BEYOND HEALTH IT
USING TECHNOLOGY TO TRANSFORM PATIENT OUTCOMES IN HEALTHCARE

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BACKGROUND

ANDHealth is the product of a collaborative group of industry leaders who came together to support our emerging digital health sector, and the innovators within it, to commercialise their technologies, globally.
WHO WE ARE

ANDHealth is Australia’s only organisation dedicated to providing commercialisation support programs designed specifically for digital health companies.
ANDHEALTH+ COHORT COMPANIES

2017

atmo BIOSCIENCES, DoseMe, perx, seer medical, SkinView, AllergyPal

2018

CancerAid, VITALIC, Health Delivered, iUFlow
COHORT COMPANY REPORTED OUTCOMES

Cohort Company Outcomes Reported to ANDHealth (as at March 31 2019).

- Raised (dilutive & non-dilutive): $15.6M
- New Revenue: $3.6M
- New jobs (FTEs): 74
- New CxO Roles: 5
- Exit of DoseMe (to Tabula Rasa NASDAQ: TRHC)
- Commercial pilots commenced: 292
- Clinical trials and studies commenced: 16
- New international market launches: 9
- New commercial customers: 126
- New patients served: 19,360
- New operational sites: 166
- New partnerships formed: 23
- New product releases: 31
DIGITAL HEALTH

A fast growing sector which is characterised by the use of digital technologies, either alone or in combination with physical products, to treat, diagnose, cure, mitigate and/or prevent disease or other conditions. Includes Health IT – but is not limited to it.
Digital Health is NOT just about collecting and sharing patient information.

The FDA defines digital health broadly as including:

✓ Mobile health (mHealth)
✓ Health information technology (HealthIT/ e-health)
✓ Connected & wearable devices
✓ Telehealth and telemedicine
✓ Personalized & precision medicine

Increasingly Digital Health technologies treat, diagnose, cure, mitigate and/or prevent disease or other conditions.

Source: http://www.fda.gov/MedicalDevices/DigitalHealth/default.htm
DEFINING DIGITAL HEALTH II

Technology
- Mobile health (mHealth)
- Health information technology (IT)
- Wearable & connected devices
- Telehealth and telemedicine
- Personalised & precision medicine

Providers
- Reduce inefficiencies
- Improve access
- Reduce costs
- Increase quality
- Make medicine more personalized for patients

Patients
- Monitor Health & Wellbeing
- Track activities, symptoms, actions
- Improve adherence
- Communicate with physicians
- Data-based healthcare conversation

Source: http://www.fda.gov/MedicalDevices/DigitalHealth/default.htm
A COMPLEX LANDSCAPE

Pharmaceutical Companies
- Compliance
- Dosing
- Delivery
- Interaction between drug effects and device therapy
- Medication monitoring

Public and Private Payers
- Patient education
- Disease management
- Fraud prevention
- Risk management
- Social media data

Employers
- Benefit Plan Design
- Health and Wellness Programs

Transaction Services
- Claims processing
- Banks: health savings
- Accounts and payments

Regulators
- Healthcare policy
- Medical research
- Regulatory compliance
- Consumer rights

Life Sciences
- Clinical Development
- Clinical Trials
- Medication Compliance
- Medical Devices
- Consumer relationships
- Wellness and Care services

Public Health
- Pandemic Readiness
- Vaccine inventory and distribution
- Sanitation and public safety
- Healthy lifestyles and diet
- Living with chronic disease

Multinational Medtech
- Data Connectivity
- Diagnosis
- Clinical Decision Support
- Big Data
- Proprietary platforms
- Patient & provider interfaces
- Consumer reach

Healthcare Providers
- Electronic Medical Records
- Health information exchange
- Patient ID and eHealth
- Social Media data
- Telehealth
- Hospital in the Home

Medical Research Centres
- Clinical Research
- Cohort Studies
- Clinical Trials

Retail Clinics
- Consumer Services

Government Policy
- Health programs
- Health data for decision making
- Reimbursement

Pharmacies
- E-prescribing
- New Services

Health clubs
- Health and wellness programs

“If the problem you want to solve is industry wide, it’s crucial to understand why the market has failed to address it.”

