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Advancing public health with digital regulatory compliance

Virginia Chan
Head of Digital Transformation, APAC
Siemens Digital Industries Software

Siemens at a glance

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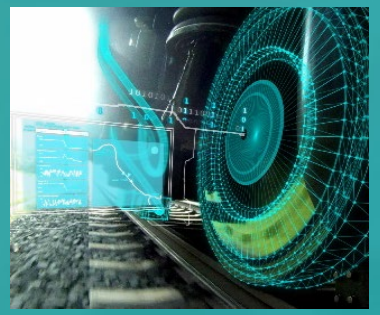
Operating Companies

Gas and Power

Smart Infrastructure

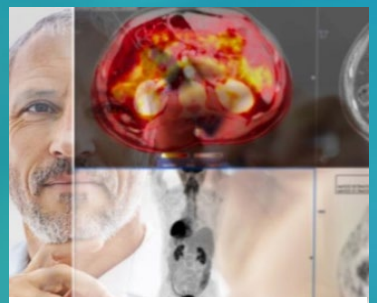
Digital Industries

Strategic Companies



Mobility

SIEMENS Gamesa
RENEWABLE ENERGY



SIEMENS Healthineers

Service Companies

Financial Services

Global Business Services

Real Estate Services

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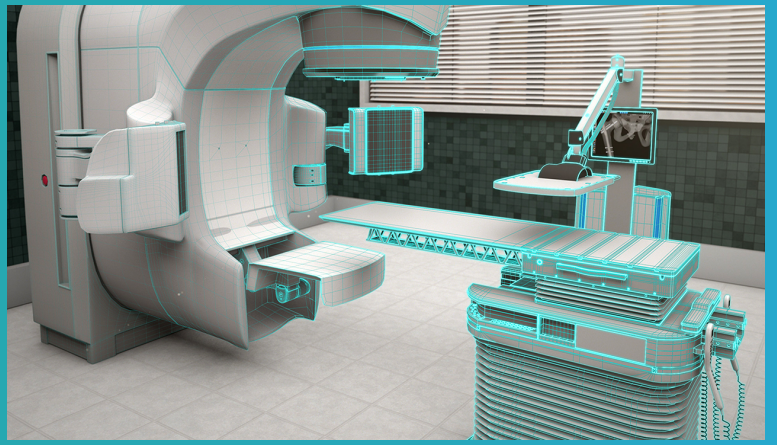
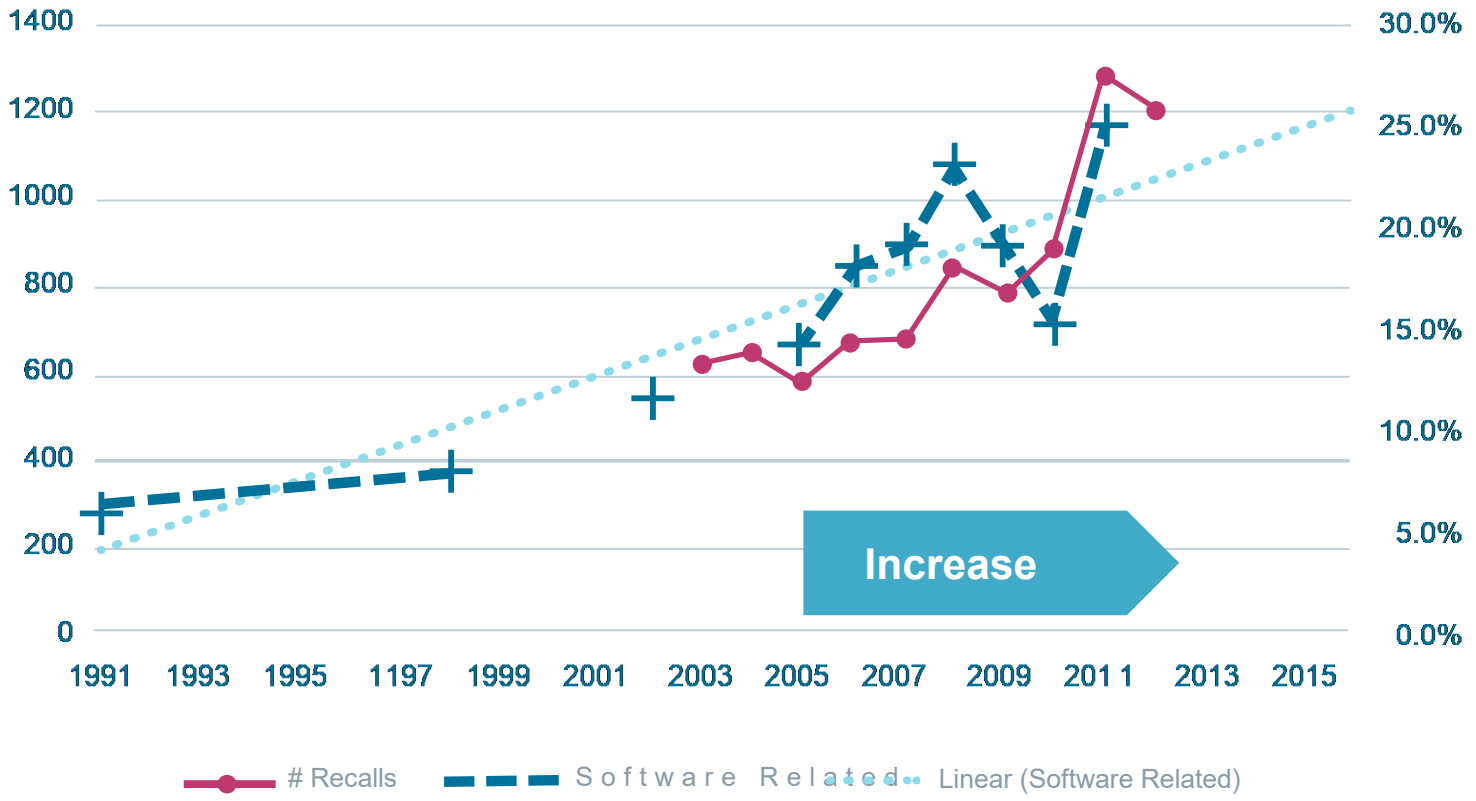
Global Public Health Challenges call for
Safe, Effective use of Software & Digitalization

Global Demographics	Value-based Healthcare	Complexity vs. Maturity
Highest population growth in regions with least ability to pay Insufficient HCPs Familiar chronic disease patterns	Volume procurement Reimbursement tied to total “episode of care” and patient outcomes	Faster product turns for differentiation & margin retention Software-based innovation Precision medicine Global Regulatory Variation



Industry performance

Total FDA Recall Events with Software Contribution



Source: Software-Related Recalls: An Analysis of Records
by: Lisa K Simone, Software Engineer with the Center for Devices and Radiological Health at the US FDA

3X
Increase in adverse events

50%
Increase in recall events

120%
Increase in software related recall

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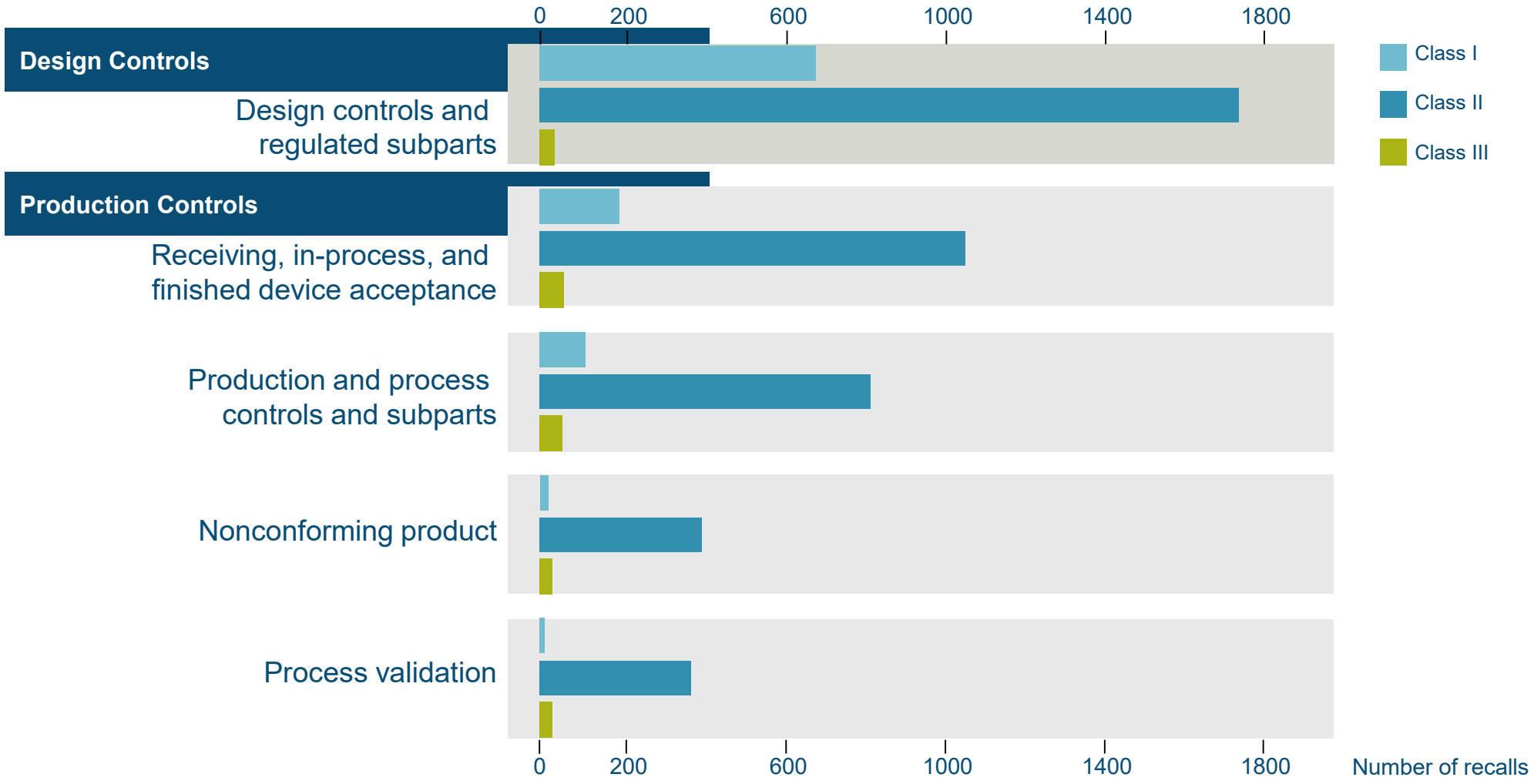
Recall causes by regulation



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US FDA's Collaborative Relationship with Industry Ecosystem Stakeholders

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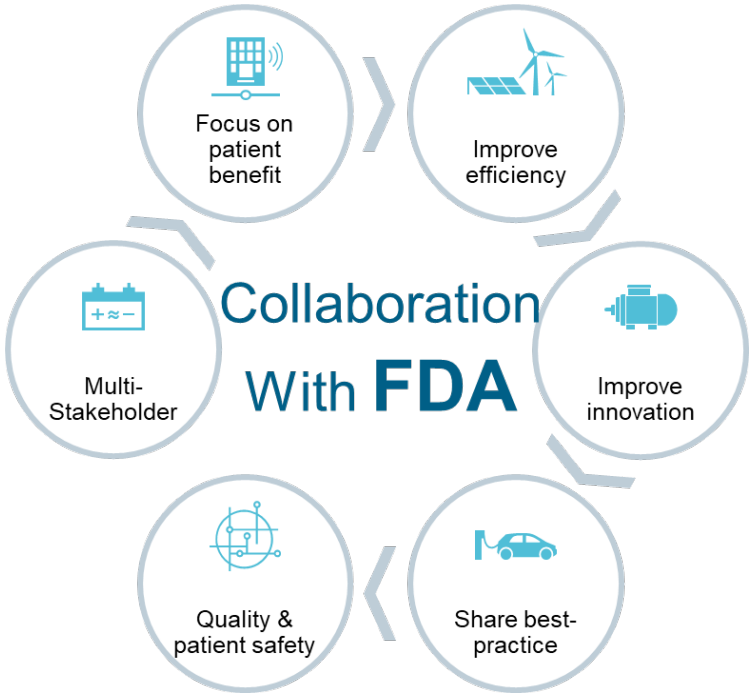

Case for Quality

Move from compliance to quality

Digital Evidence

Promote Modeling & Simulation

Digital Regulatory Review

Re-use Existing Digitalization Assets

Siemens collaborates with FDA to define R&D + Manufacturing best-practice

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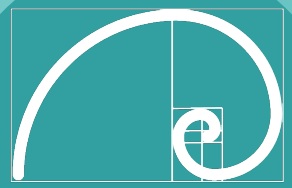
2021

USD136 BILLION

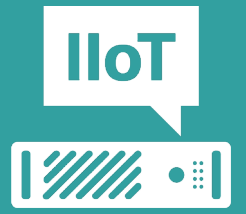
IoMT

Making sense of data is essential...



GENERATIVE DESIGN

ADDITIVE MANUFACTURING



IoT/ EDGE

AI

ANALYTICS

…to manage and thrive in complexity.

