Patterns
Working Group

Virtual Verification, Validation,
and Visualization Institute

Attachment 2:

Example Extract from Application of Model VVUQ S*Pattern and Medical Device S*Pattern

Includes contributions by Marc Horner,
from ANSYS and ASME VV40.

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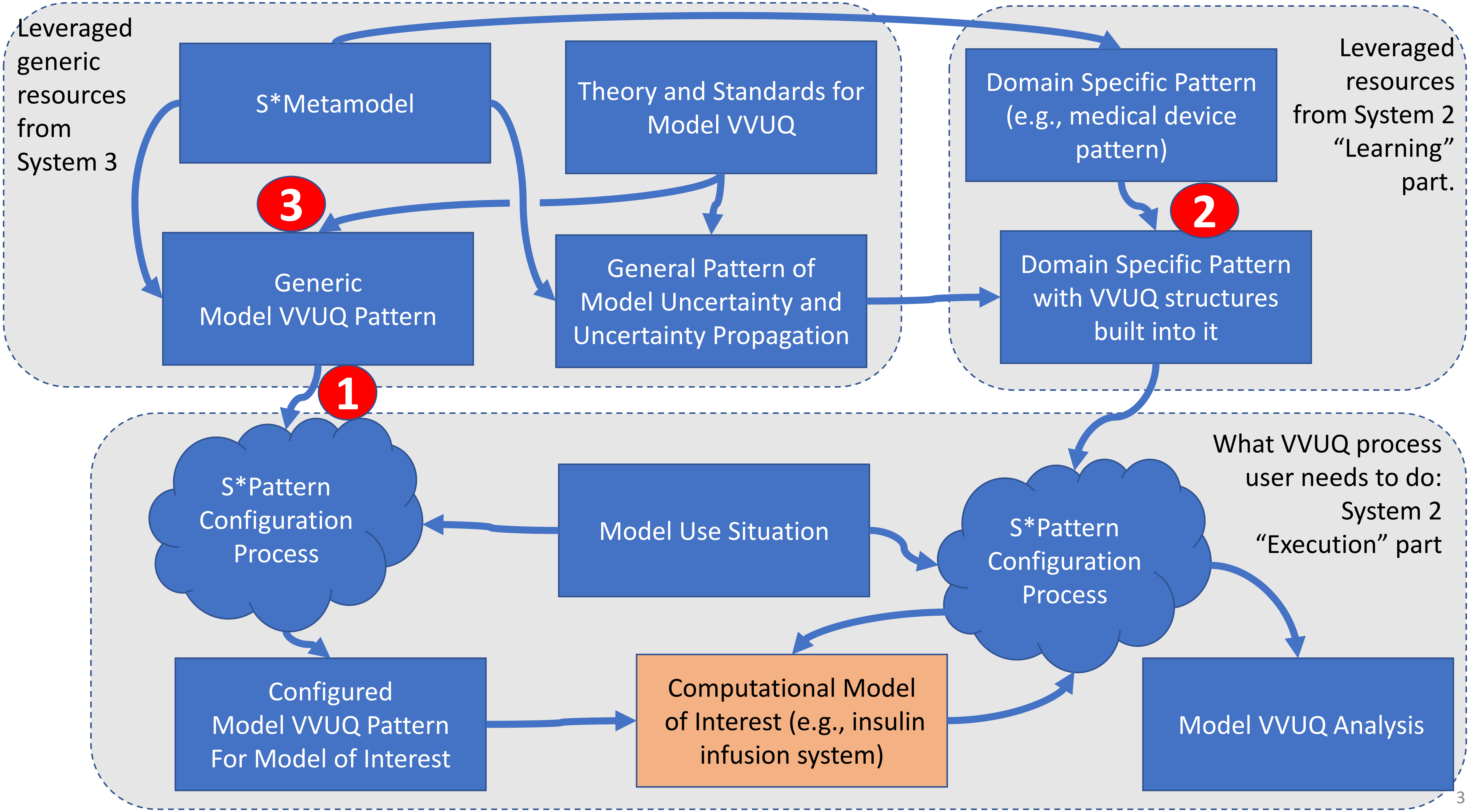
Oct. 22-23, 2018
V1.3.1

Overview of Initial (exists) and Enhanced (in progress) Model VVUQ Pattern, Medical Device Pattern, related work

1. Initial (2017) version of the Model VVUQ Pattern: Basic configurability of the Pattern to reflect required and resulting VVUQ of the model of interest—model "wrapper" metadata.
2. Integration with generic domain patterns (e.g., General Medical Device Pattern) to pre-capture or suggest potential sources and propagators of uncertainty in specific domains. (Underway, 2018, shown here.)
3. Integration with ASME VV40 standard to include built-in Credibility Factors, other VV40 guidance. (Underway, 2018, shown here.)


Leveraged generic resources from System 3
S*Metamodel
Theory and Standards for Model VVUQ
3
Generic Model VVUQ Pattern
General Pattern of Model Uncertainty and Uncertainty Propagation
Leveraged resources from System 2 "Learning" part.
Domain Specific Pattern (e.g., medical device pattern)
2
Domain Specific Pattern with VVUQ structures built into it
1
S*Pattern Configuration Process
Model Use Situation
S*Pattern Configuration Process
What VVUQ process user needs to do: System 2 "Execution" part
Configured Model VVUQ Pattern For Model of Interest
Computational Model of Interest (e.g., insulin infusion system)
Model VVUQ Analysis

Medical device example being used as basis for illustration

- To provide a concrete example of use, Marc Horner (ANSYS, and AMSE VV40 vice chair) has been collaborating with us by providing an example that he used in public presentations at the 2018 INCOSE Heath Care Conference and the 2018 INCOSE Great Lakes Conference.
- That example involves an insulin infusion pump, with emphasis on computational models of (a) human insulin absorption and metabolism uptake and (b) the pump's feeder tube flow characteristics.

V&V 40 Analysis of Two Insulin Pump Failure Modes

Marc Horner

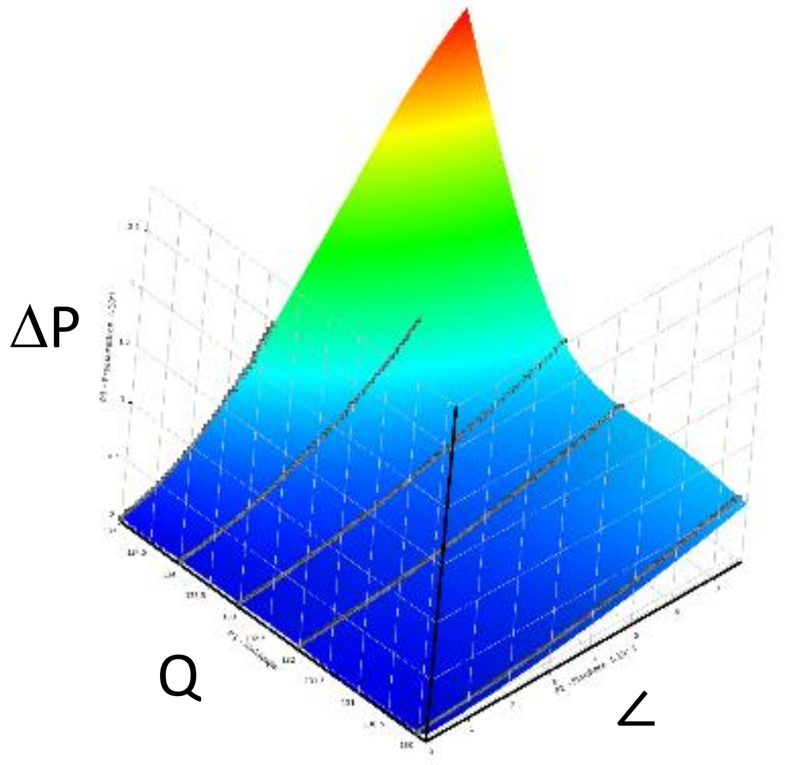
Failure Mode 1

- The patient does not receive the expected insulin therapy because there is an occlusion (kink) in the infusion set, potentially resulting in hyperglycemia.

QOI/COU

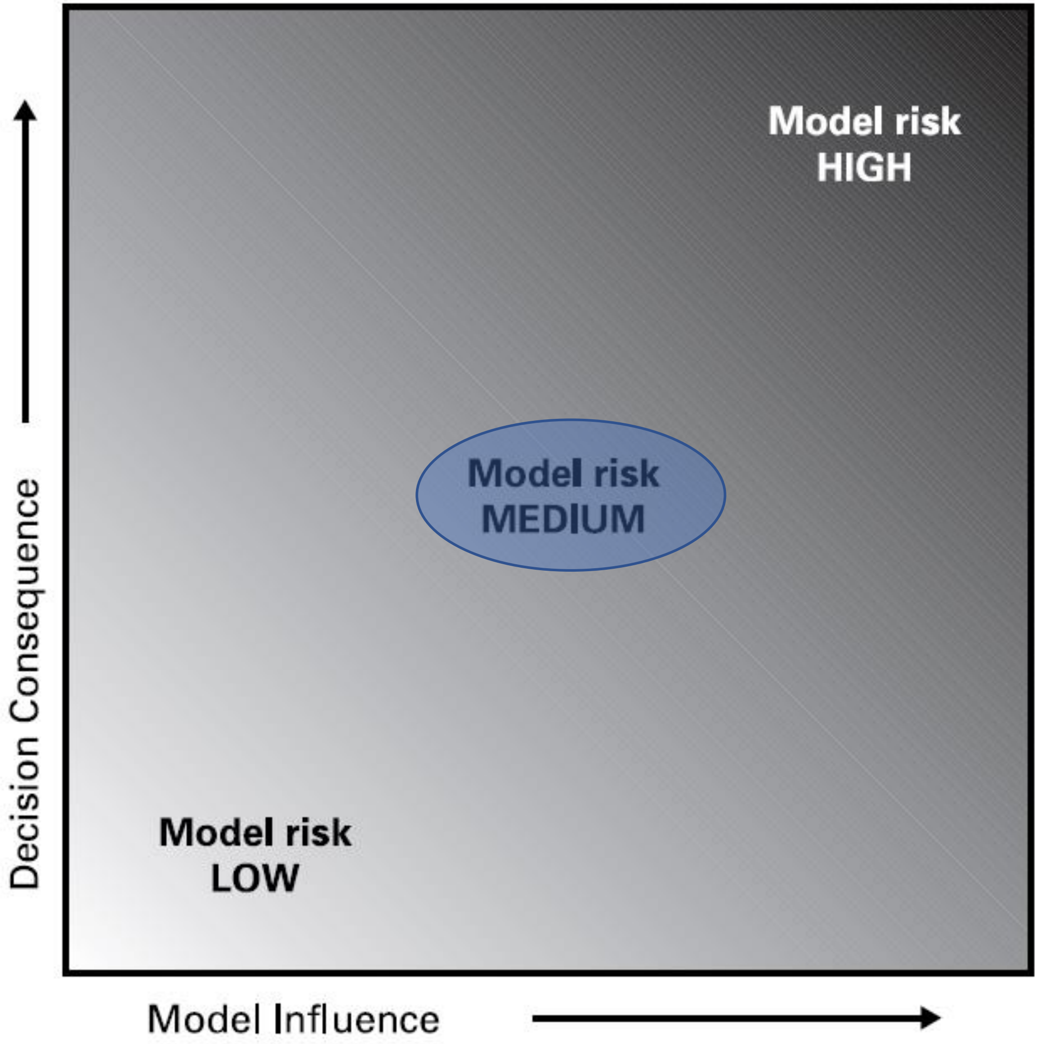
Question of Interest: Will the infusion pump properly warn the patient when an occlusion in the flow path is obstructing insulin delivery?

Context of Use: A reduced-order model for the relationship between bend angle (∠), flow rate (Q), and pressure rise (ΔP) will be used to predict occlusion by the system control software.



Risk Analysis

- *Model Influence* is MEDIUM since there are other sources of information available for predicting occlusion, e.g. CGM readings predicting occlusion and/or monitoring the flow rate of the insulin delivery over time.
- *Decision Consequence* is MEDIUM since patients can quickly drift away from the target blood glucose concentration, but can administer a correction bolus return to a normal glycemic state if/when the occlusion is detected via other means.



Credibility Factors

Activities (Paragraph)	Credibility Factors (Paragraph)
Verification (5.1)	
Code (5.1.1)	Software quality assurance (5.1.1.1)
	Numerical code verification (5.1.1.2)
Calculation (5.1.2)	Discretization error (5.1.2.1)
	Numerical solver error (5.1.2.2)
	Use error (5.1.2.3)
Validation (5.2)	
Computational model (5.2.1)	Model form (5.2.1.1)
	Model inputs (5.2.1.2)
Comparator (5.2.2)	Test samples (5.2.2.1)
	Test conditions (5.2.2.2)
Assessment (5.2.3)	Equivalency of input parameters (5.2.3.1)
	Output comparison (5.2.3.2)
Applicability (5.3)	Relevance of the quantities of interest (5.3.1)
	Relevance of the validation activities to the COU (5.3.2)

Code Verification

- A heavily used commercial software platform is used for these analyses (Mechanical, Fluent, and DesignXplorer from ANSYS). The code developer is ISO9001:2015 certified and code verification has been performed internally by the code developer. Mesh refinement studies are performed to ensure a converged solution. Owing to the fact that the physics are relatively straight-forward, sensitivity to numerical parameters is only cursorily investigated.

Code Verification	Credibility
SQA	HIGH
NCV	MEDIUM
Calculation Verification	
Discretization Error	MEDIUM
Numerical Solver Error	MEDIUM
Use Error	MEDIUM

Computational Model Credibility

- The computational model will recreate a series of idealized catheter occlusion scenarios. The resistance to flow will be modeled using a one-way FSI approach, first bending the tube and then modeling the insulin flow over a range of expected flow rates.
  - *Mechanical Model*: The geometry of the occlusion will be modeled as a tube under varying degrees of bending. The catheter and cannula materials are readily characterized. Cannula insertion and other skin interactions will not be modeled.
  - *Flow Model*: The flow is laminar and the density/viscosity of insulin is readily characterized. The inlet flow rate is well characterized. Peripheral flow resistance due to the presence of skin tissue at the bolus site will not be modeled.

Computational Model	Credibility - Model Form	Credibility - Model Inputs
Governing Equations	HIGH	HIGH
System Configuration	MEDIUM	MEDIUM
Material Properties	HIGH	HIGH
Boundary Conditions	MEDIUM	MEDIUM

Comparator Credibility

- An experimental set-up that varies the bend angle of the catheter in a highly controlled manner will be compared to the computational model results. An optical system will be used to measure the bend angle of the catheter. A pressure sensor upstream of the occlusion will measure the total pressure. System response will be investigated for a range of flow rates and catheter bend angles.

