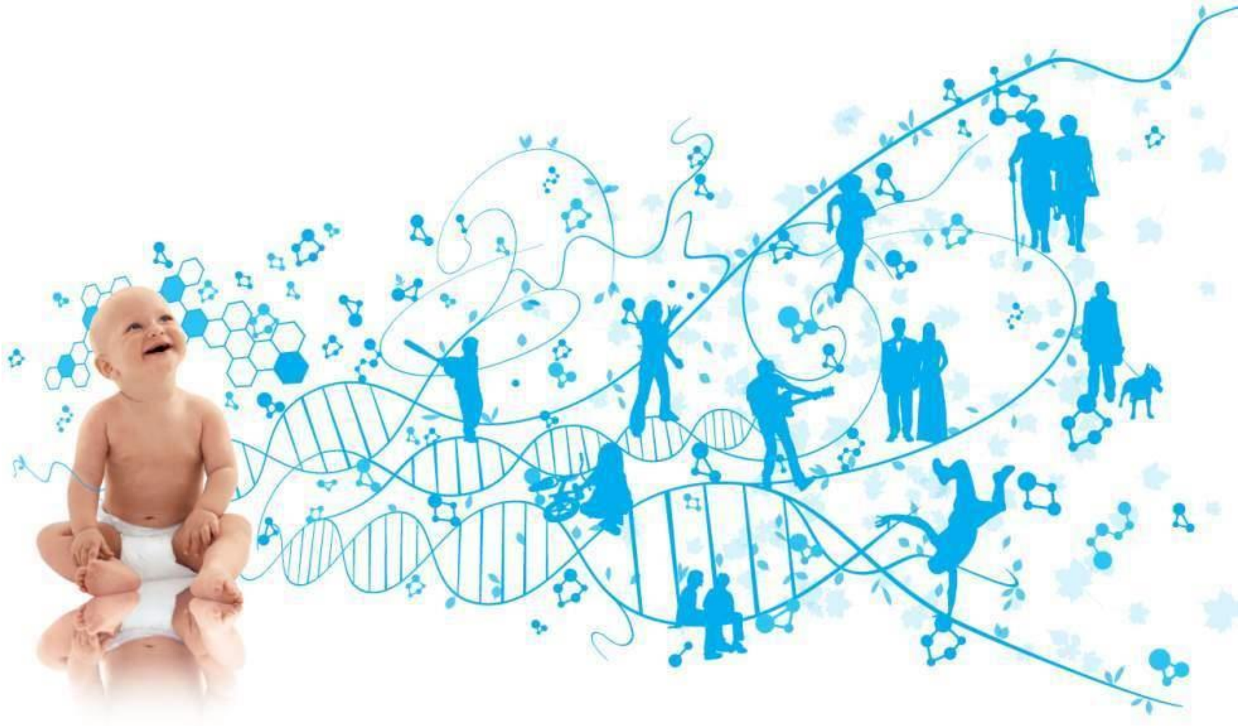
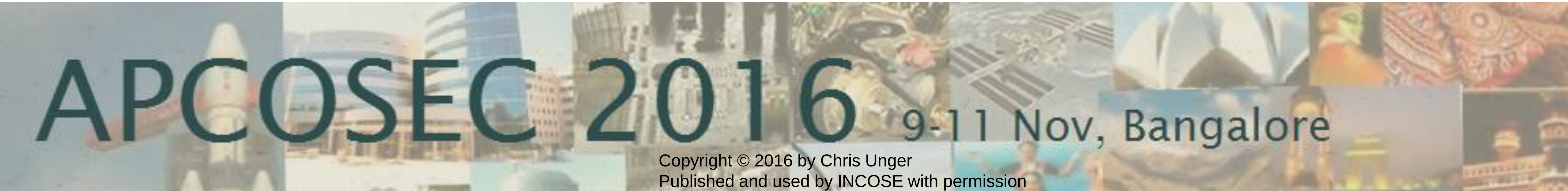
Applications of Systems Engineering to Healthcare



