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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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HMA/EMA multistakeholder AI and Data Forum 2026

Day 1 – 12 November 2026

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

08:30 Joining and technical checks

09:00 Welcome and introduction

Peter Arlett (EMA, NDSG) 5’

09:05 Opening remarks

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

Emer Cooke 5’
EMA Executive Director

Karl Broich 5’
BfArM, HMA, NDSG

09:25 Keynote

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

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

09:55 Session 1: Data governance and accessibility as foundations

Chairs: Ana Lopez de la Rica (AEMPS, CMDh, NDSG) 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

Chair: Peter Arlett (EMA, NDSG)

AI perspective: Catelijne Muller (President of ALLAI, EU expert) 20’

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

Chairs: Kit Roes (Radboudumc, MWP) and Pavel Balabanov (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, NDSG)

AI in the medicine's lifecycle: finding the right regulatory pathway 15'

Falk Ehmann (EMA)

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, organised under the umbrella of the ACT EU initiative.

AI use cases in clinical trials 40'

Patient identification, recruitment and selection (enrichment):

- Federated AI-assisted molecular diagnosis and patient stratification in paediatric clinical trials – Donato Bonifazi and Daniel Weiss (TEDDY)
- Visual field endpoints for neuroprotective trials: a case for AI driven patient enrichment - Dr Giovanni Montesano (EU EYE)

Clinical trial simulation / prediction:

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

Trial management:

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

Endpoint assessment:

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

Network perspective 15'

Gabriel Westman (MPA, CHMP/MWP, NDSG)

Open questions and answers from registered participants 15'

	General discussion	25’

18:05 Closing Day 1

	Wrap-up & next day overview Peter Arlett (EMA, NDSG)	5’

18:10 End of Day 1

Day 2 – 13 November 2026

Chair: Peter Arlett (EMA, NDSG)

08:30 Joining and technical checks

09:00 Welcome to Day 2

Peter Arlett (EMA, NDSG) 5’

09:05 Keynote

Chair: Helena Panayiotopoulou (CY MOH, EMA MB)

‘Mega trends’ that will impact medicines regulation 20’
Magdalena Pajewska (URPL)

09:35 Session 5: Trustworthy AI in action: regulatory readiness, guidance development and research

Chairs: Tobias Fellinger (MWP) and Marcel Hoefnagel (CBG-MEB)

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)

AI@MPA user survey – insight into use cases, experience, and trust in AI for medicines regulation 10’
Rebecka Isaksson (MPA)

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’

10:45 Spotlight talk

Chair: Peter Arlett (EMA, NDSG)

Marco Marsella 10’
European Commission, Acting Deputy Director General for Health, Director for DG SANTE.C

11:00 Networking coffee break

11:20 Session 6: The future of medicines regulation: reimagining regulatory work in the age of data and AI

Chairs: Grainne Power (HPRA) and Franck 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): Jesper Kjaer (EMA)
EMRN perspective (V): Rico Slingerland (MEB, NDSG)
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’

13:00 Closing Day 2

Wrap-up 5’
Peter Arlett (EMA, NDSG)

13:05 End of the event

Day 1

Opening session



Emer Cooke

Executive Director of the European Medicines Agency

Emer Cooke has been the Executive Director of the European Medicines Agency, based in Amsterdam, since November 2020. She served as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for five years, from the beginning of her EMA mandate until the end of October 2025.

Between November 2016 and November 2020, she was the Director responsible for all medical product related regulatory activities at the World Health Organization in Geneva.

Ms Cooke is a pharmacist with Master's degrees in Science and Business Administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and held management positions at the EMA as Head of Inspections and Head of International Affairs respectively from 2002 until 2016.

Between 1998 and 2002 she worked in the Pharmaceuticals unit of the European Commission, where intra-alia, she was responsible for international collaboration, EU enlargement and the orphan medicines regulation. Prior to this, Ms Cooke worked at the European Federation of Pharmaceutical industries and Associations (EFPIA) (1992–1998), in the Czech Republic as an independent pharmaceutical policy advisor (1996–1998) and in the Irish pharmaceutical sector (1985–1990).

