



Introduction to IDMP

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Drug Development Information Governance

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janssen

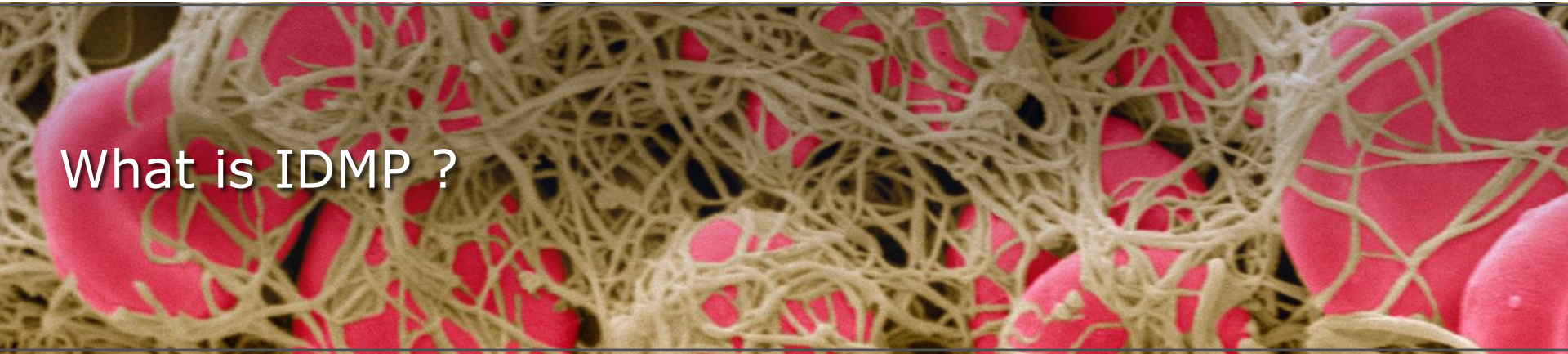
PHARMACEUTICAL COMPANIES
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Agenda

- What is IDMP ?
- Benefit of standardised data across business functions
- IDMP can provide value to business operations

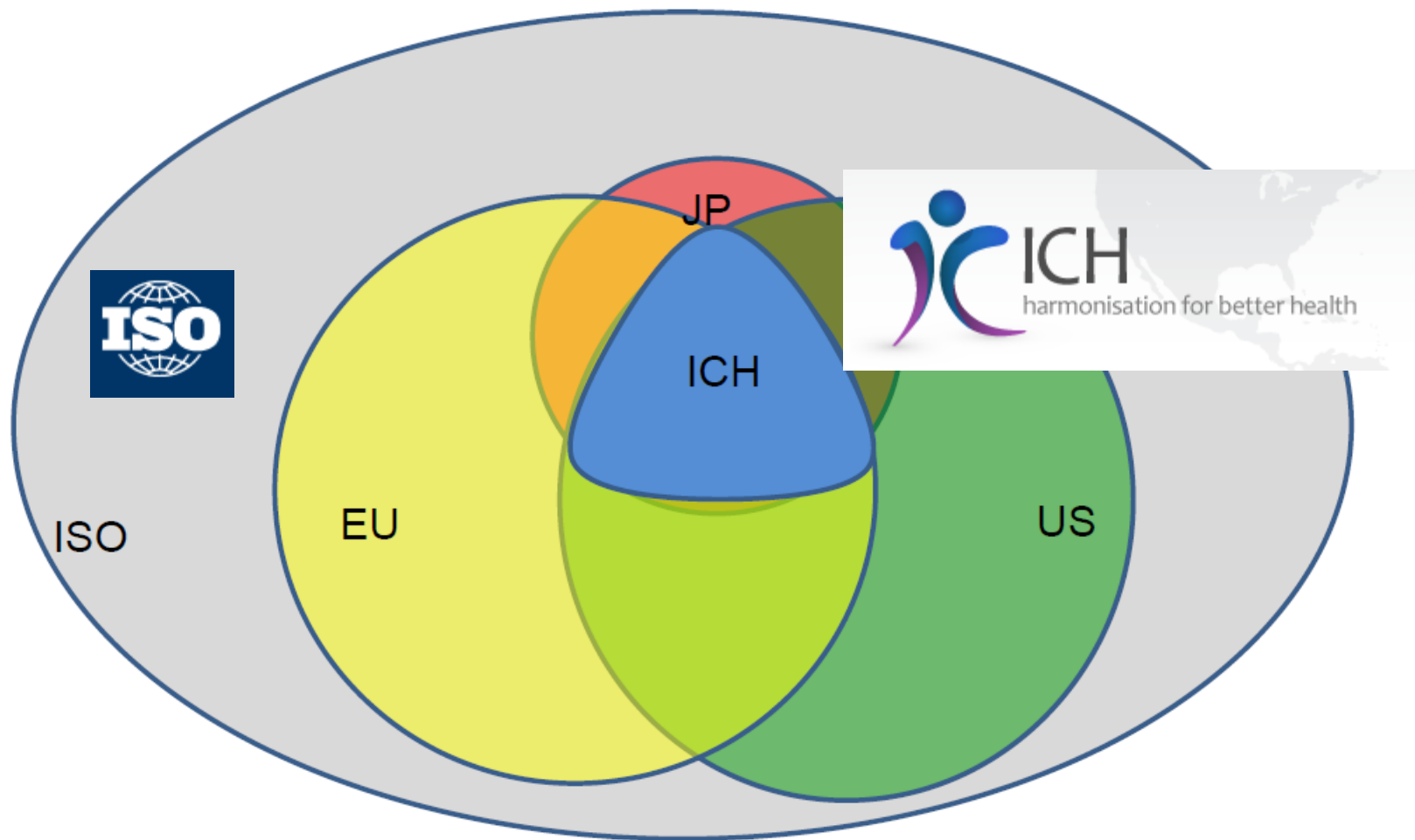


What is IDMP ?

