

Novartis – TRD
GDPD



MBSE in Pharma

Introducing MBSE for Combination Product development

Ettore Marzocchi, Oliver Bleisinger
Zürich
18Sep2023

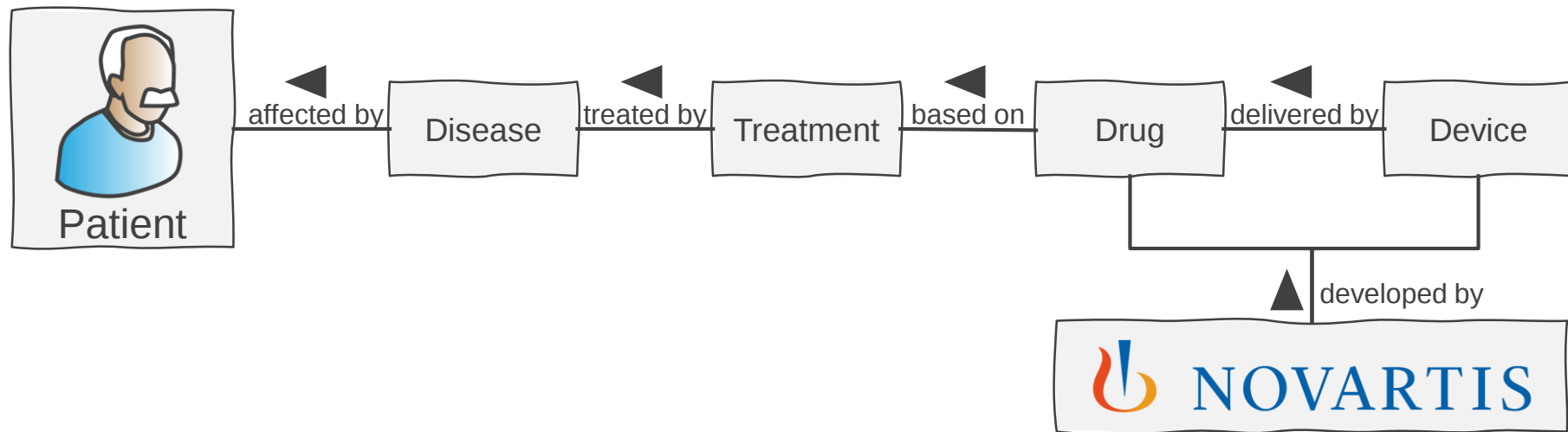
Agenda



1. Our products
2. Our challenges
3. MBSE as key enabler
4. MBSE journey

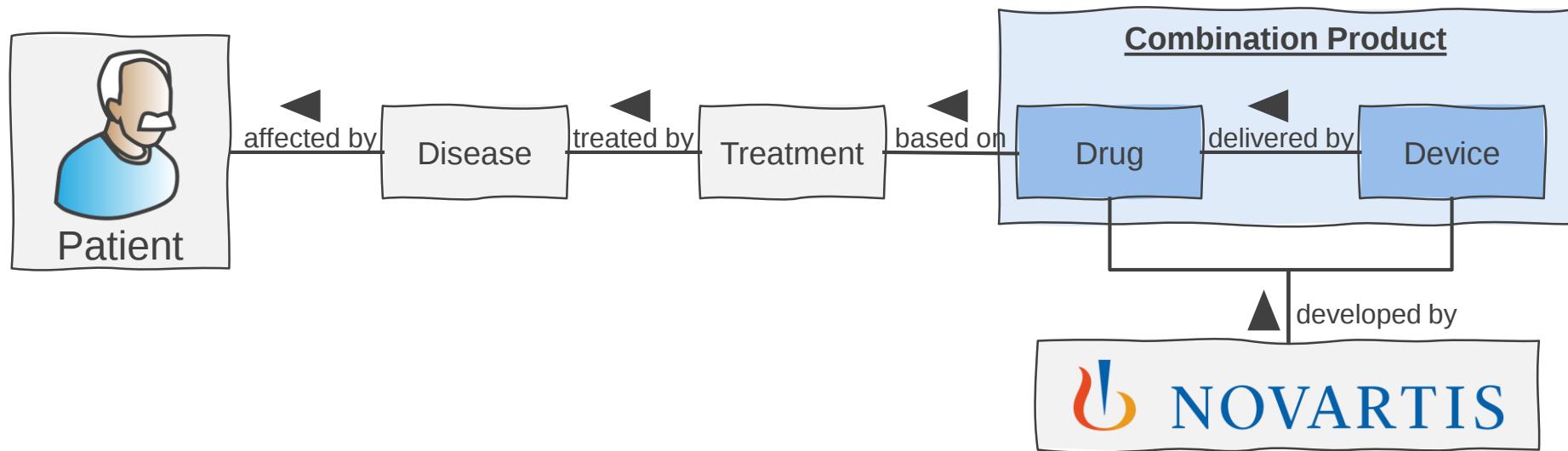
Our products

What do we do?



