



# **SIMCor**

In-Silico testing and validation  
of Cardiovascular IMplantable devices



**SIMCor**



# ESB 2023

Pre-course 3: In-silico clinical trials  
and virtual cohorts

09.07.2023; Maastricht



**SIMCor**



# A statistical shape model of the porcine and human pulmonary artery for evaluation of medical devices

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A series of white, thick, rounded lines on a blue background. The lines start from the left edge and branch out to the right, resembling a stylized circuit board or a tree structure. The top line is a single horizontal bar. The second line branches into two, the third into three, and the fourth into four. The bottom-most line is a single horizontal bar with a circular end on the right.

# Motivation



# Motivation



**VIRTUAL COHORT  
GENERATION & VALIDATION**



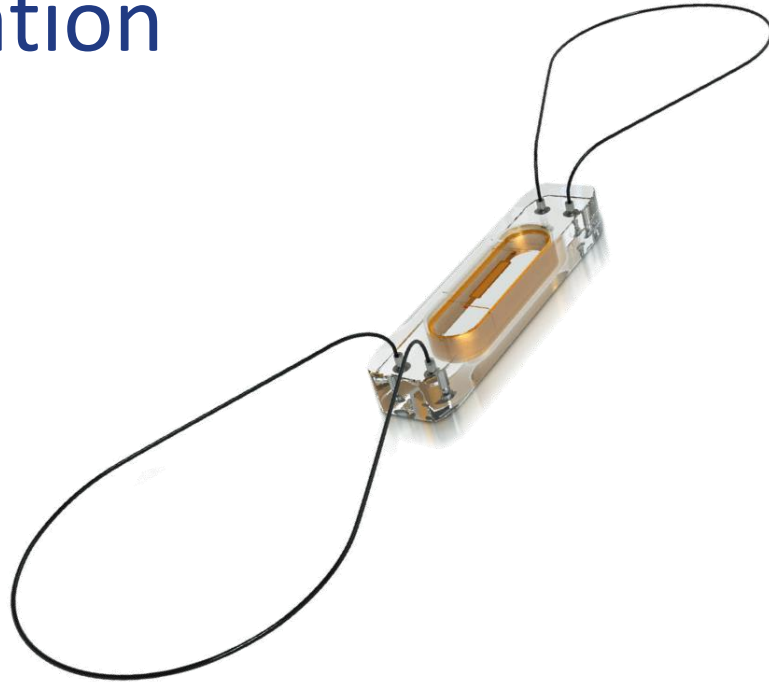
**SIMULATION OF DEVICE  
IMPLANTATION & PERFORMANCE**



## **RESOURCES**

Data, models, methodologies, standards, guidelines

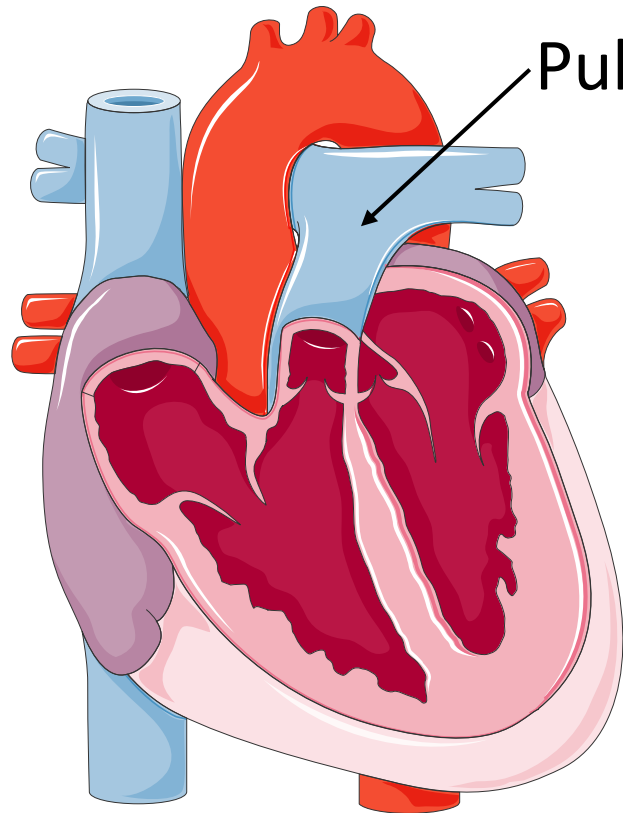
# Motivation



[www.abbott.com](http://www.abbott.com)

