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MEETS
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26.–27. SEPTEMEBER
DIN. E.V. | BERLIN

2023

THE REGULATORY REVOLUTION

MDKU

MEDICAL DEVICE KNOWLEDGE UNITS

potential of the open source data model & status update

Sarah Panten
Speaker of the Board

THE REGULATORY REVOLUTION

MDKU

MEDICAL DEVICE KNOWLEDGE UNITS

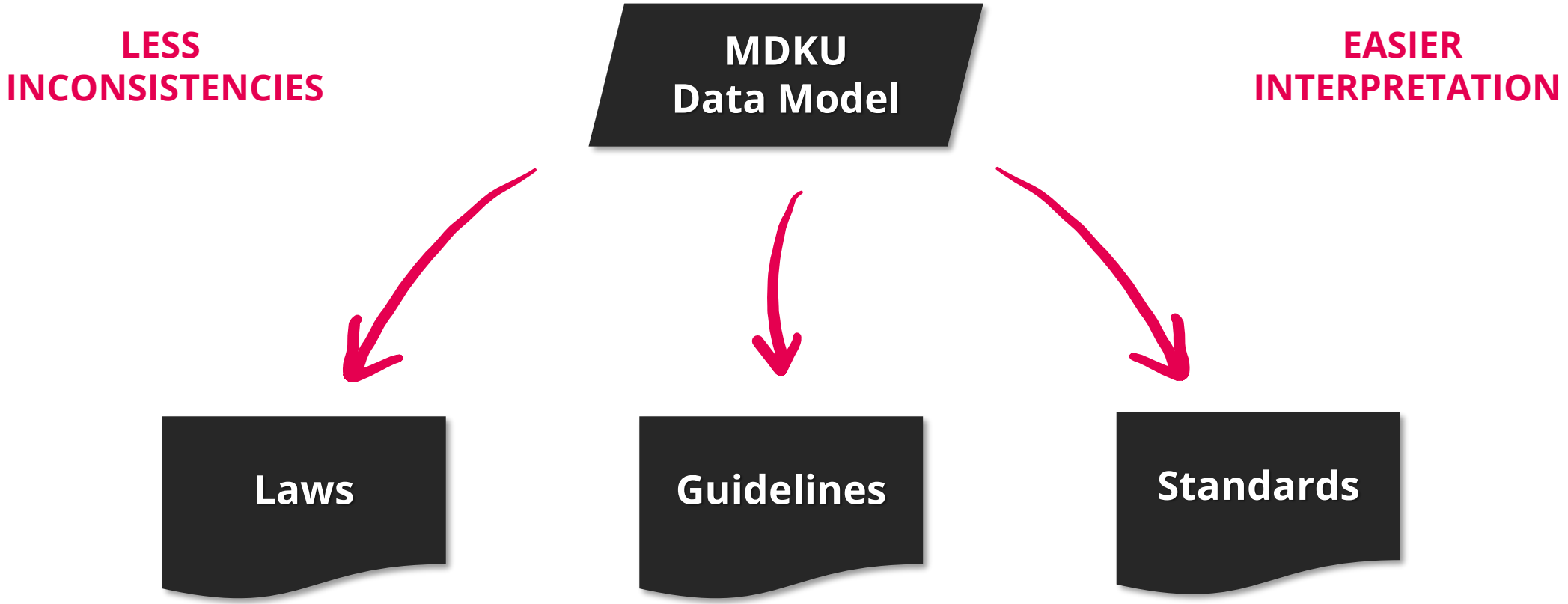
Benefits of the Data Model

The MDKU data model will be published free of charge in order to support the industry.

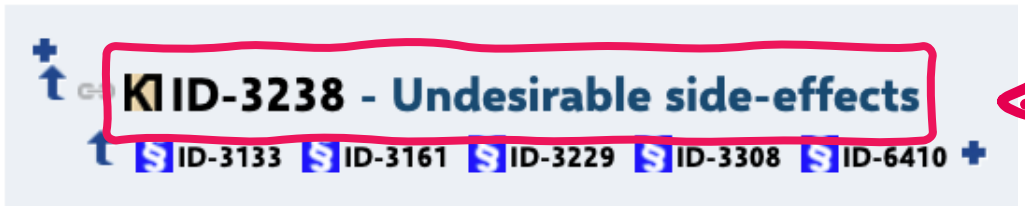
1.
STANDARDIZED REGULATORY LANGUAGE

2.
ACCELERATION OF DIGITALIZATION

INPUT FOR REGULATORY DOCUMENTS



CONTENT OF KNOWLEDGE TOPIC (KT) DEFINITION



Unique ID / Name of KT

General KT information

Description: Side-effect means an unintended effect, usually undesirable, on patients, users or other persons, which occurs during the inter
device in connection with the desired effect and which is related to the use of the device, and which is not due to a malfunctic
characteristics or performance, or inadequacy in the information supplied by the manufacturer.

KT Attributes:

- Expected (known)
- Unexpected (unknown)

Clear description and list of attributes (if available)

CONTENT OF KNOWLEDGE TOPIC (KT) DEFINITION

Information for application of the KT

How is the KT term used?

