Virtual Journal club

THE LANCET
Digital Health

Advancing digital health applications

Priorities for innovation in real-world evidence generation

March 8th, 2022 11a ET

Jen Goldsack
CEO
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Ariel Dora Stern
Associate Professor
Harvard University

Nirosha M. Lederer
Director, RWE Strategy
Aetion

Julia Hagen
Director, Regulatory and Politics
Ex-hih

Smit Patel
Clinical Innovation Lead
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But first, housekeeping

- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
    - Either 'raise your hand' in the participant window and moderator will unmute you to ask your question live, or
    - Type your question into the chat box
- Slides and recording will be available after today's session

Overview of the DiMe-hih partnership

- Series of **three roundtable discussions** hosted by DiMe-hih for discussion and interactive knowledge sharing
  - Joined by **50+ experts** from **38 organizations**
  - Stakeholder representative from **researchers, regulators, payer, clinician leaders, academia** and so on.
  - **Shared goal:** Advancing innovation in evidence generation to support broad acceptance of digital health applications

Roundtable 1

Discussed **DiGA evaluation** and how to improve **diversity and representation** in the evaluation of medical products through the use of real-world data

Roundtable 2

Discussed pragmatic trials that use RWD/RWE – designing **alternative evidence generation approaches** for DVG pipeline digital health products.

Roundtable 3

Discussed about **advancing the regulatory science** to drive innovation in evidence generation to support broad acceptance of digital health applications

Series of three roundtables

DIGITAL MEDICINE SOCIETY

hih

Digital Medicine Week(s)

- **Digital Medicine Week** in spring and fall of 2021 that included:
  - **Medical Venture Con** – How do ideas for digital healthcare turn into successful businesses?
  - **Evidence Con & Researchathon** – How to generate evidence for digital health applications (DiGA)?
  - **MDR Con** – How can MDR requirements be adapted for digital medical devices?
  - **DiGA Con** – How do the already-approved DiGAs function in the care delivery setting?

Publication in The Lancet Digital Health

Advancing digital health applications

Global priorities for innovation in real-world evidence (RWE) generation

Ariel D Stern, PhD
Jan Brönneke, LLM
Jörg F Debatin, MD
Julia Hagen, MPA
Henrik Matthies, PhD
Smit Patel, PharmD
Ieuan Clay, PhD
Prof Bjoern Eskofier, PhD
Prof Annika Herr, PhD
Kurt Hoeller, PhD
Ashley Jaksa, MPH
Daniel B Kramer, MD
Mattias Kyhlstedt
Katherine T Lofgren, PhD
Nirosha Mahendraratnam, PhD
Holger Muehlan, PhD
Simon Reif, PhD
Lars Riedemann, MD
Jennifer C Goldsack, MA

Summary of global priorities

***Panel 2:* Topic areas where precompetitive collaboration, research, and the development of best practices will speed broad acceptance of high-quality evidence to support digital health applications**

Missing data
Handling and understanding the implications of missing data during study design and evaluation

Study endpoints
Selecting, defining, validating, and establishing both clinical and non-clinical endpoints

Comparator group
Identifying whether application plus standard of care versus standard of care alone is sufficient and whether washout periods are indicated

Multimodal interventions
Testing individual modules or components of digital health applications alone—when, why, and how?

Study question
Understanding and standardising hypothesis testing around whether digital health products are complements or substitutes to existing standards of care

Equity
Disambiguating digital application use from phone ownership in the evaluation of safety and effectiveness

Generalisability
Characterising the generalisability and transportability of findings to broad populations

Confounders
Controlling for clinical professionals who play a critical role in deploying digital tools—especially in the context of research studies—and might be differentially supportive of the product in the clinical study context compared with the real world

Fit for purpose
Generating a clear, broadly accepted conceptual framework for when certain approaches are acceptable with respect to data, study design, analytical methods, etc

Source: https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00292-2/fulltext

