23 July 2025
EMA/241078/2025

Final Minutes – HMA-EMA joint Network Data Steering Group meeting

17 July 2025, 15:00-17:00pm, Webex

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
1.	Adoption of the draft agenda & minutes	Karl Broich, Peter Arlett	For adoption	5’
2.	Progress on RWE: Darwin EU and annual RWE experience report	Patrice Verpillat	For information	15’
3.	RWE change management strategy	Patrice Verpillat	For discussion	25’
4.	Progress on clinical study data pilot	Flora Musuamba Tshinanu	For information	15’
5.	Clinical study data pilot: change management strategy • Including review/adoption of the mandate of the Industry group focusing on clinical study data	Stefanie Prilla	For discussion/adoption	25’
6.	AI change management strategy	Joris Wiemer	For discussion	25’
7.	A.O.B. • Overview of planned stakeholder engagement and public facing events	All Francois Domergue /Aina Staisiuniene	For information	5’

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Patrice Verpillat (EMA), Anne Cambon-Thomsen (CNRS, FR), Aina Staisiuniene (EMA), Francois Domergue (EMA), Stefanie Prilla (EMA), Luis Pinheiro (EMA), Hans-Joachim Bigalke (EDQM), Katrien Oude Rengerink (CBG-MEB, NL), Francisco Penaranda (EMA), Pedro Pina Ferreira (EMA), Hilmar Hamann (EMA), Edurne Lazaro (AEMPS, ES), Patricia McGettigan (PRAC), Dmitry Etin (EMA), Vincent Gazin (ANSM, FR), Jacobus van Wyk (EMA), Mart Slomka (Payers), Pero Ivanko (CIPH, HR), Joerg Zinserling

	(BfArM, DE), Flora Musuamba Tshinanu (SAWP), Jerome De Barros (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Carla Torre (CHMP), Laure Baduel (CVMP), Angelo Molinaro (AIFA, IT), Rico Slingerland (CMDv), Alexandra Pacurariu (EMA), Julianna Fogd (EMA), Marie Orre (EMA), Stine Mogensen (DKMA), María Clara Restrepo-Méndez (EMA), Joris Wiemer (EMA).
Apologies:	Paul Lynn (EMA), Marianne Lunzer (AGES, AT), Pelle Persson (MPA, SE), Niklas Hedberg (HTA), Florian Klinglmueller (AGES, AT), Siobhán O'Sullivan (Ethics), Gabriel Westman (MPA, SE), Eleonora Agricola (EU-IN), Aimad Torqui (MEB, NL), Vaia Apostolidou (EC), Claus Møldrup (DKMA, DK), Julien Delaye (Eurordis), Kristin Karlsson (MWP), Konstantina Boumaki (EPF), Georg Neuwirther (AGES, AT), Dag Jordbru (NOMA, NO), Kimmo Porkka (EHA), Kaisa Immonen (EMA), Christina Kyriakopoulou (EC), Pier Paolo Olimpieri (AIFA, IT), Sandra Bertulat (BVL, DE (vet)), Markus Kalliola (SITRA, FI), Bruno Delafont (CHMP).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The NDSG members were invited to submit their final comments on the draft minutes of 27th June NDSG meeting by close of business 24th July 2025. In the absence of any substantial comments, the minutes will be considered as adopted and published thereafter.

The group welcomed Pero Ivanko (HR), as the new Health Data Access Bodies (HDABs) representative, who replaced Johanna Seppänen. The group thanked Anne Cambon-Thomsen for her contributions to the group's work. Anne Cambon-Thomsen will be replaced by Siobhán O'Sullivan and Alessandro Blasimme, as ethics representatives from September 2025.

2. Progress on RWE: Darwin EU and annual RWE experience report

Patrice Verpillat (EMA) presented the progress update on real-world evidence (RWE), highlighting the publication of the 3rd report on the experience gained with regulator-led studies, which was published on 30 June 2025 together with an infosheet. The report focuses on RWE generation via three RWE generation pathways (DARWIN EU®, studies commissioned via the framework contracts and in-house studies) and covers value of EMA-generated RWE for regulatory decisions, progress on operational aspects and methodological advice on the use of RWD and methods within regulatory submissions. To further accelerate and standardise RWE, some additional steps were identified to be undertaken in the coming years.

In addition, the updates on the HMA-EMA Catalogues of RWD sources and studies, Real-World Data Quality Framework and activities linked to the RWE guidance development, were provided to the group.

3. RWE change management strategy

Patrice Verpillat (EMA) presented the revised change management strategy for RWE, with the aim to optimise the use of real-world evidence to support medicines regulatory decision making. The list of

stakeholders impacted by the change was presented to the group, noting that currently the change management activities is focused on two priority stakeholder groups: Committees/Working Parties and NCAs/Assessors. Several objectives targeting these two stakeholder groups were identified and activities to reach these objectives in the areas of engagements and communications, knowledge building and sharing were presented.

