# SaMD: Agile software development in a highly regulated environment

## A management perspective

Lukas Ackermann, 25.03.2021

# Starting Point

**Where I‘m coming from**

- My passion: Digitalization in Healthcare
- Head IT & Digital Services Galenica Group and CEO of HCI Solutions AG (since 1.1.2021)
- My Mission: Bringing IT together under one roof and introduction of an agile organization

**My perspective in this talk**:

- Management perspective, top down
- Where we want to go from a strategic point of view
- How we plan to integrate Medical Device development paradigms and agile business requirements

# Agenda

Where we start from

Where we want to go to

Our measures

Our learnings

# Where we start from

# Galenica - Health and wellbeing are at the heart of what we do.

1927

GaleniCare

coop vitality

2000

2002

2004

AMAVITA

2005

MEDI SERVICE

2007

Galexis
DZN

2008

SUN STORE

2009

Galenica Santé

2013

medifilm

2014

2017

VERFORA

care product

2018

bichsel

CURAREX Healthcare Consulting SWISS AG

2019

Carmol

2020

Turnover: CHF **3'479.8** Mio. (2020)
# of employees: 7'205

SIX Swiss Exchange
IPO 7.4.2017

# It’s not all about products!
# Importance of organizational capabilities is growing

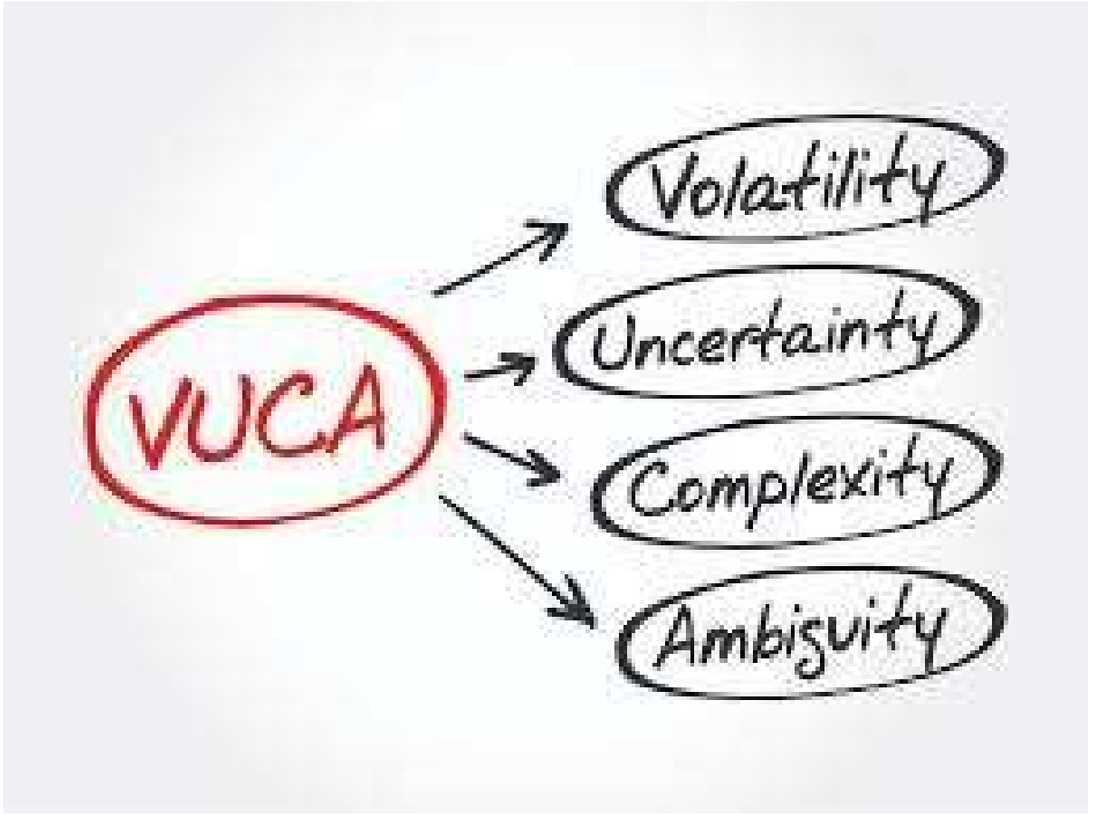
GALENICA

**«Some of the next important innovations will not result from new technologies but from new ways of working together and organizing work»**

Thomas Malone, MIT

# Business Trends we see…

- Digitalisation & Data Driven Business
- Continous Development instead of „Man on the moon projects“
- Decision competencies close to the customer interaction
- Interdisciplinary work, less hierarchies, organizational silos replaced by interdiszplinary teams
- Servant leadership, agile organizations
- …



