

Electronic Product Information (ePI)

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MEDICINAL PRODUCT INFORMATION (DRUG LABEL)

Medicinal Product Information Management Today

- **Regulated & Validated resource that explains how a medicine should be used safely and effectively**
- **Targeted for use by Regulator, healthcare professionals, patients**
- **Fragmented formats in use by each region and mostly as static PDF and non-machine readable**

Item	USA	Europe	Other Countries
Referred as	Prescription Drug Label	Summary of Product Characteristics (SmPC) or Package Leaflet	Japan (Package insert)
Format	SPL (Structured Product Labeling) (XML)	IDMP (Identification of Medicinal Products) (ISO based, default global standard)	XML/PDF

Many emerging markets still rely on unstructured or PDF labels

CHALLENGES WITH DRUG LABEL



Fragmented formats creates challenges across operations, financial and interoperability areas

Challenge	Details
Format	Unstructured and fragmented format, cause delays in label lifecycle management from creation to ongoing updates
Limited interoperability	Fragmented formats, non-machine readable, restricts global data exchange & between healthcare systems, limiting automation opportunities, less consumable
Operations	Manual tasks to manage different formats, complex and lengthy authoring processes for ongoing label updates
Regulatory Approvals	Regulatory approval during initial and ongoing updates becomes lengthy process
Financial	Costly for manufacturers due to heavy operational burden



WHAT IS EPI?



ePI – One Global Standard to manage Medicinal Product Information

- 1. ePI – Digital first, Structured, and Regulator-approved version of a drug label**
- 2. Combines Label Content + Product Data + Interoperability layer**
- 3. Machine readable, API-accessible and dynamically consumable**
- 4. Reusable across regulatory, clinical, and patient Channels**
- 5. Builds on HL7 FHIR as One Global standard**
- 6. Semantically structured and Flexible to adapt to regional regulatory requirements**

Medicinal drug products for human use (SmPC, SPL, PIL and Instructions for Use (IFU))

Type	Core FHIR Resources	Primary Value & Use Cases
Type 1	Bundle, Composition, Binary	Digital Reproduction: A faithful digital version of the approved labeling (SmPC, PIL, carton). Acceptable as a legal document of record.
Type 2 RECOMMENDED STARTING POINT	MedicinalProductDefinition, RegulatedAuthorization, Organization, PackagedProductDefinition, ManufacturedItemDefinition, AdministrableProductDefinition, Ingredient, Substance	Product Identification: Enables accurate lookup in hospital systems and national medicine databases. Supports Drug Shortage management (therapeutic alternatives), Allergen/Excipient Safety (e.g., lactose, gluten), and Digital Interoperability (ePrescribing).
Type 3	ClinicalUseDefinition, MedicationKnowledge	Clinical Guidance: Structured indications, contraindications, and dosing. Enables Interaction Alerts (Drug-Drug, Drug-Food) in EMRs and clinical apps.
Type 4	All resources used in Types 1 to 3	Digital-First Components: Links Composition sections to structured resources to enable full support for personalization and batch-specific label variations.

Future Phases : Medical devices, Veterinary Drugs, and Natural Health Products

Advantages of ePI

Benefit	Advantages
Interoperability & Integration	Can integrate with EHRs, pharmacy systems, and clinical decision support 👉 Enables Context-aware drug information at point of care
Real-time Updates	Label changes can propagate instantly across systems Eliminates outdated PDFs and static documents
Better Patient Access	Delivered via apps, QR codes, portals Supports multilingual and accessibility features
Reusability & Efficiency	• Same structured data reused across Regulatory submissions, Medical information platforms. 👉 Reduces duplication across regions and systems
AI & Analytics Ready	Structured content enables Automated summarization, Signal detection (pharmacovigilance) and Knowledge graph creation
Global Harmonization Potential	Bridges regional differences Aligns with IDMP and emerging global frameworks



