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Model-based Engineering in Medical Device Development – Issues & Solutions

INCOSE
Internatioal Workshop
Phoenix, AZ, USA
January 29, 2011

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Goals of this Talk

- Discuss the **experiences using engineering models (**in different phases of product development of a next generation imaging platform)
- Identify and share **needs and requirements** with colleagues from diverse industries **to advance** product **development** tooling

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Siemens Healthcare
THE Integrated Healthcare Company

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in-vivo diagnostics (imaging)

X-Ray

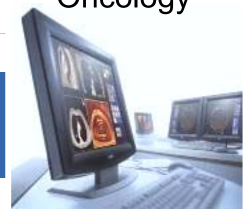
Computed Tomography

Magnetic Resonance

Molecular Imaging

Ultrasound

Oncology



***syngo*.via**

in-vitro diagnostics (laboratory systems)

Immunodiagnostics

Nucleid Acid Testing

Clinical Chemistry

Hematology

Urin Analysis

Lab Automation

Near Patient Testing

Siemens Healthcare
Development of Sales and Employee Numbers

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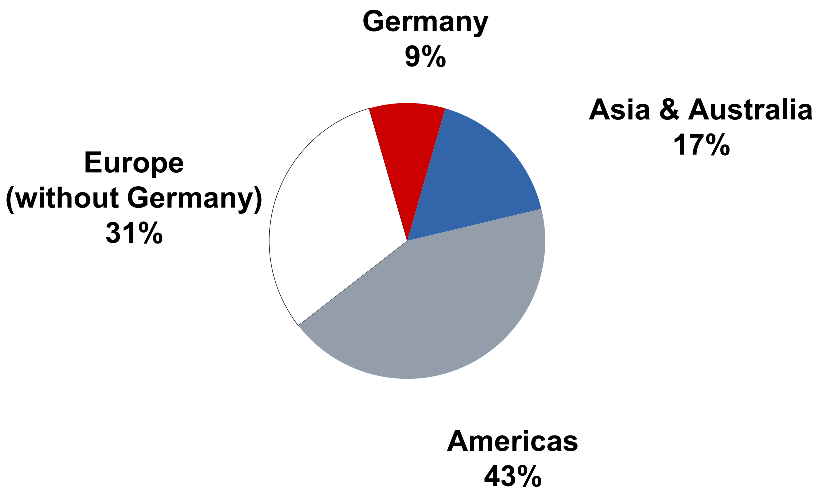
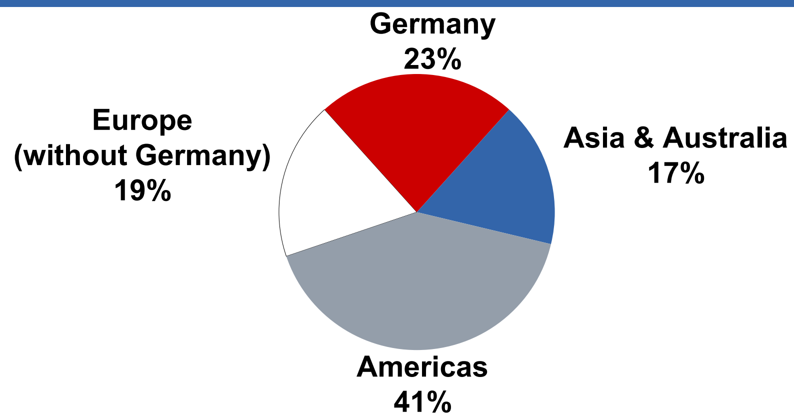
Sales according to region[1)]



Employees according to region[2)]



[1)] Basis: FY 2009 acc. To customer locations. [2)] Figures worldwide as of Sept. 30, 2009

Siemens Healthcare
Major SYNGO Development Sites

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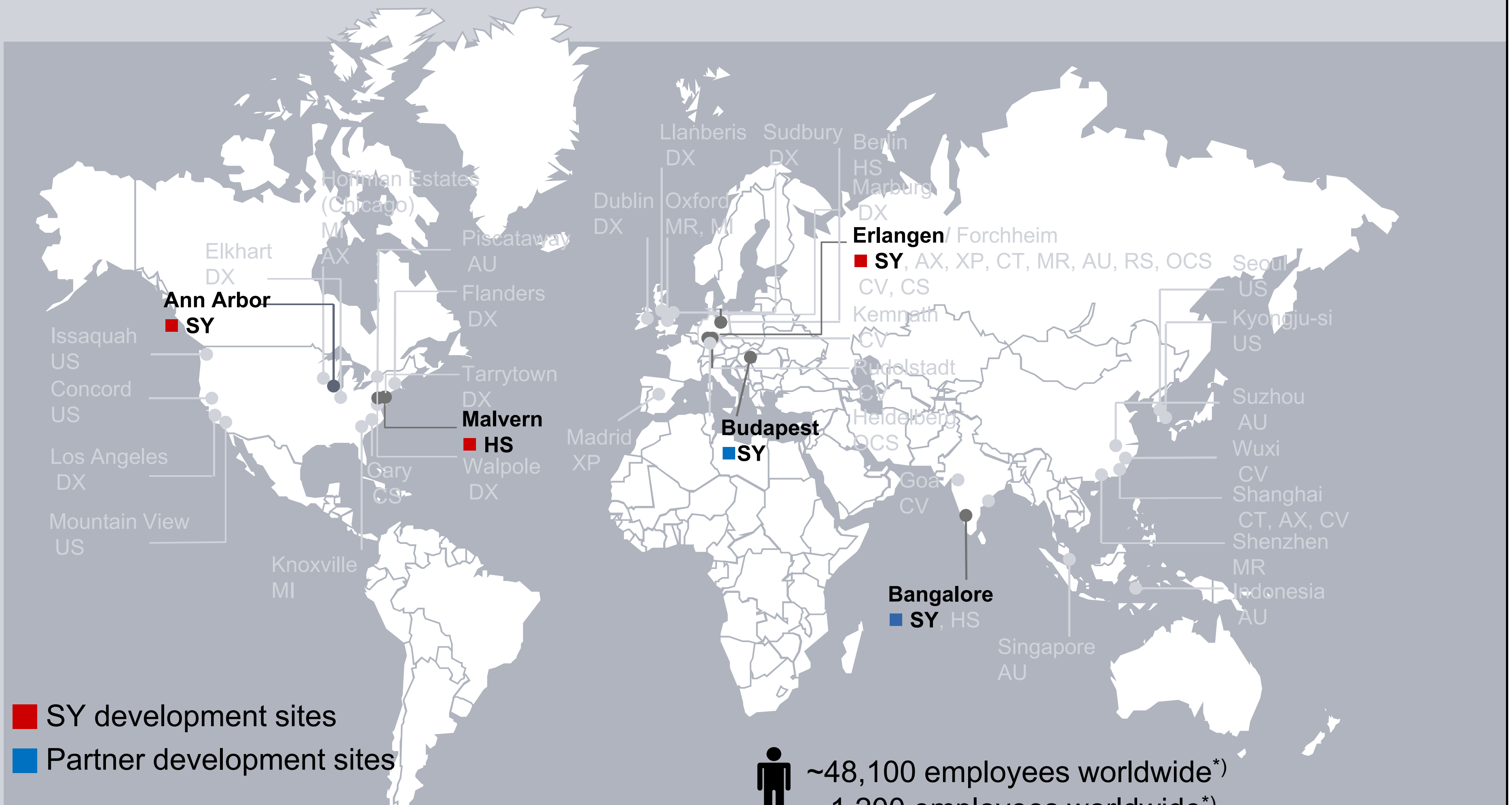

*) as of Sept. 30, 2009

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SYNGO Products

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- Clinical Imaging Applications
- Radiology Image Management (PACS)
- Radiology Information Systems (RIS)
- Cardiology IT Systems
- Enterprise Image and Information Access
- Multi-Site and Regional Solutions
- Services

syngo.via

syngo.plaza

syngo.via Product

Project Summary

***syngo*.via:** Next generation imaging software covering the entire reading process

Project data:

- > 5,000 single product requirements
- 7+ million lines of code C++/C#
- Several hundred developers in 5 locations
- Clinical applications for Radiology, PACS, X-Ray, CT, MI, Oncology, Particle Therapy and MR.

