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

Agile Product Development for Digital Medicines

Eli Snell

Proteus Digital Health

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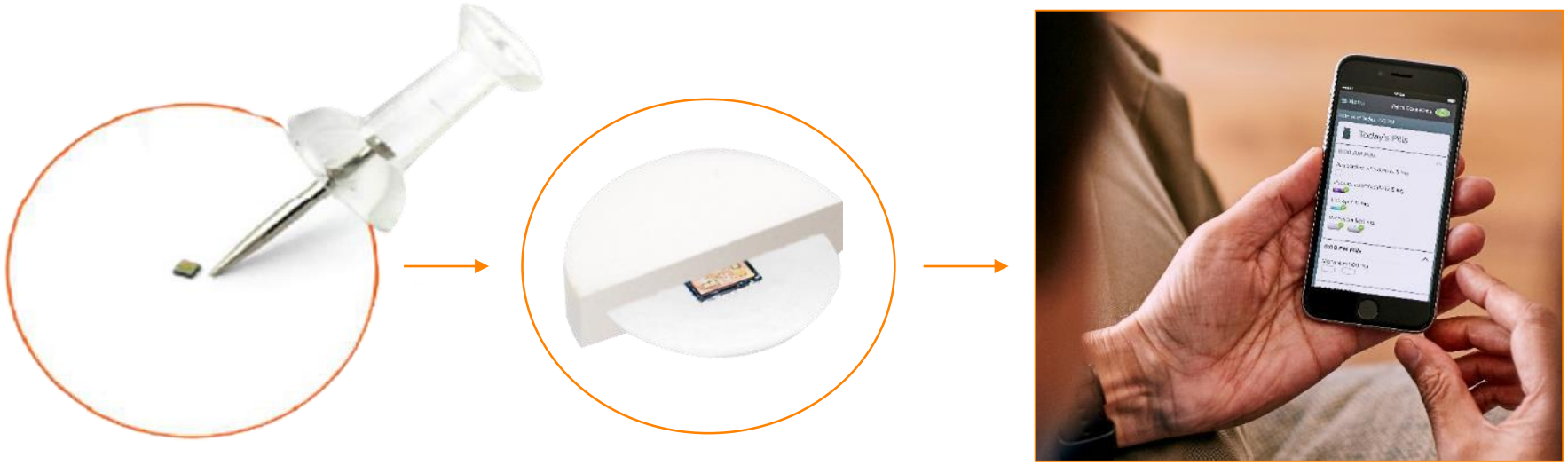
Eli Snell
VP, Software Solutions

- 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

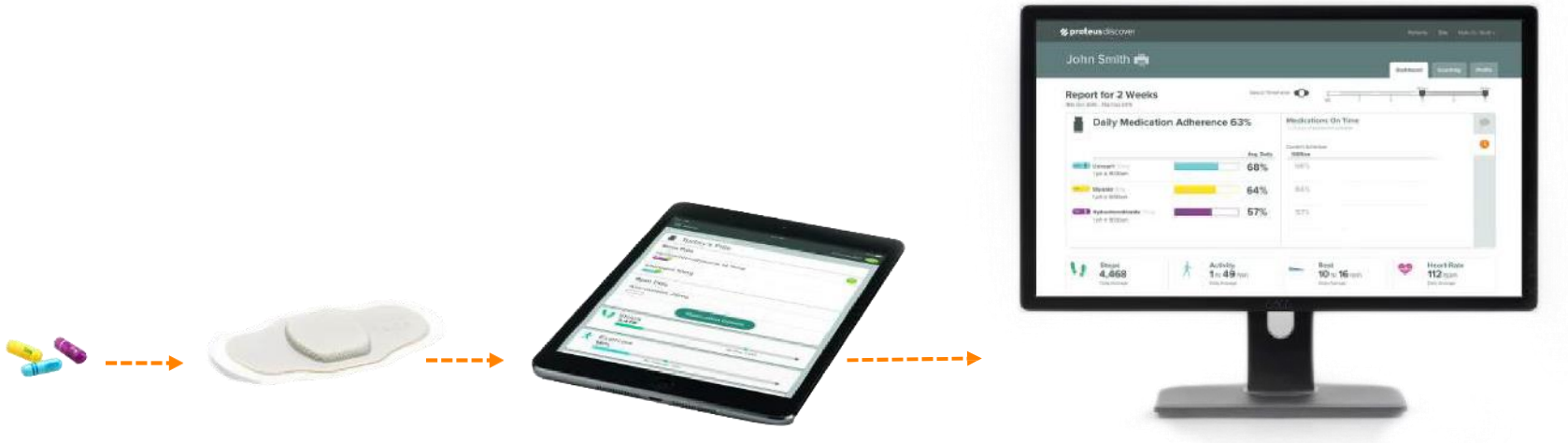
Answering the age-old questions: Did the patient take their medications as prescribed, and did they work?