Starting her mandate as EMA's Executive Director in November 2020 amid a public health crisis of unprecedented scale she announced "My number one priority will be to drive forward EMA's response to the pandemic and the work already ongoing to support the development and approval of safe and effective COVID-19 vaccines and treatments." Doing precisely that, has earned her various awards including the 'European of the Year 2022' award by European Movement Ireland and Honorary Doctorates in Science (Royal College of Surgeons in Ireland – 2023 and National University of Ireland – 2025).



Karl Broich, Prof. Dr. med.

President of the Federal Institute for Drugs and Medical Devices

Prof. Broich is a physician (neurology, psychiatry, cognitive behavioural therapy) and has been President of the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn since 2014.

His current activities in the European Medicines Regulatory Network are Member of the Management Board of the European Medicines Agency and Member of the HMA Management Group. He is the acting co-chair of the Executive Steering Group on Shortages and Safety of Medicinal Products, the Darwin EU Advisory Board, the Network Data Steering Group and the HMA/EMA Strategic Resource Oversight Group.

His scientific focus is on clinical psychopharmacology, neurodegenerative diseases, and the potential of biomarkers as well as the methodology of clinical studies. Prof. Karl Broich is the author and co-author of over 250 articles (original scientific papers, reviews, book contributions).



Peter Arlett

Head of Data Analytics and Methods Taskforce EMA, Co-chair HMA-EMA Network Data Steering Group, Honorary Professor, London School of Hygiene and Tropical Medicine

Head of the Data Analytics and Methods Task Force and Co-chair of the Network Data Steering Group at the European Medicines Agency. He has twenty-five years of experience of drug benefit risk management and of delivering programs of major change in regulation and legislation. This experience has been gained through organizations at national, European, and international level.



Konstantina Boumaki

MD, Board Member European Patients' Forum

Konstantina is a medical doctor and a patient advocate, living with type 1 diabetes since 2005. She currently serves as a Board Member of the European Patients' Forum and is a member of the Network Data Steering Group, serving as the main patient representative.

Session 1



Ana López de la Rica

Deputy Head of the Department of Medicines for Human Use at the AEMPS, ES

Ana López de la Rica is currently Deputy Head of the Department of Medicines for Human Use at the AEMPS. She has more than 22 years of experience in Regulatory Affairs and among them 15 years in the AEMPS. She has also been working in the Pharmaceutical Industry and in Farmaindustria, the National Trade Association of Innovators. She is a member of the WHO INN expert group. She has a degree in Pharmacy from the University of Valencia and a master's degree in drug development, registration and regulation from the Autonomous

University of Barcelona and another one in Pharmacoeconomics and Health Economics from the Pompeu Fabra University of Barcelona.



Trygve Ottersen

Director General, Norwegian Medical Products Agency

Trygve Ottersen is a medical doctor with a PhD in priority setting and global health. He chairs the Heads of HTA Agencies Group (HAG), a European network of health technology assessment agencies. He combines his leadership responsibilities with academic work at the University of Oslo and clinical practice as an emergency physician.



Alexandre Templier

Independent expert, Chair of EURAICA

Alexandre Templier is an engineer with 30 years in healthcare decision support and digital twins. He founded and led Quinten for 17 years, building analytics and disease models on clinical and real-world data for pharmaceutical companies. An independent AI expert, he chairs EURAICA, a workshop on AI-enabled clinical evidence.



Markus Kalliola

Programme Director, The Finnish Innovation Fund Sitra

Markus is a director in Sitra's Future of Well-being solutions programme and a coordinator in the EU's Joint Action Towards the European Health Data Space (TEHDAS2) and Nordic VALO project. Beside his daily work he is also active in consulting and advising several international digital health projects and an active contributor to EU health policy. Before joining Sitra he worked in the European Commission in the directorate for health in cross-border healthcare policies. He holds a master's degree in computer science and has been engaged in digitisation projects in both public and private sectors.

