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Up-scaling the global univocal identification of medicines

Reading the Variation FHIR Message
Friday 15th of July 2022
Noel Diamant

Agenda

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1 **Introduction, Motivation**
09:30 – 09:40
> *Georg Neuwirther*
  UNICOM WP3 Lead, Austrian Medicines Agency

2 **Creating a FHIR message (Short Demo)**
09:40 – 09:55
> *Noel Diamant*
  Product Co-Owner for DADI, Austrian Medicines Agency

3 **Variation FHIR Message Conceptual Model**
09:55 – 10:10

4 **Mapping of Fields DADI UI --> FHIR Message**
10:10 – 10:20

5 **Extracting information of a FHIR message**
10:20 – 10:30
> *Noel Diamant*
  Product Co-Owner for DADI, Austrian Medicines Agency
> *Rik Smithies*
  FHIR Expert DADI Project, NProgram / HL7
> *Luis Gouveia*
  FHIR Developer, DADI Project, Microsoft

6 **Open Forum: Your experience in eAF Import development**
10:30 – 10:50
> *Everybody is invited to talk*

7 **Closing**
10:50 – 10:55
> *Georg Neuwirther*
  UNICOM WP3 Lead, Austrian Medicines Agency

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# Introducing the „Austrian Medicines Agency"

- ▶ **AGES MEA** is a division of
  the Austrian Agency for Health and Food Safety (AGES),
  which is the leading expert organisation
  for risk minimisation in the fields of health, food safety
  and consumer protection.

- ▶ 350 FTEs are working at AGES MEA

- ▶ 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**)

Introducing „DADI & UNICOM WP 3"

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Context

> The **Digital Application Dataset Integration (DADI) Network Project** will replace current interactive PDF format electronic application forms with **new web-based application forms** hosted on a **dedicated portal**

> The new web-forms will facilitate compliance with **ISO Identification of Medicinal Products (IDMP)** standard for human medicinal products in accordance with Commission Implementing Regulation (EU) No 520/2012 (art. 25 and 26)

> DADI will provide a human readable PDF output in line with the Notice to Applicants requirements

> The PDF output will contain a machine-readable component with a larger dataset in a **FHIR** xml format, that facilitates exchange of the applications information across different systems
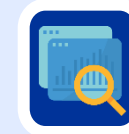
DADI will change:

> **PDF and XML-format for electronic application forms to web forms for:** Variations; Initial marketing authorisations; Renewals (human only); Forms for other procedures under consideration
> **Human** and **veterinary** forms
> **Centrally authorised product (CAPs)** applications at initial release of the form, and **Nationally authorised product (NAPs)** applications at second release.

DADI will NOT change:

> The **current PDF** *output* format
> The process to apply for or submit **Variations** and **Marketing authorisation applications**
> The content of the **application form in the submission package**

Disclaimer

Motivation, Business Case & lessons learnt

Automatized data import into IT systems

Motivation

Manual import

- Keying in application form data is time consuming and an administrative burden for regulators

- Manually keying in application form data is error prone

- Keying in IDMP compatible data is very complex due to the extended structural definitions according to IDMP

Automated import

- The eAF/FHIR message offers possibilities to minimize this administrative effort via electronic data import

- No manual typing

- The extraction and import job can handle the complex structures
- The extraction and import job can handle SPOR terms – IDs and narrative texts

