15 December 2023
EMA/130876/2023
European Medicines Agency

Final Minutes – HMA-EMA joint Big Data Steering Group F-2-F meeting / teleconference

5 December 2023, 09.00am - 13.00pm (CET time)

Co-Chair: Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters	Action	Time
1.	Adoption of the draft agenda & minutes	All	For adoption	5’
2.	Multi-annual AI workplan – next steps and implementation	G.Westman (MPA) / L. Pinheiro (EMA)	For discussion	20’
3.	Demo series of AI tools: Scientific explorer	J.Moseley (EMA)	For information	20’
4.	ACT EU priority action 5: Clinical Trials analytics workshop	F.Grell Nørgaard (DKMA) / I. den Rooijen (EMA)	For discussion	10’
5.	Draft revised 3-year work plan for the Methodology Working Party - focus on 2024	K.Karlsson (MWP) / I.Rondak (EMA)	For discussion	25’
6.	EU Network data strategy	N.Halsey (EMA)	For discussion	25’
7.	Follow-up on RWE HORIZON-HLTH-2022-TOOL-11-02 call: REALM project presentation	M.Dumontier / G.Ertaylan	For information	30’
8.	Big Data Change Management	A.Staisiuniene (EMA) /P.Arlett (EMA)	For discussion	85’
4.	A.O.B.	All	For information	5’

Role	Name
Attendance	Joerg Zinserling (BfArM, DE), Peter Arlett (EMA), Aina Staisiuniene (EMA), Francois Domergue (EMA), George Paliouras (Demokritos, GR), Gabriel Westman (MPA, SE), Luis Pinheiro (EMA), Paolo Alcini (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Antti Hyvärinen (FIMEA, FI), Eleonora Agricola (EU-IN), Florian Klinglmueller (AGES, AT), Patricia McGettigan (PRAC), Patrice Verpillat (EMA), Vincent Gazin (ANSM, FR), Christina Kyriakopoulou

	(EC), Kaisa Immonen (EMA), Pyry Eskelinen (EMA), Ana Vidal (EMA), Sandra Bertulat (BVL, DE (vet)), Jerome de Barros (EC, DG SANTE), Markus Kalliola (SITRA, FI), Peter Bachmann (EU NDB), Kristin Karlsson (MWP), Carla Torre (CHMP), Paul Lynn (EMA), Fia Westerholm (EMA), Flora Musuamba Tshinanu (SAWP), Marjon Pasmooij (MEB, NL), Frank Petavy (EMA), Jane Moseley (EMA), Lorenzo Guizzaro (EMA), Ana Luiza Oliveira (EMA), Anna-Sofia Joro (EMA), Ina-Christine Rondak (EMA), Nick Halsey (EMA), IJsbrand den Rooijen (EMA), Achilleas Voutsas (EMA), Lorenzo De Angelis (EMA), Luis Pinheiro (EMA), Zoltan Thinsz (EMA), Pyry Eskelinen (EMA), F.Grell Nørgaard (DKMA),
Apologies:	Jesper Kjaer (DKMA), Juan Garcia (EMA), Hugues Malonne (FAGG, BE), Licinio Kustra Mano (EC, DG SANTE), Joaquim Berenguer (EMA), Gunilla Andrew-Nielsen (CTCG), Ioana Agache (EAACI, RO), Emmanuel Bacry (Health Data Hub FR), Sara Rafael Almeida (EC), Ricardo Carapeto García (CVMP), 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 October BDSG meeting were adopted without change. The BDSG meeting minutes are regularly published on the EMA website (here).

Action Gabriel Westman: A demo on the AI tool rolled out by MPA in December 2023 to be planned in January 2024 (Gabriel Westman to present to BDSG members).

Action Flora Musumba Tshinanu: A presentation on the Regulatory Science project (led by FAGG, BE) to be scheduled in Q1 2024 (Flora Musuamba Tshinanu to present to BDSG members).

2. Multi-annual AI workplan – next steps and implementation

Luis Pinheiro (EMA) presented the draft multi-annual AI workplan to 2028 and focussed on the deliverables planned for 2024 with the immediate priority areas/actions identified.

The group had its first discussion on the priority actions for 2024 and supported a closer collaboration on these activities to ensure a common contribution within the EU Network, including a timely consultation with the BDSG members.

