

## RWE over the lifecycle of ATMPs to meet the HTA(R) Needs

Tuesday 10 October 2023 | 15.00 – 16.30 CEST

### SPEAKER BIOGRAPHIES

#### **Karen Facey** (*co-moderator*)

**Senior Adviser on HTA, FIPRA International; RWE4Decisions Facilitator**



Karen Facey, PhD, CStat HonMFPH, is a Senior Adviser on HTA to FIPRA and drives the RWE4Decisions Secretariat's work. In her work within the RWE4Decisions multi-stakeholder initiative, Karen lead 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. In the past, she has worked as 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, Karen has been an independent consultant on health policy, HTA and patient involvement. She has served as Non-Executive Director on Scottish health boards and led research at the University of Edinburgh on appraisal of rare disease treatments in the IMPACT HTA project. She is passionate about holistic HTA to determine value and use of health service data to improve patient care.

#### **Eric Sutherland** (*co-moderator*)

**Senior Health Economist, Organisation for Economic Co-operation and Development (OECD)**



Eric Sutherland is 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. As of April 2023, Erci is also member of the RWE4Decisions Steering Group. In his role at the OECD, 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 Health Data and Information Governance Framework and Toolkit and has taught courses in data science, health data governance, and privacy.

## Ana Hidalgo-Simón

**Associate Professor, Leiden University; reNEW Translational Ambassador**



Ana Hidalgo-Simón MD, PhD, is associate professor at Leiden University and is the reNEW Translational Ambassador. In her role, Ana continues to work on advanced therapies, advocating for the increased translation of advanced medicines, from the lab to the patients. Prior to dedicating herself to the academia, Ana has worked for about 20 years as regulator at the European Medicines Agency, holding the positions of scientific administrator (2003- 2009), Head of Signal Detection (2009-2011), Head of Risk Management (2011-2013), Head of Specialised Scientific Disciplines (2013-2020) and Head of Advanced Therapies (2020-2022). Ana is a medical doctor by training, and hold a master's degree in Health Economics from the University of York, and a PhD in endothelial cell preservation for transplantation from the University of London.

## Niklas Hedberg

**Chief Pharmacist, Swedish Dental and Pharmaceuticals Benefits Agency (TLV)**



Niklas Hedberg is Chief Pharmacist at the Swedish Dental and Pharmaceuticals Benefits Agency (TLV), and member of the RWE4Decisions Steering Group. Within TLV, Niklas held positions as Medical Assessor, Project Leader and Head of Department for New Submissions (between 2009 and 2014). He is Chair of the Consortium Executive Board for EUnetHTA21 and was Chair of the EUnetHTA Executive Board between 2018 and 2021. In November 2022, Niklas has been appointed Co-Chair of the HTA Coordination Group, tasked to to coordinate and adopt the implementation of the HTA Regulation. 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 Real-World Data.

## **Christoph Rupprecht**

**Head of Department Health Policy & Health Economics, Allgemeine Ortskrankenkasse Rheinland/Hamburg (AOK)**



Christoph Rupprecht is Head of Department of Health Policy & Health Economics at the Allgemeine Ortskrankenkasse (AOK), a German public health insurance organisation, where he has worked at for the past 22 years. Christoph holds degrees from the University of Cologne, the University Diderot Patis VII and the Freie Universität Berlin. His main interests are in regulatory innovation and value, disease management, as well as cross-border cooperation.

## **Simone Boselli**

**Public Affairs Director, EURORDIS-Rare Diseases Europe**



Simone Boselli is Public Affairs Director at EURORDIS-Rare Diseases Europe, and is member of the RWE4Decisions Steering Group. As member of the European and International Advocacy team within EURORDIS, Simone contributes to European policy development and specifically represents EURORDIS in policy discussions on access to therapies, with a focus on reducing delays and inequalities, on the underlying challenges in the field of the value assessment, pricing and reimbursement of orphan medicines, and on current initiatives towards improved access. With a view to advance rare diseases as a public health priority at a global level, Simone also supports advocacy activities at Rare Diseases International and the further development of NGO Committee for Rare Diseases. He has in-depth expertise in healthcare having devised and implemented advocacy campaigns at EU and national level on a range of global health issues.

## **Alexander Natz**

**Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)**



Dr. Alexander Natz is Secretary General of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), a position he holds since 2010, and is also member of the RWE4Decisions Steering Group. In the past, he has worked as a lawyer for the law firm Novacos and advised pharmaceutical and biotech companies in regulatory and pricing & reimbursement decisions from a EU and German law perspective. From 2008 to 2013, he was head of the Brussels office of the German Pharmaceutical Industry Association (BPI). Alexander 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.