EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Advancing Regulatory Science Research - Agenda

18 November 2024, 13:30 – 17:30 (CET)
Virtual meeting / EMA, Amsterdam

Advancing regulatory science can aid in improving medicine development and evaluation, enabling patient access to medicines that better meet their needs. Collaboration and dialogue between regulators and researchers are crucial to keep regulatory science in step with innovation and to enhance its impact on the regulatory system.

The European Medicines Agency (EMA) is organising a public event on 18 November 2024 on Advancing Regulatory Science Research. Two initiatives will be launched: the 2024 draft update of the EMA Regulatory science research needs (RSRN) and the EMA/HMA European Platform for Regulatory Science Research, a new initiative to enhance collaboration between academic researchers and regulators across Europe and beyond. The event aims to stimulate interactions and collaborations to advance regulatory science research addressing key regulatory science needs. The event will combine presentations and moderated panel discussions.

Topics addressed during the event include:

- Regulatory science research landscape and progress in Europe
- Introduction to the new EMA/HMA European Platform for Regulatory Science Research
- Introduction to EMA's 2024 update of the Regulatory Science Research Needs

- Opportunities for researchers to collaborate on and receive support for regulatory science research

Presentations will be given by EMA, national competent authorities, representatives of academia, and funders. The event will feature an interactive Q&A session and a panel discussion to address audience questions.

Primary audience: researchers from academic, public and non-for-profit institutions working on medicines development, development of tools with potential application to the medicine lifecycle or other types of regulatory science research, regulators, research funders, industry and trade organizations, patient associations, and healthcare professionals. Virtual participation to the event is open to all stakeholders. Prior registration is required.

The event will be broadcast and recorded, and the recording will be made available on the EMA event page a few weeks after the event.

Contact point: regulatory.science@ema.europa.eu

Event objectives

- To introduce and present the nature and scope of regulatory science research
- To highlight opportunities for academia to collaborate with regulators on and receive support for regulatory science research
- To exemplify the usefulness of regulatory science research for application in regulatory context
- To introduce the EMA/HMA Platform for Regulatory Science Research and highlight how it will enable advancing and accelerating regulatory science research
- To introduce EMA's 2024 update of the Regulatory Science Research Needs and highlight how it can stimulate researchers and funding organisations to consider addressing these needs
- To gather input and suggestions from multiple stakeholders on the proposed Platform for Regulatory Science Research and the revised Regulatory Science Research Needs

Event overview

The event is planned as a four-hour virtual event, split into two main segments, with a break in between. The first segment will concentrate on highlighting the EMA 2024 update of the Regulatory Science Research Needs. The second segment will focus on introducing the new EMA/HMA European Platform for Regulatory Science Research.

Advancing Regulatory Science Research - Agenda

Monday 18 November 2024, 13:30 – 17:30 (CET)

13:15 Joining and technical checks

13:30 Welcome and opening speech

Regulatory science research to support scientific and technological advances and inform their evaluation — **10 min**

Harald Enzmann (Federal Institute for Drugs and Medical Devices, BfArM, Germany)

Introduction to the agenda and the strategic approach of the regulatory science research lifecycle — **10 min**

Ralf Herold (EMA)

13:50 Session 1: Regulatory Science Research Needs

Co-Chairs: Spiros Vamvakas (EMA), Kit Roes (Radboud University Medical Center and Dutch Medicines Evaluation Board, the Netherlands)

Session introduction — **5 min**

Spiros Vamvakas, Kit Roes

Introduction to the Regulatory Science Research Needs and consultation on the 2024 update — **10 min**

Pierpaolo Moscariello (EMA)

Researcher – regulator panel on regulatory science gaps, research and translation — **30 min**

Alessandro Faia (EMA) – moderator

Ivo Claassen (EMA) – panellist

Marco Cavaleri (EMA) – panellist

Kit Roes (MEB & RU) panellist

Evangelos Giamarellos-Bourboulis (National and Kapodistrian University of Athens, Medical School) – panellist