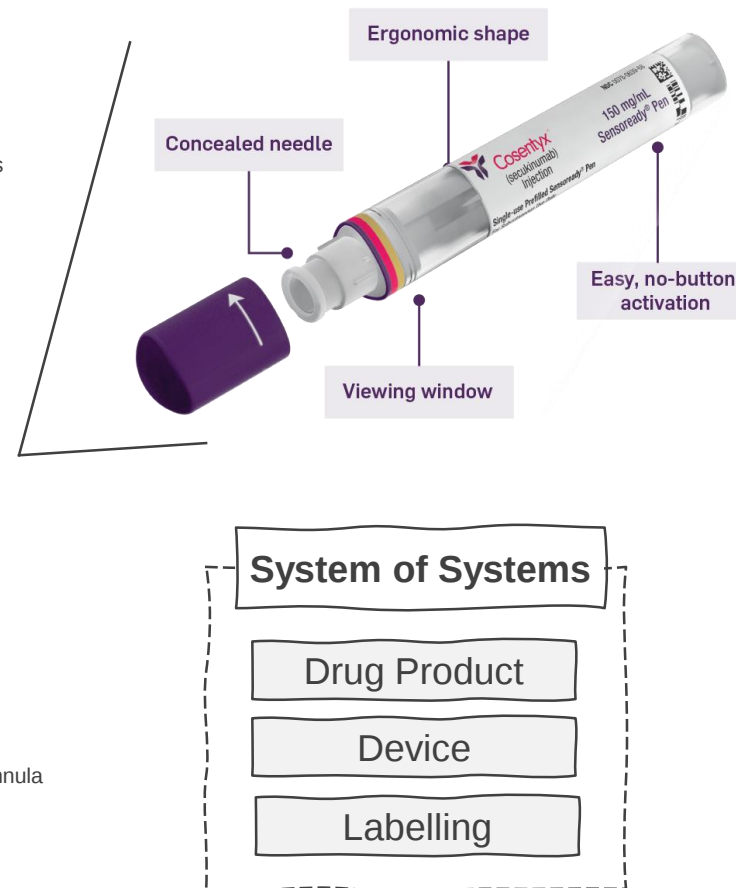
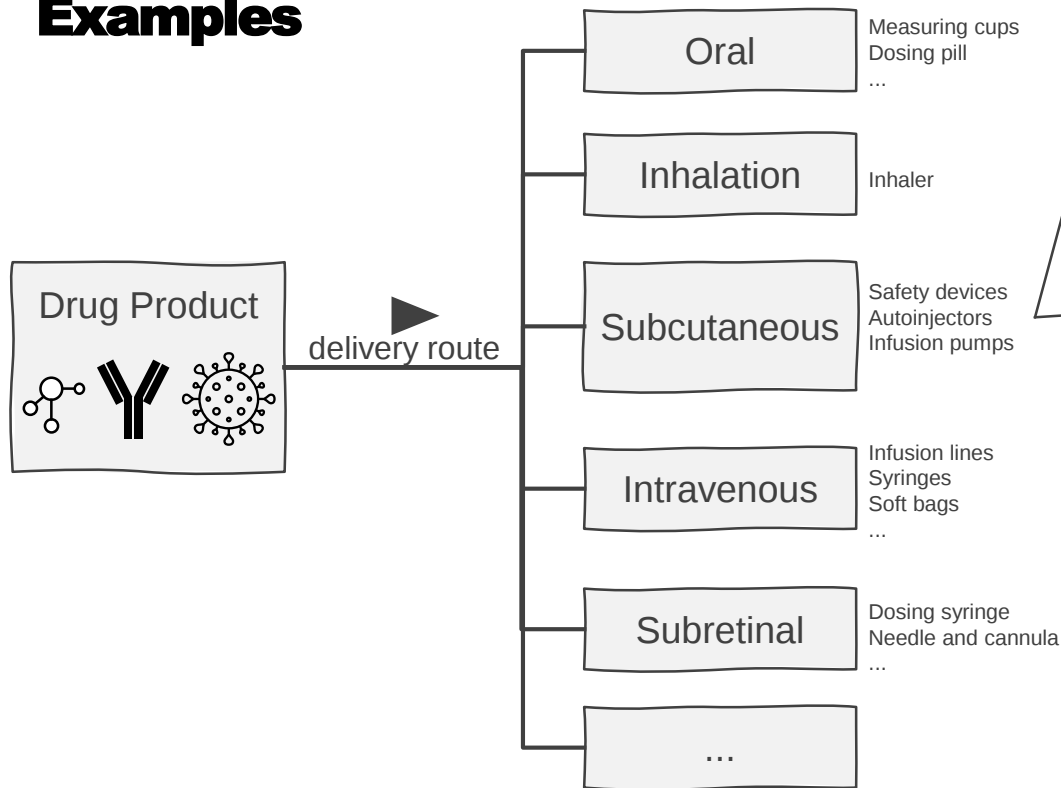
Our products

What is a Combination Product?