Comparator	Credibility - Test Samples	Credibility - Test Conditions
Quantity	MEDIUM	HIGH
Range	MEDIUM	HIGH
Measurements	LOW	HIGH
Uncertainty	LOW	MEDIUM

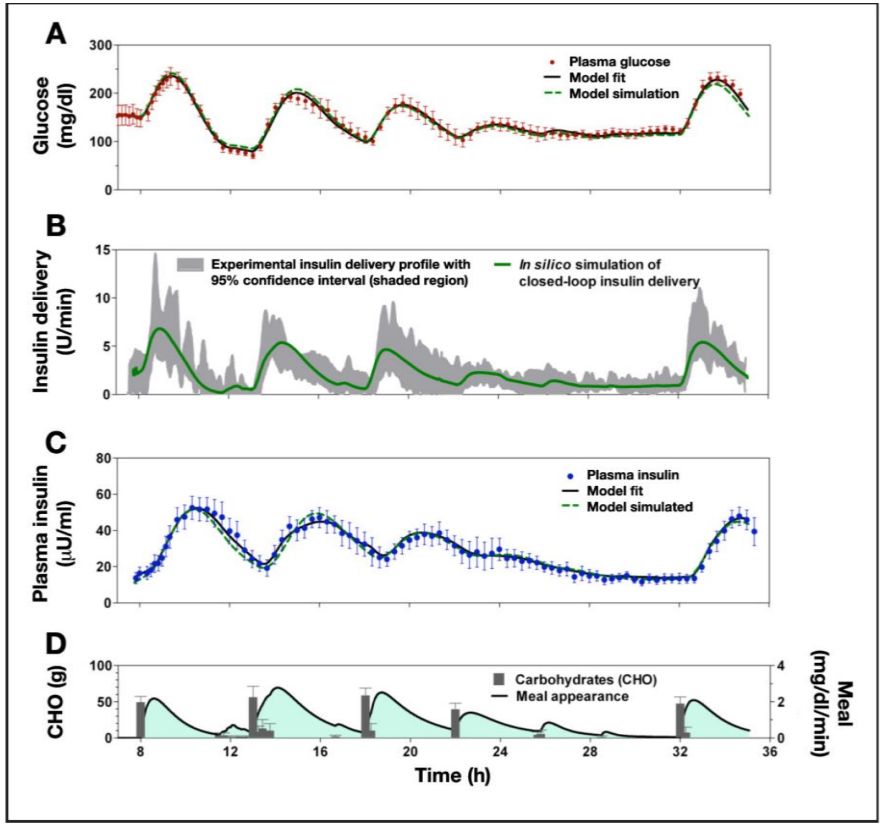
Failure Mode 2

- The insulin pump embedded software does not predict the correct amount of drug needed to maintain desired glycemic levels after a meal.

QOI/COU

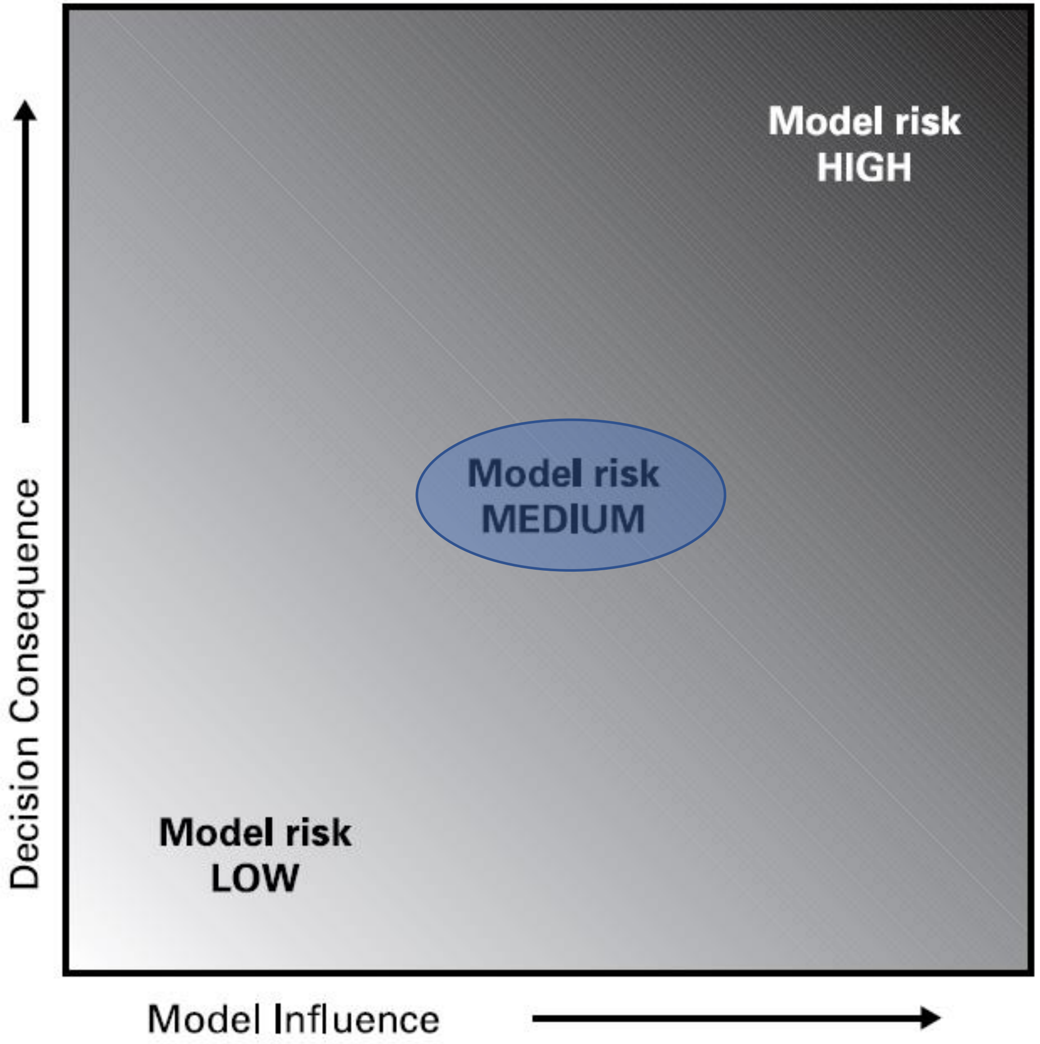
<u>Question of Interest</u>: Can the insulin pump control software maintain each patient’s target blood glucose concentration?

<u>Context of Use</u>: A 5-equation PK/PD model of insulin absorption and glucose metabolism will be developed and tuned using patient historical data.



Risk Analysis

- *Model Influence* is MEDIUM since there are other sources of information available for determining the insulin needs, e.g. blood glucose calculators/apps.
- *Decision Consequence* is MEDIUM since patients can quickly drift away from the target blood glucose concentration, but can administer a correction bolus return to a normal glycemic state if/when the occlusion is detected via other means.



Credibility Factors

Activities (Paragraph)	Credibility Factors (Paragraph)
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Code Verification

- A popular object-oriented modeling language (Modelica) is used for these analyses. Code verification has been performed by the user for this application. Mesh refinement studies are performed to ensure a converged solution. Owing to the fact that the physics are relatively straight-forward, sensitivity to numerical parameters is only cursorily investigated.

Code Verification	Credibility
SQA	HIGH
NCV	HIGH
Calculation Verification	
Discretization Error	MEDIUM
Numerical Solver Error	MEDIUM
Use Error	MEDIUM

Computational Model Credibility

- The 5-equation PK/PD model representing the absorption into the plasma will be modeled. The appearance of glucose and elimination by insulin will also be included. The PK/PD model will be calibrated using the clinical data from all patients over a 48 hour period and then used to predict the glucose concentration in those same patients for an additional 72 hours.

Computational Model	Credibility - Model Form	Credibility - Model Inputs
Governing Equations	HIGH	HIGH
System Configuration	MEDIUM	MEDIUM
Material Properties	HIGH	HIGH
Boundary Conditions	HIGH	MEDIUM

Comparator Credibility

- A clinical trial will be used to collect the data required to develop the PK/PD model for multiple patients. The patients will be checked into a hospital and their carbohydrate intake, insulin delivery, and blood glucose concentration will be measured throughout the day. At each time point, only a single sample will be collected from each patient. Multiple meal types and snacks will be given to the patient to test model robustness.

Comparator	Credibility - Test Samples	Credibility - Test Conditions
Quantity	MEDIUM	HIGH
Range	MEDIUM	HIGH
Measurements	MEDIUM	MEDIUM
Uncertainty	LOW	LOW

1. Basic configurability of the initial Model VVUQ Pattern

- To reflect required and resulting VVUQ of the model of interest,
  - As well as many other characteristics of the model of interest

(Using the existing 2017 version of the Model VVUQ Pattern.)

	A	B	C	D	E	G	H	I	J	K	L	M
1						Multiple Configuration IDs						
2	Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Config 1	Config 2	Config 3	Config 4	Config 5	Config 6	Config 7
3	**Identifies the main subject or focus of the model**											
4	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	Insulin Pump Infusion Set						
5		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.)	Patient Environment & Use						
6	**Describes the scope of content of the model**											
7	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)	Patient, Health Care Provider						
8		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.			Yes						
9		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.			Yes						
10		Physical Architecture	The capabiliy 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.			Yes						
11		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.			Yes						
12		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.			No						
13		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).			Yes						
14		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)	Yes						
15		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.	Yes						
16				Pattern ID	The identifier of the trusted configurable pattern.	Medical Device Pattern						

	A	B	C	D	E	G	H	I	J	K	L	M
1						Multiple Configuration IDs						
2	Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	*Config 1*	Config 2	Config 3	Config 4	Config 5	Config 6	Config 7
17		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.			*Yes*						
18	**Describes the credibility of the model**											
19		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.	*Range of bend angles, flow rates, viscosities*						
20				Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the conceptual model compared to the system of interest.	*Tube Crimping Model Study A9*						
21		Validated Conceptual Model Credibility	The validated capability of the conceptual portion of the model to represent the System of Interest, with acceptable Credibility.	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.	*Tube Crimping Model Study A9*						
22				Uncertainty Quantification (UQ) Reference	The specification reference describing the degree of uncertainty of the Credibility of the conceptual model to the system of interest.	*Tube Crimping Model Study A9*						
23				Model Validation Reference	The reference documenting the validation of the conceptual model's Credibility to the system of interest.	*Tube Crimping Model Study A9*						
24	Model Credibility			Quantitative Accuracy Reference	The specification reference describing the quantitative accuracy of the executable model to the conceptual model.	*Tube Crimping Simulation Study B4*						
25				Structural Accuracy Reference	The specification reference describing the structural (presence or absence of elements) accuracy of the executable model to the conceptual model.	*Tube Crimping Simulation Study B4*						
26				Uncertainty Quantification (UQ) Reference	The specification reference describing the degree of uncertainty of the Credibility of the executable model to the conceptual model.	*Tube Crimping Simulation Study B4*						
27		Verified Executable Model Credibility	The verified capability of the executable portion of the model to represent the System of Interest, with acceptable Credibility.	Speed	The specification reference describing the execution run time (speed) for the executable model.	*Tube Crimping Simulation Study B4*						
28				Quantization	The specification reference describing the quantization error of the executabl e model.	*Tube Crimping Simulation Study B4*						
29				Stability	The specification reference describing the level of stability of the accuracy and uncertainty of the executable model error characteristics.	*Tube Crimping Simulation Study B4*						
30				Model Validation Reference	The reference documenting the verification of the executable model's Credibility to the conceptual model.	*Tube Crimping Simulation Study B4*						
31	**Identifies the type of representation used by the model**											

	A	B	C	D	E	G	H	I	J	K	L	M
1						Multiple Configuration IDs						
2	Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	*Config 1*	Config 2	Config 3	Config 4	Config 5	Config 6	Config 7
32	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.	*Neural Net, 4 Layers*						
33				Conceptual Model Interoperability	The degree of interoperability of the conceptual model, for exchange with other environments	*High*						
34		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.	*Matlab NN*						
35				Executable Model Interoperability	The degree of interoperability of the executable model, for exchange with other environments	*Low*						
36	**Describes the intended use, utility, and value of the model**											
37	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.	*Define Design; Verify Design by Simulation*						
38		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)	*Device Designer, ME Discipline*						
39				Level of Annual Use	The relative level of annual use by the segment	*At time of Design Changes*						
40				Value Level	The value class associated with the model by that segment	*Moderate*						
41		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	Accepting Authority	The identity (may be multiple) of regulators, agencies, customers, supply chains, accepting the model	*FDA*						
42		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	*Low*						
43	**Describes related model life cycle management capabilities**											
44		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)	*Version Management; Baselining*						
45		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	*Acme Enterprise IT SOE*						
46		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	*31-Dec-28*						
47		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.	*Review at times of model feedback or design change*						
48		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.	*Acme Enterprise PLM*						

	A	B	C	D	E	G	H	I	J	K	L	M
1	Feature Group	Feature Name	Feature Definition	Feature Attribute	Attribute Definition	Multiple Configuration IDs						
2						*Config 1*	Config 2	Config 3	Config 4	Config 5	Config 6	Config 7
49	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	*USD 25,000.*						
50				Operational Cost	The cost to execute and otherwise operate the model, in standardized execution load units	*USD 1,000/year*						
51				Maintenance Cost	The cost to maintain the model	*USD 800/year*						
52				Deployment Cost	The cost to deploy, and redeploy updates, per cycle	*USD 500/cycle*						
53				Retirement Cost	The cost to retire the model from service, in a planned fashion	*USD 1500*						
54				Life Cycle Financial Risk	Risk to the overall life cycle cost of the model	*Low*						
55		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	*01.30.2020*						
56				First Availability Risk	Risk to the scheduled date of first availability	*Low*						
57				Life Cycle Availability Risk	Risk to ongoing availability after introduction	*Low*						
58		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)	*None yet*						
59				Impacted VVUQ Feature	The impacted existing, modified, or additional feature of the VVUQ Pattern.	*None yet*						
60				VVUQ Pattern Version	The version of the VVUQ Pattern in current use before change.	*None yet*						
61				Project	Identifies the project in which the exception was noted	*None yet*						
62				Person	Identifies the person describing the exception	*None yet*						

2. Integration with generic domain patterns (e.g., General Medical Device Pattern)

- To pre-capture potential sources and propagators of uncertainty,
  - and build them into the work process.
  - and create some common expectations across community of designers, analysts, regulators

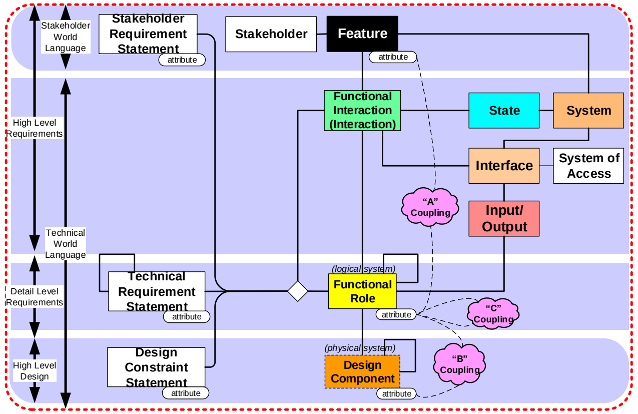
(This is interim material, work on (2) is still in progress.)

