

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

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Europe)



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

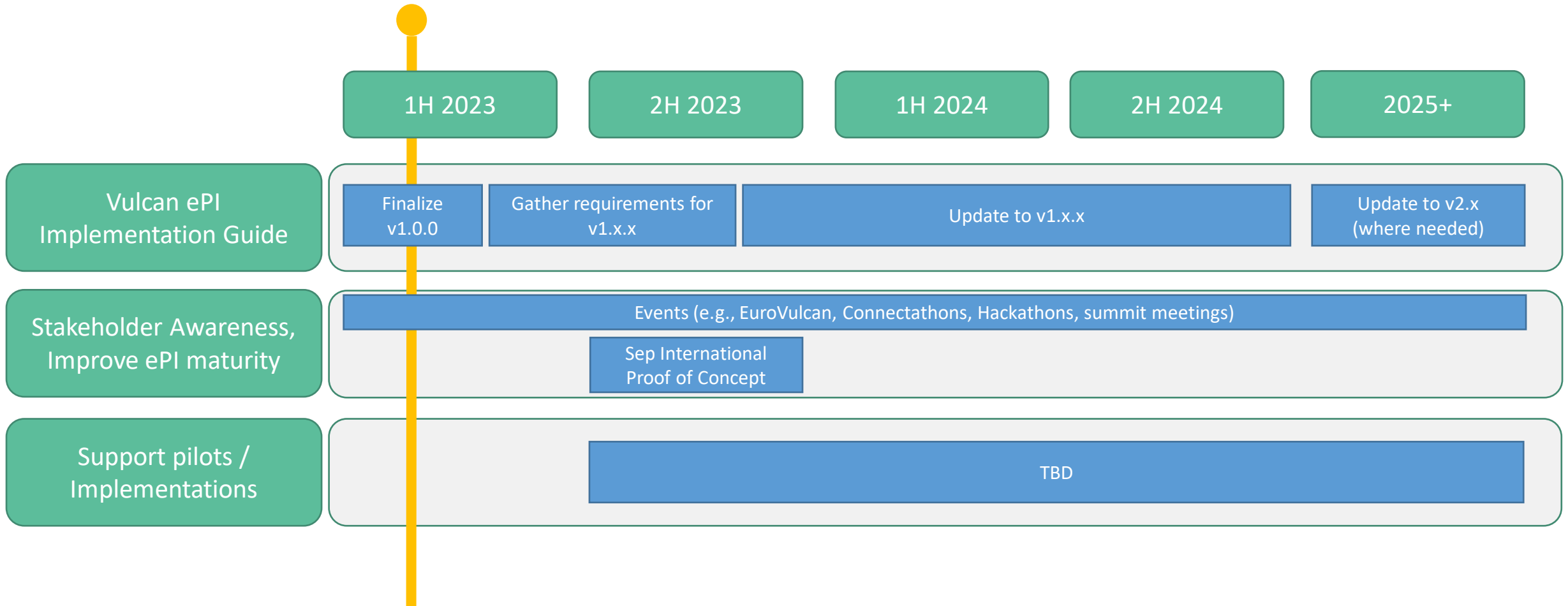
For discussion

What is needed to achieve these goals?



Draft Roadmap (Work in progress, need your input)

We are here



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
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7	MedicinalProductDefinition
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12	ClinicalUseDefinition
13	Substance

