

Vulcan Gravitate Health **ePI/IPS and SPL-FHIR Track** 34 Connectathon

September 5th 2023



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The Gravitate-Health Consortium



40 partners in
Europe and USA



60 months
11/20 – 10/25



18.5 mill €



European start
Global Outreach

ACADEMIA / RESEARCH INSTITUTES

Universitetet i Oslo (UiO) (Coordinator)
Karolinska Institute (KI)
Universidad Politécnica de Madrid (UPM)
Empirica (EMP)
Norwegian Center for eHealth research (NSE)
The European Institute for Innovation
through Health Data (i-HD)
Università Cattolica del Sacro Cuore (UCSC)
University of Copenhagen (UCPH)
Trinity College Dublin (Trinity)
University College Dublin (UCD)

REGULATORS & PRODUCT INFORMATION PROVIDERS

Norwegian Medicines Agency (NoMA)
Spanish Drug Agency (AEMPS)
Dutch Medicines Evaluation Board (CBG)

STANDARDISATION & OTHER STAKEHOLDERS

HL7 Europe
PredictBy*

PATIENT ORGANISATIONS & CONSUMER GROUPS

Forum Européen des Patients (EPF)



DISSEMINATION & COMMUNICATION

European Connected Health Alliance (ECHA)
HIMSS Europe
MINDVIEW*
The Synergist*



HEALTH CARE PROVIDERS & PAYERS

Akershus University Hospital (AHUS)
Shared Services of Ministry of Health (SPMS)
Servicio Madrileño de Salud (SERMAS)
Beth-Israel Deaconess Medical Center (BIDMC)
Karolinska Institute (KI)

DIGITAL TECHNICAL EXPERTISE

Datawizard SRL*
GuardTime*
Norsk e-Helse*
FrisQ*
Trifork

EFPIA & IMI2 Associated PARTNERS

Pfizer Limited (Project Lead)
AstraZeneca
Bayer
Grünenthal
Eli Lilly
Medidata
Viatris
Novartis
Roche
UCB Biopharma SRL
Datapharm

