What is IDMP?

**IDMP**
Identification of Medicinal Products

Data Elements and Structures
For unique identification and exchange

- **Data Structure**
  - Data model with attributes that define and detail a medicinal product and supporting concepts
- **Unique Identifiers**
  - Definition and guidelines on unique identifiers of the medicinal product and supporting concepts
- **Messaging Format**
  - Business Rules and Messaging specifications using HL7 for electronic exchange of medicinal product information

The IDMP Documents

- **ISO IDMP Standards**
  - ISO 11615: Medicinal Product Info & IDs
  - ISO 11616: Pharmaceutical Product Info & IDs
  - ISO 11239: Substance Info & ID
  - ISO 11240: Unit of Measurement

The ISO IDMP Standards

- **Group of 5 standards**
  - ISO 11615: Medicinal Product (MPID)
  - ISO 11616: Pharmaceutical Product (PPID)
  - ISO 11239: Substance (IDMP)
  - ISO 11240: Unit of Presentation

Each standard defines data elements and structures for unique identification and exchange of a certain aspect of a medicinal product

High Level Example

**ISO 11240**
Unit of Measurement

- **ISO 11615**
  - **Medicinal Product**
    - Paracetamol Capsules
    - 16 capsules
    - Oral Capsules containing of
      - Per Capsule
      - 200 mg

**ISO 11239**
Pharmaceutical Product

- **ISO 11616**
  - **Pharmaceutical Product**
    - Paracetamol
    - Chemical substance
    - USP grade
    - Manufactured in XYZ

**Components of an Authorized Medicinal Product**

- **Authorization of an agency in a country
- Authorization by an organization
- Approved indications
- Approved trademarks
- And sold with approved trade names

Who will be impacted within the organization?

Compliance for IDMP primarily lies with 2 departments

**Regulatory Affairs**
- Submits and owns product information as defined in IDMP
  - There is a legally binding deadline for IDMP submission in EU
  - PA responsible for regulatory compliance to EMA
- Information might be sourced from multiple departments – manufacturing, QA, clinical, safety, etc.

**ArisGlobal Solution for IDMP Compliance**

- **agIDMPTM** and **agXchange RSM™**
- **IDMP Data Collection, Manual Entry and Validation**
  - Electronic submission using agIDMP™
  - Missing info using agIDMP™
  - Missing terms using agXchange RSM™

Benefits of IDMP

- **Improved Safety**
  - Information consumes the IDMP product identifiers
  - Optional today but need to ensure step

- **Improved Efficiencies**
  - Improvement of the accuracy of the medicinal product and supporting concepts
  - Regulatory Affairs
  - Safety
  - Clinical
  - Supplies

- **Integrated Data Systems**
  - Electronic submission to authorities using agXchange RSM™
  - National to international

- **Improved Consistency**
  - Achieves consistency in product identifiers from the IDMP standard

- **Improved Human Safety**
  - Major human safety benefits
  - Provides major human safety benefits

- **Improved Financial Savings**
  - Improves the accuracy of information exchange
  - Achieves financial savings for the life sciences industry

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