Information for KT application:

Information for KT Application:

- Expected side-effects must be evaluated in the Risk Analysis AND Clinical Evaluation
- Expected side-effects must be mentioned in the Instruction Manual (IFU).
- (New) Unexpected side-effects are identified via PMCF/PMS data or Clinical Evaluation and sideeffects. should be considered in the PSUR/PMS Report
- (New, unknown) unexpected side-effects are later expected side-effects, when documente

Application for PMS:

MDR ANNEX III: 1.1 (a): The post-market surveillance plan shall address the collection and utiliz undesirable side-effects;

MDCG 2022-21, ANNEX III: The manufacturer should assess the data in relation to the threshol benefits intended to be gained.

Binding Force of KT Title: **Regulatory - Mandatory**

How binding is the use of the term?

Limitations: **Unknown (not defined)**

Description of known Limitations: NA

Is the term applicable to all medical device types?

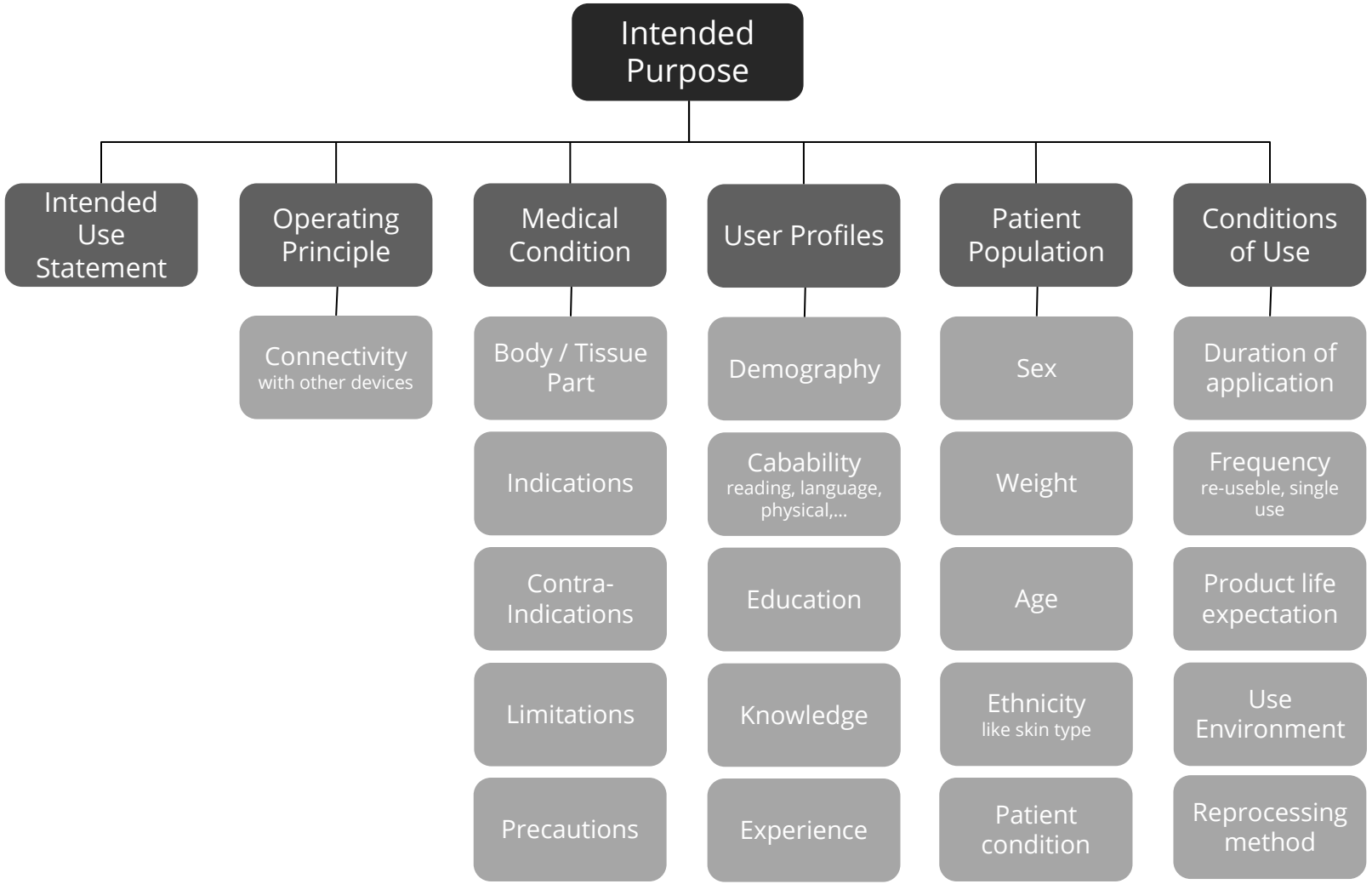
CONTENT OF KNOWLEDGE TOPIC (KT) DEFINITION

