FGAI4H-L-037-A01

E-meeting, 19-21 May 2021

Source:	Editors DEL2.2	
Title:	Updated DEL2.2: Good practices for health applications of machine learning: Considerations for manufacturers and regulators – Att.1: Presentation	
Purpose:	Discussion	
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Abstract:	This PPT summarizes the content of L-037 for presentation and discussion during the meeting.	

AI4H Guideline

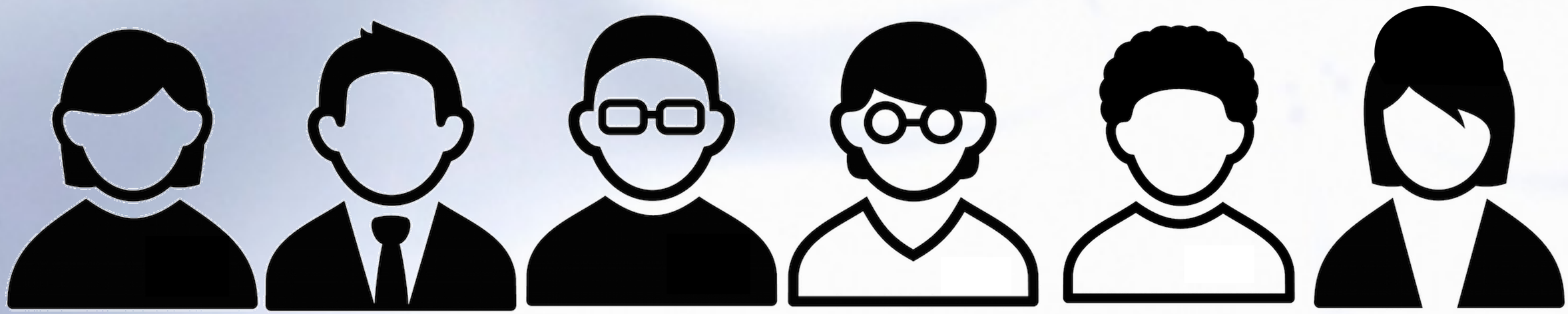
A Project Update

By Pradeep Balachandran, Luis Oala, and Christian Johner

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

Situation	Complication	Solution
Increasing use of AI/ML in Medical Devices	Patient safety at risk	Commonly agreed guideline for all stakeholders
Increasing number of AI/ML Standards, Guidelines, ...	Increasing (regulatory) complexity	
Increasing number of AI/ML related problems	Increasing confusion (manufactures, authorities, ...)	
New regulatory and technological trends	Problems in audits and approval processes	

The guideline addresses the relevant stakeholders.



Developers, Data Scientists

Regulatory Affairs

Quality Managers

(Medical Professionals)

Notified Bodies

Authorities

The guideline gives specific guidance.

