Designing health research projects that leverage digital technology

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What is digital health?

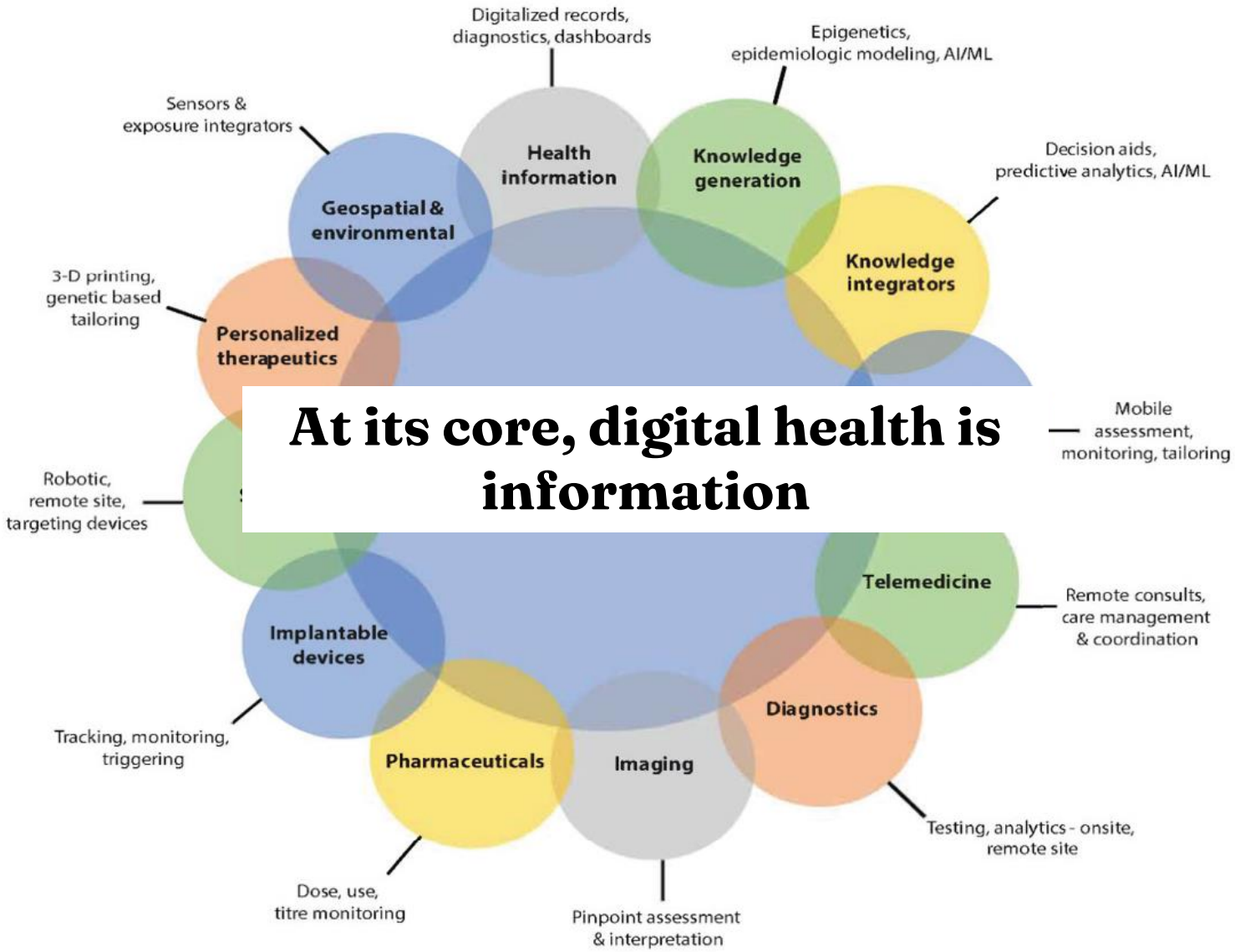
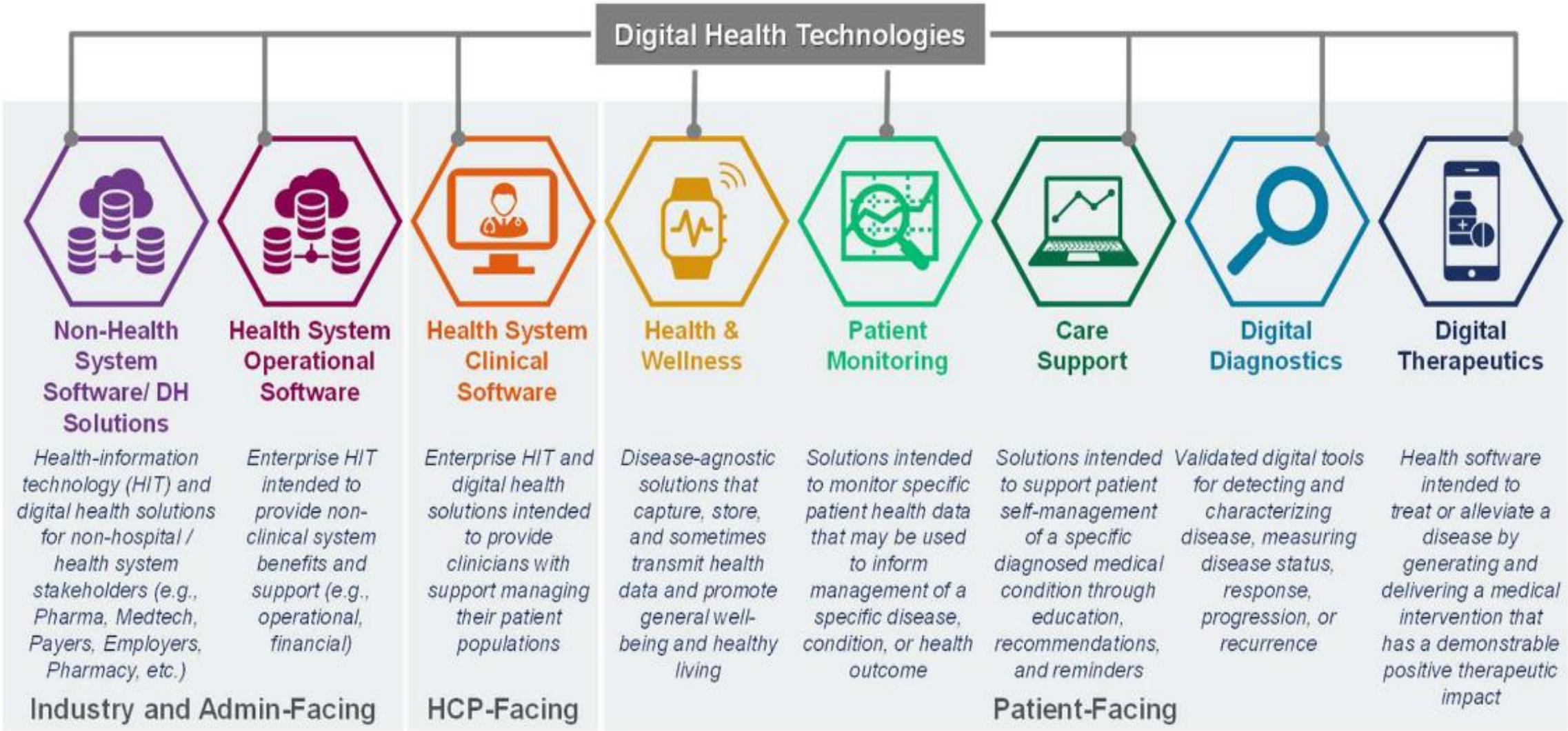


