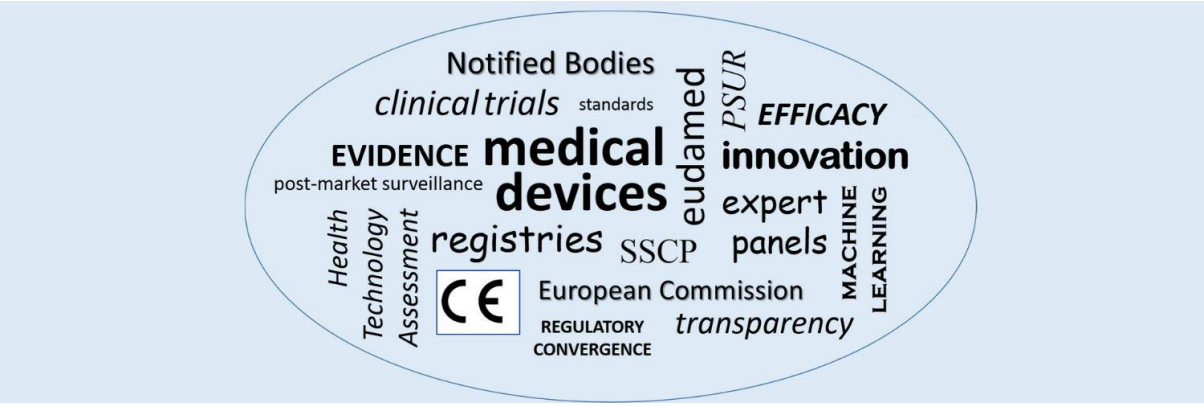
CORE-MD

Coordinating Research and Evidence for Medical Devices



Project Handbook

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246.

30.06.2021

Executive Summary

This handbook explains how the CORE-MD project is coordinated. More specifically, it describes the procedures and information needed to manage and support the project's activities, including tools for collaboration and communication. It also defines the Project Management Plan, which is designed to provide guiding principles that can ensure a high-quality outcome throughout the project's lifetime. Finally, it contains sections devoted to Quality, Risk Management, Ethics, and the Consortium Members.

This handbook shall be used as a guide by all consortium partners and members. It will promote best practices and lead CORE-MD to its foreseen and desired success.

Reference	
Source Activity	Work package 5, Deliverable 5.5
Title	Project Handbook
Lead Beneficiary	ESC
Nature	Report
Dissemination level	Public
Editor	Alan Fraser
Author (s)	Alan Fraser (ESC), Cinzia Ceccarelli (ESC), Elsa Pacella (ESC), Polyxeni Vairami (ESC), Anett Ruszanov (ESC)
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1 Introduction

This document intends to fulfil two purposes.

Firstly, it serves as:

- a reference document for consortium partners.
- a guide addressing details regarding the day-to-day project management.
- an internal reference for scientific standards.
- a link to additionally required resources (e.g., presentation and report templates).

Secondly, it outlines standard procedures, e.g., related to:

- reporting.
- financing.
- and others.

The document will be updated yearly and in general according to the needs during the lifetime of the CORE-MD project.

The general principles for the project execution are defined in the Grant Agreement (GA) No 965246 and the Consortium Agreement (CA). The Project Handbook does not replace any of these established agreements, nor does it replace any of the EU guidelines for project implementation and documentation.

2 Project Overview and Workflow

2.1 Project Overview

CORE–MD will translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

Implementation of the new Medical Device Regulation (EU) 2017/745[1] challenges the medical community to engage with regulators, notified bodies and industry to develop transparent, rigorous and proportionate methods for evaluating the clinical aspects of devices and monitoring their performance. Experts will advise on how high-risk medical devices are investigated so that regulators can achieve an appropriate balance between innovation, safety, efficacy and cost-effectiveness.

The CORE–MD consortium will address this challenge by bringing together medical associations, EU regulators, national public health institutes, notified bodies, academic institutions, patients' groups, and health technology assessment agencies, with participation of manufacturers' trade associations.

CORE-MD is the first formalised group of stakeholders in Europe working together to identify ways to enable the scientific, fair, and systematic evaluation of medical devices. Led by the European Society of Cardiology (ESC), in close collaboration with the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), the **consortium** includes 22 partners (Figure 1)involved in the development, evaluation, approval, clinical use, and monitoring of medical devices.

CORE-MD is a H2020 project responding to the call whose implementation is monitored by the European Health and Digital Executive Agency (HaDEA), later referred to as 'Agency'.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

Figure 1 Map of consortium partners

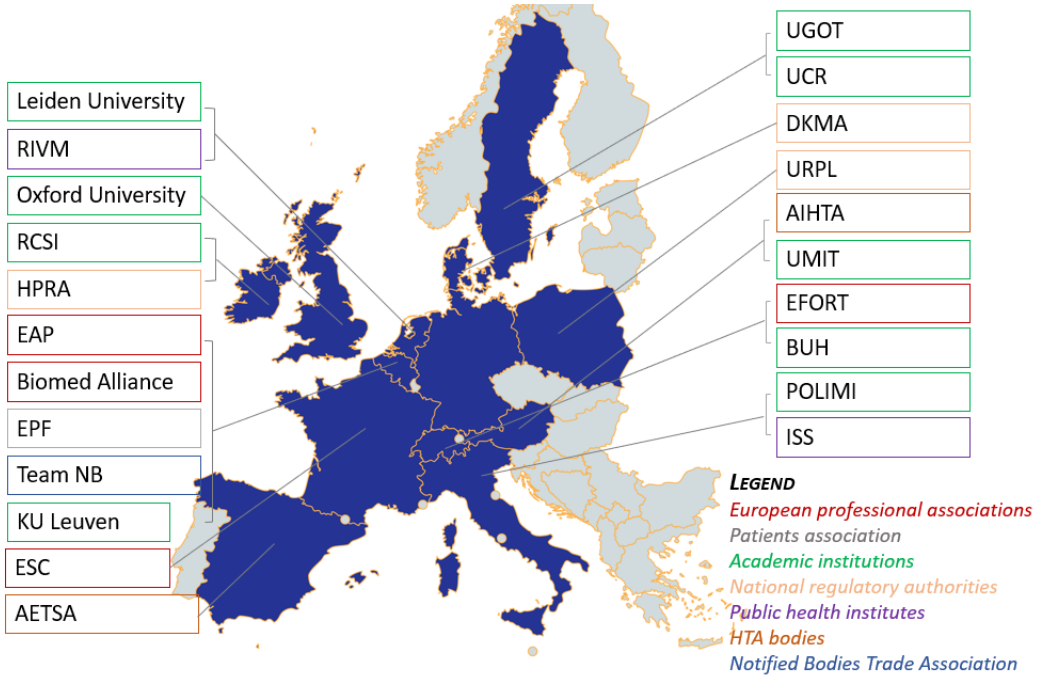


Table 1 List of consortium partners

ORGANISATION	ACRONYM	COUNTRY
SOCIETE EUROPEENNE DE CARDIOLOGIE	ESC/SEC	France
EUROPEAN FEDERATION OF NATIONAL ASSOCIATIONS OF ORTHOPAEDICS AND TRAUMATOLOGY	EFORT	Switzerland
ALLIANCE FOR BIOMEDICAL RESEARCH IN EUROPE	Biomed Alliance	Belgium
EUROPEAN ACADEMY OF PAEDIATRICS	EAP	Belgium
European Patients' Forum	EPF	Belgium
ACADEMISCH ZIEKENHUIS LEIDEN	LUMC	Netherlands
THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD	UOXF	United Kingdom
REGION UPPSALA	RU	Sweden
ROYAL COLLEGE OF SURGEONS	RCSI	Ireland
INSEL Gruppe AG	AG	Switzerland
KATHOLIEKE UNIVERSITEIT LEUVEN	KU Leuven	Belgium
UMIT- PRIVATE UNIVERSITAT FUR GESUNDHEITSWISSENSCHAFTEN, MEDIZINISCHEINFORMATIK UND TECHNIK GMBH	UMIT	Austria
GOETEBORGS UNIVERSITET	UGOT	Sweden
POLITECNICO DI MILANO	POLIMI	Italy
HEALTH PRODUCTS REGULATORY AUTHORITY	HPRA	Ireland
LAEGEMIDDELSTYRELSEN	DKMA	Denmark

URZAD REJESTRACJI PRODUKTOW LECZNICZYCH, WYROBOW MEDYCZNYCH I PRODUKTOW BIOBOJCZYCH	URPLWMIPB	Poland
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM	Netherlands
ISTITUTO SUPERIORE DI SANITA	ISS	Italy
HTA AUSTRIA - AUSTRIAN INSTITUTE FOR HEALTH TECHNOLOGY ASSESSMENT GMBH	AIHTA GMBH	Austria
FUNDACION PUBLICA ANDALUZA PROGRESO Y SALUD	FPS	Spain
EUROPEAN ASSOCIATION OF NOTIFIED BODIES FOR MEDICAL DEVICES	Team-NB	Belgium

2.2 Project Workflow

The Project is developed through five interrelated Work Packages (WPs).

WP 1 aims at understanding the methods that have been used to generate clinical evidence for high-risk medical devices.

WP 2 aims at strengthening the clinical evidence for high-risk medical devices by exploring new methods for generating data about their performance.

The main objective of WP 3 is to extract maximal value from medical device registries and real-world evidence.

WP 4 and WP 5 focus respectively on engagement with stakeholders, and project management.

Figure 2 summarises the CORE–MD work packages.

Figure 2 CORE-MD Work Packages

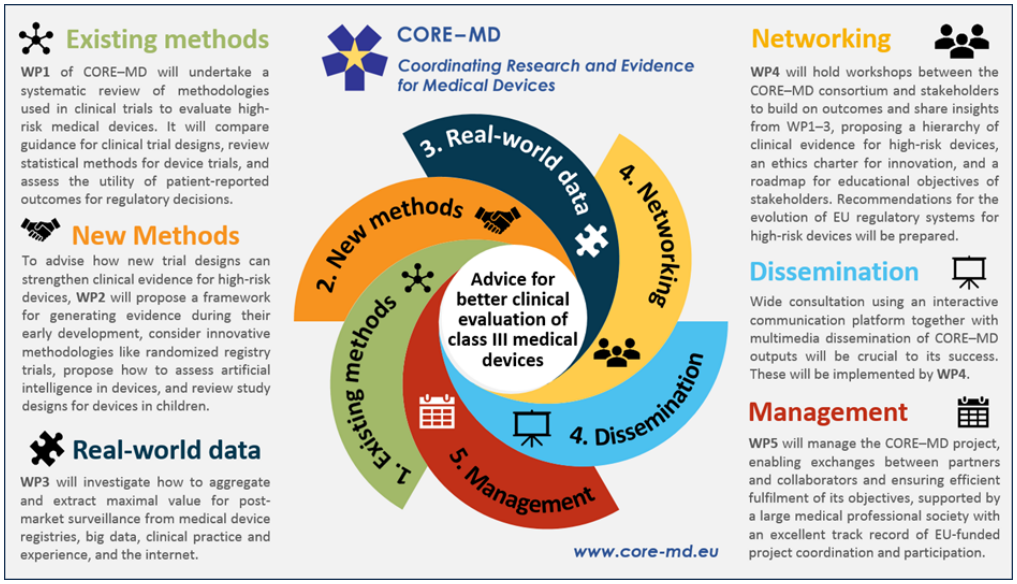
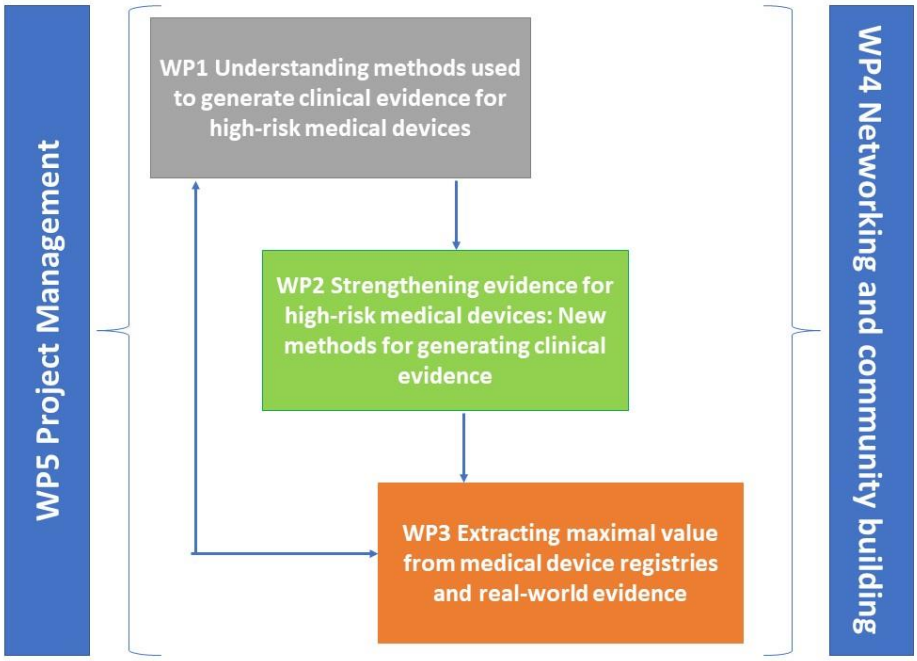


Figure 3 illustrates the main dependencies among the work packages, providing an overview of the flow of activities.

