THE REGULATORY REVOLUTION

MEDICAL DEVICE KNOWLEDGE UNITS

MEDXD 2026 – SESSION B1

Dr. Holger Brünner & Frank Münzinger

2026-03-19

OVERVIEW

01 **INTRODUCTION**
Who we are, today’s goals

02 **BASICS**
What we are talking about

03 **KNOWLEDGE TOPICS & UNITS**
Definitions and application

04 **FROM DOCS TO DATA**
Transforming document content into structured data

05 **HANDS ON**
Let's get into it!

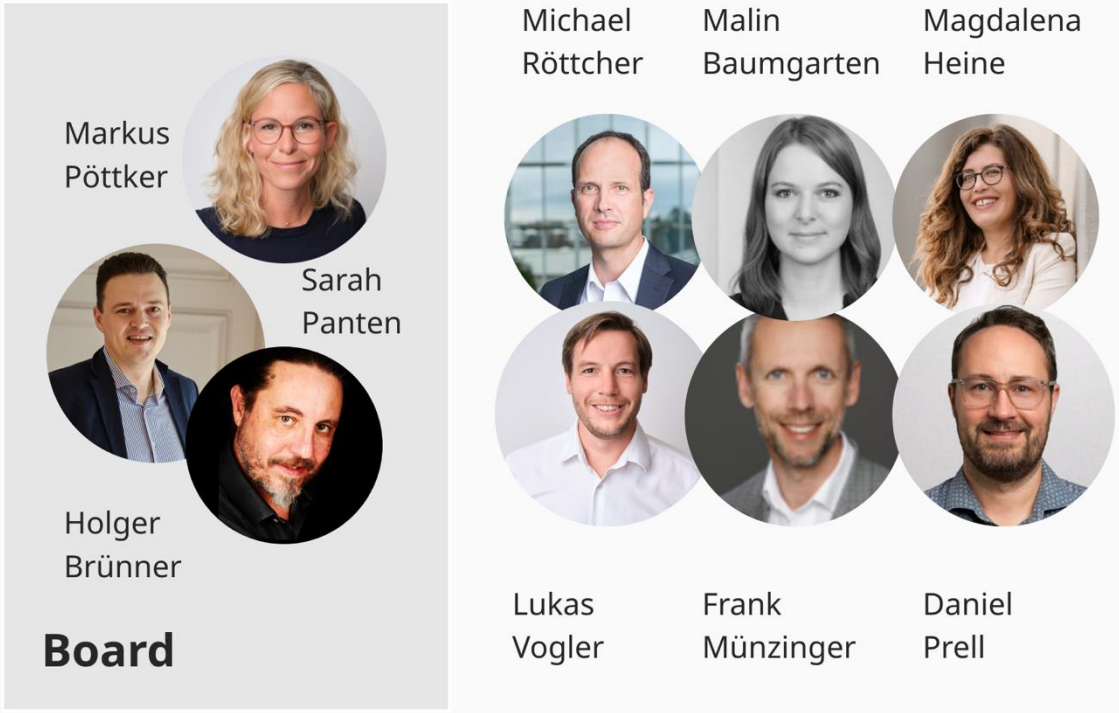
06 **WRAPUP**
Summary and conclusions

01

INTRODUCTION

Who are we?

WHO WE ARE



Medical Device Knowledge Units (MDKU) e. V.

- Founded in 2021, recognized non-profit-organization (AG Munich, VR209416)
- currently ~ 90 members (D/A/CH, some outside)
  - Individuals, QMRA experts, consultants
  - MedTech-Companies from SME to corporate
  - Industry associations and notified bodies

Organized in „**expert groups**“

- Data Model
- Technical Documentation
- Product Development
- Risk Management
- Usability Engineering
- Clinical Evaluation incl. PMCF
- Post- market Surveillance incl. Vigilance
- ...more to come

TODAY'S GOALS:

We want to show you what we do,

and how we are trying to transform the regulatory landscape,

and invite you to participate!

Let's start ...

02

BASICS

What’s about all of this?

MEDTECH "PAIN"

New/changed regulatory requirements from legislation, guidances, standards
Goal: safe devices

REGULATORY BODIES

Wasting of time for creation of TD (copy & paste / consistency checks)

80-90% of review time needed for search of information within TD

Digitization costs too much / takes too long

MANUFACTUER

Unnecessary high costs

Less Innovation

Patients do not profit from innovations

NOTIFIED BODY

Findings for missing content and form

Uncessesary rework to eliminate findings from Notfied Body

Delayed product approval, sales and profit

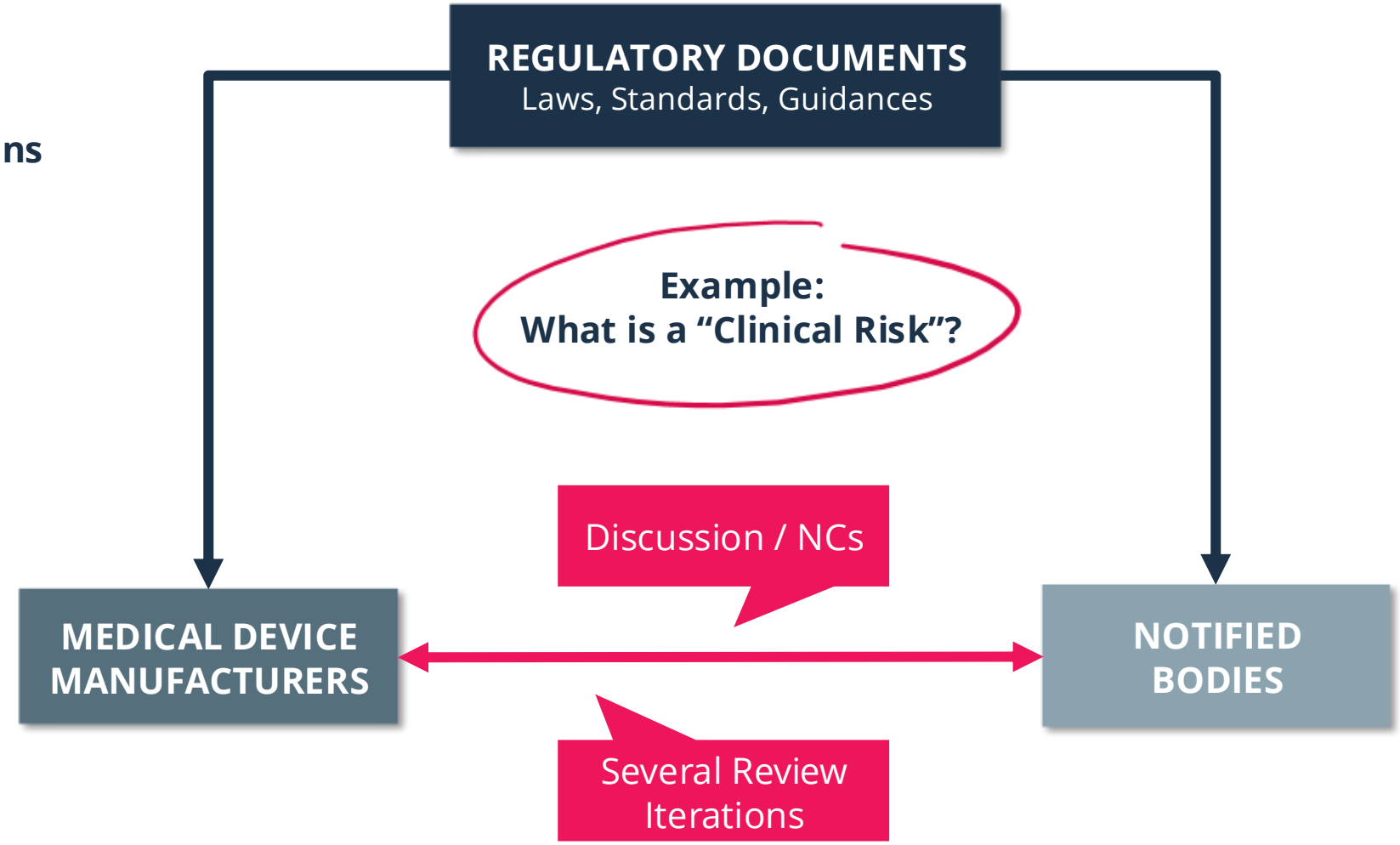
Delayed product approval, high costs

No time for in depth review of all safety and performance aspects

CHALLENGE #1 INTERPRETATION OF REGULATORY DOCUMENTS

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

Different interpretations!



CHALLENGE #2:
AMOUNT OF DOCUMENTS 2017 vs 2023

600 % Increase
in Quantity of Documents!

