22 November 2024
EMA/548191/2024
European Medicines Agency

Final Minutes – HMA-EMA joint Big Data Steering Group teleconference

15 November 2024, 10.00-11.30am (CET time)

Co-Chairs: Peter Arlett (EMA) & Jeppe Larsen (DKMA)

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes	All	For adoption	5’
2.	RWD data quality chapter: update and next steps	Ana Cochino (EMA)	For endorsement (before public consultation)	20’
3.	Revised final report on social media data to support EU regulatory decision making: discuss and agree next steps	Denise Umuhire (EMA)/ Francois Domergue (EMA) BDSG discussants: Sandra Bertulat, Ioana Agache, George Paliouras, Eleonora Agricola, Anne Cambon-Thomsen, Kaisa Immonen, Juan Garcia	For discussion	20’
4.	Drafting of PED reflection paper: update and discussion before the launch of the public consultation	Rosa Gonzalez-Quevedo (EMA)	For discussion	30’
5.	Methodology Working Party workplan review: update and next steps	Jorg Zinserling (BfArM, BDSG member)	For discussion	10’
6.	A.O.B.	All		5’

Role	Name
Attendance	Peter Arlett (EMA), Antti Hyvärinen (FIMEA, FI), Britta Haenisch (BfArM), Ana Cochino (EMA), Paolo Alcini (EMA), Carla Torre (CHMP), Aleksandra Dacic-

	Pilcevic (EMA), Jeppe Larsen (DKMA), Florian Klinglmueller (AGES, AT), Kaisa Immonen (EMA), Katrien Oude Rengerink (CBG-MEB, NL), Patricia McGettigan (PRAC), Flora Musuamba Tshinanu (SAWP), Ana López de la Rica Manjavacas (AEMPS, ES), Sandra Bertulat (BVL, DE (vet)), Denise Umuhire (EMA), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Francois Domergue (EMA), Anne Cambon-Thomsen (CNRS, FR), Régis Lassalle (Health Data Hub, FR), Joerg Zinserling (BfArM, DE), Fia Westerholm (EMA), Rosa Gonzalez-Quevedo (EMA).
Apologies:	Eleonora Agricola (EU-IN), Markus Kalliola (SITRA, FI), David Asturiol (EC), George Paliouras (Demokritos, GR), Kristin Karlsson (MWP), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), Steffen Hess (BFARM, DE), Frank Petavy (EMA), Julia Schmitz (EC), Paul Lynn (EMA), Gabriel Westman (MPA, SE), Christina Kyriakopoulou (EC), Ioana Agache (EAACI, RO), Ricardo Carapeto García (CVMP), Juan Garcia (EMA), Gunilla Andrew-Nielsen (CTCG), Hugues Malonne (FAGG, BE), Emmanuel Bacry (Health Data Hub FR), Claus Møldrup (DKMA, DK).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 4th October 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website (here).

2. RWD data quality chapter: update and next steps

Ana Cochino (EMA) presented the draft Real World Data chapter of the Data Quality Framework for BDSG's endorsement before its launch for public consultation.

The document was drafted based on the initial analysis of existing frameworks and informed by stakeholders' feedback collected during a dedicated 2-day workshop that focused on RWD quality and RWE. The first draft was consulted with the regulatory network colleagues in summer 2024. The document was endorsed by Methodology Working Party (MWP) in September 2024 and is now ready to undergo a wider consultation with stakeholders.

The document provides a thorough look at the data quality framework and its connection to the EU data quality framework. The draft is structured in three different categories, and these were presented to the group in more details. The chapter includes examples, checklists, and visuals to make it more user-friendly, as well as proposes a simple template to quality of a data source using dimensions like reliability and timeliness.

The group was informed that a data quality chapter on Adverse Drug Reaction reporting is being finalised and prioritisation exercise with the network for development of additional chapters is being planned for 2025. In addition, timely related to this work, a new topic proposal has been submitted to ICH to develop a guideline on use of real world evidence (RWE), and if accepted the scope will include terminology / definitions, metadata general principles for appraising RWE studies with a focus on effectiveness studies.

