Improving the Economics of the Medical Device Value Stream with Scaled Agile

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The **Continuous Engineering** Experts™

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Size Shrinking, Lines of Software Expanding

“Problems in medical device software result largely from a failure to apply well-known systems engineering techniques, especially during specification of requirements and analysis of human factors.”

https://www.ncbi.nlm.nih.gov/books/NBK209656/

321 Gang

Agenda

- ❑ Case Studies
- ❑ Components of Better Economics
- ❑ A Tale of Two Systems
- ❑ Practical Transformation Roadmaps
- ❑ Your Economics Worksheet

Case Studies

Royal Philips

Industry: Medical Technology

> *Philips is continuously driving to develop high-quality software in a predictable, fast and Agile way. SAFe addresses this primary goal, as well as offering these further benefits: reduced time to market and improved quality, stronger alignment across geographically distributed multi-disciplinary teams, and collaboration across teams to deliver meaningful value to customers with reduced cycle time.*
>
> —**Sundaresan Jagadeesan**,
> Program Manager – I2M Excellence SW Development Program

Results

- Average release cycle time down from 18 months to 6 months
- Feature cycle time reduced from >240 to <100 days
- Sprint and PI deliveries on time, leading to “release on demand”
- Quality improvements—zero regressions in some business units
- 5 major releases per train per year on demand

SAFe® CASE STUDY

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What we have gained through the introduction of SAFe

- Insufficient work on design and architecture
- Silos between scrum teams
- Dependency and integration issues
- Unclear overall objectives & plan
- Lack of visibility of the big picture
- Scrum of scrum not being effective

- Improved quality
- Cross site and cross functional collaboration
- PI Planning provides both vertical and horizontal alignment
- Transparency through Rally, reports & SAFe ceremonies
- Agile Portfolio estimation & planning drives realistic Portfolio plan

Elekta Medical Radiotherapy:

https://www.scaledagileframework.com/elekta-case-study/

Emulators

Elekta Medical Radiotherapy:

The software teams/program uses emulators of the hardware for frequent integration testing. At critical milestones (identified in Program Increment planning, based on the nature of the work) the software is installed into devices in a testing “bunker”. This is usually at least twice per Program Increment.

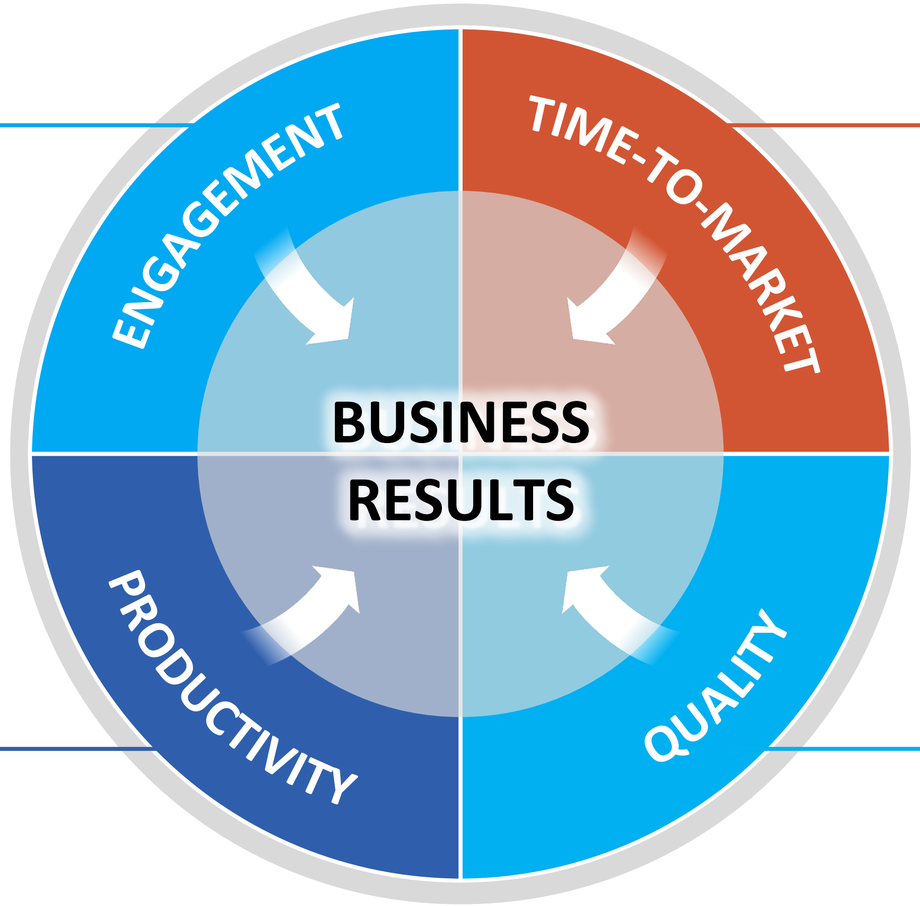
https://www.scaledagileframework.com/elekta-case-study/

