MEDxD – Medtech meets Digital 2024

Hands-on Workshop (07.11.2024, 14:30-16:30): Systems Engineering für die Medizintechnik

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Digital Enterprise & Academics

https://medtechx.digital/

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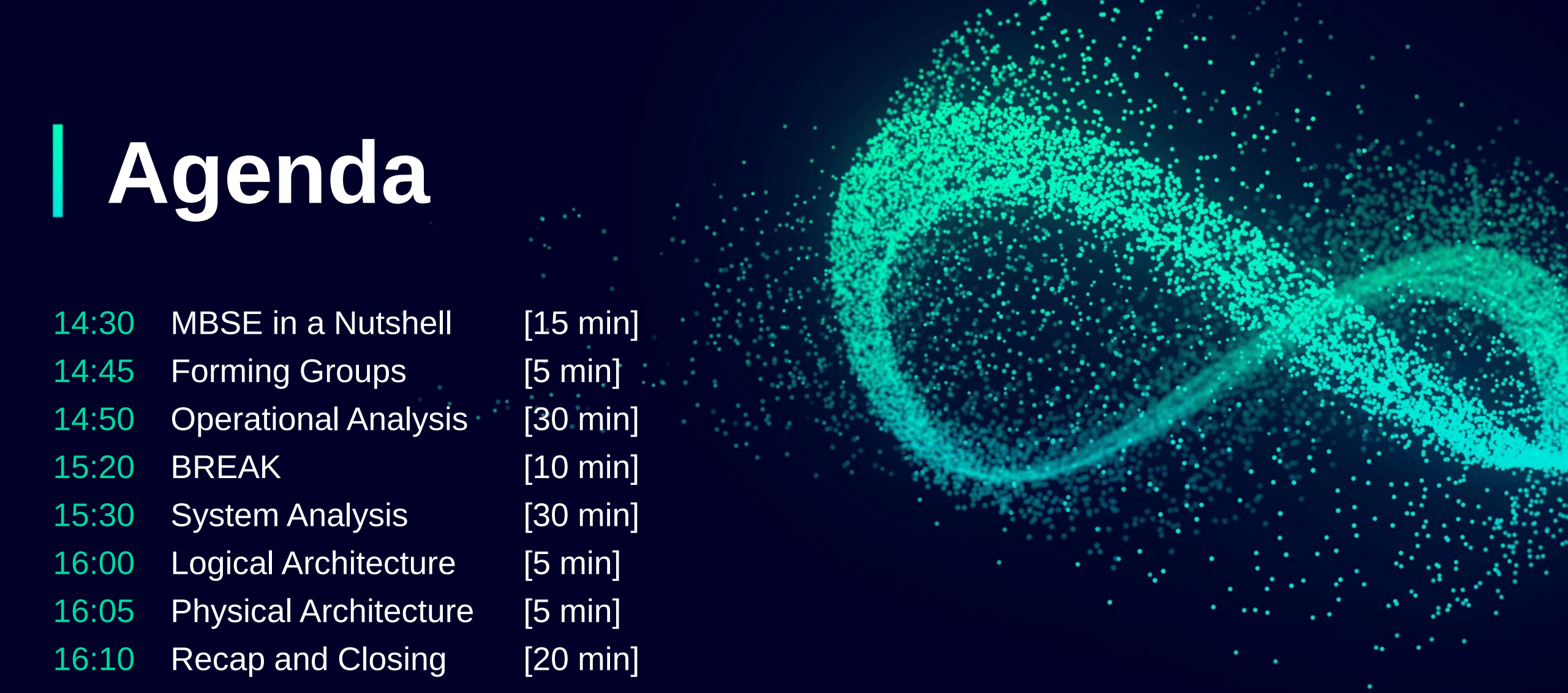
Agenda

14:30	MBSE in a Nutshell	[15 min]
14:45	Forming Groups	[5 min]
14:50	Operational Analysis	[30 min]
15:20	BREAK	[10 min]
15:30	System Analysis	[30 min]
16:00	Logical Architecture	[5 min]
16:05	Physical Architecture	[5 min]
16:10	Recap and Closing	[20 min]



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Model-based Systems Engineering (MBSE)

Short Introduction

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Global megatrends according to INCOSE and the need for Ecosystems

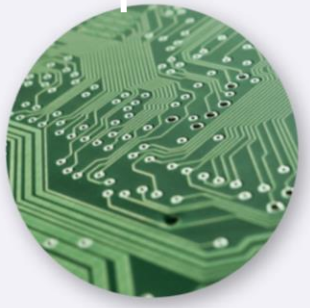
Lifecycle-spanning topics ask for a wider perspective in Systems Engineering.

"Digital" is the new standard for Systems like products, companies or infrastructure.

SD-X (software defined everything) is one of the key-paradigms and enabler for Smart Systems.

1. Sustainability

2. Interdependent World

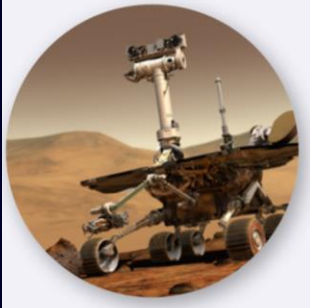


3. Digital Transformation

4. Industry 4.0/ Society 5.0

5. Smart Systems

All megatrends have in common, that they add to the already high complexity of Systems as well as their Engineering.



6. Complexity Growth

Systems of Systems emerge and interrelate over boundaries of countries, industries and domains.

Systems Engineering successively extends its viewpoints to fields like Manufacturing or Lifecycle Engineering.

Adapted from INCOSE Systems Engineering Vision 2035, p. 3

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Systems Engineering is a transdisciplinary and integrative approach to enable the successful realization, use, and retirement of engineered systems, using systems principles and concepts, and scientific, technological, and management methods.

INCOSE Systems Engineering Handbook, 5e (2023)

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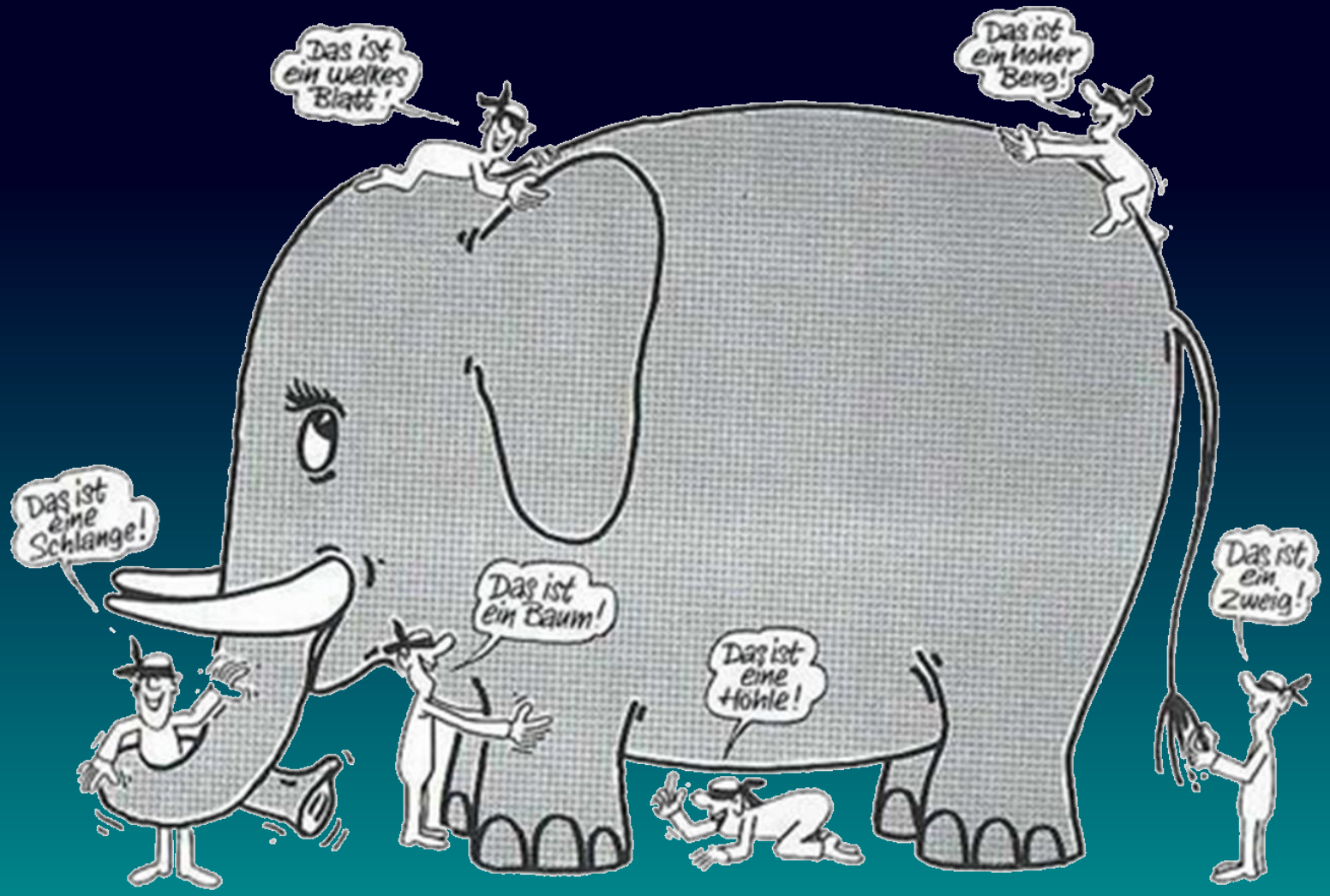
System Theory – Today it is often not easy for the individual to interpret details correctly and to recognize the big picture



System Thinking means the capability to view and describe Systems holistically.

