



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

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

Consortium Partners

Coordinator

Leader





Scoping of community activities:

- Focus on ePI creation mechanisms and enrichment/augmentation which is important to disseminate higher value ePI post approval, specifically for 'G-lens' ready ePI with focusing mechanisms
 - accelerate implementation of 'value add' ePI with structured elements/ metadata to help focus content relevant to user situation and context of use
 - encourage maintenance and management of alignment of the ePI to Implementation Guides, and related standards (e.g. IDMP).
- Participants in this meeting may include representatives of companies that compete with one another in the marketplace. Discussions, plans, consensus, agreements, strategies, etc., may be unlawful if they relate to topics like:
 - Current or future prices or bidding information
 - Limits on production or product lines
 - Individual company marketing strategies, projections and assessments
 - Establishing a practice of dealing with customers or suppliers
- Company internal business processes are out of scope.



Gravitate-Health Open E2E ePI Community

Aim / purpose:

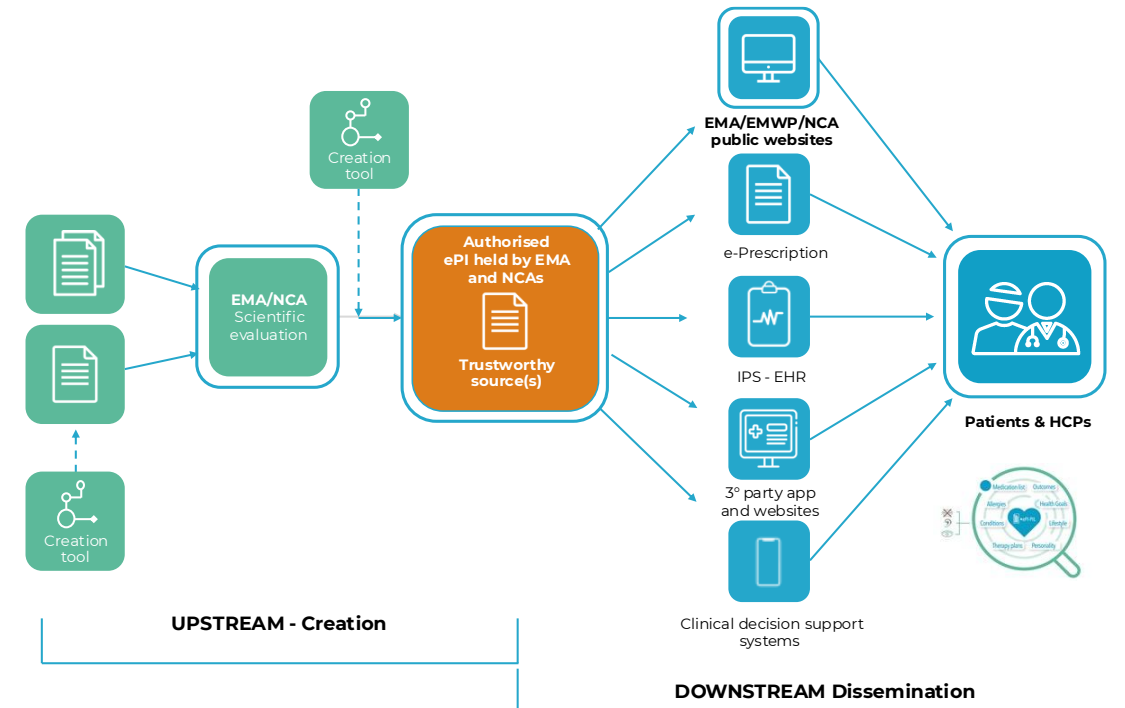
- Transform access and use of trusted health information / ePI to advance research & innovation
- Engage “end-end value chain” to drive sustainable use of ePI in the wider digital health landscape

Outputs:

- Upstream Creation - Downstream Dissemination of ePI for value added services, incl. G-lens®
- Support transformation towards greener patient-safe first health systems

Founding members:

- Gravitate-Health public-private partnership
- Corneo (DocuVera, EXTEDO – Rote Liste®)





Impact of our approach - a global FHIR ePI Standard



Gravitate-Health has connected key initiatives and foster collaborations globally, building on developments in the EU and drive uptake of a global HL7 FHIR ePI standard (2023)

