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08 Oct, 2024

Informatica IDMC for Life Sciences

- Kamal Abrol, Sr Principal, CSA

Where data & AI come to LIFE

Housekeeping Tips

- Today’s Webinar is scheduled for 1 hour
- The session will include a webcast and then your questions will be answered live at the end of the presentation
- All dial-in participants will be muted to enable the speakers to present without interruption
- Questions can be submitted to “All Panelists" via the Q&A option and we will respond at the end of the presentation
- The webinar is being recorded and will be available on our Success Portal - where you can download the slide deck for the presentation. The link to the recording will be emailed as well.
- Please take time to complete the post-webinar survey and provide your feedback and suggestions for upcoming topics.

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Where data
& AI come to LIFE

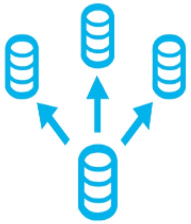
Agenda

- IDMP Compliance-Challenges for Pharmaceutical Companies
- Intelligent Data Management Cloud (IDMC) for Life Sciences
- MDM SaaS addressing IDMP challenges
- Global identifiers with Prebuilt validation rules
- Pre-Package Solution to Master Medicinal +Packaged Products
- **Live Demo-**Product 360 for Life Sciences- Implementing IDMP Standards

IDMP Compliance-Challenges for Pharmaceutical Companies

Departments

- Product Data generated across multiple systems & BU’s

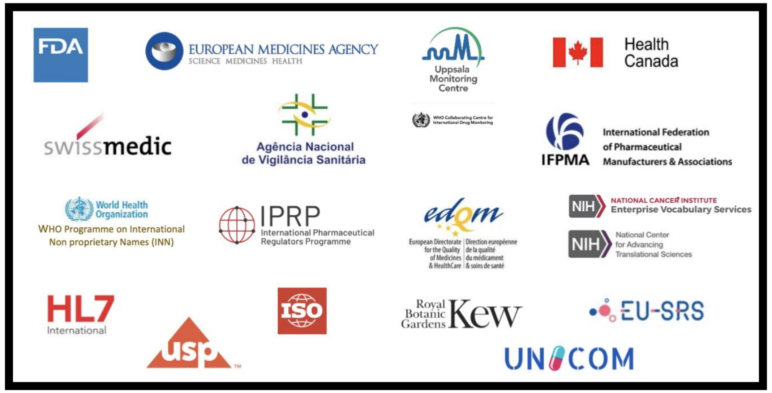


- Inconsistent Standard/data format across different data sources

LOCALIZATION

- Different terminology for same product across different regions

- Cross Functional Collaboration & Multiple Sponsorships


FDA
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
Uppsala Monitoring Centre
Health Canada
swissmedic
Agência Nacional de Vigilância Sanitária
IFPMA
International Federation of Pharmaceutical Manufacturers & Associations
World Health Organization
WHO Programme on International Non proprietary Names (INN)
IPRP
International Pharmaceutical Regulators Programme
edqm
NIH
NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services
NIH
National Center for Advancing Translational Sciences
HL7 International
usp
ISO
Royal Botanic Gardens Kew
EU-SRS
UNICOM

- Multiple controlled vocabularies across various regulatory authorities and jurisdiction

