ANDHealth Submission to the Digital Economy Strategy Consultation Paper

December 2017

Background

ANDHealth (Australia's National Digital Health Initiative) is funded by MTPConnect and a consortium of industry partners representing a cross section of companies within Australia's digital health ecosystem. ANDHealth's mission is to create an integrated and connected ecosystem for the development, commercialisation and implementation of evidence-based digital health products. We work towards achieving this by bringing together participants from the medtech and pharmaceutical sectors with a broader stakeholder group drawn from a wide range of sectors involved in the evolution of digital health technologies including ICT, and by putting in place the key elements required to create a cohesive and collaborative digital health industry.

ANDHealth aligns itself with 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.

Providers and other stakeholders are using digital health 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 to better manage and track their health and wellness related activities.

The use of technologies such as smart phones, social networks and internet applications is not only changing the way we communicate, but is also providing innovative ways for us to monitor our health and well-being and giving us greater access to information. Together these advancements are leading to a convergence of people, information, technology and connectivity to improve health care and health outcomes."[1]

Response

1. **How are advances in digital technology changing the way you work, your industry and your community?**
   Digital health includes technologies that can assist in diagnosis, prevention, healthcare delivery, and patient monitoring. Consequently, the benefits to the community and the economy have the potential to be enormous – the possibilities include alleviating demand on hospital beds through early intervention; reduced unscheduled healthcare system access; access to quality healthcare for remote and rural populations; improved health and wellbeing for all Australians (leading to productivity improvements and diminished healthcare costs); delivery of in-home care through better social connectedness for aged the aged and disabled; a shift in treatment from hospital to

[1] https://www.fda.gov/medicaldevices/digitalhealth/

the home; and an informed, data driven healthcare conversation between patients, caregivers and clinicians.

The digital health industry is relatively new, and international reports highlight the exponential growth expected over the next 10 years: the global digital health market is predicted to grow from USD79 billion in 2015 to USD206 billion by 2020[2] and Australia's contribution could have significant positive effects for the digital economy. In fact, a 2015 analysis suggests that the Australian healthcare IT market (which is only one component of digital health) is expected to grow at a compound annual rate of 12.3 per cent between 2013 and 2020, reaching an estimated market value of $2.21 billion by 2020.[3] This points to digital health as an advancing industry contributing to the economic growth and health outcomes of Australia, and also an investment opportunity – 2016 saw over $8 billion invested in over 500 digital health companies.[4]

Australia's success in the digital health space will be underpinned by our world class excellence in research – Australian research performs at or above world standards particularly in health and medical research but is also highly competitive in technology, and information and computing sciences[5] - combined with a world leading public health care system where we can boast a value based healthcare.

Digital health technologies are set to reduce the burden on the health system dramatically. As an example, in Canada, it is estimated that the consequences of uptake of digital health in the past ten years has produced an estimated CAD 13 billion in savings from avoiding duplicate tests, electronic drug information systems and telehealth advances.[6]

ANDHealth exists because of the extensive breadth of industries and stakeholders involved in Australia's digital health landscape which have pushed advances in with the ability to fundamentally change patient outcomes. This has provided an opportunity for ANDHealth to provide a conduit for Australian and international-led innovation to access our rich local ecosystem. Australia has a fledgling digital health sector including early and mid stage startups and SMEs Bringing together historically siloed disciplines to create new collaborations between ICT, medical technologies and pharmaceuticals, will strengthen the developing digital health sector.

2. **What is your vision for an Australia that thrives in a digital economy? Where would you like to see Australia in five, 10 and 20 years' time?**
ANDHealth envisions that Australia recognises the role of connectivity in a modern society, and leverages its world class position as a leader in health and medical research and its leading healthcare system, to become a global leader across health, medical research and digital and connected healthcare. Australia would be a desirable destination for the development, testing, clinical trials and implementation of connected healthcare technologies from around the world, driving inward investment and better outcomes for Australians and delivering significant technology advancements in healthcare to the world. To this end, ANDHealth envisions an Australia with a healthier, more productive population, with a global reputation for its informed, technology

[2] https://www.ama.org/publications/enewsletters/marketing-news-weekly/documents/ama_dom_digitalhealth_052017.pdf
[3] Frost & Sullivan Analysis of Healthcare IT spending in Australia. http://www. frost.com/c/10024/sublib/display-report. do?id=9AB9-00-11-00-00
[4] The Health Moonshot Movement, 2016 Digital Health Funding Rankings. https://www.startuphealth.com/marketing/insights/51625
[5] http://www.arc.gov.au/sites/default/files/filedepot/Public/ERA/ERA%202015/ERA_2015_National_Report/ERA2015_Section1.pdf
[6] https://www.infoway-inforoute.ca/en/component/edocman/resources/reports/2821-infographic-report-on-digital-health-the-economics-of-digital-health

savvy and health literate population that yields informed and empowered patients, and flexible, dynamic clinicians.