For the AI Masterclass, BDSG indicated that the scope and the target audience should be on regulatory assessment activities, as compared to general AI training. In addition, the group supported having a series of masterclass organised throughout 2024. As a priority, masterclasses on security, data protection and use of large language models (LLM) should be considered, with additional masterclass on the AI Reflection paper to be planned for later in 2024. Also, a need to collaborate with the ongoing training initiatives within the EU Network was flagged and a careful consideration on how to link with the new joint action initiative (IncreaseNet), should be given. This initiative will be launched in January 2024 to deliver training to NCAs through academia collaboration on innovation topics, including AI. The group also supported the use of the already available tools within the Network and flagged the need to invite additional participants during the discussions on the IT tools (e.g. IT directors).

Action EMA (Luis Pinheiro): a dedicated session on planning the work on AI to be scheduled at the January BDSG meeting, this to include a discussion on how to optimise use within the network, deliverables split between various groups (i.e. MWP, Special Interest groups etc).

3. Demo series of AI tools: Scientific explorer

The group was presented a demo on Scientific Explorer (as part of demo series of AI tools), which is an Artificial Intelligence (AI) enabled tool for EU regulators that facilitates easy, focused and precise searches within regulatory procedure documents. Jane Moseley (EMA) gave a short overview and a demo of the tool which is expected to be launched in March 2024.

It supports scientific decision-making by providing access to relevant scientific information and in its first version the information is based on the Scientific Advice letters.

Some further clarifications were provided to the group on the technology being used, compliance to security requirements, access to the tool, use of LLM to address different spelling and different terms used for search function, basic search function enabled. The use of this tool for the veterinary domain is also being explored.

As the next steps the team will continue developing the tool and perform user acceptance testing. Further NCA testing will take place in February 2024 and its roll out is anticipated in March 2024 for the EU Network.

The group thanked Jane Mosley (EMA) and the team for the presentation and expressed the full support to further develop this tool, which is highly anticipated by the NCA assessors.

Action Marjon Pasmooij: Marjon Pasmooij (MEB, NL) to take part in the NCA users testing in February 2024.

4. ACT EU priority action 5: Clinical Trials analytics workshop

IJsbrand den Rooijen (EMA) presented the Accelerating Clinical Trials in the EU (ACT EU) initiative and the key milestones identified as part the ACT EU priority action 5: Clinical Trials analytics. Frederik Grell Nørgaard (DKMA) then presented the key objectives of the Clinical Trials analytics workshop and invited the BDSG members to engage with the event, which is scheduled to take place on 25 and 26 January 2024.

Action IJsbrand den Rooijen (EMA): IJsbrand den Rooijen and Frederik Grell Nørgaard to contact George Paliouras to explore whether the Clinical Trial data collected at the Duchenne Data Foundation can be considered as a potential use case.

5. Draft revised 3-year work plan for the Methodology Working Party - focus on 2024

Kristin Karlsson (MWP) presented the revised work plan for the Methodology Working Party (MWP), which will be finalised in January 2024. The guideline development in the workplan is structured under five main areas: Clinical Pharmacology, Real World Evidence, Clinical Trial Modernisation, Pharmacogenomics and Data Science & AI and the detailed overview of planned guideline documents under each pillar was presented. In addition, the support to the ICH activities is being planned as well as the development of the training modules and specific workshops to be held. The group noted that the plan is very ambitious, and some prioritisation may be required to deliver on the workplan, as well

as a careful planning and engagement of the resource across the Network (not only the MWP and ESEC members).

The BDSG members can submit comments on the revised workplan for 2024 activities to MWPSecretariat@ema.europa.eu.

6. EU Network data strategy

Nick Halsey (EMA) gave a introduction on the development of the EMRN data strategy, which is foreseen to be delivered under the BDSG workplan in 2024. The kick off meeting for the strategy scoping will be organised in January 2024 and a call for volunteers to participate in the drafting was raised at the meeting. The initial estimated time commitment would be around 2-3 hours in Q1 2024. The following volunteers were identified at the meeting: Peter Bachmann (NDB representative), Gabriel Westman (MPA), Jerome De Baros (EC), Marjon Pasmooij (MEB, NL), Fia Westerholm (EMA), Nick Halsey (EMA) and Sandra Bertulat (as Vet observer).

Action BDSG members: The BDSG members willing to contribute to the EMRN data strategy scoping exercise should inform the BDSG secretariat accordingly.

7. Follow-up on RWE HORIZON-HLTH-2022-TOOL-11-02 call: REALM project presentation

Michel Dumontier and Gokhan Ertaylan presented the Real-world-data Enabled Assessment for heaLth regulatory decision-Making (REALM) project, its architecture and the use cases. The project aims to establish a regulatory framework and architecture for enabling the assessment of medical AI software device including the real-world data and synthetic data.