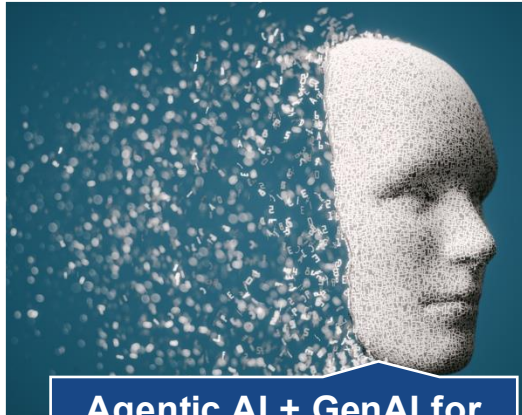
Intelligent Platform for Electronic Product Information

(Patent Pending)

**AN EPI IMPLEMENTATION FROM
DEEVITA**



DEEVITA EPI System - Autonomous, Generative AI ePI Platform



Agentic AI + GenAI for End-to-End ePI Lifecycle



Seamless FHIR Conversion



Intuitive Authoring Tools



Central FHIR Repository



Flexible Export Options



Dynamic Drug Label Presentation



Interoperability Ready

Key Benefits



Agentic AI Automation

Reduce manual effort



Regulatory Confidence

Ensure FHIR compliance



Accelerated Authoring

Speed up ePI creation



Legacy Migration

Convert SPL, IDMP, PDF



AI-Powered QA Chat

Instant information access



Interoperable & Scalable

Seamless system integration

Faster, accurate, and interoperable product labeling.

DEEVITA EPI Platform – Conversion Hub

Conversion Hub
Convert legacy label documents into structured FHIR ePI

Start Conversion Agent | Create ePI Document

SPL → FHIR | IDMP → FHIR | Word/PDF → FHIR

656 Total Conversions | 601 Successful | 0 Partial | 103 Failed | 85.4% Success Rate | 13.6s Avg Duration

Conversion History
Track and view past conversion activities

Status | Source Type | Date Range | Date ↓ Newest

Item	Status	Source Type	Date	Duration	Actions
AMPICILLIN TRIHYDRATE - SPL.xml	Success	SPL	Mar 21 at 12:30 PM	35.6s	JSON, XML, Source
OPSUMIT® (macitentan)	Success	Form	Mar 21 at 12:29 PM	29ms	JSON, XML, Source
ERLEADA® (apalutamide) tablets	Success	Word/PDF	Mar 21 at 12:24 PM	24.2s	JSON, XML, Source
ERLEADA® (apalutamide) tablets	Success	Word/PDF	Mar 21 at 12:10 PM	22.8s	JSON, XML, Source
ERLEADA® (apalutamide) tablets	Success	Word/PDF	Mar 21 at 12:10 PM	25.4s	JSON, XML, Source
OPSUMIT®	Success	Form	Mar 21 at 10:45 AM	22ms	JSON, XML, Source
ERLEADA® (apalutamide) tablets	Success	Word/PDF	Mar 21 at 10:36 AM	33.3s	JSON, XML, Source
TRANDOLAPRIL TABLETS USP	Success	Form	Mar 20 at 08:59 AM	29ms	JSON, XML, Source
Cetirizine.xml	Success	SPL	Mar 20 at 08:57 AM	33.5s	JSON, XML, Source
ERLEADA® (apalutamide) tablets	Success	Word/PDF	Mar 20 at 08:56 AM	37.0s	JSON, XML, Source

Showing 1 – 10 of 200 records

OPSUMIT® (macitentan) - FHIR Quality Score: 97.0% Overall (Grade A | High). Extraction: 60%, Mapping: 98%, Validation: 100%. Status: Passed.

DEEVITA EPI Platform – FHIR Quality Score

Review Conversion Details

FHIR Score | **FHIR Output**

FHIR Bundle document created successfully with FHIR quality Score : 97.0/100

Conversion Score
Accuracy of content extraction and mapping to FHIR resources

A 94.5 /100

Extraction: 60 /100 · wt 5%

Mapping: 98 /100 · wt 50%

Compliance Score
FHIR schema & validation quality

A 100.0 /100

Validation: 100 /100 · wt 45%

Passed SCHEMA | Valid STRUCTURE | None WARNINGS

Composition ✓ | Medication ✓ | Organization ✓ | Bundle=document ✓ | Profiles ✓ | Validation passed ✓ | 11 resources

Strengths (2)

- Core FHIR resource types (Composition, Medication/Product, Organization / RegulatedAuthorization) are all present.
- FHIR validation passed with no errors.

