FGAI4H-M-053

E-meeting, 28-30 September 2021

Source:	Editors DEL2.2	
Title:	DEL2.2: Good practices for health applications of machine learning: Considerations for manufacturers and regulators – Progress Report	
Purpose:	Discussion	
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Abstract:	This PPT contains a progress report on DEL2.2	

AI4H Guideline

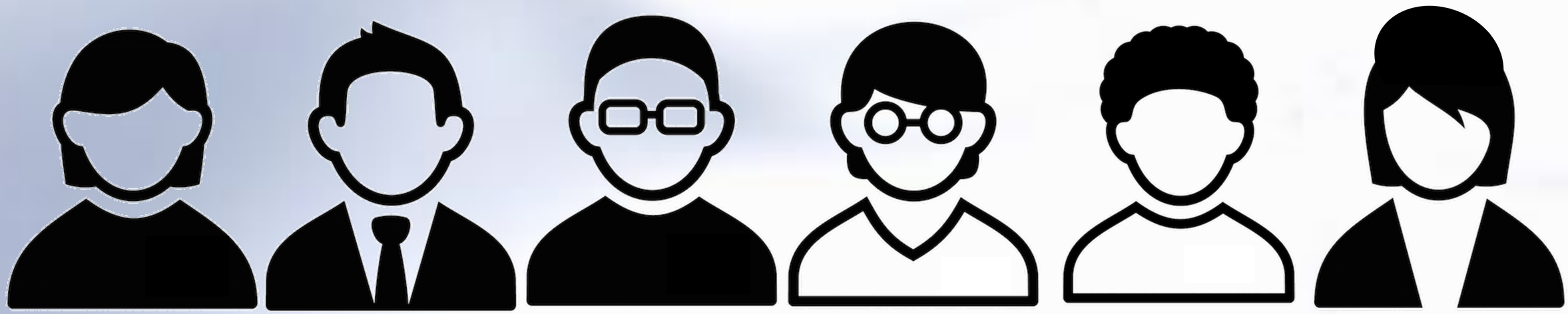
A Project Update

By Pradeep Balachandran, Luis Oala, Pat Baird, Peter Goldschmidt, Alixandro Werneck, and Christian Johner

The project consists of two parts (at least).

1. Compile checklist for regulatory compliance of AI-based systems
2. Develop a software application to maintain and use this checklist

The guideline and software address the relevant stakeholders.



Developers, Data Scientists

Regulatory Affairs

Quality Managers Auditors

(Medical Professionals)

Notified Bodies

Authorities

The guideline gives specific guidance.

