# HMA/EMA Big Data Stakeholder Forum 2024

**28 November 2024 (09:00 – 17:30 CET)**

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

As the journey towards data-driven medicines regulation continues, a new phase for the regulatory network is starting. The value of real-world data for evidence generation is becoming more established and technological advances, e.g. in the area of artificial intelligence (AI), have occurred more rapidly than originally anticipated. At the same time, the EU Network is accelerating its efforts to strengthen data governance, to share more data across the Network and to foster high level of data interoperability and standardization.

The fifth annual Big Data multi-stakeholder forum will take place on 28 November 2024 at the EMA building in Amsterdam.

It aims to:

- Inspire with keynotes speakers;
- Discuss progress on evidence generation, interoperability, use and exchange of medicines data across the EU network, to support regulatory decision-making and improve medicines development and the EU;

- Inform the fifth update of the HMA-EMA Big Data Steering Group workplan and therefore strengthen collaboration with stakeholders and partners on the delivery of the data activities included the Network Strategy.

Join us in person to guide the future of data-driven medicines regulation while enjoying a networking lunch, engaging in insightful discussions, and connecting with EU regulators, industry leaders, innovators, patients and data enthusiasts.

# HMA/EMA Big Data Stakeholder Forum 2024

## 09:00 Joining and technical checks

## 09:30 Welcome and introduction

**Peter Arlett (EMA)** 5'
EMA, BDSG co-chair

## 09:35 Opening remarks

*Incorporating patients' voices and collaboration across the EU regulatory network is at the core of the work of the Big Data Steering Group to enable a data driven decision-making. The forum will be opened by an Heads of Medicines Agencies (HMA) lead on the European Medicines Agencies Network Strategy to 2028 and a patient representative. In a keynote speech, the European Commission will provide its vision and priorities in the context of the new EU presidency and European Parliament, and several ongoing key European initiatives.*

**Rui Santos Ivo** 5'
Infarmed, PT

**Marco Greco** 5'
European Patients' Forum

**Keynote: Lorena Boix Alonso** 15'
European Commission

## 10:00 Session 1: Implementation of the HMA/EMA Big Data Task Force priority recommendations

Chairs: Eleonora Agricola (AIFA, BDSG member), Claus Moeldrup (DKMA, DK)

*This year will mark the fifth year on the journey to realise HMA/EMA vision of a data-driven regulatory system. Guided by the Big data steering group workplan 2023-2025, this session will look at the key progress on the delivery of the HMA/EMA big data priority recommendations and hear from stakeholders on gaps and priorities.*

**5th year into our journey for a data-driven regulatory system** 20'
Peter Arlett (EMA, BDSG co-chair)

**Veterinary big data strategy and workplan implementation** 10'
Paul Lynn (EMA, BDSG member)

**Panel discussion with stakeholders' representatives:** 30'
*Learnings, gaps and priorities for the future*

- Regulator: Bruno Sepodes (Infarmed, CHMP chair)
- Industry/SME: Jing Wang-Silvanto (Astellas, EFPIA)
- Patients: Marco Greco (EPF)
- HCP: Rosa Giuliani (HCPWP co-chair)

- Academia: Helga Gardarsdottir (Utrecht University)
- HTA bodies: Camille Thomassin (HAS)

Open questions and answers 15’

## 11:15 Coffee break

## 11:30 Session 2: Evidence generation to advance regulatory excellence, here and now

Chairs: Kristin Karlson (MPA, BDSG member), Patrice Verpillat (EMA, BDSG member)

*This session will explore the critical role of evidence generation in enhancing regulatory decision-making and the key progress being made for the use of real-world data and clinical trial raw data. In this context,* convergence with international *partners also remains essential.*

**Seeing the totality of evidence generation** 15’
Bruno Sepodes (Infarmed, CHMP chair)

**Analysis of RWD to support regulatory decision-making** 15’
Patricia McGettigan (PRAC, BDSG member)

**International collaboration progress** 10’
Melissa Kampman (Health Canada)

**Clinical study data pilot – interim results and learnings** 15’
Florian Klinglmueller (AGES, BDSG member)

Panel discussion with stakeholders’ representatives: 30’
*Learnings, gaps and priorities for the future*

- Industry/SME: Juha-Pekka Perttola (Roche)
- Patients: Christine Dehn (European Heart Network)
- Regulator: Peter Mol (MEB, NL)
- Academia: Antoine Pariente (University of Bordeaux)
- Academia: Mira Zuidgeest (UMC Utrecht)
- HTA bodies: Camille Thomassin (HAS)

Open questions and answers 10’

**Key takeaways from BDSG** 10’
Ana López de la Rica Manjavacas (AEMPS, BDSG member)

## 13:15 Lunch break

## 14:00 Session 3: Evidence generation to advance regulatory excellence, preparing for tomorrow

Chairs: Christian Roes (MWP chair, Radboud UMC), Flora Musuamba Tshinanu (SAWP, BDSG member)

