Virtual

Nov 15, 2023 1:00 PM - Nov 16, 2023 6:40 PM

DIA Innovating Clinical Trials in Europe

This year's must-attend virtual live conference for pharmaceutical innovators and clinical researchers alike!

Print Agenda

Day 1 Nov 15, 2023

1:00 PM — 1:15 PM

Participants Log-in and Connect

1:15 PM — 1:30 PM

Welcome and Introduction by DIA

1:30 PM — 2:00 PM

Opening Keynote

Join us for an inspiring keynote as we explore the abundance of clinical trial innovation opportunities and our state of adoption readiness. We'll discuss pandemic-driven momentum and tackle obstacles that limit progress. Discover actionable steps to sustain innovation in clinical trials.

Session Chair(s)

Craig H Lipset, MPH

Managing Partner
Clinical Innovation Partners, United States

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials & Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant Professor in Health Informatics at Rutgers University, and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at Home. Craig was previously the Head of Clinical Innovation and Venture Partner at Pfizer, and on the founding management teams for two successful startup ventures.

Speaker(s)

2:00 PM — 3:10 PM

Session 1: Requirements and Opportunities for Innovation in Clinical Trials in Europe: Navigating the Legislation Landscape

Session will inform about the legislation landscape with impact on Clinical Trials with focus on experiences on CTR implementation and outlook to further environment opportunities.

Session Chair(s)

Elke Stahl, PhD

Senior Expert, Clinical Trials Department
Federal Institute For Drugs and Medical Devices (BfArM), Germany

Dr. Elke Stahl, Clinical Trial Unit BfArM, Germany. Clinical Trials Senior Expert. CoChair of the Clinical Trial Facilitation Group (CTFG) till 2022. Involved in EMA's EU CTIS groups as BfArM's representative, National Contact Point for the CTR in Germany, representative in European Commissions CT working groups. Prior BfArM 10 years experiences as a pharmacokineticist at Bayer HealthCare AG, Germany, in early research up to candidate selection. PostDoc at Hoffmann-La Roche Inc and University of North Carolina (UNC). Ph.D. in pharmacology and licenced pharmacist.

Marianne Lunzer, DrMed

Assessor, Dept of Clinical Trials, Federal Office for Safety in Health Care
AGES, Austria

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.

Speaker(s)

How Can The Clinical Research Environment in Europe be Improved?

Susan Bhatti, PhD

Director EU Global Regulatory and Scientific Policy, Global Regulatory Affairs
Merck Healthcare, Netherlands

Susan Bhatti has been working in Regulatory Affairs in the pharmaceutical and clinical research industry for more than 25 years. At Merck BV she is Director EU Global Regulatory and Scientific Policy and is responsible for supporting the development of regulatory and scientific policies as well as responding to regulatory & legislative issues that impact product development. She is co-chair of the Clinical Research Expert Group at EFPIA as well as a co-chairing subgroup focussed on patient engagement. She is currently co-leading a 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 and EFPIA.

Industry Feedback on a Successful Adoption of EU CTR and Challenges and Opportunities in Landscape

Martin O'Kane, PhD, RPh

Regional Head RA EU Policy & Liaison
Novartis Pharmaceuticals, United Kingdom

Dr Martin O'Kane, MRPharmS, studied pharmacy at University of Aston and after completing a PhD and a post-doctorate research project at the University of Glasgow, he moved to Japan to work within the pharmaceutical industry. He joined the MHRA in 2005 as a Pharmacopoeial Scientist with the British Pharmacopoeia and was a member of the European Pharmacopoeia Commission's Working Party on Cell Therapy Products. He moved to the Clinical Trials Unit as a Pharmaceutical Assessor in 2007 and was involved in the assessment of chemical and biological CTA applications for all phases of study. In 2023, becoming the Regional Head RA EU Policy & Liaison at Novartis.

