

# APAC e-Labeling Session

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# ePI is a result of international collaboration

FHIR ePI was developed by and is maintained by an international collaboration experts from Gravitate Health, HL7's Vulcan Accelerator, EMA, Uppsala Monitoring Centre (UMC) / Global IDMP Working Group (GIDWG)



# Healthcare use of FHIR

- FHIR is becoming the technical foundation for national healthcare systems.
- FHIR is the foundation for EMA’s regulatory content strategy (e.g., IDMP, application forms, ePI, drug shortages).
- Opportunity to adapt FHIR to regulatory use cases like ePI, CMC, AEs, Trials.
- Opportunity to make ePI interoperable with EHR, and ePrescription systems.

## USA




CERTIFICATION

**CURIES ACT FINAL RULE**

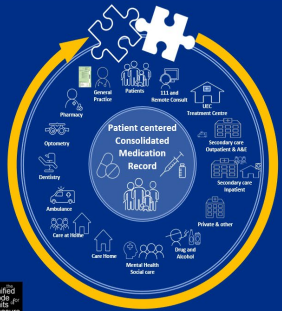
Standards-based Application Programming Interface (API) Certification Criterion


ONC has adopted a new secure, standards-based API certification criterion in § 170.315(g)(10) to implement the 21st Century Cures Act's requirement that developers of certified health IT publish APIs that can be used "without special effort." This new certification criterion requires standardized API access for single patient and population services and is limited to API-enabled "read" services using the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard. The FHIR standard, in addition to a set of adopted implementation specifications, provides known and consistent technical requirements for software developers.

## UK

The ambition for interoperable medicines... 

"To create fully interoperable, computable medication and prescription information across the NHS enabling seamless transfer of care and ultimately a patient centred consolidated medication record."