The Components of Better Economics

SAFe® - Business Results

10 – 50% happier, more motivated employees

30 – 75% faster time-to-market



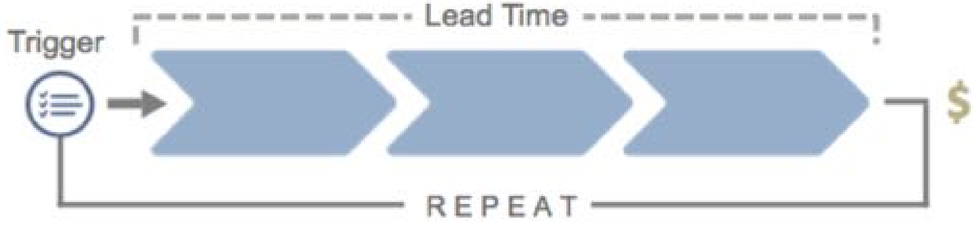
20 – 50% increase in productivity

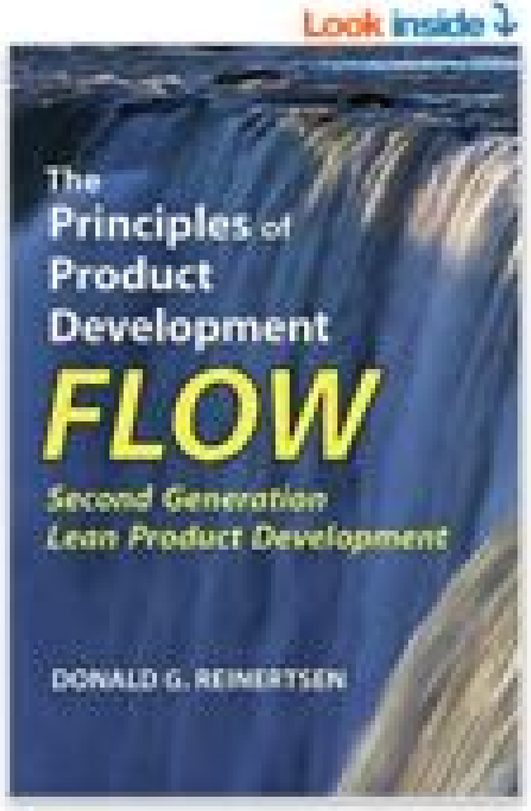
25 – 75% defect reduction

See scaledagile.com/**case-studies**

Apply Systems Thinking

- Identify customer value and map flow of work towards delivery
- Take systems view in organizing, planning, and executing delivery
- Eliminate waste across the entire value stream
  - Anything that doesn't create value for customer is waste
  - Examples of waste – features not used, delays, handoffs/dependencies, context switching (many project assignments), defects





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Follow the Author

Donald G. Reinertsen

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The Principles of Product Development Flow: Second Generation Lean Product Development Hardcover – 2009

by Donald G. Reinertsen (Author)

81 customer reviews

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"...the dominant paradigm for managing product development is wrong. Not just a little wrong, but wrong to its very core." So begins Reinertsen in his meticulous examination of today's product development practices. He carefully explains why invisible and unmanaged queues are the underlying root cause of poor product development performance. He shows why these queues form and how they undermine the speed, quality, and efficiency in product development. Then, he provides a roadmap for changing this.

Read more

Components of Better Economics

Small Batch Sizes

Fast Feedback Cycles

Collaboration

Relentless Improvement

Batch Size Optimization

Big enough to
- Demonstrate value
- Learn from
- Validate assumptions

2 weeks, 90% capacity

3 weeks, 75% capacity

Small enough to
- Keep focus
- Keep errors from propagating
- Support adjustment economics

The goal is to reduce the risk of late integration breakage.

