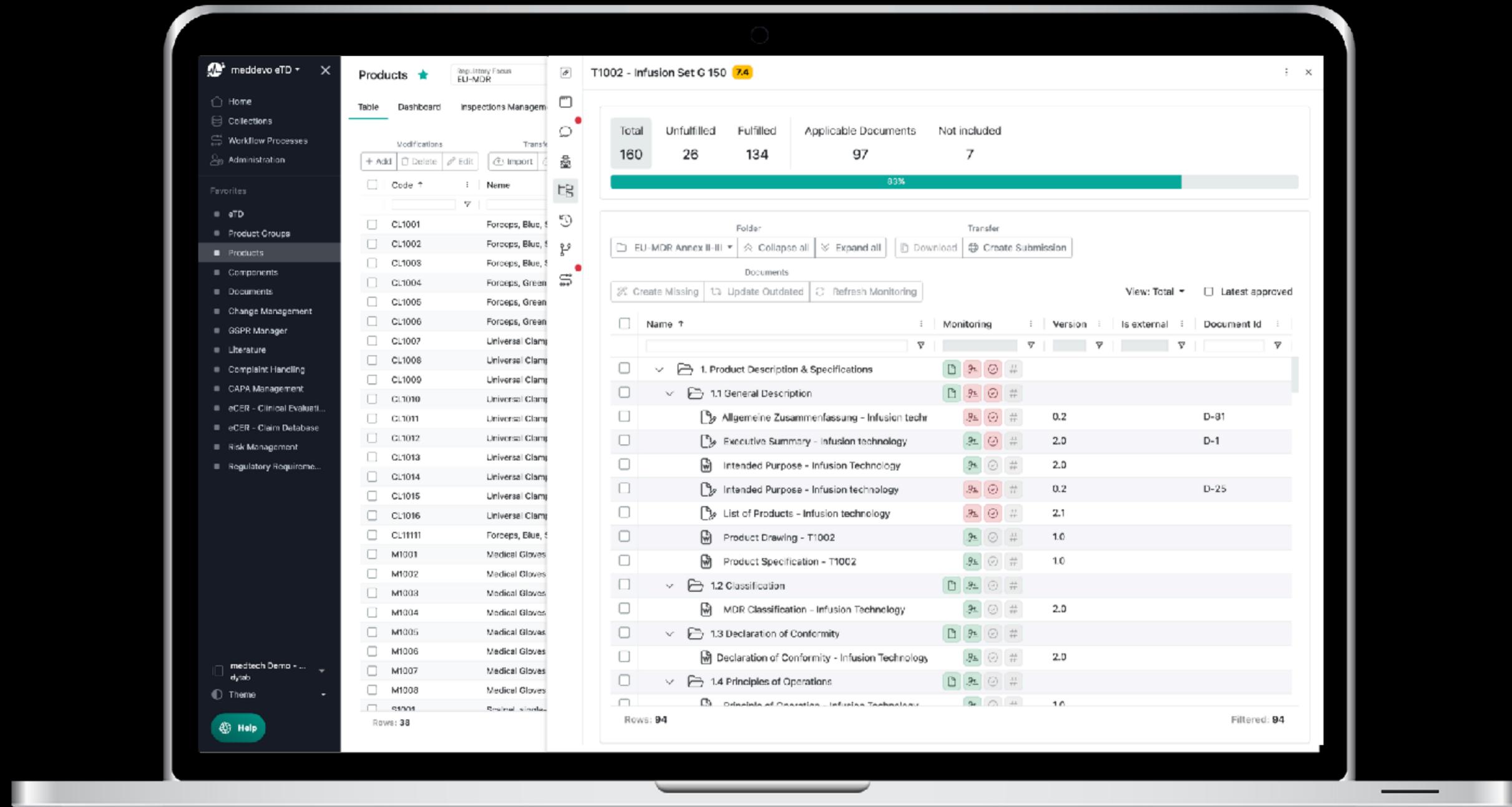
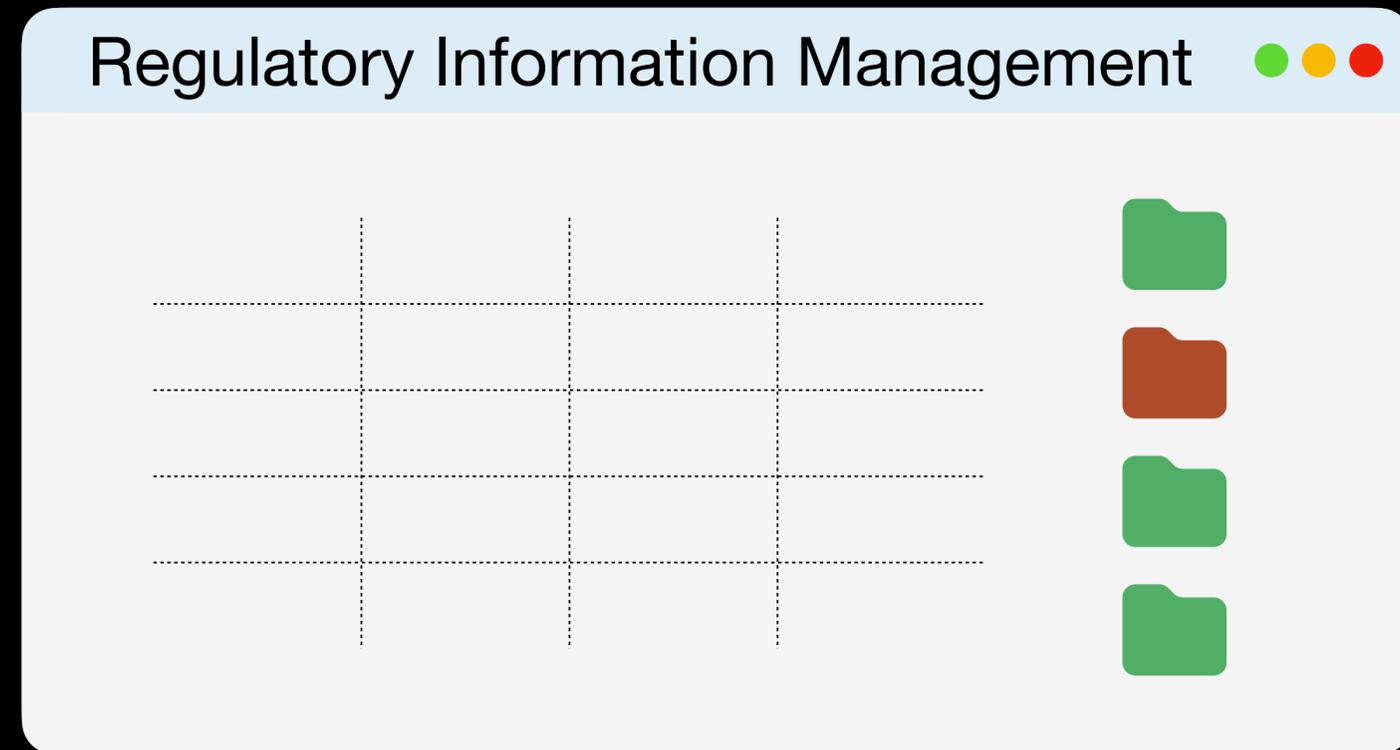