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

Same foundation, different implementation models

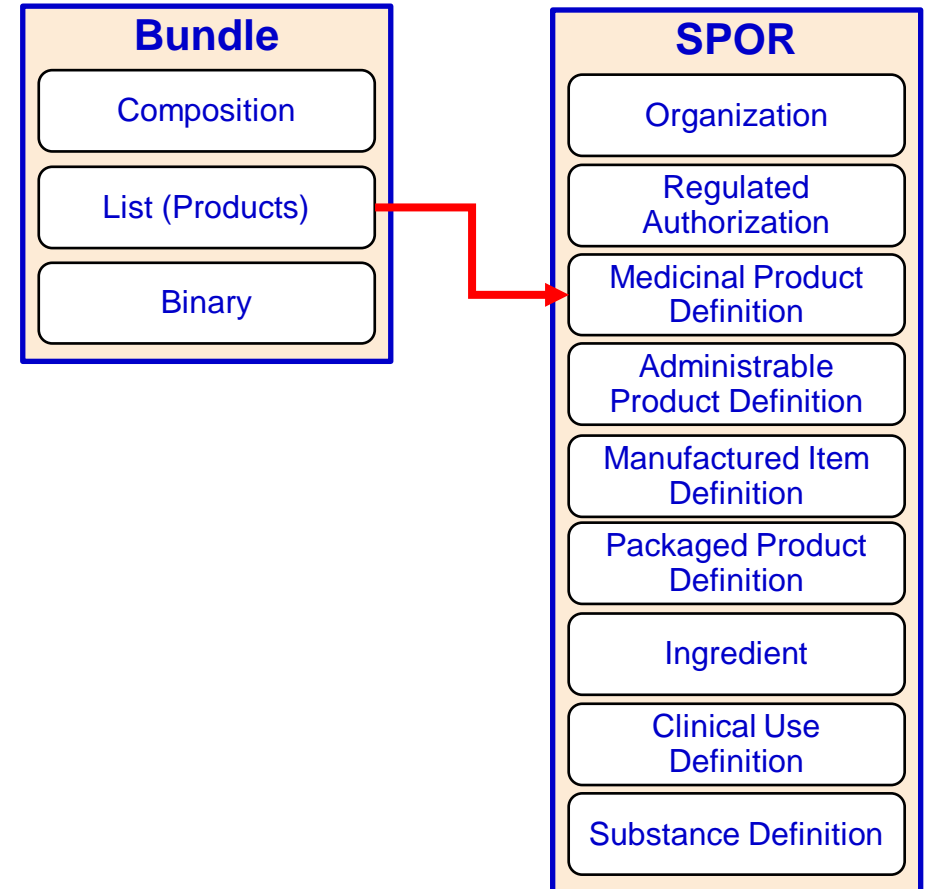
'Common' Approach

- 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

- GH/Vulcan FHIR ePI**
- Composition
- Organization
- Regulated Authorization
- Medicinal Product Definition
- Administrable Product Definition
- Manufactured Item Definition
- Packaged Product Definition
- Ingredient
- Clinical Use Definition
- Binary

Name	Flags	Card.	Type	Description & Constraints
PackagedProductDefinition				
identifier			DomainResource	
name				
type				
ingredient				
identifier	Σ	0..*	Identifier	Business identifier for this issue
type	Σ	1..1	code	indication contraindication interaction ClinicalUseIssueType (Required)
category	Σ	0..*	CodeableConcept	A categorisation of the issue, primarily for areas such as "Pregnancy and Lactation", "drug and Use Machines"
subject	Σ	0..*	Reference(MedicinalProductDefinition Medication ActivityDefinition PlanDefinition Device DeviceDefinition Substance)	The medication or procedure for which this is
status	Σ	0..1	CodeableConcept	Whether this is a current issue or one that is
contraindication	Σ	0..1	BackboneElement	Specifics for when this is a contraindication
diseaseSymptomProcedure	Σ	0..1	CodeableReference(ObservationDefinition)	The situation that is being documented as
diseaseStatus	Σ	0..1	CodeableReference(ObservationDefinition)	The status of the disease or symptom for th
comorbidity	Σ	0..*	CodeableReference(ObservationDefinition)	A comorbidity (concurrent condition) or coi
indication	Σ	0..*	Reference(ClinicalUseDefinition)	The indication which this is a contraindication
otherTherapy	Σ	0..*	BackboneElement	Information about the use of the medicinal described as part of the contraindication
relationshipType	Σ	1..1	CodeableConcept	The type of relationship between the medication or contraindication and another therapy
therapy	Σ	1..1	CodeableReference(MedicinalProductDefinition Medication Substance SubstanceDefinition ActivityDefinition)	Reference to a specific medication (active s of products) as part of an indication or conl
indication	Σ	0..1	BackboneElement	Specifics for when this is an indication
diseaseSymptomProcedure	Σ	0..1	CodeableReference(ObservationDefinition)	The situation that is being documented as
diseaseStatus	Σ	0..1	CodeableReference(ObservationDefinition)	The status of the disease or symptom for th
comorbidity	Σ	0..*	CodeableReference(ObservationDefinition)	A comorbidity (concurrent condition) or coi
intendedEffect	Σ	0..1	CodeableReference(ObservationDefinition)	The intended effect, aim or strategy to be
duration	Σ	0..1	Quantity	Timing or duration information
undesirableEffect	Σ	0..*	Reference(ClinicalUseDefinition)	The specific undesirable effects of the medi
otherTherapy	Σ	0..*	see otherTherapy	Information about the use of the medicinal described as part of the indication
interaction	Σ	0..1	BackboneElement	Specifics for when this is an interaction
interactant	Σ	0..*	BackboneElement	The specific medication, food, substance or
item[x]	Σ	1..1		The specific medication, food or laboratory
itemReference			Reference(MedicinalProductDefinition Medication Substance ObservationDefinition)	or a
itemCodeableConcept			CodeableConcept	(ient salt)
type	Σ	0..1	CodeableConcept	The type of the interaction e.g. drug-drug i drug-lab test interaction
effect	Σ	0..1	CodeableReference(ObservationDefinition)	The effect of the interaction, for example " medication"
incidence	Σ	0..1	CodeableConcept	The incidence of the interaction, e.g. theor
management	Σ	0..*	CodeableConcept	Actions for managing the interaction

