Member	Frank McGuire	Electorate	Broadmeadows
Period	01 April 2022 to 30 June 2022		

Regulation 6 - Expense allowance and electorate allowance	
Total amount paid to member for electorate allowance	$10,917.48
Total amount paid to member for expense allowance	$897.75

Regulation 7 - Motor vehicle allowance	
Total amount paid to member for motor vehicle allowance	$5,366.20
Member did not receive the motor vehicle allowance in the previous quarter and member has elected to receive the motor vehicle allowance for this quarter	Yes

Regulation 9 - Parliamentary accommodation sitting allowance	
Total amount paid to member for parliamentary accommodation sitting allowance	$0.00
Suburb in which the member's parliamentary accommodation is located	n/a

Regulation 10 - Travel allowance claims					
Date from	Date until	Reason for travel	Total amount paid	Town or city in which accomodation was located	Value of the accomodation

Total number of nights for travel allowance claims   **0**

Total amount paid to member for travel allowance   **$0.00**

Taken as certified.   1

Regulation 11 - Commercial transport allowance claims

Date from	Date until	Reason for travel	Total amount paid	Mode of transport	Value of transport

Total number of nights for commercial transport allowance claims   0
Total amount paid to member for commercial transport allowance $0.00

Regulation 12 - International travel allowance claims

Date from	Date until	Reason for travel	Total amount paid
24-Jun-22	21-Jul-22	Delegate & speaker at Australian British Health Catalyst (flights only)	$5,964.21

Total number of nights for international travel allowance claims   0
Total amount paid to member for international travel allowance $5,964.21

Taken as certified.   2

Creating Lifesaving Opportunities

AUSTRALIAN
BRITISH
CHAMBER
of COMMERCE

AUSTRALIAN BRITISH HEALTH CATALYST 2022

Monday 27 June - Wednesday 29 June
London, UK

THE FUTURE OF HEALTHCARE IN THE UK AND AUSTRALIA:
DIGITAL AND PEOPLE

NSW GOVERNMENT — NSW Health

pwc

Health UK

Contents

Frank McGuire

Member for Broadmeadows

Parliamentary Secretary for Medical Research

Parliamentary Secretary for Crime Prevention

Chair Broadmeadows Revitalisation Board 4.0

Executive Summary

As Victoria's Parliamentary Secretary for Medical Research, I represented the Victorian Government at the Australian British Health Catalyst 2022 on "The Future of Healthcare in the UK and Australia: Digital and People." It proved vital and urgent in the time of pandemic and highly valuable for the opportunities I uncovered and have pursued. "Creating Opportunity from Adversity" was the title of my presentation on establishing the health precincts of the future in built and virtual forms; sharing intellectual property; leveraging value; cutting costs and accelerating results. I identified more valuable investment opportunities through the European Australian Business Council's mission in London and Italy. These featured:

- Multi-billion-euro opportunities for life-changing and lifesaving collaborations.
- Access to breakthrough technologies against cancers, including the so-called Australian disease, melanoma.
- Lessons learned from the COVID-19 pandemic.
- New digital technologies to reduce hospital waiting lists, crucial in the time of pandemic.

Such leads were followed up on the spot and continue to be pursued. Projects remain confidential but the leader of Italy's biomedical sector publicly acknowledged the potential value:

Marco Baccanti · 1st
Managing Director Fondazione Enea Tech Biomedical
1d · 🌐

Great meeting at Ministry of Economic Development in Rome with Hon Frank McGuire, Government of Victoria, and Professor Doron Ben-Meir Deputy VC Monash University, discussing interesting collaboration scenarios with Italian Biomedical sector, through ENEA Tech e Biomedical Foundation

Expanding Victoria's International Leadership

The aim of my presentation was to highlight Victoria as the beating heart of Australia's internationally acclaimed medical research and health system, and to harness the Australian British Health Catalyst 2022 for collaboration with UK health leaders and international innovators to deliver results at home and abroad.

- Victoria is home to 22 world-class medical research institutes. Many played a critical role during the COVID-19 pandemic, including the Peter Doherty Institute for Infection and Immunity, named after Australia's Nobel Prize winner for Medicine. Victoria's medical research sector supports more than 30,000 jobs across institutes, universities and industry, in a community generating defining breakthroughs.[1]

- Many of these medical research institutes are located within Victoria's thriving health precincts alongside universities, hospitals, and industry leaders.

- Two of these epicentres, the Monash Precinct in Clayton, and the Melbourne Biomedical Precinct in Parkville, are home to World Top 20 universities for Medicine. Monash University has risen to world number one ranking for Pharmacy and Pharmacology.

- Australia's is one of a small number of countries manufacturing vaccines. Victoria is Australia's manufacturing base with CSL making more than 50 million doses of Astra-Zeneca from Britain in Broadmeadows. Another $1.8 billion deal to manufacture vaccines nearby against influenza extends this ecosystem. Victoria won the highly contested national bid to manufacture next generation mRNA vaccines with Moderna. I have advocated to the Australian Government that saving lives is the best diplomacy and the new Australian Government subsequently delivered extra vaccines in the South Pacific.

- This growing eco-system in Victoria is Australia's competitive advantage. Proximity of these institutes to industry, often within walking distance, has created innovation precincts with critical mass.

- Capitalising on the research and innovation potential and expanding precincts is a feature of the Victorian Government's Innovation Statement through investments driving economic development.[2]

- The Victorian Government's Leadership is defined by the $400 million investment to establish the largest centre of infectious disease expertise in the Southern Hemisphere, the Australian Institute for Infectious Disease (AIID).[3]

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[1] https://djpr.vic.gov.au/medical-research/strengths
[2] https://djpr.vic.gov.au/innovation-victoria/about/our-agenda
[3] https://aiid.edu.au/

Digital and Sustainable Health Precincts

- Investments like the AIID will build the capabilities of health precincts, helping them become bigger, more sophisticated hubs for research and economic growth.
- Physical connectedness is an established focus of precinct design, but the COVID-19 pandemic has highlighted the increasing importance of digital connectedness.
- This report highlights how health precincts of the future must adapt to changes from digital technology to capitalise on the new opportunities innovations are generating.
- The Victorian Government is working to ensure local health precincts adapt to digital transformation and make the most of the new opportunities it provides including:
  - The Digital Strategy 2021- 2026[4] released last year outlines the Government's ambition to propel Victoria through investment in digital infrastructure and skills.
  - The $2 billion Breakthrough Victoria Fund has been launched to invest in advances across priority sectors, including digital technologies.
  - Victoria's start-up agency, LaunchVic, supports programs targeted at Victoria's HealthTech start-ups, generating a range of economic and health benefits including more efficient health services and improved results in patient care.
  - $123.8 million was invested to create a shared electronic medical records system across the Melbourne Biomedical Precinct's health services. This investment will improve patient care and deliver data insights that medical researchers will use to accelerate better health results.
- Environmental factors in expanding health precincts are being included in creating new health precincts and how they can become paradigms for the broader community.
- The University of Melbourne is an example through its recently launched 'Sustainability Plan 2030' outlining a whole-of-University approach to address the global climate and sustainability crisis that strengthens the University's commitment to climate leadership.[5]

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[4] https://www.vic.gov.au/a-future-ready-victoria
[5] https://www.unimelb.edu.au/newsroom/news/2022/may/university-of-melbourne-launches-climate-action-plan#:~:text=The%20Sustainability%20Plan%202030%20renews,safe%20climate%20for%20the%20planet.

Achieving a Net Zero health care system

- Health care systems use significant amounts of energy and water and generate large volumes of waste, a concern the COVID-19 pandemic exacerbated.
- In Victoria, the Department of Health, and funded agencies, including public hospitals and health services, undertake a wide range of emission reduction initiatives across the health system[6] including activities associated with the Whole of Victorian Government's Emissions Reduction Pledge to use 100 per cent renewable electricity for all its operations from 2025.[7]
- Through programs like the Breakthrough Victoria Fund, the Government is supporting innovative ideas for a clean economy, in the health sector, and across the entire economy.

Bringing Value Home

Benefits and opportunities from this health catalyst and business mission have been reported to the Victorian Minister for Medical Research, the Victorian Government's Health and Medical Research Strategic Advisory Committee, of which I am a member, and Parliament. Here is an edited version of my Parliamentary contribution on August 2 defining the significance of the catalyst and mission:

This is one of our world-leading areas. Victoria's health and medical research sector is one of the state's most significant and productive industries. Every $1 invested in the sector generates $3.90 of activity in the economy. Medical research has the best of our intellect, and it is how we drive the bigger picture ideas and then deliver the results for people to save lives and change lives at home and abroad. Here is how we take care of people, we build a better system, and we drive economic activity and benefit for the community.

I have been pursuing how we can get multi-billion-euro investment opportunities from the UK and Italy to save lives at home and abroad. This stems from my address to the Australian British Health Catalyst, "Creating Opportunity from Adversity." That was the theme I was prosecuting, and it has led to new opportunity. We had a great response from the Italian Ministry of Economic Development. It has hundreds of millions of euros to invest.

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[6] https://www.health.vic.gov.au/environmental-health/climate-change-strategy
[7] https://www.health.vic.gov.au/environmental-health/climate-change-strategy

The leader of their biomedical sector publicly described the meeting on partnership scenarios as 'great', so there is an immediate connection and willingness to collaborate with what we are doing in Victoria, as Australia's leader. That is the key. These proposals offer outstanding benefits for medical research, education, and industry development at home and abroad. Monash University has the competitive advantage, with a campus in Italy and a world number one ranking for commercialising intellectual property in pharmacy, and it is one of the epicentres of Victoria's acclaimed ecosystem. The projects remain confidential, but this is a collaboration scenario that is being pursued.

The second initiative I pursued is an Australian research collaboration with the UK, which has €2 billion it wants to invest in science and medical research. The problem it has is the European Union is blocking the UK from the world's largest research and development investment fund, the €95 billion Horizon Europe fund. This provides a lucrative opportunity for Australia, with Victoria as the beating heart of our medical research. This gives us the best chance to make progress on these issues and to land a deal and a benefit for all of Australia, based predominantly in Victoria.

ec_rtd_he-investing-to-shape-our-future_0.pdf (europa.eu)

The third initiative has already secured access to new digital technologies to enable health breakthroughs featuring the fight against cancer, especially the so-called Australian disease, melanoma, and how we address hospital waiting lists, which is critical, and how we use digital technology and other breakthroughs on mental health. This is the result of the investment from this government over a long period of time to build these ecosystems.

Here is a connection where we can bring our best and brightest in the same way that we did with the Cancer Moonshot. We internationalised President Barack Obama's Moonshot quest to cure cancer where he put then Vice-President Joe Biden in charge of "Mission Control," and he came to Victoria in 2016 for the launch of our billion-dollar jewel in Australia's medical research crown, the Victorian Comprehensive Cancer Centre. We are doing world-leading research. We have had the Royal Commission into Victoria's Mental Health System. The rest of the world is looking at what Victoria is doing as Australia's leader. We recently won the highly contested national bid to manufacture mRNA vaccines. This becomes another part of our competitive advantage, and one development leads to another.

Looking at how sophisticated the Monash sector is, you have the university, you have CSIRO connected by Innovation Walk, and we are going to have the heart hospital there as well. This is how we keep driving the sector and how it has the impact on saving lives at home and abroad. The point I want to make is how national governments from Italy and the UK see the opportunity that we can provide. That is what I have tried to do: create opportunity, and then deliver the results. These are key strategies that will be pursued.

The situation that the UK finds itself in, it has the €2 billion that it wants to invest, but it has now been frozen out by the European Union from the world's largest investment in research and development, the €95 billion Horizon Europe fund. That is because of Brexit, and the situation in Ireland. So here is the opportunity. We are reaching out, saying, 'We can partner with you. If you want to invest with the best, you invest in Victoria'. That is how we have built this system, and that gives us the leadership position in medical research, not just nationally but also of international significance.

I argue simply that you look at the three biggest cities: Boston, with Harvard and MIT; London, with Imperial College and Oxbridge; and Melbourne, with the sophistication of the Parkville precinct, with all our medical research leaders (connected to the University of Melbourne). Then you reach across to the 'great southern hub,' which is Monash University and CSIRO, and then you look at the manufacturing of vaccines, and we have the manufacturing arm in Broadmeadows with CSL. We have the extra $1.8 billion deal, with the former federal government, for new vaccines against influenza nearby. So, there is your manufacturing hub. There will be others to come, no doubt, with the manufacturing of mRNA.

New Innovations and Insights

www.consultmed.co

Memorandum 2022

We partner with clinicians and healthcare organisations to shape a future that is connected, digital and data-driven.

The problem

In Australia, the majority (>80%) of referrals from primary care to specialists are **sent via fax, post or hand delivered.**

Paper referrals may be misplaced, lost in transit or have relevant clinical information missing. At no stage does the patient or GP have any visibility as to whether the referral has been received, triaged or processed.

Appointment wait time 4-6 weeks

| 15+ million	9+ million	> 80%
referrals to specialists	referrals to allied health	referrals sent via fax or post

Paper-based referral systems contribute to:

⊗ Long wait times for specialist appointments

⊗ High administrative costs

⊗ Unnecessary and repeat investigations

⊗ Poor patient and provider experience

⊗ Risk to patient safety due to missed referrals

⊗ Inaccurate and incomplete healthcare data

"Hello, Dr Allen here. Just wondering if you received a referral for my patient?"

"Thanks doctor, please hold..."

"Sorry, your referral has expired. Could you please get another one faxed from your GP?"

Let's improve the way we deliver healthcare

Consultmed is a user-friendly and integrated referral management platform that connects primary care providers (e.g. GPs, physiotherapists) directly to specialists and hospital networks.
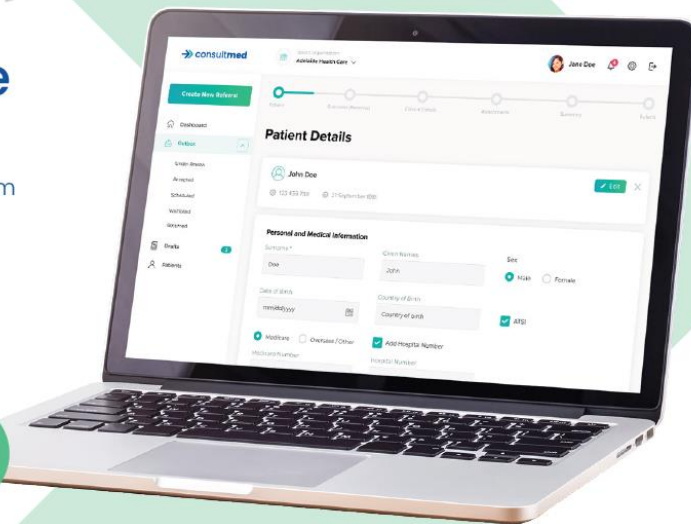
→ consult**med**.co

Digital referrals are finally here

Our web-based referral platform facilitates secure, digital communication between healthcare providers and automates laborious administrative workflows.

Patients and healthcare providers benefit by having complete visibility of the referral pathway. Referrals are tracked and users notified when the referral has been received, triaged and an appointment scheduled.

Patient

GPs + nurses
+ allied health

Hospitals +
specialist clinics
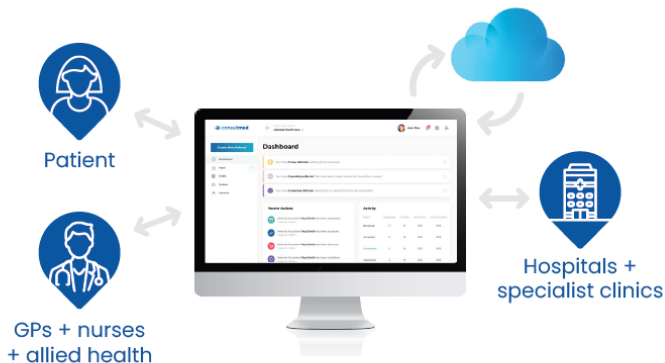
20%
Unnecessary outpatient visits that can be prevented with remote advice and guidance

50%
Reduction in missed outpatient appointments

75%
Reduction in administrative time spent processing each referral

85%
Patients who receive their appointment within 7 days of referral

*Published NHS England data in 2018

Technology enabled care

Our referral portal is **integrated** with GP practice management software and hospital electronic medical record systems. This allows for **seamless** referrals between healthcare providers.
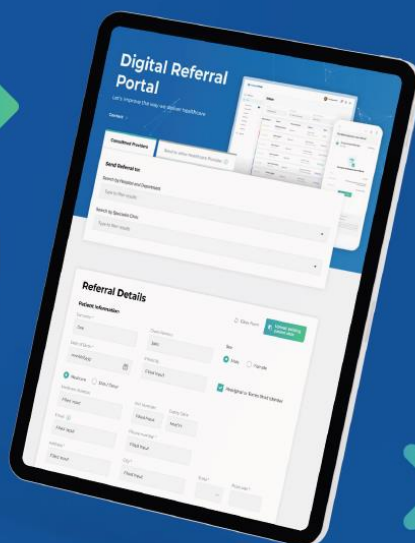
Advice & Guidance, virtual triage, expert opinion

Our A&G portal allows specialists to securely provide remote clinical advice, virtual triage and second opinion services.
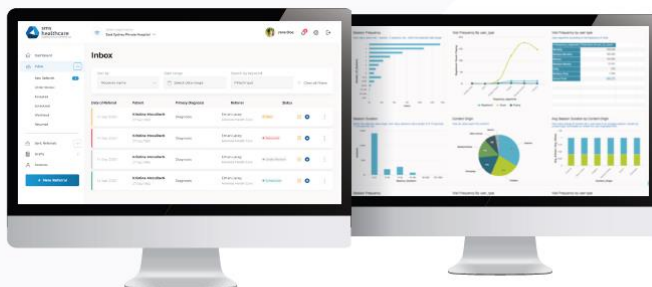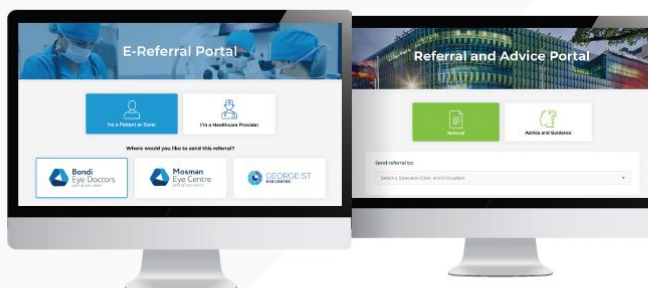
Data analytics & user insights

We provide real-time, referral data for healthcare organisations to generate actionable insights and to inform evidence-based decisions.

consultmed.co

We take the privacy and security of patient data very seriously

Our platform has been designed and built to meet the highest standards of security, storage and data privacy.

» HIPAA and Australian Digital Health Standards compliant

» Health Level 7 (HL7) clinical messaging and exchange standard

» All data is encrypted in transit and storage. We are working towards meeting ISO27001 certification

» Healthcare data is stored locally in Government endorsed data centres

» We maintain an information security management system with regular quality assurance and security penetration testing
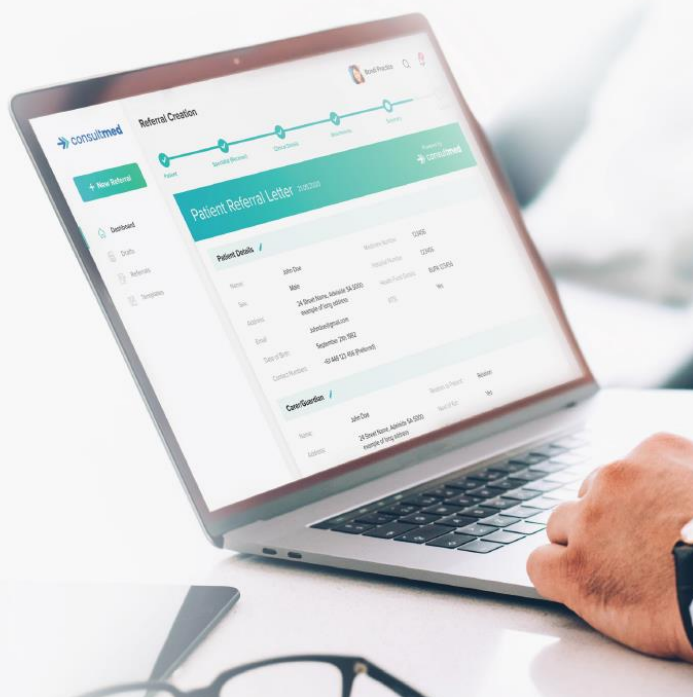
Better, connected care

Empower patients with better outcomes

Patients can self-refer and directly access their referrals via the platform

Eliminate paper referrals

Secure and paper-less message delivery between healthcare providers

Faster referral to treatment times

Instant messaging reduces turnaround time for specialist appointments

Complete visibility and peace of mind

Referrals are tracked and users notified when referrals have been received, triaged and an appointment scheduled

Increased efficiency and cost-saving

Less administrative costs, missed appointments and increased patient-facing time for staff

Advice and Guidance

Access expert specialist opinion easily and remotely with our A&G feature

Commercial Partner

Sydney Children's Hospitals Network (SCHN)

We are proud to partner with the largest paediatric health service in Australia.

Paediatric specialist referrals have increased by over 25% in the last 3 years. SCHN has adopted the Consultmed solution to offer digital referrals, clinical triage and advice and guidance. Our platform improves access to specialist care for children and adolescents across NSW.
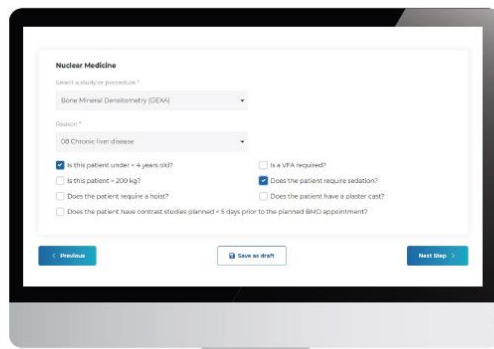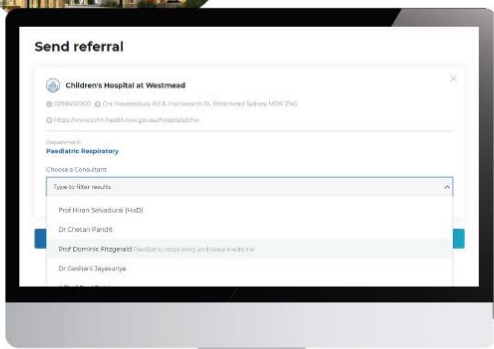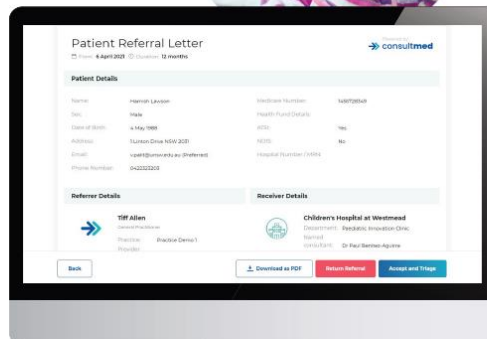
Our service is being used everyday by **hundreds of GPs, specialists and administrators** to send and receive digital referrals.

For outpatient clinics at Westmead and Randwick hospitals, automating resource-intensive workflows reduces administrative costs and frees up patient-facing time for staff.

Business model
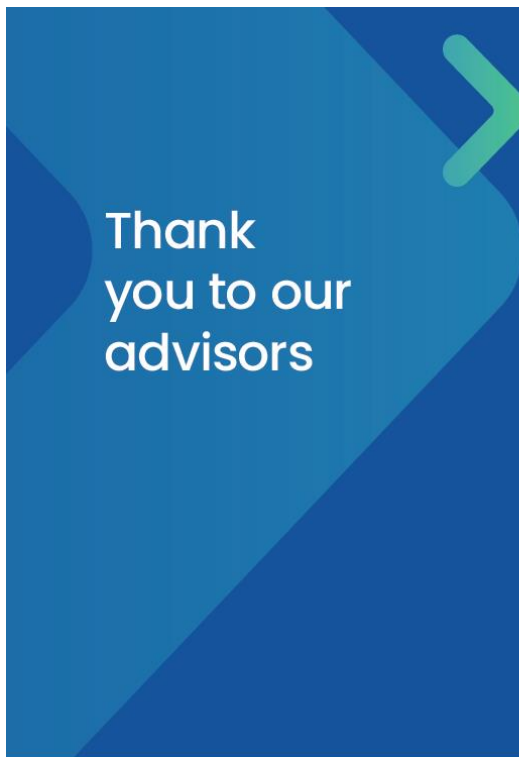
Enterprise-grade solution that connects healthcare providers (HCPs) seamlessly to an integrated and secure ecosystem.

Subscription delivery

Specialist clinics, hospitals and healthcare networks pay an annual fee to license our software.

Healthcare network
- Multiple hospitals and clinics
- Advice and Guidance tool
- Second opinion services
- Unlimited users
- Unlimited referrals

Specialist clinic
- 1-10 specialists
- < 3 locations
- Unlimited referrals

Hospital
- < 200 specialists
- 1-20 departments
- Unlimited referrals
- Advice and Guidance tool

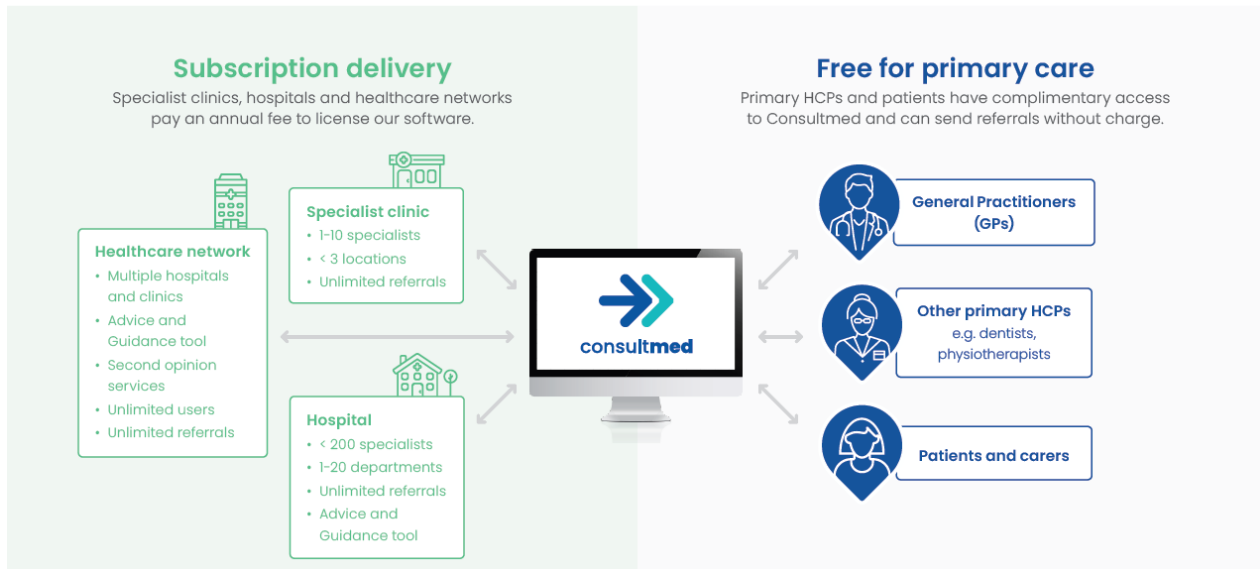consultmed

Free for primary care

Primary HCPs and patients have complimentary access to Consultmed and can send referrals without charge.

General Practitioners (GPs)

Other primary HCPs
e.g. dentists, physiotherapists

Patients and carers

The team that ditched the fax machine

Dr Vikram Palit
Founder and CEO
Paediatrician
Snr Lecturer Health
Management UNSW

Richard Kwan
Chief Technology Officer
CEO of Kiratech Pty Ltd

Stephanie Hodgson
Head of Product
Healthcare Manager
Clinical Physiotherapist

Dr Abidev Kuhasri
Analyst
Medical doctor

Tiffany Allen
Implementation Consultant
Research analyst

Vlad Vasilenko
Project Manager
Software Engineer

Iskandar Kunishev
Lead UI/UX Designer

Tommy Ang
Software Engineer

Sal Cavallaro
Creative Consultant

Thank you to our advisors

Dr Paul Benitez-Aguirre
Paediatric Endocrinologist
Chief Clinical
Information Officer

Jeeva Suresh
CEO of Helix Collective
Mentor at Antler

Dr Ashley Kras
Ophthalmologist
Medical Informatics
Specialist

Rama Kumble
Healthcare IT Consultant
CTO at MedTech Global

Fergus Koochew
Founder, Investor,
Commercial Advisor

Dr Raghav Murali-Ganesh
CEO of Canceraid
Radiation Oncologist

NSW • Microsoft for Startups • Government of South Australia • The Sydney Children's Hospitals Network • investible

COVID-19 in NSW – Experiences, Lessons and Challenges into the Future

Susan Pearce
Secretary, NSW Health
27 June 2022

The health environment in NSW, 2019-2022

NSW's COVID response structure was built on the back of BAU

Statewide

Public Health/Operational Health response structures
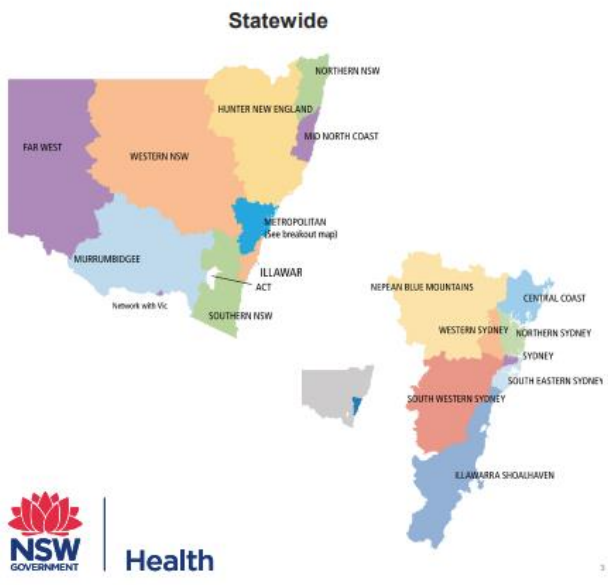
Established pre COVID:

- Human Influenza Emergency Plan
- NSW Health Influenza Pandemic Plan
- State and NSW Health Emergency Management Plans and structures

Key statistics

700+ Vaccination clinics established

289,153 People through hotel quarantine

8 'Health hotels' established

93% Double vaccination rate 16yo+

Qudos Bank Arena Mass Vaccination Centre
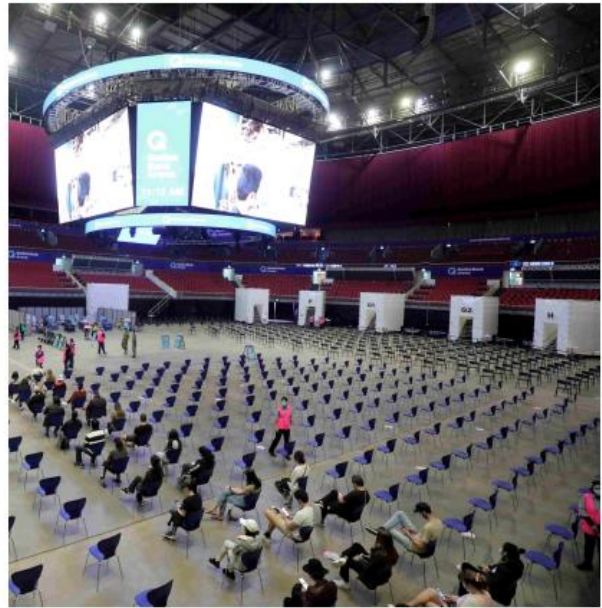
Sydney Olympic Park Mass Vaccination Centre

Culturally safe care

- Mobile outreach vaccination clinics
- Motorhomes to enable isolation or distancing

Agility, innovation and partnerships

- Combat agency role
- State Emergency Operations Controller
- RFS facilities at Homebush

Delta Microstrategy Timeline

COVID Care in the Community patient flow model

Delta Microstrategy Governance model

Executive Committee: NSW Health and NSW Police

Health	Health	Health	Health with Treasury + Resilience NSW	Multicultural NSW	Small Business Commissioner	Public Service Commission	Aboriginal Affairs
Intensify vaccine roll-out, focusing on priority at-risk people and locations	Broaden testing modalities and protocols to target and expand overall volume	Identify risks and support people to comply with public health orders	Provide direct payments to individuals and businesses to increase local cooperation	Empower community groups to deliver local services and support	Partner with businesses to reduce mobility and minimise exposure	Support NSW Public Service to reduce mobility and minimise exposure	Aboriginal Rural & Regional delta response

Delta Coordination Team
- Coordination/PMO
- Clinical Evidence
- Data & Quantitative Tools
- Design & Implementation Support

Input/coordination
- Data Analytics Centre
- Education
- Transport

Emergency Management, Relief and Recovery — **NSW Police**   **Resilience NSW**
Via established SERM Act arrangements, e.g., SEOC/REOC/LEOC structures for operations

Delta Communications and Micro Engagement   **Department of Customer Service**
With coordination through PIFAC

Implementation in line with established SERM Act arrangements

---

The one-system environment – COVID care in the community

Partnerships design and commission services appropriate for local needs, leveraging existing services and providers

Systems and technology enablers:
- Health Pathways
- Regional providers
- Patient Flow Portal
- LUMOS
- PRMs*

*For further development

Wheel labels:
- Clinical Assessment & Triage service
- GP led clinical management
- Patient education & onboarding
- Patient monitoring and support
- Virtual Care, APPs, remote monitoring
- Phone consults and follow-up
- Community care visits (nursing, AH, MH, social care)
- Aged Care services
- 24 access service
- Specialist supported telehealth
- Escalation & transfer to acute care

11

11

Agility, innovation and partnerships

- Virtual care, eg rpaVirtual

- Text messaging by NSW Pathology

- Sharing data and information across all government agencies

- Fast tracking capital projects

- Private hospital viability contracts

NSW GOVERNMENT | Health

Lessons learned and looking to the future

- We couldn't have done it alone. A pandemic has domains far beyond health.

