InSilicoTrials.com: the first cloud-based platform for a modeling and simulation driven medical product lifecycle

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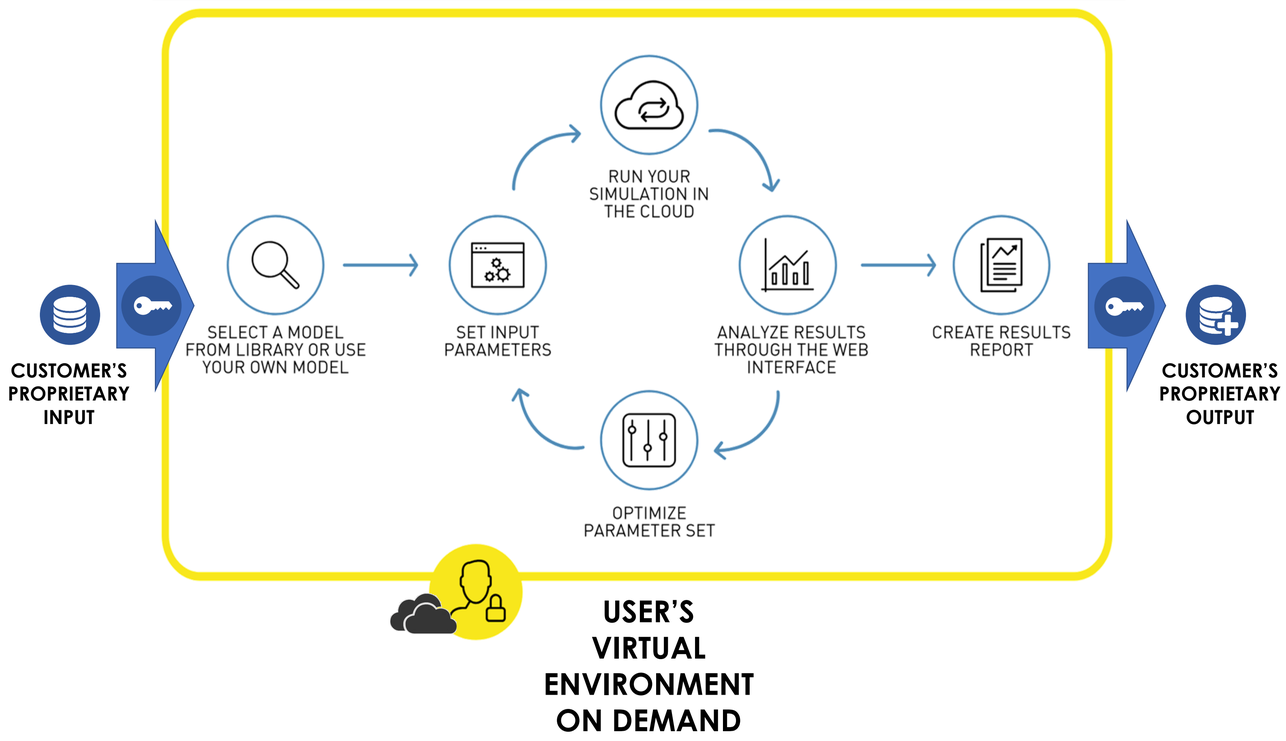
Introduction

For decades, researchers have been applying computer modeling and simulation (CM&S) to medical devices and pharmaceutical development, coining the new expression **in silico trials**[1]. However, Its use is **still limited across the product lifecycle**, and to a restricted pool of specialists. It is here proposed an **easy-to-use cloud-based collaborative platform** to support the overall lifecycle of medical devices and drugs through CM&S.

Materials and Methods

InSilicoTrials.com is the first **user-friendly web-based platform** with several **solutions for each medical product's development phase**, from concept design to post-market monitoring. Digital tools are built on **collaborations with first-rate scientific partners**.



InSilicoTrials platform user workflow

InSilicoTrials.com tools and digital libraries include, but are not limited to, **structural, fluid-dynamics, electromagnetic and pharmaceutical CM&S** to evaluate the performance of a medical product.

