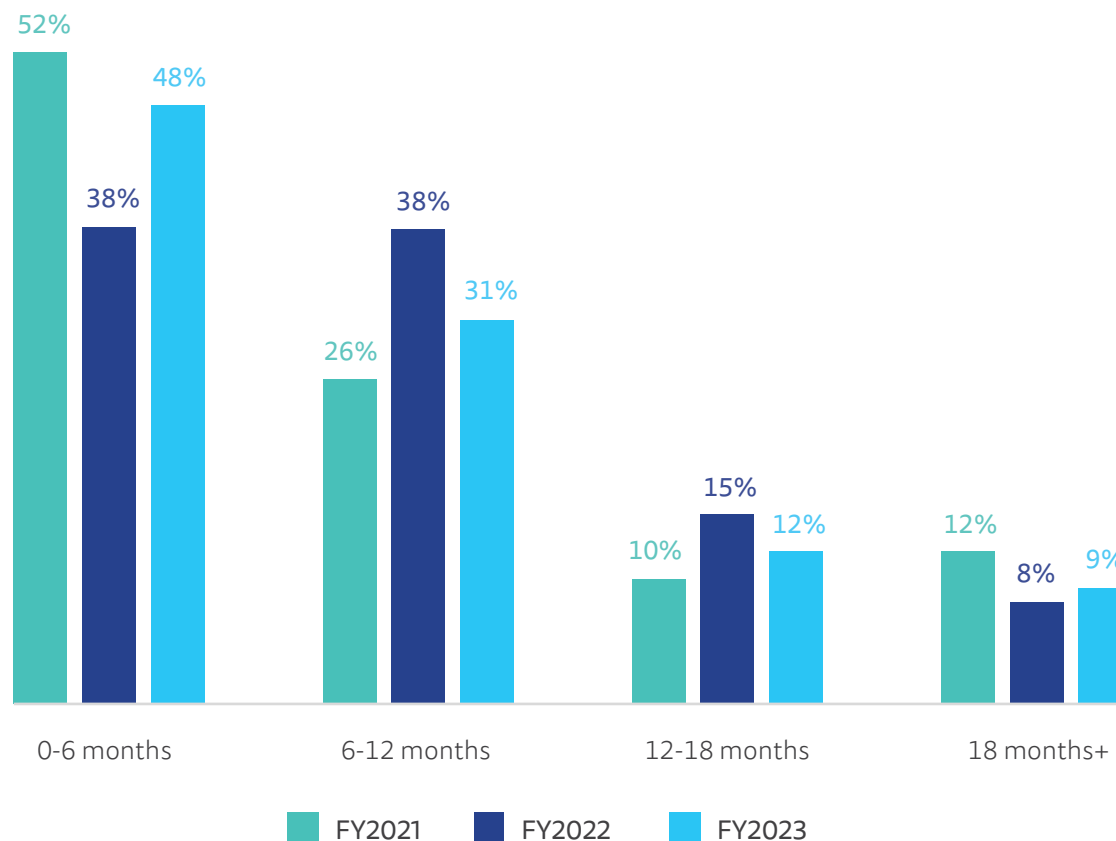
The time taken to raise capital has not materially increased, even though there are clear market indicators that capital markets are tougher to access in FY2023.

19% of companies reported taking in excess of 12 months to raise capital, however, the vast majority of companies (79%) are closing their rounds in under 12 months.

As recent events in the US market and broader economic contraction begins to take hold in Australia, these timeframes may extend in future years.



What has been the average timeframe for your company to raise funding?



Average timeframe to raise funding | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=65, FY2022 n=39, FY2021 n=NA

Future Funding & Investment

84% of companies are planning to raise funding in future compared to **80% in FY2022**

