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

## Technical Report

## D8.3: Intellectual Property Management Plan

## Work Package 8 (WP 8)
## Project Coordination & Management

**Task Lead: Inria, France**

**WP Lead: Inria, France**

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## DELIVERABLE INFORMATION

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# EXECUTIVE SUMMARY

This document describes how intellectual property rights are handled in the SimCardioTest project. It summarises the general IPR agreement, which is part of the project's consortium agreement. In addition, this document addresses the main issues related to IPR management. These issues are ownership, protection of background and foreground knowledge, dissemination, access rights and confidentiality.

This plan will be completed throughout the life of the project and will only become final at the end of the project. The plan is intended to raise awareness of opportunities, but also should be used as a "knowledge sharing" initiative, as a platform for fostering new links with industry, SMEs and academic stakeholders. This document is an updated version.

# 1. Objectives

It is critical that Europe demonstrates its capacity to leverage in-silico technology in order to be competitive in healthcare innovation. SimCardioTest, funded by the European Commission, aims at developing simulation of cardiac pathologies on a cloud-based platform to test new medical devices and drugs. The project will act as a major economic impact on the European pharmaceutical and cardiac devices industry through the results exploited by the partners. SimCardioTest will position the project outcomes for future market replication, commercial exploitation and training. This will enable accelerated development, certification and exploitation of new medical devices and drugs and will produce a strong societal impact contributing to personalised healthcare.

A Preliminary Exploitation strategy plan will be delivered at M24 and will include the definition of how partners will interact during and after the project. A fluid exploitation strategy as "Software as a Service" (SaaS) of the developed in-silico trials platform through the project partner InSilicoTrials Technologies (IST) will be further defined and a final exploitation and market uptake strategy will be delivered at M48. Commercial agreements among partners will be defined to assure the sustainability and socioeconomical impact of the project after completion. The exploitation plan will discuss all the challenges including

1) individual exploitation plans;
2) joint exploitation plans and agreement; and
3) IPR strategy.

Intellectual Property management plays an important role in maximising the impact of research and innovation projects safeguarding that bright ideas and ground-breaking research findings are turned into value-creating goods and services. IPR management is a prerequisite to make project results available to those who need them and will benefit from them: along these lines, SimCardioTest Consortium intends to ensure that IPR is properly handled, protection measures are activated where and when opportunities emerge, while openness is promoted as driving force meant to amplify impacts for society at large.

The objective of this document, is to prepare an Intellectual Property Rights management plan for the consortium of SimCardioTest and anyone outside the project who wants to use the methodology and technology to be developed in it.

In addition, as the sharing of confidential information between members of the SimCardioTest consortium is essential to the success of the consortium, it is important that members understand how and under what conditions confidential information will be shared.

The purpose is to set out the rules and procedures on how IP matters will be addressed among and between the consortium members.

This document has been updated at the mid-course of the project.

## 2. Introduction

SimCardioTest is producing a wide variety of results that will have an impact on society, industry, regulators and the research community, as summarised in Figure 1.

Such a system is open to the possibility of new exploitations of the results, or of accessing a multitude of SimCardioTest results on fair terms.

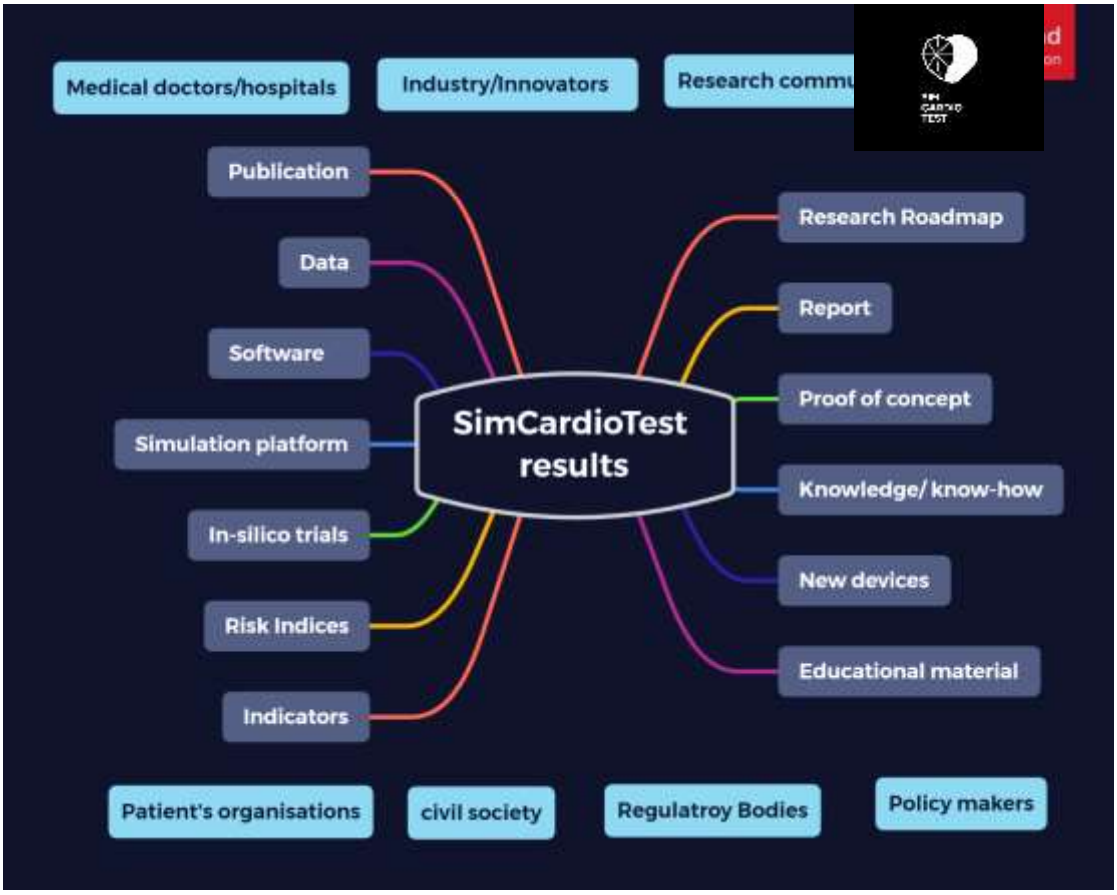



***Figure 1**: Schematic spectrum of possible project results (realized with XMind)*

The present deliverable is aimed to illustrate principles, practices and measures that have been planned by SimCardioTest Consortium as far as knowledge and IPR management is concerned.

The IP management strategy for SimCardioTest aims to promote rapid dissemination of information and access to the in-silico platform for the public good which requires:

- the control of activities of stakeholders commercialising project results. by adapting the fields of use appropriately and developing appropriate benchmarks;
- coordination of the exploitation of jointly owned results.

This document touches various IPR-issues that need to be overcome to be able to:

- disclose knowledge and ideas safely
- prove the ownership
- profit from commercial exploitation
- prevent or discourage its unauthorized use by others.

This report is complementary with deliverable 8.7 (Data Management Plan), and is characterized by two goals:

- **Illustrate internal procedures for knowledge and IPR management** adopted by SimCardioTest Consortium according to SimCardioTest Grant Agreement and SimCardioTest Consortium Agreement.

- **Identify current knowledge and the state of intellectual property rights** in SimcardioTest, thus, setting the scene for appropriate innovation management during the rest of the grant period.

This document targets different stakeholders, both internal (e.g., SimCardioTest principal investigators in various partner organizations) and external (e.g., European Commission as funding agency, scientific/regulatory allies) to SimCardioTest consortium.

## 2.1 Alignment with the legal framework

All knowledge and IPR management measures have been defined by SimCardioTest Consortium in pursuance of provisions contained in the Grant Agreement and in the Consortium Agreement, which are the main references in terms of legal framework.

The Grant Agreement (101016496) is the legal implementation of the project as agreed between the European Commission and the Consortium partners. All partners are signatories to the Grant Agreement. An important part of the Grant Agreement defines the rules for handling Intellectual Property Rights. This topic is discussed in section 3 of the Grant Agreement, which has to do with rights and obligations related to background and results: whilst subsection 1 sets forth general principles, rights and obligations pertaining to project background and foreground are dealt with respectively in subsections 2 and 3.

In specific areas, the Grant Agreement allows consortia to agree on their own rules. These individual rules are then included in the Consortium Agreement. As part of such an agreement, Consortium members specify binding commitments among themselves in terms of roles, responsibilities and mutual obligations. SimCardioTest Consortium Agreement is based on the DESCA (Development of a Simplified Consortium Agreement) template 121.

The Consortium Agreement stipulates rules and procedures related to knowledge and IPR management in several parts, namely results (section 8), access rights (section 9), and non-disclosure of information (section 10).

**The Consortium Agreement (CA) was signed by all the project partners and has come into force on 19th December 2020, and shall continue in full force and effect until complete fulfillment of all obligations undertaken by the Parties under the EC-GA and the Consortium Agreement.**

The main concerns are naturally linked to the software and models transfers mandatory in order to achieve project results, but also to know-how, design of new devices or publication.

## 2.2 Related document

**SimCardioTest Grant Agreement** establishes the rights and obligations of beneficiaries towards the European Commission.

**SimCardioTest Consortium Agreement** sets out the legal basis for the share of rights, obligations and responsibilities related to the implementation of the project among the beneficiaries themselves.

**SimCardioTest D8.2: Project Quality Plan** defines the general approach for SimCardioTest quality assurance and the procedures to be followed for project governance, partner communication and meetings, reports and deliverable production.

**SimCardioTest D8.7: Data Management Plan**, describes SimCardioTest management procedures when dealing with data, including collected datasets, generated datasets, and research data.

