FGAI4H-J-039-A01

E-meeting, 30 September – 2 October 2020

Source:	Editors
Title:	Updated DEL2.2 – Att.1: Presentation
Purpose:	Discussion

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Abstract: This PPT summarizes the content of J-039 with the updated text of DEL2.2 "Good practices for health applications of machine learning: Considerations for manufacturers and regulators", for presentation and discussion during the e-meeting, 30 September – 2 October 2020.

AI4H Guideline

A Project Update

By Pradeep Balachandran, Luis Oala, Sven Piechottka, and Christian Johner

Target

Contribute to medical devices with highest possible

- Safety
- Performance
- Clinical benefit

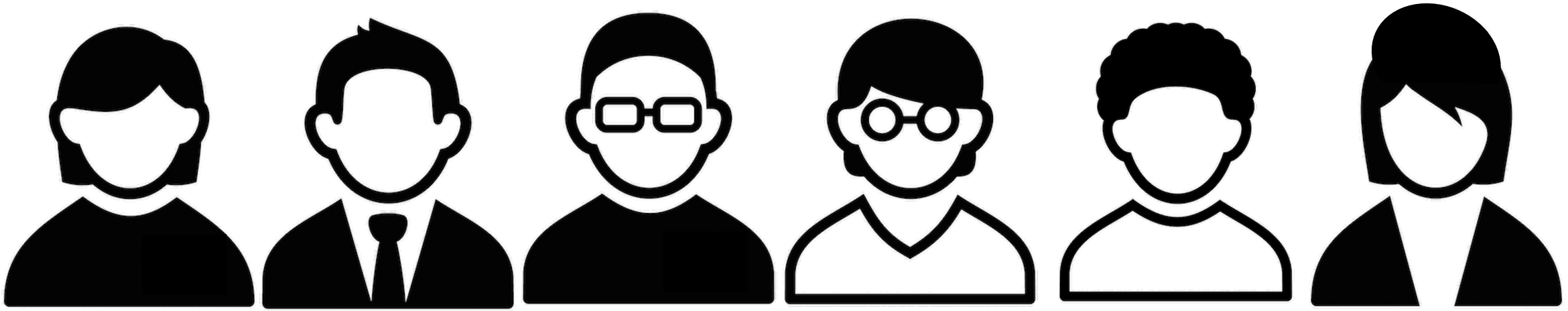
Promote common understanding of AI Best Practices

- Manufacturers
- Notified Bodies
- Authorities

Accelerate Time to Market

- Development
- Verification and Validation
- Approval

Target Audience



Developers, Data Scientists

Requlatory Affairs

Quality Managers

(Medical Professionals)

