



26th annual **INCOSE**
international symposium

Edinburgh, UK
July 18 - 21, 2016

Improve Medical Device Development by Expanding Systems Engineering

Carissa Black

syncroness[™]
complex problems inspired solutions



Best Ideas Ever

Water
Roller



Citrus Spritzer



Baby Mop



Das Boot

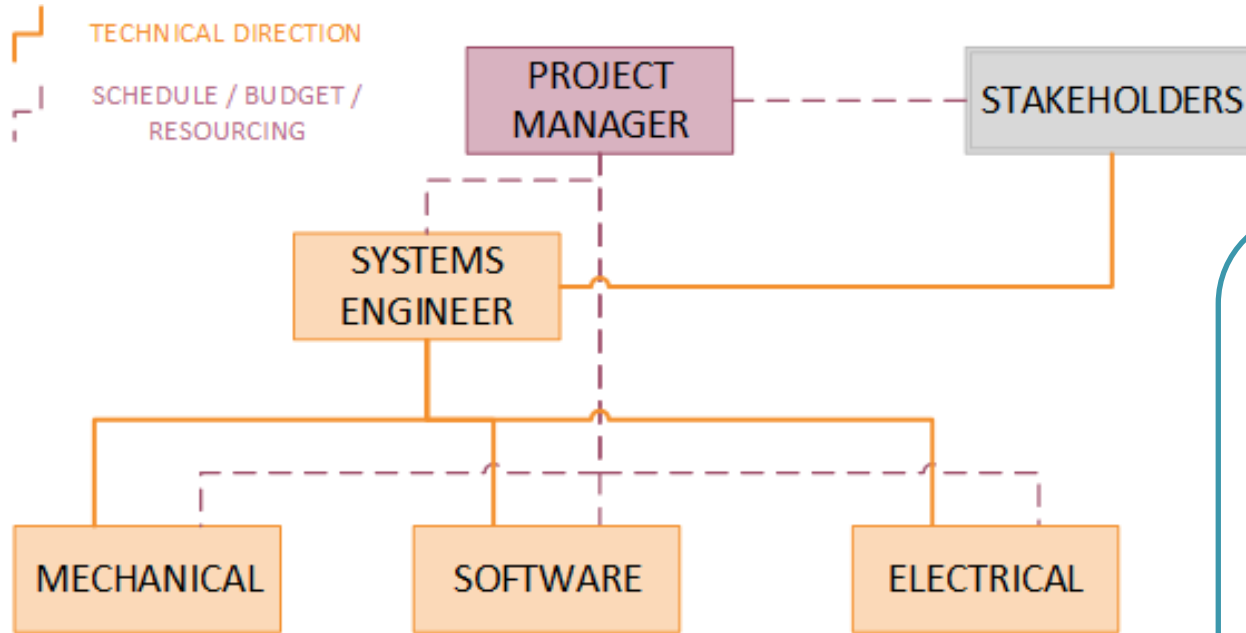


Lead Systems Engineering



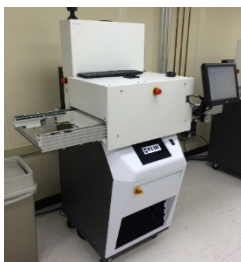
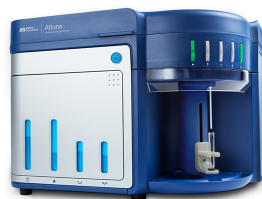
26th annual **INCOSE**
International Symposium

Edinburgh, UK
July 18 - 21, 2016



To Maximize Value:

The SE has overall ownership of the **traceability**, the **system design**, and serves as **technical lead** for the project



syncroness[™]
complex problems inspired solutions



26th annual **INCOSE**
International Symposium
Edinburgh, UK
July 18 - 21, 2016

Excuses from Med. Industry



26th annual **INCOSE**
International Symposium

Edinburgh, UK
July 18 - 21, 2016

*It costs too
much*

Oh, we'll
provide the
requirements

*Can't the
PM be the
technical
lead*

This project
isn't big
enough to
need a SE

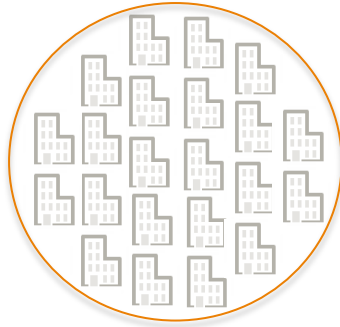
Shouldn't the
engineers do
their own
traceability

