Unlocking the potential of mHealth data for evidence generation

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Session 3 of the HMA/EMA Big Data Stakeholder Forum: Evidence generation to advance regualtory excellence, preparing for tomorrow

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Background and scope

- Increasing number of products and applications using data from digital technologies over the last 5 years.
- The role of digital data, specifically data from mobile devices in drug development and regulation, is only expected to grow.
- More and more patients are now using personal health monitoring and mobile devices leading to vast amounts of mHealth data continuously being generated.
- After key progress on RWD/E and CT raw data analysis, BDSG continues to explore how to strengthen regulatory decision making with possible use of additional data type
- This expert report part of *Big Data Workplan 2023 - 2025*

Background and scope

mHealth (mobile health):

The practice of medicine using technology to facilitate data collection to support self-management, clinical care, and research, and eventually to improve outcomes through the use of digital interventions.

Examples of mHealth data sources:

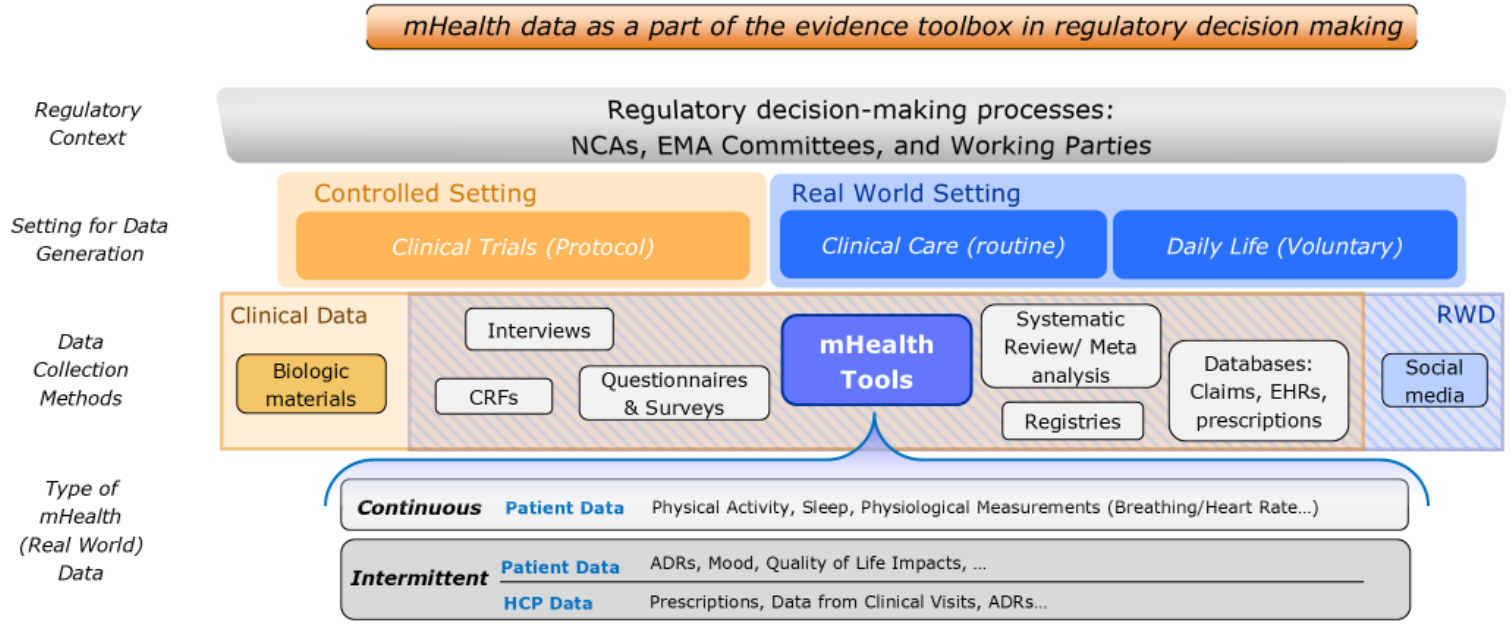
- mobile phones,
- tablet computers,
- apps,
- wearables

Unlocking the potential of mHealth data for evidence generation ?

