CORE-MD

Coordinating Research and Evidence for Medical Devices

Educational Resources

Deliverable 4.5

Deliverable factsheet

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Acronyms and abbreviations

AEPC	Association for European Paediatric and Congenital Cardiology
DoA	Description of Action
EMA	European Medicines Agency
FDA	Food and Drug Administration
HRMD	High-risk Medical Devices
ISO	International Standards Organization
JRC	Joint Research Centre
MD	Medical Devices
MDR	Medical Device Regulation
ODEP	Orthopedic Data Evaluation Panel
PROMs	Patient reported outcome measures

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Executive Summary

The CORE-MD consortium undertook many studies and research within the framework of the project. As stated in the DoA Annex 1, each CORE-MD task prepared a *"1-hour webinar to summarise its activities and conclusions, to be made available for subsequent viewing on-line via the CORE–MD website as a continuing educational resource*".

CORE-MD webinars were designed to present the findings stemming from the studies and tasks performed by partners, as well as engaging the audience in constructive discussions on the issues covered in each webinar.

CORE-MD webinars offered a large variety of topics and involved many different experts, including invited experts external to the consortium. All target groups identified in the project's Dissemination and Communication plan were involved as either panellists or participants in these webinars. Clinicians, notified bodies, regulatory authorities, scientific and academic experts, patient organisations and manufacturers were all offered the possibility to present their findings, share their viewpoints, challenges and expectations through the CORE-MD webinars.

The impact of the webinars as measured by the live attendance, their interactivity, and their availability beyond the project's lifespan, has been overall satisfactory.

All video recordings of the webinars are published on the CORE-MD YouTube channel.

Beside the webinars, the CORE-MD consortium also produced three short videos and five podcasts to complement and strengthen the dissemination of CORE-MD's outputs to a wider audience thus contributing to the awareness raising, educational and advocacy aims of the project.

1 Introduction

The CORE-MD consortium undertook many studies and research in the framework of the project. As stated in the grant agreement, "*Each CORE-MD task will prepare a 1-hour webinar to summarise its activities and conclusions, that will be made available for subsequent viewing on-line via the CORE–MD website as a continuing educational resource*".

The CORE-MD Steering Committee – in close collaboration with WP and task leaders - therefore planned a series of webinars to present the project's outputs but also to encourage expert-based discussion on the given topics which insights could contribute to the ongoing work of each task. This way, the webinars fulfilled both the objective to provide useful, clear and educational contents for all the target audiences of CORE-MD – including clinical professional and regulators, but also manufacturers, notified bodies' staff and patient representatives – and to contribute to enrich the stakeholder dialogue generating consensus on the project's outputs and recommendations. External experts to the consortium were invited to provide different but complementary viewpoints thereby not only increasing the quality of the CORE-MD webinars but also offering the audience with a variety of perspectives that fostered fruitful reflection on the challenges of the implementation of the medical device regulation (MDR).

CORE-MD webinars have been designed to present the findings stemming from the studies and tasks performed by partners as well as engaging with the audience in constructive discussion on the issues covered by the webinar.

Thanks to dedicated communication activities on social media, special newsletters and the CORE-MD website it was possible to achieve a wide reach, also with the support of the communication staff and established channels of the partner organizations that actively helped with disseminating the information.

Feedback received from participants to webinars was very positive, and there was also a high level of panellists' satisfaction. Interaction with the audience was also important though variable from one webinar to another.

As indicated in the grant agreement, the CORE-MD consortium organized 13 webinars between January 2023 and March 2024, all of which were made available on a dedicated webpage of the CORE-MD website as well as on the CORE-MD Youtube channel.

Beside the webinars, the CORE-MD consortium produced three short videos and five podcasts to complement the dissemination of CORE-MD's outputs to a wider audience.

1.1 Deliverable structure

This deliverable presents the different stages of the organization of this webinar series from the design, planning and organization (Section 2) to their impact (Section 3) on the various target audiences formerly identified in the dissemination and communication plan (D4.7). Furthermore, Section 4 describes the process followed to create the podcast episodes and the other videos that contributed to enrich the offer

of educational resources produced in the frame of CORE-MD. Last, Section 5 presents the additional three general short videos produced in the occasion of the second Project Board meeting held in Leuven (Belgium) in April 2023.

2 Designing, planning, and organizing the CORE-MD webinar series

As it was anticipated in the description of Task 4.3 of the CORE-MD DoA, each task would organise a webinar to share its results. The Steering Committee therefore set up a simple and smooth process to achieve this.

2.1 Designing webinars

The webinars were organized leveraging internal managerial staff effort and the capacities of the communication specialists in charge of the communication and dissemination of the project. Namely, the whole process of setup, running, recording, processing and publishing the webinars was led by partner EFORT under the scientific guidance of the Project Coordinator, Alan Fraser (ESC). Having examined the progress of the activities undergoing in each task an initial proposed calendar of webinars was prepared with the aim to align the webinars' schedule with each task's rollout to completion. A standard structure for the webinars' programme was designed with a fixed duration of 1 hour and 15 minutes allowing task leaders to both present their findings and to engage in stimulating debates with external discussants.

In general, the webinar's design was tuned to fulfil three main objectives: (i) generate accurate and useful educational resources based on the CORE-MD's results; (ii) confront the results of the CORE-MD tasks to various viewpoints in the stakeholder community; (iii) foster a constructive dialogue with the audience.