Questions from the audience and answers — **10 min**

Ralf Herold (EMA)

Wrap up — **5 min**

Pierpaolo Moscariello (EMA)

14:50 Coffee break

15:10 Session 2: A European Platform for Regulatory Science Research

Co-Chairs: Ralf Herold (EMA), Günter Waxenecker (Austrian Federal Office For Safety In Health Care, Austria)

Opening remarks from EMA **10 min**

Emer Cooke (EMA)

Session introduction **5 min**

Ralf Herold, Günter Waxenecker

Evolution of regulatory science in the Netherlands **10 min**

Marjon Pasmooij (Dutch Medicines Evaluation Board and Utrecht University, the Netherlands)

Introduction to and consultation on the European Platform for Regulatory Science Research **10 min**

Liese Barbier (EMA)

Researcher – regulator panel discussion on regulatory science research collaboration **30 min**

Alessandro Faia (EMA) – moderator

Francesco Pignatti (EMA) – panellist

Andrew Thompson (EMA) – panellist

Sophia Samodelov (University of Zürich, Switzerland) – panellist

Franz König (Medical University of Vienna, Austria) – panellist

Funding programmes and regulatory science research **10 min**

Tomasz Dylag (DG Research and Innovation, European Commission)

Niklas Blomberg (Innovative Health Initiative, Brussels)

Questions from the audience and answers **10 min**

Ralf Herold (EMA)

Wrap up **5 min**

Liese Barbier (EMA)

16:40 Multi-stakeholder panel on Regulatory Science Research

Co-moderators: Bert Leufkens (Utrecht University, the Netherlands), Ralf Herold (EMA)

Panel discussion **45 min**

Panellists:

Steffen Thirstrup (EMA)

Rosa Giuliani (Guy's and St Thomas' NHS Foundation Trust, UK, EMA HCPWP)

Claudia Louati (European Patients' Forum)

Harald Enzmann (Federal Institute for Drugs and Medical Devices, BfArM, Germany)

Kit Roes (Radboud University MC, Dutch Medicines Evaluation Board, the Netherlands)

Thomasz Dylag (DG Research and Innovation, European Commission)

Sophia Samodelov (University of Zürich, Switzerland)

Magda Chlebus (European Federation of Pharmaceutical Industries and Associations)

17:25 Closing remarks

Wrap up **5 min**

Emmanuel Cormier (EMA)

List of speakers

Harald Enzmann	German Federal Institute for Drugs and Medical Devices (BfArM)
Ralf Herold	European Medicines Agency (EMA)
Spiros Vamvakas	European Medicines Agency (EMA)
Kit Roes	Dutch Medicines Evaluation Board, Radboud University Medical Center (MEB, RU)
Pierpaolo Moscariello	European Medicines Agency (EMA)
Alessandro Faio	European Medicines Agency (EMA)
Ivo Claassen	European Medicines Agency (EMA)
Marco Cavaleri	European Medicines Agency (EMA)
Evangelos Giamarellos	National and Kapodistrian University of Athens, Medical School (NKUA)
Günter Waxenecker	Austrian Federal Office For Safety In Health Care (AGES)
Emer Cooke	European Medicines Agency (EMA)
Marjon Pasmooij	Dutch Medicines Evaluation Board, Utrecht University (MEB, UU)
Liese Barbier	European Medicines Agency (EMA)
Francesco Pignatti	European Medicines Agency (EMA)
Andrew Thomson	European Medicines Agency (EMA)
Sophia Samodelov	Zurich University Hospital (USZ)
Franz Koenig	Medical University of Vienna (MUW)
Tomasz Dylag	DG Research and Innovation, European Commission (EC, DGR&I)
Niklas Blomberg	Innovative Health Initiative Joint Undertaking (IHI)
Bert Leufkens	Utrecht University (UU)
Steffen Thirstrup	European Medicines Agency (EMA)
Rosa Giuliani	Guy's and St Thomas' NHS Foundation Trust (GSTT)
Claudia Louati	European Patients' Forum (EPF)
Magda Chlebus	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Emmanuel Cormier	European Medicines Agency (EMA)

