ePI Simplified:
One Platform, Fewer Tools

Pierre STANISLAWSKI – Ennov
Vasu RANGANATHAN – InteliNotion

17 October 2025

2:30pm - 3:30pm	**ePI Simplified: One Platform, Fewer Tools** Ennov & InteliNotion	**Unified Brands through a Unified Platform: Artwork and Promotional Materials: Core Model and Demo** Grégory Desgrandchamps	**- PV and Signal Detection -** **- Clinical -** **- Project Support & Customer Success -** **- DocShifter -**
3:30pm - 4:00pm	**Afternoon Break**		
4:00pm - 5:00pm	**Ennov Regulatory: Wishlist, Use Case Demo and Open Discussion** Nicolas Thomas, Pierre Stanislawski & Elya Shaffer	**Ennov Quality: Wishlist, Use Case Demo and Open Discussion** Grégory Desgrandchamps & James Deleuse	

Presenters

Bringing together the best in the industry

Vasu RANGANATHAN

Co-founder - InteliNotion

Working with clients to drive business value through strategic planning, content process optimization, and governance.

Pierre STANISLAWSKI

Product director - Regulatory

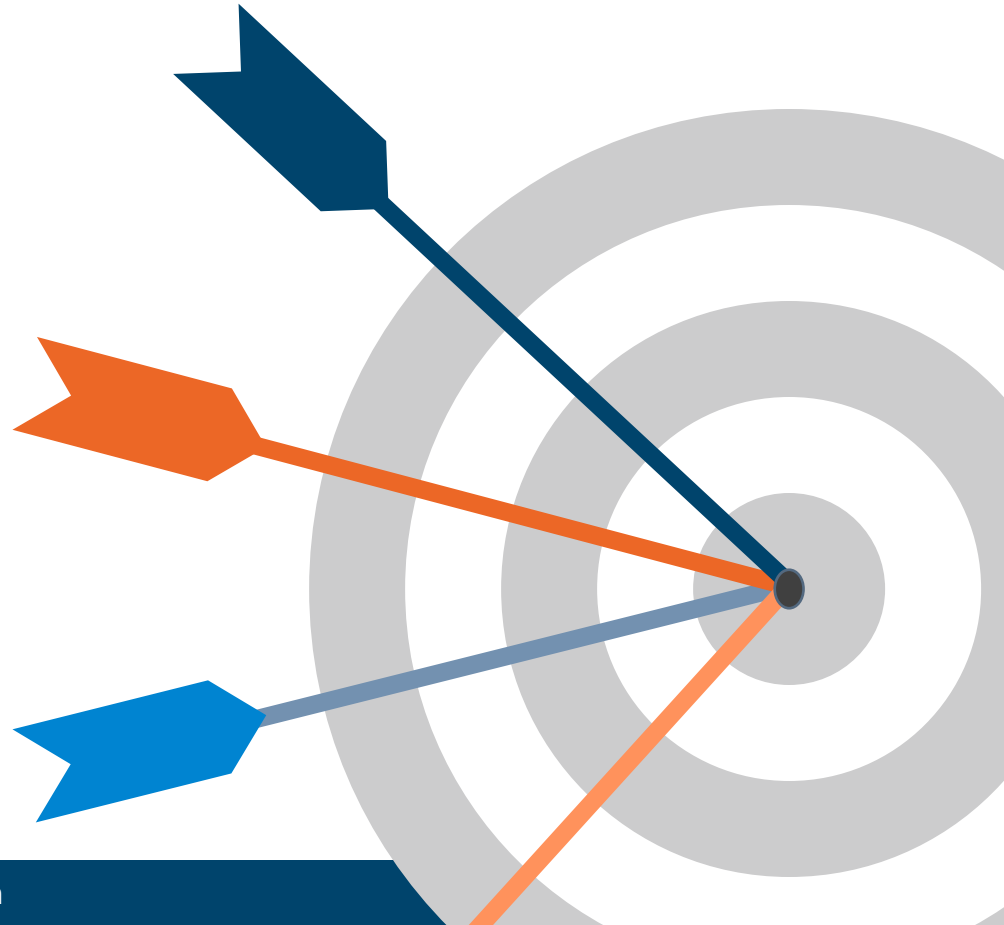
Pierre has joined Ennov team 17 years ago. He has a wide experience in service and customer implementation, validation, and product development.

He currently drives the Regulatory solutions including RIM, xEVMPD and IDMP in relation with other Core Model and Ennov modules

Objectives

Learn about ePI

Benefits of a single Regulatory ePI platform



Agenda

1. What is ePI (and why it's important)
2. Ennov + InteliNotion unified solution
3. InteliNotion presentation + demo

ePI Quiz

- https://pe.app/epi

Share Responses

Respond at pe.app/epi

Poll Everywhere

What does ePI mean ?

