2018 Annual INCOSE
Great Lakes Regional Conference
SYSTEMS AT THE CROSSROADS
17 - 20 October 2018 | Indianapolis, Indiana

Platinum GLRC Sponsor Tutorial

Trusted Models, Collaborative Learning, Accelerated Capability

TUTORIAL ABSTRACT

- Are you ready? The idea of a connected, transparent community focused on learning and accelerating the realization of new products and processes is not just for the future. It's needed now in support of the "digital" transformation—not just for each enterprise, but for whole supply chains, regulators, and the life cycle management processes. With this transformation come unexpected complexities…in coordination, the digitization of systems involved in realization, security, and more importantly…how work is performed.
- Now, emerging systems challenges and opportunities are leading to a new wave of "virtual" (model-based) methods, high performance computing resources, technical disciplines, and standards. Computational and similar models, whether human-made or machine-learned, are increasingly being applied to the most critical issues of health and medicine, critical infrastructure systems, advanced manufacturing materials and processes, safety-critical systems, and socio-technical webs of interdependent systems and processes.
- For it to work, the new system and its models must demonstrate they are trustworthy, through "trust" standards developed in partnership with regulators to fully realize the value to industry and the community.
- The V4 Institute is an Indiana-based, private-led, public-private collaboration of member enterprises and institutions for the purpose of promoting collaboration, facilitating integration and establishing trust in the models and processes needed in the digital transformation. The V4 Institute is now launching five public projects in this space, and invites participation of additional collaborators interested in joining the V4 Institute.
- Attendees at this half-day Institute will gain an awareness of the significance of these opportunities and challenges, V4i's process and capabilities as a potential accelerator, and how related projects advance our common cause

1. Introductions, V4 Institute, Workshop Attendees

1.0 Safety Moment

1.1 Introducing the V4 Institute

1.2 Workshop Objectives and Materials

1.3 Workshop Attendee Introductions and Interests

1. Koeneman, Veranese

Tutorial Summary Outline

12:00–12:20 1. Introductions: V4 Institute, Tutorial Attendees

12:20–12:40 2. Context: Challenges and Opportunities

12:40–2:30 3. Two Decades of Related Progress on Related Methods and Standards

2:30–3:00 BREAK

3:00–4:15 4. V4 Institute: Targeted Outcomes, Roadmap, Properties, Collaboration Projects

4:15–5:00 5. Invitation to Collaborate

5:00 6. Adjourn

Vision:

An advanced product & services supply chain, digitally integrated through virtual validation, verification and visualization.

Mission:

Enable the use of digital data, modeling and simulation across supply chains to accelerate the introduction of new materials, manufacturing processes and product systems & services to market while meeting demanding regulatory requirements.

Context & Rationale: Data Driven Decisions

- **Virtual**: Existing outside of (for example: digitally, in graphic or computational form) and representing a physical reality.
- **Verification** – "The evaluation of whether or not a product, service, system or model thereof complies with a regulation, requirement, specification, or imposed condition."[1]
- **Validation** – "The assurance that a product, service, system or model thereof meets the needs of the customer and other identified stakeholders."[2]
- **Visualization** – "The formation of mentally accessible images; the act or process of interpreting in visual terms or of putting into visible form."
- **Decision Making** – "Irrevocable allocation of resources"[3]
- **V4I Value Proposition**: Increasing the scientific use, reliability, and effectiveness of virtual testing reduces cost and time to market

Industry Value – Return on Investment

- Defense Aerospace [4]
  - 50% Research and Development cost savings
  - 25% Research and Development time reduction
- Life Sciences: Medical Devices [5,6]
  - 50% Research and Development cost savings
  - 50% Research and Development time reduction
- Improved Product Quality, Safety, Reliability
  - Higher customer Satisfaction
  - Sustainable Product Lines and Lifecycles through Innovation
- Improved Manufacturing Process Safety, Reliability, Efficiency
  - Higher return on investment

Learning Objectives:

- Awareness of the landscape-Challenges & Opportunities
- Understand the history & core tenants of “trust”
- Understand V4i Role, Processes & Capabilities
- Stimulate ideas by sharing examples of current projects
- Advocate for action to advance our common cause

EIM: Providing insights and answers into what it takes to be ready.

1.3 Workshop Attendee Introductions and Interests

Challenge: How can you take full advantage of the digital transformation to accelerate the realization of new products and process? Are you ready?

- This is complex, but others have been working this agenda for the better part of 2 decades…with great results.
- The language and precision in use is important to navigate and align to establish trust across the breadth of stakeholders.
- V4i is positioned to create a connected, transparent community focused on learning and provide a system with unique capabilities to help you …start.

Our focus: Establishing Trust, Promoting Collaborative Learning and Facilitating Integration to Accelerated Capability

2. Context: Challenges and Opportunities

2.1 Digital Engineering Has Arrived

2.2 Challenges to Innovation: Complexity, Regulatory and Other Risks, Development Costs and Time, Expectations

2.3 Opportunities: Virtual Models, Model VVUQ as a Proxy for Learning and Mutual Trust, Economic Leverage of Model-Based Patterns

2.1 Digital Engineering Has Arrived

John Matlik's related panel slides at this conference may be viewed at:
http://www.omgwiki.org/MBSE/lib/exe/fetch.php?media=mbse:patterns:incose_coa_patterns_panel_rr_matlik_v4.pdf

2.2 Challenges to Innovation: Complexity, Regulatory and Other Risks, Development Costs and Time, Expectations

ASME V&V 40 Standard

Credibility: the trust, obtained through the collection of evidence, in the predictive capability of a computational model for a context of use

- Focus is on ***HOW MUCH*** V&V is necessary to support using a computational model for a context of use.
  - should be commensurate with model risk; the concept of "model risk" has been also been used by NASA[1].

FDA

ASME V&V 40-2018

Assessing Credibility of Computational Models through Verification and Validation: Application to Medical Devices

Summer 2018!

http://go.asme.org/VnV40Committee

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

ASME SETTING THE STANDARD

1, NASA-STD-7009, https://standards.nasa.gov/documents/detail/3315599

Source: INCOSE IS2018 July 2018 MBSE Panel-INCOSE 2018—Morrison.pdf

Life Sciences: Medical Devices

Challenges

- Establishing model credibility
- Mindset: Innovation starts in the scientific model (what's possible), not in the engineering model (how do I know)
- Where to access know-how, capability and capacities
- How and where to start
- How to protect background Intellectual property in this model.

Opportunities

- 50% reduction in research & development cost
- 50% reduction in research & development time
- Enhanced reliability throughout the life cycle
- Developed and Aligned supply chain

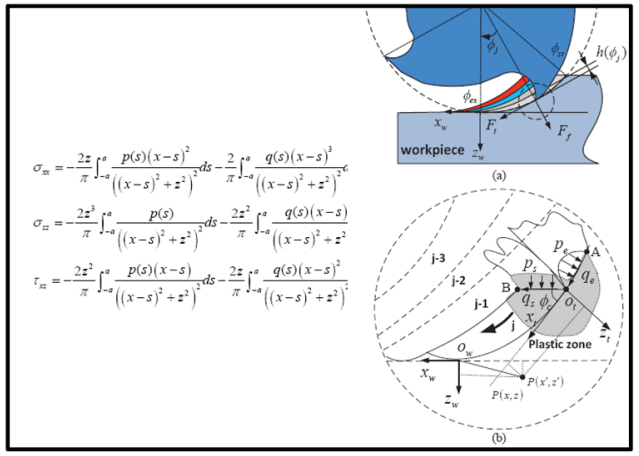
2.3 Opportunities

- Virtual Models of All Types
- Model Verification, Validation and Uncertainty Quantification (VVUQ)
- Model VVUQ as a Proxy for Learning and Mutual Trust
- Economic Leverage of Model-Based Patterns

Virtual Models of All Types

Physics-Based PDE Model

Example Manufacturing Model: Milling of Titanium, Resulting Residual Stress, from From: Huanga, Zhanga, Dinga, "An analytical model of residual stress for flank milling of Ti-6Al-4V", 15th CIRP Conference on Modelling of Machining Operations



Data-Driven Bayesian Network Model

Example Bayesian Network Manufacturing Model: Nannapaneni, Saideep, Sankaran Mahadevan, and Sudarsan Rachuri. "Performance evaluation of a manufacturing process under uncertainty using Bayesian networks." *Journal of Cleaner Production* 113 (2016): 947-956.

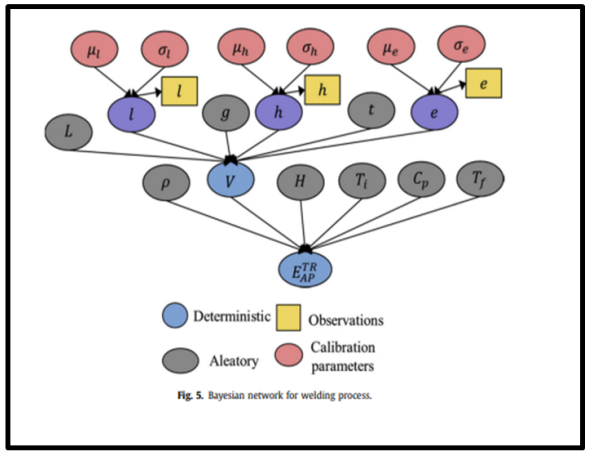
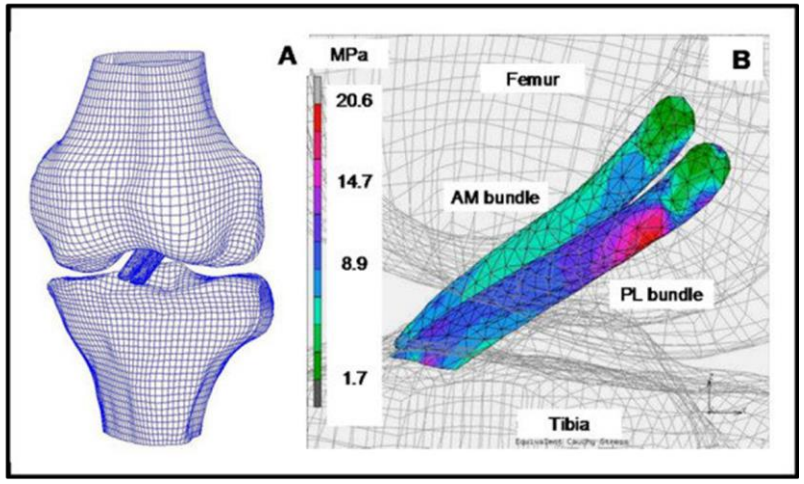


Fig. 5. Bayesian network for welding process.

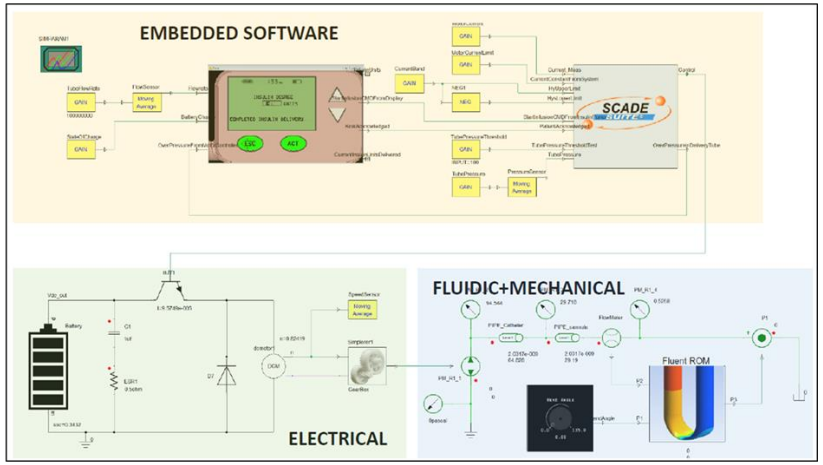
FEA Model

Example FEA Model: Ho-Joong Jung, Matthew B Fisher, Matthew B Fisher, Savio L-Y. Woo, Savio L-Y. Woo, "Role of biomechanics in the understanding of normal, injured, and healing ligaments and tendons", June 2009, *Sports Medicine Arthroscopy Rehabilitation Therapy & Technology* 1(1):9 DOI: 10.1186/1758-2555-1-9, Source PubMed License CC BY 2.0



Multi-Domain System Model

Example Medical Device Multiple Domain Model: From M. Horner, "Closing the Loop in Medical Device Systems Simulation", INCOSE Agile Health Care Systems Conference, May, 2018.



Virtual Models of All Types

CFD Model

Manoj R. Rajanna, et al, "Optimizing Gas-Turbine Operation Using Finite Element CFD Modeling", Proc. of AIAA Propulsion and Energy Forum, July 9-11, 2018, Cincinnati, OH.

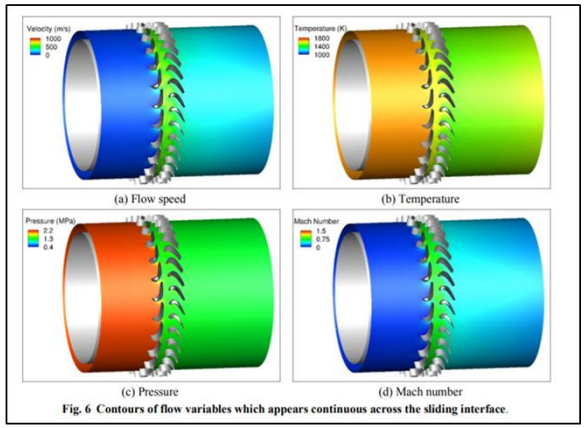
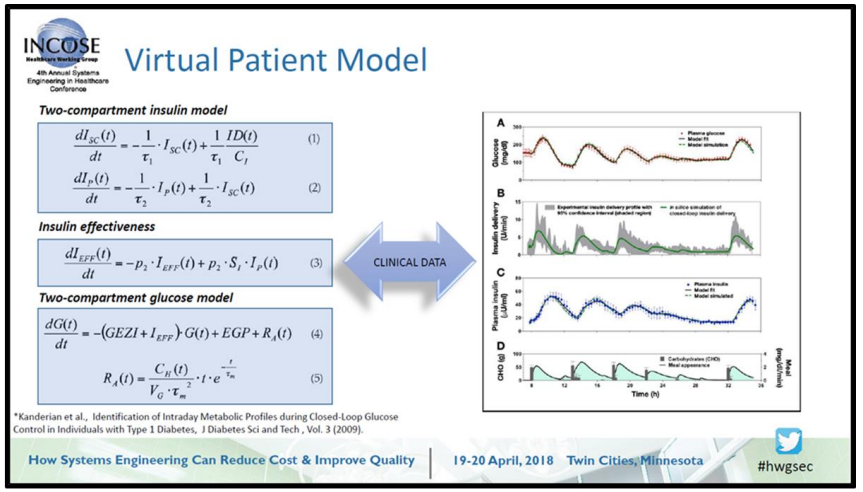


Fig. 6 Contours of flow variables which appears continuous across the sliding interface.

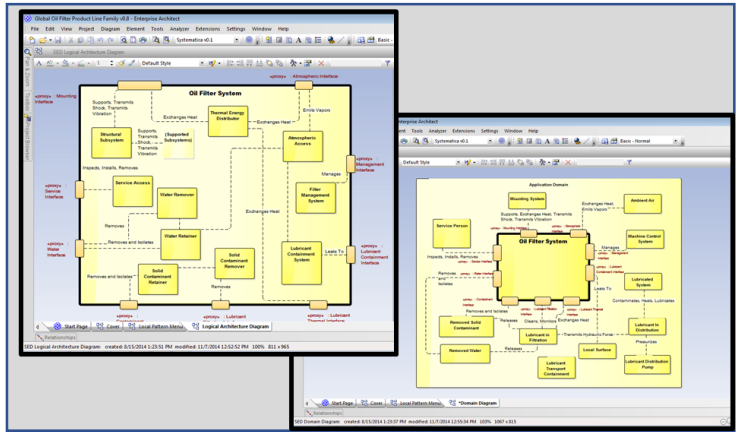
ODE Model

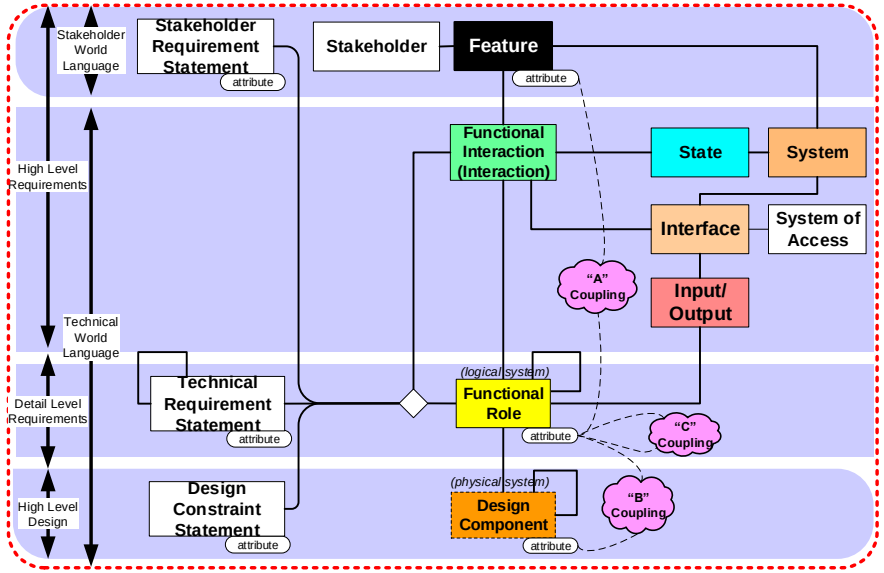
Kanderian, et al, "Identification of Intraday Metabolic Profiles during Closed-Loop Glucose Control in Individuals with Type 1 Diabetes", illustrated in M. Horner, "Closing the Loop in Medical Device Systems Simulation", INCOSE Agile Health Care Systems Conference, May, 2018.