FIGURE 1 | Evolving Applications of Digital Technology in Health and Health Care
SOURCE: National Academy of Medicine. 2019. *Digital Health Action Collaborative, NAM Leadership Consortium: Collaboration for a Value & Science-Driven Health System.*


Digital Health Technologies
Non-Health System Software/ DH Solutions
Health-information technology (HIT) and digital health solutions for non-hospital / health system stakeholders (e.g., Pharma, Medtech, Payers, Employers, Pharmacy, etc.)
Health System Operational Software
Enterprise HIT intended to provide non-clinical system benefits and support (e.g., operational, financial)
Industry and Admin-Facing
Health System Clinical Software
Enterprise HIT and digital health solutions intended to provide clinicians with support managing their patient populations
HCP-Facing
Health & Wellness
Disease-agnostic solutions that capture, store, and sometimes transmit health data and promote general well-being and healthy living
Patient Monitoring
Solutions intended to monitor specific patient health data that may be used to inform management of a specific disease, condition, or health outcome
Care Support
Solutions intended to support patient self-management of a specific diagnosed medical condition through education, recommendations, and reminders
Digital Diagnostics
Validated digital tools for detecting and characterizing disease, measuring disease status, response, progression, or recurrence
Digital Therapeutics
Health software intended to treat or alleviate a disease by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact
Patient-Facing

What isn’t digital health?

- Its not just medical technology (e.g., new devices)
- Its not just advanced software, like artificial intelligence
- Its not just the infrastructure/EMRs

All of healthcare in 2025 involves digital health

Why do we need digital health?

1. Information is at the core of all healthcare
2. The four biggest challenges facing Australian healthcare in 2025 are:
    - an aging population
    - increasing chronic diseases
    - workforce shortages
    - rising costs



What is the potential of digital health?

The US has reached near universal adoption of electronic health record (EHR) system

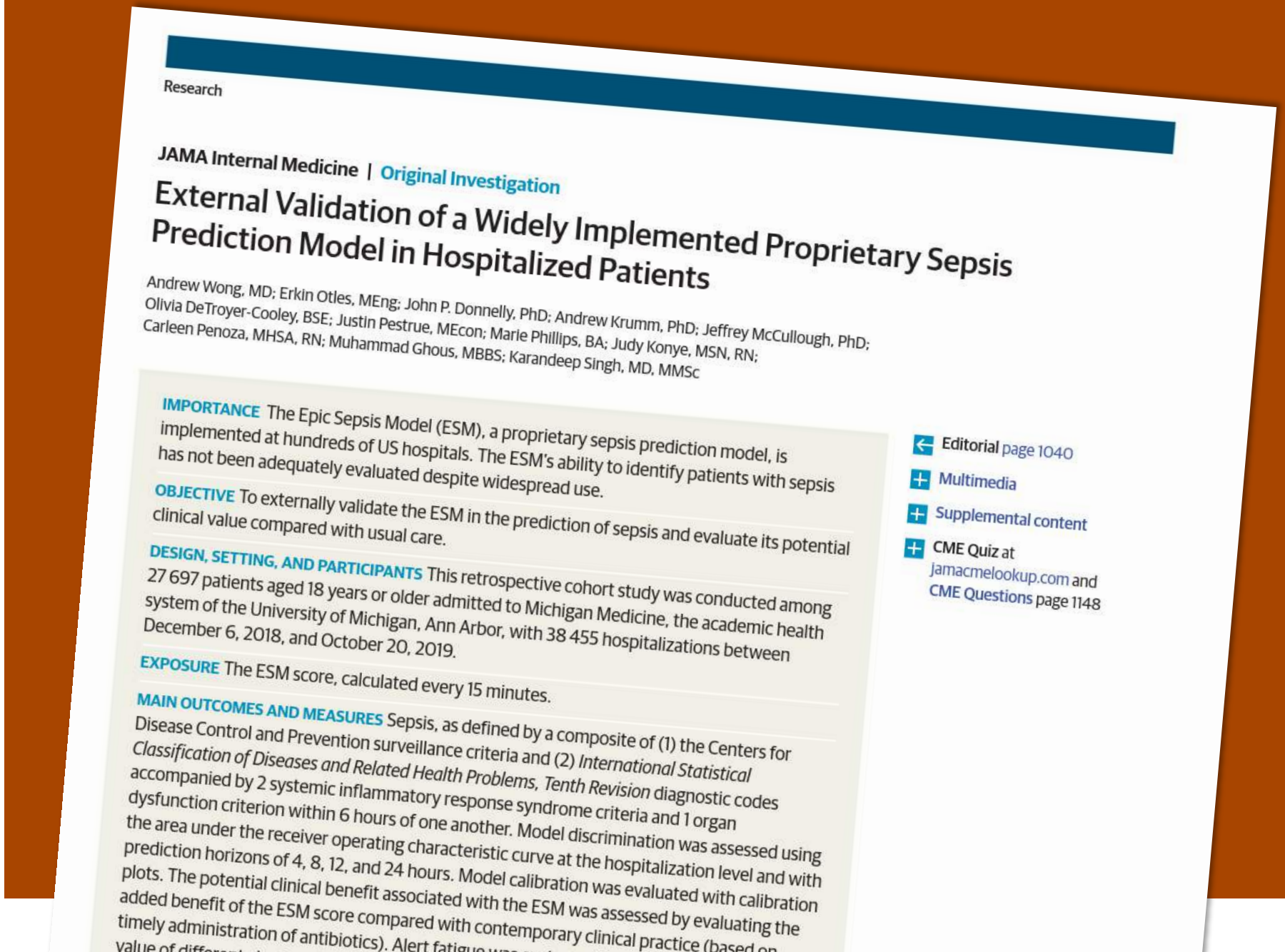


What are the impacts?

