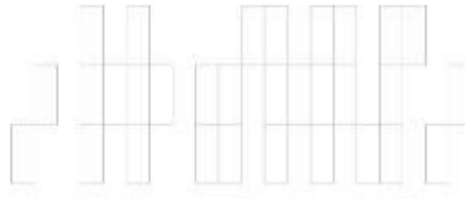


Startup of a Requirements Engineering process in the MedTech environment: Risks, opportunities and side effects.

Lukas Müller
9.4.2014



Agenda

- Tecan
- Environment / starting point
- Risks of RE process startup
- Journey through 5 prototyping steps
- Side effects and outlook

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Startup of a Requirements Engineering process in the MedTech environment



- Head office in Switzerland, >1100 employees
- Development sites in US, DE, and AT
- Market leader in lab automation
- Products and OEM-instruments in Biotechnology, Pharma, Diagnostics, Life Sciences, Forensics, etc.



Lab automation - sample to result

Sample Preparation

Analysis

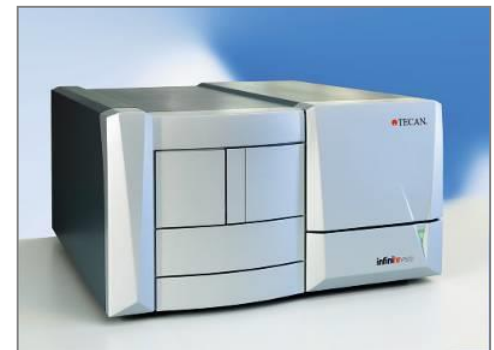
Consumables



Lab Automation



Detection

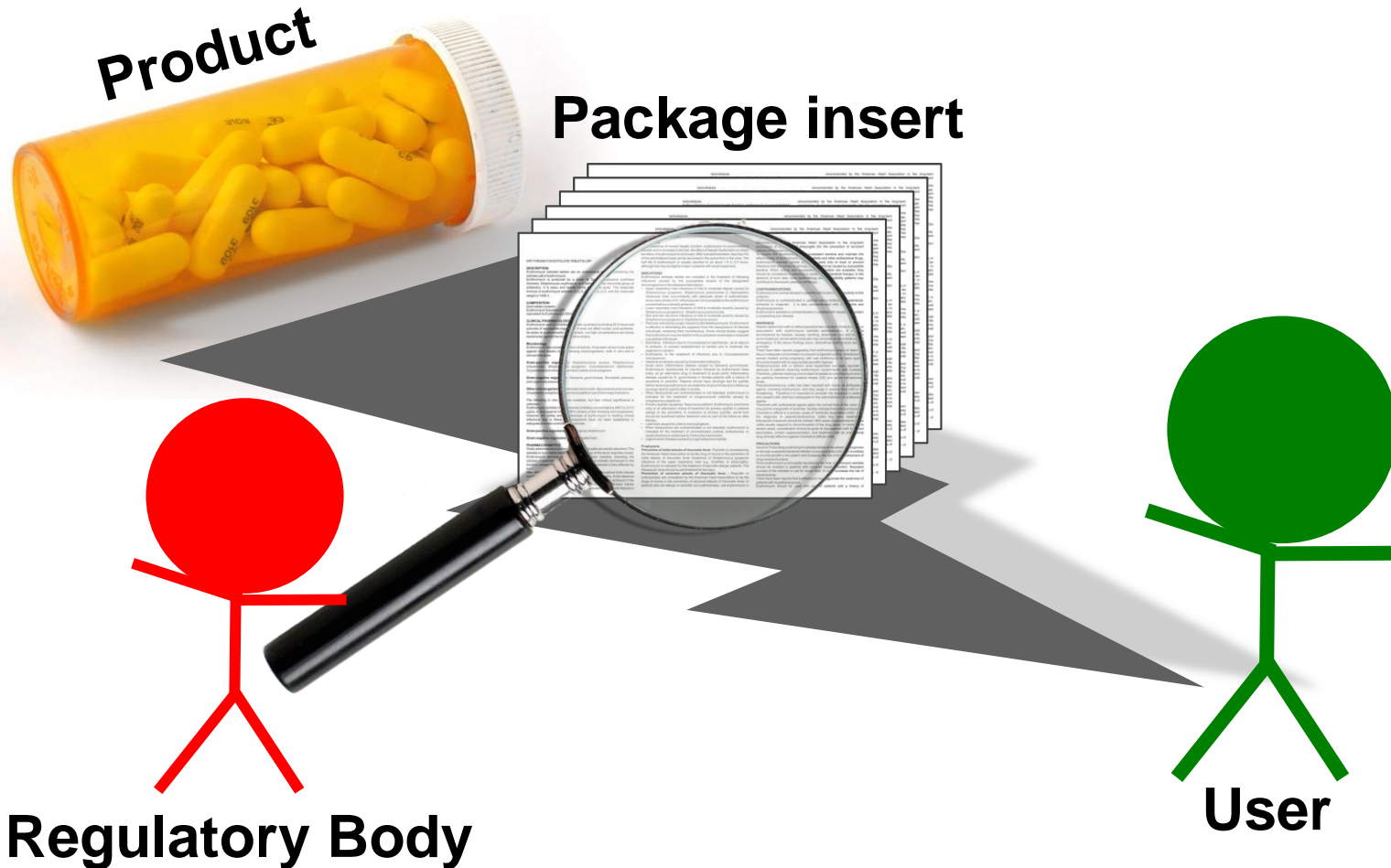


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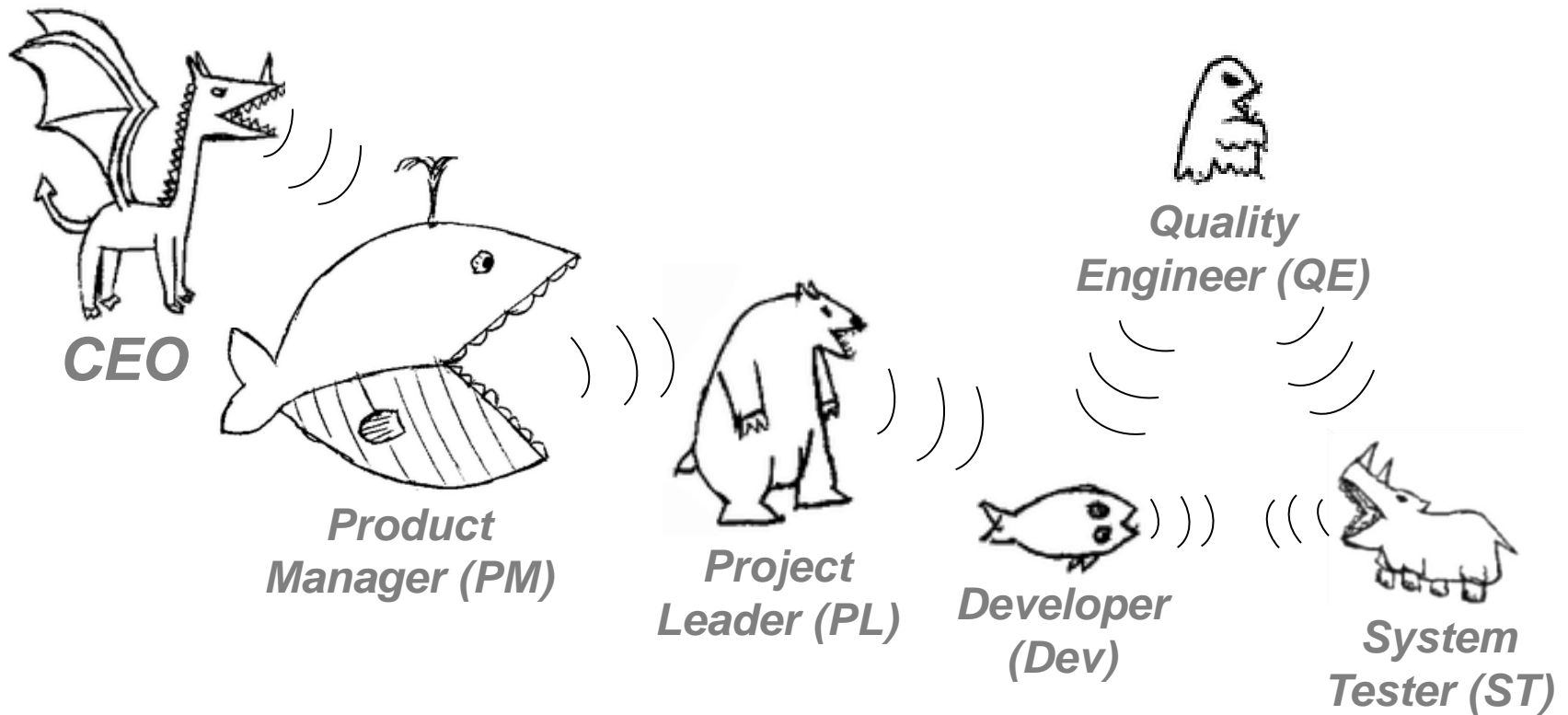
Startup of a Requirements Engineering process in the MedTech environment



A MedTech analogy...



