

Novartis – TRD  
GDPD



# MBSE in Pharma

**Enhancing Systems Thinking, MBSE and Cross-Team  
Collaboration in Regulated Industries on example of Novartis**

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09<sup>th</sup> September 2024

 **NOVARTIS** | Reimagining Medicine

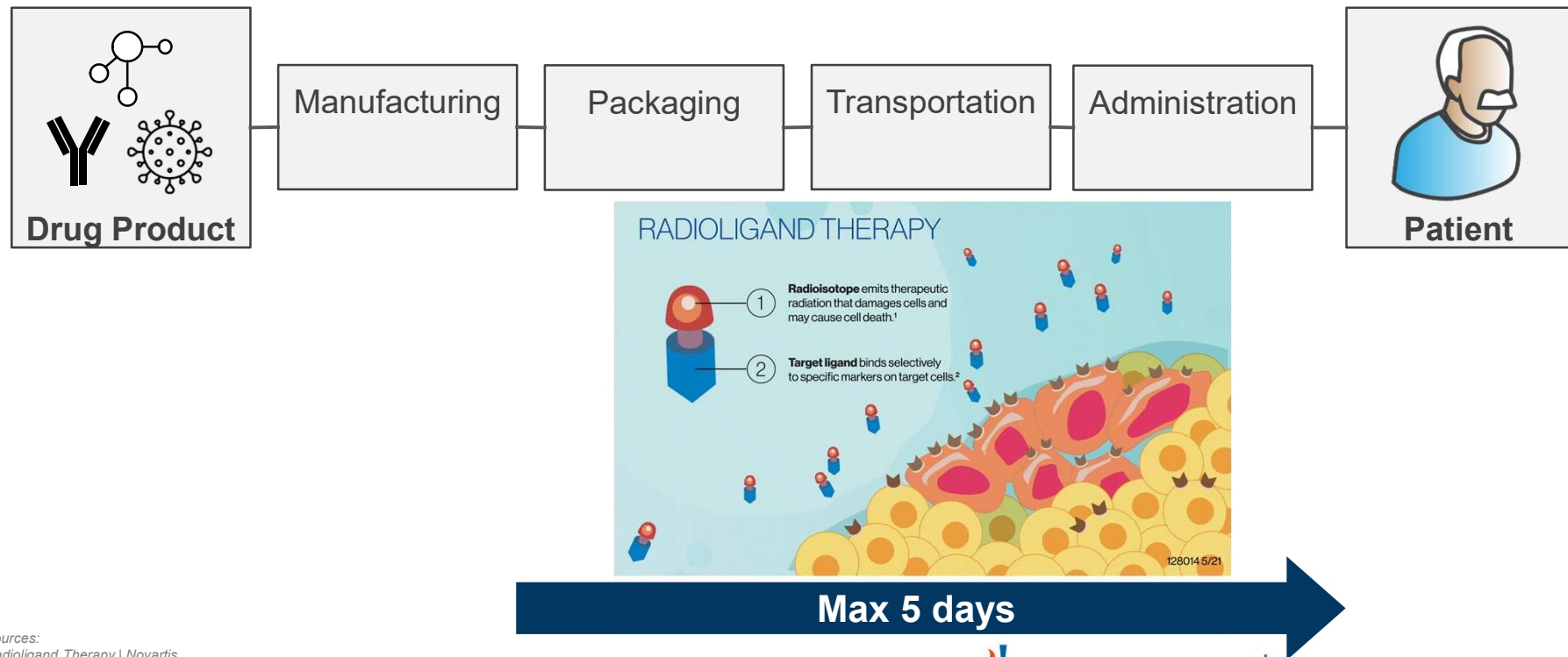
# Agenda



1. Our products & challenges
2. Novartis MBSE methodology
3. Stakeholder-specific viewpoints
4. Outlook: Sustainable Change & Change Management in MBSE