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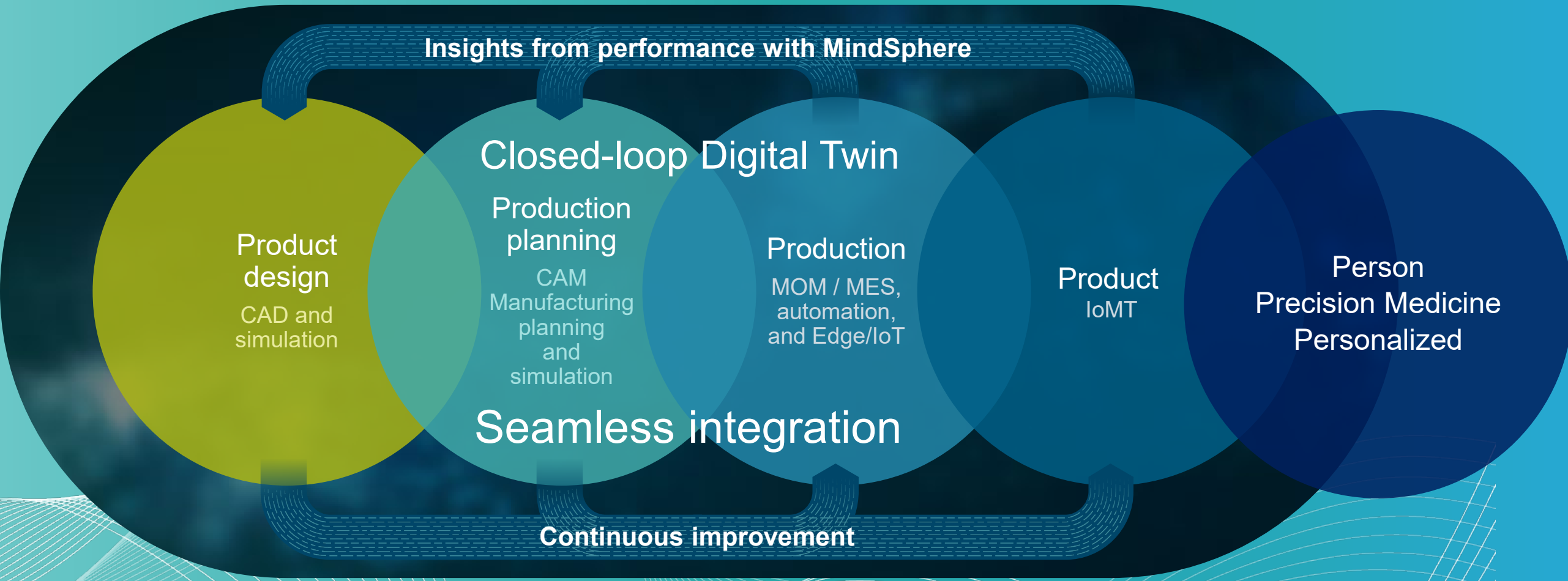
Healthcare 4.0 – Harness the power of data with digitalization



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Medical Device digitalization "blueprint" aligned with Regulatory Requirements

Value Drivers

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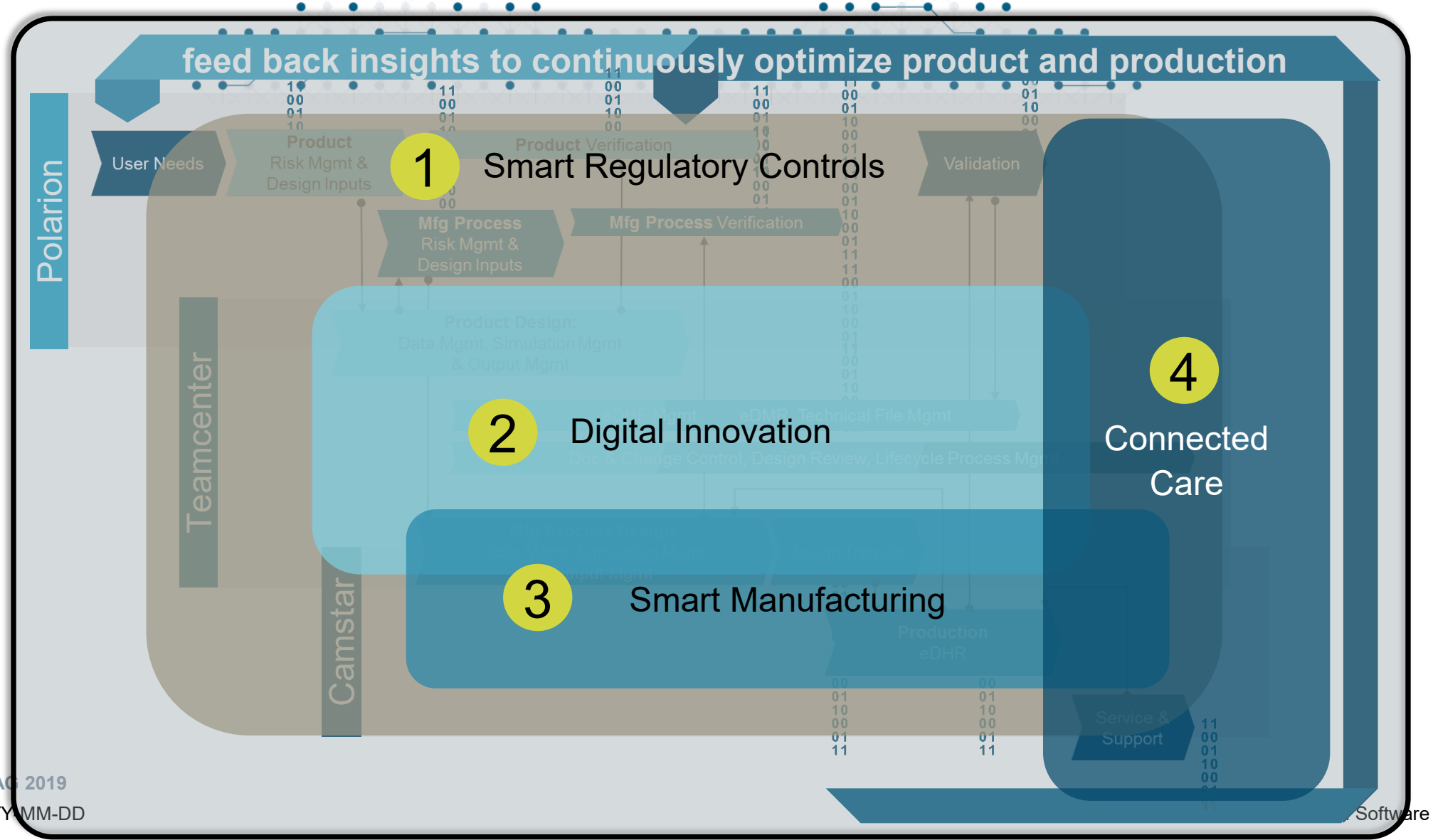
Unique Differentiated Solution

Integrated ALM, PLM, MOM Platform

Industry Catalysts

Multi-disciplinary Engineering Apps

IoT Platform & Integrated Apps



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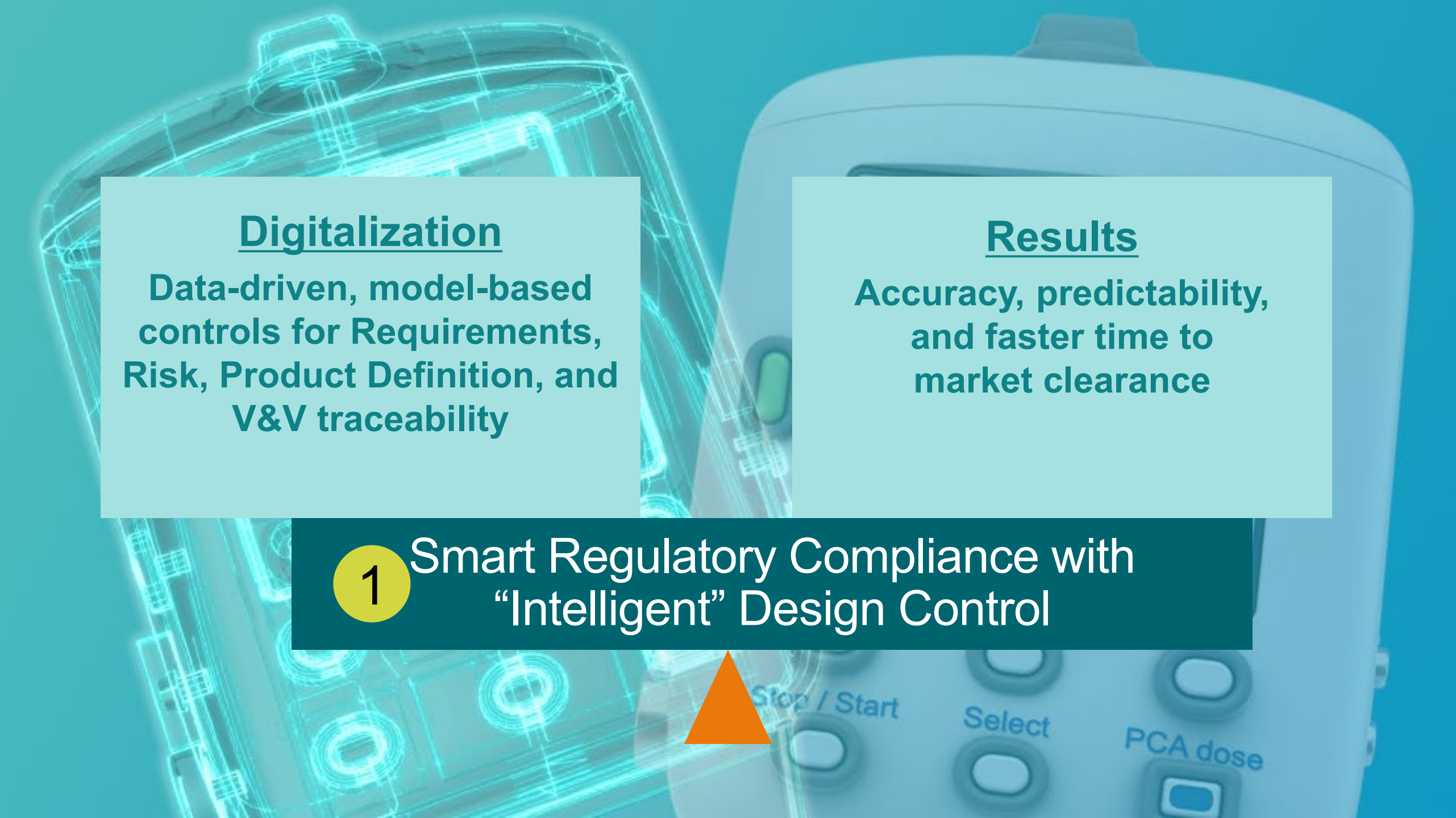

Digitalization

Data-driven, model-based controls for Requirements, Risk, Product Definition, and V&V traceability