Notified Bodies

Authorities

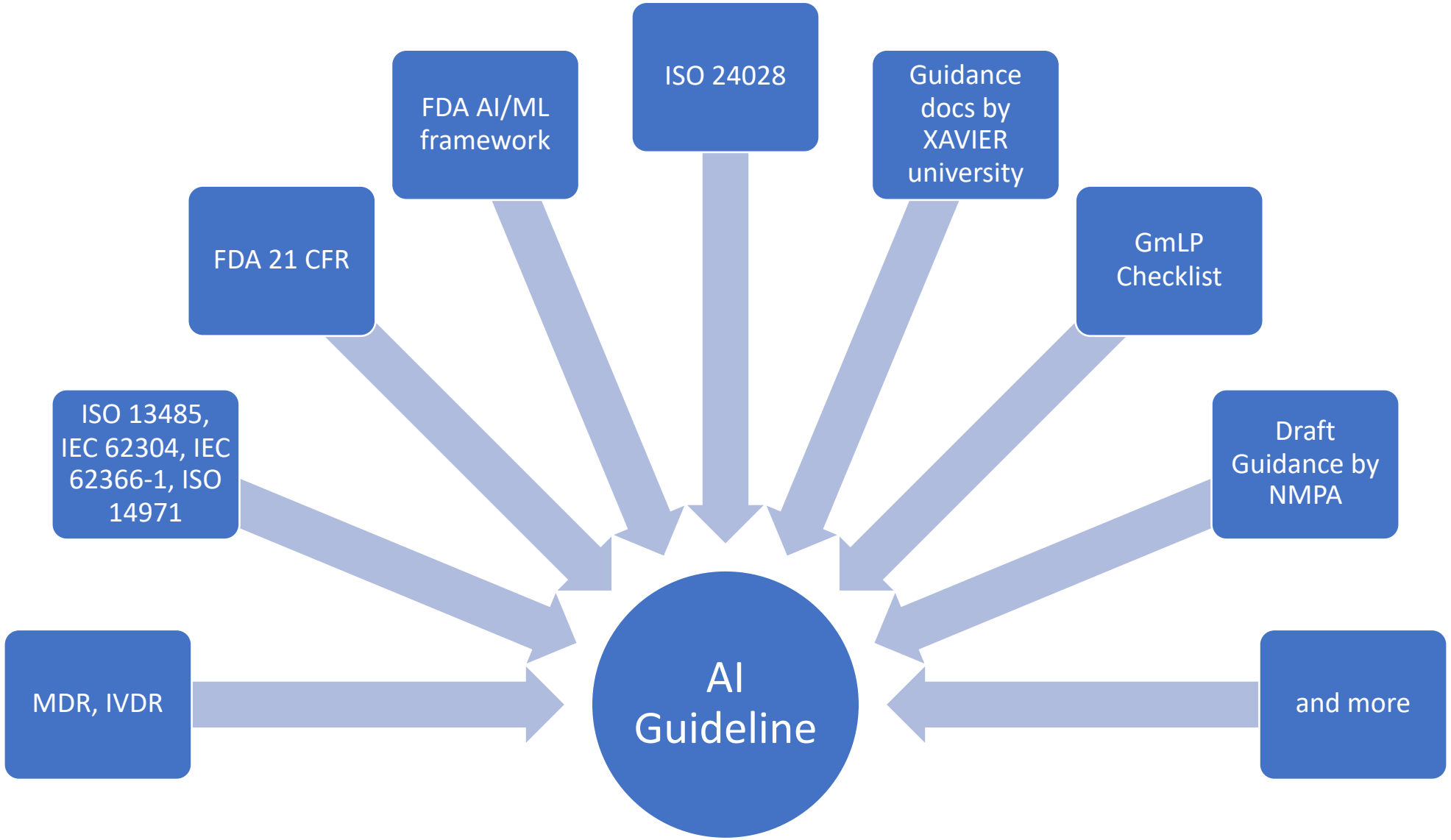
Structure, Example

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"

Included Regulations & Best Practices



Additional accomplishments

- Integration of IT security aspects
- Compilation of „marketing flyer“
- Alignment with guideline by German Notified Bodies (NBs)
  (this NB guideline builds on the roots of our guideline)

IG·NB
Interessengemeinschaft der Benannten Stellen für Medizinprodukte in Deutschland

die Anwendung der Verfahren des maschinellen Lernens ergeben?	4.4.
➢ Hat der Hersteller die Risiken analysiert, die sich ergeben, wenn andere als die spezifizierten Nutzer das Produkt nutzen?	• ISO 14971, 5.
➢ Hat der Hersteller die Risiken analysiert, die sich durch die Nutzung in einer anderen als der spezifizierten Nutzungsumgebung ergeben?	• 2017/745/EU Anhang 1 Nr. 14.2. Buchstabe d • ISO 14971, 5. • IEC 82304, 4.1. c
➢ Hat der Hersteller die Risiken analysiert, die sich ergeben durch Inputs, die nicht den spezifizierten Formaten genügen und/oder nicht entsprechend den spezifizierten Voraussetzungen generiert wurden?	• ISO 14971, 5. • IEC 82304, 4.1. c