



ACT EU multi-stakeholder platform annual meeting agenda

29 October 2025, 09:30 – 17:00 (CET/CEST)
Hybrid meeting/ EMA, Amsterdam, Room 1A

Innovation is reshaping the future of clinical trials in Europe—driving better, faster, and smarter research that is more inclusive and responsive to patient and societal needs. This year’s annual ACT EU Multistakeholder Platform meeting offers an in-depth exploration of the strategic importance of innovation in strengthening Europe’s clinical trials ecosystem.

Across four thematic sessions— patient-oriented research, AI and digitalisation, methodological and biotechnology advances, and ethics and regulatory preparedness—we will explore how innovation can improve trial design, execution, and impact. The programme features insights from patient, healthcare professional, industry and academic representatives, regulators and global experts, showcasing real-world use cases and highlighting opportunities to enhance inclusiveness, ethical integrity, and readiness for emerging technologies.

The multi-stakeholder platform (MSP) annual meeting aims to:

- Support alignment of innovation efforts in clinical trials with the EMAN to 2028 strategy and ACT EU priorities
- Showcase domain-specific innovations and their potential to improve trial outcomes and patient impact.

- Facilitate multistakeholder dialogue to identify good practices and strengthen collaboration across sectors.
- Explore regulatory and ethical readiness across domains and identify where further enablers are needed to support inclusive and responsible innovation.

This workshop is open to all stakeholders through the broadcast link.

Broadcast link available at the event webpage: [ACT EU multi-stakeholder platform annual meeting | European Medicines Agency \(EMA\)](#)

ACT EU multi-stakeholder platform annual meeting agenda

Chaired by Marianne Lunzer (AGES MEA/CTCG) and Denis Lacombe (EORTC)

09:00 Joining and technical checks

09:30 Welcome and opening remarks

Co-chairs welcome and opening of the meeting	10 min
<i>Marianne Lunzer (AGES MEA/CTCG) and Denis Lacombe (EORTC)</i>	
Opening remarks	5 min
<i>Emer Cooke (EMA)</i>	
Opening remarks	5 min
<i>Sandra Gallina (European Commission)</i>	
Opening remarks	5 min
<i>Nils Bjerregaard (HMA/DKMA)</i>	

09:55 Keynote speaker

AI in science and innovation – Building a future together	20 min
<i>Cesar Velasco (EFPIA)</i>	
Q&A session	10 min

10:25 Session 1: Innovation in patient-oriented research

Moderators: Begoña Nafria (eYPAGnet) and Juan Garcia Burgos (EMA)

Update on EMA's work on patient experience data	15 min
<i>Rosa Gonzalez-Quevedo (EMA)</i>	
Involving patients in clinical trial design - where can we innovate?	15 min
<i>Amelia Hursey (Parkinson's Europe)</i>	
Panel discussion	50 min
<i>Michal Rataj (EPF)</i>	
<i>Mirjam Crul (ESOP)</i>	
<i>Madeline Pe (EORTC)</i>	
<i>Susan Bhatti (EuropaBio)</i>	

Delphi Coppens (KWF)
Ruth Cohen (CCMO)

11:45 **Coffee break**

12:05 **Session 2: The convergence of innovative methodology and evolving biotechnology**

Moderators: Lada Leyens (EFPIA) and Isabelle Clamou (European Commission)

Concrete examples of trials approved with innovative design **15 min**
Oscar Della Pasqua (UCL)

ATMP Innovation in the current EU CT landscape: A case study **15 min**
Marianne Astic (EUCOPE)

Panel discussion **50 min**

François Houyez (EURORDIS)
Matteo Della Porta (EHA)
Peter van de Ven (UMC Utrecht)
Elizabeth Theogaraj (EFPIA)
Nathalie Seigneuret (IHI)
Vasee Moorthy (WHO)

13:25 **Lunch**

14:05 **Session 3: Innovation in AI and digitalisation**

Moderators: Amélie Michon (ECRIN) and Peter Arlett (EMA)