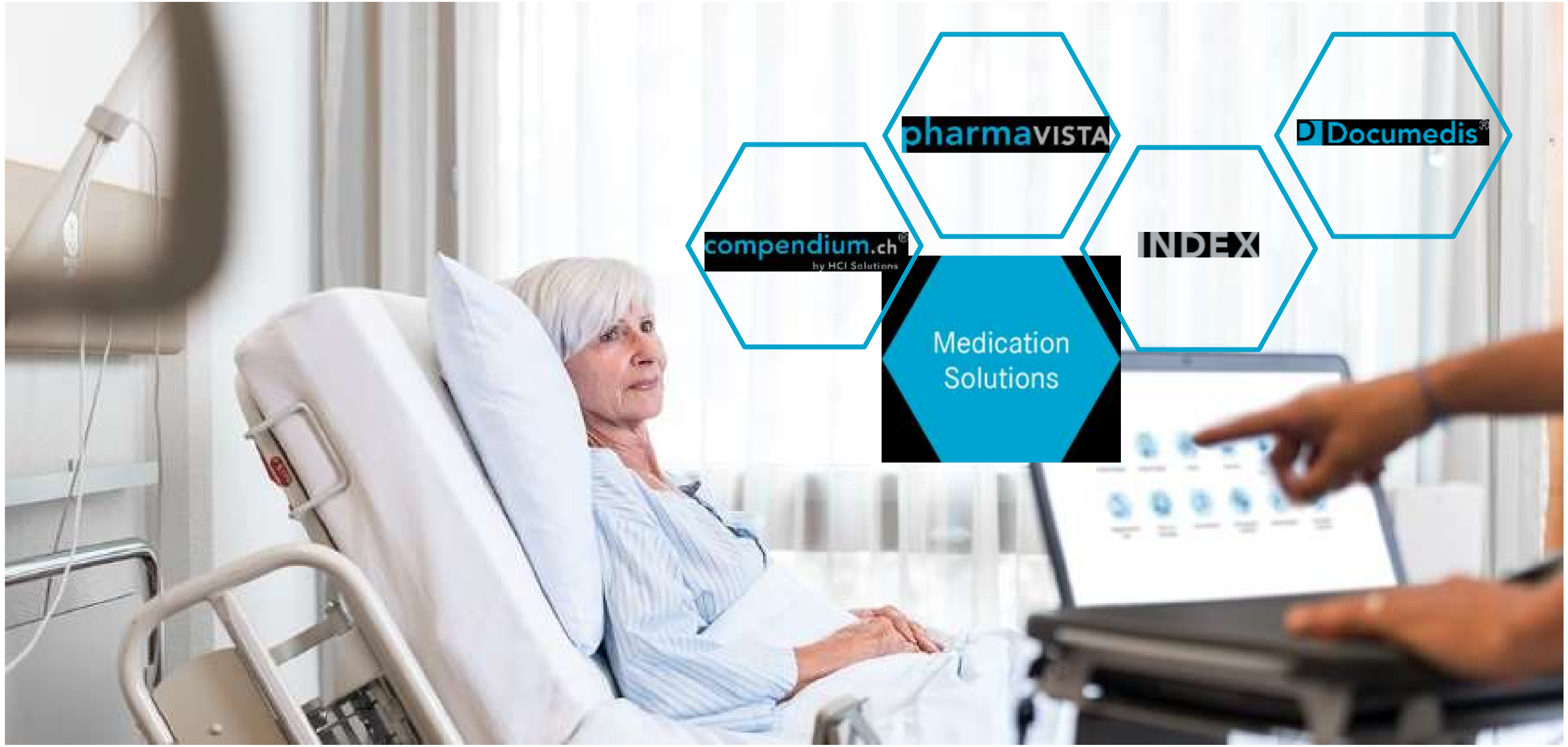

  

# Business trends shape our IT

- Collaboration:
  Business – Development – Operations
- Agile Software Development, continous deployment
- „Product increments“ instead of large software releases
- Monolithical applications are replaced by Microservice Architectures
- Cloudification: IaaS -> PaaS -> SaaS

# Example Documedis (a HCI Solutions product)



# Facts & Figures about Medication errors (Switzerland)

- Increase in drug purchase: +**12,1 %** von 2013 – 2016 [1]
- **20‘000 Hospitalizations/year** due to drug-related problems[2]
- **40 %** of chronically ill people do not adhere to treatment plan[3]
- Non-adherence costs **30 Billions CHF/Year** [4]
- **3 billion CHF/year** savings in healthcare costs by promoting compliance / adherence[5]

**There is a need for eHealth support in order to protect patients and safe money**


1) Helsana-Arzneimittelreport für die Schweiz 2017, Ausgabe 2017.
2) Stiftung Patientensicherheit Schweiz: https://www.patientensicherheit.ch/fachliche-themen/medikation, aufgerufen am 24.09.2018
3) Schützen S. Therapietreue könnte für Einsparungen in der Höhe von über drei Milliarden Franken sorgen: Dank SMS zum Erfolg? Infosantésuisse, 2016/06 16-17
4) Fakten und Zahlen: Schweizer Apotheken 2017. pharmaSuisse 2017, Auflage 8000
5) Schützen S. Therapietreue könnte für Einsparungen in der Höhe von über drei Milliarden Franken sorgen: Dank SMS zum Erfolg? Infosantésuisse, 2016/06 16-17

# Documedis® - medication toolbox
# for convenient services and clinical decision support

GALENICA

- **12 clinical decision support checks (CDS.CE-Check)** MD
- Electronic medication plan (eMediplan)
- Electronic prescription (eRezept)
- **Primary care algorithms (PCA.CE)** MD

CDS-Check

eMediplan

eRezept

PCA

**Our SaMD / SaaS modules are used in most KIS/PIS in Switzerland. SaMD Moduls are an important and growing pilar in our documedis product strategy**

# Documedis® CDS.CE checks risks regarding…


Wirkstoff-Allergie


Hilfsstoff-Allergie


Doping


Dosierung


Doppelmedikation

Fortgeschrittenes Alter


Leber-insuffizienz


Nahrungsmittel-Interaktion


Niereninsuffizienz


Reproduktion


Arzneimittel-Interaktion


Führen von Fahrzeugen

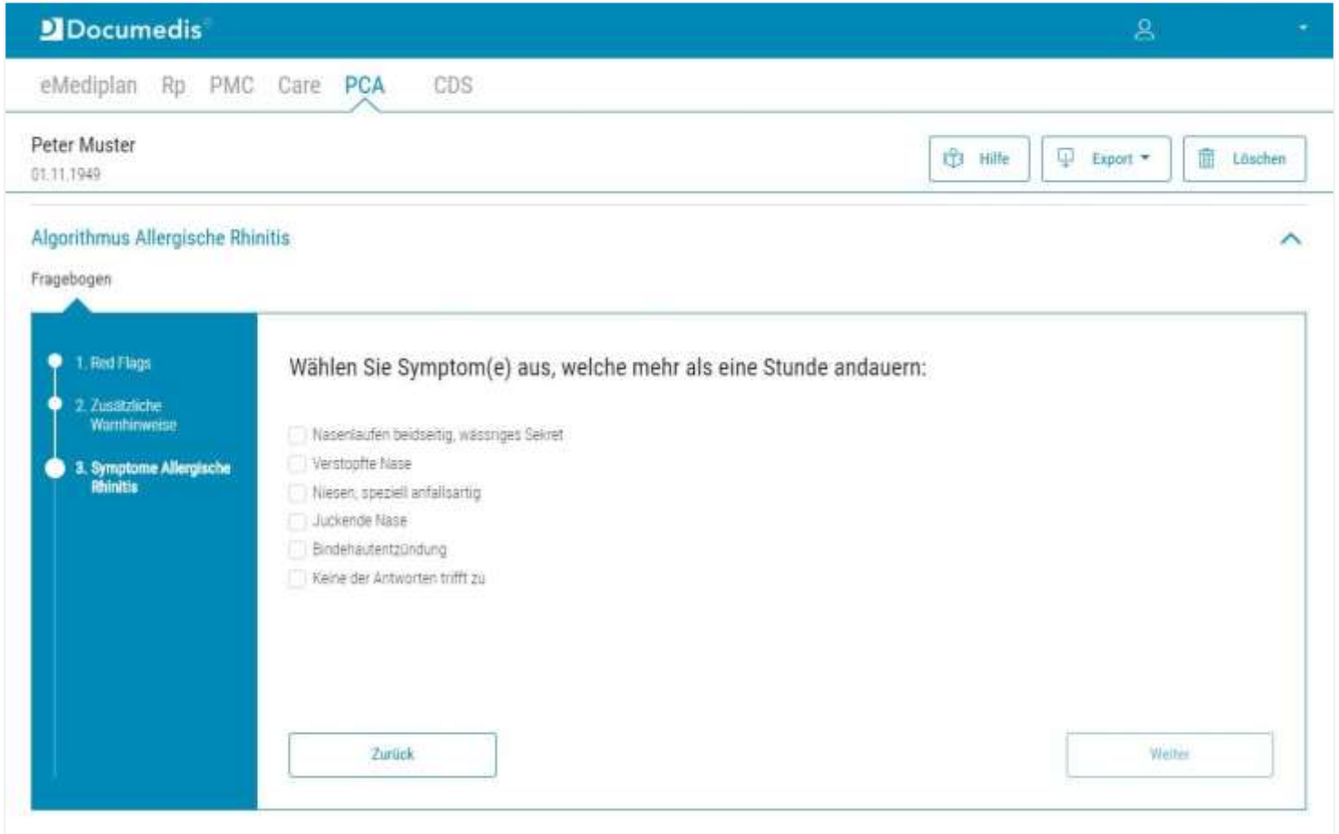
# CDS.CE – Clinical decision support

- Set of checks to review patient's medication for known risks
- Comparison of individual patient data with prescribed medications
- Potential risks are displayed with appropriate warnings
- Less over-alerting with the individual display filter

