Innovations in Model-Based Systems Engineering (MBSE)

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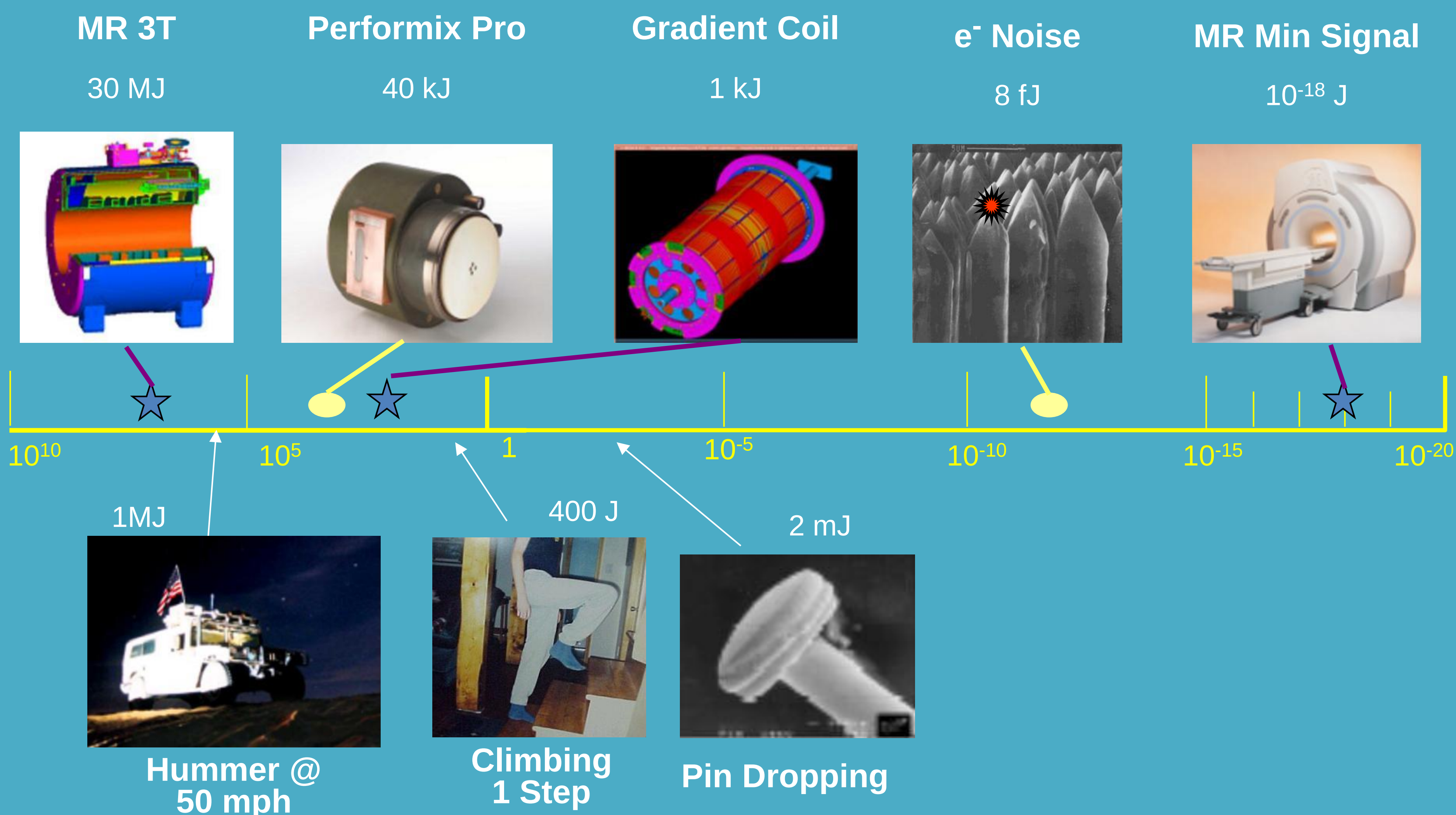
The Challenge… Energy Conversion & Detection



GEHC Approach to New Product Introduction

Tradition NPI process

Program Kickoff | System Req'ts Freeze | Hardware Freeze | Verification Complete | Pilot Release | Full Production | Customer Satisfaction

Traditional artifacts

Requirements = DOORs/Trace (text based)
Systems diagrams in "Visio" (FBD, state machines, activity diagrams, …)
"Quantitative" performance simulations

Challenges

- Lack of customer focus
- Scope creep
- Late integration issues
- Lack of model integration
- Poor requirements leveling (capturing design as reqts)

Recent additions

- Formal Reliability process & team
- Formal Usability process
- Agile methodology (for SW)
- Design for Producibility
- Design for Six Sigma (revitalization)

How Modelling fits in

Systems

- Physics (IQ)

Systems

- *Behavioral*
- *Customer FoM model*

HW: Performance Models

- EE: Cadence/Mentor (Chip->Board)
- ME: Thermal, Structural, Acoustic/Vibration, Life
- Reliability allocations and models
- Should cost modelling

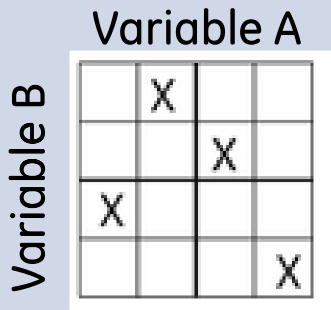
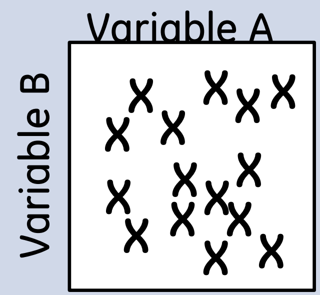
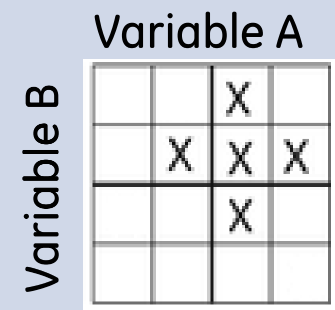
SW: UML models