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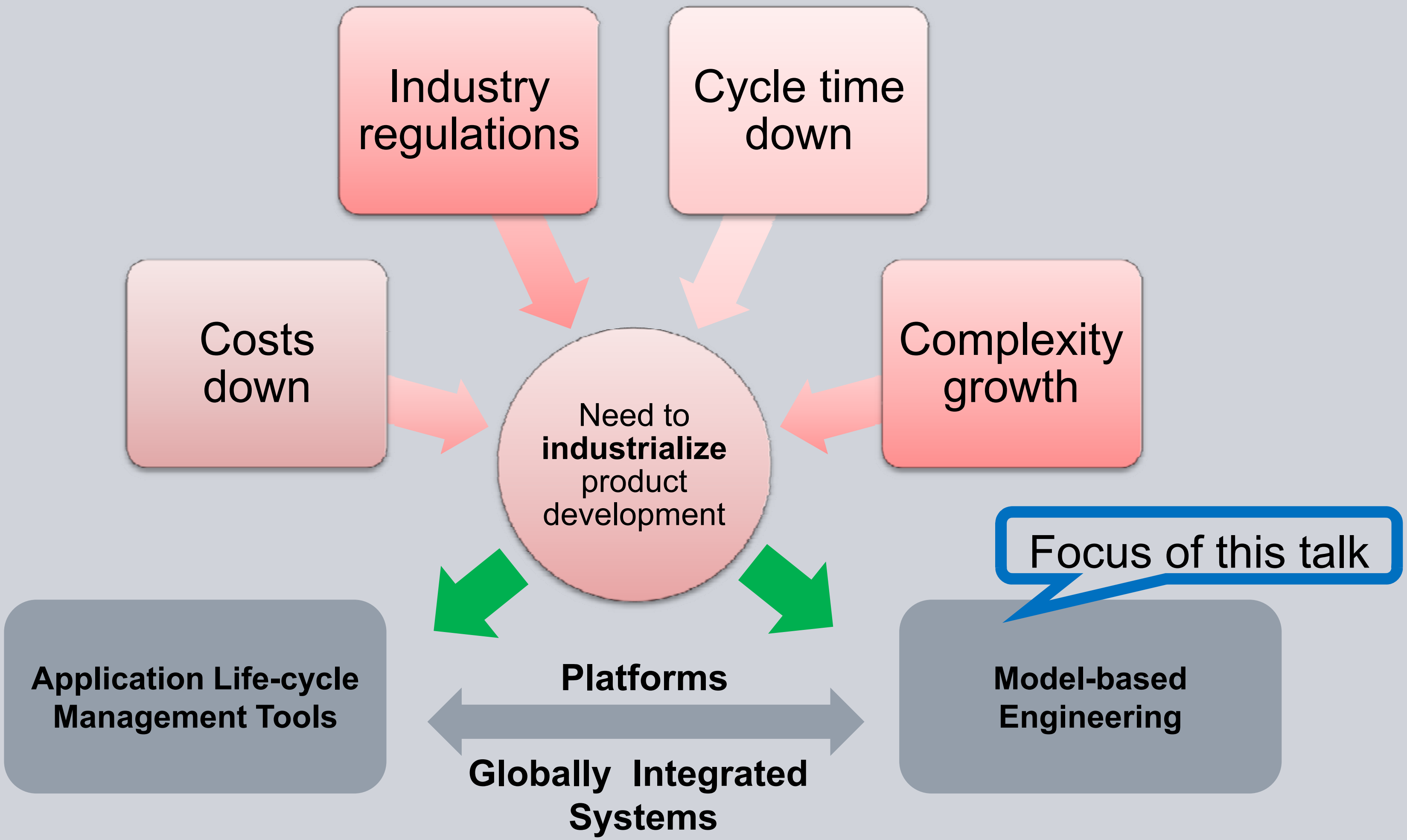
Business Challenges in Medical Device Industry



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Disclaimer:

The content discussed in this presentation needs

to be considered as work in progress.

Contents

Industry Issues and Pain Points

Pain Points	Business Impact
❶ Product structure intransparent, domain model partially incomplete	**Technology-driven product platform, no link to business drivers** ▪ Opaque relationship between problem & solution space ▪ Re-scoping sessions w/ customers on basis of 50+ specs.
❷ Ambiguity and lack of accuracy of specifications	**Textual-based specifications are subject to interpretation** ▪ Textual use case descriptions work only for smaller projects ▪ Natural language subject to interpretation, inconsistent, incomplete
❸ Controlling architectural complexity	**Redundancy of architecture components due to lack of understanding of problem- and solution space** ▪ Business needs not consistently linked to features ▪ Too much variability in software architecture
❹ Lack of V&V efficiency	**Test specifications in natural language are mostly executed in a manual way only** ▪ Test cases manually created ▪ 5000+ pages of requirements

Pain point 1: Product Structure Intransparent, Domain Model Partially Incomplete

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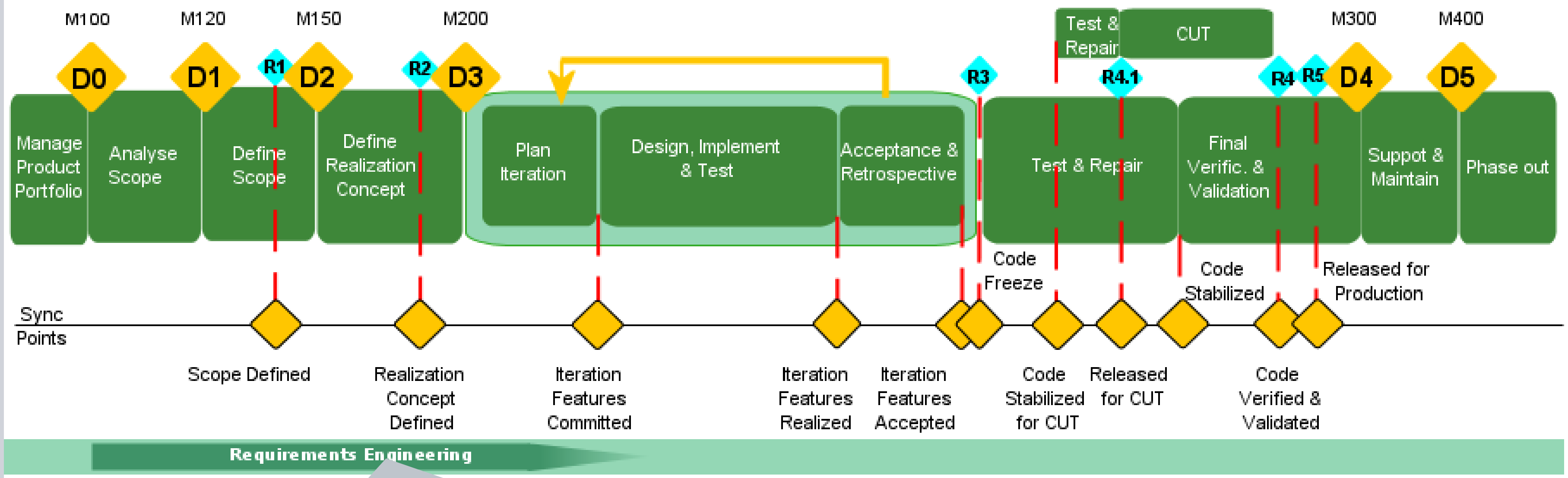

Selected issues:

- Opaque relations between problem- & solution space
- Re-scoping sessions w/ customer on basis of 50+ engineering specs.

Solutions:

A. Requirements Engineering Meta-model

B. Feature Model

Solution A: Requirements Engineering Meta Model – Benefits & Tool Requirements (1)

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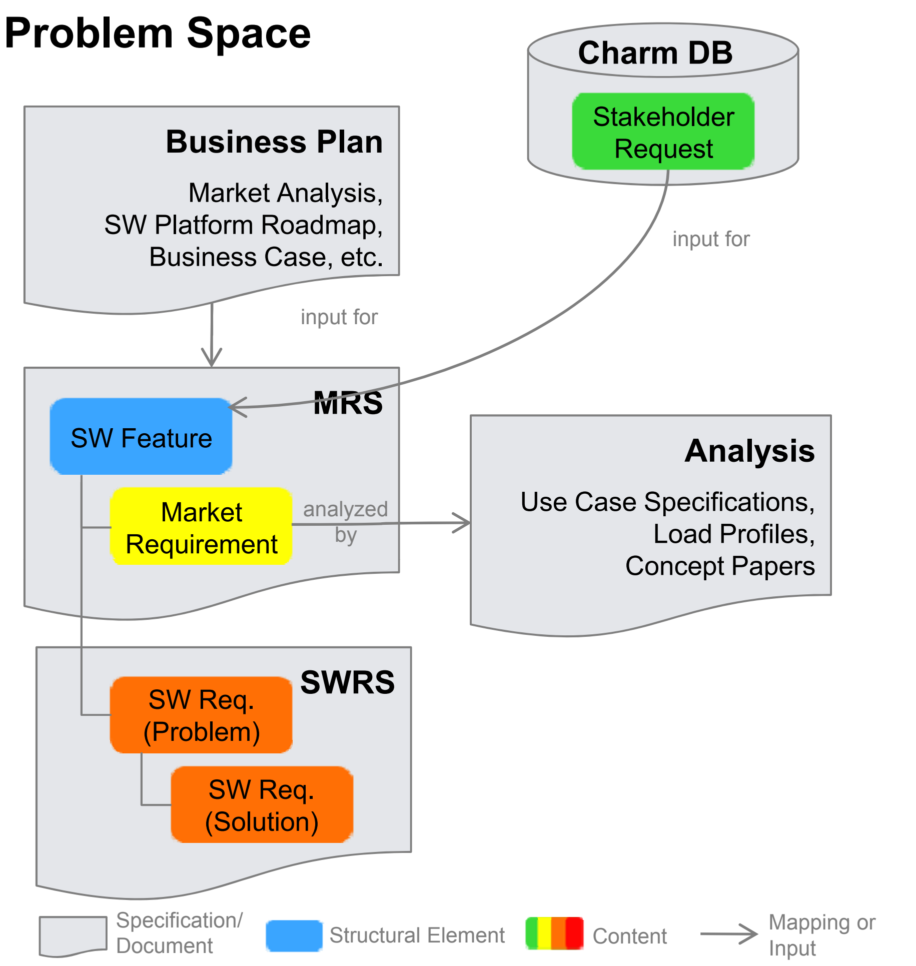

Characteristics:

- Provides needed artifacts, their attributes and relationships to each other.
- Using meta-model, it is also possible to prescribe the way how / which data are captured .

