First "Show and Tell" Stakeholder meeting

Realising the Potential of Real-World Evidence for Learning Healthcare Systems

22 September (14:00-17:30) **Zoom Webinar: https://zoom.us/j/94687128568**

14.00-14.15 INTRODUCTION

Introductory remarks & House keeping rules

Jacki Davis *(moderator)*

Keynote: The EU Health Data Space and cross-country collaboration on real-world evidence

Andrzej Rys*, Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission*

14.15-15.30 SESSION 1: EXPERIENCE TO DATE IN THE USE OF RWE - WHAT DO WE KNOW?

What does it take to use real-world evidence to enable decisions? - The role of real-world evidence in scientific advice and in novel outcomes-based reimbursement approaches

Jo De Cock*, CEO, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)*
Peter Mol*, Professor of Drug Regulatory Science (University Medical Center Groningen), Clinical Assessor Dutch Medicines Evaluation Board, Vice-chair EMA Scientific Advice Working Party*
Etienne Jousseaume*, Head of Market Access Cell & Gene Europe, Novartis*
Adrian Jonas*, Associate Director for Data and Analytics, UK National Institute for Health and Care Excellence (NICE)*

Q&A, interactive debate

Moderated by ***Jacki Davis***

Special interventions by: ***Denis Lacombe****, Director General, European Organisation for Research and Treatment of Cancer (EORTC) and Co-Chair of the European Cancer Organisation's Health Systems and Treatment Optimisation Network;* ***Yann Le Cam****, Chief Executive Officer, EURORDIS;* ***Wim Goettsch****, Special Advisor HTA, Zorginstituut Nederland (ZIN)*

15.30-15.45 Break

15.45-17.15 SESSION 2: HOW TO REALISE A LEARNING HEALTHCARE SYSTEM?

How a Learning Network should involve all stakeholders and the role of a 'Data Analysis and Real-World Interrogation Network'

Karen Facey*, Senior Research Fellow, University of Edinburgh and lead author of RWE4Decisions Actions for Stakeholders*
Peter Arlett*, Head of the Data Analytics and Methods Task Force & Co-Chair of the EMA-HMA Big Data Taskforce, European Medicines Agency*
Piia Rannanheimo*, Pharmacoeconomist, Finnish Medicines Agency (FIMEA)*
Jakub Boratyński*, Acting Director in charge of Digital Society, Trust and Cybersecurity, DG CONNECT, European Commission*

Q&A, interactive debate

Moderated by ***Jacki Davis***

Special interventions by: ***Matthias Rose****, Medical doctor at the Charité – Universitätsmedizin Berlin;* ***Nicola Bedlington****, Special Advisor, European Patients' Forum;* ***Ansgar Hebborn****, Head – European Access Policy Affairs, Roche*

17.15-17.30 CONCLUDING SESSION: THE WAY FORWARD

Moderated by ***Jacki Davis***

Jo De Cock, *CEO, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)*
Andrzej Rys*, Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission*

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

Speaker Biographies

(by speaking order)

Andrzej Rys

Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission

Andrzej Rys is the Director responsible for health systems, medical products and innovation at the Directorate-General for Health and Food Safety (DG SANTE). He is a medical doctor by background specialized in radiology and public health. Rys is the founder and a former Director of the Centre for Innovation and Technology Transfer at Jagiellonian University. Prior to joining the European Commission, he was Deputy Minister of Health in Poland (1999 to 2002) and a member of the negotiation team for Poland's accession to the EU. In addition to his role at DG SANTE, Andrzej Rys is also an Alternate Member of the European Medicines Agency (EMA) Board.

Jo De Cock

CEO, INAMI

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.

Peter Mol

Professor of Drug Regulatory Science (University Medical Center Groningen); Clinical Assessor Dutch Medicines Evaluation Board; Vice-chair EMA Scientific Advice Working Party

Peter Mol is a principal clinical assessor at the Dutch Medicines Evaluation Board, Vice-Chair of EMA's Scientific Advice Working Party, and chair of the EMA Cross-Committee Task Force on Registries. On 1st August 2020, he was appointed as Professor of Drug Regulatory Science at the University Medical Center Groningen. His research focus is on regulatory science and on how to optimize regulatory decision-making, particularly the impact of personalised medicines and real-world evidence, how to improve knowledge transfer and risk management and risk communication.