- **The CDS.CE module is qualified as a class I medical device under MDD (IIa under MDR)**
- Easy extension of any primary system, including background queries (> 2.5 Mio queries per month), web-based detailed view or PDF report

# PCA.CE – Primary care algorithms
## Diagnosis and prescription support for pharmacists

- Personalized advice, serves to support decision-making
- Question construct for dispensing medications in the pharmacy without a doctor’s prescription
- PCA.CE is considered a class I medical device (MDD) since 2019
- **Constantly being further developed with new algorithms**



# Where we want to go

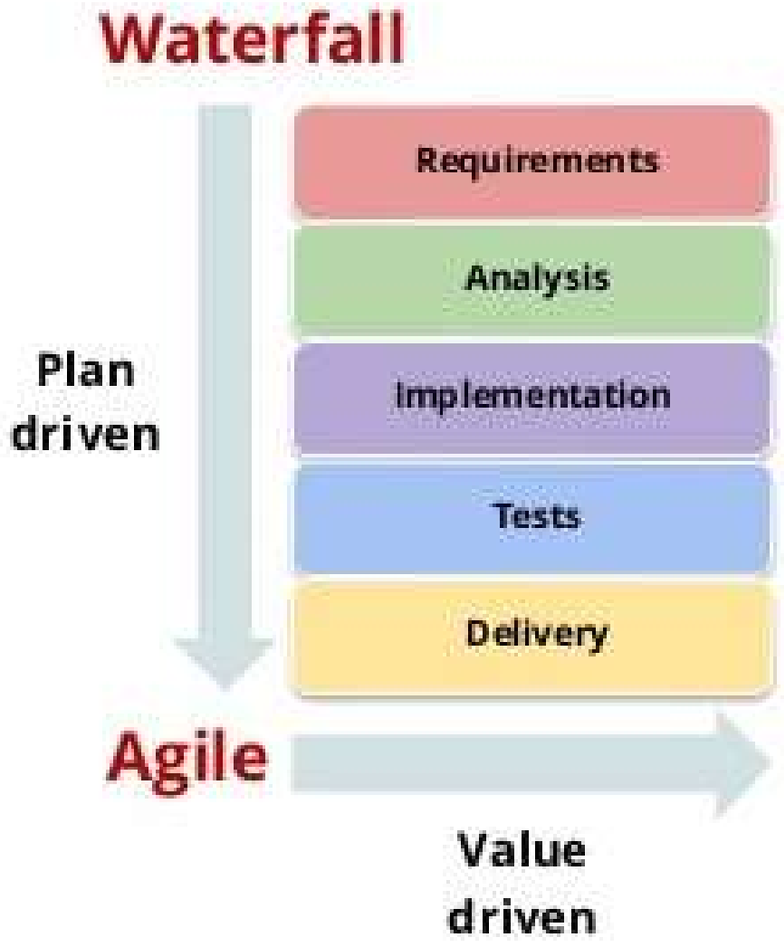
# Ambition for our future SW processes

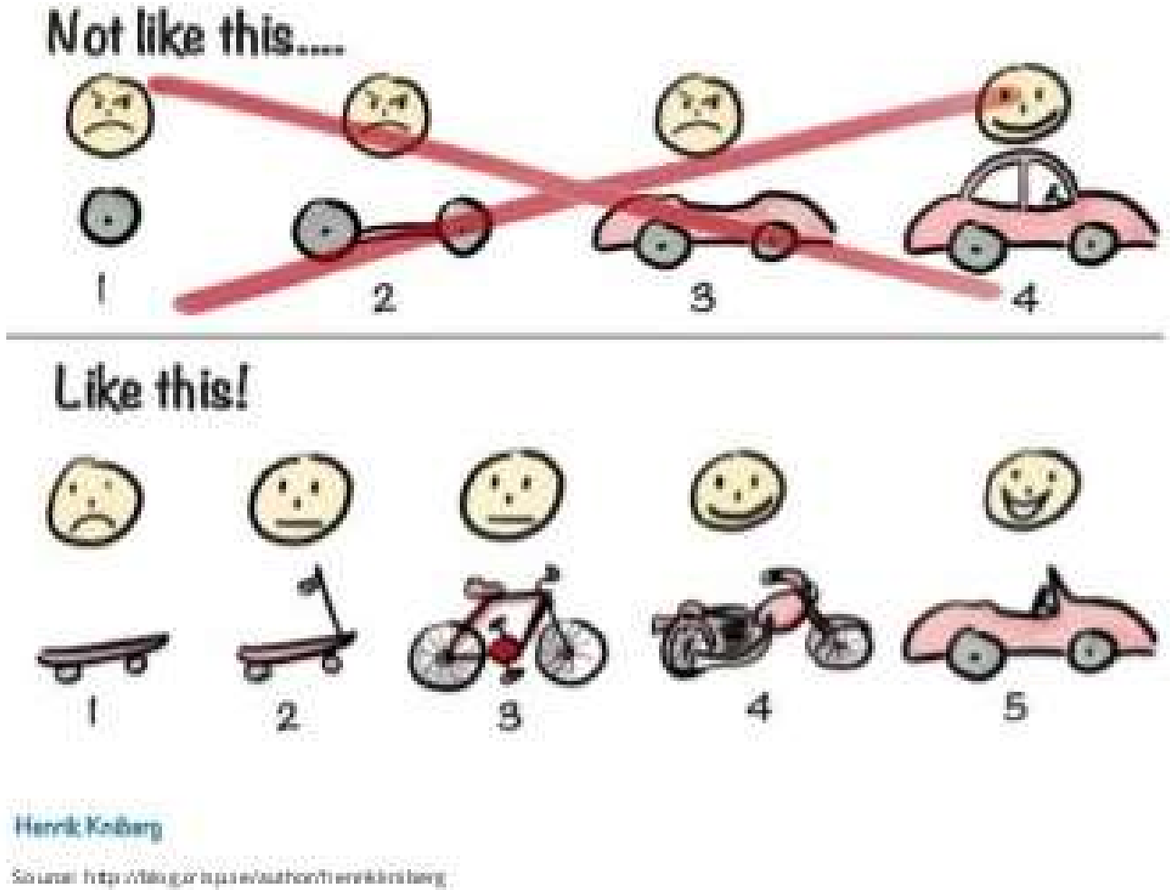
- **Customer centricity** (incorporate feedback from customers at all times, close exchange)
- **Frequent and fast releases** (continuous delivery pipeline)
- **Flexibility/quick** adaptability to new circumstances (reacting to market)
- **Cross-functional** and self-organized teams
- **Traceability tool** (from customer-centric request to release)
- **Certified SaMD modules** interacting with other non-certified software components

