HMA/EMA Annual Data Forum 2025

9 December 2025 (09:00 – 17:30 CET)

In-person at the EMA building, Amsterdam + virtual enabled

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

The European medicines regulatory network continues to advance its efforts to harness the power of regulatory and health data, to drive innovation, support evidence-based decision-making, and ultimately benefit public and animal health.

Building on the last five years of progress under the Big Data Steering Group, this annual forum – now coordinated by the Network Data Steering Group – offers an opportunity to engage with regulators and stakeholders from across Europe and share progress and insights to co-create the future of data use in medicines regulation.

This year's forum will aim to:

- strengthen collaboration by enabling stakeholders and partners to share their views, priorities and needs to inform the update of the HMA-EMA Network Data Steering Group workplan, aligned with the data-related activities of the Network Strategy to 2028;
- showcase progress in evidence generation, data interoperability, and the use and exchange of data across the EU network;

- foster dialogue through inspirational keynote speakers and discussion.

Help shape the future.

Join us in person to guide the next chapter of data-driven medicines regulation, engage and connect with EU regulators, industry leaders, innovators, patients and data enthusiasts.

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09:00 Joining and technical checks

09:30 Welcome and introduction

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

09:35 Opening remarks

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

The forum will be opened by a Heads of Medicines Agencies (HMA) lead on data related activities of the European Medicines Agencies Network Strategy to 2028. A keynote speech will ground the event in what truly matter - impacting the lives of patients – and explore the transformative convergence of data in healthcare and medicines regulation.

Karl Broich 5'
President of BfArM, DE, NDSG co-chair, HMA management group

Keynote: Data Renaissance, a new era for medicines and health data 20'
Speaker: Mencía de Lemus Belmonte, CAT member

10:00 Session 1: Transformation to data-driven regulatory system, from plan to practice

Chairs: Konstantina Boumaki (EPF, NDSG member) and Melanie Carr (EMA)

The European medicines regulatory network is strengthening its efforts to harness the power of regulatory and health data. Guided by the Network Data Steering Group 2025-2028 workplan, this session will highlight key progress in delivering actions that drive innovation and support evidence-based decision-making

Progress for a data-driven regulatory system: NDSG workplan highlights from 2025 and looking forward 10'
Karl Broich (BfArM HMA, NDSG co-chair)

Fireside chat with stakeholders' representatives 30'
From plan to practice: experience, learnings and priorities of stakeholders for the future

Open questions and answers from registered participants 15'

11:00 Networking coffee break

11:30 Session 2: Opportunities in Data, Policy, and Ethics

Chairs: Karl Broich (BfArM, HMA, NDSG co-chair) - Markus Kalliola (Sitra, NDSG member)

This session explores opportunities of upcoming European legislations for faster and better access to medicines. The session also reflects on the ethical foundations needed to guide innovation and use of data responsibly. Together, it aims to highlight how policy and ethics can shape a trusted, data-driven future for health.

How new EU legislations will transform medicines regulation 15'
European Commission

The Ethics of Data in a Digital Age 15'
Siobhán O'Sullivan - Royal Irish Academy, NDSG member

Fireside chat with stakeholders' representatives 20'
Stakeholders' preparations to exploit these new opportunities

Open questions and answers from registered participants 20

12:45 Event photo

13:00 Networking lunch break

14:00 Session 3: Building a connected medicines data ecosystem

Chairs: HMA (TBC) and Hilmar Hamann (EMA)

This session will discuss the first data strategy for the EU medicines regulation, a major step accelerating EU regulatory agencies use of data for impactful decisions and improved patient and animal health. This session will also explore the use of Medicinal product master data as one of the key pillar to enable data to drive better regulation.

The EMRN data strategy 15'
Speaker TBC

Medicinal product master data as the backbone of regulatory innovation 15'
Aimad Torqui (MEB NL, NDSG member, ROG member)

Open questions and answers from registered participants 15'

15:00 Networking coffee break

15:30 Session 4: Evidence generation for regulatory decision-making, what if we're only just beginning?

Chairs: Kristin Karlsson (MWP co-chair, MPA) and Steffen Thirstrup (EMA)

This session will challenge the audience to think beyond current frameworks. It will explore how innovative/advanced methods and new types of data could change medicines regulation and regulatory decision-making.

Setting the scene 10'
Session co-chairs

Future trends for evidence generation 40’
A series of 5 minutes pitches to explore how innovative/advanced methods and new types of data could change medicines regulation and regulatory decision-making.

Session co-chairs comments 10’

Open questions and answers from registered participants 15’

17:00 Closing keynote

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

Late-breaking keynote 15’

17:15 Closing remark

Wrap up 15’
Karl Broich (BfArM, NDSG co-chair, HMA), Peter Arlett (EMA, NDSG co-chair)

17:30 End of the forum