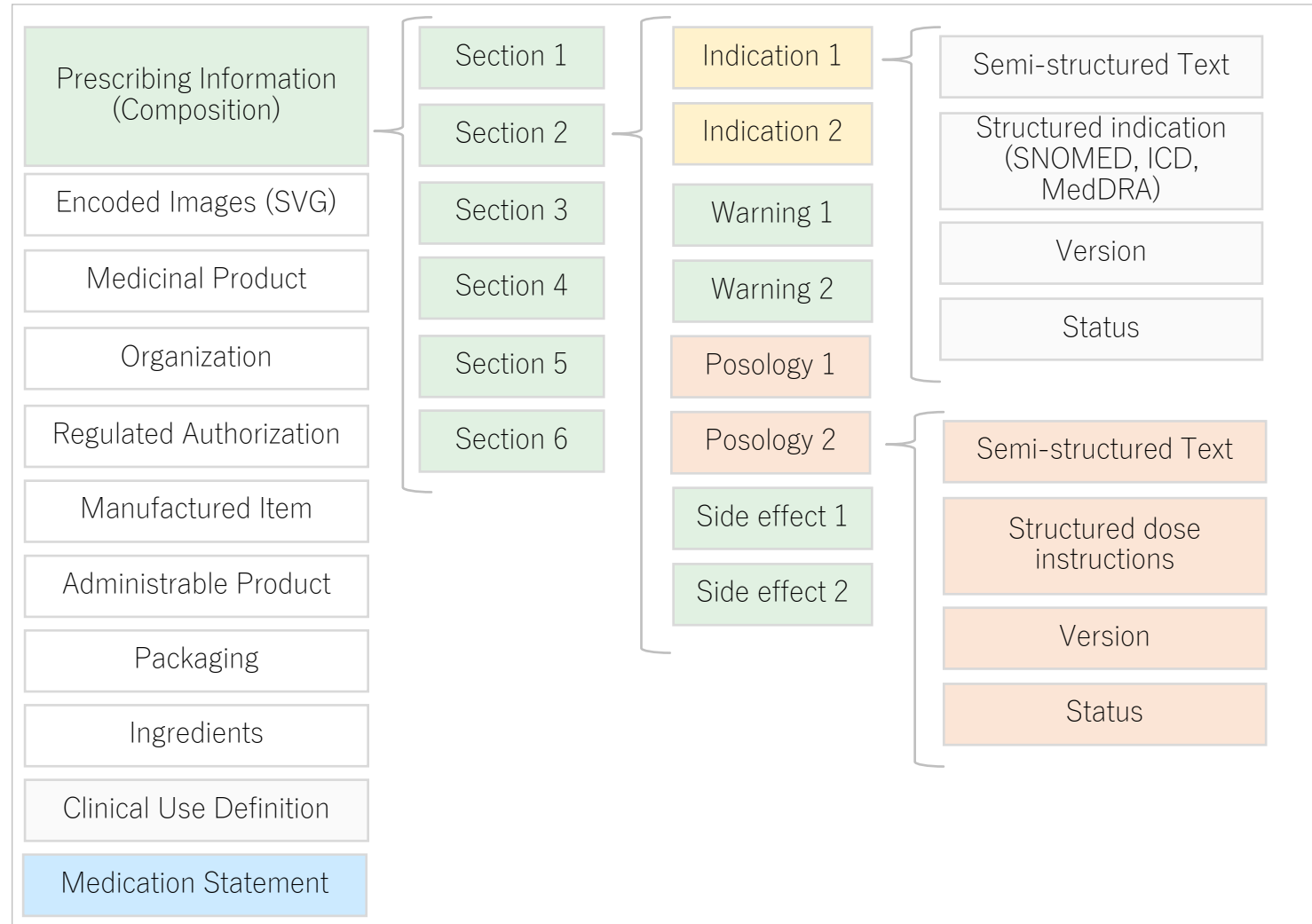
## Japan

FHIR standard	JP Core	Healthy Living	Project individual
Observation	JP LabResult	1 Fujitsu LabResult	4 Fujitsu Genomic Variant
BodyWeight		3 Fujitsu BodyWeight	
Specimen		2 Fujitsu Specimen	