PMS Documents

- PMS Plan
- PMS Report
- PSUR
- Canada SR

320 % Increase

Clinical Evaluation & PMCF Documents

- CEP
- CER
- PMCF ER
- SSCP

280 % Increase

Not included:

- ad-hoc reports due to internal or external requests
- Tailored data analysis and responses as part of NB Submissions & Review

Some documents did not increased substantially year over year, however, the complexity has increased significantly.

PERSPECTIVE: MANUFACTURERS & NOTIFIED BODIES

CREATION BY MANUFACTURER

TECHNICAL DOCUMENTATION

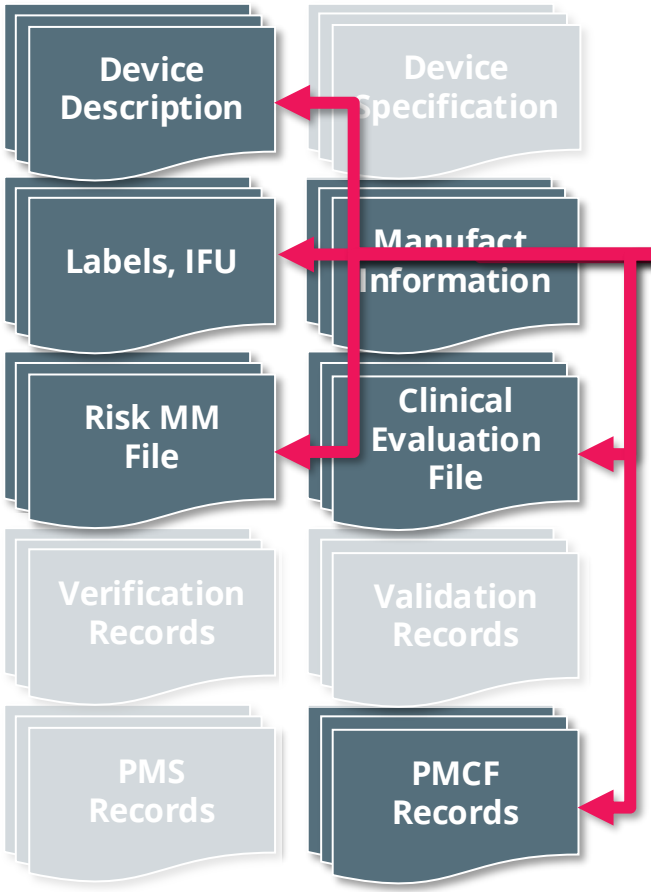
according to MDR, Annex II + III

- Device description & specification
- Information supplied by manufacturer
- Design and manufacturing information
- General safety & performance req.
- Benefit-risk analysis / risk management
- Product verification & validation
- PMS Plan incl. PMCF Plan
- PMS Report / PSUR

ASSESSSMENT NOTIFIED BODY

CHALLENGE #2 CONSISTENCY OF INFORMATIONEN

CREATION BY MANUFACTURER

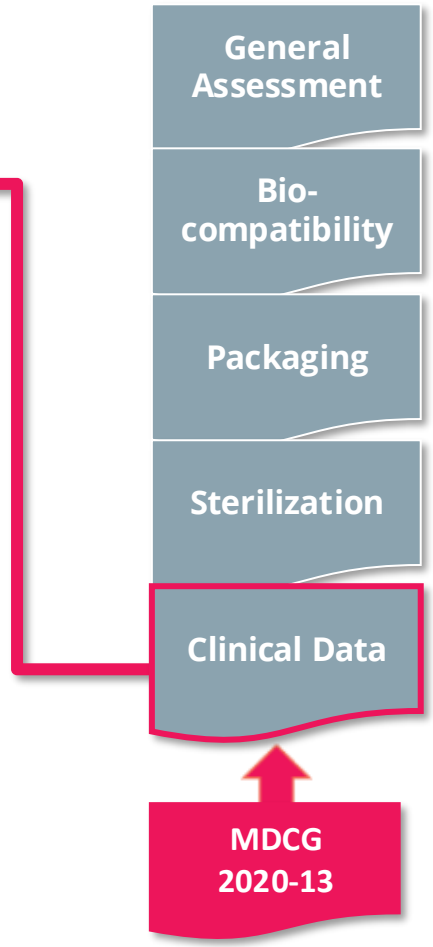


TECHNICAL DOCUMENTATION

according to MDR, Annex II + III

- **Device description: Intended Use**
- Information supplied by manufacturer
- Design and manufacturing information
- General safety & performance req.
- Benefit-risk analysis / risk management
- Product verification & validation
- PMS Plan incl. PMCF Plan
- PMS Report / PSUR

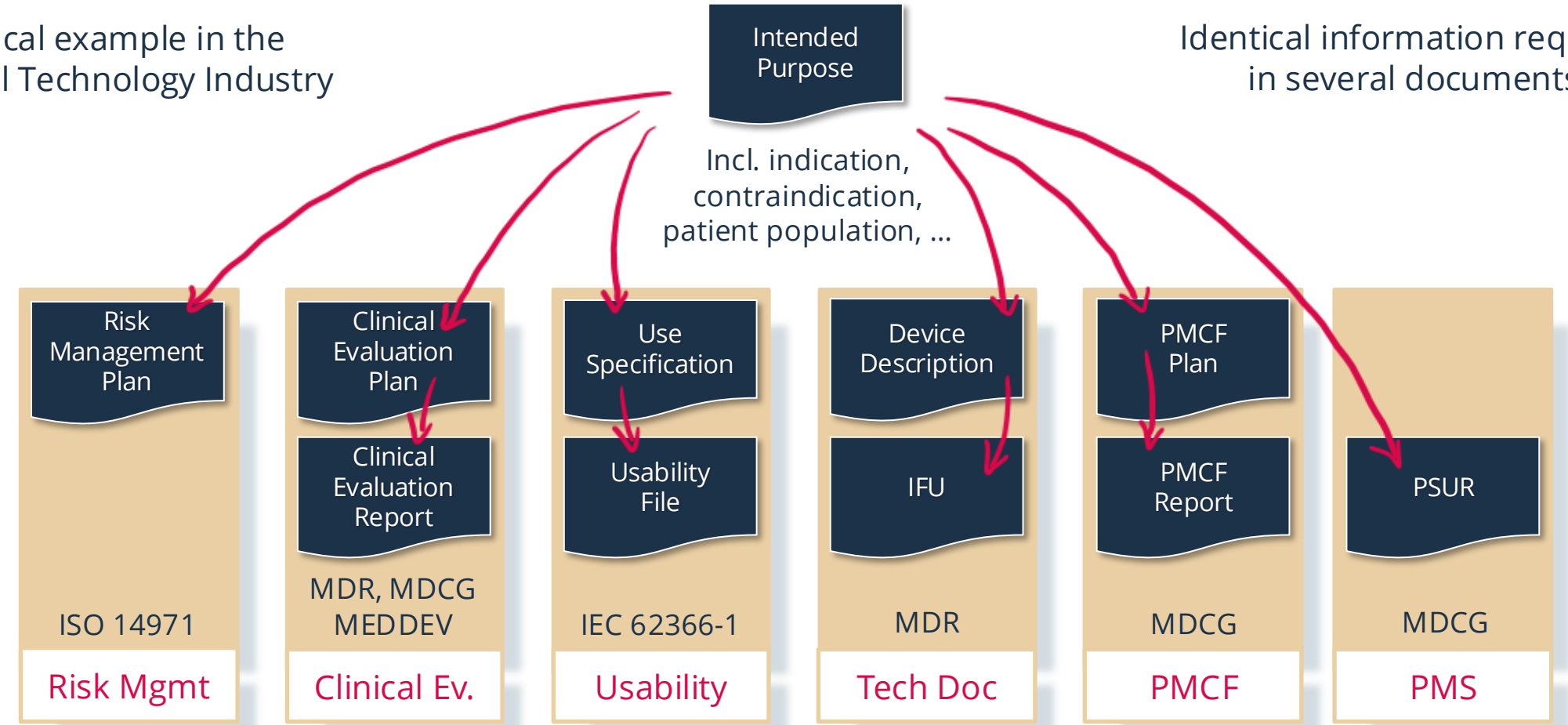
ASSESSMENT BY NOTIFIED BODY



PARADIGMA:
REUSE & CONSISTENCY OF INFORMATION

Typical example in the Medical Technology Industry

Identical information required in several documents



KEY POINT
REUSE & CONSISTENCY OF INFORMATION

+ Reuse for Product Variations!

