Data Consistency through Production, Supply Chain & Regulatory Business Processes

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YOUR INFORMATION

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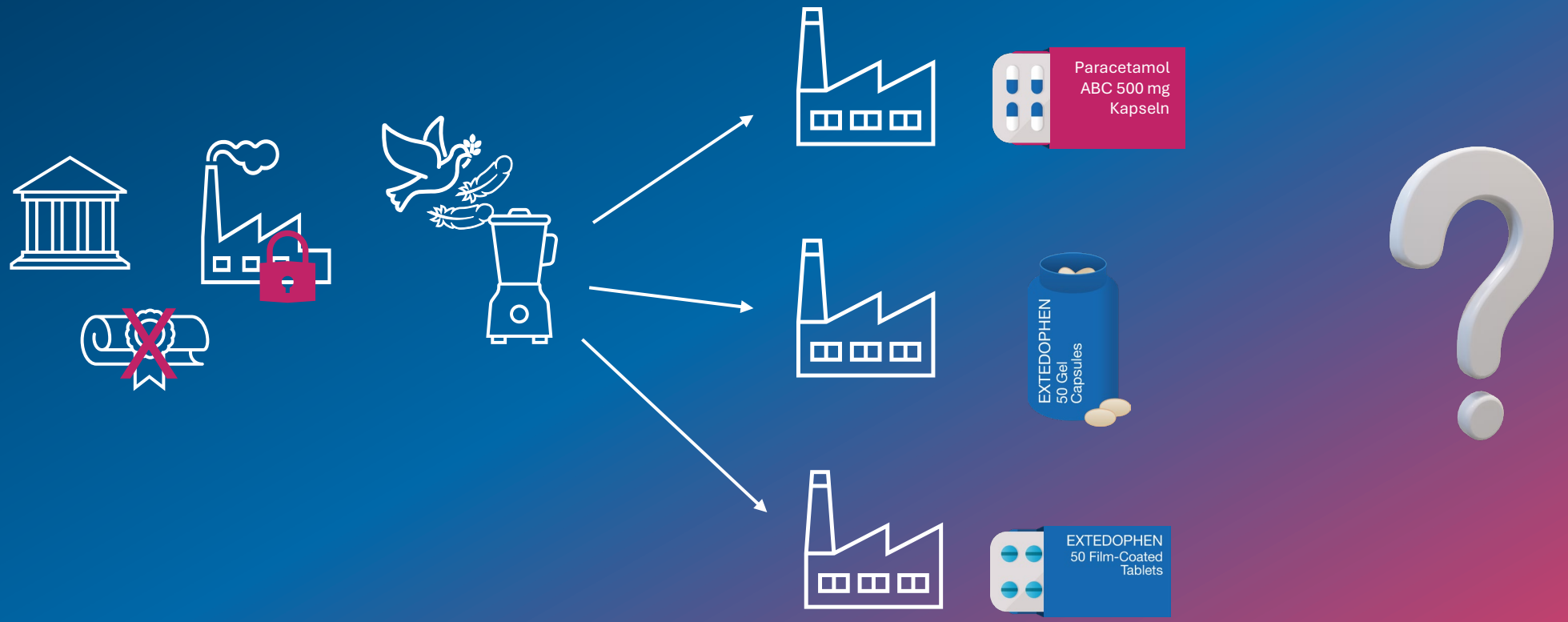
Regulatory Affairs is a central department within pharmaceutical companies to collect and compile medicinal product information for submission, and to distribute approved product information within the organisation.

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

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- Clinical Development
  - Clinical Operations
  - Medical Writing
  - Medical Sciences
- Data Sciences
  - Data Management
  - Data Safety
- Drug Safety
  - Pharmaco-vigilance
  - Medical Affairs
- R&D
  - Pharmaceutical Development
  - Product Development
  - Regulatory Management
  - Regulatory Affairs
  - Regulatory Operations
- QA/QC
  - QA Clinical & Product
  - QC Clinical & Product
  - Quality Systems & SOPs
  - Supplier Management
- Business & Marketing
  - Production
  - Supply Chain
  - Marketing & Portfolio MGMT
- Corporate MGMT
  - Legal
  - IP
- Administration & Support Services
  - HR
  - IT

