Proof of Concept of Model-based Cardiovascular Prediction

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Outcome of the strategic exploitation seminar

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List of Contributors

Name	**Affiliation**
Mirko De Maldè	LYNKEUS

List of reviewers

Name	**Affiliation**
Edwin Morley-Fletcher	LYNKEUS

Abbreviations

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Introduction

In view of the preparation of the forthcoming First Exploitation Plan (due at M20), an exploitation seminar was foreseen in the DoW, with the aim of "identifying the most likely scenarios within which to position the project's expected exploitable outcomes".

The seminar was conceived in order to preliminarly discuss the exploitation perspectives, the possible contents of the exploitation plan, and to identify potential joint exploitation initiatives.

A good basis for the discussion have been the exploitation questionnaires prepared, at the end of January, under request of the EC's reviewers, as well as the preliminary statements about the exploitation contained in the DoW.

The present document aims to briefly report on the discussion and to present the main action points that will lead to the preparation of the First Exploitation Plan. Eventually, this document will constitute the basis for the Exploitation Plan itself, which will try to expand the brief information herewith contained.

An outlook on the identified exploitable results and initiatives

The exploitation in the DoW

The discussion has started with an overview of the preliminary statements about exploitation, which were included in the DoW.

In the DoW, three partners, the more commercially steered ones, were indicating their expectation with regard to the future exploitation of the developed tools and services:

ESI

- *Enhance the potential for fluid flow simulations (for academic and industrial applications) in diverse medical and other areas.*
- *Demonstrate and promote the mesh less (SPH) CFD solution for intra-cardiac flow and the haemodynamics across valves.*
- *Employment of the numerical tools to impose the structural deformations as boundary conditions, also for different application fileds.*
- *Usability, also in other applications, of enhanced SPH model to allow for inflow and outflow along moving boundaries, and the intialization of the flow field from the MRI-VEC data*

SAG

- *Access the marketplace by applying for, obtaining and/or maintaining the relevant patent protection or any other intellectual property rights linked to model development.*
- *Boost the links between imaging and therapy for the benefit of the patient, bearing a high market potential, also thanks to the preliminary clearance process conducted in CARDIOPROOF.*

Fraunhofer MEVIS

- *Exploit the resulting modelling and simulation framework scientifically by using it as a platform for software development for new applications. This will go beyond cardiac applications and will include modelling of*
- *Therapies, which influence blood flow in different anatomic regions.*
- *Strengthen expertise in the field of modelling and simulation, thus opening new markets for collaboration.*
- *Reuse, in new projects, of the developed and evaluated integration and workflow concepts for image-based patient-specific modelling in a web infrastructure*

For the time being, these individual exploitation plans are still vaguely defined, also due to the completion of the relevant implementation and validation process, which will proceed during the entire project.

Still, within the first preparation phase of the exploitation plan, these partners, together with the other more academically-minded ones, will be asked to better define their approach to exploitation, providing some details and a brief plan on the following steps, as it is explained in the relevant section of this document.

In any case, it is worth noting that, as explained below, the outcomes of the innovation questionnaires have somehow reflected these initial declarations of intentions, which are now expected to be concretely pursued by the relevant partners.

Beside these individual declarations, a specific joint exploitable result was specifically mentioned, namely the common infostructure allowing access to the validated cardiac disease modelling. This outcome is closely linked with the expected joint exploitable result of MD-Paedigree, thus allowing to foresee a

common path of the two EC projects, toward a more effective exploitation of the combined outcomes. This aspect will be better explained in the dedicated section.

Expected exploitable results (as per the exploitation questionnaires)

During the First Periodic Review in Brussels, in Decembre 2014, the Cardioproof consortium was asked to respond to an innovation questionnaire, specifically aimed at understanding the expected innovations which will be likely to be implemented during the project, also providing information about the needs for the market uptake and the steps already performed in this direction.

The Consortium, after a dedicated discussion on this topic, decided to present three different questionnaires, for three specific innovations that will be pursued during the project lifetime.

During the Exploitation Seminar, these innovations were again discussed amongst the partners, to summarise the possible innovation paths deserving to be outlined in the Exploitation Plan.