Session 2



Rúna Hauksdóttir Hvannberg

Executive Director, Icelandic Medicines Agency (IMA)

Director of IMA since 2015, bringing almost 20 years' experience in pharmaceutical regulation, pricing and reimbursement. She co-chairs the HMA/EMA Regulatory Optimisation Group, leads the EMANS 2028 focus area "Sustainability of the Network," and is an observer on the EMA Management Board. Her degrees span pharmacy, health economics and bio pharmacy.



Isabel Chicharo

Head of Regulatory Data Management, European Medicines Agency

Works in the Agency since 2010, currently is a head the Regulatory Data Management.
Education: Postgraduate in Regulation and Assessment of Medicinal and Health Products, University of Lisbon, Portugal (2006). Postgraduate in Pharmacy and Medicinal Law, University of Coimbra, Portugal, (2002). Master's degree in Pharmaceutical Sciences, University of Lisbon, Portugal (2000).



Quentin Darrasse

Data Strategy Principal, F. Hoffmann – La Roche Ltd.

Quentin Darrasse (Pharm. D., MSc. ESCP EUROPE Paris) is a trained Regulatory professional with 15 years of experience in the field. Taking opportunities to transform digitally the Organization, with both Business & IT expertise as well as a strong appetite for data, Quentin has also helped shaping the external Regulatory Information Management ecosystem, via ISO TC215, via the IDMP Roundtable and via the IDMP-O initiative especially. He is currently taking part in bringing Roche up to speed with AI, through an educational program, and with sponsoring innovation projects.



Aimad Torqui

Deputy director Medicines Evaluation Board, NL

Aimad Torqui is deputy director and division head at the Medicines Evaluation Board (MEB), serving on the executive management team since 2022. In this capacity, he leads national and European policy initiatives, regulatory science efforts. His responsibilities also extend to veterinary medicines and initiatives aimed at improving the use of medicines. At the European level Aimad serves as vice-chair of the Management Board of the EMA and serves on the Agency's Executive Steering Group on Shortages and Safety of Medicinal Products MSSG. He is a co-opted member of the HMA Management Group, strategic advisor to the joint HMA/EMA Regulatory Optimisation Group, observer to the Network Data Steering Group, and serves on the Network Portfolio Advisory Group.

With nearly 20 years of experience in regulatory affairs, Aimad has held roles in both government and industry. He joined the MEB in 2006, initially as a regulatory case manager, before transitioning into various roles. In 2010, he was appointed as the alternate member to CMDh. From 2013, Aimad worked in the pharmaceutical industry, where he gained experience as a regulatory affairs manager and later as a regional lead for global regulatory policy. Aimad holds degrees in biotechnology from HAN University of Applied Sciences and molecular biology from Radboud University Nijmegen.

Session 3

Kit Roes

Kit Roes is Professor of Biostatistics at Radboud University Medical Center Nijmegen (Netherlands). He is co-opted member Committee for Human Medicinal Products for Biostatistics and Clinical Trial Methodology and chair of the Methodology Working Party of the European Medicines Agency. His research focus is design and analysis of clinical trials in the context of regulatory science, with an emphasis on innovative designs, rare diseases and bridging the gap between clinical trials and real-world evidence. His experience further includes over 25 years in clinical research in the pharmaceutical industry and academic life sciences, serving as expert and in different (international) senior management positions.



Pavel Balabanov

Head of Therapies for Neurological and Psychiatric Disorders office at the European Medicines Agency

I am a clinical neurologist who before joining the EMA worked as a consultant neurologist at the Clinic of Neurology, University Hospital – Plovdiv, Bulgaria. I have a PhD in Neurology from the Medical University of Plovdiv.

Currently I lead the office for Therapies for Neurological and Psychiatric Disorders at the EMA. I am the human medicines division lead in AI-related topics.