- Pulmonary Artery Pressure Sensors (PAPS)

# Motivation



Pulmonary Artery

- minimally invasive implantation via catheterization
- monitoring of blood pressure in heart failure patients
- early prediction of acute decompensation and reduction of rehospitalization and mortality

# Motivation



- high-risk medical device, with several potential adverse events
  - thrombosis
  - device migration
  - vessel perforation



# The Porcine PA



# Porcine Pulmonary Artery

## Usefulness of the pig model

Many similarities to humans



The heart size relative to body weight



Ventricular performance and electrophysiology



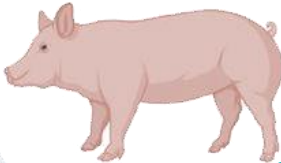
Negligible collateral circulation



Lipid profiles and lipoprotein metabolism



Neutrophils are the predominant circulating blood cell population

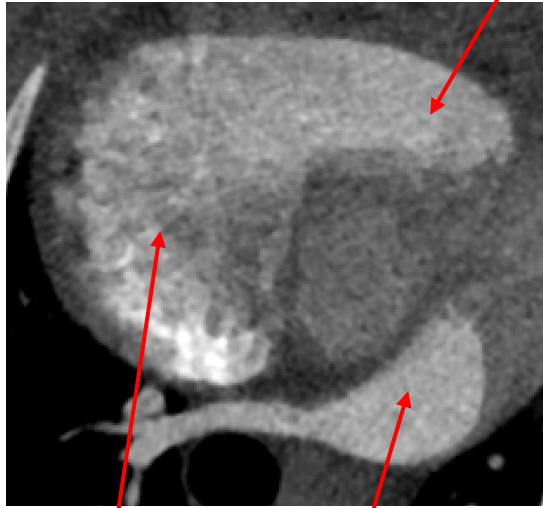


- animal experiments still a requirement for evaluation of medical devices
- the pig is a commonly used large animal model for cardiovascular therapies
- porcine data available for validation of device implantation and effect simulations