...with MedTech species...

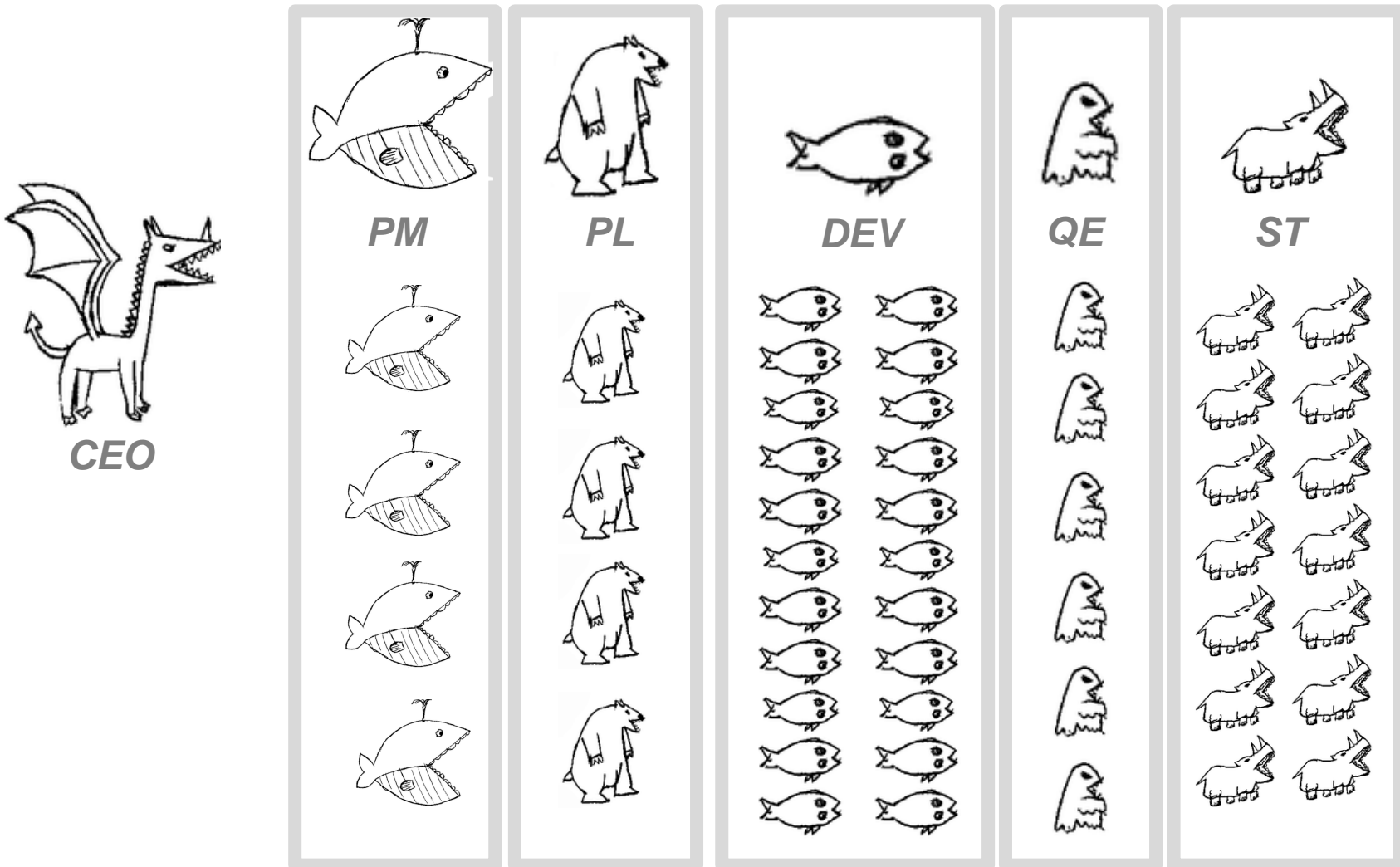


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...their tribal structure...

