

Agile Product Development for Digital Medicines

Eli Snell
Proteus Digital Health

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How Systems Engineering Can Reduce Cost & Improve Quality

19-20 April, 2018 Twin Cities, Minnesota



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Eli Snell

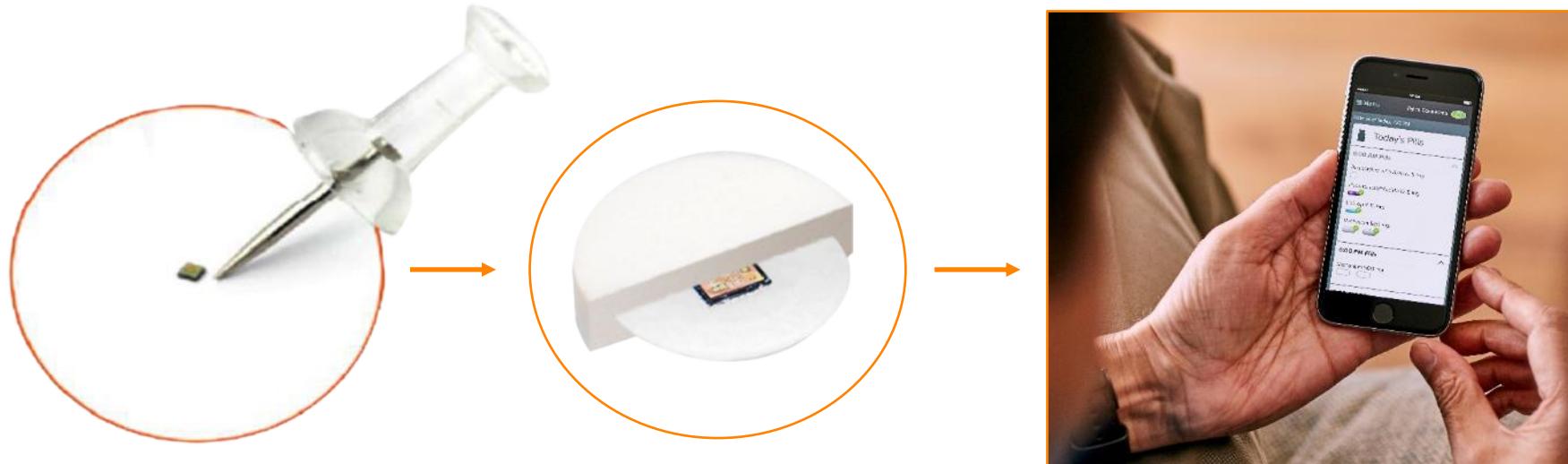
VP, Software Solutions

- Eli Snell leads the Software Engineering organization at Proteus Digital Health, responsible for development and verification of all product software, including firmware for wearable detectors, mobile applications, web applications, cloud services, software architecture, and systems engineering. He also leads a new function called Software Solutions, responsible for software product strategy and integration with pharmaceutical corporate partners.
- Eli holds a B.S. degree in Computer Engineering and a M.S. degree in Electrical Engineering from California Polytechnic State University, San Luis Obispo.



Proteus Digital Health Introduces the World's First Digital Medicines

Answering the age-old questions: Did the patient take their medications as prescribed, and did they work?



Proteus Digital Health has created a new category of pharmaceuticals: DigiMeds™: Oral pharmaceuticals formulated with an ingestible sensor that, when swallowed, communicate with the patient's mobile device.

Digital Medicines

Sensors, software and analytics revolutionizing pharmaceuticals and healthcare delivery



Proteus Product Development organization includes a broad range of disciplines

Product Development

Product Management

- Product Managers
- Product Owners
- Agile Leadership: Agile Coach and Scrum Masters

Design

- User Researchers
- Product Designers
- Copywriters
- User Experience Designers
- Human Factors Engineers

Software Engineering

- Systems Architects
- Systems Engineers
- Firmware Engineers
- Software Engineers
- Manual Test Engineers
- DevOps
- Data Scientists
- Analysts
- Quality Engineers
- Support Specialists

Key Messages

- We're following agile processes because we believe that doing so produces high quality, safe, and effective products
- Our agile processes produce the same design controls deliverables expected by and familiar to the FDA; we just arrive at them in a different way
- Our agile processes help us understand user needs earlier and then more quickly translate those into product requirements
- Our agile process promotes continuous improvement of product and process

Journey towards an agile product development process

Three stages in our journey

Scrum Essentials

- Scrum for Teams training for the entire Product organization and other key functions
- Formed new teams, emphasizing cross-functional participation
- Began following scrum best-practices at the team level

Quality System

- Revamped quality system to address compliance gaps and align with agile principles
- Created new Software Development Life Cycle SOP, with cross-functional participation
- Updated tools and infrastructure to support the quality system