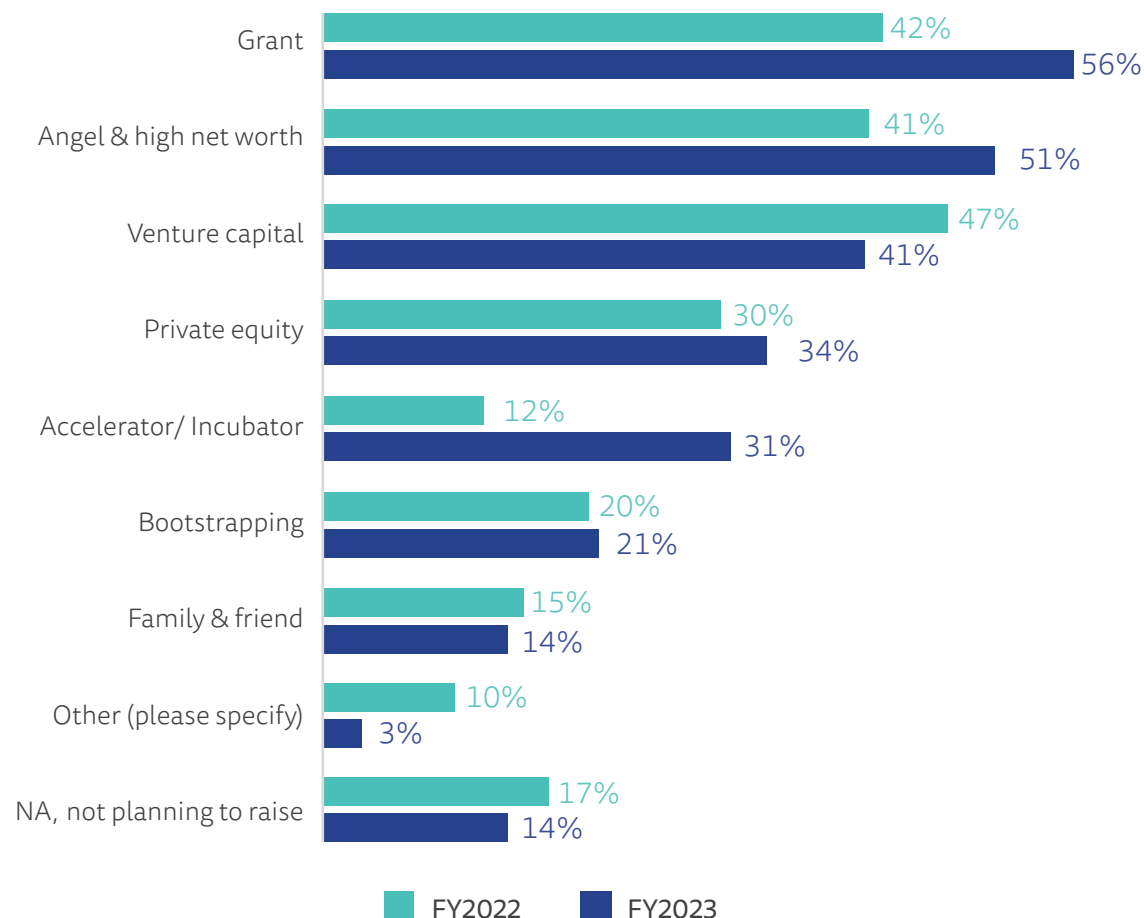
31% of companies were also planning to raise larger amounts of funding in the next 12 months in the range of **\$3M up to \$10M**, up from **23% in FY2022**.

Planned Sources Of New Capital

When looking to the future, a greater number of companies are looking to grants, angel investors and high net worth individuals and accelerator/incubators for funding compared to FY2022, while a smaller proportion are looking to venture capital.

It is possible that this is related to the top two challenges identified by respondents being a lack of access to capital and a lack of investors with specific expertise in digital health (see *Commercialisation Challenges* section). It may also be due, in some part, to the widespread data suggesting that venture capital is contracting in the current environment, and so companies may be expecting less venture investment to be available.¹⁶

Where do you plan to raise future funding?



Future raising funding plans | Companies could select more than 1 response | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101 with 266 responses, FY2022 n=60 with 139 responses | Other included partnership with a tech company in the health field; Strategic Pharma, and Sales