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



Digital Medicines | Wearable Sensor | Patient Mobile App

Provider Web/EHR app

Used by Patients

Used by Healthcare Teams

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

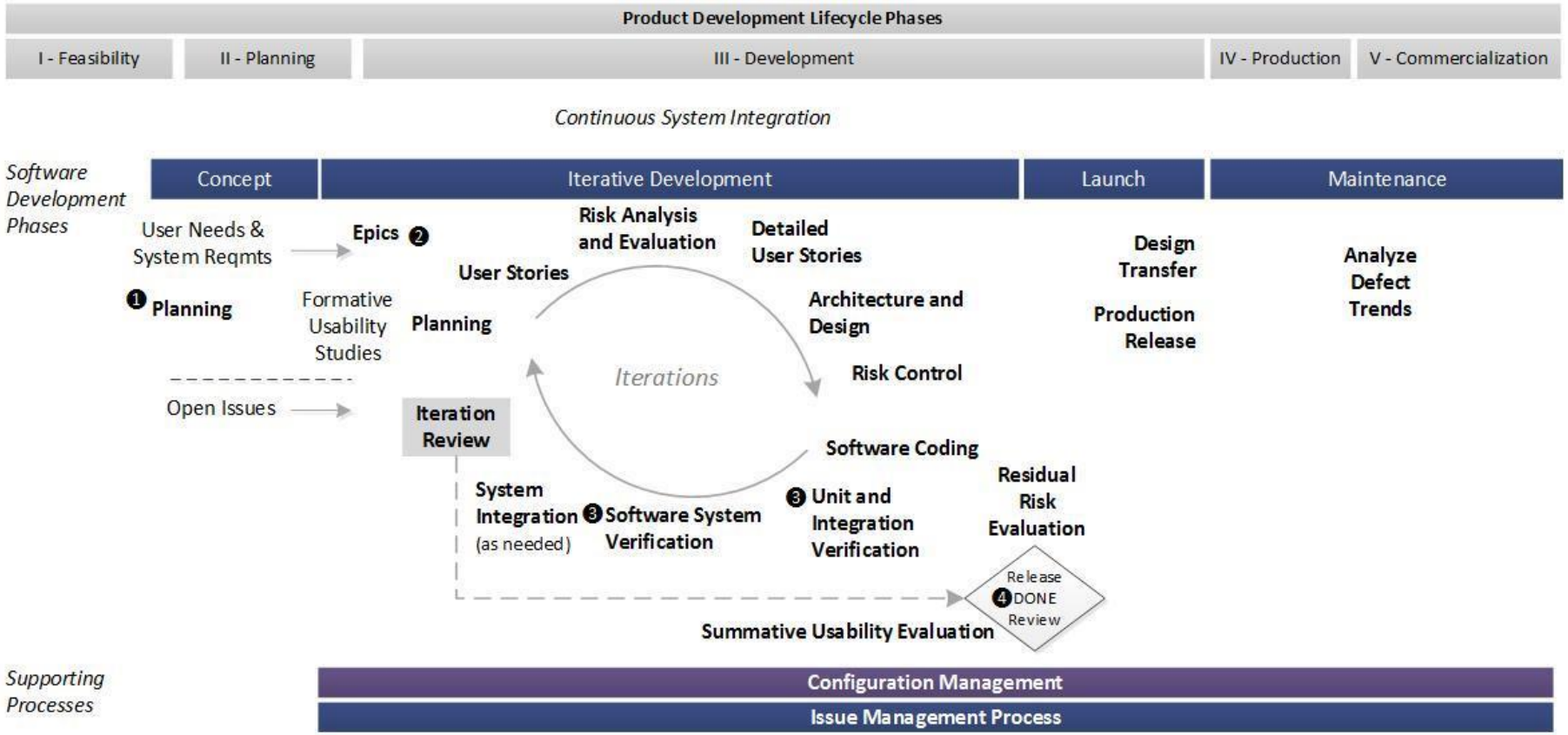
Scale

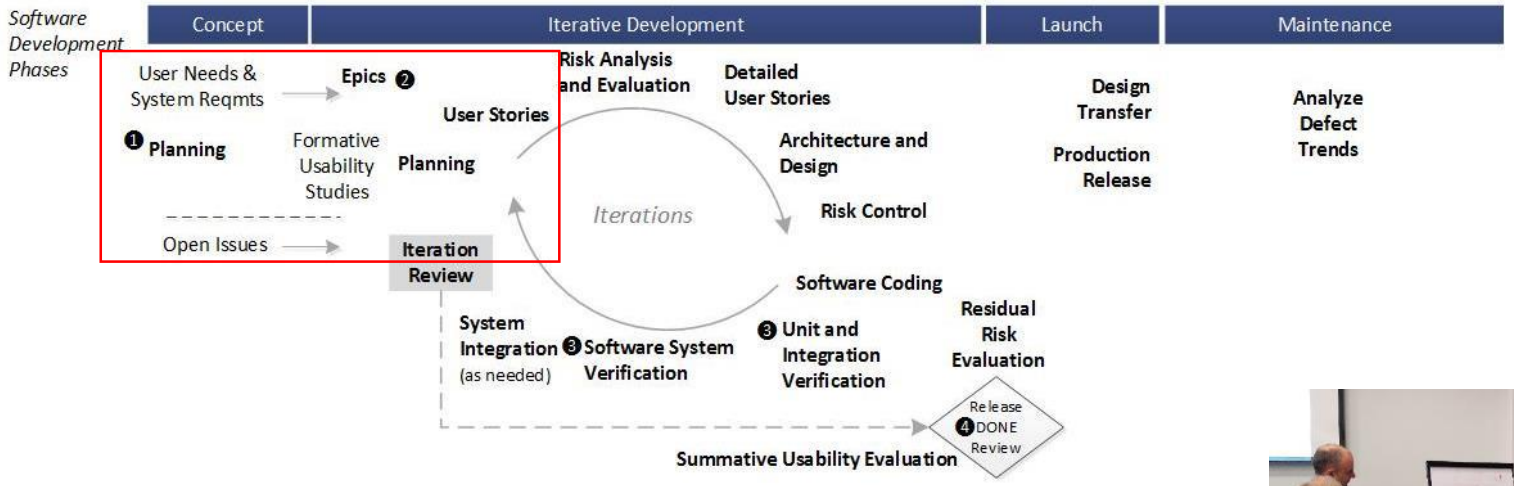
- Developed agile product development framework to coordinate across teams
- Formed “trains” to align similar teams

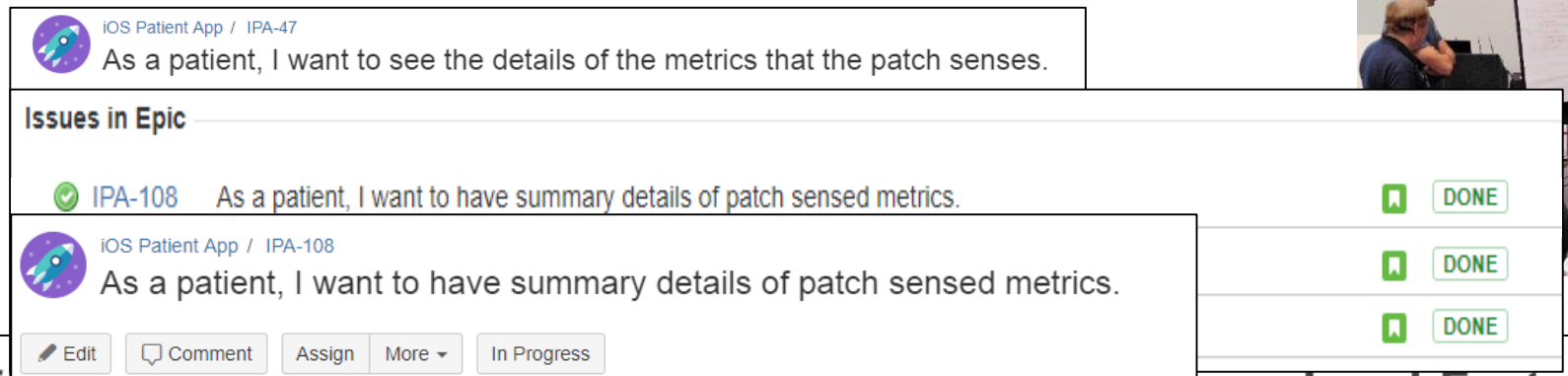
Proteus Medical Device Software Development Life Cycle