**Horizon 2020 Rules for Participation**, namely EU Regulation No 1290/2013 of the European Parliament and of the Council, which lays down the rules for participation and dissemination in Horizon 2020 Framework Programme.

**European IPR Helpdesk,** a first-line intellectual property (IP) service providing free-of-charge support to help European SMEs and beneficiaries of EU-funded research projects manage their IP in the context of transnational business or EU research and innovation programmes.

## 2.3 Definitions

**"Access Rights"** means licenses and user rights to Results or Background under the terms and conditions of the Grant Agreement and further specified in the Consortium Agreement.

**"Background"** means all information, deliverables, materials, services and other tangible and intangible work product, whether or not they can be protected by intellectual property rights, which are developed or controlled by a Party prior to the Effective Date of this Consortium Agreement or created independently from the Project and this Consortium Agreement without any reference to or use of the other Parties' Confidential Information, intellectual property rights and/or related documentation and which a Party chooses to deliver or make available for use to the other Party for the purposes hereof. A list of Background is described in Attachment 1.

**"Confidential Information"** means any technical, commercial and strategic information in whatever form and/or material support exchanged between the Parties under this Consortium Agreement, including but not limited to this Consortium Agreement and its content, the fact that discussions are taking place on any transaction contemplated in this Consortium Agreement, and any analysis, notes or documents drafted or drawn up by a Party on the basis of or relating to the said technical, commercial and strategic information.

**Dissemination** - Public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium.

**"Fair and Reasonable conditions"** means appropriate conditions, including financial terms conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

**"Joint Owners"** means Parties who are co-owners of Results.

**"Object Code**" means software in machine-readable, compiled and/or executable form including, byte code form and in form of machine-readable libraries used for linking procedures and functions to other software.

**"Parties"** means the Parties to this Agreement which are signatories to the Grant Agreement and members of the consortium responsible for the core work, tasks and activities comprising implementation of the Project.

**"Results"** means any tangible or intangible output of the project, such as data, knowledge or information, that is generated in the project, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

**"Software"** means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression. as well as the associated documentation.

o Basic Software: this term refers to the software owned by a Party prior to the coming into force of the Agreement and listed in Attachment 1 as Background.

o Derivative Software: this term refers to the software created from the Basic Software as part of the Agreement. There are two categories of Derived Software: Adaptations and Extensions.

- Adaptation: this term designates the Derivative Software using the same algorithms as the Basic Software from which it is derived and/or rewritten in another language.
- Extension: this term designates the Derivative Software allowing access to new functions or performance compared to the Basic Software from which it is derived.

o New Software: this term refers to the Software created from scratch in the context of the Agreement.

# 3. Governance structure for IPR

## 3.1 Allocation of responsibilities

As far as knowledge and IPR management is concerned, this report clearly states that IPR potential of technical innovations in the SimCardioTest project is systematically evaluated and prioritised. **In the context of WP7 (Communication Exploitation and Dissemination), project partners will maintain a list of candidate exploitable results that will be reviewed on every General Assembly by the Governing Board.**

This has its roots in a structured procedure that SimCardioTest Consortium puts in place for an effective knowledge and IPR governance.

In SimCardioTest, the governance of Intellectual property Rights is ensured by four important entities in addition to the Parties of SimCardioTest:

- **The Governing Board (GB)** as the ultimate decision-making body of the consortium; to be consulted for any contractual decision, and patenting/licensing/publishing process.

- **The EX Com (ExCom)** is the supervisory body for the execution of the project: *inter-alia* Day-to-day decision-making; Assessment of the results obtained and possible minor adaptation of the future work; Deciding on technical reviews; Approving and releasing the WP deliverables

- The **Project Coordinator (PC)** as the legal entity acting as the intermediary between the Parties and the Funding Authority. The Project Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement. The Project Coordinator chairs the Governing Board meetings.

- The **Exploitation Manager (EM)**, who is responsible, together with the Parties willing to exploit the Results for (*i*) the tracking of the Results of the Project their potential exploitation and (*ii*) ensuring the authorship and knowledge property during the dissemination and communication obtained during the Project. This role will be carried out by the Project Manager with the support of Inria's Innovation Transfer and Partnerships Department (STIP).

## 3.2 Governance tools

The overall governance of SimCardioTest knowledge and IPR is facilitated by a number of working tools that support SimCardioTest partners on daily basis. The spectrum of such supporting tools encompasses, for the time being, the following entities:

IST will use different tools including CRM (Customer Relationship Management) system in order to design, monitor and plan different phases of the exploitation process.

**Management documentation**

Collaborative tools for Knowledge Management allowing SimCardioTest partners to collect and codify relevant insights in a structured format with the intent to enable SimCardioTest partners to achieve organisational objectives by making the best use of knowledge generated by SimCardioTest endeavor.

- **IPR Registry** – made up of the various IPR Identification Sheets – which is the internal tool instantiated in MyBox allowing all partners to stay abreast with IPR-related project developments.
- **Recourse to European IPR Helpdesk**, which can be contacted free of charge for first-line support on IPR matters.
- **Recourse to an external IPR advisory firm** to be contracted in case ad-hoc legal arrangements are needed for accessing, re-using and/or commercializing part of project results.
- **Training offered by the Horizon Europe Booster in 2023:**
  - *Exploitation Strategy (with Meta Group - IST)*
  - 1 hour Exploitation Strategy Online Seminar: Introducing Exploitation on 28/11/2023
    Definitions of exploitation, Key Exploitable Results, exploitation vs dissemination, the Exploitation plan; Q&A

- Different forms have been shared with the consortium that all partners collaborated in filling in, coordinated by IST. Compiled documents have been sent back with Meta Group in advance before the next seminar.
- 6 hours Exploitation Strategy Online Seminar on 12/12/2023
- This work will be part of the next discussions among the partners for the preparation of the Exploitation Workshop (M42) and of the final Exploitation Strategy (M48)
- *IPR Service Pack (with De Tullio & partners -IST, Inria):* 2 hours introductory IP webinar on 29/11/2023
- *Go-to-market (with PNO Innovation - IST):* 1 hour introductory online seminar on 5/12/2023
- *Business plan development (with Meta-Group – UPF, Inria):* First steps & guidelines

### 3.3 Dispute resolution

The partners shall endeavour to settle their disputes amicably. The Consortium Agreement is the legal document that each partner has signed.

Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon.

Conflicts resolution will be based on the principle that any dispute should be resolved by consent and as near the source as possible. Thus, conflicts on a local sphere will be managed by the people involved. If a conflict cannot be resolved within the local sphere, it will be raised to the higher level (Task, WP), and if necessary to the Project Coordinator (PC) and finally to the Governing Board (GB). If the issue is submitted to GB, the PC will coordinate the whole decision-making process and notify the members of the GB with all the necessary information. The issue will be discussed during the first scheduled GB meeting or, if the situation gets to a serious crisis that jeopardizes the success of the entire project, the PC will call for a special GB meeting. The GB will decide which procedure will be followed to solve the conflicting situation, and the corresponding correction measures that should be taken. If the conflict cannot be resolved, the GB will declare the participant that generates the conflict “not in line” with the project execution and the Consortium will ask for a contract termination for the participant concerned, with the contractually stated consequences. The Project Officer (PO) will be immediately notified of the situation and of the measures to be taken in order to solve it. An appropriate review of the work plan will be suggested by the PC and ExCom, approved by GB and sent to the PO for acceptance. In case it is decided (by the PC or GB) that a conflict resolution will involve a voting procedure among partners, a majority of the 3/4 will be required for the decision to go ahead (Attachment 6, point 16 of CA).

For dispute regarding the ownership and the exploitation of results (patenting, licensing) or know how the video recording of each meeting between partners, stored in MyBox, will be viewed and used a proof of ownership.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 calendar days of the commencement of the mediation, the courts of Brussels shall have exclusive jurisdiction plan will be suggested by the PC and ExCom, approved by GB and sent to the PO for acceptance. In case it is decided (by the PC or GB) that a conflict resolution will involve a voting procedure among partners, a majority of the 3/4 will be required for the decision to go ahead (Attachment 6, point 16 of CA).

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 calendar days of the commencement of the mediation, the courts of Brussels shall have exclusive jurisdiction.

# 4. Management of results

## 4.1 Definition of result ownership

According to the Horizon 2020 Rules for Participation, the results of the project belong to the participant(s) generating them.
Where several partners have jointly carried out work generating results and where their respective share of the work cannot be ascertained – or the work result is by nature indivisible – they shall have joint ownership of such result. Given the collaborative nature of SimCardioTest project, a wealth of project results can be jointly developed by several participants.

## 4.2 Access to Background and Results

### 4.2.1 During the project

During the implementation stage, project partners need to give access rights to their background and results being created in order for other partners to carry out their work on the project and/or exploit their results.

To ensure a smooth execution of the project, SimCardioTest partners have agreed to grant non-exclusive, royalty-free access to both results and background IP for implementation purposes throughout the project period. Access rights shall also be free of any administrative transfer costs. Moreover, it is worth noting that any access rights granted expressly exclude any rights to sublicense (unless expressly stated otherwise).

Moving from implementation purposes to exploitation purposes, SimCardioTest Consortium Agreement differentiates between foreground and background:

- If needed **for the exploitation of a party's own results**, **access rights to results shall be granted on fair and reasonable conditions**. Conversely, access rights to results for internal research activities shall be granted on a royalty-free basis.