Clinical Trials in Europe: Opportunities for changes on the way

Isabelle Clamou

Policy Officer, DG SANTE Unit D2
European Commission, Belgium

3:10 PM — 3:25 PM

Coffee Break

3:25 PM — 4:35 PM

Session 2: Platform Trials in Europe: EU PEARL Project and the ACT EU Vision

The European Union-Patient-cEntric clinicAl tRial pLatform (EU-PEARL) initiative has developed new methodologies and tools to expand the master protocol approach into Integrated Research Platforms (IRPs) in collaboration with patient representatives and through consultation with FDA and EMA stakeholders. This session will highlight the deliverables now available to the clinical trial community, the path forward for IRPs in Europe, and the connection to the broader Accelerating Clinical Trials (ACT) EU vision.

Session Chair(s)

Daniel Millar, MBA

Senior Director, Strategic Business Transformation
Johnson & Johnson, United States

Daniel Millar leads Strategic Business Transformation in Quantitative Sciences at Janssen R&D. He is an advocate for utilizing quantitative innovation to advance patient-centric R&D while simultaneously delivering transformational efficiencies. Daniel is a founding leader and champion for multi-stakeholder engagement in the recently launched Innovative Medicines Initiative (IMI) public-private partnership for Integrated Research Platforms. Daniel obtained a MBA from the University of Chicago Booth School of Business and a BA in Mathematics from the University of Pennsylvania. He lives in Manhattan and enjoys traveling. His current “country number” is 115.

Speaker(s)

Integrated Research Platform concept and key deliverables from EU PEARL

Cecile Spiertz, MSc

Netherlands

Cecile Spiertz is a senior director at J&J, Head External Innovation, Clinical Trial Platforms and current project lead for the IMI Project EU-PEARL. She has a strong operational track record in successful delivery of global clinical development programs for Janssen Immunology R&D in her most recent positions as Global Operations Head and Strategy&Operations Lead for the Immunology clinical development organisation. She brings > 25 years of experience in phase 1, 2, 3 of drug development in various scientific and operational leadership roles, in different companies and is highly skilled in leading global cross-functional teams and innovation projects.

IRP for Major Depressive Disorder

Stefan Gold

Professor
Charité Universitätsmedizin Berlin, Germany

IRP for Major Depressive Disorder

Fanni-Laura Mantyla

Patient Community Representative, Switzerland

Study Design and Statistical Methods for platform trials, including Regulatory guidance

Franz Koenig, MSc

Associate Professor
Medical University of Vienna, Austria

Franz König is Associate Professor at the Section of Medical Statistics at the Medical University of Vienna, Austria. He regularly serves as member of ethics committees and DSMBs. From 2008 till 2010 he was seconded to the European Medicines Agency as statistical expert. His main research interests are multiple testing and adaptive designs. For more information see www.meduniwien.ac.at/medstat

Study Design and Statistical Methods for platform trials, including Regulatory guidance

Benjamin Hofner, PhD

Head of Data Science and Methods
Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany

Benjamin Hofner is Head of Data Science and Methods at the Paul-Ehrlich-Institut (PEI). In this role he is involved in the assessment of Clinical Trial Applications and Marketing Authorisation Applications, and provides Scientific Advice to stakeholders. He is member of the EMA Methodology Working Party ESEC and Adjunct Lecturer for Biostatistics at the medical school at FAU Erlangen-Nuremberg. Benjamin was involved in the IMI project EU-PEARL on patient centric research platforms as regulatory task lead and is member of the temporary drafting group (tDG) for the EMA reflection paper on platform trials.

Regulatory Perspective on IRPs: Experience with EU CTR to support Complex Clinical Trials.

Olga Kholmanskikh Van Criekingen, MD, PhD

Clinical assessor
Federal Agency for Medicines and Health Products, Belgium

Olga Kholmanskikh is a clinical assessor at the Federal Agency for Medicines and Health Products (FAMHP), a Belgian National Competent Authority, since 2012. She is an MD by training and holds PhD in Biomedical and Pharmaceutical Sciences. She leads the Complex Clinical Trials (CCTs) working subgroup at Clinical Trials Coordination Group (CTCG) of the Heads of Medicines Agencies (HMA).