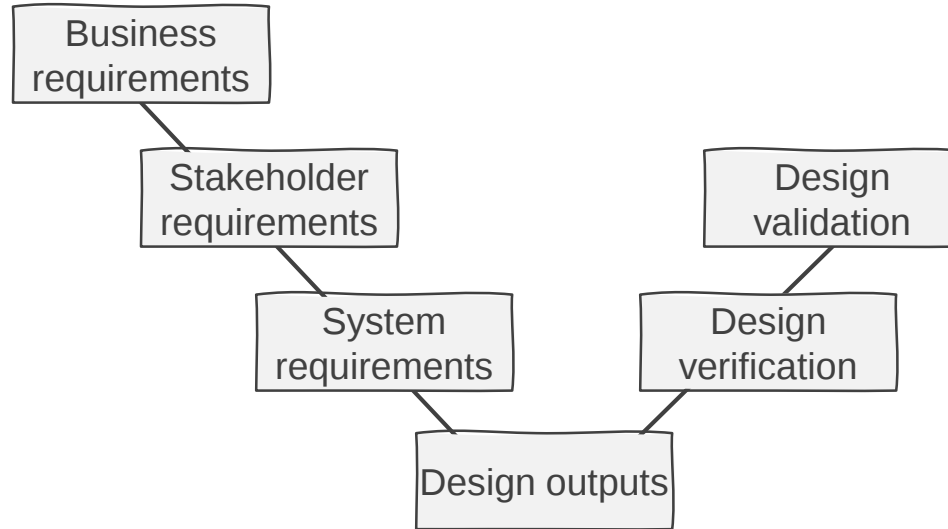
Our products

Examples



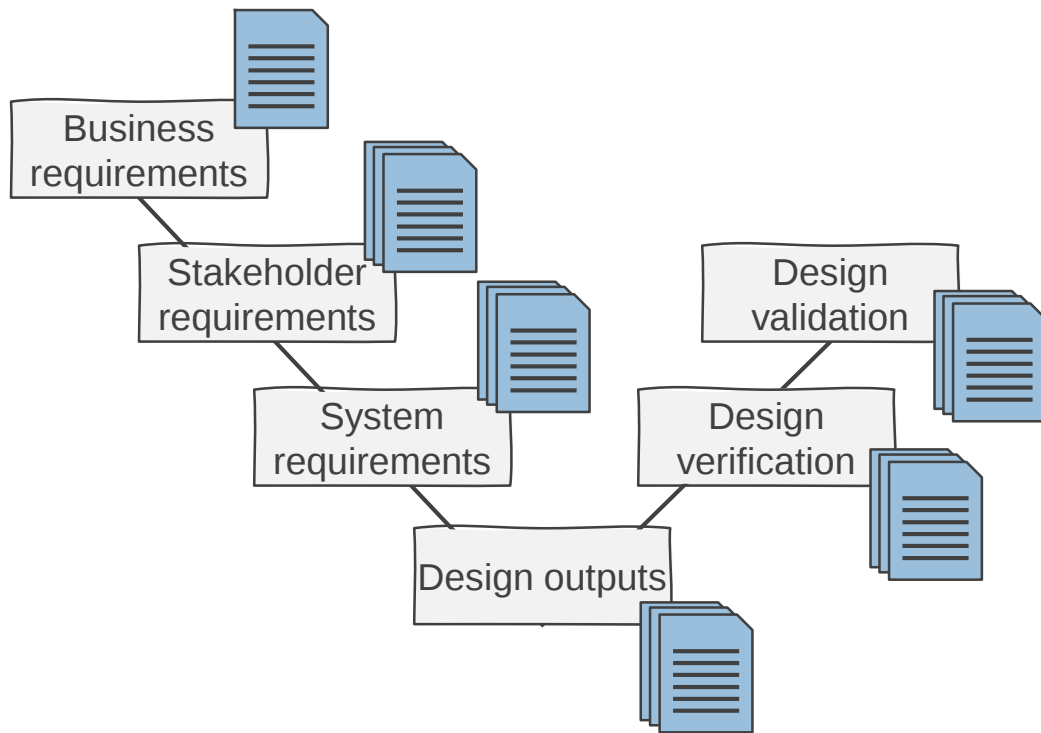
Our challenges

Development model



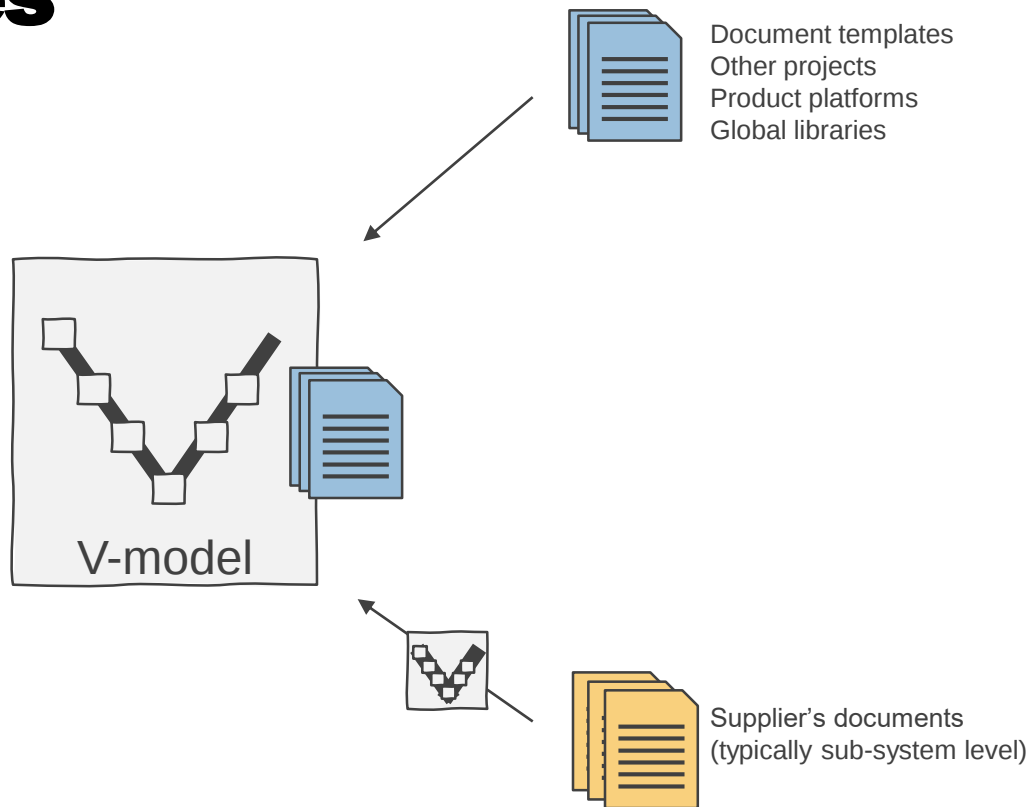
Our challenges

