

Hackathon – Gravitate Health

17th JANUARY 2024

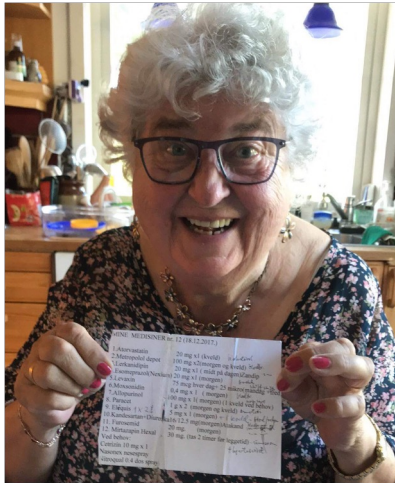


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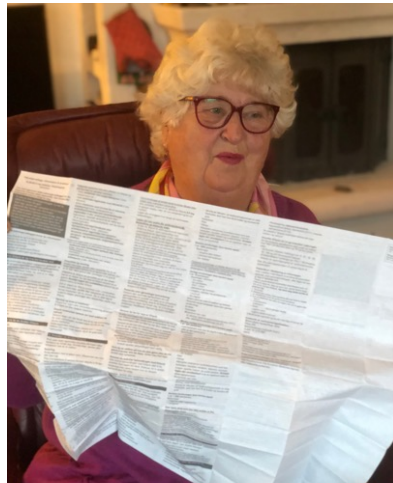


Gravitate-Health project in a nut-shell

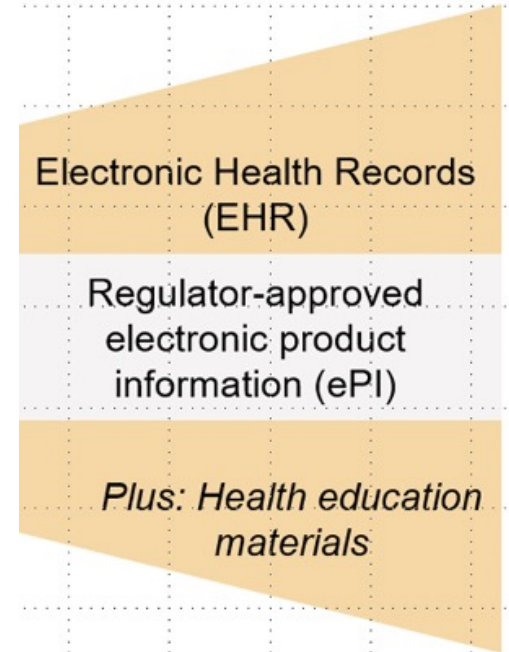
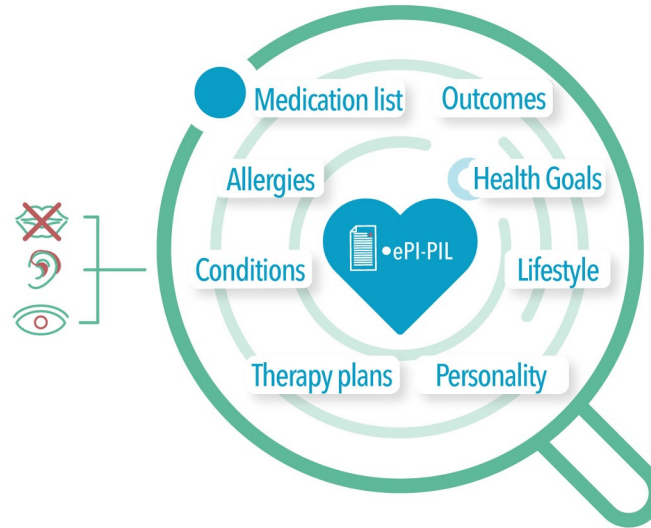
Maria and her medicines



