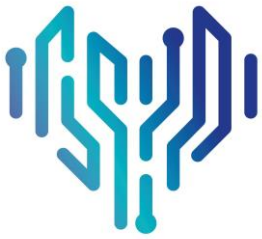

SIMCor

In-Silico testing and validation of Cardiovascular IMplantable devices

Call: H2020-SC1-DTH-2018-2020 (*Digital transformation in Health and Care*)

Topic: SC1-DTH-06-2020 (*Accelerating the uptake of computer simulations for testing medicines and medical devices*)

Grant agreement No: 101017578

Deliverable 1.3

Project handbook

Due date of delivery: 30 April 2021

Actual submission date: 29 April 2021

Start of the project: 1 January 2021
End date: 31 December 2023

This project has received funding from the European Union's Horizon 2020 research and innovation programmeunder grant agreement N° 101017578

Reference

Name	SIMCor_D1.3_Project handbook_LYN_29-04-2021
Lead beneficiary	Lynkeus (LYN)
Author(s)	Anna Rizzo (LYN)
Dissemination level	Public
Type	Report
Official delivery date	30 April 2021
Date of validation by the WP Leader	29 April 2021
Date of validation by the Coordinator	**29 April 2021**
Signature of the Coordinator	Titus Kuehne Digital unterschrieben von Titus Kuehne Datum: 2021.04.29 17:20:37 +02'00'

Version log

Issue date	Version	Involved	Comments
06/04/2021	1.0	Anna Rizzo (LYN)	First draft by LYN
21/04/2021	2.0	Mirko De Maldè (LYN)	Internal review by LYN
26/04/2021	3.0	Jan Brüning (CHA)	Project Coordinator's review
28/04/2021	4.0	Representatives from BIO, ECRIN, IHS, IIB, PHI, TUE, TUG, UCL, UTBV, VPH	Whole consortium's review on specific roles of partner members
29/04/2021	5.0	Anna Rizzo (LYN)	Final review and formal checking by LYN
29/04/2021	Final	Jan Brüning, Grischa Gabel (CHA)	Submission by PC

Executive summary

The deliverable represents a reference document at consortium partners' disposal for day-to-day project management. The document recapitulates project legal and ethical aspects, consortium partner composition and roles, management structure, procedures and tools, reporting guidelines, financial and budget issues, as well as guidelines for dissemination and communication of results.

Table of contents

List of figures

List of tables

Acronyms

Acronym	Full name
BIO	Biotronik
CA	Consortium Agreement
CHA	Charité - Universitätsmedizin Berlin
CC	Creative Commons
D	Deliverable
DoA	Description of Action
DPO	Data Protection Officer
ECRIN	European Clinical Research Infrastructure Network
ELSI	Ethical, legal and social implications
FR	Final report
GA	Grant Agreement
IHS	Institut für Höhere Studien – Institute for Advanced Studies
IIB	Institut für ImplantatTechnologie und Biomaterialien e.V.
IQPR	Internal quarterly progress report
IPR	Intellectual property right
LYN	Lynkeus Srl
PHI	Philips Electronics Netherlands B.V.
PC	Project Coordinator
PM	Project Manager
PR	Periodic report
SME	Small and medium size enterprise
TAVI	Transcatheter aortic valve implantation
TUE	Eindhoven University of Technology
TUG/TU Graz	Graz University of Technology
UCL	University College of London
UTBV	Universitatea Transilvania Din Brașov
VPH/VPHi	Virtual Physiological Human Institute for Integrative Biomedical Research VZW

Introduction

The present report is meant to serve as a reference document at consortium partners' disposal in regard to day-to-day project management and internal reference for scientific, reporting, financing and other standards.
The document recapitulates general principles for project execution, as defined in the project *Grant Agreement* (GA) and its technical annex, the *Description of the action* (DoA), EU guidelines for project implementation and documentation, as well as regulations for the relations between partners of the consortium included in the *Consortium Agreement* (CA), bringing them up in simplified terms and complementing them with practical rules and standards.

Legal framework

Grant Agreement

The Grant Agreement forms the legal basis for the implementation of the project. It consists of:

- *Terms and Conditions (this is the core contract);*
- *Annex 1 Description of the Action (DoA);*
- *Annex 2 Estimated budget for the action;*
- *Annex 3 Accession Forms;*
- *Annex 4 Model for the financial statements;*
- *Annex 5 Model for the certificate on the financial statements;*
- *Annex 6 Model for the certificate on the methodology.*

The contract is signed between the EU and the Coordinator, however by signing the Accession Forms all partners have become individual contract partners with the Commission. The GA must be kept by all partners and should be provided to the auditor in case of an audit. The GA is downloadable in the participant portal and in the project Google Drive *(SIMCor > Proposal, GA, CA > 2_Grant Agreement)*.

Amendments

Circumstances may arise during the project to require an amendment of the GA, in relation to a series of issues including change of partner, legal entity, budget, DoA.

In case an amendment is needed, the PC shall submit such a request after an autonomous decision by all partners in the Governing Board. After approval of the amendment, the PC shall distribute the revised GA, replacing former versions, and inform the Project Officer. Amendments may be requested by any of the project partners. Budget changes that do not affect the content of DoA can be taken care of by the consortium itself.

Consortium Agreement

The Consortium Agreement is signed between the partners of the consortium and organises in detail the provisions of the GA in terms of financial issues, payments, management, decision making, conflict resolution, intellectual property rights and liability. The CA must also be kept by the partners and must be shown in case of audits.

Consortium

The SIMCor consortium consists of 12 partners from 8 countries (i.e., Austria, Belgium, France, Germany, Italy, Netherlands, Romania, United Kingdom), including academia (universities, spin offs and clinical centres), industry and a *medium-sized enterprise* (SME), illustrated below.

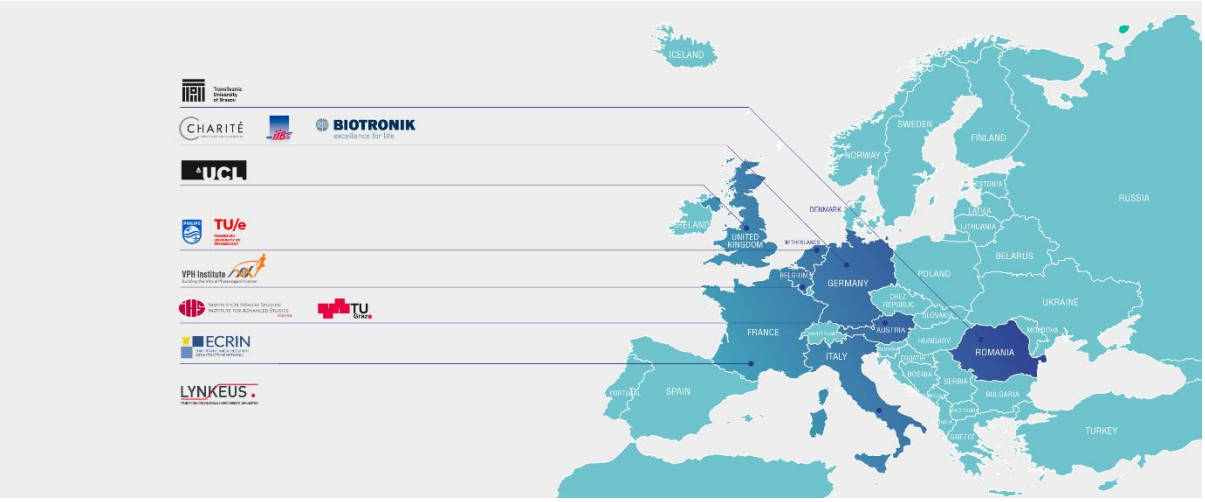

Figure 1: SIMCor consortium overview map.

