

EU Horizon 2020 Research & Innovation Program Digital transformation in Health and Care SC1-DTH-06-2020 Grant Agreement No. 101016496

SimCardioTest - Simulation of Cardiac Devices & Drugs for in-silico Testing and Certification



Technical Report D7.1 Dissemination and Communication strategy plan

Work Package 7
WP7 - Exploitation, Dissemination & Communication

Task Lead: VPHi, Belgium

WP Lead: VPHi, Belgium



DELIVERABLE INFORMATION

Deliverable number	D7.1								
Deliverable title	Dissemination and Communication Strategy Plan								
Description	Report on the communication and dissemination								
	activities strategy for the project.								
Lead authors	VPHi								
Contributors	Martina Contin, Liesbet Geris, Raphaelle Lesage								
	(VPHi), Michèle Barbier (Inria)								
Due date	M3								
Submission date									
Comments	A first version has been submitted on 31 March								
	2020. This version has been revised upon								
	evaluators' request.								

Document history	y		
Date	Version	Author(s)	Comments
23/02/2021	V1.0	M. Contin, L. Geris (VPHi) M. Barbier (Inria)	Submitted version
01/12/2022	V2.0	M. Contin, R. De Michele, R. Lesage (VPHi), M Barbier (Inria)	Revised version after periodic review meeting

PUBLIC Page 2 of 20



Table of Contents

TABL	E OF CONTENTS	3
Acro	DNYMS	4
1.	EXECUTIVE SUMMARY	5
2.	Introduction	6
3.	SIMCARDIOTEST COMMUNICATION AND DISSEMINATION	7
4.	COMMUNICATION ACTIVITIES	7
5.	TARGET AUDIENCES, GOALS AND CHANNELS	8
6.	STAKEHOLDER ENGAGEMENT STRATEGY	10
6.1	SCIENCE	10
6.2	Industry	11
6.3	REGULATORS, STANDARDIZATION BODIES AND POLICY MAKERS	11
6.3.1	PUBLIC CONSULTATIONS ON EUROPEAN POLICIES	11
6.3.2	WORKSHOPS AND INTERACTIONS	12
6.3.3	GOOD SIMULATION PRACTICES	12
6.4	CLINICAL COMMUNITY	12
6.4.1	LIST OF RELEVANT SOCIETIES	12
6.4.2	Working group on Clinical Community	14
6.5	SOCIETY AT LARGE AND PATIENT ORGANIZATIONS	14
6.5.1	DEFINITIONS AND GUIDANCE DOCUMENTS FOR PATIENT ENGAGEMENT AND HEALTH TECHNOLOGIES	14
6.5.2	2. IDENTIFICATION OF PATIENT ASSOCIATIONS	15
7.	DISSEMINATION	17
8.	EXPLOITATION	18
9.	Conclusion	19

PUBLIC Page 3 of 20

Acronyms

AA: Avicenna Alliance AB: Advisory Board AI: Artificial Intelligence

ASME: The American Society of Mechanical Engineers

CM&S: Computer Modelling & Simulation

EC: European Commission

EHDS: European Health Data Space

EIT Health: European Institute of Technology on Health

EMA: European Medicine Agency ESC: European Society of Cardiology

EU: European Union

EUPATI: European Patients' Academy on Therapeutic Innovation

EPF: European Patient Forum ExCom: Executive Committee

FC: Focus Group

FDA: US Food and Drug Administration

GB: Governing Board

GSP: Good Simulation Practices

HERA: Health Emergency preparedness and Response Authority

Inria: Institut National de Recherche en Sciences et Technologies Du Numerique

IST: Insilicotrials Technologies Srl KPI: Key Performance Indicator

MDIC: Medical Device Innovation Consortium MEPs: Members of the European Parliament

PE: Patient Engagement RPP: Rohde Public Policy

RRI: Responsible Research & Innovation

SFC: French Society of Cardiology ('Société Française de Cardiologie')

SG: Stakeholder group

SOFA: Simulation Open Framework Architecture

STACOM: Statistical Atlases and Computational Modelling of the Heart

SRL: Simula Research Laboratory

SUURPh: Summer School on Computational Physiology

UC: Use Case

UPF: Universidad Pompeu Fabra

VPHi: Virtual Physiological Human Institute:

WP: Work Package WG: Working Group

PUBLIC Page 4 of 20



This report belongs to Work Package 7 (WP7) and outlines the initial strategy of the dissemination, communication and stakeholder outreach activities of the project. The document analyses in depth the different target audiences and gives an overview of the strategy (goal, channels and approach) for each one of them.