Background information, why and how the KT was defined

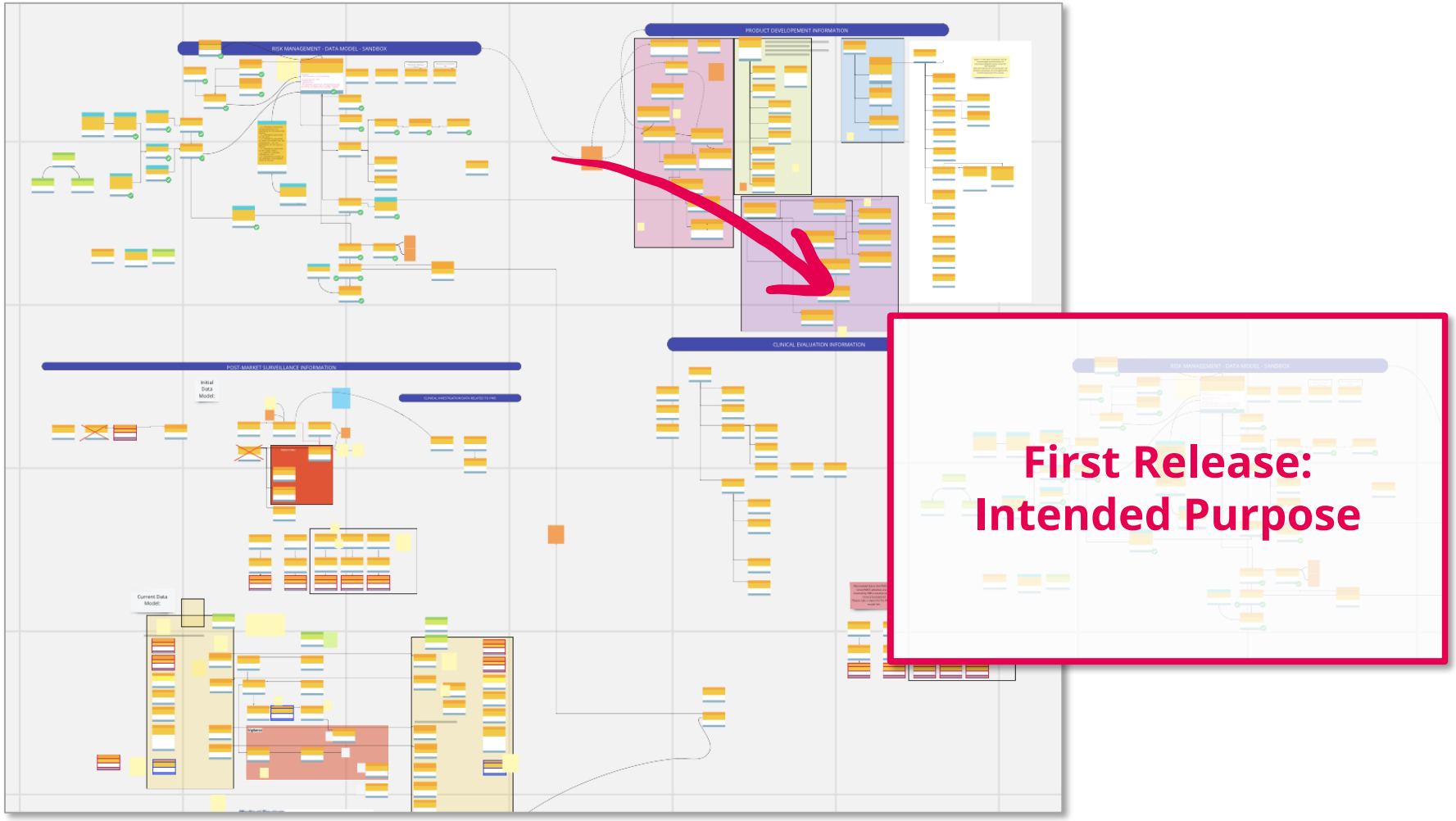
Background information

Source of KT Definition:	**MDKU Specific**
Justification of KT Definition:	German definition available that has been translated.
Existing regulatory definitions:	**1) German definition** from "Nationalen Arbeitskreis zur Implementierung der EU-Verordnungen MDR/IVDR (Source: BMG - FAQ Vigilanz: *„Nebenwirkung" bezeichnet einen unbeabsichtigten, meist unerwünschten Effekt bei Patienten, Anwendern o Gebrauch eines Medizinprodukts im Zusammenhang mit dem gewünschten Effekt auftritt und auf die Anwen der nicht auf eine Fehlfunktion, Verschlechterung der Eigenschaften oder Leistung oder eine Unzulänglichkeit Informationen zurückzuführen ist.* **2) MDCG 2023-03 8.:** An 'undesirable side-effect' under the MDR should be understood as any unintended and unwanted medical consequence of the normal use of a device.17 Undesirable side-effects are not the result of a malfunction, de performance, or an inadequacy in the information supplied by the manufacturer. An unsuccessful treatment (considered an undesirable side effect. For the purpose of this guidance, undesirable side-effects can be expec incidents under the MDR (Article 2(64) MDR).