Inactive

15

7%

Enterprise Performance Improvement

93%

Electronic Product Information

0%

Electronic Pharmaceutical Information

0%

Epidemiology Product Investigation

Add Choice

When Presented

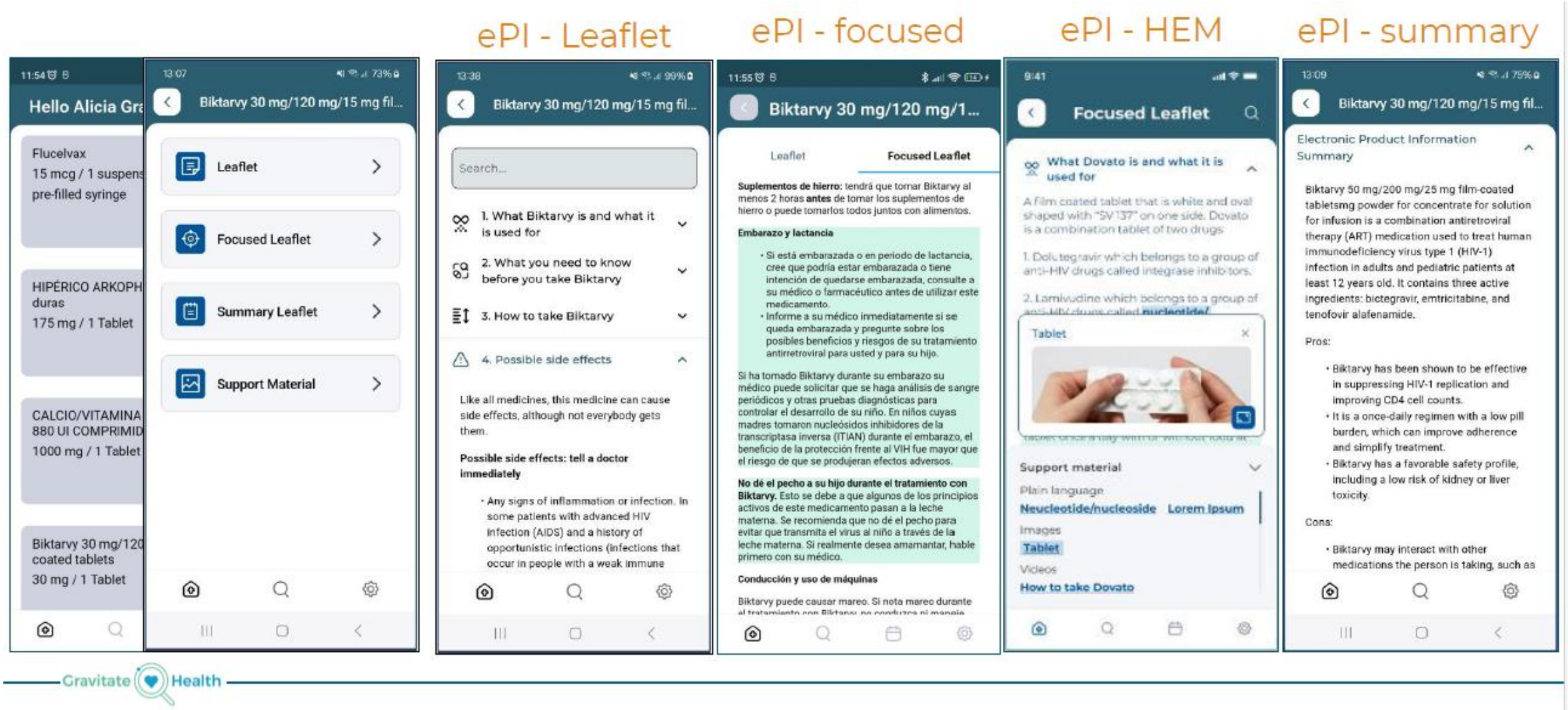
Responses Lock Correctness

What is ePI ?

Electronic product information (ePI)

- authorized, regulator-approved information about a medicinal product (SmPC, Package Leaflet, labeling)
- published and distributed in an electronic format using structured data standards.

ePI for end users – progress from Gravitate Health



Gravitate Health

Expected ePI Benefits

1. Improved access and usability

- Users: Patients, healthcare professionals (HCPs), regulators
  → instant access the most up-to-date approved product information online.
- Multiplatform/accessibility: smartphones, computers, different screen readers accessibility tools

2. Enhanced data quality and consistency

- Structured format (FHIR, XML): enables automated comparison, integration, and reuse
- Single source of truth

3. Regulatory efficiency and interoperability

- Data reuse
- Cross-system interoperability integration with health (electronic health records) or clinical apps