Key Processes Product Development

- Development
- Clinical Evaluation
- Risk Management
- Usability

37%

Source: avasis

„MDR als Chance zur digitalen Transformation: Wechsel von Dokumenten zu Informationseinheiten“

World Café Workshop, 15.05.2019, Zürich
World Café Workshop, 24.09.2019, Munich

Post-market Clinical Follow-up & Surveillance

- PMCF
- PMS

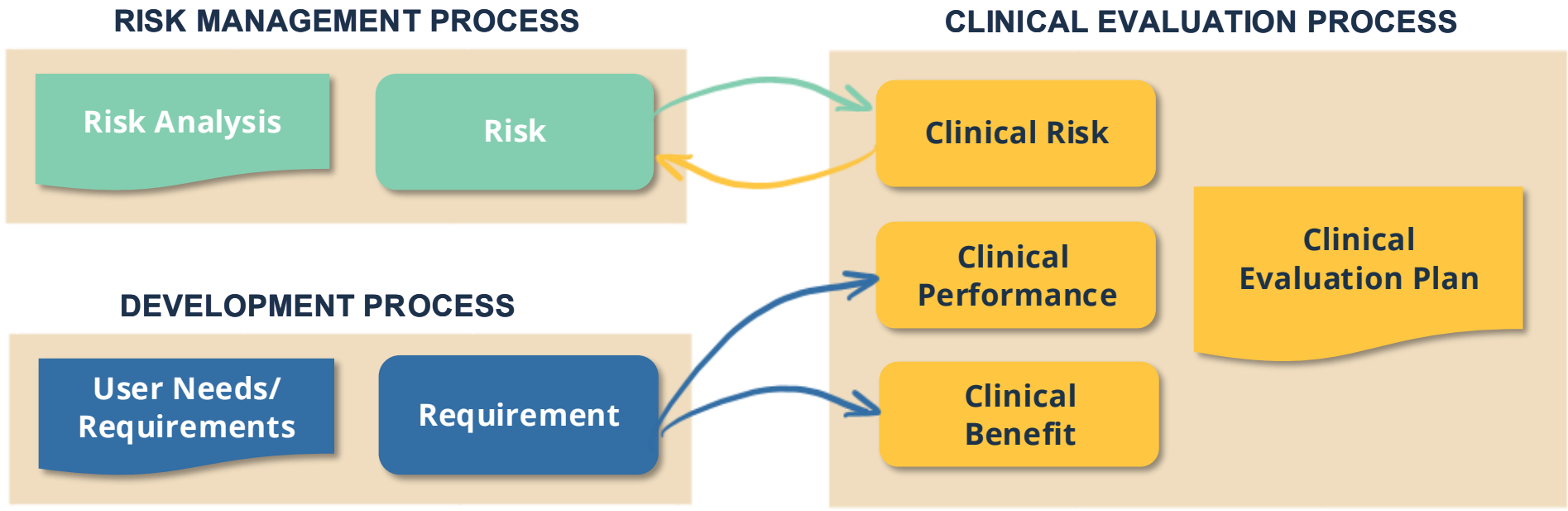
> 70%

Source: avasis

Analysis of content required in PMS/PMCF documents acc. to related MDCG guidances

For details see avasis Webinar „PMS & PMCF“

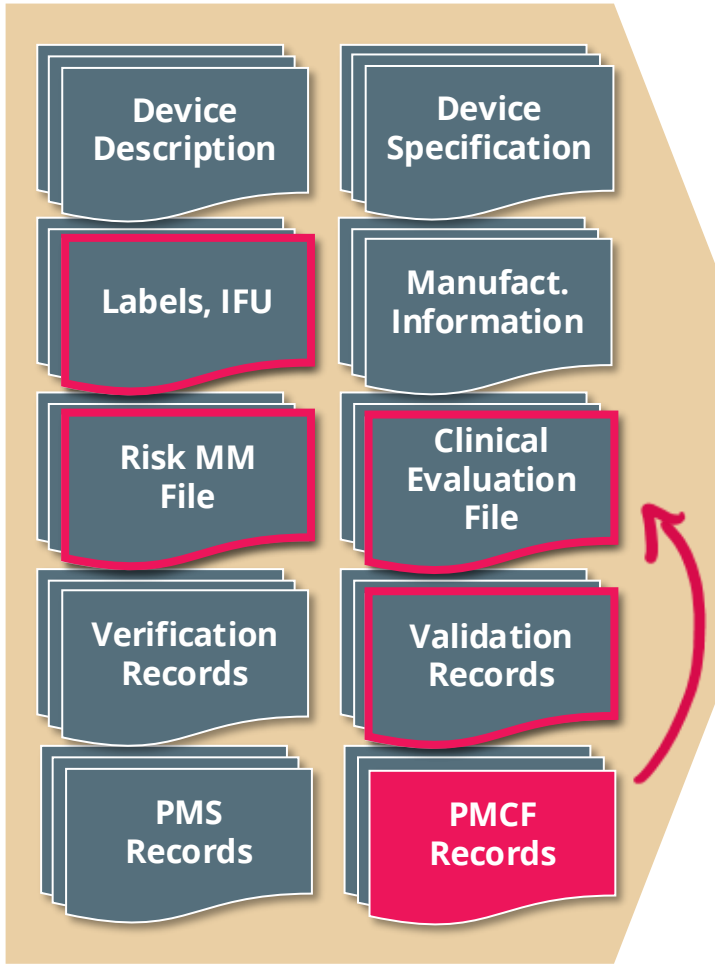
CHALLENGE #3: COMPLEXITY & TRACEABILITY



- Interdependency of processes and related ~~documents~~ DATA
- Connection of single input and output of processes
- Connection on data level, not document level required

CHALLENGE #3: COMPLEXITY & TRACEABILITY - CHANGES

CREATION BY MANUFACTURER



TECHNICAL DOCUMENTATION

according to MDR, Annex II + III

- Device description & specification
- Information supplied by manufacturer
- Design and manufacturing information
- General safety & perform
- Benefit-risk analysis / risk management
- Product verification & validation
- PMS Plan incl. PMCF Plan
- PMS Report / PSUR

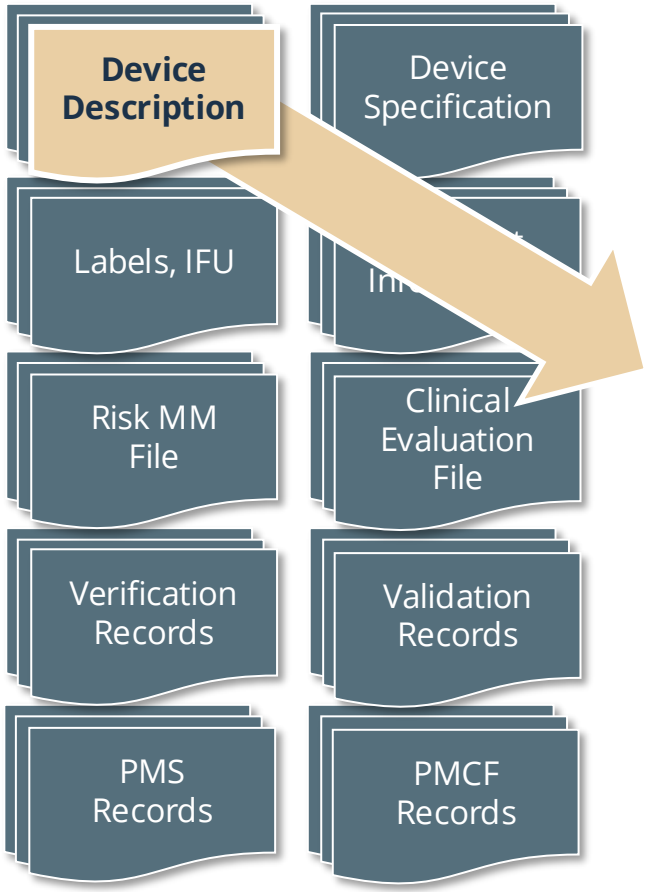
Review of changes

ASSESSMENT BY NOTIFIED BODY

IMPACT OF CHANGE AS RESULT OF PMCF/PMS!