Results

Accuracy, predictability, and faster time to market clearance

1 Smart Regulatory Compliance with "Intelligent" Design Control

Focus on Design elements – Intelligent Design Control

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Intelligent Design Control

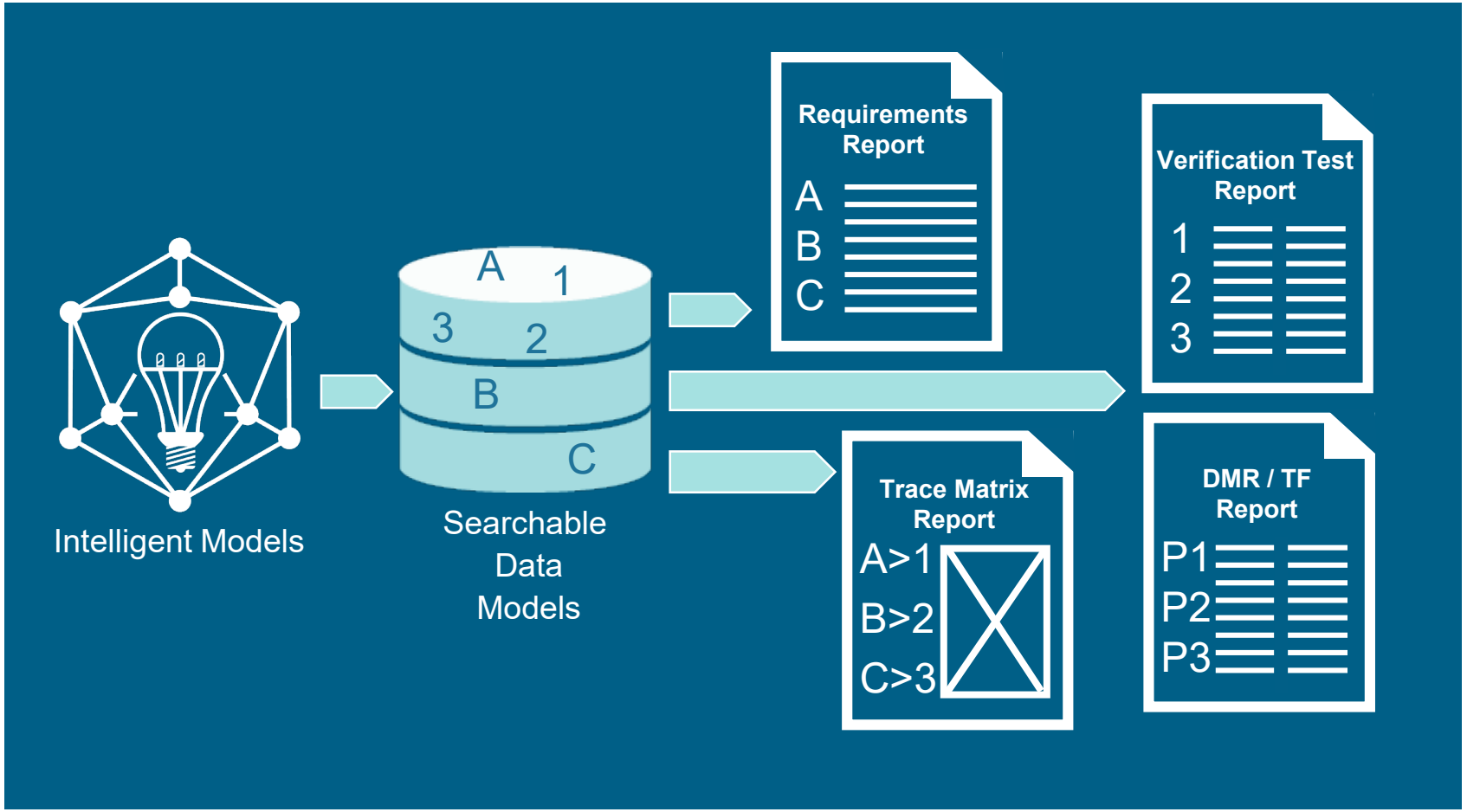
Reduces copy mistakes

Maintains data integrity

Enables extensive search, re-use, analysis

Links design elements, e.g., hazard situations to requirements to test cases

Creates trace reports



Re-organize design elements for presentation to different stakeholders

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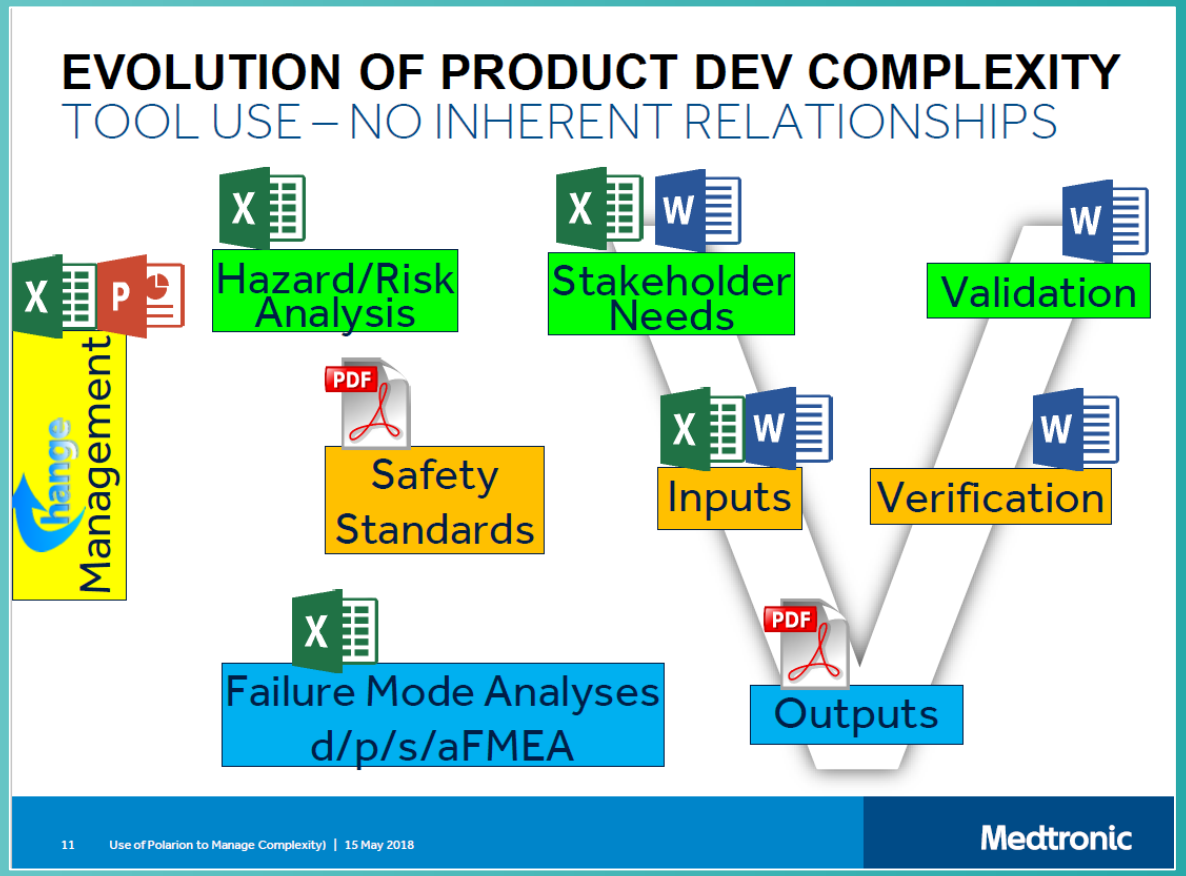
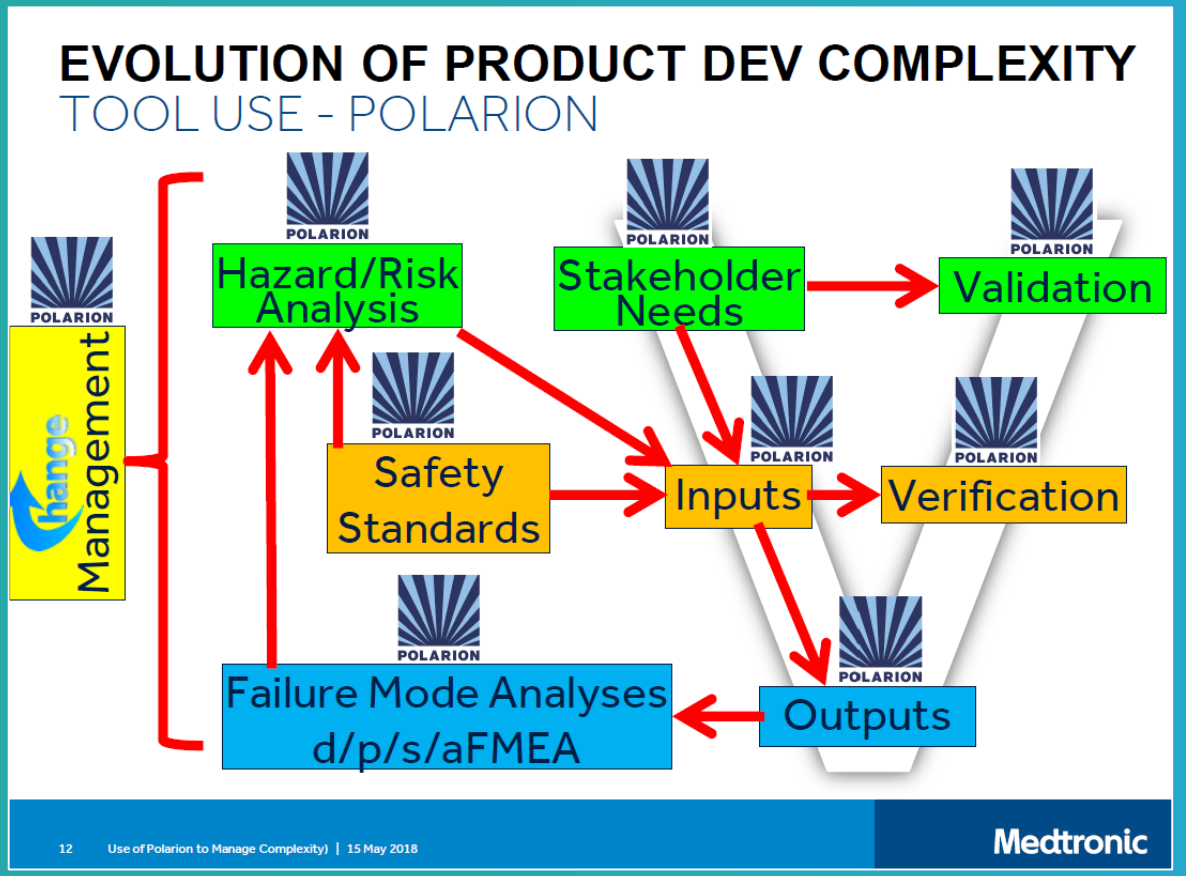
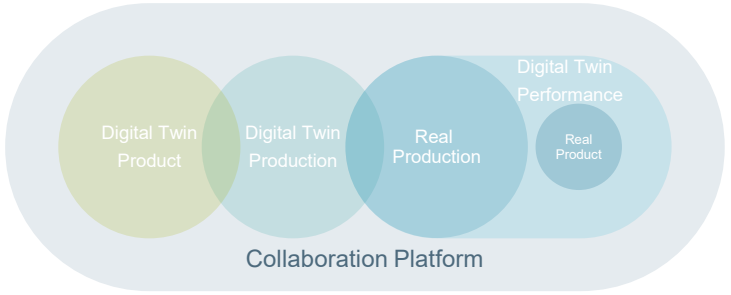
Intelligent Design Control: Integrated Risk Management





Before **After**

Presented by John Vantuno at Siemens-Medtronic-FDA Design Excellence Event, May 15, 2018



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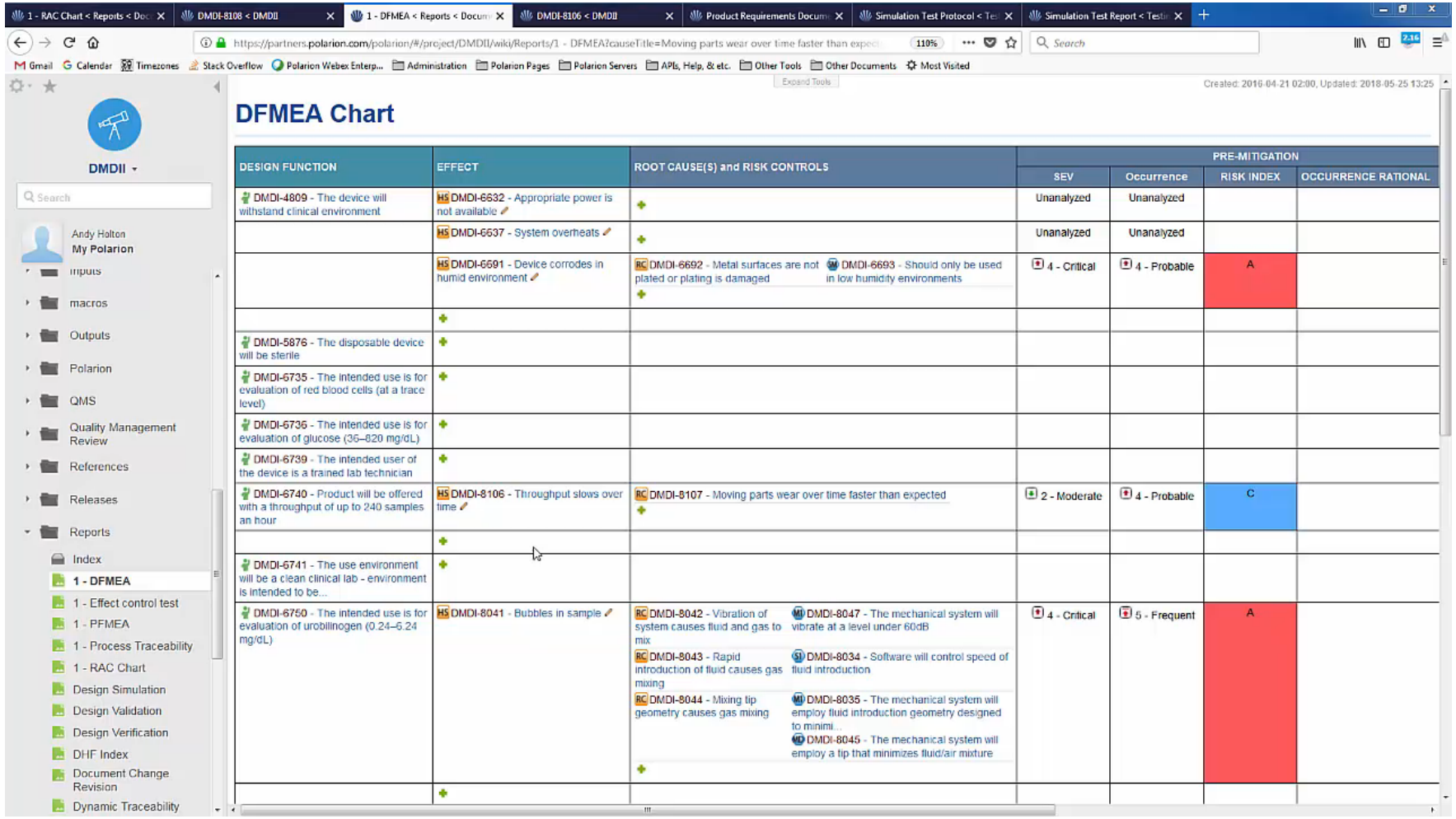
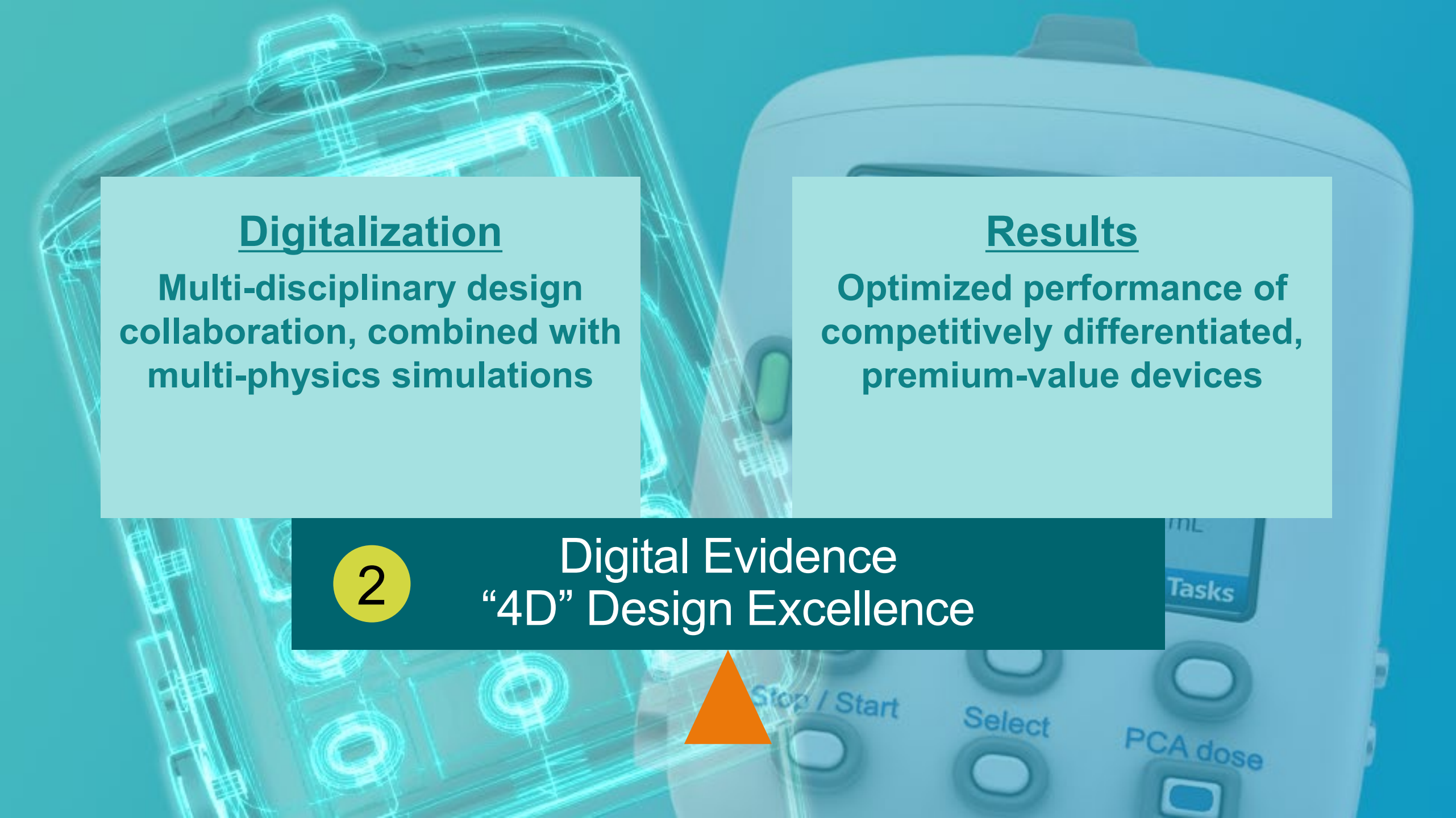
Requirements Management