The three selected innovations are the following :

1. **The proof-of concept validation**

The first innovation is the "*proof-of-concept validation of expected impact of cardiac modelling tools as compared to current practice on clinical decision making and associated economic costs, setting also a method for designing future clinical trials"*.

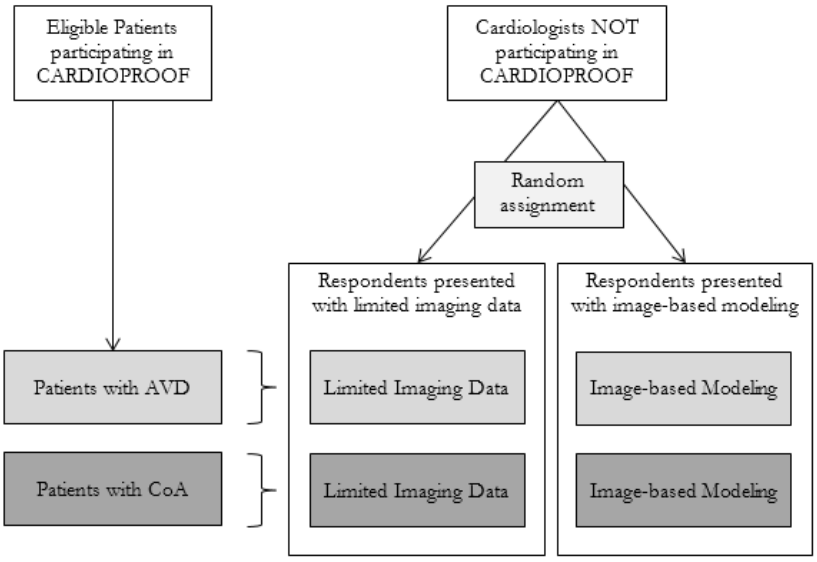
This has been presented as an organisational innovation, mainly delivered by the clinical partners with the key cooperation by LSE and LYNKEUS.

The idea is to pursue a direct exploitation of the comparative validation, effectiveness and cost-effectiveness methodologies developed within Cardioproof by applying them in other EC funded projects.

The idea is to proceed with a randomised controlled experiment, involving two groups of interventional cardiologists, the first of which will receive a "limited" dataset (information usually available from traditional diagnostics), while the second one will receive the a detailed dataset, including simulation modelling for the same set of patients.

The analysis, which will focus on each individual patient and compare the proportions of cardiologists making different types of intervention decisions in the two randomly allocated groups, will make it possible to understand the concrete impact of modelling in the clinical decision making.

The design of the experiment, which is explained in depth in the appendix to WP9 report (included in the Half-Yearly Report) is as follows:



To ensure the successful enrolment of a sufficient number of cardiologist to conduct the experiment, if this number cannot be reached involving cardiologists (not directly participating in the project) from the three clinical partners involved in CARDIOPROOF, an effort will be made to involve such specialists through specific conferences (i.e. the European Society of Pediatric Cardiology's Annual Meeting) asking them to participate to the experiment. This strategy would also allow a wide dissemination of the project among specialised and highly qualified potential stakeholders.

If successful, this experiment could be proposed as standard for future evaluation of the impact of the availability of simulation and modelling tools in clinical the everyday decision making process.

2. **<u>The virtual stenting software</u>**

The second innovation is the "*Haemodynamical (CFD) Model of the Aorta and Virtual Stenting Software Tool, capable to lead to optimal treatment decision. The model allows to optimise the stent position and the preferred outcome of the intervention, starting from anatomic and phase contrast MR image data".*

