HMA/EMA Big Data Stakeholder Forum 2023

4 December 2023 (09:00 – 17:30 CET)

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

Understanding when to have confidence in novel technologies and the evidence generated from Big Data will benefit public health by supporting medicines development, improving treatment outcomes and facilitating earlier patient access to innovative treatments.

As the journey towards data-driven medicines regulation accelerates, the fourth annual Big Data multi-stakeholder forum will take place on 4 December 2023 at the EMA building in Amsterdam (+ enabled virtual participation). It aims to:

- inspire with opportunities for the future thanks to keynotes speakers;
- discuss with stakeholders data-enabled opportunities to improve medicines development and the EU;
- inform and strengthen collaboration with stakeholders and partners on the delivery of the data activities included the Network Strategy to 2025 (fourth update of the HMA-EMA Big Data Steering Group workplan).

HMA/EMA Big Data Stakeholder Forum 2023

09:00 Joining and technical checks

09:30 Welcome and introduction

Emer Cooke 5′
Executive Director (EMA)

09:35 Opening remarks

Lars Bo Nielsen 5′
Director General (DKMA)

Olga Solomon 5′
Head of Unit D1: Medicines: policy, authorisation and monitoring, EC

Marco Greco 5′
President (EPF)

09:50 Session 1: Implementation of the HMA EMA Big Data Task Force priority recommendations

Chair: Jesper Kjær (DKMA, BDSG co-chair)

This year will mark the fourth 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 the EU Network strategy to 2025.

4th year into our journey for a data-driven regulatory system 15′
Peter Arlett (EMA, BDSG co-chair)

Questions and answers 10′

10:15 Session 2: Enabling the use and establishing the value of Real-World Evidence

Chairs: Carla Torre (CHMP, BDSG member) and Patrice Verpillat (EMA, BDSG member)

Step by step, progress is made to enable the generation of RWE and its integration into the EU regulatory and down-stream decision-making in Europe. This session will discuss enabling the discoverability of data sources and observational studies, work to improve data quality in EU, learnings and future plans from DARWIN EU®, RWE pilots and participation in the EHDS2 pilot, and progress on convergence with international partners.

How are RWE transforming the EU regulatory network 10′
Christian Roes (MWP chair, Radboudumc)

Changing the discoverability and data quality of EU data ecosystem 15'
Susana Perez-Gutthann (RTI Health Solutions, ENCePP)

EHDS2 pilot first insights 10'
Denise Umuhire (EMA)

Progress on convergence with international partners 10'
Melissa Kampman (Health Canada)

Front row comments with speakers and additional stakeholders' representatives: 25'

- Payers: Wim Goettsch (Zorginstituut Nederland, Special Advisor HTA)
- Industry/SME: Álmath Spooner (AbbVie, EFPIA), Marieke Schoonen (Amgen, EUCOPE)
- Patients: Nikos Dedes (Greek Patients' Association)
- Health care professional: Kimmo Porkka (EHA)

Questions and answers 15'

11:40 Coffee break

11:55 Session 3: Patient Experience Data (PED): realising the potential of PED in EU medicine regulation

Chairs: Julian Isla (DSEF) and Juan Garcia Burgos (EMA, BDSG member), Peter Arlett (EMA, BDSG co-chair)

Reinforcing patient relevance in evidence generation is a key priority in the EMA's Network Strategy and the realisation of a data-driven regulatory network. Despite much progress in the EU in recent years, more efforts are needed to include Patient Experience Data (PED) in development and regulation. This session will discuss the current state of play, challenges and opportunities for enhancing impactful use of PED, and ultimately establish the value of PED in regulatory decision making and beyond.