4. Faster implementation of safety updates

- Rapid deployment
- Improved pharmacovigilance linkage

Timeline for Safety Update implementation in Labeling

Stage	Typical Duration	Description
1. Signal detection & assessment	2–8 weeks	Safety signal identified from pharmacovigilance data; evaluation and internal decision to update labeling.
2. Preparation of variation / labeling update dossier	4–8 weeks	Drafting revised SmPC / PIL / labeling text, translations, and regulatory justification.
3. Regulatory submission and review	2–6 months 	Health authority review (e.g., EMA Type IB/II variation, FDA labeling supplement, MHRA notification). Duration depends on type of change.
4. Approval to implementation (artwork, packaging, distribution)	**3–9 months** 	Artwork updates, printing, stock depletion, and new packaging release. Often the longest step due to manufacturing and logistics constraints.
TOTAL	**9-18 months**	Full cycle from signal detection → updated labeling in the market.
TOTAL with ePI	**4-9 months**	

Share Responses

Respond at pe.app/epi

Poll Everywhere

What is FHIR ?

Inactive

14

0%

A methodology to optimize management of health IT system

7%

A set of best practices for firefighters in Europe

0%

A Framework for data governance

93%

A standard for exchanging healthcare information electronically

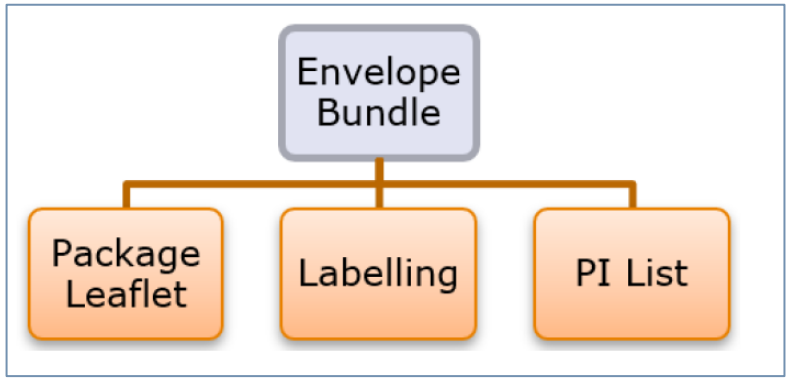
Add Choice

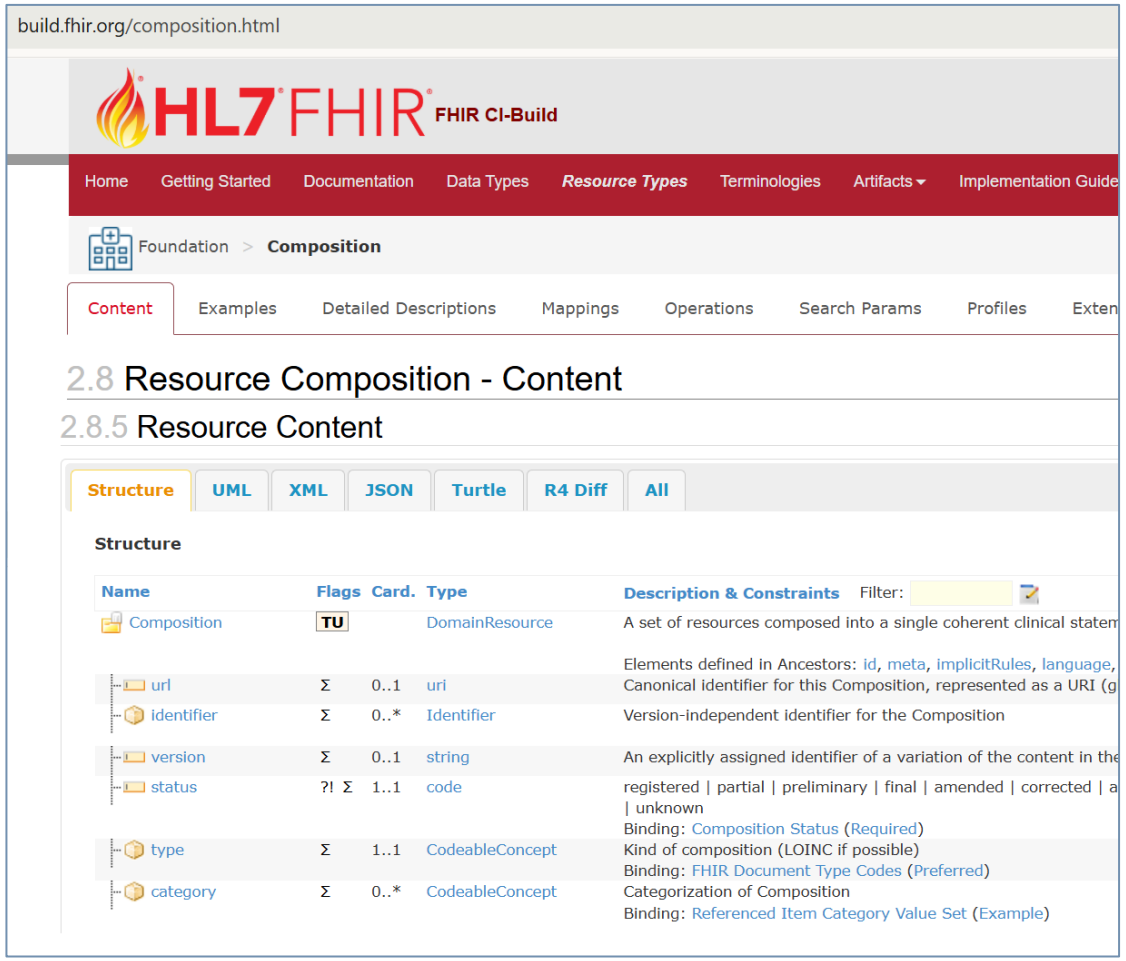
When Presented

Responses Lock Correctness

Effort for standardization

- No common global standard
- FHIR ePI: standardized framework developed by
  - HL7 Vulcan Accelerator
  - EMA
  - EFPIA, Gravitate Health
  - National Health Authorities
- FHIR defines core technology components
  - data model & format (xml, json)
  - exchange & interoperability (API)





ePI FHIR information

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).

Share

Respond at pe.app/epi

Poll Everywhere

Which countries/regions have a ePI/eLabel program ?

Inactive

0

0% Europe

0% Europe + North America

0% Europe + North America + Asia-Pacific

0% Europe + North America + Asia-Pacific + Middle East

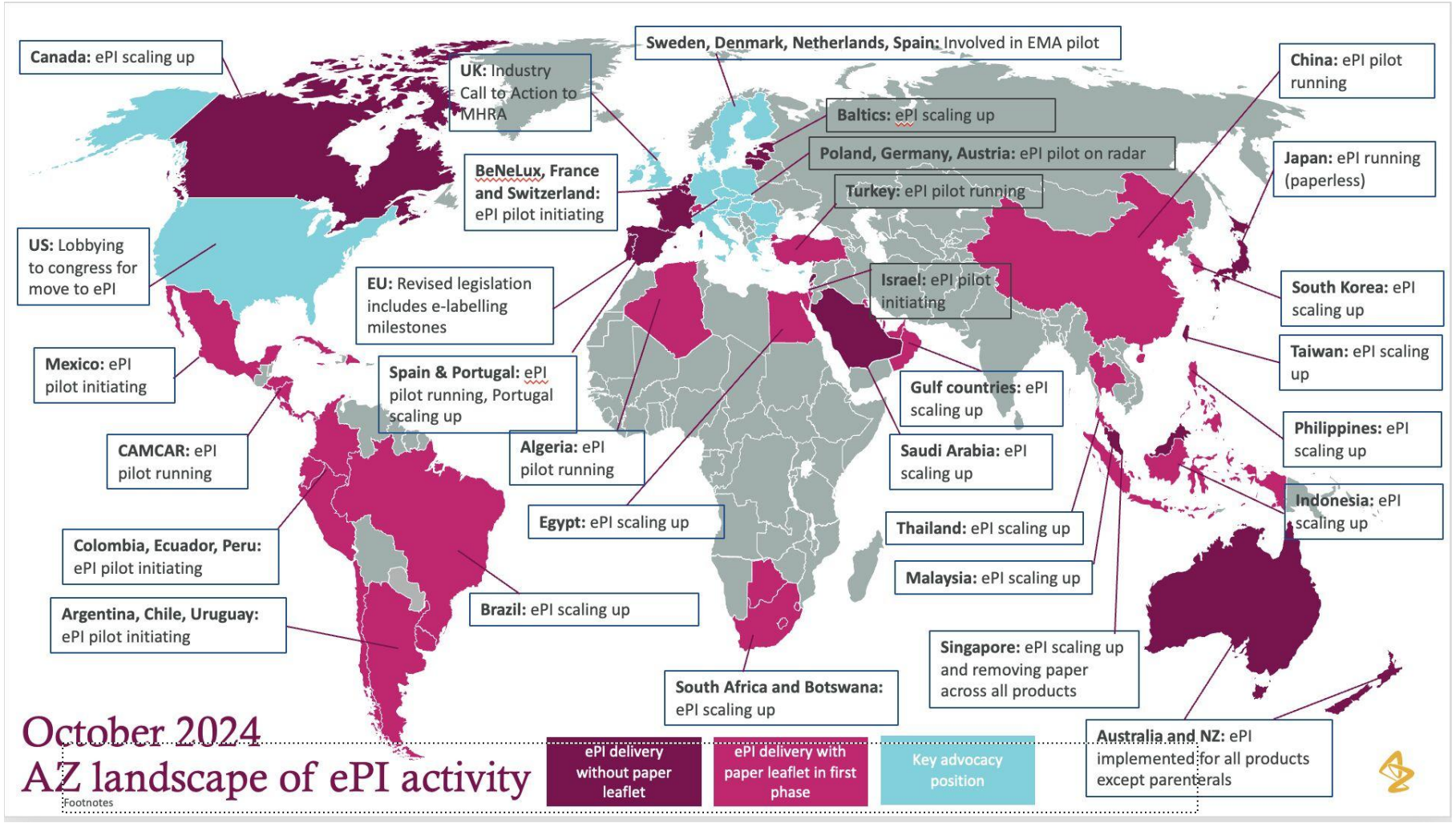
0% Europe + North America + Asia-Pacific + Middle East + Africa