CM&S solutions are embedded in a **privacy-preserving environment** that **protects partners' intellectual property against download and copy of their tools**. 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[2]**.

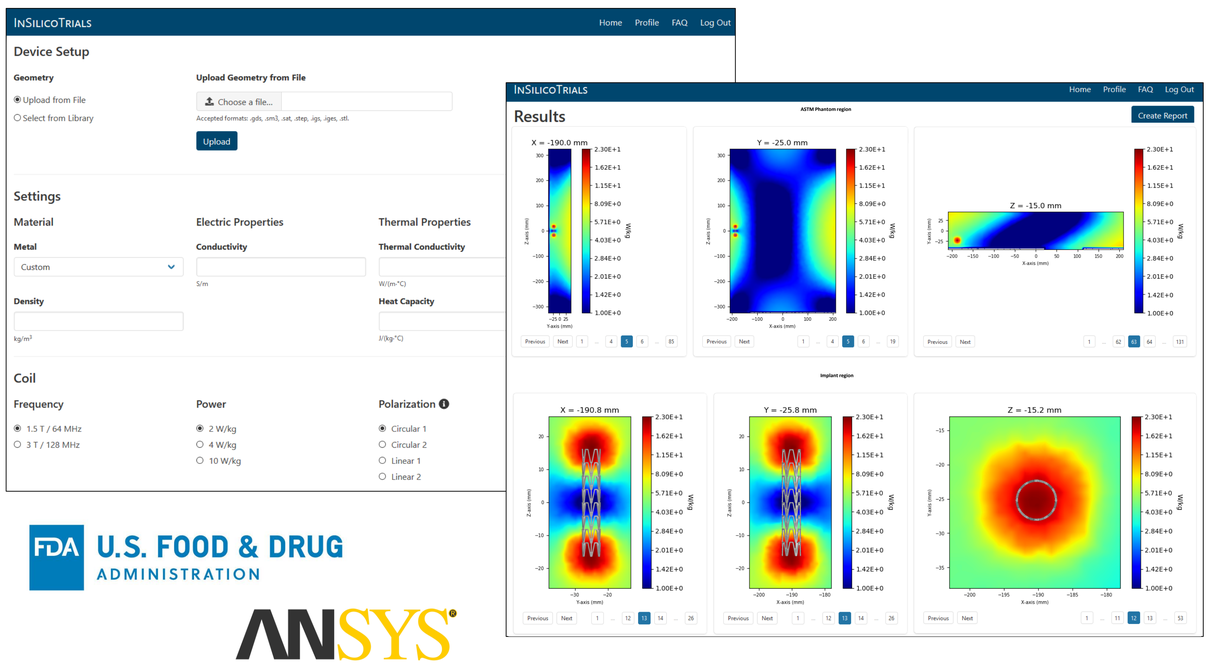
Results

Two digital tools have already been integrated in the InSilicoTrials.com platform: **NuMRis** is dedicated to the MRI-safety assessment of metal medical devices, and **QT/TdP Risk Screen** is a pharmaceutical application to the cardiotoxicity of new drugs.

NuMRis[3]

Safety assessment of MRI RF-heating on passive implants as indicated by the Standard Test Method ASTM F2182[4]

- Includes model developed, tested and provided by with the **U.S. F.D.A. Center for Devices and Radiological Health**
- Tool implemented in collaboration with **ANSYS**
- **Tool objective**: assessment of MRI imaging radiofrequency (RF) safety for medical implants (e.g., stents, TAVI stent frames).
- **Computational time per run**: 2.5 hours on 44 CPUs and 352 GB of RAM