# Products and challenges

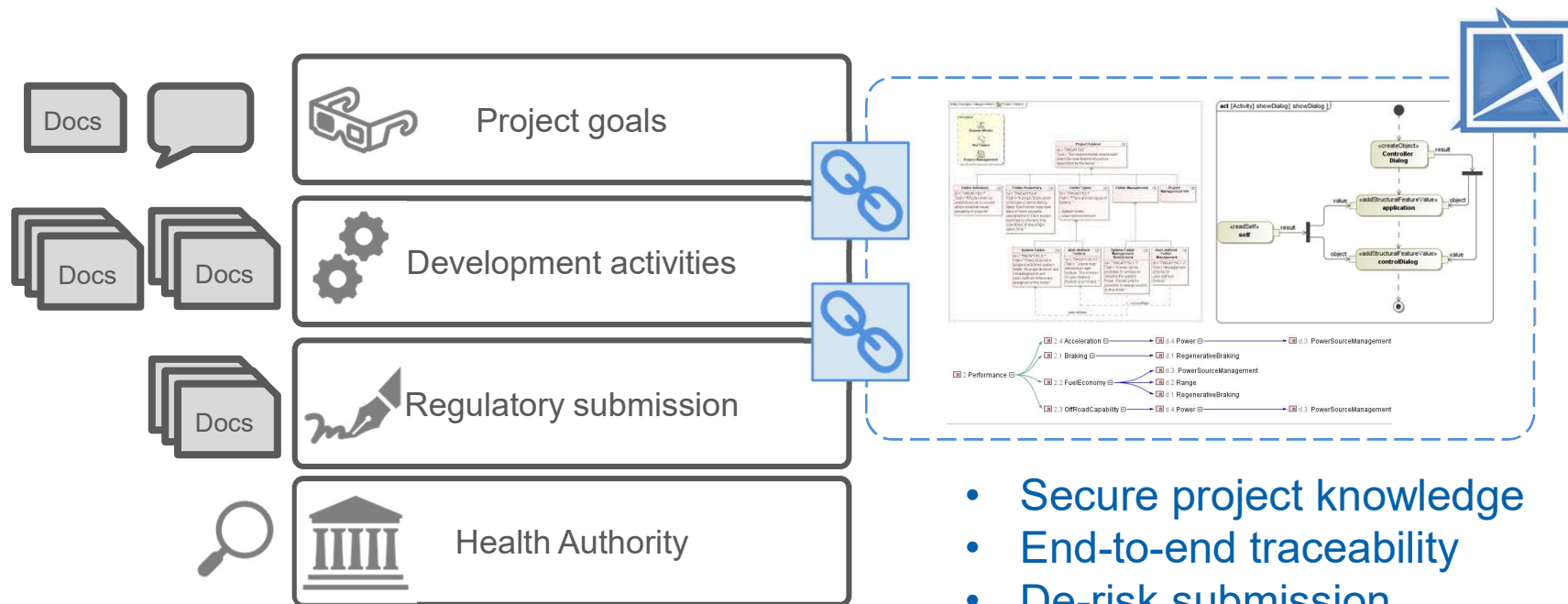
## Radioligand therapy



Sources:  
[Radioligand Therapy | Novartis](#)