MBSE Model

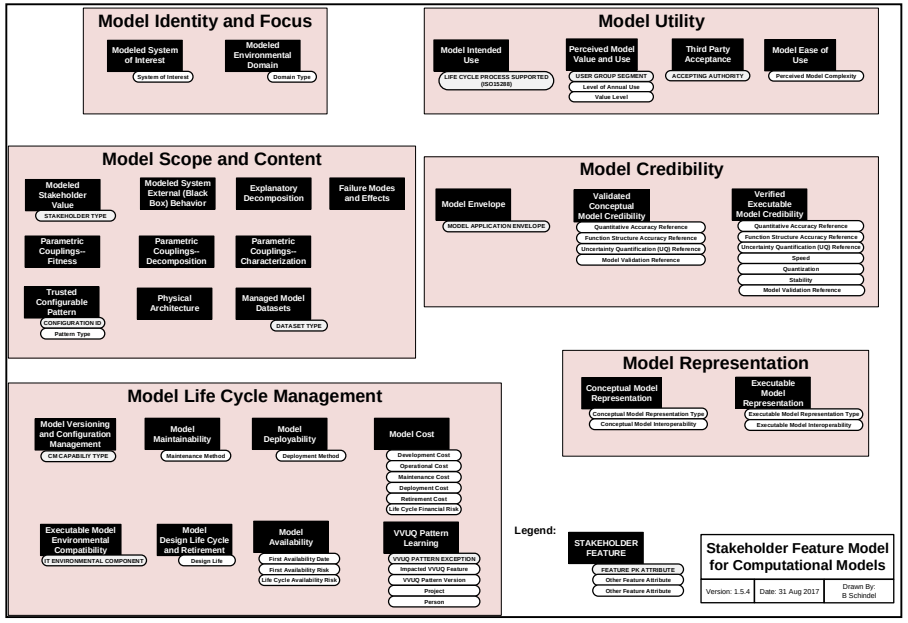
Example System Model: SysML Model of Lubricant Filtration System: Schindel, Lewis, Sherey, Sanyal, "Accelerating MBSE Impacts Across the Enterprise: Model-Based S*Patterns", *Proc. of INCOSE International Symposium*, 2015.





S*Metamodel:

- Used by Patterns Working Group as a "model of models" (metamodel).
- Chosen as the smallest set of model ideas found to be necessary for the purposes of engineering and science.
- S*Model: any model conforming the S*Metamodel.
- S*Pattern: reusable, configurable S*Pattern.
- Used across numerous domains for several decades.

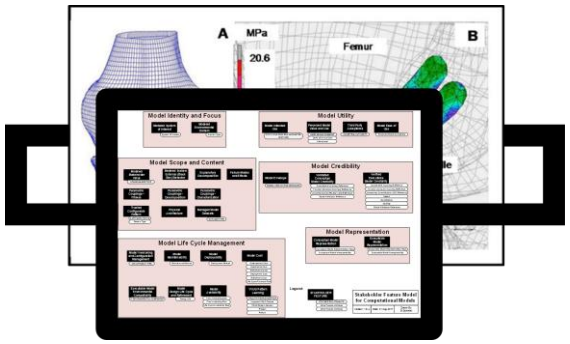


Model VVUQ S*Pattern:

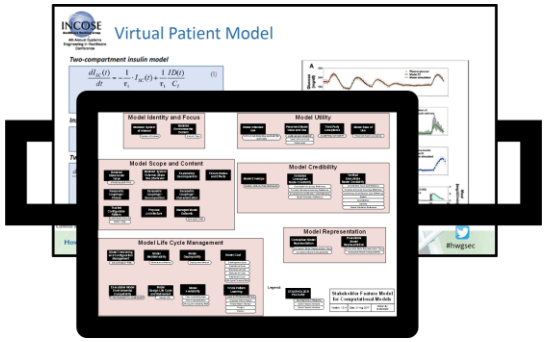
- Specialized for UQ purposes, from INCOSE Model Planning and Assessment Pattern.
- Supporting ASME Model VVUQ Standards work.
- Describes 29 Model Stakeholder Features, across 6 Feature Groups, and 75 Model Technical Requirements.
- Configurable to plan or describe any computational or other model, as a metadata model "wrapper".

VVUQ Pattern, after being configured to specific model: Uniform handles/wrappers/metadata for inherently diverse models

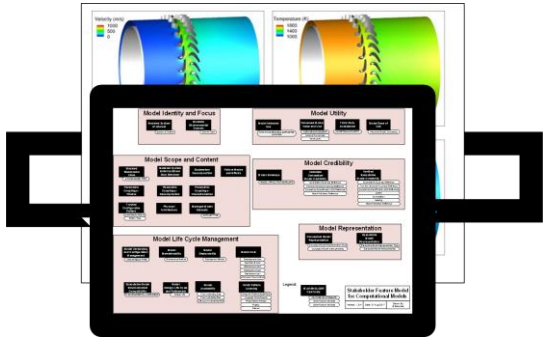
FEA Model



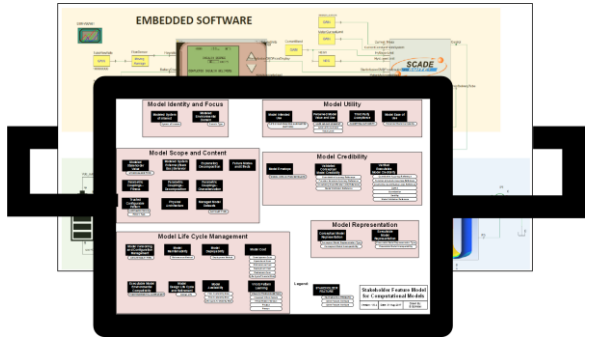
ODE Model

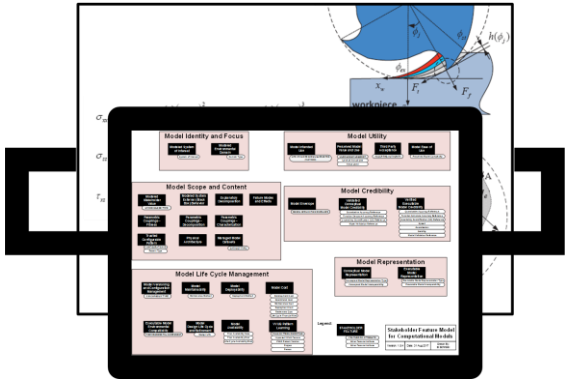


CFD Model

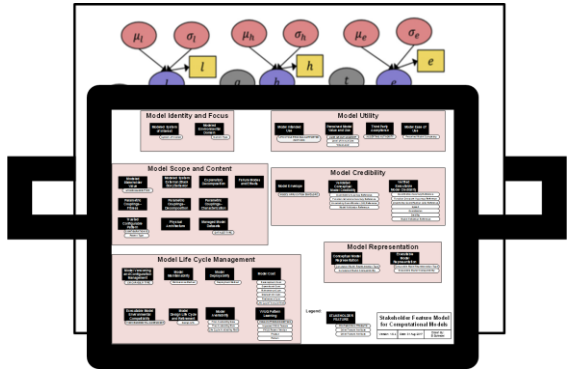


Multi-Domain System Model

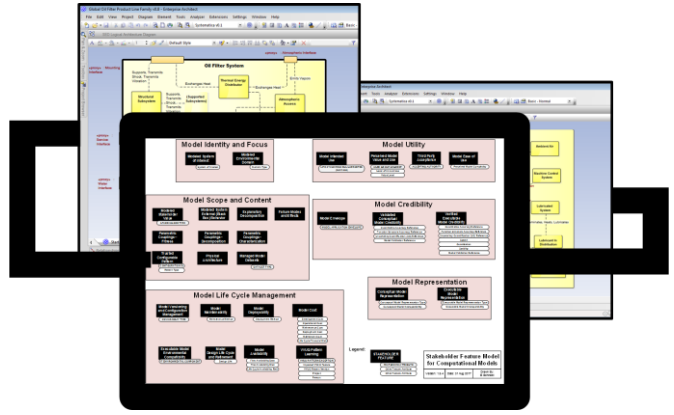




Physics-Based PDE Model

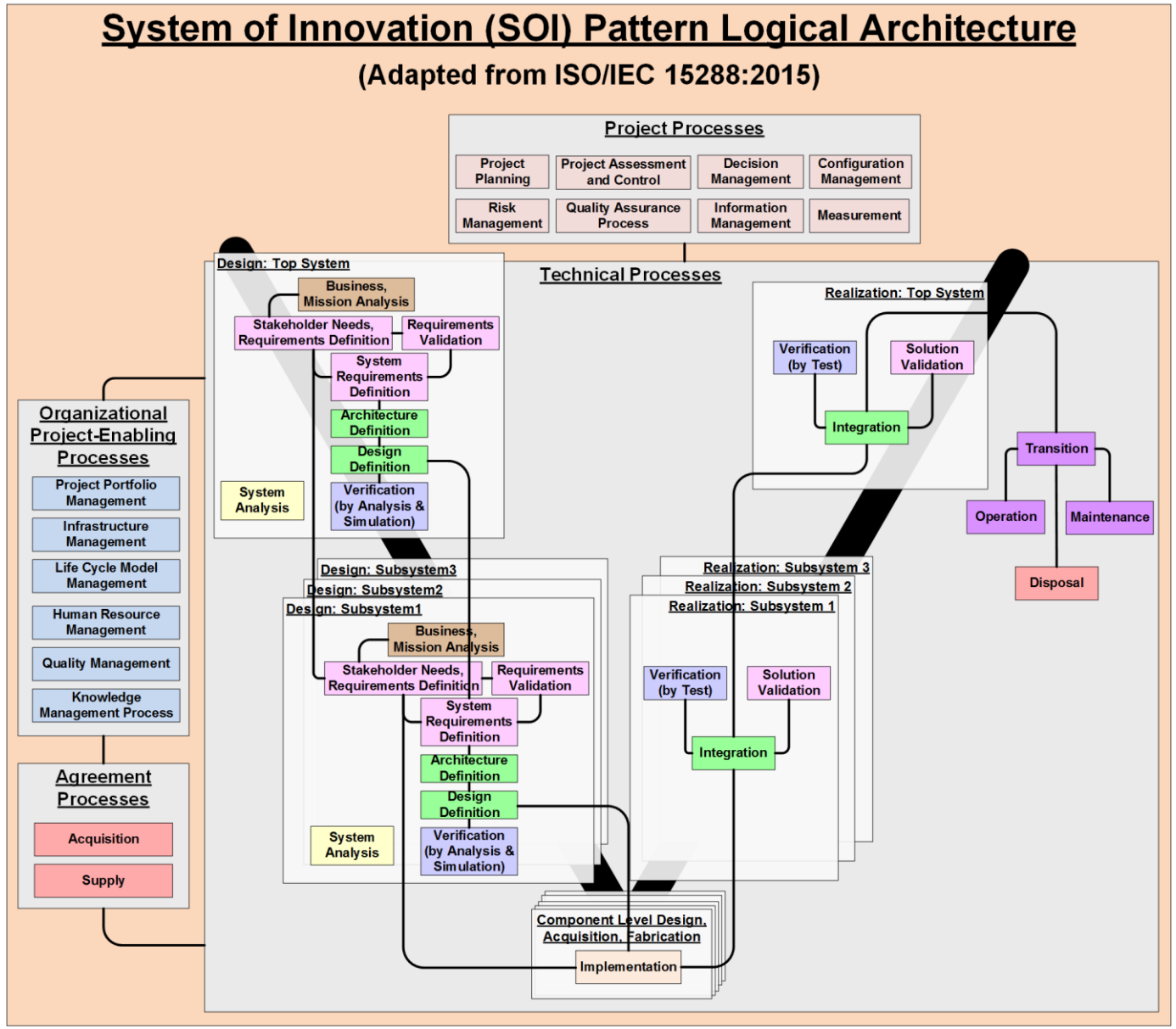


Data-Driven Bayesian Network Model



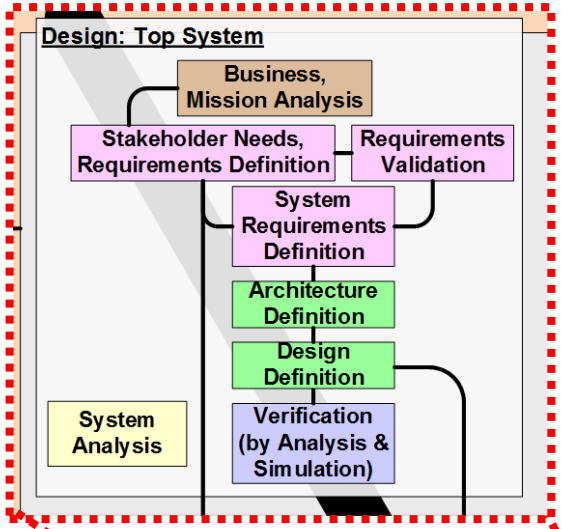
MBSE Model

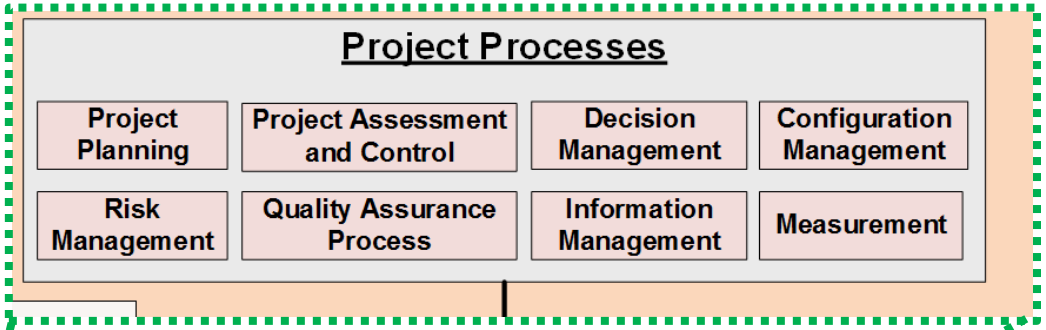
Models for what purposes?



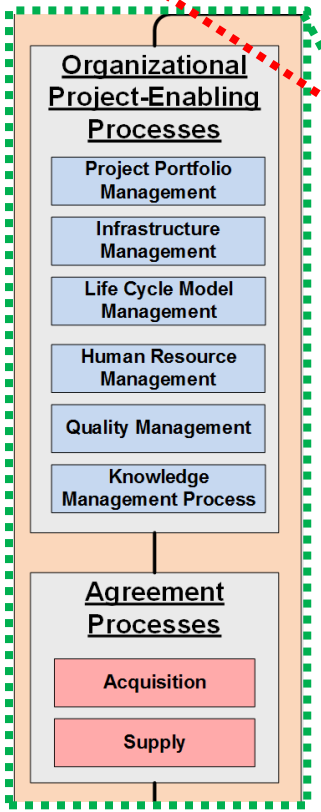
Potentially for any ISO 15288 processes:

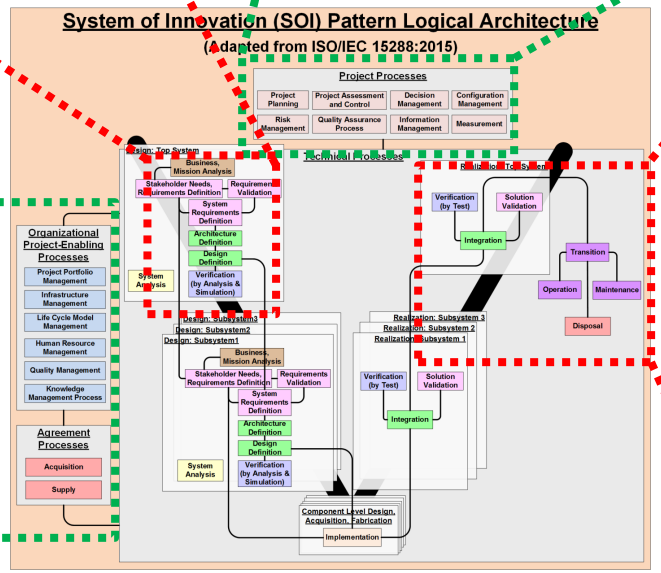
- If there is a net benefit . . .
- Some more obvious than others.
- Covers the whole life cycle of systems.
- Basis of the INCOSE SE Handbook.
- Effectively a reference framework of “model purposes”

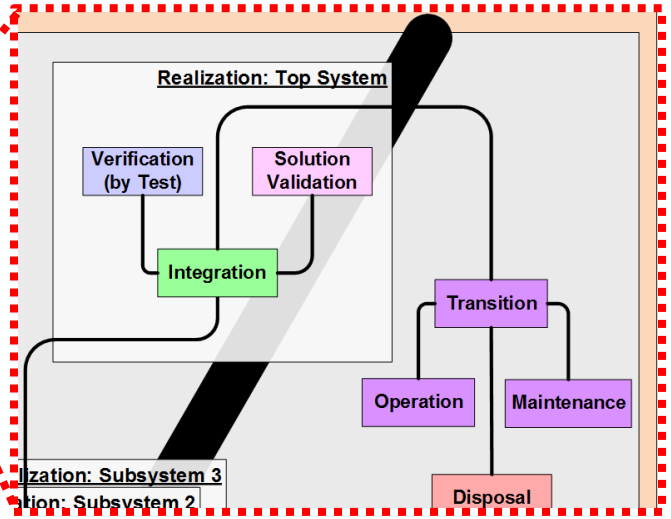




Many potential purposes for models







V&V of *Models*, Per Emerging ASME Model V&V Standards

Does the Model adequately describe what it is intended to describe?

