Project Title: *In silico* trials for drug tracing the effects of sarcomeric protein mutations leading to familial cardiomyopathy

Project acronym: SILICOFCM

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Disclaimer

Executive summary

This report presents the deliverable *D9.6. Road map on Business Model* for both joint exploitation by the consortium as well as individual exploitation and proposes a business plan depending upon the key exploitable results of the project as identified and envisaged in M11 of the project. This report is prepared, taking into consideration, many of the key elements of the exploitation, such as (a) the SILICOFCM software tools, (b) the cloud computational platform (c) the experimental database, and (d) the elements of the market research needed for the planning and the structuring, which are ongoing at this stage of the project. However, the planning at the initial stage of the project will cover and possibly enhance the research work towards the exploitable results and strategically and efficiently structured exploitation.

This deliverable will serve as a road map to business model, but the prospective business model will be developed further in the coming months and updated deliverable will be published in M24, M36 and M42 together with the consortium members to trigger the economically viable commercialization of the project outcome and its potential competitiveness in the market.

As of M11, the main elements of the Road map on Business Model are Chapter 1 highlighting the scope and objectives of the SILICOFCM project and task description as described in GA. Chapter 2 explains the Key Exploitable Results of the project. Chapter 3 gives the market analysis including the broad list of various stakeholders involved in the sector and specific list of end users. This chapter also describes the classical market analysis result and methodologies for product and network analysis which will be updated in M24 deliverable. Chapters 4 and 5 describe SWOT analysis and IPR. Chapter 6 explains in detail FCM Services which is presented as a case study. This chapter also details on the ownership, start-up summary, key partners, customer relationships, resources and potential offerings.

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List of Abbreviations

Abbreviation	Explanation
ARVC	Arrhythmogenic right ventricular cardiomyopathy
BSC	Barcelona Supercomputing Center
CEG	Core Exploitation Group
DCM	Dilated cardiomyopathy
EC	European Commission
FCM	Familial cardiomyopathies
HCM	Hypertrophic cardiomyopathy
IPR	Intellectual property rights
ISO	International Organization for Standardization
KER	Key exploitable results
MRI	Magnetic resonance imaging
RCM	Restrictive cardiomyopathy
R&D	Research and development
R&I	Research and innovation
SME	Small and medium enterprise
TRL	Technology readiness level
WP	Work package

1 Introduction

1.1 Scope of the Project

Cardiac diseases remain the leading cause of morbidity and mortality in the developed world despite the efforts made by anatomists, physiologists, mathematicians, physicists, biologists, biochemists and geneticists who have studied the cardiovascular system. Conventional treatment practices that rely on trial and error methods do not provide optimal health care, so multi-scale computational modelling can provide a powerful tool to perform the integration of data, both structural and functional, at molecular, cellular, tissue, and organ level into a consistent framework necessary for prediction of outcomes of therapeutic interventions.

According to the 2014 European Society of Cardiology Guidelines, cardiomyopathies are defined as structural and functional abnormalities of the ventricular myocardium that are unexplained by flow-limiting coronary artery disease or abnormal loading conditions. There are four major classifications of cardiomyopathy: hypertrophic (HCM), dilated (DCM), restrictive (RCM), and arrhythmogenic right ventricular (ARVC).

Familial cardiomyopathies (FCM) are most commonly diagnosed, or progress of the disease is monitored, through in vivo imaging, with either echocardiography or, increasingly, cardiac magnetic resonance imaging (MRI). Treating the symptoms of FCM with established therapies could only partially improve a patient's outcomes; therefore, novel therapies need to be developed to affect the disease process and time course more fundamentally.

The SILICOFCM project will develop an *In silico* computational cloud platform which will integrate from stopped-flow molecular kinetic assays to magnetic resonance imaging of the whole heart, bioinformatics and data analytics tools with state of the art computer models with the aim to reduce animal and clinical studies for a new drug development and optimized clinical therapy of FCM.

The developed system will be distributed on the cloud platforms in order to achieve efficient data storage and high performance computing that can offer end users results in reasonably short time. Technical partners IIT, UOI, UL and BSC will be responsible for the development and integration of the *In silico* cloud computational platform with multi-scale cardiac muscle modelling which include experiments on protein mutation in vitro from UNIKENT, UNIFI and UW. The Company, SBG, will integrate Bioinformatics tools. Clinical partners UNEW, ICVDV, and UHREG will do retrospective and prospective studies. BIOIRC and R-Tec as SMEs, h will be in charge of regulatory issues and preparing the reports to FDA and EMA., SILICOFCM - Objectives

1. Defining processes and set standards for the *In silico* trials and their integration in the drug development chain (WP1)
2. Identifying and relating specific gene or genes to protein structural, kinetics and functional changes for specific drugs interaction (WP2)
3. Performing experimental determination of material characteristics of heart muscles, from for example LV wall, along with biomechanical parameters, gene expression, protein kinetics and the whole organ functional images/movies (WP2)
4. Performing clinical studies for determination of risk factors associated with drugs interaction for DCM, HCM, RCM and ARVC on a clinically relevant number (200-300) of patients from 4 clinical partners (WP3)

