



OPEN SOURCE REVOLUTION

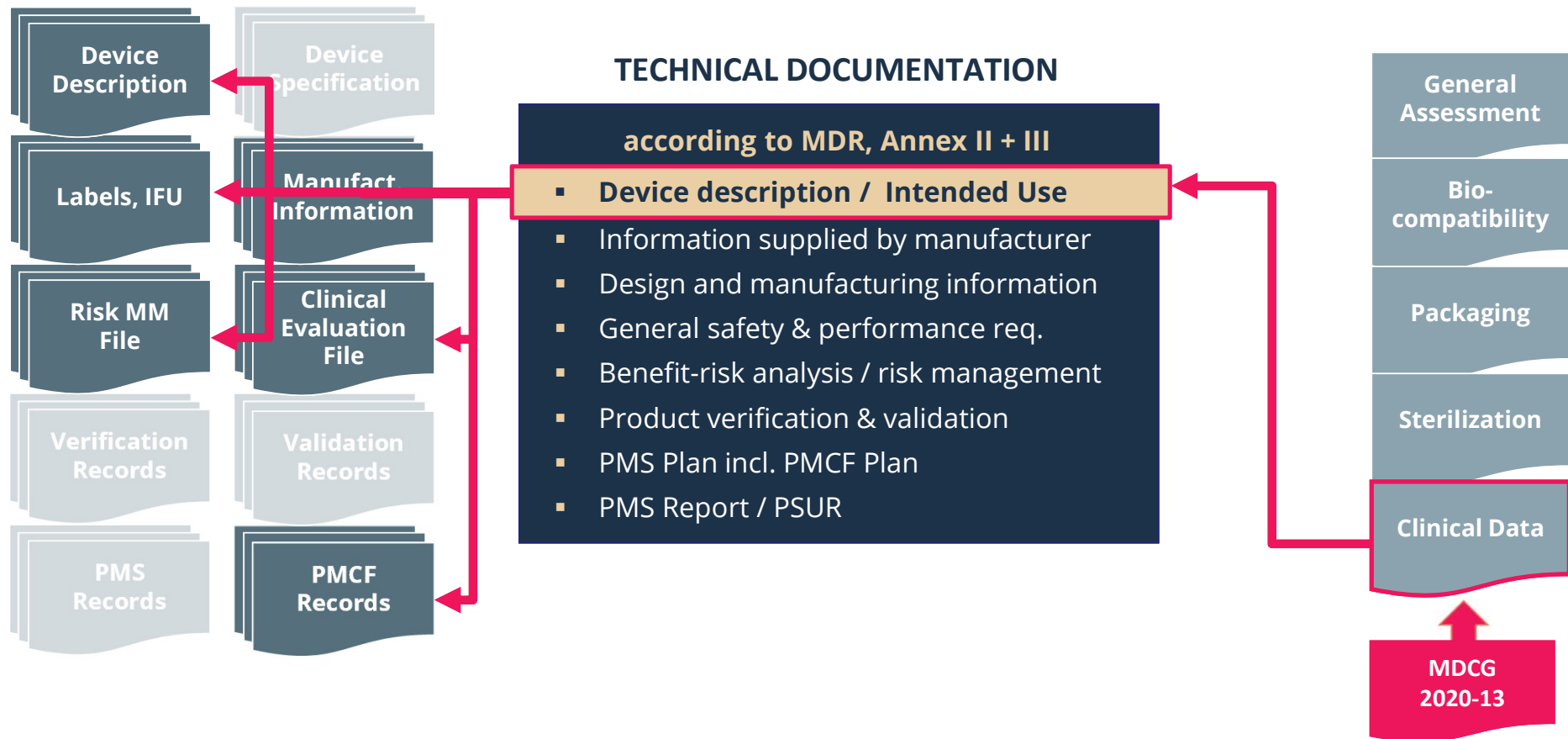


MEDICAL DEVICE KNOWLEDGE UNITS

CHALLENGE: CONSISTENCY OF INFORMATIONEN

CREATION BY MANUFACTURER

ASSESSMENT BY NOTIFIED BODY



HOW BIG IS THE POTENTIAL FOR INCONSISTENCIES?