4:35 PM — 4:45 PM

Coffee Break

4:45 PM — 5:55 PM

Session 3: Part I: Real-World Evidence in Regulatory and HTA Decision Making: Report on MetReal Cluster covering 5 European Horizon Europe Projects

A total of five EU Horizon Europe projects have been funded for 4 – 5 years of research into what can make RWE regulatory acceptable. Participants come from patient organisations, hospitals, technology vendors, pharmaceutical industry, HTA bodies and medicines regulatory agencies. We will in this session explore the topics of real world and synthetic data and the use of artificial intelligence to create digital twins in clinical trials across the five projects. The output from these initiatives will create the principles for regulatory acceptance of new types of data and methods in clinical trials in the years to come.

Session Chair(s)

Jesper Kjær, MS

Global Director for Public, Private Partnerships, Strat Ops, Global Med Affairs
Novo Nordisk, Denmark

Director of Data Analytics Centre at the Danish Medicines Agency and co-chair of HMA / EMA Big Data Steering Group. 20 years for life science experience in academia and industry. Been leading EU framework programme workpackages, IMI and TransCelerate Biopharma workstreams in the past. Currently active in development of FHIR for clinical research and use of AI/ML in life science.

Speaker(s)

Real4Reg Project

Britta Hänisch

Head of Division Research
BfArM, Germany

More-Europa Project

Peter Mol, PharmD, PhD

European representative (alternate),
MEB, Netherlands

Peter Mol is a principal assessor at the Dutch Medicines Evaluation Board and a member (vice chair) of EMA's Scientific Advice Working Party. He is chair of the EMA Cross-Committee Task force on Registries. He is also a professor of drug regulatory science at the University Medical Center Groningen. His research interest is in the area of regulatory science; from new tools to optimize regulatory decision-making (especially impact of personalised medicine and real world evidence), to improve knowledge transfer and with a specific interest in safety communication.

REDDIE Project

Martina Radanovic

Project Manager
RISE - Research and Innovation Services, Croatia (Hrvatska)

Realm Project

Gokhan Ertaylan

Research Lead
VITO, Belgium

Oncovalue Project

Pekka Kahri

Technology Officer
HUS, Finland

I work at the strategy & development group of Helsinki University Hospital and am coordinating an EU funded ONCOVALUE-project (2023-2026). ONCOVALUE is part of the European Cluster for Methods to use Real-world and synthetic data for regulatory purposes and health technology assessment. ONCOVALUE project aims to increase the capabilities of European cancer hospitals to easily and timely collect real-world data (RWD). Systematic collection and analysis of clinical data is needed for the continuous development of treatment and improvement of outcomes. Real-time high-quality clinical data also supports the decision making of regulatory and HTA bodies on the value of novel cancer therapies.

5:55 PM — 6:10 PM

Recap of the Day

Day 2 Nov 16, 2023

1:30 PM — 1:40 PM

Welcome and Introduction by DIA

1:40 PM — 2:40 PM

Session 4: Digital Health Technologies in Clinical Trials: Update on the State of Play: Decentralized Clinical Trials

The European Medicine Regulatory Network published a recommendation paper on clinical trials with decentralised elements last year. In this session perspectives from ethics, patients, industry and regulatory is given. Their experiences and challenges in practice and future considerations will be discussed.

Session Chair(s)

Elke Stahl, PhD

Senior Expert, Clinical Trials Department

Federal Institute For Drugs and Medical Devices (BfArM), Germany

Dr. Elke Stahl, Clinical Trial Unit BfArM, Germany. Clinical Trials Senior Expert. CoChair of the Clinical Trial Facilitation Group (CTFG) till 2022. Involved in EMA's EU CTIS groups as BfArM's representative, National Contact Point for the CTR in Germany, representative in European Commissions CT working groups. Prior BfArM 10 years experiences as a pharmacokineticist at Bayer HealthCare AG, Germany, in early research up to candidate selection. PostDoc at Hoffmann-La Roche Inc and University of North Carolina (UNC). Ph.D. in pharmacology and licenced pharmacist.

Monique Al, PhD

Special advisor CCMO
Central Committee on Research Involving Human Subjects (CCMO), Netherlands

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 the lead of the CTCG ethics advisory group. 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.

