



**Mayuresh  
KANKEKAR**

Senior Expert  
Novartis Pharmaceutical  
Manufacturing GmbH

## COMBINATION PRODUCT DEVELOPMENT WITH MBSE



# Outline



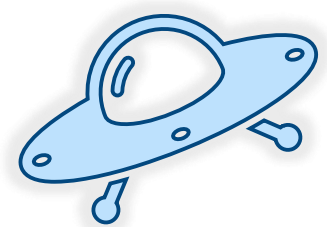
**Our products**



**Our challenges**



**Our MBSE journey**



**Looking forward**



# Our products

## What do we do? – as company



*Develops*

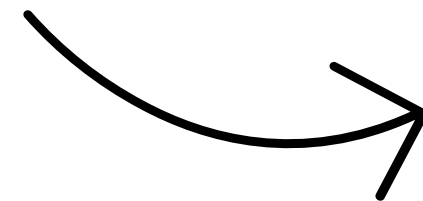


### Innovative Medicine

- Biotherapeutics
- Radioligand therapy
- Gene and cell therapy

**250mn+ patients reached across the globe in 2023**

*treats*



### Disease

- Cardiovascular, renal and metabolic
- Immunology
- Neuroscience
- Oncology

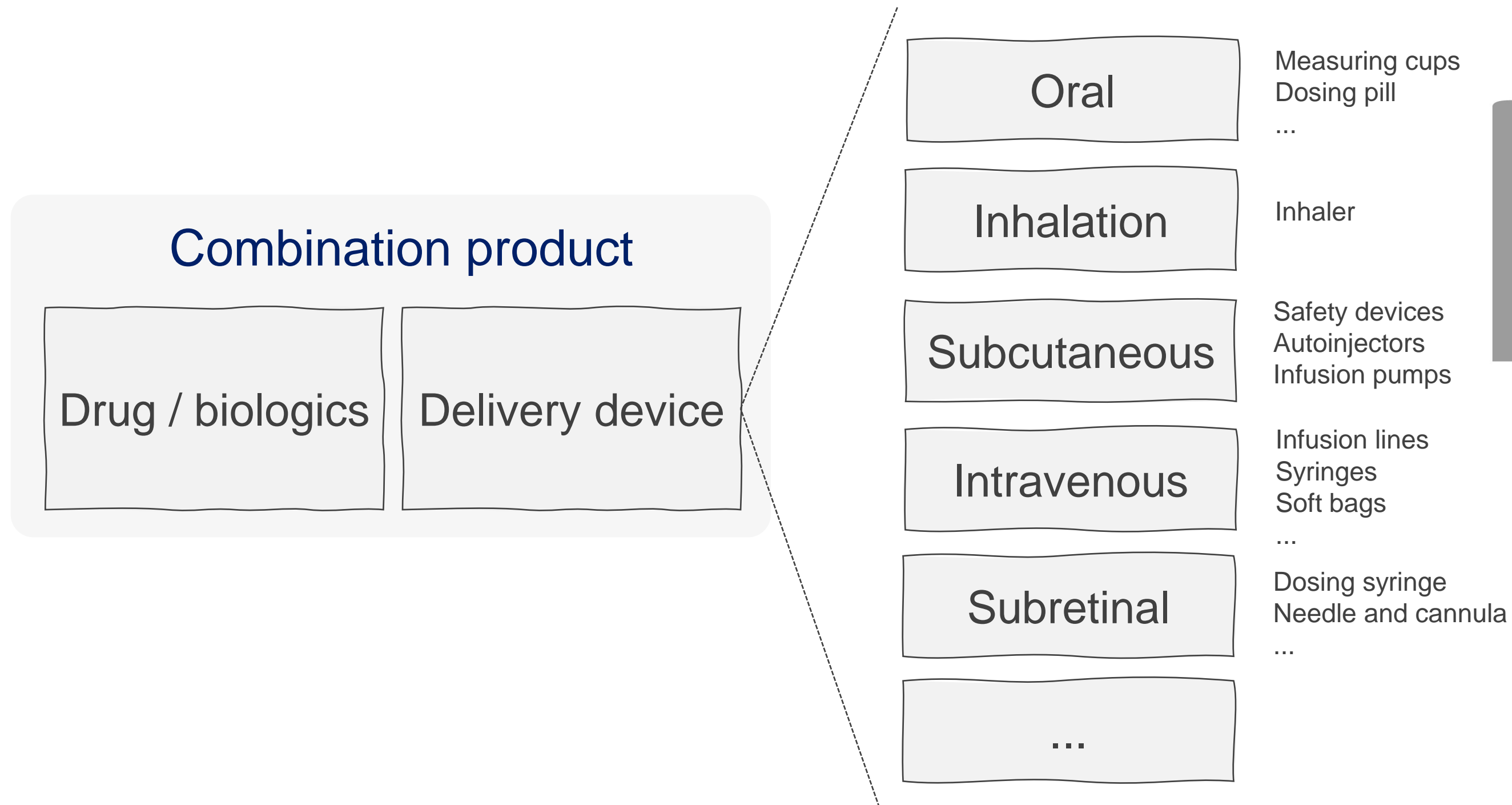
*affects*





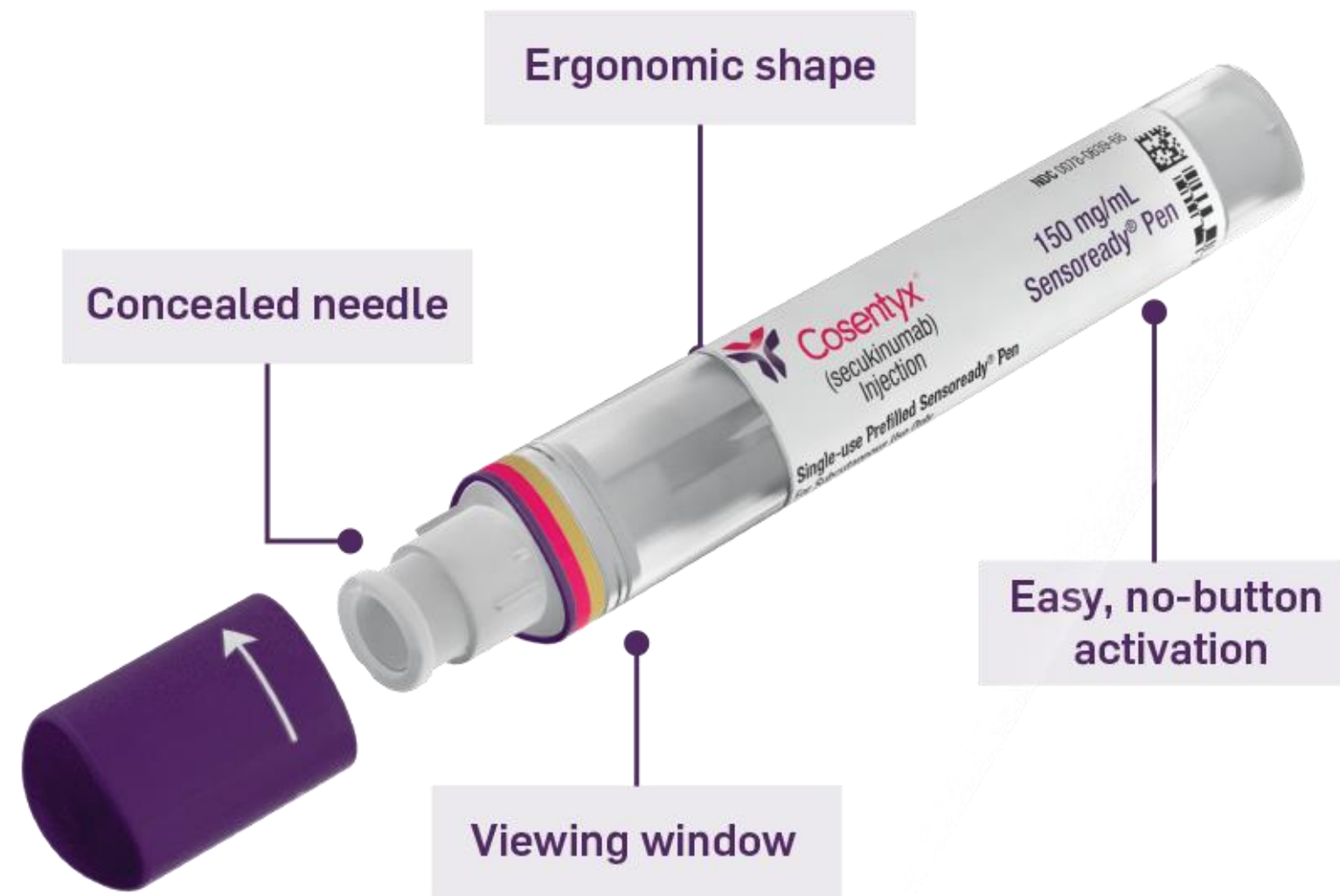