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO



Research question

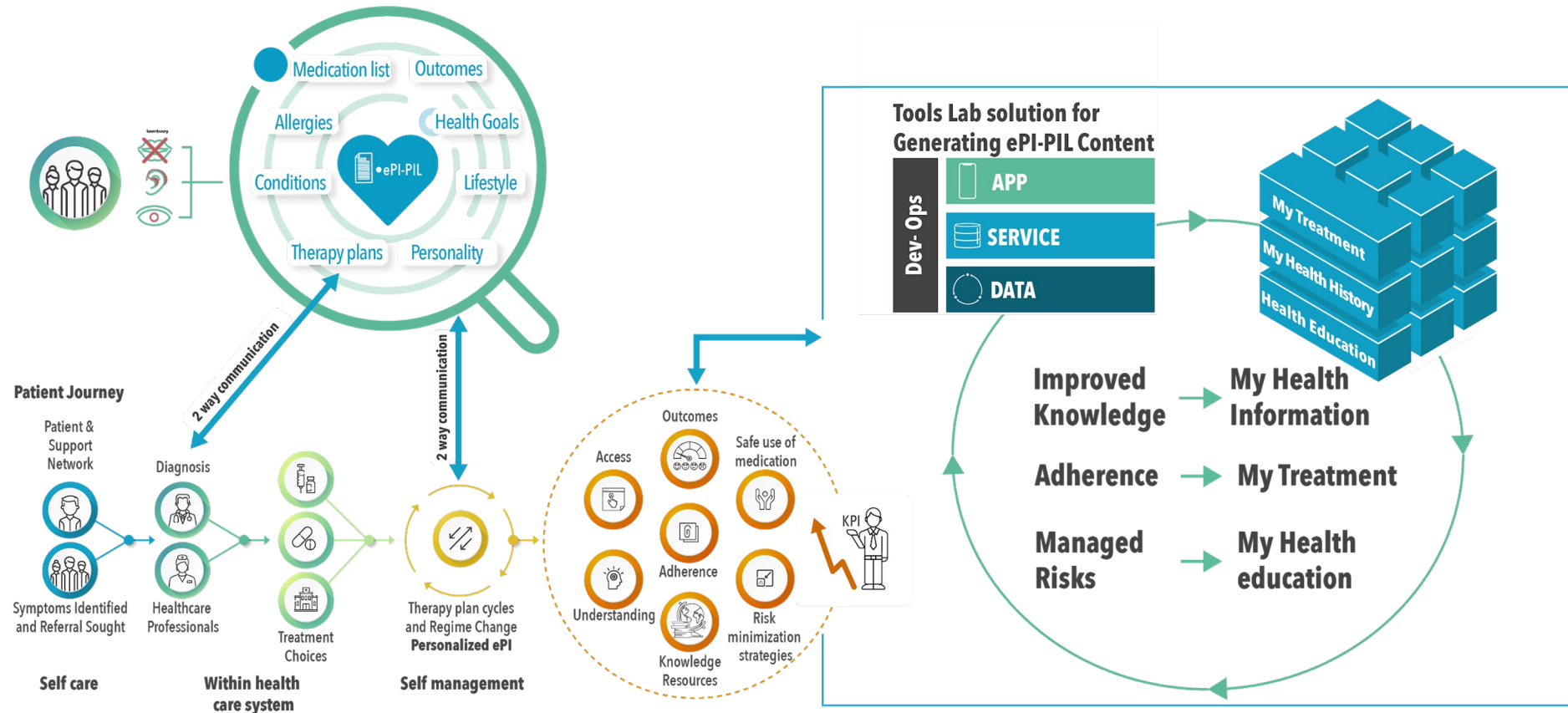
How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?

Key deliverables

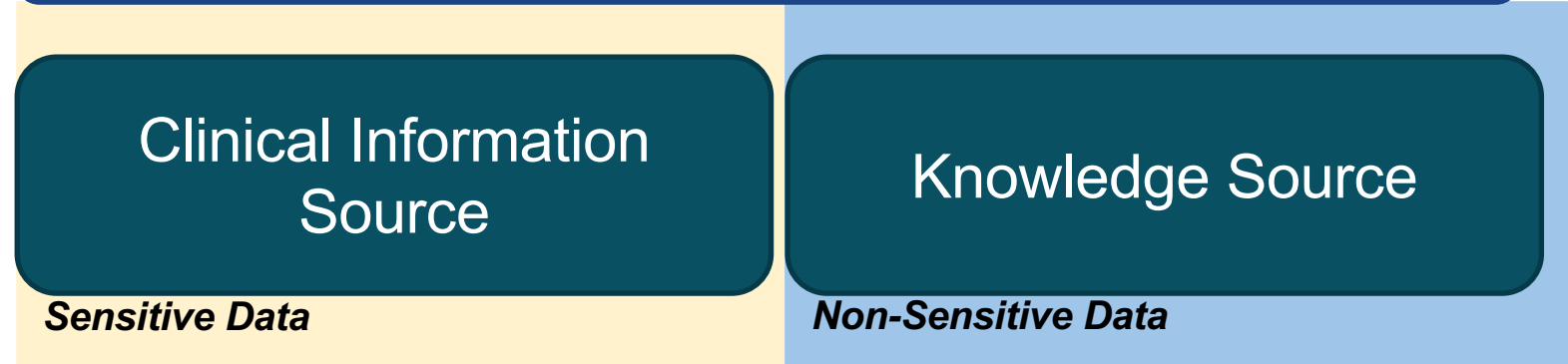
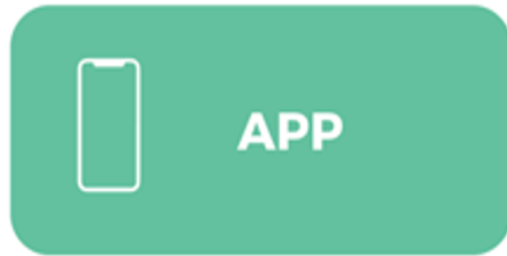
- Federated open source platform with G-Lens services
- White Paper on strategies for future use of ePI
- Pilot studies evaluation
- Sustainable impacts