Model Validation

Model validated?

Model verified?

Model Verification

Does the Model implementation adequately represent what the Model says?

Model

Describes Some Aspect of

System of Interest

V&V of *Systems*, Per ISO 15288 & INCOSE Handbook

Do the System Requirements describe what stakeholders need?

System Requirements Validation

Requirements validated?

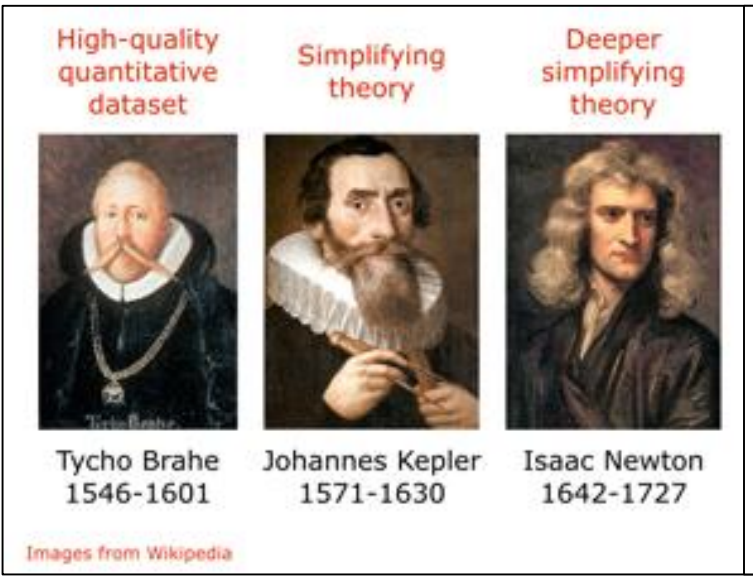
Design verified?

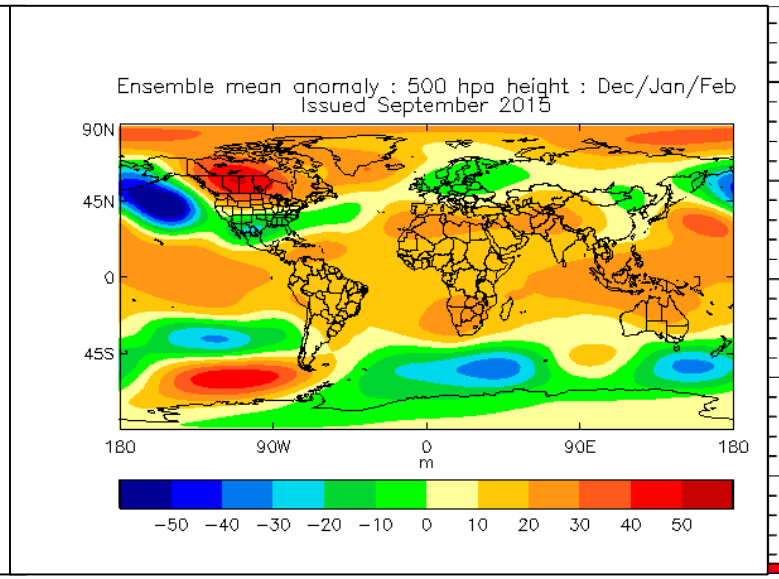
System Design Verification

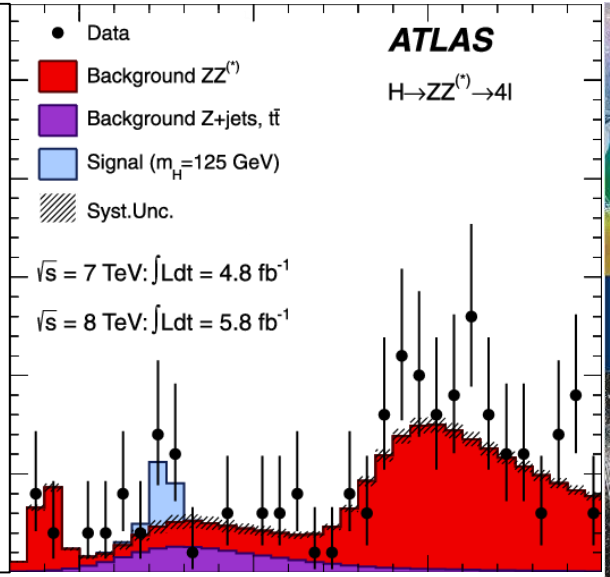
Does the System Design define a solution meeting the System Requirements?

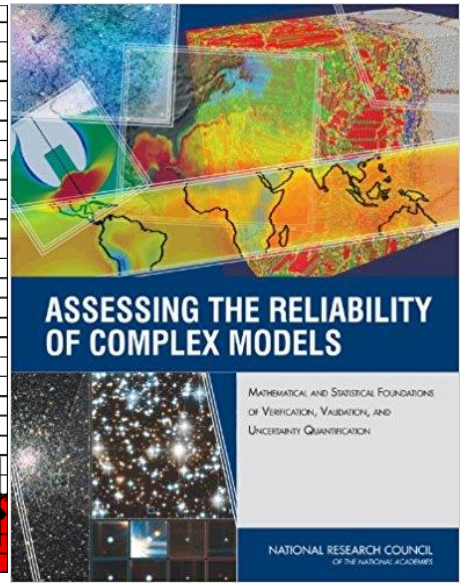
Don't forget: A model (on the left) may be used for system verification or validation (on the right!)

At the Heart of Physical Science: Model Verification, Validation, and Uncertainty Quantification (VVUQ)



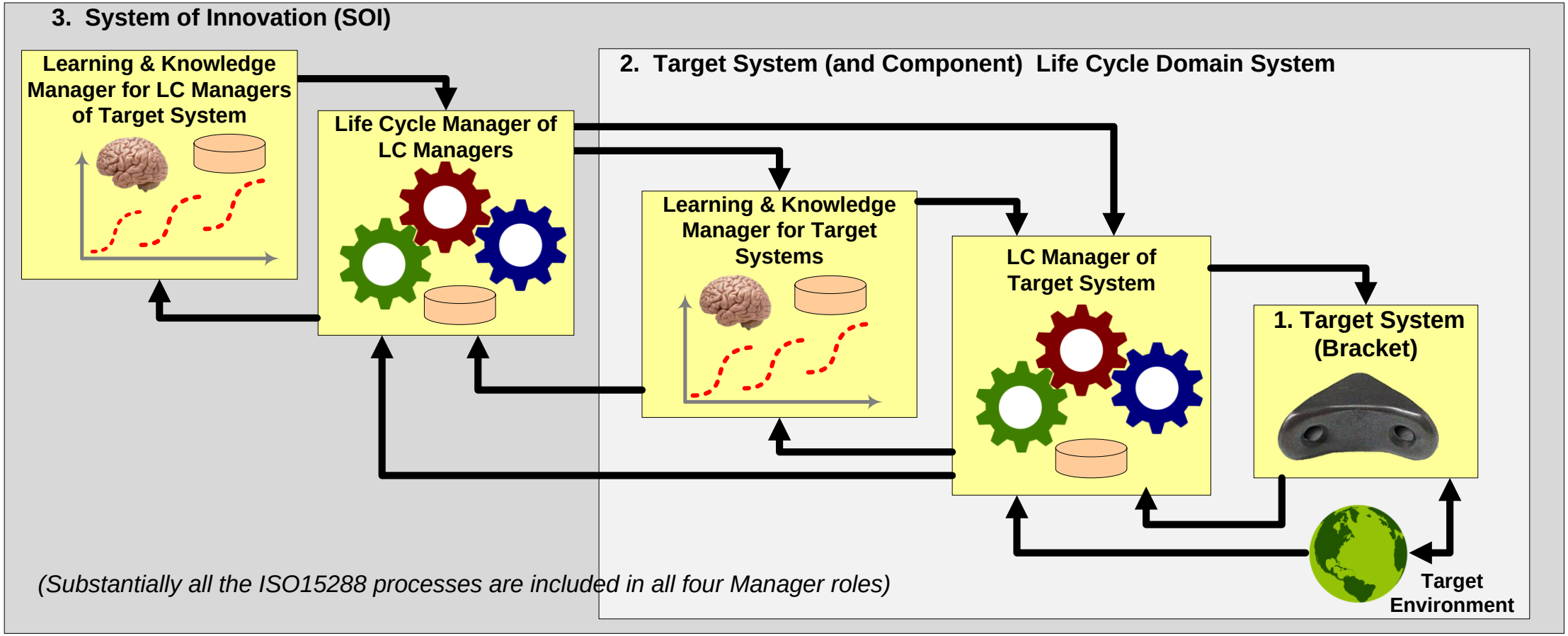






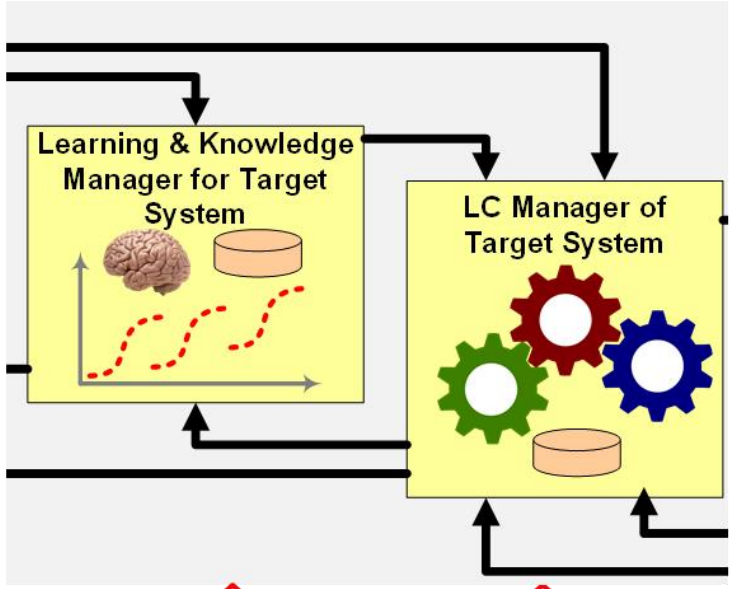
Three centuries of scientific experience, with tremendous positive impact on the human condition.

The System of Innovation Pattern: Model VVUQ as a Proxy for Learning and Mutual Trust

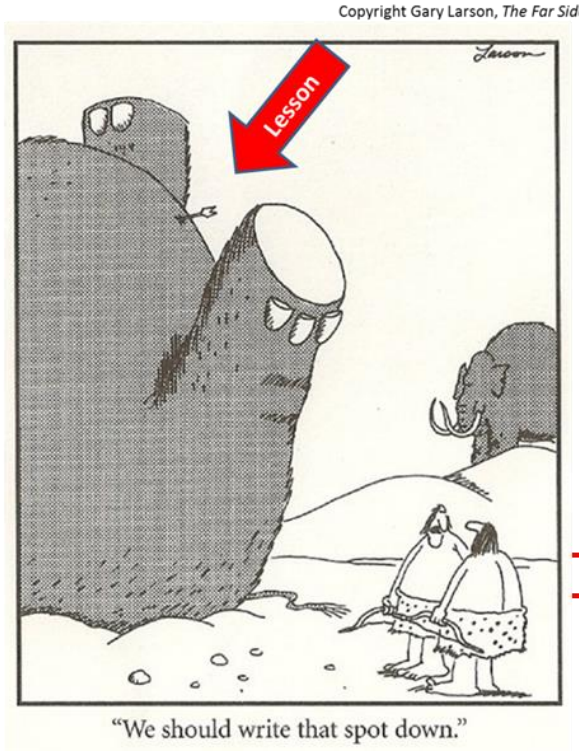


System 1: Target System, to be understood, designed, produced, supported, or otherwise life cycle managed.
System 2: Discovers, plans, designs, produces, operates, deploys, supports, otherwise manages life cycle of **System 1**.
System 3: Discovers, plans, designs, produces, operates, deploys, supports, otherwise manages life cycle of **System 2**.

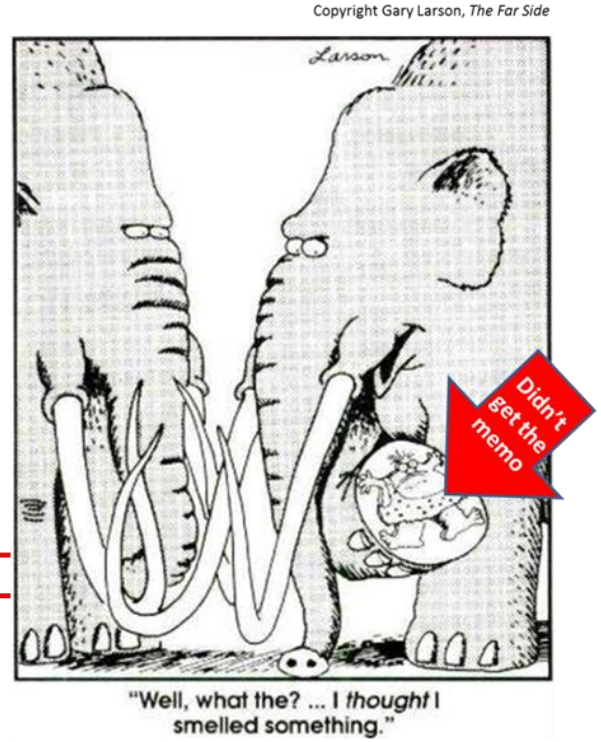
Learning



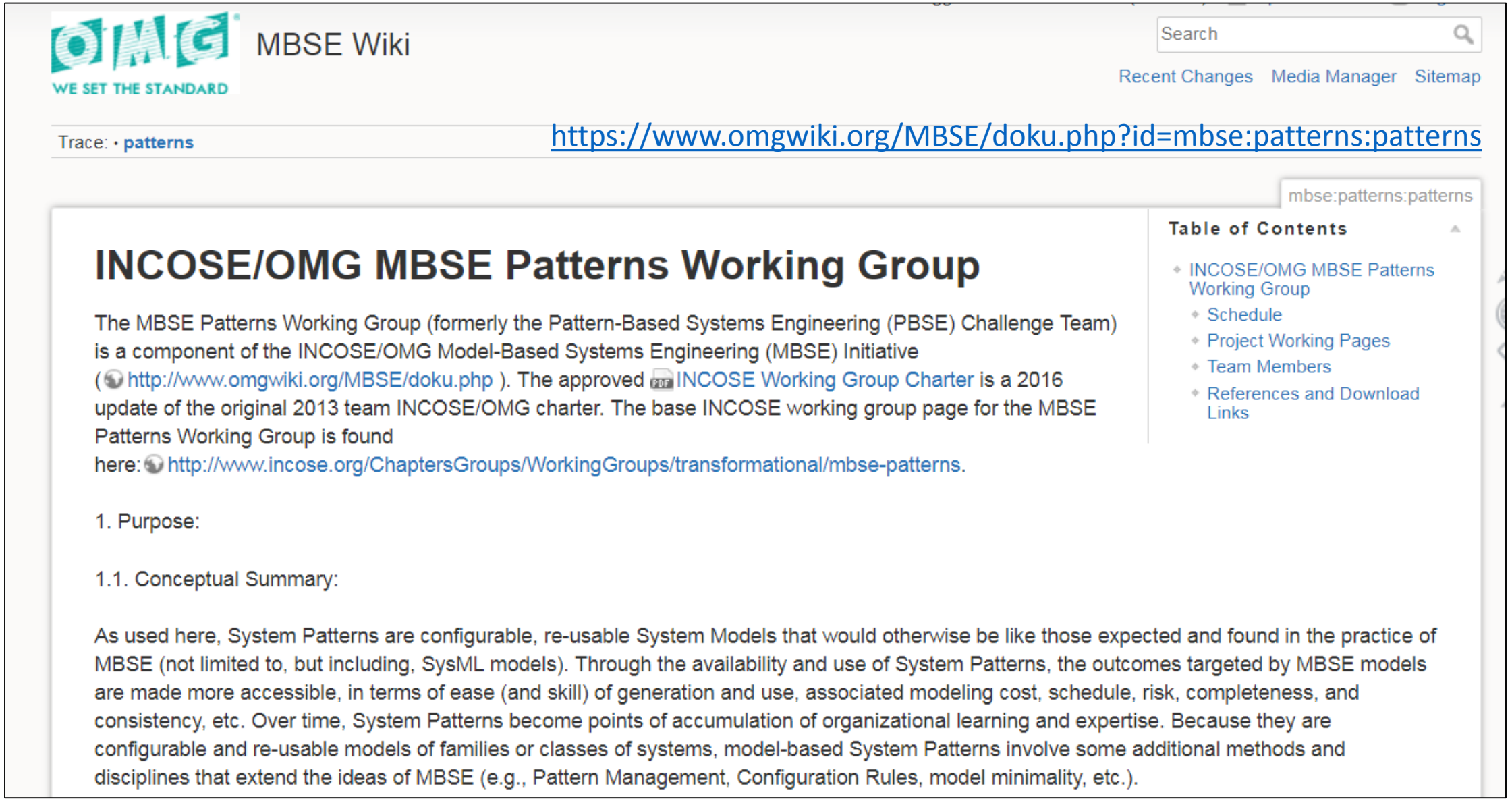
Executing



"Lessons Learned?"