Speaker(s)

The Regulatory Perspective

Mårten Wendt

Physician, Clinical Investigator
Swedish Medical Products Agency , Sweden

The Ethical Perspective

Kasper Bendix Johnsen

Head of Section
Danish National Center For Ethics, Denmark

Patient perspective: How to Tailor Decentralised Clinical Trials to Patient Needs

Eric Vermeulen

Policy Officer,
VSOP - Patient Alliance for Rare and Genetic Diseases, Netherlands

Current Experiences and Challenges from a Sponsor Perspective

Jianmei Wang

Senior Principal Statistical Scientist
Roche, United Kingdom

With Additional Participation of

Craig H Lipset, MPH

Managing Partner
Clinical Innovation Partners, United States

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials & Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant Professor in Health Informatics at Rutgers University, and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at Home. Craig was previously the Head of Clinical Innovation and Venture Partner at Pfizer, and on the founding management teams for two successful startup ventures.

With Additional Participation of

Abba Elizabeth Theogaraj, PhD

Regulatory Senior Group Director
Roche, Switzerland

Elizabeth Theogaraj is a Global Regulatory Leader at Roche. Elizabeth is a seasoned regulatory professional with extensive experience across the full project lifecycle including developing strategies and leading major Regulatory submissions. Elizabeth has a PhD in Neuroendocrinology from Imperial College, London. At Roche, Elizabeth is working in Oncology Precision Medicine. Elizabeth led the team developing the first fully decentralized clinical trial (DCT) in oncology (Alpha-T). Using this experience, she has been leading HA interactions to help shape HA thinking for DCTs. The has resulted in very positive discussions with various global HAs and helped shaped the regulatory guidances released on DCTs.

2:40 PM — 2:50 PM

Coffee Break

2:50 PM — 4:00 PM

Session 5: Leveraging Artificial Intelligence (AI) In Clinical Trials - Opportunities and Ethical Considerations

The recent advancements in artificial intelligence have ignited a surge of hope regarding its groundbreaking potential, while simultaneously raising concerns about the societal consequences it may bring.

This session explores the opportunities of artificial intelligence (AI) in medicines development and health care. As a counterpoint, the session delves into the ethical considerations surrounding AI-driven healthcare around fairness, privacy, and transparency. The panel discussion brings both perspectives together to explore harnessing the potential of AI in medicines development in an ethical way.

Session Chair(s)

Florian Lasch

Biostatistics Specialist, Data Analytics and Methods Task Force
European Medicines Agency, Netherlands

Florian is a Biostatistician with a degree in mathematics and a PhD from Hannover Medical School. Florian works as a Biostatistics Specialist at the European Medicines Agency, providing scientific support to development and evaluation throughout all stages of marketing authorisation assessments of medicinal products, and leads the ACT EU Priority Action on Clinical Trial Methodologies.

Gunilla Andrew-Nielsen

Head of Clinical Trials
Swedish Medical Products Agency (läkemedelsverket), Sweden

Speaker(s)

A Vision for AI Driven Health Care

Antonio Estrella

Managing Director, Author, & Strategic Futurist,
Taliossa, Singapore

Unlocking the Potential of AI in Medicines Development

Nicole Mahoney, PhD

Executive Director US Regulatory Policy & Intelligence
Novartis Pharmaceuticals Corporation, United States

Nicole Mahoney is an Executive Director for Regulatory Policy at Novartis, and global regulatory policy lead for data and digital technologies, including real-world evidence and artificial intelligence. Prior to Novartis, she led Regulatory Policy at Flatiron Health, helping support the acceptance of real-world evidence for regulatory decision making in oncology. Nicole developed and advanced anti-infectives policies as a Director of Global Regulatory Policy at Merck, senior officer for the Pew Charitable Trusts' antibiotics and innovation project, and FDA Commissioner's Fellow. She earned a doctorate in biochemistry from the Albert Einstein College of Medicine and was a postdoctoral fellow at the University of California, San Francisco.

Ensuring Ethical AI: Implications for Medicines Development

Arnaub Chatterjee, MHA, MPA

Chief Product and Solutions Officer
TriNetX, United States

Arnaub Chatterjee is Chief Product and Solutions Officer at TriNetX, a health technology platform focused on improving clinical research, evidence generation and safety. He also serves as Senior Advisor at the Carlyle Group where he evaluates investments in the life sciences and healthcare sectors. Additionally, Arnaub is passionate about teaching and is a member of the faculty in the Department of Health Care Policy at Harvard Medical School.