Synchroness' Potential Customers Say
They Don't Need a Systems Engineer

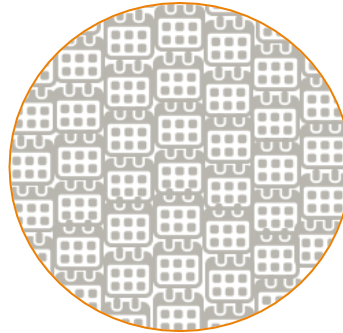
INTERVIEWS: Why doesn't (most of) the medical device industry think a Systems Engineer is valuable?



7 senior
medical
R&D-ers



22 different
companies



115 years
experience

Questions:

- What is it?
- Who does it?
- Is it valuable?

Interview Findings

Negative impressions from:

- Limited Implementations of SE
- 'Disjointed' SE

Positive impressions from:

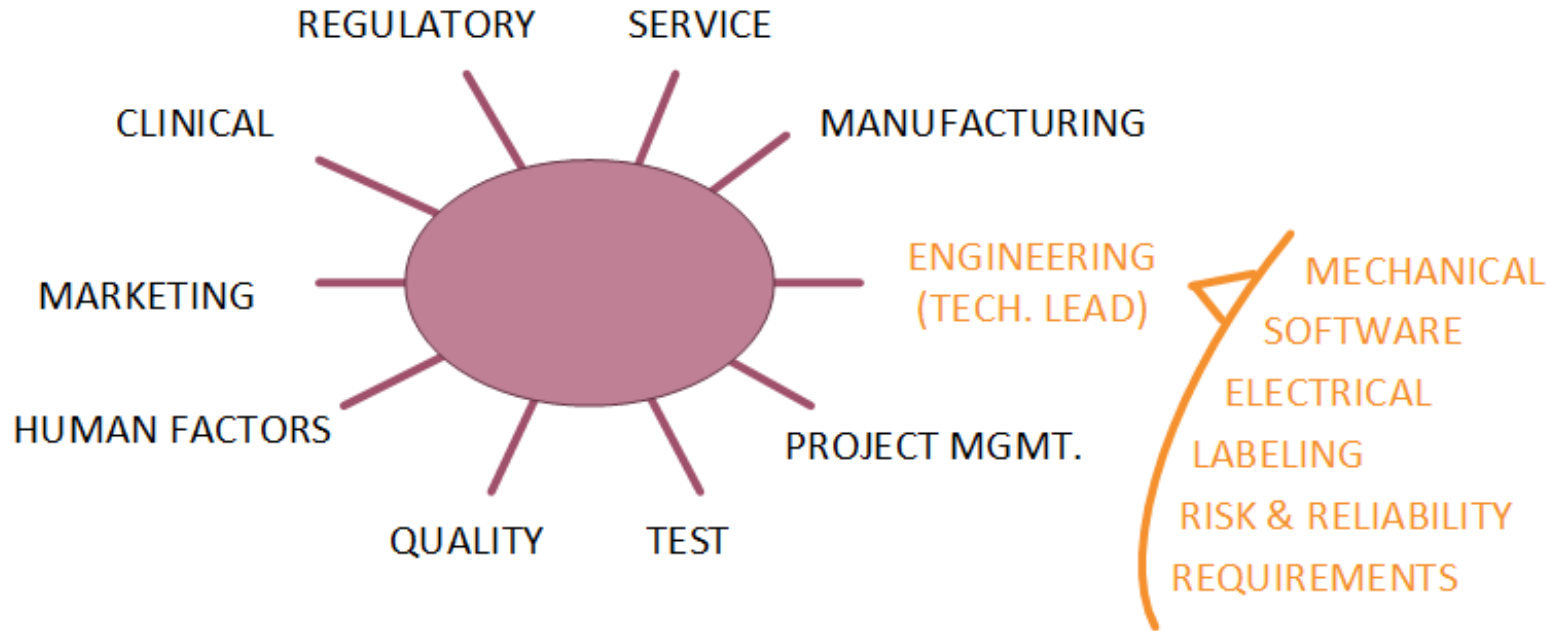
- Past experience with a talented (and empowered) SE

