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Engineering the extraordinary

Medtronic Presents

Digital Engineering Platform Automation

and Use Cases within the Medical Device Industry

October 2025
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Agenda

01 Medical Device Industry

02 AGILE Paradigm

03 Example Use Case

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Medical Device Industry

Product Development (and V&V) Process

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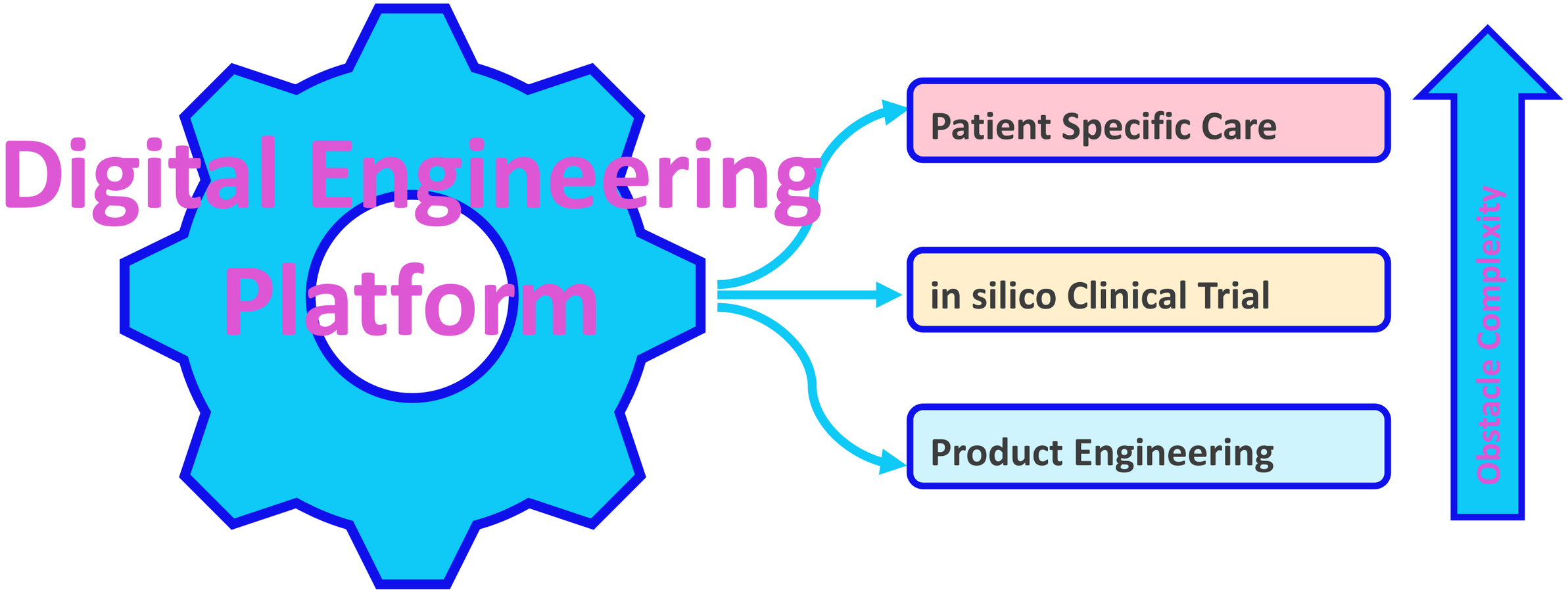
Digital Engineering

In the Medical Device Industry



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Product Development (and V&V) Process

In the General Industry

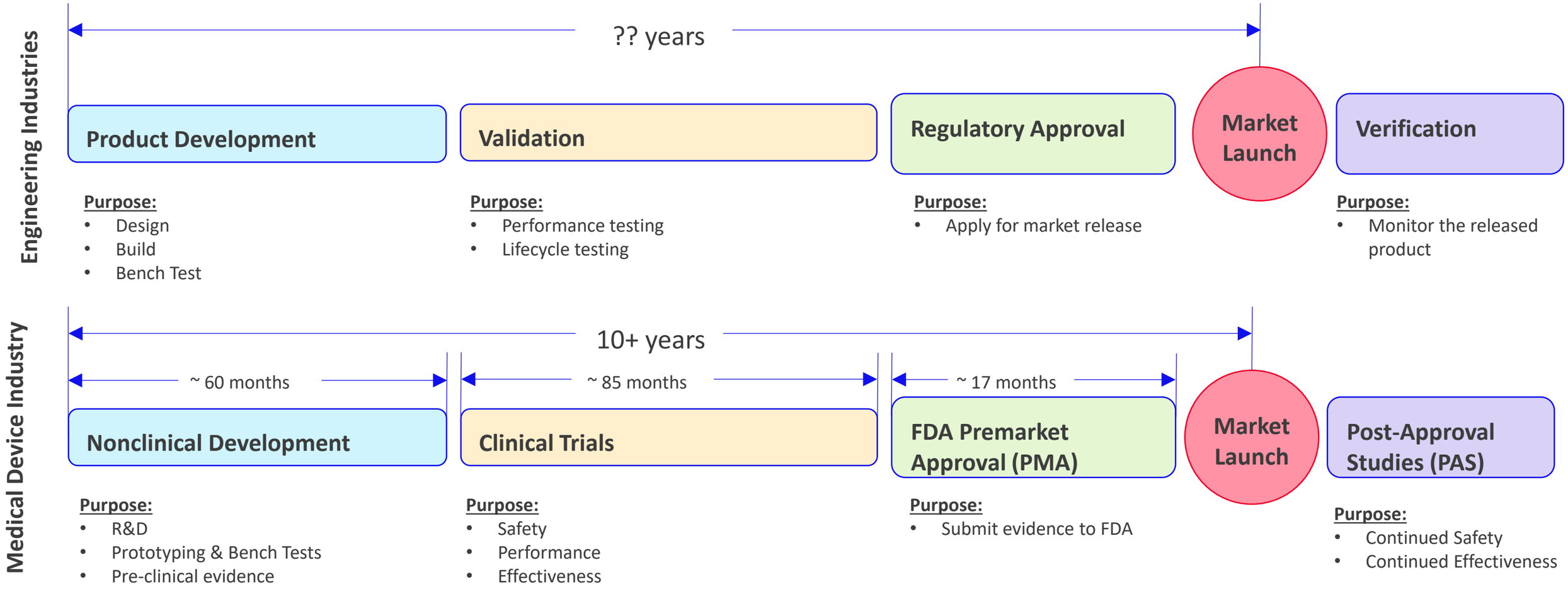

Chart and data adapted from:
Sertkaya A, DeVries R, Jessup A, Beleche T. Estimated Cost of Developing a Therapeutic Complex Medical Device in the US. *JAMA network open*. 2022;5(9):e2231609. doi:10.1001/jamanetworkopen.2022.31609

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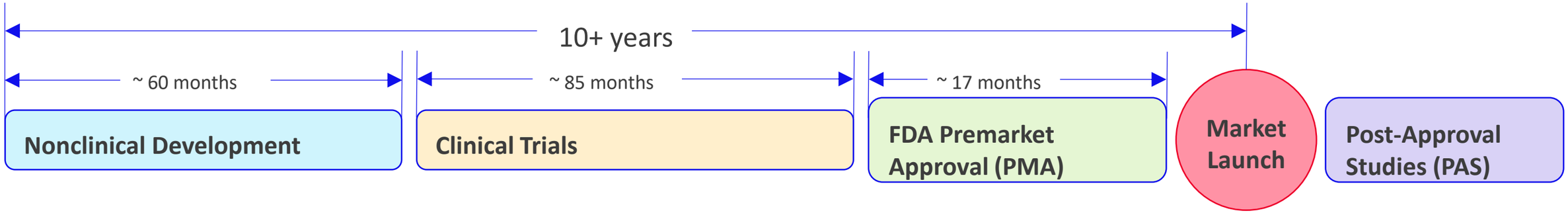
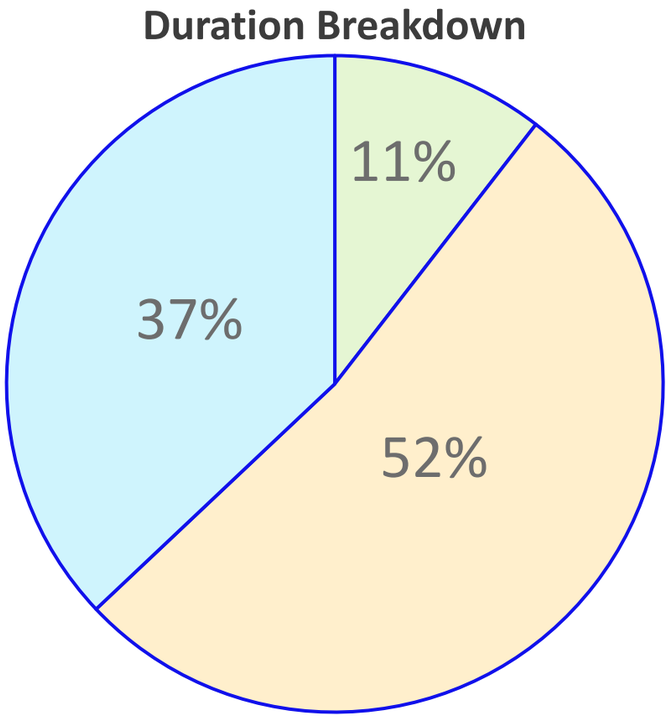
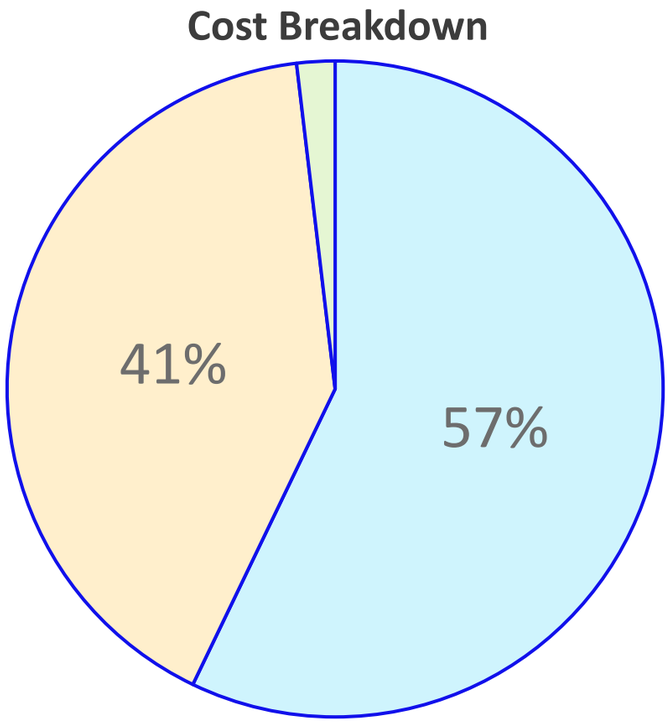
Product Development (and V&V) Process

