This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299

UNICOM

Up-scaling the global univocal identification of medicines

FHIR 4 NCAs:
Track Changes on medicinal product variations
Friday 13th of October 2023

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Work package lead: Georg Neuwirther (AGES)
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Introduction, Motivation
10:00 – 10:20
➢ Georg Neuwirther

References – Where to start?
10:20 – 10:25
➢ Noel Diamant

Introduction to Variation Changes
Types of provenances in Present/Proposed
10:25 – 10:45
➢ Noel Diamant

Examples of Variation Changes
Examples of different types of changes
10:45 – 11:15
➢ Gianluca Risi, Noel Diamant

National FHIR Survey outcome
eAF import at different NCAs
11:15 – 11:20
➢ Noel Diamant

Closing / Q&A
11:20 – 11:45
➢ Georg Neuwirther
1. **Data availability in regulator systems (HMA/EMA)** becomes more essential ➢ see also HMA/EMA strategy to 2025 and EMA/HMA announcements.

1. The "technical new" application forms (PLM Portal/DADI) will provide improved opportunities to import application and medicinal product data into our IT system

2. A pan-European project "UNICOM" and EMA are working on the implementation of new data standards called **ISO – IDMP** ➢ This will help us to represent and store medicinal product data in a common approach – like eCTD standards to structure dossiers!

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**Source:** EMA - High-quality data to empower data-driven medicines regulation in the European Union (europa.eu)
Let's use this meeting to understand the new opportunities and get technical info on how I can use them.
What is UNICOM?

This innovation action is expected to support two goals:

(i) the cross-border mobility of European patients by offering safer eDispensations across borders,
(ii) the implementation of the IDMP standards in Member States drug databases (including a possible linkage to the EU SPOR - Substance, Product, Organisation and Referential master data database) allowing the identification of locally available medicinal products which are equivalent to the one identified in a foreign prescription. .."

- UNICOM has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
- Further detail can be found here: https://unicom-project.eu/ or on LinkedIn
- Focus for EMRN - is objective ii), “.. to foster the implementation of IDMP in Europe. ..”
Introducing ISO IDMP compliant application forms

► Applying for authorisations for medicinal products and managing their life cycles is a regulated process supported by electronic application forms and supporting electronic tools.

► At the moment neither application forms nor the tools for initial authorisations, variations and renewals are compliant to the ISO IDMP standards. Thus, it is currently not possible to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data in EU-wide eHealth services.

The aim of this UNICOM work package is to adapt the application forms and required tools towards the ISO IDMP standards and to increase the usage of EMA's SPOR. It will therefore deliver web-based application forms compatible with IDMP standards.
Introducing ISO IDMP compliant application forms

- **7 National competent authorities** are working together in this topic in the UNICOM project
  - Spain (Development of the PDF representation – Implementation of the variation FHIR profiles)
  - Austria (Product Owner PLM Product Owner together with a Product Owner from EMA)
  - Contribution of Expertise, Knowledge, Testing, Communication, etc. of the Netherlands, Germany, Ireland, Sweden, Norway

- **EMA is developing the core IT service Product Lifecycle Management Portal**
  - EMA is not an UNICOM partner!

AS-IS: Electronic Application Forms for Medicinal Products

PDF-based forms including a PDF-proprietary Data Exchange Format

Applicants

Initial Applications

Lifecycle Management

Regulators

Substance Terms, Organisations, Controlled Dictionary (EMA, providing master data from EUTCT, RMS, OMS)

Regulatory IT-Systems

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TO-BE and status of development

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Web Tool supporting IDMP/FHIR compatible application dataset formats

DADI

Variation Application
Initial Application
Renewal Application

Initial Applications
Lifecycle Management

Regulators

New Retrieving master data

Substance Terms, Organisation data, Referentials
MA, providing controlled dictionaries)

Medicinal Products
(PMS, providing master data for medicinal products)

UAT partly achieved, first Variation Application
From release in production since 04/11/2022

