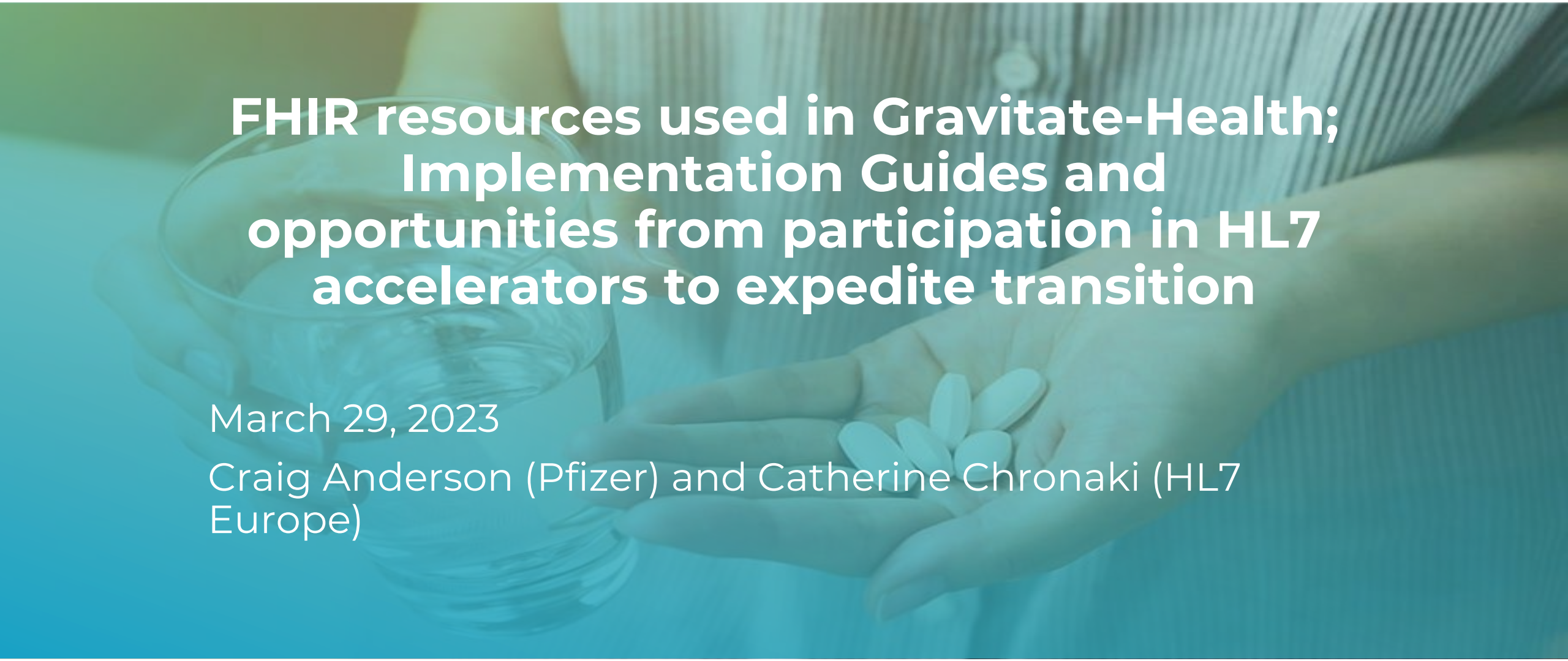


FHIR resources used in Gravitate-Health; Implementation Guides and opportunities from participation in HL7 accelerators to expedite transition

March 29, 2023

Craig Anderson (Pfizer) and Catherine Chronaki (HL7 Europe)

