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

Technical Report

D8.5 Intermediate Advisory Board recommendations and stakeholder group request

Work Package 8 (WP 8)

Project coordination & management

Task Lead: Inria, France
WP Lead: Inria, France

PUBLIC

DELIVERABLE INFORMATION

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10/05/2023	V1	R. Setzu, O. Camara, B. Trenor	Advisory board meeting report correction
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14/06/2023	VF	M. Sermesant (Inria)	Quality Check
30/06/2023	VF	Governing Board members	Validation

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EXECUTIVE SUMMARY

SimCardioTest has implemented an Advisory Board (AB) with representatives from non-partners who can guide SimCardioTest with reference to the needs and viewpoints of key stakeholders. Among the stakeholder's groups, SimCardioTest is targeting the medical community. This is why, beside the feedback received by the various stakeholders represented in the Advisory Board, clinicians and patient organisations were also consulted through an online survey and through a focus group workshop.

This deliverable reports on the stakeholder's request, feedback or questions to increase quality, appeal, and ultimately to ensure that the needs of key stakeholders are met.

1- INTRODUCTION

One of the strategies of SimCardioTest is to establish a continuous assessment of the project's impact by independent scientific experts through an Advisory Board and stakeholder groups through two-way dialogue in order to help keep pace with the latest developments and to define new strategies to maximise the project's ultimate societal impact.

1.1. The Advisory Board

The Advisory Board consists of representatives from non-partners who can guide the partnership SimCardioTest with reference to the needs and viewpoints of key stakeholders. It is intended to be representative of various stakeholder communities interested in model simulation and in-silico trials.

Advisory Board composition:

Name	Position	Role	Organisation
Flora Musuamba-Tshinanu	Vice chair	EMA Modelling and Simulation	EMA
Richard Gray	Senior Scientist	Center for Devices and Radiological Health, Cardiac Modelling Research Program	FDA
Duchateau Nicolas	Associate Professor	ESC Regulatory Affairs, ESC e-Cardiology, ESC Digital Health Committee	Lyon University
Levine Steven	Executive Director	Living Heart Project	Dassault Systèmes
Wang Ken	Principal Scientist	Translational modelling & simulation group	CH Roche
Virag Nathalie	Senior Principal Scientist	Modelling and devices	Medtronic
Peter Hunter,	Director	Model standardisation	Auckland Bioengineering Institute

Indeed, SimCardioTest Advisory Board members are already very active on the topic of in-silico trials, including CM&S for medical device regulation since 2018 with its Office of Science and Engineering Laboratories, as well as for drug cardiotoxicity assessment (CiPA initiative). These initiatives set the stage for the current project, which will take a step forward by incorporating in-silico tools in the regulation routine for cardiac devices and drugs of European companies.

EMA, FDA and ESC involvement in the advisory board will ensure that efforts will be in line with current regulatory and clinical standards.

The Auckland Bioengineering Institute (Prof. Peter Hunter, SimCardioTest Advisory Board member) has been pioneering this standardisation work, and whose seminal work inspired such activity within the Virtual Physiological Human (VPH) program.

In addition, uncertainty quantification and parameterisation of such models is currently a subject of major interest and has also been studied by members of the consortium. A commercial product exists for cardiac electromechanical simulations (the Living Heart Project from Dassault Systèmes), however it does not enable personalisation of parameters, therefore comparison with validation data is not yet feasible.

Interactions with Policy-makers involved in healthcare, industry and innovation policy, are assured through the participation of Flora Musuamba-Tshinanu (EMA) and with American regulators thanks to interactions with the FDA assured through direct participation of Richard Gray (FDA) to the Advisory Board.

1.2. Stakeholder group consultation

The purpose of the Stakeholder Group is to raise awareness towards the end-users of the medical devices being developed with the in-silico technology proposed by SimCardioTest, and allow key players to connect and co-design the approaches and priorities of the transition towards digitalized in-silico trials initiatives. The work on establishing the SG has begun at the proposal phase from interactions with partners and the VPHI.

Ultimately, the goal of SimCardioTest is to improve patient health by making cardiovascular devices and drugs safer and more efficient. Hence, patient groups were considered key stakeholders to consult in the course of the project. Among the stakeholder's groups, SimCardioTest is also targeting the medical community. This is why, beside the feedback received by the various stakeholders represented in the Advisory Board, clinicians were also consulted through focus groups and through an online survey.