In progress

pending

New IDMP/FHIR format

Regulatory IT-Systems

See also collaboration with UNICOM WP4

UNICOM
WP 3
The first release of Variation Application Forms is successfully online since 04.11.2022
➢ This version covers variations of centrally authorised medicinal products
➢ Link: Home · PLM (powerappsportals.com)
References – Where to start?
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**eAF variation API Milestone plan**

1. **eAF DES → FHIR**
   - Transform eAF XML data to IDMP.
   - Publish Data mapping specification (eAF → FHIR).
   - Create extensions and adapt the standard with HL7.
   - Done

2. **Create FHIR message**
   - Implement the feature to create FHIR messages in the PLM Portal.
   - Done

3. **FHIR → eAF PDF**
   - Create the API "PDF Creator" to consume a FHIR message, validate it and create the eAF PDF representation with the FHIR message attached.
   - Done

4. **(Opt.) Update regulators**
   - Ensure regulatory authorities are capable of understanding the new message format which has transformed from DES to FHIR.
   - 40%

5. **Create validation Profiles**
   - Publish an Implementation guide with profiles and all used value sets.
   - Profiles will provide a detailed specification to create the FHIR message (for RIM Systems).
   - 40%

6. **Open PDF API for all**
   - Open "PDF Creator" API for Industry to provide a valid PDF to RIM Systems capable of sending the FHIR message.
   - 40%
How to get involved?

Previous Trainings

The following training will focus on specific elements of the medicinal product part of the variation message.

Previous trainings were given to

- Get an overview of the full product:
  FHIR Training: The **Medicinal Product part of FHIR**  
  --> [recording] <--

- Get an overview of the variation message:
  FHIR Training: **FHIR on Variations**  
  --> [recording] <--

- Top 10 most wanted IDMP fields
  FHIR Training: Top 10 IDMP fields through XPath  
  --> [recording] <--

How to contribute

Business Focus

- Give your input to the:
  - PMS SMEs and Network PO
  - eAF SMEs and Network PO

- Get in contact with Vet colleagues and:
  Learn from the upload to UPD and give feedback

Standardisation Focus

- Be part of the Connecthatons "Vulcan stream" at HL7
- "BR & R group" at HL7 also handles the medicinal product
Cost-free References – Where to start?

**ISO IDMP EU IG v2.1.1**
Start by looking at the ISO diagram in the EU IG Chapter 2 Page 30
[Link to EU IG](#)

**FHIR Documentation**
Get familiar with the basics in FHIR or attend a training
Getting started: [http://build.fhir.org/documentation.html](http://build.fhir.org/documentation.html)

**Data models and Mappings (eAF & DES to FHIR)**
Link to be added

**Training materials and Examples**
Link to be added
Scope of today

► Track changes...
Variation Changes

Present / Proposed values for variations and medicinal products
Concepts to represent changes to master data

The future variation application form minimises free text changes and enables applicants to directly propose changes in structured data elements.

The proposed changes are automatically logged and made visible in the PDF form.

Behind the scenes they are not text but references to data elements in order for national IT systems to consume them.

So called "FHIR Provenances" can be used to import this "Change Log"
What is a provenance?

Provenance of a resource is a record that describes entities and processes involved in producing and delivering or otherwise influencing that resource. Provenance provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility. [...] 

Definition from http://build.fhir.org/provenance.html

Who did it?
What was done?
What is affected?
Every proposed change on master data will know its relation to the **Scope, Product** and **package**.

There are 3 types of changes. Free text is always included:

- **Organisation changes**
  - Organisation reference (present, proposed)

- **Free Text changes**
  - Rich text & Pictures
  - Reference to scope
  - Ref to product / package

- **Product changes**
  - Present field value
  - Proposed reference
Variation and its Scopes - Relevant attributes

A Task (variation and contained task (scope) resource for each variation classification

- Task (Variation)
  - Identifier: Variation Procedure Nr
  - Code: Procedure type (MAA, Variation, Renewal)

- (contained) Task (Scope)
  - Identifier: Scope as known from the variation regulation + Type + ID
  - Code: Scope RMS Id
  - Input key value pairs for Type, Documentation and Conditions
A free text change with old (current) and new (proposed) texts