ePI Objectives

Goals

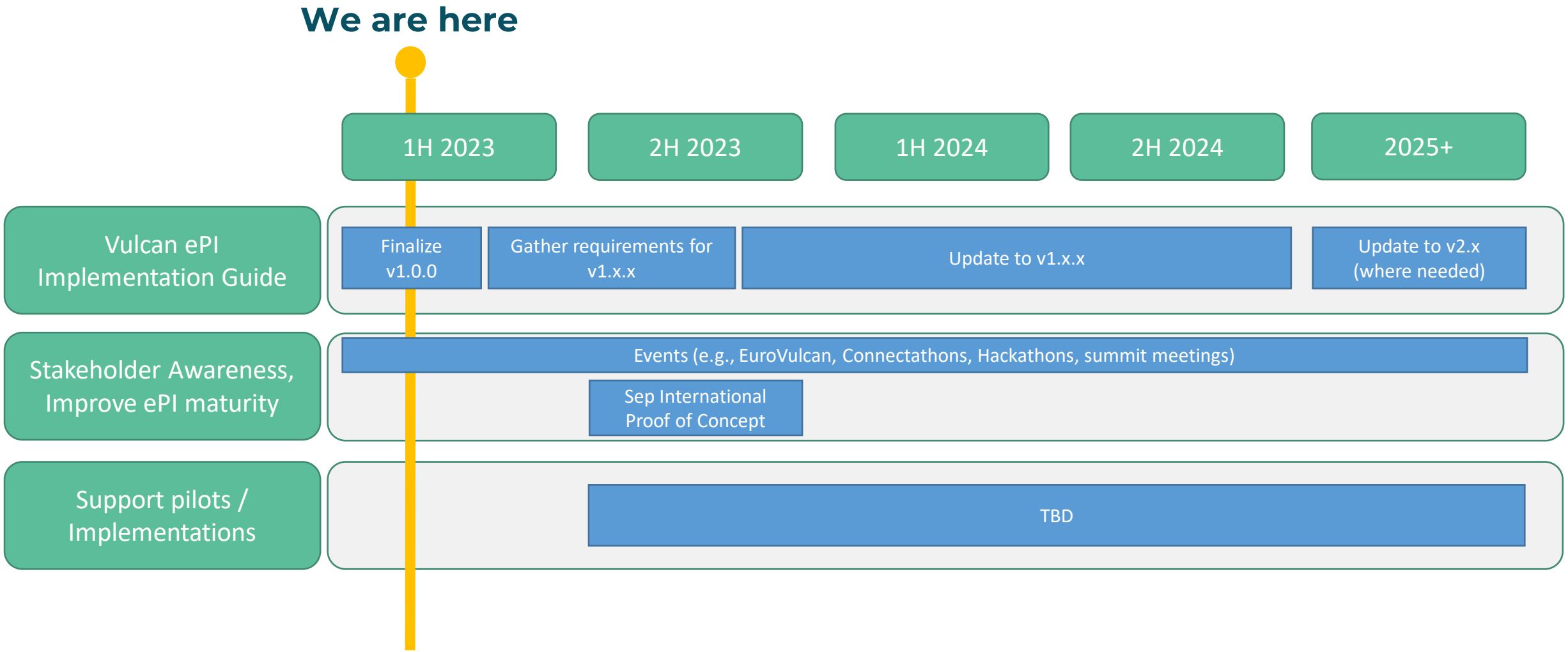
1. Develop a path to achieve critical mass (i.e., 80% of ePIs converted to FHIR) within two years.

2. Gain support from stakeholders to help achieve Goal #1

For discussion

What is needed to achieve these goals?

Draft Roadmap (Work in progress, need your input)



Same foundation, two implementation models

EMA Profile - FHIR Resource Names[1]	
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition
13	Substance

[1] Rows 1 to 4 make up the ePI. The ePI cross references out to SPOR which is made up of rows 5 to 13.

Common Profile - FHIR Resource Names[2]	
1	List
2	Bundle
3	Composition
4	Binary
5	Organization
6	RegulatedAuthorization
7	MedicinalProductDefinition
8	PackagedProductDefinition
9	AdministrableProductDefinition
10	ManufacturedItemDefinition
11	Ingredient
12	ClinicalUseDefinition
13	Substance

[2] Common ePI is managed as a single self-contained document.

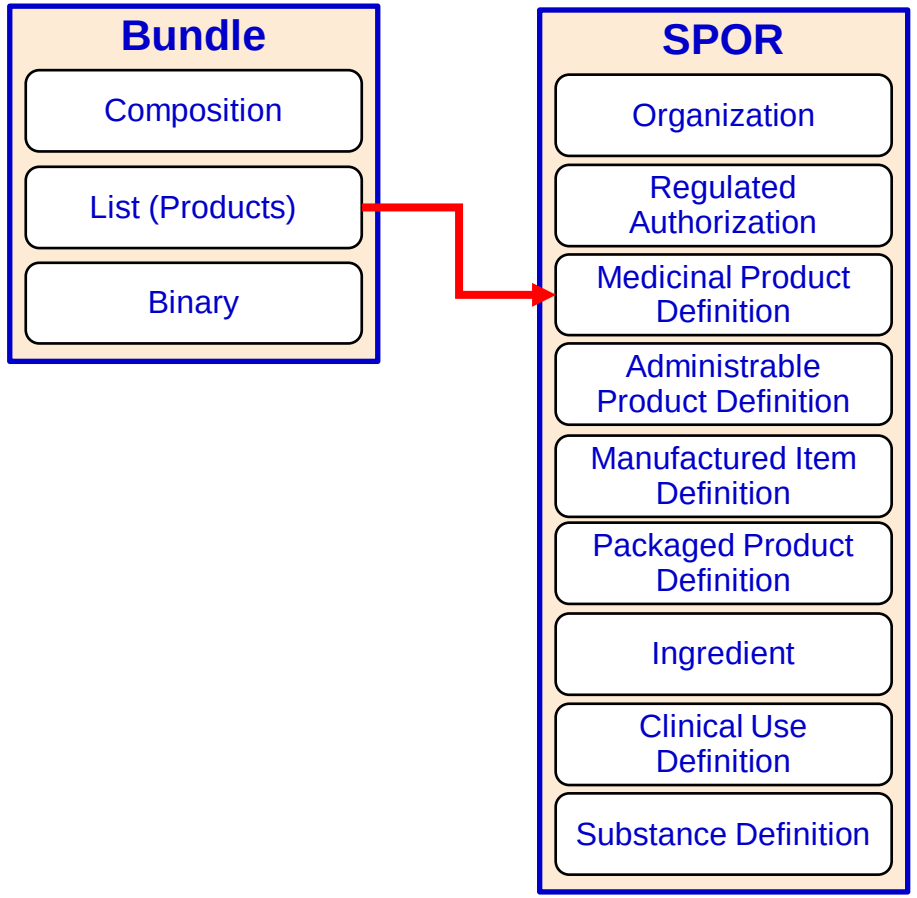
Same foundation, different implementation models

