

Data Consistency through Production, Supply Chain & Regulatory Business Processes

Nicole Sagner
EXTEDO GmbH

YOUR INFORMATION



Nicole Sagner

Senior Pre-Sales Manager

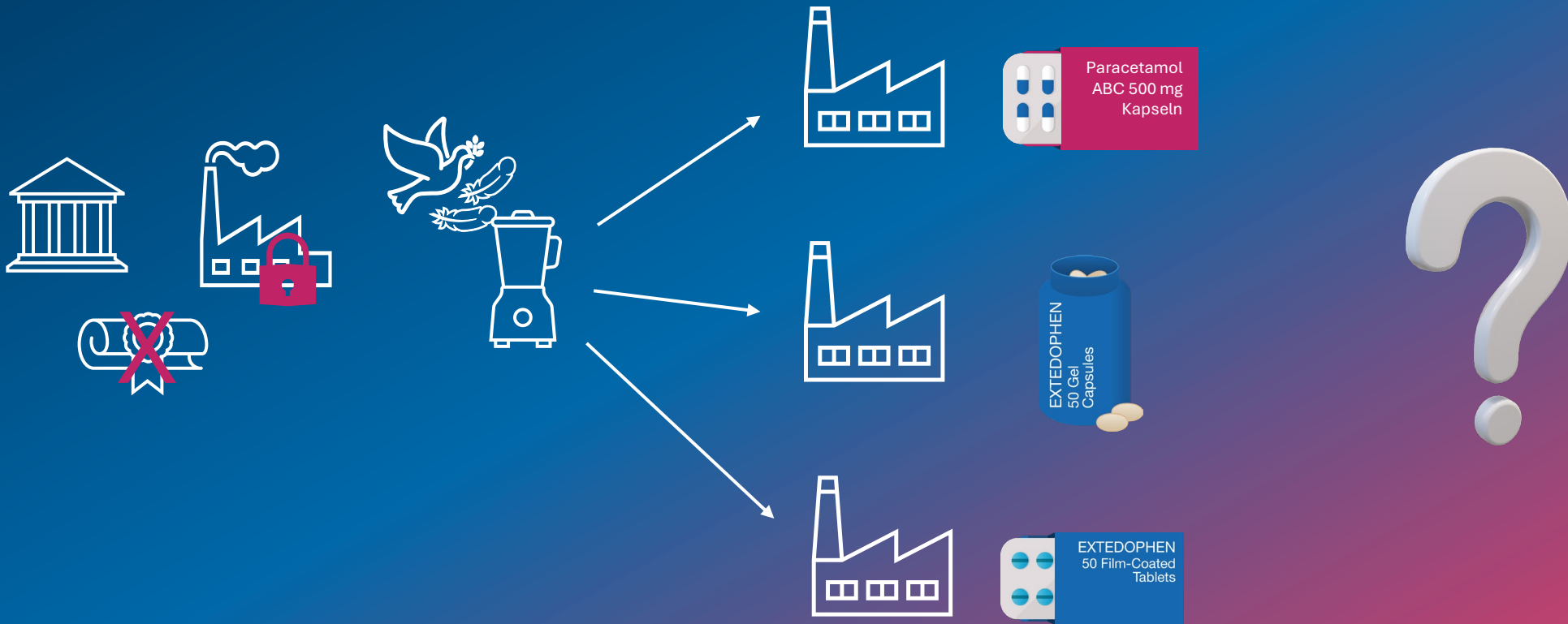


Regulatory Affairs is a central department within pharmaceutical companies to collect and compile medicinal product information for submission, and to distribute approved product information within the organisation.

Coming from Regulatory Affairs with touch points to other departments, I am clearly aware of the importance of reliable, consistent and valid data.

To achieve this, a strong and harmonised master data management is base and key towards a successful data consistency.