➢ **Provenance**
  - type – fixed value equal to 90000000997
  - Variation grouping Id: not used for free text change
  - Present and proposed text in html form – may contain images and rich text
  - Present and proposed ASMF number
  - Agent: the org making the change
A change of an organisation with old (current) and new (proposed) organisations

- **Provenance**
  - type – fixed value equal to 90000000998
  - Variation grouping Id: to group free text and different organisation changes (they share affected products/packages and scope(s))
  - Present and proposed organisations: two references to organisation resources included in the bundle
  - Agent: the org making the change
Product change - Relevant attributes

▲ Target the resource(s) affected by the change
(Note: not always a MedicinalProductDefinition
or a PackagedProductDefinition resource)

➢ Target element the element of the resource affected by the change
(CREATE and UPDATE changes). Note: not always a
MedicinalProductDefinition or a PackagedProductDefinition

➢ Target activity type of the modification made to the element of the resource (all changes)

➢ Target path contains information about the element being deleted
(only DELETE changes)
✓ Target parent reference to the resource whose element is being deleted
✓ Path the path in the parent element where the element being deleted was (FhirPath – segments separated by ".")
✓ Current value element being deleted
Target the resource(s) affected by the change (Note: not always a MedicinalProductDefinition or a PackagedProductDefinition resource)

- Target element: the element of the resource affected by the change (CREATE and UPDATE changes). Note: not always a MedicinalProductDefinition or a PackagedProductDefinition
- Target activity: type of the modification made to the element of the resource (all changes)
- Target path: contains information about the element being deleted (only DELETE changes)
  - Target parent reference to the resource whose element is being deleted
  - Path: the path in the parent element where the element being deleted was (FhirPath – segments separated by ".")
  - Current value: element being deleted
Provenance Conceptual Model

Date

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This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
Free text change - Business context

2. PRODUCTS CONCERNED BY THIS APPLICATION

- Active Substance:
  - Mercaptamine

- MA Holder name:
  - UAT ORG (ORG-200000096)
  - Germany
  - Gastro-resistant capsule, hard

- Product Name:
  - BackboneElement
  - string

- Type:
  - CodeableConcept

- Name Part:
  - BackboneElement
  - string

- Part:
  - CodeableConcept

- Country Language:
  - BackboneElement
  - CodeableConcept

- Country:
  - CodeableConcept

- Jurisdiction:
  - CodeableConcept

- Language:
  - CodeableConcept
Free text change provenance - Basics

► **Purpose:** model a free text change with old (current) and new (proposed) texts

► **Relevant attributes**

► **Provenance type** – fixed value equal to 9000000997

► **Variation grouping Id**: to group all the provenances belonging to the same "UI change" (they share affected products/packages and scope(s))

► **Present and proposed text** in html form – may contain images and rich text

► **Present and proposed ASMF number**

► **Agent**: the org making the change

► **Scope**: variation type (e.g.: "A.3 Change in name of the active substance or of an excipient")
XPath basic rules

- All elements belong to a namespace. FHIR one is http://hl7.org/fhir
- Nodes are targeted by their name
- Location paths are defined using the / symbol between node names in the path
- Attributes are targeted by their attribute name prefixed by the @ symbol
- Predicates (filters) can be defined using the [...] sintaxis
- Support for functions (e.g.: trim(), local-name()…)
- Several versions of the specification