Ensure new requirements have appropriate V&V test plans





Digitalization

Multi-disciplinary design collaboration, combined with multi-physics simulations

Results

Optimized performance of competitively differentiated, premium-value devices

2

Digital Evidence
“4D” Design Excellence

“Digital Evidence” → Use Modeling & Simulation to augment Clinical Trials & Traditional Testing Methods

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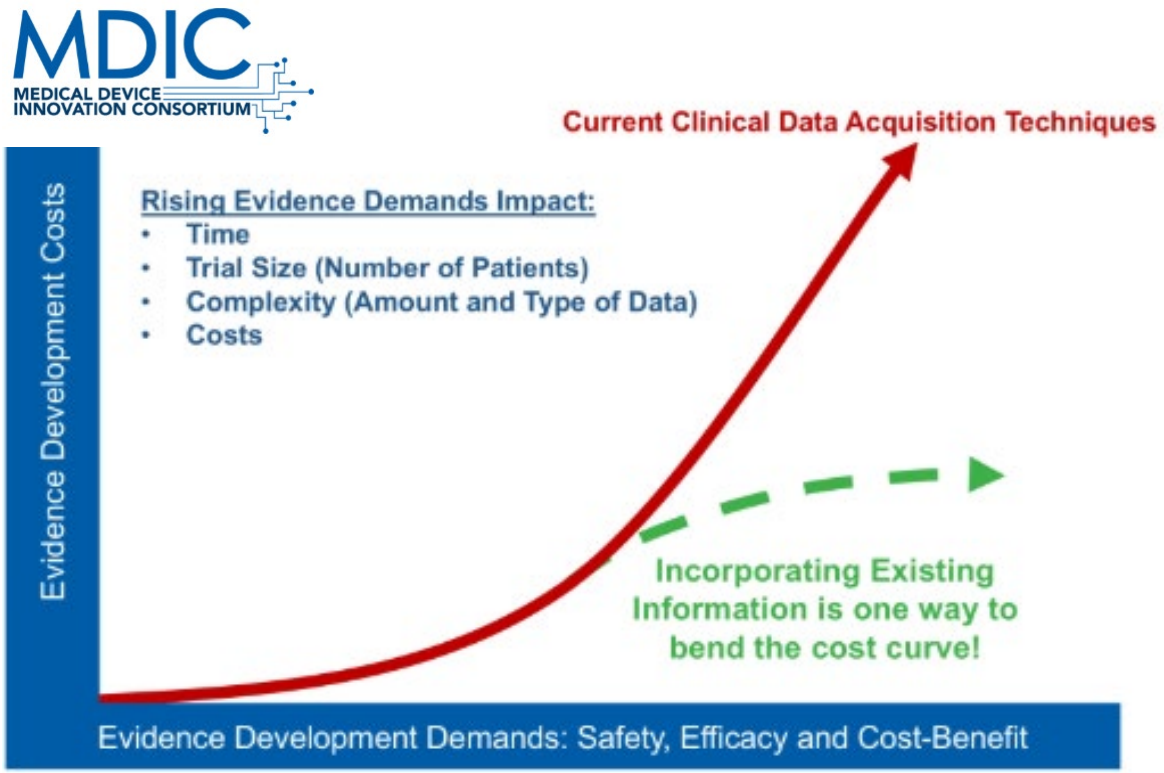

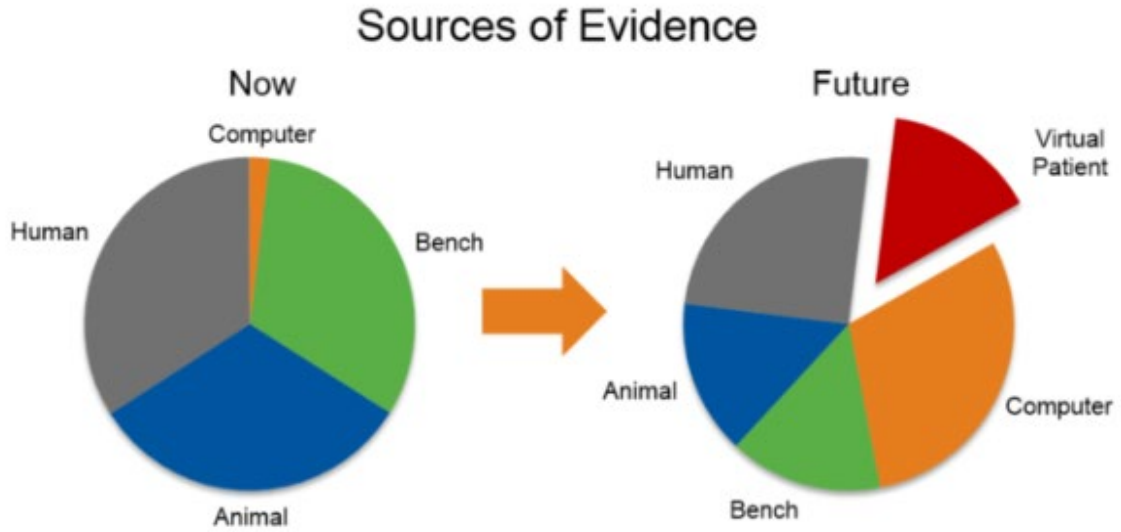

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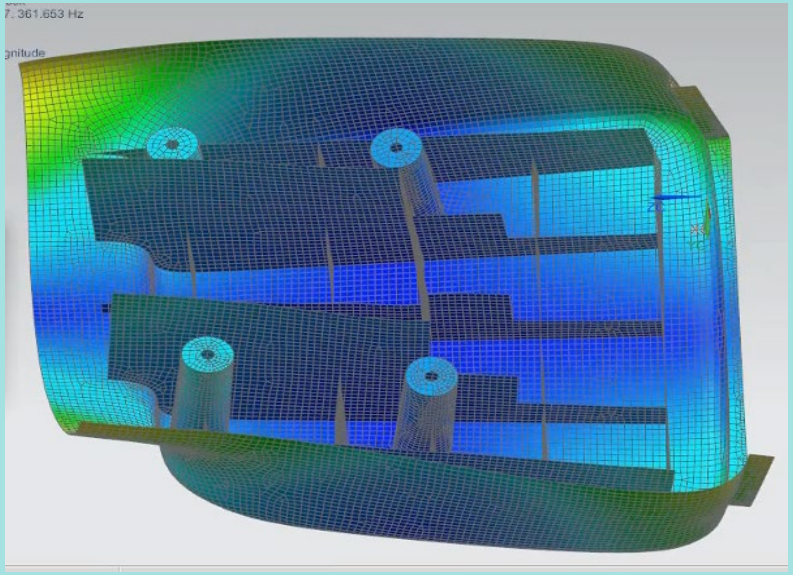
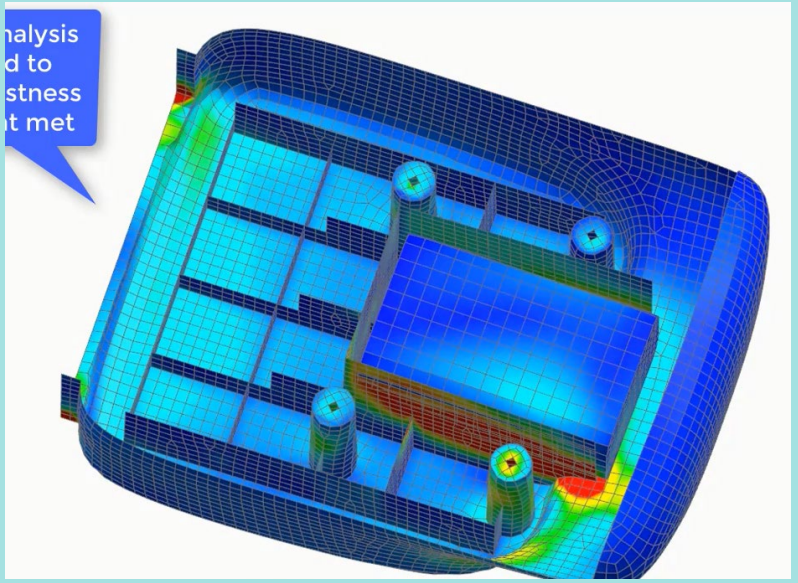
“Classic” Mechanical Modeling & Simulation

Work out Quality Problems early in the Product Lifecycle



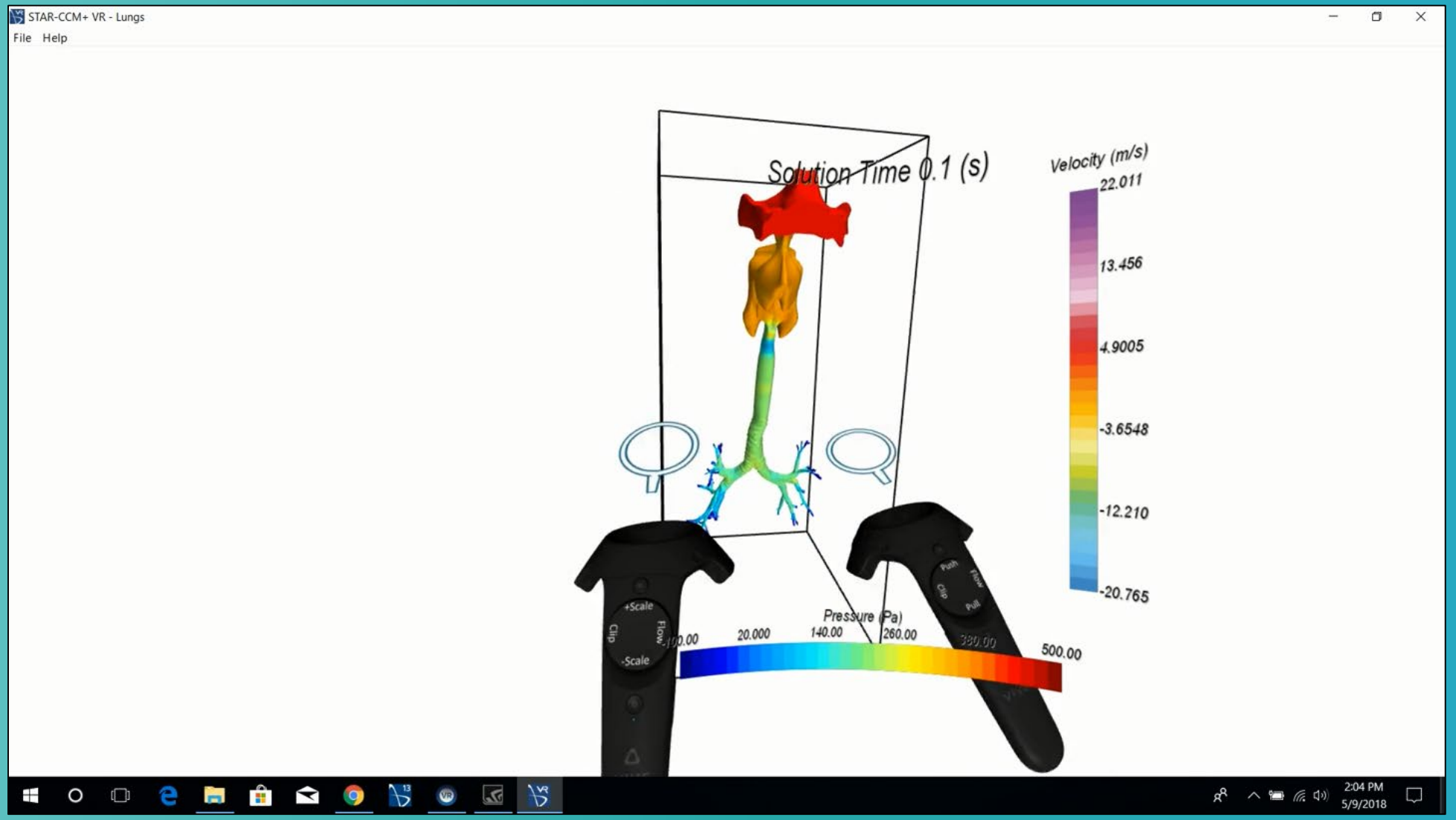
3D Modal Analysis



3D Impact Analysis

Computational Fluid Dynamics (CFD)

