RWE4Decisions Symposium

Mobilising Real-World Data to Enhance HTA/Payer Decision-Making

20 NOVEMBER 2025 | 14:00-17:00 CET (3 HOURS) | ZOOM

Co-moderators & Speakers' biographies

Karen Facey, RWE4Decisions facilitator

Karen Facey worked as a statistician in the pharmaceutical sector and UK medicines regulation, before becoming founding Chief Executive of the first national HTA agency in Scotland. Since 2003, Karen has been an independent HTA consultant with special interests in RWD, rare diseases and patient involvement. She is passionate about holistic HTA to determine value and use of health service data to improve patient care. Karen also works with the University of Oxford as a Senior HTA Advisor in the IHI Guidelines for RWE Generation project and with Utrecht University in the SUSTAIN HTA Coordinating Support Action.

François Meyer, RWE4Decisions facilitator

François joined the management team of HAS in 2005, leading the setup of the HTA Division across key areas like pharmaceuticals, medical devices, interventional and diagnostic procedures, and public health programs. He expanded HAS's role in economic analysis within France's HTA field. He then focused on international cooperation, serving on the HTAi Board for two terms, coordinating EUnetHTA activities, and representing HAS in projects including Post Launch Evidence Generation with HTA-EMA cooperation. Before joining HAS, François held management roles at the French Medicines Agency (now ANSM). He was active at the EMA, serving on the Committee for Orphan Medicinal Products.

Maya Matthews, Deputy Director General for Digital, EU4Health and Health Systems Modernisation, DG SANTE, European Commission

Maya Matthews is Deputy Director and Head of the Health Technology Assessment (HTA) Unit within the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission. With over two decades of experience in public health, she has played a pivotal role in shaping EU health policy, particularly through the implementation of the EU HTA Regulation aimed at improving patient access to innovative technologies and fostering collaboration among Member States. Previously, Maya headed the Performance of Health Systems Unit and worked as deputy head of the Strategy and Coordination Unit. She has also represented the EU at the United Nations in Geneva on health issues. Prior to joining the Commission in 2008, she worked with EuroHealthNet and consulted on reproductive health, HIV prevention, and tuberculosis.

Hans Juul Hedegaard, Head of Unit, Director General's Office, Danish Medicines Agency

Hans Juul Hedegaard is Head of Unit, Director General's Office, Danish Medicines Agency, where he has worked since 2022. He has for the past decade worked with advancing use of real-world data for decision making and have been active in the preparation for the European Health Data Space (EHDS). Before this role, Hans Juul worked as Section Head at the Danish Health Data Authority and as a Special Consultant at the Ministry of Health. His career reflects a strong focus on digital health, secondary use of health data, and international cooperation on evidence-based policy. Academically, he holds a Master's degree in Political Science from Aarhus University.

Denise Umuhire, Pharmacoepidemiology & RWE Specialist, Data Analytics and Methods Task Force, European Medicines Agency (EMA)

Denise Umuhire is a Pharmacoepidemiology and Real-World Evidence Specialist at the European Medicines Agency (EMA), where she works within the Data Analytics and Methods Task Force to advance the use of real-world data in regulatory science and health technology assessment. She is involved in projects such as DARWIN-EU and the EMA Big Data Steering Group, focusing on improving data quality and integrating patient experience data into decision-making. Before joining EMA, Denise held roles in pharmacovigilance and regulatory affairs in the pharmaceutical industry.

Elizabeth Vroom, Chair, World Duchenne Organisation

Elizabeth Vroom is co-founder and chair of the World Duchenne Organization since 2005. In 1994 she started the Duchenne Parent Project in the Netherlands. She is the mother of a 35-year-old son with Duchenne MD.
She was a board member of EURORDIS. She is involved in the training of other patient advocates/experts. She serves on several advisory boards regarding Care, Research, Ethics, Development of new medicines and Regulatory Issues in the Netherlands as well as international.
At the European Medicines Agency, she is patient expert at Scientific Advice and member of the Patient Consumer Working Party. Elizabeth is a member of the Advisory Board of EMA's Data Analysis and Real-World Interrogation Network (DARWIN EU). She is a strong advocate for optimal (re)use of health data and took the initiative for projects and workshop regarding data collection with patient organisation in the lead, FAIRification of health data, personal health data-lockers and development of PRO(M)s.