‘Common’ Approach

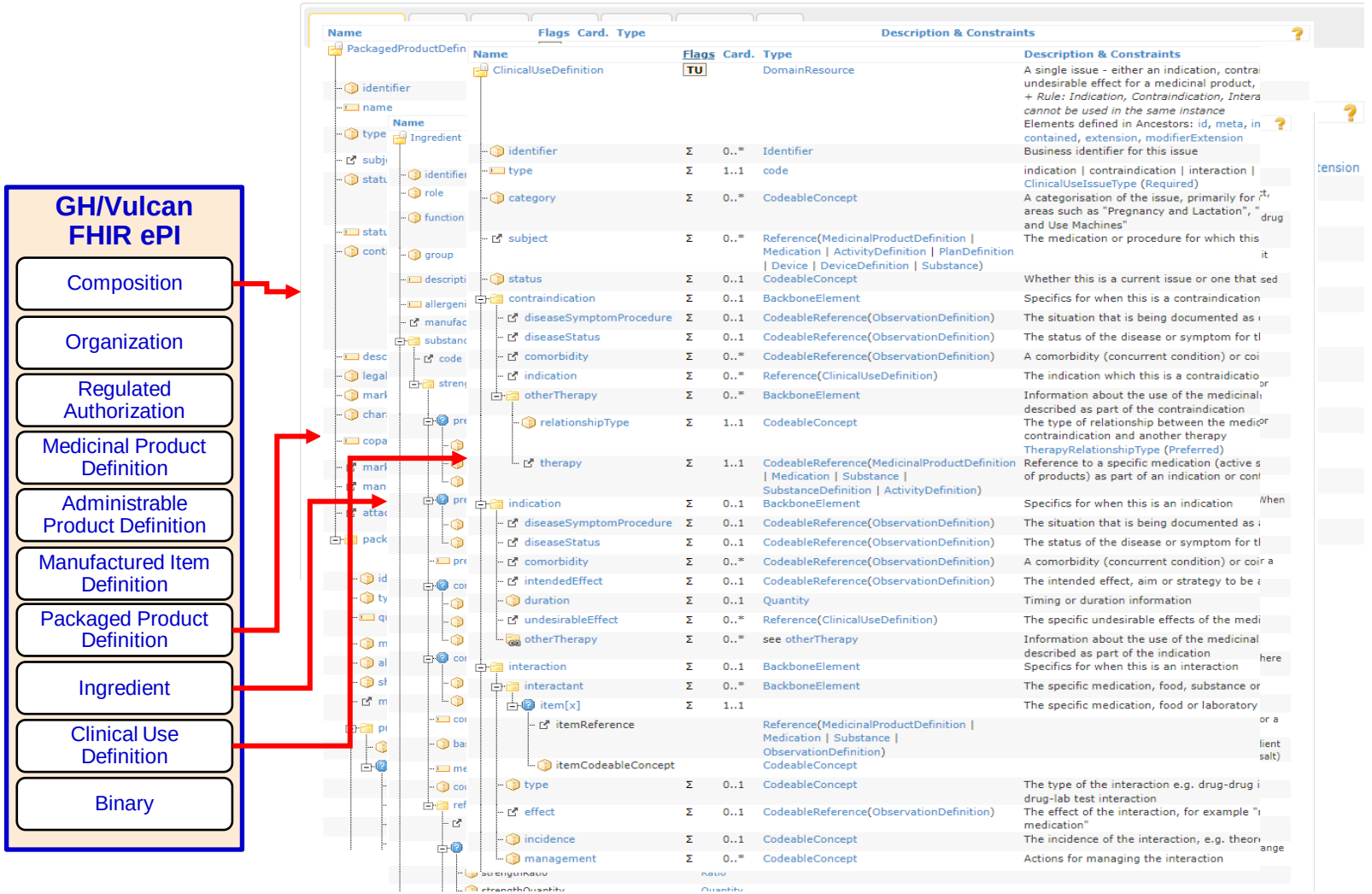
- All resources self contained in one Bundle.
- Same resources as the SPOR approach.