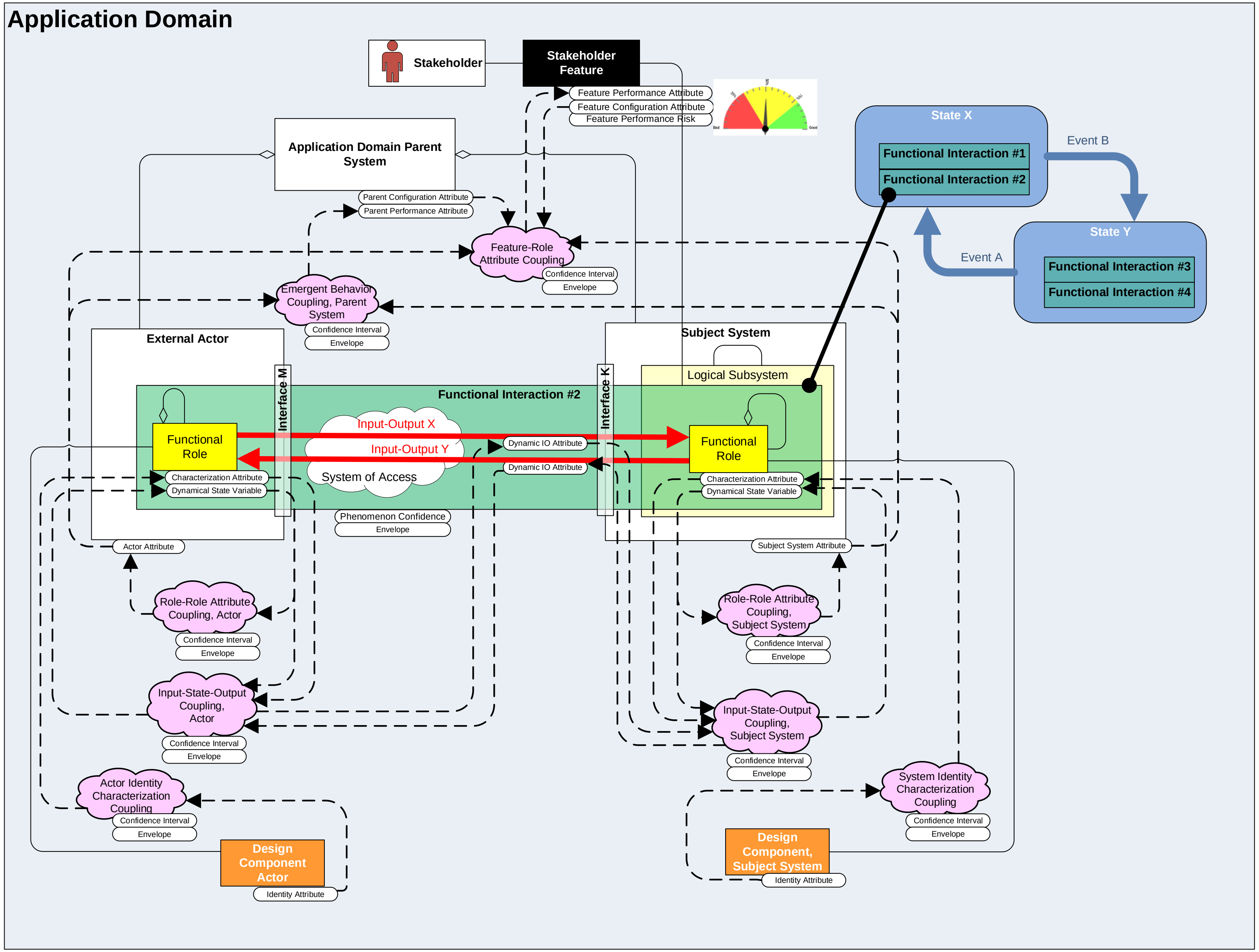
More detailed VVUQ Pattern aspects, general systems case first

- Who needs to understand the following?
- A user of the Model VVUQ Pattern need not have studied, understood all of, or even see the following, since that pattern should be placed in the related tooling to simplify application, with most of this “behind the scenes”
- However, a specialist interested in understanding what is being/inside the Model VVUQ Pattern could study these details to analyze, for example, the comprehensiveness of its coverage of model VVUQ issues with respect to principles of V&V 40, V&V 10, etc.
- The General System (generic) case is shown first.
- Then the (general) Controlled Medical Device Pattern case is shown, as a specialization.
- A Configured Model will be created for the illustrative example.

More detailed VVUQ Pattern aspects, general systems case first

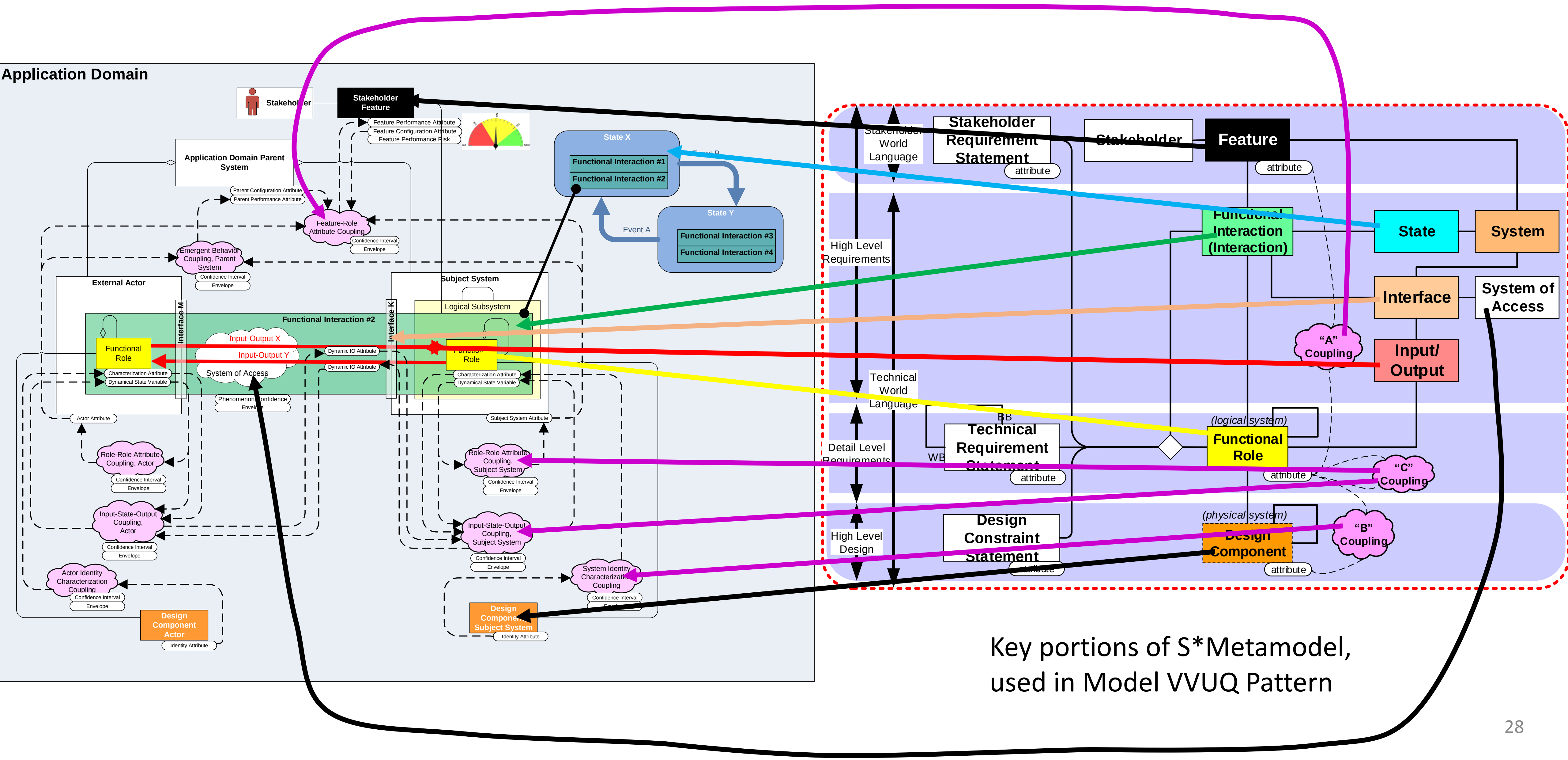
General setting, using S*Metamodel elements to describe a System of Interest interacting with its environment.





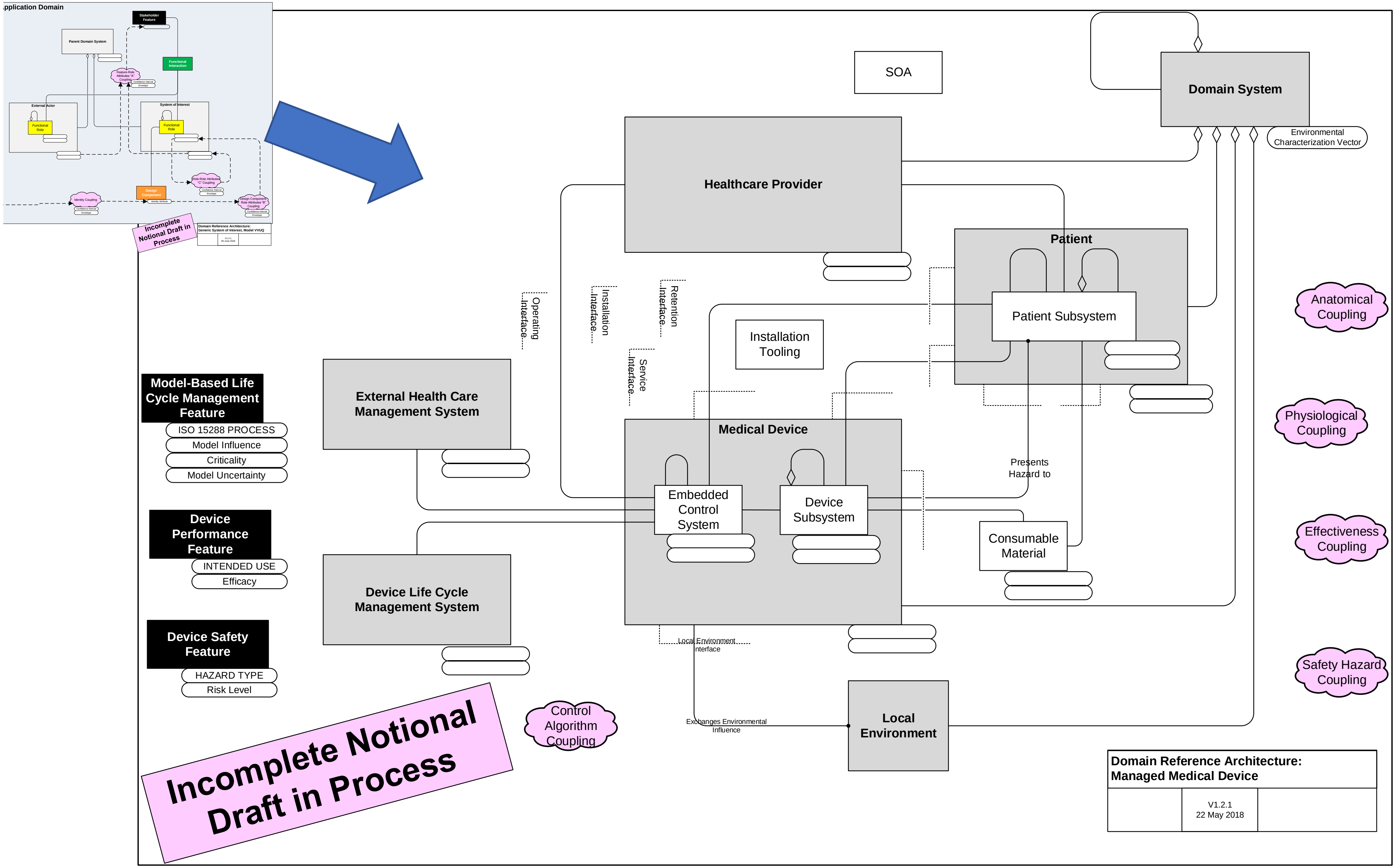
System models, their use and credibility, and VVUQ of same can be described in this framework.