- **Access rights to background** – if needed for the exploitation of a party's own results, including for research on behalf of a third party – **shall be granted on fair and reasonable condition**

In case new parties enter SimCardioTest Consortium – as regards results developed before the accession of the new party – the new party will be granted access rights on the conditions applying for access rights to background. Regarding the premature termination of participation of a partner in SimCardioTest consortium in no way affect the obligation of that participant to grant access rights to the remaining partners in the same project (as if it had remained a party for the whole duration of the project). Concerning access rights granted to a leaving party, access rights granted to a defaulting party – which the Governing Board has identified to be in breach of the Consortium Agreement and/or the Grant Agreement – shall cease immediately upon receipt by the defaulting party of the formal notice of the decision of the Governing Board to terminate its participation in the Consortium. Conversely, a non-defaulting party leaving voluntarily and with the other parties' consent shall have access rights to the results developed until the date of the termination of its participation.

### 4.2.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 26.2 and the Joint Owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('joint ownership agreement'), to ensure compliance with their obligations under this Agreement. Unless otherwise agreed in the joint ownership agreement.

When it comes to the joint ownership regime, SimCardioTest Consortium Agreement differentiates non-commercial research activities from exploitation actions.

**For non-commercial research activities**, each of the Joint Owners shall be entitled to use jointly owned results on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).

**For exploitation**, each of the Joint Owners shall be entitled to exploit the jointly owned results and to grant non-exclusive licenses to third parties (without any right to sub-license) if the other joint owners are given at least 45 calendar days advance notice as well as a fair and reasonable compensation (upon negotiation).

#### Joint ownership agreement

Going beyond standard provisions encompassed in a general collaboration agreement, a joint ownership agreement shall define in concrete terms the allocation and terms of exercising the ownership as well as all protection measures and the division of related costs.

As clarified by the IP Joint Ownership Fact Sheet[1] published by the European IPR Helpdesk, a joint ownership agreement – when needed – should cover these three areas:

- **Allocation of the shares between joint owners** – Usually the choice is between equal share among partners and share proportional to their involvement in the development of the results.

1 https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/Fact-Sheet-IP-Joint-Ownership.pdf

● **Conditions of use and exploitation of the joint results** (IP) – Co-ownership arrangements usually grant each party an unrestricted use of the jointly owned IP. Should, however, restrictions on one party's use be necessary due to the interests of other partners or its use in further research activities, two options can be envisaged:

(1) **the joint ownership regime is maintained with the provision of mutual restrictive conditions on the joint results use**;

(2) **one party is assigned the property of the entire asset** – hence supporting all the related costs – and grant licenses to other partners on an as-needed basis. Joint ownership arrangements should also define the conditions under which each co-owner can assign, license and in general exploit jointly owned results. Such activities can be done with or without the consent of the other parties, depending on the partners' interests. One important issue to be agreed from the outset is the compensation that the other partners will have in respect of the exploitation of the joint results.

**Software joint ownership rules in SimCardioTest**

**For Basic software, adaptation and extension**

In SimCardioTest Consortium Agreement, it is agreed that **the Basic Software** remains the property of the Party that holds the grandfather rights. Any **Adaptations**, whether or not they have been developed by a Party other than the Party that owns the Basic Software, are the property of the Party that owns the Basic Software. Under this Agreement, the Party responsible for developing the Adaptation assigns, free of charge, to the Party that owns the Basic Software, the worldwide right to reproduce, translate, adapt, and arrange it, or make any other modification, as well as the right to market that Software for all possible applications and for the legal duration of the intellectual property rights, for all utilisation or exploitation purposes.

Any **Extensions** developed by a Party remain the sole property of that Party. Extensions developed by the Joint Owners are owned jointly by them. Nevertheless, the Basic Software to which the Extensions were added remains the property of the Party that developed it.

**New software**

**New Software** developed by one Party alone is the property of that Party, who is responsible for protecting it (patent, APP registration, etc.). New Software developed by several Parties will be jointly owned by those Parties. Under this heading, the **Joint Owners alone will be authorised to decide on the arrangements for the distribution and exploitation of the Jointly-Developed new Software**. A joint ownership agreement will be established by the Joint Owners as soon as it becomes necessary and, in any case, before any industrial and/or commercial exploitation of the Software.

**With regard to the dissemination** of the project research results, parties can agree on the limit and means to disclose data and research materials, bearing in mind that disclosures can be an impediment to future IP rights registration (i.e., patents, utility models, industrial design). When dissemination activities take place, careful attention should be paid to confidential information used to carry out the research: more precisely, partners might want to keep secret the know-how and other knowledge related to the collaboration project. By virtue of contractual clauses, parties should therefore abide by confidentiality rules.

● **Management of the jointly owned results** (IP) – It refers to the protection, maintenance and defence of the results generated under the collaborative project. Contractual rules should set forth how confidential information, Intellectual Property Rights (IPR) filing, maintenance and infringement (e.g., governing law and jurisdiction) should be dealt with by the co-owners.

### 4.2.3 Transfer of results

Transferring the ownership of results to other parties is a possibility for partners participating in a Horizon 2020 action. Should it be the case within the scope of SimCardioTest, it is fundamental that – whenever transferring the ownership of their results – participants follow the requirements established in their Grant Agreement (Article 30).

The transfer should be done through a written agreement since beneficiaries must ensure that the obligations of the participant(s) under the Grant Agreement are passed on to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

**It is also compulsory that prior notice is given at least 45 days before the intended transfer to the other Consortium partners that still have (**or still may request) **access rights to the results, with sufficient information about the new owner.**

The right to prior notice can be waived in the case of transfers to a specifically identified third party but, in the case of SimCardioTest, there are no entities mentioned in the list of third parties for simplified transfer (Attachment 3 of the Consortium Agreement).
Finally, it remains intended that – as per SimCardioTest Consortium Agreement – any addition to afore-mentioned Attachment 3 requires a formal decision of the Governing Board.

## 4.3 Protection of results

Should project results be reasonably expected to be commercially or industrially exploitable and their protection possible, reasonable and justified, then participants must provide for adequate protection of the results during an appropriate period and in a suitable territory.

Although IP protection is vital for a prospective commercial or industrial exploitation, on the other hand it is not always mandatory. In fact, the choice of the most suitable form of IP protection, as well as the duration and geographical coverage depends on the results at stake, but also the business plans for their exploitation and legitimate interests of Consortium partners.

The overall strategy of the SimCardioTest Consortium is to seek IP protection in cases where:

1. The project results are clearly capable of commercial application.
2. The rationale for protection is sound.
3. The potential economic benefits clearly outweigh the financial cost of seeking such a protection.

Regulation of the IP rights consists of many coexisting and complementing layers, hence forms of result protections are manifold. In the case of SimCardioTest, possible avenues for IPR protection are summarised in Table 1.

From the procedural standpoint, although it is not mandatory to inform other partners about individual protection activities, SimCardioTest Consortium endorses the good practice of consulting with other partners – primarily the Project Coordinator and the Governing Board– before deciding whether to protect results or not, especially in cases of potentially joint IP (See procedure Table 2, p26).

***Table 1:*** *SimCardioTest possible avenues for IPR protection*

| Subject matter (IPR help desk) | Example SimCardioTest context | Patent[2] | License[3] | Copyright[4] | Trade mark[5] | Confidential information[6] |
|---|---|---|---|---|---|---|
| **Invention** | To be defined | X | | | | X |
| **Software** | Models for use cases | X | X | X | | X |
| **Scientific article** | Open access, peer reviewed papers | | | X | | |
| **Design of a product** | Medical devices | X | | | | X |
| **Name of a product/service** | Access to the Simulation platform for in-silico trials | | X | X | X | |
| **Know-how** | Iteration with regulatory bodies | | X | | | X |
| **Website** | SimCardioTest official website & logo | | | | X | |

### 4.3.1 Patents

A patent is a legal title that allows the patent holder to prevent any third party from exploitation of his/her invention, even if it is developed independently. The patent law protects the invention having technical character, provided that it is new, involves an inventive step and is susceptible of industrial application. The patent protection lasts for a limited period of time and requires formal filing with competent authorities.

Patents are regulated mostly at national and international level. It is a national law that grants the protection by patent and defines its condition and scope. A national patent is valid only within the territory of the state who granted it. Several international conventions regulate patents.

2 https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/europe-glossary/glossary-p_en

3 https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/europe-glossary/europe-glossary-l_en

4 https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/europe-glossary/glossary-c_en

5 https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/europe-glossary/glossary-t_en

6 https://intellectual-property-helpdesk.ec.europa.eu/regional-helpdesks/european-ip-helpdesk/europe-glossary/glossary-c_en

**The European Patent Convention (EPC)** is of particular importance for the European legal landscape. The Convention provides the possibility of a single patent application through the European Patent Office (EPO), but also regulates certain substantive aspects of patent protection. The single procedure for granting patents does not mean a single title. On the contrary, European patents consist in fact of the bundle of national titles: a European patent needs to be validated in each State for which it has been granted and has the same effect as a national patent granted in the respective territory.
The EPC defines conditions for patentability and grants protection for inventions in all fields of technology. In principle, all technical inventions fulfilling appropriate criteria are subject to protection, but EPC excludes from the patent protection certain subject matters, including discoveries, scientific theories and mathematical methods as well as programs for computers.

**As regards computer programs, Article 52(2) of the EPC convention expressly excludes ordinary computer programs from patentability. The Convention allows, however, for the patentability of so called 'computer-related inventions'[7], which produce a further technical effect going beyond the ordinary physical interaction between program (i.e., software) and the computer (i.e., hardware).**

It cannot be excluded that some SimCardioTest results may qualify as computer-related inventions eligible for protection by European patents. However, definite determination in that respect requires very careful consideration which goes beyond the scope of this initial report. Patent applications (if any) relating to SimCardioTest results, filed by or on behalf of a partner, must include the following statement to indicate that said foreground has been generated with the assistance of financial support from the European Union: "The work leading to this invention has received funding from the European Union Horizon 2020 Programme under Grant Agreement no. 101016496".

