CORE–MD
Coordinating Research and Evidence for Medical Devices

Regulatory science for high-risk medical devices: CORE–MD and beyond

Final Conference

De Warande Club, Brussels (and online)

15th March 2024

Conference objectives:

- ◊ To review the current state of implementation of the EU Medical Device Regulation.
- ◊ To present the results of the EU Horizon H2020 CORE–MD project (2021–2024).
- ◊ To consider how clinical experts should contribute to the EU regulatory system.
- ◊ To consider what developments and reforms are needed.

09:00 – 10:00	***Registration***
10:00 – 10:10	**Welcome – Franz Weidinger** *President, European Society of Cardiology*
Introduction to the CORE–MD Coordination & Support Action	**Alan Fraser**, CORE–MD Scientific Coordinator, *European Society of Cardiology*
10:10 – 11:00	**Session 1: Reflections on the European regulatory system for medical devices**
Franz Weidinger, President, *European Society of Cardiology (Co-Chair)*	
Per Kjærsgaard-Andersen, Chair EU Affairs Committee, *European Federation of National Associations of Orthopaedics and Traumatology (Co-Chair)*	
Rainer Becker, Director, *European Commission, Directorate-General for Health and Food Safety, Medical Products and Innovation (SANTE.D):* **Update on the MDR/IVDR implementation**	
Jan Bertels, Chief of Cabinet for Public Health and Social Affairs, of the *Belgian Health Minister (EU Presidency)*, **The EU Health Agenda**	
Peter Liese, MEP, IVDR Rapporteur, *European Parliament*, **A view from the European Parliament**	
11:00 – 11:30	***Coffee break***
11:30 – 13:00	**Session 2: Main outcomes of the Horizon 2020 CORE–MD project**
Paul Piscoi, Scientific Policy Officer, *European Commission, DG SANTE, Medical Devices (SANTE.D.3) (Co-Chair)*	
Anne Lübbeke-Wolff, Associate Professor, Division of Orthopaedics and Trauma Surgery, *Geneva University Hospitals (Co-Chair)*	
Clinical evaluation and transparency of evidence	**Robert Byrne**, Chair of Cardiovascular Research, *Royal College of Surgeons of Ireland*
Improving the quality of post-market surveillance	**Perla Marang-van de Mheen**, Associate Professor, *Delft University of Technology*
Regulation of AI medical devices	**Frank Rademakers**, Emeritus Professor, *KU Leuven*
Providing medical devices for children	**Berthold Koletzko**, President, *European Academy of Paediatrics*

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Panel discussion	
13:00 – 14:00	***Lunch***
14:00 – 15:15	**Session 3: Science-based regulatory policy for medical devices**
Rob Nelissen, Secretary General, *European Federation of National Associations of Orthopaedics and Traumatology (Co-Chair)* **Rita Redberg**, Professor of Clinical Medicine, *University of California, San Francisco (Co-Chair)*	
Recommendations from the CORE–MD consortium	**Alan Fraser**, CORE-MD Scientific Coordinator, *European Society of Cardiology*
Regulatory science at the European Medicines Agency	**Miguel Antunes**, Senior Scientific Officer, *Expert Panels and Groups, European Medicines Agency*
The perspective of patients	**Penilla Gunther**, President, *European Patient Safety Foundation*
Public responsibilities of the notified bodies	**Sabina Hoekstra**, Co-Chair, *EU Notified Body Coordination Group (NBCG-Med)*
Panel discussion	
15:15 – 15:30	**Coffee break**
15:30 – 16:30	**Session 4: Global regulatory convergence – priorities for development**
Elizabeth Macintyre, President, *Biomedical Alliance in Europe (Co-Chair)* **Alan Fraser**, Chair, *Regulatory Affairs Committee, Biomedical Alliance in Europe (Co-Chair)*	
Review by the European Commission	**Flora Giorgio**, Head of Unit, *European Commission, DG SANTE, Medical Devices (SANTE.D.3)*
The view from a national regulatory agency	**Niall McAleenan**, Director of Medical Devices, *Health Products Regulatory Authority, Ireland*
The view of European manufacturers	**Petra Zoellner**, Director Regulatory Affairs (IVDR & MDR), *MedTech Europe*
Comments from the FDA and IMDRF	**Kenneth Cavanaugh**, Deputy Director, *Office of Health Technology, Cardiovascular Devices, U.S. Food and Drug Administration*
Panel discussion	
Summary and conclusion	

All times are CET.

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