Business Use Case



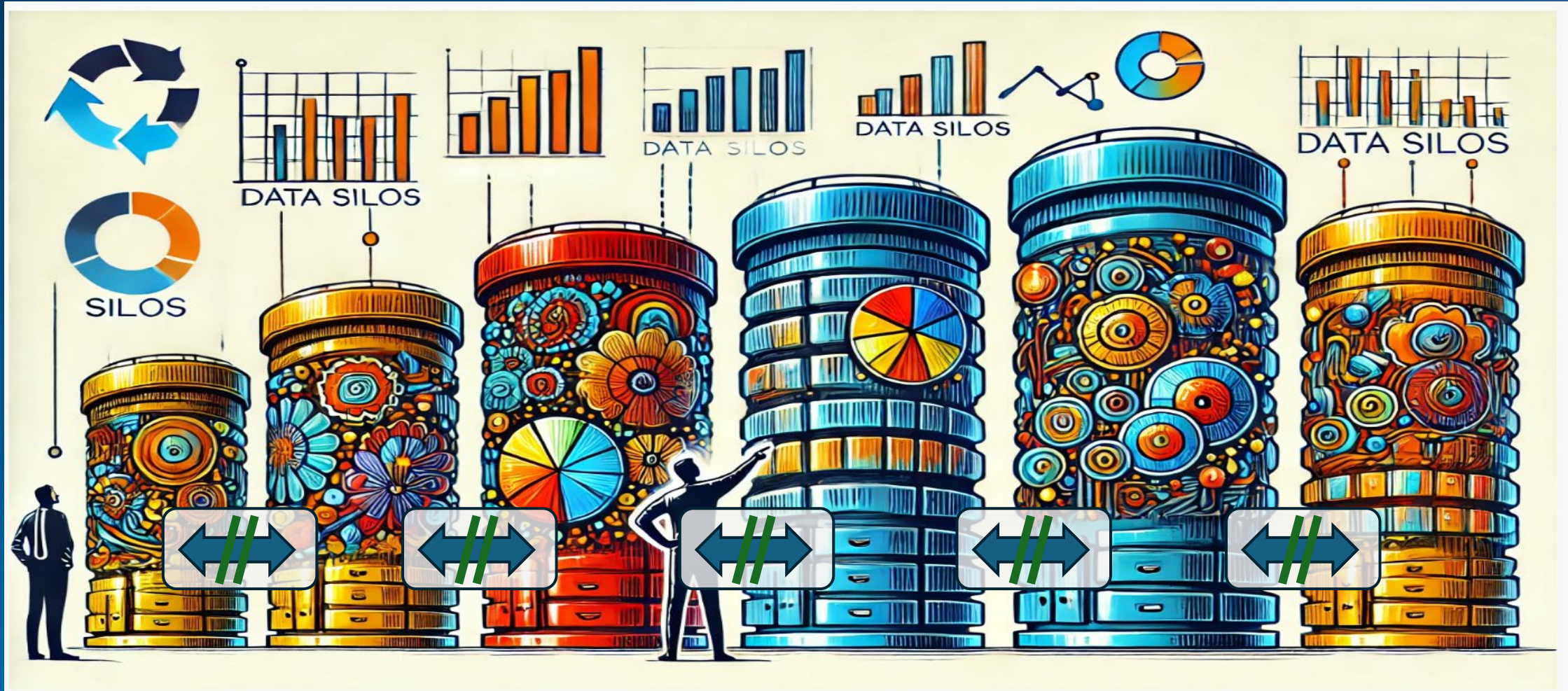
Business Use Case



Business Use Case

Registered Product Name	Dosage Form	Country	MAH	Authorisation Status	Marketing Authorisation Number	Procedure Type	Procedure Identifier	Is RMS/CMS	Authorisation Expiry Date
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	Canada		Valid	CA 12222	NAT	N/A		
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	Denmark	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		Decentralised Procedure	DK/H/0586/001		
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	Finland	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		Decentralised Procedure	DK/H/0586/001		
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	Germany	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Valid	12345.00.00	National Procedure			2028-07-18
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	Hungary	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		National Procedure			
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	IN		Presubmission		NAT	N/A		
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	SE	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		Decentralised Procedure	DK/H/0586/001		
Acetylcystein 100 mg Powder for Oral Solution	Powder for Oral Solution	US	Food And Drug Administration (ORG-100006066), United States, 10001 New Hampshire Avenue, 20903-1707, Silver Spring (LOC-100012452)	Presubmission		Abbreviated New Drug Applications			
Amoxicillin 150mg/ml Suspension for Injection (VET)	Suspension for Injection	AT	Univet Limited (ORG-100014260), Ireland, Tullyvin, H16 T183, Cootehill (LOC-100020114)	Presubmission		Decentralised Procedure	IE/H/0589/001	CMS	