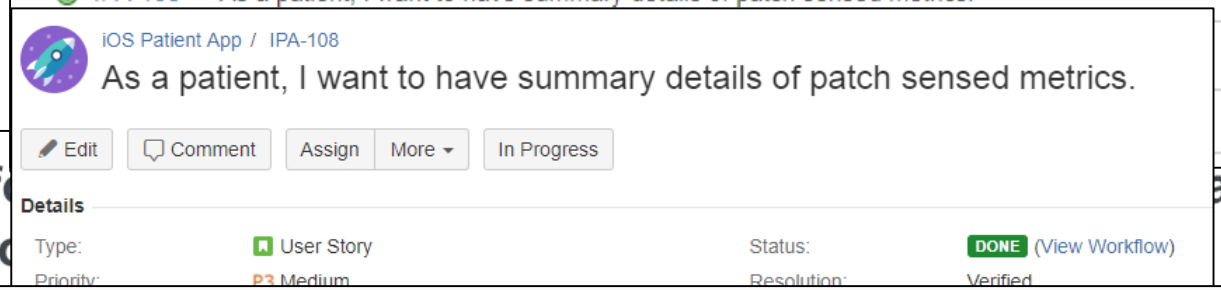
Compliant with regulations and standards and aligned with agile principles

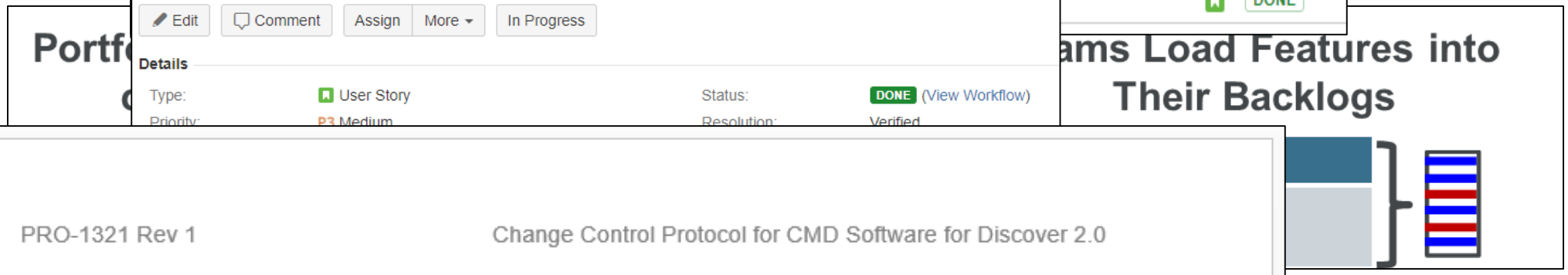
Proteus Software Development Life Cycle Process Overview

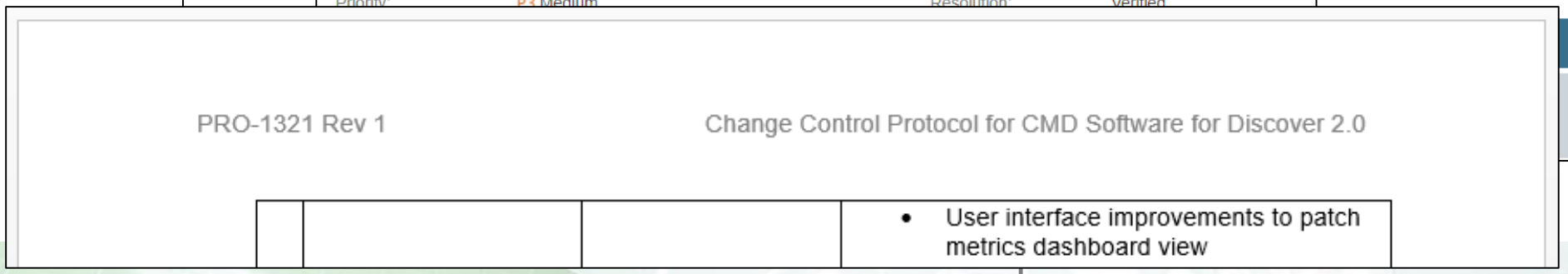


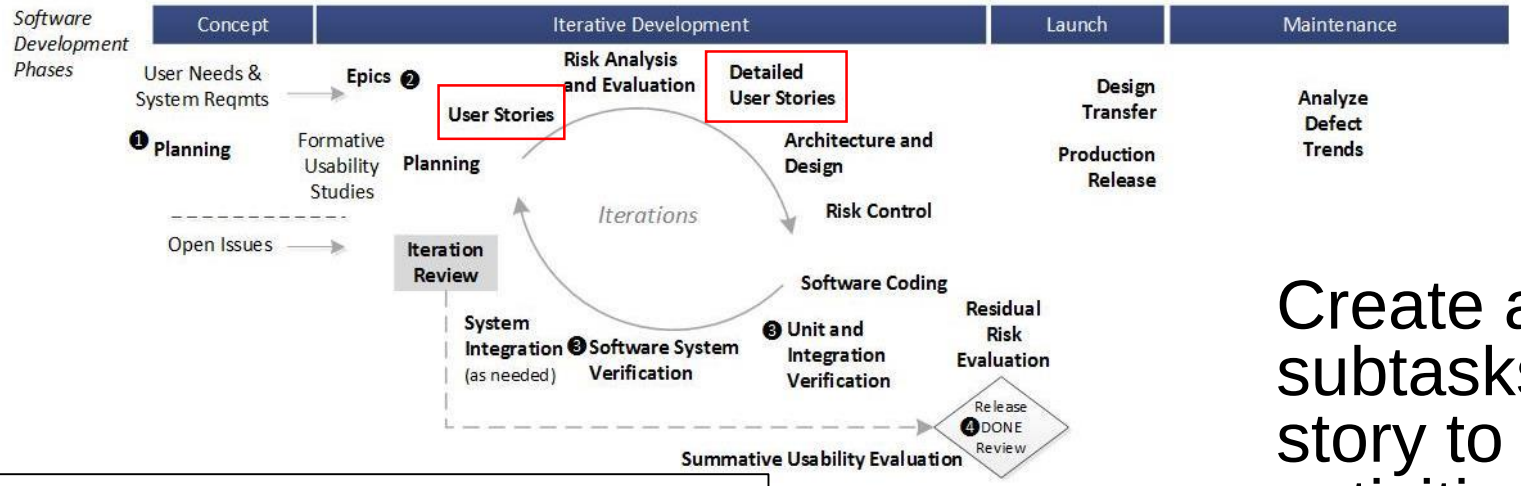

Software Development Phases
Concept
Iterative Development
Launch
Maintenance
User Needs & System Reqmts
Epics
User Stories
Planning
Formative Usability Studies
Planning
Open Issues
Iteration Review
Risk Analysis and Evaluation
Detailed User Stories
Architecture and Design
Risk Control
Iterations
Software Coding
System Integration (as needed)
Software System Verification
Unit and Integration Verification
Residual Risk Evaluation
Release DONE Review
Summative Usability Evaluation
Design Transfer
Production Release
Analyze Defect Trends


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.
DONE
DONE
DONE


iOS Patient App / IPA-108
As a patient, I want to have summary details of patch sensed metrics.
Edit
Comment
Assign
More
In Progress
Details
Type: User Story
Status: DONE (View Workflow)
Priority: P3 Medium
Resolution: Verified


ams 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
2. Mobile Implementation
3. UX Design Review
4. Ensure adequate AC coverag
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 Criteria L
10. Update RQC Risk Assessment