5.3.1 Data collection

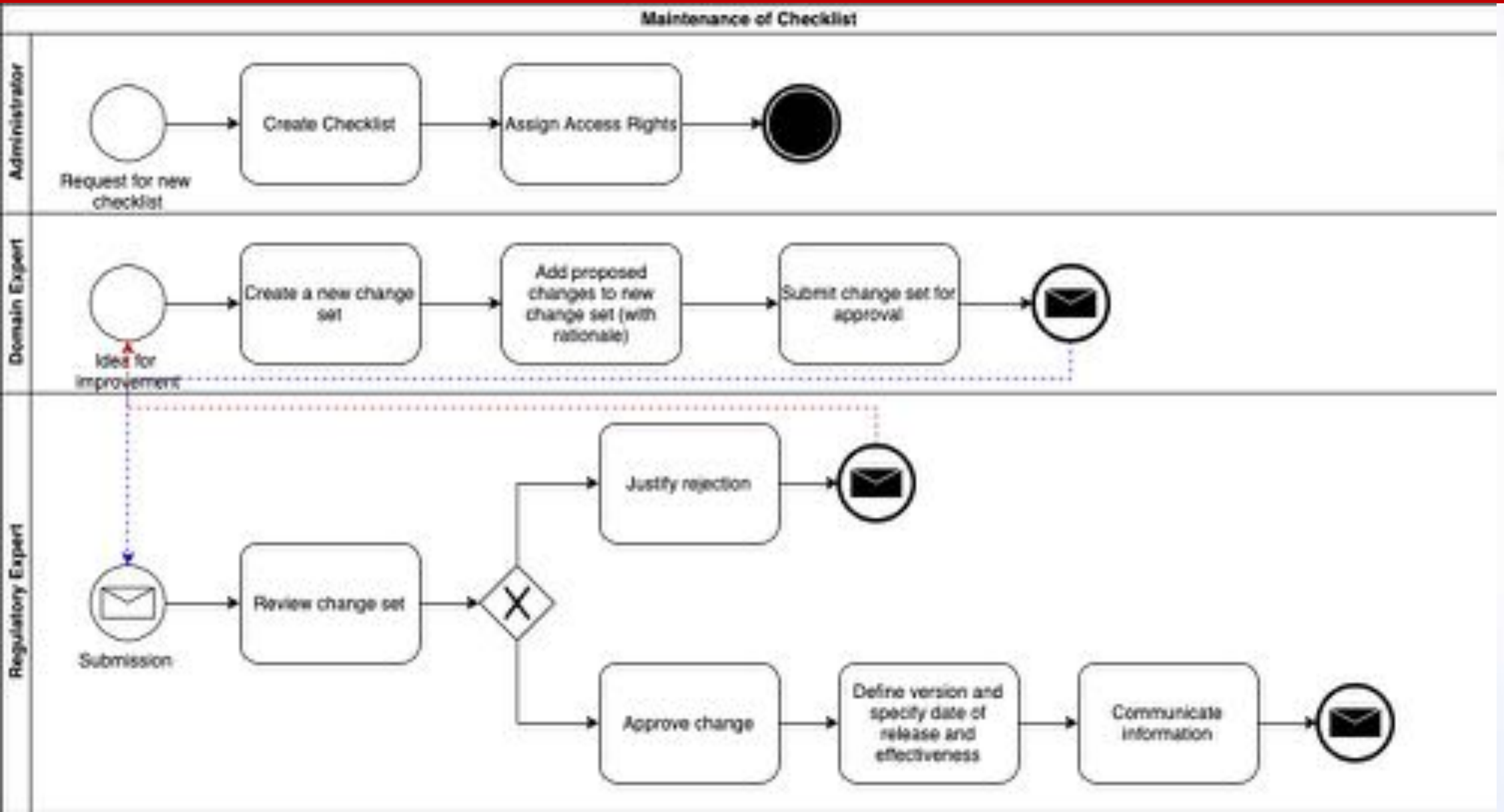
Table 11: Data collection requirements

REQ. ID	Requirement(s)	Checklist item(s)	Checklist examples and comments	Priority	Standards / Regulations applicable
DAT_CL-1	The manufacturer should specify the number of required data sets.	– There is a specification of number of data sets. – There is a rationale for this number.	The division into training, test and validation data sets is scope of chapter 5.4.1.		ISO 13485 clause 7.3.7 FDA proposed regulatory framework for modifications to AI/ML based SaMD: "statistical analysis plan"
DAT_CL-2	The manufacturer should specify the inclusion and exclusion criteria for individual data sets.	– There is a specification of technical requirements. – There is a specification of patient attributes that have to be met to include a data set.	Technical inclusion / exclusion criteria may include for each attribute: – data ranges – data type (numeric (float, integer etc.), ordinal, categorical, String / text, date / time, image / binary) – data formats (e.g. date and number formats) – unit of measure – precision of numbers – attributes values	Data Management	ISO 24028 XAVIER University "Building Explainability an Trust for AI in Healthcare"

