Gravitate Health

FIFARMA

Ronnie Mundair

JOINT SESSION

ePI is on FHIR around the globe – Part 2

18 March 2026
16:00–17:30 CET | 12:00–13:30 BRT
10:00–11:30 COT | 09:00–10:30 CST
Virtual

Yaneth Giha

Diego Salas

Anne Moen

Erol Hofmans

Craig Anderson

Leonardo Semprun

innovative medicines initiative

efpia

Datapharm

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This means the following data will be recorded about you:

- your name and the registration details you provide
- your image if you choose to turn on your camera at any time
- your voice if you choose to ask a question or make a comment orally, as well as any text you may choose to write in the zoom tool

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If you do not consent to your data being recorded, you should not take part in the meeting.

Agenda

Gravitate Health

🥂 **Welcome, Agenda & Introductions** – Mrs Ronnie Mundair, Senior Director, GRS, Pfizer

🧑‍⚕️ **Strengthening FIFARMA's commitment to healthcare** – Mrs Yaneth Giha, Executive Director, FIFARMA

📓 **LATAM ePI Playbook** – Mr Diego Salas, Director, FIFARMA

⚓ **An update from Gravitate-Health** – Prof. Anne Moen, Academic Coordinator, University of Oslo

🤝 **Advancing the National ePI Journey through Gravitate Health: An NCA perspective** – Dr Erol Hofmans, Innovation Advisor, MEB

🏷️ **FHIR ePI and the impact on global digital labeling strategies** – Mr Craig Anderson, Business Product Director, J&J

👤 **Closing Remarks** – Mr Leonardo Semprun, Global Regulatory Policy Lead LatAm MSD & FIFARMA Regulatory Group Co-Chair

Yaneth Giha - Executive Director, FIFARMA

Mr Diego Salas, Regulatory Affairs Director, FIFARMA

LatAm Playbook for Electronic Product Information (ePI) Implementation

March 18th, 2026

How do we ensure that patients and professionals always have the most up-to-date information about medicines?

Nowadays, we still rely on paper leaflets — often outdated, sometimes months behind regulatory changes.

Global Context:
Digital Health

*"With limited years to achieve the Sustainable Development Goals, the time for action to achieve **health for all by 2030 is now.** WHO is committed to supporting countries to achieve this goal, and we believe that appropriate, digital strategies will accelerate our pace in getting there."*
Dr. Alain Labrique, Director, Department of Digital Health and Innovation, WHO

Global Initiative on Digital Health

Coordinated support for country-led digital health transformation

Department of Digital Health and Innovation — World Health Organization

The WHO Global Initiative on Digital Health (GIDH) brings together governments, institutions, and international organizations to support national digital health transformation.

| Assess and prioritize countries' digital health needs | Align resources and investments to accelerate digital health transformation | Support implementation of the WHO Global Strategy on Digital Health 2020–2025 | Strengthen capacity and promote sustainable digital health solutions |

Reference: World Health Organization. (2024). Global initiative on digital health: Coordinated support for country-led digital health transformation. World Health Organization. https://www.who.int/initiatives/global-initiative-on-digital-health

Global Context: Digital Health

**Global strategy on digital health 2020-2027** (World Health Organization)
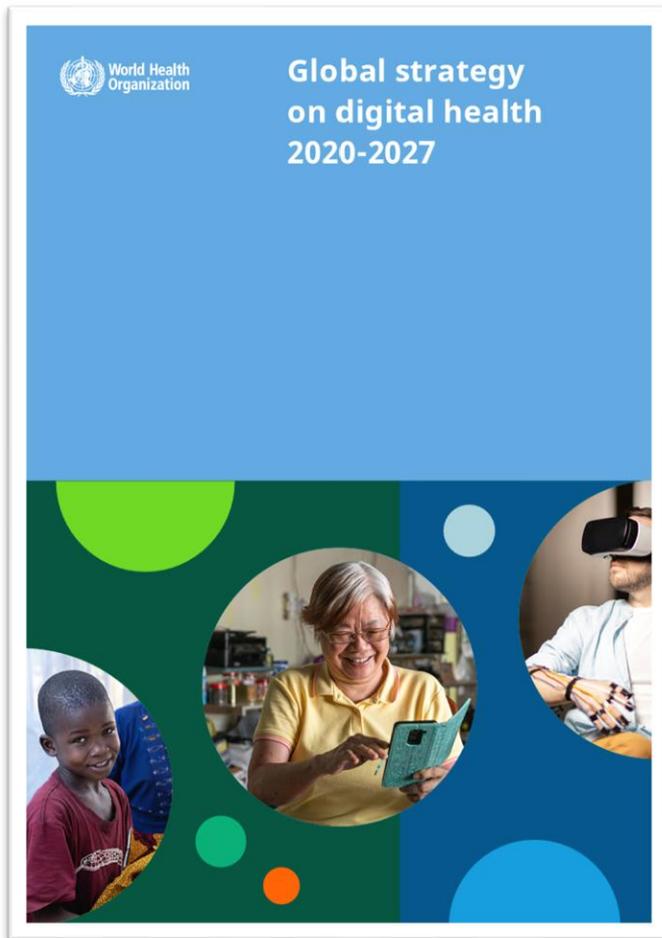
Global Strategy on Digital Health 2020 - 2027

Information and communications technologies present new opportunities and challenges for the achievement of all 17 Sustainable Development Goals

The global health community increasingly recognizes that strategic and innovative use of digital technologies is essential to strengthen health systems.

Digital health is a key enabler to achieve the WHO **"Triple Billion"** targets:
- 1 billion more people benefiting from universal health coverage
- 1 billion more people better protected from health emergencies
- 1 billion more people enjoying better health and well-being
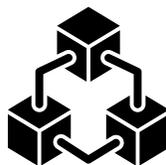
Digital health must be integrated into health priorities to deliver solutions that are ethical, secure, reliable, equitable and sustainable.

Digital Health in the Latin America Context

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PAHO has defined...
8 Guigind Principles for Digital Transformation of the Health Sector

1	Universal connectivity		**Ensure** universal connectivity in the health sector by 2030
2	Digital public goods		**Co-create** digital public health goods for a more equitable world
3	Inclusive digital health		**Accelerate** towards inclusive digital health with an emphasis on the most vulnerable
4	Interoperability		**Implement** interoperable, open, and sustainable digital health and information systems
5	Human rights		**Mainstream** human rights in all areas of digital transformation in health
6	Artificial intelligence		**Participate** in global cooperation on artificial intelligence and any emerging technology
7	Information security		**Establish** mechanisms for trust and information security in the digital environment of public health
8	Public health architecture		**Design** public healthcare architecture in the era of digital interdependence

Digitalizing health services requires significant **cultural and systemic changes** for both healthcare professionals and the general population.

To guide countries in this process, **PAHO established eight guiding principles for the digital transformation of public health in the Americas.**

These principles aim to support countries in:

01 Making evidence-based decisions

02 Setting short- and long-term strategic goals

03 Ensuring that no one is left behind

04 Developing sustainable public health policies

But why do we need digital transformation in health?

What challenges do we still face in access to healthcare and medicines in our region?

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What are the current challenges in access to healthcare and medicines in our region?

Avances hacia la salud universal en la Región de las Américas

Abordar las necesidades insatisfechas de atención de salud, las brechas en la cobertura y la falta de protección financiera mediante la atención primaria de salud

OPS — Organización Panamericana de la Salud / Organización Mundial de la Salud, Región de las Américas

PAHO and its report *"Progress towards universal health in the Region of the Americas"*

This report analyzes the progress and challenges of the Region of the Americas on the path towards universal health, highlighting unmet care needs, coverage gaps, and the persistent lack of financial protection.

It found that **one third of the population in the Region of the Americas continues to face barriers that hinder access to care,** and there are major disparities in the availability of health personnel as well as in access to essential medicines and technologies.

Reference: Pan American Health Organization. (2024). Progress toward universal health in the Region of the Americas: Addressing unmet healthcare needs, coverage gaps, and lack of financial protection through primary health care. Pan American Health Organization. https://doi.org/10.37774/9789275329474

What are the current challenges in access to healthcare and medicines in our region?

Avances hacia la salud universal en la Región de las Américas

Abordar las necesidades insatisfechas de atención de salud, las brechas en la cobertura y la falta de protección financiera mediante la atención primaria de salud

OPS

Unmet Needs

- In high-income countries, 23% of the population has unmet health care needs, while in **upper-middle- and lower-middle-income countries the percentages rise to 35% and 49%, respectively.**

- Across 17 countries, unmet health care needs range from 3.2% to 73.3%. **The regional average is 35.2% and has remained stable in recent years.**

Coverage of Essential Health Services

- The growth of the health service coverage index slowed after an initial rapid increase, **shifting from a 10-point rise (2000–2005) to a 2-point drop (2019–2021),** with a particularly marked impact on the infectious diseases sub-index.

- The service coverage index related to universal health coverage **rose from 66 to 80 points between 2000 and 2019, then fell to 74 in 2021.**

Financial Protection

- **In 2019, between 1.5% and 7.8% of the population in the Region of the Americas faced catastrophic health expenditures,** affecting 15 to 79 million people.