EXAMPLE: KT HIERARCHY



PRIORITIES & FOCUS



EXCHANGE WITH OTHER COMMUNITIES

eCLASS - STAN
FOR MASTER I
AND SEMANTI
FOR DIGITIZAT

DIN DKE IDiS – Initiative Digitale Standards

Unternehmen

HANNING ELEKTRO-WERKE · GLOBALNORM · HEKUMA · VDE VERLAG · Dräger · PE·SYSTEMS
STRATEGION Strategie. Innovation. Technologie. · parson we create knowledge · material.one powered by adesso · i²ps Institute for International Product Safety · Beuth publishing DIN · VBG Ihre gesetzliche Unfallversicherung · SCHAEFFLER
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PROSTEP integrate the future · BOSCH · EMPOLIS INFORMATION MANAGEMENT · imat validation & consulting · ESR Pollmeier GmbH Servo-Antriebstechnik · WAGO · VISIOCRAFT

Verbände & Behörden

DKE · STANDARDIZATION COUNCIL INDUSTRIE 4.0 · MDKU MEDICAL DEVICE KNOWLEDGE UNITS · DAkkS Deutsche Akkreditierungsstelle · BAM Bundesanstalt für Materialforschung und -prüfung · SNV standards connect the world
DIN · ZVEH · LNI4.0 LABS NETWORK INDUSTRIE 4.0 · SVGW SSIGE · PTB

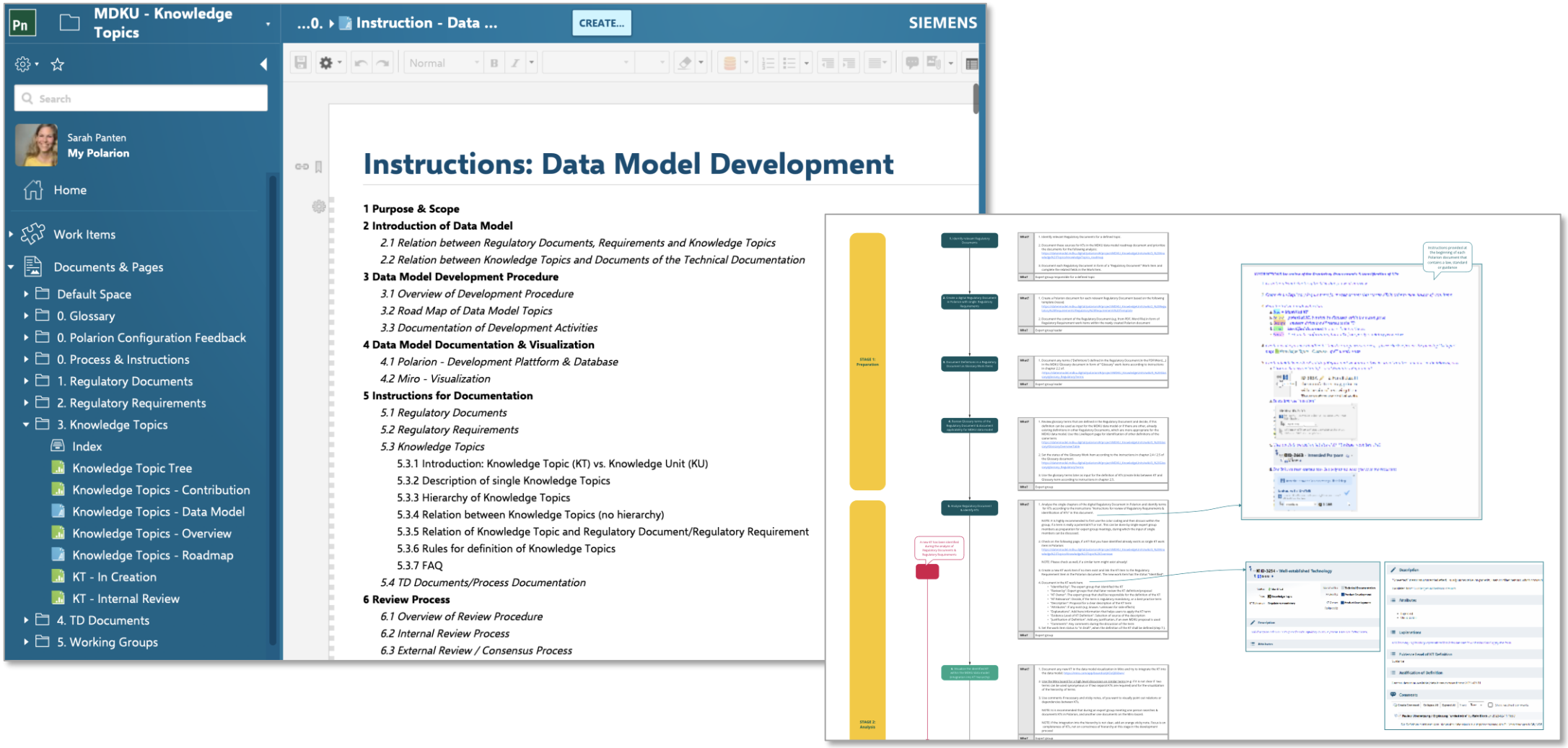
Wissenschaft

Fraunhofer ISE · UNIVERSITÄT DUISBURG ESSEN · HELMUT SCHMIDT UNIVERSITÄT · Fraunhofer IOSB-INA