- Translation of public health considerations into government decision making

- The psyche of the Australian population and behavioural insights

- The role of media and comms in pandemic management

NSW GOVERNMENT | Health

What digital skills do our health professionals need to practice?

Tim Shaw
Professor of Digital Health
University of Sydney

Flagship Research Lead | Digital Health CRC

Digital Health Education Frameworks for Workforce

The University of Sydney

Page 3

Linking skills with growing complexity of digital health
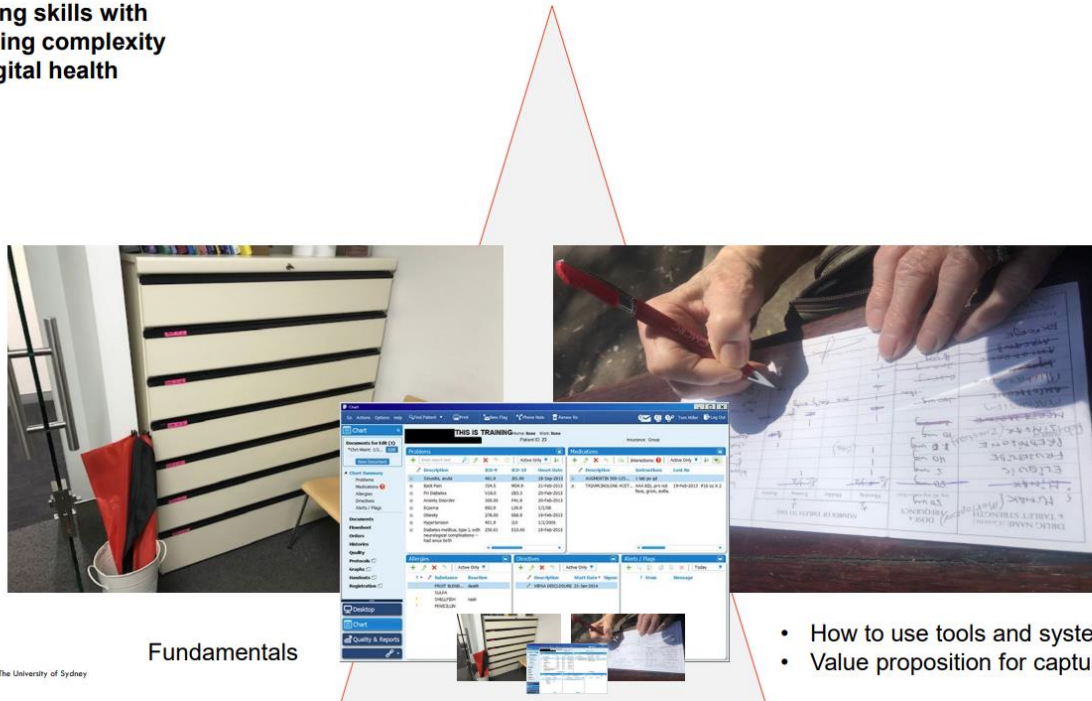
Fundamentals

The University of Sydney

- How to use tools and system
- Value proposition for capturing data

Linking skills with growing complexity of digital health

Substitution and monitoring

Fundamentals

- Technical competency
- Which patients for telehealth?
- Which part of clinical pathway?
- Maintaining therapeutic relationship

- How to use tools and system
- Value proposition for capturing data

The University of Sydney

Linking skills with growing complexity of digital health

Integrated and personalised model

Equity of access
Evaluating AI
Integrating new data sets
- Using digital tools for collaboration
- Skills for new practitioners (navigators, behavioural scientists)
- Health skills for tech developers

Substitution and monitoring

- Technical competency
- Which patients for telehealth?
- Which part of clinical pathway?
- Maintaining therapeutic relationship

Fundamentals

- How to use tools and system
- Value proposition for capturing data

The University of Sydney

Linking skills with growing complexity of digital health

Direct to Consumer
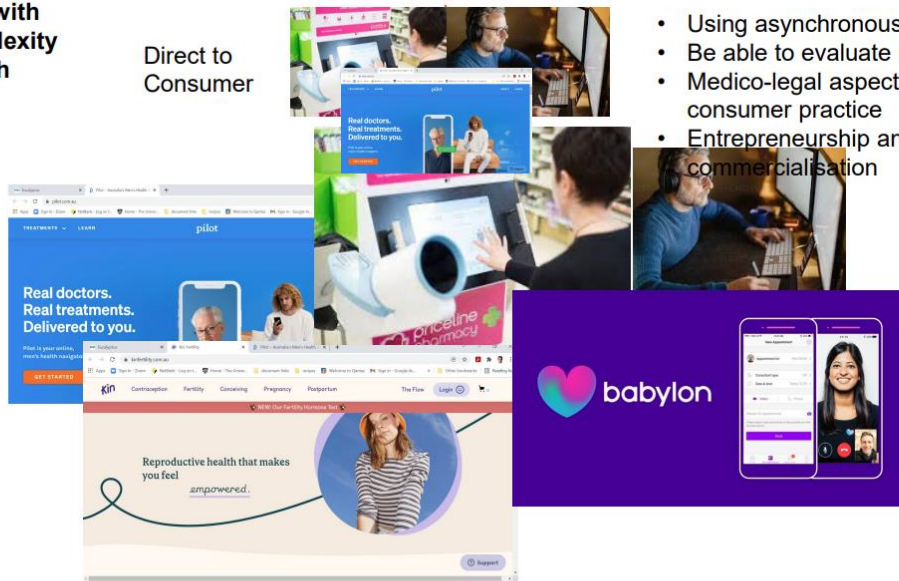
- Using asynchronous communication
- Be able to evaluate DTx
- Medico-legal aspects of direct to consumer practice
- Entrepreneurship and commercialisation

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...ship

Fundamentals

- How to use tools and system
- Value proposition for capturing data

The University of Sydney

Linking skills with growing complexity of digital health

Providers of learning

- Universities
- Government
- Service providers
- Professional Colleges
- Commercial providers
- DHCRC
- ANDHealth
- CXIOs
- Peers
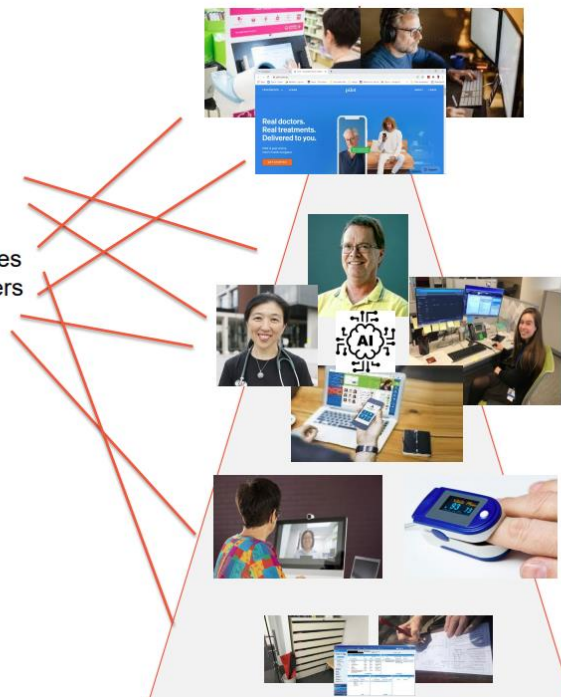
- Using asynchronous communication
- Be able to evaluate DTx
- Medico-legal aspects of direct to consumer practice
- Entrepreneurship and commercialisation

- Equity of access
- Evaluating AI
- Integrating new data sets
- Using digital tools for collaboration
- Skills for new practitioners (navigators, behavioural scientists)
- Health skills for tech developers

- Technical competency
- Which patients for telehealth?
- Which part of clinical pathway?
- Maintaining therapeutic relationship

- How to use tools and system
- Value proposition for capturing data

The University of Sydney

Learning from our consumers and co-design

Collaboration

Health Education England and Australian Medical Council already sharing a discussion on collaborating in Digital Health Workforce Development

Could we expand and join this?

What other opportunities are there to work together?

Australian Government
Department of Health
Therapeutic Goods Administration

AUSTRALIAN BRITISH HEALTH CATALYST 2022

Regulation of Digital Health Solutions

Tracey Duffy
First Assistant Secretary
Medical Devices & Product Quality Division
Australian Government Department of Health

June 2022

AUSTRALIAN BRITISH CHAMBER of COMMERCE

TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration - TGA

Who we are and what we do

- Regulate supply, import, export, manufacturing and advertising of **therapeutic goods**
- **Cost recovered** organisation (through fees and charges), but part of the Department of Health
- **Safety** and **performance** of medical devices - pre-market and post-market
- Small regulator therefore a range of **comparable overseas regulator** (recognition) arrangements in place
- A founding member of the **International Medical Device Regulators Forum** – and current Chair

1

How can digital technologies improve patient outcomes?

- **Easier access to services and information, e.g.**
  - E-scripts (50 m issued in Australia so far), telehealth (91 % of healthcare providers have used), electronic health records (68 m consumer views in last 12 months)
- **Digital therapeutics** – virtual reality for psychological conditions, diabetes and heart disease monitoring apps, apps and smart pills to increase medication adherence
- More **complete, continuous/ remote monitoring of patients**
- More **objective and consistent measures** e.g. reduce physician variation
- Better **Clinical trials**
  - **Endpoints can be more relevant**, especially if data is entered by patients
  - More **subtle clinical trial measures** e.g. in Parkinson's disease
  - **Round the clock monitoring** of patient measures
  - **Remote monitoring/ clinical trial conduct**

General wellness apps
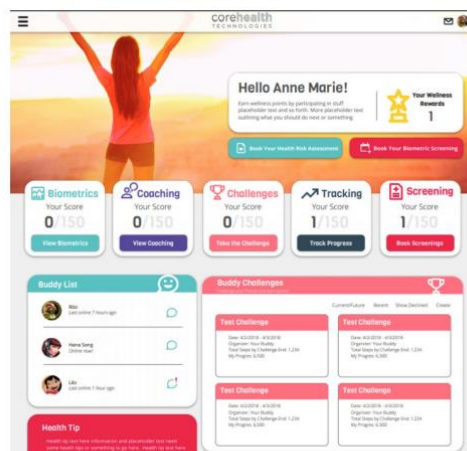
4

Mental health apps

5

Apps to assess pain in non verbal people
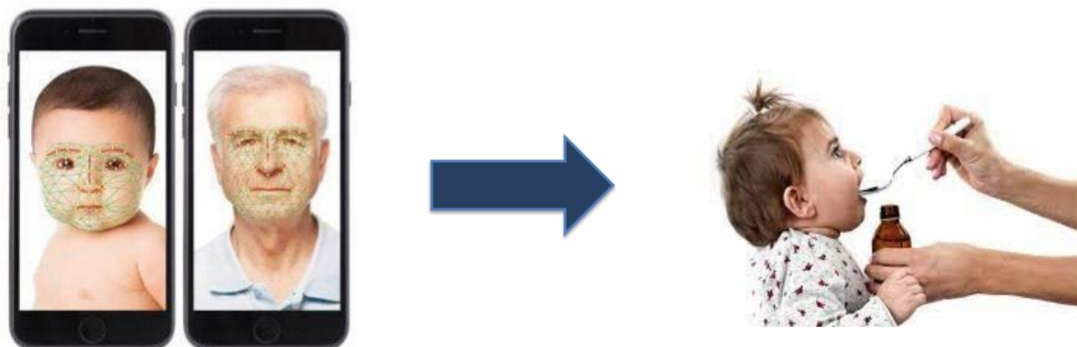
Increasing the power of GP consultations
Eye disease AI screening system TGA-approved

- New AI software system for GPs to screen for 3 major eye diseases (class IIa device)
- Can automatically screen people at risk of developing diabetic retinopathy, age-related macular degeneration and glaucoma
- Software used in combination with retinal imaging devices
- Once high-resolution images of the eye have been captured and submitted, screening results available in under 60 seconds
- if referable stage disease is detected the iPredict report recommends a visit to an ophthalmologist for treatment
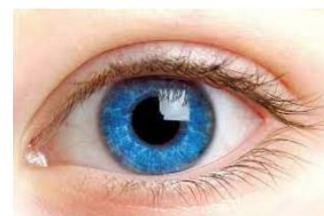
Wearable devices

- 305 million sold globally in 2021 (ABI research data)
- Fitness/ lifestyle - Steps, sleep, exercise, heart rate, bioimpedance (body fat)
- Medical device applications – ECG (atrial fibrillation), SpO2 (oxygen saturation)

Plusses

- Detect changes over time, monitor under stress, continuous monitoring
- More accurate than reporting from memory
- Can encourage greater physical activity

Minuses

- Need to understand context for lay user
- Lower accuracy than clinical tests

8

Which digital / software products are regulated as medical devices ?

- Software is a medical device when the manufacturer intends for its product to be used for **diagnosis, prevention, monitoring, treatment, alleviation of disease, injury or disability**

- It's a rather wide definition – includes **software such as mobile apps through to software that runs dedicated medical devices**

- Depending on the **intended purpose**, a particular product could be
  - **Software as a medical device** (SaMD) – regulated by the TGA, OR
  - SaMD **carved out from TGA regulation**, OR
  - **Consumer health software** – not regulated formally

9

Australian Government
Department of Health
Therapeutic Goods Administration

When is software regulated as a medical device?

- A **medical device** is: any instrument, apparatus, appliance, **software**, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, for:
  - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability

- This means:
  - digital - software on **any computing platforms** (computers, tablets, smartphones, browsers);
  - software that is **part of a medical device** - is regulated as part of that device;
  - apps that **control a medical device** - are regulated as an accessory or a device;
  - apps that **rely on medical device hardware** in addition to a general computing platform (e.g. sensors) - are part of a medical device.

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Australian Government
Department of Health
Therapeutic Goods Administration

So….. there are apps/ software that are medical devices and those that are consumer wellness Apps

- **TGA's regulatory framework** for apps that are medical devices in place for several years but further fine tuned since 2019

- There is no regulatory framework for consumer wellness apps but since early 2019 the possibility of a **national mHealth Applications Assessment framework** has been under discussion

- Led by Australian Digital Health Agency, **a framework was designed and public consultation held in late 2021**
  - But no decision at this stage on whether or not to implement an assessment framework or how it would be funded

When it comes to regulation there is a fork in the road

11

**Australian Government
Department of Health
Therapeutic Goods Administration**

How can good regulation improve things?

12

**Australian Government
Department of Health
Therapeutic Goods Administration**

It's only software … so why regulate it ?

- **Need confidence that apps work consistently**
  - ➢ Analytical and clinical performance, consistent results

- **Risk of poor performance** for software is just as great than for physical devices, and
  - ➢ Software developers have **not done as thorough clinical testing as for physical** devices
  - ➢ **There is more limited information** in the refereed literature on clinical or analytical validation

- While software apps are improving, there are several **examples of products incorrectly diagnosing or monitoring serious conditions** e.g. melanoma, arrhythmia or diabetes

**Australian Government
Department of Health
Therapeutic Goods Administration**

Actual and potential harm caused by medical software
A rapid literature review of safety and performance issues

Version 1.0, July 2020

TGA Health Safety Regulation

13

Software is regulated under medical device frameworks but with some fine tuning

Clarifications or specific requirements for:

- management of data and information, including cyber security
- development, production, and maintenance.
- the current version and build number for the software to be made identifiable to users

Changed classification rules for software intended for:

- diagnosing and screening for a disease or condition
- monitoring the state or progression of a disease or condition
- specifying or recommending a treatment or providing therapy (via provision of information)
- differences between end users – consumers versus health professionals

14

TGA carves out particular software from regulation as a device

- If the device presents a **low risk to safety**

  OR

- If **alternative oversight schemes** are in place

- The scope of 'health software' is broader than 'medical device software'

- **Most health software is not a medical device and is not regulated by TGA**

Health software
IEC 82304-1

Health software products
IEC 82304-1

Software as a Medical Device

15

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Department of Health
Therapeutic Goods Administration
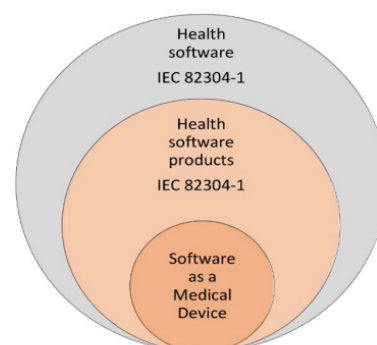
Software "carved out" with conditions

- Some **Clinical Decision Support Software** exempted from <u>some aspects</u> of regulation; and

- 15 product types (grouped into 5 categories) excluded from regulation
    - **Consumer** health products - prevention, management and follow up devices that do not provide specific treatment or treatment suggestions
    - **Digital mental health tools**
    - **Enabling** technology - for telehealth, remote diagnosis, healthcare or dispensing
    - **Digitisation** - of paper based or other published clinical rules or data including simple calculators and Electronic Medical Records
    - **Analytics** - population based
    - **Laboratory Information Management Systems**

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Therapeutic Goods Administration

Classification of digital devices – risk of harm

Classification	Class I	Class Im	Class IIa	Class IIb	Class III
Risk	Low risk	Low-Medium risk		Medium-High risk	High risk
Software Example	Hearing loss diagnosis	Goniometer	ECG app	ICU breathing monitoring	Melanoma diagnosis to consumer

Classification principles and rules are defined in
Therapeutic Goods (Medical Devices) Regulations
2002, Part 3 Division 3.1 and Schedules 2

RISK

17

Challenges for digital devices

- Many new players innovating who are new to regulation (or not aware)
- Breadth of applications of digital technology and increasing sophistication
- Direct to consumers – consequences different for health professional users
- "Move fast, break things" – speed of getting to market compromises quality
- Human factors – how people use software vs its design (intended purpose)
- Change control and user configuration of software after release (function creep)
- Traceability of errors and their role in adverse events
- Collecting enormous quantity of data (driving machine learning, artificial intelligence – use of real world data), cloud storage, privacy, consent
- Real world evidence: how, what, where? Bias?
- Are standards and guidance keeping up?

18

Some key differences from other jurisdictions

- Classification rules in Australia consider items that EU rules do not:
  - **user** – if a consumer or health professional
  - **public health** risk
  - **software** and also programmed and programmable hardware – much broader scope

  (Australian classification the same or lower in most cases)
- EU rules account for "**inform or drive treatment**" – Australian rules do not
- Digital **mental health** excluded from Australian framework (conditionally) – EU and US do not exclude these
- **Clinical decision support** software exempt in Australian framework (conditionally) – not medical devices in US/Canada
- **Wearables** - Australian approach (e.g. for smart watches) for SaMD apps – require evidence of validation against the sensor – EU and US do not

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International collaboration

- Australia is chair of the International Medical Device Regulators Forum (IMDRF) for 2022

- Collaboration with MHRA and Regulatory Horizons Council

- Alignment and sharing experience with other countries eg: UK, EU, Health Canada, US, for example via multilateral Digital Health Technology Think Tank and bilateral meetings

- Working with World Health Organization on apps using machine learning

- Standards Liaison Program in international standards development (IEC TC62 and ISO/TC 210)

21 February 2022

20

M M
MOTT MACDONALD

What does the health precinct of the future look like?

29 June 2022

What does the health precinct of the future look like?

Health…

The state of being free from illness or injury

Is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Precinct…

The area that surrounds a building or place, especially one with a wall around it.

The area within the walls or perceived boundaries of a particular building or place.

An enclosure between buildings, walls, etc.

An area in a town designated for specific or restricted use, especially one which is closed to traffic.

Mott MacDonald

A world of conflicting pressures

CLIMATE CRISIS
Direct and indirect effects of climate change

INEQUALITY CRISIS
Socio-economic inequalities
Lack of access and opportunity
Lack of empowerment

HEALTH CRISIS
Aging populations
Complex and multiple conditions

SOCIAL JUSTICE
Lack of just democracy
Government corruption

ECOLOGICAL CRISIS
Biodiversity loss
Ecosystem degradation

ECONOMIC CRISIS?
Upcoming recession?

Mott MacDonald

Societal Redesign
Doughnut Economics
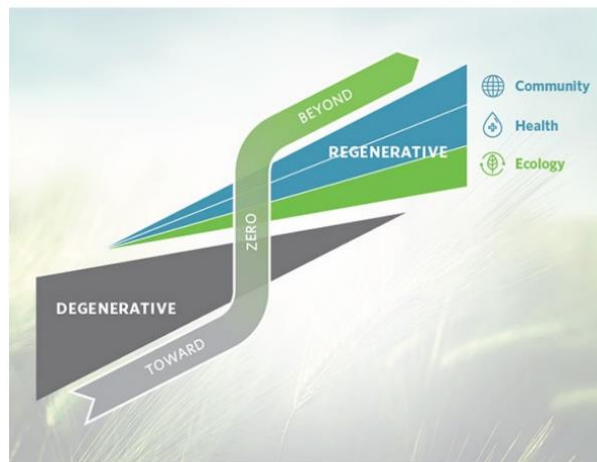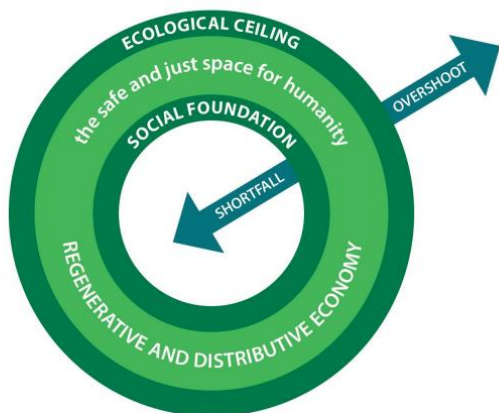
Ref HDS Architects

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Drivers of change

INVESTOR PRESSURE - ESG

POLICY - LEVELLING UP

GOVERNMENT COMMITMENTS

CUSTOMER EXPECTATIONS

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East Vancouver Integrated Healthcare and Social Housing, HDR

Integrated social facilities
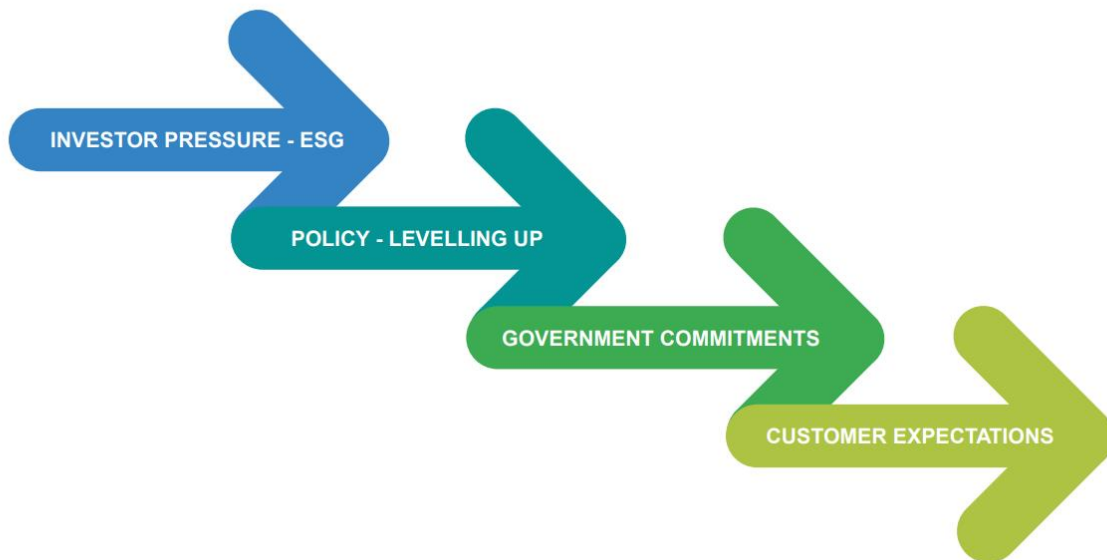
Our Hospital, Jersey, UK

Integrated functions

Design for diversity and disability

Oriel Eye Hospital, London

Accessibility

Southmead Hospital, Bristol, UK

Social empowerment
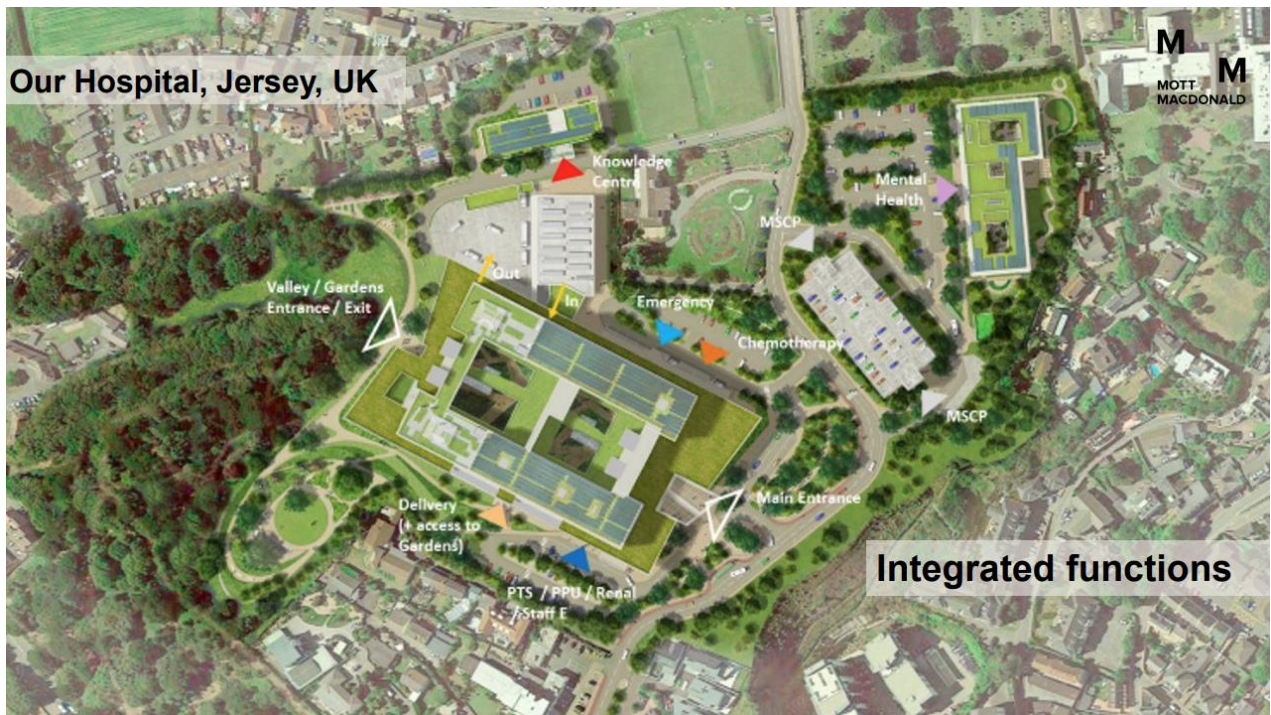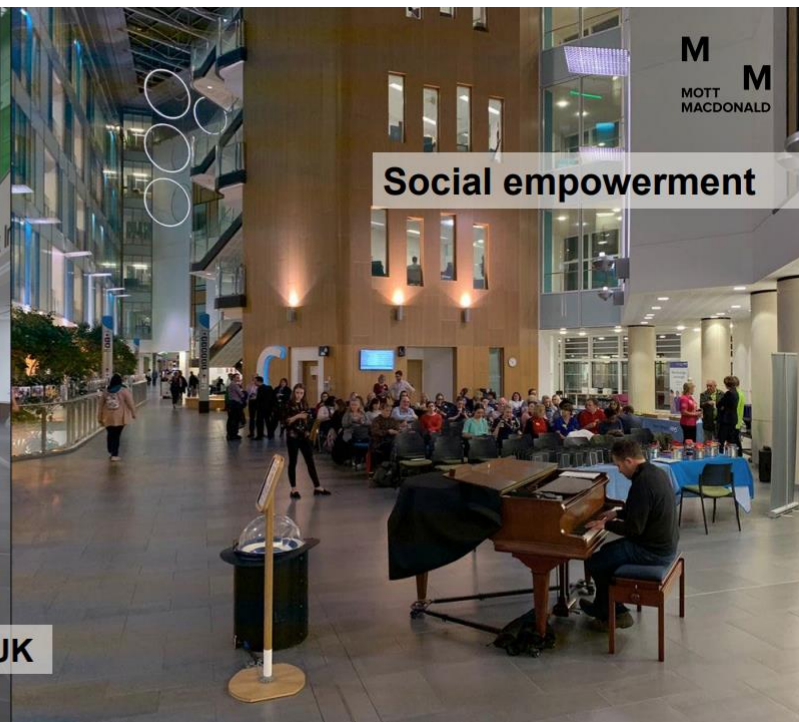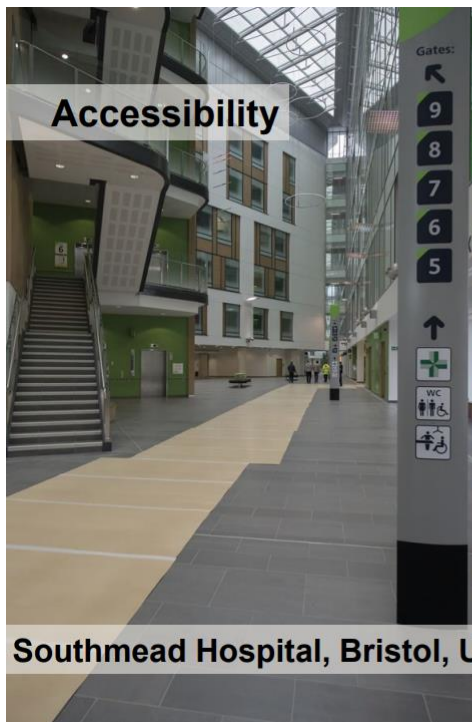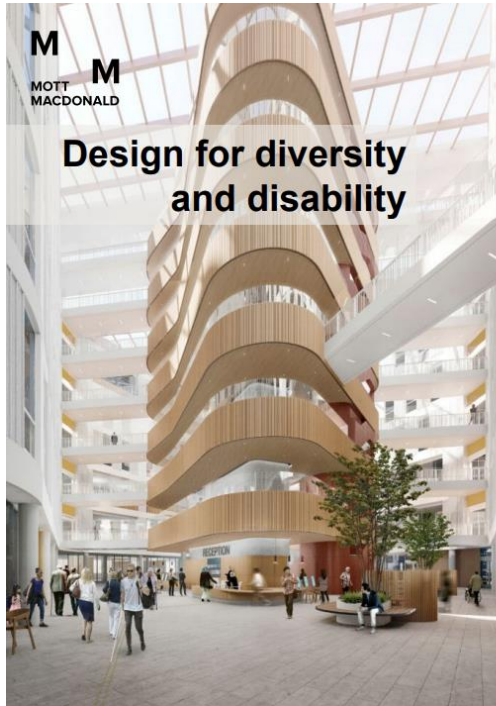
Joseph Bracops Hospital, Brussels
Adaptability