Scale

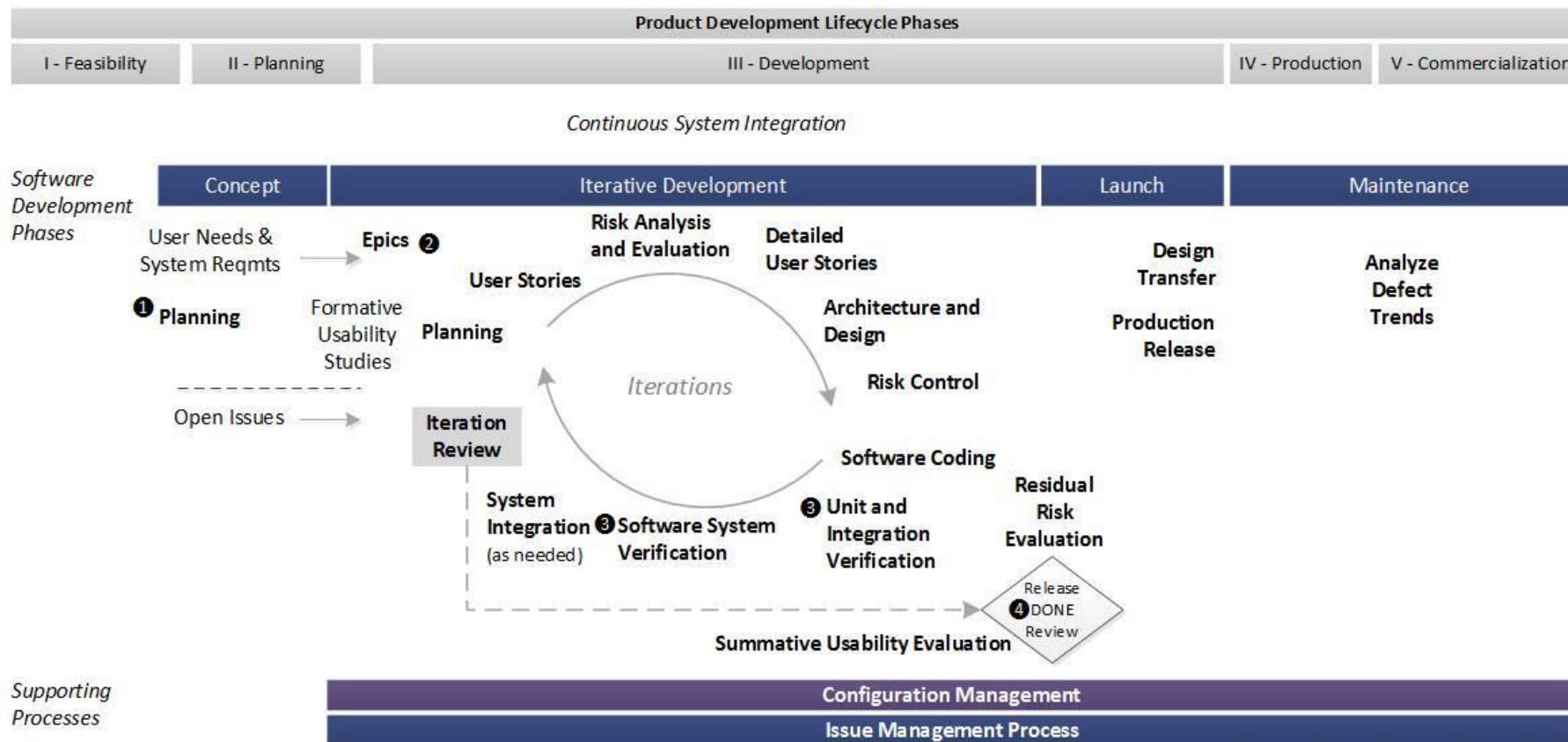
- Developed agile product development framework to coordinate across teams
- Formed “trains” to align similar teams

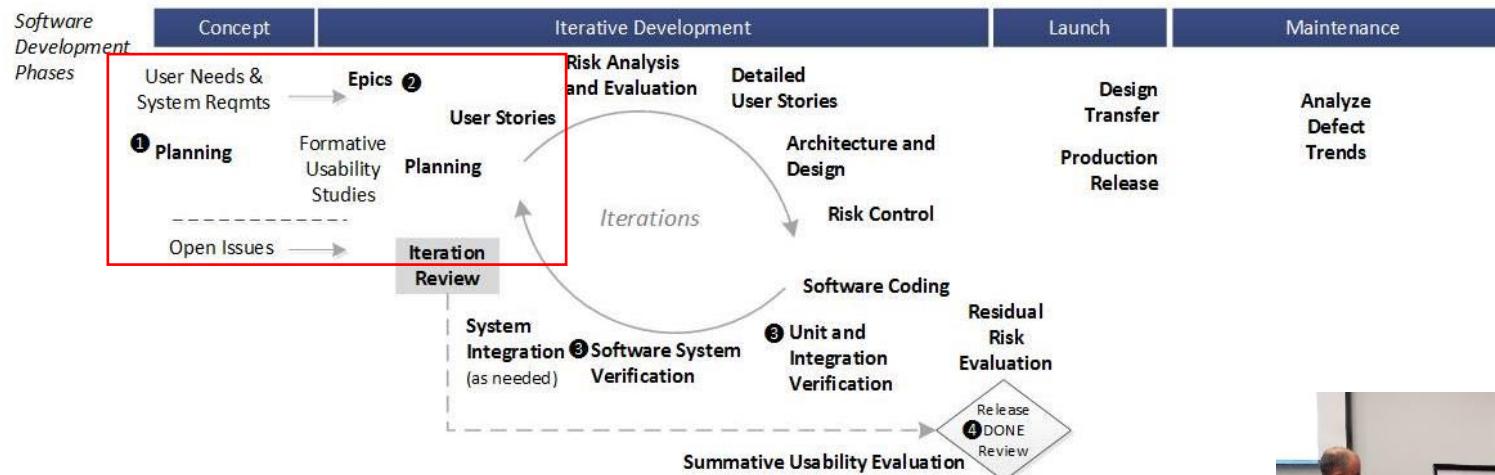
Proteus Medical Device Software Development Life Cycle

Compliant with regulations and standards and aligned with agile principles



Proteus Software Development Life Cycle Process Overview





 iOS Patient App / IPA-47
 As a patient, I want to see the details of the metrics that the patch senses.

Issues in Epic

 IPA-108 As a patient, I want to have summary details of patch sensed metrics.

 iOS Patient App / IPA-108
 As a patient, I want to have summary details of patch sensed metrics.

