

HMA/EMA AI and Data Forum 2026: Build trustworthy AI on strong data foundations

12 and 13 November 2026

In-person at the EMA building, Amsterdam, meeting room 1C + virtual enabled

Join us to shape the future of data-driven medicines regulation – Your voice matters

The European Medicines Regulatory Network (The Network) is strengthening its use of data and AI, to support innovation, enable more efficient regulatory processes, and reach better decisions for public and animal health.

Data and AI are increasingly interdependent: good data provide the foundation for scalable, trustworthy AI which, in turn, can unlock greater value from data.

Building on previous events, this workshop - coordinated by the Network Data Steering Group (NDSG) in collaboration with the CHMP Methodology Working Party and the ACT EU initiative - brings together regulators and stakeholders to share progress, exchange insights, and shape the future of data and AI in medicines development and regulation.

The workshop aims to:

- Showcase state-of-the-art AI and data applications across the medicines' lifecycle,
- Discuss the evolving EU regulatory landscape for data and AI,
- Hear from stakeholders on data foundations, governance, quality, and interoperability across the Network,
- Strengthen stakeholder collaboration to accelerate the adoption of trustworthy AI,
- Input to the NDSG workplan in alignment with the Network Strategy to 2028.

Join us in person in the EMA building or online to shape the future of data-driven medicines regulation across the human and veterinary domains.

HMA/EMA multistakeholder AI and Data Forum 2026

Day 1 – 12 November 2026

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) and Peter Arlett (EMA, NDSG co-chair)

08:30 Joining and technical checks

09:00 Welcome and introduction

Peter Arlett (EMA, NDSG co-chair) 5'

09:05 Opening remarks and Keynote

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) and Peter Arlett (EMA, NDSG co-chair)

Emer Cooke 5'
EMA Executive Director

Karl Broich 5'
BfArM, HMA, NDSG co-chair

European Commission 5'
Speaker TBC

9:25 Opening keynote

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) and Peter Arlett (EMA, NDSG co-chair)

Patient perspective: Konstantina Boumaki (NDSG, EPF) 20'

9:55 Session 1: Data governance and accessibility as foundations

Chairs: Ana Lopez de la Rica (NDSG, CMDh) and Trygve Ottersen (NOMA)

In an increasingly data-driven regulatory landscape, trusted regulatory decisions depend on trusted data that can be found, understood, accessed, and appropriately governed. This session will explore how data governance and findability/accessibility enable regulatory collaboration, support trustworthy evidence-based regulatory decision-making and foster the responsible use of AI.

Data flows to data flaws: why AI governance needs data governance? 10'
Alexandre Templier (Independent expert, founder & chair EURAICA)

Open questions and answers from registered participants 10'

Findable and accessible data: the foundation for analytics and AI 10'
Markus Kalliola (TEHDAS2, SITRA, NDSG)

Front row comments 30'

11:10 Networking coffee break

11:40 Session 2: Interoperable and high-quality data as foundations

Chairs: Runa Hauksdottir Hvannberg (IMA IS, ROG PMS OG) and Isabel Chicharo (EMA)

Building strong data foundations requires more than governance - it requires high-quality, standardised, and interoperable data. This session will explore how master data, data quality, and data standards enable seamless data exchange across the European Medicines Regulatory Network (EMRN), strengthen evidence generation and analytics, and accelerate the adoption of analytics and AI.

Data standards and semantic interoperability: enabling regulatory collaboration, evidence generation and AI 10'
Quentin Darrasse (Roche, EFPIA)

Open questions and answers from registered participants 10'

Master data and data quality: the foundations of trusted regulatory data 10'
Aimad Torqui (CBG-MEB, NDSG, ROG)

Front row comments 30'

12:55 Event photo

13:00 Networking lunch break

13:55 Keynote

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) and Peter Arlett (EMA, NDSG co-chair)

AI perspective 20'

14:25 Session 3: Navigating AI in medicines regulation: regulation, guidance and regulatory engagement

Chairs: Kit Roes (Radboudumc, MWP) and Alexis Nolte (EMA)

This session provides a high-level overview on the evolving AI regulatory landscape and how the EMRN is addressing guidance development as well as practical pathways for engagement with regulators. Rather than a deep dive into specific technical or legal topics, the session aims to offer transparency, predictability and insight into ongoing activities across the network.