Documentation



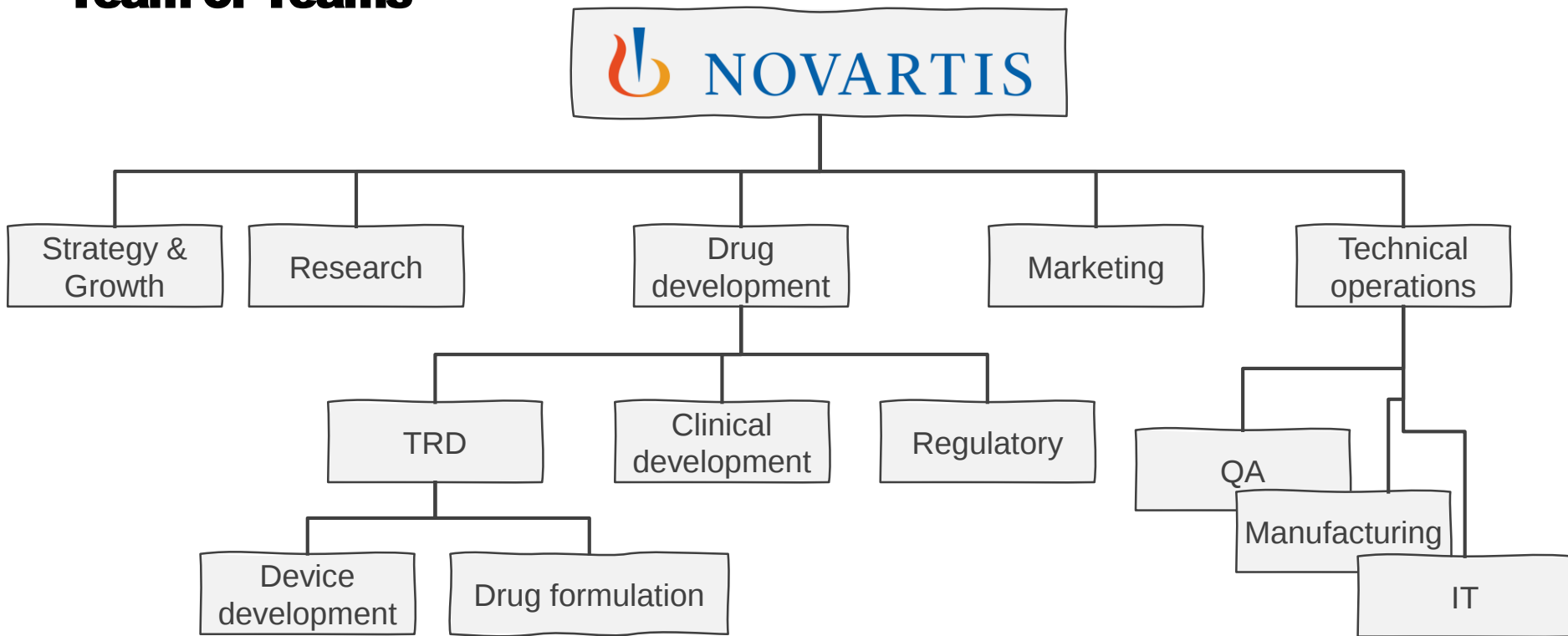
Our challenges

Documentation



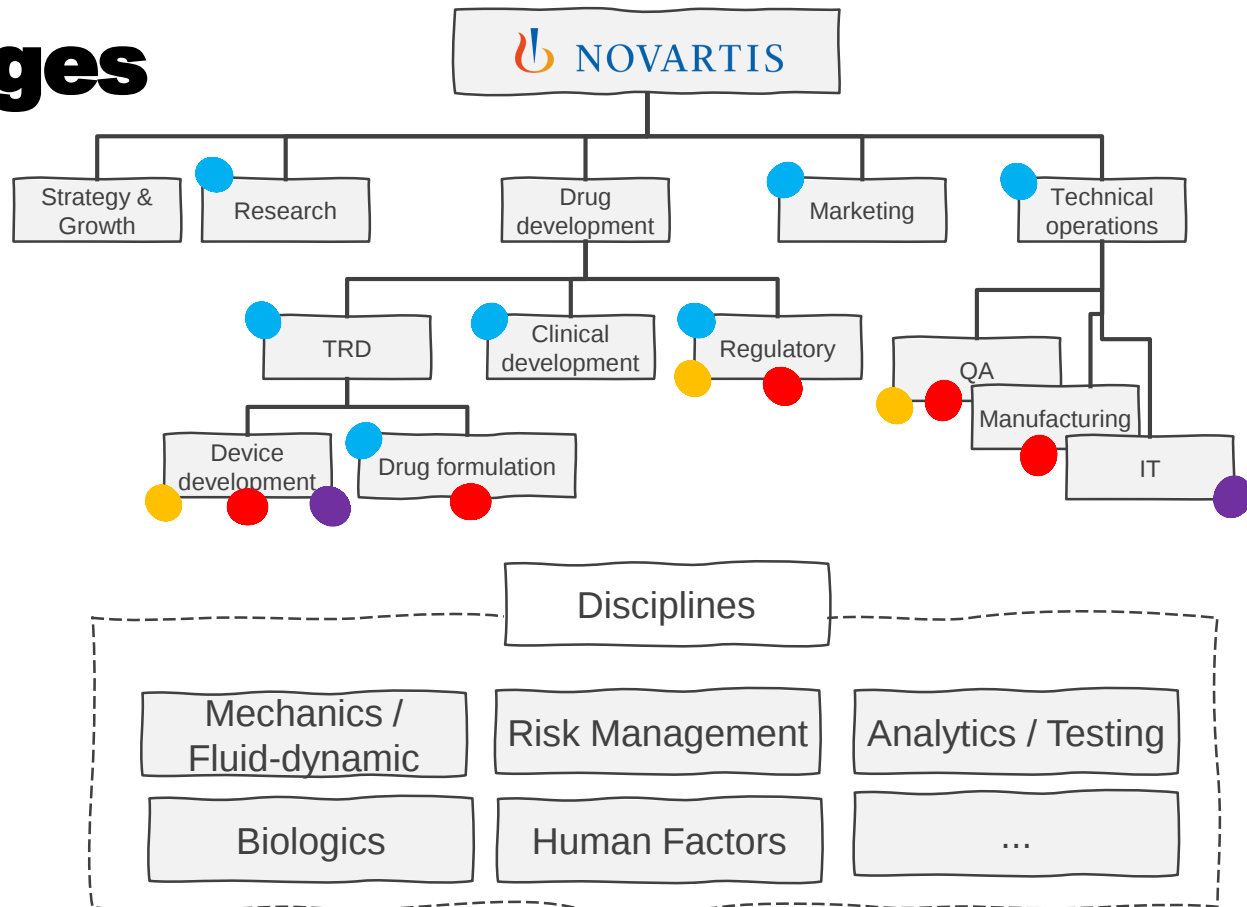
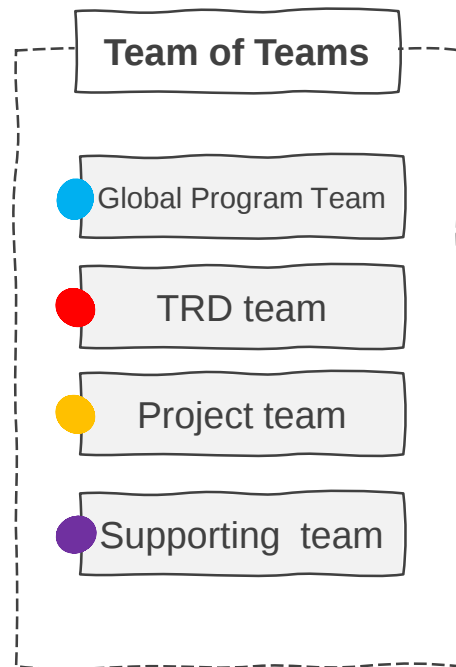
Our challenges