Chris Unger
Chief Systems Engineer, GE Healthcare



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Medical industry faces many challenges

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

Courtesy of Kim Cobb, IBM Rational

Market Driven vs. Contract Driven

GEHC "Extension"

- Customer of "systems engineering" is internal (marketing, product management)
- Requirements, dates, budgets are more 'flexible'…success is judged by the market, not by a single customer

Systems Engineering: *From Needs to Solutions*

Systems Engineering Is

- Every product **seamlessly** integrates into the customer's workflow, **reliably** meets all their needs, and **delights** the customer,
- technical **work is clearly tied to market impact**,
- technical **risks** are **retired early and robustly**,
- design **decisions** are identified and closed predictably (and **stay closed**),
- quality problems (when they exist) are **found and resolved early**, and
- **creative ideas** come from all; designs are **optimized across organizational boundaries**,

Systems Engineering Is Not (Just)

- Requirements capture and allocation/decomposition
- Verification and Traceability
- ***NOT just Documentation***

Winning Products happen when **Systems** ~~Engineers~~ **Thinkers** are effective

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The Challenge… Energy Conversion & Detection

MR 3T

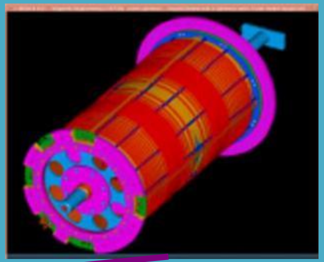
30 MJ

Performix Pro

40 kJ

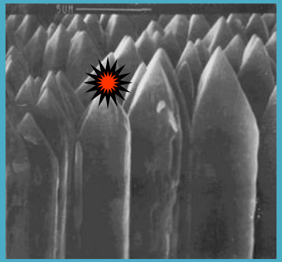
Gradient Coil

1 kJ



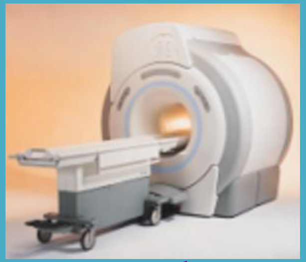
e^- Noise

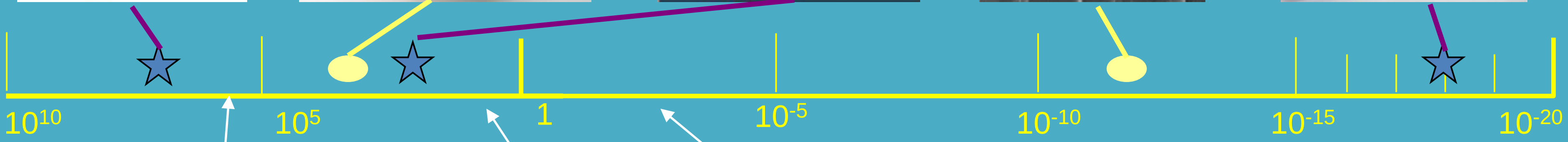
8 fJ



MR Min Signal

10^{-18} J





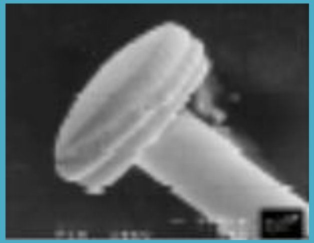
1MJ

Truck @ 50 kph

400 J

Climbing 1 Step

2 mJ



Pin Dropping

Orders of magnitudes

Everyday: 12

Xray: 16

MR: 25

(Like hearing the pin drop on the other side of the earth)

Normal Everyday Energies

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What is Systems Engineering at GEHC?