2.1.1 Co-designing CORE-MD webinars

Webinars were designed by Task leaders with the active support of the Scientific Coordinator and the EFORT staff in charge of the operationalization of this process. Titles, agendas, contents of the interventions, duration, and panellists were discussed and agreed with a view to keep the balance between internal consortium representatives' views and external perspectives.

The webinars focused on relevant topics aligned with the current challenges of the MDR implementation as well as on the most relevant CORE-MD findings as long as they become available. Careful attention was paid to avoid overlaps in different webinars, ensure gender balance and geographical coverage, and provide equal opportunities to express voices and concerns of different stakeholder groups. Additionally, while the moderator role was preliminarily assigned to the respective task leader or the Scientific Coordinator, several partners have been involved as speakers.

The Scientific Coordinator also mobilized his large network of clinicians and various professionals in the field of medical devices to take part in CORE-MD webinars. This contributed to involve external experts from a wide range of organizations such as ISO, JRC, FDA, EMA, or the European Commission.

Table 1. Distribution of roles and workflow in the design and setup of webinars

Scientific Coordinator	Task leader	EFORT Officer
Preparation		
- **Propose title** - **Suggest external experts** - **Make first contact**s with invited external discussants	- Validate title - Set a date - Contact possible panellists - Prepare and share presentations with panellists - Attend rehearsal meetings	- Prepare and update draft programme - Schedule rehearsals for panellist - Contact panellists - Create the event on zoom - Monitor registrations - Create back-ups of presentations - Disseminate the information (X, LinkedIn, newsletters, website)
Event management		
- **Attend the webinar** - **Moderate the webinar (when appropriate)**	- Attend the webinar - Participate in the discussion - Answer some Q&A - Moderate the webinar (when appropriate)	- Launch the webinar - Monitor participation
Follow up		
- **Promote webinars in meetings and conference**	- Share the replay as widely as possible	- Prepare a short report - Collect consent from speakers to publish the recordings - Create a webinar replay and upload it on YouTube

2.1.2 A flexible webinar structure

CORE-MD webinars consisted in a 1h15 live event divided into 2 parts: the presentation of the challenge and the findings produced by the involved task to date (40-45 min) and the discussion (30 min). Additionally, a moderator from the CORE-MD consortium acted as responsible partner in charge of coordinating panellists and moderating questions and answers from the audience. Finally, each webinar had specific learning objectives to help participants understand its purpose.

To facilitate the identification of CORE-MD webinars by the audience, it was decided to organize them preferably on Mondays. In order to allow the external experts from outside Europe (i.e., predominantly experts from FDA or the USA), CORE-MD webinars were mainly scheduled as of 17.00 CET.

Still, in the co-design phase, the timing and date were left flexible to accommodate for the busy agendas of panellists as well as their countries of residence.

2.1.3 Collecting feedback to adjust the content

After the first semester series, a quick survey was conducted to collect feedback from participants who attended the webinars no. 4 and 5.

The survey was a 7-question questionnaire with short quantitative and qualitative questions delivered via a GoogleForm. It was sent out to registered participants after webinars #4 (10 July 2023) and #5 (17 October 2023). 42 responses were collected.

The survey showed that 40,5% of respondents had received the information thanks to CORE-MD mailing. This contributed to adjust our communication strategy (see section 2.3). Overall, 83.3% of respondents found the webinars interesting or very interesting. Moreover, the programme, its duration, the panellists, and the tool used were rated very positively. Further details on the results collected through it are provided in Appendix 1.

It enabled the Steering Committee to adjust the content of webinars to meeting the participants' expectations. For instance, more interactivity was requested by several respondents. As a result, the Steering Committee decided that CORE-MD webinars would have not more than 4 panellists per webinar with the possibility of having a discussant for the second part of the webinars with the aim to allow more time and interactivity in the discussion part.

2.2 Planning the webinar series

CORE-MD webinar series were planned as the project's outputs were unfolding and becoming available in the second half of the project's lifespan, starting from early 2023. In the framework of the steering committee, the CORE-MD webinar series was planned well ahead of the webinars per semester.

At the Leiden Project Board meeting (25-26 April 2022), partners were informed about the upcoming organisation of webinars and preliminary plans were shared with several partners. In December 2022, webinars from January 2023 until June 2023 were scheduled with titles, dates and possible moderators identified. In April 2023, in the framework of the Project Board meeting in Leuven, the second wave of webinars was tentatively planned. In December 2023, the third and last series of webinars for 2024 was planned up until the end of March 2024.

2.3 Communicating on the webinars

The EFORT Officer in charge of the operational management of the webinar was assisted by a communication colleague to prepare and disseminate information on webinars.

Capitalising on EFORT experience in the organisation of webinars, the communication plan on webinars consisted in a sequence of mailing, and the creation of a dedicated webpage. Moreover, in line with the Dissemination and Communication plan (D4.7), multi-channel communication was used to maximise outreach and diversify the types of stakeholder groups informed. Partner organisations also supported the communication effort of the consortium on webinars using their institutional communication departments and channels to back-up CORE-MD's communication, whether through posting or re-posting LinkedIn articles or disseminating through their newsletter (e.g., EFORT Today, Biomedical Alliance monthly update, etc.). Dissemination was also made through the EU Health Policy Platform

(https://webgate.ec.europa.eu/hpf/), a European interactive tool funded and maintained by the European Union to stimulate discussion about public health concerns and provide an easy way for stakeholders to share knowledge and disseminate actions among a wide audience (+6000 registered members, as of March 2024)..