About the speakers

Harald Enzmann

Head of European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

A physician by training (graduation 1985), Harald received his MD from the Karl Ruprechts University, Heidelberg, Germany. Subsequently, he held positions at the German Cancer Research Center, at the Institute of Pharmacology and Toxicology at the University of Erlangen, at R&D at Bayer AG, Wuppertal and at the American Health Foundation in Valhalla, NY, USA.

Since 2002, he held various positions at the Federal Institute for Drugs and Medical Devices (BfArM), the German regulatory authority for medicines. From 2018 to 2024, he was chairperson of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's. Currently, he is head of European and International Affairs at BfArM.

Ralf Herold

Head of Regulatory Science and Academia, European Medicines Agency (EMA)

Ralf Herold MD PhD is the head of EMA’s Regulatory Science and Academia Workstream, part of the Regulatory Science & Innovation Taskforce, coordinating research and engagement with researchers and developers from the academic sector and not-for-profit organisations. Previously, he worked on cancer and paediatric medicines as well as horizon scanning and foresight at the EMA. He was the Pediatric development leader of Bayer AG Regulatory affairs and an ICH E11A expert group member. At Charité – Universitätsmedizin Berlin, he obtained an experimental research PhD, board certified in paediatric and adolescent medicine, trained in paediatric oncology and haematology, and managed a national research network.

Spiros Vamvakas

Scientific Adviser on Human Medicines, European Medicines Agency (EMA)

Spiros Vamvakas is a medical Doctor (University of Würzburg, Germany), a board certified specialist in pharmacology and toxicology (Bavarian Chamber of Physicians) and associate Professor for pharmacology and toxicology (University of Wūrzburg, Germany).

Since 1984 he held positions in the department of pharmacology and toxicology in the university clinic of Würzburg and in the department of pharmacology at the medical centre of the university of Rochester (NY, USA). He joined EMA in 1999 and his activities over the years included the establishment of orphan drug designation, scientific advice/ protocol assistance including the qualification of novel methodologies and parallel scientific advice with health technology assessment bodies and payers. Between 2003 and 2016 he had various roles representing EMA in ICH.

In 2020 he was appointed CHMP scientific lead and adviser on human medicines including COVID-19 products and guidelines. He has an active teaching appointment in clinical pharmacology at the university clinic of Würzburg.

Since 2019 he is associate editor of the Clinical Pharmacology and Therapeutics journal. In 2023 was appointed EMA's strategic Advisor to C-Path Consortium and member of the C-Path US Board.

Kit Roes

Professor of Biostatistics, Radboud University Medical Center (RU), Dutch Medicines Evaluation Board (MEB), The Netherlands

Kit Roes is Professor of Biostatistics at Radboud University Medical Center Nijmegen (Netherlands) and is chair of the Methodology Working Party of the European Medicines Agency. His research focus is design and analysis of clinical trials, with an emphasis on innovative designs, rare diseases and bridging the gap between clinical trials and real world evidence. His experience includes over 25 years in clinical research in the pharmaceutical industry and academic life sciences, serving clinical research and drug development as expert as well as in different (international) senior management positions.

Pierpaolo Moscariello

Scientific Specialist, European Medicines Agency (EMA)

Pierpaolo Moscariello is a biotechnologist by training. He holds a PhD in Biology from Mainz University (Germany) and has worked as senior post-doc at the Max Planck Institute for Polymer Research in Germany on projects to address biomedical challenges bridging biology and material science. During his scientific career he has built expertise in complex in vitro models, neuroscience and biomedical applications of nanomaterials. He joined the EMA in January 2023 as scientific expert in the Regulatory Science and Innovation Task Force where he aims to identify regulatory gaps and facilitate research on pressing regulatory science needs.