# Our products

## What do we do? – as GDPD



# Our products

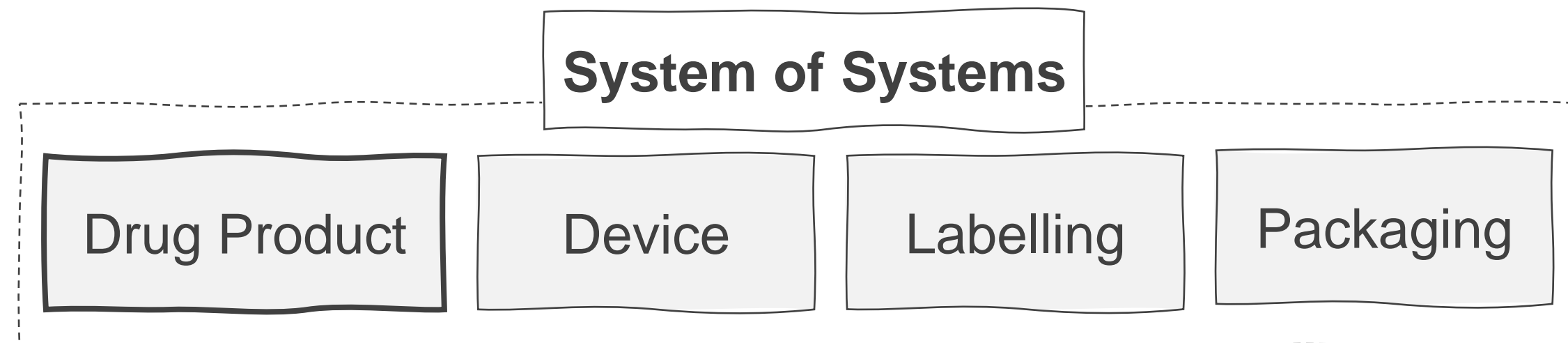
## An example of Combination product (drug/biologic + delivery device)



### INDICATIONS

COSENTYX® (secukinumab) is a prescription medicine used to treat:

- people 6 years of age and older with moderate to severe plaque psoriasis (PsO) that involves large areas or many areas of the body, and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light alone or with systemic therapy)
- people 2 years of age and older with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) and objective signs of inflammation
- people 4 years of age and older with active enthesitis-related arthritis (ERA)
- adults with moderate to severe hidradenitis suppurativa (HS)