Overall, the project's newsletters designed and sent via Mailchimp, the website and the LinkedIn project's handle were the main communication channels to promote the webinars. Due to the limited resources available in the projects, the CORE-MD consortium did not use paid ads and campaigns to increase the number of subscribers.

Figure 1. Step-by-step communication process to advertise webinars

As of September 2023, witnessing the increasing interest in the CORE-MD webinar and the willingness expressed by several stakeholders to be kept informed about the upcoming initiatives of the projects and the next appointments in the webinar series, the project team has adopted a GDPR-compliant opt-out mailing approach. Registered participants' email addresses were therefore added to the mailing list and were given the option to withdraw from it at any time by sending an email to eu@efort.org. Only two recipients requested their emails to be withdrawn from the CORE-MD distribution list. This contributed to increase significantly the number of people receiving the information on the upcoming webinars and thus expand the audience. Further details on the collection and treatment of newsletter recipients' data are provided in the project's updated version of the Data Management Plan (D5.6).

2.4 Running the 13 webinars

From January 2023 until March 2024, the CORE-MD consortium organised 13 webinars covering all tasks of the grant application. All task leaders were involved in the design, planning, and running of the webinars. It contributed to promote their results and highlight their role in the project.

Table 2. List of webinars

Date	Title	Moderators and panellists	**Organization**	CORE-MD task
30 January 2023	Orthopaedic implants and European Medical Device Regulations	**Rob Nelissen** Anne Lübbeke *Keith Tucker*	LUMC Insel Gruppe AG *ODEP*	1.1
6 March 2023	The origins of European regulations	**Per Kjærsgaard-Andersen** Alan Fraser Tom Melvin *Paul Piscoi*	EFORT ESC Trinity College Dublin *European Commission*	-
3 April 2023	Objective performance criteria	**Ewout Steyerberg** **Alan Fraser** Robert Byrne *Gary Grunkemeier*	LUMC ESC RCSI *Oregon Health & Science University*	1.2
10 July 2023	Training and education for regulators, notified bodies and clinicians	**Claudia Wild** Sabine Ettinger Tom Melvin Elisabeth Macintyre *Stephanie Shedd* *Ken Cavanaugh* *Esther Martinez* *Dimitri Panidis*	AIHTA AIHTA Trinity College Dublin Biomedical Alliance *FDA* *FDA* *EMA* *EMA*	4.3
17 October 2023	Recommendations for the clinical evaluation of AI medical devices	**Frank Rademakers** *Eva Van Steijvort* *Claudius Greisinger*	KU Leuven KU Leuven *Joint Research Center*	2.3
6 November 2023	Evidence for high-risk cardiovascular devices	**Robert Byrne** Arjola Bano Georgios Siontis	RCSI Insel Gruppe AG Insel Gruppe AG	1.1
27 November 2023	Pivotal clinical investigations of high-risk medical devices: "what guidance do we need and by whom?"	**Alan Fraser** Petra Schnell-Inderst Richard Holborow Gearoid McGauran	ESC UMIT BSI/Team-NB HPRA	1.4
5 December 2023	IT tools for regulatory science (the CORE-MD search engine)	**Alan Fraser** Enrico Caiani Rob Nelissen Sanjeev Yoganathan *Miguel Antunes* *Paul Piscoi*	ESC POLIMI LUMC/EFORT DMA *EMA* *European Commission*	3.2
14 December 2023	Providing high-risk medical devices for children – problems and proposals	**Alan Fraser** Kathrin Gürlich Berthold Koletzko *Marc Gewilig*	ESC EAP EAP	2.4

		Rachel Evans Neubrander	*AEPC* *FDA*	
8 January 2024	Early clinical investigations of new high-risk medical devices	**Alan Fraser** Peter McCulloch Claudia Louati *Marc Slack* Gearoid McGauran	ESC UOX EPF *CMR Surgical* HPRA	2.1 & 3.3
19 February 2024	Monitoring life cycle of an implant in real life	**Tom Melvin** Perla J. Marang-van de Mheen Richard Holborow Rob Nelissen *Joshua Bridgens*	Trinity College Dublin TU Delft BSI/Team-NB LUMC/EFORT *Dupuy Synthes*	1.1
4 March 2024	The use of patient reported outcome measures in clinical evaluation of medical devices	**Ola Rolfson** John Chaplin Yasemin Zeisl *Philip Moons*	UGOT UGOT EPF *KU Leuven*	1.3
26 March 2024	The notified body role & the conformity assessment process	**Alan Fraser** Richard Holborow *Suzanne Halliday* Françoise Schlemmer	ESC BSI/Team-NB *NBCG-MDE* Team-NB	-

Legend**: Moderator**, partner, *guest*

Two webinars out of 13 were not directly linked to a specific task (webinars #2 and #13). Webinar 2 aimed at setting the scene on the history of the regulatory framework on medical devices. It would serve as background information that would facilitate the understanding of the challenges and pave the way for upcoming issues presented in the other webinars. Webinar 13 was dedicated to the role of notified bodies.

