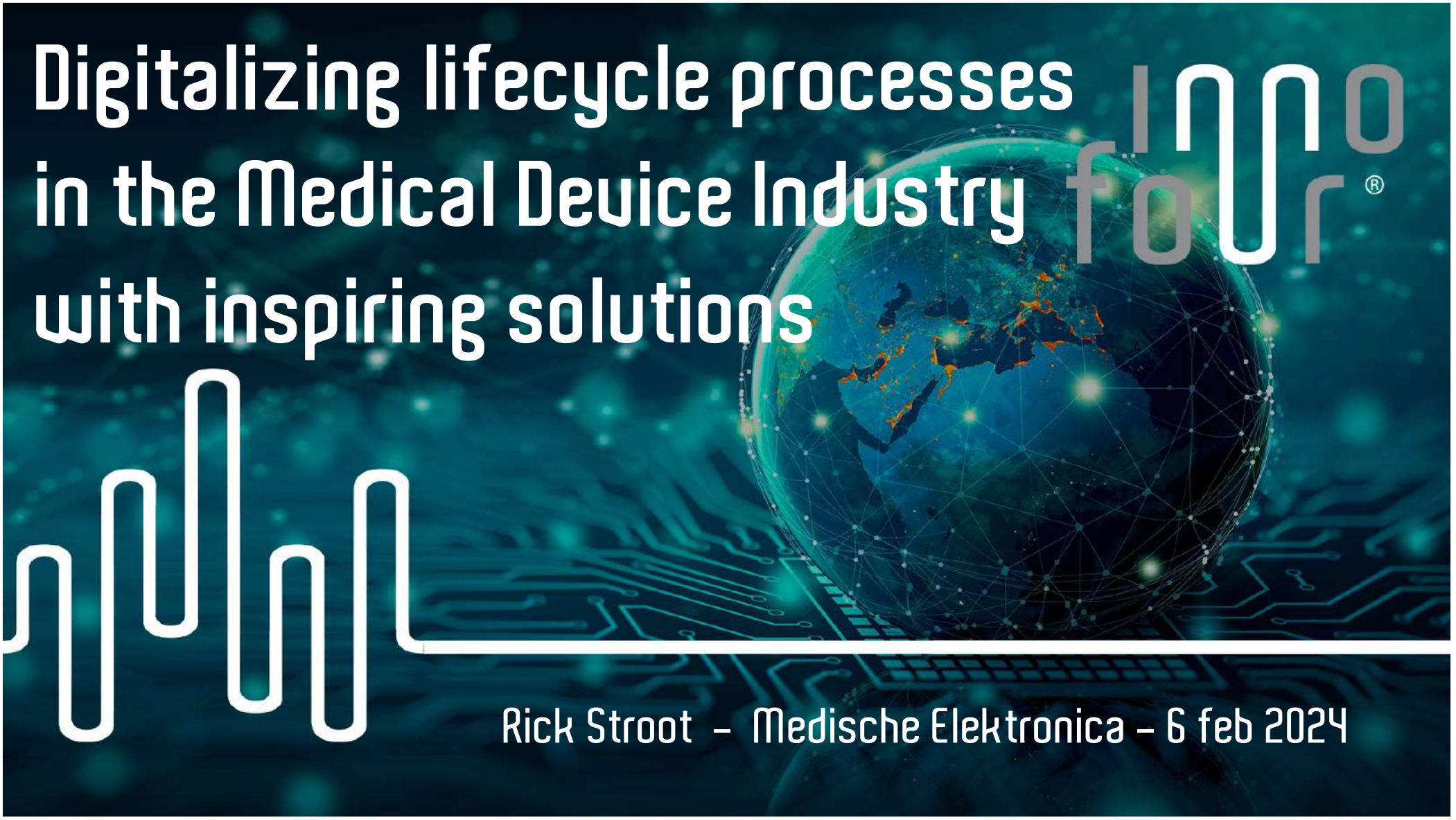
Digitalizing lifecycle processes in the Medical Device Industry with inspiring solutions

