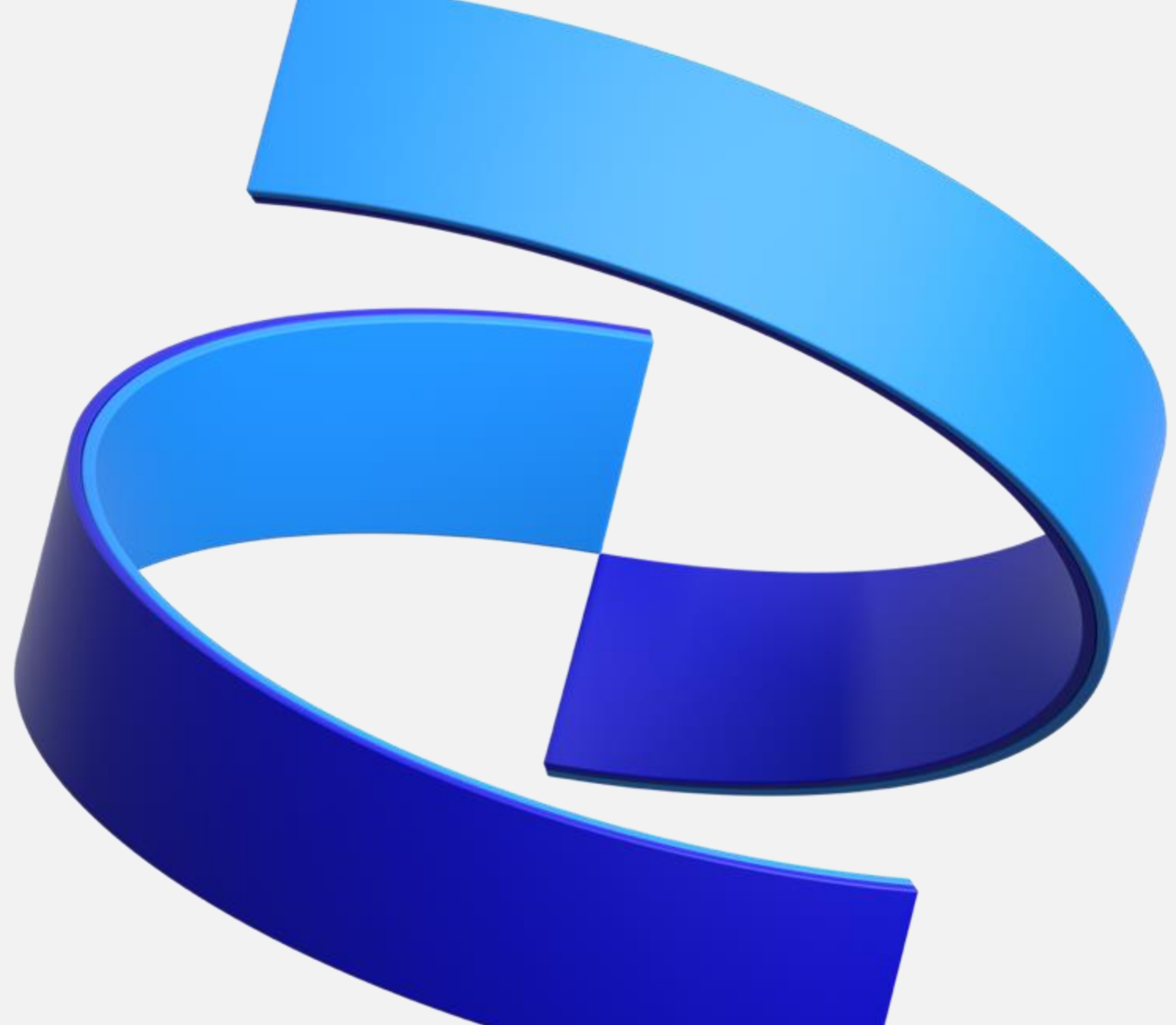


26th DGRA Annual Congress: Electronic Product Information

Craig Anderson

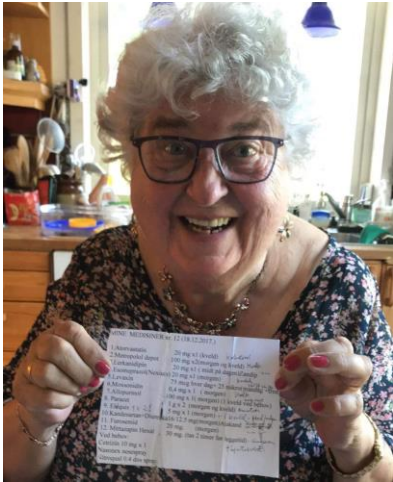
Director, R&D labeling Lead,
International Labeling Group

2024-06-21

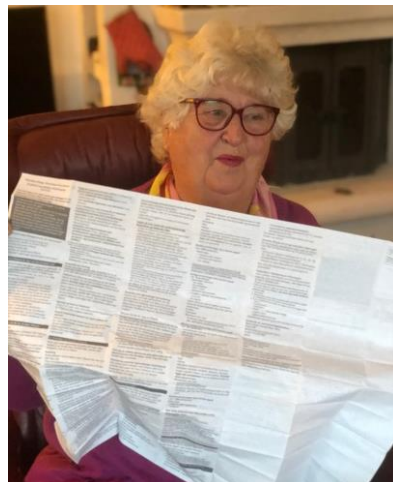


How best to improve patient experience?

“Maria and her medicines”



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO

Personal Health Record

Capable Maria Persones

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

ePI content tailored to the individual

Capable Maria Persones

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. Rådfor 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.

Rådfor 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.

Intak av Skilarence sammen med alkohol
Unngå sterke alkoholdrikkevarer (mer enn 50 ml brennevinn 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

Applied criteria: Demographics, conditions, allergy and intolerance

Pregnancy related - suppressed

Lactose Intolerance related - highlighted

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

Cross-project collaboration: International FHIR ePI standard

- **Innovative Medicines Initiative (IMI) - Gravitare-Health**

