IDMP
IDENTIFICATION OF MEDICINAL PRODUCTS

18. DGRA Jahreskongress
AGENDA / CONTENT

- Introduction to IDMP as a means of identification of products
  - IDMP – what is it? And why?
  - Hierarchy of identifiers and simplified view of use cases for these identifiers
  - Initial scope of data associated to each identifier

- IDMP from a business process perspective
  - Setting the scene
  - Time lines and overall goal
  - Implementation: Global – Europe – Member States
  - Industry involvement
  - Future Vision and Lessons Learned
WHAT MAKES UP A “PRODUCT”?  

Multiple Specified Substances go into a…  

Pharmaceutical Product which is…  

presented as a specific Packaged Product  

which is manufactured in batches  

and has regulator approval as a Medicinal Product
SETTING THE SCENE

Multiple Specified Substances go into a...

![Chemical structure of Acetaminophen (APAP)](image)

362O9ITL9D = SSID
IN IDMP EACH OF THESE ENTITIES HAS AN IDENTIFIER

- Specified Substance ID’s (SSID)
- Pharmaceutical Product ID (PhPID)
- Packaged Product ID (PCID)
- Manufactured Batch ID (BAID_1/BAID_2)
- Medicinal Product ID (MPID)
IDENTIFICATION OF MEDICINAL PRODUCT (IDMP)

Where does it come from?

- 5 ISO standards to uniquely identify a medicinal product
- 4 Implementation Guides to bring theory into real life
- Maintenance organisation(s) to assign unique identifiers
- A set of control vocabularies and terms
- A messaging standard to exchange data
ISO IDMP TIMELINES
But still early enough for Q1/2017 readiness
IDMP ROADMAP - SUBSTANCES

19844
IG Substances

11238
Substances

Publish i.1
NP i.2
DTS i.2
publish
DTS

05/2016
11/2016
04/2017

6 month delay, publication 05-06/2017

Source: Presentation by Christian Hay; ISO Amsterdam May 2016
SO? WHEN IS IT COMING?

Full set of ISO Implementation Guides and all basic standards revised to be complete and published by

Q2 2017

(up to know !!!)
“THE DEADLINE CONFUSION“ – ART 40

- The obligation on the part of marketing authorisation holders, national competent authorities and the Agency to use the terminology provided for in points (c) to (g) of Article 25 shall apply from

  - 1 July 2016

- BUT:
  “The European Commission, the European Union (EU) Network Data Board and the EU ISO IDMP Task Force have endorsed a phased implementation of the ISO IDMP standards. The phased implementation will commence in July 2016 with the release of terminologies, or so-called controlled vocabularies, and organisation identifiers.”
SPOR (IDMP) TIMELINES

SPOR ???
"Every time you've learned all the answers, they change all the questions."

Oliver Otis Howard (1830-1909), American founder of the Howard University, Washington D.C.
Article 57 Database: Content (1)

Structured Medicinal Product Information:
- P1: MAH (Legal Entity)
- P2: QPPV
- P3: PhV Enquiries
- P4: PSMF
- P5: Authorisation country code
- P6: Authorisation procedure
- P7: Authorisation status
- P8: Authorisation number
- P9: Authorisation date
- P10: MRP/DCP/EU number
- P11: Date of withdrawal/revocation/suspension
- P12: Package description
- P13: Orphan drug designation
- P14: Comments (e.g. paediatric use)
- P15: Medicinal product name
- P16: Medicinal product invented name
- P17: Product generic name
- P18: Product company name
- P19: Product strength name
- P20: Product form name
- P21: Pharmaceutical Form
- P22: Route of administration(s)
- P23: Active ingredient(s), Adjuvant(s)
- P24: Excipients
- P25: Medical device(s)
- P26: Strength of active ingredient(s)/adjuvant(s)
- P27: Therapeutic Indication(s)
- P28: ATC code

Unstructured Medicinal Product Information:
- P29: Summary of Medicinal Product Characteristics