# Products and challenges

## MBSE introduction



# Novartis MBSE Methodology

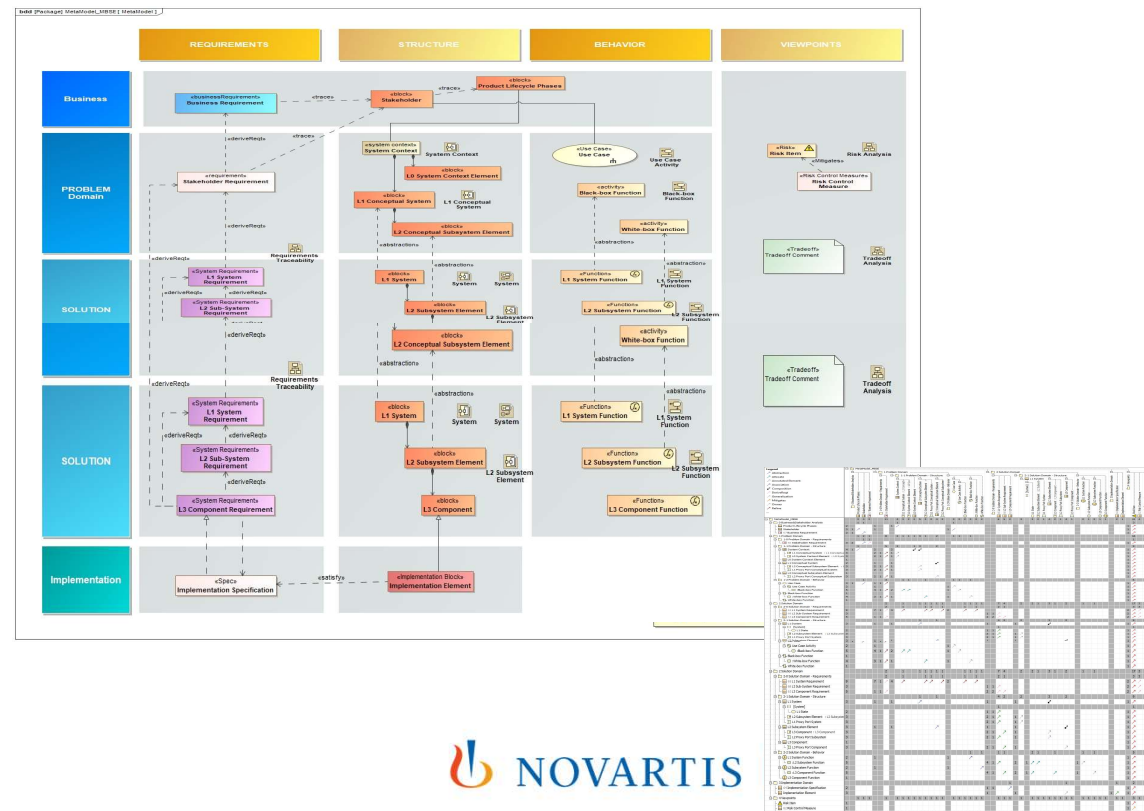
			Pillar			
			Requirements	Structure	Behavior	Viewpoints
Domain	Problem	Business	Business Requirements	Lifecycle Phases & Stakeholder Analysis		<div>Risk Analysis</div> <div>Impact Analysis</div> <div>Tradeoff</div> <div>Solution-dependent Context</div>
		Black Box	Stakeholder Requirements	System Context	Use Cases	
		White Box		Conceptual Subsystems	Functional Analysis	
	Solution	L1	System Requirements	System Structure	System Behavior	
		L2	Subsystem Requirements	Subsystem Structure	Subsystem Behavior	
		L3	...	...	...	
	Implementation		Implementation Specification	Implementation Structure		

# Novartis MBSE Methodology

## Metamodel for a seamless traceability

Enabling:

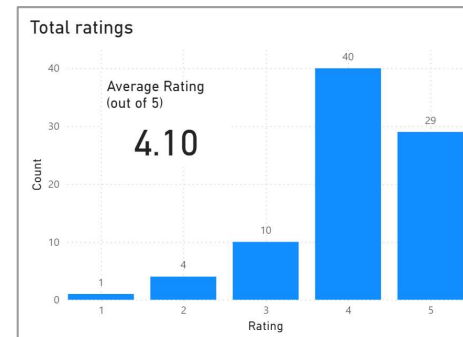
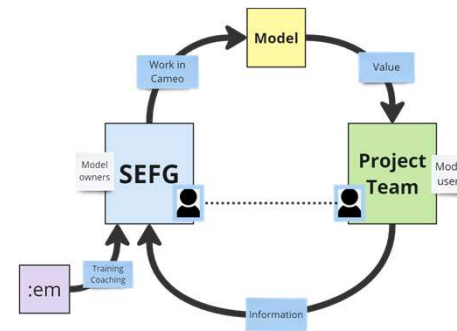
- Traceability **evaluation** of all model artefacts
- **Cross-aspect** relationships
- Impact **analysis**
- **Story-telling**
- Configuration of Data/Tool-synchronization



# Novartis MBSE Methodology

## Implementation journey

- System Model created
- Model-based creation of requirements for DHF/Regulations
- Story-telling and traceability from Stakeholder to Implementation
- Systems thinking:
  - Problem/Solution domain
  - Use case modelling and requirements derivation
  - Considering complete lifecycle: Product+Packaging+Transportation
- Pilot project evaluation and collaboration