**SME (small and medium sized enterprises)*

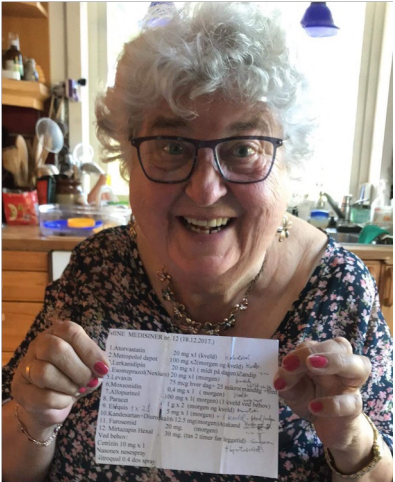
Consortium Partners



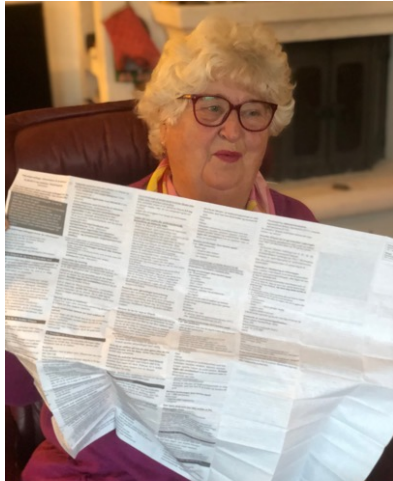


Gravitate-Health project in a nut-shell

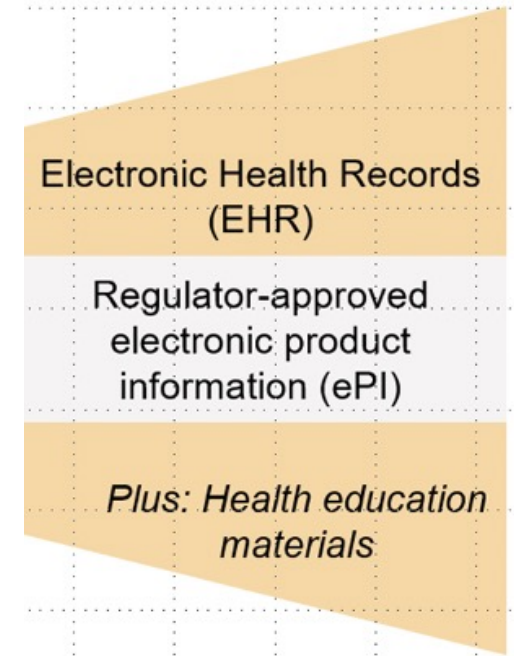
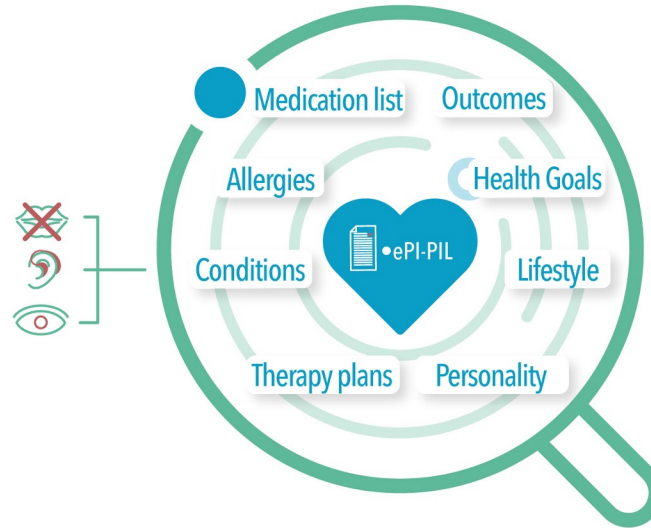
Maria and her medicines



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO



Research question

How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?

Key deliverables

- Federated open source platform with G-Lens services
- White Paper on strategies for future use of ePI
- Pilot studies evaluation
- Sustainable impacts



Illustrating the work of Gravitate-Health

Defining the G-lens design methodology - personas

User experience – information services

User advisory group and healthcare ecosystems – ‘patient voice’ and capacity building. Active external engagement, connections and presence.



Accessing cross-border product information (preferred EU language)*



Example of basic G-lens focusing of product information*



* A global HL7 FHIR standard for ePI is in development based on this work. See [here](#).



Gravitate-Health... unlock the value of the ePI in practical terms

Common interoperability standards, “ePI on FHIR”, can drive an integrated ‘digital health information’ approach combining personal health data and trusted health information

Committed to develop and test ePI resources and digital tools so they maximize and add end-user value, e.g., user needs, content focusing approaches, technical requirements, compliance

Collaborate globally to accelerate progress to address both current needs and future opportunities, e.g., facilitate cross-border care, support multiple languages, product supply, improved quality of care

Multilateral and international leadership

Public Private Partnerships and Standards Development

- Innovative Medicines Initiative (IMI) - Gravitate-Health
- Health Level 7 (HL7) Vulcan - FHIR Accelerator
- HL7 Biomedical Research and Regulation (BR&R)
- Univocal Identification of Medicinal Products (UNICOM)



New ePI consortia (Industry, academia, regulators):

- UK
- US
- Japan

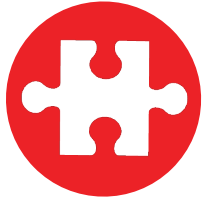
UK ePI Task Force



HL7® FHIR® Accelerator Program

The HL7 FHIR Accelerator Program is designed to assist communities and collaborative groups across the global health care spectrum in the creation and adoption of high quality FHIR Implementation Guides or other standard artifacts to move toward the realization of global health data interoperability.





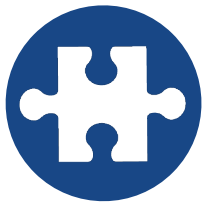
Why Vulcan?

Fully integrate research into the delivery of healthcare by streamlining data collection and exchange into a singular process.



What are we doing to reach that vision?

- Collaborating with the international research community to align clinical data and clinical research data at the point of collection.
- Developing out the HL7 FHIR standard to support the bidirectional flow of data.



How will we accomplish this?

- Bridge existing gaps
- Strategically connect industry collaborations
- Maximize collective resources
- Deliver integrated tools and solutions

Status of FHIR Implementation Guides

- [FHIR Implementation Guide for Electronic Medicinal Product Information \(ePI\)](#) Approved 27 July 2023
- [Gravitate-Health/HL7 Vulcan press release](#) and social media ([LinkedIn](#), [Twitter](#))
- HL7 press release: [Vulcan and Gravitate-Health announce publication of FHIR implementation guide for ePI](#)
- Statement of collaboration to support the EU ePI common standard
 - Gravitate Health - European Medicines Agency (EMA) statement about our collaboration and alignment regarding the EU ePI Common Standard



PRESS RELEASE

The Vulcan HL7® FHIR® Accelerator & Gravitate Health announce the publication of a FHIR® implementation guide for ePI

28 JUL: THE VULCAN HL7 FHIR ACCELERATOR AND GRAVITATE HEALTH PUBLISH A FHIR® IMPLEMENTATION GUIDE FOR EPI

The Vulcan HL7® FHIR® Accelerator and Gravitate Health announce the publication of a FHIR® implementation guide (IG) for ePI The Vulcan HL7® FHIR® Accelerator and Gravitate Health are pleased to...