Isabelle Clamou

Team leader Clinical Trials, European Commission, DG SANTE, Unit D2 Medical Products: Quality, Safety and Innovation

Isabelle Clamou is a French regulatory affairs professional with over 20 years experience in the field of European pharmaceutical legislation. She joined the European Commission as policy officer in 2018 and worked at DG HERA on COVID 19. She is now leading the team in charge of clinical trials policy in DG SANTE.



Joerg Zinserling

Senior assessor and Deputy Head of Unit for Biostatistics and Special Pharmacokinetics at the Federal Institute for Drugs and Medical Devices (BfArM), DE

Joerg Zinserling is statistician and physicist by background and holds a PhD with an interdisciplinary doctorate in physics and medicine. He is member of the Scientific Advice Working Party and the Methodology Working Party of CHMP at EMA. Before joining the agency, he worked in academia at university hospitals on clinical trial design, conduct and analysis as well as research projects, including lung imaging in radiology and nuclear medicine and pharmacometrics.



Falk Ehmann

Head of the Innovation and Development Accelerator at the European Medicines Agency

Falk Ehmann is leading early stakeholder interactions on Innovation and Business Pipeline / Portfolio and Forecasting activities including Horizon Scanning at the European Medicines Agency (EMA). Falk co-chairs the EU-Innovation Network driving EU pharma policy and strategy with current focus on the New Pharmaceutical Legislation.

Falk is a medical doctor with a PhD in Experimental Medicine and a degree in European and International law.

Session 4



Aurora M. Rojo Sanchís, PharmD, PhD

Head of GCP & GVP Inspection Area, Spanish Agency of Medicines and Medical Devices (AEMPS)

Aurora M. Rojo Sanchís leads the Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP) Inspectorate at the Spanish Agency of Medicines and Medical Devices (AEMPS). She is a member of the AI Guideline Coordination Group (AIGCG) and EMA's GCP and PhV inspection working groups. In her role at AEMPS, she coordinates the Spanish GCP and GVP inspectorate and conducts national and international GCP and GVP inspections. She is a pharmacist with a PhD and a specialist in Hospital Pharmacy.



Günter Waxenecker
Head of the Austrian Medicines and Medical Devices Agency

Günter Waxenecker jointed the Austrian Medicines & Medical Devices Agency in 2007 and has held his current management position since 2023. He is also a procedural member of the Federal Office for Safety in Health Care (BASG) and responsible for scientific advice procedures, marketing authorisations of medicinal products, clinical trials of medicinal products and medical devices, pharmacovigilance and vigilance in the field of medical devices, blood and tissues, quality of medicinal products, inspections and market surveillance of medicinal products and medical devices on the Austrian market.

He is a member of the EC Pharmaceutical Committee and the EMA Management Board, member of the Executive Steering Group on Shortages and Safety of Medicinal Products, Co-chair of the European Shortage Monitoring Platform, Steering Group Member of the European Platform for Regulatory Science and Member of the Network Portfolio Advisory Group.



Donato Bonifazi

Chair of the Board of Directors – TEDDY, European Network of Excellence for Paediatric Clinical Research

He has over twenty years' experience in paediatric and rare disease research, European project coordination, multinational clinical trial management and research infrastructure development, mainly at CVBF where he is the Strategy Leader. With his expertise in innovative clinical trials, paediatric and rare diseases drug development, health data and patient involvement, he serves on the EPTRI Board of Directors, the ACT EU Multistakeholder Platform Advisory Group and the Enpr-EMA's Coordinating Group.



Daniel Weiss

Computer Scientist | Dr. von Hauner Children's Hospital, LMU Klinikum

Daniel Weiss is a computer scientist at Dr. von Hauner Children's Hospital, LMU Klinikum. His work spans the digital research stack, from bioinformatics and AI-supported clinical text analysis to data platforms, translational projects and business models. A generalist by design, he connects technical, clinical and strategic perspectives.



