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

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HL7 FHIR

CHALLENGES WITH DRUG LABEL

Key Challenges Today

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

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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

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ePI Maturity Model & Use Cases

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

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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

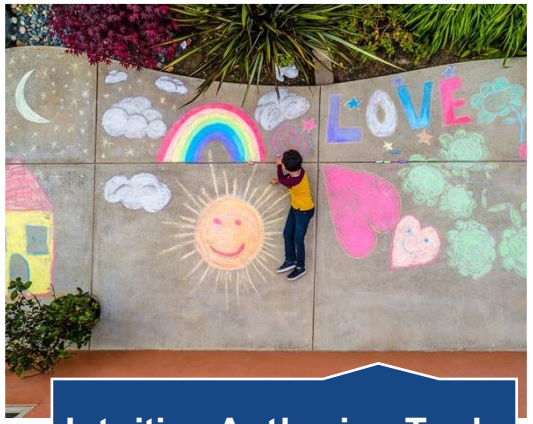
(Patent Pending)

AN EPI IMPLEMENTATION FROM DEEVITA

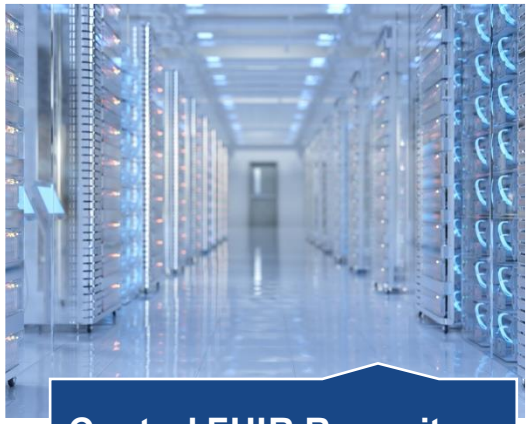
DEEVITA EPI System - Autonomous, Generative AI ePI Platform

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

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DEEVITA EPI System - Autonomous, Generative AI ePI Platform