Furthermore, all filed patent applications (if any) relating to SimCardioTest results will be reported in D7.3 (Preliminary Exploitation strategy and market assessment) and D7.5 (Final exploitation and market uptake strategy), including sufficient details and references to enable the European Commission to trace the patent application. Any such filing arising after the final report must be notified to the European Commission including the same details and references.

**SimCardioTest result**

**The patient-specific fluid simulation pipeline** developed by UPF for the use case focused on left atrial appendage occluder devices has led to a patent submission, and a start-up company will be created based on the VIDAA platform, due to the commercial interest of planning interfaces in these clinical interventions.

Patent title: "Computer-implemented method for the in silico surgical planification of a left atrial appendage occlusion"

CONFIDENTIAL INFORMATION (embargo until May 2025)

7 https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_6.htm

### 4.3.2 License

The Intellectual Property Licensing. No.1, June 2019[8], issue sheds light on different aspects of IP licensing and provides professional firsthand insights into real-life licensing practice.

Setting up a new business or introducing innovative products or services to the market does not necessarily imply that an organisation has to start from scratch – even less does it mean that it needs to hold all necessary knowledge, knowhow or technologies itself. Nowadays, most successful innovations are based on collaboration and many innovative companies provide products or services to their customers building on intellectual property (IP) or inventions that already exist, held by someone else and – very often – used for completely different purposes. This is where licensing comes into play. In principle, licensing means that the holder of a certain IP (licensor) grants permission for the use of this IP to another party (licensee) within the limits set by the provisions (e.g.in a certain time or territory) included in a contract called license agreement. There are two basic modes of licensing: "licensing in" and "licensing out". "Licensing in" refers to the process in which a company acquires and uses knowledge or technologies held by another party. "Licensing out" describes the converse process in which an organisation makes their IP available and grants the right to use it to others.

Apart from the distinction between "licensing in" and "licensing out", one can differentiate different types of licenses: exclusive and non-exclusive.

**An exclusive license type** can be sub-divided into:

- **Exclusive:** only the licensee is able to use the licensed IP or technology (the licensor cannot use or license it);
- **Sole**: the licensor agrees not to grant any additional licenses but retains the right to make use of the licensed IP.

**A non-exclusive license** grants both, licensee and licensor, the right to use the licensed IP or technology. The licensor is also allowed to negotiate further non-exclusive licenses with other companies. Each license agreement is unique depending on the kind and nature of the individual IP concerned. Moreover, the choice of the most appropriate type of license should be made by carefully considering:

- the overall business strategy and goals of the licensor
- the target market conditions• the capabilities of the licensee

Given the specific nature and varying complexity of each licensing case and agreement, it is highly recommended to seek professional legal advice before entering into concrete licensing negotiations. Although licensing is unquestionably a significant way to exploit IP, it is nevertheless just one option to reap the (commercial) benefits of an organisation's intangible assets. And, it may take place in various settings and kinds of transactions. One of the most common forms of IP licensing is technology licensing.

8 https://op.europa.eu/en/publication-detail/-/publication/3ae24438-9c73-11e9-9d01-01aa75ed71a1/language-en/format-PDF/source-164622948

There are different kinds of technology licenses. Licenses may be for certain IP rights only (e.g. a license to practice an identified patent or to copy and distribute a certain work of authorship). Licenses may be for all the IP rights of any kind that are necessary to reproduce, make, use, market, and sell products based on a type of technology (e.g. a license to develop a new software product that is protected by patent, copyright, trademark and trade secret law). A license may also be for all the IP rights necessary in order to create and market a product that complies with a technical standard or specification (e.g. a group of enterprises has agreed on a technical standard to ensure interoperability of devices and owners of IP essential to practice the standard pool their IP rights and license to anyone who wishes to use the standard on reasonable and non-discriminatory terms.

When negotiating the terms of a license, there are many variations for each term – and each term usually has economic impact, i.e. can be a subject for negotiation.

1. **The Subject of the License**

It is important to be clear about what you are licensing. Usually this involves several pieces of IP and IP Rights (IPR). In addition to IP protected by formal legal rights (e.g. patent, copyright, design right, etc.), it may also include secrets protected by a non-disclosure agreement, or know-how to be transferred though consultancy and/or post-deal support.

2. **The Type of License**

A license can be exclusive, non-exclusive or sole. It may also be limited by geographical territory or field of use.

3. **The Length of the License**

The length of the license is usually determined by the lifetime of the IPR. Patents expire after 20 years in most countries. In the case of pharmaceuticals, this might be extended. Other forms of IP have different lifetimes. There are rights which could go on indefinitely, such as trademarks (provided they are used and registration fees are paid), or secrets (as long as they are kept secret).

4. **The Territory**

This can extend to wherever the IPR exists. It is possible to license different people exclusively (or non-exclusively) for different territories.

5. **Field of Use**

It is possible to only grant (or exclude) rights for a particular market or technological sector – for example “only for use in the healthcare market” – or “excluding telecommunications applications”. It is possible to license different people exclusively (or non-exclusively) for different fields of use.

6. **The Payment**

This is normally divided into a down payment on signature of the agreement, and royalties. It is also possible to include milestone payments (for agreed milestones). Each of these may have several variations.

7. **Auditing**

The licensor should also ensure that they have the right to audit the licensee, to ensure that royalty payments are correct.

**8. Improvements, Developments and Modifications**

There are many ways of handling this, but the first thing is to agree is how to determine what is an improvement on the licensed IP, and what is new.

**9. Performance Criteria**

It is important that the licensee performs well if value is to be returned to the licensor (and ultimately the inventor). This is particularly important for exclusive licenses, so consideration should be given to performance minimums to retain exclusivity.

**10. The Licensor's Obligations**

For the licensor, typical obligations include transferring the IP, and maintaining the legal rights, but there could be many others.

**11. The Licensee's Obligations**

The obligations placed on the licensee, on the other hand, include exploiting the invention in the best interests of both parties. It may also include obligations to install and maintain efficient systems to monitor use and hence royalty payments.

**12. Sublicensing**

Sublicensing rights should be explicitly granted or explicitly prohibited. This is particularly important for software.


*Source: European Commission helpdesk*

Licensing may play a vital role in a company's commercialisation strategy, providing substantial benefits to licensor and licensee alike, ultimately aiming to reach a "win-win" situation for both parties. Besides, license agreements can also be seen as an instrument for the distribution of risks between the licensor and the licensee.

### 4.3.3 Copyright (including software protection)

Several important international conventions have been adopted in the field of copyrights, including the Berne Convention of 1886 and the WIPO Copyright Treaty (WCT). The EU has enacted a number of directives in the field of copyrights, providing a relatively high level of harmonization of the substantive copyright within the EU. **The Information Society Directive[9] (2001/29/EC) is central to the EU copyright protection system**, as it harmonizes more global concepts of copyright in a horizontal manner.

9 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0029:EN:HTML

While copyright covers a variety of works, the European directives do not define the subject matter of the copyright protection but refer in this respect to the Berne Convention, which provides protection for authors in their "literary and artistic works". Along these lines, **copyright protects the form of expression of ideas, but does not protect mere facts, data, ideas or principles**. The protection by copyright lasts for the lifetime of the author and 70 years after his/her death.

As far as protection is concerned, E**uropean copyright law provides the right to authorize or prohibit reproduction and any communication to the public,** by wire or wireless means (including online distribution of works).

The SimCardioTest platform will neither create, nor handle or distribute works that are traditionally considered as literary or artistic. However, copyright protection becomes vital apropos of – *inter alia* – software and literary production (*e.g.* academic papers, white papers, case studies).

**Software copyright protection is regulated by the Computer Programs Directive [10] (Directive 2009/24/EC)**. Even if the Directive does not define what can be considered to be a 'computer program', the recitals clarify that the term 'computer program' shall include programs in any form, including those which are incorporated into hardware. The copyright protection of software relates to the expression of the computer program. All forms of expression of programs are protected, including source code, assembly code and object code. The copyright protection does not extend to the principles and ideas underlying the software, software interfaces or logic, algorithms themselves and programming languages as far as they comprise the ideas and principles.

**Under the Directive, only original computer programs are protected**. The originality criterion requires that the program must be the author's own intellectual creation, but it does not impose qualitative or aesthetic merits on the program. The author and initial holder of the right is a natural person who has created the program, unless the computer program was created by an employee in the execution of his duties, in which case the right is vested with the employer.

The holder of the copyright of computer programs has the right to

(i) permanent or temporary reproduction of the program,
(ii) translation, adaptation, arrangement and any other alteration (and the reproduction of those), and
(iii) any form of distribution to the public of original or copies of the computer program.

The Computer Programs Directive provides for some limitations to the exclusive rights. The exceptions that limit the software copyright protection relate to:

- acts necessary for the use of the computer program by the lawful acquirer in accordance with its intended purpose, including error correction;
- the making of a backup copy by a person having the right to use the program, if it is necessary for that use;
- observing, studying or testing the functioning of the program in order to determine its underlying ideas and principles by a person having the right to use the program.

10 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0024&from=EN

Given that In-silico trials platform contains multiple software components, all of them are *de jure* automatically under copyright protection, which does not depend on compliance with any formalities such as registration or deposit of copies. This process and IPR management measures have been defined by SimCardioTest Consortium in pursuance of provisions contained in the Grant Agreement and in the Consortium Agreement.

Plenty of other outcomes generated by a Horizon 2020 project like SimCardioTest are covered by traditional copyright protection by default, including project deliverables, scientific publications and various other contents (e.g., white papers, case studies).