Investor Capabilities

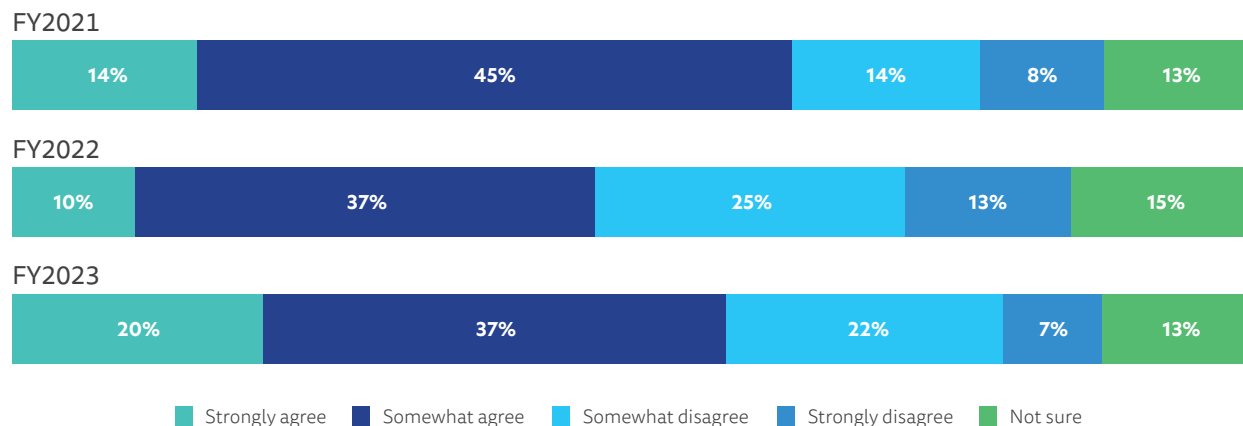
The respondents this year are more confident in the ability of local investors to provide support than in FY2022, with almost double the proportion of companies (20% versus 10% in FY2022) strongly agreeing that local investors adequately possess the knowledge, skills and ability to provide their company with appropriate support.

However, confidence in international investors remains much higher than in domestic investors (38% versus 20%). This may be linked to the challenge in accessing investors with specific expertise in digital health (being the second ranked challenge for respondents), or a perception that international investors have greater expertise in the digital health sector.

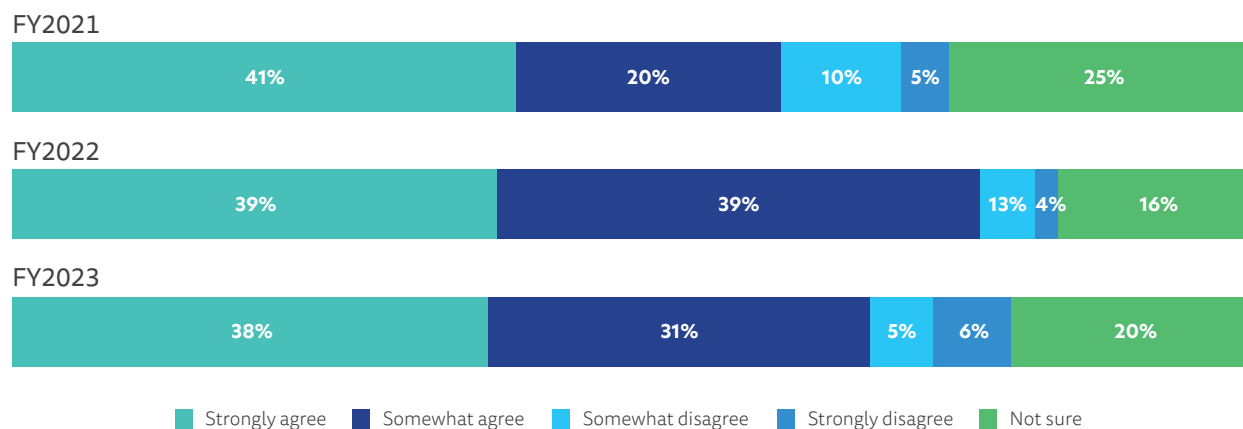
Confidence Levels



Do you feel that local investors have the knowledge, skills and ability to best supports your company?



Do you feel that international investors have the knowledge, skills and ability to best supports your company?



Investor capabilities - local and international | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=51

9. Impacts of COVID

In FY2023, the industry has seen some evidence of returning to pre-pandemic settings. In some international markets, preferential regulatory and reimbursement settings that were in place during the pandemic have expired.¹⁷















In other areas, the utilisation rates of healthcare accessibility technologies such as telehealth and telemedicine have dropped as people return to more traditional face-to-face models of care.¹⁸

However, it cannot be denied that the COVID-19 pandemic has 'shifted the needle' for digital health, with significant transformation in healthcare delivery here to stay. As we look to a world where COVID-19 becomes endemic, remote patient monitoring has, for the first time, overtaken telehealth as the area most likely to grow as a consequence of the pandemic.

