21 October 2026
EMA/236006/2026

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

15 October 2026, 15:00-17:00pm, 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.	New pharmaceutical legislation: opportunities on data -20’ *Group discussion – 20’*	Vaia Apostolidou, Lilia Luchianov	For discussion	40’

3.	Annex II high-level principles on data, digitalisation and AI
	• AI – 10’
	  ○ Luis Pinheiro (EMA)
	• Raw data (non-clinical, clinical, RWD, Quality) – 10’
	  ○ Christian Gartner (AGES)
	• eSubmission/eCTD – 10’
	  ○ Kristiina Puusaari (EMA)
	• PMS Master data – 5’
	  ○ Georg Neuwirther (AGES)
	
	Group discussion on feedback on principles and gaps - 20’
		Discussants:
		• Georg Neuwirther
		• Ana López de la Rica Manjavacas
		• Karlsson Kristin
		• Persson Pelle
		• Oude Rengerink Katrien
		• Peter van Meer, MEB (Non-clinical/Raw data/3Rs)
		• Rui Pedro da Costa Vilar, PT
		• Andrzej Czesławski, PL
			For discussion	55’

4.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Georg Neuwirther (AGES, AT), Flora Musuamba Tshinanu (SAWP), Edurne Lazaro (AEMPS, ES), Harald von Aschen (BfArM, DE), Carla Torre (CHMP), Katrien Oude Rengerink (CBG-MEB, NL), Vaia Apostolidou (EC), Joerg Zinserling (BfArM, DE), Claus Møldrup (DKMA, DK), Anne-Marie van Nederkassel (EMA), Siobhán O’Sullivan (Ethics), Paul Lynn (EMA), Gabriel

	Westman (MPA, SE), Kristin Karlsson (MWP), Rico Slingerland (CMDv), Momir Radulovic (Jazmp, SI), Ivelina Gushlekova (CTCG), Laure Baduel (CVMP), Konstantina Boumaki (EPF), Dag Jordbru (NOMA, NO), Kaisa Immonen (EMA), Pelle Persson (MPA, SE), Patricia McGettigan (PRAC), Francisco Penaranda (EMA), Stefanie Prilla (EMA), Luis Pinheiro (EMA), Gianmario Candore (EMA), Vincent Gazin (ANSM, FR), Christina Kyriakopoulou (EC), Pero Ivanko (CIPH, HR), Paolo Alcini (EMA), Sandra Bertulat (BVL, DE (vet)). Additional participants: Kristiina Puusaari (EMA), Lilia Luchianov (EC), Christian Gartner (AGES, AT), Martin Thomas (EMA), Klara Tiitso (EMA), Lorenzo De Angelis (EMA), Eftychia-Eirini Psarelli (EMA), Elizabeth Scanlan (EMA), Angeliki Loulo (EMA), Rui Vilar (Infarmed, PT), Christelle Bouygues (EMA).
Apologies:	Angelo Molinaro (AIFA, IT), Eleonora Agricola (EU-IN), Niklas Hedberg (HTA), Aimad Torqui (MEB, NL), Anja Jeriha Zavrtanik (Jazmp, SI), Markus Kalliola (SITRA, FI), Ana López de la Rica Manjavacas (AEMPS, ES), Patrice Verpillat (EMA), Anthony Oshea (EDQM), Pier Paolo Olimpieri (AIFA, IT), Iordana Eleftheriadou (EC), Karl Broich (BfArM, DE), Florian Klinglmueller (AGES, AT), Marta Slomka (Payers), Christopher Javris (EDQM), Javier Martínez Arribas (Payers), Anastasia Pagida (EC), Michael Vogl (EMA), Hilmar Hamann (EMA), 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 and adopted the draft agenda. The consultation period to adopt the draft minutes from the September NDSG meeting was extended until 23 October 2026. In the absence of substantial comments, the minutes will be adopted and published thereafter.

2. New pharmaceutical legislation: opportunities on data

Lilia Luchianov (EC) and Vaia Apostolidou (EC) presented the main data and digitalisation opportunities arising from the new pharmaceutical legislation, noting that the legislative text is not yet final.

The new pharmaceutical legislation provides a unique opportunity to create a more integrated regulatory framework, connecting medicines and related initiatives with broader developments such as the Critical Medicines Act, Biotech Act, Medical Device Regulation revision, European Health Data Space and AI Act.

The revision provides a legal basis for electronic-by-default regulatory procedures, submission and possible regulatory use of raw data, wider use of health data and real-world evidence, trusted algorithms, EU-wide databases, electronic product information and better data exchange between authorities. The product master data (PMS) and data quality were highlighted as critical for database-driven regulatory procedures and reuse of information across EU and national systems. The strategic objective of the new pharmaceutical legislation is to submit information once, reuse it across EU and national systems, make regulator-led evidence routine, and use AI with human oversight and verifiable results.

