

29 September 2026
EMA/218256/2026

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

10 September 2026, 09:00-11:00am, MS Teams Meeting

Chair: Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
1.	Adoption of the draft agenda & minutes	Peter Arlett	For adoption	5'
2.	PMS master data - Scene setting	Isabel Chicharo	For information	10'
3.	Consultation on PMS data quality chapter	Ana Cochino	For discussion	15'
4.	PMS ROG OG update: Data qualification	Georg Neuwirther	For discussion	15'
5.	Review of new data types for evidence generation: Genomic data (v)	Jasmine Gratton, Jessica Mwinyi	For discussion	50'
6.	RWE change management activities update	Julianna Fogd, Patrice Verpillat	For discussion	15'
7.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Georg Neuwirther (AGES, AT), Angelo Molinaro (AIFA, IT), Harald von Aschen (BfArM, DE), Katrien Oude Rengerink (CBG-MEB, NL), Momir Radulovic (Jazmp, SI), Rico Slingerland (CMDv), Aimad Torqui (MEB, NL), Pelle Persson (MPA, SE), Ana Cochino (EMA), Sandra Bertulat (BVL, DE (vet)), Anne-Marie van Nederkassel (EMA), Ivelina Gushlekova (CTCG), Eleonora Agricola (EU-IN), Niklas Hedberg (HTA), Patricia McGettigan (PRAC), Anja Jeriha Zavrtanik (Jazmp, SI), Joerg Zinserling (BfArM, DE), Markus Kalliola (SITRA, FI), Jasmine Gratton (EMA), Vaia Apostolidou (EC), Flora Musuamba Tshinanu (SAWP), Vincent Gazin (ANSM, FR), Gabriel Westman (MPA, SE), Kaisa Immonen (EMA), Dag Jordbru (NOMA, NO), Gianmario Candore (EMA), Isabel Chicharo (EMA), Ana López de la Rica Manjavacas (AEMPS, ES), Laure Baduel (CVMP), Edurne Lazaro (AEMPS, ES), Konstantina Boumaki (EPF), Paolo Alcini (EMA), Jacobus van Wyk (EMA), Patrice Verpillat (EMA), Catherine Cohet (EMA), Bastian Hornung (MEB, NL), Anthony O Shea (EDQM), Stefanie Prilla (EMA), Pier Paolo Olimpieri (AIFA, IT), Frank Petavy (EMA), Julianna Fogd (EMA), Steven Le Meur (EMA), Iordana Eleftheriadou (EC), Kristin Karlsson (MWP).

	Additional participants: Jessica Mwinyi (MPA, SE), Rune Nisbeth (DKMA, DK), María Gordillo Marañón (AEMPS, ES), Olga Kholmanskikh (FAGG-AFMPS, BE), Joerg Engelbergs (PEI, DE), Viola Macolic (EMA), Aab Krööt (EE).
Apologies:	Karl Broich (BfArM, DE), Florian Klinglmueller (AGES, AT), Marta Slomka (Payers), Paul Lynn (EMA), Christopher Javris (EDQM), Javier Martínez Arribas (Payers), Anastasia Pagida (EC), Claus Møldrup (DKMA, DK), Pero Ivanko (CIPH, HR), Michael Vogl (EMA), Christina Kyriakopoulou (EC), Hilmar Hamann (EMA), Francisco Penaranda (EMA), Siobhán O’Sullivan (Ethics), Carla Torre (CHMP), Kimmo Porkka (EHA), Alessandro Blasimme (Ethics representative).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The meeting chair welcomed members to the meeting, including the new EC representative Iordana Eleftheriadou. The draft agenda was adopted. The draft minutes from the July NDSG meeting were adopted as final.

2. PMS master data - Scene setting

Isabel Chicharo (EMA) presented the multi-year Product Management Service (PMS) roadmap, which covers the Network Data Steering Group (NDSG), Regulatory Optimisation Group (ROG), and agile/IT delivery activities to establish PMS as the shared centralised repository of human medicinal product information for the network. The roadmap aims to provide a comprehensive overview of the key drivers, use cases and data, process and IT delivery activities. Key regulatory use cases include medicines shortages, new pharmaceutical legislation (e.g. electronic product information rollout and Type 1A variation simplification) and the European Health Data Space. The progress report against the 2026 NDSG work plan was noted as being largely on track, including the release of the public PMS application programming interface (API) and completion of the legacy data qualification feasibility study. The work on future network working arrangements document is ongoing and will continue into 2027.

The group discussed the upcoming activities and the need to keep PMS objectives aligned with the new pharmaceutical legislation and related implementing acts. More discussion will continue at the next NDSG meeting where EC colleagues will present the opportunities in data and digitalization from the new pharmaceutical legislation.

3. Consultation on PMS data quality chapter

Ana Cochino (EMA) presented the first draft of the PMS Data Quality Framework. The framework describes the current controls and processes in place to ensure that PMS data are fit for purpose for the network use cases and describes how these arrangements will evolve as PMS becomes the reference system for more use cases.

The group supported a fit-for-purpose and use-case-led approach to data quality and highlighted the need to clearly separate between current and future operating model, to better reflect the role and expertise of national competent authorities in the PMS related processes, and to consider the synergies between European and national use cases.

The NDSG also discussed the potential for increased use of automation and AI in product data management. It was clarified that automated checks are already implemented where feasible and that AI is being explored, with appropriate human oversight. The group also supported the inclusion in the framework of a short forward-looking statement of PMS in the framework and organising a dedicated discussion to identify suitable opportunities, safeguards and expertise for the controlled use of AI in PMS data management.

