

Reference: QSE:MedInf
Topic: Software Engineering for Medical Processes with AI Capabilities
Course Type: Bakk-/Master Thesis, ASE or CS Project
Start: As soon as possible
End: To be defined
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Background

In the development of *Software as a Medical Device*, a critical communication gap often emerges between domain experts (such as clinicians, business and regulatory stakeholders) and technology experts (software solution architect, technical team). As these stakeholders speak different professional languages, critical domain knowledge often remains trapped in isolated knowledge silos. This lack of shared understanding regularly leads to misaligned requirements, architecture flaws, and design missteps in complex, safety-critical medical environments, and ineffective solutions [3].

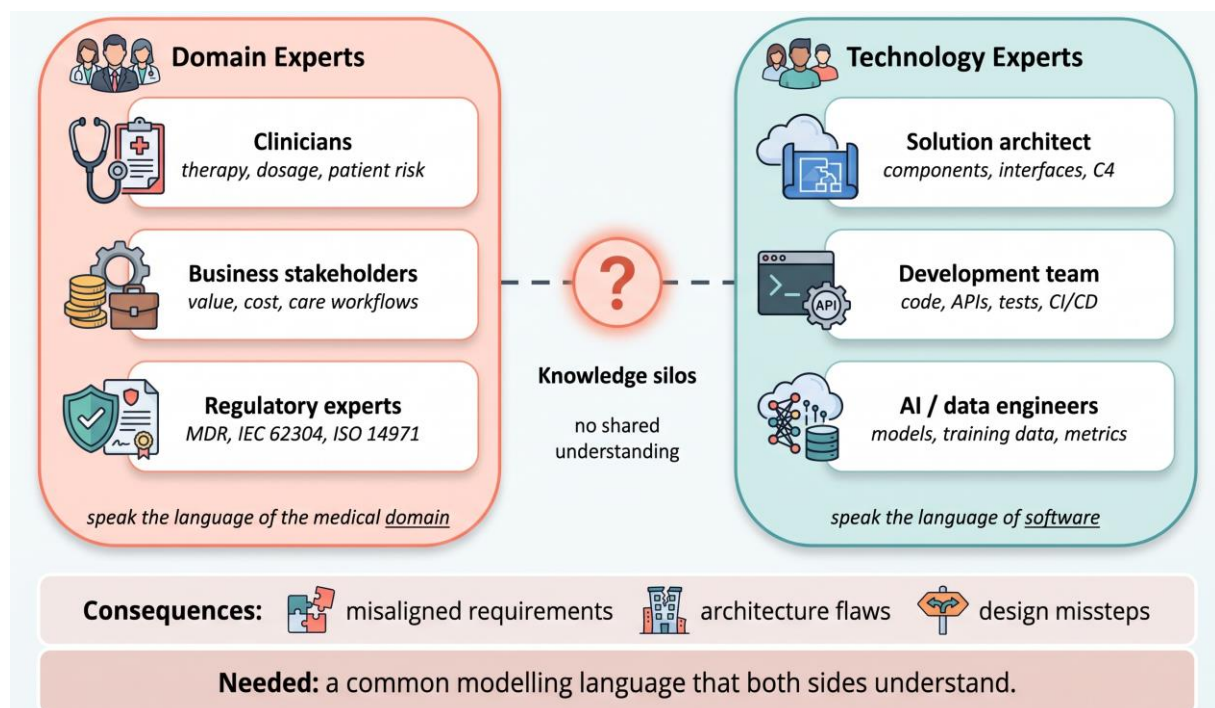


Figure 1: Domain experts and software architect perspectives, missing a common language [3].

Goal

The goal of this project is to design and validate **models and methods for a tutorial** to develop and analyze software as a medical device incorporating AI capabilities, starting from initial stakeholder requirements through to a system architecture and prototypes for proof of concept. By utilizing *System Impact Architecture Modeling* (SIAM) [1], the project aims to systematically bridge the gap between regulatory requirements, clinical intent, and concrete software architecture [3]. Students at Med Uni Wien and in the course *Advanced Software Engineering for BioTech* shall use this tutorial to experience the roles product owner or solution architect in a medical context with AI.