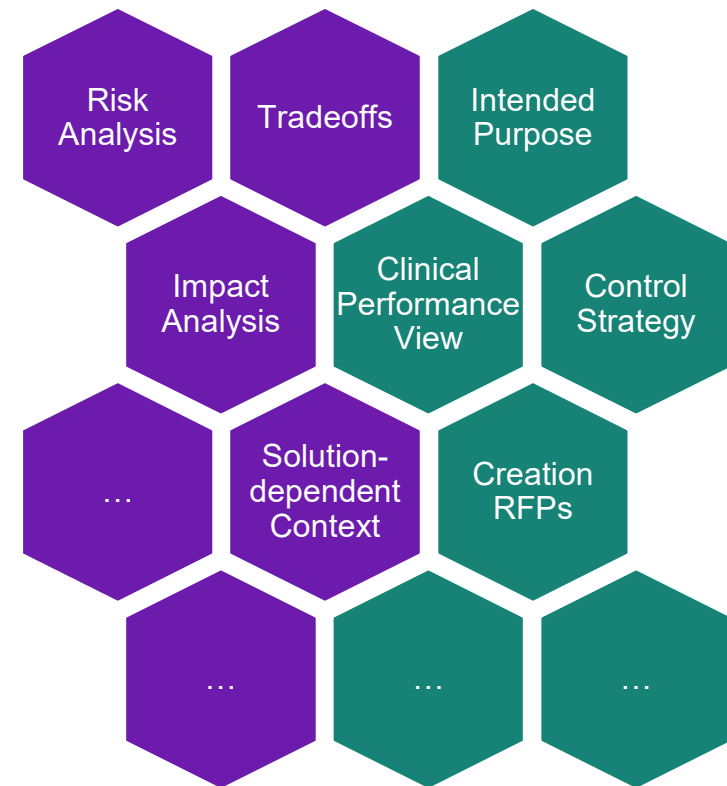




# Stakeholder-specific Viewpoints

Viewpoints are added to the system model for analysis and visualization

- **Existing model elements** and traceability are used for investigations
- Required **properties** of model artefacts has to be ensured or created by stereotyped attributes (e.g. functional requirements classified by „EPR“)
- Additional **stereotyped model elements** used to inter-related elements (e.g. risk item, tradoff comment)
- **Export/Exchange** of views for collaboration and documentation





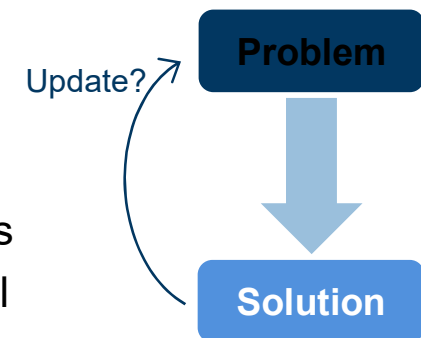
# Stakeholder-specific Viewpoints

## Example: Solution-dependent Context

### When to update problem domain and when it is solution-dependent?

#### Guidance note:

- Update problem domain...
  - ...if an issue can not be influenced by developed solution
  - ...if it is not caused by the selected solution
  - ...if it is required by (new) business or stakeholder requirements
- Update solution domain for any issue that arises with the technical implementation/realization of the selected solution.