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

Regulatory Quality Compliance / RQC-257
As a patient, I want to have summary details of patch sensed metrics

Agile Board

Details
Type:
Priority:
Affects Version/
Component/s:
Labels:

Issue Link
created

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

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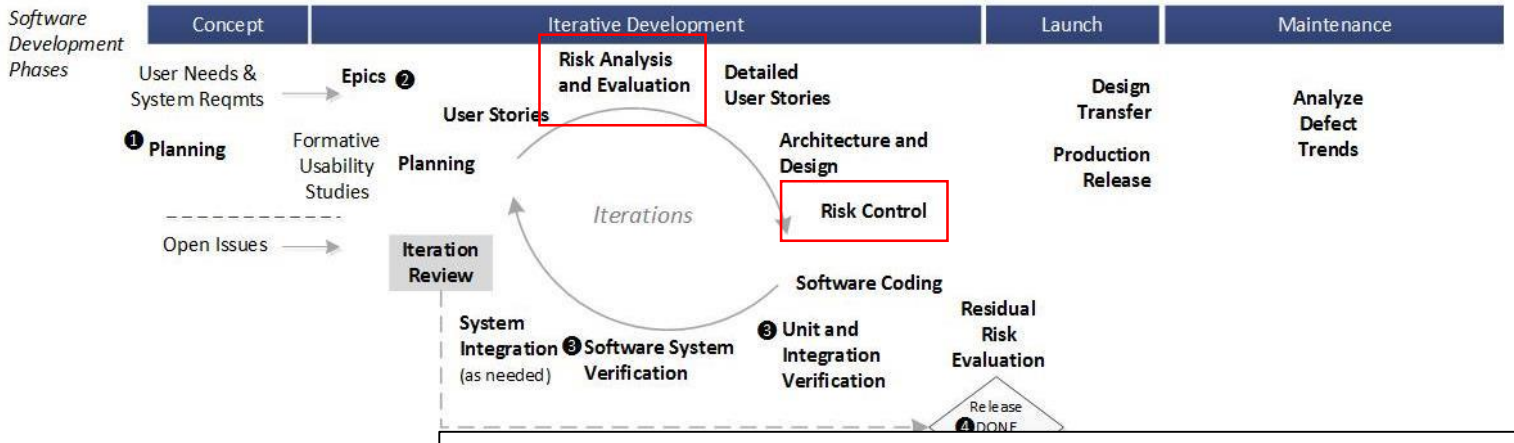
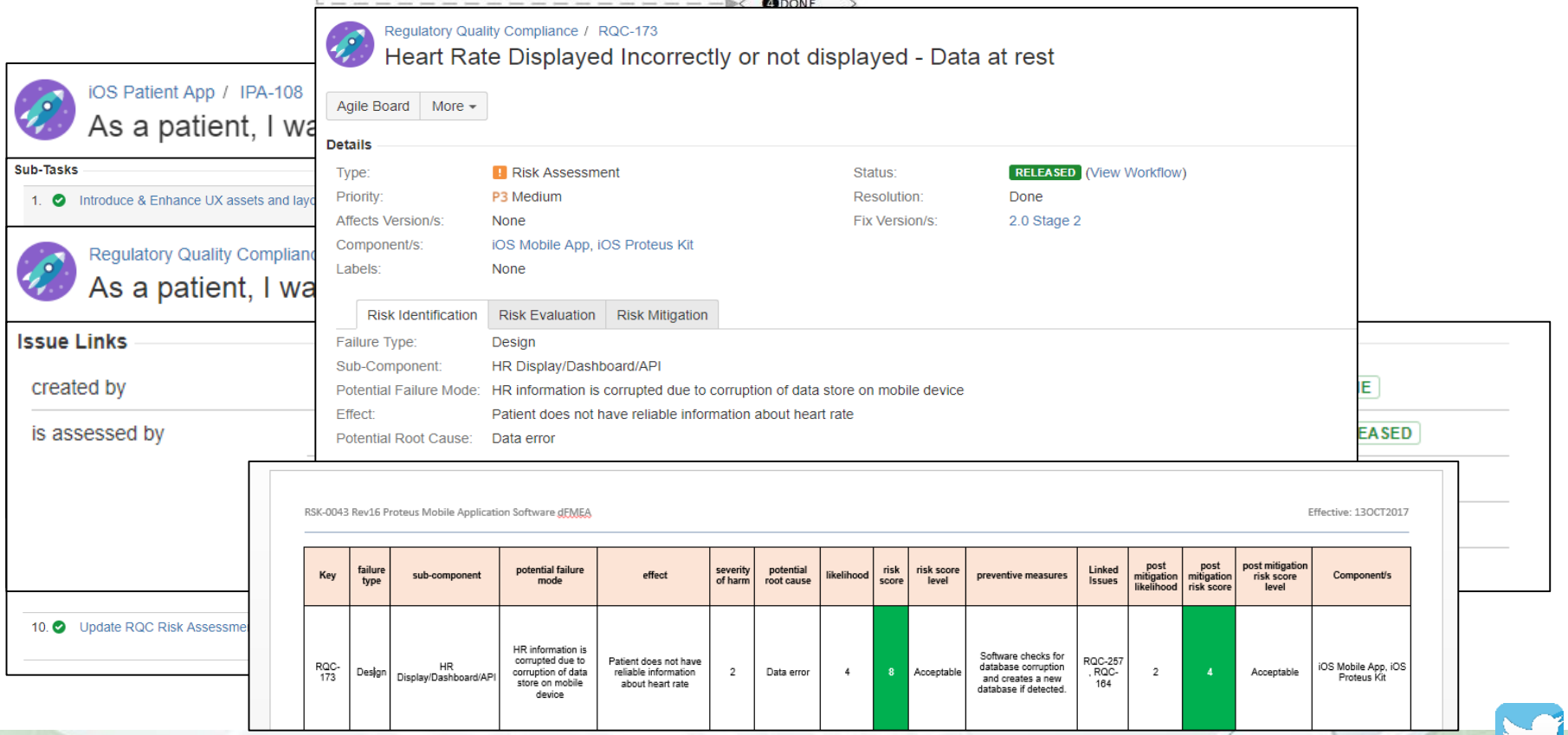
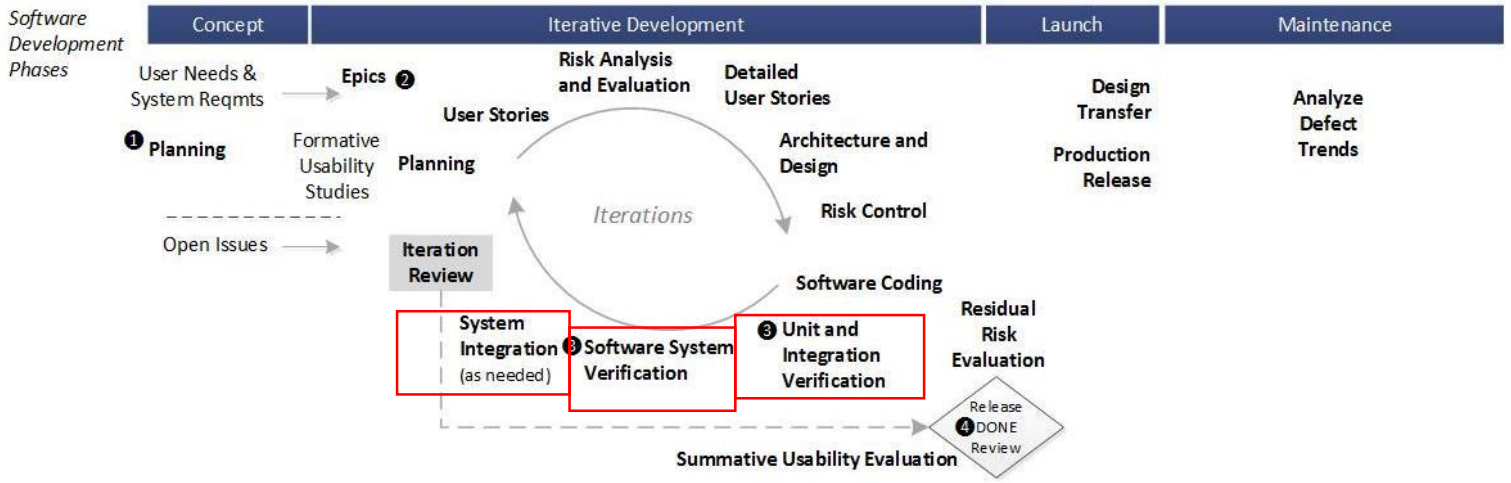
Create and assign subtasks for each story to track all activities required to bring the story to "DONE"