Alessandro Faia

Communication Specialist, European Medicines Agency (EMA)

Alessandro Faia is a Communication Specialist with extensive experience in public health communication.

He works in EMA's media and public relations team, dealing with a range of projects including corporate storytelling, managing interactions with journalists, and crafting communication campaigns.

Ivo Claassen

Head of the Veterinary, European Medicines Agency (EMA)

Dr Ivo Claassen is head of the Veterinary Medicines Division and Deputy Executive Director at the European Medicines Agency. Since he joined the Agency in 2018, he has been responsible for the implementation of Veterinary medicinal products regulation. Furthermore, he was involved in the development of the Veterinary Regulatory Science Strategy and the EMA Veterinary Big Data strategy. He has also over 30 years of experience in vaccine production, QC/QA, R&D and regulatory affairs, both for human and veterinary vaccines.

Marco Cavaleri

Head of Public Health Threats, European Medicines Agency (EMA)

Marco Cavaleri is the head of the office of biological health threats and vaccines strategy at the European Medicines Agency (EMA). He is the Chair of the EMA Emergency Taskforce and responsible for EMA activities for emergent pathogens, vaccines and AMR.

Marco is a pharmacologist who has spent several years in the industry within research and development mainly in the area of anti-infectives covering different positions in preclinical and clinical development. In 2005 he joined the EMA as scientific administrator in the scientific advice and orphan drugs sector, specifically being in charge of anti-infectives and vaccines scientific advice procedures. In 2009, he was appointed as head of section for anti-infectives and vaccines in the safety & efficacy Sector, Human Medicines Development and Evaluation Unit. Specialities include clinical trials and approval pathways and commercialization of antibacterial drugs and vaccines.

Evangelos Giamarellos

Professor of Internal Medicine and Infectious Diseases, National and Kapodistrian University of Athens (NKUA), Greece

He is Professor of Internal Medicine and Infectious Diseases at the Medical School of the National and Kapodistrian University of Athens since 2018. In 2012 and 2013 he served as guest Professor of the Department of Critical Care Medicine of Jena University Hospital in Germany. Since 2019 he is the director of the MSc program of Infectious Diseases at the University of Athens. His main research contribution is immunomodulation in sepsis and in auto-inflammatory disorders. He has 547 publications in international peer-reviewed journals with more than 37,000 citations and h-index 92. He has contributed to the development of clarithromycin for immunomodulatory treatment of severe infections and in the recognition of hidradenitis suppurativa (HS) as an auto-inflammatory disorder and in the licensing of adalimumab for HS treatment. He is the current chairman of the European Sepsis Alliance and the current President of the Hellenic Society of Chemotherapy. His main achievement is the approval of anakinra for COVID-19 pneumonia in adults by the European Medicines Agency and the Food and Drug Administration through the phase 2 and 3 trials SAVE and SAVE-MORE that he designed and conducted.

Günter Waxenecker

Head of the Austrian Medicines and Medical Devices Agency (AGES), Austria

Günter Waxenecker studied food science and biotechnology and holds a Masters degree in drug regulatory affairs. He has 20+ years of experience in drug development and drug regulatory affairs with a comprehensive research experience. He started in Vienna based SMEs and works since 2007 for the Austrian Federal Office for Safety in Health Care. Since 2023 he is Head of the Austrian Medicines and Medical Devices Agency.

Emer Cooke

Executive Director, European Medicines Agency (EMA)

Emer Cooke has been the Executive Director of the European Medicines Agency, based in Amsterdam, since November 2020. She also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).

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.

She has also 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 for the European Pharmaceutical Industry Association (EFPIA) and in various industry and regulatory positions in Ireland.

