WORKSHOP ON MEDICAL DEVICE REGISTRIES – PROVIDING EVIDENCE FOR REGULATORS

Monday, 17 June 2019 | Square de Meeûs 29, 1000 Brussels (BE)

DRAFT 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, Committee on Registries, European Society of Cardiology (ESC)

10.10–11.30 **SESSION 1: THE EU REGULATORY ENVIRONMENT**
Chairpersons:
Per Kjærsgaard-Andersen, European Federation of National Associations of Orthopaedics and Traumatology (EFORT)
Peter van den Bergh, European Academy of Neurology (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 **Lessons learned from coordinating EU cancer registries**
Speaker TBC from Consumers and Reference Materials Directorate, EU Joint Research Centre, Ispra

10.50–11.05 **Post-market surveillance of drugs: EMA approval of professional registry data**
Xavier Kurz, Head of Surveillance & Epidemiology, European Medicines Agency

11.10–11.25 **The EU Digital Health Strategy: interacting with new policy initiatives**
Ceri Thompson, Unit for e-Health, DG CNECT, European Commission, Luxembourg

11.30 **COFFEE BREAK**

11.50–13.00 **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

ESC European Society of Cardiology

Biomedical Alliance in Europe

EFORT – JOINT EFFORTS

11.50–12.05 **Early signals of device failure: providing signals to regulators and manufacturers**
Rob Nelissen, Chair of NORE, the Network of Orthopaedic Registries of Europe, EFORT

12.10–12.25 **Monitoring clinical practice: linking standards to improved outcomes**
Aldo Maggioni, Director, EurObservational Research Programme, ESC

12.30–12.45 **Registries related to the treatment of diabetes**
Reinhard Holl, involved in data management of the SWEET initiative, European Association for the Study of Diabetes

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, EFORT
Alan Fraser, Chairman, Task Force on Regulatory Affairs and Medical Devices, Biomedical Alliance in Europe

Panel:
Paul Piscoi, DG GROW, European Commission
Chris Gale, European Society of Cardiology
Christa Cobbaert, Chair, Working Group on Test Evaluation, European Federation of Laboratory Medicine
Oliver Bisazza, Director for Regulations, MedTech Europe
Nicole Denjoy, Secretary General COCIR

16.00 Conclusions