The group discussed the revised RWE change management approach and how to reach out to NCAs and assessment teams. The following feedback was noted:

- The importance of data quality, comparability in real-world evidence studies and representativeness of data sets were highlighted.
- To encourage the use of DARWIN@EU by assessors, the use of simple queries (e.g. on disease prevalence, drug utilisation) should be promoted to assessors to gain quick/easy responses.
- There is a need for assessors to learn how to formulate clear, answerable questions to optimise the timelines to conduct DARWIN EU studies.
- More interpretation of the study should be added in the study reports to ease NCA assessors' evaluation.
- A need for better training and communication to NCAs to enhance understanding and benefits of RWE was flagged.
  - The group called on Committees' experts and NDSG members to support NCAs assessors with the use of DARWIN@EU framework within their respective organisations and groups.
  - Consider working with EMA committees to collect examples of questions where RWE would have been useful for procedures.
  - Consider focusing the short-term studies and feasibility of studies to demonstrate benefits of RWE studies.
  - The EU Real4Reg project can facilitate training needs.
  - Extrapolation, particularly from a small clinical trial population to a wider audience, can facilitate a better use of real-world data.

The NDSG supported the revised change management strategy and endorsed actions targeted towards the two priority stakeholder groups. **Action:** EMA to incorporate the additional feedback from the group into the RWE change management strategy and its implementation.

4. Progress on clinical study data pilot

Flora Musuamba Tshinanu (SAWP representative) presented a progress update on the clinical study data proof-of-concept pilot (formerly known as raw data pilot). The group was also reminded of the current legal basis and the provision of the new pharmaceutical legislation that foresees an inclusion of electronic submissions of Clinical study data for all new marketing authorisation applications. Launched in 2022, the pilot investigates the benefits of visualising and analysing clinical study data to support the scientific assessment of medicinal products. The clinical study data are submitted voluntarily by applicants or marketing authorisation holders as part of their respective applications. The first phase of the pilot was completed in 2024. based on the learnings so far, included in the interim report, which was published in October 2024, the pilot has been extended beyond 2025 and entered the second phase. The second phase will focus on continue gathering learnings in the areas of: how to optimise the use of clinical study data to support the Rapporteurs and the Agency's scientific committees in the

regulatory decision making and will focus on the characterisations of the data packages and how to support the network with on-demand interactive pre-defined and pre-programmed analysis and visualisations. The group then discussed the benefits and practicalities of joining the pilot and noted that any queries related to the pilot or an application to take part in the pilot should be sent to rawdatapilot@ema.europa.eu.

5. Clinical study data pilot: change management strategy

Stefanie Prilla (EMA) presented the change management strategy for submission and analysis of clinical study data, highlighting the key timelines and planned activities in 2025-2027. Whilst continuing with the Clinical study data pilot and gathering business requirements, the focus of change management activities will be on engagement and communication with stakeholders; update of business processes, including workshops to collect needs/priorities; training and guidance development. The change management activities will be channelled mainly through two key vehicles representing the priority stakeholders of the pilot: Network Advisory Group on Raw Data and Industry group focusing on clinical study data.

A call for expression of interest was launched to NDSG members representing NCAs to co-chair the industry group focusing on clinical study data. In addition, the need to intensify the collaboration within the Network was noted and a call to join the Network Advisory Group on Raw Data was issued to NDSG members. **Action**: NDSG members or relevant experts within NCAs willing to join the Network Advisory Group on Raw Data should submit their interest by 31 July 2025 to rawdatapilot@ema.europa.eu.

The group supported the change management approach for Clinical study data pilot and provided additional feedback for consideration:

- Clarify the decision-making process, including the working model, software selection, assessor training needs, potential AI use for data analysis, and shared dossier analysis to improve efficiency and data interpretation.
- A use of common data analysis tool was suggested. Additionally, network should explore the availability and feasibility of the tool, which is being developed by the Swedish Medicines Agency as part of AI@MPA toolbox.
- The scope, objectives, and key elements of any future Clinical Study data guidance should be clearly defined before drafting.
- Collaboration across the network is the key.

Action: EMA to incorporate the additional feedback from the group into the Clinical study data pilot change management strategy and its implementation.

6. AI change management strategy

Joris Wiemer (EMA) presented the change management strategy for AI, noting that many change management aspects have already been included in the NDSG workplan for AI workstream. The goal of these change management activities is to promote engagement, clarify, amplify and fill any knowledge gaps, with the main areas for 2025 identified as AI literacy and training. The key stakeholders affected by the change were discussed, highlighting that the primary responsibility for AI change management lies within individual national organisations. Areas for improvement across the network include shared

training, communication best practices, and support for champions and experts to strengthen collaboration and engagement.

The change management approach was supported by the group, noting that many activities are pre-planned in the AI workstream of the NDSG workplan, and content is already available. Ongoing communication and stakeholder engagement is essential and discussion on communication aspects will be taken offline to determine the best forum for it. Moving forward the involvement of industry via the industry group focused on AI will be important. A written consultation of the industry group focused on AI mandate will be launched shortly to NDSG for adoption.

7. A.O.B.

An overview of planned stakeholder engagement and public facing events was circulated to NDSG for information.