



*Patterns
Working Group*

*Virtual Verification, Validation,
and Visualization Institute*

Introductory Seminar for FDA:

- S*Models and S*Metamodel
- S*Patterns
- Model VVUQ S*Pattern
- System of Innovation S*Pattern



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Oct. 22-23, 2018
V1.2.9



In a nutshell . . .

1. The INCOSE Patterns Working Group has been active over years with model-based patterns, called S*Patterns, based on the S*Metamodel framework, including application to the System of Innovation (SOI), leading to the Agile Systems Engineering Life Cycle Management (ASELCM) Pattern.
2. In the ASME Model VVUQ Standards Committee, we have been applying the above to create a model-expressed standard approach to model VVUQ, advancing traditional prose-based standards.
3. The Model VVUQ Pattern provides INCOSE practitioners a metadata-based asset for model planning or characterization, neutral as to model type, tooling, or domain—a consistent model “wrapper”, itself model-based.
4. INCOSE and ASME work has recently been incorporating ASME VV40 draft standard prose-expressed guidance into a model-expressed update to the Model VVUQ Pattern, improving ability to plan, express, and assess evidence in a more uniform manner, as a part of “System 2” of the SOI Pattern.
5. We are pursuing this for a Generic System, a General Medical Device, and a Specific Medical Device.
6. Stimulated by this technical society work, the public-private V4 Institute formed to accelerate growth in related capabilities of V4I Members, using a set of Launch Projects as platforms for collaboration, including inviting regulatory observation and feedback.
7. This seminar is intended to advance your awareness of key elements behind the above.

Seminar objectives

1. Learn about S*Metamodel we use in INCOSE Patterns Working Group and in our ASME VV50 work, including the Model VVUQ Pattern.
2. Learn about use of S*Patterns we use in the Patterns Working Group to improve leverage of S*Models, and how model VVUQ, group learning, trust, and S*Patterns connect.
3. Learn how S*Models/S*Patterns are related to computational models of various sorts, as a kind of metadata about them and the toolchains they inhabit.
4. Review how we are embedding the VV40 structures into the Model VVUQ Pattern, and implications for UQ and otherwise of doing so.
5. Learn about the medical device S*Pattern we are constructing as an example of above, controls and other aspects, UQ aspects, etc.
6. Learn about V4 Institute public projects that V4I invites regulators to observe, collaborate in, or otherwise interact for mutual community benefit.
7. Learn about related FDA perspectives, priorities, concerns, etc.
8. Discuss how related interactions involving additional regulators (e.g., FAA) or their DoD equivalents as well as technical societies might advance the overall practices of virtual life cycle management in the interests of the larger communities and society.
9. Other objectives important to you?

Seminar Outline / Timeline / Contents

- Seminar objectives, agenda
- Introductions, individual interests and concerns
- Challenges of diversity in domains, models, styles, and approaches
- S*Metamodel, S*Models, S*Patterns, PBSE, UTP, with examples
- The System of Innovation S*Pattern: System 1, 2, and 3
- The Model VVUQ Pattern and its embedding in the SOI Pattern
- Physics-Based Models, Data-Driven Models, Hybrid Models, System Models
- The Model VVUQ S*Pattern, advanced by VV40, applied to Medical Device S*Pattern
- Tooling
- V4I Collaboration Projects
- Discussion, issues, next steps

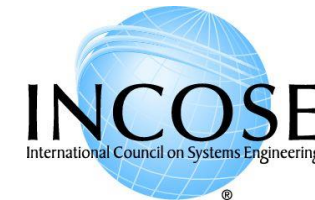
**Oct 22
(PM)**

**Oct 23
(AM)**

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- References
 - Attachment 1: Example extracts from S*Patterns
 - Attachment 2: Extracts from Model VVUQ S*Pattern application to Medical Device S*Pattern

Introductions, individual interests and concerns

- FDA participants
- INCOSE MBSE Patterns Working Group
- ICTT System Sciences
- V4 Institute



Challenges of diversity in domains, models, styles, and approaches

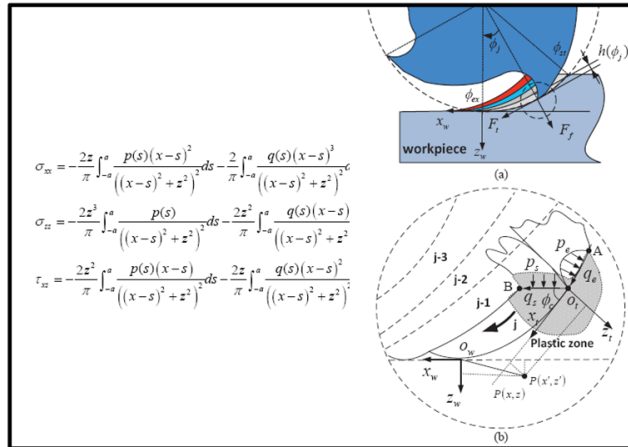
- Challenges of model-related diversities:
 - Modeled domains, subjects
 - Mathematical and other conceptual methods and representations
 - Numerical methods, computational tools, platforms, languages
 - Modeling styles of individuals, groups, enterprises
 - Other diversities

- Even with standards!

Virtual Models of All Types

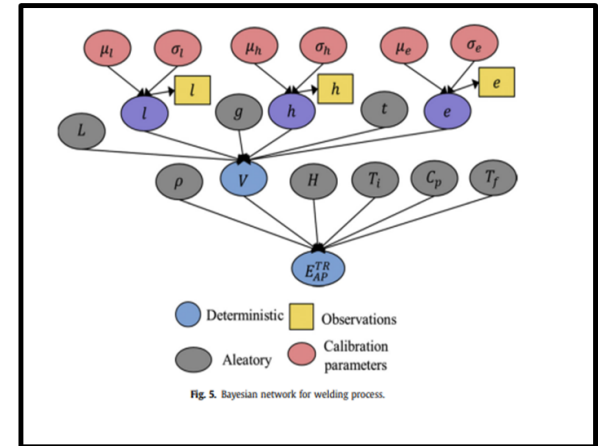
Physics-Based PDE Model

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



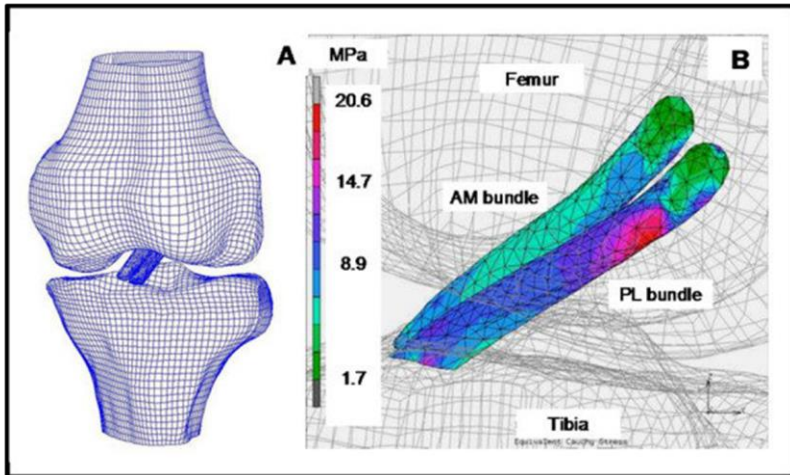
Data-Driven Bayesian Network Model

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.



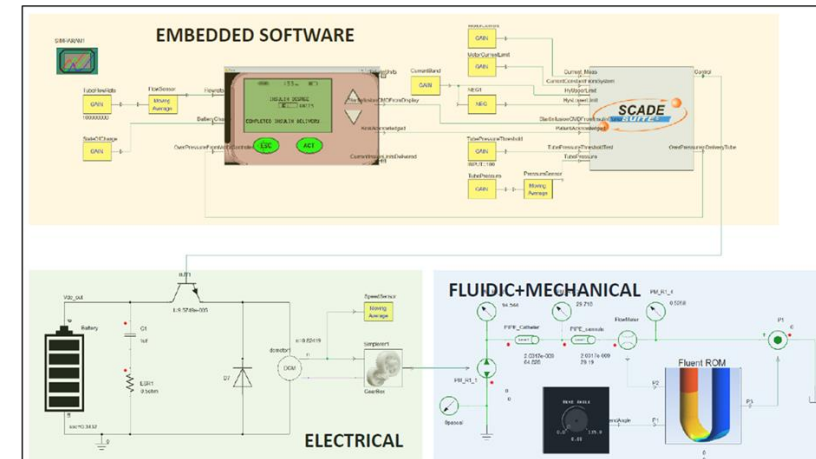
FEA Model

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

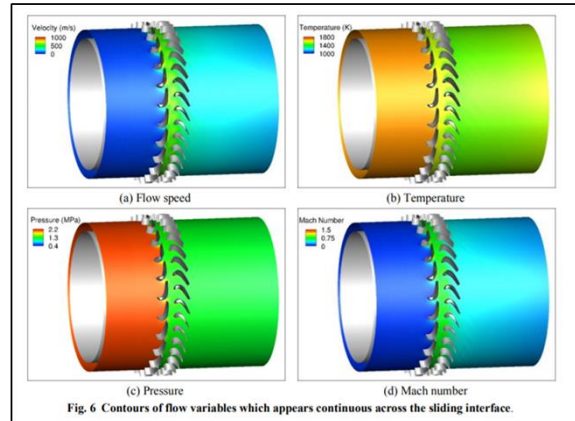
Example Medical Device Multiple Domain Model: From M. Horner, "Closing the Loop in Medical Device Systems Simulation", INCOSE Agile Health Care Systems Conference, May, 2018.



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.



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.

INCOSE Virtual Patient Model

Two-compartment insulin model

$$\frac{dI_{SC}(t)}{dt} = -\frac{1}{\tau_1} \cdot I_{SC}(t) + \frac{1}{\tau_1} \cdot \frac{ID(t)}{C_I} \quad (1)$$

$$\frac{dI_P(t)}{dt} = \frac{1}{\tau_2} \cdot I_P(t) + \frac{1}{\tau_2} \cdot I_{SC}(t) \quad (2)$$

Insulin effectiveness

$$\frac{dI_{EFF}(t)}{dt} = -p_2 \cdot I_{EFF}(t) + p_2 \cdot S_I \cdot I_P(t) \quad (3)$$

Two-compartment glucose model

$$\frac{dG(t)}{dt} = -(GEZI + I_{EFF})G(t) + EGP + R_A(t) \quad (4)$$

$$R_A(t) = \frac{C_{H(t)}}{V_G} \cdot \tau_m^{-1} \cdot e^{-\frac{t}{\tau_m}} \quad (5)$$

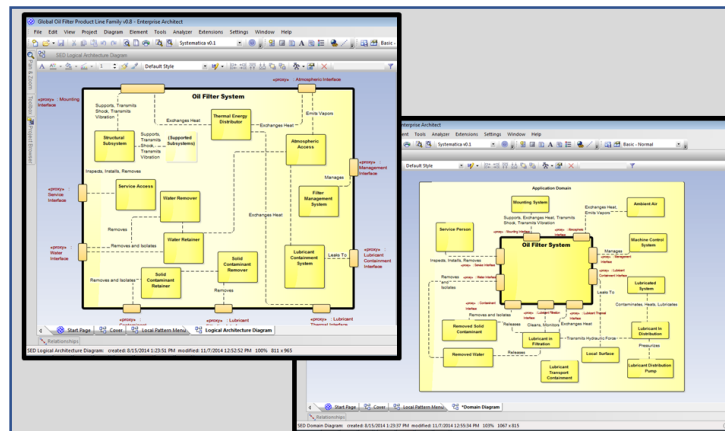
CLINICAL DATA

*Kanderian et al., Identification of Intraday Metabolic Profiles during Closed-Loop Glucose Control in Individuals with Type 1 Diabetes, 1 Diabetes Sci and Tech, Vol. 3 (2009).

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MBSE Model

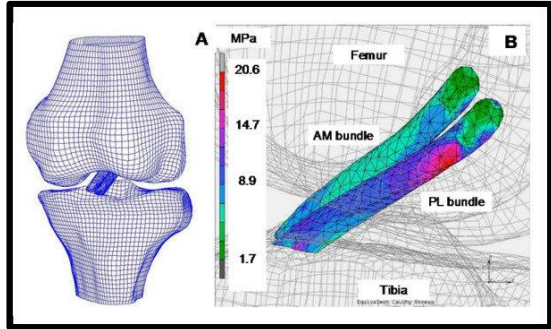
Example System Model: SysML Model of Lubricant Filtration System: Schindel, Lewis, Sherey, Sanyal, "Accelerating MBSE Impacts Across the Enterprise: Model-Based S*Patterns", Proc. of INCOSE International Symposium, 2015.



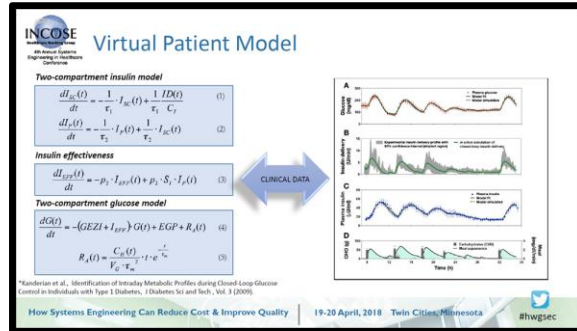
And many others . . .
 . . . system dynamics, . . . discrete events, etc.

Diverse Virtual Models of All Types

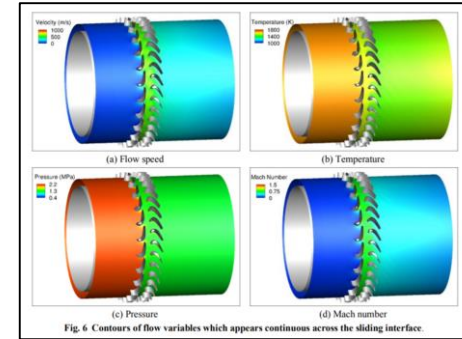
FEA Model



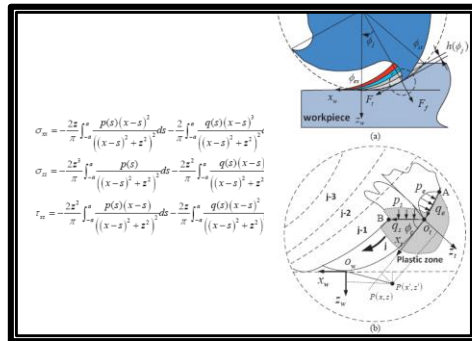
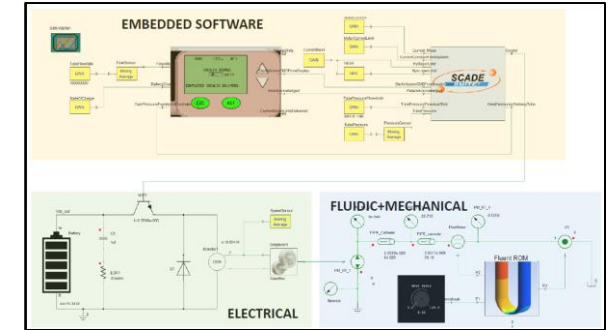
ODE Model



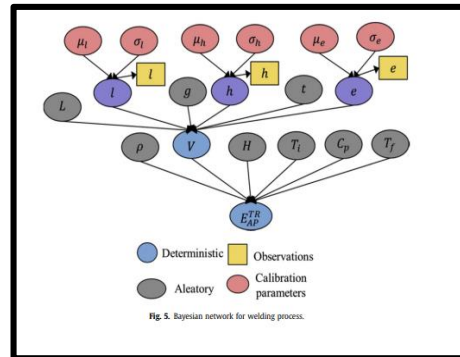
CFD Model



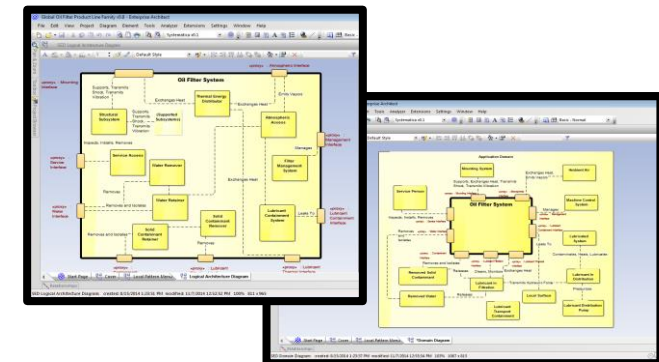
Multi-Domain System Model



Physics-Based PDE Model

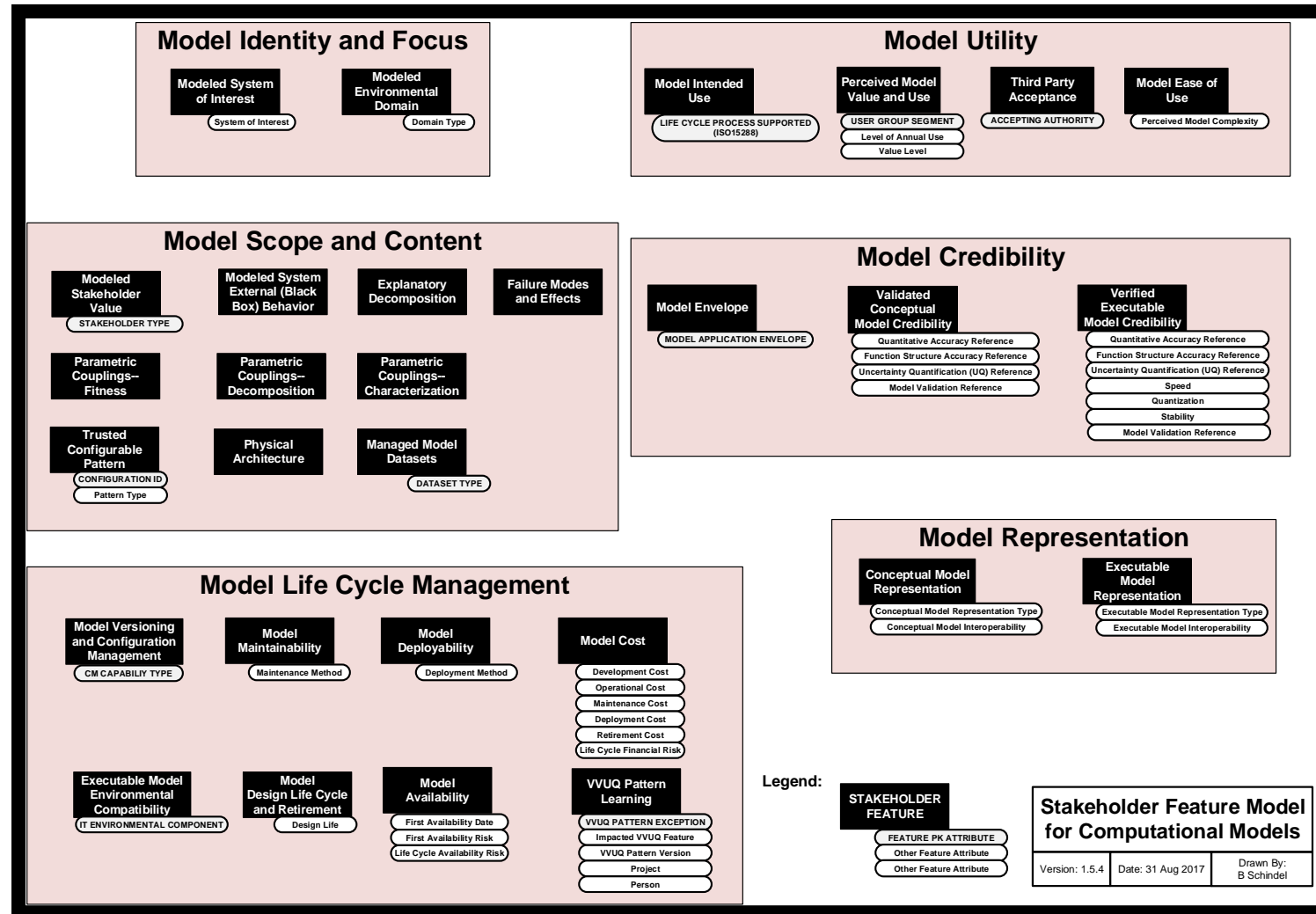


Data-Driven Bayesian Network Model



MBSE Model

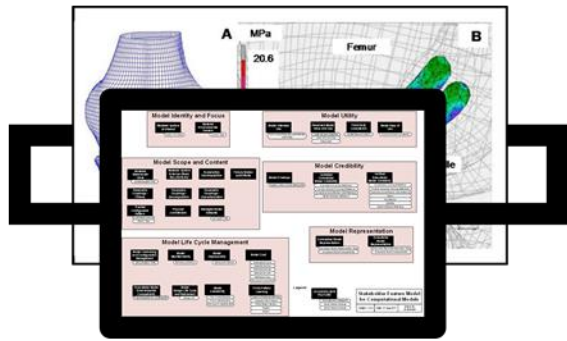
Model VVUQ S* Pattern—Model Metadata “Wrapper” (Configurable Model of the Virtual Models)



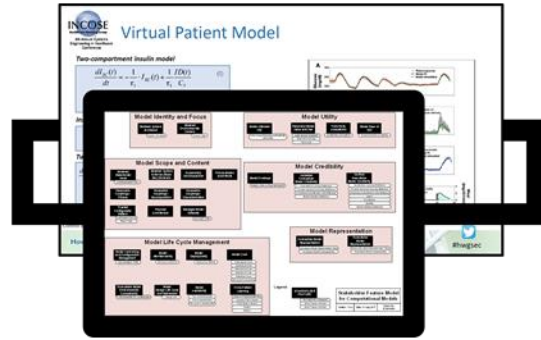
(An S* Pattern, based on S* Metamodel)

Uniform handles/wrappers/metadata for inherently diverse models:

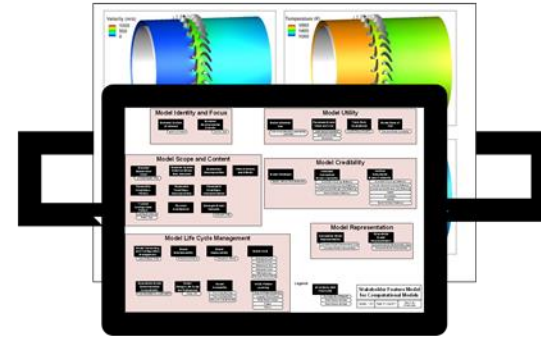
FEA Model



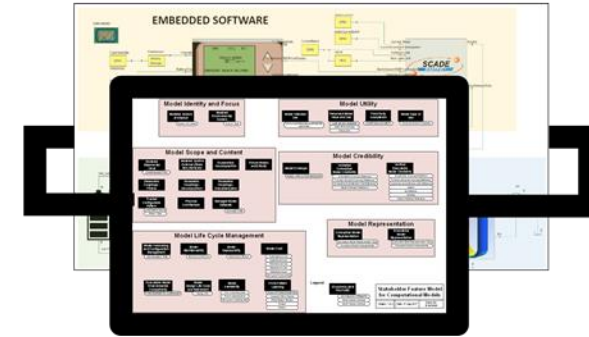
ODE Model



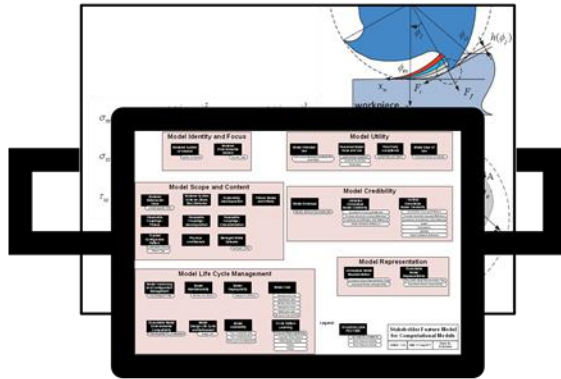
CFD Model



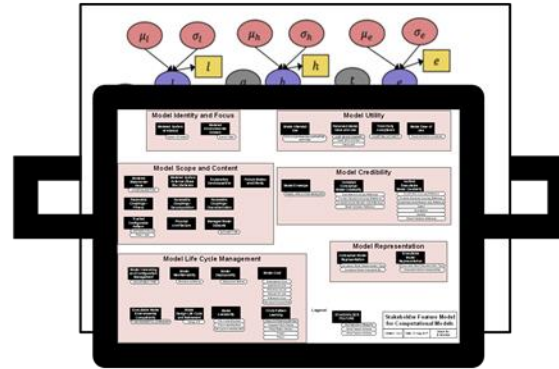
Multi-Domain
System Model



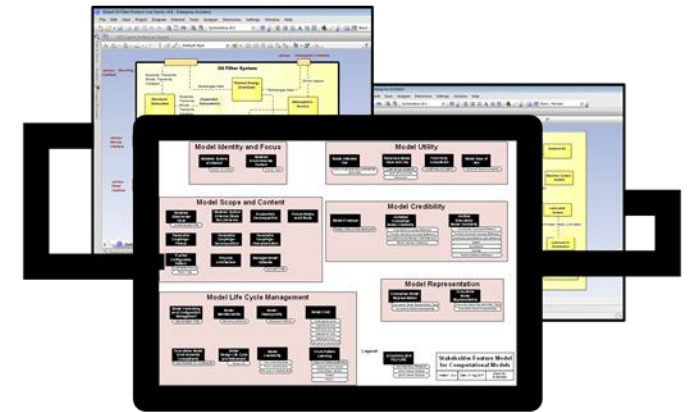
Physics-Based
PDE Model



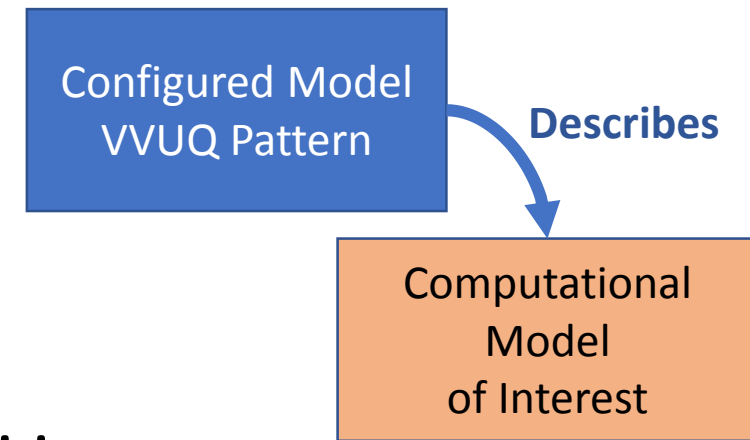
Data-Driven Bayesian
Network Model



MBSE Model

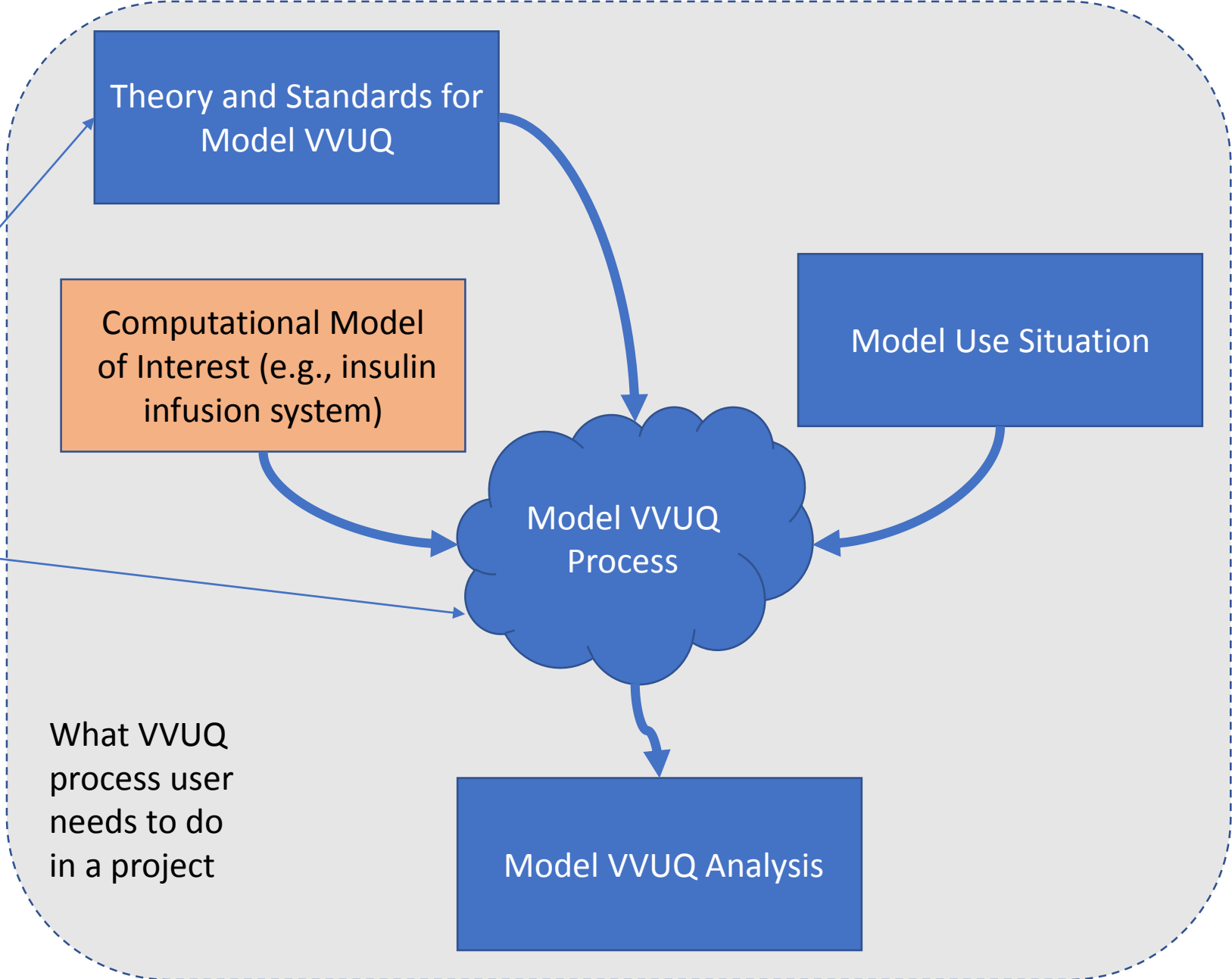


Goals of Applying S* Patterns to Model VVUQ and other Model Life Cycle Issues: Medical Device Example



- “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.

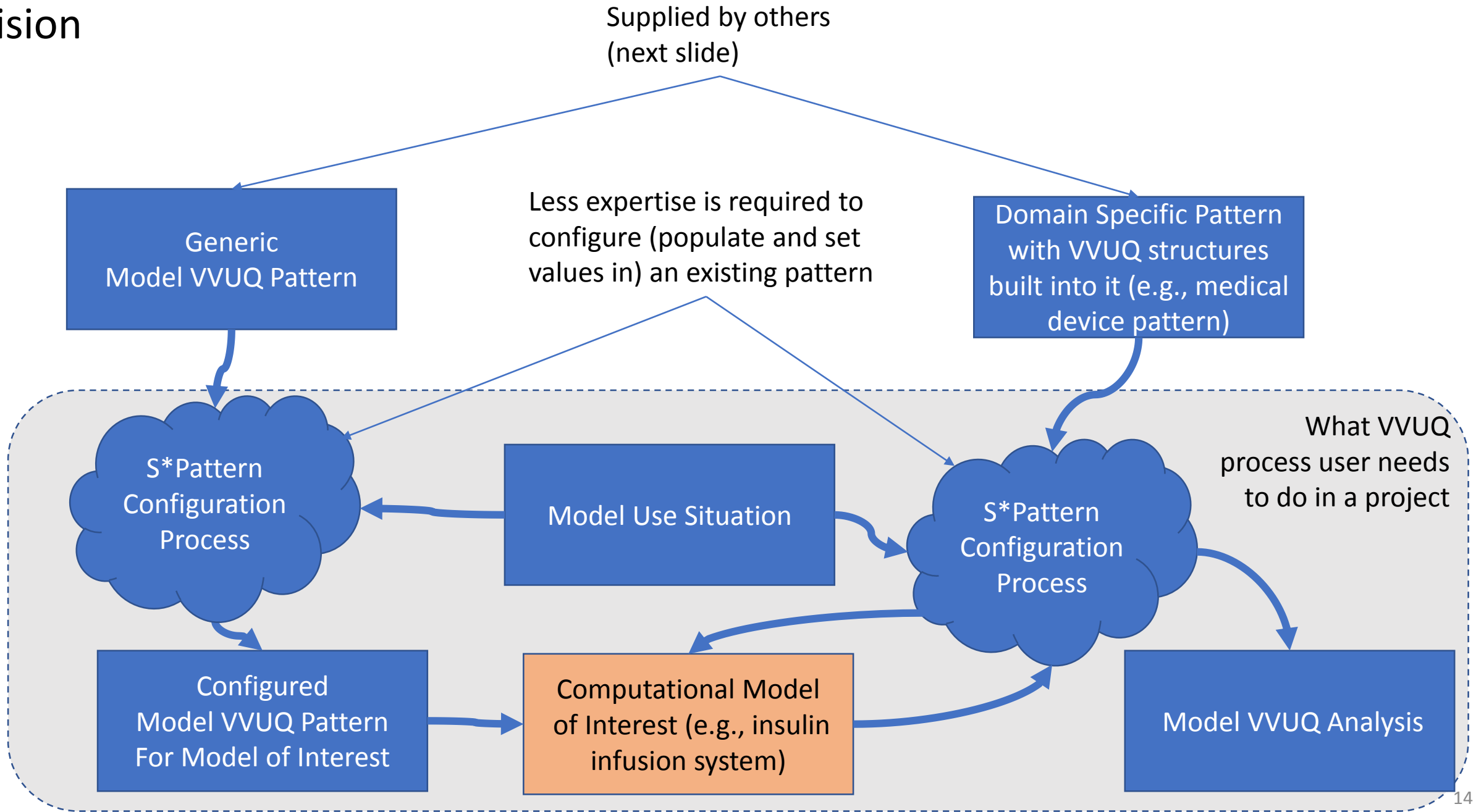
Current Practice

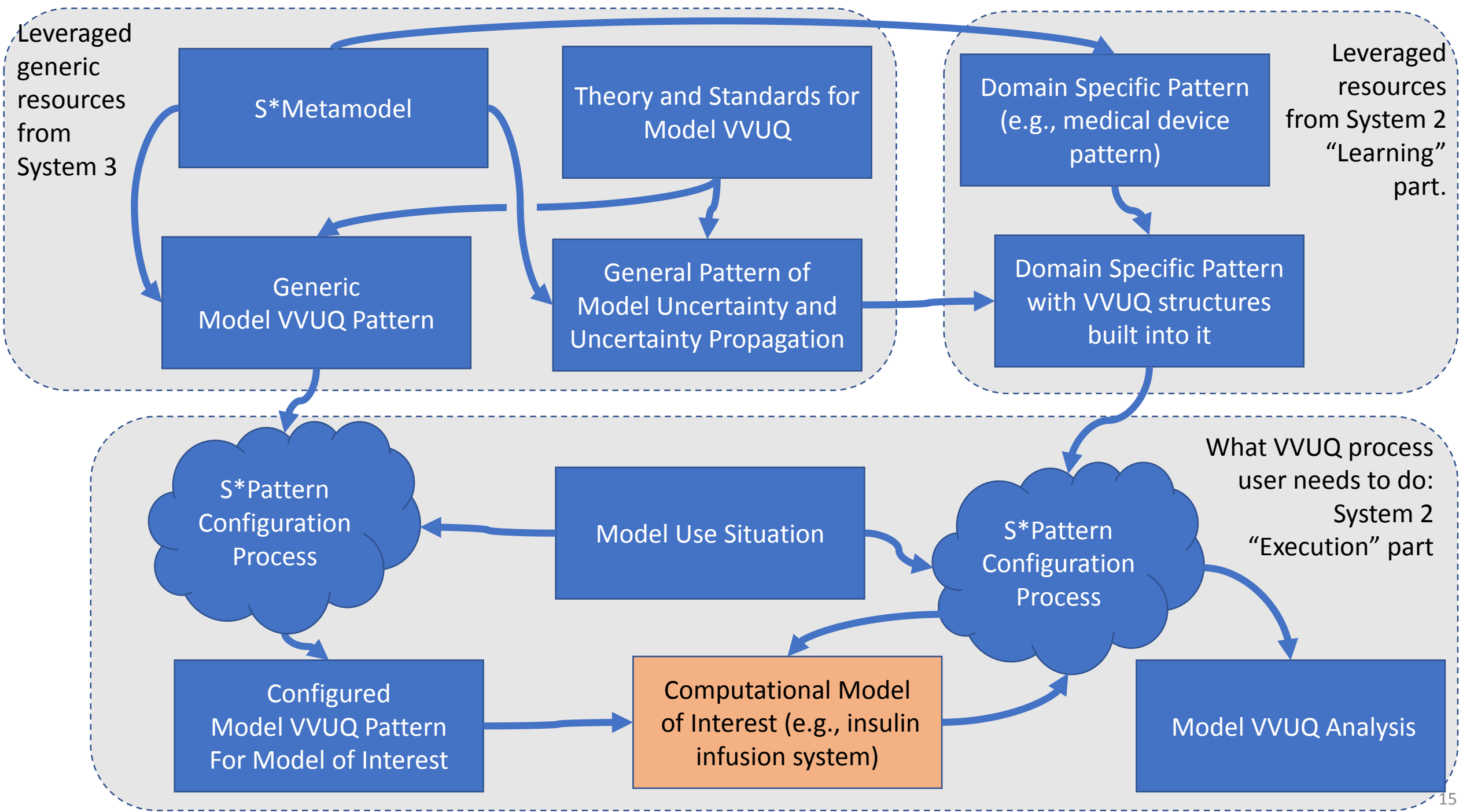


Expertise in these two areas may typically be limited. Practitioner knows more about Model Use Situation and Computational Model of Interest.

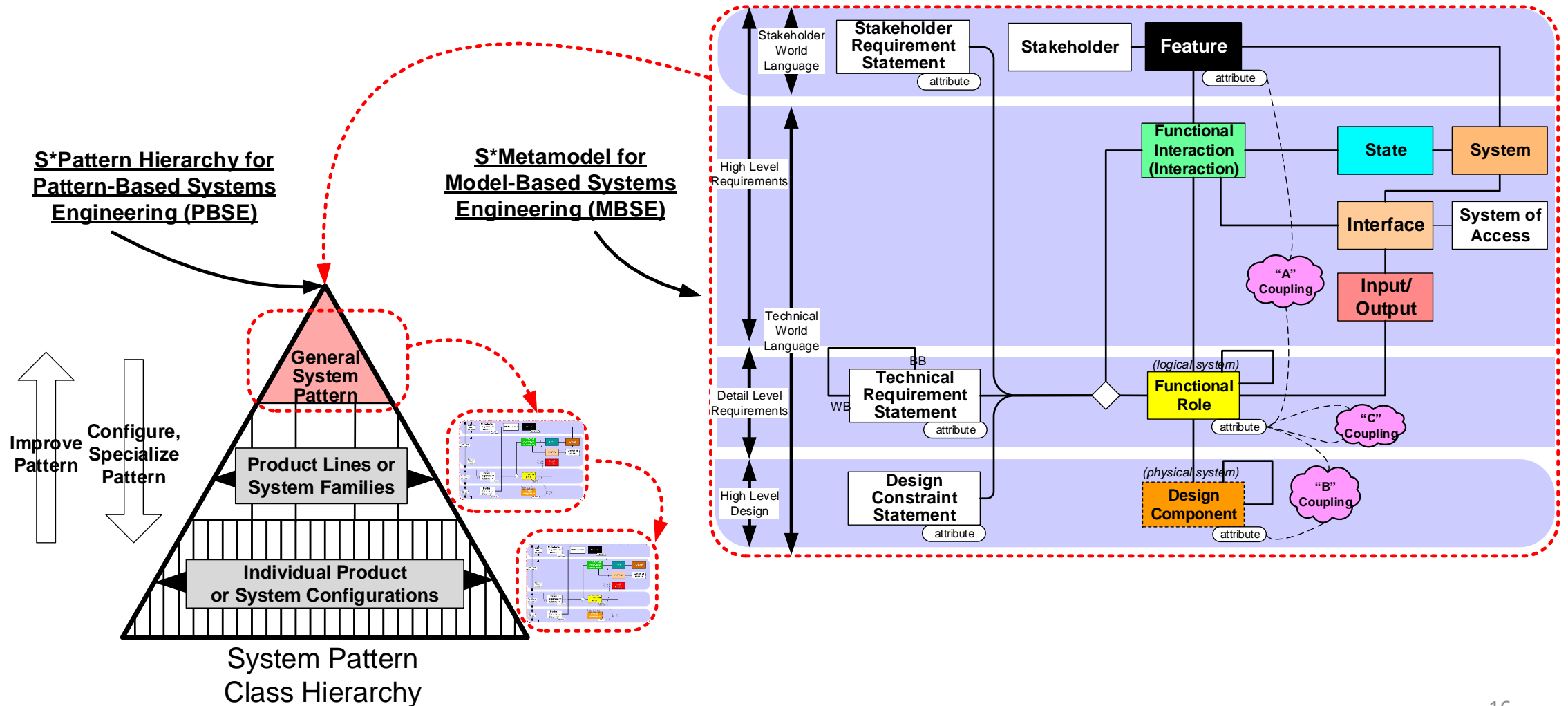
What VVUQ process user needs to do in a project

Vision





S*Metamodel, S*Models and S*Patterns, PBSE, examples



Representing System Patterns: The S* Metamodel Framework

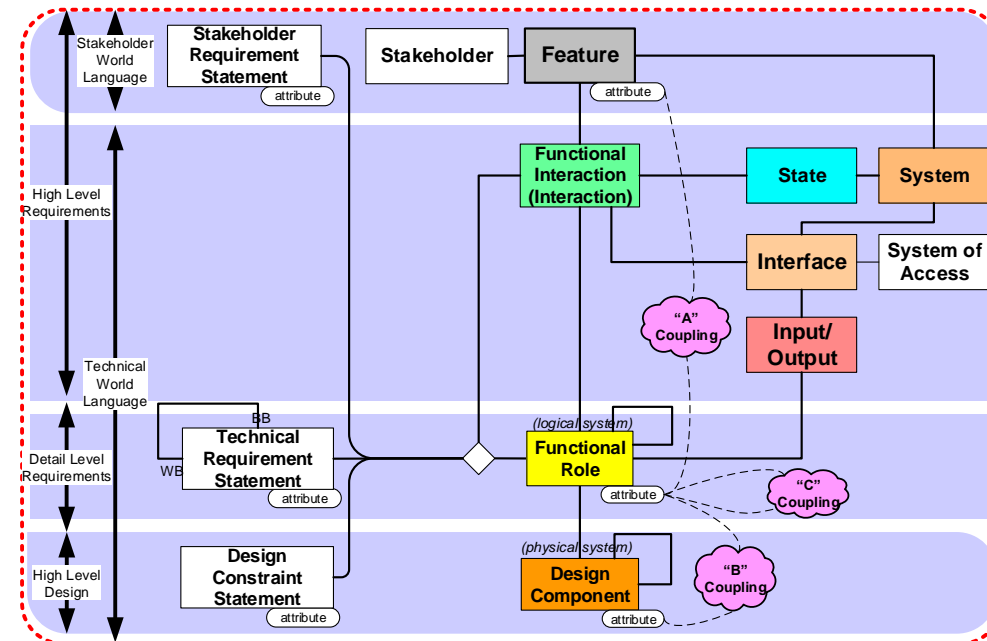
- What is the smallest amount of information we need to represent pattern regularities?
 - Some people have used prose to describe system regularities.
 - This is better than nothing, but usually not enough to deal with the spectrum of issues in complex systems.
- We use S* Models, which are the minimum model-based information necessary:
 - This is not a matter of modeling language—your current favorite language and tools can readily be used for S* Models.
 - The minimum underlying information classes are summarized in the S* Metamodel, for use in any modeling language.
- The resulting system model is made configurable and reusable, thereby becoming an S* Pattern.