5. Developing software tools for collection and analysis of patient-specific data and development of patient-specific models for monitoring and assessment of patient condition from current through the progression of disease (WP4)
6. Providing a library of virtual patients for re-use in pre- and post-competitive testing of drugs using data mining approach (WP6)
7. Delivering a software platform for *In silico* efficacy and safety tests and integrate the platform in the drug development chain to support design and regulatory approval processes (WP8)
8. Evaluating the *In silico* trial platform in representative scenarios to demonstrate the capabilities of this approach and propose measures of validation for *In silico* trials (WP5, W6, WP7)

In addition to these project objectives, which would underpin the success of SILICOFCM, these following points will be equally important in paving road to success of the project:

9. Acceptance of the in-silico efficacy cloud platform methodology and the to-be-developed tools by regulatory bodies such as FDA or EMA, at least at a level of a recommended practice.
10. Enriching the knowledge base with real, practical case studies from a variety of users and researchers and industries.
11. Developing the best practices for the delivery of and then delivering highly satisfactory assessments and analyses.
12. Developing strong relationships with potential clients.

1.2 Description of the Task according to GA

The SILICOFCM project has a strong aim to bring the computational platform with *In silico* trials for hypertrophic cardiomyopathy. At the end of the project, SILICOFCM will develop in silico computational cloud platform for FCM. SILICOFCM project is funded under Horizon 2020 research & innovation actions classified as a TRL 6 (Technology readiness level 6 - technology demonstrated in relevant environment) at the end of the project. However, considering the expected project outcome and its readiness and competitiveness in reaching the market it is highly relevant to make a business plan to exploit the project outcome. The Deliverable D9.6 – Road map on Business Model, reports on the work performed in WP9 - Exploitation and Dissemination, which accounts for the projects' exploitable results, IPR and regulatory aspects, conditions for the commercialisation such as market analysis, SWOT analysis, proposals for exploitation, funding estimates and other financial projections. The deliverable will be updated yearly by R-Tech (M24, M36, M42) taking into account the progress of the project and the subsequent changes in the market. The document will be a public deliverable.

2 Exploitable results

The key factor in producing a Road map on Business Model is to identify the exploitable results which are expected to be developed during the project lifetime.

2.1 Overview of Project Key Exploitable Results (KER)

This section presents the overview of the expected Key Exploitable Results of the project and the partners who will be responsible or can claim the interest in exploiting them.

Table 1. Exploitable results and individual exploitation.

Key Exploitable result	Use/Potential	Key Partners	Exploitation form	KER No.
3D image segmentation tool	Software for fully automatic image segmentation and 3D reconstruction from MRI images and ventricles measurements according to the recommendations of the European Society of Cardiology from Echocardiography assessment. User can define mesh density, boundary condition and very fine mesh generation for both fluid and solid domain.	BioIRC, UOI, UNEW, ICVDV, UHREG, UNIFI	***Software tool***	KER 1
Bioinformatics tool	With the obtained genetic data, bioinformatics tool will be developed to construct reference graph genome for cardiomyopathy.	SBG, BioIRC, IIT, UOI, UL, ICVDV, SU, UNEW, UHREG, UW	***Software tool***	KER 2
MUSICO tool	MUSICO PLATFORM for multiscale modeling of protein structure, protein-protein interaction and cross-bridge kinetics.	UNIKENT, UNEW, UNIFI, ICVDV, SU, UHREG, UW	***Software tool***	KER 3
Finite Element tool	Fluid-structure interaction, electro-mechanical coupling. These computer model simulations are designed to predict the personalized physiology, functional disorders and other diseases.	IIT, BioIRC, UNIKENT, UOI, BSC, SBG	***Software tool***	KER 4
Data analytics tool	Software for prediction of cardiomyopathy disease and reliable identification of disease patterns from large volumes of heterogeneous and noisy data. Visualized medical knowledge that explains interdependencies between patterns	UL, R-Tech, UOI, BioIRC, UNEW, ICVDV, UHREG, UNIFI	***Software tool***	KER 5

	in data, disease progression and risk stratification of FCM patients.			
Virtual patient population	Development of virtual FCM patients models repository to perform pattern identification from heterogeneous data by using data mining algorithms. The method visualizes the explained knowledge and thus explain interdependences between patients' features, medical examination results, diseases, their causes and therapy outcomes. Finite element meshes of heart, biological, genetic, pharmacological data.	UL, BioIRC, UOI, BSC, R-Tech	***Database***	KER 6
Physiological and clinical experiments **Virtual experiments**	The experimental work connects kinetic data associated with myosin ATP-ase and thin filament regulation by calcium. They also evaluate response to a novel break-through pharmacological treatment for heart failure. Virtual experiments are simulations from MUSICO used to mimic real experiments	UNIKENT, UNEW, UNIFI, ICVDV, SU, UHREG, UW	***Database***	KER 7

2.2 Analysis of Key Exploitable Results and other exploitable forms

In addition to the above exploitable results, efforts will be made to identify any new result generated during the project and will be reported in the update of the D9.6 (M24, M36, M42).

Apart from the above exploitation forms (Software tools and databases), other possible forms for exploitation of the KERs could be:

- ***Trainings for the software tools developed in the project***
- ***Online training courses*** for project related topics (different tools, multiscale platform etc.) using open source platforms by developing relevant content to develop the courses.