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

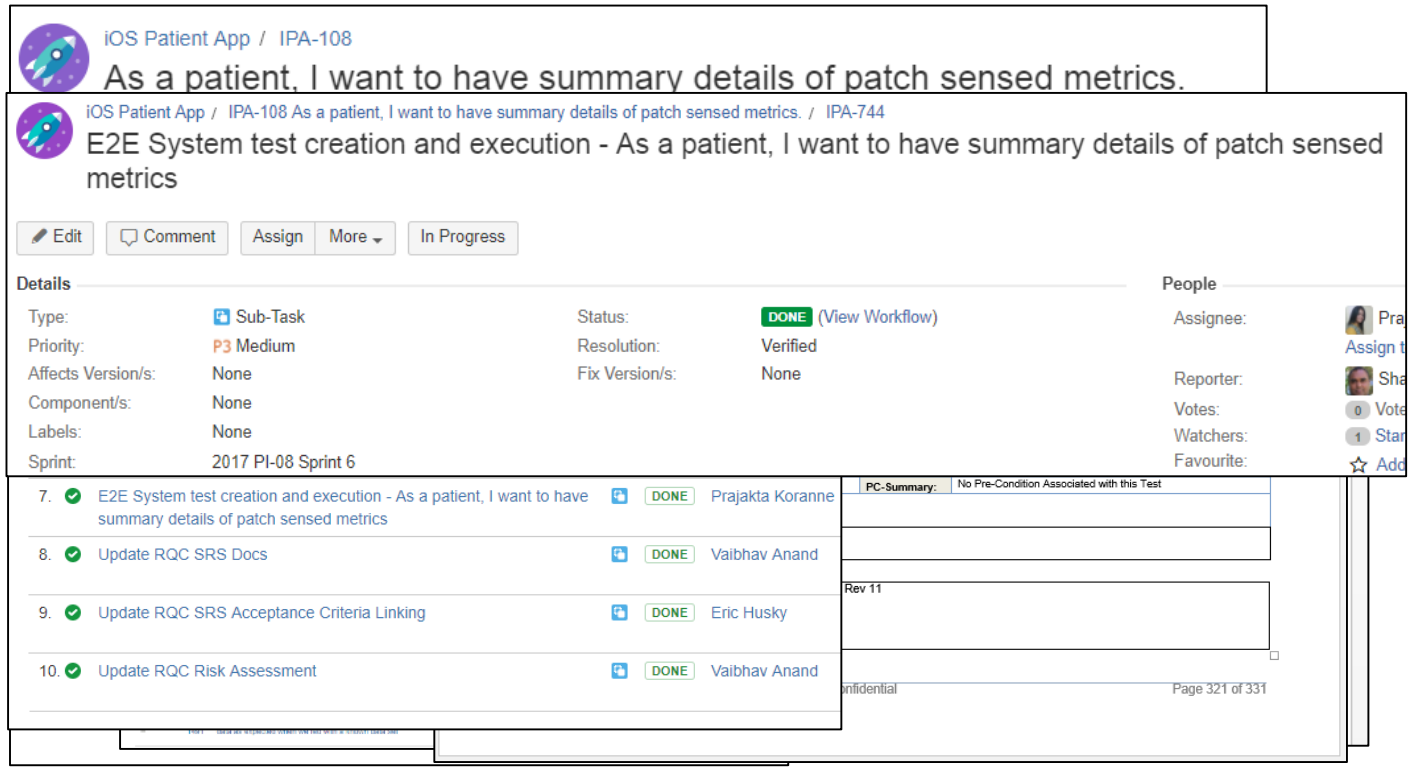


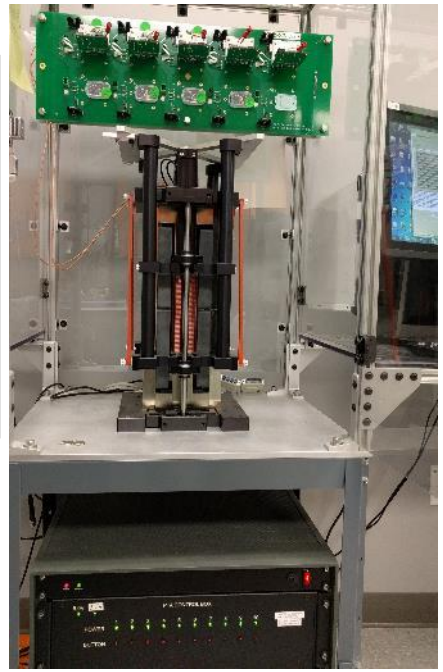
- Evaluate risk and safety classification for each story
- Ensure that hazardous situations are controlled to an acceptable level of risk through the use of inherently safe design and designed risk controls
- Assess cybersecurity vulnerabilities