Representing System Patterns: The S* Metamodel Framework

- A metamodel is a model of other models;
 - Sets forth how we will represent Requirements, Designs, Verification, Failure Analysis, Trade-offs, etc.;
 - We utilize the (language independent) S* Metamodel from Systematica™ Methodology:

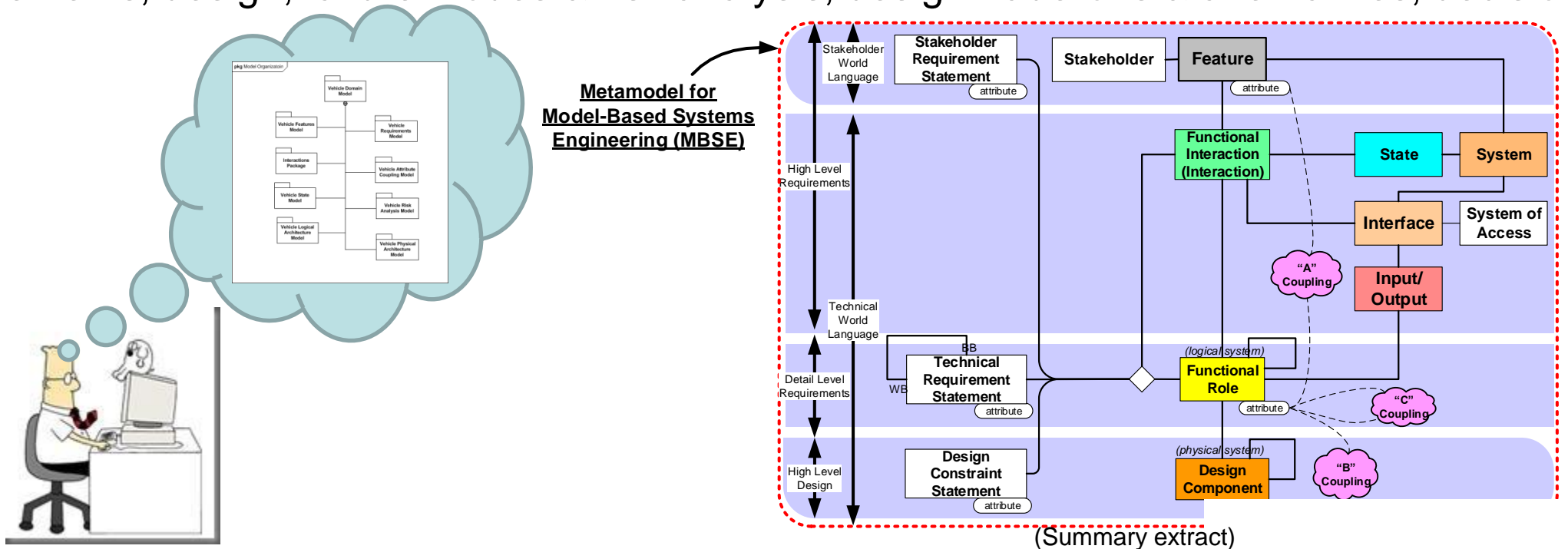
- The resulting system models may be expressed in a wide variety of third party COTS and enterprise information systems, based on S*Metamodel mappings to those environments.
- Has been applied to systems engineering in aerospace, transportation, medical, advanced manufacturing, communication, construction, other domains.

Simple summary of detailed S* Metamodel.



Taking advantage of Model-Based Systems Engineering (MBSE)

- **An S* Model** is any model conforming to the S*Metamodel.
- Typically expressed in the “views” of some modeling language or modeling conventions (e.g., mathematical ODE/PDEs, SysML™, free body diagram, etc.)—can be mapped into any third party COTS tool
- The S* Metamodel: The smallest set of model information sufficient to describe a system for purposes of engineering or science, over the system’s life cycle.
- Includes not only the physical Platform information, but all the extended system information (e.g., requirements, design, failure modes & risk analysis, design trade-offs & alternatives, decisions, etc.):

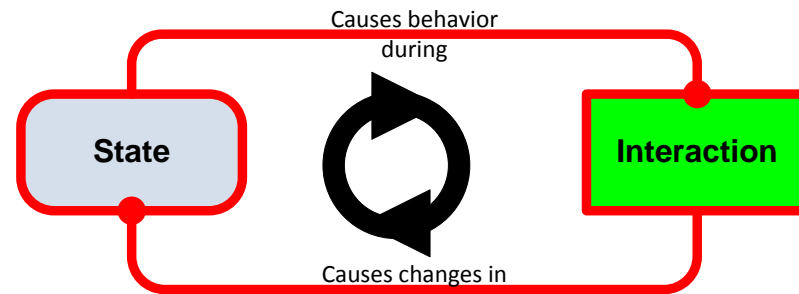
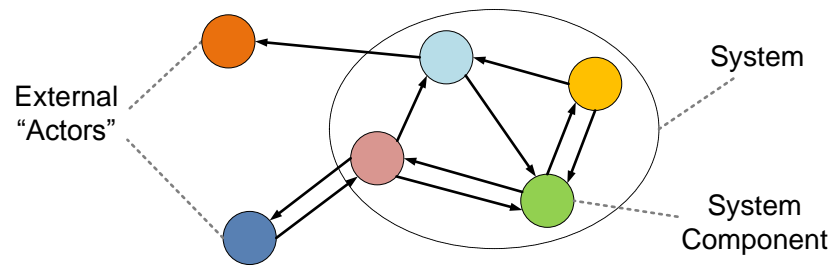


Over two decades of S*Model and S*Patterns practice, experience using S*Metamodel

Medical Devices Patterns	Construction Equipment Patterns	Commercial Vehicle Patterns	Space Tourism Pattern
Manufacturing Process Patterns	Vision System Patterns	Packaging Systems Patterns	Lawnmower Product Line Pattern
Embedded Intelligence Patterns	Systems of Innovation (SOI) Pattern	Consumer Packaged Goods Patterns (Multiple)	Orbital Satellite Pattern
Product Service System Patterns	Product Distribution System Patterns	Plant Operations & Maintenance System Patterns	Oil Filter Pattern
Life Cycle Management System Patterns	Production Material Handling Patterns	Engine Controls Patterns	Military Radio Systems Pattern
Agile Systems Engineering Life Cycle Pattern	Transmission Systems Pattern	Precision Parts Production, Sales, and Engineering Pattern	Higher Education Experiential Pattern

The System Phenomenon

- In the perspective described here, by system we mean a collection of interacting components:

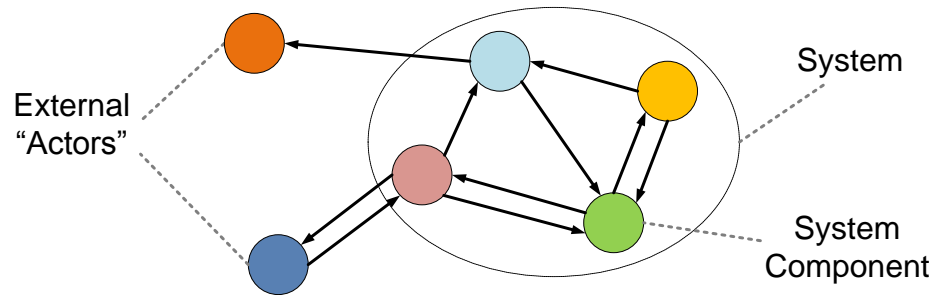


- Where interaction involves the exchange of energy, force, mass, or information, . . .
- Through which one component impacts the state of another component, . . .
- And in which the state of a component impacts its behavior in future interactions.

The System Phenomenon

- Phenomena of the hard sciences are in each case instances of the following “System Phenomenon”:
 - *behavior emergent from the interaction of behaviors (phenomena themselves) a level of decomposition lower.*
- In each such case, the emergent interaction-based behavior of the larger system is a stationary path of the action integral:

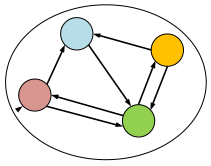
$$\mathcal{S} = \int_{t_1}^{t_2} L(x, \dot{x}, t) dt$$



- Reduced to simplest forms, the resulting equations of motion (or if not solvable, empirically observed paths) provide “physical laws” subject to scientific verification.

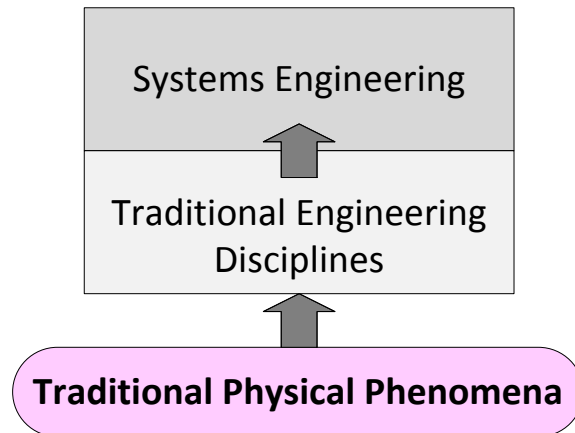


(Hamilton's Principle)

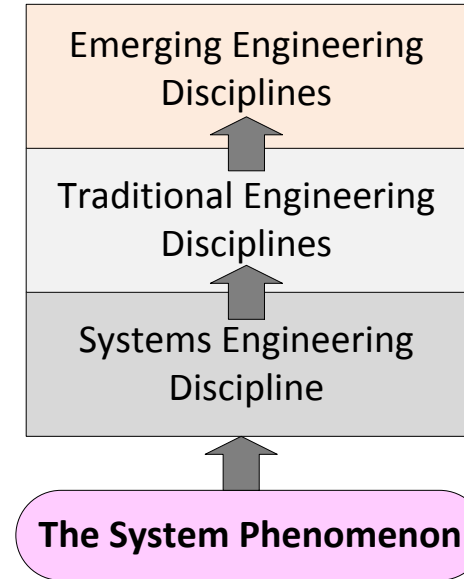


The System Phenomenon

A traditional view:



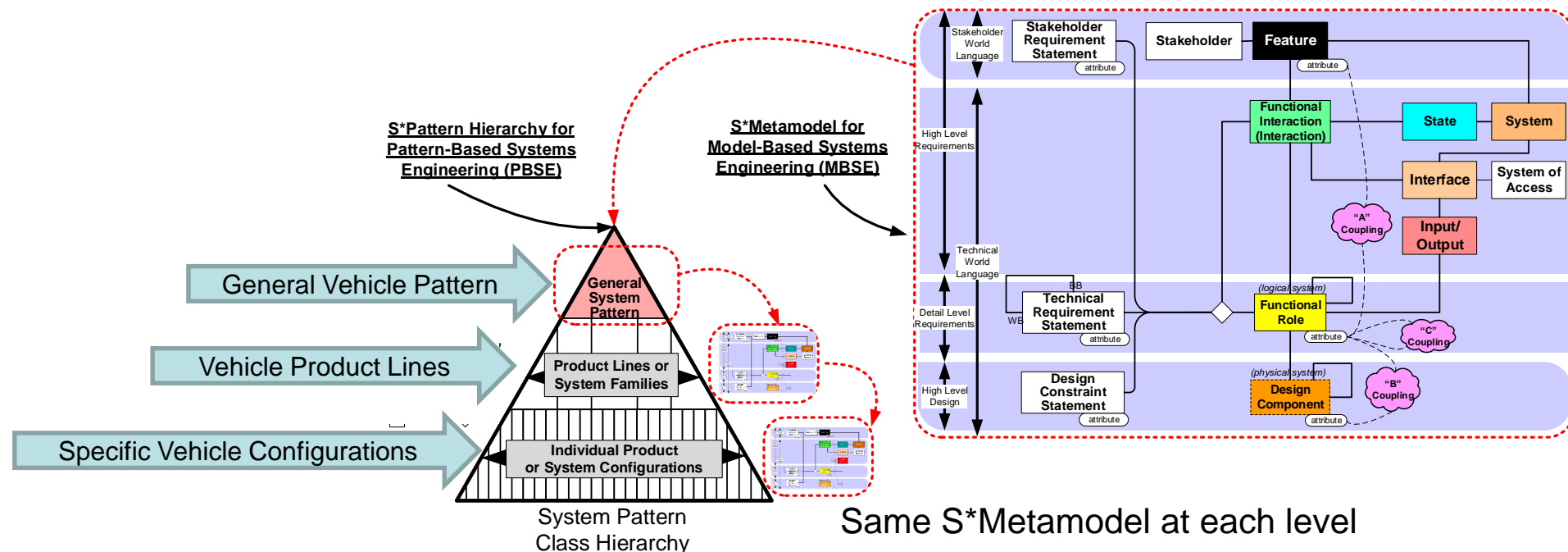
Our view:



- It is not Systems Engineering that lacks its own phenomenological foundation—instead, the System Phenomenon has been providing the foundation for all the other disciplines all alone!

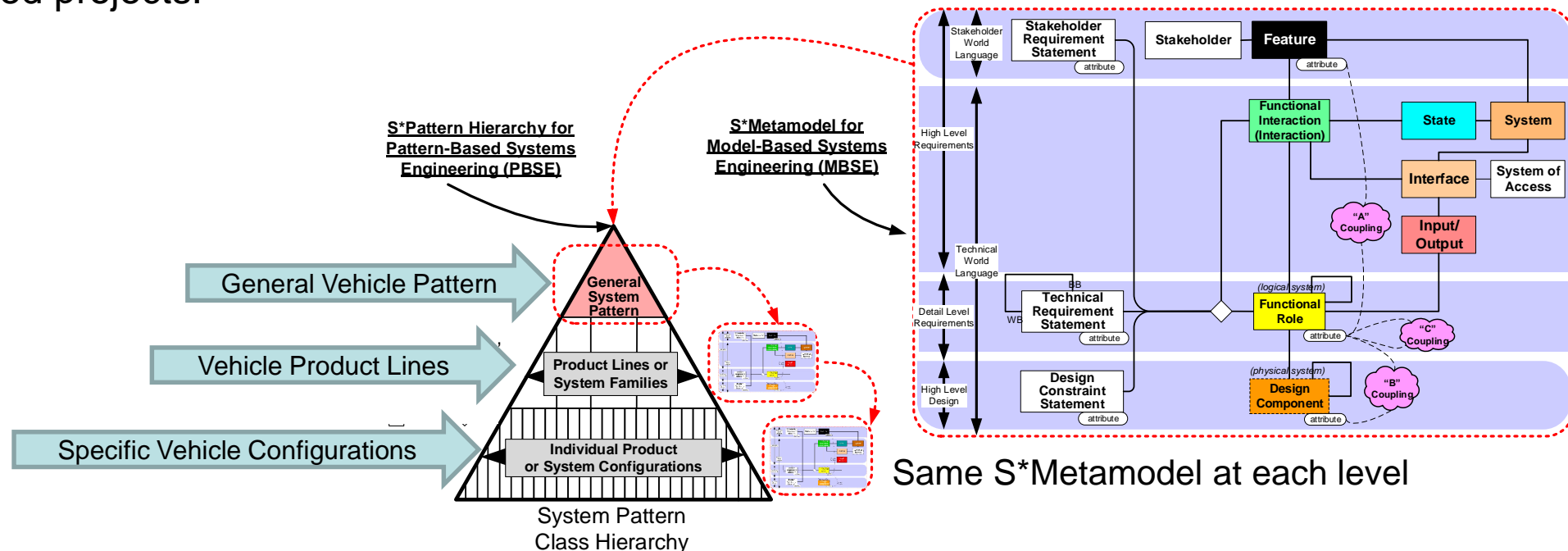
Extending the Concept to Patterns, and Pattern-Based Systems Engineering (PBSE)

- An **S* Pattern** is a configurable, re-usable S* Model. It is an extension of the idea of a Platform (which is a configurable, re-usable design) or Enterprise / Industry Framework.
- The Pattern includes not only the physical Platform information, but all the extended system information (e.g., requirements, design, failure modes & risk analysis, design trade-offs & alternatives, decisions, etc.):



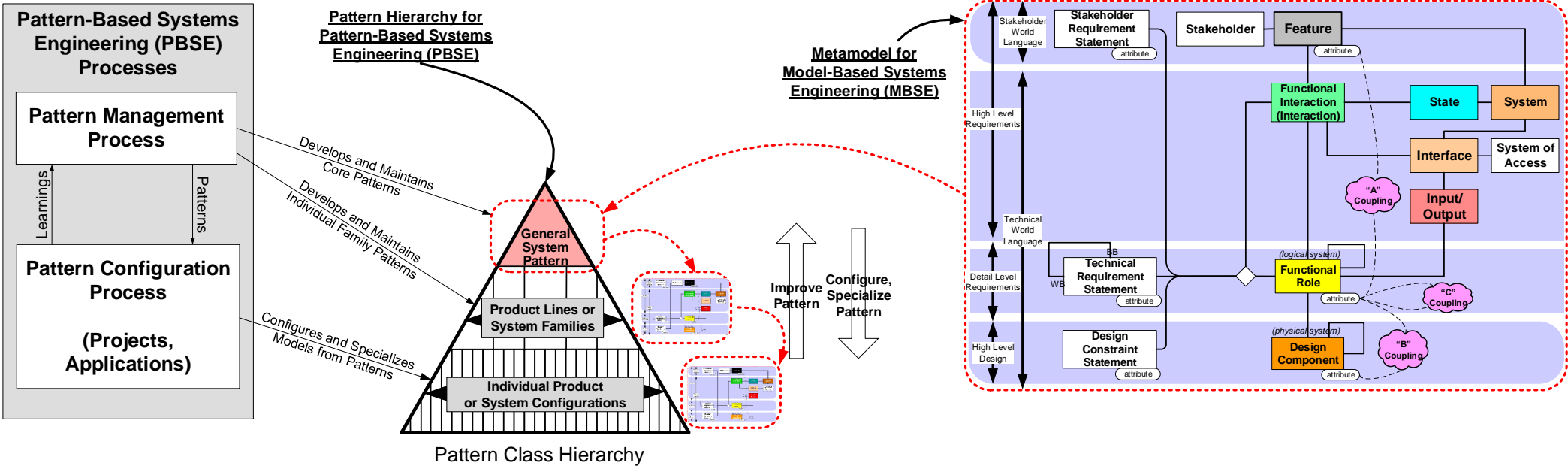
Concept Summary: Pattern-Based Systems Engineering (PBSE)

- By including the appropriate S* Metamodel concepts, these can readily be managed in preferred modeling languages and tools—the ideas involved here are not specific to a modeling language or specific tool.
- The order-of-magnitude changes have been realized because projects that use PBSE rapidly start from an existing Pattern, gaining the advantages of its content, and feed the pattern with what they learn, for future users.
- The “game changer” here is the shift from “learning to model” to “learning the model”, freeing many people to rapidly configure, specialize, and apply patterns to deliver value in their model-based projects.



Concept Summary: Pattern-Based Systems Engineering (PBSE)

- PBSE provides a specific technical method for implementing:
 - Platform Management and Product Line Engineering (PLE)
 - Enterprise or Industry Frameworks
 - System Standards
 - Trusted Experience Accumulation for Systems of Innovation
 - Lean Product Development & IP Asset Re-use



S*Models and S*Patterns: Examples

- See Attachment 1 for extracts from examples of S*Models and S*Patterns
- Farther below, we will also discuss Attachment 2 for extracts from example of Medical Device Pattern

Definitions of Some S* Metamodel Classes

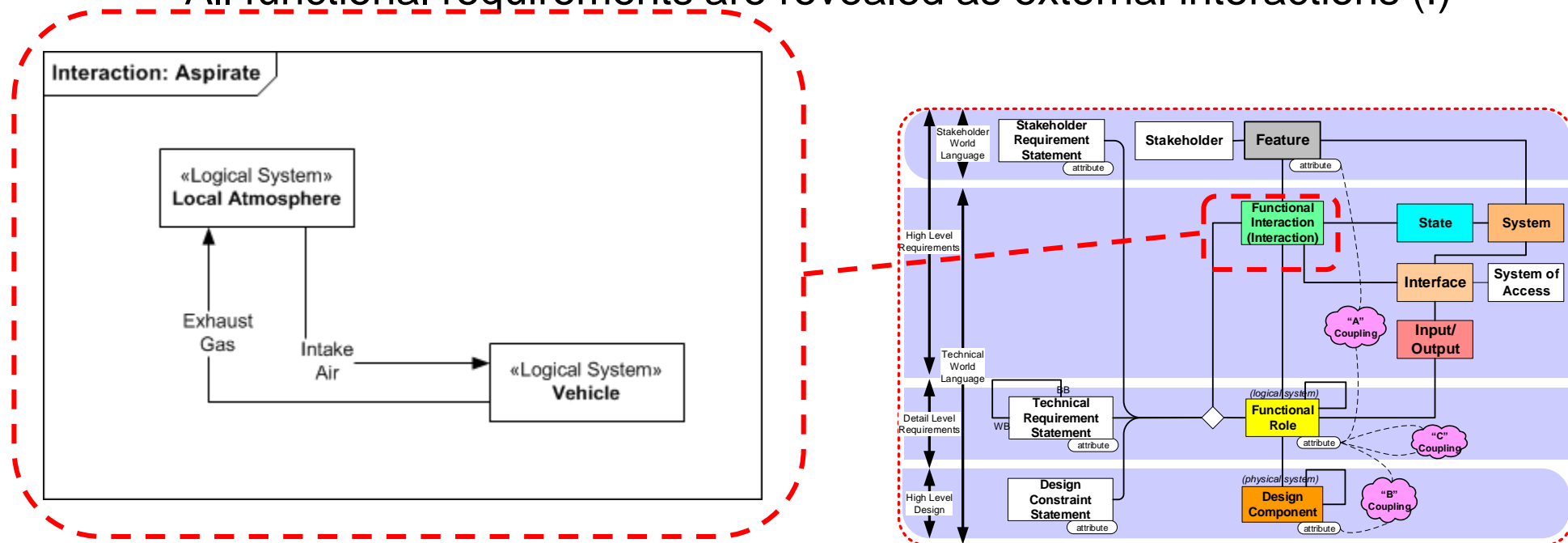
- **System**: A collection of interacting components. Example: Medical Device; Hospital Domain, Health Care Delivery System Domain.
- **Stakeholder**: A person or other entity with something at stake in the life cycle of a system. Example: Patient; Health Care Provider; Enterprise Shareholder
- **Feature**: A behavior of a system that carries stakeholder value. Example: Automatic Infusion Feature; Patient Safety Features; Device Connectivity Features
- **Functional Interaction (Interaction)**: An exchange of energy, force, mass, or information by two entities, in which one changes the state of the other. Example: Deliver Infusion; Transmit Shock and Vibration
- **Functional Role (Role)**: The behavior performed by one of the interacting entities during an Interaction; identified only by its externally visible behavior during interaction. Example: Patient; Device Operator; Injectable Storage Subsystem
- **Input-Output**: That which is exchanged during an interaction (generally associated with energy, force, material, or information). Example: Injected Material, Pressure, Status Signal

Definitions of some S* Metamodel Classes

- **System of Access**: A system which provides the means for physical interaction between two interacting entities. Examples: Control Button; Status Indicator; Temperature Sensor; Drive Actuator; Catheter; Tube Fitting; Beeper
- **Interface**: The association of a System (which “has” the interface), one or more Interactions (which describe behavior at the interface), the Input-Outputs (which pass through the interface), and a System of Access (which provides the means of the interaction). Examples: Injection Interface; Device Control Interface
- **State**: A mode, situation, or condition that describes a System’s condition at some moment or period of time. Example: Device Off; Starting Up; Loading; Performing Injection; Diagnosing Failure; Shutting Down
- **Design Component**: A physical entity that has identity, whose behavior is described by Functional Role(s) allocated to it. Examples: 316 L Stainless Steel; Sodium Chloride; Model 300 Infusion Pump; Department 516 Laboratory
- **Requirement Statement**: A (usually prose) description of the behavior expected of (at least part of) a Functional Role. Example: “The System shall complete any injection cycle within 2 seconds.”

Physical Interactions: At the heart of S* models

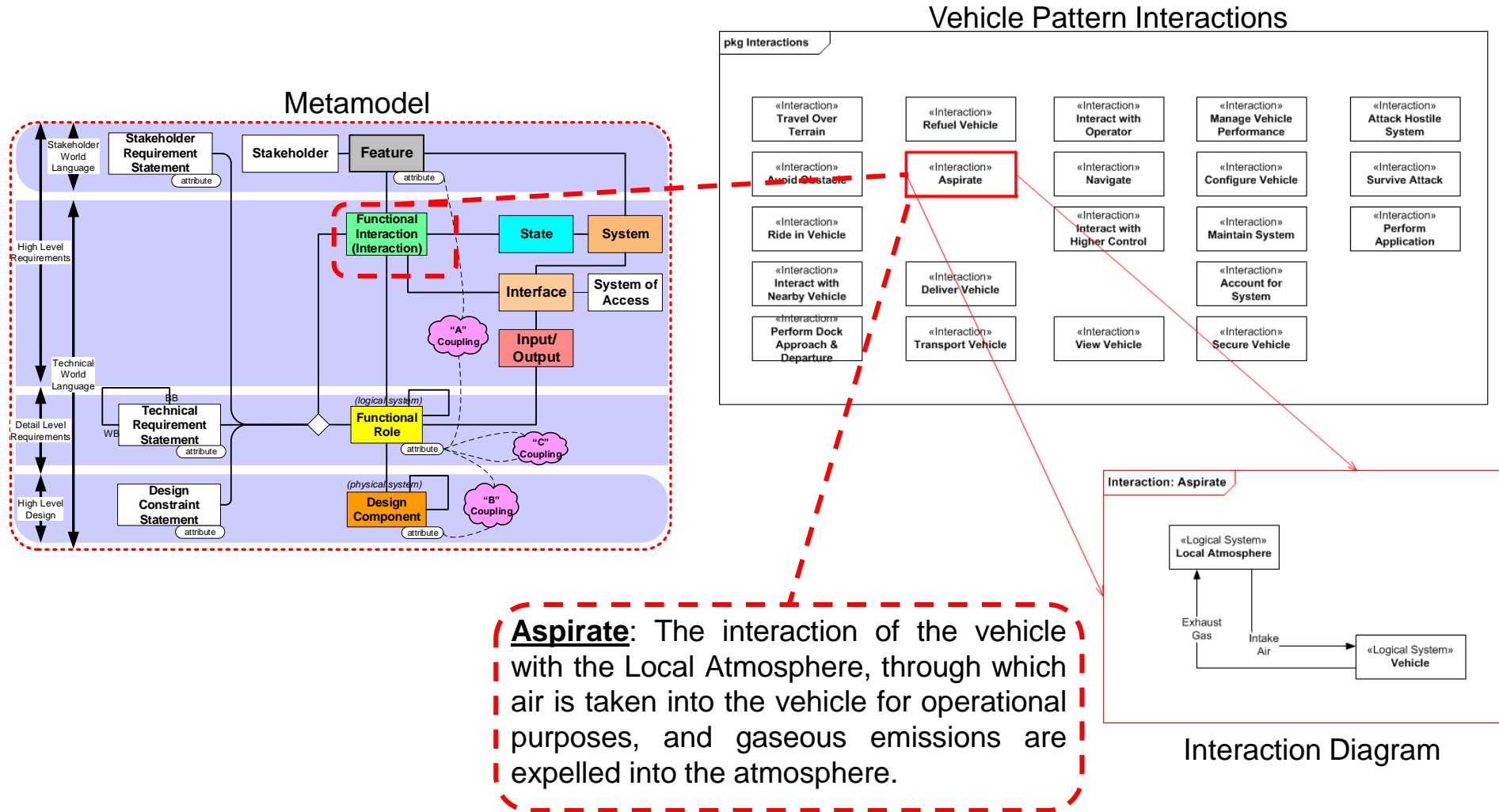
- S* models represent Interactions as explicit objects:
 - Goes to the heart of 300 years of natural science of systems as a foundation for engineering, including emergence.
 - All physical laws of science are about interactions in some way.
 - All functional requirements are revealed as external interactions (!)



- See Attachments 1 and 2 for other example Interactions

Physical Interactions: At the heart of S* models

- S* models represent Physical Interactions as explicit objects:



- See Attachments 1 and 2 for other example Interactions

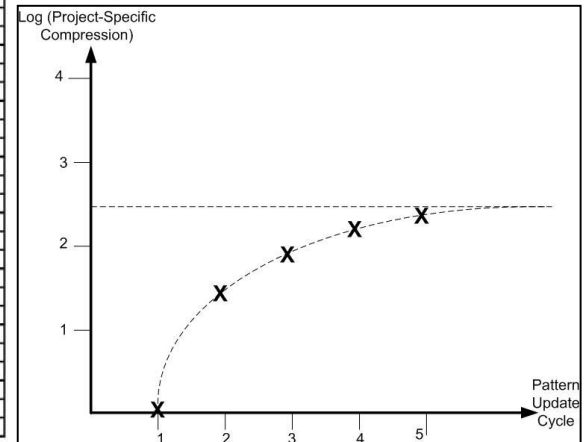
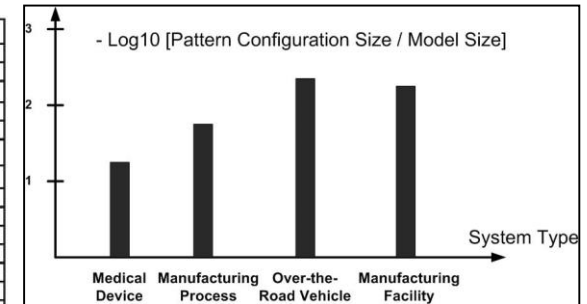
Pattern-based systems engineering (PBSE)

- Model-based Patterns:
 - In this approach, Patterns are reusable, configurable S* models of families (product lines, sets, ensembles) of systems.
 - A Pattern is not just the physical product family—it includes its behavior, decomposition structure, failure modes, and other aspects of its model.
- These Patterns are ready to be configured to serve as Models of individual systems in projects.
- Configured here is specifically limited to mean that:
 - Pattern model components are populated / de-populated, and
 - Pattern model attribute (parameter) values are set
 - both based on Configuration Rules that are part of the Pattern.
- S*Patterns based on the same S*Metamodel as S*Models.

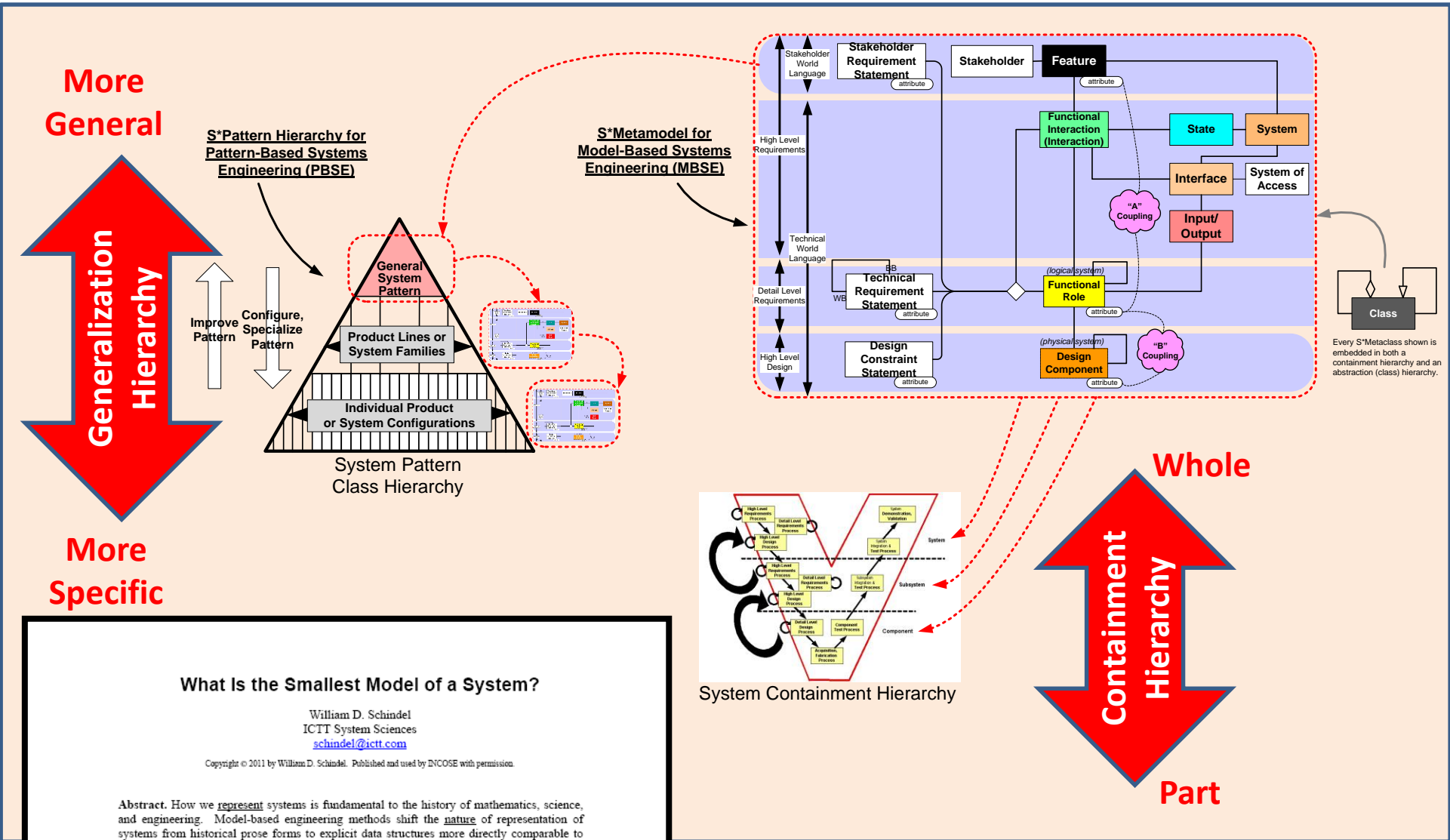
Pattern configurations

- A table of configurations illustrates how patterns facilitate compression;
- Each column in the table is a compressed system representation with respect to (“modulo”) the pattern;
- The compression is typically very large;
- The compression ratio tells us how much of the pattern is variable and how much fixed, across the family of potential configurations.

Lawnmower Product Line: Configurations Table									
		Units	Walk-Behind Push Mower	Walk-Behind Mower	Walk-Behind Self-Propelled	Riding Rider	Riding Tractor	Riding Mower Tractor	Autonomous Autonomous
			M3	M5	M11	M17	M19	M23	M100
			Sm Resident	Med Resident	Med Resident	Lg Resident	Lg Resident	Home Garden	High End Suburban
Power	Engine Manufacturer		B&S	B&S	Tecumseh	Tecumseh	Kohler	Kohler	Elektroset
	Horsepower	HP	5	6.5	13	16	18.5	22	0.5
Production	Cutting Width	Inches	17	19	36	36	42	48	16
	Maximum Mowing Speed	MPH	3	3	4	8	10	12	2.5
	Maximum Mowing Productivity	Acres/Hr			1.6				
	Turning Radius	Inches	0	0	0	0	126	165	0
	Fuel Tank Capacity	Hours	1.5	1.7	2.5	2.8	3.2	3.5	2
	Towing Feature						x	x	
	Electric Starter Feature				x	x	x	x	
	Basic Mowing Feature Group		x	x	x	x	x	x	x
Mower	No. of Anti-Scalping Rollers		0	0	1	2	4	6	0
	Cutting Height Minimum	Inches	1	1.5	1.5	1.5	1	1.5	1.2
	Cutting Height Maximum	Inches	4	5	5	6	8	10	3.8
	Operator Riding Feature					x	x	x	
	Grass Bagging Feature		Optional	Optional	Optional	Optional	Optional	Optional	
	Mulching Feature		Standard	Factory Installed	Dealer Installed				
	Aerator Feature					Optional	Optional	Optional	
	Autonomous Mowing Feature								x
	Dethatching Feature					Optional	Optional	Optional	
Physical	Wheel Base	Inches	18	20	22	40	48	52	16
	Overall Length	Inches	18	20	23	58	56	68	28.3
	Overall Height	Inches	40	42	42	30	32	36	10.3
	Width	Inches	18	20	22	40	48	52	23.6
	Weight	Pounds	120	160	300	680	705	1020	15.6
	Self-Propelled Mowing Feature			x	x	x	x	x	x
	Automatic TransmFeature							x	
Financials	Retail Price	Dollars	360	460	1800	3300	6100	9990	1799
	Manufacturer Cost	Dollars	120	140	550	950	1800	3500	310
Maintenance	Warranty	Months	12	12	18	24	24	24	12
	Product Service Life	Hours	500	500	600	1100	1350	1500	300
	Time Between Service	Hours	100	100	150	200	200	250	100
Safety	Spark Arrest Feature		x	x	x	x	x	x	



Two entirely different hierarchies are involved:



What Is the Smallest Model of a System?

William D. Schindel
 ICTT System Sciences
schindel@icct.com

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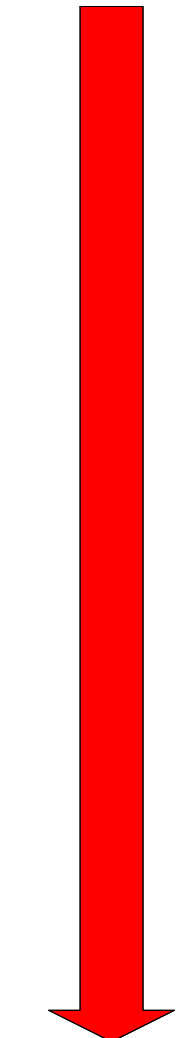
Abstract. How we represent systems is fundamental to the history of mathematics, science, and engineering. Model-based engineering methods shift the nature of representation of systems from historical prose forms to explicit data structures more directly comparable to those of science and mathematics. However, using models does not guarantee simpler representation--indeed a typical fear voiced about models is that they may be too complex.

Minimality of system representations is of both theoretical and practical interest. The mathematical and scientific interest is that the size of a system's "minimal representation" is one definition of its complexity. The practical engineering interest is that the size and redundancy of engineering specifications challenge the effectiveness of systems engineering processes. INCOSE thought leaders have asked how systems work can be made 10:1 simpler to attract a 10:1 larger global community of practitioners. And so, we ask: What is the smallest model of a system?

