EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA experience on mHealth technology

Francesca Cerreta – Scientific Advice

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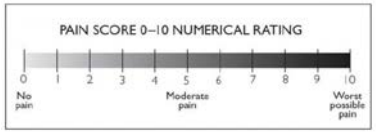
An agency of the European Union

What's important to patients is how they feel or function as a result of treatment

How Do We Measure How Patients Feel or Function?

Traditional Approaches



Novel Approaches

Complement rather than Substitute

Function

Feel (?)

Possible Benefits of mHealth technologies in Clinical Trials

- Patient functioning in real-world setting
- Potential to streamline clinical investigations in rare diseases, pediatrics, sleep studies
- Allows for off-site and remote data capture
- Access to patients in distant locations
- Support Adherence?
- Decrease missing data?
- Potential for rapid response?

mHealth technology data must be linked to meaningful clinical benefit (e.g., patient functioning)

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

Select or Develop Outcome Assessment Using Wearable Technology & Pilot Test

Evaluate Measurement Properties

Develop Meaningful Change Guidelines

Selecting or Developing a Fit-For-Purpose Wearable Technology

- Safety and user acceptance?
- How well do we understand the wearable device performance characteristics in terms of its **sensitivity, specificity, accuracy, precision,** and other relevant performance characteristics?
- Is the wearable technology derived data **reflective of a defined clinical benefit that's relevant and important** to patients daily life functioning?

Patient input is critical!

EMA experience

- Development of novel outcome measures (e.g., COA, biomarker) for use in multiple drug development programs (e.g. Sarcopenia, Duchenne)
- 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).
- Likelihood of multiple stakeholder responsibilities and **remit**.
- May be more straightforward to **validate** as PRO rather than clinical outcome.
- **HTA** involvement welcome – ADL and function
- Fine line between adherence and “promotion”?

Background information:

Guidance on qualification of novel methodologies

Ingestible sensor qualification opinion

Data privacy workshop

"Big data" workshop

Thank you for your attention

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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