Economic Leverage of Model-Based Patterns: "What about what we already know?"



MBSE Wiki

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mbse:patterns:patterns

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INCOSE/OMG MBSE Patterns Working Group

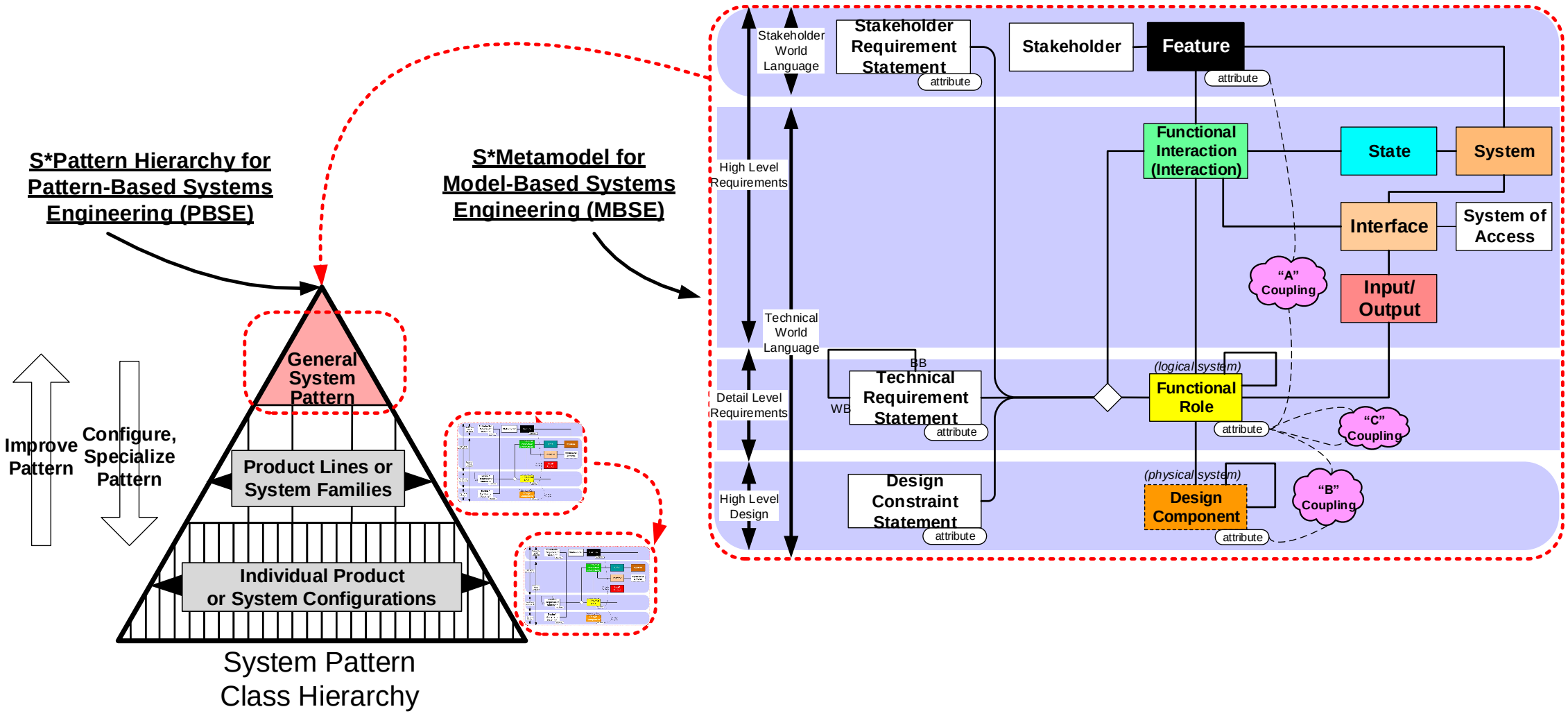
The MBSE Patterns Working Group (formerly the Pattern-Based Systems Engineering (PBSE) Challenge Team) is a component of the INCOSE/OMG Model-Based Systems Engineering (MBSE) Initiative (http://www.omgwiki.org/MBSE/doku.php). The approved INCOSE Working Group Charter is a 2016 update of the original 2013 team INCOSE/OMG charter. The base INCOSE working group page for the MBSE Patterns Working Group is found here: http://www.incose.org/ChaptersGroups/WorkingGroups/transformational/mbse-patterns.

1. Purpose:

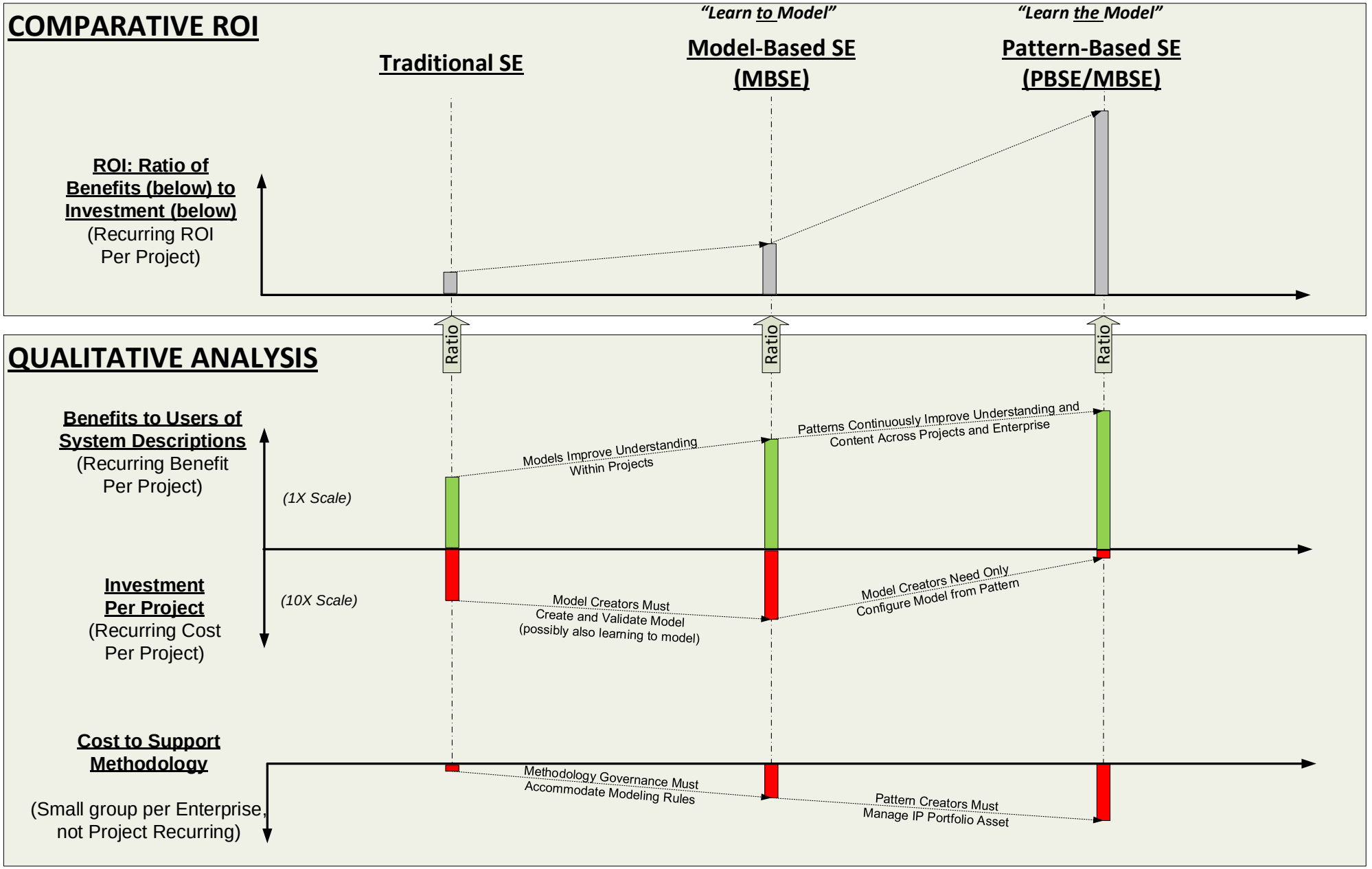
1.1. Conceptual Summary:

As used here, System Patterns are configurable, re-usable System Models that would otherwise be like those expected and found in the practice of MBSE (not limited to, but including, SysML models). Through the availability and use of System Patterns, the outcomes targeted by MBSE models are made more accessible, in terms of ease (and skill) of generation and use, associated modeling cost, schedule, risk, completeness, and consistency, etc. Over time, System Patterns become points of accumulation of organizational learning and expertise. Because they are configurable and re-usable models of families or classes of systems, model-based System Patterns involve some additional methods and disciplines that extend the ideas of MBSE (e.g., Pattern Management, Configuration Rules, model minimality, etc.).

Economic Leverage of Model-Based Patterns



Economic Leverage of Model-Based Patterns



3. Two Decades of Related Progress on Related Methods and Standards

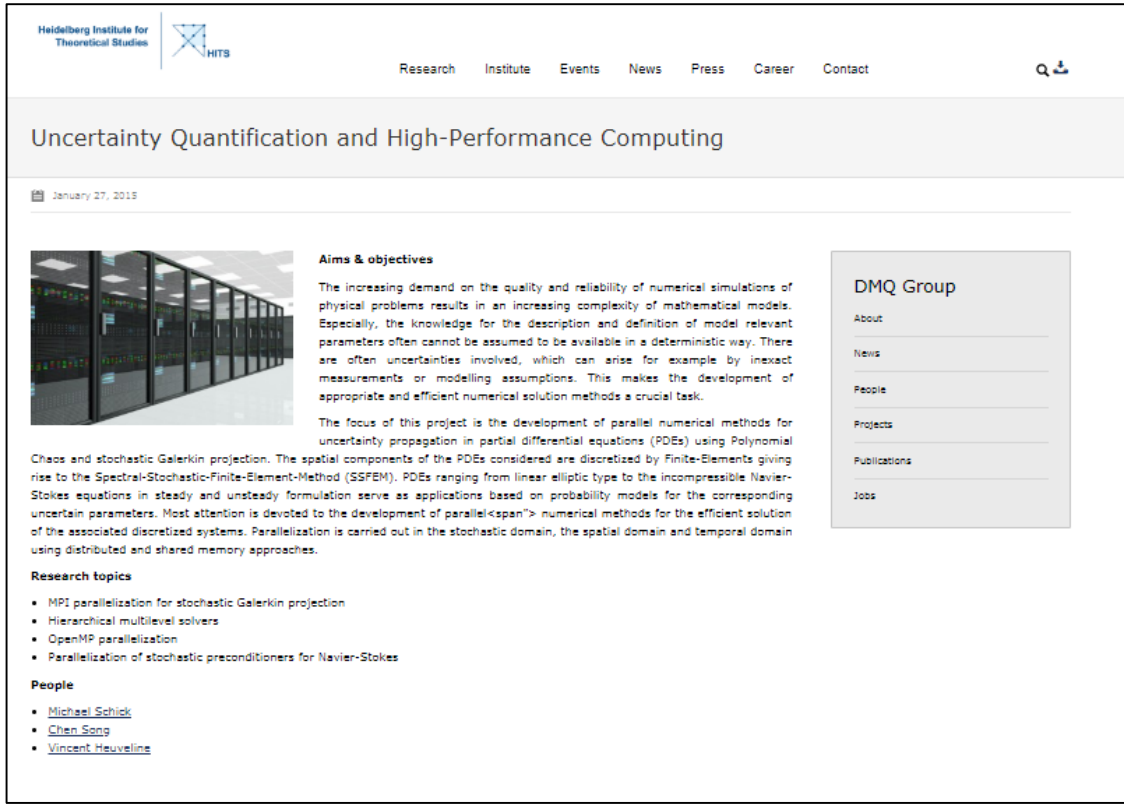
3.1 System V&V versus Model V&V, Model VVUQ for Trustable Models, Physics-Based Models, Data-Driven Models, Hybrid Models, Tools, History

3.2 Decades of Advancement in the Discipline of Trustable Computational Modeling in Critical Domains: Supporting Mathematics, Sandia, NASA, ASME Committees,

3.3 Collaboration by Regulatory, Engineering Society, and Enterprise Players: Introduction to Underlying Model VVUQ Discipline, Guides, Standards, Examples

3. Schindel, Mahadevan, Schindel

3.1 System V&V versus Model V&V, Model VVUQ for Trustable Models, Physics-Based Models, Data-Driven Models, Hybrid Models, Tools, History

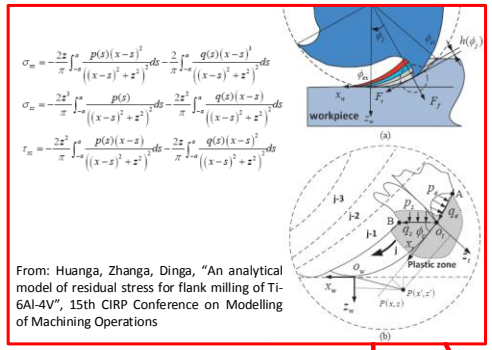


Physics-Based Model

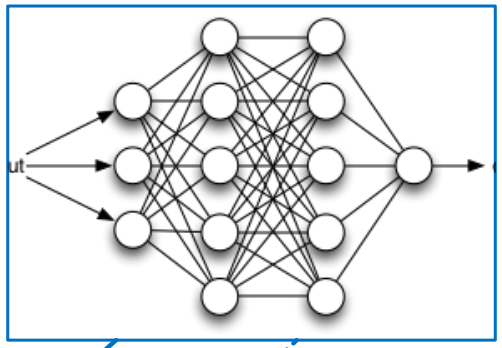
- Predicts the external behavior of the System of Interest, visible externally to the external actors with which it interacts.
- Models internal physical interactions of the System of Interest, and how they combine to cause/explain externally visible behavior.
- Model has both external predictive value and phenomena-based internal-to-external explanatory value.
- Overall model may have high dimensionality.

Data Driven Model

- Predicts the external behavior of the System of Interest, visible to the external actors with which it interacts.
- Model intermediate quantities may not correspond to internal or external physical parameters, but combine to adequately predict external behavior, fitting it to compressed relationships.
- Model has external predictive value, but not internal explanatory value.
- Overall model may have reduced dimensionality.