- 40 partners in Europe and USA; 60 months 11/20 – 10/25; €18.5m
- Delivering the Gravitare 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.





Gravitate-Health - the wider collaborative community

Government / regulators



Projects



Gravitate-Health ePI tech community



“The Web should be open, accessible, and free for all” Tim Berners Lee



Prescribing and Safety Content

Product Details

Structured Data Model



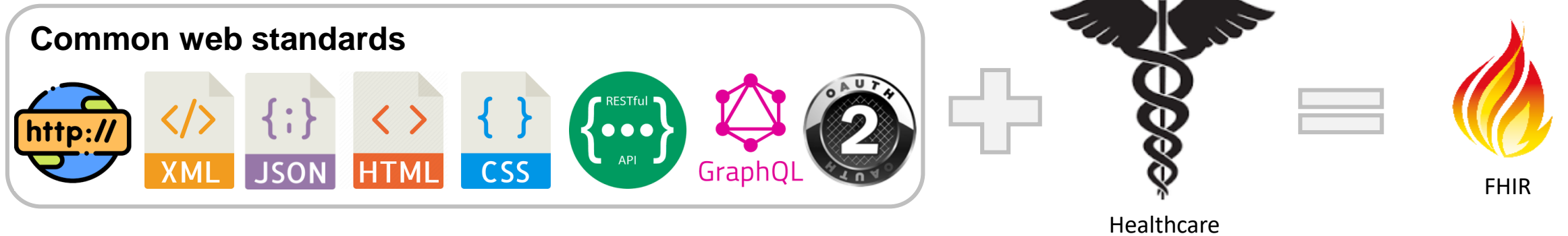
- Patient Information Leaflet Sections 1 to 6
- Encoded Images
- Medicinal Product
- Organization
- Regulated Authorization
- Manufactured Item
- Administrable Product
- Packaging
- Ingredients
- Clinical Use



```
{
  "resourceType": "Ingredient",
  "id": "cfsb16394925469687",
  "identifier": {
    "system": "https://gsrs.ncats.nih.gov/ginas/app/beta/home",
    "value": "EWQ57Q8I5X",
    "use": "official"
  },
  "role": {
    "coding": [
      {
        "code": "/#100000072082",
        "system": "https://spor.ema.europa.eu/rmswi/"
      }
    ],
    "text": "excipient"
  },
  "description": "Lactose monohydrate",
  "allergenicIndicator": true,
  "manufacturer": [
    {
      "reference": "cfsb16394925469682"
    }
  ]
}
```