- Majority of studies found patient benefits
- 65% of studies found a positive effect on documentation, such as an improved completeness or guideline adherence, 35% found positive and negative effects
- Overall, implementation led to cost-savings

- 19% of studies found no overall benefit
- There were unintended consequences including:
  - failed expectations
  - vendor oligopoly
  - a reduction in innovation
  - physician burnout
  - data obfuscation

Colicchio et al., 2019



Research

JAMA Internal Medicine | Original Investigation

External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients

Andrew Wong, MD; Erkin Otles, MEng; John P. Donnelly, PhD; Andrew Krumm, PhD; Jeffrey McCullough, PhD; Olivia DeTroyer-Cooley, BSE; Justin Pestrue, MEcon; Marie Phillips, BA; Judy Konye, MSN, RN; Carleen Penoza, MHSA, RN; Muhammad Ghous, MBBS; Karandeep Singh, MD, MMSc

IMPORTANCE The Epic Sepsis Model (ESM), a proprietary sepsis prediction model, is implemented at hundreds of US hospitals. The ESM's ability to identify patients with sepsis has not been adequately evaluated despite widespread use.

OBJECTIVE To externally validate the ESM in the prediction of sepsis and evaluate its potential clinical value compared with usual care.

DESIGN, SETTING, AND PARTICIPANTS This retrospective cohort study was conducted among 27 697 patients aged 18 years or older admitted to Michigan Medicine, the academic health system of the University of Michigan, Ann Arbor, with 38 455 hospitalizations between December 6, 2018, and October 20, 2019.

EXPOSURE The ESM score, calculated every 15 minutes.

MAIN OUTCOMES AND MEASURES Sepsis, as defined by a composite of (1) the Centers for Disease Control and Prevention surveillance criteria and (2) *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* diagnostic codes accompanied by 2 systemic inflammatory response syndrome criteria and 1 organ dysfunction criterion within 6 hours of one another. Model discrimination was assessed using the area under the receiver operating characteristic curve at the hospitalization level and with prediction horizons of 4, 8, 12, and 24 hours. Model calibration was evaluated with calibration plots. The potential clinical benefit associated with the ESM was assessed by evaluating the added benefit of the ESM score compared with contemporary clinical practice (based on timely administration of antibiotics). Alert fatigue

Editorial page 1040
Multimedia
Supplemental content
CME Quiz at Jamacmelookup.com and CME Questions page 1148

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"At our selected score threshold of 6, the ESM had a **hospitalization-level sensitivity of 33%, specificity of 83%.**"

Wong et al., 2021

Why?

The model predicting sepsis “learned” from notes in the EMR **where the clinician already suspected the patient had sepsis**

Clinical AI: the model is not the product.

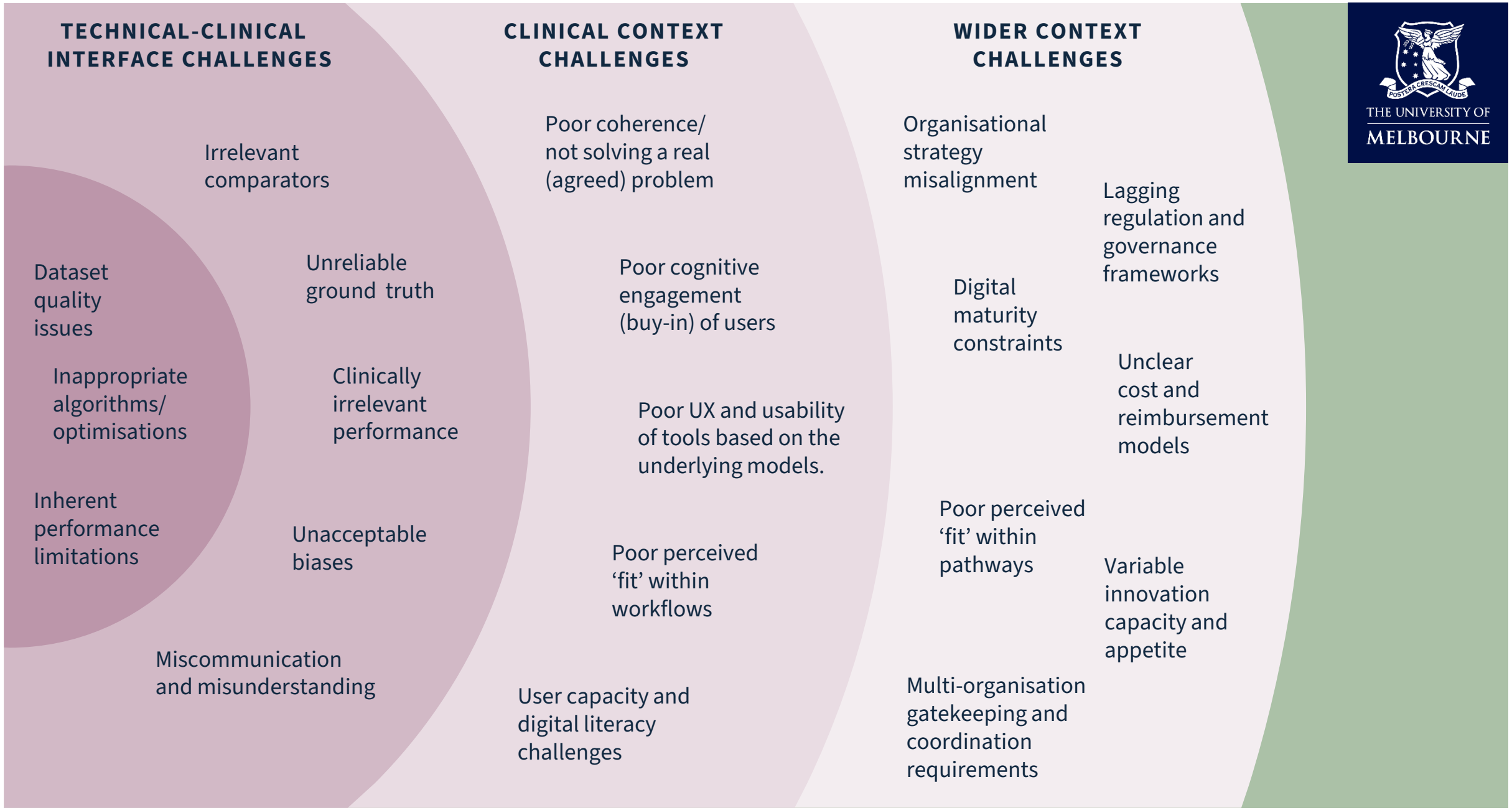
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AI/ML quality discourse has often emphasized **technical challenges**.