Exemplary Org Chart

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-100013152)	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

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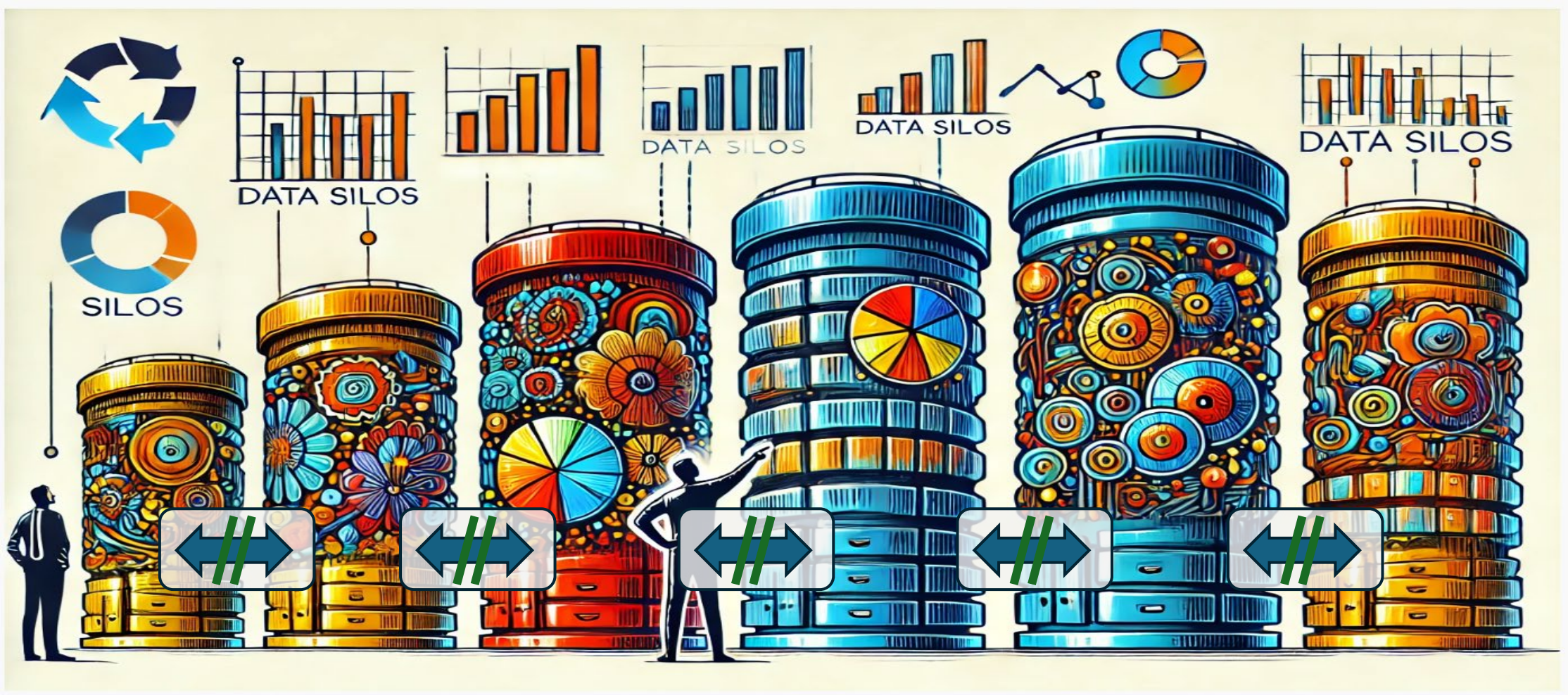

RIM Systems and Data Integrity

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, ...