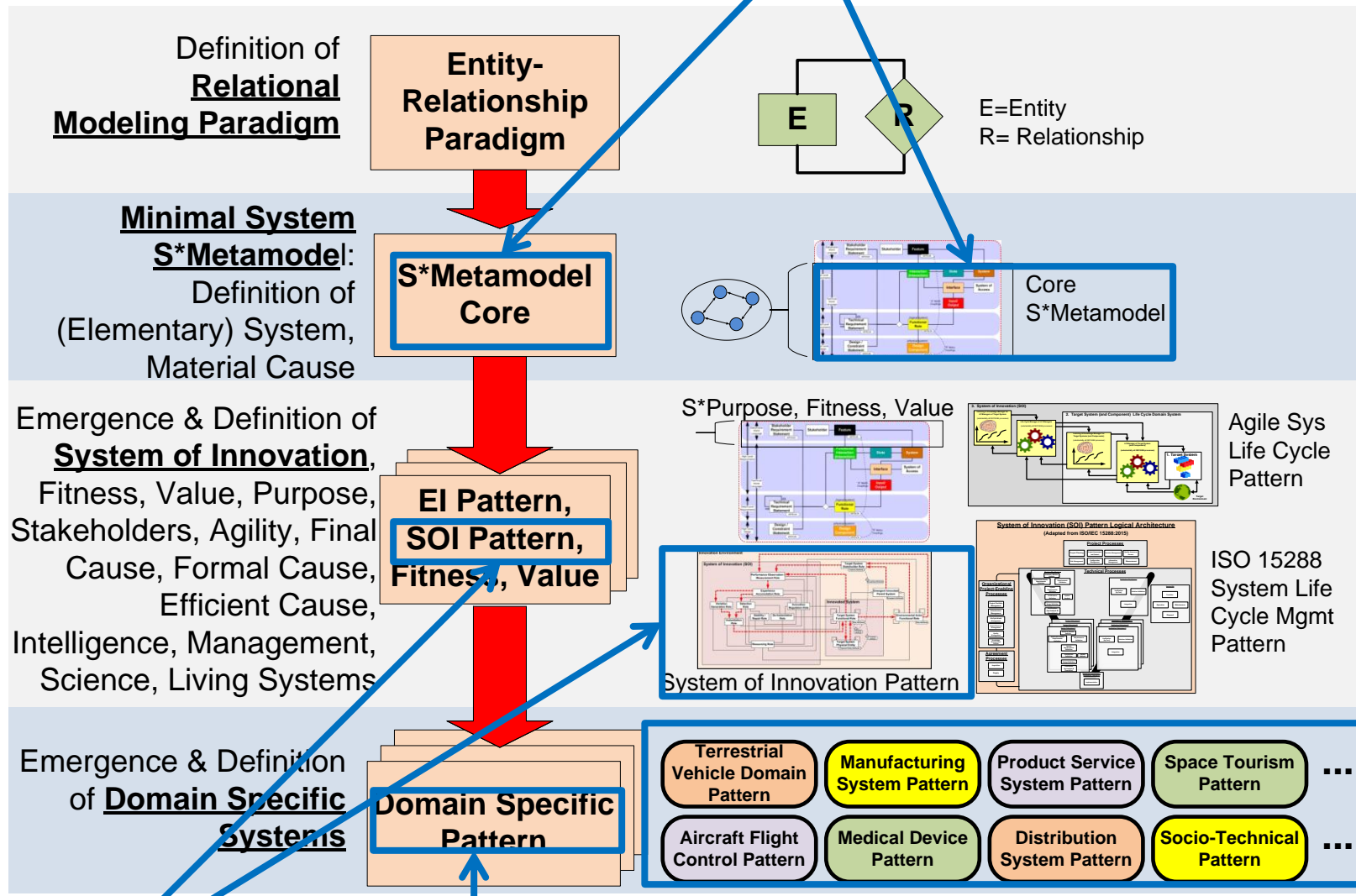
Universal systems nomenclature, domain-independent.

Emergence of Patterns from Patterns: S*Pattern Class Hierarchy

More General



More Specific



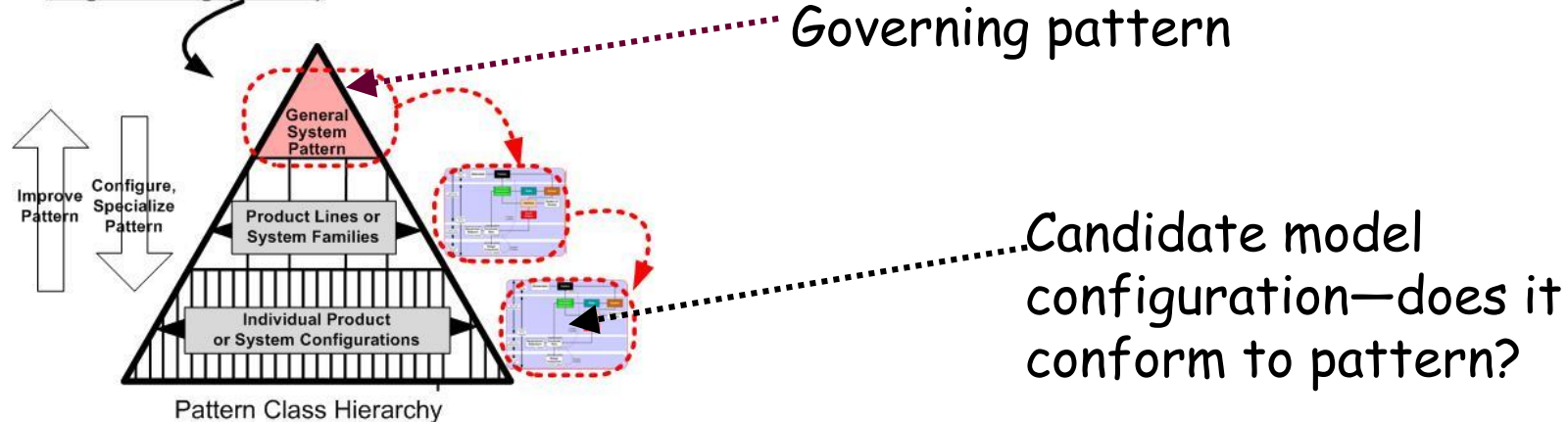
Domain-specific languages, frameworks, ontologies.

Generator of “new systems”; also maintainer, destroyer

Checking holistic alignment to a pattern

- Gestalt Rules express what is meant by holistic conformance to a system pattern:
 - Expressing regularities of whole combination of things, versus same “parts”
 - Putting car parts together does not guarantee that you will get a car!

Pattern-Based Systems Engineering (PBSE)

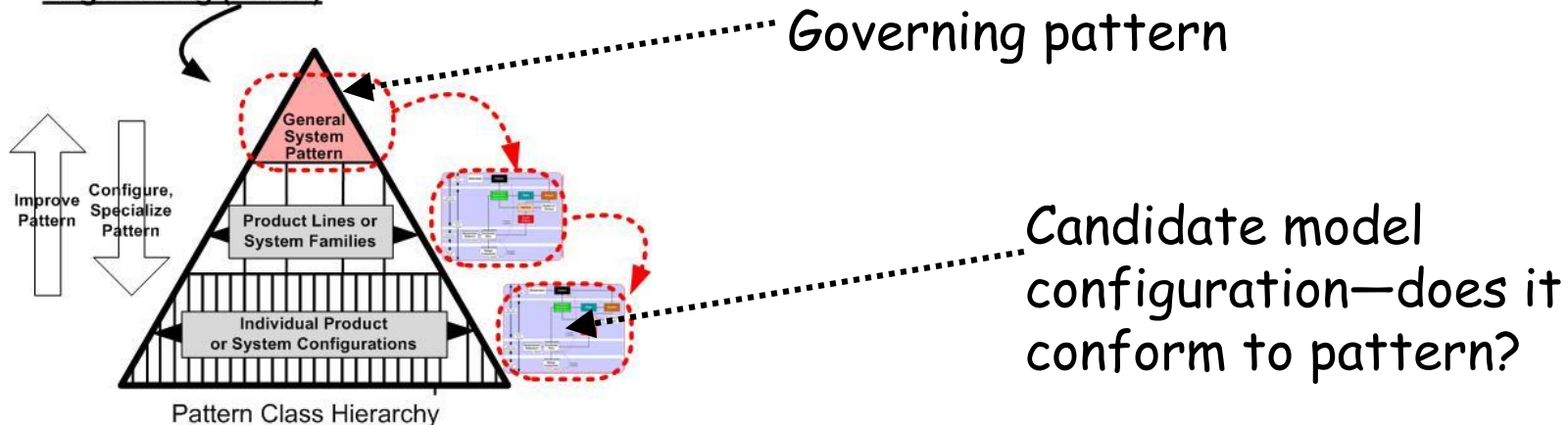




The Gestalt Rules

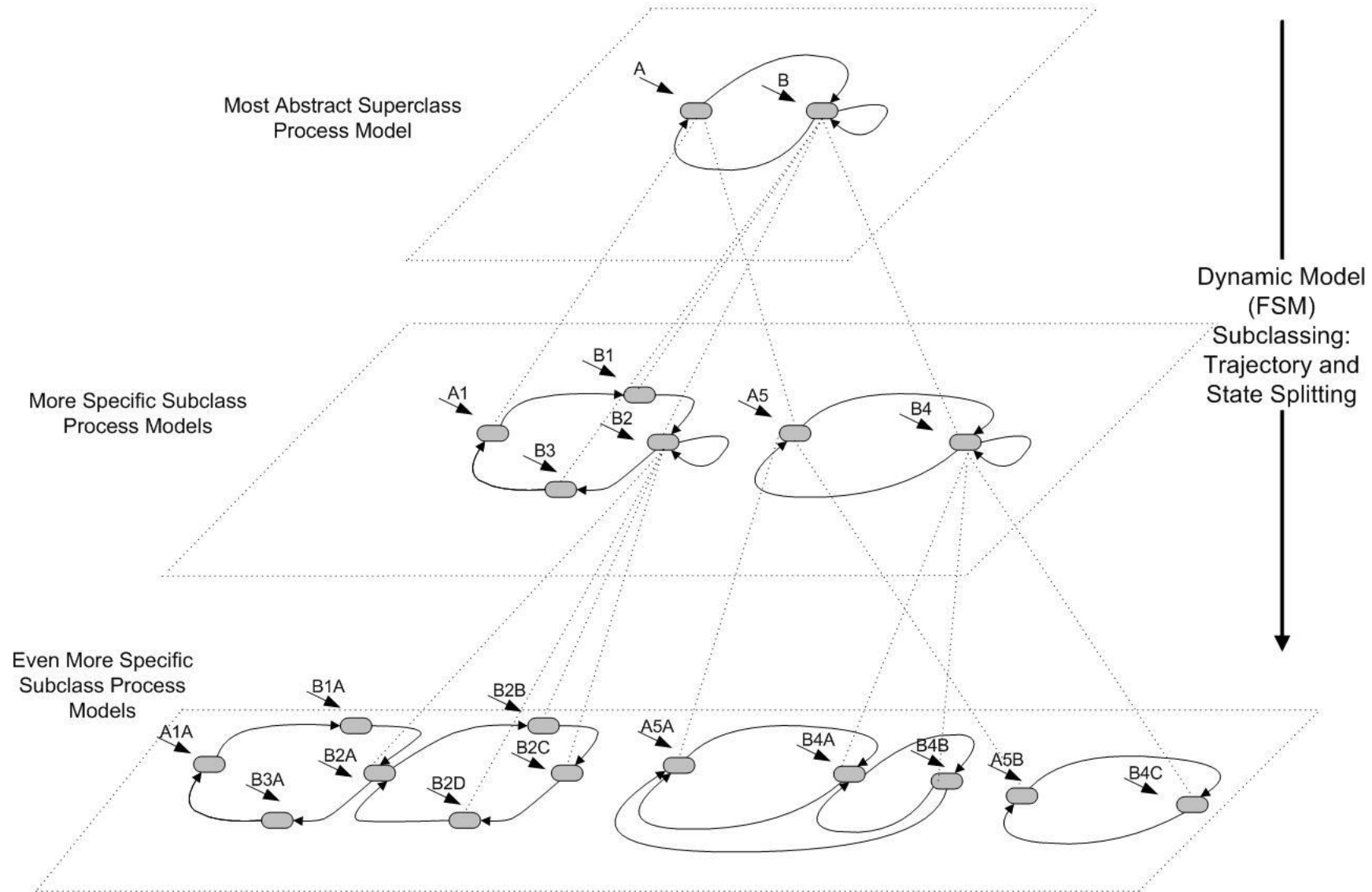
1. Every component class in the candidate model must be a subclass of a parent superclass in the pattern—no “orphan classes”.
2. Every relationship between component classes must be a subclass of a parent relationship in the pattern, and which must relate parent superclasses of those same component classes—no “orphan relationships”.
3. Refining the pattern superclasses and their relationships is a permissible way to achieve conformance to (1) and (2).

Pattern-Based Systems Engineering (PBSE)

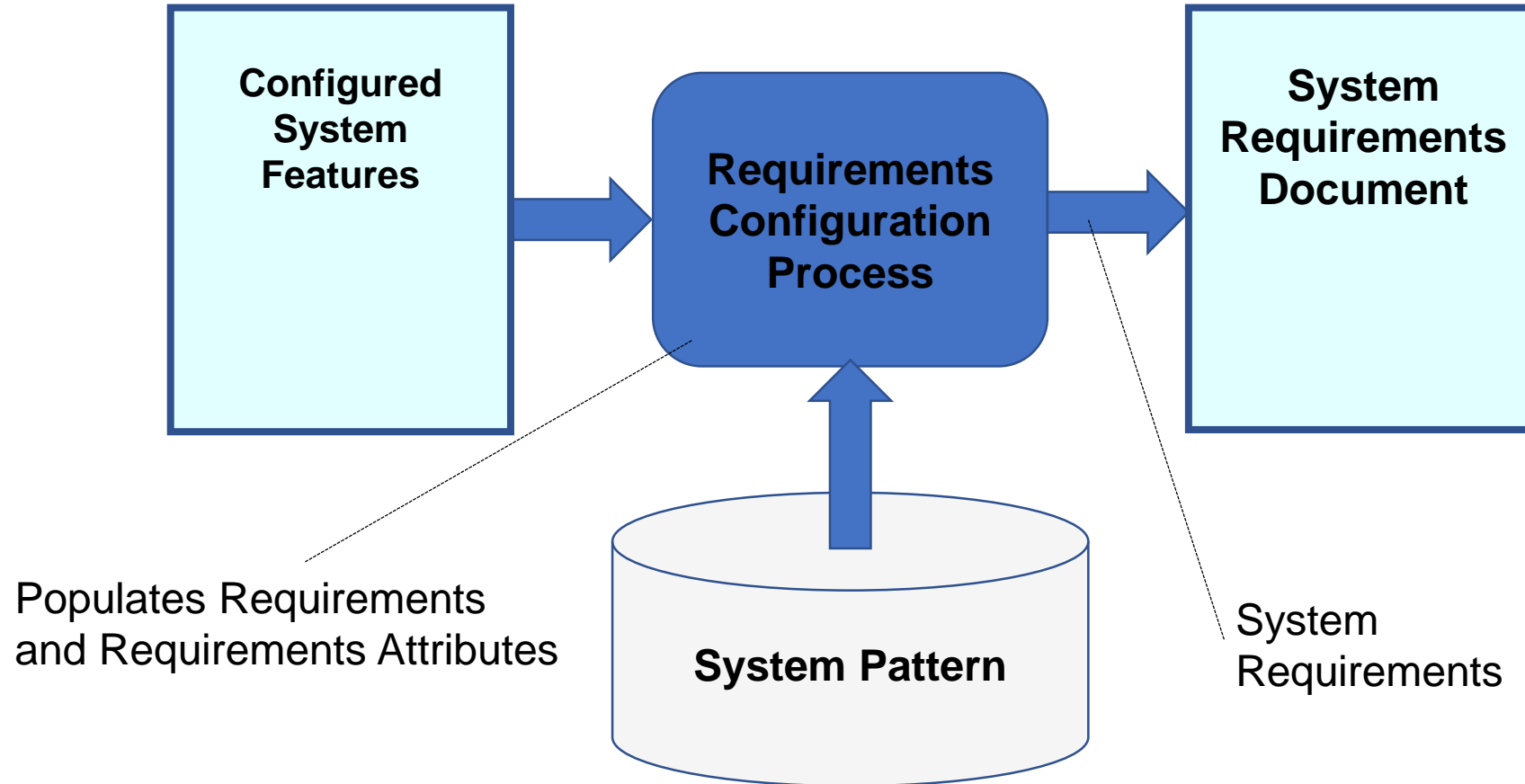


Example: State Model Pattern—illustrates how *visual* is the “class splitting” and “relationship rubber banding” of the Gestalt Rules

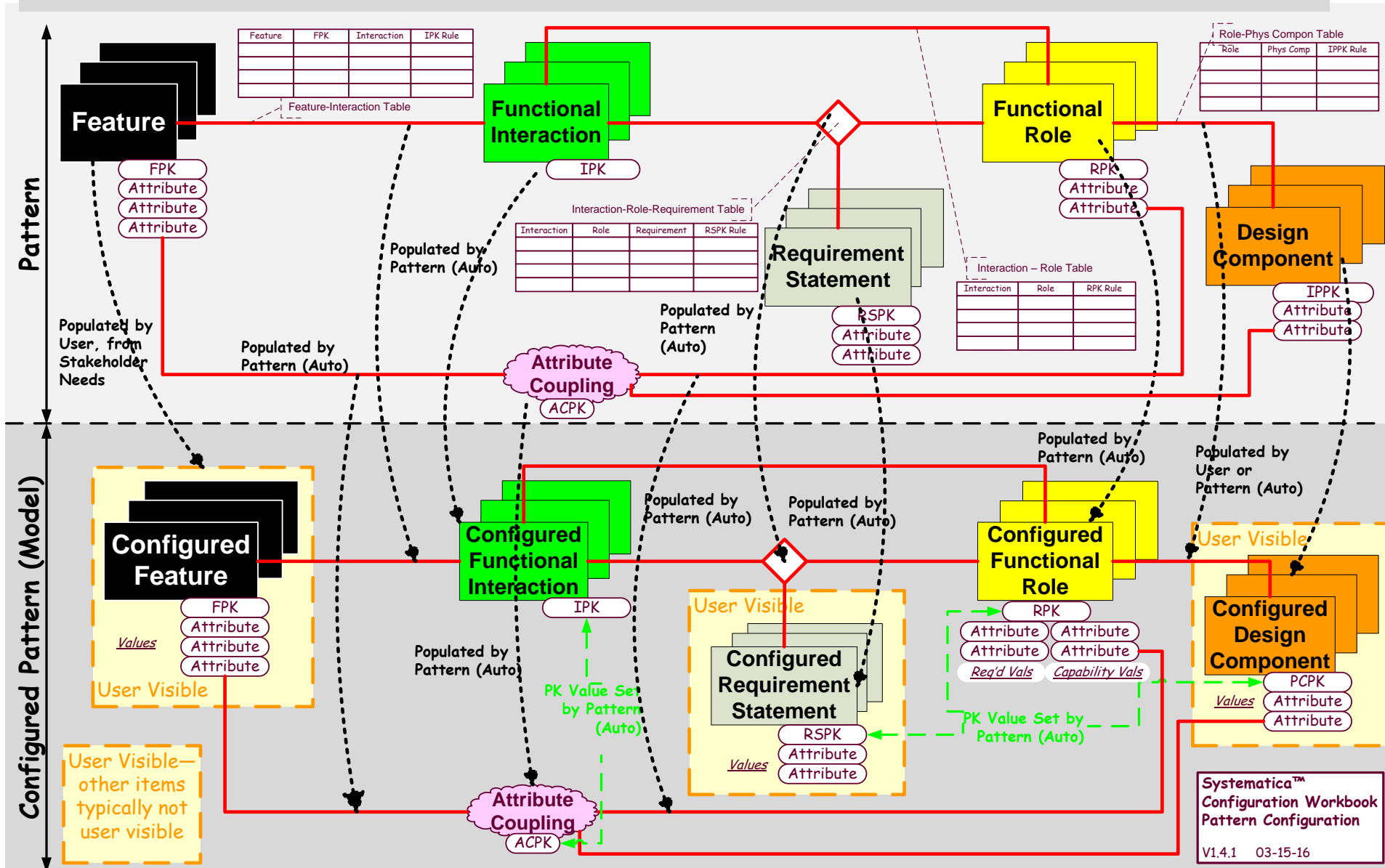
Class Hierarchy of Dynamic Process Models (Finite State Machines)



Using Pattern Configuration to generate better System Requirements faster: Example

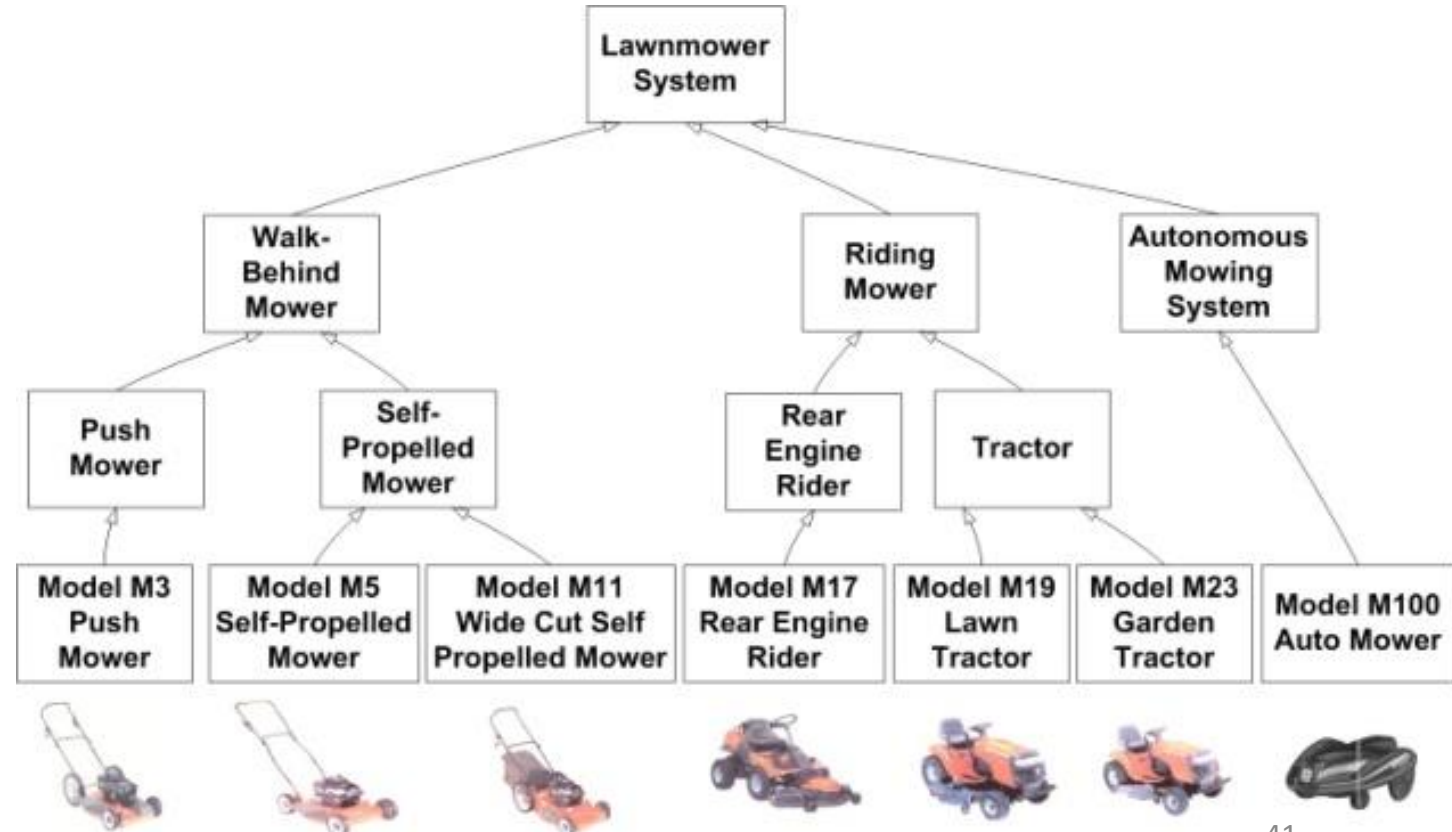
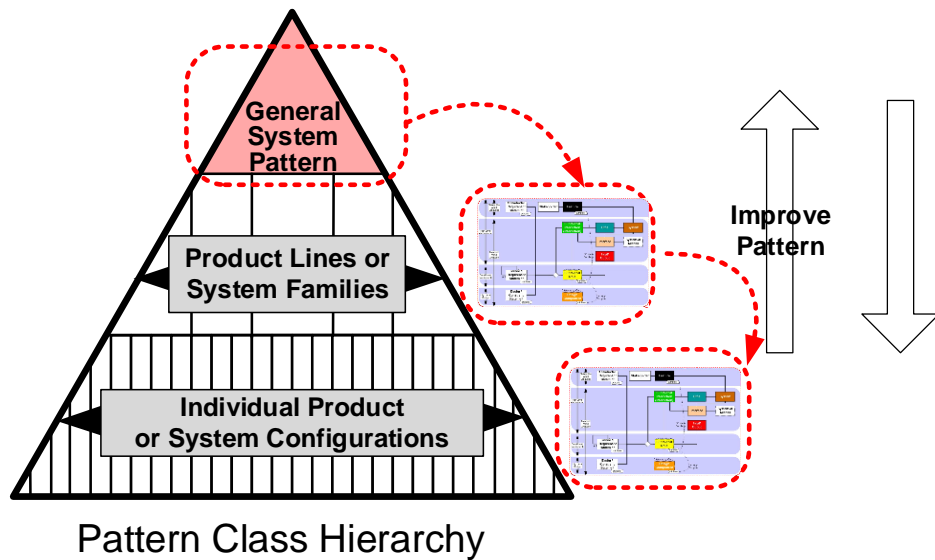


- The S*Pattern links Features to Requirements:
 - This means that populating a configuration of Features can automatically populate a configuration of Requirements--



S*Models as Configurations of S*Patterns

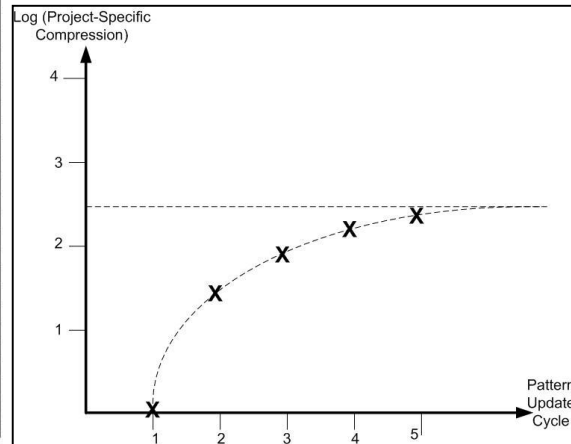
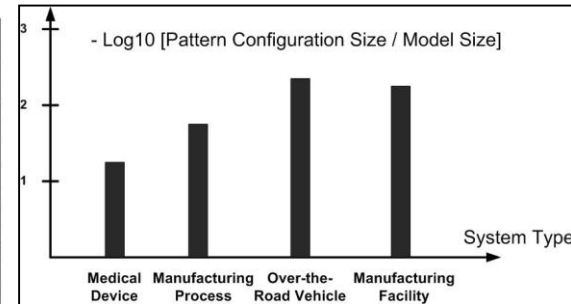
- Patterns as Compression: Lawnmowers; IEEE 802.11



Pattern configurations

- A table of configurations illustrates how patterns facilitate compression;
- Each column in the table is a compressed system representation with respect to (“modulo”) the pattern;
- The compression is typically very large;
- The compression ratio tells us how much of the pattern is variable and how much fixed, across the family of potential configurations.

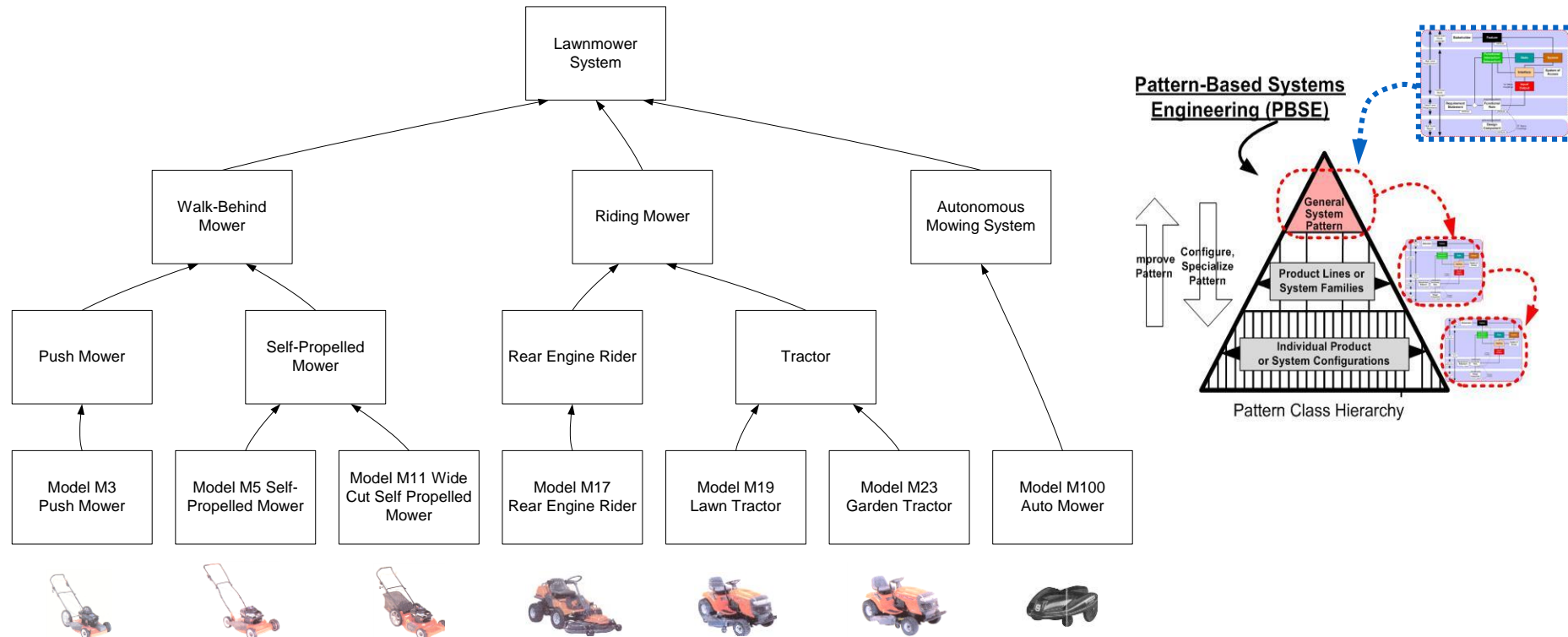
Lawnmower Product Line: Configurations Table									
		Units	Walk-Behind	Walk-Behind	Walk-Behind	Riding	Riding	Riding Mower	Autonomous
			Push Mower	Mower	Self-Propelled	Rider	Tractor	Tractor	Autonomous
			Push Mower	Self-Propelled	Wide Cut	Rider	Lawn	Garden	Auto Mower
	Model Number		M3	M5	M11	M17	M19	M23	M100
	Market Segment		Sm Resident	Med Resident	Med Resident	Lg Resident	Lg Resident	Home Garden	High End Suburban
Power	Engine Manufacturer		B&S	B&S	Tecumseh	Tecumseh	Kohler	Kohler	Elektroset
	Horsepower	HP	5	6.5	13	16	18.5	22	0.5
Production	Cutting Width	Inches	17	19	36	36	42	48	16
	Maximum Mowing Speed	MPH	3	3	4	8	10	12	2.5
	Maximum Mowing Productivity	Acres/Hr			1.6				
	Turning Radius	Inches	0	0	0	0	126	165	0
	Fuel Tank Capacity	Hours	1.5	1.7	2.5	2.8	3.2	3.5	2
	Towing Feature						x	x	
	Electric Starter Feature				x	x	x	x	
	Basic Mowing Feature Group		x	x	x	x	x	x	x
Mower	No. of Anti-Scalping Rollers		0	0	1	2	4	6	0
	Cutting Height Minimum	Inches	1	1.5	1.5	1.5	1	1.5	1.2
	Cutting Height Maximum	Inches	4	5	5	6	8	10	3.8
	Operator Riding Feature					x	x	x	
	Grass Bagging Feature		Optional	Optional	Optional	Optional	Optional	Optional	
	Mulching Feature		Standard	Factory Installed	Dealer Installed				
	Aerator Feature					Optional	Optional	Optional	
	Autonomous Mowing Feature								x
	Dethatching Feature					Optional	Optional	Optional	
Physical	Wheel Base	Inches	18	20	22	40	48	52	16
	Overall Length	Inches	18	20	23	58	56	68	28.3
	Overall Height	Inches	40	42	42	30	32	36	10.3
	Width	Inches	18	20	22	40	48	52	23.6
	Weight	Pounds	120	160	300	680	705	1020	15.6
	Self-Propelled Mowing Feature			x	x	x	x	x	x
	Automatic TransmFeature							x	
Financials	Retail Price	Dollars	360	460	1800	3300	6100	9990	1799
	Manufacturer Cost	Dollars	120	140	550	950	1800	3500	310
Maintenance	Warranty	Months	12	12	18	24	24	24	12
	Product Service Life	Hours	500	500	600	1100	1350	1500	300
	Time Between Service	Hours	100	100	150	200	200	250	100
Safety	Spark Arrest Feature		x	x	x	x	x	x	



The Family Configurations Model directly addresses a key SE challenge by providing Class Hierarchy Models with Configuration Rules (Gestalt Rules) that govern Platforms and Portfolios of Products, Systems, and Technologies.

Family Configurations Model

- The Family Configurations Model supports multiple configurations, technologies:

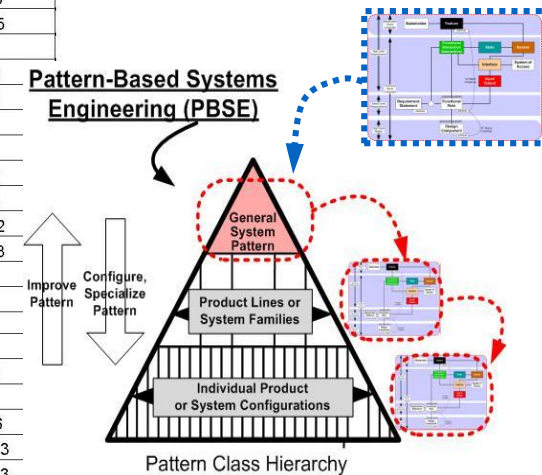


- This can be exploited by partitioning the model to integrate with existing Portfolio Roadmaps for Markets, Technologies, and Products

Family Configurations Model

Lawnmower Product Line: Configurations Table									
		Units	Walk-Behind Mower	Walk-Behind Mower	Walk-Behind Mower	Riding Mower	Riding Mower	Riding Mower	Autonomous Mowing System
			Push Mower	Self-Propelled Mower	Self-Propelled Mower	Rear Engine Rider	Tractor	Tractor	Autonomous Mowing System
			Push Mower	Self-Propelled Mower	Wide Cut Self-Propelled Mower	Rear Engine Rider	Lawn Tractor	Garden Tractor	Auto Mower
	Model Number		M3	M5	M11	M17	M19	M23	M100
	Market Segment		Small Residential	Medium Residential	Medium Residential	Large Residential	Large Residential	Home Garden	High End Suburban
Power	Engine Manufacturer		Briggs & Stratton	Briggs & Stratton	Tecumseh	Tecumseh	Kohler	Kohler	Elektroset
	Horsepower	HP	5	6.5	13	16	18.5	22	0.5
Production	Cutting Width	Inches	17	19	36	36	42	48	16
	Maximum Mowing Speed	MPH	3	3	4	8	10	12	2.5
	Maximum Mowing Productivity	Acres/Hr			1.6				
	Turning Radius	Inches	0	0	0	0	126	165	0
	Fuel Tank Capacity	Hours	1.5	1.7	2.5	2.8	3.2	3.5	2
	Towing Feature						x	x	
	Electric Starter Feature				x	x	x	x	
	Basic Mowing Feature Group		x	x	x	x	x	x	x
Mower	Number of Anti-Scalping Rollers		0	0	1	2	4	6	0
	Cutting Height Minimum	Inches	1	1.5	1.5	1.5	1	1.5	1.2
	Cutting Height Maximum	Inches	4	5	5	6	8	10	3.8
	Operator Riding Feature					x	x	x	
	Grass Bagging Feature		Optional	Optional	Optional	Optional	Optional	Optional	
	Mulching Feature		Standard	Factory Installed	Dealer Installed				
	Aerator Feature					Optional	Optional	Optional	
	Autonomous Mowing Feature								x
	Dethatching Feature					Optional	Optional	Optional	
Physical	Wheel Base	Inches	18	20	22	40	48	52	16
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	Width	Inches	18	20	22	40	48	52	23.6
	Weight	Pounds	120	160	300	680	705	1020	15.6
	Self-Propelled Mowing Feature			x	x	x	x	x	x
	Fully Automatic Transmission Feature							x	
Financials	Retail Price	Dollars	360	460	1800	3300	6100	9990	1799
	Manufacturer Cost	Dollars	120	140	550	950	1800	3500	310
Maintenance	Warranty	Months	12	12	18	24	24	24	12
	Product Service Life	Hours	500	500	600	1100	1350	1500	300
	Time Between Service	Hours	100	100	150	200	200	250	100
Safety	Spark Arrest Feature		x	x	x	x	x	x	

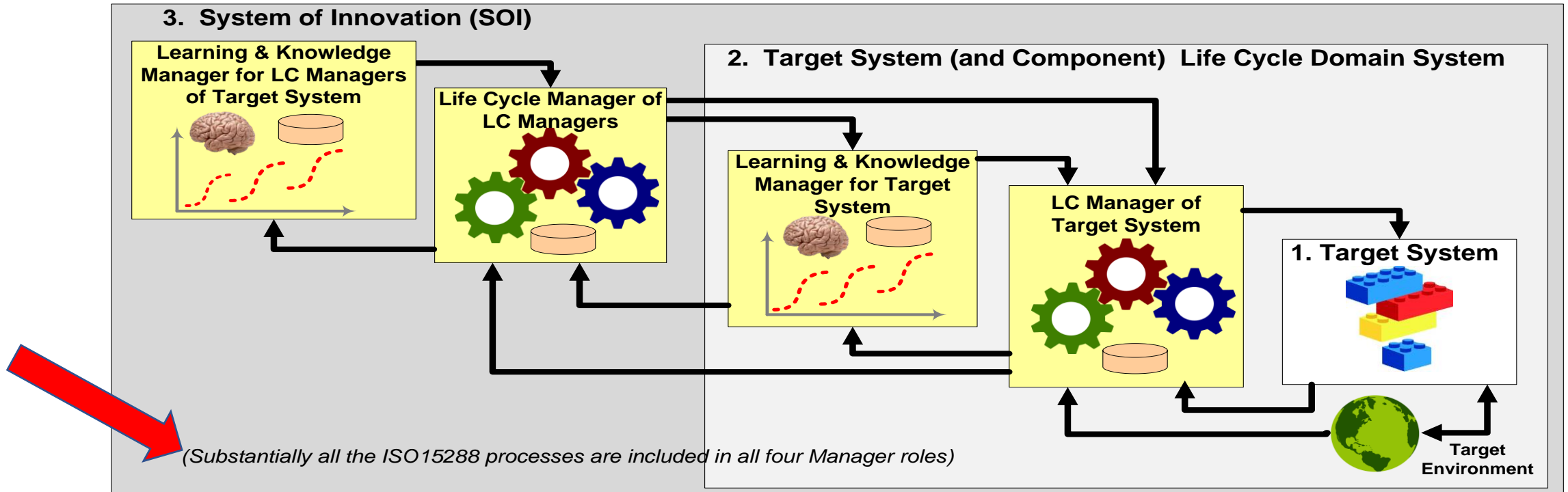
Pattern-Based Systems Engineering (PBSE)



The System of Innovation S*Pattern: System 1, 2, and 3

(Used for INCOSE Agile SE Project, INCOSE CIPR WG, etc.)

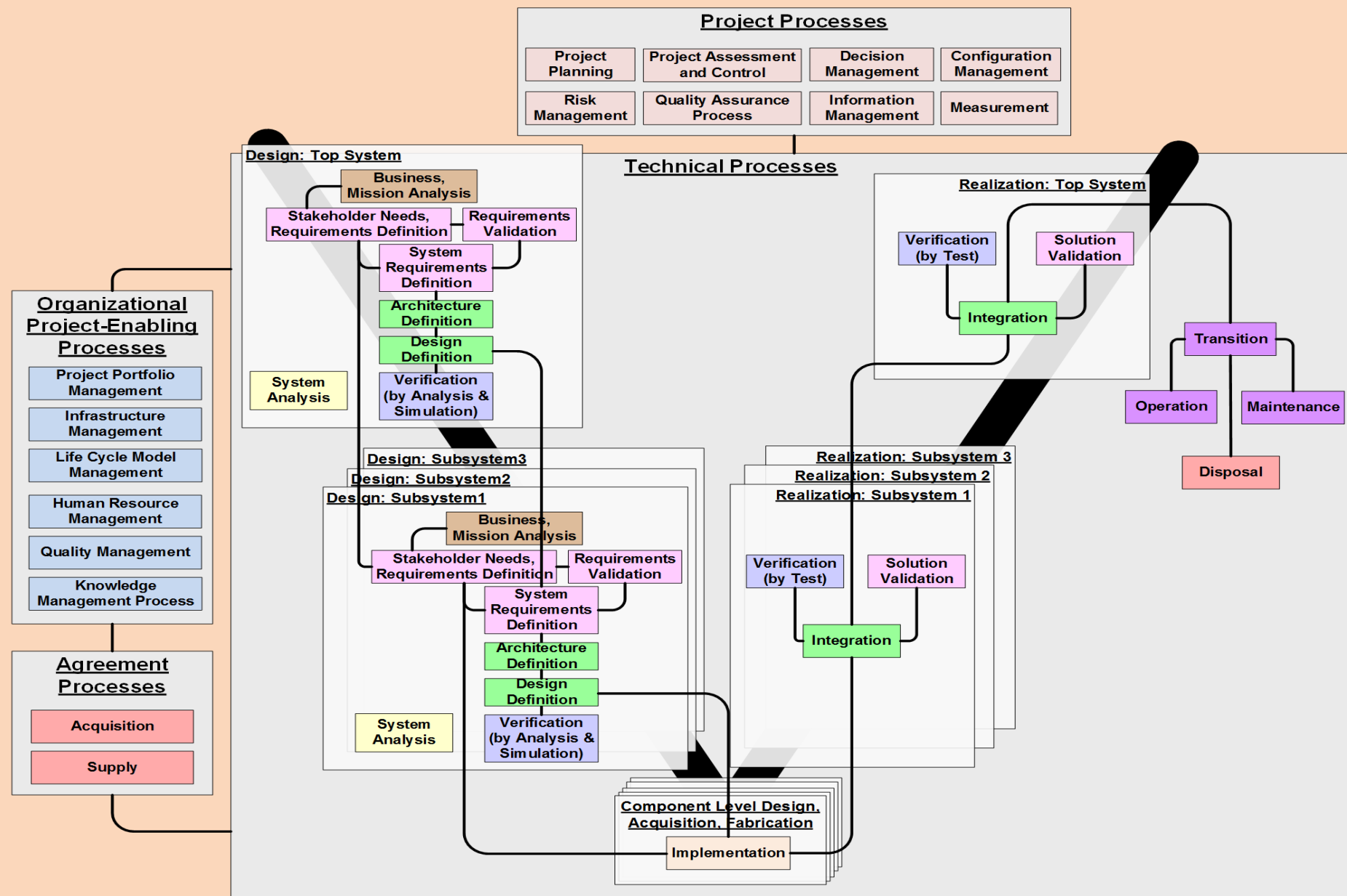
generic innovation reference model: Descriptive, not prescriptive.)