*With a changing regulatory and technological landscape, the regulatory network needs to seize every opportunity to generate of evidence from diverse types of data, e.g. pharmacogenomic data, social media data and mobile health data. This session will continue to explore the future of evidence generation in enhancing regulatory decision-making.*

**Harnessing the value of genomics data for evidence generation** 10'
Jessica Mwinyi (MPA)

**Unlocking the potential of mHealth data for evidence generation** 10'
Denise Umuhire (EMA)

**Can social media data be used to support evidence generation?** 10'
Eleonora Agricola (AIFA, BDSG member)

Panel discussion with stakeholders' representatives: 30'
*Learnings and priorities for the future*

- Industry/SME: Lianna Ishihara (GSK, EFPIA)
- Patients: Angela Bradshaw (Alzheimer Europe)
- Regulator: Carla Torre (Infarmed, BDSG member)
- Ethic representative: Anne Cambon-Thomsen (BDSG member)

Open q*uestions and answers* *10'*

## 15:10 Coffee break

## 15:30 Session 4: Unlocking the value of data with the EMRN network data strategy

Chairs: Georg Neuwirther (AGES, NDB member), Hilmar Hamann (EMA, NDB co-chair)

*Increasing the value of data for the benefit of public and animal health is the network vision on data. This session will explore how to maximise the generation of evidence, the use and exchange of data to support regulatory decision-making. For this, a robust network data strategy is essential to ensure the network data assets are appropriately managed and have a high level of interoperability, standardisation and quality.*

**Building a unified Network data strategy for operational excellence** 15'
Georg Neuwirther (AGES, NDB member)

**Engaging with the objectives of the Network data strategy:** 45'

- Data Governance, Data Cataloguing and Metadata Management
  Hans-Joachim Bigalke (EDQM, NDB member)
- Data Quality Management and Interoperability
  Isabel Chicharo (EMA, NDB member)

- Analysis of data and use of tools, Knowledge and change management
  Kristine Aasen (NOMA, NDB member)

Panel discussion with stakeholders' representatives: 30'
*Feedback and priorities for the future*

- Industry/SME: Marieke Schoonen (Amgen, EUCOPE)
- Patients: George Paliouras (BDSG member)
- HCP: Ioana Agache (EAACI, BDSG member)
- EC: David Asturiol (EC, DG SANTE)
- ISO: Christian Hay (ISO/TC 215, WG6 convenor)
- Ethic representative: Anne Cambon-Thomsen (BDSG member)

Open *questions and answers* *15'*

## 17:15 Closing remarks

**Wrap up** 15'
Peter Arlett (EMA, BDSG co-chair)

## 17:30 End of the forum

## List of speakers

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| **Ana López de la Rica Manjavacas** | Spanish Regulatory Authority (AEMPS), ES |
| **Angela Bradshaw** | Alzheimer Europe |
| **Anne Cambon-Thomsen** | National Centre for scientific research (CNRS), FR |
| **Antoine Pariente** | University of Bordeaux |
| **Bruno Sepodes** | CHMP chair, INFARMED, Universidade de Lisboa (Portugal), PT |
| **Camille Thomassin** | Haute Autorite de Sante (HAS), FR |
| **Carla Torre** | CHMP, INFARMED, BDSG member |
| **Christian Hay** | ISO/TC 215, WG6 convenor |
| **Christian Roes** | Methodology Working Party (MWP) chair, Radboudumc |
| **Christine Dehn** | German Heart Foundation, DE |
| **Claus Møldrup** | Danish Medicines Agency (DKMA), DK |
| **David Asturiol** | DG SANTE, European Commission |
| **Denise Umuhire** | European Medicines Agency (EMA) |
| **Eleonora Agricola** | Italian Medicine Agency (AIFA), IT |
| **Flora Musuamba Tshinanu** | Belgian federal medicines agency (FAMHP), BE |
| **Florian Klinglmueller** | Austrian Agency for Health and Food Safety (AGES), AT |
| **Georg Neuwirther** | Austrian Agency for Health and Food Safety (AGES), AT |
| **George Paliouras** | National Centre for Scientific Research (NCSR) "Demokritos"; DDF |
| **Hans-Joachim Bigalke** | European Directorate for the Quality of Medicines & HealthCare, EDQM, FR |
| **Helga Gardarsdottir** | Utrecht University, NL |
| **Hilmar Hamann** | European Medicines Agency (EMA) |
| **Ioana Agache** | European Academy of Allergy and Clinical Immunology (EAACI) |
| **Isabel Chicharo** | European Medicines Agency (EMA) |
| **Jessica Mwinyi** | Swedish Medical Products Agency (MPA), Uppsala University, SE |
| **Jing Wang-Silvanto** | Astellas Pharmaceutical Ltd |

