Gravitate Health

Gravitate-Health Open E2E ePI Community

Reshaping processes to create and share enriched electronic medicinal product information (ePI) to prepare for the future

Join us!

Sign up to join this Community

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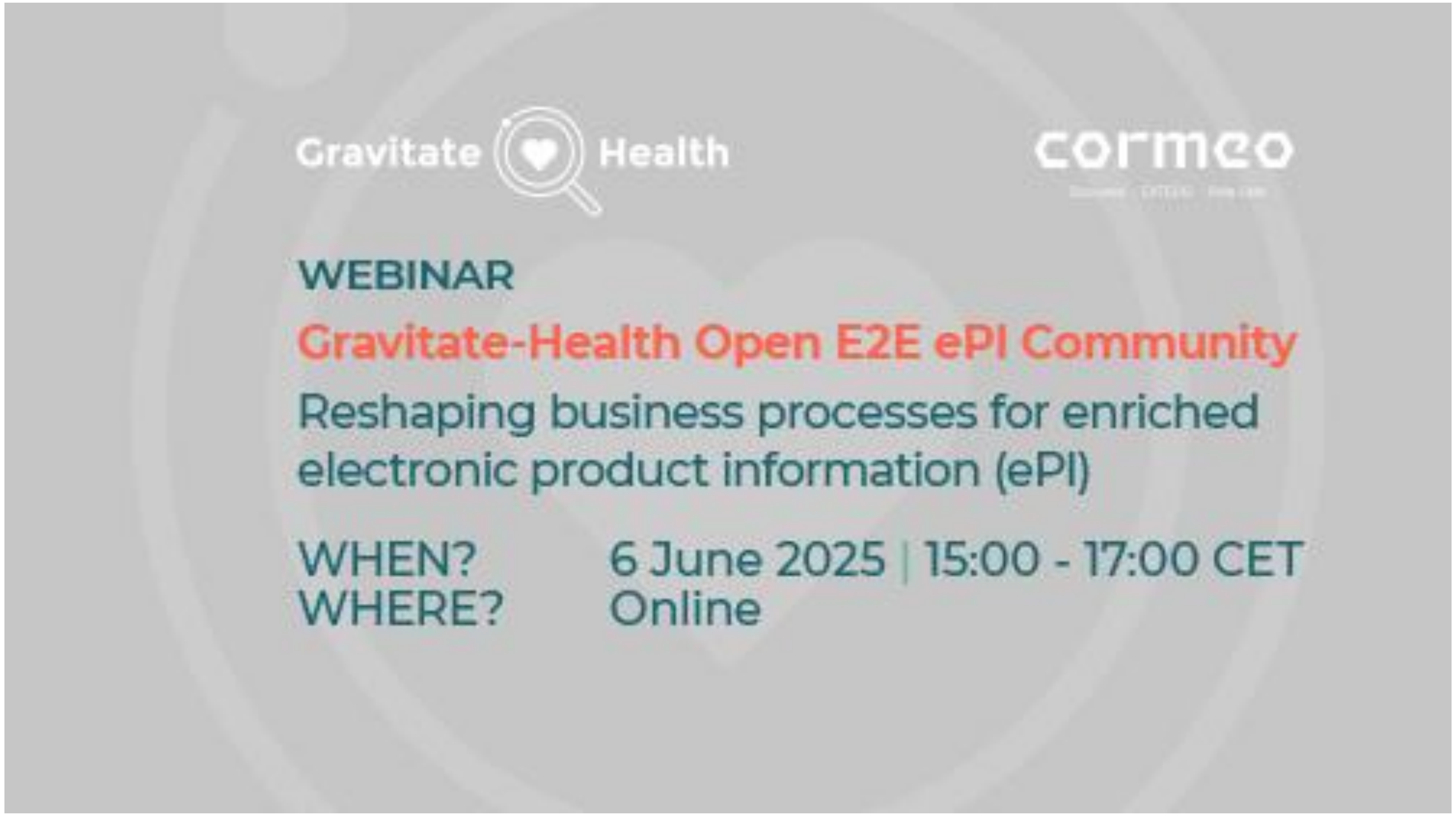
TODAY'S WEBINAR


Gravitate Health
cormeo

WEBINAR

Gravitate-Health Open E2E ePI Community

Reshaping business processes for enriched electronic product information (ePI)