Dataset quality issues

Inappropriate algorithms/ optimisations

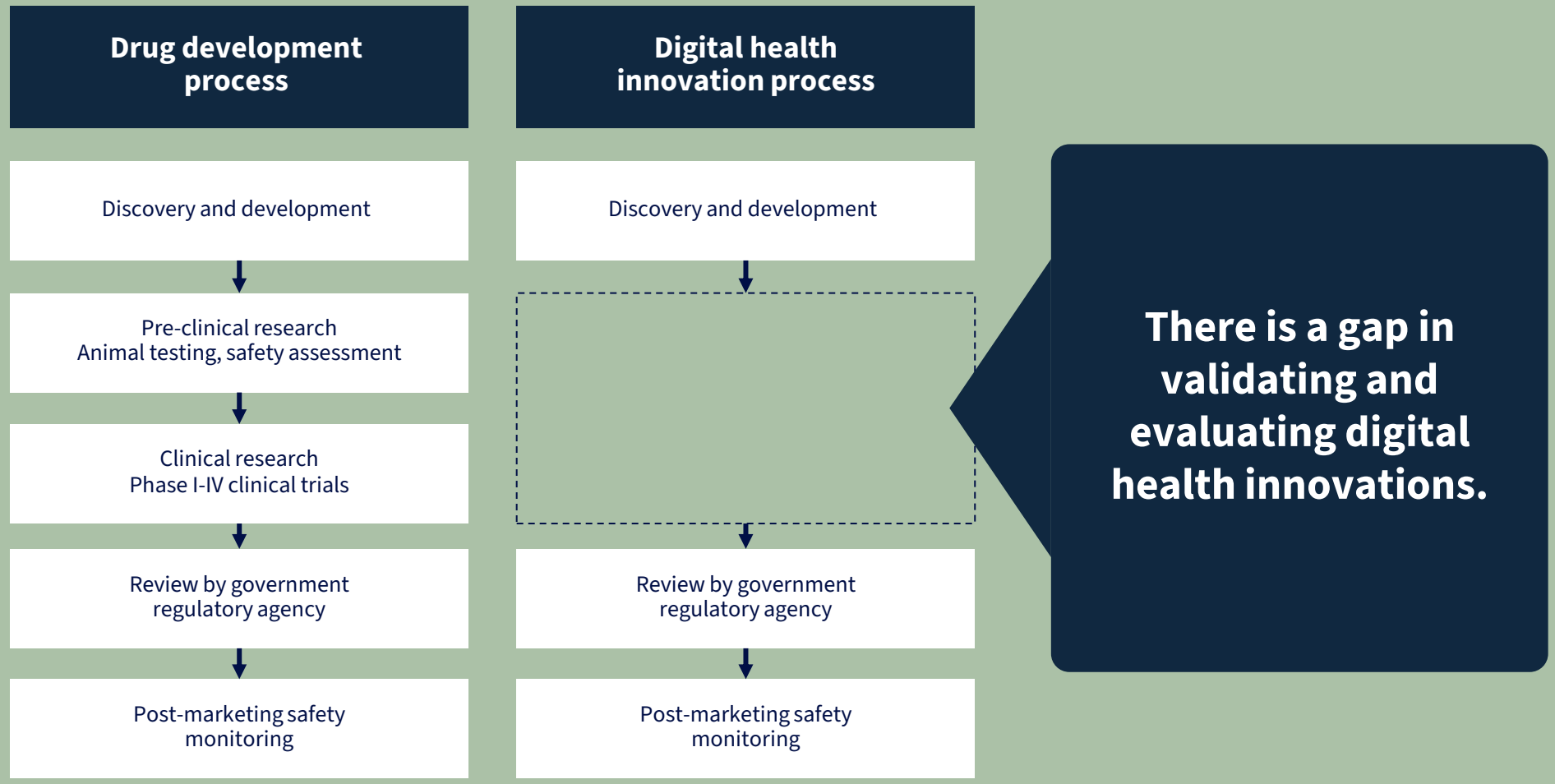
Inherent performance limitations


TECHNICAL-CLINICAL INTERFACE CHALLENGES
CLINICAL CONTEXT CHALLENGES
WIDER CONTEXT CHALLENGES
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Irrelevant comparators
Poor coherence/ not solving a real (agreed) problem
Organisational strategy misalignment
Lagging regulation and governance frameworks
Dataset quality issues
Unreliable ground truth
Poor cognitive engagement (buy-in) of users
Digital maturity constraints
Inappropriate algorithms/ optimisations
Clinically irrelevant performance
Poor UX and usability of tools based on the underlying models.
Unclear cost and reimbursement models
Inherent performance limitations
Unacceptable biases
Poor perceived 'fit' within workflows
Poor perceived 'fit' within pathways
Variable innovation capacity and appetite
Miscommunication and misunderstanding
User capacity and digital literacy challenges
Multi-organisation gatekeeping and coordination requirements

Challenges with digital health are the rule, not the exception.

There is no standard development pathway for digital health.

