

# Gravitate Health

A DIGITAL HEALTH INFORMATION JOURNEY

**Empowering and equipping  
Europeans with health  
information for active personal  
health management and  
adherence to treatment**



# Gravitate Health

## Key facts

**Project acronym:** Gravitate-Health

**Project Title:** Gravitate-Health: Empowering and Equipping Europeans with health information for Active Personal Health Management and Adherence to Treatment

**Call identifier:** H2020-JTI-IMI2-2019-18

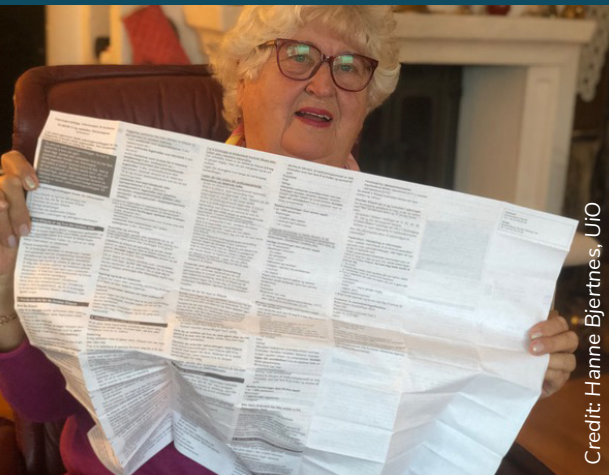
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# Patients find printed medicinal product information sheets too long, complicated to navigate and hard to understand

It is difficult to find the right information when it is most needed



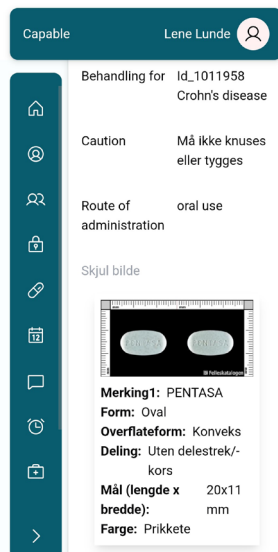
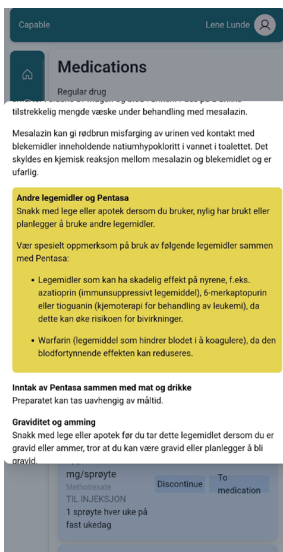
“When and how should I take this medicine?”

“Which side-effects should I really look out for, given my age and health conditions?”

“If I forgot my dose yesterday, should I take double today?”

“Do I need to book a hotel with a fridge when I go on holiday?”

## Gravitate-Health provides patients with clear, friendly and searchable electronic product information (ePI)



Personalized using their demographic and medical summary information

Prioritized by highlighting what is most likely to be relevant to them

Enriched with relevant health educational material from trustworthy sources

Enabling the safer use of medicines, greater patient confidence and better health outcomes



# Transforming access to medicinal product information

## Medication adherence is a significant health burden

- On average only 1 out of 2 patients take their medication as prescribed or directed by their healthcare professional.
- OECD estimates that around 200,000 premature deaths annually in Europe relate to poor medication adherence.
- A lack of understanding of medicines can contribute to increased multimorbidity, mortality, and health care costs, and influence how patients perceive the quality of - and trust - in the relationship to their health provider.
- Medicinal product information is currently disseminated as static, text-intensive documents in local languages, primarily as a paper leaflet and information on the medication package.
- This limits possibilities for updates or alerts. Information in the leaflet may not be up to date by the time the patient receives their medicine.

- ▶ Patients read leaflets selectively – usually only side effects, contraindications, and purpose of drug.
- ▶ Language is too scientific. Layout is not user-friendly (small fonts, dense text, long documents).
- ▶ Often fail to meet comprehension targets despite regulatory readability testing.
- ▶ Different populations show variable understanding, the elderly and low-literacy users are disadvantaged.
- ▶ Overloaded risk information can provoke anxiety and avoidance.

## The Gravitare-Health challenge is to improve access to updated information and support patient understanding of their medication.

Digital ePI platforms which support interoperability with e-Prescription and EHR systems mean trustworthy medicines information is accessible, trustworthy and up-to-date at the right time and in the language of choice.

Patients who know why they are taking their medicines are likely to have better health outcomes.