N	Full name and link	Acronym	Country	Type
1 (*Coordinator*)	Charité - Universitätsmedizin Berlin	CHA	DE	academia
2	Lynkeus Srl	LYN	IT	SME
3	Biotronik	BIO	DE	industry
4	European Clinical Research Infrastructure Network	ECRIN	FR	academia
5	Institut für Höhere Studien – Institute for Advanced Studies	IHS	AU	academia
6	Institut für ImplantatTechnologie und Biomaterialien e.V.	IIB	DE	academia
7	Philips Electronics Netherlands B.V.	PHI	NL	industry
8	Eindhoven University of Technology	TUE	NL	academia
9	Graz University of Technology	TUG[1]	AU	academia
10	Universitatea Transilvania Din Braşov	UTBV	RO	academia
11	University College of London	UCL	UK	academia
12	Virtual Physiological Human Institute for Integrative Biomedical Research VZW	VPH[2]	BE	academia

Table 1: Partners of the SIMCor consortium.

[1] TU Graz for external communication
[2] VPHi for external communication

Expertise and role in the project

The consortium integrates expertise in cardiovascular research and modelling, health informatics and AI, biomechanics and biomedical engineering, medical device design and piloting, ethics and legal competences on human and animal research, data privacy and security management, regulatory frameworks on in-silico clinical trial workflows, as well as scientific communication, dissemination, IPR management and exploitation. The specific expertise brought in by different consortium partners, along with their main role in the project, is summarised in the table below.

Partner	Specific expertise	Main role in SIMCor
CHA	Translational research combining imaging, data science and biophysical modelling for clinical decision support in cardiology	Scientific and clinical coordination, data processing for anatomical and functional modelling, preclinical studies
LYN	Project management, dissemination and exploitation, data privacy and security management for healthcare data	Project management, communication, dissemination and exploitation, privacy and security assessment
BIO	Product development for cardiac rhythm management, electrophysiology, vascular intervention, intravascular implants, class III device regulatory approval procedures	Computer-aided simulation for the evaluation of device effects, constitutive device models and vessel device interaction during implantation, regulatory approval strategies for in-silico testing of medical devices
ECRIN	Clinical trial research methodology, design and operational management, regulatory frameworks for data sharing and reuse	Assessment of predictive value of in-silico trials vs human trials, contribution for reduction of animal and human testing and improved patient outcomes
IIB	Fluid-, structure-mechanical and material-technical optimization of medical implant structures	Device-specific effect modelling (TAVI-related thrombosis, paravalvular leakage and durability), based on device, patient and animal vessel models
IHS	Mixed methods research, economics, governance, innovation and societal change	Evaluation of industrial and socio-economic effects of computer-based simulation and in-silico clinical trials
PHI	Digital Twin concepts for the evaluation of patient-devices interaction	Virtual device implantation and 3D finite element simulations of the device and device tissue interaction
TUE	Virtual cohort generation, patient-specific physiological modelling and in vivo validation, isogeometric analysis	Development and validation of virtual cohorts, uncertainty quantification and sensitivity analysis, isogeometric analysis for virtual TAVI deployment
TUG	Computational biomechanics and mechanobiology of soft tissues, blood vessels and CVD therapeutic interventions	Analysis of vessel-wall structure, development of constitutive models for simulation of vessel wall material behaviour and device-vessel interaction
UCL	Big data applications for personalised medicine and modelling in cardiology, advanced imaging, cardiac transplantation	(Pre)clinical data acquisition and quality review, clinical standards development, creation of synthetic data of anatomical models and boundary conditions
UTBV	HP computing, physiological modelling for cardiovascular applications, AI solutions	Cloud-based virtual research environment implementation, virtual cohort and device validation
VPH	In-silico medicine research and regulatory policy	Generation of standards, guidelines and protocols, liaison with regulatory authorities

Table 2: Expertise of the different partners in the SIMCor consortium and respective roles in the project.

Personnel involved

The **personnel involved** for all partners, including their role in the project, are described in the table below. Besides those, each partner includes its **administrative staff**, to support on legal and financial issues, and **communications and press office professionals**, that will be involved in the context of engagement, dissemination and communication activities.

Partner	Member	Main roles
CHA	Titus Kühne	Project Coordinator (WP1 and all WPs), Principal Investigator
	Jan Brüning	Scientific coordination (WP1 and all WPs) - WP5, WP6, WP8, WP9
	Leonid Goubergrits	WP5, WP6, WP8, WP9
	Anja Hennemuth	WP6 Leader
	Friederike Fenske	Technical coordination (WP1)
	Grischa Gabel	Technical coordination (WP1)
	Lars Walczak	WP8
	Nina Krüger	WP6
	Jannes Magnusson	WP6
LYN	Anna Rizzo	Scientific Project Manager (WP1 and all WPs), WP2 Leader, WP3
	Mirko De Maldè	Legal Project Manager (WP1)
	Davide Zaccagnini	Support to scientific coordination (WP1), Exploitation and IPR Manager (WP2)
	Ludovica Durst	Ethical, legal and regulatory issues (WP3)
	Edwin Morley-Fletcher	Principal Investigator, General management (WP1)
	Antonella Trezzani	Financial management (WP1)
	Beatrice Bressan	General management (WP1)
BIO	Andreas Arndt	Principal Investigator, WP9 Leader, WP8
	Torsten Luther	WP9, WP8
	Ingmar Stade	WP9, WP8
	Jan Romberg	WP9, WP8, bench tests (WP5)
	Sonja Meine	WP9, WP8, bench tests, preclinical tests (WP5)
	Franziska Wegerich	WP10
ECRIN	Jacques Demotes	Principal Investigator, WP10 Leader, WP7
	Christian Ohmann	WP10, WP8
	Maria Panagiotopoulou	WP10, WP7, WP2
	Sergei Gorianin	WP10, WP7
	Martina Esdaile	WP2
IHS	Thomas Czypionka	Principal Investigator, WP10 Leader
	Markus Kraus	WP10
	Miriam Reiss	WP10
IIB	Klaus Peter Schmitz	Principal Investigator
	Michael Stiehm	WP4, WP7, WP8, WP9
	Sebastian Kaule	WP8, WP9
	Finja Borowski	WP8, WP9
	Jan Oldenburg	WP4, WP7
PHI	Valentina Lavezzo	Principal Investigator, WP8 Leader, WP9 support
	Olaf van der Sluis	WP8
TUE	Wouter Huberts	Principal Investigator, WP7 leader
	Clemens Verhoosel	WP8
TUG	Gerhard A. Holzapfel	Principal Investigator, WP8, WP9
	Malte Rolf-Pissarczyk	WP8, WP9
	Michele Terzano	WP8, WP9
UTBV	Lucian Itu	Principal Investigator, WP3 Leader

	Robert Demeter	WP3
	Alex Cracanel	WP3
	Alina Itu	WP3
UCL	Silvia Schievano	Principal Investigator
	Claudio Capelli	WP5 Leader, Ethics Manager, WP4, WP6
	Emilie Sauvage	WP5, WP4, WP6
VPH	Liesbet Geris	Principal Investigator, WP4 Leader
	Raphaelle Lesage	WP4
	Bernard Staumont	WP4
	Federica Orsi	WP2
	Martina Contin	WP2

Table 3: Personnel involved from each consortium partner and respective roles in the project.

