22 June 2026
EMA/143308/2026

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

16 June 2026, 13:00-15:00pm, MS Teams Meeting

Chair: 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.	Update on EC initiatives • BioTech Act proposal and impact on AI • Information on Apply AI strategy *Group discussion*	Vaia Apostolidou, Yiannos Tolias	For discussion	30’
3.	Update on AI guidance • Mandate for governance group to develop further AI guidance • Overview of planned guidance • Industry survey on scope of guidance on AI in Pharmacovigilance *Group discussion*	Luis Pinheiro Kristin Karlsson Julie Durand	For endorsement For discussion For discussion	25’
4.	Update on collaboration: • International activities, including FDA/EMA terminology on AI and ICH topic proposal • Publication of AI research priorities and 2025 Observatory report • IncreaseNet collaboration *Group discussion*	Luis Pinheiro	For discussion	25’

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
5.	Publication of RWE annual report incl. change management activities update *Group discussion*	Pacurariu Alexandra	For discussion	30’
6.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Georg Neuwirther (AGES, AT), Anastasia Pagida (EC), Jacobus van Wyk (EMA), Kristin Karlsson (MWP), Claus Møldrup (DKMA, DK), Aina Staisiuniene (EMA), Flora Musuamba Tshinanu (SAWP), Gabriel Westman (MPA, SE), Vaia Apostolidou (EC), Jerome De Barros (EC), Pero Ivanko (CIPH, HR), Paolo Alcini (EMA), Konstantina Boumaki (EPF), Joerg Zinserling (BfArM, DE), Harald von Aschen (BfArM, DE), Angelo Molinaro (AIFA, IT), Yiannos Tolias (EC), Rico Slingerland (CMDv), Michael Vogl (EMA), Patricia McGettigan (PRAC), Paul Lynn (EMA), Luis Pinheiro (EMA), Niklas Hedberg (HTA), Edurne Lazaro (AEMPS, ES), Julie Durand (EMA), Sandra Bertulat (BVL, DE (vet)), Christina Kyriakopoulou (EC), Katrien Oude Rengerink (CBG-MEB, NL), Anthony Oshea (EDQM), Anne-Marie van Nederkassel (EMA), Marta Slomka (Payers), Florian Klinglmueller (AGES, AT), Ivelina Gushlekova (CTCG), Ana López de la Rica Manjavacas (AEMPS, ES), Hilmar Hamann (EMA), Frank Petavy (EMA), Steven Le Meur (EMA), Alexandra Pacurariu (EMA), Stefanie Prilla (EMA), Julianna Fogd (EMA), Francisco Penaranda (EMA), Pelle Persson (MPA, SE).
Apologies:	Karl Broich (BfArM, DE), Siobhán O’Sullivan (Ethics), Eleonora Agricola (EU-IN), Aimad Torqui (MEB, NL), Vincent Gazin (ANSM, FR), Kaisa Immonen (EMA), Laure Baduel (CVMP), Christopher Javris (EDQM), Gianmario Candore (EMA), Dag Jordbru (NOMA, NO), Carla Torre (CHMP), Momir Radulovic (Jazmp, SI), Javier Martínez Arribas (Payers), Markus Kalliola (SITRA, FI), Pier Paolo Olimpieri (AIFA, IT), Kimmo Porkka (EHA), Patrice Verpillat (EMA), Alessandro Blasimme (Ethics representative), 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 draft minutes from the May NDSG meeting were circulated on 9 June 2026 and no comments have been received so far. It was agreed to extend the deadline for the final review of the May meeting minutes until 19 June 2026. In the absence of comments, the minutes would be considered adopted.

Post meeting note: No additional comments were received and the minutes from the May NDSG meeting were adopted as final.

2. Update on EC initiatives

Vaia Apostolidou (EC) and Yiannos Tolias (EC) presented an overview of the European Biotech Act legislative proposal, focusing on the AI-related provisions. Vaia Apostolidou explained that the Biotech Act legislative proposal is a central regulatory pillar for the EU life sciences strategy. The Biotech Act legislative proposal was adopted by the Commission in December 2025, with negotiations ongoing in Parliament and Council. It includes several AI-related provisions: Article 31 proposes EMA, in collaboration with the Commission, to develop guidance for AI across the medicine's lifecycle; Articles 32 and 33 focus on creating trusted AI testing environments and data quality accelerators; Article 53 addresses biosecurity; and Article 27E concerns AI in clinical trials.

Yiannos Tolias then presented the Apply AI Strategy, which seeks to move towards the effective deployment of AI, particularly through sectoral flagships. In healthcare, this includes initiatives such as AI-enabled screening centres, a European expertise network on AI deployment (including the Compass AI project), and activities supporting drug discovery and medical device development.

In addition, the group noted that EC together with the Irish presidency, will host a European AI Innovation Month in Autumn 2026 (14 October-17 November 2026). A pharma-focused sectoral dialogue is scheduled on 2 July to identify high-value AI use cases in R&D and inform policy and funding priorities.

The group noted the importance of continued monitoring of the Biotech Act and related initiatives, particularly as they progress through the legislative process and begin implementation. The group discussed the potential impact on the NDSG activities and noted that the main effect of the Biotech Act is foreseen on the development of AI guidance, which is already planned in both the NDSG and MWP workplans.

