

# Pacemaker *In Silico* Approval



## Medical Challenge

- Predicting the behavior of a new pacemaker on different patients
- Reduce the number of implants of non approved device on patients
- Time and cost-effectively assess the innovation

## *In Silico* Solution

- Creating a validated computer model of the pacemaker and the heart
- Include human variability in the model to demonstrate the quality of the solution for the target population
- Get the system model approved by regulatory authorities

## Policy Relevance

- Address additional regulatory questions faster
- Release new treatment to patient 2 years earlier
- Improved reliability and patient safety
- Facilitate medical innovation including for smaller companies

2 years

The product was released 2 years earlier

256

Reduction of the number of patients involved in the clinical trial

\$10M

Cost reduction due to the reduced number of patients

10,000

Number of patients treated during these 2 years with the product