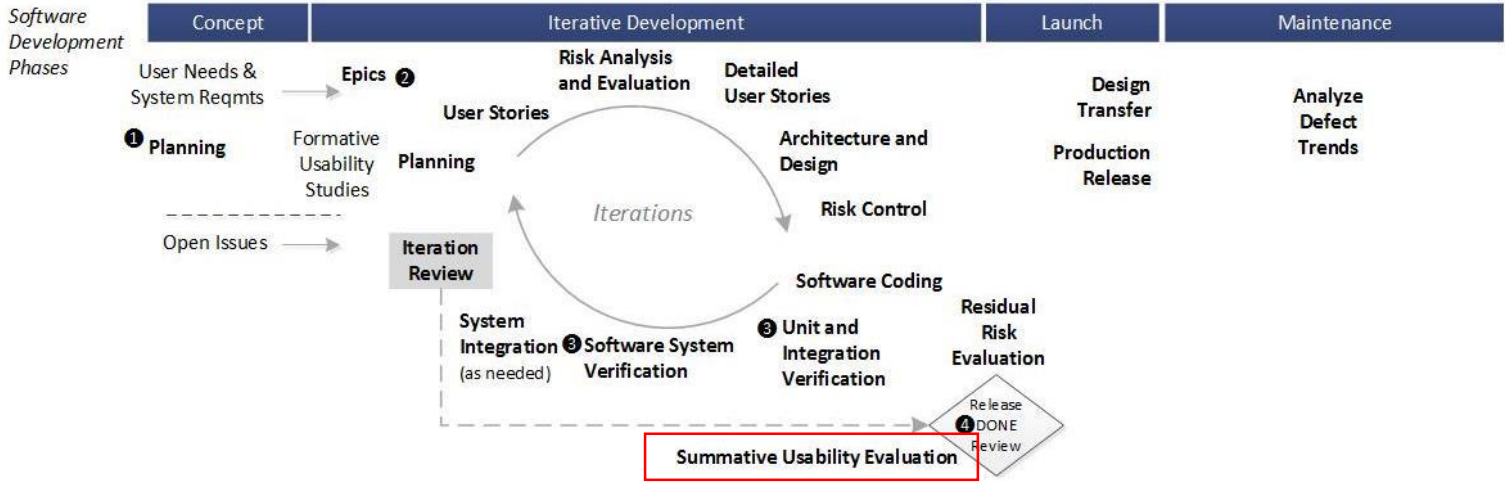




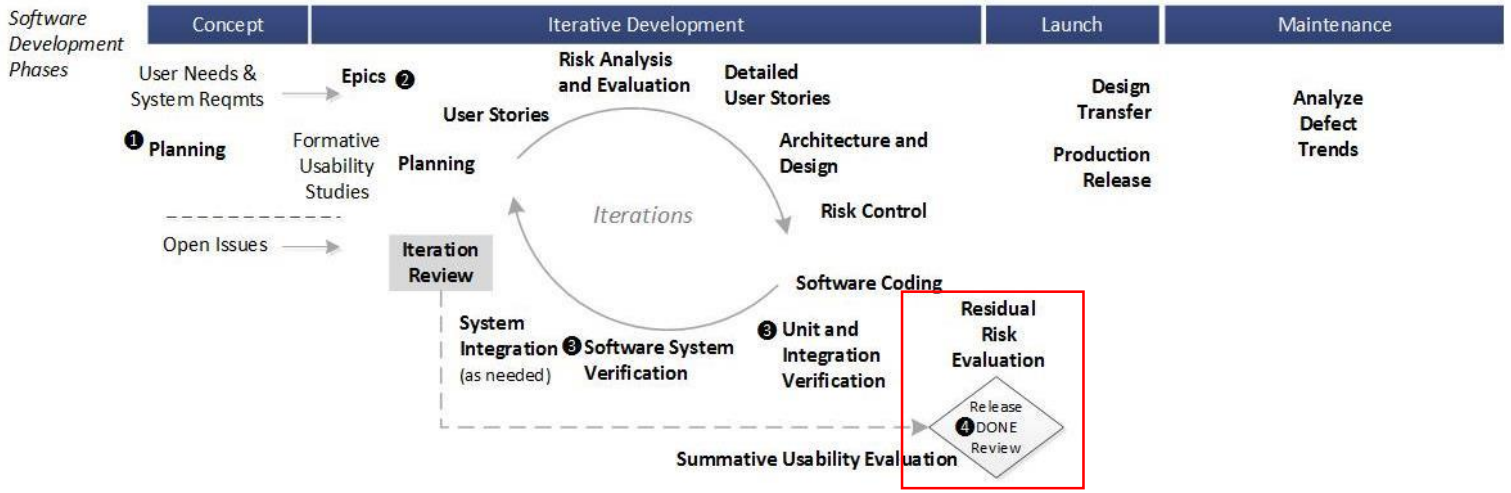
- Develop and execute integration-level and system-level verification testing
- Document the test results and a list of defects
- Evaluate test failures
- Re-test any changes



