



AHMED: Agile and Holistic Medical Development

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Introduction to AHMED project

- Co-Innovation project partially funded by Business Finland
- Project duration 1.7.2020 – 31.6.2022
- Total budget €3.3M
- Six participating companies + two research organizations



Project participants & roles

Companies

- Bittium
 - Medical devices/software provider
- MyLab
 - Medical software & service provider
- Solita
 - Medical software & service provider
- Terveystalo
 - Medical software development

- Atostek
 - Medical software & service provider
- Taipuva Consulting
 - Dev process & tool provider

Research partners

- VTT
 - Regulatory research
- University of Helsinki
 - Continuous software development research



Motivation and background

- Agile development has become commonplace in almost all imaginable domains of software
 - Fast feedback & rapid changes are at the center of agile methodologies
 - Continuous software engineering pushes the envelope even further towards multiple deployments per day
 - AI/ML features imply that additional effort must be invested in associated training data sets
 - Unfortunately, this is in sharp contrast with regulated domains, such as medical devices, avionics, etc.
- 3 key characteristics of regulation which must be reconsidered with continuous software engineering:
 - Risk management
 - Several categories that call for different treatment
 - Traceability and verification
 - Tool chains play a core role in this; tools such as JIRA or Polarion can provide support also for regulated development
 - Continuous tool improvement and validation is crucial part of medical software development
 - Compliance checks on code commits
 - Whenever new code is introduced, compliance requirements apply; however compliance treatment can also be made agile



Problems and status quo today

- Rapid software deployment technologies contradict regulation requirements
- Some practices meaningful for HW but not for SW (e.g. tolerance for one fault required)
- HW typically has primary use, SW however can be easily adapted to different roles
- How to deal with AI related features that are statistical and not discrete in nature?
- How to deal with features such as reinforcement learning that accumulates and changes behavior over time?
- How to create consistent visualisation / AI environment without prejudicing data privacy?
- Traceability without automation is next to impossible
- Today, the mainstream approach is to develop the software in an agile fashion, following (partly) the same practices as in continuous software engineering
- Then, when enough features, bug fixes, etc. are completed, regulatory things are rerun like for completely new release
- Typically, the frequency of new releases is 1-4 times per year, depending on the organizations involved
- Downside is two-fold:
 - It takes time to start using the new features & get bugs fixed
 - Delay on receiving feedback from users, which in turn means that it takes even longer to get the new bugs fixed



Ahmed goals

- Research project to create *continuous approach to regulatory requirements*:
 - Construct concrete case studies inside companies, directly associated with company needs
 - Identify best recognized patterns and practices in agile medical device development following continuous software practices
 - Understand the regulatory basis for required process practises and therefore tool capabilities
 - Test different tool chains that can provide support for traceability, risk management, etc.
 - Build a joint demonstrator between participants: participants free to build their own research prototypes towards client demos, reusable component, etc.
 - Cover both data centric features needed for AI&ML as well as software functions, including testing as well as potential applications for further demonstration and productization which are attractive for global market
 - Making impact to European regulation by providing input to regulators and their working groups



Company presentations

- **ML/AI challenges in regulated context**
Antti Siipola, Senior Project Manager, Bittium Oyj
- **Solita Health RegOPS**
Kimmo Kivirauma, Business Director, Solita Oy
- **From documentation burden to agile advantage**
Pasi Ahola, CEO & Founder, Taipuva Consulting