Portfo

Details

Type:  User Story
 Priority:  P2 Medium

Status:  **DONE** (View Workflow)
 Resolution: Verified

Issues

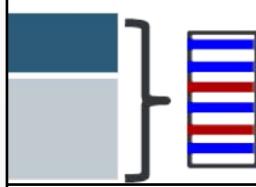
    

 **DONE**
 **DONE**
 **DONE**

Teams Load Features into Their Backlogs

PRO-1321 Rev 1

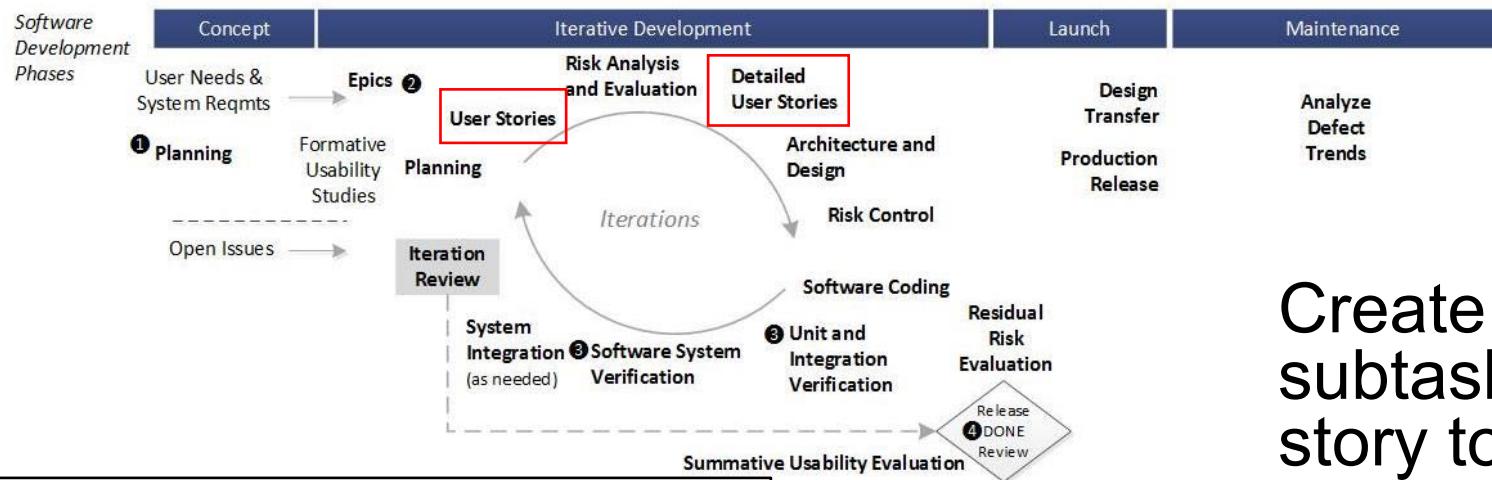
Change Control Protocol for CMD Software for Discover 2.0





- User interface improvements to patch metrics dashboard view





iOS Patient App / IPA-108

As a patient, I want to have summary details of patch sensed metrics.

Sub-Tasks

1. Introduce & Enhance UX assets and lay



iOS Patient App / IPA-108 As a patient, I want to have summary details of patch sensed metrics. / IPA-745

2. Mobile Implementation

3. UX Design Review

4. Ensure adequate AC coverage

5. Write & Execute Acceptance

6. Review & Link Acceptance C

7. E2E System test creation and summary details of patch sen

8. Update RQC SRS Docs

9. Update RQC SRS Acceptance C

10. Update RQC Risk Assessment



Regulatory Quality Compliance / RQC-257

As a patient, I want to have summary details of patch sensed metrics

Agile Board

RQC-253	medications.
RQC-412	As a patient, I'd like to share my Mobile App. screen with Proteus Customer Support for effective troubleshooting
RQC-257	As a patient, I want to have summary details of patch sensed metrics
RQC-387	As a patient I want to be able to install the latest version of the app on top of my existing app (via authenticated medium) and have all of my data migrate seamlessly (with error handling)
RQC-415	As a patient I want to be able to run the Proteus Mobile Application on Apple iPhone or iPad devices running iOS 10.0.0 or greater

Issue Link created

Proteus Digital Health, Inc.

Confidential

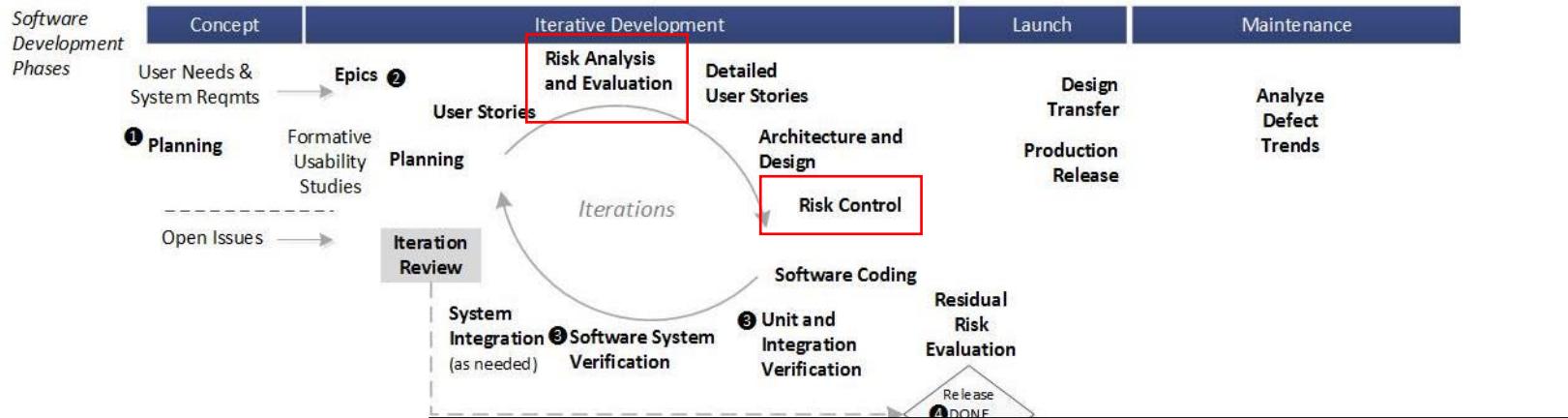
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Create and assign subtasks for each story to track all activities required to bring the story to “DONE”

- Visual Designs
- Risk Assessment
- Software Design
- Implementation
- System Integration
- Verification
- Documentation



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- Evaluate risk and safety classification for each story
- Ensure that hazardous situations are controlled to an acceptable level of risk through the use of inherently safe design and designed risk controls
- Assess cybersecurity vulnerabilities

iOS Patient App / IPA-108

As a patient, I want to be able to...