Example about variation forms /1

eAF Import at the Austrian Agency (as-is) Part I

CESP submissions

CR submissions

Other triggers
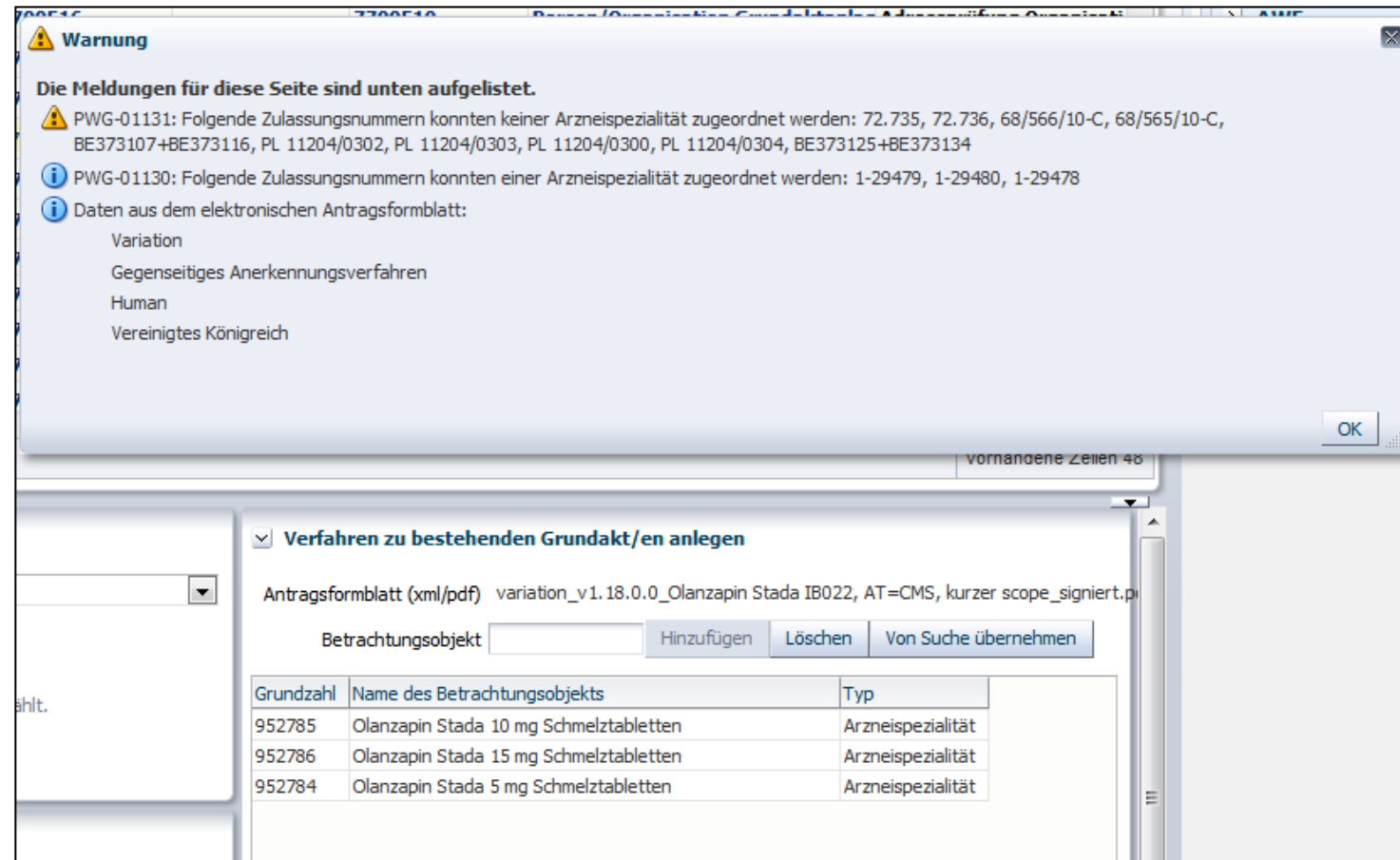
1. System or user provides eAF.

2. eAF/FHIR message will be extracted, imported and evaluated.

3. System identifies concerned Medicinal Products via e.g. the "MA number"
   - Systems notifies about not identifiable products.

4. Expert selects or confirms (regulatory) activity; essential to select the relevant workflow in the IT system.

5. System imports data from the eAF/FHIR message.

⚠ **Warnung**

Die Meldungen für diese Seite sind unten aufgelistet.

⚠ PWG-01131: Folgende Zulassungsnummern konnten keiner Arzneispezialität zugeordnet werden: 72.735, 72.736, 68/566/10-C, 68/565/10-C, BE373107+BE373116, PL 11204/0302, PL 11204/0303, PL 11204/0300, PL 11204/0304, BE373125+BE373134

ⓘ PWG-01130: Folgende Zulassungsnummern konnten einer Arzneispezialität zugeordnet werden: 1-29479, 1-29480, 1-29478

ⓘ Daten aus dem elektronischen Antragsformblatt:

    Variation

    Gegenseitiges Anerkennungsverfahren

    Human

    Vereinigtes Königreich

OK

Vorhandene Zeilen 48

✓ **Verfahren zu bestehenden Grundakt/en anlegen**

Antragsformblatt (xml/pdf)   variation_v1.18.0.0_Olanzapin Stada IB022, AT=CMS, kurzer scope_signiert.p