Management summary

- IDMP is an ISO standard developed on request of the ICH ; standards are published Nov 2012
- EMA requires compliance with IDMP ISO standard by submitting product data to authorities.
- Product data submission by legislation targeted to mid 2016 but recently changed into iterations spread across 2017-2018.
- IDMP is the reference to report ICSR (required by 2019)
- FDA is focusing on SPL as the first implementation of IDMP

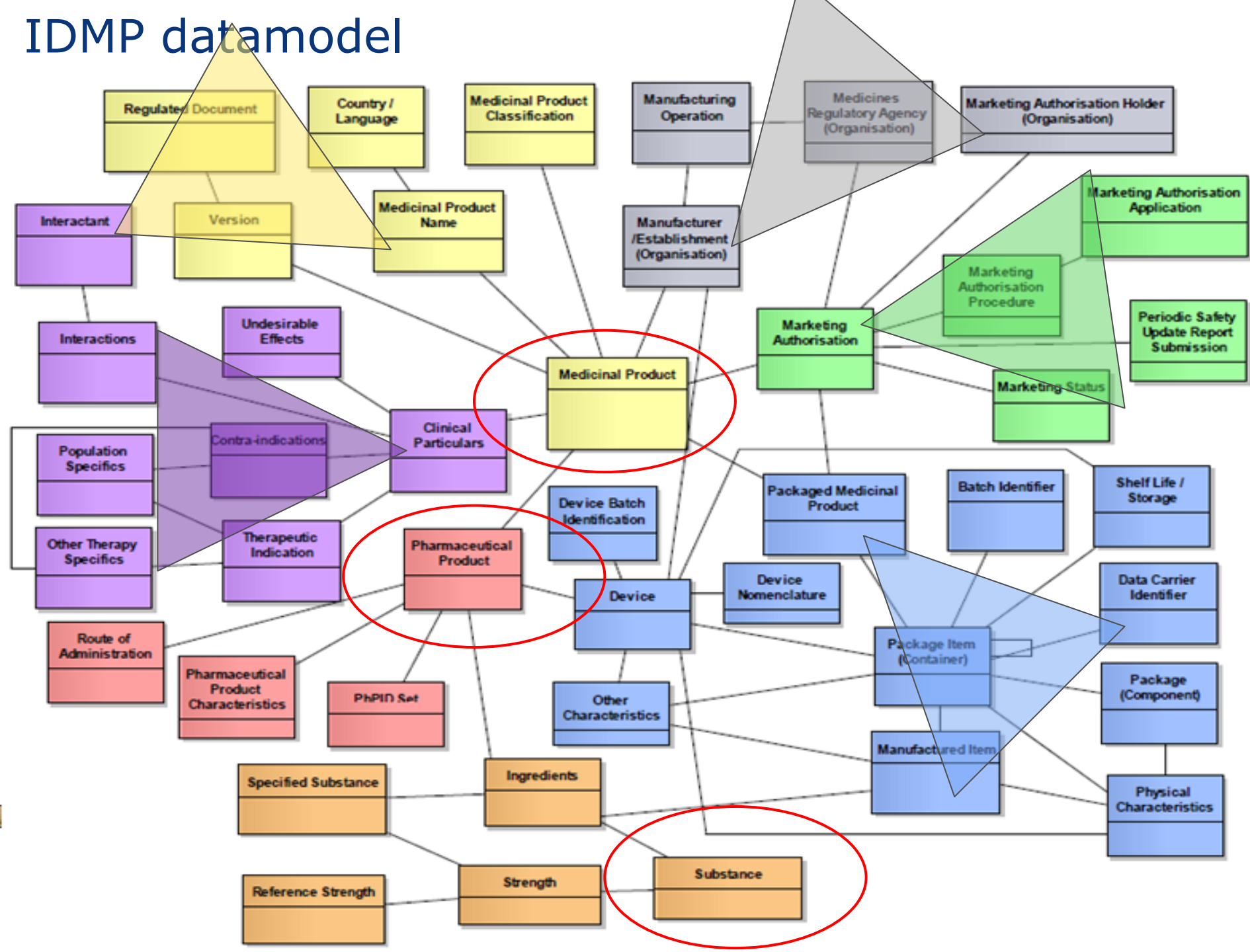
ISO and ICH



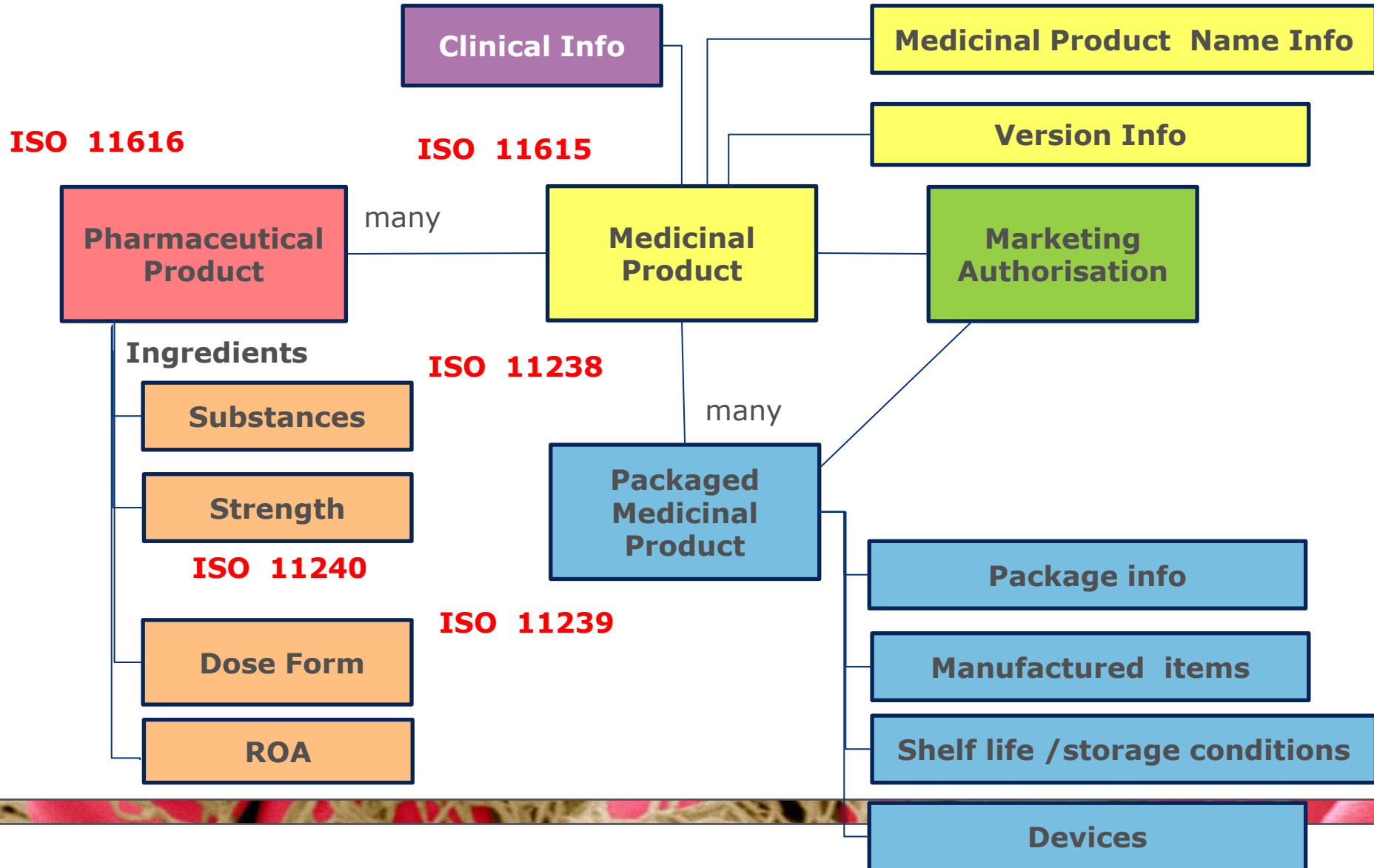
Identification of Medicinal Products

- ISO standards on Medicinal Products
- Five ISO standards (published Nov 2012) :
 - ISO 11615 Medicinal Product Information
 - ISO 11616 Pharmaceutical Product Information
 - ISO 11238 Substance Information
 - ISO 11239 Pharmaceutical Dose Forms, Units of Presentation, Routes of Administration, Packaging
 - ISO 11240 Units of Measurement
- No implementation guidelines yet (pending)
- Regional adoption and implementation required

IDMP datamodel



IDMP (simplified model)



ISO IDMP (1 of 3)

from FDA

- Developed in response to a worldwide demand for internationally harmonized specifications for medicinal products
- Provide the basis for the unique identification of medicinal products
- Facilitate the activities of medicines regulatory agencies worldwide by jurisdiction for a variety of regulatory activities
 - Development, registration and life cycle management of medicinal products
 - Pharmacovigilance and risk management