#### → New identified interfaces or functions by solution-dependent context:

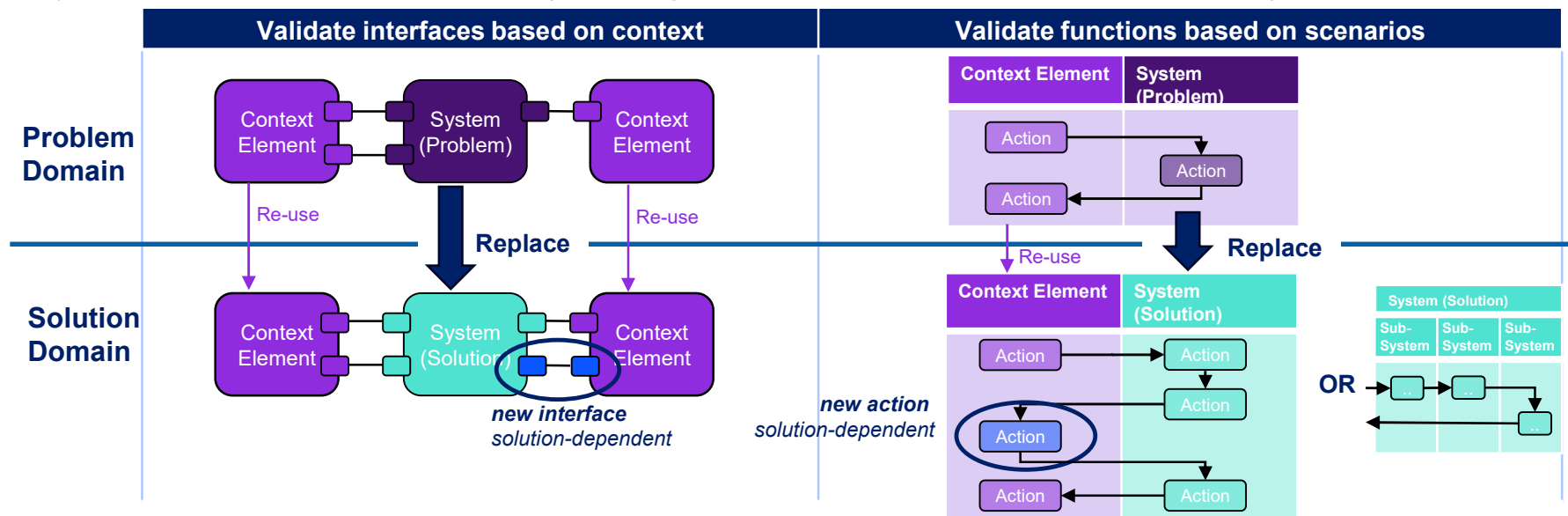
- External elements to be validated and aligned with stakeholders
- Highlight model elements by legend (problem vs. solution domain)

# Stakeholder-specific Viewpoints

## Example: Solution-dependent Context

**Goal:** designed solution (solution domain) fits to what is required (problem domain)

**Approach:** re-use problem domain diagrams and elements for context and scenarios and replace system block with solution domain (including solution interfaces and activities/actions)



# Stakeholder-specific Viewpoints

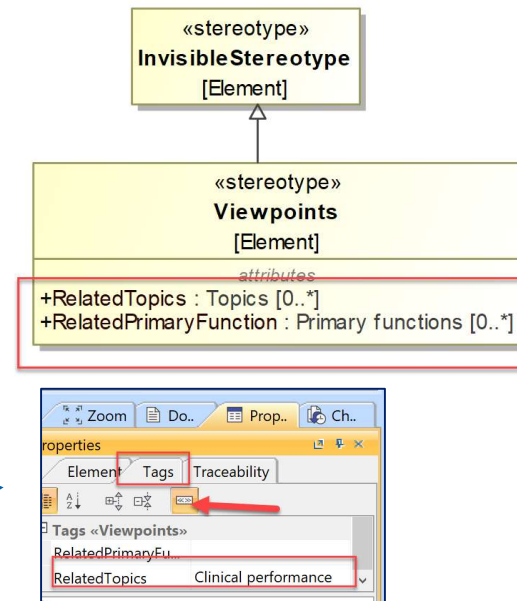
## Example: Viewpoint Implementation

### Purpose of tags:

- Tags are used – similar to properties – to indicate the relevance of a tagged model artefact to a specific topic as part of a viewpoint (e.g. like EPRs, clinical performance)