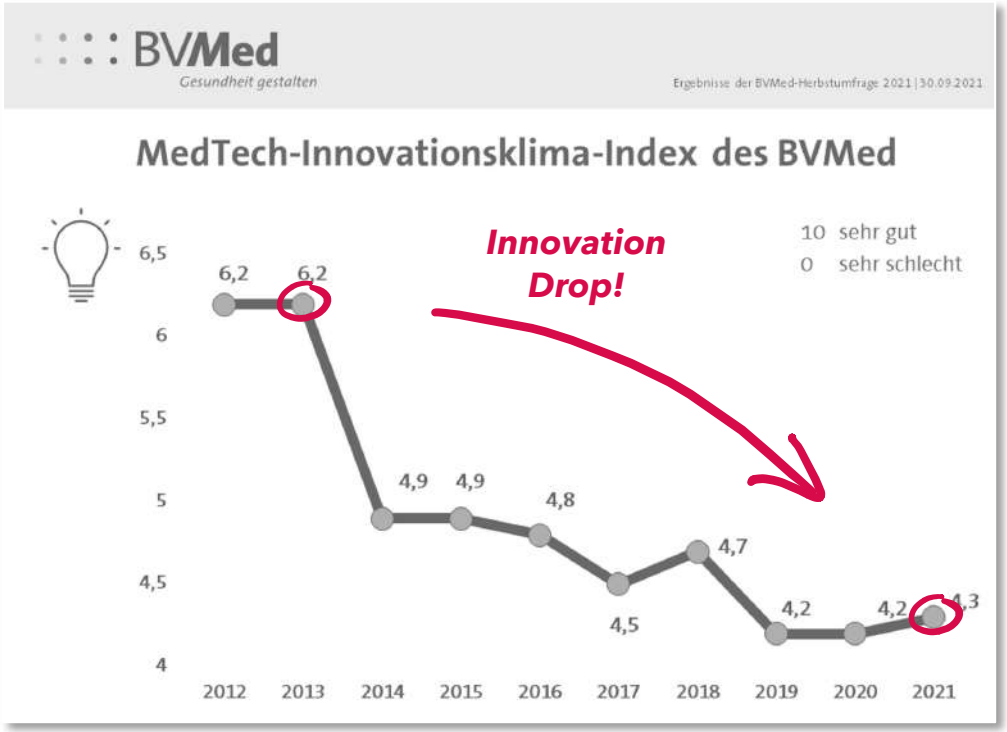


Rick Stroot – Medische Elektronica – 6 feb 2024

Agenda

- Key Challenges in the Medical Technology Industry
- Overview of inspiring solutions for the Medtech Industry

MEDTECH Industry today



Less and less innovation in Medtech in Europe

↓

Patients do not receive the care they need

+

Competition & lead from companies from other countries is increasing!

Survey results from German industry association BVMed:
Evaluation of the innovation climate index (10 = very good, 0 = very bad)

Barriers to Innovation

Example Germany:

BVMed MedTech-Marktpräsentation 27.07.2023 Seite 25

Aktuelle Herausforderungen

- Unsichere Lieferketten
- Gestiegene Kosten für Energie, Rohstoffe und Logistik
- Inflation und steigende Löhne

Hausgemachten Probleme

- Kompliziertes regulatorisches System für Medizinprodukte (MDR)
- Überbordende Bürokratisierung und Regulierungswut
- Schleppende Digitalisierung und mangelnde Datennutzung
- Unzureichende Unterstützung des Mittelstandes

Survey results from German industry association BVMed: Current challenges of the industry, key problems:

- **Too complex regulatory system** for medical devices (**MDR/IVDR**)
- **Digitalization** is far **too slow** and **lack of data usage**

DIGITALISATION supports management & implementation of complex regulatory requirements for:

1. **PROCESSES**
2. **TECHNICAL DOCUMENTATION**

Key Challenges

Problems with regard to information in regulatory processes & technical documentation (TD):