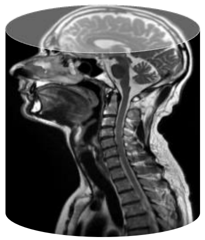
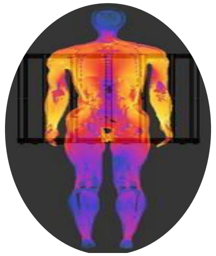
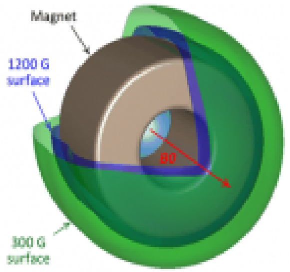


Image Quality



Safety & Regulatory

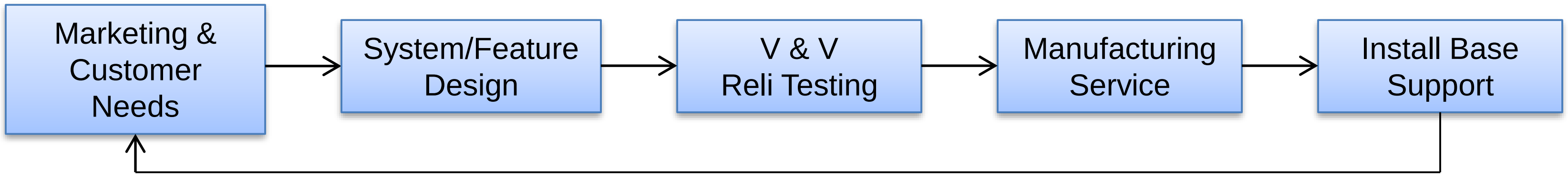
Usability



Performance

Reliability

Serviceability



Not Just Functional Requirements!

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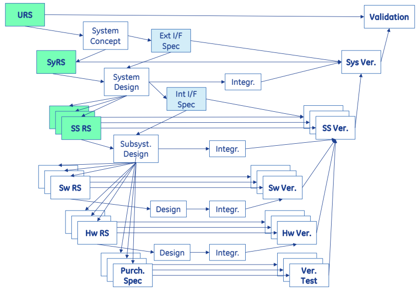
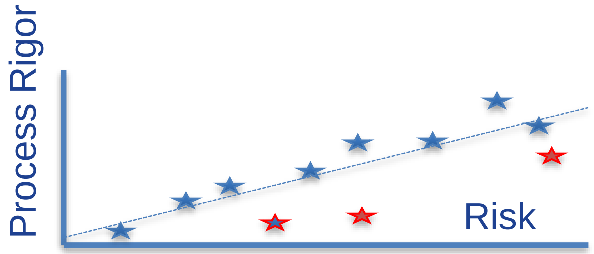
How is SE Organized and Tailored?

Common Program Milestones

Common System Lifecycle



Differing Risk Profile



Locations all over the world: organized by product line (and segment)

Size of the organization: SE team sizes vary from <10 to 100+.

Scale of programs: <10 engineers to many hundreds. Less than a year to 3+ years, with basic technology developed over a decade.

Organization: Product Centralized (SE General Manager) to decentralized (no SE managers)

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Strategies for Tailoring Systems Engineering