Giovanni Montesano, MD, PhD

NIHR Biomedical Research Centre, Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology, London, UK

Giovanni Montesano is a glaucoma consultant and clinician-scientist working at the intersection of artificial intelligence, statistical modelling and clinical trials. His research develops "digital-twin" models for glaucoma that combine disease mechanisms with clinical trial and real-world data. He also designs AI- and data-driven strategies to improve glaucoma clinical trials.



Vidya Perera, Ph.D., FACC, FESC, FAHA

Vice President and Global Head of Early Clinical Development, Bayer

Vidya Perera is Vice President and Global Head of Early Clinical Development at Bayer. A Ph.D.-trained pharmaceutical R&D executive with more than 15 years of global leadership experience, he brings expertise in early clinical development, translational medicine, quantitative sciences, precision medicine and portfolio strategy. He leads a global organization supporting cardiovascular, renal, immunology, women's health, ophthalmology and acute-care portfolios, and provides strategic development guidance from research through Phase IIb. His work focuses on accelerating evidence-based decisions, reducing development risk and translating scientific innovation into meaningful outcomes for patients.



Rafał P. Bartczuk, PhD

Head of the Paediatric Regional Centre for Digital Medicine, Children's Memorial Health Institute (CMHI), Warsaw, Poland

Rafał P. Bartczuk is a psychologist, data scientist and digital health researcher. He leads the Paediatric Regional Centre for Digital Medicine at the Children's Memorial Health Institute in Warsaw, where he works on the integration and secondary use of clinical data, advanced analytics and AI-enabled solutions for research and healthcare. His experience includes epidemiological modelling, real-world health data, clinical research infrastructure and the development of data-driven tools supporting clinical studies and decision-making. His academic research also focuses on behavioural addictions, particularly the convergence of gaming and gambling.



Marek Migdal, MD, PhD

CEO of the Children's Memorial Health Institute, Warsaw, Poland

Paediatrician and pulmonologist.

He has worked at the Children's Memorial Health Institute since 1979—initially in the Department of Paediatrics and, from 1986, in the Intensive Care Unit. He completed research fellowships in France during 1985–1986 and in 1990. Since December 2018, he is a CEO of the Children's Memorial Health Institute in Warsaw.

He is the author of over 230 publications and has organized numerous conferences focused on paediatric intensive care and clinical research in Poland.

He is an active coordinator of international scientific collaboration, having led five European grant projects at the Institute. As a member of the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) he served on its board from 2014 to 2017 as Chair of the Professional Development Committee. From 2019 to 2021, he was the Vice-Chair of the society's Ethics Section. He is a member of the European Medicines Agency's Paediatric Committee since 2007 and a board member of the European Children's Hospital Organisation since 2019. Effective March 2025, he has been appointed by the European Commission to the advisory group of hospital directors participating in the work of the European Reference Networks.



Jeppe G. Manuel

Data Science External Affairs & Intelligence Director, Novo

Jeppe works to advances regulatory, policy and governance frameworks for health data, AI and digital technologies in clinical development. With over two decades of experience across clinical development, regulatory affairs and data science, his expertise includes clinical data reuse, anonymisation and data ethics, supporting responsible innovation and the use of emerging technologies in life science.



Raja Shankar

Vice president of AI Solutions within IQVIA's AI and Technology Solutions

Raja Shankar is vice president of AI Solutions within IQVIA's AI and Technology Solutions (ATS). Raja leads an integrated team of AI scientists, life sciences experts and consultants who are building and taking to market the IQVIA Life Science Models to accelerate clinical development and commercial execution. He also chairs the AI/ML Committee of the Association of Clinical Research Organizations (ACRO).

Previously, he led IQVIA's Technology and AI Consulting practice, where he pioneered an Applied AI practice for life sciences clients. He joined IQVIA in 2010, where he has held senior roles across consulting, global client partnership, and value and access. Before IQVIA, Raja worked as a strategy consultant at the Boston Consulting Group.

Raja holds a Bachelor's degree from the Indian Institute of Technology, Kharagpur, and a Master's degree from the University of Illinois Urbana-Champaign.



