1 March 2024
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European Medicines Agency

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

26 February 2024, 13.00am - 14.30pm (CET time)

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

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes Welcome new BDSG members	All	For adoption	5’
2.	Follow up discussion: Multi-annual AI workplan – planning the work on AI	Kristin Karlsson (MPA) / Peter Arlett (EMA)	For discussion	40’
3.	Launch of the HMA-EMA Catalogues of real-world data sources and studies – short demo	Paolo Alcini / Ana Cochino (EMA)	For information	15’
4.	Demo series of AI tools: ERAMET project	Flora Musuamba Tshinanu (FAGG, BE)	For information	20’
5.	AOB RWD quality consideration: consultation process	All	For information	5’

Role	Name
Attendance	Peter Arlett (EMA), Jeppe Larsen (DKMA), Niklas Hedberg (TLV, SE), Aina Staisiuniene (EMA), George Paliouras (Demokritos, GR), Gabriel Westman (MPA, SE), Paolo Alcini (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Anne Cambon-Thomsen (CNRS, FR), Antti Hyvärinen (FIMEA, FI), Patricia McGettigan (PRAC), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Christina Kyriakopoulou (EC), Kaisa Immonen (EMA), Hugues Malonne (FAGG, BE), Flora Musuamba Tshinanu (SAWP), Marjon Pasmooij (MEB, NL), Ioana Agache (EAACI, RO), Kristin Karlsson (MWP), Carla Torre (CHMP), Markus Kalliola (SITRA, FI), Florian Klinglmueller (AGES, AT), Joerg Zinserling (BfArM, DE), Pyry Eskelinen (EMA), Sandra Bertulat (BVL, DE (vet)), Jakub Hasiec (EMA), David Asturiol (EC), Fia Westerholm (EMA), Francesca Cerreta (EMA), Peter Bachmann (EU NDB), Frank Petavy (EMA), Ricardo Carapeto García (CVMP), Ana Cochino (EMA), Florian Lasch (EMA).

Apologies:	Francois Domergue (EMA), Juan Garcia (EMA), Licinio Kustra Mano (EC, DG SANTE), Gunilla Andrew-Nielsen (CTCG), Emmanuel Bacry (Health Data Hub FR), Eleonora Agricola (EU-IN), Ana Vidal (EMA), Paul Lynn (EMA), Luis Pinheiro (EMA), Steffen Hess (BFARM, DE).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda and minutes from 30th January 2024 BDSG meeting were adopted as final. The BDSG meeting minutes are regularly published on the EMA website (here).

Peter Arlett (EMA) introduced and welcomed Niklas Hedberg from the Dental and Pharmaceutical Benefits Agency in Sweden, who joined the BDSG as an HTA representative. The BDSG members also welcomed David Asturiol, the new DG SANTE C.1 delegate to the Big Data Steering Group.

2. Follow up discussion: Multi-annual AI workplan – planning the work on AI

The group continued discussions (to identify the key milestones and deliverables, define roles and responsibilities, and appoint the BDSG sponsors) on the activities foreseen under the 'Collaboration and change management' and 'Experimentation' workstreams, with the discussions facilitated by Kristin Karlsson (MWP) and Peter Arlett (EMA).

The detailed summary of the meeting discussions for the last two workstreams of the AI workplan are captured in the attached document.

AI workplan - swimlanes2.docx

Action Luis Pinheiro (EMA) to provide feedback from the joint FDA/ Korean Ministry of Food and Drug Safety (MFDS) workshop on the use of AI in medical product development at a future BDSG meeting.

Action EMA: to launch a call for additional BDSG sponsors of the AI workplan activities via a written procedure.

3. Launch of the HMA-EMA Catalogues of real-world data sources and studies – short demo

Ana Cochino (EMA) presented a short demo of the HMA-EMA Catalogues of real-world data sources and studies. The two public electronic catalogues were launched on 15 February 2024. The Catalogue of RWD sources replaces the ENCePP Resources Database, offering a centralised repository for real-world data (RWD) sources. The Catalogue of RWD studies replaces and expands the EU PAS Register®, aiming to increase the transparency of non-interventional post-authorisation studies and other RWD based research. The Catalogues will help medicines regulators, researchers and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results.

The interested colleagues, who would like to have a more in-depth knowledge, were invited to join a dedicated webinar on the launch on the new RWD Catalogues on 4 March 2024.

Action: EMA to send a link to the webinar event to the BDSG members. The event will be live broadcast with no prior registration required.

