



Up-scaling the global univocal identification of medicines

AGES Best Practices UNICOM WP4

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Business Expert: Sonja Königshofer (AGES)**

and many other experts from our agency who contributed to this success!



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➤ *Georg Neuwirther*

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Exporting Medicinal Product Data in FHIR 5.0 format – Outlook

➤ *Noel Diamant*

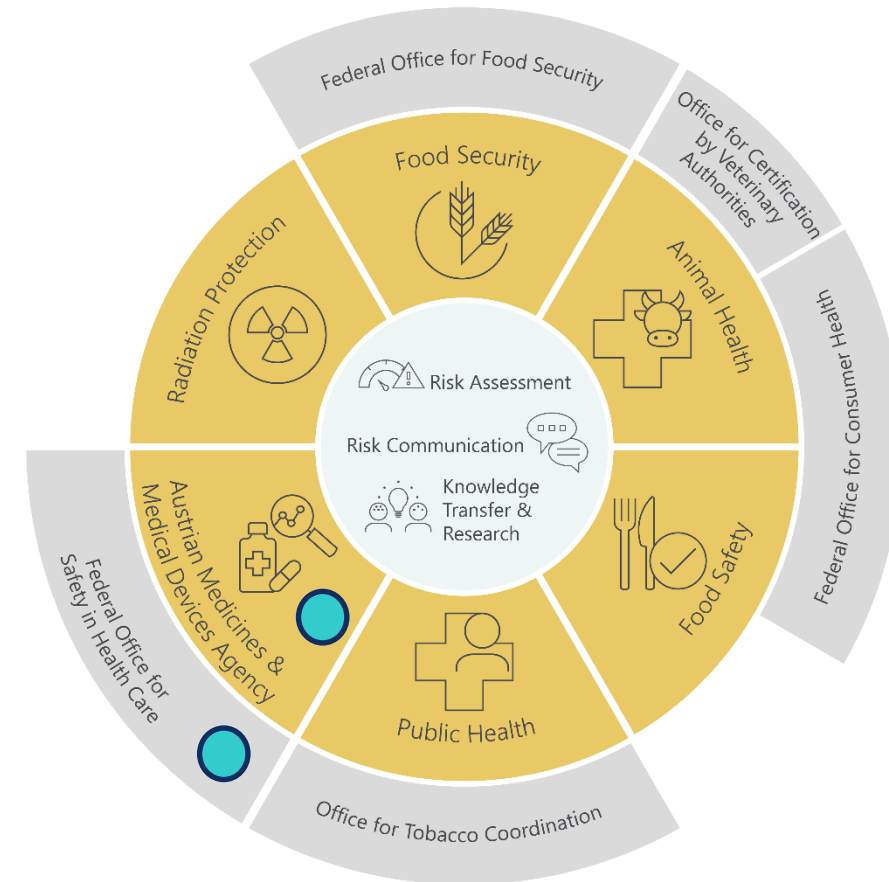
6

Take Home Message

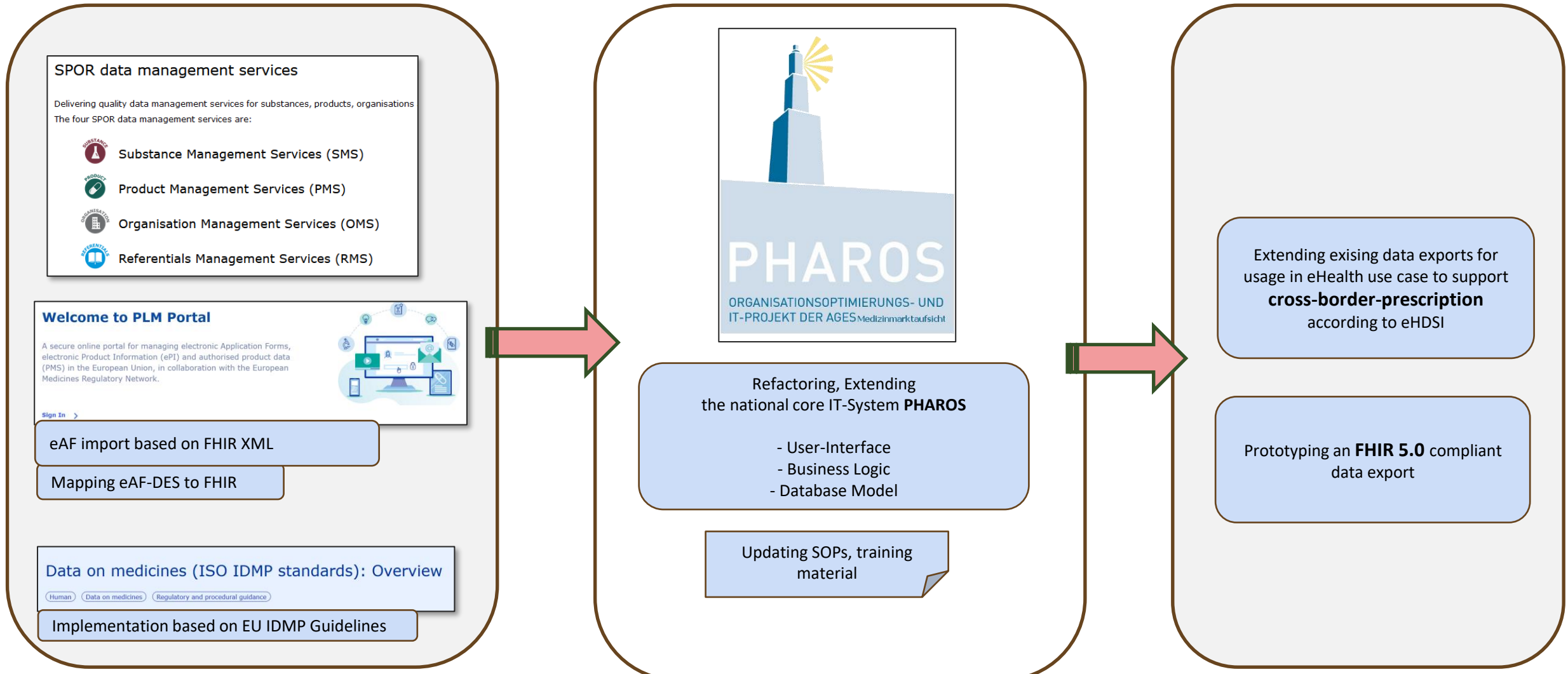
➤ *Georg Neuwirther*



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- ▶ AGES is wholly owned by the Republic of Austria.
- ▶ The **AGES MEA** business unit is the service provider for the **Federal Office for Safety in Health Care (BASG)**



UNICOM deliverables covered in the presentation



Welcome to PLM Portal

A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.



AGES (Noel Diamant) is acting as **Network Product Owner** for the implementation of the new eAF-creation tool and message exchange format
→ see UNICOM WP3

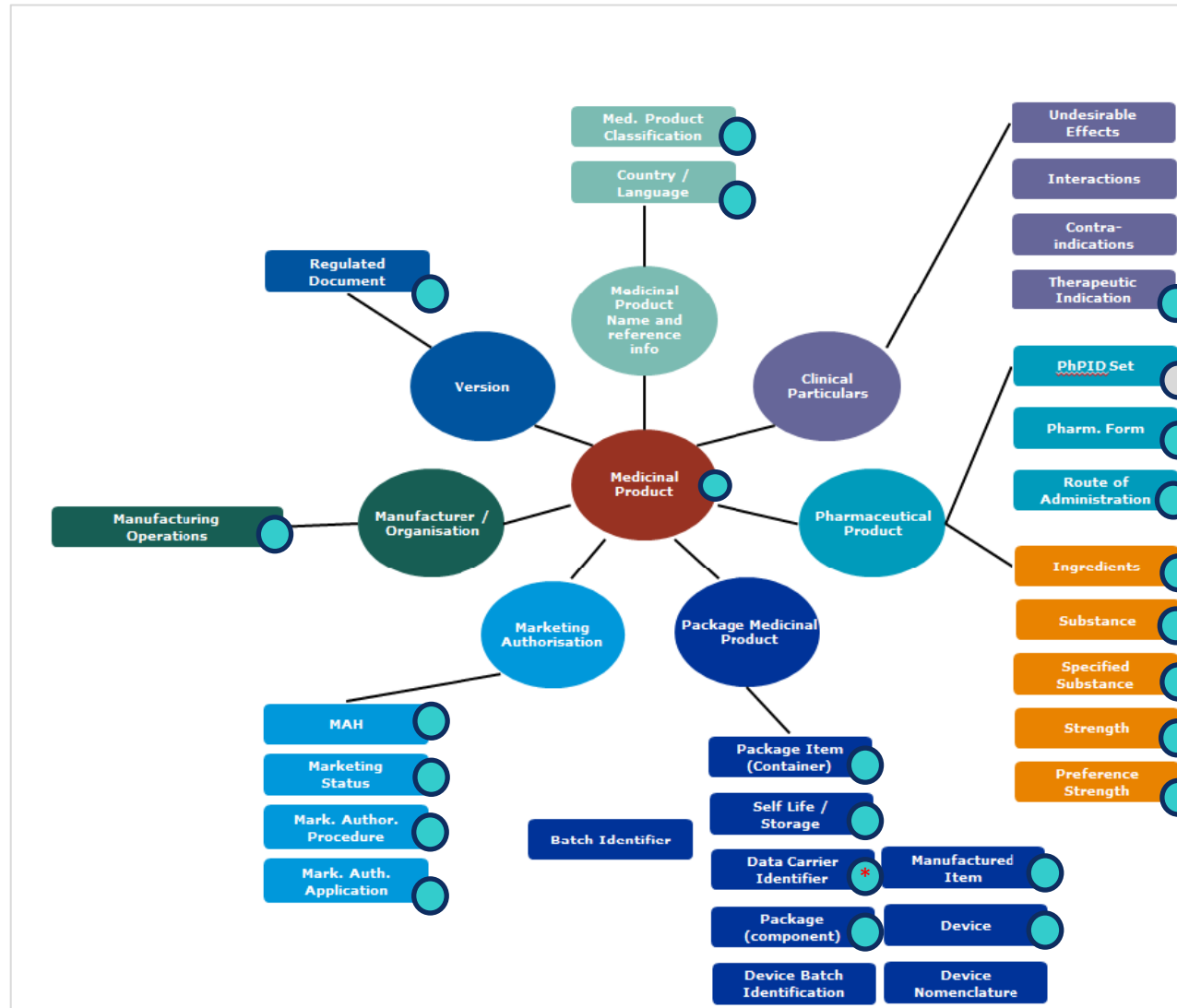
PHAROS - Implementation of ISO-IDMP concepts

