CORE-MD

Coordinating Research and Evidence for Medical Devices

Project Board Meeting – Agenda

25/04/2022, 13:30 – 18:00 CET

Leiden University Medical Center (LUMC)
Albinusdreef 2, "Collegezaal 2" (K-01-067 |2 CZ, R766, Building 01
https://escardio.zoom.us/j/97347434818 passcode : **087709***

12:30	**Lunch**	
13:30	**Welcome by the local host**	Rob Nelissen
13:35	**Welcome and CORE-MD general update**	Alan Fraser
14.00	**Developments in Regulatory Science – Perspectives of the European Commission and the European Medicines Agency**	*Chair: Piotr Szymański* Paul Piscoi, DG SANTE Leslie Pibouleau, EMA
15:00	**Coffee break**	
15.15	**WP1 Progress: update and discussion**	*Chairs: Robert Byrne & Tom Melvin*
15.15	T1.1 Methodologies in published clinical studies	Laurna McGovern Anne Lübbeke-Wolff Arjola Bano (online)
15.45	T1.2 Statistical methods	Ewout Steyerberg
16.05	T1.3 Regulatory utility of PROMs	John Chaplin
16.25	T1.4 Regulatory guidance and recommendations	Petra Schnell-Inderst
16:45	**Tea break**	
17.00	**WP2 Progress: update and discussion**	*Chairs: Per Kjærsgaard-Andersen & Jan Szulc*
17.00	T2.1 Early development of high-risk devices	Peter McCulloch (online)
17.20	T2.2 New designs	Sergio Buccheri
17.40	T2.3 Artificial intelligence	Frank Rademakers
18.00	T2.4 Medical devices in children	Kathrin Susanne Gurlich, Berthold Koletzko (online)
18:20	**Wrap-up and closing**	Alan Fraser
18:30	**End of day #1**	
20:00	**Dinner**	**Faculty Club Leiden:** Rapenburg 73

*Please be aware that the virtual meeting will be recorded for internal purposes.

Project Board Meeting – Agenda

26/04/2022, 9:00 – 15:00 CET

Leiden University Medical Center (LUMC)
Albinusdreef 2, "Collegezaal 2" (K-01-067 |2 CZ, R766, Building 01
https://escardio.zoom.us/j/97194058479, passcode: **574896***

09:00	**Development and harmonization of international and European medical device standards**	*Chairs: Alan Fraser, Robert Geertsma* Jennifer Ogbonna, CEN/CENELEC Amie Smirthwaite, ISO 14155
10.00 10.00 10.20 10.40	**WP3 Progress: update and discussion** T3.1 Registries T3.2 Mashup T3.3 Evidence after market access	*Chairs: Rob Nelissen, Ann-Sofie Sonne Holm-Schou* Perla Marang-van de Mheen Enrico Caiani Juan-Antonio Blasco
11:00	**Coffee break**	
11:30 11.30 11.40 11.50 12.10	**WP4 Progress: update and discussion** T4.1 Ethics charter T4.2 Recommendations T4.3 Capacity building T4.4 Dissemination & T4.5 Communication	*Chair: Marieke Meijer* Alan Fraser Per Kjærsgaard-Andersen Claudia Wild Jean-Baptiste Rouffet
12:20	**WP5 Progress: update and discussion** T5.1 Project management T5.2 Admin and financial coordination T5.3 Risks, ethics	*Chair: Alan Fraser, Adrian Ott* Anett Ruszanov Anett Ruszanov Anke Murillo, Anett Ruszanov
12.45	**Lunch**	
13.45 13:45 13:50 13:55 14:00 14:05	**Developing European collaborations in regulatory science for medical devices** Engagement with regulators Engagement with notified bodies Engagement with BioMed Alliance members Engagement with Advisory Board Discussion	*Chair: Paul Piscoi, Claudia Wild* Tom Melvin Erman Melikyan (online) Marieke Meijer Niall McAleenan (online)
14:45	**Questions, discussion, conclusions**	Alan Fraser
15:00	**End of day #2**	