CORE-MD

Coordinating Research and Evidence for Medical Devices

Final report on dissemination and networking

Deliverable 4.8

Deliverable factsheet

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01/09/2024	*v1.1*	*Valentina Tageo (ESC), Alan Fraser (ESC)*	*Revised version incorporating comments received from the expert reviewers in the final review report, namely adding a*

			dedicated section (9.1) listing all the final exploitable results generated by CORE-MD for further uptake by the regulatory community and also updating the current status of the list of publications in section 5.

Acronyms and abbreviations

CAMD	Competent Authorities for Medical Devices
CIE	Clinical Investigation and Evaluation (Working Group)
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EUPSF	European Patient Safety Foundation
IMDRF	International Medical Device Regulators Forum
ISAR	International Society of Arthroplasty Registries
ISPOR	The Professional Society for Health Economics and Outcomes Research
MDCG	Medical Device Coordination Group
NB	Notified Bodies
NET	New and Emerging Technologies (Working Group)
OSF	Open Science Framework
PMS	Post-market surveillance
PROSPERO	International Prospective Register of Systematic Reviews
RIAP	Registro Italiano ArtoProtesi (Italian Arthroplasty Registry)
RAPS	Regulatory Affairs Professionals Society
WG	Working Group

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Executive Summary

The CORE-MD consortium implemented its dissemination and communication plan as anticipated. In the second half of the project's lifespan, it triggered increased visibility thanks to the growing engagement of partner institutions and collaborating organizations that have progressively strengthened their commitment in building a cohesive European regulatory science ecosystem.

A wide range of stakeholders were informed and aware of CORE-MD's results and findings thanks to a dedicated newsletter, a continuously updated website and reinforced social media presence, especially over LinkedIn.

As per the scientific production itself, the consortium has achieved remarkable results and produced 17 manuscripts that have been (or will be soon) published in renowned scientific journals with several other articles in preparation, presented its findings in a broad set of events, conferences and congresses, and promoted the creation of a thriving research community offering the chance to young research fellows to work together with reputed experts and collaborate with peers across Europe.

Thanks to the webinars, partners shared their results but more importantly involved external experts (see D4.5) to fuel the discussion on the implementation of the Medical Device Regulation. Interaction with audience was encouraged in order to debate and discuss the various viewpoints, taking into account that differences existed in the perception of the MDR.

Regular presence at MDCG meetings contributed to keep regulators and notified bodies informed. A dedicated task force within the MDCG Clinical Investigation and Evaluation Working Group has been set up in 2024 to review the CORE-MD publications and recommendations and devise the best routes for their integration into the upcoming revisions of MDCG guidance documents.

The CORE-MD consortium has therefore achieved its objectives which were to systematically review methodologies for the clinical investigation of high-risk medical devices (Work Package 1), recommend how new trial designs can contribute (Work Package 2), and advise on methods for aggregating real-world data from medical device registries with experience from clinical practice (Work Package 3). Multidisciplinary workshops (20-21 Nov 2023) proposed a hierarchy of levels of evidence from clinical investigations; educational and training objectives for all stakeholders, to build expertise in regulatory science in Europe; and an ethics charter for medical device innovation (Work Package 4). Each task leader has successfully coordinated complex and interdisciplinary work streams that has led to the production of the planned deliverables and also to a series of additional spin-off/secondary studies that have further enriched the breadth of the CORE-MD scientific findings and its potential to influence policy making and help address MDR implementation hurdles. Overall, all tasks have entailed intense cross-disciplinary and international collaborations and rigorous stakeholder consultations. In this regards, three workshops, one focus group and two Delphi processes were conducted to validate the findings and recommendations drafted by task leaders and their groups.

The project's dissemination efforts culminated in the organization of a successful Final Conference in Brussels in March 2024, which gathered consortium partners, European Commission, EMA and FDA high level representatives together with national regulators, Notified Bodies, patient's groups and industry representatives, and the production of a Final Booklet presenting a summary of all the core achievements of the project.

The contribution of CORE-MD to the implementation of the Medical Device Regulation is significant. Regulators, academics, patients, healthcare providers and professionals, industry and notified bodies have experienced through CORE-MD how constructive dialogue could contribute to a mutual understanding of the needs and expectations of each key player in the field of medical devices. The recommendations stemming from the consortium will help regulators to understand better the challenges and envisage the responses to provide patients with evidence-based, safe and secure medical devices.

1 Introduction

The CORE-MD consortium has significantly intensified its communication and dissemination efforts during the second period of the project (M19-M36) putting in place a variety of actions that have allowed to successfully reach out, inform and engage the targeted stakeholder communities.

This achievement has been made possible thanks to the collective commitment demonstrated by all partners in generating high-quality dissemination outputs and activating all the relevant channels and tools at both project and partner level.

Thus, the initial 3-phase CORE-MD communication and dissemination plan exposed in deliverable D4.6 has been updated and flexibly adapted to the evolving needs of the project and the progressive attainment of its objectives with the threefold purpose of: **(i) sharing accurate information** and evidence-based findings; **(ii) build a thriving community** of specialists and interested organizations willing to commit to its further development and uptake of its results; **(iii)** preparing the ground and **advocating for the adoption** of its recommendations, e.g. via their integration to in the current working streams of European and national regulators.

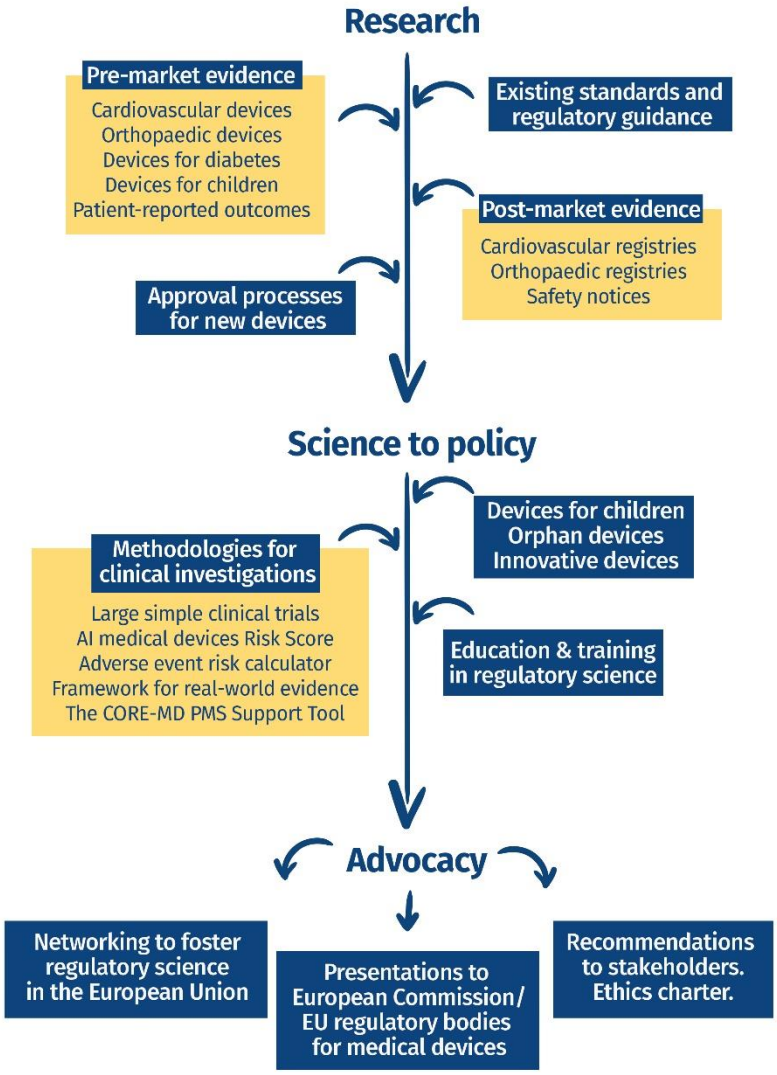


Figure 1. The CORE-MD journey

Through the extensive production of scientific publications, the continued participation of the CORE-MD partners in relevant medical professional fora and official regulatory meetings at the EU level as well as the consolidation of the project's presence in the digital media, the consortium has put in place an effective multichannel communication and dissemination strategy. This has followed closely the evolution of the regulatory landscape and has accompanied the

whole "CORE-MD Journey" (Figure 1) across its intense evidence production work (*research*), collective reflection to transfer scientific advice into policy (*science-to-policy*) and stakeholder engagement to foster the adoption of its recommendations and build a strong European regulatory science community (*advocacy*).

The premise of CORE–MD was that regulatory policy concerning medical devices should be based on scientific and clinical evidence. The primary focus concerned cardiovascular and orthopaedic devices, since together they account for >50% of all high-risk implanted medical devices, as well as devices for diabetes care. Based on this, the **primary stakeholder categories** addressed by the project's engagement strategies were **regulators and medical professionals** through their clinical societies. However, the CORE-MD consortium has successfully reached out and established relevant connections with all the **other stakeholder categories** involved in the development, evaluation, approval and certification, clinical use, and monitoring of medical devices, namely **national public health institutes, notified bodies, academic institutions, patients' groups, health technology assessment agencies,** as well as **device developers and manufacturers**.

The results of CORE-MD's tasks were **published in scientific journals** and/or presented at **scientific conferences** as abstracts or educational sessions. Once published, the papers were made available on the CORE-MD website in the library section. This, coupled with the production of high-quality educational resources, audiovisual products and printed materials as well as the commitment to adhere to **open science principles** in the dissemination of knowledge, data and tools, has allowed the project to effectively share its findings with a variety of audiences fostering interdisciplinary exchanges and enriching the final outputs with the inclusion of diverse perspectives and viewpoints.

Two principal digital **communication channels** were identified as the most effective means of communication, namely the project's website and LinkedIn (activated in April 2022 to reinforce the presence of the project on social media, besides the already existing Twitter/X account). During the project (December 2022), the consortium also setup a YouTube channel to centralize all the videos produced and the recordings of webinars.

CORE-MD partners also used their **institutional communication channels** to disseminate widely the outputs through newsletters, webinars, website page, social media accounts and featured CORE-MD in their **official events and congresses**.

At its **Final Conference**, the consortium not only presented its results but also made recommendations and proposals on the way forward on the implementation of the Medical Device Regulation. Involving decision-makers, industry, patients, clinicians, regulators, notified bodies and researchers, this event, held in Brussels on March 15th, 2024, was broadcast live on Zoom and attracted 200+ participants.

1.1 Deliverable structure

This deliverable presents the CORE-MD's action on dissemination and communication over the period M18-M36 (October 2022 – March 2024).

It presents the efforts made to enhance the project's visibility (Section 2) as well as the partner's contribution that triggered more impact (Section 3). It also highlights the production of printed materials (Section 4) and the high number and relevance of scientific outputs stemming from the project (Section 5). Section 6 is devoted to describing the widespread use of audiovisual means to amplify outreach, including the production of videos and podcasts. Section 7 provides a thorough pictures of all the different types of events and fora where CORE-MD was featured, while Section 8 is dedicated to the Final Conference organization as it represented the culminating closure event of the project and celebration of its accomplishment as well as a testament to the capacity of the CORE-MD team to create a cohesive and thriving European regulatory science community that will keep working on common challenges and shared interest well beyond the project's end.

Last, following the mid-term reviewers' recommendation to collect and present more accurate and detailed KPIs documenting the impact of dissemination and communication actions a dedicated paragraph addressing that request has also been included (Section 9). In addition to that, the final review comments also highlighted to need to clearly enumerate the key exploitable results that CORE-MD has successfully achieved and made openly available to the European regulatory community (Section 9.1).

Further details are provided in the four appendices.

2 Enhancing CORE-MD's visibility

2.1 The CORE-MD communication channels

The CORE-MD team ensured consistent communication of the project's vision and goals, progressive achievements and final results throughout the project's lifespan. During the second reporting period, following the mid-term reviewers' recommendations to intensify the communication activities and provide more "*updated information in the website, as well as on social media*", the digital communication efforts have been considerably strengthened by enriching and continuously updating the website, more frequently posting on LinkedIn and creating a new YouTube channel to host all the audiovisual products of the project that have marked a significant improvement in the project's outreach.

Moreover, beyond its own website and social media accounts, the communication strategy also relied extensively on the proactive support from partners via their institutional accounts which helped maximize the impacts (see Section 9). With over 13 posts or news per month over the period M19-M36, the consortium as a whole has put a lot of energy into advertising and promoting the project's results on social media.

2.1.1 The CORE-MD website

The CORE-MD website attracted over 7,500 users (Figure 2) which is considered a notable achievement taking into consideration that no paid campaigns were used for search engine optimization and, thus, to increase traffic.

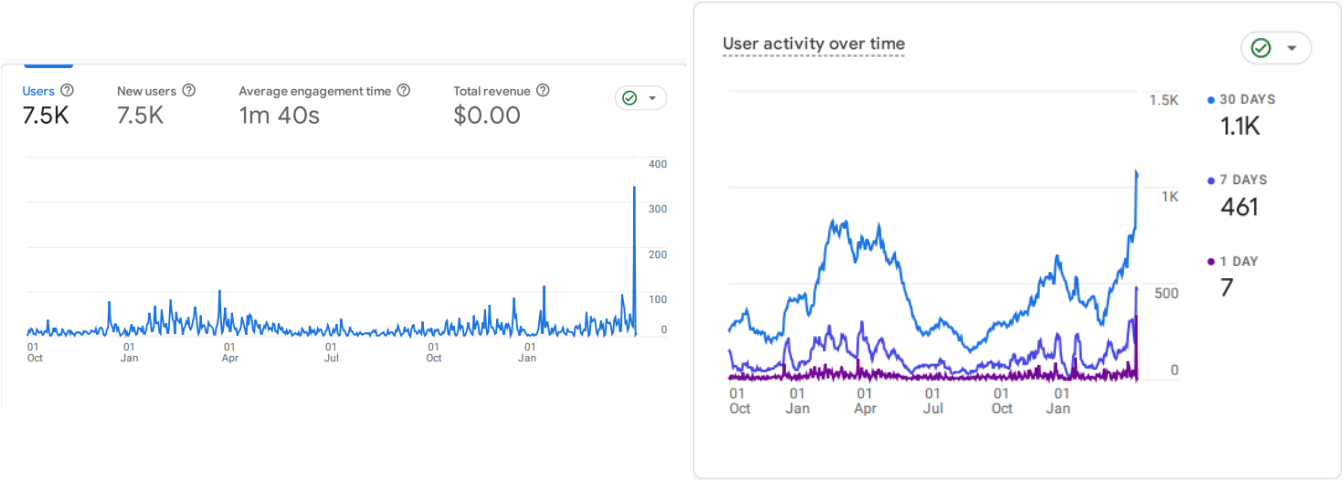


Figure 2. CORE-MD website statistics: number of users and user activity over time

Links to and from the website were available on each partner's website during the whole duration of the project (see D4.7) contributing to increase the number of users impacted by online communication on CORE-MD.

In terms of geographical coverage (Figure 3), the CORE-MD website attracted a wide audience, including a significant number of users from the US (1.8K) which demonstrates the sustained interaction and interest in mutual learning and cross-fertilization between the regulatory science communities in the EU and the US.

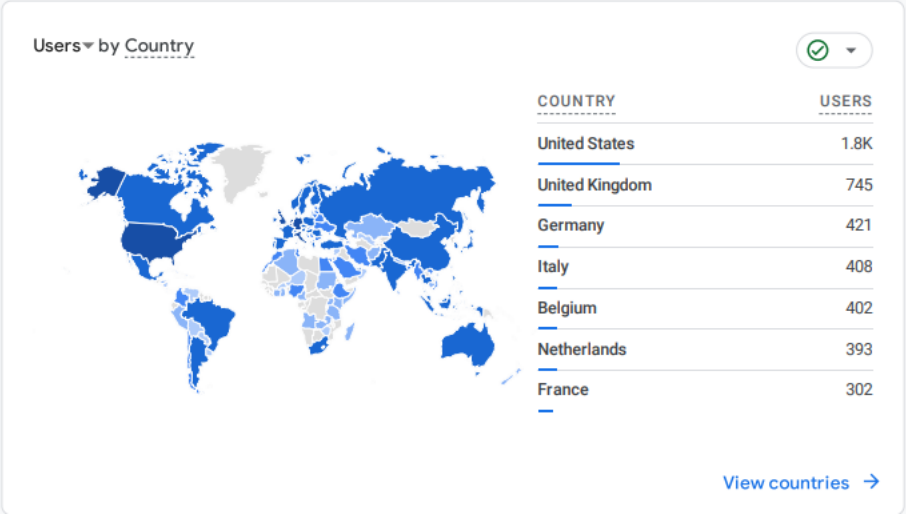


Figure 3. CORE-MD website statistics: geographical coverage

With the aim to provide frequent updates on project's progress and events, every month during the second reporting period, the CORE-MD communication team published an article on the **news section** of the website https://www.core-md.eu/news/. On average, 2 articles were published each month on the CORE-MD website disseminating project's results such as publications or outputs such as webinars. Many news articles were also inserted in the regular newsletters (see Section 2.1.4) which contributed considerably to increase the number of views on the CORE-MD website. News contents and links were also referred to on social media (see Section 2.1.2).

Publications, protocols and abstracts were published on the **library** section of the website. Once manuscripts were approved, they were uploaded on the website and disseminated in newsletters or through a news article. Most publications are available, but several are still to come (see Section XX). Three categories of outputs were uploaded in the library: **CORE-MD deliverables** (once approved), **publications**, and **media** outputs, the latter featuring the recently launched CORE-MD podcasts too (see Section 6.2). Overall, the library section webpage recorded 944 downloads demonstrating interests in available documents online.

Moreover, a new sub-page within the library section was created to store all the relevant information about the CORE-MD **webinars** (see Section 6.1.1) and provide easy access to the recordings.

2.1.2 CORE-MD presence on social media

The LinkedIn account was established in April 2022 further to the request of partners and the acknowledgement that the medical device and regulatory science topics had a larger traction on LinkedIn than on X and CORE-MD partners were largely more active on LinkedIn. Thus, **LinkedIn** gradually became the second main communication channel and got up to 686 followers without any commercial or paid sponsorship put in place. The number of impressions of LinkedIn posts also steadily increased until the end of CORE-MD with a peak up to +8,000 in March 2024 in the occasion of the CORE-MD Final Conference.

The metrics shown in Figure 4 and Figure 5 refer to the progression of the number of impressions and visitors in the last year before the project's end (March 2023 – March 2024).

Despite the fact that the most prominent interactions were recorded between individual representatives and stakeholder organizations from the clinical, research and regulatory domains, interestingly, 23,9% of followers of the CORE-MD project's LinkedIn accounts are from the medical equipment manufacturing sector (Figure 6), thus demonstrating the high interest from manufacturers on the project's results and its prospective impact via the provision of clinical evidence generation guidance and recommendations.

