

First "Show and Tell" Stakeholder meeting

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

22 September (14:00-17:30)

♀Online (Zoom for Webinar)

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