Global Harmonization Center Webinar Part 5:

The path to ISO IDMP: From a Global Data Standard to Implementation

Driving Global Exchange on Medicinal Product Information for the Benefit of Patient Health in the World

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Agenda

- Brief introduction to the IDMP Standards
- Advantages of the ISO IDMP Standards
- Example: Cross border travelling
- Data Considerations
- Master Data
- Interoperability
- Structured Data
- Data Quality



Why we need a Medicinal Product Dictionary?

- Adverse events must be reported with the suspected substances and products
- Substances and products were originally typed in — with typos and language issues
- **ICH E2B** requested selection from a dictionary instead of free text with **E2B(R2)**
- This raised the core question: What exactly is a medicinal product?



What is a Product?

- The product authorized by regulatory procedure or prescribed by a doctor?
- The product bought in a pharmacy, found in the package, or administered to the patient?
- The composition of the product?

All of these answers are correct.

That is why a formal model is required!



The five ISO Standards



Ref: Présentation PowerPoint (unicom-project.eu)

- Medicinal product information (MPID/PCID) - ISO 11615
- Pharmaceutical product information (PhPID) - ISO 11616
- Substances (Substance ID/Specified Substance ID) - ISO 11238
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
- Units of measurement (UCUM) - ISO 11240

ISO IDMP standards apply to both authorised and investigational medicinal products for Human use



Medicinal versus Pharmaceutical Product

Medicinal Product	Pharmaceutical Product	Medicinal Product
		
▪ Unique product name ▪ Unique marketing authorisation ▪ Unique packaging ▪ Etc.	▪ Same active substance ▪ Same strength + reference strength ▪ Same administrable dose form	▪ Unique product name ▪ Unique marketing authorisation ▪ Unique packaging ▪ Etc.



Medicinal versus Pharmaceutical Product

Medicinal Product

Pharmaceutical Product





Effervescent tablet

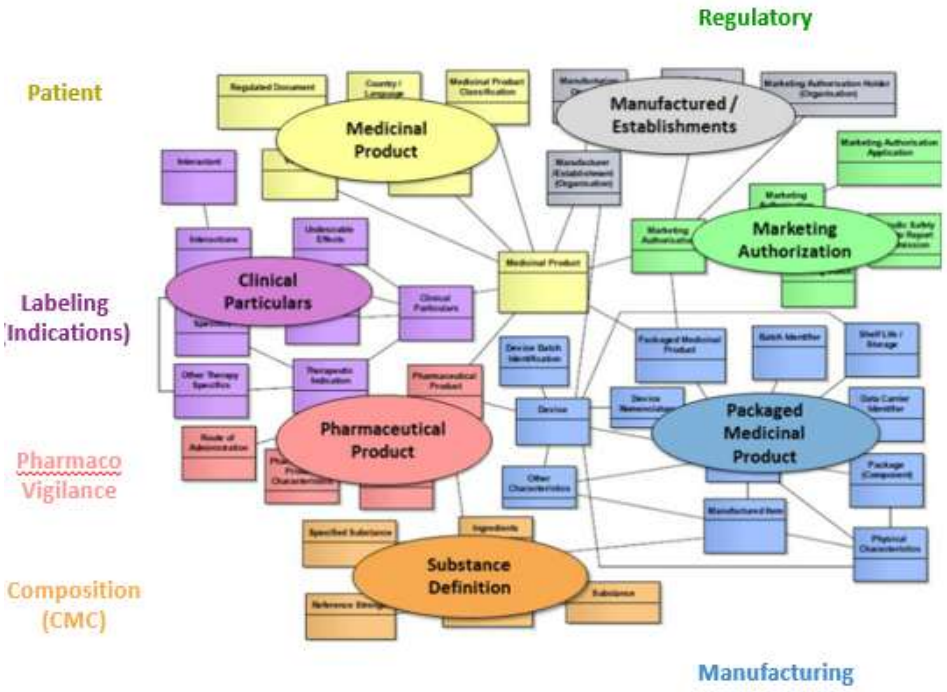
Oral solution



Advantages of the global ISO Standards

ISO IDMP has defined a product definition that connects all functional areas

- Regulatory: Marketing Authorization
- Manufacturing: Packaged Medicinal Product
- CMC/PV: Pharmaceutical Product
- Labeling: Clinical Particulars