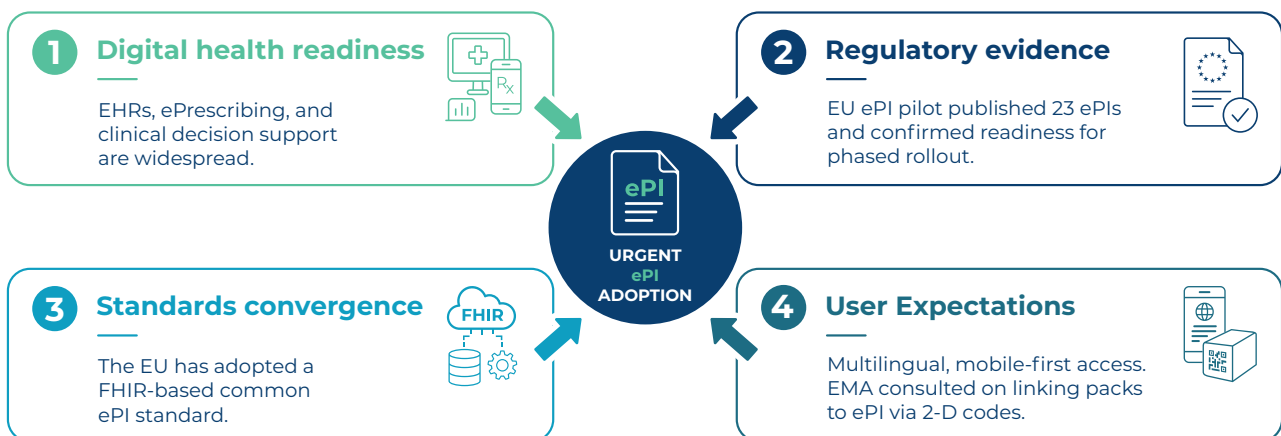
# The powerful role of electronic Product Information (ePI)

Electronic Product Information is the authorized, regulator-approved product information for human medicines consisting of the Summary of Product Characteristics (SmPC), Package Leaflet (PL), and labelling information published in a structured, digital format for use across web, e-platforms, and print. The ePI format is designed to be up-to-date, searchable, and most importantly, implements HL7

FHIR standards to future proof for interoperability with health systems.

It is expected that the revisions to the EU General Pharmaceutical Legislation (GPL) will enter into force by the end of 2026. This will bring a requirement for electronic product information to be introduced for all registered medicines - both prescribed and over the counter - within 5 years.

## Four converging drivers for urgent ePI adoption



## Technical anchors

- The EU ePI Common Standard (FHIR) defines the structure, exchange patterns, and Application Programming Interfaces for ePI.
- ePI links to International Organization for Standards (ISO) IDMP identifiers and EMA master data for SPOR, enabling consistent identification and reduced ambiguity across jurisdictions.
- Terminology mappings of Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) to Medical Dictionary for Regulatory Activities (MedDRA), a specialized terminology for regulatory safety reporting

## Operational advantages from ePI adoption

- Automated distribution of the latest Medicinal Product Information
- Efficient information management along the product lifecycle
- Decision support and safety checking due to its computable content
- Efficient information management along the product lifecycle