From: Huanga, Zhanga, Dinga, "An analytical model of residual stress for flank milling of Ti-6Al-4V", 15th CIRP Conference on Modelling of Machining Operations



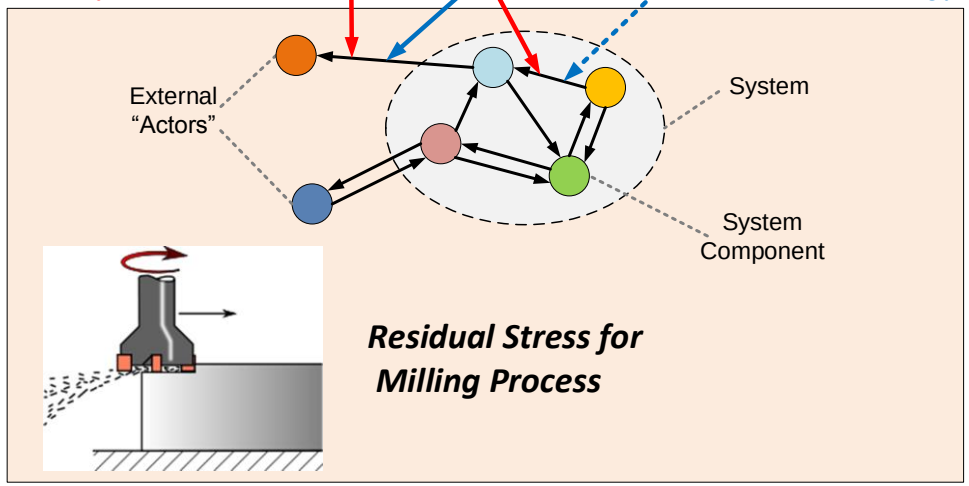
- **Physical scientists and phenomena models from their disciplines can apply here.**
- **The hard sciences physical laws, and how they can be used to explain the externally visible behavior of the system of interest.**

predicts, explains

predicts

optional

- **Data scientists and their math/IT tools can apply here (data mining, pattern extraction, cognitive AI tooling).**
- **Tools and methods for discovery / extraction of recurring patterns of external behavior.**



Real System Being Modeled

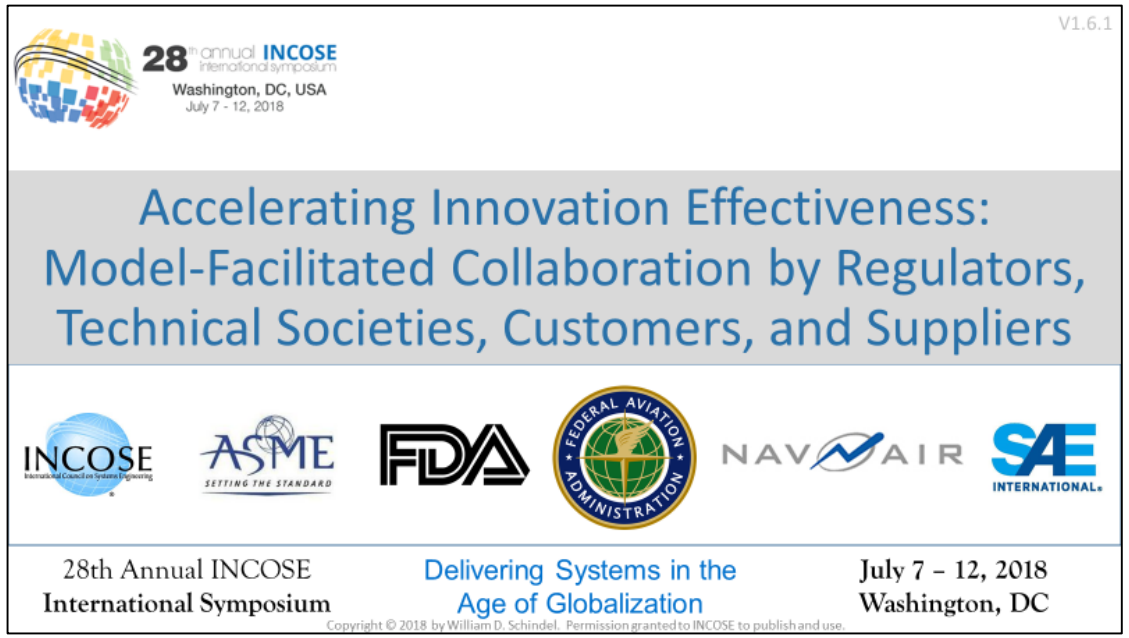
3.2 Decades of Advancement in the Discipline of

3.2 Trustable Computational Modeling in Critical Domains: Supporting Mathematics, Sandia, NASA, ASME Committees, Research

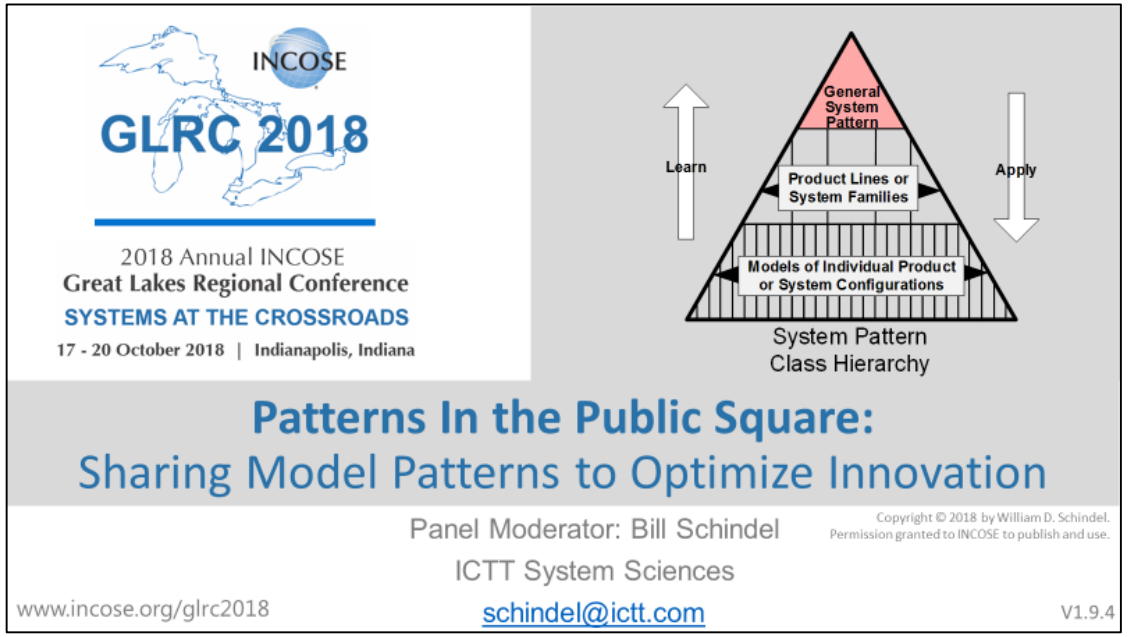
3.2 Professor Mahadevan

3.3 Collaboration by Regulatory, Engineering Society, and Enterprise Players: Pattern Support for Model VVUQ Discipline, Guides, Standards, Example

Collaboration challenges of sharing trusted patterns across domains

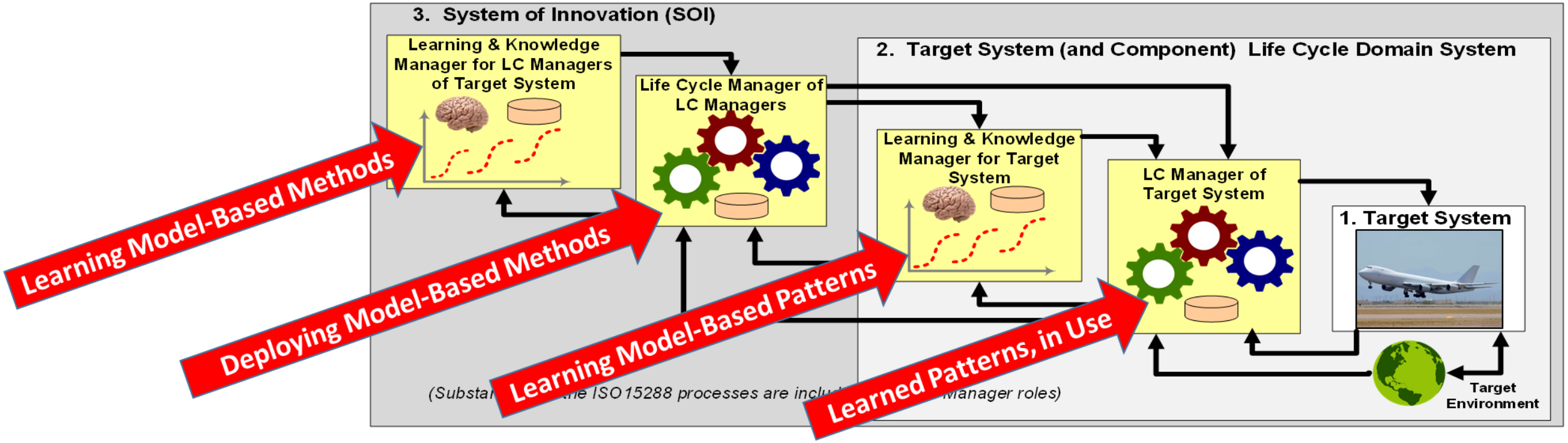


Panel at INCOSE IS 2018, Washington, July, 2018



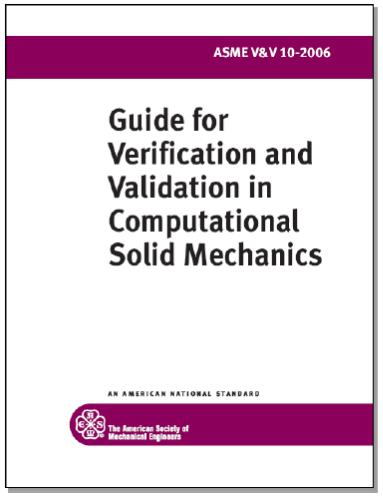
Panel at this Indianapolis conference, Fri., Oct 19

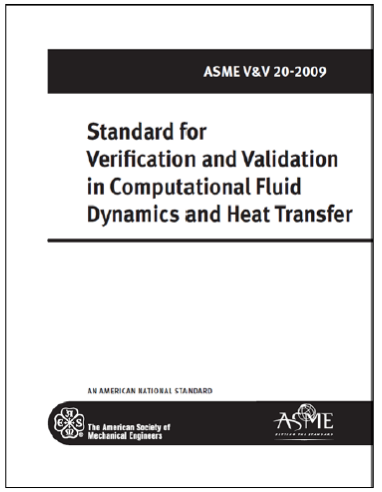
3.3 Collaboration by Regulatory, Engineering Society, and Enterprise Players: Pattern Support for Model VVUQ Discipline, Guides, Standards, Example

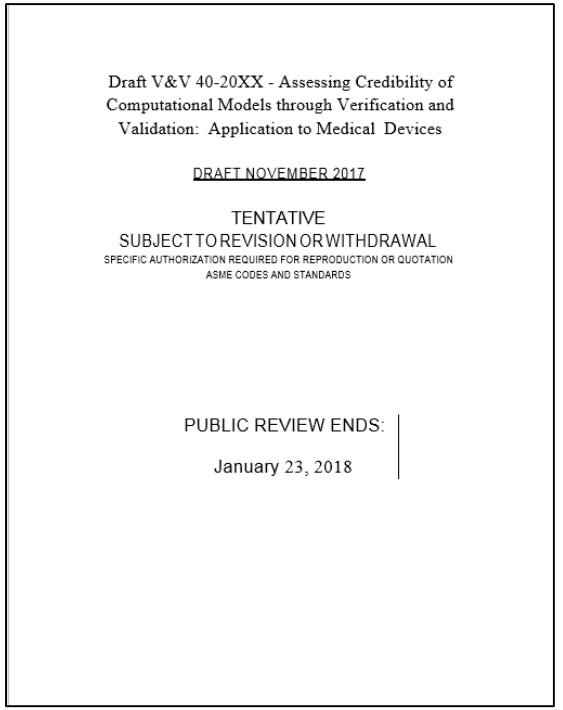


3.3 Collaboration by Regulatory, Engineering Society, and Enterprise Players: Pattern Support for Model VVUQ Discipline, Guides, Standards, Example

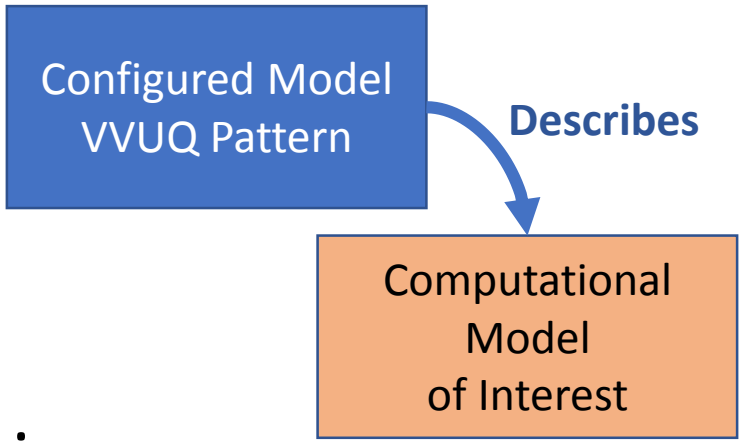
- ASME, INCOSE, FDA, FAA, Tooling, and Suppliers are engaged:
  - ASME VV 10, 20, 30, 40, 50 subcommittees, years of work
  - VV 50 Committee met here, Monday-Tuesday, Oct 15-16
  - SAE and INCOSE met on this in DC earlier this month





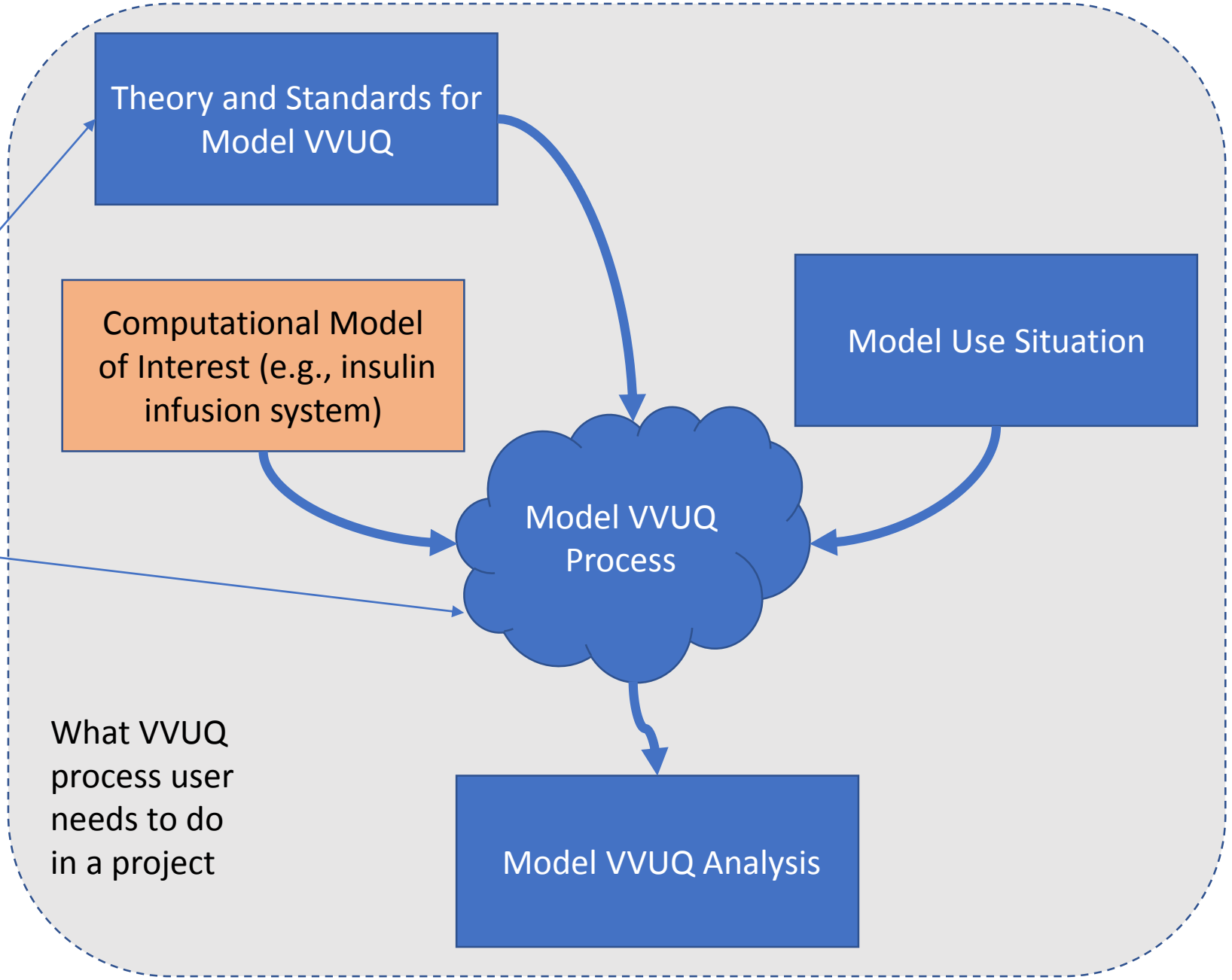


Goals of Applying S*Patterns to Model VVUQ and other Model Life Cycle Issues: Medical Device Example



