

# Gravitate-Health and HL7 Vulcan ePI Project

TECHNOLOGY COMMUNITY EVENTS – KICK OFF MEETING

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**2023-03-20**



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- (functionality found as settings by your name):

"Pfizer-Giovanna Ferrari" , "UiO-Anne Moen"

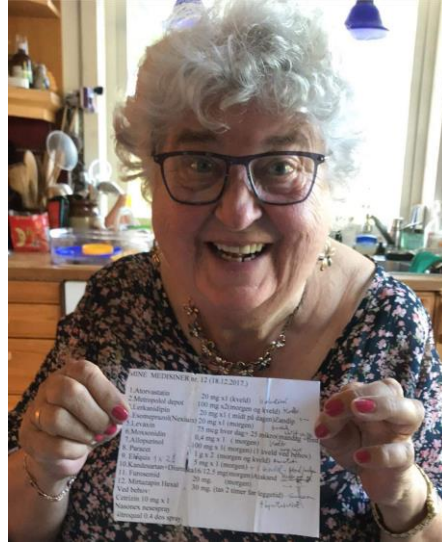
**Q&A** - post questions in Chat.

**Mute** microphone, consider your camera

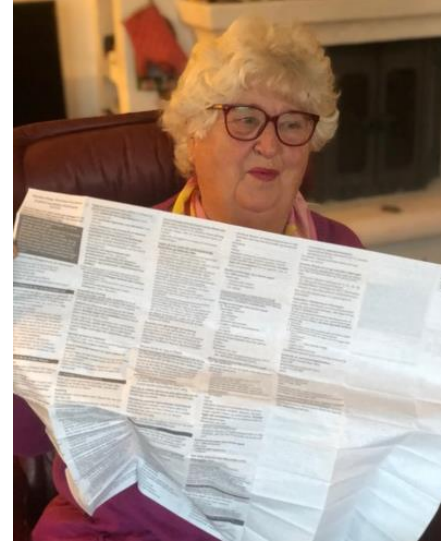
**Recording** - if presentations are recorded, they will be posted in YouTube channel "**Gravitate Health**"

1. The reason we are here
2. Objectives, Roadmap and Next Steps
3. Overview of the Gravitate-Health/Vulcan ePI project
4. Background on Gravitate-Health and HL7's Vulcan Accelerator

## Maria and her medicines



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO

### MISSION



#### The Gravitate Health mission

is to equip and empower citizens with digital information tools that make them confident, active, and responsive in their patient journey, specifically encouraging safe use of medicines for better health outcomes and quality of life.

### VISION



Engagement of citizens in their own health can only be achieved with access to actionable, understandable, relevant, reliable and evidence-based information that meets their specific needs, health context, and literacy level.

### AMBITION



To provide a key piece to advance this vision: the **Gravitate Lens (G-Lens)**, which focuses (but does not conceal or filter) approved electronic product information (ePI) content, and offers a route for patients to access trustworthy, up-to-date information that better meet their individual needs.



## Innovative Medicines Initiative (IMI) - Gravitate-Health

- 40 partners in Europe and USA; 60 months 11/20 – 10/25; €18.5m
- Delivering the Gravitate Lens (G-Lens) which focuses on ePI content and offers patients access to trustworthy, up-to-date information that better meets their individual needs



## HL7 Vulcan - FHIR Accelerator Program

- Designed to facilitate the creation and adoption of FHIR Implementation Guides (& related standards) that support global health data interoperability

## HL7 Biomedical Research and Regulation (BR&R)

- Creates standards that facilitate biomedical research and any subsequent regulatory evaluation of the safety, efficacy and quality of medical products.



## Univocal Identification of Medicinal Products (UNICOM)

- UNICOM aims to advance implementation of ISO IDMP (ID of Medicinal Products) standards in EU Member States drug databases to support safe cross-border ePrescription/eDispensation and effective pharmacovigilance.
- 19 countries are represented, including 26 national Drug and eHealth Agencies. budget € 21 MEuros.