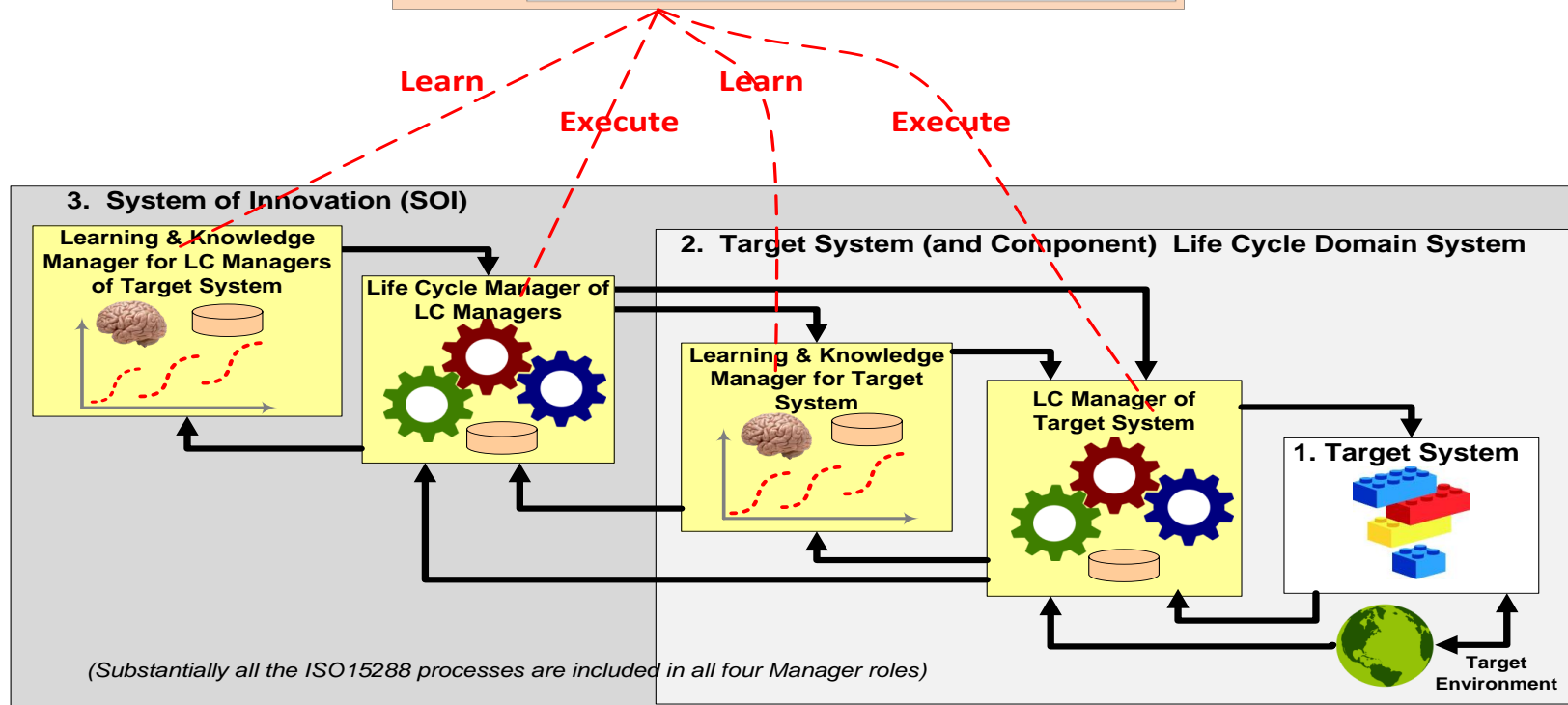
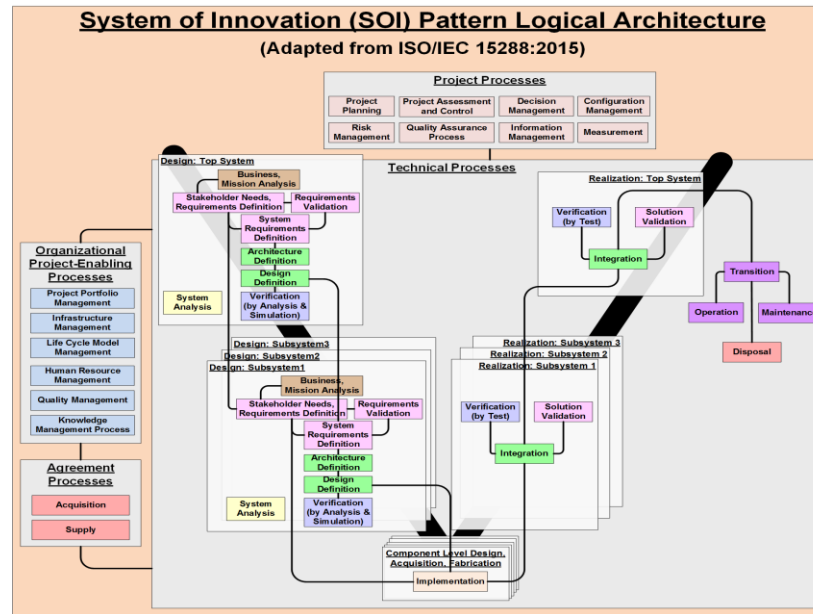
- System 1: Target system of interest, to be engineered or improved.
- System 2: The environment of (interacting with) S1, including all the life cycle management systems of S1, including learning about S1.
- System 3: The life cycle management systems for S2, including learning about S2.

System of Innovation (SOI) Pattern Logical Architecture

(Adapted from ISO/IEC 15288:2015)



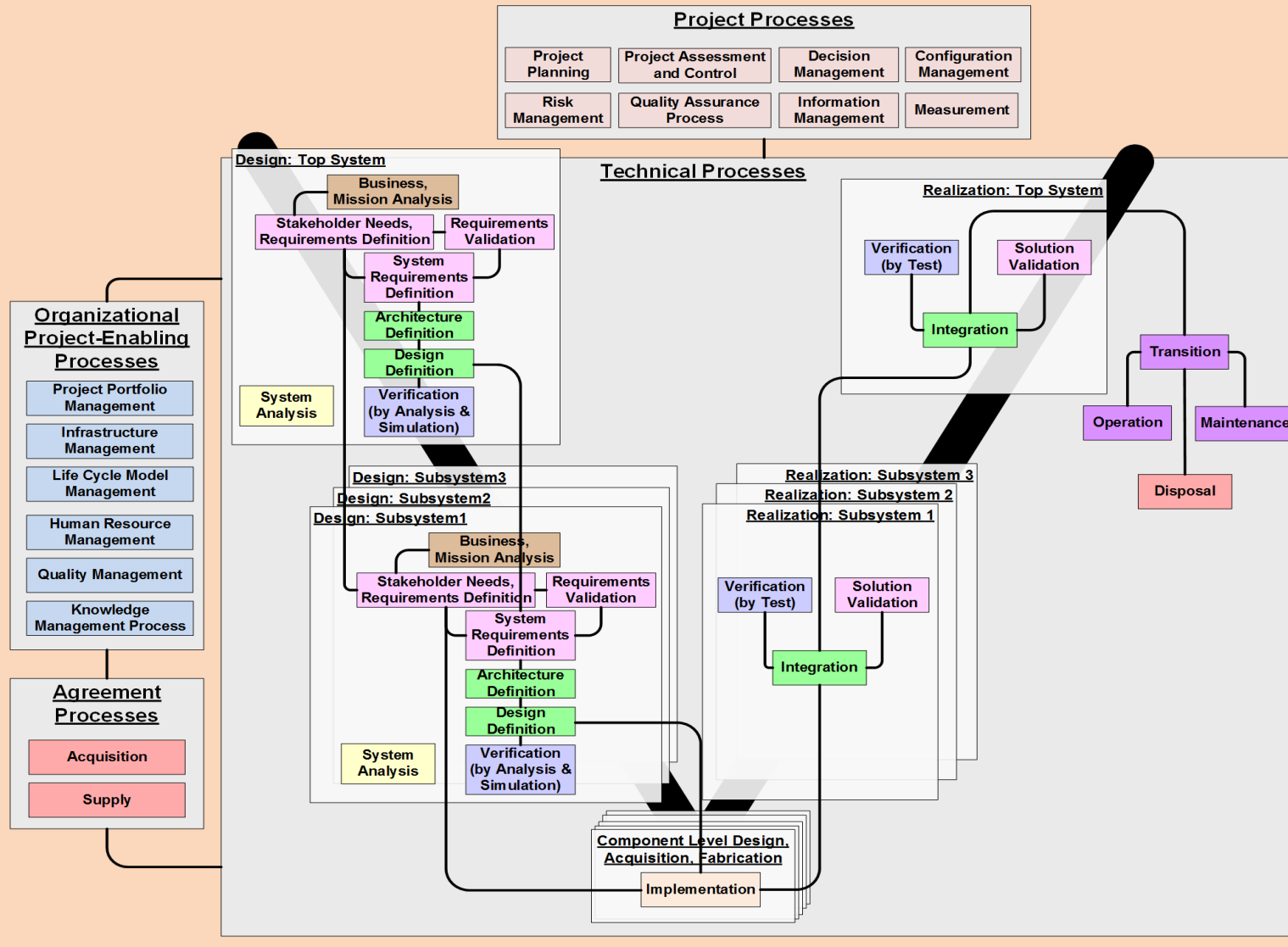
ISO 15288 processes appear 4 times, whether we recognize or not.



Models for what purposes? Possible ISO15288 answers

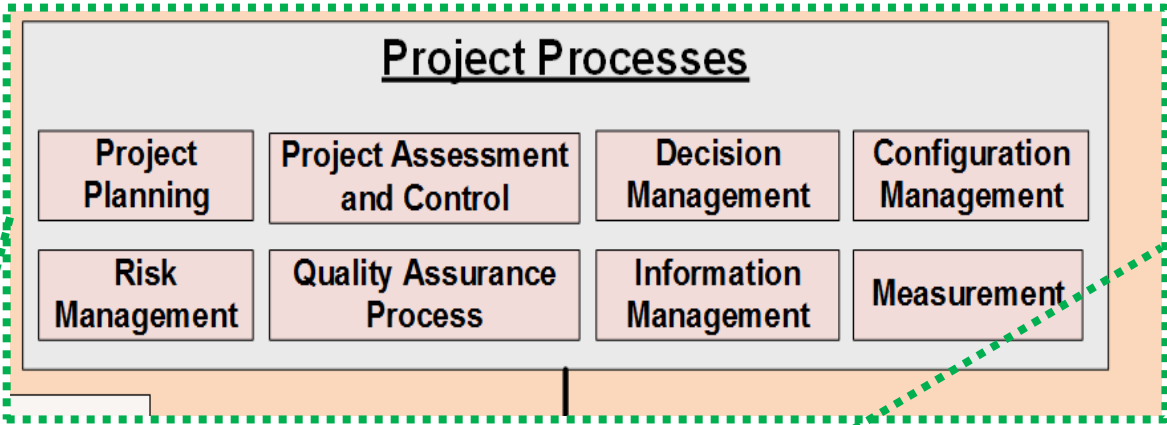
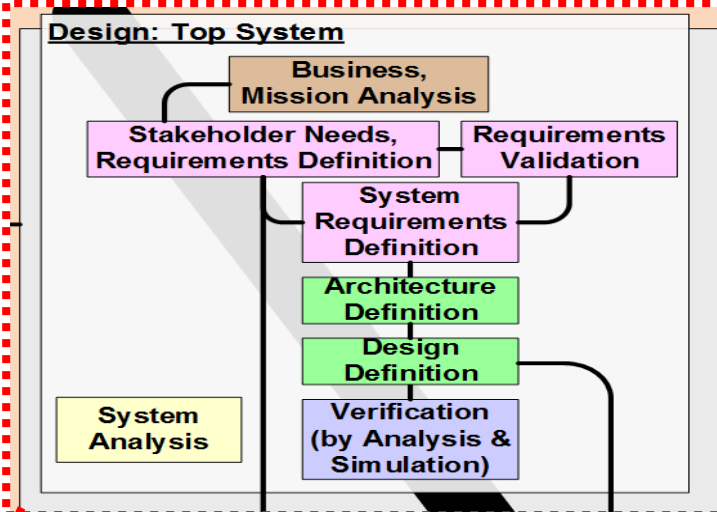
System of Innovation (SOI) Pattern Logical Architecture

(Adapted from ISO/IEC 15288:2015)

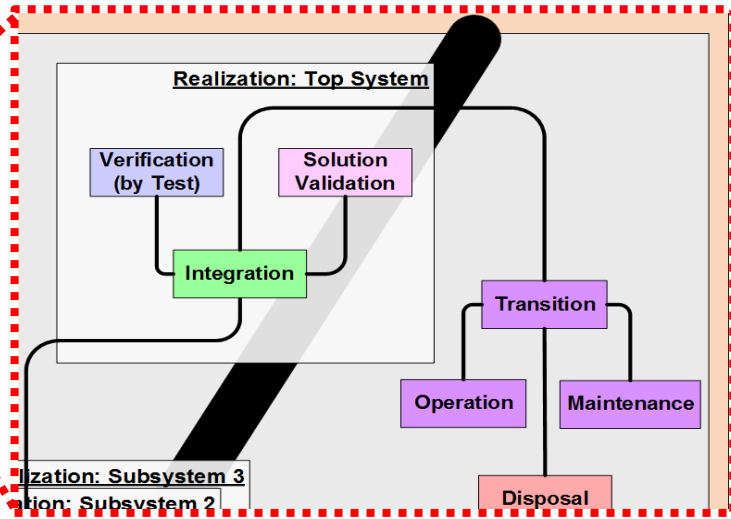
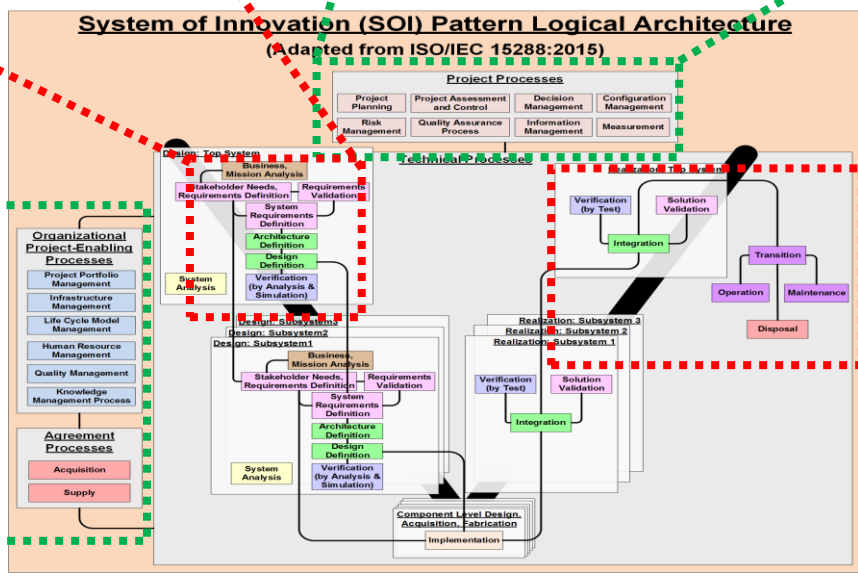
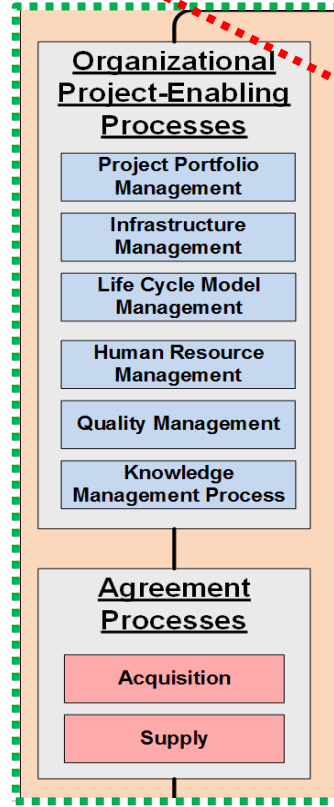


Potentially for any ISO 15288 processes:

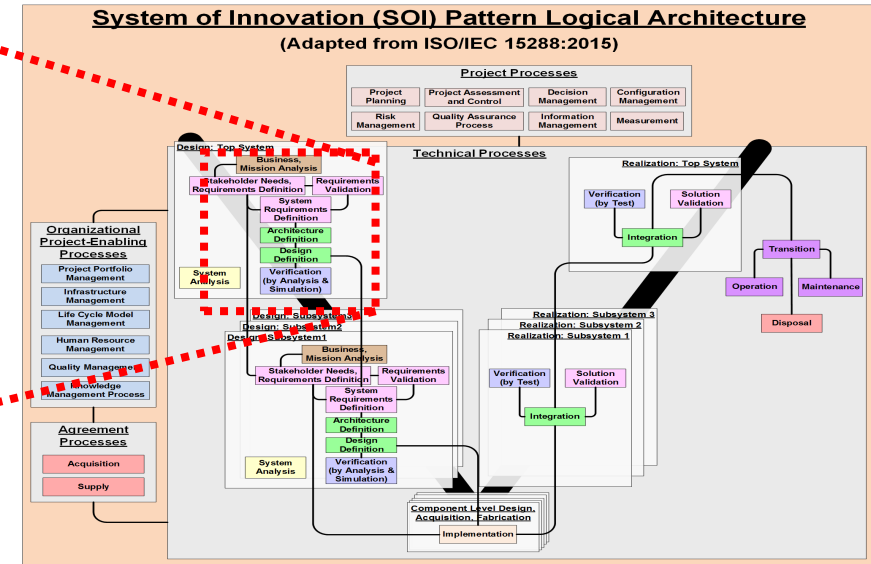
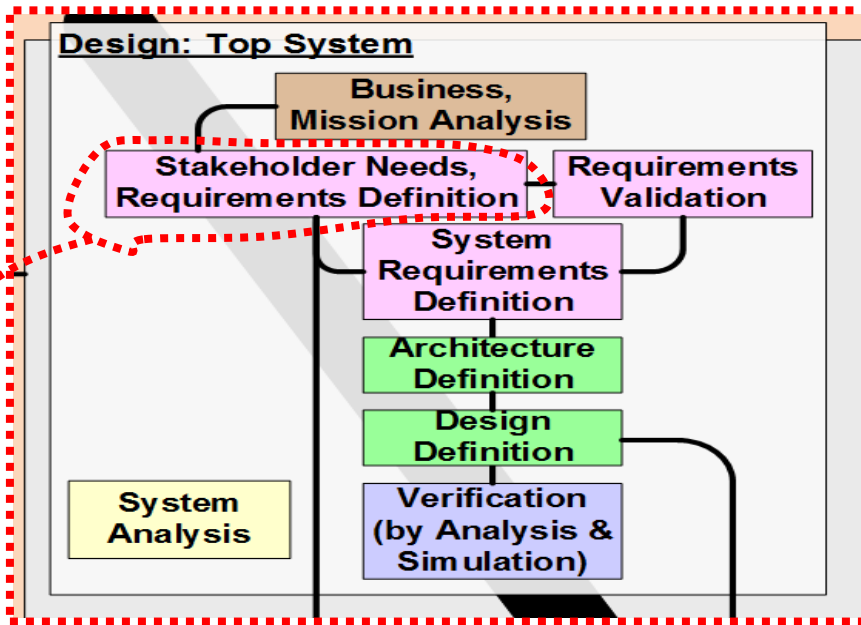
- If there is a net benefit . . .
- Some more obvious than others.
- The INCOSE MBE Transformation is using ISO 15288 framework as an aid to migration planning and assessment.



Many potential purposes for models



Each 15288 process definition suggests potentially assessable model impacts



- “Stakeholders of the system are identified.
- Required characteristics and context of use of capabilities and concepts in the life cycle stages, including operational concepts, are defined.
- Constraints on a system are identified.
- Stakeholder needs are defined.
- Stakeholder needs are prioritized and transformed into clearly defined stakeholder requirements.
- Critical performance measures are defined.
- Stakeholder agreement that their needs and expectations are reflected adequately in the requirements is achieved.
- Any enabling systems or services needed for stakeholder needs and requirements are available.
- Traceability of stakeholder requirements to stakeholders and their needs is established.”

INCOSE MB Transformation; planning and assessment

- One way to stay focused pragmatically is to be very clear about explicit purposes for models.
- Because ISO 15288 offers a (relatively) well-known and accessible reference model for the life cycle management of systems, it provides a convenient “menu” listing of potential high level purposes of models in the life cycle of systems.
- The INCOSE Model-Based Transformation team is using this as the basis of an MBSE migration and maturation planning and assessment instrument . . .

INCOSE MB Transformation; Planning and Assessment Instrument

The INCOSE MBSE Transformation products are based on identification of --

Stakeholders in the MBSE Transformation:

1. Model Consumers (Model Users);
2. Model Creators (including Model Improvers);
3. Complex Idea Communicators (Model "Distributors");
4. Model Infrastructure Providers, Including Tooling, Language and Other Standards, Methods;
5. INCOSE and other Engineering Professional Societies.

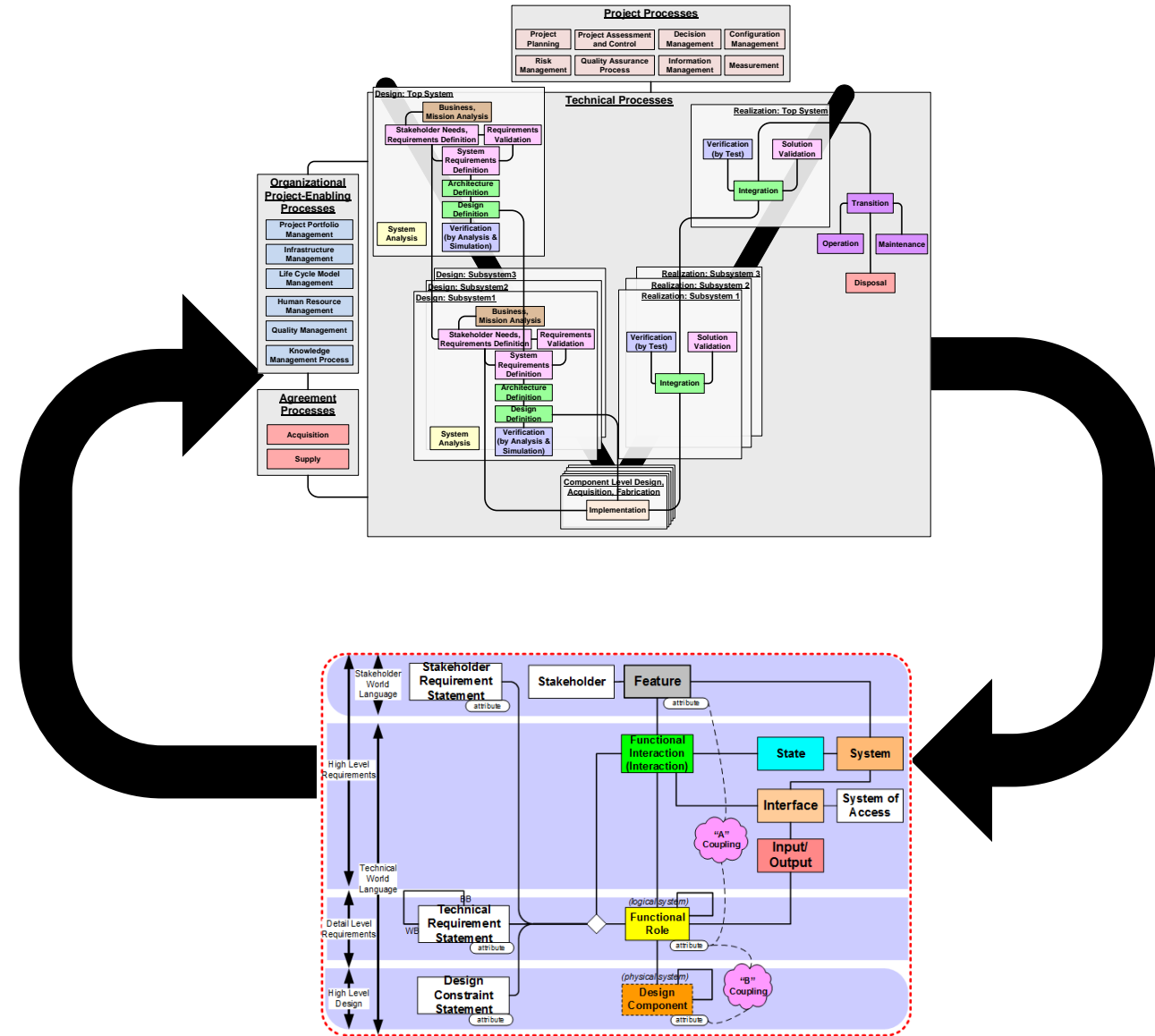
Notice that group (1) is by far the largest population of stakeholders, for future MBSE impact potential.

Innovation Process

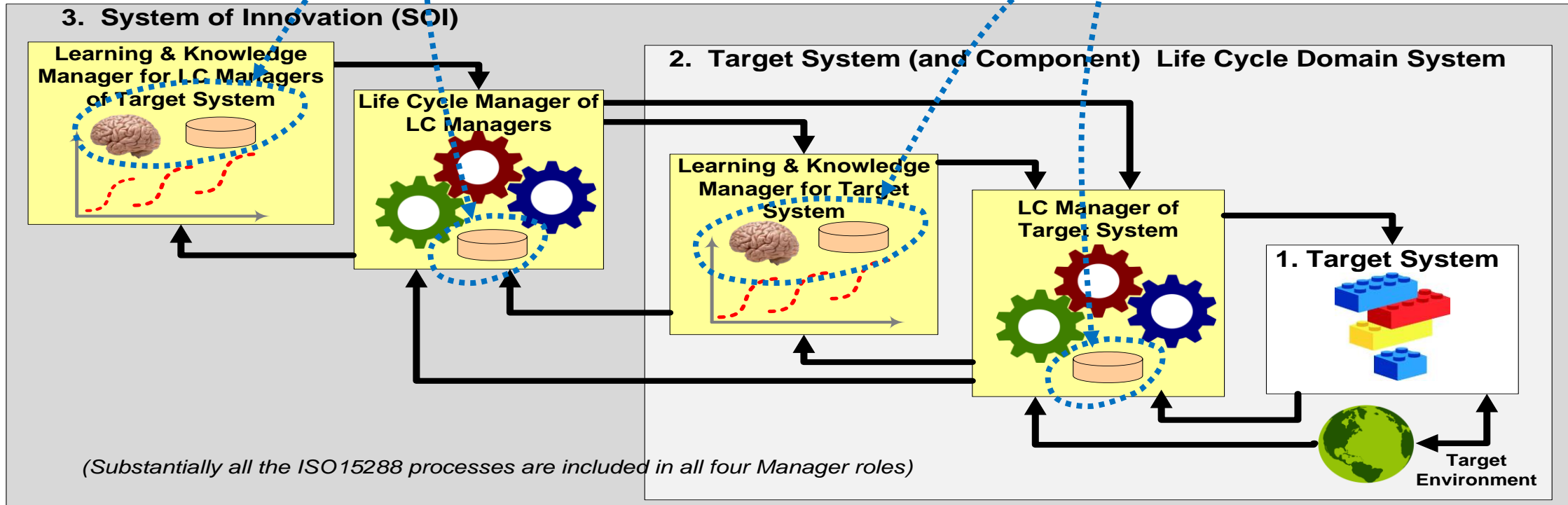
Models help make this real:

Shifting the emphasis from traditional focus on process and procedure, to greater emphasis on the state of the web of information passing through that process and procedure.

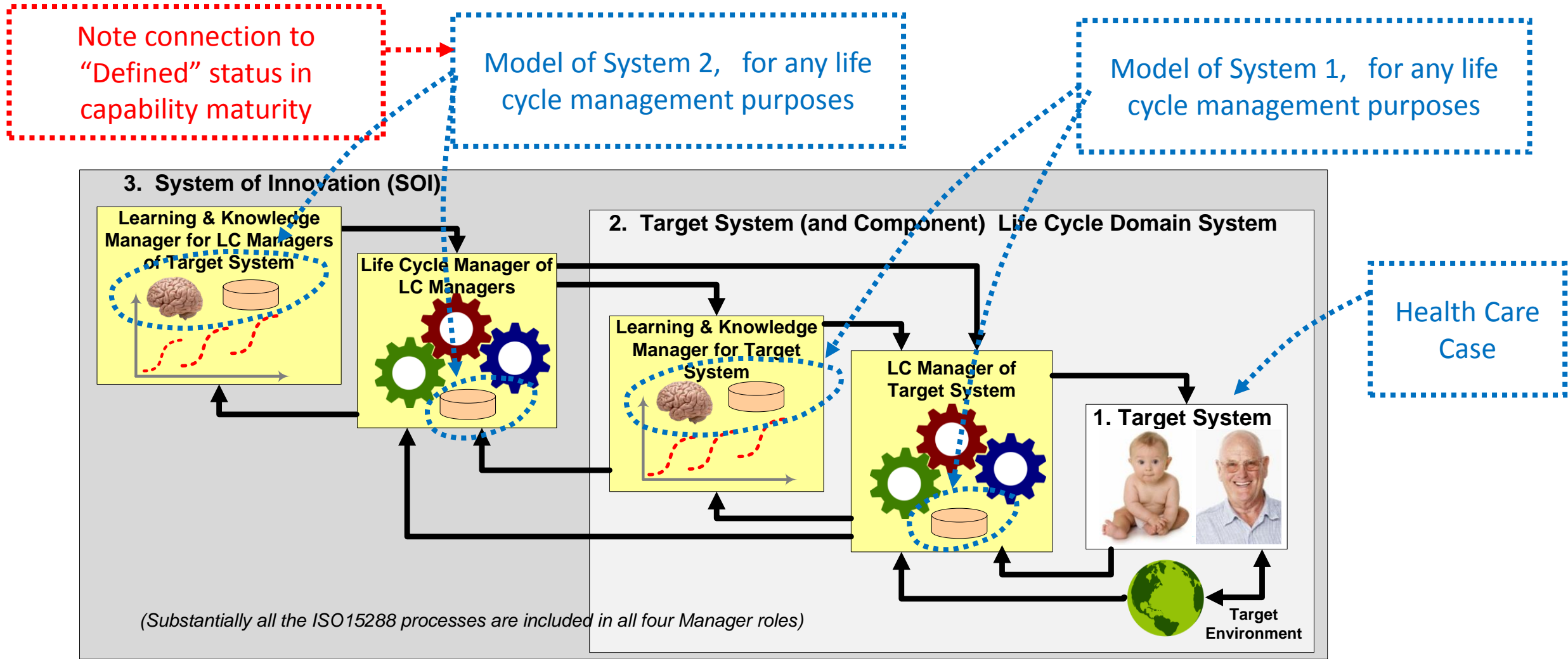
Compare to the traditional engineering disciplines.



Information Passing Through Innovation Process

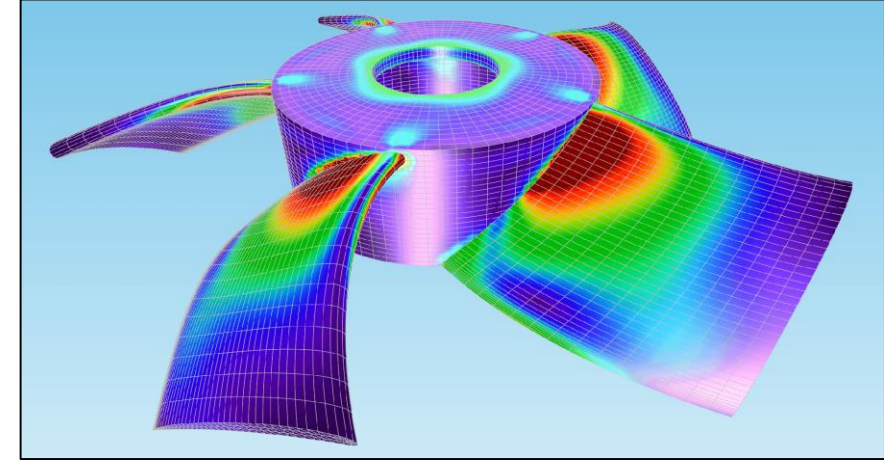
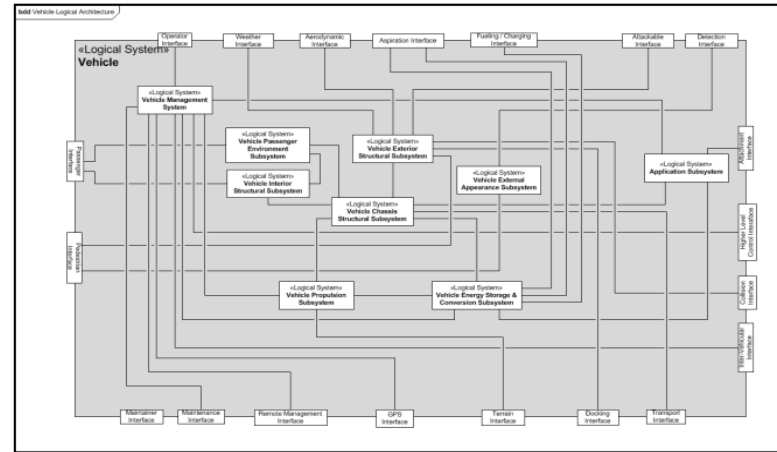


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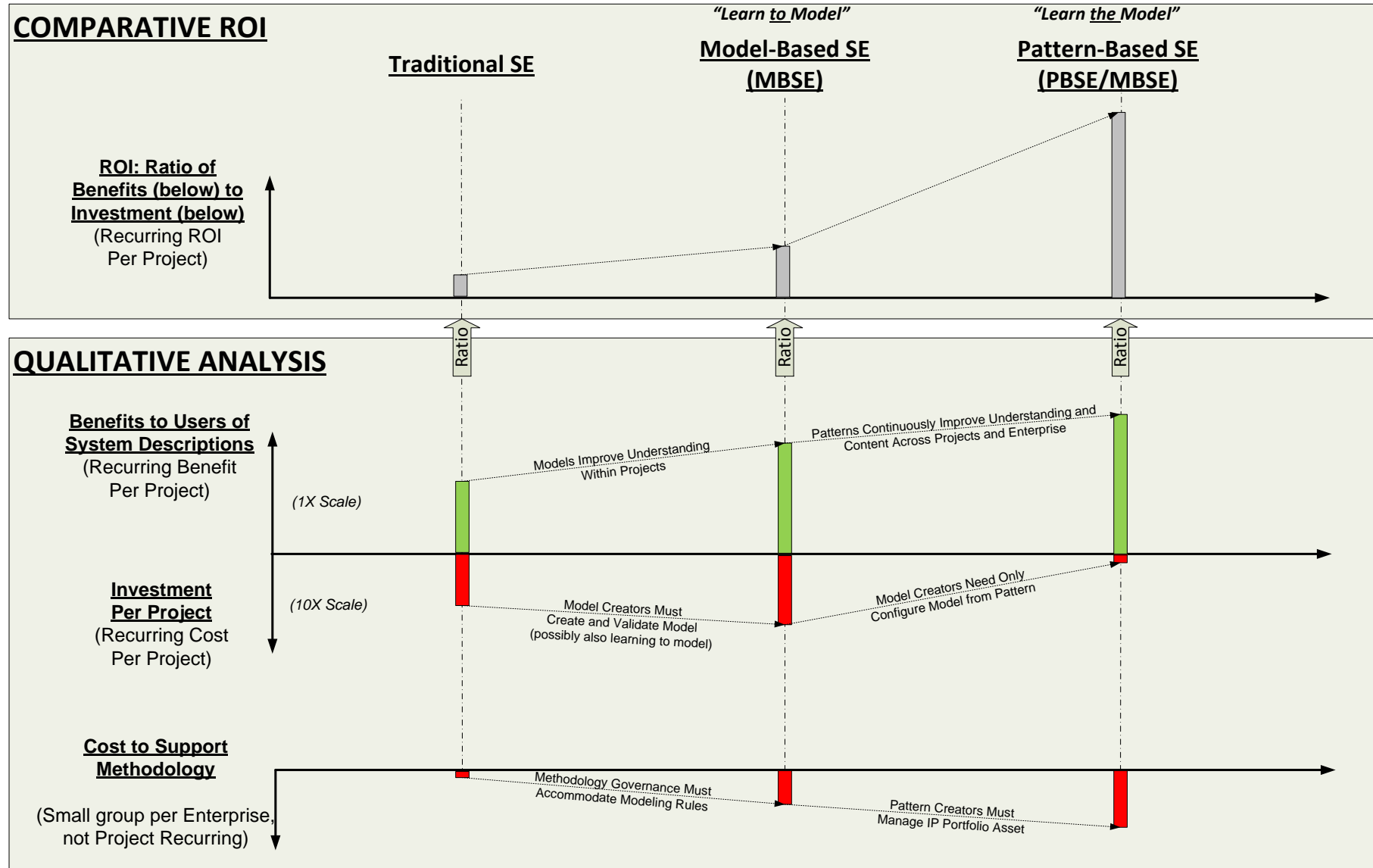
Enthusiasm for Models



The INCOSE systems community has shown growing enthusiasm for “engineering with models” of all sorts:

- Historical tradition of math-physics engineering models
- A World in Motion: INCOSE Vision 2025
- Growth of the INCOSE IW MBSE Workshop
- Growth in systems engineers in modeling classes
- INCOSE Board of Directors’ objective to accelerate transformation of SE to a model-based discipline
- Joint INCOSE activities with NAFEMS

Comparative Benefits and Costs Summary: Qualitative Relationships



Further analysis of the INCOSE MBE Transformation Stakeholders

Population ←-- Size (Log)	Stakeholders in A Successful MBSE Transformation (showing their related roles and parent organizations)						
		Industry & Govt. Initiatives	Organizations Internalizing MBSE, Including Govt. Contractors & Commercial	Vendors of MBSE Tooling and Services	Academia and Researchers	Technical Societies, Other Non- Technical Organizations	
Model Consumers (Model Users):							
****	Non-technical stakeholders in various Systems of Interest, who acquire / make decisions about / make use of those systems, and are informed by models of them. This includes mass market consumers, policy makers, business and other leaders, investors, product users, voters in public or private elections or selection decisions, etc.	X	X			X	
**	Technical model users, including designers, project leads, production engineers, system installers, maintainers, and users/operators.	X	X			X	
*	Leaders responsible to building their organization's MBSE capabilities and enabling MBSE on their projects	X	X			X	
Model Creators (including Model Improvers):							
*	Product visionaries, marketers, and other non-technical leaders of thought and organizations	X	X		X	X	
*	System technical specifiers, designers, testers, theoreticians, analysts, scientists	X	X		X	X	
*	Students (in school and otherwise) learning to describe and understand systems				X	X	
*	Educators, teaching the next generation how to create with models	X	X		X		
*	Researchers who advance the practice		X	X	X		
*	Those who translate information originated by others into models	X	X		X	X	
*	Those who manage the life cycle of models	X	X		X	X	
Complex Idea Communicators (Model "Distributors"):							
**	Marketing professionals	X	X	X		X	
**	Educators, especially in complex systems areas of engineering and science, public policy, other domains, and including curriculum developers as well as teachers	X	X	X	X		
**	Leaders of all kinds	X	X	X	X	X	
Model Infrastructure Providers, Including Tooling, Language and Other Standards, Methods:							
*	Suppliers of modeling tools and other information systems and technologies that house or make use of model-based information			X			
*	Methodologists, consultants, others who assist individuals and organizations in being more successful through model-based methods	X	X	X	X		
*	Standards bodies (including those who establish modeling standards as well as others who apply them within other standards)	X				X	
INCOSE and other Engineering Professional Societies							
*	As a deliverer of value to its membership					X	
*	As seen by other technical societies and by potential members					X	
*	As a great organization to be a part of					X	
*	As promoter of advance and practice of systems engineering and MBSE					X	

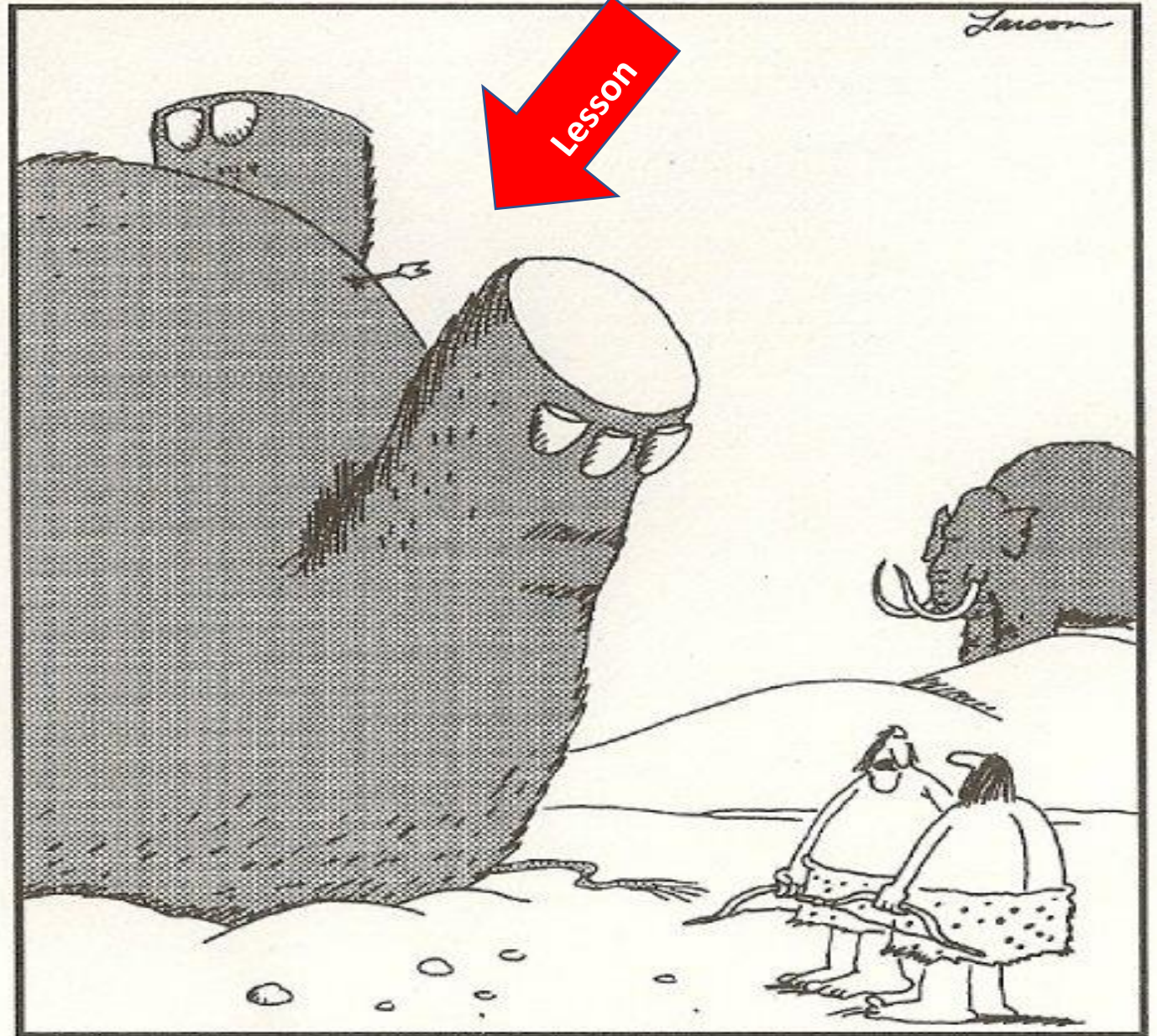
Lessons Learned: Effective Learning?