In the Medical Device Industry







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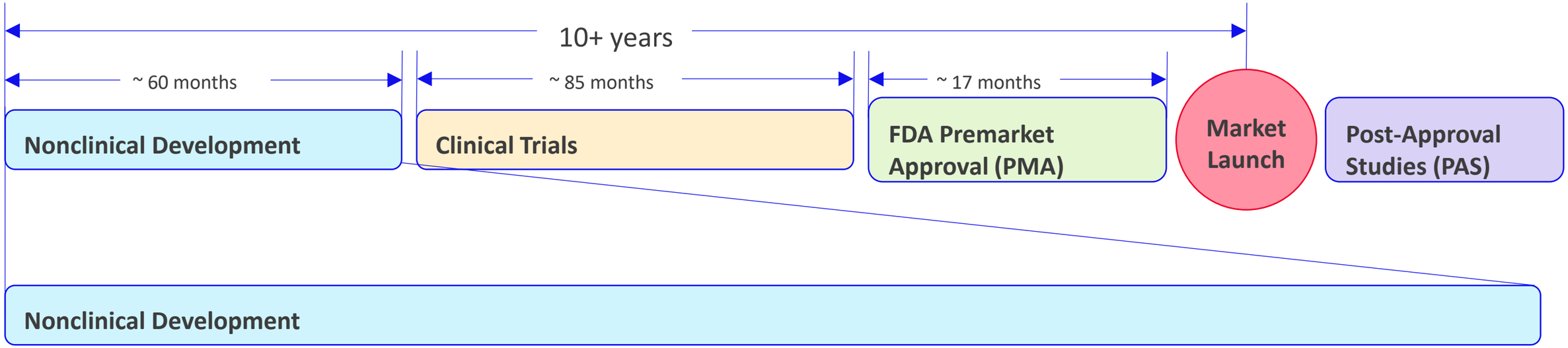
Product Development (and V&V) Process

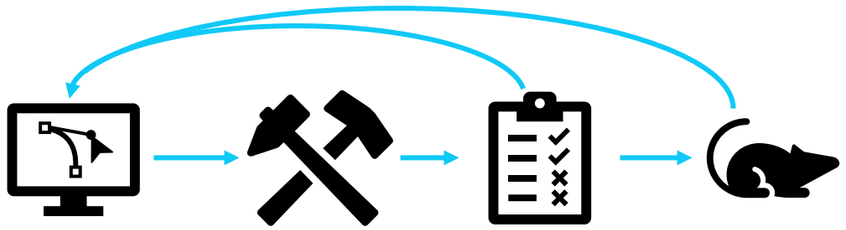
Nonclinical Development



Purpose:

- R&D
- Prototyping & Bench Tests
- Pre-clinical evidence

Total Cost[a]:
$20.0m



Prob. of Advancement	Prob. Of Approval	Cost at Launch[b]	Capitalized Cost[c]
46.9%	13.7%	$60.8m	$442.8m

[a] Represents the cash outlay at time of expense

[b] Represents the cash outlay adjusted for the cost of capital

[c] Expected capitalized costs including the cost of capital and failures

Chart and data adapted from:
Sertkaya A, DeVries R, Jessup A, Beleche T. Estimated Cost of Developing a Therapeutic Complex Medical Device in the US. *JAMA network open*. 2022;5(9):e2231609. doi:10.1001/jamanetworkopen.2022.31609

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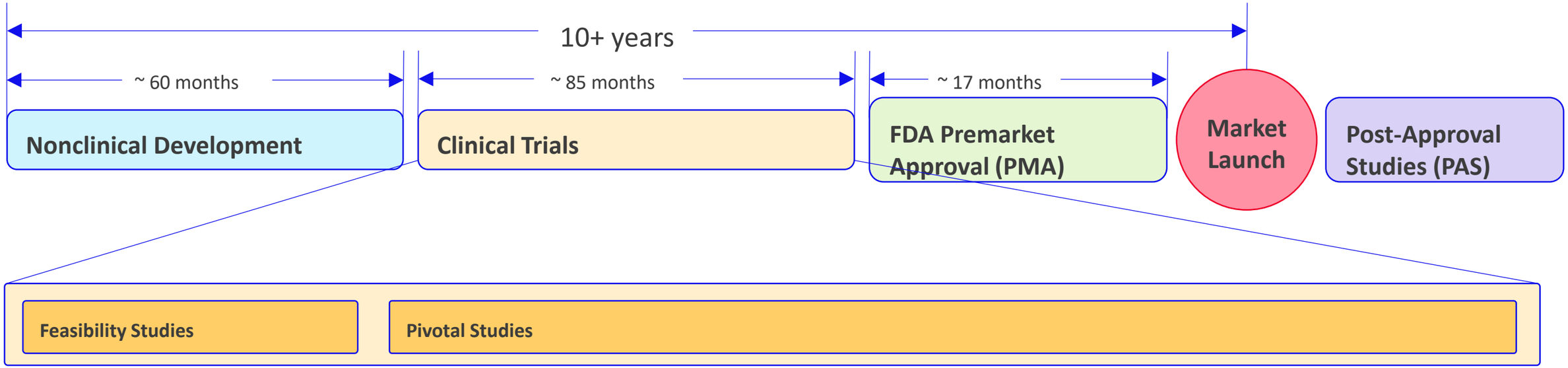
Product Development (and V&V) Process

Clinical Trials



Purpose:
- Safety
- Performance
- N=O(50) patients

Duration:
f(N) ~ 28 months

Cost per Patient:
~$30,000

Total Cost[a]:
f(N) ~ $1.4m

Purpose:
- Safety
- Effectiveness
- N=O(500) patients

Duration:
f(N) ~ 57 months

Cost per Patient:
~$54,000

Total Cost[a]:
f(N) ~ $30.7m

Phase	Prob. of Advancement	Prob. Of Approval	Expense at Launch[b]
Feasibility	48.0%	29.2%	$2.9m
Pivotal	75.7%	60.9%	$40.6m

[a] Represents the cash outlay at time of expense

[b] Represents the cash outlay adjusted for the cost of capital

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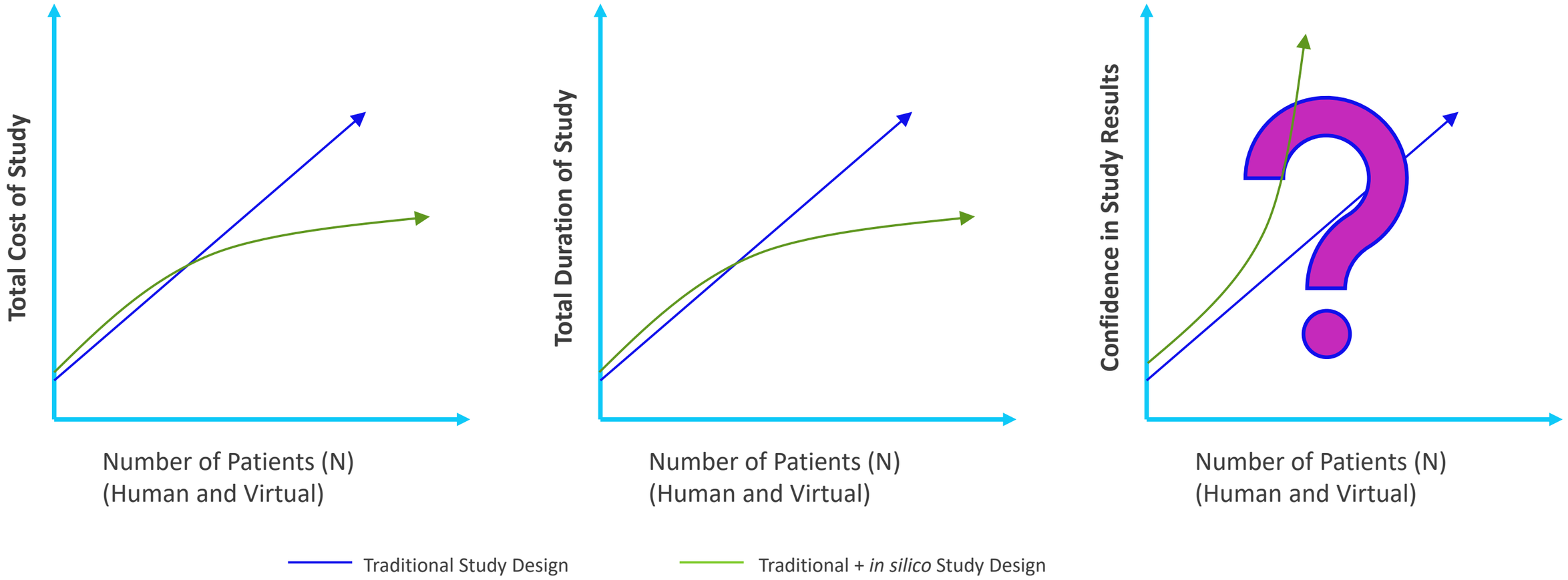
Product Development (and V&V) Process

