InSilc

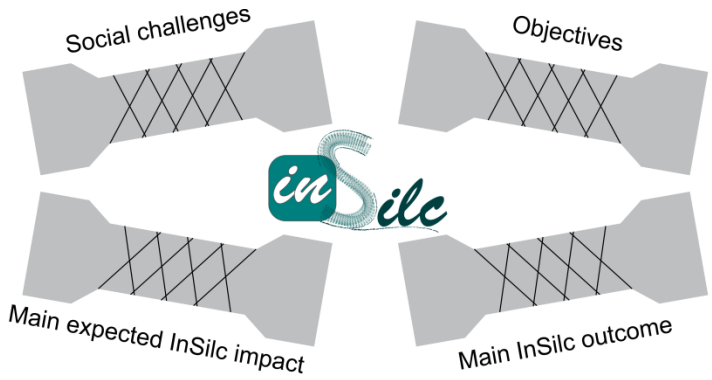
Newsletter No. 2

In Silico Trials for drug-eluting bioabsorbable vascular scaffold (BVS) development and evaluation

Aim of InSilc project

InSilc develops an *in-silico* clinical trial platform for designing, developing and assessing drug-eluting bioresorbable vascular scaffolds (BVS), by building on the comprehensive biological and biomedical knowledge and advanced modelling approaches, to simulate their implantation performance in the individual cardiovascular physiology.

InSilc platform is based on the extension of existing multidisciplinary and multiscale models for simulating the drug-eluting BVS mechanical behaviour, the deployment and degradation, the fluid dynamics in the micro- and macroscale, and the myocardial perfusion, for predicting the drug-eluting BVS and vascular wall interaction in the short- and medium/long term.



- Develop a personalised approach for drug-eluting BSV intervention
- Reduce the healthcare cost addressing the social burden incurred by complications in patients undergoing stenting intervention
- Develop network of major industry, modeling experts, technical & clinical partners in EU
- Develop novel in-silico trials solution for drug-eluting BSV design, development & assessement
- Demonstrate proof of concept of InSilc platform

- Reduce the size & duration of the human clinical trials
- Improve the prediction of human risk for new drug-eluting BSV
- Design of more effective human clinical trials
- Provide libraries of virtual patients for re-use in pre- & post-competive testing of drug-eluting BSV
- Set standards for in-silico trials
- Reduce the animal testing
- Lower drug-eluting BSV development costs
- Reduce time-to-market for new drug-eluting BSV
- Develop in Silico trials for the design, development & evaluation of drug-eluting BSV

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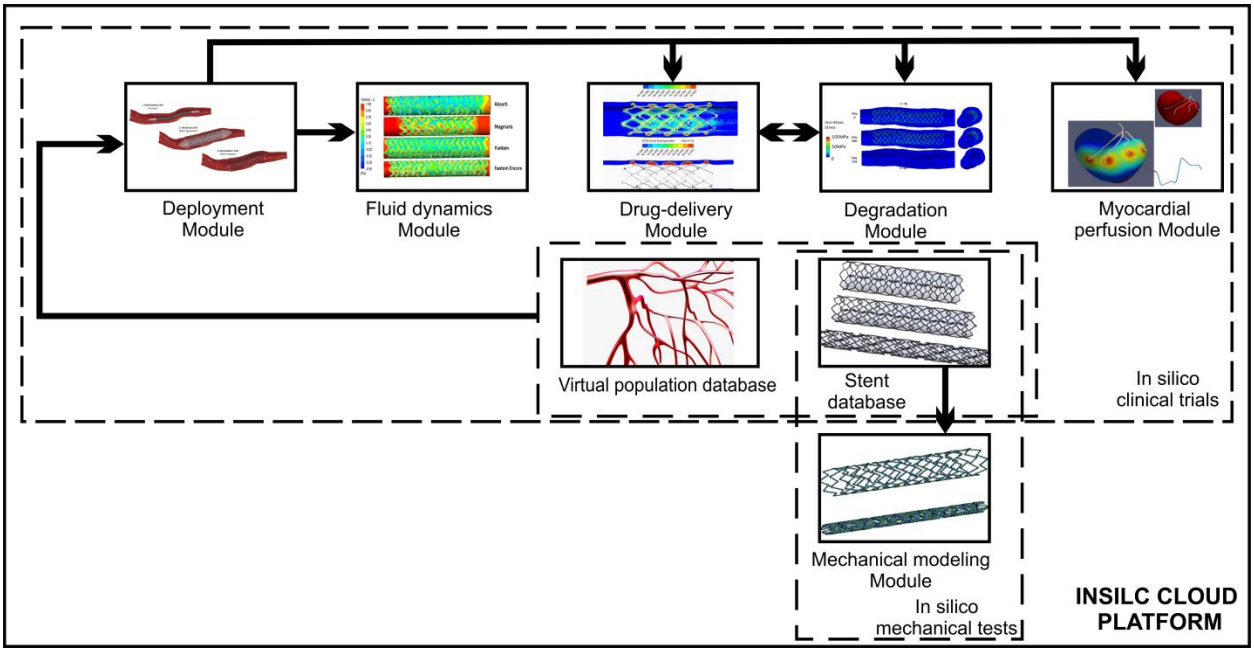
InSilc platform