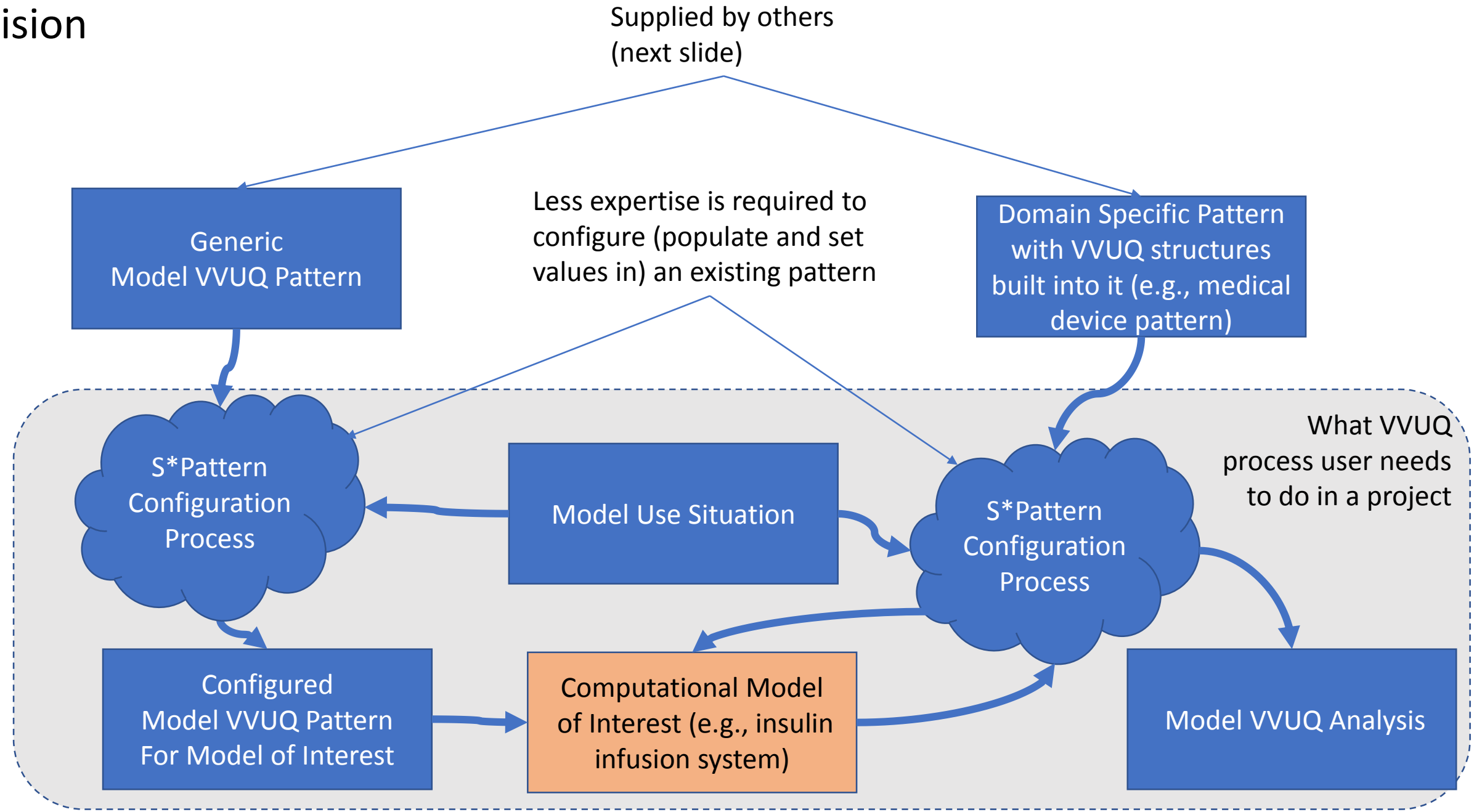
- "Models of computational models" may sound odd, so . . .
- *Why are we creating S*Models of computational models of interest?*
  1. To package decades of rich and valuable historical progress in theory of, and standards for, scientific model verification, validation, and uncertainty quantification . . . .
     - Into forms accessible by larger communities of less expert users;
     - Without diminishing, but instead gaining, VVUQ rigor, clarity, and standards alignment;
  2. Leveraging not only that theory but also hard-obtained learning about domain-specific models, into a form suitable for shared group learning as domain learning advances;
  3. Across otherwise diverse and rapidly changing virtual models, improve sharing ability of communities of enterprises, regulators, standards groups, supply chains, trade groups, lowering innovation friction while protecting critical IP;
  4. Improve ability to integrate families of diverse models across a single system or SoS;
  5. Enhance shared understanding of model planning, justification, documentation, migration, enhancement, and other model life cycle issues.

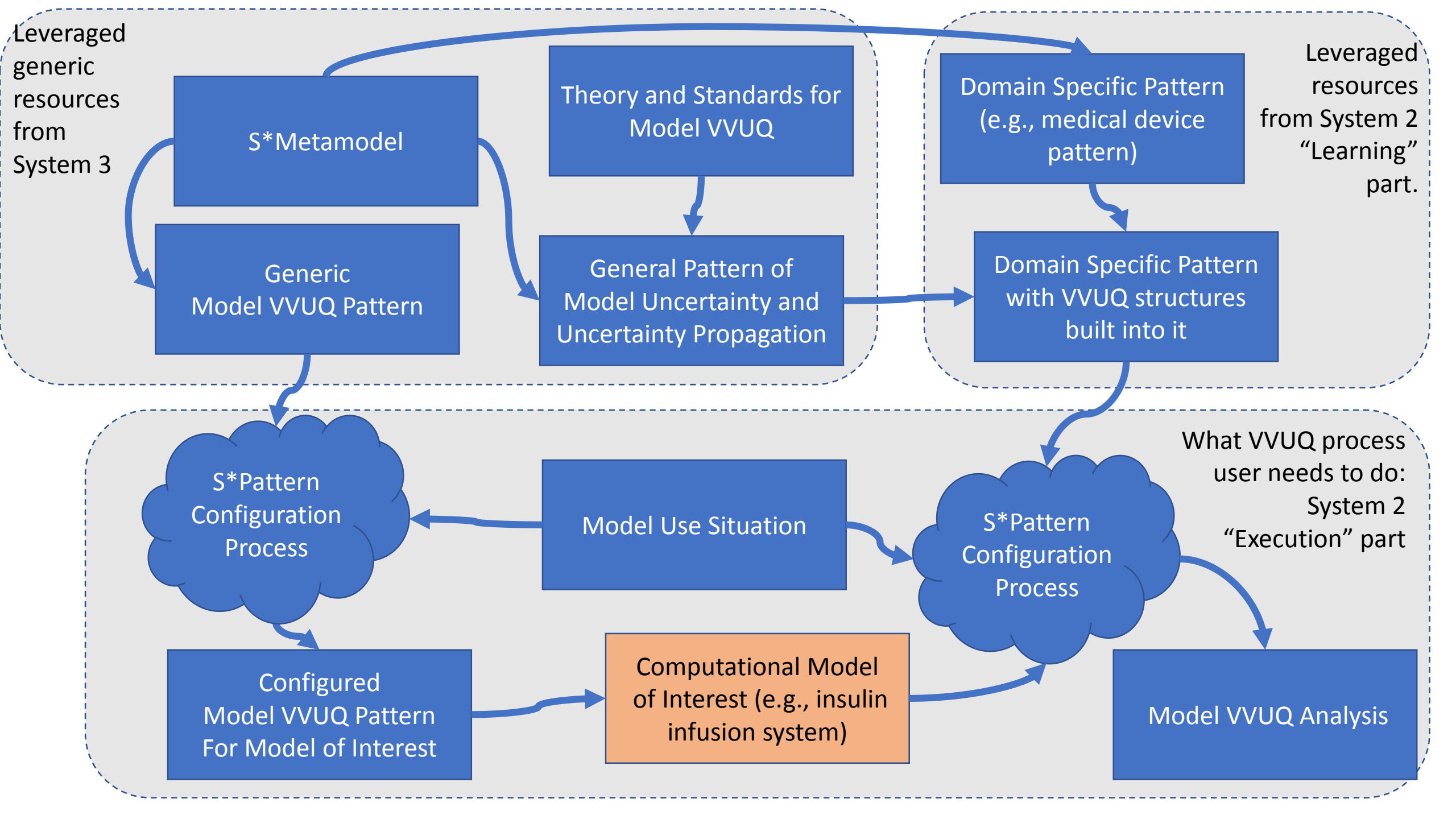
Current Practice



Expertise in these two areas may typically be limited. Practitioner knows more about Model Use Situation and Computational Model of Interest.

Vision


Supplied by others
(next slide)
Generic
Model VVUQ Pattern
Less expertise is required to configure (populate and set values in) an existing pattern
Domain Specific Pattern with VVUQ structures built into it (e.g., medical device pattern)
What VVUQ process user needs to do in a project
S*Pattern Configuration Process
Model Use Situation
S*Pattern Configuration Process
Configured Model VVUQ Pattern For Model of Interest
Computational Model of Interest (e.g., insulin infusion system)
Model VVUQ Analysis


Leveraged generic resources from System 3
S*Metamodel
Theory and Standards for Model VVUQ
Generic Model VVUQ Pattern
General Pattern of Model Uncertainty and Uncertainty Propagation
Domain Specific Pattern (e.g., medical device pattern)
Leveraged resources from System 2 "Learning" part.
Domain Specific Pattern with VVUQ structures built into it
What VVUQ process user needs to do: System 2 "Execution" part
S*Pattern Configuration Process
Model Use Situation
S*Pattern Configuration Process
Configured Model VVUQ Pattern For Model of Interest
Computational Model of Interest (e.g., insulin infusion system)
Model VVUQ Analysis

Break

4. V4 Institute: Targeted Outcomes, Roadmap, Properties, Collaboration Projects

4.1 V4I: Origin, Mission, Context, Stakeholder Features, Roadmap, Membership, Models of Products as well as Production, Protecting Proprietary Assets while Creating Shared Value

4.2 Breakout Sessions: Rotating Speed-Dating Poster Sections on Launch Projects--

- 4.2.1 Product Design Type Certification by Virtual Modeling & Simulation
- 4.2.2 Manufacturing Type Certification by Virtual Modeling & Simulation
- 4.2.3 System Level V&V by Virtual Modeling & Simulation
- 4.2.4 Verification and Validation of Models
- 4.2.5 Secure Model Repository Reference Pattern
- 4.2.6 V4I Framework: S*Metamodel, S*Patterns, Model VVUQ Pattern

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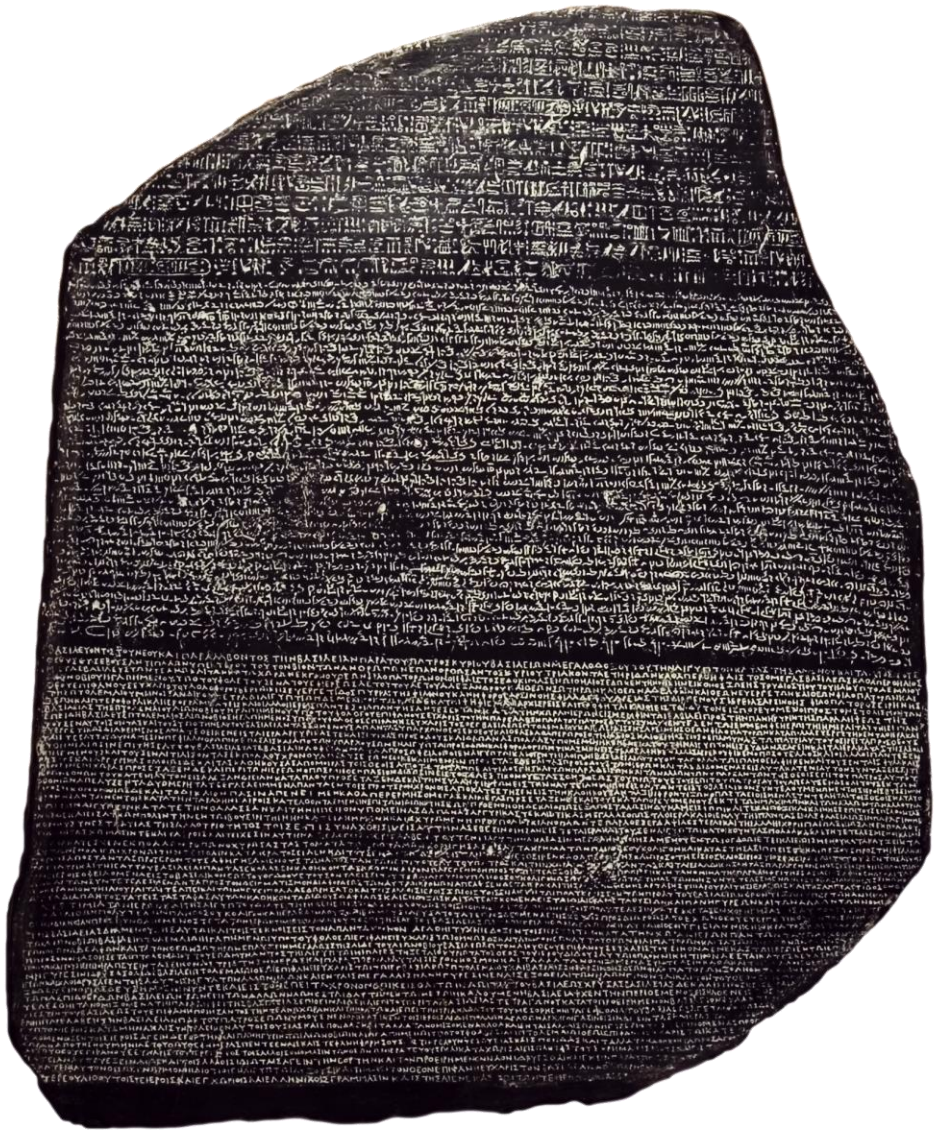
V4I Roadmap Process

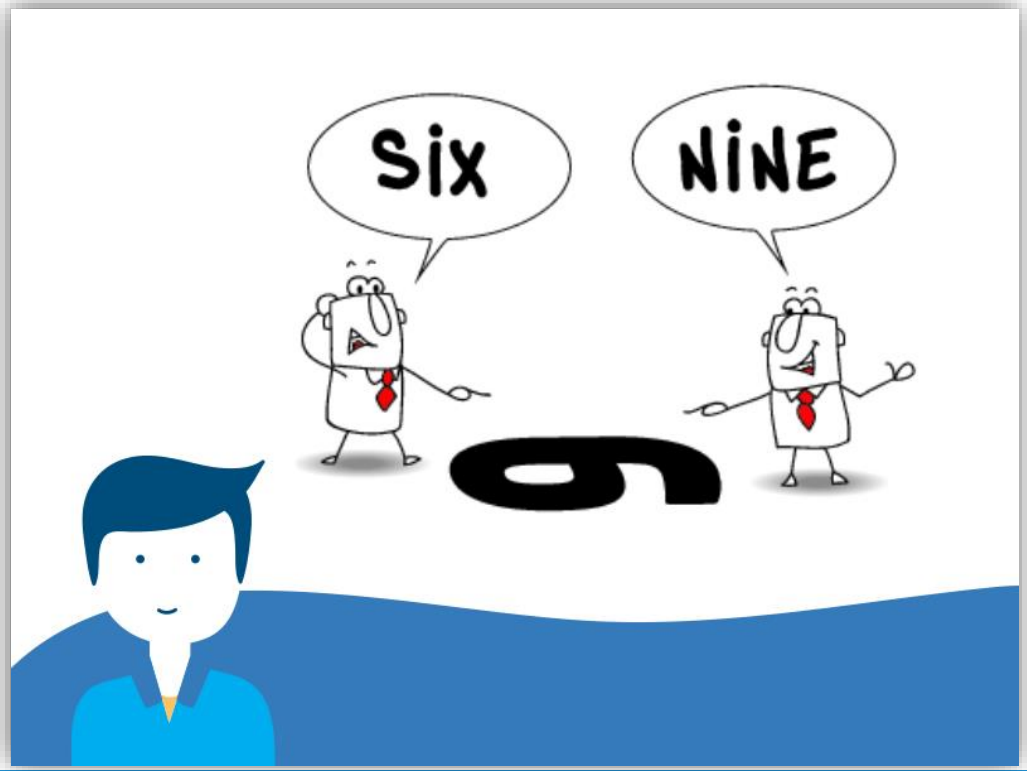


Development of a Common Language

Innovation on Purpose – It's all in the perspective…

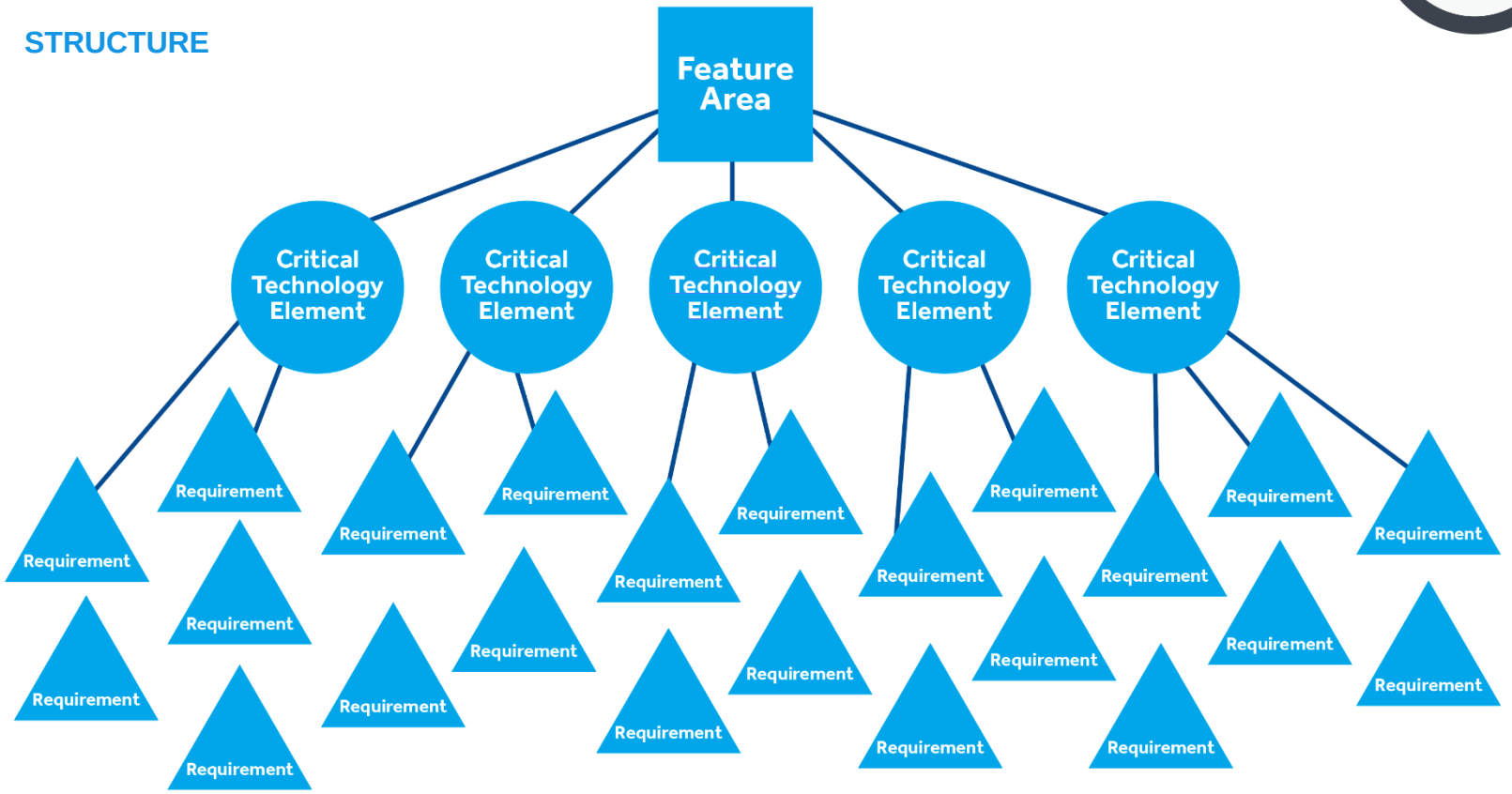
Everything is Based on Language and Communication