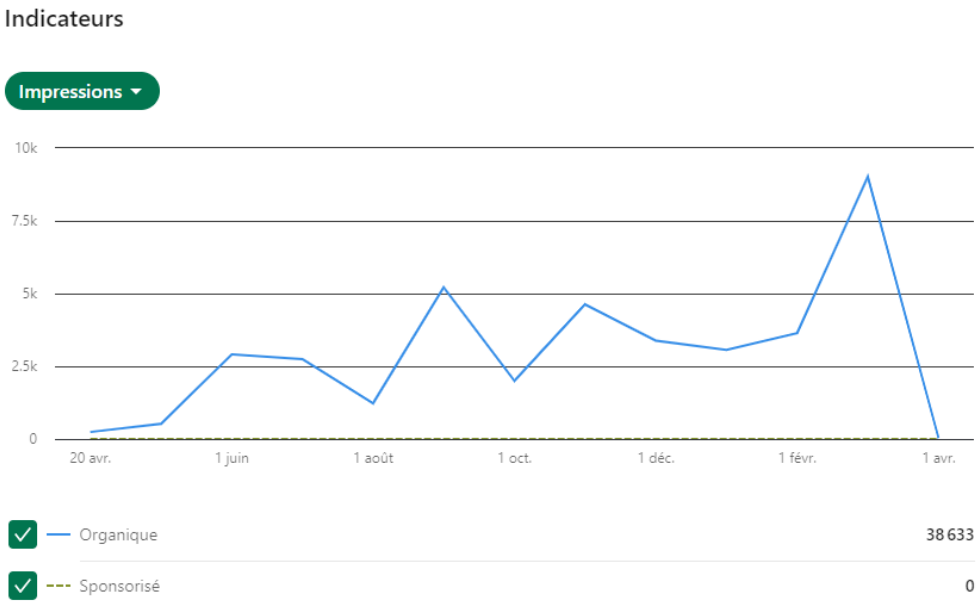


Figure 4. LinkedIn impressions (20 March 2023 – 31 March 2024)

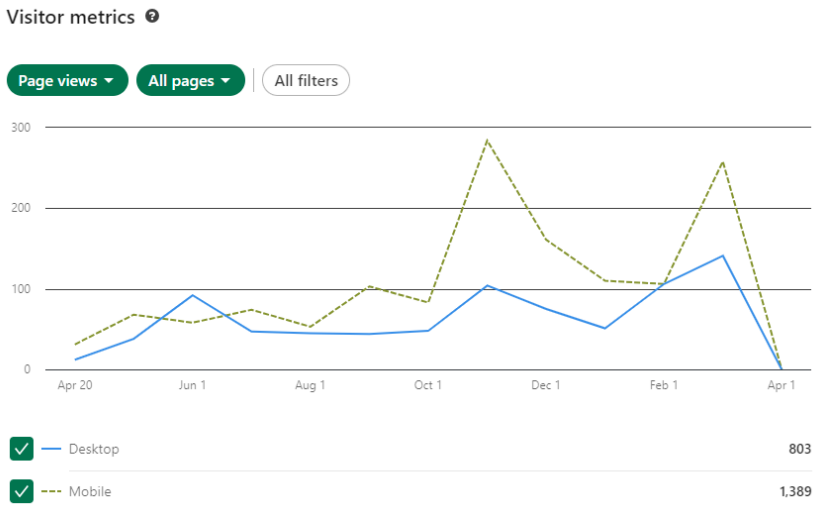


Figure 5. LinkedIn visitors (20 March 2023 – 31 March 2024)

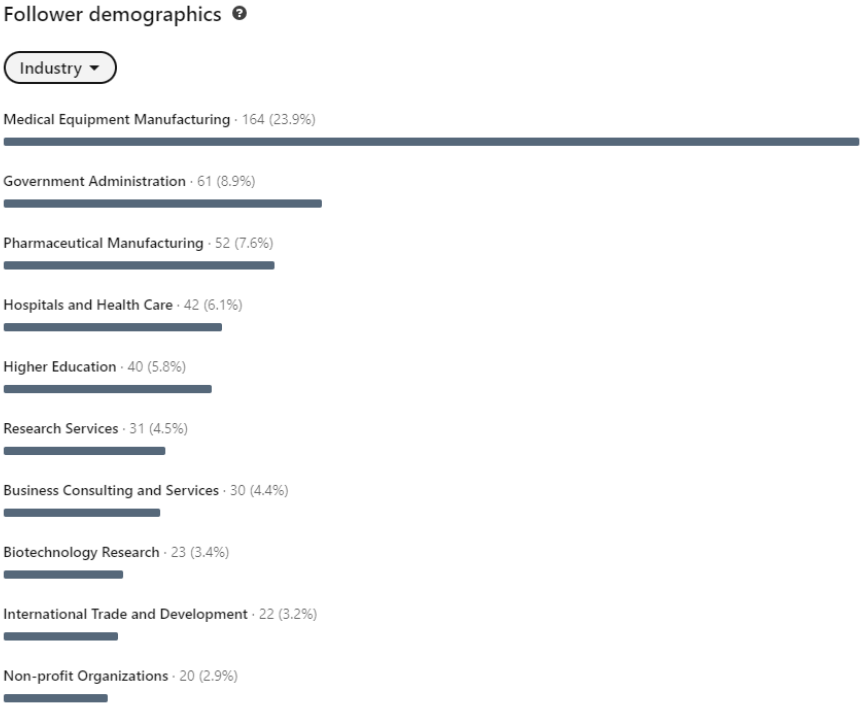


Figure 6. Follower demographics (20 March 2023 – 31 March 2024)

Many task leaders, partners, Advisory Board members as well as invited external experts used their own LinkedIn account to publish or re post CORE-MD posts. Whether through liking posts or disseminating them to their own contact list, they also contributed to share the CORE-MD results. In support to the dissemination efforts, partners also backed-up the LinkedIn posts to their followers contributing to maximise the impact of CORE-MD's communication. Besides partners institutions, external entities shared and published content deriving from CORE-MD communication. Entities such as EVNIA (5K followers), RAPS (10K followers) republished several CORE-MD posts. Moreover, fruitful collaboration links have been established with like-minded **European projects, such as NoBoCap**, which have also resulted in mutual support to spread each other news and event announcements.

This collective effort contributed to promote CORE-MD to a very wide audience thanks to cumulative numbers of followers. Up to 70k social media accounts were exposed to CORE-MD information through institutional dissemination. Many more were also exposed through individual accounts.

The CORE-MD communication team also maintained active and constantly updated the **Twitter/X** handle of the project, with more frequent posts during the period M19-M36. From October 2022 until March 2024, a consistent and strategic effort in social media engagement via Twitter/X was evidenced across all trimesters (see Appendix 2). The initiative saw a total of 46 posts on CORE-MD's profile, with several interactions/reposts from partners and other entities which helped in amplifying the outreach. The data shows a progressively engaged audience with the most interactive post achieving 69 engagements, suggesting content resonated well with the followers while the impressions totaled over 11,000.

Figure 7 and Figure 8 show two examples of posts published from partner institutions, individual consortium and Advisory Board members.

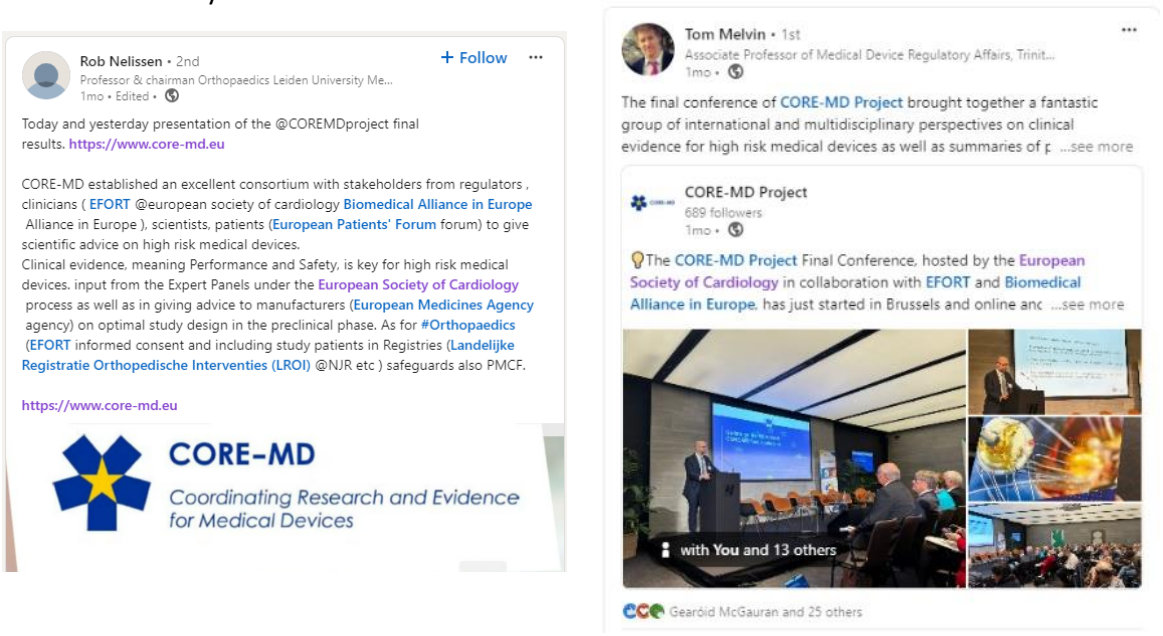


Figure 7. Examples of LinkedIn posts from individual members

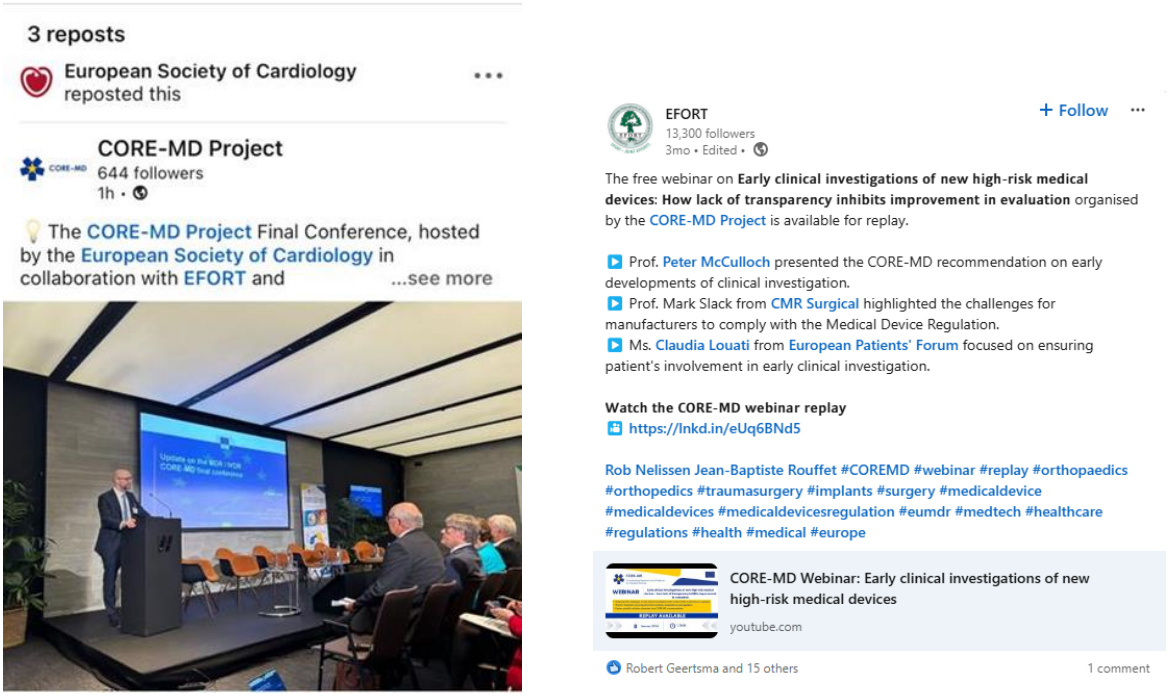


Figure 8. Examples of LinkedIn posts from institutional partners' accounts

An extensive list of exemplary posts and articles published by CORE-MD partner organizations over social media or within their newsletters and bulletins is provided in the Appendix 5. Moreover, a shortlist of external entities supporting the widespread diffusion of CORE-MD news over LinkedIn is provided below in Table 1. Examples of posts from external organizations and other EU-funded projects featuring CORE-MD contents, highlighting the diverse typologies of organizations, from specialized press outlets to patients' groups and large regulatory consultancy firms.

Table 1. Examples of posts from external organizations and other EU-funded projects featuring CORE-MD contents

Partner	# followers	Examples of posts
Global Regulatory press	6147	https://www.LinkedIn.com/posts/global-regulatory-press_perceived-training-needs-of-regulators-notified-activity-7071385753804505088-tAUP?utm_source=share&utm_medium=member_desktop
EVNIA	5146	https://www.LinkedIn.com/posts/evnia_clinicalevidence-cardiovascular-marketaccess-activity-7102935815516790784-bt48?utm_source=share&utm_medium=member_desktop

Partner	# followers	Examples of posts
		https://www.LinkedIn.com/posts/evnia_medtech-notifiedbodies-eu-activity-7174417116060631040-vWIN?utm_source=share&utm_medium=member_desktop
		https://www.LinkedIn.com/posts/evnia_cemarking-fda-rcts-activity-7174392304269463552-VBqo?utm_source=share&utm_medium=member_desktop
MD Medicals	3625	https://www.LinkedIn.com/posts/md-clinicals_medicaldevices-regulatoryscience-networkingopportunity-activity-7171856365936594944-fJWF?utm_source=share&utm_medium=member_desktop
Nobocap	537	https://www.LinkedIn.com/posts/nobocap-project_medicaldevices-medicaldevices-hadea-activity-7170099354588987392-jDCh?utm_source=share&utm_medium=member_desktop
RAPS Europe	10830	https://www.LinkedIn.com/posts/raps-europe_mdr-medicaldevices-paediatric-activity-7140334829639720961-HWTN?utm_source=share&utm_medium=member_desktop
KCRI	2066	https://www.LinkedIn.com/posts/kcri_core-md-project-website-activity-7135218741864247296-d3TP?utm_source=share&utm_medium=member_desktop
EUPSF	1144	https://www.LinkedIn.com/posts/eupsf_safe-patientsafety-medicaldevices-activity-7174488563680489473-jK1S?utm_source=share&utm_medium=member_desktop
Spanish Patient Forum	1061	https://www.LinkedIn.com/posts/foro-espa-ol-de-pacientes-fep_highrisk-medicaldevices-activity-7076942180304494592--HOI?utm_source=share&utm_medium=member_desktop

2.1.3 The CORE-MD YouTube channel

In order to make the CORE-MD webinars available, a CORE-MD YouTube channel was created. Once finalized, videos of the webinars were uploaded on the YouTube channel and also embedded on the webpage dedicated to the webinars (https://www.core-md.eu/core-md-webinars/).

With more than 2K views and 23,5k impressions over the second period, the CORE-MD YouTube channel attracted a quite large audience. Still, the average time per visualization remains quite limited although for the short presentation videos (on AI and clinical evaluation methods), visitors views more than 50% of the videos on average.

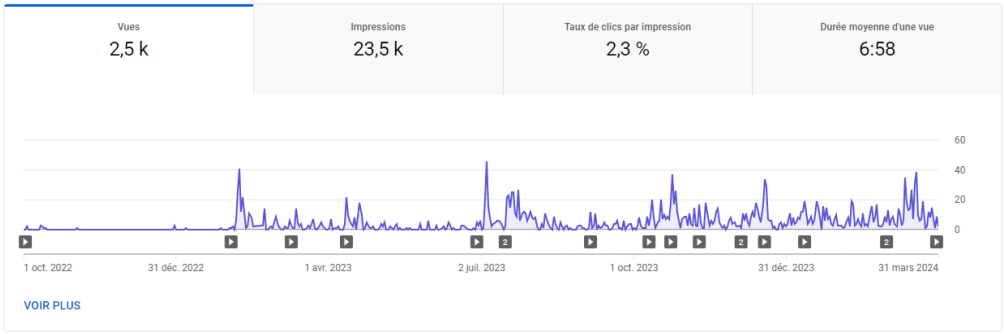


Figure 9. YouTube channel statistics (01/10/2022 – 31/03/2024)

Beside the 13 webinars available on this channel, three promotional videos of CORE-MD are available on the YouTube channel as well as the videos of two ESC TV Stage sessions recorded at the ESC Congresses 2022 and 2023 (Table 2).

Table 2. List of videos on the YouTube channel

Title	Publication date	Impressions	Views
CORE-MD Webinar: The Notified Body's Role & The Conformity Assessment Process	30/03/2024	587	7
CORE-MD Webinar: The use of PROMs in the evaluation of high-risk Medical Device	07/03/2024	1441	95
CORE-MD Webinar: Monitoring Life Cycle of an implant in Real Life	01/03/2024	542	53
CORE-MD Webinar: Early clinical investigations of new high-risk medical devices	11/01/2024	2914	124
CORE-MD Webinar: Providing high-risk medical devices for children – problems and proposals	18/12/2023	972	82
CORE-MD Webinar: IT Tools for post-market surveillance	08/12/2023	770	142
CORE-MD webinar: Pivotal Clinical Investigation in High Risk Medical Devices	04/12/2023	1174	76
CORE-MD webinar Cardiovascular and diabetic	09/11/2023	2000	129
CORE-MD Webinar - Clinical evaluation of AI	23/10/2023	3430	249

Title	Publication date	Impressions	Views
CORE-MD Video: Artificial Intelligence in Health: recommendation for clinical evaluation	11/10/2023	1412	141
ESC TV Stage CORE-MD Session 2023	05/09/2023	1126	37
CORE-MD Video: Clinical evidence in the evaluation of high-risk medical devices	20/07/2023	529	101
CORE-MD Webinar: Training and Education for regulators, notified bodies and clinicians	17/07/2023	2719	211
CORE-MD Video: Improving methods for the clinical investigation and evaluation of medical devices	29/06/2023	1254	275
CORE-MD Webinar: Objective Performance Criteria	12/04/2023	584	138
CORE-MD Webinar: The Origins and objectives of the European Medical Device Regulation	10/03/2023	432	130
CORE-MD Webinar: Orthopaedic Implants and Medical Device Regulation	03/02/2023	1298	436
ESC TV Stage CORE-MD Session 2022	03/10/2022	323	46
Total		**23 507**	**2 472**

Overall, the YouTube channel served (and will continue to serve) as a repository for CORE-MD videos be it webinar replays, general presentation, or other types of videos. The general trend on YouTube showed an increase in views over time. As a result, videos posted earlier have a higher number of views.

2.1.4 CORE-MD Newsletters

The CORE-MD management team elaborated regular newsletters during the second period of the project.

Two mass mailing softwares were used: Mailchimp and Mailjet. Mailchimp was the original solution used from the beginning of the project.

The basic Mailchimp pricing plan included mass mailing to 1000 beneficiaries per month hence the fact that we switched to another mass mailing solution provider (Mailjet) as we increased the number of mailing sent each month due to webinars.

Website visitors were encouraged to subscribe to CORE-MD newsletters through a dedicated form. Moreover, with the aim to expand the project's outreach by increasing the number of subscribers, the management team implemented an opt-out strategy whereby each registered participant to the CORE-MD webinars was included in the mailing list. Through simple e-mail to eu@efort.org, subscribers could easily unsubscribe. However, only two subscribers requested their email to be withdrawn. Moreover, during webinars, the introductory speech included a reminder to visit the website and subscribe to newsletters to stay informed.

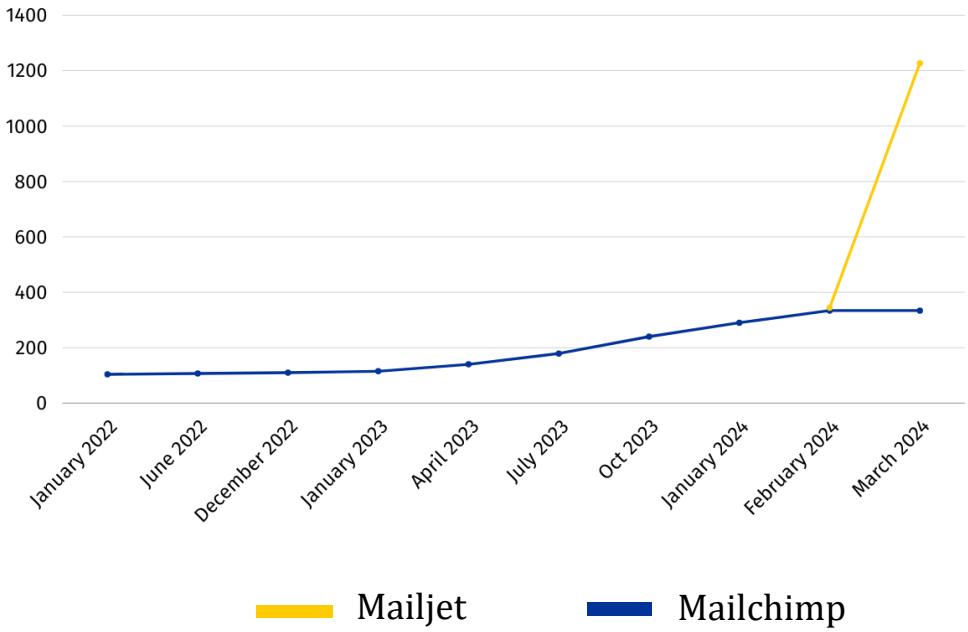


Figure 10. Progression of the number of subscribers to CORE-MD newsletter

As a result, the number of subscribers on the second period increased from 150 up to a remarkable number of 1229 recipients. The full list of newsletter issues released by the project are listed in Table 3.

Table 3. List of newsletters

Date	Category	Title & Links
25/03/2024	Thematic	Today's CORE-MD webinar on the role of notified bodies
11/03/2024	Thematic	CORE-MD Webinar | 25 March 2024 | The role of notified bodies
04/03/2024	Thematic	Today's CORE-MD webinar on PROMS
01/03/2024	Thematic	CORE-MD Webinar on Patient Reported Outcome Measures
15/02/2024	General	CORE-MD newsletter | February 2024 issue

Date	Category	Title & Links
08/01/2024	Thematic	Today's CORE-MD Webinar on Early clinical investigations of new high-risk medical devices
23/12/2023	General	CORE-MD Newsletter - December 2023 issue
05/12/2023	Thematic	Today's CORE-MD Webinar on IT tools for regulatory science
01/12/2023	Thematic	CORE-MD Webinar | IT tools for regulatory science | Tuesday 05 December 2023 | 17:00-18:15 CET
23/11/2023	Thematic	CORE-MD Webinar Reminder | Pivotal Clinical Investigations of High-Risk Medical Devices | Monday 27 November 2023 | 17:00-18:15 CET
16/11/2023	Thematic	CORE-MD Webinar | Pivotal Clinical Investigations of High-Risk Medical Devices | Monday 27 November 2023 | 17:00-18:15 CET
03/11/2023	Thematic	CORE-MD Webinar | High-risk Medical devices in the field of cardiovascular disease and diabetes | Monday 06 November 2023 | 17:00-18:15 CET
26/10/2023	Thematic	CORE-MD Webinar | Clinical evidence in cardiovascular and diabetic devices | Monday 6 November 2023 | 17:00-18:15 CET
12/10/2023	Thematic	CORE-MD Webinar | The clinical evaluation of AI and standalone software. | 17 October 2023 | 17:00-18:30 CET
21/09/2023	General	CORE-MD Newsletter - September 2023 issue
18/07/2023	Thematic	CORE-MD Webinar on Training and Education - replay available
10/07/2023	Thematic	Today's CORE-MD Webinar on Training and Education
05/07/2023	Thematic	-CORE-MD Webinar | Training and Education | Monday 10 July 2023 | 17:00-18:15 CET
23/06/2023	Thematic	CORE-MD Webinar | Training and Education | Monday 10 July 2023 | 17:00-18:15 CET
09/06/2023	General	CORE-MD Newsletter
19/12/2022	General	CORE-MD Christmas 2022 Newsletter
13/06/2022	General	CORE-MD June 2022 Newsletter
17/01/2022	General	CORE-MD January 2022 Newsletter

CORE-MD newsletters were used for general information sharing on the project's results and also for dedicated information on CORE-MD webinars. While at the start of the project, only general semestrial newsletters were issued, the number of issues increased as the activity grew. With the webinars starting on January 2023, the number of newsletter issues remained limited up until June 2023. From then on, a new staff joined EFORT and was tasked with the elaboration of dedicated mailing to promote webinars.