# Un-structured vs. Structured



Prescribing,  
Safety, and  
Product Details



# Types of ePI

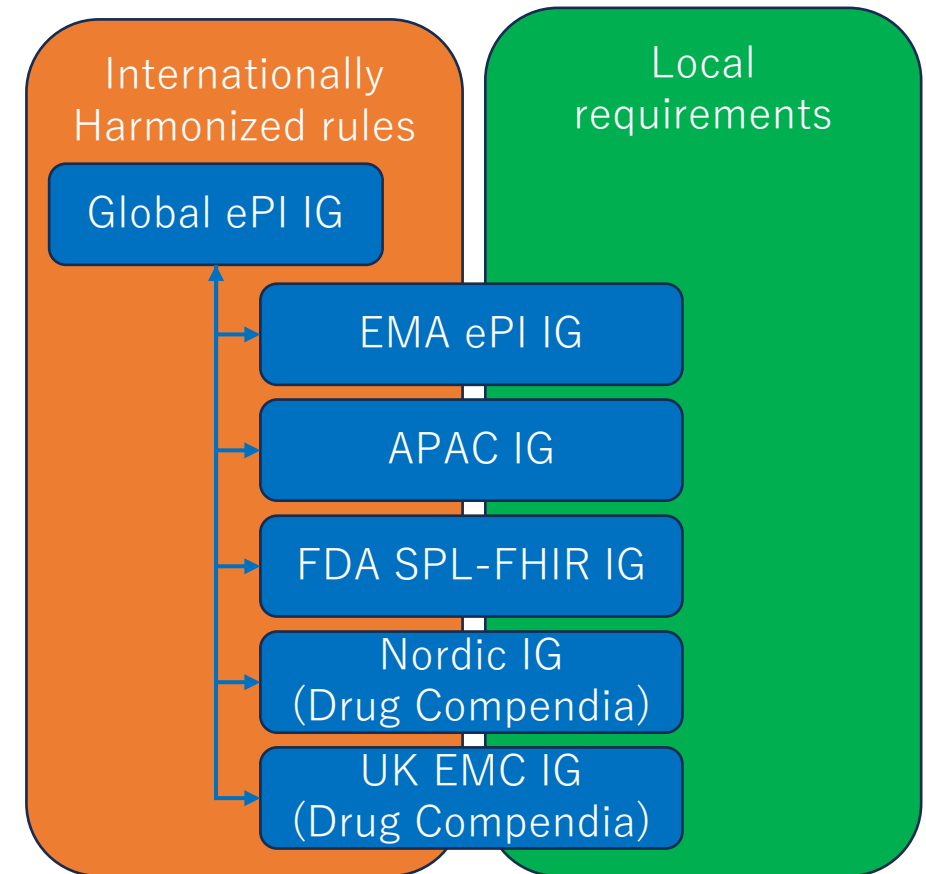
Recommended starting point

In development

ePI Type 1: Label Template Only	ePI Type 2: Product Details	ePI Type 3: Clinical Details	ePI Type 4: Full Structure
<ul style="list-style-type: none"> <li>Semi-structured text (Local template section headings, text, tables, bullets, images)</li> <li>Document metadata (language, date, identifier, version)</li> </ul>	<ul style="list-style-type: none"> <li>Type 1 and product details                             <ul style="list-style-type: none"> <li>Product Name</li> <li>Ingredients</li> <li>Packaging</li> <li>Strength</li> <li>Manufactured</li> <li>Administrable dose forms</li> <li>Organization details</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Type 1, 2, and clinical details                             <ul style="list-style-type: none"> <li>Indication</li> <li>Interactions</li> <li>Contraindication</li> <li>Undesirable Effects</li> <li>Warnings</li> <li>Population demographics</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Label content is made of structured components (E.g., Adverse event data is structured, and AE frequency tables are auto-generated)</li> <li>Maximum personalization capability</li> <li>Structured dose instructions</li> </ul>
Simple search & analysis by section headings and text	Intermediate to advanced search & analysis; interoperability with ePrescription & EHRs; personalization		Auto-generate label template; interoperable with Generative AI

# ePI Implementation Guide Hierarchy

- The Gravitate Health/Vulcan ePI Core IG provides guidance and compliance rules common to all jurisdictions (e.g., technical style guide; XML structure; validation).
- Regional or country specific IGs provide guidance and compliance rules unique to this jurisdiction (e.g., local terminology and identifiers; local label template section headings; local business validation rules).
- Global and country specific IGs are maintained in sync and through open collaboration under HL7 (e.g., transparent sharing of lessons learned and improvements).



# Implementation Guide Overview

Business guidance

Technical guidance

Compliance rules defining how to build an ePI using resources

Home Use Case ePI Creation Best Practice Artifacts Downloads Credits

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Electronic Medicinal Product Information (ePI) FHIR Implementation Guide, published by HL7 International - Biomedical Research & Regulation Work Group. This guide is not an authorized publication; it is the continuous build for version 1.0.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of <https://github.com/HL7/emedicinal-product-info/> and changes regularly. See the [Directory of published versions](#).

## 1 Home

Official URL: <a href="http://hl7.org/fhir/uv/emedicinal-product-info/ImplementationGuide/hl7.fhir.uv.emedicinal-product-info">http://hl7.org/fhir/uv/emedicinal-product-info/ImplementationGuide/hl7.fhir.uv.emedicinal-product-info</a>	Version: 1.0.0
Active as of 2024-07-15	Computable Name: EpiIG

### 1.1 Purpose

To provide guidance on the technical and business conformance rules needed to create and exchange electronic Product Information (ePI) using HL7 FHIR and standard terminologies; and, as well as to create a common global approach for structuring medicinal product information and medicinal product labelling that is based on HL7 International standards.

- Purpose
- Goals
- Objectives
- Scope
- ePI Background
- How to use this guide

### 9.0.2 Structures: Resource Profiles

These define constraints on FHIR resources for systems conforming to this implementation guide.

AdministrableProductDefinition (ePI)	AdministrableProductDefinition (ePI)
Bundle - ePI	Medicinal product information is 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 and effective use. This profile represents the constraints applied to the Bundle resource used in the Electronic Product Information (ePI) FHIR Implementation Guide.
ClinicalUseDefinition Contraindication (ePI)	ClinicalUseDefinition Contraindication (ePI)
ClinicalUseDefinition Indication (ePI)	ClinicalUseDefinition Indication (ePI)
ClinicalUseDefinition Interaction (ePI)	ClinicalUseDefinition Interaction (ePI)
ClinicalUseDefinition Undesirable Effect (ePI)	ClinicalUseDefinition Undesirable Effect (ePI)
ClinicalUseDefinition Warning (ePI)	ClinicalUseDefinition Warning (ePI)
Composition (ePI)	The Composition captures the section headings, sub-section headings, and narrative text (for example, paragraphs, bulleted lists, tables) in an ePI.

### 9.0.4 Terminology: Code Systems

These define new code systems used by systems conforming to this implementation guide.

eMedicinal Product Information Code System	eMedicinal Product Information Code System. Coded concepts defined for ePI use only.
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### 9.0.5 Example: Example Instances

These are example instances that show what data produced and consumed by systems conforming with this implementation guide might look like.