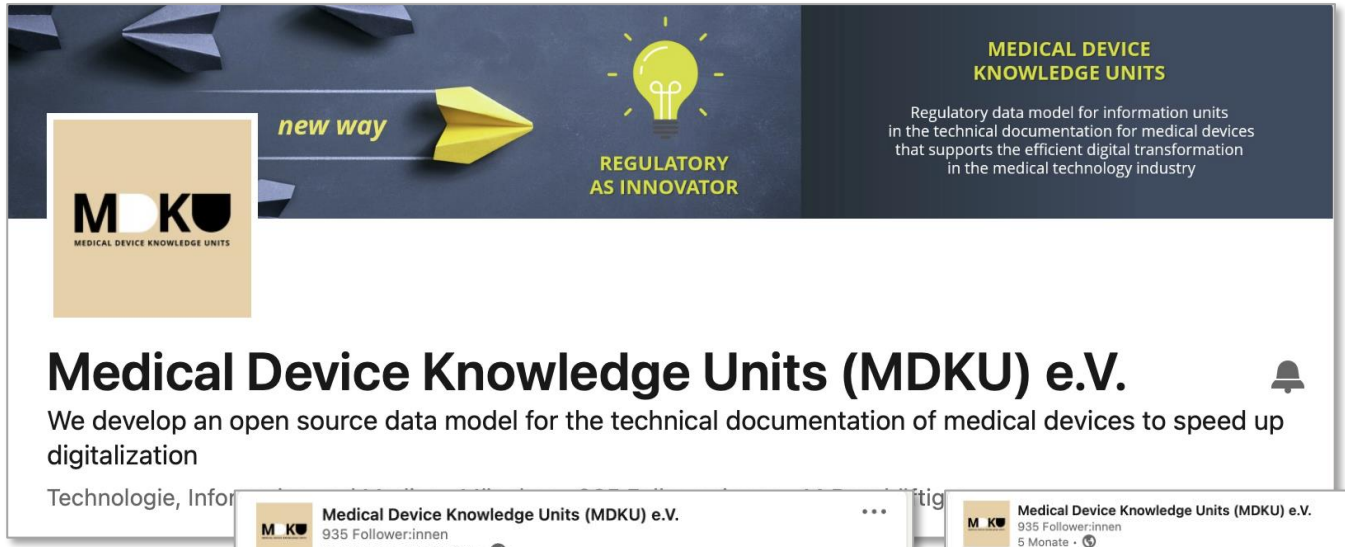
PARTICIPATION OF MDKU MEMBERS IN IDiS WORKING GROUPS