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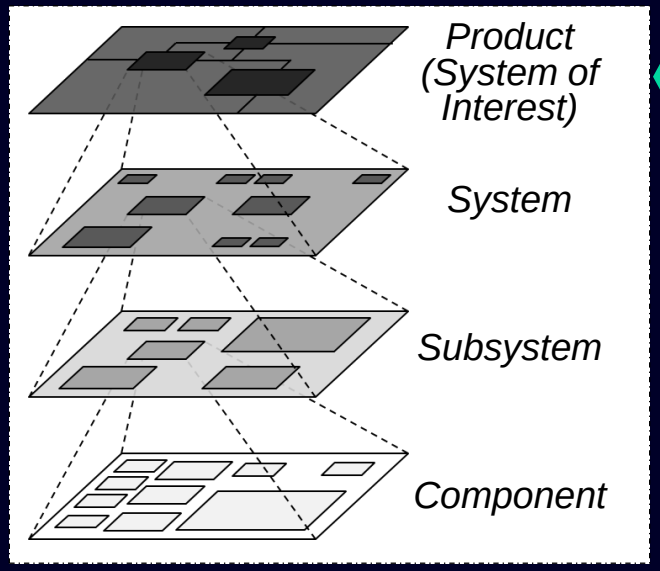
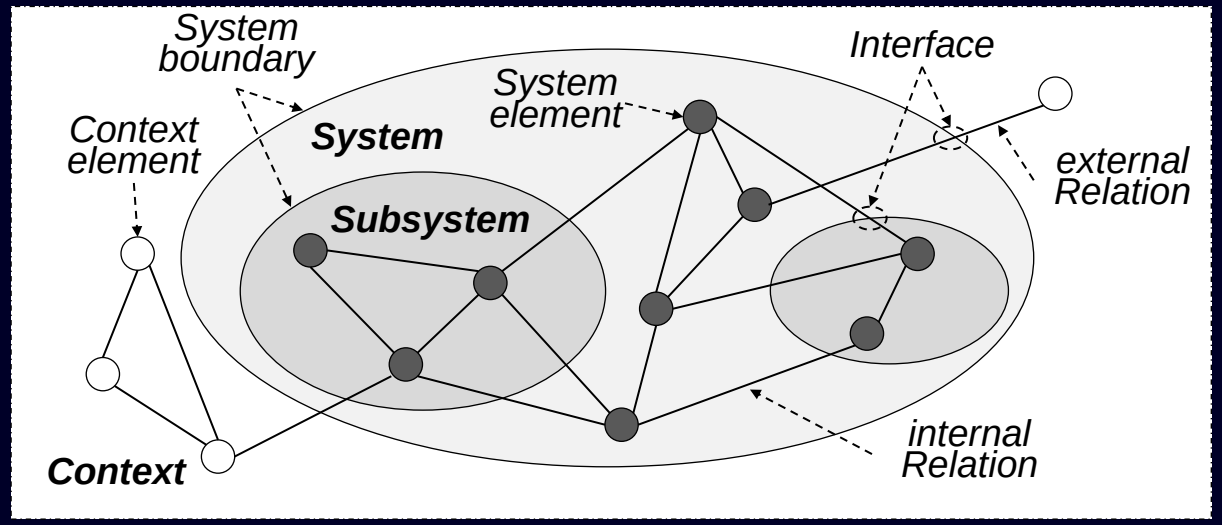
A **System** is an arrangement of parts or elements, that together exhibit a stated behavior or meaning, that the individual constituents do not.



Hierarchical Decomposition

Systemic Decomposition



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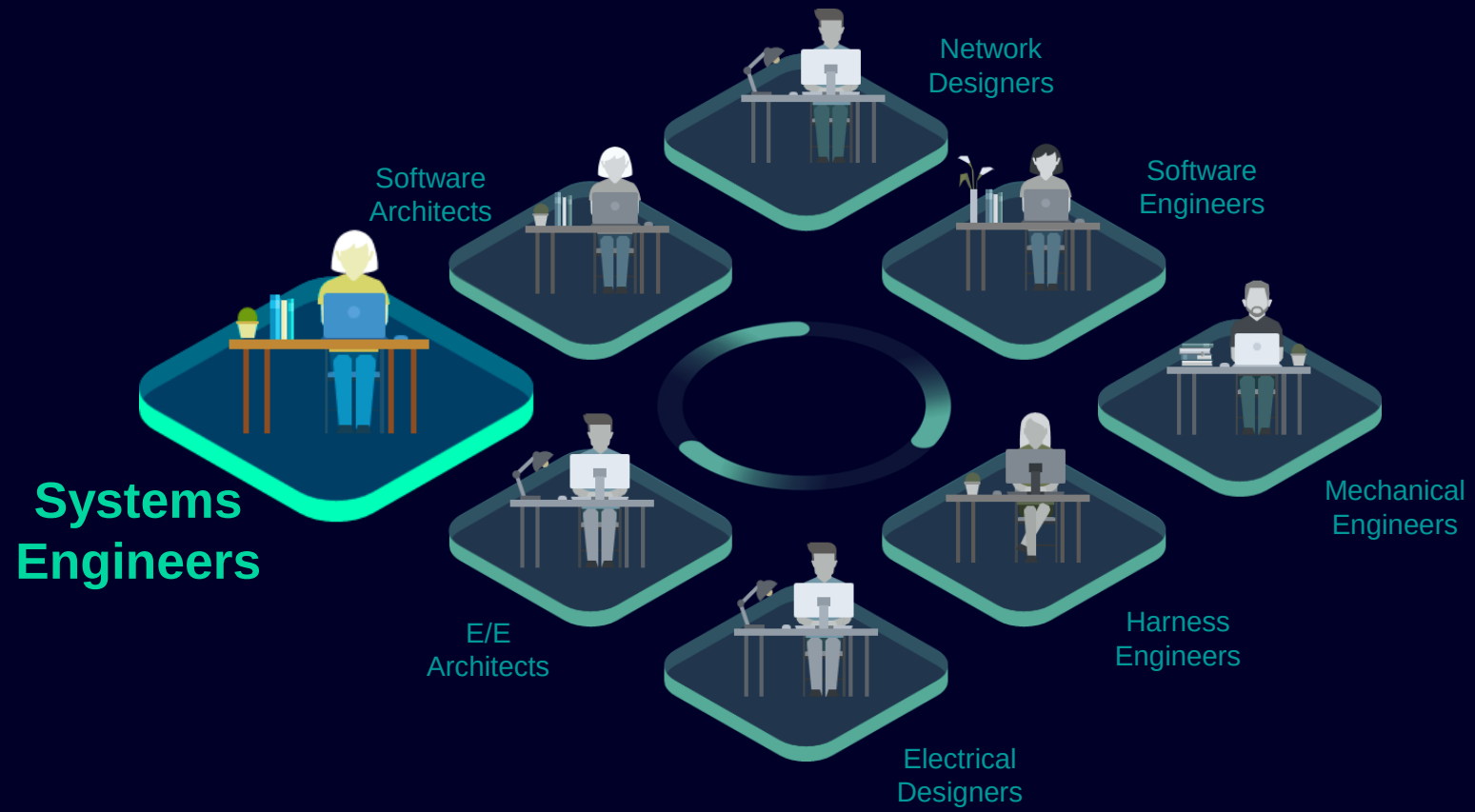
Collaboration across functional domains



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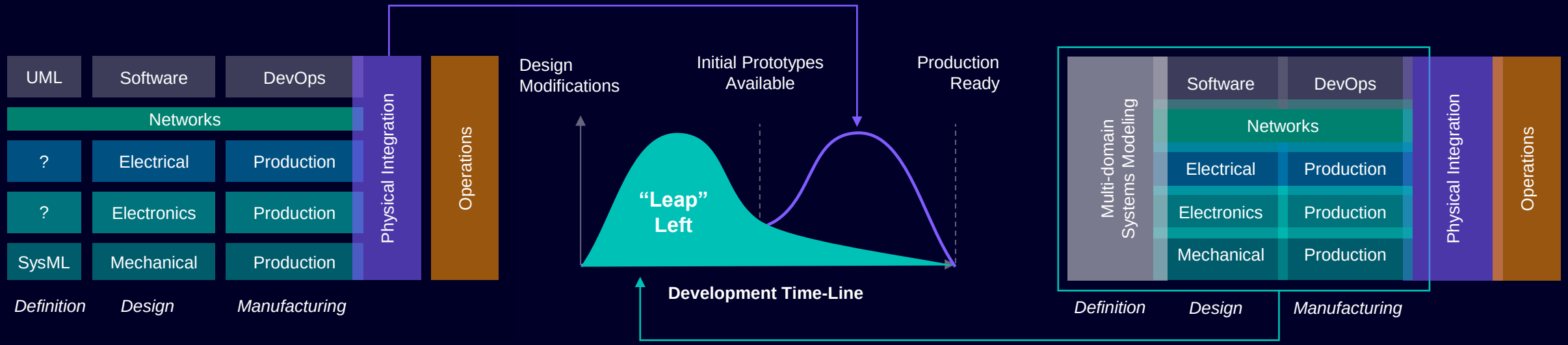
Connecting the Systems Engineering digital thread
Turning complexity into your competitive advantage

Today –
Disconnected, manual, siloes
“Build-then-integrate”

Tomorrow –
Integrated agile
“Integrate-then-build”



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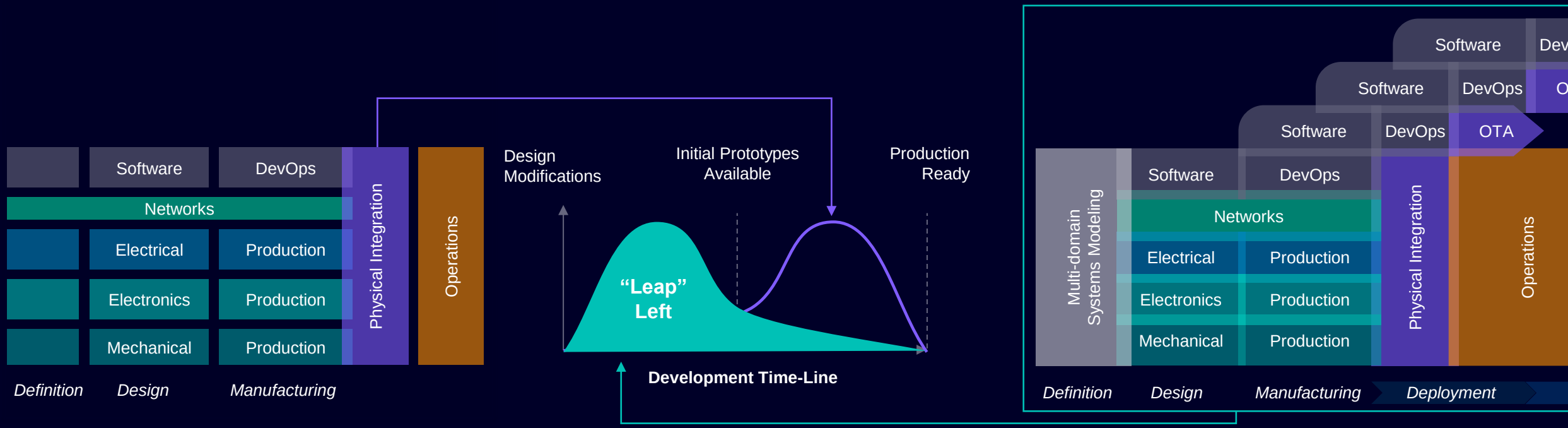
Connecting the Systems Engineering digital thread
Turning complexity into your competitive advantage

Today –
Disconnected, manual, siloes
“Build-then-integrate”

Beyond Tomorrow –
Integrated agile
“Build-then-deploy-&-iterate”



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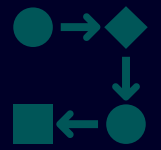
(Model-Based) Systems Engineering (INCOSE Definitions from 2023)

Systems Engineering (SE)

… is a transdisciplinary and integrative approach to enable the **successful realization, use, and retirement of engineered systems**, using systems principles and concepts, and scientific, technological, and management methods.