Management structure, procedures and tools

Governance structure

SIMCor governance structure, set up to guarantee smooth cooperation and optimal management of all operational, scientific and technical aspects of the project, can be described as follows, in relation to the main project-related functions:

1. **Coordination**, performed by the **Project Coordinator** and the **Project Managers**;
2. **Decision making**, implemented by the **Governing Board**;
3. **Operational management**, performed by the **Steering Committee** and **Work Package Leaders**;
4. **Advisory**, carried out through the **(i) Exploitation & Intellectual Property Right Advisory Board, (ii) Regulatory Advisory Board, (iii) Scientific and Clinical Advisory Board, (iv) Ethical Manager** and **(v) Ethical, Legal and Social Issues Working Group.**

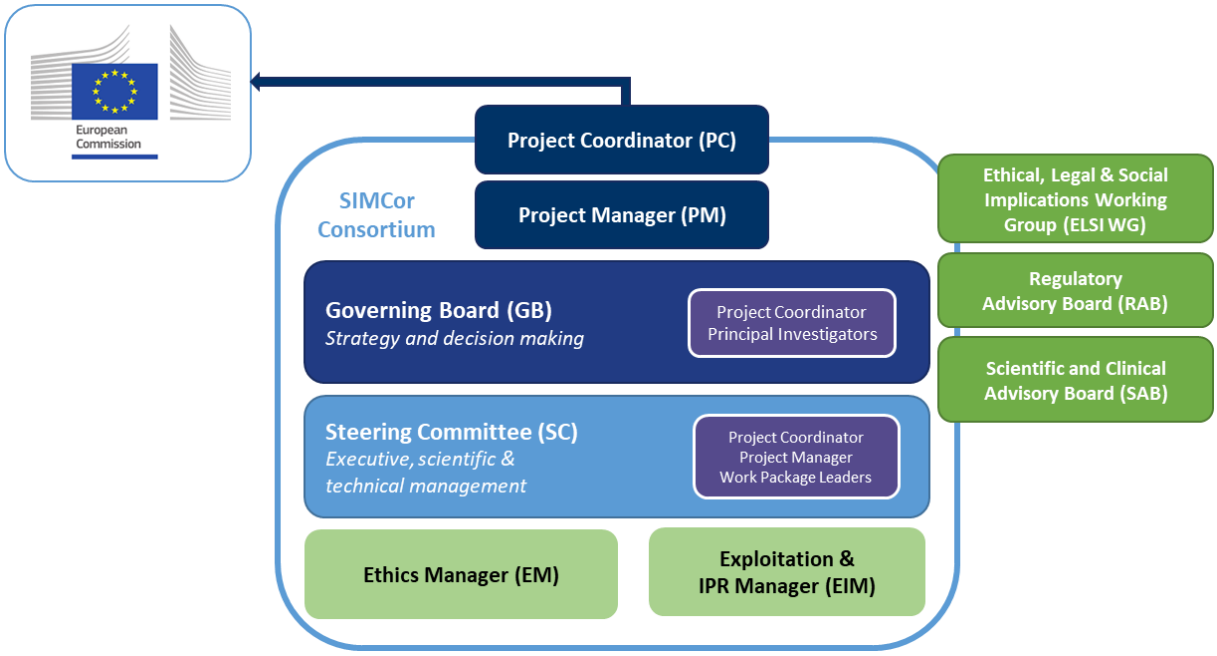

Figure 2: SIMCor governance structure.

COORDINATION: Project Coordinator and Project Manager

To optimise the overall management of the research action, coordination functions have been distributed this way:

- The ***Project Coordinator*** **(PC) supervises project implementation from a scientific and clinical standpoint**, ensuring a smooth progress of research activities according to the research plan, the quality of project results and their compliance with project objectives. In SIMCor, this function is carried out by **Titus Kühne (CHA, official Coordinator) and Jan Brüning (CHA).**
- The ***Project Manager*** **(PM) is responsible for the general management of all project activities and acts as the intermediary between the consortium and the EC**. The PM's duties include day-to-day operational coordination, quality assurance and monitoring, such as ensuring project progress according to timeline and monitoring of milestones and deliverables, preparation and submission of technical reports, drafting of minutes, organisation of scientific reviews, coordinating interactions between WPs, oversight of dissemination activities, as well as administrative and financial management. In SIMCor, these functions are carried out by **Anna Rizzo (LYN) - Scientific PM**, that oversees research activities, dissemination and communication,

and takes care of everyday management, and **Mirko De Maldè (LYN) - Legal PM**, that represents the point of reference for legal, administrative and financial matters and interfaces with the PO.

DECISION MAKING: Governing Board

The *Governing Board* (GB) is composed of **one representative per partner (*Principal Investigator*, PI) and is chaired by the PC.** It represents **the primary executive, decision making and arbitration body** and addresses high-level strategic issues, such as discussing and approving reallocation of the project budget, major modifications of the work plan and relevant amendments, request of contractual changes to the EC, resolution of conflicts within the consortium. Given its nature of a high-level decision-making body, the GB will round up on a yearly basis, but can be summoned at other times if required. A relative majority system is employed, with one vote for each partner.

OPERATIONAL MANAGEMENT: Steering Committee and Work Package Leaders

***Work Package Leaders* (WPLs)** have responsibility for **day-to-day coordination of specific WP-related activities as defined in the implementation plan**, in close collaboration with respective task leaders. The WPL will monitor the timely completion of tasks and deliverables, report the achieved progresses, identify risks and propose technical solutions. WPLs will refer to the PC for scientific and technical issues and the PM for management and financial matters. In SIMCor, WPLs are represented by **Titus Kühne (CHA, WP1 Leader), Anna Rizzo (LYN, WP2 Leader), Lucian Itu (UTBV, WP3 Leader), Liesbet Geris (VPH, WP4 Leader), Claudio Capelli (UCL, WP5 Leader), Anja Hennemuth (CHA, WP6 Leader), Wouter Huberts (TUE, WP7 Leader), Valentina Lavezzo (PHI, WP8 Leader), Andreas Arndt (BIO, WP9 Leader), Thomas Czypionka (IHS, WP10 Leader).**

The ***Steering Committee* (SC)** represents the **operational body of the project and ensures day-to-day management of research activities**. It is composed of **all WPLs and coordinated by the PC and PM**. The SC takes operational decisions regarding WP management based on the monitoring of milestones and expected results of each WP. It is also in charge of addressing and documenting internal risks which may impair progress towards WP objectives, suggesting strategies to anticipate and minimise potential risks. The SC is also responsible for implementing the decisions agreed by the GB, controlling the execution of the project in line with its agreed work plan and monitoring corrective actions.

ADVISORY: Advisory Boards, Exploitation and IPR Manager, Ethics Manager, Ethical, Legal and Social Implications Working Group

Regulatory Advisory Board

The *Regulatory Advisory Board* (RAB) assists the relevant consortium partners in the **definition of standards, procedures and guidelines for the integration of computational models in the development, validation and regulatory approval of medical devices**, as well as helps designing a strategy for early adoption in the regulatory process. The Board is composed of selected members of regulatory authorities in the field of medical device products (i.e., TÜV SÜD, *US Food & Drug Administration*-FDA) and will gather in concomitance with the annual project meetings to give initial feedback, review the work in progress and give final insights for the definition of the latest version of SOPs and a roadmap for regulatory and clinical adoption. The RAB is chaired by **Liesbet Geris (VPH, WP4 Leader)** and composed by **Jan Küfner (TÜV SÜD)** and **Tina Morrison (FDA)** as external experts.

Scientific and Clinical Advisory Board

The *Scientific and Clinical Advisory Board* (SAB) is composed of selected members of the academic community in the field of (e)cardiology and health IT, including members of clinical centres with expertise in the validation and clinical use of clinical decision support systems and research centres specialised in the development of computational models in cardiology. With analogous modalities, the Board **supports the definition of SOPs with a clinical perspective and helps formulate a credible roadmap for the adoption of in-silico tested medical devices in the clinical workflow**. The SAB is

chaired by **Titus Kühne (CHA, Coordinator)** and composed by **Joost Lumens (Maastricht University), Karim Lekadir (University of Barcelona) and Steffen Petersen (Queen Mary University of London).**

Exploitation & Intellectual Property Rights Manager

The *Exploitation & Intellectual Property Rights Manager* (EIM) **assesses opportunities to generate *Intellectual Property* (IP) and other tangible and intangible assets from project results and determine their potential for commercial exploitation or as Open Science resources**. The EIM conducts preliminary screening of existing protocols, applications and new know-how across patent office databases to reveal where the generated data can be protected and ensures that the commercial interests of the industrial partners do not result into conflict, giving support to exploitation activities. In SIMCor, the EIM is **Davide Zaccagnini (LYN)**.