Betrachtungsobjekt   Hinzufügen   Löschen   Von Suche übernehmen

Grundzahl	Name des Betrachtungsobjekts	Typ
952785	Olanzapin Stada 10 mg Schmelztabletten	Arzneispezialität
952786	Olanzapin Stada 15 mg Schmelztabletten	Arzneispezialität
952784	Olanzapin Stada 5 mg Schmelztabletten	Arzneispezialität

Example about variation forms /2

eAF Import at the Austrian Agency (as-is) Part II

7. System imports data from the eAF/FHIR message.

Friendly features:
- New organisations will be processed
  - Duplicates will be recognized
- Updates: address validation procedures will be triggered

- Notification about unknown SPOR/RMS terms are provided

Creating a FHIR Message

Short Demo - https://euema-prs-uat.powerappsportals.com/

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Variation FHIR Message Conceptual Model

Conceptual FHIR Model for Variation
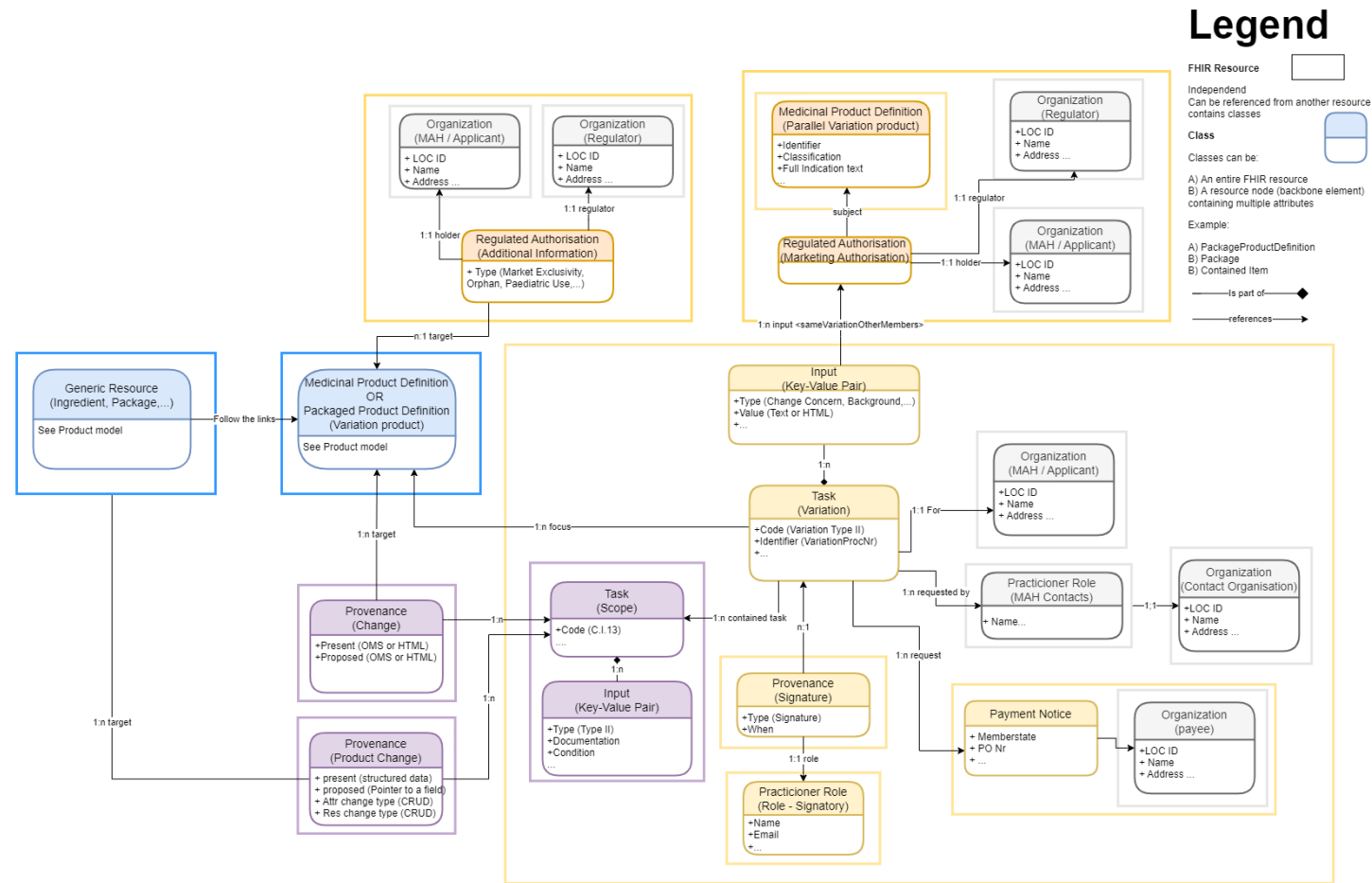
https://esubmission.ema.europa.eu/cessp/Variation%20FHIR%20CDM.png