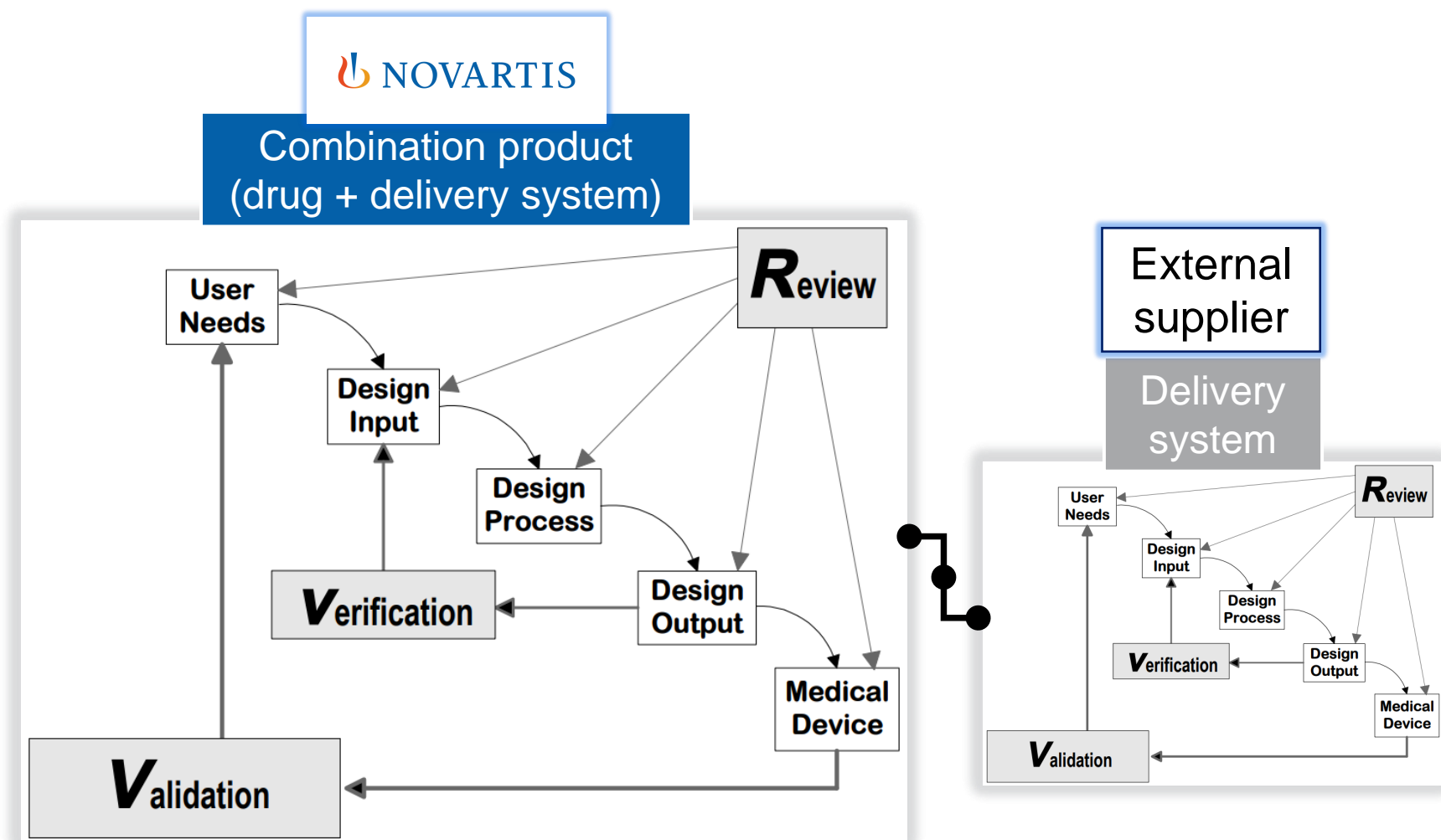


# Our challenges

Innovative medicine

New innovative therapies

Improving existing therapies



Unknown territory

Radioligand therapy where the shelf life of the drug is only 5 days

Evolving patient needs

Complex therapeutic needs

Deliver higher dose to reduce number of injections, enable self-administration

Unstructured feasibility phase

Missing requirements

Pre-selection of a solution

Lack of defined approach for platforms