Model-Based Systems Engineering (MBSE)

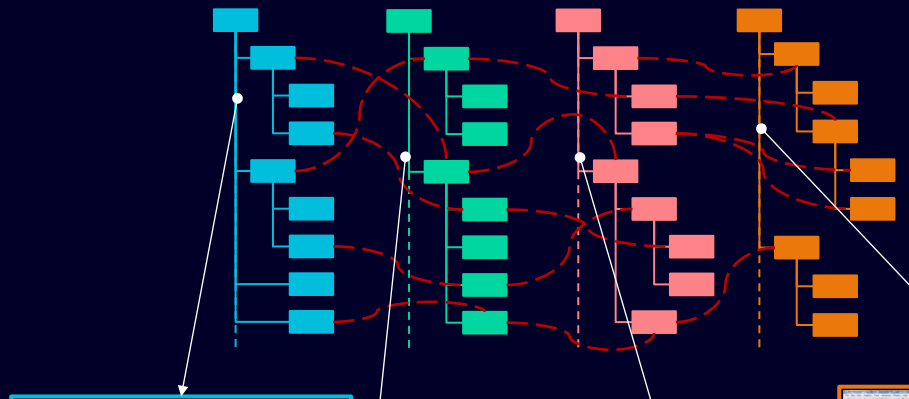
… is the **formalized application of modeling** to support system requirements, design, analysis, verification, and validation activities beginning in the [concept stage] and continuing throughout development and later life cycle [stages].

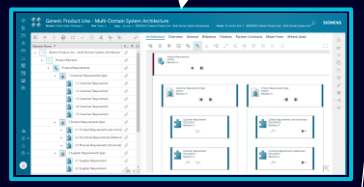
INCOSE Systems Engineering Handbook, 5e (2023)

Why MBSE? – Paradigm shift towards Multi-domain System Architecture and a Central System Model

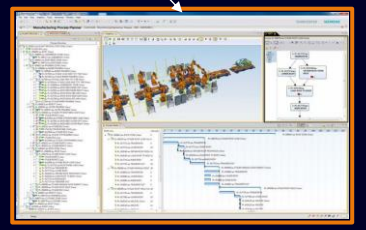
The “old” document-centered BOM-world

“Connected” Structures

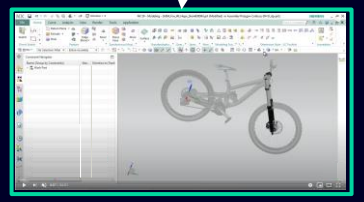




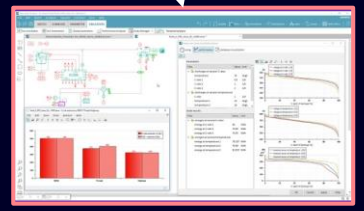
Requirements



Manufacturing



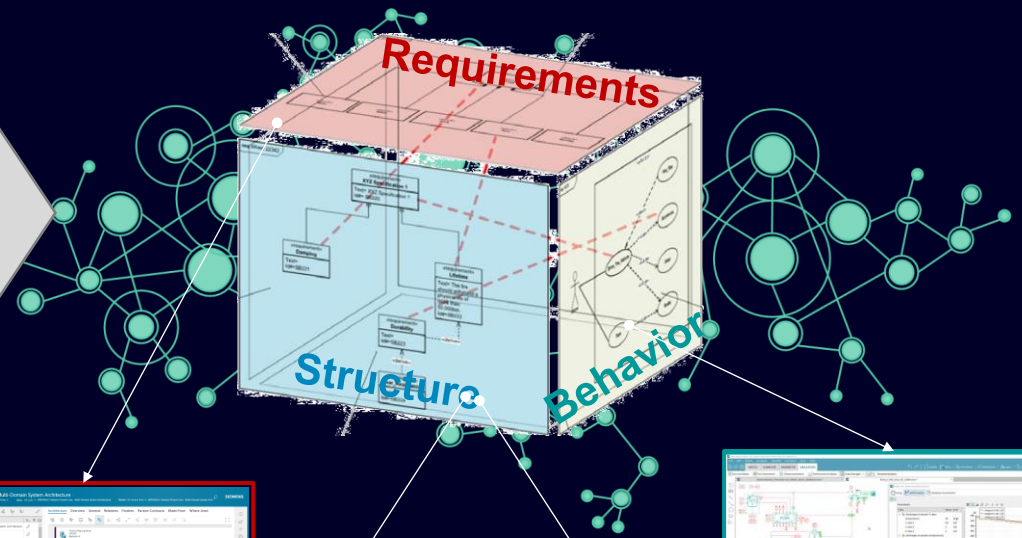
Design

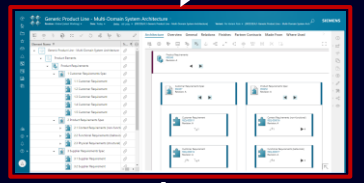


Simulation

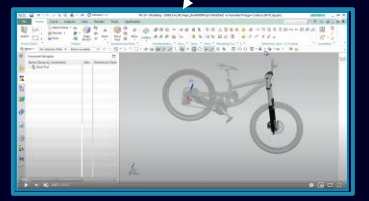
The “new” system-centered Model-world

Central System Model

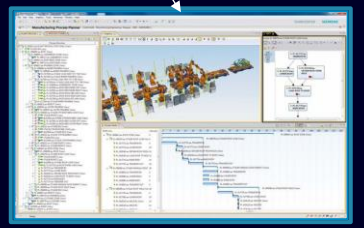




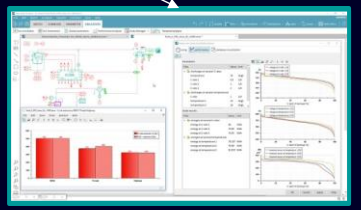
Requirements



Design



Manufacturing



Simulation

Source Cube-Image: Pfenning, M.; Muggeo, C.: „Die Rolle von MBSE und PLM im Industrie 4.0“, in: Schulze, S.; Muggeo, C. (Hrsg.): Tag des Systems Engineering, Hanser Verlag, München 2015, S. 279-287.

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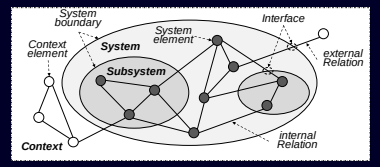
Core perspectives of the System Model

System views with interfaces are key in MBSE-perspectives



MBSE represents a particular way of thinking and mindset, strongly influenced by system thinking, which especially provides support for the innovative creation of products.

R, F, L and P provide different **views** on the same system in terms of purpose, degree of detail and hierarchy level.

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"It is the **relationships** between the elements that give the system its **added value**."

(Eberhardt Rechtin)

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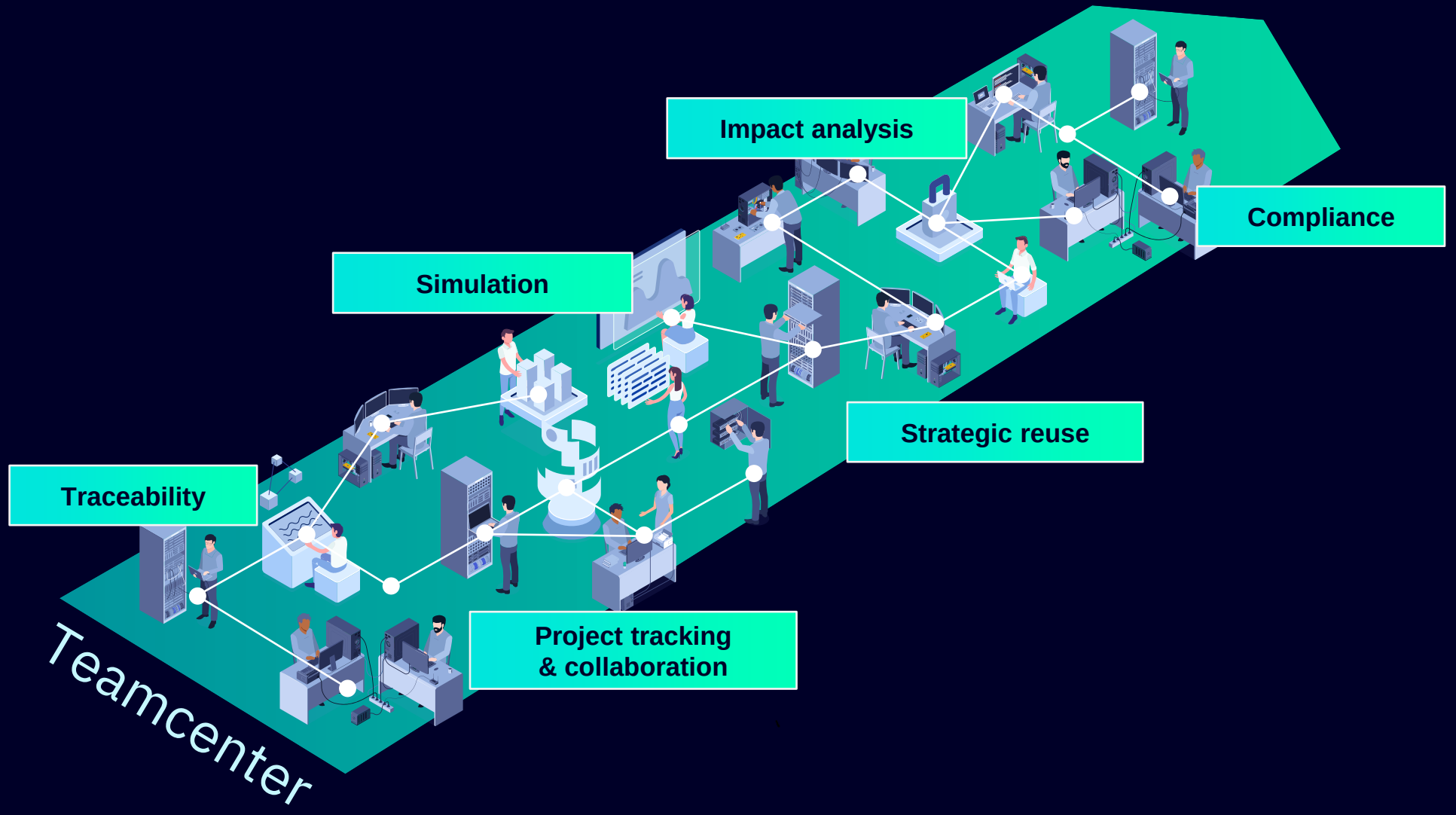
Integrated model-based Systems Engineering helps break down silos and creates a comprehensive digital thread