Reference Terminology:
- R1: Pharmaceutical form
- R2: Route of Administration
- R3: ATC codes
- R4: Units of Measurement
- R5: Units of presentation
- R6: Reference source

Substance Information:
- S1: Substance names
- S2: Substance Translations
- S3: Substance synonyms
- S4: Substance class
- S5: Reference source
- S6: International Codes

Organisation information:
- O1: MAH (Legal Entity)
- O2: QPPV
- O3: PhV Enquiries
- O4: PhV System Master File

Business Service Organization

Business Service Substances

Business Service Product
Implementing ISO IDMP through SPOR

The 5 new ISO IDMP standards are all about **master data***

In the case of the regulated EU pharmaceutical industry, there are four domains of master data:

1. **Substances**: Data that describes the ingredients that make up the medicinal product
2. **Products**: Data that describes the marketing and medicinal information relating to a product
3. **Organisations**: Data about the organisations that develop, own and manufacture the products e.g. pharmaceutical company names, their addresses, their plants, distribution centres, their regulatory agencies, and persons related to these organisations
4. **Referentials**: Lists of terms used to describe attributes of products eg. lists of dosage forms, country codes, package codes, weight codes

The SPOR programme has been established to implement services that centralise management of the four domains of master data. The programme will be a phased implementation of 4 projects; 1 for each of the domains:

*Master data is any information that is considered to play a key role in the core operation of a business*
Roll-out plan

We will be using a **phased approach** to implement the new ISO IDMP standards. RMS and OMS will be the **first projects to go live** since the Referentials and Organisations data provide the foundations for implementing PMS and SMS.
RELATIVE TIMELINE FOR IG AND ITERATION

- Publication of EU IGs to support PMS & SMS Q1 / Q2 2017
- PMS & SMS Iteration 1 Q1 / Q2 2018
- Enforcement of PMS & SMS Iteration 1 Q3 / Q4 2018
TIME SHIFT (EVERY 3 MONTH?)

EMA webpage: Human regulatory/Data submission on medicines/Implementation of ISO IDMP standards

Overall high level plan for SPOR

Jan 2016

12 month time shift

Apr 2016
BASIC PRINCIPLES OF INITIAL DATA SCOPE

Data fields required to identify product at the various levels

+ 

Current attributes submitted to XEVMPD under Article 57
(Art 57 project closed at the Agency since April 2016 and whole activity is in operation and maintenance – 10.000 products coming every month)
## Recommendation for PMS Iteration 1

<table>
<thead>
<tr>
<th>Medicinal Product</th>
<th>Marketing Authorisation</th>
<th>Pharmaceutical Products</th>
<th>Package description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPID</td>
<td>Marketing Authorisation Number</td>
<td>Administerable Dose Form</td>
<td>PCID</td>
</tr>
<tr>
<td>Combined Pharmaceutical Dose Form</td>
<td>Country</td>
<td>Unit of Presentation</td>
<td>Package Description</td>
</tr>
<tr>
<td>IMPID Cross-Reference</td>
<td>Legal Status of Supply</td>
<td>Route of Administration</td>
<td>Package Item (Container) Type</td>
</tr>
<tr>
<td>Additional monitoring indicator</td>
<td>Authorisation Status</td>
<td>PHPID Identifier Sets</td>
<td>Package Item (Container) Quantity</td>
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<tr>
<td>Orphan Designation Status</td>
<td>Authorisation Status Date</td>
<td>Device Type (combined medical device ATMP)</td>
<td>Material</td>
</tr>
<tr>
<td>Name (Med.Product)</td>
<td>Date of First Authorisation</td>
<td>Device Trade Name (combined medical device ATMP)</td>
<td>Component Type</td>
</tr>
<tr>
<td>Invented Name Part</td>
<td>Procedure Identifier/Number</td>
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<td>Component Material</td>
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<td>Scientific Name Part</td>
<td>(e.g. MRP number)</td>
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<td>Strength Name Part</td>
<td>Procedure Type (e.g. MRP/DCP)</td>
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<td>Pharmaceutical Dose Form Part</td>
<td>Country (national authorisation)</td>
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<td>Manufactured Item Quantity</td>
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<td>Formulation Part</td>
<td>Marketing Authorisation Number</td>
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<td>Device Type</td>
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<tr>
<td>Intended Use Part</td>
<td>(national authorisation)</td>
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<td>Device Trade Name</td>
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<td>Target Population Part</td>
<td>Organisation (e.g. MAH, QPPV, PSMF)</td>
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<tr>
<td>Container or Pack Part</td>
<td>Identifier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Name Part</td>
<td>Role</td>
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</tr>
<tr>
<td>Trademark or Company Name Part</td>
<td>Location Address</td>
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<tr>
<td>Time/Period Part</td>
<td>Location Role</td>
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<tr>
<td>Flavour Part</td>
<td>Entity Identifier (according to Role e.g. PSMF ID)</td>
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<tr>
<td>Language</td>
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- Around 20 data elements were removed/streamlined/re-modelled
- It is agreed to include 5 data elements to cover Shortage and Marketing information