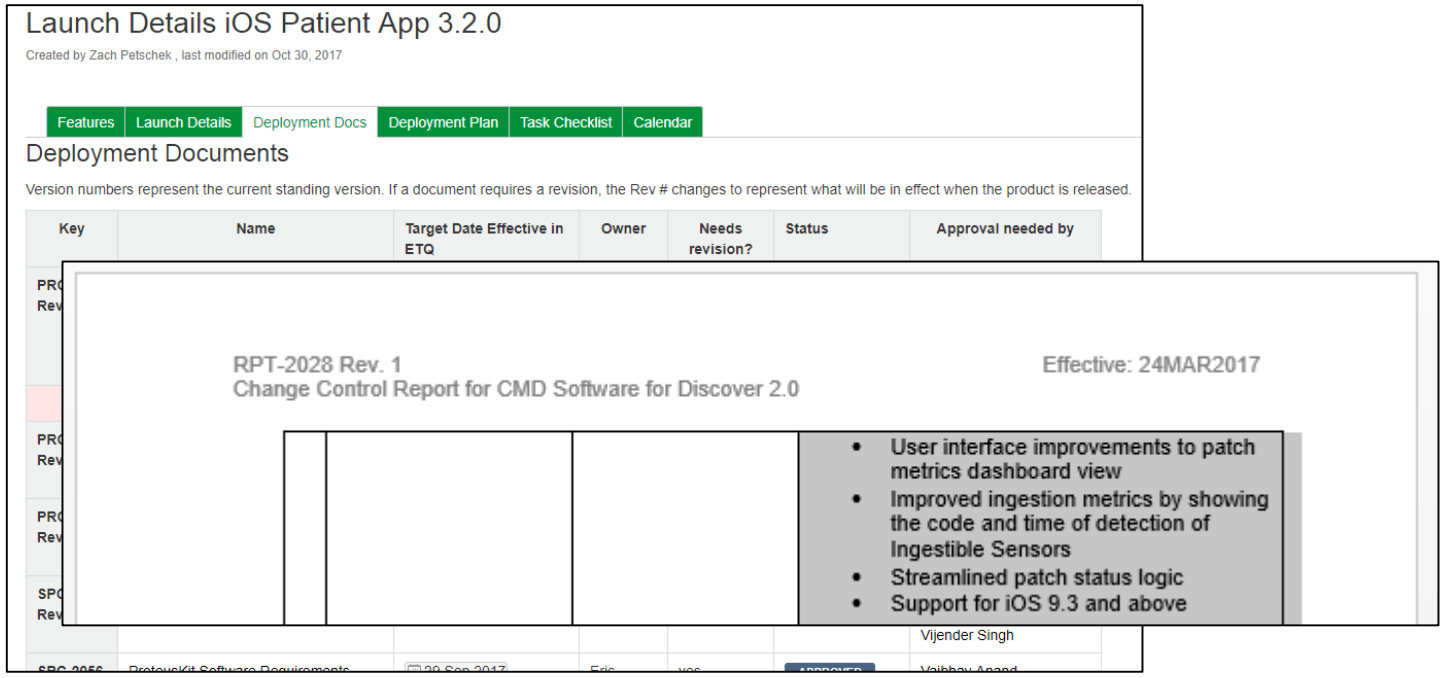




- As needed and as appropriate for the software safety class and risk profile
- After the last iteration (sprint)
- Evaluate the claim that the device is safe and effective in the hands of intended users



- 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

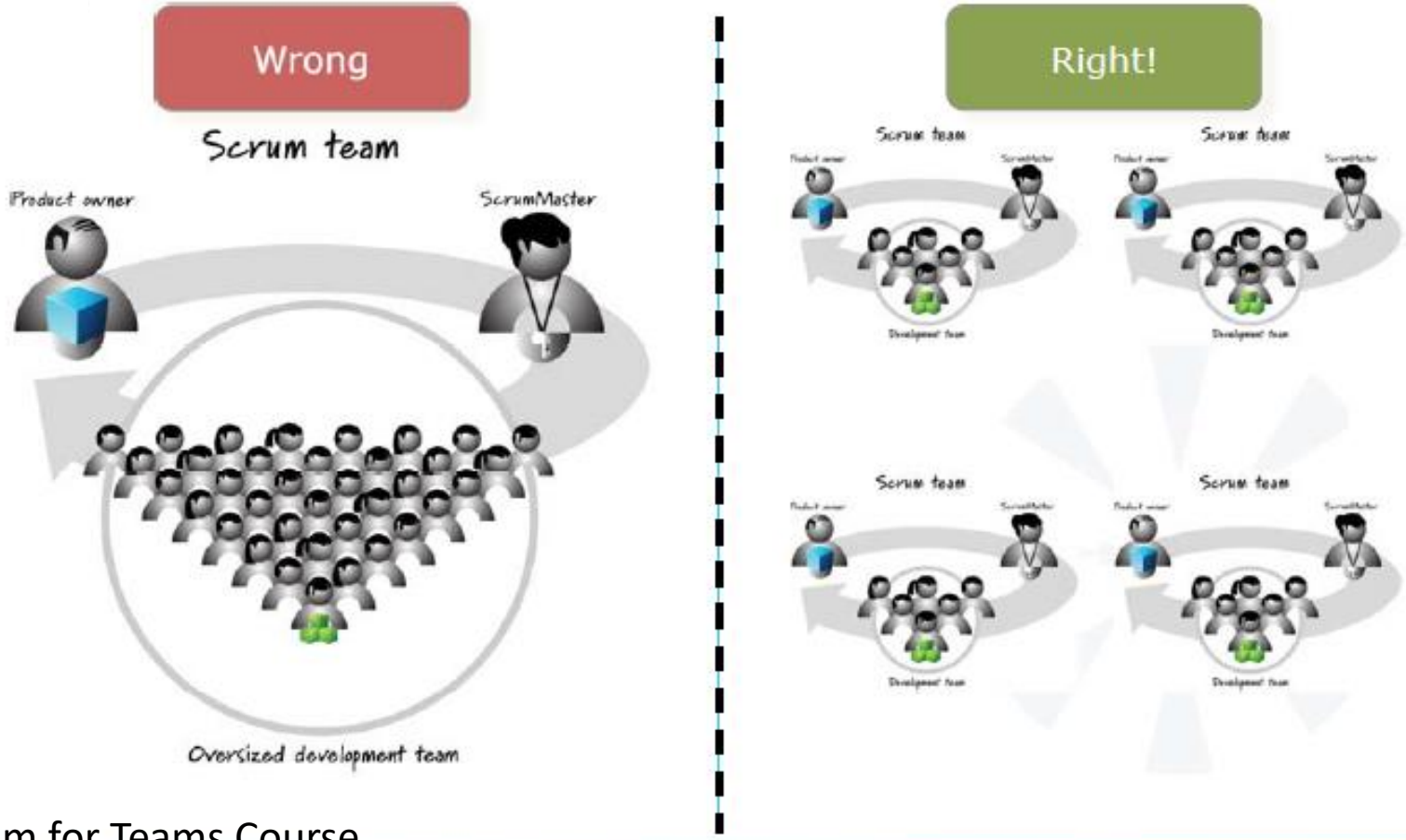


Summary of Key Messages

- 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

Teams

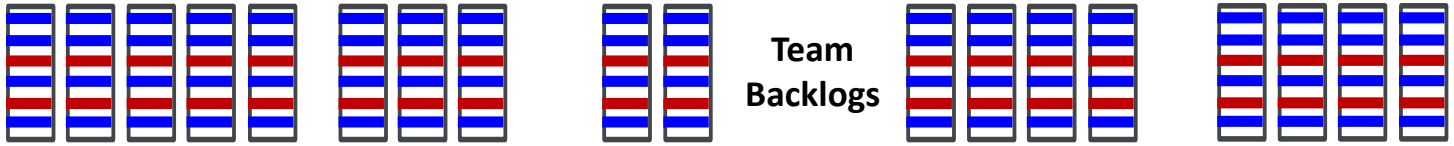
Software
- iOS A, iOS B
- Android
- Web
- Analytics

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

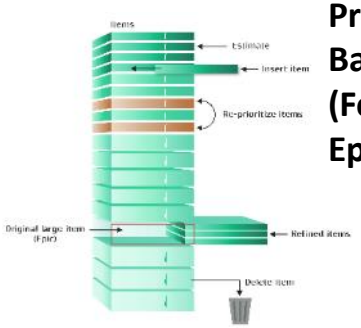


Team Backlogs

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)

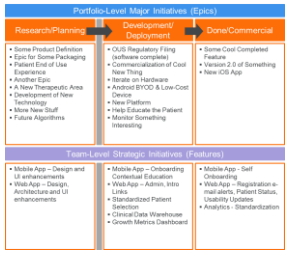
Epics, features, and initiatives tied to corporate goals – aligned and prioritized across the organization

Portfolio/Epic

- Vision
- Strategy
- Mission
- AOP

❖ **Board**
❖ **Executive Team**

Portfolio of Major Initiatives (Epics)