Gravitate – Health

Taking an integrated patient-centric health information approach throughout the patient journey



Platform architecture



Electronic Product Information (ePI)

- A pivotal source of regulated and scientifically validated information that assists healthcare professionals in prescribing and dispensing the medicine and informs consumers about its safe use.
- In Europe, these are the: Summary of Product Characteristics, Package Leaflet, and labelling. In the US, these are the Drug Product Label and Patient Package Insert.

International Patient Summary (IPS)

- An electronic health record extract containing essential healthcare information about a subject of care (e.g., list of medications and allergies).
- Designed to support the use case scenario for cross border care.

HL7 FHIR ePI Specification introduction

- FHIR ePIs are made up of the following thirteen resources

FHIR Resource Names		Description
1	List	Index for tracking all documents, versions, and translations for a product.
2	Bundle	Container that combines resources into a document.
3	Composition	For section and sub-section headings; and semi-structured narrative text (e.g., paragraphs, tables, bulleted lists).
4	Binary	For images and multimedia.
5	Organization	Defines the market authorization holder and manufacturer.
6	RegulatedAuthorization	Defines the product's authorization issued by a regulatory authority.
7	MedicinalProductDefinition	Defines the authorized product.
8	PackagedProductDefinition	Defines the products packaging.
9	AdministrableProductDefinition	Defines the product in the final form before administration to the patient (e.g., after mixing of components).
10	ManufacturedItemDefinition	Defines the product as contained in its authorized packaging.
11	Ingredient	Defines the ingredients that make up the medicinal product
12	ClinicalUseDefinition	Defines the indication, contraindication, interactions, and warnings
13	Substance	Details about an ingredient (e.g., chemical structure, molecular weight).