Figure 3 Summary of progression and links between CORE–MD work packages. Summary of progression and links between CORE–MD work packages.



The project started on 1 April 2021 and will last for three years, until 31 March 2024. Figure 3 shows the updated timing of the different work packages and their components.

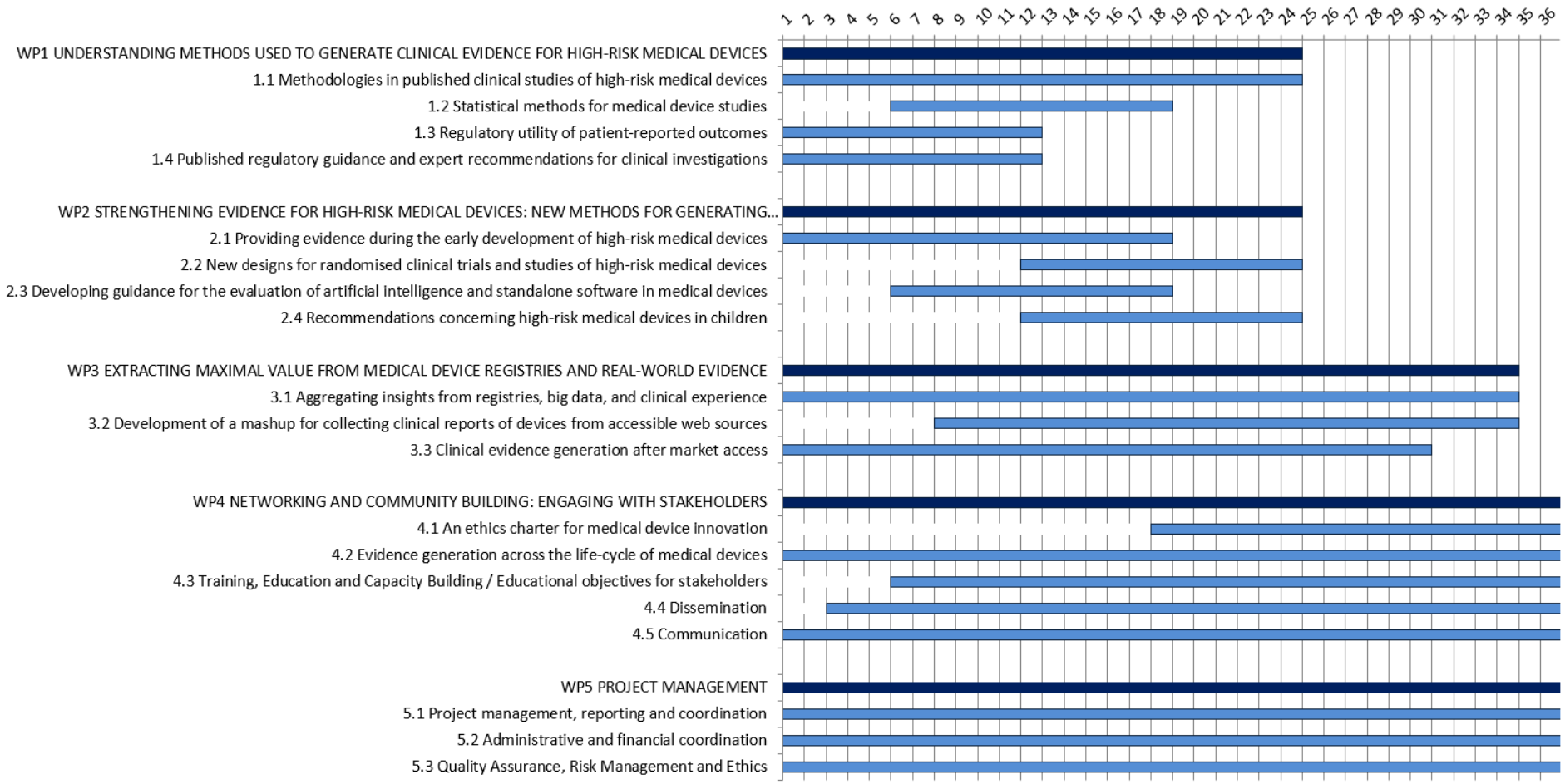
Compared to its expected timing as reported in the Grant Agreement, Task 3.1 *Aggregating insights from registries, big data, and clinical experience* started earlier in April 2021 (M1, new duration: M1-M34), instead of September 2021 (M6), to enable cross-linkage and integration of findings with WP1 to avoid any potential overlap.

Task 3.2 *Development of a mashup for collecting clinical reports of devices from accessible web sources* will start in November 2021 at M8 and will finish in January 2024 at M34 (new duration M8-M34, instead of M13-M30), to better map accessible web sources, to integrate findings with Task 2.3 *Developing guidance for the evaluation of artificial intelligence and standalone software in medical devices* and to connect with the Joint Research Centre in Ispra[2] leveraging on their relevant experience

These minor deviations will be included in a future amendment before the first reporting period.

[2] https://ec.europa.eu/jrc/en/about/jrc-site/ispra

Figure 3 Timing of the different work packages and their components



3 Project Management

This section describes the internal project management structure and techniques to be used within the CORE-MD project. It details the description currently included in the Description of Action (DoA) annexed to the Grant Agreement (GA) and in the Consortium Agreement (CA).

The CA, based on H2020 DESCA model[3], was signed in April/May 2021.

The overall management of the project is divided into three categories: Scientific, Project and Financial.

Scientific Management: This category encompasses the co-ordination of operative efforts within a scientific and technical scope, including the responsibility for the scientific and technical decisions taken in the project.

Project Management: This category encompasses the responsibility for the overall direction and major decisions of the project and the communication, control and corrections of these decisions.

Financial Management: This category encompasses the responsibility for the control of overall project expenditure, as well as for cost report collection, check and payment.

The centre of the management structure and process is the **Coordinator**, the European Society of Cardiology (ESC), that is the legal entity acting as the unique intermediary between the partners and the EC/Agency. The Coordinator monitors that the project is implemented properly, provides all information required by the EC/Agency, submits deliverables and reports to the EC/Agency. The Coordinator shall ensure that all payments from the EC are distributed to the other beneficiaries without unjustified delay.

Decisions will be taken collectively and delegated to the governing bodies defined within the project, as further detailed in this section.

3.1 Project Governance and Organisation

The project governance is made up of consortium bodies and key individuals.

The main consortium bodies of the CORE-MD project are:

- The **Project Board**.
- The **Coordinating Group**.
- The **Management Team**.
- The **Advisory Board**.
- The **Ethics Committee**.

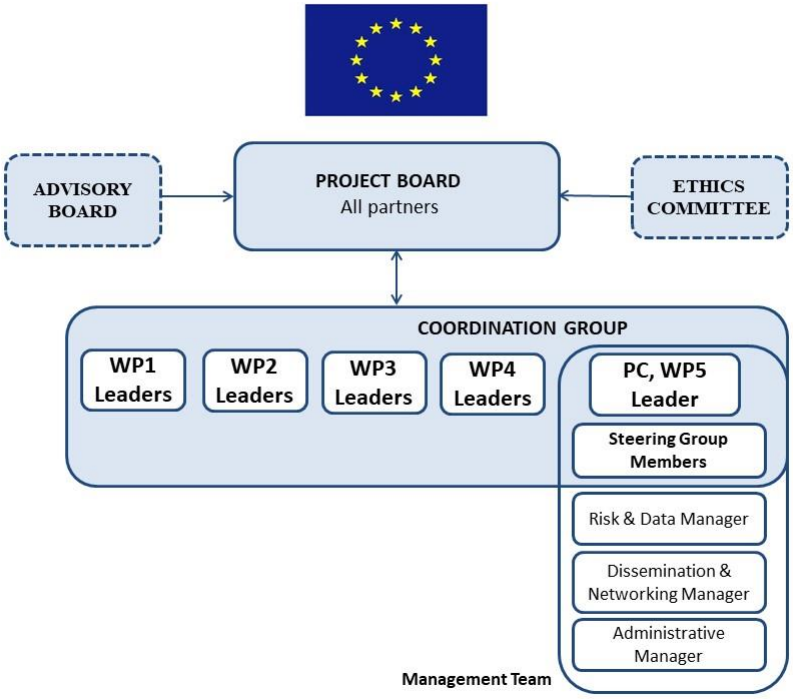
Figure 4 shows the different bodies defining the governance model of the project, while Tables 2-3-4-5-6-7 summarise the representatives per each consortium body.

In case of any change in the composition of the consortium bodies, the Coordinator shall be promptly informed, writing to core-md@escardio.org.

The members of Advisory Board might increase and be updated during the project lifetime, according to the key experts needed to advise the consortium on specific relevant topics.

[3] https://www.desca-agreement.eu/desca-model-consortium-agreement/

Figure 4 Governance structure of the project



3.1.1 Project Coordinator

The designated Project Coordinator (PC) is **Prof. Alan Fraser** from the ESC.

The PC chairs the Project Board (PB) and the Coordination Group (CG) and is directly responsible for the execution and the technical coordination of the entire project.

In particular, as chair of the Project Board (PB), he has to:

- Ensure that all PB decisions and directions are properly implemented.
- Ensure that all WPs are progressing and delivering in accordance with the work-plan objectives and schedule.
- Provide appropriate periodic reporting (including contractual and administrative ones) to the PB, and the EU.
- Immediately inform the PB of any important issue or critical problem encountered and propose the necessary actions.

3.1.2 Project Board

The Project Board (PB), consisting of one representative for each partner, acts as the **main governing body of the project**, with final authority on all the budgetary and contractual decisions.

The Project Board is free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out in the Consortium Agreement (CA). PB meetings are held **twice a year**, and at other times if required. Table 2 lists the members.

The PB has the final decisional authority in the Project and specifically administers:

- Proposals for changes to the estimated budget and the distribution of funds among the partners to be agreed by the Funding Authority (EC/Agency).
- Revisions of the work-plan implying changes in matters subject to contractual obligations.
- Handling of defaulting partners and changes in the consortium partnership.
- Organisational changes affecting key positions.
- Overall legal, contractual, ethical and financial management of the consortium.
- Appointment, if deemed necessary, of advisors.

Table 2 Overview of the Project Board

Body	Role	Responsible Person	Organisation
Project Board	Chair	Alan Fraser	ESC
	Member	Per Kjaersgaard-Andersen	EFORT
	Member	Elizabeth Macintyre	BioMed Alliance
	Member	Berthold Koletzko	EAP
	Member	Valentina Strammiello	EPF
	Member	Rob Nelissen	LUMC
	Member	Peter McCulloch	Oxford
	Member	Stefan James	UCR
	Member	Robert Byrne	RCSI
	Member	Stephan Windecker	BUH
	Member	Frank Rademakers	KU Leuven
	Member	Petra Schnell-Inderst	UMIT
	Member	Ola Rolfson	UGOT
	Member	Enrico Caiani	POLIMI
	Member	Tom Melvin	HPRA
	Member	Thomas Wejs Møller	DKMA
	Member	Jan Szulc	URPL
	Member	Robert Geertsma	RIVM
	Member	Marina Torre	ISS
	Member	Claudia Wild	AITHA
	Member	Juan Antonio Blasco Amaro	AETSA
	Member	Francoise Schlemmer	Team NB

During the project, circumstances may arise to call for a request to the EU for an **amendment** **to the Grant Agreement**. Reasons may vary, but could be:

- Changes involving beneficiaries & linked third parties.
- Change involving the coordinator/principal beneficiary.
- Changes affecting the project or its implementation.
- Changes involving the financial aspects of the grant.

In case an amendment is needed, the Project Coordinator shall promptly inform the EC Project Officer and submit such a request to the EC after a decision of the PB.

Amendments are not necessary for certain budget transfers which can be agreed by the PB itself.

3.1.3 Coordination and Steering Group

The Steering Group is composed of the PC and EFORT representatives as indicated below. The Steering group is in charge of providing scientific advice in case of conflict or major issues. It meets upon need, once or twice a month.

The Coordination Group (CG) represents the operational consortium body, ensuring day-to-day management and coordination. It consists of the Project Coordinator, the WP Leaders and the Steering Group Members; Table 3 shows its composition.

CG meetings are held **quarterly (4 times per year)**, and at other times if required. Task Leaders and external experts might be invited to join CG meetings.

Table 3 The Coordination Group

Body	Role	Responsible Person	Organisation
Coordination Group	Project Coordinator, WP5 Leader	Alan Fraser	ESC
	WP1 Leaders	Robert Byrne, Tom Melvin	**RCSI**, HPRA
	WP2 Leaders	Alan Fraser, Per Kjaersgaard-Andersen, Jan Szulc	**ESC**, EFORT, URPL
	WP3 Leaders	Rob Nelissen, Ann-Sofie Sonne Holm-Schou	**EFORT**, DKMA
	WP4 Leaders	Claudia Wild, Elizabeth Macintyre	**AITHA**, BioMed Alliance
	Steering group members	Alan Fraser, Per Kjaersgaard-Andersen, Rob Nelissen, Piotr Szymański	ESC, EFORT

3.1.4 Management Team

The Management Team consists of the Administrative Manager (AM), the Risk & Data Manager (RDM), and the Dissemination & Networking Manager (DNM). It also includes the Steering Group Members (SGM), in charge of providing scientific advice in case of conflict or major issues.