3. **What is the role of government in achieving that vision?**
Commonwealth and State Governments are well positioned to encourage innovation and growth of translation and commercialisation activities through incentives, facilitation and ecosystem development where there are unmet market needs. Governments are also key to creating an investment and regulatory landscape that is as responsive and agile as the technologies themselves, in order to implement these technologies into patient and consumer care, faster. This could be achieved in several ways:

    - Support schemes that enable low risk and subsidised technology development, prototyping and real world clinical evidence gathering. This would accelerate the process for new technologies to be either further advanced or dismissed before further investment is made.
    - Support industry-led, Australian-centric programs to discover and develop early stage innovation through the development pathway until such technologies are ready for global commercialisation. These programs should be spearheaded by Australian professionals who can point to demonstrable experience in taking Australian innovation to the world. The use of government funds to subsidise international programs, which facilitate swift transfer of talent, equity and intellectual property offshore should be avoided so that economic benefits of education and commercial talent builds the industry and economy in Australia. Moreover, the significant differences between taking technologies to global markets from Australasia, rather than the skills required to launch into the US from the US, should be recognised.
    - Creation of connected networks of clinical care organisations which provide access to new technologies to be implemented on a limited scale to collect necessary real-world evidence for both commercial and clinical validation should be created and incentivised.
    - Reimbursement for healthcare providers on the purchase and prescription of proven, accredited, evidence-based digital health products. This will encourage uptake of products by patients and consumers that could drastically reduce burdens on public health systems. Providers should be incentivised to adopt clinically backed, evidence based technologies that can demonstrate improved patient outcomes and greater healthcare system efficiencies.
    - The shift to "opt-out" for My Health Record will create significant patient data sets that should be aggregated, de-identified and provided via a controlled access regime to further improve technology development and implementation.
    - Federal regulatory requirements need to be updated to enable Australia to realise the value of this increasingly agile sector to reach markets and improve health outcomes without delays onerous and sometimes variable regulatory hurdles. Changes to regulatory requirements are addressed later in this document.

4. **What key disruptive technologies or business models do you see? What do you predict is on the horizon in five, 10, 20 years' time?**
ANDHealth believes the adoption of digital technology in healthcare is a disruption in itself. What will make a greater difference is changes in how we address the national ecosystem to allow these technologies to drive better health outcomes for Australians. These include:
    - Data driven outcomes assessment and reimbursement of technologies based on clinical outcomes.

- Financial incentives (reimbursements) to both Australians who proactively manage their own health and who are seen to take responsibility and proactively manage their conditions, and to providers who make the products available for public consumption.
- Use of data to minimise waste in global healthcare driven by human factors. In 2012, sub-optimal medication use cost the developed world USD 500 billion per annum[7]. This could be avoided with use of the extensive data collected to inform medicine use, combined with technology for monitoring and management of patient health to reduce medication errors, assisting patients with medicine usage and generally create better decision making processes. Clinical and patient errors can result in loss of human life or poor quality of life – use of data to reduce these is transformative.

6. **What opportunities do we have to accelerate the development of technologies that will underpin Australia's digital economy?**

With a globally renowned track record in health and medical research and a world class health care system, Australia is well placed to lead the globe in development and acceleration of digital health technology.

Programs that utilise the wealth of existing and growing Australian expertise in ICT, medical technologies, pharmaceuticals, technology development, healthcare and a desire to be proactive in public health to discover and develop early and mid stage innovation through the development pathway to move through to global commercialisation, would accelerate digital health technologies. Combined with a responsive regulatory system (see response to question 7), this would not only accelerate locally grown technology but also attract international players into the Australian economy, injecting further talent and know how and opening up global markets for Australian digital health technology.

Government assistance to pilot regulatory reform, and subsidise international programs to develop talent, equity and intellectual property in Australia, and preventing these from leaving our shores, would underpin and grow the sector's contribution to the Australian digital economy.

In other sectors such as fintech, accelerator programs have had success in strengthening Australia's digital economy. However digital health requires specialist knowledge around regulation, clinical needs and workflow, and clinical evidence for digital health technologies meaning that careful curation is required around the delivery of digital health accelerator programs. Emphasis should be placed on the sector specific track record of the personnel involved in any health accelerator program.

Another key element to any successful economy is a strong customer base. What Australia lacks in population could be made up for by the potentially strong purchasing power in health through our universal health care system. Australia has the opportunity to accelerate and support the digital health economy through significantly streamlining the purchasing and implementation process and incentives around digital health technologies. The My Health Record system, soon to be present throughout Australia's healthcare system, is well positioned to be an enabler to digital health implementation in hospitals and, if streamlined, positions Australia as an attractive market for digital health technology companies, both as a test bed and a customer. As the system is today, Australia risks being left behind while Australian technologies seek larger private markets or more receptive international public markets for their digital health products.