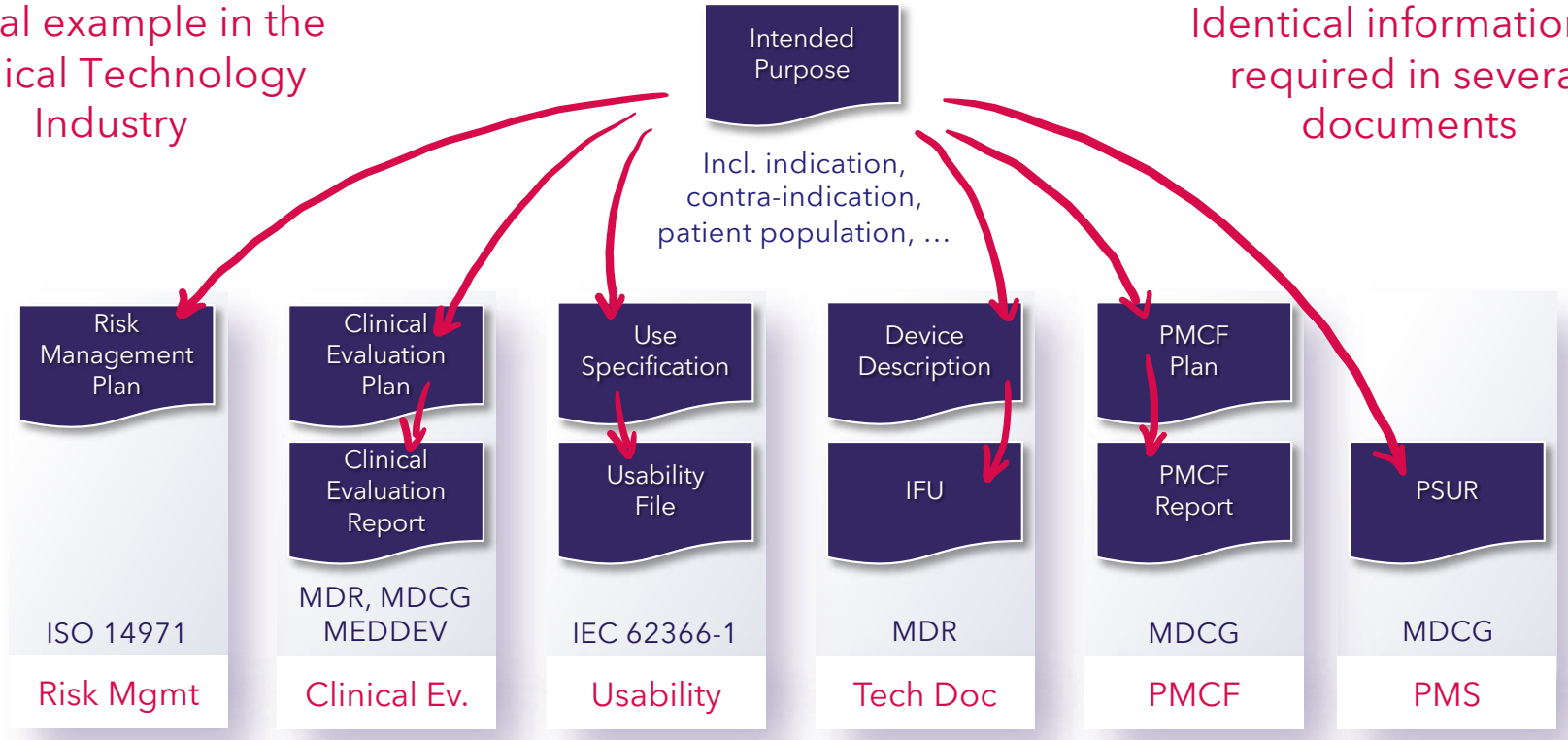
1. Consistent regulatory language
2. Reuse & consistency
3. Dependency of Information
4. Completeness of required information

Through Digitalization

Industry Challenge 2

Reuse of Information for Regulatory Compliance

Typical example in the Medical Technology Industry



Identical information is required in several documents

Industry Challenge 2

Reuse of Information: Potential of Digitalization

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

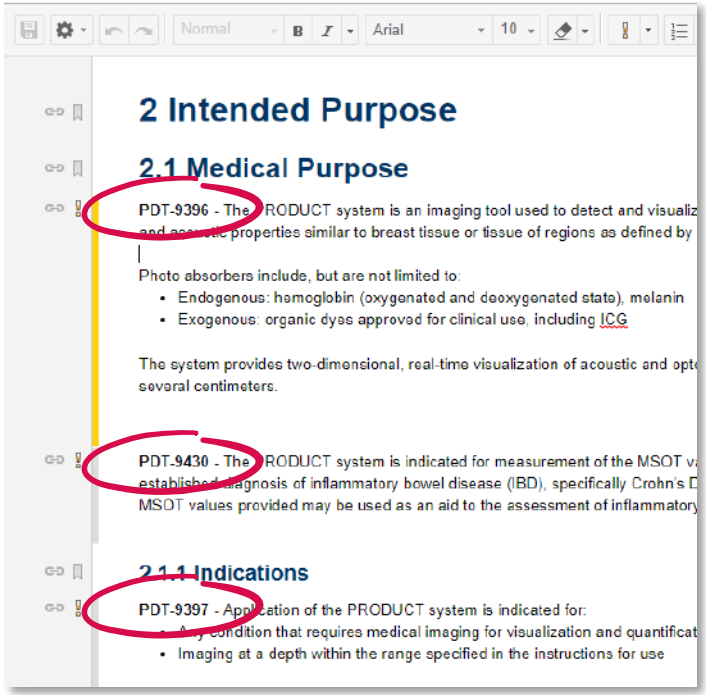
Analysis of content required in PMS/PMCF documents acc. to related MDCG guidances

For details see avasis Webinar „PMS & PMCF"

+ Reuse for Variations!