- The higher a country's poverty rate, the greater the impoverishing health spending among households. **Poorer countries are more likely to incur impoverishing health expenditures than wealthier ones.**

Electronic Product Information (ePI) as a Public Health Tool

Benefits for public Health
- Expanding access to information on medicines as a public health imperative
- Accessibility to users with diverse abilities

Efficiency gains for regulatory systems
- Enabling efficiencies in administration of regulatory procedures
- Enhancing knowledge of trends in medicines and their evolution

Electronic product information for human medicines in the EU: key principles

A joint EMA–HMA–EC collaboration
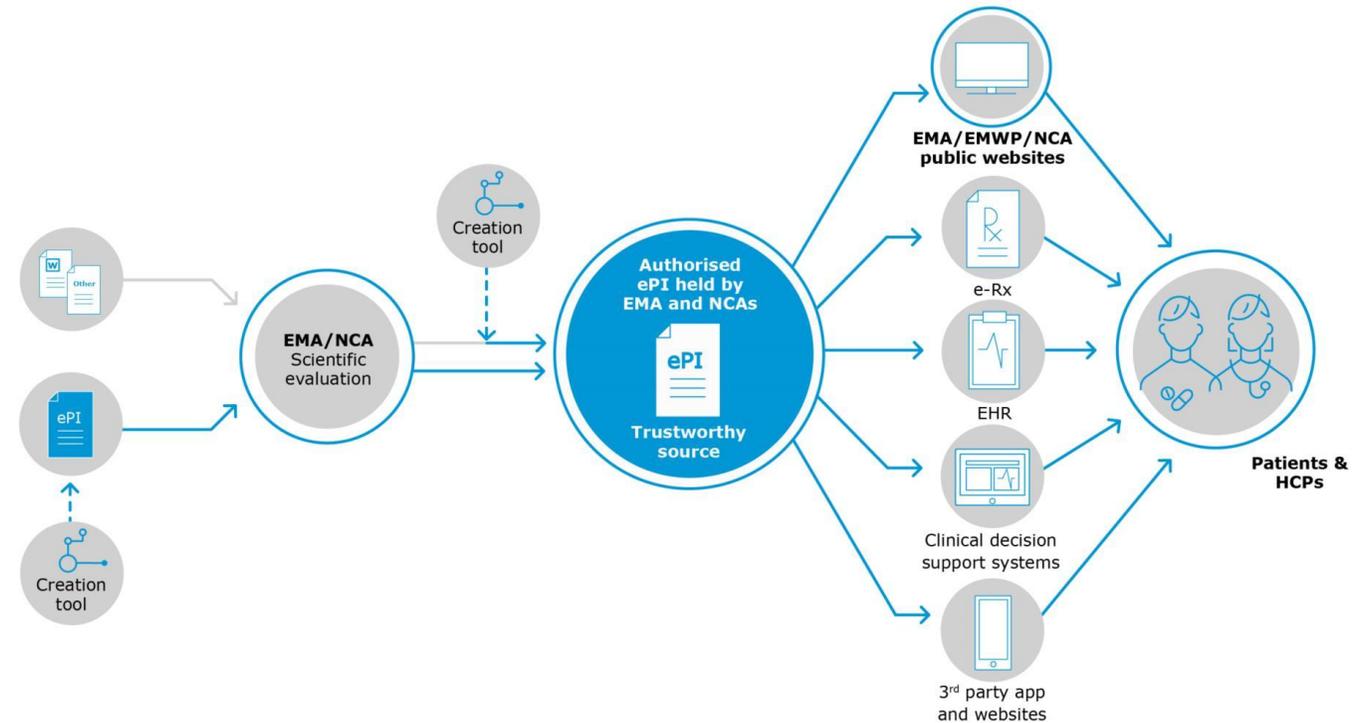
FIFARMA
Commitment

FIFARMA

Our Objective:

Promote innovative ecosystems and policies that support the strengthening of sustainable health systems of the Latin American countries. We partner with regional and national organizations to advance towards better health in the region.
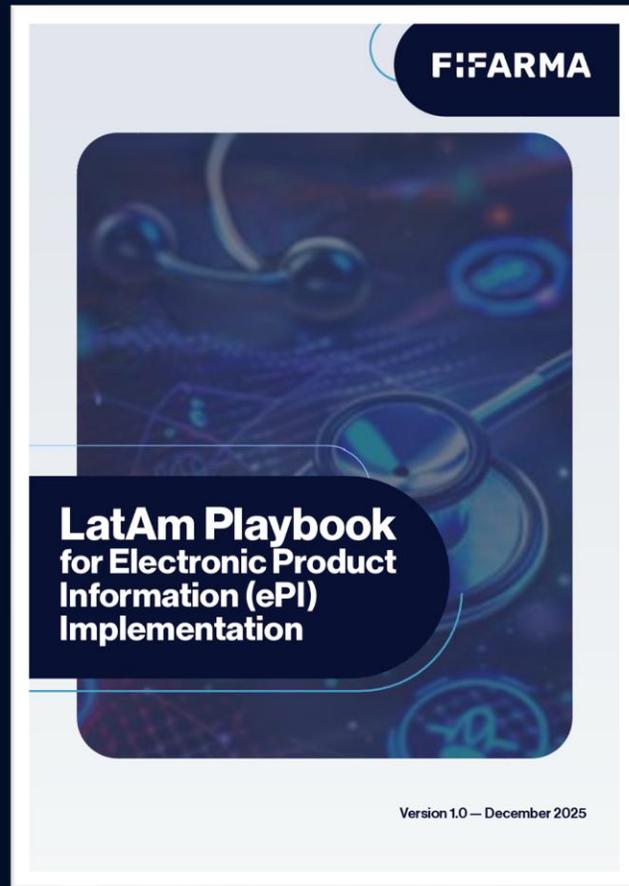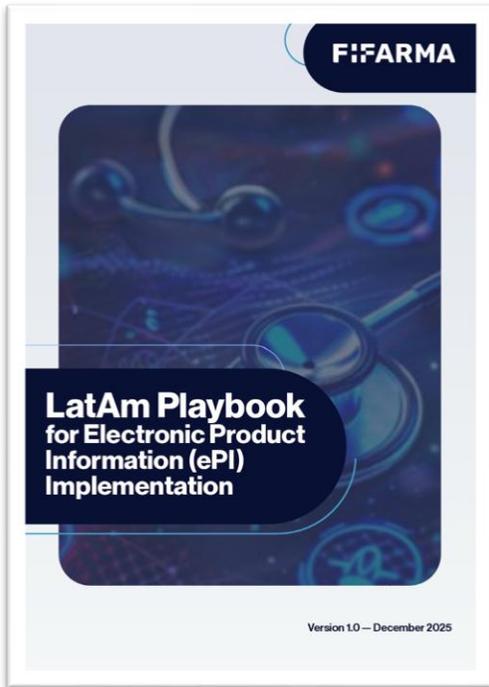
FIFARMA

Turning vision into action

With this objective in mind, FIFARMA, together with EFPIA, developed the:

LatAm Playbook for Electronic Product Information (ePI) Implementation

LatAm Playbook for Electronic Product Information (ePI) Implementation

FiFARMA

LatAm Playbook for Electronic Product Information (ePI) Implementation

Version 1.0 — December 2025

The Playbook provides a **comprehensive analysis of the current status and future prospects of ePI in Latin America and the Caribbean.**

It brings together perspectives from:

- Industry
- National Regulatory Authorities (NRAs)
- Healthcare professionals
- Patients and other stakeholders

Its goal is to support the digital transformation of medicine information in the region through a structured, step-by-step implementation approach

Electronic Product Information (ePI) is designed to enhance:

Patient experience and improve access to reliable medicine information. By tailoring information to patient needs, ePI fosters a better understanding and use of medicines, while also supporting healthcare professionals in making decisions based on the most up-to-date regulatory data.

Inclusion and accessibility for patients with disabilities and ensures multilingual access for individuals living outside their native country, thereby strengthening equity and trust in healthcare communication.

LatAm Playbook for Electronic Product Information (ePI) Implementation

The Playbook serves as a practical guide for the adoption of ePI in Latin America and the Caribbean.

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LatAm Playbook for Electronic Product Information (ePI) Implementation

Version 1.0 — December 2025
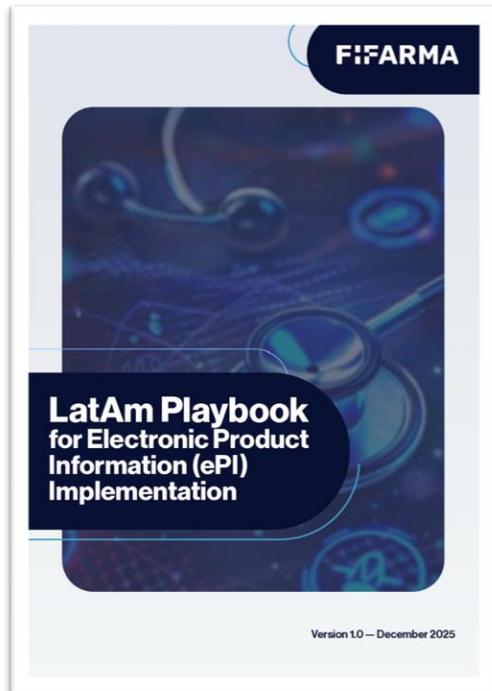
It provides:
- Analysis of the current regulatory landscape
- Overview of technological solutions and implementation approaches
- Identification of benefits and challenges of ePI adoption

The Playbook also promotes:
- Collaboration with NRAs and stakeholders
- Regulatory convergence across countries
- Adoption of best practices adapted to each national context

As digital health continues to evolve, the Playbook will be periodically updated to reflect new developments.

The playbook covers the following main topics:

01 Foundational considerations for the adoption of ePI

02 Global ePI status (guidances, pilots)

03 Latin America and the Caribbean ePI status

04 Recommendations for a Latin America and the Caribbean stepwise approach to adoption of ePI

Differences between Electronic Product Information (ePI), Electronic Labeling (e-Labeling), e-Label and Digital Leaflet/Insert?

**Electronic Product Information
(ePI)**

Electronic Product Information (ePI) and **Electronic Labeling (e-Labeling)** are interchangeable terms.

ePI, used by EMA, is the authorized and legal product information for medicines (including the summary of product characteristics, patient leaflet, and labeling), adapted for handling in electronic format (structured and coded), and disseminated via web, electronic platforms, and print

Terms such as **e-label** or **digital leaflet/insert** are more general and refer to the most up-to-date information approved by the regulatory authority, available online or on electronic platforms. Commonly in PDF format.
- They are **NOT** adapted to a structured and coded electronic format.

The official electronic format for ePI is the **global standardized format** available under the HL7 organization, called **ePI Fast Healthcare Interoperable Resources (FHIR)**.