EMA’s SPOR Approach

- Bundle cross-references out to SPOR
- Same resources as common approach.



FHIR Overview: Creating an ePI with FHIR



FHIR template for Organizations

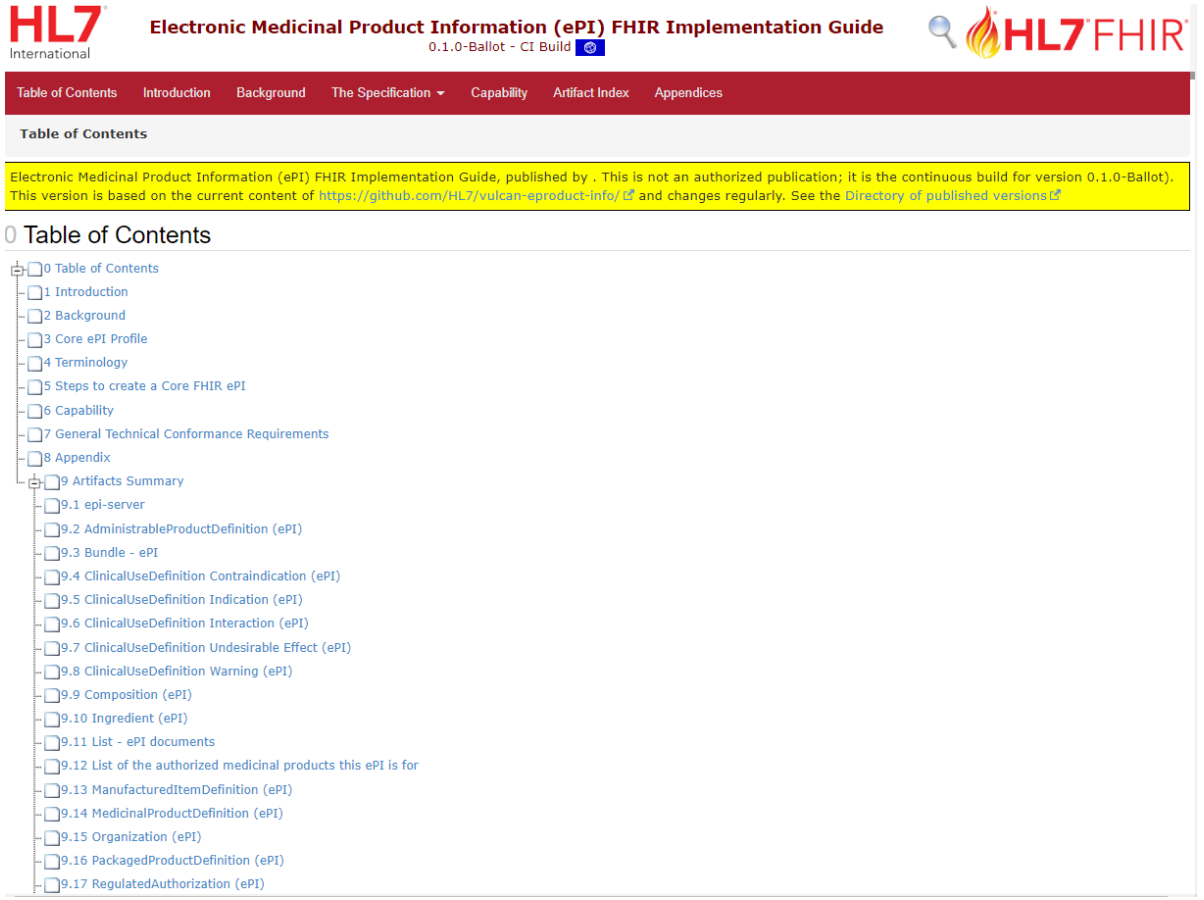
FHIR template for Packaging

FHIR template for Ingredients

FHIR template for Clinical Use

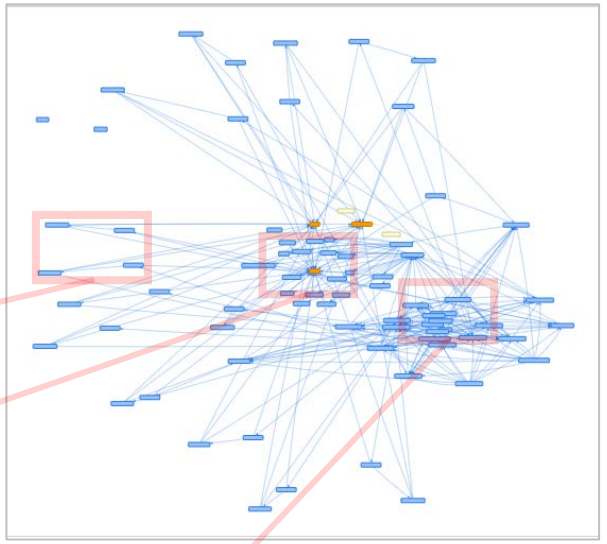
Electronic Medicinal Product - FHIR Implementation Guide

- Common technical standard for structuring and exchanging product information using FHIR and IDMP.
- A common starting point from which to build national ePIs.
- Implementation guides contain:
  - Narrative Content
  - Profiles
  - Examples
  - Capability