Clinical Trials



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in silico Clinical Trials (ISCT)

Truths and Misconceptions

in silico Clinical Trials will NOT

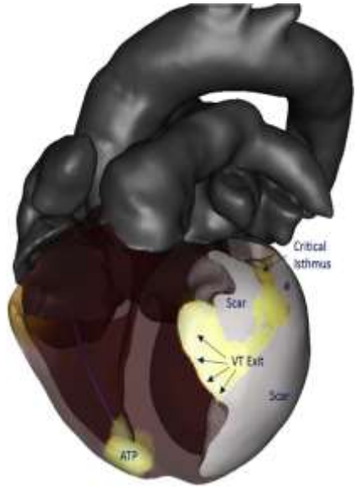
1. Replace human trials
2. Be deterministic on their own
3. Have a clearly defined execution path
4. Result in less stringent medical devices regulations

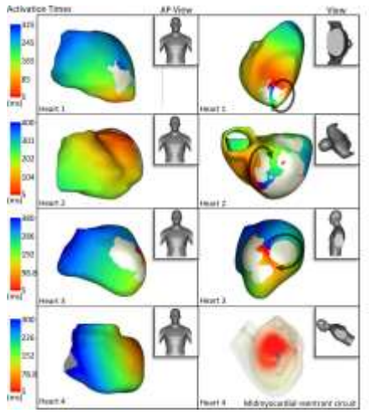
What *in silico* Clinical Trials are

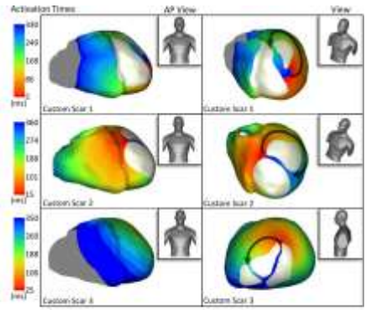
1. Intended to augment traditional clinical trials
2. *in silico* evidence supports regulatory submission, along with other necessary evidence based on risk level
3. The FDA “ISCT playbook” is an outline, but every submission will have unique requirements based on “Question of Interest” and “Context of Use”
4. The use of ISCT will result in more thorough investigation and evaluation of therapies, coupled with potentially quicker and cheaper access to the consumer

in silico Clinical Trials (ISCT)

Example Use Case







Images and video curtesy of:
Swenson DJ, Taepke RT, Blauer JJE, et al. Direct comparison of a novel antitachycardia pacing algorithm against present methods using virtual patient modeling. Heart Rhythm. 2020;17(9):1602-1608. doi:10.1016/j.hrthm.2020.05.009

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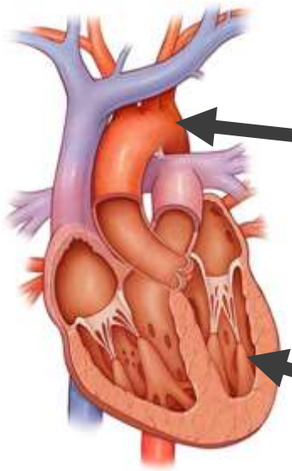
Patient Specific Care

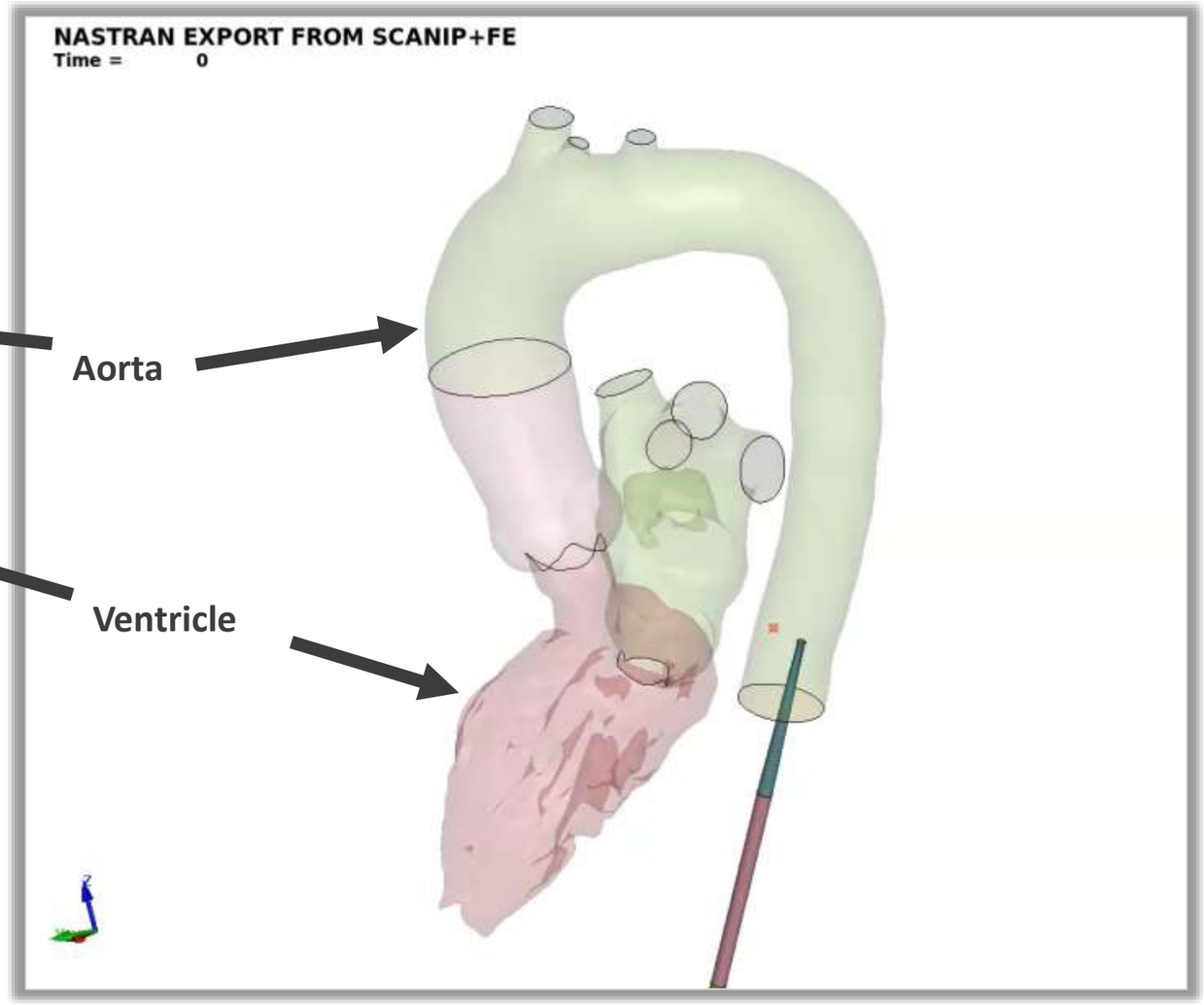
And the Role of Modeling & Simulation

Patient Specific Care

Tailoring medical decisions based on unique characteristics of each patient

- Anatomy
- Physiology
- Genetics
- Lifestyle
- Medical history





Role of Modeling & Simulation

Modeling & Simulation can help Clinicians

- Predict a specific response
- Plan or train for a procedure
- Adjust for specific disease state

Video curtesy of:
Martin, David and David Nolan. "Role of Modelling & Simulation Tools in the Development of Transcatheter Heart Valve Devices at Medtronic." SIMULIA EuroNORTH Regional User Meeting. 2025.