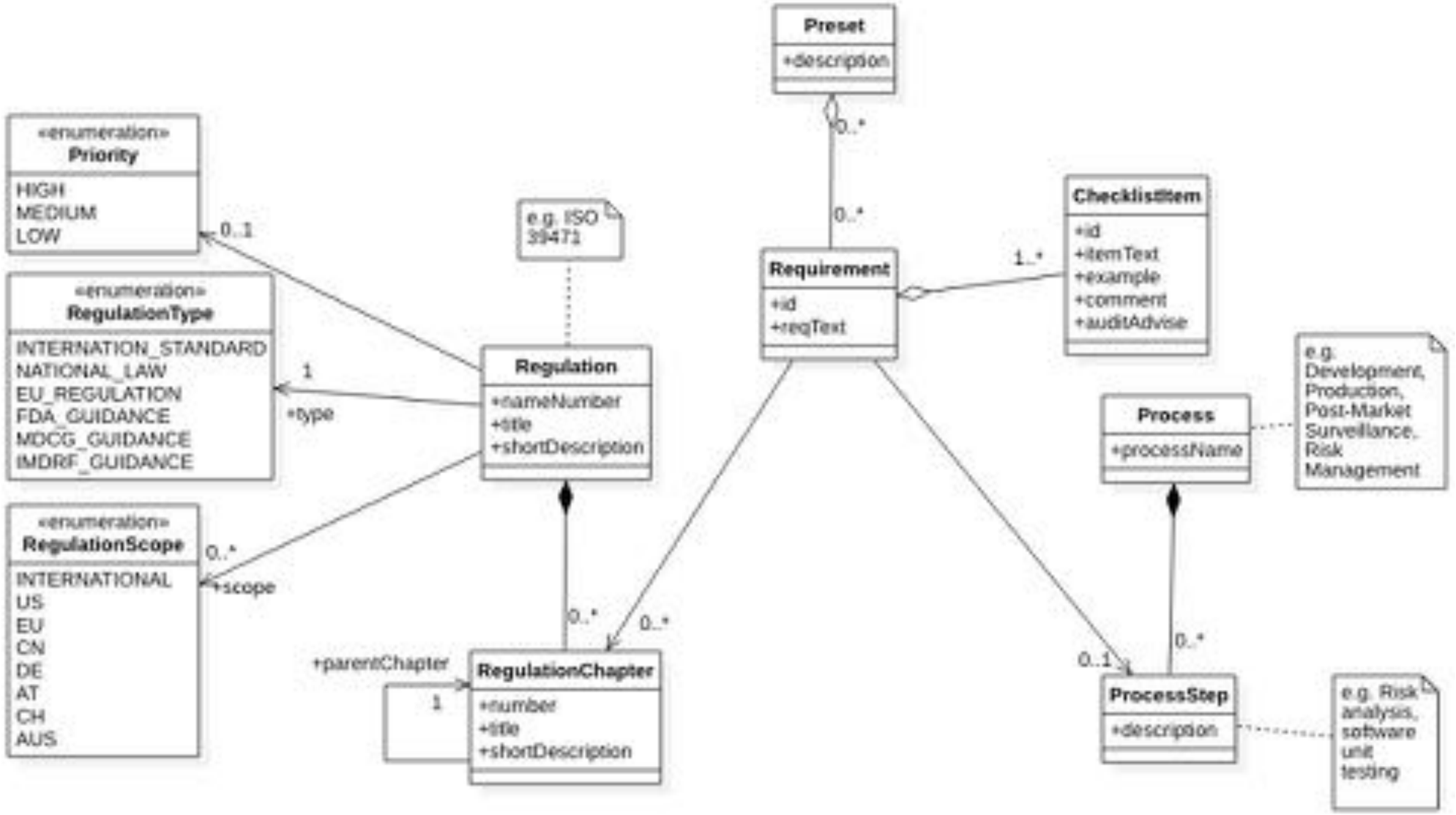
A guideline helps to apply ML in healthcare safely and compliant.

Situation	Complication	Solution
The guideline exists and is used.	There are inconsistencies and redundancies.	
Other parties develop guideline for specific medical domains.	Without updates we won't stay state of the art.	System to maintain the guideline and to compile sub-sets.
The AM/ML 'start of the art' further evolves.	There is no workflow for updating & approving changes.	
Manufacturer required approved requirements.	Time-boxed audits require definition of subsets.	