3. Update on AI guidance

Mandate for governance group to develop further AI guidance

Luis Pinheiro (EMA) presented the proposal to establish an AI guidance coordination group to ensure coherence across guidance documents and avoid duplication, inconsistencies, or gaps. The group's mandate will include to provide oversight of a guidance roadmap, support coordination between drafting groups, and ensure alignment with EU legislation and Commission initiatives. The group will report to NDSG, Scientific Coordination Board (SciCoBo), and the Commission, with the final guidance adoption remaining with the relevant scientific committees.

The NDSG discussed the need to balance scientific and legal input, carefully consider expert capacity and availability and ensure the group's role remains coordination rather than decision-making.

The NDSG also discussed the potential implications of the Digital Omnibus to the medicines regulation. **Action**: EC colleagues to prepare a synthesis based on the final adopted text of the Digital Omnibus and present to NDSG any potential implications for medicines regulation.

The NDSG noted the strategic importance and relevance of this group and endorsed the mandate and proposal to establish the AI guidance coordination group.

Overview of planned guidance

Complementary to the previous presentation, Kristin Karlsson (MPA, SE) provided a short overview of ongoing and planned AI guidance documents. The ongoing guidance development includes documents

on AI in clinical development (with an ACT EU workshop planned for early 2027), GCP Annex on computerised systems (mature draft expected late 2026), AI in pharmacovigilance (Q&A format, public consultation in Q2 2027), and GMP Annex 22 (workshop in July, publication early 2027).

The group had a follow up discussion, with the following points noted for clarification/information or action:

- The inclusion of non-clinical guidance is under discussion, with coordination needed between the relevant working parties. **Action**: Luis Pinheiro to liaise with the Non-Clinical Working Party to clarify the status and plans for AI guidance in the non-clinical domain and report back to the AI guidance coordination group.
- The scope of guidance in relation to veterinary medicines was discussed. It was agreed that the AI guidance aims to cover both human and veterinary domains by default, with specific documents or sections tailored as needed. The future roadmap developed by the AI guidance coordination group should explicitly clarify the scope of each guidance document, specifying whether it applies to human, veterinary, or both domains, due to implications for consultation and adoption processes. **Action**: Luis Pinheiro.
- The AI guidance coordination group should ensure coherence across AI-related guidance going forward, while recognising that some legacy guidance may need future rationalisation. **Action**: Luis Pinheiro to organise a dedicated discussion with relevant GMP experts around the time of the public workshop, to address alignment between GMP Annex 22 and the forthcoming general good machine learning practice guidance, to ensure coherence and avoid duplication.
- The group noted the importance of aligning guidance development with other tools and frameworks and agreed that information from the AI Observatory report, scientific advice, and the Innovation Task Force can be used to guide where future guidance is developed and what it should cover.

Industry survey on scope of guidance on AI in Pharmacovigilance

Julie Durand (EMA) presented progress on the development of AI guidance in pharmacovigilance, which is foreseen to be developed as a Q&A document to allow flexibility while experience continues to evolve.

A stakeholder survey was conducted to inform the scope, covering key topics and use cases. The responses were received from both regulators and industry, across human and veterinary domains. Early results indicated that human oversight was considered the most critical topic to address.

The feedback will be used to refine the scope of future guidance and support its drafting, with the aim of launching a public consultation in 2027.

Action: Julie Durand to report back to NDSG in collaboration with relevant NCA experts on the ongoing work by the Innovative Health Initiative (IHI) on the topic of AI-powered signal detection in pharmacovigilance.

4. Update on collaboration

Luis Pinheiro (EMA) presented general updates on other AI deliverables, including collaborations. The AI research needs document has been finalised and a preprint published, identifying priority areas for regulatory science research. The AI observatory report has also been published, providing a comprehensive overview of AI use cases, policy developments, and stakeholder engagement across the network.

International collaboration continues through bilateral work with the FDA and multilateral forums such as the International Coalition of Medicines Regulatory Authorities (ICMRA). The EMA and FDA are currently collaborating on a shared AI glossary, with about 50 terms under review and publication expected in Q4 2026.

Collaboration with IncreaseNet focuses on AI training, community building, and tool development, with proposals for supporting different user profiles and sharing AI solutions across the network.

The need to align between identified research needs and broader EU initiatives was discussed. It was agreed to have a dedicated discussion between DG Research and Innovation unit (Christina Kyriakopoulou) and EMA to review the regulatory research priorities on AI and explore mutual relevance and future collaboration, and report back to NDSG in three to four months. **Action**: Luis Pinheiro.

The group also discussed the potential for ICH guidance development on AI, noting that while proposals are emerging, progressing European guidance remains the 1st priority.

5. Publication of Real-World Evidence (RWE) annual report

Alexandra Pacurariu (EMA) presented the 4th annual report on real-world evidence activities, covering period February 2025 to February 2026. The report demonstrates continued growth in both volume and complexity of RWE studies, with a significant increase in ongoing and completed studies.

There has been a notable expansion of the DARWIN EU network, improved data quality processes, and increased analytical capabilities. Studies are addressing increasingly complex scientific and operational questions, with broader geographical coverage and more data partners involved.

In terms of impact, 30% of studies directly supported regulatory decisions, 44% contributed to scientific understanding, and 15% supported preparedness for public health needs. The results confirm the growing importance of real-world evidence in regulatory decision-making.

Participants welcomed the report and acknowledged its value in demonstrating progress and informing future priorities. Due to time constraints, it was agreed to defer the discussion on the change management activities to a future NDSG meeting.

6. A.O.B.