Complex set of stakeholders

Highly regulated space

Poor traceability

Uncaptured information

Painful Impact assessment

# Our MBSE journey

## Introducing MBSE

What is MBSE?

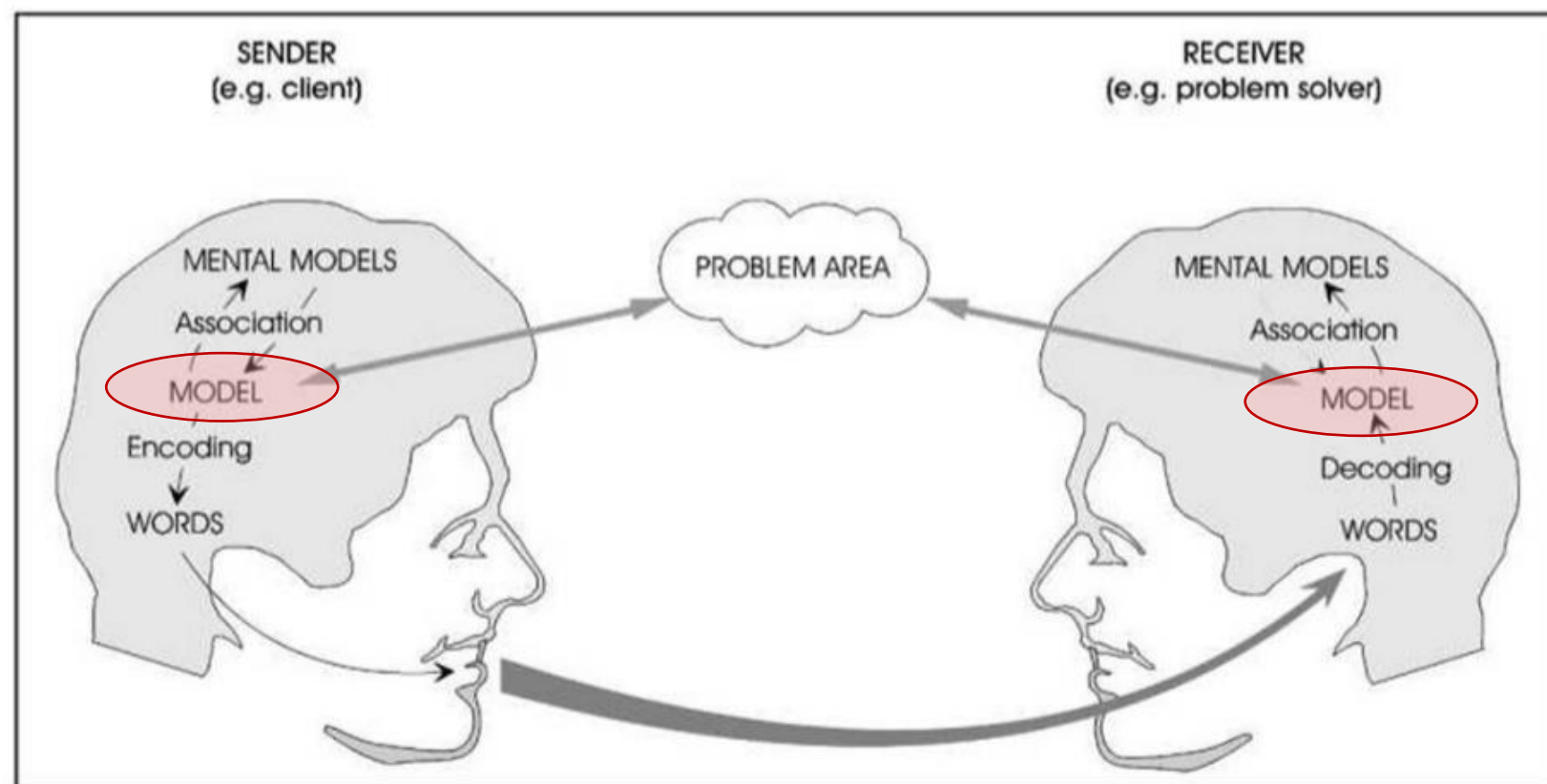
The formalized **application of modeling** to support system requirements, design, analysis, verification and validation activities beginning in the conceptual design phase and continuing throughout development and later life cycle phases.