- Link to the Vulcan Electronic Medicinal Product (ePI) FHIR Implementation Guide

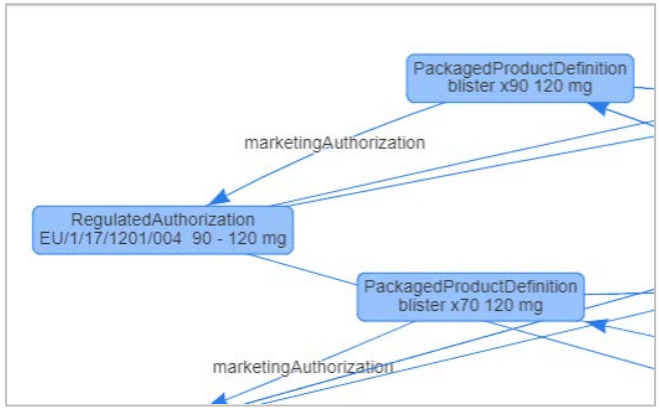


Example 1: Viewing FHIR ePI content as a graph

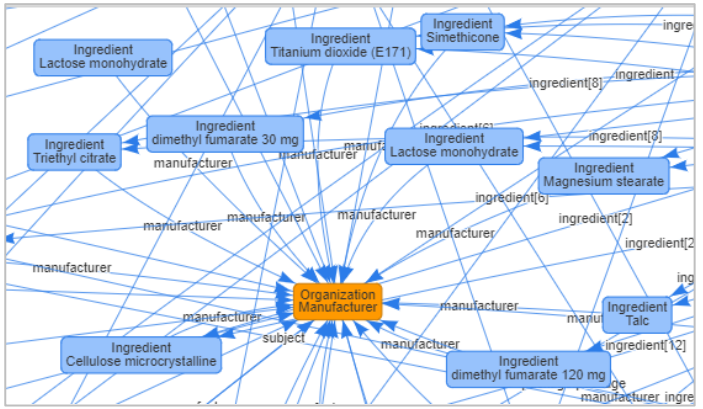
- The graph shows relationships between data objects.
- This graph shows 90+ data objects in a single ePI.
- Graphing all ePIs in a drug portfolio leads to benefits like rapid impact analysis of labelling or CMC changes (e.g., Safety updates; formulation or packaging changes).



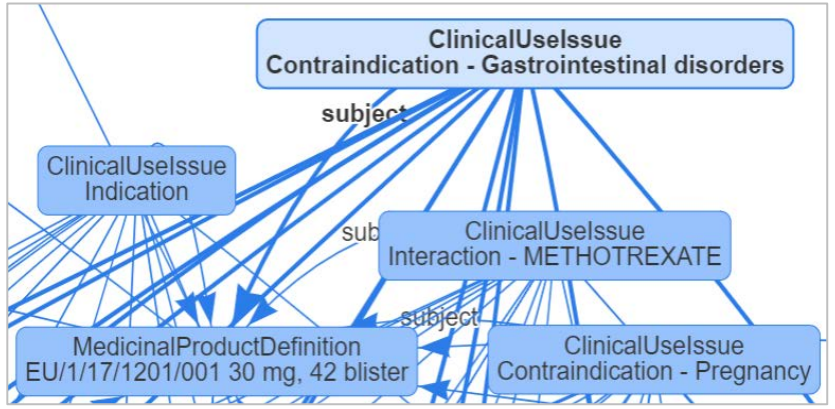
Packaging and Authorization



Ingredients and Manufacturer



Clinical Use Details



Example 2: ePI and the International Patient Summary

Gravitate Health

Header

Patient Summary (Maria Gravitate)