Georg Neuwirther



Status of implementation in PHAROS

Source: EMA – Introduction to ISO Identification of Medicinal Products, SPOR programme



- Reviewed/Implemented/Refactored/ within UNICOM project timeframe
- Pending due to missing EU IG
- Reviewed/Implemented/Refactored/ within UNICOM project timeframe considering national specifics



- ▶ **Implementing *Administrable Product* (Pharmaceutical Product)**
 - Based on existing concepts of the former database concept “RDM v3”
- ▶ **Detailing *Package* structure**
- ▶ **Implementing *Indication* Elements**
- ▶ **Detailing *Manufacturer* Details**
- ▶ **Implementing *Part Names***
- ▶ **Implementing *Additional Monitoring Attribute***
 - Additional attribute can be stored according to 1.8. Additional monitoring indicator from EU IG chapter 2
- ▶ **Migration legacy data into IDMP-compliant database model**



Implementing Administrable Product (AP) (Pharmaceutical Product - PhP)

- ▶ AP-concept had to be added to the PHAROS-world
 - Before: the Manufactured Item (MI) was the leading class
- ▶ Following principles were applied while refactoring:
 - Find synergies with business rules for legacy data migration
 - Ensure compatibility for eAF data import
 - Usage of RMS dictionaries is mandatory
 - Minimise administrative effort for data lifecycle management
 - Find a good balance in enriching the user interface
 - ✓ (complexity vs. usability)

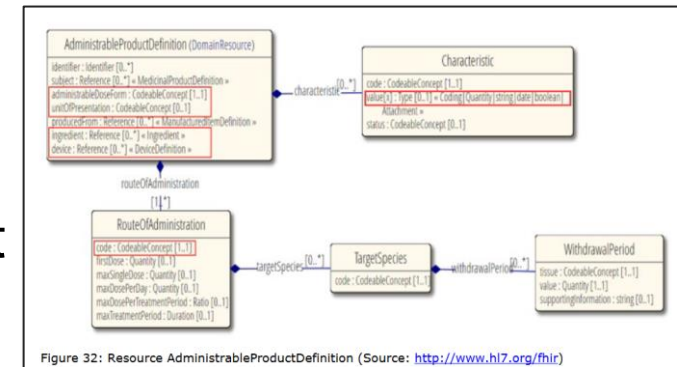


Figure 32: Resource AdministrableProductDefinition (Source: <http://www.hl7.org/fhir>)

Source: EAM EU IG ch.2



Implementation of Administrable Product (AP)

Administrable Product

Ansicht

Administrable Product Item ID - Intern	Darreichungsform	Art der Anwendung	Kommentar	ZUS bezogen auf (Presentation)	ZUS bezogen auf (Concentration)	ungültig
102104817	Infusionslösung	intravenöse Anwendung		1 Durchstechflasche	1 ml	<input type="checkbox"/>

Administrable Product Details

ungültig

Bestehend aus Manufactured Item 2036454; 2036455

Administrable Product ID - Intern 102104817

Administrable Product ID - AT

Administrable Product ID - LI

Darreichungsform des Administrable Product Infusionslösung

Kommentar zum Administrable Product

* ZUS bezogen auf (Presentation) 1 Durchstechflasche

* ZUS bezogen auf (Concentration) 1 ml

* Art der Anwendung intravenöse Anwendung

Ansicht

#	Vorkommen	Art	Substanz	Vergleichsoperator	Menge von (Presentation)	Menge bis (Presentation)	Einheit (Presentation)	Menge Überdosierung (Presentation)	Einheit Überdosierung (Presentation)	Menge von (Concentration)	Menge bis (Concentration)	Einheit (Concentration)
1		Wirkstoff	GERINNINGSFAKTOR IX	gleich						25		IE

Overview

- National ID for AP
- Placeholder for PMS identifiers

Consists of following Manufactured Items (MI)

Strength denominator (presentation, concentration) only defined once, for all ingredients in the PHP

List of ingredients of the AP

Route of Administration of AP



Implementation of Manufactured Item (MI)

This screenshot demonstrates the following scenario:
The Administrable Product is also the Manufactured Item
(applicable for all tablet presentations and any product without reconstitution)

Goal: minimizing administrative effort and error reduction

Concepts from AP were duplicated – see slide before

The screenshot shows a software interface for configuring a Manufactured Item (MI). The main window is titled 'Zusammensetzung' and contains a table for 'Manufactured Item' and a 'Manufactured Item Details' section.

Manufactured Item ID - Intern	Darreichungsform	Art der Anwendung	Kommentar	ZUS bezogen auf (Presentation)	ZUS bezogen auf (Concentration)	ungültig
2031663	Filmtablette	zum Einnehmen	;Filmtablette	1 Tablette	1 Stück	<input type="checkbox"/>

Manufactured Item Details

ungültig
Manufactured Item ident mit Administrable Product
Manufactured Item ID - Intern 2031663
Manufactured Item ID - AT
Manufactured Item ID - LI
Darreichungsform des Manufactured Item Filmtablette
Kommentar zum Manufactured Item ;Filmtablette
* ZUS bezogen auf (Presentation) 1 Tablette
* ZUS bezogen auf (Concentration) 1 Stück

* Art der Anwendung zum Einnehmen
Administrable Product ID - AT
Administrable Product ID - LI

Art	Substanz	Vergleichs - operator	Menge von (Presentation)	Menge bis (Presentation)	Einheit (Presentation)	Menge von (Concentration)	Menge bis (Concentration)	Einheit (Concentration)	Art der Zusatzinfo	Zusatzinfo	Referenzsubstanz	Umre (Refe)
<input type="checkbox"/>	Wirkstoff				mg							
<input type="checkbox"/>	Hilfsstoff				mg							

Flag to mark that MI = AP

!Notice: the AP attribute „Route of Administration“ can be entered here – only available for the scenario MI=AP



Vollbild

Ansicht ▼ Format ▼ Alles einblenden Alles ausblenden Device ASP

Ebene	Packungsgröße	Einheit (Packungsgröße)	Beschreibung DE	Beschreibung EN	Container Anzahl	Container	Container Material	Container Teil	Container Teil Material	Manufactured Item quantity	Manufactured Item Referenz	Art des Device	Anzahl Device	Device	Device Referenz	Art der Laufzeit
▼ Packung	1	Stück	1 Durchstechflasche mit 250 I.E. Pulver + 1 Durchstechflasche mit 10 ml Lösungsmittel + 1 Transferkanüle + 1 Desinfektionstupfer													
⊖ Laufzeit																Haltbarkeit des Arzneimittels in der Originalverpackung
⊖ Laufzeit																Haltbarkeit nach Auflösen oder R gemäß Anweisung
▼ Container					1	Schachtel	Karton									
▼ Container					1	Durchstechflasche	Glastyp I			1	2056934; Solvent for solution for injection; ; 1 Durchst					
⊖ Container Teil								Stopfen	Brombutylk...							
▼ Container					1	Durchstechflasche	Glastyp I			1	20378... Pulver zur Herstellung einer Injektionslösung					
⊖ Container Teil								Stopfe	Brombutylk...							
⊖ Device												Co-pack...	1	Kanüle	10000073501 - Kanüle	

Packaged Medicinal Product (PMedP) according to EU IG / 2 / ch. 4 (p.127)

Shelf life of PMedP according to EU IG / 2 / ch. 4 (p.127)