InSilc cloud platform consists of six *in silico* modules and the Virtual Population database. The *in silico* modules are the:

- Mechanical Modeling Module
- Deployment Module
- Fluid dynamics Module
- Drug delivery Module
- Degradation Module
- Myocardial Perfusion Module



InSilc Cloud platform

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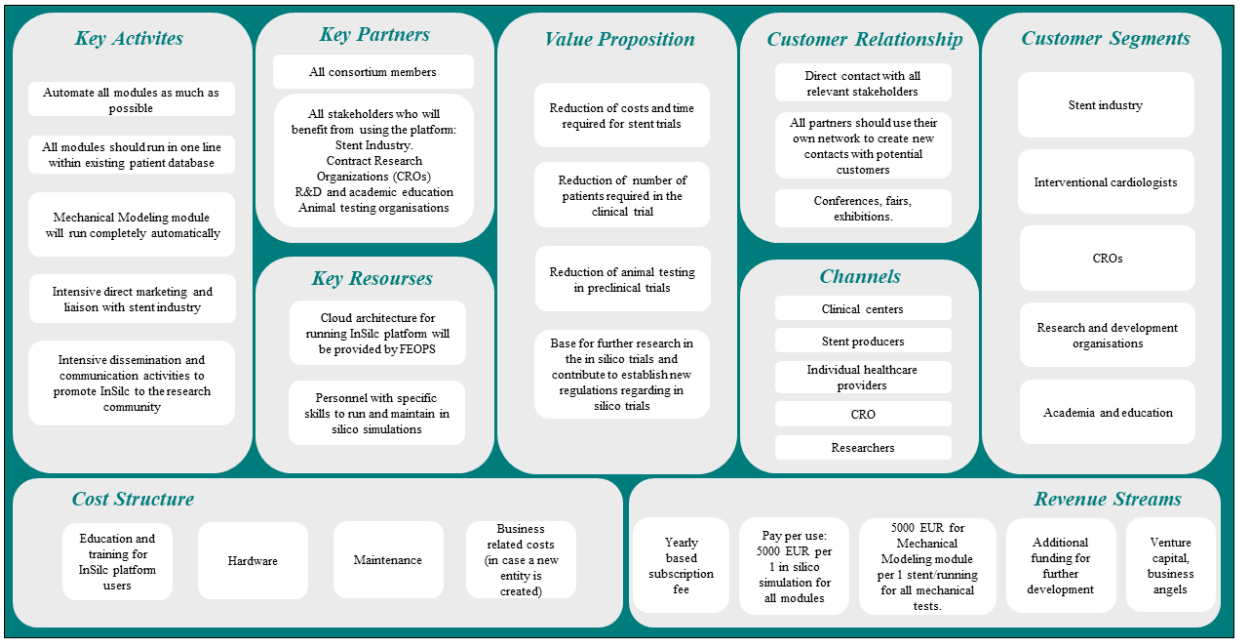
Exploitation plan

The InSilc exploitation path includes four main directions:

- Commercial exploitation (Stent biomedical industry, Hospitals/medical doctors, CROs).
- In silico clinical trials with virtual patients which will be offered as a service in the context of preliminary testing.
- Academia and Researchers (use of InSilc outputs for further research and education)
- Regulatory field

All *in silico* modules are exploited jointly as part of the InSilc platform, but also individually, as stand-alone modules. InSilc follows the Business model Canvas.



InSilc Business model

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Value proposition: The main value that is offered to potential users is a reduction of the costs and time required in all the phases of stent design, development and optimization. In addition, through InSilc the users are provided with additional valuable clinical and scientific information that cannot be provided from real clinical trials.

Key activities: The InSilc modules have been updated targeting their automation. That means that if the stent is already provided by a customer, the mesh generation should be done, only once. The Stent Deployment, Fluid Dynamics, Drug Delivery, Degradation and Myocardial Perfusion Modules will be executed in a pipeline using the available virtual arterial anatomy. The Mechanical Modeling module can be fully automatically executed on separate experiments/tests.