2. METHODOLOGY

2.1. The Advisory Board

During the 2nd SimCardioTest General assembly, an online meeting with the Advisory Board members was organised on 20 March 2023 **(Annex I).**

The members were invited at least a month before; and after a 45 min. presentation of SimCardioTest main advances (UC1, UC2, UC3 and WP6), questions and feedback were collected.
The attendees were: Nicolas Duchateau, Nathalie Virag, Ken Wang, Levine Steven
SimCardioTest: Hermenegild Arevalo, Irene Balelli, Alessia Baretta, Oscar Camara, Valerie Centis, Yves Coudière, Raphaelle Le sage,Javier Saiz, Beatriz Trenor, Maxime Sermesant & Michele Barbier
Excused: Peter Hunter, Richard Gray
Absent: Flora Musuamba Tshinanu

2.2. Stakeholder consultation

The partners of SimCardioTest have been attending symposium and conferences that members of cardiovascular medical communities typically attend. This created opportunities for direct scientific exchanges between the SimCardioTest use case developers and cardiologists. In addition, an online survey was conducted by VPHi in 2021 to assess the current level of awareness as well as the expectations and concerns of the clinical community regarding *in silico* medicine and computational modeling and simulation (CM&S) in clinical premises. The survey was shared through all VPHi channels and the VPHi network was leveraged to target diverse clinicians, it was open for a period of 3 months. The data have been analyzed and reported through a scientific publication and a brochure with info-graphics for the general public. A communication campaign has been created to allow for the dissemination of the output (including general press release) and a new clinical community working group has started to elaborate on those findings and design a new survey.

Finally, various stakeholders were invited to participate to a SimCardioTest focus group to share their expectations as well as discuss possible ethical, social or legal issues pertaining to the use of *in silico* technologies. Focus groups are a qualitative research tools allowing exploratory discussions with various stakeholders independent of their prior knowledge and level of awareness. The stakeholders targeted with that method were patients, medical practitioners and clinical trial experts. (see section 3.2 for more details on the methodology of the focus group)

3. RESULTS

3.1. Advisory board recommendations

Nicolas Duchateau: BSC is leaving the consortium, but the project has made great effort toward the WP6. How advanced is the work with clinicians and what are the connection with clinicians?

SimCardioTest members answers:

> *From the very beginning, the modelling efforts have been developed with clinicians involved in the project, to better understand the relevant questions of interest regarding different treatment options.*
> *The modelers of SimCardioTest have presented their work during conferences and symposium that are typically attended by clinicians and members of various cardiovascular medical societies, allowing for scientific exchanges. In addition, SimCardioTest has received input from the clinical community through an online survey run by VPHi and meant to identify their current level of awareness, use and trust as well as potential needs related to CM&S in clinical practice. To follow-up on that, the VPHi has initiated a clinical community working group, to create synergies around stakeholder outreach and consultation activities between various projects and interested actors. For example, a new survey is being elaborated as part of this group to allow for longitudinal analysis, 2 years after the 1st survey. Finally, clinicians were invited to participate to a SimCardioTest focus group with other stakeholders (including patients) to share their expectations as well as discuss possible ethical, social or legal issues pertaining to the use of in silico technologies.*
> *It would be good to reinforce the link with the clinician's community.*

Regarding UC1 & 2, based on previous project and the exploitation of data from echography, did you already identify some markers attached to the phantom?

For UC1, pacemaker navigation in a phantom: the challenge is to observe and measure the 3D geometrical confirmation of the lead during its navigation in the phantom, in order to obtain validation data. At the time of the general assembly, we had only tested the possibility to observe the lead with echography. We would use some known markers specific to ultrasound, if it appears to be relevant for our approach to obtain validation data.

As for UC2, we are currently gathering the first measurements from the in-vitro experimental setup performed in collaboration with MIT researchers, where a left atrial geometry is 3D printed and moved according to realistic displacements derived from dynamic computed tomography imaging. These initial measurements will be analysed to identify if additional markers/metrics/measurements are required to assess the realism of the computational fluid dynamics simulations.

Nathalie Virag: The project is of high quality, with a lot of information. In-silico trials are susceptible to replace clinical trials, so, it would be interesting to decide on one or two Question of Interest to go further and perform in vivo test.