-> we need some agility…

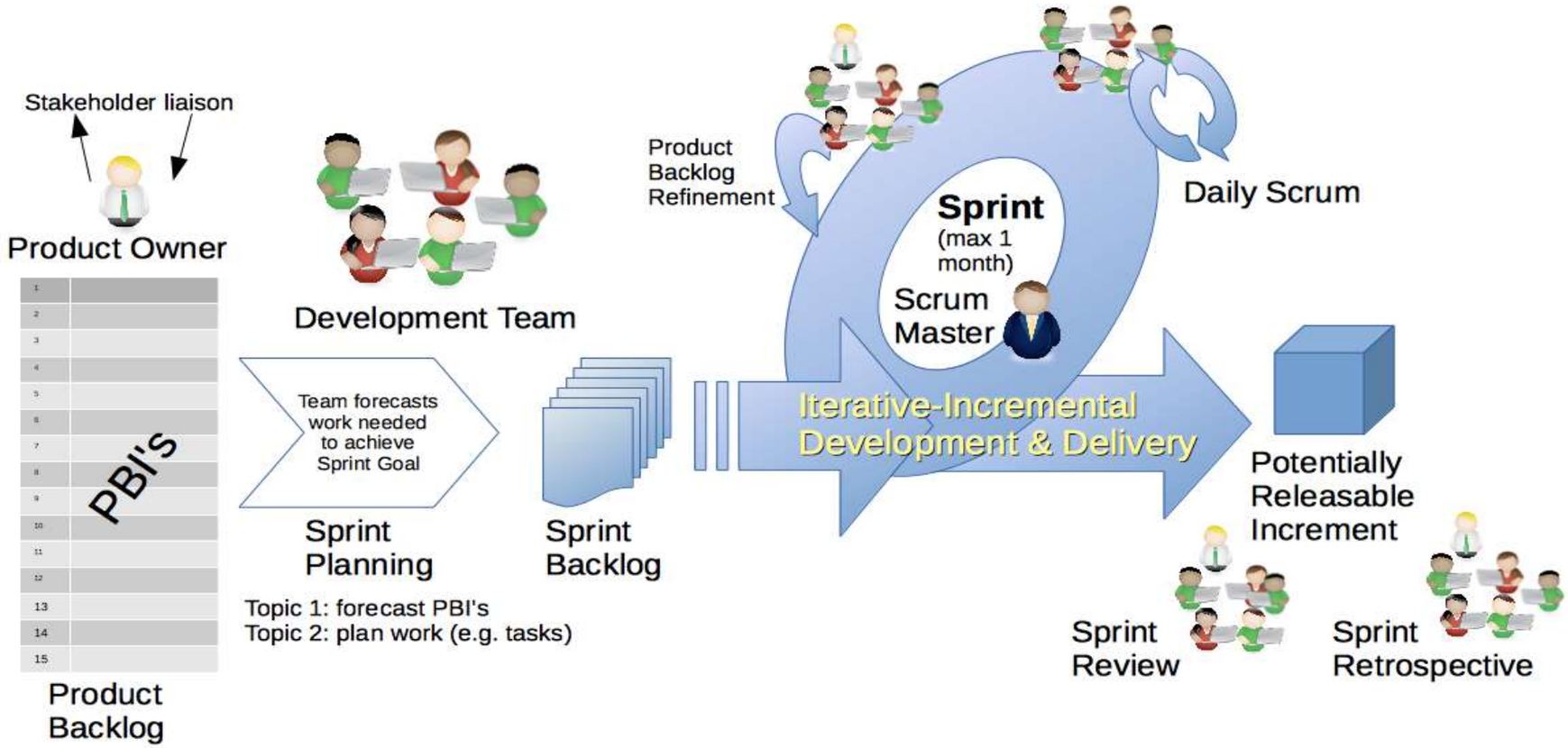
# How we (will) address agile development in our organization




outsystems

# The classical SCRUM
# Agile has nothing in common with freestyle and «cheap» results



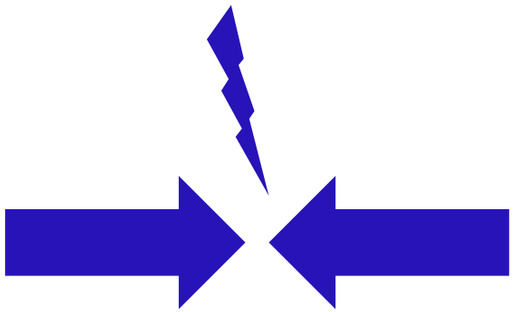

Agile development, e.g. with SCRUM; often encountered in the field, but as such does **not meet the requirements for a MD-Development** (given in IEC 62304)

# Regulated vs Agile Development – Perceived Conflicts

## MD world

- QMS – Quality through establishing and following processes
- Documentation as objective evidence
- Planning mandated by pretty much every standard (ISO 13485, IEC 62304, IEC 62366, ISO 14971)



## Agile world*

- Individuals and interactions over processes and tools
- Working software over comprehensive documentation
- Responding to change over following a plan

* Source: agilemanifesto.org

# Challenges we have to addres in SaMD Development

- Role of manufacturer: has to deliver (and maintain) a safe and effective product
  - The product is more than just the SW
    - Objective evidence of safety and performance -> Risk Management, Usability, Verification & Validation
    - Objective evidence of clinical performance –> Clinical Evaluation
    - Evtl. Update of conformity assessment procedure (CE mark)
- Role of specifier: User stories are not SW specifications (but rather user requirements)
- Role of SW-developer:  is not a risk manager, not a clinical expert