Batch Size – Components of Economics

Transaction cost

Holding Cost

Variability in flow

Risk

Motivation

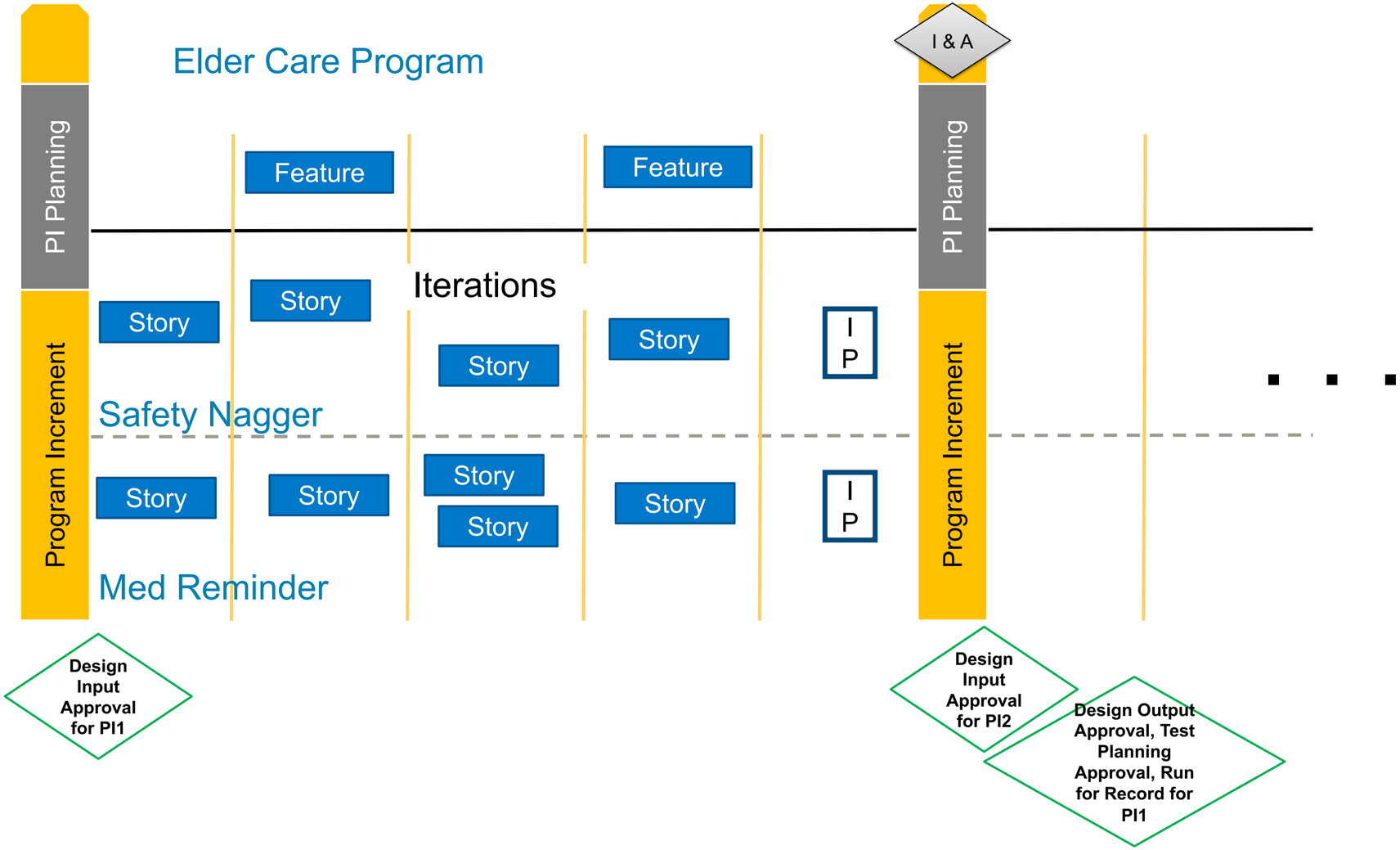
Efficiency

// **Don Reinertsen**

Large batches inherently lower motivation and urgency.

Learning Batch vs Compliance Batch

For every Program increment, 13 weeks



Design Control Milestones

Feedback Cycles – Economic Components

Leading indicators
Cost of intervention
Gold plating
Business value
Relative weighting
Dynamic goals vs static goals
Speed of learning
Locality of decisions

Colocation
Sense of control – cause and effect
Feedback speed
Decision cycle time
Problem aging
Turning radius
Capacity allocation

// **Dantar Oosterwald, The Lean Machine**

The primary cause for project failure is false positive feasibility.

. . .

Product development . . . is more dependent on what needs to be learned than on what tasks must be completed to exit a gate.

"Working software is the primary measure of progress" – the Agile Manifesto

// Don Reinertsen

As delays get longer the damage done by delay becomes geometrically larger.

Collaboration – Economic Components

Team elasticity

Skill development

Innovation

Reduced risk of late integration breakage

Focus on common goal, business value

Elekta Medical Radiotherapy

The main value that we have seen through the introduction of SAFe are:

Improved code quality already through Scrum

*The program execution provides cross site and cross function **collaboration**.*

*PI planning provides both vertical and horizontal **alignment**. Teams know what other teams are doing, **teams knows what business expect** and business what teams can deliver.*

***Transparency** through working in the same system and regular demonstrations.*

*And agile estimates and planning drives **realistic long term planning**.*

// Don Reinertsen

Operating a product development process near full utilization is an economic disaster.