LatAm Playbook for Electronic Product Information (ePI) Implementation

Electronic Product Information (ePI)

Benefits of ePI for different stakeholders

- Information security and accuracy
- Improved treatment understanding and adherence
- Labeling customization
- Inclusion and accessibility
- Advantages for national regulatory authorities
- Integration with digital health initiatives
- Environmental impact and sustainability
- Operational efficiency for the pharmaceutical industry

Patients

MAHs

Healthcare systems

Planet

NRAs

Challenges for ePI

- Equitable internet access and mobile connectivity
- Improving electronic access to PI in Latin America and the Caribbean
- Inconsistent uptake of digital health solutions
- ePI challenges for diverse populations

The implementation and effectiveness of ePI are determined by various factors, among which the main ones include:

Access (codes)

Access codes are digital mechanisms printed on pharmaceutical packaging that allow users to directly access the Electronic Product Information (ePI).

They serve as a bridge between the physical product and its digital regulatory information, enabling immediate and reliable access to the most up-to-date information and improving the experience compared to traditional paper leaflets

- **URLs (PDF or HTML)**
- **2D barcodes**
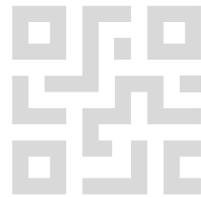
Platforms

ePI platforms are digital systems that store and manage Product Information (PI), making it accessible through apps, websites, and connected devices.

They can be centralized or decentralized, and **their main role is to facilitate the dissemination of approved PI,** enabling efficient search, reuse, and integration with other digital healthcare systems.

- **Regulatory authority-managed repositories**
- **External vendor managed repositories**
- **MAH repositories**

LatAm Playbook for Electronic Product Information (ePI) Implementation

The implementation and effectiveness of ePI are determined by various factors, among which the main ones include:

Information and user security

- **Robustness and security:** A strong, responsive, and secure ePI platform is essential to guarantee continuous access to critical product information.

- **Contingency planning:** A well-defined plan, co-created with stakeholders (NRAs, MAHs, HCPs, patients), ensures accessibility in case of technical failures or system unavailability.

- **Data protection:** Robust security measures are required to safeguard sensitive data and comply with privacy regulations.

- **Real-time updates and version control:** The repository should support updates, traceability of changes, and audit trails to maintain compliance and integrity.

- **Transparency and reliability:** Tools such as version control systems and change logs strengthen trust and regulatory compliance.

- **Enhanced user experience:** Incorporating non-promotional multimedia educational elements improves accessibility and comprehension.

Understanding for patients and HCPs

- **Patient understanding:** Address health literacy, digital literacy, and provide patient-friendly educational materials.

- **HCP support:** Offer clear educational resources for devices, solutions, and practical use of ePI.

- **Inclusive communication:** Pay special attention to elderly patients, people with disabilities, and caregivers who may face challenges with digital platforms.

- **Strategic communication plan:** Co-create with stakeholders (NRAs, MAHs, HCPs, patients) to ensure clarity and relevance.

- **Evaluation:** Assess whether messages reach the target audience, improve understanding, and influence behaviors.

- **Continuous improvement:** Identify strengths, gaps, and actionable insights to keep communication strategies effective and relevant

LatAm Playbook for Electronic Product Information (ePI) Implementation

Australia

Since 1990, flexibility has been allowed in the use of paper leaflets for non-parenteral products. In 2023, this flexibility was extended to parenteral products administered by healthcare professionals. Only self-administered injectables and devices require PI and instructions in paper format on the packaging.

Japan

Since 2021, Japan has implemented regulations to replace paper labeling with ePI for medicines and medical devices, with full transition to a digital system in 2023. The PMDA migrated from SGML to XML for Japanese product information (JPIs), with completion scheduled for March 2024.

Jordan

The JFDA launched its ePI system in July 2024, with mandatory implementation in November 2025. It uses FHIR standards and advanced technologies such as text-to-speech, augmented reality, and accessibility features for people with special needs.

United States

ePI has not yet been implemented. The FDA requires printed information when dispensing medicines, although new rules have been proposed to allow electronic options. The SPL format is used for electronic product information exchange.

Europe

The EMA adopted the Common ePI Standard in 2021, developed together with Gravitate Health and HL7. A pilot funded by EU4Health demonstrated the feasibility of integration with current systems. Spain, Denmark, the Netherlands, and Sweden participated actively. Future implementation is expected at EMA and adoption by national authorities.

LatAm Playbook for Electronic Product Information (ePI) Implementation

Proposed Roadmap
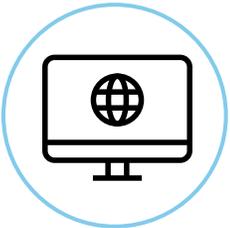
1 Approved safety information available in any electronic format on a trusted platform (hybrid model).

2 Link to electronic labeling through a code on the medicine packaging (hybrid model).

3 Flexibility to remove or reduce printed insert requirements, focusing on hospital products and vaccines (paperless model).

4 Availability of patient-friendly information and non-promotional educational material.

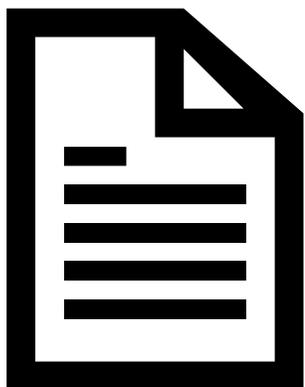**5** Transition to a structured format based on HL7 ePI FHIR.

6 Interoperability of ePI FHIR with other digital health initiatives.

LatAm Playbook for Electronic Product Information (ePI) Implementation

Other considerations for ePI implementation

Leverage global lessons: Use experiences from Brazil, Asia, and the EU to guide regional ePI implementation.

Collaborative approach: Involve NRAs, HCPs, patients, and industry associations to ensure consistency and refinement over time

Educational campaigns: Launch awareness initiatives across Latin America and the Caribbean to inform citizens, patients, and HCPs about ePI benefits
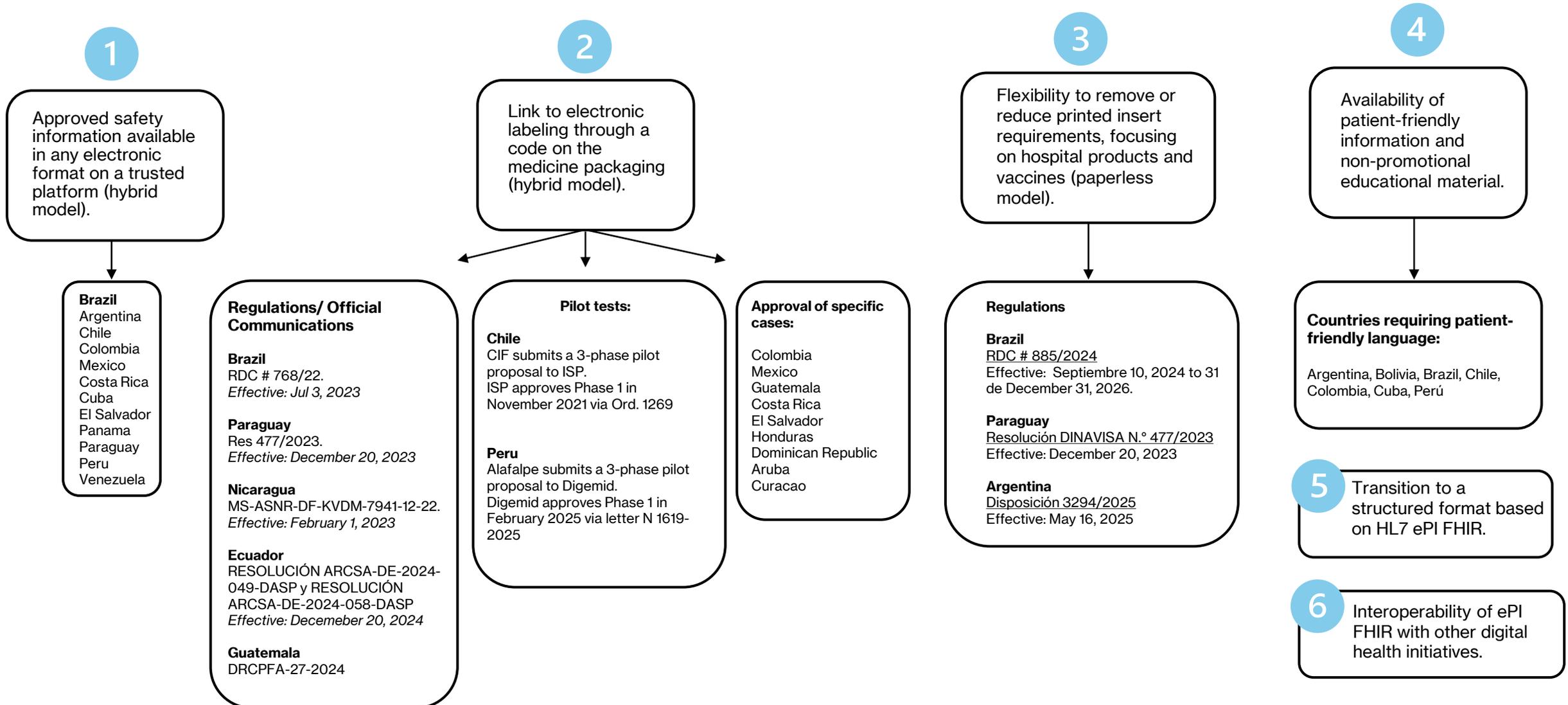
Inclusivity and accessibility: Ensure no patient is left behind; maintain printed options where needed while advancing digital solutions.

Tailored strategies: Adapt implementation to each country's context, product types, and healthcare infrastructure, testing proposals through real-life pilots.

1

Approved safety information available in any electronic format on a trusted platform (hybrid model).

Brazil
Argentina
Chile
Colombia
Mexico
Costa Rica
Cuba
El Salvador
Panama
Paraguay
Peru
Venezuela

Regulations/ Official Communications

Brazil
RDC # 768/22.
Effective: Jul 3, 2023

Paraguay
Res 477/2023.
Effective: December 20, 2023

Nicaragua
MS-ASNR-DF-KVDM-7941-12-22.
Effective: February 1, 2023

Ecuador
RESOLUCIÓN ARCSA-DE-2024-049-DASP y RESOLUCIÓN ARCSA-DE-2024-058-DASP
Effective: Decemeber 20, 2024

Guatemala
DRCPFA-27-2024

2

Link to electronic labeling through a code on the medicine packaging (hybrid model).