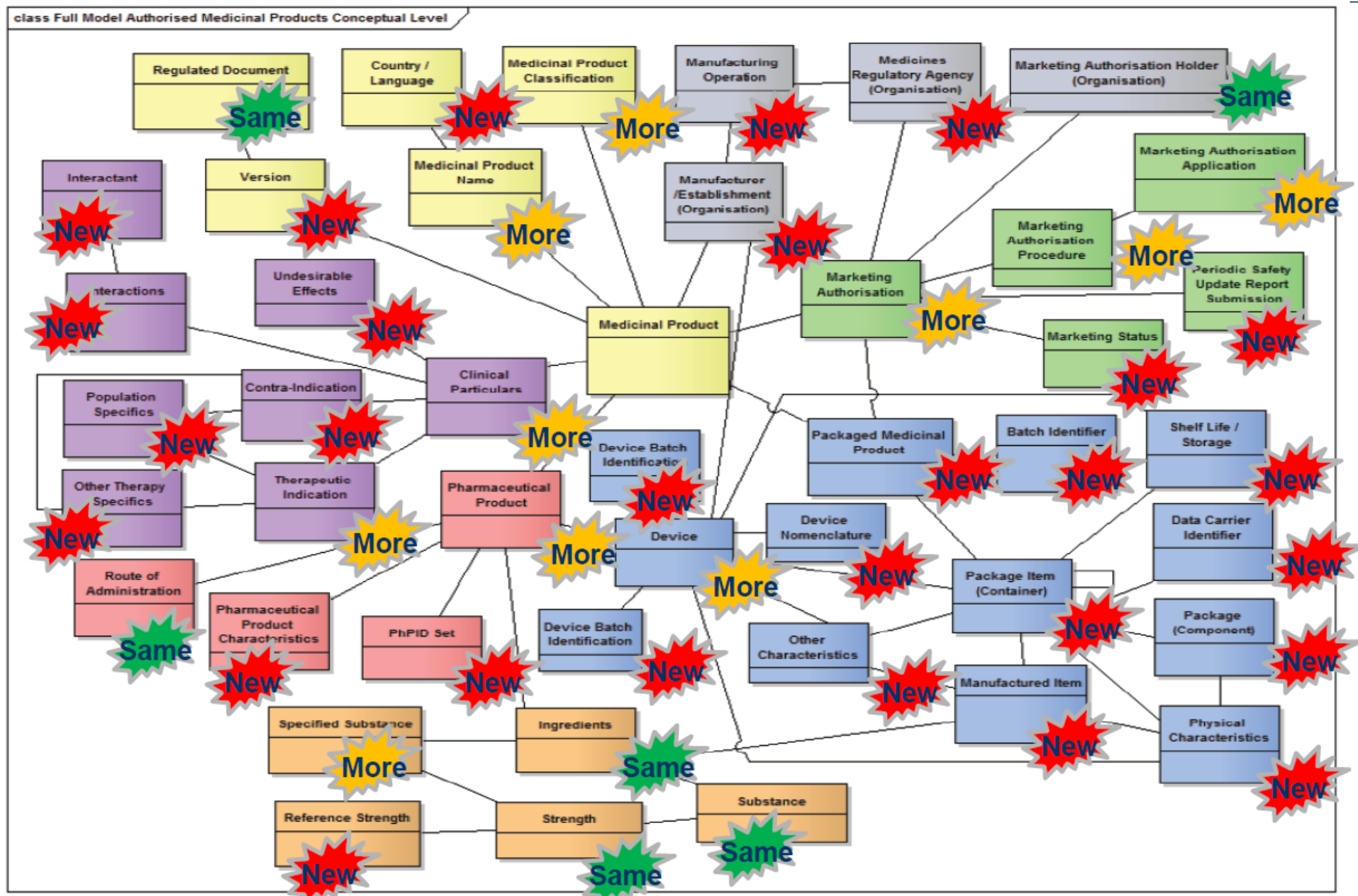
IDMP (2 of 3)

- Messaging specifications are included as an integral part of the IDMP standards
 - Describe and protect the integrity of the interactions for the submission of regulated medicinal product information in the context of the unique product identification
 - Acknowledgement of receipt including the validation of transmitted information
 - Health Level Seven (HL7) Message Exchange
 - **Normative within the ISO IDMP Standard**

IDMP (3 of 3)

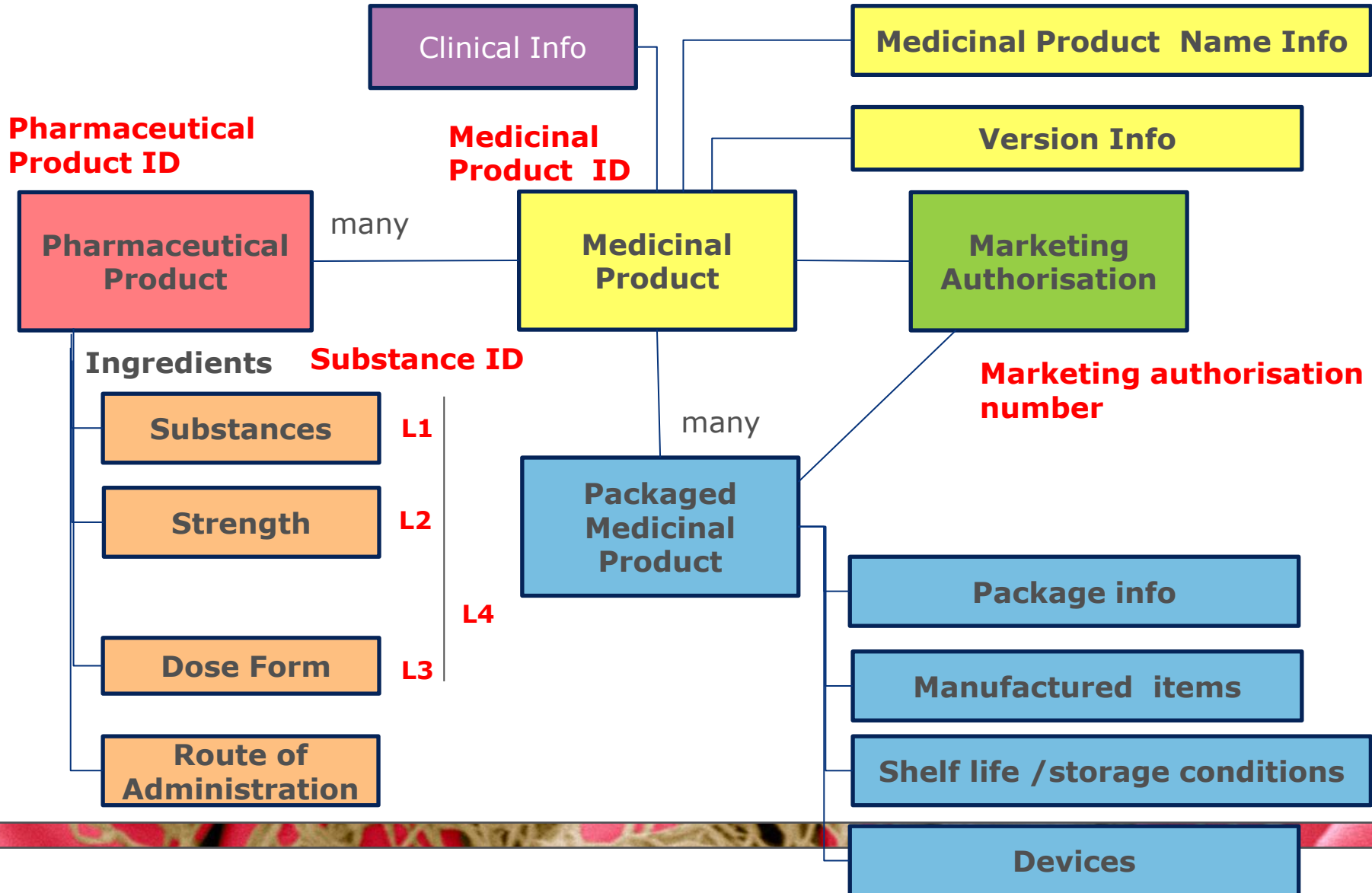
- Standards designed to allow unambiguous identification of products across regions to improve the robustness of pharmacovigilance and regulatory activities
- Can be also applied to Investigational Medicinal Products