Illustrative Use Case: Closed-Loop Insulin Dosage

To ground the theoretical framework in a real-world application, the project shall automate steps in a *medicine usage process*, e.g.,

- (i) therapy planning, documentation, and optimization [4],
- (ii) AI-supported, automated insulin therapy planning (closed-loop insulin pump support) [3], or
- (iii) planning optimal schedules for medical staff or for limited resources, such as operation rooms or lab equipment.

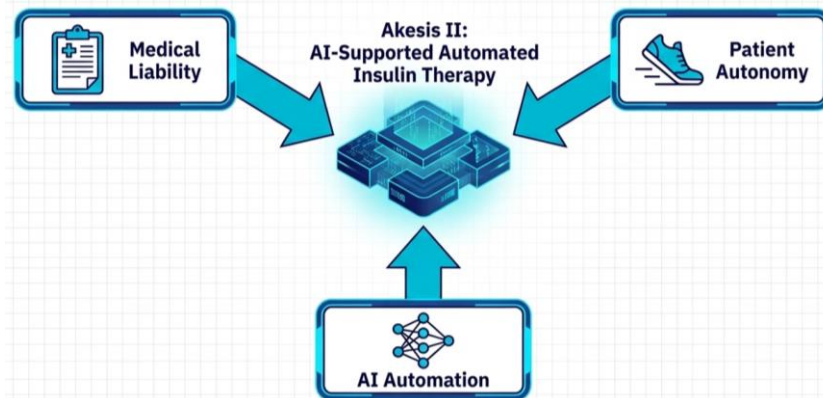


Figure 2: Stakeholder perspectives on a Closed-loop insulin dosage system, with AI functions [3].

The use case closed-loop insulin dosage [3] highlights the tension between:

- (i) Patient Autonomy and Quality of Life: The patient's desire for flexible daily activities and automated, seamless insulin dosing.
- (ii) Medical Liability and Safety: The strict regulatory, legal, and clinical requirements to prevent hypoglycemia/hyperglycemia and ensure deterministic safety boundaries.

