



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Summary report of the biannual Big Data Steering Group and industry stakeholders meeting

27 November 2023 – co-chaired by Jesper Kjaer (DKMA) and Peter Arlett (EMA), Webex

### 1. Welcome and opening remarks

The Co-chairs of Big Data Steering Group (BDSG) opened the meeting and welcomed participants representing the BDSG and pharmaceutical industry associations of ACRO, AESGP, Medicines for Europe, MedTech Europe, EFPIA, EUCOPE, EuropaBio and MPP.

As part of the opening remarks, Jesper Kjaer (DKMA) provided a short update on the new BDSG membership, mandate and highlighted the key changes of the revised BDSG workplan.

It was further clarified that the initiative of nonclinical raw data submission has been incorporated in the BDSG workplan and a proof of concept on the analysis of nonclinical raw data will be discussed in 2024. This will run in parallel with the initiative on the CHMP clinical trial raw data pilot, where an interim report is being drafted for 2024. A portfolio of RWE use cases will be published and the new use cases for genomics and patient experience data (PED) will be explored. A dedicated session on potential of PED in EU medicine regulation will be further discussed and presented at the HMA/EMA Big Data Stakeholder Forum 2023 on 4<sup>th</sup> December 2023.

### 2. Launch of the EMA-HMA catalogues of data sources & non interventional studies

#### 2.1. Industry feedback on Validation activities

Sigrid Behr (EFPIA) on behalf of the EFPIA working group and in alignment with the other Industry associations presented the Industry feedback on validation activities of the EMA-HMA catalogues of data sources and non-interventional studies. It was noted that detailed feedback has already been provided in writing to EMA and this presentation was focussed on general comments and some areas of improvement/consideration for future releases.

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## **2.2. EMA update and next steps**

Ana Cochino (EMA) presented the business processes outline for data submission, maintenance and validation the catalogues of data sources and non-interventional studies that will be launched in the first quarter of 2024. In December 2023, EMA will share with the Industry stakeholders the draft Standard Operating Procedure (SOP) for the validation, publication, and maintenance of data sources and studies. Industry associations were encouraged to provide comments/feedback through the consolidated feedback form by Tuesday 12 January 2024.

*Post meeting note:* the deadline for Industry feedback has been extended to cob 19 January 2024.

Ana Cochino (EMA) thanked Industry associations for input provided into the external validation exercise of the catalogues. A thorough review of received comments has taken place and EMA will be looking into implementation of suggestions where possible in future.

It was flagged to the meeting participants, that the catalogues of data sources and studies will be moved from the current ENCePP website to EMA website and a downtime of 2-3 weeks is anticipated to migrate the data, with further information to follow to relevant stakeholders in December 2023.

EuropaBio sought a clarification on what would be the link between the different data sources of Darwin EU ®, the EMA HMA catalogues of data sources and studies and the EHDS data catalogue. It was clarified that the EMA HMA catalogues of data sources and studies will include the data sources of the Darwin EU ® data partners. In total, for its launch, the catalogues will contain 150 data sources. For European Health Data Space (EHDS), EMA actively participates as a consortium partner in the EHDS2 pilot and there are close discussions ongoing with THEDAS joint action 1 and 2 to ensure that the EMA HMA catalogues are aligned with the EHDS infrastructure.

It was also noted that currently EMA is not actively reaching out to non-EU Data source holders for inclusion in the catalogues of data sources and studies, however there is no restriction for the non-EU data source submission, no data protection concerns, and a normal validation process will apply.

Industry also supported the value to develop a future ICH guideline on metadata for real-world data sources.

## **3. Real World Evidence**

### **3.1. Industry priorities on guidance on data and methods (to inform future workshop on RWE methodologies/research).**

Marieke Schoonen (Amgen (EUCOPE)) on behalf of Industry associations presented the key Industry priorities relating to Data and Methods Guidance and emphasised on the need for additional guidance required to understand what constitutes fit-for-purpose data, on how to transparently execute RWE studies and on how to integrate the use of AI into RWE generation. Industry acknowledged the significant progress made by the EMA and other regulators regarding the use and acceptance of RWE in regulatory decision-making and appreciated continued collaboration, and the opportunity to interact via the multi-stakeholder workshops and events.