MFG: Capacity/Cost Models

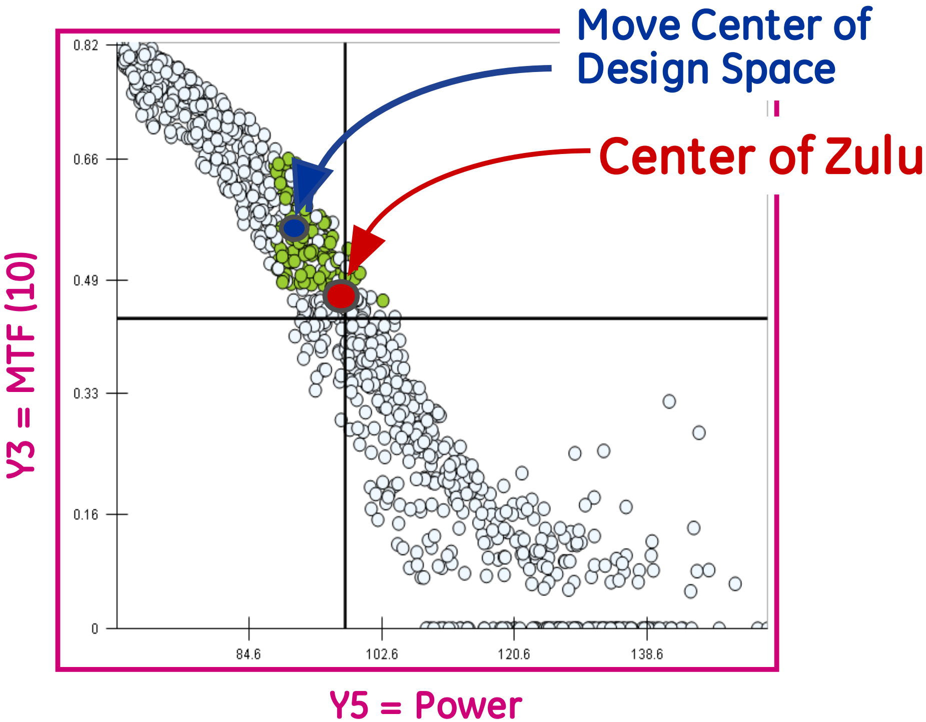
- Scrap/Cost models
- Capacity/workflow models

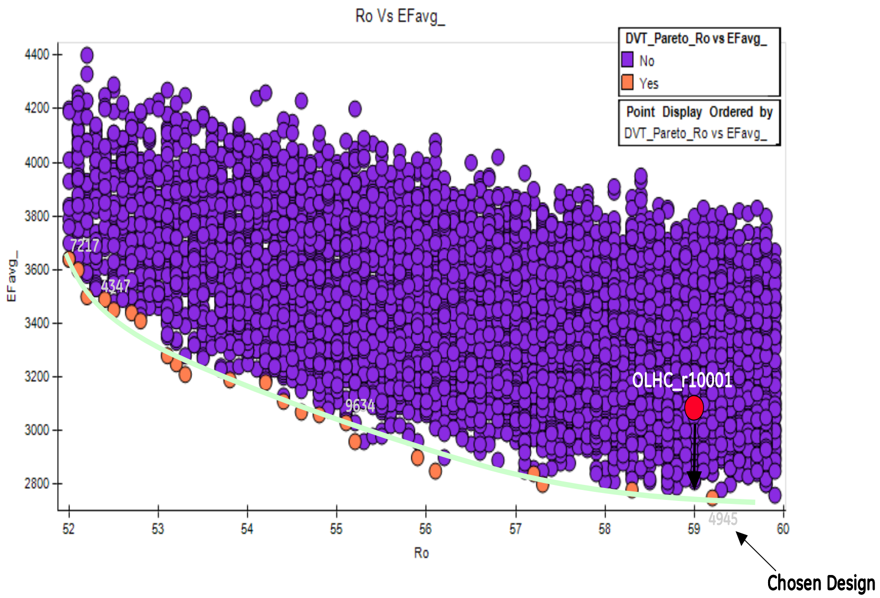
Examples of Modelling

Design Space Exploration

Method	**Latin Hypercube Sampling**	**Monte Carlo**	**Factorial DOE** Full/Fractional
Example			
Cost	Lowest	Variable / Higher	Highest (per space explored)
Where used	Sparsely filling a large design space	Exploring a broad design space	Optimizing response near a design point
Why used	Finds response function	Finding unexpected design optima	Finds local response function
When used	Medium priors Semi-expensive sims	Low prior knowledge Inexpensive simulation	High prior knowledge Expensive simulation

Robust Design using "Space Filling" computer experiments





Robustness: move design to center of feasible range

Optimality: move design along Pareto Optimal Edge to maximize a third Figure of Merit

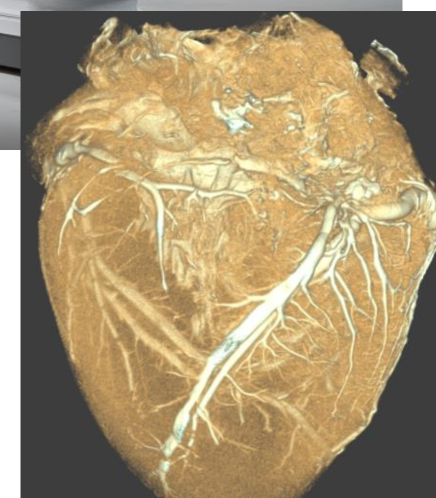
Needs: Efficient Simulation, Automated Parameterization, ***Great*** Visualization tools

Computed Tomography

Moderately complex system with complex behavior

- ~5,000 parts
- ~5M lines of code
- Triple nested control loops
  - Axial, Cradle, mA/kV

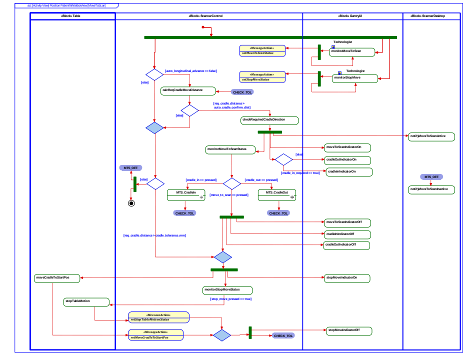
First GEHC project using MBSE
- <10 engineers using the tool
- 3 year process
- Principal engineer leads the effort
- Used several consultants to review and optimize the process
- Focused on a few applications and a few critical components

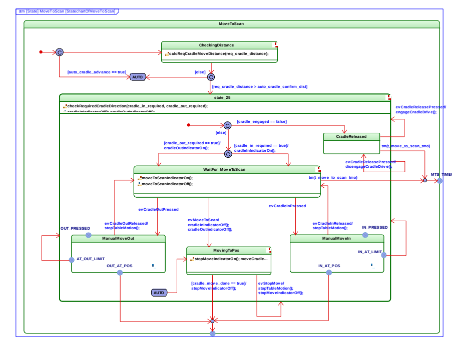


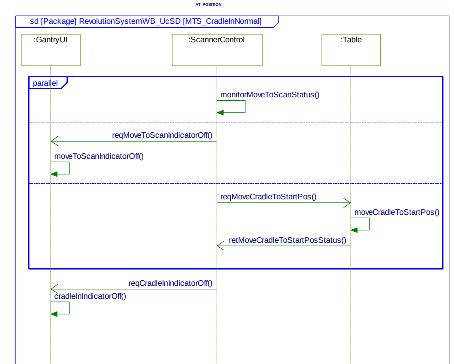
Computed Tomography

MBSE techniques are used to perform behavioral analysis of key system features and functions.