Ethics Manager

The **Ethics Manager (EM) oversees, in strict conjunction with the PC and PM, the ethical clearance of research activities and review supporting documents** (i.e., informed consent forms, information sheets, agreement number, authorisation) to ensure that they are in line with European (i.e., GDPR) and national rules. In SIMCor, the EM is **Claudio Capelli (UCL, WP5 Leader)**.

Ethical, Legal and Social Implications Working Group

The *Ethical, Legal and Social Implications Working Group* (ELSI WG) **supervises the acquisition, processing and storage of personal data**, to ensure data subjects' privacy, data security and compliance with GDPR and national data regulations, as well as **the design of prospective animal studies**, to ensure compliance with European ethical regulations and relevant legislation on animal welfare and the use of animals in research. The ELSI WG will be composed of **clinical and preclinical researchers, IT as well as ethical, legal and regulatory experts from CHA, UCL, ECRIN, BIO, TUG, UTBV and LYN**, with the occasional consultancy of **Data Protection Officers (DPOs) of CHA and UCL hospitals.**

Body	Role	Composition
Project Coordinator	Scientific and clinical supervision	Titus Kühne (CHA, Coordinator) Jan Brüning (CHA)
Project Manager	Management of research activities, interface with the EC	Anna Rizzo (LYN, Scientific PM) Mirko De Maldè (LYN, Legal PM)
Work Package Leaders	Day-to-day coordination of WP activity	Titus Kühne (CHA, WP1), Anna Rizzo (LYN, WP2), Lucian Itu (UTBV, WP3), Liesbet Geris (VPH, WP4), Claudio Capelli (UCL, WP5), Anja Hennemuth (CHA, WP6), Wouter Huberts (TUE, WP7), Valentina Lavezzo (PHI, WP8), Andreas Arndt (BIO, WP9), Thomas Czypionka (IHS, WP10).
Governing Board	Decision making and arbitration	**Project Coordinator** *Principal Investigators* (PIs) of all consortium partners
Steering Committee	Operational management of research activities	**Project Coordinator & Project Manager** WP Leaders
Regulatory Advisory Board	Definition of standards, procedures and guidelines for the in-silico trial workflow from a regulatory perspective	**Liesbet Geris (VPH, WP4 Leader)** Jan Küfner *(TÜV SÜD)* Tina Morrison *(Food and Drug Administration)*
Scientific and Clinical Advisory Board	Definition of standards, procedures and guidelines for the in-silico trial workflow from a research and clinical perspective	**Titus Kühne (CHA, Coordinator)** Joost Lumens *(Maastricht University)* Karim Lekadir *(University of Barcelona)* Steffen Petersen (*Queen Mary University of London)*
Exploitation & IPR Manager	Assessment of exploitation opportunities, IPR management	Davide Zaccagnini (LYN)
Ethics Manager	Ethical supervision of clinical and preclinical research activities	Claudio Capelli (UCL, WP5 Leader)
ELSI Working Group	Ethical, legal and regulatory supervision of acquisition, processing and storage of personal data, design and conduction of animal studies	Clinical researchers (CHA, UCL, ECRIN) Preclinical researchers (CHA, BIO, TUG) IT experts (UTBV) Ethical, legal, regulatory experts (LYN, CHA, BIO, ECRIN, TUG, UCL) Data Protection Officers (CHA, UCL)

Table 4: SIMCor management and advisory bodies and relevant consortium and external members involved.

Management procedures

Project meetings

To appropriately ensure the achievement of the project objectives, SIMCor implementation relies on a series of different procedures for effective project management, smooth cooperation of partners, continuous monitoring, periodic assessment of the results and compliance with the reporting obligations to the EC, as well as resolution of issues and conflicts.

- **Project general (e)meetings** are organised on a semestral basis (M1, M6, M12, M18, M24, M30, M36) to assess scientific progress, timely achievement of objectives and milestones according to the work plan and take appropriate measures and decisions. These will be live (M12, M24, M36) or e-meetings (M1, M18, M30), and will gather the GB and SC, to review and discuss progress and potential issues for each WP, address financial issues and other possible criticalities.
- **Periodic technical inter-WP e-meetings** will be held on a (at least) three-month basis between WPLs, task leaders, the PC and SC, to ensure continuous project monitoring, closer interactions between consortium members, assess the progress of WP-related activities and address potential technical difficulties.
- **WP- and WG- technical e-meetings** will involve components of the technical Advisory Boards (in the context of annual live general project meetings and beyond) or a limited number of partners to focus on their respective WP or specific aspects of the project with dedicated *working groups* (WGs), with a variable timing, scheduled according to specific needs.

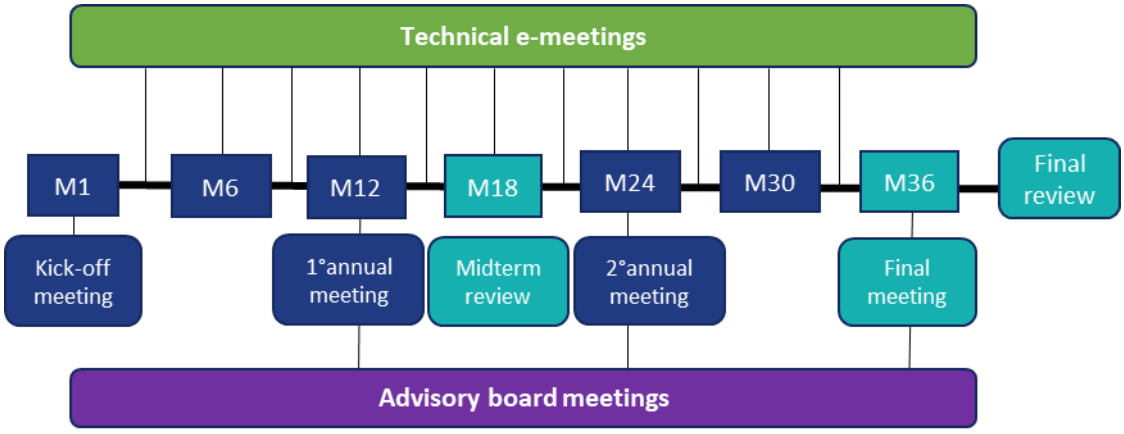

Figure 3: Scheme of SIMCor project meetings.

Working groups

An initial series of *working groups* (WGs) have been defined to focus on specific aspects of the project, at WP, inter- or intra-WP level. Some of these (e.g., SR, RI) have sub-WGs being set up to focus on different aspects of implementation. This list will be expanded in the course of the project according to project implementation needs (e.g., adding and exploitation and IPR management WG, a WP9 WG, etc.). If a WP or task leader needs to establish a new WG, s/he can make a request to the PM and PC to have the relevant mailing list and a first e-meeting organised. WGs are coordinated by a WG leader, i.e., the PI or an appointed member of the leading partner, with the support of the PM.