CT Scanner – Many requirements, complex behavior

Xray Tube – High performance, low margin technology

imagination at work

Example of Tailoring the Engineering Process

CT Scanner

~ 1000 System Requirements

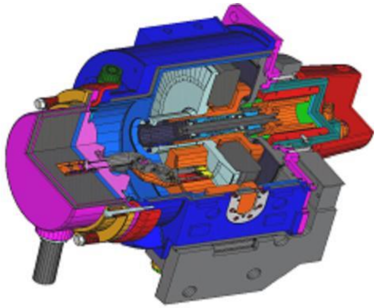
~30 options

~30 process critical parameters

<u>Response</u>

High Traceability, using DOORs and RQM

XRay Tube



~30 Subsystem Requirements

~15 **very** process critical parameters

<u>Response</u>

Design for Six Sigma/Reliability, using Minitab and Reliasoft

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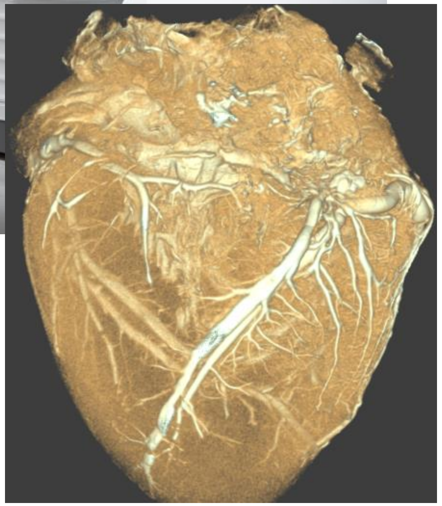
Computed Tomography

Moderately complex system with complex behavior

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

First GEHC project using MBSE

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



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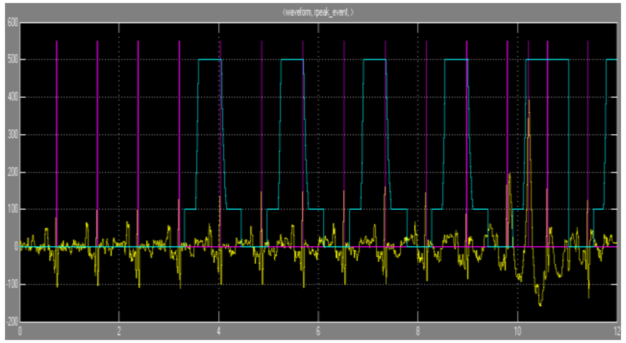
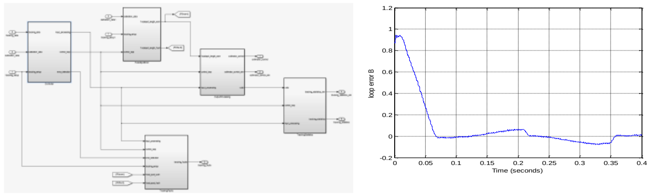
Modeling in Computed Tomography

Multiple model based designs directly to software and hardware.

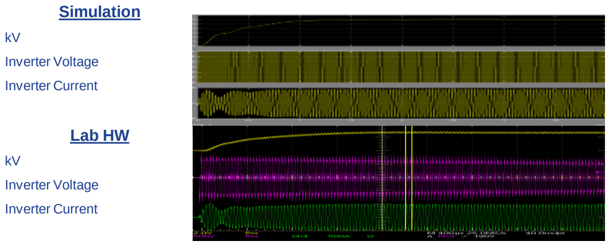
Cardiac Acquisition and Emission Modulation
- Feature analysis and simulation performed in SIMULINK
- Auto-generating C++ code



Active X-Ray Beam Position Control
- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generating C++ code



X-Ray Generator KV Control Loop
- Control/Plant models designed/analyzed in SIMULINK.
- Auto-generated vhdl



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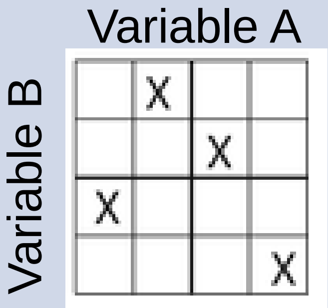
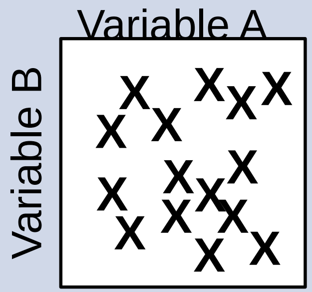
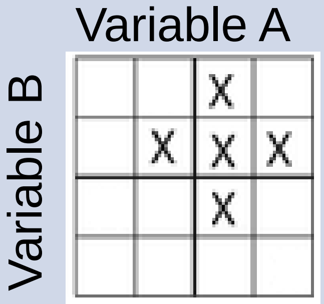
Design Space Exploration