Recommendations (1)

Information

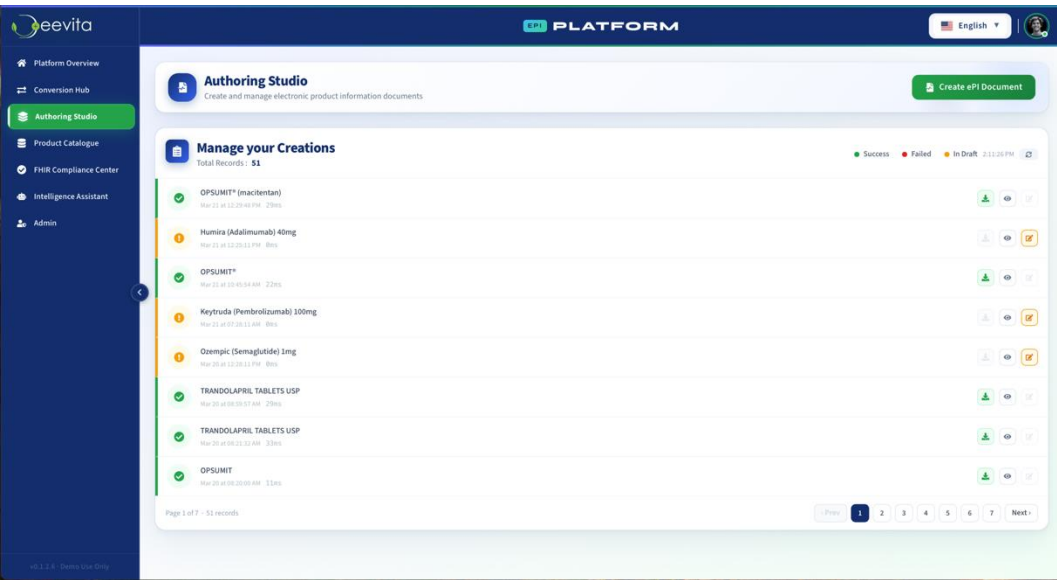
- Bundle contains 11 entries
- Bundle.meta.profile correctly declares the ePI R5 IG profile
- Composition resource present
- Product-identity resource present
- Ingredient resource(s) present
- ClinicalUseDefinition resource(s) present
- RegulatedAuthorization resource present
- FHIR Bundle resource structure is valid

No issues found. FHIR output is valid.