The African Baobab Is An Important Part of Africa's Cultural, Economic & Environmental Landscape, & They're Dying Out - Capitals Coalition

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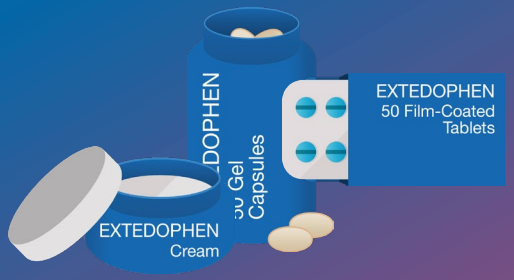
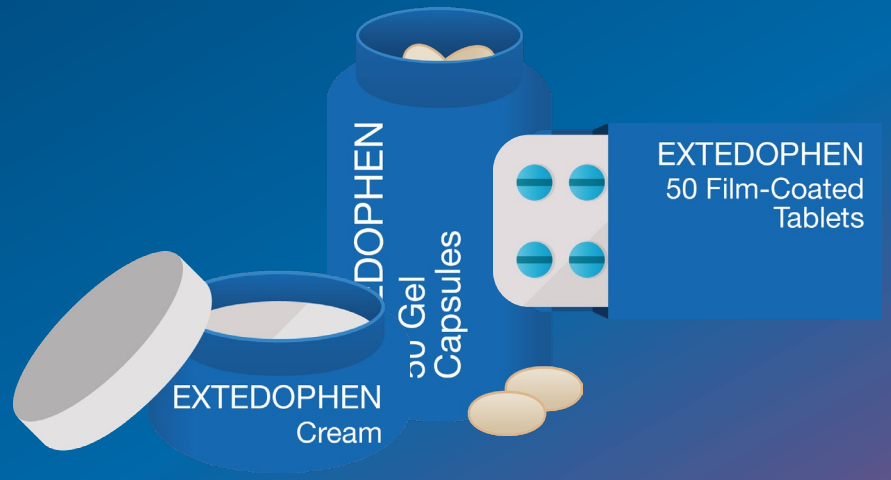
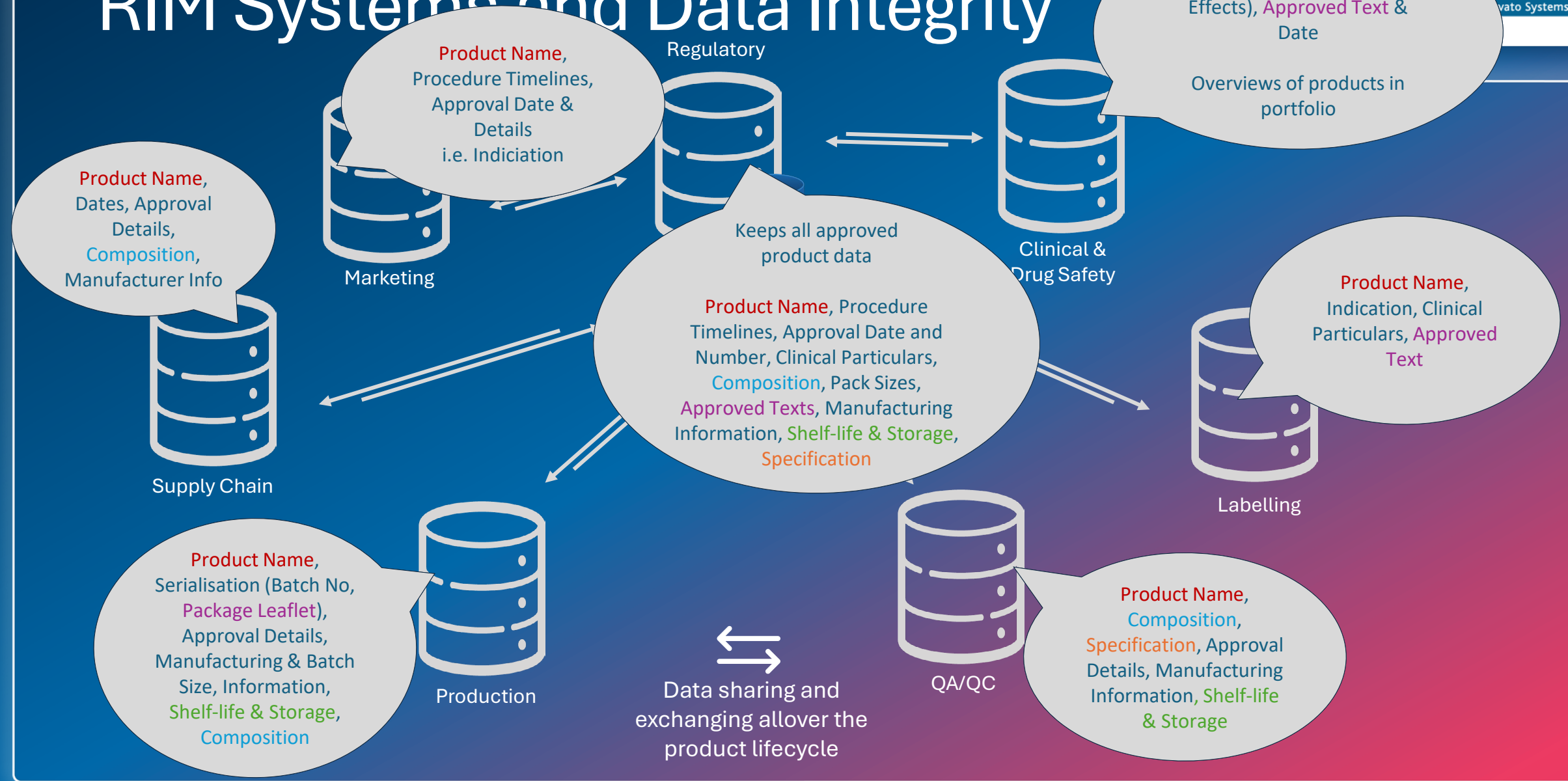