Container Material, Container parts and container part material

Reference to MI including a textual description

Enrichment of device information

Package Item Layers
e.g. Box with 2 vials (2 MIs)

Manufactured Item Quantity
(unit is taken from MI; reduces errors)



Arzneispezialität Einstufung **Klinische Angaben** ZUS Veterinär Verfahren Packung Rolle Commitment Weitere Daten Nationale Ergänzungen

▼ Indikation als Freitext




Indikation (Deutsch)

4.1 Anwendungsgebiete

- Behandlung von Blutungen und perioperative Prophylaxe von Blutungen bei einem erworbenen Mangel an Prothrombinkomplex-Blutgerinnungsfaktoren wenn eine schnelle Korrektur des Mangels erforderlich ist, wie zum Beispiel ein durch die Behandlung mit Vitamin-K-Antagonisten verursachter Mangelzustand, oder im Falle einer Überdosierung von Vitamin-K-Antagonisten.
- Behandlung von Blutungen und perioperative Prophylaxe bei einem angeborenen Mangel der Vitamin-K-abhängigen Gerinnungsfaktoren II und X, wenn gereinigte spezifische Blutgerinnungsfaktoren nicht zur Verfügung stehen

Indikation (Englisch)

▼ Indikation als MedDRA Code

Ansicht ▼ Format ▼ Alles einblenden Alles ausblenden   

MedDRA Code	Intended Effect	geprüft	Co-Morbidität	Co-Morbidität geprüft
Keine anzuzeigenden Daten				

- ▶ Indication information is now **automatically** imported from SMPC (section 4.1)
- ▶ Coded indication elements are prepared for future consumption from SPOR PMS

Implementing Name Parts


Übersicht **Arzneispezialität** Klinische Angaben ZUS Veterinär Antragsdaten Änderung Packung Rolle

Name

* Bezeichnung der Arzneispezialität: Gent: Immunate 250 I.E. FVIII/190 I.E. VWF - Pulver und Lösungsmittel

Prüfname: Immunate

Part Names

Ansicht 

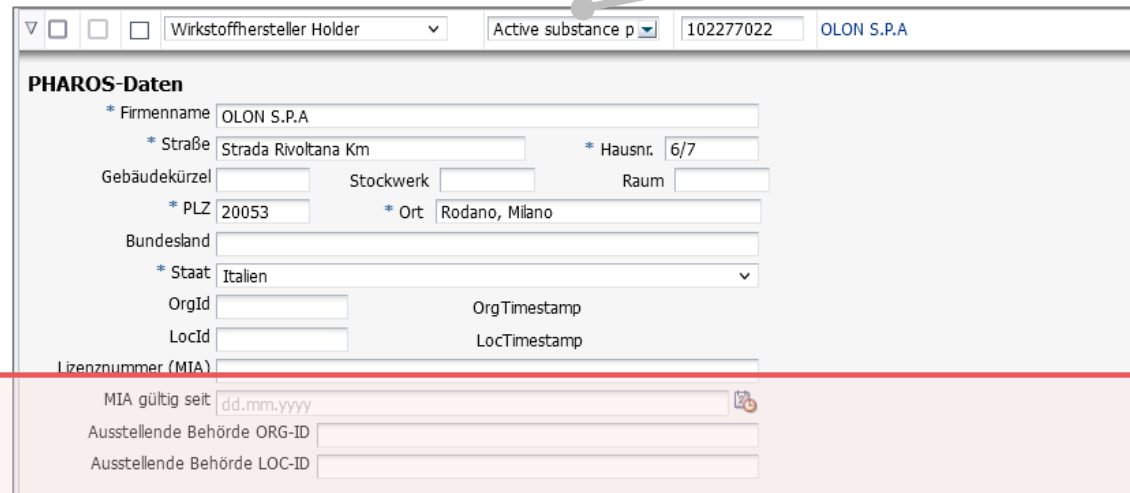
Namensteil	Text
Fantasiename	Immunate
Wirkstoffstärke	250 I.E. FVIII/190 I.E. VWF
Darreichungsform	Pulver und Lösungsmittel zur Herstellung einer Injektionslösung
Trennzeichen	-

Katalogwert	Beispiel
Fantasiename	nicht INN
Wissenschaftlicher Name	INN
Marke/Firma	MAH Name
Formulierung	forte
Wirkstoffstärke	50 mg
Darreichungsform	Injektionslösung
Container/Verpackung	in einer Fertigspritze
Medizinprodukt	Handihaler
Zeit/Zeitraum	24h
Geschmack	Orangengeschmack
Zielgruppe	für Kinder
Zieltierart	für Hunde und Katzen
Verwendungszweck	zur Diagnose
Trennzeichen	-
Historischer Name	alter Name wie in Bezeichnung der ASP bei Namensänderung

- ▶ Part Names are now prepared for future data import from eAF (FHIR)



Already imported from eAF - Manufacturing Operation (RMS list 100000160406 - Manufacturing Activity)



Wirkstoffhersteller Holder | Active substance p | 102277022 | OLON S.P.A.

PHAROS-Daten

* Firmenname OLON S.P.A

* Straße Strada Rivoltana Km * Hausnr. 6/7

Gebäudekürzel Stockwerk Raum

* PLZ 20053 * Ort Rodano, Milano

Bundesland

* Staat Italien

OrgId OrgTimestamp

LocId LocTimestamp

Lizenznummer (MIA)

MIA gültig seit dd.mm.yyyy

Ausstellende Behörde ORG-ID

Ausstellende Behörde LOC-ID

► Prepared for future data import from the new eAF (FHIR)

- ▶ Stepwise migration of legacy data – bottom-up
 - Started with MI enrichment
 - Created *APs composed of MIs*
 - Finalised with *Package* layers including links to *MIs*

- ▶ Manual preparing legacy data was needed for:
 - a limited number of “old” products
 - manufactured items to enrich “unit of presentation”
 - ✓ existing package information was helpful

- ▶ Packages could be brought into the layered structured **automatically**
 - Manual work was needed to correct “*manufactured item quantity*” information



SPOR Integration - OMS

Georg Neuwirther

UN  COM



1. Initial Import of Organisation and address data from eAF MAA, Variation, Renewals




2. Regular OMS syncs to keep PHAROS data aligned with SPOR OMS



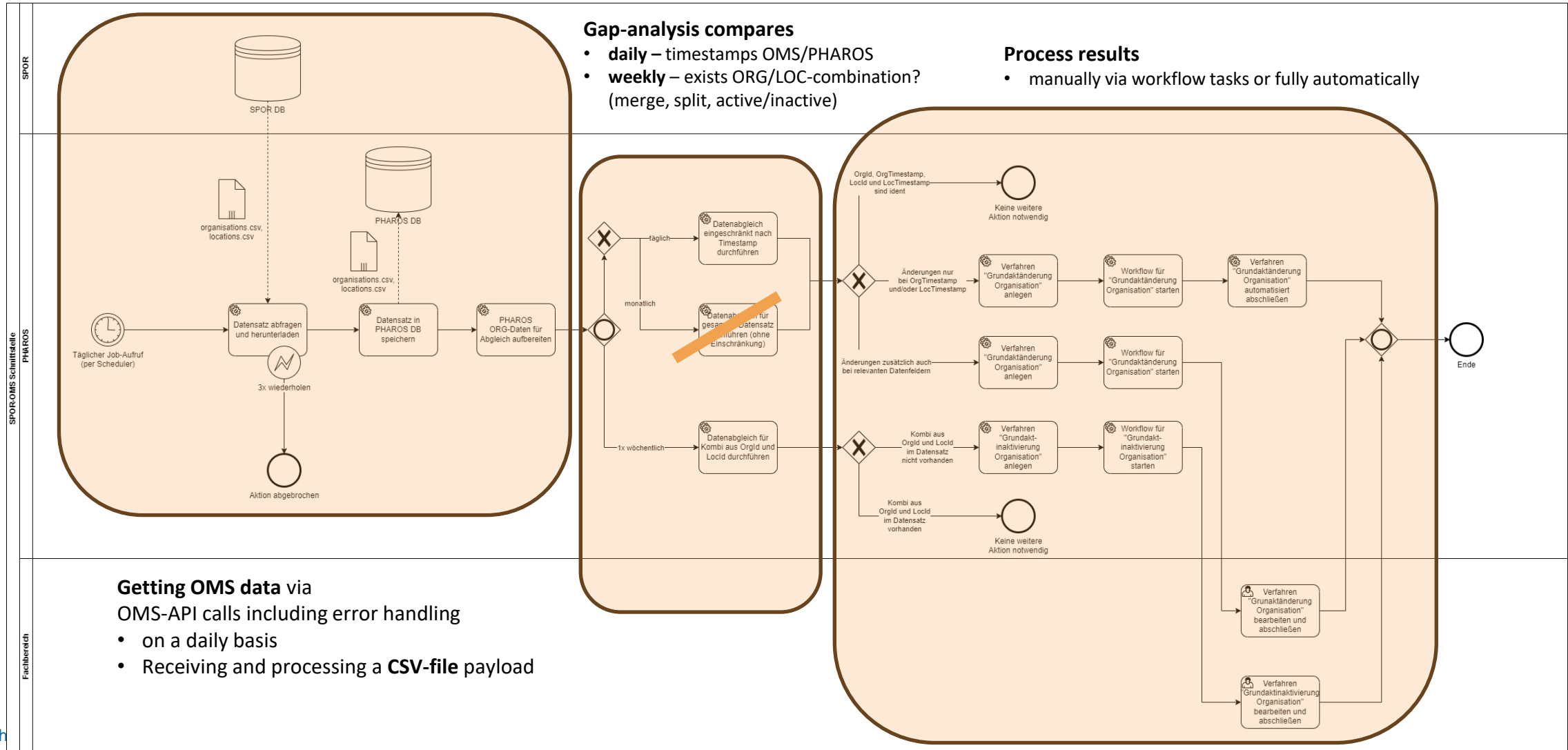
SPOR data management services

Delivering quality data management services for substances, products, organisations
The four SPOR data management services are:

-  Substance Management Services (SMS)
-  Product Management Services (PMS)
-  Organisation Management Services (OMS)
-  Referentials Management Services (RMS)

- ▶ **New organisation records will be taken ONLY from e.g.,**
 - ▶ eAF, CTs , other applications, ..
- ▶ **For official letters PHAROS data is used – might deviate from OMS data (see challenges in next slides)**
- ▶ **All relevant organisation records in PHAROS are linked to an OMS-ID/LOC-ID reference**





- ▶ Processing the CSV payload is not optimal but more stable than separate OMS-calls
 - Open service ticket that CSV data is different from OMS UI data
- ▶ High administrative manual effort when handling OMS data quality topics
 - e.g. Active/inactive, lost IDs
 - e.g. rejected OMS requests for new entries or updates
- ▶ Umlauts in names and addresses [Ö/Ü/Ä -> OE/UE/AE]
 - ß in addresses [Straße; ß -> Strasse; ss]
- ▶ Semantics in address lines do not match PHAROS address structure
- ▶ “Districts” are included in address lines which creates manual effort to delete it again
 - Otherwise districts would be included in PHAROS street elements
- ▶ Differences between DE and EN names and addresses



- ▶ Business logic to deal with names and alternative names
 - ▶ eAF story exists in PLM backlog

Organisation ID:	ORG-100002269
Organisation Name:	Angelini Pharma Italia Aziende Chimiche Riunit
Alternative Name:	IT - Aziende Chimiche Riunite Angelini Franco IT - Angelini S.p.A. IT - A.C.R.A.F. S.P.A. IT - Angelini Pharma Italia S.P.A. IT - Angelini Pharma S.P.A. IT - Acraf S.P.A.
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company



We now have OMS data in PHAROS 😊

<p>Organisation</p> <p>Firmenname G.L. Pharma GmbH Straße Schloßplatz Hausnr. 1 Stockwerk PLZ 8502 Bundesland Steiermark Staat Österreich</p> <p>Zusatzinfo Gruppierung Portalzugang <input checked="" type="checkbox"/></p>	<p>Gebäudekürzel Raum Ort Lannach</p>	<p>OMS-Daten (28.02.2024 04:06:49)</p> <p>Firmenname G.L. Pharma GmbH Address Line 1-4 Schloßplatz 1 PLZ 8502 Bundesland Steiermark Staat Österreich OrgId ORG-10000592 LocId LOC-100004168 GPS 46.945134, 15.333545</p> <p>OrgTimestamp 23-Jan-2024 13:53:24 LocTimestamp 23-Jan-2024 14:53:25</p>
--	---	---

- ▶ OMS attributes
- ▶ LOC address lines
- ▶ GPS-coordinates

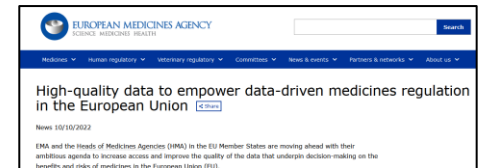


PHAROS - Importing eAF data based on the new FHIR format (Variation of CPs)

Noel Diamant



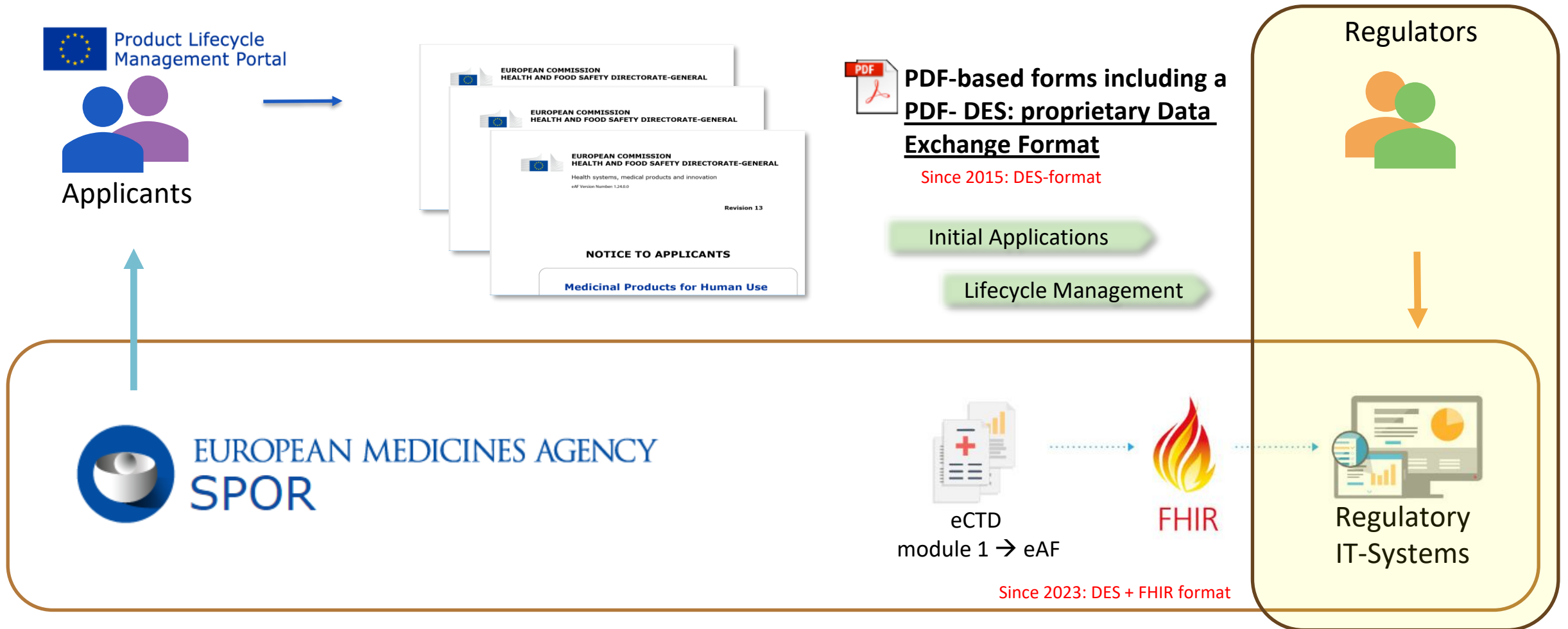
Data availability in regulator systems (HMA/EMA) is essential for multiples use cases and of strategic importance
The eAF is a vessel to provide that data