Digital innovation in healthcare: challenges and possibilities **15 min**
Johan Van Eldere (EUHA)

Opportunities for the European Health Data Space to change clinical trial recruitment **15 min**
Ashley Pitcher (ACRO/EUCROF)

Panel discussion **50 min**

Juan Ventura (CPE)
Mark Lawler (CDDF)
Catarina Madeira (CoLAB TRIALS)
Fatima Bennai - Sanfourche (MPP)

About the speakers



Alain Volny Anne

EATG

Alain Volny Anne is an HIV/AIDS Treatment activist. In the 90s, he contributed to the creation of the French CAB (TRT-5) while focusing his action on HIV research. Since those years, he has conveyed his communities' perspectives in several international scientific expert fora. Alain has been a member of the EATG since 1997 and represented the organisation in several scientific entities such as EACS and RESPOND. Until recently, Alain reported on HIV research for aidsmap.com.



Amelia Hursey

Parkinson's Europe

Amelia holds an MSc in Cognitive Neuropsychology from Oxford Brookes University and has over 15 years of experience in clinical research, project development, and public engagement. She is a Research Participation Lead at Parkinson's Europe, responsible for initiatives that increase research participation among people affected by Parkinson's, healthcare professionals, and researchers. Amelia led the creation of the innovative Parkinson's UK Take Part Hub and works closely with the Parkinson's UK Excellence Network, research teams, and external partners to strengthen research collaboration and participation.



Amélie Michon

ECRIN

Amélie is Head of Clinical Operations at European Clinical Research Infrastructure Network (ECRIN), overseeing the provision of operational services to the management of multinational clinical trials and coordinating the network of European Correspondents (local experts) in ECRIN countries. She has over 15 years of experience in clinical research. Before joining ECRIN she worked as a clinical project manager in the pharmaceutical industry covering the planning, setup, and management of multinational trials in various therapeutic areas. She joined ECRIN in 2012 as a French European Correspondent focused on coordinating multinational clinical trials and providing support to French clinical investigators and sponsors while preparing clinical proposals for European public funding. Amélie is a pharmacist and holds a Master in Clinical and Pharmaceutical development from Poitiers University (France).



Ashley Pitcher

ACRO/EUCROF

Ashley is a Senior Director at IQVIA and leads a department called Real World Evidence Innovation Strategy. She leads targeted efforts to expand the organization's innovative offerings and capabilities for real world late phase studies. She is passionate about leveraging patient healthcare data to extend and improve lives and to enhance the efficiency of healthcare systems. She holds a doctoral degree in Mathematics from the University of Oxford.



Audrey van Scharen

Vrije Universiteit Brussel

Audrey Van Scharen holds a Master degree in Political Science and a Master degree in Law from the Vrije Universiteit Brussel (VUB). During her tenure at VUB's Research Department (2010–2018), she founded the Ethics in Research Department, dedicated to strengthening legal compliance, research ethics, scientific integrity, and transparency. She is a certified Data Protection Officer (DPO) and leads the GDPR implementation at VUB, as well as for the National Councils of Doctors and Pharmacists, advising on the responsible use of health data. At University Hospital Brussels (UZ Brussel), Audrey currently serves as Manager of Ethics, Vice-President of the Medical Ethics Committee, and President of the Ethics Committee on Ethical Hospital Care. She is also an Affiliated Professor at VUB's Faculty of Medicine and Pharmacy, where she teaches Bioethics, Research Ethics, and Ethics in Health Management and Policy.



Begoña Nafria Escalera

eYPAGnet

Begoña is Head of Patient Engagement in Research at Sant Joan de Déu Children's Hospital (Spain) and 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 in a thesis project about the rights of children and young people accessing cross-border clinical trials.