The Management Team shall assist and facilitate the work of the Coordination Group and the Project Coordinator for executing the decisions of the Project Board as well as the day-to-day management of the Project.

Table 4 The Management Team

Body	Role	Responsible Person	Organisation
Management Team	Project Coordinator, WP5 Leader	Alan Fraser	ESC
	Risk & Data Manager	Robert Geertsma, Susana Laia Farinha Cabaco	RIVM
	Administrative Manager	Christina Dimopoulou	ESC
	Dissemination & Networking Manager	New colleague to be appointed	EFORT

	Steering group members	Alan Fraser, Per Kjaersgaard-Andersen, Rob Nelissen, Piotr Szymański	ESC, EFORT

3.1.5 Advisory Board

The Advisory Board (AB) is established to support the Project Board in the identification of specific needs for medical device approvals and for Health Technology Assessment (HTA), to provide independent feedback and to ensure that project outputs are fit for purpose. As shown in Table 5, it is composed by high-level experts in various fields and from different organisations. Additional experts could be appointed as Advisory Members during the duration of the project.

The Coordinator will ensure that a non-disclosure agreement is executed between all Parties and each AB member.

Table 5 The Advisory Board

Body	Role	Responsible Person	Organisation
Advisory Board	Chairperson	Paul Piscoi	European Commission, Unit B6 DG SANTE
	Advisory Member	Niall MacAleenan	Director, Medical Devices, HPRA, Ireland / EU delegate to IMDRF Management Board
	Advisory Member	Wolfgang Ecker	Hon Professor, Medical Technology, University of Applied Sciences Upper Austria / Past-Chairman, Clinical Investigation and Evaluation Working Group (for European Commission)
	Advisory Member	tbc	European Medicines Agency
	Advisory Member	tbc	US FDA
	Advisory Member	tbc	WHO Geneva
	Advisory Member	Simon Singer	Principal Medical Adviser, Therapeutic Goods Administration, Australia
	Advisory Member	Rita Redberg	Cardiologist and Professor of Medicine, University of California San Francisco / Chief Editor of JAMA Internal Medicine
	Advisory Member	Art Sedrakyan	Director, Institute for Health Technologies and Interventions, Cornell Medical College, New York / MDEpiNet Coordinating Center
	Advisory Member	John Rumsfeld	Chief Innovation Officer, American College of Cardiology
	Advisory Member	Johan Kärrholm	Professor of Orthopaedics, Sahlgrenska University Hospital, Göteborg
	Advisory Member	Danielle Giroud	Geneva / Convenor of ISO working group on clinical investigation of devices
	Advisory Member	tbc	COCIR
	Advisory Member	tbc	MedTech Europe

3.1.6 Ethics Committee

The Ethics Committee has been nominated (Table 6) to oversee the ethical concerns, to conduct an ethics screening to advise the CORE-MD Project Board and to review its conclusions. The ethic oversight committee will work in close collaboration with the Risk & Data Manager as well as the Project Coordinator.

Table 6 The Ethics Committee

Body	Role	Responsible Person	Organisation
Ethics Committee	Member	Stefaan Callens (tbc)	KU LEUVEN, Faculty of Medicine
	Member	Griet Verhenneman	KU LEUVEN, Centre for IT & IP
	Member	Sven-Ove Hansson (tbc)	Royal Institute of Technology, Stockholm.

The Coordinator will organise virtual meetings with the members of the Ethics Committee inviting the members of the consortium to conduct an ethics screening of the project; the minutes will be submitted as D6.2 GEN - Requirement No. 2 - Regular reports from the Ethics Committee at M18 and at M36.

3.1.7 WP Leaders and Task Leaders

WP Leaders (WPL) are responsible for coordinating the execution of the activities pertaining to the Tasks into which their WPs are subdivided, whereas individual **Task Leaders** (TL) oversee the day-by-day activities associated with the execution of their Tasks.
Each WP will set up regular calls with Task leaders and key personnel involved in the activity.

Table 7 CORE-MD WP Leaders and Task Leaders

WP or Task	Responsible person	Organisation
WP1 Understanding methods used to generate clinical evidence for high-risk medical devices		
WP1 Leaders	Tom Melvin	HPRA
	Robert Byrne	RCSI
Task 1.1 Leader	Stephan Windecker	Insel
Task 1.2 Leader	Ewout Steyerberg	LUMC
Task 1.3 Leader	Ola Rolfson	UG
Task 1.4 Leader	Petra Schnell-Inderst	UMIT
WP2 Strengthening evidence for high-risk medical devices: New methods for generating clinical evidence		
WP2 Leaders	Alan Fraser	ESC
	Per Kjærsgaard-Andersen	EFORT
	Jan Szulc	URPL
Task 2.1 Leader	Peter McCulloch	Oxford
Task 2.2 Leader	Stefan James	RU
Task 2.3 Leader	Frank Rademakers	KU LEUVEN
Task 2.4 Leader	Berthold Koletzko	LMU, EAP
WP3 Extracting maximal value from medical device registries and real-world evidence		
WP3 Leaders	Rob Nelissen	LUMC
	Ann-Sofie Sonne Holm	DKMA
Task 3.1 Leader	Perla Marang - van de Mheen	LUMC
Task 3.2 Leader	Enrico Caiani	POLIMI
Task 3.3 Leader	Juan Antonio Blasco	AETSA
WP4 Networking and community building: Engaging with stakeholders		
	Claudia Wild	AIHTA

WP4 Leaders	Sabine Ettinger	AIHTA
	Elizabeth Macintyre	BioMed Alliance
	Alan Fraser	ESC
Task 4.1 Leader	Alan Fraser	ESC
Task 4.2 Leader	Per Kjærsgaard-Andersen	EFORT
Task 4.3 Leaders	Sabine Ettinger	AIHTA
	Claudia Wild	AIHTA
Participant	Francoise Schlemmer	TEAM-NB
Task 4.4 Leaders	Alan Fraser	ESC
	Cinzia Ceccarelli	ESC
	Anett Ruszanov	ESC
	Polyxeni Vairami	ESC
WP4 participant	Rob Nelissen	EFORT/LUMC
WP4 participant	Adrian Ott	EFORT
WP5 Project management		
WP5 Leader	Alan Fraser	ESC
Task Leaders	Alan Fraser	ESC
	Cinzia Ceccarelli	ESC
	Anett Ruszanov	ESC
	Polyxeni Vairami	ESC
	Per Kjærsgaard-Andersen	EFORT
	Rob Nelissen	EFORT/LUMC
	Adrian Ott	EFORT
DMP	Susana Laia Farinha Cabaco	RIVM

3.2 Decision-making mechanisms

All decisions will be taken unanimously. If the members cannot come to an agreement, a voting procedure as detailed in the Consortium Agreement will take place. The main principles are listed hereafter.

The key principle in the decision process will be that the lowest adequate level must decide, considering the guidance they receive on scientific, technical and strategic policy matters from the upper levels. These principles apply to all levels of the project organisation.

Project Decisions: The Project Coordinator will present issues of strategic importance, unresolved problems and any conflicts or disputes with proposals for solutions to the Project Board (PB) to obtain a decision. In the case of major disagreement, a decision shall be taken by a majority of two-thirds of the PB according to the CA.

The Project Coordinator will ensure that the work is managed and coordinated efficiently with good information flows maintained across the project. Special attention will be given to keeping the partners informed on the project's status, planning and other important issues. It will also be important to stage interactive management and technical meetings to ensure an efficient decision-making process between the WP Leaders, the partners and the PB.

4 Information Management & Internal Communication

Information will flow within the project both vertically and horizontally. The vertical flow of information will be adopted mainly for the administrative issues (e.g. financial progress reports,

consolidated reports, meeting minutes and cost claims/advance payments), whereas technical work packages will adopt a less formal, horizontal flow, where opinions are exchanged among peers, ideas are discussed either face to face or in meetings and conference calls.

4.1 Internal Communication Procedures

The ESC, as CORE-MD coordinator, takes over the main responsibility for communication within the consortium. The main communication channels between members should be via email, telephone as well as online chat programmes and meeting software (such as Zoom and Microsoft Teams). Documentation will be exchanged via email attachments. Scanned copies should be of best possible quality to ensure their usability.

To maintain the most up to date information and official documentation in a central place and to reduce the number of sent emails, final versions of key documents will be kept and shared in a central repository, the CORE–MD Consortium collaboration tool (Clinked) https://core-md.clinked.com/. Instead of circulating documents via email, all partners will be informed, once e.g. a new deliverable is added to the central folder.

Working documents can be exchanged as desired by involved members. In the case of evolving documents, potentially worked on by different partners, it will be ensured to save all important versions, which will also be kept on Clinked.Each partner is responsible to update and save files and inform the task/WP leader.

Many people may be working on a number of different projects and are likely to receive numerous emails every day, therefore, a standard subject title is proposed. This helps to quickly recognise the project related emails.

Project related e-mails should include in the subject title: 'CORE-MD' and WP number (if applicable) followed by a more specific description of the subject, deadline for feedback or reply.

5 Communication and Dissemination

This chapter describes the procedures and activities related to the communication and dissemination of the project results. It embraces guidelines about the **visual identity** of the project, the **acknowledgements** that all official materials have to include due to the grant received, some instructions related to the peer-reviewed open access **scientific publications** and some **reporting** requirements.

5.1 Visual identity

Creating a logo is part of creating an identity for the project. Below, you can read some guidance about the correct use of the project visuals.

5.1.1 Logos

The CORE-MD logo (Figure 5**Error! Reference source not found.**)which is available in various format in the in the CORE-MD collaboration tool, must appear in all official project communication, together with the EU emblem and the acknowledgments (please read **5.2 Acknowledgments**).

Figure 5 CORE-MD logo with acronym

Figure 6 CORE-MD logo with acronym and full title

5.1.2 Illustrations

Photographs and illustrative material should be supplied in high quality (if possible). Especially for web content it is required to ensure the use of photographs, and other material, considering the GDPR and other regulations at all times. Therefore, each partner is responsible to ensure necessary copyright clearances for illustrative material within the project.

5.2 Acknowledgments

All communication related to the project (including electronic communication, publications, using social media, etc.) and all infrastructure, equipment or major results funded under the grant must:

- display the EU emblem.
- include the below text.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246.

5.3 Peer-reviewed scientific publications

Each beneficiary must ensure **open access** (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications.

   Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

b) ensure open access to the deposited publication — via the repository — at the latest:
   i. on publication, if an electronic version is available for free via the publisher, or
   ii. within **six months of publication** in any other case.

c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

As indicated previously, the funding needs to be acknowledged at all times:

"**This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246**".

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms "European Union (EU)" and "Horizon 2020";
- the name of the action, acronym and grant number "Coordinating Research and Evidence for Medical Devices, CORE-MD, grant agreement No 965246";
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020 are saved in the CORE-MD collaboration tool.

5.3.1 Publication: notice period to consortium partners

Prior notice of any planned publication shall be given to the consortium partners at least **45 calendar days before the publication**, according to art. 8.4.2.1 of the Consortium Agreement. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

Please inform the Coordinator, writing to core-md@escardio.org (subject: CORE-MD planned publication).

5.4 Share your activities

All consortium partners are requested to fill in the dissemination activities report tables regularly (at least every 6 months). In this way, the WP6 team will be able to keep the project website up to date, promote the project activities and report on them accordingly.

The tables (Figure 7, Figure 8) are available on Clinked

Figure 7 Dissemination Table - Conferences, workshops, events

CORE-MD

Dissemination Activities Report Table

1 - Conferences, workshops and other public presentations (e.g., interviews, etc.)

PLEASE HIGHLIGHT UPCOMING EVENTS FOR TIMELY PROMOTION

N	Type of activity (workshop, conference, interview, etc.)	Partner(s)	Speaker(s)	Date (dd/mm/yyyy)	Location (city, country)	Venue	Title of the event	Size/Importance/Popularity	Your role (participant, speaker, exhibitor, etc.)	Title of the presentation	Type of audience (field of expertise)	Link	Link 2	Key figures	Summary
Reporting Period 1 (01/04/2021 - 30/09/2022)															
1															
2															
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Figure 8 Dissemination Table - Publications

CORE-MD

Dissemination Activities Report Table

2 - Scientific publications (peer reviewed and ground-level)

N	Type of publication (journal article, conference proceeding, etc.)	Status (published, in press, under review, submitted)	Date of publication (dd/mm/yyyy)	Article title	Authors	Publication title (name of the journal, conference, etc.)	Number/date/frequency of the Journal/Proceedings/Book	Relevant Pages	DOI	ISBN	Repository Link	Link to the publication	Green open access (Y/N)	Gold open access (Y/N)	Peer Reviewed (Y/N)	Joint Public/Private (Y/N)	Journal Impact Factor	Your role (first, middle, last, corresponding, etc.)	Type of audience (field of expertise)
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6 Project Reporting and Document Production

Throughout the lifetime of the project, three main types of reports are required:

- Deliverables
- Periodic reports to the EU (financial & technical progress)
- Internal progress reports

6.1 Deliverables

The Deliverables of the project will be produced by the Project Coordinator, WP leaders, Task leaders, and other partners according to the responsibilities assigned in the Grant Agreement - Description of Action. Deliverables will either be paper documents or another type (i.e. toolkit, website, etc.). Other types of deliverables will always be accompanied by a report containing all the relevant information.