### 4.3.4 Other forms of protection

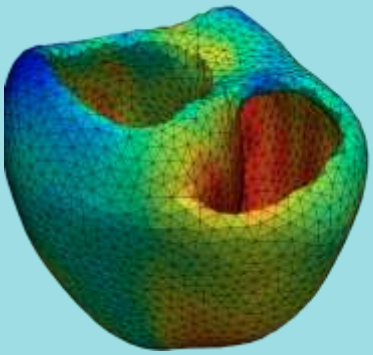
In an ambitious market-oriented H2020 action like SimCardioTest, it is worthwhile that partners think about registering acronyms – either of the project or of the commercial product – as a trademark to ensure recognition and identity in case of commercial exploitation of project results.
Therefore**, trademark registration of SimCardioTest name or of the commercial products/services** used by SimCardioTest project is an option that can be part of the SimCardioTest exploitation roadmap. This may happen before or after the completion of the grand period.

Should it be the case, SimCardioTest partner(s) involved – presumably the commercial front-end – will carefully select names and acronyms that are no identical or similar to a trademark registered or applied for identical or similar goods and/or services in order to avoid unpleasant infringement situations.

**SimCardioTest result**

Inria, in the framework of SimCardioTest, initiated the launch and organisation of the InnovaHeart workshop series, which offers to the scientific community (academia, clinicians, regulatory bodies, small start-ups and large industrial companies) an excellent place to exchange ideas and expertise on the advances of the digital twin within EU. This event was jointly organised in 2023 with the other EU-funded Research and Innovation Actions SIMCor, SimInSitu, the Coordination and Support Action EDITH and the EIT Health project inEurHeart. This workshop organised de novo at KU Leuven in 2024 offered opportunity for collaboration and joining forces for future projects. A trademark was registered by Michele Barbier & Maxime Sermesant on April 3, 2024; The brand name and concept are the brainchild of Michèle Barbier.

The associated logo is an image developed at Inria using Sofa software.



### 4.3.5 Preservation of confidentiality

Confidentiality is an extremely important issue for participants in Horizon 2020 projects, from the setting-up (even during earliest discussions on the assessment of participation) to the implementation and exploitation phases.

Exchanging valuable information with other partners is a necessity that regularly occurs in collaborative undertakings. However, it is worth noting that written or oral information given to a person who is not bound by the secrecy or confidentiality obligations constitutes a disclosure. In such cases, disclosures could be detrimental to future filings for protection of project results. Thereafter, it is vital to keep information confidential, mainly with regard to those project results for which registration has not been done or decided yet. Moreover, secrecy may be key not to jeopardize the highly competitive value characterizing some information assets.

| Definition of confidential Information within SimCardioTest |
| --- |
| Confidential information means any technical, commercial and strategic information in whatever form and/or material support exchanged between the Parties under this Consortium Agreement, including but not limited to this Consortium Agreement and its content, the fact that discussions are taking place on any transaction contemplated in this Consortium Agreement, and any analysis, notes or documents drafted or drawn up by a Party on the basis of or relating to the said technical, commercial and strategic information. |

Accordingly, **confidentiality issues and measures should be seriously taken into consideration by SimCardioTest Consortium in order to safely exchange information, facilitating the project development and ensuring the non-disclosure of sensitive technology, business or commercial confidential information;**

In terms of confidentiality, SimCardioTest Consortium defines two distinct layers of protection:

**A collection of general principles – based on SimCardioTest Consortium Agreement and internal management best practices** – is considered as reference for the business-as-usual while *ad-hoc* confidentiality agreements will be instantiated only when deemed necessary. General principles disciplined by the Consortium Agreement have to do with the duties of any recipient of confidential information for a period of 4 years after the end of the project:

- **not to use confidential information** otherwise than for the purpose for which it was disclosed;
- **not to disclose confidential information** to any third party without the prior written consent by the disclosing party;
- to ensure that **internal distribution of confidential information** by a recipient shall take place on a strict need-to-know basis;
- **to return to the disclosing party** on demand all confidential information which has been supplied to or acquired by the recipients.

The recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the project and/or after the termination of the contractual relationship with the employee or third party.

Furthermore, each party shall promptly advise the other party in writing of any unauthorized disclosure, misappropriation or misuse of confidential information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

**Additional professional good practices** chosen by SimCardioTest Consortium are as follows:

- **Each SimCardioTest party raises awareness of the importance of confidentiality** among employees and reminds them of their obligations during and after the project.

- **Each SimCardioTest party expressly undertakes not to disclose confidential information** but to the persons who need to know and to use it for their specific competences, functions or tasks inherent to the project; if such thirds parties are not employees of any of the parties', or of companies belonging to the parties' group as holding, controlled or affiliated companies, such disclosure may take place only on condition that: (*i*) such persons' details have been previously written in a list duly communicated to the other party, and (*ii*) such persons sign a confidentiality and non-compete agreement, similar to, but in any event containing obligations no less onerous than those contained in this Agreement, and *(iii*) the other party grants its consent in a written form.

- **Each SimCardioTest party considers the verbally transmitted information of any nature as 'confidential information'** either in case of a written report summarizing times, place, and modes of such verbal transmission, and that will be signed by each party's representatives at the time of such transmission; or in case same information – provided that are summarized in a sufficiently clear way so to allow its identification – are qualified as confidential by the disclosing party in a written communication sent to the receiving party within the 15 days following the disclosure date.

- **Each SimCardioTest party saves in an appropriate way all confidential information** of the other party in its use, by marking documents as "CONFIDENTIAL" and by limiting the number of persons who can access the other party's confidential information.

- **Each SimCardioTest party refrains from copying, duplicating, reproducing or recording** – in any form and with any means – the other party's confidential information, unless in the measure strictly needed to allow their circulation among persons involved in the present project.

- **Each SimCardioTest party exercises no lesser security measures and degree of care which it applies to its own confidential information handled in-house.**

**When afore-mentioned principles and practices are not sufficient**, *ad-hoc* interventions may be required. Therefore, the signature of a confidentiality agreement or non-disclosure agreement (NDA) and the subsequent compliance with confidentiality obligations during the whole life of the project and after may be the way to keep confidential information secret in order for parties to maintain a competitive edge.

To this end, SimCardioTest Consortium relied on the template made available by the European IPR Helpdesk[11], which has been meticulously tailored to meet requirements posed by specific facts or circumstances. A possible circumstance that can determine such a need is the one reported in the SimCardioTest Consortium Agreement: the granting of access rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

## 4.4 Valorisation of results

Horizon 2020 is a research and innovation programme aiming at fostering competitiveness and growth, and increasing benefits to the European Union economy and citizens. Under different funding schemes, the Framework Programme supports research and development activities resulting in new knowledge, new products and services, and also in non-technological and social innovation. It is essential that the public investment in these activities is converted into socio-economic benefits for the society. This idea is reflected in the Horizon 2020 Rules for Participation with a clear accent to the beneficiaries' obligations to exploit and disseminate the outcomes of the funded activities.

Under Horizon 2020, it is thus more important than ever to disseminate and exploit the results yielded by funded projects. In fact, as put by the European Commission[12], this means:

- maximising the take-up of the new knowledge, both for commercial purposes and for policy making;
- boosting research and innovation among participants in funding programme and others who could benefit from the research conducted;
- being accountable for expenditure and making sure that EU citizens benefit.

Further considerations on characteristics and scope of results valorization in funded projects can be obtained from the Fact Sheet on The Plan for the Exploitation and Dissemination of Results in Horizon 2020, published by the European IPR Helpdesk[10].

### 4.4.1 Dissemination of results

Result dissemination is undoubtedly an integral part of the European research and innovation funding. In fact, it aims at transferring knowledge and results to the ones that can best make use of them in order to maximize the impact of research and innovation, enabling the value of results to be potentially wider than the original focus.

Unless it goes against legitimate interests, each beneficiary must – as soon as possible – disseminate its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium). This dissemination activity does not change the obligation to protect results (Article 27of the Grant Agreement), the confidentiality obligations (Article 36), the security obligations (Article 37) or the obligations to protect personal data (Article 39), all of which still apply.

11 https://www.iprhelpdesk.eu/sites/default/files/newsdocuments/European%20IPR%20Helpdesk%20-%20mutual%20NDA%20-%202014.pdf
12 http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/grant-management/dissemination-of-results_en.htm

**During the project and for a period of 1 year after the end of the project, the dissemination of own results by one or several parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement.**

The section meticulously illustrates SimCardioTest practices related to project exploitation and dissemination while shedding light on measures promoting openness in its various forms, including open source, open data, and Open Access.

## SimCardioTest process for publishing results

**Publications**

Each SimCardioTest partner shall give prior notice of any planned publication to the other parties at least 30 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the party or parties proposing the dissemination within 21 calendar days after receipt of the notice.

In addition, SimCardioTest partners must/

- notify the Governing Board (GB) at least 20 days before publication. The process is managed by the Project Manager, and run for five weeks:
- send a draft of the article to be submitted for publication to the GB (via the project manager).
- The GB has 20 days to review the article and give its approval or request additional information or intellectual property rights.
- After consideration of the GB feedback, the author of the article then has 10 days to review and submit a revised version to the GB,
- the GB has 3 days to give its final approval/comments.

The author of the publication must acknowledge the European Commission as follow: “This project received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 101016496”.

## SimCardioTest process for conference participation

Advance notice of any conference abstract must be sent to the Governing Board at least 10 days before publication. Any objections to the abstract must be made in writing to the project coordinator and the co-owning party or parties within 7 calendar days of receipt of the notice. If no objection is made within the above-mentioned period, the conference summaries are authorised.

