Case Studies of Requirements Engineering for Medical Software

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CS 846 project Presentation

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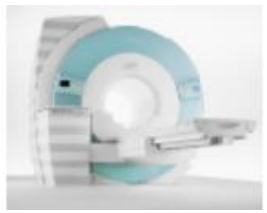
Contents

- 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 X-ray devices, CT, MR and Ultrasound scanner
- In-vitro devices such as blood, nucleic acid and near patient testing.







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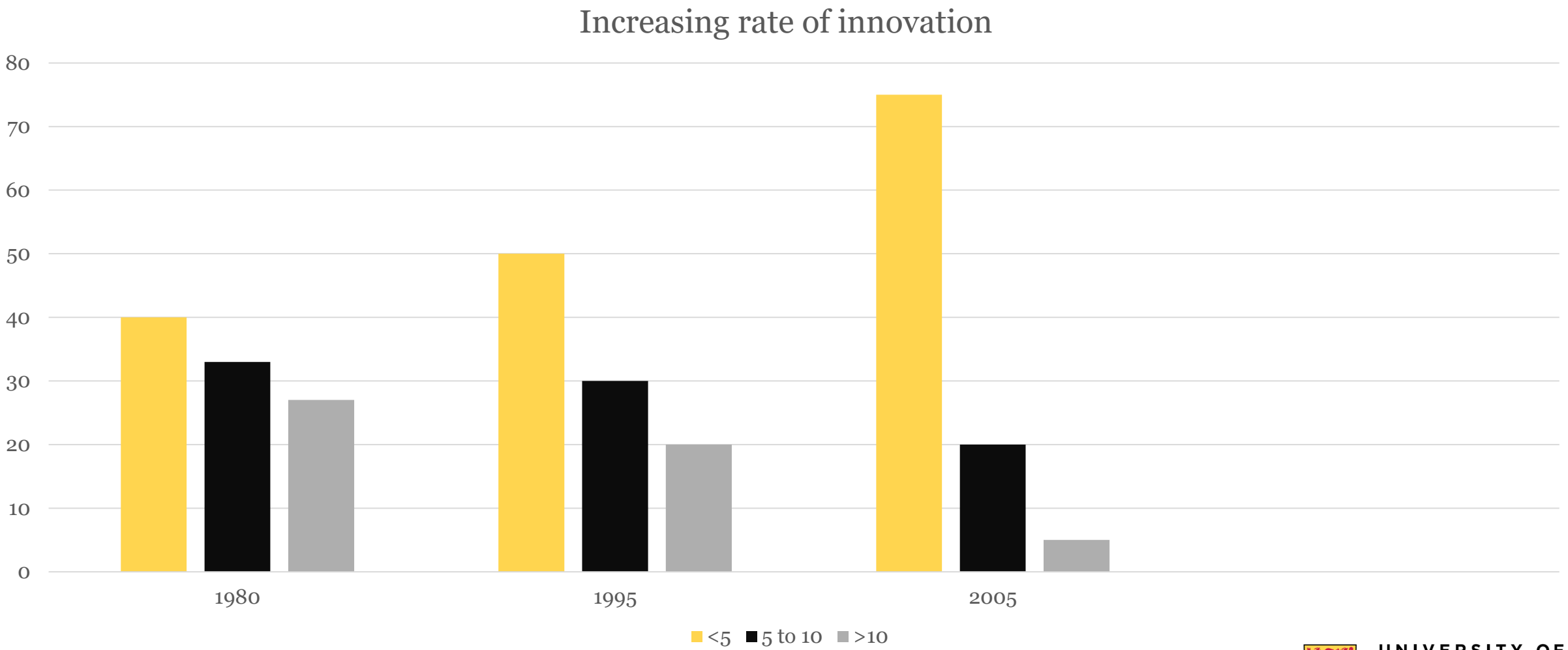
Business Trends and challenges

- 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
80
70
60
50
40
30
20
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0
1980
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5 to 10
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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

Observation	Business Impact
Insufficient RE	High likelihood of project failure • Quality requirements not done • Increase rework (>50)
Lack of end to end upstream and down stream 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