Successful innovation needs a common language, context and communicating



V4 Institute Roadmap

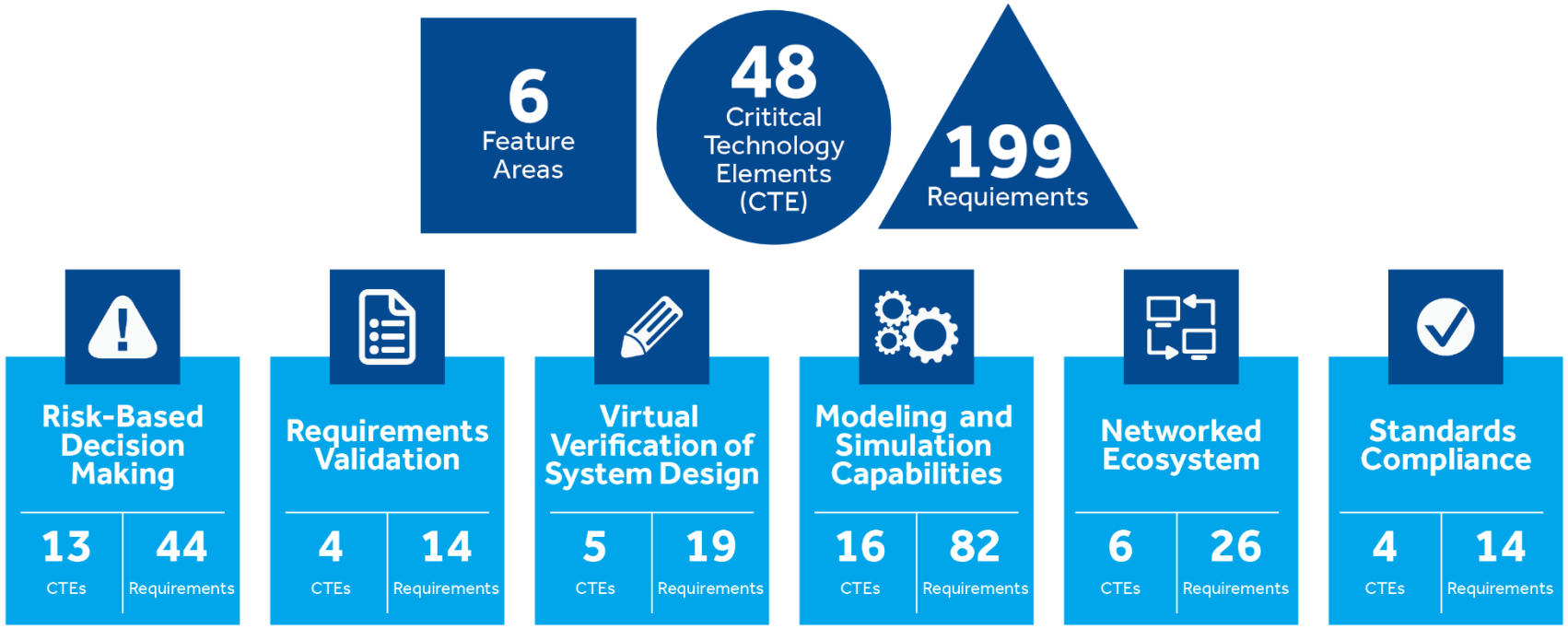
STRUCTURE



Focus Areas are defined along with **Critical Technology Elements** (CTE) and **Requirements**

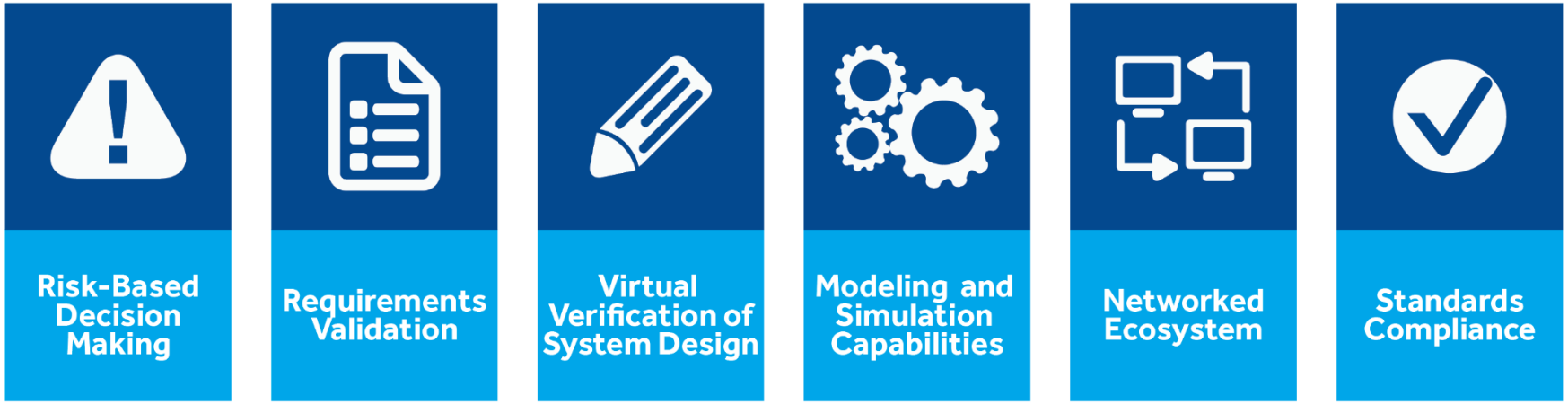
V4 Institute Roadmap

BY THE NUMBERS



V4 Institute Roadmap

FOCUS AREAS



Six focus areas are identified and defined

FOCUS AREA 1

Risk Based Decision Making

KEY MESSAGE

The use of CM&S in the right risk framework increases transparency to inform decision making.

DESCRIPTION

V4I modelling and simulation tools and methodologies will be made available for use by industry and regulators to quantitatively assess system risk and virtual verification, validation & visualization risk.

BENEFIT

Risk management for both the system and system verification, validation, and visualization will be quantified in support of robust decision-making. This will result in better and quicker risk management design and lifecycle decision-making and in regulatory compliance of virtual verification, validation & visualization. This will lead to no unintended or unexpected risk management or regulatory compliance issues with the product or virtual verification, validation & visualization.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **13** REQUIREMENTS: **44**

FOCUS AREA 2

Requirements Validation

KEY MESSAGE

Model-based requirements will be more readily validated because they are transparent and explicit.

DESCRIPTION

The capability to confirm that a specified set of requirements is fully descriptive of the needs of the stakeholders. This provides valid requirements in support of subsequent virtual verification to ensure the system meets all of the stakeholder expectations eliminating the need for redesign and additional testing.

BENEFIT

This will enable virtual verification of systems, resulting in quicker time to market and satisfaction of stakeholder expectations.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **4** REQUIREMENTS: **14**

FOCUS AREA 3

Virtual Verification of System Design

KEY MESSAGE

Verification using a trustworthy model can be done earlier to accelerate product development and facilitate system learning to reduce system risk.

DESCRIPTION

This Focus Area 3 leverages valid requirements to ensure a system design meets the specified requirements for that system through virtual (modeling and simulation) means. This will address verification readiness and planning as well as modelling the product and process.

BENEFIT

Virtual verification will mean faster, less expensive, and lower risk verification of system design. This will deliver lower life cycle cost and faster speed-to-market.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **5** REQUIREMENTS: **19**

FOCUS AREA 4

Modelling and Simulation Framework

KEY MESSAGE

Compliant, trustworthy framework and processes for achieving virtual validation, verification, and visualization.

DESCRIPTION

This Focus Area will develop explicit and credible models for optimizing management of the system across it's lifecycle. This capability will be utilized across enterprises, individuals, regions, supply chains, and trading segments.

BENEFIT

This will deliver model confidence and provide access to reusable, configurable libraries, while assuring model compatibility and interoperability. Trusted collaboration and communication across supply chain teams will be improved.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **6** REQUIREMENTS: **26**

FOCUS AREA 5

Networked Ecosystem

KEY MESSAGE

This ecosystem creates and aligns people and enterprises to realize the model based economy.

DEFINITION

This Focus Area establishes forums or networking entities needed to enable and coordinate all stakeholders using modeling and simulation for virtual verification. An ecosystem will be developed across enterprises and institutions that is V4 capable, including developing workforce and technical resources.

BENEFIT

Industry, academia & certifying/regulatory authorities will be able to efficiently and consistently communicate to accelerate use of modeling & simulation for virtual verification - reducing redundancy in capability development, increasing quality of virtual verification analysis, and reducing product development lifecycles.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **6** REQUIREMENTS : **26**

FOCUS AREA 6

Standards Compliance

KEY MESSAGE

This will guide and influence current and emerging standards while advocating adoption across the supply chain.

DEFINITION

This Focus Area will service enterprises, individuals, regions, supply chains, and trading segments that require compliance with formal standards and regulations for alignment, efficiency, and regulatory objectives. This is specifically concerned with ISO15288 lifecycle compatibility and the identification and management of standards for use on a system or with application of virtual verification, validation & visualization.

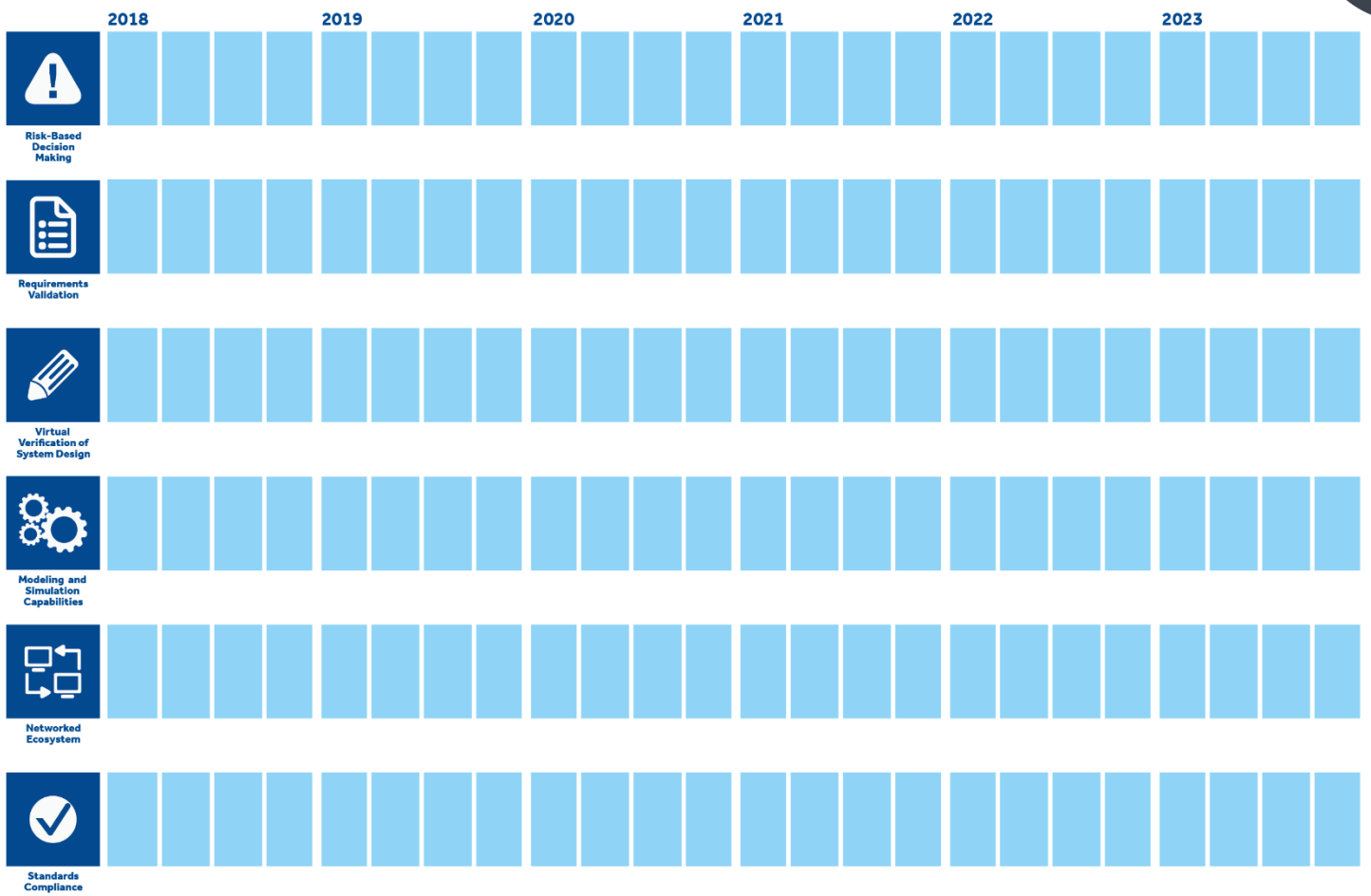
BENEFIT

This will improve alignment and use of standards across communities for efficiency and reduction of risk in partnership with regulatory authorities.

CRITICAL TECHNOLOGY ELEMENTS (CTE): **4** REQUIREMENTS: **14**

ROADMAP NEXT STEPS

Prioritize and Plot CTEs and Requirements



ROADMAP NEXT STEPS

Get involved!

We are seeking experts to share their expertise and knowledge to contribute to the mission of the institute.

You and your organization can get involved by participating in one or more of our **workshops**, by sponsoring a specific **research project**, or by **becoming a member**.

Learn more at V4i.us

What About Intellectual Property that is Developed?