Amoxicillin 150mg/ml Suspension for Injection (VET)	Suspension for Injection	IE	Univet Limited (ORG-100014260), Ireland, Tullyvin, H16 T183, Cootehill (LOC-100020114)	Presubmission		Decentralised Procedure	IE/H/0589/001	RMS	
Amoxicillin 150mg/ml Suspension for Injection (VET)	Suspension for Injection	US	Univet Limited (ORG-100014260), Ireland, Tullyvin, H16 T183, Cootehill (LOC-100020114)	Presubmission		National Procedure			
Febuxostat 150 mg Tablets	Tablets	Ireland	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		Decentralised Procedure	IE/H/0587/001	RMS	
Febuxostat 150 mg Tablets	Tablets	Netherlands	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Presubmission		Decentralised Procedure	IE/H/0587/001	CMS	
Febuxostat 150 mg Tablets	Tablets	United States	EXTEDO Inc. (167595053668646130), United States (167595055818478851)	Presubmission		NAT	N/A		
Naproxen 250 mg tbl	TBL	DE	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Approved		DCP	IE/H/1302/001	CMS	2023-11-11
Naproxen 250 mg tbl	TBL	Ireland	Extedo GmbH (ORG-100005997), Germany, Einsteinstrasse 30, 85521, Ottobrunn (LOC-100001638)	Approved		DCP	IE/H/1302/001	RMS	2023-10-05

Typical System Landscape: Data Silos



RIM Systems and Data Integrity

Pharma Industry: Common language – or lost in translation?

- **Same company, different systems?**
- Different vocabulary or data describe the same product / object (data inconsistency)
- Content maintained separately
- No connections, dependencies, etc.
- No centralized data access
- **Search for information: individually**

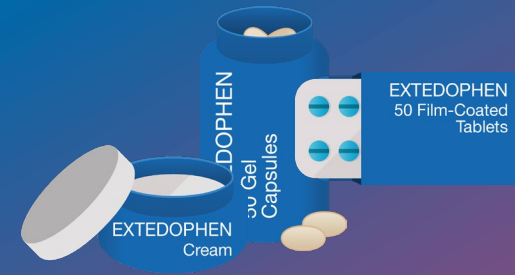


Baobab, Cream of tartar tree,
Lemonade tree, Upside-Down tree,
Monkey-bread tree, ...

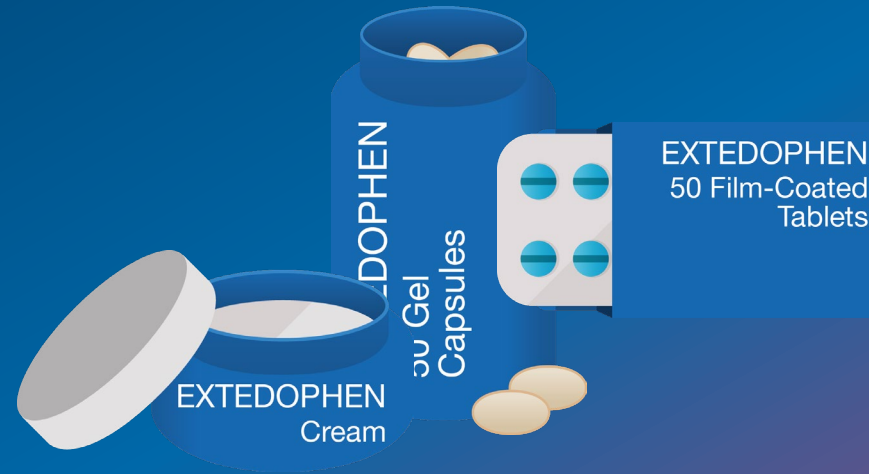
RIM Systems and Data Integrity

Pharma Industry: Common language – or lost in translation?