Benefits:

- Lean artefact infrastructure, no redundancy
- Guidance for engineering tasks with structured input
- Established link between business drivers, requirements, design and test

Solution A: Requirements Engineering Meta Model – Concepts (2)

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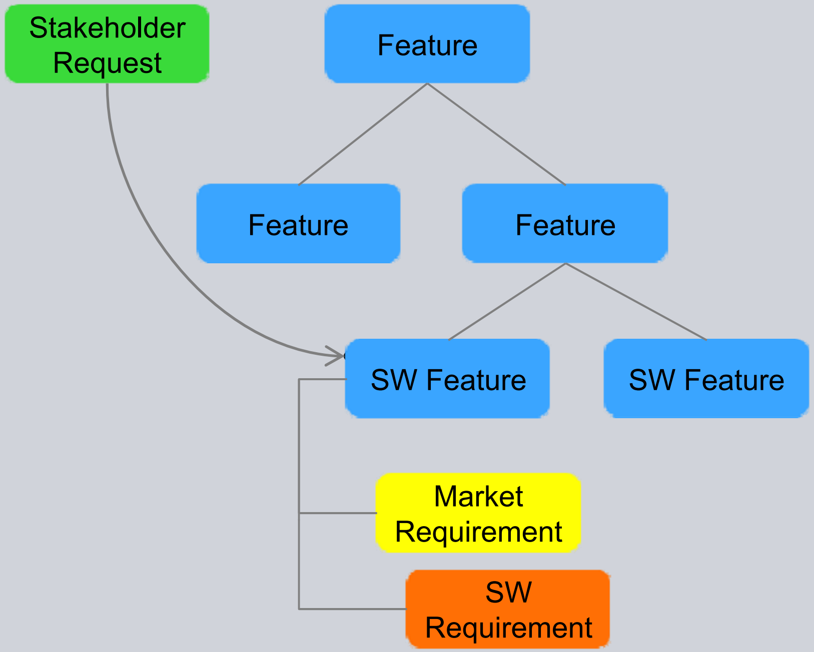

A **Feature** represents a characteristic of a product which provides a business value and supports purchase decisions […]. A Feature structure requirements in a meaningful way and is no specification in itself (only “container”).

A **Feature Model** is a hierarchical "tree" to describe the structure, dependencies, commonalities and variabilities of Features within a product or product line (e.g. SW Platform, Finished Medical Device).

Requirements specify the Feature. They represent the functionality already implemented within the product and functionality that is planned for future versions. Depending on the project phase requirements are less or more detailed (e.g. Market Req., SW Req.).

Stakeholder Requests are wishes towards an existing or future product. Stakeholder Requests (SR) are gathered from various sources (e.g. end customer, business units) and may have an impact on different levels and phases of the product lifecycle .

Solution A: Requirements Engineering Meta Model – Concepts (3)

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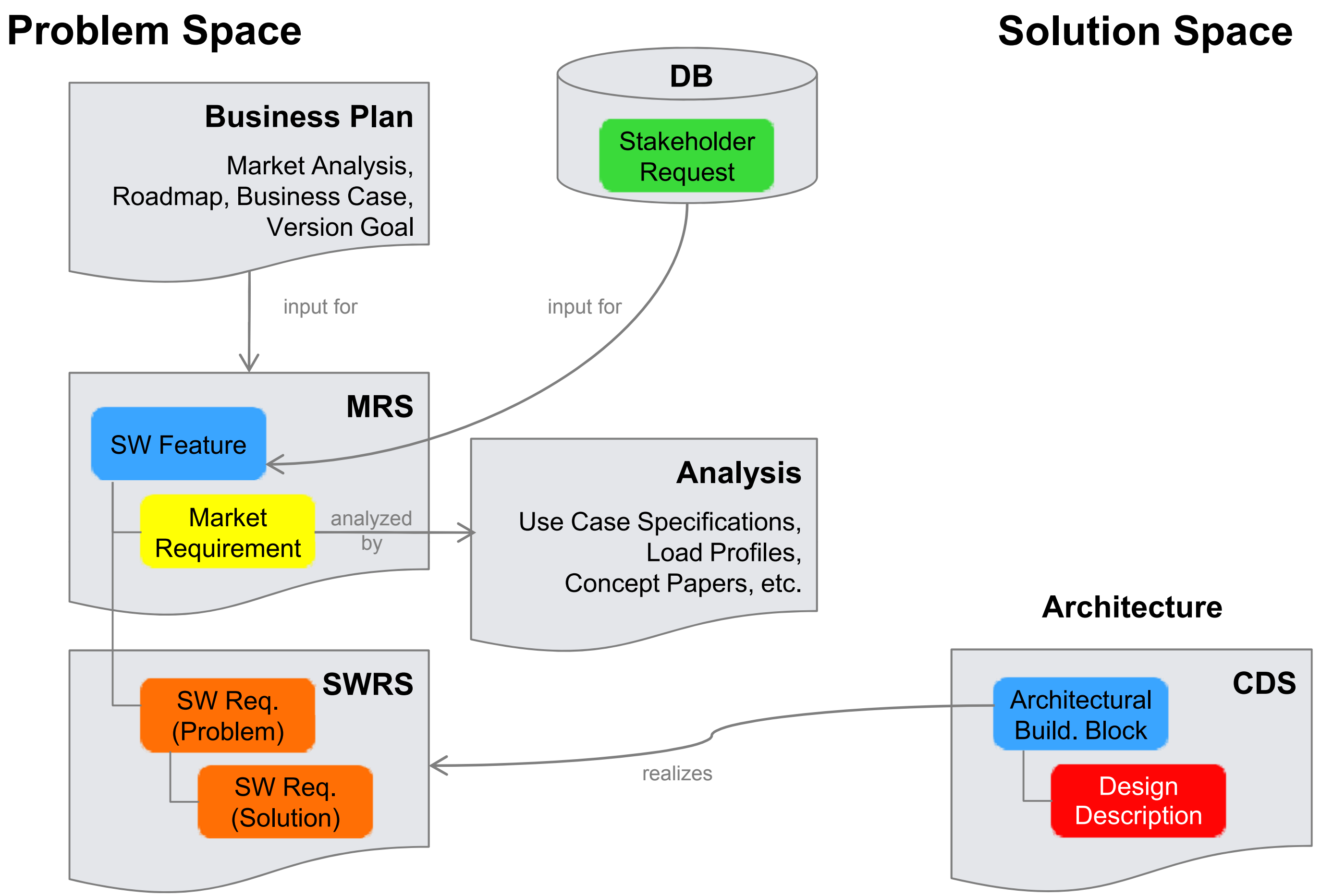

Solution A: Requirements Engineering Meta Model – Concepts (4)