IDMP versus XEVMPD



IDMP (ISO standard Legislation on Identification of Medicinal Products)

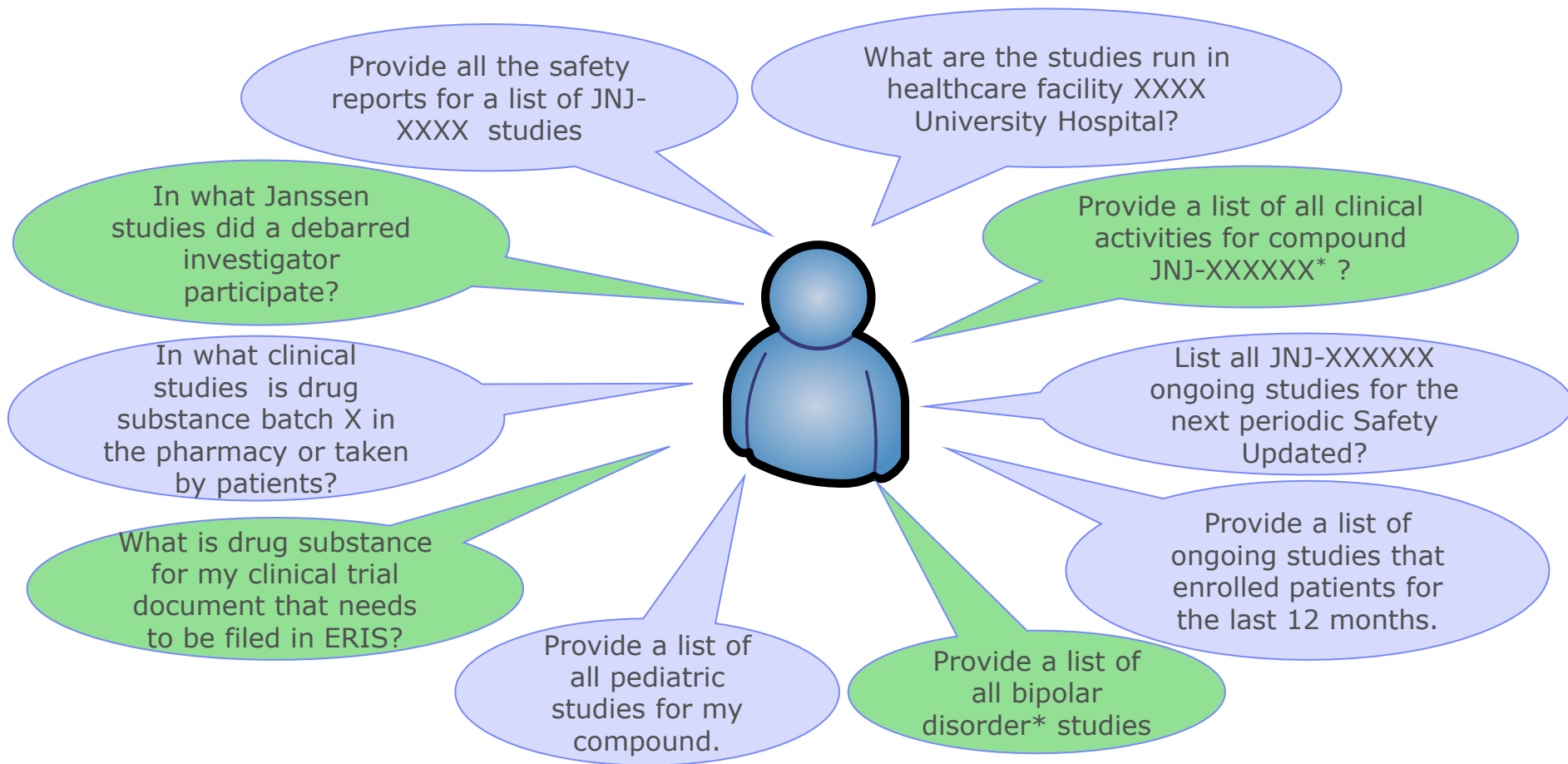
Identifiers and view layers L1, L2, L3, L4