- discover and verify system requirements
- identify and detail subsystem functions and interfaces
- seed FMEA analysis
- develop system test scenarios





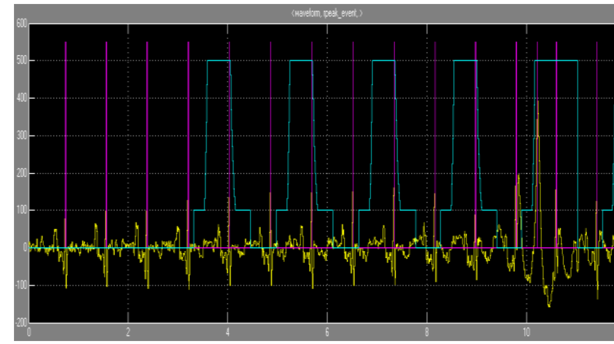


Computed Tomography

CT Systems is deploying several model based designs directly to software and hardware.

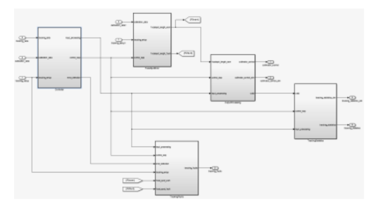
Cardiac Acquisition and Emission Modulation

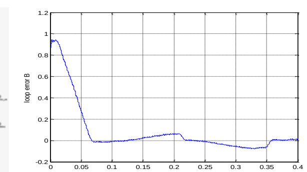
- Feature analysis and simulation performed in SIMULINK
- Auto-generating C++ code



Active X-Ray Beam Position Control

- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generating C++ code





x-Ray Generator KV Control Loop

- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generated vhdl

Simulation

kV

Inverter Voltage

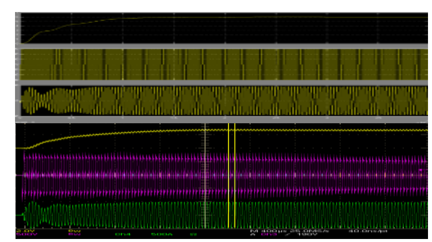
Inverter Current

Lab HW

kV

Inverter Voltage

Inverter Current



Customer Workflow Modeling

Client Scenario

Current ED old and over-crowded, client planning to dramatically expand / replace existing capacity in 3 phases while continuing to provide 24/7 emergency care services.

- Gather the requirements: observational research, data mining from records
- Proprietary GE Tool (capacity vs. staffing, equipment, layout…)
- Review conclusions and recommendations

Simulation Results

Simulation enabled client to "shell" one pod and redesign staffing

- Construction Cost $1.3M
- Staffing Costs $2M
- Reduced Waiting & LoS +25% vol

GEHC Modelling Maturity Levels

Highly Mature

- Quantitative Modelling
  - Field Strength
  - Air flow
  - Noise
  - Resolution
  - Structure / vibration
  - Electronics
  - …

Developing

- Process map/Utilization
  - Factory utilization simulations
  - Customer workflow productivity
- Customer Task QoS
  - Tumor Visualization
  - Artifacts
- Cost
  - Integrated should cost simulations
- Integrated System Models
  - Image quality from customer to components
  - Architecture model

Needs

- Customer Work Systems
  - Disease state models
  - Interoperability
  - Outcomes (health, economic)

Future Challenges

The industry faces many challenges

The medical industry product developers face problems with ……

- Extreme time to market pressures
  - 1st to market usually gains 80% of that market
- Compliance with regulations
  - FDA, IEC, ISO, HIPAA, ICD-10, ACA, etc.
- Defects are VERY costly to handle
  - Want to avoid audit, decrees, warning letters, recalls, etc...
- Most products are developed in a geographically distributed way
  - Need to communicate and define tasks
- Technology is impacting development and delivery
  - IoT, product variants, Mobile Medical Apps, complex deployment models, cloud

Key Industry Challenges for MBSE adoption

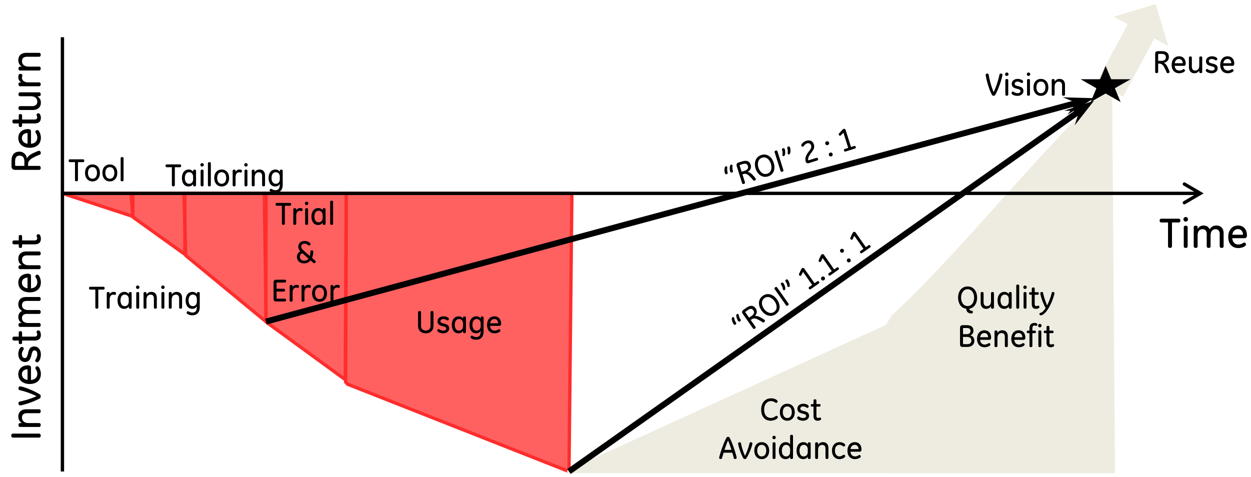
What are the most critical barriers to faster adoption of MBSE? High barrier to entry with uncertain payback

- ROI – Assured cost, Unquantified return
  - Fear of the unknown – no clear success stories with a business case
  - Many best practices…you pay for the tools and then need to pay for a consultant to tailor a process
  - Difficulty to understand how to introduce on an existing product – how to start? (not going to throw out the existing DOORS requirements database)
  - Many things don't scale…need an incredible investment…hard to justify

- Concerns about FDA acceptance
  - The tools are not validated archival mechanisms, so the archive has to be done in a document storage tool (in textual requirements)
  - If we have to capture everything in textual requirements anyway (for audits), what is the advantage of the model?