Name and WPs involved	Short name	Recurrence	Participants
WP1/3/5/6 - Data management & ethics	DME	Bi-weekly	LYN (Lead), CHA, UCL (ECRIN, UTBV later on)
WP7 - Virtual cohorts	VC/WP7	Bi-weekly	TUE (Lead), LYN, CHA, BIO, ECRIN, IIB, PHI, TUG, UCL, UTBV
WP8 - Virtual device implantation	VI/WP8	Monthly	PHI (Lead), CHA, LYN, BIO, IIB, TUE, TUG
WP3 - System requirements	SR/WP3	Upon request	UTBV (Lead), CHA, BIO, ECRIN, IIB, PHI, TUE, TUG, UCL, VPH
WP4 - Regulatory issues and SOPs	RI/WP4	Monthly	VPH (Lead) - CHA, LYN, BIO, IIB, TUE, UCL
WP2 - Communication and dissemination	CD/WP2	Three-monthly	LYN (Lead), ALL (communications or press-office professionals from consortium partners, other representatives if necessary)

(E)meetings are planned and organised by the PM, who also opens the (e)meeting. The (e)meeting is coordinated by the PC and PM (i.e., general consortium, inter-WP meetings) or the WP/WG leader (i.e., WP/WG meetings) with the PM's support. The PM takes minutes and, after informing participants and acknowledging their consent, records the session (where relevant). Minutes are reviewed by the WG leader and shared with the consortium in the WG Google Drive subfolder, together with recordings and other relevant files, e.g., research papers, internal documents, etc. Recordings are kept in the folder for a maximum of 36 months (in any case, not later than the end of the project) and then deleted.

Management tools

Reference deliverables

- ***D1.3 - Project handbook (LYN, M4)***: project management structure and procedures, internal communication and meetings, legal and ethical aspects, reporting style guide.
- ***D1.4 - Self-assessment plan (LYN, M6)***: goals and key performance indicators (KPIs) for self-assessment of each WP.
- ***D1.5 - Quality assurance guidelines (LYN, M8)***: procedures and best practices to guarantee quality of reporting.

Internal quarterly reports

Every three months, WP Leaders are required to produce a short report of the activities and signal any issue to the Project Coordinator and the Project Managers as soon as possible.

Technical tools

- **TC tool:** *GoToMeeting*. The tool allows for one-time meetings and permanent meeting rooms; these, established for all WGs and relevant recurrent calls, can be activated at any time upon WG's leader request to the PM, allowing subgroup discussions if needed.
- **Mailing lists:** *Aruba*. *Coordination-, WP-, WG-, consortium partners-* and a *general-* mailing list have been created, and others can be generated by the PM upon request.

- **Note-taking tool**: *Avoma*[3]*.* Avoma is used both as a recording and note-taking tool, to facilitate tracking of most relevant discussions and minute preparation.
- **Calendar**: *Google Calendar, Outlook Calendar.* Calendars are used for sending timely invitations to (e)meetings in a timely manner and facilitate planning.
- **Discussion and file sharing**: *Slack.* Slack channels were activated for each WG for discussion and file sharing, and others can be activated by the PM upon request.
- **Document repository (project documents)**: *Google Drive*. The project Google Drive is utilised for project-related implementation files only, i.e., GA, CA, templates, deliverables, WG recordings, files and minutes, shared tables and files (e.g., deliverables, WGs, contacts list) for project management.
- **Temporary cloud repository (data, models)**: a temporary repository was implemented by UTBV (M3) within its IT structure to serve as a temporary repository for data and simple models, to be used until the VRE is finalised and incorporated into it.

Milestones

The project implementation includes 10 Milestones, identified in the proposal development phase and reported below, plus an additional one, i.e., the final ethical approval of project research clinical and preclinical studies by ethics research committees, to be achieved by M6.

N	Milestone name	WPs	Due	Means of verification
M1	Ethical approval for data collection submitted	5	M3	Protocols for clinical data collection and animal studies defined and submitted to ethical committees
-	Final ethical approval	5	M6	Final ethical approval from ethical research committees for clinical data collection and animal studies
M2	Specification of platform requirements, components and interactions	3,4,5,6,7,8,9	M6	Technical requirements and workflows fully described in D3.1
M3	First version of PAPS model generated	8	M12	3D computational PAPS model demoed at M12 meeting and reported in D8.1
M4	First version of TAVI model generated	8	M12	3D computational TAVI model demoed at M12 meeting and reported in D8.2
M5	Data repository extensions completed	3	M18	Extended data repository, resources and features described in D3.3
M6	Data collection completed	5	M18	Clinical data collection and quality assessment reported in D5.3, D5.5, preclinical study in D5.4, synthetic data generation in D5.6
M7	Virtual research environment implementation completed	3,4,5,6,7,8,9	M36	Integration of data sources reported in D3.3, cloud facilities in D3.4, web-based interface (D3.5) demoed at M36 meeting
M8	Virtual cohort validation completed	5,6,7	M36	Validated virtual cohorts (D7.8) will be demoed at M36 meeting
M9	Device validation completed	5,6,8,9	M36	Validated device models presented at M36 meeting, reported in D9.3, D9.4, D9.5
M10	Definition of SOP completed for the entire in-silico workflow	4,5,6,7,8,9	M36	Best practices reported in D4.1-D4.6, approved by the Regulatory Advisory Board

Table 5: SIMCor milestones.

[3] www.avoma.com

Reporting guidelines

The project reporting includes three main types of reports:

- ***Deliverables* (D)**, reporting to the EC work done and results achieved on specific project relevant topics or tasks by a partner/group of partners;
- ***Internal quarterly progress reports* (IQPR)**, meant to internally assess research progress in each WP and signal potential issues and risks to the PC and PMs;
- ***Periodic reports* (PR)** to the EC, describing scientific progress and financial aspects relevant to first (M1-M18) and second (M19-M36) reporting period, and are used to monitor project progress and the compliance with all contractual obligations.
- **Final Report (FR)** to the EC, that represents a final, high-level summary of project activity and achievements in lay terms, to be used after the end of the project for dissemination purposes.

General formatting rules

- **Font:** the font used for all documents is **Calibri**, with text size of **11 points**.
- **Page numbers** should be present in every document.
- **Headings** of all official documentation shall include **document title** and **SIMCor GA n°/logo**, that is already added to available templates and can be found in the project Google Drive.
- **Figures (infographics, illustrations, photographs)** should be provided in high quality (≥300 dpi) and respect *intellectual property rights* (IPRs) of the author. Hence, these should either be designed by the consortium (with acknowledgement of the partner(s) producing the image) or, if externally sourced, be purchased or *creative commons* (CC) licensed, following specific licence indications about credits to be acknowledged to the author(s).
- **Acknowledgement of EU funding** should be included in all documents using a proper phrase or the banner provided in the Google Drive (see 'Dissemination and communication' section).
- **Acronyms** shall be reported as *full name* (ACRONYM) the first time only, then as acronyms for the rest of the document. *Example: transcatheter aortic valve implantation* (TAVI).
- **Capitalisation**: all titles, including report/deliverable names, section and paragraph headers, are in **Sentence case**, and require capitalisation at the beginning of the row only.
- **Templates** (and a **document style guide**, where necessary) for project documents (reports, deliverables), are available in the project ***Google Drive (SIMCor> 4_Templates*).**
- The **preparation, review and submission process** of project reporting documents is illustrated in ***D1.5 – Quality assurance guidelines (LYN, M9).***

Deliverables

Project deliverables, defined for each WP in the GA, describe the work done and achieved results in a defined area, mostly as the result of a specific task. The following table illustrates all project deliverables (number, title, WP, type, dissemination level, due month, date), in chronological order.