Relentless Improvement – Economic Components

Problem aging

Enabler size trends

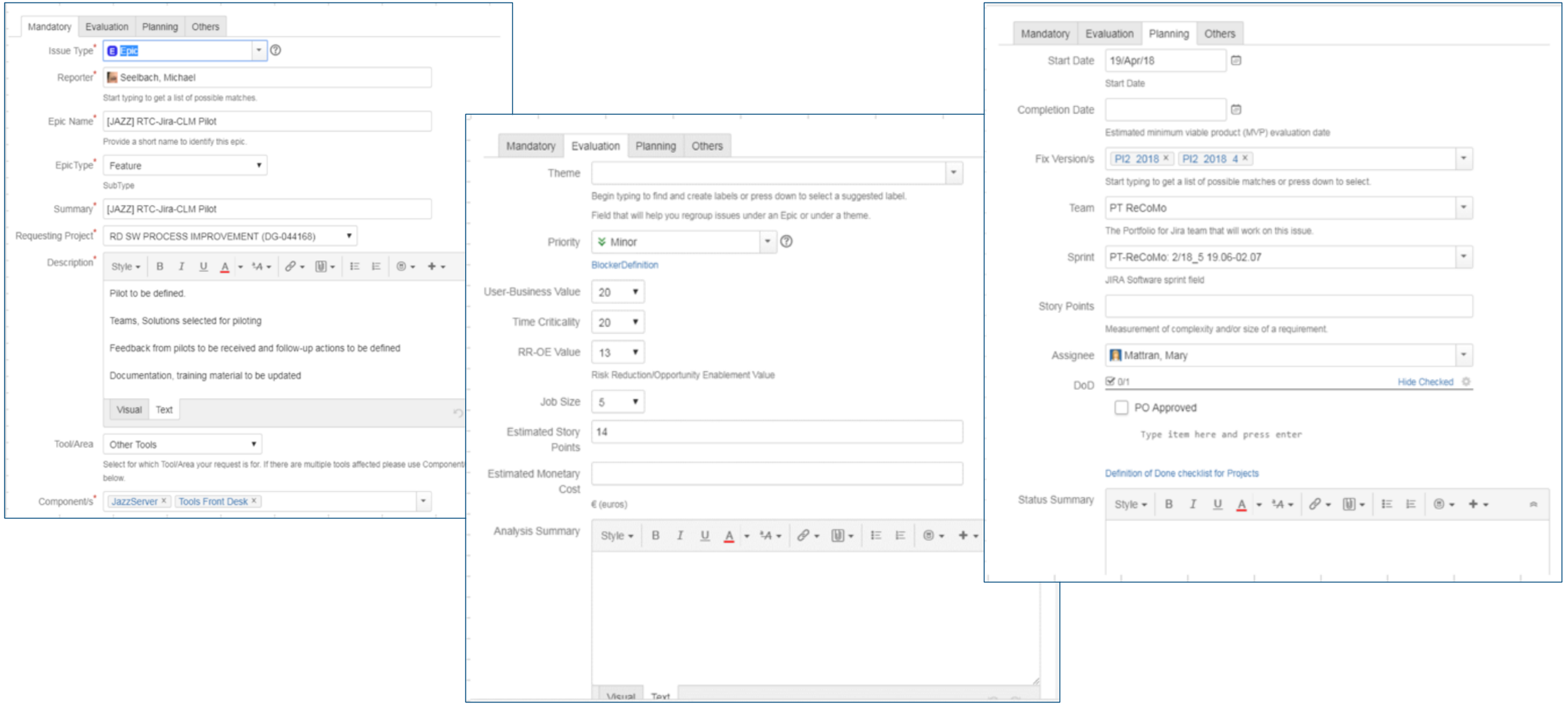
Cost to implement

Value of outcome

Motivation through ownership

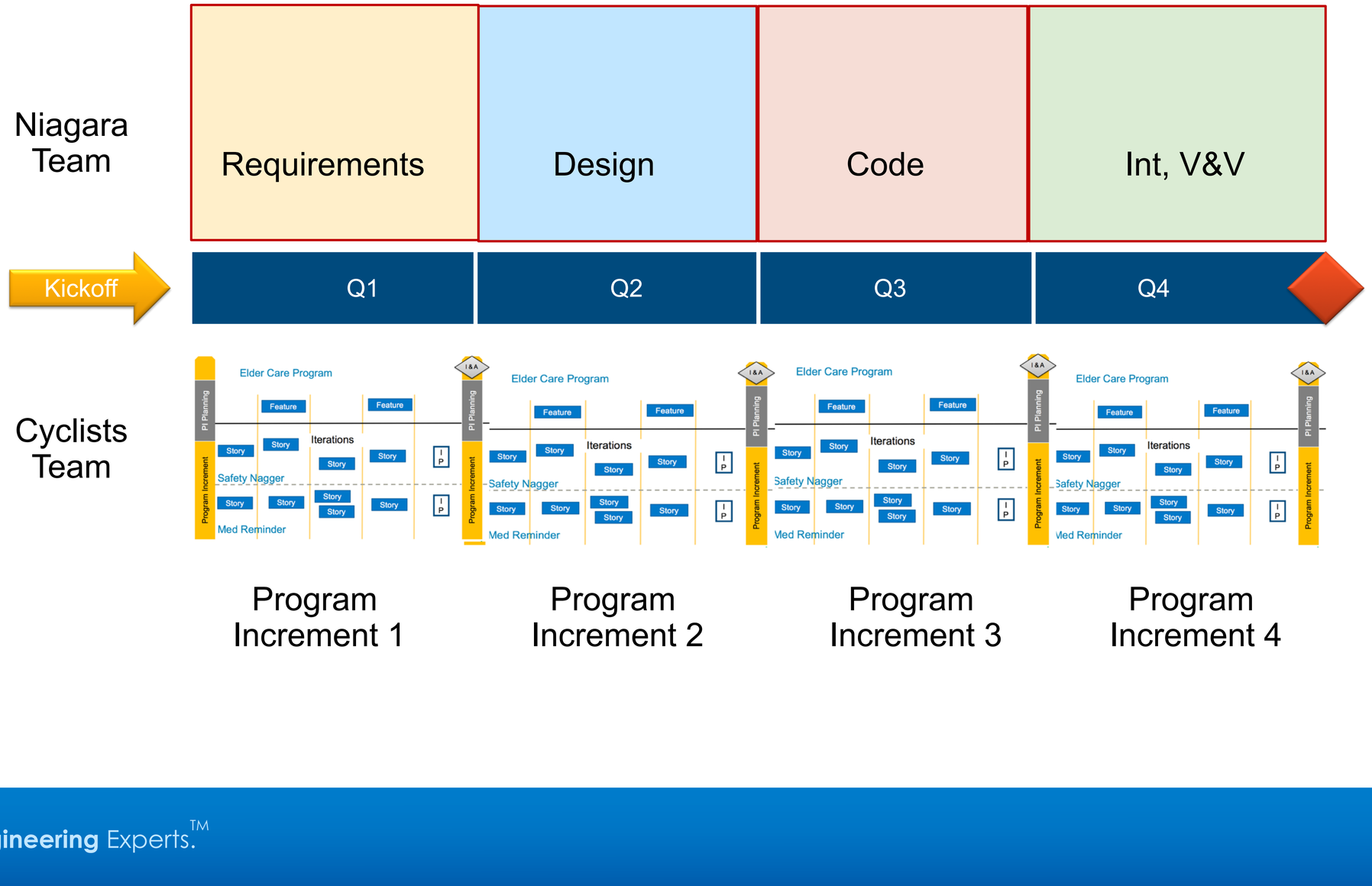
Decentralization

Example – Centralized Tool Ownership

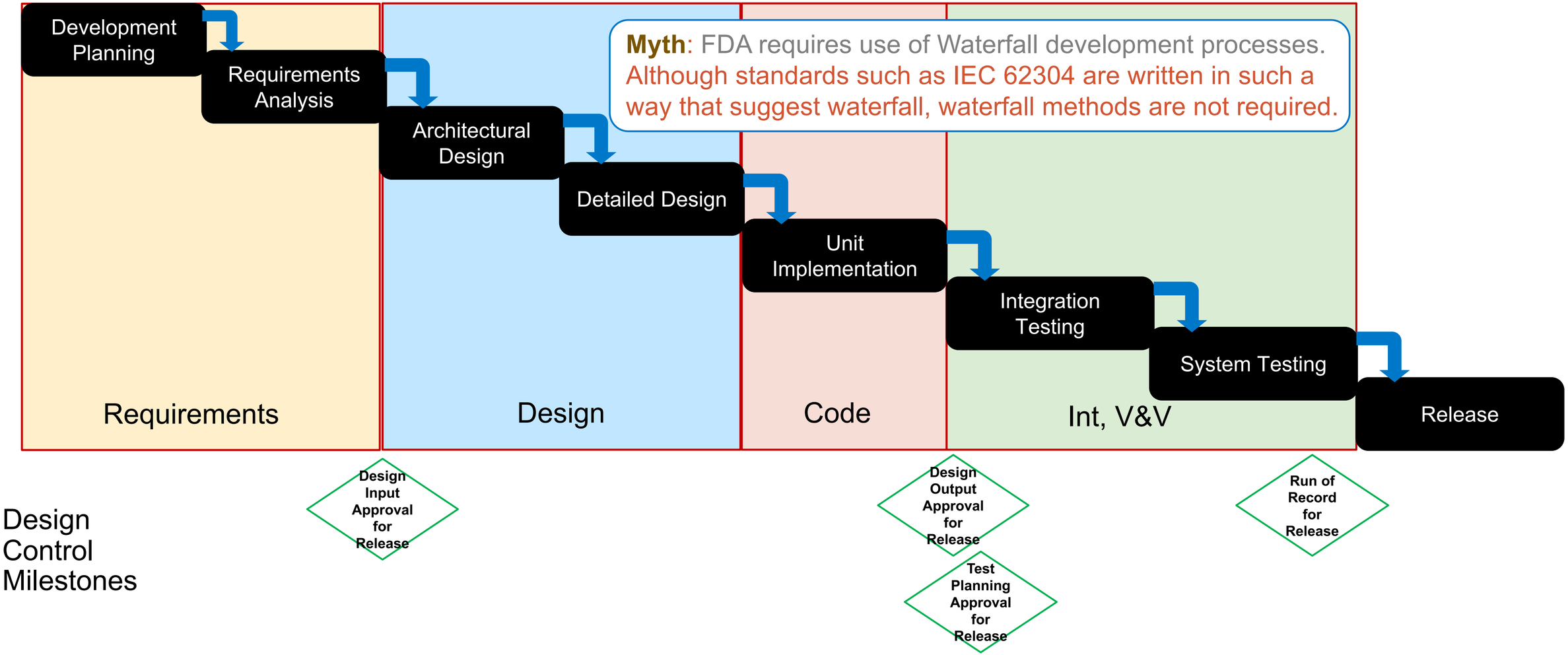


A Tale of Two Systems

Timeline and Milestones



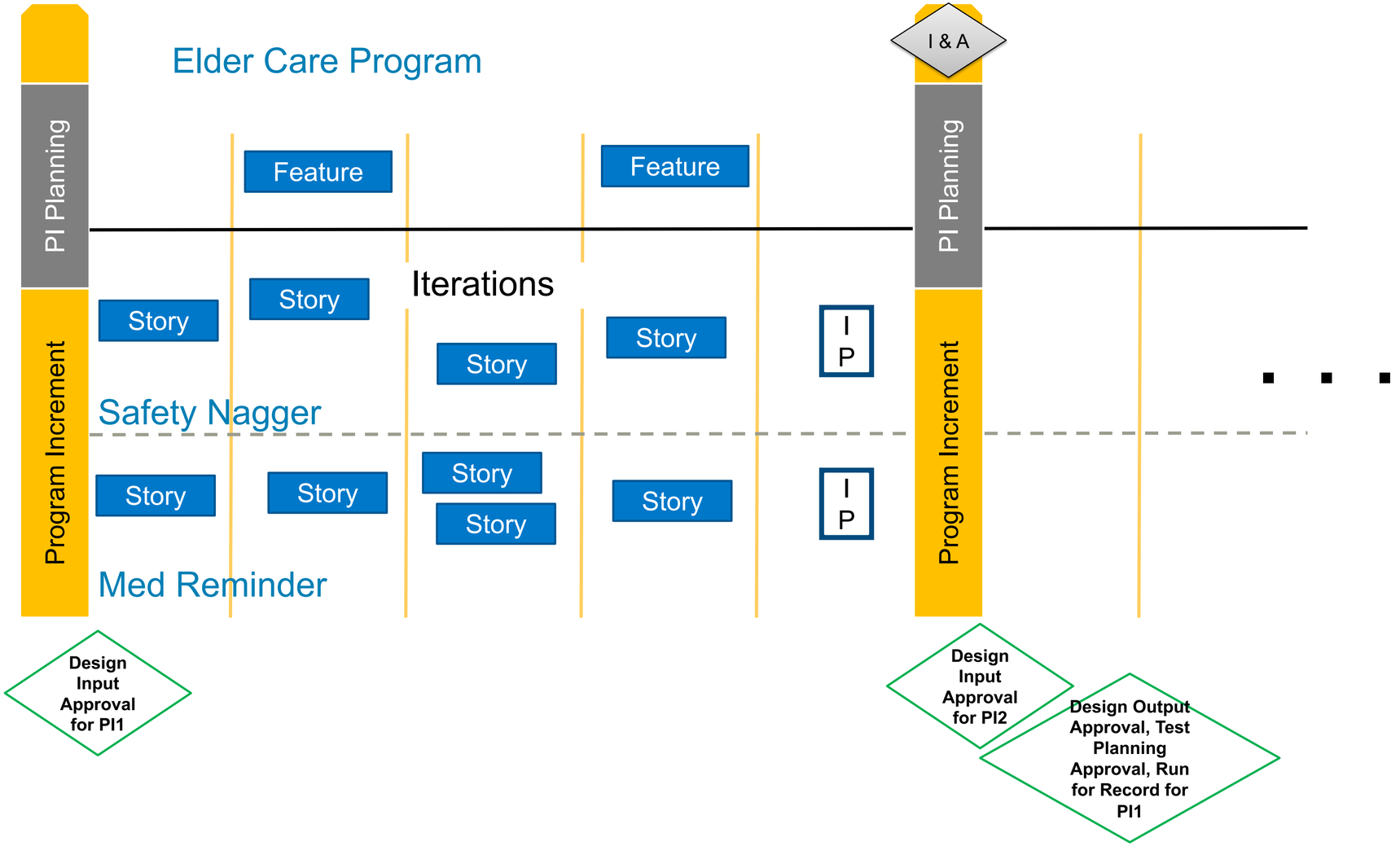