Team of Teams



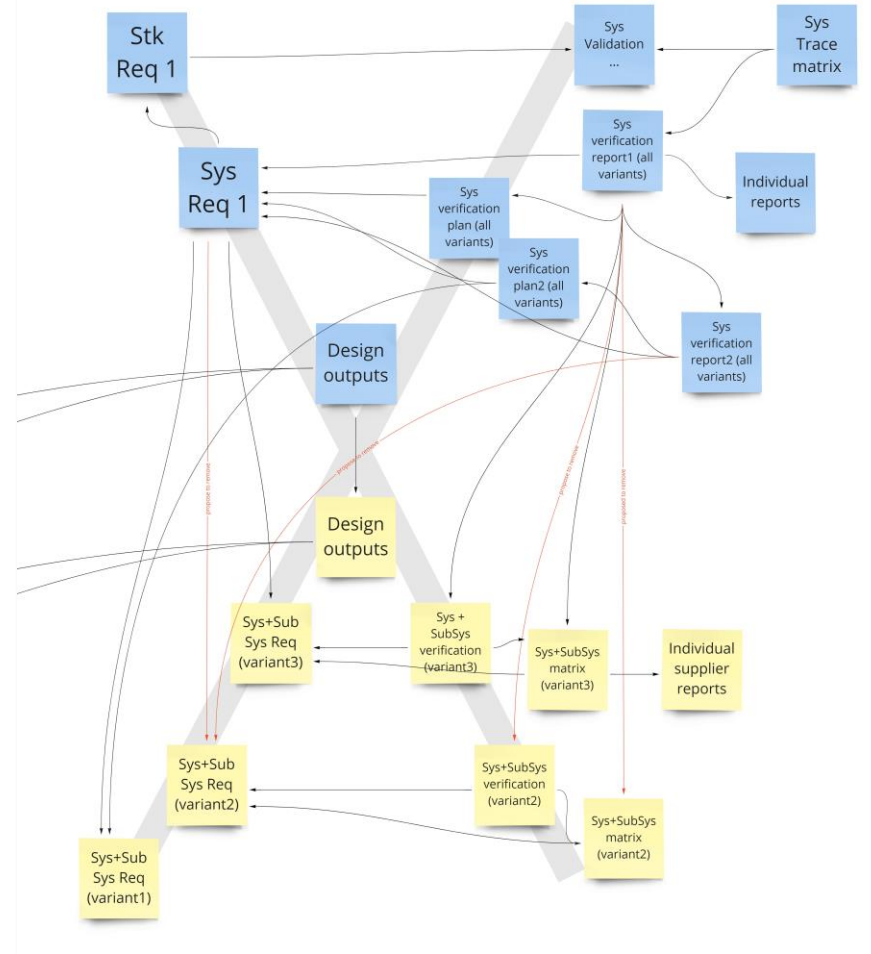
Our challenges

Organization



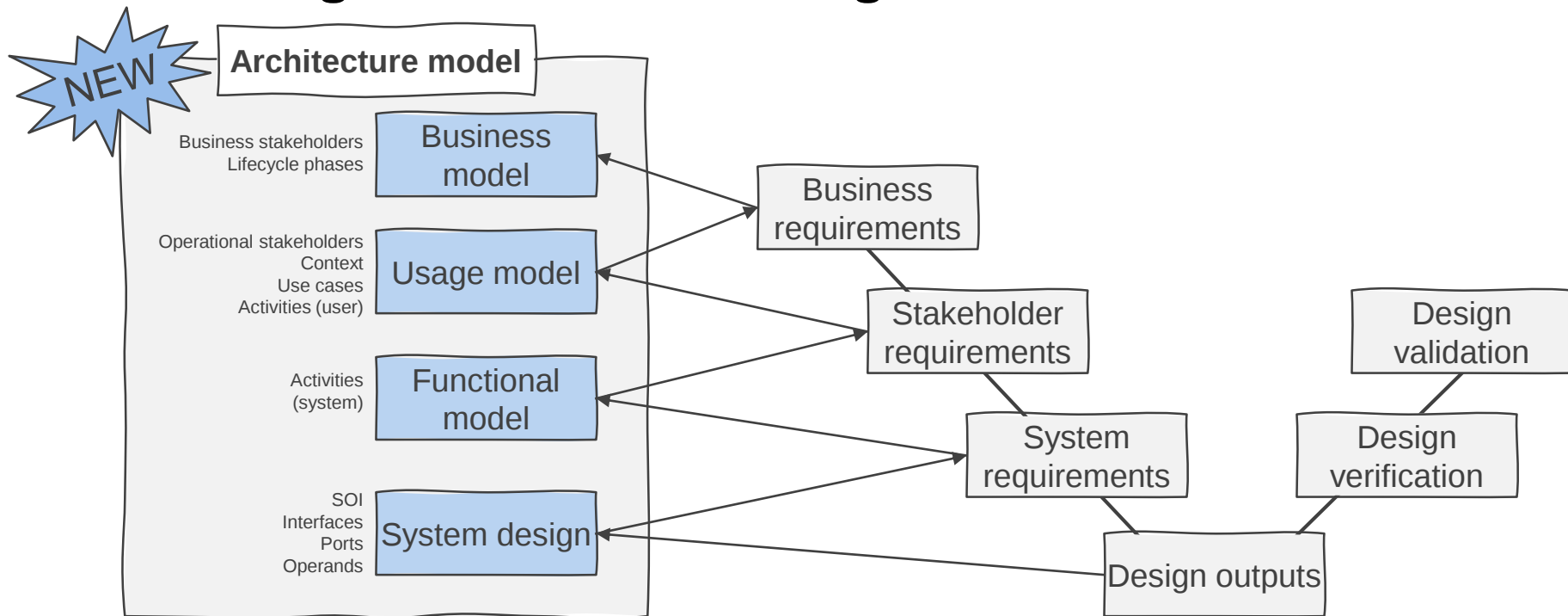
Our challenges

- Requirements elicitation
- Requirements management
- System thinking (anticipating solutions)
- Traceability
- Impact analysis
- Communication internally
- Communication externally (storytelling)

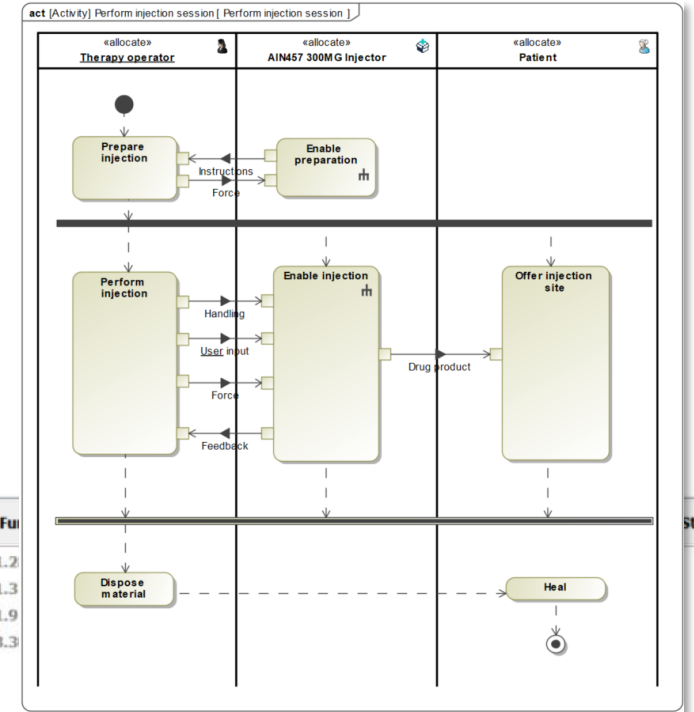
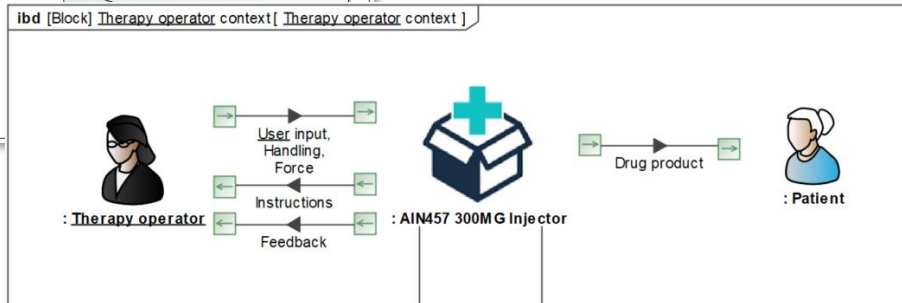
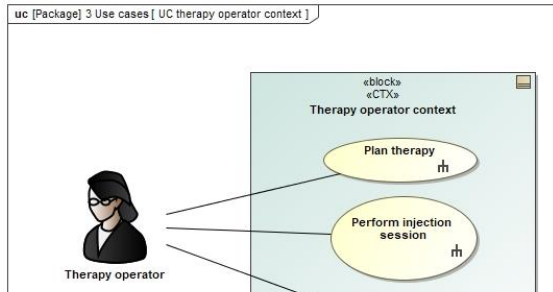