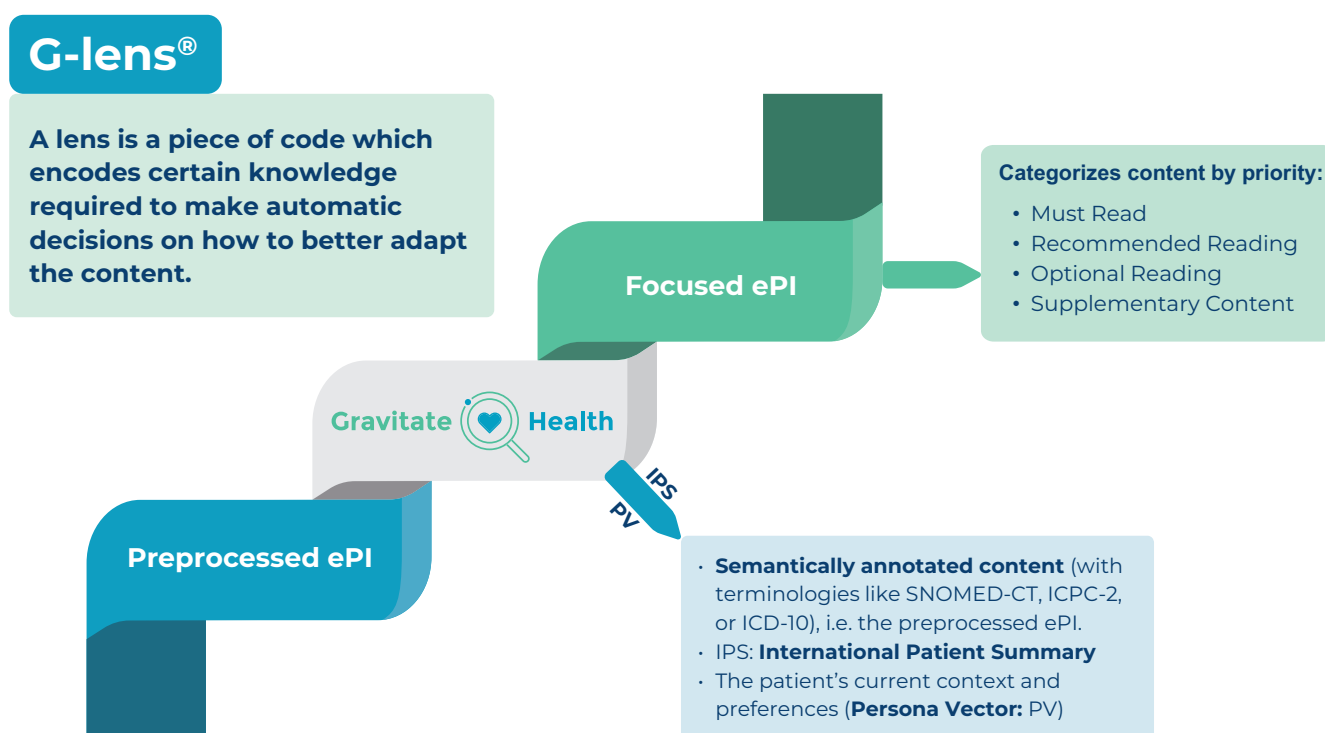
Multilingual support will lead to greater safety at the point of dispensing and better patient comprehension across borders.



# What is the G-lens® ?

G-lens® is the focusing mechanism which specifies how parts of the ePI for a medicine should be combined with information about a patient's health conditions (with consent). It works out what parts are most relevant to that patient and applies computer rules to present if:

- a particular sentence or paragraph is highlighted for a patient matching that rule.
- an information heading that is not so relevant may be collapsed (the content is hidden from view).
- a link to a video, diagram or web site.
- a translation or a simplified summary should be provided.
- warnings, and if any other information should be included.



There are different G-lens® rules for different categories of medicines information (e.g. for side effects, for storage instructions) and for different health situations (e.g. for pregnancy or intolerance) and circumstances (e.g. breast feeding).

Gravitate-Health has developed a library of G-lens® rules, which have been published so that software developers can use them. The G-lens® are subject to a trademark. The trademark is not intended to restrict access, but to control the quality, reliability

and independence of G-lenses® so that anyone who uses one can be confident that they are trustworthy.

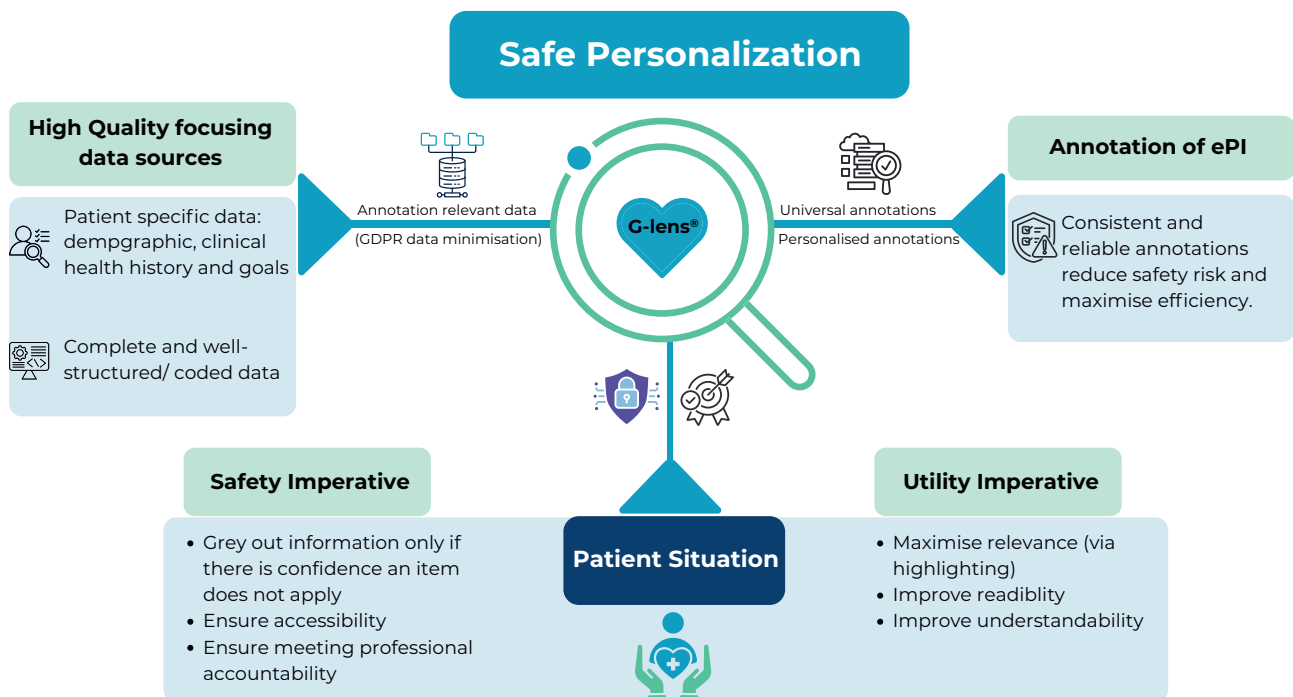
The G-lens® highlights information relevant to a patient. It does not conceal any of the information in the ePI and the full leaflet content can easily be made visible through user choice. The full ePI is a click away.