More detailed VVUQ Pattern aspects, general systems case first

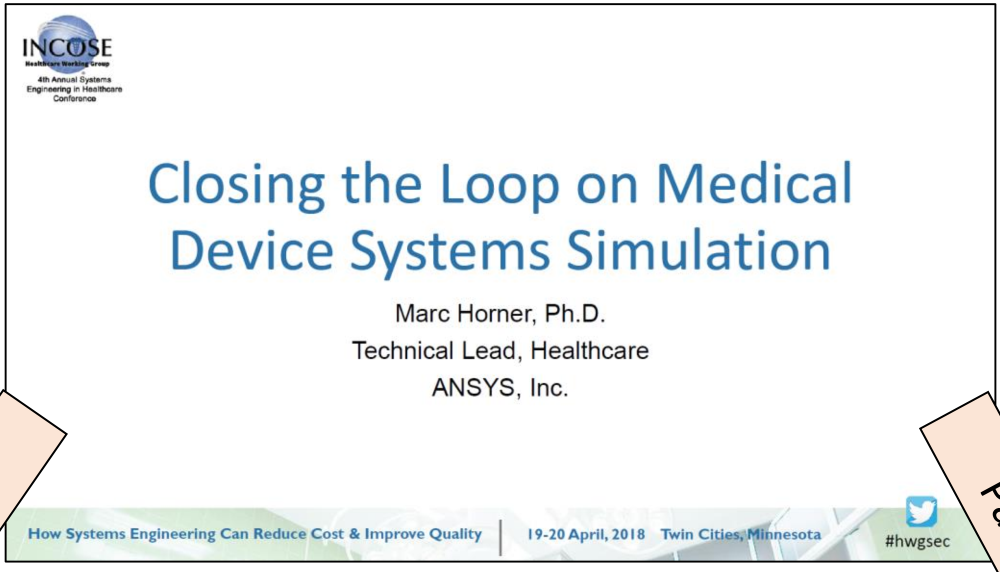


Key portions of S*Metamodel, used in Model VVUQ Pattern

Further specialized to medical device domain

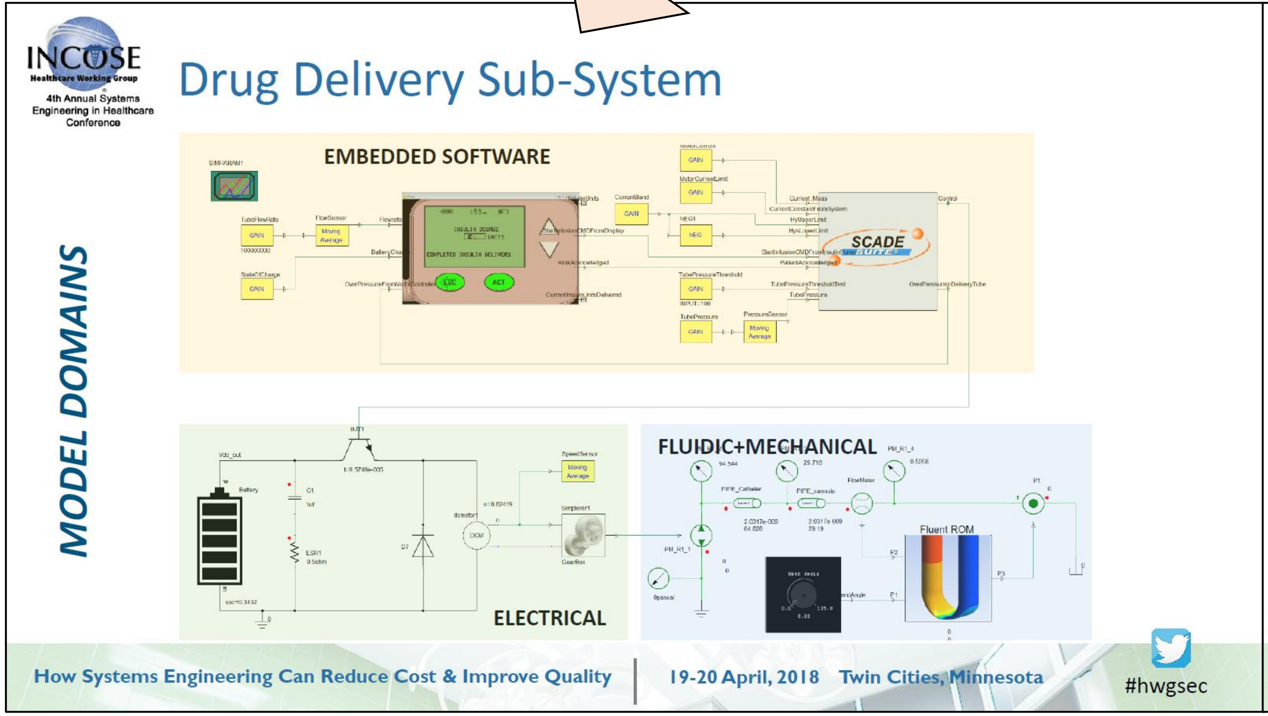


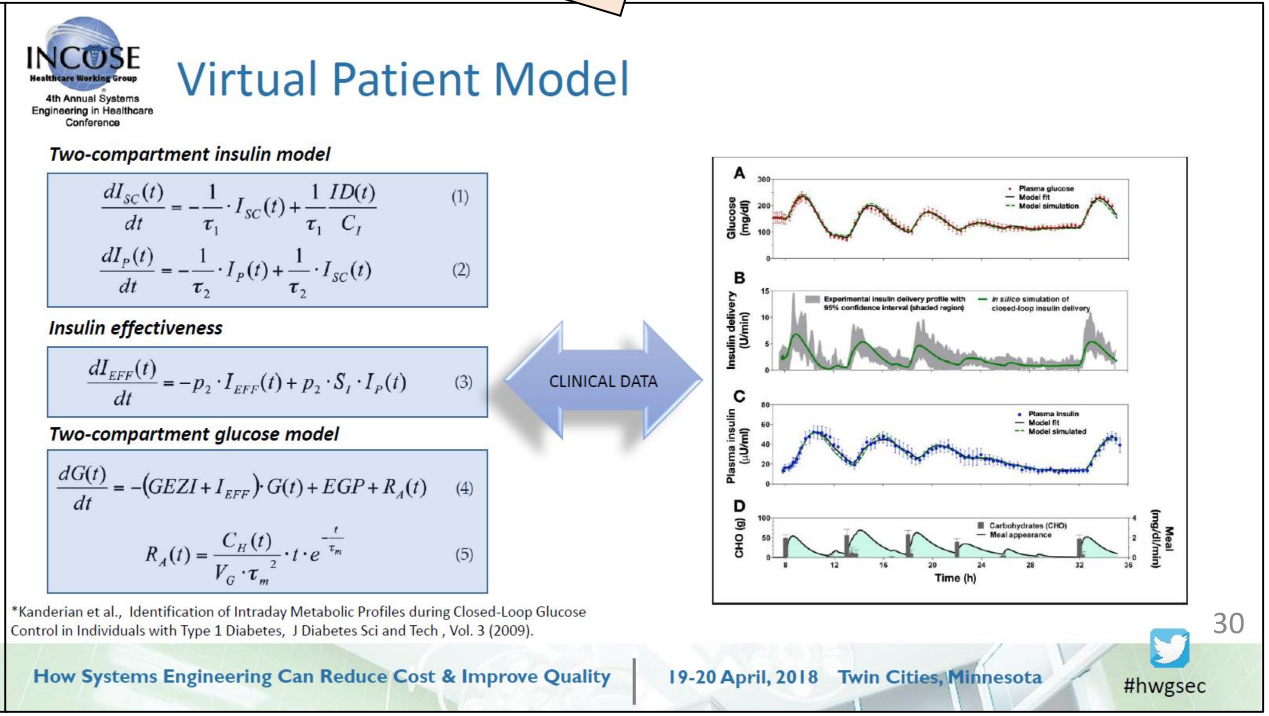
Example Model: Medical device + medication + patient: From Marc Horner's INCOSE presentation, April, 2018



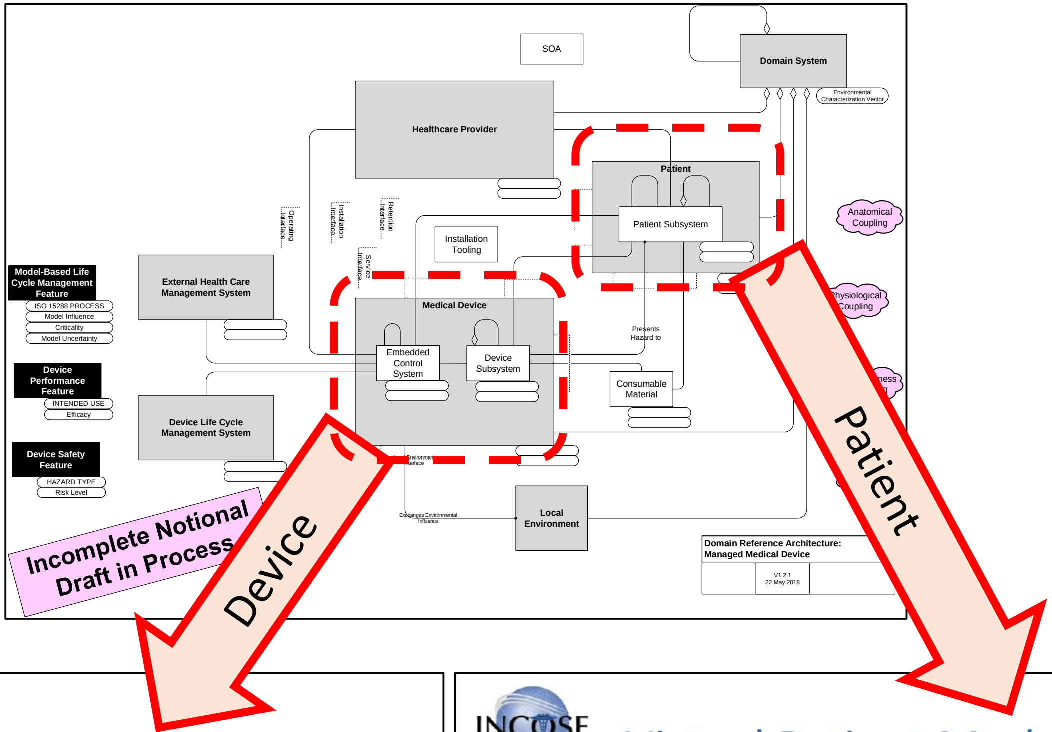
Device

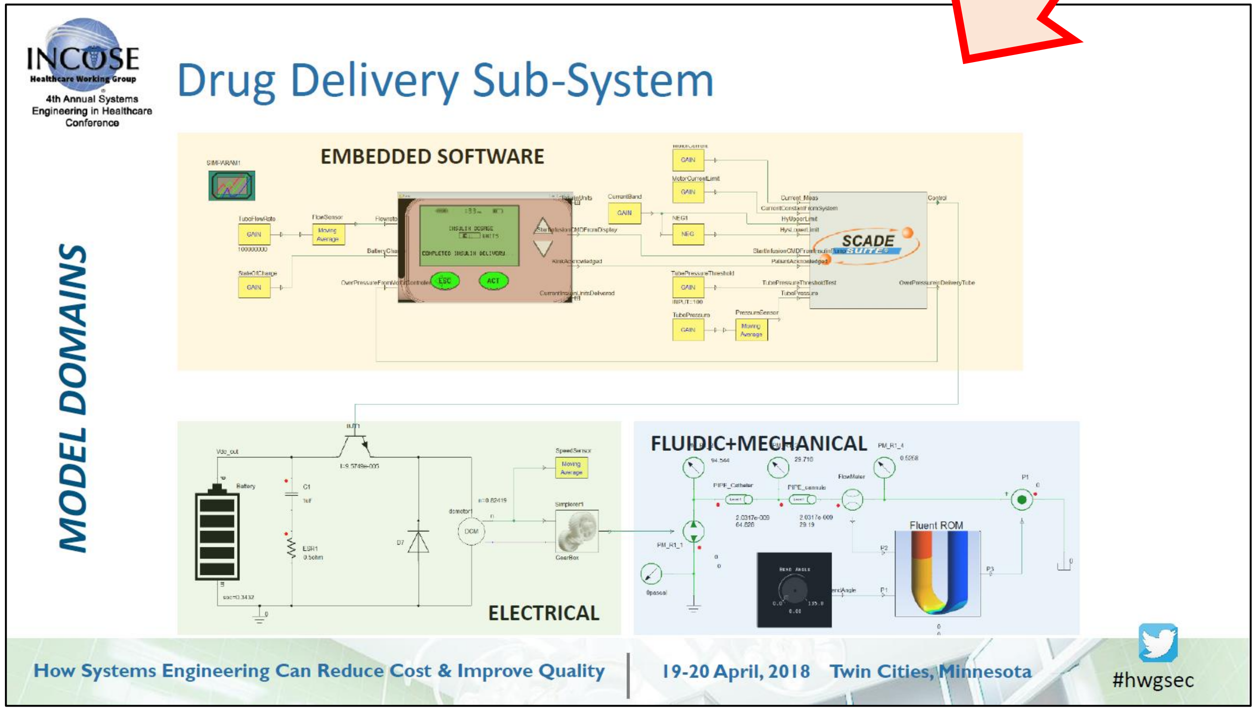
Patient





Mapping to Generic Device Draft Pattern





INCOSE
Healthcare Working Group
4th Annual Systems Engineering in Healthcare Conference

Virtual Patient Model

Two-compartment insulin model

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

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

Insulin effectiveness

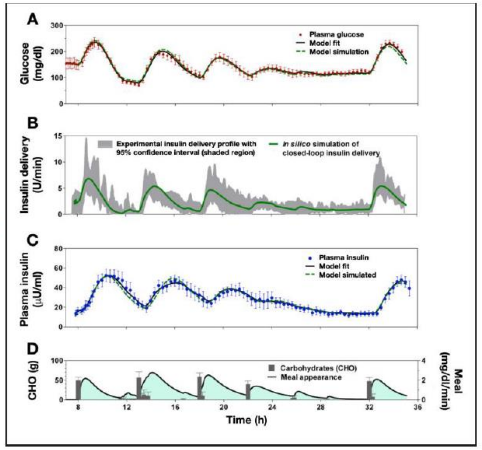
$$\frac{dI_{EFF}(t)}{dt} = -p_2\cdot I_{EFF}(t) + p_2\cdot S_I\cdot I_P(t) \quad (3)$$

Two-compartment glucose model

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

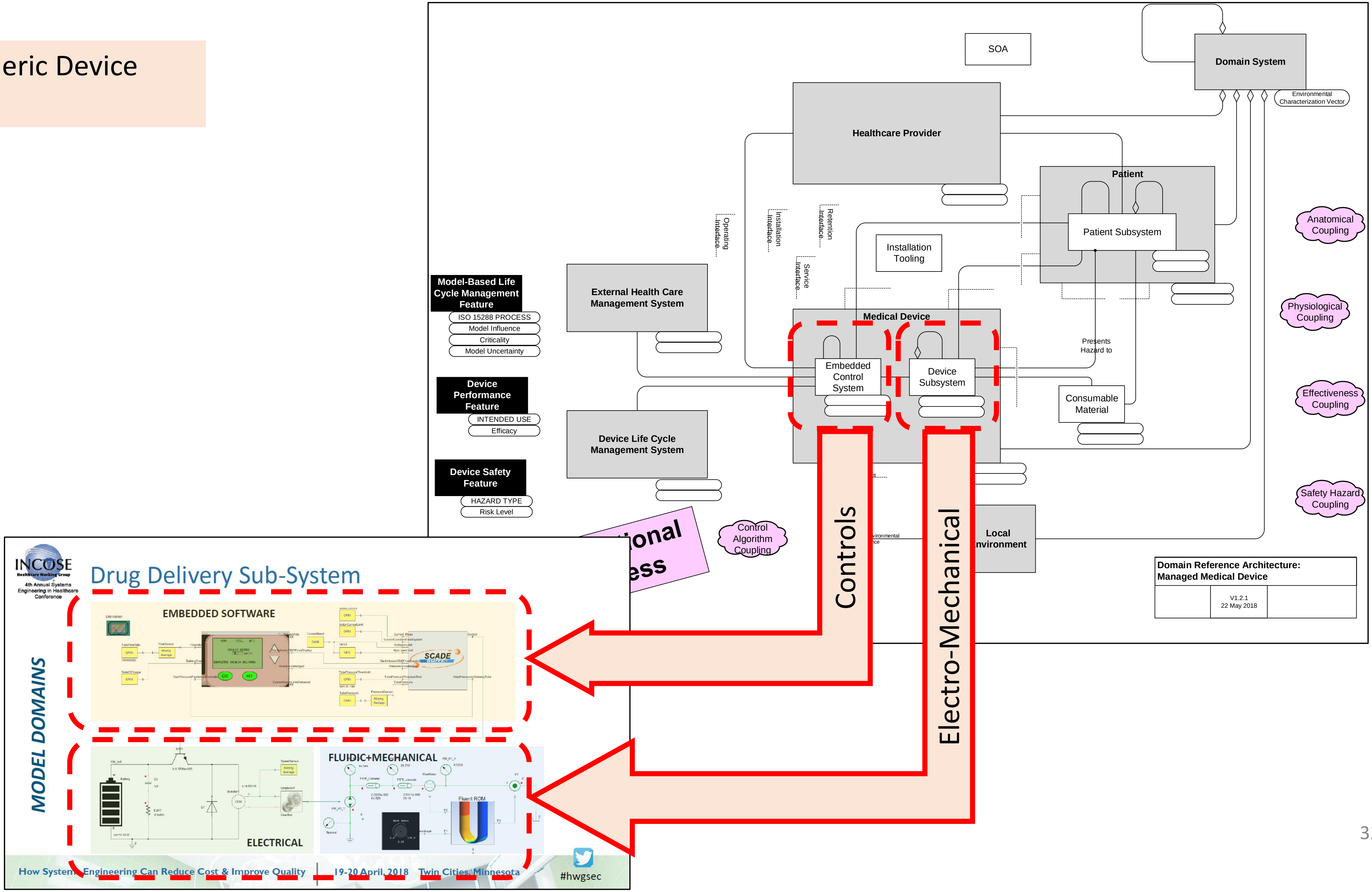
$$R_A(t) = \frac{C_H(t)}{V_G\cdot\tau_m^2}\cdot t\cdot e^{-\frac{t}{\tau_m}} \quad (5)$$

CLINICAL DATA

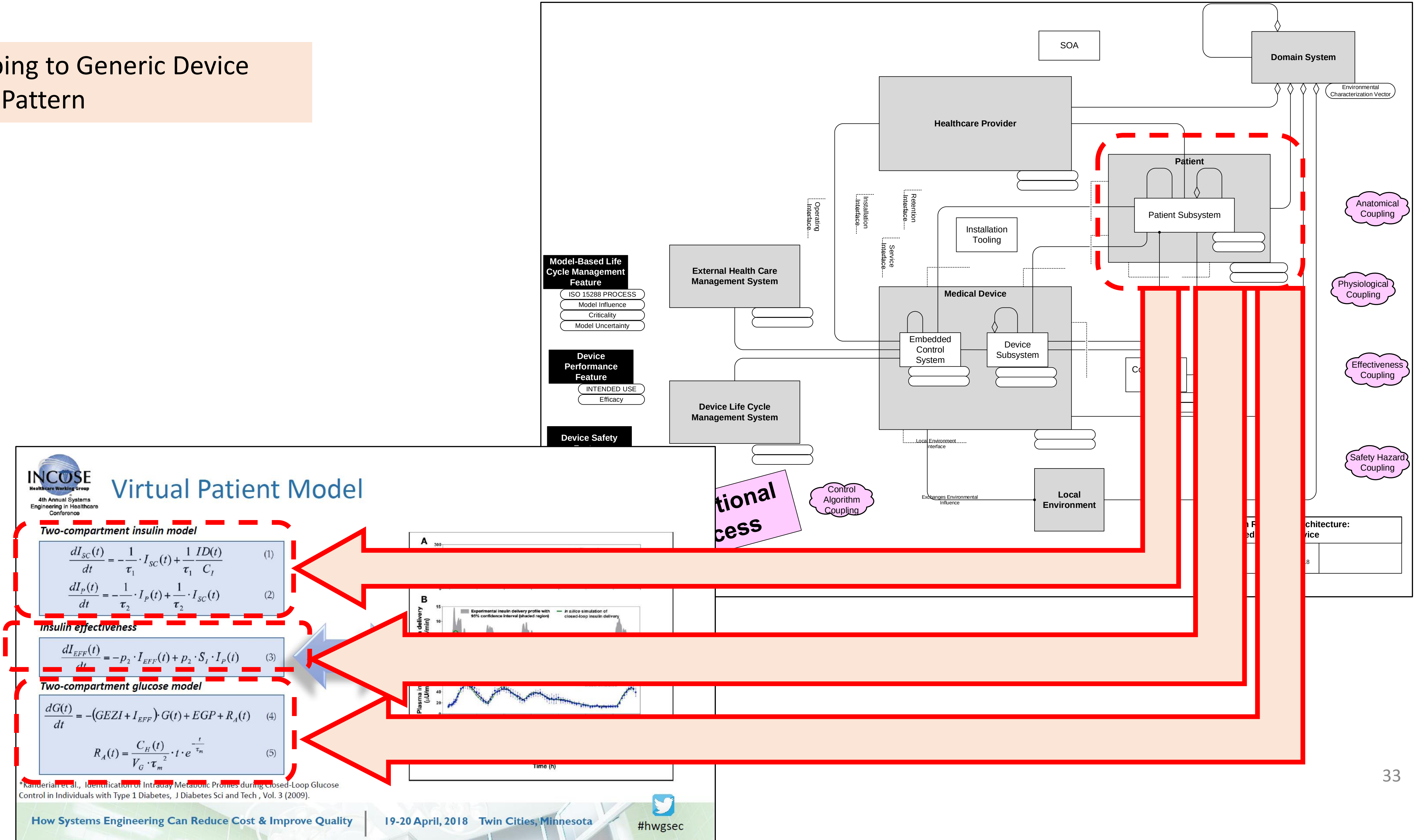


*Kanderian et al., Identification of Intraday Metabolic Profiles during Closed-Loop Glucose Control in Individuals with Type 1 Diabetes, J Diabetes Sci and Tech , Vol. 3 (2009).