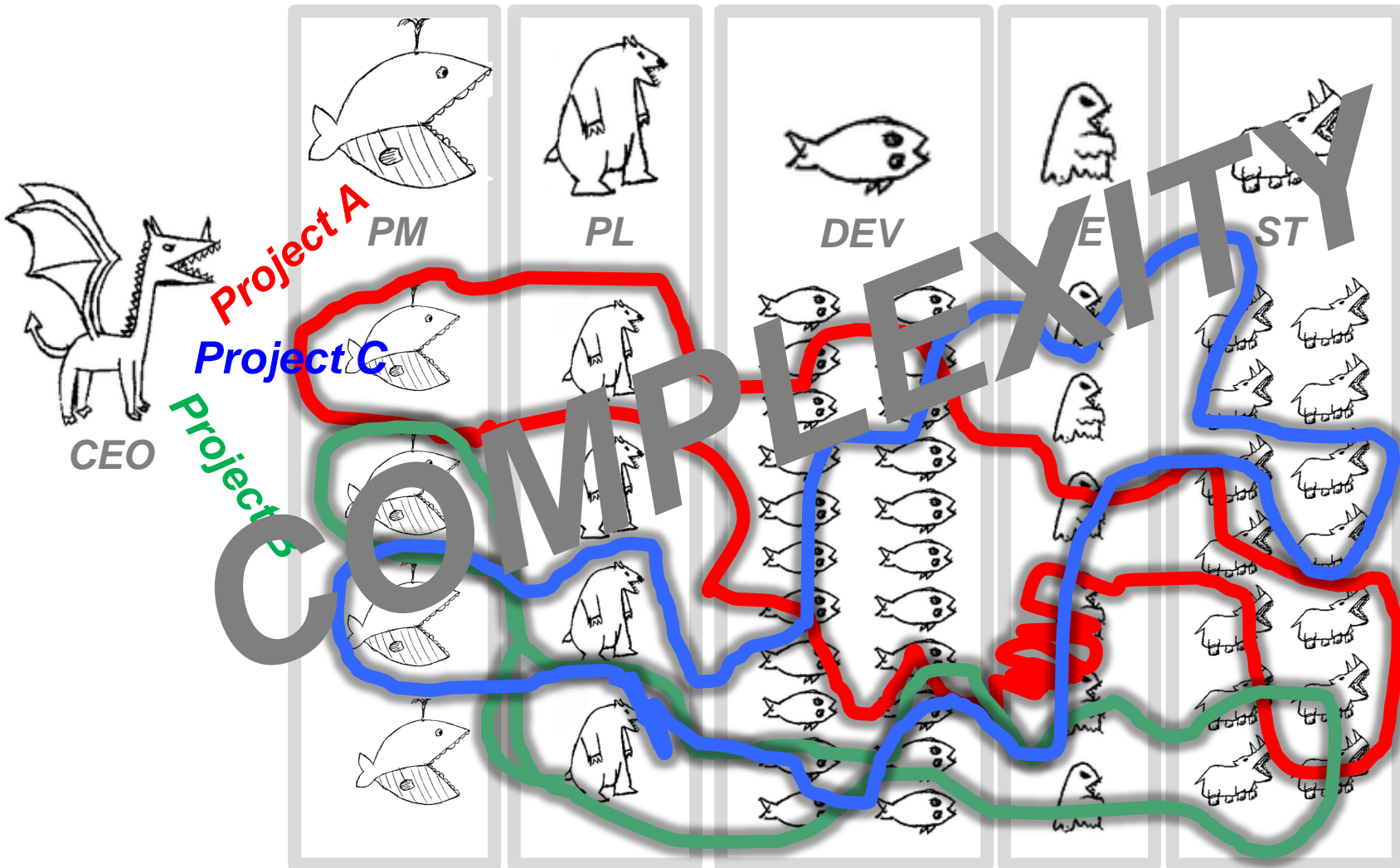


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Startup of a Requirements Engineering process in the MedTech environment