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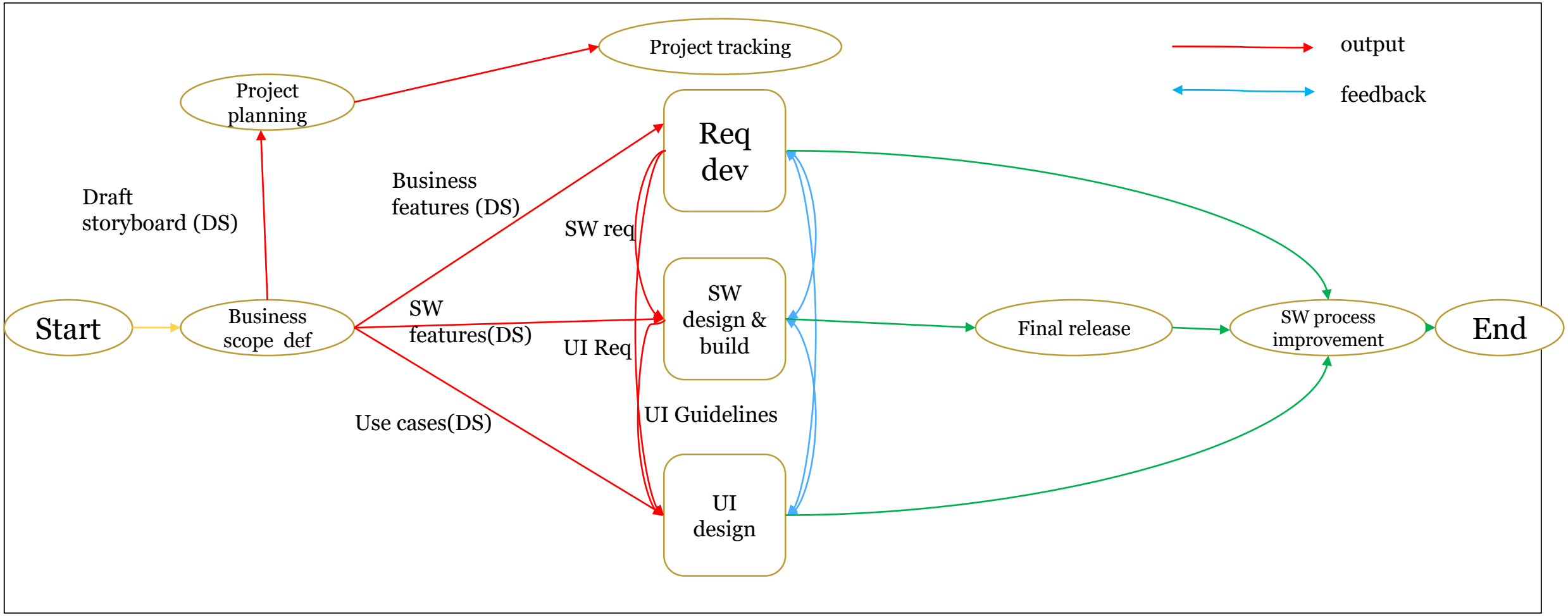
Flowchart