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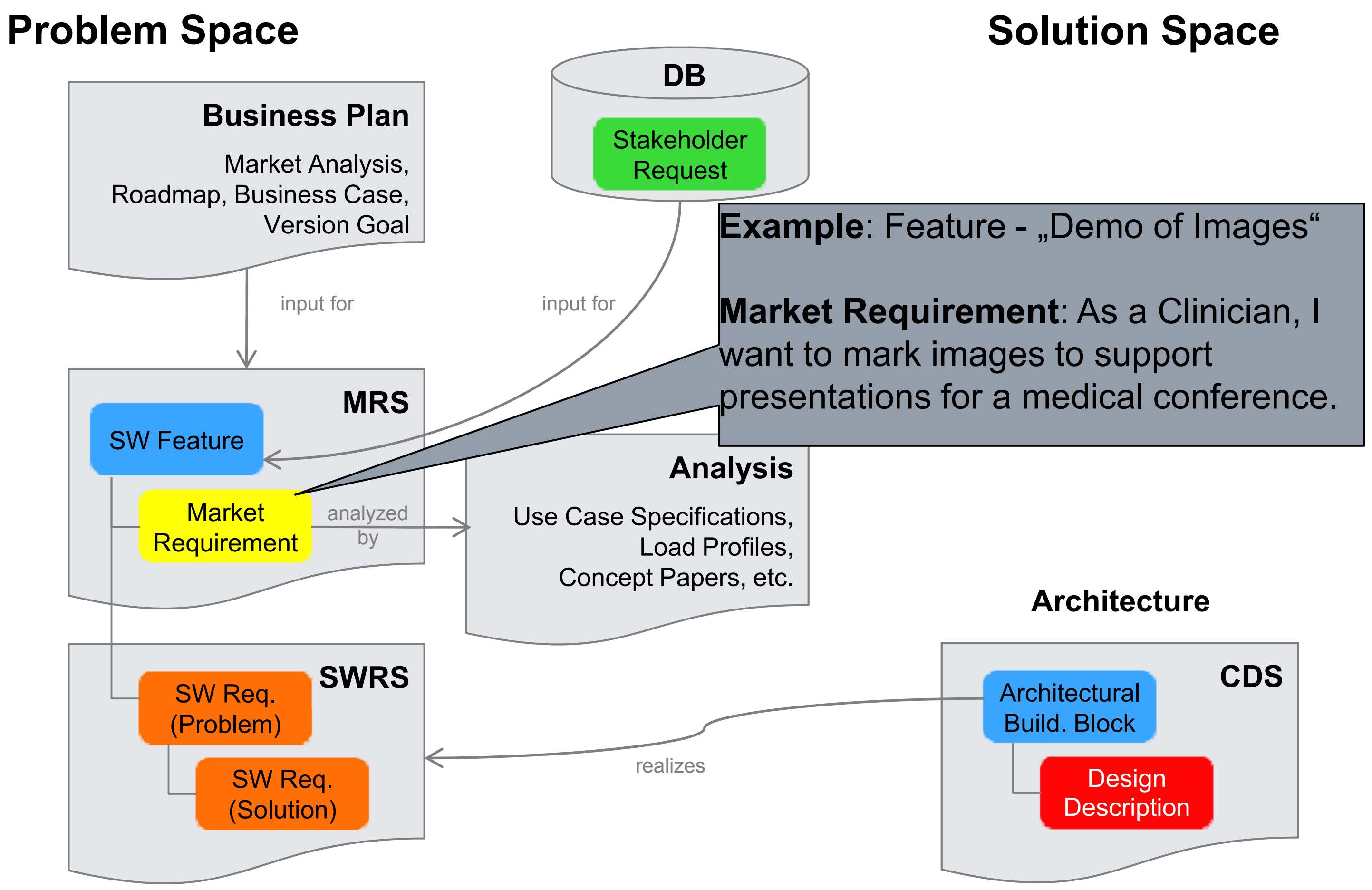
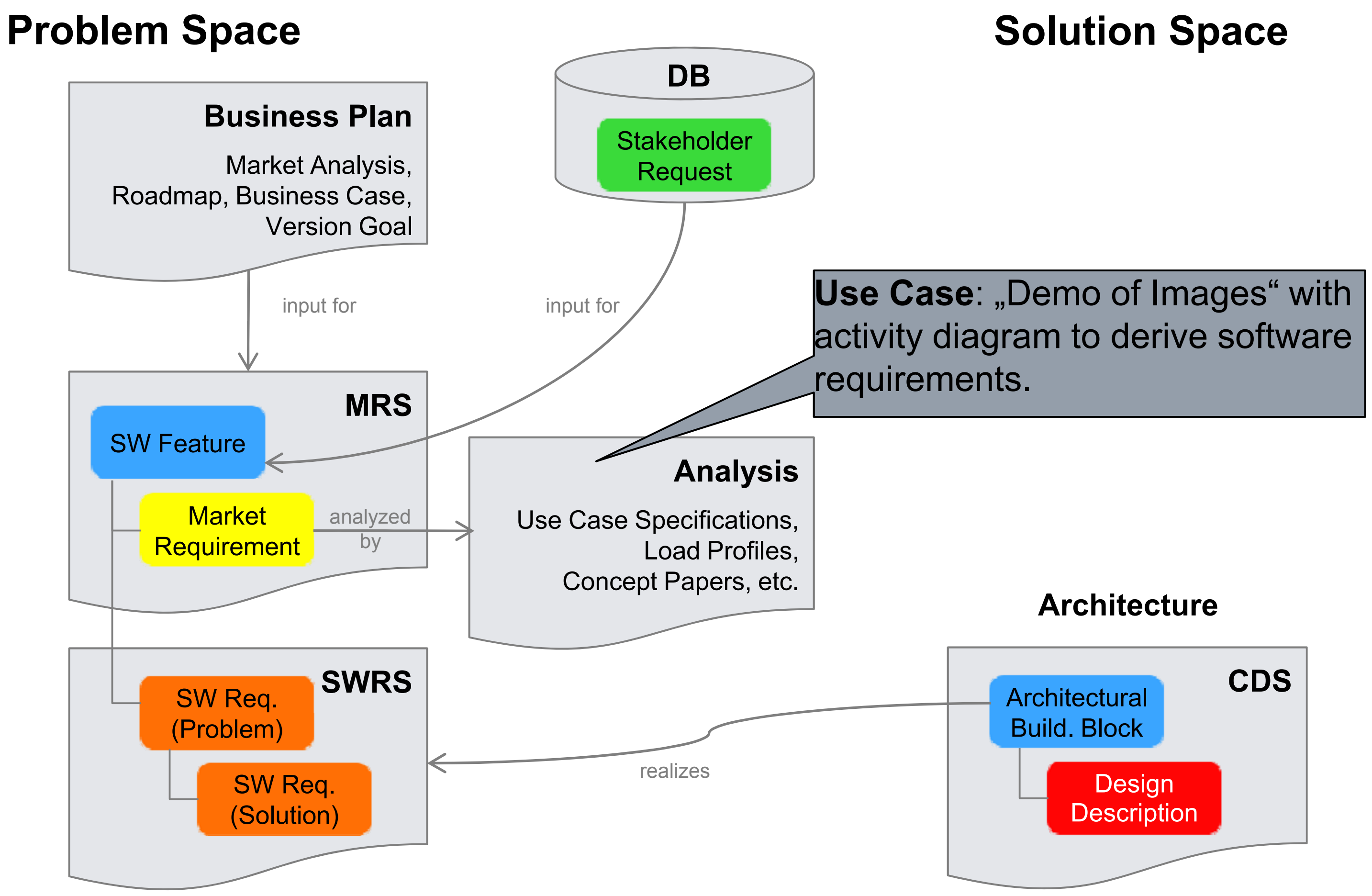
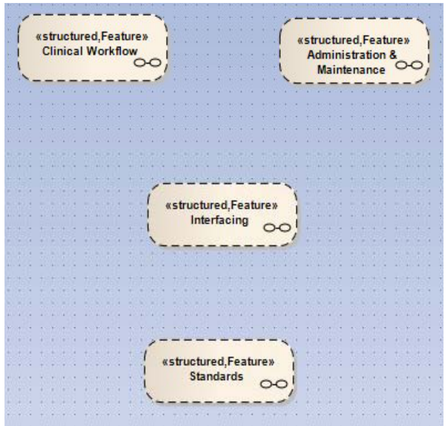


Solution A: Requirements Engineering Meta Model – Concepts (5)

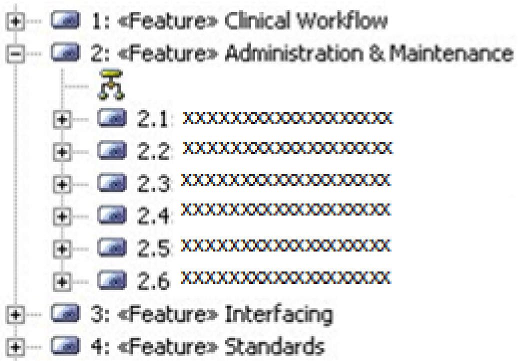


Solution B: Feature Model

Highest Level



Graphical View



Hierarchical View

Characteristics:

- Hierarchical tree to describe the structure, dependencies and commonalities
- Lays out the basics for variant management and impact analysis

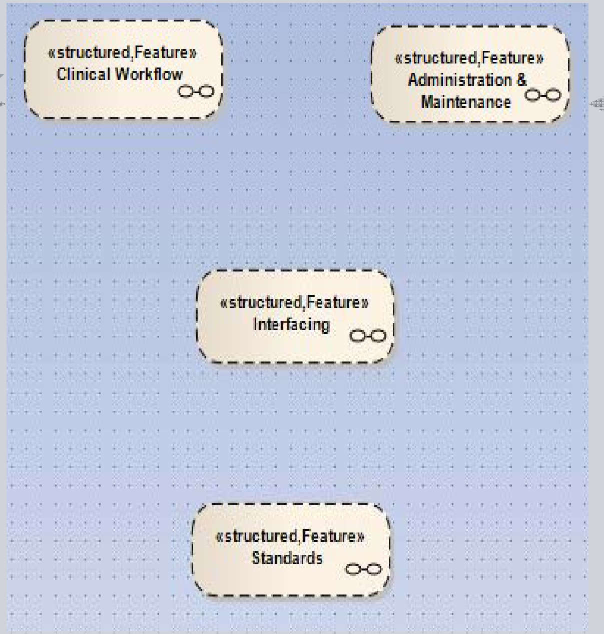
Benefits:

- Higher level abstraction of grouping of requirements into sellable units: From 5,000 product requirements to 800+ features (**factor ~ 6**)
- Visual domain model for healthcare workflows (tree & graphical)
- Reduction in time to understand aspects of the system

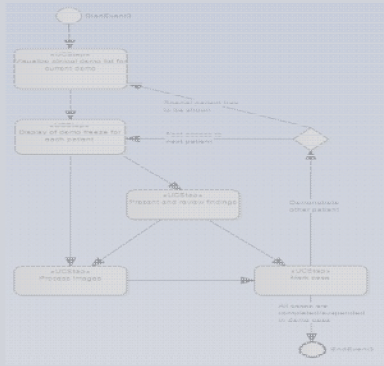
Solution B: Feature Model & Its Relations (1)

How can I manage huge amounts of Requirements?