Pilot tests:

Chile
CIF submits a 3-phase pilot proposal to ISP.
ISP approves Phase 1 in November 2021 via Ord. 1269

Peru
Alafalpe submits a 3-phase pilot proposal to Digemid.
Digemid approves Phase 1 in February 2025 via letter N 1619-2025

Approval of specific cases:

Colombia
Mexico
Guatemala
Costa Rica
El Salvador
Honduras
Dominican Republic
Aruba
Curacao

3

Flexibility to remove or reduce printed insert requirements, focusing on hospital products and vaccines (paperless model).

Regulations

Brazil
RDC # 885/2024
Effective: Septiembre 10, 2024 to 31 de December 31, 2026.

Paraguay
Resolución DINAVISA N.° 477/2023
Effective: December 20, 2023

Argentina
Disposición 3294/2025
Effective: May 16, 2025

4

Availability of patient-friendly information and non-promotional educational material.

Countries requiring patient-friendly language:

Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Perú

5 Transition to a structured format based on HL7 ePI FHIR.

6 Interoperability of ePI FHIR with other digital health initiatives.

Conclusions

The transition to ePI is a key opportunity to modernize healthcare communication in Latin America and the Caribbean. A phased, flexible, and inclusive approach—aligned with global best practices and regional realities—will enhance patient safety, regulatory efficiency, and access to reliable information.

The ePI Playbook offers a practical roadmap, fostering collaboration among stakeholders and highlighting digital readiness, engagement, and pilots tailored to diverse healthcare systems.

Moving to ePI requires a patient-centric approach. With thoughtful implementation, continuous learning, and transparent communication, Latin America and the Caribbean can ensure trusted, up-to-date PI is accessible to all.

Let this ePI Playbook be more than a guide—it is a call to action, driving stakeholders to build a connected, informed, and resilient healthcare ecosystem.

LatAm Playbook for Electronic Product Information (ePI) Implementation
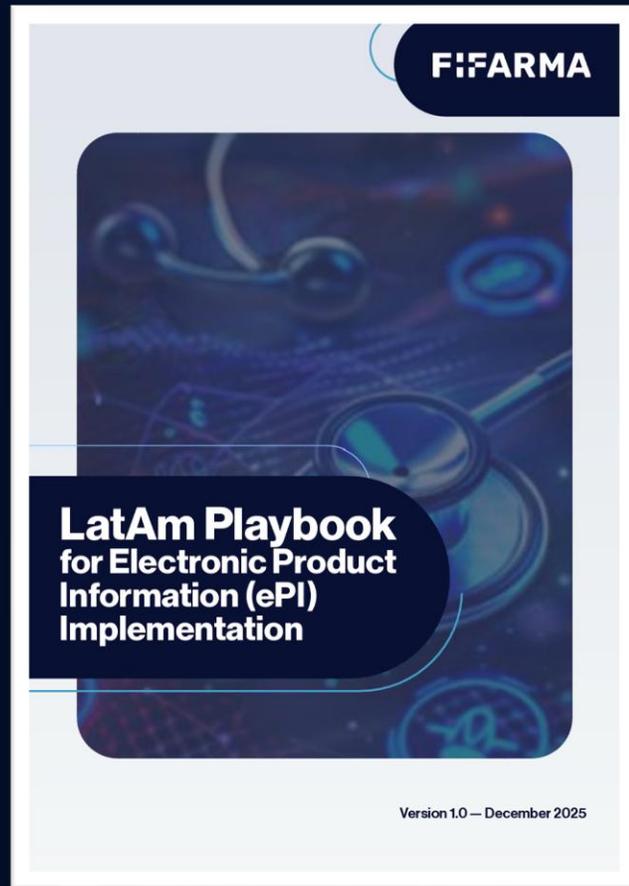
FIFARMA

**Prof. Anne Moen Program Lead
University of Oslo**

Gravitate-Health Public-Private Partnership

45 partners in Europe & USA

68 months
11/20 – 06/26

19.4 mill €

European start
Global Outreach

ACADEMIA / RESEARCH INSTITUTES

Universitetet i Oslo (UiO) (Coordinator)
Karolinska Institute (KI)
Universidad Politécnica de Madrid (UPM)
Empirica (empirica)
Norwegian Center for eHealth research (NSE)
The European Institute for Innovation through Health Data (i-HD)
Università Cattolica del Sacro Cuore (UCSC)
University of Copenhagen (UCPH)
Trinity College Dublin (Trinity)
University College Dublin (UCD)

REGULATORS & PRODUCT INFORMATION PROVIDERS

Norwegian Medicinal Product Agency (NoMA)
Spanish Drug Agency (AEMPS)
Dutch Medicines Evaluation Board (CBG)
Felleskatalogen (FK)*
Dansk Lægemiddel Information* (DLI)
Lif Services* (FASS)
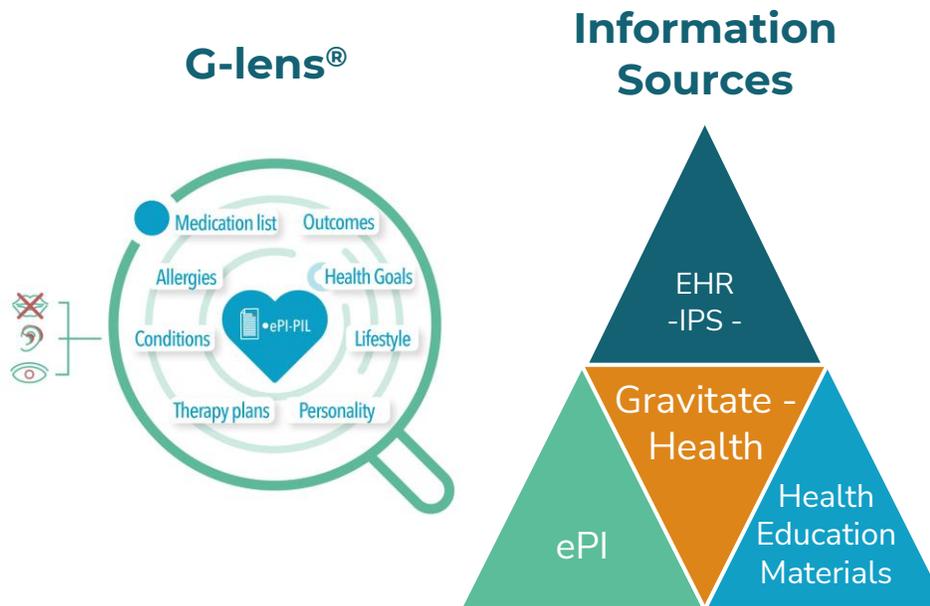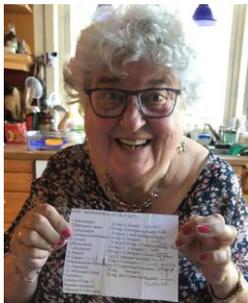Pharmaca Health Intelligence* (Pharmaca)

STANDARDISATION & OTHER STAKEHOLDERS

HL7 Europe
PredictBy*

*SME (small and medium sized enterprises)

PATIENT ORGANISATIONS & CONSUMER GROUPS
Forum Européen des Patients (EPF)

DISSEMINATION & COMMUNICATION
European Connected Health Alliance (ECHA)
HIMSS Europe
MINDVIEW* (MW)
The Synergist*

HEALTH CARE PROVIDERS & PAYERS

Akershus University Hospital (AHUS)
Shared Services of Ministry of Health (SPMS)
Servicio Madrileño de Salud (SERMAS)
Beth-Israel Deaconess Medical Center (BIDMC)
Karolinska Institute (KI)
Oslo University Hospital (OUS)

DIGITAL TECHNICAL EXPERTISE

Datawizard* (DW)
GuardTime*
Norsk e-Helse* (NeH)
Trifork

EFPIA & IMI2 Associated PARTNERS

Pfizer (Project Lead)
AstraZeneca
Bayer
Grünenthal (GRT)
EliLilly
Medidata
Viatris
Novartis
Roche
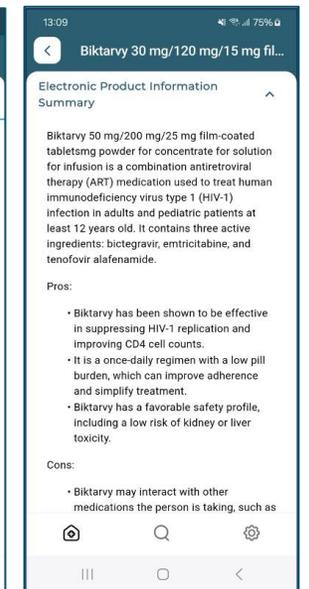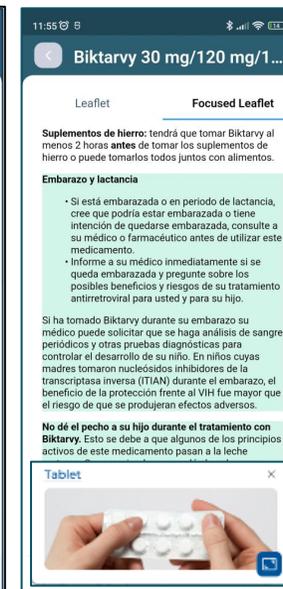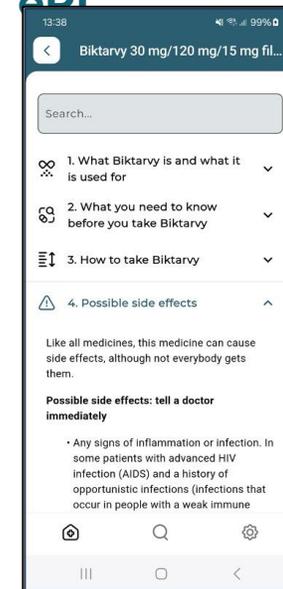UCB Biopharma (UCB)
Janssen
Datapharm

Gravitate Health

Gravitate-Health PPP's contribution … in a nut-shell

Empowering and Equipping Europeans with Health Information from trusted sources, for Active, Personal Health Management and Adherence to Treatment, starting with ePI

Maria's medicines

G-lens®

Medication list · Outcomes · Allergies · Health Goals · Conditions · ePI-PIL · Lifestyle · Therapy plans · Personality

Information Sources

EHR -IPS -

Gravitate - Health

ePI

Health Education Materials

Personalized, relevant presentation of ePI

Our testers says …

… easier to read. I had to enlarge all the little letters [print]… and it's an exact copy of the drug label.
… paying attention to people's personal data, especially age, and this detail makes a difference.