Mapping to Generic Device Draft Pattern

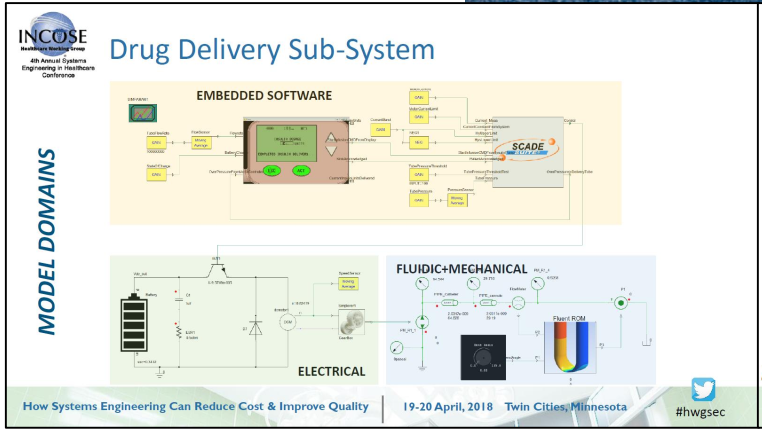


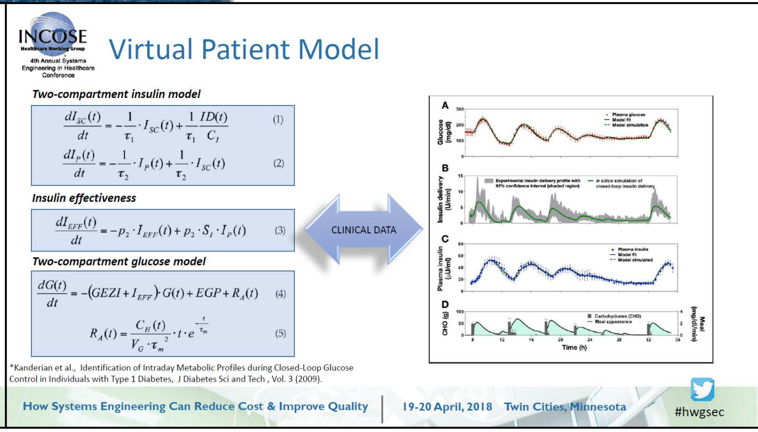
Mapping to Generic Device Draft Pattern

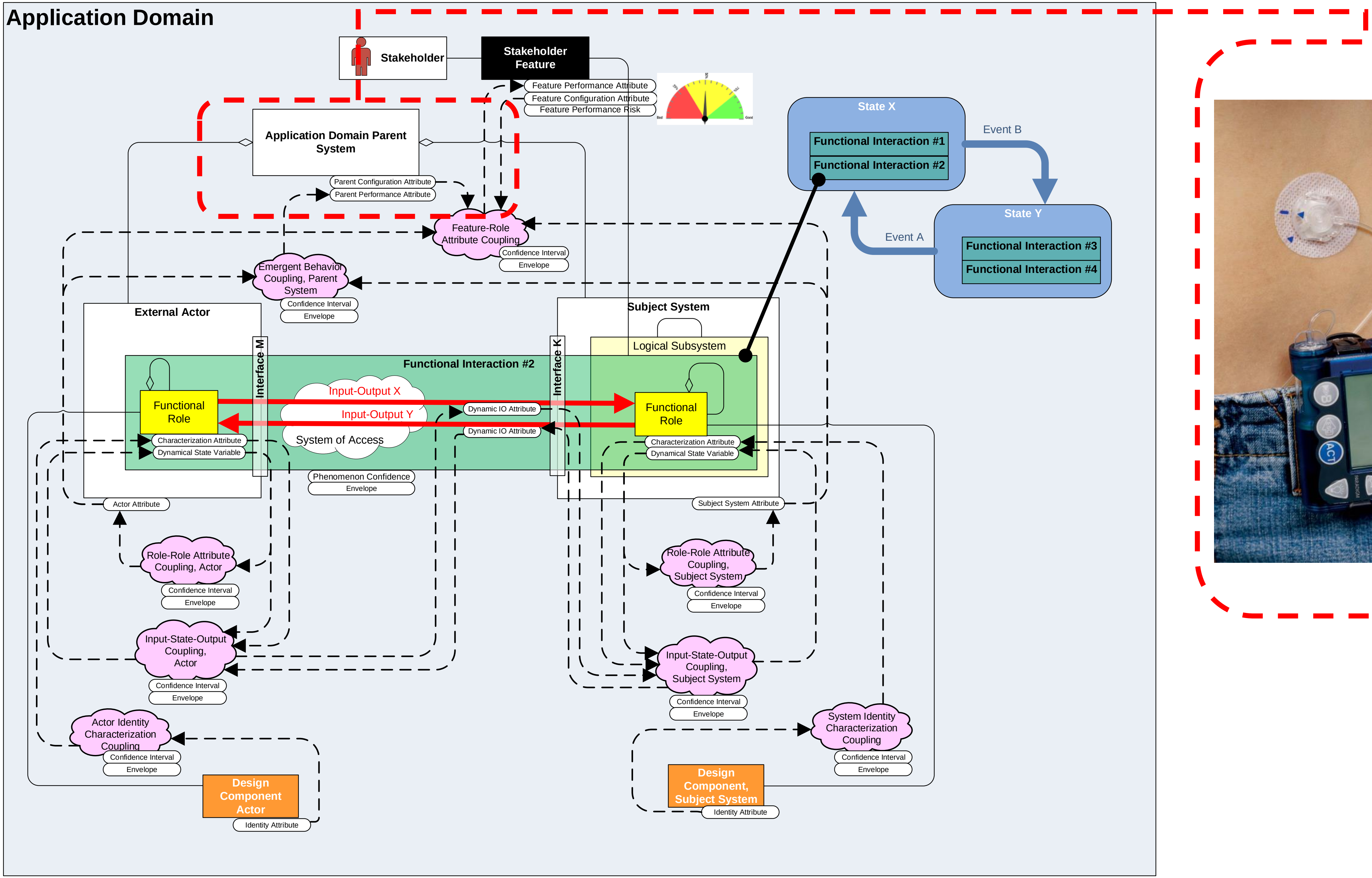


- We also often model a higher level system that emerges from the interaction of other systems, with global properties resulting from their combination.
- In this case, a good place to represent the emergent:
  - hydraulics of the combined patient anatomy, device hydraulics, and liquid
  - overall therapeutic / metabolic performance.
- Particularly if we want to represent performance model uncertainty at higher combined level.

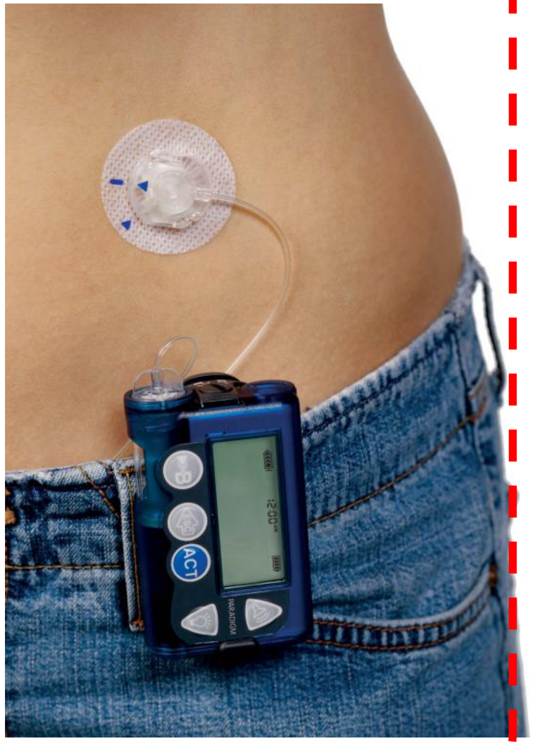
Combined System







Application Domain
Stakeholder
Stakeholder Feature
Feature Performance Attribute
Feature Configuration Attribute
Feature Performance Risk
Application Domain Parent System
Parent Configuration Attribute
Parent Performance Attribute
Feature-Role Attribute Coupling
Confidence Interval
Envelope
Emergent Behavior Coupling, Parent System
Confidence Interval
Envelope
State X
Functional Interaction #1
Functional Interaction #2
Event B
State Y
Functional Interaction #3
Functional Interaction #4
Event A
External Actor
Subject System
Logical Subsystem
Functional Interaction #2
Interface M
Interface K
Functional Role
Input-Output X
Input-Output Y
System of Access
Dynamic IO Attribute
Dynamic IO Attribute
Functional Role
Characterization Attribute
Dynamical State Variable
Characterization Attribute
Dynamical State Variable
Phenomenon Confidence
Envelope
Actor Attribute
Subject System Attribute
Role-Role Attribute Coupling, Actor
Confidence Interval
Envelope
Role-Role Attribute Coupling, Subject System
Confidence Interval
Envelope
Input-State-Output Coupling, Actor
Confidence Interval
Envelope
Input-State-Output Coupling, Subject System
Confidence Interval
Envelope
Actor Identity Characterization Coupling
Confidence Interval
Envelope
System Identity Characterization Coupling
Confidence Interval
Envelope
Design Component Actor
Identity Attribute
Design Component, Subject System
Identity Attribute

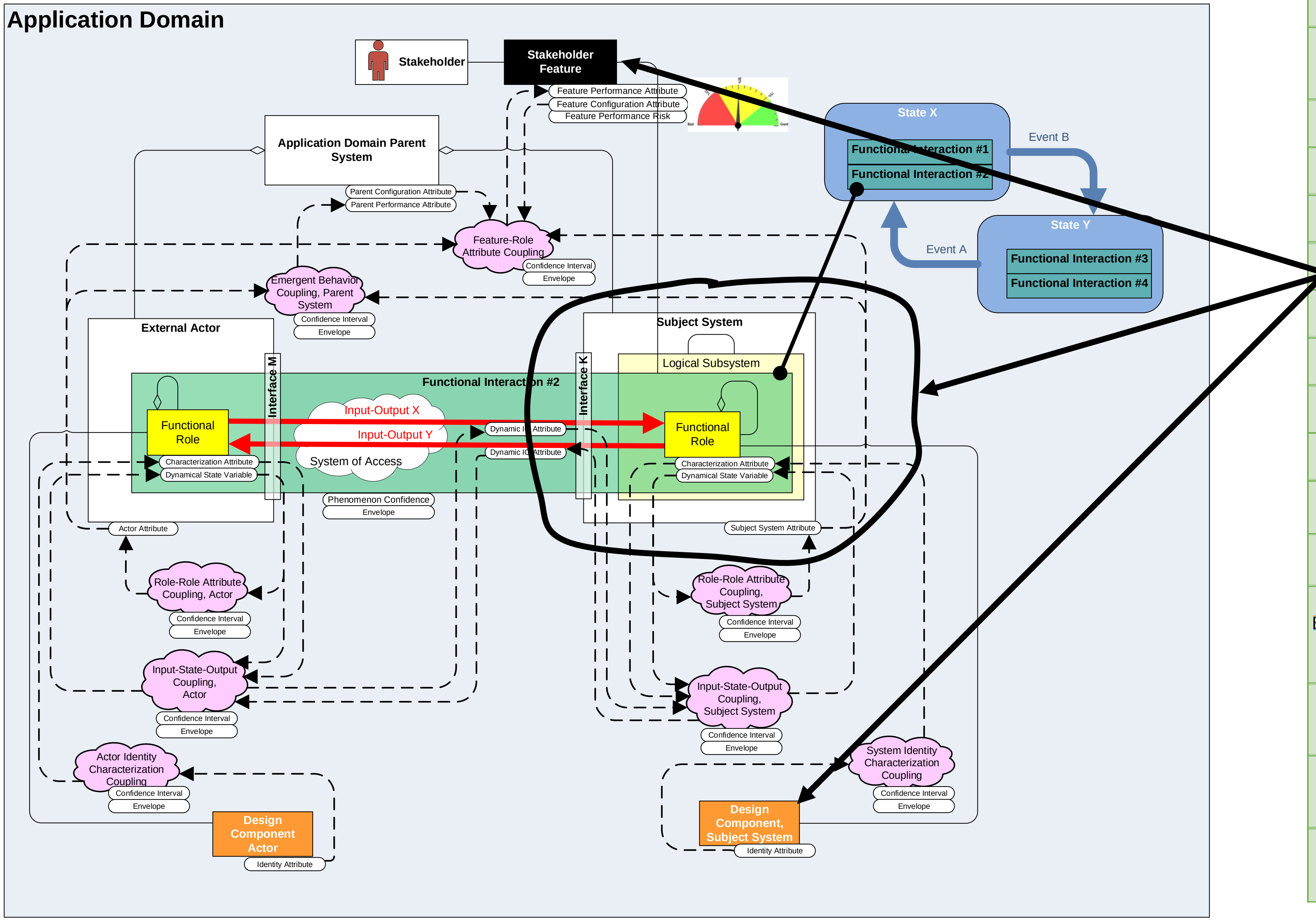


3. Incorporating ASME VV40 into the Model VVUQ Pattern

- The initial version of the Model VVUQ Pattern was generated in 2017 as a specialization of the INCOSE Model Planning and Assessment Pattern.
- The initial version of that pattern provides ability to record required and resulting information concerning VVUQ of the model of interest.
- Upon reading the draft prose of the ASME VV40 standard, we realized that certain important structures in that standard (e.g., Model Credibility Factors) could be incorporated directly into the VVUQ Pattern, as an improvement
  - thereby building them into the work process
  - and advancing some common expectations across community of designers, analysts, regulators