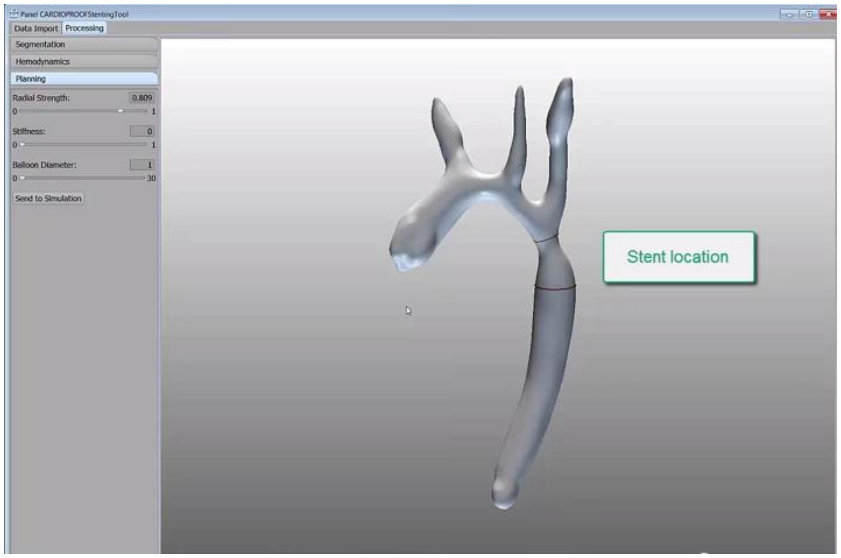
This has been presented as a new product, mainly delivered by MEVIS (with contributions also by MUG). The needed go-to-market steps have been indicated:

- Technology Transfer
- Prototyping
- Demonstration and testing
- Feasibility study

Finally, the need of developing a proper business plan and new partnerships has been mentioned.

This innovation is consistent with the initial exploitation plan indicated by MEVIS into the DoW.

The figure below shows the working software (snapshot from the youtube videoclip reachable via the Cardioproof homepage):



An important step toward the concrete opportunity of exploit this software has been recently completed: as explained in the report of WP8 (included into the Half-Yearly report), a preliminary validation of the Virtual Stent Planning Tool has been accomplished. This validation has been performed by comparing the actual post-treatment segmentations and reconstructions (based on MRI data merged with projection X-ray images), with the post-treatment geometry proposed by a Virtual Stenting tool.

3. The full heart model

The third innovation presented is the "*Electrophysiological and mechanical in silico model of the heart, allowing to simulate blood flows and pressure in the ventricles and the aorta. Model of Fluid-Structure Interaction to assess the dilatation of the ascending aorta by computing the pressure-difference field from 4D Flow data".*

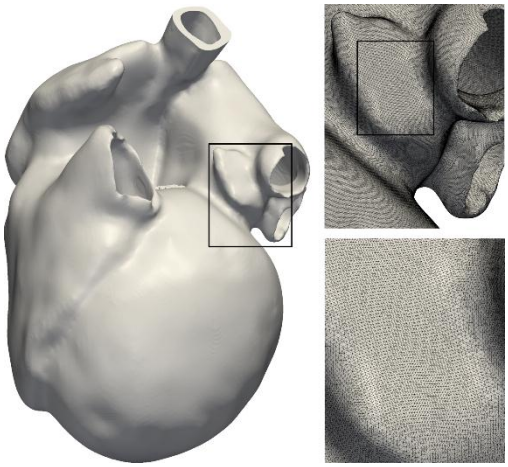
This has been presented as a significantly improved product (given the fact that part of the tools used were developed in previous EU funded projects).

The full heart model stem from the cooperation among three partners: SAG, ESI and MUG.

The needed go-to-market steps have been indicated:

- Technology Transfer
- Prototyping
- Business planning
- Demonstration and testing

Finally, the need of 1) partnering with other companies (MUG, ESI), 2) incubation (MUG); 3) expansion to new markets (SAG, ESI) has been mentioned.



It has been commonly agreed that, in order to make it possible to concretely exploit such tools, a rigorous validation process has to be completed. For some of these tools a preliminary validation process is started:

in particular, with regard to the Pressure Mapping Tool (developed by SAG), validation steps and tool requirements were discussed.

The possible link with MD-Paedigree's Exploitation

A clear link between CARDIOPROOF and MD-Paedigree was already settled in the DoW, in particular with regard to the re-use of the platform that is currently under development within MD-Paedigree, on top of which the CARDIOPROOF platform is being deployed.

