

UNOCOM

Up-scaling the global univocal identification of medicines

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



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



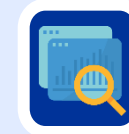
- ▶ **AGES MEA** is a division of the Austrian Agency for Health and Food Safety (AGES), which is the leading expert organisation for risk minimisation in the fields of health, food safety and consumer protection.
- ▶ 350 FTEs are working at AGES MEA
- ▶ AGES is wholly owned by the Republic of Austria.

- ▶ The **AGES MEA** business unit is the service provider for the **Federal Office for Safety in Health Care (BASG)**



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**

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Motivation, Business Case & lessons learnt

Automatized data import into IT systems

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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

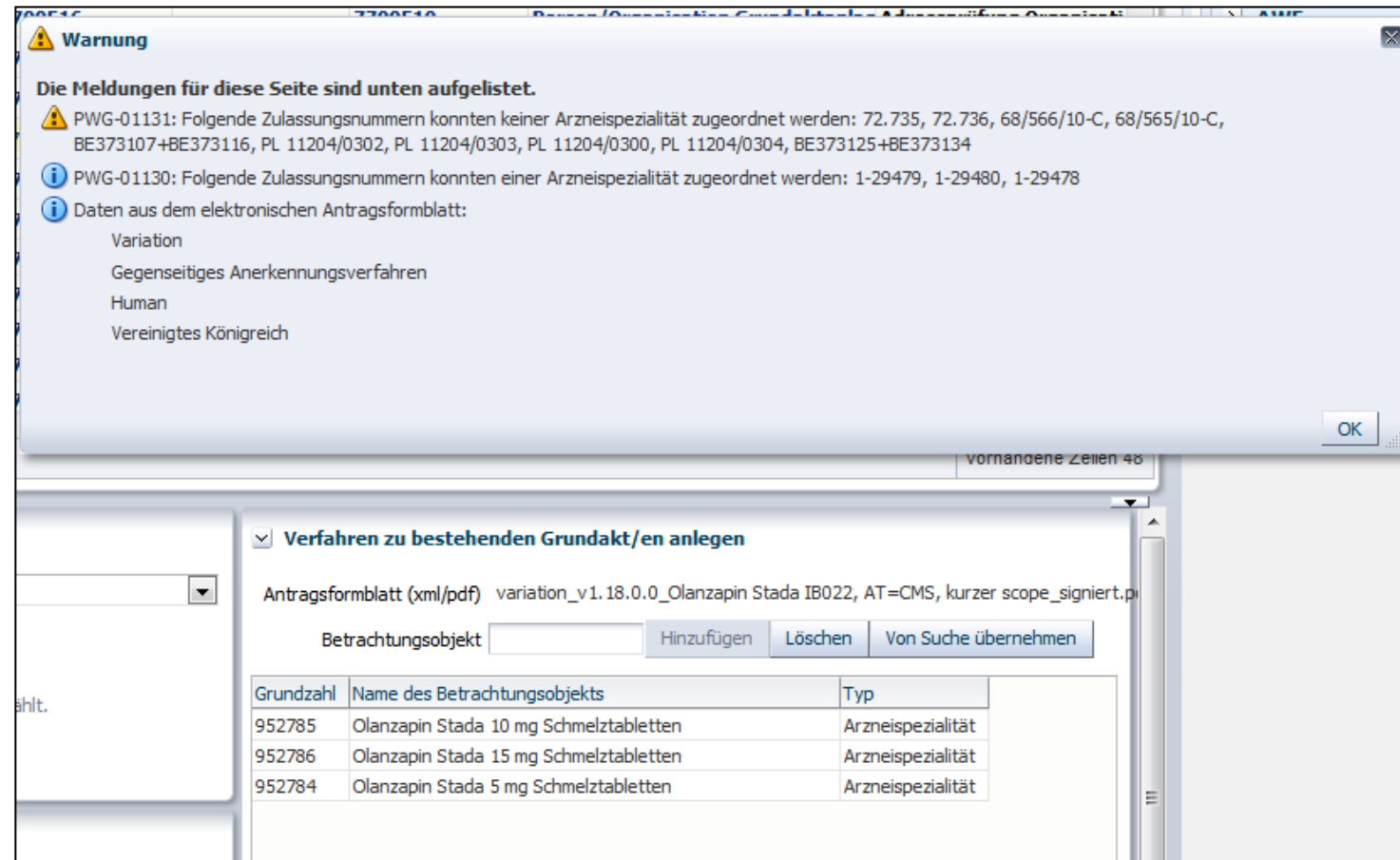
eAF Import at the Austrian Agency (as-is) Part I

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.