Lowering the barrier to entry

Management is confronted with many competing priorities for investment



Biggest cost is not the tool…need a way to make 'the pill easier to swallow'

- Big bang: full in on one project, with a complete strategy…needs business case for upper management to justify the investment
- Get your feet wet: partial implementation (one feature, one subsystem)…needs cookbook on how best to integrate a partial MBSE implementation with prior processes and tools

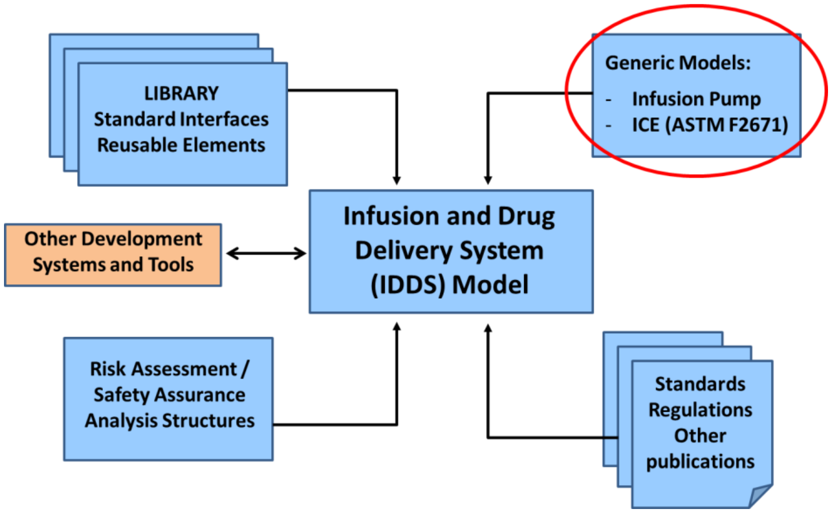
Recommendation: Develop an implementation use case/cookbook, with a library of testimonials/businesses cases for upper management

MBSE Challenge INCOSE product

INCOSE (International Council on Systems Engineering) has working groups on Biomedical Healthcare and Model Based Systems Engineering

Those WGs have sponsored a Healthcare MBSE challenge group developing a medical pump model

- Demonstrate the value and utility of MBSE for biomedical-healthcare related applications
- Develop frameworks and templates that can be used to accelerate the development and approval of biomedical devices.
- Demonstrate integration of risk management, safety assurance, and other regulatory concerns.
- Capture learnings on how to make the shift from a document-centric to a model-centric systems engineering environment



Recommendation: INCOSE publish a reference model

Concern: Regulatory Acceptance

One concern is that regulations can impede progress toward higher quality processes

- Auditors can be unclear on what is acceptable in a model, and where to poke for quality gaps
- FDA has published a draft guidance on computational (quantitative) modelling for industry and
- Gives guidance on what to include…in general, and for four types of models
- Does not address behavioral/architecture (SysML) models

A consistent approach on how to summarize, review, and document models would ease acceptance

Example CDRH Modelling Paper

Reporting of computational modeling studies in medical device submissions

Draft Guidance for Industry and FDA Staff

Owner: Tina M. Morrison, Ph.D., tina.morrison@fda.hhs.gov.

Recommendation: FDA (and industry) publish a guidance on submitting behavioral simulation results

Continuous engineering is about game-changing practices that convert innovation challenges into opportunities

Improve customer experience
Adopt customer insight and build relevant products

Manage complexity
Improve innovation speed and increase development efficiency

Embrace connectivity
Manipulate imperfect information to create larger, interconnected systems

Collaborate across disciplines
Integrate early to avoid last minute big bang integration issues

Continuous Engineering

"Turn Insight into Outcomes"

Unlocking Engineering Knowledge

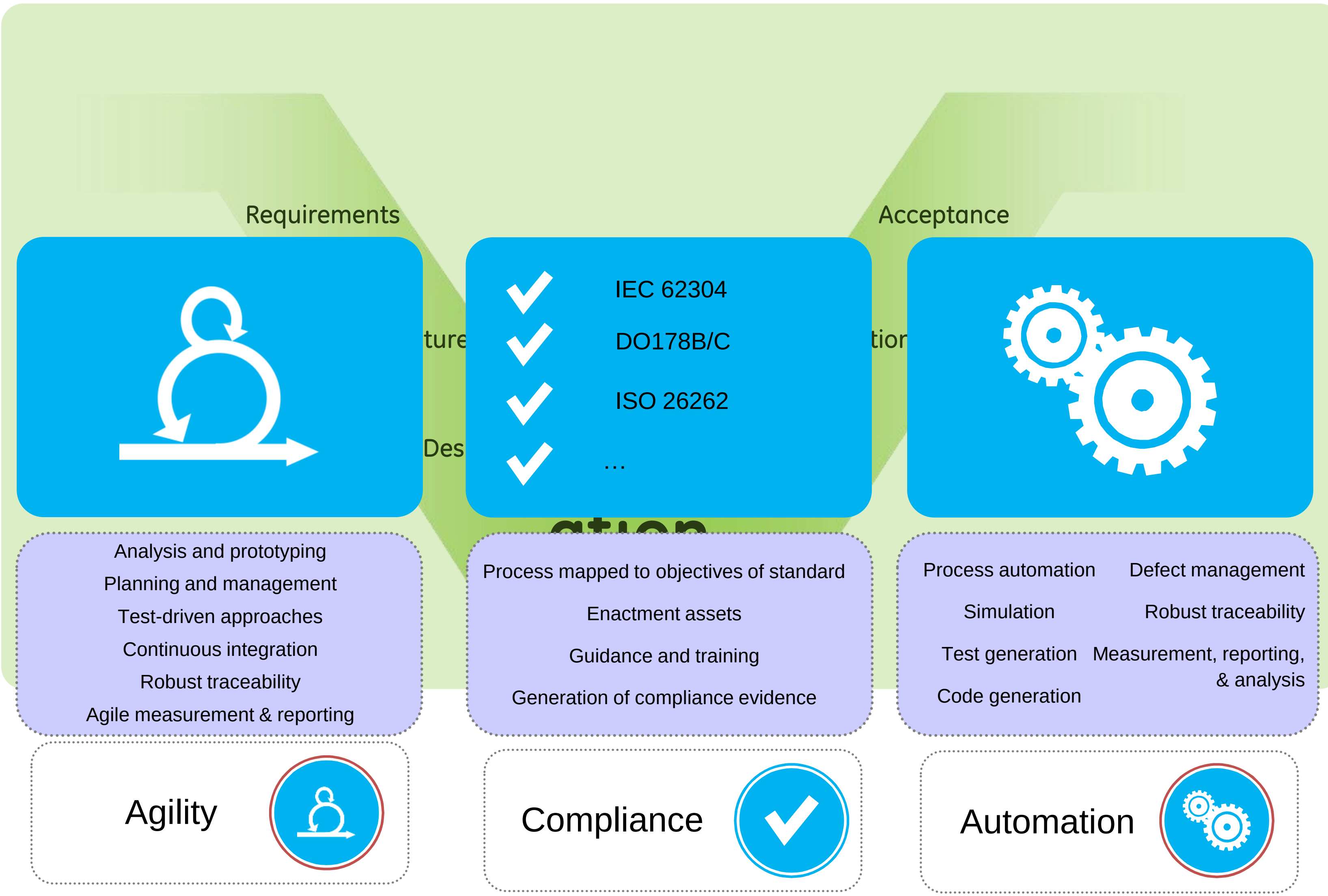
"Measure twice, cut once"