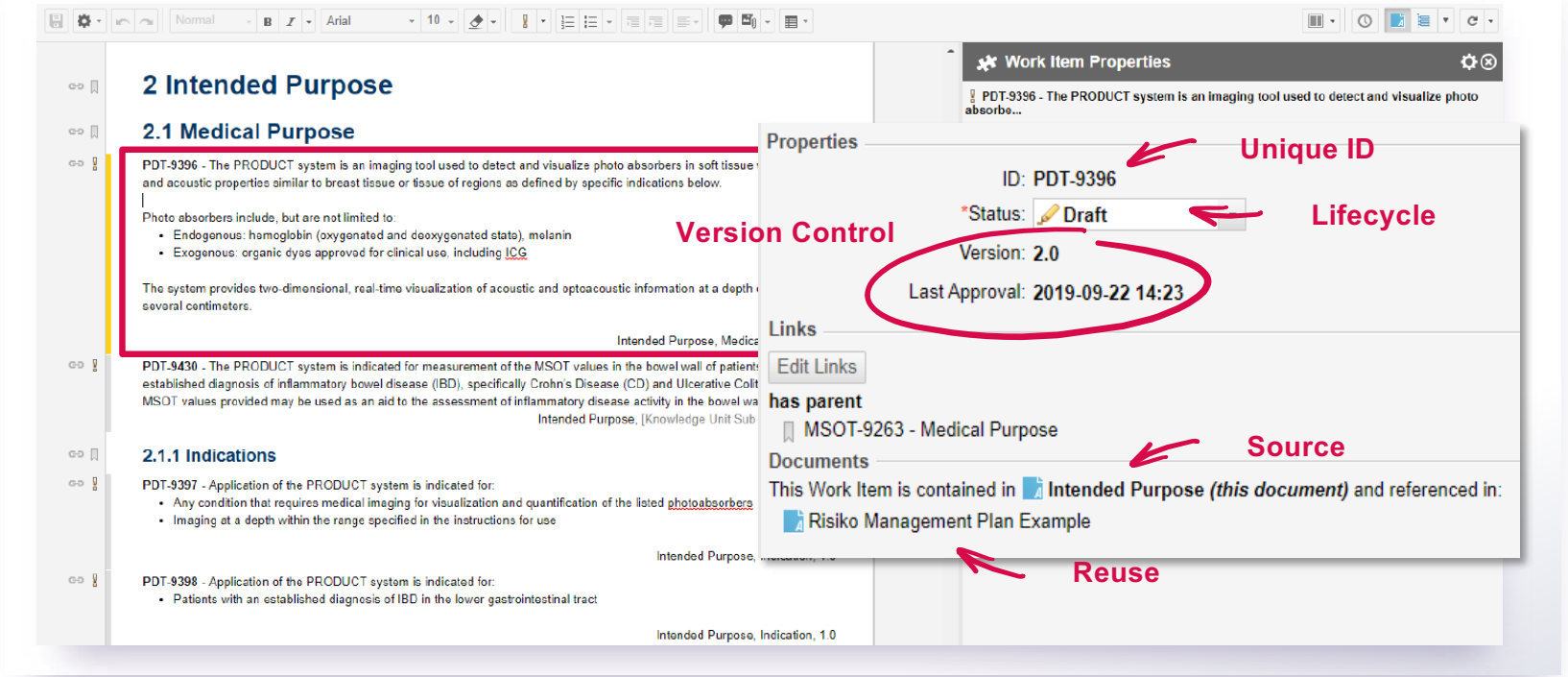
Technical Solution 3

Transformation from Documents to Knowledge



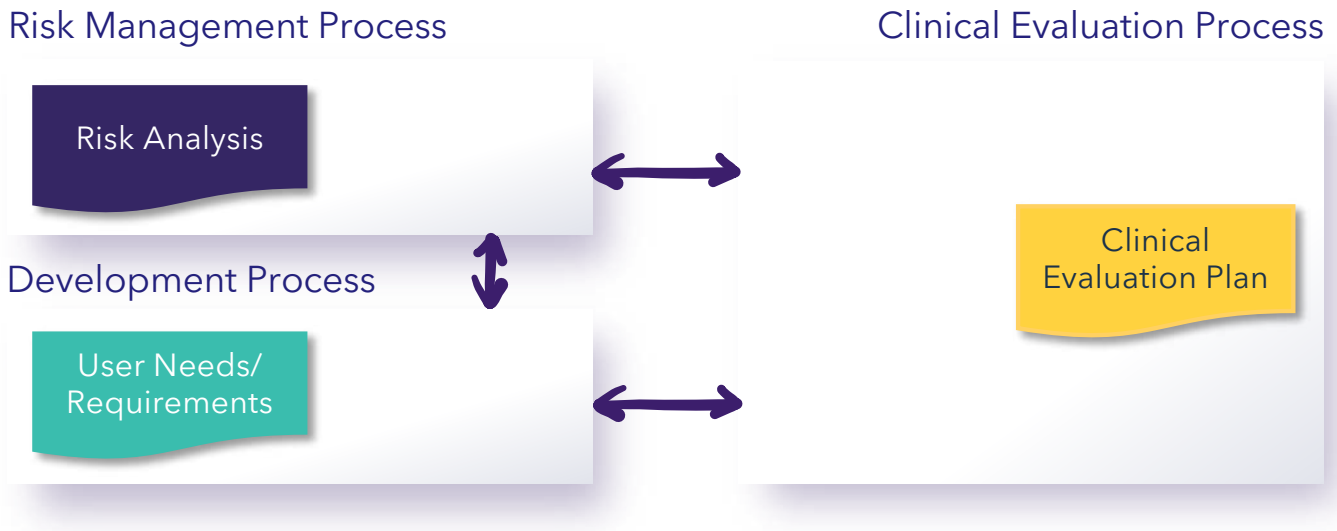
Technical Solution 3