MBSE as key enabler

Introducing architecture modelling

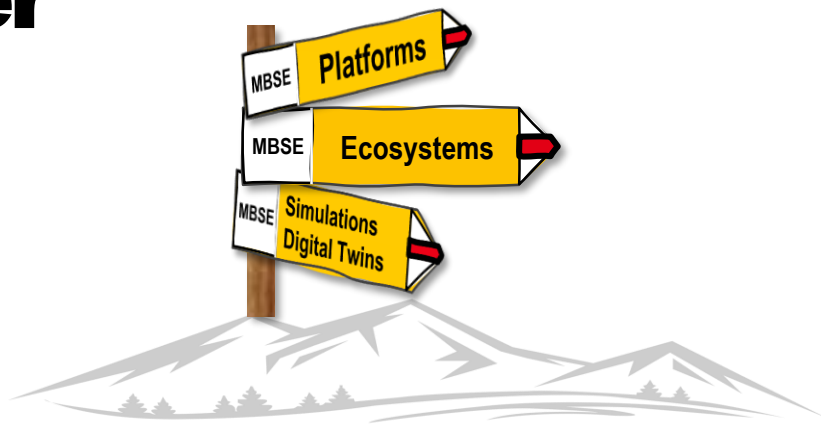
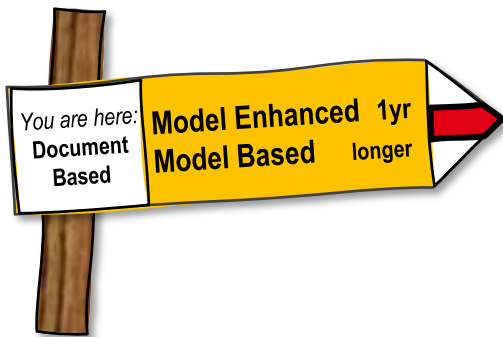


MBSE as key enabler



#	Name	DIR To functional-structure model	Functional allocated to	Fu
80	(R) (EPR) The duration of an injection of active drug into air (without resistance).	output1 : Drug product output : Drug product Deliver drug(context Fir Shift drug product(cont Release energy(context output : Drug product Flow(context Drug prod Convey the flow(context	Finished Device Stopper Autoinjector Drug product Staked needle syri	SR-1.2 SR-1.3 SR-1.9 SR-3.3
105	(R) The axial force of the plunger rod shall be ≥ 8 N at end and ≥ 15 N at the star	Enable plunger rod posi	Autoinjector	SR-4.1 The assembly of the AI should be suitable f SR-4.1 The assemb Stein Steriles

MBSE as key enabler



Document Based

Information in documents → **manual alignment (limited)**

Information mainly as text → **content not easily accessible**

Content copied from previous projects → **reinforcing status quo**

Manual checks for completeness & consistency → **effort & errors**

Impact of change unclear → **risk of bad surprises**

LCM: all aspects listed above → **change = effort + risk → avoided**

Model Based Systems Engineering

Information in models → **easier alignment ("connecting the dots")**

Models with Diagrams → **better common understanding**

Content creation with method/tools → **focus on content (new/reused)**

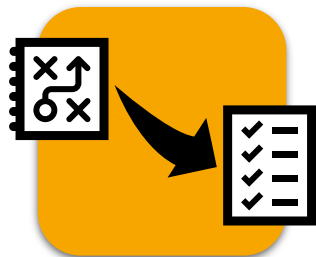
Automated checks for completeness & consistency → **speed & quality**

Impact of change transparent → **good change decision basis**

LCM: all aspects listed above → **change is welcome → innovation**

MBSE Use Case Scoping

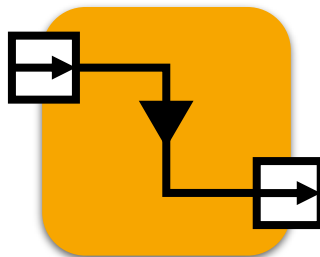
Best Practices Approaches in Industry



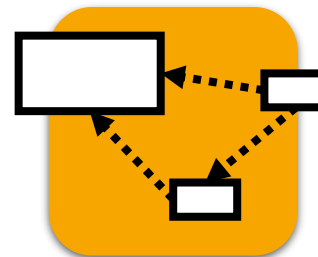
Requirement
development



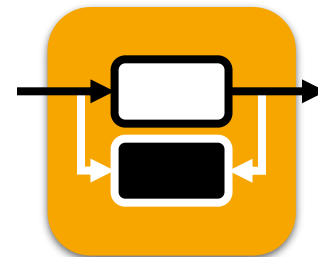
System specification,
visualization & communication