Impact of the approach - a global FHIR ePI Standard

Gravitate-Health has helped connect key initiatives and leverage collaborations globally, building on developments in the EU, to drive quickly towards a global HL7 FHIR ePI standard

EU ePI Common standard and global use via Vulcan Core ePI

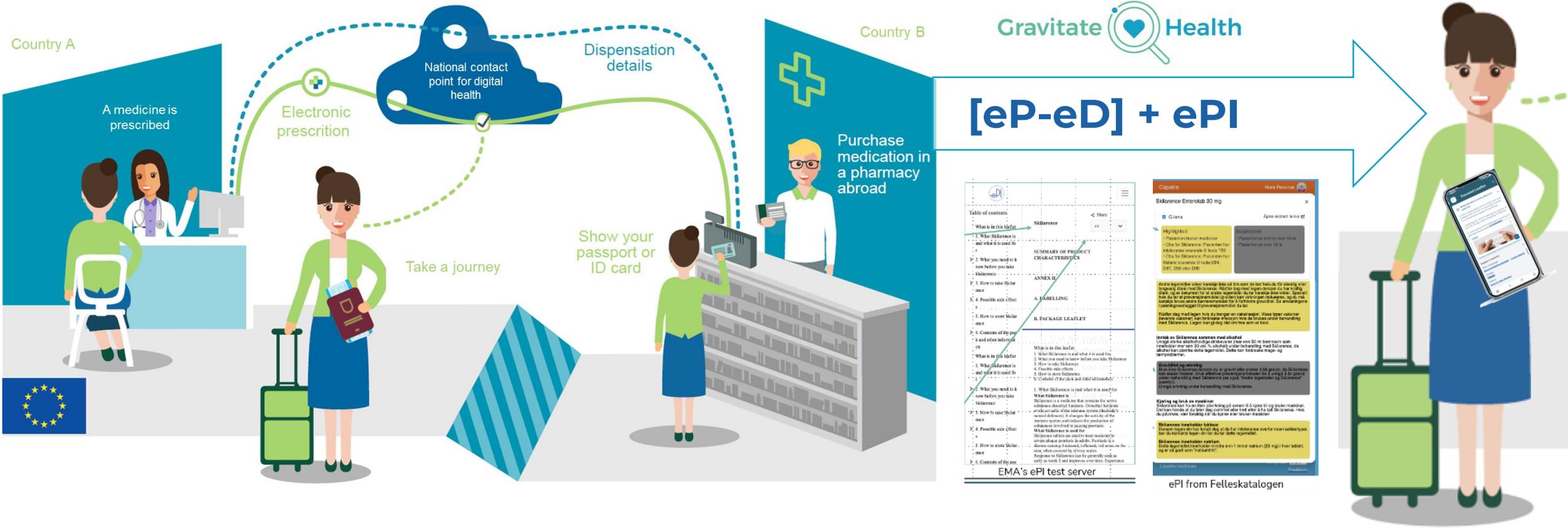| EU ePI - FHIR Resource Names[1] |
|---|
| 1 List |
| 2 Bundle |
| 3 Composition |
| 4 Binary |
| 5 Organization |
| 6 RegulatedAuthorization |
| 7 MedicinalProductDefinition |
| 8 PackagedProductDefinition |
| 9 AdministrableProductDefinition |
| 10 ManufacturedItemDefinition |
| 11 Ingredient |
| 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]
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

[2] Vulcan ePI is managed as a single self-contained document.

- The VULCAN ePI 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 (master data system for EU medicines)

- To enable global use for regions without SPOR, VULCAN ePI Profile has option to include data directly

Gravitate Health

Drive value of ePI – augmenting "ePrescription /eDispensation" Cross-border services under EHDS primary use …. [eP-eD] + ePI

Country A

A medicine is prescribed

Electronic prescription

National contact point for digital health

Dispensation details

Country B

Purchase medication in a pharmacy abroad

Take a journey

Show your passport or ID card

Gravitate Health

[eP-eD] + ePI

EMA's ePI test server

ePI from Felleskatalogen

"No harm in a [citizen focused] service in multiple languages"

Gravitate-Health growing external community

Academia | Research
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In summary; making a difference in a patient journey

Multi-lingual focused information
ePrescription – (e)Dispensation - ePI

FHIR ePI IG
medicinal product info

Cross-border mobility
- trust and safety -

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

IMPROVING ACCESS UNDERSTANDING
Language – Focusing Content
Risk Minimization – Patient Safety

INTERNATIONAL STANDARDS
FHIR Interoperability
IDMP identify product

Dispense
Demonstrate
Substitute (if need)
SUSTAINABLE DEPLOY

41

Gravitate ♥ Health

Thank You

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Get our newsletter

Dr. Erol Hofmans, Innovation Advisor
Medicines Evaluation Board -Netherlands

Advancing the National ePI Journey through Gravitate Health:
An NCA perspective

Erol Hofmans
Innovation Advisor, Medicines Evaluation Board

18 March 2026

About the Medicines Evaluation Board (MEB)

The MEB is an independent medicines authority, residing under the Netherlands Ministry of Health, Welfare and Sport (VWS). The MEB is responsible for assessing and monitoring the effects and risks of medicines for human use, and for promoting the proper use of medicines.

Core values

- Scientific
- Vigilant
- Connected to society

The Challenge: Moving Beyond Paper and PDF Package Leaflets

Critical information, but difficult to find.
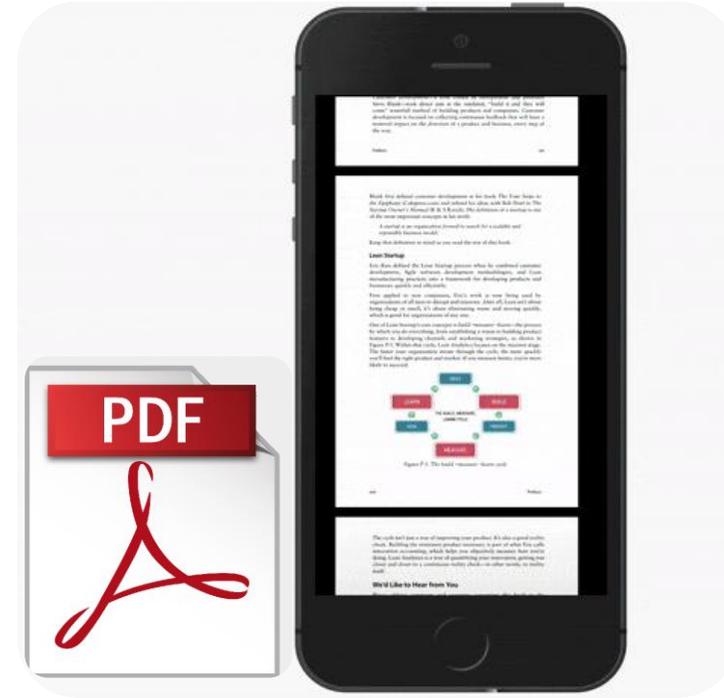
A digital format does not automatically mean digital usability.

European Cooperation: Setting the Direction for ePI

- 2018 multi-stakeholder workshop on ePI

- 2020: Key principles for ePI
  - Definition of ePI, need for a Common EU electronic standard, benefits for public health, efficiency gains for regulatory systems

- 2021: Adoption of the EU Common Standard for ePI

The ePI pilot: Testing the Future of Product Information

ASSESSMENT

POSITIVE OPINION / MA

Product Lifecycle Management Portal

eAF

ePI

Procedure management system

APPROVED TRANSLATIONS

ePI storage
FHIR server

API

EMA and EMWP-websites

NCA-websites

3rd party websites/apps

EHR systems

SPOR
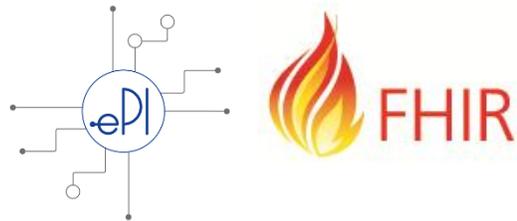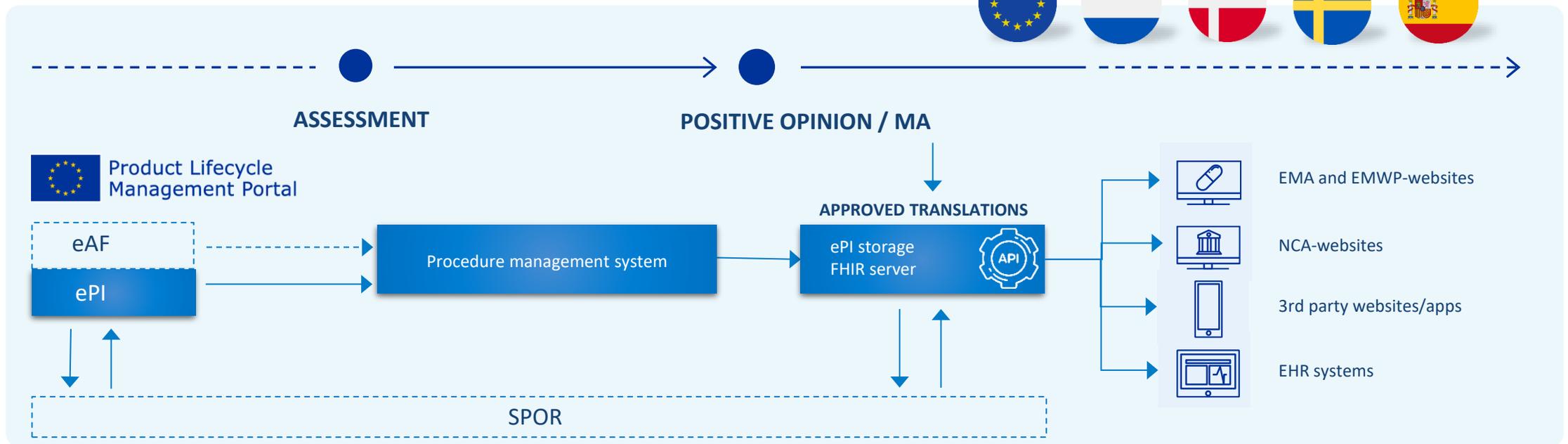
Lessons learned