3 Multiplying impact through collective effort and advocacy actions

Several partners provided a key contribution to the dissemination activities. Through the integration of CORE-MD updates in their regular communication to their members, their proactivity in promoting the project by organizing dedicated meetings and featuring CORE-MD contents in educational courses, they increased the impact of CORE-MD outreach efforts. Both EFORT and the Biomedical Alliance have done regular updates on CORE-MD in their newsletters as reported hereafter. In addition, several partners have taken action to leverage their communication assets and integrate the dissemination of CORE-MD in their statutory activities. To mention a few examples:

- The ESC has featured the project in their bulletin MyESC News addressed to the European cardiology community with +150,000 recipients. See for example: https://view.info.escardio.org/?qs=f6395660d03f6c8901a51601cf4c36f950c80116c3e61fe706d6774b2d51ad0ce223fe7561ffa40bb5357b42c7e5f4f030773f8d5f2529459cf849b92b4c4cd5f525eea210aaa0d9ecb59fd25f31a419d1ecd07a6b927b38
- The EPF has regularly shared updates on CORE-MD with patients and patients' groups in both their open newsletter 'The Patient Perspective' and their 'Weekly Insider' bulletin restricted to members. See for example: https://mailchi.mp/eu-patient/epf-patient-perspective-january2024
- The EAP has included relevant information about CORE-MD progress – with specific attention on the advocacy actions connected with the recommendations on pediatric devices – in the newsletters. See for instance: https://preview.mailerlite.com/t9e8p8z1z3
- Several partners have reported to their relevant stakeholders about CORE-MD in their official Annual Reports, such as HPRA (e.g., https://www.hpra.ie/docs/default-source/publications-forms/corporate-policy-documents/annual-report-2022.pdf?sfvrsn=8) and the Child Health Foundation (engaged via LMU, EAP third party in CORE-MD, e.g., https://www.kindergesundheit.de/Die-Stiftung/Taetigkeitsberichte/_docs/SKG_T%C3%A4tigkeitsbericht_2023_240409.pdf)
- ISS has regularly published news about the orthopedics-related webinars of CORE-MD on the website of the Italian Registry of Arthroplasty (RIAP), e.g. https://riap.iss.it/riap/en/news-and-events/news/2023/01/27/core-md-webinar-orthopaedic-implants-and-european-medical-device-regulations/
- Team-NB has published frequent updates on CORE-MD on their website to keep the NBs' community informed about progresses and relevant events. See e.g., https://www.team-nb.org/webinar-the-notified-body-role-the-conformity-assessment-process/
- FPS has published articles on national Spanish outlets, see e.g., https://www.elpespunte.es/andalucia-participa-en-un-proyecto-europeo-que-evalua-los-dispositivos-sanitarios-de-alto-riesgo/.

This collective effort has proven particularly evident and effective in:

- **disseminating key results about the insufficient clinical evidence for high-risk medical devices and calling the attention of policy makers and regulators** on how this can hinder the capacity for healthcare professionals to make informed decisions on patient care and the right of patients to safe and effective treatment. See Biomed Alliance's press release: https://www.biomedeurope.org/news/2023/408-new-core-md-press-release-highlights-lack-of-evidence-for-high-risk-medical-devices.html;
- **supporting European advocacy campaigns** such as the one steered by our partner EAP and signed by representatives of European medical associations to address limited availability of medical devices, particularly for children. See Biomed Alliance's press release and Letter to Commissioner Stella Kyriakides: https://www.biomedeurope.org/news/2023/404-doctors-call-on-the-commission-to-address-limited-availability-of-medical-devices-particularly-for-children.html.

3.1 EFORT Today

As key partner in Dissemination and Communication, EFORT involved its Communication Department to disseminate information on CORE-MD. On top of the project's own communication, a systematic integration of CORE-MD articles was made into the EFORT newsletter that reaches 27+K beneficiaries. EFORT included CORE-MD articles in 29 issues of EFORT Today (Table 4) either disseminating webinars replays or scientific publications.

Table 4. Editions of the EFORT Today newsletter that featured content related to CORE-MD

Date	Issue	Topic covered	Subscribers no.	% of subscribers opening it	Subscribers opening it
11/04/2024	EFORT Today | Volume 4 | Number 07 | 11 April 2024	The CORE-MD consortium organised its twelfth webinar on "Patient Reported Outcome Measures" (PROMs)	25977	28,9	7495
21/03/2024	EFORT Today | Volume 4 | Number 06 | 21 March 2024	Listen to Episode 1 of the CORE-MD Podcast on Understanding how EU notified bodies work	25780	26,6	6844
07/03/2024	EFORT Today | Volume 4 | Number 05 | 07 March 2024	Take part in the Final Conference	25849	44,0	11374
22/02/2024	EFORT Today | Volume 4 | Number 04 | 22 February 2024	Save the date for the CORE-MD Webinar on Patient Reported Outcome Measures	25900	34,6	8955
08/02/2024	EFORT Today | Volume 4 | Number	The CORE-MD consortium organised its tenth webinar on "Early clinical	25937	31,9	8277

Date	Issue	Topic covered	Subscribers no.	% of subscribers opening it	Subscribers opening it
	03 | 08 February 2024	investigations of new high-risk medical devices – how lack of transparency inhibits improvement in evaluation".			
25/01/2024	EFORT Today | Volume 4 | Number 02 | 25 January 2024	Webinar replay on Providing high-risk medical devices for children	26015	42,4	11038
11/01/2024	EFORT Today | Volume 4 | Number 01 | 11 January 2024	If you missed the CORE-MD Project webinar on IT tools for regulatory science: aggregating available data for assisting Expert Panels and improving post-market surveillance	26061	36,6	9525
07/12/2023	EFORT Today | Volume 3 | Number 23 | 07 December 2023	The clinical evaluation of Artificial Intelligence and standalone software: keeping the balance between benefit and risk	26152	38,3	10012
23/11/2023	EFORT Today | Volume 3 | Number 22 | 23 November 2023	Evidence from clinical trials on high-risk medical devices in children: a scoping review	26191	35,0	9171
09/11/2023	EFORT Today | Volume 3 | Number 21 | 09 November 2023	webinar announcement	26243	39,0	10225
19/10/2023	EFORT Today | Volume 3 | Number 20 | 19 October 2023	Work on Paediatric devices presented at the International Medical Device Regulators Forum	26273	41,5	10895
05/10/2023	EFORT Today | Volume 3 | Number 19 | 05 October 2023	Artificial Intelligence in Health: recommendation for clinical evaluation	26324	40,9	10764
22/09/2023	EFORT Today | Volume 3 | Number 18 | 22 September 2023	European expert recommendations on clinical investigation and evaluation of high-risk medical devices for children	26447	42,6	11278
07/09/2023	EFORT Today | Volume 3 | Number 17 | 07 September 2023	Save the dates for these upcoming CORE-MD Webinars	26612	42,9	11416
24/08/2023	EFORT Today | Volume 3 | Number 16 | 24 August 2023	CORE-MD publication: Systematic Review of Cardiovascular and Orthopaedic Registries: New publication	26672	37,6	10040
10/08/2023	EFORT Today | Volume 3 | Number 15 | 10 August 2023	Presentation Video: Clinical evidence in the evaluation of high-risk medical devices: Surveying the landscape	26779	42,3	11319

Date	Issue	Topic covered	Subscribers no.	% of subscribers opening it	Subscribers opening it
20/07/2023	EFORT Today | Volume 3 | Number 14 | 20 July 2023	Secure access to essential medical devices for children: an open letter to Commissioner Stella Kyriakides	26843	36,3	9753
06/07/2023	EFORT Today | Volume 3 | Number 13 | 06 July 2023	The CORE-MD Project webinar on Training and education for regulators, for notified bodies and clinicians	26899	37,1	9970
22/06/2023	EFORT Today | Volume 3 | Number 12 | 22 June 2023	Perceived training needs for regulators, notified bodies and clinicians: result of CORE-MD survey	26974	40,8	10991
08/06/2023	EFORT Today | Volume 3 | Number 11 | 08 June 2023	Take the survey on the EMA Guideline on registry-based studies	27050	35,5	9611
24/05/2023	EFORT Today | Volume 3 | Number 10 | 24 May 2023	On 17 and 18 April 2023, the CORE-MD consortium met at the Faculty Club of the Catholic University of Leuven	26936	40,8	10997
11/05/2023	EFORT Today | Volume 3 | Number 09 | 11 May 2023	Core-MD Webinar: Objective Performance Criteria	26669	40,5	10924
24/04/2023	EFORT Today | Volume 3 | Number 08 | 24 April 2023	Medical Device for children	27064	35,7	9658
11/04/2023	EFORT Today | Volume 3 | Number 07 | 11 April 2023	CORE-MD Webinar Origins and objectives of European regulations for medical devices	27102	32,2	8734
23/03/2023	EFORT Today | Volume 3 | Number 06 | 23 March 2023	CORE-MD Post-Market Surveillance tool	27155	32,2	8729
23/02/2023	EFORT Today | Volume 3 | Number 04 | 23 February 2023	CORE-MD methodology to develop a tool aggregating public information on medical devices	27184	32,7	8890
19/01/2023	EFORT Today | Volume 3 | Number 02 | 19 January 2023	Artificial Intelligence and Medical Devices Regulation. Discussing the legal framework and the ethical challenges within the CORE-MD project	27053	39,8	10753
20/10/2022	EFORT Today | Volume 2 | Number 20 | 20 October 2022	CORE-MD: Improved methods for clinical investigation and evaluation of high-risk medical devices	27159	40,5	10993
09/03/2022	EFORT Today | Volume 3 | Number 05 | 09 March 2023	CORE-MD Webinar: Orthopaedic Implants and Medical Device Regulation	27460	30,45	8361

3.2 The Biomedical Alliance Updates

The Biomedical Alliance also disseminated CORE-MD outputs on a regular basis through its newsletter.

Table 5. List of Biomedical Alliance updates

Date	Issue	Topic covered
29/02/2024	February 2024 Update	Join the CORE-MD Final conference on 15 March
04/12/2023	November 2023 Update	CORE-MD Workshops take a close and critical look at the evaluation of medical devices
31/10/2023	October 2023 Update	CORE-MD organises webinar on the level of evidence for high-risk medical devices in the field of Cardiovascular disease and Diabetes
29/09/2023	September 2023 Update	Participation IMDRF to disseminate CORE-MD results
01/08/2023	August 2023 Update	New CORE-MD Article on clinical investigation and evaluation of devices for children
31/07/2023	July 2023 Update	CORE-MD Project publishes new video material on the evaluation of medical devices
02/05/2023	April 2023 Update	CORE-MD Project holds annual consortium meeting
31/03/2023	March 2023 Update	CORE-MD organises third webinar on objective performance criteria for medical devices
01/06/2022	May 2022 Update	Fill out & Promote our CORE-MD Survey on educational needs in regulatory affairs
16/12/2021	December 2021 Update	BioMed Alliance continued to develop
02/12/2021	November 2021 Update	CORE-MD project: survey on education in regulatory affairs

4 Printed promotional materials

Printed materials were used to enhance the project's communication strategy and increase the recognizability of the CORE-MD brand.

4.1.1 Roll up

A custom roll-up, featuring captivating visuals of the project, was meticulously designed and printed. This sleek and eye-catching display adorned the venue at both the project board meeting and the final conference, lending a distinctive air of professionalism to the event space. Not only did it serve as a backdrop during the proceedings, but it also played a pivotal role in enhancing the aesthetic appeal of social media posts associated with the event (see e.g., Figure 11), ensuring that the project garnered attention and left a lasting impression on all attendees, both in-person and online.

Figure 11. Example of LinkedIn post from partner FPS (AETSA) featuring the CORE-MD official rollup

4.1.2 The Final Conference booklet

By the project's end, a booklet summarizing the main results achieved in its tasks was created. The final document is a rich and **comprehensive 24-page synthesis of the main project's achievements**. At the final conference and in follow-up post-project events like the ESC Cardiovascular Round Tables in April 2024, 150 printed copies were distributed. Additionally, a digital version is now accessible on the website.

Figure 12. Frontpage of the CORE-MD booklet

4.1.3 CORE-MD featured in ESC printed materials

The CORE-MD project was also featured in the EU Projects booklet and leaflet (Figure 13), showcased and distributed at events such as the ESC Spring Summits and within the ESC office. Each project within the booklet is allotted its own dedicated page, complete with a QR code directing readers to the project website for additional information.

In adherence to ESC's green policies, the distribution of this material has been carefully managed to minimize environmental impact. It is strategically disseminated during key moments when targeted audiences require concise and practical information. Additionally, during these important occasions, a presentation showcases CORE-MD's importance, featuring its logo and a brief explanation along with a QR code for easy access to the website.

Figure 13. ESC printed promotional materials featuring CORE-MD

5 Scientific dissemination and open science practices

Despite being a Coordination and Support Action (CSA), the CORE-MD project's workplan foresaw an extensive research plan that has led to a large production of high-quality outputs. The second reporting period has concentrated most of the scientific publications as the vast majority of the tasks in WP1, 2, 3 and partly 4, required the conduction of complex and lengthy systematic reviews, scoping reviews and stakeholder consultations via Delphi panels and focus groups, thus leading to the extension of the duration of the tasks until the end of the production.

The outcome is a **remarkable list of scientific publications**, most of them published in open access journals with high impact factors, as well as several abstracts and posters accepted for presentation at the most relevant scientific conference in the targeted domains.

The CORE-MD research work also significantly contributed to the consolidation of a thriving interdisciplinary research community working towards the establishment of a European regulatory science ecosystems where young research fellows had the chance to work together with seasoned experts, as witnessed by the **significant involvement of PhD students, PostDoc researchers**, the inclusion of CORE-MD scientific findings in **master lectures and the production of master theses**.

Moreover, the CORE-MD consortium has fulfilled its commitment to adopt **open science practices** as stated in the DoA, not only by publishing open access articles but also **registering study protocols** in advance in open repositories such as Prospero and Open Science Framework (OSF) and **publishing pre-prints** in specialized medical research repositories such as Medrxiv. In addition, a **dedicated CORE-MD Community has been setup on the Zenodo repository** to host the relevant datasets underlining most of the literature reviews conducted in the project as well as the dataset containing 137,720 historical safety notices that was used to test the CORE-MD post-market surveillance tool (developed in Task 3.2) and the code of the statistical risk calculator tool developed in Task 1.2.

The following Tables 6 and 7 provide respectively the full list of scientific publications published before the project's end and those that have been recently submitted or are still in preparation, which altogether sum to a total of 35 publications, thus largely beyond the expected number (18) stated in the DoA. Overall, the CORE-MD scientific production can be summarized as follows:

- Journal articles: 35, including:
  - Full manuscripts published in peer-reviewed journals: 11
  - Full manuscripts submitted and under review: 6
  - Manuscripts in preparation, not yet submitted: 15
  - Related manuscripts, published in peer-reviewed journals, where CORE-MD partners contributed to: 3
- Protocols published in journals as full papers: 3
- Protocols posted in open-access on-line repositories: 7
- Master's theses completed: 3

- Abstracts presented and/or published at scientific conferences: >10
- Open datasets uploaded on Zenodo: 4
- Risk calculator software code uploaded in Zenodo: 1

Moreover, following the recommendations expressed by the mid-term reviewers, a thorough exploitation plan for the CORE-MD PMS tool developed by POLIMI has been exposed in Deliverable D3.2.

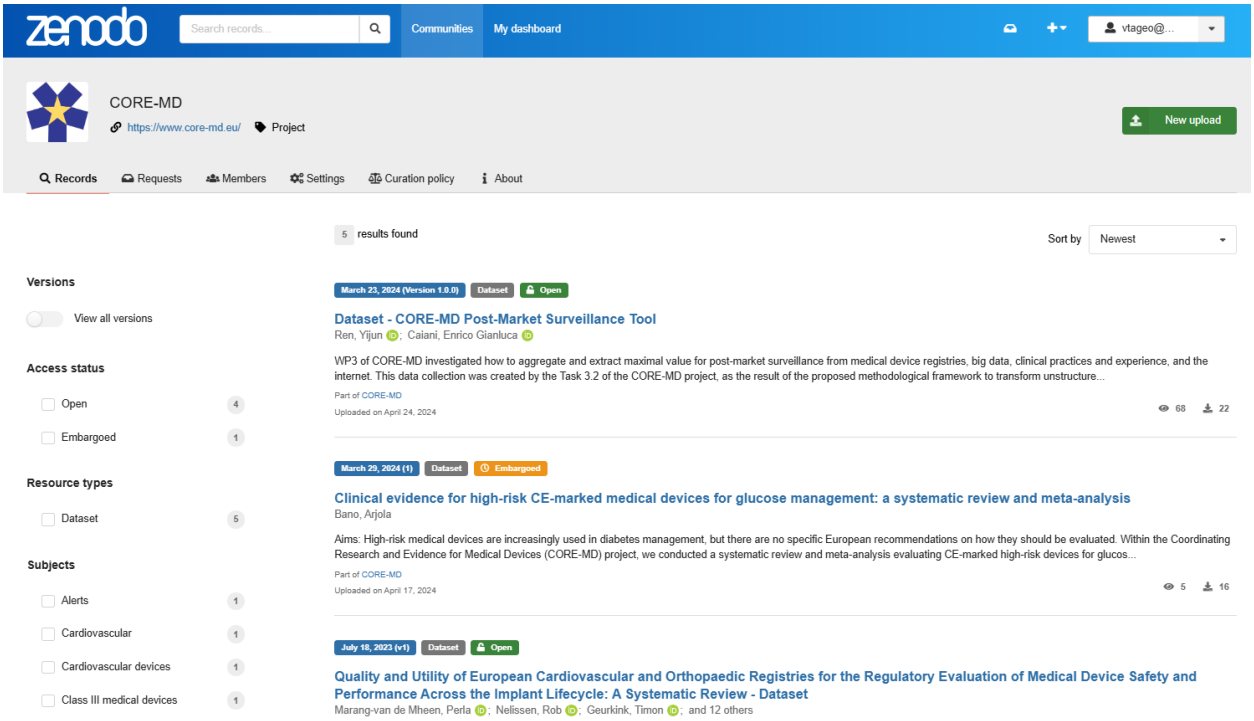


Figure 14. Screenshot of the CORE-MD Zenodo community page

For easiness of consultation, hereby the direct links to the resources (datasets and codes) uploaded on the CORE-MD Zenodo community are provided too:

- Siontis, G. (2024). Clinical investigations to evaluate high-risk cardiovascular devices: a systematic review of the peer-reviewed medical literature [Data set]. Zenodo. https://doi.org/10.5281/zenodo.10617117;
- Lübbeke, A. (2024). Clinical investigations to evaluate high-risk orthopaedic devices: a systematic review of the peer-reviewed medical literature [Data set]. In EFORT Open Reviews (Vol. 8, Number 11, pp. 781–791). Zenodo. https://doi.org/10.5281/zenodo.10623389;
- Marang-van de Mheen, P., Nelissen, R., Geurkink, T., Lubbeke, A., Buccheri, S., Schoones, J. W., Torre, M., Laricchiuta, P., Piscoi, P., Pedersen, A., Gale, C., Smith, J., Maggioni, A., James, S., & Fraser, A. (2023). Quality and Utility of European Cardiovascular and Orthopaedic Registries for the Regulatory Evaluation of Medical Device Safety and Performance Across the Implant Lifecycle: A Systematic Review - Dataset [Data set]. In International Journal of Health Policy and

Management (Vol. 12, Number 1, pp. 1–11). Zenodo. https://doi.org/10.34172/ijhpm.2023.7648;

- Bano, A. (2024). Clinical evidence for high-risk CE-marked medical devices for glucose management: a systematic review and meta-analysis (Version 1) [Data set]. Zenodo. https://doi.org/10.5281/zenodo.10894441;
- Ren, Y., & Caiani, E. G. (2024). Dataset - CORE-MD Post-Market Surveillance Tool (Version 1.0.0) [Data set]. Zenodo. https://doi.org/10.5281/zenodo.10864069.
- van Egeraat, J., Steyerberg, E., & de Vries, B. P. (2024). Source code CORE-MD Risk Calculator (1.0). Zenodo.