Typical Med. Device Team



26th annual **INCOSE**
International Symposium

Edinburgh, UK
July 18 - 21, 2016



Who's Doing the SE

Systems Engineering

- Requirements elicitation
- Requirements management
- Technical leadership
- Architecture
- System-level decision making
- Integration planning / testing
- Verification / test planning
- Risk management
- Validation test / planning
- Regulatory flow-down
- Reliability
- Design Transfer Liaison
- Technical quality-control

Project Manager or
Engineer Delegate

Quality, Well,
Sometimes the Engineers

No One



26th annual **INCOSE**
International Symposium

Edinburgh, UK
July 18 - 21, 2016

Who's Doing the SE

Systems Engineering



Who's Doing the SE

Systems Engineering

1. *Requirements elicitation*
2. *Requirements management*
3. *Technical leadership*
4. *Architecture*
5. *System-level decision making*
6. *Integration test / planning*
7. *Risk management*
8. *Verification test / planning*
9. *Validation test / planning*
10. *Regulatory flow-down*
11. *Reliability*
12. *Design Transfer Liaison*
13. *Technical quality-control*

Owned by a Lead Systems Engineer

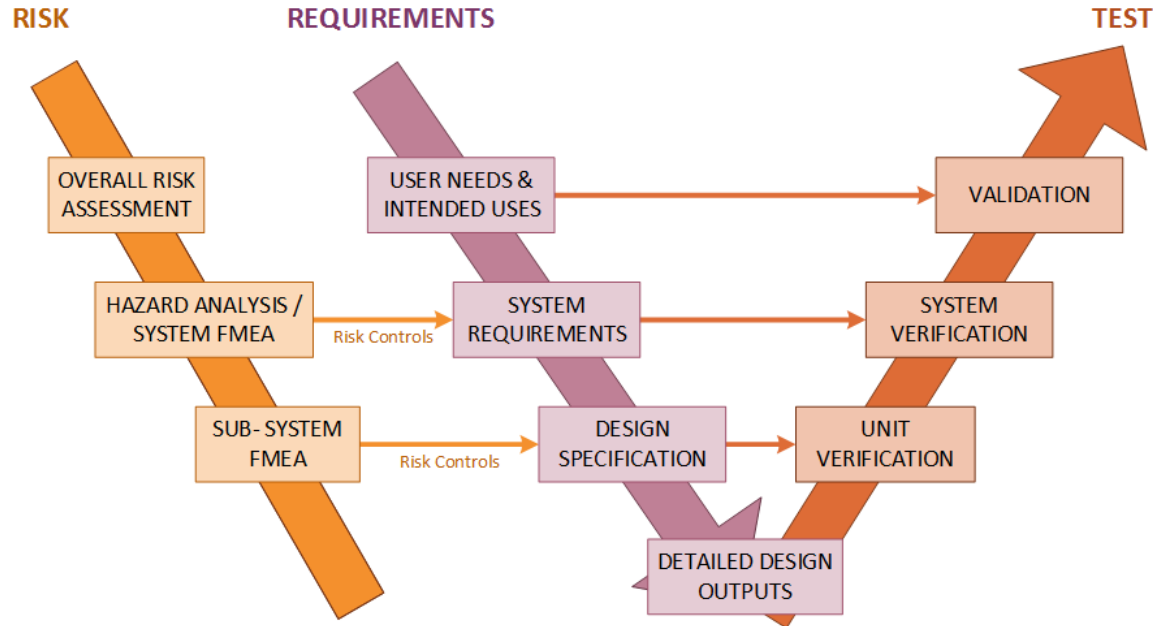
- With junior SEs to coordinate and get technical input from other functions
- With a project manager to coordinate resources, costs, schedule