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	
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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 (EU master data system for pharmacovigilance)
- To enable global use for regions without SPOR, VULCAN Profile has option to include data directly



ePI Structure and Content - FHIR ePI enrichment



- **Type 1: eLabel only**

- Semi-structured narrative text
 - section/sub-section headings
 - Paragraphs, tables, bulleted lists, images, video, pictograms
 - Document metadata (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, active ingredient,
 - Packaging, manufactured form and administrable form
 - Storage, general instructions about a medicine

- **Type 3: eLabel + product details + clinical details**

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

Simple Search

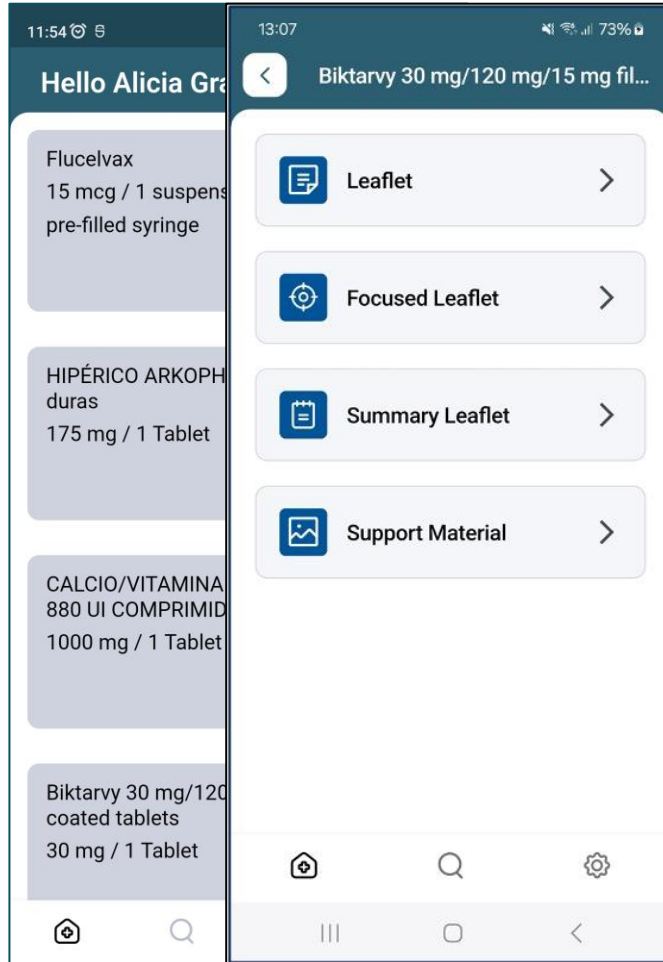
Intermediate Search

Advanced Search

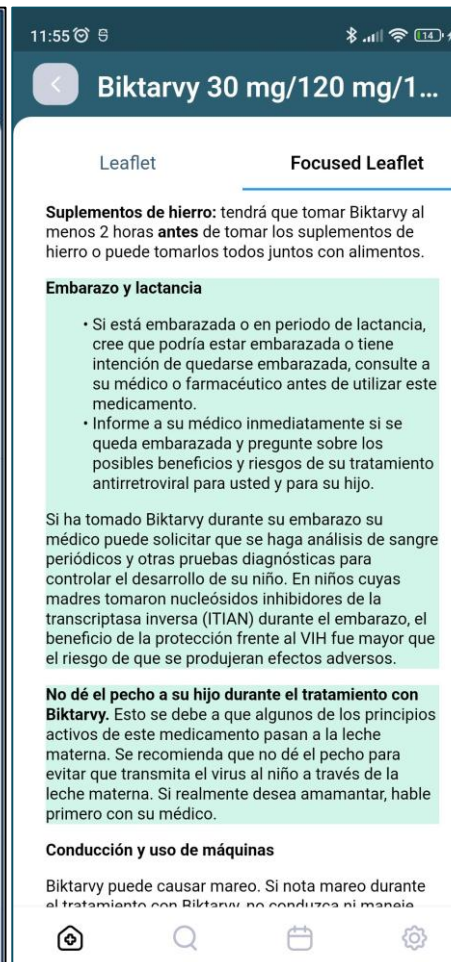
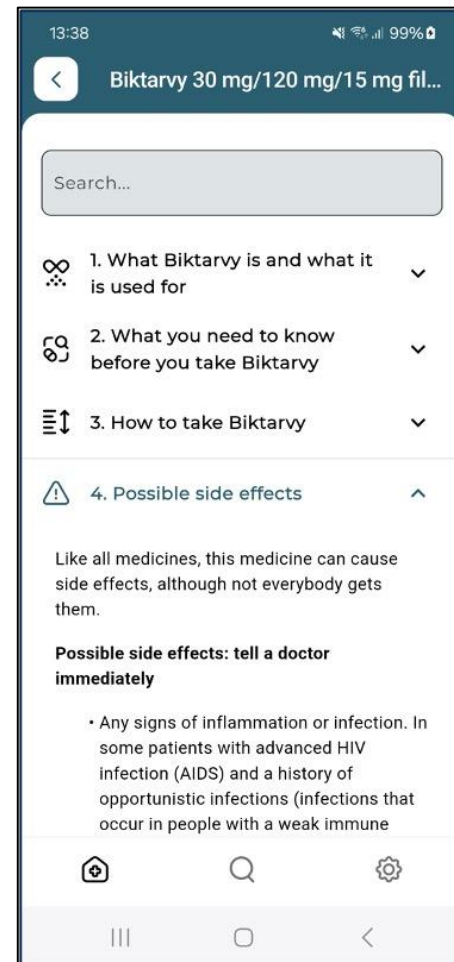


Presenting ePI to users - progress of Gravitate-Health

ePI - Leaflet



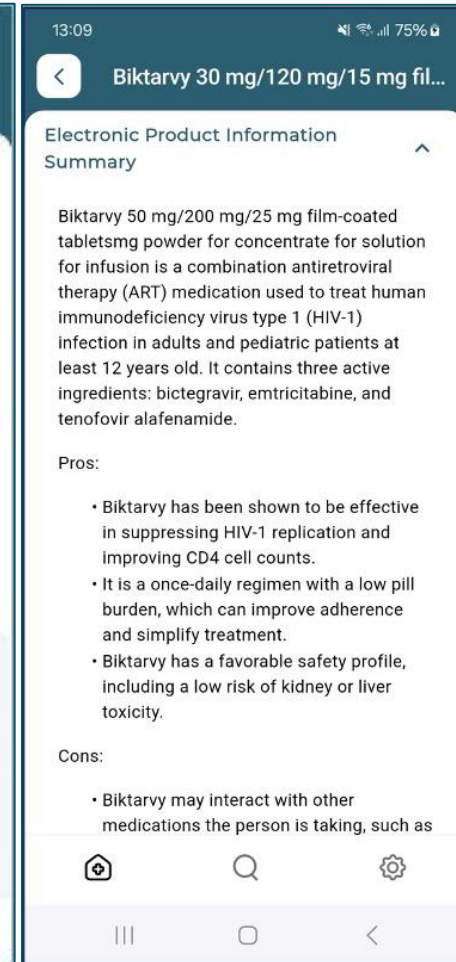
ePI - focused



ePI - HEM



ePI - summary





Overview of Testing Scenario Clusters

“test at scale”

end-end or own front end,
include real patient - data



G-lens services - patients with chronic disease (HIV), vaccines multi-morbidity, poly-pharmacy,



G-lens functionality - patients with COPD, care continuity and information management



CAPABLE – focused ePIs, medication list for IBD, illness score, supporting material

Advanced test

realistic users
and synthetic data



G-lens functionality, the Danish My Doctor app, IPS demo for Diabetes medicines,



G-lens functionality, SN24 platform patients with Diabetes and complex medication list



UAG/Ecosystems: Regular contribution on solutions

Specific research insights, or Demonstrator resources



Video presentation of the G-lens services, online survey, assess attractiveness, intention to use



Research contribution - complex medication – complex needs, adolescents gaining autonomy



Demonstrator - elderly taking medication, caregiver support drug – drug interactions



HEALTH OUTCOMES
OBSERVATORY

IBD –demonstrator
NO scenario



ISO IDMP /
Unique global ID



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