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Hands-On Workshop

Systems Engineering for Medical Device Industry

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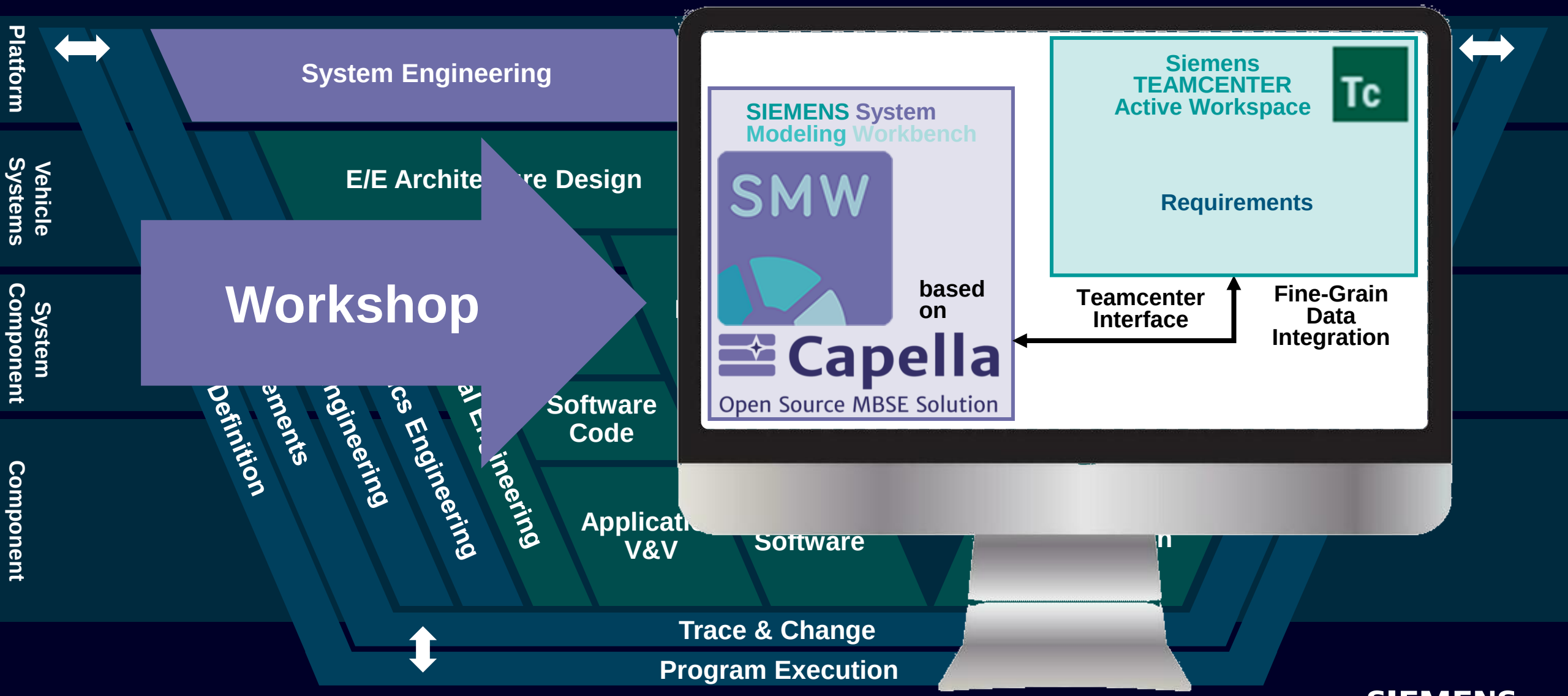
Multi Domain System Architecture Modelling by SMW

SIEMENS System Modeling Workbench



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Task: Create a first multi-domain System Architecture for an Insulin Pump based on given User Needs / Requirements

Product overview:

An **insulin pump** is a small portable device, which provides continuous delivery of insulin (pre-programmed or sensor-based) through a catheter. Insulin delivery covers basal dose (small amount for all day base demand) as well as bolus dose (additional demand for meals and corrections).

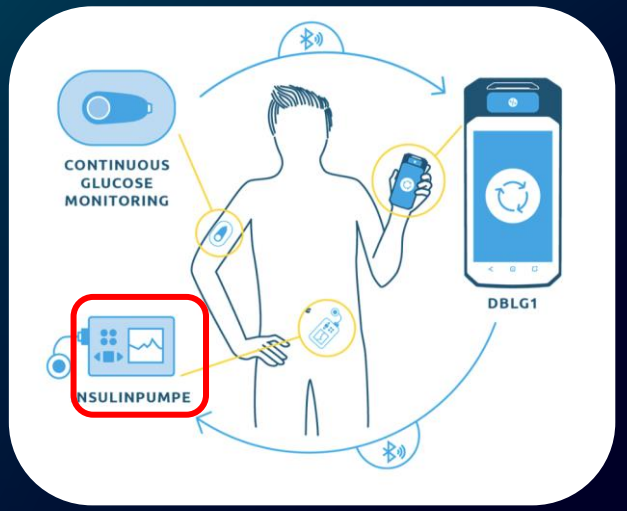
A pump replaces the need for multiple daily injections and can help to improve the patients blood sugar levels.

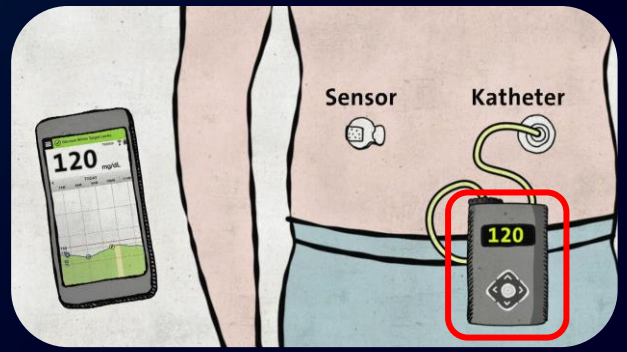
Insulin pumps are programmable and can be combined with devices for continuous glucose monitoring (CGM) and diabetic apps.

System Context:

The pump is part of the System of Systems "**Automated insulin delivery system**" when combined with the **CGM sensor**, **catheter** and **mobile diabetic app**.

Therefore respective interfaces are necessary.





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Bildquelle 2:

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Bildquelle 3:

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Bildquelle 4:

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Requirements Overview – Stakeholder Needs & Requirements

Clinical / medical Requirements

- Medical personnel must be able to install and start the Automated Insulin Delivery System (AIS) after respective training within a timeframe of 5 min.
- Pump must provide continuous deliver of insulin with accuracy of 5%.
- Pump programming must allow different basal and bolus doses.
- Pump must allow manual triggering of individual bolus doses with respective user guidance.
- Users must be able to refill the pump either by sterile self-filling or prefilled and disposable consumables.
- Alarms in sound, visual and vibration must be provided by the pump in case of a) values outside the safe zone, b) lost connection to CGM.
- Capacity for fluid insulin in the pump must be min. 3 ml / 300 units, separated by basal insulin and bolus insulin.

User Requirements

- User interface of pump must be easy to read.
- User interface of pump must have a lock function.
- User interface of pump must prevent accidental misuse.
- User interface of pump must guide user in programming process.
- User interface of pump must at least provide information on: previous/current/next dose, total units per dose, set alarms, battery level, cartridge level, time to replace infusion set, connectivity status of CGM and app.

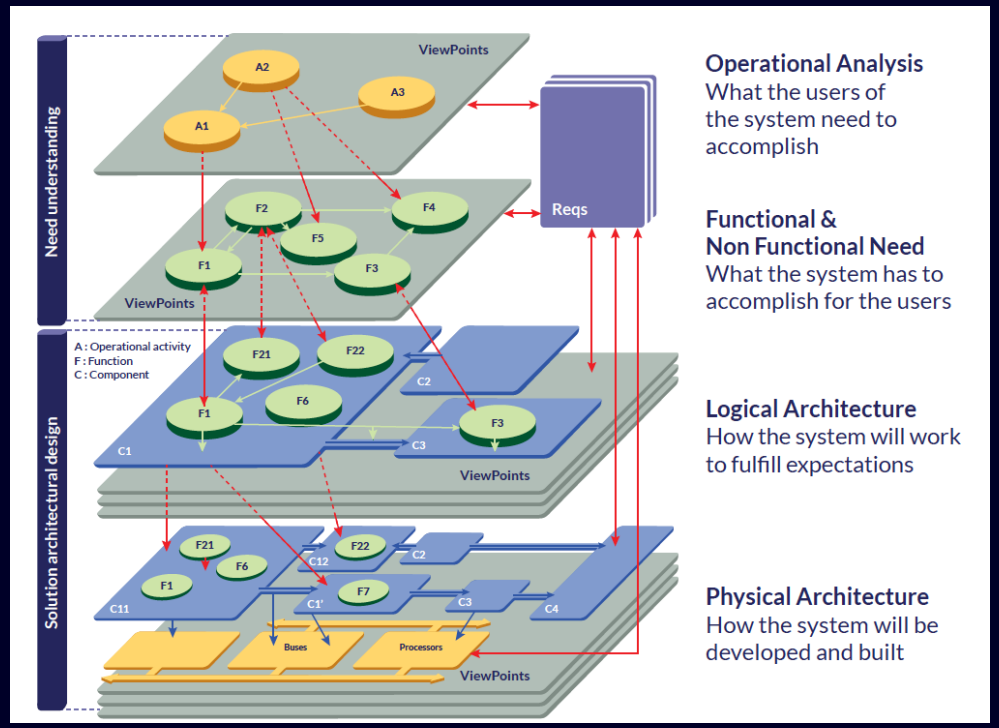
Technical Requirements

- Pump must handle to receive CGM measurement value every 5 seconds.
- If CGM measurement value is within the safe zone (70 - 140 mg/dL (3,9 - 7,8 mmol/L)), insulin shall be delivered by pump according to a predefined / programmed delivery plan.
- If CGM measurement value is below the safe minimum, no insulin shall be delivered by pump.
- If CGM measurement value is above the recommended value, insulin shall deliver continuously by pump until the value is back into the desired corridor.
- Performance of pump must be at least 35 units/hour.
- Main power supply of pump must last at least 48 h.
- User must be able to self change/charge the main power supply of pump.
- Backup power supply of pump must ensure pump function while main power supply is changed for min. 10 min.
- Pump must provide sterile interface to catheter.
- Pump-catheter-interface must ensure sterile catheter exchange.
- Pump must provide cableless interface to CGM and app.
- Pump must safe insulin delivery history for min. 90 days.