'shearing layers' design
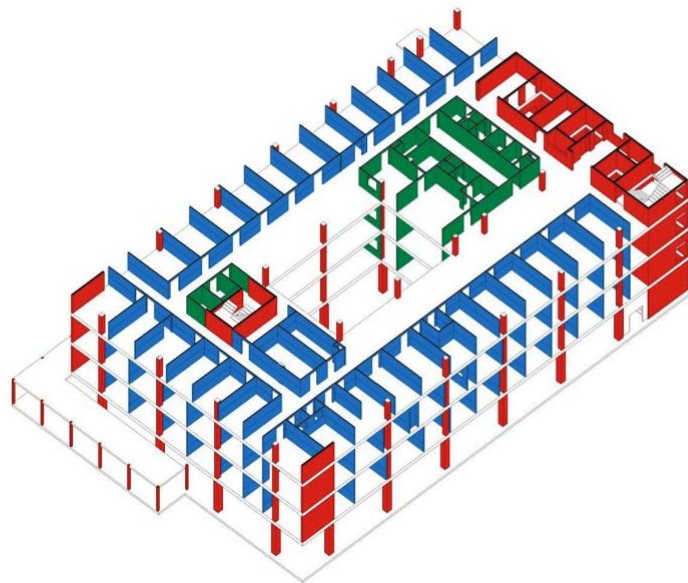
Maggie's Centre, Leeds

Biophilic design and inspiration
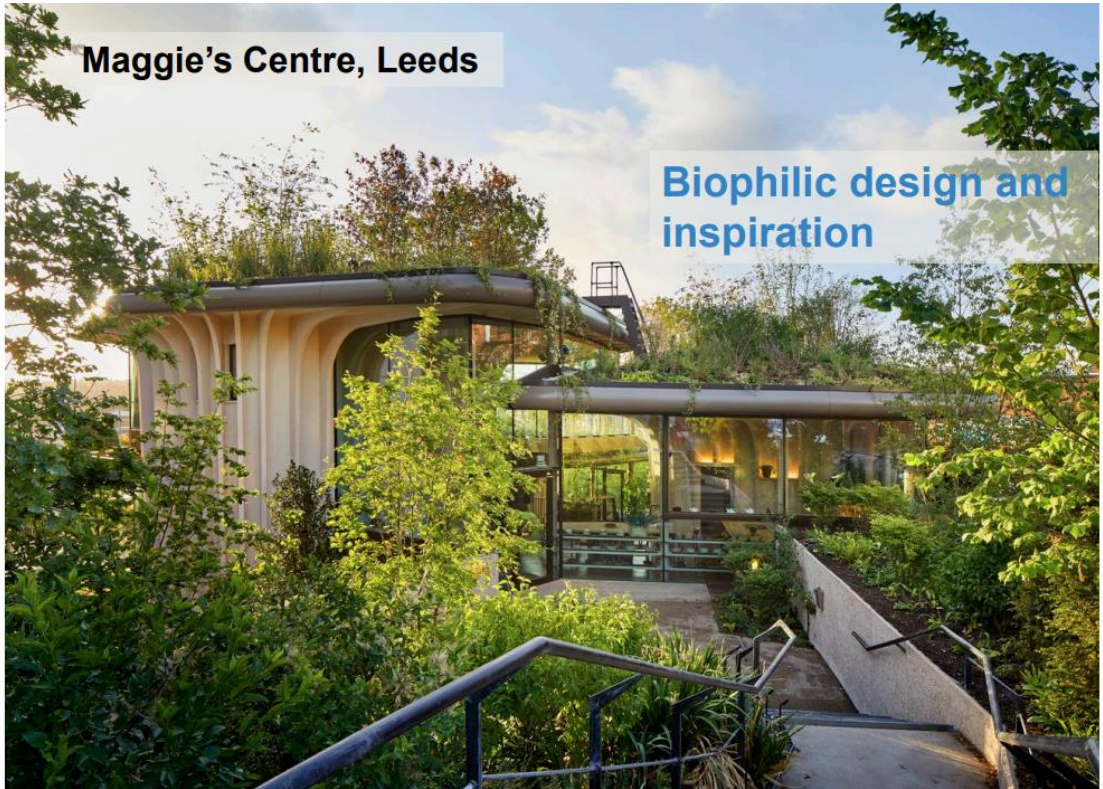
Mott MacDonald

Biophilic design and inspiration

Maggie's Centre, Leeds
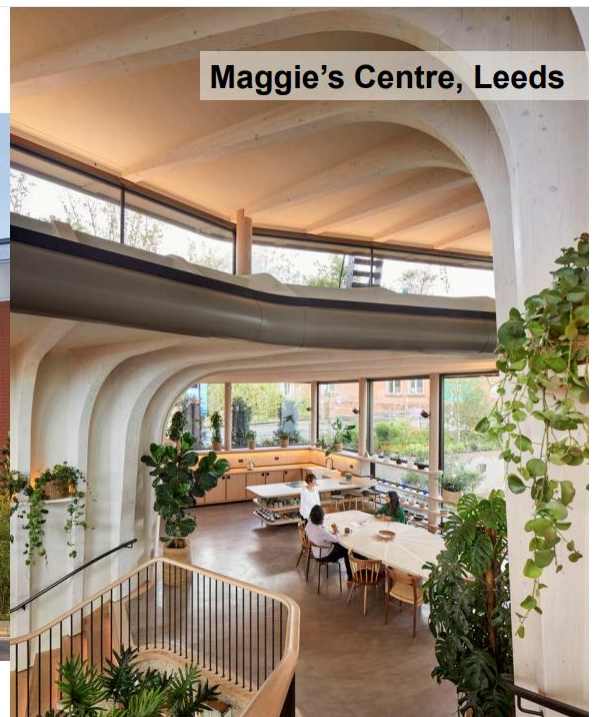
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The Spine, Liverpool

Biomimicry

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14

Nature based design

The Spine, Liverpool

Shenzen Children's Hospital

Creativity, play and discovery
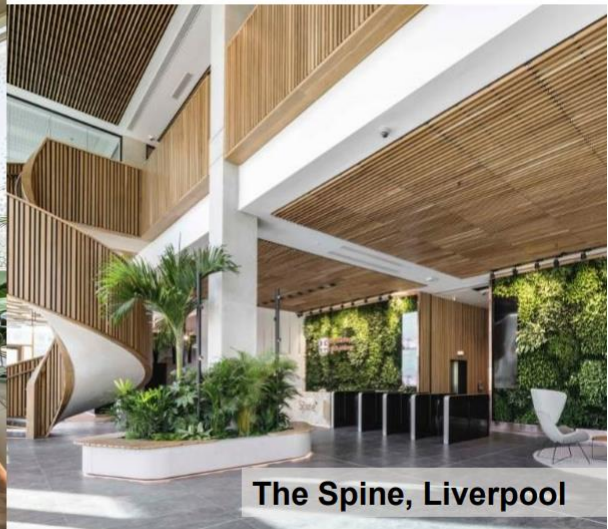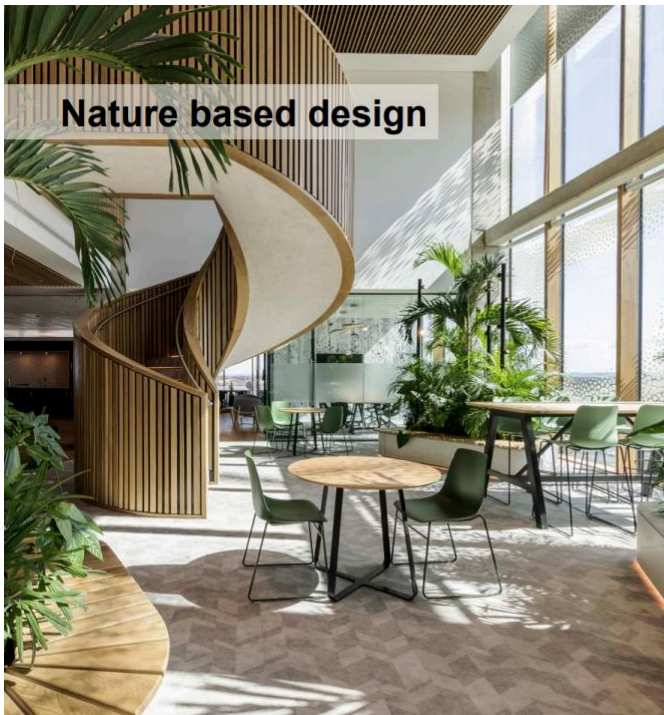
Enabling a health precinct, more than just buildings?
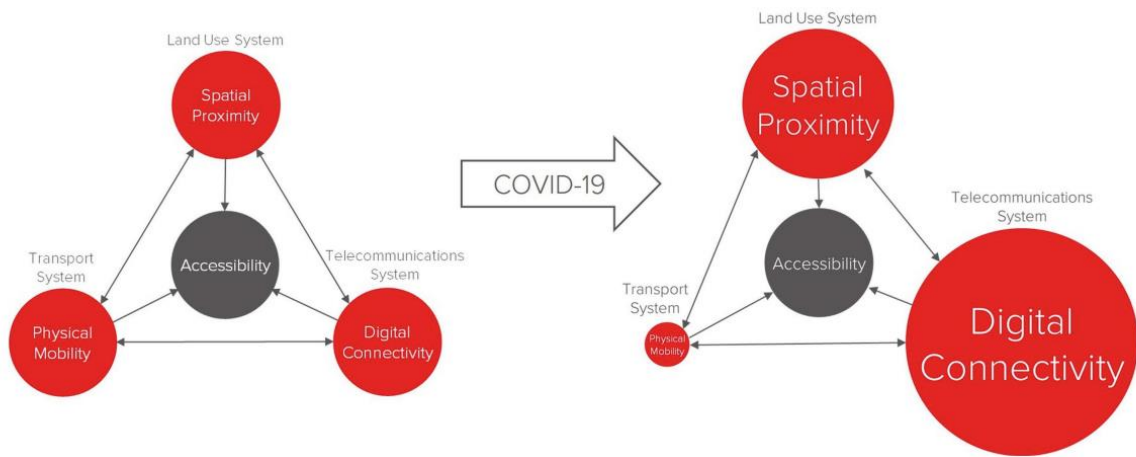
Mott MacDonald

'Heterarchy' – a system of systems

Economic infrastructure

Social infrastructure

Natural environment

Our built environment is an interconnected system of systems
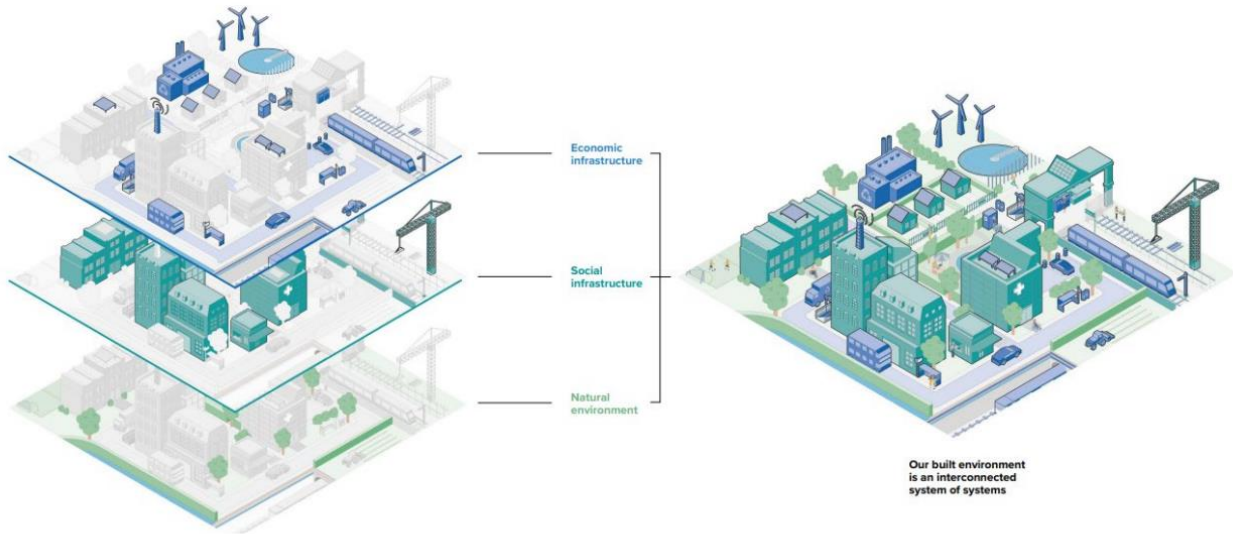
Mott MacDonald

Lowering barriers to the adoption of Digital Therapeutics

Liz Ashall-Payne Founding CEO, ORCHA

DIGITAL HEALTH. UNLOCKED.

With **365,000** digital health products to choose from, how do you know which are safe, effective, and suited to your client?

Imagine if the same were true for medication.
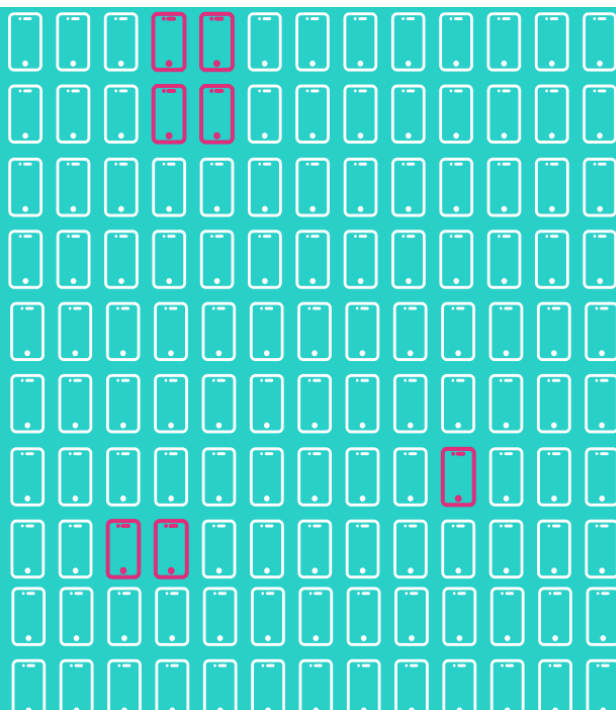
THE DIGITAL HEALTH OPPORTUNITY
LEARNING FROM OTHER AREAS

In all other areas of health and care we have the critical infrastructure in place for safe decision making and distribution...

...digital health is not different?

E-prescribing to distribute and track medicines

The BNF to know when and how to prescribe

NICE to assess impact and effectiveness

MHRA to approve and licence drugs

It all starts with trust

ORCHA

ORCHA

DIGITAL HEALTH ASSESSMENT FRAMEWORKS

There are multiple frameworks to help NHS and local authorities to assess a digital health solution.

They include universal regulations and specific measures developed purely for digital health.

There are a lot of common requirements for:
- Data and privacy
- Usability and accessibility

There is less consensus and convergence in areas:
- Clinical assurance and evidence evaluation
- Security assessment

User experience and clinical analysis is largely un-assessed.

NICE National Institute for Health and Care Excellence
NICE ESF

MHRA Regulating Medicines and Medical Devices
Medical Devices Regulations

NHS nhsx.nhs.uk
The DTAC

ISO
ISO-82304-2

MIND
Mindex

DiGA

MHealth BELGIUM APPROVED
mHealth Belgium - Validation Pyramid

n!p
NORDIC Baseline Review

ORCHA

ORCHA ASSESS AGAINST THESE INTERNATIONAL SCHEMES
HAVING HELPED CREATE MANY OF THEM

	NHS DTAC	EU ISO 82304-2	US Digital Health Assessment	Canadian MHCC	German DiGA	NetherlandG GZ/Mind	5 NORDIC Nations	NZ –Health Navigator
Enhanced Evidence Analysis		✓			✓			✓
Commercial and Financial								
Interoperability							✓	
Clinical Safety	✓	✓			✓			✓
Technical Stability	✓	✓	✓	✓	✓			
Security	✓	✓	✓	✓	✓		✓	
Enhanced Data Analysis	✓			✓				
User Experience			✓			✓	✓	
Clinical Assessment				✓			✓	
ORCHA Baseline Review								
Clinical Assurance	✓	✓	✓	✓	✓	✓	✓	✓
Usability & Accessibility	✓	✓	✓	✓	✓	✓	✓	✓
Data & Privacy	✓	✓	✓	✓	✓	✓	✓	✓
ORCHA Rapid Assessment	✓	✓	✓	✓	✓	✓	✓	✓

ORCHA

Digital Health Infrastructure
Recommending the best!
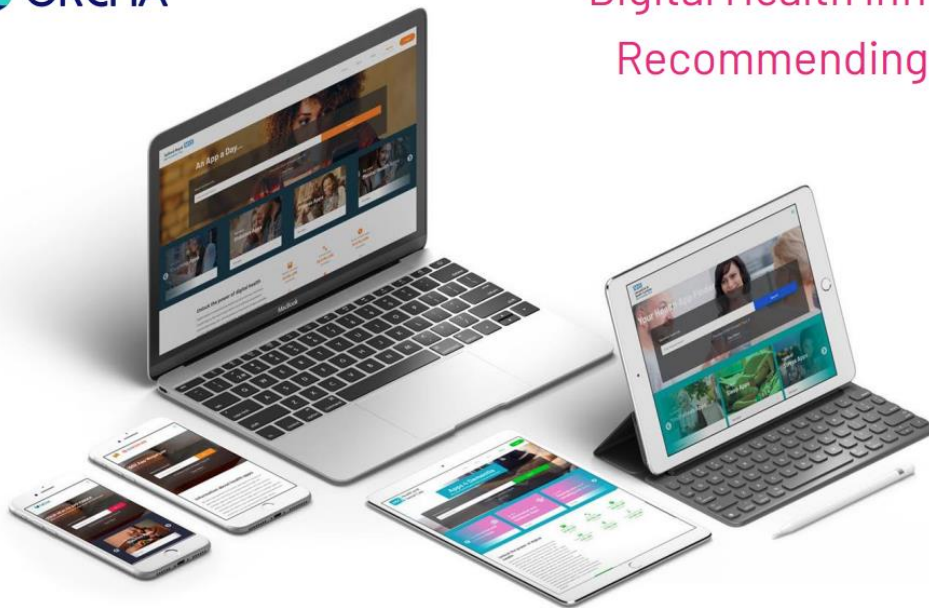
THE DIGITAL HEALTH SOLUTION

Having the right infrastructure in place

GOVERNANCE
GOVERNANCE AND REIMBURSEMENT INFRASTRUCTURE

ACCESSIBILITY
RECOMMENDATION INFRASTRUCTURE

AWARENESS
TRAINING AND ASSESSMENT INFRASTRUCTURE

TRUST
REGULATORY INFRASTRUCTURE

DATA AND INTELLIGENCE PLATFORM

Rx DTx
DIGITAL FORMULARY

x100
ASSESSMENT / TRAINING AT SCALE

DTAC
ISO 82304
DIGITAL HEALTH STANDARDS / FRAMEWORKS

Digital Health Academy
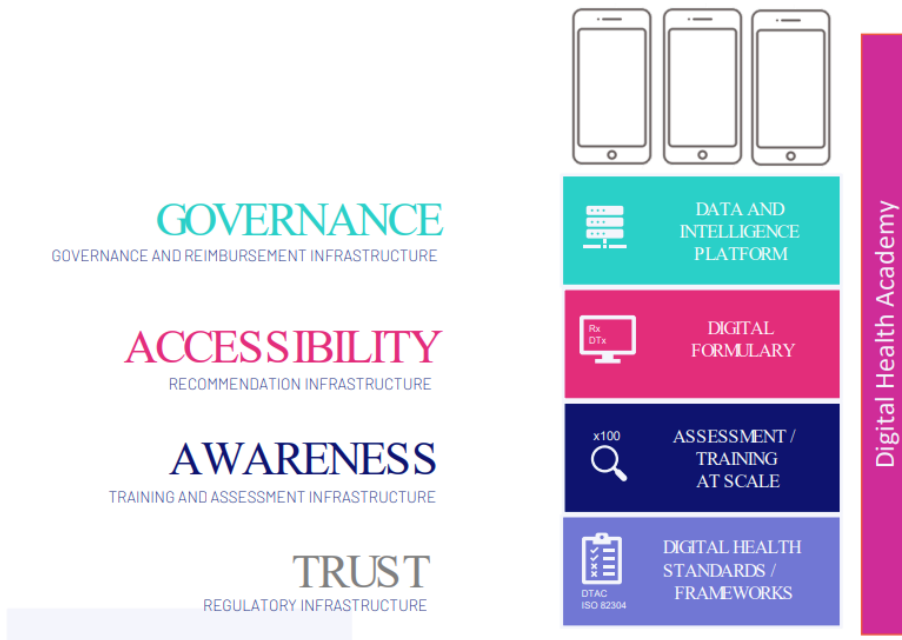
To support this revolution, we must:

- Build trust in digital health

- Overcome awareness and access barriers to deliver activated Health Care Professionals and patients and people

- Have a clear governance and risk management system

ORCHA

Trust

Activate

Governance
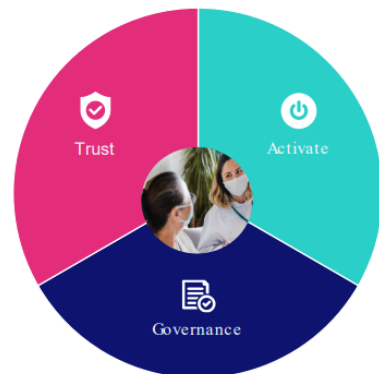
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DIGITAL HEALTH. **UNLOCKED.**

COMMERCIALISING DIGITAL HEALTH COMPANIES – A PROVEN MODEL

AUSTRALIAN BRITISH HEALTH CATALYST

BRONWYN LE GRICE
CEO and Managing Director

ANDHealth is supported by the Australian Government Department of Health

ANDHealth
Australia's National Digital Health Initiative

Australian Government
Department of Health

ABOUT ANDHEALTH

ANDHealth
Australia's National Digital Health Initiative

Australia's only organisation which designs and delivers specialised <u>technology identification, screening and commercialisation programs</u> proven to accelerate the scale up and commercial growth of digital health companies.

Manages the single largest government funded digital health commercialisation program in Australia

Works collaboratively across Australia to bring proven expertise to innovators and demonstrable commercial outcomes.

Australia's only team of specialised digital health commercialisation professionals.

Non-profit and non-equity taking, removing conflicts of interest that exist in most common accelerator and incubator models.

Companies which have participated in ANDHealth programs have impacted over 600,000 patients to date. Participants in our flagship ANDHealth+ program have a 90% financing success rate post-program.

2

ANDHEALTH AREA OF FOCUS

Digital Health is a broad category that encompasses **Digital Medicine**, which in turn includes **Digital Therapeutics**.

Different levels of claims

↳ Different levels of risk

 ↳ Different evidence requirements.

Digital Medicine: high-quality hardware or software technologies as tools for measurement and intervention of human health.

Digital Therapeutics: high-quality software (may also include hardware) to deliver evidence-based therapeutic interventions that prevent, manage, or treat a health condition.

ANDHEALTH FOCUS AREA

Digital Therapeutics

Software that delivers therapeutic intervention to:
- Prevents a disease
- Treat a disease
- Manage a disease
- Mitigates disease
- Improve a health function

> Commercial Evidence + Clinical Evidence + Real World Evidence

Digital Medicine
- E-assessments
- Digital companion
- E-assessments
- Digital diagnostics & biomarkers
- Improve a health function
- Remote patient monitoring
- Decision support software

> Commercial Evidence + Clinical Evidence

Digital Health
- Electronic Medical Records
- Clinical care admin & management tools
- Decision support software
- Telehealth
- HealthIT

> Commercial Evidence

INDUSTRY-LED COOPERATIVE COMMERCIALISATION

ANDHealth's unique model facilitates business investment into digital health product development and commercialisation

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

murdoch children's research institute · NOVARTIS · Planet Innovation · Roche · RMIT UNIVERSITY

curve · Beamtree · HPM Executive Search & Selection · healthxl

PROGRAM PARTNERS

aws activate · MTPConnect MedTech and Pharma Growth Centre · RED DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE Powered by MTPConnect · Australian Government Department of Health Therapeutic Goods Administration · Government of Western Australia · NEW INDUSTRIES WA · NSW GOVERNMENT · cicada INNOVATIONS

INTERNATIONAL PARTNERS

Anthem · DIGITAL THERAPEUTICS ALLIANCE

ECOSYSTEM PARTNERS

HEALTH ROUNDTABLE · AIDH AUSTRALASIAN INSTITUTE OF DIGITAL HEALTH · BioMelbourne Network · MTAA Medical Technology ASSOCIATION OF AUSTRALIA · MSIA MEDICAL SOFTWARE INDUSTRY ASSOCIATION · AusBiotech · informa · MEDTECH ACTUATOR · modern RISK SOLUTIONS · intelliHQ

ANDHEALTH PROGRAMS

Built on a foundation of real-world experience from those who have experienced it.

Direct, factual and verified program content from national and international leaders.

A core capability of commercialisation skills, expertise and networks specific to digital health.

A NOVEL MODEL

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

Quality In = Quality Out
Significant investment of resources and capability in ensuring the quality of the pipeline. Selection processes for later stage programs are incredibly robust.

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

Harness the Collective
Cross-sectoral & multi-disciplinary speakers & advisory teams.

Proven track records: Product development; Commercial Agreement at Scale; or Significant Capital Raising.

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

Not about "start-ups"
Focus and proven ability to scale and commercialise the existing pipeline and improve the ecosystem to create a better "flow through the funnel".

6

ANDHEALTH PROGRAM SUITE

ANDHealth Programs are designed to serve as a conduit whereby international digital health expertise is delivered to program participants. The programs involve tailored support and expert advice from idea to exit.

Needs Assessment/ Idea Generation → State of Readiness Screening → Detailed Feasibility Study → Development & Proof of Concept → Evidence Building → Market Launch

OFFICE HOURS | ELEVATE: SKILL SPECIFIC EXPERT COACHING

BRIGHT IDEATE | BRIGHT INNOVATE | MASTERCLASS

ANDHealth+ Digital Health Accelerator Fund

ANDHealth+ is focused on proof of concept stage companies undertaking necessary research and development to clinically and commercially validate their products

INDUSTRY DEVELOPMENT | ADVOCACY | POLICY SUPPORT | INTERNATIONAL PARTNERSHIPS | CAPABILITY DEVELOPMENT

7

BRIGHT: IDEATE & INNOVATE IN DIGITAL HEALTH

PROBLEM SPACE → **SOLUTION SPACE**

BRIEF → RESEARCH → IMMERSION → GENERATE → HARVEST → TOP IDEAS

DIGITAL HEALTH EXPERTS
Investors, clinicians, serial entrepreneurs, pharmaceutical executives, and more.
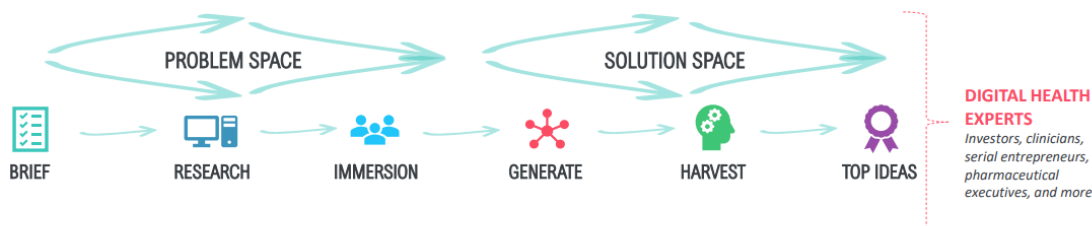
BRIGHT IDEATE: 1 Day Seminar

Designed for early stage digital health innovators who are ideating or developing their prototype, or seeking initial customers. They receive real-word advice on how to address both the technical & commercial challenges of launching a digital-based business.

BRIGHT INNOVATE: 3 Day Workshop

Designed for digital health companies with a business concept they want to develop within a proven innovation framework, establishing feasibility and seeking practical skills and insights to prepare for achieving success.

Program Partners: launchvic — Planet Innovation — RED MTP SECTOR WORKFORCE *Powered by MTPConnect*

MASTERCLASS

RED DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE *Powered by MTPConnect*

Covers topics delivered by industry experts including regulation, intellectual property, governance, finance, business strategy in digital health, health economics, voice of customer, international market entry, investment and sales, in conjunction with a suite of successful case studies.

Industry experts must have a proven track record in digital health:

- Investor, advisor or technology transfer/commercialisation professional in the digital health sector, or;
- Industry professional, consultant, or service provider that actively works with digital health companies, or;
- Academic or policy leader in digital health/health tech/health innovation.

> *"The Masterclass is a mini-MBA in all aspects of the business of digital health taught by industry experts and drawing on the real-world experience of founders of digital health start-ups. It provides invaluable insights and skills and the opportunity to discuss the issues that are most important to scaling a successful digital health product and organisation."* – Participant, Masterclass 2021

Masterclass reported outcomes 2020-21:

$23.2M
Total raised following Masterclass program

365,000+
New patients served

80
New jobs (FTEs)

20
Research projects, pilots or clinical trials commenced

70%
Experienced growth in their team since masterclass

98%
Intend to grow their team in the next 6 months
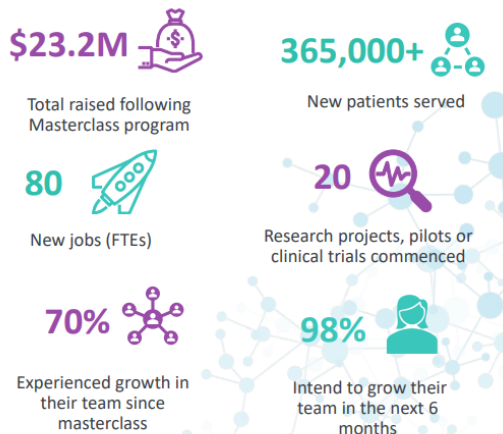
ANDHealth+

GROW

PROGRAM OVERVIEW

perx

"ANDHealth+ is without a doubt the leading digital health program in Australia."
Scott Taylor, CEO & Co-Founder, Perx Health

HIGH IMPACT COMMERCIALISATION SUPPORT

Regular intensive meetings with allocated Industry Advisory Panel members

Hands on project management and administration support, including procurement of core suppliers

Access to a network of professionals with real world "been there, done that" experience

Robust interrogation of core business assumptions & frank, fearless and unfiltered constructive feedback

A support team 100% committed to commercialisation success

Competitive allocation of funds to projects on a 'maximum impact' basis from use of funds to selection of suppliers

INTERNATIONAL INVESTMENT ADVISORY COMMITTEE (IIAC)

CHAIR
Lisa Suennen
Leader of Manatt
Phelps & Phillips
Digital & Technology
Practice; Managing Partner,
Manatt Venture Fund

Bronwyn Le Grice
CEO & Managing Director,
ANDHealth

Anand Iyer
Chief Strategy Officer,
WellDoc

Andrew Murphy
Executive Chairman &
Co-Founder, Robotify Labs
& Partner, Erisbeg Fund

Aenor Sawyer
Director, University of
California Space Health;
UCSF Skeletal Health Service

Bill Lucia
Executive Partner,
Consonance Capital &
HEP Fund

Drew Schiller
CEO,
Validic

Katherine (Kate) Merton
Principal,
Hicks Cohen

Ken Cahill
CEO,
Silvercloud

ANDHEALTH PROVEN OUTCOMES

ANDHealth's leading digital health commercialisation programs have a proven track record of scaling digital health businesses across a broad range of clinical and commercial metrics.

ANDHEALTH PIPELINE GROWTH

ANDHealth's proven commercialisation capability has had a dramatic multiplier effect on the number of Australian digital health companies within the pipeline.

National Digital Health Pipeline Growth 2017-2022
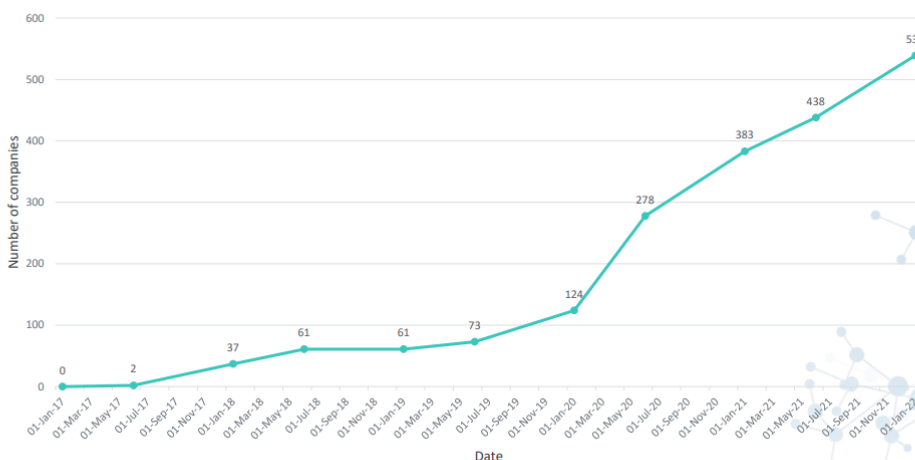
STAGES OF DEVEOPMENT | NATIONAL

ANDHealth's proven central commercialisation capability has had a dramatic multiplier effect on the volume and maturity of Australian digital health companies within the pipeline.