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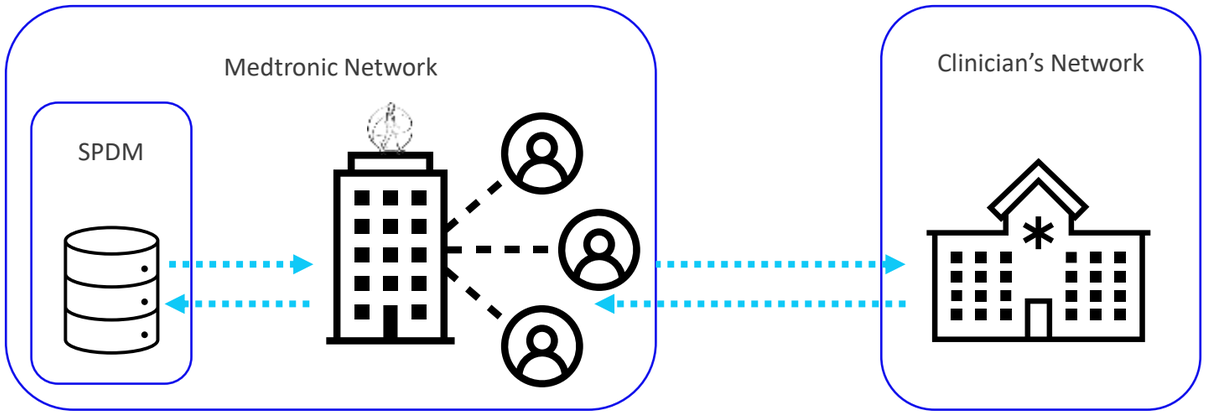
Modeling & Simulation in the Medical Device Industry

Obstacles and Challenges

- Regulatory & Clinical Alignment
- Data Acquisition & Consistency
- Logistics & Integration
- Security & Privacy
- Validation
- Data Retention & Access



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AGILE Paradigm

Facilitating Collaborative Digital Engineering

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AGILE Paradigm

Introduction

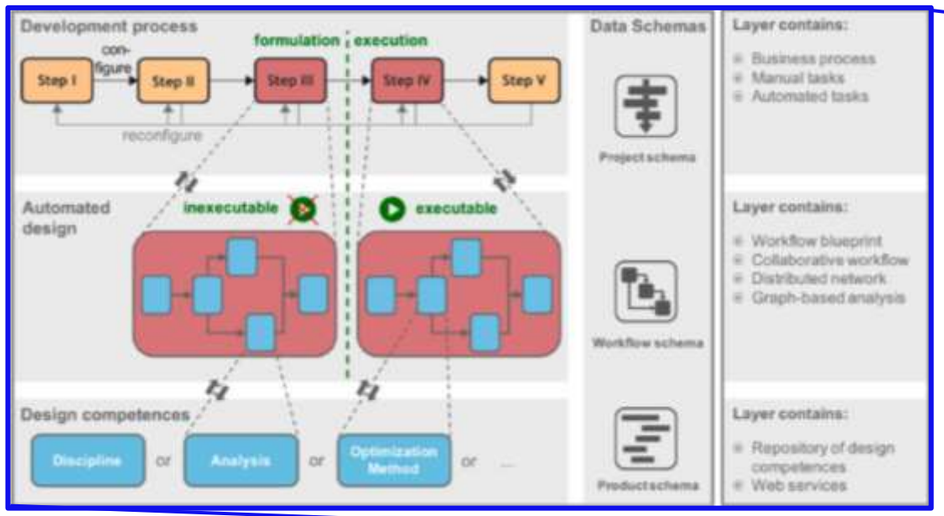
Step I: Define Requirements

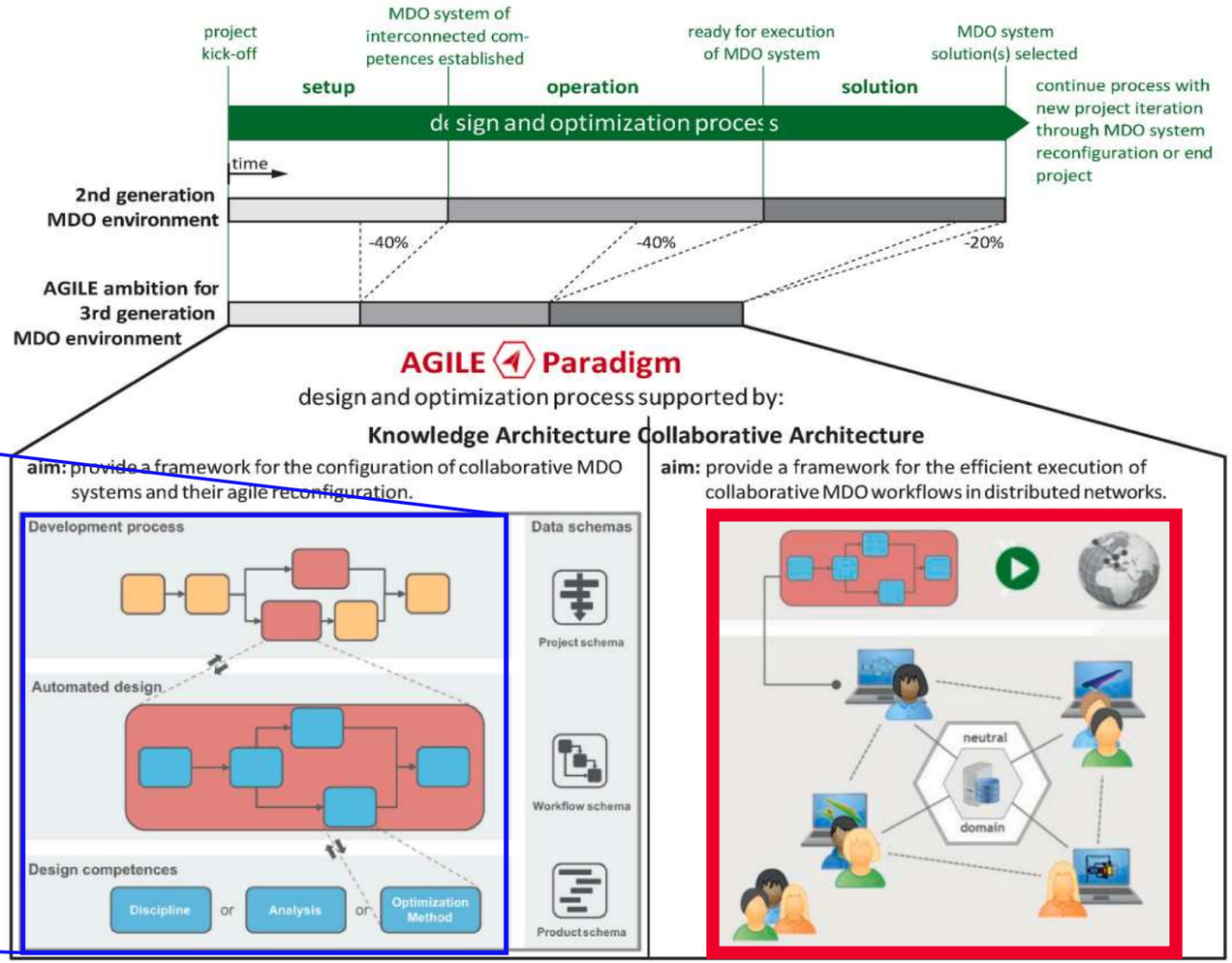
Step II: Specify competences

Step III: Formulate Problem Statement & Inexecutable Workflow

Step IV: Develop Executable Workflow

Step V: Execute Executable Workflow & Generate Results





Knowledge architecture supporting the next generation of MDO in the AGILE paradigm, Imco van Gent, Benedikt Aigner, Bastiaan Beijer, Jonas Jepsen, Gianfranco La Rocca, https://doi.org/10.1016/j.paerosci.2020.100642.

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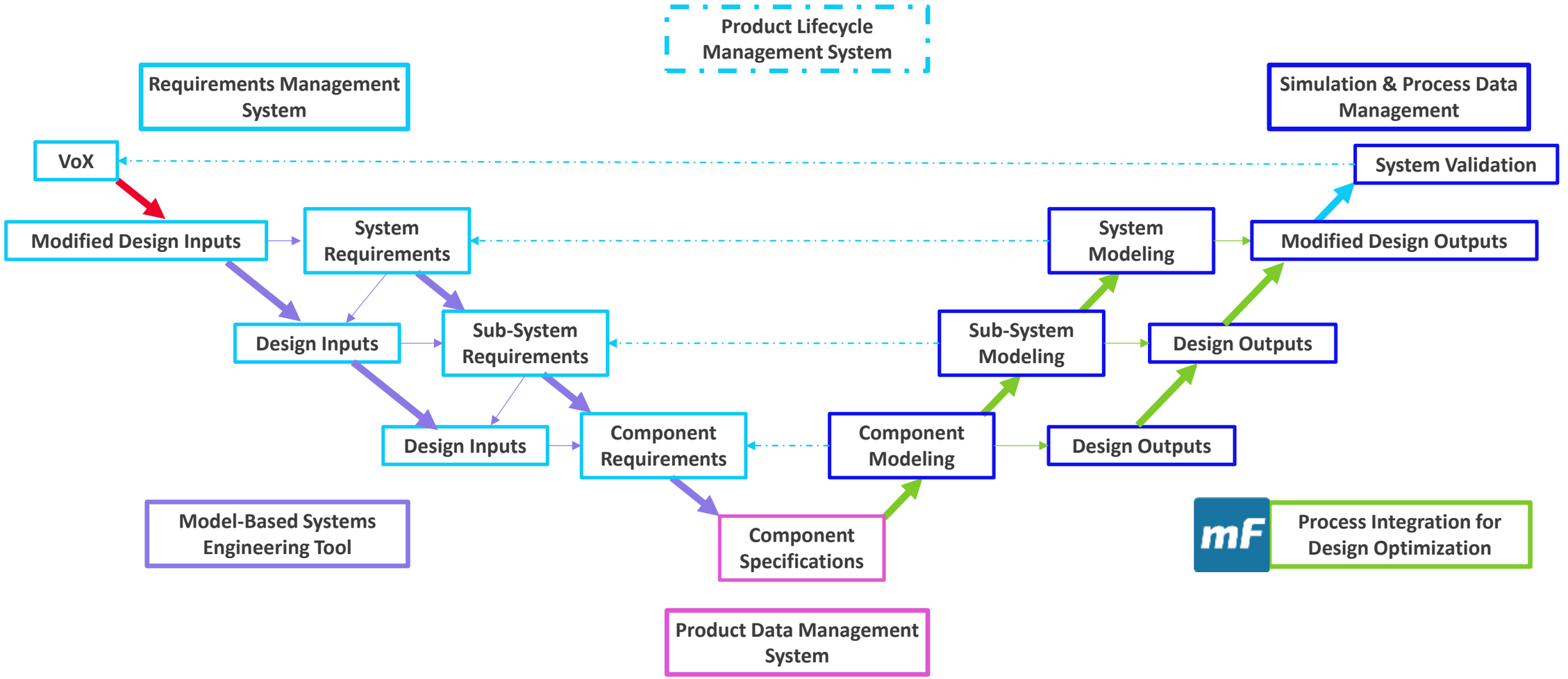
Digital Engineering Platform