Reuse for Product Variants!

Product
Development

Clinical
Evaluation

PMCF

Risk
Management

Usability
Engineering

PMS

37%

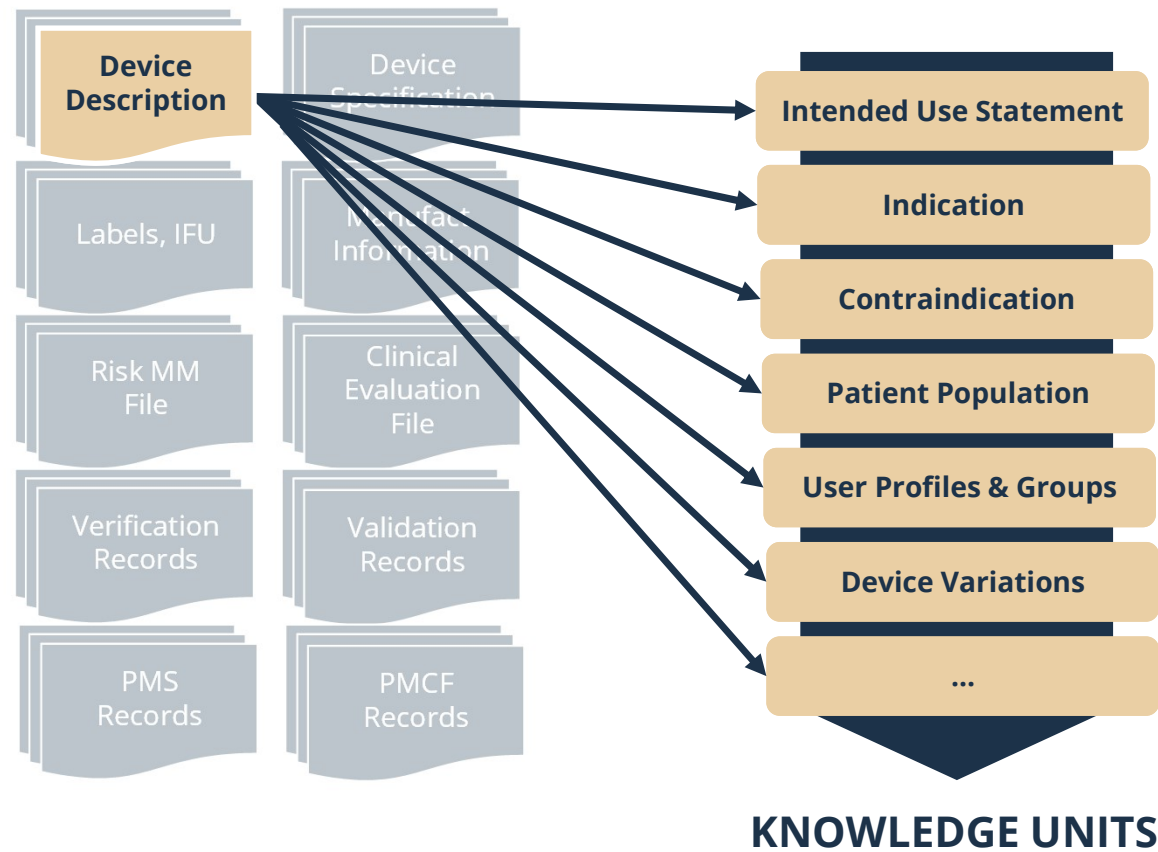
> 70%



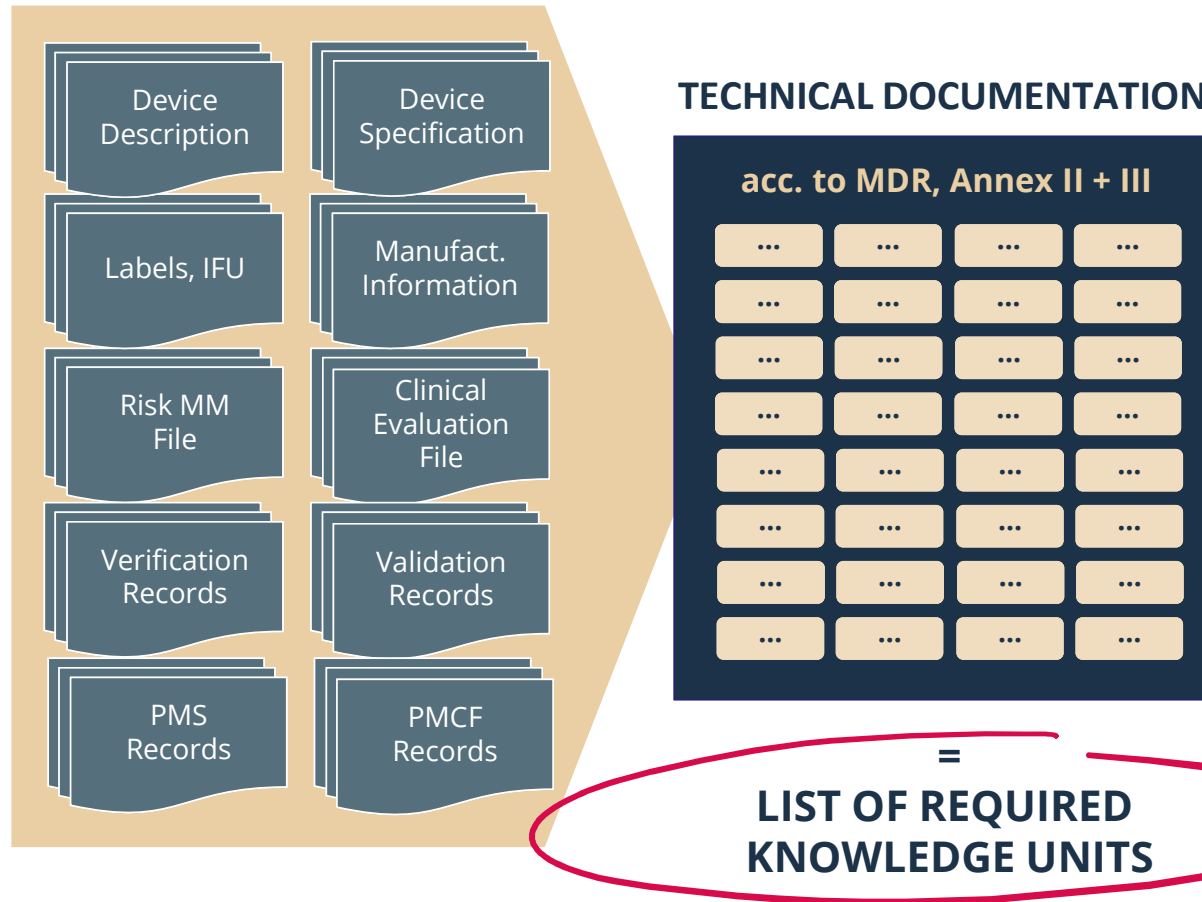
IDEA:

**UNIFIED DATA MODEL
for
TECHNICAL DOCUMENTATION
of
MEDICAL DEVICES**

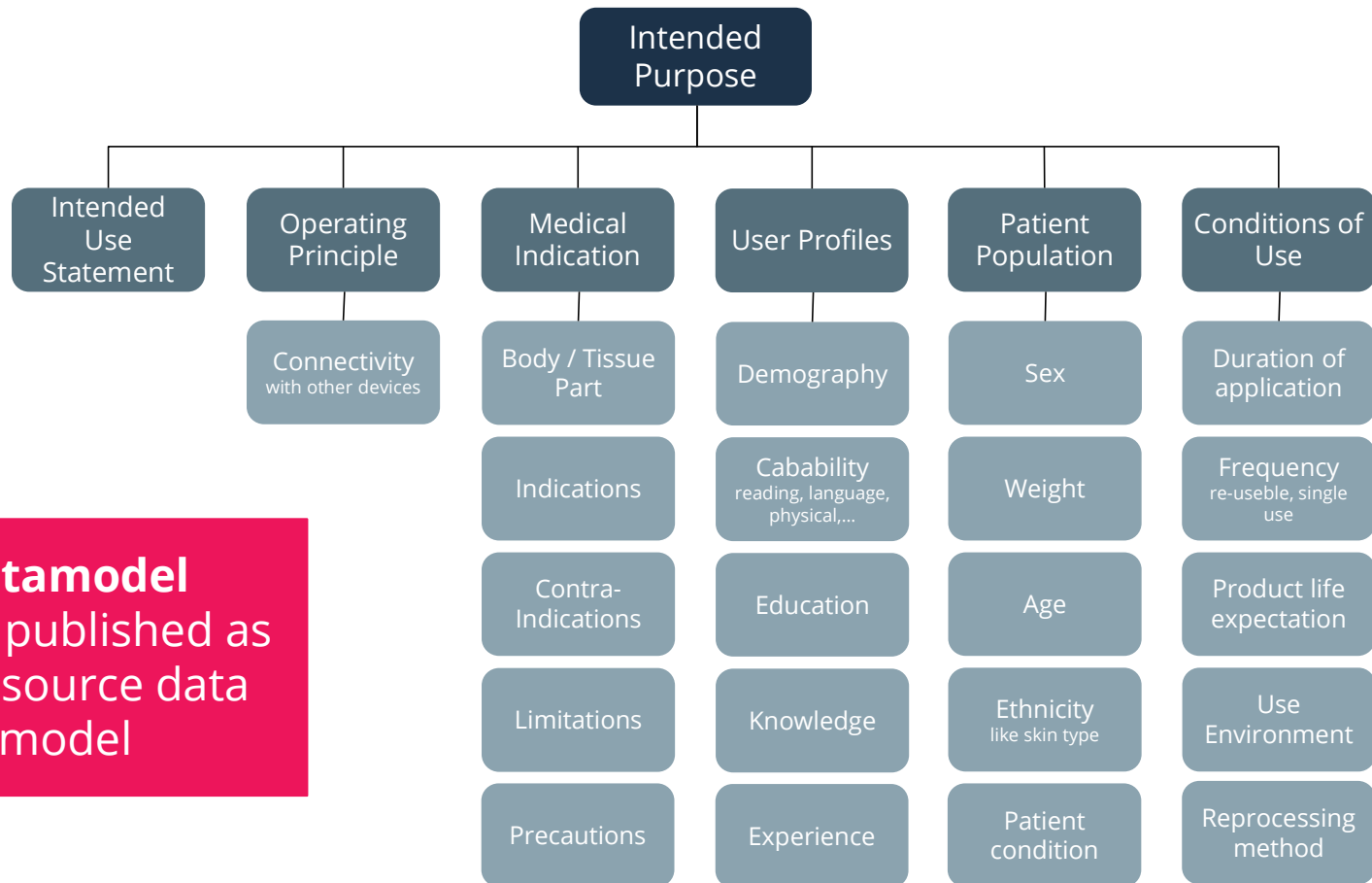
FROM DOCUMENTS TO KNOWLEDGE