The KERs listed in Table 1 and other exploitation forms listed above will be analysed in the upcoming months by circulating a survey to the partners. They will be elaborated in the updated D9.6 to be submitted in M24. The survey will be developed based on following sections and contents:

- ***Software Tools*** – For each tool developed during the project answer the following questions:
  1. Which of the following tools will be developed with your contribution?
  2. How do you foresee the use of software tool?
     a. Standalone software
     b. Supporting software for instruments
     c. Other options…
- ***Training***
  1. Are you interested in providing training for the software tools?
  2. Are you interested in providing the training courses?
  3. Will you be ready in developing the content for the online courses?

Based on the response of the survey, a ***Core Exploitation Group (CEG)*** will be formed within the project consortium.

3 Market analysis summary

Market analysis has to be done based on the interaction chain between various end users and other stakeholders. Depending upon their role, competencies and other costs/benefits, a Road map to business model has to be developed to demonstrate to the market the full potential and viability of the project outcome. To achieve this, it is important to identify various stakeholders involved in the medical sector, who are they and to map the end users.

3.1 Identifying stakeholders and end users

The stakeholder groups can be generally classified into following based on their roles:

- ***Providers*** (Involved in product development and assessment such as clinical research organisations, hospitals, consultants, data banks, hardware & software, other service providers)
- ***Producers*** (companies from medical, health and biotech sector, , third sector producers driven by non-profit organisations)
- ***Payers*** (insurance companies, health providers, assessment agencies that advise the payers on the cost-benefit ratio)
- ***Regulators*** (Food and Drug Administration (FDA) in the USA, the European Medicines Agency (EMA) in Europe, National agencies, International Organization for Standardization (ISO), and research ethical committees that monitor clinical trials)
- ***Consumers*** (patients and charities organisations)

In the above classification, SILICOFCM audience is divided into few segments; the first being the personnel or entities who would be directly using or utilizing the software tools, methodologies, cloud platform etc. and secondly, the indirect users such as other researchers or institutes which will build on the SILICOFCM approaches and methodology.

However, the **end user** refers to the stakeholders who will use the proposed SILICOFCM software tools, cloud platform and other exploitable project results listed in Table 1.
Some of the most relevant end users of SILICOFCM can be listed below:

- Pharmaceutical companies (Bayer, Sanofi, BMS, J&J etc. who are among the top companies who dominates the cardiovascular market) ;
- Researchers;
- Medical doctors;

and an extended of list of end-users could cover:

- Hospitals
- Clinical research organisations
- Universities (Maastricht University, Newcastle University etc.)
- Biotech companies,
- Bioinformatics companies
- Companies producing medical equipment for cardiovascular diseases (Endonovo Therapeutics, Inc. (OTCQB: ENDV), 22nd Century Group, Inc. (XXII), Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP), Emerald Health Therapeutics, Inc. (CVE: EMH) (OTCQX: EMHTF), and Lexington Biosciences, Inc)

- Occupational safety insures - International Social Security Association (ISSA – www. safety-work.org) is an international association with members from occupational safety insurers around the globe German Social Accident Insurance (DGUV), British Safety Council, Austria: Austrian Workers Compensation Board (AUVA), The Federal Coordination Commission for Occupational Safety (FCOS), switzerland, Korea Occupational Safety and Health Agency (KOSHA) and many more.)

The main objective of task 9.2 is to create connection to the industry and other external representation. This will promote interaction and collaboration with different stakeholder groups and will allow consortium members to be acquainted with up-to-date knowledge, to benchmark best-practice solutions, especially with the end user requirements. Also, the interaction with various stakeholders and most importantly with the end users can bring other added value to the project such as:

- Provide feedback on SILICOFCM activities and results
- Help identify priorities and tailor project activities to the needs of the end-users
- Help implement and develop services that will bring the project benefits to the end-users
- Enhance projects' visibility through promotion using the contact network
- Maximize the impact and cost-effectiveness of project activities

With these interactions, at a later stage of the project, the exploitable results can easily be reached to the targeted end users.

3.2 Market analysis and key players/competition

SILICOFCM aims to reduce animal and clinical studies and aims to provide cost and time-effective optimized therapy for FCM. The major outcome from the project will be software tools and these tools can be used in the pharmaceutical industry in the design phase, pre-clinical assessment or in post-market analysis. The use of *In silico* trials during the entire product development and assessment is not seen. SILICOFCM project also develops huge amount of physiological experiment database. Once introduced in market, it is expected to remain unique in the field where the could remain as sole developer of the computational cloud platform for FCM. By doing this, SILICOFCM can be the market leader and the primary developer of the product leveraging its position as the early adopter with a high market segment than its possible competitors. It is still very difficult to predict who will be the key players/competition during the introduction of the product to market. Once the methodology and tools are accepted by the authorities and auditing becomes more common as a product, competition from minor consultancies/independent contractors is expected to develop, mainly in niche and high risk industries.

The below table (Table 2) mapped the estimated market size, market maturity, market by application, key players and expected release for commercialization for the KERS identified in Table 1.

Table 2. The estimated market size, market maturity, market by application, key players and expected release for commercialization.