Each deliverable/report will mention the name(s) of its author(s) who must guarantee that any work or result described therein is either genuinely a result of this project or that any other source is properly referenced.

Table 8 List of Deliverables

Del.	Title	Lead Ben	Diss. Level	Date
D1.1	Database of studies of high-risk medical devices	RCSI	Public	31/12/2022
D1.2	Repository of trial designs for orthopaedic, cardiovascular and diabetic devices	RCSI	Public	31/12/2022
D1.3	Peer-reviewed manuscripts	Insel Gruppe AG	Public	31/03/2023
D1.4	Scientific report on statistical methods for medical device trials	LUMC	Public	30/09/2022
D1.5	Recommendations on PROMs for conformity assessment and post-market surveillance	UGOT	Public	31/03/2022
D1.6	Report on study design recommendations in guidance documents for high-risk medical devices	UMIT	Public	31/03/2022
D2.1	Publication on early-phase clinical studies of high-risk medical devices	UOXF	Public	31/03/2023
D2.2	A publication on the essential principles of randomised registry trials	RU	Public	31/03/2023
D2.3	Proposals for a hierarchy of clinical study designs	UOXF	Public	31/03/2023
D2.4	Expert advice on criteria for the regulatory evaluation of ML and AI	KU Leuven	Public	31/03/2023
D2.5	Consensus recommendations on a desirable regulatory policy for paediatric high-risk medical devices	EAP	Public	31/03/2023
D3.1	Decision framework to assess the performance of high-risk medical devices	LUMC	Public	31/01/2024
D3.2	An IT tool for identifying reports of high-risk medical devices	POLIMI	Confidential	31/01/2024

D3.3	Report on conditions on certificates by notified bodies	FPS	Public	30/09/2023
D4.1	Roadmap for education and training	AIHTA GMBH	Public	31/03/2024
D4.2	An Ethics Charter for Innovation in Medical Devices	ESC	Public	31/03/2024
D4.3	Recommendations for a hierarchy of clinical evidence for high-risk medical devices	EFORT	Public	31/03/2024
D4.4	Project Website	ESC	Public	30/06/2021
D4.5	Educational resources	EFORT	Public	31/03/2024
D4.6	Dissemination & Communication Plan	ESC	Public	30/09/2021
D4.7	Report on dissemination and networking	ESC	Public	30/09/2022
D4.8	Final report on dissemination and networking	EFORT	Public	31/03/2024
D5.1	Meeting Minutes - KOM	ESC	Confidential	30/04/2021
D5.2	Minutes – 2nd Meeting	ESC	Confidential	31/03/2022
D5.3	Minutes – 3rd Meeting	EFORT	Confidential	31/03/2023
D5.4	Minutes – 4th Meeting	EFORT	Confidential	31/03/2024
D5.5	Project handbook	ESC	Public	30/06/2021
D5.6	Data management plan	RIVM	Confidential	30/09/2021
D6.1	POPD - Requirement No. 1	ESC	Confidential	31/03/2022
D6.2	GEN - Requirement No. 2	ESC	Confidential	31/03/2022
D6.3	H - Requirement No. 3	ESC	Confidential	31/03/2022

* Confidential, only for members of the consortium (including the Commission Services)

Compared to its expected timing as reported in the Grant Agreement, D2.2 *A publication on the essential principles of randomised registry trials* (Lead Beneficiary: RU) will be published at M24 on 31 March 2023 (instead of M12) and D3.2 *An IT tool for identifying reports of high-risk medical devices* (POLIMI) will be submitted at M34, instead of M30. These minor deviations will be included in a future amendment before the first reporting period.

Public deliverables will be available through the project website. The confidential deliverables, together with all CORE-MD documents, will be shared by e-mail and stored on Clinked. Furthermore, relevant disclosable contents from confidential deliverables or documents will be extracted and published on the website to foster dissemination of project activities.

Milestones mark a significant point in time of the project lifetime. CORE-MD has identified nine such points. These are listed below in Table 9.

Table 9 List of milestones

Milestone	Title	WP number	Date	Lead Beneficiary	Means of verification
MS1	CORE–MD project established	1,2, 3, 4, 5	30/04/2021	ESC	Minutes of kick-off meeting. >80% attendance of task leaders.
MS2	Advisory Committee	1,2,3,4	30/06/2021	EFORT	Appointments made, first meeting held
MS3	Communication tools	1,2,3,4	30/06/2021	ESC	core-md.eu website established.

MS4	Academic collaborations	1,2,3	31/03/2022	LUMC	CORE-MD joint research staff appointed.
MS5	Review of trial methodologies	1	30/09/2022	RCSI	Academic manuscript published.
MS6	Randomised registry trials	2	31/03/2023	ESC	Recommendations published
MS7	Medical device registries	3	30/09/2023	LUMC	Successful pilot of network analysis of national registries
MS8	Hierarchy of evidence	4	30/09/2023	EFORT	Consensus report published.
MS9	CORE–MD recommendations	4	31/03/2024	ESC	Results presented to EU regulators at WG on Clinical Investigation and Evaluation

6.1.1 Deliverable Review and Approval

All deliverables must be submitted for review by consortium partners following the process described hereafter.

The identified Responsible Person should provide a final draft of the deliverable for review **15 calendar days** prior to the deadline. The **Coordination Group** (CG) has the responsibility to check all aspects and provide a quality check within **7 calendar days** prior to release. Comments must be provided to the Responsible Person.

The CG will assess the review. In the case of major comments, the deliverable will be sent back to the Responsible Person for discussion and revision. For minor comments that do not require additional experts' discussion, the Project Coordinator will proceed with the editing.

Approved deliverables will be double checked by the Project Coordinator who will then submit them to EC.

6.2 Periodic reports

The action is divided into two reporting periodic periods (Table 10):

- RP1: from month 1 to month 18
- RP2: from month 19 to month 36

Table 10 Reporting periods

RP n.	From Month	To Month	Start date	End Date
1	1	18	01/04/2021	30/09/2022
2	19	36	01/10/2022	31/03/2024

Periodic reports will be under the responsibility of the Project Coordinator. They will be submitted within 60 days of the end of the reporting periods.
The instructions to complete the forms and templates will be sent by the ESC in due time.

Periodic reports include a **periodic technical report** and a **periodic financial report**.

The **periodic technical report** consists of two parts: Part A and Part B.

Part A is generated by the IT system. It is based on the information entered by the participants through the periodic report and continuous reporting modules of the electronic exchange system in the Participant Portal. The participants can update the information in the continuous reporting module at any time during the life of the project. Part A contains:

- a summary which can be used for publications by the EC, and
- the answers to the questionnaire (covering issues related to the project implementation and the economic and social impact, open access, critical risks, impact tables on communication and dissemination, list of publications, gender, etc.).

Part B is the narrative part and includes:

- an explanation of the work carried out by the beneficiaries.
- an overview of the progress towards the objectives of the action, including milestones and deliverables identified in Annex 1 of the Grant Agreement.
- In case of differences this report needs to address and include explanations of deviations between expected and actually carried out work, in accordance with defined deliverables/ work plan/ use of resources.
- Result exploitation and dissemination needs to be covered.

WP Leaders will be requested to compile a report on their WP together with their Task Leaders and send it to the ESC, which consolidates the provided information and sends the complete periodic technical report to the consortium for review. The final approved version will be uploaded as a PDF document into the Participant Portal by the Project Coordinator.

The **financial report** contains:

- '**individual financial statement' from each beneficiary** and from **each linked third party**, for the reporting period concerned. It includes the eligible costs for each budget category. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period. The individual financial statements of the last reporting period must also detail the receipts of the action (if any).
- an explanation of the use of resources and the information on subcontracting and in-kind contributions provided by third parties from each beneficiary and from each linked third party, for the reporting period concerned.

All beneficiaries must complete their own Financial Statement, e-sign and submit it to the Coordinator. Read the process description and steps on the European Commission's webpages.

6.3 Final report

In addition to the periodic report, for the last reporting period the coordinator must submit the final report within 60 days following the end of the last reporting period. The Final report (month 36) will be released with the contribution of all the project partners.

The Final report includes a **final technical report** and a **final financial report.**

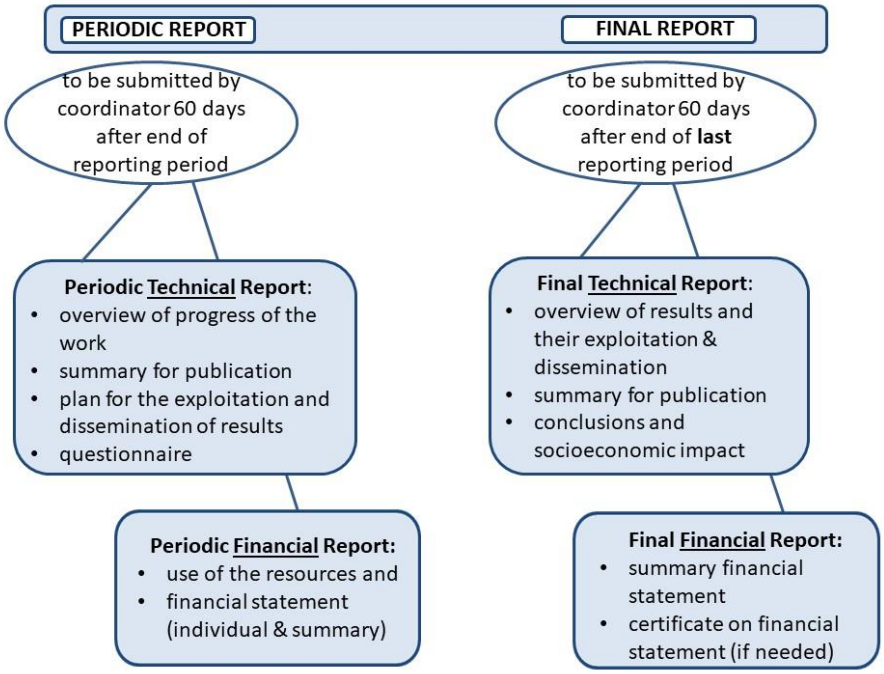
The final technical report includes a summary for publication containing:

- an overview of the results and their exploitation and dissemination,
- the conclusions on the action, and
- the socio-economic impact of the action.

The final financial report contains:

- a 'final summary financial statement', created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance, and
- a 'certificate on the financial statements' (drawn up in accordance with Annex 5 of the Grant Agreement) for each beneficiary and for each linked third party, if it requests a total contribution of EUR 325 000 excluding indirect costs.

Figure 9 Reporting periods and its structure



6.5 Reporting Guidelines

Reports throughout the project lifetime need to be delivered in a timely manner and be of the highest possible quality. This implies two key factors: content and format, both of which will be addressed in the following sections.

This approach will help to gain and maintain a corporate, standard, visual image, and to assist with clear communication and comprehension. It further makes CORE-MD clearly identifiable and allows us to gain presence across the scientific community.

In order to be consistent in our reporting and allow to identify files easily, a number of guidelines are set in place.

Documents

The template foreseen for the deliverables includes an executive summary.

Executive Summary: in one page max. It should give to the reader a view of the content, i.e. the objectives of the document, some hints on the reasoning and indicate the key conclusions.

Text

- Text will always be in **Calibri.** The minimum font size allowed is 11 points;
- Line spacing: single;
- Paragraph: justified;
- Headlines will be in **dark blue** (**Code: 003399)** to match the logos in the header. For headlines please use Heading 1, Heading 2, etc styles;
- General text will be in black using Normal style.

The text must be written, arranged and formatted to be easily read and understood.
Chapter/section numbering should be automatic. A maximum of three levels of paragraph numbering is advised.
The text must be short and pertinent, that means concrete. No statements like: the project should… Say: the project will… Avoid conceptual text.
Avoid sentences like: « we shall… » Instead say: « the project will… » or "the consortium will…"
Important points in a paragraph must be highlighted (using bold or italics) to allow quick identification of the key message by the reader (only a few words in a paragraph should be highlighted; if most of the text is in bold, there is no highlighted message anymore).
Very specialised technical terms must be defined at the first occurrence through, for instance, a footnote at the bottom of the page. If long technical developments or demonstrations are necessary, they must be put in annex with a short summary of the conclusions which the text uses for its message.

Each figure/table must have a caption[4] explaining its content:

- Each figure/table must have a title.
- All Figures/tables must be automatically numbered.
- In case of long tables encompassing more than one page, it is possible to derogate from this rule, if these are self-explanatory. Page numbers should be present in every document in the bottom right-hand corner.

6.5.1 Templates

All documents will be produced using the appropriate CORE-MD templates agreed for the specific purpose.

Deliverables will be released in pdf format and will be compiled using MS Word.

A deliverable template has been recently finalised by the Coordinator, together with a power point template.
The deliverable template has a uniform cover composed of three pages (a cover page containing the project logo, the EU emblem and the deliverable title; the second page featuring the Executive Summary and containing information about editor, authors, and the type and status of deliverable; and the third page giving the table of contents); the end page shows all partners logos, the EU emblem and the funding acknowledgement.