The majority of CORE-MD consortium members participated in the webinars as either moderator or panellists. Moreover, all partners attended the different webinars. The commitment of CORE-MD partners was a key success factor.

2.5 Providing replays

After the live event, the zoom recording was used to prepare a YouTube video and added on the website dedicated webpage.

Replays were created using the CORE-MD branding and visuals. This contributed to enhance the identification of the webinars as CORE-MD's outputs.

Webinar replays were also advertised through EFORT Today's newsletter sent to 20K+ subscriber and ensuring a wider dissemination[1].

[1] See as example https://www.efort.org/wp-content/uploads/2024/01/2024_01_11_EFORT_Today_01.html

A YouTube channel was created to host the videos and embedded on the CORE-MD webinar page.

The objective of the replay was to enable a wider audience to benefit from the wealth of expertise shared during the webinars but also provide the medical device community with updated insights on the challenges of the MDR implementation.

3 The impact of CORE-MD webinars and podcasts

CORE-MD webinars were organised and run relying on internal resources of the partners and were branded and disseminated through the various communication channels of the project. They covered the topic of medical device regulation implementation and, more specifically, the evaluation of clinical performance and safety of high-risk medical devices along their life cycle which represent a "niche" domain in the public health area. Thus, the expected target audience for the webinars was 100 participants from the medical device stakeholder community.

During the first webinar, the moderator launched a poll to collect information about the background of the participants which revealed the variety of the attendance.

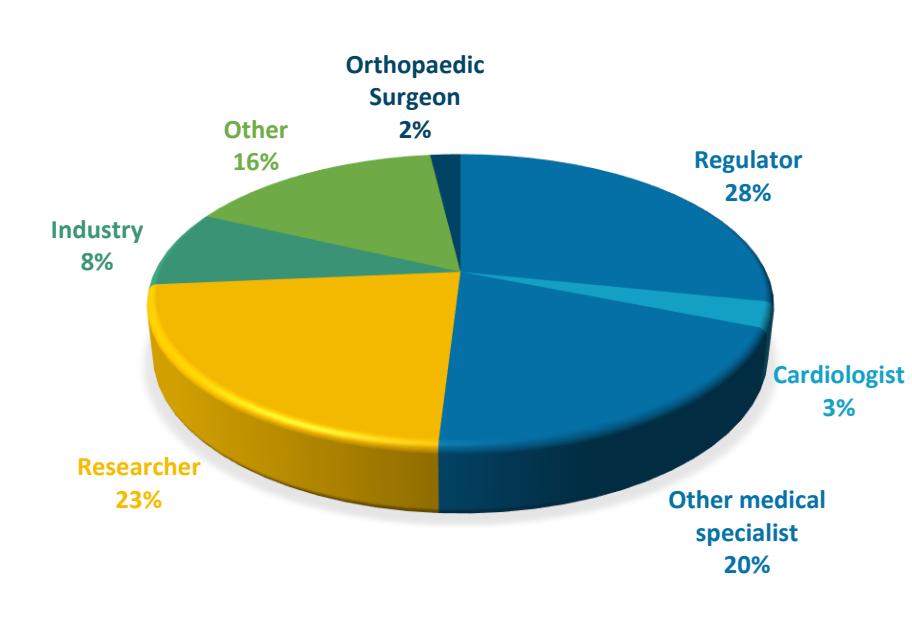


Figure 2. Background of participants webinar #1

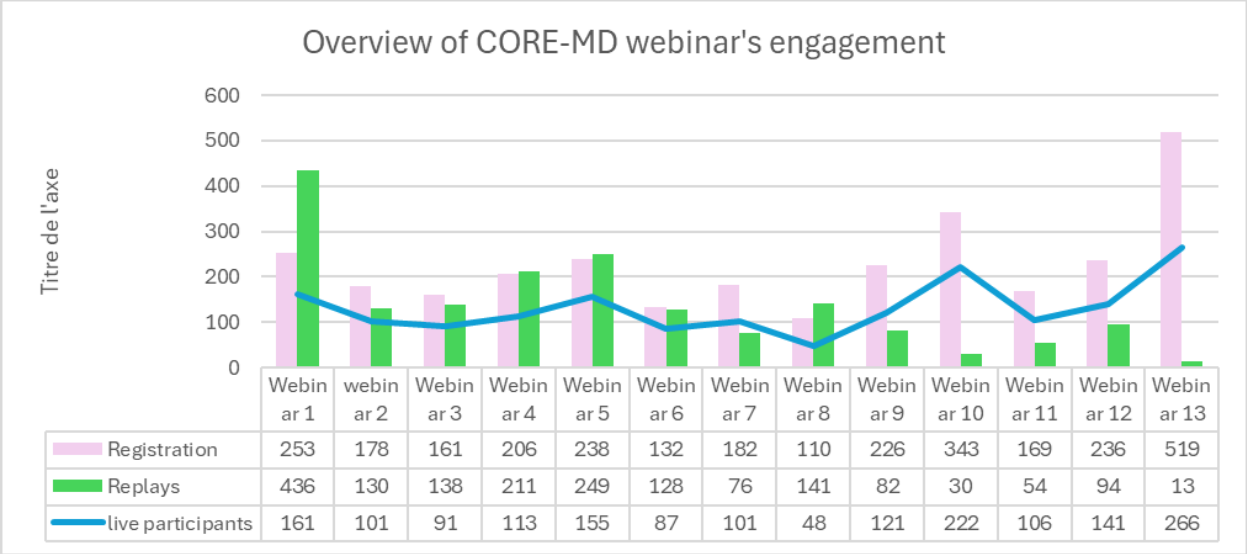
3.1 Webinar attendance and interactivity

The attendance to CORE-MD webinars was variable but largely satisfactory. Potential influencing factors were the time for dissemination and support received by the partner institutions to spread the webinar announcement as well as the proximity to other webinars.