Granularity levels on medication concepts

Paracetamol

Paracetamol Tablets 500 mg Oral usage

Paracetamol <Brand> Tablets 500 mg Oral usage

Paracetamol <Brand> Tablets 500 mg Oral usage 30 tabs

1. Clinical
2. Regulatory
3. Stock

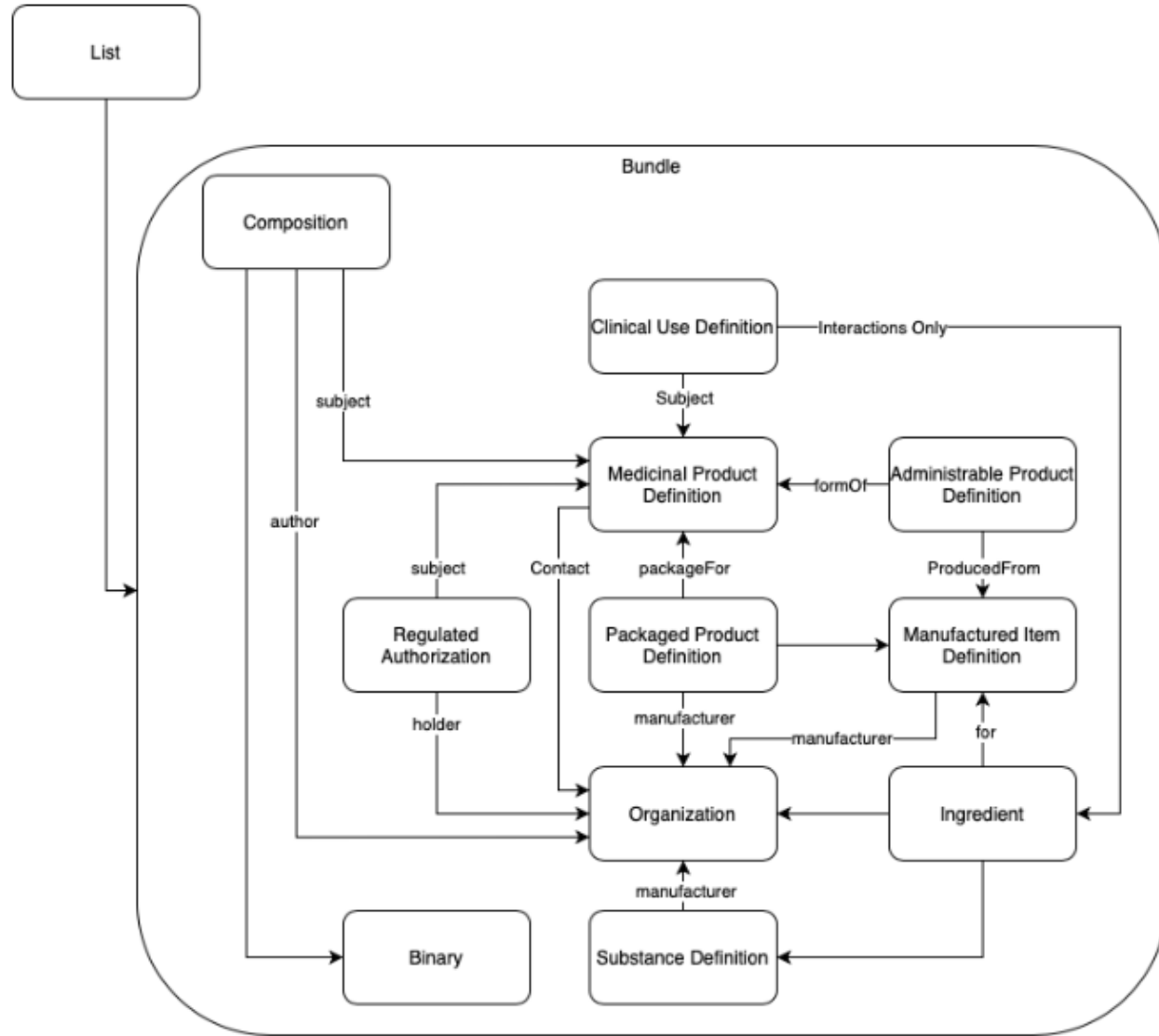
What is
prescribed

What is
dispensed

What is
administered

Regulatory

From PIL to FHIR ePI



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.

- 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

- What DrugX is and what it is used for
- What you need to know before you take DrugX
- How to take DrugX
- Possible side effects
- How to store DrugX
- Contents 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

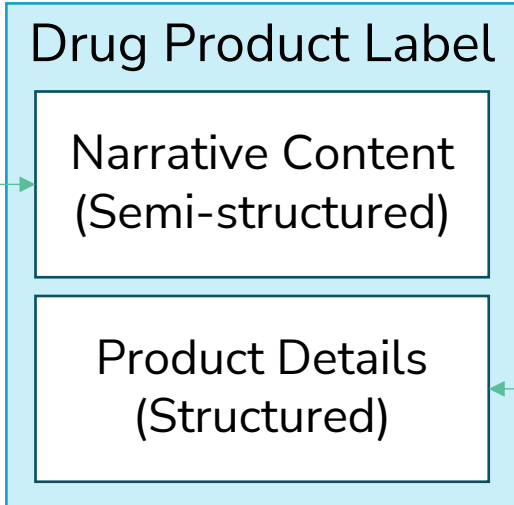
Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum 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-b9ec-4e65-bc6d-0aec39d7468
Dose form: Tablet
Presentation unit: Tablet
Manufactured Dose Form: Tablet

Ingredients

- 746207bc-936e-46ca-9800-57e9760843e
Status: Active
Role: Active
Substance: acetaminophen
- 09c13040-8645-4818-972d-0194ee16986
Status: Active
Role: Excipient
Substance: Silicon dioxide
- a4b7b60c-998f-4f93-89c7-80390a0f0c3
Status: Active
Role: Excipient
Substance: Carnauba wax
- 0f56407-83d3-42db-bc3d-60b2006d431
Status: Active
Role: Excipient
Substance: Croscarmellose sodium
- 1c18d441-62e3-4068-b14b-514e7c27790
Status: Active
Role: Excipient
Substance: Hypromellose
- 7a30b14-2473-4541-9e45-a2424ccedd7
Status: Active
Role: Excipient
Substance: Lactose Monohydrate
- ce8e5c01-321f-4bc3-b203-92d97f0472e
Status: Active
Role: Excipient
Substance: Macrogel 3000
- eeef55e8-e442-4910-9a82-7af30efac671
Status: Active
Role: Excipient
Substance: Magnesium stearate
- 1cc07bc-659f-43ff-b760-8f3a0d9970bd
Status: Active
Role: Excipient
Substance: Microcrystalline cellulose
- a8891dc-769e-4d84-b482-95e3de3b6a6
Status: Active
Role: Excipient
Substance: Titanium Dioxide