Niagara Team's Process



Design Control Milestones

Cyclists Team's Process

For every Program increment, 13 weeks



Design Control Milestones

Value Formulas

Progress Points = System Progress – Rework + Learning Boost

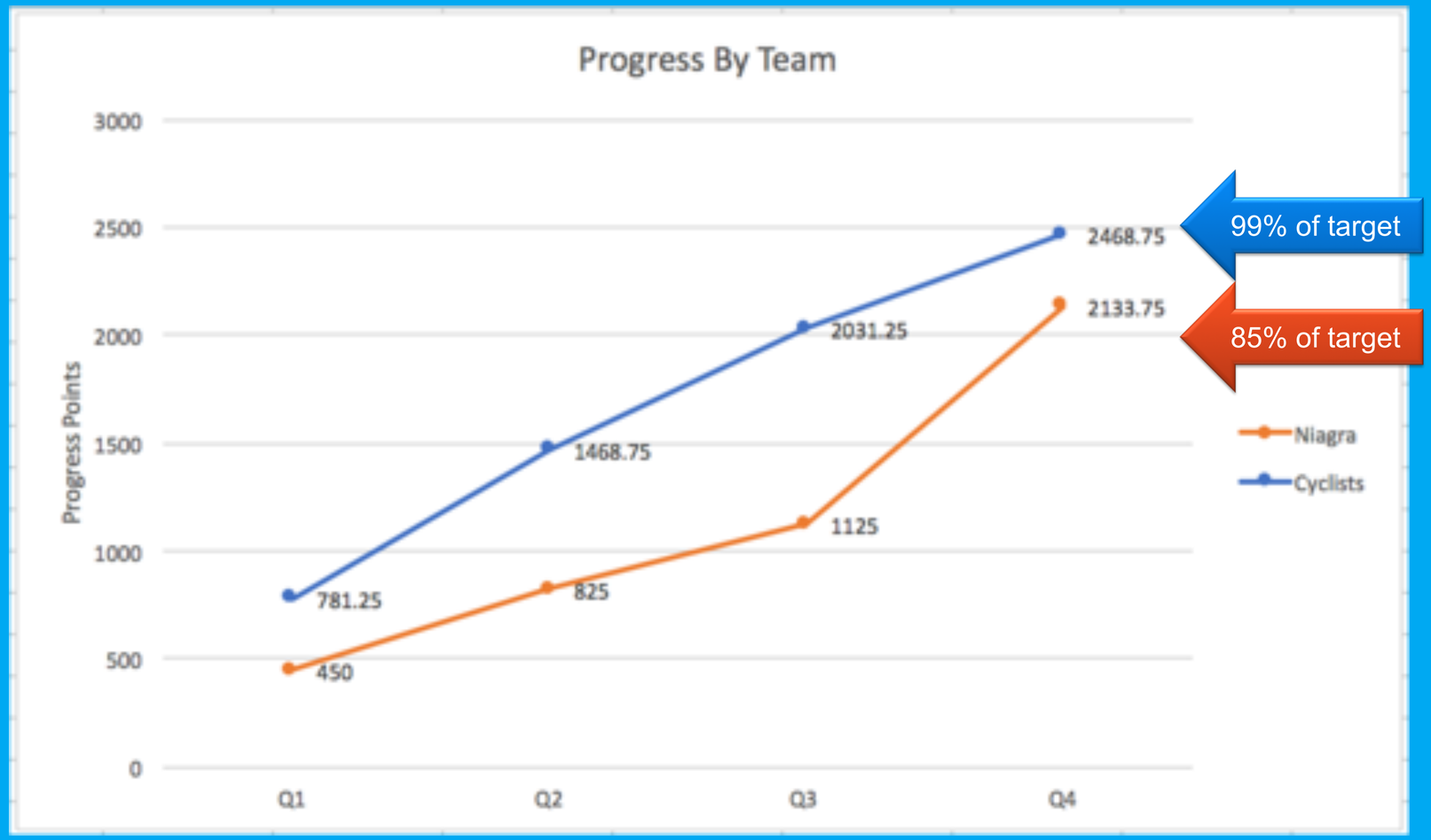
Progress in a domain (Pr) = % system built x “provenness”

System Progress = Pr(Requirements)+Pr(Design)+Pr(Code)+Pr(Int, V&V)+Pr(Risks)

Rework/fix effort = % system proven in current cycle x .05

Learning boost = (% system proven x .1) x (% schedule remaining)

Let’s Compare Progress



// **Dantar Oosterwald, The Lean Machine**

Photo by Daniel Tausis on Unsplash

A firefighting organization requires extraordinary people to achieve ordinary results. In an exceptional organization, ordinary people achieve extraordinary results routinely.