Diversity in Clinical Trials

Karen Hicks, DrMed

Deputy Director, Office of Medical Policy, CDER
FDA, United States

Dr. Hicks is the Deputy Director of the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) at the United States Food and Drug Administration (FDA). She oversees regulation and policy development for CDER and participates in cross-cutting agency initiatives. She serves as one of the executive sponsors of the Diversity Plans Implementation Committee and works closely with the Office of the Commissioner and other Centers to promote diversity and inclusion of underrepresented populations in clinical trials. Dr. Hicks came to the FDA in 2003 and previously served as a Team Leader in the Division of Cardiovascular and Renal Products and as a Deputy Director in the Office of Nonprescription Drugs II.

Standing Together

Xiaoxuan Liu

Senior Clinician Scientist in AI and Digital Health Technologies and an Ophthalmology Doctor, University of Birmingham, United Kingdom

4:00 PM — 4:10 PM

Coffee Break

4:10 PM — 5:10 PM

Session 6: Leveraging Artificial Intelligence (AI) In Clinical Trials - Regulatory Perspectives

Building on the previous session on opportunities and ethical considerations related to AI in medicines development, this session will put the spotlight on the regulatory perspectives. It will bring together an outlook on the EU strategy for AI with reflections on the use of AI in clinical trials from different regulatory perspectives.

Session Chair(s)

Florian Lasch

Biostatistics Specialist, Data Analytics and Methods Task Force
European Medicines Agency, Netherlands

Florian is a Biostatistician with a degree in mathematics and a PhD from Hannover Medical School. Florian works as a Biostatistics Specialist at the European Medicines Agency, providing scientific support to development and evaluation throughout all stages of marketing authorisation assessments of medicinal products, and leads the ACT EU Priority Action on Clinical Trial Methodologies.

Gunilla Andrew-Nielsen

Head of Clinical Trials
Swedish Medical Products Agency (läkemedelsverket), Sweden

Speaker(s)

European Strategy on AI in health care

Yiannos Tolias

Legal Lead AI and AI liability in healthcare & European Health Data Space (EHDS) Team, DG SANTE, European Commission, Belgium

Yiannos is the legal lead on AI and AI liability in Healthcare in the DG for Health and Food Safety at the European Commission. He is also part of the team that developed the European Health Data Space (EHDS) legislative initiative. Additionally, he is a member of the EC teams that developed the AI Act and Product Liability proposals. He was a Senior Emile Noel Fellow at NYU Law School carrying out research on AI in medicine and law. Prior to joining the European Commission, he was an Assistant Professor of EU law at the Universities of Edinburgh and Dundee. He

holds a Ph.D. in EU Constitutional law from the University of Edinburgh and he was later a Post-doctoral Research Fellow.

Reflecting on the Use of AI in Clinical Trials – the FDA Perspective

Tala Fakhouri, PhD, MPH

Associate Director for Policy Analysis, Office of Medical Policy, CDER
FDA, United States

Reflecting on the Use of AI in Clinical Trials from an EU Regulatory Perspective

Gabriel Westman

Head of Artificial Intelligence
Swedish Medical Products Agency, Sweden

GW 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, exploring use of real-world data, and hoping for a better and data-driven world.

5:10 PM — 5:20 PM

Coffee Break

5:20 PM — 6:30 PM

Session 7: Part II: Real-World Evidence in Regulatory and HTA Decision-Making: Global and Regional Perspectives on Moving from Pilots to Operation

This session will aim to showcase the draft report and review that has been undertaken by CIOMS and EMA, respectively, into the application of real-world evidence. We will attempt to tease out critical success factors in delivering RWD/E for multiple stakeholders' needs. The use of real-world data and real-world evidence in regulatory and HTA decision making has been under discussion for more than a decade. However, where it would have been a novelty several years ago, it is

now playing an increasingly significant role through early to late-stage drug development and in regulatory and market access decisions. This is observed in the context of rare and orphan disease and other unique patient populations such as children and women of child-bearing age (WOCBA), but it is also of relevance for broader patient populations, particularly where there is a need to demonstrate efficacy and effectiveness in the longer term.