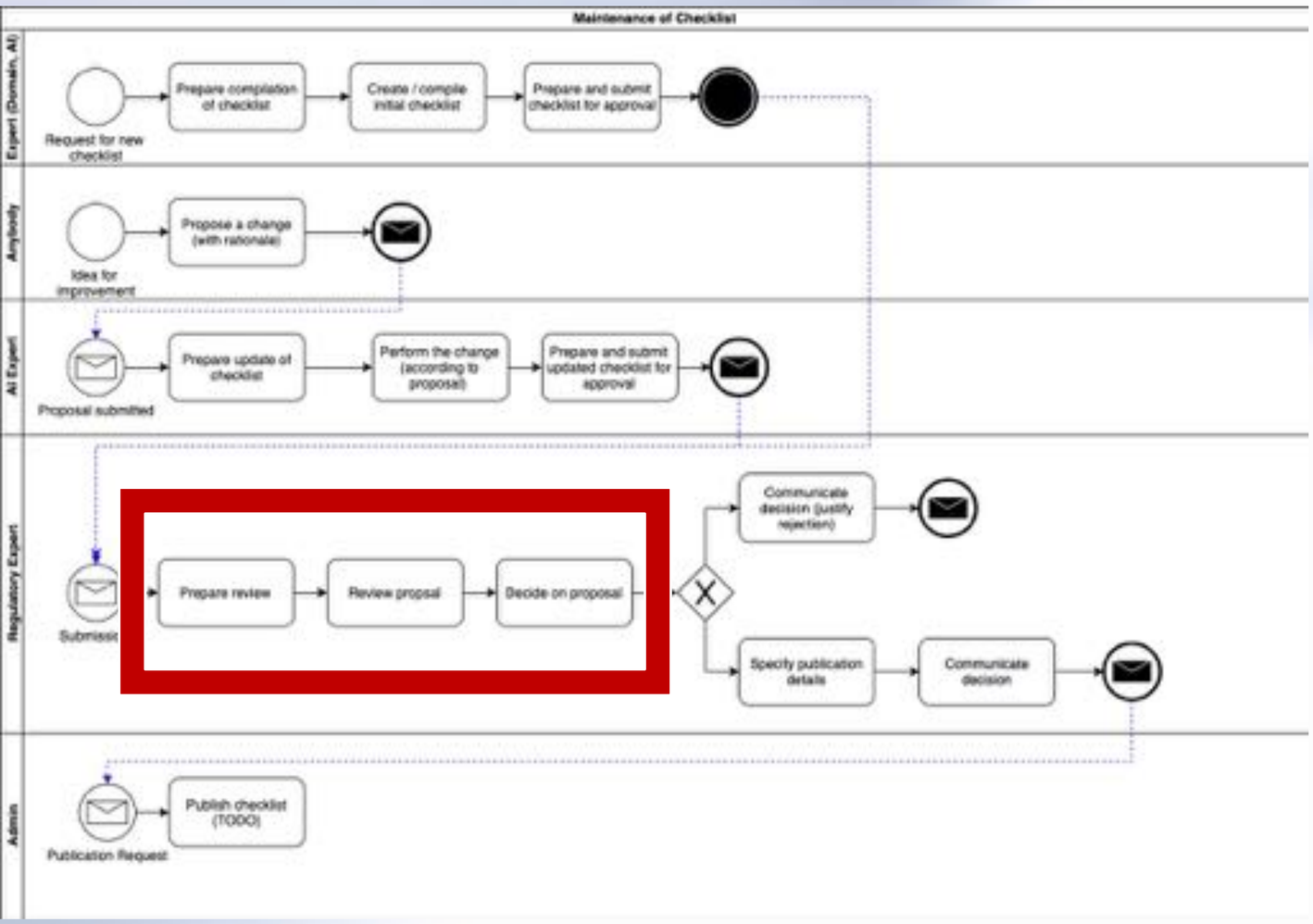
First workflows have been modelled.



The domain is modeled.