Process of Managing Intellectual Property

Consortium Developed Intellectual Property (CDIP)

Process of Managing Intellectual Property

Background Intellectual Property (BIP)

Consortium Developed Intellectual Property (CDIP)

Process of Managing Intellectual Property

Consortium Developed Intellectual Property (CDIP)

Background Intellectual Property (BIP)

Questions Around IP

- How do I protect my BIP that I bring to a project?
- Are there safeguards in place so I do not see CDIP that I do not want to be exposed to?
- Do I have the opportunity to incorporate my BIP and commercialize?
- What is in place or going to be in place to protect CDIP?
- Do I get access to all CDIP developed?
- Is there flow down of the IP policy to subs on an effort? (both members and non-members of V4I)

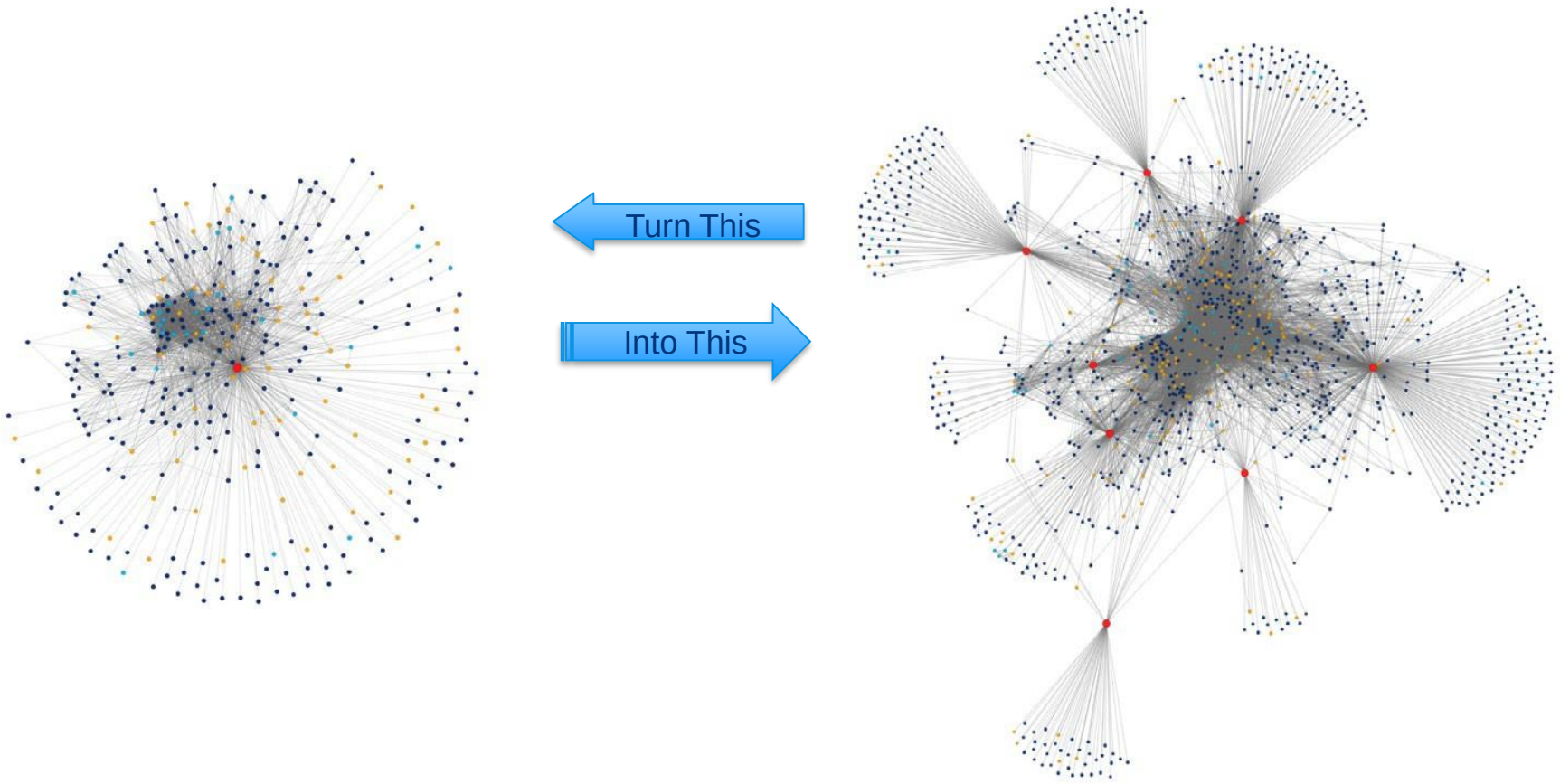
Membership Model

	Silver $15K/year	Gold $50K/year *25% Cash Minimum ($12.5k)*	Gold $50K/year (Cash-exempt)	Platinum $200K/year *25% Cash Minimum ($50k)*	Platinum $200K/year (Cash-exempt)
Organizational Eligibility:					
Small/medium organizations (<500 employees)	✓	✓		✓	
Large organizations (>500 employees)		✓		✓	
Universities and not-for-profits (exempted from cash minimum)	✓	✓	✓	✓	✓

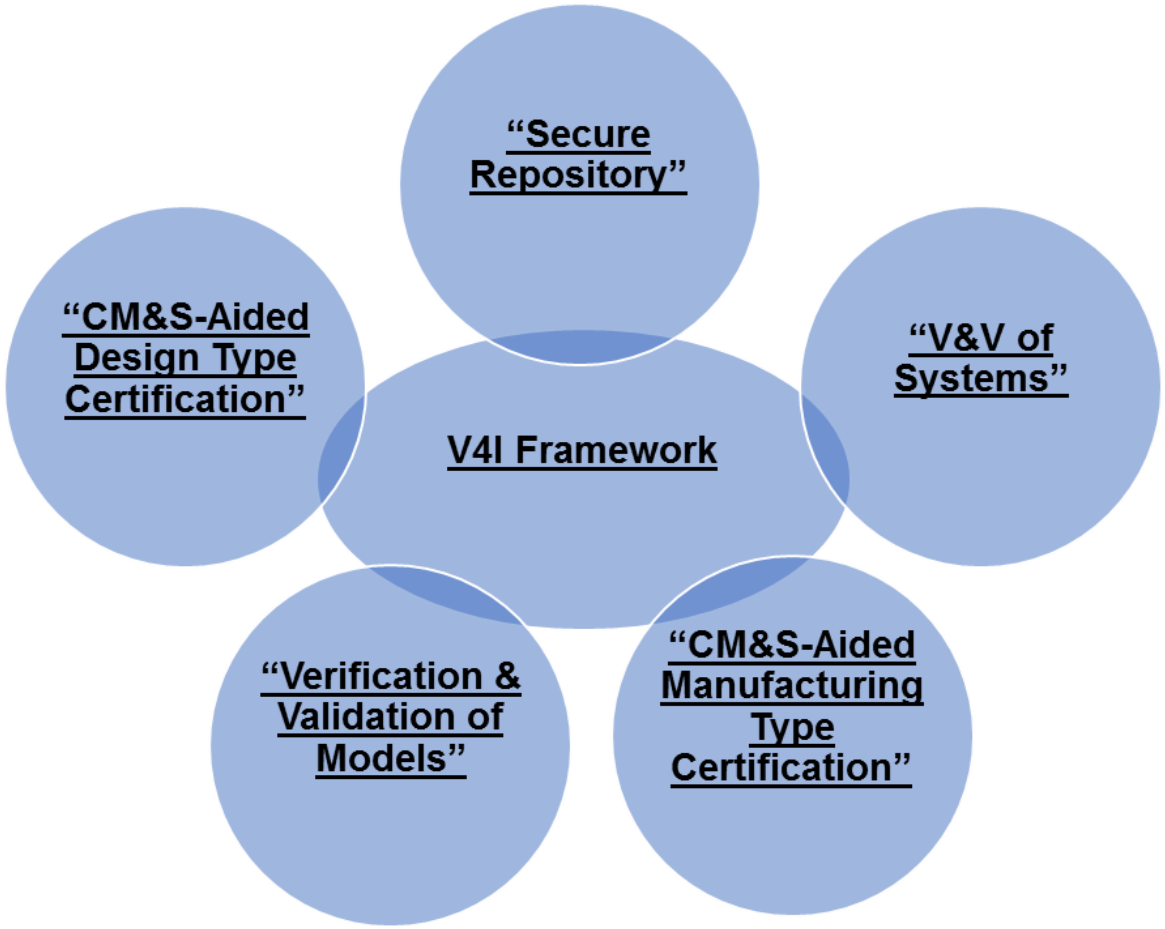
	Silver $15K/year	Gold $50K/year *25% Cash Minimum ($12.5k)*	Gold $50K/year (Cash-exempt)	Platinum $200K/year *25% Cash Minimum ($50k)*	Platinum $200K/year (Cash-exempt)
Role Eligibility:					
May compete for, participate in, and serve as project lead	✓	✓	✓	✓	✓
Governance Board Seat				1	
Advisory Role			✓		✓
Voting Rights		✓		✓	

	Silver $15K/year	Gold $50K/year *25% Cash Minimum ($12.5k)*	Gold $50K/year (Cash-exempt)	Platinum $200K/year *25% Cash Minimum ($50k)*	Platinum $200K/year (Cash-exempt)
Consortium Developed Intellectual Property (CDIP) Eligibility:					
Non-Exclusive Royalty Free (NERF) license for internal research use*	✓	✓	✓	✓	✓
Non-Exclusive Royalty Bearing (NERB) license for commercialization*		**Negotiable**			
Non-Exclusive Royalty-Free (NERF) for commercialization*				**Negotiable**	

THE POWER OF COLLABORATION



Break out poster sessions by Launch Project Teams



5. Invitation to Collaborate

5.1 Collaborate to Accelerate Your Learning; Collaborate for Early Access to Assets

5.2 Membership and Members

5.3 Discussion

Workshop Closing: Landscape

- Regulations & regulatory imprint is increasing … so how does best practice form?
- Expectations are evolving quickly and will affect the ability to compete.
- Value of innovation & understanding what it takes to accelerate/reduce the costs in realization.
- Language of SOI/MBSE…and establishing credibility in the use of virtual tools to verify, validate and visualize uncertainty in decision making.
- The need for agent to enable public-private collaboration and help integration the ecosystem.
- Role of the V4 Institute in the ecosystem to collect knowledge & tools, educate and develop/establish the processes that provide credibility and trust.

Workshop Closing

Learning Objectives:

- Awareness of the landscape: Challenges & Opportunities
- Understand the history & core tenants of “trust”
- Understand V4i Role, Processes & Capabilities
- Stimulate ideas by sharing examples of current projects
- Advocate for action to advance our common cause

Calling out the Business Challenges

Old axiom…

fail early & often

New axiom…

learn early & share openly

- Transforming the people and organizations to create understanding & trust across the ecosystem
- Establishing the Risk- Benefit relationship
- Developing Common Language
- Ability to share openly without compromising the prize (Intellectual Property)
- Building or Accessing …the resources needed to complete the mosaic
- Acceptable Process & Measurement (expectations)
- Finding an agent to integration the ecosystem

ASG ADJUTANT SOLUTIONS GROUP

Understand the history & core tenants of “trust”

Understand V4i Role, Processes & Capabilities

Stimulate ideas by sharing examples of current projects

- Product Design Type Certification by Virtual Modeling & Simulation
- Manufacturing Type Certification by Virtual Modeling & Simulation
- System Level V&V by Virtual Modeling & Simulation
- Verification and Validation of Models
- Secure Model Repository Reference Pattern
- V4I Framework: S*Metamodel, S*Patterns, Model VVUQ Pattern

Industry Value – Return on Investment

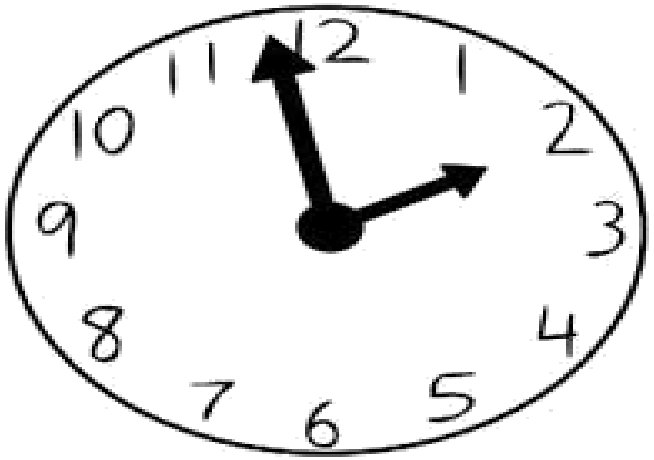
- Defense Aerospace [4]
  - 50% Research and Development cost savings
  - 25% Research and Development time reduction
- Life Sciences: Medical Devices [5,6]
  - 50% Research and Development cost savings
  - 50% Research and Development time reduction
- Improved Product Quality, Safety, Reliability
  - Higher customer Satisfaction
  - Sustainable Product Lines and Lifecycles through Innovation
- Improved Manufacturing Process Safety, Reliability, Efficiency
  - Higher return on investment

Residual Value – Sustainable Economic Impact

- **Manufacturing Excellence** – Return on Investment, Realized Innovation
- **Safety, Quality, Reliability, Cost** – Better products, processes, safer jobs
- **Education Realization** – Research opportunities, STEM durability
- **Regulatory Efficiency** – Clear decision: impact to public safety & confidence
- **Entrepreneurial Networks** – Opportunities, Agility, Markets, Job creation
- **Community** – Stability, Continuity

Differentiators – Why this strategy?

- Option: Isolated Private Corporations Only 💰
  - Each company arrives at the same scientific solution independently
- Option: University or Government Research Only
  - Application of science to business practical solutions
- Option: Entrepreneurial Network
  - Investment costs prohibitive; Expertise limited
- Option: Specialized Solution Providers
  (software, consulting, engineering)
  - Challenges: competitive IP conflicts, limited horizon



Differentiators – Why this strategy?

- **Collaboration is the Key to Sustainable Innovation**
- Industry
  - Value Driven Innovation Realization
  - Sustainable, scalable solutions
- Entrepreneurs
  - Breakthrough Innovation from proof of concept
  - Economic growth engine through STEM jobs
- University
  - Deep Science Expertise
  - Future sourcing talents, preparing high skilled workforce
- Government & Regulatory
  - Strategic Public Funding and Public Accountability
- Specialized Solution Providers
  - Technology Expertise, experience, and innovation

V4i Institute Roadmap

BY THE NUMBERS

Risk Based Decision Making	Requirements Validation	Virtual Verification of System Design	Modelling and Simulation Capability	Networked Ecosystem	Standards Compliance
13 CTEs	4 CTEs	5 CTEs	16 CTEs	6 CTEs	4 CTEs
44 Assets	14 Assets	19 Assets	82 Assets	26 Assets	14 Assets

V4

VIRTUAL
Existing outside of and representing a physical reality.

VERIFICATION
Evaluation of whether a product, service, system, or model, complies with a regulation, requirement, specification, or imposed condition. Quantification of related uncertainty and risk

VALIDATION
Assurance that a product, service, system, or model, meets the needs of the customer and other stakeholders. Quantification of related uncertainty and risk

VISUALIZATION
Representations that enable effective human communication, understanding, analysis, and decision-making.

Workshop Closing

- Role of the institute in the ecosystem collect knowledge & tools, educate and develop/establish the processes that provide credibility and trust.
- Why V4I?
  - Manufacturing Excellence
  - Safety, Quality, Reliability, Cost
  - Education Realization
  - Regulatory Efficiency
  - Entrepreneurial Networks
  - Community
- Value in membership
  - Membership structure overview
  - Early Access to Assets
  - Participate in developing Assets important to your business needs
  - Access to the emerging V4I ecosystem for capability & capacities
- Call to membership - we need you!

Thank you!

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For additional information:

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Supporting Slides

www.incose.org/glrc2018

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[5] Reporting of Computational Modeling Studies in Medical Device Submissions: *Guidance for Industry and Food and Drug Administration Staff*, Document issued on: September 21, 2016.

[6] Medical Device Innovation Consortium (MDIC)

Tutorial Detail Outline

12:00 – 12:20 1. Introductions: V4 Institute, Tutorial Attendees
- 1.1 Workshop Objectives and Materials
- 1.2 Introducing the V4 Institute
- 1.3 Workshop Attendee Introductions and Interests

12:20 – 12:40 2. Context: Challenges and Opportunities
- 2.1 Digital Engineering Has Arrived
- 2.2 Challenges to Innovation: Complexity, Regulatory and Other Risks, Development Costs and Time, Expectations
- 2.3 Opportunities: Virtual Models, Model VVUQ as a Proxy for Learning and Mutual Trust, Economic Leverage of Model-Based Patterns

12:40 – 2:30 3. Two Decades of Related Progress on Related Methods and Standards
- 3.1 System V&V versus Model V&V: Model VVUQ for Trustable Models, Physics-Based Models, Data-Driven Models, Hybrid Models, Tools, History
- 3.2 Decades of Advancement in the Discipline of Trustable Computational Modeling in Critical Domains: Supporting Mathematics, Sandia, NASA, ASME Committees,
- 3.3 Collaboration by Regulatory, Engineering Society, and Enterprise Players: Introduction to Underlying Model VVUQ Discipline, Guides, Standards, Examples

2:30 -- 3:00 *BREAK*

3:00 – 4:15 4. V4 Institute: Targeted Outcomes, Roadmap, Properties, Collaboration Projects
- 4.1 V4I: Origin, Mission, Context, Stakeholder Features, Roadmap, Membership, Models of Products as well as Production, Protecting Proprietary Assets while Creating Shared Value
- 4.2 Breakout Sessions: Rotating Speed-Dating Poster Sections on Launch Projects--
  - 4.2.1 Product Design Type Certification by Virtual Modeling & Simulation
  - 4.2.2 Manufacturing Type Certification by Virtual Modeling & Simulation
  - 4.2.3 System Level V&V by Virtual Modeling & Simulation
  - 4.2.4 Verification and Validation of Models
  - 4.2.5 Secure Model Repository Reference Pattern
  - 4.2.6 V4I Framework: S*Metamodel, S*Patterns, Model VVUQ Pattern

4:15 – 5:00 5. Invitation to Collaborate
- 5.1 Collaborate to Accelerate Your Learning; Collaborate for Early Access to Assets
- 5.2 Membership and Members
- 5.3 Discussion

5:00 6. Adjourn