 [READ MORE](#)

Impact of our approach - moving towards a global FHIR ePI Standard

Gravitate-Health has helped connect key initiatives and foster collaborations globally, building on developments in the EU to drive quickly towards a global HL7 FHIR ePI standard

EU ePI Common standard and global use via Vulcan Core ePI

EU ePI - 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 core of EMA's ePI. The ePI cross references out to SPOR, which can provide data of rows 5 to 13. Product data are from PMS, one of the 4 SPOR services.

Vulcan ePI - FHIR Resource Names ²	
1	List
2	Bundle
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4	Binary
5	Organization
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7	MedicinalProductDefinition
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13	Substance

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

- The VULCAN Profile is completely aligned with EU ePI Common Standard, both use FHIR Lists, Bundles, Composition to represent PI documents
- The EU ePI Common Standard includes a link to SPOR (master data system for EU pharmacovigilance)
- To enable global use for regions without SPOR, VULCAN Profile has option to include data directly

Type 1: eLabel only

- SmPC, Package Leaflet, Label
- Semi-structured narrative text (section/sub-section headings, paragraphs, tables, lists, images), document info (language, date), Organization details (Company address and contact information)

Type 2: eLabel + product details

- Type 1 + structured product details (full name, class, dose form, strength, packaging, ingredients, manufactured form and administrable form)

Type 3: eLabel + product details + clinical details

- Type 1 + Type 2 + structured clinical details (Encoded indication, contraindication, interaction, warnings and precautions)

Simple Search

Intermediate Search

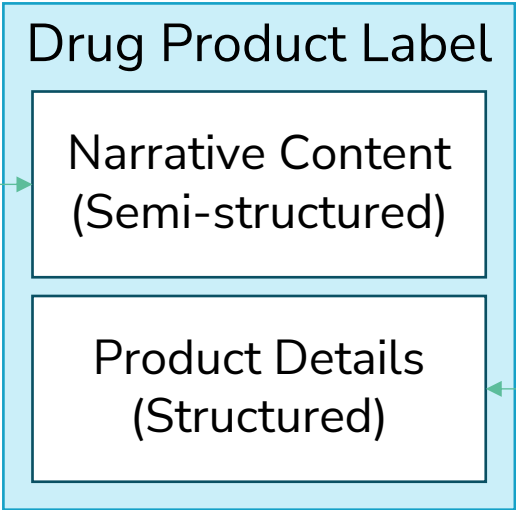
Advanced Search



FHIR ePI Structure and Content



9.40.2.1 B. Package Leaflet
9.40.2.1.1 Package leaflet: Information for the user
DrugX 75 mg tablets acetaminophen
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
<ul style="list-style-type: none">Keep this leaflet. You may need to read it again.If you have any further questions, ask your doctor or pharmacist.This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
9.40.2.1.2 What is in this leaflet
<ul style="list-style-type: none">What DrugX is and what it is used forWhat you need to know before you take DrugXHow to take DrugXPossible side effectsHow to store DrugXContents of the pack and other information
9.40.2.1.3 1. What DrugX is and what it is used for
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.
9.40.2.1.4 2. What you need to know before you take DrugX
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.
9.40.2.1.5 3. How to take DrugX
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.
9.40.2.1.6 4. Possible side effects
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.
9.40.2.1.7 5. How to store DrugX
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.
9.40.2.1.8 6. Contents of the pack and other information
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.