CHALLENGE #4 COMPLETENESS OF REQUIRED CONTENT

CREATION BY MANUFACTURER



TECHNICAL DOCUMENTATION

according to MDR, Annex II + III

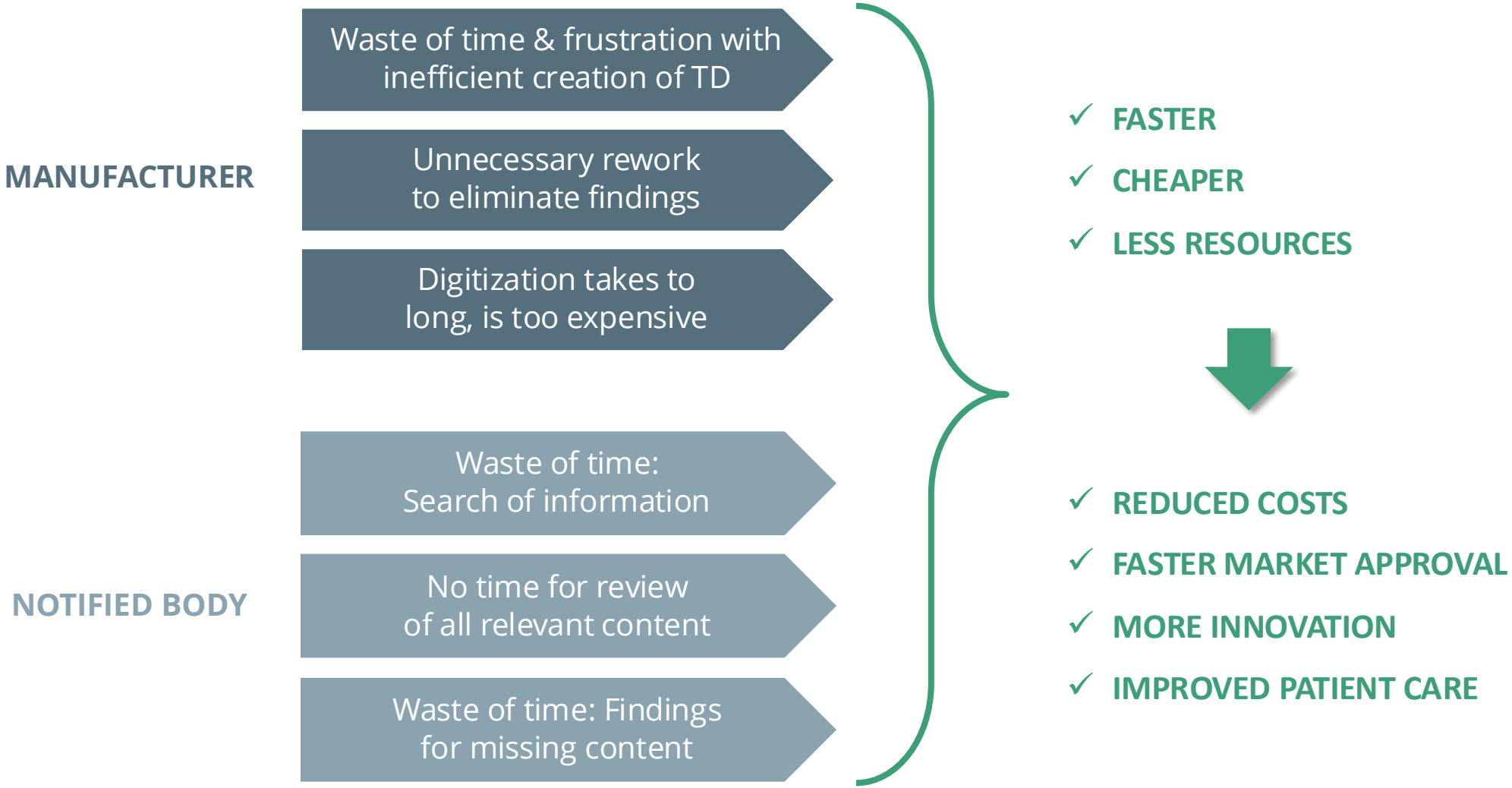
Device description, incl:

- ✓ Intended use statement,
- ✓ Indication
- ✓ Contraindication
- ✓ Patient population
- ✓ User profiles & user groups
- X **Device variations / configurations**
- ✓ Device components, materials,...
- ✓ Accessories
- X **Compatibility**

ASSESSMENT BY NOTIFIED BODY

- General Assessment
- Bio-compatibility
- Packaging
- Sterilization
- Clinical Data

