EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Important considerations for successful qualification proposals for digital technologies.

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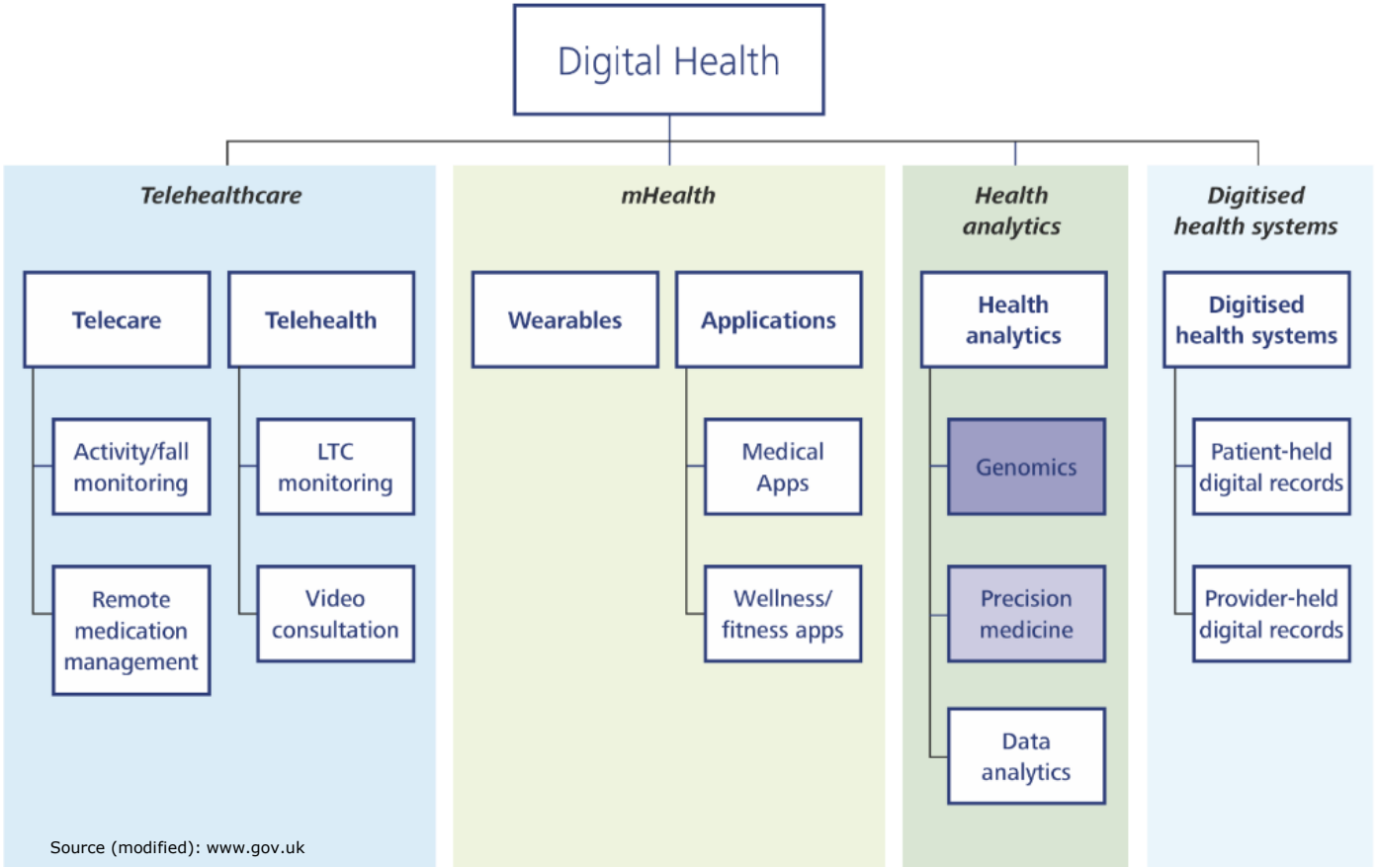

EMA ROLE

- Remit
- Awareness
- Support innovation
- Support seamless decision making
- Guidance (within remit)

Self-care ◊◊◊ HC provider/patient relationship ◊◊◊ Medicines authorisation

Possible Benefits of digital health in clinical trials

- Potential to streamline clinical investigations (rare diseases, health records, recruitment optimisation)
- Potential for rapid response
- Decrease missing data/automated checks
- Patient functioning in real-world setting
- Off-site and remote data capture
- Enrol/monitor patients in distant locations
- Support Adherence

Currently:

- ***Complement rather than substitute***
- **Function**
- **Feel (?)**
- **Data collection Systems**

Data must be linked to meaningful clinical benefit

Wearable technologies qualification is no exception

Identify Patient Population
Context of Use & Concept of Interest for Meaningful Treatment Benefit

Select or Develop Outcome & Pilot Test

Evaluate Measurement Properties

Develop Meaningful Change Guidelines

EMA Qualification Opinion/Advice

Too much of a good thing?

Some real examples:

- Fast internet speed needed for data upload (eg 100 data points/sec in 3 axes)
- Interpretation of findings may be different from investigator rated scale (Variability of mobility patterns by time of day/region; Compliance of monitor wearing drop)
- Estimands for missing data? (missing times)

Concept of Interest for Meaningful Treatment Benefit

Data collection systems

- EMA Remit
- National Competent Authority remit
- Law beyond pharmaceutical (GDPR)
- Global applicability
- Interoperablity (even at local level): burden/cost

EMA experience

- Development of novel outcome measures (e.g., COA, biomarker) for use in multiple drug development programs (e.g. Sarcopenia, Duchenne)
- eSource: GCP implications for RCTs (compliance, traceability...)
- Ingestible sensor for adherence measurement
- Scientific advices and ITF meetings on adherence / appropriate medication (chronic diseases : COPD, diabetes)
- Participation to IMI initiatives (e.g. SPRINT-T)

EMA is **interested and open to innovation** and **engagement early and throughout** clinical trial endpoint development

Challenges and opportunities

- Potential to **simplify and improve** data collection
- **Data** handling may depend on purpose (Local, Cloud, data protection, data integrity).
- **multiple** stakeholder responsibilities and **remit** (likely in EU)
- Compliance with some legal requirements required+assumed?
- May be more straightforward to **validate** as PRO rather than clinical outcome.
- **HTA** involvement welcome – ADL and function
- Strengthen/forge link with **notified bodies (?)**
- Fine line between adherence and "promotion"?

Early regulatory engagement is essential, if dossier/proposal will be heavily reliant on these data

Background information:

eSource Qualification opinion

Guidance on qualification of novel methodologies

Ingestible sensor qualification opinion

right click and open hyperlink

Data privacy workshop

"Big data" workshop

Thank you for your attention

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