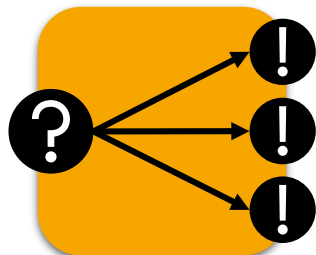
Interface specification



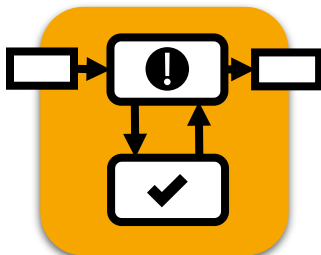
System V&V
test development



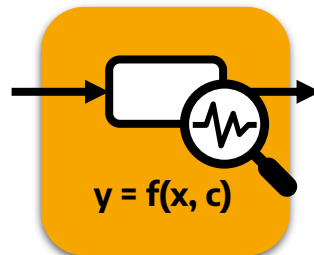
Variability modelling



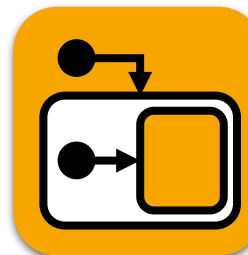
Consistency-, impact-
& coverage analyses



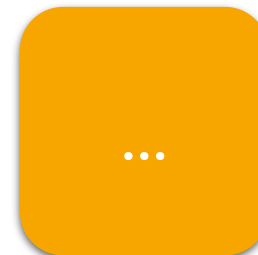
Safety and security
analyses



Parametric constraint
modelling & analyses



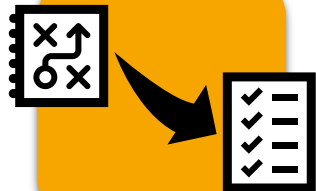
Dynamic behavior
Modeling



...and many more

MBSE Use Cases at NOVARTIS

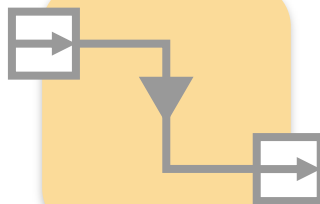
Focus on RE/RM, System Specification, Visualization & Communication, Impact Analysis



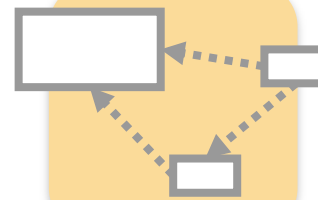
Requirement
development



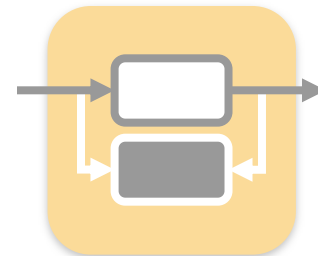
System specification,
visualization & communication



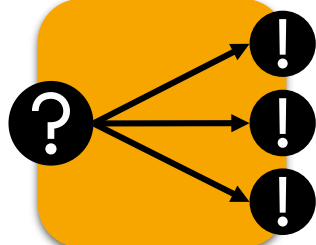
Interface specification



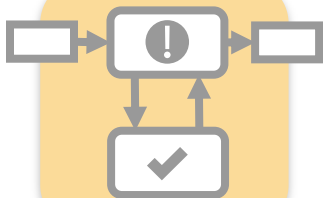
System V&V
test development



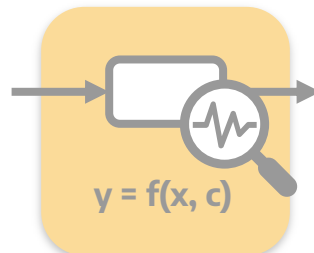
Variability modelling



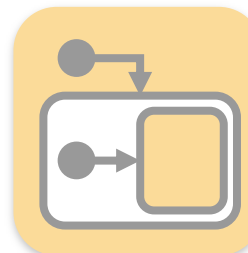
Consistency-, impact-
& coverage analyses



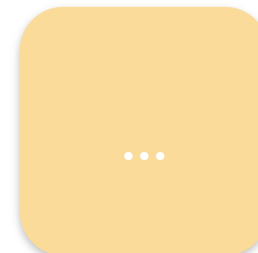
Safety and security
analyses



Parametric constraint
modelling & analyses



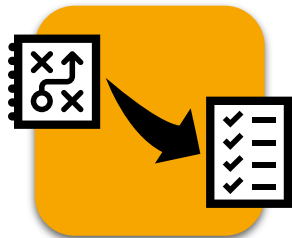
Dynamic behavior
Modeling



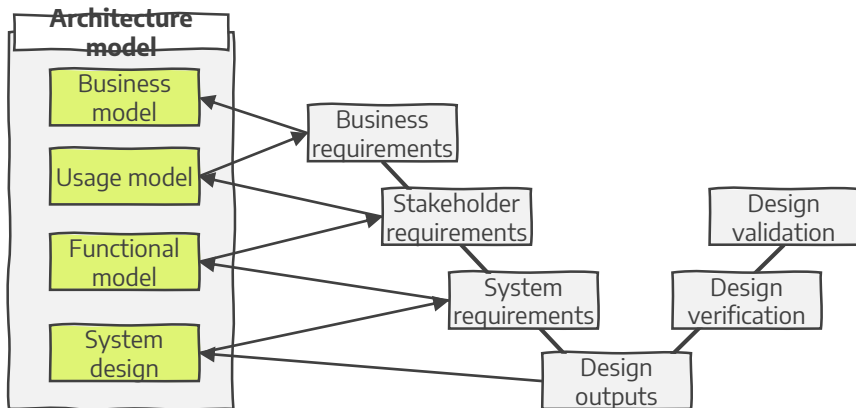
...and many more

High Priority MBSE Use Cases at NOVARTIS

MBSE Use Cases Tackling NOVARTIS Challenges



Requirement development



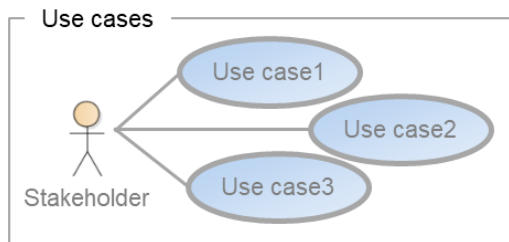
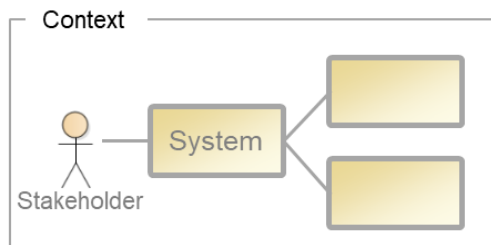
- **Stakeholder and Use Case Analysis** for combination products (360° view)
- **Requirements Elicitation and Engineering** (using Polarion)
- **Requirements Management** and **R-F-L-approach** (connecting Polarion & Cameo)

→ Benefits for NOVARTIS Challenges

- More defined accountability for stakeholders
- Better exploration of problem domain
- Traceability across tools (Polarion & Cameo)