**Tip:** use variables! (to store intermediate results)
Free text change - XML context

Steps to query text change provenances and their data

<table>
<thead>
<tr>
<th>Element/Collection</th>
<th>XPath</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$allProvenances</td>
<td>/f:Bundle/f:entry/f:resource/f:Provenance</td>
<td>All the provenances contained in the bundle</td>
</tr>
<tr>
<td>$changeProvenances</td>
<td>$allProvenances[f:activity/f:coding/f:code/@value != $const_activityCodeAttest]</td>
<td>All the change provenances (the signature one is excluded)</td>
</tr>
<tr>
<td>$provenancesInGroup</td>
<td>$changeProvenances[f:extension[@url = $extension_variationGroupingId]/f:valueId/@value = $groupingId]</td>
<td>All the changes provenances belonging to the same group, given its id value in $groupingId</td>
</tr>
<tr>
<td>$orgProvenances</td>
<td>$provenancesInGroup[f:extension[@url = $extension_provenanceType]/f:valueCoding[f:system/@value = $rmsList_provenanceType]/f:code/@value = $rmsId_provenanceType_htmlChange]</td>
<td>The (only one) text provenance contained in the group</td>
</tr>
<tr>
<td>$presentText</td>
<td>string(f:extension[@url = $extension_unstructuredCurrentValue]/f:valueString/@value)</td>
<td>The present text (current value)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Note: text is html-encoded</td>
</tr>
<tr>
<td>$proposedText</td>
<td>string(f:extension[@url = $extension_unstructuredProposedValue]/f:valueString/@value)</td>
<td>The proposed text (proposed value)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Note: text is html-encoded</td>
</tr>
</tbody>
</table>
Free text change – XML context

Present text

```
string(f:extension[@url = $extension_unstructuredCurrentValue][$currPos]/f:valueString/@value)
```

Proposed text

```
string(f:extension[@url = $extension_unstructuredProposedValue][$currPos]/f:valueString/@value)
```

Returned values is:

- &lt;div data-wrapper="true" style="font-family:'Segoe UI','Helvetica Neue',sans-serif; font-size:9pt"><div>j</div>...

Once decoded:

- `<div data-wrapper="true" style="font-family:'Segoe UI','Helvetica Neue',sans-serif; font-size:9pt"><div>j</div>`

HTML special characters must be unescaped!!
Organisation change provenance - Basics

► **Purpose:** model a change of an organisation with old (current) and new (proposed) organisations

► **Relevant attributes**
  - **Provenance type** – fixed value equal to 90000000998
  - **Variation grouping Id**: to group all the provenances belonging to the same "UI change" (they share affected products/packages and scope(s))

► **Present and proposed orgs** two references to organisation resources included in the bundle

► **Agent**: the org making the change

► **Scope**: variation type (e.g.: "A.3 Change in name of the active substance or of an excipient")
Organisation change - XML context

Steps to query organisation change provenances and their data

<table>
<thead>
<tr>
<th>Element/Collection</th>
<th>XPath</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$provenancesInGroup</td>
<td>$changeProvenances[f:extension[@url = $extension_variationGroupingId]/f:valueId/@value = $groupingId]</td>
<td>All the changes provenances belonging to the same group, given its id value in $groupingId</td>
</tr>
<tr>
<td>$orgProvenances</td>
<td>$provenancesInGroup[f:extension[@url = $extension_provenanceType]/f:valueCoding[f:system/@value = $rmsList_provenanceType]/f:code/@value = $rmsId_provenanceType_organizationChange]</td>
<td>All the organisation change provenances contained in the group (there can be many)</td>
</tr>
<tr>
<td>$presentOrgId</td>
<td>substring-after(f:extension[@url = $extension_unstructuredCurrentResource]/f:valueReference/f:reference/@value, '/')</td>
<td>Id of the current organisation resource</td>
</tr>
<tr>
<td>$proposedOrgId</td>
<td>substring-after(f:target/f:reference/@value, '/')</td>
<td>Id of the proposed organisation resource</td>
</tr>
<tr>
<td>$presentOrg</td>
<td>$allOrganizations[f:id/@value = $presentOrgId]</td>
<td>Present organisation resource</td>
</tr>
<tr>
<td>$proposedOrg</td>
<td>$allOrganizations[f:id/@value = $proposedOrgId]</td>
<td>Proposed organisation resource</td>
</tr>
</tbody>
</table>
Organisation change – XML context

Present organisation Id

substring-after(f:extension[@url = $extension_unstructuredCurrentResource]/f:valueReference/f:reference/@value, '/')

Returned values is:

- 869e1c434882b7e3f8d69a30addf073a

Proposed organisation id

substring-after(f:target/f:reference/@value, '/')

Returned values is:

- 632e1c1b3a237adf8d69a30addf073a

Organisation details

$allOrganizations[f:id/@value = $proposedOrgId]/f:name/@value

Returned values is:

- 1 0 1 Carefarm GmbH
**Purpose:** model a change on some attribute of a product

**Relevant attributes**

- **Provenance type** – fixed value equal to **9000000999**
- **Variation grouping Id**: to group all the provenances belonging to the same "UI change" (they share affected products/packages and scope(s))

**Agent**: the org making the change

**Scope**: variation type (e.g.: "A.3 Change in name of the active substance or of an excipient")
Target the resource(s) affected by the change (Note: not always a MedicinalProductDefinition or a PackagedProductDefinition resource)

- **Target element** the element of the resource affected by the change (CREATE and UPDATE changes). Note: not always a MedicinalProductDefinition or a PackagedProductDefinition

- **Target activity** type of the modification made to the element of the resource (all changes)

- **Target path** contains information about the element being deleted (only DELETE changes)
  - **Target parent** reference to the resource whose element is being deleted
  - **Path** the path in the parent element where the element being deleted was (FhirPath – segments separated by ".")
  - **Current value** element being deleted
The change affects three products (the provenance has three targets)

- First product has two changes (two targetElements extensions)
- Second product has three changes
- Third product has two changes

"Helper" links to:

- The products affected, in the productShortcut extensions
- The packages affected, in the selectedPackage extensions
The second change of the product with id **600000000057** is a **CREATE** change having:

- The created element with id **09bc5b0f-9bbd-4859-8f8d-c149e2d7b12d**

The element pointed by the change is a **classification** element representing an ATC code.
Update change

The first change of the product with id 600000000057 is an UPDATE change having:

- The current (old) value with the boolean value false
- The changed element with id d70f60e4-f74e-4352-97c8-92abfff18004

(Hyper)jumping to the proposed element, using its id, an extension inside an ATC classification element is found

- It has a valueBoolean inner element
- Its new (proposed) value is true
DELETE change

- The third change of the product with id **UAT600000001010** is a DELETE change having:
  - The deleted element with path "classification" starting from the (targetParent) MedicinalProductDefinition resource with Id of **UAT600000001010**
  - The element being deleted being a codeableConcept element representing an ATC code
Product change example #1

- Change of ATC code on several products
- CREATE and UPDATE changes
- Three products involved:
  - 600000001567 - NovoMix 100 U/ml - Suspension for injection
  - 600000000057 - Abseamed 3000 IU/0.3 ml - Solution for injection in pre-filled syringe
  - 600000002790 - Sifrol 0.26 mg - Prolonged-release tablet

Changes are

<table>
<thead>
<tr>
<th>Product</th>
<th>Changes</th>
</tr>
</thead>
</table>
| 600000001567 - NovoMix | • CREATE ATC code B03XA01  
  • CREATE ATC code N04BC05 |
| 600000000057 - Abseamed | • UPDATE ATC code A10AD05 "ATC pending" attribute from false to true  
  • CREATE ATC code B03XA01  
  • CREATE ATC code N04BC05 |
| 600000002790 - Sifrol | • CREATE ATC code B03XA01  
  • CREATE ATC code N04BC05 |

WHO ATC codes
B03XA01 is erythropoietin  
N04BC05 is pramipexole  
A10AD05 is insulin aspart

Disclaimer:  
This is not a real example!!
Product change example #2

- Change of ATC code on several products
- CREATE and UPDATE changes
- Three products involved:
  - UAT1234000 - Abacus Control gastro-resistant tablets 66 mg
  - UAT5678000 - Finacea 150 mg/g Gel
  - UAT9999000 - Aclasta 5 mg/100 ml - Solution for infusion

Changes are

<table>
<thead>
<tr>
<th>Product</th>
<th>Changes</th>
</tr>
</thead>
</table>
| UAT1234000 - Abac | CREATE ATC code A01AD06  
                           CREATE ATC code M05BA08 |
| UAT5678000 - Finace | CREATE ATC code A01AD06  
                           CREATE ATC code M05BA08 |
| UAT9999000 - Aclast | CREATE ATC code A01AD06  
                           CREATE ATC code M05BA08  
                           DELETE ATC code A01AD02 |

WHO ATC codes
A01AD06 is adrenalone
M05BA08 is zoledronic acid
A01AD02 is benzydamine

Disclaimer:
This is not a real example!!