GOALS: EFFICIENT CREATION, REVIEW AND MANAGEMENT OF TD



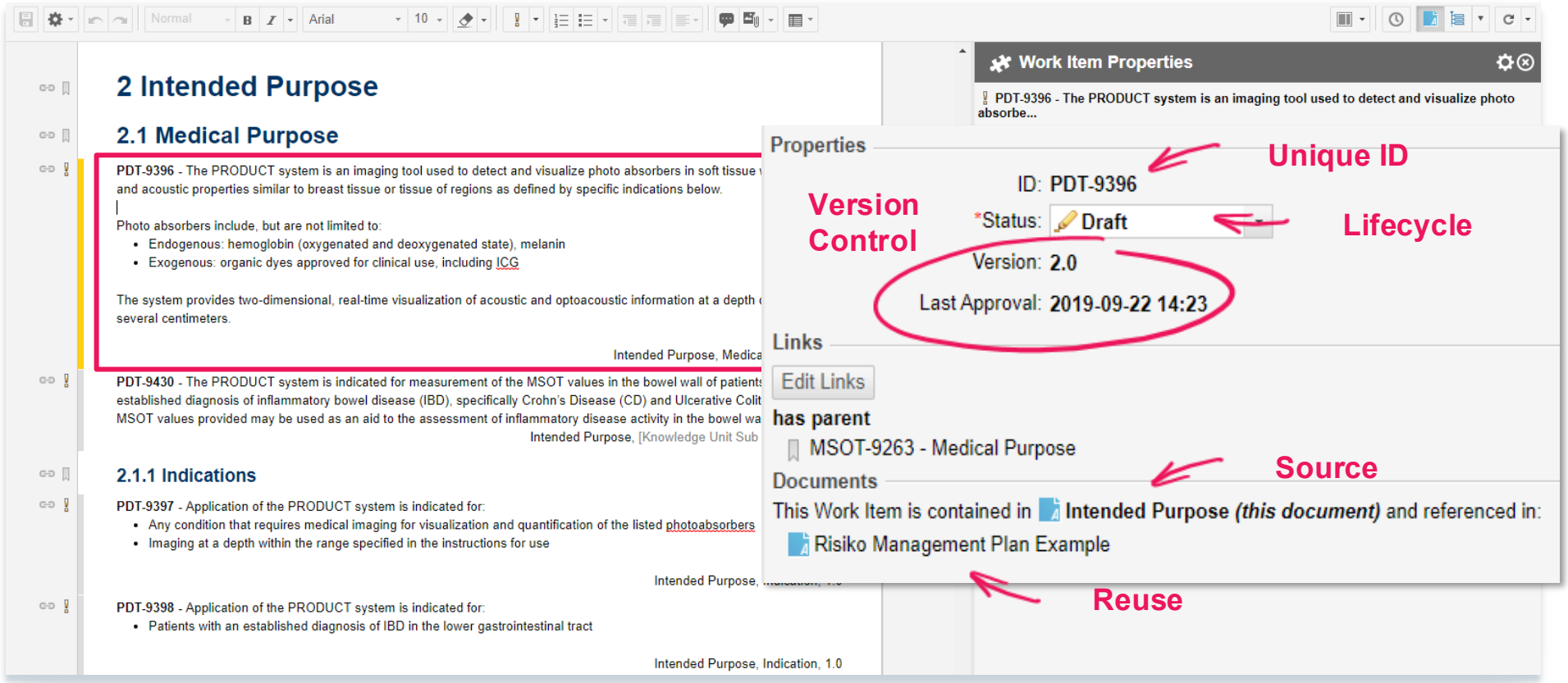
WHAT WE NEED:
DIGITAL TRANSFORMATION
FROM DOCUMENTS TO (DATA) KNOWLEDGE

03

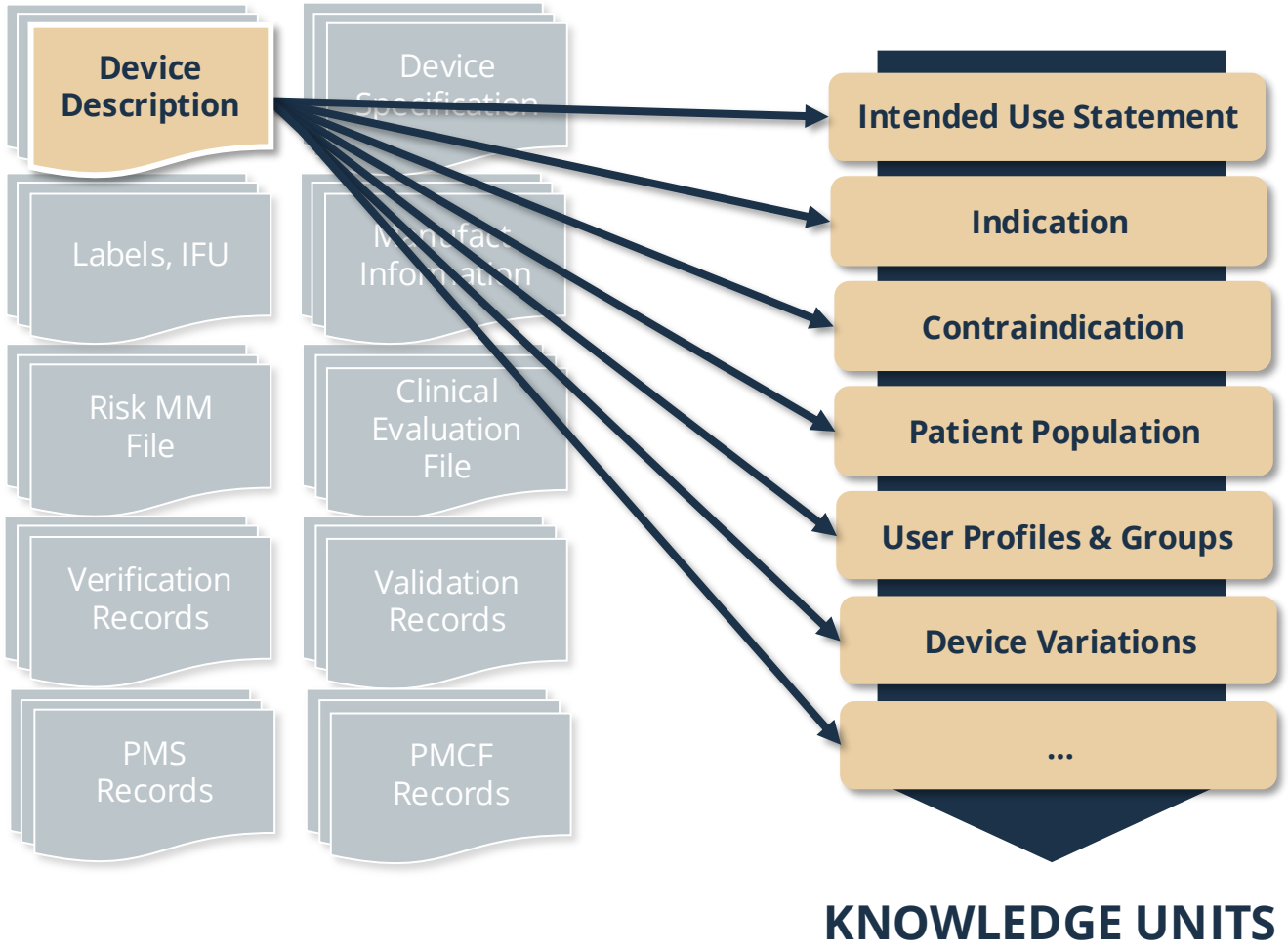
KNOWLEDGE TOPICS AND UNITS

Definitions and application

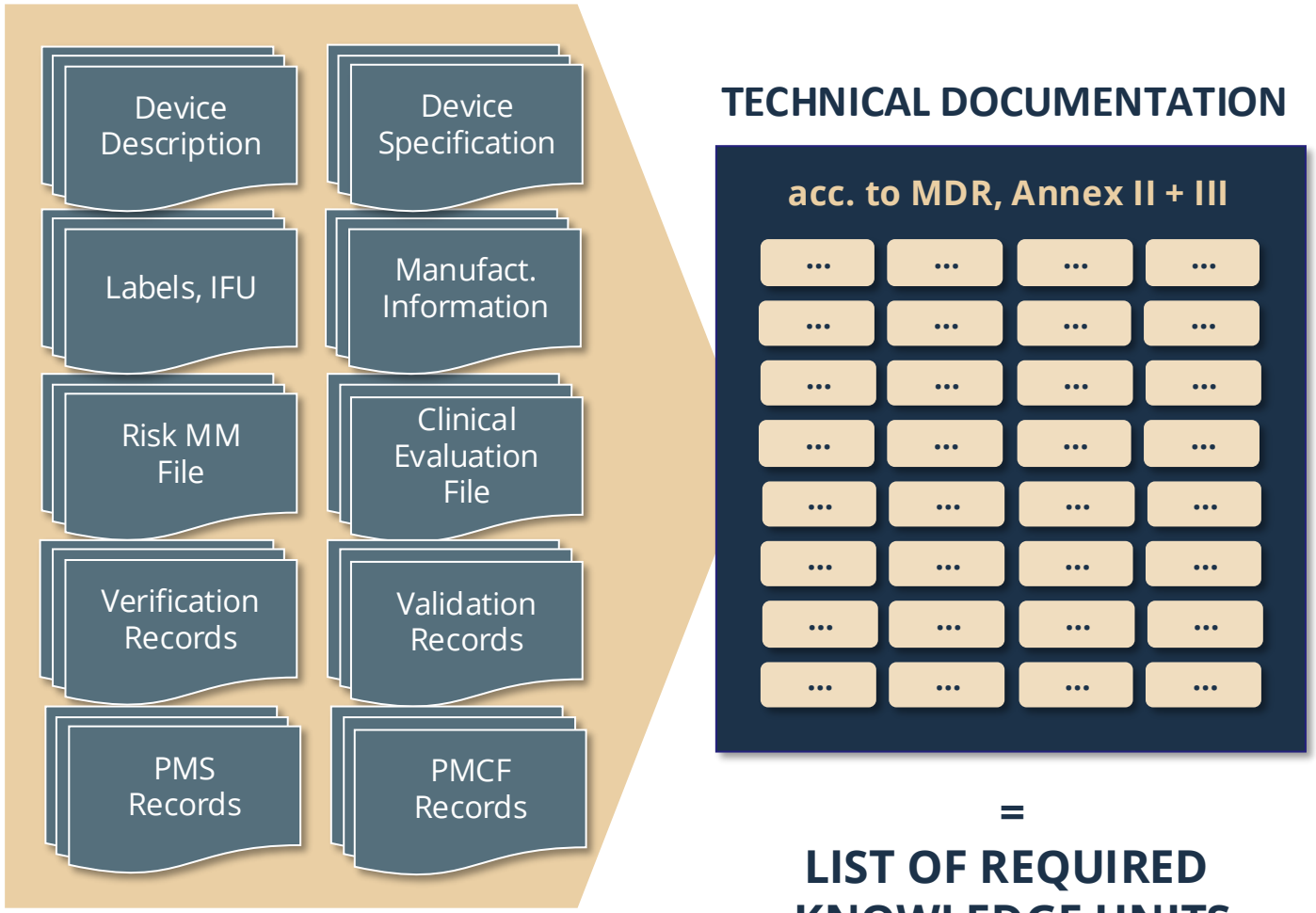
FROM DOCUMENTS TO DATA CHUNKS
PROPERTIES OF SINGLE INFORMATION ITEMS



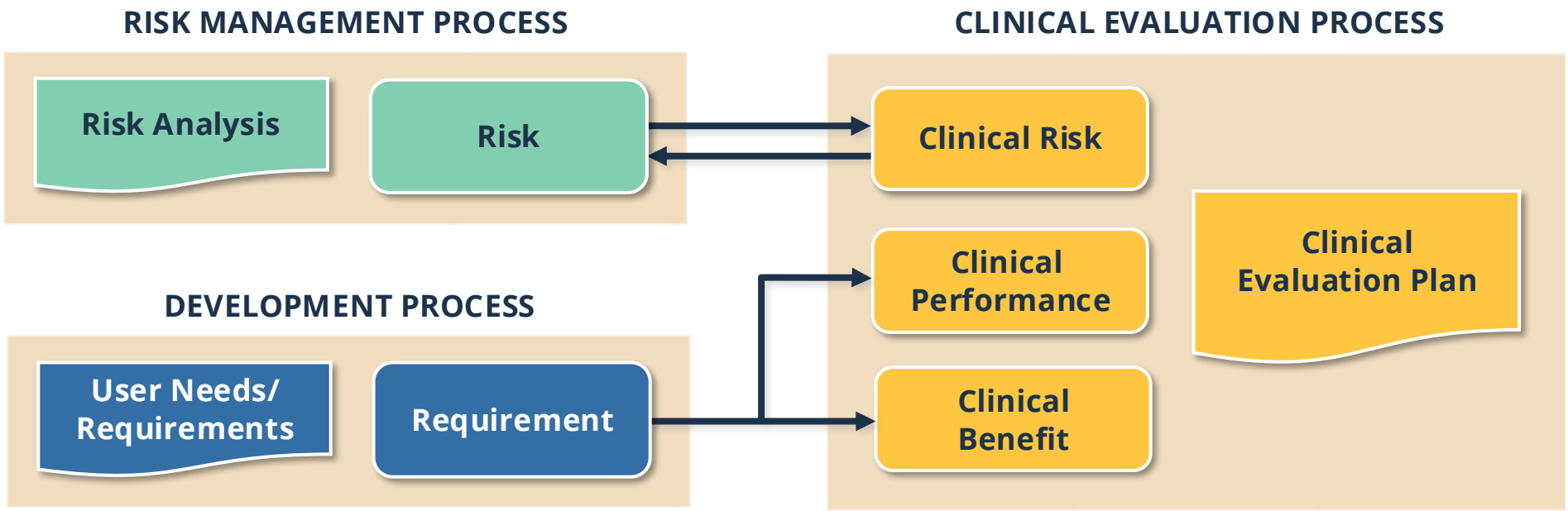
FROM DOCUMENTS TO DATA



FROM DOCUMENTS TO KNOWLEDGE



LINKS BETWEEN KNOWLEDGE UNITS



- ✓ Connection of related content in different documents
- ✓ Ensured data exchange between processes
- ✓ Automatic analysis of traceability
- ✓ Easy assessment of change impact