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

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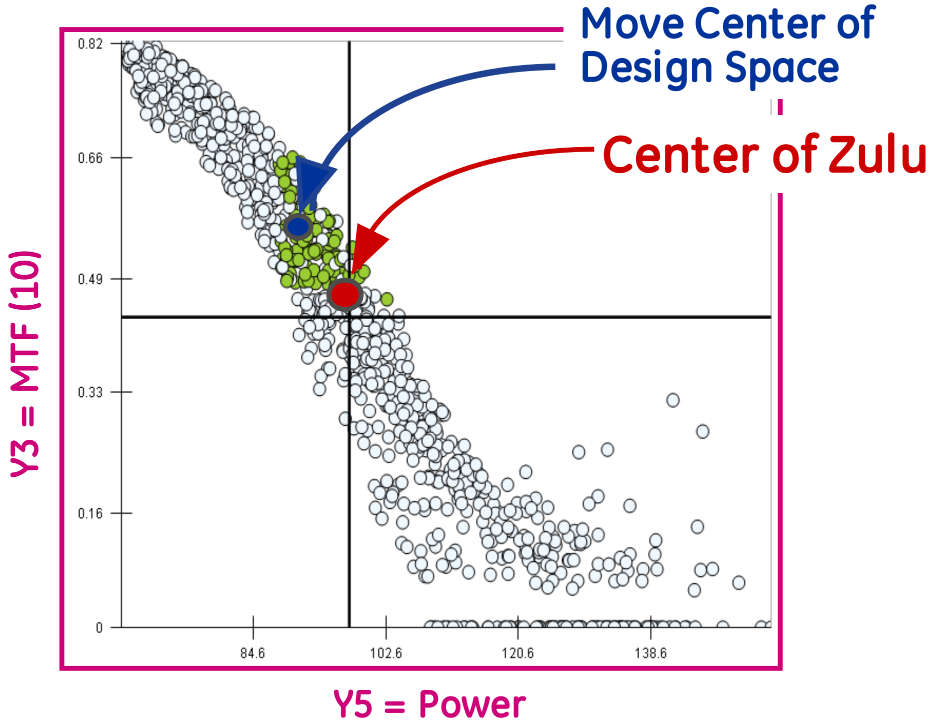
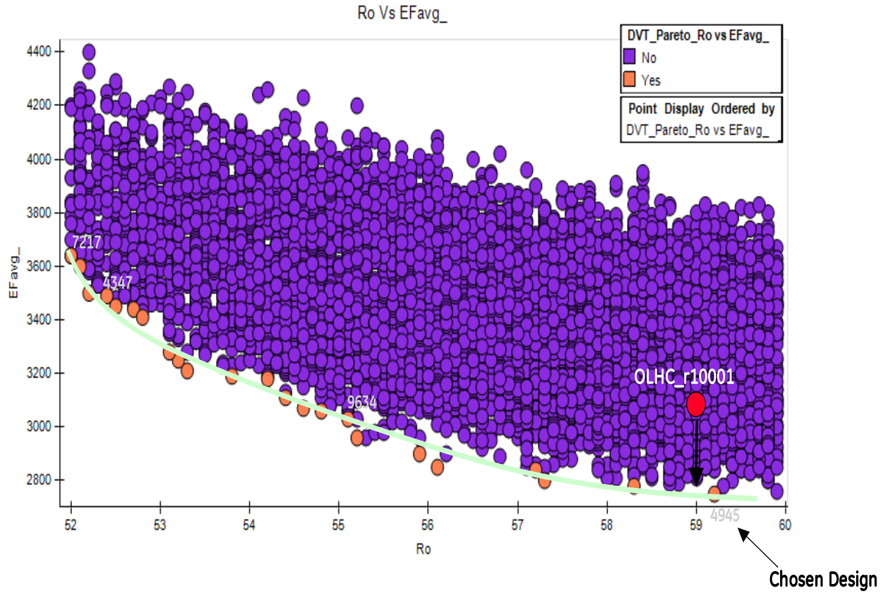
Robust Design using “Space Filling” computer experiments