### **3.2. Update on RWE and DARWIN EU ® activities**

Patrice Verpillat (EMA) gave an update on the DARWIN EU ® and RWE activities, including the onboarding of new data partners, scientific studies conducted in 2023, and industry involvement in the process to consult or inform industry on studies executed through DARWIN EU ®, as agreed with the DARWIN EU ® advisory board. Participants noted that the updated catalogue of standard data

analyses will be published in Q1-Q2 2024, following the industry consultation in 2023. The final version of the Data Quality Framework (DQF) for EU medicines regulation will be released by the end of 2023, following a public consultation earlier this year. It was also highlighted that the data quality chapter on Real-World Data is under preparation.

An overview of the current or planned guidance on use of RWE for regulatory purposes at EU and International level was also presented.

The use cases to conduct RWD studies (through Darwin EU ®), and the types of analyses and studies delivered to support the EU regulatory decision-making were discussed. The industry consultation process on complex and very complex studies was further discussed, Industry voicing their need to better prepare in view of the increased number of studies to be executed by DARWIN EU ® in the next year to come. Industry asked to have an operational guidance/process flowchart with indicative timelines to help their preparation.

An additional question was raised with regards to the transparency and communication to the industry stakeholders on the simple studies initiated under the Darwin EU ®. The meeting participants were reconfirmed that all study data are published in the EU PAS register.

In relation to the data sources onboarded in the Darwin EU ®, industry enquired whether it is possible to have a list of data sources which failed validation for onboarding into the Darwin EU ® network, to which EMA informed that such information will not be disclosed and that multiple criteria is being used to validate the onboarding of a data source in DARWIN EU ®, also a consideration should be given to the limited number of data partners that can be onboarded each year.

In response to a question regarding the need to align definitions and terminologies across different international guidance, Industry colleagues were informed that whilst the reflection paper 'on use of real-world data to generate real-world evidence in non-interventional studies' will have EU definitions listed, the alignment on the international fora should be ensured through ICH.

## **4. Artificial Intelligence**

### ***4.1. AI workshop – Smart regulation in a rapidly evolving world: next steps***

Gabriel Westman (DKMA) gave a summary of the discussions that followed the joint HMA/EMA workshop on AI on 20-21 November 2023. Peter Arlett (EMA) emphasised that the consultation on draft reflection paper 'on the use of Artificial Intelligence (AI) in the medicinal product lifecycle' will close on 31 December 2023 and feedback should be submitted using the [dedicated form](#).

Luis Pinheiro (EMA) then presented the draft multi-annual AI workplan to 2028, that already incorporated the feedback received during the joint HMA-EMA workshop on AI on 20-21 November 2023. The activities in the draft plan are clustered in four areas (Guidance, Policy and Product support; Tools and Technology; Training and Collaboration; Experimentation) and a brief overview of activities under each area was presented.

### ***4.2. Industry reflections on AI workshop (20-21 November 2023)***

Thomas Brookland (EFPIA) congratulated EMA for hosting an excellent workshop and summarised the Industry observations. Six key points were of note:

- The diversity of stakeholder invited to participate and give different perspectives, including from the US, were greatly appreciated.
- The introductory session (setting the scene) on the first day allowed a proper engagement by all stakeholders and understanding of the current state of play of evolving AI frameworks.
- Great discussions and varied stakeholder perspectives were voiced on the AI reflection paper.
- An insight into how the regulators are preparing for the AI (capability building) was highly valued.
- The detailed review of the draft multi-annual AI workplan to 2028 was much appreciated.
- Areas to be further explored: critical need to align terminologies/definitions, greater understanding of risk levels, mitigating bias in data sets, need for engagement and collaboration, support to sandboxing concept was expressed, interface between medicines and devices was highlighted, dual use cases emerging to be considered, international harmonisation etc.

## **5. Wrap up and conclusions**

The BDSG co-chairs thanked the meeting attendees for their participation and contribution to this meeting.