The document will also present a strategy for the stakeholder engagement activities as well as the project exploitation, activities that will developed as part of WP7.

PUBLIC Page 5 of 20



2. Introduction

SimCardioTest is a new project funded by the European Commission for 8 million euros under the call H2020-SC1-DTH-2020-1. Its goal is to accelerate the adoption of digital simulation for the design of cardiac drugs and medical devices and to demonstrate the feasibility, effectiveness and benefits of in-silico trials for cardiac devices & drugs.

To achieve this, the project has set three high level objectives:

- Set-up standards for in-silico tests;
- Increase availability of safe & effective devices and drugs;
- Change of paradigm in clinical trials.

The Communication and Dissemination activities are led by the Virtual Physiological Human institute (VPHi) supported by Inria and other partners. The VPHi, being an international non-profit organization for in-silico medicine, is already federating a network of stakeholders (about 10,000 members). This network will be further extended during the length of the project.

This deliverable provides an overview of the project's communication and dissemination strategy focusing on the project's target groups and the identification of the appropriate communication and dissemination channels and tools that will be used for each group, based on the specific goals.

The document will also present a strategy for the stakeholder engagement activities as well as the project exploitation, activities that will developed as part of WP7.



This plan will be reviewed and updated on a regular basis for assessing new and possible opportunities that would emerge during the course of the project. A monthly meeting with communication experts from each partner organisation will be organised to monitor these opportunities and increase collaboration.

PUBLIC Page 6 of 20



3. SimCardioTest Communication and Dissemination

SimCardioTest will use a number of tools and resources for communication and dissemination. Beyond semantics, there is a difference in our usage of the term communication versus dissemination.

Communication covers the activities and channels used by the team for general information exchange with our targeted audiences. The goal is to create public awareness and enhances the visibility of the project results, consortium and the research program, and also to encourage people to use the results, increasing the chances the research will make an impact. Some of the channels used for this purpose are, for instance, the public website, the project newsletter, the social media, etc.

Dissemination focuses on making sure the computation models deployed during the project are available to SimCardioTest target audience (scientific community, policy makers, industry, etc.) and demonstrate that use cases can predict safety and efficacy of drugs & devices.

Both these activities will be driven by WP7: "Exploitation, Dissemination & Communication ", which is led by VPHi and involves all project partners.

This communication plan supports the SimCardioTest consortium in their project-related communication and will focus on the following principles:

- Communication is critical both within the consortium and with the project's stakeholders;
- Key communication messages should be shared and used by all project partners;
- Communication targets should be well defined and analysed;
- Communication tools should be designed for specific needs, accessible and usable by the partners.

4. Communication activities

The value of effective project communication is in delivering clear messages to the project stakeholders through a set of targeted communication tools. The four key objectives of SimCardioTest in terms of communication are the following:

- Communicate on the technological progress on in-silico testing demonstration, and specifically ensure scientific dissemination of SimCardioTest results.
- 2. Generally, promote the SimCardioTest concept, highlighting its role for Europe's development of medical devices & drugs, and build visibility for the academic and industrial partners.
- 3. Inform the engaged stakeholders (regulators, companies, etc) of the project outcomes in terms of standardization and interoperability.
- 4. Start reaching out to a general audience for promoting safe in-silico clinical trials sector.

In order to achieve these objectives, the SimCardioTest communication activities will focus on these items:

- Key message: SimCardioTest is a new European Union (EU) project to provide insight into designing new predictive tools in cardiac pathologies. It will accelerate the uptake of computer simulations for testing medicines and medical devices.
- A project logo & visual identity, including presentation and document templates, will be designed at the beginning of the Project to ensure visibility at events and conferences.

PUBLIC Page 7 of 20



- Printed communication support materials: project poster, flyers and rollup will be produced in order to be distributed at events and conferences to promote and communicate on the project.
- A public website for SimCardioTest will be designed at the beginning of the project. It will be widely promoted and continuously updated. It will be written in a non-expert language to be user-friendly and welcoming for the general public. In addition, it will be well-referenced in order to be easily reached via popular search engines with relevant keywords. The partners will be invited to refer to the website for their organization's communication. Public results will be made available on the dedicated website.
- Social media, e.g. LinkedIn (https://www.linkedin.com/in/simcardiotest-eu-project-ehealth-eu-207a08204/) and Twitter (@Simcardiotest) will support the promotion of the project outcomes. Each partner is connected to these accounts and disseminate/forward news to their own networks.
- <u>Press releases on important events (i.e. Kick off, General Assembly</u>) will be shared among the partners for local/national/international dissemination.
- Project newsletters with highlights of the SimCardioTest Project, news, announcements of relevant workshops and forthcoming conferences. News will also be shared on social media and website.
 - Interviews of scientists participating in SimCardioTest will be organised to enrich the newsletters.
 - More news about the project will be shared quarterly on the VPHi newsletter, which
 is already established and currently reaches more than 6000 subscribers.