- In many enterprises, recording “lessons learned” is institutionalized as good practice:
 - At least, at the end of a project;
 - Often, in the form of a report or memorandum to file.
- Likewise, “Knowledge Management” efforts are noted, focusing on encoding what is deemed important for future work of others.
- Measuring effectiveness of such practices:
 - Instead of how often the data is referred to, how about . . .
 - how frequently related future work that could be impacted is effectively impacted, versus repeating similar work or problem consequences.

Lessons Learned?

Lessons Learned Report

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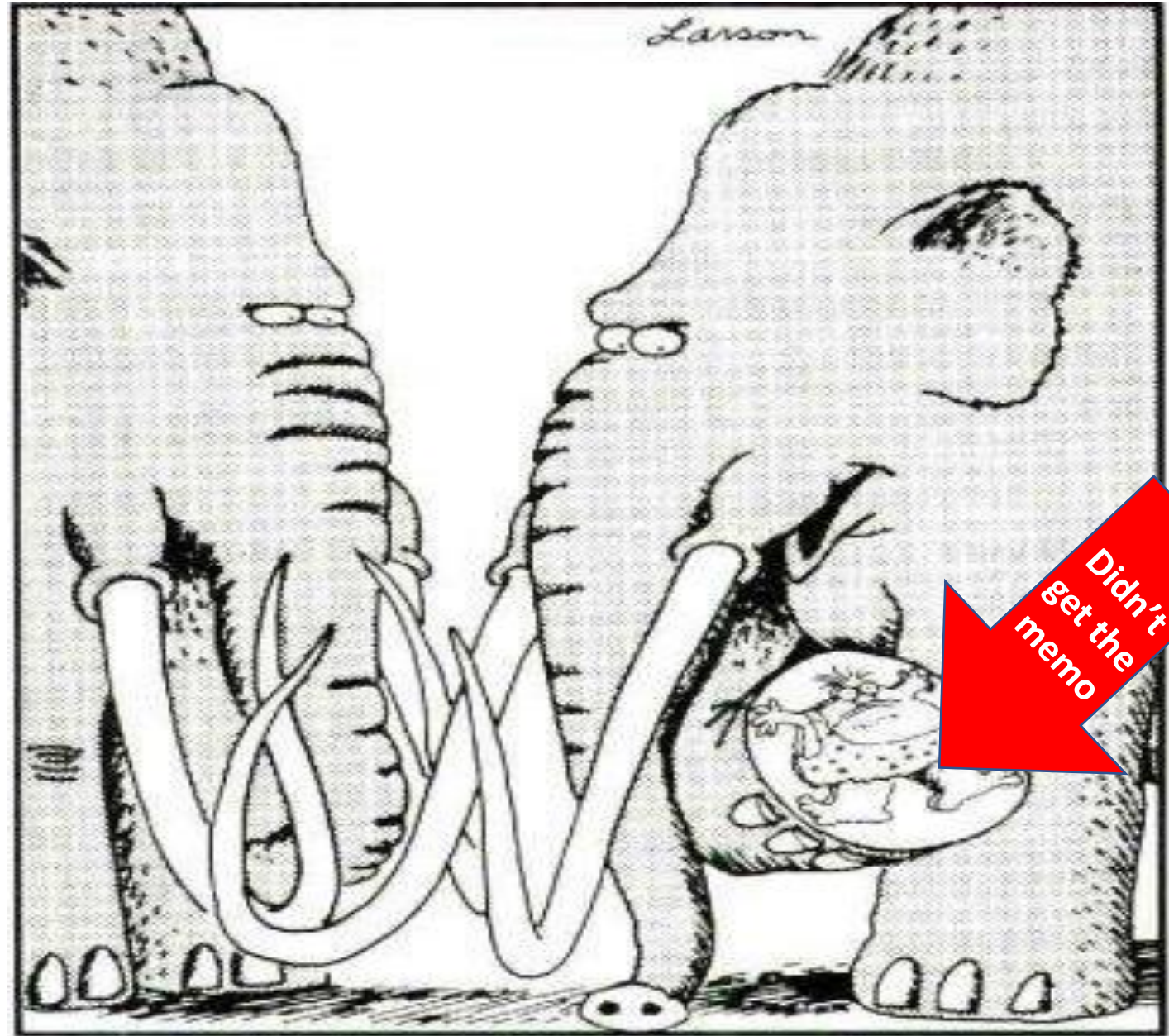


“We should write that spot down.”

Lessons Effectively Learned?

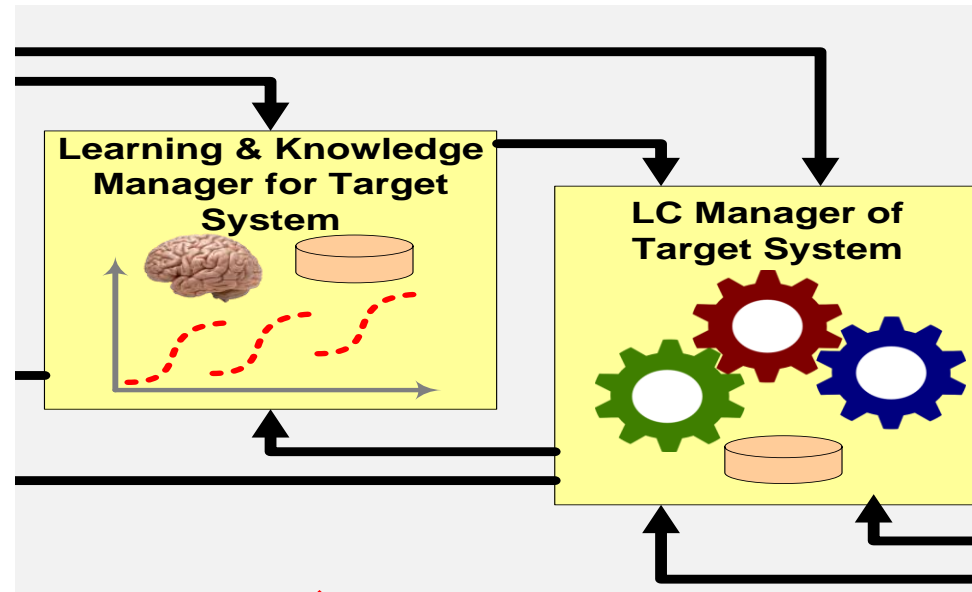
Lessons Learned Report

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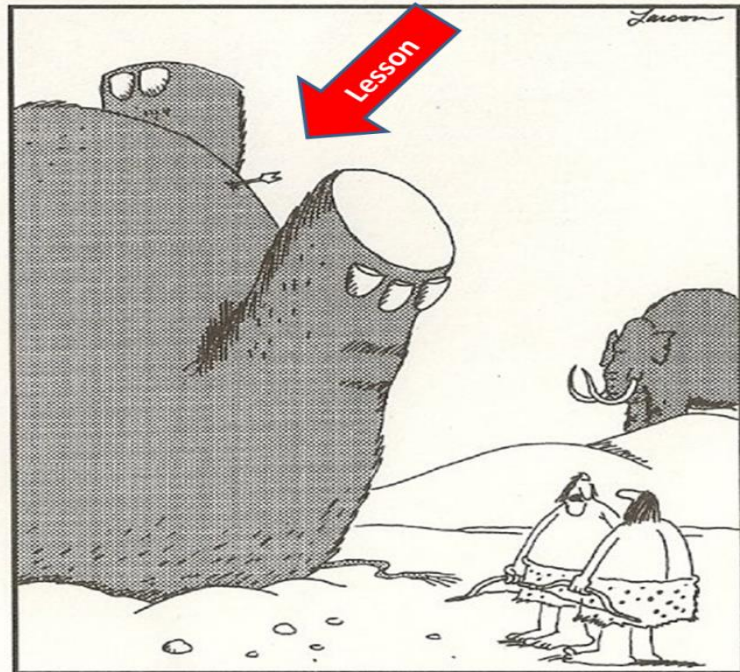
"Well, what the? ... I thought I smelled something."

Learning



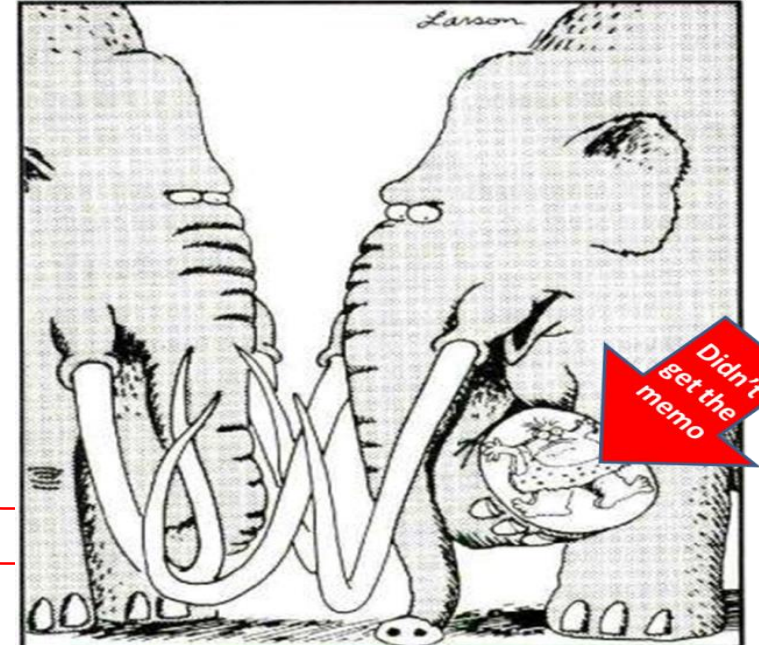
Executing

Copyright Gary Larson, *The Far Side*



"We should write that spot down."

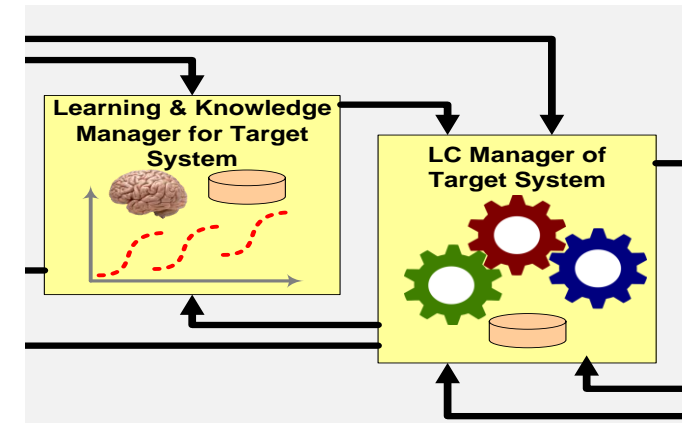
Copyright Gary Larson, *The Far Side*



"Well, what the? ... I thought I smelled something."

Lessons Learned: Effective Learning?

- Where are the “lessons learned” encoded? What would cause them to be accessed?
- Compare to biology:
 - “Muscle Memory” builds “motor” learning directly into a future situation, for future unconscious use, vs. syllogistic reasoning that may not be remembered fast enough, or at all
 - This is about “effective learning” for future agile use
 - Just having a growing file of “lessons learned”, even if text searchable, is not the same as building what we learn directly in line with the path of future related work that will have to access it in order to be executed.
- Just because we label a report “lessons learned” does not mean that those who will need this information in the future will have access to it.



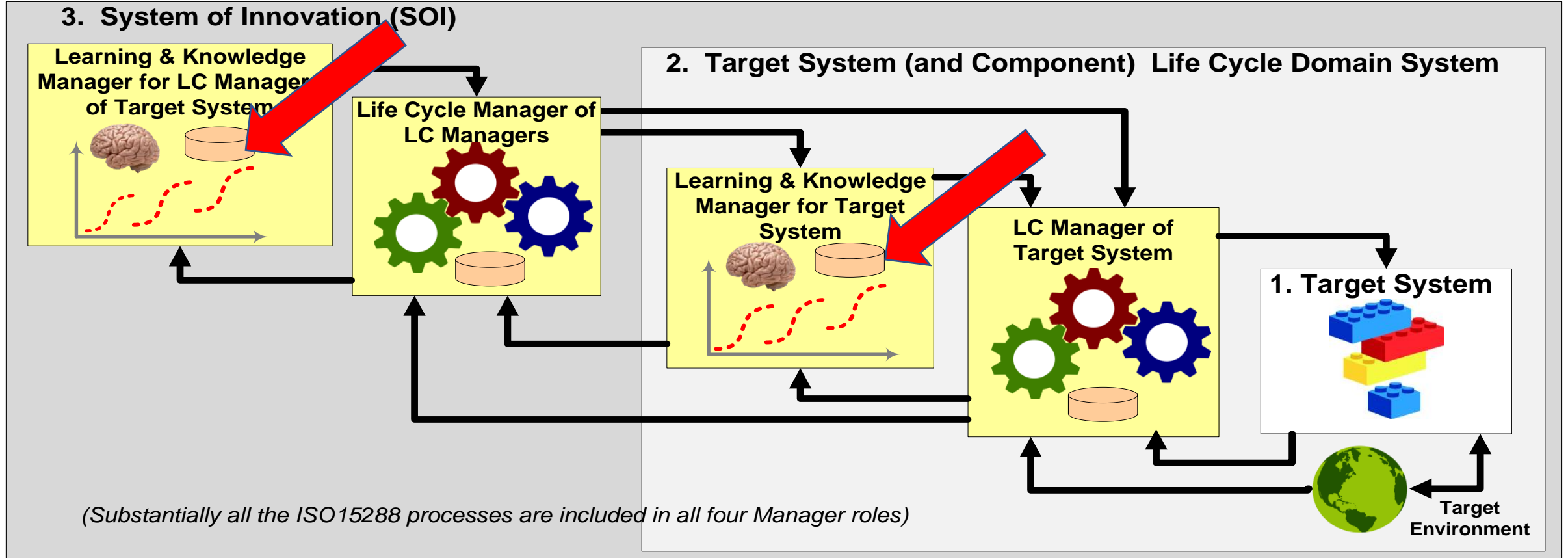
Learned models from STEM (~300 years) offer the most dramatic example of positive collaborative impact of effectively shared and validated models

- Effective Model Sharing:
 - We cannot view MBSE as mature if we perform modeling “from scratch”, instead of building on what we (*including others*) already know.
 - This is the basis of MBSE Patterns, Pattern-Based Systems Engineering (PBSE), and the work of the INCOSE MBSE Patterns Working Group.
 - S1 Patterns are built directly into future S2 project work of other people—effective sharing only occurs to extent it impacts future tasks performed by others.
 - This sharing may occur across individuals, departments, enterprises, domains, markets, society.
 - It applies not only to models of S1 (by S2), but also models of S2 (by S3).
- Effective Model Validation:
 - Especially when shared, models demand that we trust them.
 - This is the motivation for Model Validation, Verification, and Uncertainty Quantification (Model VVUQ) being pursued with ASME standards committees.
 - Effectiveness of Model VVUQ is essential to MBSE Maturity.
 - Because Model VVUQ adds significantly to the cost of a trusted model, MBSE Patterns are all the more important—they IP of enterprises, industries.

An emerging special case: Regulated markets

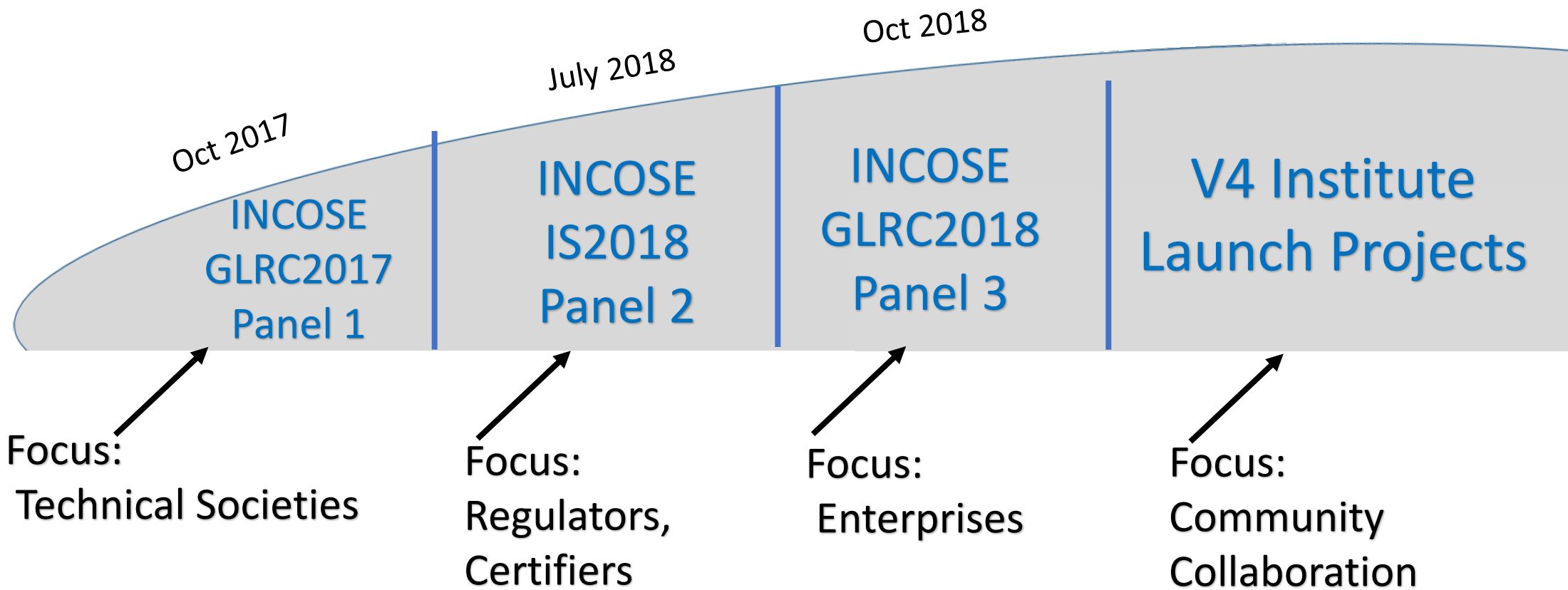
- Increasing use of computational models in safety-critical, other regulated markets is driving development of methodology for Model VVUQ:
 - See, for example, ASME V&V 10, 20, 30, 40, 50, 60.
- Models have economic advantages, but the above can add new costs to development of models for regulatory submission of credible evidence:
 - Cost of evidentiary submissions to FDA, FAA, NRC, NTSB, EPA, OSHA, when supported by models—includes VVUQ of those models.
- This suggests a vision of collaborative roles for engineering professional societies, along with regulators, and enterprises:
 - Trusted shared MBSE Patterns for classes of systems
 - Configurable for vendor-specific products
 - With Model VVUQ frameworks lowering the cost of model trust for regulatory submissions
- Further emphasizes the issue of trust in models . . .

An emerging special case: Regulated markets

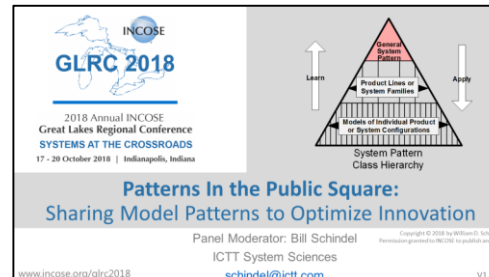


- Trusted shared MBSE Patterns for classes of systems
- Configurable for vendor-specific products
- With Model VVUQ frameworks lowering the cost of model trust for regulatory submissions

Arc of this public conversation

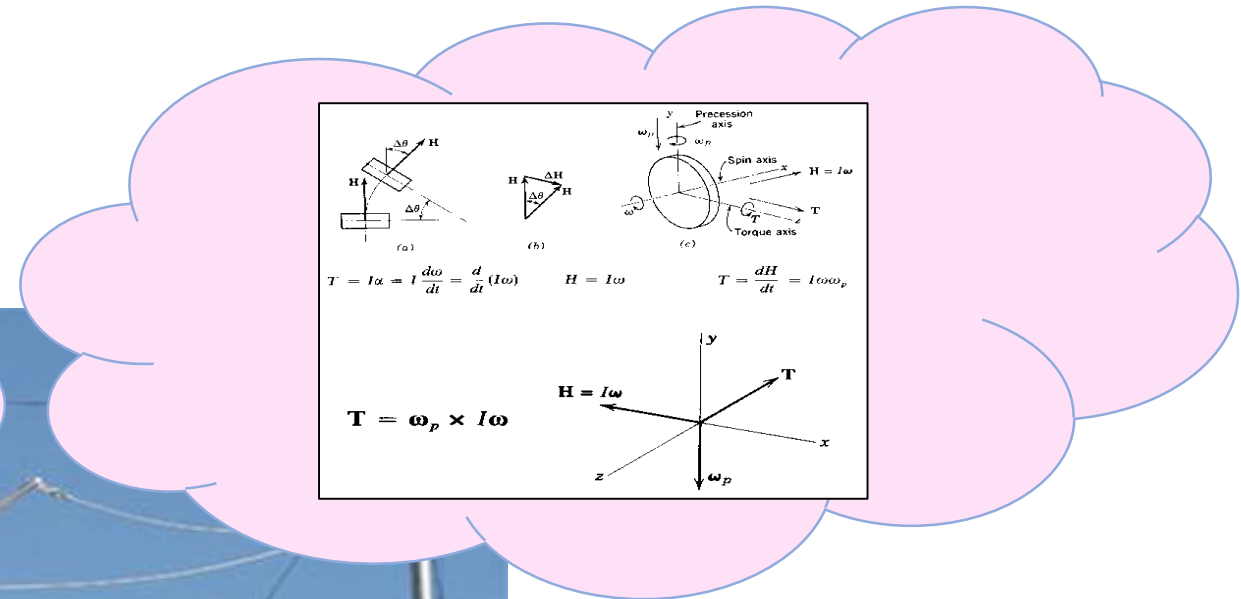


ASME, INCOSE, SAE, AIAA FAA, FDA, DoD V4I Member Enterprises, Academia, Regulators



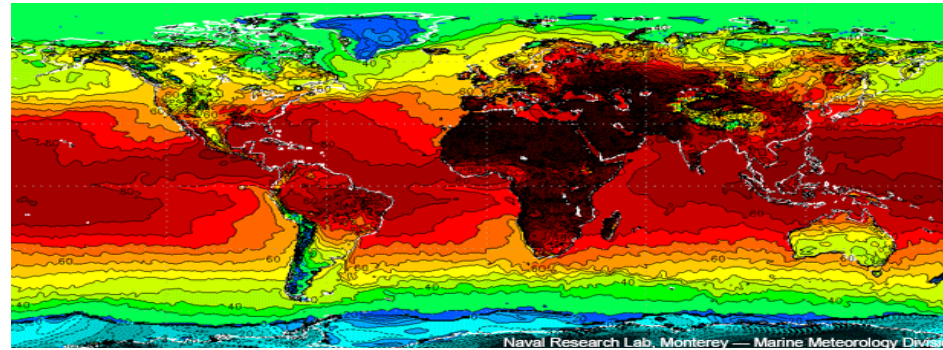
Requirements for trustable models

We cannot discuss maturity in development or use of models without discussing whether we can trust those models . . .



If we expect to use models to support critical decisions, then we are placing increased trust in models:

- Critical financial, other business decisions
- Human life safety
- Societal impacts
- Extending human capability

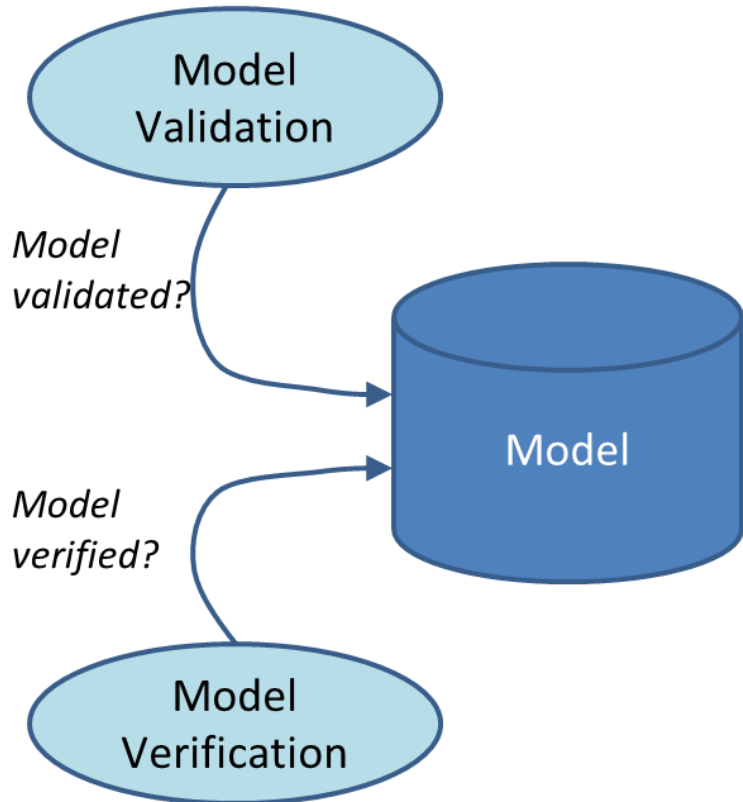


• MBSE Maturity requires that we characterize the structure of that trust and manage it:

- The Validation, Verification, and Uncertainty Quantification (VVUQ) of the models themselves.

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

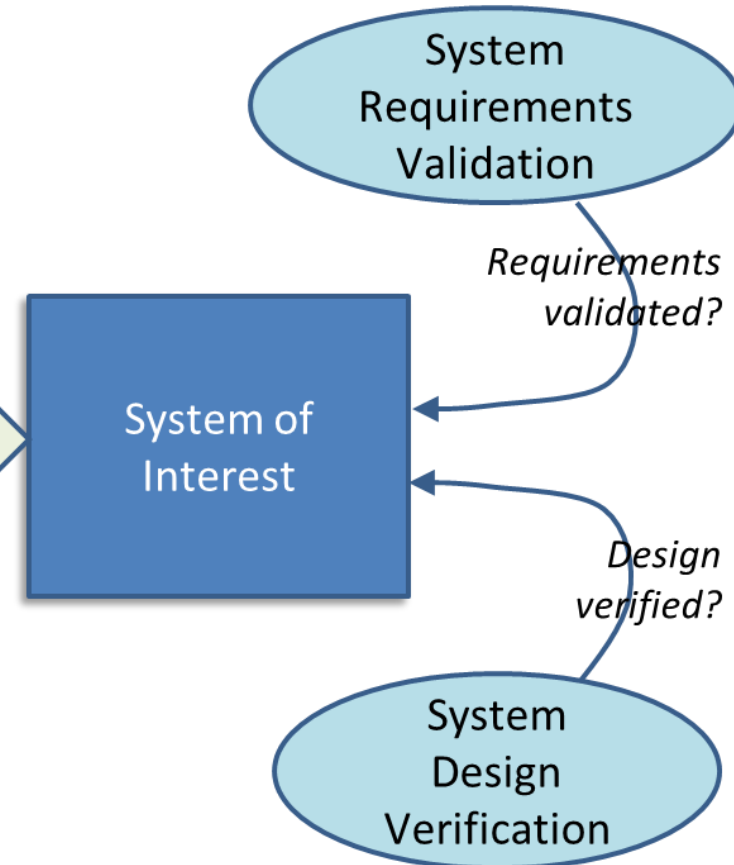
Does the Model adequately describe what it is intended to describe?



Does the Model implementation adequately represent what the Model says?

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

Do the System Requirements describe what stakeholders need?



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

Describes Some Aspect of

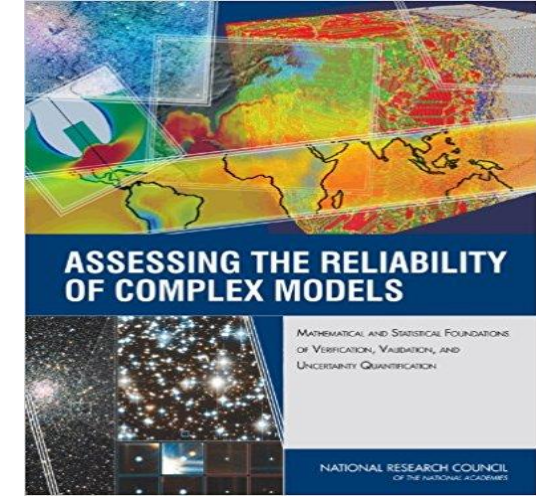
Don't forget: A model (on the left) may be used for system verification or validation (on the right!)

Quantitative Fidelity, including Uncertainty Quantification (UQ), including Systems Levels

- There is a large body of literature on a mathematical subset of the model UQ problem, in ways viewed as the heart of this work.
- But, some additional systems work is needed, and in progress, as to the more general VVUQ framework, suitable for general standards or guidelines, and illustrations of same.

General structure of uncertainty / confidence tracing:

- Do the modeled external Interactions qualitatively cover the modeled Stakeholder Features over the range of intended S1 situations of interest?
- Quantify confidence / uncertainty that the modeled Stakeholder Feature Attributes quantitatively represent the real system concerns of the S1 Stakeholders with sufficient accuracy over the range of intended situation envelopes.
- Quantify confidence / uncertainty that the modeled Technical Performance Attributes quantitatively represent the real system external behavior of the S1 system with sufficient accuracy over the range of intended situation envelopes.



Related ASME activities and resources

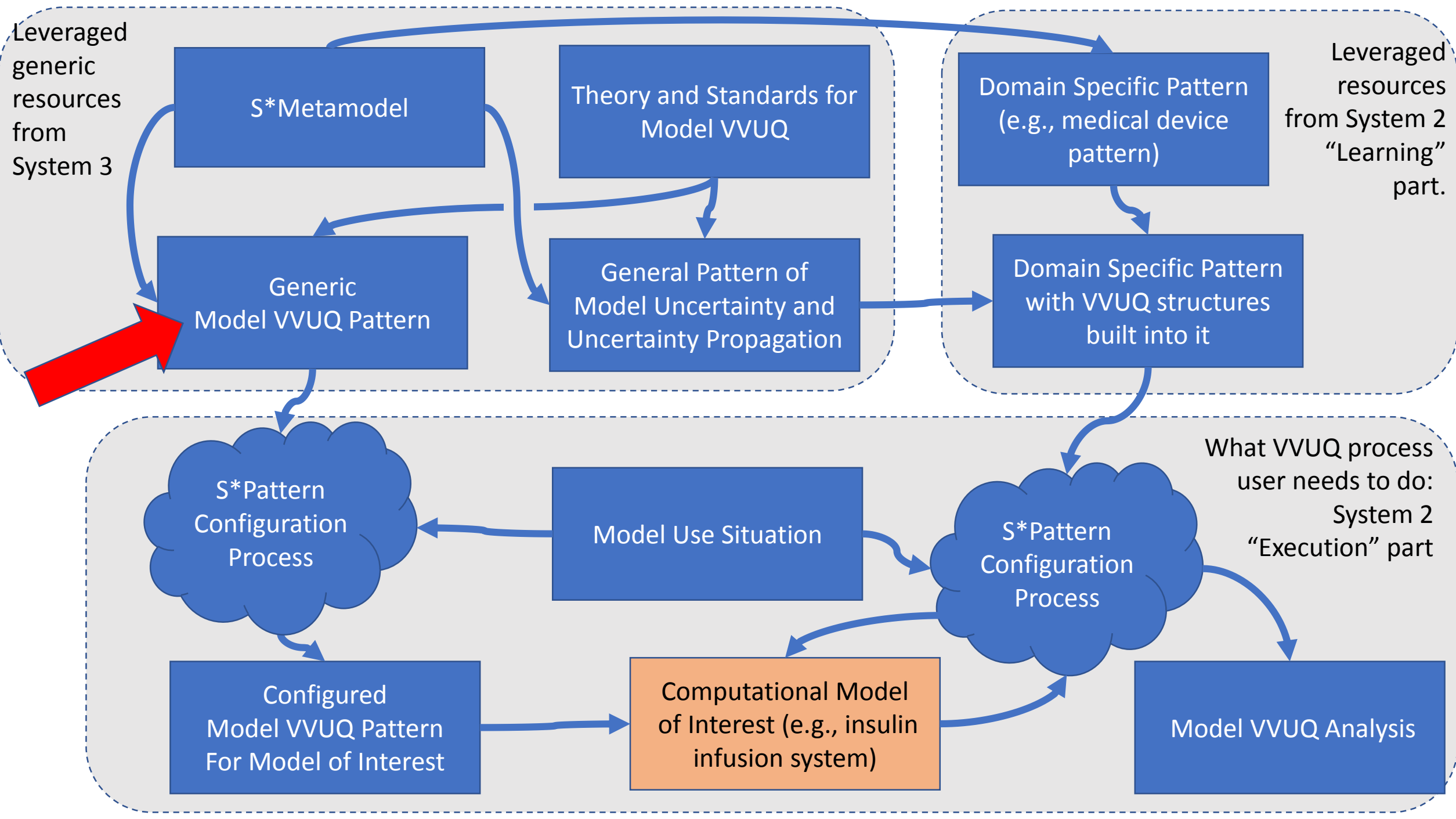
- ASME, has an active set of teams writing guidelines and standards on the Verification and Validation of Computational Models.
 - Inspired by the proliferation of computational models (FEA, CFD, Thermal, Stress/Strain, etc.)
 - It could fairly be said that this historical background means that effort was not focused on what most systems engineers would call “system models”
- Also conducts annual Symposium on Validation and Verification of Computational Models, in May.
- To participate in this work, in 2016 the speaker joined the ASME VV50 Committee:
 - With idea that the framework ASME set as foundation could apply well to systems level models; and . . .
 - with a pre-existing belief that system level models are not as different from discipline-specific physics models as believed by systems community.
- Also invited sub-team leader Joe Hightower (Boeing) to address the INCOSE IW2017 MBSE Workshop, on our related ASME activity.

ASME Verification & Validation Standards Committee

- V&V 10: Verification & Validation in Computational Solid Dynamics
- V&V20: Verification & Validation in Computational Fluid Dynamics and Heat Transfer
- V&V 30: Verification and Validation in Computational Simulation of Nuclear System Thermal Fluids Behavior
- V&V 40: Verification and Validation in Computational Modeling of Medical Devices
- V&V 50: Verification & Validation of Computational Modeling for Advanced Manufacturing
- V&V 60: Verification and Validation in Modeling and Simulation in Energy Systems and Applications

The Model VVUQ Pattern and its embedding in the SOI Pattern

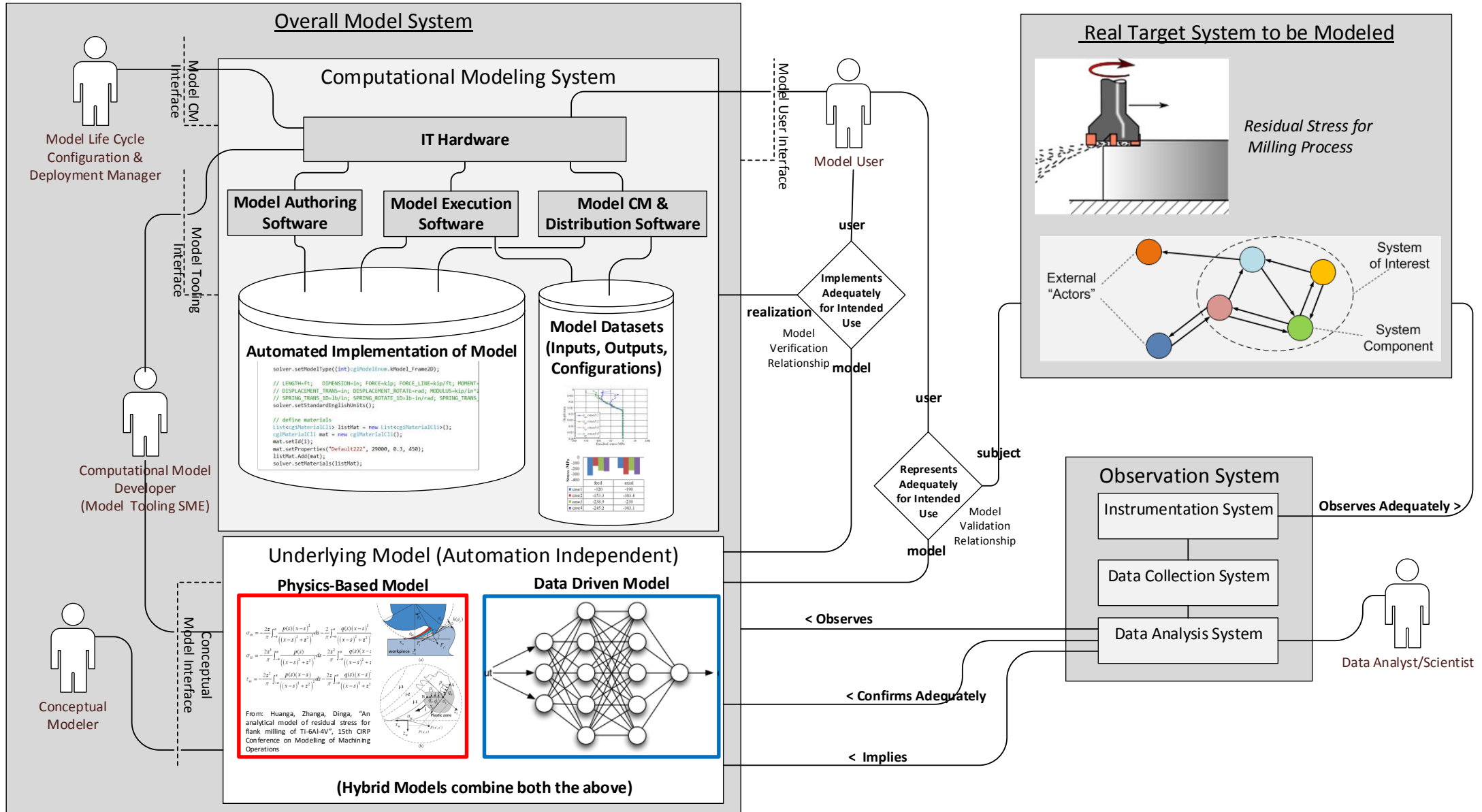
- An S*Pattern describing a computational model (strictly speaking a “computational model system”):
 - Formal stakeholder requirements for the model
 - Formal technical requirements for the model
 - The current state of satisfaction of same
 - Including in particular the VVUQ aspects of the model
- Used for many other purposes, including those noted earlier in this material.