Key exploitable result	Target market size	Market maturity	Market by application	Market competitor		Expected release for commercialization
				Companies	Key Features	
3D image segmentation tool	Expected to reach USD $21,341 million by 2022[1] and USD $41,260.8 million in 2025[2]	Competitive	✓ Government and defense ✓ Aerospace ✓ Manufacturing ✓ Architecture ✓ Health care	✓ Dassault Systems-SIMULIA[3]	✓ Uses bidirectional electro-mechanical models that can solve excitation-contraction-coupling problem of the heart ✓ Simulation of effect of genes mutation on the heart behavior	2022
				✓ Medviso Segment (Sweden)[4]	✓ MR Scar analysis ✓ MR Flow analysis ✓ MR LV and RV analysis	2022
Bioinformatics tool	Expected to reach $18,233 million by 2025[5]	Competitive	✓ Medical ✓ Academics ✓ Agriculture	✓ GenScript[6]	Bioinformatics tools focused in Molecular Biology, Peptide and Protein	2022

[1] https://www.alliedmarketresearch.com/3D-imaging-market
[2] https://www.globenewswire.com/news-release/2018/09/24/1574970/0/en/3D-Imaging-Market-is-expected-to-reach-USD-41-260-8-million-in-2025-CAGR-24-54.html
[3] https://www.3ds.com/
[4] http://medviso.com/segment/
[5] https://www.alliedmarketresearch.com/bioinformatics-market
[6] https://www.genscript.com/tools.html

MUscle SImulation COde (MUSICO) tool	Development		✓ Medical ✓ Academics	✓ Mijailovich Lab[7]	Development of computational models and quantitative analytical tools for muscle research	2022
Finite Element tool	Expected to reach $ 8.35 billion by 2022[8]	Competitive	✓ Aerospace ✓ Automotive ✓ Electronics	Materialise[9]	✓ Predict the fit of a new device ✓ Efficiently create a high-quality patient-specific FEA mesh from medical image data.	2022
Data analytics tool	Expected to reach $17.1 billion by 2021	Competitive	✓ Aerospace ✓ Hospital ✓ Electronics	Emis Health[10]	✓ Proactively identify patients at risk of unplanned hospital admission. ✓ Clinically validated and peer-reviewed algorithm, developed for use in England.	2022
Virtual patient population	Development		✓ Hospitals ✓ Pharmaceutical companies	3D4Medical[11]	✓ Carry out ✓ measurements according to the recommendations of the European Society of Cardiology	2022

[7] https://www.mijailovichlab.org/musico
[8] https://www.techsciresearch.com/report/global-simulation-analysis-software-market-by-product-type-finite-element-analysis-computational-fluid-dynamics-etc-by-end-use-industry-automotive-aerospace-defense-etc-by-region-competition-forecast-and-opportunities/970.html
[9] https://www.materialise.com/en/medical/mimics-innovation-suite/finite-element-meshing
[10] https://www.emishealth.com/
[11] https://3d4medical.com/apps/complete-heart

				✓ Can define mesh density, boundary condition for both fluid and solid domain	
Experiments, virtual experiments	Partial competition	✓ Hospitals ✓ Pharmaceutical companies	IQVIA[12]	✓ Optimisation of clinical trials ✓ Speedy and efficient access to the market ✓ Maximisation of data	2022

The above table will be updated throughout the project and will be presented in this deliverable, D9.6 released in M24, M36 and M42. The interaction and collaboration with different stakeholder groups will be promoted. These efforts will in turn help the development of the project in the right direction with great accuracy and help shape the products, which can reach the market in less time with low cost.

It is worth mentioning that at the end of the project, under WP8, a report will be developed for all the *In silico* drug testing and different anatomical geometry and boundary conditions which will be sent for EMA/FDA approval. A new drug Entresto (sacubitril/valsartan) will be given to the *In silico* patients with familial cardiomyopathies and the outcome of *In silico* study will be transformed in the standard report for EMA/FDA approval. This is highly relevant and will help in convincing the end users to adopt offered technology.

[12] https://www.iqvia.com/our-customers/medical-technology/clinical/cardio

3.3 Product oriented market analysis

For the next update of the deliverable, a product oriented market analysis will be done using the Market-Radar developed by R-Tech. This is a technique/tool used to collate the information (usually web-based) relevant for a given topic-e.g. Market analysis of SILICOFCM software tools The obtained data will be analysed in order to locate and keep the useful data and to use it further for analytics. Different analytics are performed on collected data in order to visualize the huge amount of data and to draw the useful conclusions from it.

3.4 Network oriented market analysis

Product network is very important in identifying the key players and collaborative network among them. A semantic analysis will be also done to identify the product network using web semantic tools.

An example of such analysis is done using research data obtained from web of science. Figure 1 below shows the collaborative network of organisations who published research articles on 'risk stratification tool'. The network map is created using the co-authors and organizations they are working at. This provides access to the most reliable, integrated, multidisciplinary research connected through linked co-authors and organisations from multiple sources within a single interface. The data for this study is retrieved in May, 2019 from the Web of Science using the keyword 'risk stratification tool'. 449 publications were retrieved for this search for the period of 1991-2019. For statistical analysis and visualization of the results VOSviewer is used. VOSviewer is a software tool for constructing and visualizing bibliometric networks. The coloured nodes shows different collaborative networks. In figure 1, it can be seen that University of Washington has a great collaborative network with University of Cambridge, Harvard Medical University, University of Toronto, McMaster University and many more. Similar analysis can be done for various products identified in SILICOFCM project to understand their collaborative network.