Table 6. List of scientific publications produced during the two reporting periods

Full reference	Publication type | Open Access (Y/N)	Related task	Partners involved
First reporting period (M1-M18)			
Fraser, A. G., Nelissen, R. G. H. H., Kjærsgaard-Andersen, P., Szymański, P., Melvin, T., Piscoi, P., & CORE–MD Investigators (see Appendix) (2021). **Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices)**. EFORT open reviews, 6(10), 839–849. https://doi.org/10.1302/2058-5241.6.210081	Journal article | Y	General project's vision	ESC, EFORT & the whole consortium
Fraser, A. G., Nelissen, R. G. H. H., Kjærsgaard-Andersen, P., Szymański, P., Melvin, T., Piscoi, P., & CORE-MD Investigators (2022). **Improved clinical investigation and evaluation of high-risk medical devices: the rationale and objectives of CORE-MD (Coordinating Research and Evidence for Medical Devices)**. European heart journal. Quality of care & clinical outcomes, 8(3), 249–258. https://doi.org/10.1093/ehjqcco/qcab059	Journal article | Y	General project's vision	ESC, EFORT & the whole consortium
Siontis, G. C., Frenk, A., Coles, B., Bartkowiak, J., McGovern, L., Häner, J., Tomii, D., Galea, R., Häberlin, A., Praz, F., & Windecker, S. (2022). **Clinical evidence for high-risk medical devices in cardiology: A protocol for a systematic review and meta-epidemiological investigation**. PROSPERO. https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022308593	Protocol registered on Prospero| Y	Task 1.1	Insel Gruppe, RCSI
Smith, J. A., Combescure C., Barea C., Lübbeke-Wolff A. (2021). **Clinical investigations to evaluate high-risk orthopaedic devices: systematic review and meta-analysis**. https://doi.org/10.17605/OSF.IO/9BJQV	Protocol registered on OSF | Y	Task 1.1	GUH/UOXF
Bano, A., Laimer, M., Wehrli, F., Kunzler, J., Rivero, T., Fraser, A. G., Stettler, C., Hovorka, R., & Bally, L. (2023). **Clinical evidence for high-risk medical devices used to manage diabetes: protocol for a systematic review and meta-analysis**. BMJ open, 13(4), e070672. https://doi.org/10.1136/bmjopen-2022-070672	Protocol published as paper | Y	Task 1.1	Insel Gruppe, ESC

Full reference	Publication type | Open Access (Y/N)	Related task	Partners involved
Chaplin, J., Rolfson, O., Jarke, H., Moons, P., Norekvål, T., & Holm Ingelsrud, L. (2022). **An Integrative Systematic Review of Patient Reported Outcome Measures (PROMs) Used to Evaluate Orthopedic, Cardiovascular, and Diabetes High-Risk Implantable Medical Devices**. PROSPERO. Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022344424	Protocol registered on Prospero | Y	Task 1.3	UGOT
Schnell-Inderst, P., Kühne, F., Rochau, U., Schmid, D., & Siebert, U. (2022). **Study design recommendations in guidance documents for high-risk medical devices. A systematic review**. Retrieved from https://osf.io/w9b5k/	Protocol registered on OSF| Y	Task 1.4	UMIT
Hoogervorst, L. (2022). **Orthopedic and cardiovascular medical device registries in Europe: a systematic review**. Retrieved from https://osf.io/7yuwx/	Protocol registered on OSF| Y	Task 3.1	LUMC
Second reporting period (M19-M36)			
Schnell-Inderst, P., Kuehne, F., Holborow, R., Rochau, U., & Siebert, U. (2022). MT4 **Study Design Recommendations in ISO Standards for High-Risk Medical Devices: A Systematic Review of the HORIZON 2020 Core-MD Project**. Value in Health, 25(12), S378. https://doi.org/10.1016/j.jval.2022.09.1878	Abstract | Y	Task 1.4	UMIT
Guerlich, K., Bernadeta, P., Michael, K., Paulina, D., & Berthold, K. (2022). **Clinical evidence for high-risk medical devices in children: A protocol for a scoping review**. https://doi.org/10.17605/OSF.IO/UZEKT	Protocol registered on OSF | Y	Task 2.4	EAP
Guerlich, K., Patro-Golab, B., Barnacle, A., Baumann, U., Eicken, A., Fraser, A. G., Gruszfeld, D., Haas, N. A., Jonker, A. H., Kammermeier, M., Kenny, D., Kolaček, S., Lapatto, R., Maconochie, I., Mader, S., McGauran, G., Melvin, T., Muensterer, O., Piscoi, P., Romano, A., … European Academy of Paediatrics (2023). **European expert recommendations on clinical investigation and evaluation of high-risk medical devices for children**. Acta paediatrica (Oslo, Norway : 1992), 112(11), 2440–2448. https://doi.org/10.1111/apa.16919	Journal article including project's recommendations | Y	Task 2.4	EAP, ESC, HPRA, & Advisory Board members
Melvin T., Kenny D., Gewillig M., Fraser A.G. (2023). **Orphan Medical Devices and Pediatric Cardiology - What Interventionists in Europe Need to Know, and What Needs to be Done. Pediatric cardiology**, 44(2), 271–279. https://doi.org/10.1007/s00246-022-03029-1	Journal article including project's recommendations | Y	Task 2.4	EAP, ESC, & Advisory Board Member Tom Melvin (TCD)
Lübbeke, A., Combescure, C., Barea, C., Gonzalez, A. I., Tucker, K., Kjærsgaard-Andersen, P., Melvin, T., Fraser, A. G., Nelissen, R., & Smith,	Systematic review | Y	Task 1.1	GUH/UOXF, EFORT,

Full reference	Publication type | Open Access (Y/N)	Related task	Partners involved
J. A. (2023). **Clinical investigations to evaluate high-risk orthopaedic devices: a systematic review of the peer-reviewed medical literature**. EFORT open reviews, 8(11), 781–791. https://doi.org/10.1530/EOR-23-0024.			LUMC, & Advisory Board Member Tom Melvin (TCD)
Fraser, A. G., Biasin, E., Bijnens, B., Bruining, N., Caiani, E. G., Cobbaert, K., Davies, R. H., Gilbert, S. H., Hovestadt, L., Kamenjasevic, E., Kwade, Z., McGauran, G., O'Connor, G., Vasey, B., & Rademakers, F. E. (2023). **Artificial intelligence in medical device software and high-risk medical devices - a review of definitions, expert recommendations and regulatory initiatives**. Expert review of medical devices, 20(6), 467–491. https://doi.org/10.1080/17434440.2023.2184685	Review article | Y	Task 2.3	ESC, KU Leuven, POLIMI, HPRA, & Advisory Board Members
Moons, P., Norekvål, T. M., Arbelo, E., Borregaard, B., Casadei, B., Cosyns, B., Cowie, M. R., Fitzsimons, D., Fraser, A. G., Jaarsma, T., Kirchhof, P., Mauri, J., Mindham, R., Sanders, J., Schiele, F., Torbica, A., & Zwisler, A. D. (2023). **Placing patient-reported outcomes at the centre of cardiovascular clinical practice: implications for quality of care and management**. European heart journal, 44(36), 3405–3422. https://doi.org/10.1093/eurheartj/ehad514	Journal article | Y	Task 1.3	CORE-MD partners have contributed to it (KU Leuven, ESC)
Chaplin J. (2023), **A Review of MCID in relation to Patient-Reported Outcome Measures used to evaluate orthopedic, high-risk implantable medical devices and surgeries**, Abstract 2050 published in '30th Annual Conference of the International Society for Quality of Life Research'. Qual Life Res 32 (Suppl 2), 23–220 (2023). https://doi.org/10.1007/s11136-023-03530-x	Abstract | Y	Task 1.3	UGOT
Ivan Gibanica I. (2023), **Use of patient-reported outcome measures in clinical trials of closed-loop insulin systems – a systematic review**.	Master thesis | N	Task 1.3	UGOT
Guerlich, K., Patro-Golab, B., Dworakowski, P., Fraser, A. G., Kammermeier, M., Melvin, T., & Koletzko, B. (2024). **Evidence from clinical trials on high-risk medical devices in children: a scoping review**. Pediatric research, 95(3), 615–624. https://doi.org/10.1038/s41390-023-02819-4	Scoping review | Y	Task 2.4	EAP & Advisory Board Member Tom Melvin (TCD)
Siontis, G. C. M., Coles, B., Häner, J. D., McGovern, L., Bartkowiak, J., Coughlan, J. J., Spirito, A., Galea, R., Haeberlin, A., Praz, F., Tomii, D., Melvin, T., Frenk, A., Byrne, R. A., Fraser, A. G., Windecker, S., & CORE-MD Investigators (2024). **Quality and transparency of evidence for implantable cardiovascular medical devices assessed by the CORE-MD**	Systematic review | Y	Task 1.1	Insel Gruppe, RCSI, ESC, & Advisory Board

Full reference	Publication type | Open Access (Y/N)	Related task	Partners involved
consortium. European heart journal, 45(3), 161–177. https://doi.org/10.1093/eurheartj/ehad567			Member Tom Melvin (TCD)
Siontis, G. C. M., Frenk, A., & Windecker, S. (2024). **Randomized controlled trials remain underutilized**. European heart journal, 45(7), 553–554. https://doi.org/10.1093/eurheartj/ehad806	Letter to Editor | Y	Task 1.1	Insel Gruppe
Szymański, P., & Redberg, R. (2024). **Quality and transparency of clinical evidence for high-risk cardiovascular medical devices: a long way to go**. European heart journal, 45(3), 178–180. https://doi.org/10.1093/eurheartj/ehad786	Commentary (invited editorial) | N	Task 1.1	ESC & Advisory Board Member Rita Redberg (UCSF)
Combescure, C., Smith, J. A., Barea, C., Hoogervorst, L. A., Nelissen, R., Marang-van de Mheen, P. J., Lübbeke, A., & the arthroplasty registry group. (2024). **Cumulative risk of revision after primary total hip arthroplasty in registries: Systematic review and meta-analysis of selected hip stems and cups**. medRxiv. https://doi.org/10.1101/2024.04.03.24305257.	Journal article pre-print | Y	Task 3.1	LUMC, EFORT, GUH/UOXF
Hoogervorst, L. (2023). **Achieving consensus on items needed to assess the quality and analysis of registry data for the regulatory evaluation of medical device performances during post-market surveillance: which items are the minimum requirements?**. https://doi.org/10.17605/OSF.IO/R87VT	Protocol registered in OSF | Y	Task 3.1	LUMC
Hoogervorst, L. A., Geurkink, T. H., Lübbeke, A., Buccheri, S., Schoones, J. W., Torre, M., Laricchiuta, P., Piscoi, P., Pedersen, A. B., Gale, C. P., Smith, J. A., Maggioni, A. P., James, S., Fraser, A. G., Nelissen, R. G. H. H., & Marang-van de Mheen, P. J. (2023). **Quality and Utility of European Cardiovascular and Orthopaedic Registries for the Regulatory Evaluation of Medical Device Safety and Performance Across the Implant Lifecycle: A Systematic Review**. International Journal of Health Policy And Management, 12, 7648. https://doi.org/10.34172/ijhpm.2023.7648	Systematic review | Y	Task 3.1	LUMC, EFORT, RU, ISS, GUH/UOXF, ESC
Hoogervorst, L. A., Geurkink, T. H., Schoones, J. W., Buccheri, S., James, S., Gale, C. P., Fraser, A. G., Nelissen, R. G. H. H., Marang-Van De Mheen, P. J., & Coordinating Research and Evidence for Medical Devices (CORE-MD) consortium (2023). **European cardiovascular registries as reliable data sources to assess implants safety and performances across the implant lifecycle**. European Heart Journal, 44(Supplement_2), https://doi.org/10.1093/eurheartj/ehad655.3001	Abstract | Y	Task 3.1	LUMC, RU, ESC, EFORT

Full reference	Publication type | Open Access (Y/N)	Related task	Partners involved
Ren, Y., Bertoldi, M., Fraser, A. G., & Caiani, E. G. (2023). **Validation of CORE-MD PMS Support Tool: A Novel Strategy for Aggregating Information from Notices of Failures to Support Medical Devices' Post-Market Surveillance**. Therapeutic Innovation & Regulatory Science, 57(3), 589–602. https://doi.org/10.1007/s43441-022-00493-y	Journal article | Y	Task 3.2	ESC, POLIMI
Ren Y., Bertoldi M., Caiani E.G. (2022), **Development of an IT tool to support post-market surveillance and expert panels in detecting sentinel signals relevant to serious incidents in high-risk medical devices: pilot on Italian data**. Eur Heart J. 2022; 43 (Supplement 2): ehac544.2842. https://doi.org/10.1093/eurheartj/ehac544.2842	Abstract presented at ESC Congress 2022 | Y	Task 3.2	POLIMI
Ren Y. and Caiani E.G. (2023), **Development of a Framework Dealing with Partial Data Unavailability and Unstructuredness to Support Post-Market Surveillance**, 2023 IEEE EMBS International Conference on Biomedical and Health Informatics (BHI), Pittsburgh, PA, USA, 2023, pp. 1-4, https://doi.org/10.1109/BHI58575.2023.10313402	Journal article (proceedings) | N	Task 3.2	POLIMI
Gibello R., Ren Y., Caiani E.G. (2023), **Development of an AI-based IT tool to support medical device nomenclature standardization for post-market surveillance by automated mapping from GMDN to EMDN standards**. Eur Heart J. 2023; 44 (Supplement 2): ehad655.3024. https://doi.org/10.1093/eurheartj/ehad655.3024	Abstract | Y	Task 3.2	POLIMI
Gibello, R. (2023), **Development of a mapping tool between EMDN and GMDN nomenclatures to support post-market surveillance of medical devices**.	Master Thesis | N	Task 3.2	POLIMI
López, J. A., Dobrzynska, A., Lozano, M. P. R., Parrilla, J. C. R., Epstein, D. M., & Amaro, J. A. B. (2023). **Post-approval evidence development schemes established by regulatory authorities for high-risk medical devices: A protocol for a systematic review**. PROSPERO. CRD42023431233. Retrieved from https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023431233	Protocol registered on Prospero | Y	Task 3.3	FPS & UGR
Wild C., Ettinger S. (2023), **Perceived training needs of regulators, notified bodies and clinicians for a (successful) implementation of the Medical Device Regulation: survey results**, JMDR/ Journal of Medical Device Regulation, May 2023: 20(2): 45-56. https://globalregulatorypress.com/topic/mdr-ivdr/	Journal article | N	Task 4.3	AIHTA GMBH

Table 7. List of publications under review or in preparation

Provisional reference	Publication type	Related task	Partners involved
After the project's end (with additional publications anticipated, but not yet listed)			
Bano A, Künzler J, Wehrli F, Kastrati L, Rivero T, Llane A, Valz Gris A, Fraser AG, Stettler C, Hovorka R, Laimer M, Bally L; CORE-MD investigators. **Clinical evidence for high-risk CE-marked medical devices for glucose management: a systematic review and meta-analysis**. Diabetes, Obesity & Metabolism 2024 Aug 14. doi: 10.1111/dom.15849. [Epub] http://doi.org/10.1111/dom.15849	**Systematic review | Published**	Task 1.1	Insel Gruppe, ESC
Hoogervorst L.A., van Tilburg M.M., Lübbeke A., Wilton T., Nelissen R.G.H.H., Marang-van de Mheen P.J. (2024). **Validating Orthopaedic Data Evaluation Panel (ODEP) ratings across 9 orthopaedic registries: total hip implants with an ODEP-rating perform better than those without an ODEP-rating**. Journal of Bone and Joint Surgery. 2024; 106: 1583–1593.	**Journal article | Published**	Task 3.1	LUMC, EFORT, GUH/UOXF
Chaplin J. (2024), **How are patient-reported outcome measures being used to improve meaningful and timely patient involvement in the choice of medical implants?** (accepted for presentation at GPCC Person Centred Care conference, 2024)	Abstract for presentation	Task 1.3	UGOT
Coughlan J.J. et al. (2024), **Inclusion of subjects and reporting by age, sex, and ethnicity in clinical trials of high-risk medical devices approved in the European Union**	Journal article in preparation (secondary study over T1.1 datasets)	Task 1.1	RCSI
Chaplin, J., Rolfson, O., Jarke, H., Moons, P., Norekvål, T., & Holm Ingelsrud, L. (2024). **Use of patient-reported outcome measures within evaluation of high-risk orthopedics and cardiovascular medical implants: a systematic review**	Systematic review | In preparation	Task 1.3	UGOT
Schnell-Inderst P., McGauran G., Fraser A., Melvin T., Geertsma R., Rochau U., Planinschitz T., Siebert U. (2024). **Systematic review of recommendations from regulators on study designs for pivotal clinical investigations of high-risk medical devices**.	Systematic review | In preparation	Task 1.4	UMIT, HPRA, ESC, RIVM, & Advisory Board Member Tom Melvin (TCD)
Schnell-Inderst P., Geraghty M., McGauran G., Melvin T., Geertsma R., Byrne R., Planinschitz T., Siebert U. (2024). **Systematic review on recommendations on study design of general and device-specific standards of the International Organization for Standardization**.	Systematic review | In preparation	Task 1.4	UMIT, HPRA, RCSI, RIVM, & Advisory Board Member

Provisional reference	Publication type	Related task	Partners involved
			Tom Melvin (TCD)
Baal J.W.P.M., Wissing T., Roszek B., Geertsma R.E., Coughlan J.J., Durand R., Byrne R., Coles B.M., Schnell-Inderst P., McGauran G., Fraser A.G. (2024), **Clinical studies on transcatheter mitral valve repair devices: comparison of study design and reported endpoints with recommendations in academic consensus papers from MVARC and the international standard ISO 5910**.	Journal article | In preparation (secondary study)	Task 1.1 & 1.3	RIVM, RCSI, UMIT, HPRA, ESC
Plath W., McCulloch P. (2024), **Locking innovation out: An experiential study of the barriers to adoption of novel methodology for clinical evaluation of high-risk devices in the EU system**.	Journal article | In preparation	Task 2.1	UOXF
Melvin T., Plath W., Holborow R., McCulloch P. (2024), **Clinical evidence and the Medical Device Regulation in Europe – is now the IDEAL time for improvement?**	Journal article | In preparation	Task 2.1	UOXF, Team-NB, & Advisory Board Member Tom Melvin (TCD)
Buccheri S., James S., Mafham M., Landray M., Melvin T., Oldgren J., Bulbulia B., Bowman L., Hoogervorst L.A., Marang-van de Mheen P.J., Juni P., McCulloch P., Fraser A.G. (2024), **Large simple randomised controlled trials – from drugs to medical devices. Lessons from recent experience**.	**Journal article | Submitted to Trials**	Task 2.2	RU, UOXF, LUMC, ESC, & Advisory Board Member Tom Melvin (TCD)
Rademakers F., Biasin E., Bijnens B., Bruining N., Caiani E.G., Davies R.H., Doornberg J.N., Gilbert S.H., Hovestadt L., Kamenjasevic E., Kwade Z., McGauran G., O'Connor G., Rouffet J.B., Vasey B. and Fraser A.G., for the CORE–MD consortium (2024). **A risk score to guide clinical and regulatory evaluation of artificial intelligence-based medical device software. A recommendation from the CORE–MD consortium**.	Journal article | submitted to npj Digital Medicine	Task 2.3	KU Leuven, POLIMI, HPRA, EFORT, ESC, & Advisory Board members
Biester et al. (2024), **A multi-stakeholder perspective on medical devices for children and adolescents with type 1 diabetes: huge unmet needs for the smallest**.	Journal article | In preparation (related publication)	Task 2.4	With contribution of CORE-MD partner RIVM
Hoogervorst L.A., Ren Y., Melvin T., Stratton-Powell A.A., Lubbeke A., Geertsma R.E., Fraser A.G., Nelissen R.G.H.H., Caiani E., Marang-van de Mheen P.J. (2024), **Safety notices and registry outlier data measure different aspects of safety and performance of total knee implants – A Coordinating Research**	**Journal article | Submitted**	Task 3.1 & Task 3.2	LUMC, GUH/UOXF, RIVM, ESC, EFORT, POLIMI, &

Provisional reference	Publication type	Related task	Partners involved
and Evidence for Medical Devices (CORE-MD) study. (Submitted to Acta Orthopaedica, under review)			Advisory Board Member Tom Melvin (TCD)
Hoogervorst L.A., Nelissen R.G.H.H., Melvin T., Piscoi P., Wilkinson C., Lübbeke A., Gale C.P., Epstein D., Overgaard S., Walmsley P., Szymanski P., Mohaddes M., O'Connor D.B., Geertsma R.E., Hoebert J.M., Fraser A.G., Marang-van de Mheen P.J. (2024). **Consensus recommendations to assess the quality and analysis of registry data for (post)market surveillance of medical devices: which items are the minimum requirements?** (submitted to the International Journal of Health Policy and Management, under review)	**Journal article including project's recommendations | Submitted**	Task 3.1	LUMC, EFFORT, GUH/UOXF, UGR, ESC, HPRA, RIVM, & Advisory Board Chair Paul Piscoi (ESC) and Member Tom Melvin (TCD)
Hoogervorst L.A., Ren Y., Caiani E.G., Marang-van de Mheen P.J., Smith J.A., Fraser A.G., Nelissen R.G.H.H., Lubbeke A. (2024), **Frequency of safety signals for a random selection of hip and knee arthroplasty implants**.	Journal article | In preparation	Task 3.1 & 3.2	LUMC, POLIMI, ESC, GUH/UOXF
Hoogervorst L.A., et al. (2024) **Primary knee implants across orthopaedic registries: are they used for the same patient groups?**	Journal article | In preparation	Task 3.1	LUMC
Laricchiuta P., Hoogervorst L.A., Sampaolo L., Ceccarelli S., ...Carrani E., Fraser A.G., Marang-van de Mheen P.J., Torre M. (2024), **International mapping of active national registries of cardiac implantable electronic devices and comparison of their sets of variables. Protocol for a systematic review**.	Protocol | In preparation	Task 3.1	ISS, LUMC, ESC
Laricchiuta P., et al. (2024), **International mapping of active national registries of cardiac implantable electronic devices and comparison of their sets of variables. A systematic review**.	Systematic review | In preparation	Task 3.1	ISS
Ren Y., Caiani E.G. (2024), **Natural language processing for regulatory science: aggregating information about safety notices of medical devices across the EU Member States towards an improved vigilance system**. Submitted to npj Digital Medicine.	Journal article | Revision submitted	Task 3.2	POLIMI
Ren Y., et al. (2024), **Quality evaluation of field safety notices of medical devices, across EU and non-EU countries**. Accepted for presentation as moderated poster, at ESC Congress 2024.	Abstract | Accepted	Task 3.2	POLIMI

Provisional reference	Publication type	Related task	Partners involved
Aranda J, Dobrzynska A, Rosario-Lozano MP, Rejón-Parrilla JC, Epstein D, Blasco-Amaro JA (2024). **High-risk medical devices: Regulatory perspectives on post-market evidence generation schemes. A Systematic Review**.	Systematic review | In preparation	Task 3.3	AETSA
Dobrzynska A, Rejón-Parrilla JC, Epstein D, Aranda-López J, Fraser AG, Blasco-Amaro JA. Survey of notified bodies reveals very limited use of conditional certification for high-risk medical devices.	Journal article | In preparation	Task 3.3	AETSA

6 Audiovisual production

Sharing results through audio-visual resources has gained an important role in crafting the successful dissemination strategy of a research project: video recordings or live events, conferences, masterclasses, short videos and podcasts, each method having its own ability to illustrate practical knowledge in a much more effective way, deconstruct complex phenomena and increase the outreach and impact of scientific publications. Acknowledging this trend, the CORE-MD project team has exploited the potential of audiovisual resources to convey the key project's messages, disseminate its results, raise awareness on the most pressing challenges yet to be tackled and advocate for the integration of its recommendations in the relevant policy documents and regulatory guidance.