FROM DOCUMENTS TO KNOWLEDGE



DATA HIERARCHY



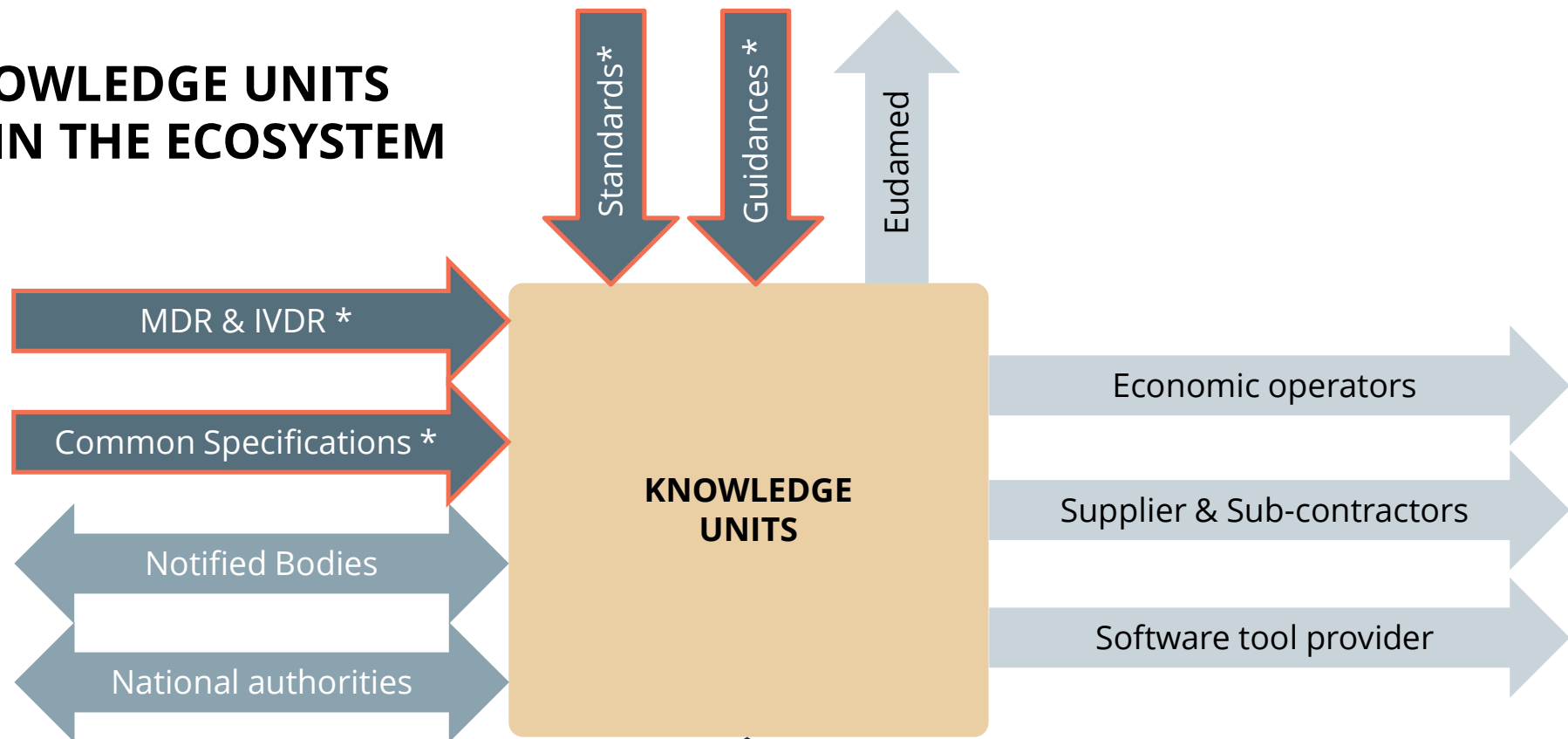
Datamodel
will be published as
open source data
model