NDSG members were invited to provide comments on the first draft by 15 October 2026. Following the NDSG consultation, the received comments will be addressed before the document is submitted for endorsement at the NDSG meeting in November. Following the NDSG endorsement, the first version will be published without a separate public consultation. Feedback from stakeholders on the published framework will be sought in 2027.

Action: Ana Cochino to revise the draft framework after receiving NDSG feedback, including clearer distinction between the current and future operating states and a brief forward-looking statement on automation and AI-supported data-quality processes.

Action: NDSG secretariat to organise a dedicated discussion to identify safe AI opportunities for PMS data management in future, involving relevant network experts (e.g. MPA NDSG member).

4. PMS ROG OG update: Data qualification

Georg Neuwirth (AGES, AT) on behalf of ROG Group PMS Operational Group presented the proposed stepwise approach to the qualification of legacy national product data. This initiative aims to ensure data consistency between PMS and NCA systems.

The feasibility study has been completed and a step wise approach to data qualification has been developed. The proposed process starts with a small group of NCAs from the ROG PMS operational group to test and improve the process for a defined subset of core data elements, then expanding to all NCAs for core data elements in subset one, followed by manufacturers and packages in subset two and structured composition and other complex elements in subset three.

The approach will include guidance, knowledge-sharing support and structured communication with industry to resolve identified discrepancies. The NDSG supported the proposed approach.

The NDSG chair asked for an update on the European Health Data Space (EHDS) decisions concerning the use of product terminologies and identifiers (for primary use of health data). It was agreed to seek an update from the EC colleagues at the next meeting under matters arising.

5. Review of new data types for evidence generation: Genomic data (v)

Jasmine Gratton (EMA) and Jessica Mwinyi (MPA, SE) presented a network review of genomics as a novel data type for regulatory evidence. The review was developed with genomic experts from the network, the Methodology Working Party (MWP), the pharmacogenomics Specialised Interest Area, PRAC, veterinary experts and EMA teams.

The work highlighted the relevance of genomics throughout the medicinal product lifecycle and highlighted existing network activities, including access to genomic data through DARWIN EU,

development of the pharmacogenomics curriculum, and expert collaboration through the Methodology European Specialised Expert Community. The group noted that EMA has published a table consolidating pharmacogenomic information found in the SmPCs of centrally authorised human medicinal products, which is being updated on an annual basis. In addition, the group was made aware that the Spanish Medicines Agency is publishing similar information and offered to work together to further develop the pharmacogenomic information table. A similar resource for veterinary medicines is not currently planned.

The review identified scientific, technical, ethical, legal and operational challenges, including data volume, standardisation, reproducibility, clinical interpretation, interoperability and the potentially identifiable nature of genomic information.

The main short-term consideration is to establish a clearer approach for identifying and using existing genomic expertise for assessments and scientific advice.

Additional considerations include: explore opportunities to better encode useable genomic information in individual case safety reports (ICSRs) for PhV purposes, increase access to genomic data and linkage to EHR for studies supporting medicines regulation (e.g. landscape analysis of genomic data sources in Europe), explore the integration of (gen)omic data within clinical drug development (e.g. monitor progress and outputs from BioCompute with FDA & PHUSE working group), investigate a potential gap in network guidance (e.g. on RNA and epigenetic sequencing, somatic variants, and ctDNA), foster standardisation of PGx information in SmPC and highlight PGx in PSUR, and continued development of training. Several regulatory science research needs were also identified.

The NDSG group welcomed the review and supported validation of these considerations with the Methodology Working Party and the pharmacogenomics Specialised Interest Area. It was noted that relevant experts should be connected through the existing expert community (Methodology ESEC) rather than through parallel structures. The discussion also highlighted that both improved identification of existing expertise and, in certain areas, further capacity development may be required. The group was reminded that there are publicly available AI tools within the network that could be used for information processing.

Action: The drafting group to validate the considerations with the MWP and the pharmacogenomics Specialised Interest Area, prioritise a limited number of actions, and return to the NDSG before the end of 2026 for possible inclusion in future work plans.

Action: Jasmine Gratton (EMA) to explore collaboration with Ana López de la Rica about the AEMPS table on pharmacogenomic information, and to contact Paul Lynn (EMA) about the feasibility of extending the approach to veterinary medicines.

6. RWE change management activities update

Julianna Fogd (EMA) and Patrice Verpillat (EMA) provided an update on the communication activities to increase awareness and capability of real-world evidence, including visual study abstracts in accessible language, thematic web content, social media, podcasts and regular network updates. The group noted that training delivery continues through the Real-World Evidence Academy and related learning resources, while engagement is being strengthened with scientific committees, assessors, patients, healthcare professionals, health technology assessment bodies and other stakeholders.

The NDSG noted that progress to date had established a strong supply of real-world evidence through network partnerships and DARWIN EU. The next priority is to embed real-world evidence more consistently in regulatory processes and decision-making throughout the medicinal product lifecycle. A

strategic workshop on real-world evidence, National Competent Authorities and the EHDS is being prepared for the first quarter of 2027.

Action: EMA to provide an update on preparations for the 2027 real-world evidence workshop at a future NDSG meeting.

7. A.O.B.

No additional items were raised. The next NDSG meeting will take place online on 15 October 2026. Invitations for the November face-to-face NDSG meeting and the subsequent public workshop will be circulated the week of 14th September 2026.