RIM Systems and Data Integrity

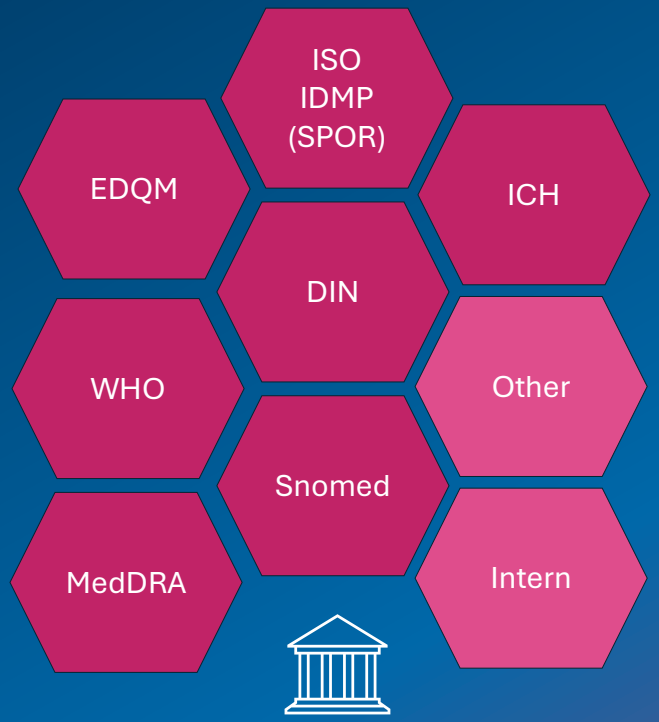


RIM Systems and Data Integrity

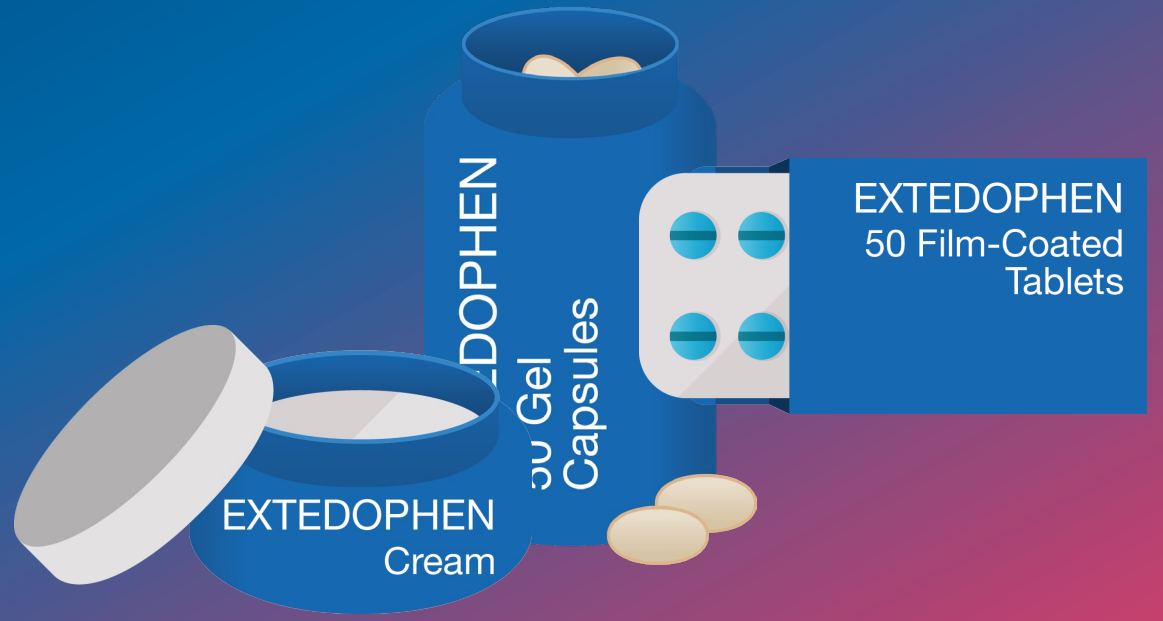


RIM Systems and Data Integrity

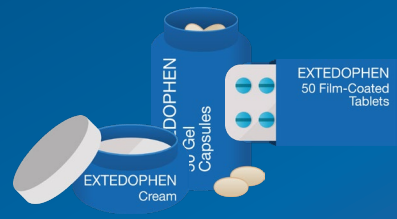
Why would RIMS play a central role?



Regulatory Master Data



RIM Systems and Data Integrity



Supply Chain

Marketing

Production

Regulatory

Clinical & Drug Safety

QA/QC

Labelling

Product Core Data

MedDRA

WHO

EDQM

ISO IDMP (SPOR)