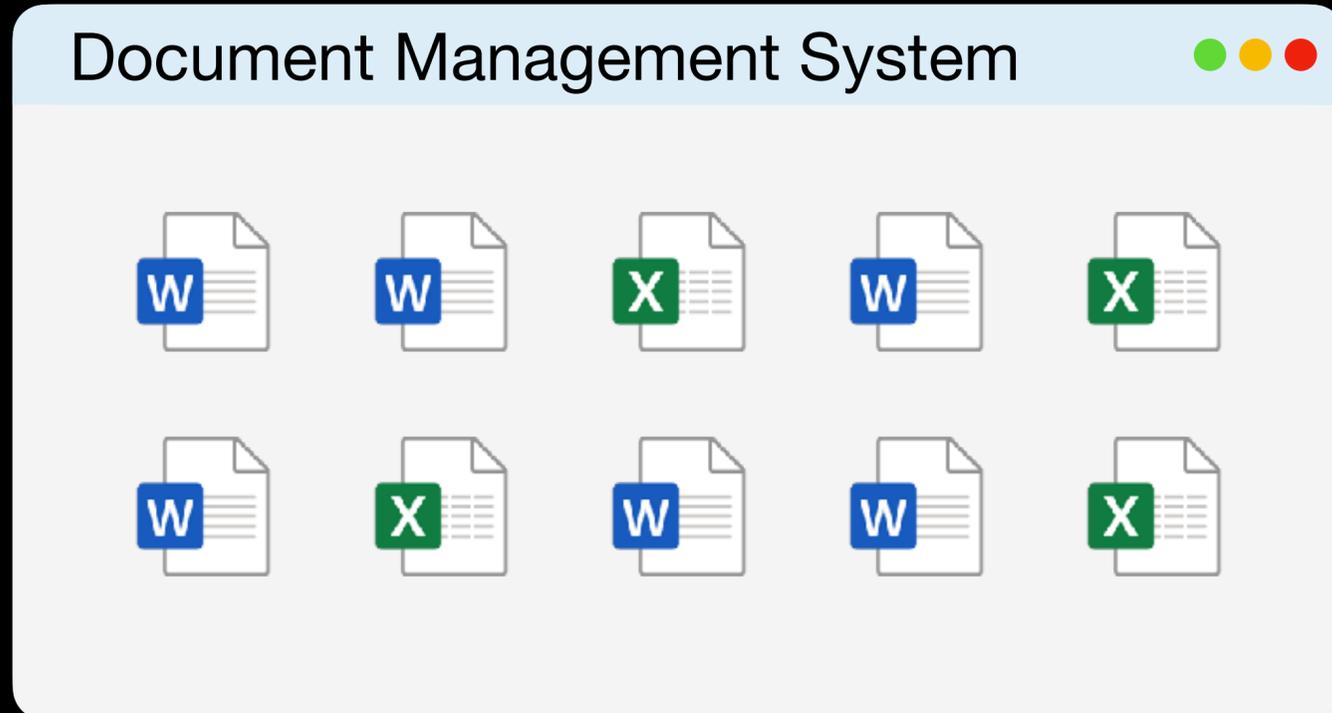