Hiroaki Osada et al. 10.5772/intechopen.105754

# Porcine Pulmonary Artery

Right Ventricular  
Outflow Tract

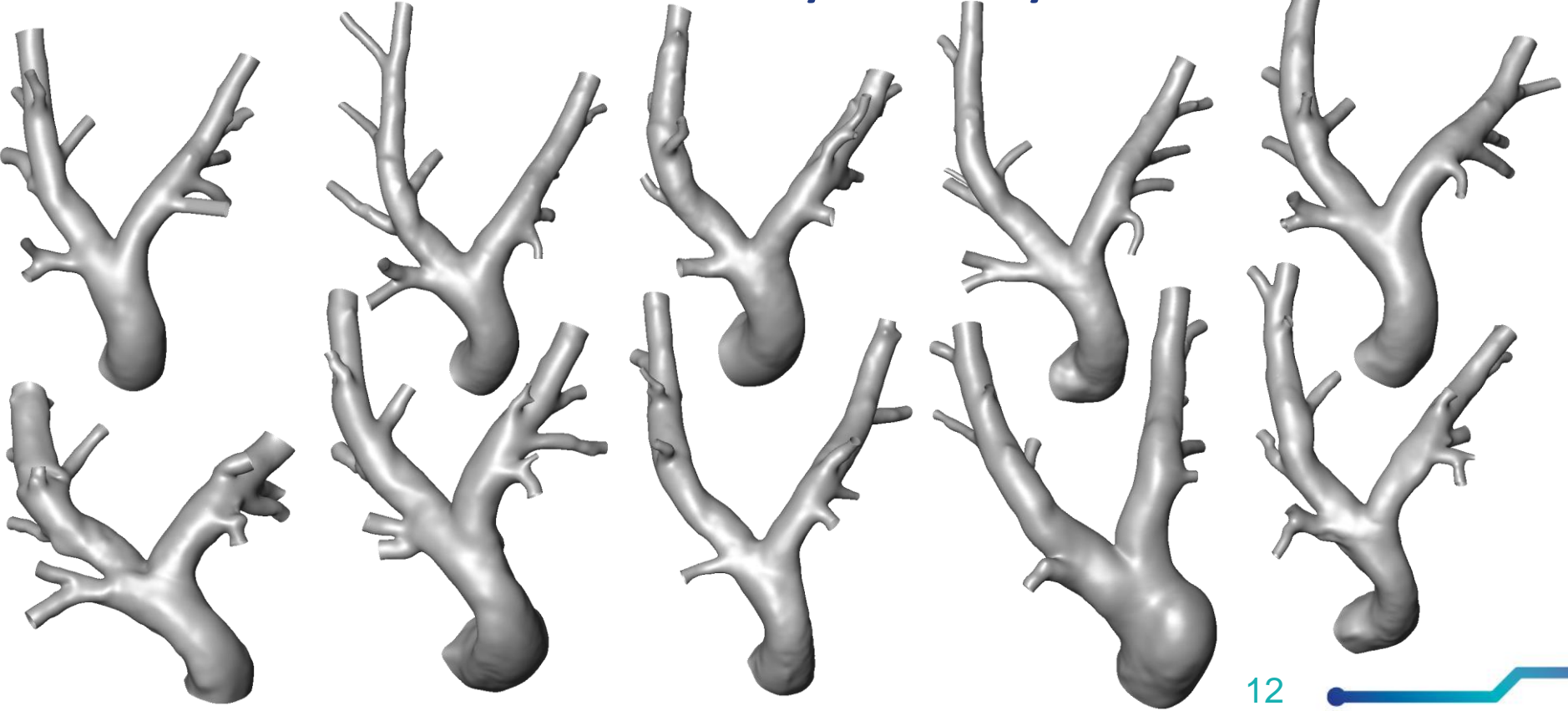


Right  
Ventricle

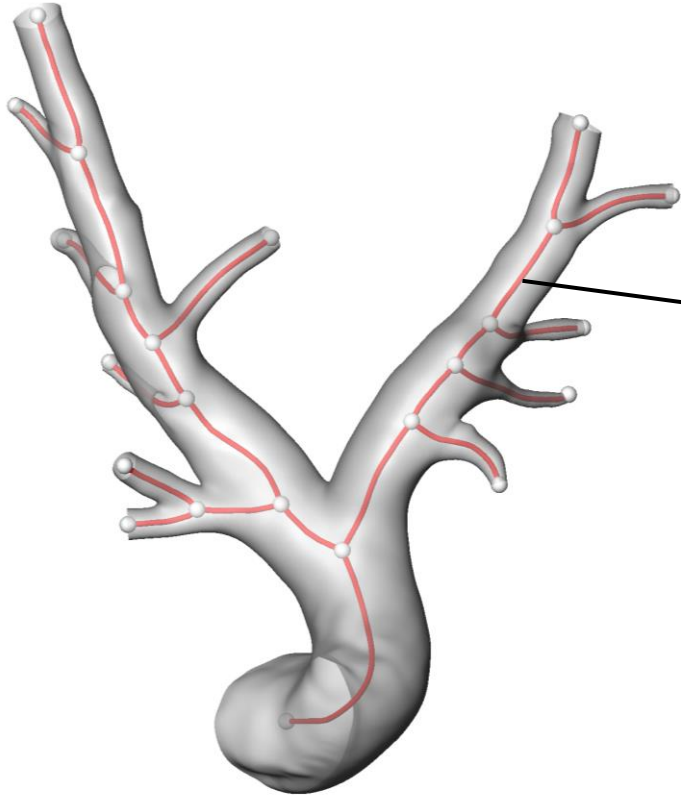
Pulmonary  
Artery



# Porcine Pulmonary Artery



# Porcine Pulmonary Artery