State of play and ongoing regulatory initiatives 10'
Rosa Gonzalez-Quevedo (EMA)

What is needed by EU regulators 15'
Bruno Sepodes (CHMP Vice-Chair, INFARMED) and Sabine Straus (PRAC chair, MEB)

BDSG workplan opportunities to enhance use of PED for regulatory decision making 15'
George Paliouras (NCSR "Demokritos"; DDF)

Front row comments with speakers and additional stakeholders' representatives: 30'

- Industry: Ebony Dashiell-Aje (BioMarin, EuropaBio)
- Patients: Maria Cavaller Bellaubi (EURORDIS) and Begonya Nafria Escalera (Saint Joan de Deus Children's Hospital)
- Health care professional: Despoina Makridaki (EAHP)
- Academia: Lonneke van de Poll-Franse (NCCO, NCI, TiU)

Questions and answers 10'

13:15 Lunch break

14:15 Session 4: Novel technologies and methods driving changes in evidence generation in medicines regulation

Chair: Jesper Kjær (DKMA, BDSG co-chair) and Kristin Karlsson (MPA, MWP vice-chair, BDSG member)

This session will explore some of the novel technologies and methods for evidence generation that could impact EU medicines regulation now and, in the future, such as artificial intelligence, large language models, quantum computing, digital twins and others.

Regulatory preparedness on Artificial Intelligence: AI workplan 10'
Gabriel Westman (MPA, BDSG member)

Front row comments with speakers and stakeholders' representatives 10'

Quantum computing: a game-changing approach for drug development 10'
Albert H. Werner (University of Copenhagen)

Front row comments with speakers and stakeholders' representatives 10'

Advances in digital technologies to enable collection of Patient Experience Data 10'
Julian Isla (DSEF)

Front row comments with speakers and stakeholders' representatives 10'

Use of external data to accelerate evidence generation: digital twins and external controls 10'
Holger Fröhlich (Fraunhofer SCAI)

Front row comments with speakers and stakeholders' representatives 10'

Disrupting drug surveillance with transformer models 10'
Mads Nielsen (University of Copenhagen)

Front row comments with speakers and stakeholders' representatives 10'

Questions and answers 10'

Front row comments in this session will be supported with speakers and additional stakeholders' representatives:

- Patients' representative: Angela Bradshaw (Alzheimer Europe)
- Health care professional: Rosa Giuliani (HCPWP co-chair)
- Industry and SME: Ebony Dashiell-Aje (BioMarin, EuropaBio)

16:05 Coffee break

16:20 Session 5: Keynotes from featured speakers

Chair: Peter Arlett (EMA, BDSG co-chair)

Today's world is moving rapidly, and new technologies are emerging. Information manipulation is becoming a risk, and reliable sources of information are critical for an

informed and engaged society and a trusted regulatory system. This session will look further ahead and discuss digitalisation and use of big data in medicines regulation and how data can be used for a better-informed society.

Data, not dogma: How data analysis can supercharge evidence-based decision making 25'

Ann Aerts (Novartis foundation)

How data can be used for a better-informed society 25'

Simon Piatek (LSHTM)

Front row comments with BDSG co-chairs: 10'

- Jesper Kjær (DKMA), Peter Arlett (EMA)

17:20 Closing remarks

Wrap up & engagement opportunities in 2024 10'

Jesper Kjær (DKMA, BDSG co-chair), Peter Arlett (EMA, BDSG co-chair)

17:30 End of the forum

List of speakers

Albert H. Werner	Quantum for Life, University of Copenhagen
Álmath Spooner	AbbVie, EFPIA
Angela Bradshaw	Alzheimer Europe
Ann Aerts	Novartis foundation
Begonya Nafria Escalera	Saint Joan de Deus Children's Hospital
Bruno Sepodes	CHMP, INFARMED, Universidade de Lisboa (Portugal)
Carla Torre	CHMP, INFARMED, BDSG member
Christian Roes	MWP chair, Radboudumc
Denise Umuhire	European Medicines Agency (EMA)
Despoina Makridaki	European Association of Hospital Pharmacists (EAHP)
Ebony Dashiell-Aje	BioMarin, EuropaBio
Emer Cooke	European Medicines Agency (EMA)
Gabriel Westman	Swedish Medical Products Agency (MPA), BDSG member
George Paliouras	National Centre for Scientific Research (NCSR) "Demokritos"; DDF
Holger Fröhlich	Fraunhofer SCAI
Jesper Kjaer	Danish Medicines Agency (DKMA), BDSG co-chair
Juan Garcia Burgos	European Medicines Agency (EMA)
Julian Isla	Dravet Syndrome European Federation (DSEF), Foundation 29, COMP
Kimmo Porkka	European Hematology Association (EHA)
Kristin Karlsson	MPA, MWP vice-chair, BDSG member
Lars Bo Nielsen	Danish Medicines Agency (DKMA)
Lonneke van de Poll-Franse	NCCO, NCI, TiU
Mads Nielsen	University of Copenhagen (UCPH)
Marco Greco	European Patients' Forum (EPF)
Maria Cavaller Bellaubi	EURORDIS
Marieke Schoonen	Amgen, EUCOPE