Sub-Tasks

1. Introduce & Enhance UX assets and layout

Regulatory Quality Compliance

As a patient, I want to be able to...

Issue Links

created by

is assessed by

10. Update RQC Risk Assessment

Regulatory Quality Compliance / RQC-173

Heart Rate Displayed Incorrectly or not displayed - Data at rest

Agile Board More ▾

Details

Type:	! Risk Assessment	Status:	RELEASED (View Workflow)
Priority:	P3 Medium	Resolution:	Done
Affects Version/s:	None	Fix Version/s:	2.0 Stage 2
Component/s:	iOS Mobile App, iOS Proteus Kit		
Labels:	None		

Risk Identification Risk Evaluation Risk Mitigation

Failure Type: Design

Sub-Component: HR Display/Dashboard/API

Potential Failure Mode: HR information is corrupted due to corruption of data store on mobile device

Effect: Patient does not have reliable information about heart rate

Potential Root Cause: Data error

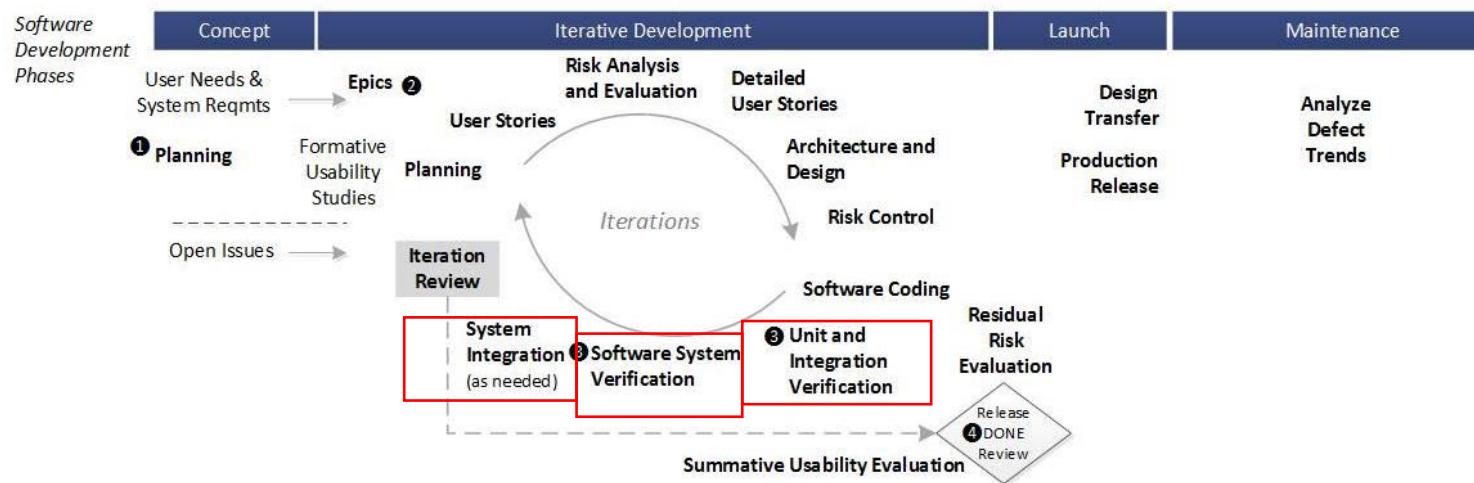
E EASED

RSK-0043 Rev16 Proteus Mobile Application Software dFMEA

Effective: 13OCT2017

Key	Failure type	sub-component	potential failure mode	effect	severity of harm	potential root cause	likelihood	risk score	risk score level	preventive measures	Linked Issues	post mitigation likelihood	post mitigation risk score	post mitigation risk score level	Component/s
RQC-173	Design	HR Display/Dashboard/API	HR information is corrupted due to corruption of data store on mobile device	Patient does not have reliable information about heart rate	2	Data error	4	8	Acceptable	Software checks for database corruption and creates a new database if detected.	RQC-257, RQC-164	2	4	Acceptable	iOS Mobile App, iOS Proteus Kit





- Develop and execute integration-level and system-level verification testing
- Document the test results and a list of defects
- Evaluate test failures
- Re-test any changes

iOS Patient App / IPA-108
As a patient, I want to have summary details of patch sensed metrics.

iOS Patient App / IPA-108 As a patient, I want to have summary details of patch sensed metrics. / IPA-744
E2E System test creation and execution - As a patient, I want to have summary details of patch sensed metrics

[Edit](#) [Comment](#) [Assign](#) [More](#) [In Progress](#)

Details

Type:	Sub-Task	Status:	DONE (View Workflow)
Priority:	P3 Medium	Resolution:	Verified
Affects Version/s:	None	Fix Version/s:	None
Component/s:	None		
Labels:	None		
Sprint:	2017 PI-08 Sprint 6		

People

Assignee:	Prajakta Koranne
Reporter:	Vaibhav Anand
Votes:	0
Watchers:	Eric Husky
Favourite:	

7. [E2E System test creation and execution - As a patient, I want to have summary details of patch sensed metrics](#) [DONE](#) Prajakta Koranne