U.S. FOOD & DRUG ADMINISTRATION

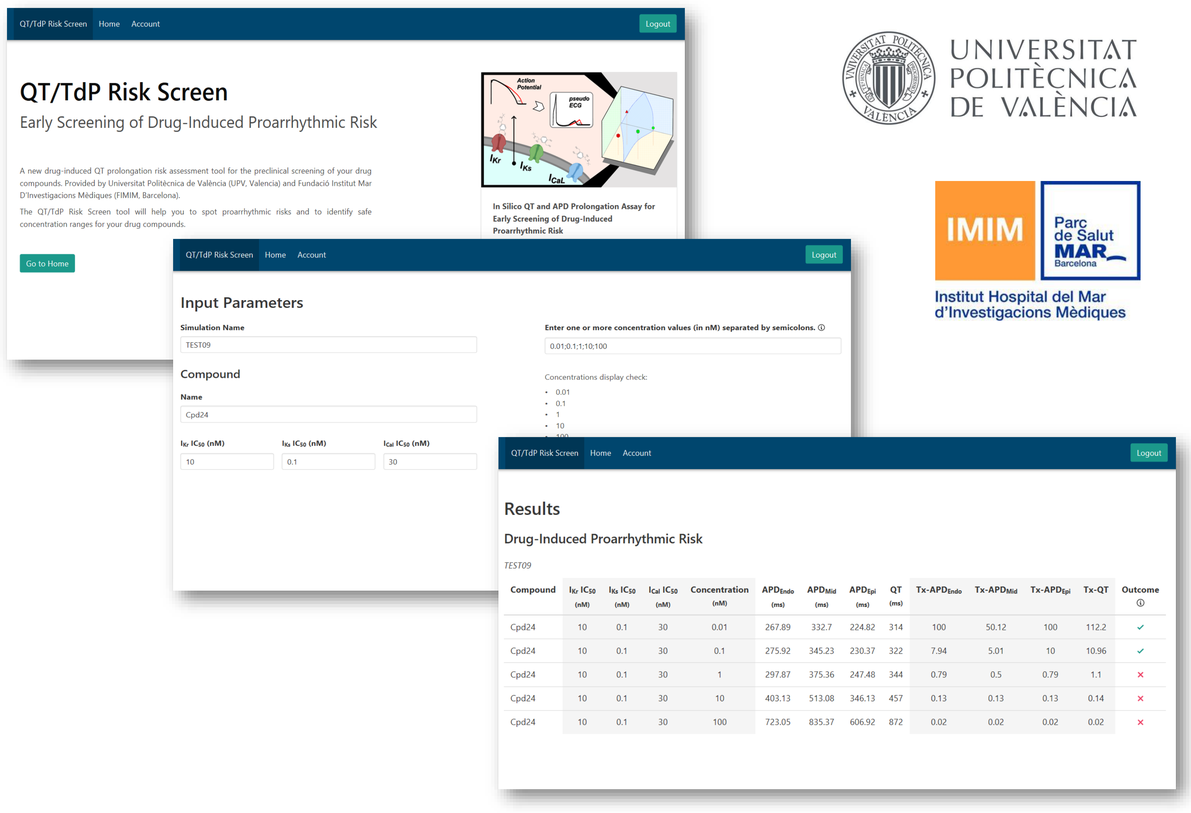
ANSYS

NuMRis web interface – Input parameters insertion and simulation results visualization

QT/TdP Risk Screen[5]

Drug-induced QT prolongation risk assessment for preclinical screening

- Model developed, validated and provided by **Universitat Politècnica de València** and **Institut Hospital del Mar d'Investigacions Mèdiques (IMIM)**
- **Tool objective**: early screening of the proarrhythmic risk of drug compounds and identification of a safe concentration range.
- **Computational time per run**: few seconds



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QT/TdP Risk Screen web interface – Input parameters insertion and results

Conclusions

InSilicoTrials.com aims at defining a **new framework in healthcare**, engaging research centers to safely commercialize their M&S, by helping healthcare companies and start-ups to **expedite the design, pre-clinical and clinical development phases,** and to **move across the regulatory approval and post-launch processes.**

References

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3. Lucano et al., 2019 BMES/FDA Frontiers in Medical Devices Conference. Available from: bit.ly/2Xh7HEs
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5. Romero et al., J. Chem. Inf. Model. 2018; 58, 867−878.