Health Innovation – The European Health Data Space and Real-World Evidence

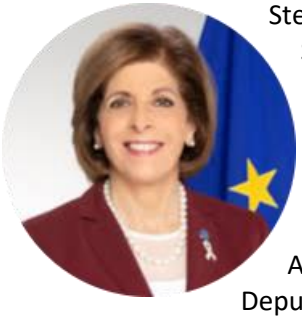
An event of the Federal Ministry of Health associated programme within Germany's Presidency of the Council of the European Union.

Speaker Biographies (by speaking order)

Véronique Trillet-Lenoir
Member of the European Parliament, Renew Europe

Dr. Véronique Trillet-Lenoir is a French Member of the European Parliament (MEP) in the Renew Europe group since 2019. She is a member of the Environment, Public Health and Food Safety committee (ENVI) and of the Employment and Social Affairs committee (EMPL). An oncologist by background, Dr. Trillet-Lenoir is the rapporteur for the European Parliament's cancer report in the recently established Special Committee on Beating Cancer (BECA) as well as the Co-Chair of the MEPs Against Cancer (MAC) group. She is an advocate for addressing inequalities in cancer prevention and care, and patient's abilities to return to normal life following treatment. She is also a shadow rapporteur on the health technology assessment (HTA) file, the recently passed EU4Health report, and the report on the shortage of medicines. Before joining the European Parliament, she was the Secretary General of the French National Oncology Council and the President of the management committee of the Canceropôle Lyon Auvergne-Rhône-Alpes (CLARA), a research cluster dedicated to cancer. Until 2008, Dr. Trillet-Lenoir was a scientific advisor to the Healthcare Quality department at the French National Cancer Institute (INCa). In 2003, she created the oncology department at the University Hospital Centre of Lyon.

Stella Kyriakides
EU Commissioner for Health and Food Safety



Stella Kyriakides is serving as European Commissioner for Health and Food Safety since 2019. As part of the Commission's response to the COVID-19 pandemic, she is member of the special task force to coordinate the European Union's response. Before joining the European Commission, she was a Member of the House of Representatives of Cyprus (2006 - 2019) and served as the 30th President of the Parliamentary Assembly of the Council of Europe (2017 - 2018), where she was the Chair of the Committee on Social Affairs, Health, and Regional Development. As an MP, Kyriakides was the Deputy Chairwomen of the House Standing Committee on Health Affairs and founded the first breast cancer advocacy organisation in Cyprus, serving as its President from 2000 to 2015. She was also President of the European Breast Cancer Coalition Europa Donna. Before being elected to the Cypriot Parliament, she graduated with a degree in Psychology and worked as clinical psychologist in the Cypriot Ministry of Health's Department of Child and Adolescent Psychiatry.

Karen Facey
Senior Research Fellow, University of Edinburgh

Dr. Karen Facey worked as a senior statistician in the pharmaceutical sector and UK medicines regulation, before becoming the founding Chief Executive of the first national HTA agency in Scotland. Since 2003, Dr Facey has been an independent consultant on health policy, HTA and patient involvement. She has served as Non-Executive Director on Scottish health boards and now leads research part-time on appraisal of rare disease treatments in the IMPACT HTA project as Principal Investigator at the University of Edinburgh. She is passionate about holistic HTA to determine value and use of health service data to improve patient care. Dr Facey has facilitated the development of the RWE4Decisions multi-stakeholder initiative and is the lead co-author of the paper on 'Real-World Evidence to Support Payer/HTA Decisions about Highly Innovative Technologies in the EU – Actions for Stakeholders', commissioned by the Belgian payer INAMI/RIZIV.

Yann Le Cam
Chief Executive Officer, EURORDIS

Yann Le Cam is CEO of EURORDIS-Rare Diseases Europe, an organisation which he founded in 1997. A patient advocate for over 30 years, he has been a frontline advocate and has called for pan-European negotiations that allow Member States to jointly agree on the value of innovative medicines, negotiate prices of orphan medicines, and agree on research activities to generate additional real-world evidence to improve access to medicine for patients with rare diseases. Yann Le Cam has previously served as a member of the European Medicines Agency's (EMA) Management Board (2016 -2019). For 9 years he served on the EMA's Committee for Orphan Medicinal Products (COMP) and was one of the first patient representatives appointed to a committee at a medicine regulatory agency.

Mercedes Echauri
Vice-President Market Access Europe and Canada, Takeda

Mercedes Echauri is Vice-President of Market Access of Europe and Canada at Takeda. Prior to this role, she was the Head of International Access Innovation at Shire (now Takeda). She also worked at Novartis where she led and developed new market access teams in over 10 countries. Throughout her professional career, Mercedes has participated in more than 50 launches across all therapeutic areas and has extensive experience in interacting with health authorities and decision-makers. Mercedes holds a pharmacy degree from the University of Barcelona as well as a post-degree diploma from the Management Development Program at the IESE Business School.