8. [Update RQC SRS Docs](#) [DONE](#) Vaibhav Anand

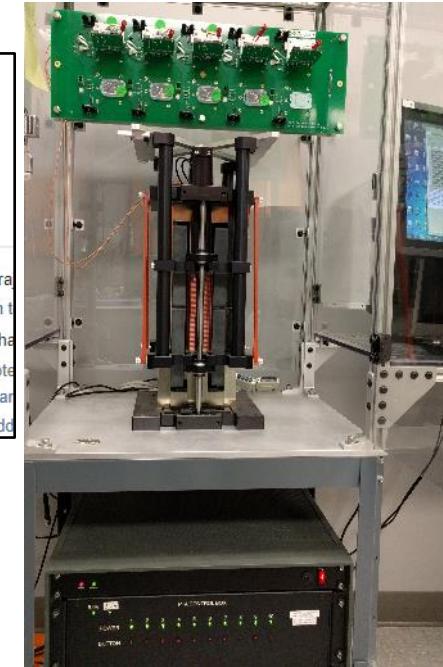
9. [Update RQC SRS Acceptance Criteria Linking](#) [DONE](#) Eric Husky

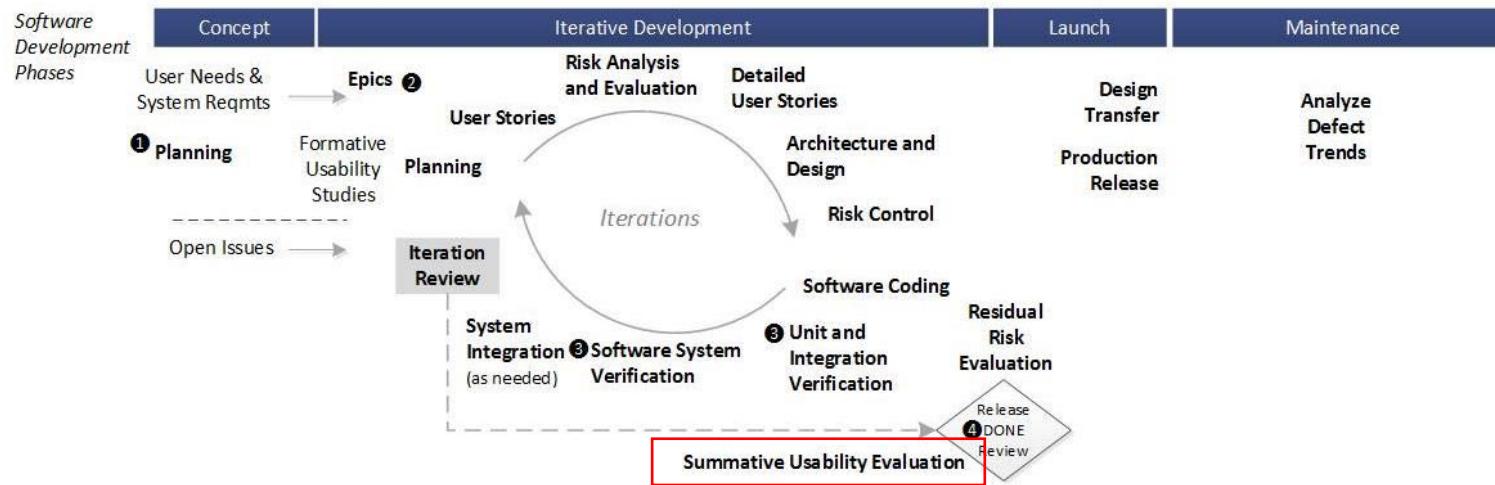
10. [Update RQC Risk Assessment](#) [DONE](#) Vaibhav Anand

PC-Summary: No Pre-Condition Associated with this Test

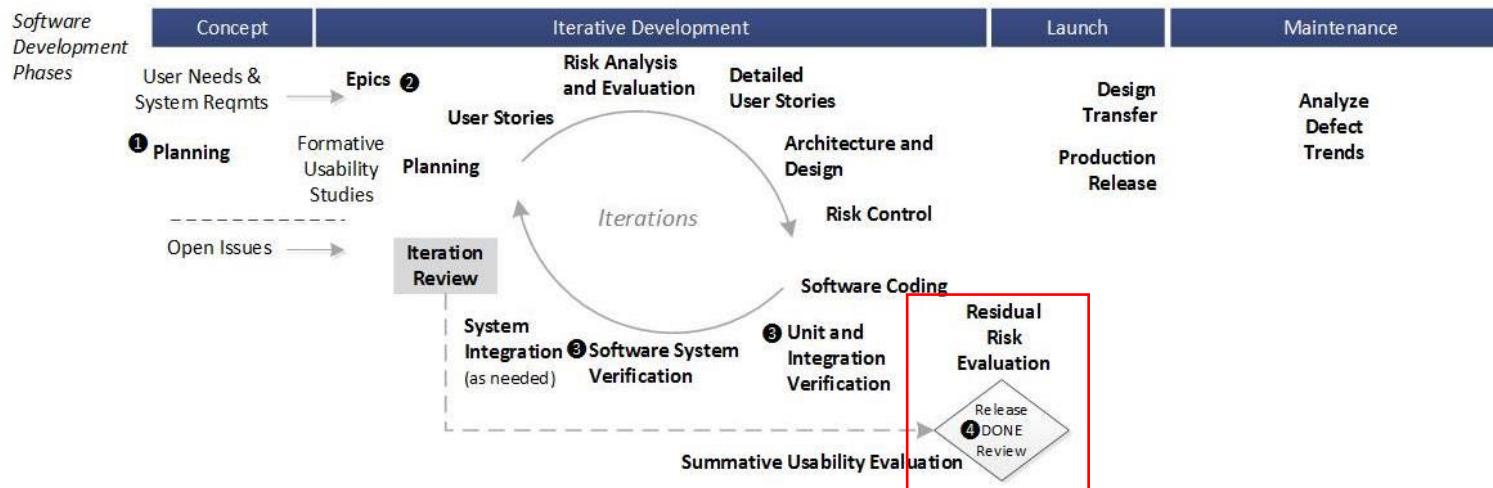
Rev 11

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- As needed and as appropriate for the software safety class and risk profile
- After the last iteration (sprint)
- Evaluate the claim that the device is safe and effective in the hands of intended users



- Conduct system demo to stakeholders
- Ensure all software verification is complete
- Evaluate residual risk for all failure modes analyzed in the risk analysis and from defects to ensure file risk is as low as possible
- Ensure all required activities, tasks, and documentation is complete
- Conduct design review to ensure the design outputs properly implement design inputs

Launch Details iOS Patient App 3.2.0
Created by Zach Petschek, last modified on Oct 30, 2017

[Features](#) [Launch Details](#) [Deployment Docs](#) [Deployment Plan](#) [Task Checklist](#) [Calendar](#)

Deployment Documents

Version numbers represent the current standing version. If a document requires a revision, the Rev # changes to represent what will be in effect when the product is released.