AUTOMATING REGULATORY





REDUNDANZEN

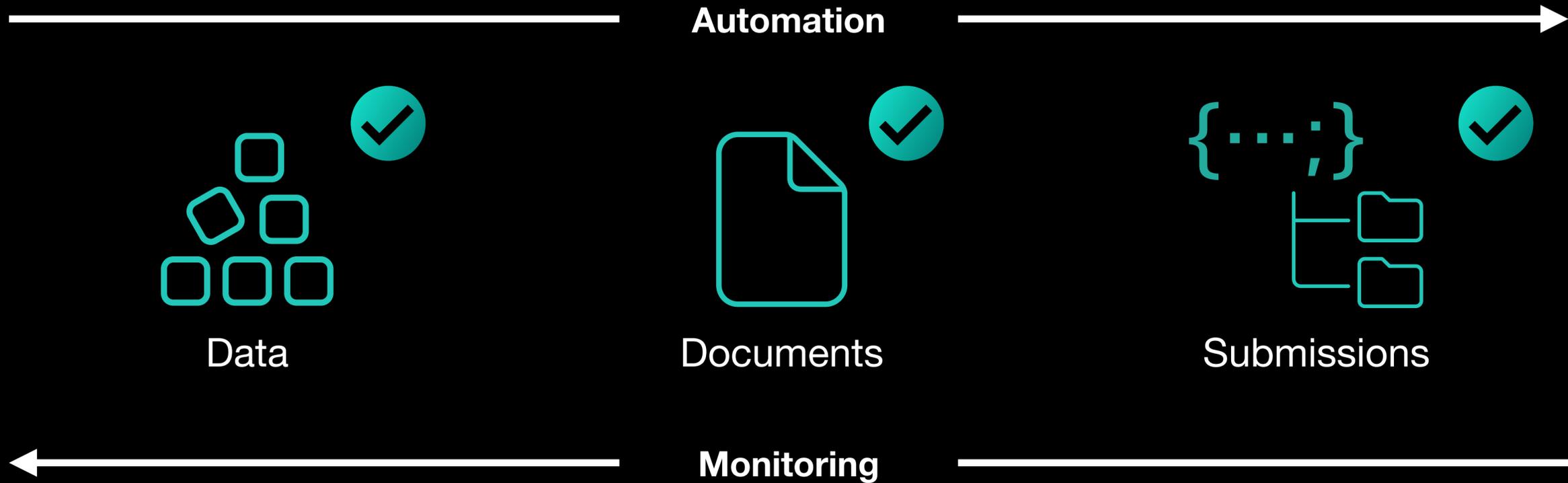
ÜBERALL REDUNDANZEN











✓ Vorkonfiguriert / Anpassbar / Erweiterbar

ERP

Portfolio Management

Standard Management

GSPR Management

Clinical Evaluation

Design Control

UDI

PMS

Standard Monitoring

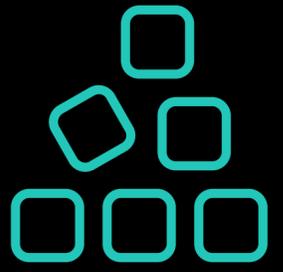
Submission Management

Risk

+

ALM

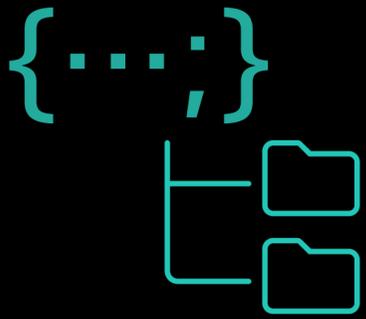
eTD Automation Foundation



Data

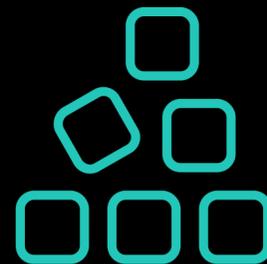
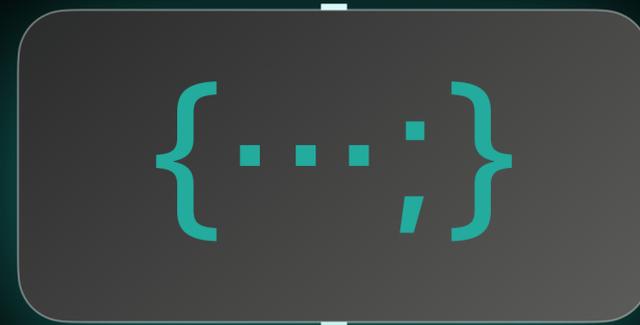


Documents



Submissions

Notified Body



- Administration
- Products
- Components
- Standard Management
- Document Management
- Documents
- Document Folders
- Registration & Audit Ma

Werden Sie Mitglied der **meddevo eTD User-Community** mit über

60.000 Produkten

Proud Partner of:



” Eine strukturierte und klare digitale Dokumentation ist der erste Schritt zum Erfolg.

Dr. Bassil Akra
meddevo Advisory Board





**ES GIBT TD SYSTEME
FÜR REGULATORY AFFAIRS?**

-  Home
-  Collections
-  Workflow Processes
-  Administration

- Favorites
- Product Groups
 - Products
 - Components
 - Documents
 - Document Folders
 - Registration & Audit Ma...
 - GSPR Manager
 - Change Management
 - Standard Management
 - Clinical Evaluation Man...