***Table 2:*** *SimCardioTest summarised process for results*

| Summarised process for reviewing SimCardioTest results before release. As an author you must inform… | | | | | |
|---|---|---|---|---|---|
| | Co-authors/ owners | ExCom or Governing Board | Receive Feedback | New version | Receive New feedback |
| **Deliverable** | 30 days prior | 14 days prior | Within 7 days | Up to 3 days | Up to 3 days |
| **Publication** | 30 days prior | 21 days prior | Within 14 days | Up to 10 days | Up to 3 days |
| **Abstract conferences** | 15 days prior | 10 days prior | Within 7 days | Up to 3 days | Up to 2 days |
| **Licensing** | ASAP, at least 90 days prior | 30 days after | Within 30 days | Up to 14 days | Up to 14 days |
| Patenting | ASAP, at least 90 days prior | 30 days after | Within 30 days | Up to 14 days | Up to 14 days |

At this juncture, it has to be clarified that an objection is justified if

(1) the protection of the objecting party's results or background would be adversely affected; or

(2) the objecting party's legitimate academic or commercial interests in relation to the results or background would be significantly harmed.

The objection has to include a precise request for necessary modifications. Then, the Consortium has to handle the objection as per SimCardioTest Consortium Agreement.

On the whole, SimCardioTest Consortium is committed to abide by the obligations related to dissemination (e.g., need to mention the EU funding, usage of the European emblem, inclusion of a disclaimer).

As far as Open Access is concerned, please refer to §4.4.3 on openness.

### 4.4.2 Exploitation of results

SimCardioTest, as an ambitious market-oriented H2020 action, considers the stream of activities related to exploitation as fulcrum for making project results sustainable over time and purveyor of impacts for project partners and well beyond. Exploitation thinking, in fact, has to provide the Consortium with a shared strategic long-term intent needed to outline the goals worthy of commitment and a clear roadmap to assure consistency in resource allocation over the project lifecycle.

Due to confidentiality reasons, the present deliverable – due to its public status – is not seen as the appropriate document to convey the business vision underpinning SimCardioTest exploitation. A detailed report of the commercial exploitation strategy and implementation will be contained in deliverable 7.3 (D7.3 - Preliminary Exploitation strategy and market assessment) and deliverable D7.5 (D7.5 - Final exploitation and market uptake strategy). On the contrary, this deliverable can highlight the role of commercial front-end and its relevance.

The partners will ensure that adequate protection is in place prior to exploitation, preventing unapproved public disclosure of respondents, tools, products and services. Access Rights, Confidentiality and Liability are addressed formally in the Consortium Agreement and section 4 of this document and these aspects will be managed in accordance with the regulations in the Grant Agreement.

**In more detail, the exploitation will provide substantial benefits from:**

- **shaping a value proposition that combines under a common roof** (i.e., into a unique platform offer) a bundle of powerful project results as well as the expertise of all partners that realized them;
- **accessing foreground and background needed** for exploitation purposes under fair and reasonable conditions;
- **accessing some project results** under exceptionally advantageous conditions (e.g., circumstances in which part of the foreground is released under an open source license);
- **allocating part of the project budget for establishing a customer acquisition pipeline;**
- **allocating part of the project budget** for attending events and rolling-out initiatives meant to accelerate the process of customer acquisition;
- **support provided by business advisory partners**
- **economies of scope** (*e.g.* use and share of existing channels, utilization of the same IT resources in the back-end, cross-selling to existing customers).

These opportunities go hand-in-hand with duties, which are as follows:

- **ensure that principles underpinning IPR management** are known by the rest of the Consortium;
- **negotiate specific agreements** with each partner that owns relevant results;
- **work on partnerships**, either inside or outside the Consortium, needed for implementing the exploitation actions;
- **drive the process meant to collect market feedback;**
- **keep partner that owns relevant results abreast of main developments**.

In such an exploitation scenario, SimCardioTest Consortium will assure that each exploitation action duly considers access rights mentioned above for exploitation purposes as well as protection measures potentially activated.

**The web-based cloud-based insilicotrials.com platform is already available publicly on the web and accessible from any browser worldwide. Computational tools developed by partners will be provided through the platform and will be part of the commercial offer by one partner. Users that want to use the tools available in the library will need to pay a fee for the specific tool.**

**There is no aim to patent technology developed as part of the project as the platform is already protected by two patents. IST's standard contract with its partners ensures that the intellectual property of the models remains their own ownership, with the agreement for IST to pay royalties to the partner on a usage-base.**

### 4.4.3 Specific Provisions for Access Rights to Software under license

#### General principles

For the avoidance of doubt, the general provisions for Access Rights provided in SimCardioTest Consortium Agreement are applicable also to Software Parties' Access Rights to Software do not include any right to receive Source Code or Object Code ported to a certain hardware platform or any right to receive Source Code, Object Code or respective Software Documentation in any particular form or detail, but only as available from the Party granting the Access Rights. The intended introduction of Intellectual Property (including, but not limited to Software) under Controlled License Terms in the Project requires the approval of the Governing Board to implement such introduction into the Consortium Plan.

#### Access to Software

Access Rights to Software that is Results shall comprise:

- Access to the Object Code; and, where normal use of such an Object Code requires an Application Programming Interface (hereafter API),
- Access to the Object Code and such an API.

Background shall only be provided in Object Code unless otherwise agreed between the Parties concerned. No Party shall be obliged to provide Results or Background in Source Code format.

#### Software licence and sublicensing rights Object Code - Results - Rights of a Party

Where a Party has Access Rights to Object Code and/or API that is Results for Exploitation, such Access shall, in addition to the Access for Exploitation, as far as Needed for the Exploitation of the Party's own Results, comprise the right:

- to make an unlimited number of copies of Object Code and API; and
- to distribute, make available, market, sell and offer for sale such Object Code and API alone or as part of or in connection with products or services of the Party having the Access Rights;

provided however that any product, process or service has been developed by the Party having the Access Rights in accordance with its rights to exploit Object Code and API for its own Results.
If it is intended to use the services of a third party for the purposes, the Parties concerned shall agree on the terms thereof with due observance of the interests of the Party granting the Access Rights.

#### Software licence and sublicensing rights Object Code - Results - Rights to grant sublicenses to end-users

In addition, Access Rights to Object Code shall, as far as Needed for the Exploitation of the Party's own Results, comprise the right to grant in the normal course of the relevant trade to end-user customers buying/using the product/services, a sublicense to the extent as necessary for the normal use of the relevant product or service to use the Object Code alone or as part of or in connection with or integrated into products and services of the Party having the Access Rights and, as far as technically essential:

- to maintain such product/service;
- to create for its own end-use interacting interoperable software in accordance with the Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs

**Background**

For the avoidance of doubt, where a Party has Access Rights to Object Code and/or API that is Background for Exploitation, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

**Specific formalities**

Each sublicense granted according to the provisions of Section 9.8.4 shall be made by a traceable agreement specifying and protecting the proprietary rights of the Party or Parties concerned.

### 4.4.4 Openness preservation (open source, ORDP and Open Access)

Within the context of EU-funded projects, Open access refers to the practice of providing on-line access to scientific information that is free of charge to the end-user and is reusable.

In the context of research and innovation, scientific information can refer to:

(i) peer-reviewed scientific research articles or
(ii) research data (data underlying publications, curated data and/or raw data).

In the design of a robust dissemination and exploitation strategy, SimCardioTest Consortium sees openness as key enabler for increasing awareness of and interest in the project's outputs and for cultivating the sustainable mobility culture on a scale sufficient to establish a 'critical mass' of innovators and advocates. Indeed, SimCardioTest's overall approach to dissemination and exploitation is rooted in the conviction that the openness of some findings resulting from the project is allow to maximise the overall impact of the research and innovation conducted.

In the sphere of Intellectual Property management, although copyright applies automatically to any new work, a right holder can renounce on a voluntary basis the full exercise of its exclusive rights. This can determine a legal sharing of knowledge and creativity in a more equitable and accessible fashion. Along these lines, copyleft is the strategy that utilizes copyright law to pursue the social goal of fostering and encouraging the equal and inalienable right to copy, share, modify and improve creative works of authorship.

Looking at the copyleft realm, SimCardioTest Consortium is committed to prioritize openness along three main axes:

- Open source
- Open Research Data Pilot - ORDP
- Open Access

SimCardioTest Consortium is in favour of exploring and using open source opportunities for some technological developments, hence some of the software results may be released under an open source license.

Open source software is computer software with its source code made available with a license in which the copyright holder provides the rights to study, change, and distribute the software to anyone and for any purpose.

In SimCardioTest project, this choice is rooted in the principle of maximizing degrees of freedom for all re-users and accelerate take-up of the project findings. Should it be the case, SimCardioTest

Consortium considers also the opportunity of resorting to GitHub platform[13] to enable the online distribution of chosen source code.

SimCardioTest partners have agreed on a general process to identify opportunities for open source licenses. If required, this process will be revisited and revised under the auspices of the Governing Board.
Regarding open data, SimCardioTest project is committed to identify on a case-by-case basis a portion of datasets that can be made publicly available in line with the Open Definition[14] ("Open data ... can be freely used, modified, and shared by anyone for any purpose"). As far as open data is concerned, the Data Management Plan (D8.7) explains management procedures that SimCardioTest Consortium follows when dealing with SimCardioTest data, including generated datasets, gathered datasets, and research data

When it comes to project materials, most of the SimCardioTest deliverables will be made available on the project website. (see Box next page).

**SimCardioTest - ORDP**

The Open Research Data Pilot – ORDP- of the European Commission enables open access and reuse of research data generated by Horizon 2020 projects.