CESP submissions

CR submissions

Other triggers



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
- i PWG-01130: Folgende Zulassungsnummern konnten einer Arzneispezialität zugeordnet werden: 1-29479, 1-29480, 1-29478
- i Daten aus dem elektronischen Antragsformblatt:
 - Variation
 - Gegenseitiges Anerkennungsverfahren
 - Human
 - Vereinigtes Königreich

OK

vormandene 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

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

The screenshot displays the UNOCOM system interface for managing variation forms. The top navigation bar includes buttons for 'Speichern', 'Tab Schließen', 'Reservieren', 'Überarbeiten', 'Abschließen', and 'Zur Bescheidfreigabe'. The main content area is divided into several tabs: 'Verfahrensdaten', 'Termine & Fristen', 'Anmerkung', 'Verfahrenszeit', 'Kommunikation', 'Referenz', 'ORG/PER', and 'Verrechnung'. The 'ORG/PER' tab is active, showing a table of roles with columns for 'Rolle', 'Kategorie', 'Grundzahl', 'Name', 'Status Grundzahl', 'Status Rolle', 'Datum Rolle', and 'User Rolle'. A table entry is visible for 'Anbringer' with Grundzahl '8304746' and Name 'Krka d. d., Novo mesto'. Below the table, there are two detailed views of variation forms. The left view is for 'Verfahrensakt 954354 CZ/H/0277/001 Escitalopram Krka 5 mg Filmtabletten' and the right view is for 'Verfahrensakt 954355 CZ/H/0277/002 Escitalopram Krka 10 mg Filmtabletten'. Both views show 'Antragsdaten' and 'Änderung' tabs, with the 'Antragsdaten' tab selected. The 'Antragsdaten' tab displays fields for 'Antragsart', 'Verfahrensart', 'Human/Veterinär', 'Liechtenstein', and 'stärkenbezogene Verfahrensnummer'. The 'Änderung' tab shows a 'Scope Variation' section with a text area containing the following text: 'Quality Overall Summary for Krka d.d. has been updated to be in line with approved ASMF have updated documentation regarding active substance manufacturer Dr. Reddyacordir approved documentation.Type II variation- update of ASMF issued by Mylan:ASMF has be'. Below this text area is a table with columns for 'Klassifikation', 'Beschreibung der Klassifikation', and 'Kurzbeschreibung'. A table entry is visible for 'B.I.z' with 'Beschreibung der Klassifikation' 'B.I.z Active Substance'.