Add Choice

When Presented

Hide Responses | Lock | Show Correctness

ePI worldwide programs



from eLeaflet October 2024

Global FHIR ePI adoption

	2023	2024	2025	2026	2027	2028
Planning		Australia, LATIN/SOUTH AMERICA: Brazil, Mexico MIDDLE EAST: Egypt, Israël, Algeria ASIA: India, Malaysia, Indonesia, Japan, Taiwan, South Korea, Singapore,				
Develop, Pilot		EMA		Brazil		
				USA		
Optional Use		Jordan		EMA		
Mandatory Use			Jordan			EMA

EMA ePI Initiative

EMA-HMA-EC: progress of ePI initiative

Key Principles

2020: ePI is authorised summary of product characteristics, package leaflet and labelling created using the EU ePI Common Standard. ePI optimises dissemination via the web, e-platforms and print.
Benefits of up-to-date timely information

EU ePI Common Standard

2021: Harmonisation using EU ePI Common Standard based on FHIR: a set of XML (and/or JSON) health data resources,
plus a REST API
for accessing them

FHIR

ePI at PLM Portal

Creation and management by companies & regulators, storage in FHIR repository

Pilot

2023-2024: Creation of **ePI in real procedures** by EMA, AEMPS, DKMA, MEB and MPA

Successful pilot paves the way for implementation of ePI

16 December 2024

Report outlines recommendations and next steps

News Human Product information

agencia española de medicamentos y productos sanitarios

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Inspectie Gezondheidszorg en Jeugd
Ministerie van Volksgezondheid, Welzijn en Sport

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Technology involved

ennov **Doc**

ennov **Process**

ennov **AI**

ennov **Analytics**

InteliNotion

ennov **Process**

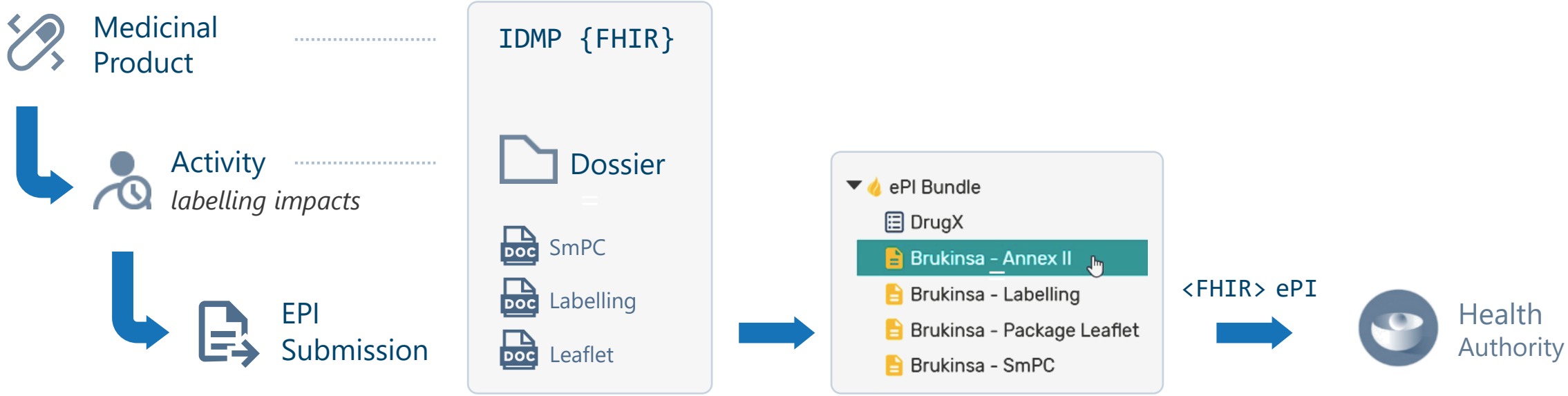
ennov **Artwork**
Core Model

ennov **IDMP**

	KEY ACTIVITIES BEING AUTOMATED
DATA MANAGEMENT	❍ Investigating data transfer agreements ❍ Connection to Master data management systems ❍ Automatic data exchange across systems
WORKFLOW MANAGEMENT	❍ Managing artwork workflow ❍ Metadata transfer ❍ Manage Labeling workflows
CONTENT AUTOMATION	❍ Real time data consolidation ❍ Artificial Intelligence ❍ SCM
METRICS MANAGEMENT	❍ Labeling Metrics Management
AUTOMATED PUBLISHING	❍ Upload to Websites and digital transformation ❍ Conversion of word documents to HTML/XML ❍ Create assembly structure and assign documents automatica based on the submission structure maintained in the DMS
AUTOMATED NOTIFICATIONS	❍ Dashboard Notifications ❍ Automated notifications ❍ Automated email notifications ❍ Process and task automations
AUTOMATED QC	❍ Technical review of artwork content ❍ All QC activities for labeling and artwork with consistent pro

from Navitas LabelTech forum Jan 2025

Ennov ePI with InteliNotion



Respond at pe.app/epi

Poll Everywhere

What does an ePI submission contains?