What is (System) Model?

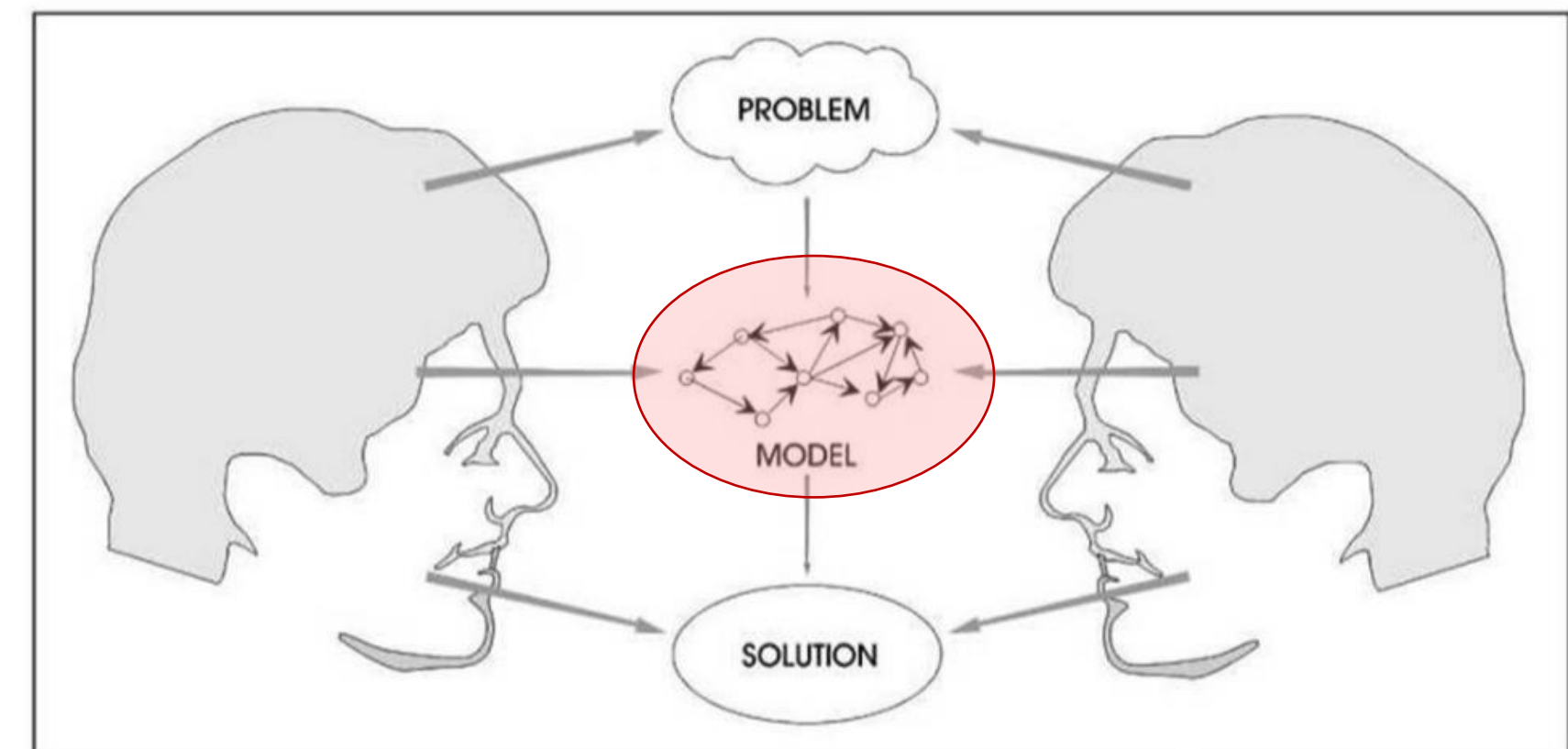
The representation of the **system of** with,

