Case Studies of Requirements Engineering for Medical Software

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Contents

- Current trends in the healthcare industry.
- Industrial Requirements Engineering challenges.
- Case Study – Health Informatics System
- Case Study – Specifications for a System for public entity.
- Best practices
The company

- World leader in healthcare IT, in-vitro and in-vivo medical devices.
- In-vivo devices such as X-ray devices, CT, MR and Ultrasound scanner.
- In-vitro devices such as blood, nucleic acid and near patient testing.
Business Trends and challenges

- Rate of innovation is increasing

- Increasing competition leads to pressure for higher efficiency.

- Challenges with regards to regulatory approval/compliance (FDA)

- Solution development fails due to insufficient requirements engineering.
Increasing rate of innovation

- 1980: Yellow bar (5 to 10) and gray bar (5 to 10)
- 1995: Yellow bar (5 to 10) and gray bar (5 to 10)
- 2005: Yellow bar (5 to 10)
RE challenges in healthcare projects

- High complexity of customer requirements.
- Unclear stakeholder expectations
- Rapidly changing technology
- Distributed teams
- Ad-hoc change management and lack to traceability
- Change of scope
## Impact of insufficient RE

<table>
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<tr>
<th>Observation</th>
<th>Business Impact</th>
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| Insufficient RE | High likelihood of project failure  
• Quality requirements not done  
• Increase rework (>50 ) |
| Lack of end to end upstream and downstream integration | Mismatch with market needs  
• Difficult to manage dev from portfolio perspective, react to changing market  
• Tracing is difficult to manage |
| Inadequate process and modelling technique | Clinical workflow requirements difficult to capture  
• Risk of implementing inadequate product features  
• Roadblock for automating dev tasks |
| Distributed teams interact inefficiently | Communicate product requirements in a global context  
• Inefficiencies in dev, expect lower quality |
| Benefits of reuse not realized | High amount of overheads and rework for variants  
• Requirements not mapped towards product lines/platforms  
• No reuse of architecture, testing or coding artifacts |
Development of Health informatics system prototype

- **Objectives**
  1. Deliver end to end high quality workflows
  2. Redesign user interface to achieve optimized usability

- **Description**
  1. 40 staff, 6 scrum teams – requirement engineer, UI designer, architect, developer, product manager, clinician
  2. Rapid prototyping jot JIT requirement development.

- **Deliverables**
  1. 15 end to end workflows implemented
  2. 160000 loc in java
  3. Novel UI for admin workflows
Flowchart

- **Start**
  - Business scope def
  - Project planning

- **Req**
  - SW design & build
  - SW features (DS)
  - SW req

- **UI**
  - UI design
  - UI Guidelines
  - UI Req

- **Final release**
  - Final release

- **End**
  - SW process improvement

- **Output**
  - output

- **Feedback**
  - feedback

- **Draft storyboard (DS)**
  - Draft storyboard (DS)

- **Business features (DS)**
  - Business features (DS)

- **Use cases (DS)**
  - Use cases (DS)
Challenges addressed:

- Medical workflow capture and visualization
- Communicate product req in a global context

Benefits:

- Reduced time to market
- Quick capture of medical workflow
Results

- Use storyboards to capture clinical workflows

- Outcomes learned
  - Establish storyboards as an artifact to serve as requirement, UI and test artifact.
    - Allows to map successful paths and failure paths
  - Review requirements with different stakeholders
  - Challenge evolution/changing scenarios
Case study 2: Public system

- Objectives
  - Develop high quality system requirement specs
  - Define RE approach including process, tools, skills

- Description
  - 4 requirement engineers to deal with more than 5000 requirements.
  - Distributed teams
  - High value project.

- Deliverables
  - System Requirement Specification
  - RE management plan

- Approved specifications will allow development team to streamline work and reduce risk.
Challenges with feature hierarchy and dependency relationships

- High complexity
- Distributed teams
- Lack of traceability/ ad-hoc change of management
- Outcomes learned
  - Late changes are expensive
  - Understanding feature dependencies and complexities is key
  - Several iterations needed
  - Work in domain logical heirarchy
Challenges with obtaining a good understanding of customer requirements

- Change of scope
- Change in tech

Outcomes learned

- Customer does not have complete understanding of requirements
- Start with domain glossary and prototyping asap
- Under promise and over deliver
Develop specifications for problem and solution space

- Requirements change as solutions are prototyped and shown to customer
- Identify risks involved in changing requirements during analysis
- Try to minimize the cost of changing requirements
- Analyze the trade-off between abstraction and detail
- Try to reduce the changes to requirements.
Challenges with consistently implementing and maintaining traceability

- Change in management
- Change in scope

Outcomes learned:
- Maintaining traceability yields an ROI over 5 years
- But it also needs effort that must be budgeted for, this will reduce overall cost in the long run
- Establish feasible traceability model from the beginning
- Insist on impact analysis, progress tracking and testing
Challenges with establishing effective RE standards and review processes

- Distributed teams
- Poor requirement quality
- Change in management
- Change in scope

Outcomes learned:

- Enforce documentation standards, industrial standards like IEEE 830 can be used.
- Value consistency, homogenise content using templates for easier documentation.
- Budget for reviews
Best RE practices for Healthcare projects

- Use storyboards for clinical workflows
- Define feature hierarchy and dependencies
- Understand the market requirements clearly
- Develop specifications for problem and solution space
- Implement traceability
- Establish effective RE standards and review processes.