3 June 2024
EMA/51677/2024
European Medicines Agency

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

27 May 2024, 10.30am - 12.00pm (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.	European Health Data Space (EHDS) - update from the European Commission	David Asturiol (EC)	For information	15’
3.	THEDAS2 project	Markus Kalliola (Sitra, FI)	For information	15’
4.	Quantum project	Enrique Bernal Delgado (Aragon Institute of Health Sciences – IACS)	For information	15’
5.	BDSG discussion on EHDS	All BDSG members	For discussion	15’
6.	Clinical Trials raw data pilot - Interim report	Eftychia Psarelli (EMA)	For discussion	30’
7.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Jeppe Larsen (DKMA), David Asturiol (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Christina Kyriakopoulou (EC), Aleksandra Dacic-Pilcevic (EMA), Flora Musuamba Tshinanu (SAWP), Eleonora Agricola (EU-IN), Florian Klinglmueller (AGES, AT), Kristin Karlsson (MWP), Marjon Pasmooij (MEB, NL), Kaisa Immonen (EMA), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), George Paliouras (Demokritos, GR), Vincent Gazin (ANSM, FR), Joerg Zinserling (BfArM, DE), Paul Lynn (EMA), Patrice Verpillat (EMA), Fia Westerholm (EMA), Paolo Alcini (EMA), Pyry Eskelinen (EMA), Gabriel Westman (MPA, SE), Sandra Bertulat (BVL, DE (vet)), Patricia

	McGettigan (PRAC), Hugues Malonne (FAGG, BE), Markus Kalliola (SITRA, FI), Emmanuel Bacry (Health Data Hub FR), Francois Domergue (EMA), Frank Petavy (EMA), Tomas Bekisas (EMA), Denise Umuhire (EMA), Zoltan Thinsz (EMA), Ana Cochino (EMA), Daniel Morales (EMA), Britta Haenisch (BFARM, DE), Claus Møldrup (DKMA, DK), Enrique Bernal Delgado (IACS), Eftychia Psarelli (EMA).
Apologies:	Steffen Hess (BFARM, DE), Ioana Agache (EAACI, RO), Carla Torre (CHMP), Francesca Cerreta (EMA), Ricardo Carapeto García (CVMP), Juan Garcia (EMA), Gunilla Andrew-Nielsen (CTCG), Ana Vidal (EMA).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 22nd April 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website (here).

2. European Health Data Space (EHDS) - update from the European Commission

David Asturiol (EC) presented an update on the European Health Data Space (EHDS) and highlighted the key points from this regulation relevant for regulators together with the implementation timelines and next steps.

It was noted that a provisional agreement on the text for EHDS was reached by co-legislators in March 2024 and was adopted by the Member States on 22 March 2024. The legislative text was adopted by the European Parliament (EP) on 24 April 2024, with the final publication expected at the end of 2024, marking the entry into force. General application will start by end of 2026, with further stepwise application of specific implementing acts by end of 2028, 2030 and 2034.

Key of points relevant to Members States on the agreement for opt-out, for secondary use, for data localisation, an accelerated data permit and the EHDS governance (i.e. EHDS board and Stakeholder forum) were presented in the meeting.

The group thanked David Asturiol (EC) for a very clear presentation on the EHDS implementation plan and governance. It was noted that some further discussions with medicines regulators and relevant agencies on the implementation of EHDS will be planned by the Commission following the adoption of the final regulation text.

During the group discussions further clarifications were made around the foreseen involvement of patients in the EHDS implementation and the processing of sensitive and patients' data. The sensitive data will need to be made available to EHDS by 2030, which will be submitted in anonymised or pseudo-anonymised format into a secure processing environment and accessible to user for analysis but will not be downloadable. The patients' data (for primary use) will be accessible to a patient owner with availability to download, however no provision is foreseen for patients to have direct information when and how their data are being used. Each Health Data Access Body (HDAB) will publish what data access was given or not.

It was also recommended to EC to provide further information to Member States on the secure process environment used to exchange data with a HDAB. David Asturiol clarified that it is foreseen that

multiple secure process environments (with different data characteristics but in the same data structure) will be created and could connect to a HDAB. A data user submitting a data access application will choose what type of server or secure process environment it needs to process the data from the HDAB.

Any specific questions on the regulation interpretation should be sent to a dedicated email address at SANTE-EHDS2@ec.europa.eu.