- The **context** with interacting actors
- The **behavior** showing system dynamics
- The **structure** with interfaces

This covers both **problem domain** (definition of the problem) and **solution domain** (specification of the product, updated along entire lifecycle)



*Without system model*



*With system model*

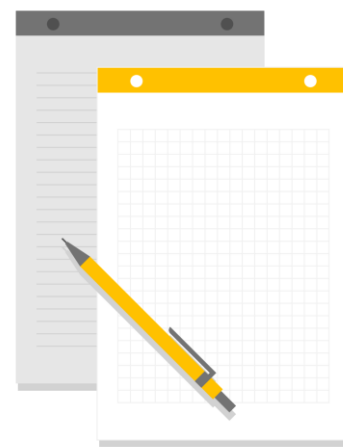


# Our MBSE journey

## Introducing MBSE

### Methodology

- Custom methodology based on MagicGrid framework
- Metamodel for seamless traceability and integration with existing process landscape



### Tool

- Initially started with basic visual tools (MS Visio, whiteboards)
- Introduced Cameo systems modeler as our formal tool



### Skills

- Coaching and trainings from external partner (Engineering Methods AG)
- Systems Engineering Focus Group trained for MBSE fundamental and advanced topics





# Our solution


## Methodology

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

# Our MBSE journey

## Methodology

		Pillar				
		Requirements	Structure	Behavior	Viewpoints	
Problem	Business	Business Requirements	Lifecycle Phases & Stakeholder Analysis		Risk Analysis	
	Black Box	Stakeholder Requirements	System Context	Use Cases		Impact Analysis
	White Box		Conceptual Subsystems	Functional Analysis		Tradeoff
Solution	L1	System Requirements	<p>Why the project exists?            What are top-level business needs?            Where the project fits in the wider program?            Key stakeholders, internal &amp; external?</p>		Solution-dependent Context	
	L2	Subsystem Requirements				
	L3	...				...
Implementation		Implementation Specification	Implementation Structure			

- Unstructured feasibility phase
- Missing requirements
- Pre-selection of a solution
- Lack of defined approach for platforms
- Poor traceability
- Uncaptured information 
- Painful Impact assessment




# Our MBSE journey

## Methodology

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

Unstructured feasibility phase

Missing requirements 

Pre-selection of a solution

Lack of defined approach for platforms

Poor traceability

Uncaptured information

Painful Impact assessment

- Depending on the context, system interactions with relevant stakeholders is analyzed
- For each context, how the stakeholder will use the system is described using use-case analysis
- Conceptual subsystems are visualized that can fulfill these use cases




# Our MBSE journey

## Methodology

		Pillar			
		Requirements	Structure	Behavior	Viewpoints
Problem	Business	Business Requirements	Lifecycle Phases & Stakeholder Analysis		Risk Analysis Impact Analysis Tradeoff Solution-dependent Context
	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		

Unstructured feasibility phase

Missing requirements

Pre-selection of a solution 

Lack of defined approach for platforms

Poor traceability

Uncaptured information

Painful Impact assessment

Solution domain contains actual physical structure of the system (L1), its subsystems (L2) down to component level, their interfaces and the functionality that the system provides.

# Our MBSE journey

## Methodology

		Pillar			
		Requirements	Structure	Behavior	Viewpoints
Problem	Business	Business Requirements	Lifecycle Phases & Stakeholder Analysis		Risk Analysis Impact Analysis Tradeoff Solution-dependent Context
	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		