Route of administration:
• Oral route

Clinical Information
Contraindication: Gastrointestinal disorders
Indication: Psoriasis
Interaction: HE THOT REXATE
Undesirable Effect: Drowsie
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)





Health record extract

- Snapshot in time of a subject of care's health information and healthcare
- **Not an EHR !**

International

- generic solutions for **global application** beyond a particular region or country.

Scoped

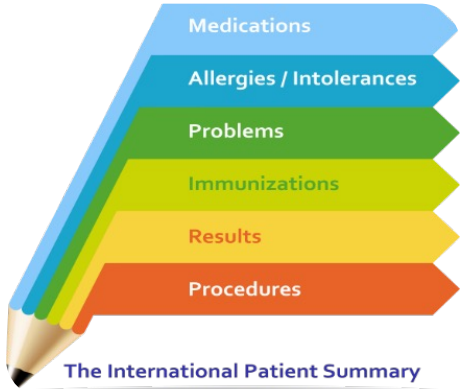
- Designed for **Unscheduled** (cross-border) **care**
- ...but it provides a **base-line usable also within other scheduled or planned care cases.**



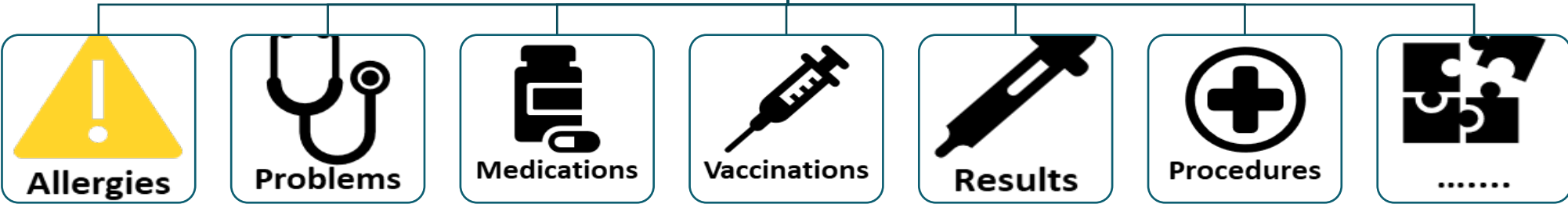
The International Patient Summary



A document composed by reusable profiles



The IPS "library" of profiles



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"
      }
    ]
  },
}

```

```

{
  "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#100000072062)

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 C#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: [
 code: "200000002135",
 system: "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#100000073864)

unitOfPresentation: Pen (Referentials Management Services CodeSystem#200000002135)

producedFrom: ManufacturedItemDefinition/cfsb164077487408

routeOfAdministration

code: Subcutaneous use (Referentials Management Services CodeSystem#100000073633)