Overview of FHIR (Fast Health Interoperability Resources)

- Next generation data standards framework created by Health Level 7 (HL7)
- Leverages web standards to make health data interoperable across systems
- Brings the internet to healthcare (e.g., data components, dynamic content, personalization, real-time exchange, auto-generate or transform content)



FHIR Overview: 150+ FHIR Resources (prefabricated templates)

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

8.6.4 Resource Content

Structure
UML
XML
JSON
Turtle
R3 Diff
All

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	Σ	0..1	Organization	Reference(Organization) The organization of which this organization forms a part
contact		0..*	ContactDetail	Official contact details for the organization
purpose		0..1	CodeableConcept	AddressUse (Required)
name		0..1	string	postal physical both AddressType (Required)
telecom		0..*	ContactPoint	
address		0..1	Address	
endpoint		0..*	Endpoint	

Structure
UML
XML
JSON
Turtle
R3 Diff
All

Name	Flags	Card.	Type	Description & Constraints
Address	Σ N		Element	An address expressed using postal conventions (as opposed to geographical coordinates) 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 be used is defined by the use of the AddressUse code.
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

Structure UML XML JSON Turtle R4 Diff All

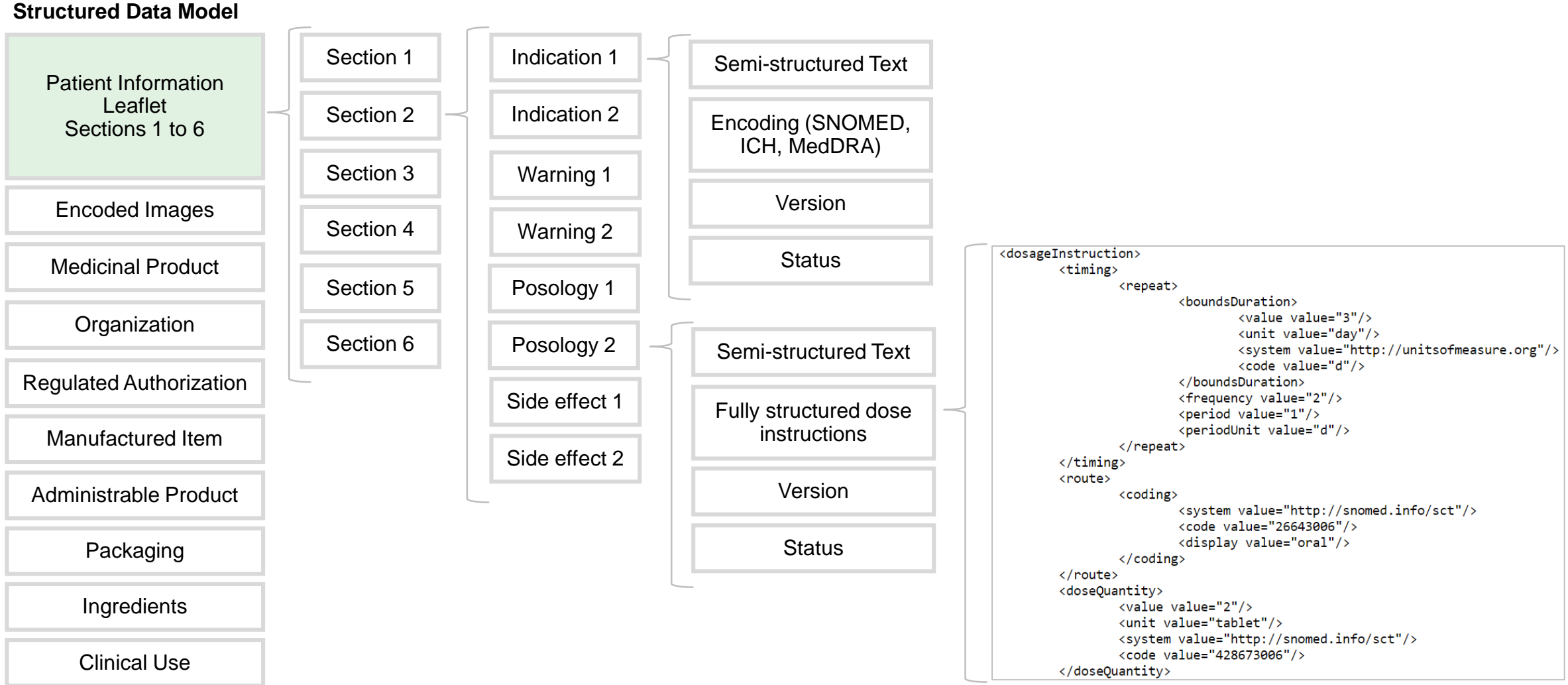
XML Template

```

<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 information 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 --></endpoint>
  <qualification><!-- 0..* Qualifications, certifications, accreditations, licenses, training, etc pertaining to the provision 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>
  