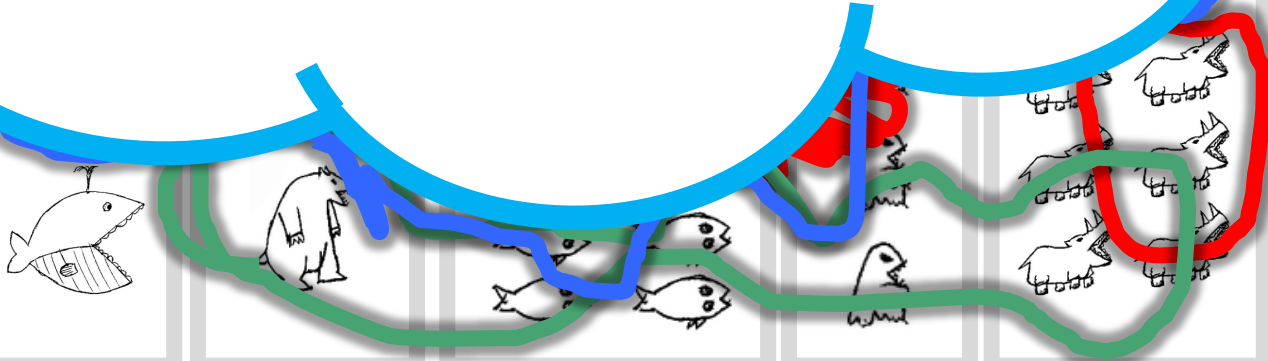


...and MedTech projects



...and then

Which are the
opportunities and
risks in the
introduction of RE???



RE startup risks – we did encounter

- **Complexity:** “I don’t want another process”
- **The wrong thing... at the wrong place:** “We are SCRUMies where RE’s write user stories.”
- **High costs:** “I already pay for 20 SW developers, 3 HW engineers and 15 testers, RE is simply too expensive”
- **No value:** “Ahm, what do you guys produce again...???”
- **No change:** “Hey, project managers can write the requirements by themselves.”
- **Inefficiency:** “Send the bullet list from our brainstorming session to the project leader for cost estimation”

RE start-up risk

What was our Vision?



sess
for cost

leader

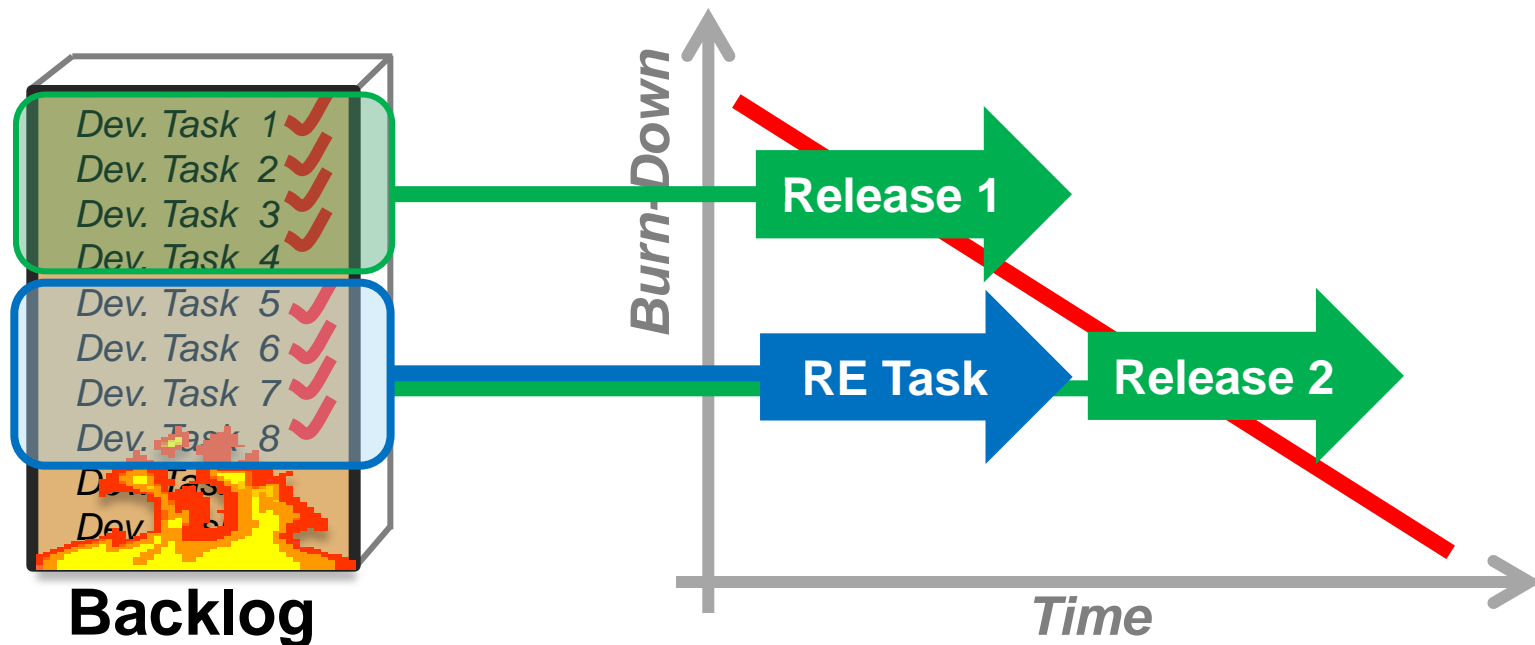
1 RE on our RE Process

- Analyze company and project environment
- Understand needs of projects and organization
- Identify key persons in projects and company
- Small steps forward