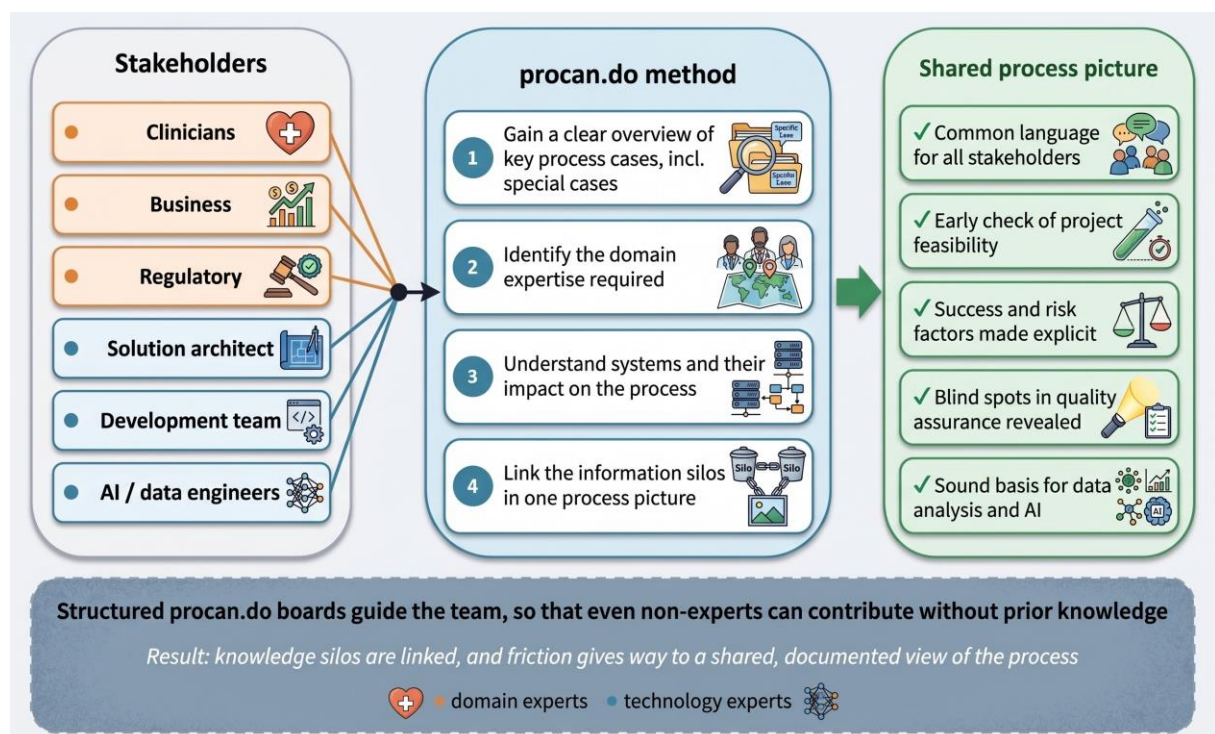


Figure 3: The procan.do method links the stakeholders' knowledge silos into a shared process picture [2].

Tasks

Depending on whether this project is conducted as an individual thesis or a team project, the tasks include model and method development and validation for a tutorial on:

- **Requirement Clarification:** Clarifying and formalizing medical requirements and acceptance criteria (taking the role of a product owner or working with a product owner).
- **Socio-Technical Environment Analysis:** Analyzing the dependencies between the software application and its socio-technical environment [2].
- **Software Architecture & Design:** Designing the software application using C4 architecture modeling and Behavior-Driven Development (BDD) scenarios (Given-When-Then format) [1].
- **Implementation:** Implementing the core software application components.
- **Validation:** Testing and validating the software application within its intended target context.

Expertise

This project is suitable for students who have prior knowledge or a strong interest in developing their capabilities in at least two of the following areas:

- Software Engineering & Requirements Engineering
- Model-Based Engineering (MBE), e.g., SIAM [1], C4 architecture modeling.
- Medical Informatics & Healthcare Domain Concepts

For this topic, a set of skills is recommended (at least two are mandatory).

- Web application development: Java/Spring Boot or TypeScript/Angular.
- UI/UX design, usability evaluation and accessibility (WCAG 2.2 AA).
- Software testing and quality assurance.
- LLMs and AI agents: prompting, tool use, MCP, agentic workflows.
- Simulation, data analysis and empirical evaluation, e.g., experiments or user studies.
- DevOps: CI/CD, Docker, databases.
- Interest in production planning, industrial engineering or teaching.

References

- [1] Biffl, S., Bein, T., Kropatschek, S., Meixner, K., Lüder, A. (2026) [SIAM DSL: Accessible Structured Text for Bridging the Architecture-Impact Gap in Cyber-Physical Production Systems](#). WiPIEC Journal Vol. 12, No. 2.
- [2] Biffl, S., Marhold, K., Musil, J., Meixner, K. (2026) [Business intelligence for value-based process and systems engineering and operation with procan.do](#). In: Business Intelligence for Multi-Domain Systems Engineering and Operation. Springer. > Section 5.2.x
- [3] Biffl S., Musil J. (2026) "[Problem Analysis in Simple Language with System Impact Architecture Modeling \(SIAM\)](#)", Presentation at the Int. Conf. Software Quality Days (SWQD 2026), Vienna, Austria.
- [4] Muhr E. (2026) Instantiating the procan.do Framework for Collaborative Medication Management. BSc Thesis, TU Wien.