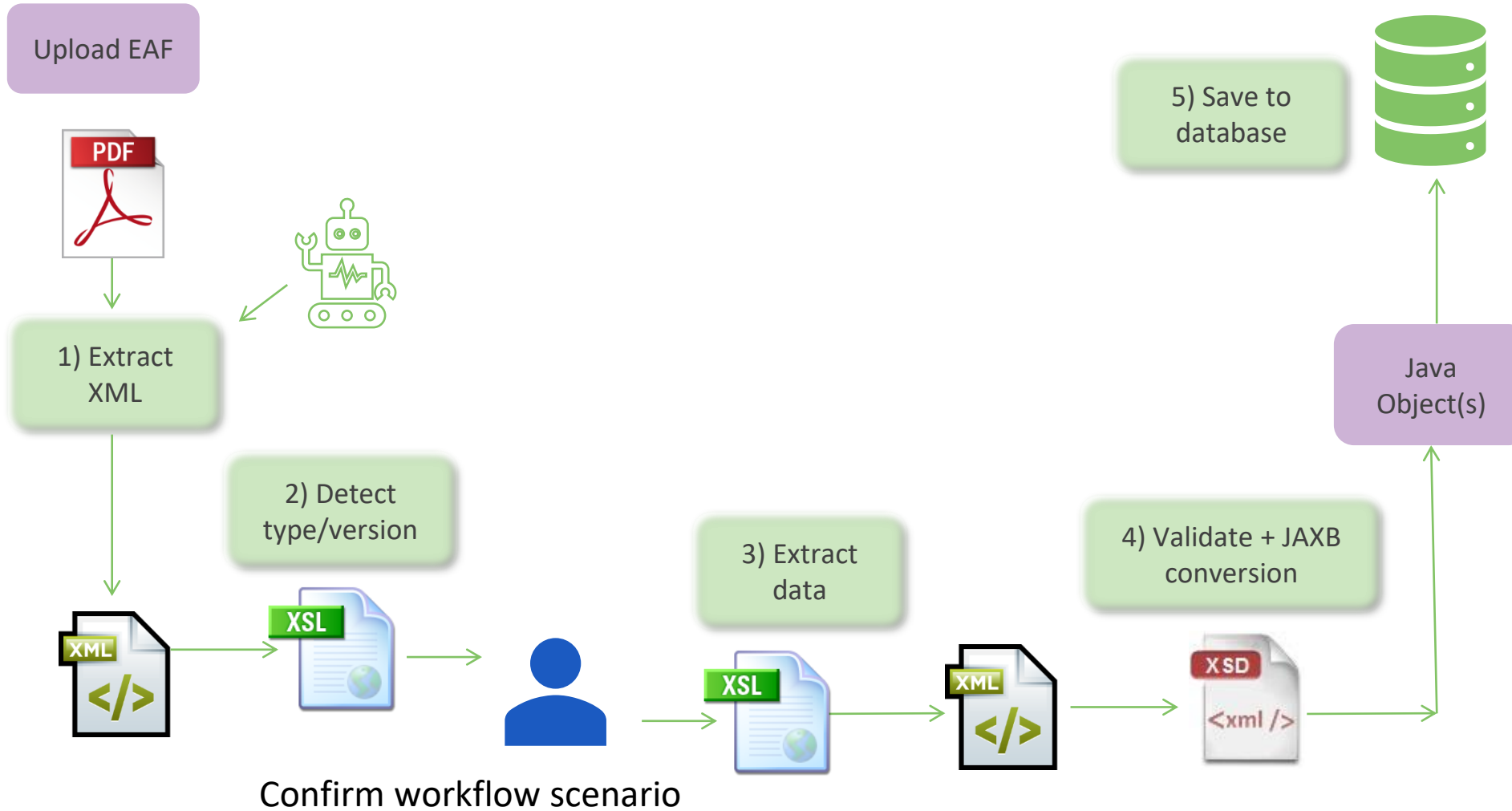


[Source: EMA - High-quality data to empower data-driven medicines regulation in the European Union | European Medicines Agency \(europa.eu\)](#)



eAF-import of Medicinal Products Data into PHAROS

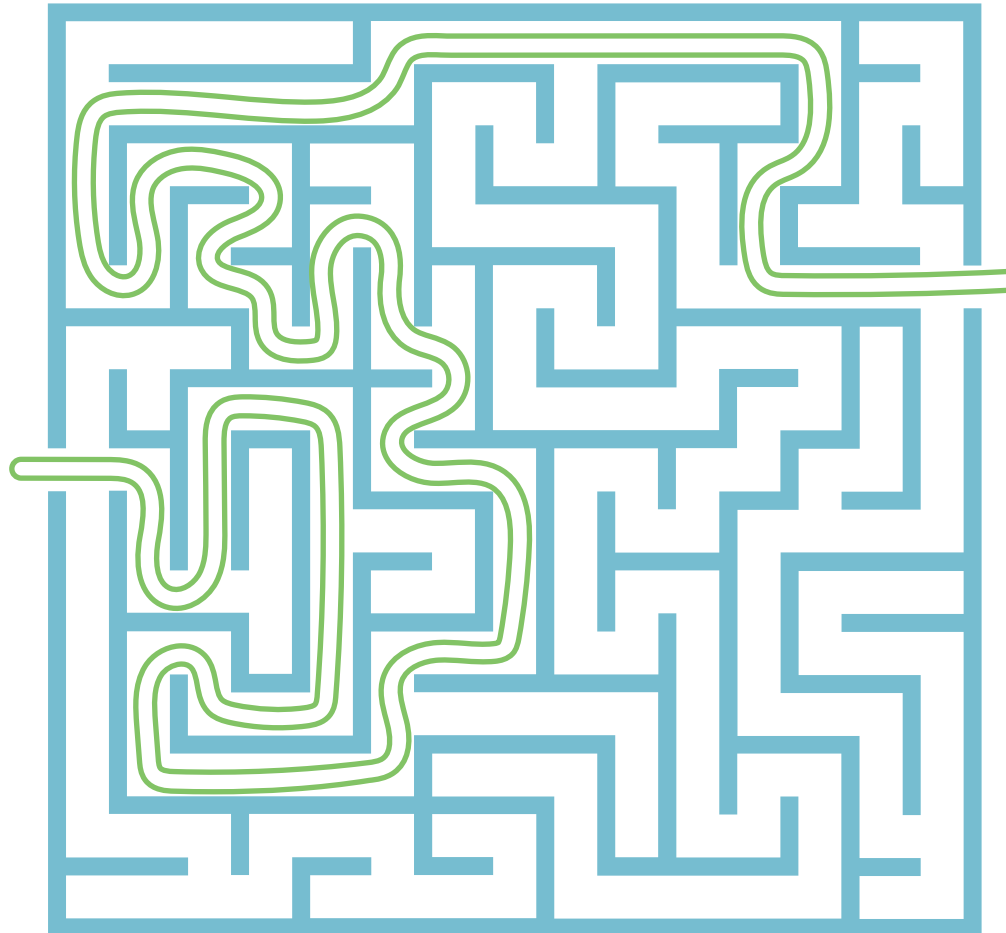




FHIR 4.6

The FHIR variation message attached to the eAF has been developed in FHIR version 4.6.0 is being released in 5.0.0 in Q2 this year.

This is the best time to start thinking about an automated import to be ready for the MRP / DCP / national variations from the PLM portal.



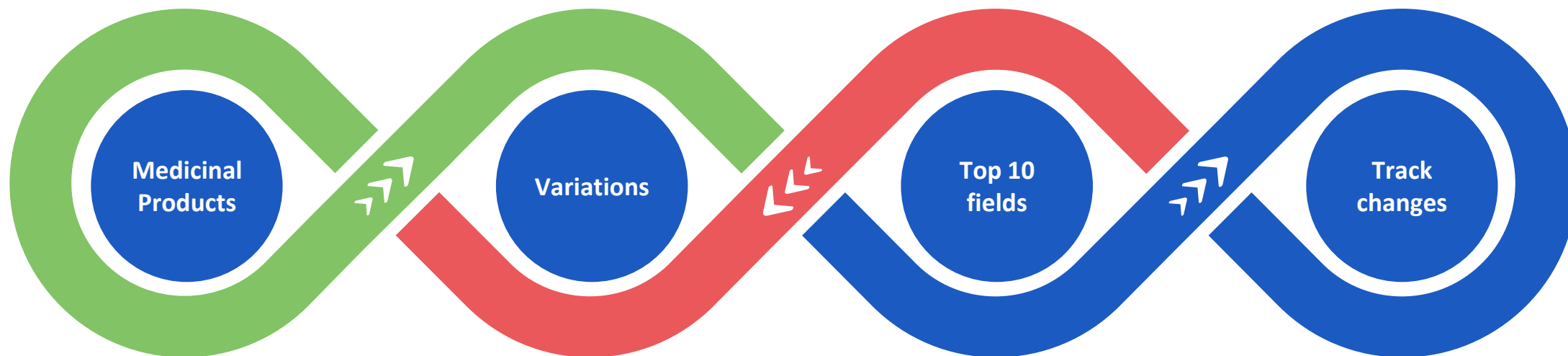
FHIR 5.0

Latest release notes on the eAF FHIR XML:

[Bookmark this Link!](#)

In the release notes you will find extensive examples

[\(here\)](#)



Get an overview of the medicinal product

The basics of the medicinal product and its references

--> ([recording](#)) <--

The procedure envelop

Get an overview of the variation message:

--> ([recording](#)) <--

What to start importing

Top 10 most wanted IDMP fields

--> ([recording](#)) <--

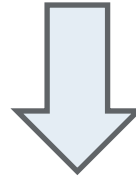
What has changed in a variation?

How to track changes on a medicinal product using FHIR provenances

--> ([recording](#)) <--



example eAF for PHAROS (FHIR 4.6).pdf



Verfahren zu bestehenden Grundakt/en anlegen

Antragsformblatt (xml/pdf) example eAF for PHAROS (FHIR ...

Aktualisieren...