Practical Transformation Roadmaps

Historical overview of our Agile Transformation

+ Increased our throughput
+ Deliverables at every sprint
+ Escalated any issues much sooner
+ Allowed agility during development (features)
+ Team could focus on one project
+ Overall happy teams

– Insufficient work on design and architecture
– Silos between scrum teams
– Dependency and integration issues
– Unclear overall objectives & plan
– Lack of visibility of the big picture
– Scrum of scrum not being effective

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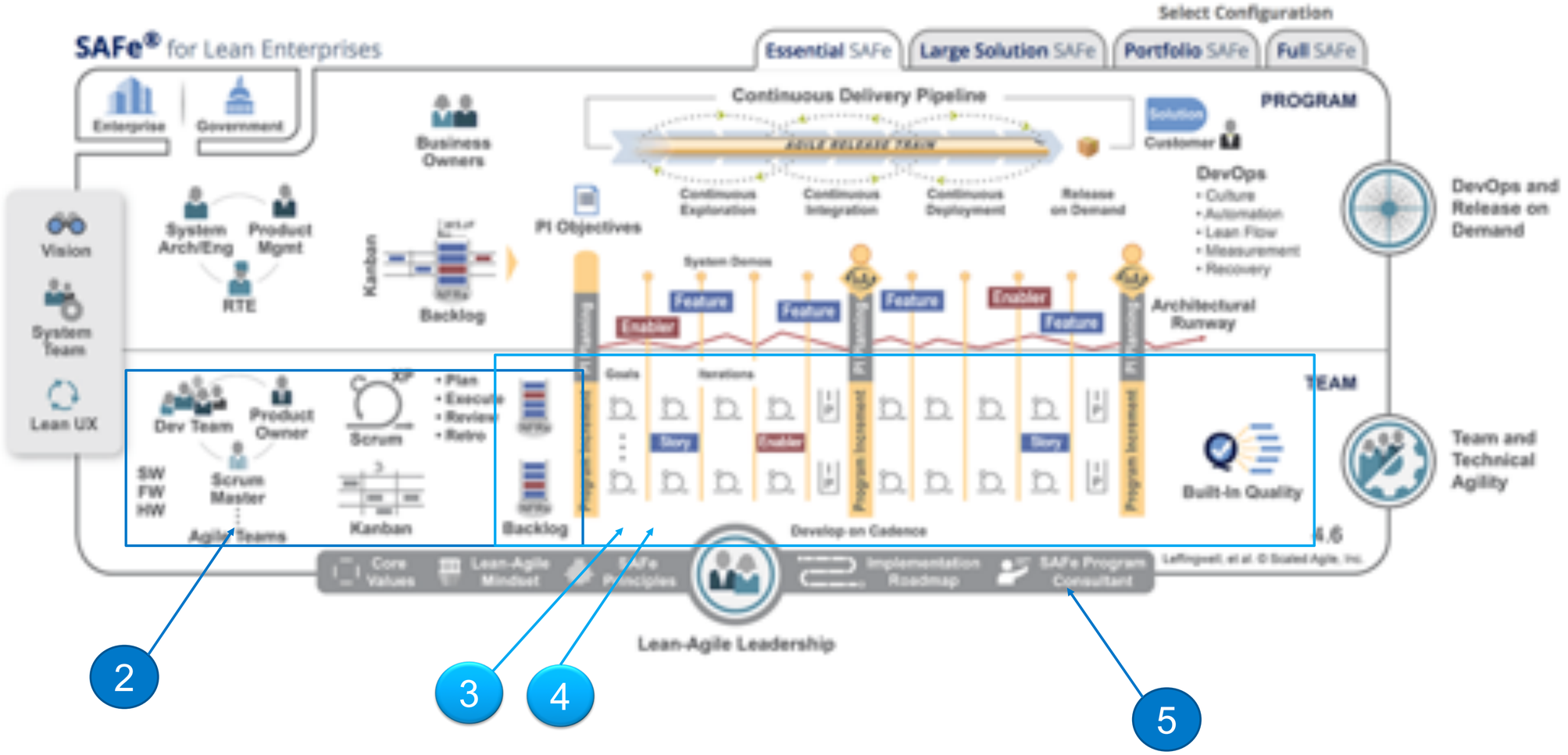
New to Agile Implementation Plan

#	Name	Days	Notes
1	Leading SAFe Class	2	2-day class for executive sponsors, key roles in the organization. Standard Scaled Agile class with custom Program Increment Planning Simulation. https://321gang.com/services/leading-safe-with-safe-agilist-cert/#1541513088587-d71bfa56-49db
2	Scrum Bootcamp	2	2-day class to equip teams to work in an agile way. https://321gang.com/services/agile-scrum-boot-camp-simulation/
3	Patterns for Agile Hardware-inclusive Systems	1	https://321gang.com/services/patterns-for-agile-hardware-inclusive-systems/
4	Facilitating SAFe Systems Engineering Specification Workshop	1	http://www.321gang.com/services/agile-systems-engineering-workshop/#1541462075593-015f2eac-4e2c
5	Agile/SAFe Coaching	10	To be used as needed to help assist team and executive levels.