A new not-for-profit Center will seek funds to grow this library of G-lenses® and will collaborate with other organizations that could develop such rules.

# Ensuring responsible G-lens® personalization

G-lens® personalization reduces the risk of information overload. It filters information that is not relevant to a patient (making this less visible, but not removing it). It also emphasizes patient relevance (what is displayed prominently is considered of importance). This aims to improve medication adherence, taking each medicine correctly and responding appropriately to situations like new unexplained symptoms or a missed dose.

The design has balanced what will be most useful and could be delivered most useably to patients. The personalization of information does not undermine clinical decision-making or the clinician patient relationship. It ensures faithful alignment with the information that has been generated by the market authorization holders and approved by regulators from pharmacologically, clinical and safety perspectives.



The personalization is critically dependent upon the quality of the personal health summary. EHR data is known to contain errors in a proportion of patients, most commonly because information is missing from another care provider e.g. a recent hospital-initiated medication change has not been updated in the GP record or Personal Health Record (PHR). The Gravitare-Health system has been designed to “fail safe”.

For example, if no allergies are documented in the health summary it will not presume that the patient has no allergies. Because the EHR might contain errors or outdated information, or patients might have conditions for which they have not yet sought medical involvement, or purchased medicines over the counter, the personal health and G-lens® activation profile can be adjusted directly by the patient.



# Responding to patient needs and opportunities for better, relevant information

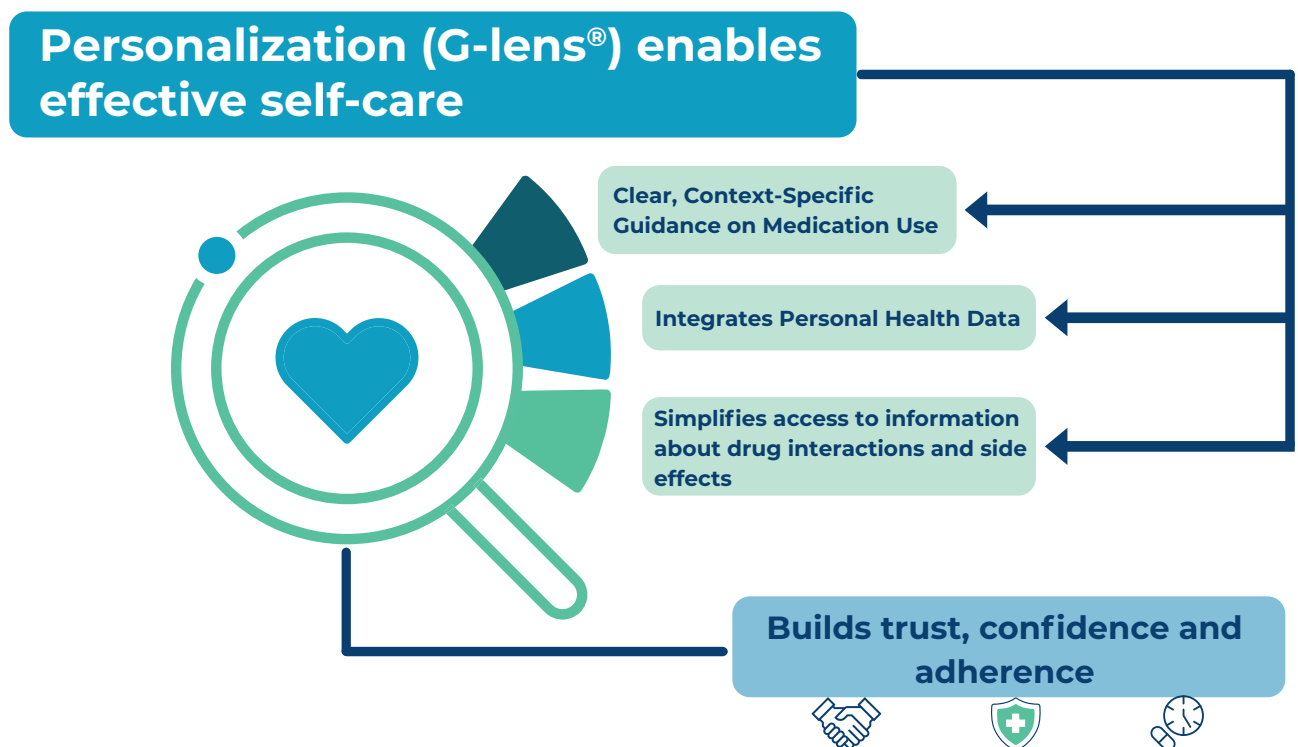
Patient information must evolve because current paper leaflets, PDFs, and portals, often fail to meet the needs of patients in real-world settings. These can be difficult to navigate, especially for those with limited digital skills or health literacy. They can be dense, jargon-heavy and disconnected from the contexts in which patients make decisions about their medicines. As a result, important safety messages may be overlooked, misunderstood or not retained, limiting effectiveness to support safe and appropriate medicine use.