Vaia Apostolidou (EC) linked the new legislation provisions to existing work already initiated under the NDSG: the clinical-study-data pilot, the SEND non-clinical proof of concept, DARWIN EU, and PMS, ESMP, and several AI tools are already available across the Network.

It was noted that the formal legislation adoption and entry into force were expected in late 2026, with general application from the fourth quarter of 2028 and some provisions earlier. The group was invited to contribute to the development of Annex II, the delegated act on variations, the implementing act on electronic transmissions and the implementing act on electronic product information, building on existing systems such as PMS, European Shortages Monitoring Platform and Clinical Trials Information System.

The group had a follow up discussion on some technical aspects on the new pharmaceutical legislation, e.g. how regulators may use real-world and other data that applicants submit for regulatory decision making, including for nationally authorised products (NAPs), how applicants can be influenced to initiate product-information changes, if needed, and the submission of registry data used as an external control in rare-disease studied.

The implementation of the new pharmaceutical legislation is in preparation, a key vehicle supporting the preparation is the drafting of concept papers that will capture and address these technical aspects that are still being worked on at the moment. The group noted t will be important that the scope of the concept papers covers also Nationally authorised products.

Additionally, NDSG members were informed that support for NCAs' digital readiness for NPL implementation will continue through dedicated projects, funded by EC.

3. Annex II high-level principles on data, digitalisation and AI

The group was presented with the draft high-level principles for the revision of Annex II. The revised Annex II will set future-proof, high-level principles for marketing authorisation application requirements, including data, digitalisation and AI, with more detailed technical requirements to be addressed via specific guidance. The review is ongoing in the drafting groups with experts from the network.

Artificial Intelligence (AI)

Luis Pinheiro (EMA) presented the draft high-level AI principles for Annex II. The discussion highlighted the following points:

- To reflect on using the term 'design space', as this may imply that machine-learning outputs are designed rather than are learning. It was suggested to consider using the term 'safe learning space,' which would focus on model behavior and safety metrics.
- To reflect on the need to include some text on the technological sovereignty for AI systems.
- To reflect on the need to include some text on the requirements for AI systems to remain safe and fit for their intended purpose, as their behaviour might changes with learning, context, and deployment.
- The group noted the need to bridge high-level principles with practical guidance.

Action: Luis Pinheiro to organise a dedicated discussion with relevant Annex II drafting group members and Siobhan O'Sullivan on the AI principles and ethical considerations.

Raw Data

Christian Gartner (AGES, AT) presented the draft raw data submission principles for Annex II, covering clinical studies, clinical trials, real-world or observational studies, and quality, manufacturing, and controls data. The discussion highlighted the following points:

- A wider implementation vision is needed to ensure network preparedness, build assessor capabilities and enable the practical use of raw data; these aspects should be addressed in the raw-data concept paper.
- To consider adding some text to clarify the authoritative "source of truth" where structured data and document versions differ.
- Challenges were identified for real-world data held by third parties, including legal or governance restrictions on transfer and the use of data, secure processing environments under the European Health Data Space. The group recommended to follow a pragmatic and relatively high-level approach for real-world data needs in Annex II, while maintaining clearer expectations for clinical trial data.

Electronic submissions/eCTD

Kristiina Puusaari (EMA) presented the draft principles covering eCTD-based applications for Annex II. The discussion highlighted the following points:

- Direct updates to central systems such as PMS may result in parts of the eCTD dossier no longer reflecting the latest approved product information. Therefore, the drafting group should further consider the relationship between eCTD and central structured-data systems, including how discrepancies and legal precedence should be addressed.
- It was noted that most current submissions remain electronic documents or PDFs and that structured-data submissions are still a very small proportion, and the main missing step is the adoption of implementation guides specifying the required formats.

Master data and general data principles

Georg Neuwirther (AGES, AT) presented the high-level data principles for Annex II.

The NDSG welcomed the proposals from the drafting groups and noted that a mature draft is expected by the end of 2026, followed by consultation of committees, working parties and the wider network in early 2027. The NDSG will be kept informed on progress and with the latest version of the high-level principles for Annex II on data and AI. The EC colleagues highlighted the usefulness of such early discussion for mapping the relationship between delegated and implementing acts.

Action: The Annex II drafting team on data and AI principles should discuss and consider NDSG feedback to update the draft principles. NDSG should be kept informed on progress and with the latest version of the high-level principles for Annex II on data and AI.

4. A.O.B.

No additional items were raised. The next NDSG meeting will take place face-to-face on 11 November 2026, followed by the Data and AI workshop on 12–13 November 2026.