N	Name	WP	Responsible partner	Type	Diss level	Due month	Due date
D2.1	Project presentation	WP2	LYN	R	PU	M1	31/01/2021
D1.2	Kick-off meeting report	WP1	LYN	R	PU	M2	28/02/2021
D2.2	Communication and dissemination strategy plan	WP2	LYN	R	PU	M3	31/03/2021
D5.1	Protocol for clinical data collection	WP5	CHA	R	CO	M3	31/03/2021
D5.2	Protocol for prospective animal study	WP5	CHA	R	CO	M3	31/03/2021
D1.3	Project handbook	WP1	LYN	R	PU	M4	30/04/2021
D1.8	Ethical and legal compliance preliminary assessment	WP1	LYN	R	CO	M4	30/04/2021
D6.1	Specification of data-processing requirements	WP6	CHA	R	PU	M4	30/04/2021

D1.4	Self-assessment plan	WP1	LYN	R	PU	M6	30/06/2021
D1.1	Research strategy plan	WP1	CHA	R	CO	M6	30/06/2021
D3.1	System requirements	WP3	UTBV	R	CO	M6	30/06/2021
D3.2	Data management plan	WP3	LYN	R	PU	M6	30/06/2021
D5.7	Ethical committees approval process reports and documents	WP5	UCL	R	CO	M6	30/06/2021
D7.1	Definition of model output	WP7	TUE	R	PU	M6	30/06/2021
D1.5	Quality assurance guidelines	WP1	LYN	R	PU	M8	31/08/2021
D1.9	Ethical and legal compliance final assessment	WP1	LYN	R	CO	M9	30/09/2021
D7.2	First version of the simulation models	WP7	TUE	R	PU	M9	30/09/2021
D1.6	First intermediate report	WP1	LYN	R	CO	M12	31/12/2021
D10.1	In-silico trial impact assessment framework	WP10	ECRIN	R	PU	M12	31/12/2021
D4.2	SOPs for data processing for in-silico models	WP4	CHA	R	PU	M12	31/12/2021
D4.4	Guidelines for documentation	WP4	IIB	R	PU	M12	31/12/2021
D6.2	Database for anatomy and function based on preclinical and clinical data	WP6	CHA	R, OTHER	CO	M12	31/12/2021
D7.3	First version of the definition of the input space	WP7	TUE	R	PU	M12	31/12/2021
D8.1	PAPS model	WP8	BIO	R, OTHER	CO	M12	31/12/2021
D8.2	TAVI model	WP8	BIO	R, OTHER	CO	M12	31/12/2021
D7.4	Sensitivity and uncertainty quantification toolbox	WP7	TUE	R	PU	M15	31/03/2022
D5.3	Review and report of retrospective data quality	WP5	UCL	R	CO	M16	30/04/2022
D8.3	Constitutive vessel model	WP8	TUG	R	PU	M16	30/04/2022
D8.8.	IGA model	WP8	TUE	R	PU	M28	30/04/2022
D3.3	Data repository	WP3	UTBV	R	CO	M18	30/06/2022
D4.1	SOPs for data acquisition for in-silico models	WP4	UCL	R	PU	M18	30/06/2022
D5.4	Completion and report of animal study	WP5	CHA	R	CO	M18	30/06/2022
D5.5	Report on retrospective clinical data collection	WP5	CHA	R	CO	M18	30/06/2022
D5.6	Completion of synthetic data creation process	WP5	UCL	R	CO	M18	30/06/2022
D7.5	Uncertainty quantification and re-definition of input space	WP7	TUE	R	PU	M18	30/06/2022
D9.1	Constitutive vessel model	WP9	TUG	R	PU	M18	30/06/2022
D2.5	Regulatory feedback report (1)	WP2	VPH	R	PU	M19	31/07/2022
D10.3	Conceptual framework report	WP10	IHS	R	PU	M20	31/08/2022
D8.4	Validated constitutive models of the vessel wall	WP8	TUG	R	PU	M20	31/08/2022
D6.3	Uncertainty quantification for input data	WP6	CHA	R	PU	M21	30/09/2022
D1.7	Second intermediate report	WP1	LYN	R	CO	M24	31/12/2022
D3.4	Cloud and HPC facilities	WP3	UTBV	R	CO	M24	31/12/2022
D4.5	SOPs for in-silico analysis of TAVI	WP4	IIB	R	PU	M24	31/12/2022
D6.3	Specification and quantification of subject-specific data-based boundary conditions	WP6	CHA	R	PU	M24	31/12/2022
D7.6	Proof of principle of the complete virtual patient generator	WP7	TUE	DEM	CO	M24	31/12/2022
D8.5	Fast device deployment model	WP8	CHA	R	PU	M24	31/12/2022
D8.6	Report on 3D finite element simulation	WP8	PHI	R	PU	M24	31/12/2022
D9.2	Device specific models	WP9	IIB	R	CO	M24	31/12/2022

D9.3	Low-fidelity validation results	WP9	BIO	R	CO	M24	31/12/2022
D6.5	Specification and quantification of synthetic boundary conditions	WP6	CHA	R	PU	M30	30/06/2023
D8.7	Reduced order model	WP8	PHI	R	PU	M30	30/06/2023
D9.4	Effect simulations of devices report	WP9	BIO	R	CO	M30	30/06/2023
D2.6	Regulatory feedback report (2)	WP2	VPH	R	PU	M31	31/07/2023
D10.2	Impact analysis on clinical and preclinical trials	WP10	ECRIN	R	PU	M36	31/12/2023
D10.4	Industry and market impact report	WP10	IHS	R	PU	M36	31/12/2023
D10.5	Socio-economic impact report	WP10	IHS	R	PU	M36	31/12/2023
D2.3	Communication channels and materials	WP2	LYN	R	PU	M36	31/12/2023
D2.4	Dissemination events	WP2	LYN	R	PU	M36	31/12/2023
D2.7	IPR and exploitation plan	WP2	LYN	R	CO	M36	31/12/2023
D3.5	Web-based interface	WP3	DEMO	R	CO	M36	31/12/2023
D4.3	SOPs for virtual cohorts generation and validation	WP4	TUE	R	PU	M36	31/12/2023
D4.6	SOPs for validation of in-silico models	WP4	BIO	R	PU	M36	31/12/2023
D7.7	Virtual cohort generation for in-silico trials	WP7	TUE	OTHER	CO	M36	31/12/2023
D7.8	Validated virtual cohorts for in-silico trials	WP7	TUE	DEM	PU	M36	31/12/2023
D9.5	High-fidelity devices validation report	WP9	BIO	R	CO	M36	31/12/2023
D9.6	Devices approval experience report	WP9	BIO	R	PU	M36	31/12/2023

Table 6: SIMCor deliverables.

Deliverable naming convention

<project>_<d-number>_<d-name><responsible-partner>_<version>/<dd- mm- yyyy>*
*the version n for intermediate versions, the submission date for the final submitted version.

Example: SIMCor_D2.1_Project presentation_LYN_v2 *(2nd draft)*
SIMCor_D2.1_Project presentation_LYN_31-01-2021 *(final submitted version)*

Deliverable style guide

This style guide is used, together with the template, to align the deliverables on a common format and style, and it is also provided as a separate document within the project Google Drive. The different aspects of the style guide are reported in the table below.

Document style	Details
Heading 1	Title style for main sections (Introduction, …., Appendix). Calibri 18, blue (hex #4472C4), bold, left alignment, in a new page.
Heading 2	Title style for subsections. Calibri 14, light blue (hex #4472C4), bold, left alignment.
Heading 3	Title style for internal paragraphs. Calibri 12, dark blue (hex #1F3864), bold, left alignment.
Heading 4	Title style for subparagraphs Calibri 11, turquoise (hex #4472C4), italic, left alignment
Normal	Body text style. Calibri 11, black, justified alignment
In-text figures/tables references	When citing figures/tables in the body text. Calibri 11, black, italic. *Example*: "(…) aortic valve leaflets and aorta (see *Figure 2*)".
Captions	Table/Figure caption style, placed under the table/figure. Calibri 9, grey blue (hex #44546A), italic, central alignment.
Footnotes	Footnotes and references style. Calibri 8, black, left alignment. No space before/after the line.
References	Inserted in the body text as footnotes, APA style

Table 7: SIMCor deliverables style guide.

Tables

Alignment: tables take all page width, with column width adapted to content.
Borders: all borders, 1 pt, black.
Header: dark blue (hex #1F3864) background, text Calibri 9 pt, white, bold, central alignment.
Sub-header: light blue (hex #B4C6E7) background, text Calibri 9 pt, normal, black, central alignment.
Text: white background, text Calibri 9 pt, normal, black, left alignment.
Caption: under the table, Calibri 9, blue, italic, central alignment.