VR walkthrough of respiratory anatomy to <u>see</u> predicted physiological behaviors



Digitalization

Use manufacturing models to schedule and execute production, enforcing routes, inspections, and rework

Results

High quality, efficient, and regulatory compliant production & eDHR

3

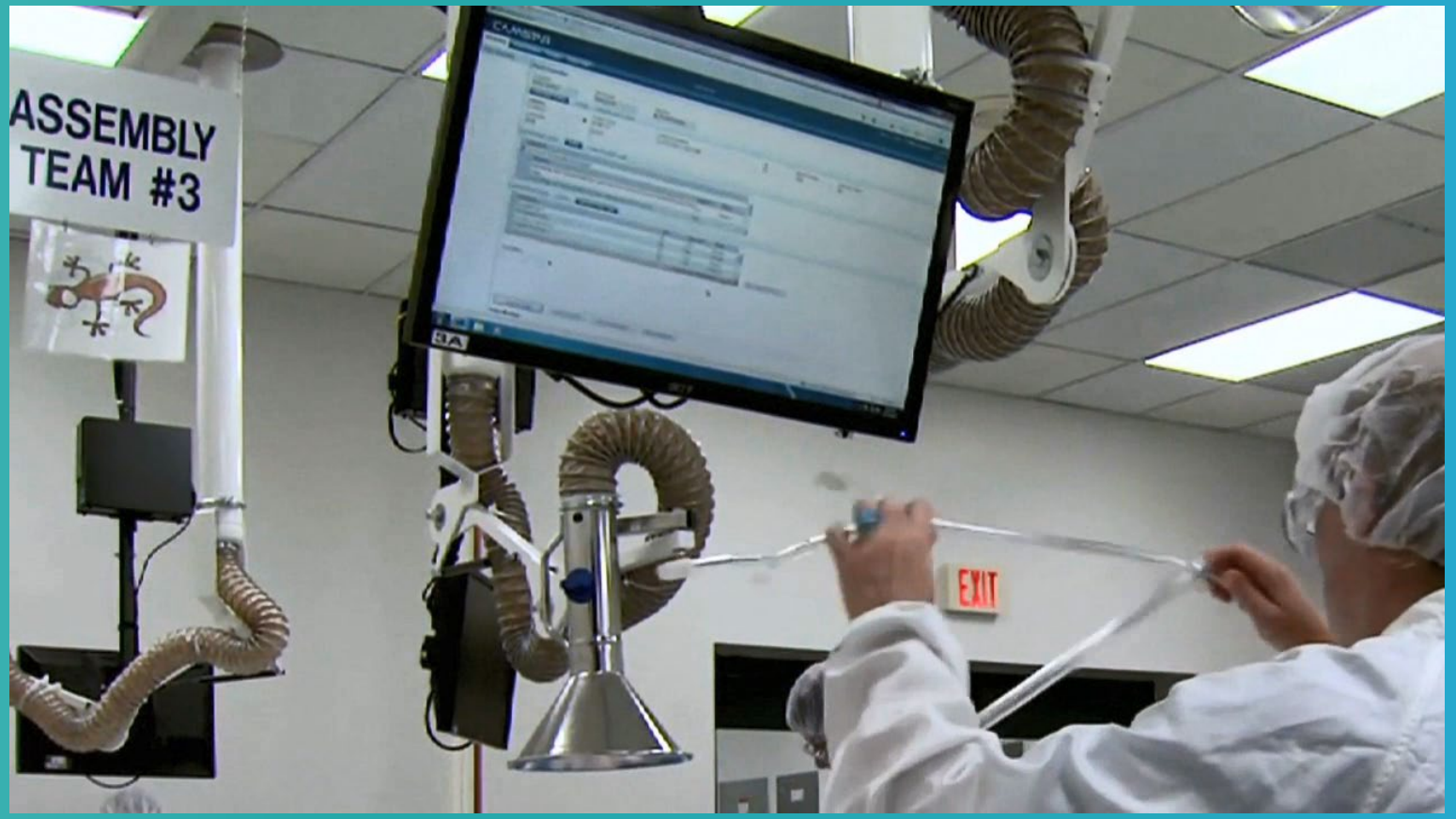
“Case for Quality” with Smart Manufacturing

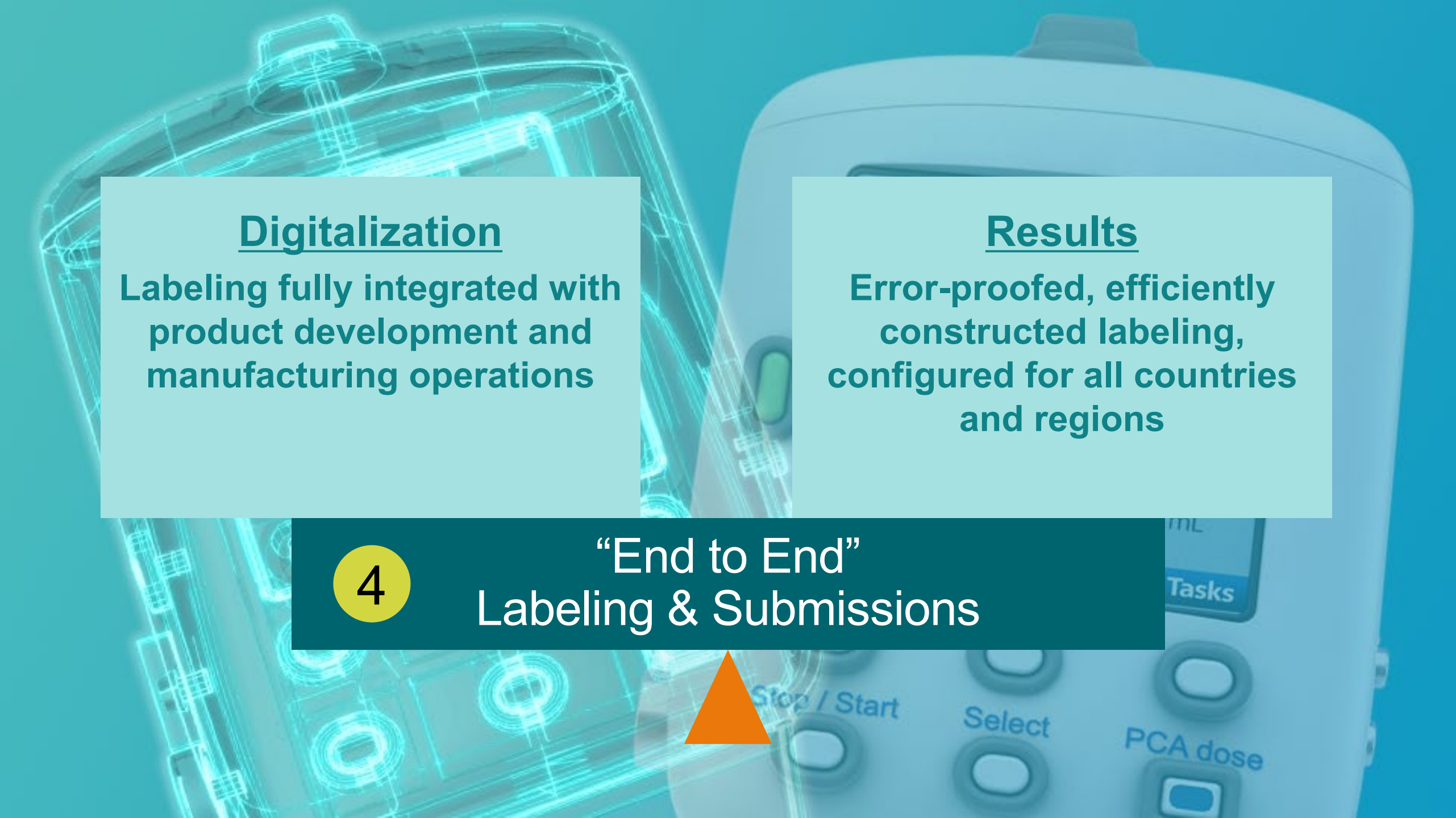
Opcenter Execution MD&D (Camstar)
Best-in-class for Medical Device & Diagnostic manufacturers

Main functionalities and benefits

Camstar Medical Device Suite

- **Paperless manufacturing (eDHR)**
- **Identify, analyze and prevent errors**
- **Advanced planning and scheduling**
- **Manufacturing enforcement and quality (5M)**
- **Closed-Loop Manufacturing & change enforcement**
- **Single as-built track & trace record**





Digitalization

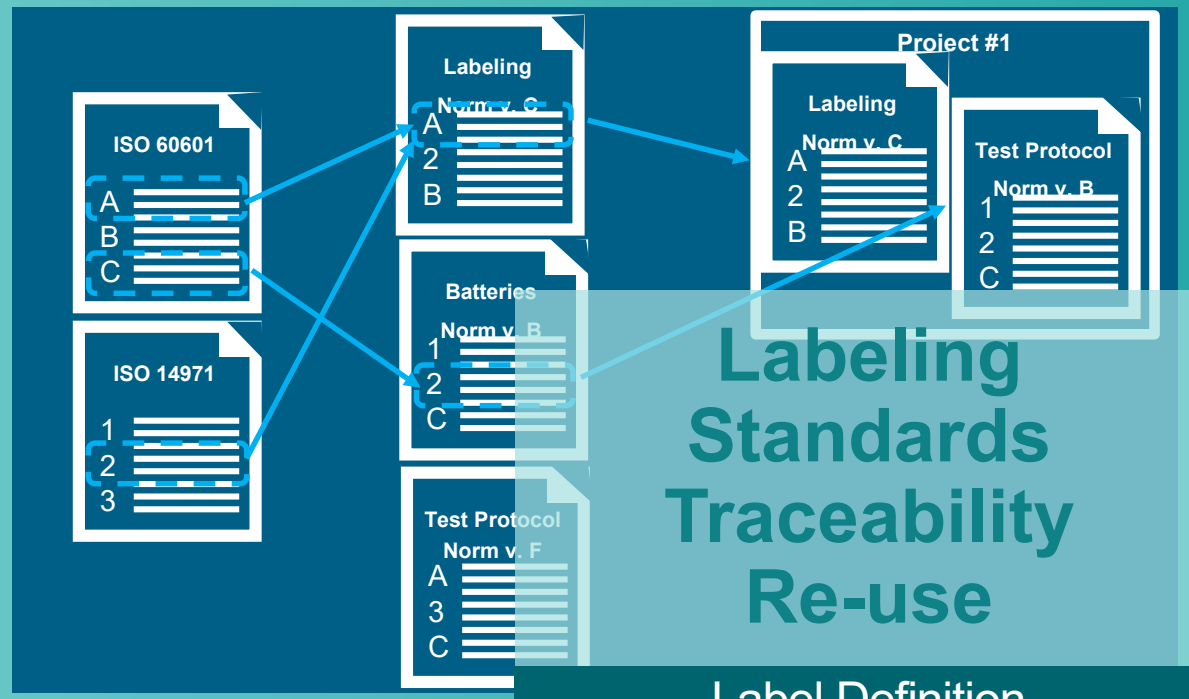
Labeling fully integrated with product development and manufacturing operations

Results

Error-proofed, efficiently constructed labeling, configured for all countries and regions