26th annual **INCOSE**
international symposium

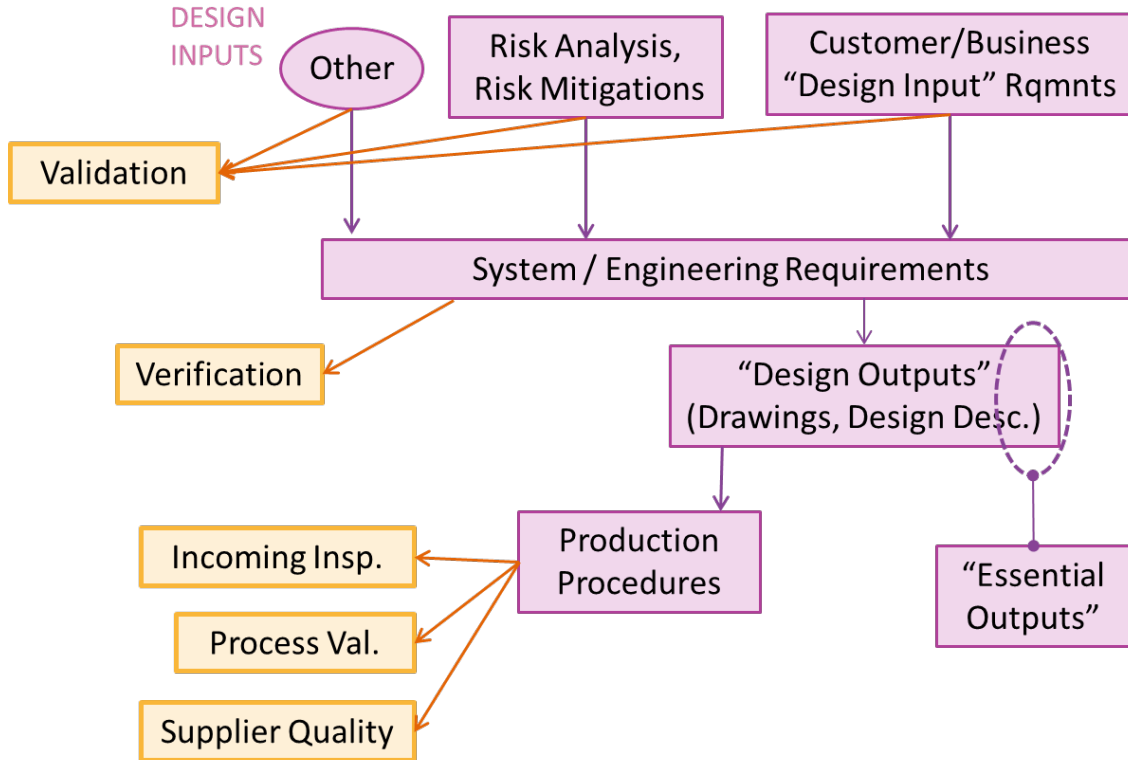
Edinburgh, UK
July 18 - 21, 2016

Coherent Submissions



Put a Lead SE in charge of telling an overall design story. Make it easier for regulatory agencies to confirm your products are safe and effective.

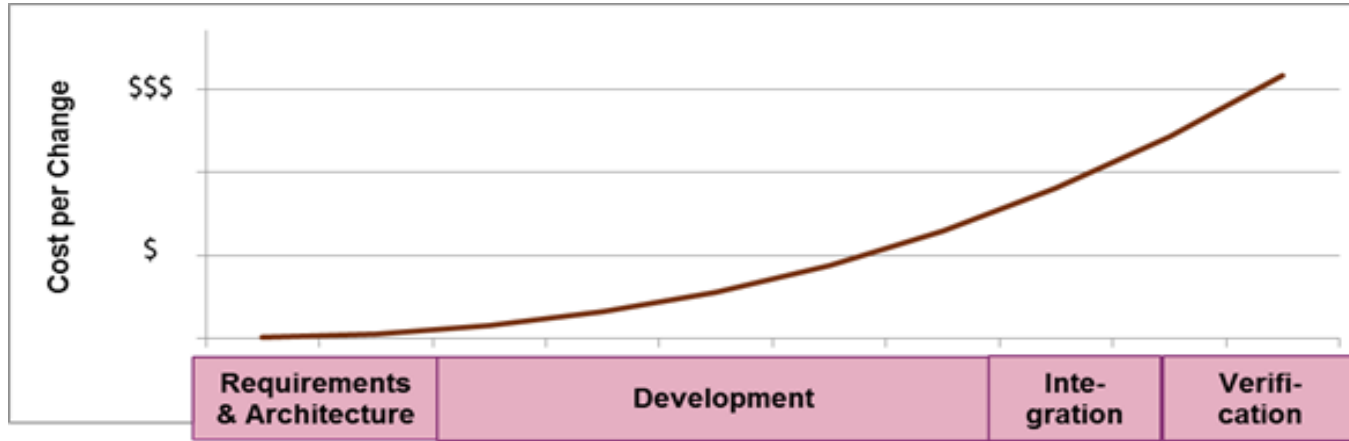
Consistently Focus Effort



Using a Lead SE can create a consistent 'Risk Based Approach'