**A certain conflict between the “SaMD world” and “Agile world” is given by nature**

# Our measures

# How we address the agile development in our organisation

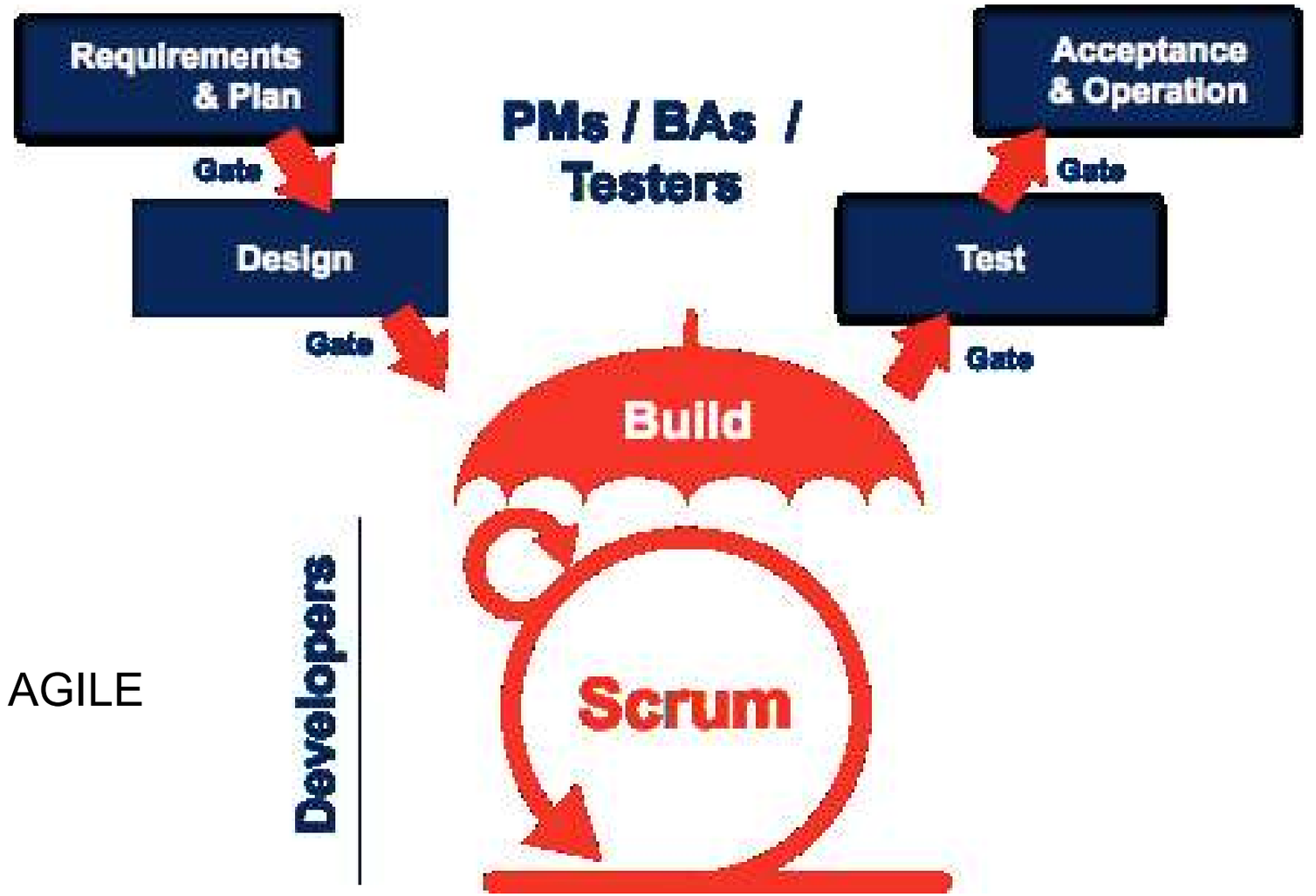
## Various approaches

- First (small) steps
- Segregation of MD-Functionalities
- Essential SAFe as knowledge base of proven, integrated principles, practices, and competencies
- Organizational level
- Partnerships
- ….

# A first (small) step: agile on the SW-developer‘s level

WATER-



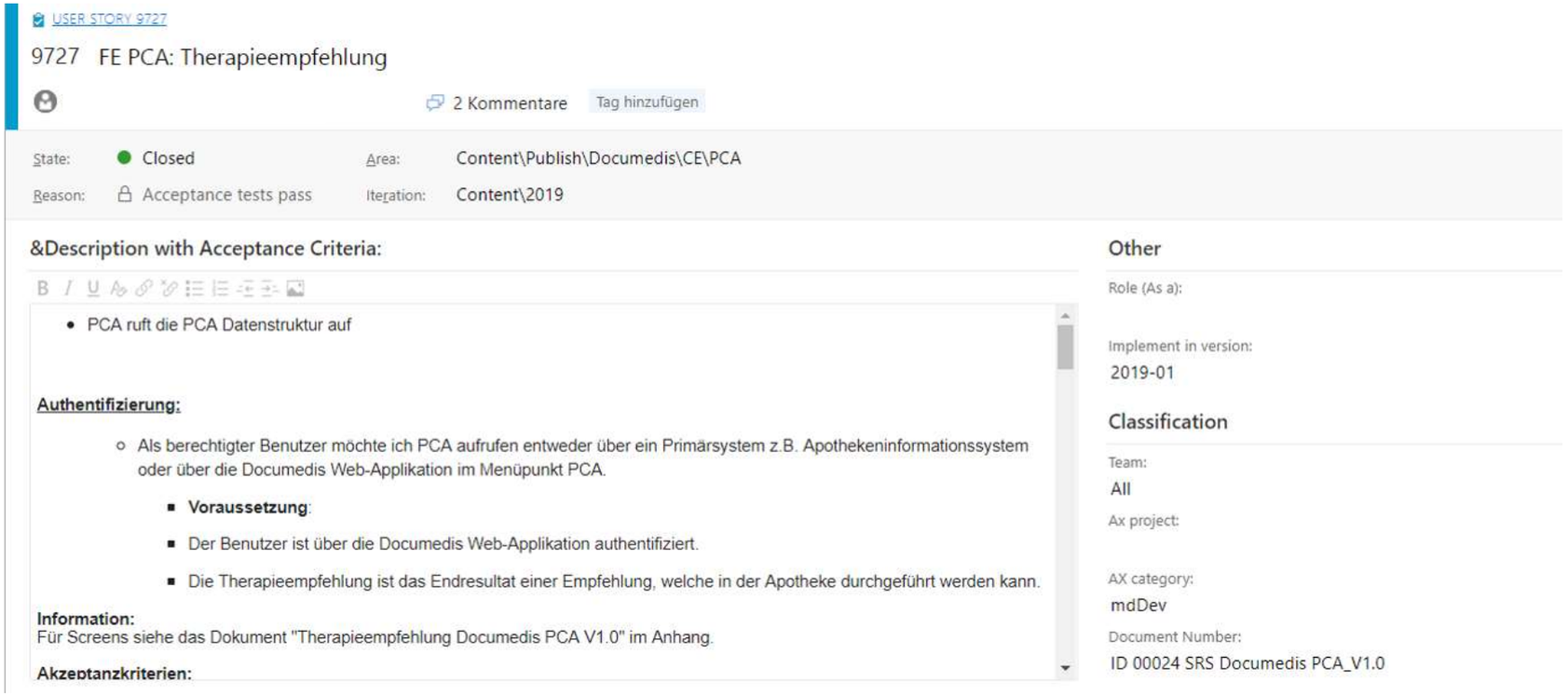

FALL

AGILE

# Development

- After a decision has been made, implementation follows (no implementation without a decision):
  - Describe requirements in form of a user story
  - User story is added to a sprint