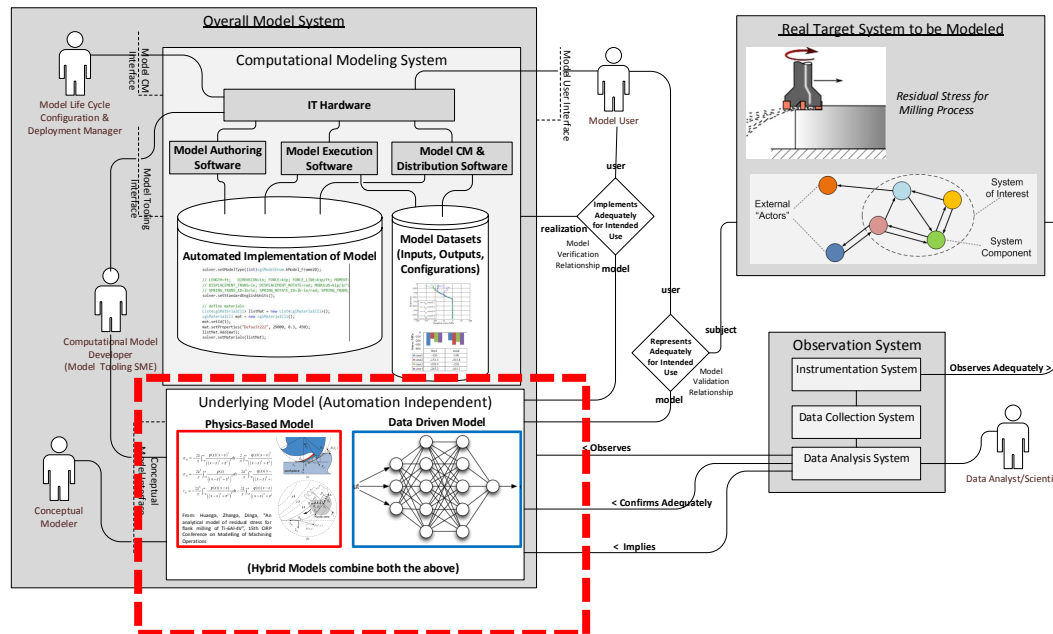


Physics-Based Models, Data-Driven Models, Hybrid Models, System Models

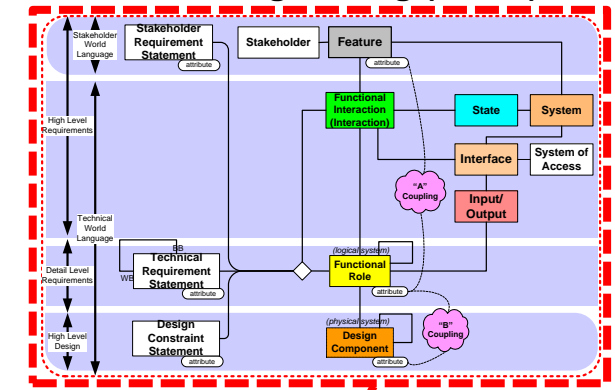
- Seen together here, in a unifying framework, so their differences are respected but also so that these models are not viewed as so isolated;
- Further connected by their appearance in the Model VVUQ Pattern, configurable for each.

Model VVUQ Pattern: Computational Modeling Domain Reference Boundaries (Manufacturing Process Example)

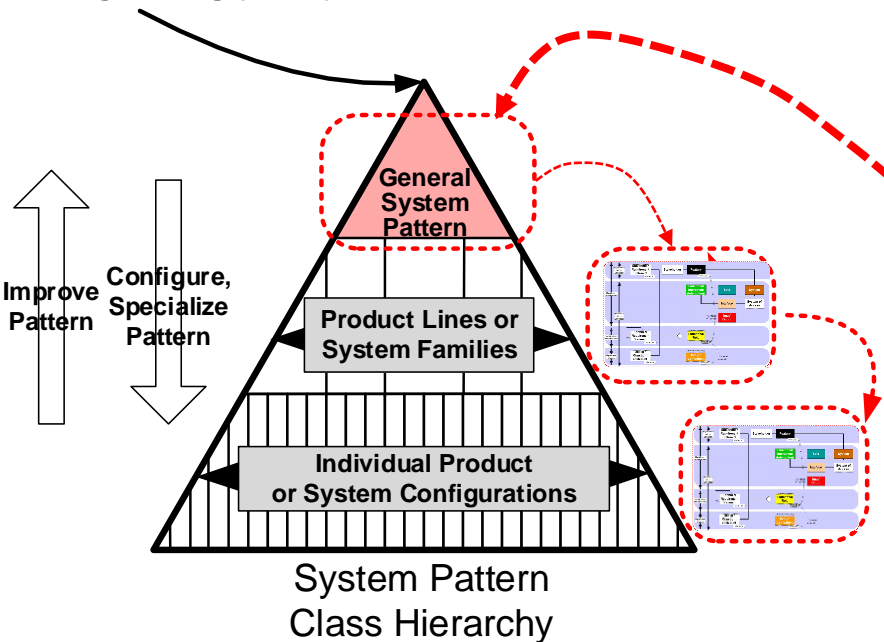




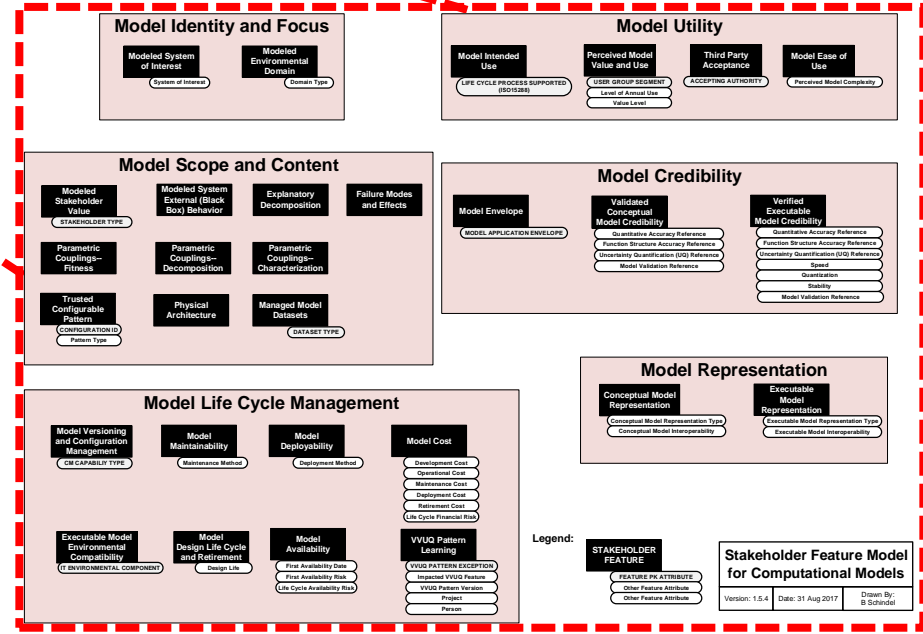
S*Metamodel for Model-Based Systems Engineering (MBSE)



S*Pattern Hierarchy for Pattern-Based Systems Engineering (PBSE)

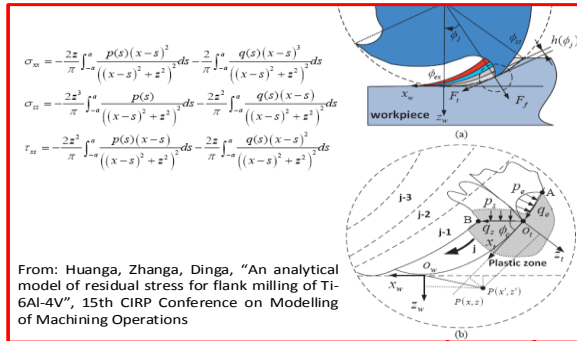


Describes Model



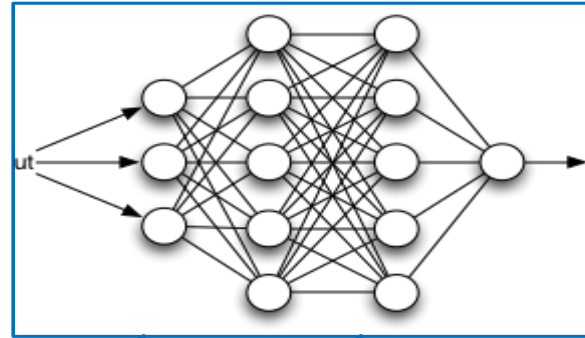
Physics-Based Model

- 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.



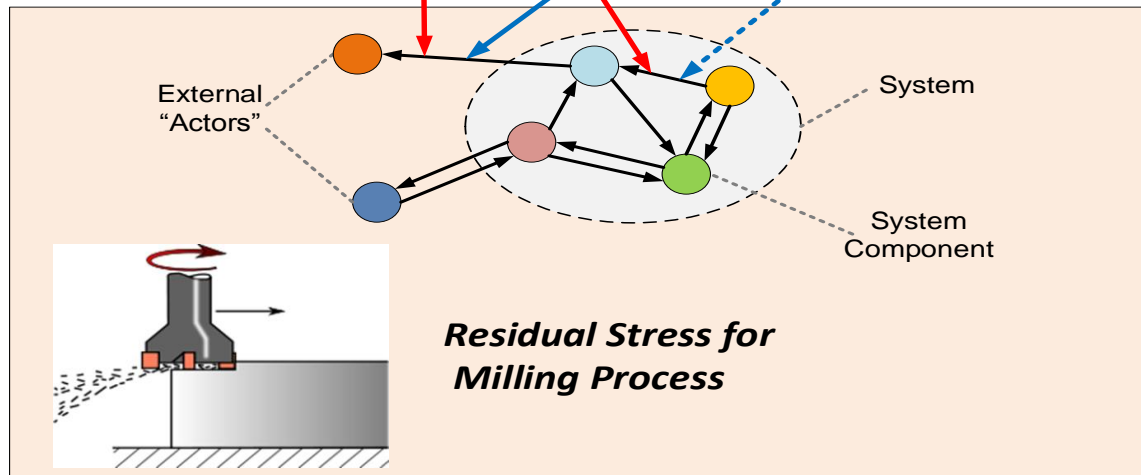
Data Driven Model

- 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.



- 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.

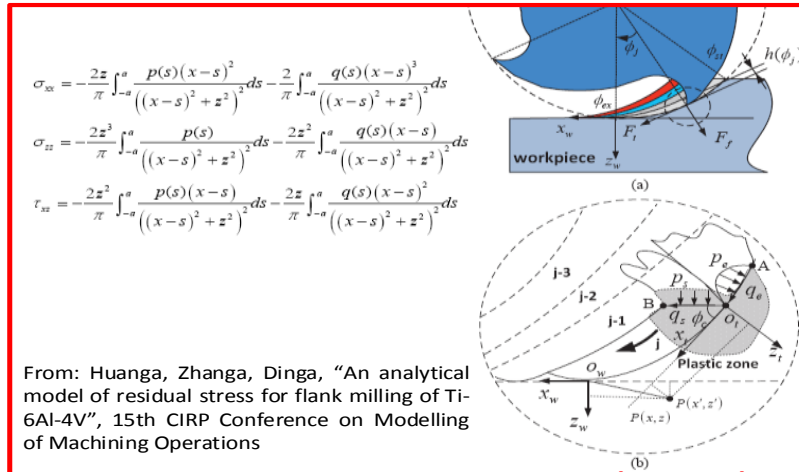
- Data scientists and their math/IT tools can apply here (data mining, pattern extraction, cognitive AI tooling).
- Tools and methods for discovery / extraction of recurring patterns of external behavior.



Real System Being Modeled

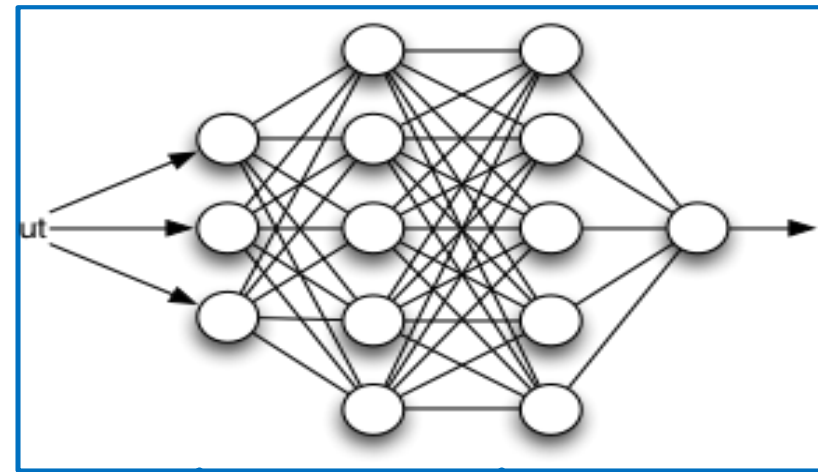
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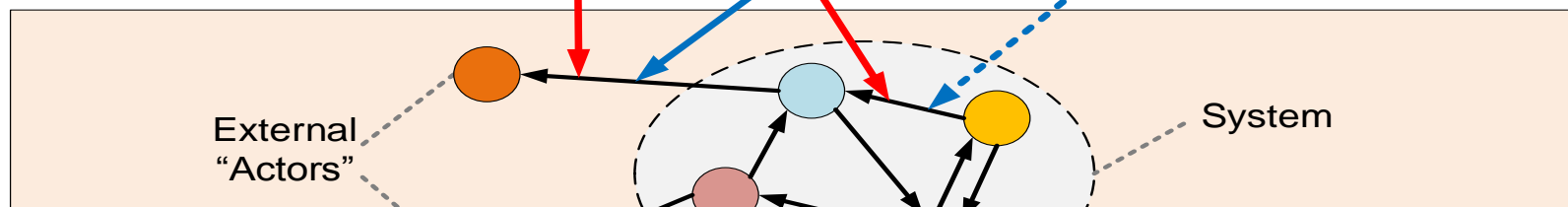
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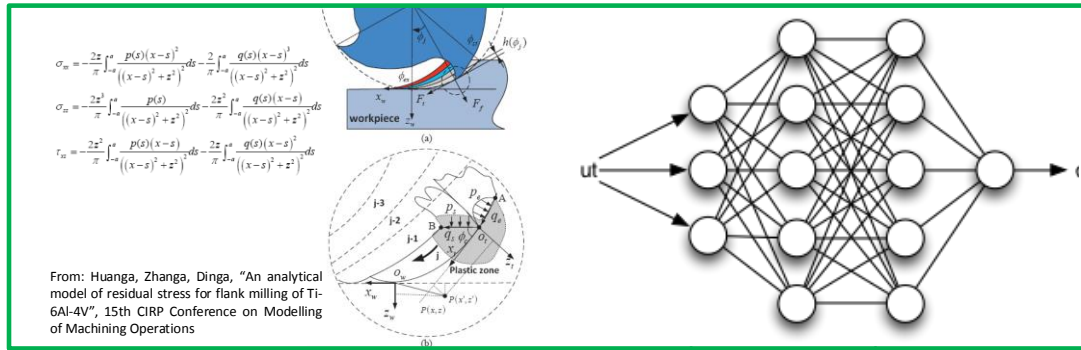
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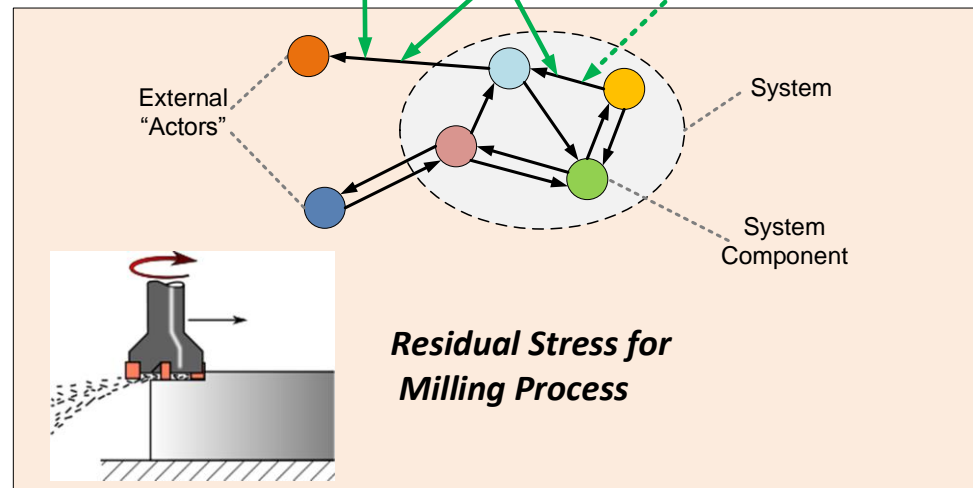
Hybrid Model: Both Data Driven and Physics-Based

- Predicts the external behavior of the System of Interest, visible externally to the external actors with which it interacts.
- Models (some aspects of) internal physical interactions of the System of Interest, and how they combine to cause/explain (some aspects of) externally visible behavior.
- Model has both external predictive value and (some) phenomena-based internal-to-external explanatory value.
- (Some) 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 (for some aspects) not internal explanatory value.



- 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.

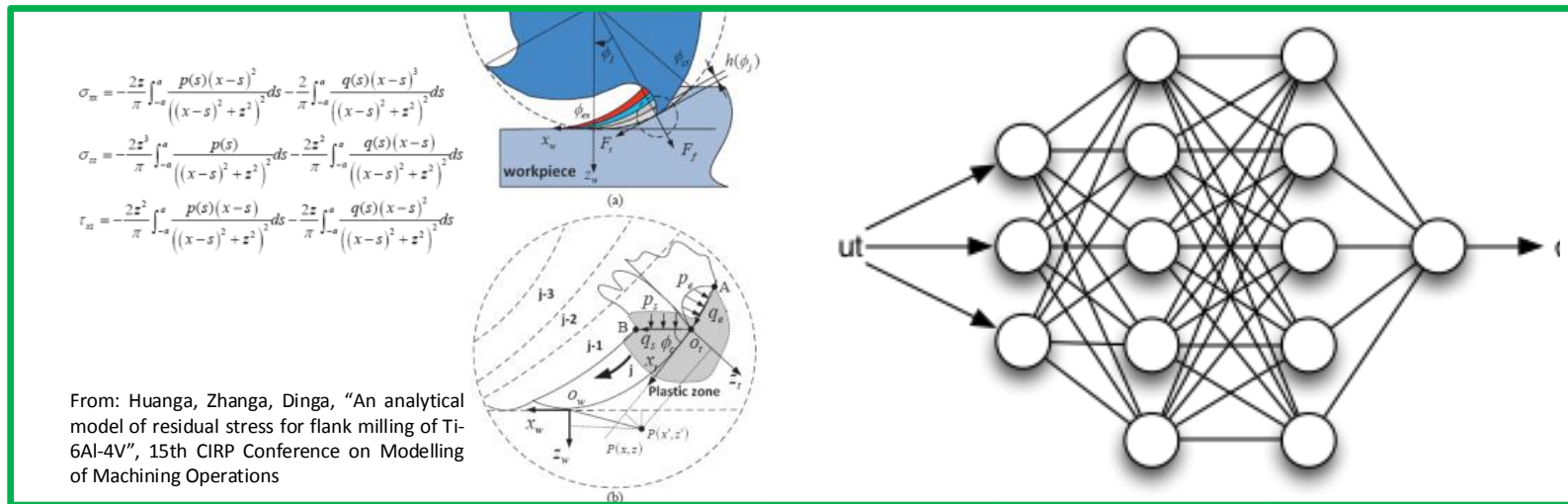
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Real System Being Modeled

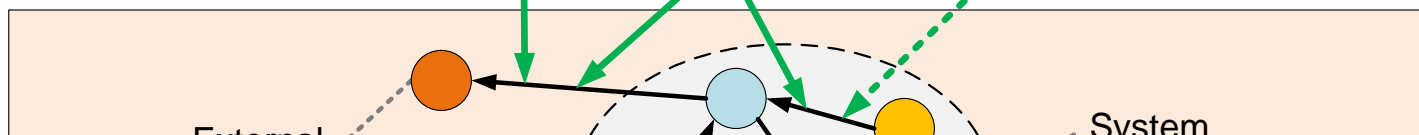
Hybrid Model: Both Data Driven and Physics-Based

- Predicts the external behavior of the System of Interest, visible externally to the external actors with which it interacts.
- Models (some aspects of) internal physical interactions of the System of Interest, and how they combine to cause/explain (some aspects of) externally visible behavior.
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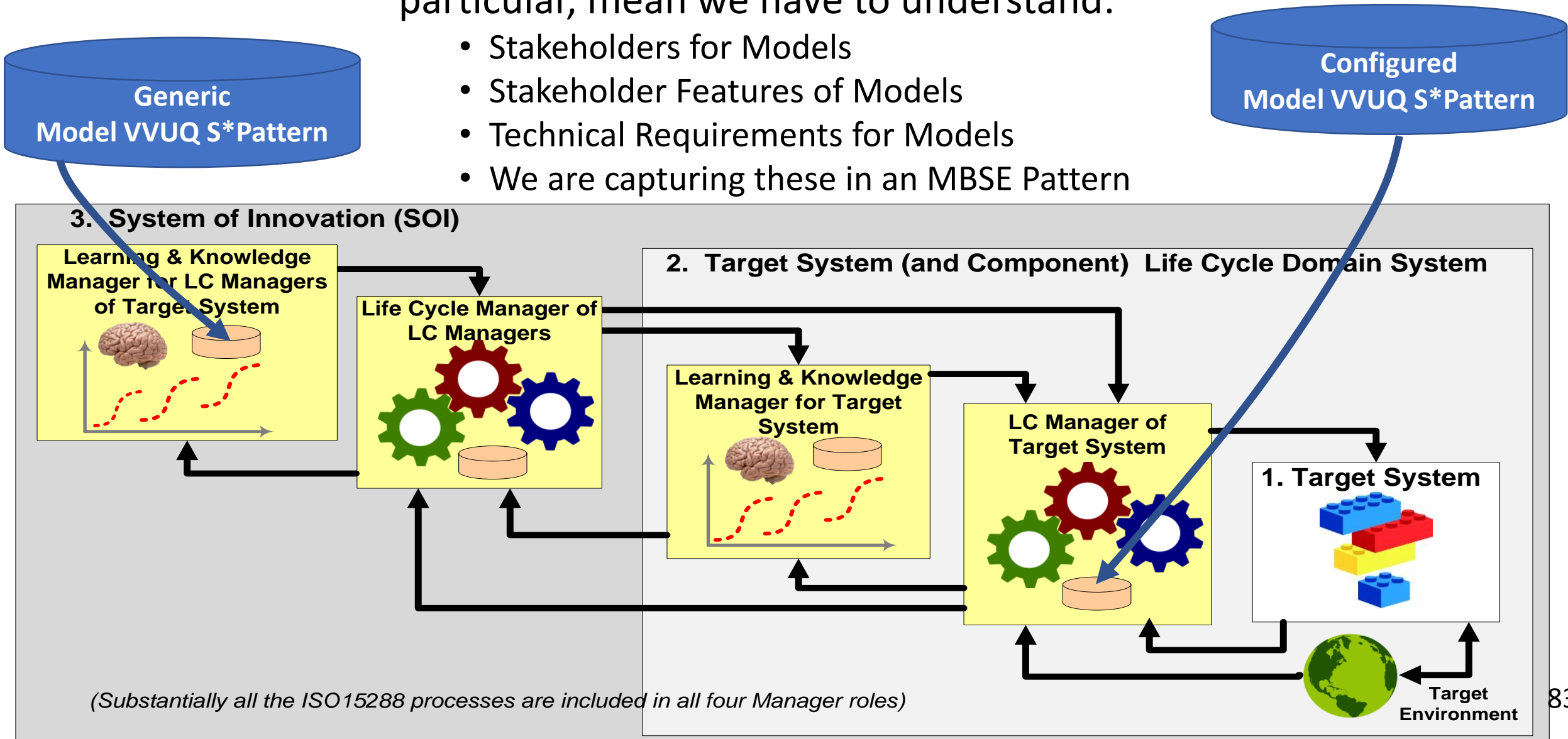
- Data scientists and their math/IT tools can apply here (data mining, pattern extraction, cognitive AI tooling).
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Requirements “template” for trustable, manageable models

MBSE Maturity in general, and VVUQ for Models in particular, mean we have to understand:

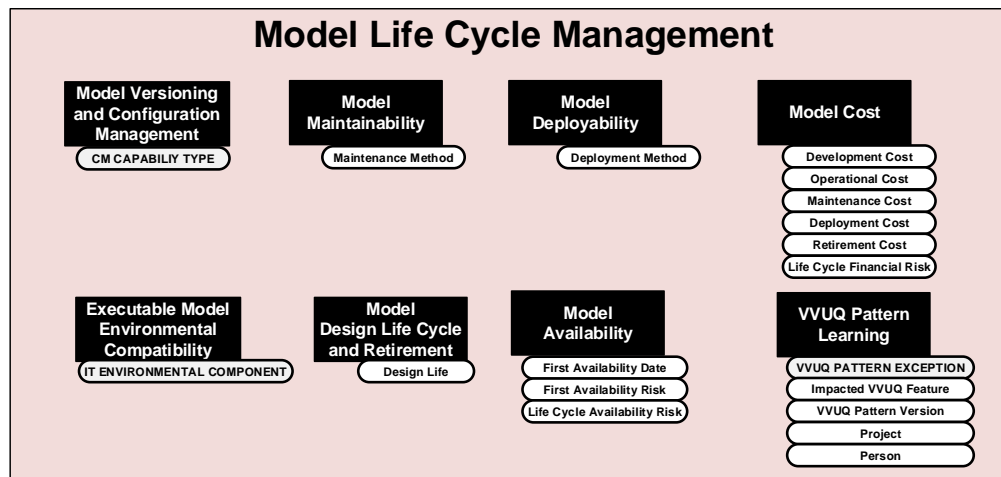
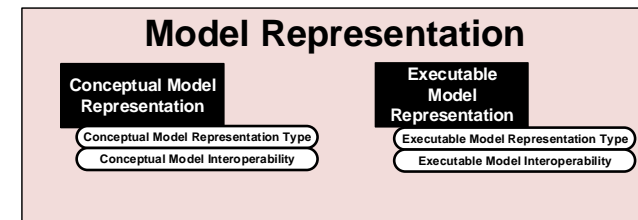
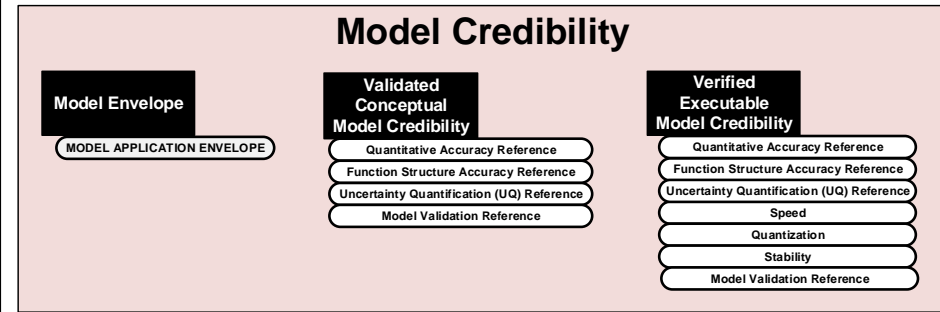
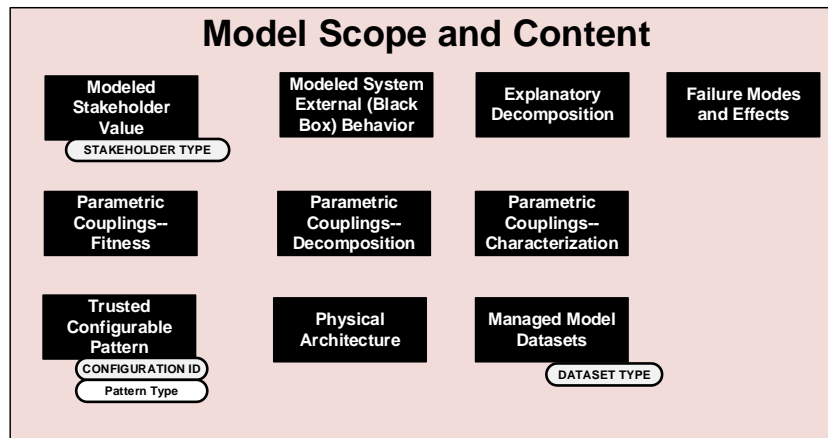
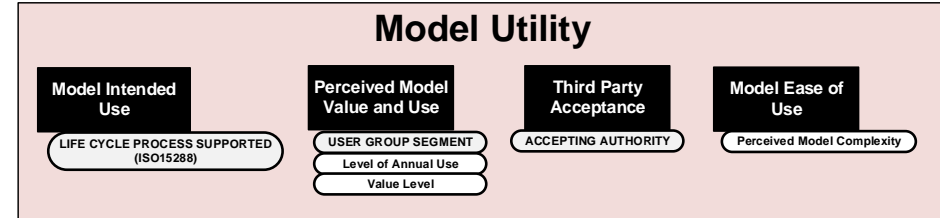
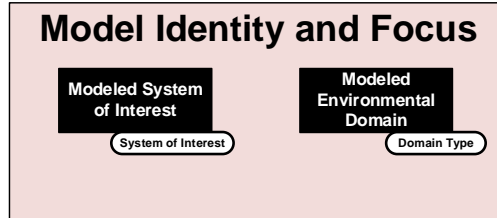
- Stakeholders for Models
- Stakeholder Features of Models
- Technical Requirements for Models
- We are capturing these in an MBSE Pattern



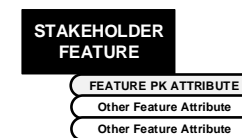
Stakeholders for Models

Model Stakeholder Type	Definition
Model User	A person, group, or organization that directly uses a model for its agreed upon purpose. May include technical specialists, non-technical decision-makers, customers, supply chain members, regulatory authorities, or others.
Model Developer	A person who initially creates a model, from conceptualization through implementation, validation, and verification, including any related model documentation. Such a person may or may not be the same as one who subsequently maintains the model.
Model Maintainer	A person who maintains and updates a model after its initial development. In effect, the model maintainer is a model developer after the initial release of a model.
Model Deployer-Distributor	A person or organization that distributes and deploys a model into its intended usage environment, including transport and installation, through readiness for use.
Model Use Supporter	A person who supports or assists a Model User in applying a model for its intended use. This may include answering questions, providing advice, addressing problems, or other forms of support.
Regulatory Authority	An organization that is responsible for generating or enforcing regulations governing a domain.
Model Investor-Owner	A person or organization that invests in a model, whether through development, purchase, licenses, or otherwise, expecting a benefit from that investment.

Model VVUQ Pattern: Model Stakeholder Features Overview



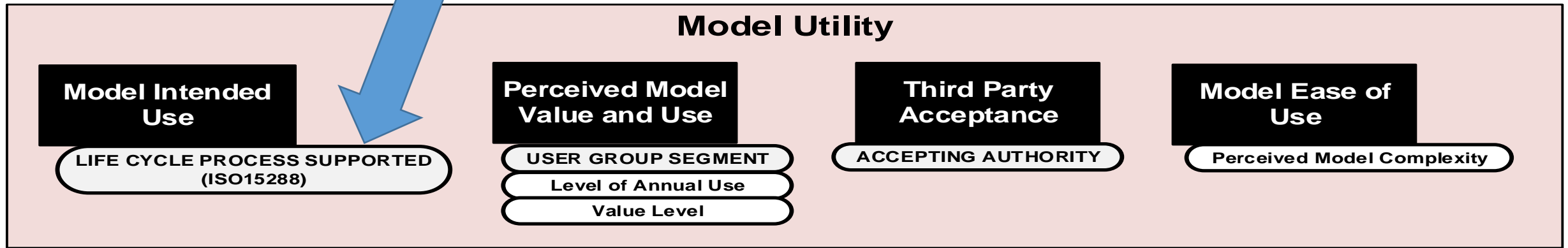
Legend:



Stakeholder Feature Model for Computational Models		
Version: 1.5.4	Date: 31 Aug 2017	Drawn By: B Schindel

The ISO 15288 Processes provide the Model Stakeholder Feature Set for Planning & Assessment

(Other Features on previous slide)



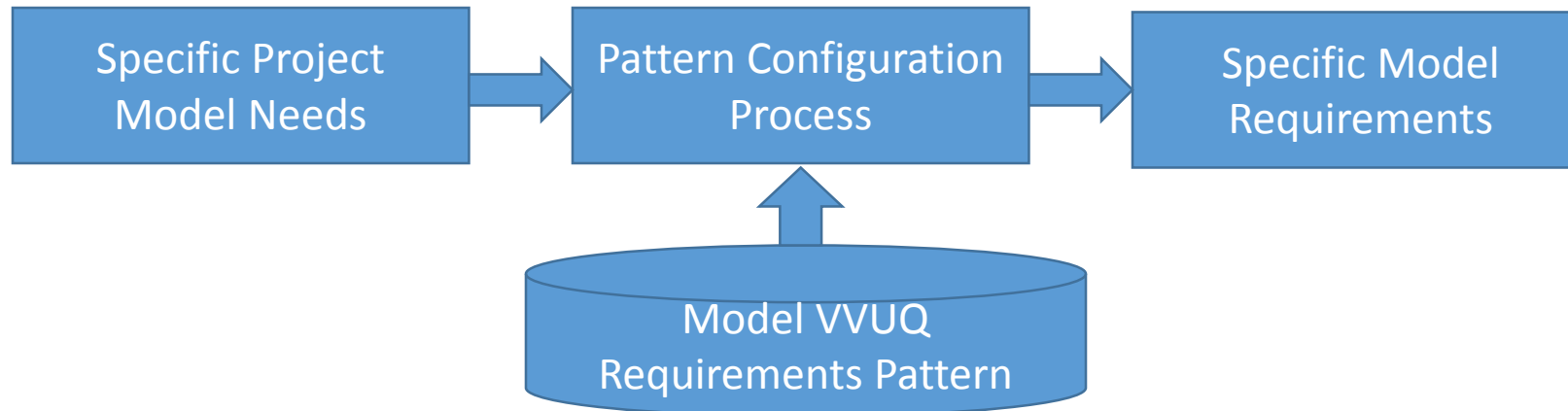
Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Describes the intended use, utility, and value of the model													
Model Utility	Model Intended Use	The intended purpose(s) or use(s) of the model.	Life Cycle Process Supported	The intended life cycle management process to be supported by the model, from the ISO15288 process list. More than one value may be listed.	X					X	X	X	X
	Perceived Model Value and Use	The relative level of value ascribed to the model, by those who use it for its stated purpose.	User Group Segment	The identify of using group segment (multiple)	X					X	X	X	X
			Level of Annual Use	The relative level of annual use by the segment	X					X	X	X	X
			Value Level	The value class associated with the model by that segment	X					X	X	X	X
	Third Party Acceptance	The degree to which the model is accepted as authoritative, by third party regulators, customers, supply chains, and other entities, for its stated purpose.	Accepting Authority	The identity (may be multiple) of regulators, agencies, customers, supply chains, accepting the model	X					X	X	X	X
Model Ease of Use	The perceived ease with which the model can be used, as experienced by its intended users	Perceived Model Complexity	High, Medium Low	X					X		X	X	

Vision for a Practical Aid to Model Community

- In establishing model credibility, a computational model is verified and validated (VV), including quantification of related uncertainties (UQ):
 - With respect to not just the system it represents, but also the Model Requirements, specifying the intended use(s), user(s), and characteristics of that model.
- This vision is to make the generation of those Model Requirements easier, more complete, and more successful than would otherwise be the case—using the Model VVUQ Pattern.

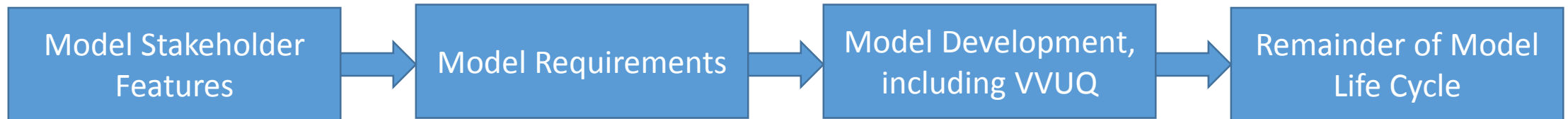
Vision for a Practical Aid to Model Community

- Vision of a guideline that includes a practical pattern for the efficient and effective planning and generation of computational models that have a higher likelihood of VVUQ and successful service.
- The smallest set of ideas necessary to achieve that goal.
- Makes use of ideas used in Pattern-Based Systems Engineering, a form of MBSE, for configurable models:

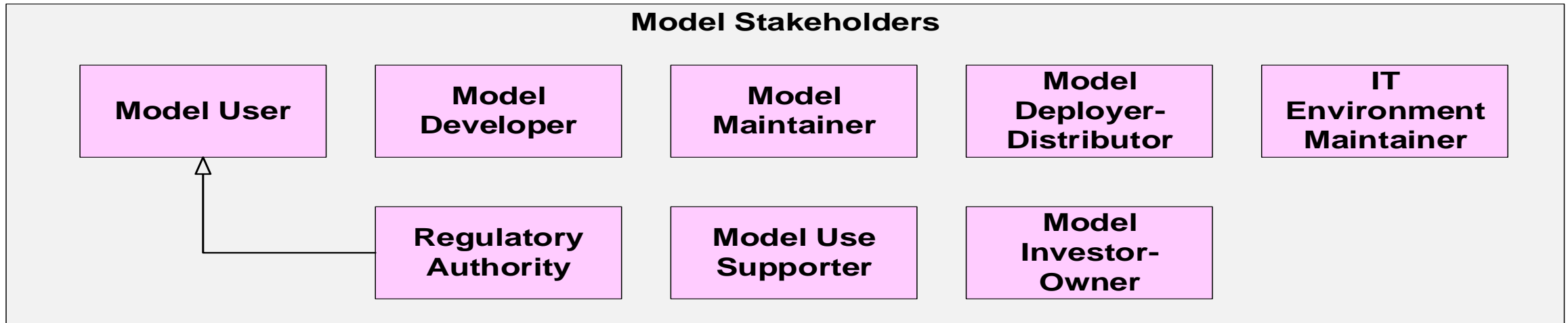


Vision for a Practical Aid to Model Community

- The foundation of this capability are the computational model's Stakeholder Features and the computational model's Requirements . . .



Stakeholders for Models



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Model Use Supporter	A person who supports or assists a Model User in applying a model for its intended use. This may include answering questions, providing advice, addressing problems, or other forms of support.
Regulatory Authority	An organization that is responsible for generating or enforcing regulations governing a domain.
Model Investor-Owner	A person or organization that invests in a model, whether through development, purchase, licenses, or otherwise, expecting a benefit from that investment.
IT Environment Maintainer	A person or organization that maintains the IT environment utilized by a computational model.

Computational Model Feature Groups: Configurable for Specific Models

Model Identity and Focus

Identifies the main subject or focus of the model.

Model Utility

Describes the intended use, user, utility, and value of the model.

Model Scope and Content

Describes the scope of content of the model.

Model Credibility

Describes the credibility of the model.

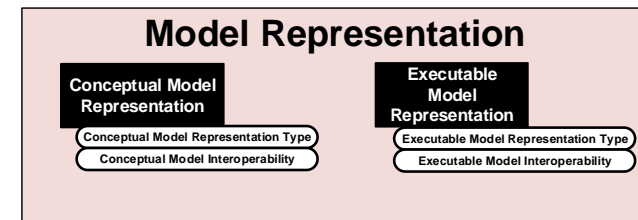
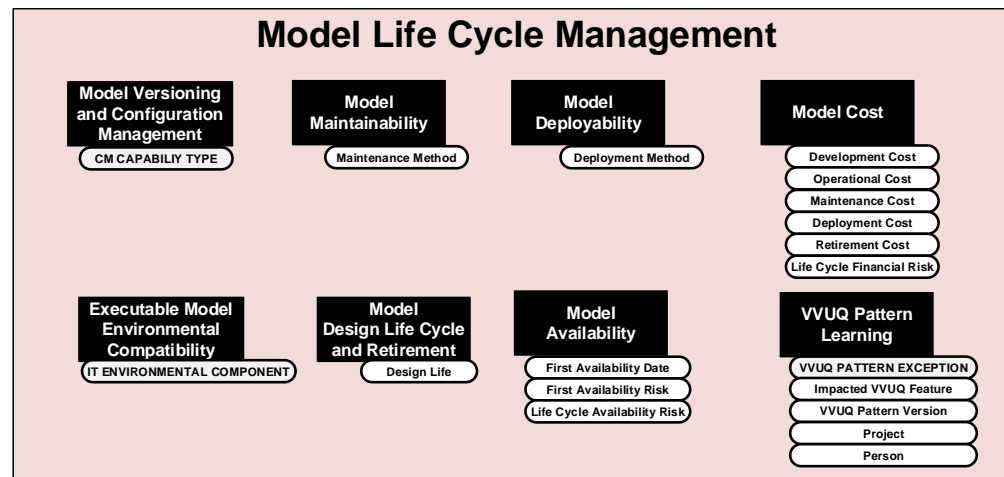
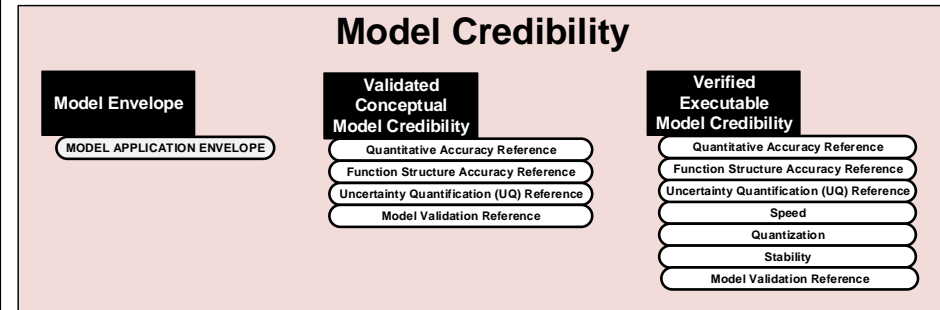
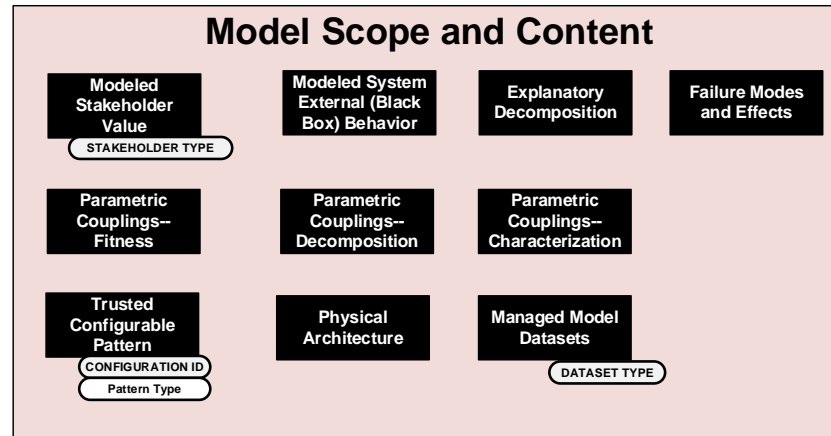
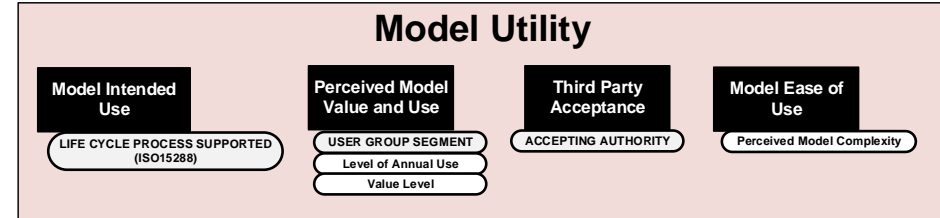
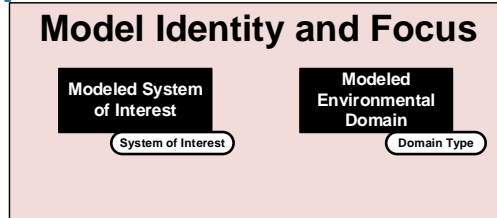
Model Life Cycle Management

Describes the related model life cycle management capabilities.