GOAL

TRUSTED,ACCURATE,CONSISTENT and timely IDMP compliant Product Info

1. Manufacturers
2. CROs
3. Regulators

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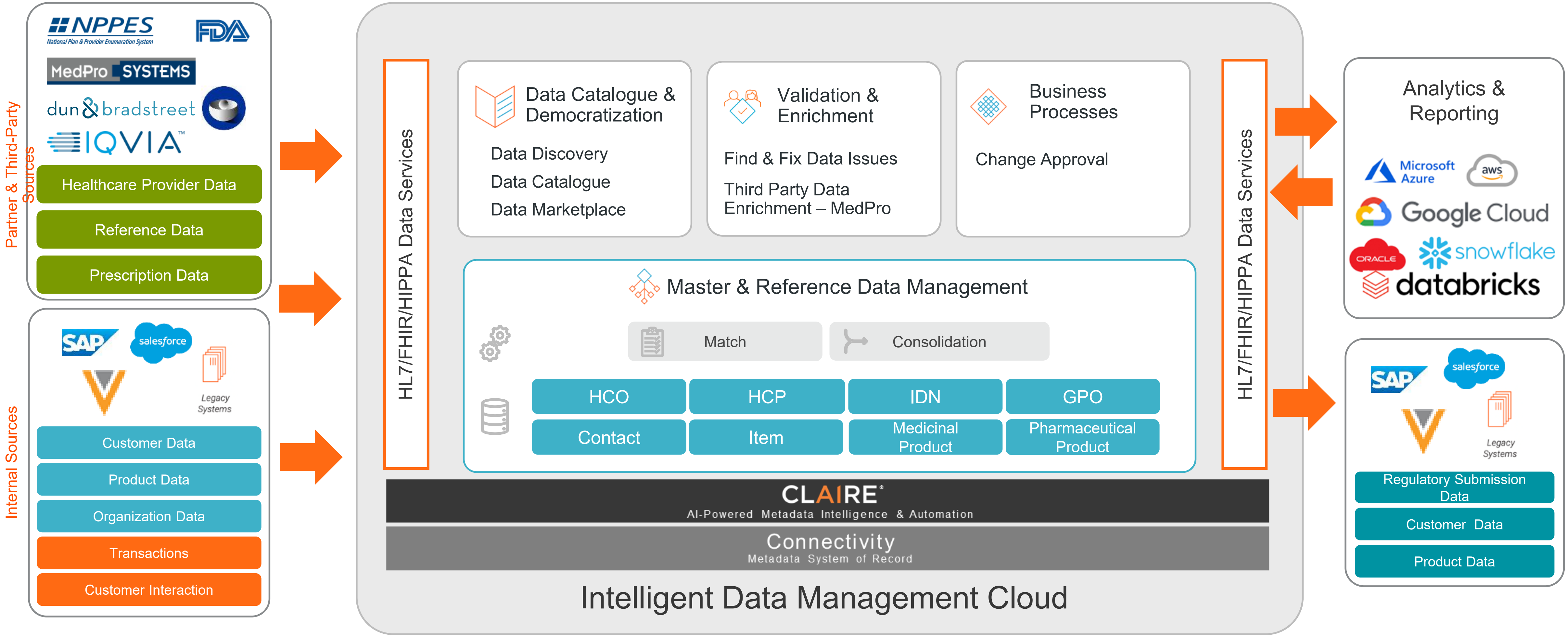
Intelligent Data Management Cloud (IDMC) for Life Sciences



Partner & Third-Party Sources

NPPES National Plan & Provider Enumeration System
FDA
MedPro SYSTEMS
dun & bradstreet
IQVIA

- Healthcare Provider Data
- Reference Data
- Prescription Data

Internal Sources

SAP
salesforce
Legacy Systems

- Customer Data
- Product Data
- Organization Data
- Transactions
- Customer Interaction

HL7/FHIR/HIPPA Data Services

Data Catalogue & Democratization
- Data Discovery
- Data Catalogue
- Data Marketplace

Validation & Enrichment
- Find & Fix Data Issues
- Third Party Data Enrichment – MedPro