Gabriel Westman

Head of AI, Swedish Medical Products Agency, SE

Infectious disease specialist and associate professor (MD, PhD) with a MSc in Engineering (Chemistry/Pharmaceuticals) and expertise in AI, bioinformatics and big data applications. Currently building regulatory AI/data science capacity and competence at the Swedish Medical Products Agency, exploring use of real-world data and hoping for a better and data-driven world.

Day 2

Keynote address



Helena Panayiotopoulou

Director, Pharmaceutical Services Ministry of Health Cyprus

Dr Helena Panayiotopoulou graduated in Pharmacy from Aristotle University of Thessaloniki. She holds a Master's degree in Public Administration, a Master's degree in Clinical Pharmacy and a PhD in Pharmacoeconomics.

She has been working at the Pharmaceutical Services of the Ministry of Health of Cyprus since 1996, holding various positions of responsibility, including Head of Clinical Pharmacy and Head of Pharmacovigilance and Clinical Trials. She served as Deputy Director from December 2020 and was appointed Director of Pharmaceutical Services in June 2022.

She currently chairs several national committees, including the Pharmaceutical Council, the Medicines Pricing Control Committee and the Named Patient Requests Committee. She is also Registrar of the Medicines Council and serves on the Boards of the Bank of Cyprus Oncology Centre and the National Cancer Institute.

At European level, she represents Cyprus on the Management Board of the European Medicines Agency (EMA), the HTA Coordination Group and the Heads of Medicines Agencies (HMA). She also represents the Ministry of Health in various European and international bodies, including the European Commission, the World Health Organization (WHO), the United Nations (UN) and the OECD, contributing to discussions on pharmaceutical policy, access to medicines, medicines shortages, pricing and reimbursement.

Dr Panayiotopoulou has published in international scientific journals, particularly in the fields of pharmaceutical procurement and tendering, and has participated in numerous international conferences and round-table discussions.



Magdalena Pajewska-Lewandowska

Director of the International Cooperation Department at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) in Poland

An experienced international relations and regulatory cooperation professional, she leads the Office's international cooperation strategy and develops partnerships within European and global regulatory networks. Her work focuses on the impact of geopolitical shifts, emerging technologies and global megatrends on the future of medicines regulation.

During Poland's Presidency of the Council of the European Union in 2025, she contributed to the Heads of Medicines Agencies' (HMA) strategic reflections on megatrends and their implications for regulatory

systems. She is actively involved in the European Medicines Regulatory Network and the International Coalition of Medicines Regulatory Authorities (ICMRA).

Previously, Ms Pajewska-Lewandowska served at the Polish Embassy in Ottawa, focusing on economic and scientific cooperation. She was also seconded to the European Medicines Agency (EMA), where she coordinated the ICMRA Secretariat during EMA's chairmanship, including the initial period of the COVID-19 pandemic. She contributed to initiatives supporting the establishment of the African Medicines Agency and the EU Innovation Network.

Ms Pajewska-Lewandowska holds a Master's degree in Political Science and a postgraduate qualification in International Law and Foreign Service. Her professional development includes the AI in Healthcare programme at Harvard Medical School, Healthcare Project Management – Harvard T.H. Chan School of Public Health, and programmes at the European Academy of Diplomacy.

She has authored publications on medicinal product regulation and received professional distinctions, including a medal for services to healthcare awarded by the President of Poland.

Outside her professional activities, she enjoys Japanese literature and running.

Session 5



Tobias Fellinger

Senior Expert at AGES

Tobias Fellinger is a senior expert in the methodology and statistics group at the Austrian Agency for Health and Food Safety (AGES) and member of the EMA methodology working party. He holds a masters degree in statistics from the University of Vienna. He previously worked at the Institute of Medical Statistics in the Center for Medical Data Science of the Medical University of Vienna.