MBSE-Modeling – Overview of ARCADIA Method's Perspectives

Full-scale Multi-domain System Architecture

- Product centered system architecture
- Based on RFLP-Concept and partially derived from standards like SysML v1 (but no interoperability)



ARCADIA Project Phases

Operational Analysis captures entire problem and helps identify the "System" with its boundary and context including its Requirements. System is treated as a "black box".

(Functional) System Analysis identifies the functions needed to be addressed by the "System", e.g. to address the system requirements. Start to treat System as a "white box".

Logical Architecture develops an abstract conceptual design that can satisfy the needs of the System by decomposing System Functions into Logical Functions and Allocating them to Logical Components.

Physical Architecture identifies the physical components that can satisfy the conceptual design, by decomposing the logical functions and allocating them to physical hardware and software components.

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Groups

Moderator

Group 1

Andreas Otte

Moderator

Group 2

Martin Michel

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How does MBSE work? – Operational Analysis with Requirements Engineering

Operational Analysis with Requirements Engineering

- Take a **black-box** perspective on the potential system
- Look at the potential system from the **outside**
- Think about **system boundary**, to define the "**system of interest**"
- Consider which framework conditions and stakeholders in the **System Context** might affect the potential system
- Define **UseCases** and **Activities** of the System itself and of Stakeholders in the System Context, that impact the system
- Collect or derive System and Stakeholder **Requirements** and **connect** them to the use cases with tracelinks

Questions to ask:

- What is the focus of our system of interest perspective, meaning do we look at a whole system or maybe only at one of its subsystems?
- What UseCases and Activities are associated with the potential system, and how do they affect each other?
- Which Requirements are already known or can be derived from the UseCases or Activities, that are recognized on this level?

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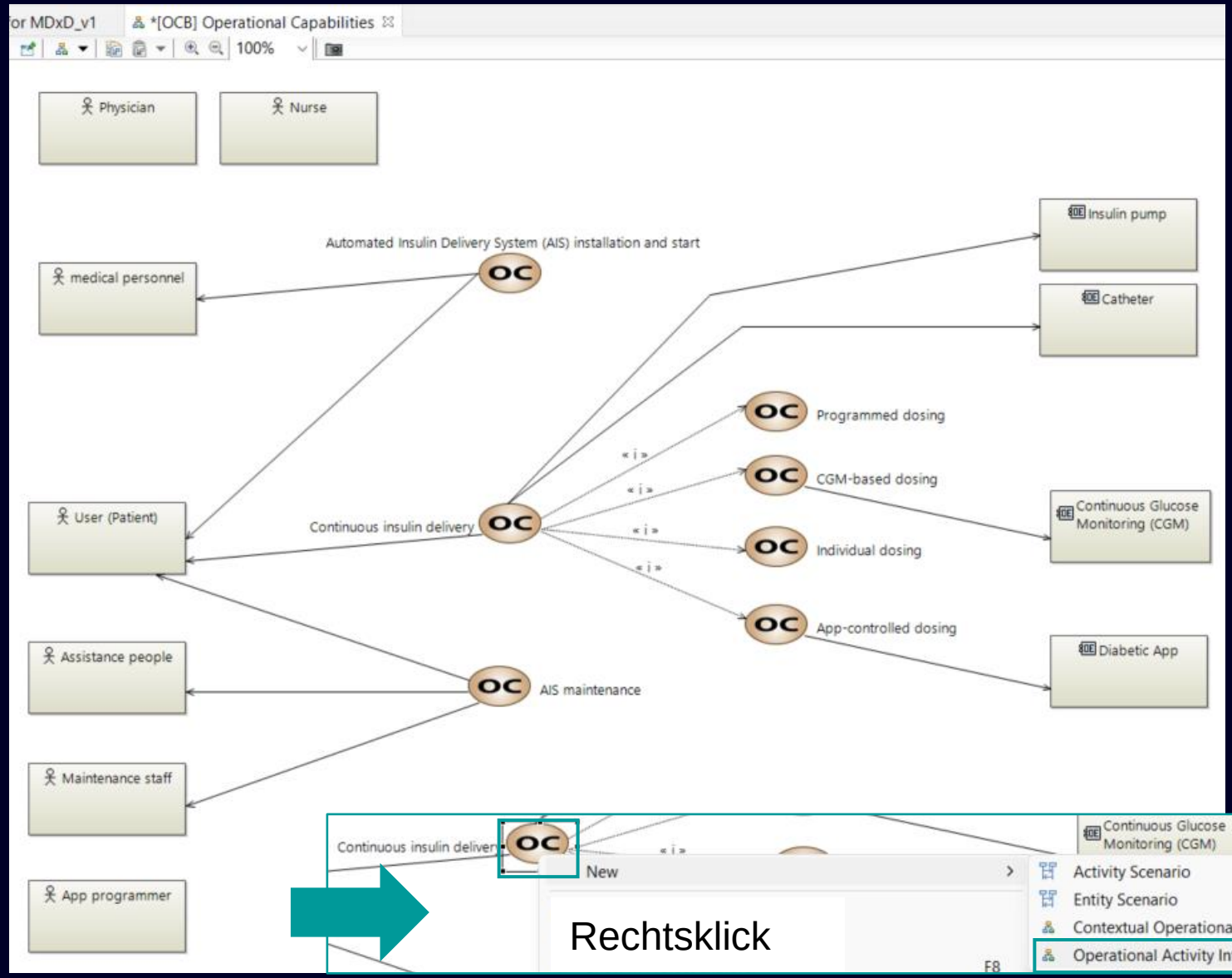
Operational Analysis – Workshop Task [30 min]

[OCB] Create a new Operational Capabilities diagram



Stakeholders: User, medical personnel, assistance people, maintenance staff, physician, app programmer, …

Capabilties: Continuous insulin delivery (includes: programmed dosing, CGM-based dosing, individual dosing, app-controlled dosing), AIS installation and start, pump maintenance, emergency operation, …

Create an Operational Capabilities Diagram …

- … to identify Stakeholders (Actors & Entities) of the potential system = insulin pump
- Describe the main Capabilities (Operational Capabilities) to which your System will contribute or will be provided by your system to the stakeholders
- Show, which Stakeholders are involved in which capabilities

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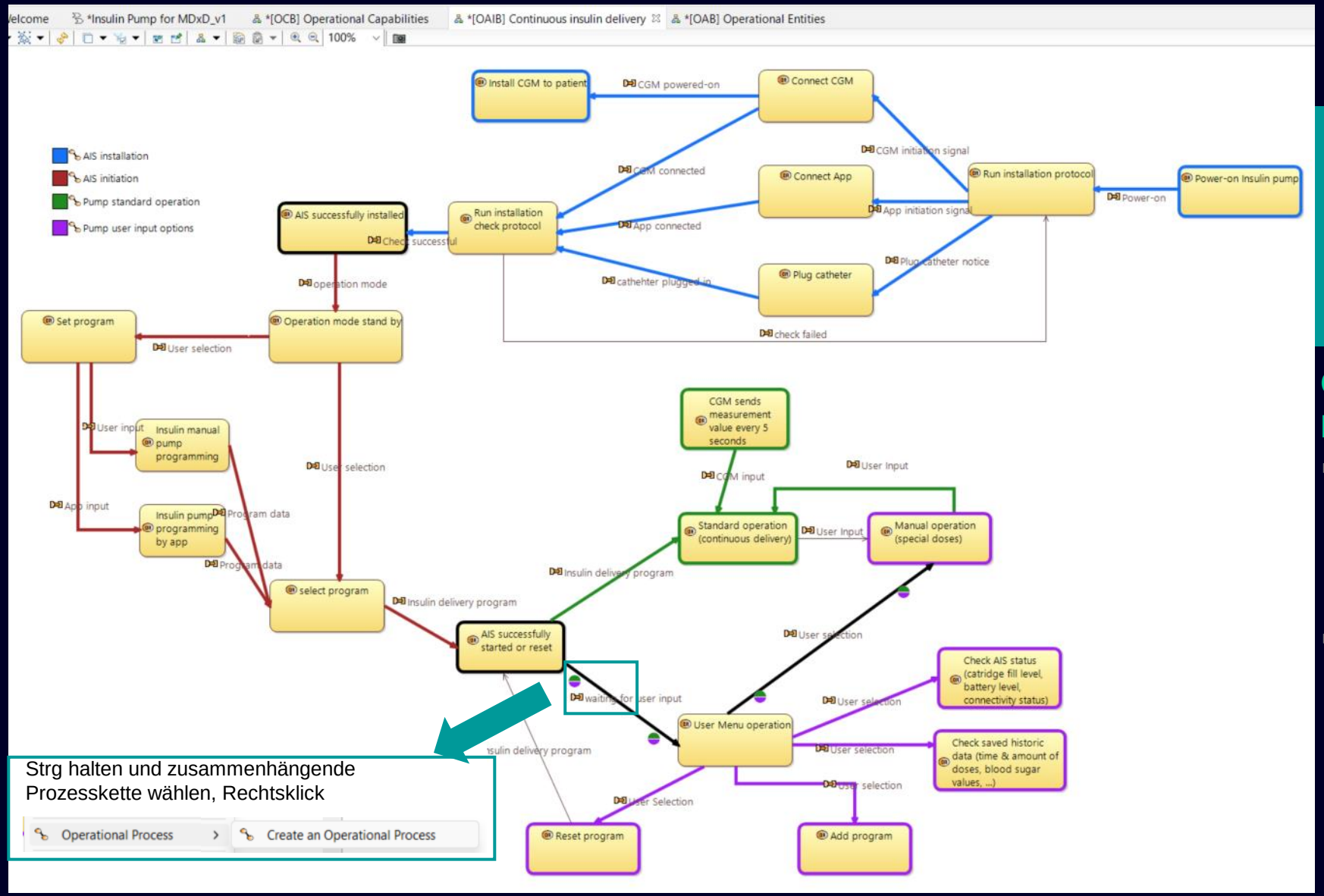
Operational Analysis – Workshop Task [30 min]



[OAIB] Create a new Operational Activity Interaction diagram

Stakeholders: User, medical personnel, …

Capabilities: Continuous insulin delivery (includes: programmed dosing, CGM-based dosing, individual dosing, app-controlled dosing), AIS installation and start, pump maintenance, …

Create an Operational Activity Interaction Diagram

- … to describe the expected behavior of stakeholders in the context of your capabilities using Activities and Interactions
- Optional: Create operational Processes to show some of the main Use Cases of the AIS / pump