Business Processes
- Change Approval

Master & Reference Data Management

Match
Consolidation

HCO	HCP	IDN	GPO
Contact	Item	Medicinal Product	Pharmaceutical Product

CLAIRE
AI-Powered Metadata Intelligence & Automation

Connectivity
Metadata System of Record

HL7/FHIR/HIPPA Data Services

Intelligent Data Management Cloud

Analytics & Reporting

Microsoft Azure
aws
Google Cloud
ORACLE
snowflake
databricks

SAP
salesforce
Legacy Systems

- Regulatory Submission Data
- Customer Data
- Product Data

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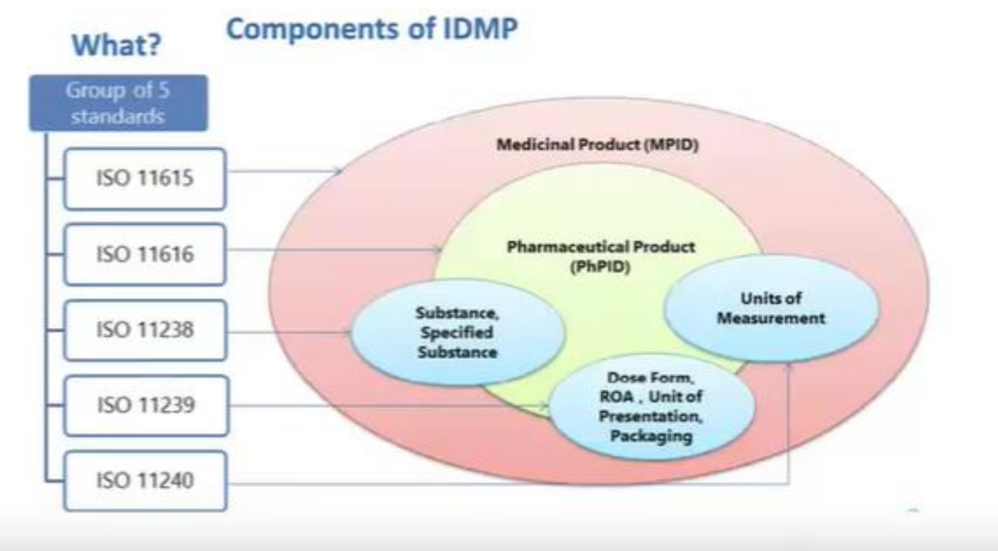
About Identification of Medicinal Products (IDMP)

A set of 5 ISO standards built jointly by ISO, US FDA, EU EMA & WHO in 2012 for unique identification of medicinal products to reliably identify and trace the use of medicinal products and the materials within medicinal products globally

FDA
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
Uppsala Monitoring Centre
WHO Collaborating Centre for International Drug Monitoring
Health Canada
swissmedic
Agência Nacional de Vigilância Sanitária
IFPMA International Federation of Pharmaceutical Manufacturers & Associations
World Health Organization
WHO Programme on International Non proprietary Names (INN)
IPRP International Pharmaceutical Regulators Programme
edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
NIH NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services
NIH National Center for Advancing Translational Sciences
HL7 International
usp
ISO
Royal Botanic Gardens Kew
EU-SRS
UNICOM

Global IDMP Working Group (GIDWG) Members

- Regulatory agencies involved – **EU EMA, US FDA, Health Canada, Brazil ANVISA, Swissmedic**
- **EMA** is the first regulatory authority to implement **IDMP** as **SPOR**
- **FDA** has shared the overlaps of PQ/CMC with IDMP and a long-term vision to fully align with IDMP
- In addition to FDA, EU endorsed HL7 **FHIR** as the data standard to supports the exchange of informa
and rel


What?
Components of IDMP
Group of 5 standards
ISO 11615
ISO 11616
ISO 11238
ISO 11239
ISO 11240
Medicinal Product (MPID)
Pharmaceutical Product (PhPID)
Substance, Specified Substance
Units of Measurement
Dose Form, ROA, Unit of Presentation, Packaging