Maurizio Scarpa
Coordinator MetabERN, Regional Coordinating Centre for Rare Diseases, Udine University Hospital, Italy

Prof. Maurizio Scarpa, MD, PhD, is the Coordinator of the European Reference Network for Hereditary Metabolic Diseases, MetabERN. He is the Founder and President of the Brains for Brain Foundation, a pan-European task force on brain and neurodegenerative diseases. Professor Scarpa is also the Director of the Coordinating Center for Rare Diseases at the Udine University Hospital and a Professor of Pediatrics at the Department of Women and Children's Health at the University of Padova, Italy. Professor Scarpa's medical degree and doctorate are in Pediatrics. He completed a postdoctoral fellowship in molecular biology and gene expression at the European Molecular Biology Laboratory in Heidelberg and in genetics/gene therapy at the Baylor College of Medicine in Houston. From 2017 to 2018, he was the Chairman of the European Reference Network Coordinators Group. He was also the Coordinator of the European Commission DG SANTE project InNerMeD-I-network (Inherited NeuRoMetabolic Diseases Information Network) which aimed to create a network of information on the diagnosis and treatment of Neuro Metabolic Disorders. His teaching and educational interests aim, amongst others, at the development of an innovative health approach for the diagnosis and treatment of metabolic inherited diseases.

Marc Van de Casteele
Coordinator expertise pharmaceuticals, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)

Dr. Marc Van de Casteele is coordinator of pharmaceutical assessments at the Belgian National Institute of Health and Disability Insurance (INAMI-RIZIV) since 2013. He joined INAMI-RIZIV in 2003, where he has been working for the Belgian Reimbursement Commission for Reimbursement of Pharmaceuticals, nowadays headed by Dr. Diane Kleinermans. Dr. Van de Casteele has been involved in the BeNeLuxA initiative since 2015 as chair of the Domain Task Force Health Technology Assessment Pharmaceuticals.

Antje Behring
Acting Head of Drug Department, German Federal Joint Committee (G-BA)

Dr. Antje Behring is head of the Pharmaceuticals Department in the Federal Joint Committee (G-BA). In the G-BA she has been involved in the early benefit assessment procedure for new drugs from the very beginning.
Before joining the G-BA in 2011, she worked as a consulting pharmacist for a German health insurance company. She completed her pharmaceutical studies and her doctorate at the Ludwig-Maximilians-University Munich. Before studying pharmacy, she worked as a physiotherapist.

Liisa-Maria Voipio-Pulkki
Director-General of Strategic Affairs and Chief Medical Officer, Finnish Ministry of Health

Dr. Liisa-Maria Voipio-Pulkki is currently serving as Director-General of Strategic Affairs and as Chief Medical Officer of the Finnish Ministry of Social Affairs and Health. She has been actively involved in the Finnish Government's "Health Growth Strategy" of personalised medicine and national competence clusters and has chaired several national working groups on health system reforms and research and innovation policies. As of 2017, she is also the chair of the Steering Committee of the European Observatory on Health Systems and Policies, a WHO hosted partnership supporting evidence-informed health policy-making. A specialist in internal medicine and cardiology, she joined the Ministry in 2010 as Director of the Health Care Group. Previously, Dr. Voipio-Pulkki was employed as the Senior Medical Adviser of the Finnish Association of Local and Regional Authorities in 2004-2009, Chief of Emergency and Acute Care of the Helsinki University Hospital District in 2000-2004 and as a specialist and Adjunct Professor of Medicine at the University of Turku, Finland.

Peter Arlett
Head of the Data Analytics and Methods Task Force, European Medicines Agency

Dr. Peter Arlett is the Head of the Data Analytics and Methods Task Force at the European Medicines Agency (EMA). He was also co-chair of the HMA-EMA joint Big Data Task Force which recommended in a recent report the creation of a **D**ata **A**nalysis and **R**eal-**W**orld **I**nterrogation **N**etwork (DARWIN) – a network of healthcare databases across the EU containing information from a variety of real-world sources that could be used to drive decision-making. In 2019, he co-authored a paper on 'Real-World Data for Regulatory Decision-Making: Challenges and Possible Solutions for Europe'. A medical doctor by background, he joined the EMA in 2008 as the Head of the Pharmacovigilance and Risk Management Department. Prior to joining the EMA, he was a Principal Administrator in the Pharmaceuticals Unit of the European Commission and an Expert Assessor at the UK MHRA.