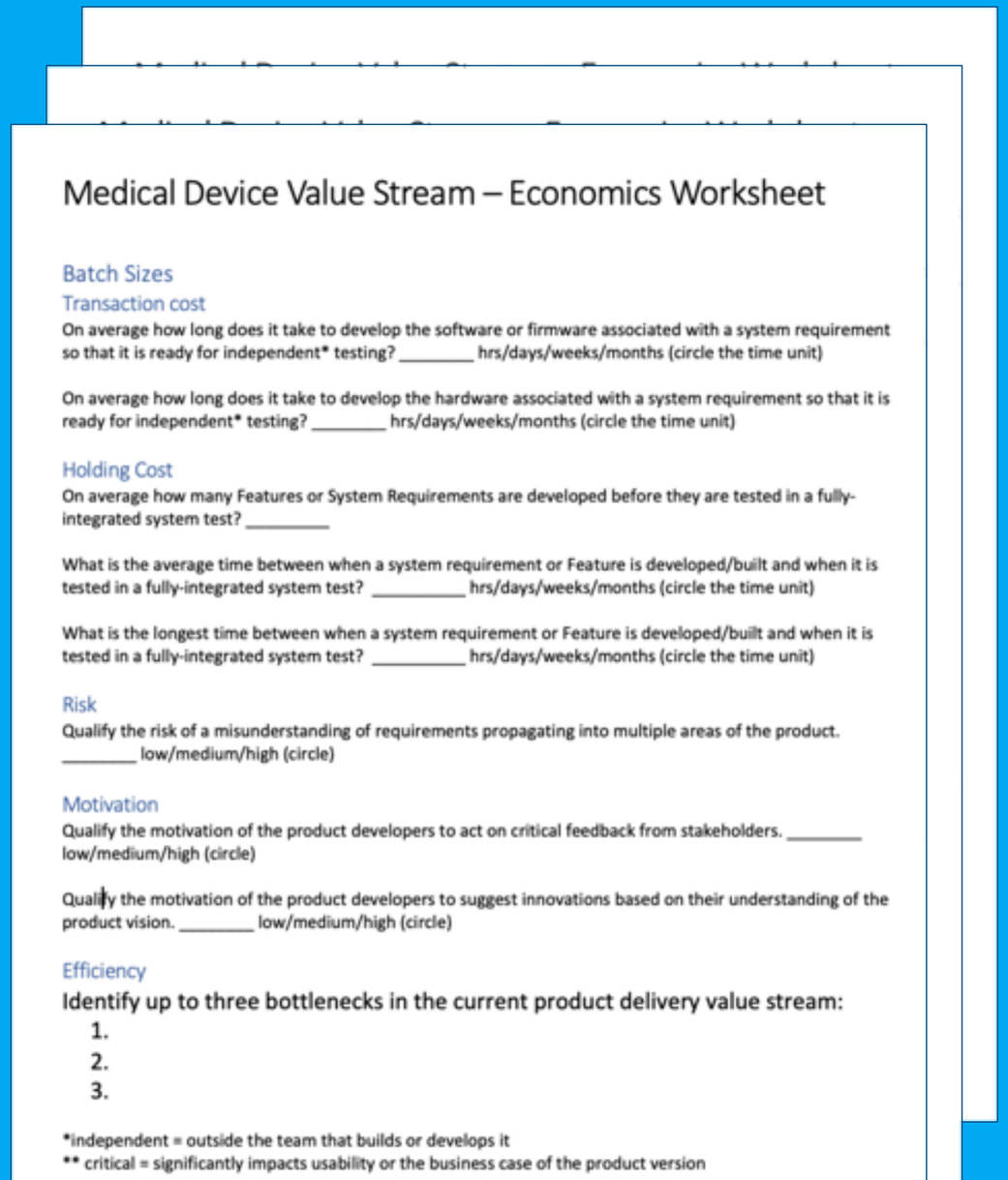
Implementation Roadmap – Strategic Thread

Implementation Roadmap – Tactical Thread

Essential SAFe 4.6



Your Economics Worksheet (handout)



Medical Device Value Stream – Economics Worksheet

Batch Sizes

Transaction cost

On average how long does it take to develop the software or firmware associated with a system requirement so that it is ready for independent* testing? _____ hrs/days/weeks/months (circle the time unit)

On average how long does it take to develop the hardware associated with a system requirement so that it is ready for independent* testing? _____ hrs/days/weeks/months (circle the time unit)

Holding Cost

On average how many Features or System Requirements are developed before they are tested in a fully-integrated system test? _____

What is the average time between when a system requirement or Feature is developed/built and when it is tested in a fully-integrated system test? _____ hrs/days/weeks/months (circle the time unit)

What is the longest time between when a system requirement or Feature is developed/built and when it is tested in a fully-integrated system test? _____ hrs/days/weeks/months (circle the time unit)

Risk

Qualify the risk of a misunderstanding of requirements propagating into multiple areas of the product. _____ low/medium/high (circle)

Motivation

Qualify the motivation of the product developers to act on critical feedback from stakeholders. _____ low/medium/high (circle)

Qualify the motivation of the product developers to suggest innovations based on their understanding of the product vision. _____ low/medium/high (circle)

Efficiency

Identify up to three bottlenecks in the current product delivery value stream:

1.
2.
3.

*independent = outside the team that builds or develops it
** critical = significantly impacts usability or the business case of the product version

OUR EXPERTISE.

Products

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- ❑ Rational Team Concert™ (RTC)
- ❑ DOORS Next Generation (DNG) Quality Manager (RQM)
- ❑ Jazz Reporting Services DOORS®/DXL
- ❑ Rhapsody
- ❑ Design Manager
- ❑ Publishing Engine
- ❑ ClearCase & ClearQuest
- ❑ Test Workbench
- ❑ Method Composer
- ❑ Engineering Lifecycle Manager (RELM)
- ❑ Urban Code Deploy
- ❑ Rational Life Cycle Integration Adapters
- ❑ Task Top
- ❑ Rational Functional and Performance Tester
- ❑ … and more

Practice

SCALED AGILE PARTNER GOLD SPCT

- ❑ Scaled Agile Framework for Lean Enterprises
- ❑ SAFe Certified Process / Practice Improvement Requirements
- ❑ Management, Configuration & Quality Assurance Management
- ❑ Verification & Validation Testing
- ❑ Real-Time Embedded & IT SW Aligning ALM & PLM
- ❑ Modeling: MBSE / MDD / MDE with UML / SysML / DoDAF
- ❑ DevOps
- ❑ CE IoT
- ❑ Product Migration, Testing & Upgrade
- ❑ Application Integration

Industry

INCOSE International Council on Systems Engineering

IEEE

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Questions?