NuMRis: Automated Computational Tool to Study MRI RF Safety of Implanted Medical Devices

Elena Lucano[1], Peter Serano[2], Marc-Antonio Bisotti[1], Alberto Palazzin[1], Marc Horner[2], Luca Emili[1]

[1]InSilicoTrials Technologies S.r.l., [2]ANSYS, Inc.

Purpose

The absorption of radiofrequency (RF) energy during a magnetic resonance imaging (MRI) procedure may cause tissue heating in the vicinity of an implanted device, potentially causing patient harm. The NuMRis (Numerical Magnetic Resonance Implant Safety) tool is proposed as a numerical web-based application that automates the set-up and solution of RF heating analysis, in line with guidelines and existing standards for in-vitro testing [1, 2].

Materials and Methods

NuMRis is part of the InSilicoMRI library of the InSilicoTrials.com platform. The tool was developed in collaboration with ANSYS and as part of a Research Collaboration Agreement with the U.S. FDA. NuMRis offers the user a web interface to define input parameters specific to an MRI exposure scenario. The model is integrated in an automated workflow (Figure 1) developed using Python and Javascript and built on ANSYS 2019 R3. Each simulation submitted by the user runs on Microsoft Azure high performance computing cloud infrastructure. Simulation results are stored in a database for later retrieval and report generation.

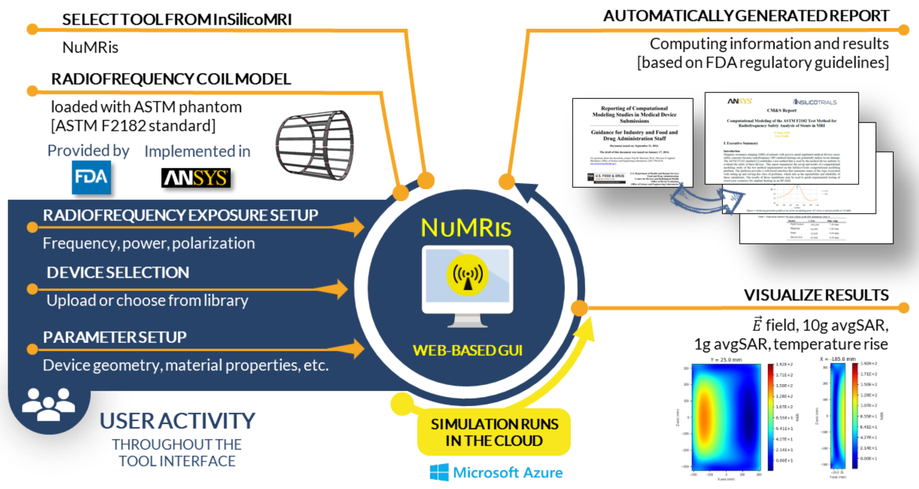

Figure 1. Overview of NuMRis simulation workflow. The free (limited functionality) version of the tool allows users to simulate a simplified single or dual stent device. The geometrical dimensions (diameter and length) and material of each stent are defined by the user before initiating a simulation.

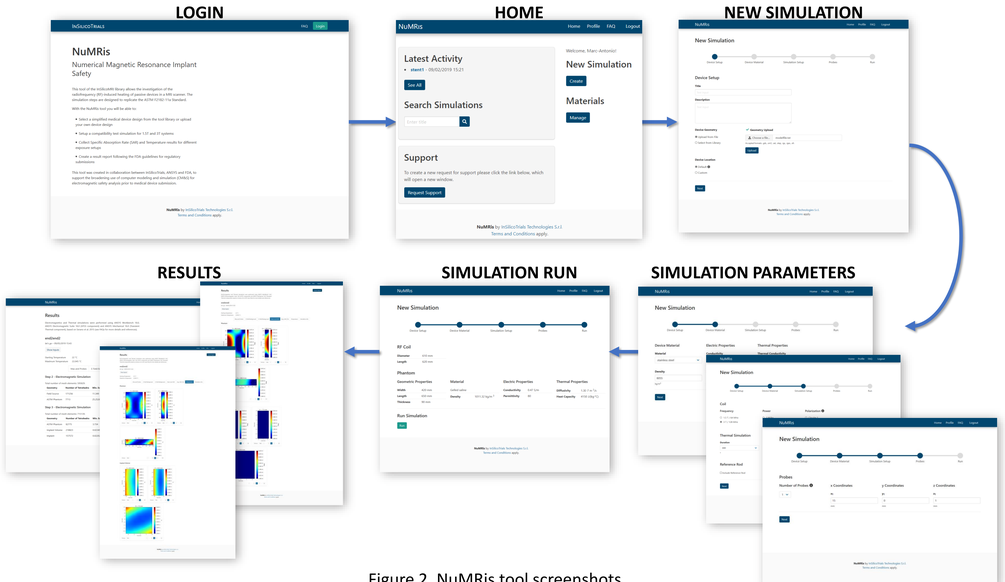

Figure 2. NuMRis tool screenshots

Results

NuMRis allows the user to(Figure 2):

- Upload the Upload the geometry of the medical device or select a simplified geometry from the library;
- Define the material properties of the device ;
- Specify the input parameters specific to an MRI exposure scenario:
  - Field frequencies (i.e., 64 MHz and 128 MHz);
  - Input powers: 2, 4 and 10 W/kg Whole body Specific Absorption Rate (WbSAR);
  - Field polarizations (i.e., two circular and two linear);
  - Exposure time (i.e., from 240 s to 900 s).
- Define extraction probes within the ASTM phantom [1].

At the end of the simulation, the users can view the results, including electromagnetic fields, local SAR, and the temperature rise over time. Finally, the simulation results are summarized in an automatically generated report that follows FDA guidance on M&S reporting [3].

Discussion and Conclusion

NuMRis enables users to access the benefits of M&S for the thermal safety assessment of implantable medical devices during an MRI scan, following established good simulation practices. Minimal training/background in computer modeling is required to use the proposed tool. 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.

References

[1] ASTM-F2182–11a, Standard Test Method; [2] Assessment of RF-Induced Heating in the MR Environment for Multi-Configuration Passive Medical Devices, FDA guidance (2016);

[3] Reporting of Computational Modeling Studies in Medical Device Submissions, FDA guidance (2016).