TOPIC RELATED EXPERT GROUPS

Status 2022-07



KNOWLEDGE UNITS WITHIN THE ECOSYSTEM



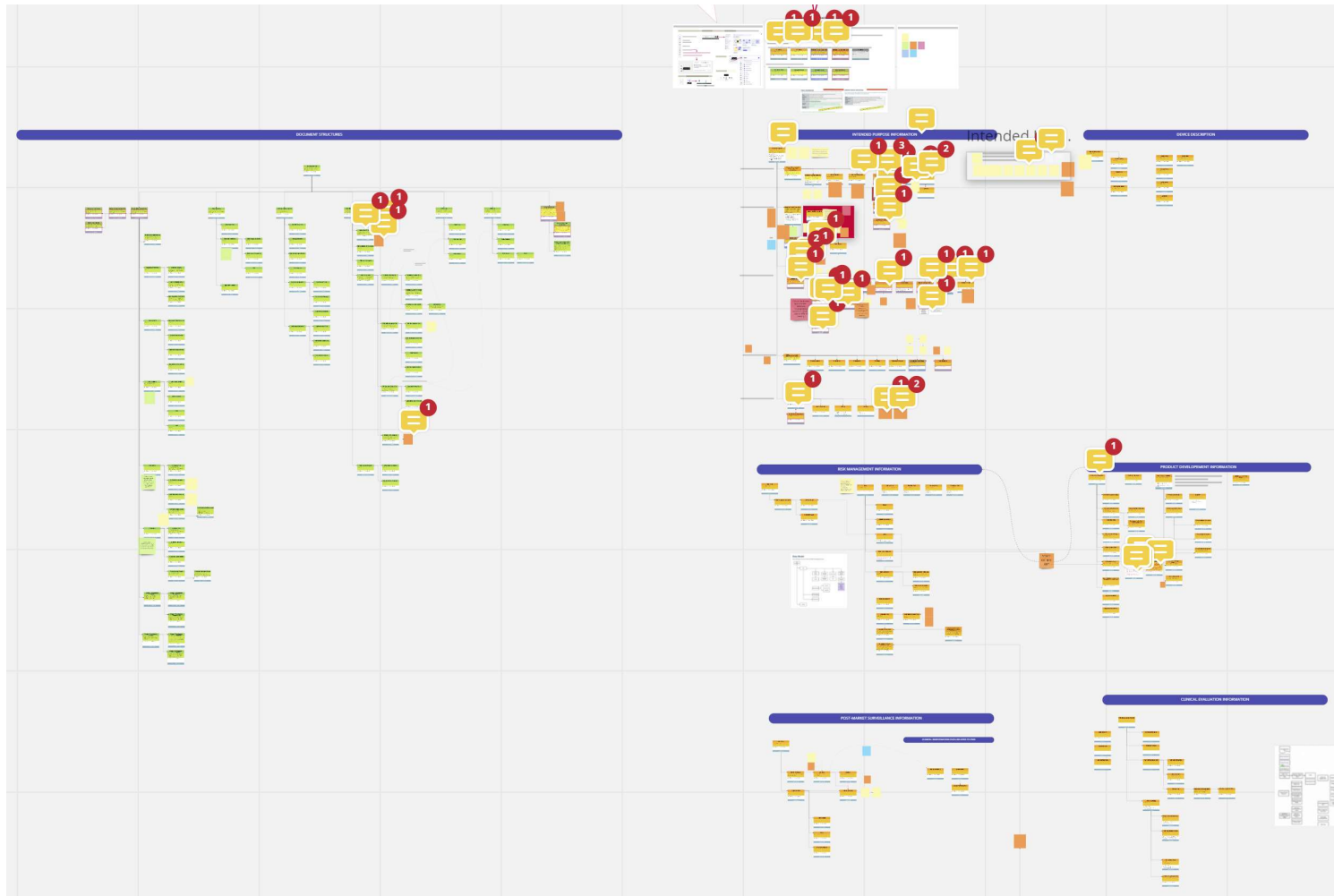
*** Basis for the data model:
regulatory requirements from
legislation, guidances, standards**

MDKU Initiative

- Stakeholder Management
- Release Management
- Configuration Management
- User guidance & Support
- ...