4

“End to End” Labeling & Submissions



Labeling Standards Traceability Re-use

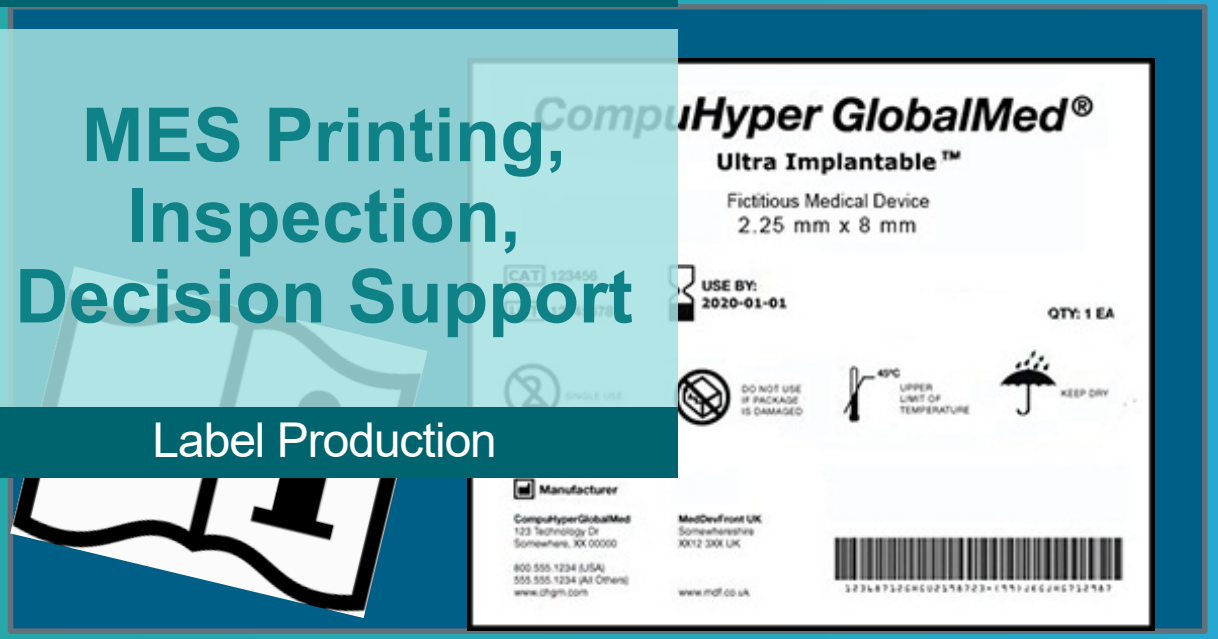
Label Definition

Layout, Design, & Workflow Management

Label Authoring

Labeling Compliance, Submissions, Maintenance

Regulatory Support



MES Printing, Inspection, Decision Support

Label Production

Digitalization

Big data analytics and AI, to track and predict KPI's

Results

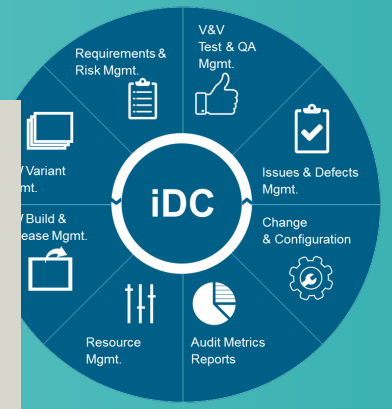
Proactively monitor and respond to performance issues, concerns & complaints

5

"Closed-loop, Predictive" Post Market Surveillance

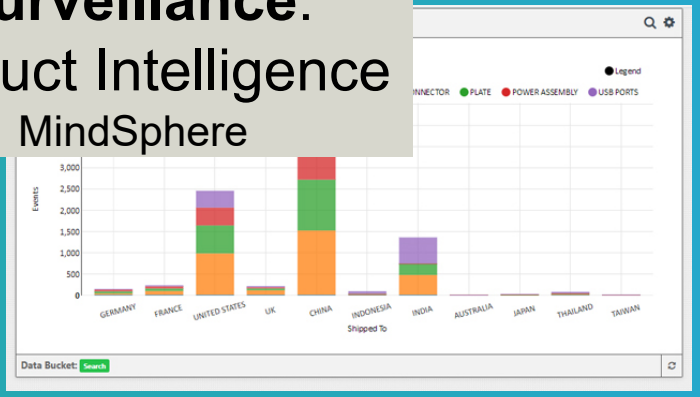
Solution: Post Market Surveillance
Closing the loop with Internet of Medical Things (IoMT)

Design Control:
Med Device Template
Polarion



Per EU MDR / IVDR

Post Market Surveillance:
Product Intelligence
MindSphere



Harm & hazard trend analysis

- Quality issue identification
- Escalation to CAPA
- CAPA root cause analysis

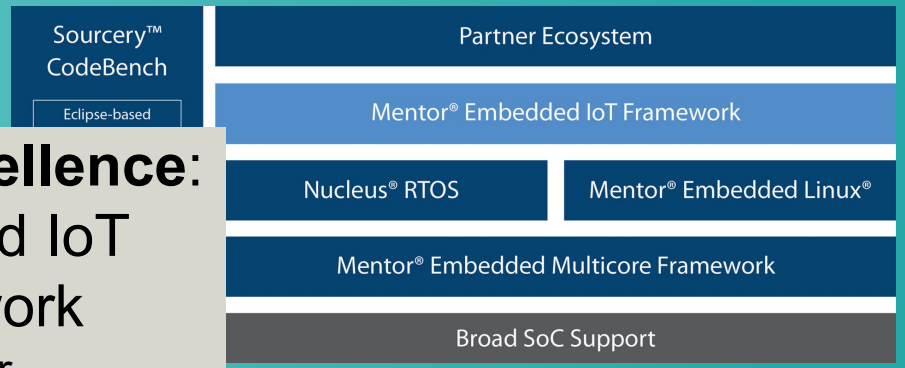
Surveillance requirements, V&V tracking

CAPA-driven revisions

Post-market surveillance data collection

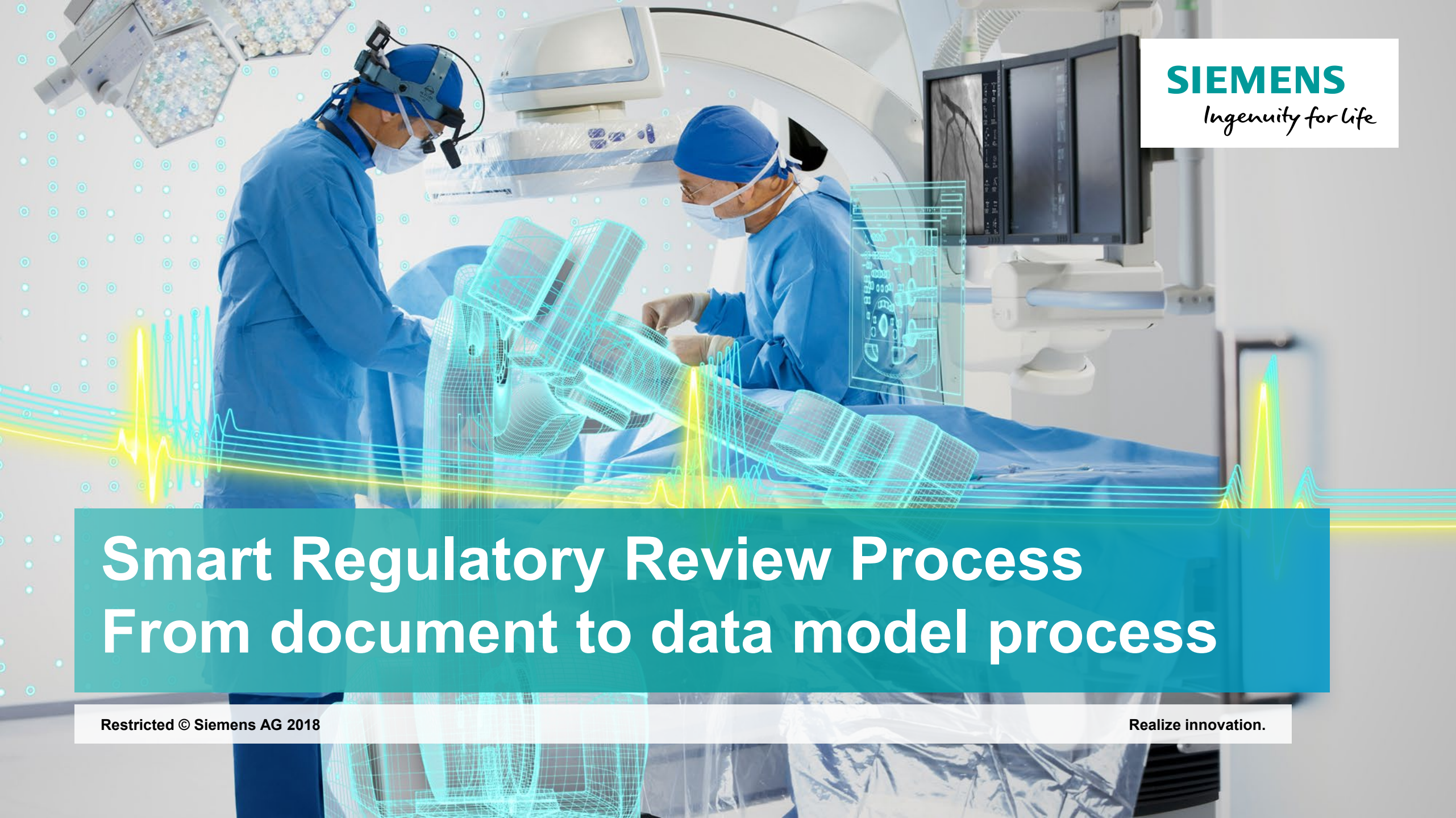
CAPA closure data

Design Excellence:
Embedded IoT Framework
Mentor



Field safety CAPA's as software updates

Mobile, Smart, Connected Device



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Smart Regulatory Review Process
From document to data model process

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Challenges of Regulators on Regulatory Review Process

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60-70% of regulatory submission in poor quality

Time and capacity wasted in administration

Delays in product introduction

Review Process

Time & Capacity spent on review precedent cases manually

Post Market Surveillance

Design control does not sufficiently address issue

eDHR is inaccurate or incomplete

PMS report is not timely

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Digitalization of Regulatory Review Process for faster, better, improved traceability and transparency

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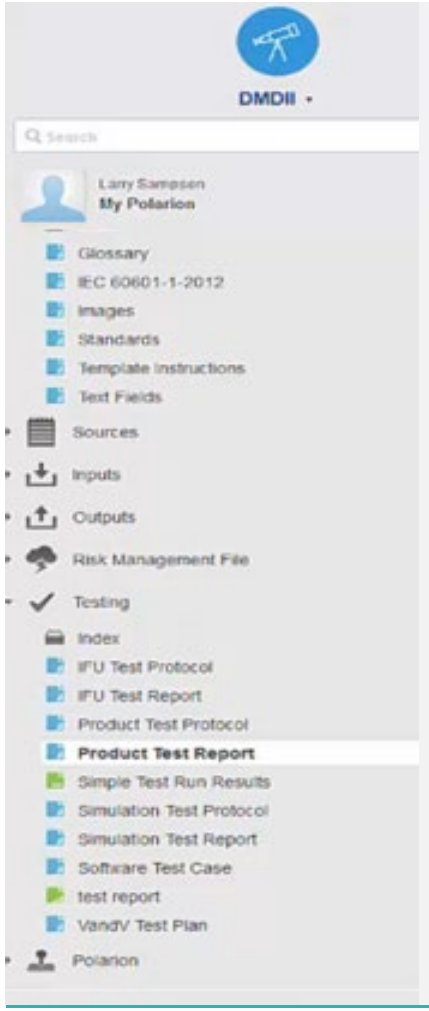
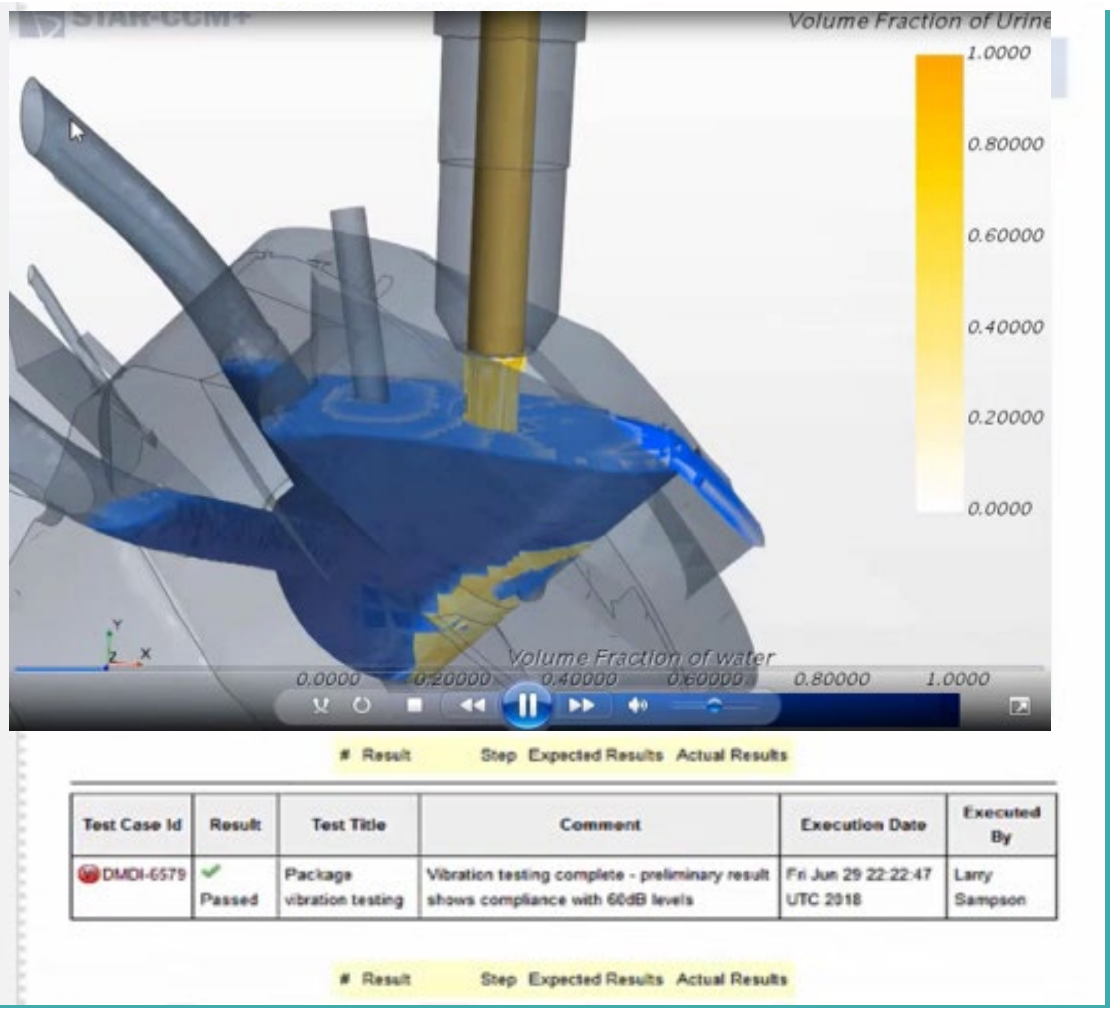
FDA