A reference/starting point

Reflections on the current data/technological landscape

Key characteristics of mHealth data



- Report focus is on the utility of mHealth **data** *(the data generated by or collected with mHealth devices)*
- As **Real World Data** (→ data collected by mHealth devices in the context of clinical trials is out of scope)

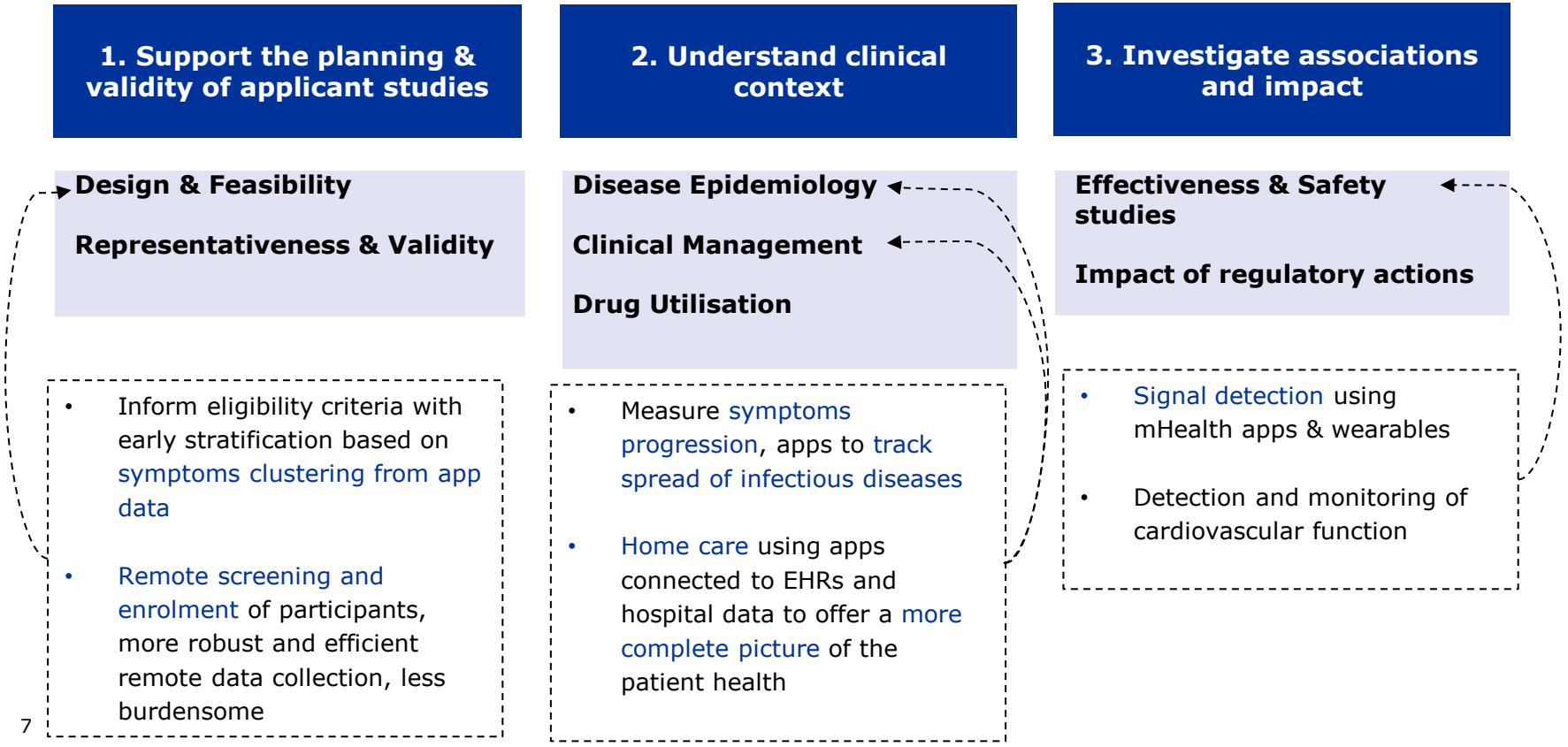
Key characteristics of mHealth data

- **Rapidly accumulating** large datasets
- **Continuous** unlabelled (untagged) data, structured data, or free-text data
- **Completeness and accuracy** vary (placement of sensor, extent of user input)
- Clarity, robustness and implementation of **data protection** measures vary
- **Access to mHealth data** varies (storage, interoperability, regulations, companies & patients willingness share data, access through registries & EHRs)
- **Data collection directly (and passively) from patients or HCPs**
- **Examples patient data**: demographic, behavioral (physical activity, eating), physiological (heart rate, temperature), spatial (location, movement), drug use data (dose, frequency), PED (HRQoL, PROs)…

Potential use cases* for regulatory decision-making – overview

Use case objective	1. Support the planning & validity of applicant studies	2. Understand clinical context	3. Investigate associations and impact
	Design & Feasibility **Representativeness & Validity**	**Disease Epidemiology** **Clinical Management** **Drug Utilisation**	**Effectiveness & Safety studies** **Impact of regulatory actions**

**Developed using the RWE-Framework*



Challenges and opportunities

Challenges

Operational

- Access conditioned by data protection regulation
- Various data storages & holders (local, cloud etc.)
- Complex regulatory landscape: different certifications and requirements for different types of mHealth tools

Technical

- Can be incomplete and unreliable.
- Differing formats, limiting interoperability
- Unlabelled/unstructured data

Methodological

- Design of studies to consider the difference in tools' features
- Not many validated digital endpoints to date
- Measurement bias from tools, representativeness bias from users

Opportunities

Operational

- Access to large amount of data passively collected from patients
- Several initiatives can be leveraged

Technical

- Technology evolution to improve accuracy and reliability of tools
- Emergence of novel approaches (AI) to help overcome some challenges

Methodological

- Easier and more efficient data collection
