Webinar:
Agile Design Controls Part 1

How to Support Rapid Design Iterations for Software-Intensive Medical Devices

February 13, 2019

Arnaud Alberts

Matrix Requirements GmbH

Wolfgang Huber

Matrix Requirements GmbH

Aaron Joseph

Sunstone Pilot, Inc.

Aaron Joseph
Principal Consultant – Sunstone Pilot, Inc.

- 20+ years medical device development over a wide range of products:
  - surgical robotics systems, digital x-ray fluoroscopy system, drug inhaler devices, robotic catheter system, x-ray catheter for brachytherapy, laser eye surgery system, heart-lung bypass machine, and multiple wearable/IOT devices

- Assist clients with all aspects of design controls: risk management, requirements management, V&V testing, refining design controls procedures, and training R&D staff

- Avid promoter of lean and agile methods for medical device development

- BSEE - Rice University and MS Bioengineering - University of Washington

- Based in Silicon Valley

Arnaud Alberts
Growth Manager – Matrix Requirements GmbH

- Helping medical device companies to build their device in an agile way facilitating the management, the documentation and the certification of their product with Matrix Requirements applications.

- QA engineer and Product Management in a Startup Medical Device company
  - Hardware + software class 2 Medical Device
  - Building the QA system for market introduction
  - Validation, Risk assessment and testing
  - Product enhancement, releases, documentation

- M.Sc. Bio-Engineering – ULB Brussels
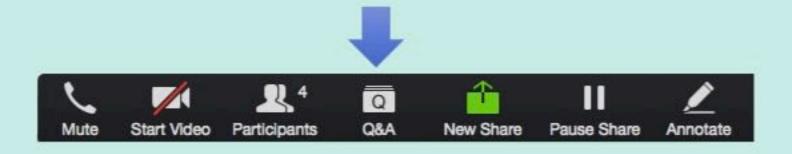
- Based in Brussels - Belgium

Wolfgang Huber
Co-Founder - Matrix Requirements GmbH

- Founder Matrix Requirements
- 15+ years managing medical device development
- 10+ years developing version control and document management systems
- 30 years experience professional software development
- Early adaptor of agile methodologies
- M.Sc. Computer Science – Karlsruhe University
- Based in Munich, Germany || Beziers, France

Webinar Outline

1. Challenges of software and connected devices
2. Managing design changes and documentation
3. Example change scenario
4. Implementing changes with JIRA and Matrix
5. Processes and tools to support rapid design iterations
6. Q&A

New Capabilities → New Challenges

- **More features** → greater complexity, more software components, more 3rd party software

- **Connected** → cybersecurity risks, privacy risks, interoperability challenges

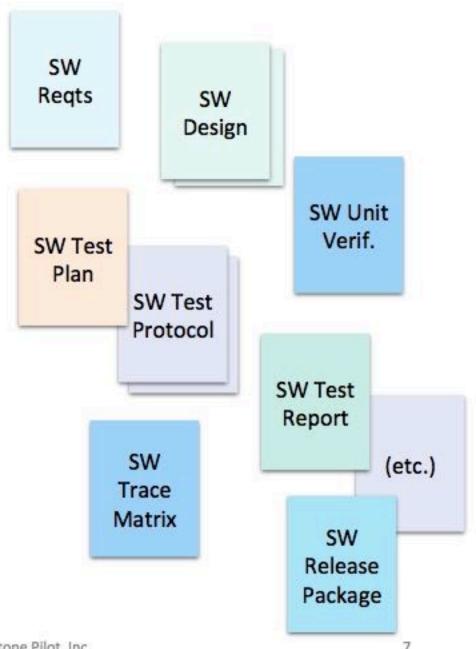+ Greater regulatory scrutiny!

Documentation Burden

- Many DHF documents for SW Release
- Each document reviewed and approved (days? weeks?)
- Information is interconnected and interdependent

- CONCLUSION: ~~only release the software once!~~

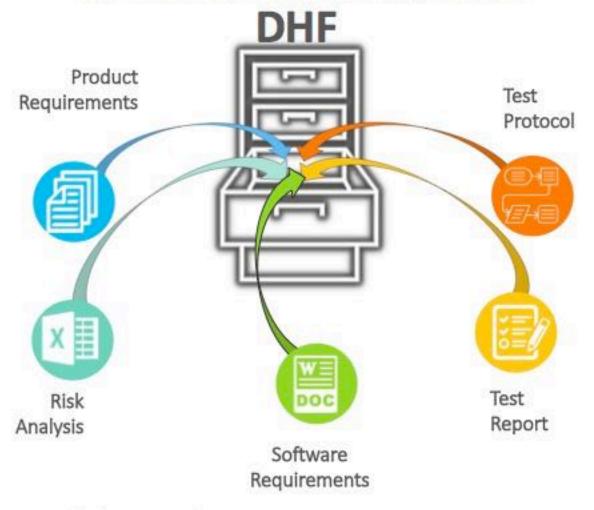No! Refine your processes and tools to be able to manage SW releases rapidly (days not weeks)

SW Reqts

SW Design

SW Unit Verif.