- Minimize unneeded effort
- Reduce duplication
- Safer, more focused products, and a more cohesive story

Find Change Faster, Save \$



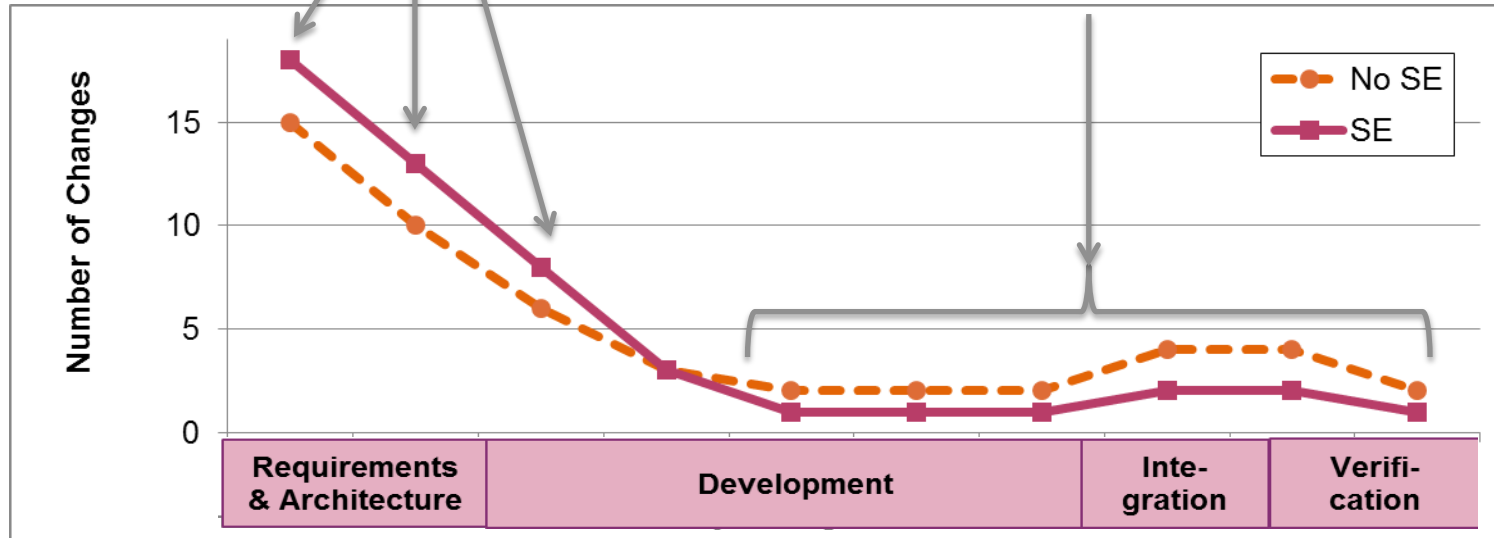
Goal: find and address changes/issues as early as possible

- Cost of change increases exponentially as R&D continues
- Changes/Issues are inevitable, it's when you find them that matter

Find Change Faster, Save \$

- 1) Assume there are 50 inevitable changes/issues.
- 2) Having an SE helps you find a few more early in the project