```

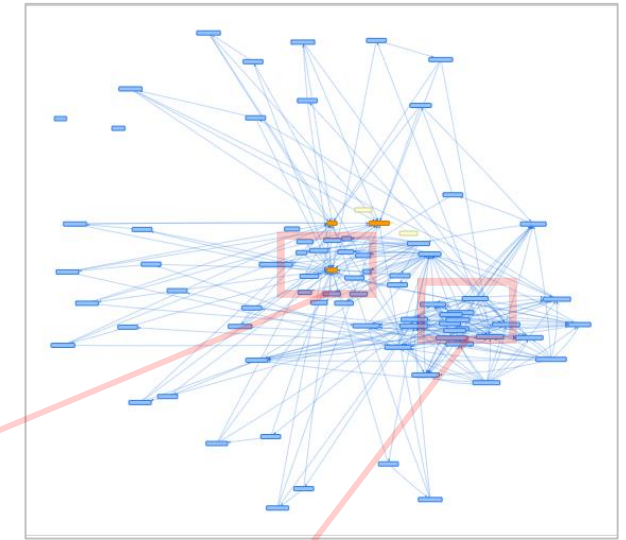


Structure product details and prescribing information



Use case example: Knowledge graphs

- Each box is a Resource and lines are relationships between Resources
- This Type 3 ePI has 90+ data objects
- Graphing all ePIs in a portfolio facilitates advanced search; data analysis (e.g., drug shortages, cross-border prescriptions); interoperability with eHealth Records and ePrescriptions.