# Testing

- No new requirements without a test case
- Verfication: each defined requirement has to be tested and it has to be documented that it has been tested
- Limitation to agile development process: the software can only be released when all defined requirements have been implemented and tested
- **Automated testing becomes crucial for speeding up the processes**

# Documentation and traceability

- Documentation is a must -> use it as a bridging tool between the two worlds
- It affects everyone in the project team, even the developers have an extra workload
- **Opportunties: tool-supported documentation and tracability**

**Dokumentenplan Documedis XXX.CE**

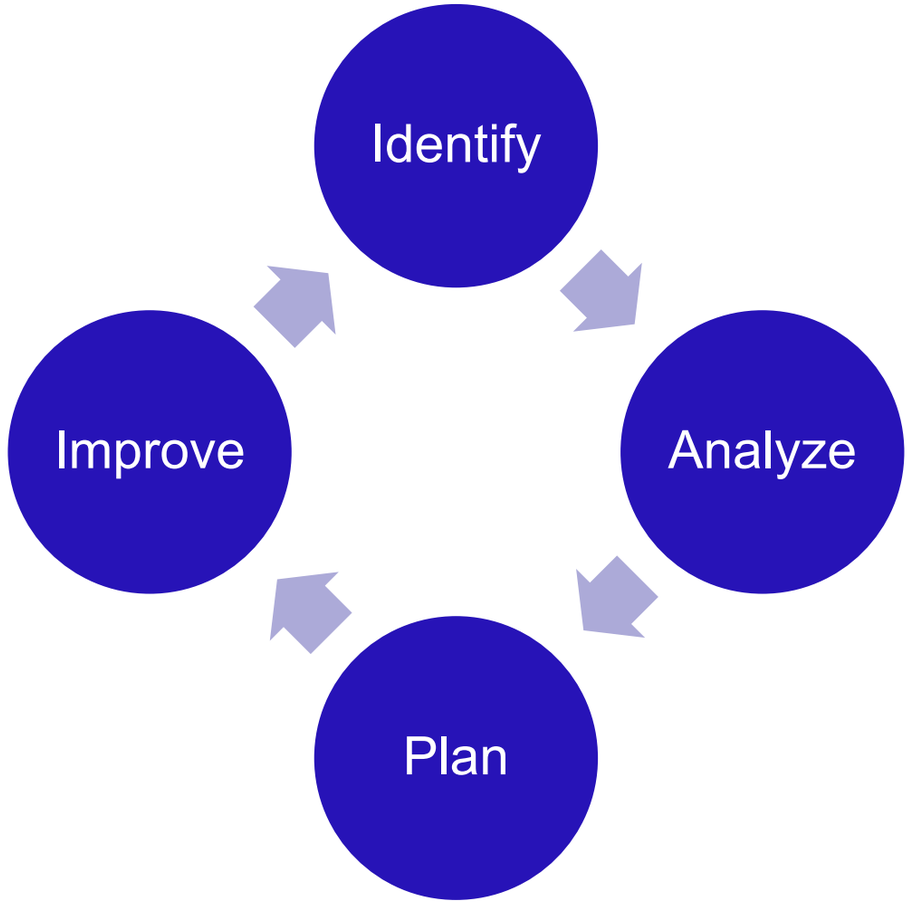
| ID | WP | Content | Document | Document Title | Document Filename | Created | Started | Usable | Finished | Released | ToDo | Comments | Verantwortliche @ HCI | Verantwortlich @ ISS | Lieferdatum | Abnahmedatum |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | Planning of product realization | ID 001 | Document Plan Documedis XXX.CE | ID 001 Document Plan Documedis XXX.CE_20191206.xlsx | | x | | | | | | | | | |
| | | | ID 002 | Project Management Plan Documedis XXX.CE | ID 002 Project Management Plan Documedis XXX.CE_V1.0.docx | | | | x | | | | | | | |
| | 7 | | ID 003 | Role Assignment Plan Documedis XXX.CE | | | | | | | | | | | | |
| | 7 | Angewandte Prozesse | ID 004 | Software Development Plan Documedis XXX.CE | | | | | | | | | | | | |
| | 10 | Validierung | ID 005 | Design Validation Plan Documedis XXX.CE | | | | | | | | | | | | |
| | 1 | Anwendbare gesetzliche und normative Anforderungen (nicht MDD) | ID 006 | List of Applicable Standards Documedis XXX.CE | | | | | | | | | | | | |
| | 1 | Grundlegende Anforderungen an ein Medizinprodukt | ID 007 | General Safety and Performance Requirements Documedis XXX.CE | | | | | | | | | | | | |
| | 7 | Klassifizierung Produkt und Softwaresicherheitsklasse | ID 008 | Classification Documedis XXX.CE | | | | | | | | | | | | |
| | 5 | Use Specification | ID 009 | Intended Purpose and Use Specification Documedis XXX.CE | | | | | | | | | | | | |
| | 4 | Risikomanagement-Akte | ID 010 | Risk Management Plan Documedis XXX.CE | | | | | | | | | | | | |
| | 4 | Risikomanagement-Akte | ID 011 | Product Risk Analysis Documedis XXX.CE | | | | | | | | | | | | |
| | | | ID 013 | Risk Management Report Documedis XXX.CE | | | | | | | | | | | | |
| | 6 | Systemarchitektur und Design | ID 014 | System Architecture and Design Documedis XXX.CE | | | | | | | | | | | | |
| | 8 | Softwarearchitektur und Design | ID 015 | Software Architecture and Design Documedis XXX.CE | | | | | | | | | | | | |
| | 3 | User Requirements | ID 016 | User (Stakeholder) Requirements Specification Documedis XXX.CE | | | | | | | | | | | | |
| | 3 | Spezfikation Software und Systemanforderungen | ID 017 | System Specification Documedis XXX.CE | | | | | | | | | | | | |
| | 3 | | ID 018 | Packaging and Labelling Specification Documedis XXX.CE | | | | | | | | | | | | |

# Risk management

- **Ongoing** risk management
- No matter where a change request comes from, it has always to be reviewed before it is implemented
  - Risk assessment: Does it affect existing features or does it create new risks?

**Important step to bring Agile and ISO 13485 together**



# Change management

- Every change has to be documented and traceable
  - Decision making and documention (any change regardless of scope, be it a bug, a new feature, a light color change, a configuration change, etc.)
  - Every step has to be documented.
  - Traceability always has to be guaranteed. Each user story/bug has to be linked to previous decision (from decision to requirement to implementation to testing).
  - Depending on the change, this may have an impact on the medical device class.