Marcel Hoefnagel

Senior Assessor Biopharmaceuticals, Medicines Evaluation Board (CBG-MEB), The Netherlands

Trained as Biologist, with a PhD in Plant Biochemistry (Leiden University, 1993). Senior Assessor of Biopharmaceuticals (since 2002). Specialised in vaccines, allergens, biosimilars, immunogenicity, and Cell and Gene therapy products.

Chair of the EMA Quality Innovation Group (since 2023). Entry point for various stakeholders to discuss scientific and regulatory issues on innovation in pharmaceutical manufacturing and control, including digitisation and AI.

Chair of the HMA Substance Validation Group (SVG; since 2020). The SVG is involved in development and maintenance of EU-SRS (EU- Substance Registration System; a database with all substances in

medicinal products with their molecular structure). Pivotal for AI approaches connecting medicinal products and safety/efficacy data.

Involved in various research projects to support innovative approaches in manufacturing of (bio)pharmaceuticals and other regulatory activities (e.g. Cell therapies, Bioinformatics, 3R). linkedin: marcel-hoefnagel



Joaquim Berenguer Jornet

AI Implementation lead – European Medicines Agency
Chair of the European Agencies Network Working Group on AI

Joaquim Berenguer is currently the AI Implementation lead, driving the implementation and responsible adoption of AI to support the digital transformation strategy of the European Medicines Agency. He is also the chair of the European Agencies Network Working Group on AI aiming to accelerate responsible AI adoption across the EU Agencies Network through collaboration, knowledge sharing and joint initiatives.

Mathematician as background, Joaquim had led different data scientist teams during his career where he aimed to use analytics and new technologies to support the digitalisation journey of different organisations. Today, Joaquim focuses on turning AI technology into practice, shaping governance and operating models, identifying and scaling high-value AI use cases, and fostering collaboration and responsible adoption needed to embed AI across the organisation.



Rebecka Isaksson

Project coordinator, Swedish Medical Product Agency

Rebecka works within the AI Unit at the Swedish MPA, where she leads efforts in AI research, the advancement of AI literacy through education, and AI governance and implementation. Rebecka holds a PhD in pharmaceutical sciences from Uppsala University and a Master of Science in Engineering in chemistry from the Royal Institute of Technology, Sweden.



Alison Dawson

Sr. Director - QA Leader Eli Lilly

Alison is a pharmacist and has worked in industry in a variety of roles. Initially in development then manufacturing with Quality Assurance teams responsible for vendor assurance, incoming goods, manufacturing, packaging and QP approval of product.

Her current role focuses on external regulations and their impact on pharmaceutical practices.



Liese Barbier

Scientific Specialist, European Medicines Agency

Liese Barbier is a Scientific Specialist in the Regulatory Science and Innovation Taskforce at the European Medicines Agency (EMA, Amsterdam, the Netherlands). She is a pharmacist by training and holds a PhD in Pharmaceutical Sciences, with a focus on Regulatory Science from KU Leuven (Leuven, Belgium). During her PhD and postdoc research (KU Leuven, research stay at Stanford University, placement at EMA), she led research projects on biosimilar evaluation and on how medicine development and evaluation can be more patient and unmet need driven. She has been part of several European and national consortia, contributing to regulatory strategy and regulatory science research studies and mentored a team of Master and PhD researchers in Pharmaceutical Sciences and Drug Development. She first joined EMA in 2019, as Seconded National Expert within the Oncology, Haematology, and Diagnostics office in the Human Medicines Evaluation Division. In her current role, she focuses on advancing regulatory science research in Europe and support to academic and non-for-profit researchers with medicines and tools development.

Spotlight talk



Marco Marsella

Acting Deputy Director-General for Health and Director for "Digital, EU4Health and Health Systems Modernisation" at the European Commission's Directorate General for Health and Food Safety (DG SANTE)

In his role as Director, Mr Marsella oversees the implementation of the European Health Data Space Regulation, the implementation of the Health Technology Assessment Regulation, DG SANTE's work on health system modernisation as well as the EU4Health Programme.