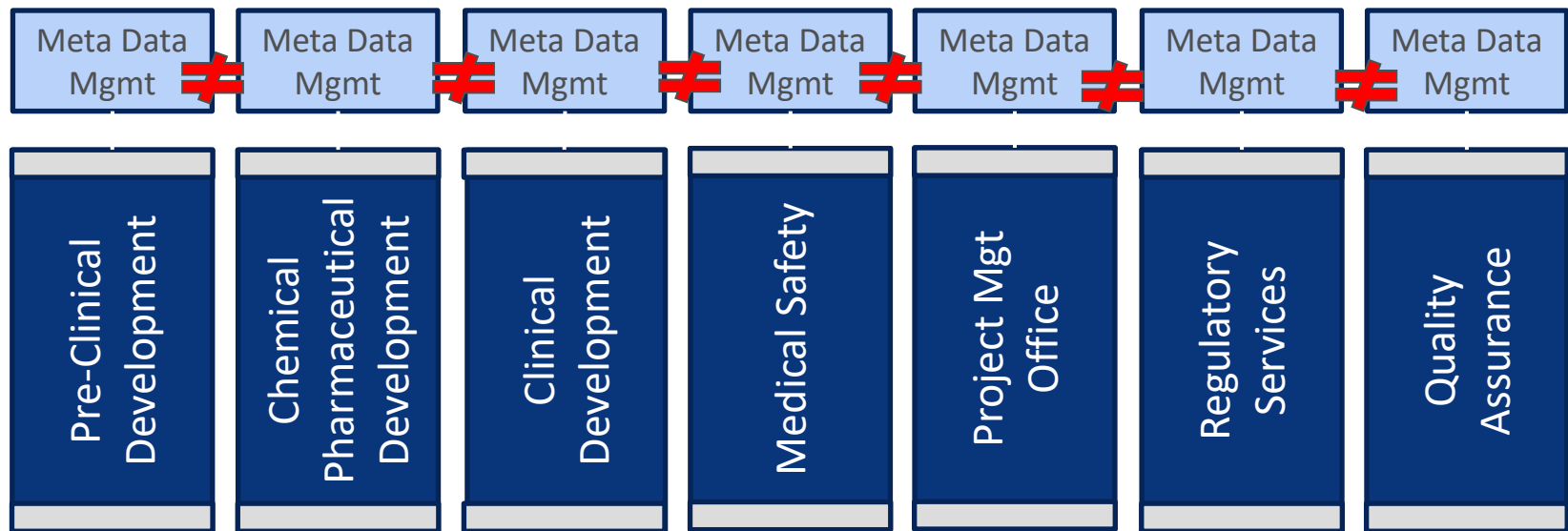
Why do we need company wide standardised data ?