Melissa Kampman	Health Canada (HC)
Nikos Dedes	Greek Patients' Association
Olga Solomon	Head of Unit D1: Medicines: policy, authorisation and monitoring, EC
Patrice Verpillat	European Medicines Agency (EMA)
Peter Arlett	European Medicines Agency (EMA)
Rosa Giuliani	Healthcare Professionals' Working Party (HCPWP) co-chair
Rosa Gonzalez-Quevedo	European Medicines Agency (EMA
Sabine Straus	Medicines Evaluation Board (MEB), PRAC chair
Simon Piatek	London School of Hygiene & Tropical Medicine (LSHTM)
Susana Perez-Gutthann	RTI Health Solutions, Barcelona
Wim Goettsch	Zorginstituut Nederland, Special Advisor HTA

About the speakers

Albert H. Werner

Associate Professor. Quantum for Life Center, University of Copenhagen

Albert H. Werner is an Associate Professor of Mathematics at the University of Copenhagen, specializing in the development of Quantum Algorithms and Quantum Software for Quantum Hardware. A key aspect of his research includes developing methods for quantum simulation and quantum learning theory. Albert earned his PhD from Leibniz University Hannover.

Álmath Spooner

Director Regulatory Policy & Intelligence at AbbVie representing industry via EFPIA

Dr. Spooner is Head of Europe Regulatory Policy and Intelligence at AbbVie. Álmath is a dual qualified pharmacist and barrister and earned her PhD at Trinity College Dublin. At AbbVie, in addition to heading up the Europe Regulatory Policy and Intelligence team, she is the global regulatory policy lead for real world evidence, patient focused drug development and pharmacovigilance and the European regulatory policy lead for digital health and clinical pharmacology. At EFPIA, Álmath is the Chair of the Integrated Evidence Generation and Use (IEGU) Working Group and additionally co-chairs an EFPIA subgroup on patient involvement in drug development and regulatory decision making. Álmath is the industry observer on the DARWIN EU Advisory Board.

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.

Ann Aerts

MD, Head of the Novartis Foundation

Ann Aerts is Head of the Novartis Foundation, an organization committed to transform the health of low-income populations, by leveraging the power of data, digital technology and artificial intelligence (AI) to reimagine health and care around the world.

Ann holds a Degree in Medicine, a Masters in Public Health from the University of Leuven, Belgium, and a Degree in Tropical Medicine from the Institute of Tropical Medicine in Antwerp, Belgium.

Before leading the Novartis Foundation, Ann was Franchise Medical Director Critical Care for Novartis Pharma in Basel and Therapeutic Area Head Cardiovascular and Metabolism for Novartis Pharma Belgium. Prior to joining Novartis, she served as Director of the Lung and Tuberculosis Association in Belgium and as Head of the Health Services Department of the International Committee of the Red Cross (ICRC) in Geneva. She has also worked as Health Coordinator for the ICRC in several countries.

Begonya Nafria Escalera

Research Coordinator, Saint Joan de Deus Children's Hospital, Spain

Patient Engagement in Research Coordinator at Sant Joan de Déu Chidren's Hospital (Spain). She has long experience in the field of the involvement of patients and families in research initiatives. She is currently a PhD student in the patient involvement in paediatrics field, specifically working in the rights of the patients accessing to cross-border access clinical trials.