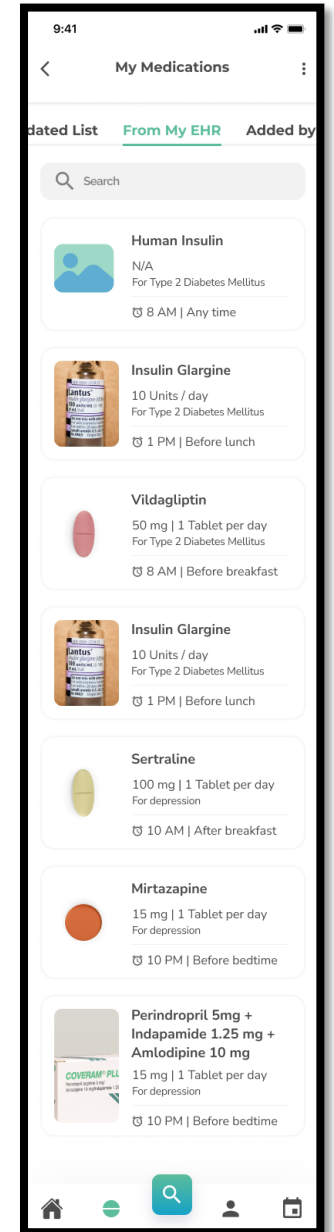
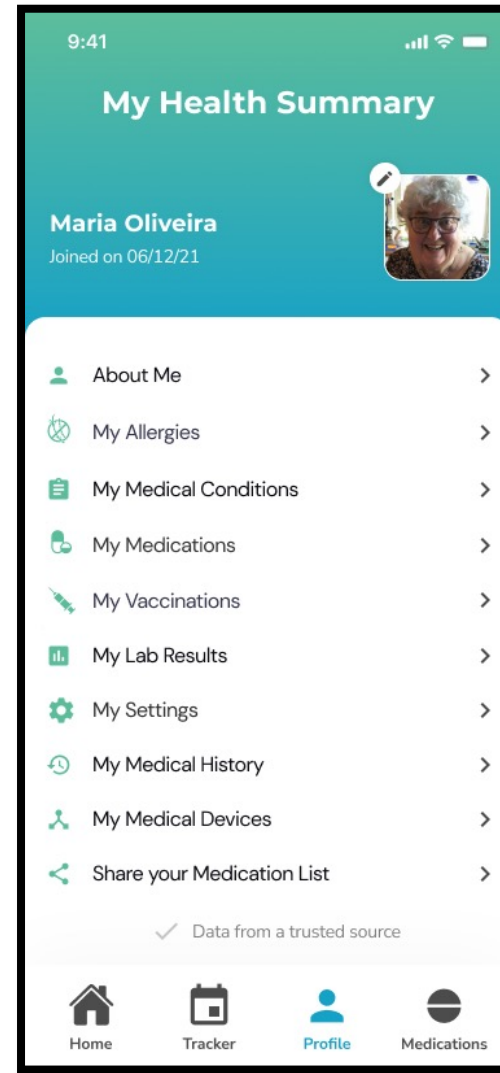
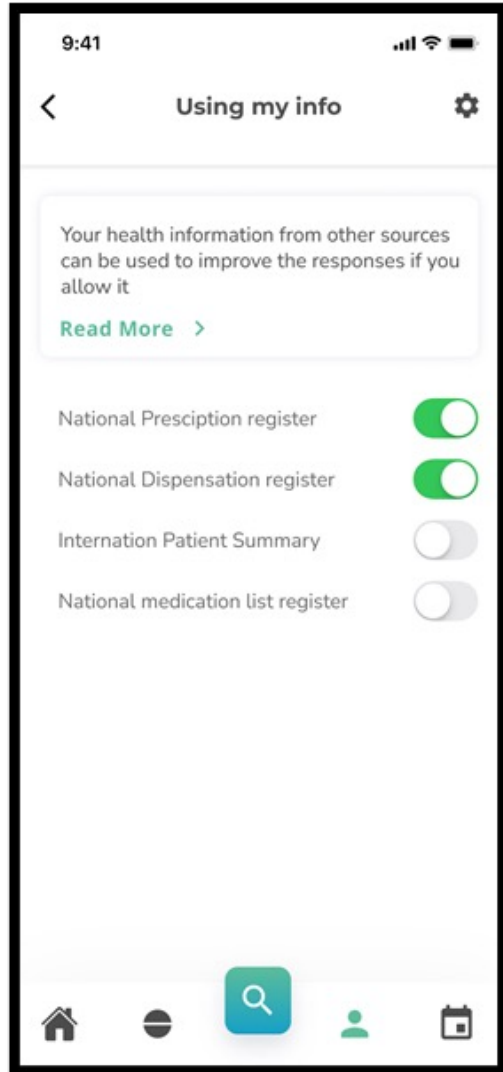
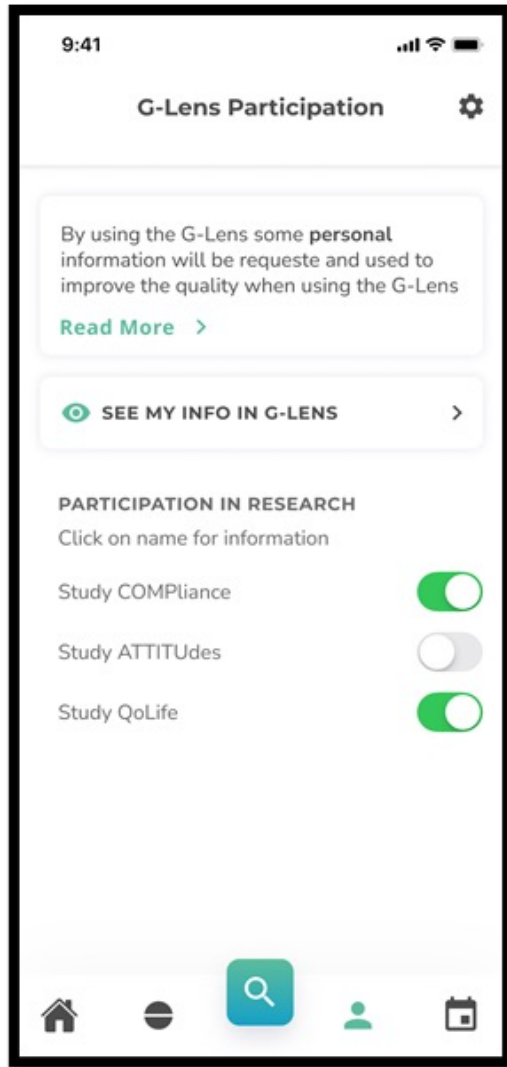
8.31.1.1 TargetSpecies