Ref: Présentation PowerPoint (unicom-project.eu)

IDMP-compliant Medicinal Product Dictionary can answer questions for the Patient

- What are the products for pain and fever (indications) that do not contain lactose (composition)?
- What is the equivalent of my medicinal product in the country of my next holiday?
- What are the alternative products if my medicine runs out of stock?



Fictitious example: Patient travelling between South Korea and France





Picture created with Copilot; Aug 10, 2026



Medicinal Product in South Korea

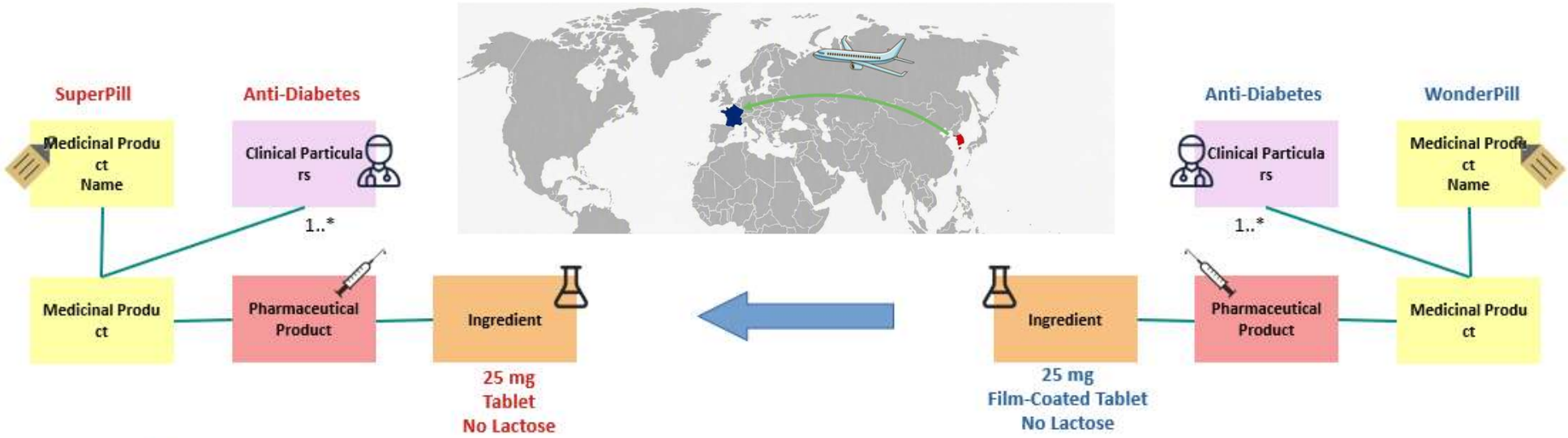
Wonder Pill 25 mg film-coated tablets, authorized in South Korea for anti-diabetes, and without lactose

At destination, Patient noticed he/she forgot his/her medicine!

What to do outside his/her home country?



Fictitious example: Patient travelling between South Korea and France





IDMP in South Korea

Find exact composition from Name as authorized in the country

IDMP in France (EU)

From the composition, indication(s) and absence of lactose, identify equivalent in France

Shared global identifiers (PhPIDs, substance IDs) play an additional role



Key Benefits of IDMP

Data Quality

- Adopters can align their data and information to provide an accurate, single source of truth.
- Leads to reduced costs; greater productivity; increased confidence in regulatory systems and data.
- National regulators and healthcare institutions should adopt a metrics-based approach to assessing data quality

Sharing Information

- Improve interoperability by making it easier to share information across jurisdictions
- Use of standards for medicinal products improves global interoperability and communications
- Internationally, regulators & healthcare institutions can work together to develop and share common systems

Safety Alerts

- Improve ability to identify, assess and respond to patient safety or medication incidents
- Improved surveilling of counterfeits
- Improved monitoring global supply chains for product quality issues and risk analytics

Medicinal Product Shortage

- Make it easier to find alternative products for anti-microbial resistance or drug shortages
- Allows the identification of pharmaceutically equivalent products across regions, to support mitigation of drug shortages.