SimCardioTest members answer:

As part of the SimCardioTest project, we have extensively worked in each use case to define several interesting Questions of Interest and prioritize them, in order to focus our efforts on the most relevant one.

Steve Levine: The work performed in SimCardioTest will provide long-term model that will be useful the community. The credibility is an important factor and the validation against the risk must be taken in great consideration.

SimCardioTest members answer:

WP6 Feedback. We agree with the Advisory Member recommendation. In order to properly address the model credibility, we engaged extensive V&V activities according to ASME VV40 guidelines. The model risk in the defined context of use is taken into consideration when model designing the validation strategy, as recognized by VV40 guidelines.

3. 2. Stakeholder group consultation

3.2.1. Clinical community survey

a. Context and setting

An exploratory approach was used to gain a better view on the current status of the clinical uptake of in silico medicine technologies and gathers insights on applications, level of acceptance and potential barriers for clinicians. An online survey of 25 questions, including demography, was disseminated in 2021 through a communication campaign (VPHi newsletter, social media, institutional collaborators, professional societies and contact of VPHi members) towards medical practitioners.

b. Results

In total, 163 respondents from various medical field answered the survey. Nearly half of the respondents were from the cardiovascular field (Figure 1).

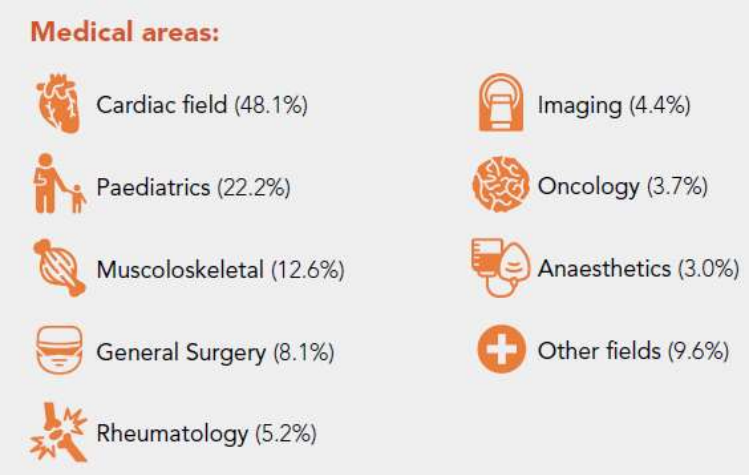

Figure 1: Medical specialisation of respondents

The results of the findings were published in an open access scientific journal[1] and an information brochure was produced to disseminate the results to a broader audience[2].

Our findings show how terms related to CM&S are generally not stranger to the clinical community. However, there is discrepancy among the different expressions which are commonly used by the modelling community, suggesting that more effort should be dedicated to efficient communication.

According to the collected data, CM&S have been used mainly to support decisions related to the planning of procedures and for teaching activities. Whilst planning is consistent with what is reported in the literature on translation of CM&S towards clinics, such extensive use for teaching activities is not properly represented and deserves follow-up and more granular future analyses.

1 Lesage R, Van Oudheusden M, Schievano S, Van Hoyweghen I, Geris L and Capelli C (2023) Mapping the use of computational modelling and simulation in clinics: A survey. Front. Med. Technol. 5:1125524. doi: 10.3389/fmedt.2023.1125524

2 Raphaëlle, Michiel, Silvia, Ine, Claudio, Giulia, Martina, Roberta, & Goran. (2023, May 26). Mapping the use of computer modelling and simulation in clinics. Zenodo. https://doi.org/10.5281/zenodo.7974392

Cardiovascular and musculoskeletal are the areas where CM&S have found their highest usage to date.

Although the overall use of CM&S in clinics is not routine yet, it was recorded how clinicians generally trust CM&S; however, the concept of trust should be investigated further for example by looking at reliability confidence.

We observed an overall confidence on the rising role envisioned for CM&S in clinical routine. The latter was found to be positively associated with the pre-existence of team members dedicated to CM&S.

The weaknesses that were identified as slowing down the adoption of CM&S tools in clinical practice relate to difficulties in accessing technical expertise and computing resources, the perceived slow turnaround time of simulations' results; and the perceived limitation of CM&S applications to a few medical areas. Important to note is that clinicians have declared they would rather rely on their personal positive experience than regulatory approval by official bodies when it comes to trusting the outcome of a computational predictive tool for their practice. This points at the need for improvement for regulatory sciences of digital health, notably in terms of credibility building, transparency, awareness building and communication to stakeholders.