At the same time, patient populations are increasingly diverse and a one-size-fits-all approach to information is no longer appropriate. For example, older adults managing multiple medications, younger digitally native users and patients with limited literacy or language barriers all require different types of support. Static information

formats are not well suited to addressing these differences.

With the aim of building trust, confidence, and adherence, Gravitare-Health collaborated with its User Advisory Group, composed of patients, caregivers, and healthcare professionals, to co-create the design of the G-lens<sup>®</sup> and reflect real-world needs.

Tailored information, as provided by digital tools such as the G-lens<sup>®</sup>, enables effective self-care support to patients by delivering clear, context-specific guidance on medication use. Patient-centered designs, which feature simplified language, audio and visual elements promote equity and empower patients, overcoming barriers like unequal access, fostering more equitable health outcomes.



Strengthening patient empowerment, confidence and adherence 

# Beyond ePI: Trust-enhancing, comprehension-focused tools

ePI is a foundational routine risk minimization measure (RMM) to drive adherence and safer use of medicines. However, ensuring safe and effective medicine use requires going further. Additional RMMs and high-quality supporting materials are needed to make information actionable, contextual, and usable in real life. These may include educational materials, patient alert cards, checklists and dialogue aids, Direct Healthcare Professional Communications (DHPCs). These are often disseminated in fragmented ways—PDFs hosted on multiple websites, print-based leaflets, or ad hoc communications—without structured integration. Gravitare-Health enables a structured approach in which both routine and additional RMMs can be linked semantically to structured ePI, delivered contextually through G-lens® personalization, presented selectively, reducing cognitive overload

and updated dynamically in line with regulatory changes.

Gravitare-Health has introduced a structured framework for assessing the trustworthiness of non-regulator-approved educational health information, combining scientific rigor with user-centered considerations:










- a material-level assessment, involving detailed evaluation of individual resources against criteria such as evidence base, transparency, usability, and alignment with regulatory information
- an organization-level assessment, which evaluates the governance, credibility, and quality assurance practices of content-producing organizations.


## Gravitare-Health operationalizes RMM trust through explicit criteria

Dimension	Requirements
Transparency	Clear authorship, organizational ownership, funding disclosure, conflict-of-interest statement
Scientific rigor	Evidence-based claims, reference to current literature, consistency with regulatory information
Governance	Editorial review processes, correction mechanisms, documented procedures
Currency	Visible update dates and version control
Usability	Plain language, appropriate literacy level, navigable design
Ethical integrity	Avoidance of sensationalism, clear separation from commercial promotion
Data protection	GDPR compliance where relevant


# Demonstrating real world value

Gravitate-Health established an agile, iterative, user-centered development process where each testing cycle feeds directly into design improvements. Nine testing scenarios were set up for the project. All of them undertook initial prototype testing, but due to logistic and approvals constraints six sites could undertake small scale user testing and three of those were able to complete large scale testing. Two parallel EC projects, IHI H2O and Horizon 2020 UNICOM, also collaborated on two proof-of-concept demonstrations.