Code
* Human (Referentials Management Services CodeSystem#100000109093)





Illustrating the work of Gravitate-Health





Illustrating the work of Gravitate-Health

Applied G-lens criteria:
Demographics, conditions, allergy and intolerance

Pregnancy related - suppressed

Lactose Intolerance related - highlighted

Capable Maria Personas

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

How to achieve this?



Example of basic G-lens focusing of product information*

So we have a ePI, what now?



FHIR Document

Structured Data

Unstructured data

So we have a ePI, what now?



Easy to deal with!

FHIR Document

Structured Data

Unstructured data

So we have a ePI, what now?



Not so easy 😞

FHIR Document

Structured Data

Unstructured data

Electronic Product Information (ePI)

Unstructured Data (free-text)

Human-
readable

Heterogeneous
information

Semi -
Heterogeneous
structure

No semantic
layer

And so...



unstructured data

Pre-processing

Semantic layer

“Adding”
information

Drugs

observations

conditions

procedures

quantities

diseases

symptoms

More
subsections

tagging
specific
information

Processed ePI - P(ePI)

Do not take

If you are allergic to irbesartan or any ingredients of this medicine

Warning and precautions

Talk to your doctor if any of the following apply to you:

- If you get excessive vomiting or diarrhoea
- If you suffer from kidney problems
- If you suffer from heart problems
- If you are going to have an operation or be given anaesthetics

Children and adolescents

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

This product contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

This product contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Processed ePI - P(ePI)

Do not take

If you are allergic to **irbesartan** or any ingredients of this medicine

Warning and precautions

Talk to your doctor if any of the following apply to you:

- If you get excessive **vomiting** or **diarrhoea**
- If you suffer from **kidney problems**
- If you suffer from **heart problems**
- If you are going to have an **operation** or be given **anaesthetics**

Children and adolescents

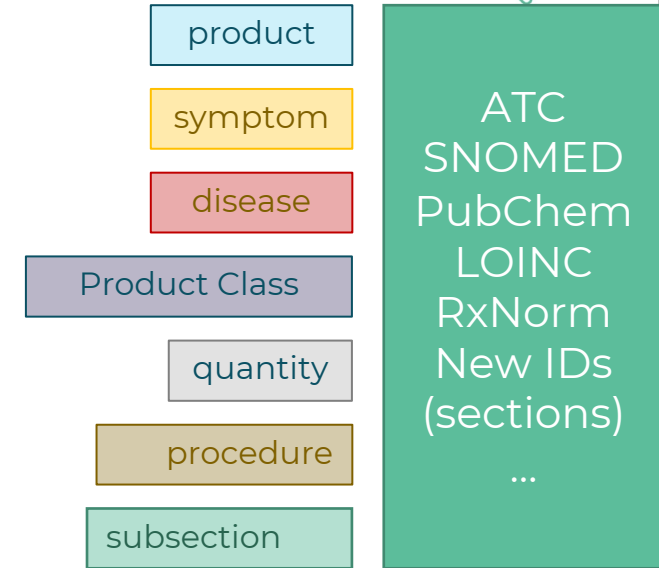
This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

This product contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. **lactose**), contact your doctor before taking this medicinal product.