6.1 Webinars and videos

6.1.1 CORE-MD webinars

As detailed in D4.5, CORE-MD webinars have been designed to present the findings stemming from the research activities performed by partners as well as engaging with the audience in constructive discussions facilitated by external invited experts on the issues covered by the project's tasks.

Table 8. List of webinars

Date	Title and link to the recording on Youtube
30 January 2023	Orthopaedic implants and European Medical Device Regulations
6 March 2023	The origins of European regulations
3 April 2023	Objective performance criteria
10 July 2023	Training and education for regulators, notified bodies and clinicians
17 October 2023	Recommendations for the clinical evaluation of AI medical devices
6 November 2023	Evidence for high-risk cardiovascular devices
27 November 2023	Pivotal clinical investigations of high-risk medical devices: "what guidance do we need and by whom?"
5 December 2023	IT tools for regulatory science (the CORE-MD search engine)
14 December 2023	Providing high-risk medical devices for children – problems and proposals
8 January 2024	Early clinical investigations of new high-risk medical devices
19 February 2024	Monitoring Life Cycle of an implant in Real Life
4 March 2024	The use of Patient Reported Outcome Measures in clinical evaluation of Medical Devices
26 March 2024	The Notified Body Role & The Conformity Assessment Process

6.1.2 CORE-MD promotional videos

The Biomedical Alliance also produced three videos in April 2023 and disseminated these in the course of the summer 2023. Involving CORE-MD partners, 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.

Figure 15. Cover image of promotion video #1

Alan Fraser (ESC), Tom Melvin (Trinity College Dublin) and Elin Karlberg (Sweden) 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 in June 2023. This video was released in June 2023 and had 279 views on YouTube.

Figure 16. Cover image of promotion video #2

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

Figure 17. Cover image of promotion video #3

Frank Rademakers (KU Leuven), Elisabetta Biasin (KU Leuven) and Leo Hoverstadt (Elekta) highlighted the promises that the use of AI-based medical devices holds in the digital transformation of the healthcare sector as well as the challenges that their regulation poses to policy makers. This video was released in October 2023 and had 141 views on YouTube.

6.1.3 CORE-MD webinar for the Dublin Cardiovascular Research Forum

On 14 March 2024, as an additional example of how partners' concerted dissemination efforts contributed to maximize the project's impact, the RCSI organized a webinar entitled "*Limitations of evidence for high-risk Medical Devices in Cardiovascular Medicine – results from the CORE-MD consortium*". Prof. Byrne presented the main results of CORE-MD to an audience of 52 healthcare professionals out of 93 registrants (56% attendance rate).

Dublin Cardiovascular Research Forum

Date: Thursday, 14 March 2024 at 19:00:00 CET
Speaker: Professor Robert Byrne

Title: Limitations of evidence for high-risk Medical Devices in Cardiovascular Medicine – results from the CORE-MD consortium (LIVE from Brussels)
Speaker: Prof Robert Byrne, Professor of Cardiovascular Research at RCSI University of Medicine and Health Sciences and Director of Cardiology at Mater Private Hospital, Dublin, Ireland.
Prof. Byrne graduated from University College Dublin, Ireland and completed his PhD in Medical Life Science and Technology at the Technical University Munich, Germany. Research awards received include the ESC Atherothrombosis Research Fellowship (2008), the TCT Thomas J. Linnemeier Young Investigator Award (2009) and the Andreas Grüntzig Research Prize of the German Cardiac Society (2016). Leadership roles include Deputy Editor at EuroIntervention and board member of EAPCI and Chair of its Patient Initiatives Committee.

GO TO EVENT

Figure 18. Dublin Cardiovascular Research Forum webinar invite and speaker bio sketch

6.2 Podcasts

As reported in D4.5, five podcasts were organized to explore the fundamental aspects of the project, including the roles of notified bodies, pediatric devices, registries, and evidence regarding high-risk medical devices. These podcasts function as an educational asset, delivering concise insights tailored for busy listeners. Their brevity, in contrast to webinars, is advantageous for our target audience who are often pressed for time, offering a succinct overview of the project's endeavors and results swiftly. Podcasts offer manifold educational advantages for projects like CORE-MD, focusing on intricate subjects. They furnish readily accessible information to a broad audience, enabling listeners to interact with the content while on the move. By delving into complex themes and engaging in discussions with experts, podcasts furnish valuable perspectives on medical device technologies, regulations, and applications. Real-life examples and case studies featured in podcasts aid listeners in comprehending the practical implications of these technologies in healthcare settings. In essence, these podcasts were crafted to function as a valuable educational resource, delivering convenient, captivating, and enlightening content for individuals seeking to deepen their knowledge of medical devices.

Table 9. List of podcasts

Title	Speakers
Understanding how EU notified bodies work	Richard Holborow & Prof. Alan Fraser
How do surgeons choose which medical device to implant?	Per Kjærsgaard-Andersen & Prof. Alan Fraser

Providing medical devices for children.	Prof.Berthold Koletzko & Prof. Alan Fraser
Real-world evidence on the performance of high-risk medical devices.	Prof. Perla Marang-van de Mheen & Prof. Alan Fraser
Medical device registries for post-market surveillance.	Prof. Anne Lubbeke Wolff & Prof. Alan Fraser

The podcast recordings were finalized towards the end of the project, coinciding with the availability of more results. As a consequence, a significant portion of the promotional efforts will occur post-project completion. With the editing phase now completed, all episodes are accessible on the CORE-MD website. Moreover, they will soon be showcased on the ESC 365 platform, ensuring broad exposure and influence. Promoting these episodes will be facilitated by integrating them into the existing "Cardio Talk" podcast series on ESC. Utilizing the existing recognition of these shows will magnify the visibility of CORE-MD's content within this established platform. While it is challenging to forecast the traction the podcast episodes will achieve, the ESC 365 platform attracted 739,000 visitors in 2023, ensuring a high level of visibility. The episodes will also be uploaded to major podcast distribution platforms such as Apple Podcasts, Spotify, Deezer, and Google Podcasts. Distributing podcasts across various platforms will extend their reach, making them accessible to a broader audience across different devices and operating systems. This enhances discoverability through platform algorithms and recommendation systems, increasing the likelihood of attracting new listeners. By offering convenience and aligning with users' existing audio consumption habits, podcasts gain visibility, potentially leading to increased recognition and followership.

7 Events

7.1 CORE-MD stakeholder workshops

As foreseen in the project's workplan, one of the key stakeholder engagement and networking activities aimed at gathering interested actors across the medical devices' community to collect viewpoint and encourage active participation in the co-production of the final recommendations was represented by the organization of three stakeholder workshops:

- In the framework of Task 2.4, **a multi-stakeholder expert panel with 18 paediatric experts** from the major paediatric subspecialities and paediatric surgery, a regulatory authority representative and an officer of the European Commission Directorate General Health and Food Safety (DG SANTE), was organized **to develop consensus recommendations for appropriate methodologies for clinical investigation of high-risk medical devices for use in children** and to comment on approaches for evaluating medical devices for market introduction. The event was hosted on January 16, 2023, at the Dr. von Hauner Children's Hospital, LMU University of Munich, Germany, followed up by a further virtual online meeting on March 23, 2023. The outcomes of this workshop are described in detail in Deliverable D2.5.
- In the framework of Task 4.2, **a multi-stakeholder hybrid workshop to guide the development of the Ethics Charter** was arranged in Brussels at the ESC/Biomed Alliance premises and hosted by the Biomed Alliance on November 20th, 2023. The outcomes of this workshop have driven the collaborative writing and consolidation of Deliverable D4.2, benefitting also from inputs of external ethics experts and the members of the Ethics Committee.
- In the framework of Task 4.3, **a multi-stakeholder hybrid workshop to build consensus on a set of recommendations for clinical evidence generation through the life cycle of high-risk medical devices** was held in Brussels at the ESC/Biomed Alliance premises and hosted by the Biomed Alliance, on November 21st, 2023. This workshop allowed to further develop the proposed hierarchy of study designs described in Deliverable 2.3, take stock of relevant insights from D2.1 and D2.2 and draft the final recommendations exposed in D4.3.

Besides these, several task-level internal workshops and meetings were held either in person of online. For instance, a **workshop was held in Oxford** on 9th November 2022, leading to a scientific manuscript on the **essential principles of simplifying the conduct of clinical trials**, based on Deliverable D2.2, that has been submitted for publication.

7.2 External events

CORE-MD's large partnership - composed by renowned academic institutions, regulatory authorities, health technology assessment agencies, public health institutes, patient organizations, notified bodies and the medical professional societies representative of the specialties where high-risk medical devices

are most largely employed – have guaranteed **massive presence and visibility in a variety of events** where the project's mission, goals and results have been discussed and presented.

Overall, the CORE-MD project has been featured in +90 events during the second reporting period and several other events after the project's end (Table 10), demonstrating the lasting impacts of its work after the conclusion of its activities and the multiple follow-up initiatives undertaken by partners to make sure that the project's results are widespread and scaled up in subsequent endeavours.

In Table 10 the events where CORE-MD has been presented and discussed are **grouped by targeted stakeholder category**, highlighting the event details, presentation or workshop titles (where applicable), links to relevant agendas, slides or proceedings if available, and partners involved.

It is noteworthy that huge emphasis has been placed on maintaining a constant presence at the **most relevant gatherings of European regulators** as well as **clinical professionals and scientists** as these were the two primary stakeholder categories addressed.

Engagement with regulatory bodies: The **Medical Device Coordination Group ('MDCG')** formed by representatives of the competent authorities of the Member States chosen for their competence and experience in the field of medical devices and in vitro diagnostic medical devices includes the consortium partners **HPRA, DKMA and URPLWMIPB**. They **regularly take part to MDCG meetings as well as to the meetings of its subgroups** that are tasked to respectively provide advice and draft guidance on their expertise field. Moreover, organizations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level are invited to attend MDCG sessions (that are usually open to external stakeholders twice per year) and the meetings of the sub-groups in the capacity of **observers**. Some partner organizations are official members of these groups (i.e., **RIVM is co-chairing the NET WG**). Furthermore, several other CORE-MD partners were invited on a case-by-case basis. In particular, during CIE and NET meetings, regular updates on CORE-MD were provided. These expert groups were closely involved in the work of CORE-MD which enabled regulators to be kept informed of the development of deliverables, research or findings. Input provided during the meetings by regulators were used to improve the deliverables when possible or to reflect on useful follow-up actions by regulators. Specifically, the **CIE Working Group** which usually meets 2/3 times a year – as stated in the section 2 of the DoA Part B – had preliminary agreed to receive regular reports and updates from the project. **CORE-MD held 3 dedicated half-day workshops with CIE, during the project, when task leaders presented their results and proposals**, on the 7th November 2022, 19th April 2023, and 8th November 2023 (the detailed agenda of the one arranged on November 8th, 2023, for instance, is provided in Appendix 4). This WG provides assistance to the MDCG on issues relating to clinical investigation and evaluation of medical devices in accordance with Regulation (EU) 2017/745 (MDR). In the field of its activities, the group prepares draft guidance, for endorsement by the MDCG. In addition, CIE develops proposals for common specifications in respect of the clinical investigation, evaluation and post-market clinical follow-up, as referred to in Article 9 MDR.

In addition, regular interactions have been maintained also with the **DG SANTE/EMA Expert Panels** designated to deliver opinions and views on the level of clinical evidence provided for certain high-risk medical devices and in vitro diagnostic medical devices (e.g., **Rob Nelissen (LUMC/EFORT) is chairing the Expert Panel on Orthopaedics**). Their role is especially important as these expert groups respond to mandatory consultation procedures by notified bodies within the Clinical Evaluation Consultation Procedure (CECP) of certain high-risk medical devices.

Engagement with medical professionals and their societies: A pivotal role in maximizing the presence of the project at **relevant medical congress** has been played by the two medical societies co-coordinating the dissemination efforts, **ESC and EFFORT**. They held **special sessions and symposia to CORE-MD at their flagship congresses** which offered its researchers the opportunity to present their work in several sessions, as exposed in the following paragraphs 7.2.1 and 7.2.2. Moreover, **regular updates about CORE-MD** were made at all the in-person and online meetings of the clinical societies that compose the **membership of the Biomed Alliance**, securing transferability and scalability opportunities for CORE-MD results beyond the three main specialties targeted in the project.

Notably, the CORE-MD partners succeeded in maximizing outreach also to all the other stakeholders' categories involved, such as notified bodies, HTA agencies and experts, researchers, and patients. Remarkably, a strong effort has been placed to **pave the way for the future exploitation of the PMS tool** developed in Tak 3.2 – as recommended by the mid-term reviewers - by arranging several **meetings with industry** players, national public health institutes and regulators as potential partners or adopters in the tool deployment and commercialization phases. The **engagement of trade associations such as MedTech Europe** via their participation in the Advisory Board and in the Final Conference as well as the attendance of the Project Coordinator at their Forum in Vienna last May 2024 has demonstrated the crucial **importance of CORE-MD results for manufacturers** and the urgent need to translate them into actionable tools and guidance to ease market access of critical and innovative medical devices while safeguarding patients' safety and optimizing clinical performance and utility.

Lastly, **international collaboration** has been strongly pursued too thanks to the attendance of partners to international congresses such as the IMDRF, ISAR, APOA, to mention a few, and the continued engagement of regulators and experts from the US and Australia as Advisory Board members.

Table 10. List of meetings, conferences and workshops attended by CORE-MD members

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Target group: regulators					
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM, Biomed Alliance	Brussels & online	24/10/2022

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
HPRA Advisory Committee	**Introduction to CORE-MD**	Internal meeting arranged by HPRA to inform regulatory authority staff on CORE-MD	HPRA	Dublin	01/11/2022
MDCG – Clinical Investigation and Evaluation working group (CIE)	**Dedicated workshop to update on the project's progress** Link to the related news: https://www.core-md.eu/core-md-expert-meet-the-clinical-investigation-and-evaluation-working-group/	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, DKMA, EAP, Biomed Alliance, UMIT, GUH/UOXF, LUMC, KU Leuven, RIVM		07/11/2022
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM, Biomed Alliance	Brussels & online	17/11/2022
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM, Biomed Alliance	Brussels & online	06/02/2023
Meeting between POLIMI and the Danish Regulatory Authority representatives	**Discussion about the CORE-MD PMS Tool application to the Danish data**	Presentation addressed to regulators	POLIMI, DKMA	Online	17/02/2023
International Medical Device Regulators Forum (IMDRF) 23rd Management Committee Meeting Link to the programme: https://imdrf2023.com/brussels/agenda	**Session 2: Real World Evidence, dedicated to explore the appropriate methods to collect, validate and use real-world evidence within a regulatory context**	Session moderated by one of the regulatory authorities partnering CORE-MD	HPRA and Advisory Board Member, Tom Melvin (TCD)	Brussels & online	27/03/2023
MDCG – Clinical Investigation and Evaluation working group (CIE)	**Dedicated workshop to update on the project's progress after the conclusions of the Project Board in Leuven**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, DKMA, EAP, Biomed Alliance, RU	Brussels & online	19/04/2023
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM,	Brussels & online	05/06/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
			Biomed Alliance		
MDCG – New Technologies (NET) Working Group	**Clinical recommendations for AI medical device software**	Presentation of the CORE-MD insights resulting from T2.3, upon invitation of the European Commission	POLIMI	Online	30/06/2023
MDCG – Clinical Investigation and Evaluation working group (CIE)	**Dedicated workshop to update on the project's progress (see Appendix 4)**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, LUMC, Biomed Alliance, AIHTA, Insel Gruppe AG, RU, KU Leuven	Brussels & online	08/11/2023
International Medical Device Regulators Forum (IMDRF) 24th Management Committee Meeting Link to the programme: https://www.imdrf.org/meetings/berlin-germany-hosted-european-commission-behalf-eu	**Paediatric Medical Devices: Challenges and Possible Solutions** Link to the presentation (from page 82): https://www.imdrf.org/sites/default/files/2023-10/Devices%20intended%20for%20specific%20patient%20populations.pdf	Presentation within the session "Devices intended for specific patient populations", which witnessed also the participation of regulatory authorities (HPRA) and the Advisory Board (FDA, Elekta)	EAP, HPRA	Berlin	26/09/2023
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM, Biomed Alliance	Brussels & online	10/10/2023
MDCG – New Technologies (NET) Working Group	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, HPRA, RIVM (co-Chair), KU Leuven	Brussels & online	01/12/2023
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, DKMA, Biomed Alliance	Brussels & online	11/12/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Meeting of the Orphan Devices Task Force established under MDCG	**Update on project's progresses**	Presentation upon invitation from the European Commission	ESC, EAP	Brussels & online	15/12/2023
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, DKMA, Biomed Alliance	Brussels & online	20/12/2023
MDCG – Clinical Investigation and Evaluation working group (CIE)	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, RIVM, Biomed Alliance	Brussels & online	04/03/2024
Target group: clinical professionals					
105º Congresso Nazionale della Società Italiana di Ortopedia e Trauma (SIOT)	**Registries: Excellence for your practice & an ally for patients!**	Invited presentation at national clinical society congress	LUMC	Rome	10/11/2022
Biomed Alliance Annual General Assembly	**Update on the BioMed Alliance's work and engagement in CORE_MD**	Ad-hoc presentation to clinical societies	BioMed Alliance	Annual conference	01/12/2022
Italian Arthroplasty Registry (RIAP) Steering Committee Workshop, followed by a virtual follow-up meeting	**Brief update on CORE-MD**	Presentation to the Steering Committee of RIAP, national registry funded by the Italian Ministry of Health and coordinated by ISS	ISS	Rome	02/12/2022
EAP virtual meeting	**Discussion on recommendations on paediatric devices**	Discussion arranged as a follow up to the stakeholder workshop on paediatric devices arranged in Munich	EAP	Online	23/03/2023
Biomed Alliance Spring Meeting	**Sub-workshop: contributing to regulatory affairs/building skills in regulatory affairs**	Workshop organized within the annual spring meeting gathering all clinical societies that are member of Biomed Alliance	BioMed Alliance	Online	11/05/2023
ISAR 2023 Annual Congress	**Revision rates after primary THA in registries: Systematic review and**	Presentation	GUH/UOXF	Montreal	13/05/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
	meta-analysis of selected hip stems and cups				
EFORT Congress 2023 Link to the programme: https://congress.efort.org/web/efort-congress-vienna-2023/advanced-scientific-programme	**Validation of the Orthopaedic Data Evaluation Panel (ODEP) rating in real-world-setting: Analysis across nine registries**	Abstract accepted for poster presentation	LUMC, GUH/UOXF	Vienna	24/05/2023
EFORT Congress 2023 Link to the programme: https://congress.efort.org/web/efort-congress-vienna-2023/advanced-scientific-programme	**Clinical investigations to evaluate high-risk orthopaedic devices: systematic review of the peer-reviewed literature**	Abstract accepted for poster presentation	GUH/UOXF	Vienna	24-26/05/2023
EFORT Congress 2023 Link to the programme: https://congress.efort.org/web/efort-congress-vienna-2023/advanced-scientific-programme	**Medical device science: the relevance for clinical practice**	Presentation within the Symposium "Beyond today's implants. Innovation and Regulation"	LUMC	Vienna	25/05/2023
EFORT Congress 2023 Link to the programme: https://congress.efort.org/web/efort-congress-vienna-2023/advanced-scientific-programme	**Quality & Safety of Implants: The Implant, The Surgeon, The Law, The Industry, CORE-MD**	Symposium entirely dedicated to CORE-MD with speakers from the consortium and the Advisory Board (including regulatory science experts, clinicians and NBs)	ESC, EFORT, GUH/UOXF, Team-NB, LUMC and Advisory Board Member, Tom Melvin (TCD)	Vienna	24-26/05/2023
Italian Arthroplasty Registry (RIAP) Steering Committee Workshop	**Brief update on CORE-MD**	Presentation to the Steering Committee of RIAP, national registry funded by the Italian Ministry of Health and coordinated by ISS	ISS	Rome	07/06/2023
Biomed Alliance Regulatory Affairs Committee Meeting	**Update on CORE-MD Project**	Presentation on progress of the project to the Committee's members	BioMed Alliance	Online	27/06/2023
ESC Congress 2023	**Development of an AI-based IT tool to support**	Abstract accepted for presentation within	POLIMI	Amsterdam	25/08/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
	medical device nomenclature standardization for post-market surveillance by automated mapping from GMDN to EMDN standards Link to Open Access presentation in ESC 365 Resources: https://esc365.escardio.org/presentation/266687	the session "Innovations in public health and health economics"			
ESC Congress 2023	**European registries as reliable data sources to assess implants' safety and performances across the implant lifecycle** Link to Open Access presentation in ESC 365 Resources: https://esc365.escardio.org/presentation/266672	Abstract accepted for presentation within the session "Innovations in public health and health economics"	LUMC	Amsterdam	27/08/2023
ESC Congress 2023	**A critical evaluation of high-risk implantable devices in cardiology: insights from CORE-MD** Link to the Open Access session in ESC 365 Resources: https://esc365.escardio.org/session/40184?query=Are%20cardiovascular%20device%20registries%20fit%20for%20regulatory%20purpose%3F	Full congress session dedicated to showcase insights from CORE-MD at the annual congress of the ESC	LUMC, RCSI, Insel Gruppe	Amsterdam	28/08/2023
Biomed Alliance General Assembly: Policy Workshop on RWE & registries	**How RWE and registries contribute to a better regulatory system for medical devices and medicines**	Presentation of the CORE-MD insights on the potential value of RWD to the clinical societies that are member of the Biomed Alliance	BioMed Alliance, GUH/UOXF	Annual conference	24/11/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Italian Arthroplasty Registry (RIAP) Steering Committee Workshop	**Brief update on CORE-MD**	Presentation to the Steering Committee of RIAP, national registry funded by the Italian Ministry of Health and coordinated by ISS	ISS	Rome	05/12/2023
Biomed Alliance Regulatory Affairs Committee Meeting	**Update on the project's progress**	Presentation on progress of the project to the Committee's members	BioMed Alliance	Online	10/01/2024
APOA Congress (Asia Pacific Orthopaedic Association Congress)	**Patient in the lead: No Innovation without Evaluation**	Speech featuring CORE-MD at medical professional congress in Asia	LUMC	Conference	29/02/2024
Target group: others (industry, researchers and students, public health institutes and authorities, notified bodies and consumer/patient groups)					
3I Pisa congress: Imaging, Innovation, International Link to the programme: https://www.santannapisa.it/sites/default/files/2022-09/Locandina%203I%20Pisa%20Congress%20FTGM%202022.pdf	**E-Health Care, Regulatory and Ethical Issues**	Presentation at National Congress featuring CORE-MD work	POLIMI	Pisa	13-15/10/2022
HPRA Webinars - Sufficient clinical evidence for legacy devices	**Session on CORE-MD**	Presentation in the frame of webinar series arranged for manufacturers, NBs and regulatory specialists by the Health Products Regulatory Authority (HPRA)	HPRA	Online	01/11/2022
Meeting of the Health Research Board Clinical Research Coordination (HRB CRCI)	**Lecture on Medical Device Clinical Study applications**	Lecture featuring CORE-MD at the integrated national clinical research network, providing centralised support in the conduct of multicentre clinical trials across Ireland	HPRA	Online	