Content Management



eTD



Product Groups



Products



Components

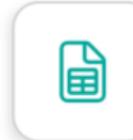
Registrations & Audits



Registration & Audit Management

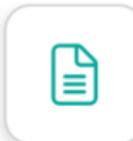


GSPR Manager



Standard Management

Document Management



Documents



Document Folders



New Document

Workflows

7

Processes I can contribute to

5

Processes I have contributed to

Collections

Contacts & Legal Entities

Intended Purposes

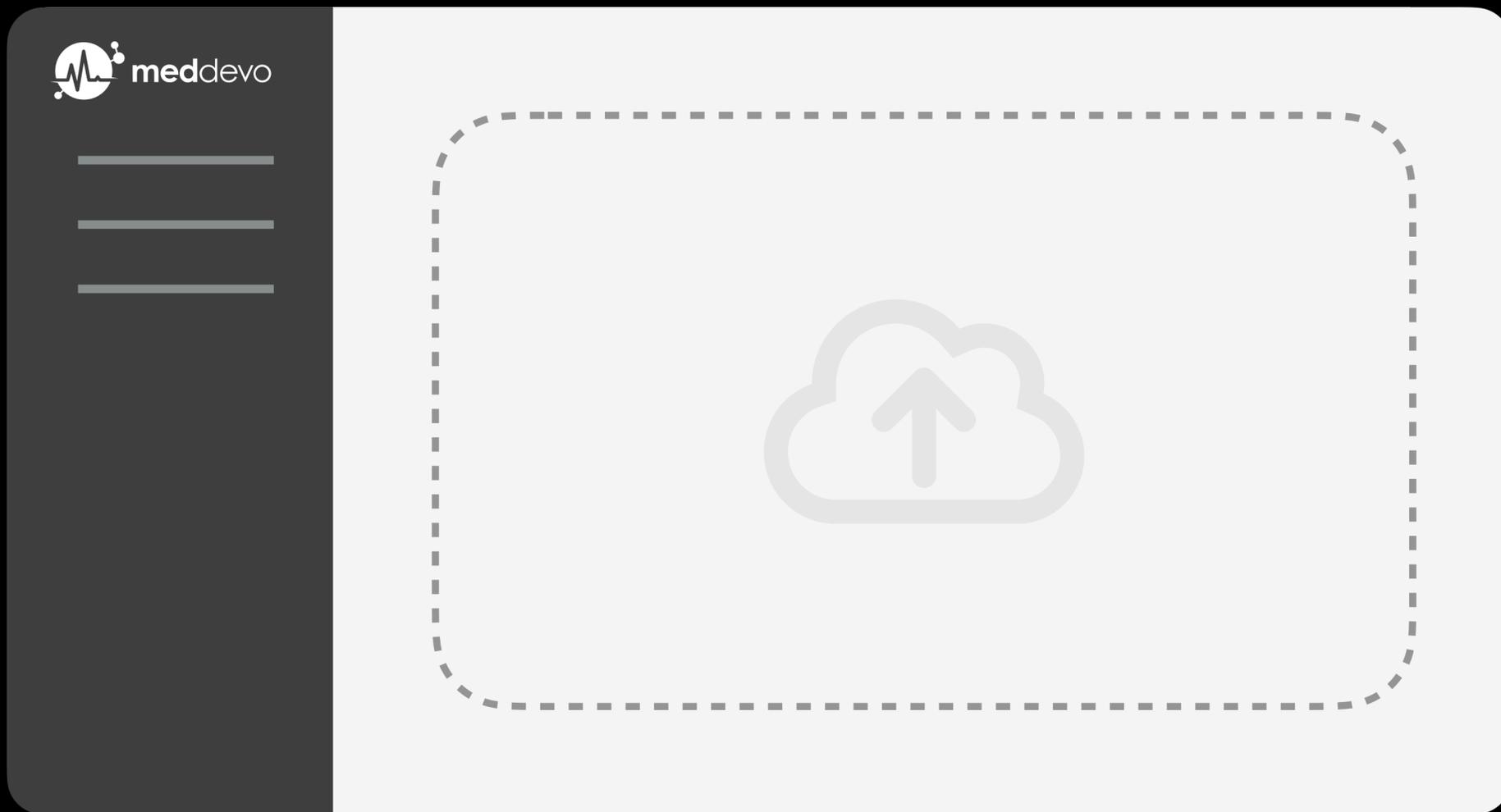
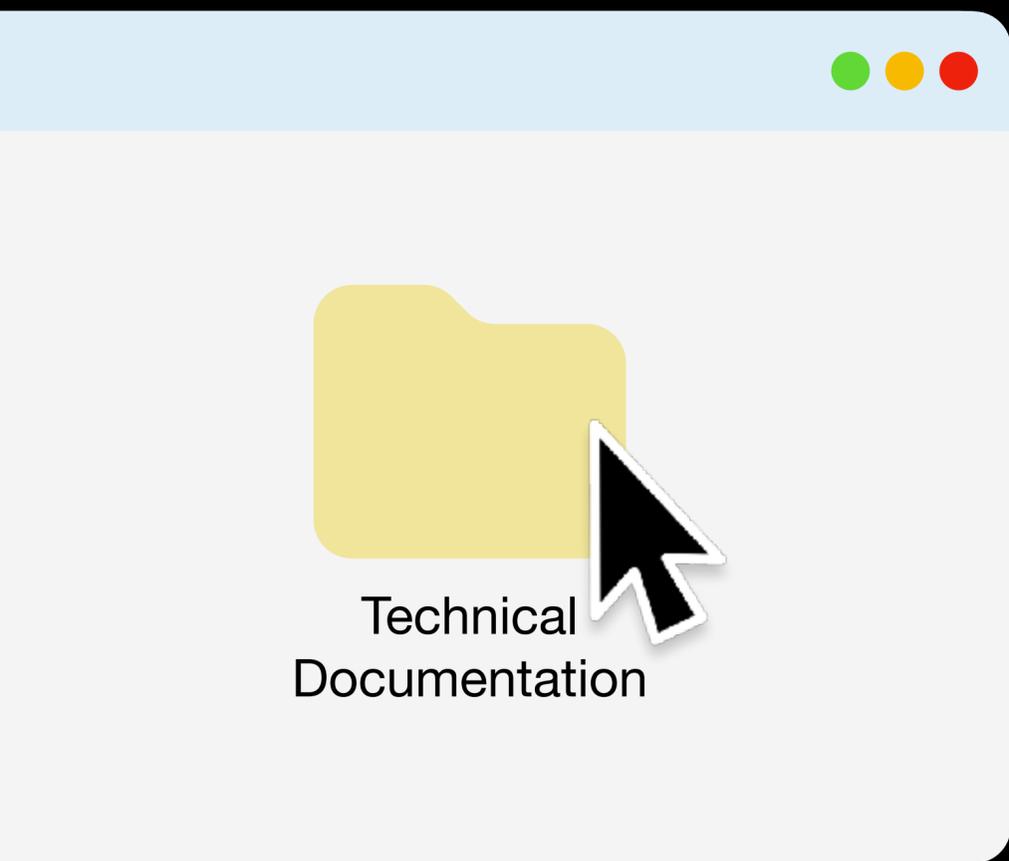
UDI-DIs