Development of ANDHealth Screened Companies 2020-22
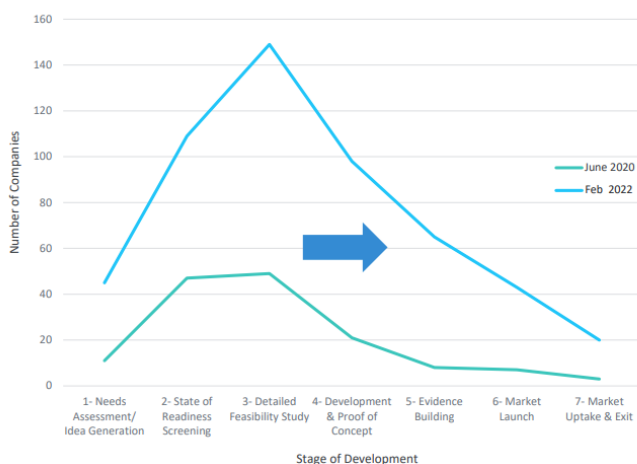
- Pipeline of companies **presents growth** in stages of development. Exhibits a notable increase in number of companies entering mature stages.

- 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 emerging companies, a strong shift in company maturity exists in the industry.

ANDHEALTH+ V1 COHORT COMPANY OUTCOMES

MTPConnect Funded Pilot ANDHealth+ Incubator = 10 Companies
(9 companies continuing & reporting. 1 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.

$74.3M
Raised (dilutive) & non-dilutive)

$31.4M
New revenue

351
New jobs (FTEs)

19
New CxO Roles

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

901
Commercial pilots commenced

45
Clinical trials and studies commenced

23
New international market launches

228
New commercial customers

244,302
New patients served

447
New operational sites

60
New partnerships formed

177
New product releases

16

ANDHEALTH+ & MASTERCLASS OUTCOMES

Since FY2018, our ANDHealth+ and Masterclass programs have been shown to drive measurable commercialisation progress and impact across both health and economic outcome metrics.

387
New jobs (FTEs)

>$85M
Raised (dilutive) & non-dilutive)

>500,000
New patients served

901
Commercial pilots commenced

54
Clinical trials and studies commenced

23
New international market launches
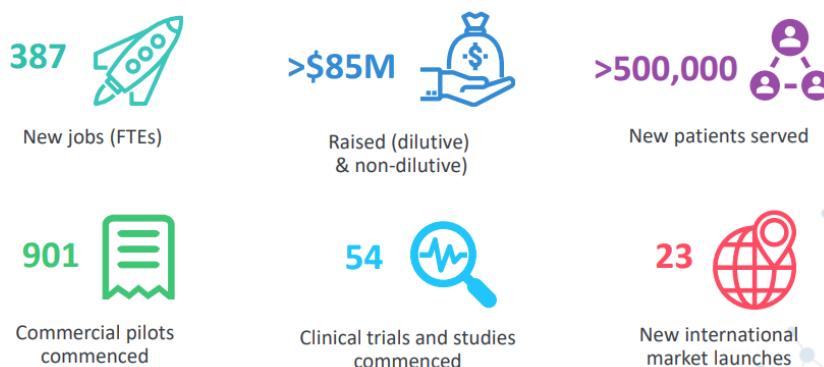
MTPConnect Funded ANDHealth+ V1 Cohort = 10 Companies (as at Dec 2021)
REDI Funded Masterclass ACCELERATE Program = 15 Respondent Companies (as at Mar 2022)

17

ANDHEALTH+ 2022 COHORT

aci.health.nsw.gov.au

Enabling Value Based Healthcare

The role of Patient Reported Measures
Australian British Health Catalyst 27 June 2022

Jean-Frederic Levesque, MD, PhD, FRCP (Canada)

@nswaci

aci.health.nsw.gov.au

I recognise and appreciate consumers, patients, carers, supporters and loved ones. The voices of people with lived experience are powerful.

Their contribution is vital to enabling decision-making for health system change.

aci.health.nsw.gov.au

The NSW Health vision

A **sustainable** health system that delivers **outcomes** that matter to patients and the community, is **personalised**, invests in wellness and is **digitally enabled**.

NSW Agency for Clinical Innovation

Why value based healthcare?

Healthcare worldwide is changing with **rising health costs** and **new technologies**

There is increasing **demand** and **complexity** of delivering care

The **needs** and **expectations** of patients, carers, clinicians and communities **continue to grow**

Patients are taking **a more active role** in their healthcare and choices about what matters to them

NSW Agency for Clinical Innovation

@nswaci

Leading Better Value Care – providing care differently

Hip fracture care	Inpatient management of diabetes	Osteoarthritis chronic care program	Osteoporotic refracture prevention	Renal supportive care
Bronchiolitis	Chronic heart failure	Chronic obstructive pulmonary disease	Chronic wound management	Diabetes high risk foot services

NSW Agency for Clinical Innovation

@nswaci

Measuring what matters first

A defining part of value based healthcare is maximising **outcomes** from the **patient's perspective**

Person-centred innovations

- Focus on what matters to patients
- Leadership in co-design
- Moving from consumer consultation to patient partnerships
- Focus on diversity and inclusivity
- Embedding patient-reported measures into clinical care and improvement

Consumer, community and staff engagement

Direct care, treatment	Service design, improvement, governance, research
Individual	Collective
Consumers, families and communities are active partners in their own health	Consumers, families and communities are partners in health innovation and improvement
We champion evidence-based and person-centred approaches that will enable people to manage their own health and wellbeing.	We meaningfully engage with consumers and partner with them to increase their influence in health innovation and improvement. We value different types of knowledge and evidence.

HEALTH LITERACY – Universal precaution approach

SOCIAL DETERMINANTS OF HEALTH – Equity to ensure equality

- Implementing and evaluating patient reported outcome measures system-wide
- Building capability to use consumer enablement approaches and tools, such as:
  - tackling shared decision making as a complex system challenge
  - addressing social determinants of health
  - using telehealth to provide access
  - gathering experiences of individual care to influence health innovation and improvement.

- Partnering with consumer representatives
- Building collaborative partnerships at all levels and using the spectrum of engagement
- Using cultural practices and protocols for engagement
- Using person-centred innovations and co-production (including experience-based co-design and co-design) to truly partner
- Implementing patient reported experience measures statewide to improve what matters most
- Producing health literate print, audiovisual, website and social media content
- Integrating social determinants as a key component of care
- Bringing together research, empirical and experiential evidence

To create the future of healthcare, and healthier futures for people of NSW

CAPABILITY   REFLECTION   CAPACITY

Patient Reported Measures Program

Patient Reported Outcome Measures

Capture the patient's perspectives about how illness or care impacts on their **health and well-being**

Patient Reported Experience Measures

Capture the patient's perception of their **experience** with **health** care or services

Individual
Improve quality of care by informing care planning and management

Service
Identify what's working well and areas for improvement

System
Evaluate system outcomes and value

NSW Agency for Clinical Innovation

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Health Outcomes and Patient Experience (HOPE) platform

- **First statewide** patient facing application

- **Interactive portal** for patients and clinicians

- **Secure sign-in** for clinicians, patients and carers

- **Dashboards summarise data** for all patients

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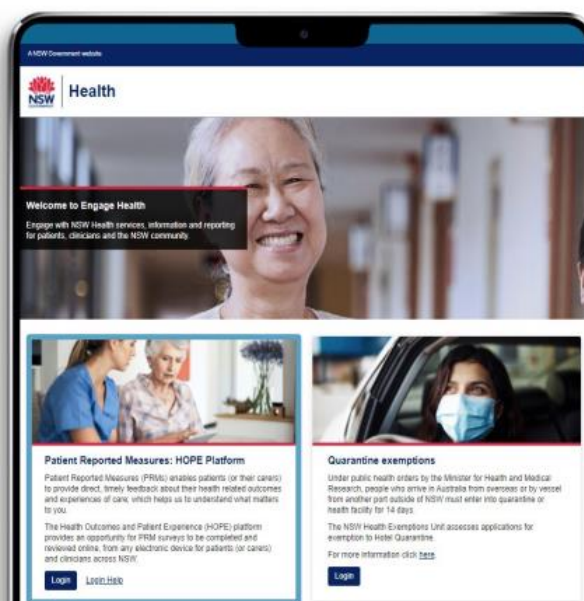
Successes

- **Co-design** involved clinicians, patients and carers

- **One shared approach** across partner organisations

- Patients are happy to **reflect on their experiences** and health outcomes

- Clinicians **value real-time data** and information

- **Accessible** for everyone (CALD, Aboriginal health, low vision)

- Clinicians and healthcare settings are **continuing to use** HOPE

NSW Agency for Clinical Innovation
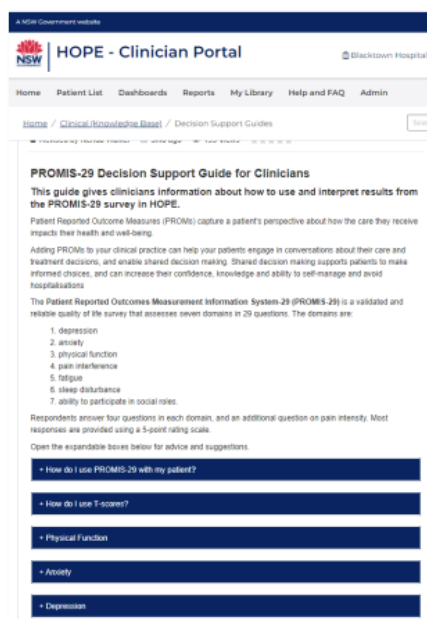
@nswaci

Challenges as we move forward

Continuing to **spread, scale and embed** collection and use of PRMs at the individual, service and systems levels

Triangulation of PRM data with other data sets – meaningful display of data

Systems level **understanding of outcomes** – determining variation

Prioritising system demands for **cohort and program inclusion** in HOPE

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What is needed to realise the benefits of PRMs data?

Individual	Service	System
✓ Patient buy-in ✓ Clinical use and response to the data ✓ Avoid response fatigue	✓ Actionability of measures ✓ Access to alternative services ✓ Service evaluation	✓ Outcomes based planning ✓ System re-design

🐦 @nswaci

12

Delivering better value care through patient-reported measures

Ineffective care Essentially ineffective care or ineffective care for a well defined subgroup	➤ **Limit**
Inefficient care e.g. Inefficient provision or inappropriate intensity	➤ **Lean**
Unwanted care e.g. Care doesn't solve patient's problem or doesn't meet patient's preferences	➤ **Listen**
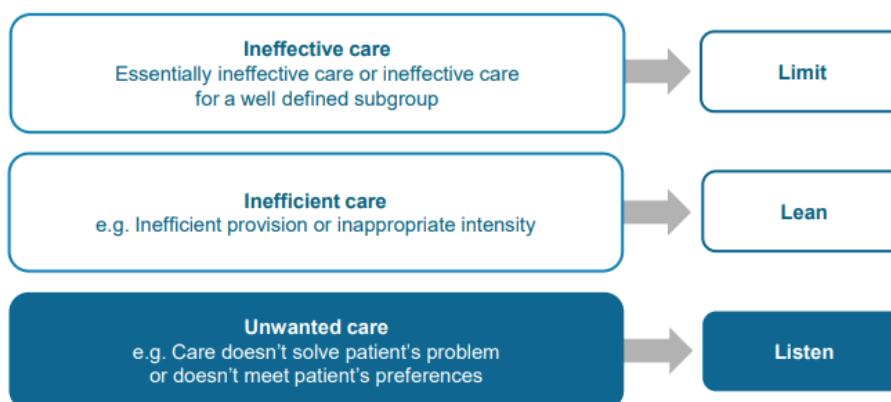
Limit, lean or listen? A typology of low-value care that gives direction in de-implementation
Eva W Verkerk, Marit AC Tanke, Ridolf B Kool, Simone A Van Dulmen, and Gert P Westert
International Journal for Quality in Health Care, 2018, 30(9), 736-739

🐦 @nswaci

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@nswaci

Building Breakthrough Genomics Startups

illumina
Accelerator

Anya Roy
June 2022

Illumina For Startups Catalyzes the Genomics Innovation Ecosystem Across Startup Stage & Geography

Partnering with VCs & entrepreneurs to create, launch and grow genomics startups across the globe

2

Illumina Accelerator is a Company Creation Engine Co-Located with Illumina R&D

Building breakthrough genomics startups in SF Bay Area & Cambridge, UK
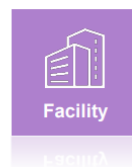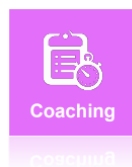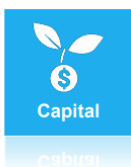
3

Illumina Accelerator is Building Upon our 7-year Track Record of Company Creation

Diverse investment portfolio across therapeutics, diagnostics, tools, synthetic biology & software
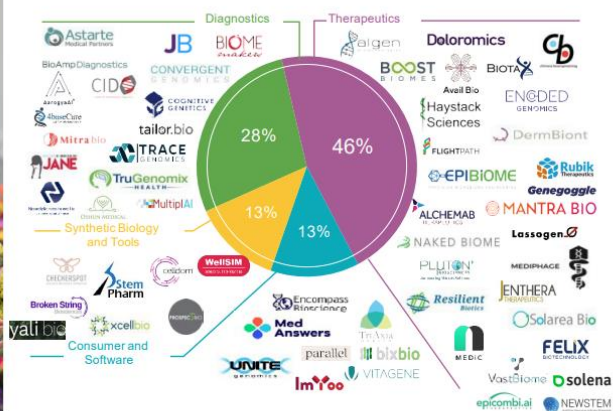
- 61 Genomics Startups
- 14 Funding Cycles, 7 Years

- $1B+ VC Funding Raised
- 93% Startups Raised Capital
- 2 Acquisitions

- 22% Female CEOs
- 56% Female Co-Founded

- SF Bay
- Cambridge UK

4

illumina Accelerator

Illumina Accelerator
Backing Diverse Founders

56% Accelerator startups with a female co-founder
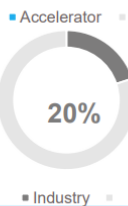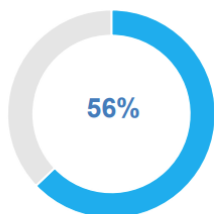
85% Funding raised by Accelerator startups with a female co-founder
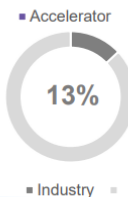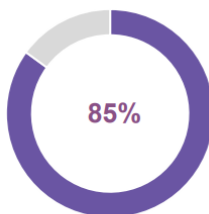
22% Accelerator startups with a female CEO
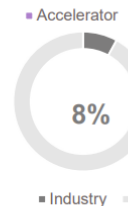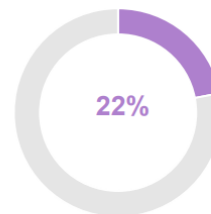
1. CrunchBase: EoY 2019 Diversity Report
2. CB Insights Study as cited in Elite
3. Association for Women in Science Leadership Report

5

4.G Startup Introductions | Illumina Accelerator Cambridge

NonExomics, Inc., a proteogenomics and AI-driven therapeutics company from Cambridge, UK and Greater Boston, is developing a proprietary platform to mine novel drug targets from the dark and uncharacterized regions of the genome.

Rethink Bio Private Limited, a synthetic biology company from India, is focused on harnessing the potential of microalgae to develop sustainable food solutions to benefit the planet and people.

illumına

6

Accelerating Research Translation and Implementation
Integration of Artificial Intelligence in Clinical Decision Making

Australian British Health Catalyst
June 2022

Annette Schmiede, CEO, Digital Health CRC
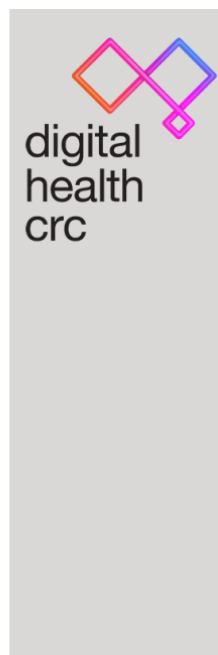
digital
health
crc

Who we are- DHCRC

Purpose

To harness the power of data and digital technologies to improve health outcomes, increase efficiencies, reduce waste in healthcare delivery, and grow Australia's digital health industry.

Funded through the Commonwealth Department of Industry, Science, Energy and Resource's Cooperative Research Program and its Participant organisations.

What we do

The DHCRC connects the technology industry, health and aged care providers (public and private), academia and government to co-invest in the acceleration of digital health infrastructure. Working collaboratively with its key partners, the Digital Health CRC also builds capability and capacity in Australia's health and aged care sectors.

Australian Government
Department of Industry, Science, Energy and Resources

AusIndustry
Cooperative Research Centres Program

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Our Participants - 65

Universities, health and aged care providers, government departments and industry technology partners.

Our Participants in attendance at the 2022 Australian British Health Catalyst include:

Health

ALCIDION

NSW GOVERNMENT | Health

THE UNIVERSITY OF SYDNEY

ANDHealth
Australia's National Digital Health Initiative

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Case Study - harrison.ai

- Established 2018 by Dimitry and Aengus Tran
- Create accurate and clinically effective medical AI solutions
- Began in IVF - AI as a medical device solution
- $129mill raised late 2021 largest series B funding round, Blackbird, Skip Capital
- AFR 2021 Top 100 most innovative companies
- Through Annalise CXR developed the most comprehensive AI clinical decision-support chest x-ray solution on the market
- Very competitive global market

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Case Study – Challenges of Research Translation and Implementation

- Research Study Developed to :

Evaluate artificial intelligence (AI) for chest radiograph interpretation in emergency departments.

Few AI Tools implemented in health services

Integration into clinical workflows the challenge

Most AI in radiology but limited evidence from published studies

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Performance of Annalise CXR in assisting radiologists to detect findings has been evaluated in a controlled setting

Effect of a comprehensive deep-learning model on the accuracy of chest x-ray interpretation by radiologists: a retrospective, multireader multicase study

Jarrel C Y Seah, Cyril H M Tang, Quinlan D Buchlak, Xavier G Holt, Jeffrey B Wardman, Anuar Aimoldin, Nazanin Esmaili, Hassan Ahmad, Hung Pham, John F Lambert, Ben Hachey, Stephen J F Hogg, Benjamin P Johnston, Christine Bennett, Luke Oakden-Rayner, Peter Brotchie, Catherine M Jones

Summary

Background Chest x-rays are widely used in clinical practice; however, interpretation can be hindered by human error and a lack of experienced thoracic radiologists. Deep learning has the potential to improve the accuracy of chest x-ray interpretation. We therefore aimed to assess the accuracy of radiologists with and without the assistance of a deep-learning model.

Methods In this retrospective study, a deep-learning model was trained on 821 681 images (284 649 patients) from five data sets from Australia, Europe, and the USA. 2568 enriched chest x-ray cases from adult patients (≥16 years) who had at least one frontal chest x-ray were included in the test dataset; cases were representative of inpatient, outpatient, and emergency settings. 20 radiologists reviewed cases with and without the assistance of the deep-learning model with a 3-month washout period. We assessed the change in accuracy of chest x-ray interpretation across 127 clinical findings when the deep-learning model was used as a decision support by calculating area under the receiver operating characteristic curve (AUC) for each radiologist with and without the deep-learning model. We also compared AUCs for the model alone with those of unassisted radiologists. If the lower bound of the adjusted 95% CI of the difference in AUC between the model and the unassisted radiologists was more than −0·05, the model was considered to be non-inferior for that finding. If the lower bound exceeded 0, the model was considered to be superior.

Findings Unassisted radiologists had a macroaveraged AUC of 0·713 (95% CI 0·645–0·785) across the 127 clinical findings, compared with 0·808 (0·763–0·839) when assisted by the model. The deep-learning model statistically significantly improved the classification accuracy of radiologists for 102 (80%) of 127 clinical findings, was statistically non-inferior for 19 (15%) findings, and no findings showed a decrease in accuracy when radiologists used the deep-learning model. Unassisted radiologists had a macroaveraged mean AUC of 0·713 (0·645–0·785) across all findings, compared with 0·957 (0·954–0·959) for the model alone. Model classification alone was significantly more accurate than unassisted radiologists for 117 (94%) of 124 clinical findings predicted by the model and was non-inferior to unassisted radiologists for all other clinical findings.

Interpretation This study shows the potential of a comprehensive deep-learning model to improve chest x-ray interpretation across a large breadth of clinical practice.

Funding Annalise.ai.

- 20 radiologists
- 2,568 cases with and without CXR AI assistance
- accuracy improved in 102 (80%) of 127 **radiological findings**

Seah et al. Lancet Digit Health 2021

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Evaluating artificial intelligence (AI) for chest radiograph interpretation in emergency medicine – Stage 1

Project team

NSW Health — Sydney Local Health District
- A/Prof Michael Dinh, Director, RPA Green Light Institute for Emergency Care
- Mr Mitchell Burger, Director, Strategy, Architecture, Innovation and Research | ICT Services, SLHD
- Dr Nidhi Abraham

MACQUARIE University — Australian Institute of Health Innovation
- Prof Farah Magrabi
- Prof Enrico Coiera
- Dr David Lyell

MACQUARIE University

NSW Health — Northern Sydney Local Health District
- A/Prof Mark Gillett, RNSH

digital health crc
- A/Prof Annette Schmiede
- Prof Tim Shaw
- Dr Shiva Sharif

annalise
- Prof Catherine Jones
- Dr Mark Phillips
- Dr Hassan Ahmad
- Dr Nalan Ektas

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Background and rationale

AI has potential but few tools implemented in clinical settings

- AI promises to augment clinical decision-making, yet translatable benefits to care quality/timeliness and patient outcomes remain largely unmeasured

- ED potential setting for AI: CXRs are frequently ordered and interpreted in advance of radiologist review

- **Key question**: How do AI findings translate to ED diagnosis and clinical management?

- **Hypothesis:** A comprehensive, expert level, CXR interpretation tool can support ED clinician decision making and improve patient outcomes by:

  ➢ increasing diagnostic accuracy

  ➢ reducing treatment delays

  ➢ ensuring reporting of non-emergent findings

- No previous studies measuring impact of CXR interpretation AI on decision-making, care delivery and patient outcomes in ED

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AI implementation: there are complex challenges at the last mile

First mile   Middle mile   Last mile

- data capture   model building   • real-world implementation
- cleaning   and testing   • routine use
- labeling   e.g. ML/DL
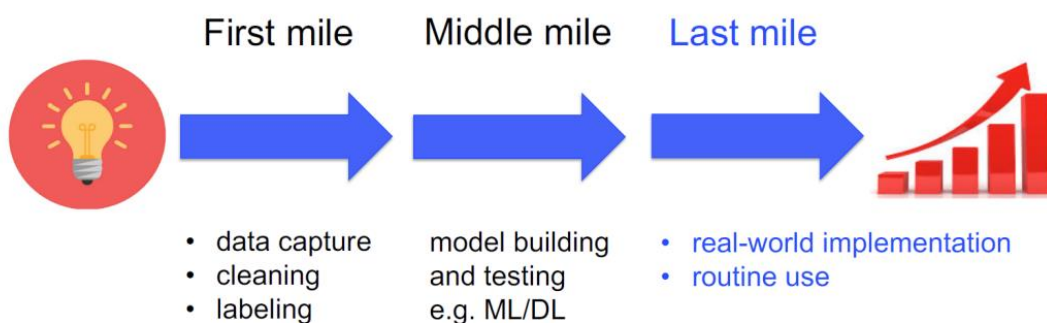
Coiera, J Med Internet Res 2019

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Digital medicine
Bridging the chasm between AI and clinical implementation

Many advances in artificial intelligence (AI) for health care using deep neural networks have been commercialised. But few AI tools have been implemented in health systems. Why has this chasm occurred? Transparency, suitability, and adaptability are key reasons. The deployment of any new technology is usually managed centrally in hospitals and health systems. For the information technology (IT) teams, there is the concern that input data are drawn from outside the health setting and the algorithm performance, source code, and input data are unavailable to review. Many commercial AI applications are in radiology, but few are supported by evidence from published studies. And there are concerns that the algorithms were tested and validated using retrospective, in-silico data that may not reflect real-world clinical practice. Regulators reviewing a company's AI data are privy to considerable data, but these data are usually unavailable to health system IT teams or clinicians. Equity, safety, and regulation are also crucial. When AI is imported from a commercial setting into a hospital or health system little is known about which data have been used to train the AI and there is uncertainty about owner-

should closely consider these concerns and barriers.

How can we bridge this chasm? Algorithmic aversion can be alleviated when an algorithm can be modified in the health setting or can learn from local data. Three steps will help optimise clinical use of AI. First, provide transparency about the datasets used for initial training of the AI tools. Second, enable the deconstruction of neural networks to make the features that drive the AI performance understandable for clinicians. Third, allow clinicians to retrain AI models with local data if the needs of their patients and hospital require it.

Progress is likely to come with the development of open-source AI trained on open data depositories and publicly shared algorithms. An example of the potential of this approach is InnerEye, a clinically validated AI for radiotherapy that has been implemented within a UK hospital and trained with hospital data and by hospital clinicians. If combined with privacy-preserving computing tools, such as federated learning, open-source AI could further remove barriers for the fast scalability of home-grown AI solutions developed in hospitals across the health system while maintaining clinician and patient trust in the ownership and regulation of data.

Aristidou, Jena & Topol, Lancet 2022

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Project Aim

To evaluate an AI system that assists clinicians with interpretation of chest radiographs (Annalise Enterprise CXR) in an **ED setting.**
  – **Focus: diagnosis and patient management**

annalise.ai
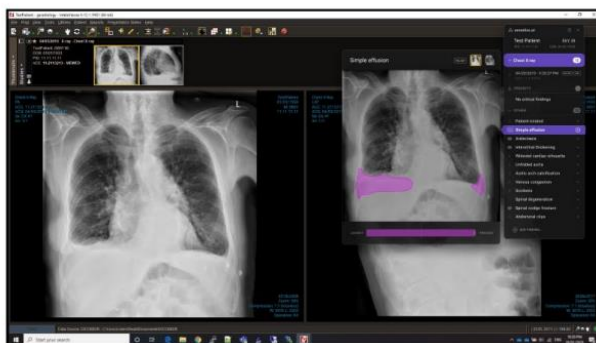
approved for use by TGA as a
Medical Device Class 1
(September 2020)

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Stage 1: Assess the impact of CXR AI on clinical decision making in a controlled environment

Objectives

1. Evaluate whether CXR AI increases **diagnostic accuracy** and improves **patient management**.

2. Identify **situations** where CXR AI has the greatest impact.

Study design: Randomized controlled experiment, two within-participant factors: 2 levels of decision support (unassisted and assisted) stratified by acuity and scenario characteristics.

Task: Diagnose and plan management for hypothetical patient scenarios, involving CXR interpretation.

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Primary outcome measures

Coiera, 2019
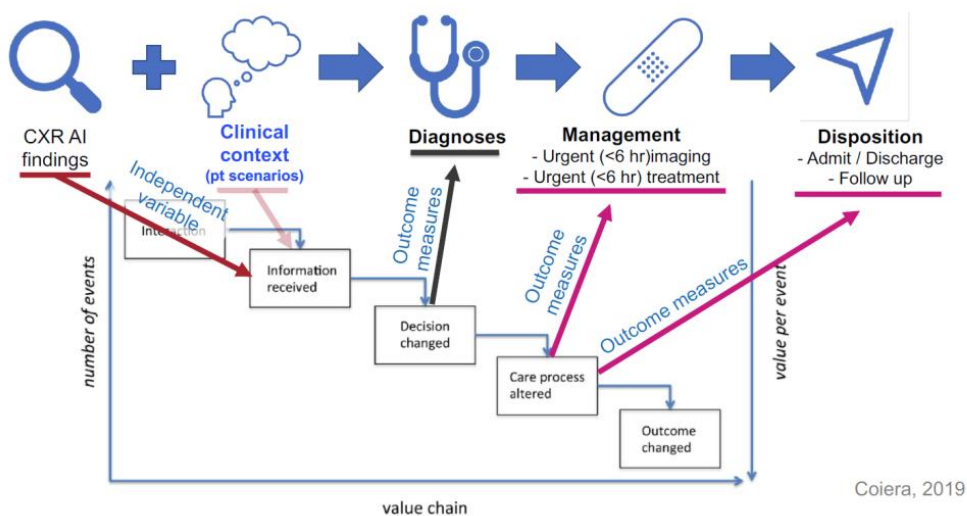
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Study objectives & measures

Primary:

Compared to equivalent trials with No CXR AI:

- Does CXR AI increase <u>diagnostic accuracy</u> for emergency doctors?
- Does CXR AI improve <u>patient management decisions</u> for emergency doctors?

Secondary:

- <u>Diagnostic accuracy</u> and <u>management decisions</u> for interns and residents?
- <u>Task time</u>, c<u>ognitive load</u> and <u>decision confidence</u>.

- Identify patient scenarios, doctor and CXR <u>characteristics modifying the benefit of CXR AI</u>.
  - **Routine:** Typical ED patient scenarios
  - **Help:** Patient scenarios where CXR AI may benefit e.g. complex patients, CXRs hard to interpret
  - **Hinder:** Patient scenarios where CXR AI may hinder

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Long Journey to Establish Research Project

- Informal discussions began with ED clinicians in large metropolitan Health District – mid 2020
- Initially rejected by District Research Committee – concerned about supporting private sector commercial organisation and probity
- District had no experience with CRC framework– outside traditional research model
- Briefing and socialising Project with District CEO led to Project support
- Ethics application and Project planning began
- Briefing with IT Dept, ED Clinicians and Research Dept.

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Conclusion

- Project to commence in Health District with existing relationship
- Strong leadership from CEO, IT Director and CMIO for Digital Transformation.
- Understanding of CRC model and role in working with Industry.
- Willing and engaged healthcare partners critical to success of research translation and implementation with industry partners.
- Engagement, patience and persistence, with leadership teams from start to finish.

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Shaping the future of digital technology in health and social care

David Maguire, Senior Analyst

The King's Fund

The Kings Fund>
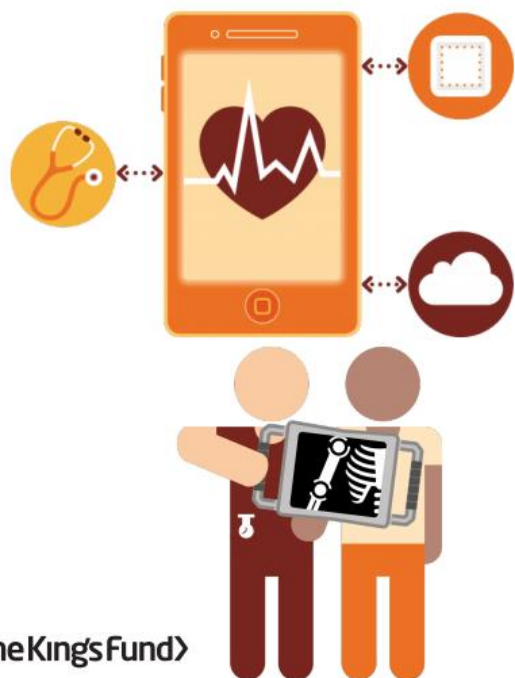
© The King's Fund 2018

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Looking into the future

Three main scenarios:

1. A health "techlash"

2. A willing system, with uneven spread

3. Spread and scale at pace

Table 3 Levels of public trust and capacity and capability in our three scenarios for the future trajectory of digital technologies in health and care

	Scenario 1: a health 'techlash'[1]	Scenario 2: a willing system with uneven spread	Scenario 3: spread and scale at pace
Public trust	Low	High	High
Capacity and capability	Low	Mixed	High

The King's Fund

© The King's Fund 2018

Recommendations

Probably the most relevant recommendations for this audience:

- Build trustworthy systems of data based on an active understanding of public expectations for the use of their data with clear communication of potential use.

- Support methodological development to overcome the challenges of evaluation and help generate data to support this while being realistic about the likelihood of cost savings as opposed to productivity increases.

- Invest in tools and programmes to answer some of the outstanding questions regarding the effect of digital exclusion on health, address exclusion in local populations and monitor the changing nature of digital exclusion

- Ensure the fair exchange of value for NHS data, with meaningful citizen involvement in their development.

