



CORE-MD

*Coordinating Research and Evidence
for Medical Devices*

CORE-MD ADVISORY BOARD

Dr Paul Piscoi (Chair)	European Commission, Unit B6 DG SANTE (Medical Technology) / Chair of Clinical Investigation and Evaluation Working Group (of EU regulatory agencies).
Dr Niall MacAleenan	Director, Medical Devices, Health Products Regulatory Authority (HPRA), Ireland / EU delegate to International Medical Device Regulators Forum (IMDRF).
Prof Wolfgang Ecker	Hon Professor, Medical Technology, University of Applied Sciences Upper Austria / Past-Chairman, Clinical Investigation and Evaluation Working Group.
Dr Isabel Scuntaro	Scientific Officer Clinical Trials and Evaluations, Division Medical Devices Clinical Investigations (MDCI), Swissmedic (Swiss Agency for Therapeutic Products).
Dr Fergus Sweeney	Head, Clinical Studies and Manufacturing Task Force, European Medicines Agency / Chair of ICH Working Party E6 (Good Clinical Practice).
Dr Ana Hidalgo-Simon	Head of Advanced Therapies (Medicinal Products and Biosimilars), European Medicines Agency.
Dr Francesca Day	Operational Lead, Office of Vaccines and Therapies for Infectious Diseases, European Medicines agency.
Melissa Torres	Associate Director for International Affairs, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), USA.
Dr Jeff Shuren	Director, CDRH, FDA (in copy).
Dr Simon Singer	Principal Medical Adviser, Director, Devices Clinical Section, Therapeutic Goods Administration (TGA), Australia.
Prof Rita Redberg	Cardiologist and Professor of Medicine, University of California San Francisco / Chief Editor of JAMA Internal Medicine.
Prof Art Sedrakyan	Director, Institute for Health Technologies and Interventions, and Professor of Population Health Sciences, Cornell Medical College, New York / Director, MDEpiNet Coordinating Center (Medical Device Epidemiology Network) / Principal Investigator, Novel Approaches to Advance Coordinated Registry Networks.





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Prof Peter Jüni	Professor of Medicine & Epidemiology, University of Toronto / Director, Applied Health Research Centre (AHRC), Li Ka Shing Knowledge Institute.
Prof Johan Kärrholm	Professor of Orthopaedics, Sahlgrenska University Hospital, Göteborg / Past Chair of the Swedish Hip Arthroplasty Registry (SHAR).
Prof Stefaan Callens	Professor of Health Law, Centre for Biomedical Ethics and Law, KU Leuven, Belgium. [Member of CORE-MD Ethics Committee]
Prof Sven-Ove Hansson	Emeritus Professor of Philosophy, Royal Institute of Technology (KTH), Stockholm / Department of Learning, Informatics, Management and Ethics, Karolinska Institutet. [Member of CORE-MD Ethics Committee]
Griet Verhenneman	Data Protection Officer, University Hospital Leuven (UZ Leuven) / Affiliated Senior Researcher, Centre for IT & IP Law, KU Leuven. [Member of CORE-MD Ethics Committee]
Danielle Giroud	CEO of MD–Clinicals, Geneva (Clinical research organisation) / Convenor of Working Group for ISO Standard 14155 (Clinical investigation of medical devices for human subjects -- Good clinical practice) / Founder, World Medical Device Organization (WMDO).
Dr Amie Smirthwaite	Senior Vice President, Intelligence and Innovation, RQM+ (consultancy) / previously Global Head of Clinical Compliance, BSI (notified body).
Annika Eberstein	Acting CEO, COCIR (the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), Brussels.
Leo Hovestadt	Director Governmental Affairs EU, ELEKTA, Veenendaal, Netherlands / Chair, COCIR Clinical Investigation & Evaluation Task Force.
Dr Roger Kessels	Director, Clinical Development, Phillips, Eindhoven, the Netherlands / COCIR
Dario Pirovano	Senior Regulatory Adviser, MedTech Europe (European trade association)
Oliver Bisazza	Director General, Industrial Policies, MedTech Europe (tbc)

Invited (in attendance):

Dr Carlos Eduardo (Cadu) Lima Da Cunha,
Science Officer, European Health and Digital Executive Agency (HaDEA)