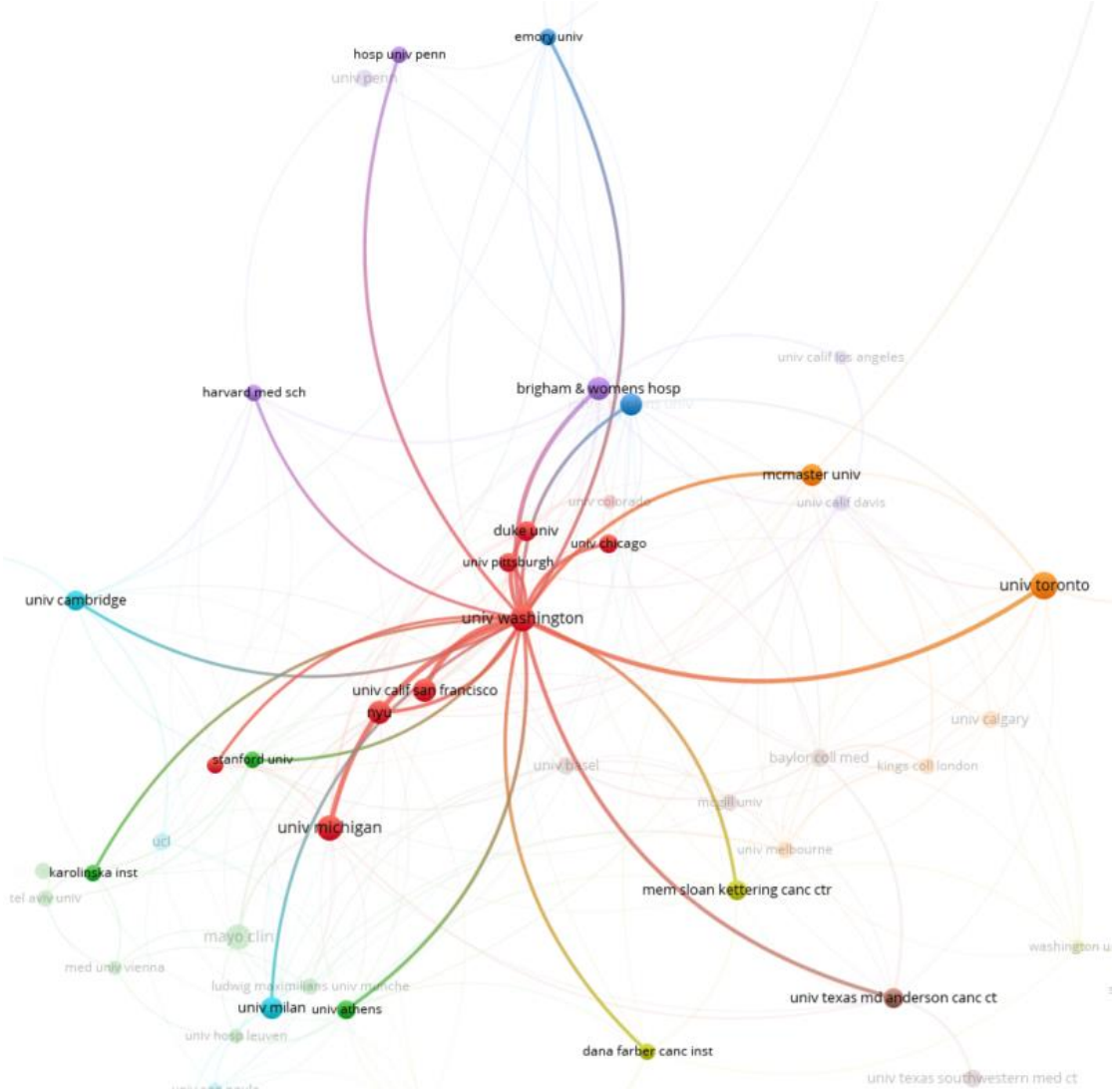

Figure 1. Bibliographic couplings of institutions publishing articles on risk stratification tool.

4 SWOT analysis for the SILICOFCM offering

Strengths	• SILICOFCM will have high impact in ***reduce animal and clinical studies***.
	• SILICOFCM conceptually addresses the ***minimization of the gaps in current Information and Communication Technologies*** solutions by
	  ○ ***Overcoming the data-model gap*** by gathering additional necessary data
	  ○ ***Overcoming the technological gap*** by the engagement of the cloud computing infrastructure that will bring better availability, scalability and a better defined Service Level Agreement (SLA).
	  ○ ***Overcoming the knowledge gap*** by continuous rebuilding of multiscale models to accommodate new findings and data collected by new experimental techniques.
	• SILICOFCM has the potential to ***develop into a computational cloud platform in all areas of health care***.
	• It will bring significant ***cost savings*** due to its inherent elasticity in computing and storage resource usage.
	• SILICOFCM will enable ***risk assessment*** with regards to the propagation of FCM genes to the offspring as well as ***individualized prediction of FCM phenotype***.
	• To help adopt computer simulated trials, measures for ***validation*** (human trials, animal studies, validation in cell cultures) ***of the In silico trials*** results is being carried out.
	• ***Report to FDA/EMA for In silico clinical trials*** for drugs and therapy optimization.
	•