# Potential ePI Use Cases

- **Personalization:** tailor ePI content to fit patient or healthcare professional's needs. E.g. , confirm if any ingredients are known allergens or a known effect.
- **Interactions:** Compare ePIs to confirm if the patient's current medications have drug:drug, drug:food interactions.
- **Contraindications:** Confirm if any of the patient's conditions are contraindicated with this medication.
- **Drug shortages:** Use ePI's product information (e.g., unique IDs for pack, drug, or manufacturer) to quickly find other drugs in the same class or category.
- **Advanced search:** Host all ePIs in a central portal (like EMA's) to facilitate content search.
- **Cross-border travel:** Allow HCPs or patients to identify the same or similar drug in another country.
- **Distribution:** Use packaging details in the ePI (e.g., product and pack identifiers) to facilitate supply chain ordering or tracking.
- **eHealth interoperability:** Reuse structured ePI content in apps like EHR, ePrescription, Apple Health or Google Health apps.



Virkestoff

MT-numre

Pakningsfoto

Produkt	Virkestoff og styrke(r)
Brakelyx 100 mg tabletter	Brakeklypten 100 mg
Brakelyx 250 mg tabletter	Brakeklypten 250 mg

MT-numre

Pakning (Vnr)	MT-nummer	Region
123456	01-1234	Norge
234567	01-2345	Norge

## Pakningsvedlegg: Informasjon til pasienten

### Brakelyx 100 mg tabletter

### Brakelyx 250 mg tabletter

### Brakeklypten

Instruksjonsfilmer

Les nye gjennom dette pakningsvedlegget før du begynner å bruke dette legemidlet. Det inneholder informasjon som er viktig for deg.

- Ta vare på dette pakningsvedlegget. Du kan få behov for å lese det igjen.
- Sørge lege eller apotek hvis du har flere spørsmål eller trenger mer informasjon.
- Dette legemidlet er skrevet ut kun til deg, ikke gi det videre til andre. Det kan skade dem, selv om de har symptomer på sykdom som ligner dine.
- Kontakt lege eller apotek dersom du opplever bivirkninger. Dette gjelder også bivirkninger som ikke er nevnt i pakningsvedlegget. Se avsnitt 4.

I dette pakningsvedlegget finner du informasjon om:

- Hva Brakeklyx er og hva det brukes mot
- Hva du må vite før du bruker Brakeklyx
- Hvordan du bruker Brakeklyx
- Mulige bivirkninger
- Hvordan du oppbevarer Brakeklyx
- Innholdet i pakken og ytterligere informasjon

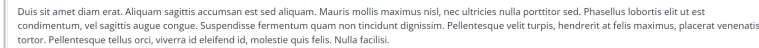
## 1. Hva Brakeklyx er og hva det brukes mot

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Integer cursus pulvinar nisl vitae lobortis. Nam auctor dolor at ante varius, et pellentesque nisl luctus. Phasellus a tellus elit. Vestibulum vitae consectetur nibh, non imperdiet augue. Fusce erat justo, mollis at porttitor cursus, sollicitudin in ex.

Pellentesque habitant morbi tristique senectus et netus et malesuada fames ac turpis egestas. Ut eu luctus diam. Quisque blandit rhoncus felis, eu gravida ex egestas non.

Vivamus vitae turpis nec eros luctus tempus. Proin laculis condimentum urna et laoreet. Nunc varius, sem in accumsan pellentesque, erat nunc rutrum sapien, et lobortis tui eros a ex. Aenean scelerisque, velit eget luctus auctor, lectus ipsum pharetra tortor, vitae laoreet sapien ligula ac diam.

In aliquam sem fringilla ut morbi tincidunt. In dictum non consectetur a erat nam. Nunc rhoncus viverra velit, nec eleifend enim mollis in. Sed ullamcorper vel turpis varius fringilla. Mauris gravida quam vel libero iaculis accumsan.



Nulla porttitor massa id neque aliquam vestibulum. Nulla pharetra diam sit amet nisl suscipit. Faucibus in ornare quam viverra orci.

Faucibus nisl tincidunt eget nullam non nisi est sit. Eget nulla facilisi etiam dignissim diam quis.

Turpis egestas sed tempus urna et pharetra pharetra. At tellus at urna condimentum mattis.

Ultrices eros in cursus turpis massa tincidunt dui ut ornare. Mi ipsum faucibus vitae aliquet nec ullamcorper sit. Elit sed vulputate mi sit. Etiam dignissim diam quis enim. Vitae et leo duis ut.

