Biomedical Alliance in Europe

ESC European Society of Cardiology

EFORT – JOINT EFFORTS

Save the Date

Joint Workshop on Medical Device Registries

Providing evidence for regulators

Monday 17 June 2019

10.00-16.30

Square de Meeûs, 29, Brussels

The BioMed Alliance together with the ESC and EFORT is organising a joint workshop on Medical Device Registries on 17 June in Brussels. The meeting will facilitate a discussion between EU regulators, healthcare professionals, industry and patient representatives on both regulatory and clinical needs.

The meeting will be divided into a regulatory session with officials of the European Commission exploring the EU regulatory framework, a session where expert clinicians can share best practices in registries for medical devices, and a session on future directions which discusses how to unite the interests of regulators, patients, physicians and industry.

Currently there is insufficient exchange between regulators and clinicians when it comes to registries. Regulators obtain information on adverse events mainly from industry, and clinical registries are not designed to contribute to market surveillance.

The objective of the workshop will be to:

1. Understand the needs of regulators
2. Present what clinical registers can offer
3. Identify synergies and whether a “common” framework for registries may be designed so that the needs of regulators and clinicians are met

The target audience for this workshop are physicians and experts from BioMed Alliance members, interested in registries.

More information will follow soon.

If you have any questions in the meantime, please do not hesitate to contact Marieke Meijer (BioMed Alliance Communication & Project Officer) at: office@biomedeurope.org.