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

23 May 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, Animal health Europe, Association of Veterinary Consultants, COCIR, EFPIA, EUCOPE, EUCROF, EuropaBio 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 to 2028 was provided.

2. Evidence generation

2.1. Industry feedback on early experience with DARWIN EU ® studies

Almath Spooner (EFPIA) and Brian Bradbury (EUCOPE) shared the early reflections and observations on the industry experience with the DARWIN EU® complex studies. The feedback was collected from medicines developers but also informed by broader industry experience with some of the data partners.

The speakers noted the progress made by DARWIN EU® and presented an industry view of successful DARWIN EU ® implementation: shared confidence and trust in real-world evidence used for regulatory and healthcare decision, a common framework for generating fit for purpose evidence for all actors (medicines developers, academics, regulators and third parties) and a collaborative approach principled approach to develop studies were highlighted.

The key issues shared by Industry include: a need for more clarity of the feasibility assessment, longer timelines for the review of complex study protocols, additional transparency on the choice of methodologies and assessment of fitness-for-purpose of data sources, a need for additional guidance

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for the medicines developers and clarification on a process for considering medicines developers comments.

2.2. EMA update and next steps

Patrice Verpillat (EMA) provided a progress update on RWE generation related activities, including DARWIN EU ®.

DARWIN EU® has now entered the first year of operation and aims to onboard 10 additional Data Partners and scale up the capacity for studies, thanks to access to data from ~130 million patients from 13 countries already in 2024. An overview of the different types of studies conducted within DARWIN EU ®, including the range of topics and requests to support EMA scientific committees, ECDC and HTA/payers was presented. It was noted that a guidance document (Questions & Answers) to address the most frequent questions from medicines developers is being prepared by the Agency, which will be updated on a regular basis. The timelines to conduct a review of complex study protocols will be increased up to 10 working days with an early email notification sent in advance highlighting the dates for review and request for a consolidated version of industry comments in case several MAHs are involved. the feasibility assessment template will be made available via the DARWIN EU ® coordination centre website in the coming months and an ad-hoc focus group to facilitate a more detailed dialogue on RWD/RWE will be set up between the agency and industry.

Additional updates on the other RWE generation activities included the next steps on finalisation of the Real-World Data Quality Framework chapter, the presentation of the HMA-EMA Real-World Metadata Catalogues including the development of a good practice guide for the use HMA-EMA Real-World Data Catalogues, and the upcoming joint HMA/EMA Big Data Steering Group workshop on RWE methods on 14 June 2024. Also highlighted was the **importance for data sources to register in the RW metadata catalogue to foster discoverability**; participants have been informed that they can contribute to populating the catalogues by sharing information on existing data sources with EMA (by writing to metadata@ema.europa.eu); this will allow EMA to contact them and make them aware of the catalogues, explaining the main reasons why they should register.

The Industry colleagues thanked EMA and the BDSG for considering/addressing Industry concerns. The group welcomed this bilateral dialogue and noted the right timing to engage further on progress to generate RWE.

3. Data quality

Industry assessment of data quality tools/frameworks useful for implementing EMA's data quality framework and relevant to the future RWD quality chapter

Jing Wang-Silvanto (EFPIA) presented the results from the Industry assessment of data quality tools/frameworks useful for implementing Agency's data quality framework (DQF). A comprehensive review was conducted by seven EFPIA companies, with the preliminary findings concluded that no existing tools can cover all aspects of the DQF domains, there is a diversity in terminology and implementation of DQF is complex. Based on this assessment, Industry would welcome some flexibility allowing sponsors to tailor a data quality tool to the specific use case or research questions and strengthen the stakeholder collaborations to ensure a broad implementation of DQF concepts. Also, a need to harmonise or map DQF elements to other global frameworks to ensure consistency in data quality assessments and interpretability of results was highlighted.

Ana Cochino (EMA) thanked Industry for sharing the preliminary results and focussed on some of the findings from this initial assessment. The Agency is looking forward to the publication of the final assessment report from the Industry's review to further reflect on the key findings. EMA reminded the group of its willingness to further collaborate on the implementation of the EMA's Data Quality Framework and finalisation of the RWD quality chapter, which could be facilitated via the above mentioned ad-hoc Industry focus group. Stakeholders' feedback on the drafting of an RWD DQF chapter can be submitted during the public consultation planned later this year.

4. BDSG and Accelerating Clinical Trials in the EU (ACT EU)

The topic was added to the agenda to have an initial brainstorming discussion on the interface between the Clinical Trials (CT) transformation programme and the BDSG data transformation programme. As such, the Network vision for clinical evidence foresees embracing a spectrum of methods where a research question drives the choice of evidence, being a Clinical Trial or an observational study or any other method selected.

Ana Zanoletty (EMA) presented the EMA's initiative for Accelerating Clinical Trials in the European Union (ACT EU), which support smarter clinical trials through regulatory, technological and process innovation. The ACT EU programme will deliver benefits to clinical trial stakeholders via eleven priority actions. The vision is to transform the EU into a region that supports clinical trial development and enables collaboration and innovation at all stages of the clinical research lifecycle.

EMA will aim to complete a mapping exercise between the different BDSG and ACT EU workplans for further discussion at a future Multi-stakeholder Advisory Group meeting in 2024.

Industry welcomed the presentation and concurred that addressing clinical research challenges in EU is the top priority and acknowledged the importance of ACT EU work.

5. Wrap up and conclusions

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