To be shown in the demo
Live inspection of the FHIR XML

From example #1:
- Show an UPDATE change
- Show a CREATE change

From example #2:
- Show a DELETE change
# Structured change - XML context

## Steps to query structured change provenances and their data

<table>
<thead>
<tr>
<th>Element/Collection</th>
<th>XPath</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$structuredChangeProvenances</td>
<td>$provenancesInGroup[f:extension[@url = $extension_provenanceType]/f:valueCoding[f:system/@value = $rmsList_provenanceType]/f:code/@value = $rmsId_provenanceType_productChange]</td>
<td>All the product change provenances contained in the group (there can be many)</td>
</tr>
<tr>
<td>$changeTargets</td>
<td>$structuredChangeProvenances[1]/f:target</td>
<td>All the target resources of the first product change provenance (there can be many)</td>
</tr>
<tr>
<td>$targetResourceActivity</td>
<td>$structuredChangeProvenances[1]/f:activity/f:coding/f:code/@value</td>
<td>Type of change made on the resources (CREATE, UPDATE or DELETE) Same for all the target resources</td>
</tr>
<tr>
<td>$targetResourceId</td>
<td>Substring-after($changeTargets[1]/f:reference/@value, '/')</td>
<td>The resource id of the first target resource in the change provenance</td>
</tr>
<tr>
<td>$targetElements</td>
<td>$changeTargets[1]/f:extension[@url = $extension_targetElement]</td>
<td>All the target elements of the first target resource (there can be many)</td>
</tr>
<tr>
<td>$targetElementActivity</td>
<td>$targetElements[1]/f:extension[@url = $extension_targetActivity]/f:valueCoding/f:code/@value</td>
<td>Type of the change made on the first element (CREATE, UPDATE or DELETE) Note: in case of DELETE, the targetElement is the parent of the element being deleted</td>
</tr>
</tbody>
</table>
### Structured change - XML context (Cont.)

#### Steps to query structured change provenances and their data

<table>
<thead>
<tr>
<th>Element/Collection</th>
<th>XPath</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$targetElementCurrentValue</td>
<td>$targetElements[1]/f:extension[@url = $extension_currentValue]/child::*[1]</td>
<td>Current value of the first target element. It is the first child of the currentValue extension. Its type varies in each case.</td>
</tr>
<tr>
<td>$targetElementProposedElementId</td>
<td>substring-after($targetElements[1]/f:extension[@url = 'url']/f:valueUrl/@value, '#')</td>
<td>Proposed value element id inside the first target element. It can point to any node (element) in the bundle.</td>
</tr>
<tr>
<td>$targetElementProposedValue</td>
<td>//child::*[@id = $targetElementProposedElemId]</td>
<td>Proposed value of the first target element. It can be any element inside the target resource.</td>
</tr>
</tbody>
</table>
Only changes are shown

A variation only includes the product resources that are actually changed

► Rule Nr 1: No half measures!
   If a resource is included because 1 attribute has changed, the entire resource is included;

► Rule Nr 2: Know your neighbors!
   If a resource has a link to a resource that is not being changed, the link is included. The resource that is being linked to, will not be there. This is to be able to compare resources and confirm that something/nothing has changed
Resources used in Variation

https://hl7.org/fhir/2021May/resourcelist.html

Procedure Management

► Task
  ► Task is the main entry point of the procedure. It contains most details as a key value pair on input type & value
  ► A task can be the subject of regulated authorisations (e.g. orphan, paediatric applications) and payment details
  ► A task has a subtask for every scope in a variation

► Provenance
  ► Each of the 3 types of changes are depicted in a provenance of type HTML change, Organisation change or Product Change
  ► Provenances are bundled in scopes
  ► Each change creates a new provenance
  ► A provenance can link any resource depending on what was changed
  ► A provenance can also be a signature