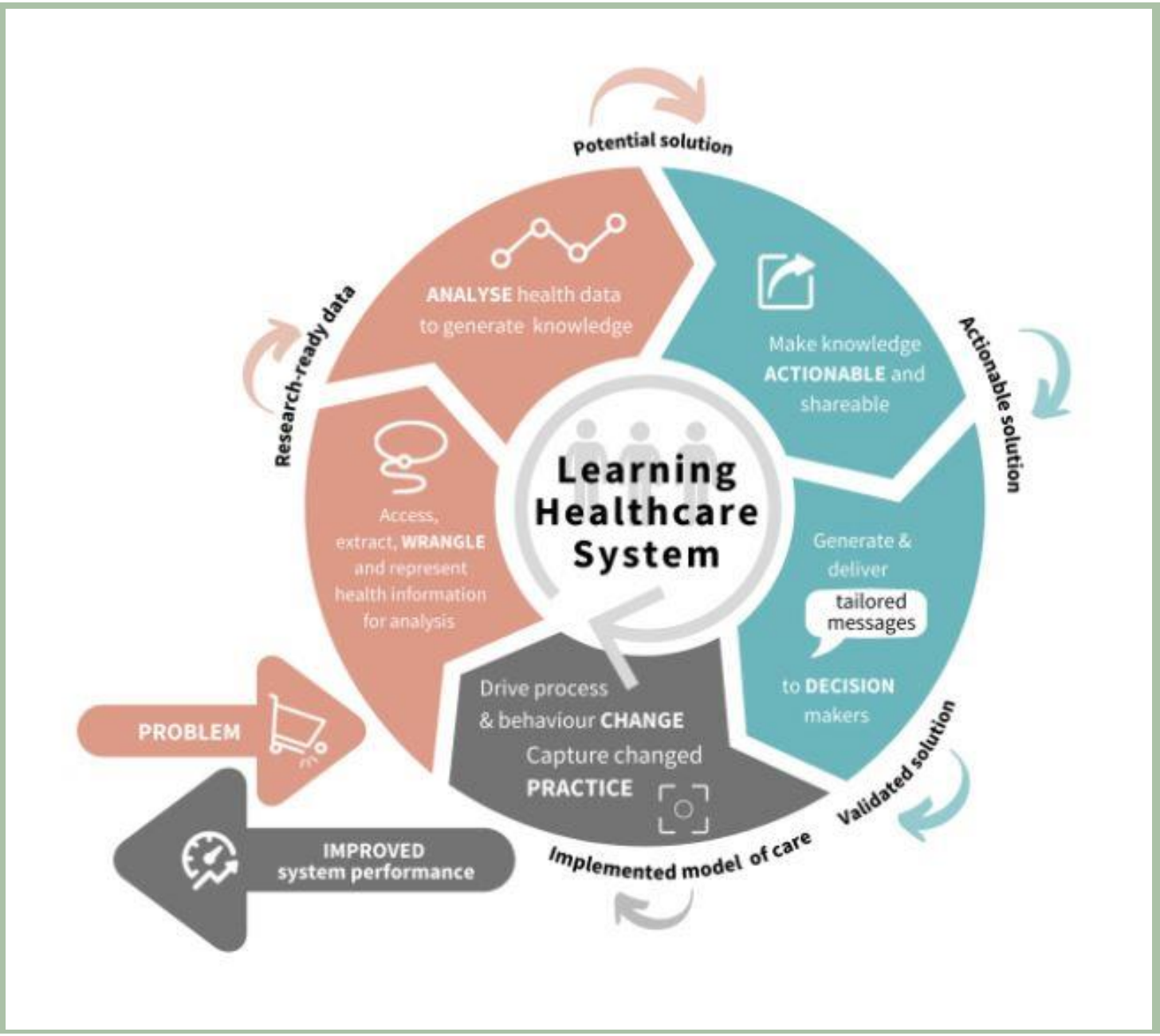
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What reduces likelihood of failure?

1. Familiarise yourself with the LHS
2. Build a multi-disciplinary team
3. Prototype, prototype, prototype
4. Conduct human factors research

The learning health system



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What reduces likelihood of failure?

1. ~~Familiarise yourself with the LHS~~
2. Build a multi-disciplinary team
3. Prototype, prototype, prototype
4. Conduct human factors research

Build a multi-disciplinary team with expertise in:

- Your clinical problem
- Digital health research expertise
- Software development expertise or folks who know how to talk to them
- Statisticians and/or big data experts to manage the data
- Consumers

What reduces likelihood of failure?

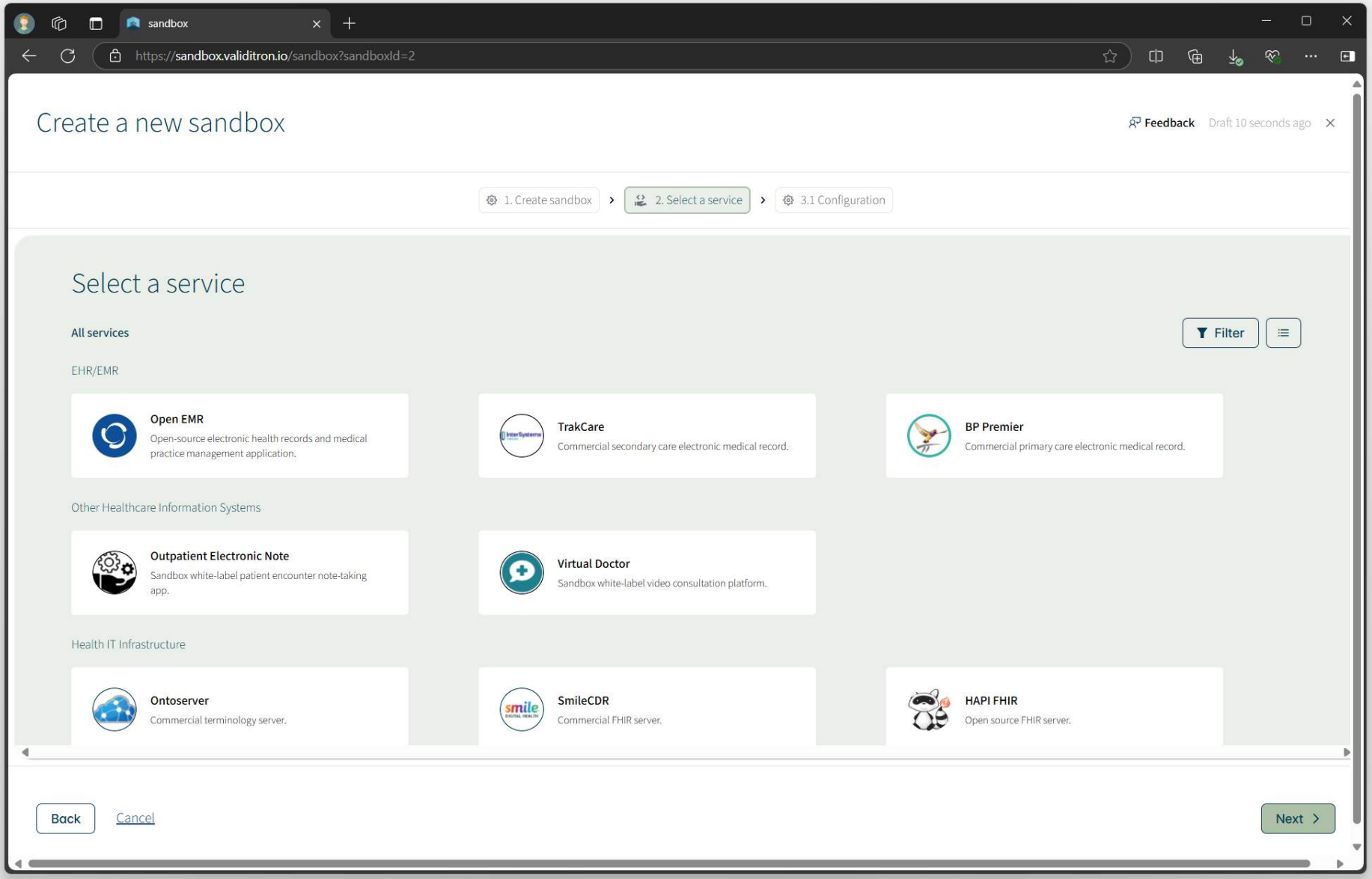
1. ~~Familiarise yourself with the LHS~~
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Jargon Buster