Five webinars attracted over 140 participants highlighting the interest of the medical device community for the topics addressed:

- Webinar #1 on Orthopaedic Implants and MD Regulation
- Webinar #5 on Artificial Intelligence
- Webinar #10 on early clinical investigations

- Webinar # 11 on PROMS
- Webinar #13 on the role of notified bodies



	Webinar 1	webinar 2	Webinar 3	Webinar 4	Webinar 5	Webinar 6	Webinar 7	Webinar 8	Webinar 9	Webinar 10	Webinar 11	Webinar 12	Webinar 13
Registration	253	178	161	206	238	132	182	110	226	343	169	236	519
Replays	436	130	138	211	249	128	76	141	82	30	54	94	13
live participants	161	101	91	113	155	87	101	48	121	222	106	141	266

Figure 3. Overview of webinar's participation

The data collected by EFFORT are shown in Figure 3 where the first column refers to the number of registered attendees, the second one to the number of visualizations of the recordings (until the 31 of March 2024) while the blue line shows the actual number of attendees.

Overall, the CORE-MD webinars attracted an **average of 132 participants per webinar,** although one webinar (#8) attracted only 48 participants due to late validation of the final programme and the little time to disseminate the information.

On average, 58% of registered participants attended the webinars, which is consistent with the experience of EFORT when organising other webinars.

One of the objectives of CORE-MD webinars was to foster dialogue with the audience. Thanks to the zoom tool and in order to keep the timing of the webinar, participants were not able to take the floor but could ask questions through the chatbox. The moderator was then able read these and ask panellists to provide answers.

On average, 14 Questions were asked during the second parts of webinars. The highest number of questions asked occurred during the last webinar on 26 March 2024. 28 questions were asked by participants demonstrating the interest of participants for the topic covered.

Table 3. Attendance to CORE-MD webinars

No.	Date	Number of registrants	Number of attendees	Number of replay visualizations	Q&A	Participation rate
# 1	30 Jan 2023	253	161	436	16	64%
# 2	6 Mar 2023	178	101	130	17	57%
# 3	3 Apr 2023	161	91	138	9	57%
# 4	10 Jul 2023	206	113	211	12	55%
# 5	17 Oct 2023	238	155	249	5	65%
# 6	6 Nov 2023	132	87	128	9	67%
# 7	27 Nov 2023	182	101	76	16	55%
# 8	5 Dec 2023	110	48	141	19	44%
# 9	14 Dec 2023	226	121	82	2	54%
# 10	8 Jan 2024	343	222	30	16	65%
# 11	19 Feb 2024	169	106	54	11	63%
# 12	4 Mar 2024	236	141	94	19	60%
# 13	26 Mar 2024	519	266	13	28	51%
Total		**2 953**	**1 713**	**1 782**	**179**	
Average		**227**	**132**	**137**	**14**	**58%**

3.2 Geographical coverage of participants

In terms of geographical coverage, the CORE-MD webinars attracted participants from all over the world (see Figure 4). In particular, besides attendees from most of the European countries, especially high participation was registered from the USA and Canada. Several participants requested and received certificates of attendance to the CORE-MD webinars. Exchanges during the Q&A sessions highlighted the existing differences and allowed to delve into interesting debates about the comparison between the European regulatory system for medical devices and the US system. The involvement of expert panellists from the Food and Drug Administration (FDA) in several CORE-MD webinars contributed to provide significant insight on how best to address the current challenges of the MDR implementation.