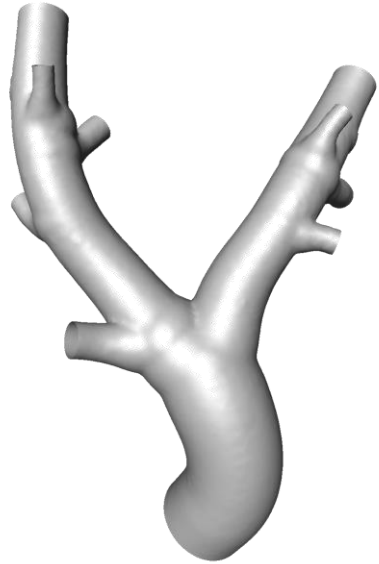


- same number of branching points and lines
- for each line

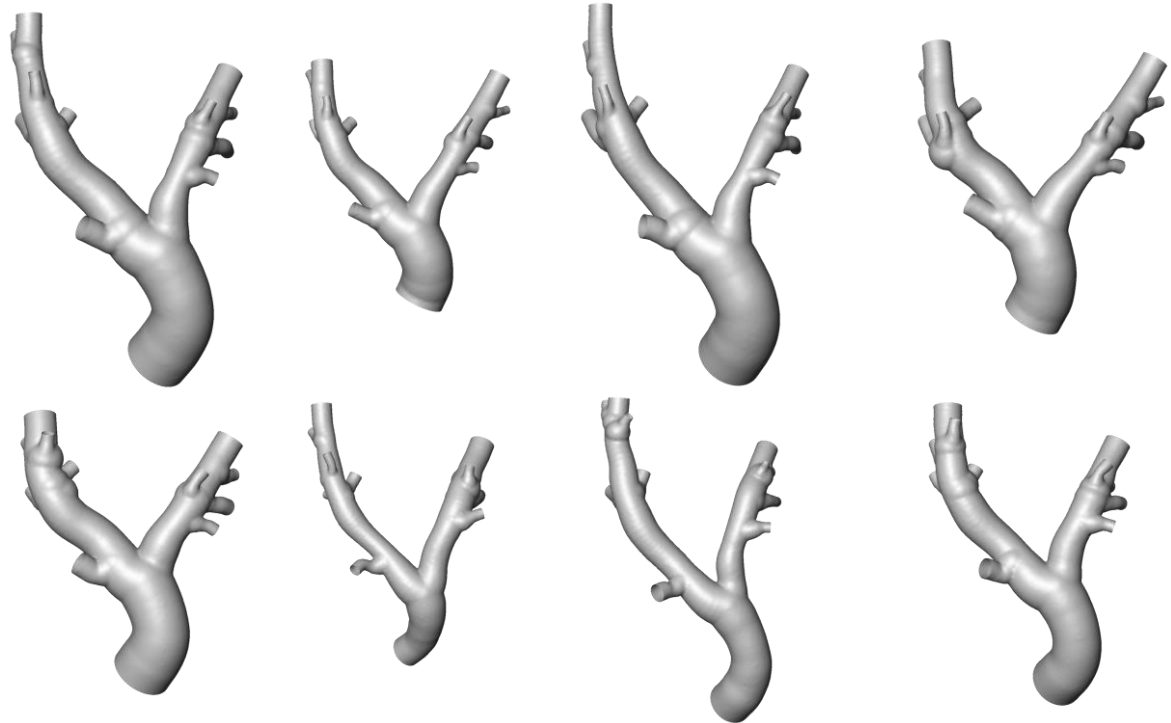
$$\begin{bmatrix} x_1 & y_1 & z_1 & r_1 \\ x_2 & y_2 & z_2 & r_2 \\ x_3 & y_3 & z_3 & r_3 \\ \dots & & & \\ x_n & y_n & z_n & r_n \end{bmatrix}$$