Templates for most standard documents are shared with all consortium members in the collaboration tool Clinked

[4] Captioning is available in MS Word in References/Insert caption

6.5.2 Typing guidelines

The project adopted language is British English. Spelling and punctuation should follow the convention of British English. For ALL punctuation characters, the general rule is therefore: no space before, one space behind. This includes the following: ?; ! :
For titles, the practice is to start the nouns with a capital letter.

7 Project administration and finance

Each partner must — for a period of five years after the payment of the balance, keep records and other supporting documentation in order to prove the proper implementation of the action and the declared costs to be eligible. The documents need to be the original documents. Digital and digitised documents are accepted if national law accepts these documents as originals.

The partners must keep the records and documentation according to their usual cost accounting practices and internal control procedures. There must be a track between the amounts declared, the amounts recorded in accounts and the amounts stated in the supporting documentation (audit trail).

The beneficiaries must keep the records and documentation supporting the costs declared, in particular for personnel costs.

The following documents are available on Clinked, the project collaboration tool (Files > WP5: Project Management > H2020 Rules):

- The **Annotated Model Grant Agreement**.
- A **short summary** of eligible costs and related supporting documents of H2020 projects, together with best practices and auditing procedure.
- A **timesheet template** in excel.
- The document **How to avoid errors when claiming costs in H2020 grants**.

7.1 Timesheets

Beneficiaries claiming personnel costs must till in timesheets on a regular basis.
Timesheets, which need to be kept locally at each partner institution, help to maintain complete records of time worked on the project.

Timesheets should include, as a minimum:

- the title and number of the action, as specified in the GA.
- the beneficiary's full name, as specified in the GA.
- the full name, date and signature of the person working for the action.
- the number of hours worked for the action in the period covered by the time record.
- the supervisor's full name and signature.
- a reference to the action tasks or work packages of Annex 1, to which the person has contributed by the reported working hours.

Information included in timesheets must match records of annual leave, sick leave, other leaves and work-related travel.

Beneficiaries may use their own model, provided that it fulfils the minimum conditions, and it contains at least the information detailed above.

As an exception, for persons working exclusively on the project, there is no need to keep time records, if the beneficiary signs a declaration confirming that the persons concerned have worked exclusively

on the project. The declaration template is available at p.178 of the Annotated Model Grant Agreement (article 18, paragraph 9. Records for personnel costs — Hours worked for the action).

7.2 Payment and budget transfers

7.2.1 Payments

The following types of payments are foreseen:

1. **Pre-financing at the start of the project**:

Pre-financing funds remain EU property until they are 'cleared' against eligible costs accepted by the European Commission.

The actual pre-financing of the project is € 1,770,733.12, corresponding to 75% of total grant amount.

The pre-financing payment was distributed pro-rata per partner by the Coordinator in May/June 2021, after the signature of the consortium agreement and the submission of the financial identification form.

2. **Interim payment**:

After approval of the first periodic report, an interim payment will be issued.

3. **Final payment**:

The final payment will be transferred after the approval of the final report and consists of the difference between the calculated EU contribution (on the basis of the eligible costs) minus the amounts already paid.

7.2.2 Issues related to the costs

When reporting on costs, many errors may be done. Here below a small summary of the most common errors:

Personnel costs

- unreliable or missing timesheets, supporting documents or insufficient alternative evidence.
- incorrect time claimed.
- incorrect calculation of productive hours.
- ineligible remuneration costs included in the calculation of the hourly rates for both actual costs and for average personnel costs.

Subcontracting and other direct costs

- costs without valid supporting documents.

Other direct costs

- lack of adequate supporting documents for other goods and services errors in equipment costs due to no direct measurement of the costs.
- travel costs not related to the action or missing supporting documents.

In case of questions or doubts, partners are kindly recommended to:

1. check the **CORE-MD Grant Agreement**.
2. carefully read the Annotated Model Grant Agreement.

3. visit the **Participant Portal** (Online Manual & FAQs).
4. consult the Coordinator.

The Coordinator can consult the Project Officers at HaDEA.

8 Quality, Ethics and Risk Management

8.1 Risk Management Plan

Throughout the Project a **Risk Register** (Table 11) will be maintained and revised whenever needed and at least each year and reported in a specific section of the periodic report. Each WP Leader will be responsible for continuously identifying, monitoring internal and external risks for the project, informing the Risk & Data Manager and the Project Coordinator, implementing the control and mitigation actions. In case of risks that concern more WPs, the involved WP Leaders will agree on the assessment and in the definition and assignment for controls and mitigation actions.

Table 11 Risk Register

Risk Number	Description of Risk	WP	Proposed risk-mitigation measures
1	**Dispute/s in the consortium** *Probability: low.* *Severity: high*	All	Proposed mitigation measures (M): Maintain close contacts with all partners. WP leaders to report any disagreement within a WP to the project coordinator. Contingency measures (C): Project coordinator to potentially take action if there is a risk for the disagreement to escalate and threaten the delivery of the work plan. Conflict resolution procedures described in the Consortium Agreement will be strictly implemented by the PB.
2	**Partner/s leaving the consortium** *Probability: low* *Severity: high*	All	Proposed mitigation measures (M): CORE-MD partners are committed to the project's work plan and have been closely working with each other well ahead of this call to shape a strong and ambitious project, making it unlikely that one partner would leave the consortium. All partners have received the support of their leadership to engage fully in the CORE-MD work plan. Contingency measures (C): The PB will discuss with the leaving partner to try to identify other potential partner to take over the leaving partner's tasks, outside the consortium. In case of failing to identify a replacing partner outside the consortium, or if the project is so advanced that it would be difficult to any new comer to take over, all pending tasks will be reassigned to the most relevant internal CORE-MD partners. External consulting will be used to guarantee the expected quality level of deliverables.
3	**Delivery delays** *Probability: low.* *Severity: high*	All	Proposed mitigation measures (M): The governance structure and work plan will allow to closely monitor progress and anticipate any potential delay in the delivery of the work plan. Contingency measures (C): Intensification of effort/mobilisation of extra resources in areas lagging

			behind will be required from concerned partners, with the PB potentially re-arranging workload if deemed necessary.
4	**Lack of synergies between relevant stakeholders** *Probability: low* *Severity: high*	All	Proposed mitigation measures (M): Consortium partners have been selected and grouped according to shared interests and in many cases pre-existing collaborations. Contingency measures (C): In order to ensure coordination, synergies and complementarities, bi-annual meetings of the Project Board and monthly conference calls of the Project Coordinator with WP leaders to discuss and manage any risks which might emerge and, in cooperation with partners, decisions to be taken on the related mitigation actions needed.
5	**Lack of awareness of the initiative** *Probability: low* *Severity: high*	All	Proposed mitigation measures (M): A strong dissemination plan will be agreed by all partners, based on the proposed plan in this application. All CORE-MD partners are involved in the dissemination plan. The support of the European Commission will be sought early on in the project to increase chances of awareness among all relevant stakeholders. Contingency measures (C): WP4 leader and partners, with project coordinator, will revise the dissemination plan with intensification or strategic reallocation of effort, including the mobilisation of partners with wide dissemination potential, increase number of events/conferences/publications within allocated budget, seek support of key partners to disseminate to their peers, etc.
6	**Limited engagement by external third parties** *Probability: moderate* *Severity: low*	Task 2.1	Proposed mitigation measures (M): Manufacturers, industry trade associations, notified bodies and national regulatory agencies are overcommitted due to the exigencies of the COVID-19 pandemic; their capacity to participate in CORE-MD tasks may be limited, but all have indicated willingness in principle. Contingency measures (C): Tasks will be led by academic and medical professional partners. All recommendations will be open to consultation, and deliverables will focus on evidence and policies. Implementation by regulators and manufacturers will not be time-limited.
7	**Access to clinical data from new devices** *Probability: moderate* *Severity: moderate*	Task 3.3	Proposed mitigation measures (M): Because this task concerns the clinical evaluation of new and prototype devices, technical or manufacturing or preclinical testing issues might reduce the number of devices ready to be evaluated in this task. Contingency measures (C): Lessons can be learned and reported concerning the relevance of the IDEAL framework to the early evaluation of new high-risk devices, even if only one device can be evaluated.

8	**Limited access to data from notified bodies** P*robability: low.* *Severity: high.*	WP4	Proposed mitigation measures (M): Consortium partner Team-NB has approved this task and nominated staff from individual notified bodies have agreed to collect data. Contingency measures (C): Data will be reported in de-identified and anonymous form so that notified bodies can maintain their duty of confidentiality. If limited data are produced the task will report on methods and practice of conditional approvals from other regulatory jurisdictions.

8.3 Ethics

The following ethics deliverables will be submitted by the Coordinator, with the support of the project partners.

Table 12 Ethics Deliverables

Del	Title	Description	Lead Ben	Date
D6.1	POPD Requirement No. 1 *(Confidential)*	1. A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable. 2. In case of further processing of previously collected personal data, an explicit confirmation that the applicant has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be submitted as a deliverable. 3. The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be submitted as a deliverable.	ESC	31/03/2022
D6.2	GEN Requirement No. 2 *(Confidential)*	Regular reports from the "Ethics Committee" must be submitted as a deliverable (along with the periodic reports).	ESC	31/03/2022
D6.3	H Requirement No. 3 *(Confidential)*	1. The procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable. 2. The informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable.	ESC	31/03/2022

		3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file and submitted upon request (to be specified in the Grant Agreement). 4. Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans must be kept on file and submitted upon request (to be specified in the Grant Agreement).		

9 The Consortium Members

The European Society of Cardiology

Prof. Dr. Alan Fraser, Past Chair, Regulatory Affairs Committee at the ESC. Alan Fraser studied medicine at Edinburgh University and trained in internal medicine and cardiology in Scotland and Wales, with a research fellowship at the Thoraxcenter, Erasmus University, Rotterdam. He is Emeritus Professor of Cardiology at Cardiff University, Consultant Cardiologist at the University Hospital of Wales, and Guest Professor in Cardiovascular Imaging and Dynamics at the Katholieke University Leuven and Chair of the Task Force on Regulatory Affairs and Medical Devices at the Biomedical Alliance in Europe. His major research interests include heart valve disease (the Cardiff Embolic Risk Factor Study), the early diagnosis of myocardial dysfunction, quantitative stress echocardiography (MYDISE), myocardial velocity imaging, largeartery function (the ETIC study), ventricular-arterial coupling (using wave intensity), and the pathophysiology of heart failure with normal ejection fraction (MEDIA, EU Framework 7).

Prof. Dr. Piotr Szymański, Chair, Regulatory Affairs Committee, European Society of Cardiology; Professor and Director of Research, Institute of Cardiology, Warsaw (PL).Piotr Szymanski is Consultant Cardiologist and a Research Director at the Institute of Cardiology, Warsaw, Poland. He is a member of the Transparency Council – an advisory body to the Polish Agency for Health Technology Assessment. His expertise is imaging in structural heart interventions and grown-up congenital heart diseases, and his research interests include heart valve disease and congenital heart disease.

Prof. Dr. Chris Gale, Professor of Cardiovascular Medicine, Honorary Consultant Cardiologist, and Co- Director of the Leeds Institute for Data Analytics at the University of Leeds. His clinical interests are general cardiology and chronic heart failure. He is a practising Clinical Cardiologist with interests in general cardiology, post-myocardial infarction survivorship, and chronic heart failure. His research incorporates the efficient use of observational and randomised data to deliver population-based studiesof cardiovascular quality of care and clinical outcomes.

Christina Dimopoulou, certified European Project Manager and has been actively engaged in the European Affairs field since 2011 with specific expertise in managing Horizon 2020 projects. She is also beingengaged as a policy advisor advocating for cardiovascular health at EU level. She has graduated from the University of Political Sciences and International Relations in Athens and the Universite Louvain La Neuve receiving BSc and MSc degrees in European studies and European policies.

Cinzia Ceccarelli, EU Projects Manager with over 10 years of experience in managing EU-funded research and innovation projects. Prior to joining the ESC, she was H2020 Project Manager at the EMF-ECBC. From 2015 to 2017 she was Research Officer at Ca' Foscari University of Venice, supporting the access to competitive research funding. From 2011 to 2015, she worked as Project Manager at Fondazione Politecnico di Milano, where she was involved in FP7 projects.

Polyxeni Vairami, EU Projects Officer for euCanSHare BigData@Heart , BETA 3_LVH, TO-AITION, CORE-MD at the ESC. Prior to this, she was working on the impact assessment of EU projects at Deloitte Belgium. She holds a BA in Political Science from Panteion University in Athens, an MA in European Studies and an MSc in Economics from KU Leuven University.

Anett Ruszanov, Project manager with almost seventeen years' work experience in Brussels. She has proven track record in regional research and innovation policy, particularly in the digital healthcare and active and healthy ageing field. Anett has extensive experience with member-based networks, in providing services to members and managing membership relations. She has the background in European studies and project management. Anett was managing European projects for than eleven years at the European Regions Research and Innovation Network (ERRIN). Prior, she was heading a regional office and worked for Business Hungary for four years.