DrugX
PRODUCT: medicinalproduct75
Status: Active
Domain: Human use
Combined pharmaceutical dose form
Legal Status of Supply: Medicinal product subject to medical prescription
Auth id: authorization75mg
Region:
Type: Marketing Authorization
Holder (Organization): acme inc (http://example.org/sid/org#ORG1)
Status: Active (2015-02-07T13:28:17Z)
Package 1 of 1
PRODUCT: EU197049001
Description:
Marketing Status: active
Contained Quantity:
• 75
Package: 28 Blister [Polyvinyl Chloride]
Administrable Product (1 of 1)
Dose form: Tablet
Presentation unit: Tablet
Contents (Manuf. Items):
32147286-b0ec-4a65-bc6d-0aee33d97468
Dose form: Tablet
Presentation unit: Tablet
Manufactured Dose Form: Tablet
Ingredients:
746c0fbc-936e-46ca-9680-57e9760843e
Status: Active
Role: Active
Substance: acetaminophen
69c13040-8625-4818-972d-0104ee16986
Status: Active
Role: Excipient
Substance: Silicon dioxide
a4b7b0c-998f-4f93-89c7-8d0396a0f0c3
Status: Active
Role: Excipient
Substance: Carnauba wax
8d58407-83d3-42db-bc3d-508b206d431
Status: Active
Role: Excipient
Substance: Croscarmellose sodium
1c1b5441-4b6d3-4068-b14b-514e7c2779b0
Status: Active
Role: Excipient
Substance: Hygromellose
7a3c0b14-2473-4541-9e45-a24d2ccedd7
Status: Active
Role: Excipient
Substance: Lactose Monohydrate
ceba5c0f1-32f1-4bc3-b203-92d97fc1472e
Status: Active
Role: Excipient
Substance: Macrogel 3000
eeef55e8-e442-491d-9a82-7af3c6bc67f1
Status: Active
Role: Excipient
Substance: Magnesium stearate
1c0fb0bc-658f-43f1-6750-8f3a0d9970bd
Status: Active
Role: Excipient
Substance: Microcrystalline cellulose
a88891dc-7d8e-4d54-b462-95e63de3b6a6
Status: Active
Role: Excipient
Substance: Titanium Dioxide
Route of administration:
• Oral route
Clinical Information
Contraindication: Gastrointestinal disorders
Indication: Psoriasis
Interaction: HEPTOTREXATE
Undesirable Effect: Drowsy
Warning: Symptomatic hypotension, especially after the first dose, may occur in patients.

- Section and subsection headings
- Paragraphs, tables, bulleted lists, images
- Prescribing information (e.g., Indication, interaction contraindication, warnings, dose / administration)

- Product full name, drug class, dose form, strength, packaging (Type, size, GTIN), ingredients
- Manufactured form and administrable form
- Clinical use (Indication, contraindications, interactions, warnings and precautions)

Product Detail Examples

6.104.1.0.1 Yaz 0,02 mg/3 mg Filmdragerad tablett
MPID: SE-100004813-00026267

Full name: **Yaz 0,02 mg/3 mg Filmdragerad tablett**
- Invented name part: **Yaz**
- Strength part: **0,02 mg/3 mg**
- Pharmaceutical dose form part: **Filmdragerad tablett**
Name usage: **Swedish (Kingdom of Sweden)**

Authorised dose form: **Film-coated tablet**
Legal status of supply: **Medicinal product subject to medical prescription**
Domain: **Human use**
Resource status: **Current**

Product classification:
• **100000095785 drospirenone and ethinylestradiol**

Marketing Authorisation 1 of 1
Authorisation number: **26267**
Region: **Kingdom of Sweden**
Marketing authorisation holder: **Bayer AB**
Identifier:
• **LOC-100016468**
Status: **Valid (2008-07-03)**

Package 1 of 1
PCID:
Description:
Blister, 3 x 28 tabletter
Marketing status:
• **Kingdom of Sweden: Marketed**
Pack size:
• **84 tablet**

Package: **1 Box (Plastic)**
Containing:
Package: **3 Box (Cardboard)**
Containing:
Package: **1 Blister (Aluminium) (PolyVinyl Chloride)**
Containing: **24 tablet**

Manufactured Item
Dose form: **Film-coated tablet**
Unit of presentation: **tablet**

Ingredient
Role: **Active**
Substance: **Ethinylestradiol betadex clathrate**
Presentation strength: **173.17 microgram(s) / 1 tablet**
Reference strength:
Ethinylestradiol 20 microgram(s) / 1 tablet

Ingredient
Role: **Active**
Substance: **drospirenone**
Presentation strength: **3 milligram(s) / 1 tablet**
Reference strength:
drospirenone 3 milligram(s) / 1 tablet

4 tablet
Manufactured Item
Dose form: **Film-coated tablet**
Unit of presentation: **tablet**

Ingredient
Role: **Excipient**
Substance: **Lactose monohydrate**
Presentation strength: **23.2 milligram(s) / 1 tablet**
Reference strength:
lactose 22 milligram(s) / 1 tablet

Administrable Product (1 of 2)
Dose form: **Film-coated tablet**
Unit of presentation:
Route of administration:
• **Oral use**
Ingredients:
Ingredient
Role: **Active**
Substance: **Ethinylestradiol betadex clathrate**
Presentation strength: **173.17 microgram(s) / 1 tablet**
Reference strength:
Ethinylestradiol 20 microgram(s) / 1 tablet

Ingredient
Role: **Active**
Substance: **drospirenone**
Presentation strength: **3 milligram(s) / 1 tablet**
Reference strength:
drospirenone 3 milligram(s) / 1 tablet