Business challenges : questions to drug development

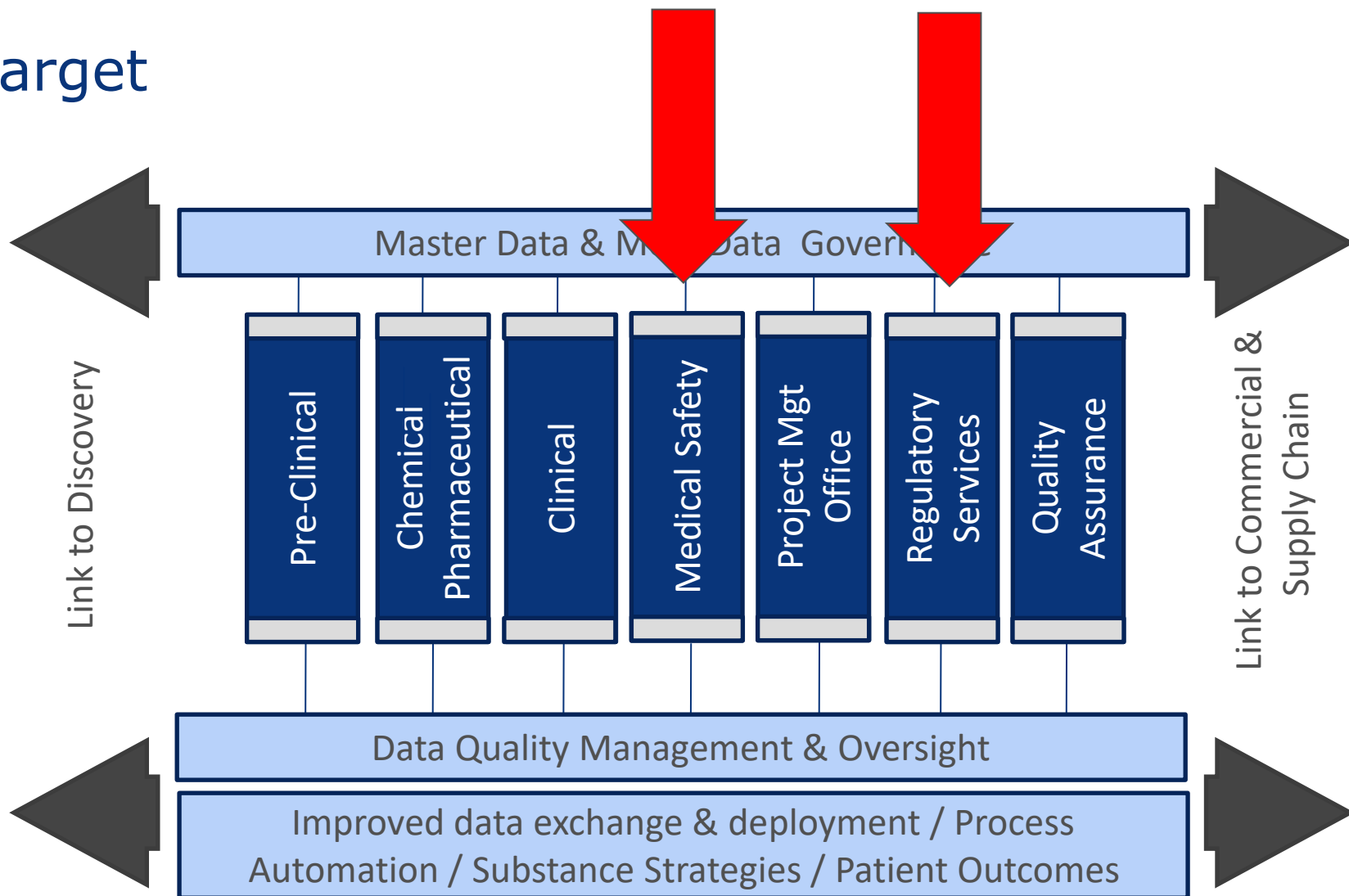


Legacy situation

No to little cross functional domain information transparency and governance : leading to silo strategies !



Target





Master Data Management as the solution

Master Data terms and definitions standardization

Substance & Product

- Substances
- Pharmaceutical Product
- Investigational Medicinal Product

Clinical Study

- Protocol
- Study Phase
- Study condition
- Study criteria
- Study arm
- Study status

Clinical Research Site

- Healthcare Professionals (Investigators)
- Healthcare Facilities
- Master Site Identification

- **Terms & definitions**
- **Data lifecycle**
- **Ownership**
- **Business rules**
- **Data quality rules**

Master data services on Substance and Product

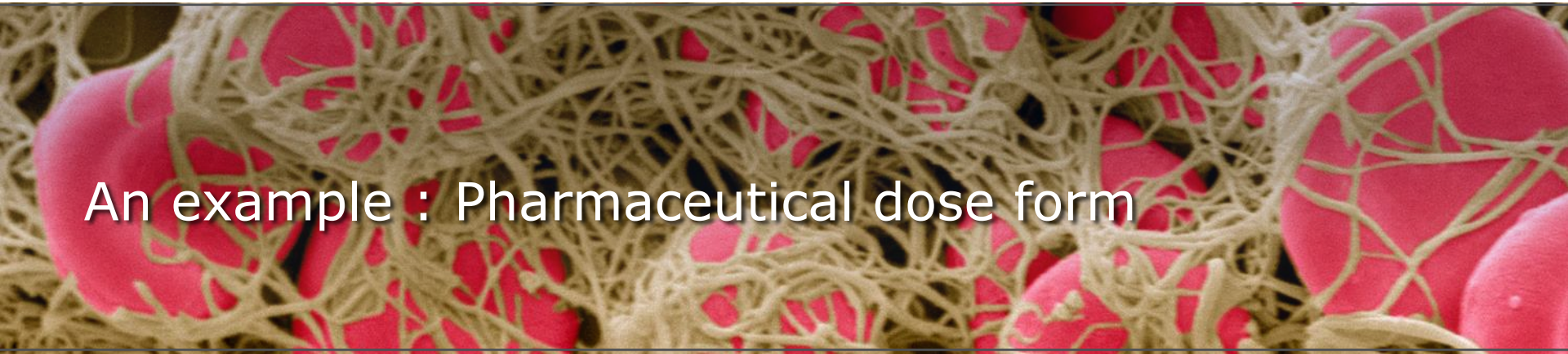




MDM and IDMP provide value for business operations

IDMP provides an common language (industry standard) for pharmaceutical business

- Defines business entities
- Provides terms and definitions
- Requires and provides identifiers for business entities
- Requires and provides key attributes of business entities
- Requires and provides list of values for attributes
- Provides (basis for) business rules on data-elements
- Encompasses all type of substances
- Encompasses investigational and authorised medicinal product



An example : Pharmaceutical dose form

EDQM Standard Terms

Internal controlled vocabularies for pharmaceutical dose forms

Version 1.0.0 – 14 November 2014

State of matter		Basic dose form	
ID	Name	ID	Name
SOM-0100	Gas	BDF-0087	Medicinal gas
SOM-0099	Liquid	BDF-0077	Collodion
		BDF-0078	Concentrate
		BDF-0079	Dispersion
		BDF-0090	Drops (unspecified)
		BDF-0080	Emulsion
		BDF-0081	Lacquer
		BDF-0082	Liquid
		BDF-0093	Shampoo
		BDF-0083	Solution
		BDF-0084	Solvent
SOM-0098	Semi-solid	BDF-0085	Suspension
		BDF-0086	Syrup
		BDF-0103	Cement
		BDF-0071	Cream
		BDF-0072	Foam
		BDF-0073	Gel
		BDF-0074	Ointment

Release characteristics	
ID	Name
RCA-0047	Conventional
RCA-0044	Delayed
RCA-0046	Modified
RCA-0045	Prolonged
RCA-0048	Unknown

Transformation	
ID	Name
TRA-0038	Dilution
TRA-0039	Dispersion
TRA-0040	Dissolution
TRA-0041	Mixing
TRA-0042	No transformation
TRA-0043	Unknown

Intended site	
ID	Name
ISI-0021	Auricular
ISI-0022	Cutaneous/Transdermal
ISI-0023	Dental
ISI-0105	Endocervical
ISI-0024	Environmental
ISI-0025	Extracorporeal
ISI-0106	Gastric
ISI-0107	Gastroenteral