Prior to his current position, Mr Marsella held various roles within the European Commission, including Head of Unit for "eHealth, Well-Being, Ageing" and Head of Unit for "Learning, Multilingualism, Accessibility" at the European Commission's Directorate General for Communications Networks, Content and Technology (DG CONNECT).

Session 6



Grainne Power

Chief Executive, Health Products Regulatory Authority (HPRA)

Grainne Power was appointed Chief Executive of the HPRA in January 2026. She joined the HPRA in 2018 and served as Director of Human Products Authorisation and Registration and Director of Compliance. She previously held senior quality assurance roles across the pharmaceutical, biopharmaceutical, veterinary medicines and medical devices sectors. Grainne holds a degree in Biotechnology from Dublin City University and postgraduate diplomas from University College Dublin and Trinity College Dublin.



Franck Foures

Head of Veterinary Medicines Division – European Medicines Agency

A veterinarian by training, Franck has more than 20 years of experience in veterinary public health, medicines regulation, scientific risk assessment, and international cooperation. Before joining EMA in September 2026, he was Director of the French Agency for Veterinary Medicinal Products and held several senior positions in the French administration.



Jesper Kjær

Head of Data Governance & Analytics, European Medicines Agency

Former director of the Data Analytics Centre at the Danish Medicines Agency and co-chair of the HMA/EMA Big Data Steering Group, with 25+ years' experience in bioinformatics, data management and analyses across academia, pharmaceutical industry and public-health organisations.

Has led the development of clinical and public-health IT systems for the World Health Organization and the University Hospital of Copenhagen, supported HIV observational research at Copenhagen HIV Programme (CHIP) and contributed to early global data and data-management standards and use of AI 20 years ago.

While at Novo Nordisk built risk-based monitoring IT, led master data management, and heading public-private partnerships programmes across the global organisation. Been leading activities in EU Framework Programmes, TransCelerate Biopharma and HL7 Vulcan.



Rico Slingerland

CMDv member for NL – Medicines Evaluation Board

Rico is a seasoned professional with over 15 years of experience in the field of veterinary medicine registration. Rico has played a role as PO and SME in the development of the UPD and has led several ICT projects within his organization. Currently, he serves as the CMDv representative within the NDSG, where he focuses on the digital and technical aspects of veterinary medicine.



Gregorio Sambataro

EU Projects Manager at the European Heart Network

For over a decade, he has worked on various action grants awarded by European, national, and regional institutions. Gregorio coordinates EHN's activities across several EU projects, contributing to the development of novel cardiovascular innovations and policy work. He holds a Master's degree in International Relations from "Sapienza" University of Rome. He speaks Italian, English and French. In his free time, he enjoys playing football and riding his bike.



Yves Jacob

Regulatory Head Key Markets and R&D Lead France - Sanofi

Yves is Regulatory Head of Key Markets and R&D Country Lead France at Sanofi, based in Paris. A pharmacist by training, he brings over 20 years of pharmaceutical industry experience, including retail pharmacy, hospital practice and leadership roles at Sanofi. He has led global regulatory teams that secured initial approvals for several major cardiology and diabetes medicines, and served as R&D Project Director for anticholesterol programs. His career at Sanofi has included roles as Country Regulatory Head for France and Head of Europe for Global Regulatory Affairs.



Charles Bagarie

Digital Quality Manager, Boehringer Ingelheim Animal Health

Charles Bagarie, PMP®, CISSP®, is an AI, Data and Digital Transformation Manager at Boehringer Ingelheim, with over seven years of international experience leading strategic initiatives in highly regulated environments. With a background in biomedical engineering, he works at the intersection of artificial intelligence, data strategy, cybersecurity, governance and technology innovation. His expertise spans enterprise AI adoption, advanced analytics, digital transformation, data governance and risk management, with a strong focus on secure, responsible and scalable solutions. He contributes to global AI and digital strategies in GxP environments, bridging emerging technologies, regulatory requirements and business objectives to support innovation and operational excellence across mission-critical industries.