- Project video:

- A video of 3 min. maximum giving an overview of the project, showing the objectives, highlighting outputs of the project, including interviews of Consortium members or other stakeholders during workshops will be released.
- o Interviews (video of 1 min to 10 min.) of scientists (PhD, post-doc and seniors) will be disseminated via the project social medias.
- Organization of events for the public at large: such as on 29 September, the International day
 of heart, in collaboration with relevant societies and federations.
- A final project workshop will be organized at the end of the Project to disseminate the knowledge acquired. All relevant stakeholders will be invited to attend, including public and private potential users of project results, policy-makers at several governmental levels, and international counterparts.

The impact of the communication actions will be continuously monitored (audience in presentations, conferences, countries addressed, etc.). Indicators will be defined for the communication, dissemination and education actions. These will include quantitative indicators (website traffic and search engine referencing; number of attendees in workshops, summer schools and conferences) and qualitative ones (post-event surveys, feedback from periodic reviews).

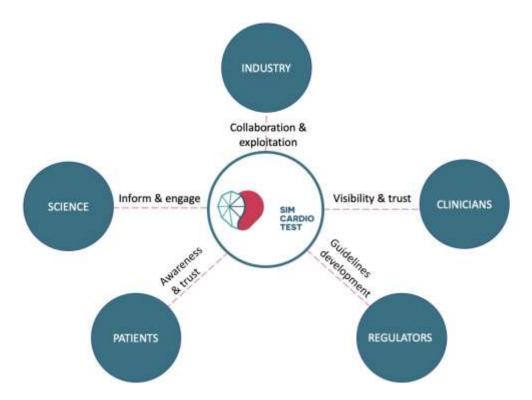
5. Target Audiences, Goals and Channels

The SimCardioTest communication target audiences are composed of variety of stakeholder groups: science, industry, regulators and standardization bodies, clinicians and associations of medical doctors, society at large and patient organizations.

PUBLIC Page 8 of 20



Here we consider stakeholders individuals and groups inside or outside the project who may influence the success of the project, be impacted by the project and/or actively support the project. For each stakeholder group the goal and channels of the communication will be different.



- Science: a diverse network of actors managing, coordinating, or conducting scientific research in the in-silico medicine field. This group includes the research community, science managers as well as students/the next generation of scientists. The science category includes actors at local, national, intergovernmental, and European levels.
 - Goal: inform the scientific community of the projects and its achievements
 - o Channels: public website, social media, press releases, newsletter, videos, events
- Industry: in the SimCardioTest context, this category includes pharma & medical device companies, software and service providers, which are well represented in the Avicenna Alliance (AA) membership, a global non-profit organization the VPHi strongly is part of.
 - Goal: generate visibility on the project and its outcomes to increase collaboration and create exploitation opportunities
 - Channels: in addition to the above creation of working groups and ad hoc workshops and events
- Regulators & Standardization bodies, such as the European Medical Agency (EMA), and Food and Drug Administration (FDA) & several EU notified bodies.
 - O Goal: increase collaboration in order to overcome the barriers for the uptake of insilico medicine technologies. The SimCardioTest consortium will focus on developing synergies with ongoing activities run by the VPHi and the Avicenna Alliance, such as the development of guidelines for validation of in-silico models in the context of drug development with EMA and the development of Good Simulation Practices (GSP).
 - <u>Channels:</u> in addition to the above publication of documents, white and green papers and guidelines for the community.

PUBLIC Page 9 of 20



Clinical community

- o Goal: increase visibility of in-silico medicine technologies and gain trusts
- Channels: specific workshops will be organized with/for clinicians to identify expectations and concerns related to in-silico technologies, starting by taking advantage of the strong connections of the consortium with the members of the European Society of Cardiology and its working groups on e-Cardiology, digital health and regulatory affairs. This will be complemented by interviews and surveys and lead to the generation of specific information packages, organization of specific sessions at e.g. European Society of Cardiology e-Cardiology conferences, and scientific publications in medical journals.
- Society at large and patient organizations: This category includes members of the society
 who have no specific knowledge on in-silico medicine, but also patients, and the
 organizations that represent them (more information follows)
 - Goal: make them aware of what in-silico medicine is and how it can improve their lives; inform them on the new available technologies developed by the project, increase visibility & trust on these technologies
 - Channels: social media, website, life science publications and generalist press, video campaigns. Also focus groups will be formed based on contacts with relevant patient societies present in the consortium. Dedicated local activities will be organized by partner organizations together with local patient organisations, e.g. for the international day of the heart, and experiences will be evaluated and good practices on patient outreach shared with other consortium members.