FHIR template for Organizations

FHIR template for Packaging

FHIR template for Ingredients

FHIR template for Clinical Use

- 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](#)



HL7[®] International Electronic Medicinal Product Information (ePI) FHIR Implementation Guide 0.1.0-Ballot - CI Build 

Table of Contents Introduction Background The Specification ▾ Capability Artifact Index Appendices

Table of Contents

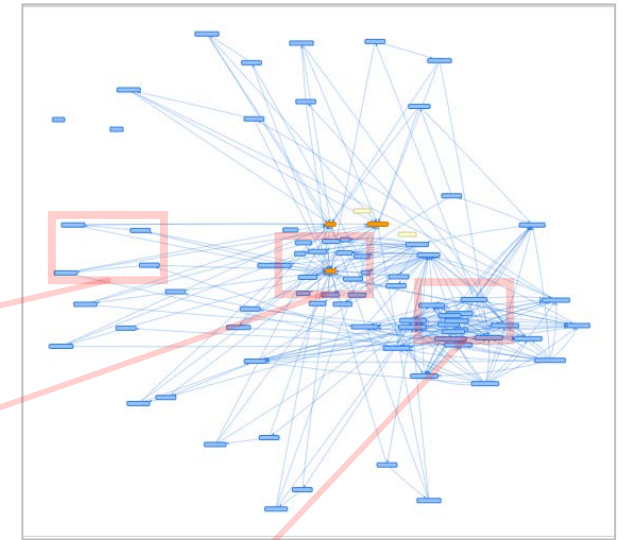
Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by . This is not an authorized publication; it is the continuous build for version 0.1.0-Ballot). This version is based on the current content of <https://github.com/HL7/vulcan-e-product-info/> and changes regularly. See the [Directory of published versions](#).

0 Table of Contents

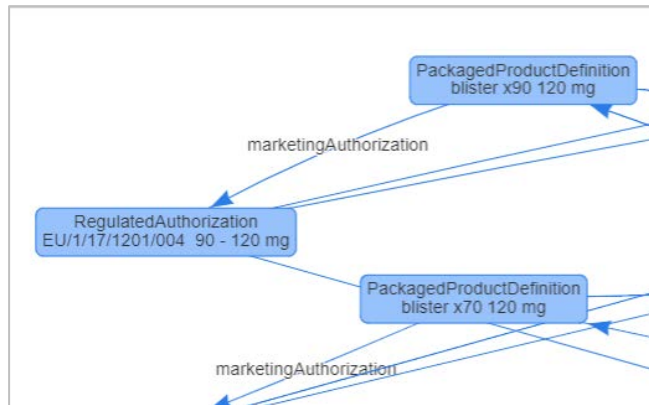
- 0 Table of Contents
- 1 Introduction
- 2 Background
- 3 Core ePI Profile
- 4 Terminology
- 5 Steps to create a Core FHIR ePI
- 6 Capability
- 7 General Technical Conformance Requirements
- 8 Appendix
- 9 Artifacts Summary
 - 9.1 epi-server
 - 9.2 AdministrableProductDefinition (ePI)
 - 9.3 Bundle - ePI
 - 9.4 ClinicalUseDefinition Contraindication (ePI)
 - 9.5 ClinicalUseDefinition Indication (ePI)
 - 9.6 ClinicalUseDefinition Interaction (ePI)
 - 9.7 ClinicalUseDefinition Undesirable Effect (ePI)
 - 9.8 ClinicalUseDefinition Warning (ePI)
 - 9.9 Composition (ePI)
 - 9.10 Ingredient (ePI)
 - 9.11 List - ePI documents
 - 9.12 List of the authorized medicinal products this ePI is for
 - 9.13 ManufacturedItemDefinition (ePI)
 - 9.14 MedicinalProductDefinition (ePI)
 - 9.15 Organization (ePI)
 - 9.16 PackagedProductDefinition (ePI)
 - 9.17 RegulatedAuthorization (ePI)