Project Weaknesses	• Innovation risks (limited test/validation) • Limited Accessibility to a wide market • Conventional tool/methods need adaption
Opportunities	• Lack of competition in the sector • Increasing concern and expenditure on healthcare • Public sentiment: generally positive
External Threats and barriers to exploitation	• Consulting is necessary to enhance wider adoption. • Competitive solutions may come up • Potential competitiors might have not been included as part of the project, and therefore there may be a need to develop indicators for these sectors to increase marketability • TRL need to be further increased

5 Overview of Intellectual Property Rights (IPR) Registry (to be updated according to KERs)

An active mangement of intellectual property (IP) is necessary for consortium's IP (Background and Foreground) as well as for the exploitation of SILICOFCM as a final platform and/or service. This will minimise the risk of related to patenting, trademark or any additional IPR infringement.

The following IPR will identified for the KERs:

- **Information**
  - **Background (B)**: information brought to the project from existing knowledge, owned or controlled by partners in the same or related fields of the work carried out in the project
  - **Foreground (F)**: information, including all kind of exploitable result, generated in the action by the project partners, whether or not they can be protected.
- **Exploitation**
  - **Licensing (L)**: selling of the software license (integrated platform or stand-alone modules)
  - **Making (M)**: Making the products, manufacturing and selling or directly implementing it through own facilities and skills
  - **Use (U)**: internal use of the result (e.g. University, other research project/end users)
  - **Other (O)**: other ways of exploitation as consultancy, maintenance, support services

The above identified IPR will be analysed for each KER by consortium members and will be tabulated as shown in Table 3.

Table 3. IPR registry.

Partner	KER1	KER2	KER3	KER4	KER5	KER6	KER7
BioIRC							
IIT							
UNIKENT							
UNEW							
UNIFI							
ICVDV							
SU							
UHREG							
UOI							
BSC							
UL							
R-Tech							
UW							
SBG							

5.1 Detailed presentation of IPRs

All partners will be asked to detail, each of their claim (at M24) as shown below

For example: when a partner puts U, in the table, then the next chapter should detail how this is intended. One can say that they adopt in their organization, one can say that they will use it for research, one can say they will use it to extend its functionality for research purposes, etc. When (L), the partner has to detail what KER or KERs they will license (thus, commercialise),

KER 1

IPR Owners

See table 1 linking the exploitable results and their respective owners.

Background knowledge

What background knowledge has been used in detail

Foreground knowledge

What knowledge has been created within the project

Exploitation by the IPR owners

How will the result be exploited by the IPR owners

Exploitation by other partners

How will the result be exploited by the other partners

More details and updates on IPR Handling, market analysis and exploitation planning will be also presented to the consortium by BioIRC in M22 as milestone document (MS22).

6 FCM Services (Case study 1)

The core idea of SILICOFCM project is to make the cloud computational platform connect:

- basic experimental research
- clinical study
- bioinformatics, data mining and data analytics tools
- high-performance finite element simulation
- drug and patient database
- Regulatory engagement and framework

The goal of the SILICOFCM project is to develop computational platform for *In silico* clinical trials. The approach will use very advanced computer models of FCM with a benefit of potentially reducing expensive and time-consuming animal and clinical studies.

At the end of the project, SILICOFCM platform will be, classified as a TRL 6 (technology demonstrated in relevant environment). Considering the output (software tools, databases, computational cloud platform etc. as described in Table 1) and its competitiveness in reaching the market, one among the several options for the exploitation of the results from SILICOFCM project will be to form a consultancy service named ***FCM Services*** consisting of SILICOFCM partners. This presented as Case Study 1 in the following section. The partners involved will be those who belong to the ***Core Exploitation Group (CEG)***, which will be formed based on the activities described in section 2.2.

The FCM Service could be an independent company formed by the ***Core Exploitation Group (CEG)*** of the project or can be established under one of the already existing consortium member partner institution/company/organization.

The interest of CEG members in taking part the company will be further discussed and confirmed in the coming months and will be identified based on the following:

- Whether the consortium member plan to exploit the results externally
- Whether they are interested in investing
- Is it possible to have a long-term commitment for this
- Are they interested in selling any other products developed in their organization using an external platform

The result of this discussion will be updated in D9.6 in M36.

6.1 Proposed Objectives of the consultancy “FCM Services”

While this deliverable focuses on proposing the road for the business model which will be implemented for SILICOFCM, this report proposes a prospective legal entity (consultancy) consisting of CEG within the project.