6. Stakeholder engagement strategy

6.1 Science

The scientific community will be engaged through:

- o permanent publication of news on social medias,
- publication in peer-reviewed journals:
 - Cardiovascular Research: Circulation, Frontiers in Physiology; J. Chem. Information & Modeling; Journal of Physiology; Journal of the American College of Cardiology (JACC); Journal of Theoretical Biology; PLoS Computational Biology; PloS One, American Journal of Physiology; Heart & Circulatory Physiology; British J.I of Pharmacology; Circulation, Circulation Arrhythmia & EP; Computer Methods in Applied Mechanics and Engineering; European Heart Journal; Frontiers in Pharmacology; Heart Rhythm Journal; Int. J. for Numerical Methods in Biomedical Engineering, Medical Image Analysis; Interface Focus; Journal of Biomechanics; Journal of Pharmacological and Toxicological Methods; Nature Communications; Pharmacology & Therapeutics;
- Participation to specific conferences:
 - Engineering: Computing in Cardiology, Med. Image Computing & Comp. Assisted Intervention; (MICCAI) & STACOM, IEEE Int. Symposium on Biomedical Imaging (ISBI), IEEE Eng. in Medicine and Biology Society (EMBS), Functional Imaging & Modelling of the Heart (FIMH), Comp. Assisted

PUBLIC Page 10 of 20



Radiology and Surgery (CARS), the Virtual Physiological Human conference, Gordon Research Conference on Cardiac Arrhythmia Mechanisms, Summer Biomechanics, Bioengineering, and Biotransport Conference, Cardiac Physiome, World Congress of Biomechanics;

- Cardiology: Heart Rhythm Society, European Society of Cardiology Congress
- Pharmacology: Society of Toxicology (SOT), Safety Pharmacology Society (SPS)
- Al: Intelligent Health, Al for Health, SophIA summit
- Virtual Physiological Human conference;
- Joint workshops with the coordinators and scientific partners of the EU funded projects: SimCor, SimInSitu, Stands4EUpm, InSilicoWorld;
- (co-)organization of workshops during conferences: e.g. about specific tools used and developed during the project, such as the SOFA framework, or about stakeholder engagement approaches.

6.2 Industry

Beside the industrial consortium partners, external industrials will be reached out in various ways. First the Advisory Board meetings will be used to regularly report the achievements of SimCardioTest and consult industrials. Then, the close collaboration with the Avicenna Alliance, whose membership is largely composed of industrials at stake in the field of computational modelling and simulation (CM&S) for healthcare, will be leveraged to communicate about the SimCardioTest outputs, e.g. during informal discussions and through the realization of short briefs (1-slide format) about the SimCardioTest use cases thereby contributing to a growing knowledge base of application cases for AA members and beyond. Finally, SimCardioTest participants will be take part and organise various events and workshops attracting digital health industrials to increase the visibility of the project and create exploitation opportunities (e.g. World AI Cannes festival, Heart Day workshop, AI for Health Summit).

6.3 Regulators, Standardization Bodies and Policy Makers

As a starting point, the VPHi will perform a desk review a compile a list of existing standards and guidelines related to CM&S in healthcare or other high-risk domains (e.g. NASA documents, etc..) to draw the existing regulatory landscape. This internal and evolving document will be available for the SimCardioTest partners to drive the future engagement activities.

6.3.1 Public consultations on European Policies

Thanks to the strategic collaboration with the <u>Avicenna Alliance</u>, the VPHi is constantly involved in public consultations by European policy makers, with the goal to raise awareness on in-silico technologies and the need for a clear regulatory path and recognition.

Here a list of former and upcoming consultations on European policies of interest for the SimCardioTest project:

- Regulation of the European Parliament and of the council on a reinforced role of the EMA in crisis preparedness and management for medicinal products and medical devices
- The European health data space (EHDS)
- The Health Emergency Preparedness and Response Authority (HERA)
- EU regulation package on AI

PUBLIC Page 11 of 20



- Revision of EU rules on medicines for children and rare diseases
- Draft amendments on EMA and cross-border threats to health regulations
- Revision of the EU Pharmaceutical Legislation

These activities will be carried on during the whole length of the project to make sure that the project views will be represented in the future documents.

Additionally, short briefs will be produced about the SimCardioTest use cases, targeting policy makers. They will be shared with the RPP group via the Avicenna Alliance for informing and supporting future conversations with Members of the European Parliament.