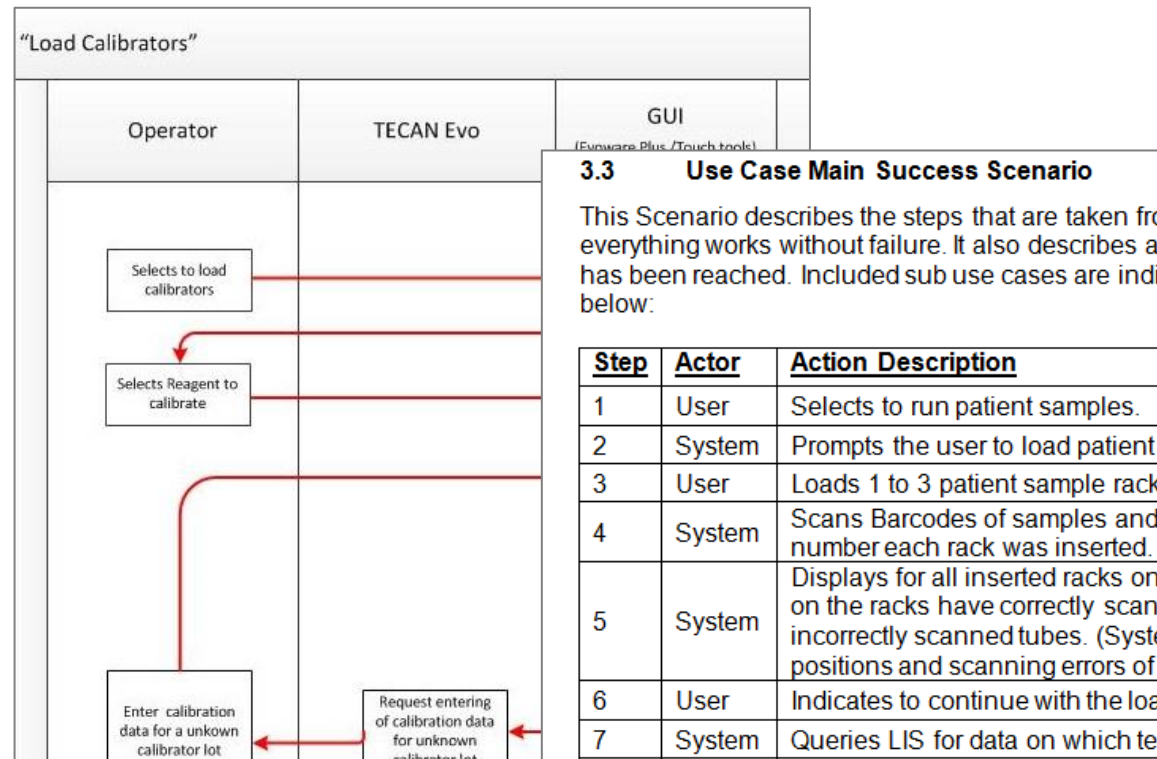


② Ongoing project – fire extinction

- Release driven Requirements Engineering (agile)
- Tool-supported traceability of requirements to task (reporting)
- Standardized requirements / UML support
- Establish change management



-



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3

RE delivers value

PRODUCT DETAILS

Customer

Prototype

Development Partner

Mocks

Design

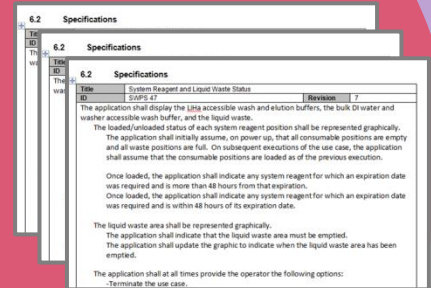
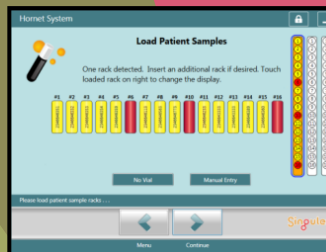
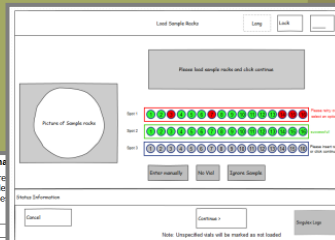
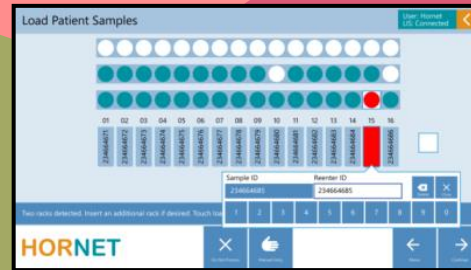
Specifications