# Objectives

## Goals

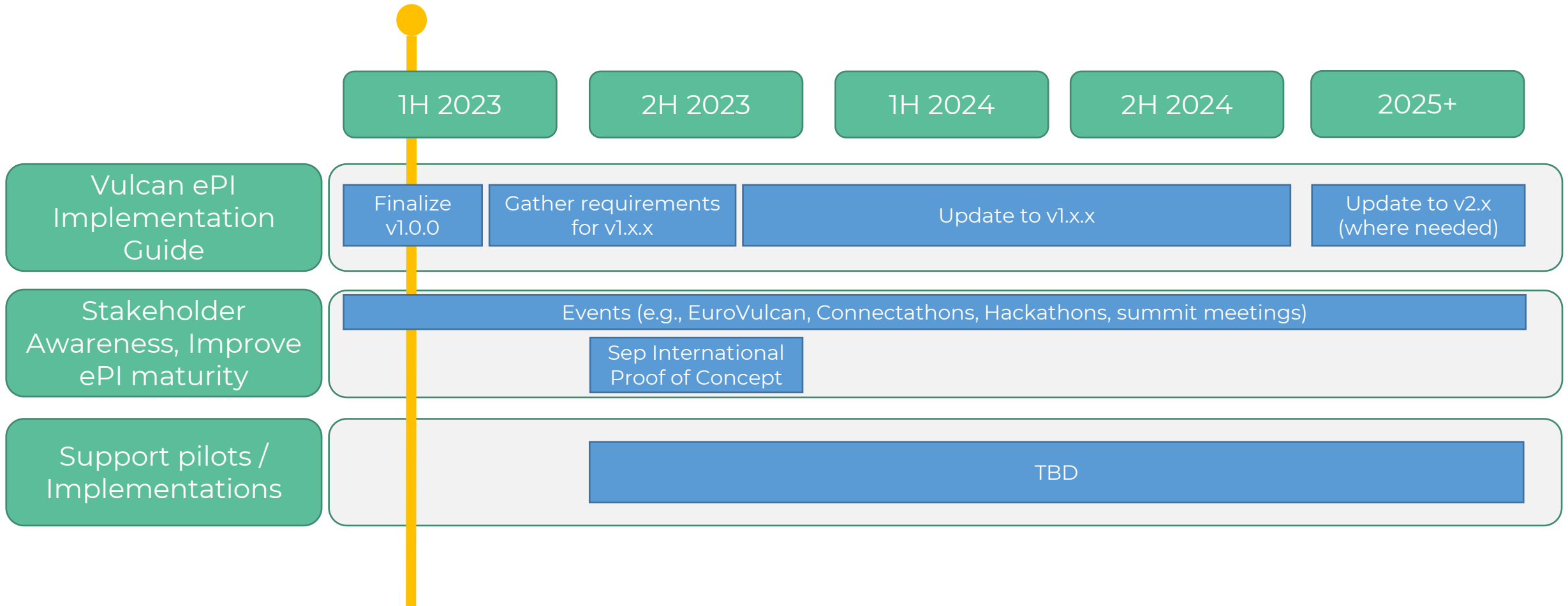
1. Develop a path to achieve critical mass (i.e., 80% of ePIs converted to FHIR) within two years.
2. Gain support from tech industry to help achieve Goal #1

## For discussion

What is needed to achieve these goals?

# Draft Roadmap (Work in progress, need your input)

**We are here**





1. What do you think is needed to ensure we can achieve the alignment across stakeholders to implement ePI as we have described (critical mass)?
2. Are there any pre-requisites or critical success factors missing from the current picture from the technology / software perspective?
3. Would you be willing to take part in collaborative open innovation workshops with this community to develop solutions for achieving our goals?

SURVEY LINK: <https://www.menti.com/alto13dje9mf>

**MENTI.COM 8109 1081**

# What is interoperability?

- The ability to easily access and exchange information across any systems.
- The internet, as a harmonized set of technical standards, introduced interoperability that revolutionized multiple sectors (e.g., eCommerce, eBanking).
- But the internet has not revolutionized health the way it did other sectors!