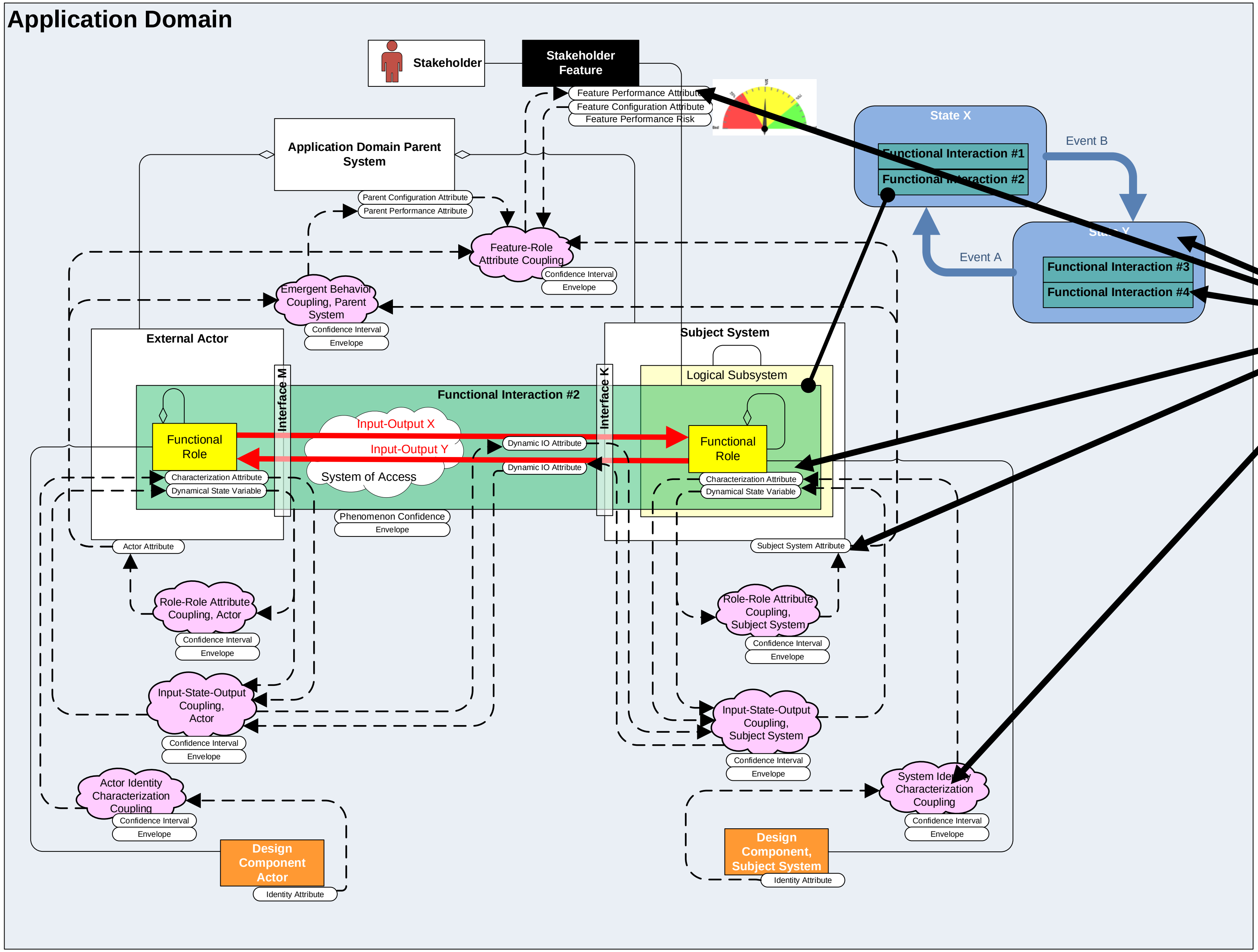
(This is interim material, work on (3) is still in progress.)

More detailed VVUQ Pattern aspects, general systems case first



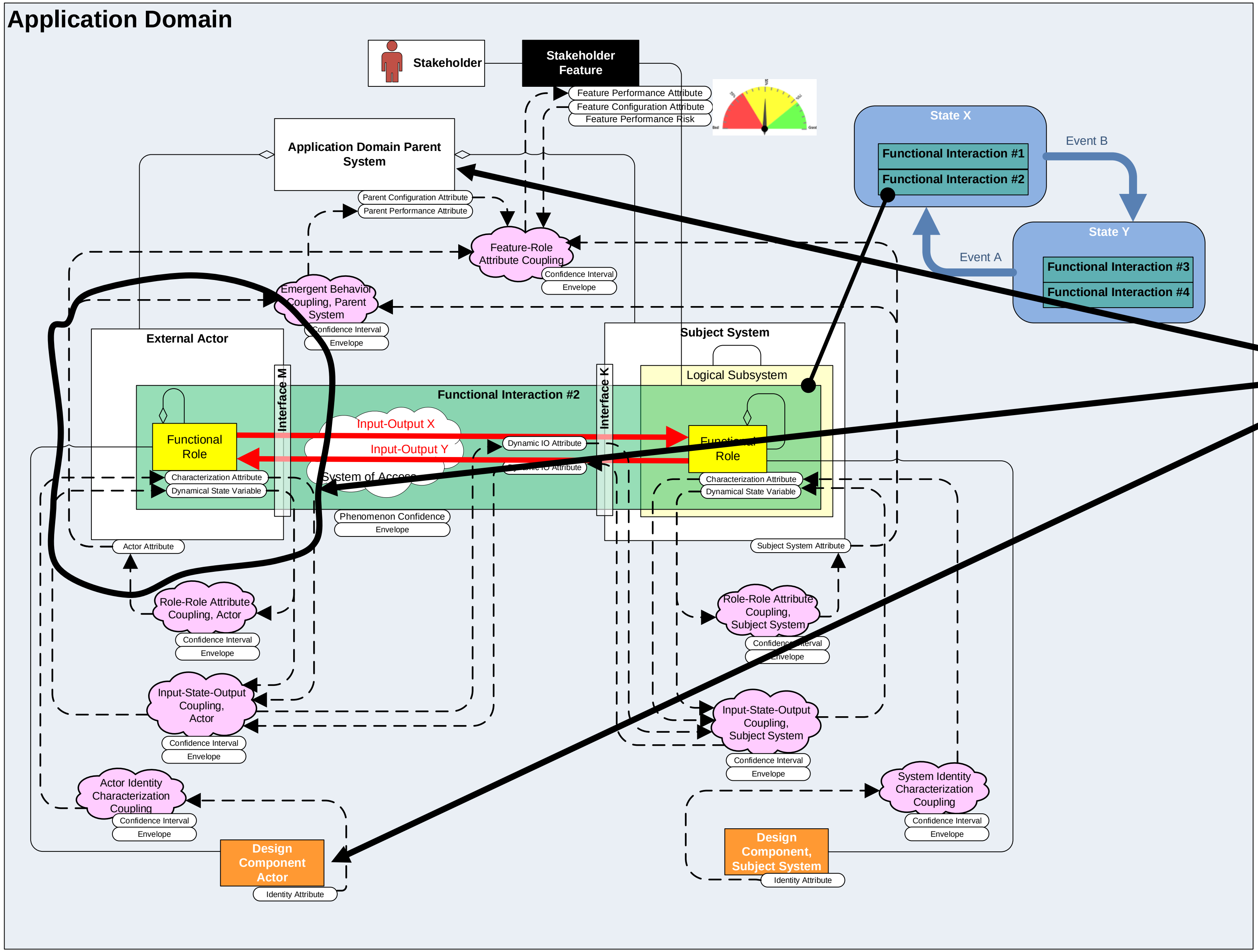
Software Quality Assurance	Code	Verification	Credibility Factors
Numerical Algorithm Verification	Code	Verification	Credibility Factors
Discretization Error	Solution	Verification	Credibility Factors
Use Error	Solution	Verification	Credibility Factors
Numerical Solver Error	Solution	Verification	Credibility Factors
System Configuration	Model	Validation	Credibility Factors
System Properties	Model	Validation	Credibility Factors
Boundary Conditions	Model	Validation	Credibility Factors
Governing Equations	Model	Validation	Credibility Factors
Sample Characterization	Comparator	Validation	Credibility Factors
Control Over Test Conditions	Comparator	Validation	Credibility Factors
Measurement Uncertainty	Comparator	Validation	Credibility Factors
Equivalency of input and output types	Output Assessment	Validation	Credibility Factors
Rigor of Output Comparison	Output Assessment	Validation	Credibility Factors
Relevance of the Quantities of Interest	Applicability		Credibility Factors
Applicability to the Context of Use	Applicability		Credibility Factors

More detailed VVUQ Pattern aspects, general systems case first



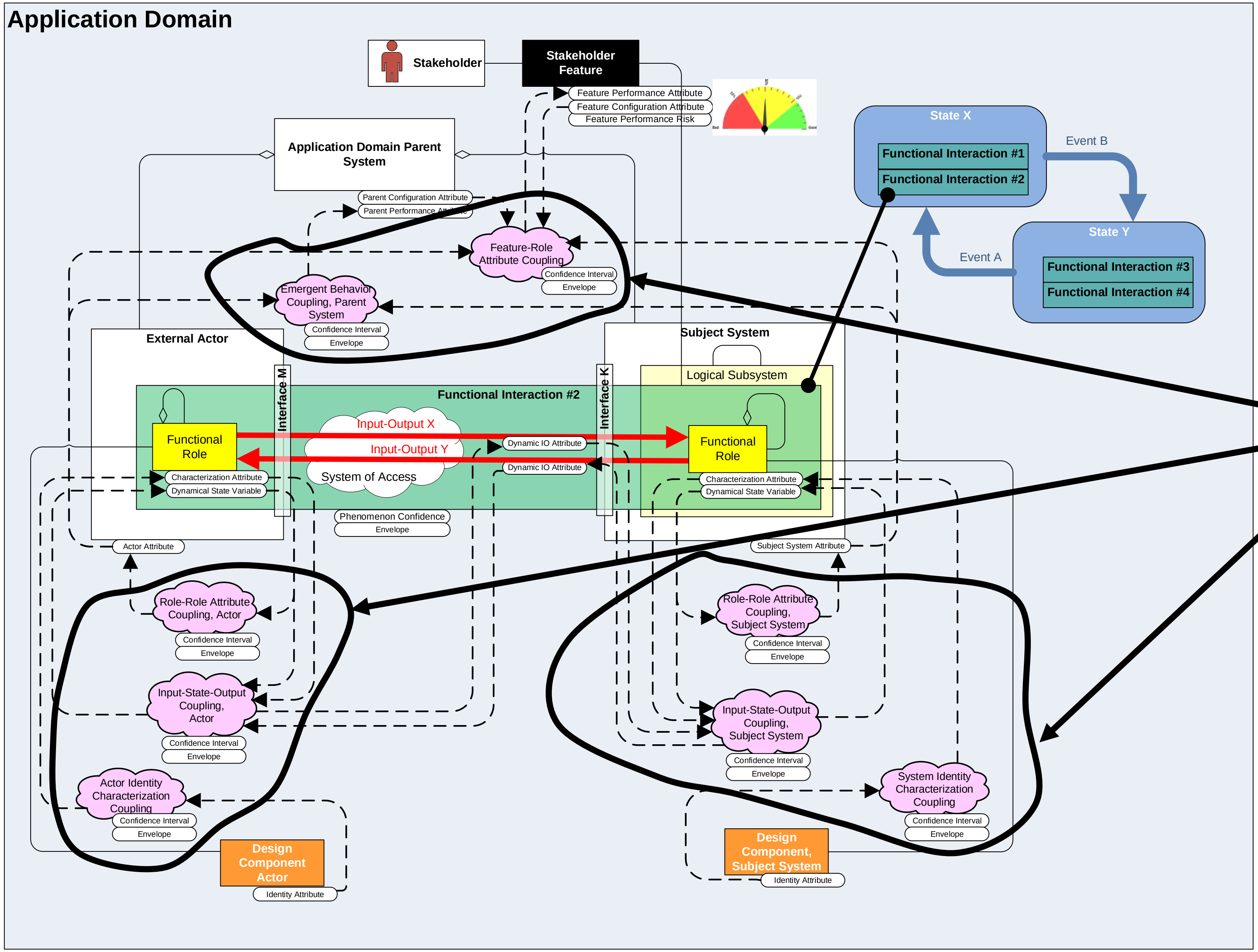
Credibility Factors		
Software Quality Assurance	Code	Verification
Numerical Algorithm Verification		
Discretization Error	Solution	
Use Error		
Numerical Solver Error		
System Configuration	Model	Validation
System Properties		
Boundary Conditions		
Governing Equations		
Sample Characterization	Comparator	
Control Over Test Conditions		
Measurement Uncertainty		
Equivalency of input and output types	Output Assessment	
Rigor of Output Comparison		
Relevance of the Quantities of Interest	Applicability	
Applicability to the Context of Use		

More detailed VVUQ Pattern aspects, general systems case first



Credibility Factors			
Verification	Code	Software Quality Assurance	
		Numerical Algorithm Verification	
	Solution	Discretization Error	
		Use Error	
		Numerical Solver Error	
Validation	Model	System Configuration	
		System Properties	
		Boundary Conditions	
		Governing Equations	
	Comparator	Sample Characterization	
		Control Over Test Conditions	
		Measurement Uncertainty	
	Output Assessment	Equivalency of input and output types	
		Rigor of Output Comparison	
Applicability		Relevance of the Quantities of Interest	
		Applicability to the Context of Use	

More detailed VVUQ Pattern aspects, general systems case first



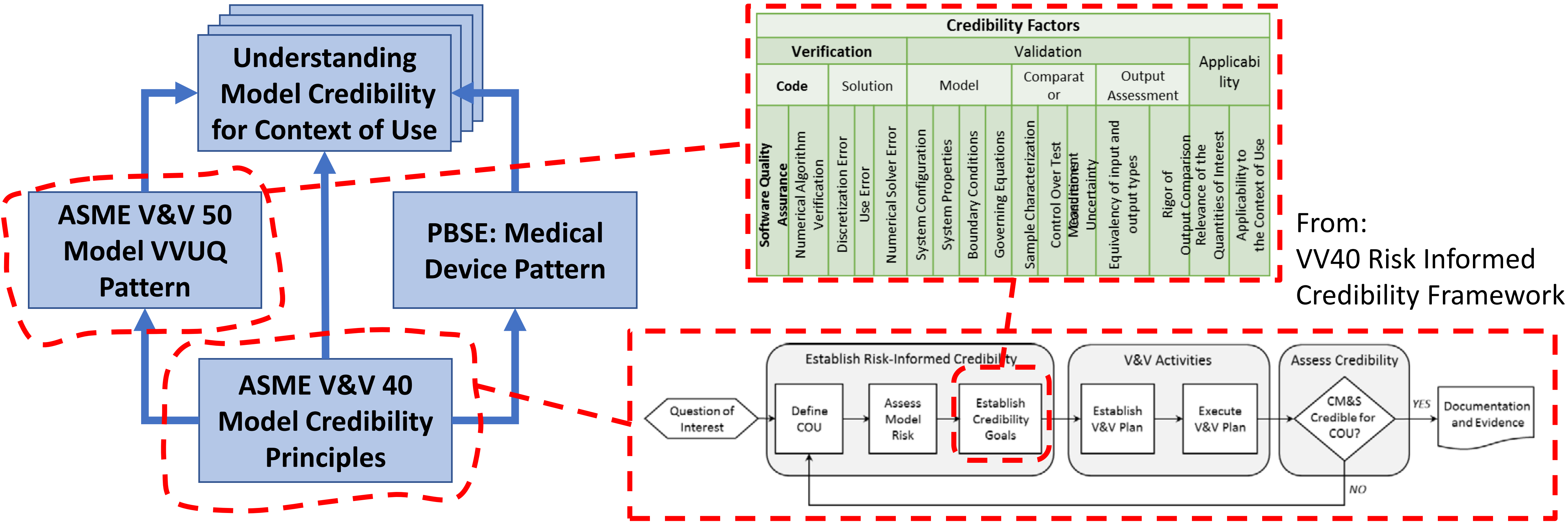
Credibility Factors		
Software Quality Assurance	Code	Verification
Numerical Algorithm Verification	Code	Verification
Discretization Error	Solution	Verification
Use Error	Solution	Verification
Numerical Solver Error	Solution	Verification
System Configuration	Model	Validation
System Properties	Model	Validation
Boundary Conditions	Model	Validation
Governing Equations	Model	Validation
Sample Characterization	Comparator	Validation
Control Over Test Conditions	Comparator	Validation
Measurement Uncertainty	Comparator	Validation
Equivalency of input and output types	Output Assessment	Validation
Rigor of Output Comparison	Output Assessment	Validation
Relevance of the Quantities of Interest	Applicability	
Applicability to the Context of Use	Applicability	