UC Specs

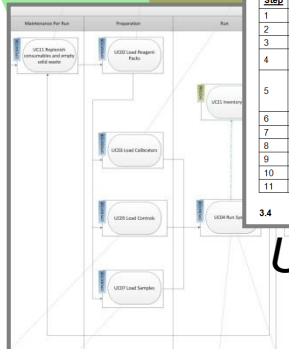
Team Tecan
(RE, PL, PM)

Processes

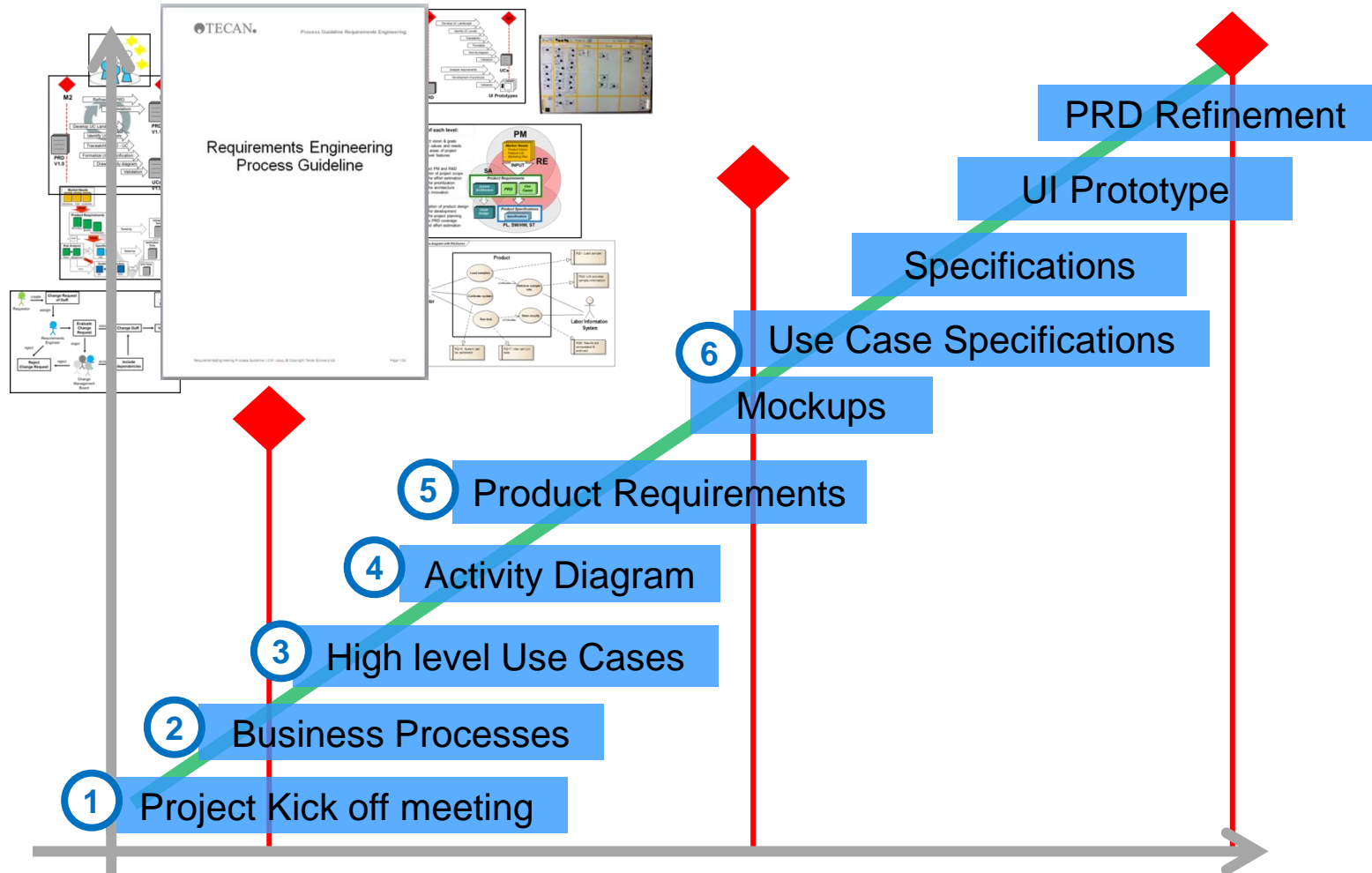
Time



3.3 Use Case Main Success Scenario		
This Scenario describes the steps that are everything works without failure. It also describes what happens if an error occurs. It also describes what happens if a sub-use case is called.		
Step	Actor	Action Description
1	User	Selects to run patient samples
2	System	Prompts the user to load patient sample
3	User	Loads 1 to 3 patient sample racks
4	System	Scans Barcodes of samples and rack numbers each rack was inserted.
5	System	Displays for all inserted racks on which of the racks have correctly scanned tubes. (System cannot detect scanning errors of a tube or rack)
6	User	Indicates to continue with the loaded sample
7	System	Queries LIS for data on which tests are to be performed
8	LIS	Sends sample test requests
9	System	Displays a summary of the tests that will be performed
10	User	Confirms
11	System	Returns to screen from which the use case was started

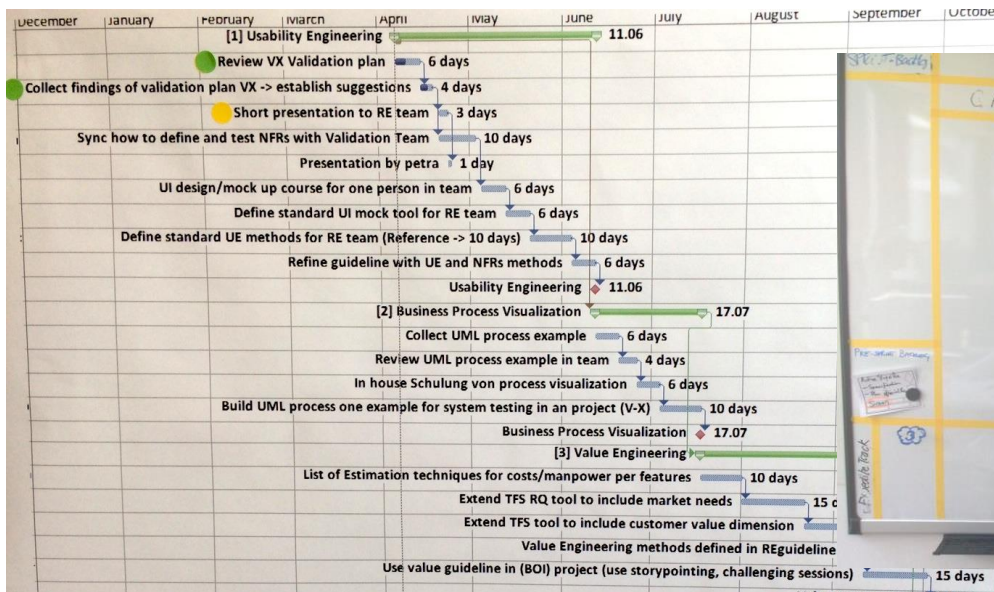
| 3.4 Use Case Scenario Alternative Flows | | |


4 RE Process Guideline



5 Management by *Agile RE*

- Task from: projects, start up and improvements
- Team commitment and transparency
- Continuous improvement cycle
- Bottom up target setting



Review of RE startup risks

- ☒ **Complexity:** Integrated in existing process by intuitive and efficient RE tool change
- ☒ **The wrong thin... at the wrong place:** Scalable RE process on system level that works across projects and disciplines
- ☒ **High costs:** Demos of success stories using a “Best practice project”
- ☒ **No value:** We use efficient, intuitive and extendible methods
- ☒ **No change:** Consulting of projects, training on RE process to RnD members, management presentation, etc.
- ☒ **Performance:** Agile RE task management process
- ☐ **Inefficiency:** Tool support (ongoing)

Side effects and outlook of RE

Established RE process...

- ...provides sprint and project structure for SW
- ...is offered as service for workshops and moderation
- ...supports the innovation (business opportunity) process
- ...provides framework for build up of Usability Engineering
- ...more focus on prioritization and value definition
- ...initiated a Global Tecan Traceability Tool Project



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Thanks a lot for your attention!

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