**Stakeholder in the
ecosystem confirm and use
the data model**

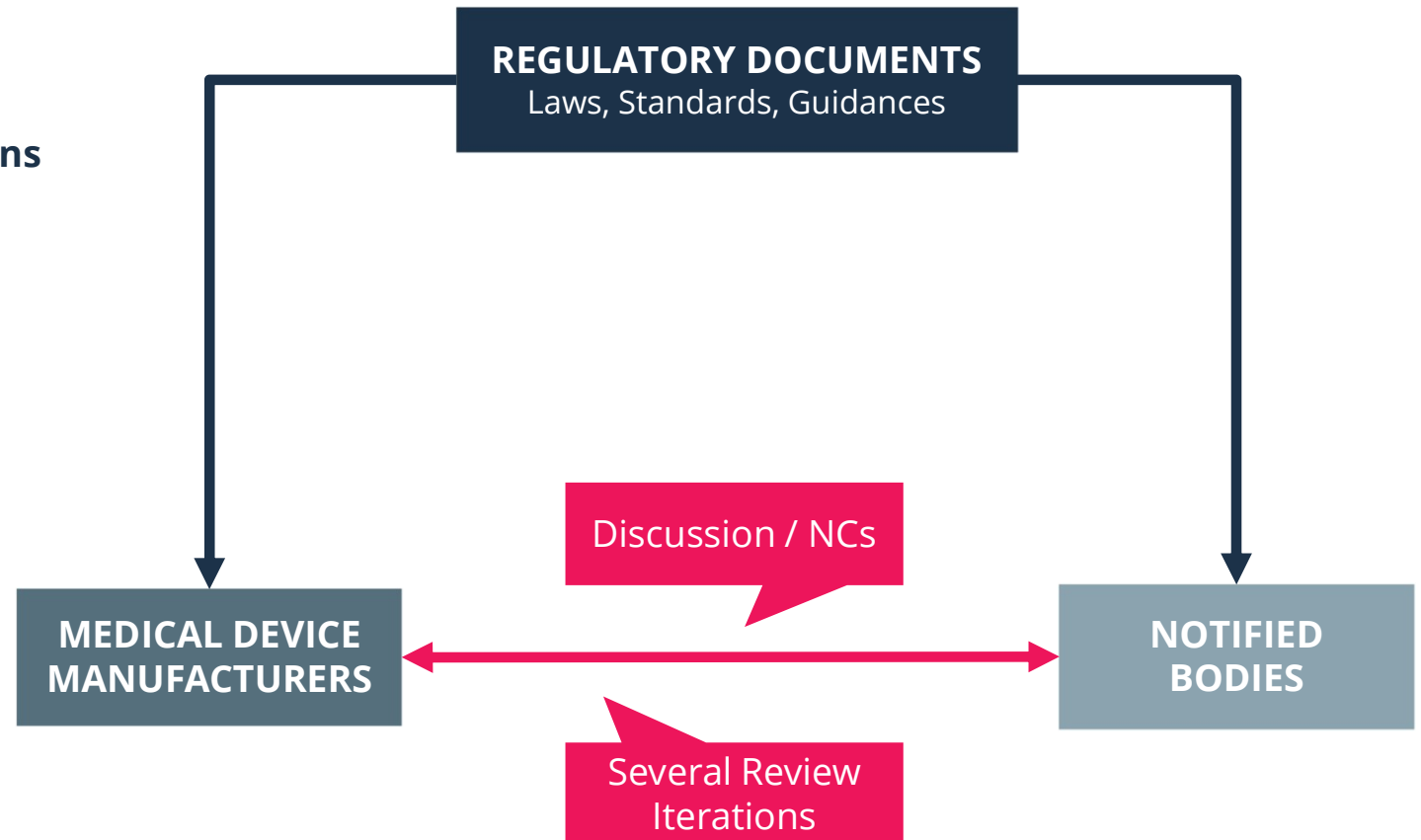
STATUS: IDENTIFICATION OF KNOWLEDGE UNITS