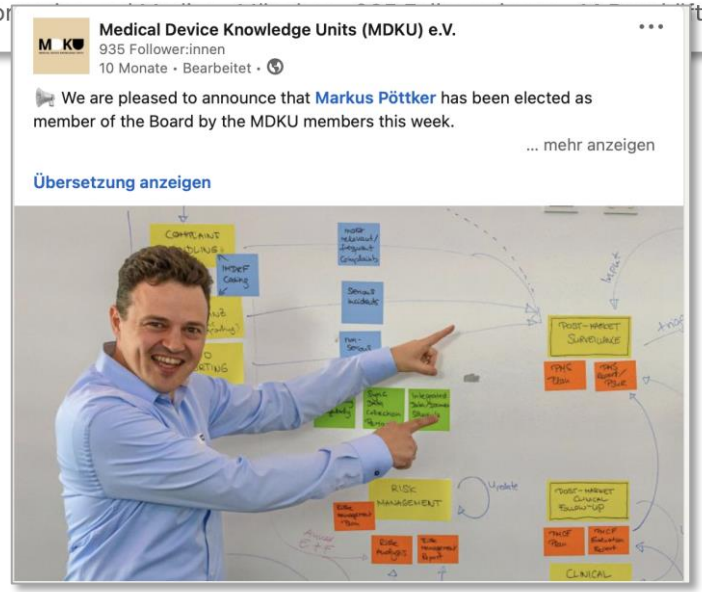
MDKU

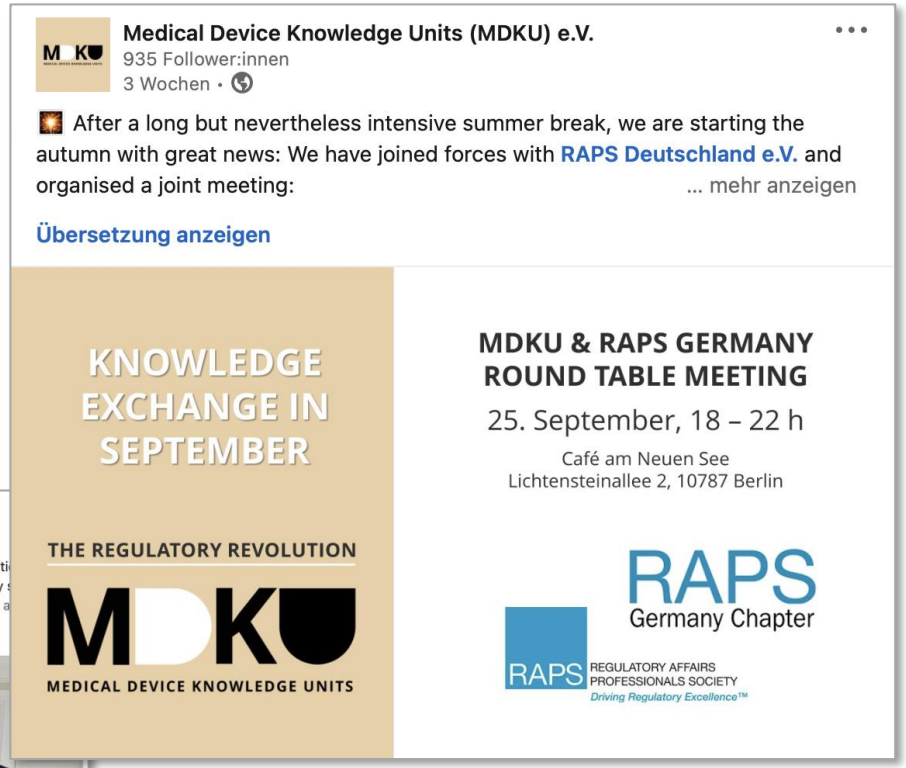
INTERNAL OPTIMIZATION



LINKEDIN ACCOUNT







NEW WEBSITE

THE REGULATORY REVOLUTION

MDKU

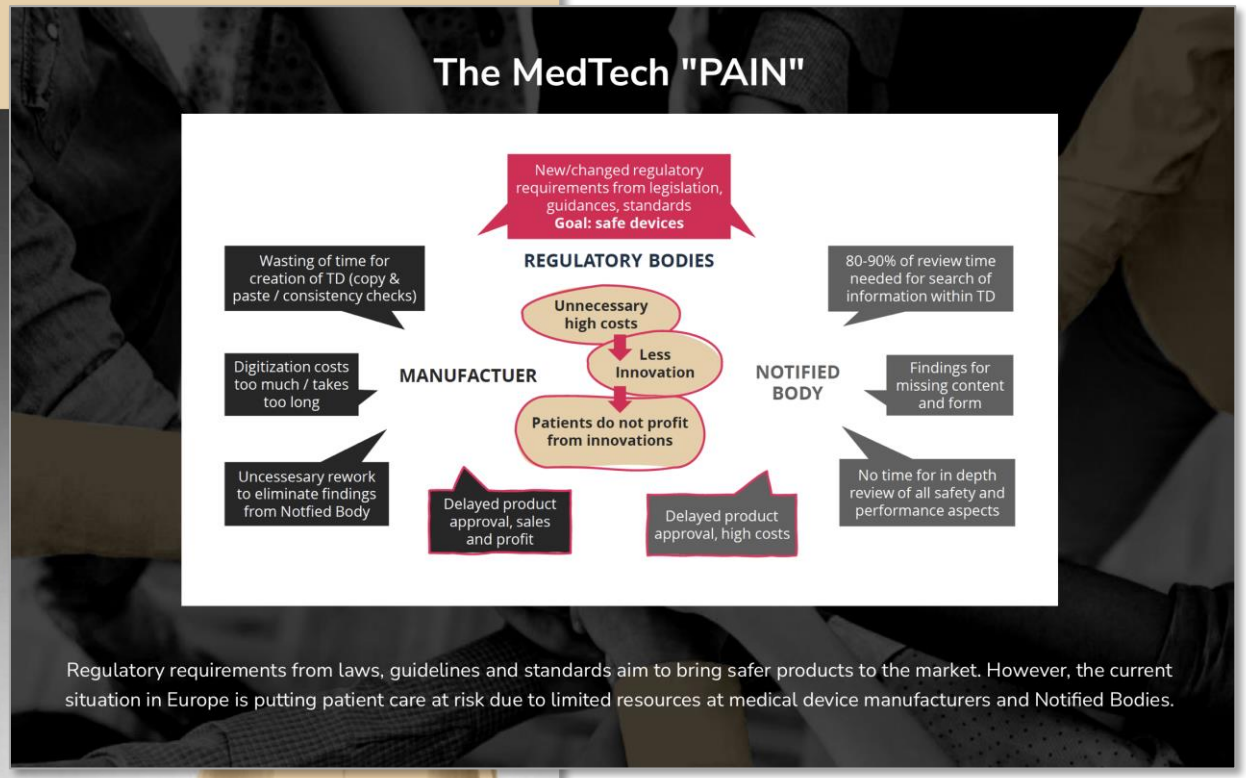
MEDICAL DEVICE KNOWLEGE UNIT

Home | About MDKU | Data Model | Participate | Contact | My MDKU

Let's imagine...
in our regulated MedTech industry we

- have a clear regulatory language that enables easier interpretation of regulatory terms in regulatory documents
- can easily digitalize regulatory processes in order to speedup creation and review of the technical documentation
- can increase efficiency of medical device development, market access and thus reduce costs in the overall medtech ecosystem
- enable more and faster innovation and thus better patient care