Continuous Verification

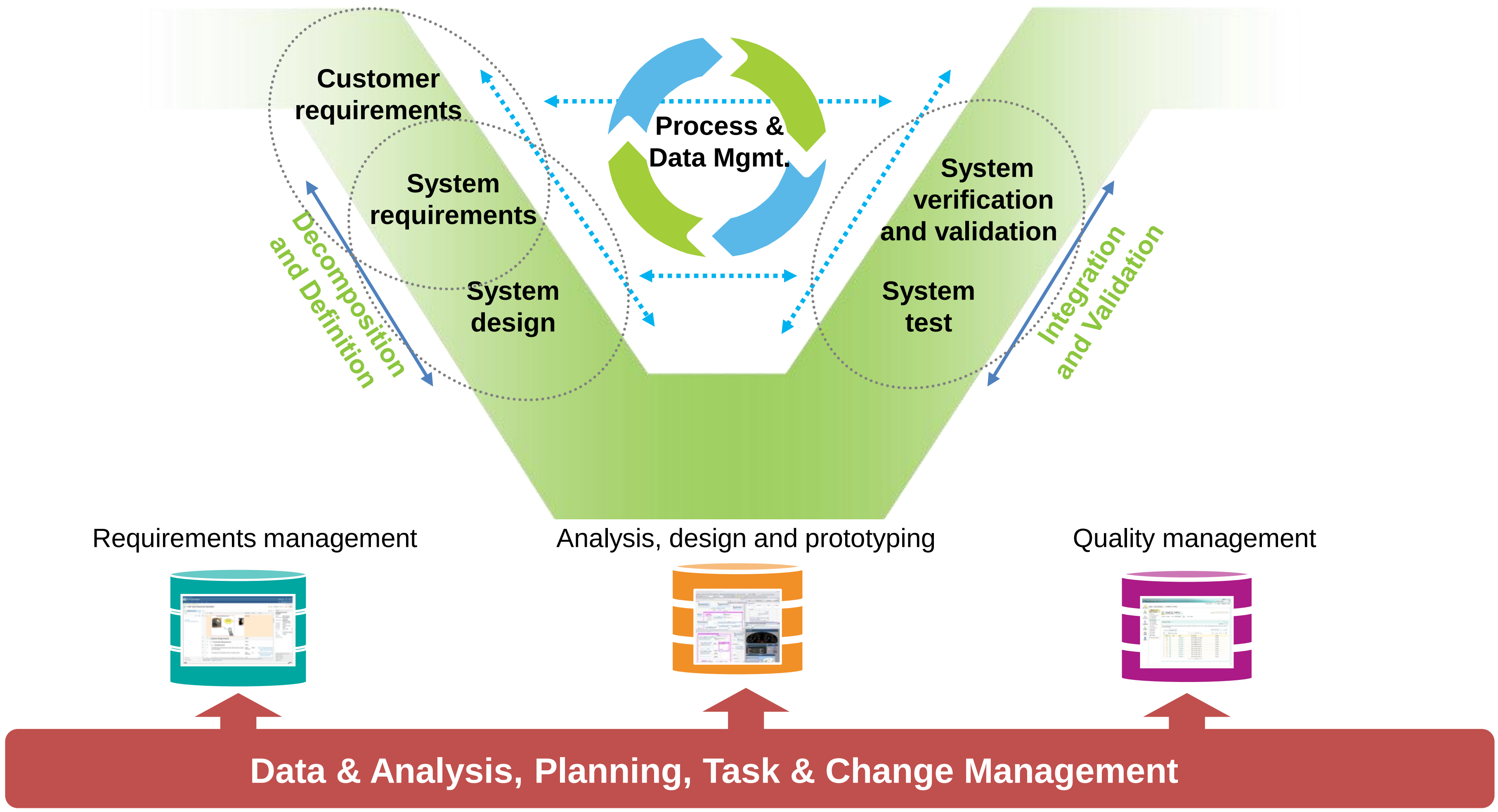
"Don't reinvent the wheel"