European Federation of the National Associations of Orthopaedics and Traumatology (EFORT)

Prof. Rob G.H.H. Nelissen, MD, PhD is trained as orthopaedic surgeon, did a total joint fellowship (USA). He did a PhD on methodological aspects of arthroplasty research. Since 2005 he is professor/chair department of Orthopaedics, Rehabilitation, Physiotherapy at Leiden University Medical Center. He also is Medical Delta professor at Technical University of Delft (2016). He is the co-founder, current chairman of the Dutch Arthroplasty Register (LROI) which is the third largest implant registry worldwide, former president (2016 - 2018) of the Netherlands Orthopaedic Association (NOV) and chairman of NORE (Network Orthopaedic Registries of Europe) an EFORT committee.

Ass. Prof. Per Kjaersgaard-Andersen joined EFORT in 2007 as a co-opted member to the Executive Committee, being the Secretary General during 2012-2016 and next President during 2018-2019. He had a fellowship in Joint Replacement in New Orleans in 1989 and later in Indianapolis in 1991.Prof Kjaersgaard-Andersen is Associate Professor in Orthopaedic Surgery at University of Southern Denmark.He is heading the Section for Hip and Knee Replacement, Department of Orthopaedics, Vejle Hospital, Denmark.

Adrian Ott is the Chief Executive Officer of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) which he joined in 2010. In his current position his focus is the strategic alignment of EFORT activities towards its mission & vision among which, raising the organisation's profile in priority within the European health agenda in the area of musculoskeletal health. Adrian holds a Bachelor of Science HES-SO in Tourism Management of the University of Applied Sciences ofWestern Switzerland.

Biomedical Alliance

Prof.Elizabeth Macintyre, Chair, Working Group on In-Vitro Diagnostics at the BioMed Alliance. Elizabeth Macintyre did her medical and hematology specialist training in the UK (FRCP, FRCPath and MD), her PhD in Paris and a Post-Doctoral period at Harvard. She is Professor of Hematology and vice-president of international affairs at Université de Paris and president of the European Hematology Association (2021-23). Her research interests are T lymphoid malignancies and molecular diagnostics..

Prof. Dr. Alan Fraser (M), Past Chair, Regulatory Affairs Committee at the ESC. Alan Fraser studied medicine at Edinburgh University and trained in internal medicine and cardiology in Scotland and Wales, with a research fellowship at the Thoraxcenter, Erasmus University, Rotterdam. He is Emeritus Professor of Cardiology at Cardiff University, Consultant Cardiologist at the University Hospital of Wales, and Guest Professor in Cardiovascular Imaging and Dynamics at the Katholieke University Leuven and Chair of the Task Force on Regulatory Affairs and Medical Devices at the Biomedical Alliance in Europe. His major research interests include heart valve disease (the Cardiff Embolic Risk Factor Study), the early diagnosis of myocardial dysfunction, quantitative stress echocardiography (MYDISE), myocardial velocity imaging, large artery function (the ETIC study), ventricular-arterial coupling (using wave intensity), and the pathophysiology of heart failure with normal ejection fraction (MEDIA, EU Framework 7).

Loredana Simulescu has been working in EU public affairs since 2009, with a successful track record ofcommunication and advocacy campaigns in a range of policy areas. Since 2014, Ms Simulescu has designed and implemented policy and communication strategies for the BioMed Alliance. Ms. Simulescu coordinates task forces activities, ensures members priorities are reflected in the Biomed Alliance's work and oversees the implementation of various actions.

Marieke Meijer has experience in working with EU health policy, research policy and digital policies. Ms. Meijer's background is in European affairs and international relations. Ms. Meijer is responsible for communications and policy activities, and she coordinates the organization of a series of meetings and events.

European Academy of Paediatrics

Prof. **Berthold Koletzko** will act as co-ordinator of EAP's contribution in his Berthold Koletzko is Professor of Paediatric at LMU Univ. of Munich, Germany. He has ample and successful experience in EU funded collaborative projects as current coordinator of 3 Erasmus+ Capacity Building projects and partner in 2 Horizon 2020 projects, and past coordinator of an ERC Advanced Grant and 4 EU framework programme projects. He is author of 1035 journal articles 224 book chapters, 40 books/monographies and co.-inventor of three patents.

Assoc. Prof. Adamos Hadjipanayis is Assoc. Professor of Paediatrics, Faculty of Medicine, European University Cyprus and head of the Dept. Paediatrics at Larnaca General Hospital, Cyprus. He was trained in paediatricsat St. Sophia Children ' s Hospital, Athens University Medical School, and in Paediatric Nephrology at Children's Hospital of Philadelphia, Pennsylvania, USA. He is member of the Steering Committee of EAPRASnet and an active partner in many European research projects including Use and abuse of antibiotics in URTI, Task-Force in Europe for Drug Development for the Young, Registration of rare infectious diseases, Epilepsy in children with Cerebral palsy, MOCHA, DEMOCOPHES and SINPHONIE.

Guest Prof. Ann de Guchtenaere is Guest Professor of Paediatrics at the Dept. of Paediatrics and Medical Genetics, Ghent University, Belgium and Chair of the Dept. Paediatrics, Zeepreventorium, De Haan, Belgium. She serves as vice-president of the Belgian Academy of Paediatrics and active partner of the Conect for Children, a novel collaboration of 33 academic and 10 industry partners from 20 European countries aiming at promoting European clinical trials for children.

Martina Scheer, B Eng will act as Project Manager and assist Prof. Koletzko in the management of project activities and tasks. Martina Scheer has ample experience in successfully supporting coordination and management as well as financial organisation of numerous research projects including EU framework Erasmus+ and ERC projects.

Dr. Hans Demmelmair, MSc will provide research support and assist in performing data collection and review for the paediatric aspects of the project. Dr. Demmelmair has successfully performed paediatricresearch since 1993. He is a co-author of 220 journal articles with an H-index of 42.

European Patients Forum

Kaisa Immonen, Director of Policy leads EPF's policy team. Personal interests include patient empowerment and involvement in healthcare improvement, patient safety and health literacy. Co-chair of the EMA PCWP since 2016. Member of OECD PaRIS advisory group and the BMJ Patient Panel.

Katie Gallagher, Senior Policy Advisor is specifically responsible for EPF's strategy on universal access to healthcare. She is in addition specifically responsible for EPF activities relating to medical devices, access to care and services, non-discrimination and social policy.

Valentina Strammiello is Head of Programmes. She is in charge of overseeing the EPF Project Portfolio. She represents EPF in HTA-related debates and fora. She is vice chair of the HTAi Patient and Citizen Involvement Interest Group and member of the Scientific Advisory Board at Vall d'Hebron Institute of Research.

Hannes Jarke is a Project Coordinator at EPF. He has extensive experience in managing large-scale and international research projects, particularly randomised controlled trials. His work and educational background are primarily in public health and behavioural sciences.

Dante Di Iulio , Communications Manager, has a strong track record as a communication expert. Dante's expertise lays in crafting consistent and compelling narratives for brands and managing teams to ensure timeliness and accountability.

Juan Jose Fernandez Romero, EPF's Policy Assistant. He is in charge of regularly monitoring of intelligence and updates on policy developments, carrying out background research for EPF's policy briefs and position statements, and assisting the policy team on membership issues. He has a background in European policies and public affairs.

Academisch Ziekenhuis Leiden (Leiden University Medical Center)

Prof Dr Ewout W. Steyerberg, PhD, professor of Clinical Biostatistics and Medical Decision Making at Leiden University Medical Center and Erasmus MC (Rotterdam, the Netherlands). He has been chairing the department of Biomedical Data Sciences since 2017. He was a Fellow of the Royal Netherlands Society for Arts and Sciences (KNAW). He spent sabbaticals at

Duke University (Durham, NC: 1996) and Harvard University (Boston, MA: 2003 and 2005).

Dr. Perla J. Marang-van de Mheen, PhD,epidemiologist with interest in quality of care and outcomes research, with a special focus on methodology. Her research focuses on measurement and evaluation of quality of care, health care performance or improvement, conducted in various clinical areas and multi-centre settings. She has extensive experience using routinely collected data e.g. arthroplasty registries.

Prof. Rob G.H.H. Nelissen, MD, PhD, trained as orthopaedic surgeon, did a total joint fellowship (USA). He did a PhD on methodological aspects of arthroplasty research. Since 2005 has bee a professor/chair at the department of Orthopaedics, Rehabilitation, Physiotherapy at Leiden University Medical Center. He also is Medical Delta professor at Technical University of Delft (2016). He is the co-founder, current chairman of the Dutch Arthroplasty Register (LROI) which is the third largest implant registry worldwide, former president (2016 - 2018) of the Netherlands Orthopaedic Association (NOV) and chairman of NORE (Network Orthopaedic Registries of Europe) an EFORT committee.

Lotje A. Hoogervorst, MD, medical doctor from the Netherlands with clinical work experience in orthopedics. Currently associated as a PhD candidate with the Department of Orthopaedics and Biomedical Data Science, Medical Decision Making at Leiden University Medical Centre.

Bas Penning de Vries, PhD candidate at the department of Clinical Epidemiology of Leiden University Medical Center (LUMC). Originally trained as a clinician, Bas pursued his Master's degree in epidemiology with a specialization in medical statistics at Utrecht University, The Netherlands. As a PhD candidate at the LUMC, he published on various topics relating to three key methodological obstacles in causal inference: missing data, confounding and measurement error. His current research interests lie with the methodological and statistical aspects of epidemiological research, particularly where they relate to causal inference.

The Chancellor, Masters and Scholars of the University of Oxford

Prof. Peter McCulloch, Professor of Surgical Science & Practice at Oxford University and Chairof the IDEAL Collaboration, an international network of scientists and clinicians dedicated to developing bettermethodology for evaluating surgery and other complex treatments. He trained and practised in surgical oncology and Upper GI surgery. He is Director of the Patient Safety Academy in Oxford and lead for the associated research

group, QRSTU. He is also Deputy Director of the Oxford Surgical and Interventional Trials Unit (SITU). He has authored approximately 200 peer-reviewed articles (h index 53).

Prof. Martin Landray, Professor of Medicine and Epidemiology at Oxford University; ResearchDirector, Health Data Research UK; Acting Director, Big Data Institute; Lead, Big Data & Computing Innovation, MRC Population Health Research Unit; Lead, Clinical Informatics & Big Data, NIHR Oxford.Biomedical Research Centre; Lead, Health Informatics Hub, UK Biobank; Honorary Consultant Physician, Oxford University Hospitals NHS Foundation Trust; Member of the Regulatory Affairs Committee and Nucleus Committee Members of the Digital Health Committee at the European Society of Cardiology.Prof Landray's work seeks to further understanding of the determinants of common diseases through the design, conduct and analysis of efficient, large-scale clinical trials and prospective cohort studies (including UK Biobank). He has led a series of major clinical trials assessing treatments for cardiovascular and kidney disease. These have enrolled over 65,000 individuals, producing results that have changed regulatory drug approvals, influenced clinical guidelines and changed prescribing practice to the benefit of patients.

Prof.Daniel Prieto Alhambra, Professor of Pharmaco- and Device Epidemiology at Oxford University. Prof Prieto Alhambra is an epidemiologist using routinely collected health data to generate reliable evidencefor improved patient care here at the Centre for Statistics in Medicine in NDORMS.Through an NIHR Senior Research Fellowship, he is investigating the use, safety, effectiveness and cost ofdrugs and devices as used in usual practice conditions and amongst older people with complex health needs. Prof Prieto Alhambra leads Pharmaco- and Device Epidemiology research at NDORMS, and has experience designing, analysing and interpreting electronic medical records from around the world. He has worked on databases like the United Kingdom's CPRD (formerly GPRD), Spain's SIDIAP Database, Denmark's Danish Health Registries, Italy's HSD, and the Netherlands' IPCI (Netherlands).

Allison Hirst, Co-ordinator of the IDEA Collaboration for the last 7 years. She is responsiblefor organising meetings and maintaining the web and social media presence of the Collaboration, but is also an active participant in the academic work of the group and author on several recent major publications. She has a long track record in clinical research methodology in Oxford, having previously worked on the CONSORT team and EQUATOR.

Region Uppsala

Prof. Stefan James, chair professor of Cardiology at the faculty of medicine Uppsala University and is a senior interventional Cardiologist at the department of Cardiology at the Uppsala University hospital. He

serves as scientific director of Uppsala Clinical Research Center. Stefan James has served as PI on steering committees for numerous international trials in cardiology and has pioneered the concept of registry based randomized clinical trials.

Dr. Sergio Buccheri, consultant and interventional cardiologist at the Uppsala University Hospital and serves a researcher at Uppsala Clinical Research Center. Sergio Buccheri conducts clinical research using the infrastructure of large registries of cardiovascular care in Sweden.

Royal College of Surgeons in Ireland

Robert A. Byrne, Professor of Cardiovascular Research at RCSI University of Medicine and Health Sciences and Director of Cardiology at Mater Private Network, 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.