She is also Steering Committee member and Founder of European Young Patients Advisory Group Network (eYPAGnet), Coordinator of

Kids Barcelona (YPAG of Sant Joan de Déu Children's Hospital), Co-chair of Children's Medicines Working Party of European Forum for Good Clinical Practice (EFGCP), and Chair of the Cross-Border Access to Paediatric Clinical Trials of European Network of Paediatric Research of EMA (EnprEMA).



Catarina Madeira

CoLAB TRIALS

Catarina is executive director of CoLAB TRIALS, leading innovation in clinical trials through strategic, financial, and stakeholder management. She is faculty member at Católica Lisbon School of Business & Economics, teaching in the Advanced Program in Project Management & Evaluation. With extensive experience in clinical research, she has coordinated multinational trials, published over 30 scientific papers, and contributed to the development of Portugal's national clinical research infrastructure (PtCRIN) and its European integration through ECRIN.



Cesar Velasco

EFPIA

Cesar is a healthcare leader with extensive experience in innovation, R&D, and digital transformation across clinical and strategic domains. He is currently Science and innovation director at AstraZeneca. Holding an MD, PhD, and MBA in Preventive Medicine and Public Health, he brings expertise in global health, real-world evidence, AI, and public-private partnerships. Cesar has a strong background in epidemiology, HIV, and vaccines, complemented by experience in clinical practice and executive management. Recognized for building high-performing teams and fostering cross-sector collaboration, he focuses on advancing responsible healthcare innovation and long-term value creation.



Delphi Coppens

KWF

Dr. Coppens is currently lead research drug development at Dutch Cancer Society (KWF) and involved in numerous academic projects in the oncology field. Daily activities are aimed to improve cancer treatment by supporting academics to develop meaningful medicinal products for patients towards clinical practice. Dr. Coppens started working at KWF after finalizing a PhD thesis on regulatory change and practices for Cell and Gene Therapies.



Denis Lacombe

EORTC

Denis is the Chief Executive Officer of the European Organisation for Research and Treatment of Cancer (EORTC), where he leads the organisation's scientific strategy, partnerships, and communications. He has been instrumental in advancing EORTC's pan-European clinical and translational research infrastructure and fostering collaboration across the oncology community. Denis is stakeholder co-chair of Multi-stakeholder platform Advisory Group (MSP AG). He earned his MD from the University of Marseilles and completed a post-doctoral fellowship in pharmacology and pharmacokinetics at Roswell Park Cancer Institute, USA. He began his career in the pharmaceutical industry as a Clinical Research Advisor before joining the EORTC, where he has held several leadership positions. With over 100 peer-reviewed publications, Denis continues to drive innovation in cancer clinical and translational research.



Donato Bonifazi

TEDDY

Donato is an economist specialised in project management and Chief Executive Officer at CVBF, a non-profit research consortium with 25 years' experience in health and pharmaceutical research. He is Chair of the Events & Training WG at the European CRO Federation (EUCROF), and Board Member at – European Network of Excellence for Paediatric Research (TEDDY). He is Coordinator of European Paediatric Translational Research Infrastructure (EPTRI) and of the OrphaDev4Kids project aimed to enhance technology-driven paediatric drug discovery and studies and to foster the development of paediatric medical devices for the treatment of children with rare diseases.



Elena Garcia Mendez

Technical Secretariat of the Ethics Committee, University Hospital La Paz, Spain, MedEthicsEU

Elena is a pharmacist, with post-graduate courses for a PhD program in Microbiology and a Master's Degree in Clinical Bioethics. She has an extensive experience in clinical research with drugs and advanced therapies in different therapeutic areas and in all phases of clinical development. She worked for 30 years in the Clinical Research /

Operations department of a multinational pharmaceutical company holding different positions with increasing responsibility (from CRA to Head of Clinical Operations). She joined the Technical Secretariat of the Ethics Committee for the Research with Medicinal Products of University Hospital La Paz - Hospital Cantoblanco - Hospital Carlos III in March 2021.