<p><b>“test at scale”</b> end-end or own front end, include real patient - data</p>	<p><b>Advanced test</b> realistic users and synthetic data</p>	<p><b>Specific research</b> insights, or Demonstrator resources</p>
 G-lens® services - patients with chronic disease (HIV, IBD), vaccines multi-morbidity, poly-pharmacy	 G-lens® functionality, My Doctor app, demo for Diabetes medicines	 Video presentation of the G-lens® services, online survey, assess attractiveness, intention to use
 FRISQ patient app, ePI from FASS -patients with COPD, care continuity and information management.	 G-lens® functionality, SN24 platform patients with Diabetes and complex medication list	 Research contribution - complex medication – complex needs, adolescents gaining autonomy
 Capable.Life – focused ePIs, medication list for IBD, illness score, supporting material	 <b>UAG/Ecosystems:</b> Regular contribution on solutions	 Demonstrator - elderly taking medication, caregiver support drug – drug interactions

 **H2O** HEALTH OUTCOMES OBSERVATORY

IBD –demonstrator  
NO scenario

 **UNICOM** ISO IDMP / Unique global ID

Engaging ~5000 end-users over the project

The evaluations comprized the user experience and usability, cognitive effects, and the economic impact of increased medication adherence.

## Evaluation summary findings

- Mean SUS ≈ 78 (“good usability”) across 196 participants.
- 73% users rated solution “good–excellent”; 10% found it hard to use.
- Structured, focused ePI helped to find relevant information faster, improved comprehension and increased confidence.
- Users liked having individualized information, focusing on what was relevant to avoid overload, and having the option to elaborate or filter if more/ less information was needed.
- Increased perception of necessity → foundational driver of adherence.
- Improvements in digital health literacy + positive shift in patient perceptions towards medication = potential to improve adherence.
- User feedback indicated a preference for personalized ePI over PDFs.

# Gravitate Center for Trusted Health Information

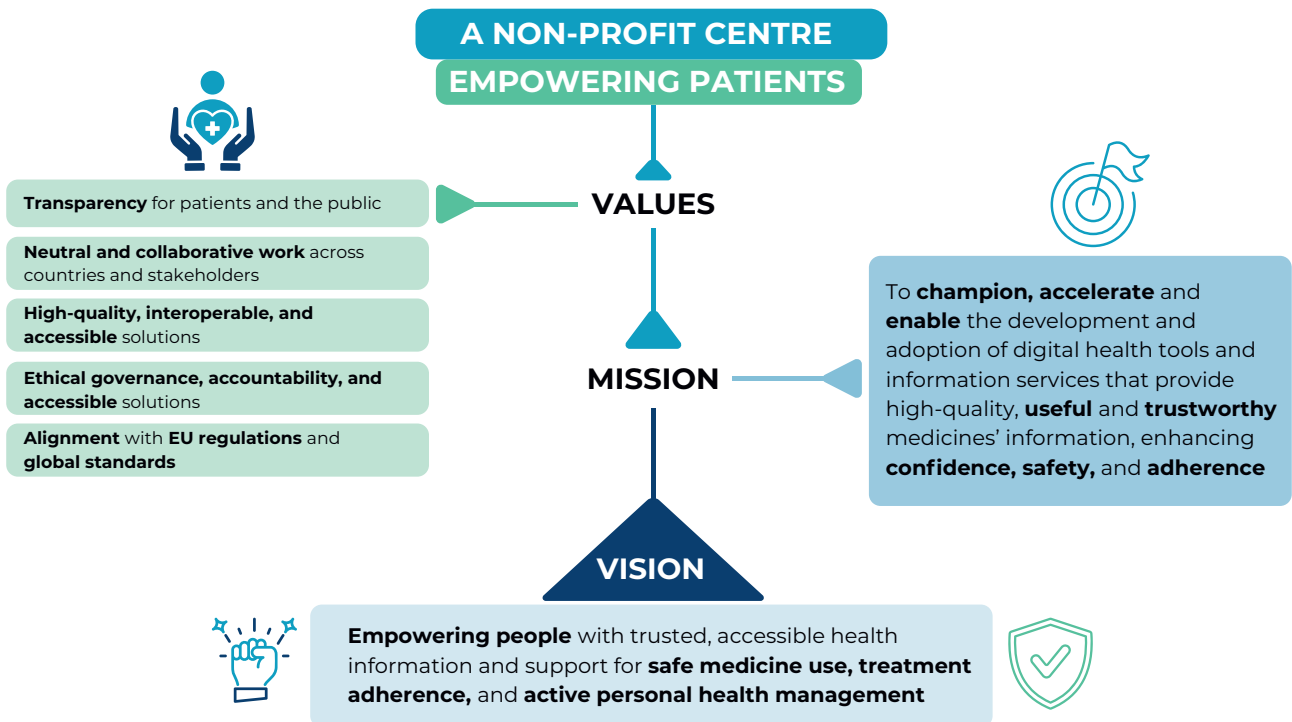
There is a longer-term need for coordination and support on the journey towards structured, interoperable and personalized ePI.