Summary Date: 2018-07-10T15:22:00+02:00

Patient

Birth Date: 1946-05-05

Name: IPS, Gravitate

Allergies and Intolerancies

- - Criticality: undefined
Pollen (256259004)

intolerance - food - Criticality: undefined
Intolerance to lactose (782415009)

Active problems / Diagnosis

undefined Psoriasis (9014002) [Uncoded text shown]: Psoriasis

1993 HT - Hypertension (38341003) [Uncoded text shown]: Hypertension

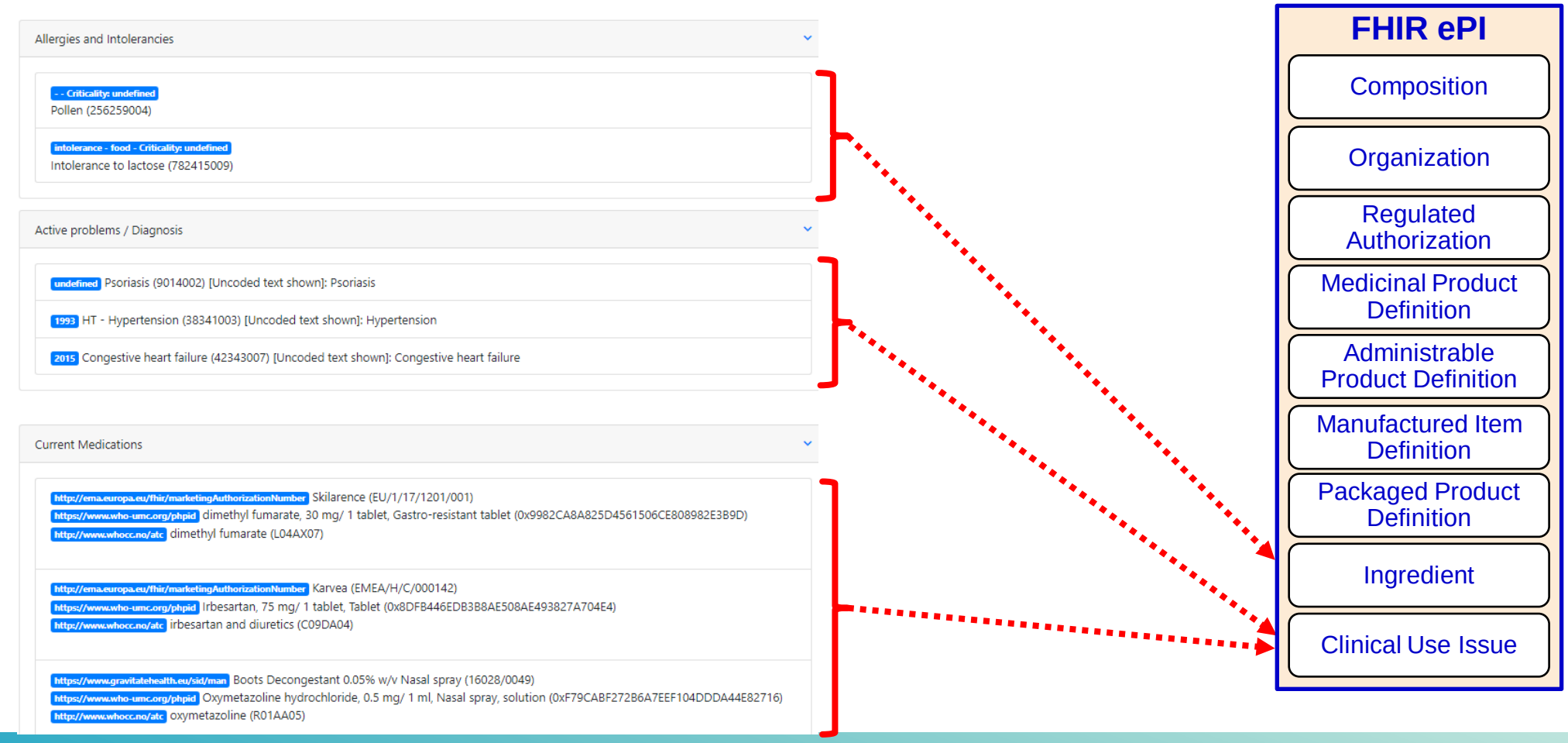
2015 Congestive heart failure (42343007) [Uncoded text shown]: Congestive heart failure