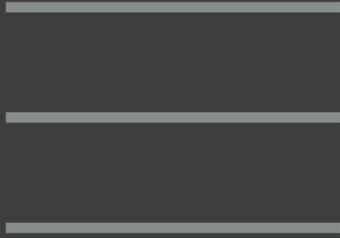
Basic UDI-DIs

Regulatory Requirements

Applicable Requirements

[Show more](#)





Fortschritt



TD Health

Error

MDR Classification

OK

Product Description

OK

ANVISA Classification

Error

BASIC UDI-DI

OK

MDA/MDN Code

RA Framework

EU-MDR

EU-MDR, ANVISA

ANVISA

EU-MDR

EU-MDR

- Home
- Collections
- Workflow Processes
- Administration

- Favorites
- Product Groups
 - Products
 - Components
 - Documents
 - Document Folders
 - Registration & Audit Ma...
 - GSPR Manager
 - Change Management
 - Standard Management
 - Clinical Evaluation Man...

Full dytab

Help

Table Dashboard Inspections Management Folder Preview Template Management

Modifications

+ Add Delete Edit

Code ↑	Name
<input type="checkbox"/>	
<input type="checkbox"/>	CL1001
<input type="checkbox"/>	CL1002
<input type="checkbox"/>	CL1003
<input type="checkbox"/>	CL1004
<input type="checkbox"/>	CL1005
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<input type="checkbox"/>	CL1007
<input type="checkbox"/>	CL1008
<input type="checkbox"/>	CL1009
<input type="checkbox"/>	M1001
<input type="checkbox"/>	M1002
<input type="checkbox"/>	M1003
<input type="checkbox"/>	M1004
<input type="checkbox"/>	S1001
<input type="checkbox"/>	S1002
<input type="checkbox"/>	S1003

Rows: 23

T1001 - Infusion set G 100 2.7

Total Unfulfilled Fulfilled

84 14 70

Progress ?



View: Total

Status	Name ↑	Level	Regulatory Frame...	Origin
Fulfilled	Description of outsource...	Warning	ANVISA, EU-MDD, EU-M...	dytab
Fulfilled	Design site	Error	ANVISA, EU-MDD, EU-M...	dytab
Unfulfilled	Device intended to admi...	Error	EU-MDR	dytab
Unfulfilled	Device labelled as Sterile	Error	EU-MDR	dytab
Fulfilled	Diagnostic function	Error	ANVISA, EU-MDD, EU-M...	dytab
Unfulfilled	Distributors	Info	ANVISA, EU-MDR, PPE, ...	dytab
Fulfilled	Duration of use	Error	ANVISA, EU-MDD, EU-M...	dytab
Fulfilled	eIFU URL	Error	EU-MDR	dytab
Fulfilled	Electrical Safety and Ele...	Info	ANVISA, EU-MDD, EU-M...	dytab
Fulfilled	FMDN	Error	EU-MDR	dytab

Rows: 84

Total Rows: 84

Medical Device 100

MDR Klassifizierung

Dropdown menu showing classification options: IIa, IIb, III. A mouse cursor is pointing at IIb.

EUDAMED Attribute

- Active Device
- Labelled as Single Use
- Containing Latex

Patientenpopulation

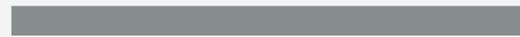
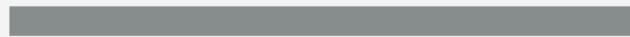
Ärzte, die auf die Diagnose von Hautkrebs spezialisiert sind.



Dokumente

Version

Überwachung



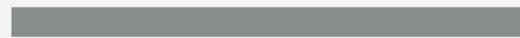
1.0

Veraltet



2.0

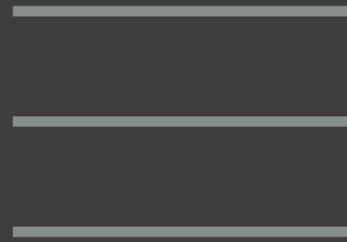
Aktuell



4.0

Aktuell





Klinische Bewertung ABC

1.0

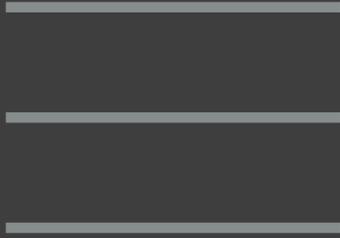
Veraltet

Dokument-Update

Deine Firma

5. Patientenpopulation





Deine Firma

5. Patientenpopulation



Document Changes

In medicine, infusion therapy deals with all aspects of fluid and medication infusion, via intravenous or subcutaneous application. A special infusion pump can be used for this purpose. A fenestrated catheter is most frequently inserted into the localized area to be treated.