Wireframe / Mockup / Prototype

	Wireframe	Mockup	Prototype
Purpose	A **quick sketch** to convey the high-level functionality	A realistic **visual design** of the functionality / feature	**Interactive simulation** the functionality
Fidelity	Low	High / Medium	High
Functionality	No	No	Yes
Skill requirement	Low	High	High
Resources	Minimal	Design tool	Design tool
Time needed	Very low	Medium	High
Product cycle stage	Discovery	Design	Prototyping and testing

1. Scan the evidence and environment for pre-existing tools and evidence
2. Co-design your digital tool with stakeholders
3. Seek extensive feedback on early wireframes/mockups before spending money on development
4. Test and model necessary changes to workflows
5. Don’t engage developers too early



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Validitron Sandbox

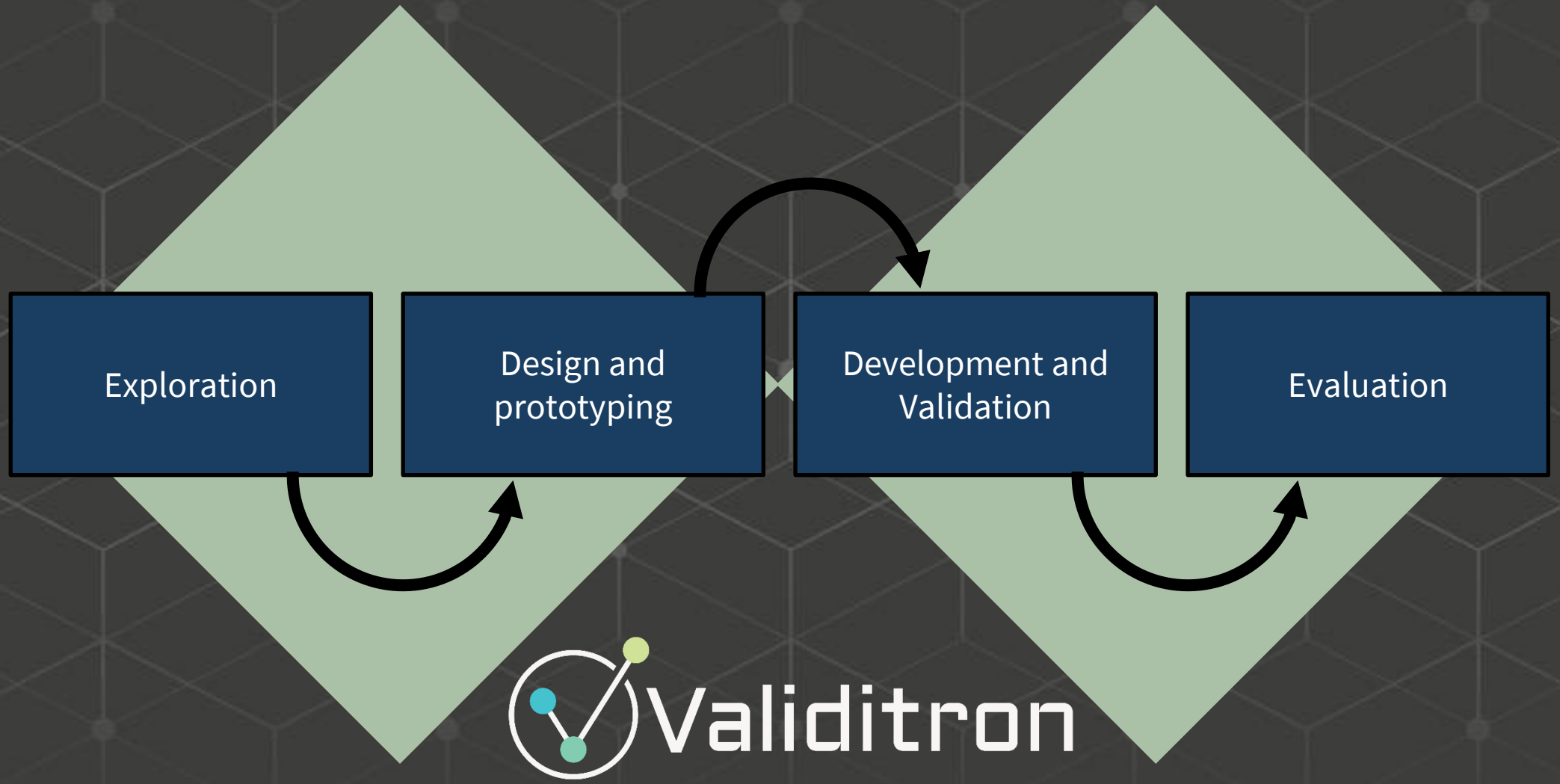
What reduces likelihood of failure?

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What is human factors and why does it matter?

- The human emotions, behaviours, and cognitions related to the design, adoption, usage, and implementation of digital health
- Intersection of several areas of scholarship including clinical science, human-computer interaction, implementation science, public health, and healthcare communication

Schueller et al, 2021


Exploration
Design and prototyping
Development and Validation
Evaluation
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Who are the users? Who are the stakeholders?

How and where can clinical information generated by this innovation best be used?

How can the usability, acceptability and safety of this innovation be optimised (for realistic clinical scenarios)?

What is the state of evidence for this innovation area?

What would a model of care built around this innovation look like?

What training, implementation and/or change processes are required?



What is a feasible payment model for this innovation?

What is needed to promote engagement and sustained, meaningful use?

What outcomes evidence is needed by payers and for compliance?

What regulatory frameworks will it need to operate within?

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How can automated digital/behavioural data collection enable outcomes/experience measurement?

Usability and workflow issues undermine digital health adoption

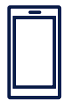
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70% of FDA software as medical device recalls relate to usability problems. Joiner Institute, 2014.



Poor workflow fit makes clinicians **50%** less likely to use decision support systems. Rosenberg et al., 2022.



Most consumers abandon digital health apps after only **5.5 days** because they find them too burdensome. Pratap et al., 2020.



Zero clinical AI/ML solutions created to tackle COVID-19 were suitable for real world use. Wynants et al., 2020.