Manage Information with Work Items



Industry Challenge 3

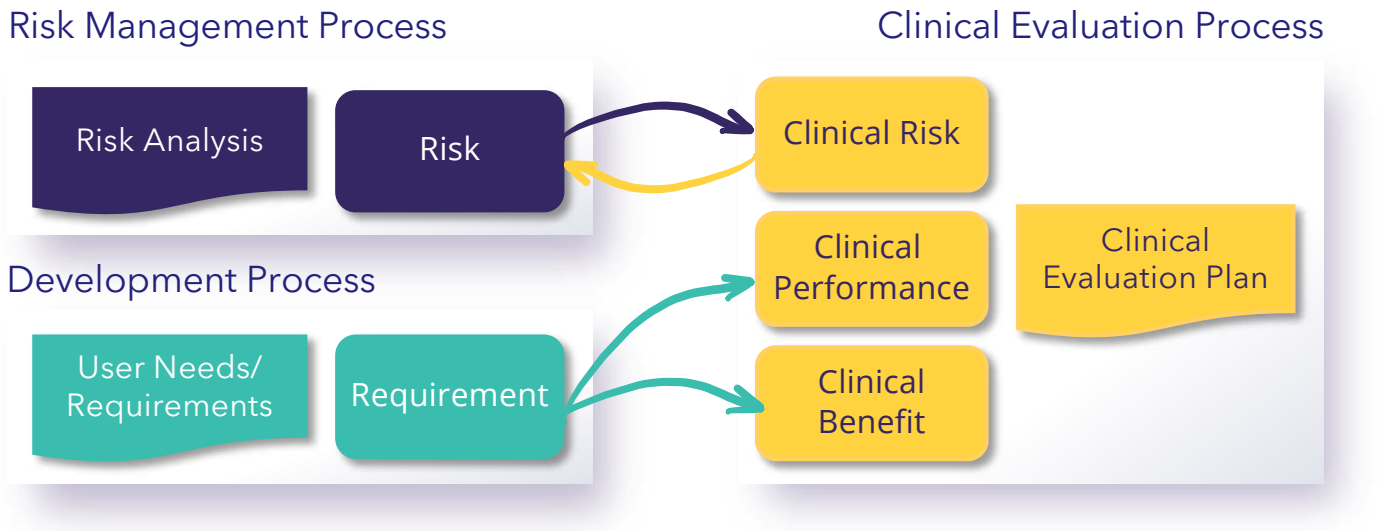
Visualization of Dependencies between Processes



