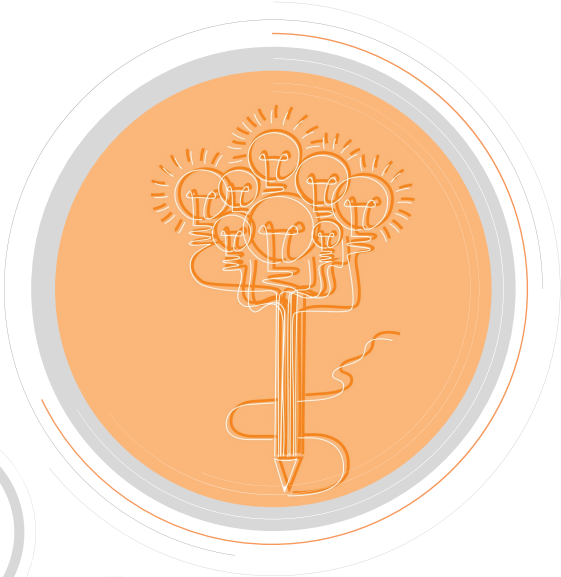
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Develop the regulatory framework for emerging clinical data generation



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Bruno Sepodes, CHMP, Anja Schiel, SAWP on 19 November 2019
Presented by Ina-Christine Rondak, Biostatistics & Methodology Support, EMA

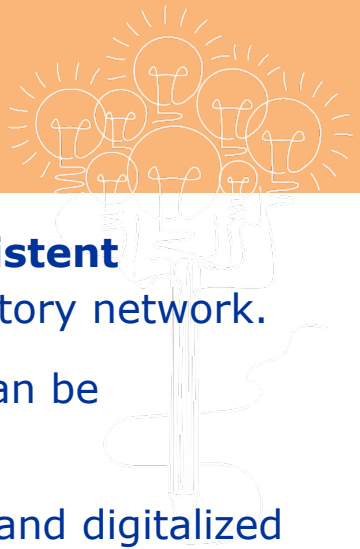
Develop the regulatory framework for emerging digital clinical data generation

- Develop methodology to incorporate clinical care data sources in regulatory decision-making
- Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual
- Develop the capability to assess complex datasets captured by technology such as wearables
- Facilitate training and understanding of healthcare professionals and patients to access and participate effectively in such trials

Develop methodology to incorporate clinical care data sources in regulatory decision-making

- A **clear framework** for **how digital measures can provide meaningful insight** into medicine development is key. Digital devices can also generate extremely large data sets. Thus, important consideration must be given for the **interpretation and analysis** of this data.
- A critical reflection on **which data is relevant** in the context of drug development processes needs to be undertaken.
- Explore the **use of real-world endpoints** in regulatory decision making, including outlining the acceptability of real-world endpoints for specific contexts of use and description of a **framework for validating** these endpoints.

Develop methodology to incorporate clinical care data sources in regulatory decision-making



- It will be important to ensure that there is a **co-ordinated and consistent approach** to the handling of these types of data across the EU regulatory network.
- The exploration of novel methods of self-measurements by patients can be supportive, as long as they represent **patient relevant outcomes**.
- Begin with some **disruptive products to set up the roadmaps**. AI and digitalized medicine is the big trend in clinical decision making. The key is the quality of the large data analyses.
- It is important to also consider the potential **consequences for society**, if data from mobile and wearable technologies are accepted for drug registration.

Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual

- Modernisation of GCP regulatory oversight must **consider technological advancements**. For instance, a truly virtual or decentralized trial would require use of technologies such digital signatures, which are currently inconsistently accepted by Member States.
- Define which **quality standards** have to be fulfilled to incorporate such data into regulatory decision-making.
- Progressing a **platform to gain multi-stakeholder input** on digital endpoints. The current processes may be lengthy which is not adapted to the agility sponsors need when determining a CT design.

Develop the capability to assess complex datasets captured by technology such as wearables

- **Training** sessions **on digital technologies** (i.e. artificial intelligence, Big Data, virtual clinical trial, sensor generated data) represent an important opportunity for the experts working in the European regulatory agencies.
- **Involvement of different professionals** (i.e. information engineers and data scientists) is required. It could be an opportunity for the EMA to establish a **multidisciplinary working party** dedicated to the application of digital technologies to drug development, authorization and post- marketing surveillance.
- Introduction of/piloting **alternative mechanism to manage large submissions** e.g. cloud submissions.

Facilitate training and understanding of healthcare professionals and patients to access and participate effectively in such trials

- **Educate** healthcare professionals **on 'precision medicine'** (mechanism-guided drug/patient matching, dose optimization and monitoring)

Clarify questions on data ownership and data security

- To **ensure data privacy** we need validated, automated de-identification systems. And advanced consent.
- There is a need to clarify the responsibility of **ownership and data security**, as well as how to make it open for research.
- Further dialogue with regulators globally on how to utilise technology enabled objective assessment of cognition, behaviour and functioning in CNS trials, as well as stakeholder alignment regarding **privacy/GDPR considerations** when utilising DHTs such as those meant for passive monitoring.

Any questions?

Further information

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