Elizabeth Theogaraj

EFPIA

Elizabeth is a regulatory affairs leader dedicated to bringing new medicines to patients navigating the path from early development to market. Her current work is at the intersection of regulatory strategy and clinical research, where she focuses on complex studies in oncology, including umbrella platform trials and master screening protocols. Committed to advancing research methodologies, Elizabeth led the first fully decentralized trial in Oncology. The insights from this trial have helped inform guidance from global health authorities on the topic. She champions this forward-thinking approach across the industry through her leadership positions, serving as Co-Chair of EFPIA's Innovative Clinical Trial group and Chair of TransCelerate's Regulatory Council Network.



Emer Cooke

EMA

Emer is Executive Director of the EMA and Chair of ICMRA. Starting her mandate as ED in June 2020 amid a public health crisis of unprecedented scale she announced, "My number one priority will be to drive forward EMA's response to the pandemic and the work already ongoing to support the development and approval of safe and effective COVID-19 vaccines and treatments." Doing precisely that has since earned her various accolades including an Honorary Doctorate for outstanding contribution to healthcare (RCSI - 2023) and the 'European of the Year 2022' title by European Movement Ireland. Ms Cooke obtained a degree in pharmacy and master's degrees in both Science and Business Administration from Trinity College in Dublin, Ireland.



Fatima Bennai - Sanfourche

MPP

Fatima is the Global Senior Director of QA&RA Compliance for Medical Devices, Combination Products, and eHealth at Bayer AG. With over 20 years of experience across the medical device, pharmaceutical, and eHealth sectors, she is a seasoned leader in regulatory affairs and quality assurance. Fatima has extensive expertise in integrating medical devices and combination products within complex pharmaceutical environments and ensuring regulatory compliance in clinical investigations. A recognized thought leader, Fatima is a member of the MSP AG, representing the Medtech & Pharma Platform (MPP), and actively contributes to European regulatory initiatives. Her leadership continues to shape best practices across the MedTech and pharma industries.



François Houÿez

EURORDIS

François Houÿez is Director of Information & Access to Therapies and Health Policy Advisor at EURORDIS – Rare Diseases Europe. A patient advocate since the early 1990s, he has been with EURORDIS since 2003 and plays a leading role in improving access to therapies for people with rare diseases. François represents EURORDIS at the European Medicines Agency’s Patients’ and Consumers’ Working Party, and the Health Technology Assessment Network. He also oversees the EuroCAB programme and serves as General Secretary of the GetReal Institute on Real-World Data. As a pioneer in patient engagement with the EMA since 1996, François has nearly three decades of experience shaping European health policy. He is also a member of the MSP AG, representing EURORDIS.



Isabelle Clamou

European Commission

Isabelle is a regulatory affairs professional with over 20 years’ experience in the field of European pharmaceutical legislation and pharmaceutical industry. She works as policy officer at European Commission, Directorate-General for Health and Food Safety (DG SANTE).



Johan Van Eldere

EUHA

Johan Van Eldere is emeritus professor of microbiology at KU Leuven, and currently secretary-general of the European University Hospital Alliance (EUHA) and president of the scientific advisory board of Vall d'Hebron Institute of Research.

After his medical degree magna cum laude from KU Leuven in 1983, he pursued his PhD, and completed postdoctoral research at Oxford University, before returning to KU Leuven. He founded the infectious

diseases research group, led the bacteriology and mycology lab, and was head of the clinical departments of laboratory medicine and pathology at University Hospitals Leuven. As medical director at UZ Leuven, he guided the hospital through JCI accreditation and established leadership and retention programs for medical staff. Johan Van Eldere has authored over 150 peer-reviewed publications, focusing on bacterial resistance, biofilm formation, and the development of novel antibiotics. Internationally, he has contributed to ESCMID, EMA, and various pharmaceutical advisory boards and KU Leuven spin-off Aelin Therapeutics to develop a new class of antibiotics.



Juan Garcia

EMA

Juan is a qualified medical doctor specialised in urology. Juan worked as a urologist surgeon at the Maranon hospital in Madrid. He joined the European Medicines Agency in 2002 and was responsible for coordinating the preparation of EU clinical guidelines for drug development. In 2005 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 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.