- Interdependency of processes and related documents
- Connection of documents in form of references

Technical Solution 3

Visualization of Dependencies



- Interdependency of processes and related data in documents
- Connection of single input and output data
- **Connection on data level and not only document level required!**

Industry Challenge 4

Ensuring Completeness of Information

Technical Documentation

Submission acc. 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**

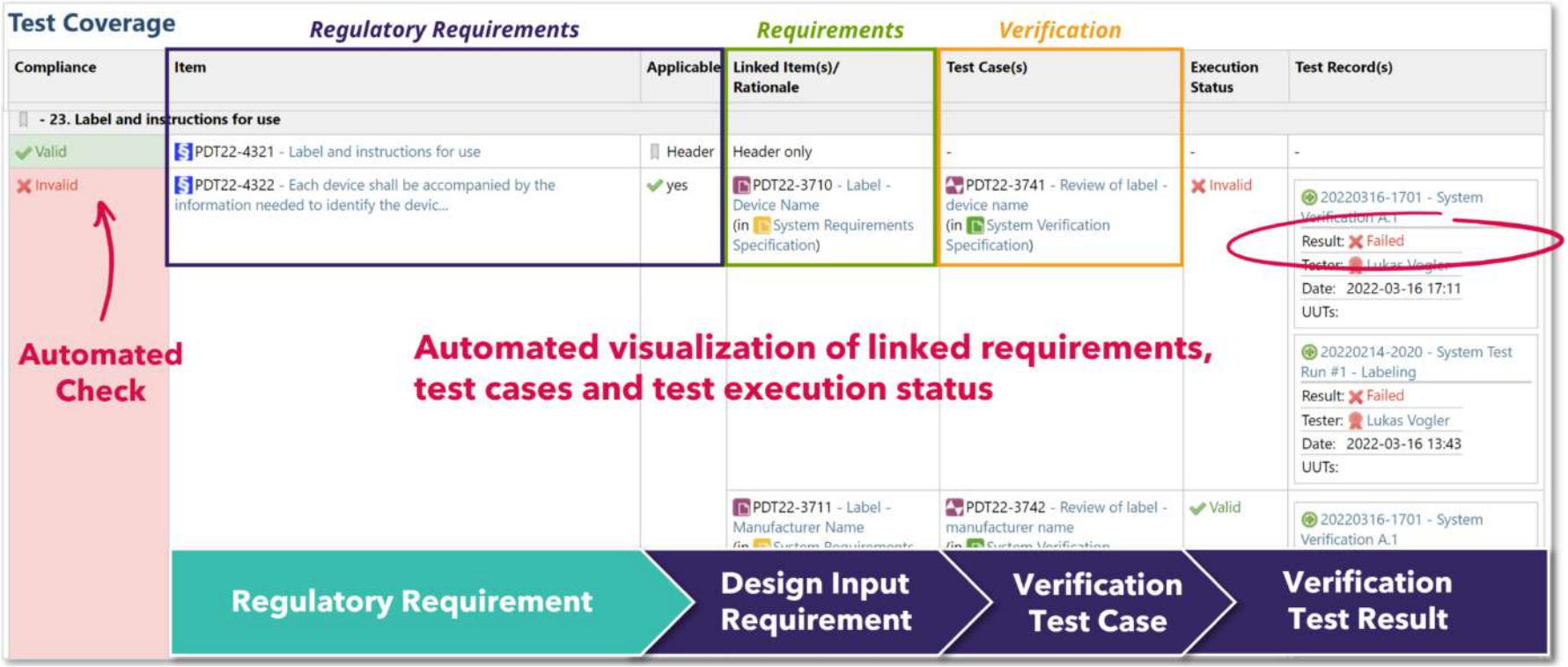
- TD Review Performance
- TD Review Biocomp.
- TD Review Packaging
- TD Review Sterility
- TD Review Clinical File

Creation by Manufacturer

Review by Notified Body

Technical Solution 4

Automated Completeness Checks



Overview

Solutions for Medical Device Lifecycle Processes

PRODUCT DEVELOPMENT
Requirements Engineering, Interface to Teamcenter for Design Development, Verification & Validation