Kontakt lege, apotek eller sykepleier dersom du opplever bivirkninger. Dette gjelder også bivirkninger som ikke er nevnt i pakningsvedlegget. Du kan også melde fra om bivirkninger direkte via meldeskjema som finnes på nettsiden til Statens legemiddelverk: [www.legemiddelverket.no/pasientmelding](http://www.legemiddelverket.no/pasientmelding). Ved å melde fra om bivirkninger bidrar du med informasjon om sikkerheten ved bruk av dette legemidlet.

Proin sagittis nisl rhoncus mattis rhoncus. Mattis ullamcorper velit sed ullamcorper morbi tincidunt ornare massa.

Quisque sagittis purus sit amet. Massa placerat dui ultricies lacus sed turpis tincidunt.

At imperdiet dui accumsan sit amet nulla facilisi morbi. Interdum posuere lorem ipsum dolor sit amet.

Brakelyx 100 mg tabletter




Brakelyx 250 mg tabletter


Eget nunc lobortis mattis aliquam faucibus purus in.

Eu augue ut lectus arcu bibendum at varius.

Dette pakningsvedlegget ble sist oppdatert 26.03.2023

# Use case: EMA's online ePI Portal


**Product Lifecycle Management Portal**


SPOR  IAM IRIS Forum [Sign in](#)

[Home](#) > [ePI for human medicines](#)

Search and browse ePI of authorised PI published in the context of the ePI pilot project.

**IMPORTANT NOTE:** ePIs are published for pilot purposes only, and may not be up-to-date. Not to be used as medicines information.

Download 



EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Published on	Medicines regulatory agency	Country of authorisation	Action
<a href="#">EPI/24/7</a>	Kyleena DK - Device breakage	SE/H/1587/001/WS/028	MRP/DCP	Bayer AB	22/08/2024 11:16 AM	Danish Medicines Agency	Denmark	<a href="#">View</a>
<a href="#">EPI/24/1</a>	Vitrakvi	EMA/H/C/004919/R/0035	CAP	Bayer AG	01/08/2024 01:02 PM	European Medicines Agency	European Union	<a href="#">View</a>
<a href="#">EPI/24/17</a>	Nuvaxovid	EMA/H/C/005808/IAIN/0074	CAP	Novavax CZ a.s.	14/06/2024 01:28 PM			
	Kyleena SE - Device				28/05/2024			

[Clear](#)

Export 

Please choose a format to export ePI

☐ Word (all ePI documents in one file with title pages)

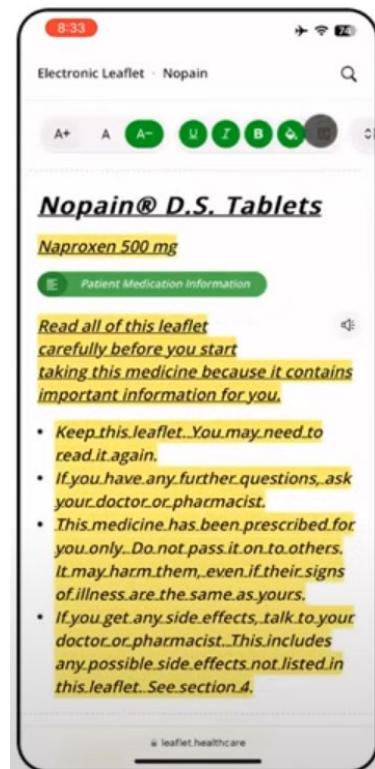
☐ Word (each ePI document in a separate file)

☒ FHIR

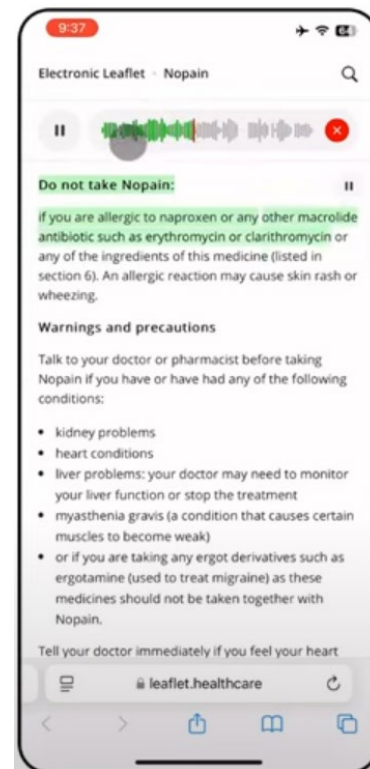
[Export](#) [Cancel](#)