Product 360 for Life Sciences- Implementing IDMP Standards

Product mastering solution for Pharmaceuticals

Enterprise view

Standardized data model

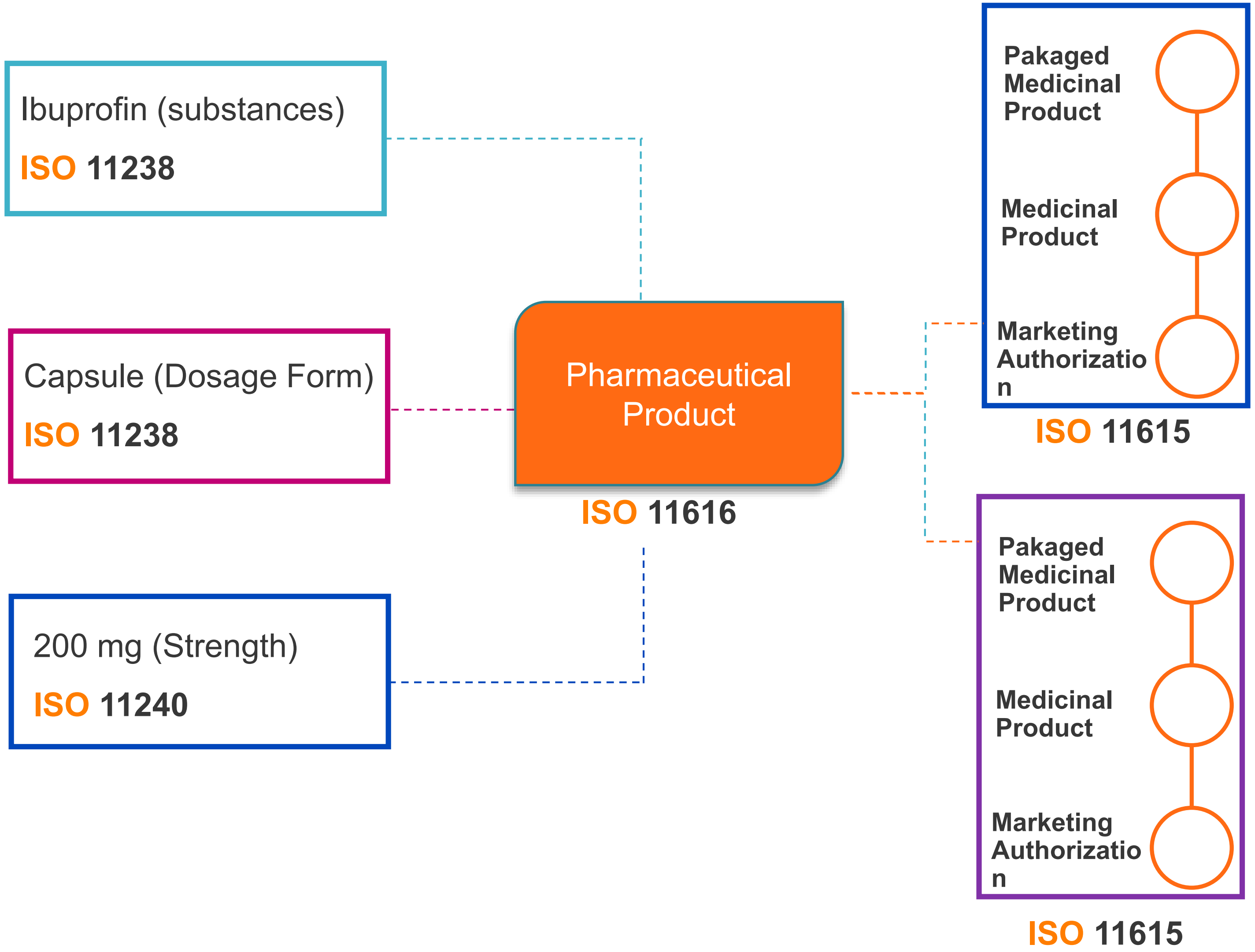
Standard reference data

Hierarchy & relationships

Data validation

- Deliver a complete picture of medicinal products, ingredients & packaging across various systems, business units and regions
- Maintain medicinal product information like clinical particulars, marketing authorization, orphan designation, product classifications etc.
- Manage medicinal products master data to comply with standards like IDMP
- Enable streamlined exchange of medicinal product information with regulatory agencies

MDM SaaS addressing IDMP challenges-Connecting Medicinal Products



Ibuprofin (substances)

ISO 11238

Capsule (Dosage Form)

ISO 11238

200 mg (Strength)

ISO 11240

Pharmaceutical Product

ISO 11616

Pakaged Medicinal Product

Medicinal Product

Marketing Authorization

ISO 11615

Pakaged Medicinal Product

Medicinal Product

Marketing Authorization

ISO 11615

Advil LIQUI-GELS
4 Liquid Filled Capsules
Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (NSAID)

Midol Liquid Gels
IBUPROFEN 200mg (NSAID)
PAIN RELIEVER/ FEVER REDUCER
NUROFEN
Ibuprofen