Juan Ventura

CPE

Juan studied Pharmacy and obtained his PhD at the University Complutense of Madrid. He has conducted basic research in international institutions such as EMBL, HHMI, CNIO, University of Cambridge and KU Leuven. He has aimed to find target cells and molecular biomarkers that could be used for diagnosis and therapy of several cancers (Liver, Colon, Lung). After switching his career path, he moved to work as patient advocate at Cancer Patients

Europe (CPE). He has participated in more than 20 EU research projects and helped to bring the voice of patients to the latest research trends.



Lada Leyens

EFPIA

Lada is a Senior Director, EUCAN regulatory affairs GI and Inflammation TA head. Lada has a background in human genetics, health economics and personalised medicine. She has worked at Health Authorities for over 8 years at Swissmedic and at EMA. At Roche, Lada worked on digital health program and Clinical Trial Innovation. At Takeda, she leads the EUCAN regulatory team in the therapeutic area of GI and Inflammation. Lada is vice-chair of EFPIA-

CREG and represents EFPIA and industry at multistakeholder platforms, such as the ACT-EU Multi-stakeholder platform Advisory Group (MSP AG).



Matteo Della Porta

EHA

Matteo is Head of the Leukaemia Unit at the Cancer Center, Humanitas Research Hospital, and Full Professor of Haematology at Humanitas University in Milan, Italy. He also leads the Center for Accelerating Leukaemia/Lymphoma Research (CALR) at the Humanitas AI Center. His research focuses on artificial intelligence in haematology, decision support systems, genomics of haematologic malignancies, and personalized medicine.



Madeline Pe

EORTC

Madeline, PhD, is the Head of the Quality of Life Department at the European Organisation for Research and Treatment of Cancer (EORTC). Madeline's expertise is on statistical and methodological research for participant/patient-reported outcomes. She is a past member of the International Advisory Board for the Lancet Oncology, a steering committee member of the EMA/HMA European Platform for Regulatory Science Research, and collaborates with different

international stakeholder groups to promote the inclusion of patient reported outcomes and quality of life into their cancer research programs.



Marianne Astic

EUCOPE

Marianne is an Associate Director in the EU Regulatory Affairs team at Regeneron. In her current role, she is responsible for leading the EU regulatory strategy for some innovative ATMPs. She successfully co-led the first IND and CTA for a first-in-class Gene Insertion Therapy. Marianne has a diverse experience in regulatory affairs, spanning early development to late post-approval. Marianne holds a French Doctorate in Pharmacy and a Master's degree in International Drug Development and Registration.



Marianne Lunzer

AGES MEA/CTCG

Marianne is a medical doctor by training and joined AGES in 2008 as a pharmacovigilance assessor. She was an alternate PRAC member between 2015 and 2017. In 2017, she joined the clinical trial unit at AGES as a safety assessor and has since been part of the Clinical Trials Facilitation and Coordination Group (CTFG) group. Since 2022 she is chairing the group now called Clinical trials coordination group (CTCG). Marianne contributed to the CTFG best practice guidelines for

safety assessors for clinical trials and is a member of the drafting team for the Commission implementing regulation for the cooperation in safety assessment of clinical trials.



Mark Lawler

CDDF

Mark is Professor of Digital Health at Queen's University Belfast and has just become President of the Cancer Drug Development Forum. CDDF brings together patients, healthcare professionals, academic researchers and industry to discuss and debate the key opportunities and challenges in cancer drug development. Mark is an international leader in the deployment of data to underpin greater understanding, drive research translation and ensure better outcomes for patients with cancer.



Michał Rataj

EPF

Michał Rataj has been over 15 years board member of Polish Neuromuscular Diseases Association. The organisation offers support to the people suffering from genetically conditioned neuromuscular diseases, commonly known as muscle atrophy. Michał is also a board member of the EAMDA - European Alliance of Neuromuscular Disorders Associations. Michał joined the European Patients Forum (EPF) Board in March 2016.