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

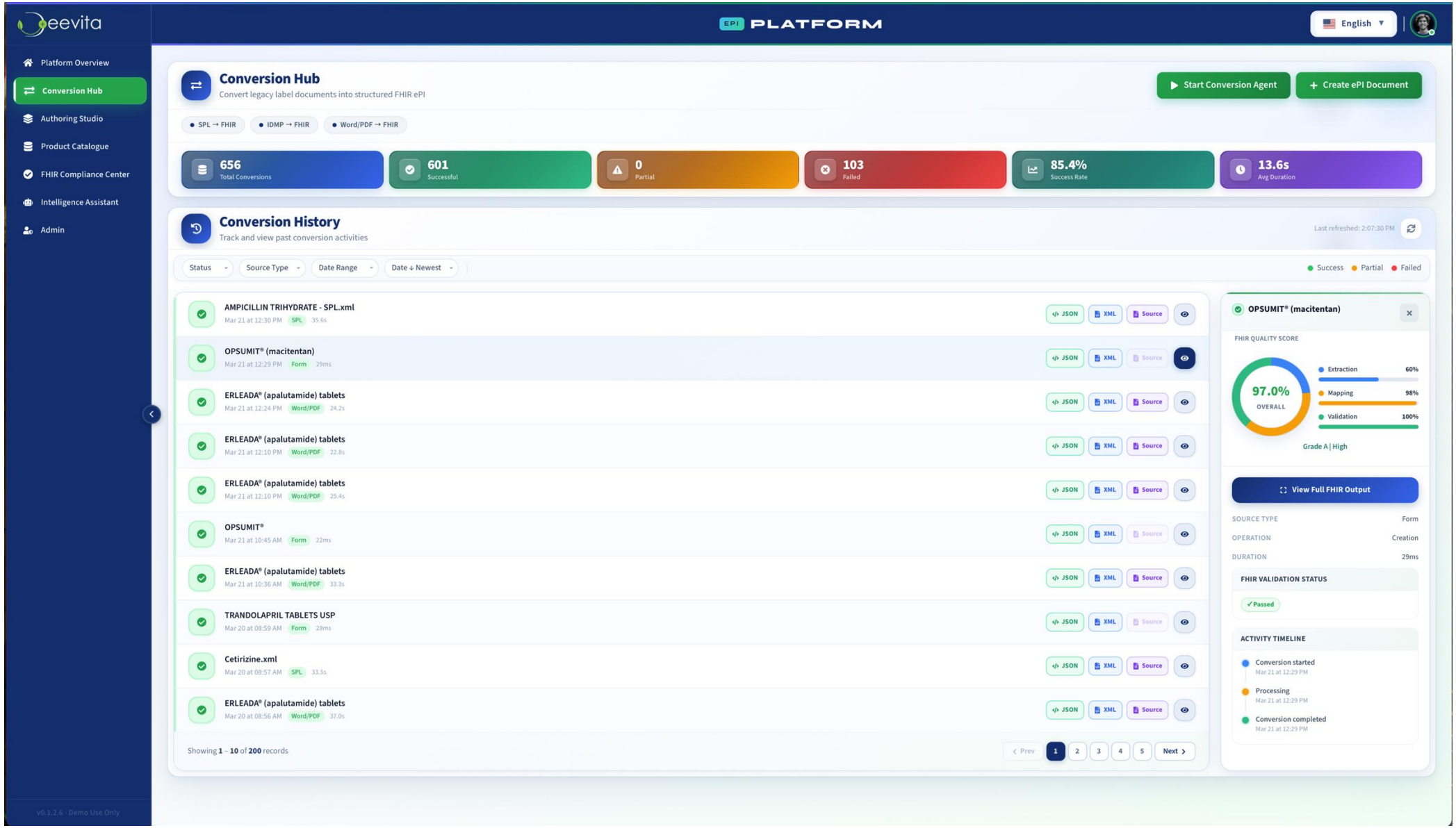
Instant information access

Interoperable & Scalable

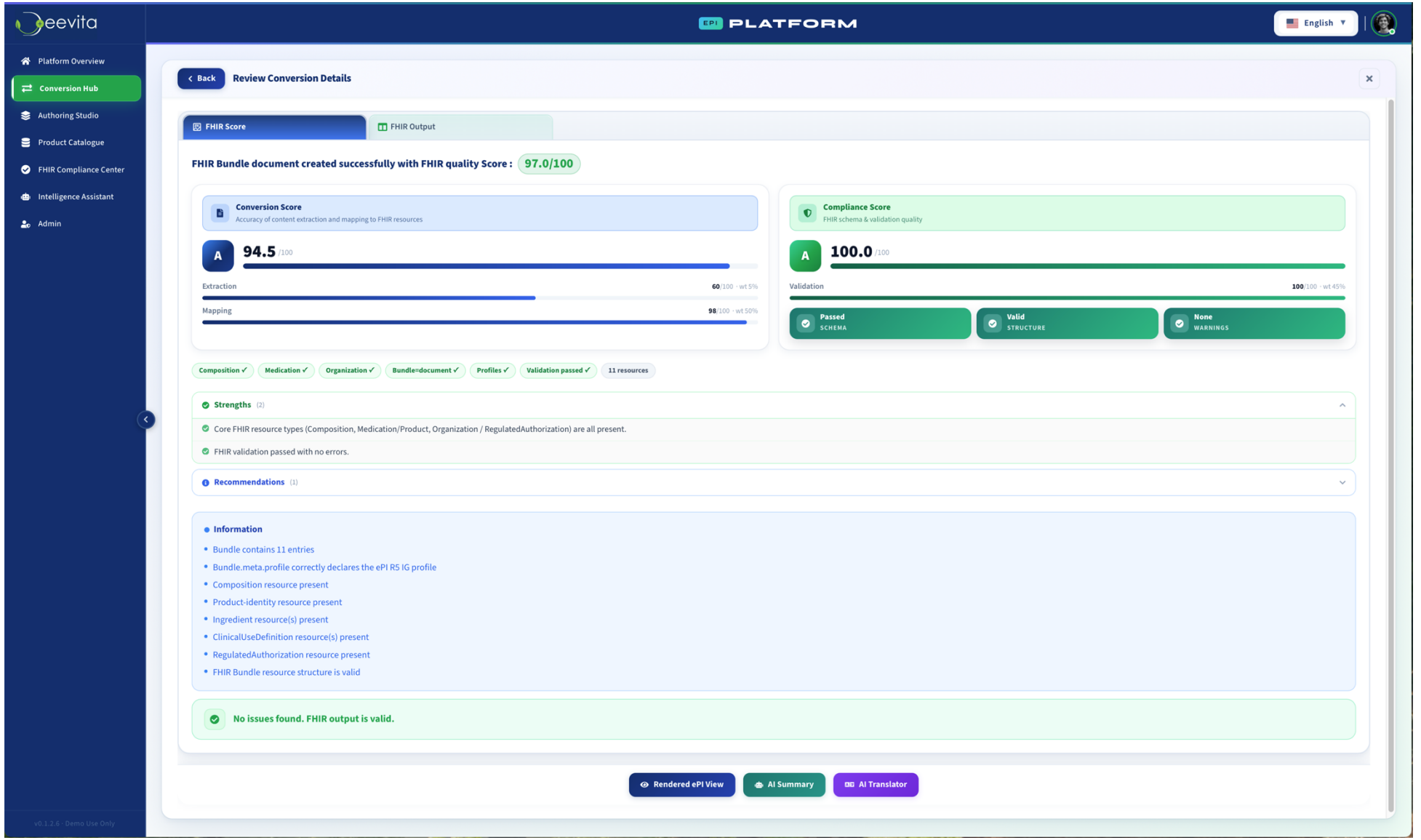