[7] http://pharmanalyses.fr/wp-content/uploads/2012/10/Advancing-Responsible-Use-of-Meds-Report-01-10-12.pdf

Indeed, investment in Australian digital health is important in accelerating the development of technologies that will underpin Australia's digital economy. The Australian health technology landscape has been strengthened by government funding and private investment such as the Biomedical Translation Fund, Medical Research Commercialisation Fund and the Medical Research Future Fund to name a few. As digital health is an emerging investment class in Australia, there is an opportunity to accelerate the investments into developing technologies through awareness and education within the investment community.

Australia's small population size and connectivity are an advantage in this space for acceleration and implementation of transformative technology in healthcare as we market ourselves as the best destination globally for the piloting and trialling of new products and business models.

All of this begins with building an agile and well educated workforce in Australia through connectivity, industry bodies and further education, as well as – at the root of it – positioning digital health within the education curriculum and initiatives that encourage science, technology, engineering and mathematics (STEM) in young Australians at secondary and tertiary levels.

Encouraging skilled migration to support the digital health sector will enrich the current landscape as will inward investment and successful technology exits for entrepreneurs.

7. **What opportunities do we have in standards development and regulation to:**
– enable digital entrepreneurship, innovation and trade?

Entrepreneurship, innovation and trade are influenced by the ability to put digital health technologies into the hands of patients and the public through key gatekeepers including healthcare providers, clinicians, international pharmaceutical and medtech companies, hospitals, GPs regulators, pharmacies, insurers and government policy. Traditional methods and pathways for device regulation do not allow for the agile nature of technology development, advancement and improvement. One method of regulation that has been useful in the automotive industry is open outcomes based regulation, where manufacturers, rather than individual products, are regulated, and evidence from actual use, rather than just pre-clinical evidence is the basis of regulation.

At ANDHealth's recent industry C-suite industry roundtable consultations, it became clear that more responsive regulation of digital health technologies would improve the technology development, investment strategy, commercialisation opportunities and timelines to implementing technologies in healthcare. Moreover, such regulation would set apart Australian approved digital health products from foreign, unregulated products such as inaccurate apps and consumer-driven devices, which would drive foreign investment into Australia as well as growth of Australian companies. Indeed, it was recognised that Australia was well positioned within its health care system and ICT-driven initiatives, to take on a global leadership position in implementing evidence-based regulation of digital health technologies.

– mitigate the risks associated with digital disruption?

Digital disruption is a certainty that will herald the innumerable benefits to public health that digital health technologies can provide. However, a lot of the risks are perceived and likely to be driven by a fear of change. Consequently the digital disruptions should be embraced as a way forward towards better healthcare, better health literacy within the general population, better health outcomes which reduces demand on health systems and boosts economic productivity. More responsive and evidence-based regulation will help to mitigate any risks through transparency of a

regulated digital health products, which then boosts consumer confidence in areas such as accuracy of products and data use.

8. **What digital standards do we need to enable Australian businesses to participate in global supply chains and maximise the opportunities of the digital economy?**
Australia's ability to implement responsive regulatory frameworks will position us as a global leader in digital health, and ensure a quality, safety and efficacy threshold so that evidence-backed health technologies can be readily identified. With this in place, governments will be in a position to limit the ability of foreign corporations to sell health technology products – such as phone apps – that make unproven accuracy and health claims, directly to consumers.

   This would then position Australia as a target for foreign direct investment in digital health technologies as our standards would be world renowned and reputable for multinational companies. A similar example is the use of "made in Australia" and TGA approval for pharmaceuticals and nutraceuticals that are then poured into the growing Asian market. It would also make Australia a desirable collaboration destination for research, proof of concept and market testing for foreign and local companies.

12. **What are barriers for business, particularly small business, in adopting cyber security and privacy practices?**

    Barriers exist for small businesses as start ups and mid-stage enterprises in understanding the risks inherent in cybersecurity, how to draw up an appropriate cybersecurity and data privacy plan, and how to implement such a plan. In digital health where companies are pairing devices with software and apps, various scenarios can come into play about data security, ownership and use. Many such companies are experts in software and medical technologies, but pairing these creates issues around user data and patient data. Guidelines around what practices are required, the consequences of these and understanding the skills required will aid small businesses in recruiting or outsourcing for the correct skills.

    In digital health, this is further complicated by the sensitivity of digital health, where identifying information and health data can be provided by the technology user, owned by the developer and used by researchers, clinicians or other parties. Clarity around the risks, regulations and requirements of these would help businesses implement good practice at the start of their technology development pathway, which would reduce risk for the company, for investors and for the consumers.

End.