The Kings Fund>

Artificial intelligence

The Kings Fund>

Mobile computing

Internet of things

TRACK YOUR HEALTH

Value Based Healthcare in NSW
The Lived Experience

Elizabeth Koff AM
Managing Director Telstra Health
formerly Secretary NSW Health

The value based health care journey in NSW

4 Driving Factors		4 Essentials of Value
• Focus on patient/citizen experience	→	• Experience of receiving care
• Clinicians wanting to do the best for their patients	→	• Experience of delivering care
• Measurement of outcomes	→	• Outcomes that matter to patients and clinicians
• Financial Pressures	→	• Effectiveness and efficiency of care
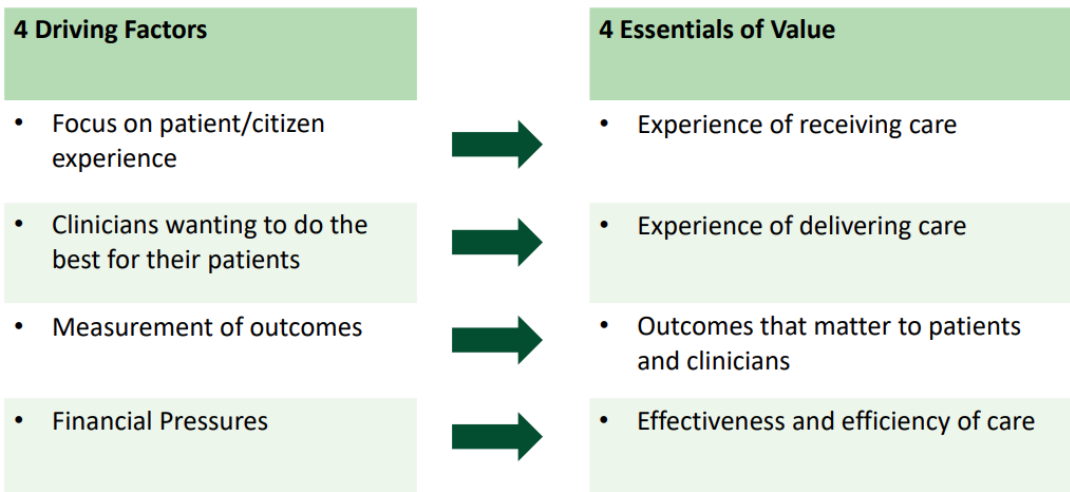
Our conceptual framework guides NSW Health's approach to value

Value based healthcare in NSW

Vision

A sustainable health system that delivers outcomes that matter to patients and the community, is personalised, invests in wellness and is digitally enabled

In NSW value based healthcare means continually striving to deliver care that improves:

- Health outcomes that matter to patients
- Experiences of receiving care
- Experiences of providing care
- Effectiveness and efficiency of care

Value based healthcare enablers

- Patient and community engagement
- Measurement and evaluation
- Research and innovation
- Delivery organisations
- People, culture, governance and capability
- Digital health and analytics
- Funding and purchasing
- Clinical leadership and engagement

The Patient/Clinician Experience

Statement of intent for NSW Health

Our commitment to patients, consumers, clients, carers, family and staff

Starting point for a **strategic approach**

Education on what is human experience

Manual for **change and innovation**

Elevating the Human Experience

Our guide to action for patient, family, carer and caregiver experiences

- Patient and community engagement
- People, culture, governance and capability

We are measuring outcomes and experiences

Measurement and evaluation

The **Health Outcomes and Patient Experience (HOPE)** system collects **Patient reported measures (PRMs)**

The **Register of Outcomes, Value and Experiences (ROVE)** brings together multiple data sets to provide complete picture of patient journey

Lumos links data from general practices to other health data

Clinician leadership and engagement

Clinical initiatives

Clinical leadership and engagement

Research and innovation

Chronic heart failure	COPD	Diabetes	Diabetic foot	Breast radiotherapy hypofractionation	Hip fracture	Direct access colonoscopy
Renal Supportive Care	Falls	Osteoarthritis	Osteoporosis re-fracture prevention	Wound management	Bronchiolitis	

Developed by clinicians and **evidence-based**

Supporting care in **appropriate settings**

Scalable and being implemented across **all health districts and networks**

Identifying opportunities to **reduce unwarranted clinical variation**

Building system capability

Research and Innovation
Embed specific VBHC criteria in the Translational Research Grants program
Publish NSW Health's System Priorities for VBHC Research

People, culture, governance and capability
Developing Value Base Healthcare capability course
Embedding VBHC in *Next Generation of Leaders and Managers* HETI course
Aligning within districts and across sector services (e.g. AoD) with VBHC

Digital Health and Analytics
Enhancing Electronic Medical Records
Expanding Virtual Care

NHS

The NHS Artificial Intelligence Lab:

Australian British Health Catalyst

Dr Francois Lemarchand, Senior Data Scientist

About the NHS AI Lab
Who are we & what do we do?

The NHS AI Labs

NHS

Demonstrate potential
of AI-driven technologies for health and care to build understanding among the public and healthcare professionals

Build trust and confidence
among the public and healthcare professionals in the use of AI

Advance regulation
with steps to ensure that health AI is safe, effective and has equal opportunities across the market

Lab Structure
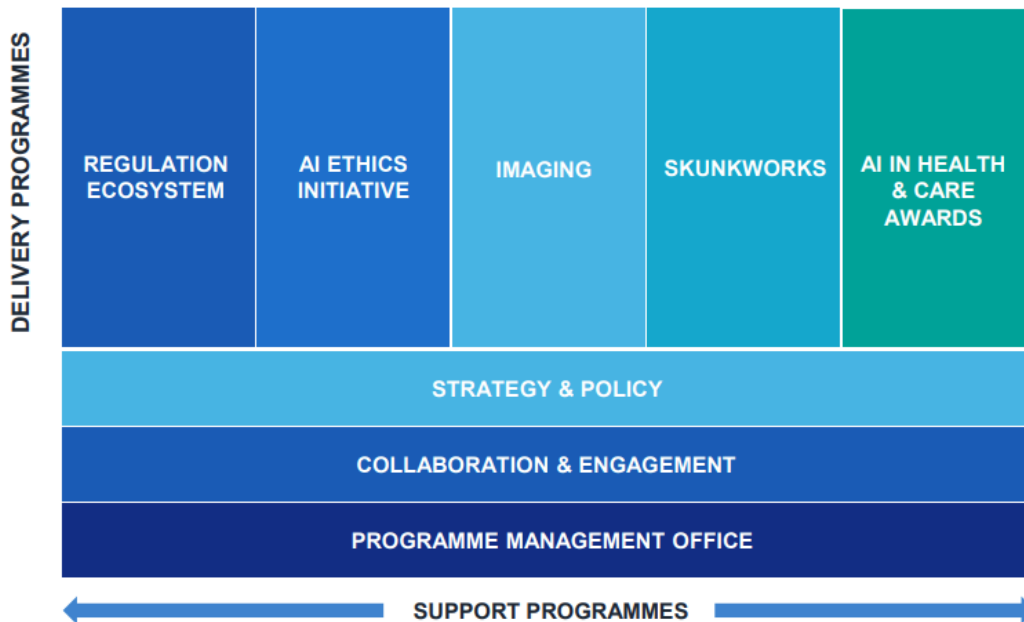
AI Imaging

The National COVID Chest Imaging Database

NHS

In early 2020, we knew little about the virus and how to prevent severe COVID-19 infections. The NHS AI Lab saw an opportunity to contribute to the efforts to fight the virus by building a **COVID-19 Chest Imaging Database** to advance research and externally validate algorithms.

27 NHS hospital Trusts have now shared data with the NCCID.

It now has over **83,000 images** (X-rays, MRIs and CT scans) from **29,000 patients.**

Context: what is the NCCID?

NHS

- NCCID is divided into 2 sets:
  - A training set for AI developers
  - A validation set to test model performance
- The data is **randomly split** (50-50) by patient between the 2 sets. NHS sites sharing with third parties are excluded from the validation set.
- Validation can be an ambiguous word. For example, in data science, it defines a dataset used to verify training is going smoothly.

https://nhsx.github.io/ai-dictionary

NHS Cloud

Training set
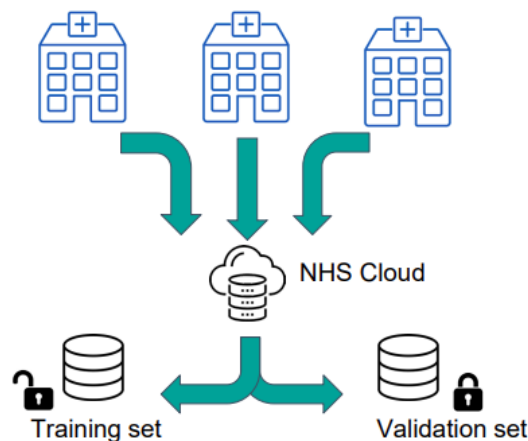
Validation set

What is AI validation?

A process of evaluating the performance of an AI model to ensure it behaves as advertised by the AI developers and uncover potential biases and risks.

Overview of the validation process
Aim was to detect COVID-19 or its symptoms

1. Curate validation dataset	2. Deploy AI models in the cloud	3. Run AI model on the curated validation dataset	4. Assess model performance	5. Report results
Used the validation dataset in the NCCID	Used NHS cloud infrastructure to deploy AI models	Checked model outputs to ensure run was successful	Performed statistical tests to assess model performance	Share findings with vendors to drive future model improvements
Tailored the validation dataset based the vendor's requirements and add new annotations if needed.	Set-up deployment environment to protect the intellectual property of model vendors	Protected validation set details from vendors to safeguard against future 'gaming' of results	Tested model robustness and compared model performance in different demographics (e.g. sex, age)	Made results accessible and understandable

NCCID validation programme

Why automating the process is important

NHS

Accelerate AI development

All AI vendors should have a chance to test their tools on pre-defined use cases and assess whether they are going in the right direction.

Deploy model upgrades

Whenever an upgrade is available for an AI tool, the performance evaluation can offer a comparison with previous versions.

Post-market surveillance

As real-world data changes, the validation process can be run to ensure performance stays the same.

Investigating errors & biases

NHS

Metrics are initially calculated for the entire validation set, as well as the **error rate**. An error is a model outcome that is not clearly interpretable.

Bias analysis can be performed on sub-groups based on **age, sex, ethnicity,** and **device**.
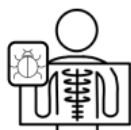
Additional robustness tests can be run to identify implicit biases based on medical devices present in the medical images (e.g. **pacemaker, tubing**).

Investigating biases

NHS

It is important to understand how complex symptom detection may vary from a group to another. (e.g. older Covid-positive patients may **display symptoms from other diseases**)

Sub-groups may also have different **behaviours towards your healthcare system** (e.g. some ethnic groups were shown to display symptoms were more severe, which leads to an easier diagnosis)

Investigating biases

NHS

It is important to understand how complex symptom detection may vary from a group to another. (e.g. older Covid-positive patients may **display symptoms from other diseases**)

Sub-groups may also have different **behaviours towards your healthcare system** (e.g. some ethnic groups were shown to display symptoms were more severe, which leads to an easier diagnosis)

Ethnicity group	Accuracy
Asian	79%
Black	84%
White	81%

Example of bias investigated on NCCID's training set - The model performs better on a minority group... Does it really?

Key takeaways

NHS

01

Collect real-world data and ensure its content (e.g demographic information) is unseen from vendors.

02

AI validation cannot be fully automated but should be optimised. Many use cases will require new annotations from radiologists or experts.

03

Identify key sub-groups in your population, and their clinical specificities and their behaviour towards your healthcare system

NSW Health

NSW GOVERNMENT

Lifting health outcomes
in rural New South Wales

Jill Ludford
Chief Executive
Murrumbidgee Local Health District

June 2022

Healthcare in rural NSW

The challenge

The opportunities

- technology enablement
- regional based training

Australian Government -Modified Monash Model-
https://www.health.gov.au/health-topics/rural-
health-workforce/classifications/mmm

The challenge

Figure 1. Number of doctors 2005 to 2019 (linear projections to 2021).
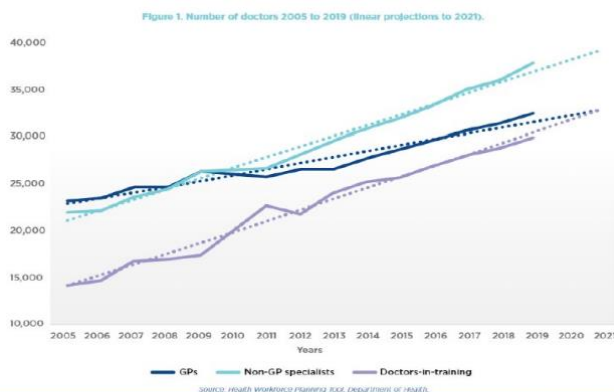
Attributes of a high-performing rural health system

Resourcefulness & innovation

Technology enablement

Partnerships & integrated care

Workforce & culture

CORE ATTRIBUTES

Monitoring & performance measurement

Safety & quality

SUPPORTING ATTRIBUTES

Patient & community engagement

Leadership & governance

Access & equity

NSW Health, *High Performing Rural Health System*, June 2019.

Murrumbidgee Health and Knowledge Precinct

Murrumbidgee Rural Generalist Training Pathway

PRE VOCATIONAL		VOCATIONAL				POST VOCATIONAL

INTERNSHIP
PGY1
Hospital intern and rural GP placement

RMO
Apply for MRGTP

2 x 6 month placements (rural practice based or hospital based)

2 x 6 month placements (rural practice or hospital based)
INTERCHANGE

Advanced Skills Training
A range of hospital based training skills positions available

FELLOWSHIP EXAM

Placements
as per individual learning requirements and completion of Fellowship exams

RURAL GENERALIST
Fellow
FACRRM or FRACGP/ FARGP

Murrumbidgee Local Health District

6

Virtual care in rural NSW

91% of the patients rated the virtual care they received as very good (69%) or good (22%)

Nine in 10 patients said they would use virtual care again

When asked to identify the benefits of virtual care, 73% said convenience, 60% said saving time and 30% said saving money.
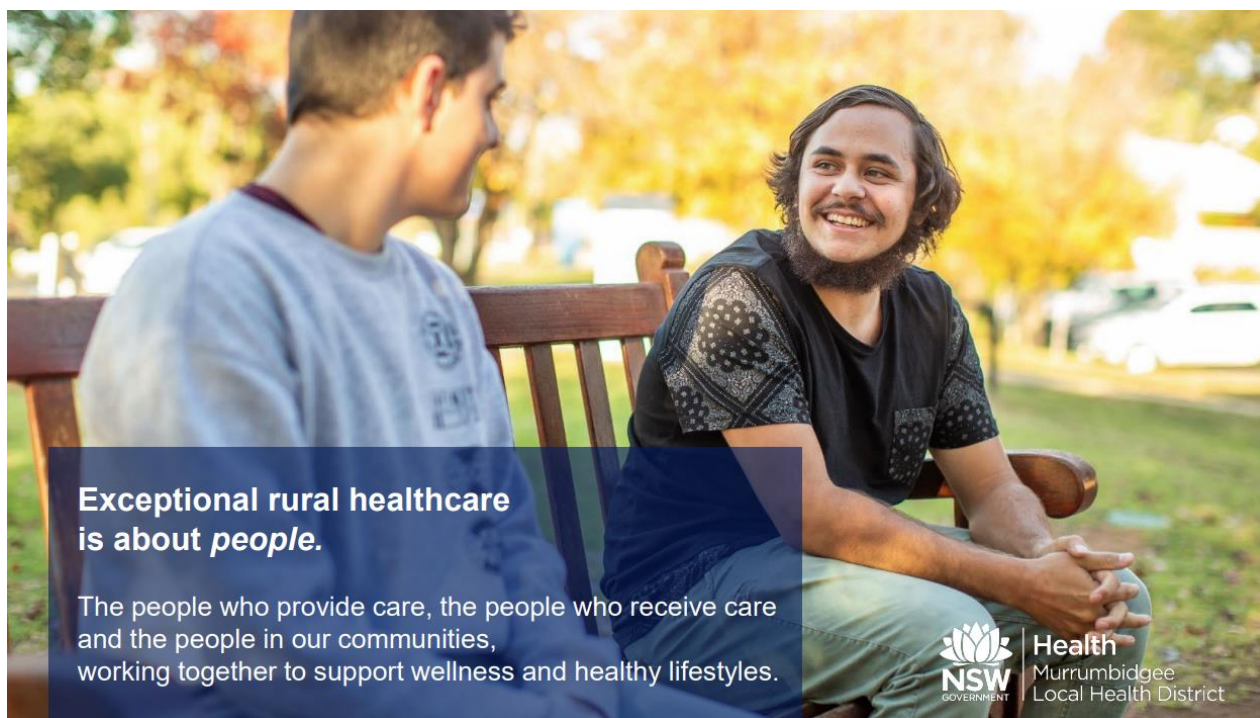
Exceptional rural healthcare is about *people.*

The people who provide care, the people who receive care and the people in our communities, working together to support wellness and healthy lifestyles.

Principles of Future Healthcare

Malcolm Pradhan, MBBS, PhD, FAIDH
CMO & Co-Founder, Alcidion Group

Is Value Based Care Possible?

ALCIDION

> Value-based healthcare is the equitable, sustainable and transparent use of available resources to achieve better outcomes and experiences for every person.
>
> CEBM, University of Oxford, 2019

- Recognize and develop strategies to overcome barriers to implementing value-based healthcare at the individual, team and organisational level

- Build capacity and capability to translate and implement the best available research evidence into effective action to increase value.

- Develop the necessary skills in value-based healthcare by training staff in how to measure outcomes, patient experience and resource use

- Ensure programmes to increase value are monitored and evaluated to provide better evidence about what is and isn't effective

- Facilitate better communication and dissemination about what works in increasing value at a local and national level

- Adopt a common terminology so that every person involved in healthcare, including patients, has a shared understanding of what value-based healthcare is

- Identify and communicate unwarranted variations in healthcare to every person, ...

Current State of Healthcare

ALCIDION

Leading Causes of Death in the USA (Prior to COVID)

Adverse events >25% of multi-day episodes

Up to 40% of lab results are not seen

30% of AMI patients not on guideline meds

25% of colorectal neoplasia missed at screening colonoscopy

Challenges of EPRs

ALCIDION

Productivity

72% workload same or worse
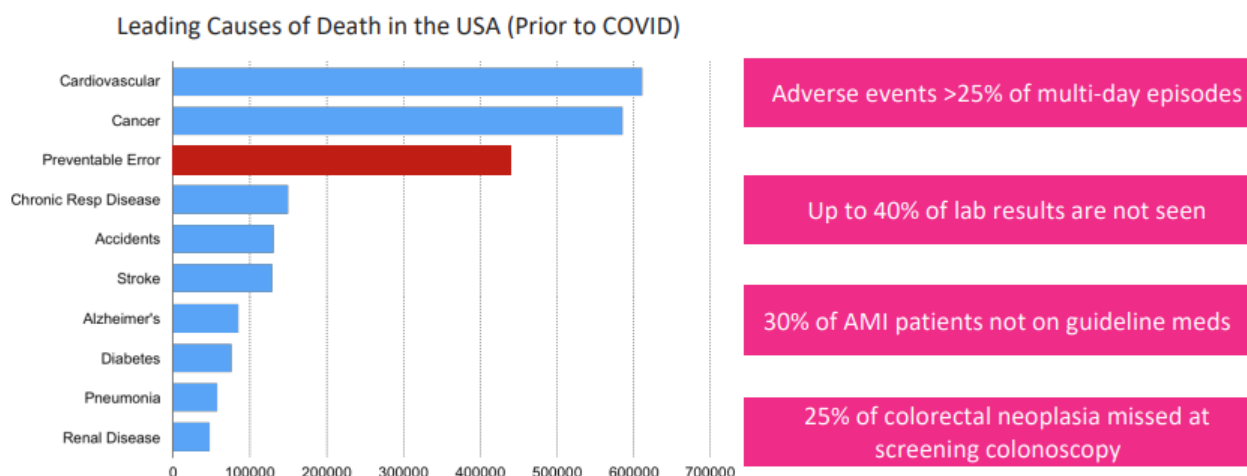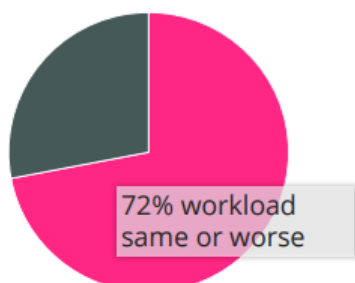
>60 min per day using EPR associated with 40% increase chance of physician burnout

Peccoralo et. al. The impact of time spent on the electronic health record after work and of clerical work on burnout among clinical faculty. Journal of the American Medical Informatics Association, Feb 2021

Pneumonia Mortality %
12.00
11.75
11.50
11.25
2008 2009 2010 2011 2012
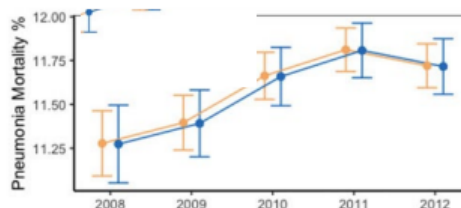
Yuan N, et.al. Electronic health records systems and hospital clinical performance: a study of nationwide hospital data. JAMIA, 26(10), 2019, 999–1009

The Evidence

ALCIDION

Safe, equitable healthcare that complies to best practice 24x7 and considers patient preferences…

is not humanly possible.

Principles for Future Healthcare

ALCIDION

- Safe by Default
- Support Clinicians
  Clinical + Logistics
- Low Variance (Equity)
- Evolve New Models
- Engage Patients

Supporting Technology

- Smart technology is fundamental to ensuring a scalable, safe and equitable healthcare system
- Health IT must be an active participant in health care, not just a passive data store
  - CDS as a core function: safety, automation, escalation
  - Allow clinicians to trust algorithms
- It must adapt to the individual patient and clinician in all models of care
- Reducing cognitive burden for clinicians — make the right thing to do the easiest thing to do
- Built on open standards & interoperability

Programme Candidate Detection Example

ALCIDION

Patients with any of the following are <u>not</u> suitable:

- Notes — Generalised peritonitis
- Observations — Temp > 38°C
- HR > 100 bpm, evidence of haemodynamic instability (e.g. systolic BP <100 mmHg)
- Labs — WCC >20, CRP>150, acute renal impairment
- Assessments — Other signs / symptoms concerning for systemic sepsis (qSOFA score ≥2)
- Pregnancy
- Medications — Immunosuppressed (e.g. neutropaenia, high dose steroids)
- ECOG status 3 or above, cardiac or respiratory failure
- Allergies — History of hypersensitivity or allergy to cephalosporins or metronidazole, or previous anaphylaxis to penicillins
- Problems — Cognitive impairment (including patients unable to provide consent to the study)
- Deemed unsuitable for the study in the judgement of the treating clinician

To assist, the computer must understand clinical data

- Data needs to be represented in codes that identify clinical concepts
- It can't be extra work (NLP, automation, smart UX)

Example: Hypoglycaemia Management
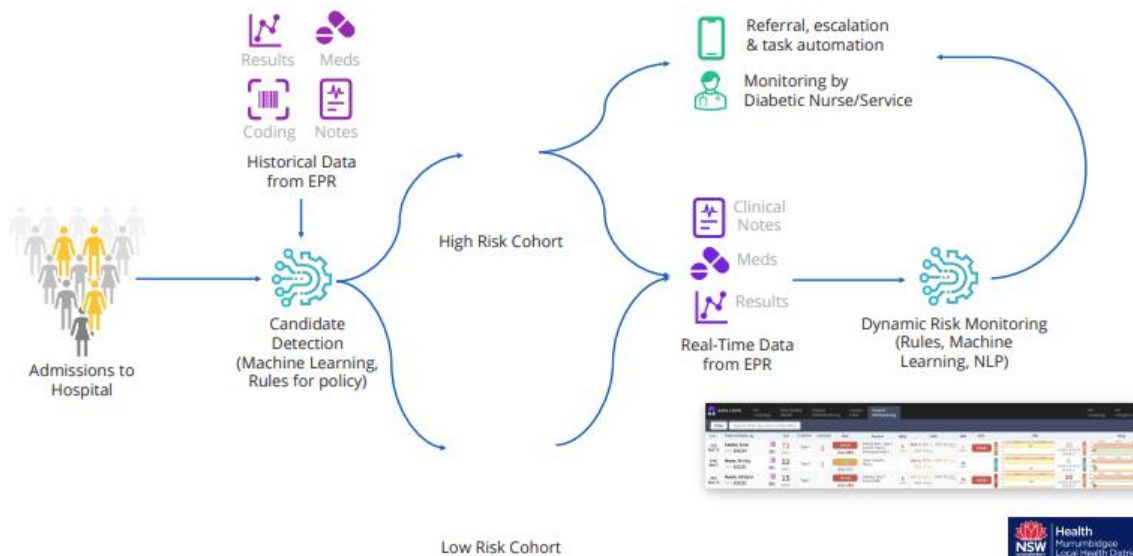
The Right Level of Care
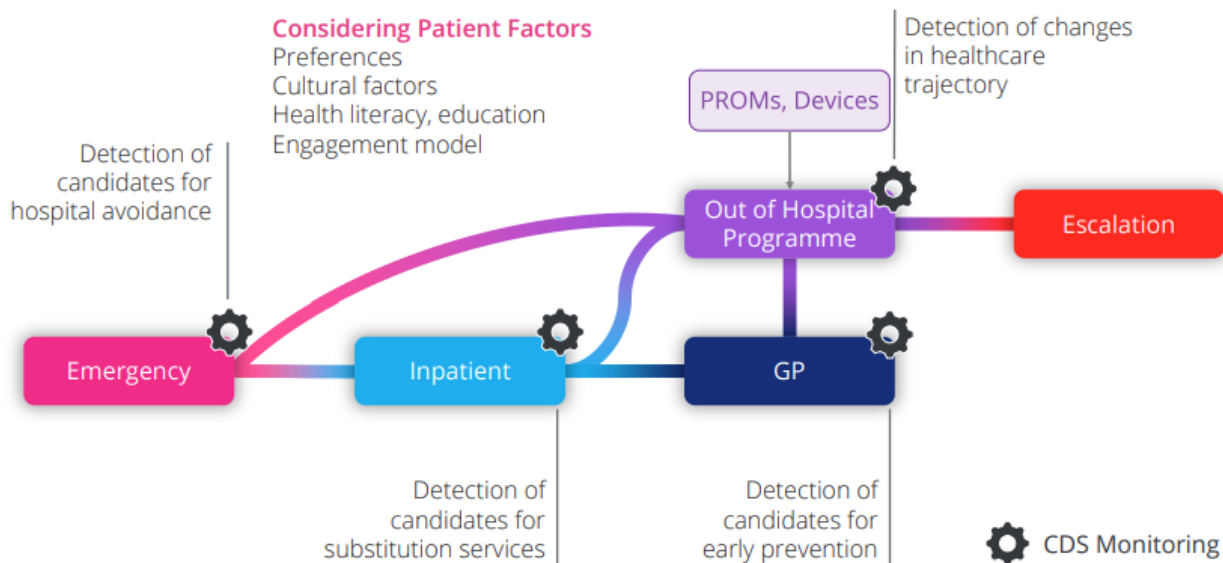
Supportive Technology

- CDS for monitoring patients and escalating changes in trajectory

- Making the right thing to do the easiest thing to do
  - Let the computer manage the memory tasks while people spend time on the judgement tasks

- Technology as an active partner
  - A smart assistant for clinicians — monitoring, detecting, automating, reminding
  - A smart concierge for patients — adapting care for preferences, healthcare literacy

- Monitoring care models for value
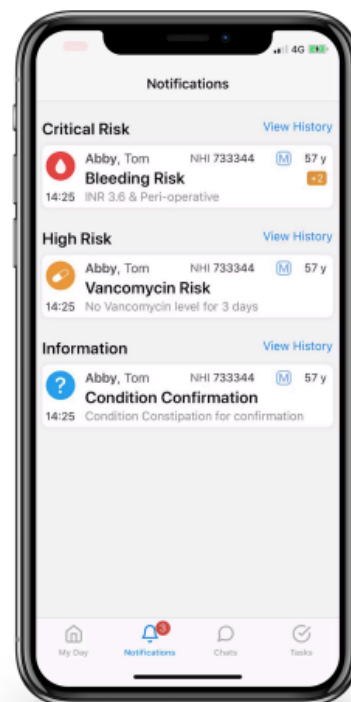
Virtual Health Accelerated
Making the most of the momentum

Margot Mains
Chief Executive

ABHC Programme 11:50am
Embracing the Digital Step Change

June 2022

NSW GOVERNMENT | Health Illawarra Shoalhaven Local Health District

Acceleration and Adoption in NSW Health

The COVID-19 pandemic triggered an accelerated adoption of virtual health. We're transforming our delivery models and our Future Health plans to consider virtual visits and develop our 'web side' manner.

●**Providing Enhanced Care – Anywhere**
Case Study Snapshot 1: ISLHD Virtually enhanced Care Coordination or (VeCC) for COVID, Chronic Care and Mental Health.

●**Expanding with Bricks & Clicks**
Case Study Snapshot 2: RPA Virtual Hospital Sydney

●**Considerations** for collaborative and virtual models

Health
NSW GOVERNMENT | Illawarra Shoalhaven Local Health District

Virtually enhanced Community Care (VeCC) at ISLHD

Our service focuses on management of patients with chronic conditions; providing- care coordination, home monitoring, health education and coaching. So far we've focused on specialised care for people with COVID-19, chronic or complex health issues and Mental Health support.

✓Allows us to provide support to individuals and households at a time of great stress or when a person can rapidly deteriorate
✓Enhance sense of security for patients and reduce sense of isolation
✓Assess people for right level of care at home to reduce impact on hospitals
✓Keeping staff safe without increased exposure to infection.
✓Relies on own GP for medical governance and oversight
✓Rapid and scalable monitoring of patients following diagnosis e.g COVID
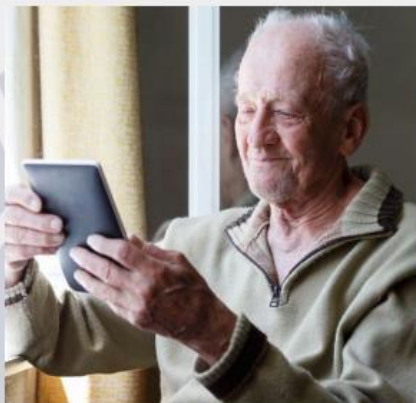
Health
NSW GOVERNMENT | Illawarra Shoalhaven Local Health District

Virtually enhanced Community Care (VeCC) at ISLHD – Chronic Care

Patients with Chronic Disease have a high health burden. In ISLHD there is an increase in presentations and re-presentations and length of stay for respiratory conditions. Patients are provided with a Philips tablet, Monitoring devices (BP, SpO_2, temp, weight, glucose) and receive virtual consultation, monitoring, health coaching and education.

2021 outcomes snapshot: Graphs show Patient Outcomes of >130 patients with respiratory illness after they received virtual care and remote monitoring.

17% moved from feeling disengaged to becoming aware. 6% moved from starting to take action to actually maintaining their behaviours. The hospitalisation risk was reduced with a **saving of $265,000 in reduced length of stay**. Our programs continue to deliver significantly reduced **ED Presentations and Hospital Admissions** for those in VeCC in the following 12 months from their enrolment.

1. **Disengaged**
2. **Aware but struggling**
3. **Taking action**
4. **Maintaining behaviours**

Before
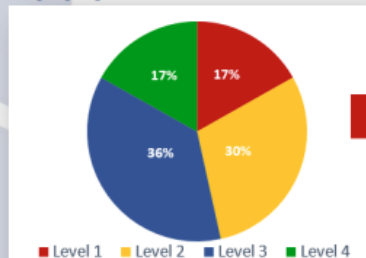
After
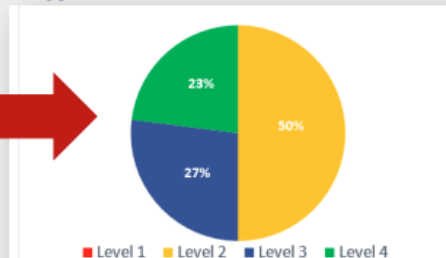
Virtually enhanced Community Care (VeCC) at ISLHD

- In home support services range from phone calls and welfare checks to installation of fully enabled remote monitoring services using enabled tablets with Bluetooth equipment such as pulse oximeters and blood pressure kits to monitor people at risk of hospitalisation. Temperature, weight and glucose may also be monitored.