Medtronic's Collaboration Architecture



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Digital Engineering Platform

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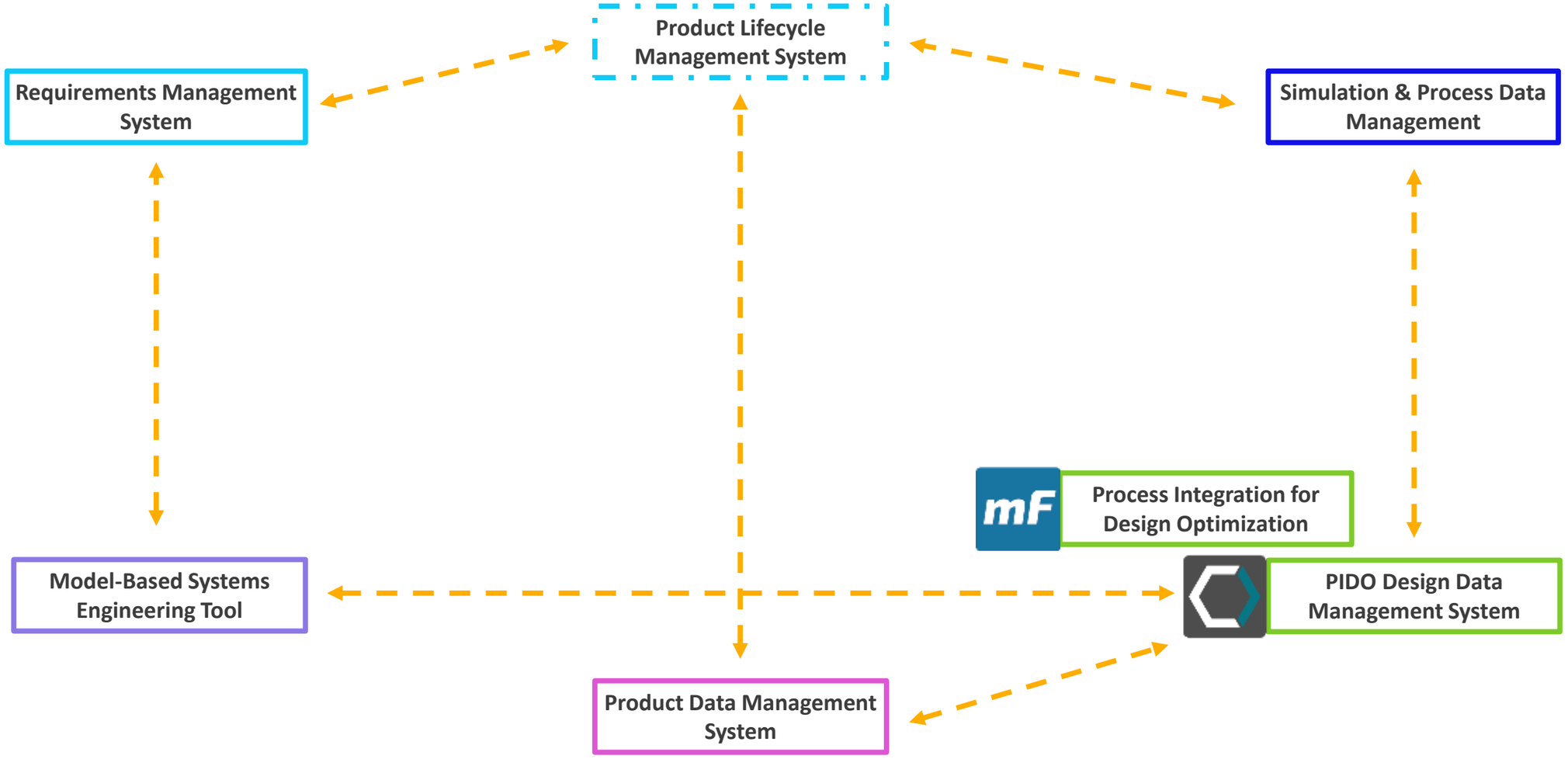

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AGILE Paradigm

Roles, Responsibilities, and Players

AGILE Roles

Customer:

- Specify Top Level Requirements
- Analyze Output
- Direct Reconfiguration (if required)

Architect:

- Manage Requirements
- Develop problem statement
- Develop solution process

Integrator:

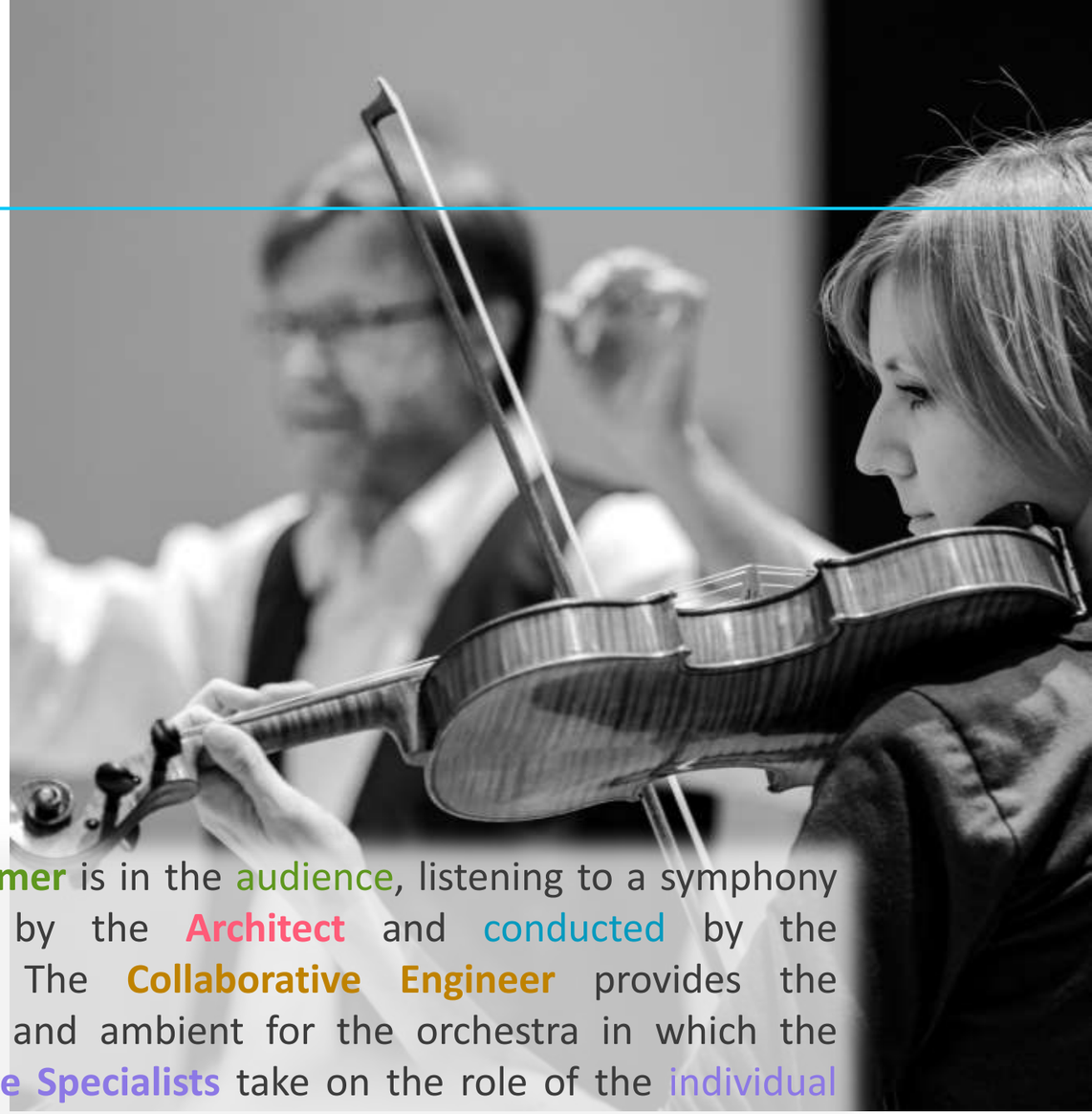
- Convert roadmap into executable workflow

Competence Specialists:

- Domain experts
- Develop individual analysis models

Collaborative Engineer:

- Supports Specialists in ensuring analyses are compliant with the requirements



"The **Customer** is in the audience, listening to a symphony composed by the **Architect** and conducted by the **Integrator**. The **Collaborative Engineer** provides the auditorium and ambient for the orchestra in which the **Competence Specialists** take on the role of the individual musicians."

-Moerland et. al.

Erwin Moerland, Pier Davide Ciampa, Sascha Zur, Erik Baalbergen, Nikita Noskov, Roberto D'Ippolito, Riccardo Lombardi, Collaborative Architecture supporting the next generation of MDAO within the AGILE paradigm, 2020 https://doi.org/10.1016/j.paerosci.2020.100637.