Among the results anticipated, some reports or databases developed within the project will be directly accessible to all on SimCardioTest website hosted on Inria server. For more details, see Deliverable D8.7 on Data Management Plan accessible on www.simcardiotest.eu

The SimCardioTest reports and databases tagged as ORDP are:

- Data Management Plan (D8.7, M6)
- Database of fluid simulations in virtual population (D3.4, due M24)
- Database of virtual human cardiac models with drug interaction (D4.3, due M24)

Finally, as far the literary production is concerned, pursuant to article 29.2 of the Grant Agreement, each beneficiary must ensure Open Access (i.e., free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

SimCardioTest Consortium is fully committed to ensure Open Access to all peer-reviewed scientific publications. Therefore, Open Access principles are implemented in their various nuances in step with the following priority order:

● **Gold Open Access on Open Access Journals** based on peer-reviewed scholarly research in which the publication is free of charge for the authors and free of charge for the readers.

13 https://github.com/
14 http://opendefinition.org/

● **Gold Open Access on Hybrid Open Access journals** in which only some of the articles are Open Access depending on article processing charges. Here, SimCardioTest Consortium considers to pay a fee to grant public access to the peer-reviewed articles (i.e., free of charge for the readers but not for the authors) if the publication on that specific outlet is considered relevant for the dissemination purpose.

● **Journals permitting self-archiving of articles through Green Open Access models**. In presence of similar journal policies, SimCardioTest Consortium self-archives a version of the article in its Website or in a well-recognised central repository with the intent of giving full public access to the manuscript.

● **Delayed Open Access journals**, i.e., traditional subscription-based journals that provide free online access upon the expiry of an 'embargo' period following the initial publication date. Should it be the case, SimCardioTest Consortium is intended to ensure Open Access to the deposited publication in the timeframe specified by SimCardioTest Grant Agreement, namely 6 months of publication.

Looking at the degrees of openness of peer-reviewed scholarly publications, when compliant with journal policies, 'libre OA' will be favoured with respect to 'gratis OA': when possible, the 'libre OA' choice will allow going beyond mere free online access by adding some specific and additional usage rights, usually in the guise of licenses belonging to the Creative Commons umbrella.

In addition, SimCardioTest practices in the field of Open Access scholarly publication can be supported by digital environments in which SimCardioTest partners may upload not only journal articles and conference papers authored by them, but also store raw research data and further artifacts useful to reproduce experiments and validate research findings.

### 4.4.5 Exploitation of the results after completion of the project

If necessary for the exploitation of a partner's own results, or a partner's background, access rights to the background shall be granted while respecting the rights of third parties on fair and reasonable terms. **For exploitation of a partner's background or results, a request for access rights may be made up to twelve months after the end of the project.**

The parties will negotiate commercial agreements, including licensing agreements, for the further exploitation of the results after the completion of the project. Access rights to the Results for internal research activities and educational purposes will be granted on a royalty-free basis.

Most developments from academic partners that will be included in a commercial product will need a license grant of some form between the granting partner (the institution that developed the foreground) and the receiving partner (the institution building the product incorporating this foreground).

Regarding licencing and patenting, it is essential that a tracking of the information exchanged during partners (ideas and/or software), is ensured. This is done via video recording of each meeting (WPs meetings). These videos, stored on MYBOX, should provide clear evidence of ownership of ideas/software in case of dispute.

# 5. Knowledge and IPR state of play in SimCardioTest

Even though SimCardioTest is currently in an initial phase, an overview helps Consortium partners in the comprehension of how project results can be actually exploited by partners (i.e., Consortium members).

## 5.1 Expected roadmap

In dealing with IPR-related topics, the Consortium has to consider - first of all - what is stipulated by SimCardioTest Grant Agreement (GA). While the GA anticipates that SimCardioTest Consortium recognizes the need for a structured approach to protect the innovation that is produced and the related IPR, a clear focus on IPR exists for Task 8.2: Data, IP & knowledge management and Task 7.2: Exploitation strategy.

The first task - under which the present deliverable is released – aims at ensuring that relevant project information is made available by the generator of knowledge and those who need this knowledge or information have easy access to it; this task also enables IPR handling through appropriate legal instruments. The latter task, for its part, is geared towards the establishment of a shared exploitation strategy - which goes hand-in-hand with a full-fledged business plan - allowing each SimCardioTest partner to maximize the results obtained.

Along the lines set by the GA, first months of SimCardioTest project have brought to the fore an array of needs exhibited by partners, which could be summarized as follows:

- **Clarify ownership status** of SimCardioTest assets with the idea of avoiding hindrances to their exploitation, whatever it is.
- **Ensure a smooth roll-out of the go-to-market plan** defined by the commercial front-end, shedding light on conditions allowing the commercial front-end to access relevant project results as part of the product development roadmap.
- **Assure a sound licensing** (e.g., open source software, open data licenses) to assets that are meant to be publicly disseminated on a large scale.
- **Manage IPR policies** for making SimCardioTest results fully operational once the grant period is over.

To translate such priorities into actions for the months to come, prominent knowledge and IPR management steps - defined in accordance with procedures and roles - already illustrated in section 3 - are:

- **Inventory of SimCardioTest assets**.
- **Identification of ownership rights** on SimCardioTest assets (through the IP Registry and its IPR Identification Sheets).
- **Examination of possible IPR protection** and openness-oriented measures.
- **Consensus-based consolidation of the exploitation strategy** at Consortium-level
- **Drafting of IPR agreements** and governance models in view of the exploitation strategy.
- **Execution of exploitation actions** according to key milestones of the go-to-market journey

## 5.2 Background

'Background' means any data, know-how or information —whatever its form or nature, including any rights such as intellectual property rights —that:

- is held by the partners before they acceded to the Agreement, and
- is needed to implement the action or exploit the results.

The departure for any IPR plan resides in the project background, i.e., the list of pre-existing knowledge and IP held by participants prior to the accession to the project and needed for carrying out the action or for exploiting its results.

In the case of SimCardioTest, background assets declared by partners in SimCardioTest Consortium Agreement are summarized below and includes:

- **Open source software**, with different level of access, according to the license obtained (LGPL or BS4)
- **Owned software** under license or patent
- **Web-based Platform** licensing on-going
- **Simulation pipeline** under license
- **Table 1**: SimCardioTest possible avenues for IPR protection.

Tables 3 and 4 list the software open source, and background identified, used in SimCardioTest.

***Table 3:*** *Software open source used in SimCardioTest*

| Partner | code | Open access link |
|---|---|---|
| These Software have to be used in respect of/under the terms of GNU LGPLv3 open source license | | |
| **UBx** | **Cardiac Electrophysiology Solver** | https://carmen.gitlabpages.inria.fr/ceps/ |
| **Simula** | **Oasis – computational fluid dynamics solver** | https://github.com/mikaem/Oasis |
| **Simula** | **Pulse-Adjoint – cardiac electromechanics solver** | https://github.com/mikaem/Oasis |
| **Inria** | **SoftRobots** | https://github.com/SofaDefrost/SoftRobots |
| **Inria** | **Cosserat** | https://github.com/SofaDefrost/plugin.Cosserat |
| **Inria** | **Sofa** | https://github.com/sofa-framework/sofa/ |
| This Software has to be used in respect of/under the terms of BSD4 open source license | | |
| **Inria** | **medInria software** | License BSD4 - medInria |

***Table 4:*** *Background identified by the partners in SimCardioTest Consortium Agreement.*

| Background | Partner | Specific limitations and/or conditions for Implementation (Article 25.2 Grant Agreement) | Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement) |
|---|---|---|---|
| **Software/plugin**<br>- SOFA-MechanicalHeart<br>- SOFA-Electrophysiologie<br>- SOFA-CardiacReduction<br>- Logiciel MUSIC version 2.0<br>- -Logiciel MUSIC version 2.0 - pipeline TV<br>- Software "BeamAdapter" v1.0<br>- Software "SoftRobots.Inverse" v1.0<br>- MUSIC Carmen plugins | **Inria** | After the termination of the Consortium Agreement, the Software can no longer be used.<br><br>No access right is given to the source code | Exploitation agreements and licensing terms with other parties shall be negotiated and will require legal consent from the owner<br>No access right is given to the source code<br>Exist some Exclusive exploitation license already granted in the field of cardiology |
| **web-based platform for assessment of individual characteristics**<br><br>VIDAA and VRIDAA platform | **UPF** | Technologies co-owned with other Entities.<br>There is limited access only during the implementation of the Project for non-commercial research purposes, and until the extent it is needed by another Beneficiary for the implementation of its own tasks.<br>For other uses (research, including non-commercial research, or exploitation), a specific license shall be requested. There is no obligation to grant such license after the end of the project. | |
| **simulation pipeline –LAAO**<br><br>Fluid simulation pipeline to generate in-silico haemo-dynamics indices for estimation of LAA and post-LAAO implantation thrombo-genic risk<br><br>ML-based estimation of optimal LAAO device | **UPF** | Access only during the implementation of the project.<br>There is no obligation to grant such license after the end of the project | There is no obligation to grant such license after the end of the project |
| **Patent**<br>"Method for Controlling a Deformable Robot, and Related Module and Computer Program » | **Inria** | none | Exploitation agreements and licensing terms with other parties shall be negotiated and will require legal consent from the owner |

## 5.3 Envisaged assets composing SimCardioTest foreground

This section describes where we are and where we are heading to as far as project results are concerned. For the sake of knowledge and IPR examination, SimCardioTest foreground items can be classified as follows:

Foreground IP is the IP developed or generated from the work of a team. Foreground IP includes subject inventions (i.e., inventions made in the performance of SimCardioTest), software, simulation pipelines other copyrightable works and rights in data generated by the team.