The BDSG welcomed the draft and supported the launch of the RWD data quality chapter for a 2-month public consultation.

3. Revised final report on social media data to support EU regulatory decision making: discuss and agree next steps

Francois Domergue (EMA) presented the revised draft report on Social Media Data exploring the potential utility of such data to support regulatory decision making. The document was first presented to BDSG in September, where the group agreed to have a follow up discussion on the potential regulatory use cases and next steps.

The group was reminded on the use cases for regulatory decision making identified in the report and the proposed points for consideration for future actions.

The group endorsed the proposed BDSG position on the report and agreed to publish this report, noting that:

- The report is an expert review report that reflects the current data/technological landscape and might be used as reference/starting point for new work in the years to come.
- There is potential utility of certain social media data as a complementary source of data to generate evidence, especially for some specific cases like abuse/misuse, misinformation or stakeholder listening.
- While the potential usefulness of the data is acknowledged, many current limitations to its use were also noted.
- Some of the 'points for consideration for further action' proposed in the report might be considered in the future workplan 2025-2028, in consultation with relevant fora. The report will be presented as an input to discuss the future workplan of the network data steering group in 2025, not all points for consideration might be prioritised for future action.
- The progress in this area will be monitored. EMA is establishing a process for stakeholder listening, including the social media monitoring to screen potential misinformation and to map concerns, information gaps, capture patients experience. The first topic piloted under this initiative will be on long Covid. **Action**: Rosa Gonzalez-Quevedo (EMA) to provide a written information on communications involvement in screening social media to Vincent Gazin (BDSG member).
- More research in this area (specifically for EU) is being encouraged to help to seize opportunities for the EU regulatory system and deliver public health benefits.

4. Drafting of PED reflection paper: update and discussion before the launch of the public consultation

Rosa Gonzalez-Quevedo (EMA) reminded the group on the Patient Experience Data (PED) initiative, namely the development of the PED reflection paper and exploring how to improve PED data transparency.

The drafting of the PED reflection paper is ongoing with the subject matter experts from EMA and the Network. The final draft will be shared with the big data steering group before public consultation, which is foreseen in early 2025. The reflection paper will provide a framework for developers and patient groups to collect and submit patient experience data. The paper will cover topics such as sources of data, methods for collecting data, and the value of patient experience data.

The group was then presented with the actions undertaken to increase transparency on how PED are assessed by regulators. The updates to the CHMP assessment report template are being implemented (likely in early 2025) to better reflect different types of PED in a more structured way and explain how they have been used in the evaluation.

The group welcomed the progress report and flagged that the final draft should be presented to the new Network Data Steering Group, once finalised.

Action: Rosa Gonzalez-Quevedo (EMA) to clarify whether PRAC is also being consulted to include relevant PED for Risk management aspects and respond to Vincent Gazin (BDSG member).

5. Methodology Working Party workplan review: update and next steps

Joerg Zinserling (BfArM, BDSG member) presented the highlights of the 2025 - 2027 MWP workplan, focusing on aspects relevant to BDSG. The methodology working party has updated its work plan for 2025-2027, which was subject to a targeted consultation between Aug-Sept 2024. The main focus will remain on development of guidelines (prioritisation agreed by external stakeholders), workshops, training and development; but also contains more multidisciplinary work relevant to BDSG and new NDSG.

6. A.O.B.

Open actions list:

ID	Created on:	Description	Assigned to:	Status
98	Mar-23	EMA in collaboration with the More EUROPA project to identify possible work items for BDSG workplan.	EMA	In progress
133	Mar-24	Stefanie Prilla (EMA) to consider how best to incorporate patients input in the early stages of the RWE studies planning (e.g. design, approach, strategy).	Stefanie Prilla (EMA)	In progress
139	Jun-24	To share outcome of the EMA ChatGPT pilot with BDSG members (in writing or at an upcoming meeting).	Luis Pinheiro (EMA)	In progress
147	Jul-24	EMA to consider preparing an infographic for academia linking relevant guidance on registries.	EMA	In progress
151	Oct-24	EMA to provide an update at a subsequent BDSG meeting on the non-clinical raw data pilot (quality data, manufacturing data etc).	EMA	In progress