There are a range of delivery methods for infusion of drugs via catheter:

- Electronic Pump: Drugs are often pre-mixed from vials and stored in infusion bags to be delivered by electronic pump.
- Elastomeric pump
- Pre-Filled Infusion Therapy: with this latest technology, a unit dose can be metered to the location from a pre-filled container.

Infusion therapy has a range of medical applications including sedation, anesthesia, post-operative analgesic pain management, chemotherapy, and treatment of infectious diseases

Advantages of infusion therapy over other non-site-specific delivery methodologies are primarily efficacy through precision of medication delivery.

~~New standards for infusible pharmaceuticals have been achieved in recent years with the advent of pre-filled, ready-to-use, dose-specific products. Advanced aseptic presentation, with hermetically sealed containers, allows predictable sterility, ease of use, improved control, and lower total costs. Essentially, systematizing the delivery mechanism and standardizing the delivery container.~~

Treatments

Infusion therapy involves the administration of medication through a needle or catheter. Typically, "infusion therapy" means that a drug is administered intravenously or subcutaneously. The term may pertain where drugs are provided through other non-oral routes of administration, such as intramuscular injection and epidural administration (into the membranes surrounding the spinal cord).

Until the 1980s, patients receiving infusion therapy often had to remain in an inpatient setting for the duration of their therapy. New technologies and heightened emphasis on cost containment in health care, as well as developments in the clinical administration of the therapy, led to strategies to administer infusion therapy in alternate settings (at clinics and at home) in an effort to reduce hospital readmissions.

~~New standards intravenous for infusions infusible are pharmaceuticals commonly have referred be to achieved as in recent years with the advent of pre-filled, ready-to-use, dose-specific products drips. Advanced aseptic presentation, with hermetically sealed containers, allows predictable sterility, ease of use, improved control, and lower total costs. Essentially, systematizing the delivery mechanism and standardizing the delivery container.~~

Infusion therapy

Intravenous therapy (IV) is therapy that delivers fluids directly into a vein. The intravenous route of administration can be used both for injections, using a syringe at higher pressures; as well as for infusions, typically using only the pressure supplied by gravity. ~~Intravenous infusions are commonly referred to as drips.~~

The intravenous route is the fastest way to deliver medications and fluid replacement throughout the body, because they are introduced directly into the circulation. Intravenous therapy may be used for fluid volume replacement, to correct electrolyte imbalances, to deliver medications, and for blood transfusions.

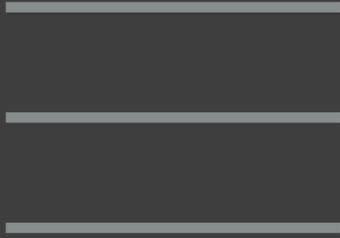
In addition to the description above, information belonging to specific product groups also applies:

Close

Save



Help



Klinische Bewertung ABC

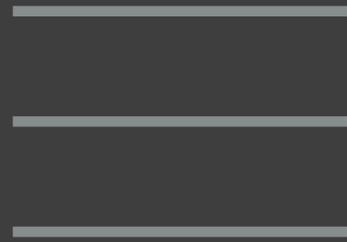
2.0

Aktuell

Freigabe

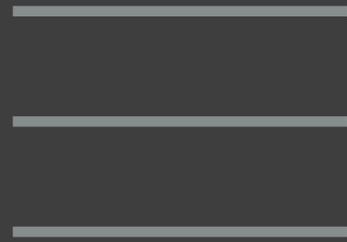
Deine Firma

5. Patientenpopulation



Regulatorischer Fokus

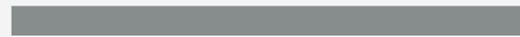
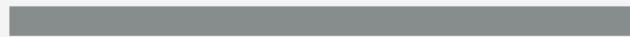
- ANVISA
- EU-MDR
- EU-IVDR
- PPE



MDR Zertifizierung TD 4.0

Version

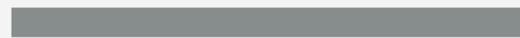
Überwachung



1.0

2.0

Error



2.0

2.4

OK



4.0

OK





MDR Zertifizierung TD 5.0

Version

Überwachung





2.0

2.0

OK



2.0

2.4

OK



4.0

OK



- Home
- Collections
- Workflow Processes
- Administration

- Favorites
- eTD
 - Product Groups
 - Products
 - Components
 - Documents
 - Change Management
 - GSPR Manager
 - Literature
 - Complaint Handling
 - CAPA Management
 - eCER - Claim Database
 - eCER - Clinical Evaluati...
 - eDesign

Table Dashboard Inspections M

Modifications

+ Add Delete Edit

Target Country

European Union (2)

United States (1)

Brazil (3)

China (1)