6.3.2 Workshops and Interactions

Regulatory science related to in-silico technologies is receiving more and more attention, hence the VPHi will organise a Triple Helix Expertise Exchange Workshop in April 2021. The triple helix format refers to the active participation of academia, regulators and industry and the focus was on in-silico models of drug-device combinations. Interactions with European regulators also happens through dedicated task forces at the VPHi/AA that typically generate joint white papers with regulators on issues of common interest. Finally, the consortium will closely follow all relevant developments and attend relevant events organized by regulators such as the launch of the Regulatory Science Research Needs initiative¹ by the EMA, or the Digital Dialogues Deep Dive session organized by the notified body TÜV SÜD "What are Notified Bodies (even) thinking?"².

6.3.3 Good simulation practices

The VPHi participates and contributes to the writing of the Good Simulation Practices (GSP)^{3,4} that is organised through the In-silico World Community of Practice, developed in the homonym project. Besides providing a consensus view and a guideline for modellers in the in-silico landscape (focus on in-silico trials), it also serves as a tool to engage with regulators and standardization bodies in order to initiate the discussion and gather their feedback, thereby enabling the identification of their needs and expectations. The outcome of this initiative will take the form of an open access book, which has a vocation for opening the path to new European standards for in-silico trials.

6.4 Clinical community

6.4.1 List of relevant societies

The engagement strategy for the clinical community will be to establish contact with specific local (European & national) clinical associations interested in cardiovascular diseases. The type of interactions should take different forms, including consultation and information/dissemination. The consultation will take place through interviews and surveys as well as invitations to workshops. The dissemination of content and information will happen following the consultation by reporting the results of the surveys and workshops but also by developing material addressing the raised concerns and expectations.

PUBLIC Page 12 of 20

¹ https://www.ema.europa.eu/en/news/ema-launches-regulatory-science-research-needs-initiative

 $^{2\} https://www.tuvsud.com/en/events/digital-dialogues?utm_medium=email\&utm_source=newsletter\&utm_campaign=2022_digital-dialogues-vol.4_de_eu_ps_mhs_lds_ts\&utm_content=event-reminder$

 $^{{\}tt 3\,\underline{https://insilico.world/community/good-simulation-practice-gsp-task-force/}$

 $^{{\}color{blue} 4\,\underline{\text{https://insilicotrials.com/towards-good-simulation-practice-international-scientific-community-refine-reduce-replace-invitro-invivo-experiments/} \\$



Here below, we list clinical societies that are potential targets for initiating the engagement activities. The geographical and language proximity to the SimCardioTest partners as well as the existence of pre-existing connections and network were also criteria used in the selection.

a. European Society of Cardiology (ESC)

SimCardioTest consortium is in contact with members of the ESC. It is located in Sophia Antipolis, Inria campus. In particular, Nicolas Duchateau (Associate professor at University of Lyon) is part of the SimCardioTest Advisory Board and member of the ESC (ESC e-Cardiology, Digital Health committee, ESC Regulatory affairs).

Up-coming important event: ESC Congress 2022 (26-29 Aug 2022, Barcelona), ESC Digital Summit 2021 (22-24 October 2021).

ESC is a European overarching society; however, a more efficient strategy could be to target national level initiatives. ESC is represented locally by ESC National Cardiac Societies⁵
Relevant national societies:

- French Society of Cardiology (SFC)⁶. Follow link in footnote for the list of upcoming events. The SFC has several working groups including of interest for the consortium: a cardiovascular research WG (GRRC Groupe de Réflexion sur la Recherche Cardiovasculaire⁷); a cardio-oncology WG⁸; a WG in rhythmology and cardiac stimulation.
- <u>Italian Federation of Cardiology</u>⁹
- Norwegian Society of Cardiology¹⁰
- Sociedad Española de Cardiologia (Spanish Society of Cardiology)¹¹ SEC22¹² (Spanish congress) is in Mallorca 20-22 Oct 2022
 - b. European Heart Rhythm Association¹³

Event: Annual congress of the European Heart Rhythm Association (EHRA) (April 2022, Copenhagen)

c. European Stroke organization

ESO¹⁴ is a scientific society for researchers and physicians, the *next conference* is in May 2022, in France¹⁵.

d. CSI

CSI¹⁶ is an association of interventional cardiologists. The equivalent at the Spanish level is CSC¹⁷. Both associations and related congress have objectives related to training of cardiologists.