Betrachtungsobjekt

Hinzufügen

Löschen

Von Suche übernehmen

Grundzahl	Typ	Name des Betrachtungsobjekts	MP/DC/CP Nummer	Status	Zulassungsnummer	PMS-ID
13763447	Arzneispezialität	Ultomiris 1.100 m...	EMA/H/C/004954	GA - zugelassen	EU/1/19/1371/003	
13763443	Arzneispezialität	Ultomiris 300 mg/...	EMA/H/C/004954	GA - zugelassen	EU/1/19/1371/002	

Verfahrenstyp

Referenzierte Verfahrensnummer

Anlegen

Abbrechen



Extracted from eAF (currently, more to come)

MA Number(s) *	Product -> RegulatedAuthorization.identifier
Member State *	Product -> RegulatedAuthorization.region
Scope(s)	Task.contained.Task[partOf.reference=#].code.coding[system=scopeType].code
Procedure type(s)	Task.contained.Task[partOf.reference=#][code.coding[system=scopeType]].input[type=procedureType].valueCoding.code
Implementation Date	Task.contained.Task[partOf.reference=#].code.coding[system=scopeType].executionPeriod
Domain	Task.input[type=Domain].valueCoding
Type of authorisation	RegulatedAuthorisation[MedicinalProductDefinition(type=marketingAuthorisation)].case.type
Variation procedure Numbers	Task.identifier type=ProcedureNr
Type of application	Task.Input[type=grouping].valuestring
Including a line extension	Task.Input[type=lineExtension].valueBoolean
Worksharing	Task.input[type=worksharing].valueBoolean? Task.input[type.coding.code="100000155556"].valueBoolean=true/false
IG / Supergrouping - grouping of type IA variations	Task.Input[type=IG].valueBoolean
Procedure type	Task.input[type=Procedure Type].valueCoding -> There can be multiple task inputs here Task.code & RegulatedAuthorisation[MedicinalProductDefinition(type=marketingAuthorisation)].case.application.type (both: only the highest type IA < IB < type II)
MA Holder	Task.for->Organisation
Member State **	Task.requestor->PractitionerRole->Location.address.country
E-mail	Task.requestor->PractitionerRole.telecom[system=email].value
Company	Task.requestor->PractitionerRole->Organization
Precise scope for change	Task.input[precisescope].valueString
Summary of product characteristics (Annex I)	Task.input[type=ProductCharacteristics].valueReference->DocumentReference
Labelling (Annex IIIA)	Task.input[type=labelling].valueReference->DocumentReference
Package leaflet (Annex IIIB)	Task.input[type=PIL].valueReference->DocumentReference

* Used for Identification of products

** Only if AT



RMS - Integration of EMA SPOR services

Noel Diamant

UN**COM**



01

Sporify API

In order to avoid the RMS throttling of 50 requests per minute as well as recent unexpected downtimes SPORIFY was chosen as an API "Proxy"



02

National Extensions

Even though we want to use RMS lists, we need national values and extensions for many lists that require its own database and UI (developed in Oracle APEX)



03

Synchronise changes

A method was chosen to only request changes since the last synchronisation:
`"v1/lists/search-terms?modified-after=$date"`
A Detail algorithm can be found in the next slide

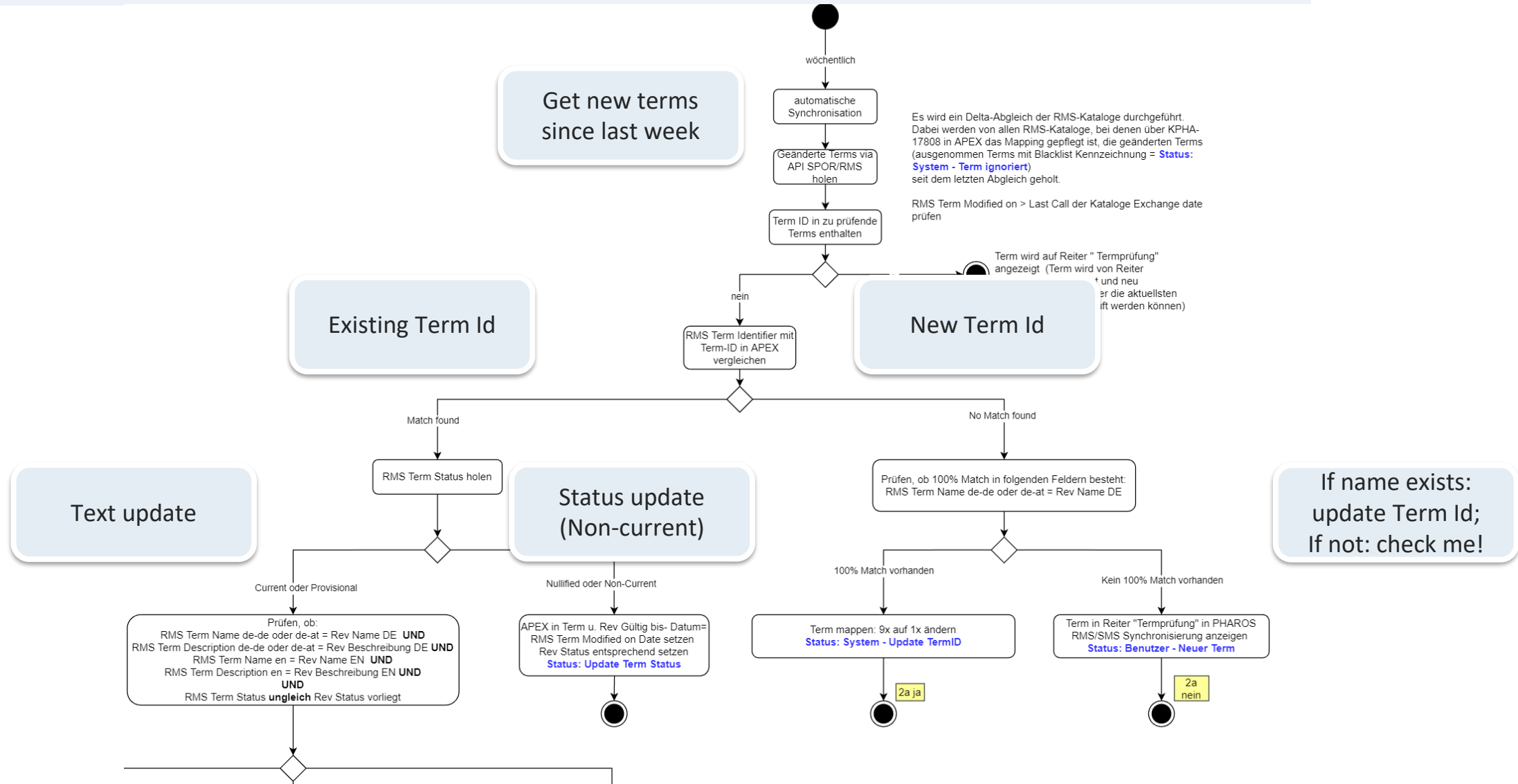


04

Validate every change

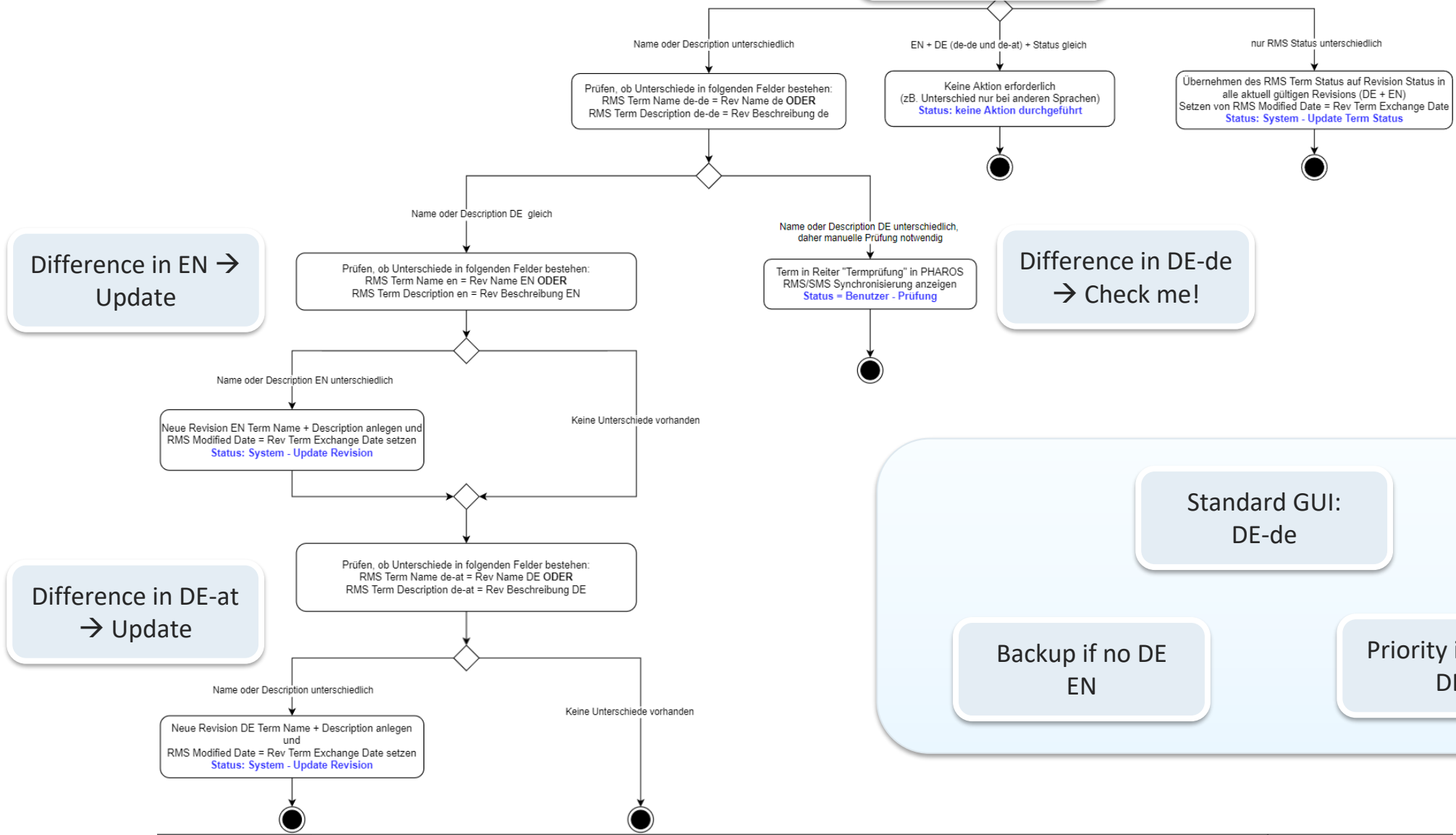
New terms, updated names / descriptions in german or changes in status need to be validated.
Terms can be blacklisted if they should never be overwritten.