Inactive

0

0%

Word + PDF + XML

0%

PDF + XML

0%

XML + image files

0%

XML with embedded images

Add Choice

When Presented

Hide Responses | Lock | Show Correctness

InteliNotion Introduction

Overview of InteliNotion

- Transforms Content Creation for Life Sciences companies

Core Technologies

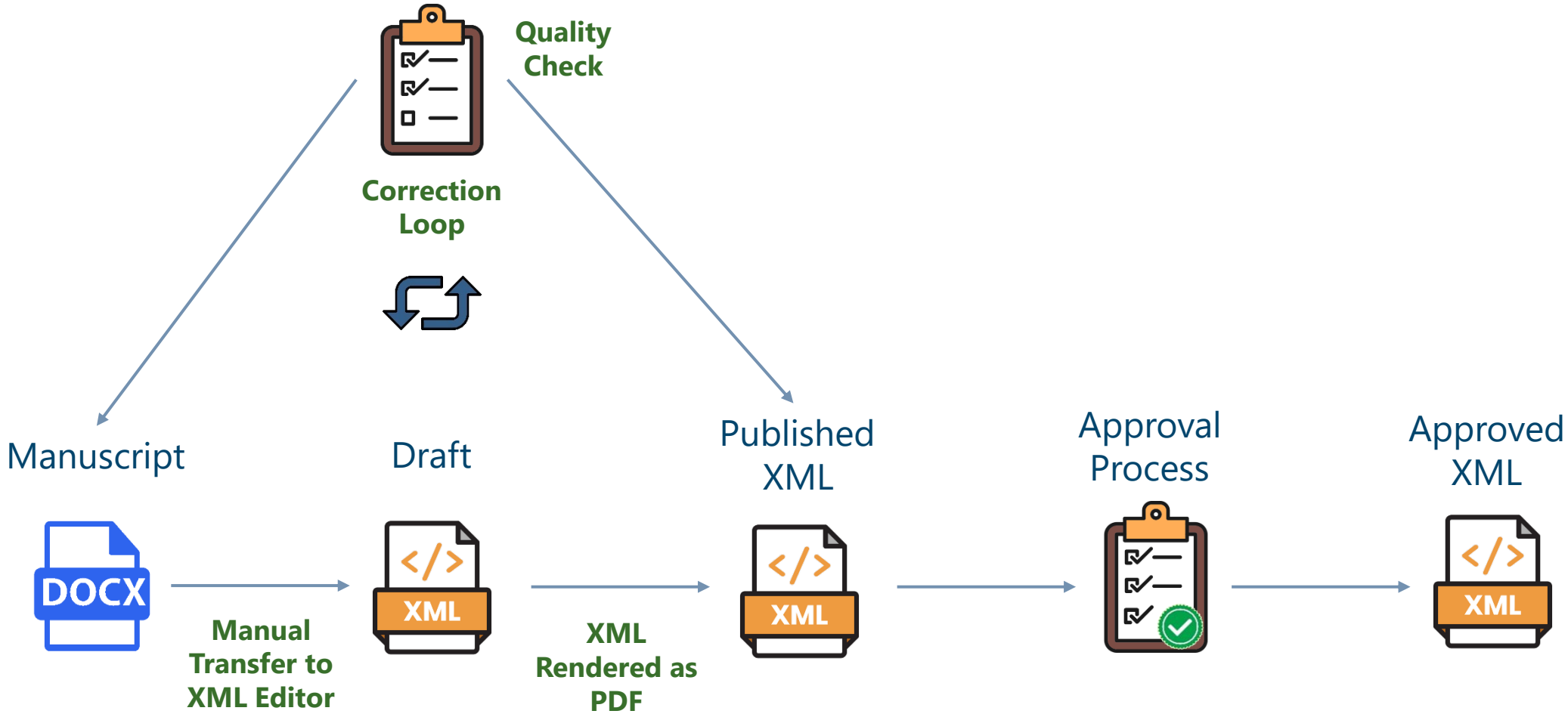
- Component Content Management
- Content Governance
- Regulatory Compliance