- e. Catalan Society of Cardiology
- f. Society of Clinicians in Cataluna¹⁸

PUBLIC Page 13 of 20

 $^{5\,\}underline{\text{https://www.escardio.org/The-ESC/Member-National-Cardiac-Societies}}$

⁶ https://www.escardio.org/The-ESC/Member-National-Cardiac-Societies/French-Society-of-Cardiology

⁷ https://www.sfcardio.fr/grrc-groupe-de-reflexion-sur-la-recherche-cardiovasculaire

⁸ https://www.sfcardio.fr/gco-groupe-de-cardio-oncologie

⁹ http://www.federcardio.it/en/

 $^{10\ \}underline{\text{https://www.legeforeningen.no/foreningsledd/fagmed/norsk-cardiologisk-selskap/resets}}$

¹¹ https://secardiologia.es/

¹² https://secardiologia.es/comunicacion/noticias-sec/13014-sec22-desembarca-en-mallorca

 $^{13\ \}underline{\text{https://www.escardio.org/Sub-specialty-communities/European-Heart-Rhythm-Association-(EHRA)/About}$

¹⁴ https://eso-stroke.org/meetings/eso-conference-2022/

¹⁵ https://2022.eso-conference.org/

¹⁶ https://www.csi-congress.org/about-csi#what-we-do

¹⁷ https://csconline.org/quienes-somos/ - mision

¹⁸ https://www.catcardio.cat/



6.4.2 Working group on Clinical Community

The VPH Institute is planning to create a WG on Clinical Community. The main goal of this group will be to foster the use and acceptance of in-silico technologies by clinicians and healthcare professionals both in clinical practice and health product development. In order to do that the group will focus on:

- Raising awareness
- Consulting and evaluate needs and concerns
- Involving clinicians in technology development and co-design
- Involving clinicians in regulatory path development for in-silico technologies

These are some of the tasks the group will take care of:

- Conduct and publish a clinical survey
- Establish privileged relation with clinical societies
- Organize focus groups or consultations
- Promote the organization of workshop & focus groups by in-silico scientists
- Evaluate need, collect and produce educational material
- Reach clinicians in regulatory bodies (clinical opinion leaders in Notified Bodies, clinical trial experts, etc..)
- Communicate clinical outreach initiatives and events for in-silico medicine.

A member of the SimCardioTest consortium will be invited to represent the project in the WG.

6.5 Society at large and patient organizations

Similar to the clinical community, the strategy will consist of having a two-way dialogue with patient groups. This will allow, on the one hand, to identify and map in-silico medicine priorities and perceptions from a patient perspective and, on the other hand, to inform and raise awareness about in-silico technologies. The interaction with this target group will mainly take the form of consolations through the organization of specific focus groups, where patients and representative of patient organisations will be invited to bring their views and expertise to help the consortium understand how to bring in-silico models closer to user of these technologies.

6.5.1 Definitions and guidance documents for patient engagement and health technologies

As defined by the European Patients' Academy on Therapeutic Innovation (EUPATI)¹⁹, the term 'patient' at large comprises different types of profiles who may or may not have the disease themselves:

- Individual patients (personal experience of living with a disease)
- Patient advocates (have the insight and experience of a larger population of patients living with a disease)
- Carers (support individual patients, e.g. family members or paid/volunteer helpers)
- Patient experts (have the technical knowledge in R&D and/or regulatory affairs through training or experience)
- Patient representatives/organizations (mandated to represent and express the collective views of a patient organisation on a specific issue or disease area)

PUBLIC Page 14 of 20

¹⁹ https://eupati.eu/



The European Medicine Agency defines "Patients' organisations" as not-for profit organisations, which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies"²⁰

Relevant documentation and guidelines about public input and Patient Engagement (PE) in relation to health technologies were collected to guide the future activities planned with that community within SimCardioTest. Here below, is a list of relevant resources and documentation about patient engagement:

- PARADIGM website: public-private partnership to provide structure framework for Patient Engagement ²¹
- PARADIGM toolbox for PE²²
- Guidance document from FDA: Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations²³.
- Guidance document from FDA: Patient-Focused Drug Development: Collecting Comprehensive and Representative Input²⁴. This document provides a methodology on how stakeholders (patients, researchers, medical product developers and others) can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making
- FDA document: "The voice of the patients": A series of reports from the FDA Patient-Focused Drug Development Initiative:
 - Report from FDA following patient consultation to hear perspectives from (Huntington disease) patients about their daily life and experience with available therapies. It gives insights on the conduct of this type of PE activities (issued Mar 2016)²⁵.
 - Same as above but for chronic pain patients (issued Mar 2019)²⁶.