- however, different number of points per line

# Porcine Pulmonary Artery



mean geometry



synthetic geometries

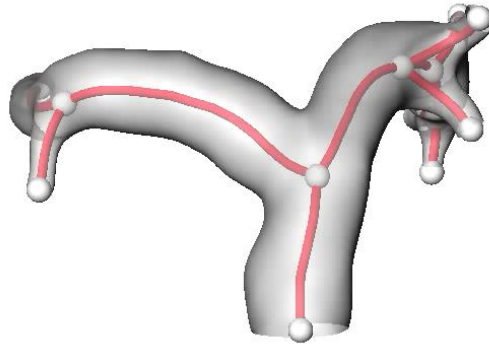
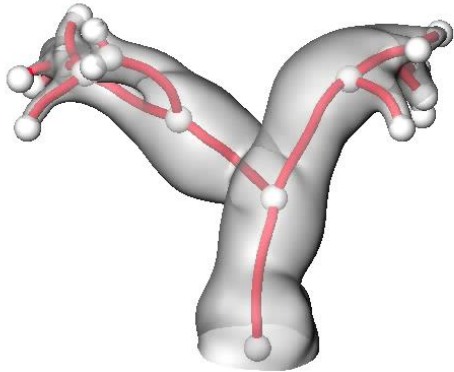
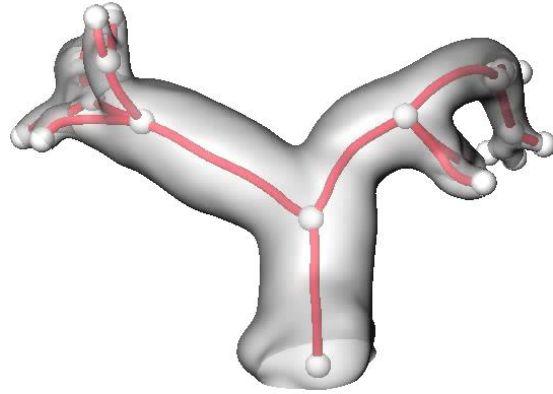
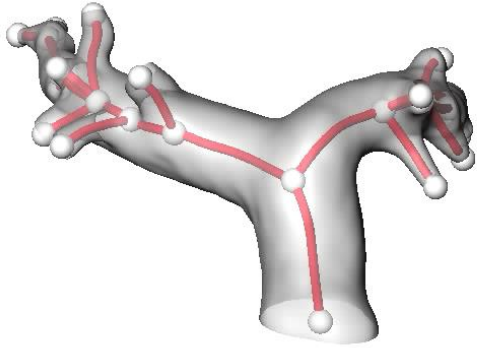
A series of white, stylized lines on a blue background. The lines are horizontal and parallel, with some having a 90-degree bend. They are arranged in a descending staircase pattern from left to right. The top line is the longest, and each subsequent line is shorter and shifted further to the right.