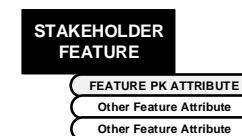
Model Representation

Describes the representation used by the model.

Computational Model Feature Groups: 29 Features, in 6 Feature Groups, Configurable for Specific Models



Legend:



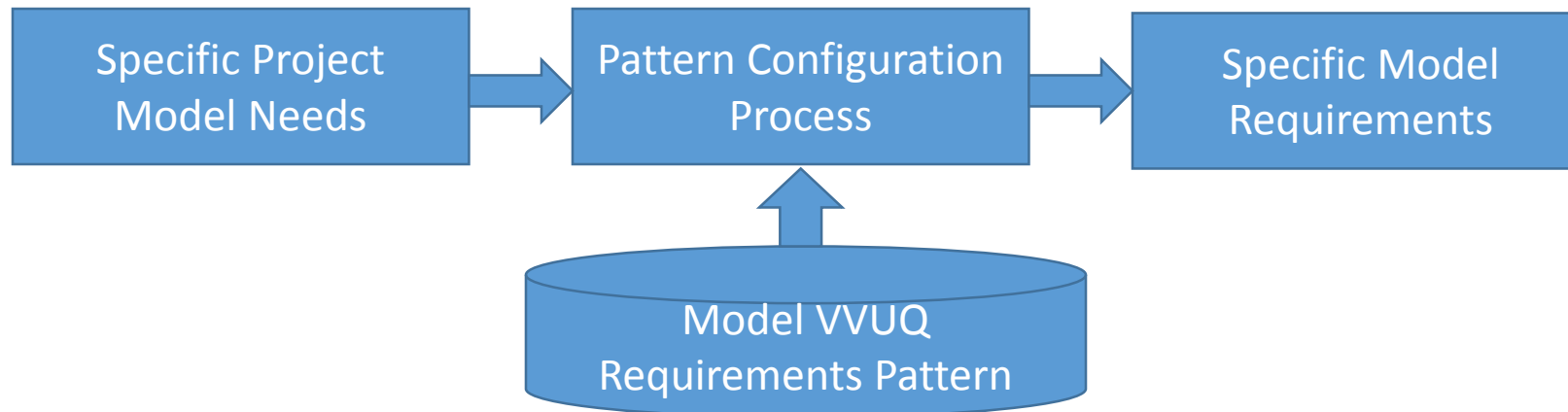
Stakeholder Feature Model for Computational Models		
Version: 1.5.4	Date: 31 Aug 2017	Drawn By: B Schindel

Computational Model Feature Groups: Configurable for Specific Models

- The Stakeholder Features are configurable Stakeholder expectations, intentions, and valued aspects for a computational model:
 - These can be “configured” like Lego® blocks, as a form of checklist to rapidly create the stakeholder-level expectations for a computational model.
 - And from them, the more technical Requirements for the model follow.

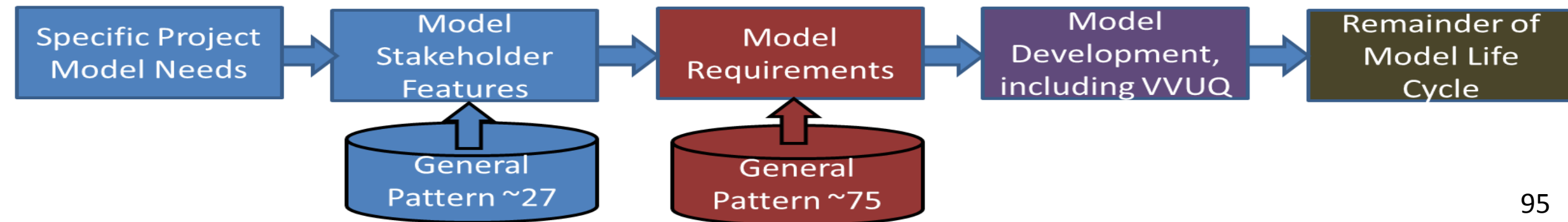
Generation of Model Stakeholder Features

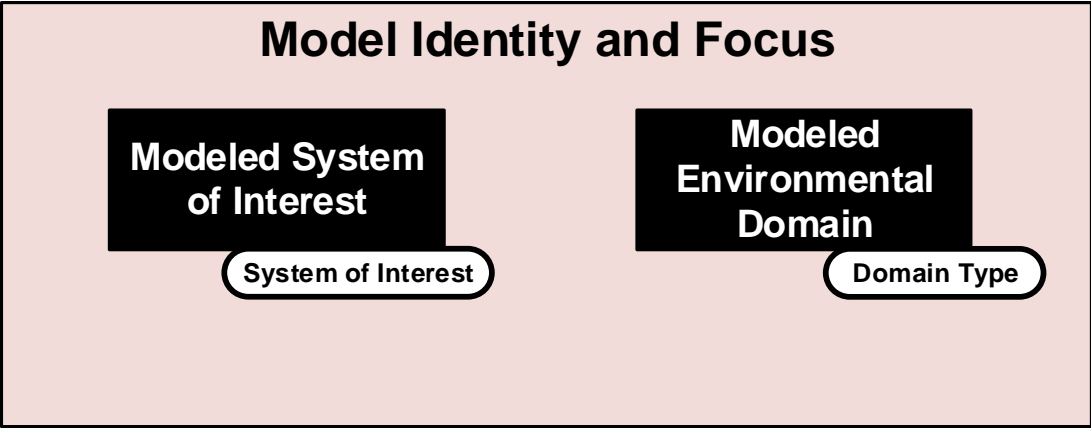
- The Model Stakeholder Feature Pattern is configured for a specific project by populating or depopulating the pattern's generic Features, and setting the values of its Feature Attributes:



Requirements for Models

- Requirements for a specific computational model are the basis of subsequent validation and verification of the model.
- The Requirements for a computational model are implied by the Stakeholder Features (see above), but with more details configured into them.
- Approximately 75 configurable general Requirements for Models have been identified and traced to the Stakeholder Features, in the current draft of the Model VVUQ Pattern.
- After these have been further vetted and polished in this project, they provide a rapid start way to generate a high quality set of Model Requirements in a production project.





Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Identifies the main subject or focus of the model													
Model Identity and Focus	Modeled System of Interest	Identifies the type of system this model describes.	System of Interest	Name of system of interest, or class of systems of interest	X					X	X	X	X
	Modeled Environmental Domain	Identifies the type of external environmental domain(s) that this model includes.	Domain Type(s)	Name(s) of modeled domains (manufacturing, distribution, use, etc.)	X					X	X	X	X

Model Utility

Model Intended Use

LIFE CYCLE PROCESS SUPPORTED
(ISO15288)

Perceived Model Value and Use

USER GROUP SEGMENT

Level of Annual Use

Value Level

Third Party Acceptance

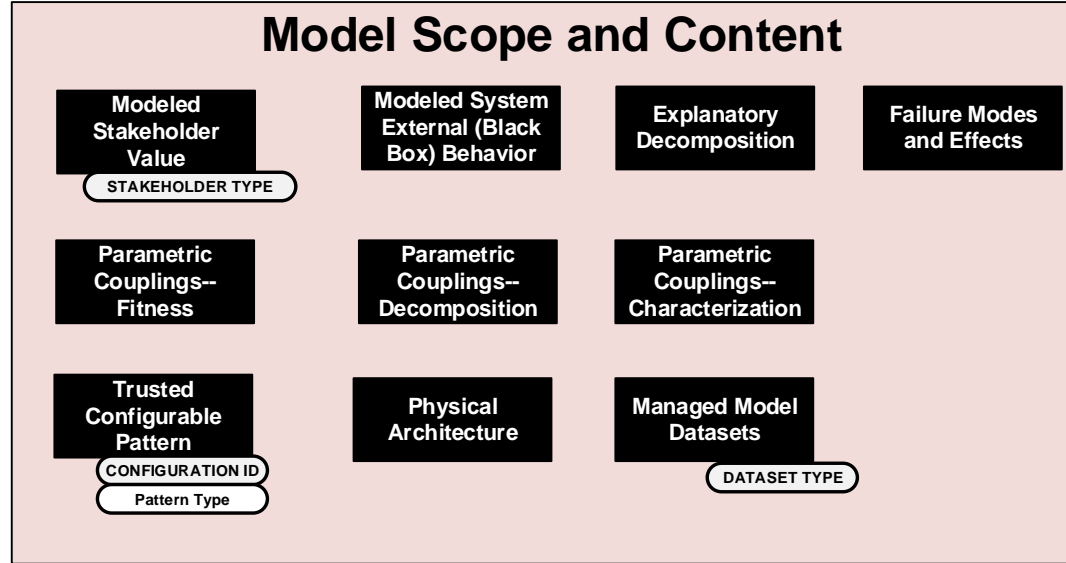
ACCEPTING AUTHORITY

Model Ease of Use

Perceived Model Complexity

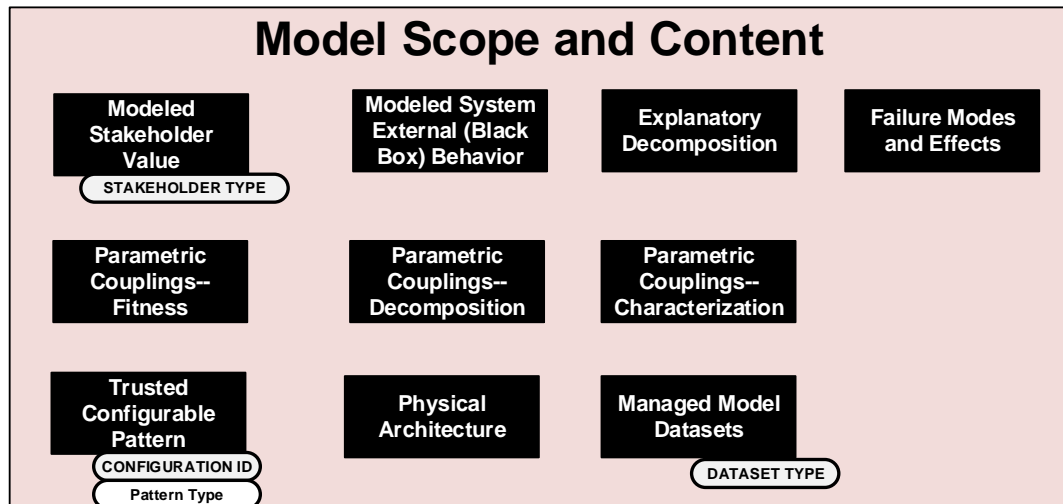
Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type					
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven				
Describes the intended use, utility, and value of the model																	
Model Utility	Model Intended Use	The intended purpose(s) or use(s) of the model.	Life Cycle Process Supported	The intended life cycle management process to be supported by the model, from the ISO15288 process list. More than one value may be listed.	X						X	X	X	X			
	Perceived Model Value and Use	The relative level of value ascribed to the model, by those who use it for its stated purpose.	User Group Segment	The identify of using group segment (multiple)	X						X	X	X	X			
			Level of Annual Use	The relative level of annual use by the segment	X						X	X	X	X			
			Value Level	The value class associated with the model by that segment	X						X	X	X	X			
	Third Party Acceptance	The degree to which the model is accepted as authoritative, by third party regulators, customers, supply chains, and other entities, for its stated purpose.	Accepting Authority	The identity (may be multiple) of regulators, agencies, customers, supply chains, accepting the model	X						X	X	X	X			
Model Ease of Use	The perceived ease with which the model can be used, as experienced by its intended users	Perceived Model Complexity	High, Medium Low	X						X		X	X				

Model Scope and Content



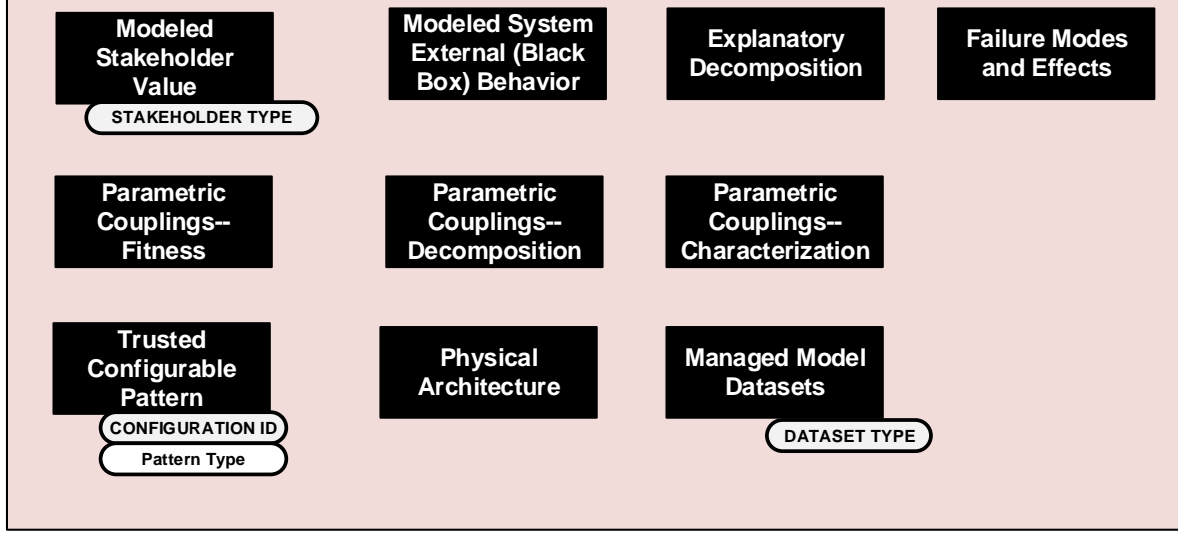
Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type		
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven	
Describes the scope of content of the model														
Model Scope of Content	Modeled Stakeholder Value	The capability of the model to describe fitness or value of the System of Interest, by identifying its stakeholders and modeling the related Stakeholder Features.	Stakeholder Type	Classes of covered stakeholders (may be multiple)	X						X	X	X	X
	Modeled System External (Black Box) Behavior	The capability of the model to represent the objective external ("black box") technical behavior of the system, through significant interactions with its environment, based on modeled input-output exchanges through external interfaces, quantified by technical performance measures, and varying behavioral modes.			X					X			X	X
	Explanatory Decomposition	The capability of the model to represent the decomposition of its external technical behavior, as explanatory internal ("white box") internal interactions of decomposed roles, further quantified by internal technical performance measures, and varying internal behavioral modes.			X					X			X	
	Physical Architecture	The capability of the model to represent the physical architecture of the system of interest. This includes identification of its major physical components and their architectural relationships.			X					X			X	

Model Scope and Content



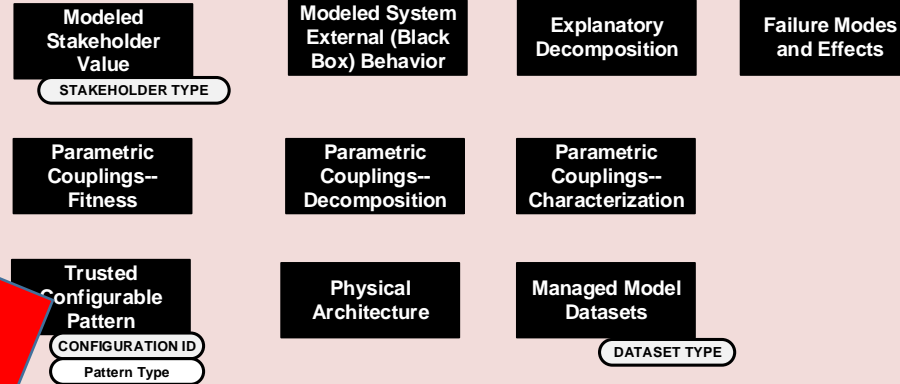
Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Describes the scope of content of the model													
	Parametric Couplings--Fitness	The capability of the model to represent quantitative (parametric) couplings between stakeholder-valued measures of effectiveness and objective external black box behavior performance measures.			X					X		X	X
	Parametric Couplings--Decomposition	The capability of the model to represent quantitative (parametric) couplings between objective external black box behavior variables and objective internal white box behavior variables.			X					X		X	X
	Parametric Couplings--Characterization	The capability of the model to represent quantitative (parametric) couplings between objective behavior variables and physical identity (material of construction, part or model number).			X					X		X	
	Managed Model Datasets	The capability of the model to include managed datasets for use as inputs, parametric characterizations, or outputs	Dataset Type	The type(s) of data sets (may be multiple)	X		X			X		X	X
	Trusted Configurable Pattern	The capability of the model to serve as a configurable pattern, representing different modeled system configurations across a common domain, spreading the cost of establishing trusted model frameworks across a community of applications and configurations.	Configuration ID	A specific system of interest configuration within the family that the pattern framework can represent.	X		X			X	X	X	X
			Pattern ID	The identifier of the trusted configurable pattern.	X		X				X	X	X

Model Scope and Content



Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type						
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven					
Describes the scope of content of the model																		
Model Scope of Content	Failure Modes and Effects	The capability of the model to include identification and analysis of system failure modes, their impact effects, causes, and liklihoods of occurrence.				X						X	X	X				

Model Scope and Content



Of special importance to the economics of trust and VVUQ

Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
				Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Describes the scope of content of the model												
Parametric Couplings--Fitness	The capability of the model to represent quantitative (parametric) couplings between stakeholder-valued measures of effectiveness and objective external black box behavior performance measures.			X					X		X	X
Parametric Couplings--Decomposition	The capability of the model to represent quantitative (parametric) couplings between objective external black box behavior variables and objective internal white box behavior variables.			X					X		X	X
Parametric Couplings--Characterization	The capability of the model to represent quantitative (parametric) couplings between objective behavior variables and physical identity (material of construction, part or model number).			X					X		X	
Managed Model Datasets	The capability of the model to include managed datasets for use as inputs, parametric characterizations, or outputs	Dataset Type	The type(s) of data sets (may be multiple)	X		X			X		X	X
Trusted Configurable Pattern	The capability of the model to serve as a configurable pattern, representing different modeled system configurations across a common domain, spreading the cost of establishing trusted model frameworks across a community of applications and configurations.	Configuration ID	A specific system of interest configuration within the family that the pattern framework can represent.	X		X			X	X	X	X
		Pattern ID	The identifier of the trusted configurable pattern.	X		X			X	X	X	X



Model Credibility

Model Envelope

MODEL APPLICATION ENVELOPE

Validated Conceptual Model Credibility

Quantitative Accuracy Reference

Function Structure Accuracy Reference

Uncertainty Quantification (UQ) Reference

Model Validation Reference

Verified Executable Model Credibility

Quantitative Accuracy Reference

Function Structure Accuracy Reference

Uncertainty Quantification (UQ) Reference

Speed

Quantization

Stability

Model Validation Reference

Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-	Model Use Supporter	Regulatory Authority	Mdl Investor-	Physics Based	Data Driven
Describes the credibility of the model													
	Model Envelope	The capability of the model to meet its Model Credibility requirements over a stated range (envelope) of dynamical inputs, outputs, and parameter values.	Model Application Envelope	The range over which the model is intended for use.	X		X			X	X	X	X
	Validated Conceptual Model Credibility	The validated capability of the conceptual portion of the model to represent the System of Interest, with acceptable Credibility.	Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the conceptual model compared to the system of interest.	X					X	X	X	X
Function Structure Accuracy Reference			The specification reference describing the structural (presence or absence of behaviors) accuracy of the conceptual model compared to the system of interest.	X		X			X	X	X	X	
Uncertainty Quantification (UQ) Reference			The specification reference describing the degree of uncertainty of the Credibility of the conceptual model to the system of interest.	X		X			X	X	X	X	
Model Validation Reference			The reference documenting the validation of the conceptual model's Credibility to the system of interest.	X		X			X	X	X	X	

Model Credibility

Model Envelope

MODEL APPLICATION ENVELOPE

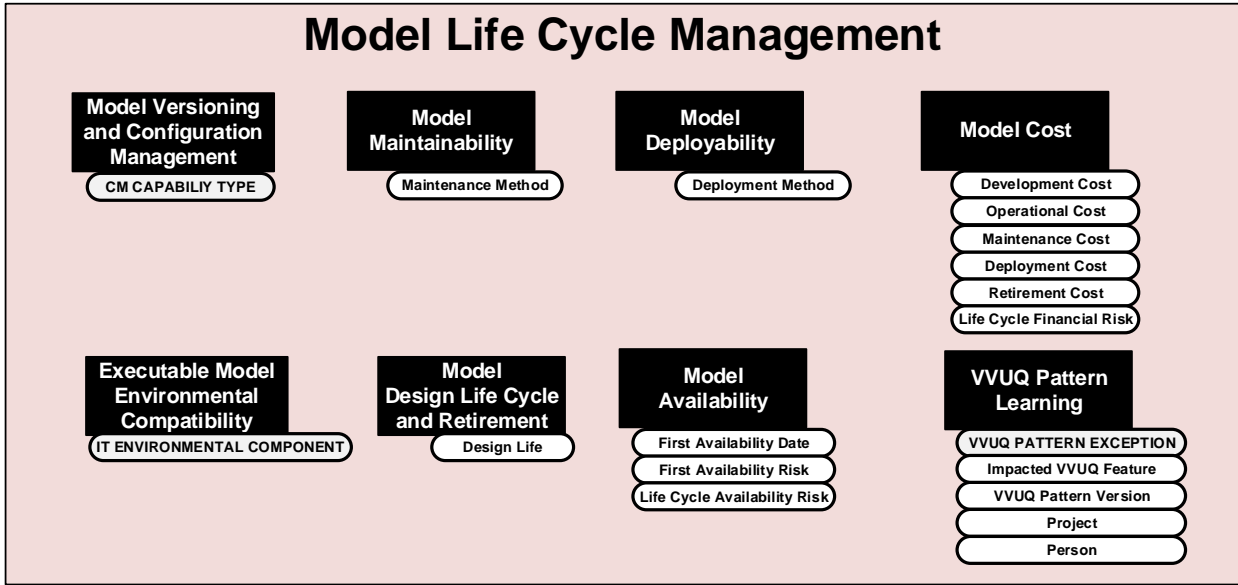
Validated
Conceptual
Model Credibility

- Quantitative Accuracy Reference
- Function Structure Accuracy Reference
- Uncertainty Quantification (UQ) Reference
- Model Validation Reference

Verified
Executable
Model Credibility

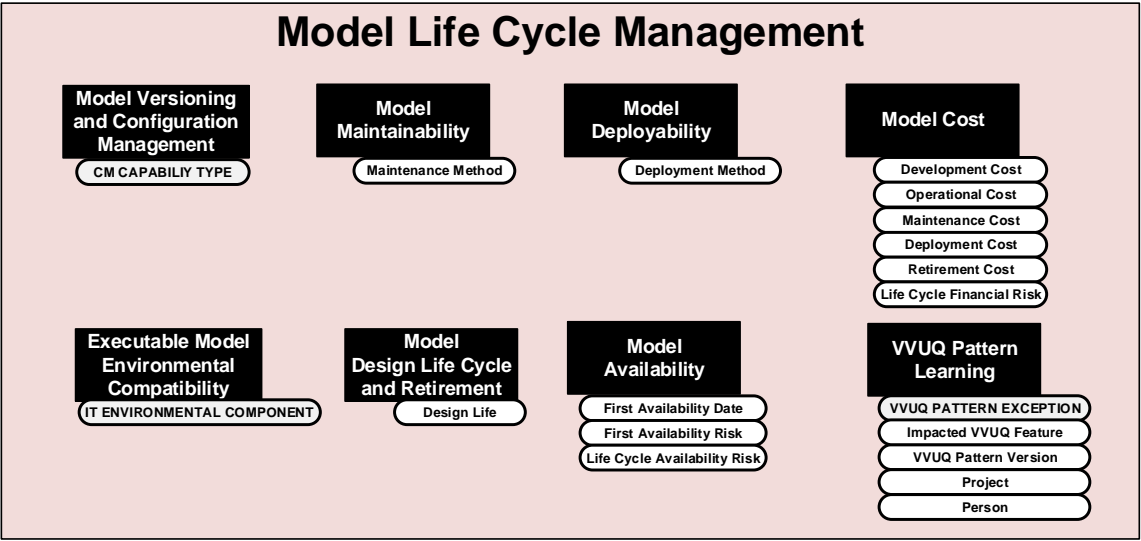
- Quantitative Accuracy Reference
- Function Structure Accuracy Reference
- Uncertainty Quantification (UQ) Reference
- Speed
- Quantization
- Stability
- Model Validation Reference

Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type		
					Model User	Model Developer	Model Maintainer	Mdl Deployer	Model Use Supporter	Regulatory Authority	Mdl Investor	Physics Based	Data Driven	
Model Credibility	Verified Executable Model Credibility	The verified capability of the executable portion of the model to represent the System of Interest, with acceptable Credibility.	Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the executable model to the conceptual model.	X		X				X	X	X	X
			Structural Accuracy Reference	The specification reference describing the structural (presence or absence of elements) accuracy of the executable model to the conceptual model.	X		X				X	X	X	X
			Uncertainty Quantification (UQ) Reference	The specification reference describing the degree of uncertainty of the Credibility of the executable model to the conceptual model.	X		X				X		X	X
			Speed	The specification reference describing the execution run time (speed) for the executable model.	X		X				X	X	X	X
			Quantization	The specification reference describing the quantization error of the executable model.	X		X				X	X	X	X
			Stability	The specification reference describing the level of stability of the accuracy and uncertainty of the executable model error characteristics.	X		X				X	X	X	X
			Model Validation Reference	The reference documenting the verification of the executable model's Credibility to the conceptual model.	X		X				X	X	X	X



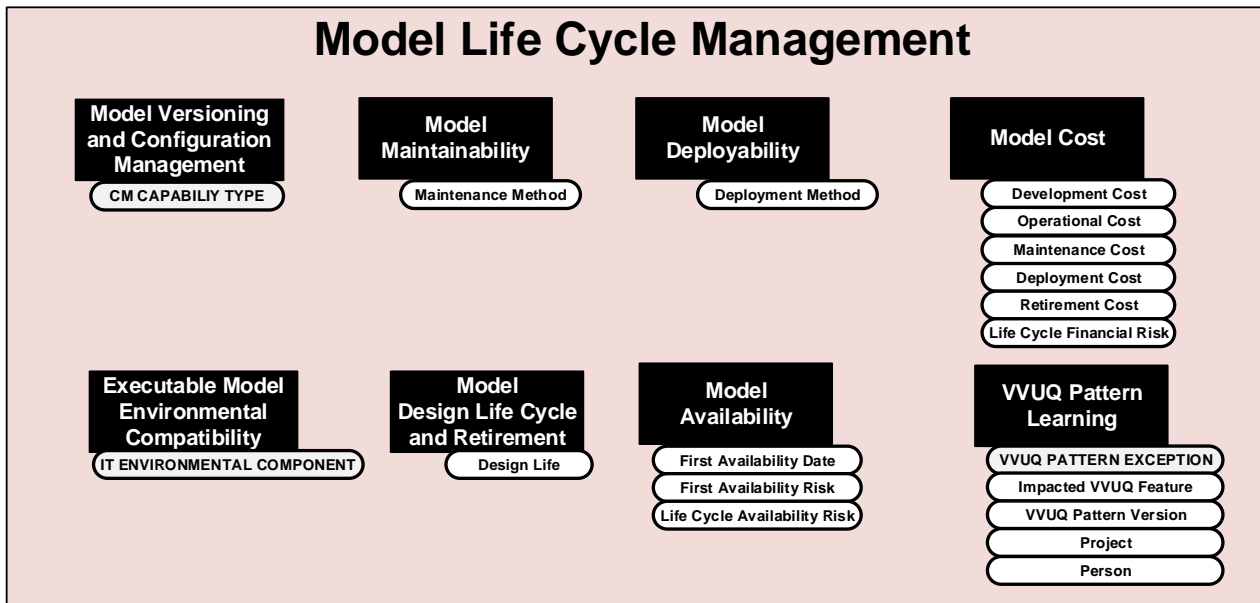
Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type		
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven	
Describes related model life cycle management capabilities														
Model Life Cycle Management	Model Versioning and Configuration Management	The capability of the model to provide for version and configuration management.	CM Capability Type	The type(s) of CM capabilities included (may be multiple)	X		X			X			X	X
	Executable Model Environmental Compatibility	The capability of the model to be compatibly supported by specified information technology environment(s), indicating compatibility, portability, and interoperability.	IT Environmental Component	The type(s) of IT environments or standards supported	X		X			X			X	X
	Model Design Life and Retirement	The capability of the model to be sustained over an indicated design life, and retired on a planned basis.	Design Life	The planned retirement date	X		X			X			X	X
	Model Maintainability	The relative ease with which the model can be maintained over its intended life cycle and use, based on capable maintainers, availability of effective model documentation, and degree of complexity of the model	Maintenance Method	The type of maintenance methodology used to maintain the model's capability and availability for the intended purposes over the intended life cycle.	X		X			X	X		X	X
	Model Deployability	The capability of the model to support deployment into service on behalf of intended users, in its original or subsequent updated versions	Deployment Method	The type of method used to deploy (possibly in repeating cycles) the model into its intended use environment.	X			X			X		X	X

Model Life Cycle Management

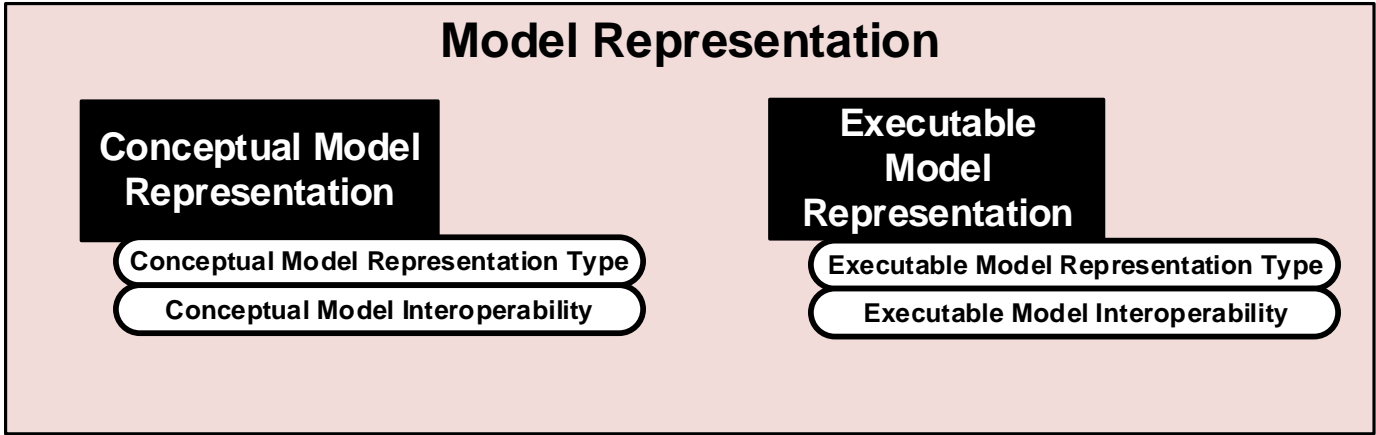


Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type		
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven	
Describes related model life cycle management capabilities														
Model Life Cycle Management	Model Cost	The financial cost of the model, including development, operating, and maintenance cost	Development Cost	The cost to develop the model, including its validation and verification, to its first availability for service date		X						X	X	X
			Operational Cost	The cost to execute and otherwise operate the model, in standardized execution load units	X						X	X	X	X
			Maintenance Cost	The cost to maintain the model			X				X	X	X	X
			Deployment Cost	The cost to deploy, and redeploy updates, per cycle				X			X	X	X	X
			Retirement Cost	The cost to retire the model from service, in a planned fashion	X						X	X	X	X
			Life Cycle Financial Risk	Risk to the overall life cycle cost of the model							X	X	X	X
	Model Availability	The degree and timing of availability of the model for its intended use, including date of its first availability and the degree of ongoing availability thereafter.	First Availability Date	Date when version will first be available	X						X	X	X	
			First Availability Risk	Risk to the scheduled date of first availability	X						X	X	X	
			Life Cycle Availability Risk	Risk to ongoing availability after introduction	X						X	X	X	

Model Life Cycle Management



Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer	Model Use Supporter	Regulatory Authority	Mdl Investor	Physics Based	Data Driven
VVUQ Pattern Learning	The ability to accumulate new discoveries about model-based methods into the VVUQ Pattern, as it is applied over model life cycles. These discoveries are exceptions to the existing VVUQ Pattern, and candidates for inclusion into future versions of that pattern.	VVUQ Pattern Exception	A summary of the exception noted to the current VVUQ Pattern (may be multiple exceptions)		X						X	X	X
		Impacted VVUQ Feature	The impacted existing, modified, or additional feature of the VVUQ Pattern.		X						X	X	X
		VVUQ Pattern Version	The version of the VVUQ Pattern in current use before change.		X						X	X	X
		Project	Identifies the project in which the exception was noted		X						X	X	X
		Person	Identifies the person describing the exception		X						X	X	X

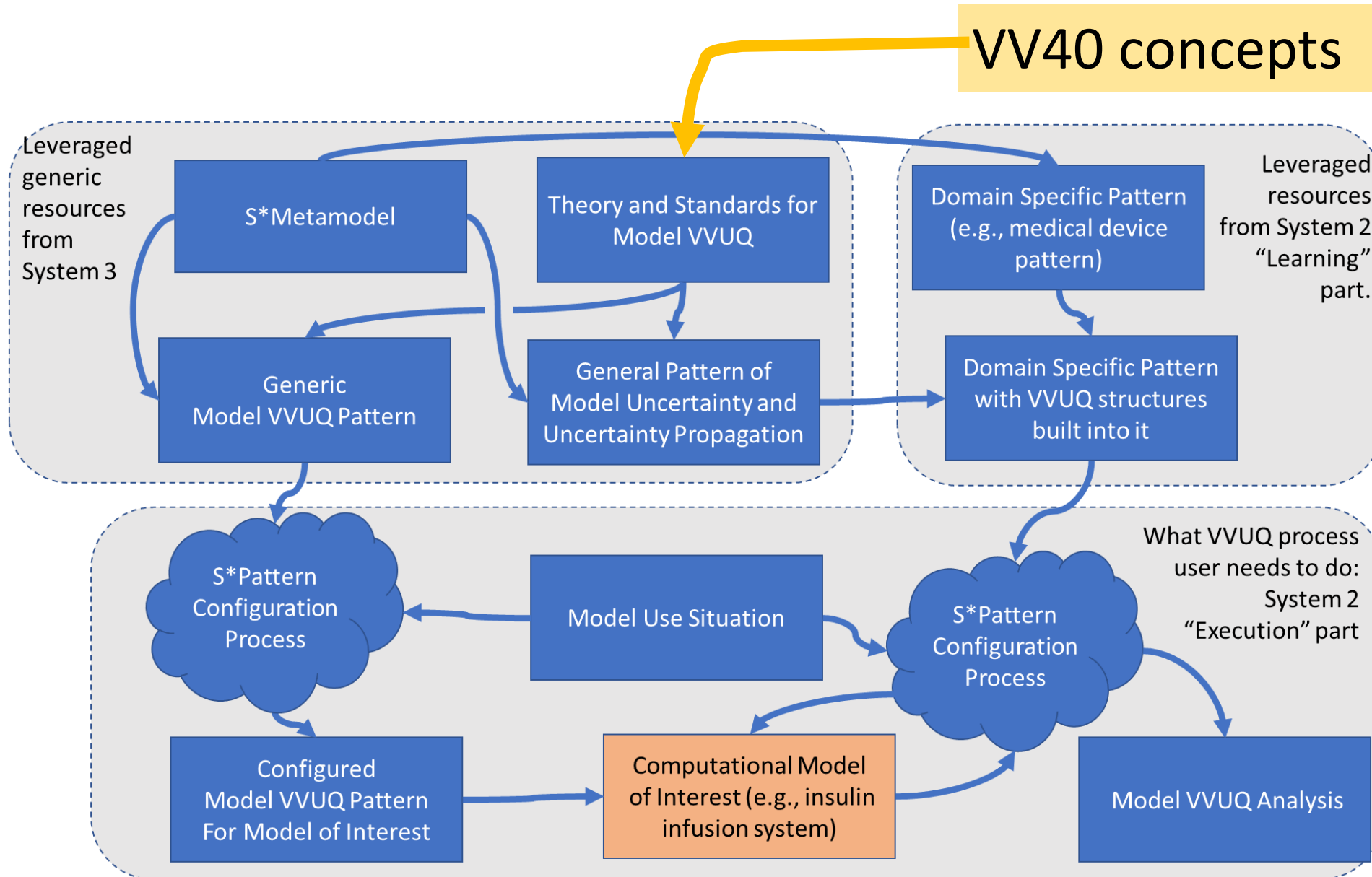


Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Feature Stakeholder							Model Type	
					Model User	Model Developer	Model Maintainer	Mdl Deployer-Distributor	Model Use Supporter	Regulatory Authority	Mdl Investor-Owner	Physics Based	Data Driven
Identifies the type of representation used by the model													
Model Representation	Conceptual Model Representation	The capability of the conceptual portion of the model to represent the system of interest, using a specific type of representation.	Conceptual Model Representation Type	The type of conceptual modeling language or metamodel used.	X		X			X		X	X
			Conceptual Model Interoperability	The degree of interoperability of the conceptual model, for exchange with other environments	X		X			X		X	X
	Executable Model Representation	The capability of the executable portion of the model to represent the system of interest, using a specific type of representation	Executable Model Representation Type	The type of executable modeling language or metamodel used.	X		X			X		X	X
			Executable Model Interoperability	The degree of interoperability of the executable model, for exchange with other environments	X		X			X		X	X

The Model VVUQ S*Pattern, enhanced by VV40

- While developing an example Medical Device Pattern use (see Attachment 2), we are also enhancing the Model VVUQ S*Pattern, by . . .
 - adding key aspects of the VV40 guideline to the structure of the Model VVUQ S*Pattern, so that a user of that pattern is also guided to populate VV40 structures supporting model VVUQ.
 - See Attachment 2.
 - Looking for feedback while still in progress.