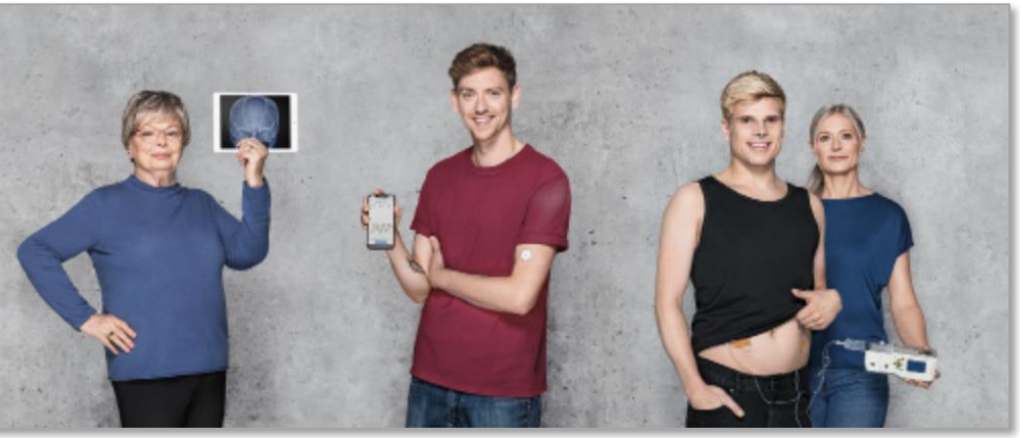
... and ensure that the European MedTech industry is well positioned for the age of digitalization and global competition.



MDKU

SUPPORT OF GERMAN INDUSTRY ASSOCIATIONS

BVMed Bundesverband Medizintechnologie e.V.



MEDIZINTECHNIK im Deutschen Industrieverband SPECTARIS

Working Group: Digitalization QM & RA

ANNUAL BVMED CONFERENCE

BVMed
Gesundheit gestalten

MDR-Branchenkonferenz
Panel | Regulatorik

11. Mai 2023
Aesculap Akademie | Berlin

DIGITALIZATION OF DOCUMENTATION

THE REGULATORY REVOLUTION

MDKU
MEDICAL DEVICE KNOWLEDGE UNITS e.V.