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Medtronic Players

Customer:

- Clinical and Regulatory Agents
- Program Manager
- Systems Engineer
- Product Design Engineer

Architect:

- Design Automation Engineer
- Modeling & Simulation Engineers
- Systems Engineer

Integrator:

- Design Automation Engineer

Competence Specialists:

- Modeling & Simulation Engineers
- CAD Designers

Collaborative Engineer:

- Systems Engineers
- Product Design Engineers
- Design Automation Engineer

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AGILE Paradigm

Roles, Responsibilities, and Players

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AGILE RACI

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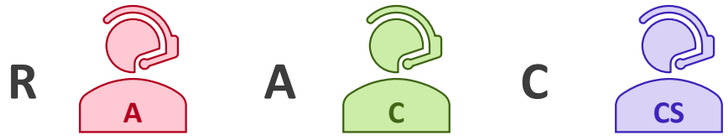
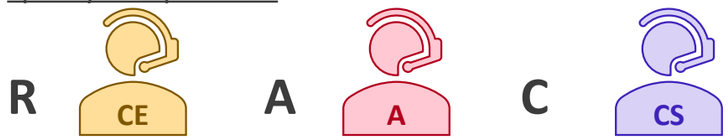


Step II: Specify Competences



Step III: Formulate Problem Statement & Inexecutable Workflow

Step IV: Develop Executable Workflow

Step V: Execute Workflow and Review Results

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AGILE Paradigm

Roles, Responsibilities, and Players

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AGILE Integrations & Tools

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Example Use Case

of the AGILE Paradigm for Product Development

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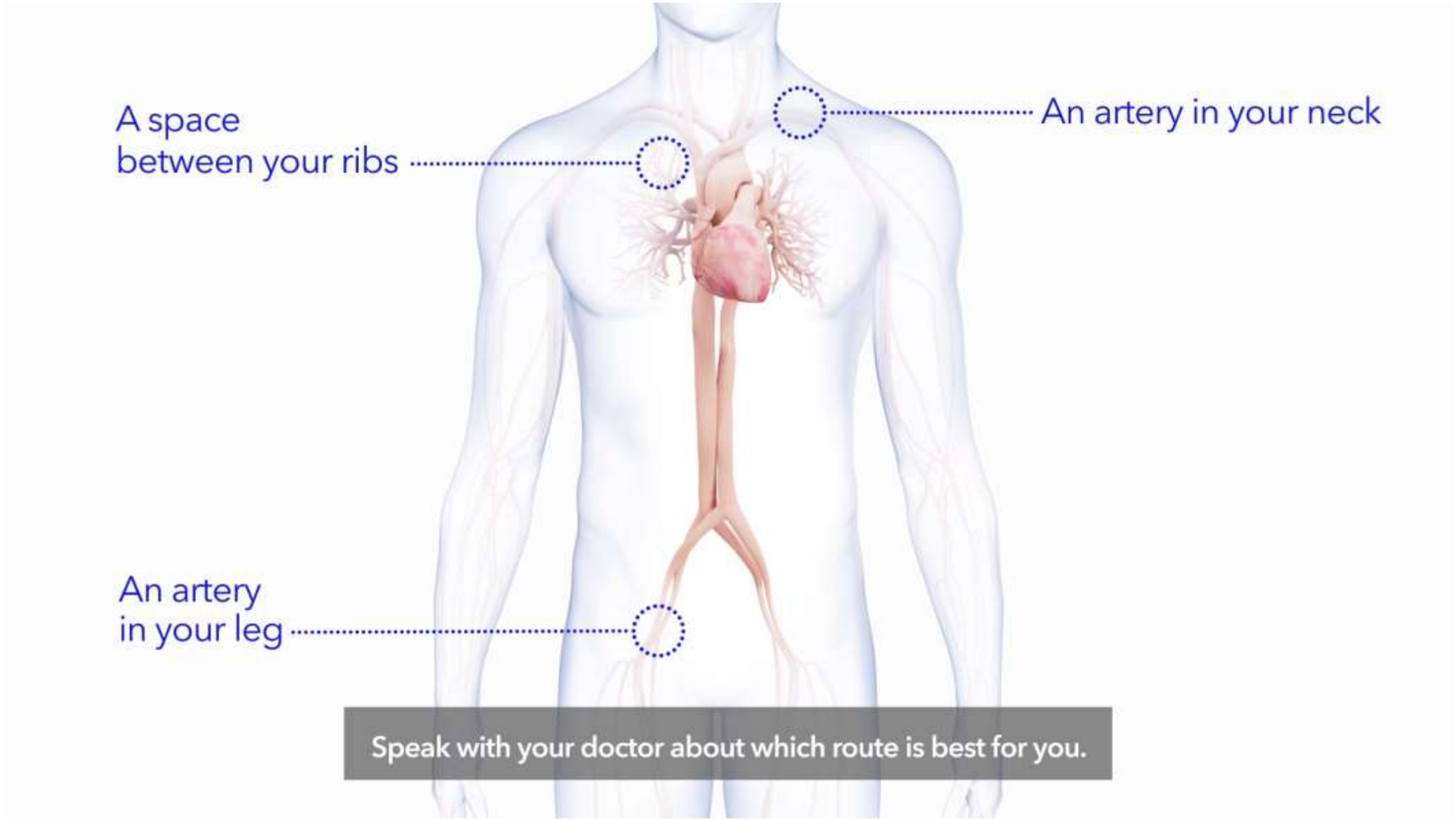
Transcatheter Valve Replacement

Device and Procedure Background



See full video on YouTube

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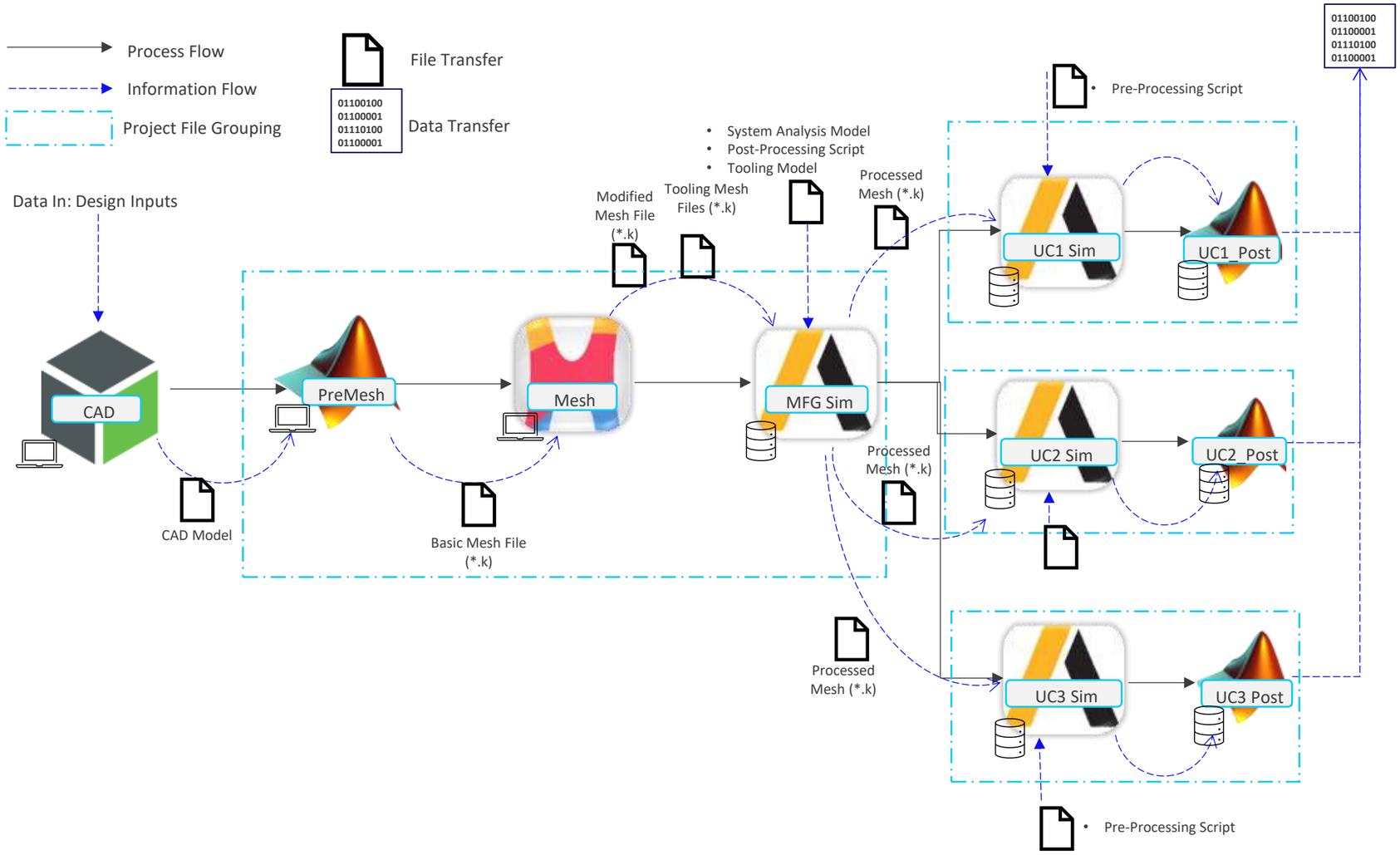
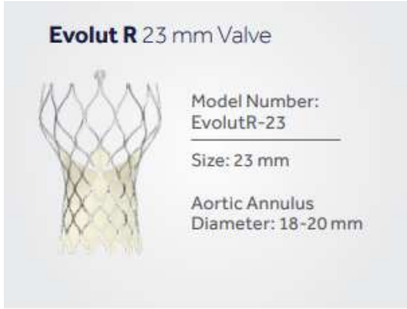
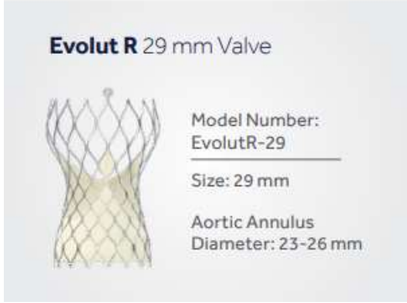
AGILE Knowledge Architecture

