# HMA/EMA Annual Data Forum 2025

**9 December 2025 (09:00 – 17:30 CET)**

In-person at the EMA building, Amsterdam, meeting room 2C + 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.

# HMA/EMA Annual Data Forum 2025

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

## 09:00 Joining and technical checks

## 09:30 Welcome and introduction

Peter Arlett (EMA, NDSG co-chair) 5’

## 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.

**Emer Cooke** 5’

EMA executive director

**Keynote: From Insight to Evidence: Strengthening the role of patient data in regulatory decision-making** 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

- Regulator: Joerg Zinserling (BfArM, NDSG member)
- Industry: Álmath Spooner, Abbvie, EFPIA
- Healthcare professional: Sakalis Vasileios (EMA HCP WP, EAU UroEvidenceHub)
- HTA: Niklas Hedberg (TLV, NDSG member)
- Veterinary representative: Rico Slingerland (CMDv, MEB, NDSG member)
- Academia: Ricard Josep Martinez (University of Valencia)

**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) and Markus Kalliola (Sitra, NDSG member)

This session will explore opportunities of upcoming European legislations for faster and better access to medicines. It will also reflect 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'

Vaia Apostolidou (DG SANTE D1, NDSG), Jerome De Barros (DG SANTE C1, NDSG)

**The Ethics of Data in a Digital Age** 15'

Alessandro Blasimme (ETH Zürich University, NDSG member)

**Fireside chat with stakeholders' representatives** 20'

Stakeholders' preparations to exploit these new opportunities

- Regulator: Eleonora Agricola (AIFA, NDSG member)
- Industry: Melpomeni Styliadou (Takeda, EUCOPE)
- Health Data Access Bodies representative: Pero Ivanko (HZJZ, HR, NDSG member)
- Patient: Merel Hennink (Cancer Patients Europe CPE)
- Payers: Marta Słomka (AOTMIT, NDSG member)

**Open questions and answers from registered participants** 15'


## 12:45 Event photo

## 13:00 Networking lunch break

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

Chairs: Karin Gröndahl (HMA, MPA, ROG member) 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. It will also explore the use of Medicinal product master data as one of the key pillars to enable data to drive better regulation.

**The EMRN data strategy** 15'
Georg Neuwirther (AGES, NDSG member)


**Medicines master data for smarter regulation** 15'
Aimad Torqui (MEB, 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, NDSG member) 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.

- Patient generated data: François Houyez (EURORDIS)
- Innovative clinical trial design: Katrien Oude Rengerink (MEB, NDSG member)
- Organoids /digital twins and Synthetic data: Janaki Raman Rangarajan (Virtual physiological human Institute)
- AI used in the (clinical) dossier: Use of AI in in clinical trials and real-world evidence: Enkeleida Nikai (Sanofi, EUCOPE)
- Digitalised clinical outcomes (biomarker data) and Behavioural and lifestyle data (data from fitness trackers, nutrition apps, and digital therapeutics), Mobile health data: Ebony Dashiell-Aje (BioMarin, Europa Bio)

- Personalised medicines data, including Omics (Genomic, proteomic, metabolomic data): Munir Pirmohamed (University of Liverpool, MHRA)
- Modelling & Simulation: Flora Musuamba Tshinanu (AFMPS - FAGG, NDSG member)

Stakeholders' vote: Which innovative methods or new data types do you believe hold the greatest potential to strengthen future regulatory decision-making on medicines? 10'


**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)

**Healthcare beyond human capabilities** 15'
Ignacio H. Medrano (Savana)

## 17:15 Closing remark

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

## 17:30 End of the forum