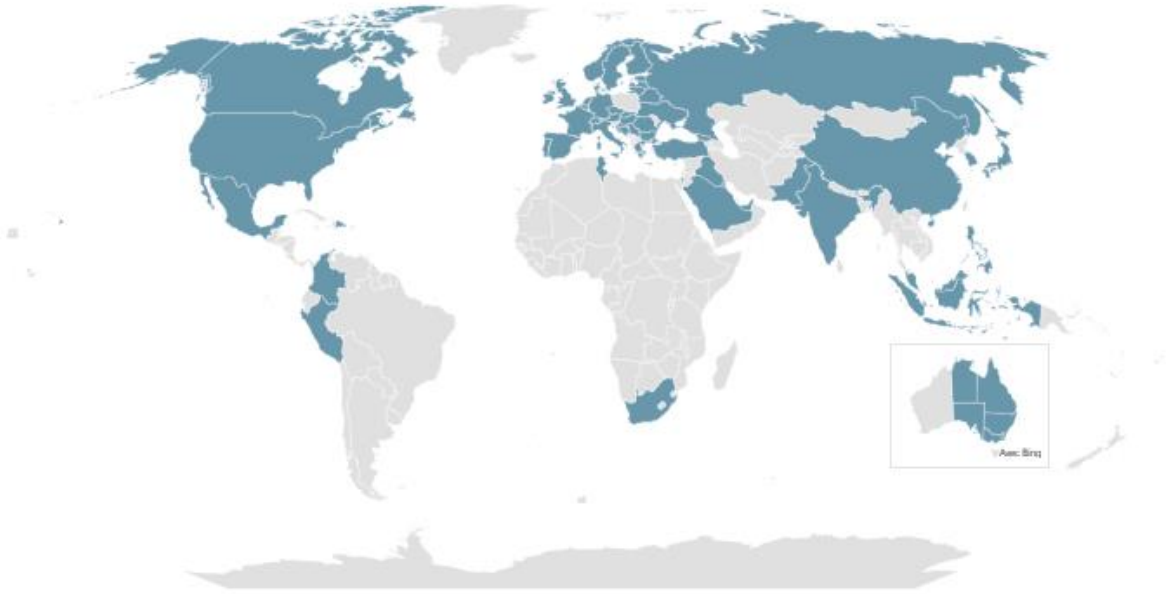


Figure 4. Overview of geographical coverage of attendees

3.3 Impact of webinars available on YouTube and website

The objective as per the grant agreement was to have CORE-MD's outputs, namely webinars, available for a wider audience. As a result, the Youtube channel was the best-placed solution to achieve this objective. CORE-MD webinars were therefore made available online both on the website and on Youtube.

The videos of the CORE-MD YouTube channel follow the social media trend so that the longer they are online, the higher the number of views is. It is expected that last webinars will also follow the same trend and contribute to ensure that CORE-MD's outputs will have continued impact even beyond the project's lifespan.

The dedicated page was ranked 2nd most seen page on the website highlighting the interest of visitors for the information provided on this page (see Figure 5).

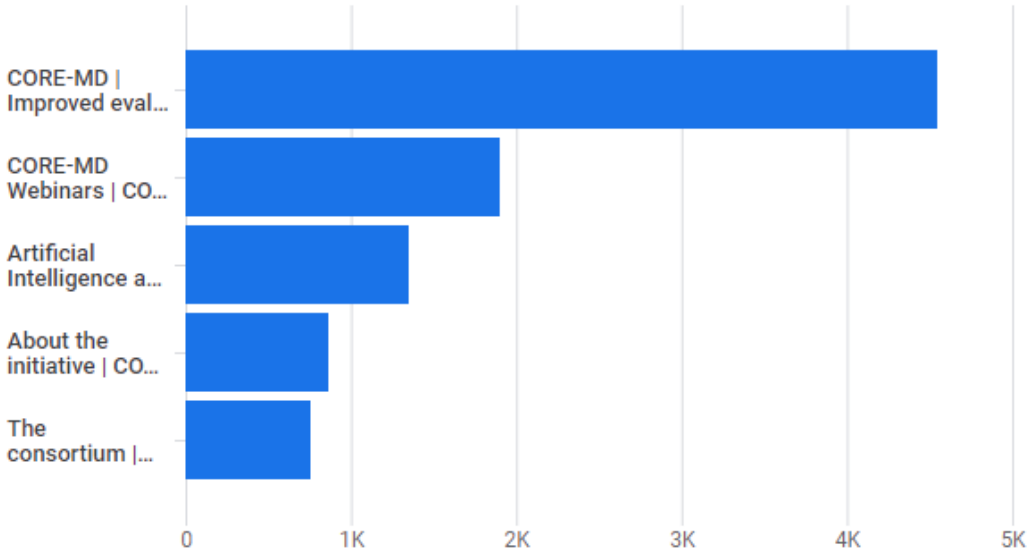


Figure 5. Number of views of website pages from January 23 to March 24

4 CORE-MD Podcasts

4.1 Designing podcasts

Five podcasts were organized to delve into essential topics within the project, covering the roles of notified bodies, paediatric devices, registries, and evidence for high-risk medical devices. Podcasts offer numerous educational benefits for projects focusing on complex subjects such as CORE-MD. They serve as an educational resource, offering concise insights for listeners on-the-go. Their brevity compared to webinars, being a plus for occasions where our target audience is busy, provides an excellent overview of the project's activities and outputs.

Through in-depth exploration of complex topics and discussions with experts, podcasts offer valuable insights into medical device technologies, regulations, and applications. Real-world examples and case studies featured on podcasts help listeners understand the practical implications of these technologies in healthcare settings.

Overall, these podcasts were designed to serve as a valuable educational tool, providing convenient, engaging, and informative content for those seeking to deepen their understanding of medical devices.

Figure 6. Example of visuals produced to disseminate the podcasts over social media

Table 4. List of podcasts

Title	Speakers
Understanding how EU notified bodies work	Richard Holborow (Team-NB) & Alan Fraser (ESC)
How do surgeons choose which medical device to implant?	Per Kjærsgaard-Andersen (EFORT) & Alan Fraser (ESC)
Providing medical devices for children	Berthold Koletzko (EAP) & Alan Fraser (ESC)
Real-world evidence on the performance of high-risk medical devices	Perla Marang-van de Mheen (LUMC) & Alan Fraser (ESC)
Medical device registries for post-market surveillance	Anne Lubbeke Wolff (UOXF) & Alan Fraser (ESC)

4.2 Recording podcasts

The podcasts were recorded in the ESC office, leveraging the opportunity of having the event's partners gathered. This facilitated more effective planning of the episodes prior to recording, as speakers could engage in a brief brainstorming session before the actual recording took place.