Cross Product Comparisons

- Make it easier to compare products across jurisdictions for pricing and reimbursement
- Reduce or share the cost of managing the same medicinal product information



Ref: Toward Global Identification of Medicinal Products (IDMP) Implementation
CDER Small Business & Industry Assistance (SBIA), January 27, 2022

Key Data Aspects

- Master Data
- Interoperability
- Structured Data
- Data Quality and Ownership



What is Master Data?

Master Data is structured data that reflects the organization and activity of a company and its market

Master Data is shared by the business and the information systems

Master Data is stable in time with little or no change by transactional or decision-making applications

Master Data possesses a long lifecycle with different states throughout time

This is not Master Data

Unstructured data (multimedia or text)

Transactional data (evolving during a business process)

Decision data (data resulting from transactions, calculated or derived)



Interoperability

Interoperability is the **ability of independent, heterogeneous systems to work together seamlessly to exchange and make data available to users in an efficient way,** without the need for special adaptations.

This typically requires that data (and organizations!) adhere to predefined standards.

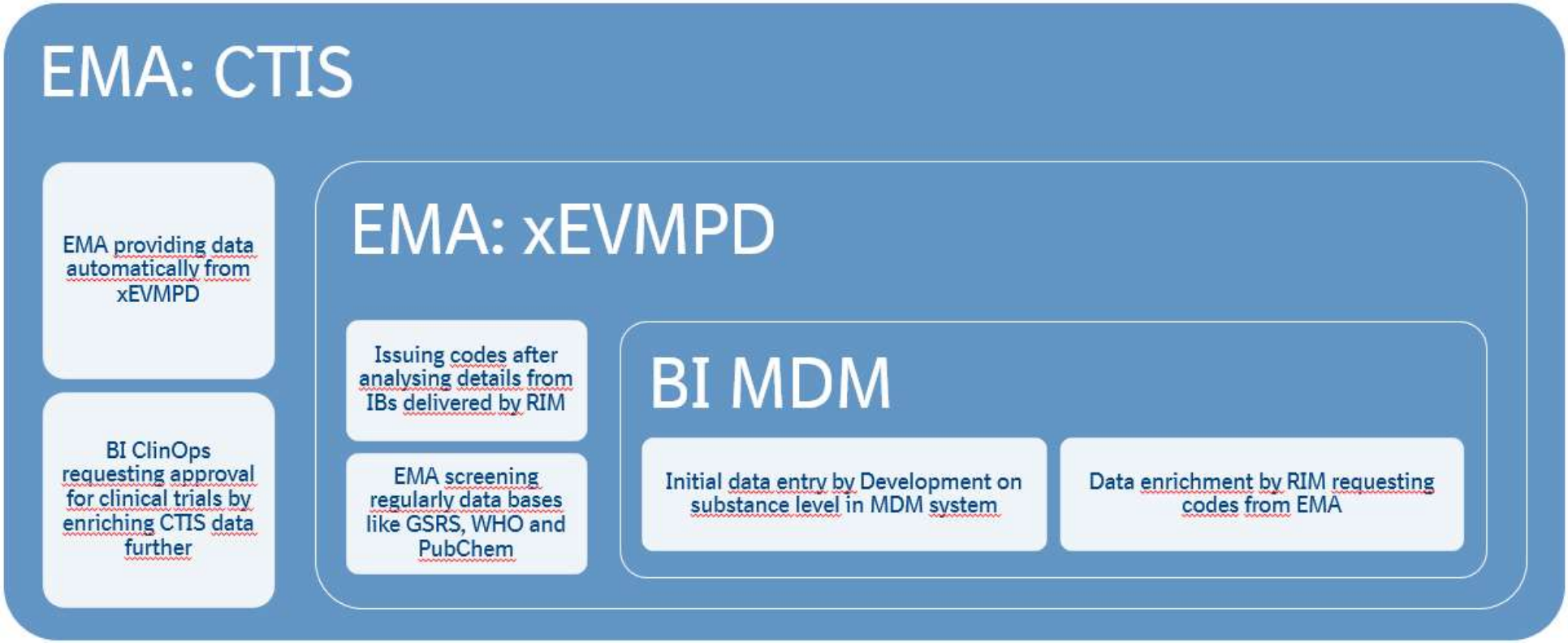
Interoperability is possible within a given company or agency