WHEN?	6 June 2025 | 15:00 - 17:00 CET
WHERE?	Online

Enrichment of ePI – Results from the May HL7 International Connectathon & Working Group Meeting

João Almeida, HL7 Europe, Gravitate-Health

Report back from Connectathon

- PhPID workflow
- ePI Style sheet
- ePI version control
- ePI Type 4

Report back from Connectathon

- **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)

HL7 FHIR ePI Specification introduction

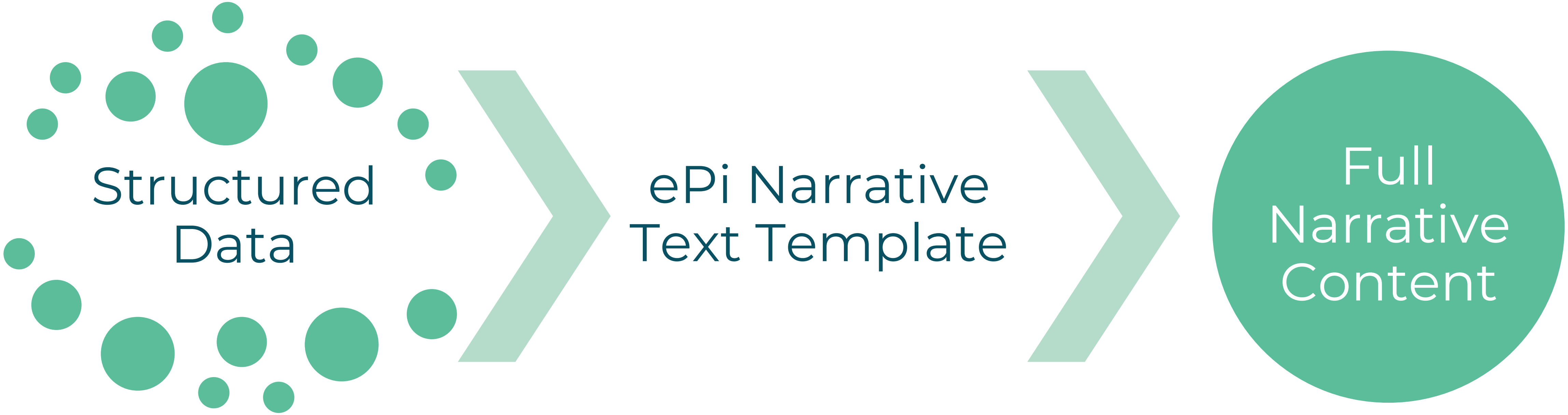
- FHIR ePIs are made up of the following thirteen resources

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).

Report back from Connectathon

- What about type 4?

The difference between the type 3 and 4 could be the linking of the content in structured format and the actual concepts.



Structured Data

ePi Narrative Text Template

Full Narrative Content

FHIR Resources

Just a skeleton to be filled with the data from FHIR Resources

Equal or similar to the current Text of the ePI

Report back from Connectathon

ePI Section	Resource(s) to be used to contain information
1.1 SmPC-NAME OF THE MEDICINAL PRODUCT	MedicinalProductDefinition
1.2 SmPC-QUALITATIVE AND QUANTITATIVE COMPOSITION	Ingredient (active principle)
1.3 SmPC-PHARMACEUTICAL FORM	MedicinalProductDefinition
1.4.1 SmPC-CLINICAL PARTICULARS-Therapeutic indications	ClinicalUseDefinition/MedicinalProductDefinition
1.4.2 SmPC-CLINICAL PARTICULARS-Posology and method of administration	MedicationKnowledge (posology) MedicinalProductDefinition (method of administration)
1.4.3 SmPC-CLINICAL PARTICULARS-Contraindications	ClinicalUseDefinition.where(type=contraindication)
1.4.4 SmPC-CLINICAL PARTICULARS-Special warnings and precautions for use	ClinicalUseDefinition.where(type=warning)
1.4.5 SmPC-CLINICAL PARTICULARS-Interaction with other medicinal products and other forms of interaction	ClinicalUseDefinition.where(type=interaction)