Thus, it makes perfectly sense to foresee a joint exploitation initiative between these two cognate projects.

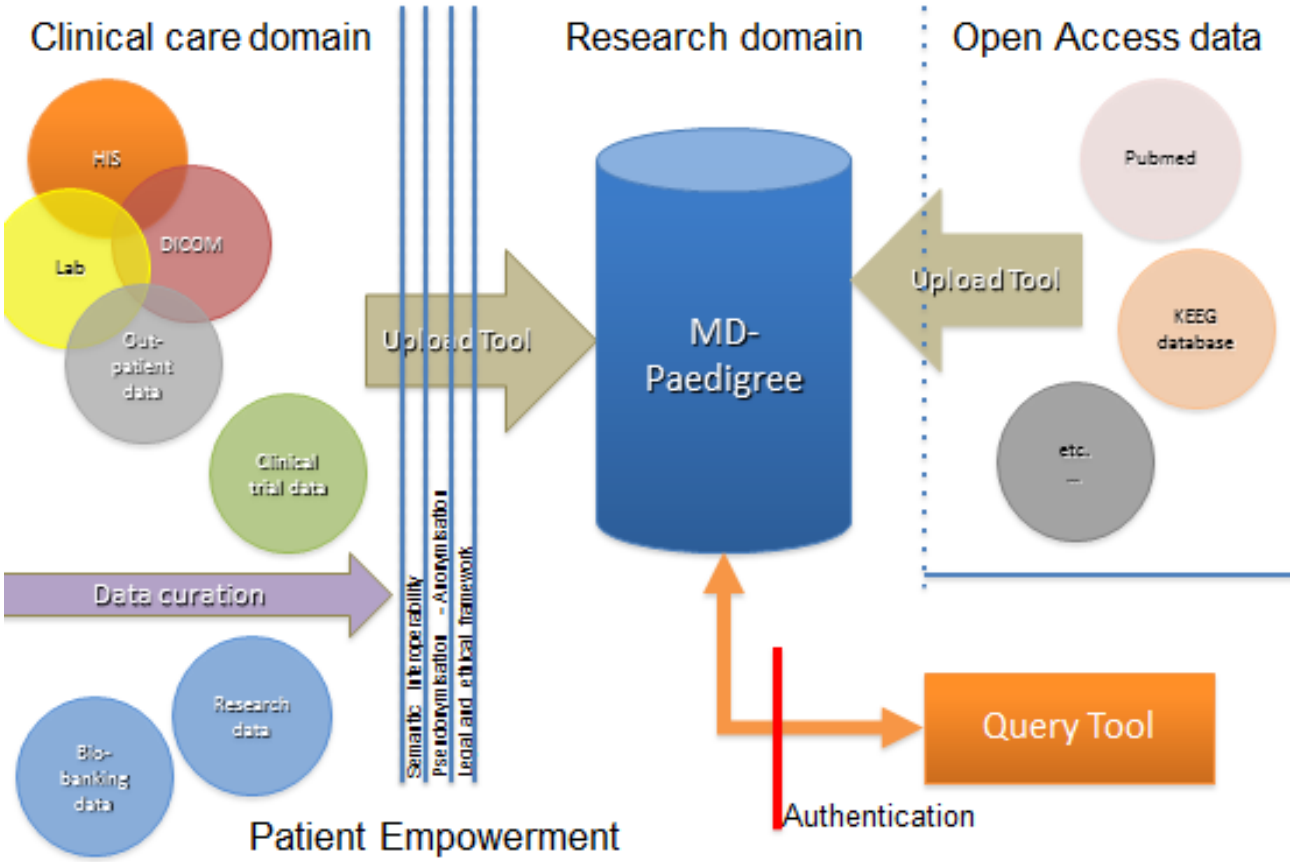
Of course, given the fact that, for MD-Paedigree, a more articulated exploitation plan has been foreseen since the very beginning of the project, CARDIOPROOF will be grafted into the MD-Paedigree Plan, providing specific additional benefits, with particular regard to validation and modelling tools.

It is worth briefly mentioning MD-Paedigree's exploitation path, as it has been presented during the Seminar.