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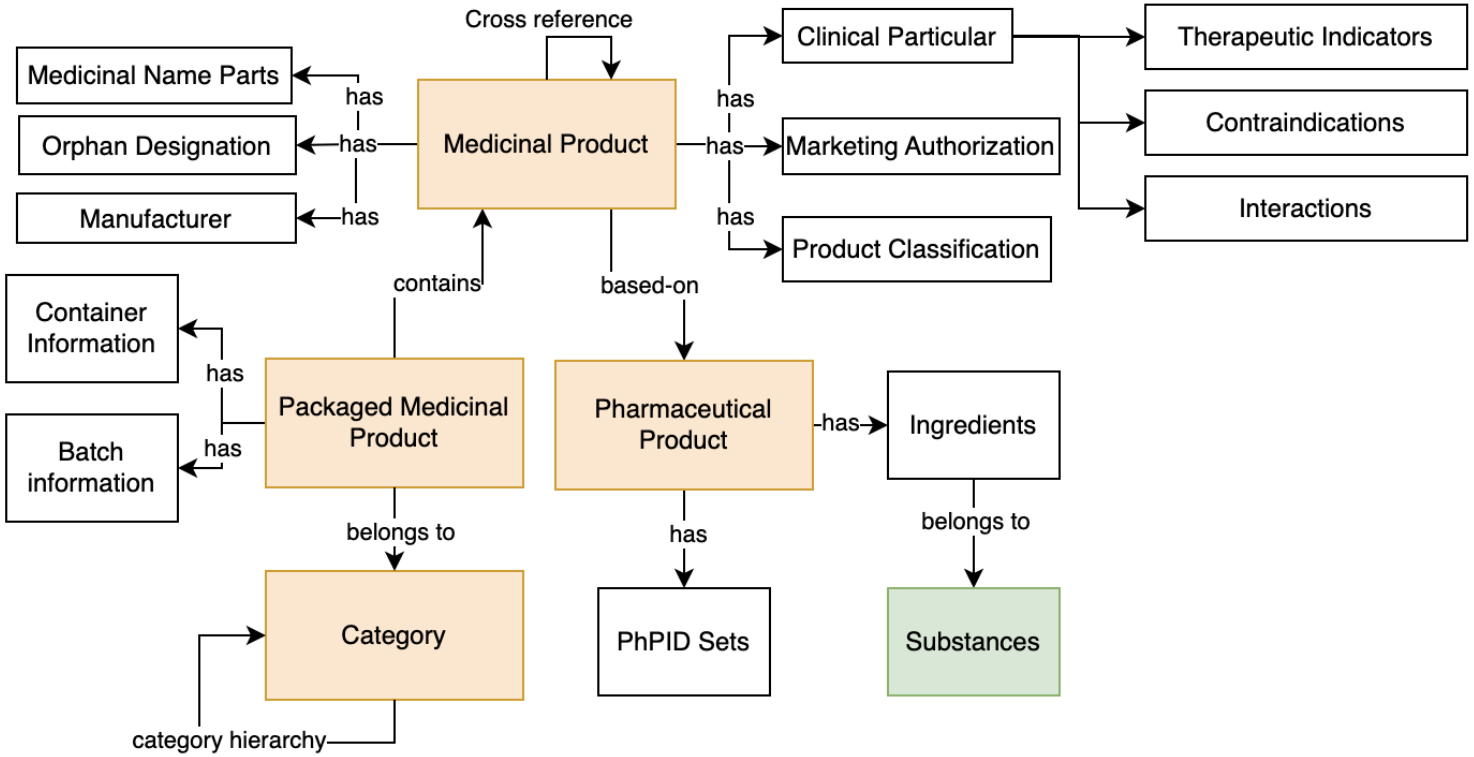
Product 360 for Life Sciences

Key Entities & relationships

🟧 Business Entities

🟩 Reference Entities


Cross reference
Medicinal Name Parts
has
Orphan Designation
has
Medicinal Product
has
Manufacturer
has
Clinical Particular
has
Marketing Authorization
has
Product Classification
has
Therapeutic Indicators
Contraindications
Interactions
contains
based-on
Container Information
has
Batch information
has
Packaged Medicinal Product
Pharmaceutical Product
has
Ingredients
belongs to
has
belongs to
Category
PhPID Sets
Substances
category hierarchy