- More comprehensive (continuous, remote, real-time data) RWD collection compared to other sources
- Access to more diverse populations
- Opportunity to leverage large granular patient experience data sets (using Big data analytics & AI approaches)

6. Points for consideration (1/2)

Operational

1. Leverage work on patient experience data and accelerate access to mHealth data

- Establish a common European Patient Data Platform to collect EU patient mHealth data

2. Increase discoverability of data sources and studies using mHealth data

- Update RWD Catalogue with more mHealth tags/filters

3. Ensure compliance with data protection and ethical use of mHealth data

- Draft guidance on mHealth data protection

4. Engage and collaborate with all actors and relevant initiatives in the healthcare sector

- Foster public-private partnerships & pre-competitive collaborations
- Promote early interaction (SA, ITF and SME meetings) with regulators
- Organise a multistakeholder workshop to discuss the outputs of the current report with stakeholders and agree and define the EMRN vision for the next 5 years regarding mHealth data

6. Points for consideration(2/2)

Technical

5. Engage with EU and international standards for mHealth data

- Draft an mHealth chapter addition to the EU Data Quality Framework for medicines regulation
- Include mHealth data topics for the review of the EMRN data standardisation strategy

Methodological

6. Increase the understanding and tracking of the use of mHealth data in EU drug development and medicine regulation

- Review mHealth use in MAAs, SAs, and ITFs and share lessons and plans for future guidance
- Include mHealth as a Regulatory Science Research Need

7. Support the development of mHealth derived measures to meet regulatory standards

- Support and promote early interaction with regulators on clinical relevance of digital measures and qualification on context of use
- Support and promote feasibility of joint SA, either parallel or integrated, for medicinal products and medical devices

Closing remarks

- mHealth media may have utility for regulatory decision-making
- mHealth tools can generate large amount of detailed patient data
- Despite challenges in data quality, compliance with data protection requirements, access, potential bias, there are opportunities.
- The HMA-EMA Big Data Steering Group will continue to monitor progress in this area. Technological advancements may help overcome some of the challenges in using such data.

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

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