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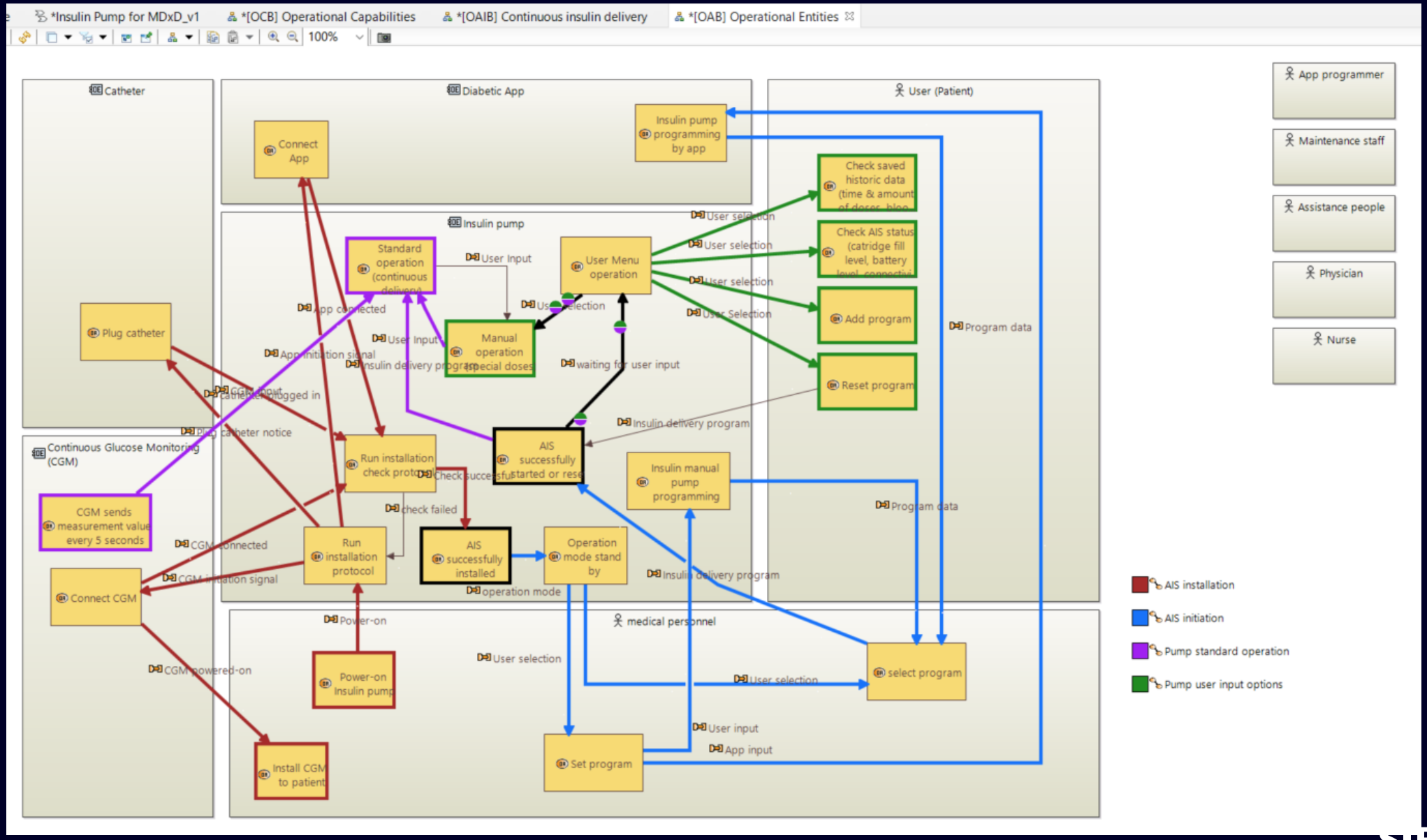
Operational Analysis – Workshop Task [30 min]



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How does MBSE work? – System Analysis with Functional Perspective

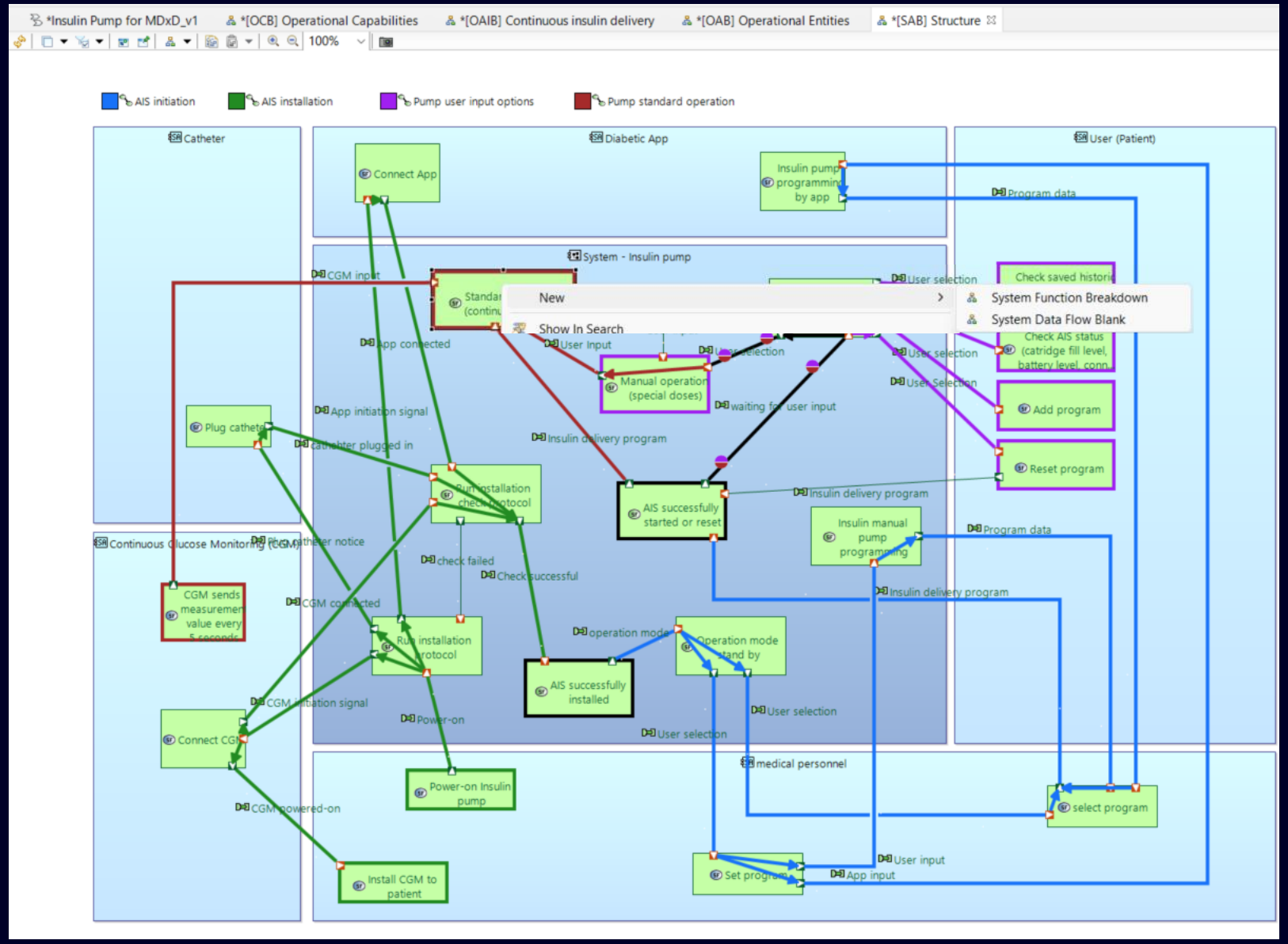
System Analysis with Functional Perspective

- Set **the system boundary** of the current **system of interest**
- Define the purposes of the system and its future parts by describing their **functions** and, if necessary, **decompose** these functions
- Describe the **interconnections** and **flows** between the functions
- **Connect** the functions with requirements and use cases or activities, which are derived from each other, with tracelinks

Questions to ask:

- Finally decide for the current modeling iteration, what will be considered as system of interest? (System vs. Subsystem vs. Component)
- What is the desired behavior of the system of interest?
- Which functions must or shall the System of Interest fulfill from System and Stakeholder Perspective?
- Which dependencies do exist between these functions?

System Analysis – Workshop Task [30 min]



[SAB] Create a new System Architecture diagram

Create a System Architecture Diagram …

- … to allocate the Stakeholder behavior to the respective stakeholders and the system functions to the system
- Target: Get an overview of functional exchanges of system and stakeholders and the system boundary

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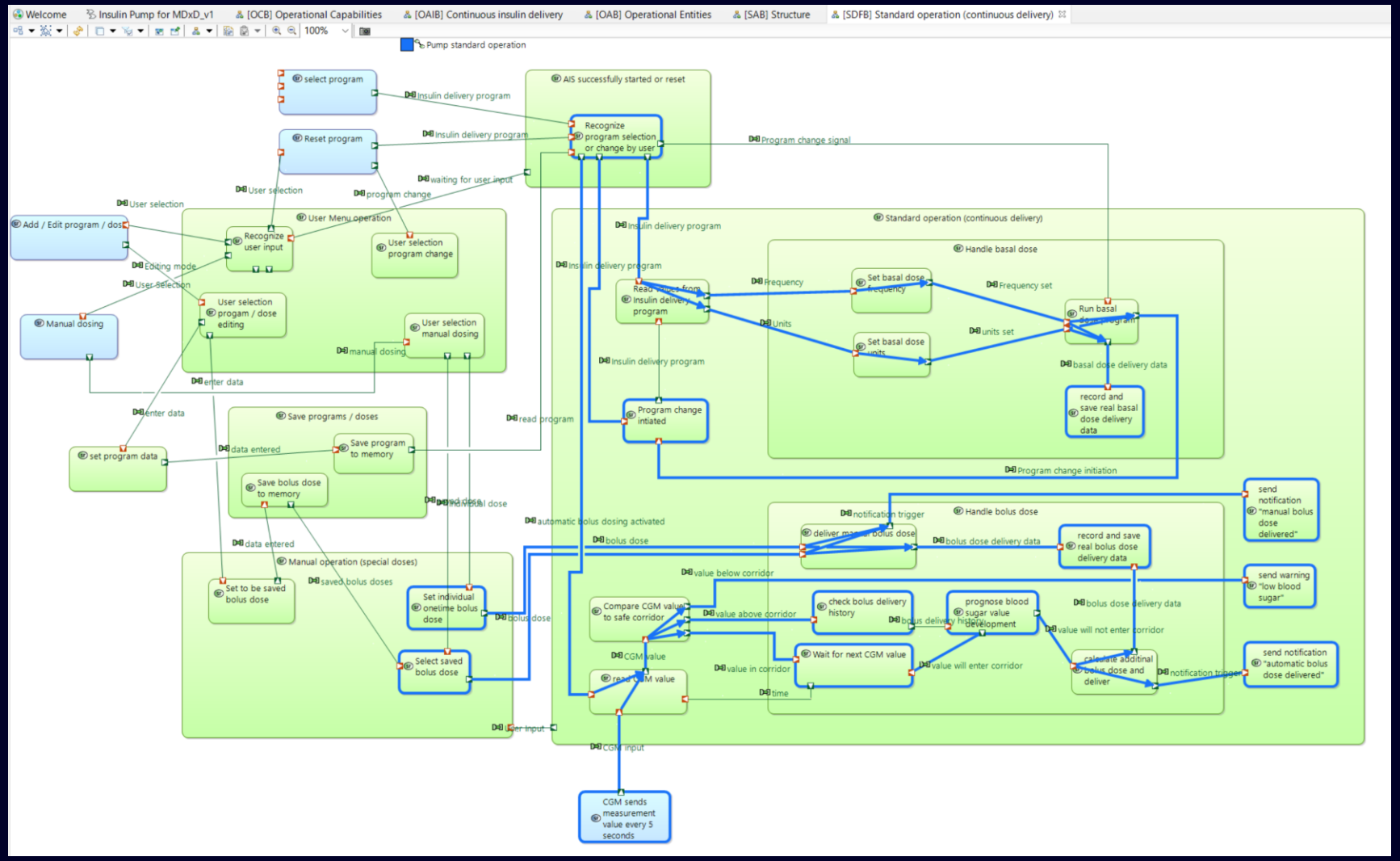
System Analysis – Workshop Task [30 min]