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| **Juha-Pekka Perttola** | People and Products Leader, Roche |
| **Kristin Karlsson** | Swedish Medical Products Agency (MPA), MWP vice-chair, SE |
| **Kristine Aasen** | The Norwegian Medical Products Agency (NOMA), NO |
| **Lianna Ishihara** | GSK, EFPIA |
| **Lorena Boix Alonso** | DG SANTE, European Commission |
| **Marco Greco** | European Patients' Forum (EPF) |
| **Marieke Schoonen** | Amgen, EUCOPE |
| **Melissa Kampman** | Health Canada (HC) |
| **Mira Zuidgeest** | University Medical Center (UMC) Utrecht, NL |
| **Patrice Verpillat** | European Medicines Agency (EMA) |
| **Patricia McGettigan** | Queen Mary University of London (QMUL), UK |
| **Paul Damien Lynn** | European Medicines Agency (EMA) |
| **Peter Arlett** | European Medicines Agency (EMA) |
| **Peter Mol** | Medicines Evaluation Board (CBG-MEB), NL |
| **Rosa Giuliani** | Healthcare Professionals' Working Party (HCPWP) co-chair |
| **Rui Santos Ivo** | INFARMED, PT |

## About the speakers

**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. He has more than 21 years of experience in Regulatory Affairs and among them 14 years in the AEMPS. He has also been working in the Pharmaceutical Industry and in Farmaindustria, the National Trade Association of Innovators.

He 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.

**Angela Bradshaw**

*Director for Research & Policy, Alzheimer Europe*

Dr. Angela Bradshaw is Director for Research & Policy at Alzheimer Europe, an umbrella organisation of national Alzheimer's Associations with 41 members from 37 countries across Europe. Alzheimer Europe aims to change perceptions, practice and policy, promoting a rights-based approach to dementia and working to make dementia a European priority. Angela obtained her PhD in vascular biology at the University of Cambridge in 2008. Prior to joining Alzheimer Europe in 2019, she worked as an assistant professor at the University of Glasgow, leading translational projects on vascular diseases associated with aging. At Alzheimer Europe, Angela leads stakeholder engagement and communications workstreams for a number of EU-funded research projects involving AI, data sharing and risk prediction, also developing policy positions and representing the organisation in working parties and steering committees at EU level.

**Anne Cambon-Thomsen**

*MD, Honorary research director CNRS, Centre of Epidemiology and Research on POPulation health, CERPOP, Inserm, University of Toulouse, France*

French medical doctor specialised in human immunogenetics and health ethics, she works on societal aspects of new technologies in health, especially genomics, and on Open Science. She co-leads an ELSI working group of the French plan of genomic medicine, is a member of the Ethics advisory board of the GDI (European Genomic Data Infrastructure) and of the EMA Big Data Steering Group (as ethics expert). She has been member of the CCNE, the European Group on Ethics (EGE), other scientific and ethics bodies or expert groups. Her Open Science (OS) activities are within the National French Plan and the Research Data Alliance.

**Antoine Pariente**

*Professor of Pharmacology and Director of the Public Health Department at the University of Bordeaux, FR*

Antoine Pariente is Professor of Pharmacology and Director of the Public Health Department at the University of Bordeaux. He leads the Inserm AHeaD research team with work both in pharmacoepidemiology (essentially in specifically in cardiovascular and mental health) and pharmacovigilance (signal detection methods). In these, he specifically contributed to optimize disproportionality analysis techniques. Since 2015, Antoine Pariente coordinates the DRUGS-SAFE® pharmacoepidemiology center, funded by the French ANSM to help guiding decision-making. In 2019, he founded the French Working Group for Pharmacoepi that originated the French Pharmacoepi Initiative, a national research network. He was member of the EMA PRAC as independent expert from 2018 to 2021 and is a founder of the ISOP SIG in Big Data.

**Bruno Sepodes**

*CHMP Chair, INFARMED, PT*

A Portuguese national, Bruno Sepodes is a specialist in pharmacology and pharmacotherapy with a master's degree in Regulatory Science from University of Lisbon, and a Master of Public Health from Johns Hopkins University (USA). He has worked as senior expert for INFARMED, the Portuguese National Authority for Medicines and Health Products, since 2005. Sepodes has extensive experience working with EMA, notably as member and vice-chair of the CHMP, member of the Committee for Advanced Therapies (CAT), member and chair of the Committee for Orphan Medicinal Products (COMP), and co-chair of EMA's Emergency Task Force (ETF)..

**Camille Thomassin**

*Head of the real-world data coordination unit, Haute Autorite de Sante (HAS)*

Camille Thomassin, PharmD, has been head of the real-world data coordination unit at the HAUTE AUTORITE DE SANTE (HAS) since October 2022. The unit's mission includes: coordinating the implementation and monitoring of post-reimbursement studies, as well as data collection for early access to medicines. The unit is also committed to meeting and supporting the holders of French and European registers and databases in the generation of data relevant to the HAS's assessment of healthcare products and technologies. The unit will also provide in-house methodological support for the production of Joint Clinical Assessments from January 2025. Previously, until 2017, Camille Thomassin was a benefit/risk assessor at the AGENCE NATIONALE DE SECURITE DU MEDICAMENT ET DES PRODUITS DE SANTE. Then, from 2017 to 2022, she prepared dossiers for the Transparency Commission in the context of drugs' appraisal. At HAS, she also coordinated the production

of scientific advices requested by pharmaceutical companies for drugs and activities with an international dimension, in anticipation of the implementation of the European HTA regulation. Camille Thomassin is also the HTA alternate member at the advisory board of DARWIN EU.

