Advancing digital health applications

Priorities for innovation in real-world evidence generation

March 8th, 2022 11a ET
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 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

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Read more
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?

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**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

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, Luxembourg, 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

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<th>Qualification</th>
<th>Risk Classification</th>
<th>Software with Multiple Functions</th>
<th>Alternative Pathways for DH</th>
<th>Pre-submission Consultation</th>
<th>Framework for AI/ML</th>
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<td>Software must have an intended purpose that fulfils the definition of a medical device in order to qualify as a medical device.</td>
<td>IMDRF’s N12 guidance describes that the two key factors that should be taken into account when assessing the risk categorization of a SaMD product are: 1. State of the healthcare situation or condition that the SaMD is intended for. 2. The significance of the information that is provided by the SaMD to the healthcare decision.</td>
<td>For software products with multiple functions, regulatory authorities exercise oversight only over those functions with an intended purpose that fulfils the medical device definition.</td>
<td>Approaches to regulatory review that are tailored to the unique needs of DH products.</td>
<td>Opportunity to engage with regulatory authorities prior to premarket submission review.</td>
<td>Guidance and/or framework describing the regulation of AI/ML technologies.</td>
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| Australia (TGA) | | | | | |
| Japan (PMDA) | | | | | |
| Singapore (HSA) | | | | | |

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.
Virtual Journal club

THE LANCET Digital Health

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March 8th, 2022 11a ET
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
Virtual Journal club

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

April 14th, 2022 12p ET
THANK YOU