Report back from Connectathon

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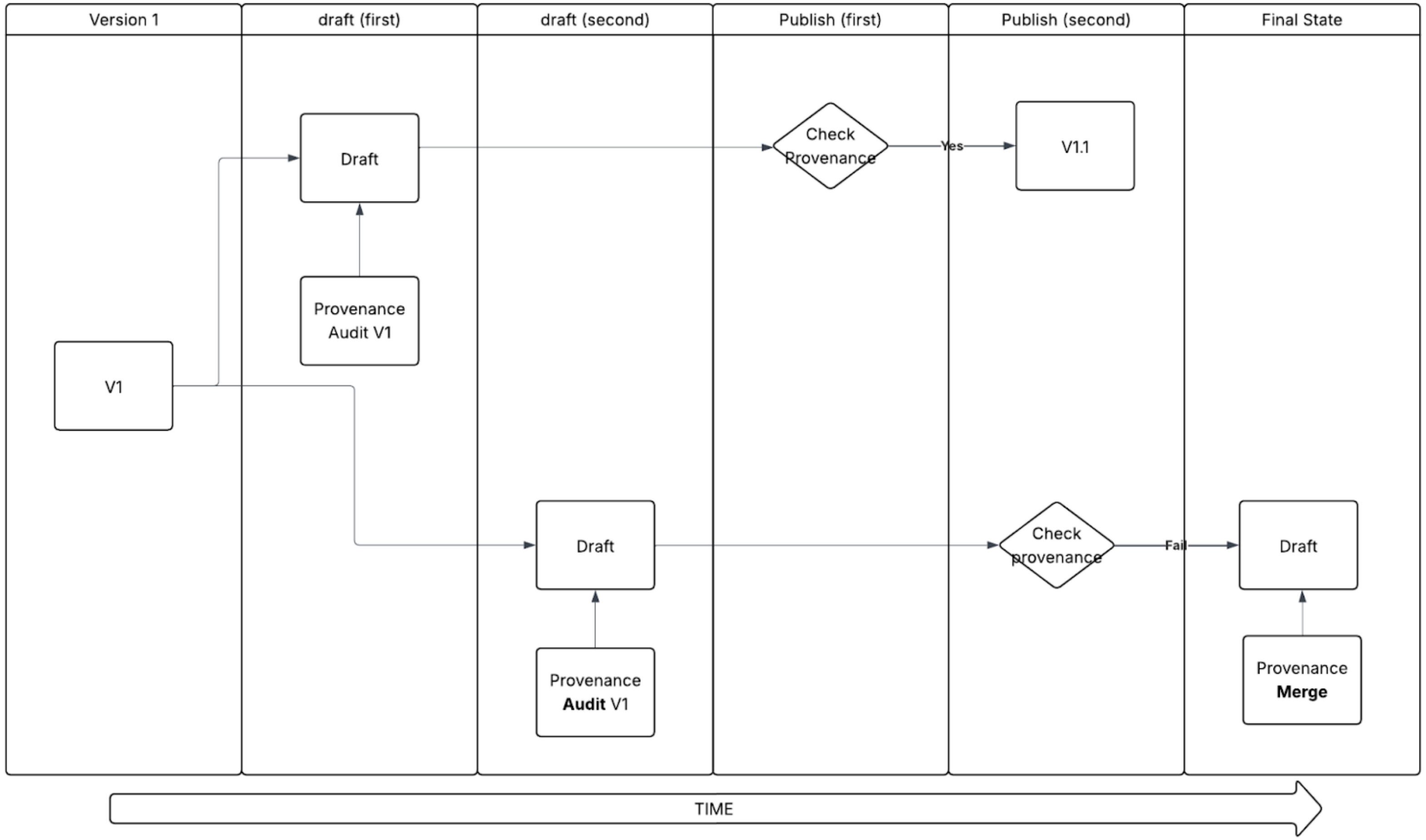
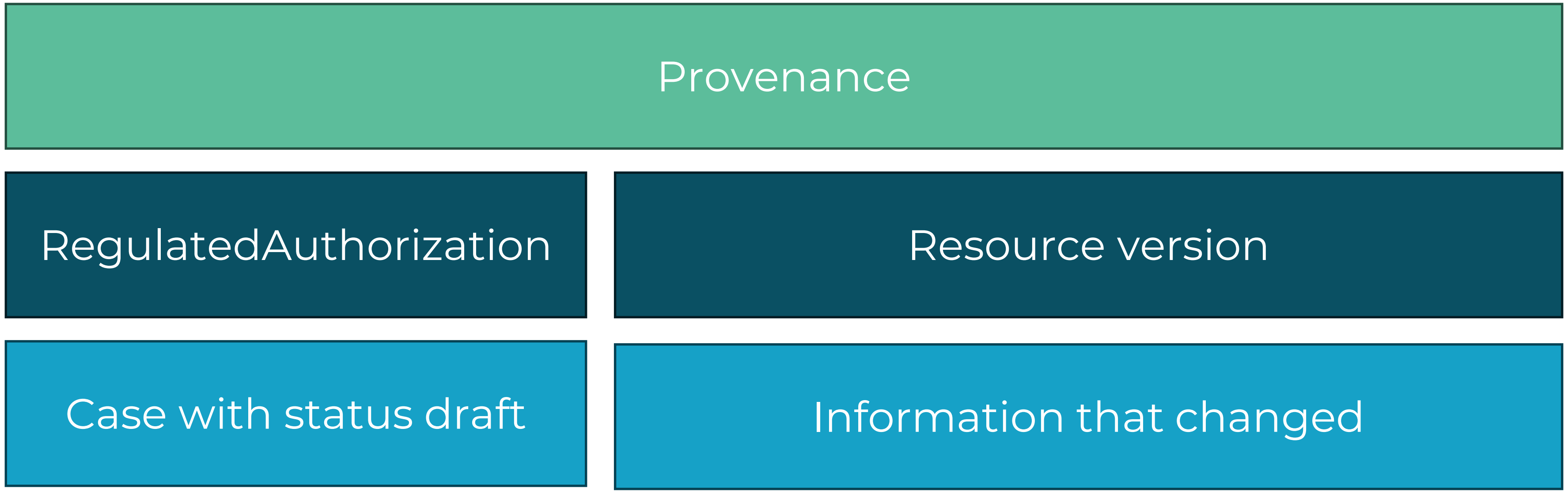
13	Substance	Details about an ingredient (e.g., chemical structure, molecular weight).
14	Medication	Data about dosage / usage