Internet



Wifi



email

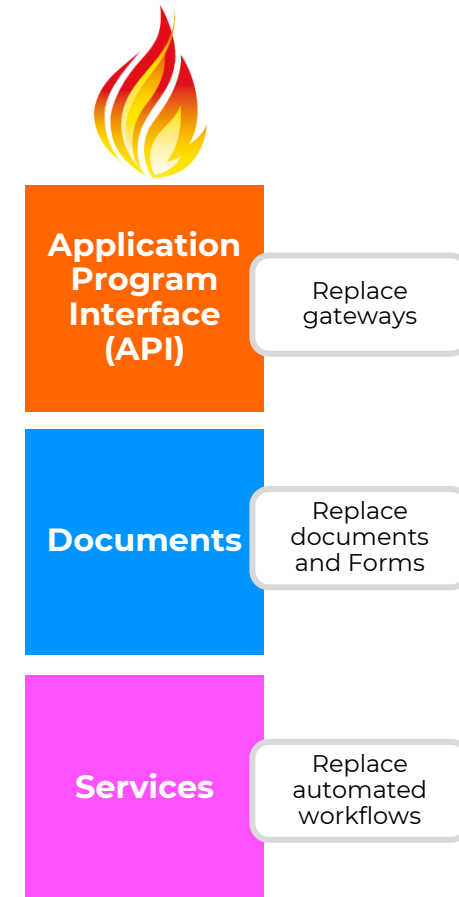


Health

FHIR

# FHIR Overview: Bringing the internet to health

- Standard for encoding and exchanging health data in a machine readable way.
- Based on common internet standards (e.g., same tech foundation commonly used by Microsoft, Amazon, Apple, Google).
- Significantly easier to work with and reduces implementation cost.
- Includes 151 pre-fabricated, ready to use templates (e.g., Medicinal Product, Organization, Ingredient).
- Multiple projects underway that will replace the technical foundation of health and biopharma (E.g., labelling, CMC, AE, Clinical)



# 151 FHIR Resources (Prefabricated Templates)

Foundation	<b>Conformance</b> <ul style="list-style-type: none"> <li>CapabilityStatement 1</li> <li>CapabilityStatement2 0</li> <li>StructureDefinition 1</li> <li>ImplementationGuide 1</li> <li>SearchParameter 3</li> <li>MessageDefinition 1</li> <li>OperationDefinition 1</li> <li>CompartmentDefinition 1</li> <li>StructureMap 2</li> <li>GraphDefinition 1</li> <li>ExampleScenario 0</li> </ul>	<b>Terminology</b> <ul style="list-style-type: none"> <li>CodeSystem 1</li> <li>ValueSet 1</li> <li>ConceptMap 1</li> <li>NamingSystem 1</li> <li>TerminologyCapabilities 1</li> </ul>	<b>Security</b> <ul style="list-style-type: none"> <li>Provenance 3</li> <li>AuditEvent 3</li> <li>Permission 0</li> <li>Consent 2</li> </ul>	<b>Documents</b> <ul style="list-style-type: none"> <li>Composition 2</li> <li>DocumentManifest 2</li> <li>DocumentReference 3</li> <li>CatalogEntry 0</li> </ul>	<b>Other</b> <ul style="list-style-type: none"> <li>Basic 1</li> <li>Binary 1</li> <li>Bundle 1</li> <li>Linkage 0</li> <li>MessageHeader 4</li> <li>OperationOutcome 1</li> <li>Parameters 1</li> <li>Subscription 2</li> <li>SubscriptionStatus 0</li> <li>SubscriptionTopic 0</li> </ul>
	<b>Individuals</b> <ul style="list-style-type: none"> <li>Patient 1</li> <li>Practitioner 3</li> <li>PractitionerRole 2</li> <li>RelatedPerson 2</li> <li>Person 2</li> <li>Group 0</li> </ul>	<b>Entities #2</b> <ul style="list-style-type: none"> <li>BiologicallyDerivedProduct 0</li> <li>Device 2</li> <li>DeviceMetric 1</li> <li>NutritionProduct 0</li> </ul>	<b>Workflow</b> <ul style="list-style-type: none"> <li>Appointment 3</li> <li>AppointmentResponse 3</li> <li>Schedule 3</li> <li>Slot 3</li> <li>VerificationResult 0</li> </ul>	<b>Management</b> <ul style="list-style-type: none"> <li>EpisodeOfCare 2</li> <li>Flag 1</li> <li>List 1</li> <li>Library 3</li> </ul>	
	<b>Summary</b> <ul style="list-style-type: none"> <li>AllergyIntolerance 3</li> <li>AdverseEvent 0</li> <li>Condition (Problem) 3</li> <li>Procedure 3</li> <li>FamilyMemberHistory 2</li> <li>ClinicalImpression 0</li> <li>DetectedIssue 2</li> </ul>	<b>Diagnostics</b> <ul style="list-style-type: none"> <li>DocumentReference 3</li> <li>DiagnosticReport 3</li> <li>Specimen 2</li> <li>BodyStructure 1</li> <li>ImagingStudy 3</li> <li>QuestionnaireResponse 3</li> <li>MolecularSequence 1</li> </ul>	<b>Medications</b> <ul style="list-style-type: none"> <li>MedicationRequest 3</li> <li>MedicationAdministration 2</li> <li>MedicationDispense 2</li> <li>MedicationUsage 3</li> <li>Medication 3</li> <li>MedicationKnowledge 1</li> <li>Immunization 3</li> <li>ImmunizationEvaluation 0</li> <li>ImmunizationRecommendation 1</li> </ul>	<b>Care Provision</b> <ul style="list-style-type: none"> <li>CarePlan 2</li> <li>CareTeam 2</li> <li>Goal 2</li> <li>ServiceRequest 2</li> <li>NutritionOrder 2</li> <li>VisionPrescription 2</li> <li>RiskAssessment 1</li> <li>RequestGroup 2</li> </ul>	<b>Request &amp; Response</b> <ul style="list-style-type: none"> <li>Communication 2</li> <li>CommunicationRequest 2</li> <li>DeviceRequest 0</li> <li>DeviceUsage 0</li> <li>GuidanceResponse 2</li> <li>SupplyRequest 1</li> <li>SupplyDelivery 1</li> <li>InventoryReport 0</li> </ul>
Clinical	<b>Support</b> <ul style="list-style-type: none"> <li>Coverage 2</li> <li>CoverageEligibilityRequest 2</li> <li>CoverageEligibilityResponse 2</li> <li>EnrollmentRequest 0</li> <li>EnrollmentResponse 0</li> </ul>	<b>Billing</b> <ul style="list-style-type: none"> <li>Claim 2</li> <li>ClaimResponse 2</li> <li>Invoice 0</li> </ul>	<b>Payment</b> <ul style="list-style-type: none"> <li>PaymentNotice 2</li> <li>PaymentReconciliation 2</li> </ul>	<b>General</b> <ul style="list-style-type: none"> <li>Account 2</li> <li>ChargeItem 0</li> </ul>	
	<b>Public Health &amp; Research</b> <ul style="list-style-type: none"> <li>ResearchStudy 0</li> <li>ResearchSubject 0</li> </ul>	<b>Definitional Artifacts</b> <ul style="list-style-type: none"> <li>ActivityDefinition 3</li> <li>ConditionDefinition 0</li> <li>DeviceDefinition 1</li> <li>EventDefinition 0</li> <li>ObservationDefinition 1</li> <li>PlanDefinition 3</li> <li>Questionnaire 3</li> <li>SpecimenDefinition 1</li> </ul>	<b>Evidence-Bas</b> <ul style="list-style-type: none"> <li>Citation 0</li> <li>Evidence 1</li> <li>EvidenceReport 0</li> <li>EvidenceVariab 0</li> </ul>		
Financial					
Specialized					