Funder and member of the Steering Committee of eYPAGnet (European Young Patients Advisory Group Network), Coordinator of Kids Barcelona (YPAG of Sant Joan de Déu Children's Hospital), Co-Chair of Children's Medicines Working Party of EFPGCP and Chair of the Cross-Border Access to Clinical Trials working group of EnprEMA (European Network of Paediatric Research of EMA).

Carla Torre

CHMP, INFARMED

Assistant Professor of Pharmacoepidemiology, Pharmacovigilance/Risk Management at University of Lisbon. Co-opted member for Pharmacoepidemiology of the CHMP, Alternate PRAC member and member of the MWP, EMA. Member of the Evaluation Board of Medicines of the Portuguese National Authority of Medicines and Health Products – INFARMED.

Bruno Sepodes

Vice-Chair of the CHMP, Co-Chair of ETF

Full Professor of Pharmacological Sciences (Universidade de Lisboa, Portugal). In 2008 joined the COMP as member nominated by the EC under EMA recommendation, and between 2012 and 2018 was the Chair of the COMP. After joining the CHMP in 2012, Bruno became Vice-Chair of this Committee in 2018, currently serving his second mandate. Since 2019, Bruno is a member of the ICH Assembly representing EC Europe and in 2022, became Co-Chair of ETF at EMA.

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.

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.

Despoina Makridaki

EAHP Director of Professional Development

Despoina Makridaki is a hospital clinical pharmacist, with 37 years of relevant experience. She is the Director of Hospital Pharmacy Services at the "Sismanoglio - Amalia Fleming" G.H. of Attica (Greece), President of Panhellenic Association of Hospital Pharmacists (PEFNI) since 2013 and Director of Professional Development at the European Association of Hospital Pharmacists (EAHP) since 2017, also member of E.A.H.P's SC since 2014. She represents Greece on EDQM/DG Sante, and represents EAHP at the EMA's HPWP, EU-HERA/member of CSF and EU SANTE-HTA-Stakeholder Network.

She was appointed as 1st Vice President of National Organization for Medicines (E.O.F) in the period April 2015-June 2018. Active member of the Greek National Committee for the Surveillance of Pharmaceutical Expenditure and Therapeutic protocols since 2015, and of the Central Health Council since 2022. Also, regular member of the Coordinating National Committee for Shortages, member of the Working Group of Greek Ministry of Health for the advancement of Clinical Studies and Biomedical Research and the Committee for the strategic design and implementation of electronic prescribing and updating the National HIV Registry.

Her EAHP portfolio (as leader or co-leader) includes Access to medicine, Pricing and Health Technology Assessment, Biologics, Common Training Framework Working Groups, Recruitment and Mobilization of members, Clinical Trials, Compounding/ready to use preparations/hazardous drugs, Advanced Therapy Medicinal Products and Orphan drugs and Procurement.

Ebony Dashiell-Aje

Executive Director & Head, Patient Centered Outcomes Science (PCOS)

Ebony Dashiell-Aje is a leading expert in clinical outcome assessment, design and implementation, digital health technology implementation and data interpretation, and study endpoint issues impacting medical development and com¬mercialization. She is currently the Executive Director and Head of Patient Centered Outcomes Science in Clinical Development at BioMarin Pharmaceutical Inc. Previously, Dr. Dashiell-Aje served in the Division of Clinical Outcome Assessments in the Office of New Drugs at the U.S. Food and Drug Administration. She has also served as an expert consultant to pharmaceutical industry clients, providing scientific leadership in the design of studies to support regulatory decision-making.

Emer Cooke

Executive Director of the European Medicines Agency

Emer Cooke is the Executive Director of the European Medicines Agency, based in Amsterdam.

She also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).

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

Ms. Cooke is a pharmacist with Masters 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 European Medicines Agency as Head of Inspections and Head of International Affairs respectively from 2002 until 2016. From September 1998 to July 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.