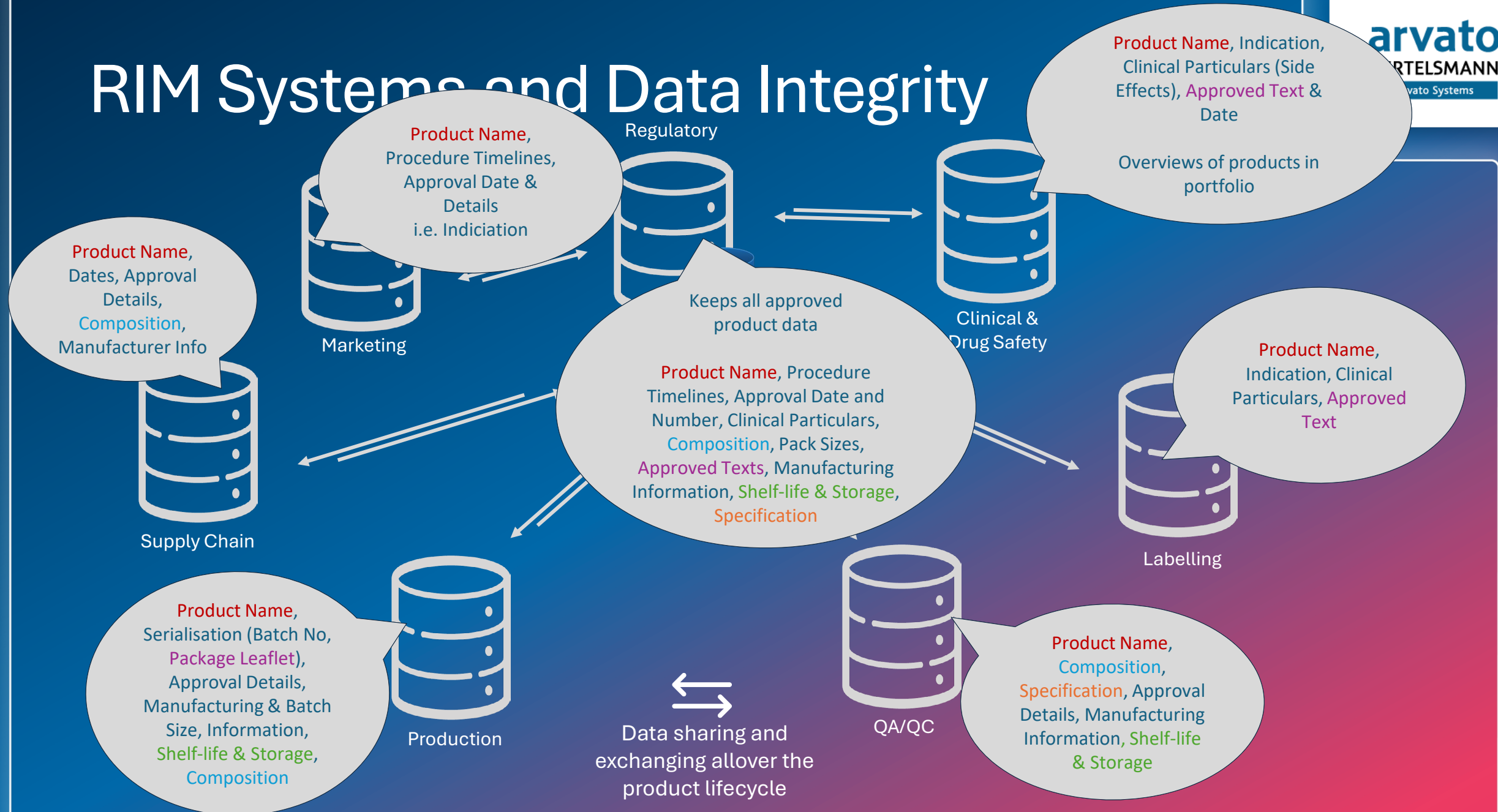
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RIM Systems and Data Integrity