- Our partnership with Phillips gives us access to state of the art remote technology integrating with the telehealth platform 'MyVirtualCare'

- Service operates 8am - 5pm weekdays but ran 7 days 7am-8pm at height of COVID-19 servicing both ISLHD and South Western Sydney LHD with internal capacity of approximately a 1000 – 1200 patients.

- Future Opportunities – weekends and longer day shifts would enable further support at busy time

✓ **ISLHD led cross regional virtual care approach 2020**

✓ **Supported 5,676 patients during COVID**

✓ **284 Chronic Care patients managed since November 2020**

✓ **Care for 4,634 Aboriginal and Torres Strait Islander patients since 2020**

Health
Illawarra Shoalhaven Local Health District
NSW GOVERNMENT

Virtually enhanced Community Care (VeCC) at ISLHD – Mental Health

Feedback from 100 Mental Health Consumers

✎ **94%** rated care as very good

✎ **79%** report experience is about the same or better than in person

✎ **82%** did not experience technical difficulty

❝ *Virtual is better than having a phone conversation because you can see the persons reactions on the other side* ❞

❝ *10/10. I work the same hours clinicians do, so if I can do my appointment at work, in my lunch break, it makes everything so much more convenient* ❞

Health
NSW GOVERNMENT | Illawarra Shoalhaven Local Health District

Virtually enhanced Community Care (VeCC) at ISLHD – Chronic Care

Of our current cohort of 105, 85.7% of patients are disadvantaged and of those 45.7% are significantly disadvantaged showing how important this kind of care is to provide to enable access to all consumers.
The scale below shows the Index of Relative Socio-economic Advantage and Disadvantage.
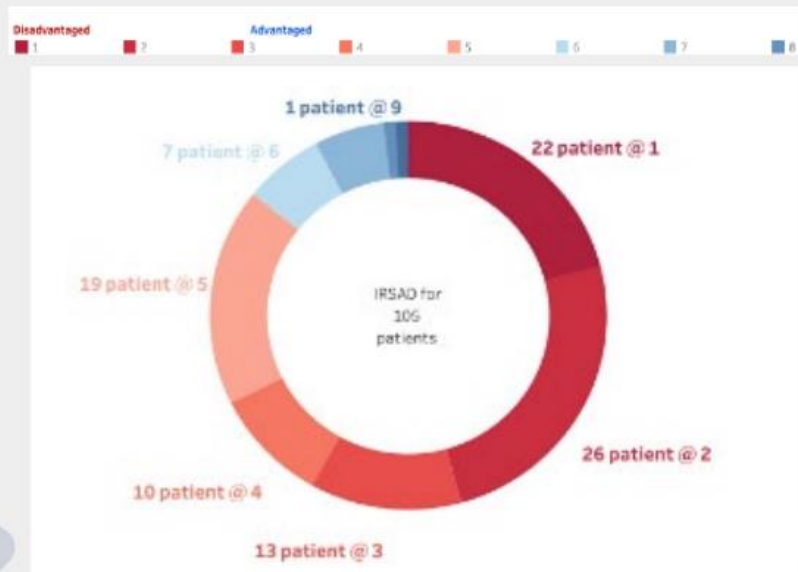
Virtually enhanced Community Care (VeCC) at ISLHD – MHAPP

The achievements of our Mental Health Ambulance and Police Project (MHAPP) team continue to grow as they provide more community based interventions resulting in ED avoidance on a daily basis.

✓ MHAPP has prevented over 1000 ED presentations this financial year to-date – doubling the number of ED presentations prevented last year and saving ISLHD $800,000.

✓ ED avoidances from Virtual MHAPP assessments alone have saved $12,000.

ED AVOIDANCES
MONTHLY & CUMULATIVE
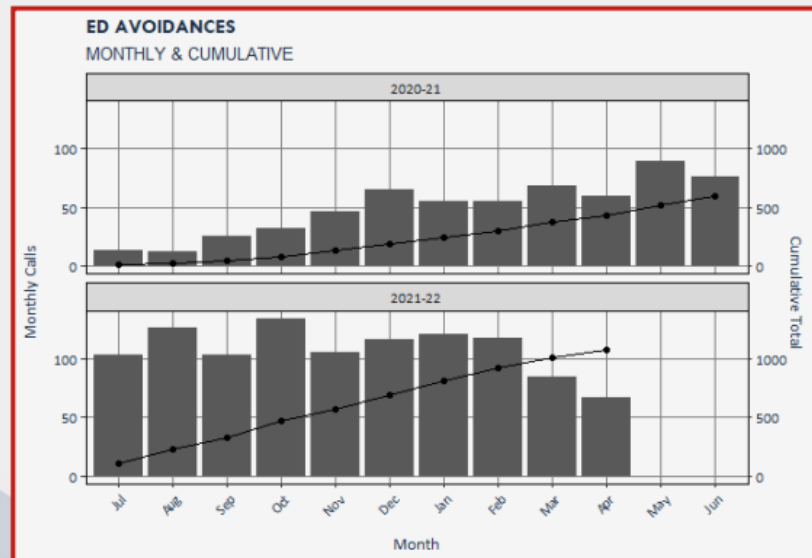
Virtually enhanced Community Care (VeCC) at ISLHD – Mental Health

Dr Ean Lup-Lo, Virtual Registrar with VC Cart

Emergency Department Virtual Expansion in Action

✐ Virtual Clinical Nurse Consultant assessments in ED

✐ Helps prioritisation and demand management

✐ Supports timely admission or discharge

✐ Brings together ED Mental Health clinicians as a team

✐ Supports across facilities especially in surge or furlough

NSW GOVERNMENT | Health | Illawarra Shoalhaven Local Health District

RPA Virtual Hospital

- Initiative of Sydney Local Health District who required a **sustainable virtual model to complement physical expansion.**
- Inner-city metropolitan area with growing and diverse population of 740,000+ residents in a densely populated 126km^2
- Exploratory planning early 2019, to leadership appointed late 2019 and operational service from February 2020.

Model designed to:
1. Support patient flow in acute hospitals by delivering more hospital-level care in the community
2. Enhance the patient experience of care by offering care that is more flexible and tailored
3. Inform understanding of the role of virtual care by articulating the model and its capabilities and demonstrating its viability.

RPA Virtual Hospital

- Org structure similar to traditional 'bricks and mortar' hospitals
- Clinician staffed 24/7 Virtual Care Centre to respond to deteriorating patients
- Virtual Care Centre complemented by 'on the ground' community nursing service
- Space efficient with majority of care delivered in 'virtual beds' in patient homes
- Virtual care pod requires 10sqm, compared to 48sqm per bed in a hospital ward and 50sqm for an outpatient clinic
- Remote monitoring using patient wearables
- Clinical management dashboard to integrate wearable device data with medical record Demonstrated ability to harness workforce and structure to support pandemic response

✓ **Care for 57,484 patients - 26,000 COVID-19+**

✓ **62% of patients are either clinically or socially vulnerable**

✓ **Complex cultural support for 2,492 Aboriginal and Torres Strait Islander patients**

✓ **In-person community nursing care for 9,132 patients (40% palliative)**

✓ **3,745 positive Patient Reported Experience Surveys**

RPA Virtual Hospital

RPA Virtual Hospital
Proof of concept trial
Evaluation Report
2020–2021

Year 1 Proof of Concept Trial Evaluation Report co-designed with Menzies Centre for Health Policy & Economics, University of Sydney

✓ Demonstrated that RPA Virtual can deliver safe, high-quality care that is efficient and highly acceptable to patients

✓ Includes cost benefit analysis of RPA Virtual role in pandemic response – delivering virtual care in the Special Health Accommodation March – June 2020

✓ Conservative estimate of avoided costs of $13m for this 3 month period

✓ For 282 non-pandemic patients, estimated 74,000 kms of travel saved and 13.4 tonnes of carbon emissions avoided

NSW GOVERNMENT | Health Illawarra Shoalhaven Local Health District

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Developing Collaborative Models of Care

1. Assess suitability of clinical condition for virtual care including review of available evidence and precedent models

2. Consult with ICT Services regarding ICT infrastructure and partners, integration of platforms and data vulnerabilities need to be worked through

3. Achieve consensus regarding clinical governance arrangements

4. Prepare detailed, descriptive model of care

5. Training – technology and privacy training are common consider helping clinicians adapt to this new approach and having strong leadership and advocates in place so people don't 'revert back'

6. Design evaluation measures, start then monitor, review, evaluate!

7. Look out for research opportunities

8. Get feedback from your clinicians and consumers

Fera. B, Shah. U, Korba.C, Shukia.M, "Virtual Health Accelerated ," Deloitte Insights, February 18, 2021. *View in Article*

Erica Teichert, "Training docs on 'webside manner' for virtual visits ," Modern Healthcare, August 27, 2016. *View in Article*

NSW GOVERNMENT | Health Illawarra Shoalhaven Local Health District

ecosystem

/ˈiːkəʊsɪstəm/
Noun
ECOLOGY
noun: ecosystem; plural noun: ecosystems; noun: eco-system; plural noun: eco-systems
- a biological community of interacting organisms and their physical environment.
    "the marine ecosystem of the northern Gulf had suffered irreparable damage"

- **(in general use) a complex network or interconnected system.**
    "Silicon Valley's entrepreneurial ecosystem"

Primary Care is a great place to start!

Snapshot of Total Australian Healthcare Volumes

25m population

124m
GP Patient Consultations Per Year

— Payments —
A$13bn
direct medical billing and payment integrations

— Government Data —
1.3bn+
health records within government-mandated EHR

11m
Hospital admissions
— Hospitals —

28m
referrals
— Imaging —

147m
referrals
— Pathology —

12m
referrals
— Specialist —

8m
referrals
— Allied Health —

117m
Medications prescribed
— Pharmacy —

MedicalDirector's software enables GP's and their patients to be fully integrated with the broader healthcare industry

3   Project Silver | Telstra Health   MedicalDirector

Fostering a healthy ecosystem

Accelerated innovation (Insert Super Cool Stuff here)		
Technical Framework		
Legal Framework		
Economics	**Governance**	**Standards**
• Creating a market that can sustain innovation • Attraction of the right type of capital for the right job • Sharing in value creation	• Risk Models that can enable safe innovation • Policies that keep the consumers privacy at the heart of all interactions • Consent frameworks to empower choice • Data use policies	• Clinical & Safety standards • Alignment of clinical coding standards • Adoption of industry wide interoperability standards • Security Standards

Sample of MD Ecosystem Outcomes.

• Supported over 20+ ecosystem partners entering the market.

• Over 80 Million moments of care interacted with these partners per annum

• Delivered Tele-Health to all MD users in 10 days of the pandemic hitting Australia

• ~1,000 patients who were hospitalised for heart or stroke conditions are now adhering to their treatments to keep them from having a secondary incident

DIGITAL THERAPEUTICS ALLIANCE

Embarking on a New Era of Digital Therapeutics

28 June 2022

Digital Therapeutics Alliance

Who We Are

Digital Therapeutics Alliance (DTA) is a trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics (DTx).

As the leading international organization on DTx thought leadership and education, DTA provides policymakers, payors, clinicians, and patients with the necessary tools to evaluate and utilize DTx products.

Evidence-based · CLINICIANS · Digital therapeutics · PATIENTS · High quality · PAYORS · REGULATORS

DIGITAL THERAPEUTICS ALLIANCE

"Not all digital products are therapeutic"

Products across the digital health ecosystem serve different, but complementary purposes. Depending on each product's intended use and risk, it is subject to increasing degrees of clinical evaluation, regulatory oversight, and real-world data requirements.

DIGITAL HEALTH TECHNOLOGIES*

Enterprise SYSTEMS & SUPPORT	Clinician SERVICES & SUPPORT	Patient-facing WELLNESS & SUPPORT	Patient-facing DIAGNOSTIC & MONITORING	Patient-facing THERAPEUTIC INTERVENTIONS
Platforms for healthcare systems, clinics, and other enterprise settings	Platforms primarily for clinicians and clinical support staff	Products that capture, store, or transmit health data	Products used to diagnose, guide diagnoses, or actively monitor patients	Products that deliver medical interventions and therapies
• Clinical administration and management tools • Predictive analytics • Clinical trial management	• Health Information Technology • Electronic medical record and prescribing systems • Point of care and workflow enhancement tools • Telehealth platforms	• Lifestyle and wellness apps • Activity and fitness trackers • Medication reminder apps • Wearables and sensors *(non-clinical grade)* • Consumer health information	• Digital diagnostics • Digital biomarkers • Remote patient monitoring tools • Wearables and biometric sensors *(clinical grade)* • Medication ingestible sensors • Connected drug delivery devices	• **Digital therapeutics** » Clinical interventions delivered directly to patients via software to treat, manage, or prevent a disease or disorder • Non-DTx medical devices (e.g., insulin pump, artificial pancreas, pacemaker, CPAP)

DTA's primary focus

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

DIGITAL THERAPEUTICS ALLIANCE

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DTx Definition

Digital therapeutics (DTx) deliver therapeutic interventions directly to patients using evidence-based, clinically evaluated software to treat, manage, and prevent a broad spectrum of behavioral, mental, and physical diseases and disorders.

Whether DTx products are used independently, in tandem with remote or in-person clinician-delivered therapy, or paired with medications, devices, and other therapies, DTA stands behind rigorous patient-centered core principles, ethical standards, and product development best practices to ensure product integrity, user-centered designs, patient privacy, and validated clinical outcomes.

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Digital Therapeutic Core Principles

DTx products should adhere to these foundational principles:

1	2	3	4	5
Prevent, manage, or treat a medical disorder or disease	Produce a medical intervention that is driven by software	Incorporate design, manufacture, and quality best practices	Engage end users in product development and usability processes	Incorporate patient privacy and security protections

6	7	8	9	10
Apply product deployment, management, and maintenance best practices	Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals	Be reviewed and cleared or approved by regulatory bodies as required to support product claims of risk, efficacy, and intended use	Make claims appropriate to clinical validation and regulatory status	Collect, analyze, and apply real world evidence and/or product performance data

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DTx Therapy Mechanisms of Action

- Provide personalized disease treatment, management, and prevention programs
- Offer therapies to address comorbidities, side effects, or affiliated conditions
- Provide treatments that produce direct neurologic changes
- Deliver cognitive behavioral therapy (CBT) and other evidence-based treatments
- Enhance, support, and optimize current in-person and medication treatments
- Deliver responsive physical exercises and behavioral interventions

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DTx Disease State Targets

Blood disorders
- Coagulation disorders, including hemophilia

Neoplasms
- Cancer, side effect management
- Cancer, drug therapy optimization

Endocrine, nutritional, and metabolic diseases
- Diabetes, type 1
- Diabetes, type 2
- Metabolic syndrome
- Obesity
- Pre-diabetes

Musculoskeletal system and connective tissue disorders
- Movement disorders
- Orthopedic conditions
- Osteoarthritis

Digestive system disorders
- Irritable bowel syndrome (IBS)

Mental, behavioral, and cognitive disorders
- Alcohol use disorder
- Attention-deficit/ hyperactivity disorder (ADHD)
- Anxiety
- Autism spectrum disorder
- Depression
- Eating disorders
- ICU delirium
- Opioid use disorder (OUD)
- Pain (acute, chronic)
- Panic disorder, panic attacks
- Post-traumatic stress disorder (PTSD)
- Schizophrenia (positive symptoms)
- Stress-related chronic diseases
- Substance use disorder (SUD)

Circulatory system disorders
- Hypertension
- Stroke

Nervous system disorders
- Epilepsy
- Insomnia, sleep disorders
- Lupus
- Migraine
- Multiple sclerosis (MS)
- Parkinson's disease (PD)

Respiratory system disorders
- Asthma
- Chronic obstructive pulmonary disease (COPD)

Skin and subcutaneous tissue disorders
- Skin disorders

Pregnancy and childbirth
- Postpartum depression

Injury, poisoning, and certain other consequences of external causes
- Traumatic brain injury (TBI)

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*As of March 2020

Scaling a New Category of Medicine

Industry Foundation – principles & standards

Care Optimization – patient & population care optimization

Regulatory Pathways – enabling market access

Patient Use – therapeutic value & impact

DTx Commercialization – providing market access

Clinical Guideline Integration – formalizing therapy use

Payor Assessment – enabling patient access

Clinician Engagement – providing patient access

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DTx Regulatory Frameworks

International Medical Device Regulators Form
Software as a Medical Device (SaMD) Framework

United States
SaMD-based Regulatory Framework

Japan
SaMD-based Regulatory Framework

South Korean
DTx-specific Regulatory Framework

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DTx Access & Reimbursement Frameworks

United Kingdom
Evidence for Effectiveness Framework

Germany
DiGA Framework

Belgium
mHealthBelgium Validation Pyramid

France
Coming Soon...

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DTA Initiatives

2017
Founded DTA: Industry collaboration

2018
DTx definition & core principles

2019
Industry awareness, product best practices & code of ethics

2020
Policy & legislative efforts

2021
Ecosystem growth
- DTx Product Library

2022
Enabling healthcare decision makers
- Regulatory & reimbursement pathways
- Legislative & regulatory engagement
- DTx Value Assessment & Integration Guide

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International Definition Setting

Building on DTA's industry definition, the Alliance is chairing an effort with standard setting bodies ISO and IEC to develop an internationally recognizable definition of a DTx.

ISO
ICS
ISO/AWI TR 11147
Health informatics – Personalized digital health – Digital therapeutics health software systems

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DTx Value Assessment & Integration Guide

- Confusion related to what is or is not a DTx product
- Lack of clarity related to necessary product requirements
- Numerous evaluations frameworks are emerging at the health system and government levels
  - Without industry-specific guidelines, HCDMs must develop their own requirements
  - Results in a patchwork of differing requirements for manufacturers
  - Therapy scalability and patient access may therefore be limited

(HCDM = Healthcare Decision Maker)

HEALTHCARE DECISION MAKER OVERVIEW

DTx Value Assessment & Integration Guide

VERSION 2.0

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Is This Product a DTx?

Does this product provide an intervention that is used in the context of healthcare? — No → Likely not a DTx

- Yes → Is the intervention primarily used for general health promotion, wellness, or fitness?
- Yes → Does the intervention solely inform, monitor, diagnose, or provide a clinician with insight?
- Yes → Does the intervention treat, manage, or prevent a disease or disorder?

Yes → Likely not a DTx

Yes → Likely not a DTx

- Yes → Does a clinician have sole responsibility for delivering the intervention (independent of software) to the patient?
- Yes → Does a standalone medication or pharmaceutical provide the intervention (independent of software)?
- Yes → Is software responsible for providing the intervention to the patient via a technology platform, medical device, pharmaceutical, etc.?
- No → Likely not a DTx

Yes → Likely not a DTx

Yes →

Has this product:
- Been designed and manufactured using quality best practices?
- Engaged end users in product development and usability processes?
- Incorporated patient privacy and security protections?
- Applied product deployment, management, and maintenance best practices?
- Published trial results inclusive of clinically meaningful outcomes in a peer-reviewed journal?
- Been authorized by a regulatory body as required to support product claims of risk, efficacy, and intended use?
- Made claims appropriate to clinical evaluation and regulatory status?
- Collected, analyzed, and applied real-world evidence and/or product performance data to patient care?

No → Likely not a DTx

Yes → This product is likely a DTx

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Where Do DTx Therapies Fit in Healthcare?

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Care options may include:*

Non-Clinical Grade Options such as:

Clinical-Grade Options such as:

Monitoring

Non-Clinical Grade:
- Activity & fitness trackers
- Patient-generated data repositories
- Smart consumer technologies (non-medical grade)
- Wearables and sensors (non-medical grade)

Clinical-Grade:
- Digital biomarkers
- Implantables
- In-person, telehealth, or virtual clinician monitoring
- Remote monitoring tools
- Wearables and sensors (medical grade)

Diagnosis

Non-Clinical Grade:
- Connected virtual assistants or consumer voice assistants
- Online consumer health information sources
- Predictive analytical tools (non-medical grade)

Clinical-Grade:
- Clinical outcome assessments
- Digital biomarkers
- Digital diagnostics
- In-person, telehealth, or virtual clinician diagnosis

Treatment Decision

Non-Clinical Grade:
- Clinical decision support tools (non-medical grade)
- Data repositories
- Wearables and sensors (non-medical grade)

Clinical-Grade:
- Clinical decision support tools (medical grade)
- Companion applications (medical grade)
- In-person, telehealth, or virtual clinician determination

Treatment & Ongoing Care

Non-Clinical Grade:
- Engagement tools (social media, online communities, etc.)
- Lifestyle options (nutrition, physical exercise program, etc.)
- Patient-generated data repositories
- Wellness & fitness apps

Clinical-Grade:
- Clinician-delivered in-person or virtual care
- Digital therapeutics (DTx)**
- Non-DTx medical devices
- Pharmaceuticals

How should decision makers start evaluating DTx products?

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Product Overview

Product name:_____
Target disease or disorder(s):_____
Intended use(s):_____
Target patient population(s):_____
Clinical issues addressed and/or gaps filled by product:_____

Product Use Considerations

Approved indication(s):_____
Directions for use:_____
Duration of therapy:_____
Dosing regimen:_____
Potential adverse events:_____
Risks or warnings:_____
Drug interaction(s):_____
Device interaction(s):_____

Check all that apply.

Intended environment of therapy delivery:

☐ Patient setting (i.e., home, work, school)
☐ Healthcare setting (i.e., clinic, hospital)
☐ Aged or disability residential care (i.e., nursing home, rehabilitation center)
☐ Other:_____

Intended environment of ongoing therapy use:

☐ Patient setting (i.e., home, work, school)
☐ Healthcare setting (i.e., clinic, hospital)
☐ Aged or disability residential care (i.e., nursing home, rehabilitation center)
☐ Other:_____

What stage of development is the product currently in?

☐ Technical and pre-clinical development phase
☐ Clinical development phase
☐ Product is undergoing initial regulatory review
☐ Product has cleared all necessary clinical and regulatory requirements in one or more jurisdictions
☐ Other:_____

How should health systems begin implementing DTx products?

DTx Product Implementation and Engagement

This framework provides HCDMs with an industry-level guide to measuring the effectiveness of practices used to implement DTx products in clinical settings. DTA does not provide advice on optimal business models or strategies for specific DTx products.

Payors are encouraged to use this framework for all DTx product types, with the recognition that each product has specific considerations to enable end user success.

Potential implementation considerations include:

DTx "Engagement Chain"[1]

The DTx Engagement Chain comprises five steps for HCDMs and DTx manufacturers to consider in relation to targeting, outreaching to, activating, engaging with, and supporting individual patients.

A. Target → B. Outreach → C. Activate → D. Engage → E. Support

A. Target

Patient targeting process for this product may include:
- » Determine which patient population is most suited for the use of the DTx therapy
  (Note: this is more selective than simply identifying all patients with a particular condition)
- » Analyze patient data to determine greatest product impact and ROI
- » Identify and target patients by disease (i.e., disease severity, urgency of medical need)
- » Prioritize individuals who will be most successful with treatment

Options to target appropriate patients may include:
- » Patient geography
- » Disease state and/or comorbidity
- » Acuity or severity of disease state
- » Demographic parameters
- » Social determinants
- » Target clinical measures

[1] The "DTx Engagement Chain" is a registered trademark of Welldoc, Inc. It has been adapted with Welldoc's permission for use by DTA.

welldoc

DTA

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Launching a Policy-focused Coalition

Engaging With…

- Health Technology Assessment (HTA) entities
- National & regional trade associations

from Europe, Australia, and the Middle East

To…

- Understand existing frameworks
- Share lessons learned from previous efforts
- Set out a vision for harmonized clinical, regulatory, and reimbursement requirements

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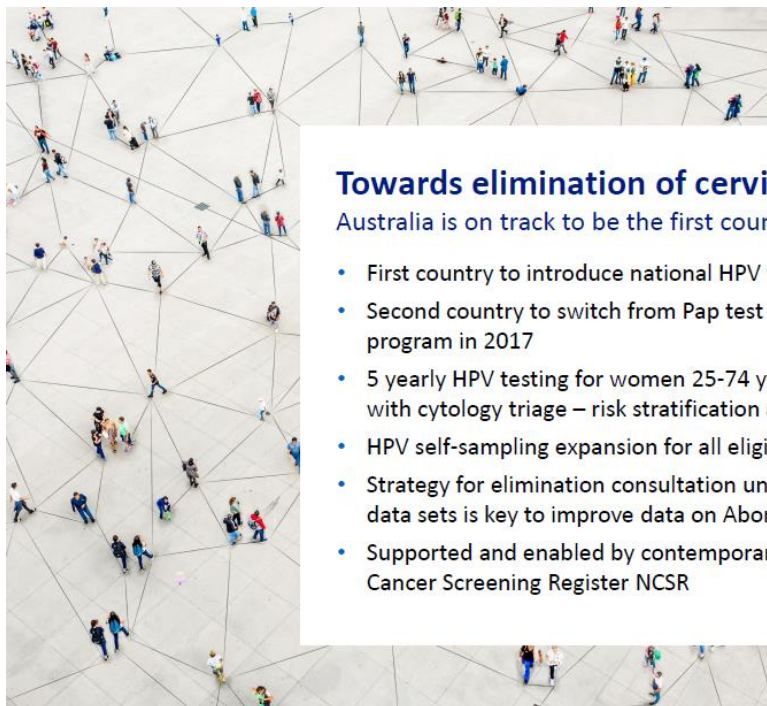
Towards elimination of cervical cancer in Australia

Australia is on track to be the first country to eliminate cervical cancer by 2035

- First country to introduce national HPV vaccination program in 2007
- Second country to switch from Pap test based program to primary HPV testing program in 2017
- 5 yearly HPV testing for women 25-74 yrs based on partial genotyping for HPV with cytology triage – risk stratification approach
- HPV self-sampling expansion for all eligible women July 2022
- Strategy for elimination consultation underway. Linkage to other government data sets is key to improve data on Aboriginal and Torres Strait Islander women
- Supported and enabled by contemporary digital infrastructure – the National Cancer Screening Register NCSR
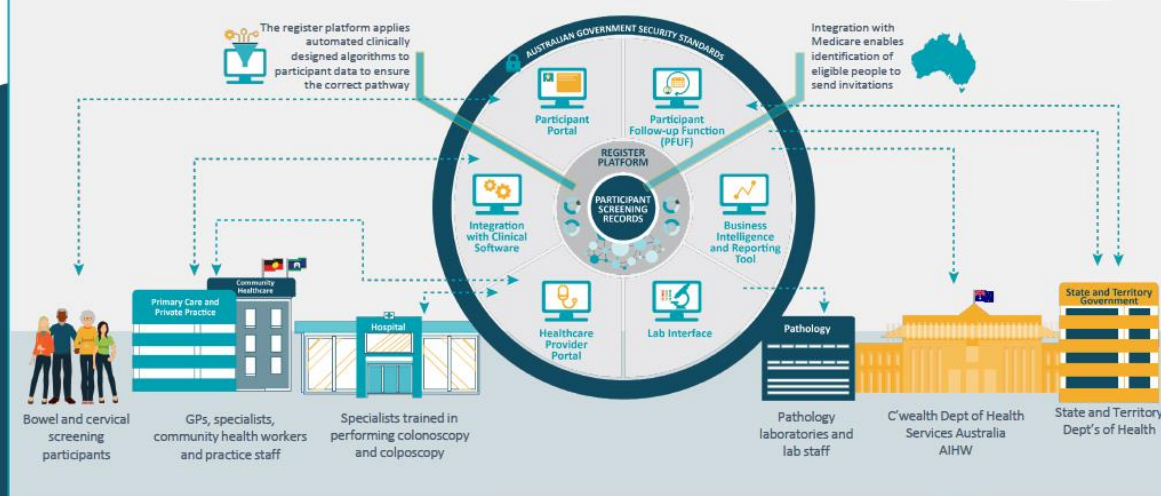
National experience in the first two years of primary human papillomavirus (HPV) cervical screening in an HPV vaccinated population in Australia: observational study

Megan A Smith,[1] Maddison Sherrah,[1] Farhana Sultana,[2,3] Philip E Castle,[4] Marc Arbyn,[5,6] Dorota Gertig,[2,3] Michael Caruana,[1] C David Wrede,[7,8] Marion Saville,[8,9] Karen Canfell,[1,10]

- Report on first 2 years of primary HPV screening in Australia 2017-2019, n=3.75 million, based on NCSR data extract
- Primary HPV screening with partial genotyping for HPV16/18 and cytology triage is viable in a vaccinated population, with digital infrastructure to support screening pathways.
- Clinical management:
  - Colposcopy should be considered for women whose first primary test is HPV16/18 positive, regardless of cytology result, owing to a high risk of detecting cancer in this group (1%).
  - Women with only HPV types not 16/18 detected (no major cytological abnormalities) are at low risk of cancer and can safely be referred for surveillance beyond 12 months.
- Analysis has changed policy and clinical guidelines
- Importance of risk stratification and "personalized" screening as vaccinated women reach screening age.

The Problem

- Early diagnosis of skin cancers is related to better outcomes <u>but</u> demand is outpacing capacity

- In the UK
  - 2WW: Skin cancer referrals has increased 5x faster than skin cancer detection over the past 10 years
  - 24% of Consultant Dermatologist posts are unfilled

- Similar picture internationally including Australia

  Report from Australiasian College of Dermatologists:

  Specialist dermatologist workforce is in shortage (~15% fewer FTE than needed) and maldistributed (.>90% in major metropolitan centres)

Trends in skin cancer detection - changes from 2009/10

Conversion (% 2WW that are cancer) — Detection (% all cancer from 2WW) — Referrals per 100,000
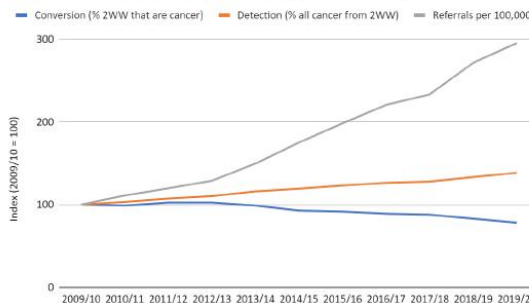
Our Foundations

Our technology has been built on foundations of:

1. **Purpose built algorithm** with focus on data quality

2. Industry leading **clinical validation** & **regulatory compliance**

3. **Deep understanding of the clinical pathways** through >5years of work in skin cancer pathways before introducing AI

JAMA Network Open.
Original Investigation | Dermatology
Assessment of Accuracy of an Artificial Intelligence Algorithm to Detect Melanoma in Images of Skin Lesions

Dermatology Practical & Conceptual
Dermatol Pract Concept. 2020; 10(1): e2020011.   PMCID: PMC6936633
Published online 2019 Dec 31. doi: 10.5826/dpc.1001a11   PMID: 31921498
Detection of Malignant Melanoma Using Artificial Intelligence: An Observational Study of Diagnostic Accuracy
Michael Phillips, Jack Greenhalgh, Helen Marsden and Ioulios Palamaras

bsi ISO/IEC 27001 Information Security Management CERTIFIED · DCB 0129 · SGS · bsi ISO 13485 Medical Devices Quality Management

MHRA · Australian Government Department of Health Therapeutic Goods Administration · CareQuality Commission

Our AI (DERM)

DERM is the only UKCA certified **Class IIa Medical Device** for dermatology

- Trained to analyse a dermoscopic image of a skin lesion where there is a suspicion of skin cancer and return classification for the most common malignant, pre-malignant and benign conditions including:
  - Melanoma
  - Squamous Cell Carcinoma (SCC)
  - Basal Cell Carcinoma (BCC)
  - Actinic Keratosis (AK) ...

- DERM is also registered with the Australian TGA on the ARTG database of medical devices

skin analytics Confidential. Skin Analytics 2022

It's been a long journey...