**Carla Torre**

*CHMP, INFARMED, PT*

Assistant Professor of Pharmacoepidemiology, Pharmacovigilance/Risk Management at the Faculty of Pharmacy of the University of Lisbon (UL), Portugal. Carla Torre graduated in Pharmaceutical Sciences, holds a master's degree in Epidemiology and a PhD in Pharmacoepidemiology. She leads the Epidemiology, Pharmacoepidemiology & Pharmacovigilance sub-group at the Research Institute for Medicines hosted at UL. Carla Torre is member of the Evaluation Board of Medicines of the Portuguese National Authority of Medicines and Health Products (INFARMED), co-opted member for Pharmacoepidemiology of the Committee for Medicinal Products for Human Use (CHMP), alternate member of the Pharmacovigilance Risk Assessment Committee (PRAC) and Methodology Working Party member at the European Medicines Agency.

**Christian Hay**

*ISO/TC 215, WG6 convenor*

Christian Hay is the ISO TC/215 WG6 Convenor since 2012. He is engaged with GS1 Global Office as liaison with Standards Development Organisations for several years, to link the supply chains standards with the health informatic domains. Christian had several responsibilities in the Health Informatic space, with IHE Switzerland, Swiss Society for Medical Informatics, University of Applied Sciences Bern, or the Joint Initiative Council for Global Health Informatics Standardization (JIC) among others. ISO TC/215 WG6 is the organisation which developed the set of standards "Identification of Medicinal Products" (IDMP) for nearly 2 decades; in the mean time ISO has engaged a "SMART" strategy which drives to direct machine usable standards; at WG6 this is reflected with increased activities on Ontologies.

**Christian Roes**

*Professor of Biostatistics, Radboud University Medical Center*

Kit Roes is Professor of Biostatistics at Radboud University Medical Center Nijmegen (Netherlands). He is chair of the Methodology Working Party of the European Medicines Agency, and senior assessor at the Dutch Medicines Evaluation Board. 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.

**Christine Dehn**

*Manager Patient Representation & EU Affairs, German Heart Foundation, DE*

Christine Dehn joined the German Heart Foundation more than 20 years ago. As a patient representative she strongly advocates for patient needs, concerns and thoughts in national, as well as international contexts. She a member of the Patient and Consumer Working Party (PCWP) on behalf of the European Heart Network (EHN) where she represents the CVD patient view. Her mission within the German Heart Foundation is to ensure that the patient's voice is heard whenever it's about the patient – be it in political discussions, research projects or clinical settings.

**Claus Møldrup**

*Director Data Analytic Center, Danish Medicines Agency, DK*

Claus Møldrup holds a PhD /Post. Doc. in pharmacy. Before his current position, he was a full professor and head of department at the University of Copenhagen in the research field of Social pharmacy. Later he joined Big Pharma as commercial director and founded two health tech companies focusing on RWE in relation to pharmaceutical products.

**David Asturiol**

*Policy officer at Digital Health Unit of DG SANTE, European Commission*

David Asturiol is a policy officer at the European Commission's Directorate-General for Health and Food Safety (DG SANTE), where he focuses on the implementation of the European Health Data Space (EHDS), particularly on the secondary uses of health data. He has also worked on the coordination of the European Reference Networks for Rare Diseases and contributed to the implementation of the European Union Digital COVID-19 Certificate.

With over 15 years of research experience in chemical toxicity, molecular modelling, and data science, Mr. Asturiol has authored more than 30 peer-reviewed publications. His expertise includes developing computational models to promote and advance predictive toxicology.

**Denise Umuhire**

*Pharmacoepidemiologist & RWE specialist, EMA*

Member of the RWE workstream that provides support on RWE related matters to different evaluation committees, delivering rapid analyses of RWD to answer regulatory related research questions.

Current responsibilities include leading some RWE studies using inhouse databases or via DARWIN EU, co-leading the EMA use case within the EHDS pilot and facilitating the work around the use of patient experience data in regulatory context. Background training is in biostatistics and health economics with more than 15-years prior experience on evidence generation to support HTA and payers decision-making.

**Eleonora Agricola**

*PhD, Innovation Office and Scientific Advice EMA, AIFA, Italian Medicine Agency, IT*

Having specialised in molecular biology as PhD, Eleonora has experienced a research activity in epigenetics and cancer. She then moved to a different research field focused on paediatric innovation and the use of web data for monitoring health events in the general population. Eleonora currently holds a position at Italian Medicines Agency's Innovation Office. She is member of European Innovation Network and the Big Data Steering Group.

**Flora Musuamba**

Pharmacist, Belgian federal medicines agency (FAMHP), BE

Flora Musuamba is a Pharmacist by background and holds a Ph.D. in Pharmacy and biomedical sciences from Université Catholique de Louvain, in Belgium.