Gabriel Westman

Head of Artificial Intelligence at Swedish Medical Products Agency

Gabriel Westman is an infectious disease specialist and associate professor (MD, PhD), member of EMA/HMA Big Data Steering Group and EMA Methodology Working Party. He also has an MSc in Engineering with experience in bioinformatics, AI and big data applications within medicine and pharmaceutics and is currently building regulatory AI/data science capacity and competence at the Swedish Medical Products Agency.

George Paliouras

Duchenne Data Foundation, The Netherlands; National Centre for Scientific Research "Demokritos", Greece

Father of a boy with Duchenne Muscular Dystrophy and voluntary Chairman of the board for the Duchenne Data Foundation. Research Director for Artificial Intelligence at NCSR "Demokritos", Head of SKEL | The AI Lab, and Chairman of the board for the Intelligence Information Systems division. Has performed research in AI and Machine Learning for more than 30 years, has coordinated European research projects, has taught postgraduate courses and has co-founded tech companies.

Holger Fröhlich

Fraunhofer SCAI

Prof. Dr. Holger Fröhlich holds a Diploma (focus area: Artificial Intelligence) and PhD in Computer Science. After positions as a postdoc at the German Cancer Research Center and as a Senior Scientist at Cellzome AG (now an enterprise of Glaxo-Smith-Kline), he was appointed an associate professorship at the University of Bonn in 2010. In 2015 he joined the global biopharmaceutical company UCB and became the Director of an AI and Data Science research team. Since 12/2019 HF is Head of the AI & Data Science group and Deputy Head of the Department of Bioinformatics at the Fraunhofer Institute for Algorithms and Scientific Computing in Sankt Augustin. In addition, he is teaching as an honorary Professor in the Master programs Life Science Informatics and Computer Science at the University of Bonn.

HF's focus is on the development machine learning (ML) algorithms for applications in Precision Medicine, early Drug Discovery and System Medicine, particularly addressing challenges in neurodegenerative disorders. For this purpose, HF has used and developed a broad spectrum of different approaches over the last 20 years. He has developed multiple ML methods for modeling longitudinal patient data, integration of different data modalities, and combination of knowledge with data driven approaches. He is (co-)author of more than 150 publications, and he has been working within a many national and international consortia, such as IDENTIREST (BMBF), AETIONOMY (IMI), RADAR-AD (IMI), The Virtual Brain Cloud (H2020), NFDI4Health (DFG), DIGIPD (ERA Per Med, coordinator), ADIS (JNPD, coordinator), IDERHA (IHI), PsychSTRATA (Horizon Europe), Real4Reg (Horizon Europe) and PREDICTOM (IHI).

Jesper Kjær

Director of The Data Analytics Centre at the Danish Medicines Agency, co-chair for HMA / EMA Big Data Steering Group

20+ years' experience in data management, analyses and data visualisation having previously worked in academia and pharmaceutical industry. Has headed up activities in EU Framework Programmes, TransCelerate Biopharma. Co-PI of PHAIR: Pharmacovigilance by AI Real-time analyses, applying FHIR resources to health care data in DK for real time safety surveillance. Involved I EHDS pilot work and member of the EMA DARWIN EU advisory board.

Juan García Burgos

Head of Public and Stakeholders Engagement Department
European Medicines Agency (EMA)

Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the

interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences.

In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.

Julian Isla

Dravet Syndrome European Federation, Foundation 29, COMP member

Julian Isla, a software engineer at Microsoft and founder of the European Dravet Syndrome Federation, established the Dravet Syndrome Foundation 13 years ago to develop treatments for Dravet Syndrome, a severe form of epilepsy. Additionally, he founded Foundation 29, a nonprofit focused on leveraging AI in healthcare. Despite not having a medical background, Julian, whose son Sergio has Dravet Syndrome, serves on the Orphan Drug Committee at the European Medicines Agency (EMA) and the Therapeutic Advisory Group for Eurordis. In Spain, he advises on rare disease research for Ciberer and the Carlos III National Health Institute. He also holds board positions in three Spanish nonprofits.