Harvard Business Review
INDUSTRY INTELLIGENCE

ANDHealth has actively screened over 180 companies since October 2017 & continues to screen increasing numbers of companies from very early stage to later stages of development. Currently, we screen more digital health companies than any other organisation in Australia.
Digital Health is one of the fastest growing investment classes, globally. Acknowledged outside of Australia as a sector in its own right, it spans ten subsectors, and received **US$14.6B billion** in investment last year.
COMPARATIVE CLINICAL TRENDS

Australia
- Diabetes & lifestyle: 17%
- Nervous system: 9%
- Heart & circulatory: 8%
- Musculoskeletal: 12%
- Mental health: 16%
- Other: 38%

Global
- Diabetes & lifestyle: 15%
- Nervous system: 6%
- Heart & circulatory: 10%
- Musculoskeletal: 7%
- Mental health: 29%
- Other: 33%

n = 179
COMPARATIVE TECHNOLOGY TRENDS

Favourable US policy and reimbursement

COMMERCIALISING DIGITAL HEALTH

Commercialisation (noun): the process of bringing new products or services to market. The broader act of commercialisation entails production, distribution, marketing, sales, customer support, and other key functions critical to achieving the commercial success of the new product or service. (Investopedia)
“If you build a business and can’t figure out pretty early on what value you are providing and how it should and will be paid for, you are on the path to certain ruin.”

Lisa Suennen

2018 Top Digital Health Evangelist, with over 20 years of investment and entrepreneurial experience in digital health
01. Sector recognition
Outside of the US digital health struggles for recognition as a sector in its own right with its own specific challenges.

02. Lack of informed capital
There are currently no Australian specialist digital health investment funds.

03. The wrong capital
Digital health companies that do attract investment often do so from investors who lack the knowledge skills and ability to support these companies.

04. Globalisation challenges
Australian companies lack the knowledge & experience to effectively penetrate major markets in this space. In addition, the Australian ecosystem lacks a point of critical mass able to generate the interest of international investors.

05. Commercial validation
Many companies lack the commercial evidence to support uptake of their technologies by providers and payers. This requirement in particular is poorly understood and is significantly different in digital health than in other sectors.

06. Clinical validation
Companies need support in accessing the right type of clinical trials and clinical evidence gathering to support evidence-based health claims.

07. Regulatory landscapes
Digital health is evolving rapidly, creating shifting regulatory landscapes difficult for companies to navigate strategically.

*Based on actual market observations and active dialogue with Australian & international innovators & investors.
WHAT DOES SUCCESS LOOK LIKE IN THIS EVOLVING MARKET?

Design personalised, sticky interventions and deploy them in a timely manner

Identify when people are at risk and knowing what they need, before they need it

Reach people wherever they are

Shift from being product based / technology push to Service based, focused on supporting an empowered healthcare consumer with sticky technology that integrates into people’s lives

Capture hearts and minds through understanding consumer behaviour

Adapted from: https://www.visualcapitalist.com/6-forces-transforming-future-healthcare/
“They think, ‘Well, I am good and it’s so goddamn cool and my grandma needed it that I will change the world’

And you say, ‘Well, who is going to pay for it?’

And they go, ‘Uh, everybody cause it’s so great.’ That drives me slightly insane.”

Lisa Suennen
IMPROVING PATIENT OUTCOMES

Healthcare providers who manage to create stronger ties to their patients and let them independently contribute to their patient journey can achieve better long-term patient outcomes.

The Product: A real-time precision dosing cloud software, used to predict the optimal dose of therapeutic drugs.

Users: Clinicians.

Customers: Hospitals.

Regulatory Status: CE, TGA, FDA Approved.
IMPROVING OUTCOMES IN CANCER PATIENTS

The Product: A behavioral change app and coaching program to achieve better clinical outcomes and improve return to wellness for cancer patients.

