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.

*Moderated by **Jacki Davis***

10 November (14.00-17.30 CET)

Virtual conference

14.00-14.20	INTRODUCTION TO RWE4DECISIONS INITIATIVE – WHAT WE NEED TO DELIVER

Welcome

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

The Von der Leyen Commission's health priorities & the EU Health Data Space

*Video intervention by **Stella Kyriakides**, European Commissioner for Health and Food Safety*

14.20-14.50	SESSION 1: ASSESSING THE VALUE OF REAL-WORLD EVIDENCE IN THE INNOVATION PROCESS

Introduction to TRUST4RD – Tool for Reducing Uncertainties in the evidence generation for Specialised Treatments for Rare Diseases

- ***Dr. Karen Facey**, Senior Research Fellow, University of Edinburgh*
- ***Simone Boselli**, Public Affairs Director, EURORDIS-Rare Diseases Europe*
- ***Mercedes Echauri**, Vice-President Market Access Europe and Canada, Takeda*
- ***Prof. Maurizio Scarpa**, Coordinator MetabERN, Regional Coordinating Centre for Rare Diseases, Udine University Hospital, Italy*

14.50-15.50	SESSION 2: STAKEHOLDER ACTIONS AND COLLABORATION TO IMPROVE LEARNINGS ON REAL-WORLD EVIDENCE

Introduction to RWE4Decisions Stakeholder Actions and Recommendation on a Learning Network

***Dr. Marc Van de Casteele,** Coordinator - expertise phamaceuticals, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)*

*Responses by stakeholders with Q&A moderated by **Jacki Davis,** including contributions from:*

- ***Dr. Antje Behring**, Acting Head of Drug Department, German Federal Joint Committee (G-BA)*
- ***Dr. Liisa-Maria Voipio-Pulkki**, Director General of Strategic Affairs and Chief Medical Officer, Finnish Ministry of Health*
- ***Dr. Peter Arlett**, Head of the Data Analytics and Methods Task Force, European Medicines Agency (EMA)*
- ***Dr. Alexander Natz**, Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)*

15.50-16.00	Break

16.00-16.40	SESSION 3: CANCER AS A CASE STUDY FOR THE USE OF REAL-WORLD EVIDENCE

Real world evidence and the mission to conquer cancer

***Dr. Christine Chomienne**, Vice-Chair of Horizon Europe Mission Board for Cancer*

*Responses by stakeholders with Q&A moderated by **Jacki Davis,** including contributions from:*

- ***Dr. Anja Tebinka-Olbrich**, Head of Unit AMNOG EBV, GKV-Spitzenverband*
- ***Dr. Tit Albreht**, Head of the Centre for Health Care, National Institute of Public Health of Slovenia*
- ***Dr. Tomáš Skácel**, Head of Medical Affairs Oncology Europe & Canada, AstraZeneca*
- ***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)*
- ***Dr. Denis Lacombe**, Executive Director, European Organisation for the Research and Treatment of Cancer and Co-Chair of the European Cancer Organisation's Health Systems and Treatment Optimisation Network*

16.40-17.30	EVIDENTIARY CHALLENGES FOR HIGHLY INNOVATIVE TECHNOLOGIES - THE WAY FORWARD TO IMPROVE SHARED LEARNINGS ON REAL-WORLD EVIDENCE FOR DECISION-MAKERS

*Discussion moderated by **Jacki Davis,** including contributions from:*

- ***Jo De Cock**, CEO, Belgian National Institute for Health and Disability Insurance (INAMI/RIZIV)*
- ***Dr. Hannah Brühl**, Division Benefit Assessment, Pricing and Reimbursement of novel Medicinal Products, Federal Ministry of Health, Germany*
- ***Dr. Cláudia Furtado,** Head of the Health Technology Assessment, Pricing and Reimbursement Division & Information and Strategic Planning Division, INFARMED*
- ***Simone Boselli**, Public Affairs Director, EURORDIS-Rare Diseases Europe*
- ***Dr. Wim Goettsch**, Special Advisor HTA, Zorginstituut Nederland (ZIN)*
- ***Jakub Boratyński**, Acting Director in charge of Digital Society, Trust and Cybersecurity, DG CONNECT, European Commission*

About the RWE4Decisions initiative

RWE4Decisions is a loose multi-stakeholder group composed of HTA authorities, payers, the EMA, clinicians, patient representatives, researchers, industry and academics, who have worked together over the past two years under the thought leadership of Jo De Cock, CEO of the Belgian National Institute of Health and Disability Insurance (INAMI-RIZIV), to identify how Real-World Evidence can support HTA/payer decisions. FIPRA has facilitated the multi-stakeholder discussions with sponsorship by the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Astra Zeneca, Gilead, Novartis, Roche and Takeda.

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