Alexander Natz
Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

Dr. Alexander Natz is the Secretary General of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), a position he holds since 2010. He also works as a lawyer for the law firm Novacos and advises pharmaceutical and biotech companies in regulatory and pricing & reimbursement decisions from a EU and German law perspective. From 2008 to 2013, he was the head of the Brussels office of the German Pharmaceutical Industry Association (BPI). Dr. Natz also worked in the field of competition law with the European Commission and in the pharmaceutical industry. He was a research assistant at Duke University (USA) where he dealt with international pharmaceutical law.

Christine Chomienne
Vice-Chair of Horizon Europe Mission Board for Cancer

Dr. Christine Chomienne is currently Vice-Chair of the Horizon Europe Mission Board for Cancer and a Professor of Cellular Biology at the Paris Diderot University. Prior to this, she was the Director of Research and Innovation at the French National Cancer Institute (INCa) and Director of the French Cancer Institute (Inserm), and a past president of the European Hematology Association. A physician specialized in Hematology, she has served on many scientific and clinical committees focused on Leukemia, Immunology, Oncology and Stem Cell Research. She was head of the Cell Biology Department at the Hôpital Saint Louis, Paris and Director of the University Inserm Research Laboratory at the Institut Universitaire d'Hématologie. Dr. Chomienne has also been involved in patient/parent participation in cancer research and in communication education on personalised medicine.

Anja Tebinka-Olbrich
Head of Unit AMNOG EBV, GKV-Spitzenverband

Since 2012, Dr. Anja Tebinka-Olbrich is Head of the AMNOG - Drug Pricing Unit at the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), which represents all statutory healthcare and long-term care insurance funds in Germany. She is in charge of AMNOG (the Arzeinmittelmarkt-Neuordnungsgesetz introduced in Germany in 2011), which imposes a systematic and formal assessment of the "added therapeutic benefit" of new medicines by the Federal Joint Committee (G-BA), and she is thereby involved in negotiating the reimbursement price of new medicines with pharmaceutical companies, based on the decision of the G-BA. From 2008 to 2012, she was a consultant in the Pharmaceutical and Remedies Department. Before joining the GKV-Spitzenverband she conducted research and taught at various universities.

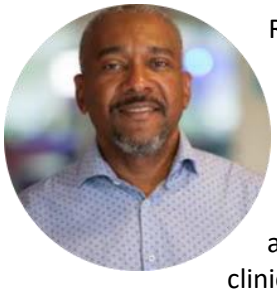
Tit Albreht
Head of the Centre for Health Care, National Institute of Public Health of Slovenia

Dr. Tit Albreht is the Head of the Centre for Health Care at the National Institute of Public Health of Slovenia. He is a member of the Scientific Committee of the European Public Health Association (EUPHA), and President of the Slovenian Preventative Medicine Society. Dr. Albreht is an Associate Professor of Public Health at the Medical Faculty of Ljubljana and teaches public health and epidemiology at the Medical Faculty of Maribor, Slovenia. Since 2006, he has been actively involved in the development of cancer policies at the European level – during the first Slovenian Presidency of the Council of the EU in 2008 and later as coordinator of Joint Actions on cancer policy at the European Union level, including the European Partnership for Action Against Cancer (EPAAC), Cancer Control (CanCon) and most recently, the Innovative Partnership for Action Against Cancer (iPAAC). He acts as a reviewer for several projects submitted for funding to the European Commission.

Tomáš Skácel
Vice President, Head of Medical Affairs Oncology Europe & Canada, AstraZeneca

Dr. Tomáš Skácel, MD, PhD, is Vice President, Head of Medical Affairs for Oncology in Europe and Canada at AstraZeneca since July 2020. With over 20 years of experience in the Biotech, Life Science, and Pharmaceutical sector he has been involved in development in multiple oncology transformative treatments in hematology, solid tumors, oncology supportive care and bone health. Dr. Skácel is trained in internal medicine and hematology and has published over 100 peer reviewed scientific publications.

Robert Greene
Patient Advocate, Founder of HungerNdThirst Foundation,
Advisory Board Member for EPF's Data Saves Lives initiative &
Board Member of the European Cancer Patient Coalition (ECPC)



Robert Greene is the founder and President of the HungerNdThirst foundation, an advisory Board Member for the European Patients Forum's Data Saves Lives initiative and a Board Member of the European Cancer Patient Coalition (ECPC). He was diagnosed and treated for colon cancer and prostate cancer. Robert Greene also advises organisations on their patient relations strategy. He has previous experience working as a nurse and assistant anesthetist. An advocate for a more patient centric approach in clinical trials, his interests include patient empowerment, diversity, personalised healthcare, cancer-related malnutrition and healthcare disparities in prostate cancer.