## 8.6.4 Resource Content

Structure
UML
XML
JSON
Turtle
R3 Diff
All

**Structure**

Name	Flags	Card.	Type	Description & Constraints
Organization	TU		DomainResource	A grouping of people or organizations with a common purpose + Rule: The organization SHALL at least have a name or an identifier, and possibly more than one Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension Identifies this organization across multiple systems
identifier	Σ I	0..*	Identifier	
active	? I Σ	0..1	boolean	Whether the organization's record is still in active use
type	Σ	0..*	CodeableConcept	Kind of organization OrganizationType (Example)
name	Σ I	0..1	string	Name used for the organization
alias		0..*	string	A list of alternate names that the organization is known as, or was known as in the past
telecom	I	0..*	ContactPoint	A contact detail for the organization + Rule: The telecom of an organization can never be of use 'home'
address	I	0..*	Address	An address for the organization
partOf		0..1		
contact		0..*		
purpose		0..1		
name		0..1		
telecom		0..*		
address		0..1		
endpoint		0..*		

Structure
UML
XML
JSON
Turtle
R3 Diff
All

**Structure**

Name	Flags	Card.	Type	Description & Constraints
Address	Σ N		Element	An address expressed using postal conventions (as opposed to Elements defined in Ancestors: id, extension
use	? I Σ	0..1	code	home   work   temp   old   billing - purpose of this address AddressUse (Required)
type	Σ	0..1	code	postal   physical   both AddressType (Required)
text	Σ	0..1	string	Text representation of the address
line	Σ	0..*	string	Street name, number, direction & P.O. Box etc. This repeating element order: The order in which lines should
city	Σ	0..1	string	Name of city, town etc.
district	Σ	0..1	string	District name (aka county)
state	Σ	0..1	string	Sub-unit of country (abbreviations ok)
postalCode	Σ	0..1	string	Postal code for area
country	Σ	0..1	string	Country (e.g. may be ISO 3166 2 or 3 letter code)
period	Σ	0..1	Period	Time period when address was/is in use