Key	Name	Target Date Effective in ETQ	Owner	Needs revision?	Status	Approval needed by
PRD Rev	RPT-2028 Rev. 1 Change Control Report for CMD Software for Discover 2.0	Effective: 24MAR2017				
PRD Rev						
PRD Rev						
SPD Rev						
SPC 2016	ProtocolKit Software Requirements	20 Sep 2017	Eric	VOC	Unknown	Vijender Singh
						Volibay Anand

RPT-2028 Rev. 1
Change Control Report for CMD Software for Discover 2.0

- User interface improvements to patch metrics dashboard view
- Improved ingestion metrics by showing the code and time of detection of Ingestible Sensors
- Streamlined patch status logic
- Support for iOS 9.3 and above

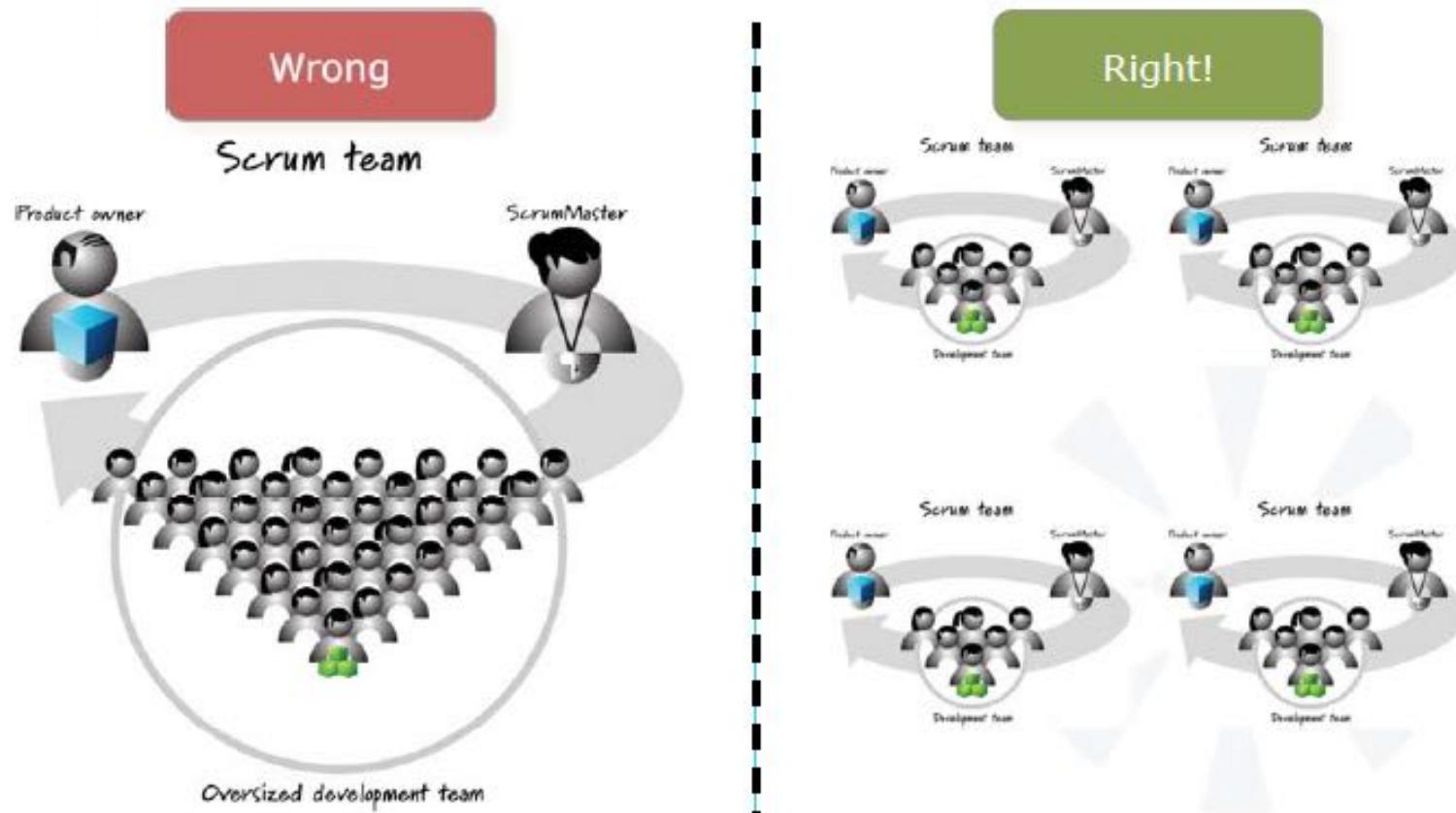


Summary of Key Messages

- Transition to an agile software development life cycle process that is compliant with the relevant regulations, standards, and guidance is a long journey...
- ... and it requires dedication from a core team, support from management, and participation from across the organization