Report back from Connectathon

How to handle variations


Version 1
draft (first)
draft (second)
Publish (first)
Publish (second)
Final State
Draft
Check Provenance
Yes
V1.1
Provenance Audit V1
V1
Draft
Check provenance
Fail
Draft
Provenance **Audit** V1
Provenance **Merge**
TIME

Report back from Connectathon



Provenance

RegulatedAuthorization

Resource version

Case with status draft

Information that changed

Change in progress

Contains the updated information

- Be able to map cases and content changed with it
- Build the narrative Text taking into account the current approved, or with draft changed and be able to highlight them as draft/in progress
- Create more automation with submission of ePIs

Report back from Connectathon

Provenance

RegulatedAuthorization

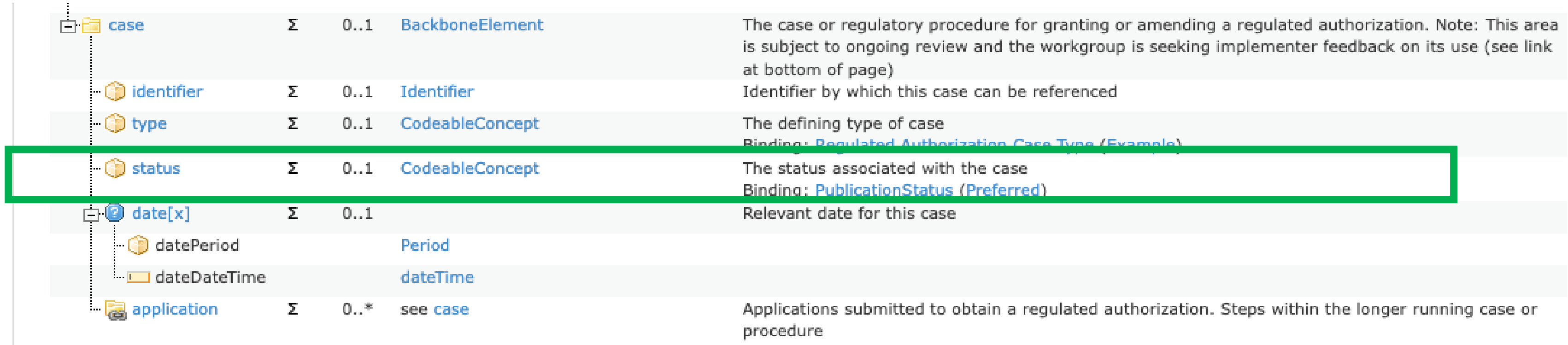
Resource version

Case with status draft

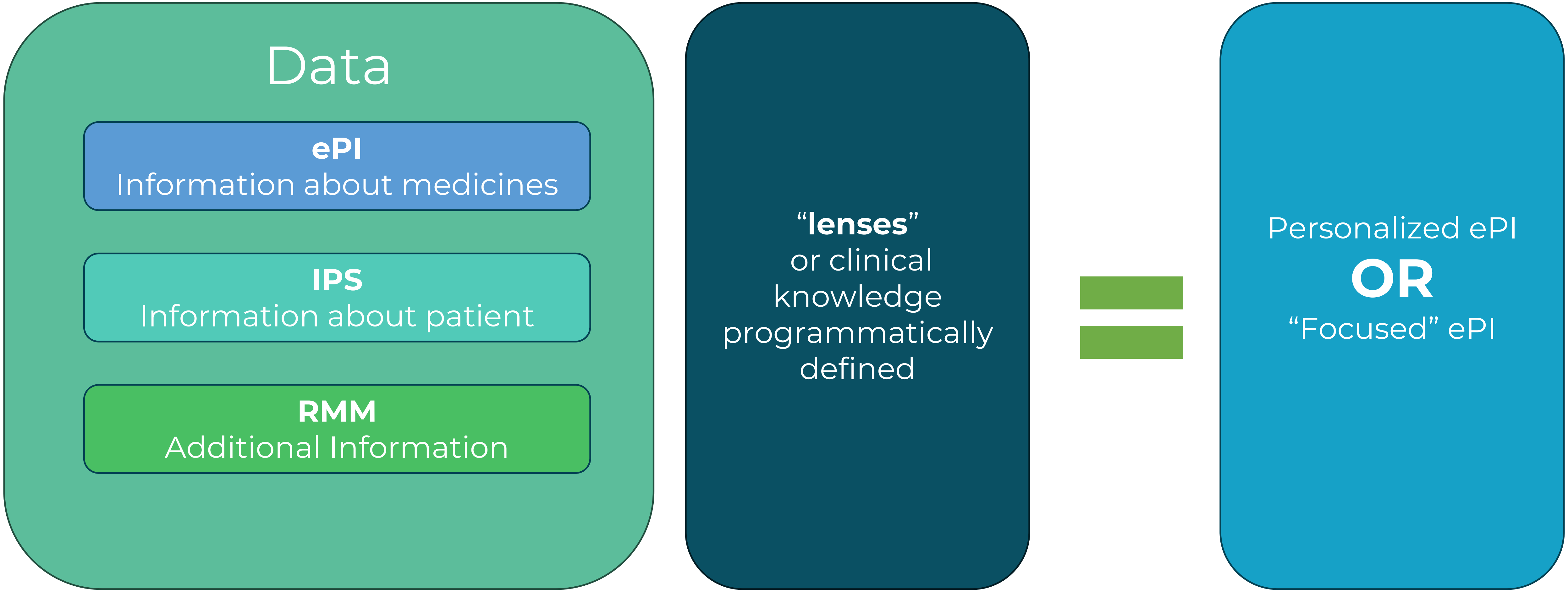
Information that changed

Change in progress

Contains the updated information



case	Σ	0..1	BackboneElement	The case or regulatory procedure for granting or amending a regulated authorization. Note: This area is subject to ongoing review and the workgroup is seeking implementer feedback on its use (see link at bottom of page)
identifier	Σ	0..1	Identifier	Identifier by which this case can be referenced
type	Σ	0..1	CodeableConcept	The defining type of case Binding: Regulated Authorization Case Type (Example)
status	Σ	0..1	CodeableConcept	The status associated with the case Binding: PublicationStatus (Preferred)
date[x]	Σ	0..1		Relevant date for this case
datePeriod			Period	
dateDateTime			dateTime	
application	Σ	0..*	see case	Applications submitted to obtain a regulated authorization. Steps within the longer running case or procedure