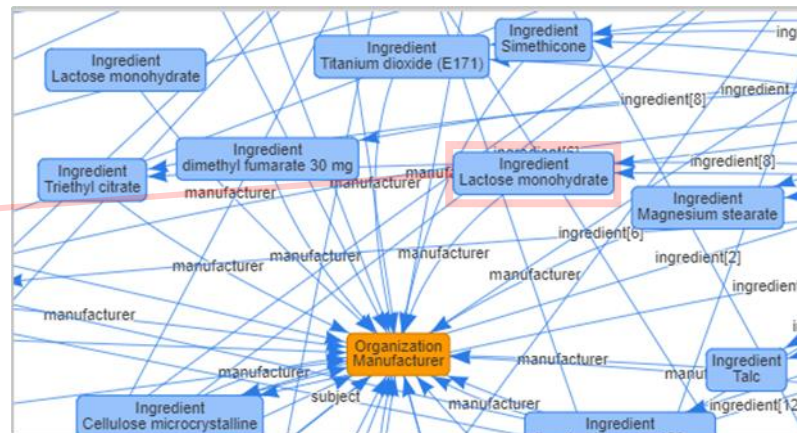
Structured Ingredient Data (JSON)

```

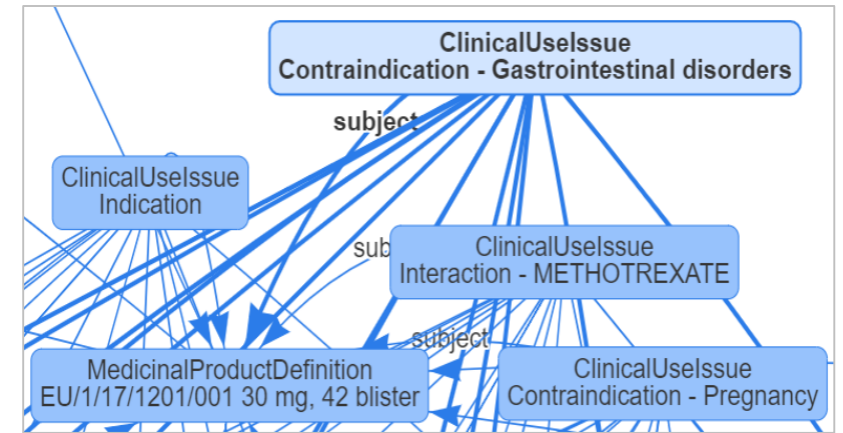
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    "use": "official"
  },
  "role": {
    "coding": [
      {
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        "system": "https://spor.ema.europa.eu/rmswi/"
      }
    ],
    "text": "excipient"
  },
  "description": "Lactose monohydrate",
  "allergenicIndicator": true,
  "manufacturer": [
    {
      "reference": "cfsb16394925469682"
    }
  ]
}

```

Ingredient to Manufacturer relationships

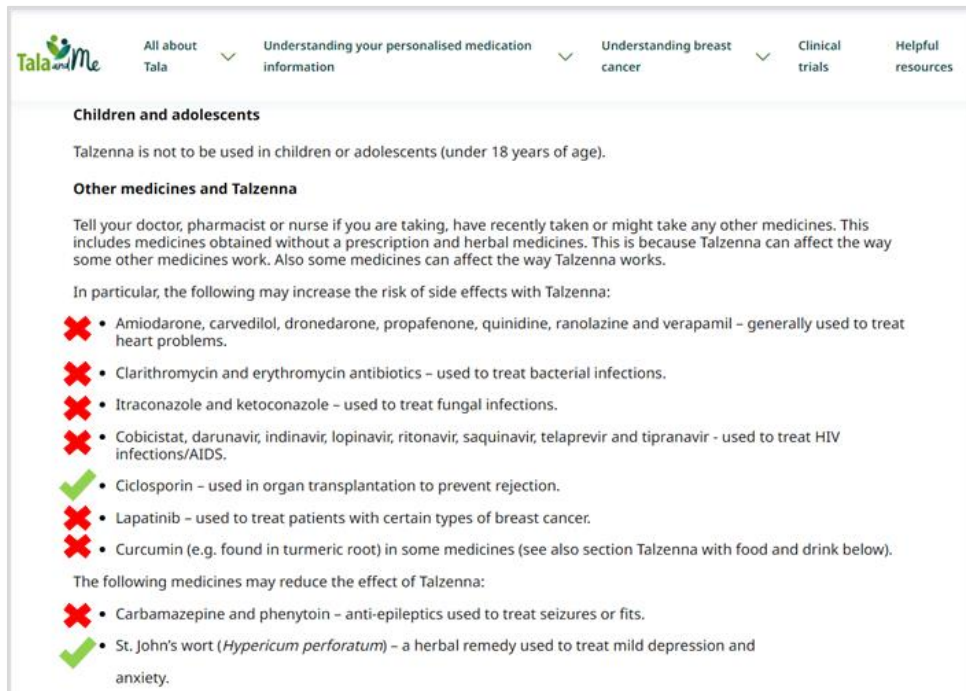


Clinical Use Details



Use case example: Personalization (Groups or individuals)