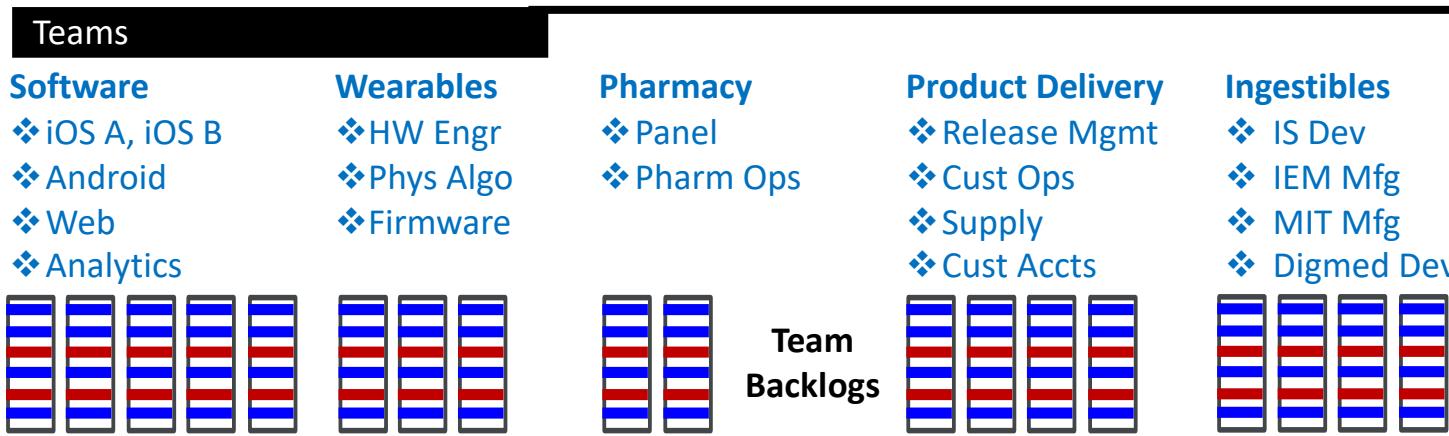
The cross-functional **scrum team** is the foundation of agile development

Scaling with Scrum



From Ken Rubin's Scrum for Teams Course

Scrum teams deliver product components, with cross-functional and Systems Engineering participation

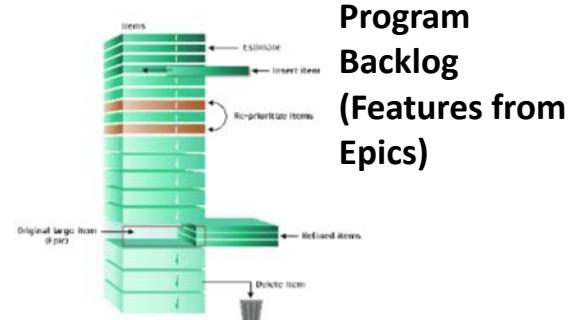


Program teams focus on integration and coordination across components

Program

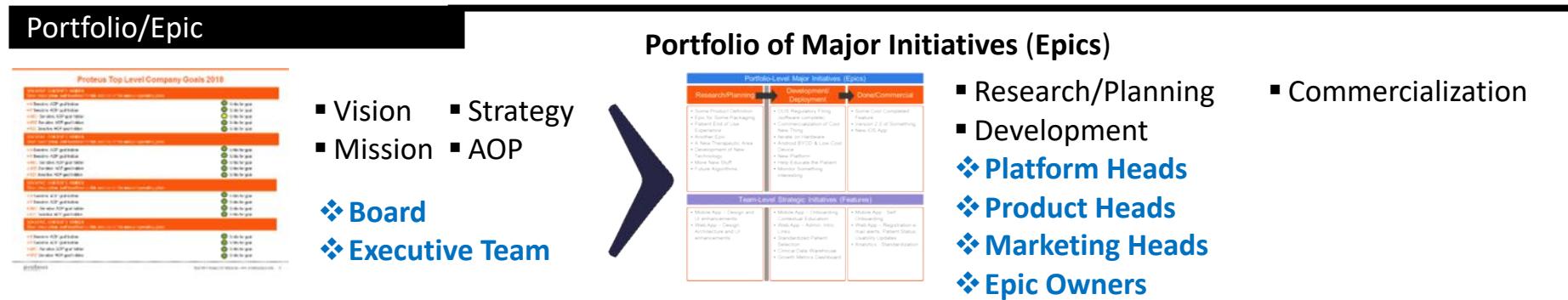
Program Teams (Teams of Teams)

- ❖ Software
- ❖ Wearables
- ❖ Pharmacy
- ❖ Product Delivery
- ❖ Ingestibles



Program Backlog (Features from Epics)

Epics, features, and initiatives tied to corporate goals – aligned and prioritized across the organization



Unified view of Proteus product development framework

Portfolio/Epic



- Vision
- Strategy
- Mission
- AOP
- ❖ Board
- ❖ Executive Team

Portfolio of Major Initiatives (Epics)



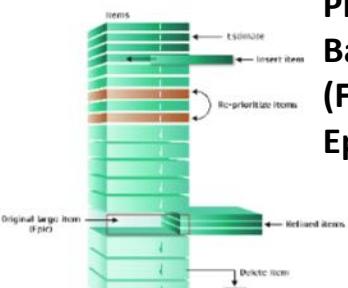
- Research/Planning
- Development
- ❖ Platform Heads
- ❖ Product Heads
- ❖ Marketing Heads
- ❖ Epic Owners

Program

Program Teams (Teams of Teams)

- ❖ Software
- ❖ Wearables
- ❖ Pharmacy
- ❖ Product Delivery
- ❖ Ingestibles

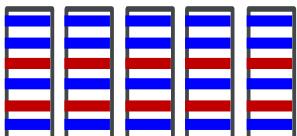
Program Backlog (Features from Epics)