She is a Pharmacometrics and Pharmacovigilance internal expert at the Belgian federal medicines agency (FAMHP).

Flora Musuamba is the Chair of the European Medicines Agency Modelling and Simulation European Specialised Expert Community (ESEC) and the Modelling and Simulation Operational Expert Group (OEG) and a member of the methodology (MWP) and scientific advice working parties (SAWP) at the European medicines agency (EMA).

She is also Professor of Clinical Pharmacology and Pharmacotherapy at University of Namur.

Flora is currenty coordinating the Horizon-Europe project ERAMET.

**Florian Klinglmueller**

*Expert Group Statistics Lead, Austrian Agency for Health and Food Safety (AGES), AT*

Florian Klinglmueller leads the Expert Group Statistics at the Austrian Agency for Health and Food Safety. He is a member of EMA's Methodology Working Party, Big Data Steering Group and Emergency Task Force. Florian holds a PhD in Mathematics and before joining the regulatory agency has spent several years in academic research focusing on clinical trial design, statistical computing and bioinformatics.

**Georg Neuwirther**

Head of IT Austrian Medicines and Medical Devices Agency (AGES MEA), AT

As Head of IT at AGES MEA, he is responsible for the agency's IT strategy and portfolio management, with a focus on solutions that enable innovation in business processes. This includes efficient data and process integration in EU and national initiatives. As a result, Mr Neuwirther introduced a new IT system called PHAROS, which replaced legacy systems. This flexible solution is the basis for ongoing and further developments and integration into Europe-wide initiatives.  Mr. Neuwirther was also a topic leader in the EU funded Horizon 2020 UNICOM consortium that supported ISO-IDMP implementation in the European Medicines Regulatory Network (EMRN)

Mr Neuwirther works closely with colleagues in the EMRN and the EMA/HMA governance, e.g. as a member of the IT Directors group and member of the EU Network Data Board.

Mr Neuwirther holds a degree in Computer Science from the Vienna University of Technology (TU Wien) and has held various IT consulting and management positions for 21 years. He has extensive experience in the execution of complex projects, software development and the transformation of IT organisations and business processes. He focuses on creating business value through agile methodologies with a clear strategic focus and dedicated execution of the portfolio.

**George Paliouras**

*Duchenne Data Foundation (DDF), The Netherlands. National Centre for Scientific Research (NCSR) "Demokritos", Greece*

Father of a boy with Duchenne Muscular Dystrophy and voluntary Chairman of the board for DDF. Research Director at NCSR "Demokritos", board chairman of the Intelligence Information Systems division. Has performed research in Artificial Intelligence and Machine Learning for more than 30 years, coordinated research projects, taught courses and co-founded tech companies.

**Hans-Joachim Bigalke**

*Head of the Publications and AI Division, European Directorate for the Quality of Medicines & HealthCare (EDQM), FR*

Hans-Joachim Bigalke studied pharmacy at the University of Würzburg (Germany) and became a pharmacist in 1984. After his military service in the analytical department of a hospital pharmacy in Kiel (Germany), he worked in the University of Würzburg from 1985, where he obtained his PhD in analytical pharmacy in 1990. In 1990 he joined the Springer-Verlag in Heidelberg (Germany), where he continued his work in the organisation team for 'Hagers Handbuch der Pharmazeutischen Praxis', which he had already begun earlier as a freelancer. From 1993 to date he has been working with the Technical Secretariat of the European Pharmacopoeia, now EDQM, first as the Secretary of groups of experts (organic chemistry) and currently as Head of the Publications and AI Division. He holds Certificates, amongst others, in TOGAF and CISA (Certified Information Systems Auditor).

**Helga Gardarsdottir**

*PharmD, PhD. Professor in use of RWD for decision making on medicines, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht University, NL*

Prof. Gardarsdottir is a trained pharmacist (SE) and pharmacoepidemiologist (NL). Her research focuses on the application and development of innovative approaches to generate and analyze real-world data on the safety and effectiveness of medicines for regulatory and clinical decision-making. She has led or participated in several international research projects, as well as multiple EMA-tendered studies through the EU Pharmacoepidemiology and Pharmacovigilance Research Network. She is currently the co-chair of the ENCePP steering group.

**Hilmar Hamann**

*Head of Information Management Division, EMA*

Dr. Hilmar Hamann joined the European Medicines Agency in January 2020 as the Head of Information Management with a focus on modernizing IM capabilities and implementing EMA's vision for a modern, efficient and data-driven agency of the future.

Prior to joining EMA from 2011 to 2020, he served as the Director for Business Informatics at the U.S. Food and Drug Administration leading the transformation of medicines regulatory data, advancing data analytics, and modernizing the scientific computational and collaboration platforms that underpin operations.

From 1996 to 2011, Dr. Hamann worked at a leading international consumer goods company in client-facing IT management roles bridging the communication gap between business and IT, where he led large-scale enterprise IT initiatives to transform commercial, manufacturing and supply chain operations across Pharmaceuticals, Health and Beauty Care business units.