- ePI is technically feasible

- Processes and guidance work, but need further refinement

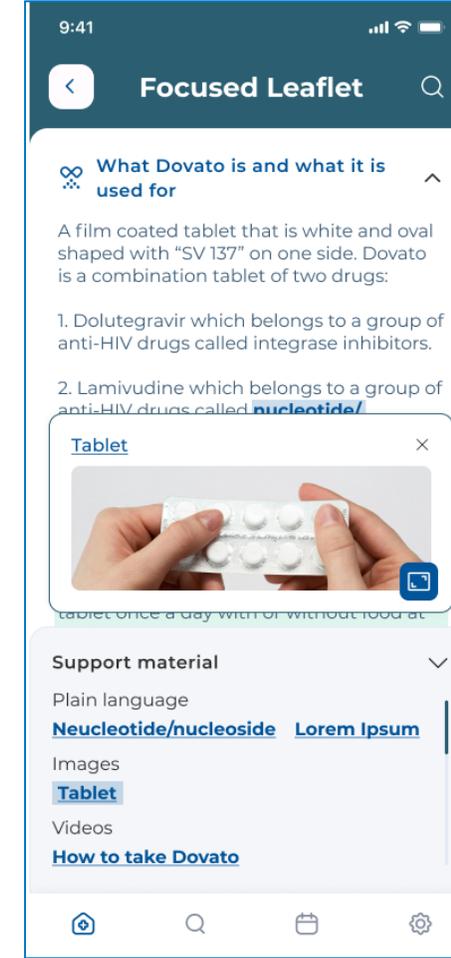- Implementation should follow a phased approach

The ePI pilot: Testing the Future of Product Information

The Regulatory Landscape: EU Pharmaceutical Legislation

The intention behind the legislation

- Enable electronic medicine information and ensure easy access, e.g. through data carrier on packaging

- Allow flexibility for national implementation

- Preserve the right to a printed leaflet

- Implementing Act establishes common standards, criteria, validation processes, ways to access ePI

TODAY			POTENTIAL DATE FOR IMPLEMENTING ACT	
	2026	2027	2028	2029
Provisional Agreement	Legal / linguistic review, translation and adoption	Transposition into local law (national legislation) 24 months		Timeline to deliver ePI
		Definition of implementing & delegated acts For ePI, availability 6 months before transposition date		

Medicines Evaluation Board

Gravitate Health: A Vision for Patient-centered ePI
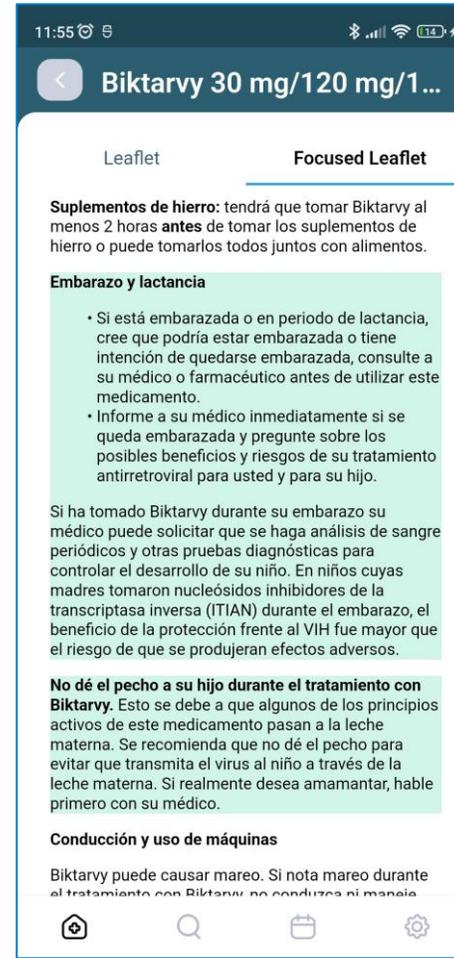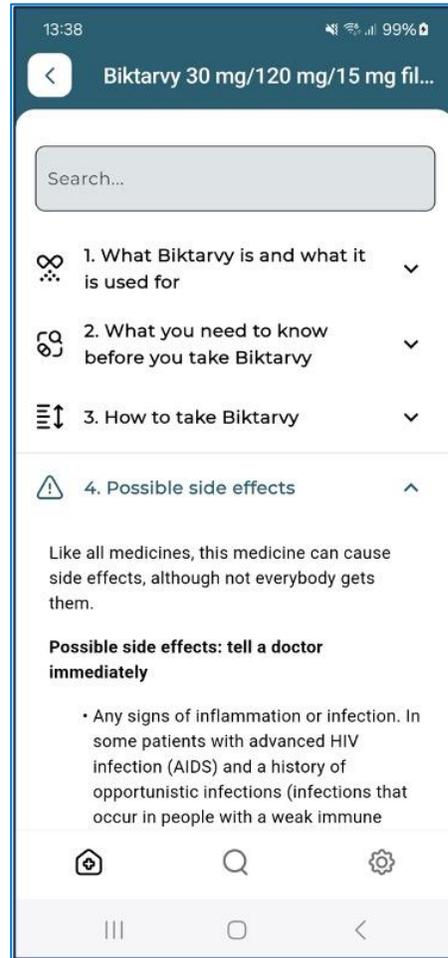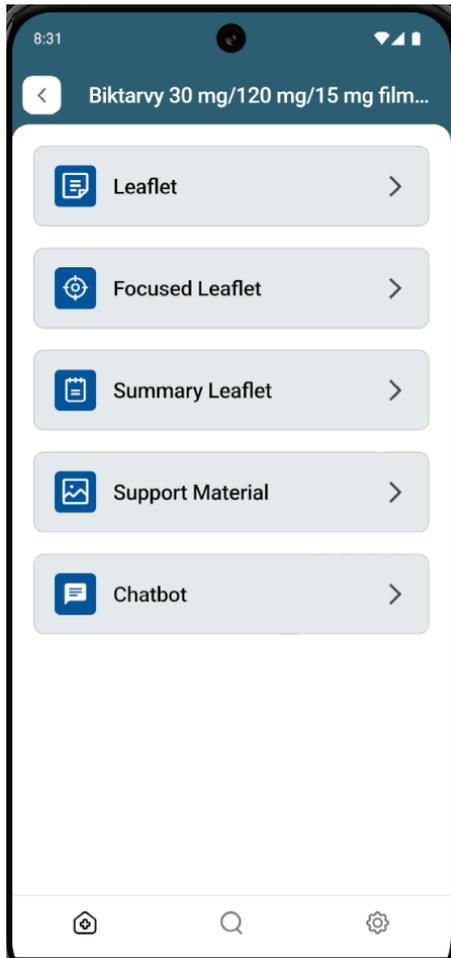
ePI in the Dutch Digital Health Ecosystem

- National vision and strategy
- National legislation on data exchange
- National standards
- Alignment with European legislation and standards (EHDS)

Patient-centric health infrastructure
"My Health Overview" & personal health environment

Medication overview

"Consult the patient information leaflet of this product"
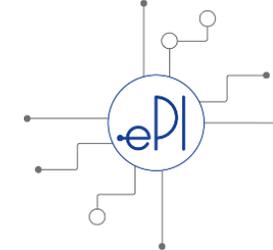
Key Takeaways

- **Trusted medicine information** should be available in **digital health environments**

- Developing ePI requires **strong collaboration between regulators and stakeholders**

- Successful implementation depends on **integration with national health systems**
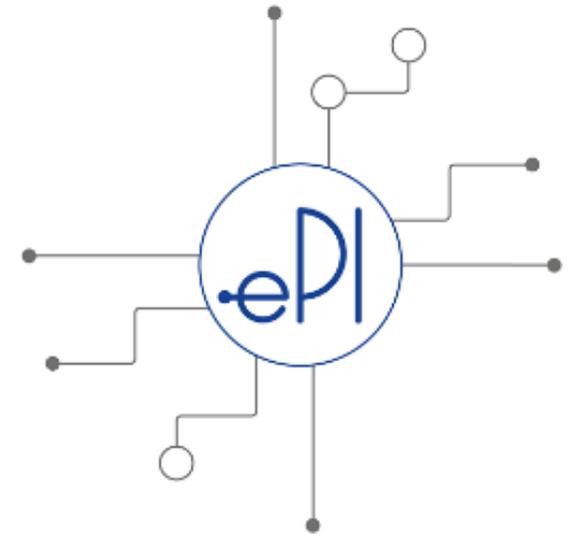
Mr Craig Anderson
Business Product Director for Labeling
Johnson & Johnson

FHIR ePI and the impact on global digital labeling strategies

Craig Anderson
Business Product Director for Labeling

Johnson&Johnson
Innovative Medicine

FHIR Overview

- Fast Healthcare Interoperability Resources (FHIR)

- The internet for healthcare

- Enables interoperable exchange of healthcare data

- Based on modern web-standards commonly used by international banking and tech companies