► PaymentNotice
  ► Payment details within the procedure
Resources used in PMS

https://hl7.org/fhir/2021May/resourcelist.html

- MedicinalProductDefinition
  - The entry point for the PMS product

- PackagedProductDefinition
  - Packages in a product

- AdministrableProductDefinition
  - Pharmaceutical Product with links to ingredients

- ManufacturedItemDefinition
  - Manufactured Items with links to ingredients

- Ingredient
  - Each Ingredient has a substance link and represents a part of the composition

- RegulatedAuthorization
  - Any kind of authorisation (e.g. Marketing Authorisation, Manufacturing Authorisation,...)

- SubstanceDefinition
  - Contains the substance name and link to SMS

- ActivityDefinition
  - The "operation" of a manufacturer

- DeviceDefinition
  - Medical Device that is part of the product

- DocumentReference
  - Numbers of documents – no actual document or link

- ClinicalUseIssue
  - Indications of the product

- Organization
  - Contains the link to OMS and a copy of the organisation details

- PractitionerRole
  - A person (not part of any master data)
Exception: Some resources are mandatory

Some resources will always be included:

- Medicinal ProductDefinition
- IngredientDefinition
  - Reason: Substance Name
  - implicit: Link to medicinal product (extension) - not Admin product link
  - Role = Active
- RegulatedAuthorization - for selected packages and med products (Type=Marketing Authorization)
- PackagedProductDefinition - ONLY IF SELECTED IN THE UI
- All Orphan Resources
- Orphan RAs, GMP RAs, Paediatric RAs, Market Exclusivity and Market Protection RAs
- Organization (type=MA Holder and Regulator - linked to the RegulatedAuthorization)
- PackagedProductDefinition - ONLY IF SELECTED IN THE UI
- All Orphan Resources
- All parallel resources (MedicinalProductDefinition + RA)
- Substances
- PaymentNotices
Member States implementing FHIR
Currently in development
It is in production
We are planning it but unsure if we should wait for the FHIR based message

- Croatia
- France
- Germany (BFARM)
- Germany (PEI)
- Ireland
- Italy
- Portugal
- Slovenia
- Sweden
- the Netherlands
- Austria
- Spain

Date
Are you planning to import the new eAF FHIR based data backbone for variations or initial application forms in your agencies IT system?

- It is in development
- We are thinking about it
- We have it planned for later
- We have it planned for this year
How much information are you planning to extract from the message and what is the main purpose?

- Basic procedure and product information to start the Workflow
- All procedural information so assessors don't have to open the PDF
- All product information to update your national product dictionary

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Follow up?

Are you interested to join an NCA/EMA user group

- I would like to actively participate and suggest topics
- I would like to come and listen
- I am not interested

- Croatia
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Date

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
We would like to organise two RAthons (compare Connectatons)

- Q4/2023
- Q1/2 2024
Design

- Bring your own laptop
- On-site meeting to train how to extract data from eAF FHIR messages
- Participants will be trained by FHIR experts
- Participants will be supported trying out practical examples
- Participants will be able to ask and discussion questions
- Participants will be able to transfer knowledge and practical experiences into their agencies
- Business and IT-Experts can learn together
Next steps

- Agreeing on date and location
- Invitation to (UNICOM) NCA members – first come/first serve
- Identification of table hosts – Noel, Gianluca and on more needed
- Procurement FHIR experts … (agreement with EMA)

Proposal: learning experience on how Connecthaton works in Rennes September at UNICOM test day, Contact Alexander Berler, last day to register 16. June
- First NCA RAthon in UNICOM consortium meeting in Ghent, Nov 27
- Need a stable FHIR variation form and experts from NCAs to participate
- Check list prepared by Noel on what/how for NCAs participation
The full recording of this webinar will be available on the UNICOM youtube channel accessible from the UNICOM website.

On the UNICOM website, under resources, you will also find a number of important documents published as « working papers ».

Further Information on UNICOM
http://www.unicom-project.eu
Twitter (X): @ unicom_idmp
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