AI-Driven Vision

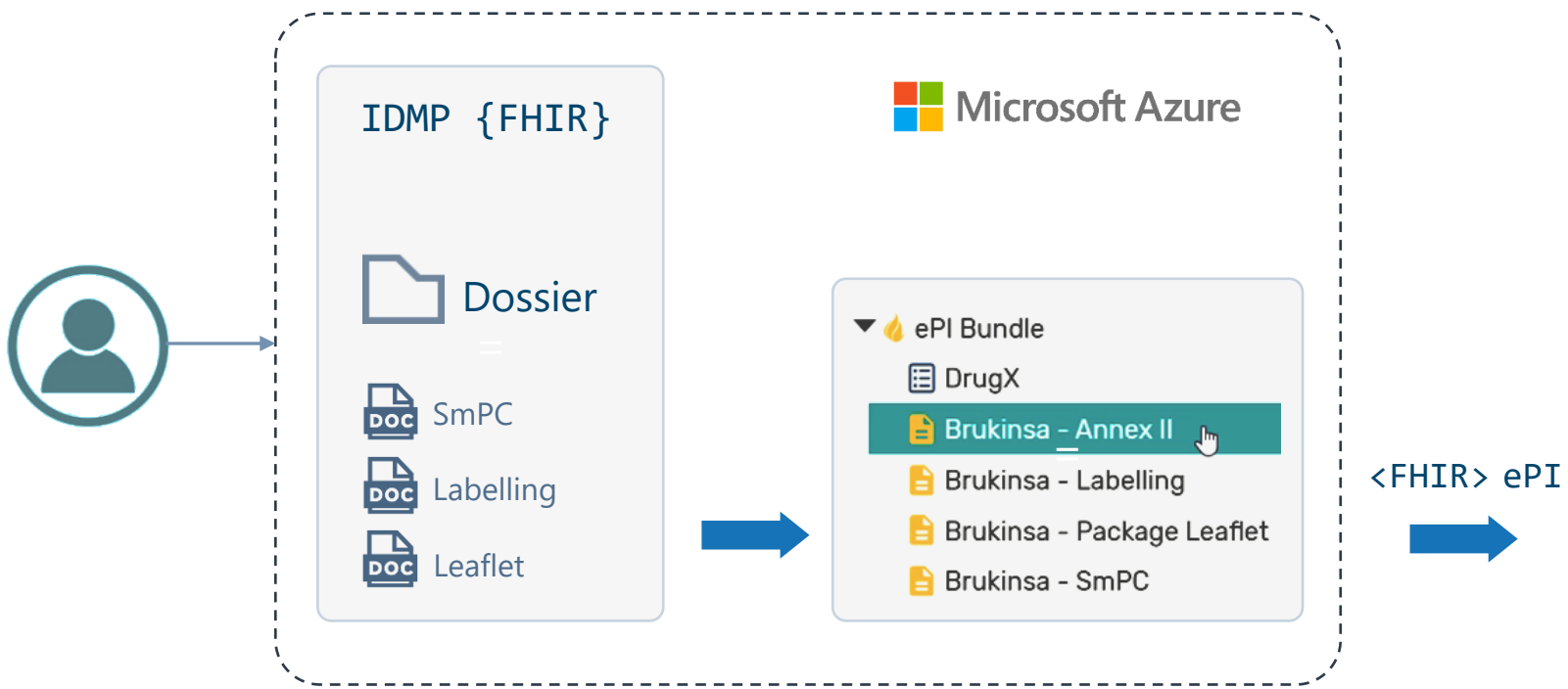
- Intelligent Content
- Component-level GenAI
- AI-Augmented Contextual Authoring