RMS / SMS syncing rules I



RMS / SMS text update

Update Name, Description or State (EN & DE)



Difference in EN → Update

Difference in DE-de → Check me!

Standard GUI: DE-de

Backup if no DE EN

Priority if it exists: DE-at

Difference in DE-at → Update



SPOR Datenkonsole noel25 [Logout](#)

Katalog-Übersicht Termpfung Term Blacklist Historie Log Test

Katalog-Übersicht

Ansicht

Katalogname Europäisch	List Identifier	Katalogname PHAROS	Synchronisieren	dd.mm.yyyy	zuletzt synchronisiert am/um	Anzahl neue Terms	Anzahl Updates	Anzahl Blacklist
Medicinal Product Name Part Type	220000000000	Name Part	nein					
Medical Device Legislative Category	200000025965	Art des Device	nein					
Material	200000003199	Material	ja	20.02.2024 10:22	21	0	0	
Medicine Profile	200000003186	Medicine Profile	nein					
Units of Presentation	200000000014	Unit of Presentation	nein					
Combination Package	200000000008	Darreichungsform	nein					
Combined Term	200000000007	Darreichungsform	ja	20.02.2024 10:22	9	7	0	
Combined Pharmaceutical Dose Form	200000000006	Darreichungsform	nein					
Pharmaceutical Dose Form	200000000004	Darreichungsform	nein					
Application Submission Type	100000155688	Typ der Änderung	nein					
Submission Mode	100000155553	Art der Änderung	nein					
EU Regulatory Authorisation/Registration Procedure	100000154442	Verfahrensart	nein					
EU Regulatory Authorisation/Registration Procedure	100000154442	Antragsart	nein					
Anatomical Therapeutic Chemical classification system - Veterinary	100000116677	ATC-Code	ja					
Marketing Authorisation Application Legal Basis	100000116045	Antragskategorie/Art der AS	nein					
Units of Measurement	100000110633	Einheit	nein					
Target Species	100000108853	Zieltierart	ja	22.02.2024 16:13	0	0	0	
Anatomical Therapeutic Chemical classification system - Human	100000093533	ATC-Code	nein					
Scientific Advice Source	100000075871	Quelle der wissenschaftlichen Auskunft	nein					
Packaging	100000073346	Verschluss	nein					
Packaging	100000073346	Behältnis	nein					
Packaging	100000073346	Applikationshilfe	nein					
Routes and Methods of Administration	100000073345	Art der Anwendung	ja	20.02.2024 10:22	27	36	0	
Special Precautions for Storage	100000073344	Art der Lagerung	nein					
Shelf Life Type	100000073343	Art der Laufzeit	ja	20.02.2024 10:22	2	0	0	



SMS - Integration of EMA SPOR services

Noel Diamant

UN**COM**

SMS: Substance List

EMA's SPOR SMS List contains over 70.000 Substances

Positive: A complete List, stable IDs, mappings

Challenges: A lot of duplicates exist, that are constantly being merged

PHAROS: CTL Substance

Our national database Pharos contains ~ 20.000 Substances. Some are used in Lifecycle management, some in Inspections, some are not used

70.000+

20.000+

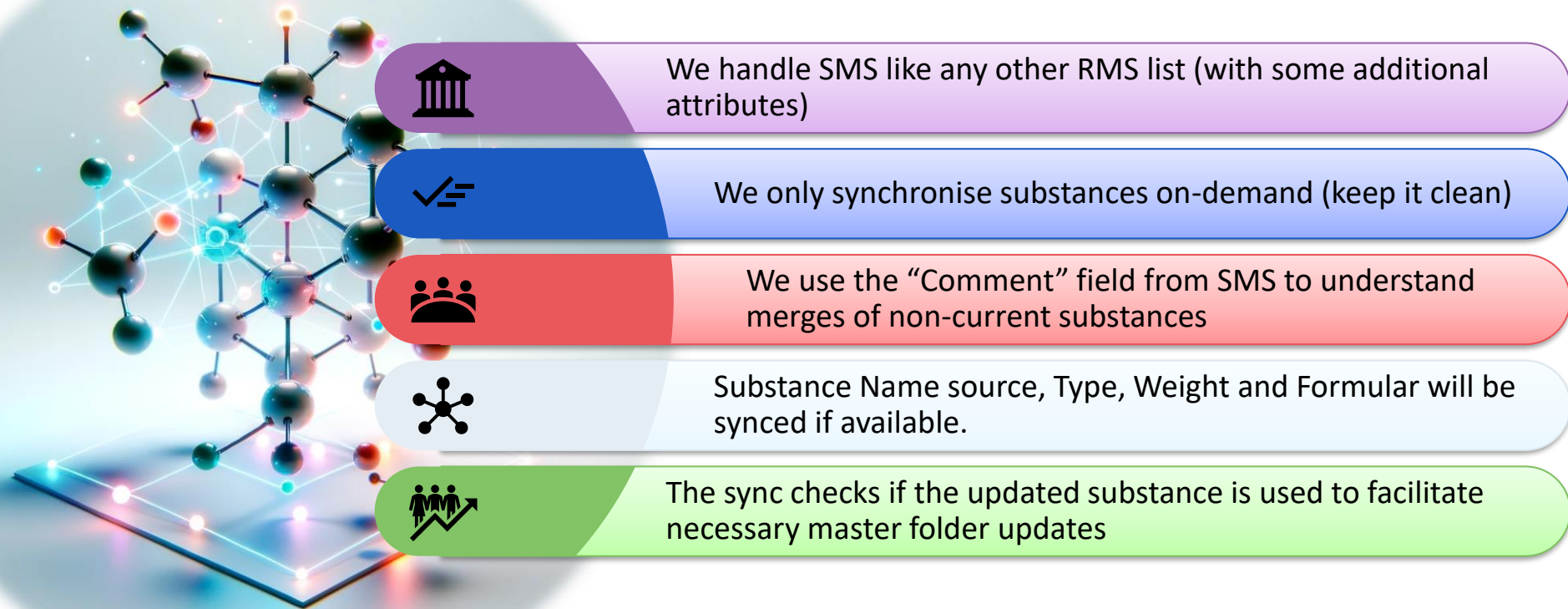
10.000+

PHAROS: Substance Master Folder

Substances used in the lifecycle of a medicinal product have a "Master Folder". These are enriched with Information on:

Synonyms, Doping, Narcotics, Psychotropics, drug interactions, PHV Issues, IDs, type, base substance calculations and documentations





How to find a substance in Pubchem using the structure from SMS:

<https://pubchem.ncbi.nlm.nih.gov/compound/WMUOPVGLPLDJIX-UHFFFAOYSA-N#section=3D-Conformer&embed=true>

<https://pubchem.ncbi.nlm.nih.gov/compound/WMUOPVGLPLDJIX-UHFFFAOYSA-N#section=2D-Structure&embed=true>

How add into an existing web application:

```
<iframe class="pubchem-widget"
src="https://pubchem.ncbi.nlm.nih.gov/compound/aspirin#section=3D-Conformer&embed=true"
style="width: 600px; max-width: 100%; height: 900px;">
```

How to get only the image via REST:

<https://pubchem.ncbi.nlm.nih.gov/docs/pug-rest-tutorial#section=How-PUG-REST-Works>

PUBCHEM > ETOFURADINE > 3D CONFORMER

CID 208942

Etofuradine

3D Conformer

Structure Search Get Image Download Coordinates

Interactive Chemical Structure Model

- Ball and Stick
- Sticks
- Wire-Frame
- Space-Filling
- Show Hydrogens
- Animate

Navigation: << First < Previous Conformer 1 of 10 Next > Last >>



Exporting Medicinal Product Data in FHIR 5.0 format – Outlook

Noel Diamant

UNOCOM

How to start your own FHIR export



FHIR version 5.0 has been released and is stable

1. We start with „2024 01 30 AF Data Requirements.xlsx“
 - <https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20eAF%20FHIR%20XML%20-%20package.zip>