→ **Total 80 Data elements in PMS Iteration 1**
## Iteration 1 Implementation Guide

### EU IDMP Implementation Guide

#### Modular Table of Content (DRAFT)

<table>
<thead>
<tr>
<th>Guide</th>
<th>Module/Process</th>
<th>Chapters</th>
<th># Author</th>
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<td>Internal Process</td>
<td>Internal process plan</td>
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<td>Internal process timelines</td>
<td>1.0bBP?</td>
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<td>Internal Process Initial Maintenance</td>
<td>1.0cBP?</td>
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<td>Merging Engines</td>
<td>Merging</td>
<td>1.0dBP?</td>
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<td>Regulation Process</td>
<td>Regulation Process</td>
<td>1.0eBP?</td>
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<td>System Functionality</td>
<td>System Functionality</td>
<td>2.0bBP?</td>
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<td>S.P.O.R. Technical Documents</td>
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<td>S.P.O.R. Managing Reference</td>
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<td>Data Access, Marketing and Reporting</td>
<td>Data Access, Marketing and Reporting</td>
<td>2.0iBP?</td>
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<td>Set Up</td>
<td>Registering an Organization (e.g., EUD-Organizations, EV)</td>
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<td>Permanent Organization Information</td>
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<td>Maintaining Substance Information</td>
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<td>Registering a New Androplid Reference</td>
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<td>Pre-Trial</td>
<td>Applying for new Scientific Advice</td>
<td>3.0fBP?</td>
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<td>Applying to Clinical Trial Application (CTA-IRB, CTA-IRB, P/TP/CTA-IRB)</td>
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<td>Requesting an ATC/MHN</td>
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<td>Submitting a P/TP</td>
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<td><strong>To the Process</strong></td>
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<td>Target Operating Model</td>
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<td>Maintaining IDMP in a Marketing Authorization (FDA)</td>
<td>4.0bBP?</td>
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<td>Specific Observations (e.g., PMME)</td>
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<td>Link to Protocol (LMP)</td>
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<td>First Approval After Launch Activity (EACO)</td>
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<td>Life Cycle Management</td>
<td>Submitting a License (e.g., Biotest/IDMP)</td>
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<td>Submitting an ICSR</td>
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<td>Maintaining Post Approval Commitments</td>
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<td>Maintaining Product Authorization (PAA)</td>
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<td>Maintaining Marketing Sleve for Shortage of Supply</td>
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<td>Withdraw Product Licence</td>
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<td>Integration Guide</td>
<td>Simulation of PPA and optimization of EU Database</td>
<td>5.0hBP?</td>
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<td><strong>Out of Scope</strong></td>
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<td>NDA Guide for how to internally IDMP Information</td>
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</table>

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**Bundesverband der Arzneimittel-Hersteller e. V.**