Denis Lacombe
Director General, European Organisation for Research and Treatment of Cancer (EORTC)

Dr. Denis Lacombe has been the Director General of the European Organisation for Research and Treatment of Cancer (EORTC) since 2015. With a background in pharmacology and pharmacokinetics, Dr Lacombe joined EORTC in 1993 as a research fellow and in 2010 became the Director of EORTC Headquarters. In 2020 he co-authored a study at the request of the Panel for the Future of Science and Technology (STOA) on 'Treatment optimisation in drug development', calling for an integrated treatment optimisation approach, incorporating both interventional and observational research to bridge the research gap. Since April 2020, he is also the Co-Chair of the European Cancer Organisation Health Systems and Treatment Optimisation Network which is considering the use of real-world data, patient reported outcomes & clinical trial endpoints amongst other topics.

Jo De Cock
CEO, INAMI - RIZIV

Jo De Cock has been CEO of the Belgian National Institute of Health and Disability Insurance (INAMI- RIZIV) since 1995. Prior to this, he was a Deputy Director and Counsellor for social affairs in the office of the Belgian Prime Minister (1985-1993) and later filled the position of adjunct general administrator of the National Social Security Office (1993-1995). Under Jo De Cock's thought leadership as CEO, INAMI-RIZIV conveyed a series of roundtables bringing together different stakeholders to consider the use of real-world evidence to ensure short term affordability, long-term sustainability and patient access in 2018 and 2019. This resulted in several papers including on 'The use of real world data throughout an innovative medicine's lifecycle', 'Outcomes based pricing and reimbursement of innovative medicines with budgetary limitations' and 'TRUST4RD: Tool for Reducing Uncertainties in the evidence generation for specialised Treatments for Rare Diseases' (published in Orphanet). Since its creation in 2019, Jo De Cock is closely involved in the International Horizon Scanning Initiative (IHSI), an independent entity legally registered at RIZIV/INAMI and a spin-off of the BeNeLuxA initiative which aims to provide data to payer organisations and decision-makers to drive better medicinal products pricing.

Hannah Brühl
Division Benefit Assessment, Pricing and Reimbursement of Novel Medicinal Products, Federal Ministry of Health, Germany

Dr. Hannah Brühl works at the Federal Ministry of Health in the Division Benefit Assessment, Pricing and Reimbursement of Novel Medicine Products. Prior to joining the Health Ministry, she worked as a scientific advisor for the German Joint Committee (G-BA). At the G-BA she was involved in the project management of the EUnetHTA work package on early scientific advice to industry.

Cláudia Furtado
Head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) and the Information and Strategic Planning Division, INFARMED

Dr. Cláudia Furtado is the head of Health Technology Assessment, Pricing and Reimbursement Division (DATS) as well of the Information and Strategic Planning Division (DIPE) at INFARMED, the Portuguese National Authority of Medicines and Health Products. As head of DATS, she is responsible for HTA evaluation, pricing and reimbursement of medicines, medical devices and health products, and for managed entry agreements. As head of the DIPE, she oversees monitoring of health consumption and expenditure and the definition and evaluation of policy measures. In addition to her role at INFARMED, she is an assistant professor at the Portuguese National School of Public Health (Universidade NOVA de Lisboa).

Wim Goettsch
Special Advisor HTA, Zorginstituut Nederland (ZIN)

Dr. Wim Goettsch has been Special HTA-Advisor at the Dutch National Health Care Institute (ZIN) since 2018. He is also an Associate Professor of International Collaboration in HTA at Utrecht University, where he is leading a H2020 consortium called HTx, new methods for Health Technology Assessment (2019-2024). Between 2017 and 2019, Dr Goettsch co-authored a number of papers on the use of real- world evidence in health technology assessment (HTA) practice. He has been actively involved in many initiatives on RWE from HTAi, ISPOR and IMI-GetReal and is currently co-leading a Dutch national initiative on patient registries for the monitoring of expensive pharmaceuticals. Previously, he was the Director of EUnetHTA Joint Action 3 from 2016 to 2018 where he introduced new models for 'Early Dialogues' and Joint Assessments that are applicable throughout the EU.

Jakub Boratyński
Acting Director in charge of Digital Society, Trust and Cybersecurity, DG CONNECT

Jakub Boratyński is Acting Director in charge of Digital Society, Trust and Cybersecurity and Head of Unit 'Cybersecurity and Digital Privacy Policy' within the European Commission's Directorate-General for Communication Networks, Content and Technology (DG CNECT). Amongst other tasks, he is involved in negotiations of the Cybersecurity Act, implementation of the Network and Information Security (NIS) Directive, preparation of the Commission's Recommendation for a common EU approach to the security of 5G networks, and the EU cyber-security strategy's actions on resilience and cooperation with the EU Agency for Network and Information Security (ENISA). Before joining the European Commission, Jakub Boratyński was a Director at the Stefan Batory Foundation in Warsaw and Policy Officer with the United Nations High Commissioner for Refugees.

This meeting is enabled by the sponsorship provided by EUCOPE, Astra Zeneca, Gilead Sciences, Novartis, Roche and Takeda