Fergal J. O'Brien, Director of Research & Innovation, Professor of Bioengineering & Regenerative Medicine, Head of the Tissue Engineering Research Group in RCSI and Deputy Director of the Advanced Materials & Bioengineering Research Centre (AMBER). He is a leading innovator in the development of advanced biomaterials for the repair of bone, cartilage, skin, respiratory, neural and other tissues. His research has seen numerous patent filings, formation of an RCSI spin-out company and translation of technologies for bone and cartilage repair to the clinic. He is a recipient of numerous prestigious awards including a €3million Advanced Grant from the European Research Council (2018). He is a Fellow of Engineers Ireland (2013), the Anatomical Society (2014), and the European Alliance for Medical & Biological Engineering Science (2017). He is a Silver Medal recipient from the Royal Academy of Medicine in Ireland, and was elected to Membership of the Royal Irish Academy in 2018.

Amy Carswell, Manager of the Cardiovascular Research Institute Dublin, a joint collaboration between RCSI University of Medicine and Health Sciences and Mater Private Network, Dublin, Ireland. Ms Carswell graduated from the Dublin Institute of Technology and completed her MSc in Leadership at the RCSI, Institute of Leadership, Dublin, Ireland. Ms Carswell has over 15 years' experience working in healthcare.

Insel Gruppe Ag (University Hospital Bern)

Prof. Stephan Windecker, full Professor and Chairman of the Department of Cardiology at Bern University Hospital, Inselspital. His research interests are clinical trials with focus on interventions for the treatment of coronary artery disease and valvular heart disease.

Dr Georgios Siontis,attending physician in the Department of Cardiology, University Hospital of Bern. Dr Siontis has worked in the fields of evidence-based medicine, clinical epidemiology and statistics. Dr Siontis has a strong interest in large-scale evidence, in applying new research methods and in appraisal and control of diverse biases in biomedical research.

Prof. Christoph Stettler, full Professor and chairman of the Department of Diabetology, Endocrinology,Nutritional Medicine and Metabolism at the Bern University Hospital. Prof Stettler is an endocrinologist with a longstanding track-record in diabetes research, including epidemiology, metabolic research and technology-oriented approaches. He is principal investigator of several projects focusing on the use artificial intelligence and computational modelling for real-time clinical decision making.

Prof. Lia Bally,Head of Research within the Department of Diabetes, Endocrinology, Nutritional Medicine and Metabolism at the Bern University Hospital. She is an endocrinologist and has strong scientific interest in medical-device clinical trials for the management of diabetes in inpatient and outpatient settings. She is principal investigator of various multi-national randomized clinical trials assessing the efficacy, safety and utility of novel automated-insulin delivery systems (closed-loop/artificial pancreas systems).

Prof. Anne Lübbeke-Wolff, working at the Geneva University Hospitals in the Division of Orthopaedic Surgery & Traumatology. Since 2018 she is Visiting Professor at the University of Oxford. She is a clinical researcher and epidemiologist specialized in joint replacement, device epidemiology, registry research, and patient-reported outcomes.

Dr. Arjola Bano, postdoctoral researcher at the Department of Cardiology, Bern University Hospital and Institute of Social and Preventive Medicine, University of Bern. She obtained the title of Privat Docentin (PD) from the University of Bern, and the PhD degree, Doctor of Science (DSc) and Master of Science (MSc) degrees in Clinical Epidemiology from Erasmus University Rotterdam. She is also a medical doctor specialized in Internal Medicine. Her research aim is to provide novel insights on cardiometabolic health,

using epidemiological approaches.

Dr. James A Smith, working at the Botnar Research Centre, Nuffield Orthopaedic Centre, University of Oxford. He is a postdoctoral scientist with an interest in meta-research and medical devices.

Katholieke Universiteit Leuven

Prof. Frank E. Rademakers (M), MD, PhD, emeritus professor at KU Leuven. He is a cardiologist who has worked in the University Hospital Antwerp and since 1998 in University Hospital Leuven. He has spent 2.5 years at Johns Hopkins University for his PhD on function and imaging of the heart with magnetic resonance. He was in the management of the hospital first as CMO until 2014 and until 2020 as CMTO, responsible for diagnostic departments, pharmacy, biobanking, IT and innovation, maintaining the connection with external industrial and startup partners. He was also responsible for the steering committee on GDPR and a member of the Medical Device and Medical Pharmaceutical Committee of the hospital.

Prof. Anton Vedder (M), Ph.D., professor of IT-Law at the KU Leuven Centre for IT and IP Law (CiTiP) since 2014. Prof. Vedder is especially interested in the interplay of technological developments and the conceptualization of basic moral and legal notions. Recent publications include articles and books on trust in e-health; innovative technologies, care, enhancement, and justice; privacy, data protection, and profiling; ethics of artificial intelligence in a big data environment.

Elisabetta Biasin,researcher in law at the KU Leuven Centre for IT and IP Law (CiTiP). She is involved in several EU funded eHealth projects (including In Silico World, CORE-MD, PharmaLedger). Her research focuses on privacy, data protection, cybersecurity, medical devices and health law, as applied to healthcare AI and in silico technologies.

Erik Kamenjasevic , LL.M., doctoral researcher in law and ethics at KU Leuven Centre for IT & IP Law (CiTiP). Previously he worked at the Court of Justice of the European Union and EFTA Court. Erik's research focuses on the legal and ethical aspects of emerging technologies applied within the e-health sector. In particular, he is interested in legal and ethical aspects of novel human enhancement technologies, healthcare cybersecurity, regulation of medical devices, AI in healthcare, and open source hardware/software healthcare solutions.

Prof. Jan D'hooge, PhD, received the M.Sc. and Ph.D. degrees in physics at the KU Leuven – University of Leuven. His dissertation studied the interaction of ultrasonic waves and biological tissues by means of computer simulation. He subsequently worked as a post-doctoral researcher at the Medical Imaging Computing (MIC) laboratory of the department of electrical engineering of the KU Leuven – University of Leuven. As from 2006, he was appointed an associate professorship in the department of cardiovascular sciences of the medical faculty and in 2014 he became a full professor. In 2019, he was awarded the IEEE Ultrasonics Hellmuth Hertz Award for his contributions to the field of ultrasonics. For the last few years, his team developed AI-based software solutions to automate the extraction of biomarkers from cardiac (ultrasound) images as well as to help interpret these biomarkers for computer-aided diagnosis. In this way, he got acquainted with AI-based medical software solutions.

UMIT - Private Universität für Gesundheitswissenschaften, Medizinischeinformatik und Technik GmbH (University for Health Sciences, Medical Informatics and Technology, Hall in Tirol, Austria)

Dr.rer. medic, Dipl.-Biol. Petra Schnell-Inderst, MPH, Senior Scientist and the Head of the Program on Health Technology Assessment at the Department of Public Health, Health Services Research and Health Technology Assessment. She participates in EUnetHTA Joint Actions since 2010, was Principal Investigator of the Clinical Effectiveness Domain of EUnetHTA's HTA core model and first author of the methodological guideline of therapeutic medical devices. With Prof. Siebert she was work package leader in the EU-project MedtecHTA (http://www.medtechta.eu/), which improved the HTA framework for medical devices for the WP on comparative effectiveness. She took an active role in using synergies and initiate collaboration between these different EU projects and initiated exchange with other HTA framework projects including also ethical, social and legal aspects such as INTEGRATE-HTA (http://www.integrate- hta.eu/)..

Felicitas Kühne, Msc, Senior Scientist at the Institute of Public Health, Medical Decision Making and Health Technology Assessment at UMIT - University for Health Sciences, Medical Informatics and Technology in Hall in Tirol, Austria. She is leading the Program on Causal Inference in Science at the Department, and is the Coordinator of the HTADS course "Causal Inference in Observational Studies and Clinical Trials Affected by Treatment Switching: A Practical Hands-on Workshop". Her research focuses developing, combining and applying methods from decision science, causal inference, epidemiology and artificial intelligence within the framework of decision analysis, HTA, and outcomes research.

Prof. Dr. Daniela Schmid, Head of the Division for Quantitative Methods in Public Health and Health Services Research at the Institute of Public Health, Medical Decision Making and Health Technology Assessment at UMIT – University for Health Sciences, Medical Informatics and Technology in Hall i. T., Austria. Prof. Schmid earned a M.Sc. in Epidemiology from Ludwig Maximilian University Munich, a Ph.D. in Nutrition from Technical University of Munich, and a habilitationin Epidemiology and Preventive Medicine from University of Regensburg. She has held visiting appointments at the T.H. Chan Harvard School of Public Health, Boston and School of Food and Nutritional Sciences, Cork. Her research focus is on systematic reviews, meta-analyses and the development and application of statistical modelling for epidemiological and clinical questions, and the development and implementation of targeted risk reduction programs for chronic disease prevention.

Prof. Uwe Siebert , MD, MPH, MSc, ScD, Professor of Public Health and HTA (UMIT) and Adjunct Professor for Health Policy and Management (Harvard University). He is also Director of the Cardiovascular Research Program at the Institute for Technology Assessment at Massachusetts General Hospital, Harvard Medical School in Boston, USA. He has a broad background in medicine and public health including health decision science, health economics and health technology assessment. He is the Past-President of the Society for Medical Decision Making (SMDM) and his research interests include applying evidence-based quantitative and translational methods from public health, epidemiology, artificial intelligence, comparative effectiveness research, health services and outcomes research, economic evaluation and decision sciences in the framework of health technology assessments (HTA) as well as in the clinical context of routine health care. His current substantive research focuses on cardiovascular disease, cancer, diabetes, hepatitis C, metabolic disorders, neurological disorders, and others.

Göteborgs Universitet (Gothenburg University)

Prof. Ola Rolfson, Head of Orthopaedics at Institute of Clinical Sciences, consultant orthopaedic surgeon at Sahlgrenska University Hospital, Director of the Swedish Arthroplasty Register, and current President of the International Society for Arthroplasty Registries. In clinical practice and research, he focuses on joint replacement surgery.

Politecnico di Milano

Prof. Enrico Caiani, Associate Professor of eHealth and Biomedical Engineering, with National Certification for Full Professorship. MS in Electronic Eng. (1996), PhD in Biomedical Eng. (2000). In 2000 and 2003, Visiting Research Fellow at the University of Chicago, USA. His current research interests are in the field of regulatory science, medical technology and digital health, biomedical signal and image processing, space physiology, health geomatics.

Lorenzo Gianquintieri. MS in Biomedical Engineering (2017), PhD candidate at Politecnico di Milano with an interdepartmental scholarship oriented to Health-Geomatics applied to emergency service data. Since 2019, official tutor of "eHealth: Applications" class. His research interests include data analytics and decision-making support tools.

Health Products Regulatory Authority (Dublin)

Dr Tom Melvin is clinical manager and part of the high-level management team of medical devices at the HPRA. Prior to this, Tom worked for the HPRA as a medical officer in medical devices. Tom holds a degree in medicine, from the Royal College of Surgeons in Ireland, in addition to a degree and masters in law from University College Dublin. Tom is Co-Chair of the Clinical Investigation and Evaluation Working Group, and in addition to chairing, Tom has led a number of taskforces at CIE, and a number of other Working Groups and European Taskforces.

Dr. Ria Mahon is a Medical Officer at the HPRA and has regulatory experience in both medicines and medical device regulations. Ria has experience working in vigilance, post market monitoring, clinical investigations and compassionate use applications. Prior to working in regulatory medicine she worked in hospital medicine in the area of Medicine of the Elderly.

Dr Michèle Meagher is a Medical Officer in the HPRA. She is a member of the Royal College of Physicians of Ireland in the Faculty of Medicine. Michèle e has a degree in Medicine from University College Cork as well as a degree in Science (Pharmacology) from University College Dublin. Michèle is a member of the Clinical Investigation and Evaluation Working Group and the *In-Vitro* Diagnostics working group.

Dr. Gearóid McGauran is a Medical Officer in the HPRA, with background training in general paediatrics and neonatology. He is a Member of the Royal College of Physicians of Ireland in the Faculty of Paediatrics. Gearóid has a degree in medicine from University College Dublin, and a master's degree in advanced healthcare practice and research from the National University of Ireland, Galway. Gearóid is also a member of the Clinical Investigation and Evaluation Working Group.

Laegemiddelstyrelsen (Danish Medicines Agency, Copenhagen)

Thomas Wejs Møller, Head of Division for Medical Devices, Danish Medicines Agency. He holds a master's degree in political science. Thomas is an experienced manager in the public sector and has achieved good results with strategy, efficiency and management projects in health care. Thomas works with the Danish healthcare sector, medtech industry and Patient-NGOs to secure patient safety.

Ann-Sofie Sonne Holm-Schou, has a Master of Science in public health and a PhD in health and medical science. Ann-Sofie has a high degree of experience working with register data and statistical analysis. As a Scientific Officer in the Danish Medicines Agency, she has experience in regulatory work and various market surveillance projects in relation to medical devices.

Urzad Rejestracji Produktow Leczniczych, Wyrobow Medzycznych i Produktow Biobojczych (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Warsaw)

Dr Jan Szulc, Deputy Director of the Department of Information on Medical Devices at URPL. He is responsible for the management of the Department and for the coordination of the MDR and IVDR implementation in Poland. Prior to this, he worked as Lawyer in a leading law firm in Warsaw, where hiskey client was the biggest in Poland association of medical devices companies, and at the Polish Ministry of Health as a lawyer. Dr Szulc graduated in Law from the University of Silesia in Katowice in 2010. Hespecialised in pharmaceutical law with the PhD thesis "Permission to operate a public community pharmacy"

Rijksinstituut Voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment, Bilthoven, the Netherlands)

Robert Geertsma is a senior scientist at the Dutch National Institute for Public Health and the Environment (RIVM), where he has worked for more than twenty-five years. He researches and provides scientific advice to regulators on quality and safety of medical technologies. His areas of expertise include regulatory frameworks, risk management, biological and clinical evaluation, medical implants, nanotechnology and emerging medical technologies. He participates actively in multiple European and international regulatory and standards committees/working groups in these areas. He is a co-chair of the

European Commission's MDCG WG on New Technologies in medical devices.