**Gravitate-Health is establishing a non-profit center for safe, trusted and sustainable health information.**

The Center will take a comprehensive, patient centric approach and accumulate/share experiences on: personalization enabling services, facilitating change and improvements for adherence to treatment, safer use of medicines, and best possible health outcomes. It will act as a community convener and change agent, providing strategies to curate/personalize ePI and more health information from trusted sources, and stimulate further activities with the ultimate goal to engage and

empower patients with trusted, accessible health information and support safer use of medicines, treatment adherence, and overall active personal health management.

The Center will be an open and inclusive collaboration hub to align approaches and foster innovation by evolving shared resources, testing possibilities and outputs. Rather than developing products itself, the Center will be a **community convener and change agent**, coordinate communities of practice, **steward information services** (assess sources, standards, methods), and **demonstration of feasibility and value** by supporting implementation guides and practical aspects of ePI implementation, and provide training, shared metrics, and technology demonstrator to **accelerate adoption**.



# Gravitate-Health: a strategic, public-private response

Gravitate-Health is a multi-stakeholder public private partnership funded by the Innovative Health Initiative (IHI) program which receives funding through the European Commission H2020 and the European Federation of the Pharmaceutical Industry Associations (EFPIA) and Datapharm through its innovative Health Initiative (IHI) program.

## OUR MISSION

To equip and empower citizens with digital information tools that make them confident, active, and responsive in their patient journey and encourage safe use of medicines for better health and quality of life.

Gravitate-Health assists individuals and their care givers with variations of treatment and personal complexity: types of medicinal products and self-care and self-management challenges, age groups, health literacy levels, to transform the patient experience.

## OUR AMBITION

To provide a key piece to advance this mission: the Gravitate Lens (G-lens<sup>®</sup>), which focuses on approved electronic product information (ePI) content, and offers a direction for patients to access trustworthy, up-to-date information that better meet their individual needs.

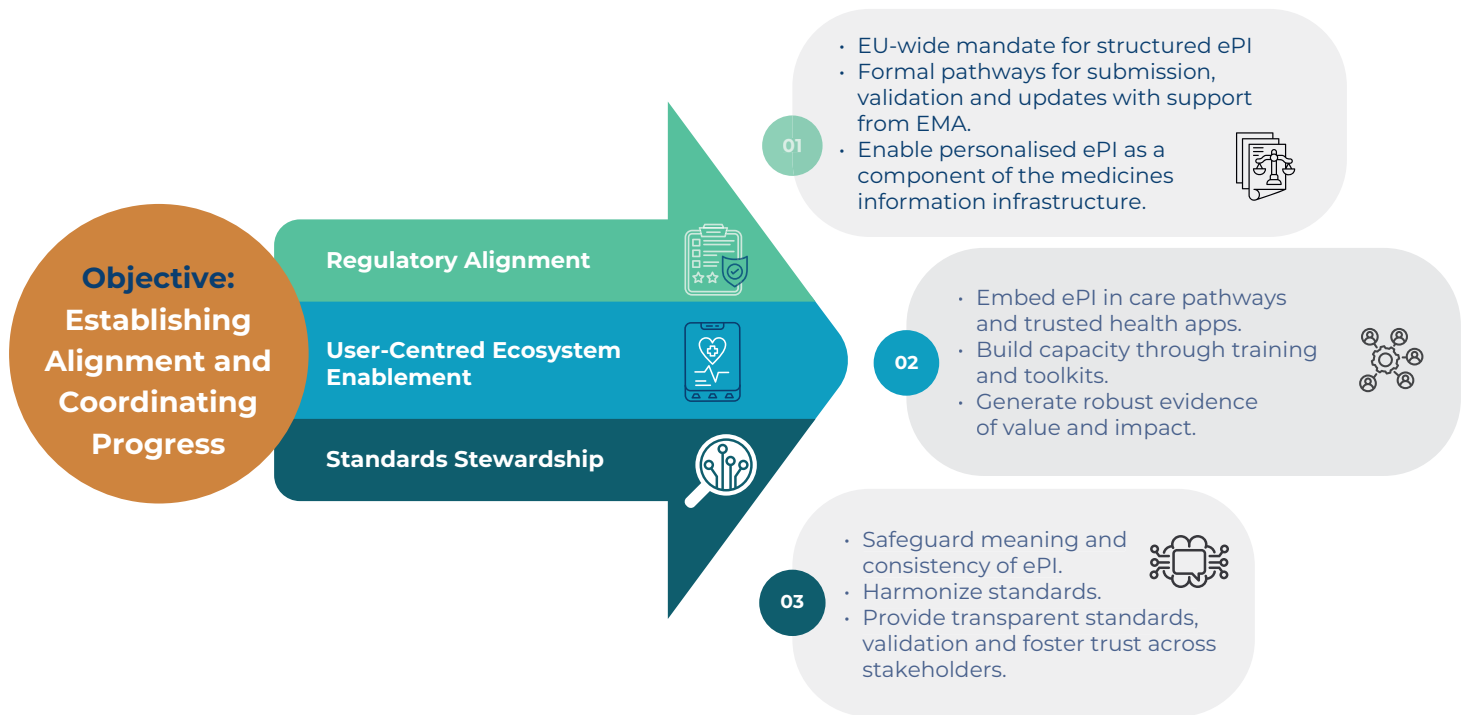
G-lens<sup>®</sup> functions bring together relevant electronic product information (ePI) for the products in the person's medication list, allergies and health history, as well as personal circumstances, to noticeably change information availability and understanding, to stimulate safe use of medicines and to help improve adherence.