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
ISPOR Europe 2022	**Study design recommendations in ISO standards for high-risk medical devices, a systematic review of the Horizon 2020 CORE-MD project** Link to the presentation: https://www.ispor.org/heor-resources/presentations-database/presentation/euro2022-3564/120620	Abstract presented at scientific congress and published in proceedings	UMIT	Vienna	06-09/11/2022
Meeting with senior managers of Tüv Süd (European notified body)	**Discussion about the current challenges of the MDR implementation, the role of NBs and the project's progresses to date**	Ad-hoc meeting arranged to engage with Notified Bodies	ESC, Team-NB	Online	03/12/2022
Biomed Alliance: Meeting with the Policy Officers of the member societies	**Update on CORE-MD**	Presentation to the policy officers of the member societies	BioMed Alliance	Online	24/01/2023
Meeting between POLIMI and EC DG SANTE responsible officials for EUDAMED	**Discussion about the IT aspects of EUDAMED development and implementation**	Presentation upon invitation from the European Commission	POLIMI	Online	03/02/2023
Meeting between POLIMI and 3aware, company offering a real-time software surveillance platform	**Discussion about potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	Online	03/02/2023
Meeting between POLIMI and ISS researchers (national)	**Discussion about the CORE-MD PMS Tool**	Presentation addressed to researchers of the Italian Institute of Health	POLIMI	Online	15/02/2023
Master Lecture in "Master di II livello: Governo clinico dei dispositivi medici e diagnostici. Università Cattolica del sacro Cuore, Facoltà di Medicina e Chirurgia, Roma"	**Presentation on traceability systems with a focus on implantable prostheses registries (including mention to CORE-MD project)**	Presentation addressed to master students (regional offices' staff for medical devices management, hospital pharmacists)	ISS	Rome	17/02/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Meeting with representatives of the EC Joint Research Centre	**Discussion between CORE-MD Scientific Coordinators and the JRC, about potential synergies between the project and JRC's own involvement in pre-normative research and standardisation activities**	Ad hoc meeting with EC JRC representatives	ESC, EFORT	Online	09/03/2023
Meeting between POLIMI and Regione Friuli Venezia Giulia	**Discussion about medical device nomenclatures**	Bilateral meeting between POLIMI and Italian regional health authority	POLIMI	online	29/03/2023
Master Lecture in "Master di II livello: Regolamentazione e Governance dei dispositivi medici. Università degli Studi di Napoli, Dipartimento di Farmacia. Module II on Classification and monitoring systems"	**Presentation on implantable prostheses registries as a tool to support EMDN (included mention on CORE-MD project)**	Presentation addressed to master students (regional offices' staff for medical devices management, hospital pharmacists)	ISS	Online	06/05/2023
Meeting between POLIMI and the company Basil Systems who offer a SaaS platform about FDA data	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	26/05/2023
Meeting between POLIMI and UCSF Health	**Bilateral meeting to discuss recalls and adverse event reporting**	Presentation to academic experts	POLIMI	online	31/05/2023
Master Lecture in "Master di II livello: Regolamentazione e Governance dei dispositivi medici. Università degli Studi di Napoli, Dipartimento di Farmacia. Module III: Clinical evaluation and vigilance of MD"	**Presentation on implantable prostheses registries (including mention on CORE-MD project)**	Presentation addressed to master students (regional offices' staff for medical devices management, hospital pharmacists)	ISS	Naples	15/06/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Workshop "Real World Evidence in health care governance: tools and opportunities"	**Post-market surveillance: how to generate valuable evidence through Internet data aggregation. Politecnico's experience within the European project CORE-MD**	Presentation at national event arranged by relevant industry players and regional health clusters (including AdvicePharma, Statinfo, ALTIS, IHPB, Cluster lombardo, SAPIO, BIOREP, POLIHUB)	POLIMI	Milan	22/06/2023
Meeting with the Health and Youth Care Inspectorate (IGJ), part of the Ministry of Health, Welfare and Sport (VWS) of the Netherlands	**Presentation of the CORE-MD PMS tool to the Dutch National Authority**	Bilateral meeting to present the PMS tool to national authorities	POLIMI, RIVM	online	21/07/2023
Meeting between POLIMI and the company InfarMed, facilitated by RIVM	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	25/07/2023
MedTech Europe Regulatory Affairs Committee Meeting	**Presentation from BioMed Alliance**	Presentation about CORE-MD outputs to the medtech trade association	BioMed Alliance	Conference	18/10/2023
30th Annual Conference of the International Society for Quality of Life Research Link to the programme: https://www.isoqol.org/events/30th-annual-conference-program-archive/	**A Review of MCID in relation to Patient-Reported Outcome Measures used to evaluate orthopedic, high-risk implantable medical devices and surgeries** Link to the open access proceedings: https://doi.org/10.1007/s11136-023-03530-x	Abstract accepted for presentation at a scientific conference	UGOT	Online	18/10/2023
Meeting between POLIMI and General Electrics	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	03/11/2023

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Meeting between POLIMI and Confindustria Dispositivi Medici	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to the Federation of Confindustria that unites, represents and enhances the companies operating in Italy in the medical device sector	POLIMI	online	07/11/2023
Master Lecture in "Master di II livello: Governo clinico dei dispositivi medici e diagnostici. Università Cattolica del sacro Cuore, Facoltà di Medicina e Chirurgia, Roma"	**Presentation on traceability systems with a focus on implantable prostheses registries (including mention to the CORE-MD project)**	Presentation addressed to master students (regional offices' staff for medical devices management, hospital pharmacists)	Rome	Online	02/02/2024
Medical Devices Coordination Group (MDCG) meeting	**Update on the project's progress**	Presentation upon invitation from the European Commission	ESC, EFORT, HPRA, DKMA, Biomed Alliance	Brussels & online	06/02/2024
Meeting between POLIMI and the Notified Bodies	**Discussion about the CORE-MD PMS Tool application to the work of the Notified Bodies**	Presentation of the PMS Tool to the Notified Bodies	POLIMI, Team-NB	online	15/02/2024
8th eHealth Stakeholders Group on EHDS and AI	**ESC and CORE-MD contribution on AI: Need for clinical evaluation and transparency**	Presentation to the official multistakeholder group gathering umbrella organizations representing the health tech industry, patients, healthcare professionals and the research community	POLIMI (in representation of the ESC)	Brussels	20/02/2024
Meeting between POLIMI and myConsulting	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	05/03/2024
Meeting between POLIMI and MedGlox	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	25/03/2024

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
Meeting between POLIMI and Lima Corporate	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	28/03/2024
Meeting between POLIMI and Medboard	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	29/03/2024
Events after the project's end					
Meeting between POLIMI and Medacta	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	03/04/2024
Meeting between POLIMI and Moretti	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	03/04/2024
Biomed Alliance Regulatory Affairs Committee Meeting / Medical Devices Task Force	**Update on the project's summary and conclusions**	Discussion about post-project follow-up activities and uptake of CORE-MD recommendations	ESC, EFORT, Biomed Alliance	Online	11/04/2024
Meeting between POLIMI and Moretti	**Bilateral meeting to discuss potential collaboration for the exploitation of the PMS tool**	Presentation to industry representatives	POLIMI	online	11/04/2024
Global Conference on Person-Centred Care: *Knowledge(s) and Innovations for Health in Changing Societies* Organized by the University of Gothenburg Centre for Person-Centred Care (GPCC): https://gcpcc.org/	**How are patient-reported outcome measures being used to improve meaningful and timely patient involvement in the choice of medical implants?**	Presentation about PROMs' use in medical implants' choice to academic and clinical professionals	UGOT	Gothenburg	14-16/05/2024
EFORT Congress 2024	**Free Paper Session: Registries & Implant Safety (Material & Technique): CORE-MD**	Abstract accepted for presentation	LUMC	Hamburg	22/05/2024

Event & Link if available	Title of the presentation/session & Link if available	**Type of participation**	Partner(s) involved	Location	**Date**
EFORT Congress 2024	**Are Safety Notices and Outlier Registry Data Signalling the Same Implants? An Analysis of Total Knee Implants**	Abstract accepted for presentation	LUMC	Conference	24/05/2024
13th Annual International Congress of Arthroplasty Registries https://www.isarhome.org/home	**Are safety notices and outlier registry data signalling the same total knee implants? – A Coordinating Research and Evidence for Medical Devices (CORE-MD) study**	Abstract accepted to present project's findings in a scientific congress	LUMC	Hamburg	01/06/2024
13th Annual International Congress of Arthroplasty Registries https://www.isarhome.org/home	**Achieving consensus on a minimum dataset to assess the quality and analysis of registry data for the regulation of medical device performance in post-market surveillance**	Abstract accepted to present project's findings in a scientific congress	LUMC	Hamburg	01/06/2024
Health Technology Assessment international (HTAi) 2024 Annual Meeting – Seville (Spain) https://htai.eventsair.com/htai-2024-annual-meeting/	**Guidance for the design of pivotal studies of high-risk medical devices by international regulatory authorities, a systematic review**	Abstract accepted to present project's findings in a scientific congress for HTA experts and practitioners	UMIT	Seville	15-19/06/2024
NLDB 2024: The 29th International Conference on Natural Language & Information Systems https://nldb2024.di.unito.it/	**Exploiting Large Language Models to Enhance Medical Device Nomenclature Interoperability and Streamline Regulatory Processes**	Abstract accepted for presentation	POLIMI	Turin	25-27/06/2024
ESC Congress 2024 https://esc365.escardio.org/ESC-Congress	**Quality evaluation of field safety notices of medical devices, across EU and non-EU countries.** Link to the session: https://esc365.escardio.org/ESC-Congress/sessions/11979	Abstract accepted for presentation as moderated poster in the session "Advancing cardiovascular care: innovations in prediction, diagnosis, and patient support"	POLIMI	London & online	30/08/2024

7.2.1 EFORT Congresses

During the project's lifespan, the CORE-MD project was presented and discussed in each EFORT Congress. Attracting 7k+ orthopaedic and traumatology surgeons from all over the world, these congresses were a good dissemination platform. At the 22nd EFORT Congress (online, 29th June - 1st July 2021), Prof. Nelissen and Ass. Prof Kjaersgaard-Andersen chaired a session presenting the ambition of CORE-MD. In the framework of the 23rd EFORT Congress (Lisbon, 22-24 June 2022), Prof. Nelissen and Ass. Prof. Kjaersgaard-Andersen chaired a session on the impact of the Medical Device Regulation in Orthopaedic and Traumatology referring to the ongoing CORE-MD project. Finally, at the EFORT Congress (Vienna, 24-26th May 2023), another **dedicated symposium on CORE-MD** was organized involving several partners (Figure 19. Tom Melvin (Trinity College Dublin) Perla Marang-van de Mheen (Delft University), Rob Nelissen Leiden University and EFORT), Anne Lübbeke Wolff (University of Geneva) and Richard Holborow (BSI Group) presented their results to the Orthopaedic and Traumatology community.

General Topics > Implants, Biomaterials & Registry Study

Symposium

Quality & Safety Of Implants: The Implant, The Surgeon, The Law, The Industry CORE-MD
Thursday 25 May 2023

14:45-15:45 hrs
Room Florence

Moderators
Prof. Rob G. H. H. Nelissen (Leiden, The Netherlands)
Prof. Tom Melvin (Ireland)

The Role Of Regulatory Science To Ensure Quality / Safety Of Implants
Prof. Tom Melvin (Ireland)

Performance And Safety Issues For Orthopedic Implants Before And After CE Marking
Ass. Prof. Dr Anne Lübbeke Wolff (Genève, Switzerland)

Benchmarking Hospitals To Improve Quality Of Care
Dr. Perla Marang-van de Mheen (Delft, The Netherlands)

How To Prevent Clinical Disasters In Orthopedics
Prof. Rob G. H. H. Nelissen (Leiden, The Netherlands)

Meeting The MDR Requirements And Impact On Availability Of Implants
Mr. Richard Holborow (United Kingdom)

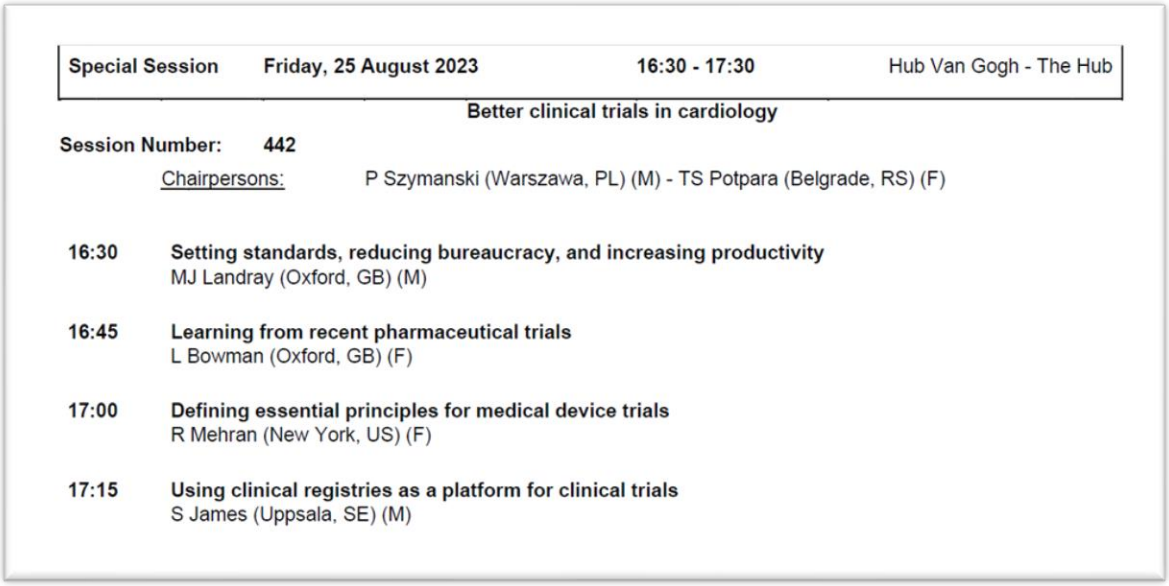
Figure 19. Agenda of the CORE-MD Symposium hosted at the EFORT Congress 2023 and group picture

The EFORT Hamburg Congress in May 2024 has also recently had a dedicated session on CORE-MD and several partners presented their results (see accepted presentation in the list of events held after the project's end, Table 10, above).

7.2.2 ESC Events

7.2.2.1 ESC Congress 2023

During the ESC Congress in Amsterdam 2023, the CORE-MD project had two sessions included in the scientific program, the first one being "Better clinical trials in cardiology", chaired by Piotr Szymanski and Tatjana Potpara and including representatives for partners UOXF and RU as speakers. This session focused on challenges related to registries, medical devices and pharmaceutical trials.



Special Session	Friday, 25 August 2023	16:30 - 17:30	Hub Van Gogh - The Hub

Better clinical trials in cardiology

Session Number: **442**

Chairpersons: P Szymanski (Warszawa, PL) (M) - TS Potpara (Belgrade, RS) (F)

16:30 **Setting standards, reducing bureaucracy, and increasing productivity**
MJ Landray (Oxford, GB) (M)

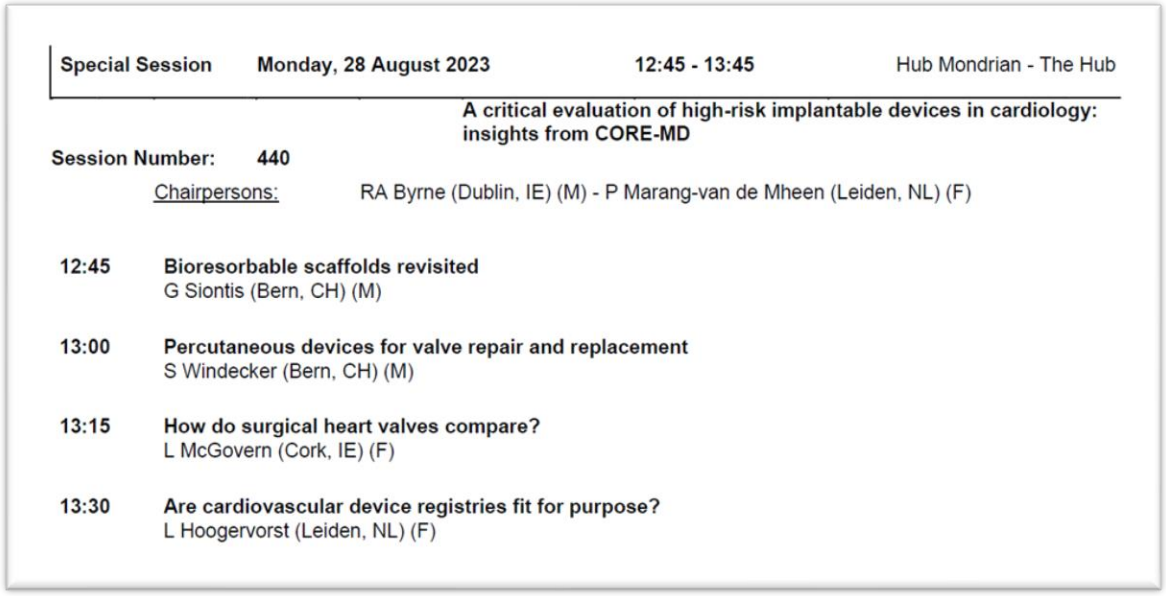
16:45 **Learning from recent pharmaceutical trials**
L Bowman (Oxford, GB) (F)

17:00 **Defining essential principles for medical device trials**
R Mehran (New York, US) (F)

17:15 **Using clinical registries as a platform for clinical trials**
S James (Uppsala, SE) (M)

Figure 20. Screenshot of the agenda of the Special Session 442 hosted at the ESC Congress 2023

The second session **"A critical evaluation of high-risk implantable devices in cardiology: insights from CORE-MD" was entirely dedicated to CORE-MD**. This session was chaired by Robert Byrne (RCSI) and Perla Marang-van de Mheen (LUMC).