- Research/Planning
- Development
- Commercialization

❖ **Platform Heads**
❖ **Product Heads**
❖ **Marketing Heads**
❖ **Epic Owners**

Unified view of Proteus product development framework

Portfolio/Epic

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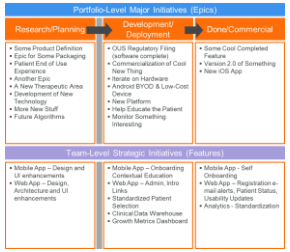
Portfolio of Major Initiatives (Epics)



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

Solutions for Customers

❖ **Pharmaceutical Partner**
❖ **Proteus Product**
❖ **Future Partners**

Program

Program Teams (Teams of Teams)
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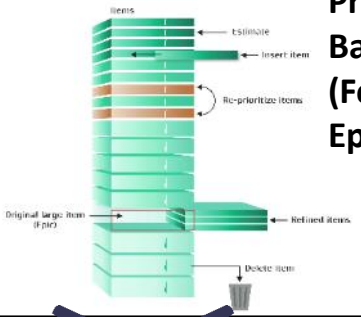
❖ **Wearables**
❖ **Pharmacy**
❖ **Product Delivery**
❖ **Ingestibles**



Program Backlog (Features from Epics)

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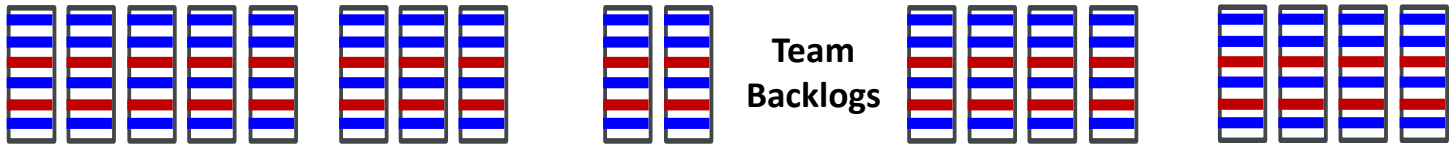
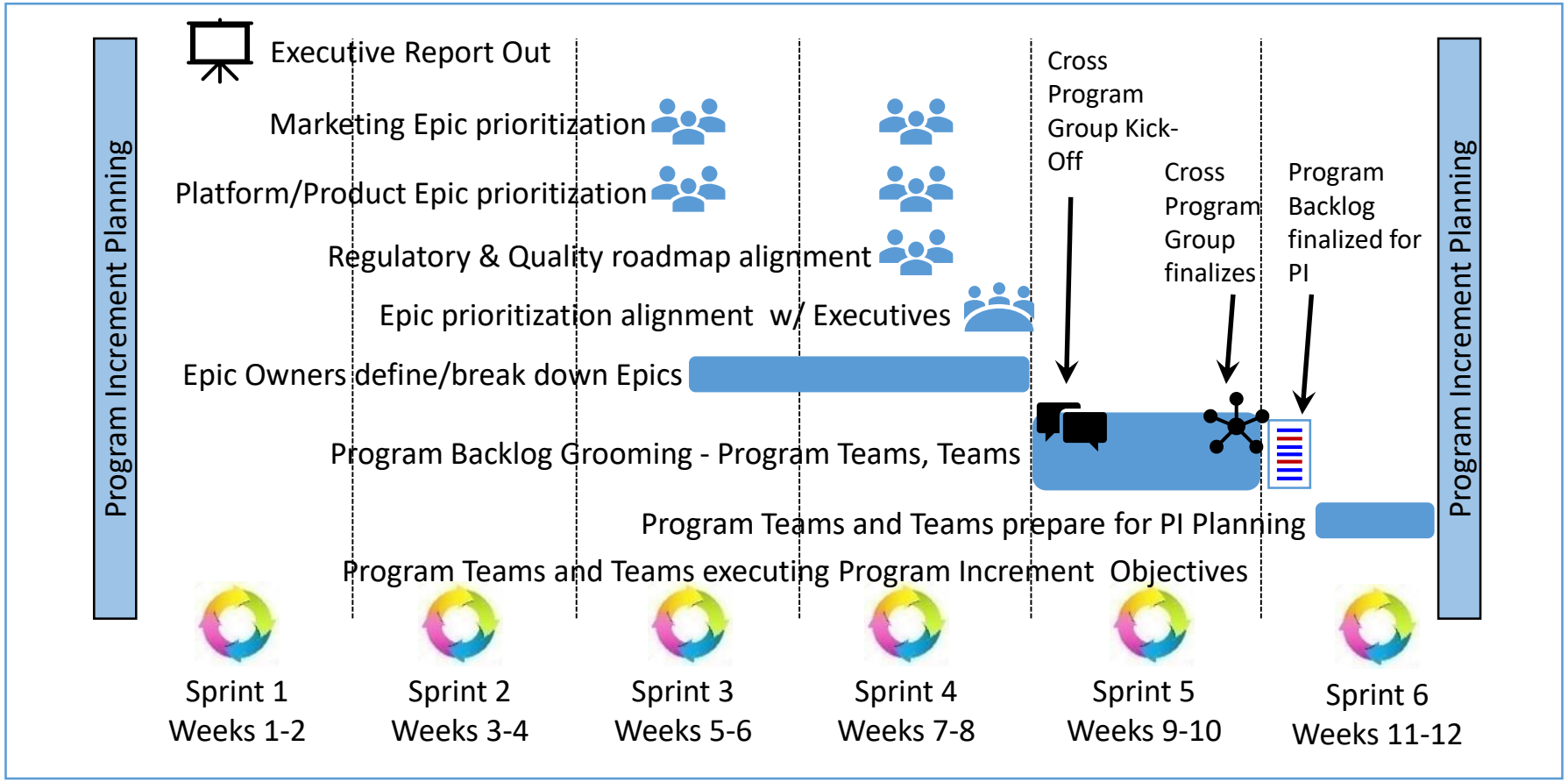


Team Backlogs

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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EXIT

SPRINT 1
SPRINT 2
SPRINT 3
SPRINT 4
SPRINT 5

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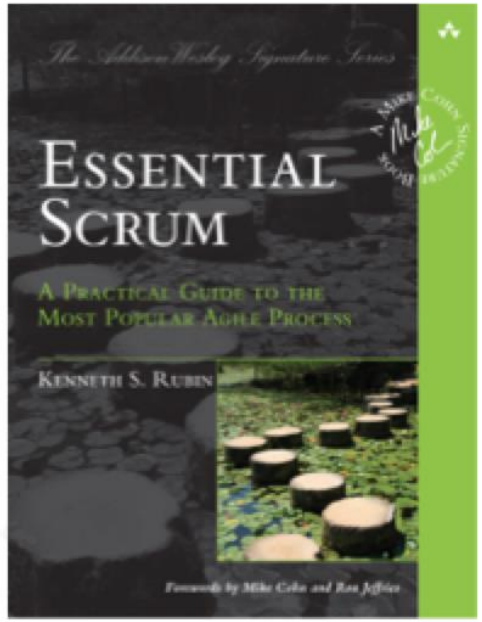

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