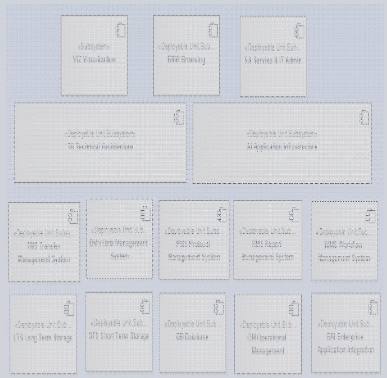
How do I scope a product version efficiently?



Application Use Cases



Architecture Model



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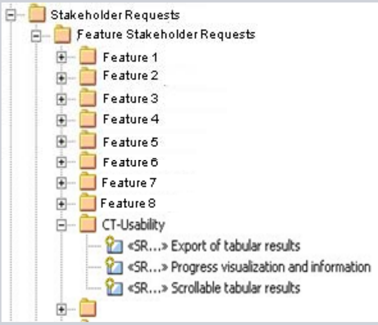
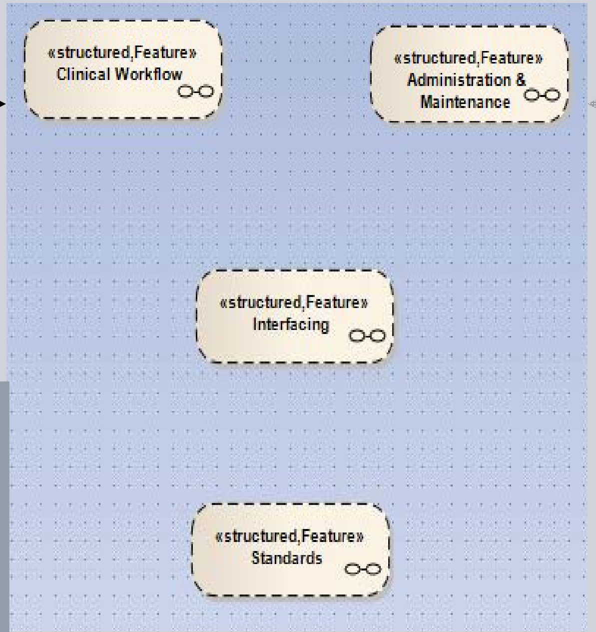
Solution B: Feature Model & Its Relations (2)

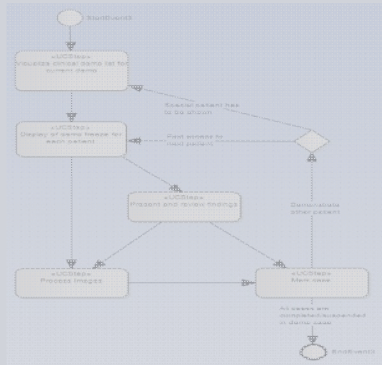
Stakeholder Requests



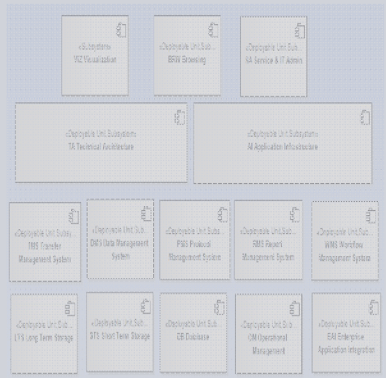


How do I manage stakeholder requests from different businesses most effectively?

Application Use Cases



Architecture Model



Pain point 2: Ambiguity and Lack of Accuracy of Specifications

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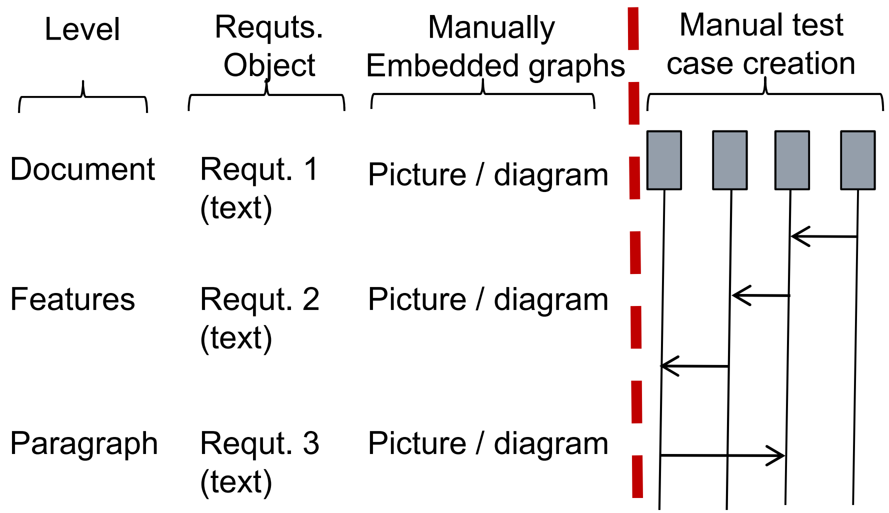
Issues:

- Textual use case descriptions work only for smaller projects < ~ 100 requirements
- Natural language subject to interpretation, usually inconsistent, incomplete with inccorrect version (and conflicting)



Root causes:

- Textual requirements engineering do not scale for platform projects
- Missing versioning
- No direct access to single requirements
- Lack of product structure
- Inconsistently executed change management process

Solutions:

C. Application Use Cases

Solution C: Graphical Modeling of Clinical Workflows (1)

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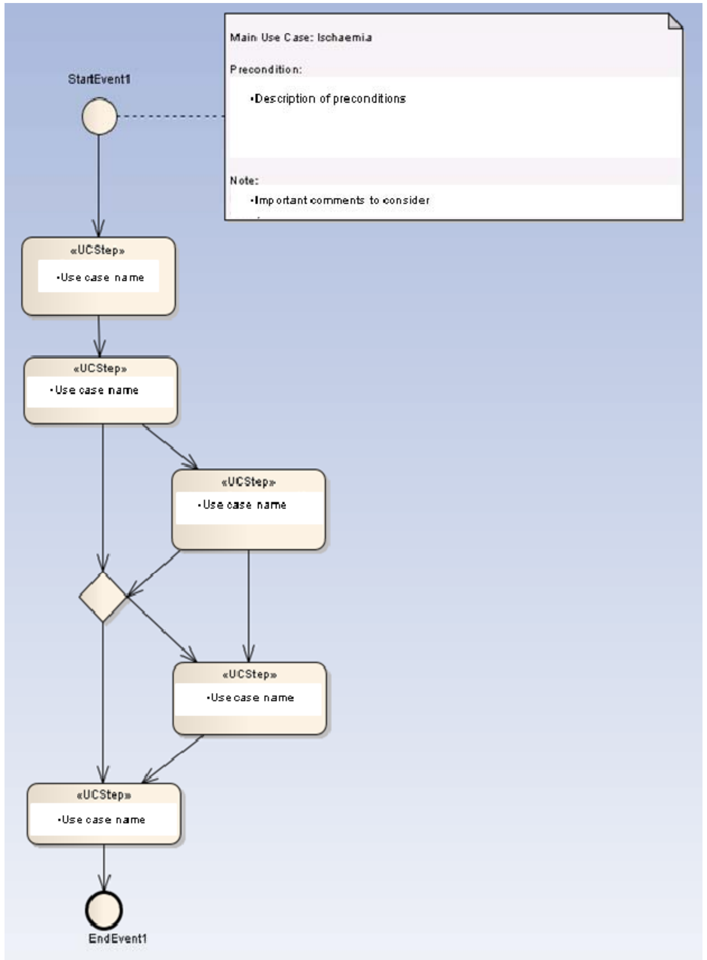


Characteristics:

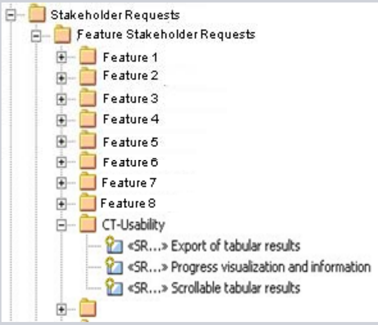
- Used to describe clinical workflows that consist of a collection of steps in a defined sequence together with accompanying specification of pre-/post-conditions, business rules, performance aspects, etc.