Users: Oncology patients, oncologists.

Customers: Insurance companies (life insurer e.g. MLC), pharmaceutical companies (e.g. Roche).

Regulatory Status: not considered a medical device in either Australia or the US at this stage.
IN-HOME DATA DRIVEN EPILEPSY DIAGNOSIS

The Product: In home hospital grade EEG and ECG monitoring for epilepsy diagnosis. (Bulk Billed)

Users: Patient, clinician (GP, neurologist, cardiologist).

Customers: Neurologists (e.g. Mark Cook), General Practitioners.

Regulatory Status: Use of third party devices means that no specific regulatory approvals are required at this stage.

+700 patients served

Waitlist now days-weeks (from months-years)
The Product: Improving medication adherence through behavioral science and extrinsic user rewards.

Users: Patients.

Customers: Insurance companies, pharmaceutical companies (e.g. Pfizer).

Regulatory Status: No specific regulatory approvals are required at this stage although compliance with Medicines Australia code has been addressed.

Over 80% adherence (vs 50% historically)

2.5 hours in app/month (vs 15 mins with physician)
MANAGING CHRONIC RESPIRATORY DISEASE

Propeller

Acquired by ResMed in Dec 2018 (ASX: RMD)

25,000 patients served over 530 healthcare providers

The Product: Connected sensors that attach to various inhalers, with associated app and web/cloud based tools for patients and providers.

Users: Patients with respiratory conditions (asthma/ COPD), healthcare providers.

Customers: Pharmaceutical companies (e.g. Novartis), Medtech companies (e.g. Orion).

Regulatory Status: FDA approved for sensor and accompanying connected platform.
LONG TERM MANAGEMENT OF TYPE II DIABETES

The Product: Type 2 diabetes digital therapeutic.

Users: Patient, clinicians.

Customers: Insurers, employers, providers (e.g. Providence Health).

Regulatory status: FDA Cleared Class II Medical Device. ISO13485 and SOC 2 certified. Over the counter version FDA 510(k) Class II.

Ave savings >US$250 per patient per month.

>30,000 Patients Served
BUSINESS MODELS

A business model describes the rationale of how an organization creates, delivers, and captures value, in economic, social, cultural or other contexts.

“Most digital health companies started with problems that are undefined. The problem is usually economic, not clinical.”

Lisa Suennen
2018 Top Digital Health Evangelist, with over 20 years of investment and entrepreneurial experience in digital health
FLATIRON | CASE STUDY (HEALTH IT)

Business intelligence for oncology hospitals

Series A
$8M (led by Google Ventures)
No Economic Model
Only 2 contracts with slow (2 year) sales cycle

Launch

Series B
$130M (Google Ventures)
Pivot
Acquires EMR for $100M. Now a cloud-based software for oncology clinics

2012

Series C
$190M (Roche)
Iteration
Data analytics & clinical trials (with 1000+ data handlers) targeting pharmaceutical companies

2014

2016

2018

ACQUIRED By Roche for $US1.9B

2M patients and $200M ARR from 280 practices and 15 largest oncology pharmaceutical companies
Critical Trial (FDA)
2.5 years
RCT (n=163)
Outcome: HbA1c
Setting: primary care
Funded by Welldoc, LifeScan, others

Primary Care Pilot
RCT (n=30)
Outcome: HbA1c
Setting: primary care
Funded by Lifescan, Nokia

FDA Approval
For subscription

Clinical Outcomes
From critical trial

Healthcare utilisation
Retrospective (n=32)
ED, hospitalisations

FDA Approval
For non-subscription (over-the-counter)

3 Sub-Analyses
From critical trial
Incl. trial protocol, distress/depression, medication changes and cost benefits

Trial recruiting
RCT (n=221)
Use in hospitals

CASE STUDY | BLUESTAR
CASE STUDY | PEAR THERAPEUTICS

Critical Trial (FDA)
- 2.5 years
- \( RCT \) (n=507)
- Outcome: abstinence
- Outpatient addiction programs
- Funded by NIDA