Special Session	Monday, 28 August 2023	12:45 - 13:45	Hub Mondrian - The Hub

A critical evaluation of high-risk implantable devices in cardiology: insights from CORE-MD

Session Number: **440**

Chairpersons: RA Byrne (Dublin, IE) (M) - P Marang-van de Mheen (Leiden, NL) (F)

12:45 **Bioresorbable scaffolds revisited**
G Siontis (Bern, CH) (M)

13:00 **Percutaneous devices for valve repair and replacement**
S Windecker (Bern, CH) (M)

13:15 **How do surgical heart valves compare?**
L McGovern (Cork, IE) (F)

13:30 **Are cardiovascular device registries fit for purpose?**
L Hoogervorst (Leiden, NL) (F)

Figure 21. Screenshot of the agenda of the Special Session 440 hosted at the ESC Congress 2023

Hosting scientific sessions at the ESC Congress significantly enhanced the impact of our CORE-MD project in numerous ways. The ESC Congress served as a premier platform for knowledge dissemination and

networking within the cardiovascular community, providing unparalleled visibility to our research findings. Presenting at such an event validated the project's credibility and facilitated collaborations and feedback from leading field experts. The global audience at the ESC Congress ensured widespread exposure, attracting interest and partnerships for further advancement. This allowed for the exchange of ideas and insights, leading to enhanced scientific rigor and innovation within our project. Moreover, the **presentations and videos of the sessions are available in Open Access upon registration on the ESC365 platform** at the following links:

- ESC 365 - A critical evaluation of high-risk implantable devices in cardiology: insights from CORE-MD (escardio.org)
- ESC 365 - Better clinical trials in cardiology (escardio.org)

Last, the ESC Congress was a significant opportunity for several other researchers to present their findings submitting abstracts and poster presentations to specific tracks, that are reported in Table 10.

7.2.2.2 ESC TV Stage during the ESC Congress 2023

During the ESC Congress 2023 in Amsterdam several CORE-MD partners presented their results during the various sessions of this major Scientific Congress. During the congress, the CORE-MD consortium had the opportunity to record an **ESC TV Stage session with Prof Alan Fraser as a chairperson in the session named "*Clinical evidence for high-risk devices*"**. An insightful discussion was engaged with Stephen Windecker and Perla Marang-van de Mheen who shared the early results of the tasks they lead within the project where the available clinical evidence on high-risk medical devices have been reviewed in the fields of cardiology, orthopaedics and diabetes as well as the quality and utility of registries for MD safety and performance assessment. The replay of this session is available on the CORE-MD YouTube channel following the link: https://www.YouTube.com/watch?v=moi_CqLAmY0&t=599s.

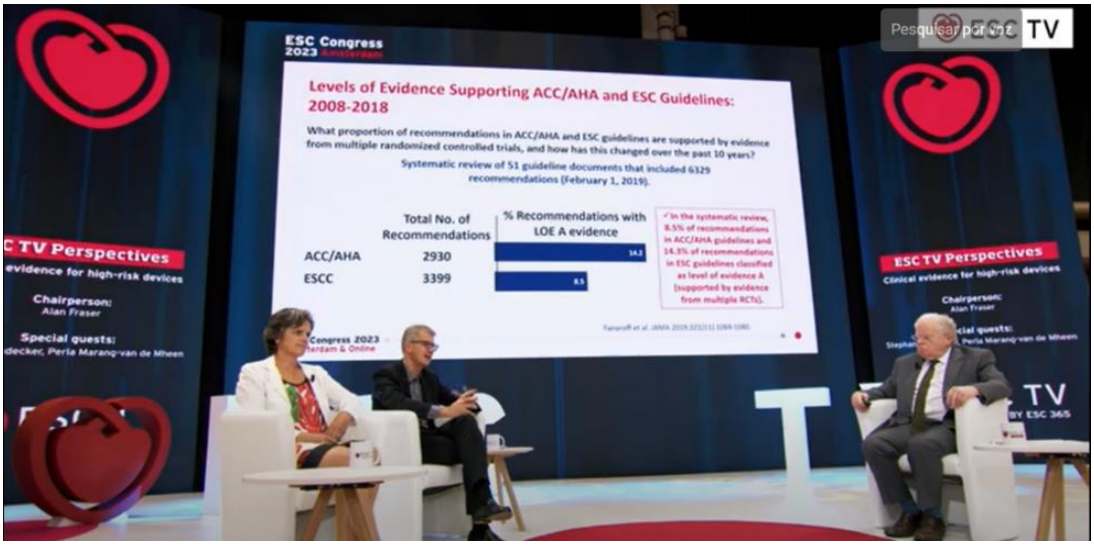


Figure 22. Picture from the CORE-MD dedicated ESC TV Stage session at the 2023 Congress

7.2.2.3 ESC Spring Summits 2023 & 2024

ESC Spring Summit takes place every year in March at the European Heart House, in Nice, France. In 2023 the two days event was aimed at strategic planning for the future of the ESC with its National Cardiac Societies, key leaders and volunteers. Attendees discovered inspiring cardiology targeted presentations. The Spring Summit is a major strategic meeting with the leaders in cardiovascular medicine who are also in the ESC constituent bodies. The focus in 2024 was on cardiovascular disease prevention and environmental risk factors: how to prioritize, meet challenges and disperse inequalities. Thanks to the EU Projects booth in both years, ESC had the opportunity to disseminate CORE-MD key project's activities and objectives with attendees coming from all over the world.

Figure 23. ESC booth at the Spring Summit showcasing CORE-MD

7.2.2.4 Beyond the end of the project: the ESC Cardiovascular Round Table

At the ESC Cardiovascular Round Table (a forum for discussion between senior ESC leaders and major pharmaceutical and device manufacturers) held on April 17, 2024, CORE-MD made a significant impact, with its scientific coordinator presenting key findings and insights. The focal point of discussion revolved around "Priorities for the Evolution of Medical Device Regulatory Approval Systems." This forum delved into the potential for global harmonization of medical device regulations, the prospects of facilitating priority access for health technology innovations, and the regulatory considerations pertaining to orphan devices.

Throughout the event, CORE-MD findings were prominently cited, underscoring its relevance and contribution to the discourse. Notable experts directly involved in the project, including Alan Fraser,

Gearoid McGauran, Piotr Szymanski, and Stephan Windecker, actively participated, enriching the conversations with their expertise. A summary of the meeting with recommendations, will be published as a peer-reviewed manuscript.

As discussions surrounding medical device regulation intensify, there is a shared aspiration to extend the reach of CORE-MD even beyond its initial scope. This commitment reflects our dedication to advancing knowledge dissemination and fostering meaningful dialogue within the healthcare community.

Figure 24. Pictures from ESC Cardiovascular Round Table 2024

8 CORE-MD Final Conference

The final conference was strategically scheduled for the project's concluding month to ensure a comprehensive array of results ready for dissemination among stakeholders participating in this event.

Planning for the conference commenced towards the end of 2023, led by the scientific coordinator who crafted a preliminary agenda and identified key speakers to enrich the program. Given the project's emphasis on engaging policy makers, the selection of Brussels as the venue was a natural choice. Recognizing the project's extensive reach, a physical gathering alone seemed insufficient. Hence, the decision was made to host a hybrid event, offering attendees the option to register for in-person attendance or access the event via online streaming. A venue capable of accommodating a minimum of 100 attendees was selected, ultimately opting for de Warande Club in Brussels. Registrations subsequently confirmed the physical presence of 100 individuals, complemented by an additional 200 participants engaging in the event online.

The first round of invitations was concentrated among the project participants and key speakers for the conference. Once the provisional agenda was completed, the public was invited through the website, social media and My ESC News bulletin (6th March 2024) that counts 155.000 recipients. A LinkedIn post about the event was also re-shared in the ESC account, this account brings a lot of visibility counting with 120.360 followers.

The event was streamed live on Zoom to increase the overall participation. Around 200 participants registered to participate in the final conference online. The online streaming counted with 78 participants throughout the entire event from 18 countries across the globe (EU, Australia, USA, Lebanon, Guadeloupe).

The final conference served as a culmination of our project's endeavors and counted on the presence of all the relevant European institutions (EC, European Parliament, EMA), stakeholder organizations and industry associations interested in the clinical evaluation and post-market surveillance of medical devices. The full programme is attached in Appendix 3.

Our outreach efforts, spanning invitations to project participants, key speakers, and broader dissemination via various channels including web, social media, and newsletters, yielded fruitful results. The decision to leverage platforms like Zoom for live streaming further enhanced accessibility, facilitating active participation from across geographies and sectors.

As evidenced by the sustained engagement of attendees throughout the conference, from start to finish, it is clear that our efforts have resonated with our audience. This successful event not only fulfilled its mandate of knowledge dissemination but also fostered meaningful dialogue and collaboration among stakeholders. Importantly, it witnessed on a large representation of regulatory authorities attending in person thanks to the concomitant organization from the Belgian Presidency of the Council of the European

Union that held the 54th meeting of the EU Competent Authorities for Medical Devices (CAMD) in Ghent, Belgium, during the same week.

In conclusion, the final conference stands as a testament to the project's impact and legacy. The full video recordings are going to be made available through the project's website and the YouTube channel, while presentations are available for sharing upon request.

Figure 25. Collection of pictures from the CORE-MD Final Conference

9 Maximizing CORE-MD's impact

The CORE-MD team has continuously tracked the impact of their communication and dissemination efforts both in qualitative and quantitative terms. As illustrated in the previous sections, outstanding targets have been achieved in all the monitored KPIs that are summarized in Figure 26.

Figure 26. Communication and dissemination KPIs: targets achieved

In the mid- and long-term, it is especially worthwhile to note that the highest achievements of the CORE-MD will consist in the contributions made by the project to the development and approval of linked guidance documents by the EU regulators – represented in the MDCG – and the European Commission, as anticipated in Section 2.1 of the DoA Part B. The project has definitely made bold steps towards this accomplishment by sharing regular updates on its progress with MDCG and its CIE sub-group, as testified by the participation of project's representatives in 14 meetings of MDCG, its subgroups and task forces. Moreover, the CIE Working Group has officially established a dedicated task force ('Work Package 28') to carefully review all CORE-MD findings and deliverables and seek the most suitable ways to leverage and integrate them in the next revision of the MEDDEV clinical evaluation guidance or otherwise within the EU regulatory system for high-risk medical devices. This work stream will kick off in June 2024 and will be part of the agenda items to be included in the programme of the next CIE meeting in September 2024. This is an undoubtedly relevant milestone since MEDDEV guidance, though not legally binding, when approved become a 'de facto standard' for manufacturers while giving other parties confidence in the marketplace.

9.1 Exploitable outputs made available by CORE-MD for the European regulatory community

Besides the relevant results highlighted in the several systematic reviews and stakeholder consultations conducted throughout the project, the exploitable outputs (tools, methods, frameworks, and recommendations) co-produced by the multidisciplinary team involved in CORE-MD constitute its tangible legacy to the broader European regulatory science community.

In this section we have listed them and anticipated the desirable exploitation routes for their uptake beyond the project's end.

Methods and tools

AI MDSW risk scoring system: this is a simple point-scoring system that can be used to estimate the overall risks associated with the use of a machine-learning algorithm or other AI MDSW in order to direct the level/depth of the pre- and post-release requirements for clinical evaluation. From a clinical perspective three parts of evidence are required, namely, valid clinical association, technical performance, and clinical performance, and for each the CORE-MD consortium has proposed scores from 1 to 3, relevant to the characteristics of the AI tool and its application, where lower values are associated with lower risk benefit. Further details are available in the public deliverable D2.4 and in the related peer-reviewed publication (under revision).

Envisaged exploitation routes: Further refinement while the AI Act is being implemented; Development of an IT-based tool for automatic risk score calculation (subject to resources/funding availability); Investigating opportunities for and barriers to its use by regulators and notified bodies, within the work of MDCG CIE Work Package 28 (see above).

Statistical tool: Due to the high-risk nature of many implantable devices, and to the absence of specific guidance about sample sizes or minimum cumulative follow-up required, limited sample sizes are common. However, this practice implies substantial uncertainty of the resulting risk estimates. We aimed to provide a practical tool to give insight into the relation between sample size and the implications for the level of risk that is accepted. The tool is available at the following link: https://core-md.shinyapps.io/RiskCalculator/. The source code and the dataset used to test the tool on data comparing the Bioresorbable Vascular Scaffold (BVS) device to the Everolimus drug eluting stent (EES) are openly available on Zenodo: https://zenodo.org/records/11366097

Envisaged exploitation routes: Conducting further testing on the utility and usability of the tool on other datasets; Performing a statistical review of methods for applying objective performance criteria which was not possible due to lack of funding in the CORE-MD CSA.

Decision framework: Post-market surveillance (PMS) is essential for monitoring the performance of high-risk medical devices; no implantable device can be guaranteed to be completely free of risks over the long term. PMS is the responsibility of manufacturers, but the best quality data are collected by medical

professional associations which conduct comprehensive registries. It is anticipated that EU regulators will consider the recommendations prepared by CORE-MD in its 'Decision framework' (Deliverable 3.1), as the basis for developing a system for recognizing which registries and other sources of post-market clinical follow-up can be used to provide reliable information that will be accepted for regulatory purposes.

Envisaged exploitation routes: Consideration by CIE WP28, and then by EU regulators at CIE and MDCG, to convert the framework in a checklist to be potentially Incorporated into, or referenced in future EU guidance. In addition to be included in the respective publicly available deliverable, the framework has also been submitted for peer-reviewed publication, so it will be available for all stakeholders.

Web-scraping tool: The CORE-MD PMS Support Tool (Deliverable 3.2) has been designed to be useful to members of Expert Panels, regulators, and evaluators in notified bodies, whenever they wish to find out if problems have been reported with a particular device or with a particular type of advice. That information will not be available in EUDAMED until it has been fully operational for some years, since it will not include any historical data. The Tool may be useful also for manufacturers when they wish to summarize the 'state of the art' relevant to a certain device.

Envisaged exploitation routes: The tool has been demonstrated to DG SANTE, the EUDAMED software team, EMA, notified bodies, and various manufacturers (see list of relevant meetings and events, Section 7.2, Table 10). Further sources of funding have been explored, so that the tool can be maintained and developed. Options for commercialisation, if necessary, or for it to be supported by regulatory bodies, will be reviewed further with WP28, as a priority.

Recommendations

Pediatric devices recommendations: The evidence collected by Task 2.4, and the recommendations prepared in the related workshop, have been presented in D2.5 and published in two peer-reviewed papers. Participants in the task continue to promote its conclusions within their own specialist paediatric communities and in interactions with regulators in many different contexts.

Envisaged exploitation routes: The leader of Task 2.4 in CORE-MD presented its recommendations to the International Medical Device Regulators Forum, in 2023. He and two other members of the expert group which prepared recommendations for the clinical evaluation and regulatory approval of medical devices in children, were active members of the writing group that prepared recent EU regulatory guidance on orphan medical devices (MDCG guidance 2024–10); that document encourages increased use of approval with conditions on the certificate of conformity. Contacts have been made with paediatric regulators within FDA.

Clinical study design recommendations: Recommendations for the conduct of registry-based randomised controlled trials of high-risk devices, have been exposed in D4.3 and submitted for publication; and the recommendations for clinical trials, as a 'hierarchy', are being prepared for publication.

Envisaged exploitation routes: Members of the CORE-MD consortium, in their roles for the Biomedical Alliance in Europe, and as consortium partners the ESC and EFORT, are currently reviewing draft guidance from the CIE Working Group of the European Commission, on "Clinical Evaluation under Regulation (EU) 2017/745". Advice will be provided, as far as possible, to ensure that insights from the CORE-MD project are provided to CIE. A planned second release of this document will consider a "Hierarchy of clinical evidence and level of sufficient clinical evidence for high-risk devices" and also "Clinical evaluation of AI based medical devices". CORE-MD partners will work with regulators through WP28 of CIE to offer its recommendations as a basis for developing appropriate regulatory guidance.

Education roadmap and recommendations: The recommendations gathered in D4.1 were made freely available in an open-access publication, and they were shared with members of the EMA who have been planning educational programmes for expert evaluators in the EU.

Envisaged exploitation routes: The BioMedical Alliance has decided to provide educational resources on EU regulations and standards, for colleagues in its member scientific and medical associations and will incorporate the CORE-MD recommendations in the design of the educational and training contents and materials. The CORE-MD roadmap (D4.1) has been shared with other stakeholders also planning educational and training activities, including TEAM-NB. It was also presented to the NoBoCap consortium[1] – aiming to improve technical knowledge at the NBs - during a dedicated meeting.

Ethics charter: The review and recommendations conducted within Task 4.1 and exposed in D4.2 are being prepared as manuscripts to be submitted for publication.

Envisaged exploitation routes: The recommendations in D4.2 are voluntary, but have been shared with the different stakeholder communities represented within the CORE-MD consortium. Possibilities for their endorsement or further promotion will be discussed with EU regulators in MDCG CIE WP28.

[1] https://nobocap.eu/.

Summary and conclusions

As shown in this deliverable, the CORE-MD consortium implemented its dissemination and communication plan as anticipated. Following the recommendations provided by the EC-appointed reviewers in the mid-term monitoring, specific actions were undertaken to intensify the communication over digital media, reach out to a diverse range of audiences through tailored tools and channels and leverage the outstanding engagement capacities of the societies and umbrella organizations involved in the project as well as the renowned international reputation of the experts and advisors contributing to its success.

A wide range of stakeholders were informed and aware of CORE-MD's results and findings thanks to a dedicated mailing list and increased social media presence. Moreover, the project triggered more visibility thanks to the involvement of partner's communication departments that used their own institutional channels to advertise CORE-MD 's outputs.

As per the scientific production itself, the consortium has produced several scientific articles in prominent scientific journals. Three in-person stakeholder workshops, two Delphi panels, one focus group and several meetings and consultations have been arranged to consolidate viewpoints, generate consensus and validate the findings and recommendations drafted by task leaders and their groups.

Thanks to the webinars, partners shared their results but more importantly involved external experts (see D4.5) to fuel the discussion on the implementation of the Medical Device Regulation. Interaction with audience was encouraged in order to debate and discuss the various viewpoints, taking into account that differences existed in the perception of the MDR.

Regular presence at MDCG meetings, and specifically to its CIE Working Group, contributed to keep regulators and notified bodies informed. **A dedicated work package in the CIE work plan been set up in 2024 composed of regulators and led by our partner HPRA**, **who will review CORE-MD findings and recommendations** and explore how they can be exploited, for example by possible inclusion into MDCG guidance documents.

The CORE-MD consortium has therefore achieved its objectives which were to systematically review methodologies for the clinical investigation of high-risk medical devices (Work Package 1), recommend how new trial designs can contribute (Work Package 2), and advise on methods for aggregating real-world data from medical device registries with experience from clinical practice (Work Package 3). Multidisciplinary workshops (20-21 Nov 2023) proposed a hierarchy of levels of evidence from clinical investigations; educational and training objectives for all stakeholders, to build expertise in regulatory science in Europe; and an ethics charter for medical device innovation (Work Package 4). Each task leader has successfully coordinated complex and interdisciplinary work streams that have led to the production of the planned deliverables and also to a series of additional spin-off/secondary studies that have further enriched the breadth of the CORE-MD scientific findings and its potential to influence policy making and help address MDR implementation hurdles.

The contribution of CORE-MD to the implementation of the Medical Device Regulation is significant. Regulators, academics, patients, healthcare providers and professionals, industry and notified bodies have experienced through CORE-MD how constructive dialogue could contribute to a mutual understanding of the needs and expectations of each key player in the field of medical devices. Many recommendations stemming from the consortium will substantially help regulators to understand better the challenges and the responses to contribute to the consistent and smooth implementation of the MDR. Ultimately, this will help manufacturers navigate all factors involved in bringing high-quality, researched-backed products to market.