# Use case: Jordan FDA's App with accessibility features

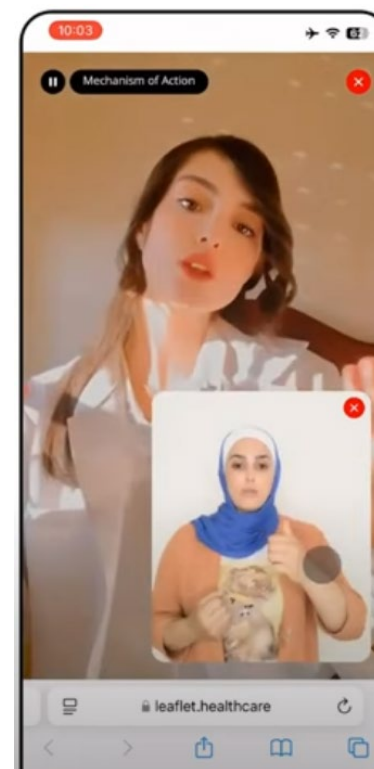
Control text size, dark mode, appearance



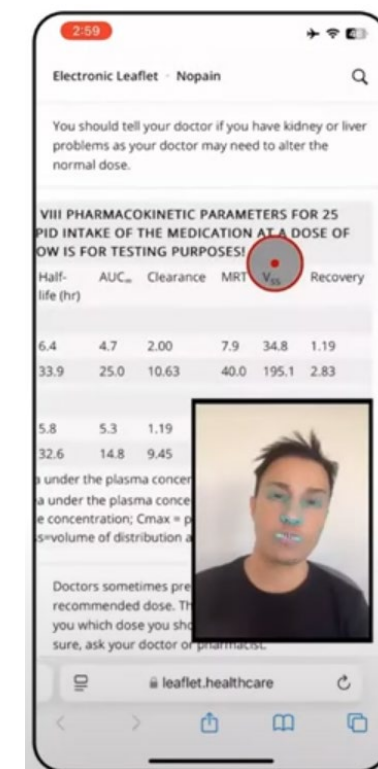
Text to speech



Sign language



Face navigation



# Use case: personalization

## Questionnaire results

**This is your personalised Patient information leaflet**

This personalised leaflet was created for you based on your choices below. Ensure your selections are accurate and up-to-date, as mistakes may result in relevant information not being shown.  
Please always read the full patient information leaflet.

Hide my personalised selections ^

*i* This is the info you have shared about yourself that has been used to create your personalised leaflet - please check all answers are correct

1/5

Biological sex: **Female**  
Currently pregnant: **No**  
Currently breastfeeding: **No**

2/5

Age: **18-64 years of age**

3/5

Taking other medicines and treatments: **Yes**  
Other medicines and treatments: **Ciclosporin, St. John's wort (Hypericum perforatum)**

4/5

Any allergies or intolerances: **No**

5/5

Strength(s) of Talazoparib prescribed: **1mg (milligrams)**

[Change my Answers](#) [See the full PIL](#)

A questionnaire helps patients personalize their ePI to only show relevant content.

## Original PIL

### Male and female contraception

**Women** who are able to become pregnant should use effective birth control (contraception) during treatment with Talzenna and for at least 7 months after the last dose of Talzenna. Since the use of hormonal contraception is not recommended if you have breast cancer, you should use two non-hormonal contraception methods.

Talk to your healthcare provider about birth control methods that may be right for you.

**Men** with female partners who are pregnant or able to become pregnant should use effective birth control (contraception), even after a vasectomy, during treatment with Talzenna and for at least 4 months after the last dose.

## Personalized PIL

### Male and female contraception

**Women** who are able to become pregnant should use effective birth control (contraception) during treatment with Talzenna and for at least 7 months after the last dose of Talzenna. Since the use of hormonal contraception is not recommended if you have breast cancer, you should use two non-hormonal contraception methods.

Talk to your healthcare provider about birth control methods that may be right for you.