Teams

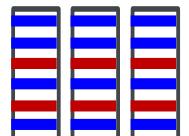
Software

- ❖ iOS A, iOS B
- ❖ Android
- ❖ Web
- ❖ Analytics



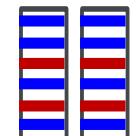
Wearables

- ❖ HW Engr
- ❖ Phys Algo
- ❖ Firmware



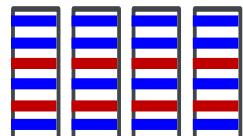
Pharmacy

- ❖ Panel
- ❖ Pharm Ops



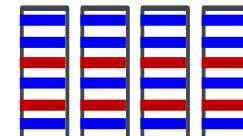
Product Delivery

- ❖ Release Mgmt
- ❖ Cust Ops
- ❖ Supply
- ❖ Cust Accts



Ingestibles

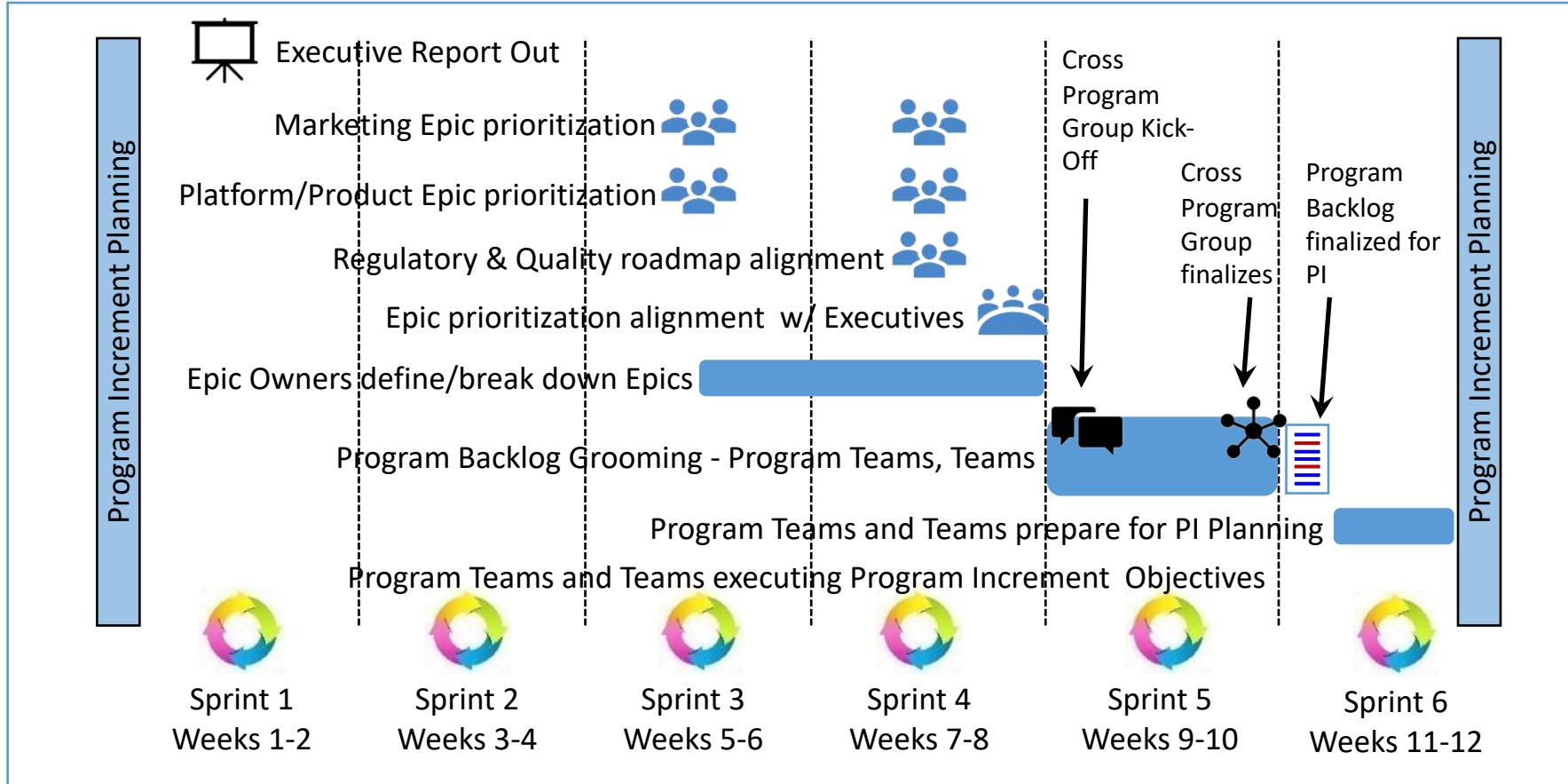
- ❖ IS Dev
- ❖ IEM Mfg
- ❖ MIT Mfg
- ❖ Digmed Dev



Solutions for Customers

- ❖ Pharmaceutical Partner
- ❖ Proteus Product
- ❖ Future Partners

Cross-functional planning and prioritization ahead of each program increment



Program Increment Planning every 12 weeks provides opportunity to re-prioritize development initiatives and synchronize Teams

- ▶ All stakeholders face-to-face at an offsite venue
- ▶ Management sets the mission, with minimum possible constraints
- ▶ Requirements and design emerge
- ▶ Important stakeholder decisions are accelerated
- ▶ Teams create and take responsibility for plans



Team Planning and Cross-Functional Collaboration at Program Increment Planning





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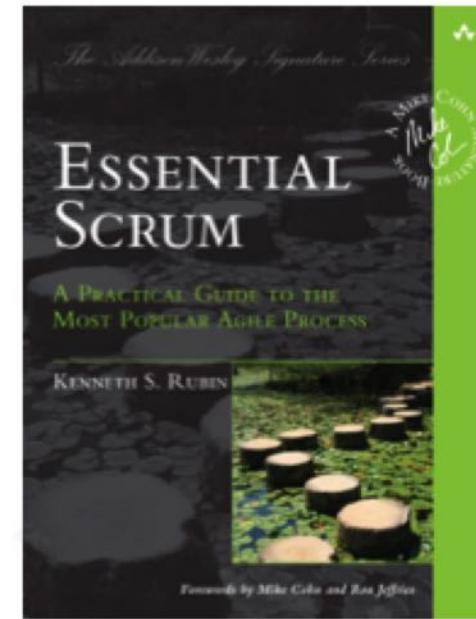


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