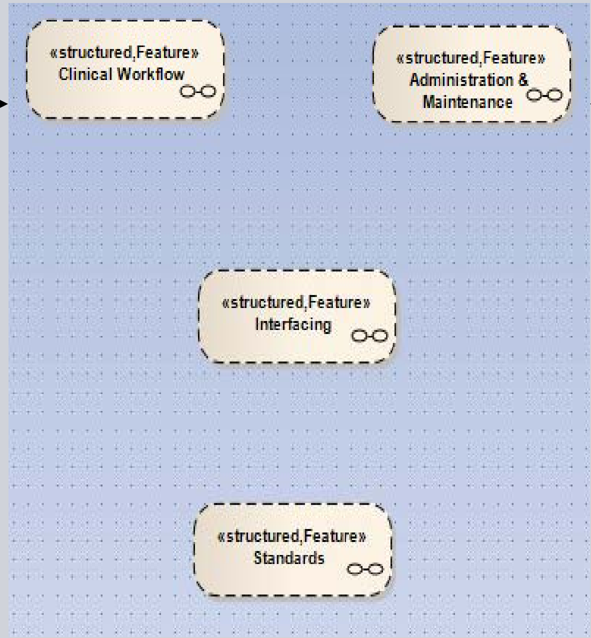
Benefits:

- Increase expressiveness of clinical workflows to describe dynamic behaviors of clinical workflows
- Early analysis of stakeholder requests from customers
- Improved impact analysis of change requests
- Joint modeling sessions to describe the needs from Jhe customer‘s point of view

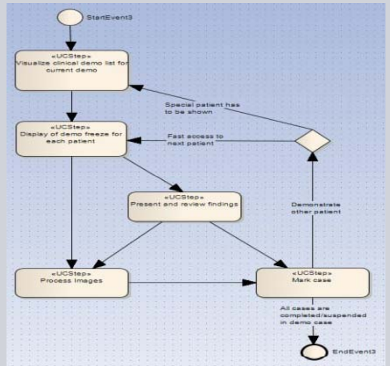
Solution C: Graphical Modeling of Clinical Workflows (2)

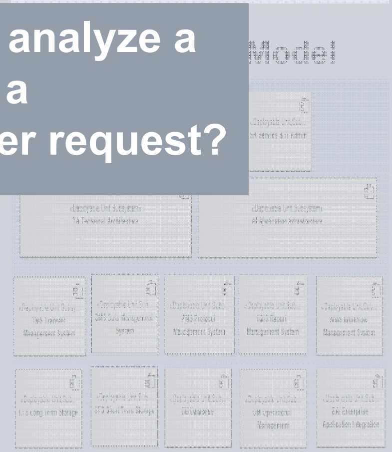
Stakeholder Requests





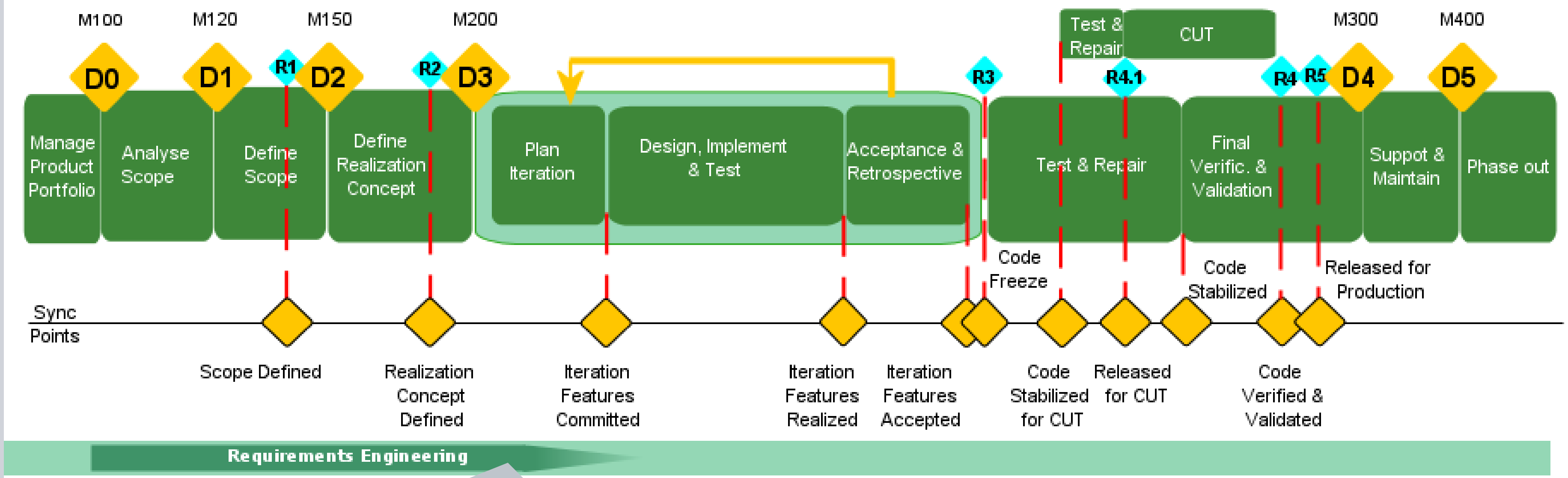
Application Use Cases





How can I analyze a feature or a stakeholder request?

Pain point 3: Controlling Architectural Complexity



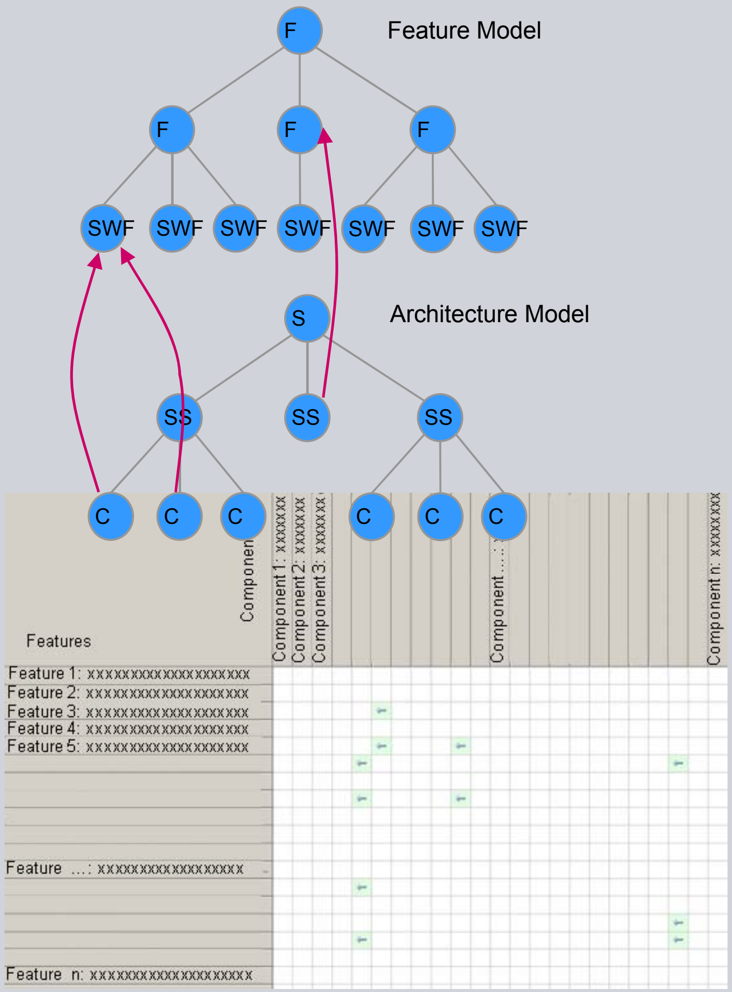
Selected issues:

- Business needs not consistently linked to features/ requirements; dependencies between features not easily visible
- Too much variability in software architecture

Solutions:

D. Architecture Model Mapping

Solution D: Architecture Model Mapping



Characteristics:

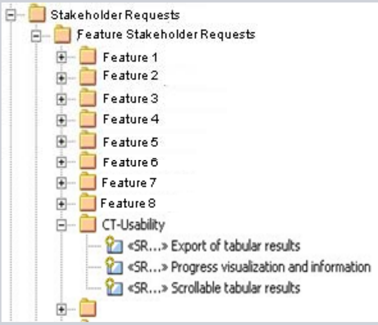
- Identifies links between features and their implementation
- Explicit modeling of variability in the architecture

Benefits:

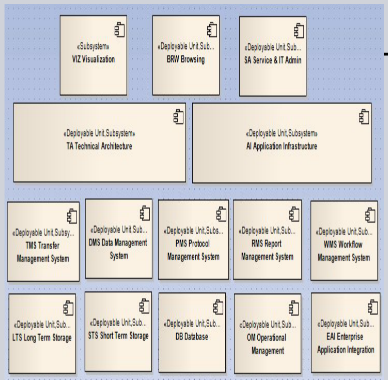
- Architectural decisions motivated by features and product-line variability
- Enabling reduction of architectural complexity
- Support impact analysis for (de-) scoping sessions
- Early identification of architectural risks
- Improved accuracy of early effort estimates
- Reduction of number of scoping sessions

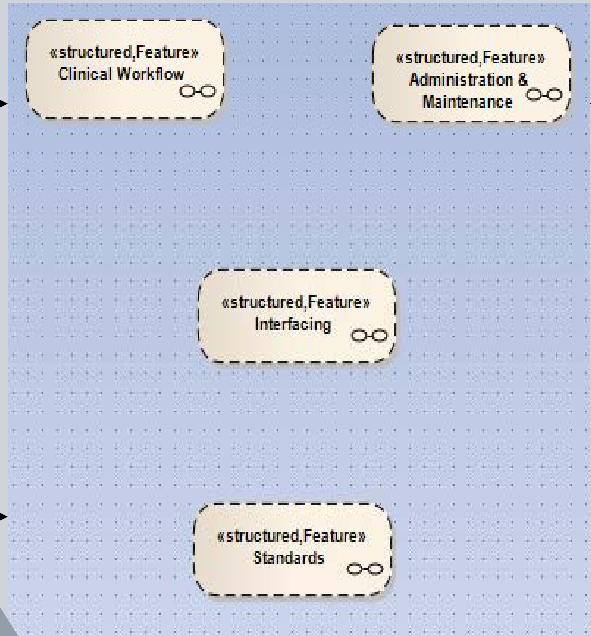
Solution D: Architecture Model Mapping

Stakeholder Requests

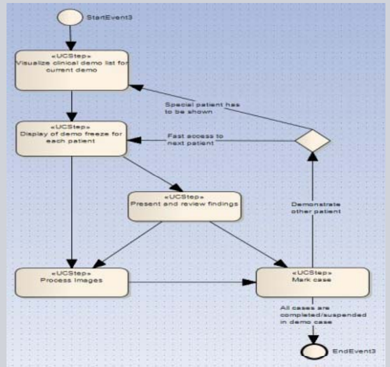


Architecture Model





Application Use Cases



Which component implements which feature?

