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EMA/172989/2022
Data Analytics and Methods Task Force

Agenda for "Data Quality Framework for medicines regulation" workshop

7 April 2022, 13:00-17:15 CEST
Virtual meeting, European Medicines Agency

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Objectives

The workshop is an initiative of HMA, EMA and TEHDAS to share the current progress on building a data quality framework for medicines regulation and to solicit the comments and ideas of experts in this field to help shape the framework. Breakout sessions will focus on particular use cases with discussion on the current data quality landscape and how the future of data quality in medicines regulation should look in the clinical and non-clinical spaces.

- Engage stakeholders in a discussion on the content and approach to a Data Quality Framework for Medicines Regulation, according to their needs.
- Collect input from experts in the field and learn from existing experiences
- Prioritise use cases to focus further in-depth analysis

Agenda details

12:30 Connection to virtual room and technical checks

13:00 Welcome and introduction

Chair: ***Peter Arlett**, EMA, Co-chair of Big Data Steering Group*

Welcome

***Emer Cooke**, Executive Director, EMA* *10'*

Opening remarks

***Peter Bachmann,** BfArM* *10'*

13:20 Plenary session 1: Current Data Quality Landscape

Chair: ***Hilmar Hamann**, EMA*

Analyses of Data Quality Frameworks

***Paolo Alcini**, EMA* *10'*

Maturity Model for Medical Devices Registries

***Danica Marinac-Dabic,** FDA* *10'*

Building a data quality framework for the European Health Data Space on secondary use

***Enrique Bernal-Delgado,** TEHDAS* *10'*

Quality Control Systems for Secondary Use Data

***Peter Berzin,** Odysseus* *10'*

Preparation for breakout sessions

***Paolo Alcini**, EMA* *10'*

14:10 Connection to breakout rooms and break

14:30 – 15:15 Breakout sessions

These sessions are design to draw out ideas, recommendations, and possible solutions for establishing a robust data quality framework in each of the breakout session focus areas. The feedback and comments from these sessions will be used to shape the overall Data Quality Framework being designed by HMA-EMA for regulatory purposes. Details on each breakout session are included at the end of this agenda.

Breakout session 1: Secondary Use of Real-World-Data (EHR, claims, registries, and wearables) *45'*

Chair: *Enrique Bernal-Delgado, TEHDAS*

Breakout session 2: Primary Use Data (Pre-clinical, Clinical trial, and Manufacturing) *45'*

Chair: *Frank Petavy, EMA*

Breakout session 3: Considerations when augmenting standardised primary or secondary use data with study-specific data (Hybrid approach) *45'*

Chair: *Xavier Kurz, EMA*

15:15 Break

15:30 Plenary session 2: Reports from breakout sessions

Chair: ***Enrique Bernal-Delgado****, TEHDAS*

Report from the breakout session 1
Rapporteur: *Luis Pinheiro* *10'*

Report from the breakout session 2
Rapporteur: *Eftychia-Eirini Psarelli* *10'*

Report from the breakout session 3
Rapporteur: *Lifang Liu* *10'*

Drafting a data quality framework structure *10'*
Christian Reich, *IQVIA*

Discussion and Q&A *50'*
Moderator: ***Peter Bachmann,*** *BfArM*

17:00 Concluding remarks and next steps

Jesper Kjær, *DKMA, Co-chair of Big Data Steering Group* *15'*

17:15 End of the meeting

Breakout sessions

Breakout session 1
Secondary Use of Real-World-Data (EHR, claims, registries, and wearables)

Objective:

Discuss how secondary use real-world data is currently governed, principles underlying high data quality, and what frameworks or guidelines are needed to ensure that the data is high quality and fit-for-regulatory purpose.

Group Questions:

1. Should secondary use of real-world data be accessible to or governed by regulatory bodies, if so, how?
2. Are existing data quality frameworks sufficient to determine the quality and fit for regulatory purpose of secondary use real-world data? If not, what are the challenges?
3. Are data standards needed and is there a need to transform the data for data quality to be assessed (i.e. standardised to common data model and language)?
4. What regulatory guidance or influence is needed for secondary use data, if any?

Breakout session 2
Primary Use Data (Pre-clinical, Clinical trial, and Manufacturing)

Objective:

Discuss how pre-clinical, clinical trial and manufacturing data is currently defined, collected, controlled, enforced, or influenced. Consider how high quality, in terms of data, is defined in these areas and what barriers to high quality data exist.

Group Questions:

1. What measure of quality should pre-clinical, clinical, and manufacturing data conform to in the context of regulatory decision making?
2. How can the existing pre-clinical, clinical, and manufacturing regulatory requirements or processes be strengthened to produce higher quality data?
3. What barriers to high quality data exist today with these data types?

Breakout session 3
Considerations when augmenting standardised primary or secondary use data with study-specific data (Hybrid approach)

Objective:

We assume that, because of the efficiency foreseen, hybrid approaches potentially lead to larger studies with more longitudinal data, less loss to follow-up, higher participation rates, and better

generalisability. Discuss approaches when existing secondary data is insufficient to reliably address a study question and needs to be complemented with primary study specific data or vice versa (e.g. RWE).

Group Questions:

We assume that, because of the efficiency foreseen, hybrid approaches potentially lead to larger studies with more longitudinal data, less loss to follow-up, higher participation rates, and better generalisability. In the experience of workshop participants:

1. What challenges and opportunities exist when secondary data for addressing a study question and needs to be complimented with primary data or vice versa (e.g. RWE)?
2. Are there any standardised / harmonised approaches (beyond existing guidance) that can be suggested for the acquisition of study-specific data?