Name	Name	Name	Name
Specification header (where necessary)			
Lorem ipsum dolor sit amet, consectetur adipiscing elit.	Lorem ipsum dolor sit amet, consectetur adipiscing elit.	Lorem ipsum dolor sit amet, consectetur adipiscing elit.	Lorem ipsum dolor sit amet, consectetur adipiscing elit.
Fusce volutpat interdum felis, a dignissim libero sodales quis.	Fusce volutpat interdum felis, a dignissim libero sodales quis.	Fusce volutpat interdum felis, a dignissim libero sodales quis.	Fusce volutpat interdum felis, a dignissim libero sodales quis.
Maecenas odio massa, lobortis tempor aliquam vel, pretium vitae lacus.	Maecenas odio massa, lobortis tempor aliquam vel, pretium vitae lacus.	Maecenas odio massa, lobortis tempor aliquam vel, pretium vitae lacus.	Maecenas odio massa, lobortis tempor aliquam vel, pretium vitae lacus.

Table 8: SIMCor deliverable table example.

Figures

Alignment: if wider than 10 cm, in line with text and centralised, AFTER the corresponding reference in the text. Else, can align right/left and wrap text, within the paragraph where the figure is cited.
Borders: no borders. **Text**: Calibri.
Caption: under the table, Calibri 9, grey blue (hex #44546A), italic, central alignment.

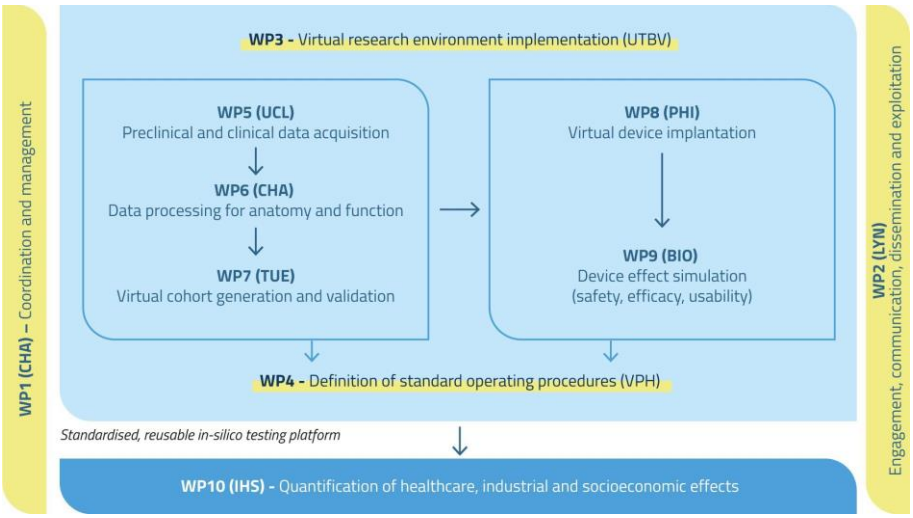

Table 9: SIMCor deliverable figure example.

Deliverable template

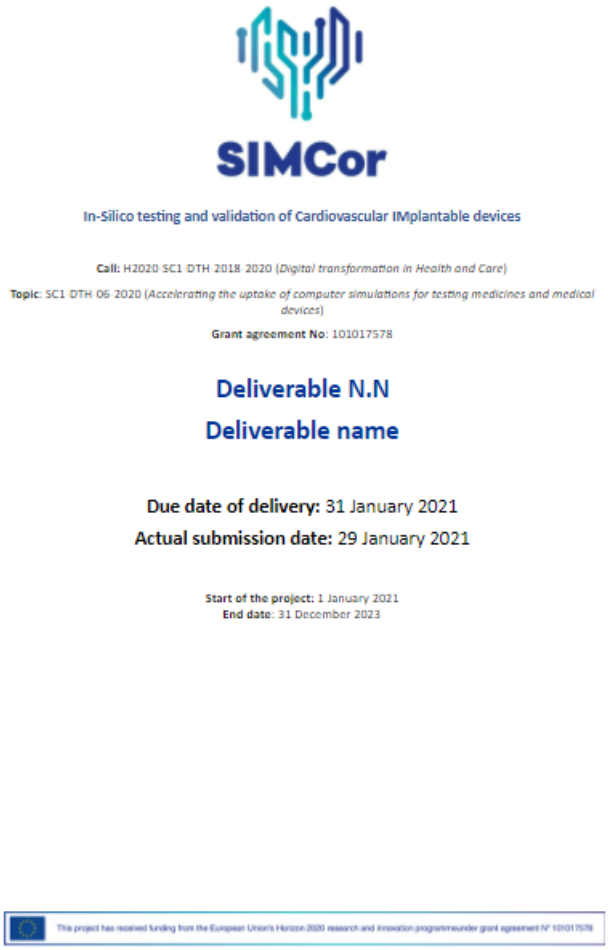

Figure 4: Page heading of the SIMCor deliverable template.

Internal quarterly progress reports

Internal quarterly progress reports (IQPRs) assess research progress in each deliverable and signal potential issues and risks to the PC and PMs. By definition, they are delivered every 3 months, where no other intermediate (M12, M24) or periodic report (M18, M36) is envisaged. Based on the template provided by the PM in the project Google Drive, reported below, they are requested and compiled at the end of each trimester by each WP Leader, and then reviewed by PM and PC to discuss project progress status and any issues emerged in the report.

IQPR template

SIMCor

SIMCor
Y1 - Quarterly report 1 (M1-M3)

WP	*WP name, number and timeframe*
WP Leader	*Leading partner*
Contributing Partners	*Other partners contributing to the WP*
Tasks	*Name, number and duration of the tasks active in this reporting period*
Activity summary	
Synthetically describe the main activities carried out in the reporting period. *Do not exceed 1500 characters spaces included (s.i.).*	
Working group(s)	
Name, composition and frequency of meetings of the corresponding WG(s), if any. *Do not exceed 500 characters s.i.*	
TCs	
N°, date, involved partners, main topic(s) of discussion.	
Dependencies/expectations from other WPs/WGs	
Interactions with other WPs and/or WGs. Do not exceed 500 characters s.i.	
Issues/risks	
Pending issues and identified potential risks, if any. Do not exceed 500 characters s.i.	
Deviations from the workplan	
Reasons for deviation from the workplan (if any) and mitigation actions. Do not exceed 500 characters s.i.	
Upcoming work	
Action items for the next reporting period and timing (i.e., bullet points with expected M of completion/delivery)	

Figure 5: SIMCor internal quarterly report template.

Periodic reports

Periodic reports are official reports to be submitted by the PC to the EC within 60 days following the end of each reporting period (i.e., M18, M36), using forms and templates provided in the electronic exchange system. The periodic reports include *1) a periodic technical report*, to report scientific progress of the project in each WP, including issues and risks, and *2) a periodic financial report*, including requests for payment. All financial statements must be drafted in euro (required conversions must be done previously). The instructions to complete the forms and templates will be sent by the PM in due time.

The periodic technical report

This part can be further divided into two parts, Part A and Part B.
Part A is automatically generated by the IT system based on the information entered by the participants in the electronic exchange system in the Participant Portal, and includes the cover page, a summary for publication, and answers to the questionnaire related to the project implementation and the economic and social impact.
Part B is the narrative part that includes the description of the work carried out by partners, including progress overview towards the objectives of the action, including milestones and deliverables, justification and explanation of differences between expected and actually carried out work, compared with objectives, deliverables and milestones defined in the DoW. This part also includes a report of dissemination exploitation, dissemination and communication activities (i.e., summary for publication by the EC, answers to the action implementation and economic and social impact questionnaire, key performance indicators).
To achieve that, the PM sends a WP form to be compiled by WPLs with the support of TLs and sent to the PM and the PC, that integrate and consolidate the provided information and sends the complete periodic technical report to the consortium for review. The final approved version is uploaded as a PDF document into the Participant Portal by the PC.