GENERAL TERMS – DEFINITION

Knowledge **TOPIC (KT)**

- Specific **TOPIC** of information
- Required in the TD
- „Template“

Knowledge **UNIT (KU)**

- Topic related information **UNIT**
- Included in a specific TD
- „Record“
  (completed template)

GENERAL TERMS – APPLICATION

MDKU

MEDICAL DEVICE KNOWLEDGE UNITS

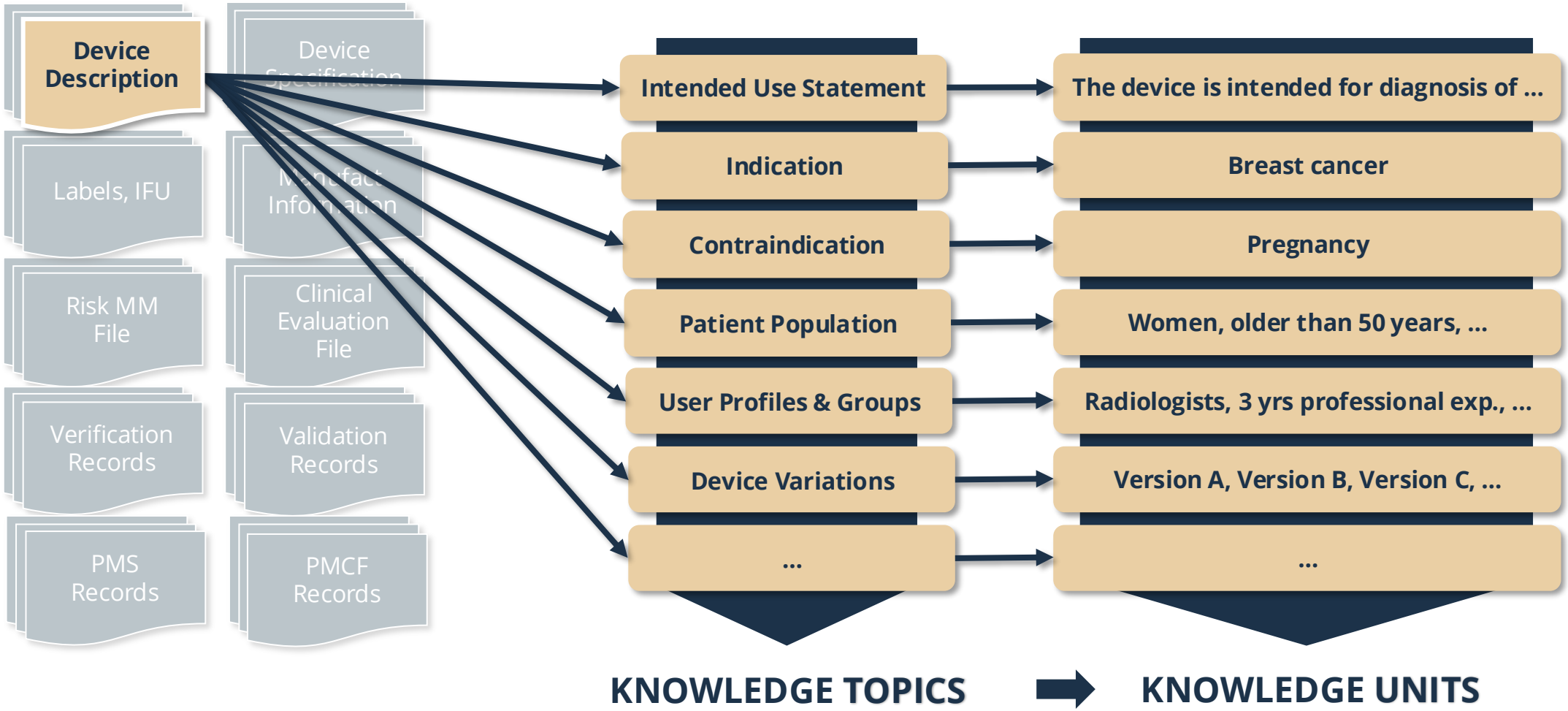
Definition of
Knowledge TOPICS

Economic Operators

Definition of
product/product group specific
Knowledge UNITS

MDKU

GENERAL TERMS – APPLICATION



CONTENT OF KNOWLEDGE TOPIC (KT) DEFINITION

Documented as part of each KT:

Information	Description	Example for KT “Intended Purpose”
ID	Centrally assigned unique ID for a single KT	#134
Name	Human readable name for the KT	Intended Purpose
Description	Description according to an existing definition in a source document or own proposal	The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation
Source	Source of definition e.g. official source or MDKU in case of missing official source	MDR, Article 2, 12
Status	Identification of KT life cycle phase within the MDKU organisation	E.g. new, in draft, ready for review, agreed, published
	Identification of KT life cycle phase when KT was published	E.g. published, under change, obsolete

CONTENT OF KNOWLEDGE TOPIC (KT) DEFINITION

Not documented as part of each KT, but as element of data model:

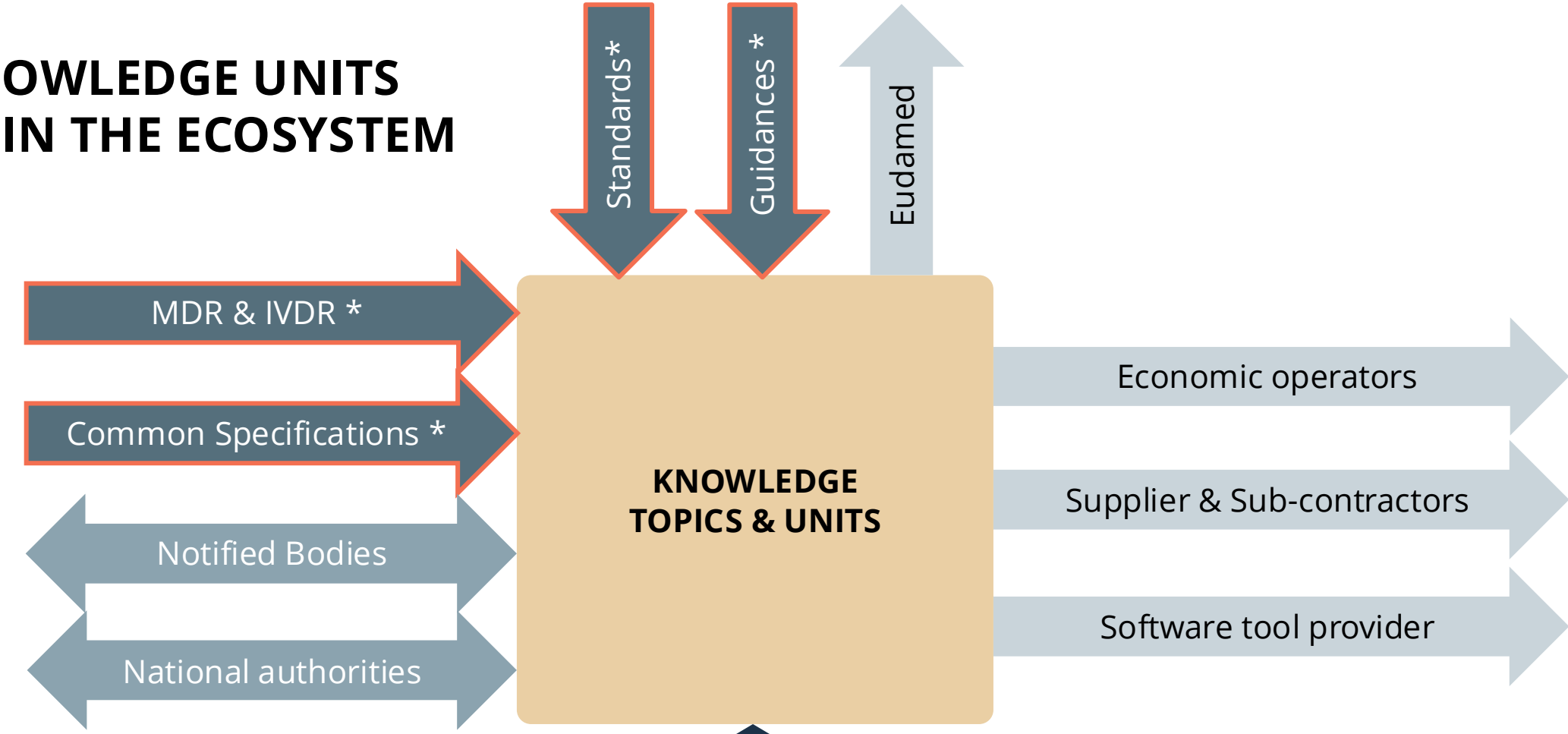
Information	Description	Example for KT “Intended Purpose”
Parent KT	Higher level KTs, automatically listed based on links between different hierarchy level.	Device Description
Child KT	Lower level KTs, automatically listed based on links between different hierarchy level.	• Indication • Contraindication • Patient population • User profiles & groups • …
Required in documents	List of documents in which the KT, respective KU, is required according to regulatory requirements	• Device description • Risk management plan • Use specification • Clinical evaluation plan • …