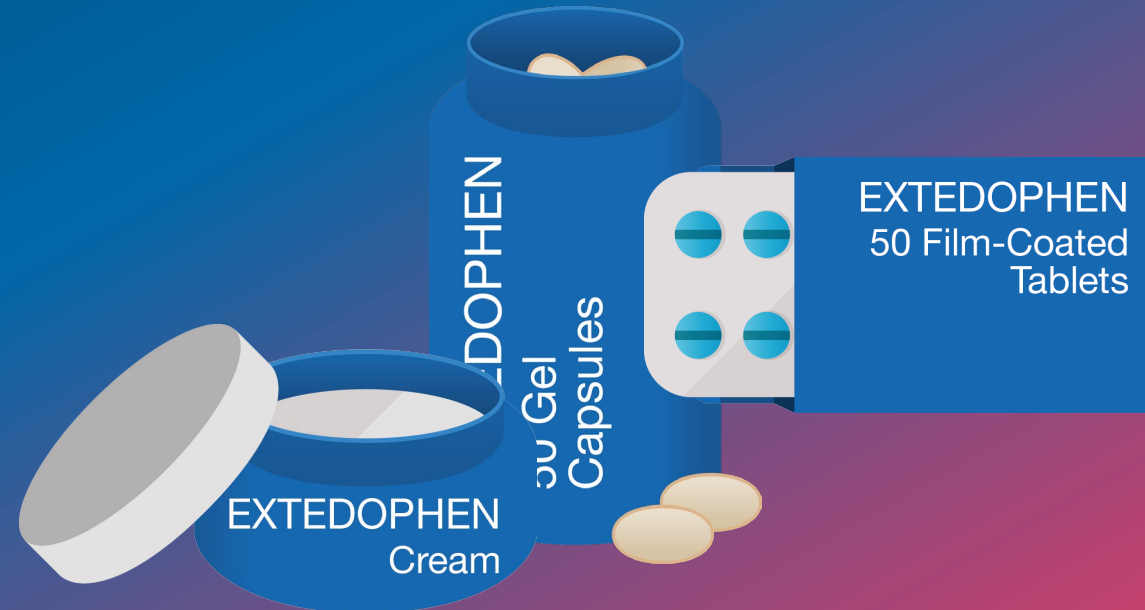
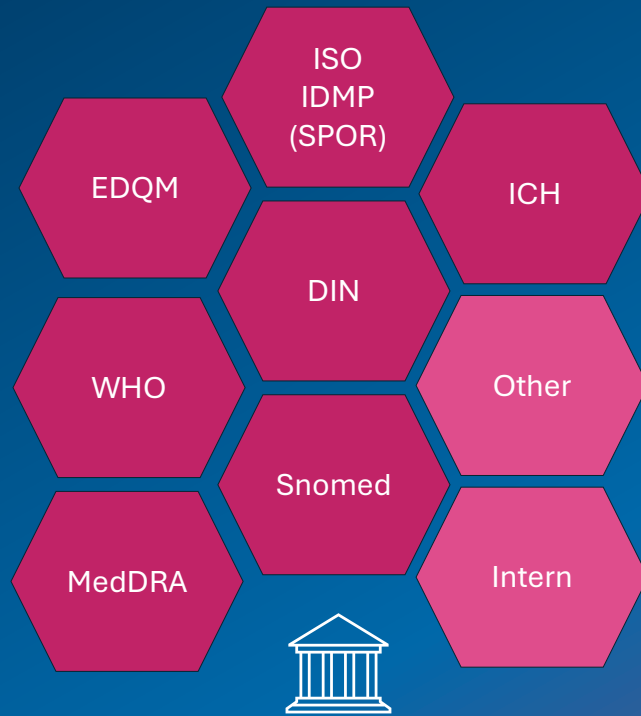