Administrable Product (2 of 2)
Dose form: **Film-coated tablet**
Unit of presentation:
Route of administration:
• **Oral use**
Ingredients:
Ingredient
Role: **Excipient**
Substance: **Lactose monohydrate**
Presentation strength: **23.2 milligram(s) / 1 tablet**
Reference strength:
lactose 22 milligram(s) / 1 tablet

Clinical Information
Contraindication: **Gastrointestinal disorders**
Indication: **Psoriasis**
Interaction: **METHOTREXATE**
Undesirable Effect: **Dysergia**
Warning: **Symptomatic hypotension, especially after the first dose, may occur in patients.**



International Patient Summary (IPS)

View IPS

Header

Patient Summary (Helen Gravitate)

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

Patient

Birth Date: 1946-05-05

Name: Helen, Gravitate

Allergies and Intolerances

- - Criticality: undefined

Lactose (47703008)

Allergies

Active problems / Diagnosis

2015 Diabetes mellitus type 1 (46635009) [Uncoded text shown]: Diabetes type 1

Problems

Current Medications

<http://ema.europa.eu/ihir/marketingAuthorizationNumber> Humalog Mix50 (EU/1/96/007/035)

<https://www.who-umc.org/phpid> insulin lispro, 100 units/ml, suspension for injection (0x073AF2E5B92AE19E8B67635AFFB3D6CA)

<http://snomed.info/sct/83821000000107> Humalog Mix50 KwikPen 100units/ml suspension for injection 3ml pre-filled pens (13884911000001102)

<http://www.whooc.no/atc> insulin lispro (A10AD04)

<http://ema.europa.eu/ihir/marketingAuthorizationNumber> Monuril (PL31654/0006)

<https://www.who-umc.org/phpid> Fosfomycin, 3g, Granules for oral solution (0xE857DA811B4A6F3BD57810C45D2EA1ED)

<http://www.whooc.no/atc> fosfomycin (J01XX01)

Medications

Medications



The Helen case....

```
"resource": {
  "resourceType": "Medication",
  "id": "9d7be868-8264-4d94-ad04-ef04ecc92e50",
  "code": {
    "coding": [
      {
        "code": "EU/1/96/007/035",
        "system": "http://ema.europa.eu/fhir/marketingAuthorizationNumber",
        "display": "Humalog Mix50"
      }, {
        "code": "0x073AF2E5B92AE19E8B67635AFFB3D6CA",
        "system": "https://www.who-umc.org/phpid",
        "display": "insulin lispro, 100 units/ml, suspension for injection"
      }, {
        "code": "13884911000001102",
        "system": "http://snomed.info/sct/83821000000107",
        "display": "Humalog Mix50 KwikPen 100units/ml suspension for injection 3ml pre-filled pens"
      }
    ], {
      "code": "A10AD04",
      "system": "http://www.whocc.no/atc",
      "display": "insulin lispro"
    }
  ], {
    "coding": [
      {
        "code": "11202000",
        "system": "http://standardterms.edqm.eu",
        "display": "Suspension for injection"
      }
    ]
  }
},
```



```
{
  "resourceType": "AdministrableProductDefinition",
  "id": "cfsb1640606978608",
  "status": "active",
  "identifier": [
    {
      "system": "https://www.who-umc.org/phpid",
      "value": "0x073AF2E5B92AE19E8B67635AFFB3D6CA"
    }
  ],
  "administrableDoseForm": {
    "coding": [
      {
        "code": "100000073864",
        "system": "https://spor.ema.europa.eu/rmswi"
      }
    ]
  },
  "presentation": {
    "coding": [
      {
        "code": "200000002135",
        "system": "https://spor.ema.eu"
      }
    ]
  }
}
```

8.45.1 Example MedicinalProductDefinition: cfsb1641212233583

Generated Narrative

Resource "cfsb1641212233583"

identifier: id: 13884911000001102

type: Marketing Authorisation (Referentials Management Services CodeSystem#10000072062)

domain: Human use (Referentials Management Services CodeSystem#100000000012)

status: Active (PublicationStatus#active)

legalStatusOfSupply: Medicinal product subject to medical prescription (Referentials Management Services CodeSystem#100000072084)

classification: Insulin lispro (WHO ATC#A10AD04)

name

productName: Humalog Mix50 Insulin KwikPen, 3ml pre-fill

type: Full name (Referentials Management Services CodeSystem#220000000001)

8.45.1.1 NameParts

Part	Type
* Suspension for injection Pharmaceutical dose form part	(Referentials Management Services CodeSystem#220000000005)

8.45.1.2 CountryLanguages

Country	Jurisdiction	Language
* European Union	(unknown#eu)	European Union (unknown#eu) English (Tags for the Identification of Languages#en)

"Suspension for injection"

```
"presentation": {
  "coding": [
```

```
le": "200000002135",
tem": "https://spor.ema.eu"
}
```