The group thanked the presenters for the interesting presentation and clarifications provided on the follow up questions. The slides presented at the meeting are linked below for the ease of reference.

Agenda item 7 - REALM_Project-EMA

The BDSG members to consider whether the foreseen regulators' validation of data and algorithms that impact on medicines use, as envisaged in the original Big Data Task Force report, could be done via the 3rd party sandboxes.

Action Patrice Verpillat (EMA): EMA RWE team to set up a follow up call with the REALM project coordinators to explore a potential collaboration/synergies between the DARWIN EU® and REALM projects.

8. Big Data Change Management

Peter Arlett (EMA) introduced the context to the change management session and highlighted the need to have an adequate Change Management strategy in place to handle the changes brought by the realisation of the BDSG workplan to the EU regulatory decision-making processes. The delivery of the BDSG workplan up until now has largely been in the design phase in terms of defining what data-driven medicines regulation will look like. As we transition to the implementation phase it is important that we reflect on the change management aspects, including stakeholder communication, engagement and training. During today's session the group reviewed the big data vision narrative including key messages on the data-driven medicines regulation transformation. The input gathered

during the meeting will feed into the big data change management strategy drafting which will be presented to the group in Q1 2024.

The following comments were noted during the discussion on the big data narrative:

- Consider highlighting the modelling and simulation area more prominently in the workplan and balance the activities throughout.
- Consider reflecting further/ clarifying use of the term/brand 'Big Data', in the scope of the BDSG activities that deliver data-driven regulation transformation.
- Clarify that the work of the BDSG on Big data including AI related activities is complimentary to the traditional methodological and biostatistics activities used for regulatory assessments.
- Complement that our strive to enhance regulatory decisions on medicines is is also guided by 'medical needs' and not only by patients.
- Consider amending the text on 'we strive to generate evidence…' to 'we use/interpret evidence that is fit for purpose…'.
- Highlight that big data activities aim to 'Support the quality/efficiency of regulatory assessment'.
- Consider including the causal inference (benefit-risk) and further emphasise better access to data and reusability in the narrative.
- Related to advanced analytics/AI consider including points on 'provenance of data and log of assumptions'.
- Reword term of 'experimentation' to potentially 'agile development'.
- We must ensure that our stakeholders understand changes being made by the delivery of the BDSG workplan and are ready to adopt them. We need to promote a different way of thinking about data, different ways of working with the new data and place trust in the new data sources.

Action Aina Staisiuniene (EMA): 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.

Action BDSG members: 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.

Open actions list:

ID	Created on:	Description	Assigned to:	Status
39	May-21	EMA to organise a dedicated discussion on EU NTC at a future BDSG meeting.	EMA	In progress
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
43	Jun-21	EMA to consider inviting the relevant EC colleagues to give an update on the Medical Devices group activities.	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
95	Jan-23	EMA to consider creating a table to include the different dimensions of the EMRB governance discussed at the meeting, i.e. type of data, role of EU network in the governance (e.g. data holder, data user, data judge/adviser), organisation of governance (e.g. centralized/decentralized) and interfaces (global)	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	
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
110	Dec-23	A demo on the AI tool rolled out by MPA in December 2023 to be planned in January 2024 (Gabriel Westman to present to BDSG members).	Gabriel Westman	In progress
111	Dec-23	A presentation on the Regulatory Science project (led by FAGG, BE) to be scheduled in Q1 2024 (Flora Musuamba Tshinanu to present to BDSG members).	Flora Musumba Tshinanu	In progress
112	Dec-23	A dedicated session on planning the work on AI to be scheduled at the January BDSG meeting, this to include a discussion on how to optimise use within the network, deliverables split between various groups (i.e. MWP, Special Interest groups etc).	Luis Pinheiro	In progress
113	Dec-23	Marjon Pasmooij (MEB, NL) to take part in the NCA users testing in February 2024.	Marjon Pasmooij	In progress
114	Dec-23	IJsbrand den Rooijen and Frederik Grell Nørgaard to contact George Paliouras to explore whether the Clinical Trial data collected at the Duchenne Data Foundation can be considered as a potential use case.	IJsbrand den Rooijen (EMA)	In progress
115	Dec-23	The BDSG members willing to contribute to the EMRN data strategy scoping exercise should inform the BDSG secretariat accordingly.	BDSG members	In progress
116	Dec-23	EMA RWE team to set up a follow up call with the REALM project coordinators to explore a potential collaboration/synergies between the DARWIN EU® and REALM projects.	Patrice Verpillat (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