GENERAL TERMS – ANALOGIES

Data model and relation of KT / KU is based on existing analogies:

Area	Knowledge Topic (KT)	Knowledge Unit (KU)
Quality Management	Template/form sheet	Record (completed template/form sheet)
Pubmed Database	MeSH (Medical Subject Headings)	Single publication linked with MeSH Term
Products, e.g. cars	Model: BMW 318i	Customer specific configuration incl. leather seats, sports steering wheel, …
Object-oriented programming	Class	Instance
Technical editorial	Topic	Snippet
Terminology	Concept	Naming

KNOWLEDGE UNITS WITHIN THE ECOSYSTEM



MDKU Initiative

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

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

Stakeholder in the ecosystem confirm and use the data model

04

FROM DOCS TO DATA

Transforming document content into structured data

CardioFlow Monitor Pro

Identification of Information about KTs

Intended Patient Population

User Group

Contra-indications

CardioFlow Monitor Pro

Device description - 1

CardioFlow Monitor Pro is a non-invasive cardiac monitoring system intended for the continuous monitoring of cardiac output, heart rate, and fluid responsiveness in haemodynamically unstable patients. The system supports clinical decision-making in the management of acute circulatory failure and is not intended to replace direct physician assessment. It is designed for use in adults (≥ 18 years) admitted to an intensive care unit or high-dependency unit. The device may also be used in adolescents between 14 and 17 years of age when prescribed and supervised by a specialist in paediatric intensive care medicine. It is not intended for use in patients with known cardiac arrhythmias that cause irregular beat-to-beat intervals, as reliable cardiac output calculation cannot be guaranteed under such conditions.

CardioFlow Monitor Pro

Device description - 2

The system operates by applying a bioimpedance-based method: low-amplitude alternating electrical currents are delivered through four skin-surface electrodes placed on the thorax. Changes in thoracic electrical bioimpedance caused by pulsatile blood flow are measured and processed by the onboard signal processor. A proprietary algorithm derives stroke volume and cardiac output from the impedance waveform in real time. The system is intended to be operated by trained ICU nurses and intensive care physicians in a clinical hospital environment. Proper device function requires the patient to be in a stable supine position; results may be unreliable in patients who are morbidly obese (BMI > 40) or who have significant thoracic fluid accumulation (e.g. pleural effusion or severe pulmonary oedema).

CardioFlow Monitor Pro

Device description - 3

The CardioFlow Monitor Pro consists of a bedside monitor unit, a reusable electrode cable set, and disposable single-use adhesive electrodes. It is a Class IIa devi to the hospita interface, allowing ained in haemodynamic monitoring are required to interpret the output values; the device itself does not provide therapeutic recommendations.

Everything is here. Is it?

What We Will Do Today

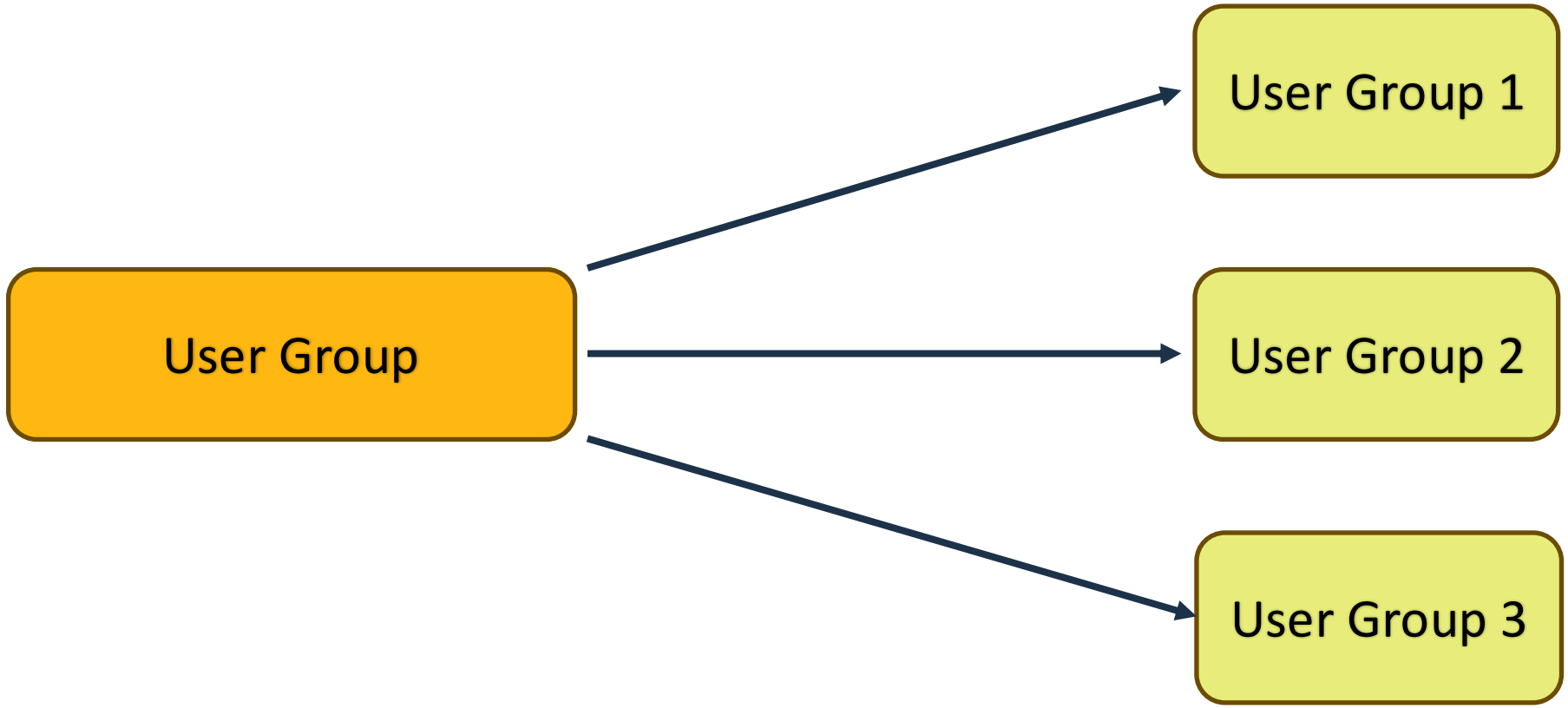
Based on KT definition we want to identify KU content in the device description

- Intended Patient Population
- User Group
- Contra-indications

Finding Types

- extractable
- gap
- misplaced

Recap: One KT can have multiple KU instances



KT - Intended Patient Population

ID: 240 | Source: MDKU Specific | Binding Force: Regulatory – Mandatory

KT-Definition: The intended patient population refers to the specific group of patients for whom the medical device is designed to be used. Referenced patient populations refer to the natural states of human being.

KT-Attributes:

- No clinical use (device is not directly used for patients)
- No restriction of the patient population
- Restrictions of the patient population

KT - Intended Patient Population

ID: 240 | Source: MDKU Specific | Binding Force: Regulatory – Mandatory

CardioFlow Monitor Pro is a non-invasive cardiac monitoring system intended for the continuous monitoring of cardiac output, heart rate, and fluid responsiveness in haemodynamically unstable patients. The system supports clinical decision-making in the management of acute circulatory failure and is not intended to replace direct physician assessment. It is designed for use in adults (≥ 18 years) admitted to an intensive care unit or high-dependency unit. The device may also be used in adolescents between 14 and 17 years of age when prescribed and supervised by a specialist in paediatric intensive care medicine. It is not intended for use in patients with known cardiac arrhythmias that cause irregular beat-to-beat intervals, as reliable cardiac output ulation under such conditions.

