WORKSHOP ON MEDICAL DEVICE REGISTRIES –
PROVIDING EVIDENCE FOR REGULATORS
Monday, 17 June 2019 | Square de Meeûs 29, 1000 Brussels (BE)

FINAL PROGRAMME

10.00–10.10 Welcome and Introduction
Per Kjærsgaard-Andersen, Immediate Past-President, European Federation of National Associations of Orthopaedics and Traumatology (EFORT)
Chris Gale, Chairman, EURObservational Research Programme Oversight Committee, European Society of Cardiology (ESC)

10.10–11.20 SESSION 1: THE EU REGULATORY ENVIRONMENT
Chairpersons:
Per Kjærsgaard-Andersen, EFORT
Peter van den Bergh, Member European Affairs Subcommittee of the EAN

10.10–10.25 Post-market surveillance of medical devices: legal responsibilities
Paul Piscoi, Scientific Policy Officer Medical Devices, Health Technology and Cosmetics Unit, DG GROW, European Commission

10.30–10.45 Post-market surveillance of drugs: EMA approval of professional registry data
Daniel Nogueras Zondag, Seconded National Expert, Surveillance & Epidemiology, European Medicines Agency

10.50–11.05 The EU Digital Health Strategy: interacting with new policy initiatives
Ceri Thompson, Unit for e-Health, DG CNECT, European Commission, Luxembourg

11.20 COFFEE BREAK

11.40–13.00 SESSION 2: EXPLOITING THE FULL POTENTIAL OF CLINICAL REGISTRIES
Chairpersons:
Hendrik Jan Ankersmit, European Association of Cardiothoracic Surgery (EACTS)
Tom Melvin, Clinical Manager, Medical Devices, Health Products Regulatory Authority, Ireland; Co-Chairman, Clinical Investigation and Evaluation Working Group, European Commission

11.40–11.55 Early signals of device failure: providing signals to regulators and manufacturers
Rob Nelissen, Chair of NORE, the Network of Orthopaedic Registries of Europe, EFORT

12.00–12.15 Monitoring clinical practice: linking standards to improved outcomes
Aldo Maggioni, Scientific Consultant, EURObservational Research Programme, ESC
12.20–12.35 Registries related to the treatment of diabetes
Reinhard Holl, involved in data management of the DPV and SWEET initiatives, European Association for the Study of Diabetes

12.40–12.55 Using clinical registries for post-market surveillance – Notified body perspective
Bassil Akra, Vice President Strategic Business Development Global Medical Health Services, TÜV Sud

13.00 LUNCH BREAK

13.45–14.45 SESSION 2 (continued)

13.45–14.00 Registries related to the treatment and outcomes in neonates and children
Dominique Haumont, Head of Clinic, Neonatology, CHU Saint-Pierre, European Society for Paediatric Research

14.05–14.20 Comprehensive publicly-funded national registries for monitoring and benchmarking individual surgical and institutional performance
Jonas Oldgren, Executive Director, Uppsala Clinical Research Center

14.25–14.40 Linking registries with the European Electronic Patient Health Record
Stefan Sauermann, Program Director, Medical Engineering and eHealth, University of Applied Sciences Technikum Wien, Vienna

14.45 TEA BREAK

15.00–16.00 PANEL DISCUSSION: EXPLORING FUTURE DIRECTIONS
Chairpersons:
Rob Nelissen, Chair of NORE, the Network of Orthopaedic Registries of Europe, EFORT
Alan Fraser, Chairman, Task Force on Regulatory Affairs and Medical Devices, Biomedical Alliance in Europe / European Society of Cardiology

Paul Piscoi, Health Technology Unit, DG GROW, European Commission
Chris Gale, European Society of Cardiology / University of Leeds
Christa Cobbaert, Chair, Working Group on Test Evaluation, European Federation of Laboratory Medicine / Leiden University
Oliver Bisazza, Director for Regulations, MedTech Europe
Leo Hovestadt, Chair, Clinical Evaluation & Investigations Task Force, COCIR

16.00 Conclusions