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Digital Document Submission ≠ Digital Process

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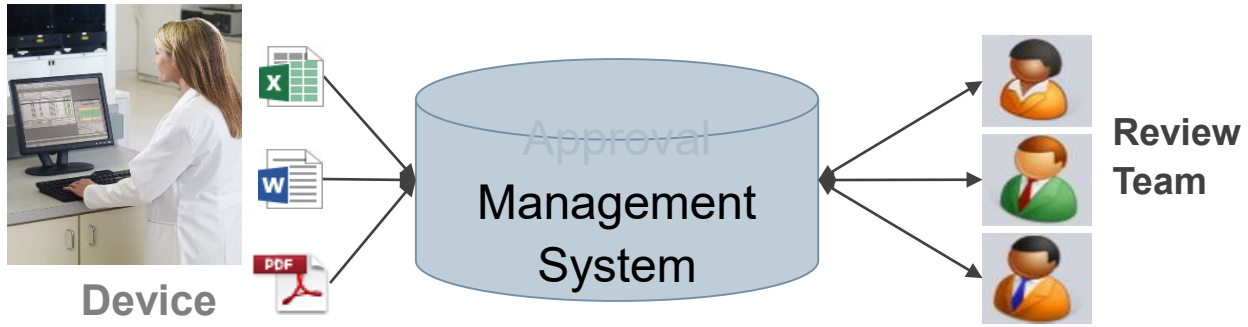
As-Is

- Manual Import, Classification, Compare
- Document (paper) based
- Request/Monitor by e-mail and phone
- Manual change history tracking

To-Be



- Automatic Import, classification, compare
- System based with workflow
- Real time visibility
- Change history tracking

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Automatically Organize Data In The Regulated Format

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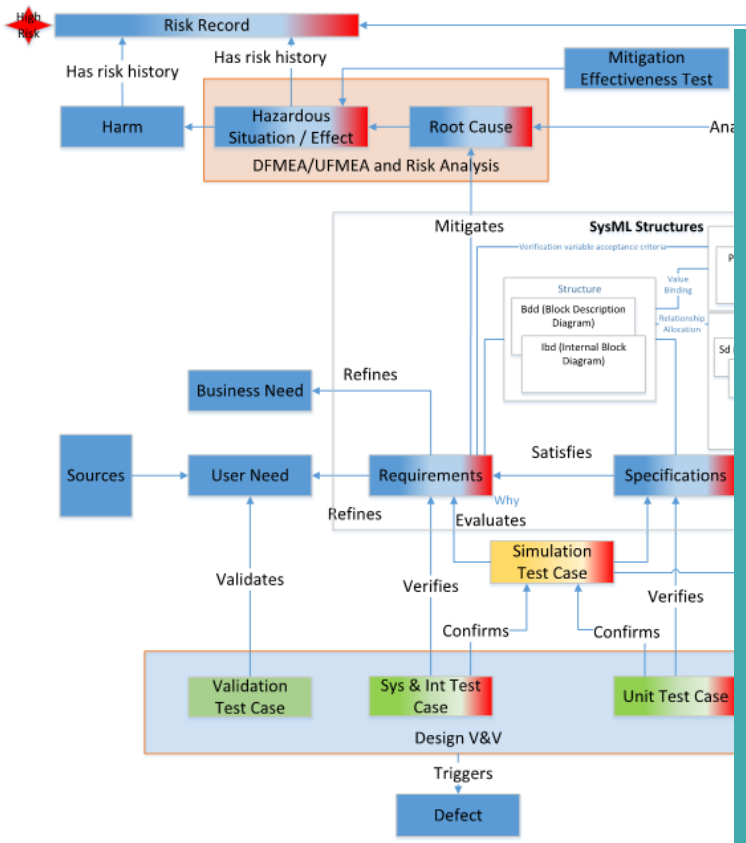

Data Model & Digital Process that Sorts, Organizes, Links, and Classifies All Data

- ▸Product Sources
- ▸User Needs
- ▸Product Requirements
- ▸Test Cases
- ▸Risk Analysis (Harm & Hazardous Situations)
- ▸Post Market Feedback
- ▸Outputs
- ▸And more…

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Standardized Regulatory Workflows Governing the Process

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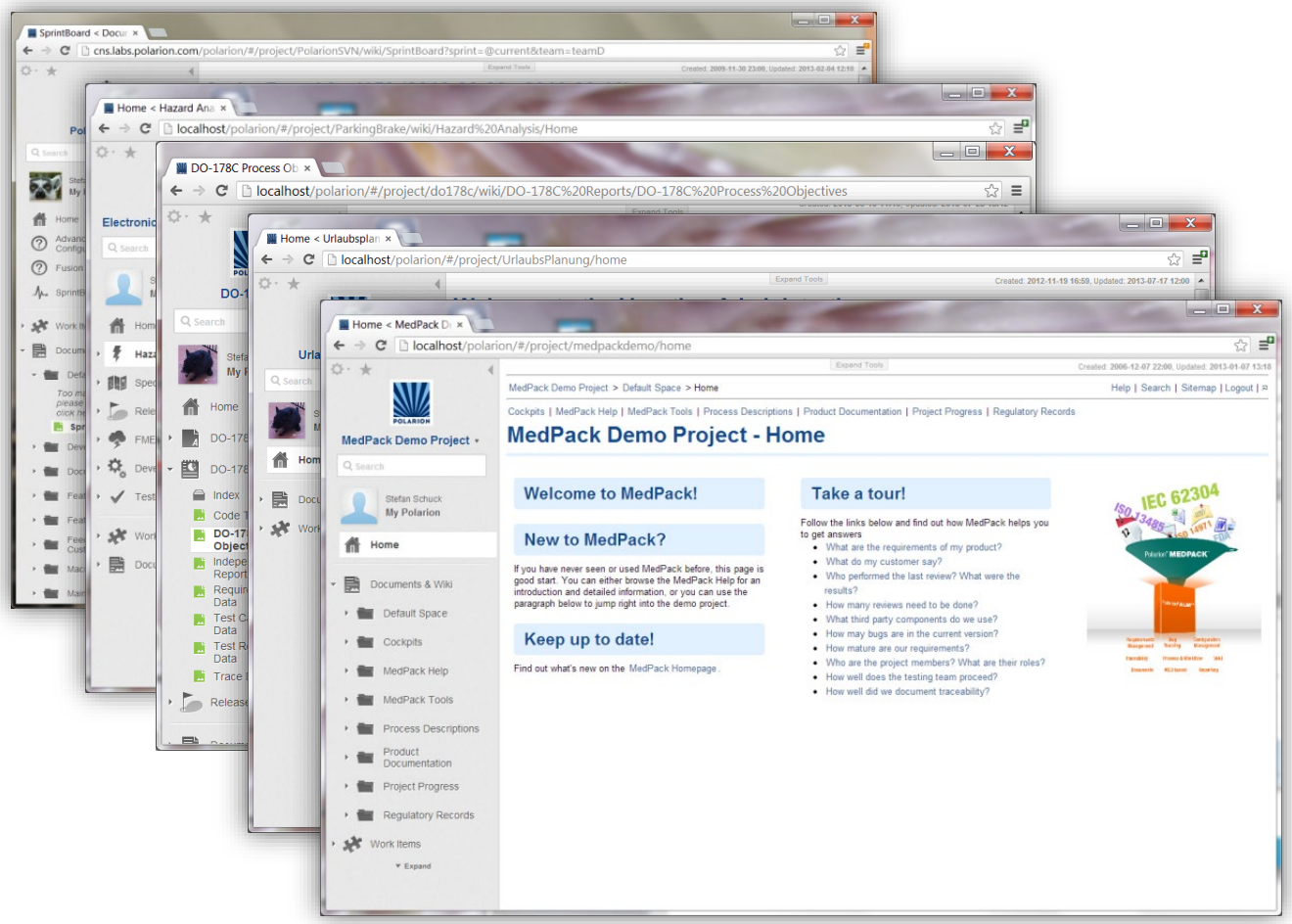

- Processes for device classes:
  - II/III/IV
- In –Vitro Diagnostics
- Local Manufacturers Application
- General Medical Devices
- Adverse Incident Report
- etc

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Visibility & Reporting, Dashboard

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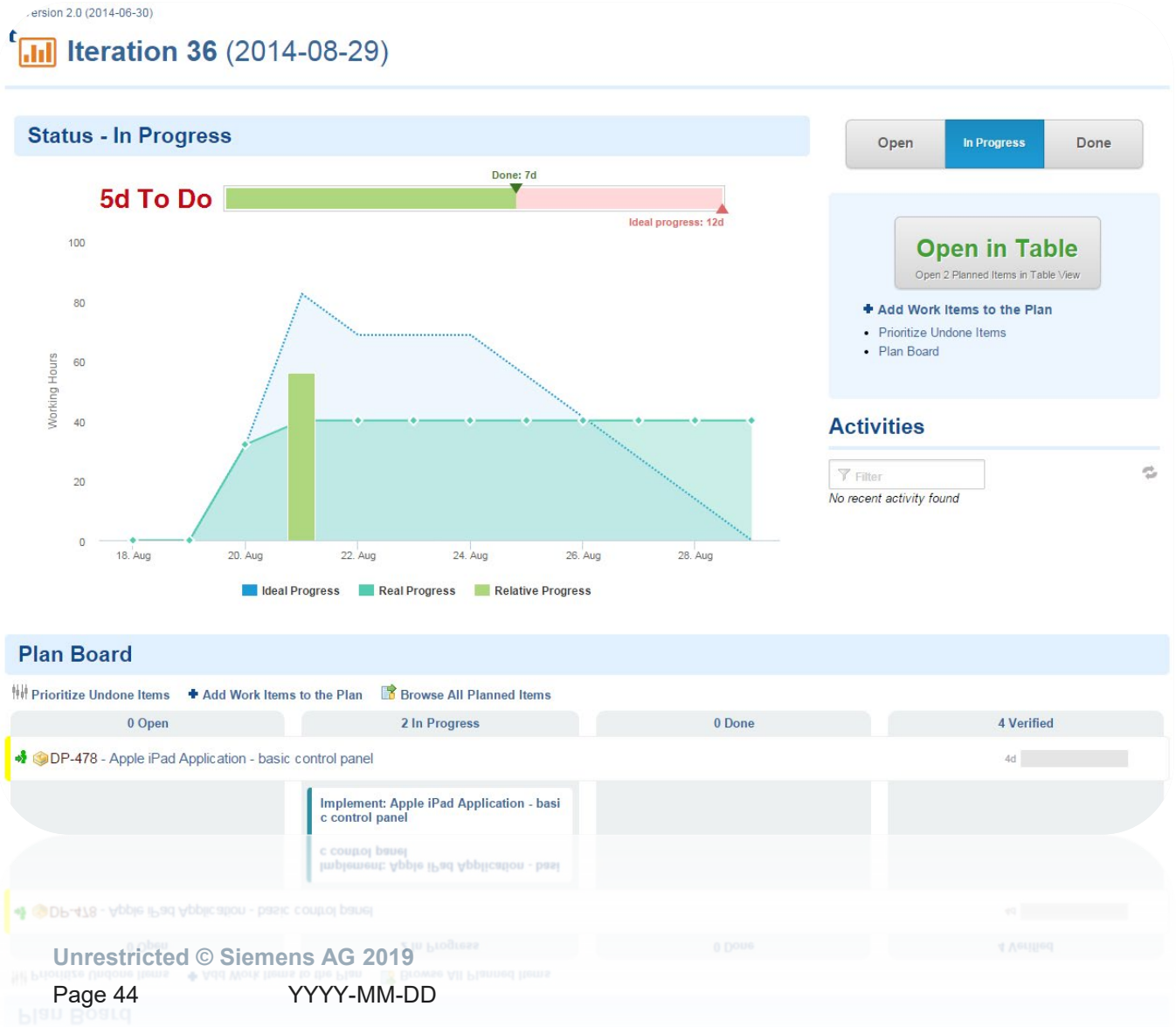

Clearly Display, Share and Collaborate

Open and closed items

Verified and completed items

Estimated complete date(s)

Assignee & owner

Automatically calculate and estimate a release date

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Reporting
Project Status – Approximate approval release