16 June 2016
GOVERNANCE UNDER THE EMA

- EMA MB
- HMA
- EU telematics management board
- IT Directors Group
- EU Network Data Board
- EU ISO IDMP Task Force
- Data Integration Programme
- EU ISO IDMP Task Force

Legend:
- Strategic
- Tactical
- Operational
MEMBERSHIP OF ISO IDMP TASKFORCE

• 6 from EMA:
  – 3 representing business
  – 3 representing IT

• 20 from the EU Regulatory Network (EUNDB):
  – 8 NCAs, 1 European Commission, 1 EDQM
  – Up to 10 additional experts

• 24 from Industry Associations (up to 3 reps each)
  – Incl. AESGP, EFPIA, EuropaBio, EGA

• 10 interested parties:
  – EDQM, EU Commission, SwissMedic, Veterinary MP
  – experts from software vendors, service providers, medical product dictionary/database solution developers
  – FDA representatives !! (learning and contributing)
EVER SEEN AN IDMP CODE ???
SSID ??
GINAS PROJECT

362O9ITL9D = SSID
EDQM – DATABASE FOR STANDARD TERMS
Guidance and change requests

The user guide and change request form can be downloaded by clicking on the following links:

- Introduction and guidance for use (v 1.0.0)
- Change request form (in preferred DOCX format; click here for DOC version)

The lists of controlled vocabularies used to characterise pharmaceutical dose forms can also be downloaded by clicking on the following link:

- Internal controlled vocabularies for pharmaceutical dose forms (v 1.0.0)

Please note: the EDQM can only accept requests for modifications or additions to the Standard Terms database from the national competent authorities of member states, the EMA or the EU.

Status definitions

Each term in the Standard Terms database is assigned a status according to the following definitions.

- Current: the Standard Term is approved for use
- Deprecated: the Standard Term is not approved for use; it is not physically removed from the database and is maintained to cover legacy data
- Rejected: the proposed term has been rejected during evaluation and is not approved for use as a Standard Term; it is included in the database in order to avoid the submission of new requests for the term.
- Pending: the proposed term is being evaluated; it is not considered a current Standard Term and is not approved for use.

Further instructions for use
<table>
<thead>
<tr>
<th>Status</th>
<th>Term</th>
<th>Domain</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>Current</td>
<td>Effervescent granules</td>
<td>Human and Veterinary</td>
<td>Current</td>
</tr>
<tr>
<td>Pending</td>
<td>Effervescent granules for oral suspension</td>
<td>Human and Veterinary</td>
<td>Pending</td>
</tr>
<tr>
<td>Current</td>
<td>Effervescent powder</td>
<td>Human and Veterinary</td>
<td>Current</td>
</tr>
<tr>
<td>Current</td>
<td>Effervescent tablet</td>
<td>Human and Veterinary</td>
<td>Current</td>
</tr>
<tr>
<td>Rejected</td>
<td>Film coated gastro-resistant tablet</td>
<td>Human and Veterinary</td>
<td>Rejected</td>
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<tr>
<td>Current</td>
<td>Film-coated tablet</td>
<td>Human and Veterinary</td>
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</tr>
<tr>
<td>Current</td>
<td>Gastro-resistant capsule, hard</td>
<td>Human and Veterinary</td>
<td>Current</td>
</tr>
<tr>
<td>Current</td>
<td>Gastro-resistant capsule, soft</td>
<td>Human and Veterinary</td>
<td>Current</td>
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<tr>
<td>Current</td>
<td>Gastro-resistant coated tablet</td>
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<td>Gastro-resistant granules</td>
<td>Human and Veterinary</td>
<td>Current</td>
</tr>
<tr>
<td>Current</td>
<td>Gastro-resistant granules for oral suspension</td>
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</tr>
<tr>
<td>Deprecated</td>
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</tr>
<tr>
<td>Current</td>
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### Detailed Information