This regulator-approved information (ePI) is focused according to the user's profile, context of use and display preferences.

Gravitate-Health supports the digital transformation of health across Europe, consistent with the aims of the EU Digital Single Market Strategy, conforms to the General Data Protection Regulation (GDPR) and aligns with the European Health Data Space (EHDS) Regulation.

# Policy implications for scaling up ePI adoption

## Three Axes for Large-Scale Adoption



### A. Provide clear regulatory guidance to support interoperability and safe personalization

The EMA, in collaboration with National Competent Authorities (NCAs), should publish comprehensive regulatory guidance covering the lifecycle of structured ePI which also allows for the possibility of personalization. This guidance should define interoperability requirements, semantic annotation and terminology expectations, conformance and validation processes and guidance for personalization that preserve the integrity of authorized content.

### B. Support healthcare systems with structured transition plans and investment

Member States should implement national transition strategies to move from paper-based or PDF product information to more structured, digital ePI within the timeframes required by the legislation. These strategies should include dedicated funding and procurement guidance for updated implementations that are integrated into national infrastructures such as EHRs, ePrescription systems, and patient portals, and accompanied by training programs.

### C. Establish programs to stimulate integration of personalization tools such as G-lens®

Funding programs at national and EU level need to support targeted initiatives to accelerate the integration of personalization tools into real-world healthcare settings.

# Urgent Calls to Action

1. Decision-makers must urgently plan, financially and with capacity provision, for large-scale digital health literacy education for all. This is vital action for multiple purposes, including making good use of personalizing solutions for medicinal product information (ePI). Align ePI with a stipulation in the EHDS Regulation for Member States to support digital health literacy.
2. Drive towards a holistic medicines ecosystem, ePI will play a key role in linking medicines information with ePrescriptions, EHRs, and cross-border health services, supporting safer and more informed care.
3. All healthcare and medicines development stakeholders must endorse the value and wider adoption of ePI, and digital health technologies that implement this, as a strategic direction for Europe and globally.
4. Stakeholders developing and approving medicinal product information content must align on global standards for representing the structure and semantics of ePI that are fit for a diverse range of medical products, are practical to adopt and support personalization
5. Decision makers must introduce or reinforce policy and financial levers to incentivize the market to develop innovative products that deliver personalized ePI and value added services to patients and their support network, and enable their procurement and/or provision to patients to be reimbursed from central budgets.
6. Legal and financial instruments that permit the adoption of medicinal product information services to patients including personalization services must be included within national and European digital health strategies and funding priorities.
7. Decision-makers should extend the list of languages in which ePI is available beyond European languages, this should include the EMA product management service. Decision-makers must also work with regulators on mechanisms to approve the authenticity and accuracy of language translations, in particular if they are increasingly made using artificial intelligence tools.
8. Priority should be given to investigations of health and medicinal product information needs of diverse patient groups across age, ethnicities, languages, educational levels, capabilities, health and digital literacy and health conditions.
9. Decision-makers, EHR vendors and healthcare professional organizations must work together, with adequate funding, to ensure that high quality, integrated patient health summary information can be used for personalization.
10. Patients and consumers of medicines information should be informed and prepared for this transition and the opportunities it brings as well as their right to a printed version remaining intact.

**Full version**



**Whitepaper**

**Website**



[gravitatehealth.eu](http://gravitatehealth.eu)

**LinkedIn**



[gravitatehealth](https://www.linkedin.com/company/gravitatehealth)



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