# Future use case: ePI Type 3 / 4 - Personalized Undesirable Effects

- Rather than a “regular” Word table, the table is generated from structured data components. This will allow us to create personalized undesirable effect tables.

```
<undesirableEffect>
  <classification>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="36225005"/>
      <display value="Blood and lymphatic system disorders"/>
    </coding>
  </classification>
  <symptomConditionEffect>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="703938007"/>
      <display value="Neutropenia"/>
    </coding>
  </symptomConditionEffect>
  <frequency value="≥10%"/>
</undesirableEffect>
```

```
<undesirableEffect>
  <classification>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="36225005"/>
      <display value="Blood and lymphatic system disorders"/>
    </coding>
  </classification>
  <symptomConditionEffect>
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      <display value="Leukopenia"/>
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  </symptomConditionEffect>
  <frequency value="≥10%"/>
</undesirableEffect>
```

Structured data  
styled into a  
table

Table 4. Adverse Reactions (≥10%) in PALOMA-2

Adverse Reaction	IBRANCE plus Letrozole (N=444)			Placebo plus Letrozole (N=222)		
	All Grades %	Grade 3 %	Grade 4 %	All Grades %	Grade 3 %	Grade 4 %
Infections and infestations						
Infections <sup>a</sup>	60 <sup>‡</sup>	6	1	42	3	0
Blood and lymphatic system disorders						
Neutropenia	80	56	10	6	1	1
Leukopenia	39	24	1	2	0	0
Anemia	24	5	<1	9	2	0
Thrombocytopenia	16	1	<1	1	0	0



# Future use case: ePI Type 3 / 4 - Structured Dose Syntax

Adults

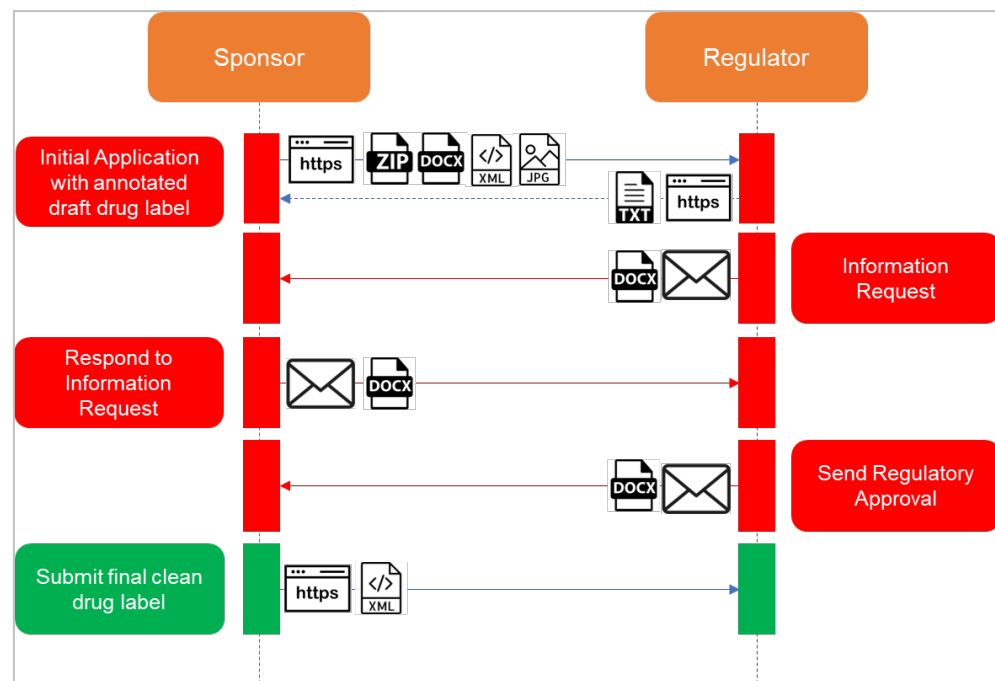
Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once daily until you are told to stop
To treat coccidioidomycosis	200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once daily until you are told to stop
To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 mg to 200 mg once daily until you are told to stop
To treat mucosal thrush – dose depends on where the infection is located	50 mg to 400 mg once daily for 7 to 30 days until you are told to stop
To stop mucosal infections affecting the lining of mouth, throat from coming back	100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection
To treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete's foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
To stop you from getting an infection caused by <i>Candida</i> (if your immune system is weak and not working properly)	200 mg to 400 mg once daily while you are at risk of getting an infection

```
<dosageInstruction>
  <sequence value="1"/>
  <text value="800 mg on the first day"/>
  <additionalInstruction>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="311504000"/>
      <display value="With or after food"/>
    </coding>
  </additionalInstruction>
  <timing>
    <repeat>
      <frequency value="1"/>
      <period value="1"/>
      <periodUnit value="d"/>
    </repeat>
  </timing>
  <route>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="26643006"/>
      <display value="Oral Route"/>
    </coding>
  </route>
</dosageInstruction>
```

```
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<method>
  <coding>
    <system value="http://snomed.info/sct"/>
    <code value="738995006"/>
    <display value="Swallow (administer orally)"/>
  </coding>
</method>
<doseAndRate>
  <type>
    <coding>
      <system value="http://terminology.hl7.org/CodeSystem/dose-and-rate-type"/>
      <code value="ordered"/>
      <display value="Ordered"/>
    </coding>
  </type>
  <doseQuantity>
    <value value="4"/>
    <unit value="TAB"/>
    <system value="http://terminology.hl7.org/CodeSystem/dose-and-rate-unit"/>
    <code value="TAB"/>
  </doseQuantity>
</doseAndRate>
</dosageInstruction>
```