SW Test Plan

SW Test Protocol

SW Test Report

SW Trace Matrix

(etc.)

SW Release Package

Challenges of Traditional Document Centric Approach

- **Traceability** is static
- No defined **workflow**
- Difficult to manage **changes**

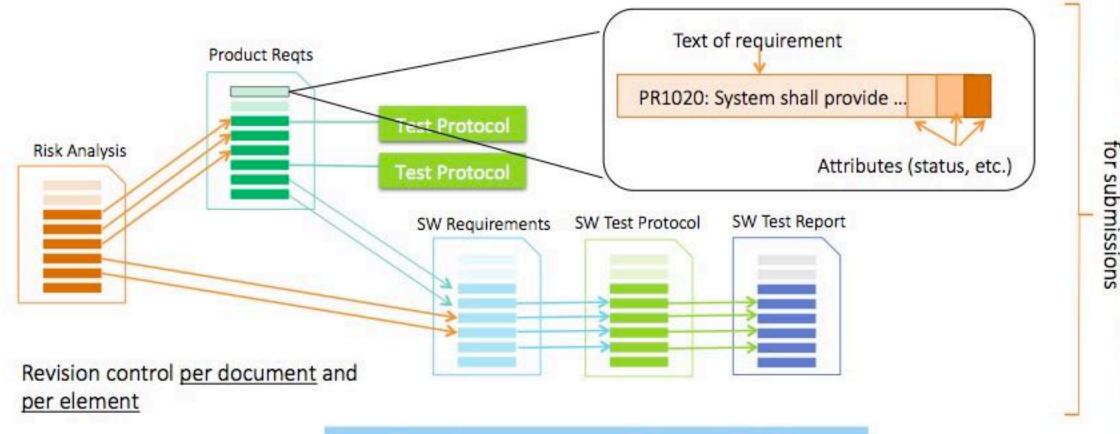Good for <u>archiving</u> but not fast moving product development

File Cabinet or Traditional IT Applications

DHF

Product Requirements

Test Protocol

Risk Analysis

Software Requirements

Test Report

New Way: Product Documentation Stored as Objects

Documents are groupings of DHF <u>elements</u>

Risk Analysis

Product Reqts

Test Protocol

Test Protocol

Text of requirement

PR1020: System shall provide ...

Attributes (status, etc.)

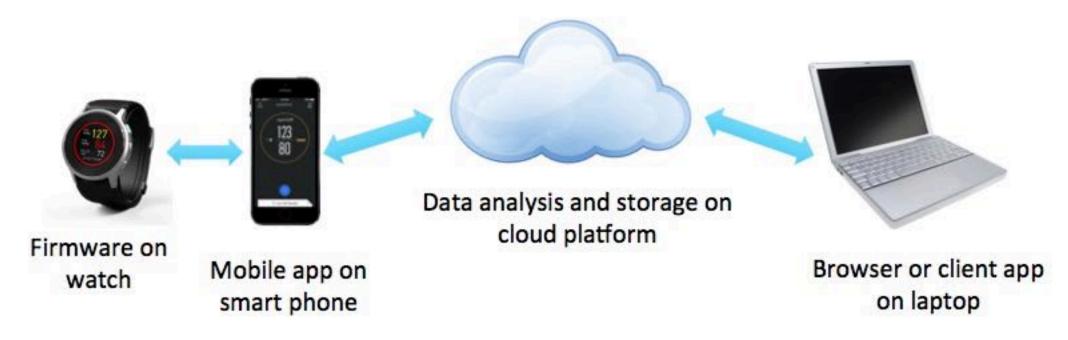SW Requirements   SW Test Protocol   SW Test Report