RIM Systems and Data Integrity

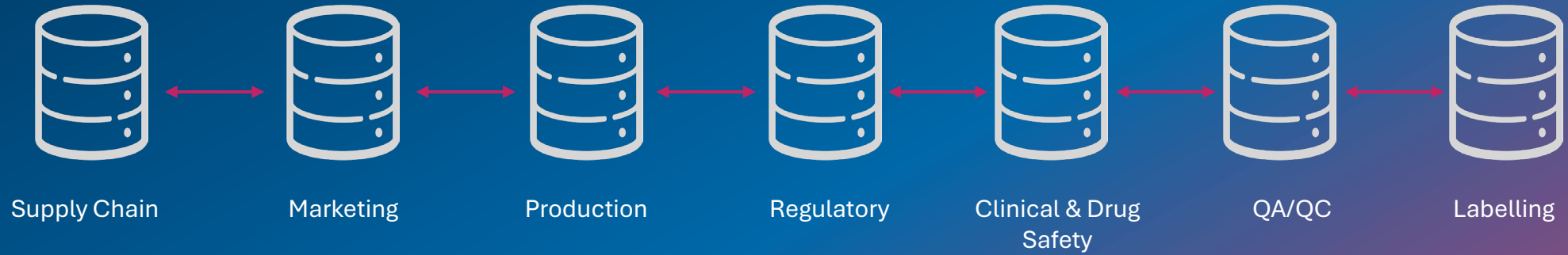


RIM Systems and Data Integrity

Why would RIMS play a central role?



RIM Systems and Data Integrity



Product Core Data

MedDRA

WHO

EDQM

ISO IDMP
(SPOR)

DIN

Snomed

ICH

Other

Intern

Approach in EXTEDOpulse

The screenshot shows the EXTEDOpulse web application interface. The top navigation bar includes 'File', 'Edit', 'Tasks', 'Tools', 'Settings', and 'Help'. A search bar is located in the top right. The left sidebar contains a navigation tree with categories like 'Tasks', 'Dashboards', 'MDM - Controlled Vocabularies', 'MDM - Product Core Data', 'QUAL - Learning Management', 'QUAL - Quality Events, CAPAs, CR and Complaints', 'QUAL - Quality Management', 'REG - Medical Device Information', 'REG - Regulatory Documents', 'REG - Regulatory Information', 'REG - Regulatory Intelligence', and 'REG - xEVMPD Data Exchange'. The 'CORE Product' tab is highlighted in the top navigation area. The main content area displays a table of search results for 'CORE Products'.

Master Data to be maintained once and used all over the organization and in all kind of data systems.

Search Results	CORE Product Name	Product Family	Domain	(Authorised) Pharmaceutic...	ATC Codes
Acetylcystein 100 mg Powder for Oral Solution	Acetylcystein 100 mg Powder for Oral Solution	Acetylcystein	Human use	Powder for oral solution	acetylcysteine (R05CB01)
Allopurinol 100 mg Tablets	Allopurinol 100 mg Tablets	Allopurinol	Human use	Tablet	allopurinol (M04AA01)
Allopurinol 300 mg Tablets	Allopurinol 300 mg Tablets	Allopurinol	Human use	Tablet	allopurinol (M04AA01)
Amoxicillin 150mg/ml Suspension for Injection (VET)	Amoxicillin 150mg/ml Suspension for Injection (VET)	Amoxicillin	Veterinary use	Suspension for injection	amoxicillin (J01CA04)
Budesonide 50 mcg Metered Dose Inhaler (MDI) (Budesonide)	Budesonide 50 mcg Metered Dose Inhaler (MDI)	Budesonide			
CTDilivium 100 Tablets (CTDilivium)	CTDilivium 100 Tablets	CTDilivium	Human use	Tablet	
EXTEDO ACID (Substance) (n/a)	EXTEDO ACID (Substance)	EXTEDO ACID			
EXTEDO ACID 1000 mg Tablets (EXTEDO ACID)	EXTEDO ACID 1000 mg Tablets	EXTEDO ACID	Human use	Tablet	Extedo Acid (EXT123EDO)
EXTEDO ACID 850 mg Tablets (EXTEDO ACID)	EXTEDO ACID 850 mg Tablets	EXTEDO ACID	Human use	Tablet	Extedo Acid (EXT123EDO)
Febuxostat 150 mg Tablets (Febuxostat)	Febuxostat 150 mg Tablets	Febuxostat	Human use	Tablet	febuxostat (M04AA03)