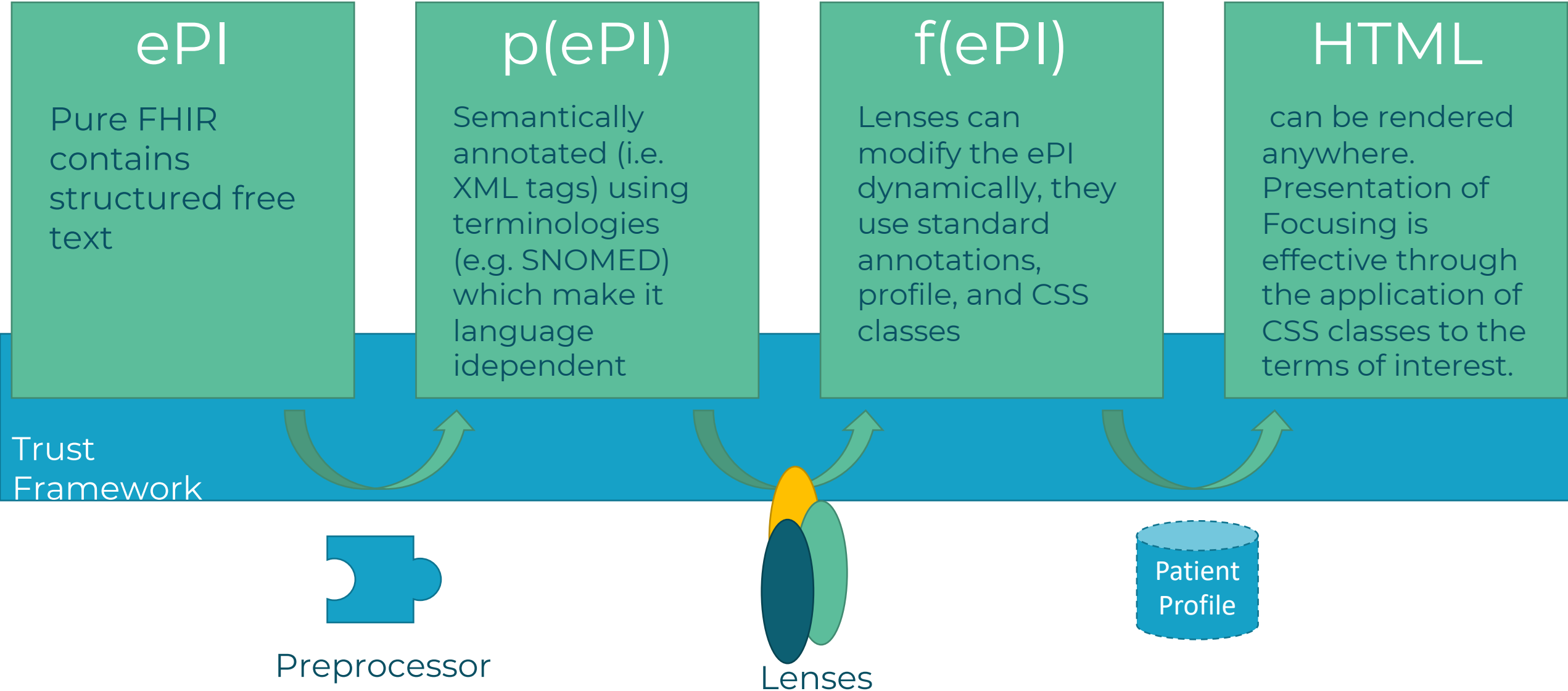
This product contains sodium.

This medicine contains less than **1 mmol sodium** (23 mg) per tablet, that is to say essentially **sodium-free**'.



NLP | Token Identification | Manual work | Other...

End-To-End focusing



Focusing Operations

Focusing applied to content (ePI)

Highlight: select certain sections to be highlighted

Hiding/Collapsing: select certain sections to be hidden/collapsed

Add hypertext: annotate information to link with other information (e.g., glossary; based on health literacy – connect with external service (FOSPS component or external services))

Multimedia: annotate to add icons, pictograms, images ... additional risk minimization materials – external service

Questionnaire: test your knowledge, validation purposes

Explaining focusing

CHALLENGE 1: EPI PREPROCESSING

Develop modules that can add explanations to electronic product information (ePI) content while maintaining it in FHIR format. We will use standard medical terms such as SNOMED-CT, LOINC, and others.

CHALLENGE 2: GRAVITATE HEALTH LENS (G-LENS) DEVELOPMENT

Create a tool, the 'G-lens,' which customises information about medications based on a patient's preferences and situation. This tool will use Gravitate Health's federated open-source platform services (FOSPS), ePIs with explanatory labels, user profiles, and other relevant components.

Everything is possible

Your imagination is the limit

But take into account reality

The less information needed, the better



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innovative
medicines
initiative