Some of the major objectives of FCM Services will be following:

- To train users on how to use the SILICOFCM computational cloud platform
- To sell the software tools developed to end users:
  - Pharmaceutical companies (Bayer, Sanofi, BMS, J&J etc. who are among the top companies who dominates the cardiovascular market.),
  - Hospitals and clinical research centers as mentioned in the European Society of Cardiology which are in Europe,

  - Companies producing medical equipment for cardiovascular diseases (Endonovo Therapeutics, Inc. (OTCQB: ENDV), 22nd Century Group, Inc. (XXII), Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP), Emerald Health Therapeutics, Inc. (CVE: EMH) (OTCQX: EMHTF), and Lexington Biosciences, Inc)
  - Universities (Maastricht University, Newcastle University etc.
- Provide training for the software tools
- Provide online training courses

In order to materialize this opportunity, the main objectives of FCM Services will include:

- To generate demand and highlight the novelty of the anticipated computational platform with *In silico* trials for hypertrophic cardiomyopathy to the end users. This will be achieved by disseminating the SILICOFCM exploitation results and the promoting them to the end users. A major effort for this activity will be already done during the project period though dissemination and communication activities.
- To improve the base platform and tools offered (as consultants) by expanding the knowledge base through partner and sponsored case studies. The impact can be measured by the [number of completed cases or assessments].

6.2 The company

The Road map on Business Model would revolve around the cloud based computational platform and the various software tools and databases as identified as the KERs which the consortium members will develop for exploitation that can be accessed by the end users. FCM Services will utilise the developing interest in using multi-scale computational modelling in heart mechanics to create a multi-scale framework to understand the heart physiology, from genes to the whole cardiovascular function which will be of high demand for the end users working on cardiovascular diseases (Pharmaceutical companies, hospitals and research organisations, universities etc. as mentioned in section 6.1).

FCM Services will provide the following:

- Leverage the tested and validated tools and services developed by SILICOFCM partners,
- Offer expert consulting service to enable prospective end users learn methodologies, best practices, tips, and techniques from experienced SILICOFCM CEG. As the platform will use very advanced computer models of FCM with a benefit of potentially reducing expensive and time-consuming animal and clinical studies the service provided will be of high value.

As the service grows, FCM Services could partner with more industry specific specialists to provide more accurate and efficient results.

6.2.1 Ownership

The FCM Service could be an independent privately held company owned by the ***Core Exploitation Group (CEG)*** of the project or can be established under one of the already existing consortium member. This will be decided at a later stage of the project (M36) through a voting process.

6.2.2 Start-up summary

The start-up expenses of FCM Services could range from 1€ to 25000€ will depend upon the following:

- Where? – which country
- What? - which type of company; GmbH, Ltd., EEIC
- How? – whether established as an independent company or under one of the already existing consortium member

Initial funding, outside of initial investment, can also be sought from initiatives such as BIC (Business Incubation Center) call for Germany, which can be supported by the German partner R-Tech