The shifting of care from the clinic to the home is a theme which is prominent in global healthcare circles.¹⁹ In FY2023, respondents feel that growth is most likely in remote monitoring (76%), wearable technologies (70%) and telehealth (73%).

We also see wearables in the top five for the first time, and self-testing (36%) makes a return after not ranking in the top 5 in FY2022. Whilst digital mental health has maintained its top 5 ranking it has dropped from third to fifth, which may indicate a decreasing sense of urgency in this area as the impacts of lockdowns are perceived to have passed.

Top 5 Areas Most Likely to Grow as a Consequence of COVID-19

	#1	#2	#3	#4	#5
FY2021	 Telehealth	 Remote Monitoring	 Data Analysis	 Digital Mental Health	 Self-testing
FY2022	 Telehealth	 Remote Monitoring	 Digital Mental Health	 Data Analysis	 Digital Therapeutics
FY2023	 Remote Monitoring	 Telehealth	 Wearables	 Self-testing	 Digital Mental Health

Top 5 areas of digital health most likely to grow as a consequence of COVID-19 | Companies selected top 3 and ranked them from 1st highest down to 3rd lowest | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=35.

Top 5 Potential Positive Impacts on the Industry Post COVID-19

#1  **Increased acceptance by the medical community**

#2  **Increased acceptance by patients**

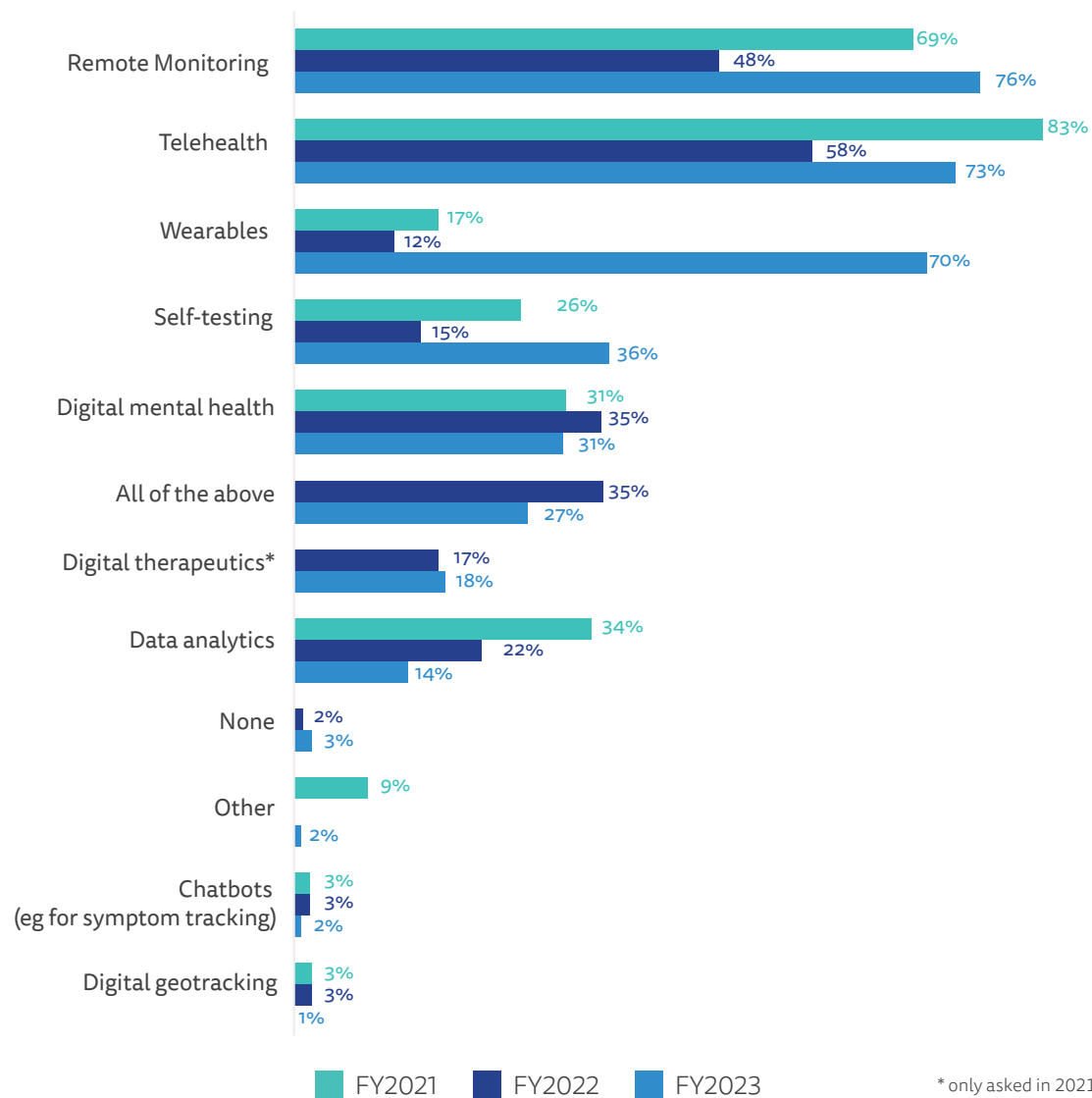
#3  **Larger market for digital health technologies**