Strategic Reuse

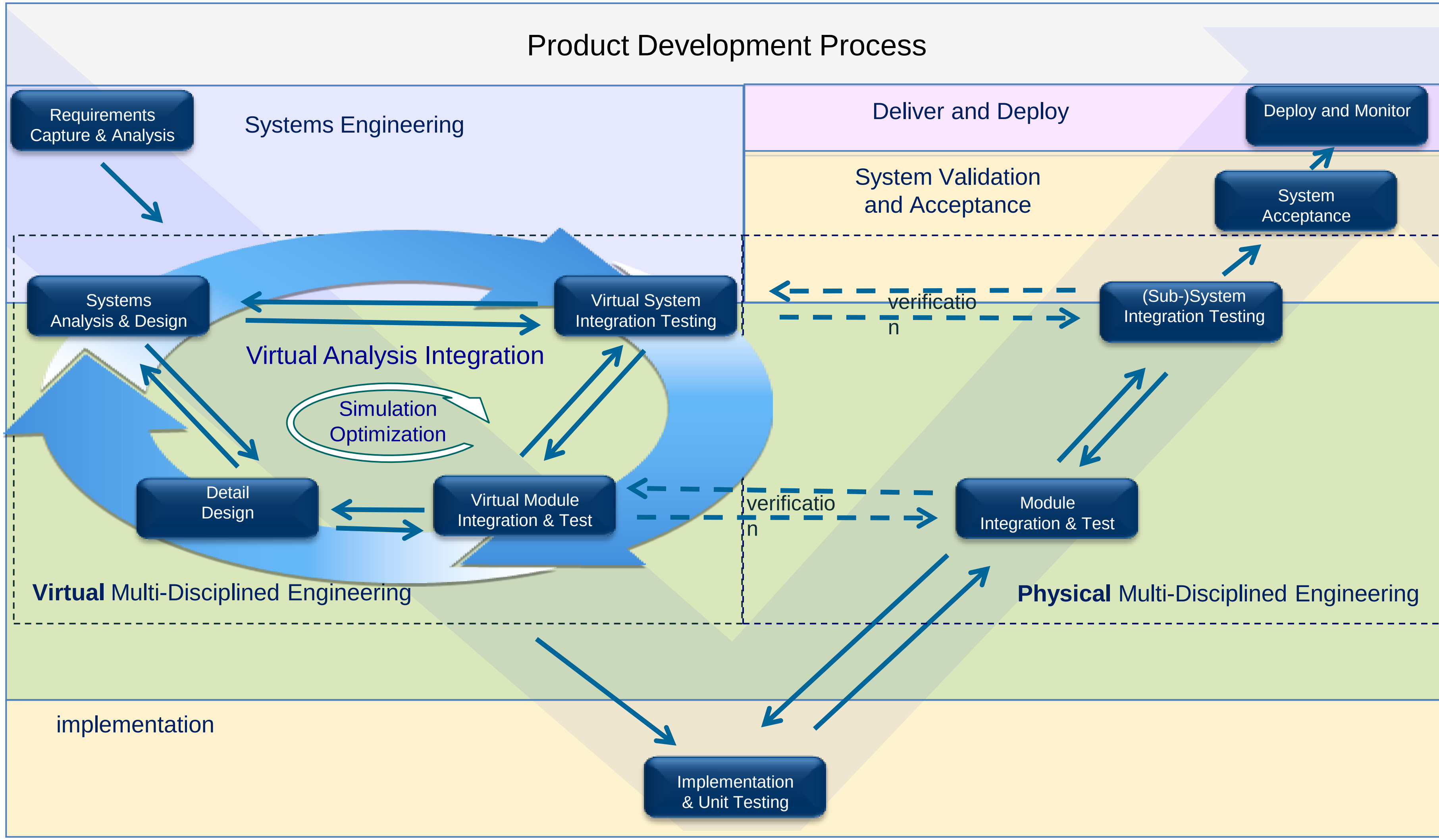
Improving software development



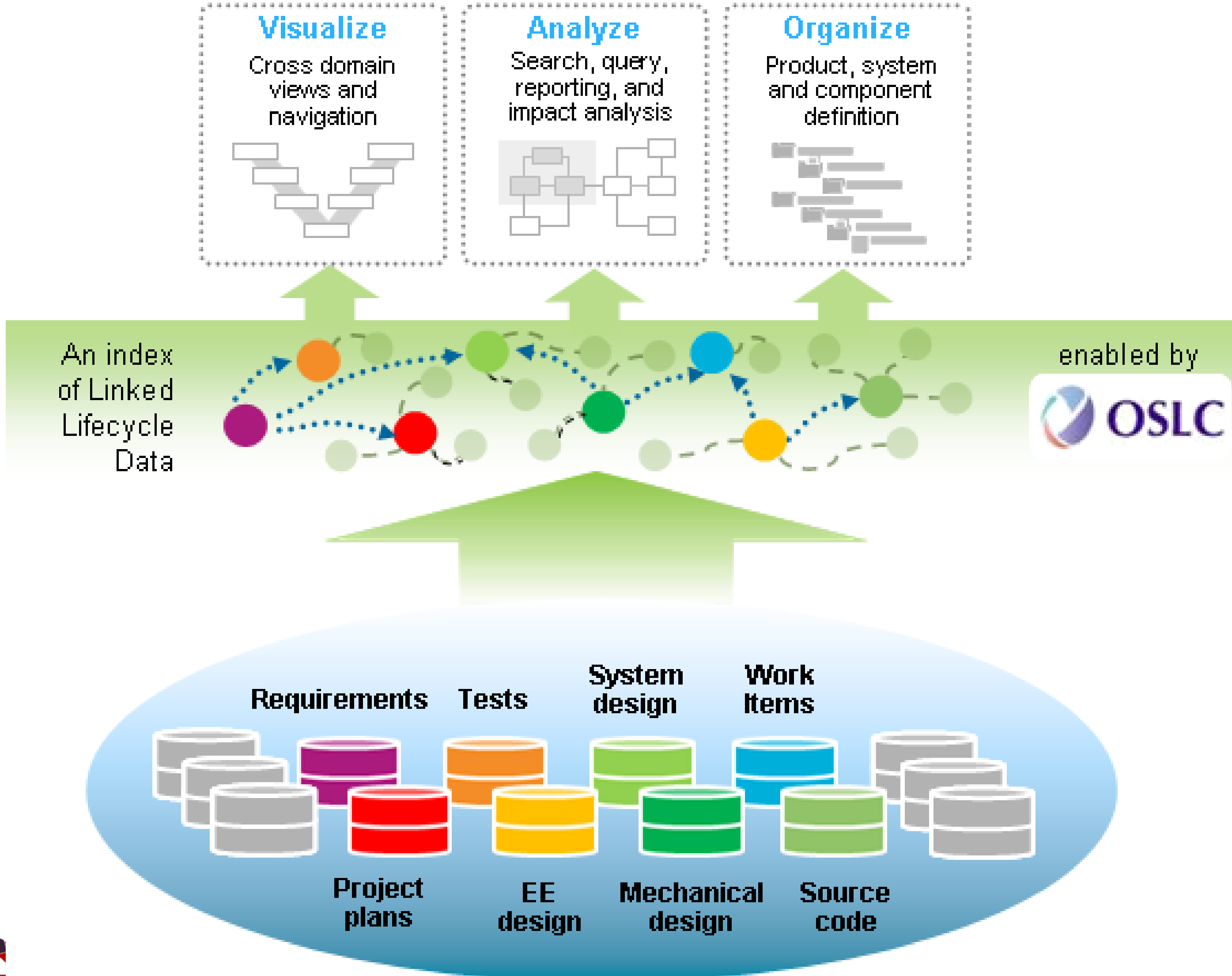
Systems engineering



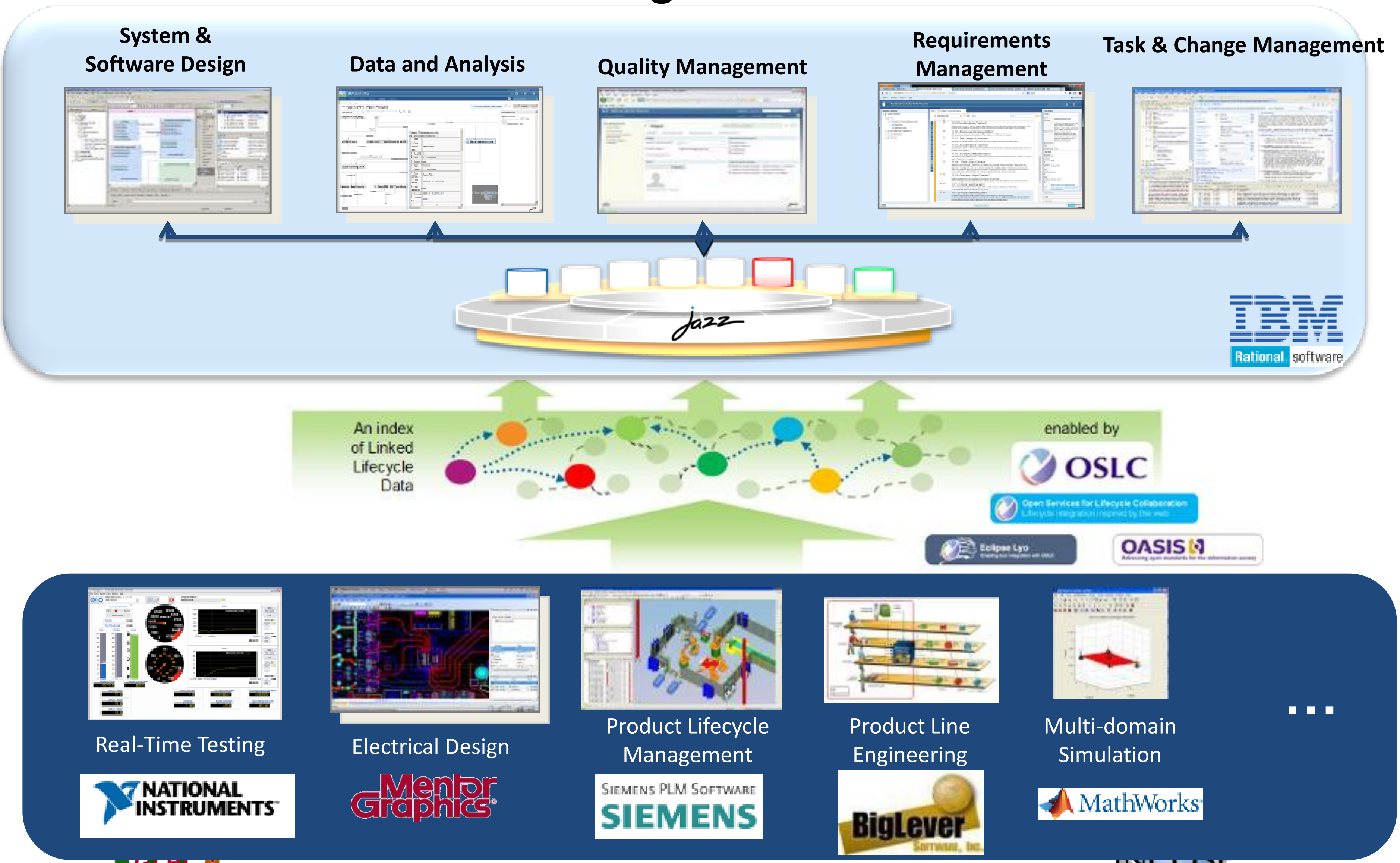
The new "V in V" process - Continuous Verification means early and continuous feedback in early systems design phases



