

InSilicoTrials.Com: A Cloud-Based Platform to Drive Technology Transfer of Modeling and Simulation Tools across Healthcare

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Introduction

For decades, universities and research centers have been applying modeling and simulation (M&S) to medical devices [1] and pharmaceutical [2] development, coining the new expression *in silico clinical trials*. Its use however is still limited to a restricted pool of specialists.

Making M&S available to a broad spectrum of potential users (medical device and pharmaceutical companies, hospitals, healthcare institutions) would require an easy and controlled access to M&S resources in a secure environment. A joint effort between academia, industry and regulatory bodies is therefore needed to reach a rapid adoption of a harmonized approach.

It is here proposed an easy-to-use cloud-based platform that aims to create a collaborative marketplace for M&S in healthcare, where developers and models' creators are able to capitalize on their work while protecting their intellectual property (IP), and medical device and pharmaceutical companies can use M&S to accelerate time and to reduce costs of their research and development (R&D) processes.

Methods

Digital libraries are built upon collaborations among high profile scientists, solver developers and cloud providers (*partners*). Their access is provided to life science and healthcare companies, clinical centers and research institutes (*users*), providing them with several solutions for the different steps of the pharmaceutical and medical devices R&D process.

Various M&S solutions, including virtual patient repositories, model templates and simulation tools, are integrated with the technical components of the cloud platform, in a secured and privacy-preserved environment that protect the IP of partners against downloading, copying and modification of their tools. The users can seamlessly select a digital tool, upload their own input parameters and/or data, set up and run simulations, and analyze results. The outcome of the simulations is reported in conformity with regulatory guidelines [3].

The InSilicoTrials.com platform is built on the Microsoft Azure cloud environment, in compliance with the highest standards of security and privacy (amongst others HIPAA Privacy and Security Rules; ISO/IEC 9001, 20000, 22301, 27017, 27018 and 27001; FDA 21 CFR Part 11 (GxP); Protection Directive 95/46/EC), ensuring that clinical data is properly managed, protected, and kept private.

Results

The first medical devices application hosted on the InSilicoTrials.com platform is **InSilicoMRI** (Figure 1), a digital library of automatic tools concerning the magnetic resonance imaging (MRI) systems (software, hardware and images). The tool NuMRis [4], implemented in collaboration with the U.S. F.D.A. Center for Devices and Radiological Health, and ANSYS, Inc., addresses

the assessment of MRI imaging radio-frequency (RF) safety for medical implants such as orthopedic devices (e.g., rods and screws), pain management devices (e.g., leads), and cardiovascular devices (e.g., stents). NuMRis promotes the broader adoption of digital evidence in preclinical trials for RF safety analysis, supporting the device submission process and pre-market regulatory evaluation.

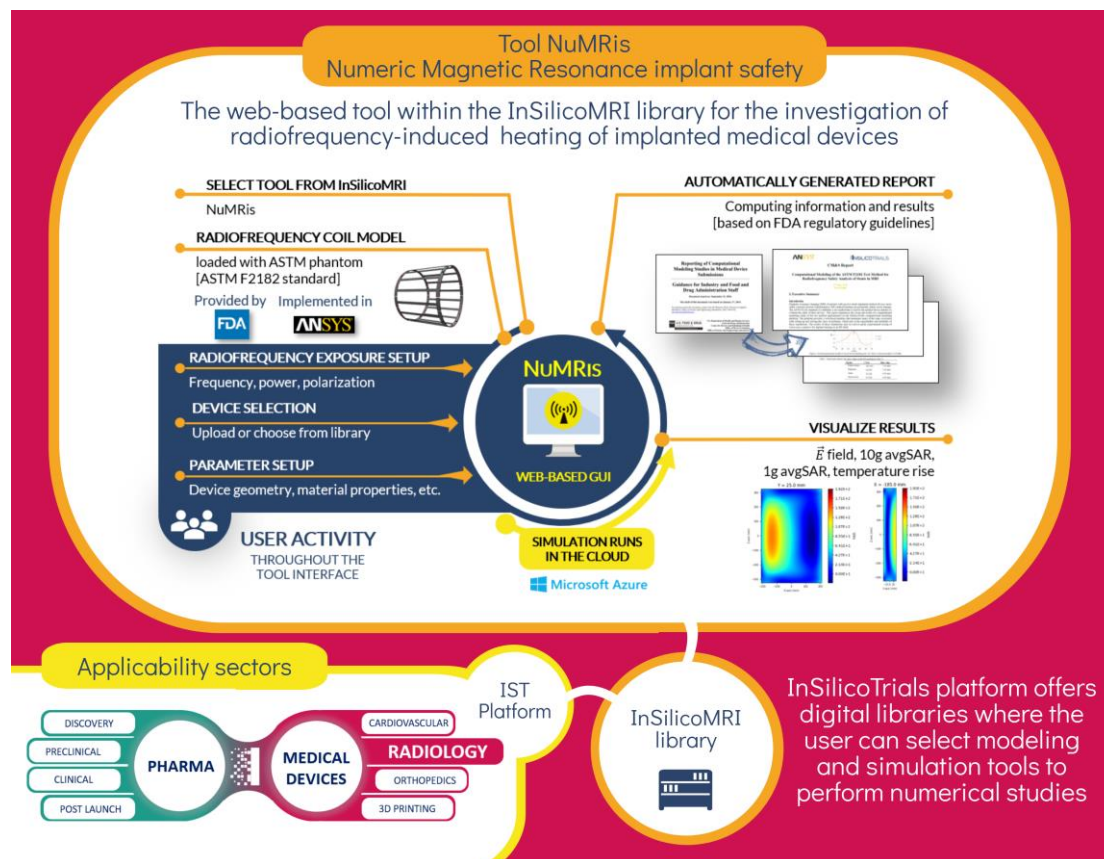


Figure 1. The InSilicoMRI digital library.