Back up reference material

-

The Computational Model Requirements Pattern (from VV50 team)

- The more detailed parts of the Model VVUQ Pattern embeds configurable model-based data structures supporting the capture and representation of guidance as from the VV40 Risk Informed Credibility Framework, including its (configurable) Credibility Factors:



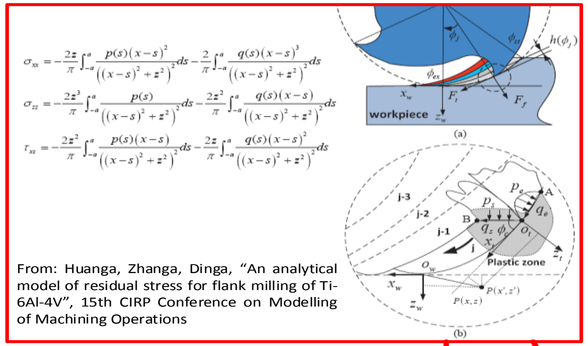
From:
VV40 Risk Informed
Credibility Framework

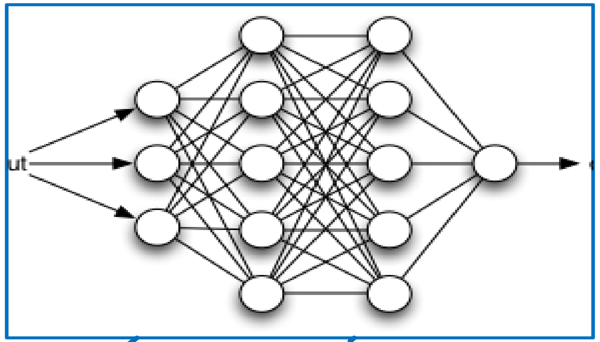
Physics-Based Model

- 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.





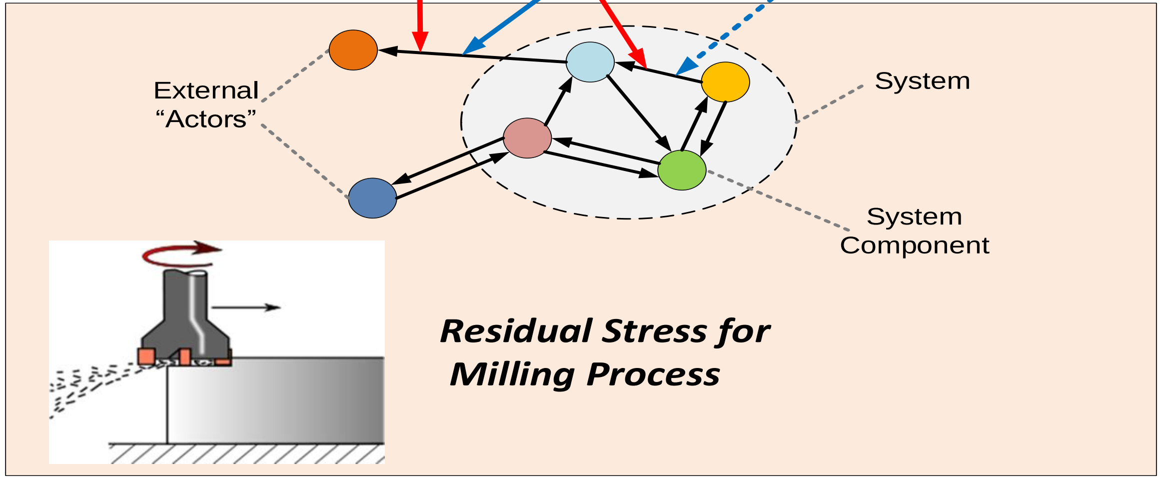
- **Physical scientists and phenomena models from their disciplines can apply here.**
- **The hard sciences physical laws, and how they can be used to explain the externally visible behavior of the system of interest.**

predicts, explains

predicts

optional

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



Real System Being Modeled

Physics-Based Model

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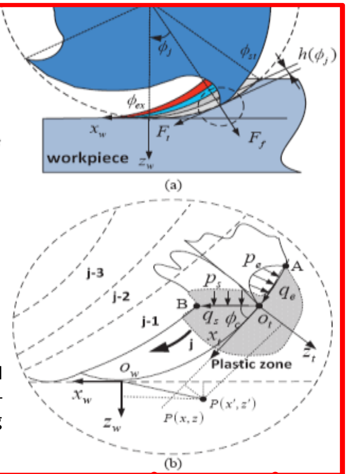
- Model intermediate quantities may not correspond to internal or external physical parameters, but combine to adequately predict external behavior, fitting it to compressed relationships.
- Model has external predictive value, but not internal explanatory value.
- Overall model may have reduced dimensionality.

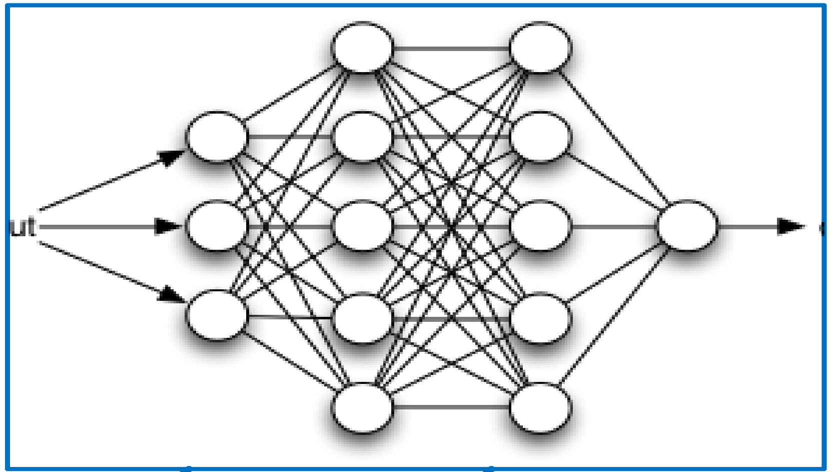
$$\sigma_{xx} = -\frac{2z}{\pi}\int_{-a}^{a}\frac{p(s)(x-s)^2}{\left((x-s)^2+z^2\right)^2}ds - \frac{2}{\pi}\int_{-a}^{a}\frac{q(s)(x-s)^3}{\left((x-s)^2+z^2\right)^2}ds$$

$$\sigma_{zz} = -\frac{2z^3}{\pi}\int_{-a}^{a}\frac{p(s)}{\left((x-s)^2+z^2\right)^2}ds - \frac{2z^2}{\pi}\int_{-a}^{a}\frac{q(s)(x-s)}{\left((x-s)^2+z^2\right)^2}ds$$

$$\tau_{xz} = -\frac{2z^2}{\pi}\int_{-a}^{a}\frac{p(s)(x-s)}{\left((x-s)^2+z^2\right)^2}ds - \frac{2z}{\pi}\int_{-a}^{a}\frac{q(s)(x-s)^2}{\left((x-s)^2+z^2\right)^2}ds$$



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



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predicts, explains

predicts

optional

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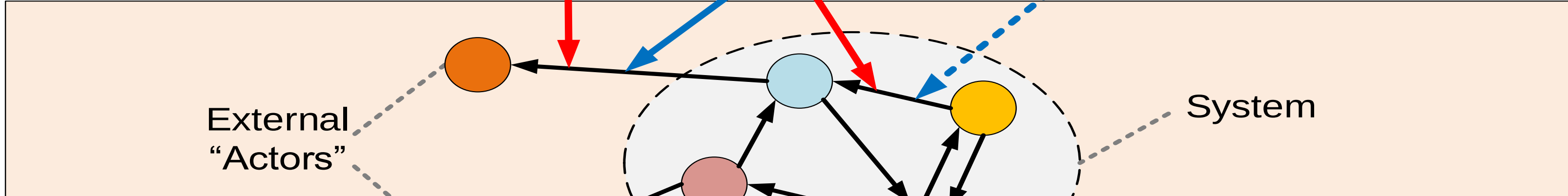
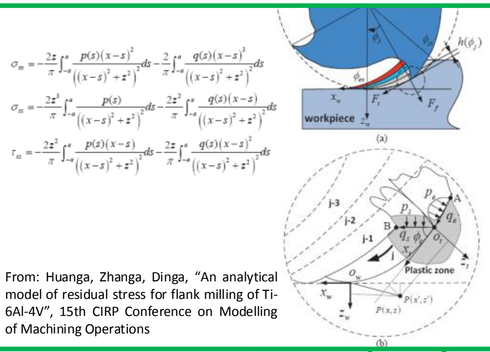


Hybrid Model: Both Data Driven and Physics-Based

- 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.



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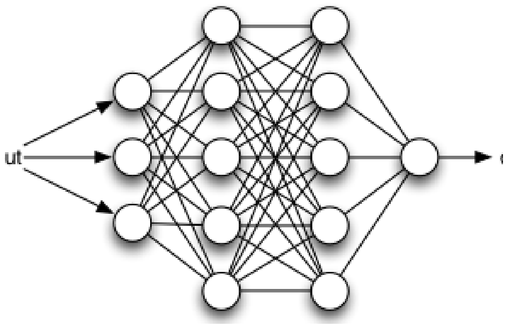

- **Physical scientists and phenomena models from their disciplines can apply here.**
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predicts, explains

predicts

optional

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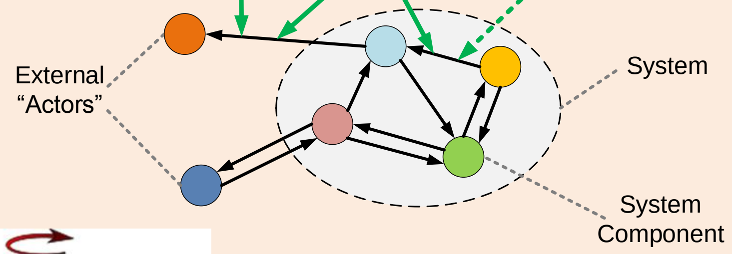

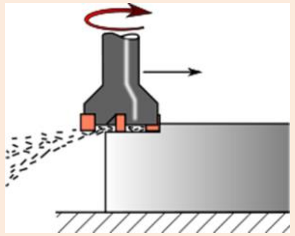

Residual Stress for Milling Process

Real System Being Modeled

Hybrid Model: Both Data Driven and Physics-Based

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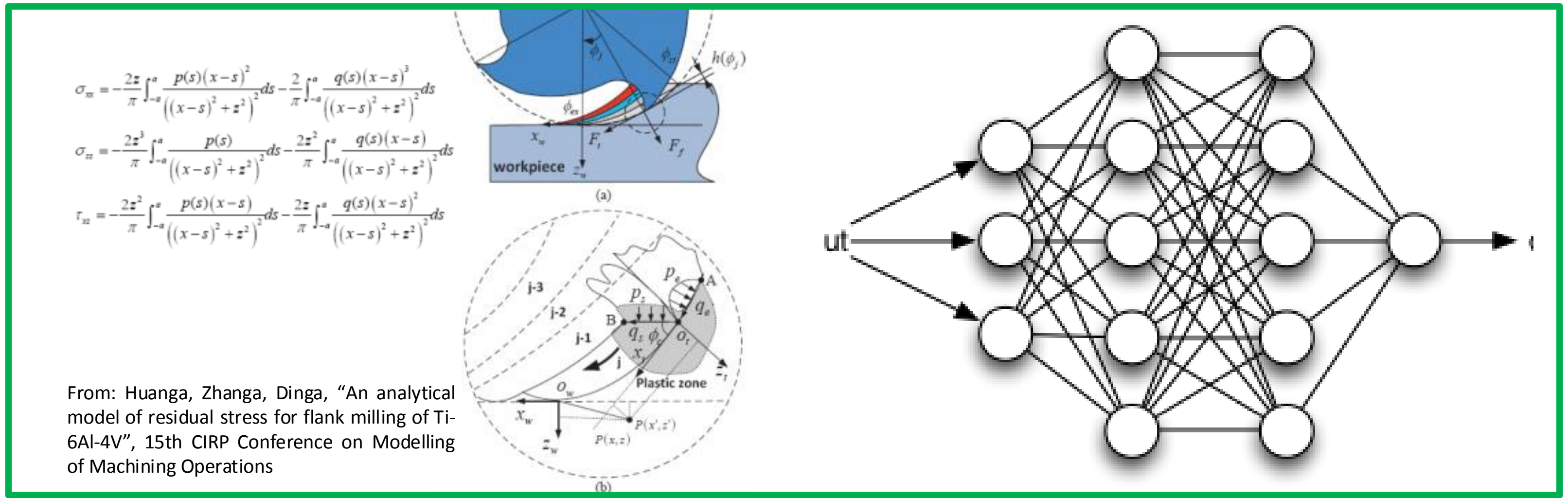