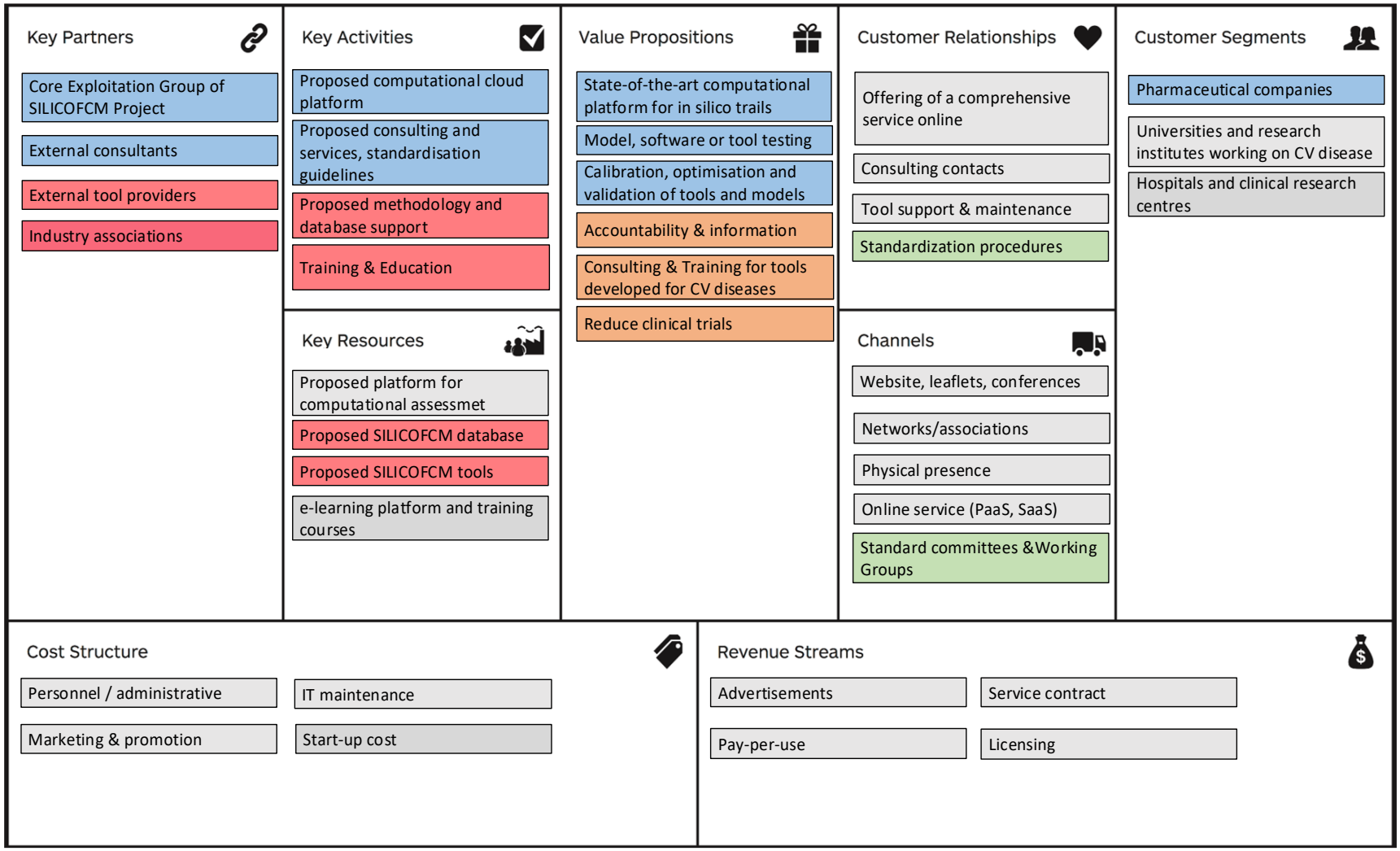

Figure 2. A business model canvas proposed for the FCM Services as a basis. Different colours are used to indicate the relationships between the elements at different sections of the Business Model Canvas. Where no colour is used (grey), the element applies to all elements of the other sections.

The following is a review of the major elements from the canvas from Figure 2:

6.2.3 Key partners

In order to optimize operations and reduce business risks, external organizations may cultivate the customer-supplier relationships so that FCM Services can focus on the core activities of the FCM services that will assist us to reach the objectives of FCM services.

- **External consultants:** External consultant may perform key activities to deliver the value of the SILICOFCM Services, implementing the to-be-developed methodologies and tools to perform Insilco trials.
- **External tool providers:** Different organizations may provide new tools complementing the SILICOFCM catalogue of tools and services.
- **Industry associations:** Industry associations may provide new tools and methodologies, and furthermore suggest improvements for the overall functionality of the platform and workings of the FCM Services.

6.2.4 Customer relationships

FCM Services will aim to fulfil the relationship models proposed by the SILICOFCM project:

- **Offering of a comprehensive service for Insilco trials:** The customer can use a variety of online tools and services online to-be-developed during the SILICOFCM project.
- **Consulting contacts:** Value may be delivered to the customers in a one-to-one approach, where FCM Services offers full services to address each customer's needs.
- **Tool support & maintenance:** FCM Services may provide support to the customers as to how to use the tool, resolve issues etc.
- **Standardization procedures:** To adopt the SILICOFCM approaches as a standard, a proposal submission is required and the interactions following the standardization procedures.

6.2.5 Key resources

FCM Services is proposed to enjoy direct access to the resources available and utilized during the SILICOFCM project and its past activities:

- **Proposed SILICOFCM Software Tools:** including 3D image segmentation tool, Bioinformatics tool, MUSICO tool, Finite Element tool and Data Analytics tool which will be developed during the project duration.
- **Proposed SILICOFCM database:** Virtual patient population database and physiological and clinical experiments databases which will be collected and stored during the project.
- **e-Learning platform & courses:** e-Learning platform and online courses for training in the state-of-the-art approach to be introduced during the SILICOFCM project.
- **The big data analytics**: It will allow users to do analysis of big data to derive valuable insights and results for various applications.

6.3 Website marketing strategy

FCM Services could build and maintains its home website as a landing page for the SILICOFCM platform, which can be connected to the project website itself. If this website is established before the end of the project, the project website can act as an effective preliminary channel to direct to FCM Services website through news articles and other awareness creation activities.

7 Deviation from the work plan

No deviation from the work plan.

8 Conclusions

The deliverable presents Road map on Business Model for the SILICOFCM project. . While many of the key results for exploitation, such as the SILICOFCM software tools, the cloud computational platform, are still under development, the road map proposed at the initial stage of the project is based on the assumption that the plan will cover and possibly enhance the research work towards the exploitable results. The key exploitation results are presented in Table and a plan is proposed to analyse them and suggest possible exploitation form in the coming months which will be submitted as part of the deliverable update. A detailed analysis of stakeholders and end users is identifies and presented in the document with target market size, market maturity, market by application, potential competitors and expected release of the KERs for exploitation and commercialization. The cost-effective and time-saving solutions produced in the project will be highly efficient when compared to already available solutions for Familial Cardiomyopathy (FCM).

This deliverable will serve as a living document, during the project, with possibly more exploitable results available, the consortium members will be able to refer to the current document and modify/implement changes in a way which best supports the objectives of the project and meets the requirements of the EC and end users. The ultimate aim would be to adapt the project towards commercialization as planned such that the product and services generated from the project activities are economically viable and has a potential to be competitive in the market

Proposals on FCM services is given with details on objectives, services and tools offered, ownership suggestions, start-up expenses etc. which will be decided and finalized among the consortium. The Core Exploitation Group which will be formed will serve as the partners who might be interested in direct exploitation of results.

The deliverable will be updated on M24, M36 and M42 involving all consortium members with the updated findings and analysis including the new exploitable results if any, updating the results obtained from the survey, details on Core Exploitation Group, changing trends in market and with a definite proposal for FCM services agreed by all.

9 References

References are not used in this document.

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