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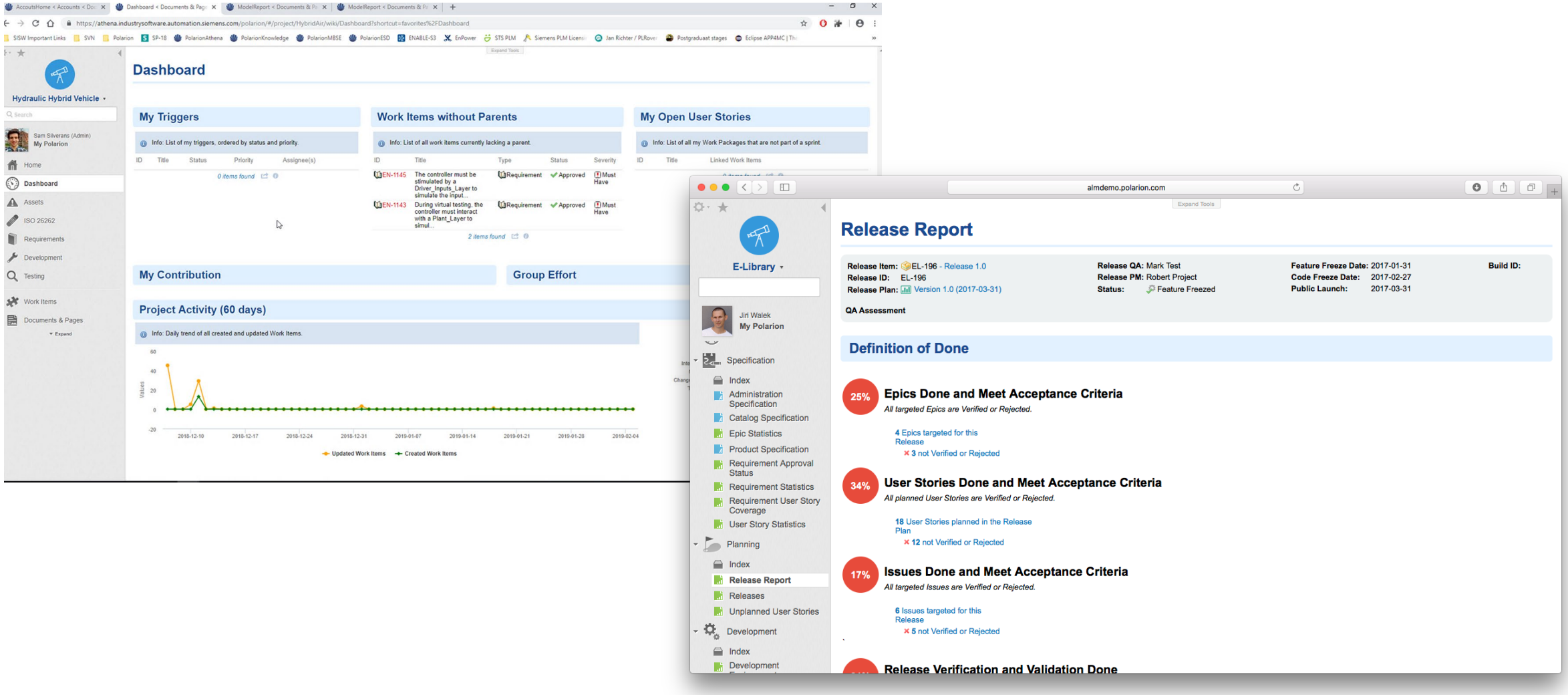

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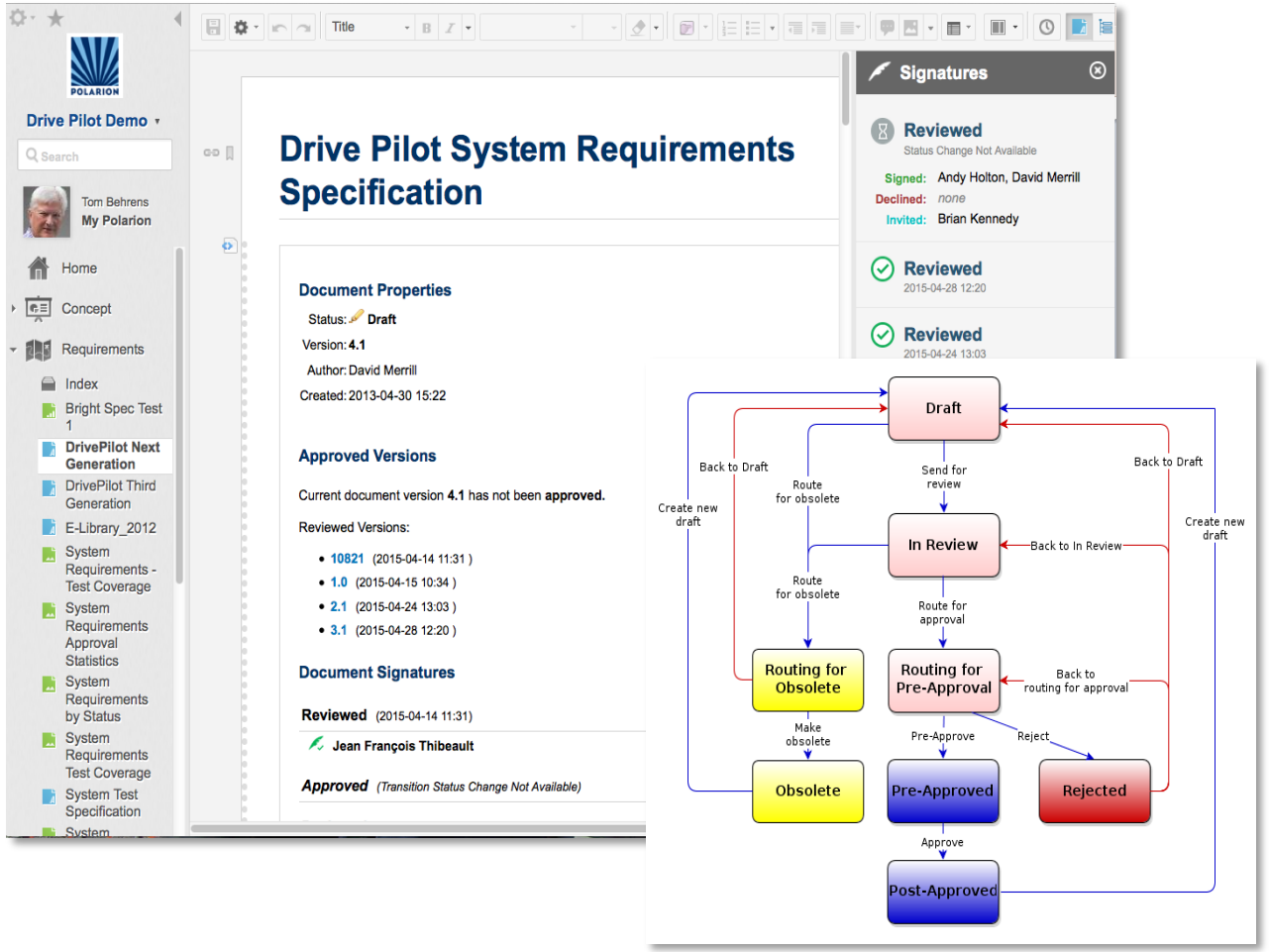
Document Workflows & Signatures



Document lifecycle control

Linked and bound together with workflows

Workflow change signatures

Multiple stakeholders for status change control

Electronic signatures conform to FDA CFR 21 Part 11

Flexible, configurable, and customizable

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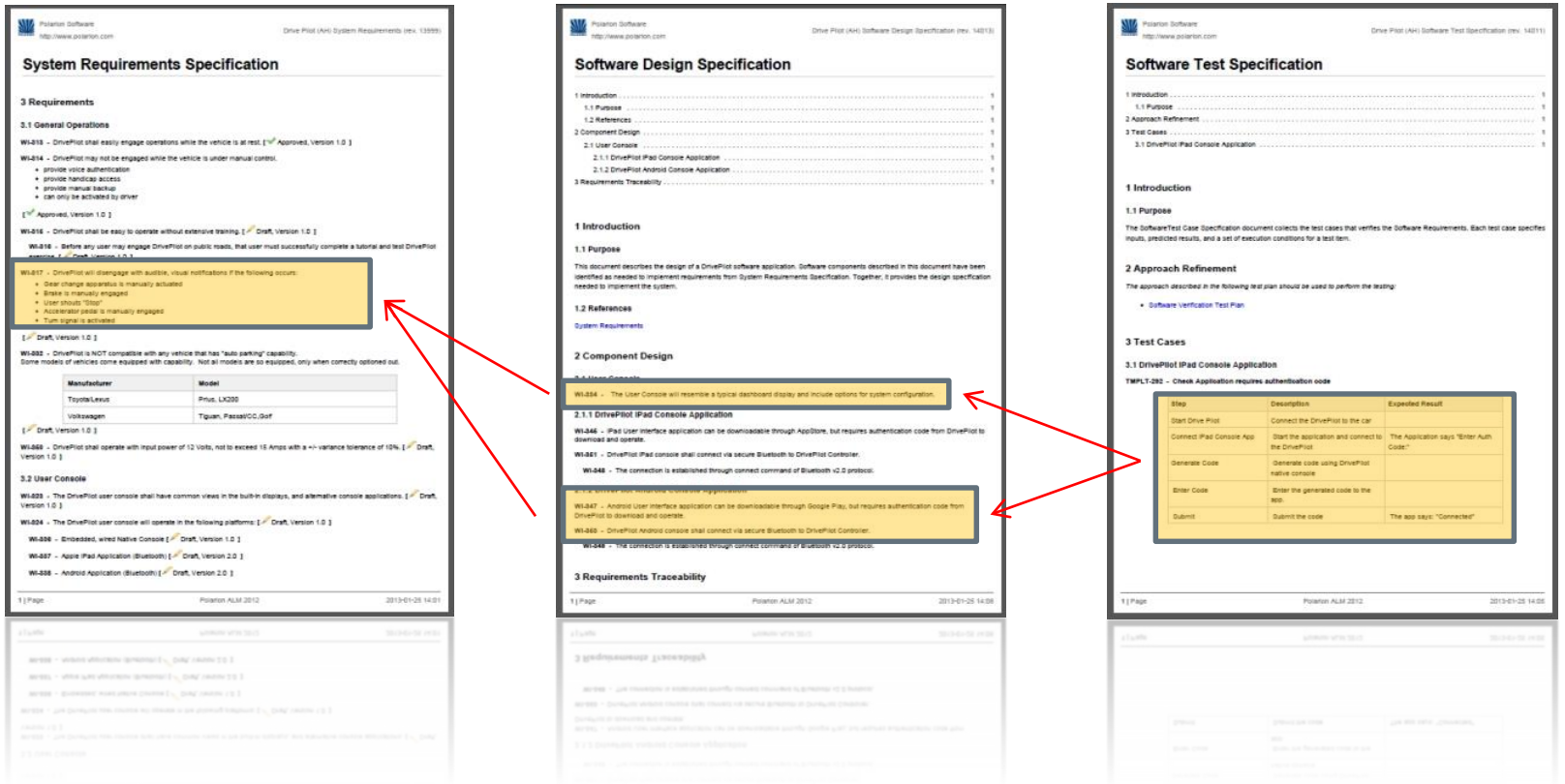
Traceability



- Application → System Requirements → Design Inputs → Test Results → Recalls
- Ensure complete coverage and adherence to processes
- Consistent and predictable
- Clearly define “complete”

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Smart Regulatory Review Process improve safety, efficacy, security

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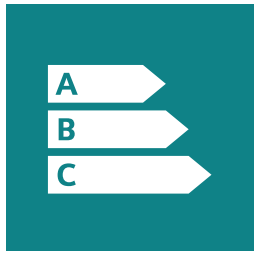

Modern Digital Process Governed by a Data Model

- Pre-screen low quality application
- Easy user interface to reduce manual operations and errors
- Always up to date
- Report and analytic for continuous improvement

Secure, Automate, Search to Effectively manage time and resources for review and renewal process

- Workflows, reviews and process control
- Control exactly who sees what information
- Leverage existing data and record more effectively and improve technical and clinical review capabilities

Collaborative, Predictability and transparency

- Track the status of your resources
- Clearly show approval process progress and estimated release dates
- What is: Open, Under Review, Requires Additional Info,
- Verified and Complete
- Predictive new product launch date with progress report
- Enhance collaboration

Analyze and monitoring post-market surveillance

- Improved diagnostics and management for continuous optimization of resource and capacity
- Increase efficiency, and reduce costs and improve overall performance
- Augment decision making process
- Enhance safety, efficacy and security to close-loop feedback

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Digitalization Strategy for Healthcare Industry 4.0
Innovations for safer, more effective, secure and affordable healthcare

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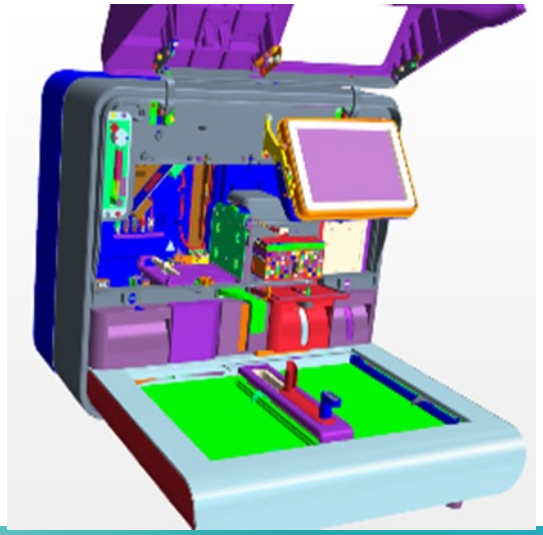
Smart Regulatory

Intelligent Design Control



Digital Evidence

Digital Twins

Speed up innovation

Case for Quality

Smart Manufacturing

UDI

Personalized Devices

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Join us for Digital Healthcare 4.0 Industry Eco-System Collaboration

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