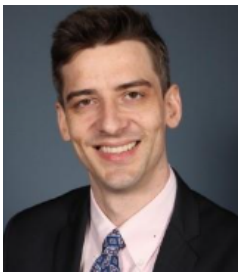
She initiated the Duchenne Accredited Care Center program and the global Duchenne Care Conference, an annual training to update healthcare professionals about Standards if Care and new developments for Duchenne. This online multiday conference is attended by approx. 700 healthcare professionals from more that 70 countries, from all continents.
Elizabeth is involved in several publications regarding Standards of Care and drug development for Duchenne Muscular Dystrophy, concerning development of outcome measures, patient

preferences, newborn screening and the role of biomarkers. She participates in several EU funded projects, such as BIND, BEAMER (IMI) and Trials@home (IMI), Share4Care as well as in the European Reference Network for Neuromuscular Disorders EURO-NMD.

Cláudia Furtado, Director of the Divisions of Information and Strategic Planning and Health Technology Assesment, INFARMED

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).

Matias Olsen, Senior Manager, Public Affairs & Policy, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)



Matias Olsen is Senior Manager for Public Affairs and Policy at the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE). Matias coordinates several thematic working groups, including the Pricing & Reimbursement/Market Access Working Group, the Genomics Working Group, and the EU HTA Regulation Task Force. Before joining EUCOPE, he worked as an advocate for European Cancer Patients Coalition and previously held positions at the Norwegian Labour and Welfare Administration.

Francis Arickx, Head of Pharmaceutical Policy Directorate, INAMI-RIZIV

Francis Arickx is the Head of the directorate Reimbursement of Medicines and Pharmaceutical Policy within the Health Care Department at the National Institute for Health and Disability Insurance (RIZIV-INAMI) in Belgium. Francis is also the former Secretary General for the Commission for Reimbursement of Medicines and acts as representative/expert for RIZIV-INAMI and Belgium on a number of national and European platforms (NM CAPR, MEDEV, MoCA). He is one of the country coordinators for the BeNeLuxA Initiative. Francis graduated in pharmaceutical sciences from the University of Ghent, Belgium and teaches ‘Health Policy’ in the Pharmaceutical Sciences Department at the University of Antwerp.

Niklas Hedberg, Chief Pharmacist, TLV

Niklas Hedberg is the Chief Pharmacist at the Swedish national governmental authority, the Dental and Pharmaceuticals Benefits Agency (TLV). Niklas is the Chair of the Consortium Executive Board for EUnetHTA21. He was the Chair of the EUnetHTA Executive Board between 2018 and 2021. Niklas has been working with pricing and reimbursement since 2001. He has held positions as medical assessor and project leader; Head of the Department for New Submissions (between 2009 and 2014) and he is now the chief pharmacist. Niklas has a broad experience of different aspects of value-based evaluation and over time has seen the increasing importance for health technology assessment (HTA) both across health care systems and on local level to prepare accurate decision making. Among Niklas' special interests have been the early development of joint scientific advice in 2009 an onward (pilots both nationally with MPA and on European level with EMA) and strategic discussions about RWD.

Eric Sutherland, Senior Health Economist, OECD

Eric is a Senior Health Economist leading the OECD's work in Digital Health, bringing together policy guidance for digital tools, integrated data, and responsible analytics including artificial intelligence. In that role, he is accountable for measuring and evolving the OECD's Recommendation on Health Data Governance (2017) and supporting digital health policy that provides data protection (e.g. security and privacy) and timely access to quality data to optimize the use of data for information, insights, and impact among individuals, health workers, policy makers, researchers, and innovators.

Prior to joining the OECD, Eric led the Secretariat for a pan-Canadian Health Data Strategy, bringing together experts and governmental leaders from across Canada to establish an integrated health data ecosystem that makes better use of data for health systems, public health, population health, research, and care. Eric authored the Pan-Canadian Heath Data and Information Governance Framework and Toolkit and has taught courses in data science, health data governance, and privacy.

Lara Wolfson, Associate Vice-President & Head, HTA Statistics, MSD

Lara Wolfson is an Associate Vice-President and Head of Health Technology Assessment (HTA) Statistics at MSD, where she has been working since 2015. She also co-leads the Europe an Special Interest Group (HTA ESIG) of the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI). Prior to her current position, Lara's career spans roles at various pharmaceutical companies and the World Health Organisation, where she focused on biostatistics, health technology assesment, vaccines, epidemiology, and health economics. She also held a teaching position at Brigham Young University (US) and the University of Waterloo (Canada). Over the years, Lara has authored of numerous scientific papers, particularly focusing on vaccination and infectious diseases. Lara obtained a PhD in Statistics from Carnegie Mellon University, with an undergraduate background from Simon Fraser University.