Current Medications

http://ema.europa.eu/fhir/marketingAuthorizationNumber Skilarence (EU/1/17/1201/001)
https://www.who-umc.org/phpid dimethyl fumarate, 30 mg/ 1 tablet, Gastro-resistant tablet (0x9982CA8A825D4561506CE808982E3B9D)
http://www.whocc.no/atc dimethyl fumarate (L04AX07)

http://ema.europa.eu/fhir/marketingAuthorizationNumber Karvea (EMEA/H/C/000142)
https://www.who-umc.org/phpid Irbesartan, 75 mg/ 1 tablet, Tablet (0x8DFB446EDB3B8AE508AE493827A704E4)
http://www.whocc.no/atc irbesartan and diuretics (C09DA04)

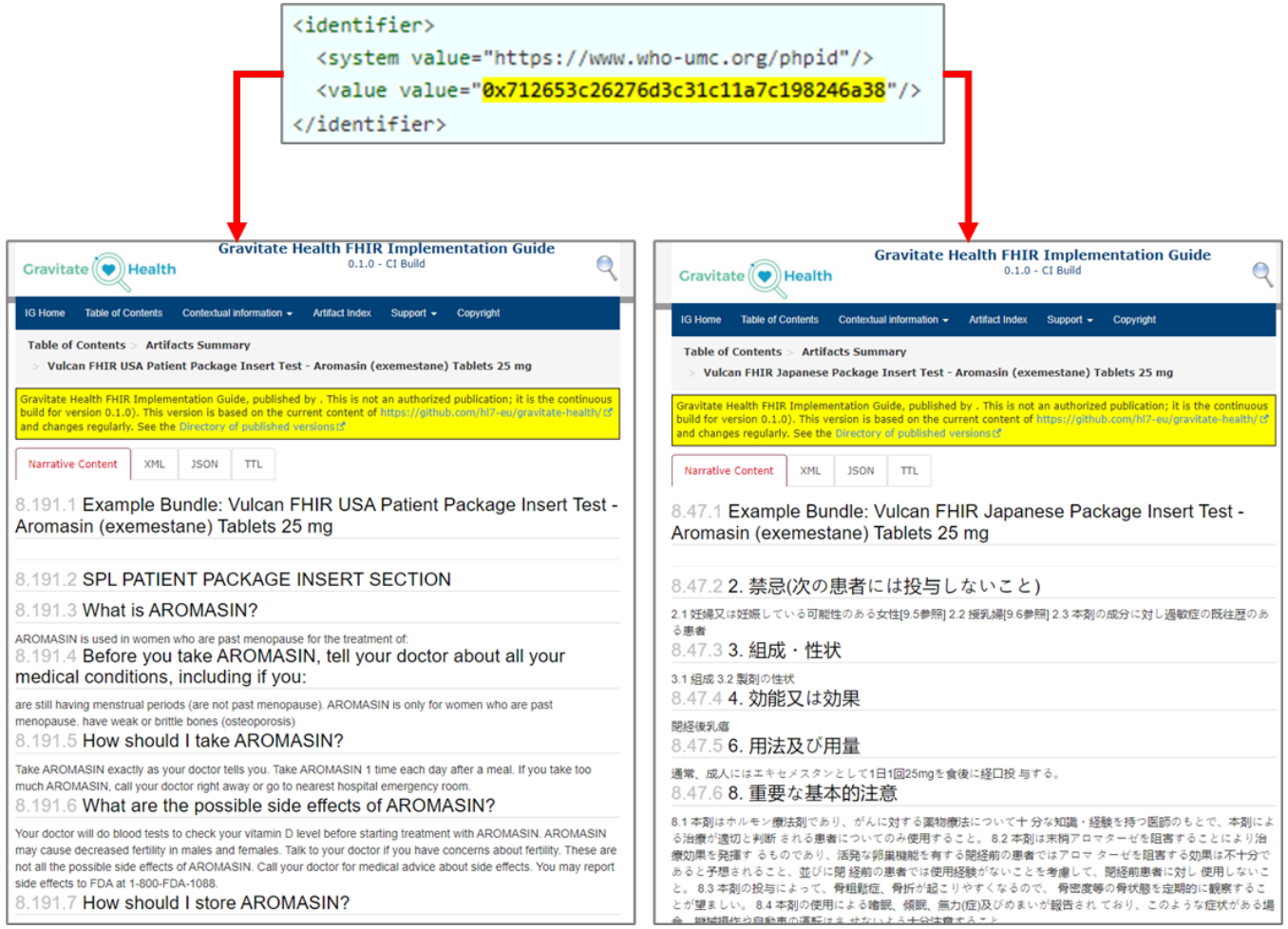
https://www.gravitatehealth.eu/sid/man Boots Decongestant 0.05% w/v Nasal spray (16028/0049)
https://www.who-umc.org/phpid Oxymetazoline hydrochloride, 0.5 mg/ 1 ml, Nasal spray, solution (0xF79CABF272B6A7EEF104DDDA44E82716)
http://www.whocc.no/atc oxymetazoline (R01AA05)



Example 3: IDMP Pharmaceutical Product Identifier (PhPID)

- US and Japanese Package Insert:
  - Two different labels.
  - Two different languages.
  - Same product: exemestane 25 mg tablets.
  - Same PhPID different formulations.