Creating a FHIR Message

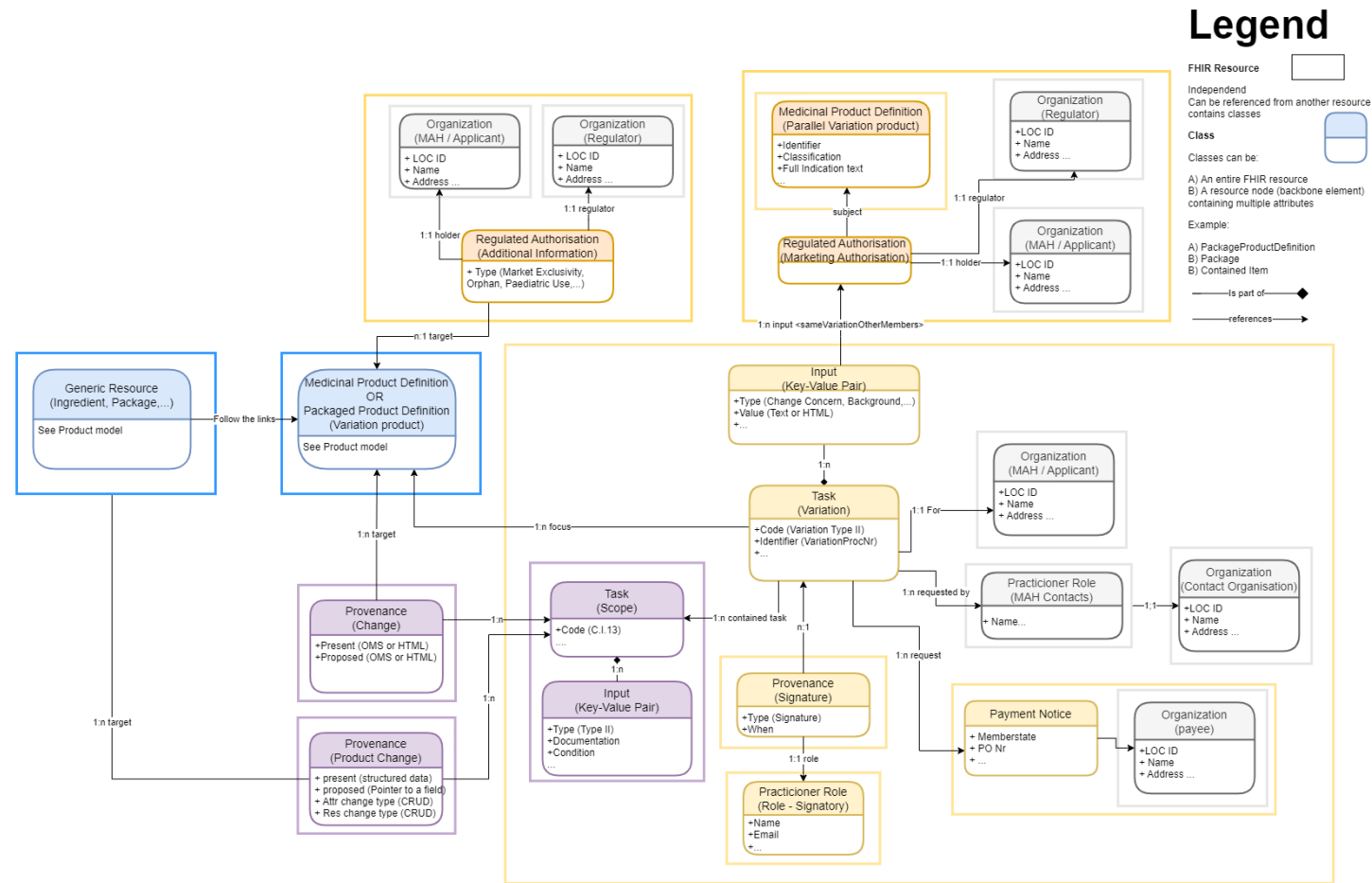
Short Demo - <https://euema-prs-uat.powerappsportals.com/>