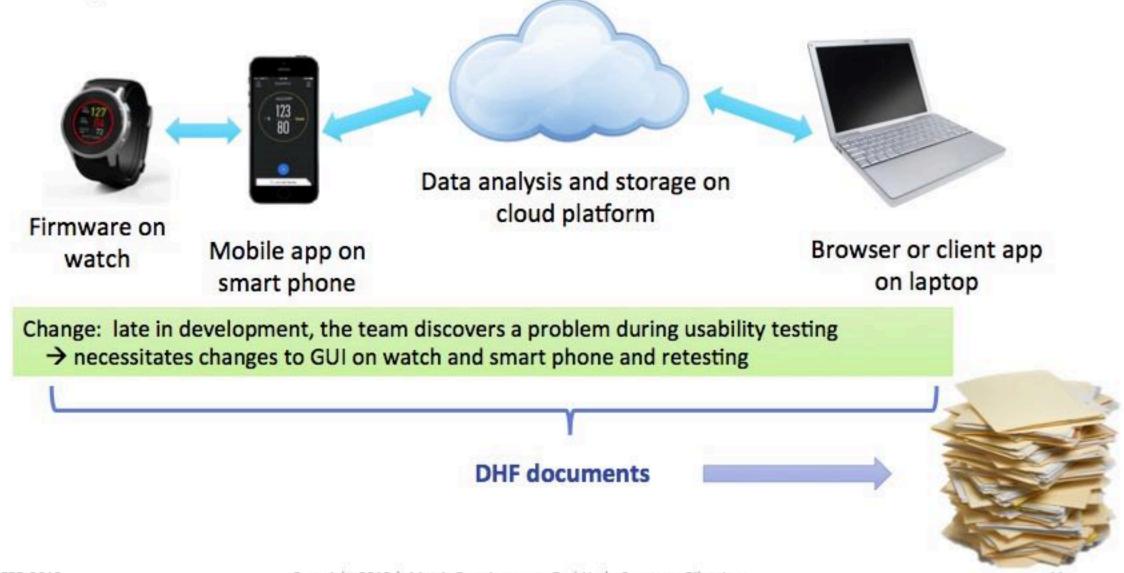Revision control <u>per document</u> and <u>per element</u>

Dynamic management of product data

Example Connected Medical Device

- Wearable device + mobile app + cloud
- Heart monitor (including analysis of other patient data)
- Distributed architecture with multiple software platforms

Firmware on watch

Mobile app on smart phone

Data analysis and storage on cloud platform

Browser or client app on laptop

Example Connected Medical Device

Firmware on watch

Mobile app on smart phone

Data analysis and storage on cloud platform

Browser or client app on laptop

Change: late in development, the team discovers a problem during usability testing
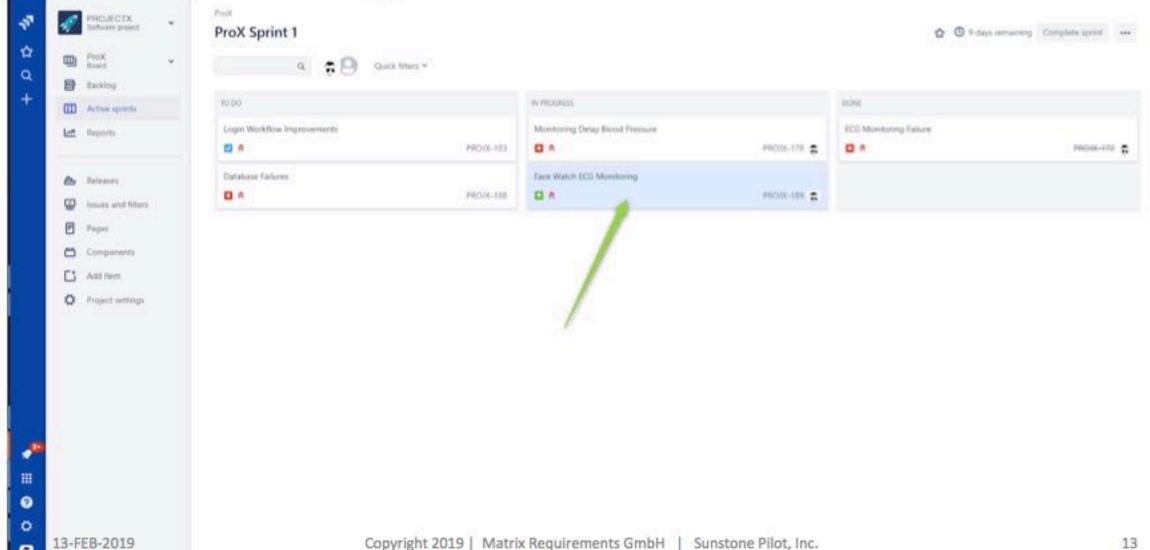→ necessitates changes to GUI on watch and smart phone and retesting

DHF documents

Change Scenario (before product release)

- PROBLEM: usability testing late in development showed that in 25% of cases the user pressed the wrong button on the watch

- SOLUTION:
    - Change GUI functions on watch and on mobile app
    - Update user manual
    - Re-test the software
    - Re-run the usability testing

- CHALLENGE: don't miss any details while making rapid changes!