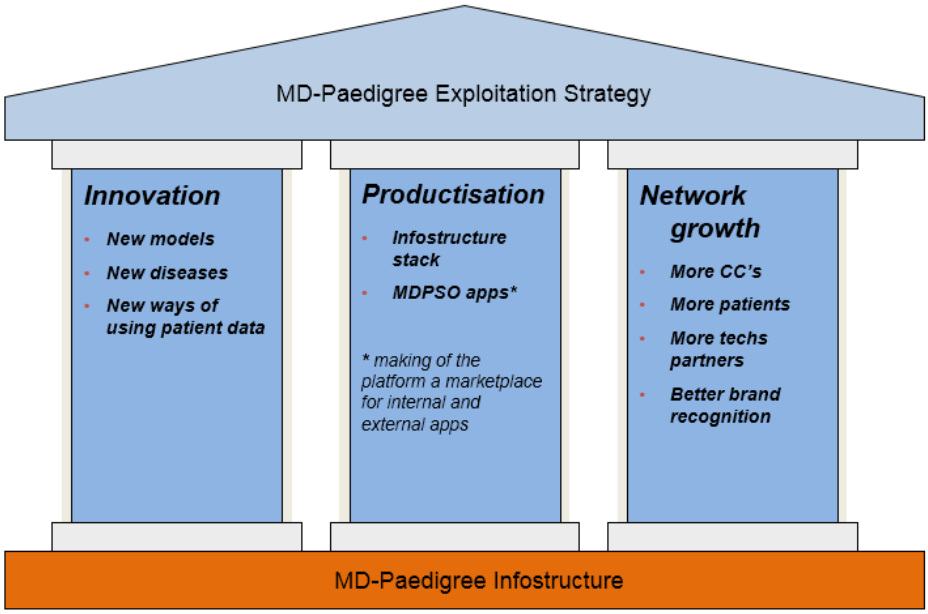
The MD-Paedigree Business plan builds upon three "bets":

- A free-access paediatric digital repository
- Similarity Search
- Patient-specific prediction and simulation

The figure below shows the MD-Paedigree general concept:



In order to concretely pursue the commercialization of these innovations, MD-Paedigree builds upon three strategic pillars:



During the discussion, it has been agreed that CARDIOPROOF could contribute to this plan, playing a key role in particular in the first pillar, by:

- Providing a proof-of-concept validation methodology for the assessment of effects of the introduction of models in a normal clinical workflow
- Re-using the heart model developed in MD-P to compare and cross-validate the results of the two projects
- Providing initial concrete applications of virtual stenting software, possibly to be further refined with models and data coming from MD-Paedigree and further research projects

In order to better explore this joint exploitation opportunity, the two projects will organise an exhibition and on-line demo at the ICT2015 conference, scheduled on October 20-22 in Lisbon (Portugal).

The path towards a First Exploitation plan

As already recalled in the Introduction, the First Exploitation Plan is due for M20.

In order to be able to complete this first fundamental step toward the formalization of a clear exploitation path both for individual partners and for the entire consortium, a number of steps have been deemed necessary:

- Articulate more in depth the three innovations already identified;
- Evaluate other results that the partners could individually exploit;
- Provide for these products details on the possible exploitation plans (brief business plan, field of application, time-to-market analysis, patents submission forecast);
- Define the common exploitation strategy and outline the subsequent business plan.

To this end, each partner will be requested to fill-in a specific template, which will include the following sections:

- The service: clear explanation of the tool implemented and of its feature
- The potential clients: what need is addressed? who can be interested in the product?
- Analysis of the existing competitors (if any) or of the current alternative products, services or workflows.
- Business model: explain if the product can be sold as single tool, and how (single purchase, subscription, etc.), or if needs to be combined with other tools or services. Specify if the product will be patented.

In the meantime, P1 LYNKEUS will define the joint exploitation strategy and will perform a preliminary analysis of the market, of the competitors, etc (along the lines defined in the sections above), also explorigin more in-depth the joint exploitation initiatives which can be undertaken with MD-Paedigre and other VPH projects.