Preparation for breakout sessions

"Data Quality Framework for medicines regulation" workshop 7 April 2022

Presenter: Paolo Alcini, Data Analytics and Methods Task Force, EMA

Breakout Sessions - Objective

Objective:

These sessions are designed 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.

Breakout Sessions – housekeeping rules

- All participants will be automatically transferred to the allocated sessions.
- The breakout sessions will be activated prior a short break (*in case of any technical issues, it can be resolved in time for the breakout sessions*). Once successfully connected to the breakout sessions, you will have time for a break.
- Each breakout session is scheduled for 45min.
- During the discussions, if you wish to speak, please raise your hand. When a chair gives you the floor, you can unmute yourself. Following your intervention, please click on the icon again to take your hand down and mute your microphone.
- Following the closure of the breakout sessions – you will be automatically transferred back to the main meeting room.
- 15min break is scheduled prior to 2nd plenary session.

Breakout Session 1: **Secondary Use of Real-World-Data**

(EHR, claims, registries and wearables)

Chair: Enrique Bernal-Delgado, TEHDAS

Aim:

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.

Breakout Session 1: Group Questions and Notes

Question (~10 mins)	Notes
Should secondary use of real-world data be accessible to or governed by regulatory bodies, if so, how?	
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?	
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)?	
What regulatory guidance or influence is needed for secondary use data, if any?	

Breakout Session 1: Group's Summary

Question	Summary
Should secondary use of real-world data be accessible to or governed by regulatory bodies, if so, how?	
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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*)*

Chair: Frank Petavy, EMA

Aim:

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.

Breakout Session 2: **Group Questions and Notes**

Question (~10 mins)	Notes
What measure of quality should pre-clinical, clinical, and manufacturing data conform to in the context of regulatory decision making?	
How can the existing pre-clinical, clinical, and manufacturing regulatory requirements or processes be strengthened to produce higher quality data?	
What barriers to high quality data exist today with these data types?	

Breakout Session 2: **Group's Summary**

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What measure of quality should pre-clinical, clinical, and manufacturing data conform to in the context of regulatory decision making?	
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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)*

Chair: Xavier Kurz, EMA

Aim:

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).

Breakout Session 3: **Group Questions and Notes**

Question (~15 mins)	Notes
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)?	
Are there any standardised / harmonised approaches (beyond existing guidance) that can be suggested for the acquisition of study-specific data?	

Breakout Session 3: **Group's Summary**

Question	Summary
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)?	
Are there any standardised / harmonised approaches (beyond existing guidance) that can be suggested for the acquisition of study-specific data?	

Thank you!

For any question on this presentation, please contact: DataQualityFramework@ema.europa.eu
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