Example 1: Viewing FHIR ePI content as a graph

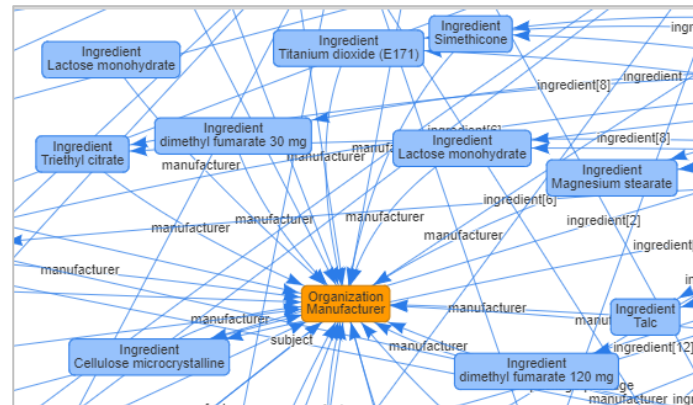
- The graph shows relationships between data objects.
- This graph shows 90+ data objects in a single ePI.
- Graphing all ePIs in a drug portfolio leads to benefits like rapid impact analysis of labelling or CMC changes (e.g., Safety updates; formulation or packaging changes).



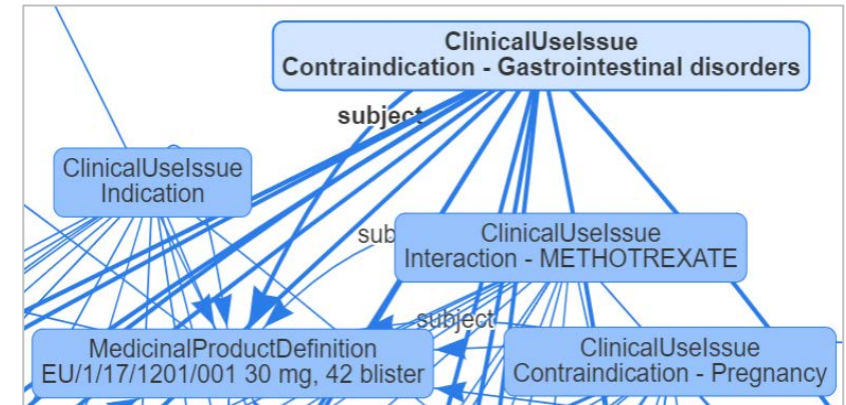
Packaging and Authorization



Ingredients and Manufacturer



Clinical Use Details



Example 2: ePI and the International Patient Summary

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 ▼

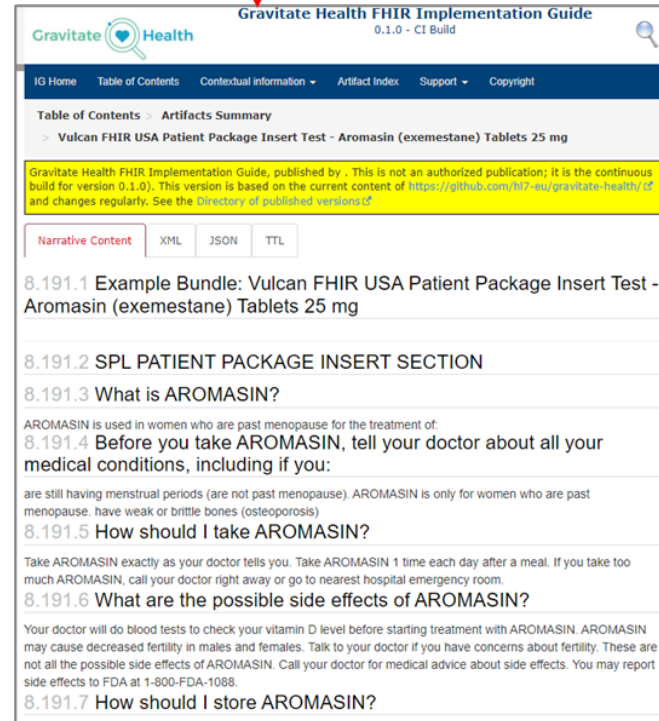
- <https://ema.europa.eu/this/marketingAuthorizationNumber> Skilarence (EU/1/17/1201/001)
<https://www.who-umc.org/phpid> dimethyl fumarate, 30 mg/ 1 tablet, Gastro-resistant tablet (0x9982CA8A825D4561506CE808982E3B9D)
<https://www.whooc.no/atc> dimethyl fumarate (L04AX07)
- <https://ema.europa.eu/this/marketingAuthorizationNumber> Karvea (EMA/H/C/000142)
<https://www.who-umc.org/phpid> Irbesartan, 75 mg/ 1 tablet, Tablet (0x8DFB446EDB388AE508AE493827A704E4)
<https://www.whooc.no/atc> Irbesartan and diuretics (C09DA04)
- <https://www.gravitatehealth.eu/sid/maa> 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)
<https://www.whooc.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.

```
<identifier>  
<system value="https://www.who-umc.org/phpid"/>  
<value value="0x712653c26276d3c31c11a7c198246a38"/>  
</identifier>
```