8.31.1 Example AdministrableProductDefinition: cfsb1640606978608

Generated Narrative

Resource "cfsb1640606978608"

identifier: id: 0x073AF2E5B92AE19E8B67635AFFB3D6CA

status: active

formOf: MedicinalProductDefinition/cfsb1641212233583

administrableDoseForm: Suspension for injection (Referentials Management Services CodeSystem#10000073864)

unitOfPresentation: Pen (Referentials Management Services CodeSystem#200000002135)

producedFrom: ManufacturedItemDefinition/cfsb164077487408

routeOfAdministration

code: Subcutaneous use (Referentials Management Services CodeSystem#10000073633)

8.31.1.1 TargetSpecies

Code
* Human (Referentials Management Services CodeSystem#100000109093)

ePI

The Helen case....

```
"resource": {
  "resourceType": "Medication",
  "id": "9d7be868-8264-4d94-ad04-ef04ecc92e50",
  "code": {
    "coding": [
      {
        "code": "EU/1/96/007/035",
        "system": "http://ema.europa.eu/fhir/marketingAuthorizationNumber",
        "display": "Humalog Mix50"
      }, {
        "code": "0x073AF2E5B92AE19E8B67635AFFB3D6CA",
        "system": "https://www.who-umc.org/phpid",
        "display": "insulin lispro, 100 units/ml, suspension for injection"
      }, {
        "code": "13884911000001102",
        "system": "http://snomed.info/sct/83821000000107",
        "display": "Humalog Mix50 KwikPen 100units/ml suspension for injection 3ml pre-filled pens"
      }, {
        "code": "A10AD04",
        "system": "http://www.whocc.no/atc",
        "display": "insulin lispro"
      }
    ]
  },
  "form": {
    "coding": [
      {
        "code": "11202000",
        "system": "http://standardterms.edqm.eu",
        "display": "Suspension for injection"
      }
    ]
  }
},
```



8.42.1 Example RegulatedAuthorization: cfsb1640870220343

Generated Narrative

Resource "cfsb1640870220343"

identifier: id: EU/1/96/007/035 (OFFICIAL)

subject: MedicinalProductDefinition/cfsb1641212233583

type: Marketing Authorisation (Referentials Management Services CodeSystem#100000072062)

region: European Union (unknown#eu)

status: Active (PublicationStatus#active)

statusDate: 2015-02-07 01:28:17+0000

holder: Organization/cfsb1640870284639 "Eli Lilly Nederland B.V."

ePI



Bigger picture

Test
scenario #1:

- Confirm how to make connections between the Vulcan ePI and SPL-FHIR by manually transforming an ePI to a SPL-FHIR.

Test
scenario #2:

- A patient travels from Europe to US and has to find the similar US medicinal product to their European prescription.

Test
scenario #3:

- A patient travels from Japan to US and has to find the similar US medicinal product to their Japanese prescription.

Test
scenario #4:

- Incorporate IDMP identifiers into the ePIs to facilitate international connections. Focus on the PhPID generation; lookup and usage; and matching identifiers cross-border to support the relevant test scenarios above.



<https://build.fhir.org/ig/HL7/fhir-spl/branches/main/index.html>

7.0.10 Allopurinol Label

Example Instances associated with the label for Allopurinol USP

AidarexPharmaceuticals	Aidarex Pharmaceuticals - labeller for Allopurinol Tablets USP
Allopurinol100Tablets	100 Tablets Bottle of Allopurinol USP
Allopurinol30Tablets	30 Tablets Bottle of Allopurinol USP
Allopurinol60Tablets	60 Tablets Bottle of Allopurinol USP
Allopurinol90Tablets	90 Tablets Bottle of Allopurinol USP
AllopurinolIngredientDefinition	Active Ingredient Information for Allupurinol USP
AllopurinolMarketing	Marketing information for Allopurinol USP
AllopurinolTablet	
AllopurinolTabletLabelBundle	A bundle containing all of the information for the Allopurinol Tablet USP Label
AllopurinolTabletLabelComposition	Header information for the Allopurinol Tablet USP Label
AllopurinolUSPActiveIngredient	Active Ingredient Strength for Allupurinol USP
AllopurinolUSPDefinition	Structured information for the Allopurinol Tablet USP Label
AllopurinolUSPIngredient1	Inactive Ingredient #1 for Allopurinol USP
AllopurinolUSPIngredient2	Inactive Ingredient #2 for Allopurinol USP
AllopurinolUSPIngredient3	Inactive Ingredient #3 for Allopurinol USP
AllopurinolUSPIngredient4	Inactive Ingredient #4 for Allopurinol USP
AllopurinolUSPIngredient5	Inactive Ingredient #5 for Allopurinol USP
AllopurinolUSPIngredient6	Inactive Ingredient #6 for Allopurinol USP

Similar to FHIR
ePI for US

Based on FHIR

Contains
narrative and
structured info

Why not align?