Kimmo Porkka

Professor, Helsinki University Hospital Cancer Center, European Hematology Association (EHA)

Kimmo Porkka is a professor of personalized cancer therapy at University of Helsinki, and Chief Physician at the Helsinki University Hospital Comprehensive Cancer Center in Finland. Dr. Porkka`s research focus is on individualized therapy of relapsed cancer and in applying novel computational tools for integration, harmonization and global networking of deep disease profiling and big clinical datasets. He is closely involved in the IHI2 HARMONY Alliance and EHDEN EU projects, and the DARWIN EU initiative. Dr. Porkka co-leads the steering group on health data of the European Hematology Association (EHA).

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).

Lars Bo Nielsen

MD, PhD, DMSc, Director General, The Danish Medicines Agency

Lars Bo Nielsen serves as Director General of The Danish Medicines Agency (DKMA) since 2021.

Before joining DKMA his occupations from 2004-2021 included clinical and research activities at Rigshospitalet, Copenhagen and Danish universities, more specifically University of Copenhagen and Aarhus University.

From 2017-2021 he served as Dean and Professor at HEALTH, Aarhus University. From 2007-2017 as Professor Functional genomics in biomedicine, Department of Biomedical Sciences, and from 2012-2017 as Head of Department of Clinical Medicine, both at University of Copenhagen.

From 2004-2017 alongside with his work at the University of Copenhagen, he served as consultant at The Department of Clinical Biochemistry, Rigshospitalet, Copenhagen. From 2010-2015 as Head of the Department.

In his early days from 1992-2004 he had different clinical and research positions as a junior doctor.

In the EU regulatory network, he is a member of the EMA Management Board and co-opted member of the HMA Management Group.

Lonneke van de Poll-Franse

Professor of Cancer Epidemiology and Survivorship, Netherlands Comprehensive Cancer Organisation (NCCO), Netherlands Cancer Institute (NCI), Tilburg University (TiU)

My research focuses on identifying and understanding the physical and psychological consequences of cancer and treatment. In 2009 we set up the Patient Reported Outcomes Following Initial treatment and Long-term Evaluation of Survivorship (PROFILES) registry, which combines population data from the Netherlands Cancer Registry with patient-reported outcomes (www.profilesregistry.nl) as well as information on nutrition and physical activity measured with apps and wearables.

At the NCI - Center for Quality of Life, I lead the survivorship research program. A key pillar of this program is the collection of PROMs and provision of personalized care and support in daily clinical care. Our observational research informs the development of evidence-based interventions to optimize care and outcomes of survivors; I am PI of several multicenter RCTs on the effectiveness of new models of survivorship care. I am an active member of the EORTC QoL group where I lead the development of several QoL modules and a data science project.

Mads Nielsen

Professor, Ph.D, University of Copenhagen (UCPH)

Mads Nielsen has a BSc, in Physics and Computer Science, an MSc and a PhD in Computer Science, University of Copenhagen (UCPH) from respectively 1989, 1992, and 1995. He was guest researcher at INRIA Sophia-Antipolis 1993/94, post doc at Imaging Sciences Institute Utrecht, 3D-Lab, Faculty of Medicine, UCPH, associate professor and professor at IT-University of Copenhagen, and Head of Department and Professor at DIKU, Department of Computer Science, UCPH, where he is member of the Pioneer Centre of AI and PI on a number of grants related to computing in biomedicine.

In 2012 he published what we believe is the first work on using deep learning in medical image analysis together with Andrew Ng, Stanford; and have since contributed to fundamental and applied work in this direction. He has been invited to host workshops on this topic at SPIE, IEEE ISBI, and more. Towards medical application, he has contributed to among other applications in musculoskeletal diseases, cardiovascular diseases, lung diseases, breast cancer, infectious diseases including Covid-19, and dementias. He has published more than 300 peer reviewed papers.

He has founded a number of companies in this area including Biomediq, AIomic, Cerebriu.

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.