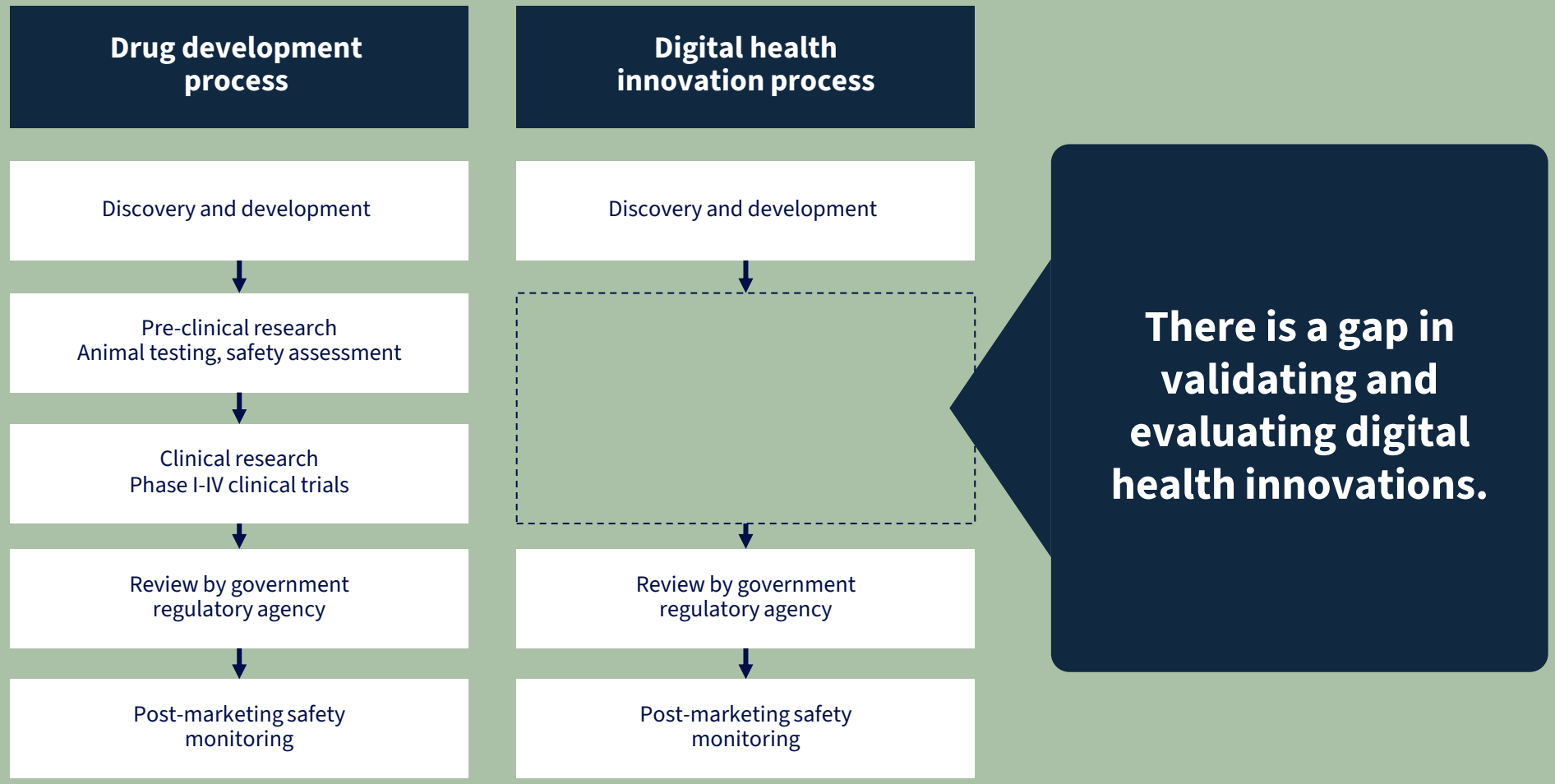


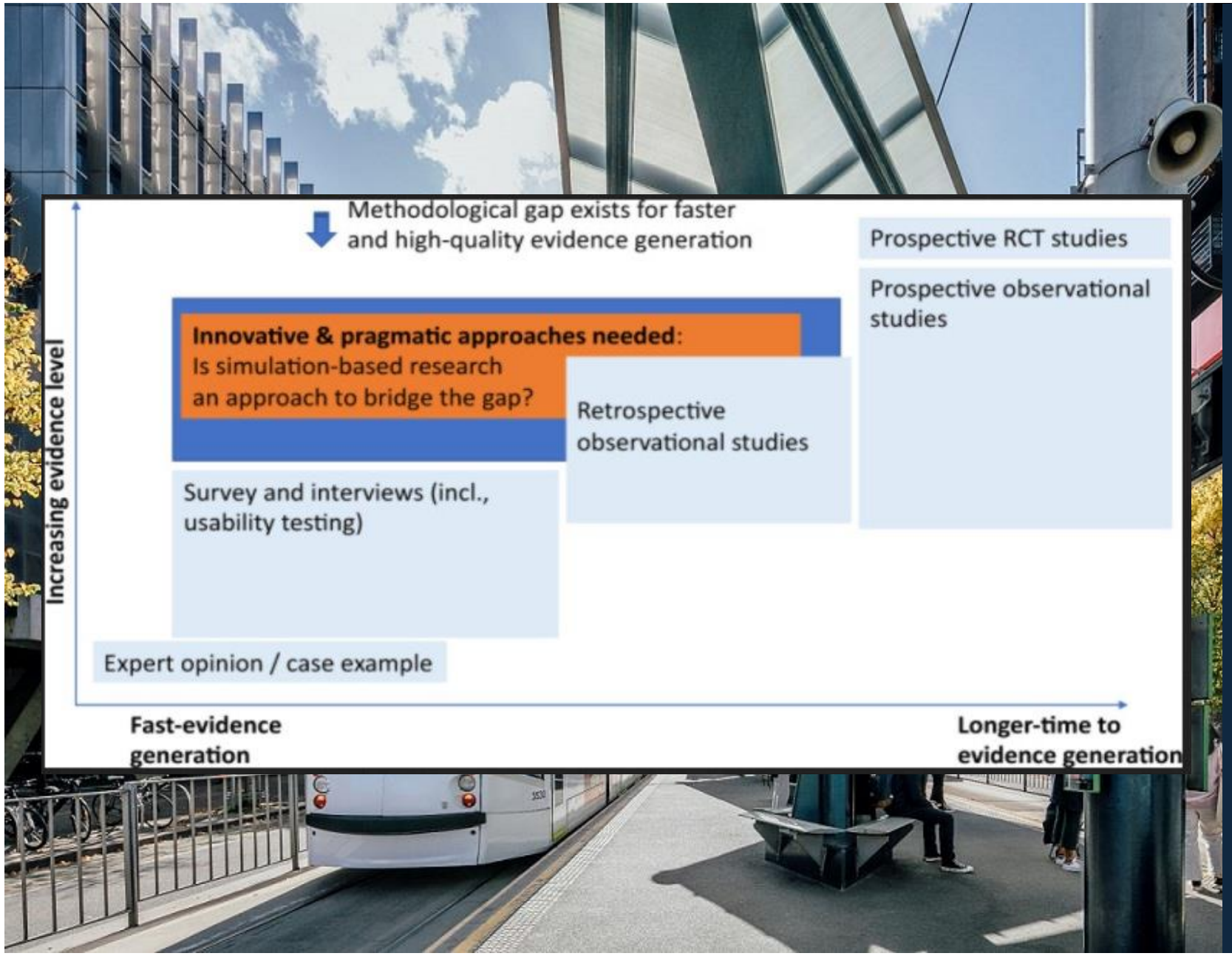
Two thirds of health apps don't have enough clinical evidence to support adoption.