- With the help of a questionnaire, a patient can personalize the Talzenna UK ePI to only show the other medicines relevant to them rather than showing the full list



The screenshot shows the Talzenna UK ePI website with a navigation menu at the top: "All about Tala", "Understanding your personalised medication information", "Understanding breast cancer", "Clinical trials", and "Helpful resources". The main content area is titled "Children and adolescents" and "Other medicines and Talzenna". It includes a paragraph about children and adolescents, followed by a section on other medicines. A list of medicines is shown, with red 'X' icons indicating those that increase the risk of side effects and green checkmarks indicating those that reduce the effect of Talzenna.

Children and adolescents

Talzenna is not to be used in children or adolescents (under 18 years of age).

Other medicines and Talzenna

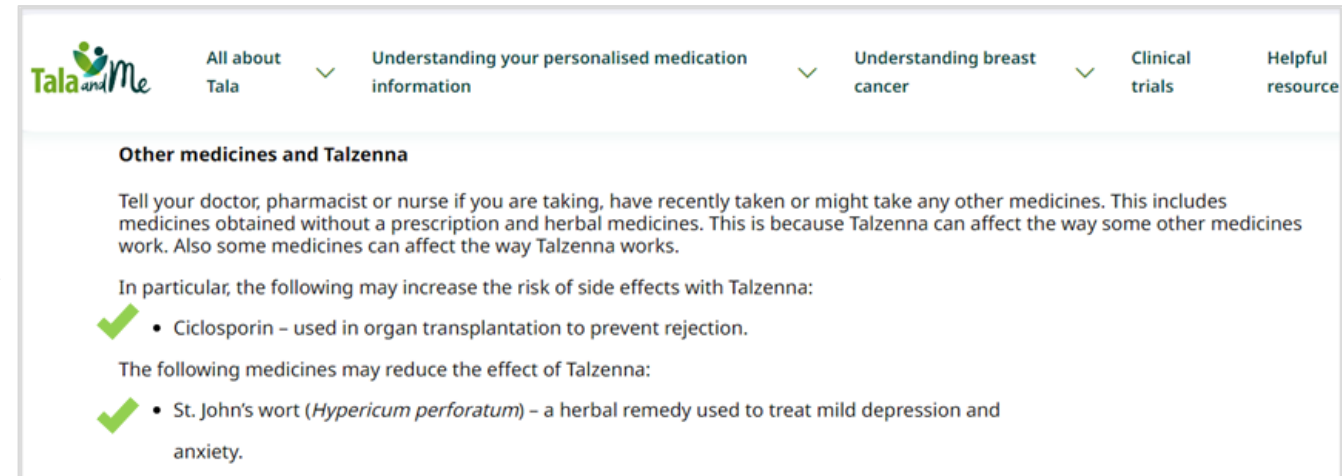
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Talzenna can affect the way some other medicines work. Also some medicines can affect the way Talzenna works.

In particular, the following may increase the risk of side effects with Talzenna:

- ✗ Amiodarone, carvedilol, dronedarone, propafenone, quinidine, ranolazine and verapamil – generally used to treat heart problems.
- ✗ Clarithromycin and erythromycin antibiotics – used to treat bacterial infections.
- ✗ Itraconazole and ketoconazole – used to treat fungal infections.
- ✗ Cobicistat, darunavir, indinavir, lopinavir, ritonavir, saquinavir, telaprevir and tipranavir – used to treat HIV infections/AIDS.
- ✓ Ciclosporin – used in organ transplantation to prevent rejection.
- ✗ Lapatinib – used to treat patients with certain types of breast cancer.
- ✗ Curcumin (e.g. found in turmeric root) in some medicines (see also section Talzenna with food and drink below).