OR

across companies and agencies



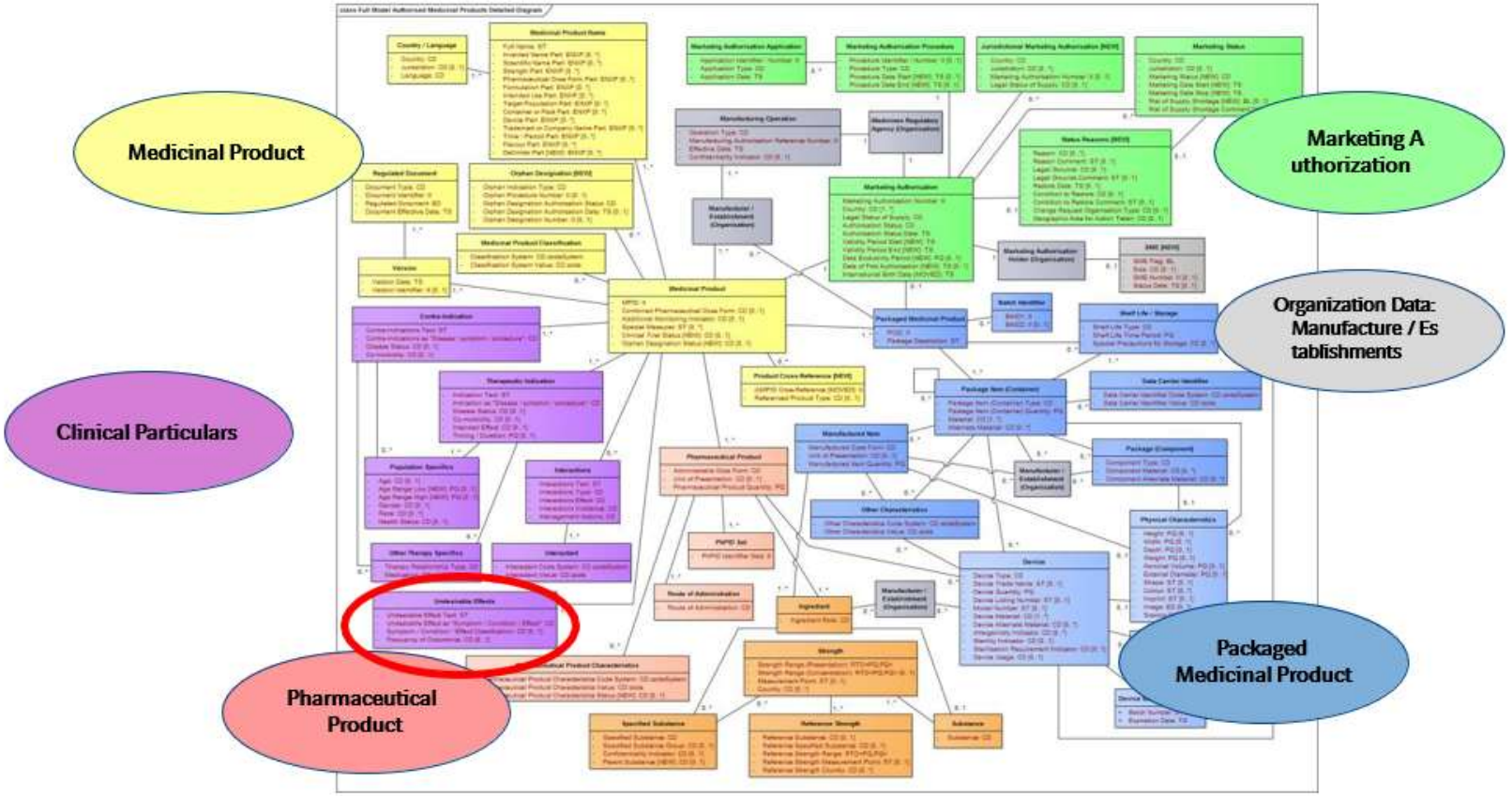
Interoperability Example



CTIS:	Clinical Trial Information System
xEVMPD:	extended Eudravigilance Medicinal Product Dictionary
BI MDM:	Master Data System of Boehringer Ingelheim



Understanding the Efforts with Data

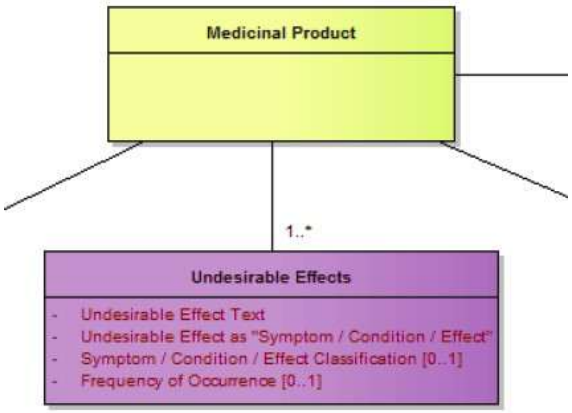




Understanding the Efforts with Data

Data amount and expertise management

- Understanding of the difference between a one-to-one and a one-to-many relationship
- A feel for the different levels of expertise needed for data processing



1 Product has on average **25** undesirable effects resulting in
25 x 4 = **100** pieces of information to be delivered for 2,500 products resulting in
100 x 2,500 = **250,000** structured elements to be **extracted** from the SmPC, **coded,** and **maintained**



Data Quality and Ownership

- **High Data Quality will enable interoperable use across systems, ensure state-of-the-art analytics and secure AI readiness**