Open and Extensible

Manual Creation of ePI

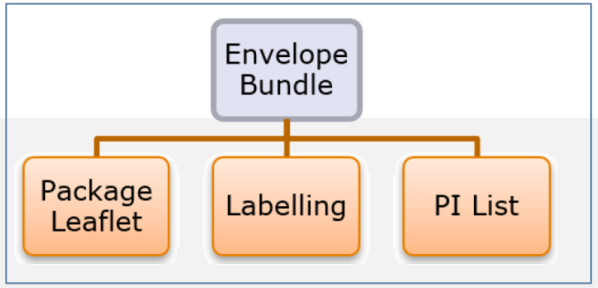


Ennov – InteliNotion Integration: Retrieve Labeling Documents



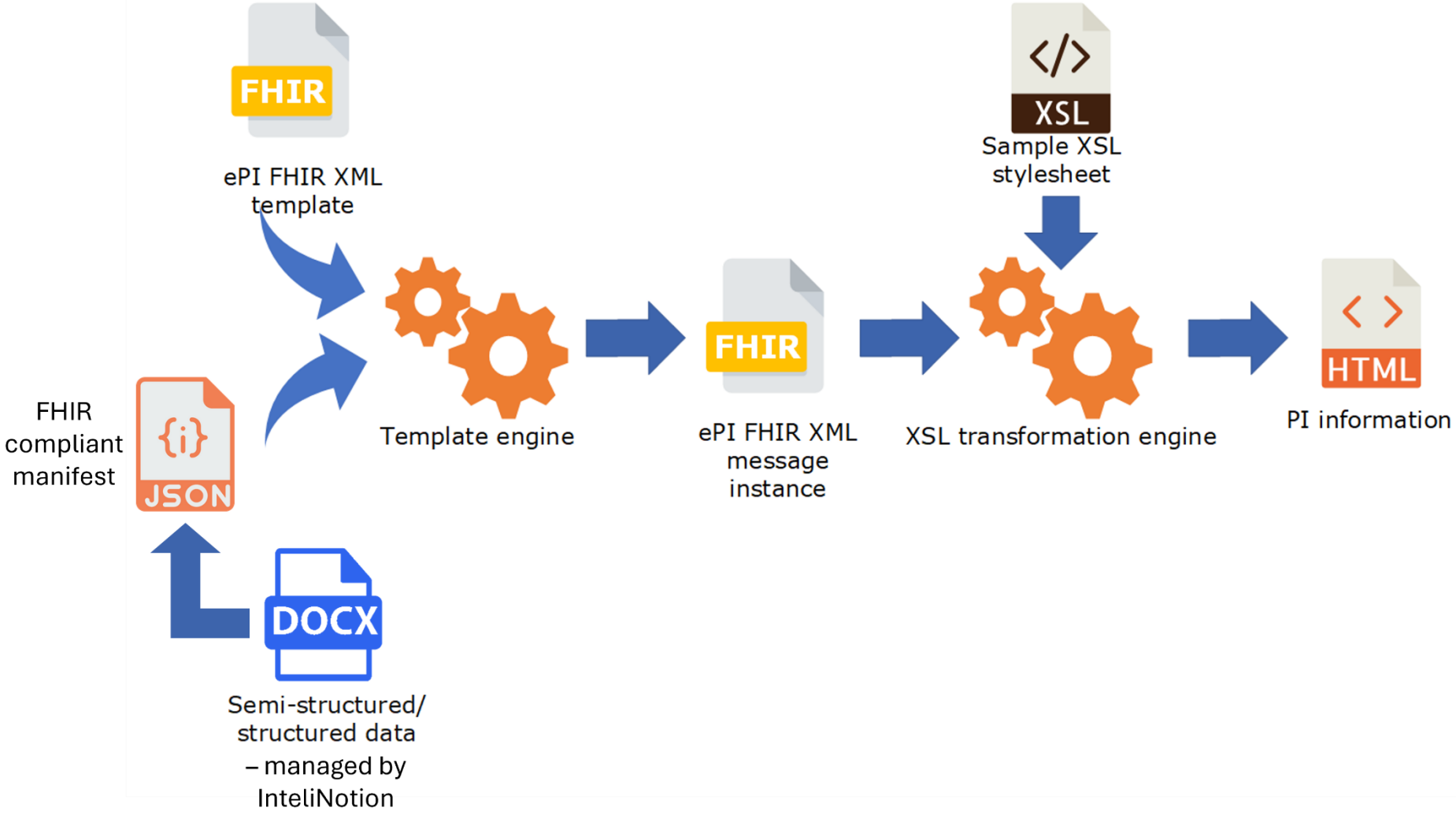
- ePI generation initiated from Ennov Dossier
- IN ePI generation service
  - IN Connector retrieves the labeling document(s)
  - Documents are ingested/structured in IN
  - The generated ePI is saved and versioned back into Ennov

IN Automated ePI Creation



Create ePI bundle	Compile bundle	Validate bundle	Upload bundle
• Create the ePI type bundle structure • Placeholders for the Resources	• Compile resources data • Link labeling document(s) into resource placeholders • Complete compilation • Review workflows	• Validate the compiled bundle – structural and semantic correctness • Finalize/ format bundle and store to GxP repository	• Regulatory approval • Regulatory upload
Labeling Specialist	Labeling Specialist	Labeling/Regulatory Specialist	Regulatory Specialist

Automated ePI Generation



ePI Generation – Demo

FHIR Configurations

InteliNotion

eNNOV Software for Life

Add FHIR Resource as Business Object	Configure FHIR JSON Transformation Rule	Configure FHIR Resources and Relationships	Configure FHIR JSON at Info Model
• Use Business Object Modeler • Create new business object • Mark it as FHIR Resource	• Use FHIR JSON Mapping • Select Business Object • Add Mapping and configure the JSON Rule.	• Use Relationship Manager • Select all Business Objects for the implementation guide (ePI type 3) • Create relations between resources • Select transformation rules per resource	• Use Info model FHIR JSON Mapping • Select Hierarchical Set • Configure each section and map the element to section.
Labeling Specialist	Labeling Specialist	Labeling/Regulatory Specialist	Regulatory Specialist

Conclusion

- ePI is coming soon – Jordan
- Ennov + InteliNotion unified platform wining combo

Thank you for your attention