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