Administration method	
ID	Name
AME-0004	Administration
AME-0005	Application
AME-0006	Bathing
AME-0111	Burning
AME-0007	Chewing
AME-0112	Dialysis
AME-0008	Gargling
AME-0113	Implantation

IG FOR 11239

Example coded concept for the release characteristic 'Prolonged'

code	RCA-0045
value	RCA-0045-EN-GB
translation	RCA-0045-FR-FR RCA-0045-JA-JP

Example coded concept for the intended site characteristic 'Oral'

code	ISI-0031
value	ISI-0031-EN-GB
translation	ISI-0031-FR-FR ISI-0031-JA-JP

Example coded concept for the administration method characteristic 'Swallowing'

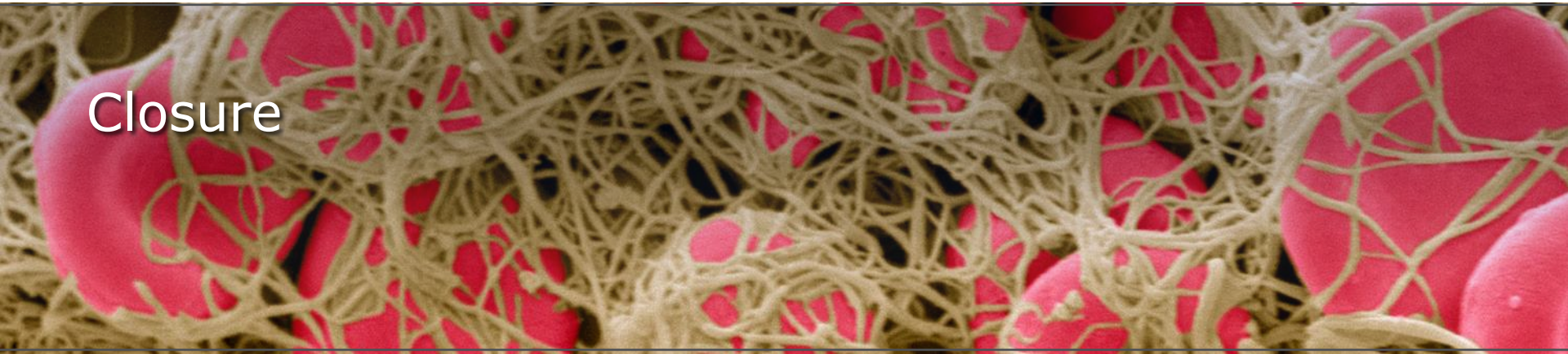
code	AME-0019
value	AME-0019-EN-GB
translation	AME-0019-FR-FR AME-0019-JA-JP

Summary of pharmaceutical dose form 'Prolonged-release tablet' and its attributes

pharmaceutical dose form	PDF-10226000
state of matter	SOM-0097
basic dose form	BDF-0069
release characteristics	RCA-0045
transformation	TRA-0042
intended site	ISI-0031
administration method	AME-0019

Example coded concept for the pharmaceutical dose form 'Prolonged-release tablet'

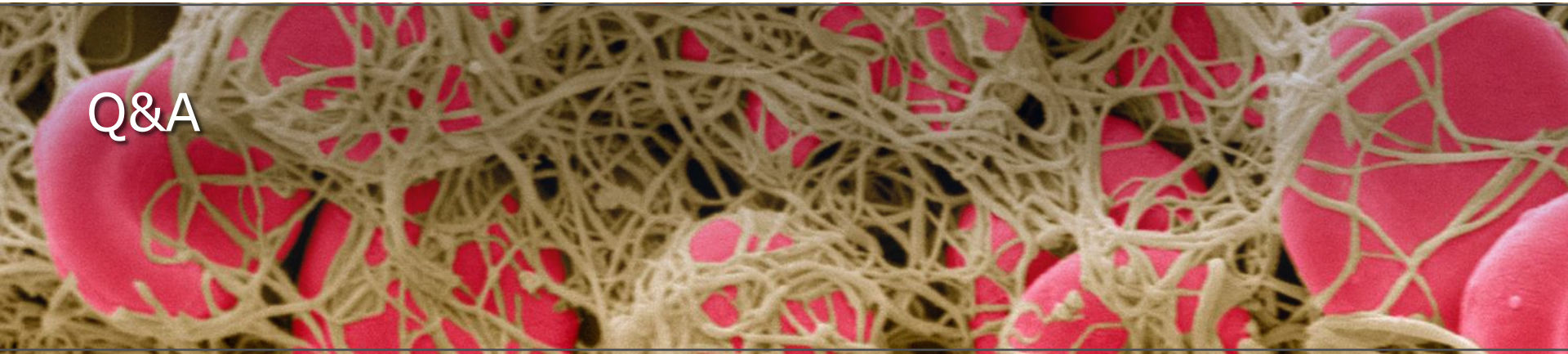
code	PDF-10226000
value	PDF-10226000-EN-GB
translation	PDF-10226000-FR-FR PDF-10226000-JA-JP



Closure

Key messages

- Enforcement of the new IDMP regulation is emerging.
- The regulation contains a lot of the data-elements relevant for Drug Development.
- IDMP data need to be kept in an IDMP compliant database from which product data will be submitted to authorities.
- For new development projects opportunities do exist for creation of high quality, well governed, IDMP compliant data
- Embracing IDMP on a enterprise level might facilitate data handling in the Clinical Supply Chain.



Q&A