View IPS

Header

Patient Summary (Helen Gravitate)
Summary Date: 2018-07-10T15:22:00+02:00


Patient

Birth Date: 1946-05-05
Name: Helen, Gravitate

Allergies and Intolerancies

-- Criticality: undefined


Lactose (47703008)

Allergies

Active problems / Diagnosis


2015

Diabetes mellitus type 1 (46635009) [Uncoded text shown]: Diabetes type 1


Problems

Current Medications

<http://ema.europa.eu/fhir/marketingAuthorizationNumber> Humalog Mix50 (EU/1/96/007/035)
<https://www.who-umc.org/phpid> insulin lispro, 100 units/ml, suspension for injection (0x073AF2E5B92AE19E8B67635AFFB3D6CA)
<http://snomed.info/sct/83821000000107> Humalog Mix50 KwikPen 100units/ml suspension for injection 3ml pre-filled pens (13884911000001102)
<http://www.whocc.no/atc> insulin lispro (A10AD04)

Medications

<http://ema.europa.eu/fhir/marketingAuthorizationNumber> Monuril (PL31654/0006)
<https://www.who-umc.org/phpid> Fosfomycin, 3g, Granules for oral solution (0xE857DA811B4A6F3BD57810C45D2EA1ED)
<http://www.whocc.no/atc> fosfomycin (J01XX01)

Medications

How to map the medication information across US, EU and JPN

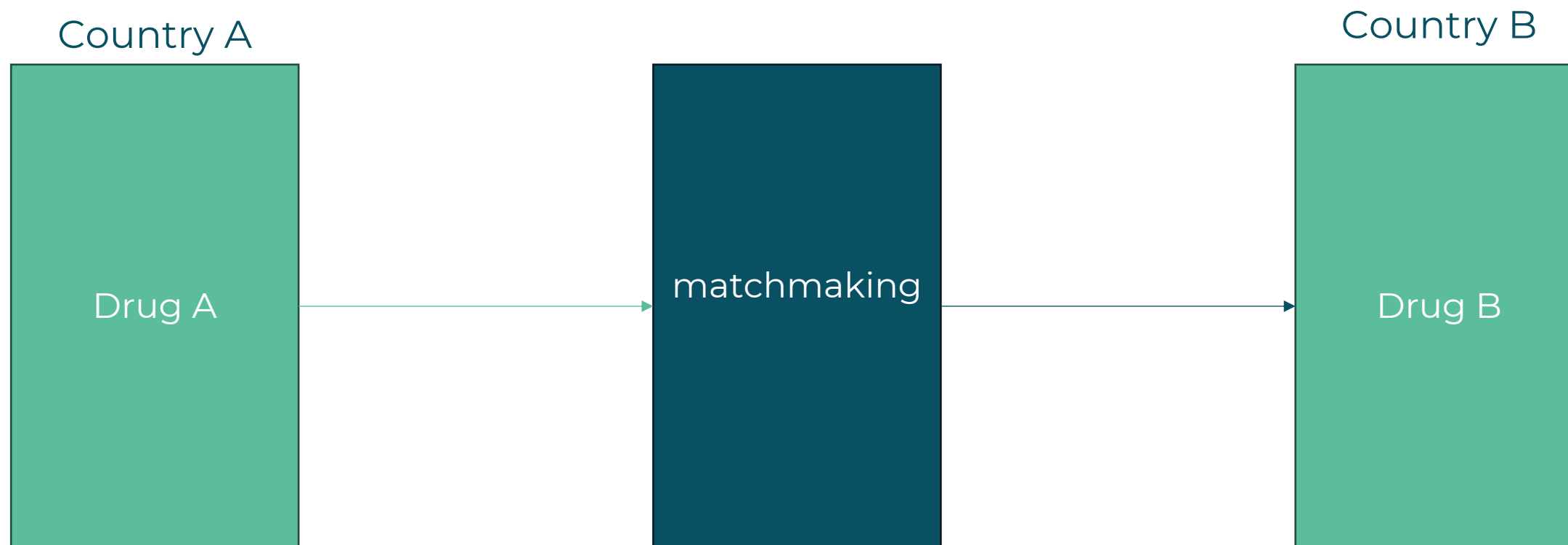
Present information in a meaningful way for the patient

Could it be possible to substitute for a similar drug/brand?

