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 TBC + virtual enabled

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

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

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

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’

9:25 Opening keynote

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

Patient perspective 20’

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

Chairs: TBC

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.

From data governance to AI governance: what changes and what stays the same? 10’
Speaker TBC

Open questions and answers from registered participants 10’

Findable and accessible data: the foundation for regulatory analytics and AI 10’
Speaker TBC

Front row comments 30’

11:10 Networking coffee break

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

Chairs: TBC

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 create 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’
Speaker TBC

Open questions and answers from registered participants 10’

Master data and data quality: the foundations of trusted regulatory data 10’
Speaker TBC

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: TBC

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'
European commission

AI guidance development: current status and outlook 15'
Speaker TBC

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: TBC

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 30'
Speaker TBC

Network perspective 15'
Speaker TBC

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’

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

Data and AI perspective 20’

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

Chairs: TBC

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’
Speaker TBC

Learnings for guidance development from GMP workshop 10’
Speaker TBC

Building Trustworthy AI: Research Collaborations and Priorities 10’
Speaker TBC

Open questions and answers from registered participants 10’

General discussion 15’

10:35 Session 6: The future of medicines regulation: reimagining regulatory work in the age of data and AI

Chairs: TBC

The EMRN is undergoing a profound transformation, driven by digitalisation, novel data sources for evidence generation, evolving legislation and rapidly advancing AI capabilities. This session will explore how these developments can reshape regulatory practice, simplify processes, enable new ways of working, and strengthen regulatory decision-making to deliver greater value for patients. The discussion will take a forward-looking

perspective, focusing on the transformation of medicines regulation and drug development life cycle rather than on technology itself.

Reimagining medicines regulation in the age of data and AI 30’
Speaker TBC

General discussion 20’

11:30 Networking coffee break

12:00 Session 6 continuation: Translating shared priorities into actionable initiatives on Data and AI

Chairs: TBC

This session will focus on translating stakeholder priorities into practical actions, identifying key initiatives, enablers, and next steps required to turn the vision for a future-ready regulatory system into reality.

NDSG workplan Data & AI: highlights from 2026 and looking forward 10’
Speaker TBC

Discussion with selected panellists representing key EMRN stakeholders and partners on Data and AI workplan delivery 60’
Speaker TBC

13:15 Closing Day 2

Wrap-up 5’
Karl Broich (BfArM, HMA, NDSG co-chair), Peter Arlett (EMA, NDSG co-chair)

13:20 End of the event