- Widely adopted and mandated internationally

Common Web Standards

Healthcare Use Cases
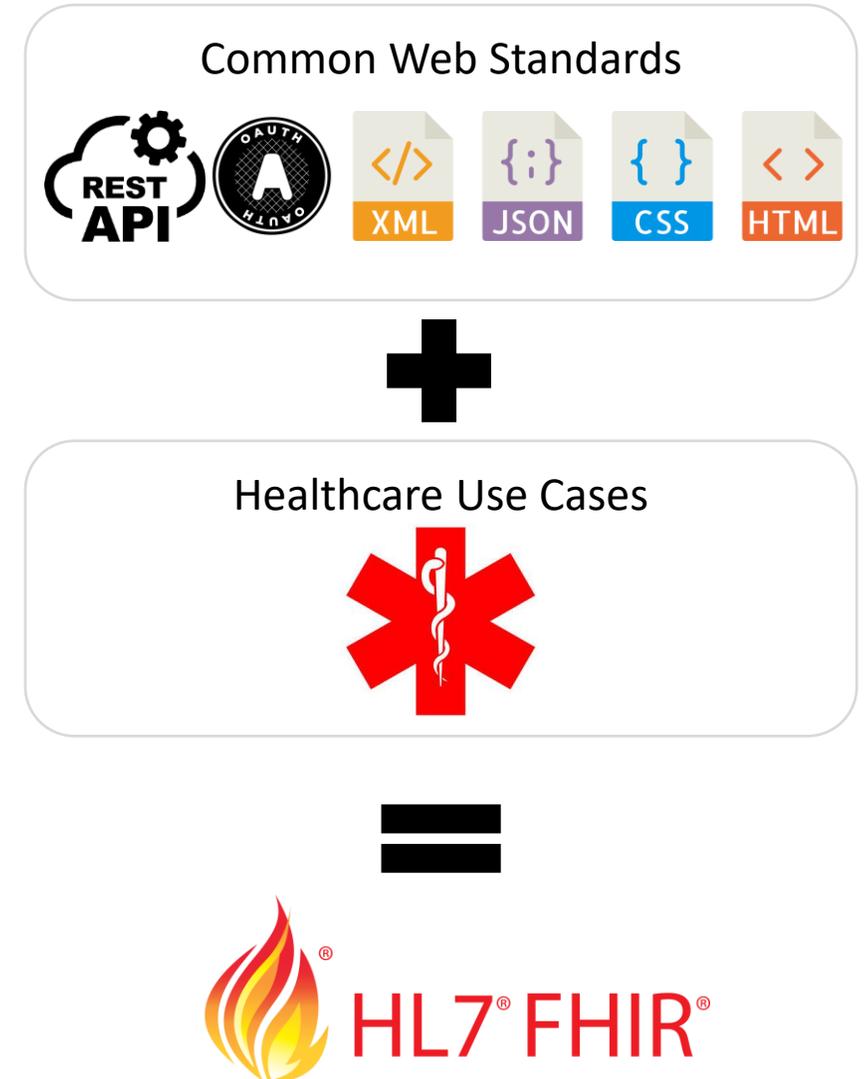
HL7® FHIR®

2025 State of FHIR Survey Results

- In 2025, HL7 International and Firely conducted a global survey to measure HL7 FHIR adoption. 82 responses were collected from 52 countries[1]

- *54% of respondents expect a strong increase in FHIR adoption in the next few years—up from 39% in 2024.[2]*

- Top 3 use case achievements[1]:

  1. Improved access to information

  2. Improved care workflows

  3. Improved health outcomes

TYPE OF FHIR USE CASES

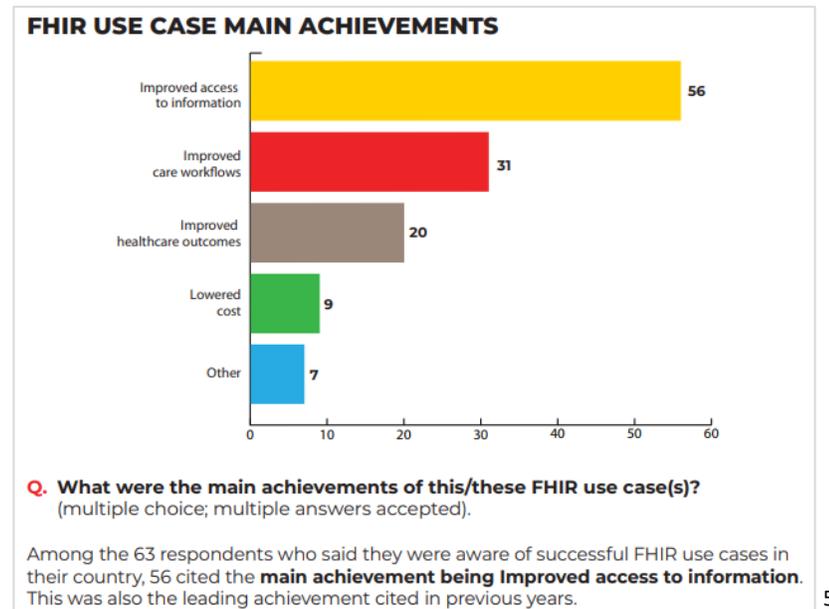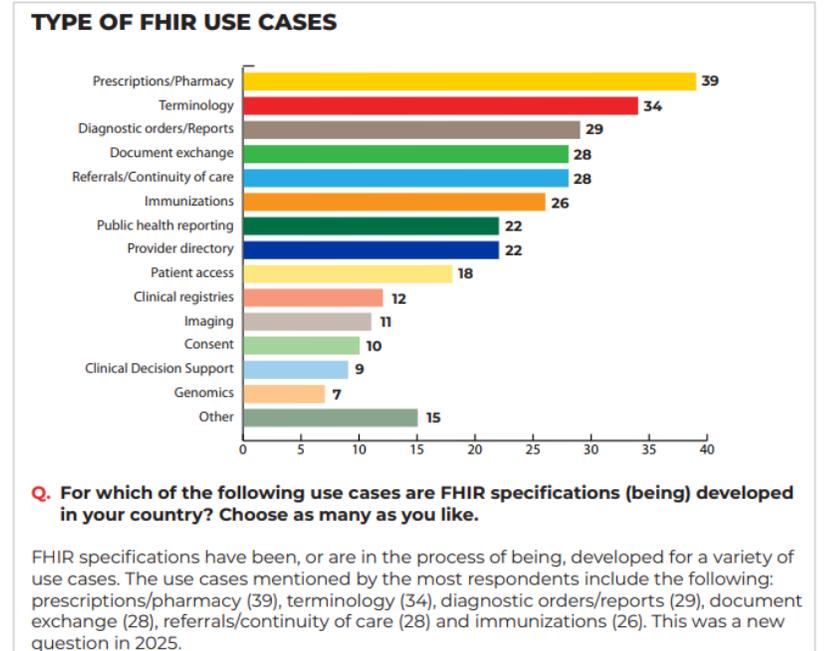| Use case	Value
Prescriptions/Pharmacy	39
Terminology	34
Diagnostic orders/Reports	29
Document exchange	28
Referrals/Continuity of care	28
Immunizations	26
Public health reporting	22
Provider directory	22
Patient access	18
Clinical registries	12
Imaging	11
Consent	10
Clinical Decision Support	9
Genomics	7
Other	15

Q. For which of the following use cases are FHIR specifications (being) developed in your country? Choose as many as you like.

FHIR specifications have been, or are in the process of being, developed for a variety of use cases. The use cases mentioned by the most respondents include the following: prescriptions/pharmacy (39), terminology (34), diagnostic orders/reports (29), document exchange (28), referrals/continuity of care (28) and immunizations (26). This was a new question in 2025.

FHIR USE CASE MAIN ACHIEVEMENTS

Achievement	Value
Improved access to information	56
Improved care workflows	31
Improved healthcare outcomes	20
Lowered cost	9
Other	7

Q. What were the main achievements of this/these FHIR use case(s)? (multiple choice; multiple answers accepted).

Among the 63 respondents who said they were aware of successful FHIR use cases in their country, 56 cited the **main achievement being Improved access to information**. This was also the leading achievement cited in previous years.

[1] 2025 State of FHIR Survey Results
[2] The State of FHIR in 2025: Growing adoption and evolving maturity

2025 State of FHIR Survey Results

- FHIR for messaging and documents are popular healthcare use cases

- High value use cases for pharma regulatory affairs

- Numerous ongoing projects to develop FHIR standards for key regulatory documents:
  - <mark>ePI (a.k.a Drug Labeling)</mark>
  - PQI (a.k.a CMC or Module 3)
  - Response to Questions (RTQ)
  - Real-Time Submissions via API (APIX)
  - Clinical Trial Protocol (UDP)

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International Adoption of FHIR ePI is growing

Pilot / Implementation Phase

- EU (expected regulatory timelines):
  - Regulation in force from Q3 2026; All MAAs require ePI from mid-2028; All products require ePI by 2031
- Jordan:
  - ePI is mandatory
- USA:
  - Developed a draft FHIR ePI implementation guide
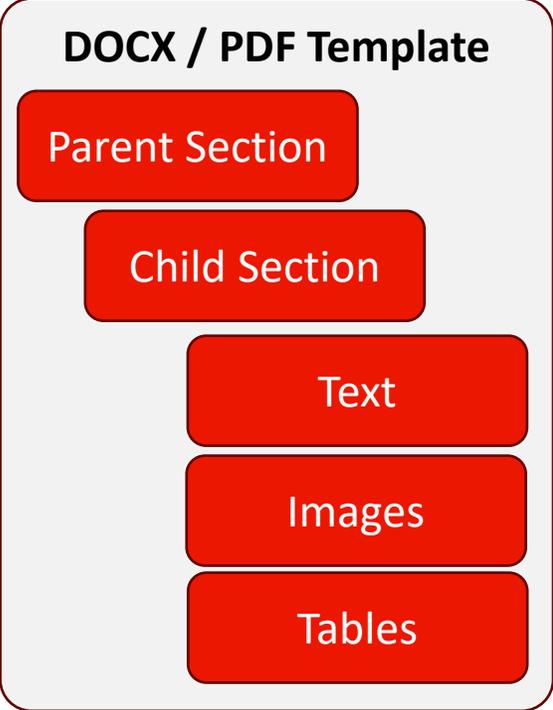 - Conducted two pilots
  - ePI transition timelines on hold