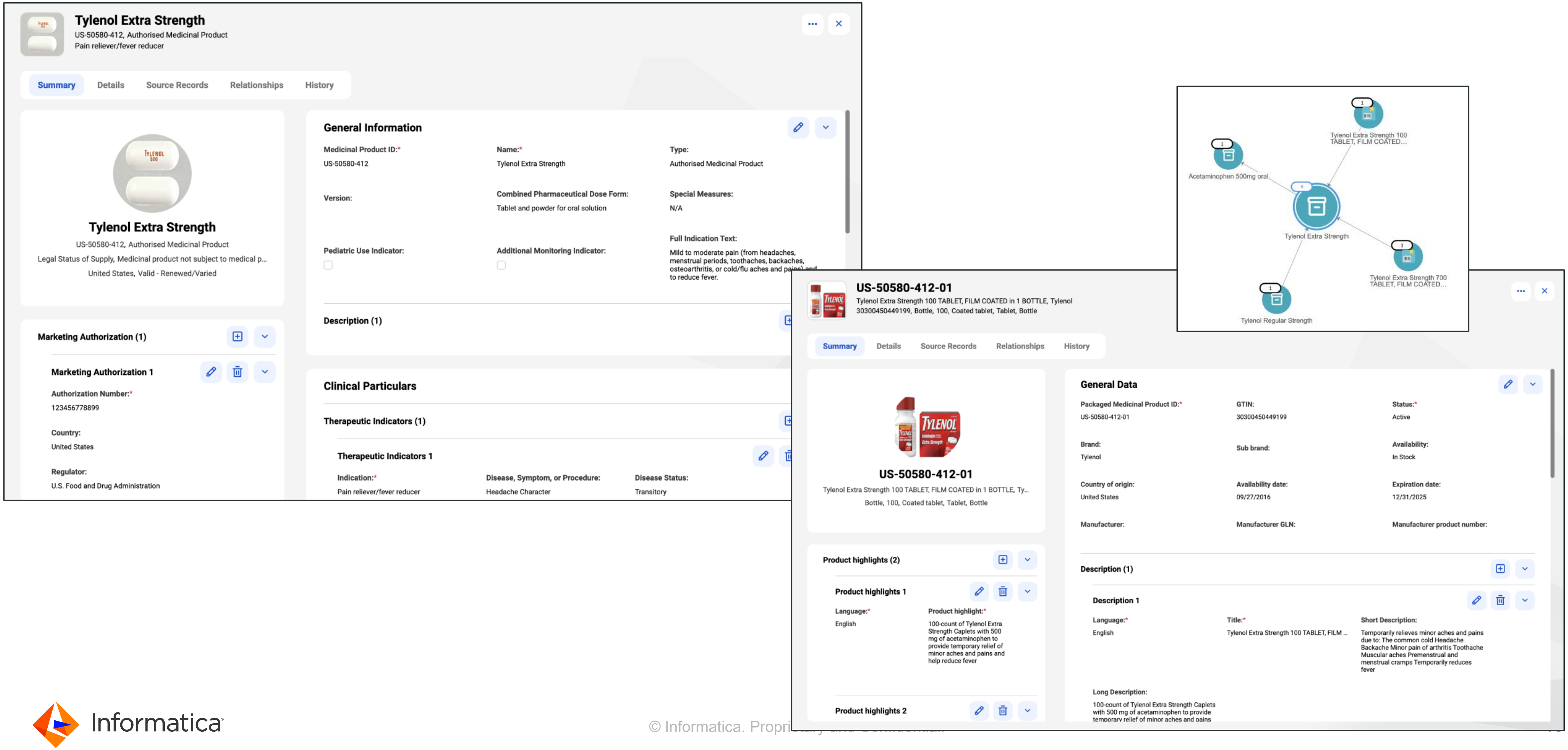
Demo

Product 360 for Life Sciences- Implementing IDMP Standards

Product 360 for Life Sciences Accelerator Assets

Data Model	Standards-based data model supporting medicinal product, pharmaceutical product & packaged medicinal product to align with guidelines from IDMP, SPOR, FHIR & FDA
Reference Data	Reference datasets based on globally controlled vocabularies and standards like SPOR & FHIR
Match Model	Predefined Match Rules for Medicinal Product, Pharmaceutical Product & Packaged Medicinal Product
Validation	Support for multiple global identifiers with validation rules
Relationship & Hierarchy	Key Relationship between medicinal product, Packaged medicinal products and pharmaceutical product information
Dashboard & reports	Predefined reports for Medicinal Product information

Screenshots



Tylenol Extra Strength
US-50580-412, Authorised Medicinal Product
Pain reliever/fever reducer

Summary
Details
Source Records
Relationships
History

Tylenol Extra Strength
US-50580-412, Authorised Medicinal Product
Legal Status of Supply, Medicinal product not subject to medical p...
United States, Valid - Renewed/Varied

General Information

Medicinal Product ID:*
US-50580-412

Name:*
Tylenol Extra Strength

Type:
Authorised Medicinal Product

Version:

Combined Pharmaceutical Dose Form:
Tablet and powder for oral solution

Special Measures:
N/A

Pediatric Use Indicator:
☐

Additional Monitoring Indicator:
☐

Full Indication Text:
Mild to moderate pain (from headaches, menstrual periods, toothaches, backaches, osteoarthritis, or cold/flu aches and pains) and to reduce fever.

Description (1)

Marketing Authorization (1)

Marketing Authorization 1

Authorization Number:*
123456778899

Country:
United States

Regulator:
U.S. Food and Drug Administration

Clinical Particulars

Therapeutic Indicators (1)

Therapeutic Indicators 1

Indication:*