2015 Published the **first ever prospective study of AI for Melanoma detection** demonstrating a similar level of accuracy to skin cancer specialists

DERM CE marked as a **class I** medical device

Skin Analytics (SA) **founded** to help people survive skin cancer

2012 Began providing **Teledermatology services**

Started the **first ever prospective study of AI for Melanoma detection** across 7 UK hospitals

2019

2020 First live deployment of Skin Analytics' AI, DERM at University Hospitals Birmingham FT

Skin Analytics **launch DERM at Mid & South Essex Helath and Care Partnerships** as an AI powered decision support tool for GPs

UHB results shared at 9th world congress of teledermatology, imagery and AI for skin diseases

Skin Analytics **win the AAC award**

Skin Analytics **launch DERM into West Suffolk NHS FT** continuing to deliver AI support into the NHS

Skin Analytics **achieve ISO 27001**

Skin Analytics **launch DERM into Univeristy Hospitals Leicester**

2021

2022 DERM is **awarded class IIa medical device** status in the UK

Skin Anlaytics **launch DERM into Chelsea and Westminster NHS FT**

Skin Analytics **launch DERM into Univeristy Hospitals Bristol and Weston NHS FT**

Initial results of **Impact study** presented at the American Association of Dermatologists AGM

skin analytics Confidential. Skin Analytics 2021

DERM in the real world

- DERM has been live in the NHS **since 2020** and is now in **6 NHS sites** on pathways that have seen **22,772 patients**

- **4,652 (>20%)** have been discharged from these pathways *without utilising trust capacity*, with the potential for this to have been **7,709 (~34%) without a second read dermatologist**

- Q1 2022 report showed that DERMv3 had a **98.3% pathway sensitivity** and **99.3% negative predictive value** for skin cancer
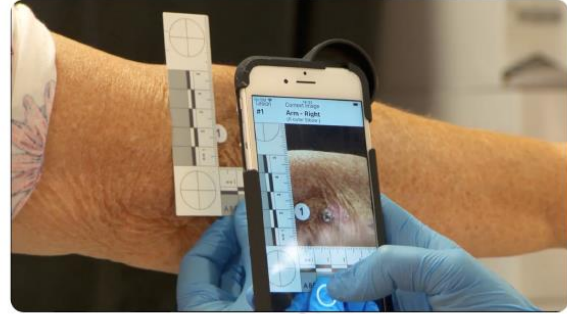
Thank you & Questions

Chelsea and Westminster Hospital **NHS** NHS Foundation Trust

NHS West Suffolk NHS Foundation Trust

NHS University Hospitals Birmingham NHS Foundation Trust

Mid and South Essex Health and Care Partnership

NHS University Hospitals Bristol and Weston NHS Foundation Trust

NHS University Hospitals of Leicester NHS Trust

dan@skinanalytics.co.uk

Health Inequalities - A Cancer Case Study

Hassan Chaudhury

Commercial Director for DATA-CAN - The UK Health Data Research Hub for Cancer
June 2022

Health inequalities are avoidable, unfair and systematic differences in health between different groups of people

- health status, for example, life expectancy
- access to care, for example, availability of given services
- quality and experience of care, for example, levels of patient satisfaction
- behavioural risks to health, for example, smoking rates
- wider determinants of health, for example, quality of housing

1. socio-economic factors, for example, income
2. geography, for example, region or whether urban or rural
3. specific characteristics including those protected in law, such as sex or ethnicity
4. socially excluded groups, for example, people experiencing homelessness.

The Health Foundation

What we do   Funding and partnerships   News and comment

Home   >   Publications   >   Reports

Health Equity in England: The Marmot Review 10 Years On

February 2020

Professor Sir Michael Marmot / Jessica Allen / Tammy Boyce / Peter Goldblatt / Joana Morrison

Publication / Report / Health Equity in England: The Marmot Review 10 Years On / Inequalities / Public health / Social determinants of health

↓ Download

This report has been produced by the Institute of Health Equity and commissioned by the Health Foundation to mark 10 years on from the landmark study *Fair Society, Healthy Lives (The Marmot Review)*.

The report highlights that:

- people can expect to spend more of their lives in poor health
- improvements to life expectancy have stalled, and declined for the poorest 10% of women
- the health gap has grown between wealthy and deprived areas
- place matters – living in a deprived area of the North East is worse for your health than

HDRUK
Health Data Research UK

- Survival from cervical cancer **decreases with socioeconomic status** which is why it is sometimes referred to as a **"disease of poverty"**
- We know that smoking and obesity, both a risk factor for cancers, are more prevalent **in deprived areas** with higher socioeconomic inequality-increasing an individual's risk of **developing a number of cancers**
- On cancer outcomes, evidence shows that those in the most deprived areas of England are **more likely** to have their cancer diagnosed at a late stage, compared to those in the least deprived areas.
- The most ethnically diverse areas are the **least likely to respond** to invitations to bowel cancer screening.
- Health literacy tends to be lower in areas with more socioeconomic deprivation meaning adherence both to screening programmes and to follow up procedures is **lower than in more affluent & racially homogenous areas.**

REDUCING HEALTHCARE INEQUALITIES

NHS

The **Core20PLUS5** approach is designed to support Integrated Care Systems to drive targeted action in health inequalities improvement

CORE20
The most deprived **20%** of the national population as identified by the Index of Multiple Deprivation

20%

Target population

PLUS
ICS-chosen population groups experiencing poorer-than-average health access, experience and/or outcomes, who may not be captured within the Core20 alone and would benefit from a tailored healthcare approach e.g. inclusion health groups

CORE20 PLUS 5

Key clinical areas of health inequalities

1 MATERNITY
ensuring continuity of care for **75%** of women from BAME communities and from the most deprived groups

2 SEVERE MENTAL ILLNESS (SMI)
ensuring annual health checks for **60%** of those living with SMI (bringing SMI in line with the success seen in Learning Disabilities)

3 CHRONIC RESPIRATORY DISEASE
a clear focus on Chronic Obstructive Pulmonary Disease (COPD), driving up uptake of Covid, Flu and Pneumonia vaccines to reduce infective exacerbations and emergency hospital admissions due to those exacerbations

4 EARLY CANCER DIAGNOSIS
75% of cases diagnosed at stage 1 or 2 by 2028

5 HYPERTENSION CASE-FINDING
to allow for interventions to optimise blood pressure and minimise the risk of myocardial infarction and stroke

DIAGNOSTICS: RECOVERY AND RENEWAL

Report of the Independent Review of Diagnostic Services for NHS England

October 2020

GOV.UK

Home > Health and social care > Public health > Health conditions

Press release

40 community diagnostic centres launching across England

Millions of patients will benefit from earlier diagnostic tests thanks to 40 new community diagnostic centres set to open across England.

From: Department of Health and Social Care, NHS England, and The Rt Hon Sajid Javid MP
Published 1 October 2021
Last updated 8 October 2021 — See all updates

Related content

NHS screening programmes: KPI reports and briefings 2015 to 2016

NHS screening programmes: KPI reports 2013 to 2014

NHS screening programmes: KPI reports and briefings 2016 to 2017

MANCHESTER CANCER RESEARCH CENTRE

Research   Study   About   Collaborate   News   Contact

Reaching all communities

Engagement with those communities most at risk of health inequalities such as late cancer diagnosis is vital if a shift to early detection and improved patient outcomes in all communities is to be realised.

Leaders and policymakers within our healthcare service need to put urgent thought into how our system can be structured towards earlier interventions. Increased and meaningful community engagement is key to achieving equitable healthcare and has the added benefits of reduced strain on the NHS from the impacts of late diagnosis. A robust and well-resourced infrastructure is needed to support this.

HDR UK's mission is to unite the UK's health data to enable discoveries that improve people's lives.

Our 20-year vision is for large scale data and advanced analytics to benefit every patient interaction, clinical trial, and biomedical discovery and to enhance public health.

We don't see a compromise between quality and diversity - in fact, we are pursuing higher quality through greater diversity

Caroline Cake, Chief Executive Officer, Health Data Research UK

HDRUK
Health Data Research UK

Lessons learned so far are:

1. Ground-breaking research insights require **diverse, linked data**

2. A complex ecosystem with multiple stakeholders requires a **strong convenor (i.e. HDR UK)**

3. Improving the quality of health data needs groundwork – **data engineering and cleaning**

4. **Public trust must be continuously earned**; patients are not only effective advocates – their involvement results in better and more trustworthy research

5. **"Build it and they will come", is not enough** – infrastructure should be developed for a purpose, driven by **user needs and research questions**

6. **The health data science challenge (and opportunity) is global**

7. We have an opportunity to champion a research culture that celebrates **creativity, inclusivity** and the values of **Transparency, Optimism, Respect, Courage and Humility.**

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Diversity and Inclusion Policy

HDRUK
Health Data Research UK

Objectives – What does this look like in practice?

DIVERSITY AND INCLUSION

DATA

PERSPECTIVES

TRAINING   PEOPLE

Data from diverse populations is more valuable for research

Diverse perspectives, experiences and engagement to create better science and innovation

Diverse skills and backgrounds in people trained to become health data scientists

Diverse workforce and our impact will benefit the whole population

Data: To support research based on diverse health data ranging from electronic health records[1] generated through routine healthcare in primary, secondary and tertiary healthcare and social care, to carefully-curated research-ready cohort data[2].

People: To be an inclusive environment supporting all people – regardless of gender, disability, sexual orientation, age, religion, race, maternity/parental status and socioeconomic background – whether they are employees, members, research participants, those being trained as health data scientists or benefitting from the research we support.

[1] An electronic health record is the collection of health data for a patient, collected during the course of routine health and social care. It is electronically-stored in a digital format – by hospitals, GPs etc. They may include a range of data, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, etc. They are an important source of data for health research.
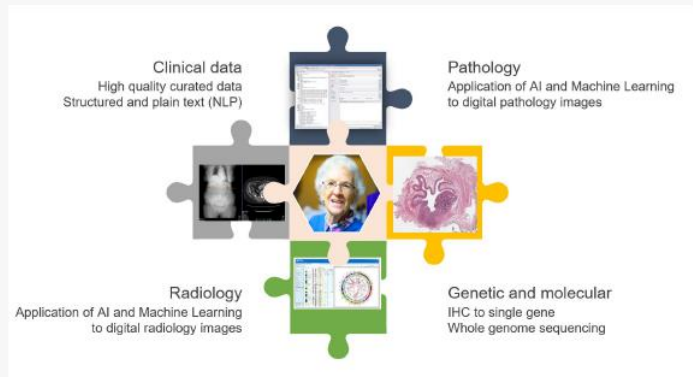
[2] Cohort data is information collected from a specific group of people over the course of their lives. Those who set up cohorts, follow the health and well-being of the volunteer participants and provide health information, which does not identify them, to approved researchers to conduct health research. Examples of cohorts include UK Biobank (group of people from the general population), and Genes & Health (one of the world's largest community-based genetics studies, aiming to improve health among people of Pakistani and Bangladeshi heritage by analysing the genes and health of 100,000 local people).

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Health Data Research UK

1. Data
2. Training
3. People
4. Perspectives

DATA-CAN: The vision
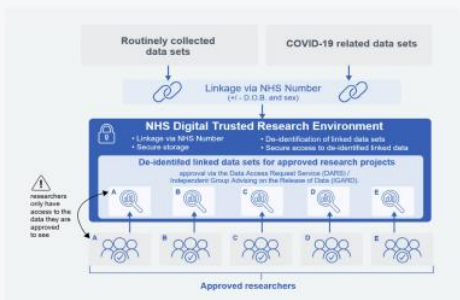
HDRUK
Health Data Research UK

- **Improve access to existing data**
  - Clinical, academic & commercial

- **Improve quality of data**
  - Better data at the point of care
  - Enhanced curation of current data

- **Improve UK coverage**
  - Four nations of the UK

- **Add new datasets at scale**
  - Genetic/molecular, imaging, pathology
  - Primary care, PROMs

- **Ensure fair value**
  - NHS & UK, Trusts & CCGs, Patients & public

Clinical data
High quality curated data
Structured and plain text (NLP)

Pathology
Application of AI and Machine Learning
to digital pathology images

Radiology
Application of AI and Machine Learning
to digital radiology images

Genetic and molecular
IHC to single gene
Whole genome sequencing

UCL**Partners** | **NHS** The Leeds Teaching Hospitals NHS Trust | UNIVERSITY OF LEEDS | QUEEN'S UNIVERSITY BELFAST | IQVIA | Genomics England

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DATA-CAN: National Data
The National Cancer TRE

HDRUK
Health Data Research UK

- National COVID data
- HES, Primary Care prescriptions
- COSD, SACT, RTDS plus Rapid Cancer Registrations

Impact of COVID-19 on
- Cancer referrals, diagnosis, treatment
- Cancer-specific outcomes

Impact of Cancer on
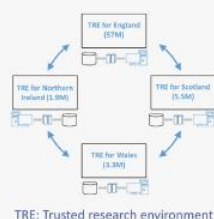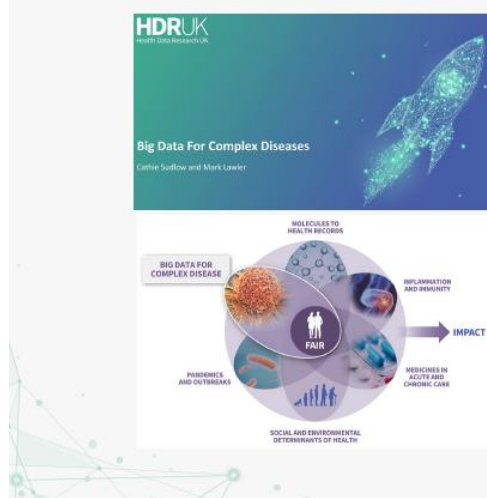- COVID diagnosis & severity
- COVID outcomes

Hospital admissions in cancer patients by age

DATA-CAN 2.0:
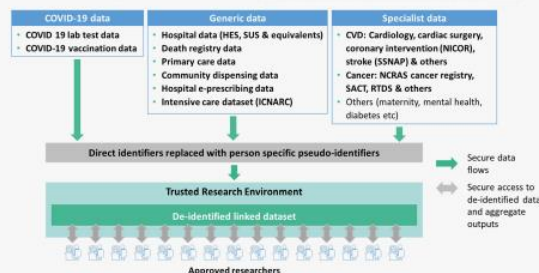### HDRUK QQ2 – Big Data for Complex Diseases

DATA-CAN: PPIE
Embedded in everything we do

- PPIE involvement in every commercial discussion, including power of veto

- Publications of PPIE best practice

- Delivery of 'commercial' PPIE services

- Support to our PPIE team to take part in complex data discussions, inside and outside DATA-CAN

- Comprehensive learning materials, training and guidance

- Support for use MY data, including patient webinars, advocacy, lobbying and patient voices

"DATA-CAN's approach is radically different from other experiences as a patient advocate. From the outset we were supported, invited and empowered to participate in all discussions on the project's direction and operation. This required courage from DATA-CAN and confidence in the contributions and decisions of our PPIE group. It has also required bravery, determination and hard work from us to judiciously and democratically represent the interests of all patients."

Pete Wheatstone, cancer survivor and Chair of the DATA-CAN PPIE group

Wheatstone P, Gath J, Carrigan C, Hall G, Cook Y, DATA-CAN Sujenthiran A, Peach J, Davie C, Lawler M.
DATA-CAN: a co-created cancer data knowledge network to deliver better outcomes and higher societal value. *BMJ Partnerships in Practice* 2021
https://blogs.bmj.com/bmj/2021/08/11/data-can-a-co-created-cancer-data-knowledge-network-to-deliver-better-outcomes-and-higher-societal-value/

| 14

Australian British Health Catalyst 2022 - Programme

MONDAY 27 JUNE

Location - Royal College of Physicians, 11 St Andrews Place, London NW1 4LE

09:10 Welcome: **David Slessar OBE,** Co-Chair, Australian British Health Catalyst

09:20 Ministerial Address

09:40 **Healthcare in Australia and the UK - Similarities and Differences**

- ▶ **Sir Malcolm Grant CBE,** Former Chair, NHS England
- ▶ **Prof Ian Jacobs,** Former President and Vice-Chancellor of the University of NSW

    Followed by a discussion moderated by **Emeritus Prof Christine Bennett AO,** Co-Chair, Australian British Health Catalyst

10:20 Morning Tea

10:50 **Pandemic Lessons Learned, Preparedness for the Future**

- ▶ What can we do together from the lessons learned?
- ▶ How do we keep the gains achieved and learning from models that allowed swift change?
- ▶ How to improve readiness for future pandemics and health crises

    Keynotes
- ▶ **Susan Pearce**, Secretary, NSW Health
- ▶ **Prof Neil Ferguson OBE,** Infectious Disease Epidemiologist, Imperial College London

    Followed by a panel discussion moderated by **Elizabeth Koff AM,** Managing Director, Telstra Health

11:50 **Embracing the Digital Step-Change**

- ▶ Creating an ecosystem for smart use of data for better health outcomes
- ▶ Virtual Care: video-consultations, remote patient monitoring and asynchronous clinical consults

    Keynotes
- ▶ **Prof Tony Young OBE,** National Clinical Lead for Innovation, NHS England
- ▶ **David Maguire,** Senior Analyst, The King's Fund
- ▶ **Margot Mains,** CEO, The Illawarra Shoalhaven Local Health District
- ▶ **Matt Bardsley,** CEO, MedicalDirector, Telstra Health

    Followed by a panel discussion moderated by **Prof Tony Young OBE,** National Clinical Lead for Innovation, NHS England

13:00 Lunch

14:00 **What does success look like in the Future of Healthcare?**

- ▶ The 5 key principles of the future of healthcare systems
- ▶ Delivering on integrated, value-based healthcare
- ▶ The role of patient reported measures

    Keynotes
- ▶ **Matthew Swindells,** Chair, North West London Acute Hospitals
- ▶ **Elizabeth Koff AM,** Managing Director, Telstra Health
- ▶ **Dr Jean-Frederic Levesque,** CEO, NSW Agency for Clinical Innovation
- ▶ **Dr Malcolm Pradhan,** Chief Medical Officer, Alcidion

    Followed by a panel discussion moderated by **Noel Gordon,** Chair, Telstra Health UK Strategic Council and Former Chair, NHS Digital

MONDAY 27 JUNE CONT'D

15:20 Afternoon Tea

15:50 Addressing Equality and Health Inequalities

- ▶ Health inequalities through a population health approach
- ▶ Rural and regional healthcare gains and challenges

   Keynotes
- ▶ **Dr Nav Chana MBE,** Director of National Association of Primary Care (Former Chair)
- ▶ **Jill Ludford,** CEO, Murrumbidgee Local Health District
- ▶ **Hassan Chaudhury,** Global Digital Health Specialist, Healthcare UK

- ▶ Video Message from **Dr Bola Owolabi,** Director, Health Inequalities, NHS England and NHS Improvement

   Followed by a panel discussion moderated by **India Hardy,** Partner, PwC

17:00 End of Day One Content

17:15 Coach pick up from the Royal College of Physicians to the Ironmongers' Hall

18:00 Catalyst Reception - supported by Investment NSW

Location - Ironmongers' Hall, Off Shaftesbury Pl, Aldersgate St, Barbican EC2Y 8AA

TUESDAY 28 JUNE

Location - Royal College of Physicians, 11 St Andrews Place, London NW1 4LE

08:30 Welcome: **Emeritus Prof Christine Bennett AO,** Co-Chair, Australian British Health Catalyst

08:40 Harnessing Data to advance Public Health

- ▶ How are we transforming healthcare systems by using data to advance health?
- ▶ Leveraging Data and Integration platforms to manage Care in the Community
- ▶ Requirements for leveraging routine hospital data for secondary use at scale
- ▶ Emerging findings from Australia's national cervical screening programme

Keynotes:
- ▶ **Ming Tang,** Chief Data and Analytics Officer, NHS England and NHS Improvement
- ▶ **Dr Amith Shetty,** Clinical Director, NSW COVID Care in the Community
- ▶ **Prof Neil Sebire,** Chief Research Information Officer, Great Ormand Street Hospital (GOSH) and Managing Director, GOSH DRIVE
- ▶ **Prof Dorota Gertig,** Medical Director, Population Health Solutions, Telstra Health

   Followed by a panel discussion moderated by **Dr Amith Shetty,** Clinical Director, NSW COVID Care in the Community

10:00 Morning Tea

10:30 How AI and Digitised Health Data can Inform Decision Making

Keynotes:
- ▶ **Dr David Hansen,** CEO and Research Director of the Australian e-Health Research Centre at CSIRO
- ▶ **Dominic Cushnan,** Head of AI Imaging at NHS AI Lab
- ▶ **Alex Ide,** Head of Europe, Prospection
- ▶ **Dr Stefan Harrer,** Chief Innovation Officer, Digital Health CRC

   Followed by a panel discussion moderated by **Emeritus Prof Christine Bennett AO**

TUESDAY 28 JUNE CONT'D

11:40 Beyond Health Data and e-health: Digital Medicine and Digital Therapeutics, and their role in a modern healthcare system

Keynotes
- ▶ **Dr Megan Coder,** Executive Director, Digital Therapeutics Alliance
- ▶ **Liz Ashall-Payne,** CEO, ORCHA

Followed by a panel discussion moderated by **Bronwyn Le Grice,** CEO, ANDHealth

12:30 Lunch

13:30 Research and Translation

- ▶ Accelerating research translation and implementation

Keynotes
- ▶ **A/Prof Annette Schmiede,** CEO, Digital Health CRC; Chair, Research Australia
- ▶ **Suzie Ali-Hassan,** Director of Enterprise, UCLPartners; Deputy Director, National NHS Innovation Accelerator
- ▶ **Rosie Hicks,** CEO, Australian Research Data Commons

Followed by a panel discussion moderated by **Dr Jean-Frederic Levesque,** CEO, NSW Agency for Clinical Innovation

14:30 Afternoon Tea

15:00 Innovation and Commercialisation

- ▶ The role of industry in effective commercialisation
- ▶ Enabling clinician led commercialisation

Keynotes
- ▶ **Prof Tony Young OBE,** National Clinical Lead for Innovation, NHS England
- ▶ **Bronwyn Le Grice,** CEO, ANDHealth
- ▶ **Anya Roy,** Head of Illumina Accelerator Cambridge

Followed by a panel discussion moderated by **Hassan Chaudhury,** Global Digital Health Specialist, Healthcare UK

16:00 Innovation Showcase

- ▶ Three minute pitches from eight innovation companies.

17:00 End of Day Two Content

19:00 Catalyst Dinner with **Sir Jonathan Van-Tam MBE**

Location - The Ned, 27 Poultry, London EC2R 8AJ (Tapestry Room, Level 6)
Note: It is recommended to arrive via the Ground Floor Entrance at 5 Princes Street and take the main lifts up to Level 6

WEDNESDAY 29 JUNE

Location - Royal College of Physicians, 11 St Andrews Place, London NW1 4LE

09:00 Welcome: **Emeritus Prof Christine Bennett AO,** Co-Chair, Australian British Health Catalyst

09:05 **Health Data Science and the Fourth Industrial Revolution**

Keynote
► **Prof Andrew Morris CBE,** CEO, Health Data Research UK

Followed by a conversation with **Hassan Chaudhury,** Global Digital Health Specialist, Healthcare UK

09:30 **Cyber Security: How are we keeping data safe?**

► **Karen Dooley,** Deputy National Chief Information Security Officer, Department for Health and Social Care
► **Andrew Fitzmaurice,** CEO, TemplarExecutives

Followed by a discussion moderated by **Emeritus Prof Christine Bennett AO,** Co-Chair, Australian British Health Catalyst

10:30 Morning Tea

11:00 **What does the health precinct of the future look like?**

► How do we develop health precincts to be environmentally sustainable and fully digital?
► How do we create a net zero health care system?

Keynotes
► **Dr Nick Watts,** Chief Sustainability Officer, NHS
► **Rebecca Stubbs,** Principal Net Zero Carbon Consultant, Mott MacDonald
► **Frank McGuire MP,** Parliamentary Secretary for Medical Research, Victorian State Government

Followed by a panel discussion

12:00 Lunch

13:00 **Regulation of Digital Health Solutions**

Keynotes
► **Tracey Duffy,** First Assistant Secretary, Medical Devices and Product Quality Division, Therapeutic Goods Administration
► **Johan Ordish,** Head of Software and AI, Innovative Devices Division, MHRA

Followed by a panel discussion moderated by **Stuart Harrison,** CEO of ETHOS

14:00 **Investing in People**

► New skills to leverage technology and data science in health care
► Addressing supply challenges
► Workforce wellbeing and wellness

Keynotes
► **Sir David Behan CBE,** Chair, Health Education England
► **Dr Amandeep Hansra,** Founder, Creative Careers in Medicine
► **A/Prof Marc Budge,** Centre for Digital Transformation of Health, University of Melbourne
► **Margot Mains,** CEO, The Illawarra Shoalhaven Local Health District

Followed by a discussion moderated by **Margot Mains,** CEO, The Illawarra Shoalhaven Local Health District

WEDNESDAY 29 JUNE CONT'D

15:30 Afternoon Tea

16:00 **Data, Research, Talent and Collaboration: The Potential Upsides of the AUS-UK Free Trade Agreement**

- ▶ How does the FTA enable us to build the convergence we want to see to enable digital health workforce, regulatory alignment and commercial enabler to support innovative exchange?
- ▶ A potential Health Tech Bridge
- ▶ Next steps?

   Panel Discussion moderated by **David McCredie AM OBE,** CEO, Australian British Chamber of Commerce

- ▶ **Julian David,** CEO, techUK
- ▶ **Larissa Briedis,** Board Director, Medical Software Industry Association (Australia)

16:50 Closing Comments: **Emeritus Prof Christine Bennett AO,** Co-Chair, Australian British Health Catalyst

17:00 Catalyst Ends

EABC Mission

On Sunday July 3, I joined the EABC's mission when it arrived in London, meeting the acting High Commissioner of Australian to the United Kingdom, Lynette Wood, with a senior adviser to the Prime Minister of the United Kingdom. The once in a generation Australia-UK Free Trade Agreement redefining Australia's relationship with the UK has been signed and must be passed by both national Parliaments. I proposed the benefits of this deal be reframed to highlight vaccines and health innovations, defining its life-saving benefits in the time of pandemic, and raising public appreciation above vegemite and marmite. The UK Prime Minister's senior adviser supported this strategy for the forthcoming debates.

EABC chair and former Australian Trade Minister, Simon Crean, re-joined the mission after newly elected Australian Prime Minister, Anthony Albanese invited him to Paris for meetings with French Government officials to reset bilateral relations between Australia and France. Both countries have officially moved past the submarine row, paving the way for future diplomatic and business opportunities after President Macron and Prime Minister Albanese committed to build a "closer and stronger bilateral relationship based on mutual trust and respect." Both countries have agreed to a new agenda for cooperation founded on defence and security, resilience and climate action, and education and culture.

EABC chair, Simon Crean, participated in the Business Forum hosted by MEDEF International with the Australian Prime Minister. Key areas of collaboration are opportunities in the hydrogen sector, infrastructure projects and diversification of supply chains. The mood of leading European countries has advanced significantly, from polite indifference to a European Union Free Trade Agreement with Australia before the pandemic, to public support and urgency, especially after the war in Europe delivered fuel and food crises. The need to build stronger ties with like-minded countries is recognised as crucial. EABC reports positive momentum to conclude an EU-Australia Free Trade Agreement and that a deal could be reached by early 2023. President Macron may visit Australia after the G20 in Bali on November 15-16 this year.

3. Trade policy

- **Foreign Subsidies Regulation political agreement reached:** The new trade tool will be applicable in 2023. It will allow the Commission to scrutinise the impact of financial contributions from non-EU countries on M&A, public procurement, and business activity in the EU. If it finds that the subsidies are distortive, it can apply redressive measures to level the playing field. Uncertainty remains as to the exact application of the Regulation.

4. Energy crisis

- **Tight gas markets:** Russia's invasion of Ukraine has exacerbated the tightening supply of natural gas underway since mid-2021, further pushing up prices for consumers and leading to fuel switching and demand destruction. It also casts longer-term uncertainty on market prospects for natural gas, especially in developing markets where it was to play a central role in energy transitions. Natural gas demand is expected to decline in 2022 and remain subdued up to 2025. Europe's surging pursuit of LNG to phase out Russian pipeline supply and limited global LNG export capacity additions raise the risk of prolonged tight markets (see Gas Market Report, Q3-2022).
- **IEA calls for a major role of nuclear in the energy transition:** According to the IEA, global nuclear power capacity needs to double by mid-century to reach net-zero emissions targets and help ensure energy security as governments try to reduce their reliance on imported fossil fuels (see IEA June 2022 special report). While plant lifetime extensions require substantial investment, they generally yield a cost of electricity that is competitive with wind and solar in most regions.
- **Diversification of solar supply chains required:** To ensure a secure transition to net zero emissions, the world also needs more diverse solar panel supply chains. However, China has driven down solar PV manufacturing costs, helping spur the vital technology's success while at the same time resulting in a major concentration of global PV supplies (see IEA July 2022 special report).

5. Economy

- **Europe:** The war in Ukraine and the lockdown in China weighed heavily on the rebound in activity in Europe. They also strongly amplified and extended to consumer prices the rise in producer prices, initially driven by rising energy and raw material prices. Public debt burdens have ratcheted up again (notably in Italy, Greece, and Spain) - a worry in an environment of rising interest rates. Eurozone inflation rose to record high of 8.1% in May. According to ECB's recently published projections, Euro area real GDP is expected to grow by 2.8% on average in 2022 (of which 2.0 percentage points relates to carry-over from 2021) and by 2.1% in both 2023 and 2024. This baseline scenario also includes higher and more persistent inflation, of 6.8% in 2022, 3.5% in 2023 and 2.1% in 2024. The projections are complemented by a downside scenario that reflects the possibility of a severe disruption to European energy supplies. In this scenario, inflation averages 8.0% in 2022 and 6.4% in 2023, before dropping below the baseline projection to 1.9% in 2024. Supply chains are not back to pre-COVID-19 level and many European firms are rethinking their investments in China as its zero-COVID strategy continues to hinder supply chains.

- **France:** The Banque de France expects the French economy to grow by 2.3% in 2022. If European imports of Russian oil and gas stop from Q3, the increase in GDP would be limited to 1.5% this year, before a recession next year. Inflation is at 5.2% - remaining lower than that of the Euro zone thanks to the tariff shield on gas and electricity prices

(assuming that it is maintained until the end of 2022). Without it, inflation would be 1.2 points higher. Inflation is expected to recede to 2% in 2024. Public debt soared to 114.5% of GDP end of Q1 2022 (2,901.8 billion euros) but is expected to stabilise around 110% in 2023. In Q1 2022, the unemployment rate was stable at 7.3%. Purchasing power per capita has been forecast to decline by 1% in 2022 (after having increased by 2% in 2021) and business margins to drop. To address rising prices, an "*emergency bill*" was announced on 6 July by the newly appointed Prime Minister including an extension of the tariff shield (see more here). She also indicated her intention to move forward with the contentious plan to raise the retirement age. Negotiations are expected to be complex in Parliament due to a lack of a clear majority. France also emerged with Germany as Europe's top issuer of green bonds in the first quarter of 2022. A further rise in corporate sustainable debt issuance is anticipated in 2022, driven by increased supply of sustainability-linked bonds. Whether this will fuel inflation remains to be determined.

- **United Kingdom**: According to HSBC, it is extremely unlikely the UK will face a recession unless Russia closes its gas tap. However, it is expected that the cost-of-living squeeze will hit people's spending and that will start to cool the economy. Inflation rate rose to a 40-year high of 9.1% in May but the Bank of England expects it to climb further, reaching 11% in the autumn. HSBC expects it to reduce to 1.3% in Q5 2025. The Bank of England also increased its key base rate by 0.25 percentage points to 1.25% in mid-June, and some economists forecast that the central bank could raise rates to as high as 3% by the end of 2022. The spending power of UK households fell the most in 21 years as wage increases were eaten up by the fastest inflation in decades - when adjusted for prices, average earnings excluding bonuses were 3.4% lower in April 2022 than a year earlier, the biggest drop since modern records began in 2001. The impact of Brexit and of the COVID-19 pandemic have also sparked one of the biggest worker shortages in years - the number of job vacancies rose to a new high of 1.3 million from March to May 2022. This is over half a million more than before the pandemic. An estimated 2 million people in Britain had lingering COVID-19 symptoms more than four weeks after their initial infection, which is classified as long COVID.

- **Italy**: Italy faces certain recession if faltering Russian gas supplies stop completely. To date the spill over effects from the war in Ukraine exacerbate existing supply-chain disruptions and price pressures. It is said this year's growth in Italy is mostly attributable to a carryover effect from brisk recovery of 2021 from the COVID-19 induced slump. The Italian economy's return to pre-crisis output levels has been postponed to the second half of 2022 as a result. A 2.4% GDP growth has been forecasted for 2022, down from the 4.1% predicted in February. Inflation rate is set to climb to close to 6% this year and average 2.3% in 2023. Government deficit and debt are projected to decline to 4.3% and 146.8% of GDP by 2023, as pandemic-related policy support is phased-out. Italy's annual consumer inflation increased to 6.8% in May, its highest level in more than 23 years. This marked the highest annual jump since the country adopted the euro in 1999. Italy has seen average wages decline by 2.9% since 1990. On a more positive note, the tourism sector has successfully bounced back, and the infrastructure sector is doing well (tax incentives).