Robustness: move design to center of feasible range



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

Needs: Efficient Simulation, Automated Parameterization, ***<u>Great</u>*** Visualization tools

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Uses of Modeling in Healthcare

GEHC Approach to New Product Introduction

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

Traditional artifacts

Requirements = DOORs/Trace (text based)

Systems diagrams in "Visio" (FBD, state machines, activity diagrams, …)

"Quantitative" performance simulations

Challenges

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

Recent additions

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

How Modelling fits in

Systems

- Physics (IQ)

Systems

- *Behavioral*
- *Customer FoM model*

HW: Performance Models

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

SW: UML models

MFG: Capacity/Cost Models

- Scrap/Cost models
- Capacity/workflow models

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GEHC Modelling Maturity Levels

Highly Mature

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

Developing

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

Needs

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

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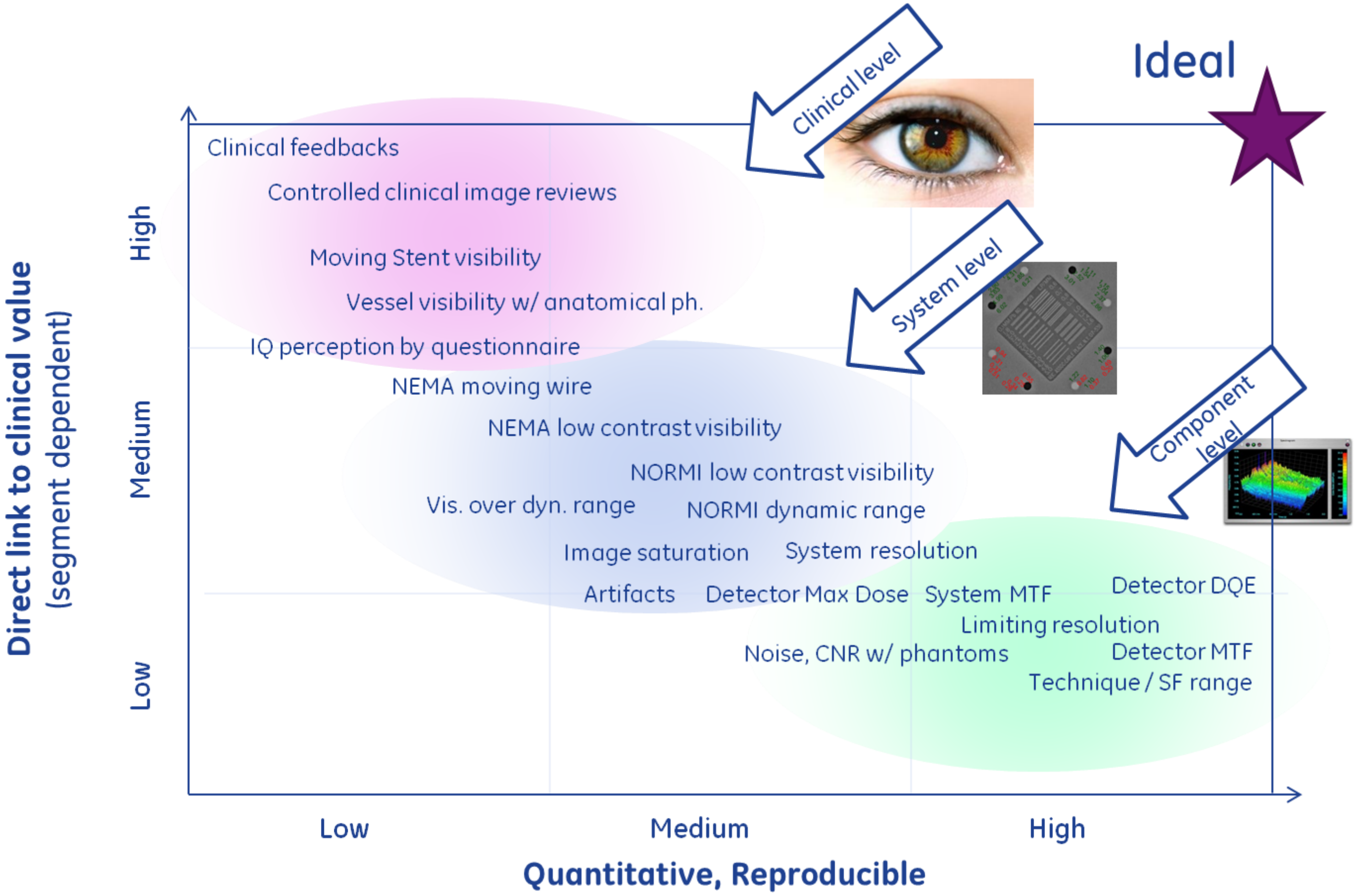
Hierarchy of Modelling