Pain reliever/fever reducer

Disease, Symptom, or Procedure:
Headache Character

Disease Status:
Transitory

1
Acetaminophen 500mg oral
1
Tylenol Extra Strength 100 TABLET, FILM COATED...
4
Tylenol Extra Strength
1
Tylenol Extra Strength 700 TABLET, FILM COATED...
1
Tylenol Regular Strength

US-50580-412-01
Tylenol Extra Strength 100 TABLET, FILM COATED in 1 BOTTLE, Tylenol
30300450449199, Bottle, 100, Coated tablet, Tablet, Bottle

Summary
Details
Source Records
Relationships
History

US-50580-412-01
Tylenol Extra Strength 100 TABLET, FILM COATED in 1 BOTTLE, Ty...
Bottle, 100, Coated tablet, Tablet, Bottle

General Data

Packaged Medicinal Product ID:*
US-50580-412-01

GTIN:
30300450449199

Status:*
Active

Brand:
Tylenol

Sub brand:

Availability:
In Stock

Country of origin:
United States

Availability date:
09/27/2016

Expiration date:
12/31/2025

Manufacturer:

Manufacturer GLN:

Manufacturer product number:

Product highlights (2)

Product highlights 1

Language:*
English

Product highlight:*
100-count of Tylenol Extra Strength Caplets with 500 mg of acetaminophen to provide temporary relief of minor aches and pains and help reduce fever

Product highlights 2

Description (1)

Description 1

Language:*
English

Title:*
Tylenol Extra Strength 100 TABLET, FILM ...

Short Description:
Temporarily relieves minor aches and pains due to: The common cold Headache Backache Minor pain of arthritis Toothache Muscular aches Premenstrual and menstrual cramps Temporarily reduces fever

Long Description:
100-count of Tylenol Extra Strength Caplets with 500 mg of acetaminophen to provide temporary relief of minor aches and pains

Speaker: KAMAL ABROL

Kabrol@informatica.com

Q/A Panel: Aishwarya

THANK YOU
MERCI
GRAZIE
OBRIGADO
ASANTE
MATONDO
TERMAKASIH
MULTUMESC
CHOKRANE
SPASIBO
MATURNUWUN
WELALIN
MAAKE
CAMONBAN
VINAKA
RAIBHMAITHAGAT
MOCHCI

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