6. Sustainable Finance & ESG

- **Gas & nuclear approved as sustainable investments:** The European Parliament voted on 6 July in favour of plans to award a green investment label to nuclear and gas projects as of 2023 should strict conditions be met. Before it becomes law, the proposal must also face a vote in the EU Council of Ministers representing the EU's 27 member states. However, a majority of 20 countries is needed to veto the proposal in the Council, which makes a rejection highly unlikely. Luxembourg and Austria announced they will challenge the text before the European Court of Justice to avoid further "*greenwashing*". France's nuclear newly nationalised state-company EDF is seen as the prime beneficiary of the taxonomy.
- **Coming up:** Criteria for the remaining four environmental objectives of the EU Taxation Regulation (water, the circular economy, pollution prevention and biodiversity) are expected to be published in Q4 2022 and Q1 2023. The Commission is still trying to come to terms with the opportunity of a social taxonomy (report to come out soon).

7. Australia in Europe & Europe in Australia

- Little market profile of Australian products in Europe. To remediate Austrade launched a punchy digital campaign and an agribusiness expansion initiative.
- Defence will become a key market in the EU – France has also expressed interest in future defence procurement market in Australia.
- Australia is a very compelling case for FDI. However, investment is challenging for EU investors in Australia (visas not fast enough / labour and skills shortage / regulatory issues). There is further uncertainty for investors on the Australian roadmap for green hydrogen and where opportunities arise. Costs of participation to public procurement bids in Australia are also reported to be too high and EU business have called for further risk allocation in infrastructure contracts.
- Great interest in Australia's innovation cycle and success in integrating business in the ecosystem as well as in Australia's Carbon Capture Storage research. Nuclear waste is also seen as a further area of cooperation.
- Strong opportunities between Australia and Italy are seen in the space industry, technology transfer (e.g., quantum computing) and greening the supply chains. Sustainability is perceived as tool to ensure competitiveness.

Monday 4 July 2022 - Rome

07.00-08.30	Breakfast at **Sofitel Roma Villa Borghese** (Via Lombardia 47, 00187)
08.30-09.30	Transfer to **Confindustria** (Viale dell'Astronomia 30, 00144 Rome)
09.30-11.30	**Business Roundtable** hosted by Confindustria Director-General **Francesca Mariotti**
11.30-12.30	Transfer to **Palazzo della Farnesina**
12.30-13.30	Meeting with Undersecretary of State for Foreign Affairs / Minister for Trade **Manlio di Stefano**
13.30-15.00	Transfer to **Piazza Colonna** & Light Lunch
15.00-15.30	Transfer to **Palazzo Chigi** (Piazza Colonna 370, 00186 Rome)
15.30-16.30	Meeting with **Alessandro Aresu**, Chief Economic Adviser to Italian Prime Minister Mario Draghi
16.30-17.00	Transfer to **Palazzo Colonna** (Piazza SS. Apostoli 66)
17.00-18.00	Private Tour of **Palazzo Colonna**
18.00-19.15	Transfer to **Sofitel Roma Villa Borghese** & Free Time
19.15-19.30	Transfer to **Hotel Eden** (Via Ludovisi, 49, 00187, Rome)
19.30-21.15	Delegation Dinner with Senator the Hon Dr **Francesco Giacobbe** OMRI OAM, and the Hon **Nicolas Caré MP**, at La Terrazza
21.15-21.30	Return to **Sofitel Roma Villa Borghese**

Tuesday 5 July 2022 - Rome

07.00-08.30	Breakfast at **Sofitel Roma Villa Borghese** (Via Lombardia 47, 00187)
08.30-09.30	Transfer to **ENEL Green Power** (Via Luigi Pianciani 30, 00185 Rome)
09.30-10.30	Meeting with ENEL Green Power CEO **Salvatore Bernabei**
10.30-11.30	Transfer to **Italian Space Agency** (Via del Politecnico, 00133 Rome)
11.30-12.30	Meeting with Italian Space Agency President **Giorgio Saccoccia**
12.30-14.00	**Delegation Lunch**
14.00-14.30	Transfer to **FAO** (Viale delle Terme di Caracalla, 00153 Rome)
14.30-15.30	Meeting with **Rein Paulsen**, Director of Emergencies & Resilience, and **Josef Schmidhuber**, Director of the Markets & Trade, UN Food and Agriculture Organisation
15.30-16.00	Transfer to **Piazza di Montecitorio**
16.00-16.30	Arrive & Security Clearance at **Palazzo Montecitorio**
16.30-17.30	**Private Tour of Italian Chamber of Deputies**
17.30-18.30	Meeting with the Hon **Ettore Rosato MP**, Deputy Speaker of the House
18.30-19.00	Meeting with Democratic Party Board Member and Head of European and Foreign Affairs **Lia Quartapelle MP**
19.00-20.00	Return to **Hotel Sofitel Roma Villa Borghese**
20.00-21.30	**Delegation Dinner** at Vladimiro's

Wednesday 6 July 2022 - Rome & Milan

06.30-07.00	Breakfast at **Hotel Sofitel Roma Villa Borghese** (Via Lombardia 47, 00187 Rome)
07.00-07.30	Transfer to Station - **Roma Termini**
08.20-11.35	**Frecciarossa: Roma Termini to Milano Centrale**
11.35-12.30	Transfer to **MIND Milano** (Via Strobel Pellegrino 3, 20133 Milan)
12.30-14.30	**Site Visit of MIND Innovation District Milan** hosted by **Andrea Ruckstuhl**, CEO Lendlease Europe
14.30-15.30	Meeting with **Benedetto Della Vedova**, Deputy Minister for Foreign Affairs
15.30	**Delegation Programme Concludes**
19.00-21.00	(Informal Dinner— Giacomo Duomo Milano, Milan)

The collaborative strategy I have implemented combining the three-tiers of Government, business and civil society through the Global Learning Village and Broadmeadows Revitalisation Board 4.0 has accelerated my plan to reimagine Broadmeadows from a rustbelt to green-belt and brain-belt. This vision is being delivered through the $1 billion investments I have inspired to transform the derelict Ford site creating a predicted 5,000 cleaner, greener jobs at no cost to taxpayers and defining Broadmeadows as a national vaccine manufacturing epicentre. CSL is manufacturing more than 50 million doses of Astra-Zeneca vaccine in Broadmeadows with a $1.8 billion deal for new vaccines against influenza to begin nearby soon. Technology empowered leadership is connecting the disconnected. Delivering such strategies were of significant interest to the Milano Innovation District (MIND).

EABC Australian Business Mission
Milan 6 July 2022

Schedule of the meeting

12.30 Arrival of the delegation at MIND Hive pavilion

12.30 - 12.45 - Institutional greetings by the Australian Consul General, Naïla Mazzucco, the Lombardy Region Undersecretary in charge of international relationships Alan Rizzi and LendLease's Head of sustainability continental Europe, Nadia Boschi

12:45 - 13:00 – An introduction to MIND: Andrea Ruckstuhl (CEO, Lendlease Continental Europe) and Stefano Minini (Lendlease, MIND project director)

13:00 - 13:20 – networking lunch

13:20-13:30 – Meet the pioneers: Astrazeneca @MIND Francesca Patarnello (Vice President Market Access & Government Affairs, AstraZeneca)

13:30 - 13:50 – MIND's innovation engine: focus on Federated Innovation @MIND Giacomo Cavalli (Federated Innovation @MIND stakeholder manager) and Matteo Tarantino (FI Ambassador of the thematic area Urban Digital Tech e initiative leader of Rethinking School Spaces) with the participation of Giorgio Ramenghi (WindTre, Innovation Manager) and Alessandro Filigenzi (Poste Italiane, Innovation initiative leader)

13:50 - 14:05 - Human Technopole presentation by Marica Nobile (Head of Institutional Relations) with MAEC video projection

14:05 - 14:30 – Q&A and networking while visiting the Intesa Pavilion and Human Technopole

14:30 - 15:00 – Meeting with Mr Benedetto della Vedova, Undersecretary of the Ministry of Foreign Affairs and International Cooperation

15:00-15:30 – Networking

Village Pavilion
The district landmark where to breathe innovation and discover MIND's vision. A full immersive experience to discover more about MIND and its main features.
DesignTech is the first technological innovation hub dedicated to Design.

Human Technopole labs:

Cryo-Electron Microscopy Facility

The Cryo-Electron Microscopy Facility's mission is to provide access to a highly productive, world-class scientific hub, capable of solving at high resolution, from tissue to amino acid side-chains, the many questions faced by contemporary life science.

Light Imaging Facility

Optical microscopy is a more traditional microscopy technique that allows you to observe samples with the magnification of a lens with visible light.

Image Analysis Facility

Solutions for image restoration, (semi-)automated downstream processing, smart microscopy or real-time image analysis, big data management and big data visualisation are key to the success of image- and imaging-centric research.

Image Analysis Facility

Modern imaging techniques in light and electron microscopy and computational approaches are changing the way biomedical research is conducted. Solutions for image restoration, (semi-)automated downstream processing, smart microscopy or real-time image analysis, big data management and big data visualisation are key to the success of image- and imaging-centric research.

Genomics Facility

The mission of Human Technopole's Genomics Facility is to provide high throughput analysis potential for large projects and single-cell level analysis, allowing to analyse various types of samples with an increasing level of sensitivity and specificity.

Automated Stem Cell and Organoid Facility

The Automated Stem Cell and Organoid Facility constitutes a particularly innovative endeavour and is aimed at streamlining, via dedicated automation pipelines, the key rate-limiting steps in disease modelling based on human cells and tissues, i.e. cell reprogramming, genome editing and longitudinal organoid culture.

Participants

Australian Government

Naïla Mazzucco is Australian Consul-General, Milan and Trade & Investment Commissioner to Italy, the Czech Republic, Israel. She has Sixteen years' experience in business development, marketing and international public affairs roles in emerging and developed markets. She worked across government, private and multilateral institutions in nine countries. As a market entry strategist helping Australian clients go global, she specialises in connecting international commercial opportunities with Australian products, services and expertise. She also works with international investors to identify investment opportunities in Australia across the major infrastructure; resources and energy; agribusiness and food; health; services and technology; and advanced manufacturing and defence industry sectors.
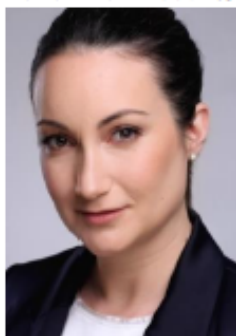
Italian Government

Benedetto Della Vedova is Undersecretary of the Ministry of Foreign Affairs and International Cooperation. A graduated in Economics and social sciences from Bocconi University, he served as Deputy Minister from 2014 to 2018, and as Secretary of Più Europa, the movement he helped to found with Emma Bonino, from 2019 to 2021. A member of the Radical Party for 30 years, he is been a Member of the European Parliament between 1999 and 2004, a Member of the Italian Parliament from 2016 and 2013, and a Senator between 2013 and 2018.

Lombardy Region

Alan Christian Rizzi is Undersecretary of the Lombardy Region in charge of relationships with international delegations. He's a professional journalist and has been a counsellor for the Municipality of Milan from 1997 to 2011.

MIND stakeholders

Astrazeneca

Francesca Patarnello is VP Market Access & Government Affairs at Astrazeneca, she deals with HTA, drug pricing and reimbursement, national and regional patient access to drugs and she is also responsible for relations with institutions and patient associations and external communication.

After graduating in Statistics in 1987 in Padua with a thesis on Meta-analysis of clinical trials, she started working in the pharmaceutical industry in various companies. From the role of biostatistician in Farmitalia Carlo Erba she moved on to Fidia, GlaxoSmithKline, Amgen and finally to AstraZeneca.

Human Technopole

Marica Nobile is Institutional Relations Manager at Human Technopole. She was formerly Senior Manager for Stakeholder and Association Relations at CDP – Cassa Depositi e Prestiti. After 10 years in Confindustria as Manager for Africa and the Middle East and then Senior Advisor for EU International Cooperation, she served for four years as Head of Institutional and International Relations of the Trevi Group, the leading Italian company in ground engineering and Oil & Gas. Marica holds a Degree in Political Science and a PhD in Political Theory from LUISS University.

Maria Grazia Magro is Head of Strategy and Scientific Affairs at Human Technopole.

She worked as a postdoctoral scientist at the Paul Langerhans Institute Dresden, managing research projects in the area of pancreatic beta-cell biology and then later assumed the strategy development and analysis role at the European Molecular Biology Laboratory (EMBL).

Dr. Magro holds a master's level Degree in Biological Sciences from the University of Naples Federico II (Naples, Italy) and a Ph.D. in Cell Biology from the International Max Planck Research School for Biomedicine and Bioengineering and the TU Dresden (Dresden, Germany).

LendLease

Andrea Ruckstuhl is currently Head of Continental Europe of Lendlease, with a particular focus on large-scale urban regeneration schemes. As part of this activity Andrea is leading initiatives to explore innovative ways of delivering sustainable urban regeneration, including how to tackle some of the biggest challenges cities are facing such as attracting and retaining talent, providing cutting edge research and social infrastructure, and accelerating the green and digital transitions. Andrea has over 20 years of experience in the infrastructure and property industry in international markets. He joined LL as Senior Project Manager in 2004 with responsibilities over a PPP hospital project, the start-up of over €1,5b urban regeneration project in Milan and a large PPP scheme of over €5b in Montecarlo. In 2007 he was appointed Country Manager and since then worked to reposition the business in the contracting and PPP sector. In 2012 he took the role of Executive General Manager for the CEMEA region overlooking the restructuring of the business in the Region with over 18 countries. In 2014 he joined the Regional Board in EUROPE in London and become a member of the Regional Investment Committee.

Nadia Boschi is Head of Sustainability Italy and Continental Europe Lendlease where she leads the development of climate fit strategies for urban re-development.
She has been Professor of Building Construction at Virginia Polytechnic Institute & State University (US). Her expertise includes collaboration with the United States government, the European Union and the World Health Organization on the development of policies and regulations of environmental and health.

Stefano Minini is MIND Milano Innovation District Project Director. Civil Engineer with a global track record in infrastructure development, Stefano has experience in transport (railways, roads, airports), real estate, travel retail and hospitality. Within these areas, Stefano has topic expertise in early scheme development, financial feasibility, M&A, operational pricing and turnaround.

Cariplo Factory

Giacomo Cavalli is Federated Innovation @MIND Relationship Manager. He has 15 years of experience in institutional relations at national and international level in both the public - European Union and European Commission - and private sides.

Plusvalue

Fiorenza Lipparini is Plusvalue managing partner. She has extensive experience in Eu affairs, the impact economy and urban regeneration projects in Italy and the UK, with a focus on public-private partnerships and place-based innovation. Since 2020, she is part of the technical support team working with the 21 Italian municipalities funded by the Social Innovation Fund promoted by the Italian Cabinet Office, and since 2021 she is a member of the National Council of the Third Sector reporting to the Italian Ministry of Employment. She is also a strategic Adviser to the Italian Minister of Employment on European Affairs concerning the social economy. She is a Research Fellow at UCL's Institute of Finance and Technology and Senior Researcher at the Global Institute for Innovation Districts.

Francesco La Loggia. Francesco joined PlusValue in 2017 as Stakeholder manager. The main project he is involved in is MIND - Milano Innovation District, where he managed several initiatives - related to innovation in the life science sector - for the development of the district. Francesco graduated in Law from Bocconi University and is a qualified lawyer. In 2019, he obtained a master's degree in Public Relations from the University of the Arts in London with a thesis on crisis communication.
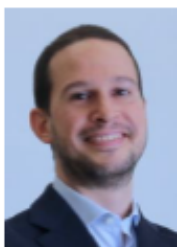
WindTre

Giorgio Ramenghi is Innovation Manager for WINDTRE, the largest mobile telco operator in Italy. Electronic Engineer with a master in Project Management, he is also a Lecturer at the Catholic University of Milan and founder of the community Innovation Manager Hub. He has global experience in marketing, business development and partnership management. He is currently in charge of special projects for Large&Top clients.

Poste Italiane

Alessandro Filigenzi Alessandro Filigenzi, electronic engineer. In Poste Italiane since 2003. During his past activities he tested high frequency OCR systems on main sorting plans network. Since 2019, he is a member of the Innovation team in the Mail and parcel division, designing autonomous driving and augmented reality applications for logistics.

Universities

Politecnico di Milano

Alberto Redaelli is the responsible of the Computational Biomechanics Laboratory and coordinator of the Biomechanics Research Group of the Department of Bioengineering at Politecnico di Milano.

His teaching activities are in the field of Biomechanics and Computational Biomechanics and has been involved in the development of manifold industrial research projects.

He is local coordinator the Horizon 2020 project RISE. His activity includes the coordination of manifold National public and private projects with 5 patents transferred to the industry.

Università degli studi di Milano Statale

Roberto Tiezzi is the Managing Director, Innovation & Knowledge Transfer Unit (TTO) at Università degli Studi di Milano. In this capacity, he deals with intellectual property management, licensing and support for the creation of innovative companies. He is a member of the board of Netval, an association composed of various Italian universities that aims to enhance research in relation to the private and public entrepreneurial system. He was previously Director of UNIMITT - University Centre for Innovation and Technology Transfer at the University of Milan.

Università Cattolica di Milano

Matteo Tarantino Ph.D. is assistant professor at the Catholic University of Milan, where he teaches Data, Information & Society and Information and Communication Systems; he is also a lecturer at the University of Geneva, where he teaches Cities in Transition and Urban Futures. His research focuses on the nexus between culture, data and sustainability in cities. He has collaborated with several UN agencies including UN-ECE, WHO and UN-Habitat. He is currently the coordinator of the Urban Digital Tech thematic area in the Federated Innovation network within Milan's MIND project. He has authored over 50 publications.

Conclusion

Constancy of purpose counts. "Creating Opportunity from Adversity" is my driving theme in the time of pandemic. It is at the heart of the health precincts of the future in built and virtual form, in the partnerships we build to share intellectual property, leverage value, cut costs and accelerate results. Collaborations are more important now than ever in confronting the catastrophes of our times. Existential threats have converged from climate change and the global pandemic to the worst recession since the Great Depression, and the consequences of a new war in Europe.

Creating opportunity, leveraging assets, and building collaborations delivering results is the theme I beat like a drum. It has proved successful internationally through the Cancer Moonshot with the White House, the Australian British Health Catalyst and EABC mission. The Free Trade Agreement between Australia and the United Kingdom and the AUKUS alliance provide mechanisms to expand collaboration and deliver a brain gain instead of a brain drain.

Understanding global uncertainties is vital. China is on a trajectory to overtake the United States in research and development in two years. The UK is suffering a "brain drain" after being blocked by the European Union from continuing in the €95 billion grant scheme, "Horizon Europe." I drew these themes together to create an international vision to deliver community results, avoid cultural blind spots and placed-based disadvantage that have proved devastating during globalisation and the pandemic.

The people and institutions at the Catalyst provided a wonderful opportunity, especially because politics has too often failed, or sidelined science. In a new period of Counter-Enlightenment, the worst pandemic in more than a century has stalked inequality, exposing systemic fault-lines like an X-ray.

As Victoria's first Parliamentary Secretary for Medical Research, I have committed eight years to help define a state, national and international vision and strategy for this sector in collaboration with the Premier, Daniel Andrews, Ministers, public servants, leaders of institutes and industry. My other critical aim is to avoid Einstein's definition of insanity. When the fatigue and fog of the pandemic clears, we do not return to doing the same thing over and over again expecting different results because the focus of contemporary politics can shift in the blink of a tweet. All we must defeat is the silo mentality, turf wars, institutional ego, bureaucratic inertia, the political cycle and the fog and fatigue of the pandemic. Add to this list the triumph of politics over rational decision making and Einstein's definition of insanity repeating cultural, generational, and systemic failures.

My pursuit is expanding international eco-systems. We should think of data as infrastructure, collaborate across organisations and not abandon postcodes of disadvantage like orphans.

Therefore, through the Broadmeadows Revitalisation Board 4.0, I have been coordinating the implementation of key strategies I have written: "Creating Opportunity: Postcodes of Hope," 2016; "Building Smarter Cities: Stronger Communities," 2017; and "Homes for Community Heroes" 2021. They establish Broadmeadows as a prototype converting a rust belt to a green belt and brain belt and are being delivered under the "Comeback" implementation strategy 2020.

> https://www.frankmcguire.com.au/wp-content/uploads/2016/12/Creating-Opportunity-Postcodes-of-Hope-Strategy-Launch.pdf

> https://www.frankmcguire.com.au/wp-content/uploads/2018/10/2018-Building-Smarter-Cities-Stronger-Communities-Final-1.pdf

The Victorian Government is investing $2 billion in the Breakthrough Victoria Fund to create the industries and jobs of tomorrow by fast tracking commercialisation and innovation featuring scientific, digital, health and life sciences. The Governor of Victoria is leading a mission of our universities in the top 1 per cent internationally to the UK to expand collaboration. The Medical Research Future Fund is rising to $20 billion, and we have former leaders of Research Australia here to help build collaboration.

On genomics, the Generation Victoria or GenV Project, is one of the world's most exciting child and parent research initiatives to define a picture of the health and wellbeing of a generation of children and parents, and assess predispositions to allergies, anxiety and other health problems, headed by the Murdoch Children's Research Centre.

The Victorian Government has invested $400 million in the Australian Institute for Infectious Disease founded on the Doherty Institute with Nobel Laureate for Medicine, Prof. Peter Doherty. The University of Melbourne invested another $250 million into this project.

Healthcare in the UK has improved dramatically since the Victorian era, yet the geography of the coronavirus deaths closely follows the pattern of poor health in the 19th Century defining "deeply entrenched" disadvantage and ill-health stretching back at least 170 years, according to the Chief Medical Officer for England, Prof. Chris Whitty.

Nobel Laureate, Prof. Peter Doherty defined a significant cultural gap, the historic lack of scientists among elected leaders, in his aptly titled book, "The Knowledge Wars." This gap has contributed to a new period of Counter-Enlightenment. The reality is we know where inequality lives. It's the same place as poverty and crime. As the last great Emperor of Rome, Marcus Aurelius defined "poverty is the mother of crime?"

As the Parliamentary Secretary for Crime Prevention, I have driven the initiative for a whole of Government response to change the social determinants of life. The political reality is the survival instinct too often trumps the public interest, gifting resources to marginal seats ahead of those of greater need and disadvantage, leading to compounding complexity and place-based disadvantage.

Developing medical research is emblematic of Australian leadership and excellence. The Victorian Government's record investments during the past eight years are landmark achievements, from building infrastructure to the significance of elegant science in breakthrough to save lives and livelihoods at home and abroad. Delivering the health precincts strategy has proved defining and will add increasing value with every dollar invested in this sector generating $3.90 of activity in the economy.

The Melbourne Biomedical Precinct in Parkville and the Monash Precinct in Clayton, with the vaccine manufacturing epicentre in Broadmeadows and the forthcoming mRNA hub are key sources of innovation and economic growth that must continue to evolve, especially in the time of pandemic, through investment to change and save lives.

I highlighted these themes in my presentation "Creating Opportunity from Adversity" and panel discussion at the Catalyst and the EABC mission, underscoring the importance of investment, international collaboration for breakthroughs and sustainability.

- New health precincts must be global in reach and ambition to get the de-personalised data to the best and brightest to accelerate breakthrough and remedies.

- It must also be local with a high priority to convert Postcodes of Disadvantage into Postcodes of Hope.

It has been a humbling privilege to serve as Victoria's first Parliamentary Secretary for Medical Research for eight years with some of the most eminent leaders who are overwhelmingly culturalists, not monetarist, competitors and colleagues collaborating to improve and save lives, especially given how often politics has failed or sidelined science. This is a cause I will continue to try to rectify in the public interest.

MEDIA RELEASE
15 Aug 2022
Prime Minister, Premier of Victoria, Minister for Health and Aged Care, Minister for Industry and Science

Onshore manufacturing of life-saving mRNA vaccines took a major step forward today, with the Australian Government, Moderna and the Victorian Government finalising all arrangements for the 10-year partnership.

Under the agreements, an mRNA vaccine manufacturing facility will be built at Monash University, helping protect Australians against future pandemics, supporting local industry and creating highly skilled local jobs.

Moderna will also establish its headquarters and a Regional Research Centre in Victoria.

Once operational, the facility will be able to produce up to 100 million vaccine doses every year.

Once this critical onshore mRNA capability is established, Australia will reduce its dependence on imported mRNA vaccines and our vulnerability to supply disruptions or delays.

It will give Australians local and ongoing access to Moderna's COVID-19 vaccine – Spikevax – and give us an onshore mRNA manufacturing capability in the event of a new pandemic, such as avian influenza or another new pathogen, vaccine-resistant COVID-19 variants or a global resurgence of infections.

The partnership will lead to a world-class mRNA ecosystem based in Melbourne, attract highly skilled staff and expand local capability through joint ventures with leading Australian research organisations.

Quotes attributable to Prime Minister Anthony Albanese:

"The COVID-19 pandemic is a once in a generation challenge that gives us a once in a generation opportunity to come back stronger and better than ever."

"The pandemic has shown us how important local manufacturing capability is to our security and to our health."

"This significant deal will protect Australians and Australian sovereignty."

Quotes attributable to Premier of Victoria Daniel Andrews:

"This agreement means that Victoria will be home to Moderna's only mRNA manufacturing and finishing centre in the Southern Hemisphere."

"We have the skills and the equipment needed to deliver this vital onshore capability - it will save lives, create jobs and strengthen Victoria's position as a national leader in medical manufacturing."

"The pandemic has shown us how important it is to have strong sovereign capacity – we're not wasting a second in making sure we have access to the vaccines we need to keep Victorians safe."

Quotes attributable to Minister Butler:

"I was honoured to sign an agreement today with my Victorian Government counterpart – Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford – to finalise this 10-year strategic partnership."

"It was a pivotal step in helping protect Australians against future pandemics while supporting local industry.

Quotes attributable to Minister Husic:

"Australia has the world-class capabilities needed to develop and produce the next generation of medical technology, matched with leading researchers and a highly skilled workforce.

"This landmark agreement signals the Australian Government's commitment and support for sovereign manufacturing capability in critical industries."

Quotes attributable to Minister Pulford:

"We warmly welcome Moderna to Melbourne - this facility and research centre together with Victoria's world-class science and health tech will generate major medical breakthroughs."

"We'll keep making the big, bold investments needed to make sure we have the best research, the best facilities and the best treatments to keep Victorians safe and healthy."

Quote attributable to Moderna General Manager Australia & New Zealand Michael Azrak:

"We look forward to being a part of the Monash Clayton precinct and contributing to the R&D ecosystem in Melbourne and across Australia."

Frank McGuire MP ✔ @Frank_McGuire · Aug 15

Great day for Australia and life saving medical research against COVID and cancers. World first mRNA manufacturing facility on a university campus announced at Monash with Moderna. #auspol #vicpol #springst

Frank McGuire MP ✔ @Frank_McGuire · Aug 15

Joined Prime Minister, Premier, Federal and State Ministers; Monash University leaders including Deputy Chancellor Simon Crean and Prof. Doron Ben-Meir in this defining announcement for health and science at home and abroad and for Australia's national security. #auspol #springst
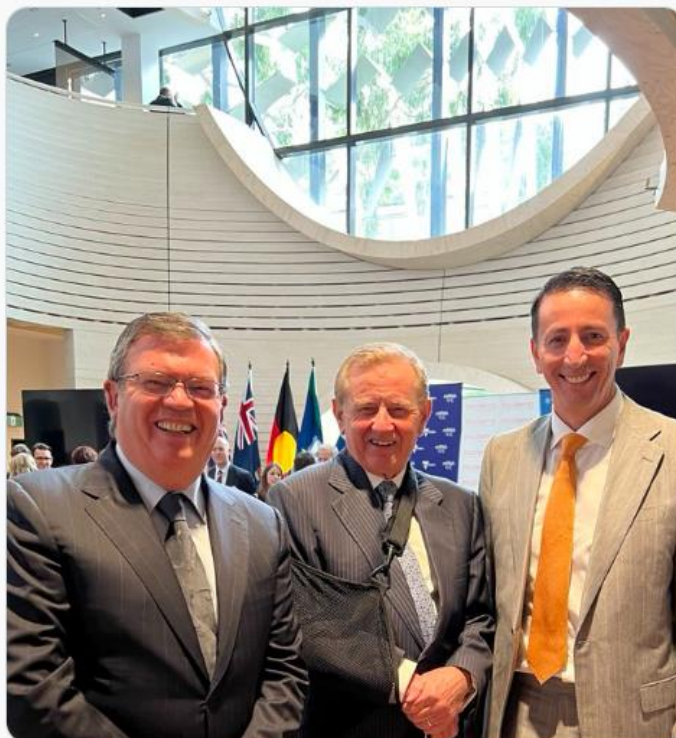
Frank McGuire MP ✔ @Frank_McGuire · 1h

Melbourne, like Boston and London, is a world leader in medical research based on universities. Monash will be first to manufacture mRNA on campus with Moderna. CSL makes Astra-Zeneca in Broadmeadows with $1.8 bill deal for new doses against influenza nearby soon @AlboMP #auspol

> **Dan Andrews** ✔ @DanielAndrewsMP · 13h
>
> There's only a handful of places in the world that can manufacture mRNA vaccines.
>
> And soon – we'll be one of them.
>
> Today @AlboMP and I signed a partnership with Moderna to open an mRNA vaccine manufacturing facility at Monash University Clayton.
>
> Show this thread
>
>

Member's Statement to the Victorian Parliament, August 16, 2021:

In the era of distraction, value can too often be lost in the blink of a tweet.
 So, I want to highlight that a world-first mRNA manufacturing facility on a university campus was announced yesterday at Monash with Moderna.

Melbourne, like Boston and London, is a world leader in life-changing and life-saving medical research emanating from our internationally acclaimed academies, especially the University of Melbourne and Monash. mRNA provides next generation vaccines against the pandemic and is crucial for breakthroughs against cancers and other diseases.

I was delighted to join Prime Minister, Anthony Albanese, the Premier, Federal and State Ministers for this defining announcement for health, science, and national security.

As Victoria's first Parliamentary Secretary for Medical Research my driven pursuit has been internationalising collaborations and delivering community results. Initiatives range from identifying new multi-billion-euro opportunities with the United Kingdom and the European Union and advocacy internationalising the Cancer Moonshot with the White House that brought Joe Biden to Melbourne in 2016 for the opening of the billion-dollar jewel in Australia's medical research crown, the Victorian Comprehensive Cancer Centre.

I have also driven plans to redefine the social determinants of life in postcodes of disadvantage, designing Broadmeadows as the prototype. I look forward to new investments in public health addressing the causes of pandemic outbreaks and lockdowns by coordinating the expansion of the Broadmeadows Hospital, the Broadmeadows Super clinic, and training the nurses and allied health workers vital for our most vulnerable communities with Kangan Institute. Such investments remain vital.

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So does the constancy of purpose and the appreciation of value, focused on preventing Einstein's definition of insanity.
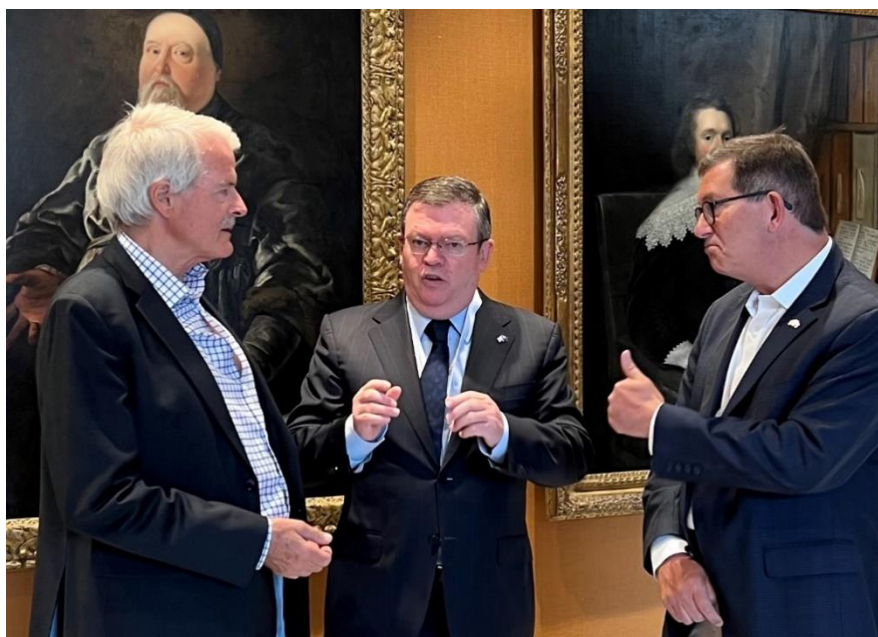
Positive response on how to leverage ideas and innovations from former chair of NHS England, Sir Malcolm Grant CBE, and former Vice Chancellor, UNSW Sydney, Prof Ian Jacobs.