In addition, MDIC has developed a Science of Patient Input (SPI) program²⁷ which regularly provides resources for helping various stakeholders to interact with patient. The MDIC's 2020 patient Engagement Forum was meant to provide the opportunity for various stakeholders to "learn and share challenges and best practices for communicating uncertainty, benefit and risk of medical devices to patients". It was hold virtually and recording of sessions are available online²⁸, which represents a valuable resource for SimCardioTest WP7.

6.5.2 Identification of patient associations

We will target national coalitions mainly, and possibly pan-European organizations too (i.e. umbrella organisations gathering national patient organizations active in the same disease-area across EU). If possible and accessible, we could also interact with patient groups (sub-group active within broader organizations or alliances, which include other stakeholders such as healthcare professionals). Online patient communities (on social media etc..) won't be targeted for consultation

PUBLIC Page 15 of 20

²⁰ https://www.eu-patient.eu/Members/what-is-a-patient-organisation/

²¹ https://imi-paradigm.eu/

²² https://imi-paradigm.eu/petoolbox/

 $[\]textbf{23} \ \underline{\text{https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations}$

²⁴ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input

²⁵ https://www.fda.gov/media/96196/download

²⁶ https://www.fda.gov/media/124390/download

²⁷ https://mdic-spi.org/

²⁸ https://mdic.org/event/patient-engagement-forum-virtual/



since their natures and missions are often less well defined (according to EUPATI) although they might be a good channel for dissemination of outputs and information. Importantly the language barriers should be considered in engagement activities, some patients populations may not be English speaking.

Below a list of patient associations relevant for SimCardioTest that takes into account the country in which the leading partners are based:

- [France] Alliance du Coeur²⁹:
- [France] Fédération Française de Cardiologie³⁰
- [France] AVEC (Association Vie Et Cœur)³¹
- [Europe] SAFE Stroke Alliance for Europe³² is a member of the European patient forum (EPF).
 - Stroke foundation of Catalonia (Fundacio Ictus³³). They are part of the SAFE alliance. It is targeted for patients but they have a 'professionals'. They were part of an EU project, Ictusnet ³⁴ between different research, medical and patient association partners of Spain, France and Portugal (interreg). Ictusnet offers a search engine for stroke foundations³⁵
- [Europe] Global Heart Hub The Alliance of Heart Patient Organisations³⁶ is also aprt of EPF.
 They have a Heart Failure Patient Council³⁷ and national affiliates:
 - [Spain] Cardio Alianza³⁸ "The Spanish Association of Heart Patients", based in Barcelona, brings 16 organization of patient with CDV in spain.
 - [Spain] GICOR³⁹ (Associació Gironina de Prevenció i Ajuda a les Malalties del Cor (GICOR) in Barcelona.
- [Belgium] Belgian heart foundation⁴⁰
- [Spain] Fundacion espanola del corazon ⁴¹: Spanish heart association. Prevention of cardiovascular diseases among population through communication.
 - Inside the Spanish fundation, there are several regional patient associations. The one
 in Catalonia is from Girona, GiCor⁴² World thrombosis day provide campaign and
 educational resources for patients and healthcare professionals⁴³
- [Italy] EU STRUCTURAL HEART DISEASES COALITION (SHD)

 https://fondazionecuore.it/fipc/coalizione-europea-sulle-malattie-cardiache-strutturali/
- [World] Arrhythmia Alliance (https://www.heartrhythmalliance.org/)
- [Italy] Associazione Italiana di Aritmologia e Cardiostimolazione (AIAC) https://aiac.it/ Next congress: 16/17 June 2022, Bologna (Italy)

PUBLIC Page 16 of 20

²⁹ https://www.alliancecoeur.fr/

³⁰ https://www.fedecardio.org/nous-connaitre/presentation-de-la-federation-en-90-secondes/

³¹ https://www.avec-france.com/

³² https://www.safestroke.eu/

³³ https://www.fundacioictus.com/es/fundacion

³⁴ https://ictusnet-sudoe.eu/en/

³⁵ https://platform.ictusnet-sudoe.eu/red-ictusnet/buscador-asociaciones-y-fundaciones-de-pacientes/

³⁶ https://globalhearthub.org/

³⁷ Aistė Štaraitė: Chair, Heart Failure Patient Council. info@globalhearthub.org

³⁸ https://cardioalianza.org/

³⁹ https://www.gicor.org/

⁴⁰ https://www.belgianheartfoundation.be/NI/

⁴¹ https://fundaciondelcorazon.com/

⁴² https://www.gicor.org/



Beside disease (cardiac) oriented associations, patients' groups interested in digital health and insilico technologies at large are also of interest.