The screenshot shows the Gravitate Health FHIR Implementation Guide (0.1.0 - CI Build) for the USA Patient Package Insert Test - Aromasin (exemestane) Tablets 25 mg. The page includes a navigation menu, a table of contents, and a list of sections such as 8.191.1 Example Bundle, 8.191.2 SPL PATIENT PACKAGE INSERT SECTION, 8.191.3 What is AROMASIN?, 8.191.4 Before you take AROMASIN, tell your doctor about all your medical conditions, including if you: are still having menstrual periods (are not past menopause), 8.191.5 How should I take AROMASIN?, and 8.191.6 What are the possible side effects of AROMASIN?.



The screenshot shows the Gravitate Health FHIR Implementation Guide (0.1.0 - CI Build) for the Japanese Package Insert Test - Aromasin (exemestane) Tablets 25 mg. The page includes a navigation menu, a table of contents, and a list of sections such as 8.47.1 Example Bundle, 8.47.2 禁忌(次の患者には投与しないこと), 8.47.3 組成・性状, 8.47.4 効能又は効果, 8.47.5 用法及び用量, and 8.47.6 重要な基本的注意.

Example 4: Gravitare Health @ FHIR Connectathon – Focusing

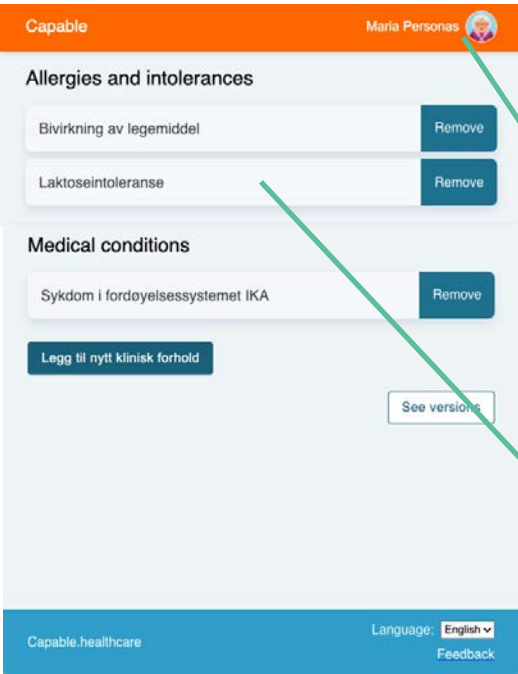
Case:

- Highlight and suppress 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 *Condition* templates
- Demographic information
- Software for highlighting and suppressing text

Personal Health Record

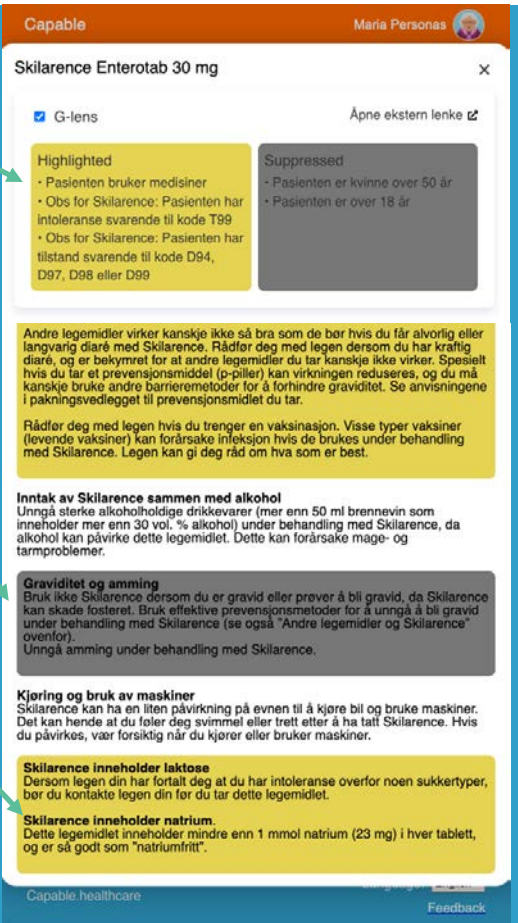


Applied criteria:
Demographics,
conditions, allergy
and intolerance

Pregnancy related -
supressed

Lactose Intolerance
related - highlighted

ePI content tailored to the individual



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