CORE-MD
Coordinating Research and Evidence for Medical Devices

Project Board Meeting

Faculty Club, Leuven University, Groot Begijnhof 14, 3000 Leuven

17th – 18th April 2023

Day 1 – Agenda

Room: Lemaire (located on the ground floor of the Infirmary building)

8:00 – 8:30	***Coffee and Registration*** – Infirmerie Room

Time	Item	Moderator / Lead presenter(s)
8:30 – 8:45	**Welcome and Introduction**	Frank Rademakers – Local host Jan D'hooge – Vice Rector of Research Policy, KU Leuven
8:45 – 10:30 **Session 1**	**Insights into current EU regulatory practices for high-risk devices**	Robert Byrne Gearoid McGauran
	Evidence for cardiac devices (20') • for coronary bioresorbable scaffolds • for atrial appendage closure devices • for leadless pacemakers, and subcutaneous defibrillators • for percutaneous valve repair and replacement • for surgical heart valves	Bern / Dublin : Laurna McGovern Robert Byrne André Frenk
	Evidence for devices used in diabetes mellitus (10')	Arjola Bano (on line)
	Evidence for devices used in children (10')	Kathrin Gürlich
	Comparisons across device types (10') including evidence for hip and knee joint replacements	André Frenk
	A risk calculator for sharing uncertainty with patients, physicians, and regulators (20')	Ewout Steyerberg
	Discussion (35')	

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10:30 – 11:00	***Coffee break*** – Infirmerie Room

11:00 – 12:45 Session 2	**Insights into generic EU regulatory processes**	Per Kjærsgaard-Andersen Jan Szulc
	Regulatory utility of patient-reported outcomes	Ola Rolfson
	Challenges with the early-phase evaluation of new high-risk devices	Peter McCulloch
	Conditional approval, and use of conditions on certificates of conformity	Agnieszka Dobrzynska Juan Antonio Blasco
	Challenges for medical devices in children	Bernadeta Patro-Golab
	Discussion	

12:45 – 13:45	***Lunch*** – Infirmerie Room

13:45 – 15:30 Session 3	**Developments in regulatory standards and recommendations**	Robert Geertsma Tom Melvin
	Regulatory guidance on methodologies for clinical investigation	Petra Schnell-Inderst
	Clinical investigation methodologies – best practice for trials and studies	Sergio Buccheri
	Clinical evaluation of artificial intelligence medical devices	Frank Rademakers
	Discussion	

15:30 – 16:00	***Coffee break & Consortium photograph*** – Infirmerie Room

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16:00 – 18:00 Session 4	**Discussion with Advisory Board: Engaging clinicians in regulatory science**	Paul Piscoi Alan Fraser
The discussion will be focussed around 4 themes, each introduced by a short introductory talk that will be followed by questions for all the advisers.		
1	Progress and challenges with the EU Medical Device Regulations. • **How can CORE-MD insights contribute to tangible benefits for the EU system?**	Paul Piscoi and Elin Karlberg, Co-Chairs, Clinical Investigation and Evaluation Working Group, MDCG / EC
2	A US perspective on accelerated approvals and breakthrough designations. • **Can CORE-MD recommend regulatory approaches for innovative devices?**	Rita Redberg, University of California San Francisco
3	Real-world data besides registries. **Are current EU data sources adequate to support regulatory decisions?**	Art Sedrakyan, Weill Cornell Medical College, NY
4	Clinical investigations of medical devices. • **Can CORE-MD develop a hierarchy of clinical trial and study designs?**	Isabel Scuntaro, Swissmedic Amie Smirthwaite / ISO
Discussion on regulatory developments and convergence		**All**

19:30 – 20:00	***Reception*** – Lemaire Room
20:00 – 22:00	***Consortium Dinner*** – Lemaire Room

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Day 2 – Agenda

Room: Willem Van Croy (located in the attic of the Convent van Chièvres)

8:00 – 8:30	***Welcome Coffee*** - Van Hamaele Room	

08:30 – 10:30 Session 5	**Post-market surveillance and real-world evidence**	Rob Nelissen Sanjeev Yoganathan
	Quality and utility of orthopaedic and cardiovascular device registries in Europe	Lotje Hoogervorst
	Standards and methods for integrating other sources of real-world data	Perla Marang
	An Australian perspective on trials, registries, and real-world data	Simon Singer *tbc*
	A web search engine for combining reports of problems with devices	Enrico Caiani / Yijun Ren
	Discussion	

10:30 – 11:00	***Coffee break*** - Van Hamaele Room	

11:00 – 13:00 Session 6	**Preparation for CORE-MD recommendations 1**	Claudia Wild Marieke Meijer
	Recommendations for education and training (60')	Sabine Ettinger
	An Ethics Charter for device innovation (30')	Janos Meszaros, William Plath Alan Fraser
	Discussion	
12:30 – 13:00	**Update on Project Management**	Valentina Tageo
	Data management	Robert Geerstma

13:00 – 14:00	***Lunch*** - Van Hamaele Room	

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14:00 – 15:20 Session 7	**Preparation for CORE-MD recommendations 2**	Petra Schnell-Inderst Alan Fraser
	Hierarchy of methodologies for clinical evaluation	**ALL**
	General discussion and planning of workshops	**ALL**
	New Horizon Europe call from HaDEA; proposals for application from our consortium	**ALL**
15:20 – 15:30	**Wrap up and end of the meeting**	**Alan Fraser**

Venues

Faculty Club consists of two main venues: the thirteenth-century Infirmary and the sixteenth-century Convent of Chièvres.