Variation FHIR Message Conceptual Model



Conceptual FHIR Model for Variation

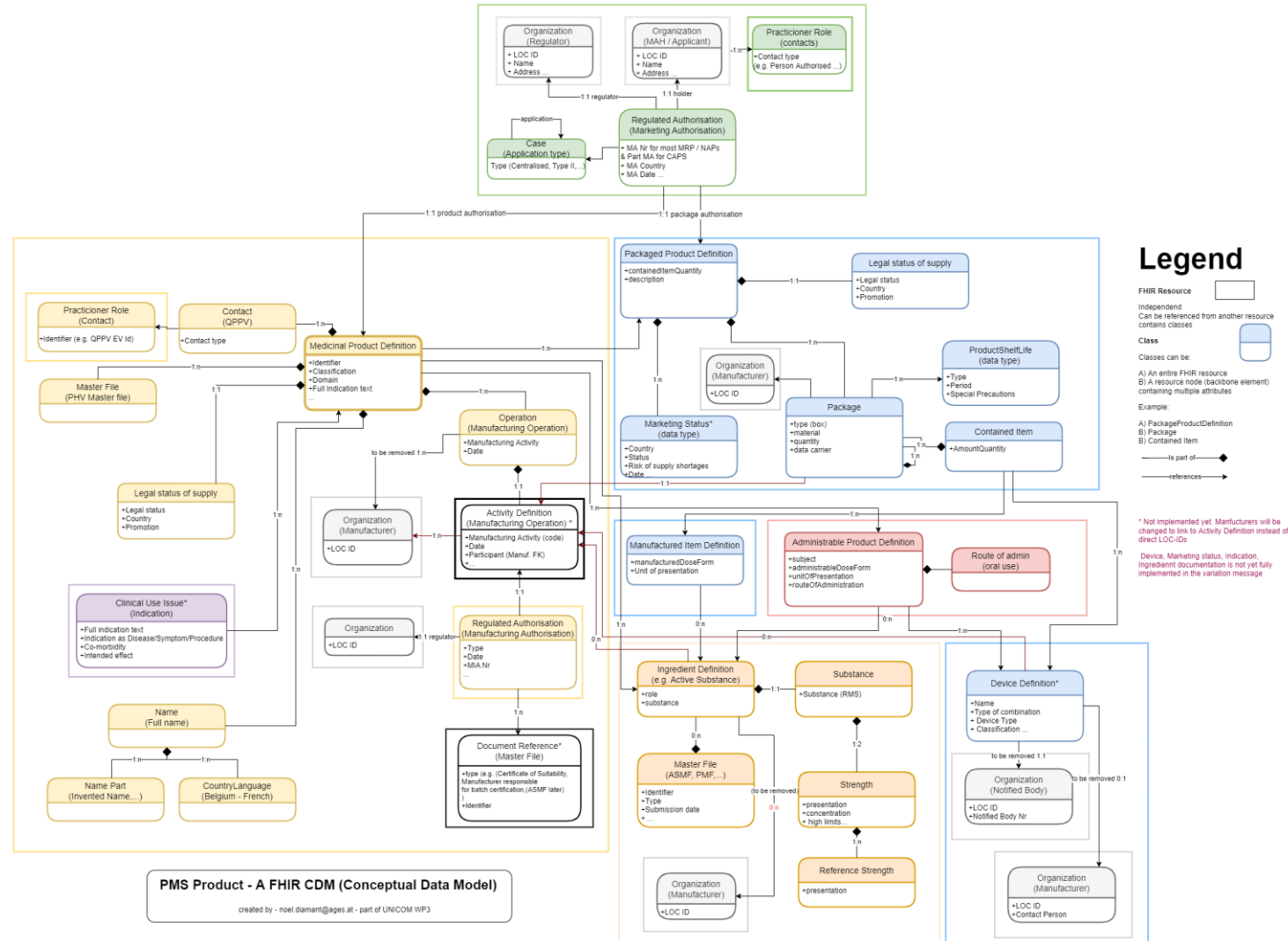


<https://esubmission.ema.europa.eu/cessp/Variation%20FHIR%20CDM.png>

Variation - A FHIR CDM (Conceptual Data Model)
 created by - noel.diamant@ages.at - part of UNICOM WP3



Conceptual FHIR Model for Product







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

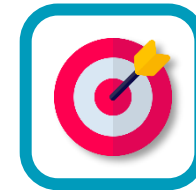


Mapping of Fields DADI UI --> FHIR Message



The mapping for Variation contains

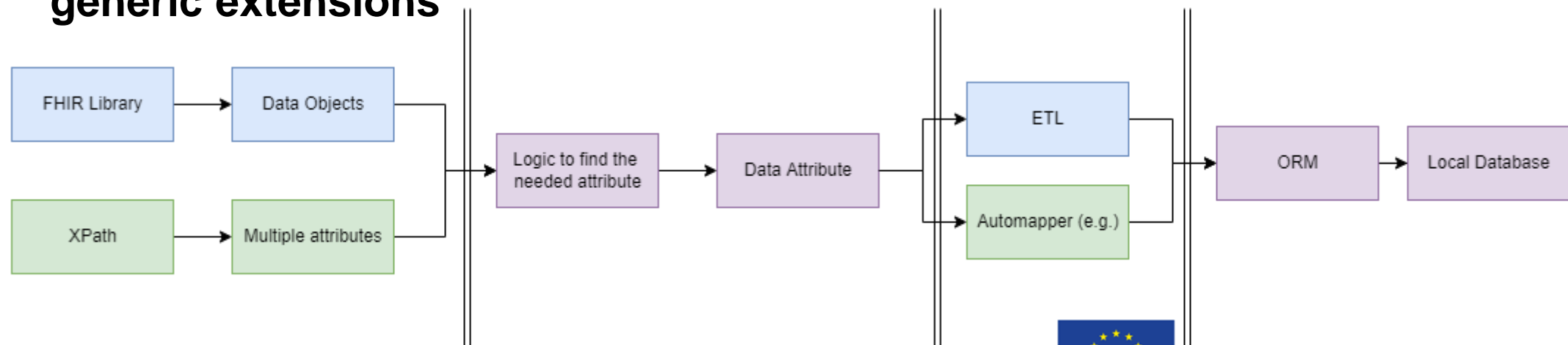
-  • **Name of the Field**
as seen in the DADI UI
-  • **Additional Information**
(e.g. cardinality, hierarchy,...)
-  • **RMS Lists ID & Name**
~ 10 additional lists are being created in RMS at the moment and don't have an ID yet
-  • **FHIR Attribute**
+ additional path information



<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**



- ▶ 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>

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[linkedin.com/company/unicom-idmp](https://www.linkedin.com/company/unicom-idmp)

And for Further information on DADI visit:

<https://esubmission.ema.europa.eu/cessp/cessp.htm>

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