Maria Cavaller Bellaubi

Patient Engagement & Therapeutic Development Senior Manager, EURORDIS-Rare Diseases Europe

Maria is a pharmacist by training and joined EURORDIS in 2018, as Patient Engagement Manager managing the process of patient engagement in protocol assistance procedures at the European Medicines Agency and coordination of patient engagement for European initiatives. Maria is also responsible for following the development of orphan medicinal products as an EURORDIS expert on the Committee for Orphan Medicinal Products (COMP) at the EMA and

member of the Therapies Scientific Committee of IRDiRC (International Rare Disease Research Consortium). She also coordinates the EURORDIS Therapeutic Action Group, the group of patient representatives who are members of the EMA Scientific Committees.

Marieke Schoonen

Director Observational Research, Amgen

Marieke Schoonen is a Director of Observational Research in Amgen's Center for Observational Research, where she leads the European team of epidemiologists, data scientists and programmers, leveraging their expertise to generate real-world evidence (RWE) that helps inform healthcare decision-making across the drug development lifecycle. Marieke obtained an MSc in Biomedical Health Sciences at Radboud University (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.

Nikos Dedes

Chair, Greek Patients' Association

Nikos Dedes is President of the Greek Association of People Living with HIV, "Positive Voice" and General Secretary of the Greek Patients' Association. He has been long involved in European organisations and initiatives and currently is a member of the Steering Committee of European Network for the Treatment of HIV, Hepatitis and Global Infections, member of the European AIDS Clinical Society HIV Treatment Guidelines Group and a member of the Steering Committee of the HIV Outcomes and EuroTEST. He has served as Chair of the European AIDS Treatment Group, a former member of the Board of the European Medicines Agency and a former member of the WHO Strategic and Technical Advisory Committee on HIV. Nikos has been advocating for universal access to evidence-based and cost-effective care and prevention services for all people as a moral imperative and a prerequisite for a prosperous and just society.

Olga Solomon

Head of Unit D1: Medicines: policy, authorisation and monitoring

I hold a degree in Chemistry from the University of Thessaloniki and a Master's degree in Food Science from the University of Gothenburg. My professional journey has shaped my expertise in various domains.

Following my five-year experience at a prominent beverage company in Greece, I joined the European Commission in 2001. Over two decades, I gained experience in the field of food safety, in areas such as food additives, enzymes, and food contact materials and in the past 12 years in the area of pharmaceuticals.

Since May 2017, I am Head of Unit SANTE D.1 'Medicines: policy, authorisation, and monitoring' and have taken up the role of acting Director in SANTE D: 'Medical products and Innovation' from March until October 2023.

My professional journey has equipped me with extensive knowledge and skills in health policies, risk assessment, management and communication. Throughout my career, I have navigated complex stakeholder landscapes and negotiated with the European Parliament and the Council on proposals related to food and pharmaceuticals. In close collaboration with Member States and European Agencies, such as the European Food Safety Authority and the European Medicines Agency, I have fostered fruitful partnerships. Beyond the European stage, my influence has extended to international forums. Notably, I successfully negotiated food standards within the Codex Alimentarius and spearheaded activities pertaining to bilateral and multilateral relations with global partners in the pharmaceutical field.

I have guided my team through preparedness and crisis management activities during crucial events such as Brexit and the COVID-19 pandemic, including the expedited authorisation of vaccines and therapeutics. One of my notable achievements lies in my pivotal role in shaping the Pharmaceutical Strategy for Europe. Moreover, I led the implementation of this strategy, including the adoption in April 2023 of a comprehensive package of proposals for the revision of the pharmaceutical legislation.

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.

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.

Rosa Giuliani

Co-chair of the Healthcare Professionals' Working Party (HCPWP)
Dr Giuliani is a consultant in medical oncology currently working at the Clatterbridge Cancer Centre, Liverpool, U.K. where she is the research lead for the breast cancer Site Reference Group (SRG).

Dr Giuliani worked at the European Medicines Agency, EMA, as National Expert on secondment (2011-12) and she continues 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.

She is member of the ESMO European Policy Committee and on behalf of ESMO she joined the EMA Healthcare Professional Working Party (HCPWP) and the stakeholder forum of the Health Technology Assessment Network (HTAN) coordinated by the European Commission. Dr Giuliani has been elected as Co-chair of the HCPWP for its 4th mandate (2022-25).