Key partners: All members of the consortium, but also all other stakeholders who will benefit from developing such an integrated solution and are, therefore, willing to invest in further optimization of the platform and its market breakthrough.

Customer relationship: Stent industry through significant decrease of costs of preclinical and clinical trials. Contract Research Organizations (CRO) will be able to drastically reduce costs of stent trials. R&D institutions and academia will have the base for future research in the area of stent deployment, fluid mechanics, nonlinear contact problem, fluid-structure interaction and large scale virtual population for testing and validation open source scientific modeling tools. Animal testing organizations can partially replace in vivo testing with in silico testing.

Key resources: Cloud architecture where the InSilc platform will run will be provided by FEOPS. If necessary, some of the commercial cloud platforms, such as Amazon and Microsoft will be considered.

Cost structure: Costs required for establishing a new entity, costs for platform maintenance and use, costs for education and training for using the InSilc platform (should be performed within the offered price), helpdesk costs, etc.

Revenue stream: Pay per use: 5150 EUR per 1 stent/running per 1 patient for all modules (Deployment, Fluid dynamics, Drug delivery, Myocardial perfusion, Virtual database), 5000 EUR for Mechanical Modeling module per 1 stent/running for all mechanical tests. Yearly based fee subscription should be considered (eg. 50.000 EUR/year with the assumption that at least 10 different stents will be used per year).

Channels: Stent industry, Clinical centres, Individual healthcare providers, CROs, Researchers, etc.

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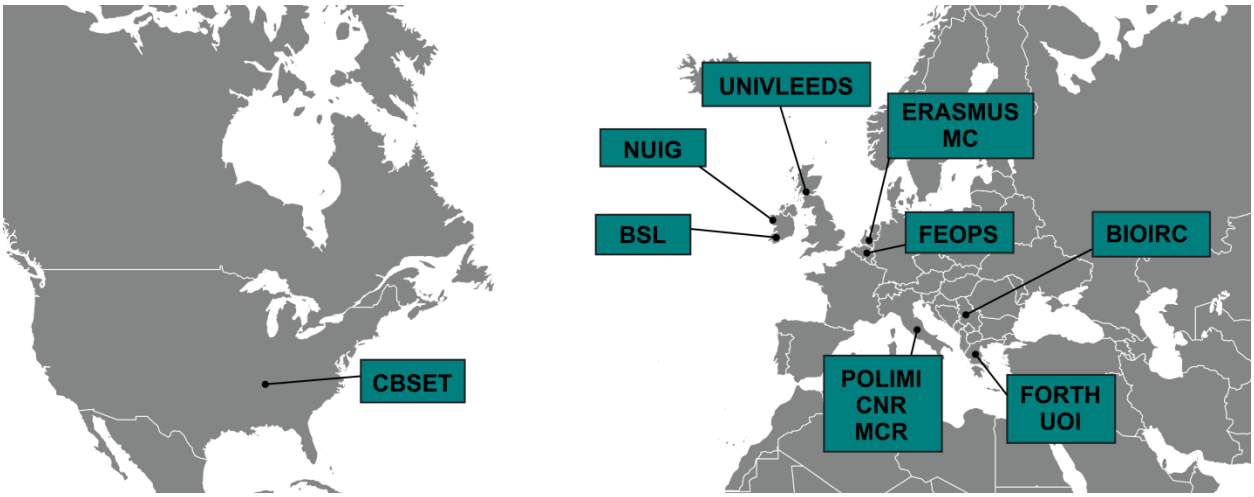
InSilc Consortium

InSilc is a multidisciplinary Consortium with complementary expertise and experience to support the value chain that the project envisages to achieve. Interventional cardiologists, technical partners with extensive expertise in the field of computer modelling and simulation: (i) biomedical imaging (UNIVLEEDS, FORTH), (ii) coronary fluid dynamics (ERASMUSMC, UNIVLEEDS, CBSET), mechanical modelling and biomechanics (POLIMI, FORTH, NUIG, UNIVLEEDS, BIOIRC), experts in the field of *in vitro* mechanical testing (BIOIRC) and animal studies (CBSET), biology experts (CNR, FORTH), CRO with significant experience in providing services for regulatory authorizations and clinical trials for biomedical products (MCR), Cloud experts for platforms development and integration (FEOPS), Stent Biomedical Industry with high expertise in the design, development and manufacture of coronary stents (BSL) will join forces to accomplish the InSilc objectives and deliver all the intermediate and final project expected outcomes. The InSilc Consortium includes 12 partners from 8 different EU countries and one US partner (CBSET).



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