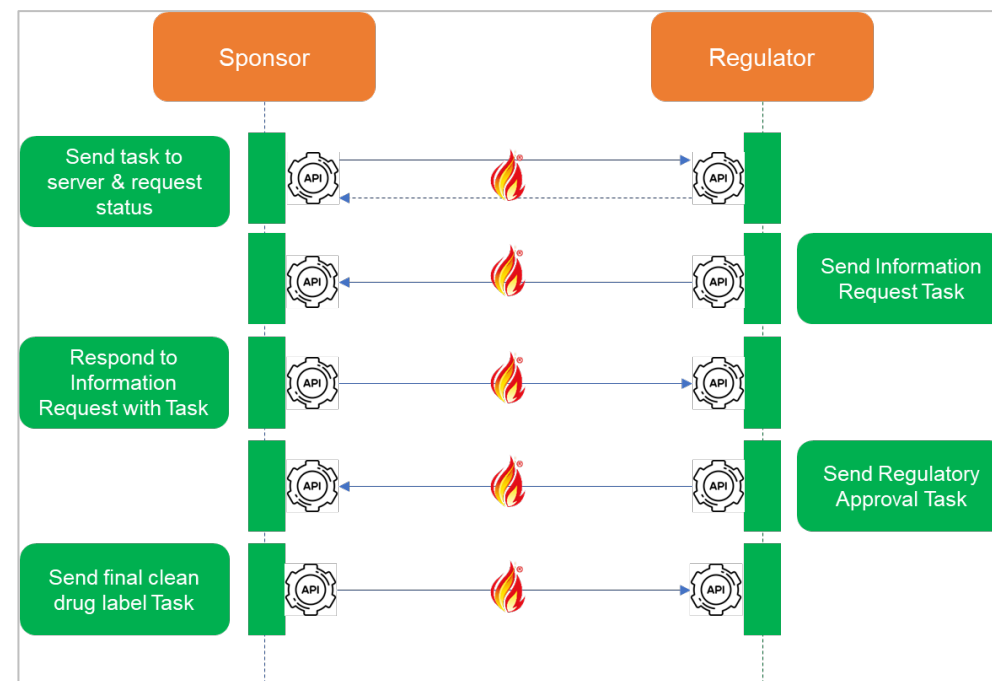
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once daily until you are told to stop
--	---

# Future use case: End-to-end FHIR Regulatory Workflow



**Current State**

- Workflow depends on DOCX during assessment
- Exchange via portal, email, media, manual steps
- Sponsor needs to convert between DOCX and XML



**Future State**

- All FHIR workflow (including assessment; no DOCX)
- Exchange via Application Program Interface (API)
- Advanced features (e.g., Subscription service)



# Lessons Learned: EMA/FDA pilots and Gravitare Health/Vulcan project work

- Recommend starting with ePI Type 2
- Remain harmonized with EMA and Vulcan Implementation Guides where possible
- Recommended roadmap:
  - Phase 1: Create a prototype ePI as a gold standard
  - Phase 2: Technical pilot
  - Phase 3: Production Pilot (Voluntary)
  - Phase 4: Production (Voluntary)
  - Phase 5: Production (Mandatory)
- Aim for a two-year timeframe to go from Phase 1 to Phase 4. Allow grace period between Phase 4 and 5 to allow industry time to get ready.
- Communicate roadmap in advance so industry has time to procure tools