### Principle How To:

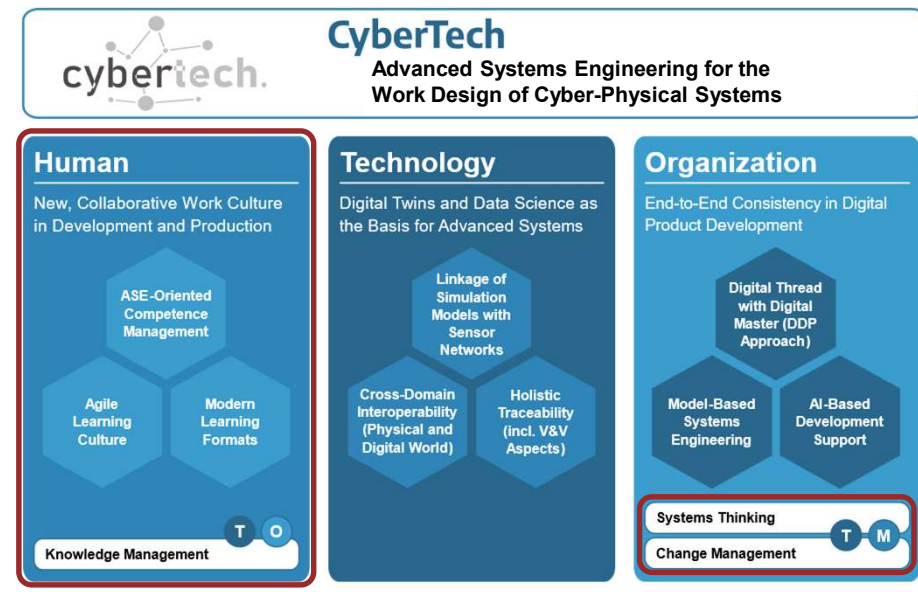
- Use the **InvisibleStereotype** to add potential tag to any element in the model by predefined enumerations
- Tag** relevant model elements
- Register all model elements tagged in **smart package** and visualize in a diagram if required



# Sustainable Change & Change Management in MBSE

Considering Change Management and people/humans in deployment

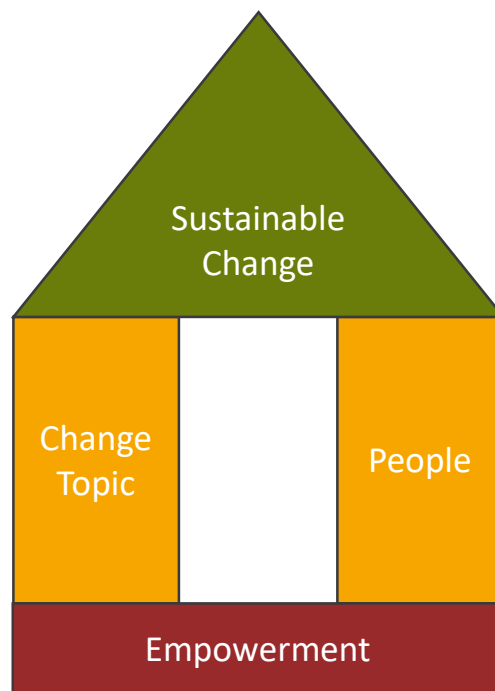
- **Deployment** is a major part of the MBSE transformation journey **often neglected**, but crucial for **sustainable change**.
  - **Collaboration between disciplines** and teams is key to **address the majority** of impacted people and achieve acceptance.
  - **Current practice** in deployment is mostly **focused on technology & organization** (frameworks, tools, models, ontologies, ...).
- How can the **gap between practice and science** be bridged to empower individuals?



Picture Source: O. Bleisinger, S. Kleiner, K. Avdejuk, B. Röhm, T. Steinbach, Y. Arslanparcasi, O. Karasek (2024), "Ein Leitbild zu Advanced Systems Engineering für die Arbeitsgestaltung von Cyber-technischen Systemen", Tag des Systems Engineering 2024