In 2021 she received the Muckross (her alma mater) Woman of the Year award. In 2022 she received European Movement Ireland's "European of the Year" award. In 2023 she was awarded an honorary doctorate by the Royal College of Surgeons Ireland (RCSI) University of Medicines and Health Sciences.

Marjon Pasmooij

Head of the Science Department, Dutch Medicines Evaluation Board (MEB) & Associate Professor of Drug Regulatory Science, Utrecht University (UU), The Netherlands

Marjon Pasmooij is head of the Science Department at the Dutch Medicines Evaluation Board (MEB), Associate Professor of Drug Regulatory Science at Utrecht University, and co-chair of the Regulatory Science Network Netherlands (RSNN). Marjon studied Cell Biology in Wageningen, and did her PhD at the University Medical Center Groningen on a rare genetic skin disease. Marjon heads the Science Department since 2018, and her team coordinates the Regulatory Science activities where the MEB is involved in. She is also part of

the EMA-HMA EU-Innovation Network, which facilitates the development of innovative medicines and associated technologies and aims to strengthen engagement with innovators, and is a member of the Therapeutic Scientific Committee of the International Rare Diseases Research Consortium.

Liese Barbier

Scientific Specialist, European Medicines Agency (EMA)

Liese Barbier is a scientific officer in the Regulatory Science and Innovation Taskforce at the European Medicines Agency (Amsterdam, the Netherlands). She is a pharmacist by training and holds a PhD in Pharmaceutical Sciences with focus on Regulatory Science from the Catholic University of Leuven (KU Leuven, Belgium). During her postdoc research (at KU Leuven and research stay at Stanford University, US), she focuses on advancing biosimilar evaluation and access, and investigating how medicine development and evaluation can be more patient and unmet need driven, also as part of national and European consortia. She first joined EMA in 2019, as part of the Oncology, Haematology, and Diagnostics office in the Human Medicines Evaluation Division, contributing to biosimilar evaluation and cross-Agency biosimilar initiatives. In her current role, she focuses on developing pathways to advance and facilitate regulatory science research and support academic and non-for-profit researchers with medicines and tools development.

Francesco Pignatti

Scientific Adviser for Oncology, European Medicines Agency (EMA)

Francesco Pignatti graduated as Medical Doctor. In 1995 he became Research Fellow at the EORTC Data Center in Brussels, Belgium. In 1997 he obtained a Master of Science degree in Biostatistics from the University of Limburg, Belgium. In 1999 he joined the European Medicines Agency (EMA). From 2009 to 2023, he held the position of Head of the Office of Oncology, Haematology and Diagnostics in the Human Medicines Evaluation Division. In 2023 he has been appointed as the EMA Scientific Adviser for oncology. His main regulatory science interests include cancer drug regulation, benefit-risk analysis, and stated preference studies.

Andrew Thomson

Statistician, European Medicines Agency (EMA)

Andrew Thomson is a statistician in the Taskforce dedicated to Data, Analytics and Methodology at the European Medicines Agency. He provides methodological advice and guidance across all stages of development, and across all therapeutic areas and is the lead scientific secretariat of the Methodology Working Party. He also is the lead of the Statistics subgroup of ICH E11A on paediatric extrapolation, sits on ICH E6 R3 Annex 2 group, and is the Regulatory Chair of both groups. Before joining EMA, he headed the Epidemiology Unit in the Vigilance and Risk Management of Medicines Division of the MHRA, the UK regulator and was also previously a Statistical Assessor within the Licensing Division of the MHRA.

Sophia Samodelov

Project Coordinator of the TransBioLine IHI consortium, Zurich University Hospital (USZ), Switzerland

Sophia Samodelov is currently the academic Project Coordinator of the TransBioLine IHI consortium, representing the University of Zürich. TransBioLine focuses on the development, clinical validation, and regulatory qualification, with the EMA and FDA, of novel safety biomarkers of drug-induced kidney, liver, pancreas, vascular, and nervous system injury, as useful tools to supplement in decision-making processes across clinical drug development stages.