European digital health regulatory landscape is soaring

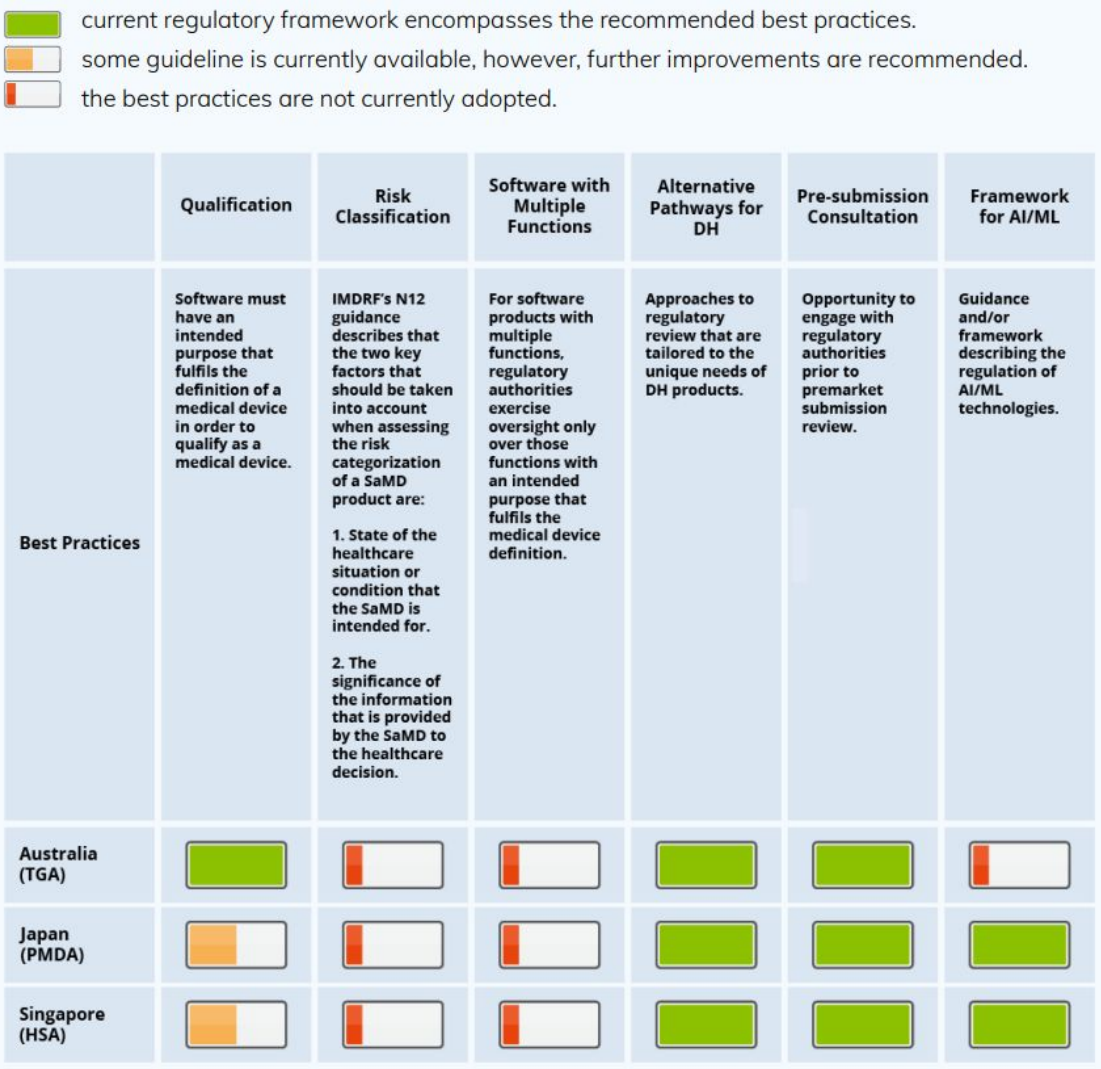
- In Oct'21, **France's** President announced plans to replicate the DiGA reimbursement scheme
- In Nov'21, **European Council** agreed on a new, harmonised regulation on health technology assessments across EU
- In partnership between ORCHA and 7 ICS, now 5.6 million people in England will have access to digital health libraries.
- Belgium, Denmark, Finland, Scotland, Ireland, Luxemburg, Spain and Sweden are discussing market access for reimbursable medical apps

Source: PalmHealth.co

So is Asia-pacific region making strides...

- In Mar'20 **Australia's** TGA released a comprehensive overview of software products qualifications and selection requirements. In Feb'21, they also released their SaMD classification.
- **Japan's** MHLW and PMDA launched a process called "SAKIGAKE", which allows for accelerated regulatory pathways for products designated as breakthrough devices addressing high, unmet medical needs
- **Singapore's** Health Sciences Authority (HSA) has published guidelines on software medical devices with intentions to

Source: APACmed



Regulatory process aren't the limiting factor for digital innovation. Rather an optimal regulatory strategy is critical part of successful digital product strategy

Optimizing digital health product and regulatory strategy

25% *of digital health product developers did not know whether the solution they were developing was regulated*

Those respondents who knew their product was regulated, ***75%*** *reported not knowing the optimal regulatory pathway.*

100% *of respondents said they would use some form of such a tool, with* ***87.5%*** *being willing to participate in user testing.*

Lack of regulatory strategy in product development

Challenges to identify fit-for-purpose regulatory pathway for digital health product

Opportunity to optimize regulatory pathways for digital health products

Project
(Launching in Q2)
To increase the efficiency and impact of digital health product development and deployment by supporting developers to identify and pursue optimal regulatory pathways that support their product strategy and the patients our field exists to serve.

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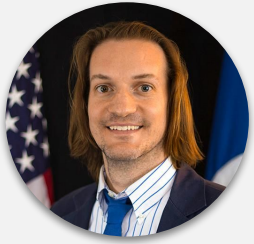
Securing healthcare systems in the digital era: Tools you can use from the US Federal Cybersecurity and Infrastructure Security Agency (CISA)

March 24th at 11a ET



Thomas Millar
Senior Advisor
US Federal Cybersecurity and Infrastructure Agency (CISA), DHS

Jennifer Goldsack
Chief Executive Officer
Digital Medicine Society

Ask me anything

Virtual Journal club

Rapid Development of a Telehealth Patient Satisfaction Survey Using a Multi-Stakeholder Approach

April 14th, 2022 12p ET

From the Abigail Wexner Research Institute Nationwide Children's Hospital

Mounika Guntu, PharmD, MHI
Data scientist

Deborah Lin, PhD
Project Scientist

Emre Sezgin, PhD
Project Scientist

Yungui Huang, PhD
Director

Moderator: **Jen Goldsack**
CEO
DiMe

THANK YOU

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