Conceptual FHIR Model for Product

https://esubmission.ema.europa.eu/cessp/Product%20FHIR%20CDM.png

Mapping of Fields DADI UI --> FHIR Message

Excel mapping
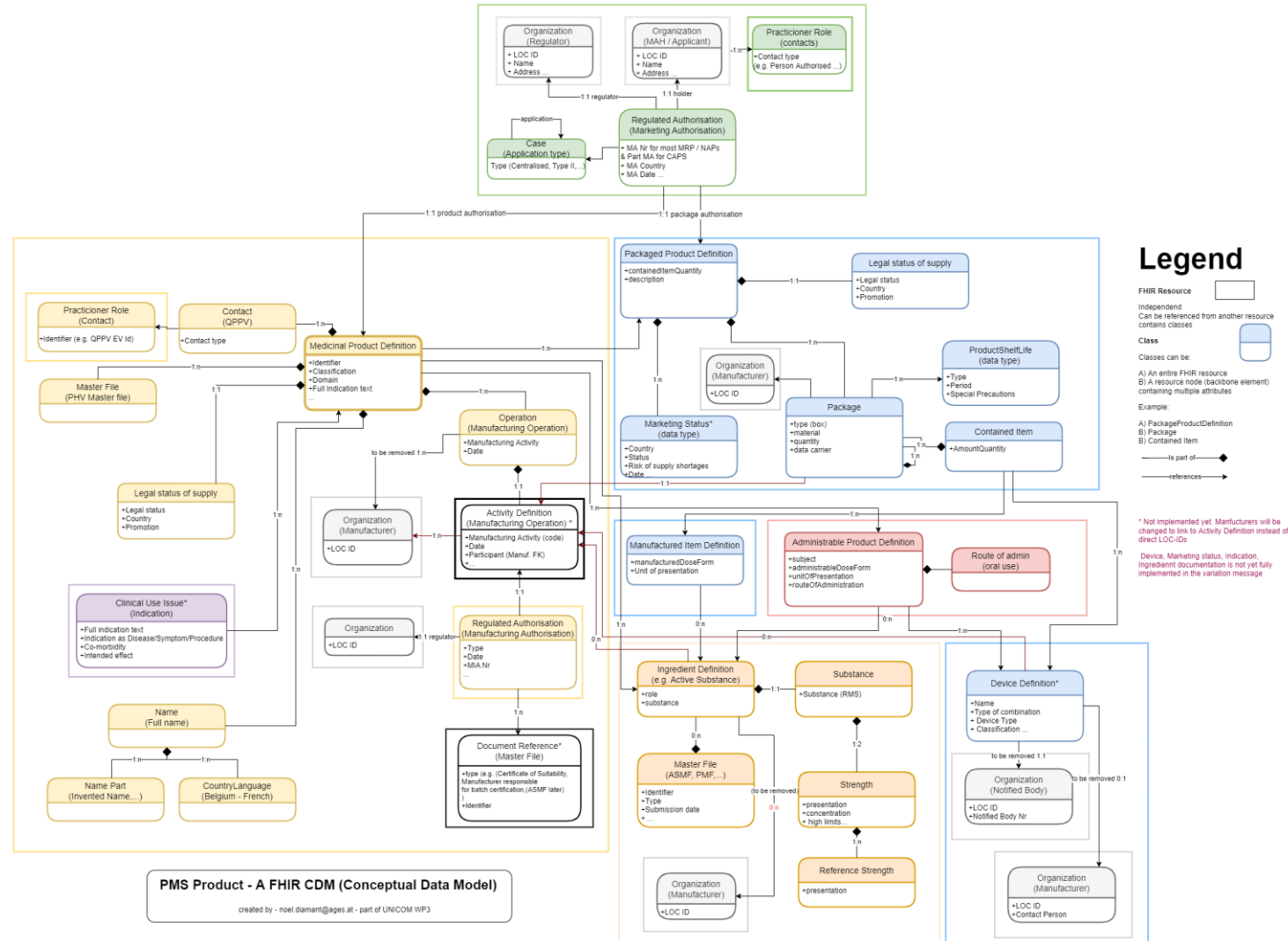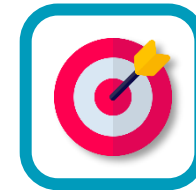
The mapping for Variation contains