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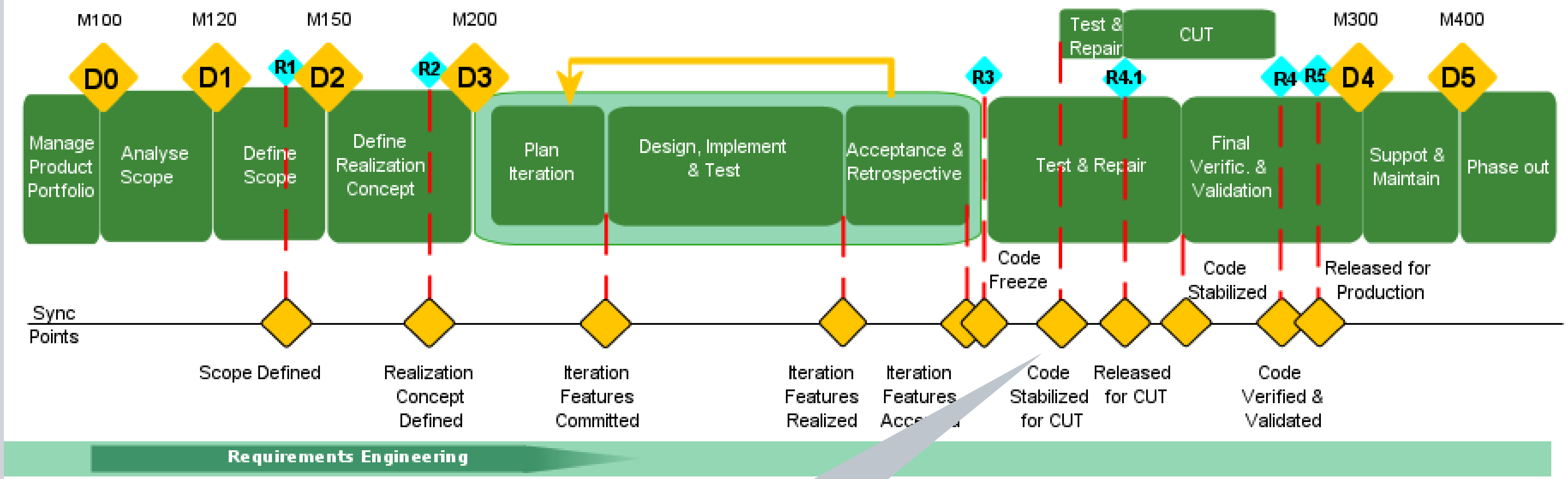
Pain point 4: Need to Increase V&V Efficiency (*)



Issues:

- Test cases partially manually generated from textual use cases
- Cycle times for system test too long
- Compliance requirements QSR 21 CFR §820.30, ISO 13485, EU MDD 93/42

Solutions:

E. Model-based System Testing

(*) Not yet piloted

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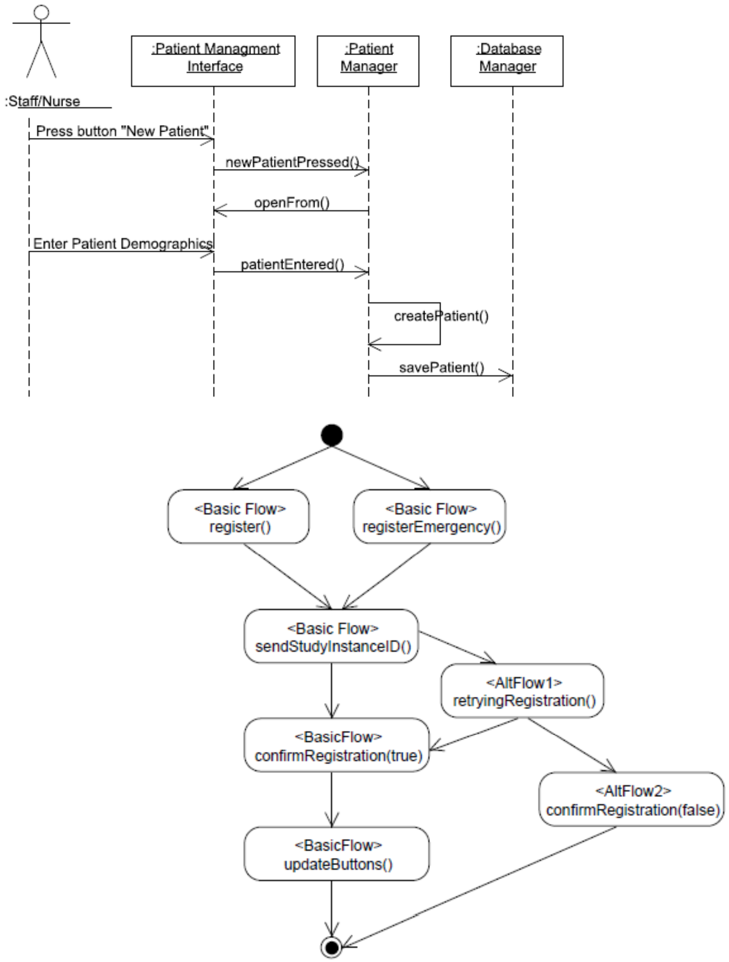
Solution E: Model-based System Test (2)



Benefits:

- Early identification of requirements defects through validation by testers
- Effort reduction for test (cycle time, cost ~ -30%) and increase of test coverage
- Decrease number of defects
- Model-based testing is highly structured, reproducible and efficient
- Increase reuse of development artifacts
- Quicker impact analysis by parsing model for late requirements changes

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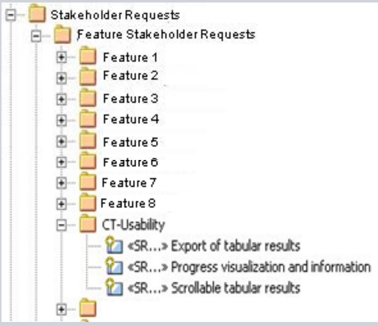
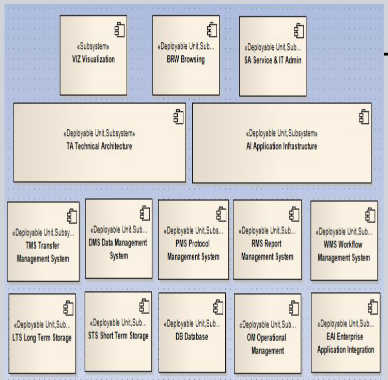
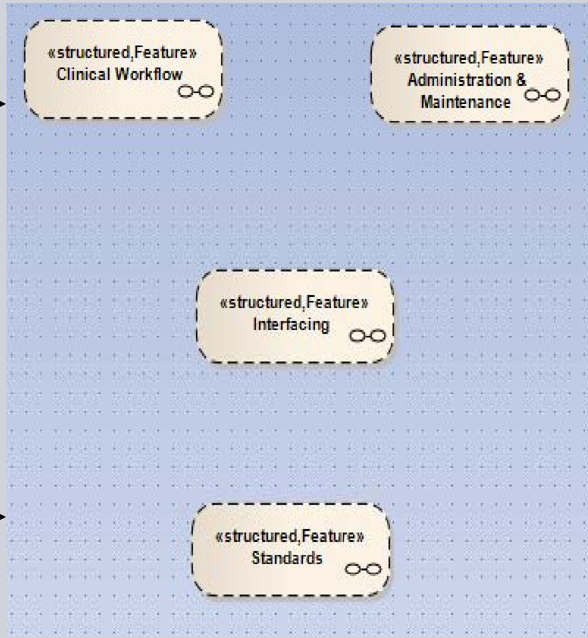
Solution E: Model-based System Test