- General Information
- Project Information
- Submission Documents

General Information Project Information Submission Documents

Overview of all Documents of this Submission/Registration

Folder Transfer Documents

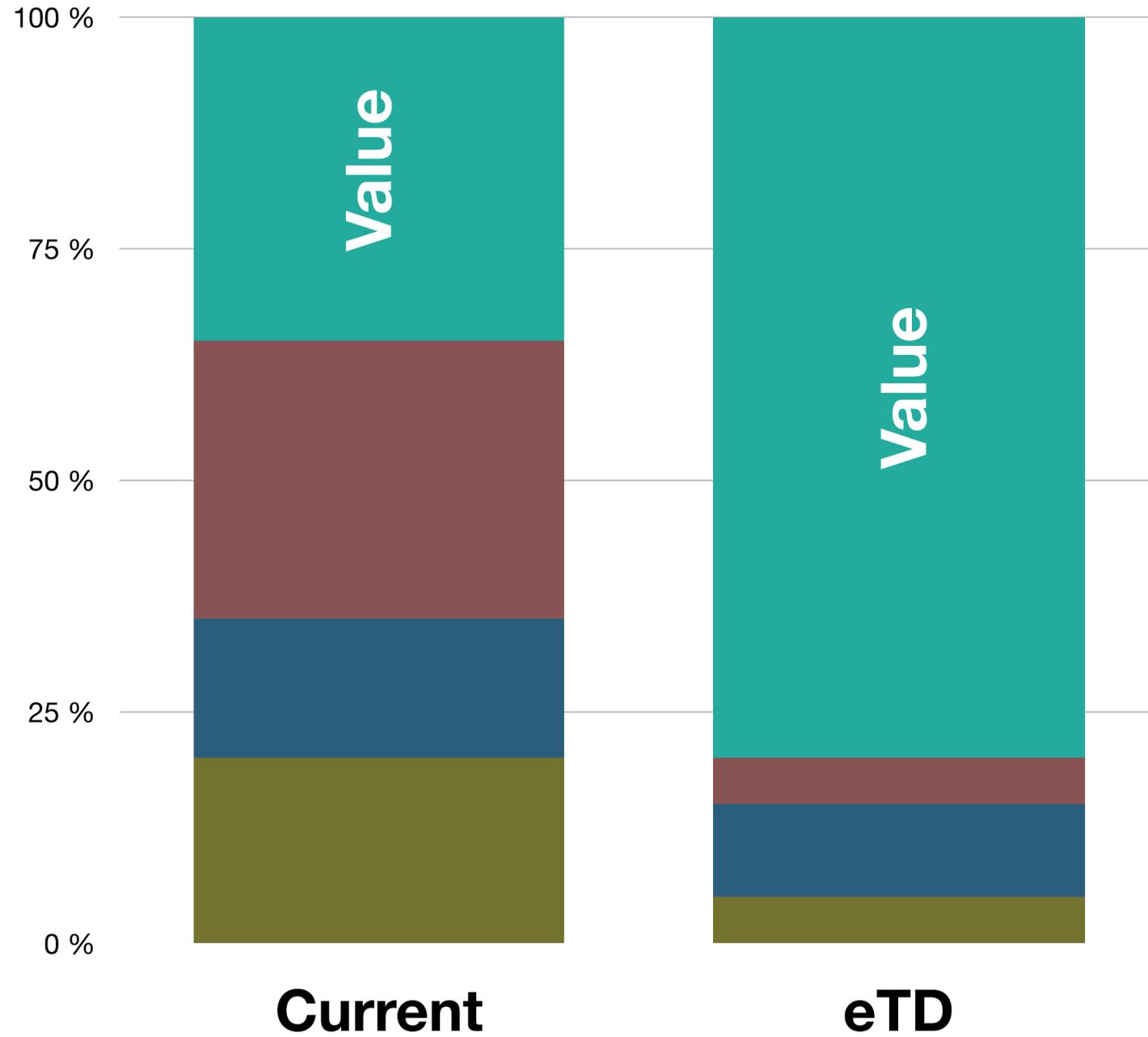
Collapse all Expand all Download Update to Latest Update to Approved

Name ↑	Monitoring	Version	Is external	Document Id
1. Product Description & Specifications				
1.1 General Description				
Executive Summary - Infusion technology		2.0		D-1
Intended Purpose - Infusion Technology		2.0		
List of Products - Infusion Technology		2.0		
Product Drawing - T1001		2.0		
Product Drawing - T1002		1.0		
Product Drawing - T2001		1.0		
Product Specification - T1001		1.0		
Product Specification - T1002		1.0		
Product Specification - T2001		1.0		
1.2 Classification				
MDR Classification - Infusion Technology		2.0		
1.3 Declaration of Conformity				
Declaration of Conformity - Infusion Technology Gravity		2.0		

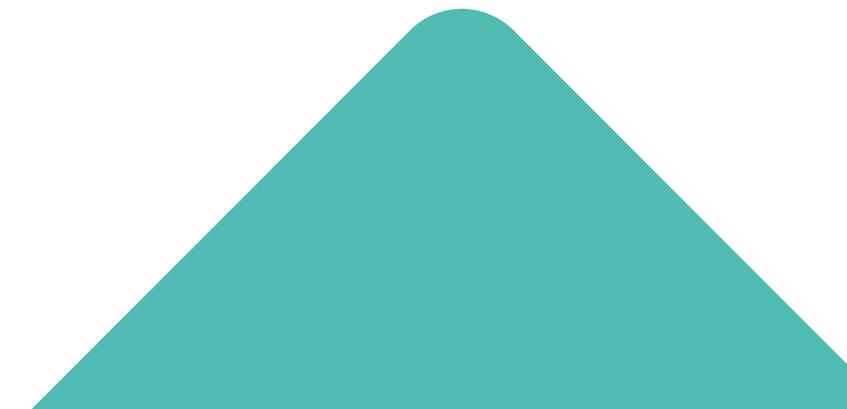
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Filtered: 102