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Approach in EXTEDOpulse

The screenshot displays the EXTEDOpulse web application interface. The top navigation bar includes 'File', 'Edit', 'Tasks', 'Tools', 'Settings', and 'Help'. A search bar is located on the right. The left sidebar contains a navigation tree with categories like 'QUAL - Learning Management' and 'REG - Regulatory Documents'. A central table lists change requests (CR-00021 to CR-00014). A modal window titled 'Change Request: CR-00024' is open, showing a table of affected activities. A red speech bubble points to the 'QUAL - Quality Management' section in the sidebar.

Example: Reuse of Master Data in the Quality area

Change Request	Risk Assessment	Affected Activities	Affected Documents	Supporting Documents
Application	Name	Activity Type		
Acetylcystein 100 mg Powder for Oral Solution - NAT DE (ENR 1245789)	Initial Marketing Authorisation Application (Submitted, n/a) - Acetylcystein 100 mg Powder for Oral Solution - NAT DE (ENR 1245789)	Initial Marketing Authorisation Application		
Acetylcystein 100 mg Powder for Oral Solution - NAT US (ANDA) (125478)	Initial Marketing Authorisation Application (Submitted, n/a) - Acetylcystein 100 mg Powder for Oral Solution - NAT US (ANDA) (125478)	Initial Marketing Authorisation Application		
Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Variation Type IB (Approved, 2023-04-25) - Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Variation Type IB		
Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Variation Type IB (Approved, 2024-04-25) - Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Variation Type IB		

Displaying 6 record(s)

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Approach in EXTEDOpulse

EXTEDO PULSE powered by cara

File Edit Tasks Tools Settings Help

Smart Search

Quality - Multitenant - EXTEDOpulse

Search

Tasks Dashboards

MDM - Controlled Vocabularies

MDM - Product Core Data

QUAL - Learning Management

QUAL - Quality Events, CAPAs, CR and Complaints

QUAL - Quality Management

REG - Medical Device Information

REG - Regulatory Documents

REG - Regulatory Information

REG - Regulatory Intelligence

REG - xEVMPD Data Exchange

CORE Product Registered Product Regulatory Application Regulatory Activity

Properties Duplicate Delete Lock Unlock Promote Demote Pending Registered Products Related Tasks Dump