- Allows for an international search of all label documents with this PhPID.



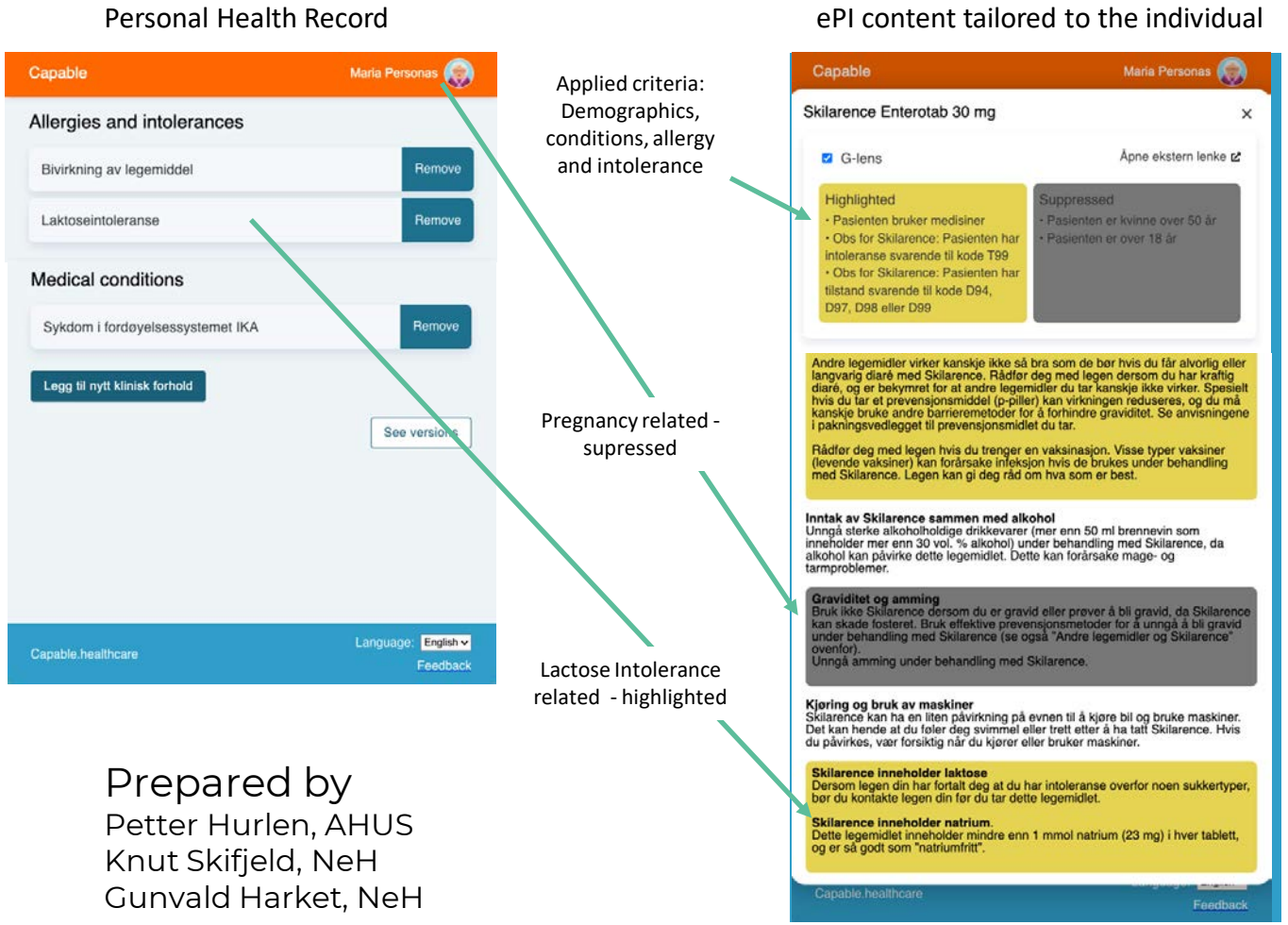
Example 4: Gravitate Health @ FHIR Connectathon – Focusing

Case:

- Highlight and supress ePI sections based on patient information

Approach:

- Identify ePI sections from Felleskatalogen
- Manually extracted knowledge, coded by ICPC-2, linking sections, represented as *FHIR Clinical Use Templates*
- Patient information, coded as ICPC-2, represented as *FHIR AllergyIntolerance* and *Condiction* templates
- Demographic information
- Software for highlighting and supressing text



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