Reliance on IDMP identifiers



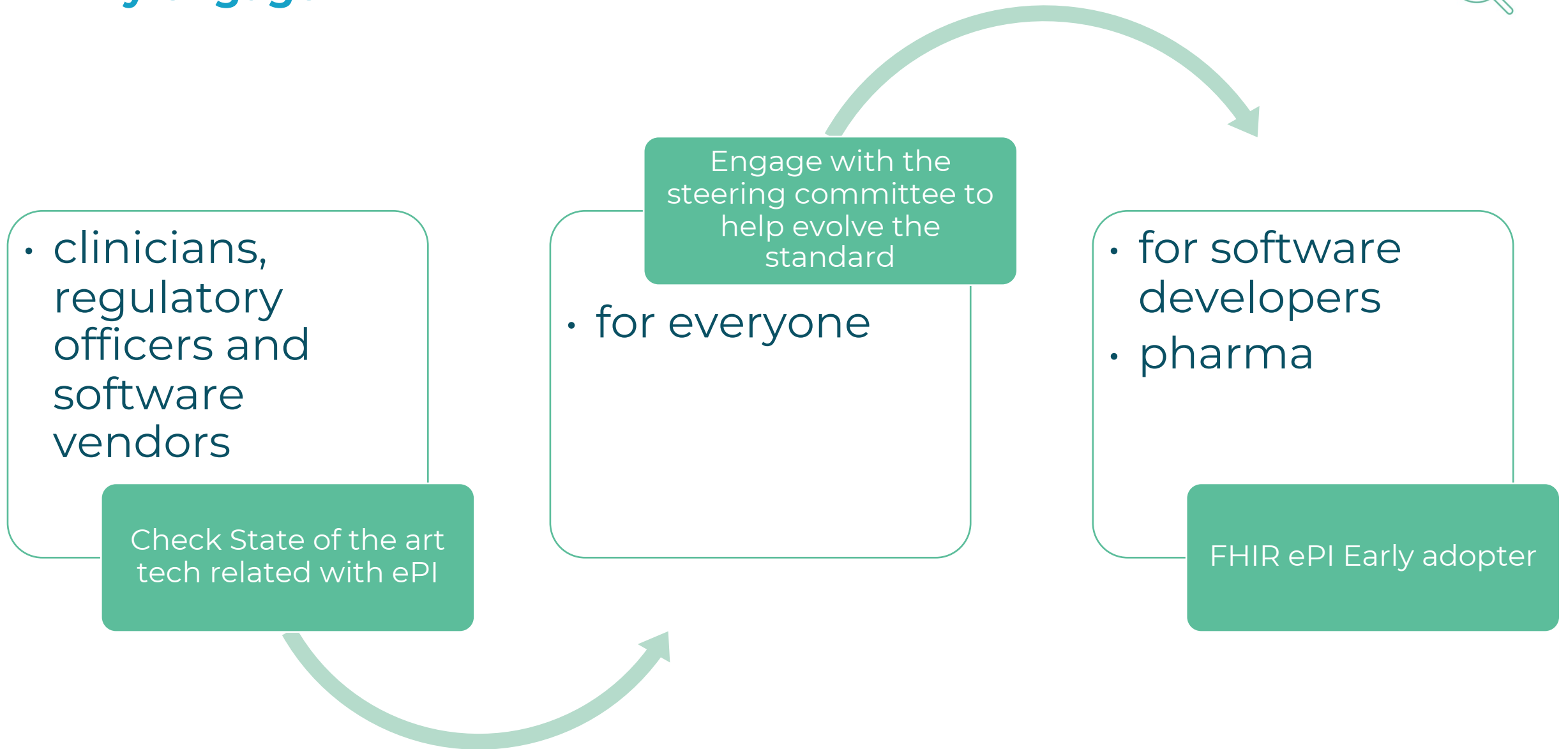
Implementation of the International Organization for Standardization (ISO) suite of [IDMP](#) (**ID**entification of **M**edicinal **P**roducts) standards.



Testing how it works with the testing scenarios #1-3



Why engage



Now what??

Ask all your
questions and
doubts

Engage with
the
community

Share your
work

Participate in
the
connectathon

<https://chat.fhir.org/#>. -> all things FHIR community

<https://chat.fhir.org/#narrow/stream/296557-Vulcan.2FePI>. -> the link for the stream dedicated to the ePI

<http://build.fhir.org/ig/hl7-eu/gravitate-health/toc.html>. -> gravitate health IG

<http://build.fhir.org/ig/HL7/emedicinal-product-info/toc.html>. -> FHIR ePI IG

<https://confluence.hl7.org/pages/viewpage.action?pageId=175610822#id-202309Vulcan/GravitateHealthePI/IPSandSPLFHIR-Callforparticipants>. -> Connectathon page





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