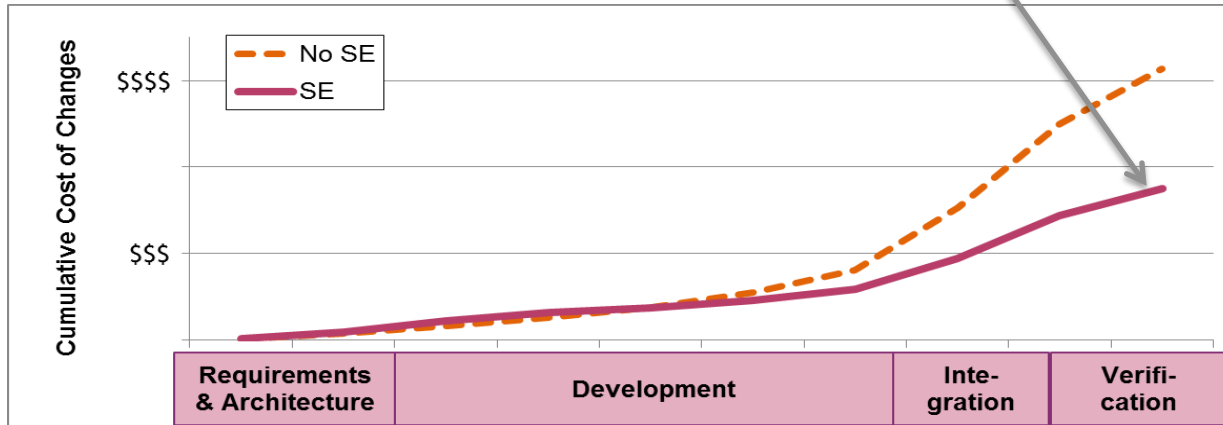
(Which means less later on)



Find Change Faster, Save \$

Finding changes a little
earlier leads to big savings

- SE clarifies / finds requirements up front
- Capitalize by keeping a Lead SE involved to identify and address changes earlier



Sys Thinkers = Tech. Leads



26th annual **INCOSE**
International Symposium

Edinburgh, UK
July 18 - 21, 2016

“Big Picture” thinker

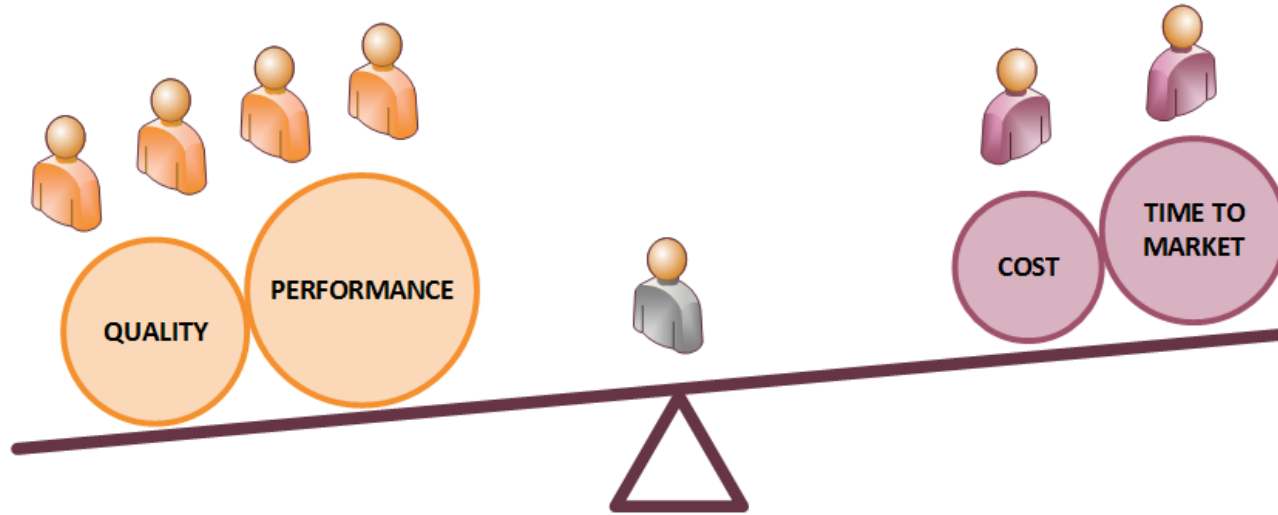
Agile mental ability – Can change perspectives