XML Template

```

<organization xmlns="http://hl7.org/fhir">
  <!-- from Resource: id, meta, implicitRules, and language -->
  <!-- from DomainResource: text, contained, extension, and modifierExtension -->
  <identifier<!-- [ 1 ] 0..* Identifier Identifies this organization across multiple systems --></identifier>
  <active value="[boolean]"><!-- 0..1 Whether the organization's record is still in active use -->
  <type<!-- 0..* CodeableConcept Kind of organization --></type>
  <name value="[string]"><!-- [ 1 ] 0..1 Name used for the organization -->
  <alias value="[string]"><!-- 0..* A list of alternate names that the organization is known as, or was known as in the past -->
  <!--
  <description value="[string]"><!-- 0..1 Additional details about the Organization that could be displayed as further informa
  tion to identify the Organization beyond its name -->
  <contact<!-- 0..* ExtendedContactDetail Official contact details for the organization --></contact>
  <partOf<!-- 0..1 Reference(Organization) The organization of which this organization forms a part --></partOf>
  <endpoint<!-- 0..* Reference(Endpoint) Technical endpoints providing access to services operated for the organization --></e
  ndpoint>
  <qualification> <!-- 0..* Qualifications, certifications, accreditations, licenses, training, etc pertaining to the provisio
  n of care -->
  <identifier<!-- 0..* Identifier An identifier for this qualification for the organization --></identifier>
  <code<!-- 1..1 CodeableConcept Coded representation of the qualification --></code>
  <period<!-- 0..1 Period Period during which the qualification is valid --></period>
  <issuer<!-- 0..1 Reference(Organization) Organization that regulates and issues the qualification --></issuer>
  </qualification>
</organization>
  
```

# Overview of the GH/Vulcan FHIR ePI Model

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

Name	Flags	Card.	Type	Description & Constraints
<b>ClinicalUseDefinition</b>	<b>TU</b>		DomainResource	
identifier		Σ 0..*	Identifier	Business identifier for this issue
name				
type		Σ 1..1	code	indication   contraindication   interaction   ClinicalUseIssueType (Required)
ingredient		Σ 0..*	CodeableConcept	A categorisation of the issue, primarily for areas such as "Pregnancy and Lactation", "drug and Use Machines"
category		Σ 0..*	CodeableConcept	The medication or procedure for which this
subject		Σ 0..*	Reference(MedicinalProductDefinition   Medication   ActivityDefinition   PlanDefinition   Device   DeviceDefinition   Substance)	Whether this is a current issue or one that is used
status		Σ 0..1	CodeableConcept	Specifics for when this is a contraindication
contraindication		Σ 0..1	BackboneElement	The situation that is being documented as
diseaseSymptomProcedure		Σ 0..1	CodeableReference(ObservationDefinition)	The status of the disease or symptom for th
diseaseStatus		Σ 0..1	CodeableReference(ObservationDefinition)	A comorbidity (concurrent condition) or coi
comorbidity		Σ 0..*	CodeableReference(ObservationDefinition)	The indication which this is a contraindication
indication		Σ 0..*	Reference(ClinicalUseDefinition)	Information about the use of the medicinal described as part of the contraindication
otherTherapy		Σ 0..*	BackboneElement	The type of relationship between the medicof
relationshipType		Σ 1..1	CodeableConcept	TherapyRelationshipType (Preferred)
therapy		Σ 1..1	CodeableReference(MedicinalProductDefinition   Medication   Substance   ActivityDefinition)	Reference to a specific medication (active s of products) as part of an indication or con
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	lient 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 "i 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