Latest Versions Search For... Advanced Search Found 42 items in 12ms

	Activity Status	Activity Type	Activity Identifier	Activity Description
Injection (VET) - NAT US (ANDA) (986532)	Planned	Abbreviated New Drug Application - ANDA	986532	Initial MAA for Amoxicillin 150mg/ml Suspension for Injection (VET) - NAT US (ANDA)
... - NAT US (ANDA) (FDA 777777)	Planned	Abbreviated New Drug Application - ANDA	FDA 777777	Initial Submission of Extedo Acid to US
Gabapentin EXTEDO TAB - NAT US (ANDA) (986532)	Planned	Abbreviated New Drug Application - ANDA	986532	Initial MAA for Gabapentin EXTEDO - NAT US
Naproxen 250mg/500mg Tablets - NAT UK (N/A)	Approved	Initial Marketing Authorisation Application	N/A	Initial MAA for Naproxen 250 mg & 500 mg Tablets - DCP EU
ZEPZELCA - NAT CA (NDS) (02520834)	Approved	Initial Marketing Authorisation Application	02520834-0001	Initial MAA for ZEPZELCA - NAT CA (NDS)
Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Approved	Initial Marketing Authorisation Application	NO/H/0896/001/DC	Initial MAA for Acetylcystein 100 mg Powder for Oral Solution - DCP EU
Naproxen 250mg/500mg Tablets - DCP EU (IE/H/1302/001-002)	Approved	Initial Marketing Authorisation Application	IE/H/1302/001-002/DC	Initial MAA for Naproxen 250 mg & 500 mg Tablets - DCP EU
Acetylcystein 100 mg Powder for Oral Solution - NAT ZA (N/A)	Planned	Initial Marketing Authorisation	ZA 89898	Initial MAA for Acetylcystein - NAT ZA

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Insights to Best Practices: The Pathway towards a unified RIM Framework (and Central Intelligence)

Preparation
is key

Business
is the Driver

Connection
is Power

Data + Analytics + Receiver
= Intelligence

What do we want to achieve for the moment, for the future and for the organisation?

- Define a unified vocabulary **across your organization** to avoid misunderstandings and ensure you're speaking **the same language across departments** (stay pragmatic!)
- Setup **predefined and measurable targets** to stay controlled at any point in time (project plan)
- Understand data structures, relations, and how they are/can be used in the business (holistically/integrated!)
- Identify reporting, tracking, and trending opportunities
- Define **KPIs/Metrics**
 - ▶ BEFORE you start implementing any type of technology (whether simple SP/Teams, ECMS/EDMS or complex data lakes) > "what do I need and not, what can I get"
- **Automated data exchange** through validated interfaces is a must
- **Avoid (manual) duplication** of data; instead have one single source of truth that shares data with other systems/applications
- Data itself has little value. It must be connected to advanced analytics to be translated into real information. **Automate where possible.**
- Information has little value if it is not used. Predictive Quality and Business decisions require a clear process of which information, reaches who, when, in which format, and for which purpose. **Automate where possible**

Benefits of a Unified Data Approach : Data Integrity and Efficiency all over

- Centralised and reliable storage point:
 - ‚Single source of truth‘ with consistent data all over the organisation
- Standardization and Normalization: A unified data model improves data quality and consistency by standardizing and normalizing data across disparate sources. This minimizes errors and discrepancies, enhancing the reliability of analytical results.
 - Ensured (data) consistency and compliance
 - Reduced data duplication
 - Reduced errors
 - Reduced data complexity
- Streamlined (data management) processes
 - Improved operational efficiency
- 360 Degree view of data / Faster insights
 - By consolidating data from disparate sources into a unified model, organizations gain a comprehensive view of their data assets. This holistic perspective enables better decision-making, improved operational efficiency, and enhanced strategic planning.
 - Unified data models facilitate faster data analysis, allowing businesses to access real-time insights, identify trends and respond swiftly to market changes, thereby gaining a competitive edge.
- AI and Machine Learning
 - A unified data approach supports the development of AI and machine learning models by providing clean and consistent data, enabling organizations to leverage advanced analytics and predictive capabilities.

Challenges

- Budget, Time and Resources (get management support)
- Proper Project Management
- Organizational alignment and data responsibility (harmonise terms, removing duplicates, implementing data governance)
- Change management and resistance
- Data mapping and migration (during running business)
- Technical topics, i.e. integrations

Summary

- A unified data approach not only enhances **operational efficiency** and **data-driven decision-making** but also supports strategic initiatives like **innovation**, and (regulatory) **compliance**, making it a valuable asset.
- For implementation: make a proper plan, take your time and bring experts into the project before you make a decision that you have to work with in the next years.
 - Be fit for now and the future

Thank You for Your Attention!