Workflow Architecture and Tools







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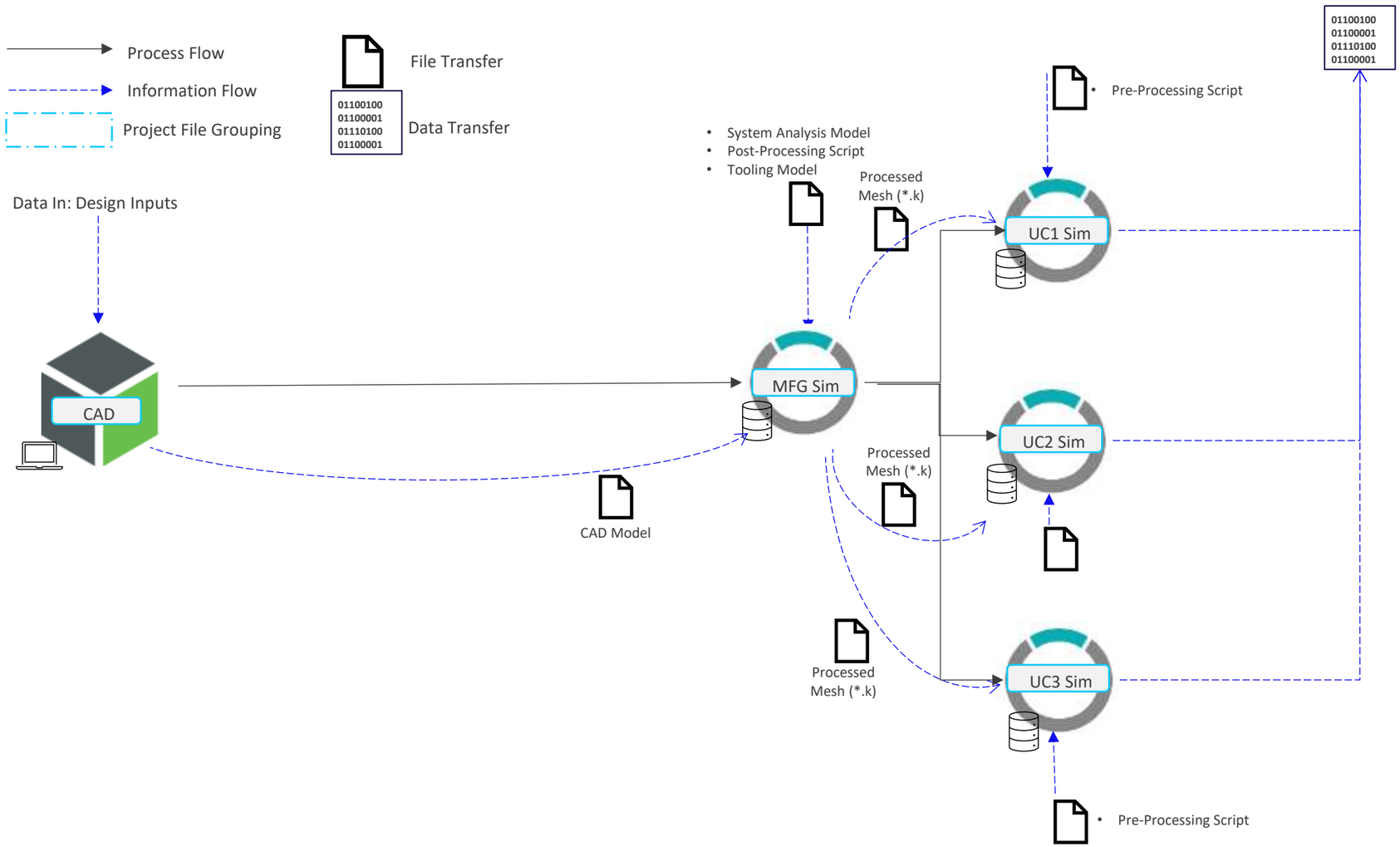
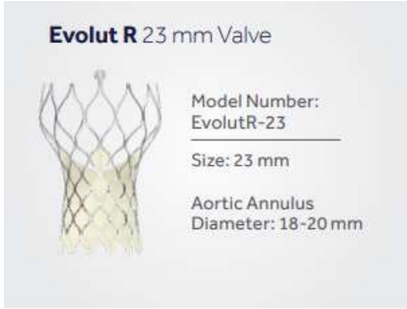
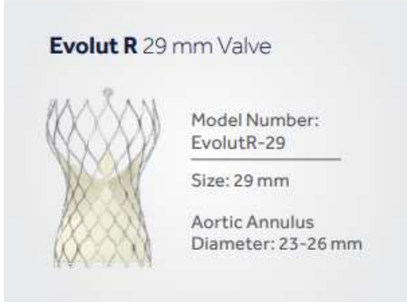
AGILE Knowledge Architecture

Workflow Architecture and Tools







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AGILE Collaborative Architecture

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Pr. R&D Engineer

Arric McLauchlan
Pr. Design Automation Engineer

Adithya Lakkur Venugopal
Sr. FEA Engineer

Arric McLauchlan
Pr. Design Automation Engineer

Amin Joukar
Sr. FEA Engineer

Adithya Lakkur Venugopal
Sr. FEA Engineer

Amin Joukar
Sr. FEA Engineer

Enda Boland
Sr. R&D Engineer

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Structural Heart Valve Design

Mult-Objective Design Optimization

Objectives:

- Minimize SI (Type 1)
- Minimize SI (Type 2)
- Maximize MR
- Maximize PE

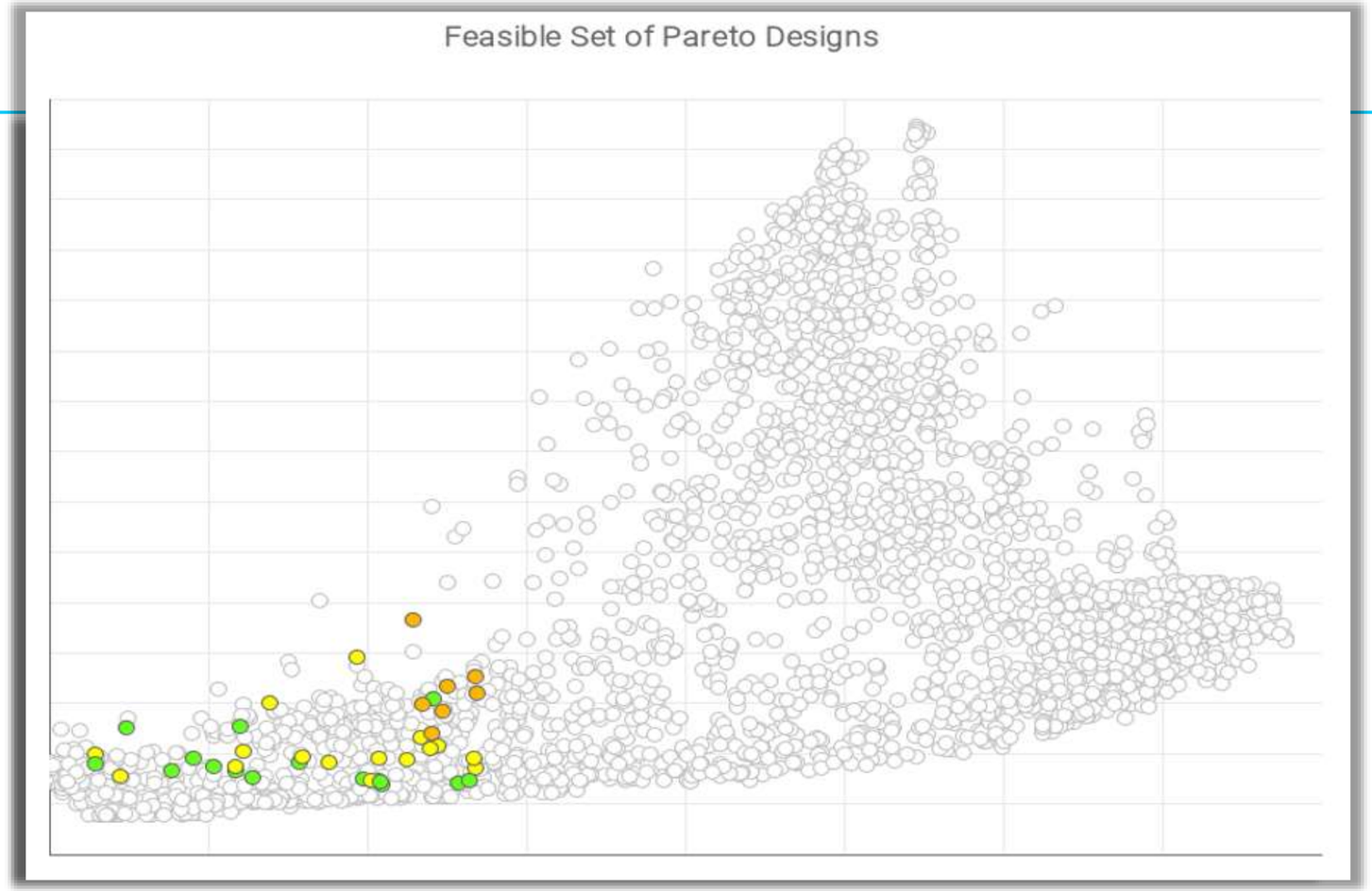
Optimization Algorithm:

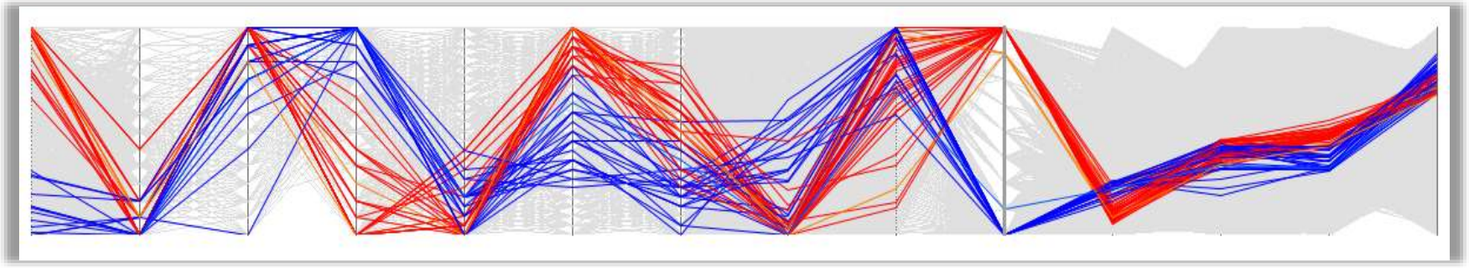
MOGA-II with ULH Space Filler

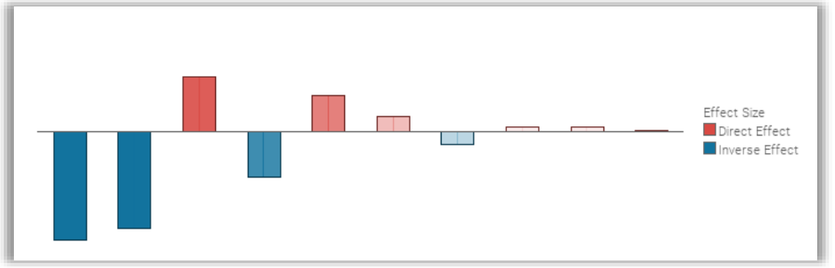
- 500 Generations
- 87 Agents

Results:

- 43,500 Designs Total
- 2,831 Non-Dominated Pareto Designs
- *39 Designs in Target Region*







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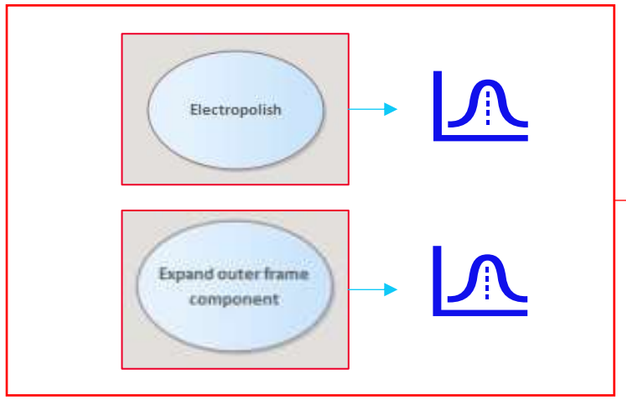
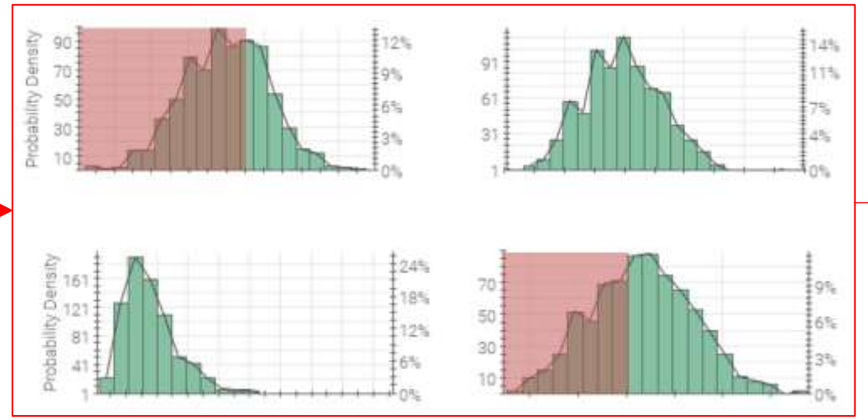
Structural Heart Valve Design

Multi-Objective Robustness Design Optimization



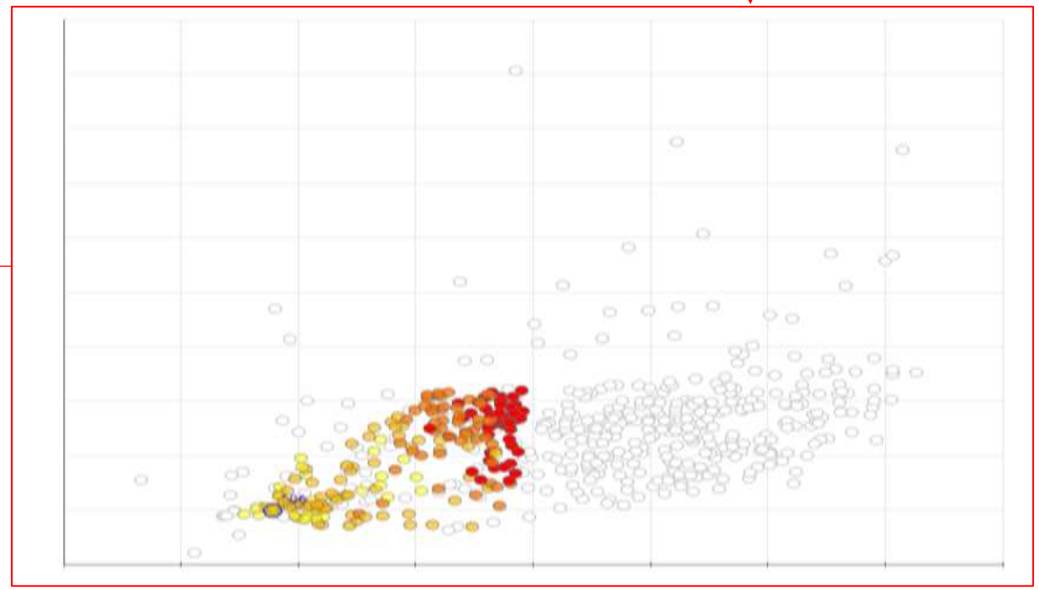


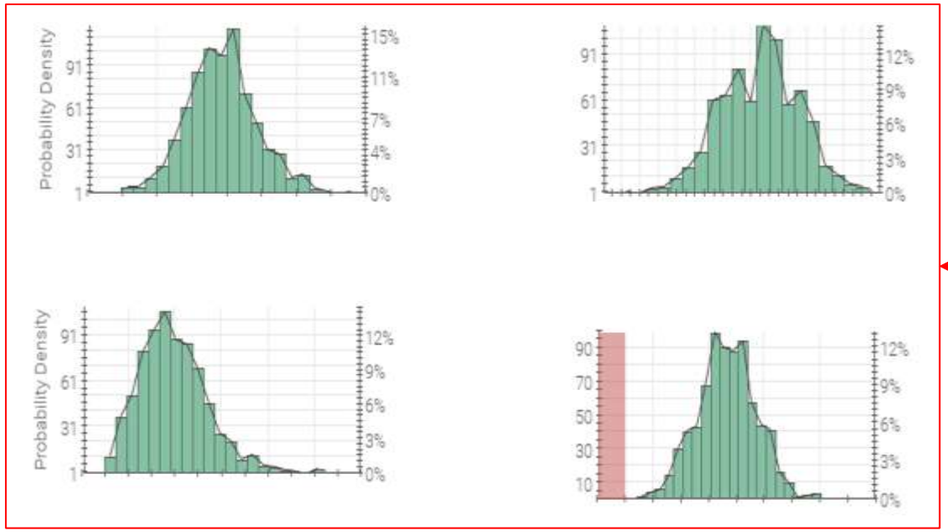
Objectives:

$$\max(\overline{PE})$$
$$\max(\overline{MR})$$
$$\min(\overline{SI_{Type1}})$$
$$\min(\overline{SI_{Type2}})$$

Constraints:

$$\overline{PE} - 3\sigma_{PE} \geq PE_{Min}$$
$$\overline{MR} - 3\sigma_{MR} \geq MR_{Min}$$
$$\overline{SI_{Type1}} + 3\sigma_{SI_{Type1}} \leq SI_{Max1}$$
$$\overline{SI_{Type2}} + 3\sigma_{SI_{Type2}} \leq SI_{Max2}$$





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AGILE Paradigm

Testimonials

“The collaboration process was seamless and highly impactful. By dividing responsibilities clearly, our team focusing on design and analysis, while [the Integrator] built and optimized the modeFRONTIER workflow, we were able to run large, complex DOE studies that would have otherwise taken much longer. The developed infrastructure not only automated repetitive tasks but also made the workflow robust and scalable, allowing us to explore more design space with greater confidence. This division of labor and the infrastructure [the Architect] provided had a direct impact on accelerating our program, enabling faster iteration and more informed design decisions.”

This is a prime example of Medtronic playing big and leveraging its vast pool of technical talent. Our team has invested in a LS DYNA FEA workflow to speed up iteration and innovation. modeFRONTIER integration has built our existing workflow into a DOE power house coming online with multiple design limit DOE’s just in time for our Phase 0 exit and Phase 1 work. Our speed through Phase 1 with an innovative design has a chance to be extremely fast, in part due to this collaboration.

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Engineering the extraordinary

Thank You!

References

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