The periodic financial report

The financial report is a financial statement compiled by each partner covering the entire reporting period, where eligible costs are detailed for each budget category, including justification for the use of resources and information on subcontracting (if any) and in-kind contributions provided by third parties. Amounts not declared in financial statements will not be taken into account by the EC.
A periodic summary financial statement is automatically created by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and includes the request for interim payment.
The PM and PC will have a final check on the statements and accept or revoke them and ask for clarifications and resubmission by the concerned partner(s), if needed. If any of the partners fails to respect the deadlines, the PC will submit the PR on time.
Missing data from one or more partners will not be considered. This procedure ensures to avoid delays in payment of other partners. 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.
Once the complete PR has been verified and deemed correct and complete, the PC submits it to the EC participant portal.

Final report

In addition to the second PR, the final report (FR) is delivered at the latest 60 days after the end of the second reporting period (M36). The FR includes:

1. a technical report in the form of a summary for publication, including overview of the work carried out, results overview, foreseen socio-economic impacts, exploitation and dissemination potential;
2. a final financial report, including a final summary financial statement, automatically created by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance; a financial statement certificate for each beneficiary as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices.

An overview of all types of reports is included in the table below. The table also includes D1.6 and D1.7, that are annual reports even if included in the form of deliverables.

Type	Short name	Period covered	Prepared by	Submitted to the EC platform
First internal quarterly report	IQR1	M1-M3	WPLs and TLs	N
Second internal quarterly report	IQR2	M4-M6	WPLs and TLs	N
Third internal quarterly report	IQR3	M7-M9	WPLs and TLs	N
D1.6 - First intermediate report (LYN, M12)	**D1.6**	**M1-M12**	**WPLs and TLs, PM, PC**	**Y**
Fourth internal quarterly report	IQR4	M3-M15	WPLs and TLs	N
First periodic report	**PR1**	**M1-M18**	**WPLs and TLs, PM, PC**	**Y**
Fifth internal quarterly report	IQR5	M19-M21	WPLs and TLs	N
D1.7 - Second intermediate report (LYN, M24)	**D1.7**	**M13-M24**	**WPLs and TLs, PM, PC**	**Y**
Sixth internal quarterly report	IQR6	M25-M27	WPLs and TLs	N
Seventh internal quarterly report	IQR7	M28-M30	WPLs and TLs	N
Eighth internal quarterly report	IQR8	M31-M33	WPLs and TLs	N
Second periodic report	**PR2**	**M19-M36**	**WPLs and TLs, PM, PC**	**Y**
Final report	**FR**	**M1-M36**	**WPLs and TLs, PM, PC**	**Y**

Table 10: SIMCor reports, including internal quarterly reports, intermediate annual reports, period reports and final report.

Payments and budget transfers

The payment will be distributed as follows:

1. **Pre-financing (project start, 60%)**: pre-financing funds remain EU property until they are 'cleared' against eligible costs accepted by the European Commission.
2. **First instalment (M12)**
3. **Second instalment (M18)**
4. **Third instalment (upon receipt of the interim payment by the EC)** after formal approval of deliverables submitted in the first reporting period.
5. **Final payment (upon receipt of the final payment by the EC)** after formal approval of deliverables submitted in the first reporting period.

Payment	Amount (%)	Deadline
Pre-financing	60%	Project start, on receipt of advance payment
First instalment	15%	M12
Second instalment	10%	M18
Third instalment	10%	Retention to be paid at acceptance of submitted deliverables in period 1
Final payment	5%	Retention to be paid at acceptance of submitted deliverables in period 2

Table 11: SIMCor payment scheme.

Budget transfers

Upon a decision of the Executive Board, a re-distribution of budget between partners may be considered. This is allowed without requesting an amendment provided that it does not imply a substantial change to the action as described in the DoW. All other budget reallocations need to be discussed in order to decide whether to apply for an amendment to the EU GA. The maximum grant amount can however never be increased.

Documentation records

Each partner has to keep **records and documentation** (as original copies, or digital if they are accepted as original by national legislation) to prove the proper implementation of the action and the declared eligible costs, according to their internal best practices and control procedures, for a period of five years after the final payment, with a track between the amounts declared, the amounts recorded in accounts and the amounts stated in the supporting documentation (audit trail).

Timesheets are also required to be kept at partner institutions, to maintain complete records of time worked on the project, in any desired format and in accordance with institution best practices. A model time sheet can be supplied by the PM upon request. Partners are not required to submit time sheets but they have to be available for inspection upon request.

Dissemination and communication

Peer-review publications

Acknowledgment of EU funding

All project-related results, including prototypes, software, publications, patents, etc. msu acknowledge funding from the European Commission. This should be done:

- where applicable, by using the **acknowledgment of EU funding banner** available in the project Google Drive (*SIMCor> C&D materials > 3_EC acknowledgment banner*);

Figure 6: SIMCor banner for acknowledgment of EU funding.

- alternatively, the relevant phrase including:
  a. European Union
  b. Funding programme (H2020)
  c. Grant Agreement number (101017578)
  d. Project name & acronym (if possible).

  Example: *"This work has been funded under the European Union's Horizon 2020 research and innovation programme under grant agreement N° 101017578 (SIMCor: In-Silico testing and validation of Cardiovascular IMplantable devices)."*

Open access

All peer-reviewed scientific publications must be fully open access. This should be done:

- **on the publishers' website (gold open access or open access publishing route):** publishing in open access journal or hybrid journals upon article processing charges (APCs); in this case, remember that APCs costs are eligible for reimbursement only within the project duration;
- **depositing a machine-readable electronic copy of the full text (i.e., accepted manuscript, pre-print or published version**) upon publication or at the end of the embargo period (green open access or self-archiving) in the Zenodo project archive (with the support of the PM) or other institutional open access archive.

In either case, timely communication should be made to the WP2 Leader/PM to effectively disseminate the publication through the project website and social media.

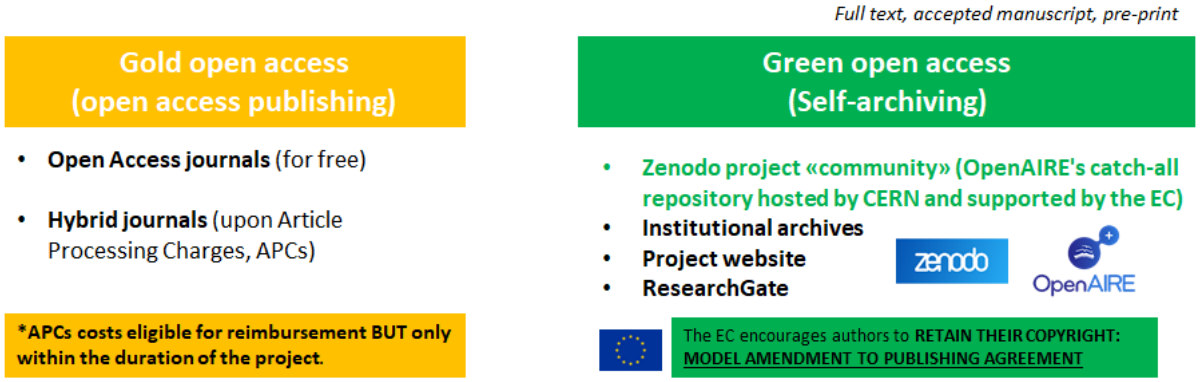

Figure 7: Open access modalities for SIMCor peer review publications.

Other dissemination activities

Consortium members are highly encouraged to share their activities, including presentations at conferences, press releases, educational publications or others, via pre-announcement to the WP2 Leader and/or documenting on social media. Please do so at an early appropriate stage/to your earliest convenience.

Branding and C&D materials will be available on the project Google Drive (*SIMCor> C&D materials)* at consortium disposal. For any support/specific needs, you can get directly in touch with the WP2L.