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.

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

Rosa Gonzalez-Quevedo, PhD

Senior Liaison Specialist, Stakeholders and Communication Division, European Medicines Agency
Rosa is a pharmacist with a PhD in molecular oncology and postdoctoral studies at Stanford University (USA) and Medical Research Council (UK). Rosa works at EMA since 2010, first as a quality specialist and, since 2011, implementing communication and engagement strategies to foster understanding of regulatory science. Since 2022 she coordinates EMA's work on Patient Experience Data.

Sabine Straus

PRAC chair, MEB, NL

Dr. Sabine Straus has been with the Medicines Evaluation Board (MEB) in the Netherlands since 1997, where she started as an assessor Pharmacovigilance.

Prior to working at the MEB she held different positions in the pharmaceutical industry, the last one as medical director. She holds a PhD from the Erasmus Medical Center in Rotterdam (title "Drugs, Qtc prolongation and sudden cardiac death"). Since the start of the Pharmacovigilance Risk Assessment Committee (PRAC) in 2012 she has been the Dutch PRAC member and staff member at the MEB. In that period she co-chaired the Signal Management Review Team (SMaRT), and has been active in several drafting groups for guidance and guidelines. Since 2018 she chairs the PRAC.

In addition to her work at the MEB she holds a position as associate professor at the Erasmus Medical Center, department of Medical Informatics in Rotterdam.

Simon Piatek

Digital Lead - London School of Hygiene & Tropical Medicine

Simon Piatek is a Social media researcher and practitioner interested in social listening, audience engagement and Information Politics. He currently leads the digital team at the Vaccine Confidence Project at the LSHTM focusing on the analysis of public confidence in immunisation programmes and public sentiment. He is one of the founders and leaders of IRIS - a research group funded by the UK's Cabinet Office, dedicated to understanding infodemics and promoting healthy information ecosystems, and is a member of the advisory board for NODES consortium in the European Narrative Observatory to fight Disinformation post-COVID.

Susana Perez-Gutthann

RTI Health Solutions, Barcelona

Susana Perez-Gutthann holds medical and doctoral epidemiology degrees. She is Vice President and Global Head of Epidemiology at RTI since 2007. Previously she was Global Head of R&D Epidemiology at several pharmaceutical companies. Dr. Perez-Gutthann has over 30 years of experience in the research-driven international pharmaceutical environment, developing and leading teams of epidemiologists and driving strategy and research programs for safety, pharmacovigilance, risk management, development, real world evidence, and regulatory activities applying public health and epidemiologic methods. She is an active leader and past president of the International Society of Pharmacoepidemiology (ISPE) and the Co-Chair of the Steering Committee of the European Medicines Agency European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

Wim Goettsch

Zorginstituut Nederland, Special Advisor HTA

Wim Goettsch, PhD is currently Special Advisor Health Technology Assessment (HTA) at the Dutch National Health Care Institute. Since December 2022, he also has a position as a Professor and Chair on HTA of pharmaceuticals at Utrecht University (NL) where he is leading a H2020 consortium with fifteen partners around Europe, called HTx, new methods for Health Technology Assessment (2019-2024). He was the Director of the EUnetHTA JA3 (2016- 2020) Directorate and Chair of the Executive Board of EUnetHTA between June 2016 and March 2018. He is involved many activities on real world evidence (RWE) such as the GetReal Institute, the ISPE-ISPOR taskforce on RWE transparency, CIOMS WG XII on RWE and the EU stakeholder Advisory Board on DARWIN-EU. Before joining the National Health Care Institute, he worked as a research manager for the PHARMO Institute and was responsible for the coordination of numerous pharmacoepidemiological and outcomes studies for international offices of pharmaceutical companies such as AstraZeneca, Novartis, Pfizer and GSK. He has a PhD in immunology and an advanced education in (pharmaco)- epidemiology and pharmaco-economics. He has more than 130 publications in peer-reviewed international journals.