# The human PA

Activity summary, critical points and open issues, planning and action items



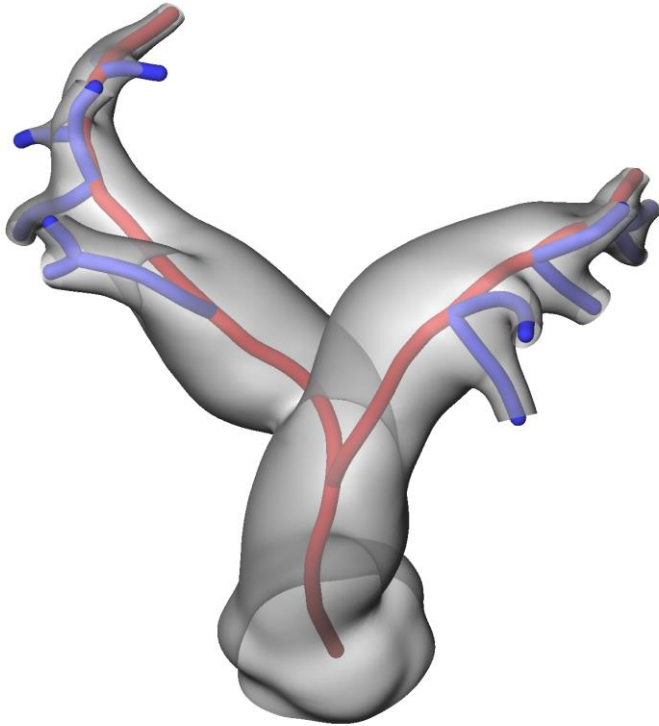
# Porcine Pulmonary Artery



- 50 patients investigated
- number of branching vessels: 2 - 12

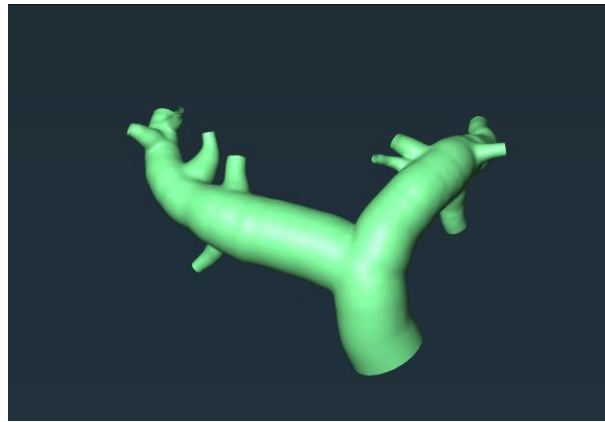
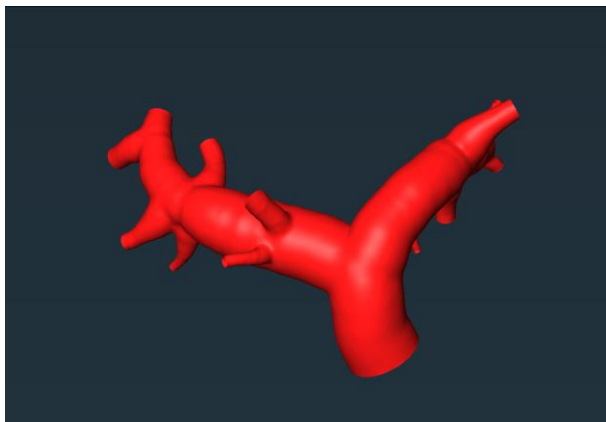
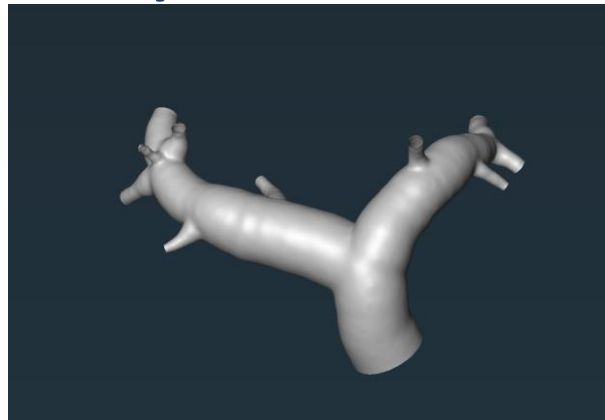
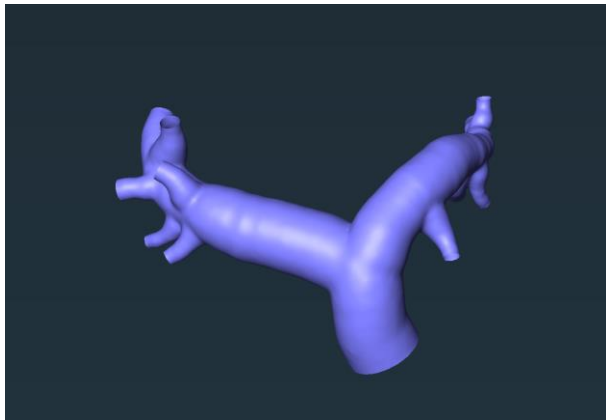