Data

ePI
Information about medicines

IPS
Information about patient

RMM
Additional Information

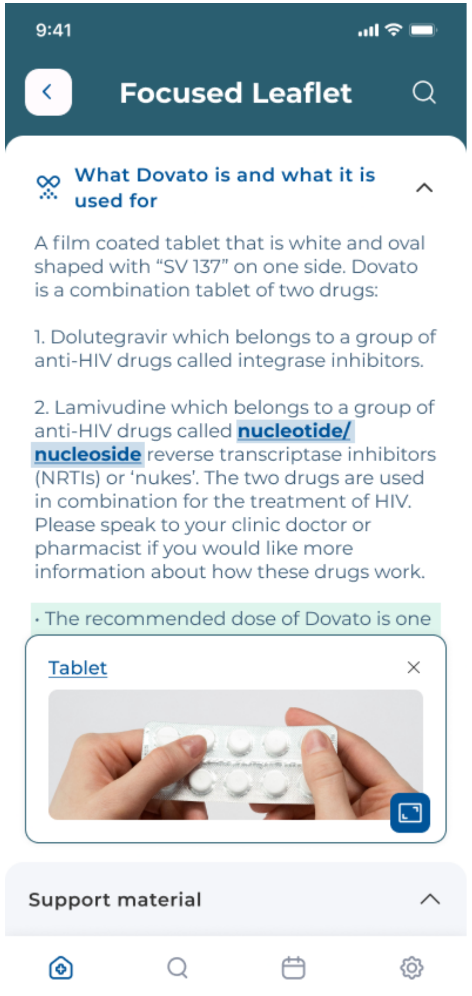
“**lenses**”
or clinical
knowledge
programmatically
defined

=

Personalized ePI
OR
“Focused” ePI

Gravitate and go beyond the ePI

Tag/ Objective	Resource(S)
Indication	ClinicalUseDefinition
Interaction	ClinicalUseDefinition
Warning	ClinicalUseDefinition
undesirable-effect	ClinicalUseDefinition
contraindication	ClinicalUseDefinition
Image	Binary / DocumentReference
Video	Binary / DocumentReference
URL	DocumentReference
Text	DocumentReference
PDF / Document	DocumentReference


9:41
Focused Leaflet

What Dovato is and what it is used for

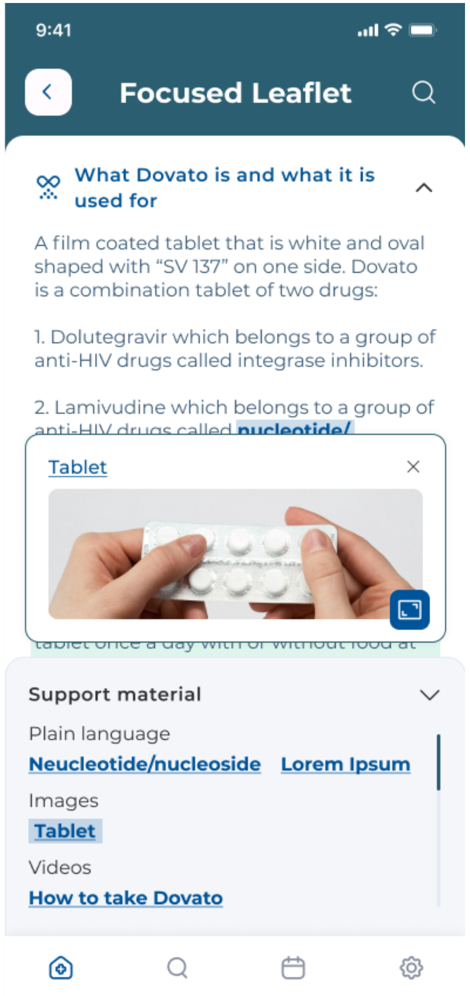
A film coated tablet that is white and oval shaped with "SV 137" on one side. Dovato is a combination tablet of two drugs:

1. Dolutegravir which belongs to a group of anti-HIV drugs called integrase inhibitors.

2. Lamivudine which belongs to a group of anti-HIV drugs called **nucleotide/ nucleoside** reverse transcriptase inhibitors (NRTIs) or 'nukes'. The two drugs are used in combination for the treatment of HIV. Please speak to your clinic doctor or pharmacist if you would like more information about how these drugs work.