Dr. Hamann received his Ph.D. and Master's Degree in Chemistry from the University of Göttingen where he worked on experimental and theoretical investigations in the field of molecular physics and chemical kinetics and the development of complex algorithms for simulating and modeling intra-molecular dynamics of small molecules in the stratosphere. He was awarded the FedHealthIT 100 Award three years in a row between 2018-2020 and received the FedHealthIT Innovation Award in 2018.

**Ioana Octavia Agache**

*Faculty of Medicine, Transylvania University Brasov, RO*

Ioana Agache is Professor of Allergy and Clinical Immunology at Transylvania University, Brasov, Romania and Past President of the European Academy of Allergy and Clinical Immunology (EAACI) 2017-2019 and past Chair of the EAACI Research and Outreach Committee. Her research in the field of Asthma and Allergy and Clinical Immunology focuses on asthma phenotypes and endotypes, biomarkers, immune modulation, AI/machine-learning and integrated management of allergic diseases, with a special focus on exposomics and One Health.

**Isabel Chicharo**

*Head of Regulatory Data Management, EMA*

I am responsible for Regulatory Master Data Management Services, currently on Substances, Products, Organisations and Referential data (also known as SPOR) as well as xEVMPD/Art 57 data. I also coordinate the implementation of ISO IDMP in EU.

I have a Pharmacy Masters degree, a post graduate degree in Pharmaceutical regulation and over 20 years of data management experience in the field of Medicines.

My past experience covers clinical pharmacy in a Hospital, a Software company producing medical dictionaries for Pharmacies and the Portuguese authority (INFARMED). Since 2008 I have worked for EMA where I have been involved in or coordinated many projects (e.g. EUTCT, ECD, SIAMED II implementation, Data Integration/SPOR...). As a Head of service, in addition to data management, I have also been responsible for areas such as standards and enterprise content management.

**Jessica Mwinyi**

Associate Professor, *MPA Sweden and Uppsala University, SE*

Jessica Mwinyi, MD, MSc in Bioinformatics, PhD, and Associate Professor of Clinical Pharmacology, has expertise in pharmacology, bioinformatics, and regulatory science. She currently holds a position as Adjunct Senior Lecturer at the Swedish Medical Products Agency (Läkemedelsverket) and Uppsala University, Sweden. As an assessor in the area of vaccines/infectious diseases at the MPA Sweden since 2016, she joined the ESEC leadership group in pharmacogenetics at the European Medicines Agency (EMA) in 2023/2024. In parallel, she holds an academic role at Uppsala University, focusing on precision medicine, particularly in pharmacogenomics, neurovascular diseases including migraine, and metabolic diseases, with a strong scientific publication track record in these areas.

Her academic journey includes serving as a Docent and Scientist at University Hospital Zurich, Switzerland, for several years. She also gained scientific and clinical experience at the Clinical Pharmacology Department, Karolinska Hospital, and the Karolinska Trial Alliance in Stockholm, and by conducting research in pharmacogenetics during her PhD (Molecular Genetics) at the Karolinska Institute, Stockholm, Sweden.

Dr. Mwinyi's educational background includes medical studies at the Free University Berlin and Humboldt University Berlin, Germany, an MSc in Bioinformatics from the Free University of Berlin, and an MD thesis from Charité, Humboldt University. She is a Certified Specialist in Clinical Pharmacology in Germany, Sweden, and Switzerland.

**Jing Wang-Silvanto**

*Senior Director, Global Health Economics Outcomes Research, Astellas Pharmaceutical Ltd*

Jing Wang-Silvanto currently represents Astellas Pharmaceutical Ltd at the European Federation of Pharmaceutical Industries and Associations (EFPIA) in the Integrated Evidence Generation and Use (IEGU) group, where she plays a key role interacting with HMA/EMA Big Data Stakeholder Forum, advocating for efficient integration of real-world data and evidence (RWD/E) to enhance regulatory and HTA decision-making processes. Previously holding senior roles at leading pharmaceutical companies such as GlaxoSmithKline, Novartis, and Bristol-Myers Squibb, she focused on driving the pharmaceutical industry towards a more data-centric, patient-accessible future; her work at these forums is critical in shaping Europe's evolving data-driven regulatory landscape, the future of healthcare systems across Europe and beyond, promoting collaboration between industry stakeholders, regulatory bodies, and patient groups.

**J-P Perttola**

*People and Products Leader, Roche*

J-P started his journey of analysing clinical data in 2000 at Leiras Finland. Since relocating to Roche Basel in 2006 he has been a Statistical Programming project lead and manager over several large-scale molecule projects. Currently he works in a team establishing ways for Roche Data scientists to deliver the portfolio innovatively and efficiently. J-P holds an MSc in Statistics from the University of Helsinki and is a firm believer that through open collaboration we can fundamentally improve the way we build Data Science products to help patients.