# Use example 1: Same foundation, two implementation models

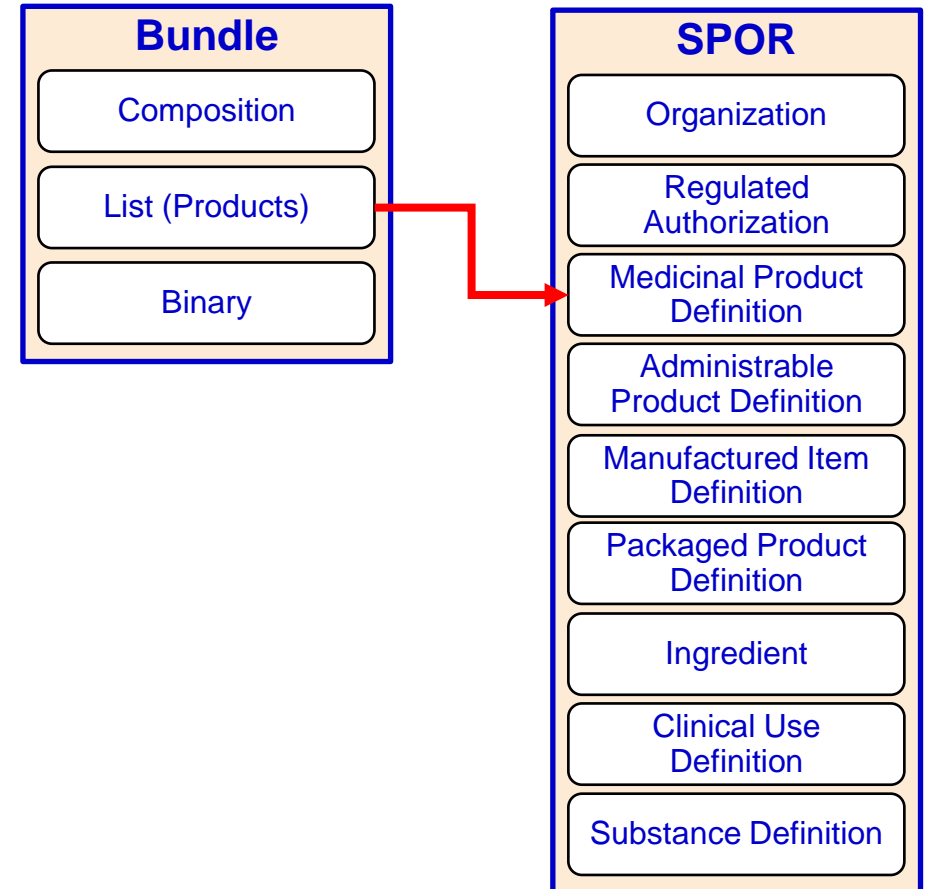
## 'Vulcan' Approach

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



## EMA's SPOR Approach

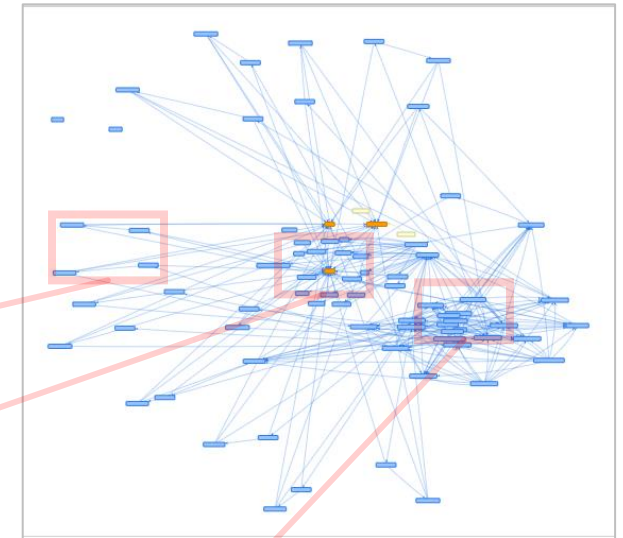
- Bundle cross-references out to SPOR
- Same resources as Vulca approach.