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There is no standard development pathway for digital health.

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The need for new methods in digital health



Validitron SimLab

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Easily test usability in a controlled, realistic setting.

Using **immersion** and **simulation** to prime high quality feedback and insight.

PROJECT CASE STUDY

Improving patient experience of telehealth with a consultation summary tool

MOTIVATING PROBLEM

Patients leave telehealth consultations without a summary of what has, and will happen.

VALIDITRON APPROACH

- Co-design
- Environmental scanning
- Experiential simulation study

KEY INSIGHT

Experiential simulation showed that **clinician time increased paradoxically** when using a tool designed to **improve efficiency**.

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IMPACT

- Paradoxical workflow impacts were detected.
- Produced a range of implementation considerations to ensure uptake and equity.

CHIEF INVESTIGATOR

- A/Prof Rashina Hoda

  DEPARTMENT OF SOFTWARE SYSTEMS AND CYBERSECURITY
  MONASH UNIVERSITY

KEY PARTNERS

Monash Health

digital health crc

healthdirect Australia

Takeaways

1. All of health is digital
2. Digital health tools are seen as the solution to our biggest problems – but successful implementation is the exception, not the rule
3. Clinicians are the most important enabler of success
4. Addressing human factors, using new research methods, and the learning health system all help

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The University of Melbourne's healthtech studio.

Specialists in the design and delivery of bespoke validation and evaluation campaigns for digital health.

Making sure digital health **actually works** for patients and professionals.

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Because going digital is more than technology.

Masterclass series:

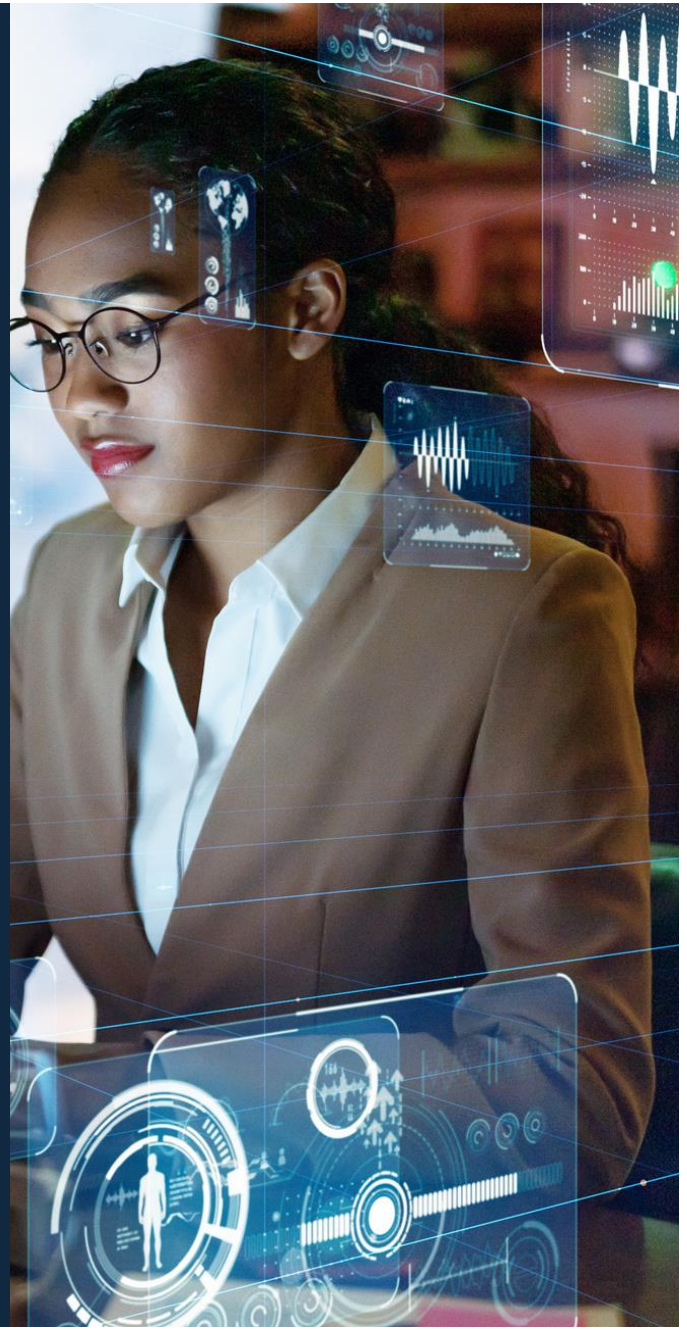
2.5h, Online, $200pp

- Implementation science for transformation
- AI in healthcare - health analytics
- AI in healthcare – panel discussion
- AI in healthcare – clinical decision support
- AI in healthcare - gen AI and natural language processing

Short courses:

13 weeks (3h pre-class, 2.5h in-class), Online, $1650pp

- Digital Learning Health Systems
- Transforming healthcare with data & AI



Surveillance considerations – clinical AI

Technical	Algorithm	Human-AI Interaction
Data flows, quality, and consistency	Domain-specific KPIs and benchmarks	Underuse and blind distrust *Tool or result results are ignored.*
Response time	Human vs AI disagreements	Misuse and literacy issues *Tool or results are not understood.*
Classification loads (appropriate and inappropriate)	Safety reports	Overreliance and complacency *Changing acceptance of AI results.*
Classification rejections	Population/site specific performance	Deskilling and trainee performance
System uptime and errors	Threshold and alert appropriateness	
Software updates		
Cost		

Extended from Dean, 2025