Etienne Jousseaume

Head of Market Access Cell & Gene Europe, Novartis

Etienne Jousseaume has been the Head of Market Access Cell and Gene Europe at Novartis since 2017, in charge of CART access activities in this area. In this capacity, he has been contributing to various international conferences such as the 2020 DIA-EUCOPE workshop on ATMPs, Innovative Gene and Cell Therapies in the EU, which focused on the challenges and opportunities in securing access for patients to advance therapy medicinal products in Europe. He was previously the Head of Oncology Market Access in France and served as Franchise Head Rare Diseases for Novartis.

Adrian Jonas

Associate Director for Data & Analytics, National Institute for Health and Care Excellence (NICE)

Adrian Jonas leads the central data and analytics team in the UK National Institute for Health and Care Excellence (NICE). This provides central oversight, advice and support on all aspects of data and analytics; spearheading the transformation programme to enable more sophisticated collection, management, storage and exploitation of data across NICE to enable better evidence based decisions across all its business. Adrian joined NICE in 2018 following ten+ years working in a variety of roles in central government including as an Assistant Director within HMRC, Principal Analyst for Home and Foreign Affairs & Head of Profession for Operational Research within the Cabinet Office, and Head of Analysis and Management Information within the Foreign and Commonwealth Office

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 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.

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. 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.

Wim Goettsch

Special Advisor HTA, Zorginstituut Nederland (ZIN)

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.

Karen Facey

Senior Research Fellow, University of Edinburgh

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.

Peter Arlett

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

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.

Piia Rannanheimo

Pharmacoeconomist, Finnish Medicines Agency (Fimea)

Piia Rannanheimo is a pharmacoeconomist at the Finnish Medicines Agency (Fimea). She joined Fimea's HTA-team in 2010. With a background in Pharmaceutical Sciences, Rannanheimo has contributed to numerous national, Nordic and European HTAs and worked as a visting researcher at CADTH and Center for Health Economics at University of York. She also serves as an expert for the Council for Choices in Health Care in Finland. She's also been a member in several working groups led by the Ministry of Social Affairs and Health in Finland, including a working group that defined a national enterprise architecture for pharmacotherapy related data management. Currently she is authoring a report, commissioned by the Ministry, on medical product data and information management in Finland. In 2018, Rannanheimo submitted a report, also commissioned by the Ministry, on the use of RWD describing the uses of RWD from the perspectives of regulation of medicines and medical devices, HTA and rational use of medicines. She is one of the co-authors of the RWE4Decisions paper on 'Real-World Evidence to Support Payer/HTA Decisions about Highly Innovative Technologies in the EU – Actions for Stakeholders', commissioned by INAMI/RIZIV.

Jakub Boratyński

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

Acting Director of Directorate CNECT H, Digital Society, Trust and Cybersecurity and Head of Unit 'Cybersecurity and Digital Privacy Policy' within the European Commission (Directorate-General Communication Networks, Content and Technology). Among others, 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, the EU cyber-security strategy's actions on resilience and cooperation with the EU Agency for Network and Information Security (ENISA). He also directly contributed to the production of the EU Cybersecurity Strategy.

Previously Head of Unit 'Organised Crime and Relations with EMCDDA' at the European Commission (Directorate-General Home Affairs), which has the lead responsibility for the fight against cybercrime, corruption, sexual abuse of children and confiscation of criminal assets. In relation to cybercrime, involved in negotiation and drafting of two directives (on cyber-attacks and sexual exploitation of children) and establishment of the European Cybercrime Centre (EC3). Previously worked on EU relations with Russia (Directorate-General External Relations).

Before joining the European Commission, a Director at the Stefan Batory Foundation in Warsaw and Policy Officer with the United Nations High Commissioner for Refugees. Graduate of the London School of Economics and the University of Warsaw (international relations, law).