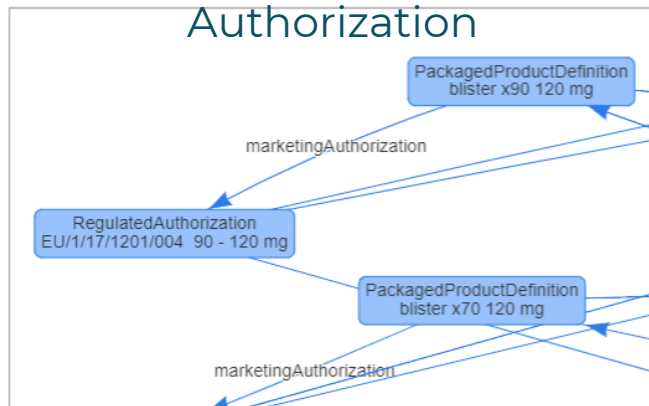


# Use Example 2: Viewing FHIR ePI content as a graph

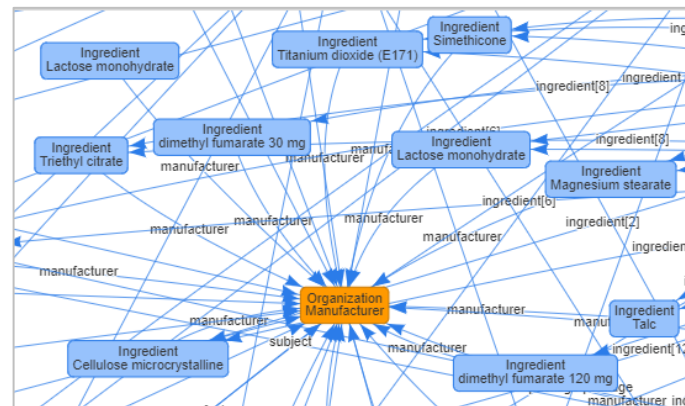
- The graph shows relationships between data objects.
- This graph shows 90+ data objects in a single ePI.
- Graphing all ePIs in a drug portfolio leads to benefits like rapid impact analysis of labelling or CMC changes (e.g., Safety updates; formulation or packaging changes).



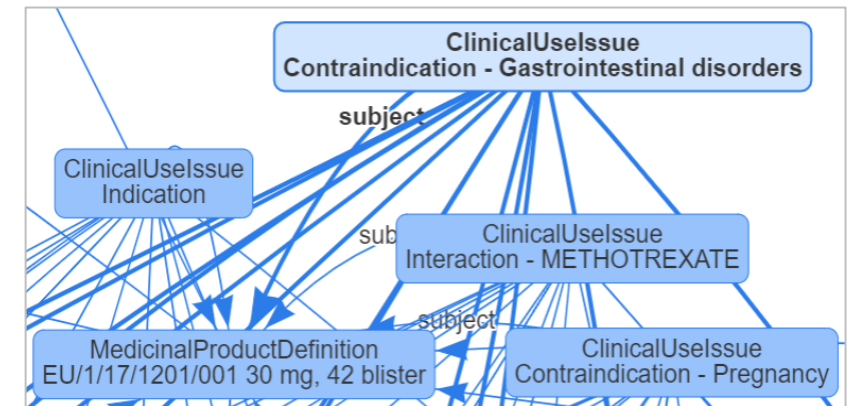
Packaging and Authorization



Ingredients and Manufacturer



Clinical Use Details



# Use example 3: Tailored ePI

## 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

Capable Maria Personås

Allergies and intolerances

Bivirkning av legemiddel Remove

Laktoseintoleranse Remove

Medical conditions

Sykdom i fordøyelsessystemet IKA Remove

Legg til nytt klinisk forhold

See versions

Capable.healthcare Language: English Feedback

Applied criteria: Demographics, conditions, allergy and intolerance

Pregnancy related - suppressed

Lactose Intolerance related - highlighted

ePI content tailored to the individual

Capable Maria Personås

Skilarence Enterotab 30 mg

G-lens Åpne ekstern lenke

**Highlighted**

- Pasienten bruker medisiner
- Obs for Skilarence: Pasienten har intoleranse svarende til kode T99
- Obs for Skilarence: Pasienten har tilstand svarende til kode D94, D97, D98 eller D99

**Suppressed**

- Pasienten er kvinne over 50 år
- Pasienten er over 18 år

Andre legemidler virker kanskje ikke så bra som de bør hvis du får alvorlig eller langvarig diaré med Skilarence. Rådfrå deg med legen dersom du har kraftig diaré, og er bekymret for at andre legemidler du tar kanskje ikke virker. Spesielt hvis du tar et prevensjonsmiddel (p-piller) kan virkningen reduseres, og du må kanskje bruke andre barrieremetoder for å forhindre graviditet. Se anvisningene i pakningsvedlegget til prevensjonsmidlet du tar.

Rådfrå deg med legen hvis du trenger en vaksinasjon. Visse typer vaksiner (levende vaksiner) kan forårsake infeksjon hvis de brukes under behandling med Skilarence. Legen kan gi deg råd om hva som er best.