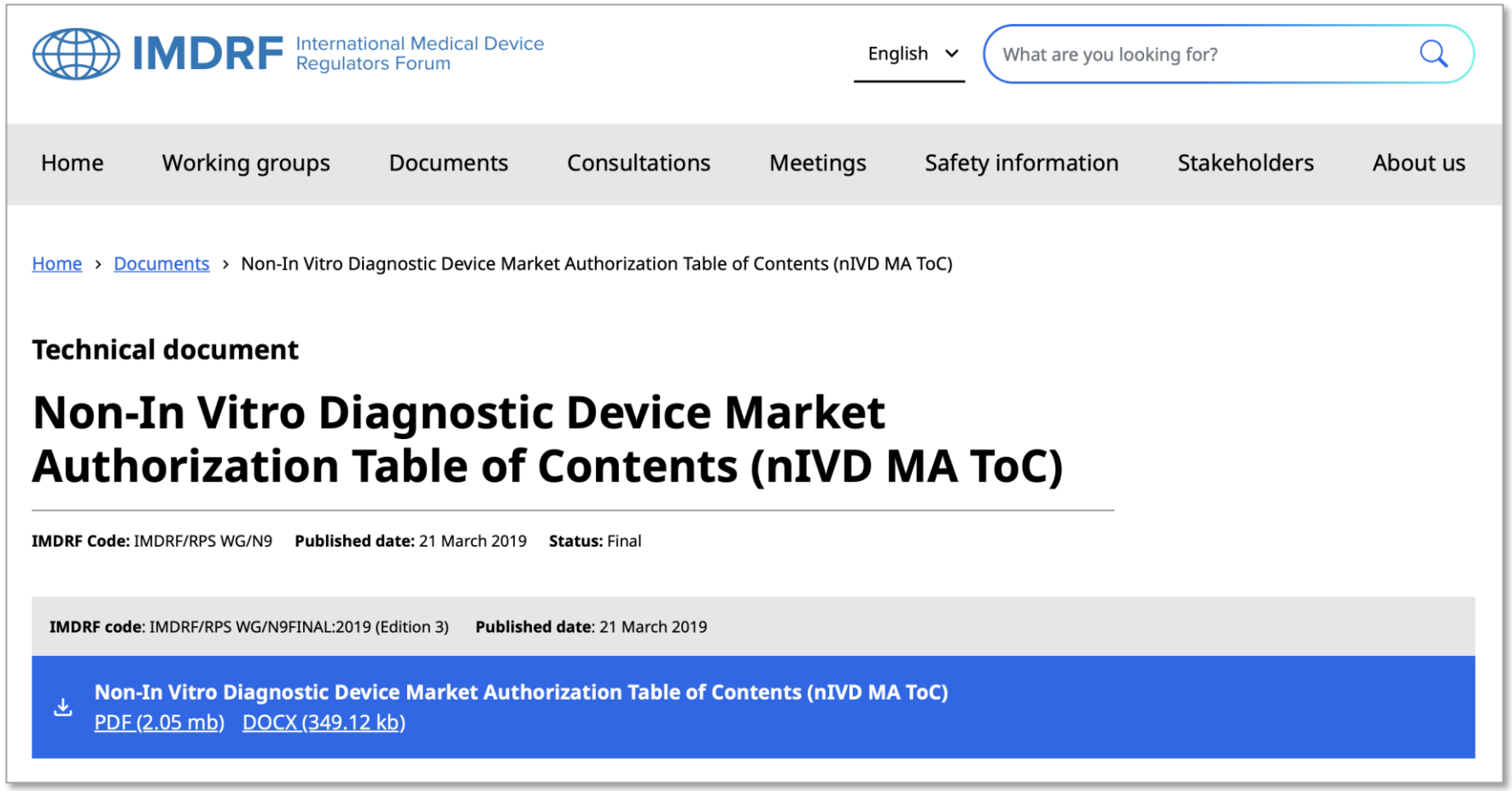
SARAH PANTEN & MARKUS PÖTTKER

Members of the board and expert groups
Medical Device Knowlede Unit (MDKU) e.V.

Contact: vorstand@mdku.digital

MDKU

IMDRF WORKING GROUP



IMDRF International Medical Device Regulators Forum

English

What are you looking for?

Home | Working groups | Documents | Consultations | Meetings | Safety information | Stakeholders | About us

Home › Documents › Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Technical document

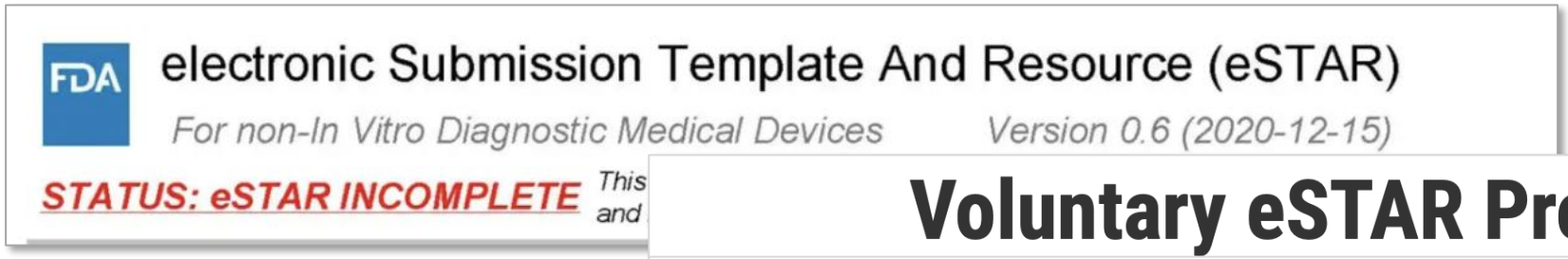
Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

IMDRF Code: IMDRF/RPS WG/N9 **Published date:** 21 March 2019 **Status:** Final

IMDRF code: IMDRF/RPS WG/N9FINAL:2019 (Edition 3) **Published date**: 21 March 2019

Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)
PDF (2.05 mb) DOCX (349.12 kb)

eSTAR = DIGITAL SUBMISSION?!



Voluntary eSTAR Program

Update: June 9, 2023 The electronic Submission Template and Resource (eSTAR) for Pre-Submissions is now available for submissions to CDRH. Please refer to the new eSTAR template.

Starting **October 1, 2023**, all 510(k) submissions, unless exempted, must be submitted as electronic submissions using eSTAR, as noted in the:

Electronic Submission Template for Medical Device 510(k) Submissions final guidance.

- eSTAR is the only available electronic submission template to facilitate the preparation of 510(k) electronic submissions.

IMDRF WORKING GROUP
REGULATED PRODUCT SUBMISSION

Regulated Product Submission Working Group

PDF (259.98 kb)

www.imdrf.org/meetings/berlin-germany-hosted-european-commission-behalf-eu

IMDRF International Medical Device Regulators Forum

Regulated Product Submission Working Group

Patrick Axtell, US Food and Drug Administration

Daniel Yoon, Health Canada

Provide your feedback on this Working Group!

Follow this link and let us know:

https://forms.office.com/e/uXzAhHFxs8

IMDRF 24th Session – Berlin, Germany

Provide your Feedback!

COOPERATION DIN – CONSENSUS PROCESS

bsi.

TÜV SÜD

TEAM NB
The European Association
Medical devices
Notified Bodies

Consensus procedure based on DIN SPEC process

BUT: modified for MDKU specific licence, data and processes

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FUNDING OPPORTUNITY

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