<table>
<thead>
<tr>
<th>Concept Code</th>
<th>Expanded code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>50026250</td>
<td>PDF.50026250-EN-GB</td>
<td>Gastro-resistant prolonged-release tablet</td>
</tr>
</tbody>
</table>

Use discouraged. The important characteristic is that the tablet is a prolonged-release formulation.
BASIC DOSE FORM „TABLET“

Table 5 – Example code term pairs for the basic dose form category ‘Tablet’

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>term</td>
<td>tablet</td>
<td>comprimé</td>
<td>錠剤</td>
</tr>
<tr>
<td>definition</td>
<td>category of solid pharmaceutical dose forms that are usually compressed volumes of particulate solids (but may be obtained by other means), formed into a shape that is appropriate for their intended use</td>
<td>catégorie des formes pharmaceutiques solides qui sont généralement des volumes compressés des particules solides (mais qui peuvent être obtenues par d'autres moyens), créées dans une forme qui est appropriée pour l'usage prévu</td>
<td>固形製剤の分類は、通常、固体粒子を圧縮し（なお、他の製造方法を用いる場合もある）、使用目的に適した形状に成形する。</td>
</tr>
<tr>
<td>languageCode</td>
<td>EN</td>
<td>FR</td>
<td>JA</td>
</tr>
<tr>
<td>regionCode</td>
<td>GB</td>
<td>FR</td>
<td>JP</td>
</tr>
</tbody>
</table>

Table 6 – Example coded concept for the basic dose form category ‘Tablet’

<table>
<thead>
<tr>
<th>code</th>
<th>BDF-0069</th>
</tr>
</thead>
<tbody>
<tr>
<td>value</td>
<td>BDF-0069-EN-GB</td>
</tr>
</tbody>
</table>

Remember: tablet = BDF-0069
Example coded concept for the release characteristic (RCA) ‘Prolonged’

- **Code**: RCA-0045
- **Translation**: RCA-0045-EN-GB, RCA-0045-FR-FR, RCA-0045-JA-JP

Example coded concept for the intended site characteristic (ISI) ‘Oral’

- **Code**: ISI-0031
- **Value**: ISI-0031-EN-GB

Example coded concept for the administration method characteristic (AME) ‘Swallowing’

- **Code**: AME-0019
- **Value**: AME-0019-EN-GB
- **Translation**: AME-0019-EN-GB, 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

Same for State of Matter (SOM), Basic Dose Form (BDF) and Transformation (TRA)
“GLOBAL IDENTIFIER“ (MPID)

The assignment of the MPID is to provide a unique identifier to reliably recognize, monitor and trace the use of Medicinal Products. It also states that the MPID shall be allocated supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction.

Country code
EU = Centralised Procedure product only. All other authorisations (DCP/MRP/NP) are country specific and would have the ISO country code.
Note: Iceland, Norway and Liechtenstein would have separate MPIDs in the Centralised Procedure as they are different authorisations.

GB-12345-7654321
EU-54321-1234567
BE-45678-1234567

MAH code
The MAH holder would be the Organisation ID (as per IDMP) but there would be no specific reason why the existing EV Code could not be used, at least as an interim.

Medicinal Product code
This should be different from the EV Code. The code segment does not have to be unique by but in combination with the other parts it must be unique.
The IG states that the Medicinal Product code utilises the following defining attributes:
• Marketing authorisation
• Legal status of supply
• Medicinal Product Name
• Pharmaceutical dose form
• Ingredient substance(s) & strengths
• Devices (for ATMPs)
• Therapeutic indications

A new medicinal product code segment would be generated for each instance of the above.
XEVMPD – LESSONS LEARNED
IDMP – FUTURE VISION
Take a broader view without loosing the focus.
## Potential IDMP Process Impact