The use scenarios are modeled and the user requirements identified.



iii) Task: Review, approve or reject changes

Pre- and Postconditions

Preconditions	• A proposal for a new checklist or a change of an existing checklist exists
Postconditions	• The proposal is confirmed (and thereby ready for publication) or rejected (with comments)

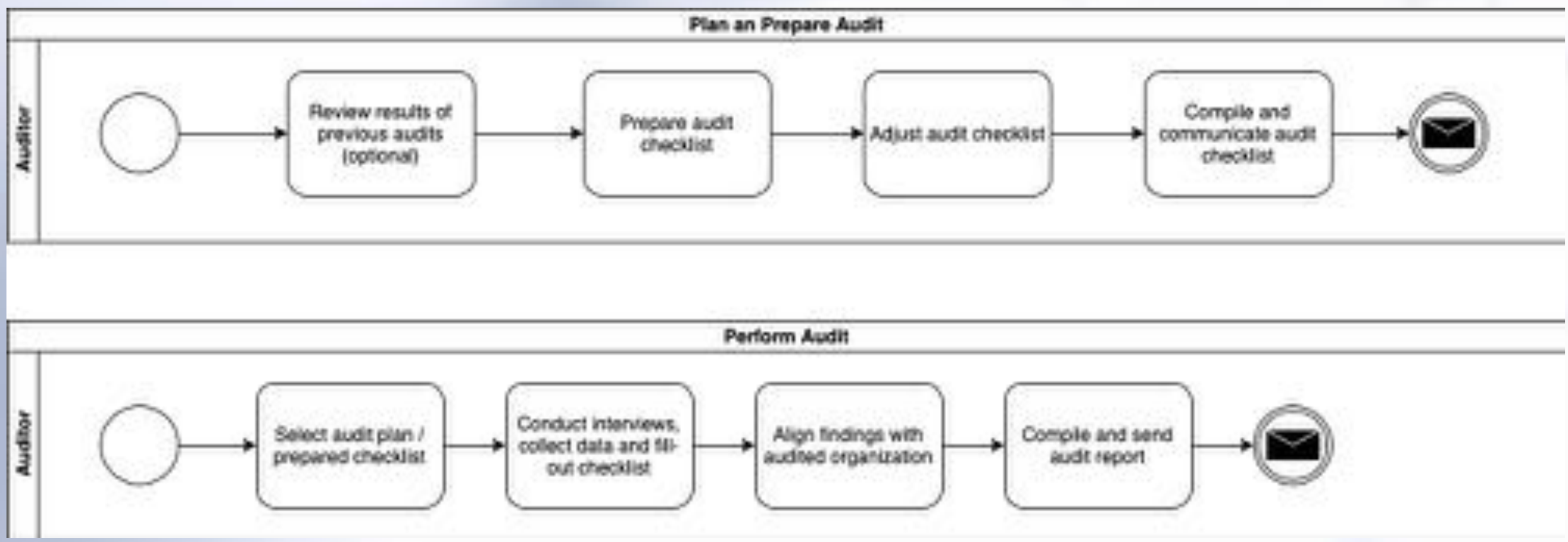
Subtasks

#	Subtask	User requirements (and additional stakeholder requirements)

1	Prepare review	The user must be able to
		• see the list of proposals with
		  ○ affected checklist (incl. topic)
		  ○ workload for review e.g. type of proposal (new, minor change, major change) or number of checklist items to be reviewed
		  ○ date of proposal
		  ○ person asking for proposal (i.e. compiling new checklist or making change request)
		• select a proposal for review

2	Review proposal	The user must be able to • see all checklist items (including the attributes mentioned above) • see what has been changed • select rating (e.g. accepted, not accepted, accepted with conditions) for each checklist item • enter comment / suggestion for

The system will support auditors and the auditing process, too.



The next steps have been defined.

Specify remaining use scenarios

Specify system (including UI/UX design)

Evaluate usability e.g. by cognitive walkthrough

Specify software architecture

Develop system