The following medicines may reduce the effect of Talzenna:

- ✗ Carbamazepine and phenytoin – anti-epileptics used to treat seizures or fits.
- ✓ St. John's wort (*Hypericum perforatum*) – a herbal remedy used to treat mild depression and anxiety.



The screenshot shows the Talzenna UK ePI website with a navigation menu at the top: "All about Tala", "Understanding your personalised medication information", "Understanding breast cancer", "Clinical trials", and "Helpful resource". The main content area is titled "Other medicines and Talzenna". It includes a paragraph about other medicines, followed by a section on medicines that increase the risk of side effects and a section on medicines that reduce the effect of Talzenna. The list of medicines is shorter than in the full view, with green checkmarks indicating those that increase the risk of side effects and green checkmarks indicating those that reduce the effect of Talzenna.

Other medicines and Talzenna

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Talzenna can affect the way some other medicines work. Also some medicines can affect the way Talzenna works.

In particular, the following may increase the risk of side effects with Talzenna:

- ✓ Ciclosporin – used in organ transplantation to prevent rejection.





The following medicines may reduce the effect of Talzenna:


- ✓ St. John's wort (*Hypericum perforatum*) – a herbal remedy used to treat mild depression and anxiety.

Use case example: Auto-generate graphical dose instructions

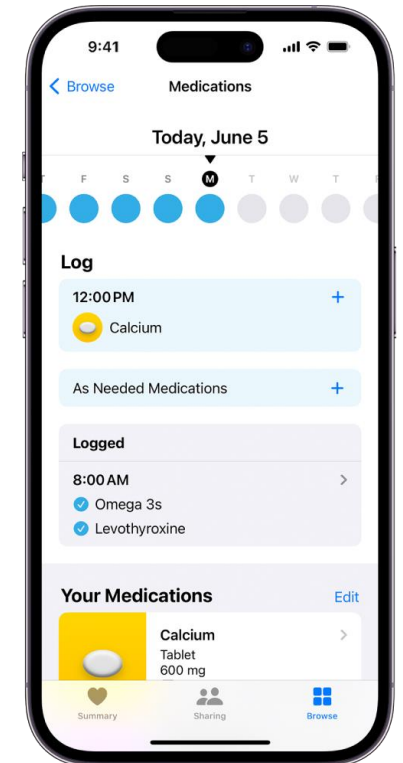
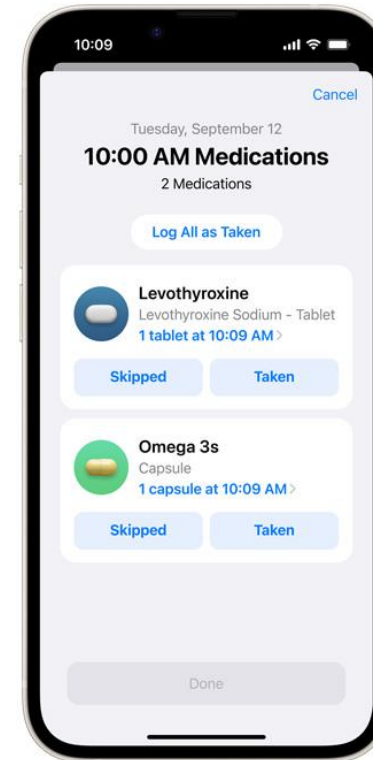
clarithromycin 50 MG/ML Oral Suspension
This medicine is used to treat an infection caused by bacteria.

How to take medicine
Take the medicine by mouth twice a day.
Use 10 mL each time.

			
Morning	Noon	Evening	Bedtime
10 mL		10 mL	



[Patient Medication Instructions | Medication | FDB \(First Databank\) \(fdbhealth.com\)](#)



[iOS - Health - Apple](#)

How to achieve critical mass quickly?

Easter morning 1900: 5th Ave, New York City. Spot the automobile.



Source: US National Archives

Easter morning 1913: 5th Ave, New York City. Spot the horse.



Source: George Grantham Bain Collection.