1. Management of regulatory documents & requirements from laws, standards, guidances, interface to development

2. Creation & management of the risk mgmt. file, interfaces to dev., usability engineering, clinical ev.

3. Documentation of usability engineering activities, creation of usability file, interfaces to dev. & risk mgmt

4. Documentation of clinical evaluation activities, creation of Clinical Evaluation File, execution & documentation of literature reviews, interfaces to development risk mgmt

5. Management of PMCF activities and creation of PMCF Files, interfaces clinical ev. & risk mgmt

6. Management of PMS activities and creation of PMS Files, interfaces clinical ev. & risk mgmt

1. Development Input & Regulatory Input
2. Risk Management & FMEA
3. Usability Engineering
4. Clinical Evaluation & Literature Reviews
5. Post-market Clinical Follow-up
6. Post-market Surveillance

Benefits of presented Solutions

Speeds up processes & Document Creation

Completeness and easy reuse of information in different processes and documents:

- **Save up to 30% of time*** for creation of regulatory documents
- Ensure completeness and consistency of information in different documents
- Visualize the source document of an information unit and documents in which it is reused
- Decide, if changes of information in the source document shall be automatically implemented in other documents as well

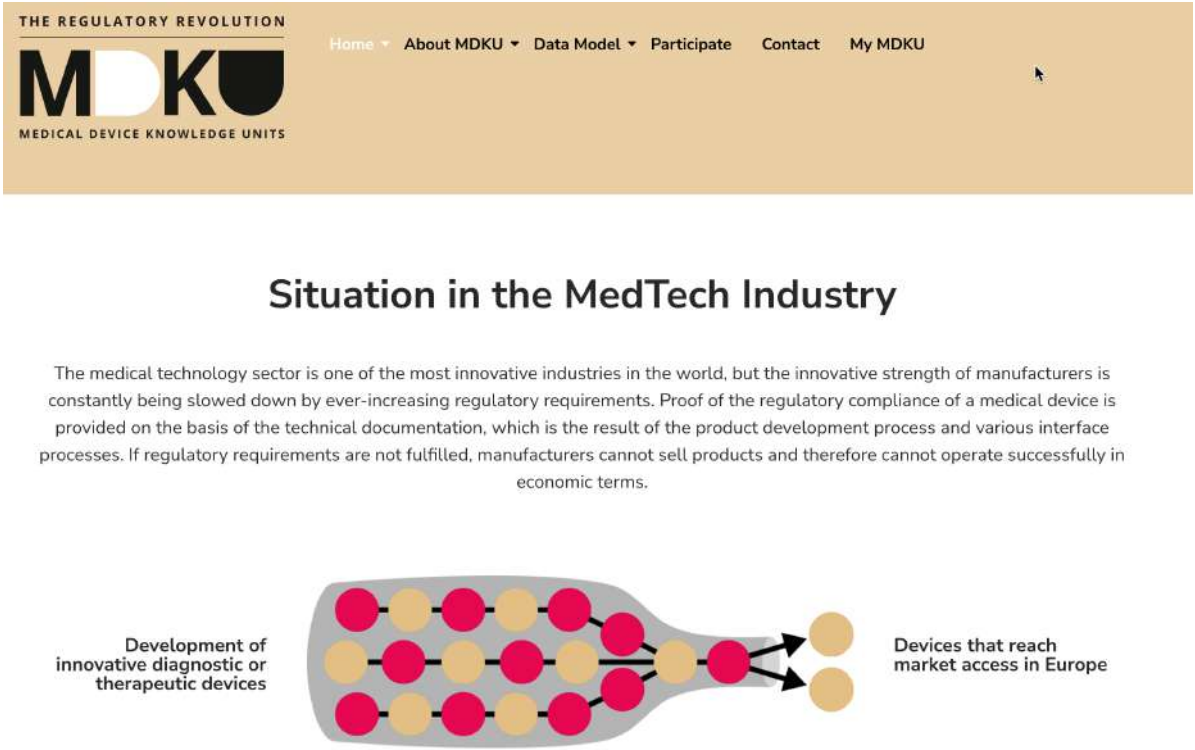
Visualize dependencies between single data sets instead of references to documents:

- Fulfill regulatory requirements for traceability between processes and documents
- Analyze automatically the impact of changes across different processes and documents

* Estimated by avasis customers based on calculation of time for „copy & paste“ / „review of consistency“ – Contact provided on request

References

More information check this website: https://mdku.digital/



Questions?

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