Action: EMA to organise a dedicated discussion between Anne Cambon-Thomsen (CNRS, FR) and BDSG co-chairs on ethics elements (mapping the ethics touch points) for the AI and BDSG workplans.

4. Demo series of AI tools: ERAMET project

Flora Musuamba Tshinanu (SAWP) gave an introduction of the ERAMET project to BDSG members. ERAMET will provide an integrated approach for developers and regulators' decision-making for paediatric and orphan drugs, centred on the drug development questions. This will establish a transparent ecosystem for drug development and assessment, and will facilitate the adoption of modelling and simulation (M&S) methods and related data types (including real word data such as registries and electronic healthcare data).

The overall objective of ERAMET is to provide and implement a framework for establishing the credibility of M&S methods and related results as sources of evidence within regulatory procedures.

The ecosystem proposed by ERAMET will be based on three pillars:

(1) A repository connecting Questions, Data and Methods.

(2) The development and validation of high-quality standards for data and analytical methods (including M&S and hybrid approaches). These will cover computational M&S, digital twins, AI, hybrid approaches, standard statistics and pharmacometrics, as analytical methods and alternative data types and sources such as RWD, eHealth data, registries, historical regulatory submissions, scientific and (non)clinical trials).

(3) An AI-based platform that will automate and optimise the data collection, formatting and modelling and simulation analysis and implement the credibility assessment.

As part of ERAMET project, five use-cases will be applied, including paediatric extrapolation and characterisation of drug benefit/risk in four groups of rare diseases, namely ataxia, transfusion dependent haemoglobinopathies, bronchopulmonary dysplasia, and degenerative neuromuscular diseases.

Each of the use-case is planned to lead to submission and regulatory approval of at least one validated M&S tool via the EMA qualification procedure. Training packages will be proposed to familiarise regulatory assessors, drug developers and clinical researchers with this new approach.

Action: Flora Musuamba Tshinanu (SAWP) to consider whether a collaboration between ERAMET project and the ECHO community could be beneficial (https://www.sttinfo.fi/tiedote/70037229/eu-awards-large-funding-to-develop-data-driven-collaboration-between-european-pediatric-hospitals?publisherId=23980819&lang=en)

5. A.O.B.

RWD quality consideration: consultation process

Ana Cochino (EMA) briefly presented the consultation process and associated timelines for the endorsement of the Real World Data chapter of the Data Quality Framework. As the immediate next step, the draft chapter will be circulated for consultation to the BDSG by mid-March 2024. The topic was presented for information and awareness.

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
46	Jul-21	EMA to plan for the October meeting, with more MS examples presented, further discussion on how CoE will interact and work with the EMA Working Parties, within the European Regulatory Network governance, EC and TEHDAS.	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	In progress
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
100	May-23	Further discussion should be held to explore how the experience on RWE generated via national data sources could be integrated in the future to provide a comprehensive EU network perspective.	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
106	Sep-23	EMA to consider presenting a demo on the ChatGPT pilot and lessons learned on its use to understand technology and limitations for different use cases.	EMA	In progress
107	Oct-23	Peter Arlett to share lessons learnt from the risk assessment (from Microsoft Azure) with BDSG and consider organising a dedicated webinar.	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
117	Dec-23	EMA to send a dedicated email to BDSG members with the updated key messages defining the meaning of the data-driven medicines regulation transformation for further reflection and comments. Discussion on the big data stakeholders and communication and engagement approach will take place at a future meeting.	Aina Staisiuniene (EMA)	In progress
118	Dec-23	BDSG members willing to get engaged in the definition and execution of the Change Management deliverable of the BDSG workplan are welcome to contact the BDSG secretariat.	BDSG members	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

124	Feb-24	Action EMA to provide feedback from the joint FDA/ Korean Ministry of Food and Drug Safety (MFDS) workshop on the use of AI in medical product development at a future BDSG meeting.	Luis Pinheiro (EMA)	In progress
125	Feb-24	EMA to launch a call for additional BDSG sponsors of the AI workplan activities via a written procedure.	EMA	In progress
126	Feb-24	EMA to organise a dedicated discussion between Anne Cambon-Thomsen (CNRS, FR) and BDSG co-chairs on ethics elements (mapping the ethics touch points) for the AI and BDSG workplans.	EMA	In progress
127	Feb-24	Flora Musuamba Tshinanu (SAWP) to consider whether a collaboration between ERAMET project and the ECHO community could be beneficial.	Flora Musuamba Tshinanu (SAWP)	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