The system operates by ng a bioimpedance-based method: low-amplitude alternating electrical currents a four skin-surface el aced on the thorax. Changes in thoracic electrical bioimpedance caused by pulsa ard signal processor. A proprietary algorithm derives stroke volume and ca system is intended to be operated by trained ICU nurses and intensive care physicians in a evice function requires the patient to be in a stable supine position; results may be unreliable in > 40) or who have significant thoracic fluid accumulation (e.g. pleural effusion or severe

s of a bedside monitor unit, a reusable electrode cable set, and disposable single-use adhesive electrodes. It is a Class IIa device under MDR Regulation (EU) 2017/745. The device connects to the hospital's central patient data management system via a standard HL7 interface, allowing real-time data transmission to the nursing station. Clinicians trained in haemodynamic monitoring are required to interpret the output values; the device itself does not provide therapeutic recommendations.

No sentence in the paragraph addresses age groups below 14 or any other exclusion — negative scoping of the population is absent

This describes who the user must be – not who the patient is

KT - Intended Patient Population

Extracted KUs and Findings

- Haemodynamically unstable
- Adult patients ≥ 18 years admitted to an ICU / HDU

Negative scoping absent — age groups below 14 not explicitly excluded; no further patient population attributes (e.g. physiological characteristics) per KT attribute structure

Adolescent patients 14-17 years

Supervision requirement → does NOT belong to Intended Patient Population; belongs to **User Group (ID: 150)** — carried forward to next example

KT – User Group

ID: 150 | Source: Standards (IEC 62366-1) | Binding Force: Regulatory – Mandatory

KT-Definition: A user group summarizes a subset of users who are differentiated from other users by factors that are likely to influence their interactions with the medical device.

KT-Attributes: N/A

KT – User Group

ID: 150 | Source: Standards (IEC 62366-1) | Binding Force: Regulatory – Mandatory

CardioFlow Monitor Pro is a non-invasive cardiac monitoring system intended for the continuous monitoring o
rate, and fluid responsiveness in haemodynamically unstable patients. The system supports clinical decision-m
management of acute circulatory failure and is not intended to replace direct physician assessment. It is desig
18 years) admitted to an intensive care unit or high-dependency unit. The device may also be used in ad
years of age when prescribed and supervised by a specialist in paediatric intensive care medicine. It is not inte
with known cardiac arrhythmias that cause irregular beat-to-beat intervals, as reliable cardiac output calculation cannot be guaranteed

Transfer from context of KT Intended Patient Population (supervisory user group)

Not much information on user profile, e.g., knowledge level, education, training requirements, for any user group

mpedance-based method: low-amplitude alternating electrical currents are delivered through
e thorax. Changes in thoracic electrical bioimpedance caused by puls
d signal processor. A proprietary algorithm derives stroke volume and ca output from the
ystem is intended to be operated by trained ICU nurses and intensive care physicians in a
clinical hospital environment. Proper device function requires the patient to be in a stable supine position; results may be unreliable in patients who are morbidly obese (BMI > 40) or who have significant thoracic fluid accumulation (e.g. pleural eff
pulmonary oedema).

Primary user group

The CardioFlow Monitor Pro consists of a bedside monitor unit, a reusable electrode cable set, and disposable
electrodes. It is a Class IIa device under MDR Regulation (EU) 2017/745. The device connects to the hospital's centra t data management system via a standard HL7 interface, allowing real-time data transmission to the nursing station. Clinicians trained in haemodynamic monitoring are required to interpret the output values; the device itself does not provide therapeutic recommendations.

Scattered content, separated from the rest of the user information

MDKU

KT – User Group

Extracted KUs and Findings

ICU nurses and intensive care physicians (primary user group)

- Secondary user groups (e.g. staff responsible for electrode placement, device maintenance) not mentioned
- Content for KT User Profile missing

- Paediatric ICU specialist
- Clinicians trained in haemodynamic monitoring

- Transferred from KT – Intended Patient Population
- Scattered content: Sentence at the end belongs here

KT – Contra-Indications

ID: 210 | Source: MDKU Specific | Binding Force: Regulatory – Mandatory

KT-Definition: A contra-indication is a condition or factor related to the patient that makes the use of a medical device or procedure improper or inadvisable.

KT-Attributes:

- **Absolute** - using the device/procedure poses **unacceptable risk** to the patient
- **Relative** - using the device/procedure poses **additional risk** to the patient, while the benefits may outweigh risks

KT – Contra-Indications

ID: 210 | Source: MDKU Specific | Binding Force: Regulatory – Mandatory

Neither paragraph carries an attribute (absolute / relative) as required by KT

is a non-invasive cardiac monitoring system intended for the continuous monitoring of cardiac output, heart ess in haemodynamically unstable patients. The system supports clinical decision-making in the ulatory failure and is not intended to replace direct physician assessment. It is designed for use in adults (≥ ntensive care unit or high-dependency unit. The device may also be used in adolescents between 14 and 17 years of age when prescribed and supervised by a specialist in paediatric intensive care medicine. It is not intended for use in patients with known cardiac arrhythmias that cause irregular beat-to-beat intervals, as reliable cardiac output calculation cannot be guaranteed under such conditions.

The system operates by applying a bio ing electric four skin-surface electrodes placed on dance caus measured and processed by the onboa es stroke volume an utput from the impedance waveform in real time. The system is inte o be operated by trained ICU nurses and intensive ca hysicians in a clinical hospital environment. Proper device function requires the patient to be in a stable supine position; results may be unreliable in patients who are morbidly obese (BMI > 40) or who have significant thoracic fluid accumulation (e.g. pleural effusion or severe pulmonary oedema).

This is not a contra-indication. It concerns a user action and belongs to limitations of use.

Located in the operating principle paragraph: Contra-indication or limitation of use?

The CardioFlow Monitor Pro consists of a bedside monitor unit, a reusable electrode cable set, and disposable single-use adhesive electrodes. It is a Class IIa device under MDR Regulation (EU) 2017/745. The device connects to the hospital's central patient data management system via a standard HL7 interface, allowing real-time data transmission to the nursing station. Clinicians trained in haemodynamic monitoring are required to interpret the output values; the device itself does not provide therapeutic recommendations.

KT – Contra-Indications

Extracted KUs and Findings

Patients with cardiac arrhythmias causing irregular beat-to-beat intervals.
Attribute: **absolute** contra-indication (reliable calculation not possible) not assigned in document

No attribute assignment (absolute / relative) for either KU

Morbidly obese patients (BMI > 40).
Attribute: **relative** contra-indication (unreliable results, not unacceptable risk)

Misplaced content to KU: embedded in Operating Principle paragraph

From Knowledge Topics to Knowledge Units

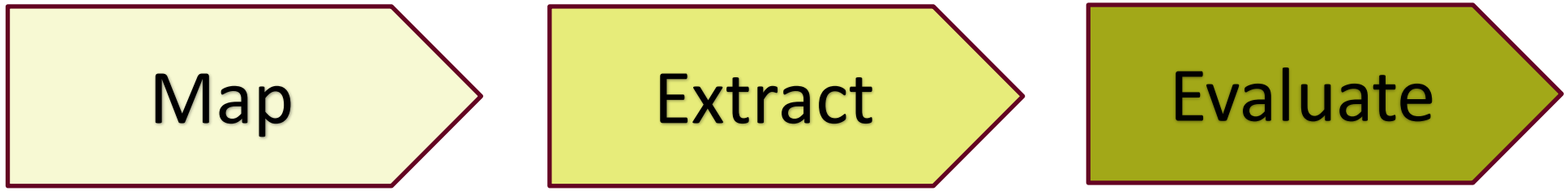
What the Three Examples Show Us

KT (ID)	What looks fine in the document	What the KT lens reveals
Intended Patient Population	Two patient groups are described	Negative scoping missing; user role embedded in patient section
User Group	Users are named	Content scattered across the paragraph; User Profile (a separate mandatory KT) entirely absent
Contra-indications	Limiting conditions are mentioned	Content split across two paragraphs; mixed with Operating Principle text; mandatory attributes not assigned

"The data model does not find new problems. It makes existing ones visible, locatable, and addressable."

From Observation to Action

The three-step Workflow



Identify which KTs apply to the document section under review

Create KUs, applying the KT definition and its attribute structure as a precision filter

Determine for each KU: complete · gap · or misplaced?

Transforming Document Content into Structured Data

This approach transforms a completeness review from a subjective document read-through into a structured, repeatable, and auditable process.

05

HANDS-ON

Let's get into it

06

WRAP-UP

Summary and conclusions

THE REGULATORY REVOLUTION

MEDICAL DEVICE KNOWLEDGE UNITS

www.mdku.digital
mailto: info@mdku.digital