3. THEDAS2 project

Markus Kaliolla (Sitra, FI) introduced the THEDAS2 project, which is the second joint action towards the EHDS implementation. The project started its work in May 2024 and will last for 32 months. The project focuses on the secondary use of the health data and aims to create guidelines and technical specifications for the Member States, so that EHDS can be implemented in the harmonised matter. This will facilitate better preparedness, coordination and reduced fragmentation on policies and practices for the secondary use of health data. The work is divided into thematic areas, with the country leads assigned. The timelines for delivery of the guidance by TEHDAS2 were aligned to the EC requirements for the EHDS regulation. The TEHDAS2 project should finish at the end of 2026, after publication of the implementing acts.

4. Quantum project

Enrique Bernal Delgado (IACS) presented the Quantum project to the group. The project will facilitate the implementation of the new EHDS regulation by addressing Article 56: data quality and utility label. The work has been divided into five work packages and will cover the following elements: data documentation, assessment of technical quality, data quality management processes, assessment of coverage, information on access and provision, information on data modifications and sufficient documentation to the health data access body for that body to confirm the accuracy of the label.

The group thanked Enrique Bernal Delgado for a concise presentation and sought some clarifications on exchange of information across different projects (Quantum, TEHDAS2 and EHDS2 pilot), where similar elements are being addressed (e.g. metadata). It was noted that projects are continuously collaborating to build on the work initiated during TEHDAS1 and communication exchange is ensured via inter-institutional liaison and common events.

Peter Arlett (EMA) thanked all session speakers and acknowledged the importance of the ongoing work. Further updates on the implementation on the EHDS regulation will be scheduled at the future BDSG meetings, with a focus on more specific projects' deliverables and key milestones.

5. Clinical Trials raw data pilot - Interim report

Eftychia Psarelli (EMA) provided an update on the Clinical Trials raw data pilot, reminded the group of the current legal basis and the provision of the new pharmaceutical legislation that foresees an inclusion of electronic submissions of raw data for all new marketing authorisation applications. In December 2023, a survey was conducted to gather feedback from pilot participants and based on the survey results the interim pilot report has been prepared. The survey looked at 4 areas of feedback: added value for assessment and decision making; capacity and capability; governance and processes and technical aspects. Overall findings are positive and supportive.

The preliminary learnings and insights of pilot participants across these four areas were presented to the group, together with selected recommendations for future implementation and for the second part of the pilot. As a next step, the preliminary findings will be presented to CHMP before furtherly disseminated across the network, with the short summary of the interim pilot report being made publicly available in Q3 2024. The final pilot report with the recommendations for the decision-making bodies will be prepared in 2025.

The group congratulated the team on the progress made and on the very positive feedback on feasibility and utility of raw data analysis in support of medicines evaluation. The group highlighted the need to include the Network's capability and capacity issues in the final report, as part of the pilot recommendations. In addition, for the second part of the pilot it was recommended to consider onboarding procedures covering different resourcing scenarios for raw data analyses which have not yet been covered in the pilot's first part.

Action: BDSG members to provide any additional comments on the interim pilot report to the following functional email address rawdatapilot@ema.europa.eu.

6. A.O.B.

Open actions list:

ID	Created on:	Description	Assigned to:	Status
42	Jun-21	EMA to prepare a discussion on how to align the BDSG work with clinical trials activities, for a future BDSG meeting.	EMA	In progress
66	Feb-22	The results of the RSRN relevant to BDSG should be discussed with BDSG members when available.	EMA	In progress
67	Feb-22	Input from the BDSG to inform the new RSRN lists should be added in the new BDSG workplan.	EMA	Planned for Q3/Q4
89	Oct-22	BDSG members noted the need to further explore how ideas from the BDSG on the use of big data to support the EU regulatory network can be fed back to IHI or DG RTD D2 calls in the future.	EMA	In progress
98	Mar-23	EMA in collaboration with the More EUROPA project to identify possible work items for BDSG workplan.	EMA	In progress
104	Jun-23	EMA to liaise with ESEC specialist interest area on AI to organise to survey to establish an inventory of AI related projects in the Network. This survey should also involve the NCAs of the CoE.	EMA	In progress
109	Oct-23	The BDSG secretariat to consider organising a follow up session on ongoing AI activities in the EU Network in 6-month time.	EMA	In progress
122	Jan-24	EMA to reflect the launch and roll out of several national initiatives on AI under the experimentation topic of the AI workplan to 2028 to map the Network AI activities and signpost to the different AI tools available for the EU Regulatory Network.	Luis Pinheiro (EMA)	In progress
128	Feb-24	Jakub Hasiec (EMA) to clarify internally the delivery timelines for the offerings by Digital Academy and feedback to BDSG.	Jakub Hasiec (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
135	Apr-24	The drafting team to consider validating the reflection paper with the relevant national guidance (on use of RWD in non-interventional studies to generate RWE) during the public consultation period.	Juan Jose Abellan	In progress