1st EMA/HMA Multi-Stakeholder Forum on EudraVigilance and Signal Detection

5 November 2025 (09:00 – 17:00 CET)

The Forum's main objectives are to inform stakeholders on ongoing and forthcoming developments in international guidance, adverse drug reaction case processing, signal management and data analysis in EudraVigilance, and to foster stakeholder engagement and collaboration to further strengthen these areas.

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09:00 **Joining and technical verifications**

09:05 **Welcome**

Peter Arlett (EMA) 5'
EMA, Head of Data Analytics and Methods Task Force

09:10 **Opening remarks**

Alexis Nolte (EMA) 10'
EMA, Head of Human Medicines Division

09:20 **Session 1: Updates to EU legislation, guidance and international standards**

Chair: Anja van Haren (CBG-MEB, NL)

New Commission Implementing Regulation (EU) No 520/2012 and update of GVP Module IX 25'
Georgy Genov, Eleni Savvaidou (EMA)

ICH E2D and E2B 20'
Gilles Touraille and Tom Paternoster-Howe (EMA), Anja van Haren (CBG-MEB, NL)

ADR data quality framework 25'
Tom Paternoster-Howe (EMA)

10:30 **Coffee break**

11:00 **Session 2: Signal management**

Chair: Liana Martirosyan (CBG-MEB, NL)

Industry perspective on signal management 30'
Raphael Van Eemeren (EFPIA), Jelena Zanetic and Amit Kubavat (Medicines for Europe)

Best practice for signal assessment 30'
Bianca Mulder (CBG-MEB, NL)

12:00 Lunch break

13:15 Session 3: EudraVigilance data quality and medical literature

Chair: Paolo Alcini (EMA)

Automated compliance monitoring 25'
Richeal Nic An Rí (EMA)

Pharmacovigilance inspections - common findings and use of EV data 30'
Eva-Maria Jahn (PEI, DE)

Achievements and impact of the MLM service – a retrospective review of the first 10 years 30'
Tom Paternoster-Howe (EMA)

14:40 Coffee break

15:00 Session 4: New perspectives on data analysis

Chair: Georgy Genov (EMA)

SMART methods methodologies 25'
Cosimo Zaccaria (EMA)

Artificial intelligence in pharmacovigilance 45'

- Industry perspective
  Claudia Lehmann (EFPIA), Attila Oláh (Medicines for Europe)
- CIOMS on use of AI in pharmacovigilance
  Julie Durand (EMA)

16:10 Session 5: Looking at the future

Chair: Paolo Alcini (EMA)

Medicinal product reporting / ISO IDMP 25'
Ana Cochino (EMA) and Anja van Haren (CBG-MEB, NL)

Updates on EudraVigilance 15'
João Caetano (EMA)

16:50 Conclusion and closing remarks

Wrap up 10’
Georgy Genov (EMA)

17:00 End of the Forum