[SDFB] Create a new Functional Dataflow Blank diagram

Create a Functional Data Flow Blank Diagram …

- … to elaborate and detail the system functions and connect it to the corresponding behavior of stakeholders
- Target: Define/detail the main System Functions and their Sub-Functions

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How does MBSE work? – Logical Architecture with Logical Solution Space Perspective

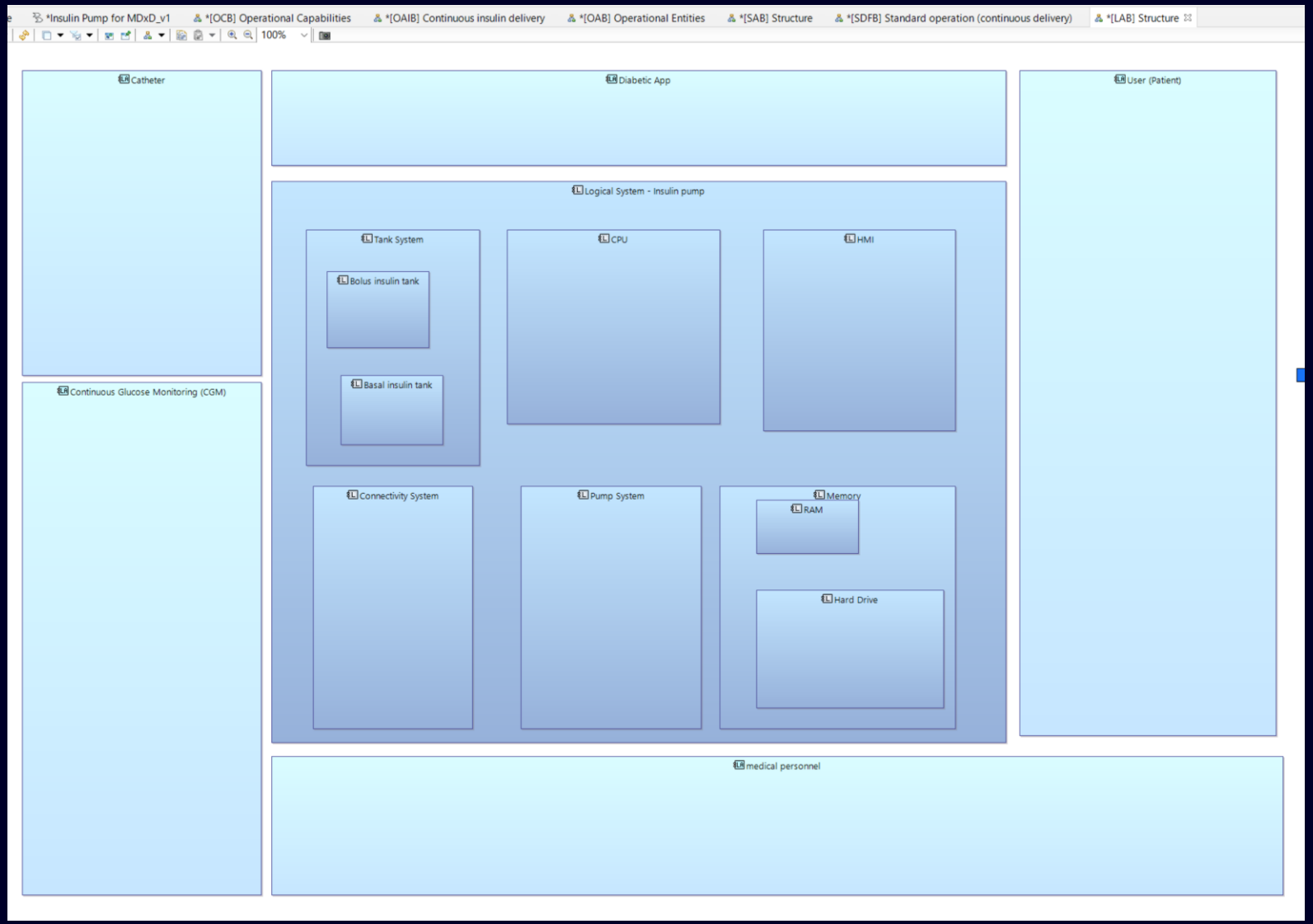
Logical Architecture with Logical Solution Space Perspective

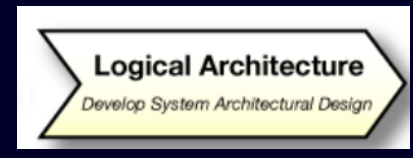
- Which **possible solutions** do exist to realize the defined functions?
- How do these solutions interact with each other and is there a **global optimum** when combining these principal solutions?
- **Decide** about the principal solutions for each defined function
- **Connect** principal solutions and functions using tracelinks
- Create a first, **logical system architecture with logical blocks,** based on the decisions made for the solution alternatives
- Describe the interactions between the logical blocks of the system
- **Connect** the logical blocks with the functions using tracelinks

Questions to ask:

- Which types of technical solutions would basically be able to fulfill the defined purposes/functions and, if applicable, which alternatives exist for them?
- What could a logical system architecture look like?
- How should the desired solution principles be associated with the architecture blocks?

Logical Architecture – Overview of logical Components [5 min]





[LAB] Create a new Logical Architecture diagram

Create a Logical Architecture Diagram …

- … to define logical System Components.
- Logical System Components structure the system based on the afore described functions in a technologically open (solution agnostic) way.

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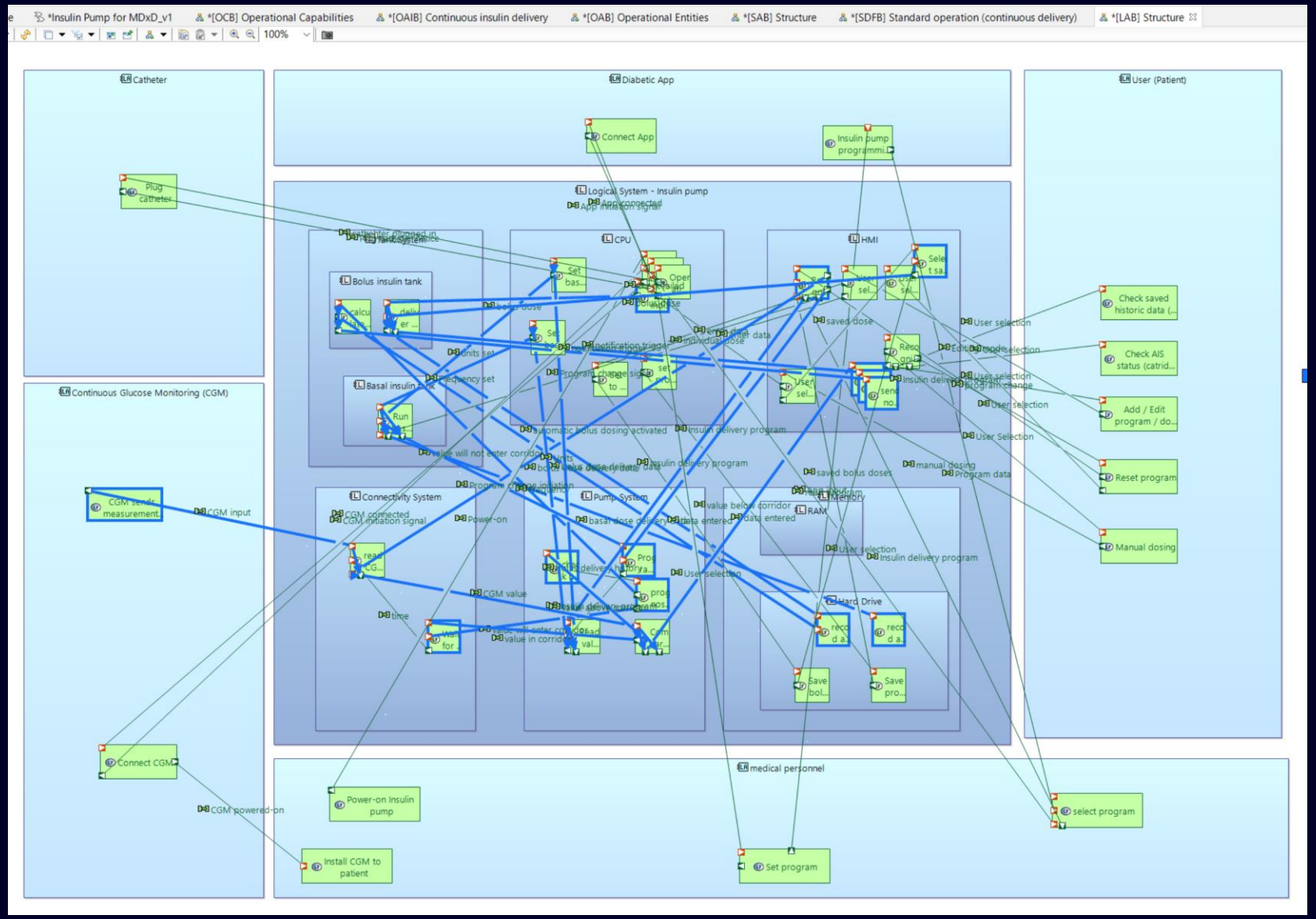
Logical Architecture – Allocation of Functions to Components [5 min]



Enhance the Logical Architecture Diagram …

- … by associating the functions to the newly defined Logical Components.
- Associating Functions to Logical Components helps to understand the purpose of each logical component and is the starting point to search for technological solutions to realize the functions in the physical world.