Stakeholder Requests

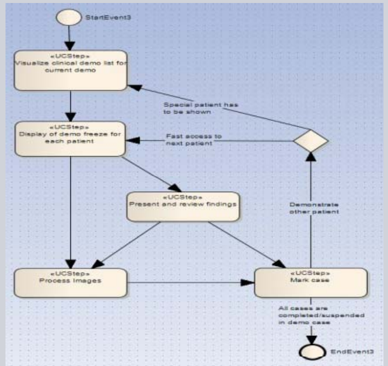


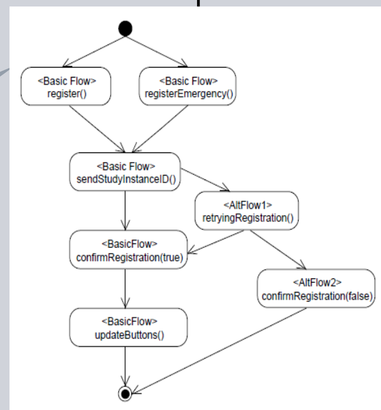
Architecture Model





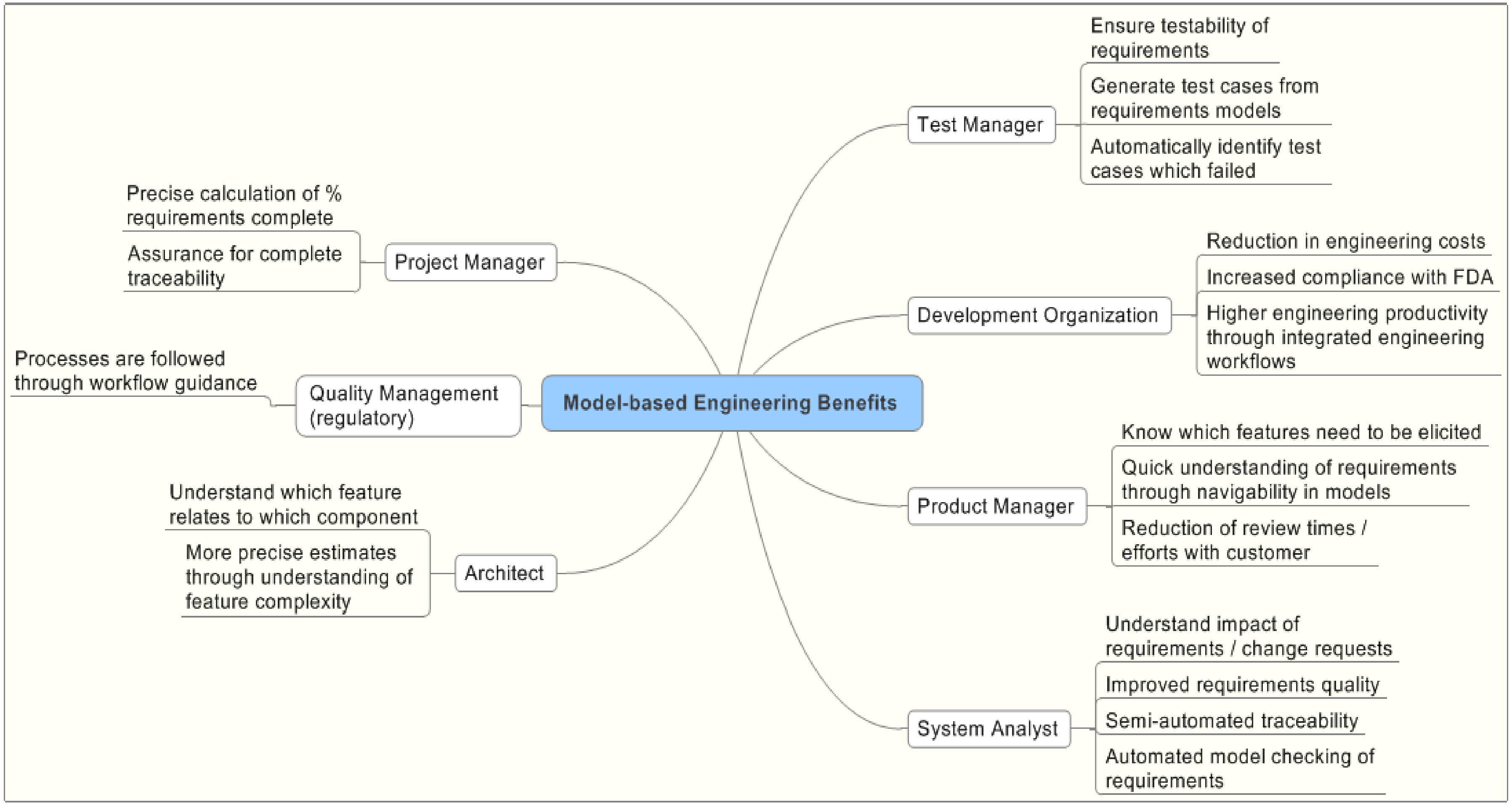
Application Use Cases





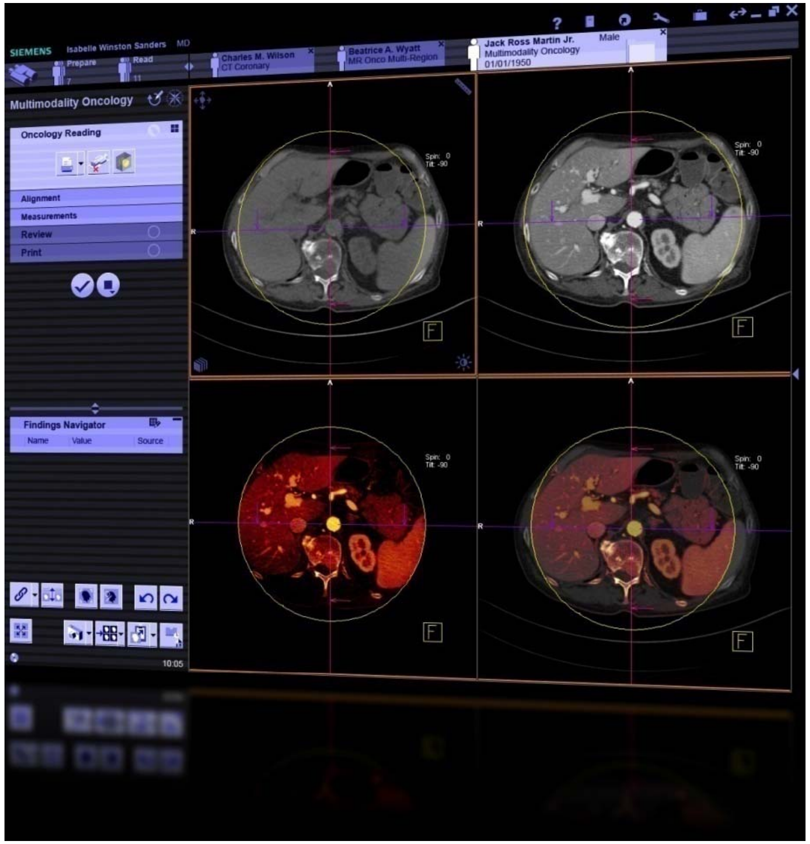
Which application use case is covered by which test case?

Benefits from Model-based Engineering



Major Changes to Development Approach
Model-based Engineering

- Requirements Engineering Meta-Model
- Feature Model
- Graphical Modeling of Clinical Workflows
- Architecture Model Mapping
- (Model-based System Test)



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Potential Business Impact using Model-based Engineering

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- Model-based engineering approach can cut development cycle-time by ~ 20% (*)
- Reduction of review effort by ~30% due to feature reviews (*)
- Model-based testing can cut effort by ~30% while increasing test coverage (*)

(*) Data from large-scale inudstry projects

Key Take-Aways for Model-based Engineering

- Seamless model-driven engineering is only partially tool-supported; the biggest gap remains in requirements engineering.
- Tool vendors need to stronger leverage the experience of leading development organizations and uptake it into technology roadmaps.
- Acceptance of model-based engineering is a huge organizational change management endeavor, only 10% of organizations have already gained practical experience.
- Continuous assessment and verification of business benefits for model-based engineering is a must to maintain sponsorship from management.

Thank you for your attention!

Contents

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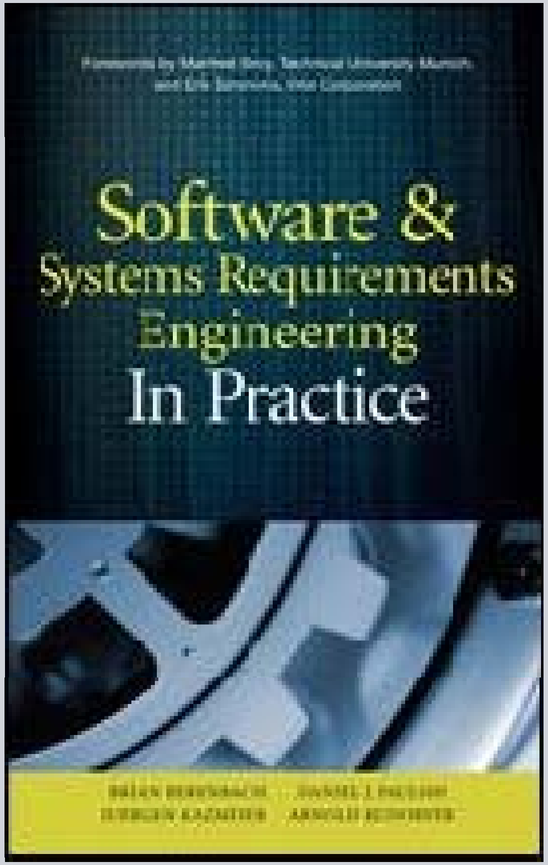
Documented Experiences and Best Practices from Various Industry Projects



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2009
McGrawHill

[Link to web site McGrawHill]

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