· The recommended dose of Dovato is one

Tablet
Support material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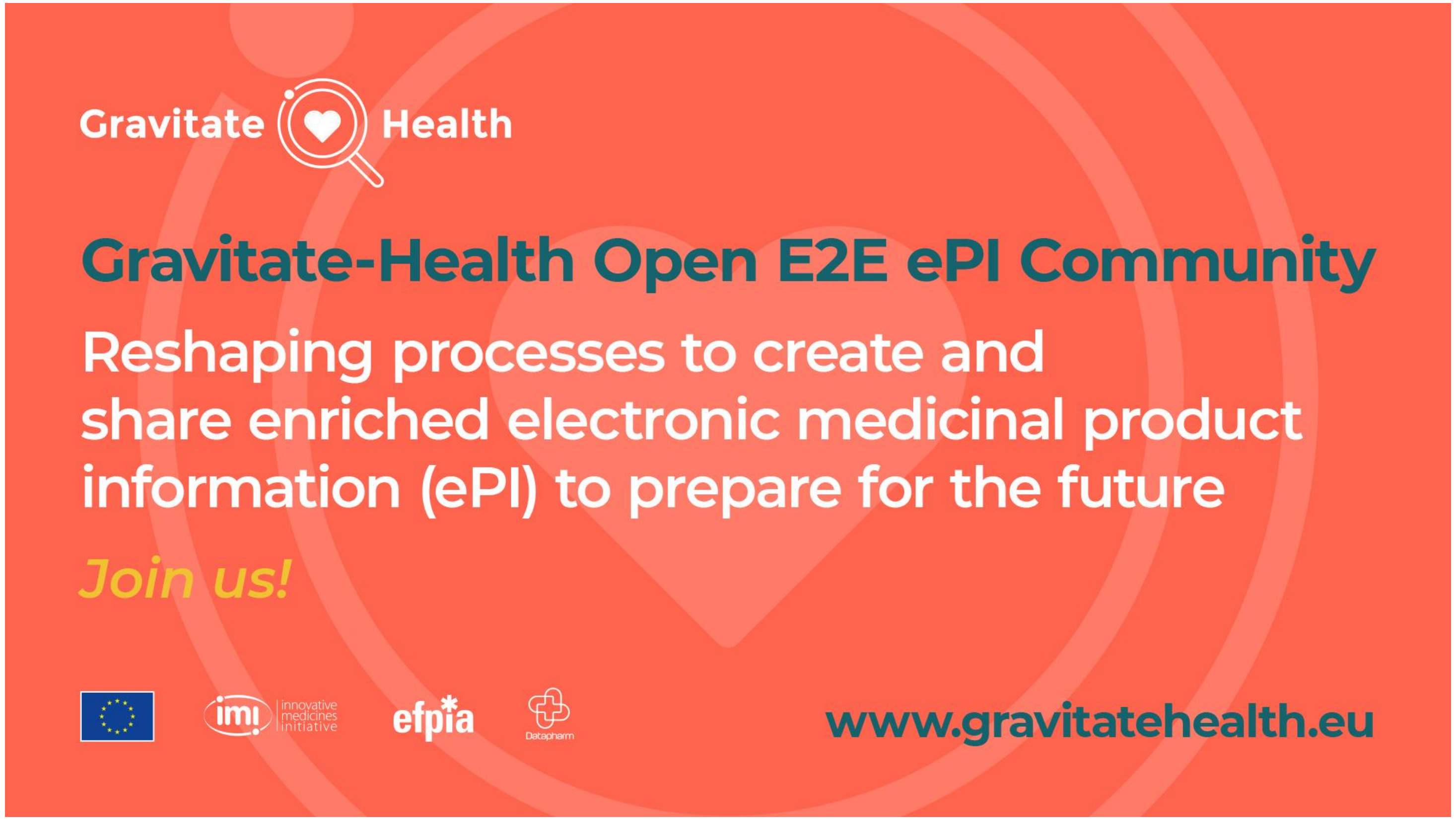
2. Lamivudine which belongs to a group of anti-HIV drugs called **nucleotide/**

Tablet
Support material
Plain language
Neucleotide/nucleoside
Lorem Ipsum
Images
Tablet
Videos
How to take Dovato

Learn more about the Gravitate-Health Open E2E ePI Community

**Sign up
to join
this Community!**
↓



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Join us!

imi innovative medicines initiative efpia Datapharm

www.gravitatehealth.eu

Thank You

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The Gravitate-Health project has received funding from the Innovative Medicines Initiative Joint Undertaking under grant agreement No 945334.