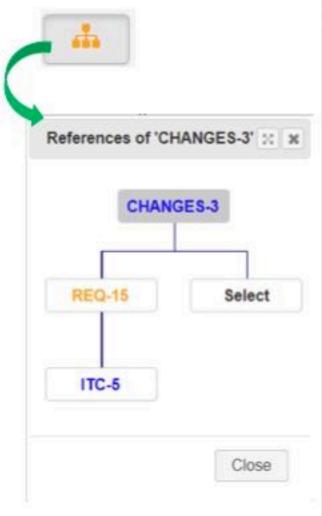| Planned	Tracked	Synchronized	Completed

Plan the change in Jira
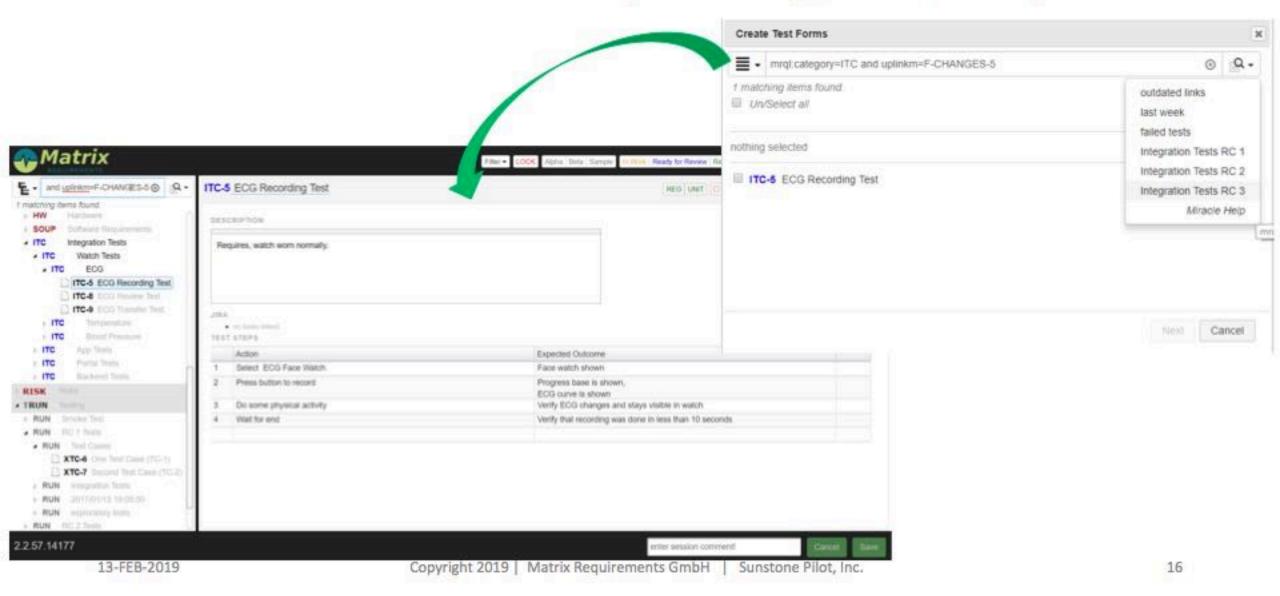
Link the ticket with a change object in Matrix