The first pharma application hosted on the InSilicoTrials.com platform is **InSilicoCARDIO** (Figure 2), a digital library of easily accessible user-friendly tools for the assessment of the proarrhythmic and torsade de pointes risk of drugs compounds and new chemical entities. Part of this library is QT/TdP Risk Screen [5], a user-friendly tool implemented in collaboration with Universitat Politècnica de València and Fundació Institut Mar D'Investigacions Mèdiques. QT/TdP Risk Screen enables a highly accurate classification of drug compounds, paving the way to a potential break-through in *in silico* proarrhythmic risk assessment.

Discussion

The proposed platform allows exploitation of M&S through a Software as a Service (SaaS) delivery model. The pay-per-use pricing: 1. provide partners with a strong incentive to commercialize their high-quality M&S solutions; 2. permit users with limited budget, such as small companies, research centers and hospitals, to use advanced M&S as well. Pricing of the M&S tools is based on specific aspects, such as particular features and computational power required, in agreement with the developing partner, and is distinct for different types of users (i.e. academia or industry).

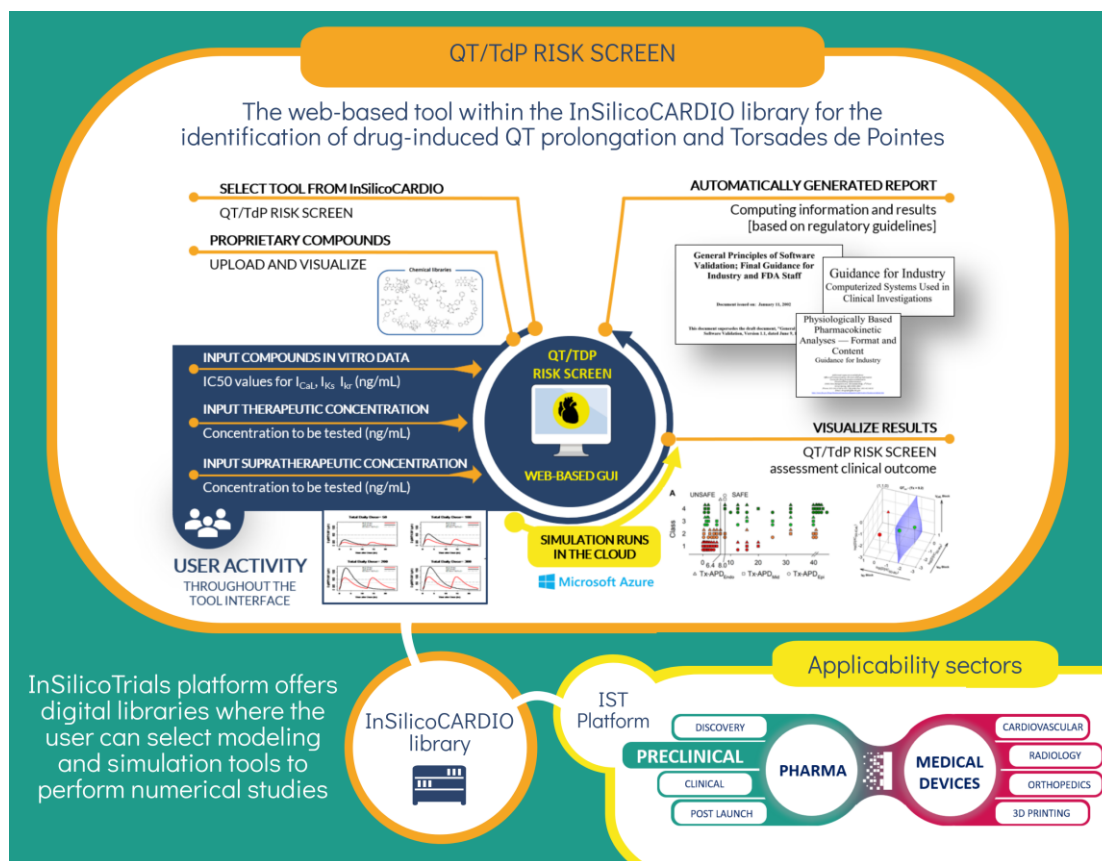


Figure 2. The InSilicoCARDIO digital library.

Conclusions

InSilicoTrials.com aims at defining a new collaborative framework in healthcare, engaging research centers to safely commercialize their IP, i.e. model templates, simulation tools and virtual patients, by helping medical device and pharmaceutical companies to significantly expedite the pre-clinical and clinical development phases, and to move across the regulatory approval and HTA processes.

References

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