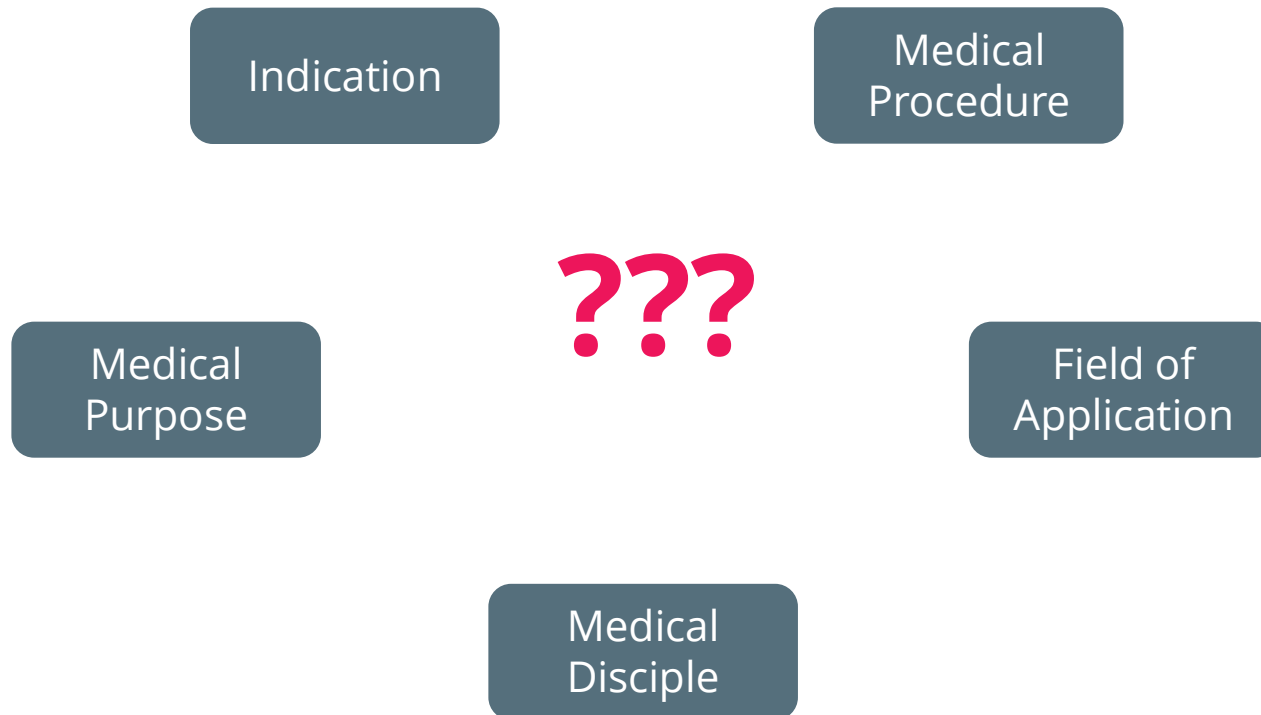
MAIN CHALLENGE: INTERPRETATION OF REGULATORY DOCUMENTS

- Missing definitions
- Unclear/incomplete definitions
- Inconsistent use of terms


**Different
interpretations!**



EXAMPLE: UNCLEAR DEFINITIONS USED IN INTENDED PURPOSE CONTEXT





MEDICAL DEVICE KNOWLEDGE UNITS



**MEDTECH
MEETS
DIGITAL**

14.-15.09.2022 | Frankfurt, Percuma



Abendessen
ab 18:30 Uhr
im Erdgeschoss



**Haben Sie
Feedback
für uns?**