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predicts, explains

predicts

optional

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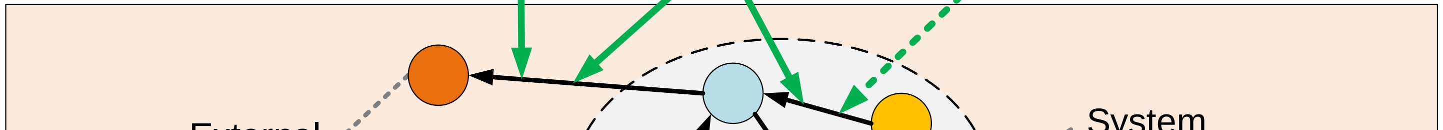
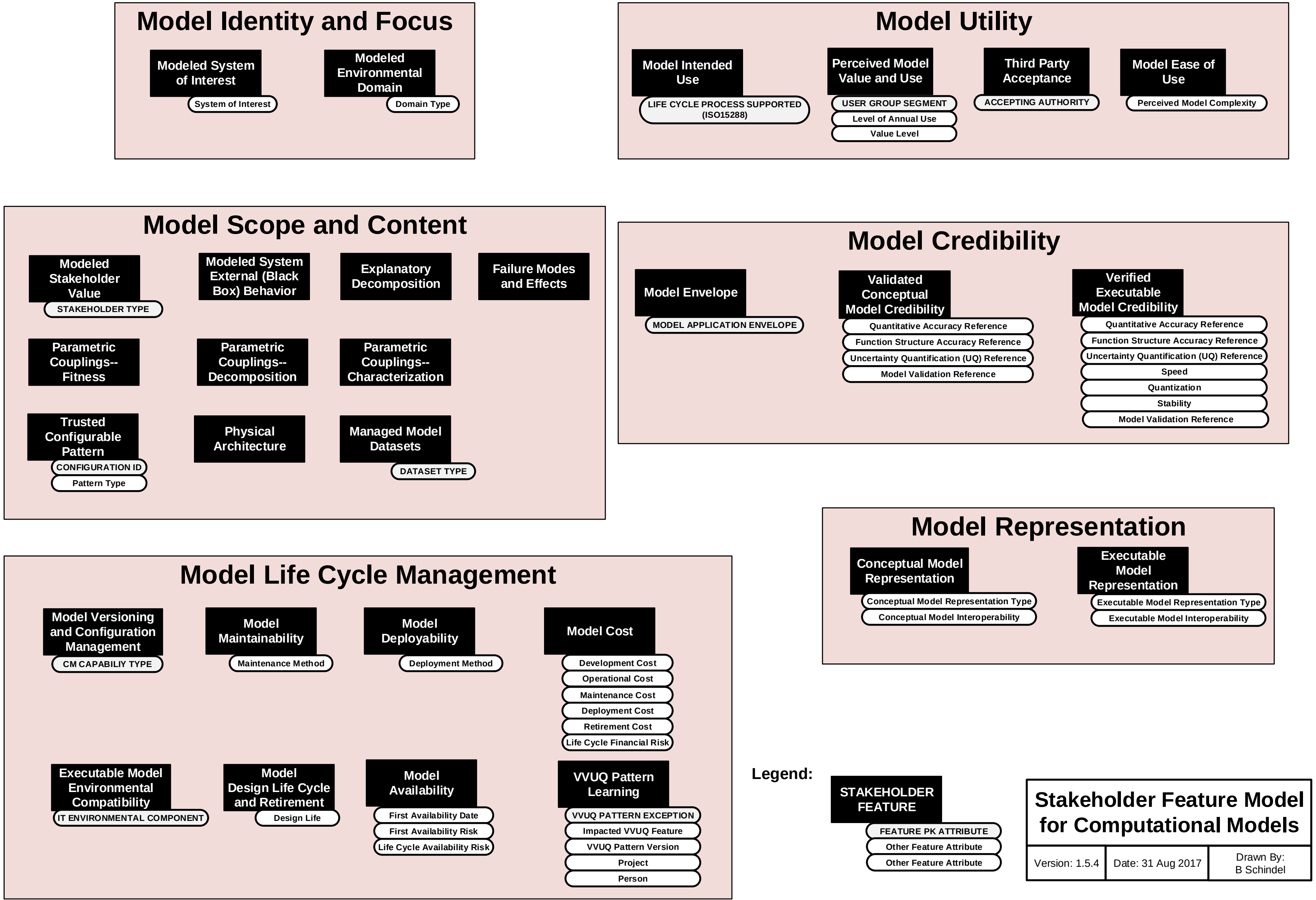
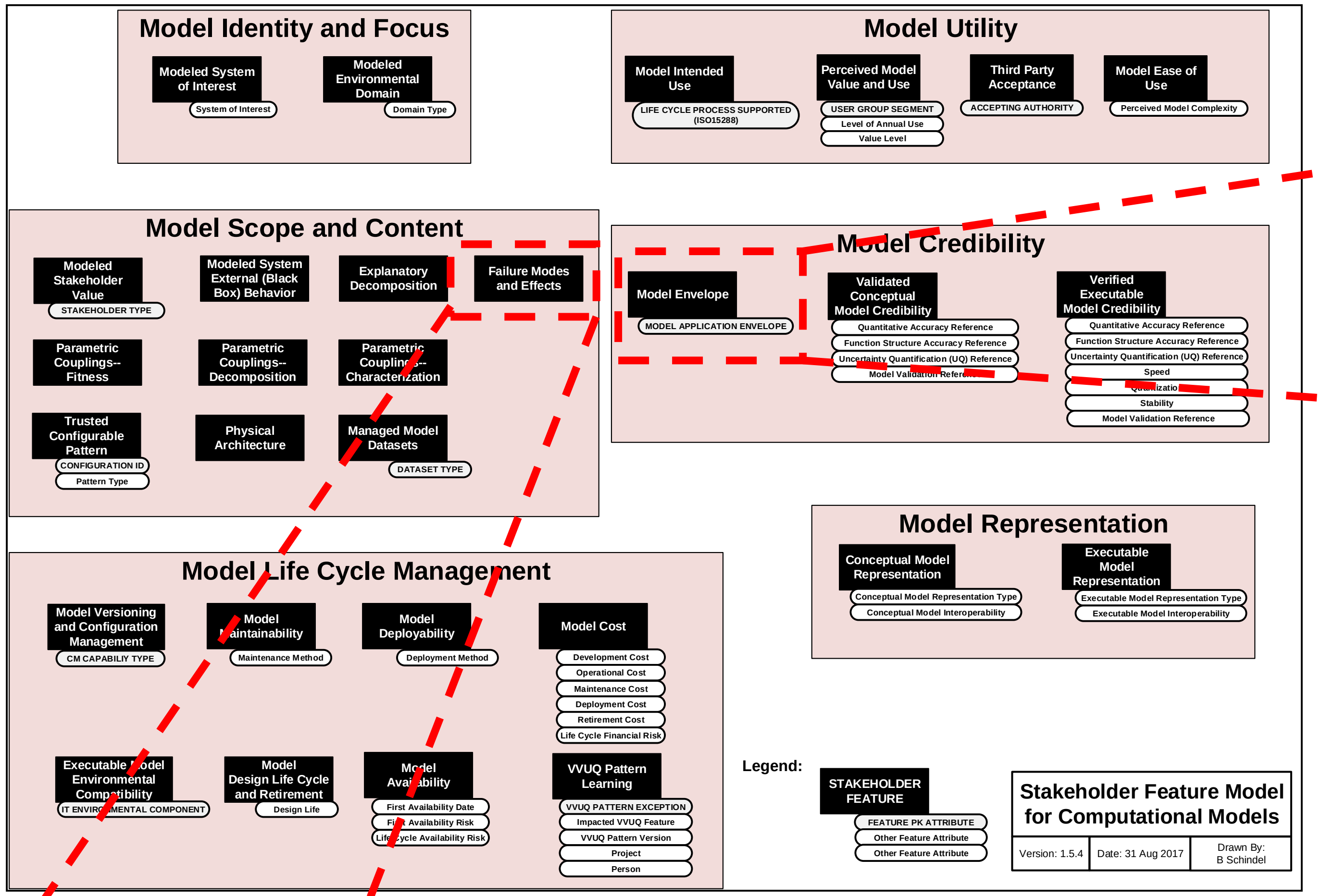
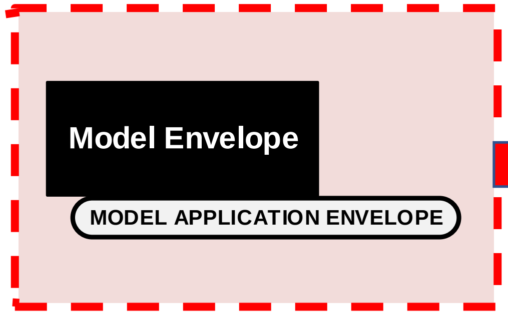


Model VVUQ Pattern:
Model Stakeholder Features Overview





Model Feature, from Configurable VVUQ Pattern



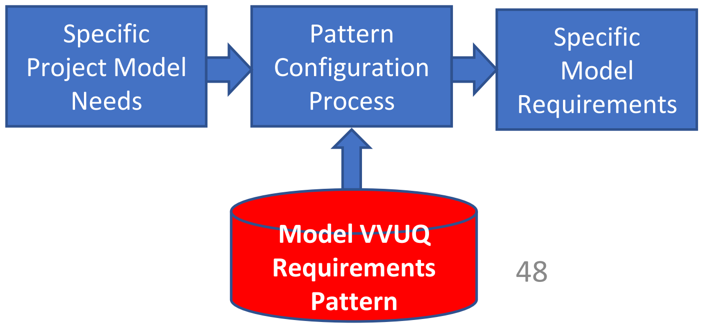
Model Requirement, from Configurable VVUQ Pattern

3.1.2 Modeled Envelope, External Technical: The model shall represent the system of interest over a specified (discrete or continuous) range or envelope of technical external environment interaction configurations.

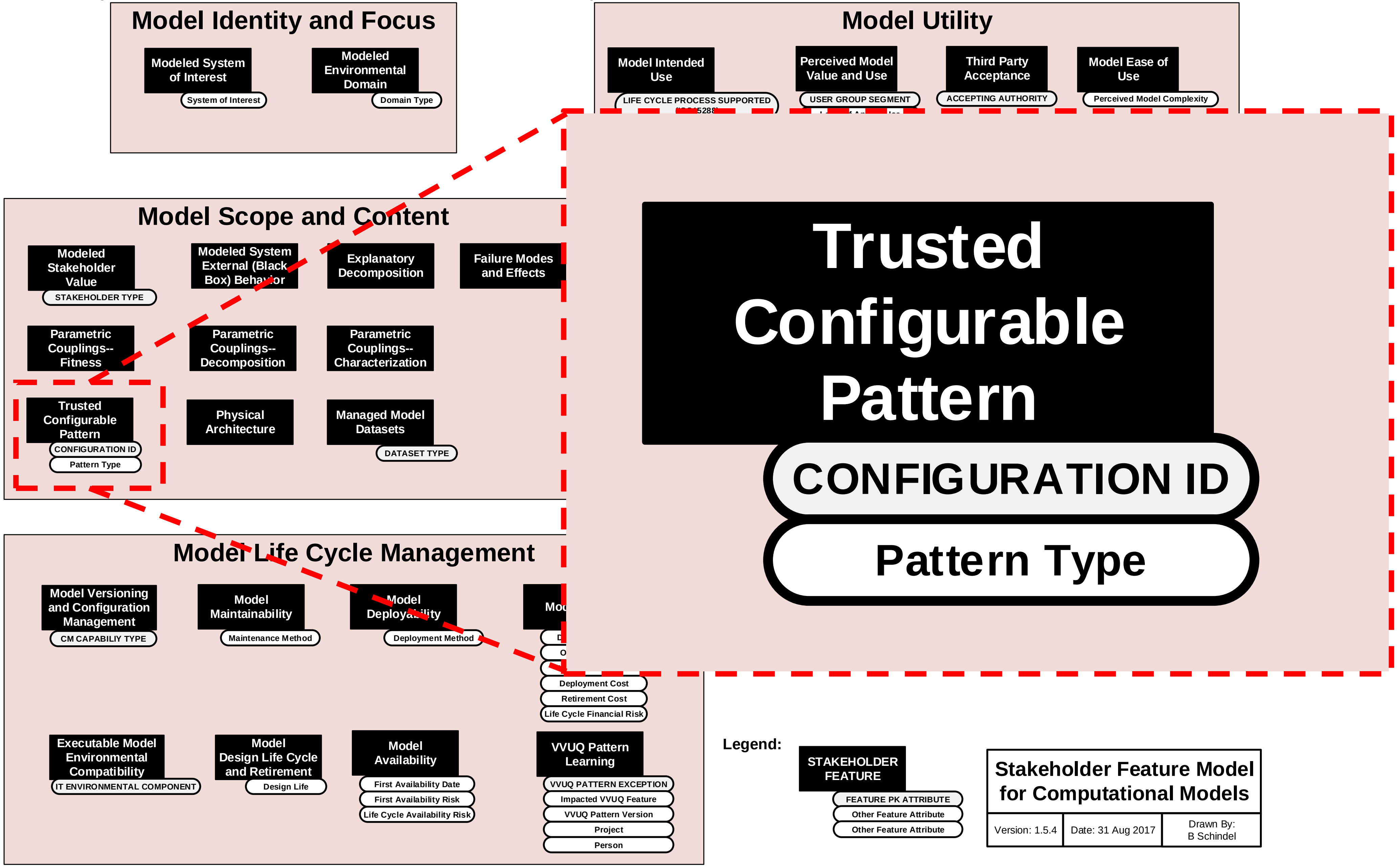
Model Requirement, from Configurable VVUQ Pattern

2.6.1 Failure Mode: The model shall include identification of component failure modes, as to underlying state leading to predicted failure.

Model Feature, from Configurable VVUQ Pattern



The Computational Model Requirements Pattern (from VV50 team)



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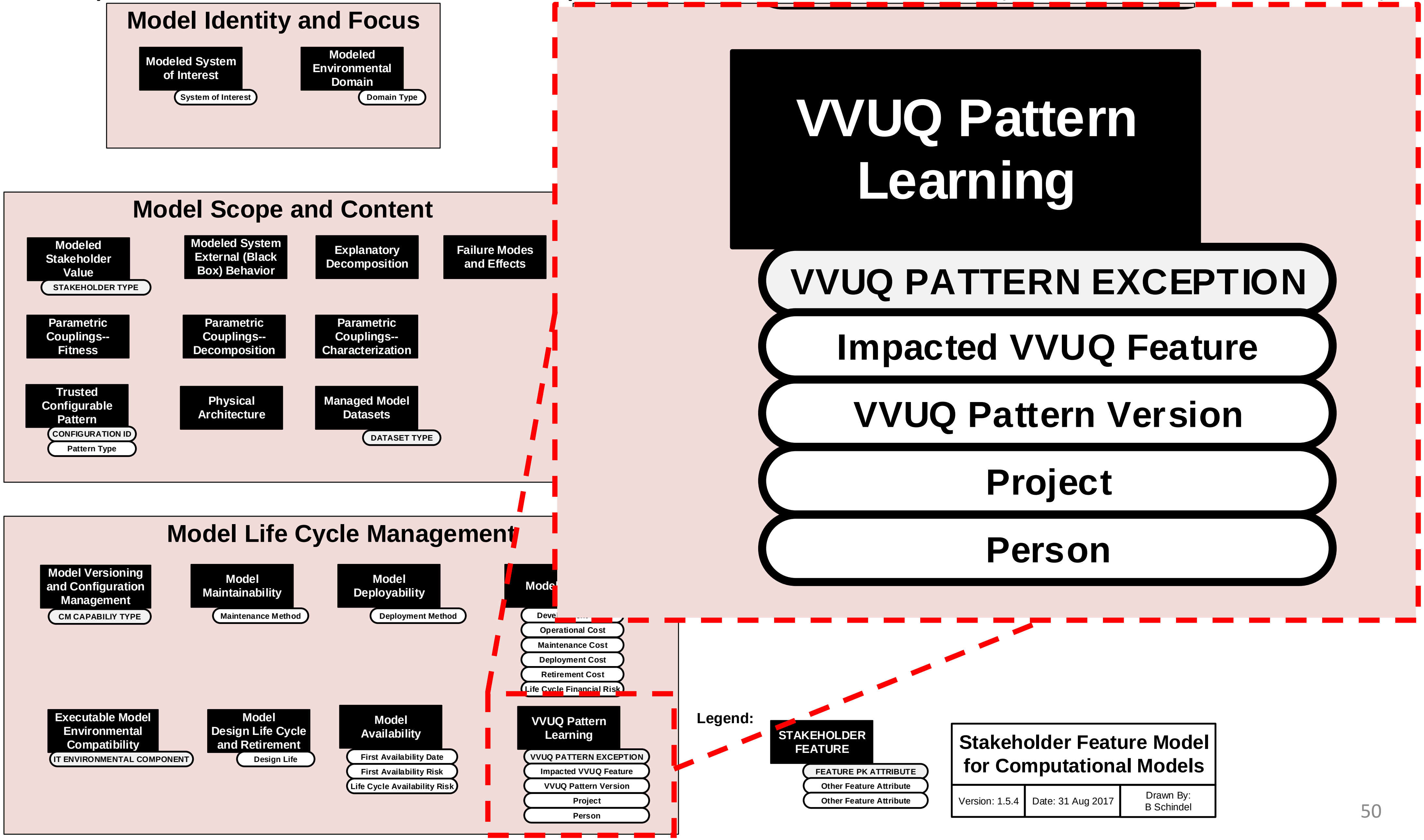

- Med device generic features
- Med device generic interactions
- Med device generic states