Mirjam Crul

ESOP

Mirjam holds a master's degree in pharmacy and earned her Ph.D. from the Netherlands Cancer Institute, where she researched the clinical pharmacology of novel anticancer agents. She trained as a hospital pharmacist and now works at Amsterdam University Medical Center as Head of the Aseptic Compounding Unit, with pharmaceutical responsibility for the Oncology Department. She previously served on the Board of the Dutch Hospital Pharmacists Association (NVZA) and

currently chairs the European Cancer Organisation Board while serving as Vice-President of the European Society of Oncology Pharmacy (ESOP).



Monique Al

CCMO

Monique Al is currently special advisor at the Central Committee on Research Involving Human Subjects (CCMO) in The Netherlands. Since May 2023 she is the vice-chair of the Clinical Trial Coordination Group. She is also co-chair of MedtEthicsEU, a group of national representatives of Medical Research Ethics Committees in EU/EEA launched in February 2024. Her background is Clinical Nutrition with a PhD in Human Biology. She has worked for several nutritional and

pharmaceutical companies in the field of clinical research before she started in 2001 as a scientific staff member at the CCMO.



Nathalie Seigneuret

IHI

Nathalie is a senior scientific project manager at the Innovative Health Initiative (IHI) within the Scientific Operations team, with responsibilities ranging from the coordination of activities within the team, the management of large and complex research projects and support to public-private consortia, to engagement with stakeholders with particular focus on regulatory bodies. Prior to joining the Innovative Medicines Initiative (now IHI) in 2011, Nathalie, a Doctor

of Pharmacy was a scientific administrator at the European Medicines Agency (EMA).



Nils Bjerregaard

HMA DKMA

Nils is Director General of the Danish Medicines Agency. A medical doctor and specialist in anaesthesiology, he holds an MSc in Medicine from Aarhus University. Before joining the Danish Medicines Agency, he served as Medical Director at Horsens Regional Hospital and was part of the Group Management in the Central Denmark Region, bringing extensive leadership experience from complex, interdisciplinary healthcare environments.



Oscar Della Pasqua

UCL

Oscar is Chair of Clinical Pharmacology and Therapeutics at University College London (UCL). With over two decades of experience in pharmaceutical R&D, he provides clinical pharmacology expertise across multiple therapeutic areas and stages of drug development. His research focuses on personalised medicine and the application of quantitative approaches to evaluate medicinal products in clinical development. An Associated Fellow at the National

Research Council in Rome, he has authored more than 200 publications in international journals and supervised numerous Ph.D. and postdoctoral projects. He also serves as Senior Editor of the British Journal of Clinical Pharmacology.



Peter Arlett

EMA

Peter Arlett EMA Peter Arlett is Head of the Data Analytics and Methods Taskforce at the European Medicines Agency. In this role he leads on operations and transformation on clinical evidence at the EMA including clinical trials, real world evidence, safety reporting and data science including AI. He is Chair of the EMA Data Board, Co-Chair of the HMAEMA Network Data Steering Group, Co-chair of the EMA AI Coordination Group, Co-chair of the Vaccine Monitoring Platform

Steering Group, and Member of the ACT EU Steering Group. Prior to taking up this role in 2020, he held leadership roles within the EMA in the areas of pharmacovigilance, epidemiology, and risk management. He has a medical degree from University College London. In addition to his role at EMA, Peter is Honorary Professor at the London School of Hygiene and Tropical Medicine. He is also a Fellow of the Royal College of Physicians of Edinburgh and of the Faculty of Pharmaceutical Medicines of London.



Peter van de Ven

UMC Utrecht

Peter van de Ven is a biostatistician and associate professor in clinical trial methodology at the University Medical Center Utrecht (UMCU), where he leads the Clinical Trial Methodology & Statistical Consultation team. At UMCU, he and his team provide methodological and statistical expertise for clinical studies, including trials with innovative designs. Peter is a work package leader for the adaptive early-phase clinical trial platform in the ONCODE-ACCELERATOR project, and a seconded methodology assessor for the Dutch Medicine Evaluation Board.