She obtained her PhD in Biology at the Albert-Ludwigs-Universität Freiburg im Breisgau, Germany, and has a background largely based in molecular biology and translational research. She completed a post-doc within the Department of Clinical Pharmacology and Toxicology at the University Hospital of Zürich, with a focus on translational mechanistic studies surrounding drug-induced kidney and liver injury.

Franz Koenig

Associate Professor, Medical University of Vienna, Austria

Franz König is Associate Professor at the Section of Medical Statistics at the Medical University of Vienna, Austria. He is also member of the ethics committee in Vienna. From 2008 till 2010 he was seconded to the European Medicines Agency (London, UK) as statistical expert in the Unit Human Medicines Development and Evaluation. His main research interests are multiple testing, adaptive designs and interim analyses, data safety monitoring boards (DSMB) and master protocols focusing on platform trials. For example he was involved in the EU FP7- funded research project IDEAL, co-WP lead in the IMI project EU-Pearl on platform trials; and the ITN network IDEAS on early drug development studies. Currently is part of the European projects Share CTD and Invents.

Tomasz Dylag

Head of Sector for Health Industry, European Commission's Directorate General For Research And Innovation (DG RTD)

Tomasz Dyląg works at European Commission's Directorate General for Research and Innovation where he is Head of Sector for Health Industry. His responsibilities cover industrial research and innovation in the health area, fostering regulatory science and the daily follow-up of the Innovative Health Initiative (IHI), EU's flagship public-private partnership that brings together academia and the industry sectors of pharmaceuticals, medical devices, diagnostics, biotech and digital technologies. Prior to his current role, he was in charge of policy development and project management in various areas of health research and innovation including personalised medicine and new technologies. Tomasz Dyląg holds PhD in chemistry from the Jagiellonian University in Kraków, Poland, with special interest in pharmacology and neuroscience.

Niklas Blomberg

Executive Director, Innovative Health Initiative Joint Undertaking (IHI)

Dr Niklas Blomberg joined IHI as Executive Director in January 2024. He brings to the role extensive experience in both research and leadership roles in the life sciences.

A Swedish national, he has a bachelor's degree in chemistry from the University of Gothenburg, and a PhD in structural biology and bioinformatics from the European Molecular Biology Laboratory (EMBL) in Germany.

He worked as a research scientist for AstraZeneca in Sweden for 14 years, taking on increasingly senior roles in the company, and leading the establishment of a team for data driven drug discovery in the respiratory and inflammation fields. During this time, he was industry co-lead of Open PHACTS, a project funded by the Innovative Medicines Initiative (IMI), the forerunner to IHI.

In 2013, he joined the fledgling research infrastructure ELIXIR. As its founding director, he oversaw the final negotiations between the member states to formally establish and launch ELIXIR. Under his leadership, the organisation built up its operational and project management capacity, grew to include 23 member states, and secured funding from both the member states and an extensive portfolio of EU-funded projects, including projects from IMI2, the European Open Science Cloud and the European Genomic Data Infrastructure.

Bert Leufkens

Emeritus Professor of Pharmaceutical Policy and Regulatory Science, Utrecht University (UU), The Netherlands

Bert is emeritus professor of Pharmaceutical Policy and Regulatory Science at Utrecht University. He obtained his PharmD and PhD degree from the same university. He is research and policy-wise active at several (inter)national platforms on regulatory science, drug safety, pharmaceutical policy and international health (e.g. past-member EMA Pharmacovigilance Working Party 2005-2009, chair of Dutch Medicines Evaluation Board (MEB) 2007-2017, past-member of the EMA CHMP 2009-2015, past-President of ISPE, former Scientific Director of the Utrecht Centre for Pharmaceutical Policy and Regulation). He is affiliate professor at the Faculdade de Farmácia da Universidade de Lisboa and (co) authored >500 papers in peer reviewed journals, book chapters and research reports.