The Project Board Meeting takes place:

1. **On the 1st day (Monday, April 17th, 2023) in the Lemaire Room, located on the ground floor of the Infirmary building**. The same room will also host the Consortium Dinner on Monday evening.
2. **On the 2nd day (Tuesday, April 18th, 2023), in the Willem Van Croy room. This is the largest meeting room in the Convent van Chièvres located in the former attic**, originally only intended as a storage place, which occupies the entire rectangular area of the building. To reach this building, you walk from the car park some distance into the Grand Beguinage (Begijnhof in Dutch) (see map below).

Arrival

For attendees to take the most advantage of this in-person meeting, **participants are encouraged to arrive in Leuven the day before the start of the event (Sunday 16th April 2023)**.

By public transport: https://www.facultyclub.be/wp-content/uploads/2015/09/Toegangsplan_openbaar-vervoer-E2017.pdf

By car: Faculty Club is situated along the ring road of Leuven, just off the E40/E314 and has parking facilities for 250 cars – only a 15-minute drive from the airport by train or car – 20 minutes from Brussels. For more information, check out the following link: https://www.facultyclub.be/wp-content/uploads/2015/09/Toegangsplan-E-2017.pdf

The access code for the parking and for the entrance door of the building where the meeting will take place on the second day is 5585#.

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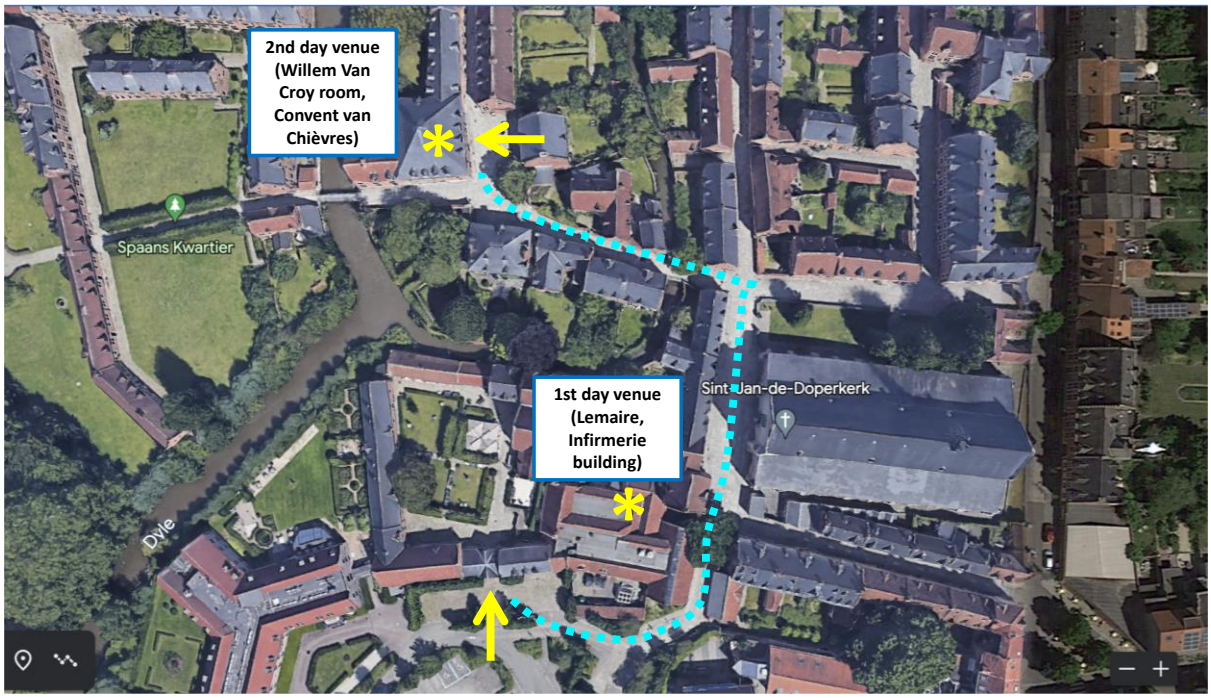

Online attendance

Zoom connection details are provided primarily with the purpose to allow hybrid participation to the Advisory Board session which will be held on Monday 17th April from 16:00 to 18:00 CEST.

However, the Zoom link will be also open and available for the whole duration of the meeting upon request of few speakers and attendees who cannot join in person.

Here below the details to connect:

https://escardio.zoom.us/j/86315662296

Meeting ID: 863 1566 2296

Passcode: 696162

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