2. Chose the fields we want to use:

Product Data			
Name of the medicinal product	Header	n	1 m
Country	Select	n	m
Language	Select	n	m
Full Product Name	Text	1	R/O
Name Parts	Header	n	d
Name Part	Text	1	m
Name Part Type	Select	1	m
<small>For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC</small>	Header	1	d

3. Use the FHIR paths in the documentation
4. Add national requirements (E.g. PZN Nr for every package)
5. Coordinate with national HL7 FHIR Austria for the extension names
 - E.g. [MedicinalProductDefinition.identifier.system=https://www.datacare.at/](https://www.datacare.at/)
 - [RegulatedAuthorization.status.extension\[url=https://www.ages.at/fhir/extension/positiveAuthStatus\]](https://www.ages.at/fhir/extension/positiveAuthStatus)

6. Create the the xml or JSON message using  in case of JAVA



- ▶ Currently medicinal product data will be provided to eHealth-organisations in a proprietary data format („ClAML“):

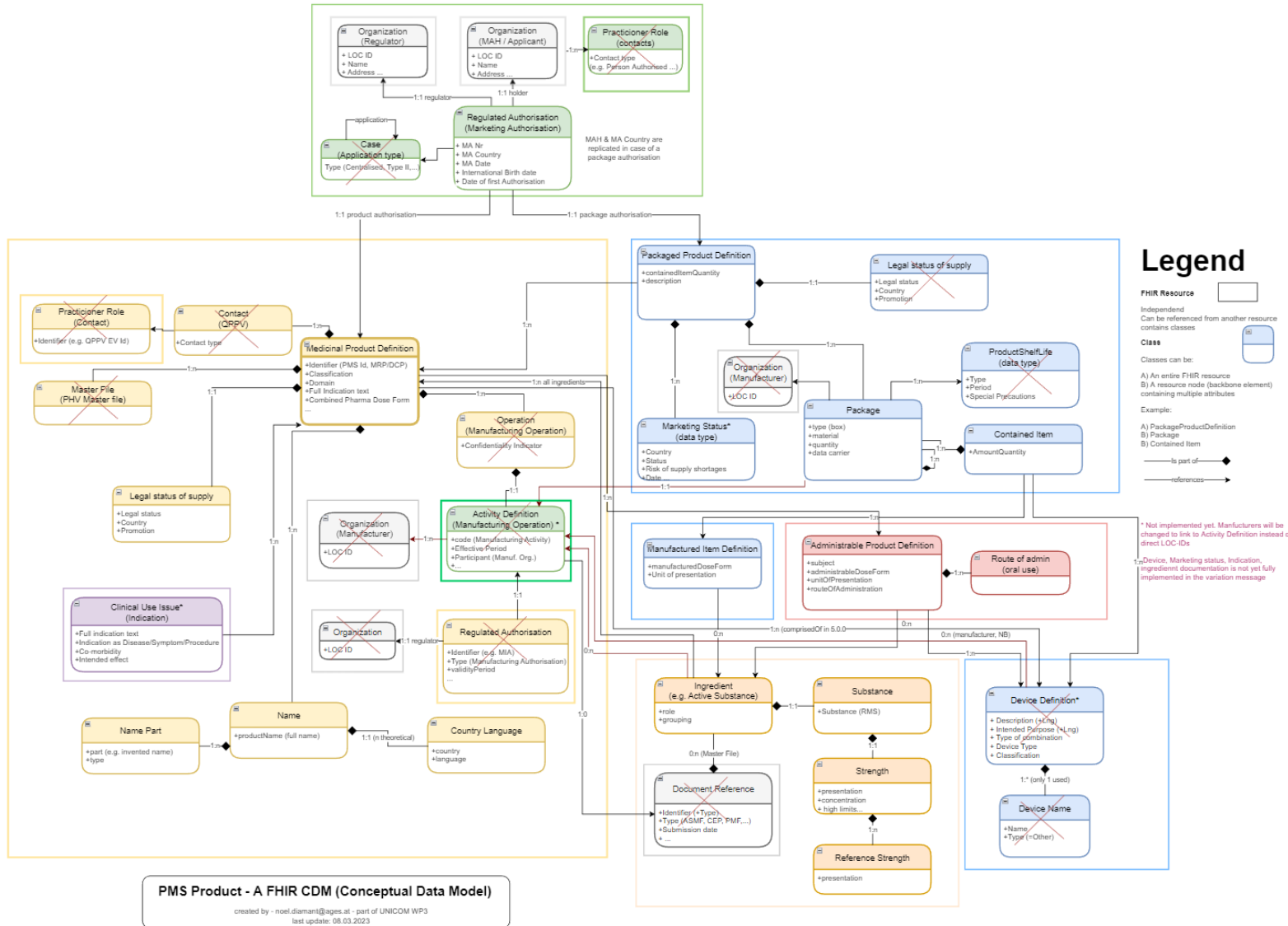
```
...<Class·code="0012581">
...<<Rubric·kind="preferred">
...<<<Label·xml:lang="de"·xml:space="default">CONTRACTUBEX·GEL</Label>
...</Rubric>
...<<Meta·name="Bezeichnung_Arzneispezialitaet_Zulassung"·value="Contractubex·Gel"/>
...<<Meta·name="Zulassungsnummer"·value="1.2.40.0.34.4.17:13883"/>
...<<Meta·name="ELGA_Gueltigkeit"·value="true"/>
...<<Meta·name="ELGA_MedikationPackungsstatusLieferbar"·value="true"/>
...<<Meta·name="GroesseGewicht"·value="50"/>
...<<Meta·name="ELGA_MedikationMengenart_code"·value="2.16.840.1.113883.6.8:g"/>
...<<Meta·name="ELGA_MedikationMengenart_text"·value="Gramm"/>
...<<Meta·name="ELGA_MedikationRezeptpflichtStatus_code"·value="1.2.40.0.10.1.4.3.4.3.7:100000072076"/>
...<<Meta·name="ELGA_MedikationRezeptpflichtStatus_text"·value="Arzneimittel·zur·Abgabe·ohne·aerztliche·Verschreibung"/>
...<<Meta·name="ELGA_whoATC_01_code"·value="2.16.840.1.113883.6.73:D03AX"/>
...<<Meta·name="ELGA_whoATC_01_text"·value="Andere·Wundbehandlungsmittel"/>
...<<Meta·name="ELGA_MedikationArtAnwendung_01_code"·value="1.2.40.0.10.1.4.3.4.3.4:100000073566"/>
...<<Meta·name="ELGA_MedikationArtAnwendung_01_text"·value="Anwendung·auf·der·Haut"/>
...<<Meta·name="ELGA_Substanz_01_code"·value="1.2.40.0.34.5.156:1712596"/>
...<<Meta·name="ELGA_Substanz_01_text"·value="ALLII·CEPAE·BULBUS·(AUSZUG)"/>
...<<Meta·name="ELGA_Substanz_02_code"·value="1.2.40.0.34.5.156:1705858"/>
...<<Meta·name="ELGA_Substanz_02_text"·value="ALLANTOIN"/>
...<<Meta·name="ELGA_Substanz_03_code"·value="1.2.40.0.34.5.156:1708475"/>
...<<Meta·name="ELGA_Substanz_03_text"·value="HEPARIN·NATRIUM"/>
...<<Meta·name="ELGA_MedikationDarreichungsform_01_code"·value="1.2.40.0.10.1.4.3.4.3.5:100000073726"/>
...<<Meta·name="ELGA_MedikationDarreichungsform_01_text"·value="Gel"/>
...<<Meta·name="ELGA_MedikationWechselwirkungsRelevant"·value="false"/>
...<<Meta·name="Domaene"·value="human"/>
...</Class>
```



- ▶ With EMA's decision to use FHIR as a messaging format and the ongoing establishment of FHIR in the eHealth domain, FHIR is gaining in importance for the exchange of Medicinal Product Data.
- ▶ In a prototyp we will export master data from PHAROS in FHIRv5 format
- ▶ The result will be discussed with eHealth-organisations to discuss the benefit und plan next steps:
 - **The object oriented structure of FHIR allows for more complex datasets**
 - **- not always needed for eHealth-scenarios!**



MVP approach for eHealth exports



Conclusions

▶ **Implementing ISO-IDMP has not been a sprint, but a marathon and we expect additional effort over the next years, for e.g.**

- ▶ Upcoming EMA's IDMP Guidelines
- ▶ Upcoming FHIR versions
- ▶ UX-improvements
- ▶ Data enrichment, e.g. importing data from the new eAFs and synchronisation
- ▶ Sync data with SPOR PMS
- ▶ OMS improvements
- ▶ Mapping national terms to SPOR (e.g. for remaining SMS terms)

▶ **PHAROS is now structurally IDMP-ready to store data according to EU IGs**

- ▶ We will use data from the “MAA and Variation eAF” (FHIR) via an automatised data import
- ▶ We are evaluating the use of the PMS-API to download CPs

▶ **IDMP-concepts are complex, perhaps too complex for some data consumers**

- ▶ We are evaluating this together with national eHealth organisations



Thanks for your attention!

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