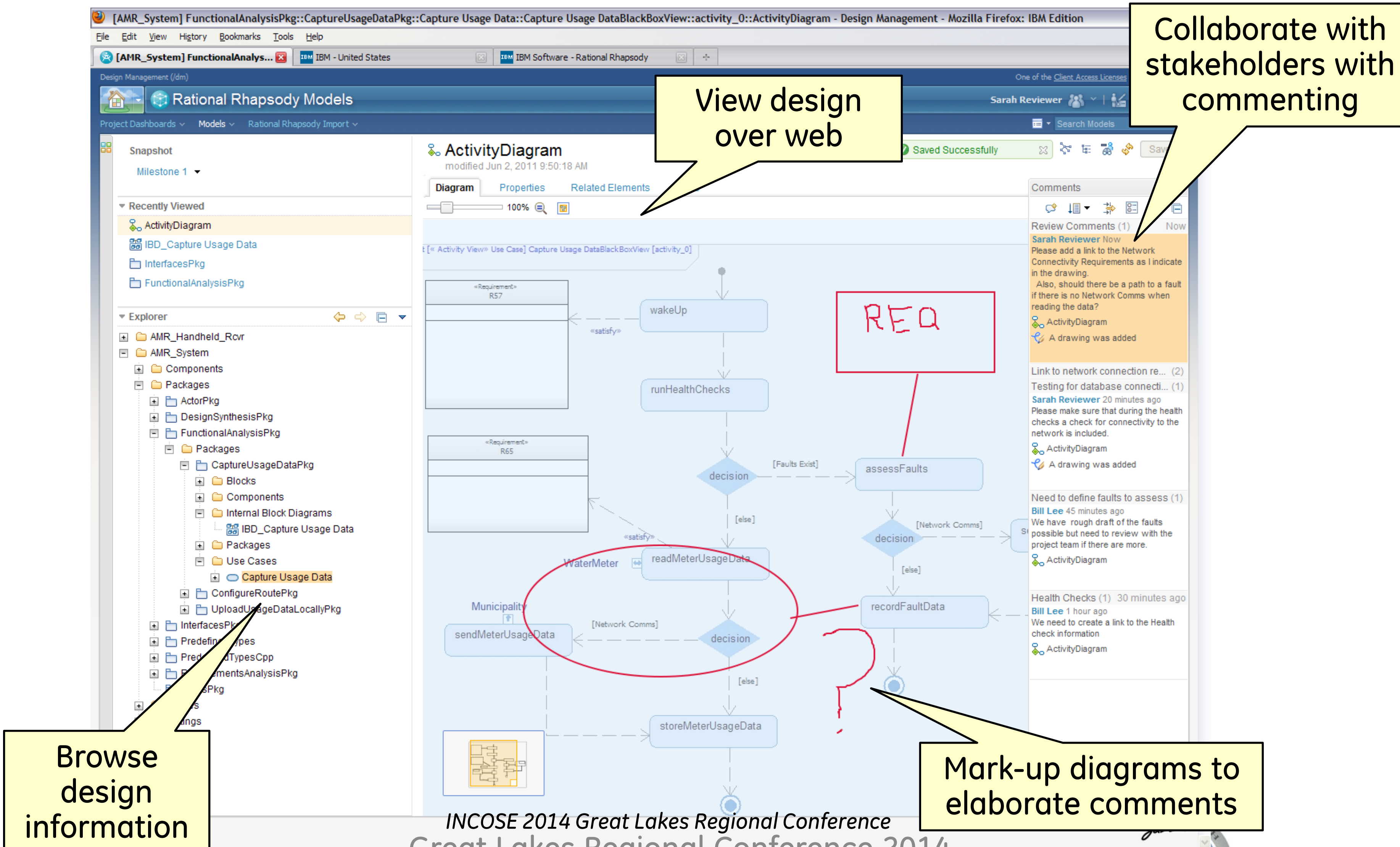
More informed engineering decisions with an open approach