Inquisitive, thoughtful, values other perspectives

Makes decisions (ONLY) when appropriate

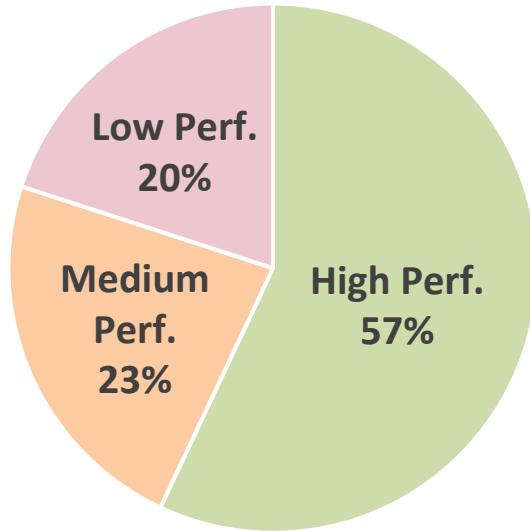
Identifies and trades risks - Surfaces and tests assumptions

Maintain Project Balance



- Let Project Management focus on cost targets and time to market
- Let a Lead Systems Engineer be neutral and evenly weigh both sides

Research Shows



**Project Performance with
High SE Capability Scores²**

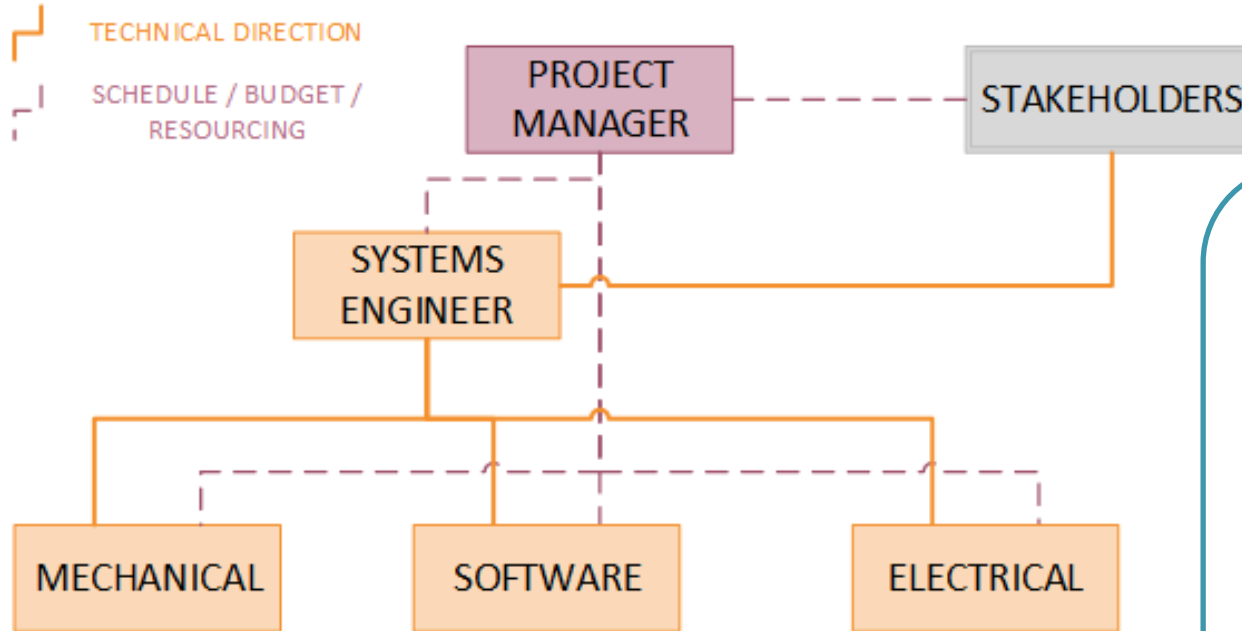
HOW YOU ADD SE MATTERS

- Research shows that SE practices benefit projects, on average.^{1,2}
- But, results are variable

¹[Honour, 2013]

²[Elm and Goldenson, 2012]

Lead Systems Engineering



To Maximize Value:

The SE has overall ownership of the **traceability**, the **system design**, and serves as **technical lead** for the project

Improve your
Medical Device
Development with a
Lead Systems
Engineer

*They improve
project success*

They create stronger
submissions

They focus
effort where it
matters

They help
find changes
faster which
saves money

They make
good
tech. leads

*They balance
the scales so
cost & time to
market matter
as much as
quality and
functionality*



26th annual **INCOSE**
international symposium

Edinburgh, UK
July 18 - 21, 2016

Improve Medical Device Development by Expanding Systems Engineering

syncroness[™]
complex problems inspired solutions

Carissa Black