Important step to combine Agile and ISO 13485

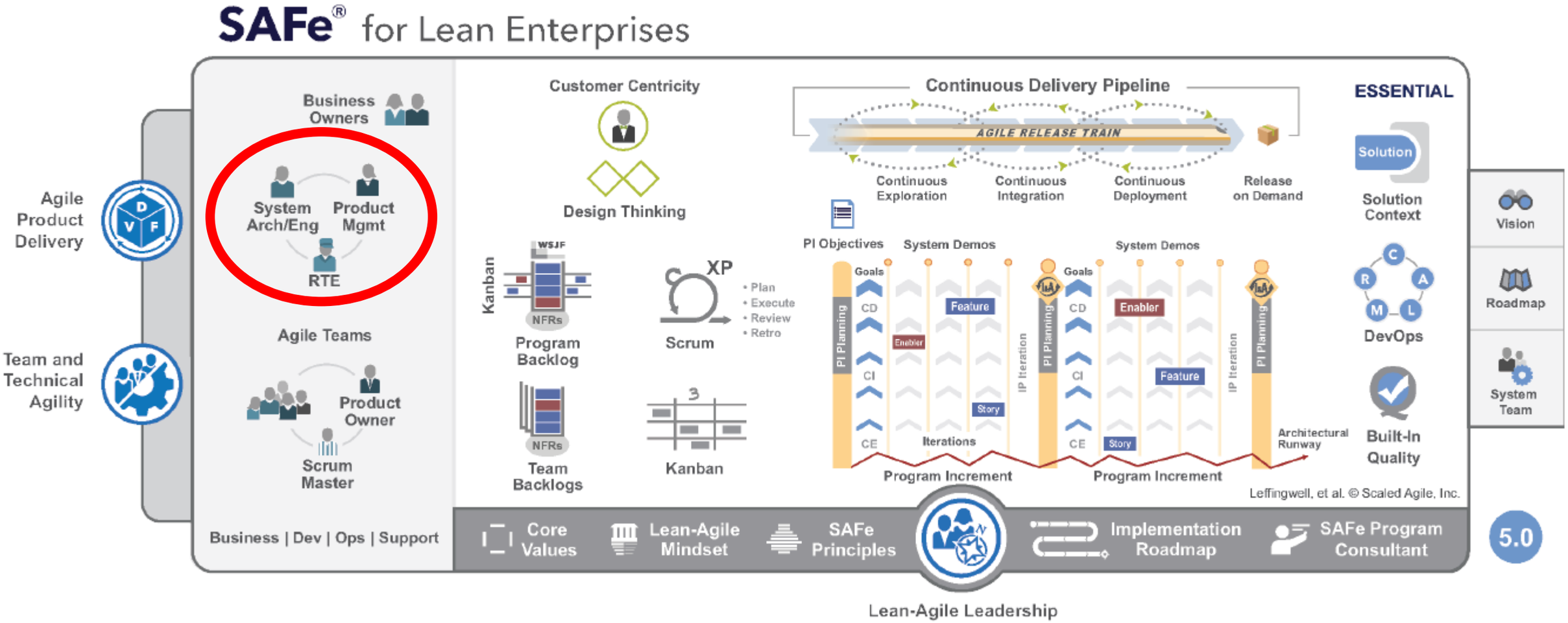
# Actual software life cycle (under 13485/IEC 62304)

- Specific development process for medical devices in our ISO 13485 system (requirements, architecture, implementation, testing etc.)
- Limitation in the software lifecycle: fewer releases, releases of a medical device are more complex due to documentation