- **Data need to follow standards**
- **Ownership and a governance framework needs to be in place**

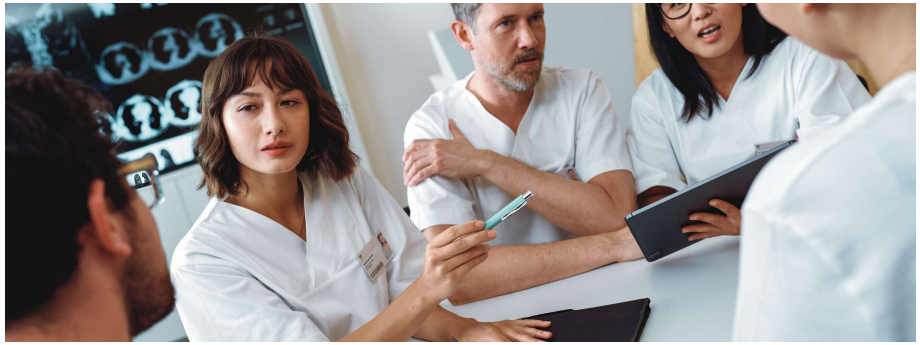
Food for thought:

Who owns the data in complex industry – agency interoperability settings?

- The regulator?
- The Marketing Authorization Holder?
- Both?



Overall benefits of implementing IDMP



Compliance

- Fulfilling all IDMP related legal requirements of health authorities worldwide
- Enabling structured data submissions to health authorities for various use cases
- Further improving pharmacovigilance aspects



Beyond compliance

- Becoming data driven
- Allowing for data-based, real-time decisions
- Enabling prospective reporting
- Overcoming internal “silo” approaches
- Living end-to-end quality aspirations
- Creating the foundation for digitalization and automation



….in order to get medications to patients faster