Unstructured feasibility phase ✓

Missing requirements

Pre-selection of a solution

Lack of defined approach for platforms

Poor traceability ✓

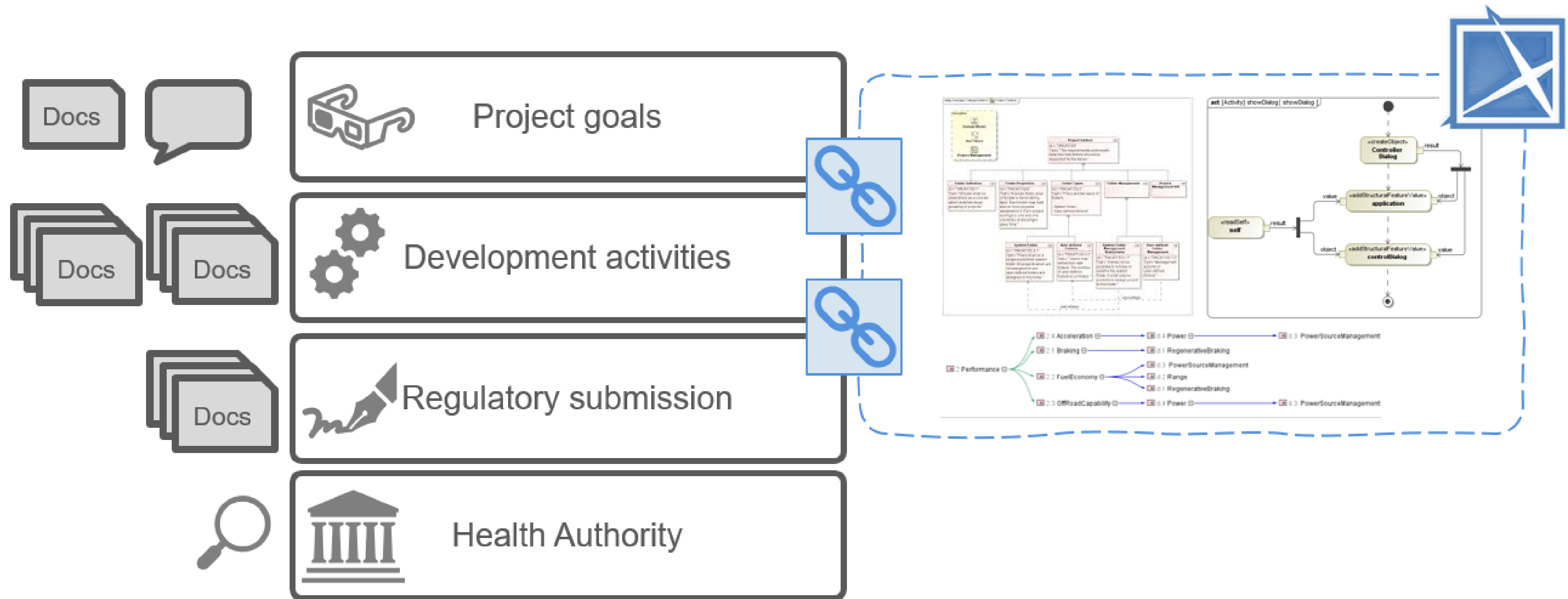
Uncaptured information

Painful Impact assessment ✓

Stakeholder specific viewpoints to only present relevant information for a certain stakeholder