The Model VVUQ S*Pattern, enhanced by VV40



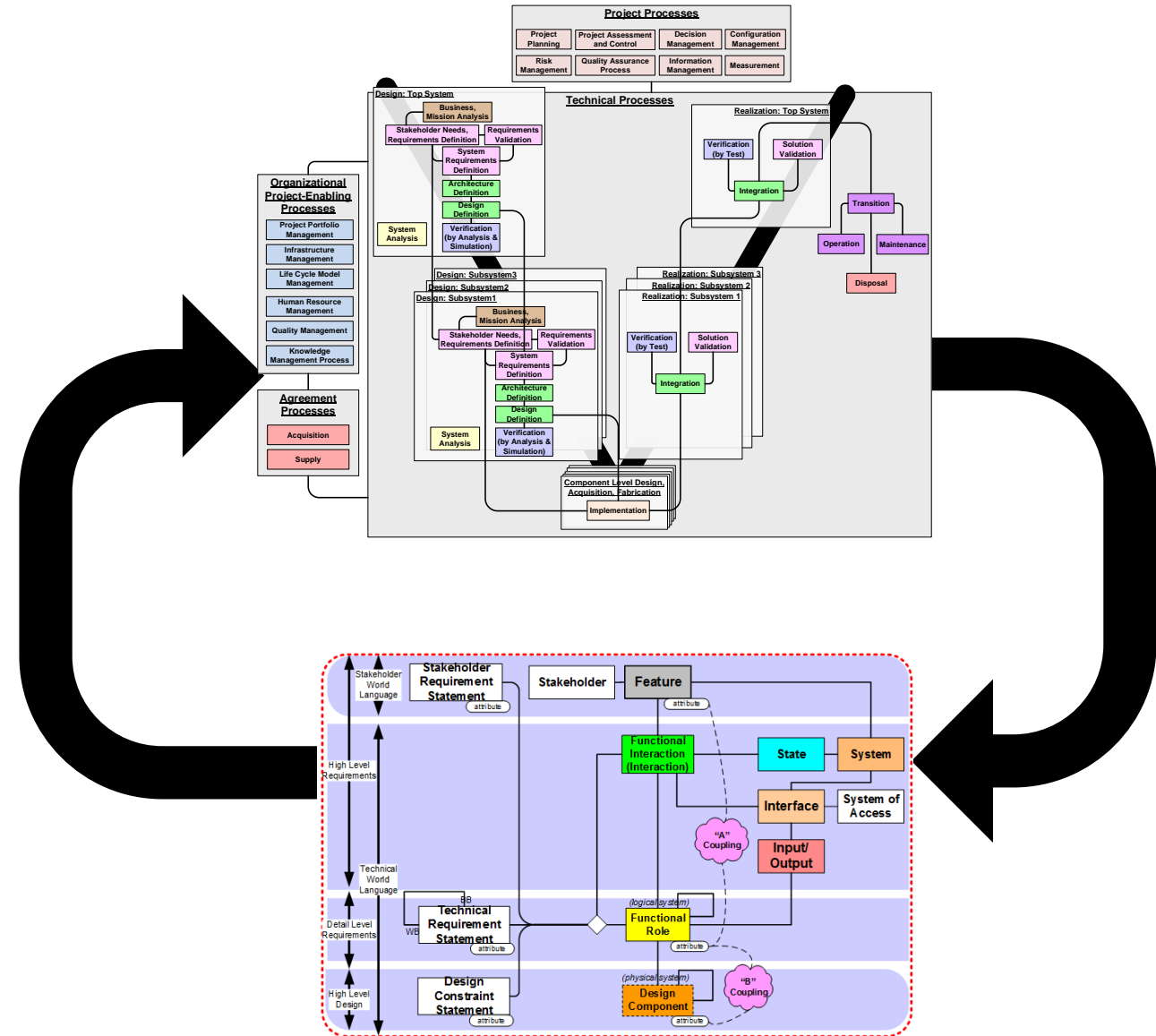
Applying Model VVUQ Pattern to the General System of Interest Pattern

- The general strategy includes:
 - Capture of the sources and propagators of uncertainty in the General System Pattern;
 - Specializing the General System Pattern to derive the Medical Device Pattern, in the process of which the sources and propagators of uncertainty are populated for us;
 - Configuring the Medical Device Pattern to a Specific Medical Device Model, so that the sources and propagators of uncertainty are in significant part populated by model-augmented human intelligence;
 - Thereby amplifying the effect of VV40 guidance.
 - For a concrete medical device example, Marc Horner has been collaborating to include his example content from an infusion pump device model.
 - See Attachment 2.

Innovation Process

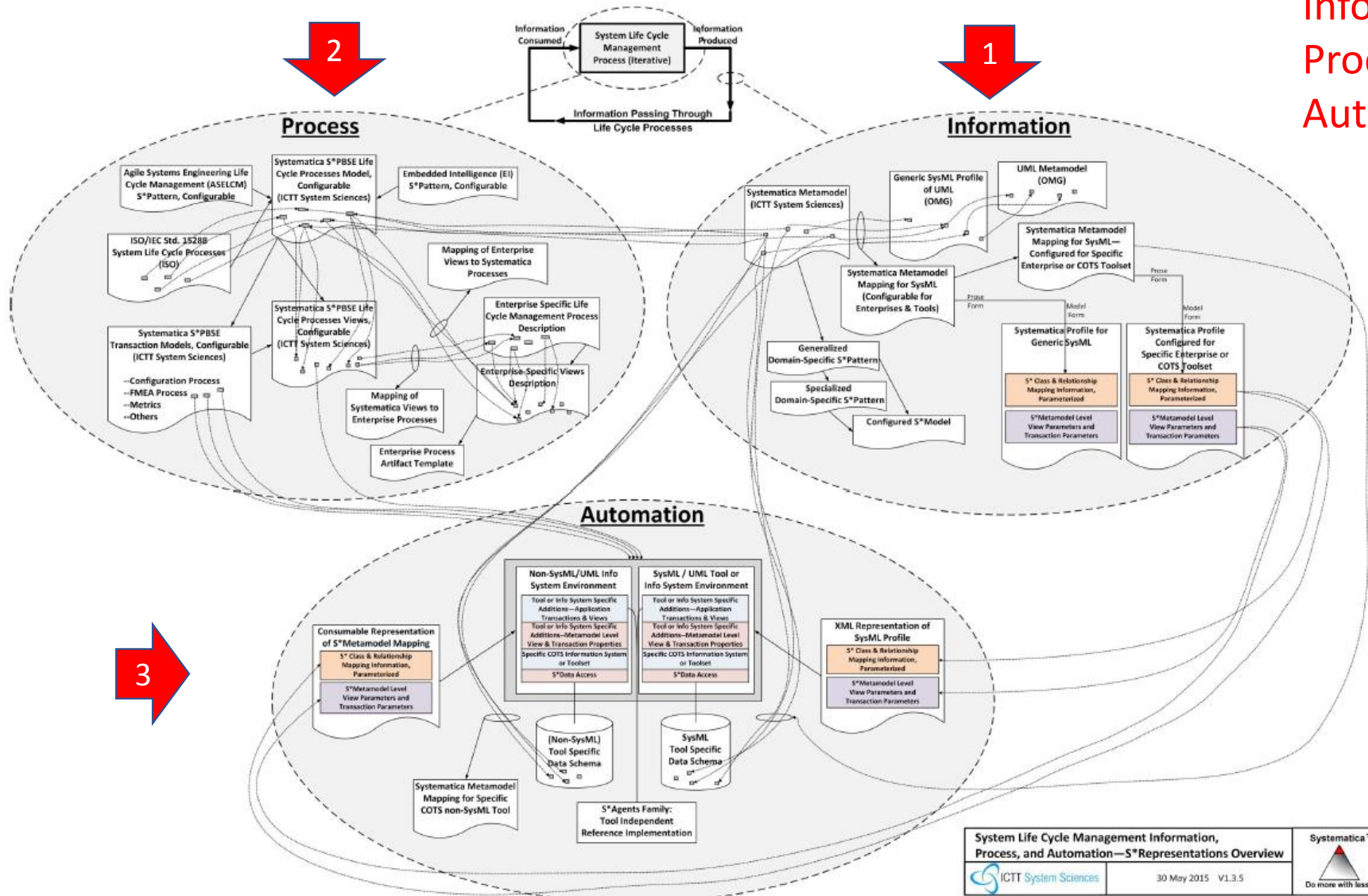
Tooling

- Information First
- Process Second
- Automation Last



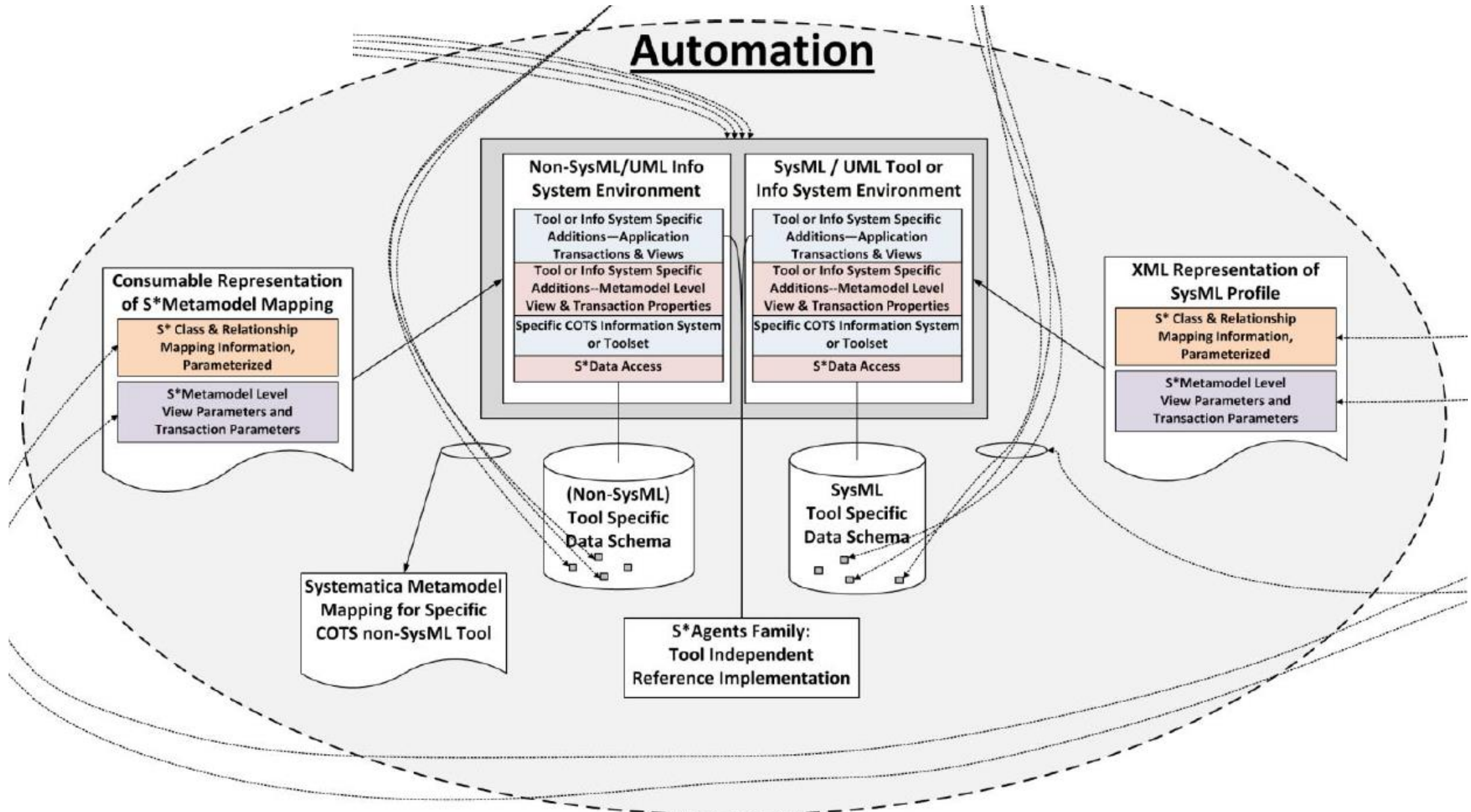
Information Passing Through Innovation Process

Information First
 Process Second
 Automation Last



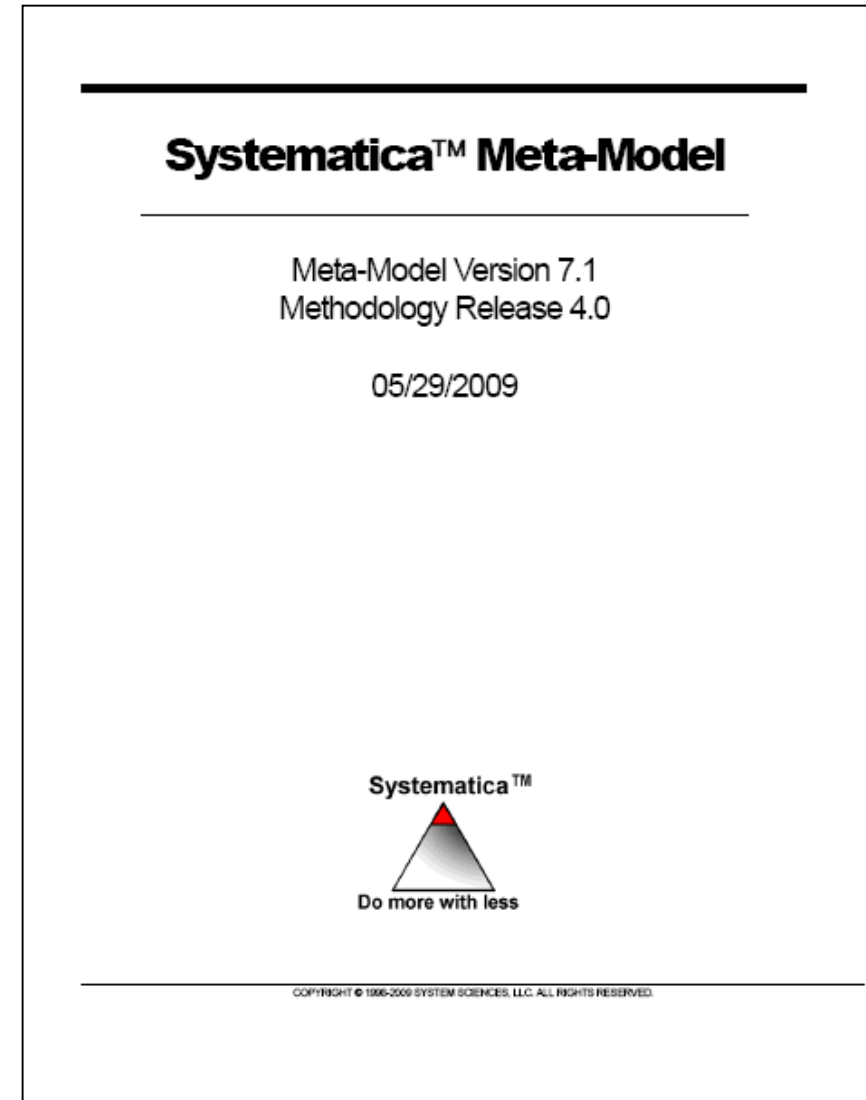
System Life Cycle Management Information, Process, and Automation—S*Representations Overview		Systematica™
ICTT System Sciences	30 May 2015 V1.3.5	Do more with less

Automation

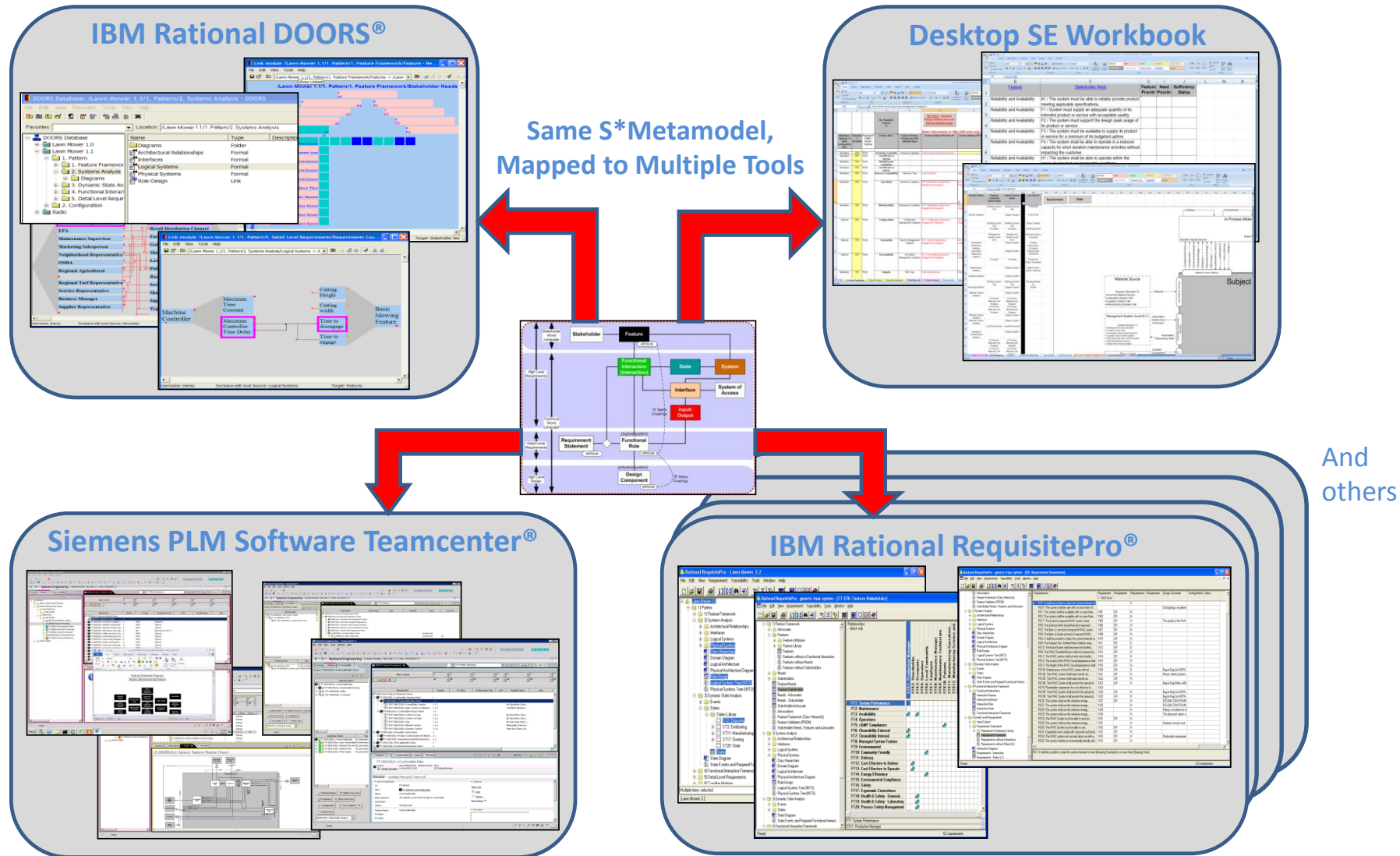


Mappings of S*Metamodel into COTS and Enterprise Tools and Languages

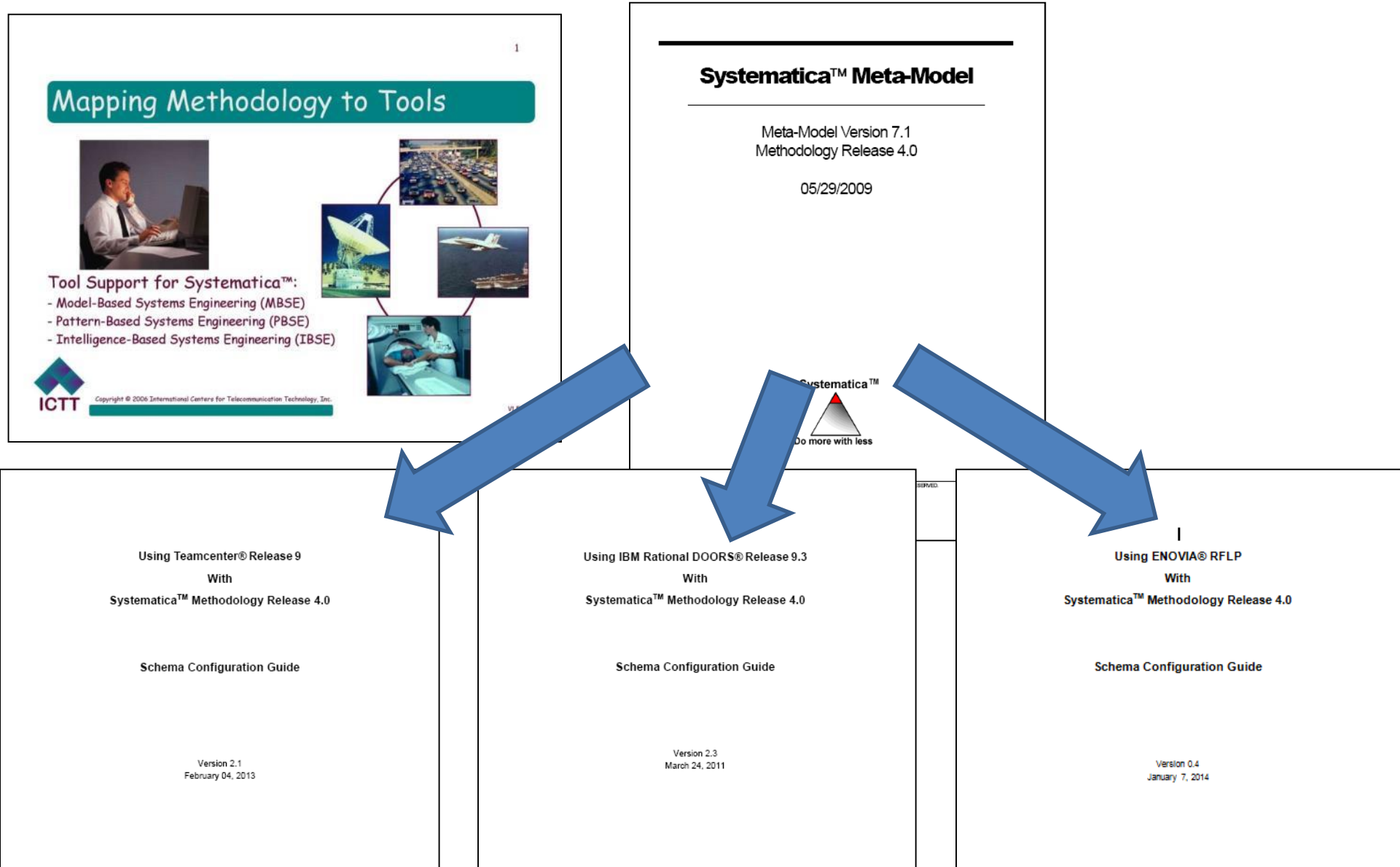
- The formal generic S*Metamodel is mapped to individual COTS and Enterprise tools and information systems, as well as modeling languages
- A formal mapping for each tool . . .



Tool Neutral: Readily mapped to different IT vendor toolsets and database schema:



Mappings of Generic S*Metamodel to Specific Third Party COTS IT Tools & Enterprise Systems



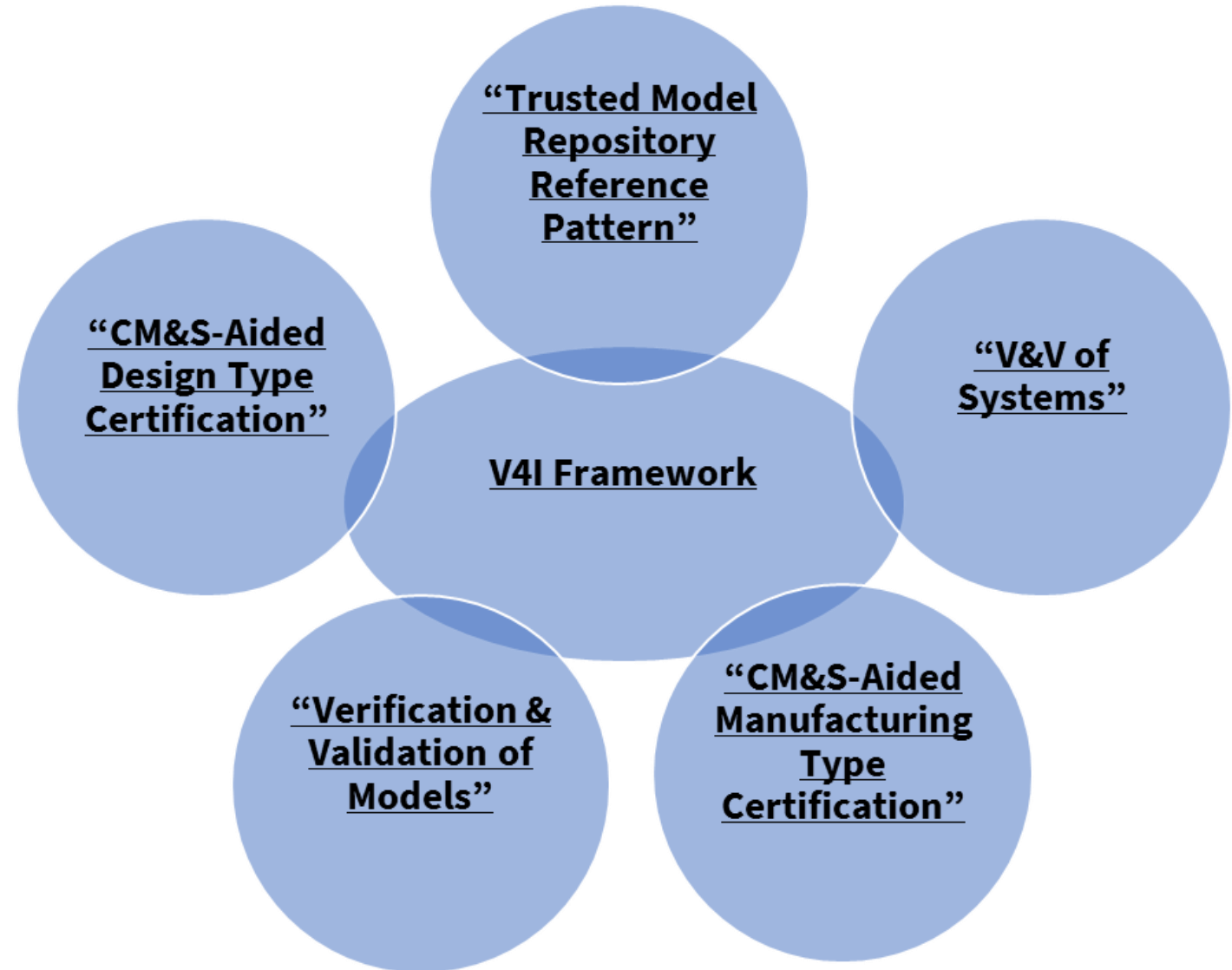
V4 Institute Collaboration Projects



*Virtual Verification, Validation,
and Visualization Institute*

- 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 membership model is focused on collaborative planning, development, and sharing of assets and capabilities helpful to V4 Institute members in the practice of virtual verification, validation, and visualization—the America Makes membership model has been adapted and adopted, from NCDMM, the National Center for Defense Machining and Manufacturing.
- V4I is now launching five public projects in this space, and invites participation of additional collaborators interested in joining the V4 Institute.
- These projects include pilot uses of the Model VVUQ S*Pattern.
- FDA and FAA in particular are invited to participate, and discussion of an appropriate form of this interaction is sought.
- www.V4i.us

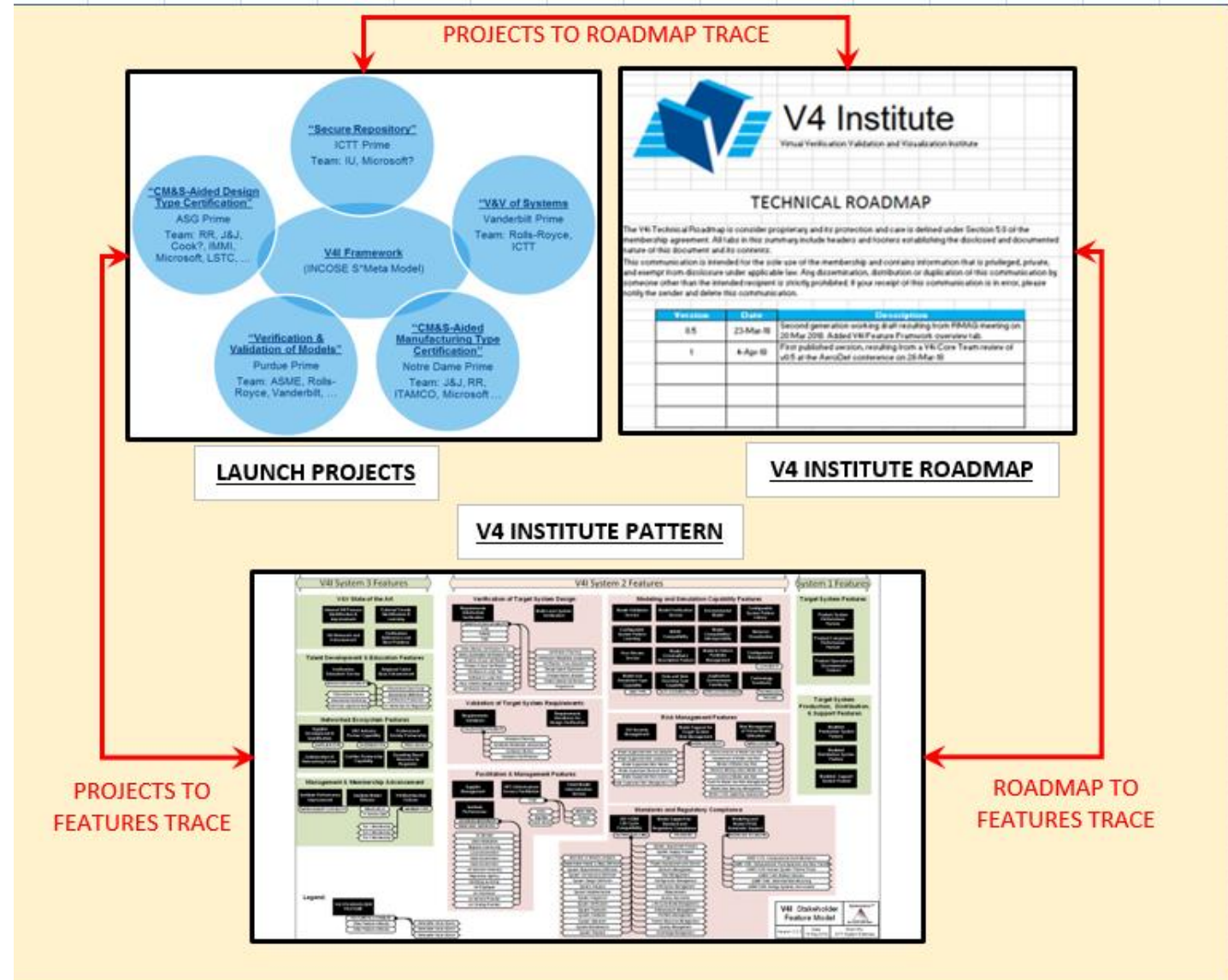
V4I Launch Projects:



Project Name	Project Short Description	Medicine	Flight
CM&S-Aided Design Type Certification	Identify and illustrate principles, process, methods, and resources for regulatory acceptance of model-based evidence about performance of designed product types to reduce physical experiments. Project performed within the V4I Framework and across targeted domain specific examples.	X	X
CM&S-Aided Manufacturing Type Certification	Identify and illustrate principles, process, methods, and resources for regulatory acceptance of model-based evidence about performance of specified manufacturing processes to reduce physical experiments. Project performed within the V4I Framework and across targeted domain specific examples.	X	X
V&V of Systems	Identify and illustrate principles, process, methods, and resources for regulatory acceptance of model-based system-level evidence about performance of specified systems to reduce physical experiments. Project performed within the V4I Framework and across targeted domain specific examples.	X	X
Verification & Validation of Models	Identify and illustrate principles, process, methods, and resources for verification, validation, and uncertainty quantification (VVUQ) of models, in support of their intended uses in the life cycle of systems of interest, including but not limited to the V&V of the systems of interest. Project performed within the V4I Framework and across targeted domain specific examples.	X	X
Trusted Model Repository Reference Pattern	Construct and illustrate configured uses (across V4I Launch Projects) of the V4I Repository Pattern, a reusable MBSE reference pattern describing configurable stakeholder feature trade space and system requirements for model and pattern portfolio life cycle repositories and their integrated applications over model life cycles. Project performed within V4I Framework and across targeted domain specific examples.	X	X 120

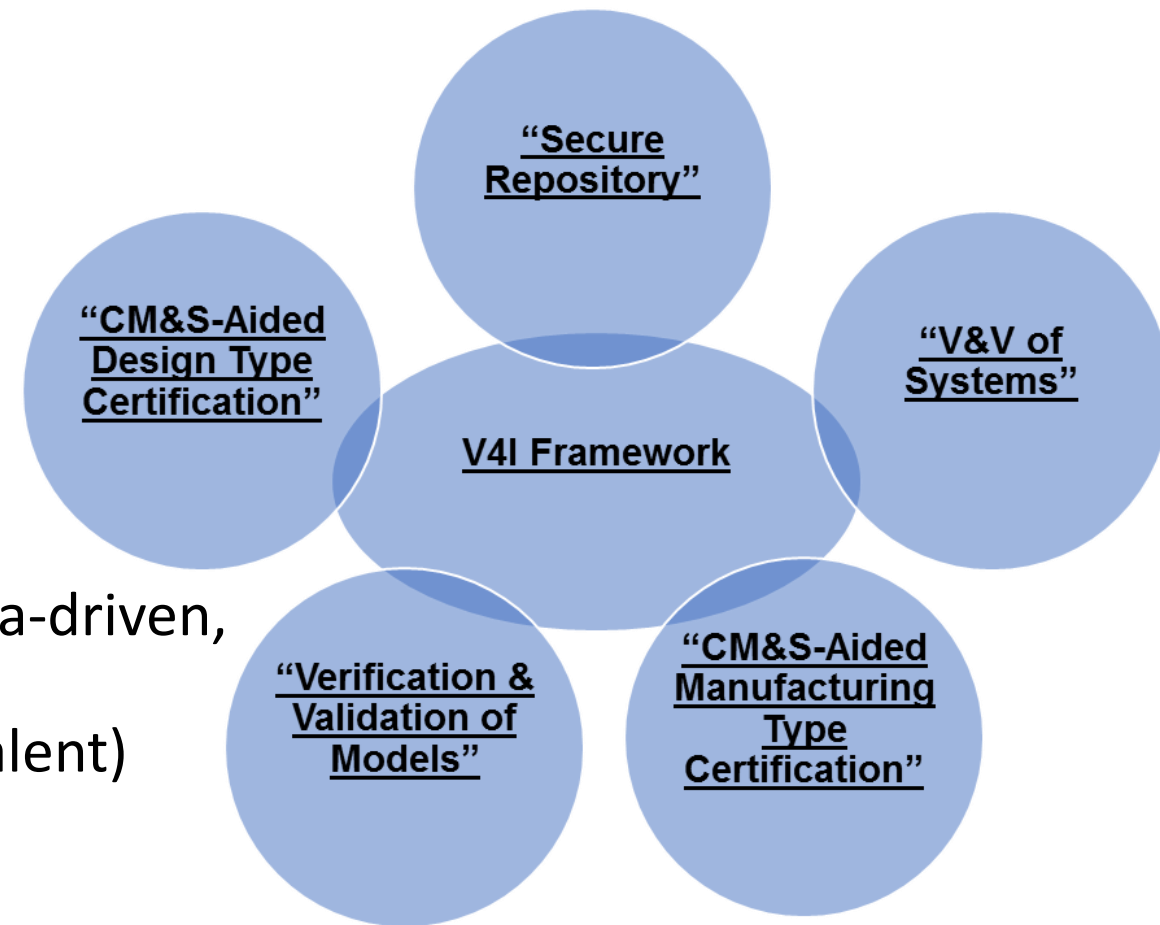
The V4I Launch Projects--summary

Five inter-related V4I Launch Projects, plus their shared V4I Framework, aligned to the V4I Roadmap and V4I Enterprise Features

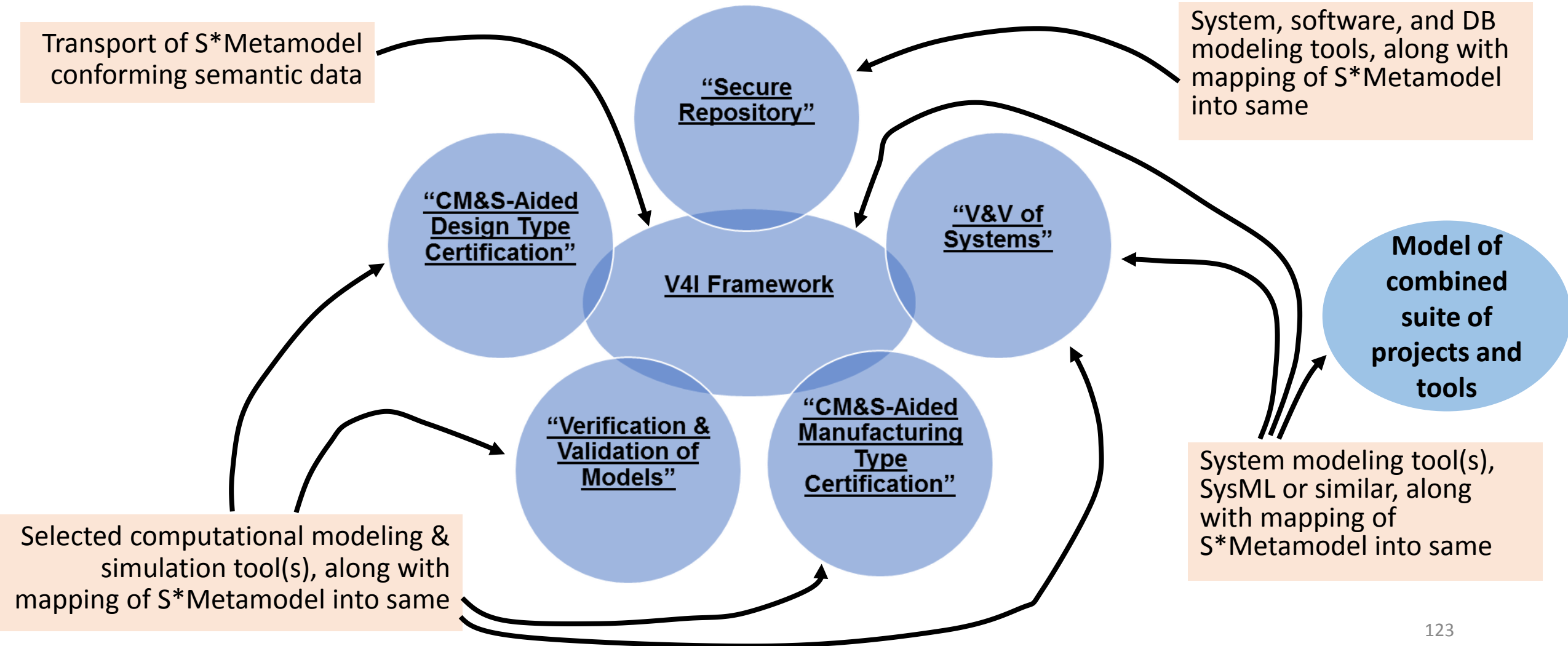


Tooling

- Tool types expected may include:
 - Computational M&S tools (physics-based, data-driven, systems dynamics, etc.)
 - Systems modeling tools (e.g., SysML or equivalent)
 - Software and DB modeling tools
 - Project & specialized tools
 - Inventory of same to be established by teams
- Models to include System 2 as well as System 1
- Modeling tools semantically integrated by mappings to S*Metamodel



Tooling: Projected automation/tooling associated with the V4I Launch Projects, *for discussion*—



Discussion, issues, next steps

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Pre-Reading References

Download from this link:

[http://www.omgwiki.org/MBSE/doku.php?id=mbse:patterns:m
bse_patterns_wg_participation_in_fda_pbse_seminar](http://www.omgwiki.org/MBSE/doku.php?id=mbse:patterns:m
bse_patterns_wg_participation_in_fda_pbse_seminar)

1. Schindel, W., “INCOSE Collaboration In an ASME-Led Standards Activity: Standardizing V&V of Models”, in *Proc. of INCOSE International Workshops*, Jacksonville, FL, Jan, 2018.
2. INCOSE Patterns Working Group, “MBSE Methodology Summary: Pattern-Based Systems Engineering (PBSE), Based On S*MBSE Models”, V1.5.5A.
3. Schindel, W., and Dove, R., “Introduction to the Agile Systems Engineering Life Cycle MBSE Pattern”, in *Proc. of INCOSE 2016 International Symposium*, 2016.
4. Schindel, W., “What Is the Smallest Model of a System?”, in *Proc. of the INCOSE 2011 International Symposium*, International Council on Systems Engineering (2011).
5. Schindel, W., “Got Phenomena? Science-Based Disciplines for Emerging Systems Challenges”, in *Proc. of the INCOSE 2016 International Symposium, International Council on Systems Engineering*, Edinburgh, UK. 2016.
6. Schindel, W., “System Interactions: Making The Heart of Systems More Visible”, in *Proc. of INCOSE Great Lakes Regional Conference*, 2013.
7. Schindel, W., “Hamilton’s Principle and Noether’s Theorem as a Basis for System Science”, *Proc. of 2018 Annual Meeting of the International Society for the System Sciences*, July, 2018.

Seminar logistics and contacts

- Seminar dates / times:
 - Mon, Oct 22 12:00 – 4:00 PM EST (Part 1)
 - Tues, Oct 23 9:00 – 12:00 PM EST (Part 2)
- Seminar location:
 - FDA, 10903 New Hampshire Ave., Silver Spring, MD
 - Monday: FDA Bldg 62 Room 2100
 - Tuesday: FDA Bldg 62 Room 3100
- Seminar participation:
 - Contact Dr. Tina Morrison, FDA
 - Email: Tina.Morrison@fda.hhs.gov
 - Tel: 301-796-6310
- Seminar provider, contact for content matters:
 - Bill Schindel, ICTT System Sciences, schindel@icctt.com,
 - Office: 812-232-2062 Mobile: 812-239-5358

Seminar pre-requisites and pre-reading

- Seminar attendees are expected to already:
 - Be aware of the uses, methods, and contemporary challenges and opportunities of model-based engineering, model VVUQ and related standards, and interests in the use of models in support of innovation and regulated offerings;
 - Be familiar and able to speak to the interests of their organization in the subjects of this seminar;
 - Have read over the seminar Pre-Reading listed in the References.

Bill Schindel, President, ICTT System Sciences



- Bill Schindel chairs the MBSE Patterns Working Group of the INCOSE/OMG MBSE Initiative. He is president of ICTT System Sciences, and has practiced systems engineering for over thirty years, across multiple industry domains.
- Bill serves as president of the INCOSE Crossroads of America Chapter, and is an INCOSE Fellow and Certified Systems Engineering Professional. An ASME member, he is part of the ASME VV50 standards team's effort to describe the verification, validation, and uncertainty quantification of models. He leads ICTT System Sciences participation in the V4 Institute.
- Bill served as a Trustee of Rose-Hulman Institute of Technology, chairing its board committee on academics for ten years. His earlier roles included service on the faculty of Rose-Hulman Institute, founding and running a telecom electronics company for two decades, and aerospace engineering methods advancement for the Federal Systems Division of IBM Corporation.