Rendered ePI View | AI Summary | AI Translator

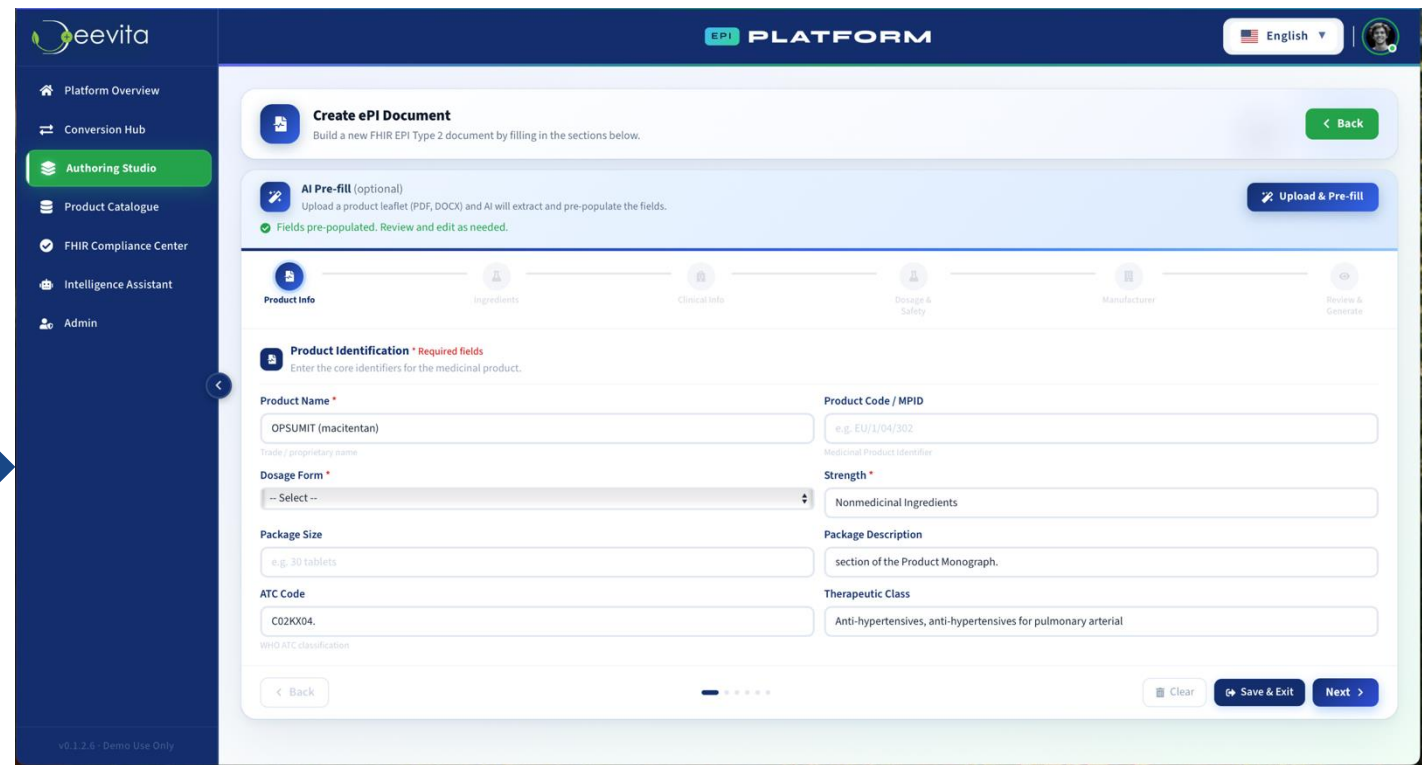
v6.1.2.6 - Demo Use Only

DEEVITA EPI Platform – EPI Authoring Studio



Manage all EPI creations in One Place

AI-Powered New ePI (FHIR) creation



DEEVITA EPI Platform – Patient Leaflet (from FHIR)

ERLEADA®
60 mg · Film-Coated Tablet · Bottle of 120

Last updated: **March 2025** Language: **English**

DOSAGE FORM Tablet | **MANUFACTURING STATUS** Approved | **NDC** 59148-0006-71

Overview | **Before Use** | Dosage | Side Effects | Storage & Ingredients

What you need to know before you take ERLEADA

Do NOT take ERLEADA

- If your doctor has told you not to take this medicine
- ERLEADA has not been studied in women or children and must not be used by them

Warnings and precautions — Talk to your doctor before taking ERLEADA if you:

- Have a history of falls or bone fractures
- Have heart problems, including ischemic heart disease
- Have had a stroke or mini stroke
- Are at risk of seizures
- Have lung problems or develop new or worsening breathing symptoms

Important safety information

- Falls and fractures may occur. Your doctor may assess your risk and recommend bone strengthening medicines.
- Heart related problems, including fatal events, have occurred. Your doctor will monitor heart health.
- Severe skin reactions (such as Stevens Johnson syndrome or DRESS) have been reported.
- Seizures are rare. ERLEADA must be permanently stopped if a seizure occurs.
- Interstitial lung disease (ILD) has been reported; treatment may be stopped if lung inflammation is suspected.

Seek medical help immediately if you experience:

- Chest pain
- Sudden weakness, speech difficulty, or loss of vision
- Severe skin rash, blistering, or peeling
- Breathing difficulty
- Seizure

v0.1.2.0 - Demo Use Only

Electronic Product Information — ERLEADA® (apalutamide) 240 mg · For full prescribing information consult your healthcare professional.

 Thank you !

EPI IG

<https://hl7.org/fhir/uv/emedicinal-product-info/>



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