Dr. Jantine van Baal is a senior biomedical scientist and project leader working for 4 years at the Dutch National Institute for Public Health and the Environment (RIVM). She advices several regulators on various medical technologies. This includes market surveillance studies, analyzing scientific literature on clinical outcomes, performance and safety data. Before she started working at RIVM, she worked as a senior scientist at the University Medical Center of Utrecht (the Netherlands) and as a post-doc at the University of Illinois at Chicago (USA). She holds a PhD in Medicine from the University of Amsterdam (The Netherlands).

Jeroen Pennings, bioinformatician with a broad expertise in responses to chemical substances or disease. He obtained his doctorate on molecular microbiological research at the Radboud University, Nijmegen. During two postdoctoral positions at the same university, he further specialized in genomics and bioinformatics. Since 2001, he has been working as a bioinformatician at RIVM. There, he performs, supervises and teaches data analyses on various projects, with recurrent themes being toxicology, infectious diseases, lifestyle, aging, perinatal screening, and disease mechanisms and biomarkers. He also advises policymakers how best to implement results or analytic approaches in future policy. He has ample experience with multidisciplinary data (meta)analysis, integration, and prediction modelling.

Joëlle Hoebert is a senior scientist and project leader working for 8 years at the Dutch National Institute for Public Health and the Environment (RIVM). As a project leader and/or researcher she works on various projects on the safety and cost-effectiveness of medical implants, European regulation of medical products, pharmaceutical care and medicines utilization. As of 2017 she is the project coordinator of the Dutch Reporting centre for adverse effects of medical implants. This centre collects spontaneous reports from both patients and healthcare professionals. Analysis of reports may lead to signals about possible adverse effects of implants. These signals are made publicly available on the website.

Dr. Martijn van Rooijen, data steward working at the Dutch National Institute for Public Health andthe Environment (RIVM). Formerly, he was working at the STI clinic and the regional laboratory of the public health center of Amsterdam. During this employment, he worked as a data manager with large focus on the dissemination of data from the electronic patient files and the laboratory information system for management and scientific purposes. He was member of the SOAP steering committee that had to decide which information from STI clinics had to be send in for surveillance reasons. In addition, he was also responsible for the implementation of the GDPR at the STI clinic.

Dr. Boris Roszek is a scientist working at the Dutch National Institute for Public Health and the Environment (RIVM) for 20 years. He researches and provides scientific advice to regulators on quality and safety of medical technologies and is affiliated to the Dutch centre for reporting adverse effects of medical implants. He was a member of the Dutch national standardization committee and the ISO working group on clinical investigation of medical devices, and the EC working group on clinical investigation and evaluation. Previously, he was a postdoc at the Neural Rehabilitation Engineering Laboratory (Catholic University of Louvain, Brussels). He obtained his doctorate at the Institute for Fundamental and Clinical Human Movement Sciences (Amsterdam) and graduated as a biomedical researcher (Radboud University Nijmegen).

Dr. Susana Cabaço, data steward working at the Dutch National Institute for Public Health andthe Environment (RIVM). Previously she was a researcher at the Netherlands Interdisciplinary Demographic Institute (NIDI/ KNAW) working in the Generations and Gender Programme. Before joining NIDI, she was a postdoctoral researcher in the Adam Smith Business School at the University of Glasgow. Susana holds a PhD in Government from the University of Essex and her interests include political parties, research methods and research data management.

Istituto Superiore di Sanità (Italian National Institute of Health, Rome)

Marina Torre, MEng, senior researcher at the ISS Presidency's Scientific Secretariat. She has a valuable experience in the field of medical devices with particular reference to orthopaedics. Project leader of EUPHORIC (PHP 2003-2008) and WP leader in EURHOBOP and EUROTRACS (PHP 2008-2013). On the mandate of the Italian Ministry of Health, she has been the leader of the Italian Arthroplasty Registry since 2006 and of the Italian Implantable Prostheses Registry since 2019.

Paola Laricchiuta, MA, MLIS, researcher at the ISS Presidency's Scientific Secretariat. Her work focuses on the establishment of the Italian Registry of Implantable Devices. Prior to this, her focus was on guideline development and promotion while working for the Italian National Guideline System since 2008 and the National Centre for Rare Diseases since 2011. She was involved in the FP7 project RARE-Bestpractices as member of the coordination team and task leader.

Eugenio Carrani, Computer Science, IT Research Assistant at the ISS Presidency's Scientific Secretariat. He has valuable experience in Information Security Management, IT support for national and international scientific projects, and setting up implantable medical device registries. The National Ministry of Health has charged him as an expert member of the Good Laboratory Practice coordinating group.

Stefania Ceccarell, MBA Business Administration, technical assistant at the ISS

Presidency's Scientific Secretariat. She has more than 10 years' experience in managing projects at EU level. She was involved as project manager in two EU projects within FP6. She is part of the Italian Arthroplasty Registry and the Italian Implantable Prostheses Registry working groups.

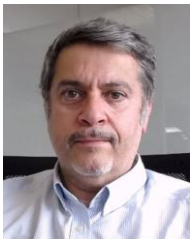
Filippo Boniforti (External expert), MD, Medical Director of Orthopedics and Traumatology Fondazione Giglio, Cefalu (I). Joint Replacement Surgery Center, Galeazzi Orthopedic Institute, Milano. Clinical fellow at the Nuffield Orthopedic Center, Oxford and Great Ormond Street Hospital, London UK. Girdlestone Orthopedic Society, Oxford (UK). Delegate of the Sicilian Region in the Scientific Committee of the Italian Arthroplasty Registry, Istituto Superiore di Sanita', Rome (I).

HTA Austria - Austrian Institute for Health Technology Assessment GmbH (Vienna)

Claudia Wild, Priv.-Doz. Dr. phil. is Chief Executive Officer (CEO) of HTA Austria, Austrian Institute for Health Technology Assessment (AIHTA) GesmbH since 2020. Until then she has been Director of the Ludwig Boltzmann Institute for HTA since its establishment in 2006. Her main focus is on the evaluation of high-risk medical devices and in oncology as well on European HTA collaboration in EUnetHTA.

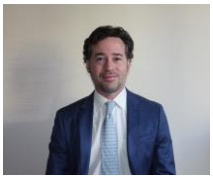
Sabine Ettinger, Mag. rer.nat., MSc is a Researcher and Scientific Project Manager in EUnetHTA at AIHTA GesmbH since 2016. Within EUnetHTA she coordinates European assessments (medical devices and other non-pharma interventions).

Fundacion Publica Andaluza Progreso y Salud (Progress and Health Foundation, Sevilla)



Juan Antonio Blasco, MD, MPH, MHTA, MHE, specialized in preventive medicine and Public Health, is the Scientific Coordinator of the Health Technology Assessment Unit in the Fundación Pública Andaluza Progreso y Salud (AETSA-FPS). Juan Antonio is also the Scientific Director of EuroScan. He has published >80 manuscripts and >40 Health Technology Assessment (HTA)Reports in Urology, Oncology, Surgery, and other medical specialties. His HTA group has 14

professionals covering a wide range of disciplines. The group is specialized in the development of HTA reports,Systematic Reviews and clinical practice guidelines. AETSA-FPS is member of the European Network for Health Technology Assessment (EUnetHTA) and of the International Network of Agencies for Health Technology Assessment (INAHTA).



Juan Carlos Rejon-Parrilla, MSc, MPharm, is a health economist with a Master's degree in Pharmacy. He currently holds a senior researcher position at the Andalusian Regional Department of Health (area of HTA, AETSA-FPS). His role involves identifying strategic priorities for AETSA-FPS, developing project proposals to address them, identifying research funding opportunities to carry those proposals forward, and representing AETSA-FPS as the lead researcher in national and European projects such as those funded by the European Commission or the Innovative Medicines Initiative (IMI). Before that, he worked as scientific adviser at the National Institute for Health and Care Excellence (NICE), where he worked in European HTA research projects such as the IMPACT HTA project. Previously, he also worked as a health economist at the Office of Health Economics(OHE),where he worked on consulting and research projects, and as a health economist at the National Clinical Guidelines Centre in London.

Agnieszka Dobrzynska, PhD, PhD degree in Biotechnology and Chemical Technology, and MSc degree in Molecular Biology, currently holds a HTA technician position at the Andalusian Regional Department of Health (AETSA-FPS). She is involved in preparation of HTA reports, systematic reviews, participates in the European H2020 project "AllerScreening. Point-of-care device based on KETs for diagnosis of food allergies" and in the projects of the European network for Health Technology Assessment (EUnetHTA). Before that she was a researcher in Andalusian Centre for Developmental Biology first as a PhD student, then as a postdoctoral researcher involved in several research projects on the cellular and developmental biology. She is author of 8 articles in international journals (4 as first author, 1 as corresponding author).

David Epstein, associate professor at the Department of Applied Economics, University of Granada, Spain. His research interests include health technology appraisal, meta-analysis and cost-effectiveness analysis. David Epstein has participated as principal health economist in major clinical trials and other projects at national and international level. He has published extensively with co-authors in major economic and clinical journals. He is associate editor of Value in Health and Gaceta Sanitaria, co-coordinator of the Economic Evaluation group of the Spanish Health Economists' Association, and member of the International Society for Pharmacoeconomics and Outcomes Research, the UK Chartered Institute of Management Accountants and the UK Royal Statistical Society.

Françoise Schlemmer, Director of Team-NB (the European Association of Notified Bodies in the Medical Devices sector). Dhr hold a Master's degree in biochemistry in Liege University, certificate of ICHEC Entreprise, Brussels School of Management. She ~~has~~ worked for 4 years in pharmaceutical and medical device manufacturers. She has also worked for 6 years in a Notified Body designated against the medical device directives. She obtained the diplomas of auditor EN46000 and 93/42/CEE Directive for the medical devices and of auditor ISO 9000 (Lead Auditor) Since 2001, she is director of TEAM-NB, an association that brings together 28 notified bodies in the medical devices sector.

Dr. Marianna Mastroroberto, Clinical Expert for ECM NB1282 since 2017,carried out the assessment of about 200 devices, both active and non-active, including innovative devices based on clinical investigations and devices for unmet medical needs: about a quarter are currently certified. She graduated in Medicine and Surgery (2010) and obtained a Phd in surgical sciences (2016) acquiring six years of experience in hepatologc transplant area and in elastographic diagnosis techniques as Fibroscan operator. She has also served as first aid volunteer. Marianna has acquired expertise in biostatistics by obtaining a Post-doctoral research fellow in biostatistics (2016-1017) and completed her experience by obtaining a diploma at the School of Higher Education in Medical Statistics (2018).

Dr. med. Christoph Ziskoven , clinical expert and the global head of the Technical Competence Center clinical evaluation at TÜV Rheinland LGA Product GmbH, Medical department, Notified Body 0197 for Medical Devices under Regulation (EU) 2017/745. Dr. Ziskoven studied human medicine at the University of Cologne and is specialist physician for trauma and orthopaedic surgery. He trained in maximum care and university hospitals in North Rhine Westphalia.

Dr. Sabina Hoekstra-van den Bosch, PharmD FRAPS, Regulatory Strategy Principal Medical Health Services at TÜV SÜD Product Service and candidate member of the Administrative Committee of Team-NB. Hoekstra studied pharmaceutical sciences and holds a PharmD from Leiden University. In her current role as Regulatory Strategy Principal at TÜV SÜD Medical Health Services, she is acting as representative of TÜV SÜD and other Notified Bodies in several regulatory working groups at European level.

Dr. Michael Hahn, Manager Clinical Affairs at Medcert GmbH. Michael Hahn studied medicine at Frankfurt and Naples and trained in internal medicine and respiratory diseases in Hamburg. As a medical specialist in pulmonology he joined a clinical research organization and worked as a principle investigator in numerous clinical studies. Subsequently he joined an international pharmaceutical company as an real word evidence manager and was responsible for the implementation of real world evidence generation and evaluation. Accompanying he acquired a Master degree in health system management and health economics.

Richard Holborow, Head of Clinical Compliance for the Global Regulatory Compliance Team of BSI NL. Richard leads the clinical oversight process at BSI NL. Before joining BSI, Richard was a former Consultant Clinical Physiologist in the NHS who specialised in Cardiology and Implantable Devices. Richard is based in Cardiff, UK.

Erman Melikyan, MD, FRCS, MAcadMEd is the Principal Clinician at Intertek Medical Notified Body and Consultant Orthopaedic Surgeon. Erman studied medicine at Istanbul University. He specialized in Trauma and Orthopaedic Surgery followed by Hand Surgery. He published the first randomized double-blinded study into Extracorporeal Shock Wave Treatment (ESWT) for orthopaedic use. His research led to various journal articles and book chapters. Erman has been crucial in setting up the clinical team at IMNB and its MDR designation process.