**Inntak av Skilarence sammen med alkohol**

Unngå sterke alkoholholdige drikkevarer (mer enn 50 ml brennevin som inneholder mer enn 30 vol. % alkohol) under behandling med Skilarence, da alkohol kan påvirke dette legemidlet. Dette kan forårsake mage- og tarmproblemer.

**Graviditet og amming**

Bruk ikke Skilarence dersom du er gravid eller prøver å bli gravid, da Skilarence kan skade fosteret. Bruk effektive prevensjonsmetoder for å unngå å bli gravid under behandling med Skilarence (se også "Andre legemidler og Skilarence" ovenfor). Unngå amming under behandling med Skilarence.

**Kjøring og bruk av maskiner**

Skilarence kan ha en liten påvirkning på evnen til å kjøre bil og bruke maskiner. Det kan hende at du føler deg svimmel eller trett etter å ha tatt Skilarence. Hvis du påvirkes, vær forsiktig når du kjører eller bruker maskiner.

**Skilarence inneholder laktose**

Dersom legen din har fortalt deg at du har intoleranse overfor noen sukkertyper, bør du kontakte legen din før du tar dette legemidlet.

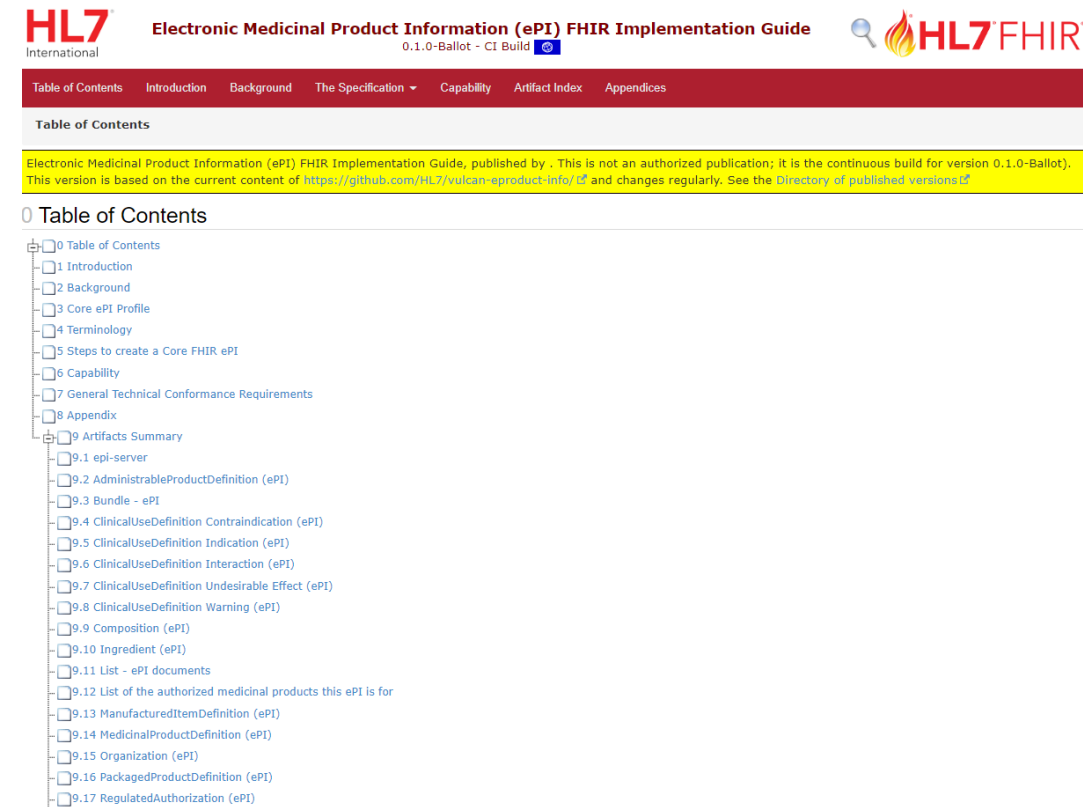
**Skilarence inneholder natrium.**

Dette legemidlet inneholder mindre enn 1 mmol natrium (23 mg) i hver tablett, og er så godt som "natriumfritt".

Capable.healthcare Feedback

Prepared by  
Petter Hurlen, AHUS  
Knut Skifjeld, NeH  
Gunvald Harket, NeH

- Common technical standard for structuring and exchanging product information using FHIR and IDMP.
- A common starting point from which to build national ePIs.
- Received quorum in HL7's Jan '23 ballot
- [Link to 2023-Jan ballot version of the 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)