Professor Alan Fraser, the scientific coordinator of the project, was responsible for proposing the speakers and designing the titles and contents of each episode upon consulting the communication and dissemination team. Before recording each episode, he briefed the speakers on the structure of the questions and the depth of responses expected, considering the available time and the significance of delving into various aspects of the subject matter.

Although the recording itself presented some challenges in terms of setting up recording equipment including microphones, audio interfaces, and recording software in a quiet environment, most of the background noises and the audio issues encountered during the recording was edited out during the review and editing process. All the episodes were edited to resemble a series, with the same jingle, format and size. We tried to keep them as harmonious as possible, with the same introduction and the same ending.

4.3 Advertising podcasts

The majority of podcast recordings were completed towards the end of the project, coinciding with the availability of more results and opportunities to gather necessary content. Consequently, a significant portion of the advertising efforts will take place post-project completion. Now that the editing phase is finalized, all episodes are accessible on the CORE-MD website.

Additionally, they will be featured on the ESC 365 platform, promising widespread exposure and impact. Promotion of these episodes will be facilitated by integrating them into the existing "Cardio Talk" family

of podcasts on ESC. Leveraging the existing recognition of these shows will amplify the visibility of CORE-MD's content within this established platform. While it is not possible to predict the traction the podcast episodes will have, the ESC 365 platform had 739.000 visitors on in 2023, ensuring an excellent level of visibility.

The episodes will be uploaded in the main podcast platforms such as Apple Podcasts, Spotify, Deezer and, Google Podcasts. Posting podcasts on various platforms will expand their reach, making them accessible to a wider audience across different devices and operating systems. This enhances discoverability through platform algorithms and recommendation systems, increasing the chances of attracting new listeners. By offering convenience and aligning with users' existing audio consumption habits, podcasts gain visibility and credibility, potentially leading to increased recognition and followership.

5 Other videos

In additional to the informative and educational resources mentioned in the former sections, the Biomedical Alliance also produced three videos in April 2023 that were recorded on the occasion of the Project Board Meeting and Advisory Board Meeting held in Leuven and disseminated in the course of the summer 2023. Involving CORE-MD partners and members of the Advisory Board, these three-minute videos aimed to present in a nutshell the work of CORE-MD on a given topic. Available on CORE-MD YouTube channel and disseminated through the CORE-MD newsletters, these videos attracted over 100 views each.

Alan Fraser (ESC), Tom Melvin (Trinity College Dublin) and Elin Karlberg (Swedish Medical Products Agency) explained the rationale underpinning the project as well as its challenges and expectations with regard to the implementation of the Medical Device Regulation. It was released on June 2023. This video was released in June 2023 and had 279 views on YouTube.

Per Kjaersgaard-Andersen (EFORT), Robert Byrne (RCSI) and Rob Nelissen (LUMC/EFORT) presented the work undertaken by CORE-MD partners to strengthen clinical evidence for high-risk medical devices (HRMD). The partners surveyed the landscape of studies available for HRMD that already received CE marking. Key findings indicate that the majority of trials are non-randomized trials, and the size of the studies were quite small with a short duration of follow-up. This video was released in July 2023 had 101 views on YouTube.

Frank Rademakers (KU Leuven), Elisabetta Biasin (KU Leuven) and Leo Hovestadt (Elekta) highlighted the specific promises and challenges that the use and evaluation of AI-enabled medical devices pose to the modern healthcare and regulatory systems. This video was released in October 2023 and had 141 views on YouTube.

6 Summary and conclusions

This deliverable presents the results of the CORE-MD consortium's efforts to disseminate its results using webinars, podcasts and short videos as a mean to translate its key findings into accessible and useful educational resources. All these materials are available on the CORE-MD website and were promoted through several channels.

CORE-MD partners were highly involved in the design and co-productions of the webinars, podcasts and videos and demonstrated their commitment to contribute to the dissemination and communication of the CORE-MD project.

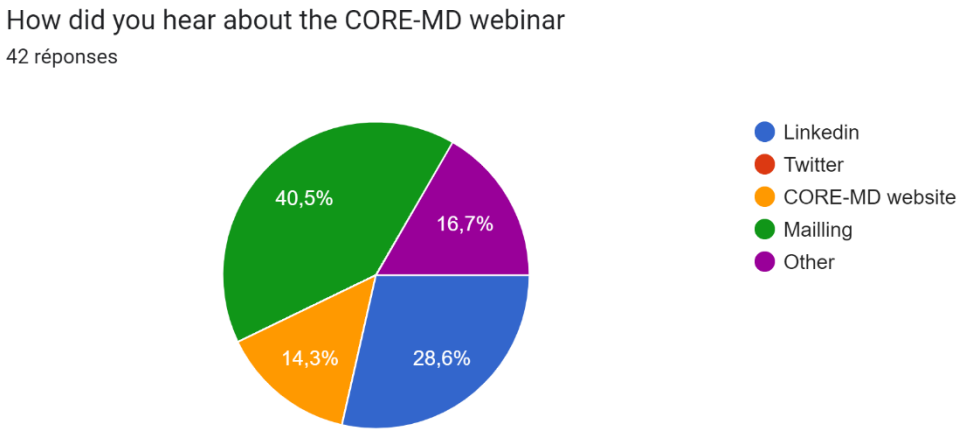
CORE-MD webinars offered a large variety of topics and involved many different experts, including external experts from the consortium. All target groups of the Dissemination and Communication plan were involved both as panellist or participants in these webinars. Clinicians, notified bodies, regulatory authorities, scientific community, patient organisations and manufacturers were all offered the possibility to present their findings, challenges and expectations.