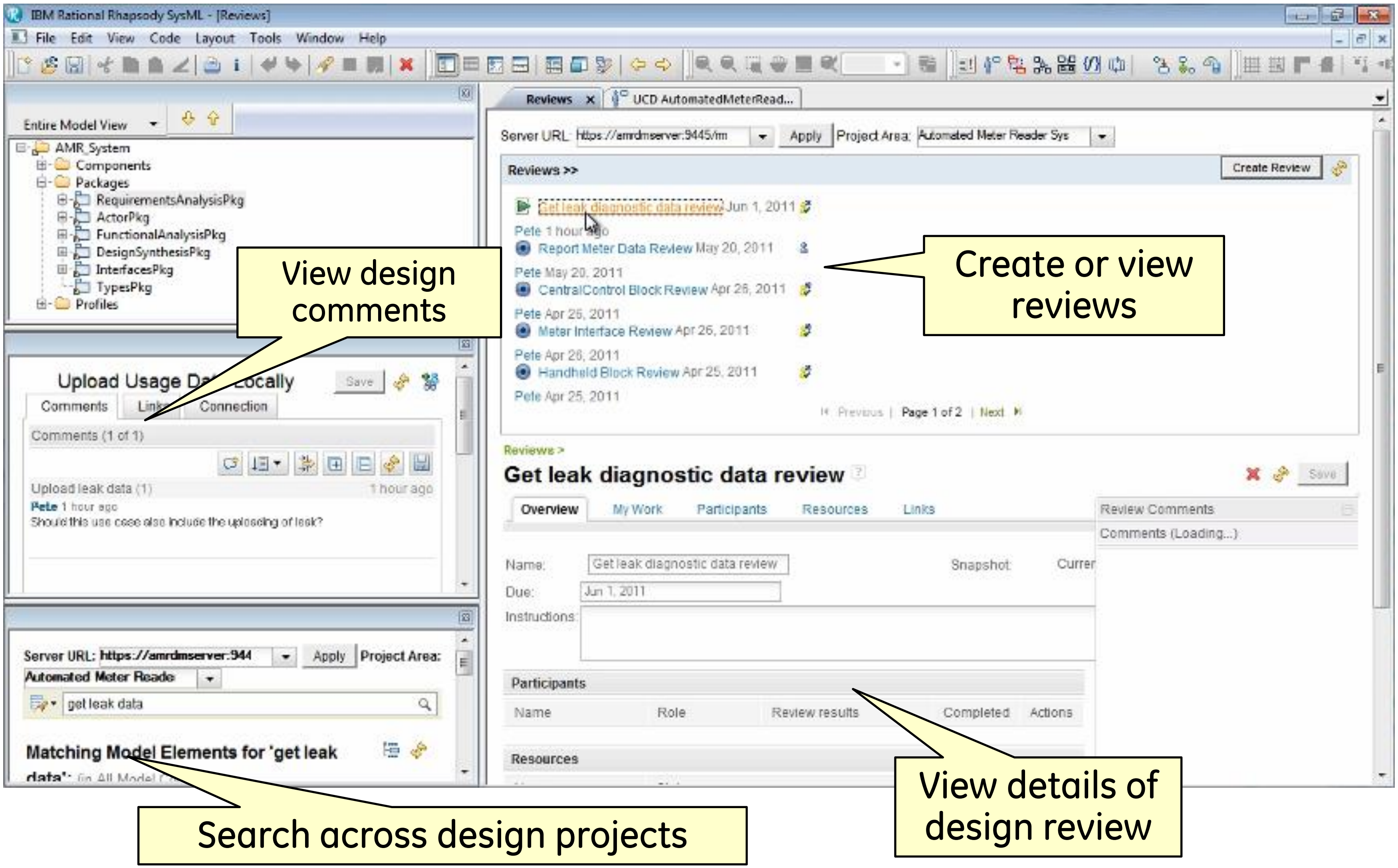
Broaden the solution with an ecosystem of industry integrations



Design Management Web Client

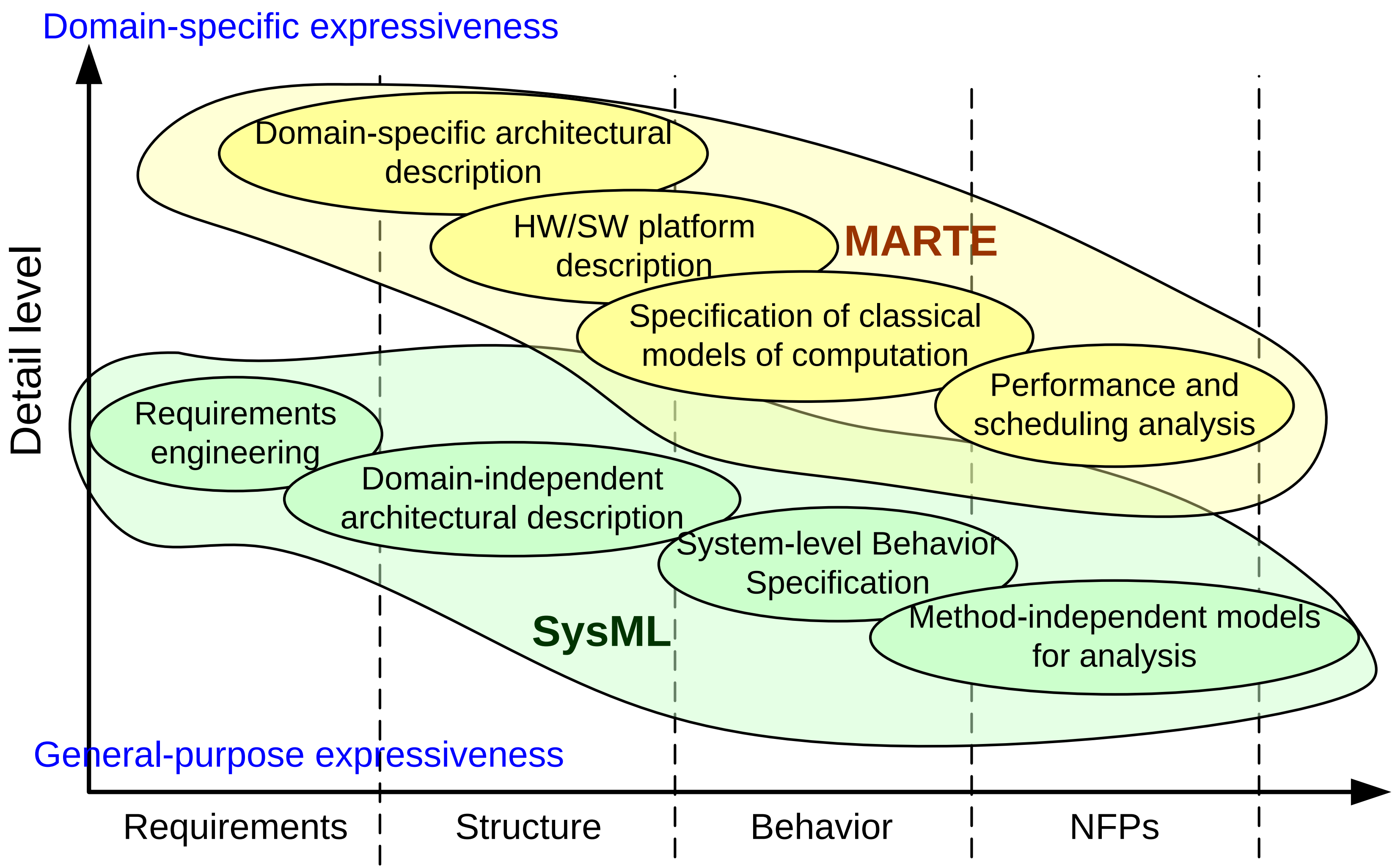


Collaborative development in Rhapsody client



Using best-in-class modeling solutions

MARTE-SysML Expressive Power



H. Espinoza (CEA LIST); B. Selic (Malina Software Corp.); D. Cancila (CEA LIST); S. Gérard (CEA LIST)
ECMDA'09, The Netherlands, June 2009

Summary – Benefits to Industry of MBSE

Improved Systems Thinking

- Use Case/Performance/Interface Analysis critical for a complete design specification.
- Logical model to provide high level of abstraction for ease of understanding, improved reuse or design sharing

Improved Communication

- Visual vs. Textual leads to Clearer, more precise communication & better reviews
- Visual designs & models are easier for global teams (less language barrier)

Improved Quality

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved design of test cases, derived from weaknesses exposed in the model

Improved Predictability and Efficiency (Time to Market)

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved leveling of requirements (efficiency in verification and documentation)
- Auto code generation (no translation errors in implementation)

Questions?

INCOSE GLRC

INCOSE