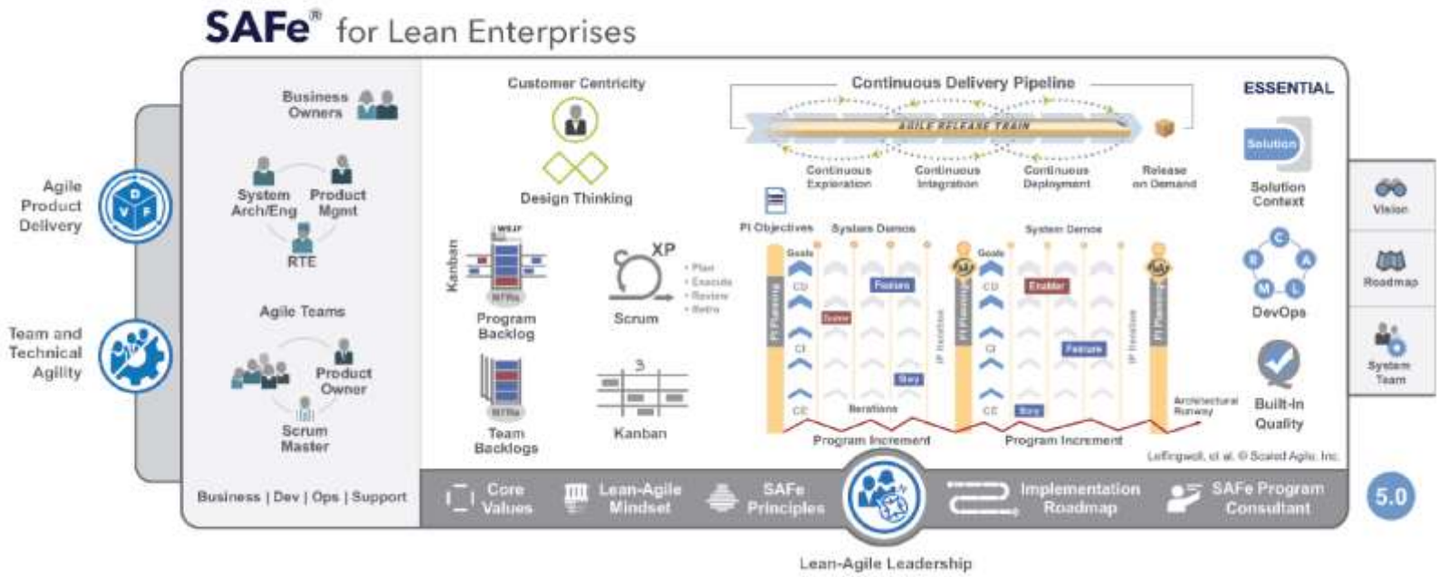
**OK, but with room for improvement….**

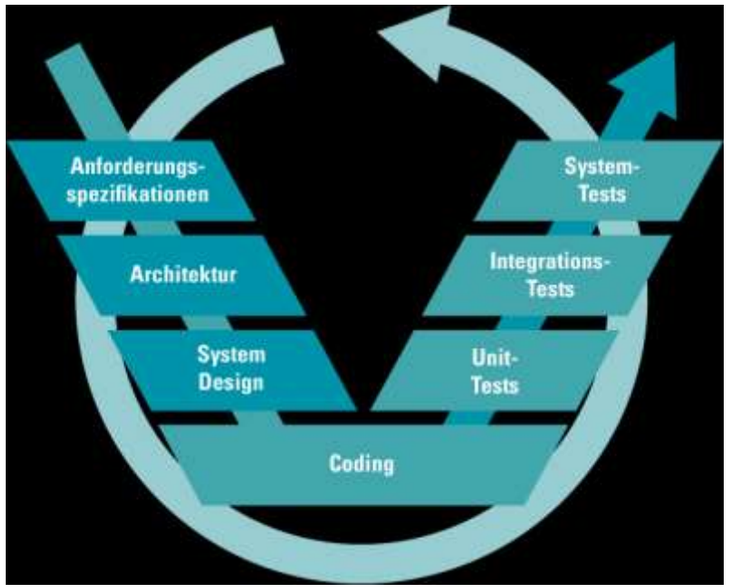
  

# Agile Framework – Essential SAFe
## Interdisciplinary cooperation for continuos and effective outcomes

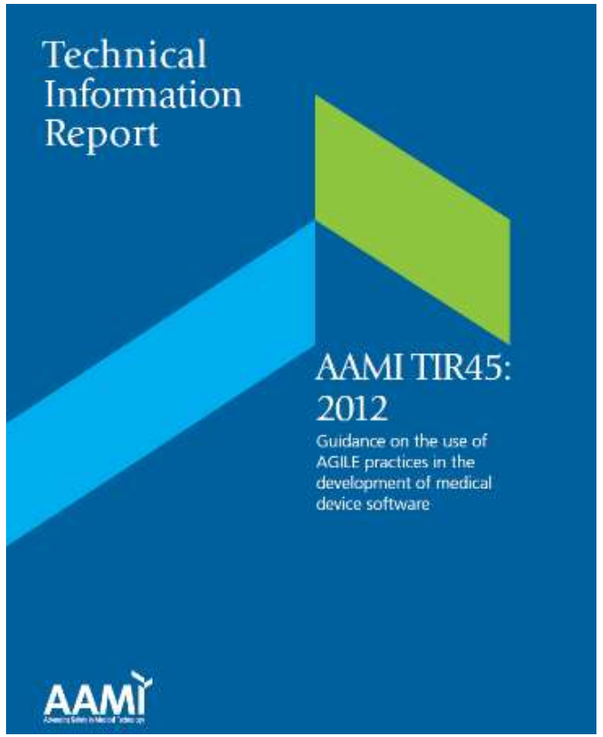


# Our challenge: how to merge the Agile Framework  with IEC 62304

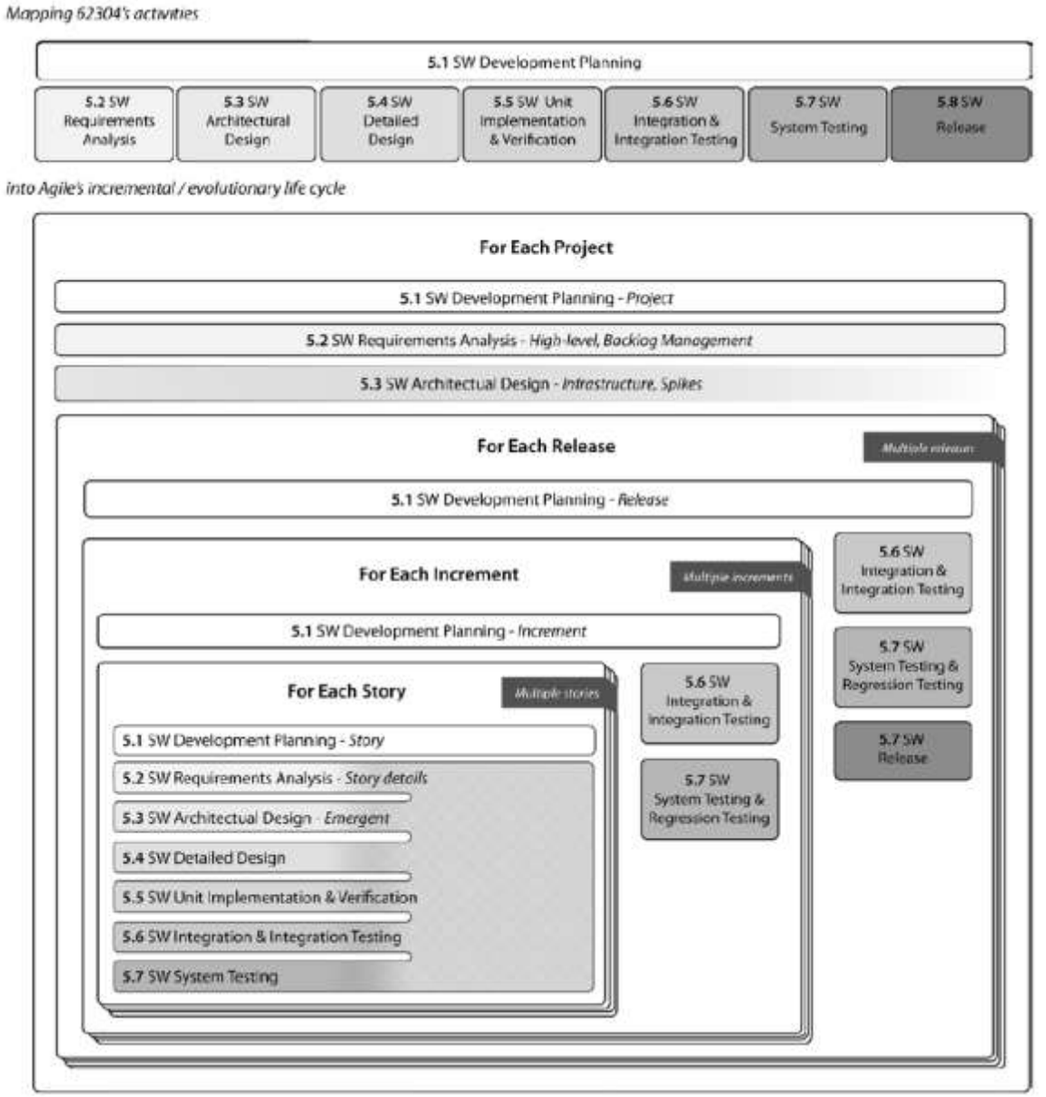


# Guidance on the use of agile practices in the development of medical device software




Solution proposed:
AAMI TIR45:2012 - Guidance on the use of Agile practices




Source: AAMI TIR 45:2012

# Partnerships

## Architecture Perspective: CDS.CE is a great example for a segregated SaMD-functionality (lean modules which are incorporated in complex PIS/KIS)

- 160 software vendors => reduction of costs and complexity
- Medflix as a joint project with ISS for further scalability in SaMD development
- SaaS - Microsoft Azure Cloud
- Not for profit organizations: Pharmasuisse defines Primary Alghorithms, eHealthSuisse promotes standardization (ePrescription / eMediplan), Collaboration with University Hospitals …

# Our learning

# Lessons learned

- It’s not easy, it is a long way, it’s expensive
- Agile methods have a hard time in a regulated environment (but still a lot of common goals)
- Agile methods can be applied, but have to be adapted
- Still a lot of documentation is required => digitalization required
- Ongoing risk management is important
- Traceability of each step is important => digitalization required
- Quality agreements should be in place with suppliers and should cover ISO 13485 and IEC62304
- Supplier audits are helpful
- There are parts (e.g. Clinical Evaluation Report) which can’t be agile by definition => accept it

GALENICA

Health and wellbeing are
at the heart of what we do.

# Thank you!

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