



Biomedical Alliance in Europe



**-PRESS RELEASE-**

**Embargoed for release: Monday, 17 June 00:30 AM**

## **Providing Evidence for Regulators - Workshop on Medical Device Registries**

**Brussels, 17 June 2019:** Today, the Biomedical Alliance in Europe (BioMed Alliance), together with the European Society of Cardiology (ESC) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), is holding a workshop on Medical Device Registries.

Under the new EU Regulation on medical devices (EU 2017/745), post-market surveillance and post-market clinical follow-up of implantable and high-risk medical devices – such as heart valves and hip replacements – are responsibilities of manufacturers, but the sources of information that they are encouraged to use include registries conducted by medical professional associations.

Effective monitoring of the outcomes of using high-risk medical devices is essential so that unexpected events are detected early and risks are avoided.

The workshop brings together policy makers, researchers, industry representatives, and experts working with registries, to explore what role clinical registries should play in informing regulators responsible for market surveillance, and to identify a possible common framework for EU registries.

Professor Alan Fraser, Chairman Regulatory Affairs Committee, ESC and Chair, Regulatory Affairs and Medical Devices Taskforce, BioMed Alliance said: *“The focus of this workshop is to address how information from independent registries conducted by academic bodies or medical professional associations can be provided to manufacturers or used by regulators. It is not yet clear how this will be implemented under the new Regulation, so we need to develop collaborations now between all those involved.”*

Professor Rob Nelissen, Chair of NORE, the Network of Orthopaedic Registries of Europe, EFORT, said: *“Medical professional associations already conduct a wide range of registries of medical devices – especially in orthopaedic surgery. This workshop showcases success stories in various medical fields and explores how best practices can be scaled up to improve clinical outcomes.”*

The programme and more information can be found [here](#).

**ENDS**



Biomedical Alliance in Europe



**ESC**

European Society  
of Cardiology



### [About the BioMed Alliance](#)

The Biomedical Alliance in Europe is a non-profit organisation representing 30 leading European research and medical societies uniting more than 400,000 researchers and healthcare professionals.

### [About the European Society of Cardiology](#)

The European Society of Cardiology brings together health care professionals from more than 150 countries, working to advance cardiovascular medicine and help people lead longer, healthier lives.

### [About the European Federation of National Associations of Orthopaedics and Traumatology](#)

The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) works on behalf of the European orthopaedic and traumatology community to restore and secure mobility, musculoskeletal health and quality of life.

### **Contact information :**

Loredana Simulescu, [info@biomedeuropa.org](mailto:info@biomedeuropa.org), 003222741073