DIN

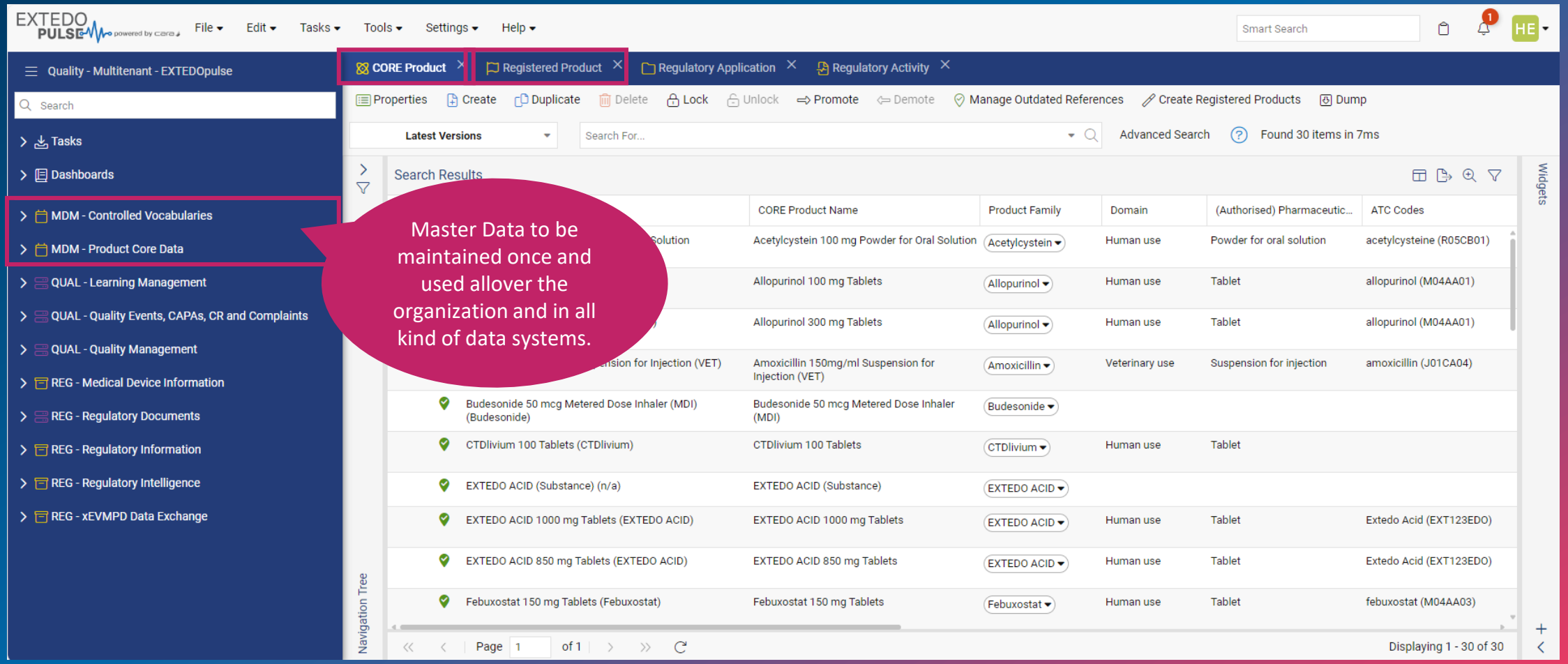
Snomed

ICH

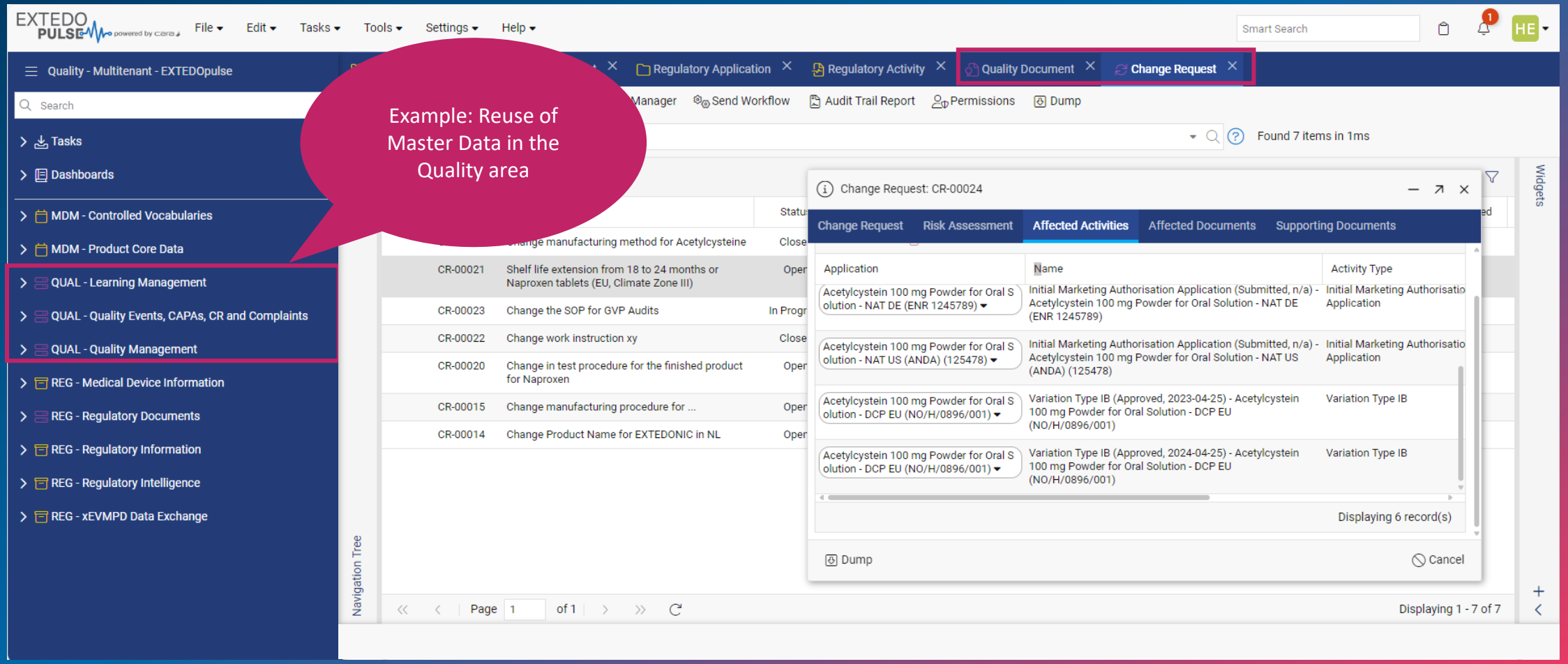
Other

Intern

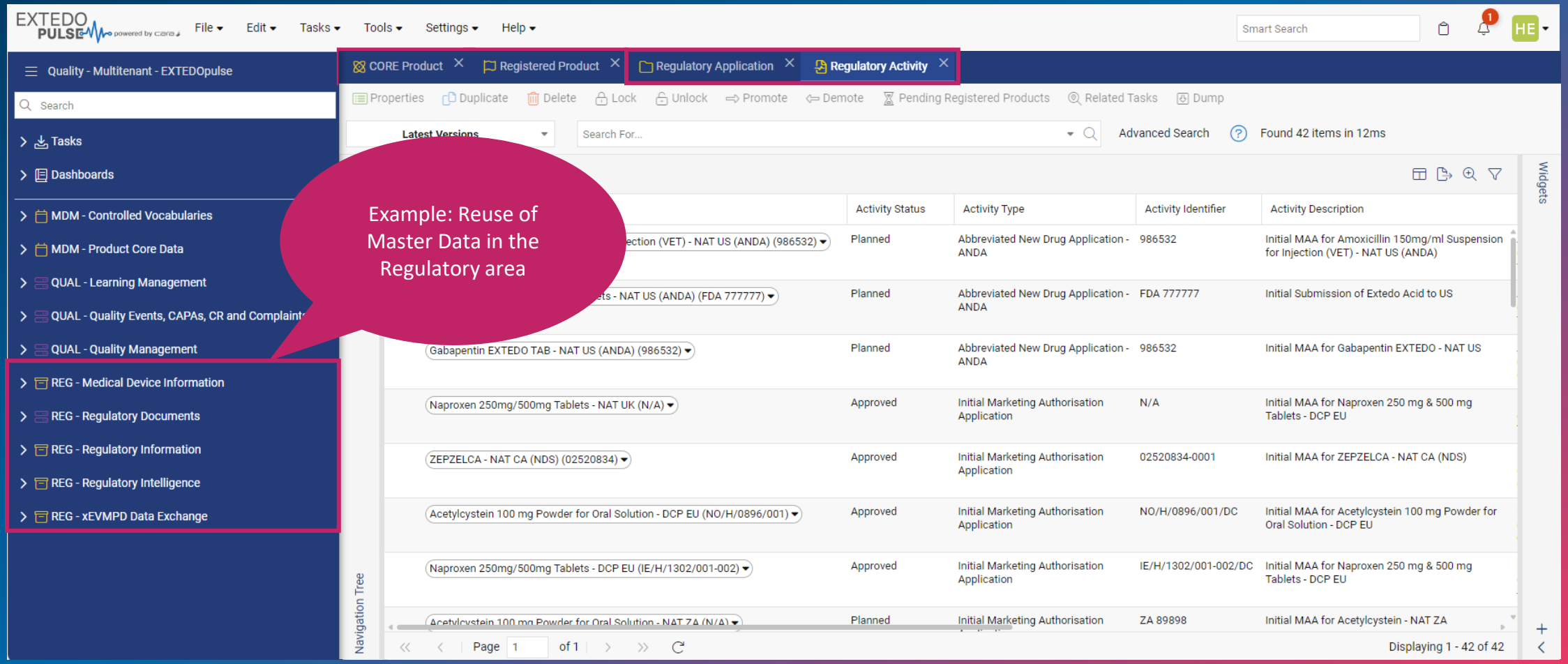
Approach in EXTEDOpulse



Approach in EXTEDOpulse



Approach in EXTEDOpulse



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

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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 missunderstandings and ensure you're speaking the same language across departments (stay pracmatic!)
- 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 allover the organisation
- Standardization and Normalization: A unified data model improves data quality and concistency by standardizing and normalizing data across disparate sources. This minimizes erros and disrepancies, 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 competetive edge.
- AI and Machine Larning
  - A unified data apporach supports the development of AI and machine learning models by providing clean and consistent data, enabling organiztation to leverage advanced analytics and predivte 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!

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