High Priority MBSE Use Cases at NOVARTIS

MBSE Use Cases Tackling NOVARTIS Challenges



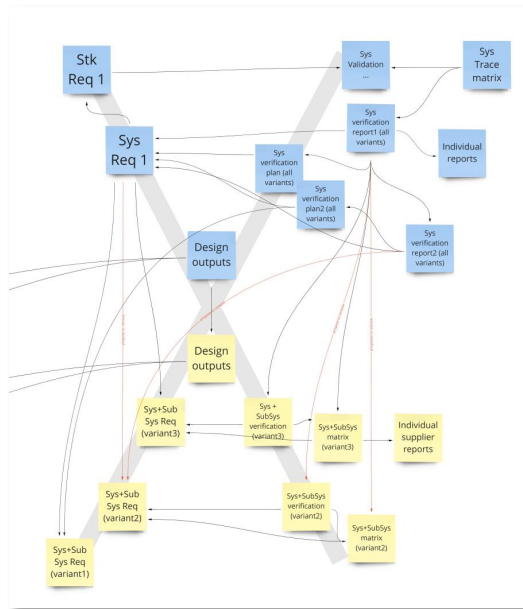
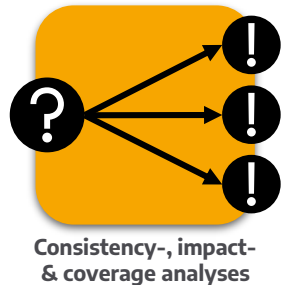
- Introducing **Systems Thinking** as a mindset and foundation for MBSE (using CAMEO)
- **System Architecture Design** based on MBSE method using SysML (e.g. Magic Grid)
- **Easy-to-understand MBSE diagrams** (including icons) for visualization/communication)

→ Benefits for NOVARTIS Challenges

- Increase space for innovative solutions
- Clear organization of system and subsystem levels
- Visual presentation of data in systems development

High Priority MBSE Use Cases at NOVARTIS

MBSE Use Cases Tackling NOVARTIS Challenges

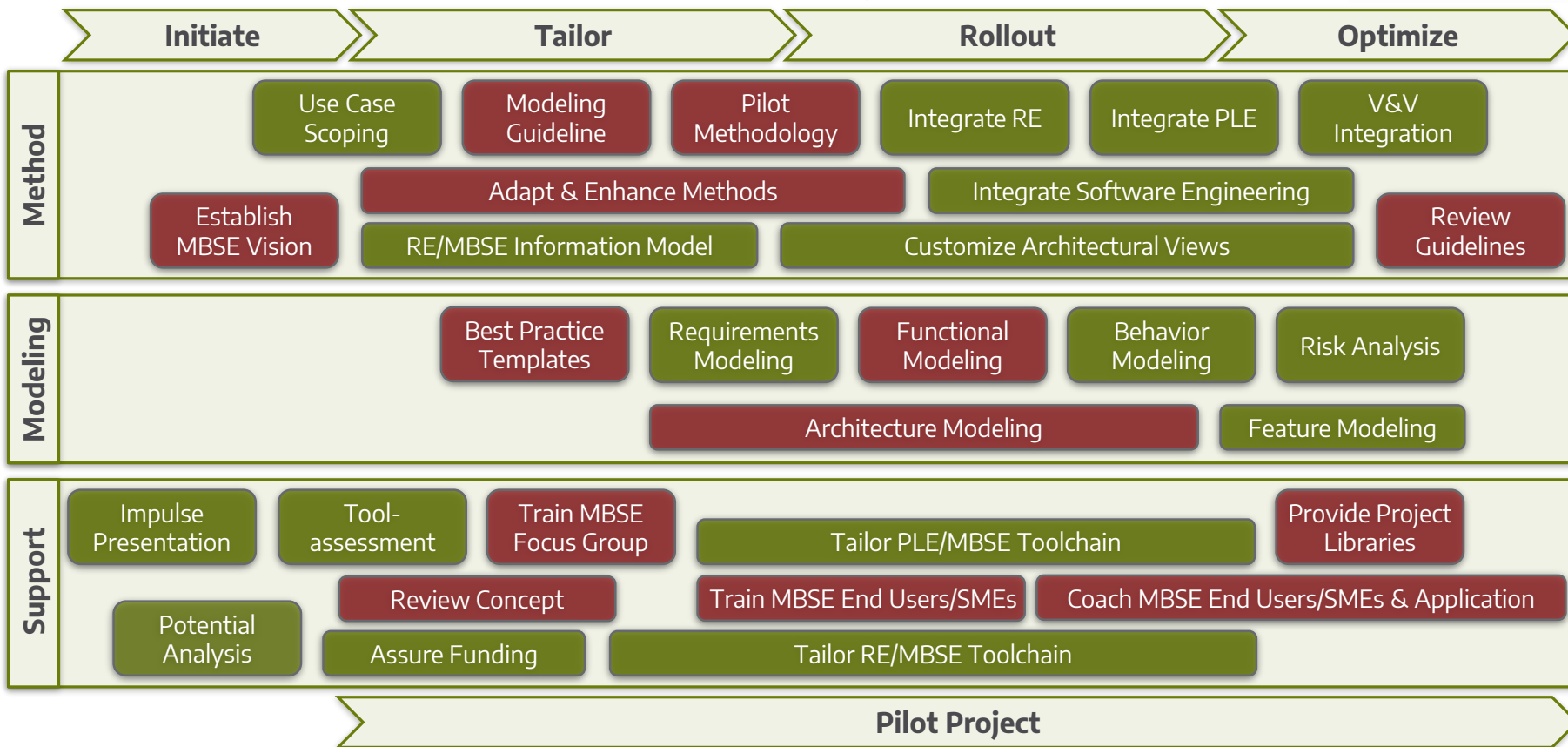


- **Traceability and Impact Analysis** for visualization of dependencies and what-if-queries
- **Coverage analysis** in order to check fulfillment of requirements, functions, etc.
- Supporting **trade-off studies** and **design decisions**)

→ Benefits for NOVARTIS Challenges

- Introduce functional analysis
- Improved trace from requirements to V&V
- Model centric access to data (across document layers)

Novartis MBSE Journey and Pilot Project Approach



We deliver the digital future of engineering.

Thank you for your attention!

Contact Details presenter Novartis AG

Ettore Marzocchi, PhD

Senior Expert Engineering

ettore.marzocchi@novartis.com

Contact Details presenter :em engineering methods AG

Oliver Bleisinger

Team Leader Model-Based Systems Engineering

oliver.bleisinger@em.ag