Matthias Rose

Professor and Chair, Center for Internal Medicine and Dermatology, Department of Psychosomatic Medicine, Charité - Universitätsmedizin Berlin

Dr. Matthias Rose is Chair of the Department of Psychosomatic Medicine at the Charité in Berlin, which is one of the largest University clinics in Europe. Dr. Rose has worked in the field of health outcome research for almost two decades. He implemented an electronic Patient-Reported Outcome (ePRO) measurement system that used Computer Adaptive Test (CATs) on Personal Digital Assistants in daily clinical contexts. In 2004, he participated in the NIH roadmap initiative to build one of the most comprehensive Patient-Reported Outcome Measurement Information Systems (PROMIS) today. More recently, he was also been involved at EU level in the IMI Health Outcomes Observatories project which aims to set up a platform allowing patients to measure their outcomes in a standardized manner.

Nicola Bedlington

Special Advisor, European Patients' Forum (EPF)

Nicola Bedlington has been EPF's Special Advisor since 2019. She was previously the Secretary General of the EPF (2014 – 2019) and the Executive Director (since 2006). In these roles, she has worked on greater patient involvement throughout the whole life cycle approach – from identifying unmet needs rights through to real-world evidence collection. Nicola chairs the" Data Saves Lives" multi-stakeholder initiative, led by EPF, which aims to raise wider patient and public awareness about the importance of health data and how it is used. She is Co-chair of the European Patient Academy on Therapeutic Innovation (EUPATI) and Co-lead of the PARADIGM project on patient engagement. Prior to her time with the EPF, she worked for the Swiss Government (2004-2006) on education for sustainable development, and was an external expert for the European Commission on disability policy and NGO cooperation. Bedlington was also the founding Director of the European Disability Forum from 1996 to 1999.

Ansgar Hebborn

Head – European Access Policy Affairs, F. Hoffmann-La Roche AG

Ansgar Hebborn is Roche Pharma's Head of European Access Policy. In this role, he focuses on evidence development and HTA, pricing and reimbursement decision making frameworks and their impact on patient access and biopharmaceutical innovation. He has taken an active role as advisor and stakeholder representative in various HTA collaboration networks including EU HTA Network, EUnetHTA and the HTAi Policy Forum Committee, and also has been involved in the foundation of other initiatives in this field e.g. the Green Park Collaborative, the HTAi Asia Policy Forum and Swiss HTA. In an earlier role as health economist and outcomes research specialist for Roche in the US, he has gathered extensive experience with real-world data research.

Webinar link

https://zoom.us/j/94687128568

Real-world Evidence to Support Payer/HTA Decisions about Highly Innovative Technologies in the EU – Actions for stakeholders

The RWE4Decisions paper was published in the International Journal of Technology Assessment in Health Care in August 2020 and will be discussed on 22 September.

Objectives. There are divergent views on the potential of real-world data (RWD) to inform decisions made by regulators, health technology assessment (HTA) bodies, payers, clinicians, and patients. This RWE4Decisions initiative explored the particularly challenging setting of highly innovative technologies, which require Payers/HTAs to make decisions on a small evidence base with major uncertainties. The aim was to go beyond strategic intent to consider actions that each stakeholder could take to improve use of RWD in this setting.
Results. Case studies of recent Payer/HTA decisions about highly innovative technologies were considered in light of recent international initiatives about RWD. This showed a lack of clarity about the Payer/HTA questions that could be answered by RWD and how the quality of real-world evidence (RWE) could be assessed. All stakeholders worked together to create a vision whereby stakeholders agree what RWD can be collected for highly innovative technologies based on principles of collaboration and transparency. For each stakeholder group, recommended actions to support the generation, analysis, and interpretation of RWD to inform decision making were developed. For HTA bodies, this includes cross border HTA/regulatory collaboration to agree RWD requirements over the technology life cycle to inform initial recommendations and reassessment, data analytics methods development for HTA, and promotion of transparency in RWE studies.
Recommendations. Stakeholders need to collaborate on demonstration projects to consider how RWE can be developed to inform healthcare decisions and contribute to a learning network that can develop systems to support a learning health system and improve patient outcomes through best use of RWD.

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