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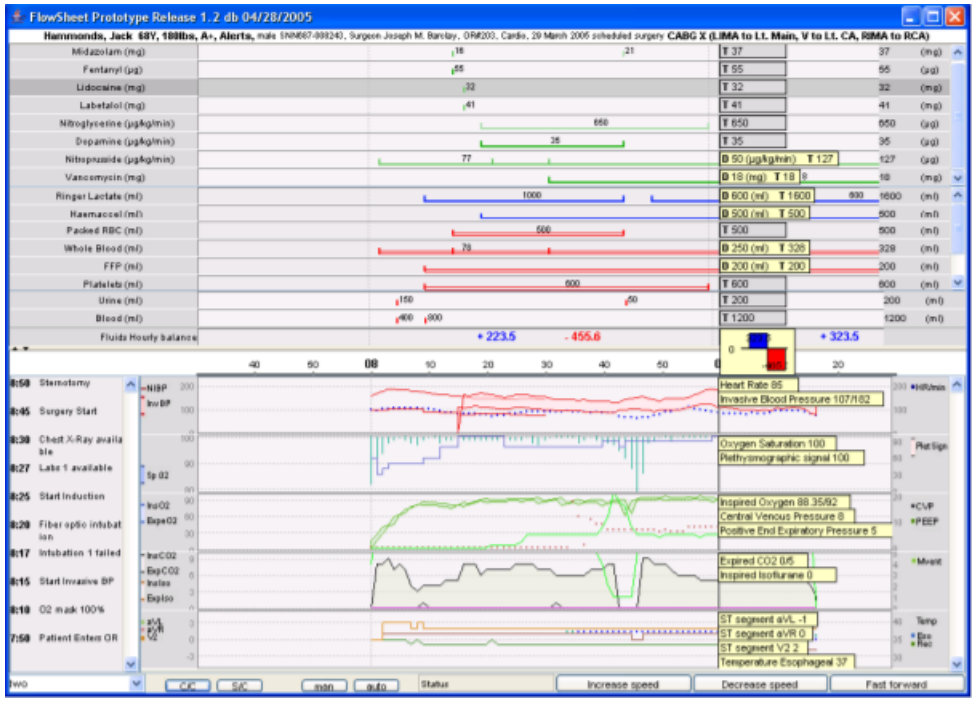
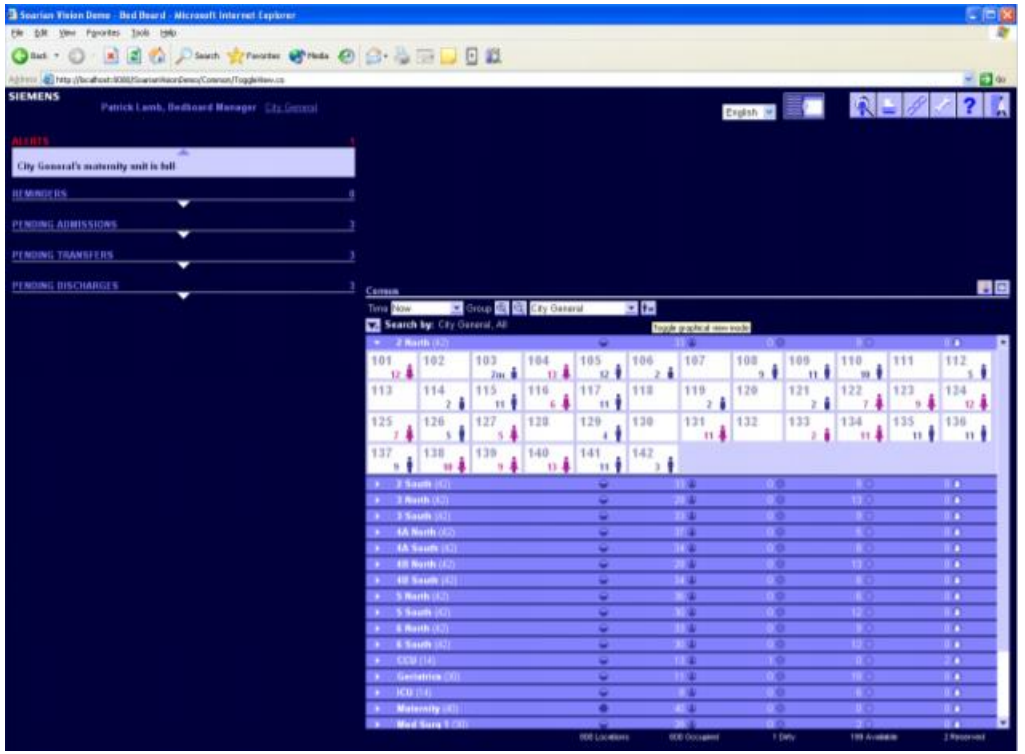
- Challenges addressed:
  - Medical workflow capture and visualization
  - Communicate product req in a global context

- Benefits:
  - Reduced time to market
  - Quick capture of medical workflow

Electronic flow sheet prototype



Bed management system prototype



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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

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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.