The evolving regulatory landscape for AI and Pharma	15'
Isabelle Clamou (EC)	
AI guidance development: current status and outlook	15'
Joerg Zinserling (BfArM, SAWP, MWP)	
Regulatory interaction pathways on AI in the medicines' lifecycle	15'
Speaker TBC	
Open questions and answers from registered participants	15'
General discussion	25'

15:55 **Networking coffee break**

16:25 **Session 4: AI in clinical trials: practical applications and future guidance needs**

Chairs: Aurora María Rojo Sanchís (AEMPS) and Günther Waxenecker (AGES)

This session will examine three or four use cases of AI in clinical trials, selected from the call for abstracts to industry and Academia, privileging use cases that are being developed or used in real-life, and those that illustrate or describe how validation of the model(s) was performed. The selected use cases will be used to steer guidance development ahead of a dedicated workshop on AI in Clinical Trials.

AI use cases in clinical trials 30'

Endpoint assessment:

- Use of AI for image analysis and DEXA body scans - Jeppe Manuel (Novo Nordisk, EFPIA)
- Use of AI in epilepsy prevention and a new model for early treatment - Dr Marek Migdał (IPCZD, EPISTOP project)

Trial management:

- AI-enhanced trial management platform - Dr Rafał Bartczuk (IPCZD, EPISTOP project)

Clinical trial simulation / prediction:

- Predictive model for trial success to inform study design and protocol development - Vidya Perera (Bayer, EFPIA)

Use of synthetic control arms / digital twins:

- Foundation-Model Digital Twins as Synthetic Control Arms: Reducing Control-Arm Size in Clinical Trials While Preserving Regulatory-Grade Evidence - Raja Shankar (IQVIA, ACRO)

Patient identification, recruitment and selection (enrichment):

- Federated AI-Assisted Molecular Diagnosis and Patient Stratification in Paediatric Clinical Trials – Donato Bonifazi and Daniel Weiss (TEDDY)
- AI-assisted patient identification and trial enrichment: identifying high-risk patients to reduce the number of patients needed or study duration required to meet clinical trial endpoints - Dr Giovanni Montesano (EU EYE)

Network perspective 15'

Gabriel Westman (CHMP/MWP, MPA, NDSG member)

Open questions and answers from registered participants	15'
General discussion	25'

17:55 Closing Day 1

Wrap-up & next day overview	5'
Karl Broich (BfArM, HMA, NDSG co-chair), Peter Arlett (EMA, NDSG co-chair)	

18:00 End of Day 1

Day 2 – 13 November 2026

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) and Peter Arlett (EMA, NDSG co-chair)

08:30 Joining and technical checks

09:00 Welcome to Day 2

Karl Broich (BfArM, HMA, NDSG co-chair)

5'

09:05 Keynote – 30'

Chair: Helena Panayiotopoulou (CY MOH, EMA MB)

'Mega trends' that will impact medicines regulation

20'

Magdalena Pajewska (URPL)

9:35 Session 5: Trustworthy AI in action: regulatory readiness, guidance development and research

Chairs: Tobias Fellingner (MWP) and Evdokia Korakianiti (EMA)

The session focuses on trust building, through sharing a high-level overview of how the network is implementing AI, how it engages with stakeholders in guidance development and learns from it, and how research and evidence generation activities contribute to transparency and achieving common goals for the benefit of patients.

Use of AI in regulatory operations: an overview of network initiatives

10'

Joaquim Berenguer Jornet (EMA)

Learnings for guidance development from GMP workshop

10'

Alison Dawson (Eli Lilly, EFPIA)

Advancing AI through research: Research Collaborations and Priorities

10'

Liese Barbier (EMA)

Open questions and answers from registered participants

10'

General discussion

15'

10:35 Networking coffee break

11:00 Session 6: The future of medicines regulation: reimagining regulatory work in the age of data and AI

Chairs: Grainne Power (HPRA) and Frank Foures (EMA)

Digitalisation, novel data sources, evolving legislation, and AI are reshaping the regulatory landscape. This session will examine how these developments can transform medicines regulation and the drug development lifecycle, improving efficiency, enabling new ways of working, and supporting better regulatory decisions. Together with stakeholders, we will identify practical priorities, enablers, and next steps to build a future-ready regulatory system that delivers greater value for patients

Introductory statement by session co-chairs 10'

Reimagining medicines regulation in the age of data and AI 30'

EMRN perspective (H): Speaker TBC

EMRN perspective (V): Rico Slingerland (MEB)

Patient perspective: Gregorio Sambataro (European Heart Network)

Industry perspective (H): Yves Jacob (Sanofi, Vaccines Europe)

Industry perspective (V): Charles Bagarie (Boehringer Ingelheim - Animal Health)

Comments from session/event co-chairs and live audience 20'

Discussion: Identifying the common priorities that drive the change 40'

12:40 Closing Day 2

Wrap-up 5'

Karl Broich (BfArM, HMA, NDSG co-chair), Peter Arlett (EMA, NDSG co-chair)

12:45 End of the event