One integrated model (even for "image quality") is unrealistic today

Need a cohort of models with simple interfaces (and possibly a "Monte Carlo"/statistical wrapper)

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Customer Workflow Modeling

Client Scenario

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

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

Simulation Results

Simulation enabled client to “shell” one pod and redesign staffing

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

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Key Industry Challenges for MBSE adoption

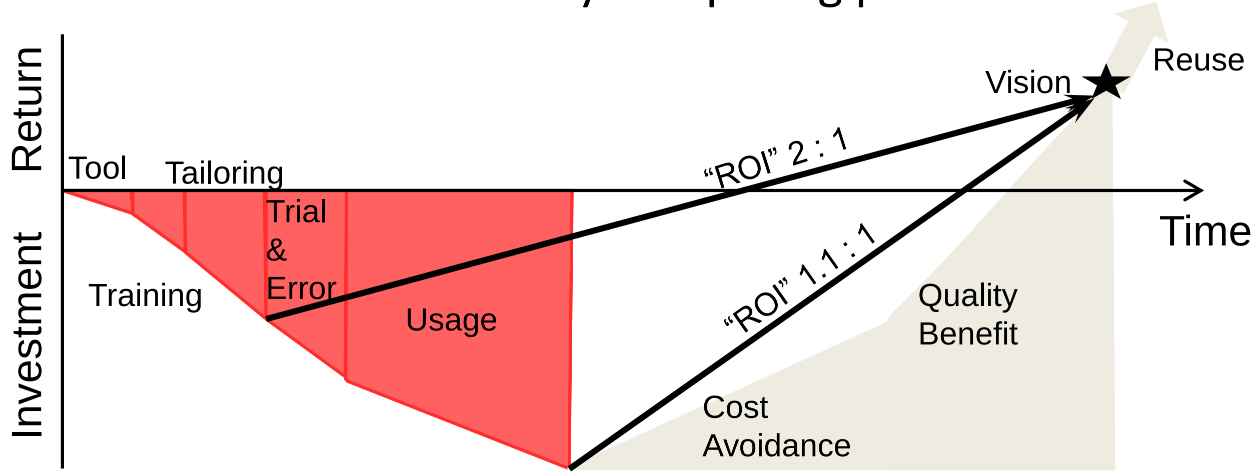
What are the most critical barriers to faster adoption of MBSE? High barrier to entry with uncertain payback

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

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

Lowering the barrier to entry

Management is confronted with many competing priorities for investment



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

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

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

Conclusions

- Systems Engineering is relatively “ill-defined” for most organizations in healthcare and medical device development
- Healthcare projects are market driven, not contract driven, so “traditional” Systems Engineering needs to be tailored
- Modeling can be used extensively…both performance/physics and behavioral models
- Start with focused domain models…but tie the results to quantitative customer value
- Think through the entire adoption curve and costs…include sufficient training and coaching, and start with a small trial before full adoption

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