Rebecca Stanbrook

EIPG

Rebecca Stanbrook has worked in the pharmaceutical industry, as a regulator at the MHRA and at various pharmaceutical companies for over 30 years. Her main areas of interest are clinical trials and pharmacovigilance. She is a pharmacist by profession and holds a Diploma in Research Quality Assurance.



Rosa Gonzalez-Quevedo

EMA

Rosa began her career as a research scientist after earning a Pharmacy degree and a PhD in Molecular Oncology. She specialised in cell biology at Stanford University before joining the National Institute for Medical Research (now the Crick Institute) in London, where she focused on neural stem cell research. She later joined the European Medicines Agency (EMA) to support the scientific evaluation of biological medicines and subsequently moved to the Stakeholders and

Communication Division, leading initiatives to explain regulatory science to patients and healthcare professionals. Rosa now coordinates the Agency's work on Patient Experience Data (PED), driving related activities and contributing to the Reflection Paper on PED.



Ruth Cohen

CCMO

Ruth has received a PhD in oncology, working on antibody-drug conjugates. She left research to work the field of clinical trials, for academia, CRO, start-up and big pharma, with a focus on regulatory affairs, leading to a role as non-clinical assessor at the Central Committee on Research Involving Human Subjects (CCMO), the competent authority for clinical trials in the Netherlands. She is currently leading a project focused on patient involvement in clinical

trial design, initiated by the Clinical Trials Coordination Group.



Sandra Gallina

Directorate-General for Health and Food Safety

Sandra Gallina joined the European Commission in 1988. She is today Director General for Health and Food Safety. Before joining DG SANTE, between 2018 and 2020 she was Deputy Director General for DG TRADE. Between 2014 and 2018 she was Director for DG TRADE Directorate D "Sustainable Development; Economic Partnership Agreements - African, Caribbean and Pacific; Agri-food and Fisheries". Sandra Gallina was also the EU chief negotiator for the EU-MERCOSUR Free Trade Agreement.



Susan Bhatti

EuropaBio

Susan has been working in Regulatory Affairs in the pharmaceutical and clinical research industry for more than 25 years. She is Director of Global Regulatory and Scientific Policy at Merck BV and supports the development of regulatory and scientific policies in Europe. She is co-chairing the patient engagement pillar of the Clinical Research Expert Group at the European Federation of Pharmaceutical Industries and Associations (EFPIA). She is also co-leading the multi-stakeholder

initiative on cross-border access to clinical trials in Europe (EU-X-CT), which is a joint undertaking by the European Forum for Good Clinical Practice (EFGCP) and EFPIA.



Tarec Christoffer El-Galaly

DK MREC/EMA

Tarec is a professor of haematology at Aarhus University Hospital and Aarhus University. His clinical work is focused on lymphoma, and he chairs the Danish lymphoma group. His research areas are within epidemiology and outcomes research. Tarec is chair of one of the national medical research ethics committee in Denmark and a seconded national expert to EMA.



Vasee Moorthy

WHO

Vasee is an internal medicine and infectious diseases physician, T cell immunologist, and clinical trialist with expertise in data, sample, and genetic sequence sharing policy. He is currently Senior science and strategy advisor at World Health Organisation (WHO). He holds a B.A. and M.A. in Natural Sciences from the University of Cambridge, a B.M.B.Ch. in Clinical Medicine from the University of Oxford, and a Ph.D. in Malaria Immunology from the Institute of Molecular Medicine, University of Oxford.



Wolfgang E. Berdel

AKEK, MedEthicsEU

He is a Professor of Haematology and Oncology at the University Hospital of Münster. He serves as a board member of the Association of Medical Ethics Committees in Germany (AKEK) and of MedEthicsEU.