<table>
<thead>
<tr>
<th>#</th>
<th>Process</th>
<th>Description</th>
<th>IDMP</th>
<th>#</th>
<th>Process</th>
<th>Description</th>
<th>IDMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-Trial</td>
<td>Scientific Advice</td>
<td>?</td>
<td>7</td>
<td>Safety Reporting</td>
<td>Submit ICSRs Maintain PSMF (GVP Inspections Investigator Initiated Studies/P4</td>
<td>Y</td>
</tr>
<tr>
<td>2</td>
<td>CTA/IND</td>
<td>Organization and User Registration New Substance Registration (SID) Submit CTAs and INDs (IMPID) Publish CT Information</td>
<td>Y</td>
<td>8</td>
<td>Manufacturing/CMC</td>
<td>Update BAIIDs Update Manufacturing information GMP Inspections</td>
<td>Y</td>
</tr>
<tr>
<td>3</td>
<td>Development</td>
<td>Submit CTA/IND Amendments Submit ATC/INN Requests Provide GCP Information Maintain Trial Master File Submit PIPs/DSURs/PSPs</td>
<td>Y</td>
<td>9</td>
<td>Variations</td>
<td>Submit Variations (Update Clinical Particulars etc) Maintain XEVMPD Information Maintain PACs/FUMs</td>
<td>Y</td>
</tr>
<tr>
<td>4</td>
<td>MA Submission</td>
<td>Submit MAA Orphan Drug Designation MAPPS/Breakthrough</td>
<td>Y</td>
<td>10</td>
<td>New Country MAA</td>
<td>Submit MAA in new Country Apply for new MPID, PCID, BAID?</td>
<td>Y</td>
</tr>
<tr>
<td>5</td>
<td>MA Review</td>
<td>Maintain current CTD File during Q&amp;A Request MPID and PhPID</td>
<td>Y</td>
<td>11</td>
<td>MAH Transfer</td>
<td>Apply for License transfer (new IDs?)</td>
<td>Y</td>
</tr>
<tr>
<td>6</td>
<td>Approval to Launch</td>
<td>Submit XEVMPD Data Request PCID and BAID Linguistic Review/Translate Label</td>
<td>Y</td>
<td>12</td>
<td>Withdrawal</td>
<td>Update Marketing Status of Product (retire IDs?)</td>
<td>Y</td>
</tr>
</tbody>
</table>
THE FUTURE

Structured data for either RA, PcV, clinical, manufacturing information

Data is captured and submitted only once

MAA, variation, Renewal, ICSR, CTA

Agencies

Europe:
- Austria
- Belgium
- Council of Europe
- Croatia
- France
- Ireland
- Italy
- Luxembourg
- Malta
- Netherlands
- Norway
- Portugal
- Romania
- Spain
- Sweden
- Switzerland
- United Kingdom

Business Process Discovery
Business Process Automation
Business & IT Service Innovation
DATA WITHIN PHARMACEUTICAL COMPANIES

• Data in silos used from different functions (RA, PhV, R&D, manufacturing...)
• Data is available, but might not be structured or the same in different places according to very different business needs (e.g. Packs vs. Formulation/Registration)
• Different environment: SAP, Linux, Windows...
FIRST USE CASE

- On 19 October 2015 the Agency launched a new service to national competent authorities, providing them with **continuous access to key Article 57 data**. National competent authorities can access product details based on the latest version of information submitted for medicinal products with a valid marketing authorisation in the European Economic Area, by creating a new report in the EudraVigilance Data Analysis System (EVDAS).

- The EMA Management Board considered the Article 57 database functionality for notifying changes to the QPPV and PSMF at its **December 2015 Management Board meeting**. The Board agreed that the database is functional for the purpose of notifications of changes to QPPV and PSMF information and that this **takes effect from 1 February 2016**. From that date companies no longer need to notify EMA (for centrally authorised products) or national competent authorities (for nationally authorised products) of changes to the QPPV or PSMF data by submitting a type IA\textsubscript{IN} variation. No final variation is required to notify an explicit cross reference to Article 57 as the source of QPPV and PSMF information.
EU HUB in the project to fight falsified medicines (FME) (until Feb 2019)

Leaner Data Model achieved by efficient utilisation of IDMP data.
Thank you for your attention

Any questions?

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