There is a working group on digital health within the European Patient Forum (EPF)⁴⁴ which is open to the participation of external expert individuals. Approaching them and collaborating with them could be a strategy to meet some of the SimCardioTest WP7's objectives. In addition, the 2021 EPF congress will be on the digital transformation of healthcare – the added value of patient partnership⁴⁵. The 2022 edition plans to continue that conversation and is planned for April 2022, Brussels⁴⁶.

The EPF has 77 official members (i.e. national/local patient organizations that are affiliated): see list⁴⁷.

7. Dissemination

The dissemination activities are driven by WP7, but each partner also has effort and a specific budget to facilitate their contribution. This financial provision will cover travel to conferences, gold open access fees, publication costs, etc.

SimCardioTest will strictly follow the open access policy of Horizon 2020 by providing online access to scientific information that is free of charge and can be reused by the end-user. In the context of this project, scientific information refers to peer-reviewed scientific research articles (published in scholarly journals), articles, conference papers and research data. As such, the project will combine different measures to foster open access to knowledge as much as possible.

The academic partners already planned some specific dissemination activities. For instance, UPF aims to contribute to an open source culture where models, data for benchmarks and best practices are made freely and openly available to the community for research purposes; encourage technology transfer of the developed computational tools to companies; connecting with leading European medical institutions and disseminating the scientific results in these institutions. Moreover, specific dissemination goals include generate Open Access data from advanced flow imaging for benchmark of fluid simulations.

Similarly, Simula Research Laboratory (SRL) modelling software will be open source and made available to the wider scientific community to foster development of the computational cardiology field. The project will also produce populations of cardiac geometries that can be used for further studies on related cardiac problems. Finally, the knowledge produced during the project timeline is in line with Simula educational goals. The tools and techniques developed in the project will be implemented in the SUURPh Summer School on Computational Physiology to train future researchers in the field.

Dissemination will be achieved through the following means:

- Publications in scientific and general journals: consortium members will publish papers in scientific journals, in particular open access journals, with high impact factor, but also in more generalist ones such as Nature Communications.
- Papers and presentations at international conferences

https://www.eu-patient.eu/policy/workinggroups/working-group-on-digital-health/

https://epfcongress.eu/

https://www.eu-patient.eu/

https://www.eu-patient.eu/Members/The-EPF-Members

PUBLIC Page 17 of 20



- <u>Participation in and co-organisation of technical workshops</u> on in-silico trials targeted thematic with the VPHi, VPH conference, and STACOM workshop
- Wide dissemination of project public reports will be promoted:
 - Publication on open access online repositories (e.g. HAL-Inria)
 - Publication on SimCardioTest website (public reports and deliverables will be accessible and downloadable)
 - Publication on the project's partners web portals
 - Via the communication channels described in the next section
- <u>Patenting:</u> prior to publication, possibilities for intellectual property generation will be investigated as part of SimCardioTest's exploitation strategy.

Some of the key communication outputs are featured in this Gantt chart. The list includes only the activities for which the timeline has been already defined.

		2021											2022													
	Tasks	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	
	Press release																									
	Social media																									
Task 7.1: General project	Website																									
communication	Newsletter online																							П		
	Newsletter paper																							П		
	Poster/roll up																							П	Π	
Communication public at large	World Heart day																							П	Π	
Stakeholder Awareness building	Workshop																								Π	
Scientific dissemination	Publication																									
	Patent																									

		2023												2024													
	Tasks	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12		
	Press release																							П			
	Social media																										
Task 7.1: General project	Website																										
communication	Newsletter online																										
	Newsletter paper													П										П			
	Poster/roll up													П										П			
Communication public at large	World Heart day													П										П	П		
Stakeholder Awareness building	Workshop																							П	П		
Scientific dissemination	Publication																										
	Patent																										

8. Exploitation

The main exploitable output of SimCardioTest will focus on the web-based computational tools, which are being developed and integrated in a joint effort by all consortium partners. Another relevant exploitable output is represented by apps and e-health tools developed by the ExCom.

The exploitation strategy definition is ongoing and includes: market and competitor assessment of each use case solution, business model, exploitation roadmap and IPR strategy. The business model

PUBLIC Page 18 of 20



will define key partners, key activities, key resources, unique value proposition, competitive advantage, customer segments, cost structure and revenue stream.

A first version of the exploitation strategy and market assessment will be released in the Deliverable D7.3 at M24.

9. Conclusion

The dissemination and communication strategy was drafted from the beginning of the project and it is continuously updated according to project activities and relevant requirements. The dissemination plan will be regularly assessed during the course of the project. To allow an adequate monitoring of the activities and understand the generated impacts, partners are requested to register the activities and actions carried out on regular basis.



This project received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016496

PUBLIC Page 19 of 20



PUBLIC Page 20 of 20