Future action: Beside briefing in silico experts, policy makers and regulators about the relevant recommendations coming out of that consultation, new public consultations will be initiated and an information package will be produced. To that end, a clinical working group, gathering actors from SimCardioTest, as well as external actors interested in clinical community engagement activities, has been formed (monthly online meeting coordinated by VPHi). One of the objectives is to design a new follow-up survey that aims at carrying a longitudinal analysis (comparison of the 2021 and the 2023 situations) and further study some concepts such as trust, regulatory needs, usage in practice, etc.

3.2.2. Focus group

a. Methodology overview

On March 21st 2023, a focus group was held in Bordeaux, as an integral part of work package 7 of the SimCardioTest project. To align with the purpose of this group discussion, which is to collectively explore and comprehend the potential ethical, legal, and social consequences related to the adoption of in silico technologies, different stakeholders from the surroundings of Bordeaux were invited. An effort was made to gather a diverse range of stakeholders, including, patients from patient organizations, in silico experts, clinical trial experts and clinicians. As such, the participants differed in their knowledge and awareness of in silico medicine. To allow the participants to comfortably express their opinions in a non-threatening environment, the focus group was conducted in the local language, French. In general, a focus group is a qualitative research method that involves bringing together a group of participants to engage in a structured discussion on a specific topic.

The purpose is to gain insights, opinions, and perspectives from multiple individuals in a group setting. In this case, the structuring was carried out by selecting and discussing three predetermined use cases that fit within the scope of SimCardioTest. The focus group was guided by a moderator,

who was assisted by multiple note-takers, who were in charge of the audio-recording. Participants were informed that the session would be audio-recorded for research analysis, and the resulting data, which did not include any names or affiliations, was then translated from the local language to English. Lastly, the software Atlas.ti was used for the coding-process.

The course of the focus group was the following: The first part consisted of a brief introduction to focus groups, the project, and in silico medicine in general. Afterward, three use cases were discussed in a random order. In addition, the participants were encouraged to take a look at a list of values, that was derived from a survey preliminary conducted towards experts. As the discussion concluded, participants were given the opportunity to reflect on their involvement, as a means of feedback.

b. Consultation outcome

In this part two notable insights from the focus group will be discussed. A scientific publication will be drawn up for a more in-depth discussion of the findings.

Patient vs. clinician: unraveling the expertise

Participants initially expressed a lack of confidence in their own expertise and knowledge regarding in silico medicine, which even led to questioning the value of their contribution to the group discussion. Despite acknowledging the significance of effective doctor-patient communication, they maintained a general belief that doctors hold the role of experts, assigning them a teacher-like position in the healthcare dynamic.

> *"I don't know, I'm me, I'm not competent." (ARC expert)*
> *"He told me that the standards have changed, that's how it is, I'm changing your treatment. Thank you doctor. That's 50 € and there you go, you were disciplined you know." (Patient)*

This conviction of a lack of knowledge about in silico techniques and applications among the participating patients also reflected in a blind faith in the experts. There is little questioning of a clinician's decision when it comes to a change in medication or treatment. One patient hereby points out that you can easily gather extra information by talking to the clinician, however this person in particular does not feel the need to do so. This ultimate trust is illustrated in the following quote:

> *"But I don't really see what I, as a patient, could contribute given my lack of general knowledge on these subjects... I didn't understand why they put a defibrillator in me, they didn't tell me what pathology I had because there was no clinical diagnosis. What I mean by that is that there was a kind of absolute trust in the whole team of the hospital and I don't question the approach." (ARC expert)*

But what if the clinician makes a mistake? How does this affect the relationship, and the trust in general? It is once mentioned during the focus group to be detrimental to the faith a patient has in their clinician, trust thus proves crucial.