# Human Pulmonary Artery

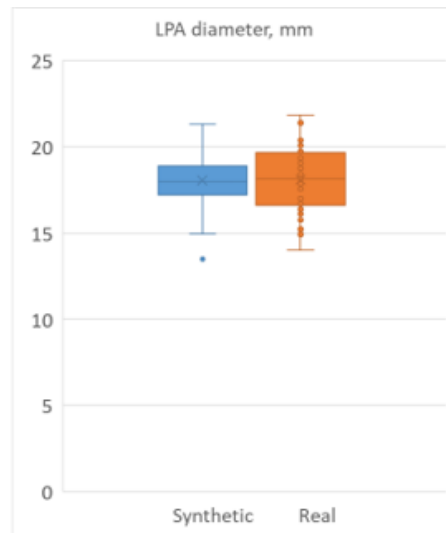
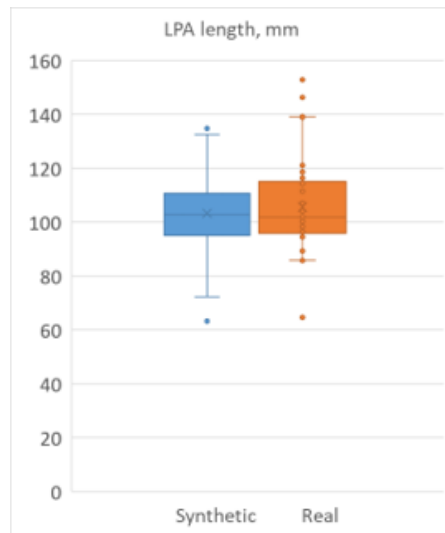
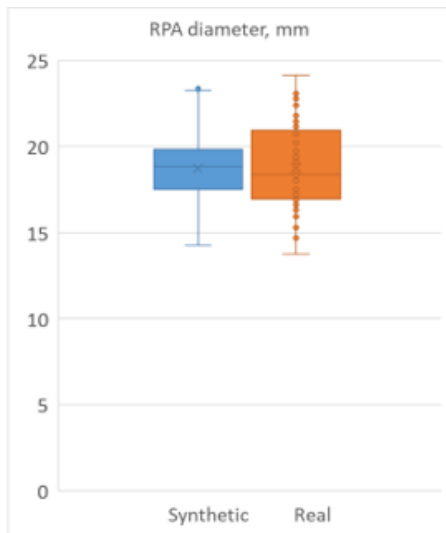
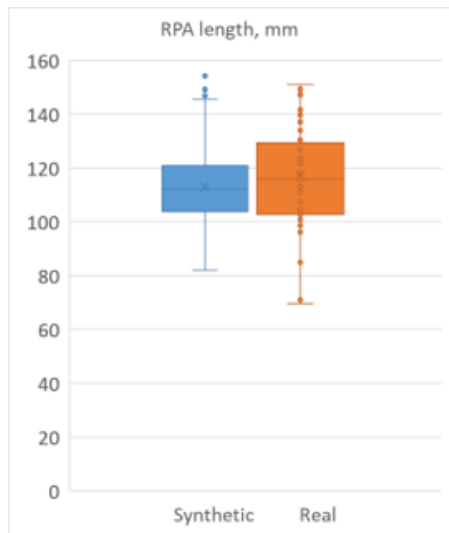


- centreline-based SSM for main, left, and right Pulmonary Artery
- side branches are attached by randomly sampling their parameter distributions
  - number of side branches
  - average diameter
  - rotation and inclination angle

# Human Pulmonary Artery



# Validation



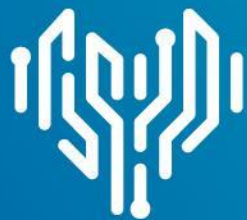
# Validation

Validation using only anatomical data

- patient-specific: successful
- self-validation: successful
- cross-validation: open

Validation using functional parameters

- open for all steps → calculation of hemodynamic parameters before and after PAPS implantation and comparison between real and virtual cohorts



**SIMCor**

**Thanks!**

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