**Kristin Karlsson, PhD**

*Senior assessor of pharmacometrics at the Swedish Medical Products Agency*

Kristin Karlsson is currently employed as a senior assessor of pharmacometrics at the Swedish Medical Products Agency and is the vice-chair of the EMA Methodology Working Party. Kristin Karlsson has been part of the pharmacometrics community for 20 years and has experience with modelling and simulation within regulatory assessment, academic research, and the pharmaceutical industry. Kristin Karlsson has an MSc in Chemical Engineering and earned a PhD in Pharmacometrics at Uppsala University, Sweden. Furthermore, Kristin is the regulatory chair of the ICH M15 expert working group (Model Informed Drug Development), and a previous member of the ICH E11A expert working group and the former SE delegate of EMA Paediatric Committee (PDCO).

**Kristine Aasen**

*Enterprise Architect, The Norwegian Medical Products Agency (NOMA), NO*

Kristine Aasen has the role as senior enterprise architect in NOMA. In this role she is working for national and international interoperability through data standardisation. Kristine has a master's degree in information science, and she is certified for TOGAF and ITIL. Her experience spans from work with master data, to primary use of data in hospital and to secondary use of data for research. Kristine is a member of the European Medicines Agency's Network ICT Advisory Committee and has been a member of the Network Data Board.

**Lianna Ishihara**

*Sr Director, Real World Data Strategy and Partnerships, GSK*

Lianna is an experienced epidemiologist who has been working with Real World Data for over 20 years in the pharmaceutical industry. She is passionate about improving human health through science, innovation, technology and collaboration.

**Lorena Boix Alonso**

*Deputy Director General for Health in the Directorate General for Health and Food Safety (DG SANTE), EC*

Lorena Boix Alonso is Deputy Director General for Health in the Directorate General for Health and Food Safety (DG SANTE), at the European Commission. Formerly, she worked in the Directorate General for Communications Networks Content and Technology (DG CONNECT), where she held the positions of Director for Digital Society, Trust and Cybersecurity - covering e-health, e-identification, privacy and cybersecurity-, as well as Acting Director for Policy Strategy and Outreach, Head of Unit for Policy Implementation and Planning and Head of Unit for Converging Media and Content. Previously, she was Deputy Head of Cabinet of Vice President Neelie Kroes, Commissioner for the Digital Agenda and also during Ms Kroes' mandate as Commissioner for Competition. She joined the European Commission, in the Directorate-General for Competition, in 2003. Prior to the Commission, she worked at the European Court of Justice, as well as Deputy Director and Legal Coordinator of the IPR-Helpdesk Project and in private practice in Brussels. She holds a Master of Laws from the Harvard Law School and a Licence Spéciale en Droit Européen from the Université Libre de Bruxelles. She graduated in Law from the University of Valencia.

**Marco Greco**

*President of the European Patients' Forum*

Marco Greco has been President of the European Patients' Forum since 2014.

He was chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) from 2008 to 2014. He was the founder of the EFCCA Youth Group, and its leader from 2003 till 2007.

He was appointed as patient representative by the European Commission in the Pharmacovigilance Risk Assessment Committee at the European Medicines Agency (EMA) from 2013 to February 2019. He has recently been selected as patient representative to EMA's Management Board for a three-year term starting on 15 June 2019.

He holds a degree in Law from UCSC MILAN and a Ph.D. in Law and Religious Freedom. He is currently working as an attorney in his law firm.

**Marieke Schoonen**

*PhD, Senior Director Observational Research, Amgen*

Marieke Schoonen is a Senior Director of Observational Research in Amgen's Center for Observational Research, where she leads the European team of epidemiologists, data scientists and programmers, who generate real-world evidence (RWE) that helps inform healthcare decision-making across the drug development lifecycle. Marieke has 18 years of experience working as epidemiologist in the pharmaceutical industry. She obthelned an MSc in Biomedical Health Sciences at Radboud University Nijmegen (the Netherlands) and a PhD in Pharmacoepidemiology at the London School of Hygiene and Tropical Medicine (United Kingdom).

**Melissa Kampman**

*Manager, Data Analytics and Real world Evidence Division, Health Canada*

Melissa Kampman, BSc, MSc, PhD, is a Manager and Senior Epidemiologist in Health Canada's Marketed Health Products Directorate where her team focuses on data analytics and real world evidence. Her training is in pharmacoepidemiology and pharmacovigilance. Her main areas of interest are population health, study design methodology for pharmacoepidemiologic research, drug safety and effectiveness, real world evidence, and regulatory policy and decision-making.

**Mira Zuidgeest**

*Associate Professor, University Medical Center (UMC) Utrecht, NL*

Mira Zuidgeest works as Associate Professor at the UMC Utrecht. Trained as pharmacist and epidemiologist, with a PhD in pharmacoepidemiology, her work focuses on clinical trial innovation, the interaction between methodology and operations, how RWE can be generated through interventional research and the effects of trial approaches on diversity of participants. She is academic lead of the IMI Trials@Home project (www.trialsathome.com) and board member of the GetReal Institute.