5.3.1 Data collection

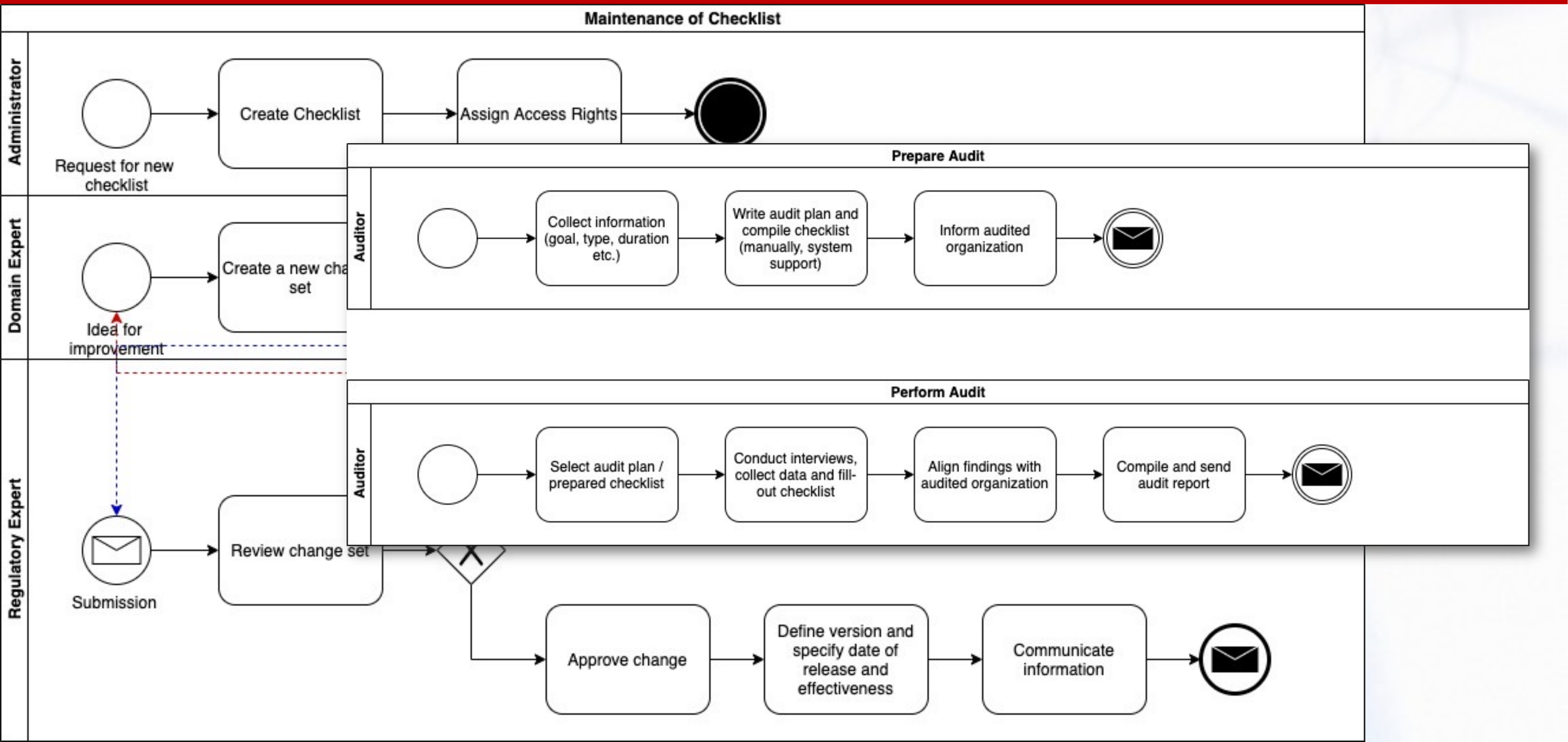
Table 11: Data collection requirements

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"

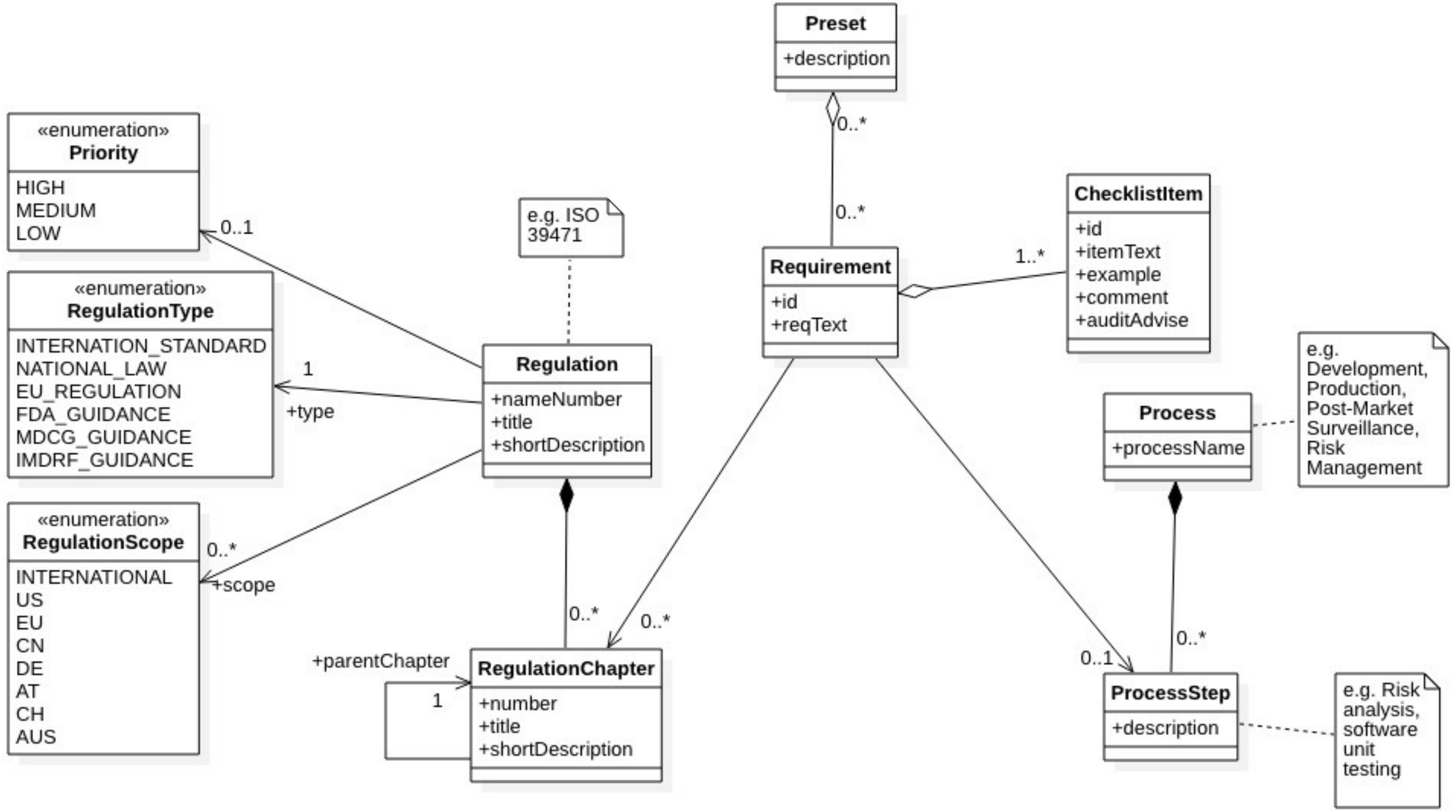
A guideline helps to apply ML in healthcare safely and compliant.

Situation	Complication	Solution
The guideline exists.	There are inconsistencies and redundancies.	
Other parties develop guideline for specific medical domains.	There is no workflow for updating the guideline.	System to maintain the guideline and to compile sub-sets.
AM/ML further evolves.	There is no workflow for approving changes.	
Other guidance documents are published.	Time-boxed audits require definition of subsets.	

First workflows have been modelled.



There is a first version of a data model to ensure consistency.



The next steps have been defined.

Finish modeling of data model.

Finish modeling of workflows.

Specify use scenarios

Specify system (including UI/UX design)

Develop system