Expected SimCardioTest foreground includes tangible and intangible results. The potential results and outcomes from the project are from new software to new device, and from confidential to open access information/product/software. It is summarised in the Table 5.

***Table 5:*** *Expected SimCardioTest foreground*

| | |
|---|---|
| **New software/Models** | and software protocols compliant with regulatory requirement from US and EU regulatory bodies |
| **Simulation platform with use cases models** | to verify and validate new designs of device or new drugs |
| **Devices** | New device design including safety & efficacy of new product design |
| **Experimental platforms** | for testing and validating models |
| **Indices/ biomarker** | to improve clinical trial designs/ methodologies |
| **Know how** | Experience gained within the project duration |
| **Data and databases** | See D8.7 on DMP |
| **Report/data/database/deliverables** | Confidential, Public or ORDP |
| **publication** | Open access as much as possible |
| **conference** | Open access |

Each type of asset, as explained above, will be covered by a specific IPR Identification Sheet.

### Software assets

SimCardioTest software assets are project results that represent software components (models) of the 3 use cases outcomes defined according to GA specification and included in the simulation cloud platform.

Each discernible software asset - belonging to one of the 3 SimCardioTest use cases outcomes will be described in the IPR Identification Sheet according to a number of dimensions:

- Name
- SimCardioTest use case outcome Description (model, pipeline, etc.)

- Expected TRL, proxy of the technological maturity estimated through the scale - ranging from 1 to 9 - adopted by the European Commission15
- Ownership, intended as partner(s) that generate the software asset
- Background underlying assets (if any), namely background item(s) on which the software asset is built upon
- Other underlying assets (if any), non-background item(s) on which the software asset is built upon
- IP condition, e.g., proprietary,
- License, e.g., copyright, 1
- Public availability, e.g., no, GitHub, Source

### Device, experimental platforms, hardware assets

Devices, experimental platforms, 3D mannequins' assets are project results that represent any tangible material designed based on the use cases modelisation outcomes needed for running the simulation cloud platform.

Each material – designed based on one of the use case models- will be described in the IPR Identification Sheet according to a number of dimensions (see Table 3)

- Name
- SimCardioTest Materials Description
- Expected TRL, proxy of the technological maturity estimated through the scale - ranging from 1 to 9 - adopted by the European Commission16
- Ownership, intended as partner(s) that generate the device
- Background underlying assets (if any), namely background item(s) on which the software asset is built upon
- Other underlying assets (if any), non-background item(s) on which the device is built upon
- IP condition, e.g., proprietary,
- License, e.g., copyright,

### Data assets

When it comes to the portfolio of SimCardioTest data assets, for a thorough examination of these assets the user is redirected to D8.7: Data collected within the scope of SimCardioTest project.
These data include also indices, indicators
These data can be obtained via 6 possible origins of the data (further details in this regard are available in D8.7):

- Open data
- Data entirely generated by SimCardioTest action
- Derivative data

15 http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf
16 http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016_2017/annexes/h2020-wp1617-annex-g-trl_en.pdf

As a result, SimCardioTest data assets - derivative data or entirely generated by SimCardioTest action – are expected under the following SimCardioTest data families mentioned by GA specification:

- User behaviour data
- User profile data
- Environmental data

As it happens for hardware assets and data assets, each discernible data asset will be described in the IPR Identification Sheet according to a number of dimensions (see Table 6)

- Name
- Data family, such as user behaviour data, user profile data, environmental data
- Description
- Ownership, intended as partner(s) that generate the data asset
- Underlying background datasets (if any), namely background data item(s) on which the data asset is built upon (for derivative data)

### 5.4 Other underlying datasets (if any), namely non-background data item(s) on which the data asset is built upon (for derivative data)

- Data type, e.g., dataset, data stream, data model
- Format, e.g., XML, JSON, relational
- License, e.g., copyright, Creative Commons
- Privacy level, e.g., personal, non-personal data
- Confidentiality level, e.g., confidential, to be disclosed

The outline of the IPR Identification Sheet for SimCardioTest data assets is schematized in Table 6, p40.

### 5.5 Know-how and ownership

Regarding know-how assets, they are intangible entities underpinning the conceptualization, testing and delivery of SimCardioTest fit-for-purpose product. These intangible knowledge assets can take different forms such as - *inter alia* - business models, algorithms, practices, procedures, models, and data visualization approaches.

In terms of know-how assets, a substantial coverage will be expected in areas that lie at the core of SimCardioTest endeavor. Without any claim of being exhaustive, possible areas in which the generation of knowledge assets is foreseen are as follows:

- the integration activities of the in-silico platform
- the procedures adopted for the creation of disruptive clouds
- the procedures for regulation, for standardisation
- device design iterations
- the anatomies of population

Data assets belonging to SimCardioTest foreground - and the same holds true for all information resources used as input for SimCardioTest - will be managed in view of confidentiality measures already explained above. When appropriate, measures meant to foster openness will be considered.

The Intellectual Property management plays an important role in maximising the impact of research and innovation projects, safeguarding that bright ideas and ground-breaking research findings are turned into value-creating goods and services. IPR management is a prerequisite to make project results available to those who need them and will benefit from them. Along these lines, SimCardioTest Consortium intends to ensure that IPR is properly handled, protection measures are activated where and when opportunities emerge, while openness is promoted as a driving force meant to amplify impacts for society at large. Nevertheless, Inria has designed a questionnaire to clarify on how IP is managed in SimCardioTest (Table 6).

### Questionnaire at M30

A questionnaire (summarized version below) designed by Inria has been sent to SimCardioTest partners in 2023 to identify the assets and corresponding ownerships. The detailed questionnaire is available in Table 6 (p41).

| **New result** | **Result type** | **Result Description** | **Any background IP used in that result?**<br>**2- who owns it**<br>**Any constraint?** (Open-source license, patent, licenses already given to others, only research use, etc) | **Contribution to the asset**<br>**What % for each contributor?** |
|---|---|---|---|---|
| ***ABC Module*** | *Software* | *A software module that converts A into B* | *A software called D useful to compress images?*<br>*50% Inria 50% UCA - GPLv3 license* | *XXX, YYYY*<br>*50%, 50%* |

| **Does the asset require support/maintenance from partners, or require further development to be used in an industrial setup?** | **Is the result already protected by a patent, or registered for anteriority, or distributed under a given (open source) license?** | **does the asset embed third party components** | **Who will use the results?** | **Exploitation type** |
|---|---|---|---|---|
| *The software is fully documented for self-installation and operation* | *The software has been protected at the APP* | *The software uses GPLv3 libraries* | *External* | *Commercial licensing* |

This questionnaire is also related to the exploitation strategy of the in-silico trials platform. The rules and procedures on how IP matters is being addressed among and between the consortium members and is a pre-requisite for the exploitation plan (preliminary plan delivered at M24). A new questionnaire is shared among the partners to collect the outputs of their work with the associated ownerships. This will be part of the Final Exploitation plan.

## 6. Concluding remarks and next steps

SimCardioTest, an ambitious market-oriented H2020 action, considers the flow of activities related to the exploitation as an essential element to make the project results sustainable over time and generate impacts for the project partners and far beyond the boundaries of the SimCardioTest

consortium. Thinking about exploitation inevitably involves knowledge and IPR management, which is seen as a key activity.

The present deliverable, released in the initial phase of SimCardioTest and updated at mid-term of the project, illustrates principles, practices and measures that have been planned by the Consortium for handling knowledge and IPR management in a systematic manner. This is done by presenting internal procedures for knowledge and IPR management adopted according to SimCardioTest Grant Agreement and SimCardioTest Consortium Agreement as well as by portraying initial asset types that are the backbone for forthcoming exploitation actions.

During the General Assembly - to be held in February 2022 - a report of the IPR state of play will be provided. As per the planning defined at Consortium-level, written updated reports will be given in the following deliverables (listed in chronological order):

D8.7 Data Management Plan
D7.3 Preliminary Exploitation strategy and market assessment
D7.5 Final exploitation and market uptake strategy

In the meantime, should the need arise, the Consortium can reach out to the European IPR Helpdesk and/or to an external IPR advisory firm to get support.

***Table 6**: IPR Identification Sheet for SimCardioTest software assets illustrated with an example*

| | | | **Any background IP used in that result?** | | | **Contribution to the asset** | |
|---|---|---|---|---|---|---|---|
| **New result** | **Result type** | **Result Description** | **1- description** | **2- who owns it** | **Any constraint?** (Open-source license, patent, licenses already given to others, only research use, etc) | **Who contributed to the result during the project** (list of authors/inventors with affiliations). | **What % for each contributor?** |
| ***ABC Module*** | *Software* | *A software module that converts A into B* | *A software called D useful to compress images* | *50% Inria 50% UCA* | *GPLv3 license* | *John XXX - Inria*<br>*Jane XXX - Inria* | *50%*<br>*50%* |

| **Does the asset require support/maintenance from partners,** or can it be operated by anybody without difficulty | **Does the asset require further development to be used in an industrial setup?** | **Is the result already protected by a patent, or registered for anteriority, or distributed under a given (open source) license?** | **does the asset embed third party components such as open-source libraries, side ground IP (results developed independently from the project) with exploitation constraints?** | **Who will use the results?**<br>**1- IST platform**<br>**2- consortium members**<br>**3- External** | **Exploitation type: transfer of software license, royalties, possibility of creating a start-up or spin-off company, etc** | **Comments** |
|---|---|---|---|---|---|---|
| *The software is fully documented for self-installation and operation* | *Yes, this is a prototype that only runs on Windows machines and that has only been tested on a limited set of data* | *The software has been protected at the APP* | *The software uses GPLv3 libraries* | *External* | *Commercial licensing* | *Lien Github : github.com/ghudgzud/ezdhiezhd* |

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