Steffen Thirstrup

Chief Medical Officer, European Medicines Agency (EMA)

Steffen Thirstrup is a medical doctor and board-certified specialist in clinical pharmacology and therapeutics. He holds a PhD in pharmacology and has a long background in clinical internal medicine with special emphasis on adult respiratory medicine. Additionally, Dr. Thirstrup was appointed adjunct professor in pharmacotherapy at the Faculty of Health Sciences, University of Copenhagen, in 2012.From 2004-09 Steffen Thirstrup worked at Danish Medicines Agency first as

the Danish member of CHMP at the European Medicines Agency (EMA) for five years including 10 months as joint CHMP- and CAT-member, followed by a short period as head of Danish Institute for Rational Pharmacotherapy dealing with HTA and best practice guidelines for primary care. In 2011 Prof. Thirstrup rejoined the licensing division at the Danish Medicines Agency acting as Head of

Division for Medicines Assessment and Clinical Trials. During this period Prof Thirstrup co-chaired the

European Commission's working group on market access for biosimilars medicinal products.

Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands.

Rosa Giuliani

Consultant Medical Oncologist, Guy's and St Thomas' NHS Foundation Trust, United Kingdom, EMA Healthcare Professional Working Party (HCPWP)

Rosa Giuliani is a consultant medical oncologist at Guy's and St Thomas' NHS Foundation Trust, London, U.K. Her main interests are breast cancer, clinical and regulatory development of innovative drugs. She served as National Expert on secondment at the European Medicine Agency, EMA, (2011-12) and core member of the EMA Scientific Advisory Group in Oncology (SAG-O, April 2012-June 2021). She is the co-chair of the Healthcare Professional Working party (2022-2025).

Claudia Louati

Head of Policy, European Patients' Forum (EPF)

Claudia Louati joined the European Patients' Forum as Head of Policy in May 2023. She leads EPF's policy and advocacy work and steers EPF's engagement with EU and international stakeholders on key policy issues. Before joining EPF, she worked for almost seven years at the Europe Office of the U.S. Food and Drug Administration, based at the U.S. Mission to the EU in Brussels, where she promoted EU-U.S. regulatory collaboration on medical products. She started her career as a communications and public affairs consultant in Brussels. Claudia holds two master's degrees in European Affairs from SciencesPo Paris and the London School of Economics.

Magda Chlebus

Executive Director of Science Policy & Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Magda Chlebus is Executive Director Scientific & Regulatory Affairs at the European Federation of Pharmaceutical Industries and Associations (EFPIA), representing the R&D-based pharmaceutical industry in Europe.

Magda and her team oversee policy and legislative developments that influence the research and regulatory environments for the healthcare industry in Europe. Their main goal is to enable fast translation of science and technology advances into research, medical and regulatory practice from medicines discovery and development to production and healthcare delivery.

Magda joined EFPIA in 1995. Her experience covers public affairs, science and innovation policies and research partnerships (including IMI and IHI). She is also a Board member of the Children's Tumor Foundation Europe since 2019.

Magda, a Polish national, holds a Master Degree in Applied Linguistics from the University of Warsaw.

Emmanuel Cormier

Head of Regulatory Science and Innovation Task Force, European Medicines Agency (EMA)

Emmanuel is the head of the Regulatory Science and Innovation Task force since November 2023. He has 25 years of leadership experience in all phases of drug and vaccine development. His experience is cross-functional (Discovery, CMC, Clinical development and operation, regulatory science) and cross-sectorial in both Pharm and Medical Devices. He has recently emphasized development in the field of Health data, AI, RWE and the European Health Data Space framework, by taking a leading role in European Commission-funded Public-Private-Partnership program.

Emmanuel holds a PhD in Molecular Virology from the University of Paris VII. He also holds a Master of Sciences in Microbiology and Medical Virology from the University of Paris VI, France.