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

25 October 2024 – co-chaired by Jeppe Larsen (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, Association of Veterinary Consultants, EFPIA, EUCOPE and Vaccines Europe.

As part of the opening remarks an update on key achievements and upcoming stakeholder events for the BDSG workplan and the AI Multi-annual workplan was provided.

2. Real World Evidence generation

2.1. EMA progress update

Patrice Verpillat (EMA) provided a progress update on RWE generation related activities, including the creation of an ad-hoc Industry/EMA focus group on use of RWD and generation of RWE. This group was established in summer 2024, with the kick off meeting took place on 25 September 2024, where the ways of working for these expert discussions were agreed.

The key highlights from the 2nd report on conducting studies with real-world data were presented. The report focuses on the European Medicines Regulatory Network's continued efforts to better integrate real-world evidence (RWE) into regulatory decisions on medicine development, authorisation and monitoring. It builds on the previous report and provides a progress update on new studies, expanded data partners, lessons learned, and further recommendations and actions.

Additional updates on the other RWE generation activities included the next steps on DARWIN EU®, international RWE activities and RWD sources and studies catalogues. The imminent release of the Data Quality Framework - Real-World Data Chapter for public consultation and a launch of a survey to understand and increase usability of the catalogues by the EU Regulatory Network and Industry were also highlighted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In addition, the meeting participants were informed about the publication of the Patient Registries workshop report, which took place in February 2024. The document includes a set of recommendations and suggested actions to address opportunities and challenges identified during the two-day plenary and breakout sessions. As a next step, EMA will identify the relevant channels to follow-up on the recommendations. Close interactions will be maintained with all stakeholders to ensure appropriate experts' involvement and consultation on the suggested actions.

2.2. Industry feedback

Marieke Schoonen (EUCOPE) and Almath Spooner (EFPIA) thanked EMA and the BDSG for the status update and appreciated the ongoing stakeholder engagement efforts. The establishment of the RWE focus group was welcomed to share and discuss experience with use of RWD and generation of RWE.

It was noted that DARWIN EU® remains the area for close collaboration, especially around transparency of the feasibility assessment, assessment of fitness-for-purpose of data sources, reporting of the studies' results and use of these results for the regulatory decision making. Additionally, further clarifications are needed on processes and procedures for DARWIN EU® studies and development of a Q&A document, to clarify on information flows and consultation processes, are encouraged.

The group was informed that a report on EFPIA's findings on the wide array of tools available for the data quality assessments will be published soon and findings of the report are aligned with the elements of EMA data quality framework. To drive a better data quality, more guidance/good practice guide is needed on the use of registries for decision making supplemented by the RWD data quality chapter, which will be released for public consultation shortly.

In addition, a review by EFPIA of the existing data quality frameworks and guidance from global regulators is being conducted, which aims at understanding how quality terminology is being used across borders and highlighting the opportunities for regulatory convergencies. The results will be available in early 2025.

Some clarifications were made on the availability of study results and study protocols in the RWD study catalogue, noting that further discussions on aspects related to DARWIN EU® studies will be addressed at the next RWE Industry/EMA focus group on 3 December 2024.

3. Rationalisation of the network data governance

Francois Domergue (EMA) informed the participants that the creation of the Network Data Steering Group (NDSG) and its mandate was endorsed by HMA at the 117th HMA meeting on 12 September 2024 and by EMA Management Board at the 125th Management Board meeting on 3 October 2024. The NDSG is the strategic advisory group established to maximise data interoperability, exchange and use across the EU network, the generation of evidence, and the beneficial utilisation of AI. It results from the unification of the two existing data governance bodies, the Big Data Steering Group (BDSG) and the Network Data Board (NDB) into one group, to deliver the activities of the EMANS to 2028 (Theme 2: Leverage data, digitalization and AI) and to oversee the implementation of the data governance artefacts. The aim is to have the composition complete by the end of November and for the first meeting to take place in January 2025.

The group discussed the format and composition of the future interactions between NDSG and Industry stakeholders on data governance. It was agreed that a high-level stock-take meetings between Industry and the NDSG should continue to be organised periodically, with more technical level discussions with relevant technical experts taking place in between.

4. Clinical study data pilot – interim results

Eftychia-Eirini Psarelli (EMA) provided an update on the Clinical study data pilot (previously called Clinical Trials Raw Data pilot), the publication of the pilot's interim report and the next steps that includes the pilot's extension. The pilot extension for another two years will build on the previous experience and learnings so far, validate a future target operating model, and focus on capacity and capability requirements across the network and technical requirements. It will also allow to work on intensifying the exploration of systematic use of clinical study data in support of regulatory assessment and decision-making, exploring IT solutions and intensifying the change management activities, including training. A call for new procedures to be included in the pilot extension remains open.

Industry congratulated the team on the work done so far and acknowledged good collaboration with the pilot team, while highlighting some unresolved remaining key challenges in the areas of transparency for access to data and concerns around the network's capacity.

It was noted that the pilot team is continuing its collaboration with the EMA transparency office to agree the next steps of application of the EMA's transparency rules in the pilot and explore measures to minimise resourcing requirements from the network, e.g. application of targeted analysis, automation of tasks and adequate training. EMA together with the network are working towards a future model focusing on running additional analyses (e.g. sensitivity, visualisation etc) to better understand the complex dossier and not to replicate analyses provided by the developers.

5. Wrap up and conclusions

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