Traceability

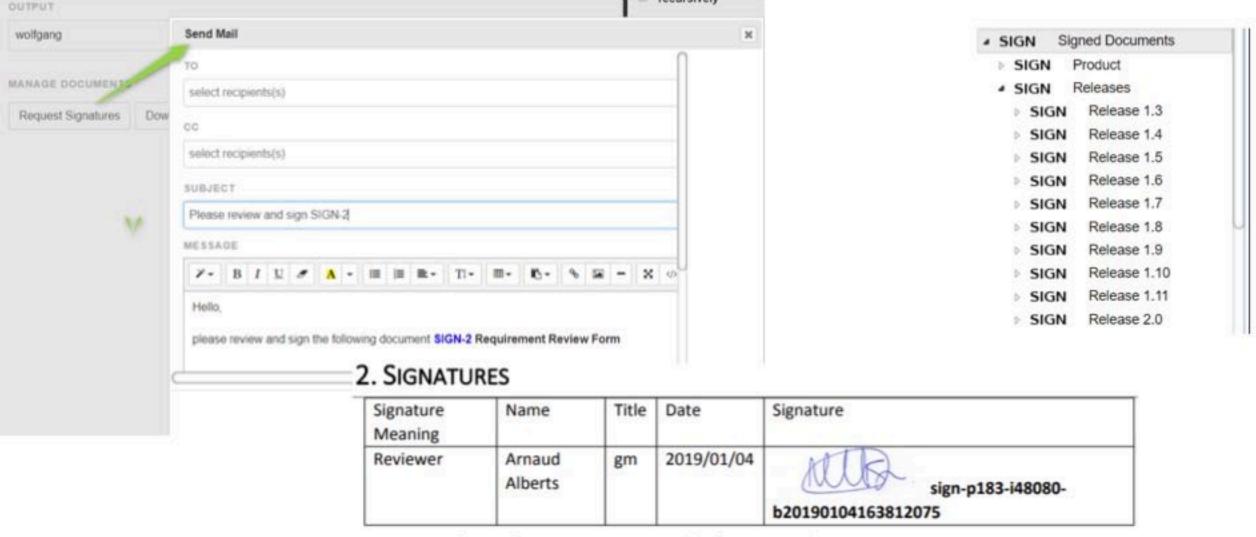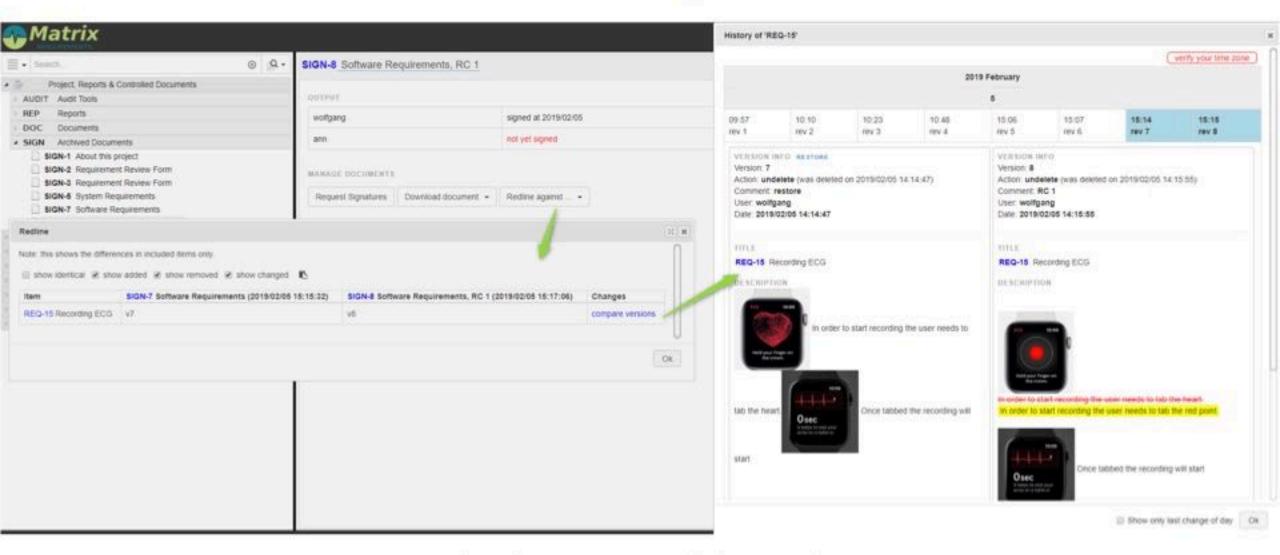# Filter to see the corresponding tests only

DHF update

Archiving docs with electronic signature

Document version history

Processes Prepared for Change

- Agile methods for product development
  - Design iterations are expected during development (and after product launch)
  - Design controls are not forced to be sequential (don't create a "waterfall" framework)
  - Multiple iterations of risk management, design inputs, design outputs, V&V testing
- Streamlined compliance
  - Minimize delays in review, approval, and release
  - Eliminate redundant records
- Centralized issue tracking (not compartmentalized)
- Test automation
- Documentation automation
- Product testing vs. confirmational (formal) testing

Key Characteristics for SW Tools

- Configurable defect tracking and task management (day-to-day changes)
- Integrated test management (to enable "paperless V&V")
- Support for risk management (risk assessment and traceability of risk controls)
- Highly configurable reporting to generate DHF documents automatically
- Electronic signatures and audit trail (FDA Part 11 compliance)
- Straightforward to validate (and tool will not be automatically updated outside of your control)
- Efficiently support multiple versions of products (keep track of v1.0 while also managing v1.1 and v2.0)

Q & A

Arnaud Alberts
Wolfgang Huber

Matrix Requirements GmbH - matrixreq.com

Aaron Joseph
Sunstone Pilot, Inc. - sunstonepilot.com