# Sustainable Change & Change Management in MBSE

Value of empowerment & people acceptance for SE deployment

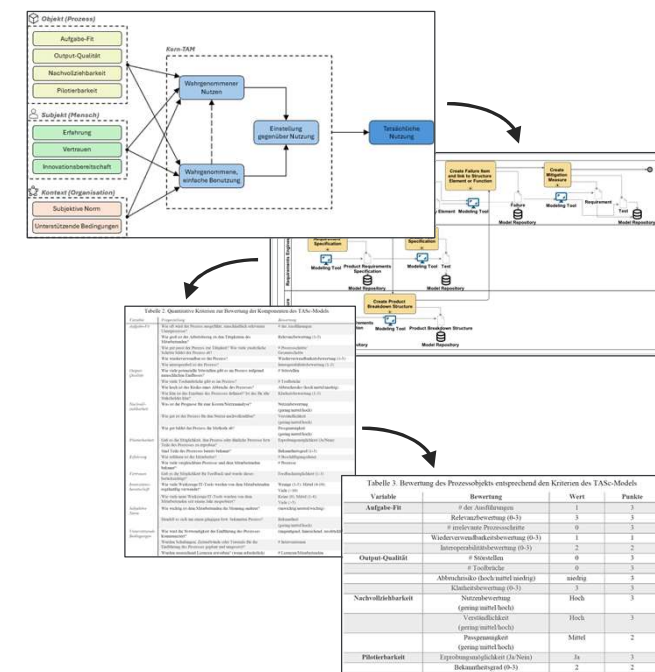


- **Change in an organization** requires next to the actual **Change Topic** involved **People** that are doing the change.
  - People only will sustain the change, if they are enabled by an **empowering environment**. Otherwise, they will not adapt.
    - Empowerment = Enable conversion of intention to action
    - Acceptance = Positive attitude towards technology (intention – “I would use...”)
    - **Active Acceptance** = Actual use of technology/tools (action – “I will use...”)
- ➔ Main tasks need to be done:
- **Pilot/Rollout** the presented models, tools, methods
  - **Understand and scope the targeted audience needs.**
  - Empower people and **create active acceptance** for technology.

# Sustainable Change & Change Management in MBSE

What about means to achieving active acceptance?

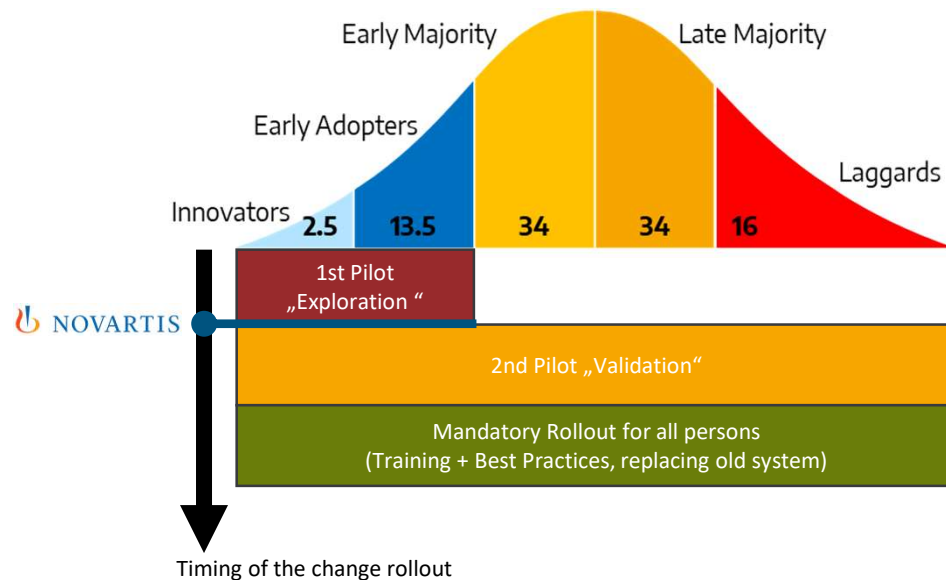
- In practice, active acceptance is often treated as low priority and “done by gut feeling”.
- Currently for SE/MBSE there are **ongoing applied research results** and implementations in practice.
- The **TASc-Model** (Technology Acceptance Scoring Model) is a more **objective mean to assess acceptance** before rollout.
  - The model divides the active **acceptance scoring in three regions** evaluating acceptance from different perspectives.
  - Furthermore, a **procedure is defined for acceptance scoring** and some perspectives can be evaluated without considering people.
  - For other regions involvement of change impacted people is key.



Source: J. Heinrich, O. Bleisinger, K. Avdejuk, M. Hohmann (2024), “Das Technology Acceptance Scoring Model (TASc-Model) für die Einführung von Model-Based Systems Engineering“, Tag des Systems Engineering 2024

# Sustainable Change & Change Management in MBSE

MBSE Journey @Novartis – it's not done after one pilot project!



Multiple phases are needed for a sustainable rollout



## Exploration:

- Understand, how new system replaces old system
- Define “way of work” with the new system



## Validation:

- Gain practical knowledge about what works in daily business and what needs optimization
- Possible re-evaluation of previously defined practices, even major changes



## Rollout:

- Mandatory rollout for persons impacted by the change
- All enablement material must be available
- No major changes in methodology allowed in early stage





# Thank you

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