#4  **Increased awareness among investors**

#5  **Increased government funding**

Potential positive impacts of COVID-19 on the Australian Digital Health Industry
| Ranked from 1st highest down to 5th lowest | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey

Areas of digital health most likely to grow as a consequence of COVID-19?



Areas of digital health most likely to grow as a consequence of COVID-19 | Companies selected top 3 and ranked them from 1st highest down to 3rd lowest | Commercialising Digital Health in Australia: FY2023 Industry Sentiment Survey | FY2023 n=101, FY2022 n=60, FY2021 n=35

Future Outlook

Off the back of record global growth in digital health in recent years, the future picture remains positive for Australian digital health companies as local companies continue to mature and grow.

However, the challenging global economic environment is beginning to take a toll on Australian digital health SMEs, with around half of companies indicating that it is now affecting their decision-making.

Despite the uncertain economic landscape, in a positive sign for the industry, many companies are still actively seeking to expand their staffing levels, and more clinical trials will go ahead than in years prior.

The state of gender diversity in the industry is also slowly moving towards parity, with 54% of companies surveyed female-founded and 78% of organisations having at least one female appointed at the executive level. In addition, 38% of companies have reported having a female CEO or Managing Director.

Future priorities for digital health SMEs include increasing their revenue and forging new partnerships. There is a large opportunity for

Australian SMEs to expand overseas in the coming years, as the lucrative global digital health market is predicted to reach US\$1004B by 2031, up from US\$216.7B in 2022.²⁰

Companies are identifying areas of digital health most likely to grow that are aligned to the global trend toward patient-centred healthcare in the home, including remote health monitoring, wearable devices and other connected health initiatives, which represents an upshift from previous surveys.

In further positive news, SMEs are increasingly confident navigating the regulatory environment in Australia.

Notwithstanding this positivity, significant policy challenges exist domestically as considerable uncertainty remains ever-present related to the lack of a clear reimbursement pathway and access to customers.

To build on previous gains and realise a thriving digital health ecosystem in the future, we need to look at additional digital health specific funding opportunities and greater revenue certainty through expanded reimbursement coverage for health technologies,

whilst prioritising local procurement. For digital health and digital therapeutics (DTx), for instance, that are used to prevent, manage, or treat a disease, lack of reimbursement is a key blocker to patients accessing these products. Many of our most promising companies also leave Australia and see success in global markets before Australian healthcare systems will consider them (and often even then our procurement system prefers to undertake large contracts with multinationals over purchasing and deploying fit-for-purpose Australian technologies).

If the right policy settings can be achieved by governments, the scalability of digital health products represents an enormous opportunity for Australia to invest in homegrown innovation which can start locally, but scale globally, retaining significant economic and health gains for Australia, whilst servicing a global patient population.



Authors: This report has been prepared by ANDHealth® Pty Ltd. ANDHealth would like to thank all who contributed to this document for their time, experience and input.

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