**Patrice Verpillat**

*MD, MPH, PhD*

Dr. Verpillat is the Head of the Real World Evidence (RWE) Workstream at the European Medicines Agency (EMA). He is a medical doctor, specialist in epidemiology. He has worked previously in several international pharma companies, dealing with real world data (RWD) to bring RWE into research, access and life-cycle management.

**Patricia McGettigan**

*Professor at Queen Mary University of London (QMUL), UK*

Patricia McGettigan is Professor of Clinical Pharmacology and Medical Education at Queen Mary University of London and a Consultant Physician at Barts Health NHS Trust in London, UK. She is a Fellow of the Royal College of Physicians in Ireland, the Royal Australasian College of Physicians and the British Pharmacological Society, and is a Senior Fellow of the UK Higher Education Academy. As a past seconded national expert at the European Medicines Agency, she worked extensively on the Patient Registry Initiative. Currently, she is appointed as an Independent Scientific Expert on EMA's Pharmacovigilance and Risk Assessment Committee (PRAC) and represents PRAC on the Big Data Steering Group.

**Paul Damien Lynn**

*Lead data scientist Veterinary Division, EMA*

Paul studied at Trinity College Dublin and Cambridge University and built his career working with data and technology. Since 2015 Paul has specialised in Big Data and Data Science, working on large scale transformational Big Data programs in the UK, Denmark and the Netherlands. His efforts have accelerated regulatory reporting processes and advanced multiple at-scale data analytics use cases. Now leading the Veterinary Data Analytics team, his focus is on application of technology to realise data value and implement the goals of the Veterinary Big Data Strategy.

**Peter Arlett**

*Head of Data Analytics and Methods Taskforce EMA, Co-chair HMA-EMA Big 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 Big Data Task Force 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.

**Peter Mol**

*Professor, Dutch Medicines Evaluation Board (CBG-MEB), NL*

Peter Mol is the Committee for Medicinal Products for Human Use (CHMP) member for the Dutch Medicines Evaluation Board. He was from 2012 to 2023 member (vice chair 2016-2022) of EMA's Scientific Advice Working Party. He has coordinated over 300 EMA and national scientific advice procedures for drug development programs for cardiometabolic, gynecology and hematology products. He was chair of the EMA Cross-Committee Task force on Registries (2016-2023). He is also professor of drug regulatory science at the University Medical Center Groningen. His research focus is on developing new tools to support regulatory decision-making and the exchange of knowledge between regulatory authorities, health care professionals and lay people. He is currently involved in projects around personalized medicine, new data sources (RWE), patient-centric ways to weigh drug benefit-risk; e.g., using Patient Relevant Outcomes, Quality of Life, and Patient Preference information, and on risk communication (Direct Healthcare Provider Communication). He is Principal Investigator of the HORIZON More-EUROPA project (More-Europa - Research (umcgresearch.org)).

**Rosa Giuliani**

*Co-chair of the Healthcare Professionals' Working Party (HCPWP)*

Dr Giuliani is a consultant in medical oncology working at Guy's and St Thomas' NHS Foundation Trust, London, U.K.

Dr Giuliani worked at the European Medicines Agency, EMA, as National Expert on secondment (2011-12) and continued the collaboration with EMA as core member of the EMA Scientific Advisory Group in Oncology (SAG-O) for over nine years, from April 2012 till June 2021. Dr Giuliani was Director of Public Policy of the European Society for Medical Oncology (ESMO) 2020-2022, Chair of the ESMO Global Policy Committee and was a Member of the ESMO Executive Board and ESMO Council.

On behalf of ESMO she joined the EMA Healthcare Professional Working Party (HCPWP) and she has been elected as Co-chair of the HCPWP (2022-25).

Dr Giuliani is the author of peer reviewed articles and she regularly lectures at international meetings.


**Rui Santos Ivo**

*President of INFARMED – National Authority of Medicines and Health Products, PT*

Rui Santos Ivo is currently President of INFARMED – National Authority of Medicines and Health Products, I.P. (since july 2019), and Invited Associate Professor at the Faculty of Pharmacy of the University of Lisbon in the area of Medicines Regulation (since 2009). At European level, he is the Vice-Chair of the Management Board of the European Medicines Agency (EMA) (since October 2024), and Chair of the Heads of Health Technology Assessment Agencies Group (HAG) (since September 2021). Rui Santos Ivo graduated in Pharmaceutical Sciences from the University of Lisbon in 1987. Specialist in Hospital Pharmacy by the Ministry of Health (1992) and the Portuguese Pharmaceutical Society (2006) and in Regulatory Affairs, honorary by the Portuguese Pharmaceutical Society (1997). With postgraduate training in Health Law (Faculty of Law, University of Lisbon and National School of Public Health, 1997), Pharmaceutical Medicine (University of Basel, 1999), Regulation (London School of Economics and Political Science, 1999), Management of Health Units (Portuguese Catholic University, 2000 and AESE Business School, 2015).

Gold Medal for Distinct Services by the Ministry of Health (2015).