# Our MBSE journey

## Pilot project – Radioligand therapy

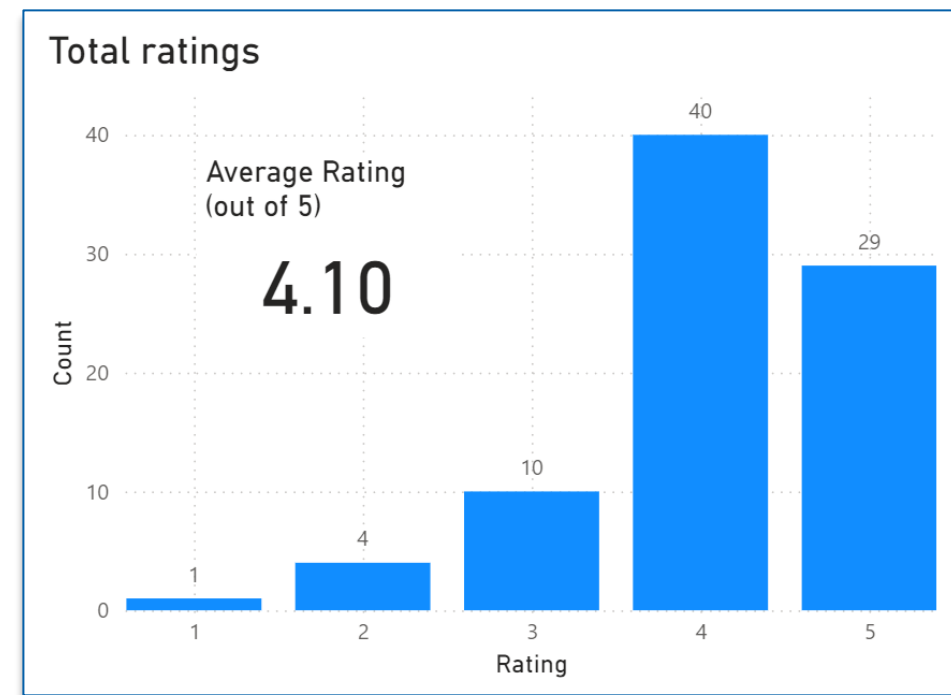




# Our MBSE journey

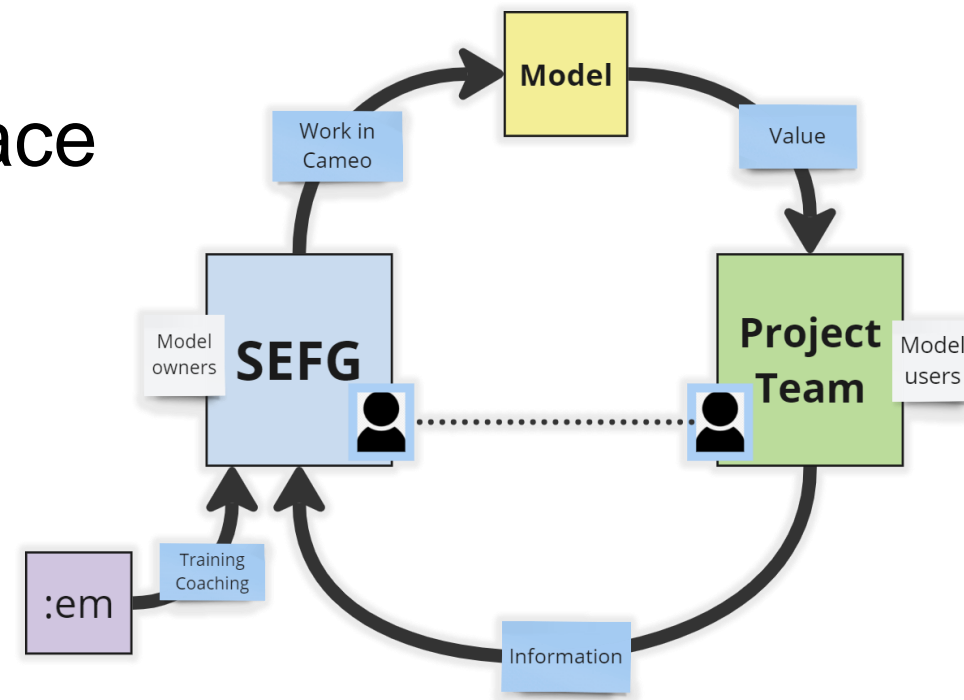
## Distance covered so far

Pilot project in progress  
 Model-driven feasibility phase  
 Model-driven DHF documents

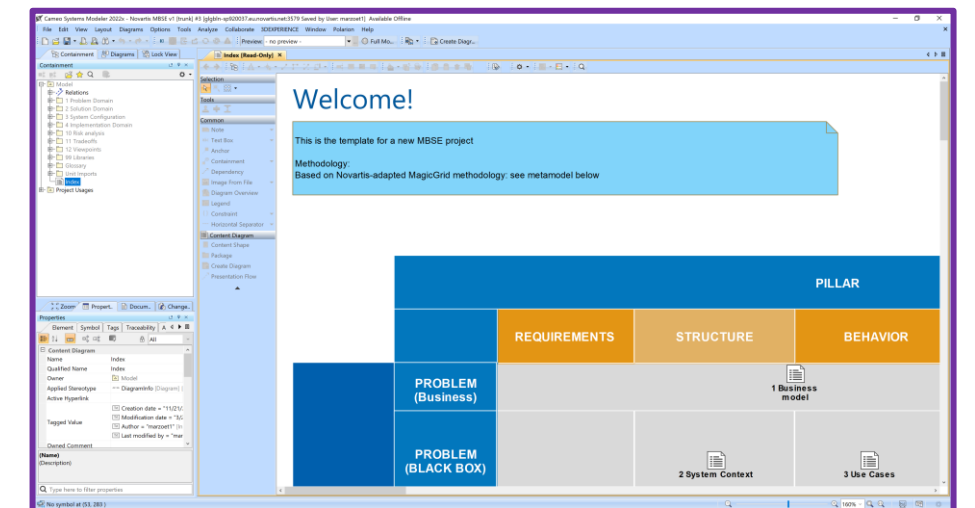


Templates and guidelines created for easier roll-out

Tool established  
 Methodology in place  
 Skilled SEFG



Pilot project evaluation with positive feedback



# Our future

## Next steps



### Demonstrate

Continue to build on pilot project to demonstrate the value promised by MBSE



### Establish

Extend the reach by applying MBSE to key projects & involve all the line functions



### Sustain

Stay up-to-date with the tool, explore opportunities to automate, interface with existing ALM system



### Expand

Explore additional use-cases e.g. from drug development to improve the reach of this initiative

**Mayuresh Kankekar**  
mayuresh.kankekar@novartis.com

**Thank you**



THANK YOU FOR YOUR INTEREST