- **Name of the Field**
  as seen in the DADI UI

- **Additional Information**
  (e.g. cardinality, hierarchy,…)

- **RMS Lists ID & Name**
  ~ 10 additional lists are being created in RMS at the moment and don't have an ID yet

- **FHIR Attribute**
  + additional path information

https://esubmission.ema.europa.eu/cessp/Updated%20FHIR%20mapping%202022%2005%2020%20AF%20Data%20Requirements.xlsx

Extracting information of a FHIR message

► **There are many ways to extract data from FHIR**

  ➢ **Xpath (+ optional XSLT) as done today**

  ➢ **Making use of the standard (library)**

  ➢ **… Share your preferred option!**

► **Versioning is always an issue**

  ➢ **Xpath can use XSLT to trim the message down a bit**

  ➢ **Libraries get updated with FHIR releases and intermediate changes will be generic extensions**

Useful links for FHIR Implementations
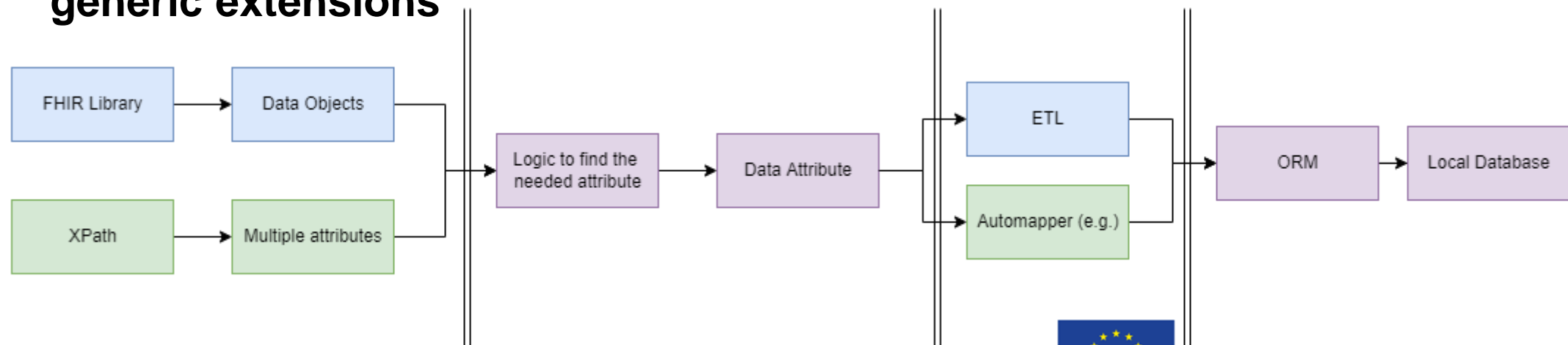
► eAF is currently using FHIR v 4.6.0 and will upgrade to 5.0.0 next year
http://hl7.org/fhir/directory.html

► Open Source Implementations
Most common used libraries to extract FHIR content

  ➢ **JAVA**: **https://github.com/jamesagnew/hapi-fhir** - James Agnew / University Health Network

  ➢ **.NET Client - Firely .NET SDK**: **https://github.com/FirelyTeam/firely-net-sdk**

► Many other libraries can be found here:
https://confluence.hl7.org/pages/viewpage.action?pageId=35718838

► Many Implementation tools can be found here:
http://build.fhir.org/downloads.html

Open Forum: Your experience in eAF Import development

Or any other questions?

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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: @ unicom_idmp
linkedin.com/company/unicom-idmp

And for Further information on DADI visit:
https://esubmission.ema.europa.eu/cessp/cessp.htm

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