Appendices

A.1 Website news

Table 11. List of news articles published on the website

Date	Title and hyperlink
19/03/2024	CORE-MD Podcast – Providing Medical Devices for children
16/03/2024	Upcoming Webinar on The Notified Body's Role & The Conformity Assessment Process
12/03/2024	CORE-MD Podcast – How do surgeons choose which Medical Device to implant?
29/02/2024	Upcoming Webinar on Patient Reported Outcome Measures for medical devices
15/02/2024	CORE-MD Podcast – Understanding how EU Notified Bodies work
05/02/2024	CORE–MD Final Conference
03/01/2024	Upcoming Webinar on Early Clinical Investigation of Medical Devices
08/12/2023	CORE-MD Webinar: Providing high-risk medical devices for children – problems and proposals
30/11/2023	CORE-MD webinar on 5 December 2023: IT Tool for for regulatory science: aggregating available data for post-market surveillance
24/11/2023	A dedicated session on medical devices and the contribution of CORE-MD at the Biomedical Alliance General Assembly
23/11/2023	CORE-MD workshop on high-risk medical devices
14/11/2023	Upcoming CORE-MD Webinar on Pivotal Clinical Investigations of High-Risk Medical Devices: "What Guidance Do We Need and by Whom?"
13/11/2023	CORE-MD Webinar on the high-risk medical devices in the field of cardiovascular disease and diabetes available for REPLAY

Date	Title and hyperlink
06/11/2023	A systematic review of the peer-reviewed medical literature
03/11/2023	Upcoming CORE-MD Webinar on high-risk medical devices in the field of Cardiovascular Disease and Diabetes
24/10/2023	CORE-MD Webinar on AI available for REPLAY
10/10/2023	Upcoming CORE-MD Webinar on clinical evaluation of Artificial Intelligence
03/10/2023	Evidence from clinical trials on high-risk medical devices in children: a scoping review
26/09/2023	CORE-MD work on Paediatric devices presented at the International Medical Device Regulators Forum
11/09/2023	Lack of published evidence for high-risk medical devices in Europe – new findings from CORE-MD
07/09/2023	CORE-MD partners presented their results at the ESC Congress
21/08/2023	European expert recommendations on clinical investigation and evaluation of high-risk medical devices for children
08/08/2023	Public consultation on WHO guidance for best practices for clinical trials
01/08/2023	Systematic Review of Cardiovascular and Orthopaedic Registries: new publication
27/07/2023	CORE-MD video: Surveying the landscape
18/07/2023	New Webinar available for REPLAY
11/07/2023	Use of real-world evidence in regulatory decision making
29/06/2023	Upcoming CORE-MD Webinar
27/06/2023	Open letter to Commissioner Stella Kyriakides to secure access to essential medical devices for children
05/06/2023	Perceived training needs for regulators, notified bodies and clinicians: result of CORE-MD survey
01/06/2023	Survey on the EMA Guideline on registry-based studies
25/05/2023	CORE-MD project discussed at EFORT Congress, Vienna 24-26 May 2023
21/04/2023	CORE-MD Project Board meeting – Leuven 17-18 April 2023

Date	Title and hyperlink
10/04/2023	Webinar on Objective Performance criteria now available in replay
31/03/2023	Employment, Social Policy, Health and Consumer Affairs Council discuss medical devices
21/03/2023	CORE-MD webinar: Objective Performance Criteria
16/03/2023	International Medical Device Regulators Forum – IMDRF23 – Join the Open Stakeholder Session, Brussels, 27 – 28 March 2023
13/03/2023	CORE-MD webinar replay: the origins and the objectives of the Medical Device Regulation
23/02/2023	Second CORE-MD webinar: The origins and objectives of European regulations for medical devices
23/02/2023	Medical Device for children
08/02/2023	Post-Market Surveillance tool: input from CORE-MD
06/02/2023	CORE-MD first webinar available in replay
19/01/2023	Promising results for CORE-MD Support Tool aggregating Information on Medical Devices
17/01/2023	First CORE-MD webinar: Orthopaedic implants and European Medical Device Regulations
19/12/2022	CORE-MD Christmas Newsletter
06/12/2022	Artificial Intelligence and Medical Devices Regulation. Discussing the legal framework and the ethical challenges within the CORE-MD project
02/12/2022	Biomed Alliance's call for action on essential medical devices
09/11/2022	CORE-MD expert meeting the Clinical Investigation and Evaluation Working Group
31/10/2022	New MDCG guidance document

A.2 Twitter/X posts

Table 12. Quarterly Twitter/X statistics

Quarter	Summary	Likes	Repost	Impressions	Engagement	Detail expand	Most engaged post
(Oct-Dec) 2022	Throughout the trimester, the publications recorded a total of 7 posts on CORE-MD's profile, of which 4 were reposts	10	6	989	64	19	https://twitter.com/coremdproject/status/1600757335848546304 (46 engagements, 6 likes, 5 reposts, along with 752 impressions and 14 detail expands)
(Jan – Mar) 2023	Throughout the trimester, the publications recorded the total of 6 posts on CORE-MD's profile, of which 1 was a reposts	14	10	4314	126	55	https://twitter.com/coremdproject/status/1638512190842892290 This post achieved the highest engagement with 69 engagements, including 6 likes and 5 reposts, along with 3536 impressions and 27 detail expands.
(Apr – Jun) 2023	Throughout the trimester, the publications recorded the total of 11 posts on CORE-MD's profile, of which 3 were reposts	37	7	2737	127	46	https://twitter.com/coremdproject/status/1647970938506338305 This post achieved the highest engagement with 20 engagements, including 7 likes and 1 reposts, along with 462 impressions and 8 detail expands
(Jul – Sep) 2023	Throughout the trimester, the publications recorded the total of 5 posts on CORE-MD's profile, of which none were reposts.	14	2	755	59	21	https://twitter.com/coremdproject/status/1647970938506338305 This post achieved the highest engagement with 32 engagements, including 5 likes and 2 reposts, along with 498 impressions and 32 detail expands
(Oct – Dec) 2023	Throughout the trimester, the publications recorded the total of 8 posts on CORE-MD's profile, of	14	5	1076	79	45	https://twitter.com/coremdproject/status/1734170516531925457 This post achieved the highest engagement with 31 engagements,

Quarter	Summary	Likes	Repost	Impressions	Engagement	Detail expand	Most engaged post
	which 2 were reposts						including 2 likes and 1 reposts, along with 551 impressions and 26 detail expands
(Jan – Mar) 2024	Throughout the trimester, the publications recorded the total of 9 posts on CORE-MD's profile, of which 5 were reposts	4	4	1259	40	21	https://twitter.com/coremdproject/status/1754785436193501257 This post achieved the highest engagement with 32 engagements, including 5 likes and 2 reposts, along with 498 impressions and 32 detail expands
Total		93	34	11130	485	216	

A.3 Programme of the Final Conference

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** **Paul Ballegeer**, *representing* 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*
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	

A.4 Agenda of the CORE-MD workshop at MDCG CIE WG held in Brussels on 8 November 2023

EU Working Group on Clinical Investigation and Evaluation (CIE)

Meeting of the EU WG Clinical Investigation and Evaluation (CIE)
Regulators only

Agenda

update to be provided shortly

Date &Time **8 November 2023** from **14:00 – 18:00** (tentative)

Place **Conference Centre Albert Borschette (CCAB)**
36 rue Froissart, B-1040 Brussels
+ link to virtual room: to follow

	8 November 2023 14:00 – 18:00		
	Workshop with CORE-MD **Improved methods for clinical investigation and evaluation of high-risk medical devices – Update on progress**		
1	**Introduction**		
(a)	Update from Project Board meeting 2023	Alan Fraser (in person), Rob Nelissen (online), Per Kjaersgaard-Andersen (online)	30'
2	**Evidence for certified high-risk cardiovascular devices**		
(a)	CORE-MD Systematic Review	Georgios Siontis (in person)	30'
3	**Registry-based randomised clinical trials and recommended study methodologies**		
(a)	Analysis and recommendations from CORE-MD	Sergio Buccheri (online)	30'
Coffee break (15.30 – 16.00 minutes)			
4	**Regulatory standards for the clinical evaluation of AI in MDSW**		
(a)	CORE-MD recommendations / consultations	Frank Rademakers (in person)	60'
5	**Requirements and recommendations for training and education**		
(a)	Results of the CORE-MD survey	Claudia Wild (online)	30'
6	**General summary and next events**		
(a)	Workshops and Final Conference	Alan Fraser (in person), Marieke Meijer (in person)	30'

A.5 Consortium communication effort on digital media

This Appendix compiles an overview table of exemplary posts on social media, articles and mentions to CORE-MD in institutional newsletters through which the consortium partners collaboratively supported the communication efforts and contributed to amplify the project's outreach via digital channels.

Table 13. Examples of posts, articles and mentions of CORE-MD in partners' digital communication channels

Date	Partner	Medium	Link	Type of audience
28/04/2024	FPS (AETSA)	LinkedIn	https://www.linkedin.com/posts/fundaci-n-progreso-y-salud_andaluc%C3%ADa-participa-en-un-proyecto-europeo-activity-7184142222395666432-dupB/?utm_source=share&utm_medium=member_desktop	Spanish healthcare actors, HTA experts and practitioners
11/04/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 07 | 11 April 2024	EFORT Members (medical professionals)
02/04/2024	BioMed Alliance	Update March	https://mailchi.mp/d404d6065486/march2024	Clinicians, staff medical societies, stakeholders, policy makers
21/03/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 06 | 21 March 2024	EFORT Members (medical professionals)
15/03/2024	EPF	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7174456826170609664	General public on social media
15/03/2024	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7174431594084982785	Clinicians, staff medical societies, stakeholders, policy makers
07/03/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 05 | 07 March 2024	EFORT Members (medical professionals)
06/03/2024	ESC	My ESC News	https://view.info.escardio.org/?qs=f6395660d03f6c8901a51601cf4c36f950c80116c3e61fe706d6774b2d51ad0ce223fe7561ffa40bb5357b42c7e5f4f030773f8d5f2529459cf849b92b4c4cd5f525eea210aaa0d9ecb59fd25f31a419d1ecd07a6b927b38	ESC Members (medical professionals)
06/03/2024	Team-NB	Team-NB website	https://www.team-nb.org/webinar-the-notified-body-role-the-conformity-assessment-process/	Notified Bodies

Date	Partner	Medium	Link	Type of audience
01/03/2024	EPF	X	https://twitter.com/eupatientsforum/status/1768691128084164791	General public on social media
29/02/2024	BioMed Alliance	Update February	https://mailchi.mp/414e5d643164/february2024	Clinicians, staff medical societies, stakeholders, policy makers
29/02/2024	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7168982198333722625	Clinicians, staff medical societies, stakeholders, policy makers
28/02/2024	EFORT	LinkedIn/X/facebook	https://www.linkedin.com/posts/efort_core-md-webinar-early-clinical-investigations-activity-7158874840513331200-8Wrz/	General public on social media
22/02/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 04 | 22 February 2024	EFORT Members (medical professionals)
21/02/2024	EPF	LinkedIn	https://www.LinkedIn.com/posts/european-patients-forum_new-webinar-alert-patient-reported-outcome-activity-7166103888918495232-N-se?utm_source=share&utm_medium=member_desktop	General public on social media
21/02/2024	EPF	X	https://twitter.com/eupatientsforum/status/1760338402753368377	General public on social media
21/02/2024	EPF	Facebook	https://www.facebook.com/EuropeanPatientsForum/posts/pfbid02847kd5ESm4fVeZCpHr1zfZKjnNqpqhnDCnUg4kGHkhkvjbEutwf4CisghiuFrCdYl	General public on social media
21/02/2024	EFORT	Linkedin/X/facebook	https://www.linkedin.com/posts/efort_coremd-final-conference-activity-7165267772527099905-hBvt?utm_source=share&utm_medium=member_desktop	General public on social media
19/02/2024	EFORT	LinkedIn/X/facebook	https://www.linkedin.com/posts/efort_understanding-how-eu-notified-bodies-work-activity-7165978518856654849-	General public on social media

Date	Partner	Medium	Link	Type of audience
			Y3Fg/?utm_source=share&utm_medium=member_desktop	
08/02/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 03 | 08 February 2024	EFORT Members (medical professionals)
06/02/2024	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7160664791303208960	Clinicians, staff medical societies, stakeholders, policy makers
26/01/2024	EPF	The Patient Perspective	https://mailchi.mp/eu-patient/epf-patient-perspective-january2024	Health stakeholders
25/01/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 02 | 25 January 2024	EFORT Members (medical professionals)
24/01/2024	EPF	Weekly Insiders	Link with restricted access to members	EPF members (patients and patient organisations)
11/01/2024	EFORT	EFORT Today	EFORT Today | Volume 4 | Number 01 | 11 January 2024	EFORT Members (medical professionals)
19/12/2023	BioMed Alliance	Update December	https://mailchi.mp/943aefd165f7/december-update	Clinicians, staff medical societies, stakeholders, policy makers
19/12/2023	POLIMI	LinkedIn	https://www.linkedin.com/posts/dipartimento-di-elettronica-informazione-e-bioingegneria_startcuplombardia2023-pni2023-activity-7127655983350231040-DBFX/?utm_source=share&utm_medium=member_desktop	Italian IT and biomedical engineering researchers
07/12/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 23 | 07 December 2023	EFORT Members (medical professionals)
04/12/2023	BioMed Alliance	Update November	https://mailchi.mp/9f2c330026ed/november2023	Clinicians, staff medical societies, stakeholders, policy makers
01/12/2023	EFORT	LinkedIn/X/facebook	https://www.linkedin.com/posts/efort_coremd-webinar-orthopaedics-activity-7137489411520266240-JeK-?utm_source=share&utm_medium=member_desktop	General public on social media

Date	Partner	Medium	Link	Type of audience
28/11/2023	EPF	Weekly Insiders	Link with restricted access to members	EPF members (patients and patient organisations)
24/11/2023	BioMed Alliance	Twitter/X	https://x.com/coremdproject/status/1728003834440470914	Clinicians, staff medical societies, stakeholders, policy makers
23/11/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 22 | 23 November 2023	EFORT Members (medical professionals)
21/11/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7132665951476412416	Clinicians, staff medical societies, stakeholders, policy makers
21/11/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1726902377041842262	Clinicians, staff medical societies, stakeholders, policy makers
09/11/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 21 | 09 November 2023	EFORT Members (medical professionals)
31/10/2023	BioMed Alliance	Update October	https://mailchi.mp/725a379d98fb/october2023	Clinicians, staff medical societies, stakeholders, policy makers
19/10/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 20 | 19 October 2023	EFORT Members (medical professionals)
05/10/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 19 | 05 October 2023	EFORT Members (medical professionals)
29/09/2023	BioMed Alliance	Update September	https://mailchi.mp/d11315f1e887/september2023	Clinicians, staff medical societies, stakeholders, policy makers
25/09/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7111989363193827328	Clinicians, staff medical societies, stakeholders, policy makers
25/09/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1706222408774934572	Clinicians, staff medical societies, stakeholders, policy makers
22/09/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 18 | 22 September 2023	EFORT Members (medical professionals)

Date	Partner	Medium	Link	Type of audience
11/09/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7107002162286600192	Clinicians, staff medical societies, stakeholders, policy makers
11/09/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1701237141009743983	Clinicians, staff medical societies, stakeholders, policy makers
07/09/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 17 | 07 September 2023	EFORT Members (medical professionals)
31/08/2023	BioMed Alliance	Update August	https://mailchi.mp/cf0f50fe935b/august2023	Clinicians, staff medical societies, stakeholders, policy makers
24/08/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 16 | 24 August 2023	EFORT Members (medical professionals)
16/08/2023	LMU (for EAP & Child Health Foundation)	X (Twitter)	https://x.com/lmu_uniklinikum/status/1691798719979462825?s=46	LMU Klinikum Follower
10/08/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 15 | 10 August 2023	EFORT Members (medical professionals)
31/07/2023	BioMed Alliance	Update July	https://mailchi.mp/569c4eeb86ef/july2023	Clinicians, staff medical societies, stakeholders, policy makers
28/07/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1674042223975866370	Clinicians, staff medical societies, stakeholders, policy makers
20/07/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 14 | 20 July 2023	EFORT Members (medical professionals)
13/07/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7085168495671291904	Clinicians, staff medical societies, stakeholders, policy makers
13/07/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1679408864192524288	Clinicians, staff medical societies, stakeholders, policy makers

Date	Partner	Medium	Link	Type of audience
06/07/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7082638547777646592	Clinicians, staff medical societies, stakeholders, policy makers
06/07/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 13 | 06 July 2023	EFORT Members (medical professionals)
30/06/2023	BioMed Alliance	Update June	https://mailchi.mp/7cb7b89e74c8/june2023	Clinicians, staff medical societies, stakeholders, policy makers
28/06/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/company/17973412/admin/feed/posts/	Clinicians, staff medical societies, stakeholders, policy makers
27/06/2023	EPF	Weekly Insiders	Link with restricted access to members	EPF members (patients and patient organisations)
22/06/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 12 | 22 June 2023	EFORT Members (medical professionals)
20/06/2023	EPF	Weekly Insiders	Link with restricted access to members	EPF members (patients and patient organisations)
08/06/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 11 | 08 June 2023	EFORT Members (medical professionals)
24/05/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 10 | 24 May 2023	EFORT Members (medical professionals)
11/05/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 09 | 11 May 2023	EFORT Members (medical professionals)
02/05/2023	BioMed Alliance	Update April	https://mailchi.mp/8dc477c727ef/april2023	Clinicians, staff medical societies, stakeholders, policy makers
27/04/2023	Team-NB	Team-NB website	https://www.team-nb.org/core-md-project-board-souvenir/	Notified Bodies
24/04/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 08 | 24 April 2023	EFORT Members (medical professionals)
24/04/2023	EFORT	LinkedIn/X/facebook	https://www.linkedin.com/posts/efort_core-md-project-board-meeting-leuven-17-activity-	General public on social media

Date	Partner	Medium	Link	Type of audience
			7060554069794271232-pvCZ/?utm_source=share&utm_medium=member_desktop	
19/04/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1648629577328017409	Clinicians, staff medical societies, stakeholders, policy makers
18/04/2023	BioMed Alliance	LinkedIn	https://www.LinkedIn.com/posts/biomedicalalliance_medicaldevices-activity-7054068077717524480-HdWH?utm_source=share&utm_medium=member_desktop	Clinicians, staff medical societies, stakeholders, policy makers
18/04/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1648300713020215297	Clinicians, staff medical societies, stakeholders, policy makers
11/04/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 07 | 11 April 2023	EFORT Members (medical professionals)
31/03/2023	BioMed Alliance	Update March	https://mailchi.mp/fdcc0f3b7ef3/march2023-15656661	Clinicians, staff medical societies, stakeholders, policy makers
23/03/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 06 | 23 March 2023	EFORT Members (medical professionals)
22/03/2023	BioMed Alliance	Twitter/X	https://x.com/coremdproject/status/1638512190842892290	Clinicians, staff medical societies, stakeholders, policy makers
09/03/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 05 | 09 March 2023	EFORT Members (medical professionals)
28/02/2023	BioMed Alliance	Update February	https://mailchi.mp/43c20367aa36/february2023	Clinicians, staff medical societies, stakeholders, policy makers
24/02/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1629144583635361792	Clinicians, staff medical societies, stakeholders, policy makers
23/02/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 04 | 23 February 2023	EFORT Members (medical professionals)

Date	Partner	Medium	Link	Type of audience
01/02/2023	EAP	Newsletter	https://preview.mailerlite.com/t9e8p8z1z3	EAP Members (Medical professionals)
19/01/2023	BioMed Alliance	Twitter/X	https://x.com/Biomedalliance/status/1616068005171023873	Clinicians, staff medical societies, stakeholders, policy makers
19/01/2023	EFORT	EFORT Today	EFORT Today | Volume 3 | Number 02 | 19 January 2023	EFORT Members (medical professionals)
08/01/2023	EPF	LinkedIn	https://www.LinkedIn.com/posts/european-patients-forum_clinicalinvestigations-medicaldeviceregulation-activity-7150073929414410240-QKwi?utm_source=share&utm_medium=member_desktop	General public on social media
08/01/2023	EPF	X	https://twitter.com/eupatientsforum/status/1744308339532542172	General public on social media
04/01/2023	EPF	LinkedIn	https://www.LinkedIn.com/feed/update/urn:li:activity:7148604188749361152	General public on social media
04/01/2023	EPF	X	https://twitter.com/eupatientsforum/status/1742896432787390800	General public on social media
04/01/2023	EPF	Facebook	https://www.facebook.com/EuropeanPatientsForum/posts/pfbid027KrRUe9fUpgQKNEb8AervdB1WPwk4joH6Uw3FHLHF3MfeR6hiAdjafgC6tCkKKnUl	General public on social media
19/12/2022	BioMed Alliance	Update November & December	https://mailchi.mp/0de062a3710a/december-update	Clinicians, staff medical societies, stakeholders, policy makers
25/10/2022	BioMed Alliance	Twitter/X	https://twitter.com/Biomedalliance/status/1584918330510610437	Clinicians, staff medical societies, stakeholders, policy makers
20/10/2022	EFORT	EFORT Today	EFORT Today | Volume 2 | Number 20 | 20 October 2022	EFORT Members (medical professionals)

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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