"In the communication between us, it's important because the doctors have to understand that there are things that we can do now, when we become a professional." (patient)
"If you're a professional in a situation, there are things that you can't hear. Now after, we can understand the benefit, the risk, all that." (patient)

In silico medicine allows patients to become more empowered individuals, as shown in the quotes above. However, follow-up research is appropriate to ascertain how far this role of patient as expert extends? In the final dialogue, also experts acknowledge the added value of patients to the discussion of barriers of in silico medicine. For instance, one of the experts believes he, through this focus group, gained insight into the information that patients oftentimes lack, where additional clarification in communication is appropriate. To this, another expert replies that it is indeed important to have clear conversations with your patient, to explain the pathology well, for example. There is unanimity about the importance of good clinician-patient communication in order to involve patients more in both their treatment and the progress of in silico medicine in general.

The future of in silico: complementing or replacing in vivo & in vitro methods?

Next, a substantial part of the discussion of the second use case revolved around the role of in silico throughout the process of developing medical devices. Is it desired to replace in vivo or in vitro testing with in silico testing? How much power do we want to assign to the use of computer modeling and simulation when it comes to healthcare outcomes? Generally, there is a tendency among the respondents that, regardless of their overall positive attitude toward these innovative techniques, in silico trials should complement traditional trials, rather than fully replace them. When discussing the potential of using models to understand and explain phenomena that sometimes cannot be tested directly on patients, the clinician acknowledges that the element of surprise in the predictions of an in-silico model is considered as a plus, but believes that many clinicians remain cautious and hesitant to actually work with these models. This could indicate a level of uncertainty or distrust in the accuracy and credibility of in silico predictions, but this is a layer that has to be investigated further.

In this regard, an interesting dialogue took place between a patient and an in-silico expert, where a comparison was made between an in-silico model for an airplane, whose mechanical structure is well-known and an in-silico model for medical purposes. The complexity of the human body, and the unpredictability of the heart, oftentimes leads to uncertainties and risks in predictions, which has led to the mention that clinical trials should not be completely replaced, as certain visible aspects that occur during clinical trials cannot be predicted by computers. However, the respondents also point out the complementary advantages of using predictive modeling. As such, it reduces costs and time, and you can implement more factors in your model. The advantages that an in-silico trial has can thus complement the shortcomings of a traditional clinical trial, and vice versa.

"So 100%, it's not to criticize the project, but it's to say that there are things that we don't know or that we think we know, but in fact we're wrong and that's why we need to do clinical studies. In fact, they are even strategy studies. That is, I'm going to have a strategy guided by this technology where I'm going to implant in my patient and I'm going to compare that to another strategy. And I'm still going to be interested in what happens in the patients. And maybe one way to have the best of both worlds is to implement these techniques to replace things that would be costly and potentially quite risky and, on the other hand, to do follow-ups behind them because there is a kind of vigilance or reinforced pharmacovigilance materials that allow for a feedback." (In silico expert)

"That's why clinical trials, there are things that I know that I think the visible part, the part of a mechanical part that we have confidence in ourselves. And then there is a part, the code part that goes into clinical trials, there are more uncertainties and more difficulties, it will never replace a clinical trial." (In silico expert)

Related to validation, animal testing comes up during the discussion. Remarkably, the economic savings associated with the in-silico trials, rather than the reduction in animal testing, are highlighted. One patient making the following noteworthy statement:

"Anyway, that's for sure to explain why eventually a patient might find that digital is good. It would be for those things anyway, it seems obvious. But there's the animal side. Most of us never bothered to know on whom and what, which pig it had been treated, tried. I bless all the pigs that have had defibrillators implanted or resynchronized. I like them a lot but hey." (Patient)

Furthermore, the ARC expert highlights the social implication of the existing inequality in access to drugs, emphasizing that countries without access often bear the risks of clinical trials without benefiting from the resulting treatments. In response to this, one of the patients makes the trade-off that these digital technologies, aimed at improving the efficiency of healthcare, have an overall benefit for society as a whole.

c. Conclusion and future plans

Overall, the discussion started off with patients lacking confidence in their knowledge of in silico medicine but recognizing the importance of clinician-patient communication. However, as the discussion progressed, there was a growing recognition of the importance of patients' role and their potential contribution to the dialogue. Furthermore, the participants generally believed in complementing, rather than replacing, in vivo and in vitro methods with in silico testing while acknowledging the advantages and uncertainties associated with predictive modeling and traditional clinical trials.