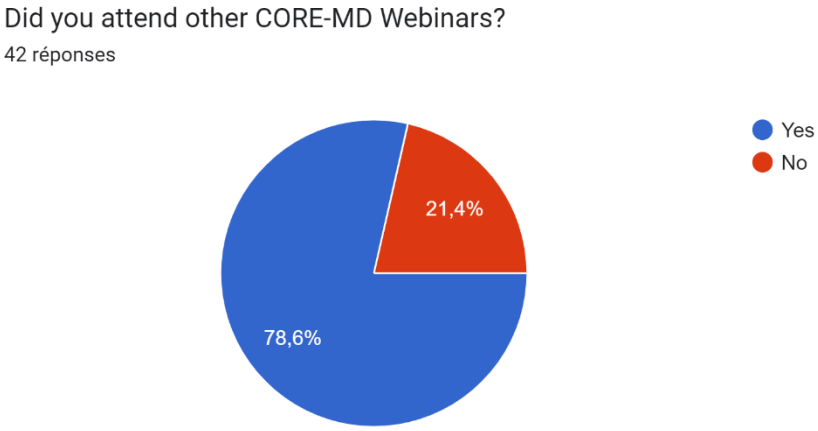
The impact of this activity as measured by live attendance, interactivity and content availability beyond the project's lifespan is very important. It contributes to share knowledge, fuel the debate over the implementation of the MDR and raise awareness on the complexity of actors, interests and needs involved.

Appendices

Appendix 1. Feedback survey on webinars #4 and #5

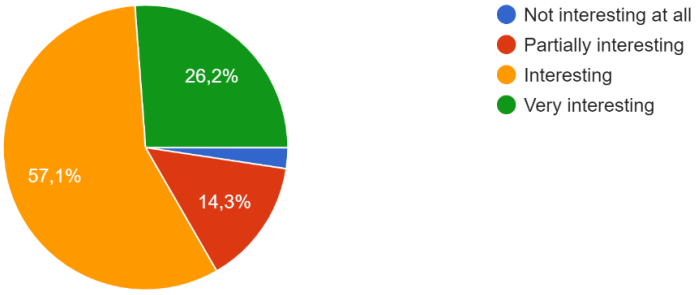
One post-webinar survey was sent to the participants of the webinars no. 4 and 5 with the aim to collect relevant feedback. 42 responses were collected providing interesting insights on attendees' satisfactions. Results are outlined in the graphs below.



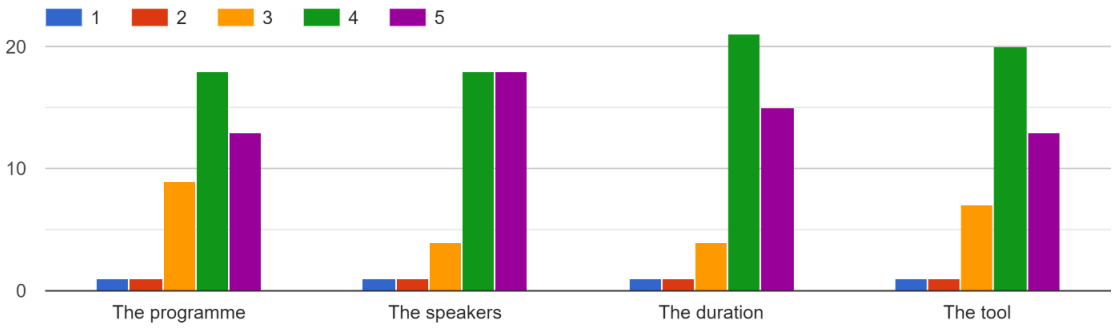


Can you rate the webinar you attended

42 réponses

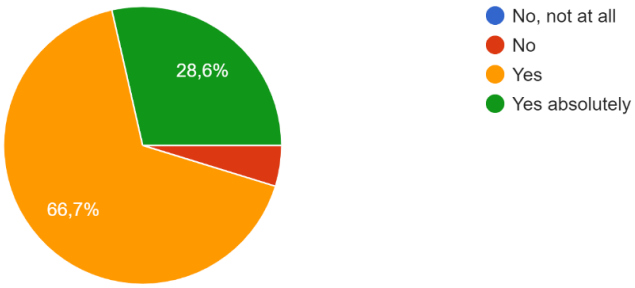


Can you rate each part of the webinar (1: low performance to 5: high performance)



Would you recommend CORE-MD webinars to your network?

42 réponses



CORE-MD

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

For more information, visit: www.core-md.eu

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