Value

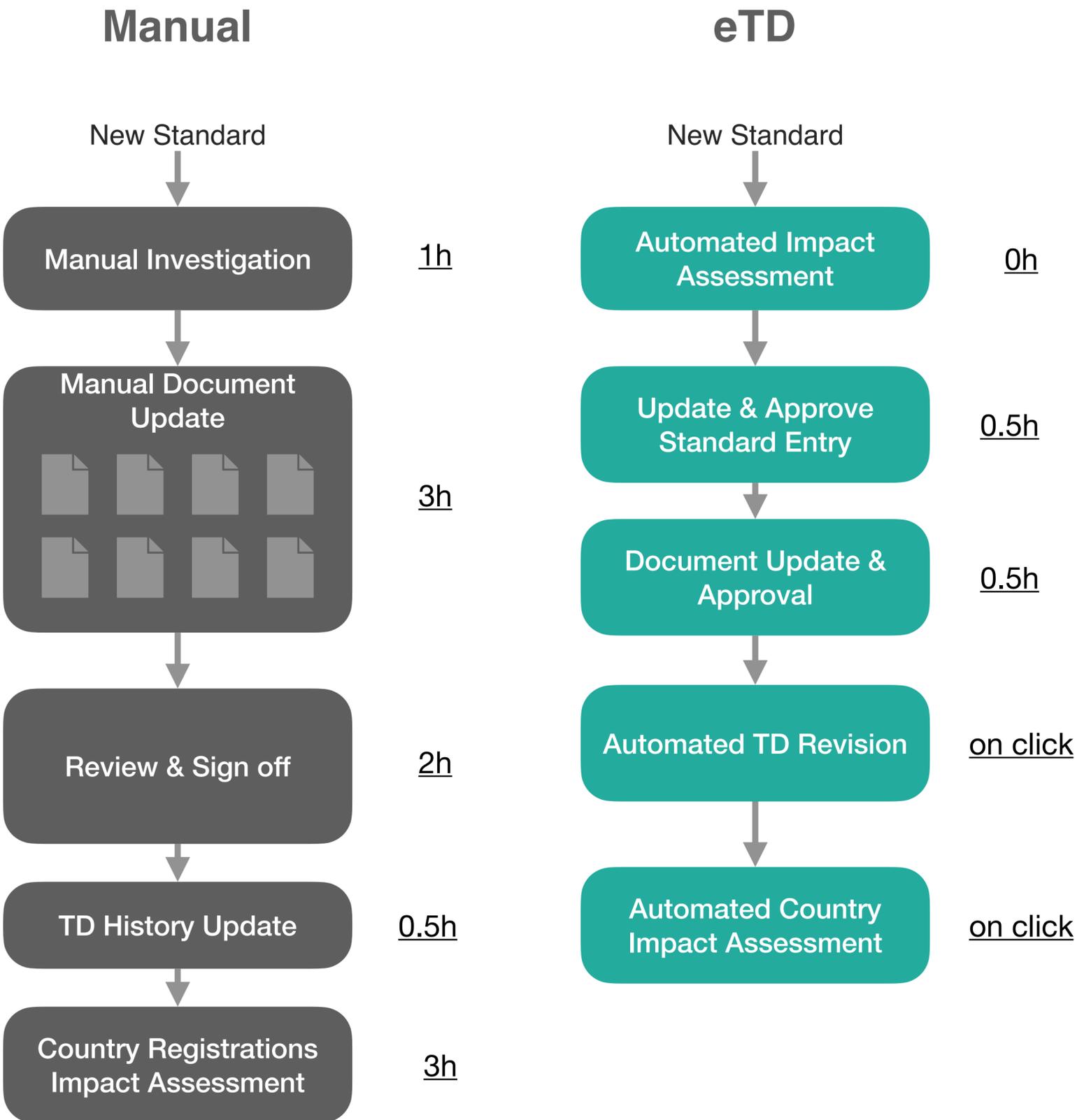


- Value generating work
- Administrative work
- Project Management
- Data search



Business Case Example

Update of TD and check of Submissions due to a standard update



	Manual	eTD
h per TD	9,5	1
No. of TDs	5	5
Total Time	47,5	5
Cases per year	6	6
h per year	285	30
h Saving		255
FTE saving		15 %
Savings €		€ 12.702,57

Based on real use case data. Average salary of € 71.000,-





meddevo eTD x

Home Regulatory Framework EU-MDR x

Home Collections Workflow Processes Administration

Favorites

- eTD
- Product Groups
- Products
- Components
- Documents
- Document Folders
- Registration & Audit Ma...
- CAPA Management
- GSPR Manager
- Change Management
- Standard Management
- Clinical Evaluation Man...

Full dy:ab

Content Management

- eTD
- Product Groups
- Products
- Components

Registrations & Audits

- Registration & Audit Management
- GSPR Manager
- Standard Management

Document Management

- Documents
- Document Folders
- New Document

Workflows

- 7 Processes I can contribute to
- 5 Processes I have contributed to

Collections

- Contacts & Legal Entities
- Intended Purposes
- UDI-DIs
- Basic UDI-DIs
- Regulatory Requirements
- Applicable Requirements

Show more