Planning / Development Phase

- Japan: Ongoing research project for ePI use cases
- Singapore: planning for an ePI pilot
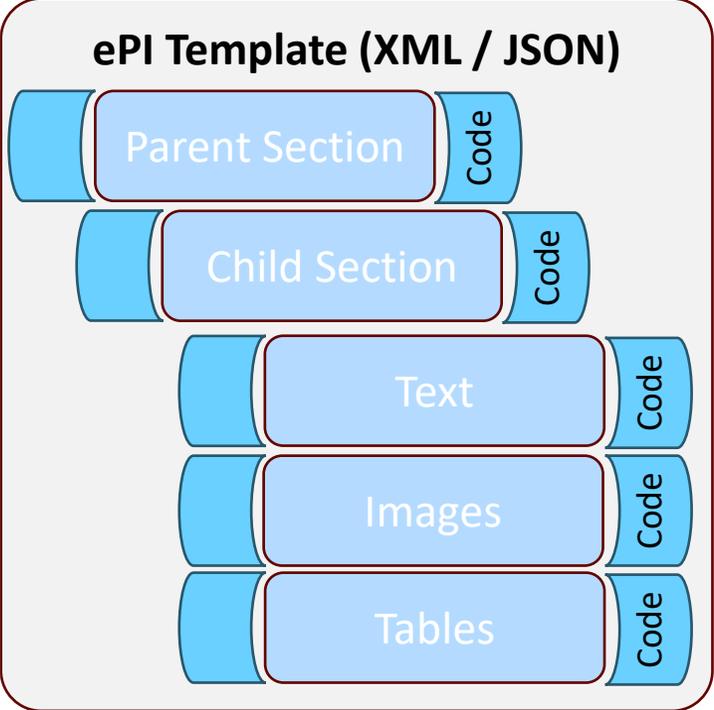- ePI discussions ongoing with Thailand, Taiwan, South Korea, Malaysia

Pharma / Regulatory use cases linked to labelling

Use Case	What It Enables
Digital Reproduction	Replace static PDF of the regulator-approved content with a faithful digital version
Product Identification & Interoperability	Accurate product lookup across EHRs, ePrescribing, pharmacy, and national registries with consistent identifiers
Safety & Substitution (Shortages, Allergens, Excipients)	Rapid identification of therapeutic alternatives during shortages/recalls and automated screening for allergens
Digital-First Personalization & Lifecycle Management	Batch-specific and patient-friendly views (QR code-linked, language/segment), structured indications, contraindications, dosing, and warnings powering real-time alerts.
Operational Efficiency & Lifecycle Management	Advanced reuse, version control, and impact analysis; auto-generate high quality content (e.g., pack artwork)

J&J Innovative Medicine

Simple steps to create an ePI

DOCX / PDF Template

Parent Section

Child Section

Text

Images

Tables

STEP 1: Convert from DOCX to ePI XML

ePI Template (XML / JSON)

Parent Section — Code

Child Section — Code

Text — Code

Images — Code

Tables — Code

STEP 2: Add metadata and additional structure

+

Product Metadata — Code

Clinical Metadata — Code

Example of semi-structured text in ePI

Semi-structured text in the ePI.xml

```
<section>
   <!-- Subsection 4.1: Therapeutic indications -->
   <section>
    <title value="4.1 Therapeutic indications"/>
...
   <!-- Indication subsection #1 -->
   <section>
    <title value="Indication: Schizophrenia"/>
    <text>
     <status value="generated"/>
     <div xmlns="http://www.w3.org/1999/xhtml">
      <p><b>INVEGA</b> is indicated for the treatment of <b>schizophrenia</b> in adults and in adolescents 15 years and older.</p>
     </div>
    </text>
   </section>
   <!-- Indication subsection #2 -->
   <section>
    <title value="Indication: Schizoaffective disorder"/>
    <code>
    <text>
     <status value="generated"/>
     <div xmlns="http://www.w3.org/1999/xhtml">
      <p><b>INVEGA</b> is indicated for the treatment of <b>schizoaffective disorder</b> in adults.</p>
     </div>
    </text>
   </section>
  </section>
 </section>
```
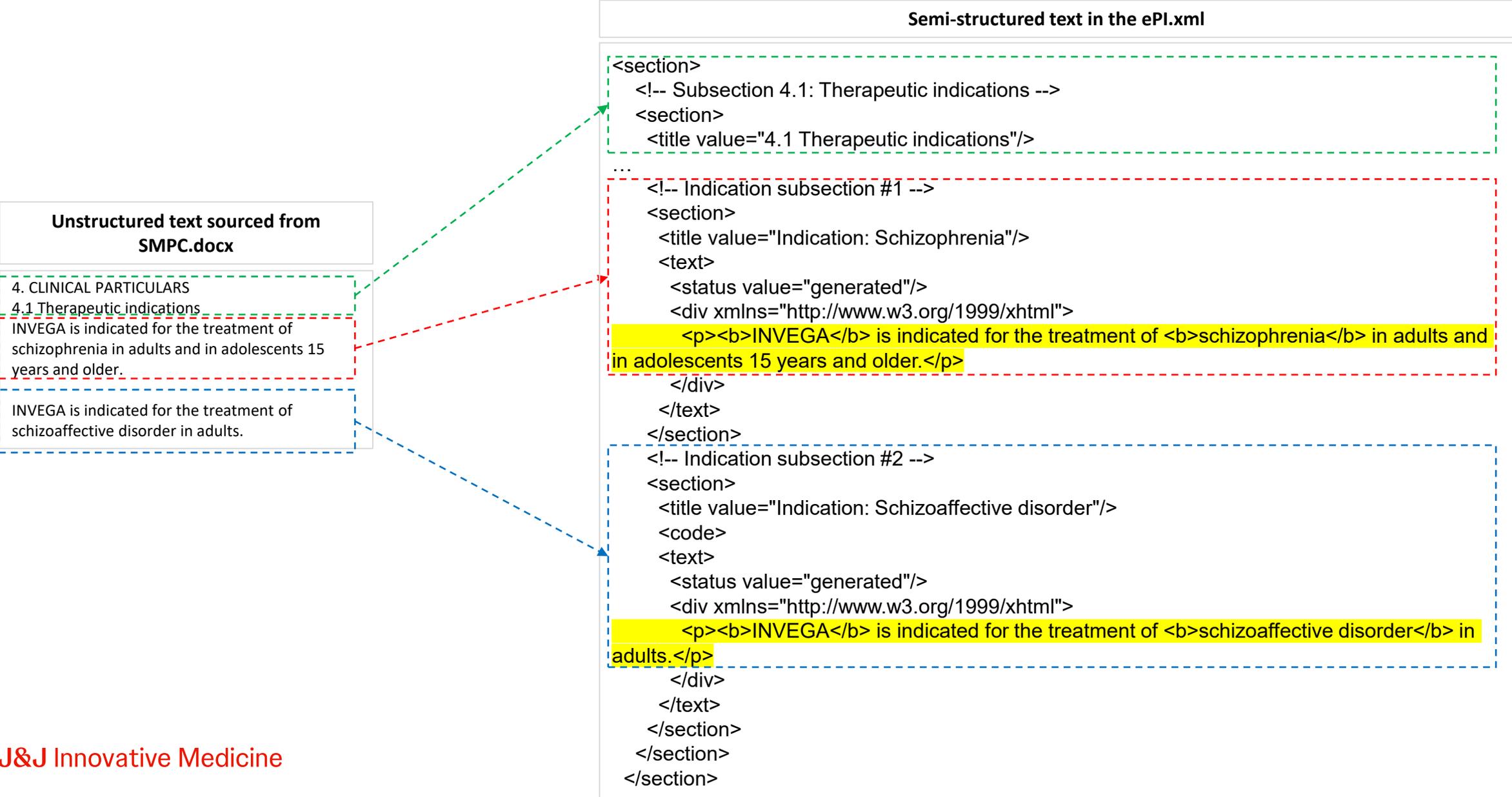
Unstructured text sourced from SMPC.docx

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

INVEGA is indicated for the treatment of schizophrenia in adults and in adolescents 15 years and older.

INVEGA is indicated for the treatment of schizoaffective disorder in adults.

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Example of clinical details that can be applied

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

INVEGA is indicated for the treatment of schizophrenia in adults and in adolescents 15 years and older.

INVEGA is indicated for the treatment of schizoaffective disorder in adults.

1. Indication: Schizophrenia (Adults & Adolescents 15+)
- Disease/Condition:
  - SNOMED CT: 191526005 |Schizophrenic disorders (disorder)|
  - ICD-10-CM: F20.9 (Schizophrenia, unspecified) or F20* (Schizophrenia)
  - MedDRA: 10039866 (Schizophrenia)
- Age/Population Limitation:
  - FHIR Expression: age > 14 years (covers 15 years and older) or age >= 15 years
  - SNOMED CT: 133936004 |Adolescent (10-17 years)| and 308910008 |Adult (disorder)|

2. Indication: Schizoaffective Disorder (Adults)
- Disease/Condition:
  - SNOMED CT: 191535003 |Schizoaffective disorder (disorder)|
  - ICD-10-CM: F25.9 (Schizoaffective disorder, unspecified) or F25.x
  - MedDRA: 10039862 (Schizoaffective disorder)
- Age/Population Limitation:
  - FHIR Expression: age >= 18 years
  - SNOMED CT: 308910008 |Adult (disorder)|
  - Therapy Context (Optional in ClinicalUseDefinition):
  - SNOMED CT (Monotherapy): 424124008 |Schizoaffective disorder treated with monotherapy|
  - SNOMED CT (Adjunct): 446738002 |Schizoaffective disorder treated with adjunct therapy
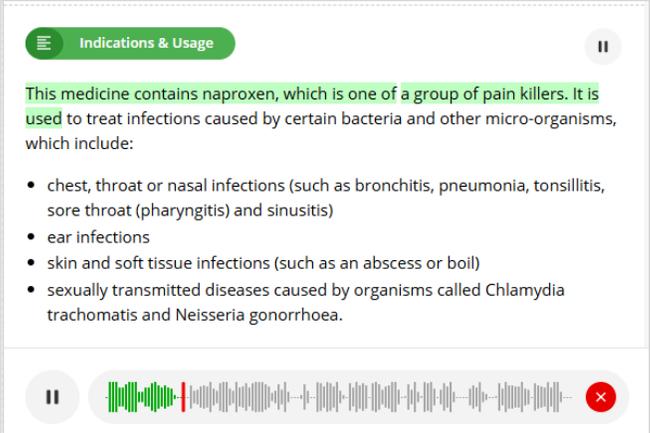
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Finished product: ePI with the Jordan FDA's eLabeling app

Data Matrix code leads to the ePI

ePI app includes accessibility features

Text to speech

Sign language

Hands free (Beta)

Closing Remarks

Mr Leo Semprún
Global Science and Regulatory
Policy Lead - LATAM
MSD