The findings that came out of the focus group are not limited to the insights discussed. In the future, a more detailed report will be written to communicate the output to the whole consortium and

collectively reflect of possible short-term actions that could be considered in the scope of the project. Notably, the lessons learned will guide us in the design of an information package for helping in silico experts with patient engagement activities. As similar focus groups were and will continue to be conducted for several EU-funded projects on the uptake and development of in silico medicine, the output should ideally be juxtaposed at a later stage so that a more comprehensive picture can be formed of the ethical, legal and social (ELSI) barriers to the uptake of in silico medicine. From this, policy recommendations will be formulated to tackle these concerns and other actions points in terms of training and communication will be proposed.

4. CONCLUSON

The interaction of SimCardioTest leaders with the Advisory Board (AB) and the Focus Group has been successful and should facilitate the extensive networks of the consortium partners. Stakeholders will be informed of project progress and will be invited to participate to targeted project workshops and meetings. The results of the clinical survey and their analysis has been published in a scientific report to inform the in-silico scientific community but a general communication brochure with accessible info-graphics was also produced t to reach out and inform non-in silico experts' stakeholders (clinicians but also regulators, policy makers and so on). We will also use that material to incentivize more stakeholders to participate in the next stakeholder consultation rounds (surveys and workshops).

At M40 an exploitation workshop involving all project partners together with the Advisory Board and the Stakeholder group members will present the outcomes of the preliminary market assessments and facilitate early discussion on exploitation scenarios.

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

ANNEX I

Agenda of the SimCardioTest general Assembly

SIM CARDIO TEST

SimCardioTest - Agenda

General Assembly 2023.

At University of Bordeaux,
Campus Victoire, France
20 & 21 March 2023

Links to online access

Day 1 - 20 March - Bordeaux University, Campus Victoire -
Amphitheater PITRES

14h00-14h10 Overview SimCardioTest - Maxime Sermesant, Inria

14h10 -17h00 WPs progress including coffee break

- **WP1** - Hermenegild Arevalo, Simula - 10 min. + Q&A
- **WP2** - Yves Coudière, IHU Liryc - 15min. + Q&A
- **WP3** - Oscar Camara, UPF - 15min. + Q&A
- **WP4** - Beatriz Trenor, UPV - 15min. + Q&A

15h30 - &15h50 *Coffee break*

- **WP5** - Irène Balelli, Inria - 10 min. + Q&A
- **WP6** - Romano Setzu, Microport - 10 min. + Q&A
- **WP7** - Liesbet Geris/Raphaelle Lesage VPHi & SimCardioTest exploitation Alessia Baretta, IST - 10 min. + Q&A
- **WP8** - Michele Barbier, Inria - 10 min. + Q&A

17h00-18h30 - Advisory Board meeting * - *Room Arnozan*

From 19h30 - Convivial event at the Mama Shelter,19 rue Poquelin Molière, Bodeaux downtown

*Meeting restricted to Governing Board members

How to get to Campus Victoire, Bordeaux University

moovit

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SIM CARDIO TEST

Links to access online

At University of Bordeaux, Campus Victoire, France
20 & 21 March 2023

Day 2 - 21 March - Bordeaux University, Campus Victoire *Amphitheater PITRES*

9h00 - 9h30 - SimCardioTest Introduction to hands-on on in-silico trials, Irene Balelli, Inria

9h30-10h30 - Round table on V&V - Progress on V&V implementation and data collection, Romano Setzu, Microport

10h30-10h55 - *Coffee break - ATRIUM*

11h00 - 12h30 - SimCardioTest Hands-on on in-silico trials, Use case parallel sessions- *Use Case 1: Room 33 - Use case 2: Room 35 - Use case 3: Room 34*

12h30 - 13h30: Lunch, ATRIUM

13h30-13h50 Demonstration Insilicotrials platform - Alessia Baretta, IST
Amphitheater PITRES

14h00- 16h00 - Parallel sessions

14h00- 16h00 - SimCardioTest Hands-on on in-silico trials, Use case parallel sessions- Use Case 1: Room 33 - Use case 2: Room 35 - Use case 3: Room 34

14h00-16h00: SimCardioTest stakeholders' meeting - Room 30

Coffee break - ATRIUM open from 15h00 to 16h00

16h00-17h30 - SimCardioTest Hands-on on in-silico trials, Use case parallel sessions- *Use Case 1: Room 33 - Use case 2: Room 35 - Use case 3: Room 34*

17h30 - 18h30 Restitution & conclusion Hands on, Irene Balelli, Inria-
Amphitheater PITRES

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