Session Chair(s)

Álmath Spooner, PhD

Head of Europe Regulatory Policy & Intelligence (RPI)
AbbVie, Ireland

Álmath is Head of Europe Regulatory Policy at AbbVie. Álmath dually qualified as a pharmacist and a barrister-at-law with a PhD from Trinity College Dublin and postgraduate qualifications in statistics and pharmaceutical medicine. Álmath has extensive experience in regulation and policy having held management and assessment roles at the Irish HPRA (2007-2019) and at EMA's PRAC (Vice Chair 2012-2018). Álmath was called to the Bar of Ireland in 2018 and practiced in Commercial Law prior to joining AbbVie in 2020. At EFPIA, Álmath chairs the Integrated Evidence Generation Working Group. She has prior experience in various global initiatives including at ICH. She is a member of the DIA Regional Advisory Council.

Lembit Rago, DrMed, MD, PhD

Secretary General
Council for International Organizations of Medical Sciences (CIOMS), Switzerland

Dr Lembit Rägo was a Professor of Clinical Pharmacology and Director General of the Estonian State Agency of Medicines until joining WHO Geneva in 1999. When retiring WHO in 2016 Dr Rägo served as the Head of the WHO's Unit, Regulation of Medicines and Other Health Technologies (RHT), which covered norms and standards, safety, prequalification and regulatory strengthening for medicines, vaccines and diagnostics. 2000-2016 he served also as WHO observer to the ICH Steering Committee, ICH GCG and MedDRA MB, IPRF and ICMRA. Since 2016 he works as a Secretary-General of Council for International Organizations of Medical Sciences (CIOMS). Under his leadership CIOMS joined ICH as an observer in 2016 and increased its number of working groups.

Speaker(s)

Global and regional harmonization initiatives relating to RWE

Gracy G Crane, PhD, MS

Policy Lead
Roche, United Kingdom

Gracy holds a Ph.D. in Molecular Oncology from King's College Hospital, an M.Sc. in Biomedical Research from King's College. She did her postdoctoral training at Oxford (UK) and at MIT (USA). Gracy brings broad experience in clinical research, medical affairs and health outcomes within the pharmaceutical industry. She currently works as a Regulatory Policy Lead at Roche Pharmaceuticals, focusing on RWD Policy.

Regulator-led RWE Studies – an EMA Review of the Experience Gained

Stefanie Prilla, DrSc

RWE Coordinator
European Medicines Agency, Netherlands

Dr. Stefanie Prilla is a pharmacist and doctor of natural sciences. Stefanie has more than 15 years of experience in the field of regulatory science with a focus on EU marketing authorisations. Since 2007, she has been working for the European Medicines Agency (EMA). Before joining the EMA data analytics task force, Stefanie held the post of PRIority MEdicines (PRIME) Scientific Coordinator. Previously, Stefanie supported the set up of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) as well the IMI PROTECT project which was led by EMA. In her current role, Stefanie coordinates EMA studies using real-world data to support EU regulatory decision making.

Executing Real-World Studies – Use Case

Daniel Prieto-Alhambra

Section Head - Health Data Sciences at Botnar Research Centre
and Professor at University of Oxford and Erasmus MC, United Kingdom

Application of RWE in HTA decision-making: use case

Elena Petelos

Lecturer of Evidence-Based Medicine and Evidence-Informed Policy
University of Maastricht, HTAi, Netherlands

Panel Discussion: Real world evidence in regulatory decision making – critical success factors?

Estelle Michael

RWE Policy & External Engagement Lead
UCB, Belgium

Estelle Michael majored in science and law, and is a recognized global industry policy leader who aims to positively impact people's lives and to develop sustainable ecosystems, that facilitates patient access to health care solutions. She has partnered with DIA for over twenty years and in collaboration with patient groups, policy makers, academia and industry delivered thought provoking and forward looking panel discussions and workshops. She strives for excellence as a leader, and strongly believes that we need to continuously learn and improve, failing fast and succeeding slow and long

6:30 PM — 6:40 PM

Closing words and key take-aways