Community Pilot
- \( RCT \) (n=28)
- Outcome: abstinence
- In community setting
- Funded by NIDA

Cost-Effectiveness
- From clinical trial

Clinical Outcomes
- From clinical trial

FDA Approval
- For subscription (defined safety, efficacy profile) and marketing
- 16 month duration

4 Sub-Analyses
- From clinical trial
- Incl. engagement, drug specific, phone use, patient factors

Commercialise
- As digital therapeutic with strategic partner

Pilot
- \( RCT \) (n=135)
- Outcome: abstinence
- In research clinics
- Funded by NIDA
FDA Approval
For Late-Onset Alzheimer's Disease, Parkinson's Disease and Hereditary Thrombophilia genetic health risk reports.

FDA Approval
For a genetic cancer test for three BRCA mutation.

FDA Declaration
Of an “unapproved medical device”. Suspends marketing “based on inaccurate information.”

Pfizer Inflammatory Bowel Disease Trial
10,000 patients with colitis or Crohn's disease enrolled.

+435K Data Set Meta-analysis
Confirmed genetic variants already associated with Parkinson's & discovered 17 new ones.

Genetic Research on Lupus
5000 participant cohort study to understand genetic associations and assist in drug discovery efforts.

FDA Approval
For genetic risk information, but only for a few conditions.

Founded
2006

Started selling direct to consumer genetic testing

CASE STUDY | 23ANDME | SETBACKS

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**The Product:** Cancer patients get their tumour sequenced and are matched to clinical trials and treatments all over the world.

**Users/ Customers:** Cancer patients.

**Business and Revenue Model:** with a network of more than 30 of the world’s largest cancer hospitals, the business model was to charge cancer patients $3,000. Cancer patients would also pay a monthly subscription of $20.

**Raised:** $90 Million.

**Lead Investor:** Horizon Ventures, Hong Kong, 2015.

**Founded:** May 2015.

**Product Launch:** Sept 6, 2018.

**Close:** Nov 11, 2018.
**The Product:** personalized health coaching informed by genomic testing, blood analysis and microbiome analysis

**Users/ Customers:** Patients.

**Business and Revenue Model:** initially, launched at $3,500 per year, settled on $99 a month for pure health coaching to services $199 for data-informed data approach.

**Raised:** $52.6 Million- $3M 2014, $36M 2015, $13.6M 2017.

**Lead Investors:** Maveron, Polaris Partners and ARCH Venture Partners.

**Founded:** 2014.

**Product Launch:** 2015.

**Close:** April 24, 2019.

"the cost of providing the service exceeds what our customers can pay for it."

April 24, 2019 Arivale official statement
We’re going to sell the devices, but really the commercial model here is to “monetise the data”

Really? You sure about that? Any comparable deals/examples you can show me?

We have the world/universe/galaxy’s largest data set in “x”. We will lead the world in diagnosis/treatment/care

I doubt that very much. And even if you do… So what?

Can you prove actionable insights delivered into workflow?

Q: “Who will pay for it?”
A: Governments, Clinicians, Hospitals, Insurers… and Patients…

Really? You sure about that? All of them? Wow… (disbelieving)

We know it works because we have trained the algorithm on our data set.

Q: “Have you done any real world evidence clinical studies?”
A: “No”

But there’s something called regulatory approval – and you will need real world clinical evidence. PLUS customers will need a clear economic imperative.

By leveraging our algorithm the healthcare system will save $x per patient per year…. Will it? Does that mean there’s budget to pay for it? Savings ≠ Spending

Just because…
…it works, doesn’t mean people will use it
…it saves costs, doesn’t mean someone has the funds/ incentive to buy it
…it works on screen/ in the lab, doesn’t mean it works in real life
…it could transform lives, doesn’t mean there is an economic model that will support a business.
THANK YOU

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