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How does MBSE work? – Physical Architecture with Real World Object Perspective

Physical Architecture with Real World Object Perspective

- Deals with actual **physical components** of the system
- Determines the actual assemblies and parts to be part of the system of interest and creates a **first (incomplete) BOM**
- In addition to purpose fulfillment, the issues physical feasibility and producibility play a crucial role
- Describe the interactions / interconnections between the physical objects of the system
- **Connect** the physical objects with the system blocks and the requirements (to indicate their fulfilment) using tracelinks

Questions to ask:

- Which are the necessary physical components of the desired System?
- Do these components have physical, electrical or information connections?

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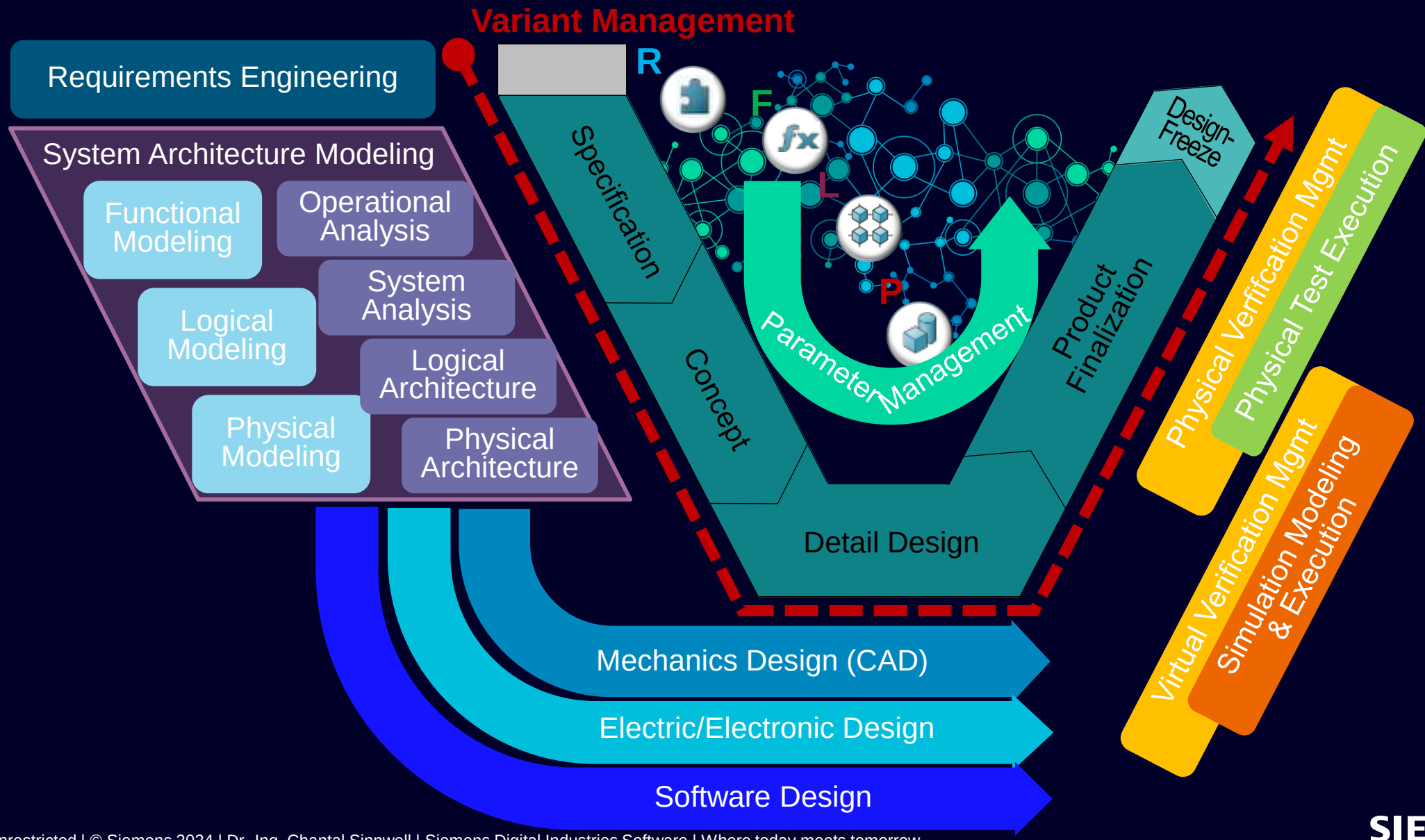
Overview of MBSE Business Process and Solution Landscape



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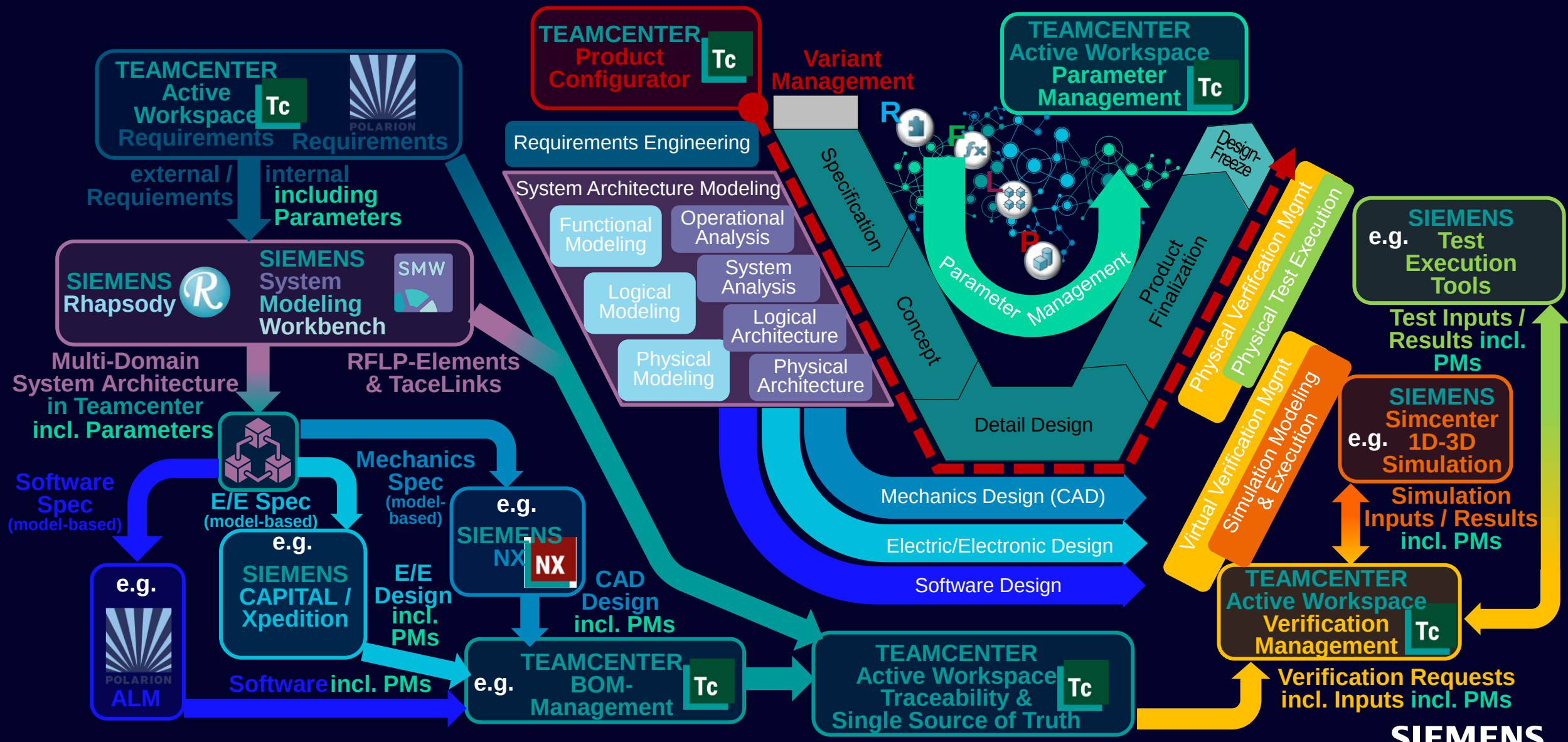
Overview of MBSE Business Process and Solution Landscape



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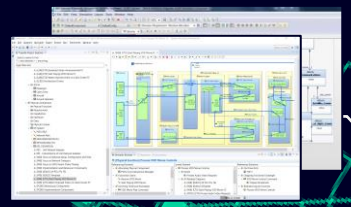
Siemens System Modeling, Simulation and Lifecycle Traceability
Use Model Data for Downstream Domain Design and Simulation

TEAMCENTER
Multi-Domain System Architecture and Simulation

Multi Domain System Architecture Modeling



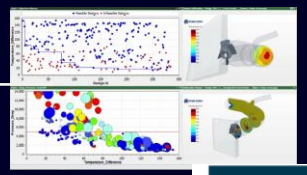
Teamcenter Requirement
Targets, Conditions

IBM DOORS
POLARION

MCAD - NX
Geometry characteristics

NX
CATIA
Pro|ENGINEER WILDFIRE 4.0

Architecture
Verification
Requirements
Simulation
Traceability
Software
CAD
E/E

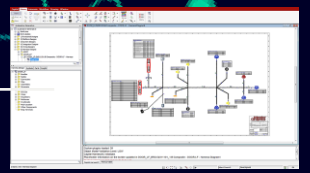


Multi-disciplinary Design Analysis and Optimization

HEEDS MDO

Simulation and Verification

SC AME
SC STU
SC CCM



Model-based E/E Systems Development

CAP SA
CAP ND
CAP IC

Capital

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Why MBSE? – Values and Benefits of an integrated MBSE-Approach

Benefits and Values of MBSE

- **Coherent system models** – no redundancies
- System models is **single source of truth** – with stakeholder-individual perspectives / views (cutouts)
- Explicit modeling of interconnections and **causal chains** –traceability of **decision paths** and impact analysis
- Graphical representations is “**common language**” – to support collaboration and avoid misunderstandings
- **System thinking** and systemic analysis – facilitates complexity management and unbiased ideation

Project conditions, that necessitate MBSE

- High **system complexity** – e.g. through involvement of different disciplines like mechanics, E/E and software
- **System-centricity** – overall system solution and optimization is leading, while interfaces of different disciplines must be aligned
- **Inhomogeneous expert teams** – risk to lose view of the overall system in favor of technically optimal local solutions
- **Shift Left** – shift attention to **earlier phases**, where errors are easier to recognize with system perspective and cheaper to correct
- **Embrace organizational change** – Silo-free environment, where System Engineers advocate for the overall system

Discussion

How are you feeling right now?

Why do you feel like that?

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