Seamless system integration

Faster, accurate, and interoperable product labeling.

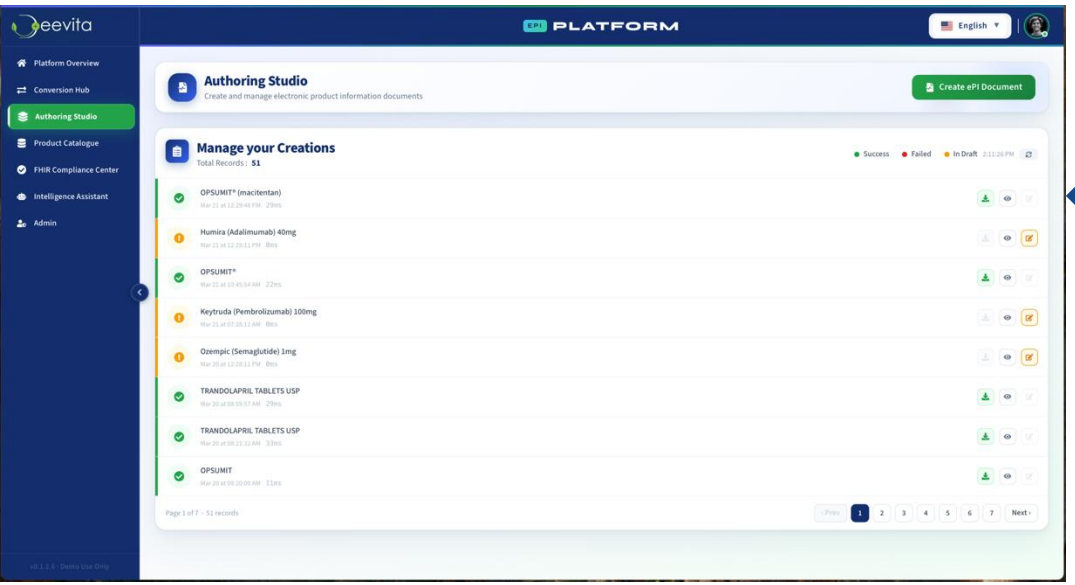
DEEVITA EPI Platform – Conversion Hub



DEEVITA EPI Platform – FHIR Quality Score

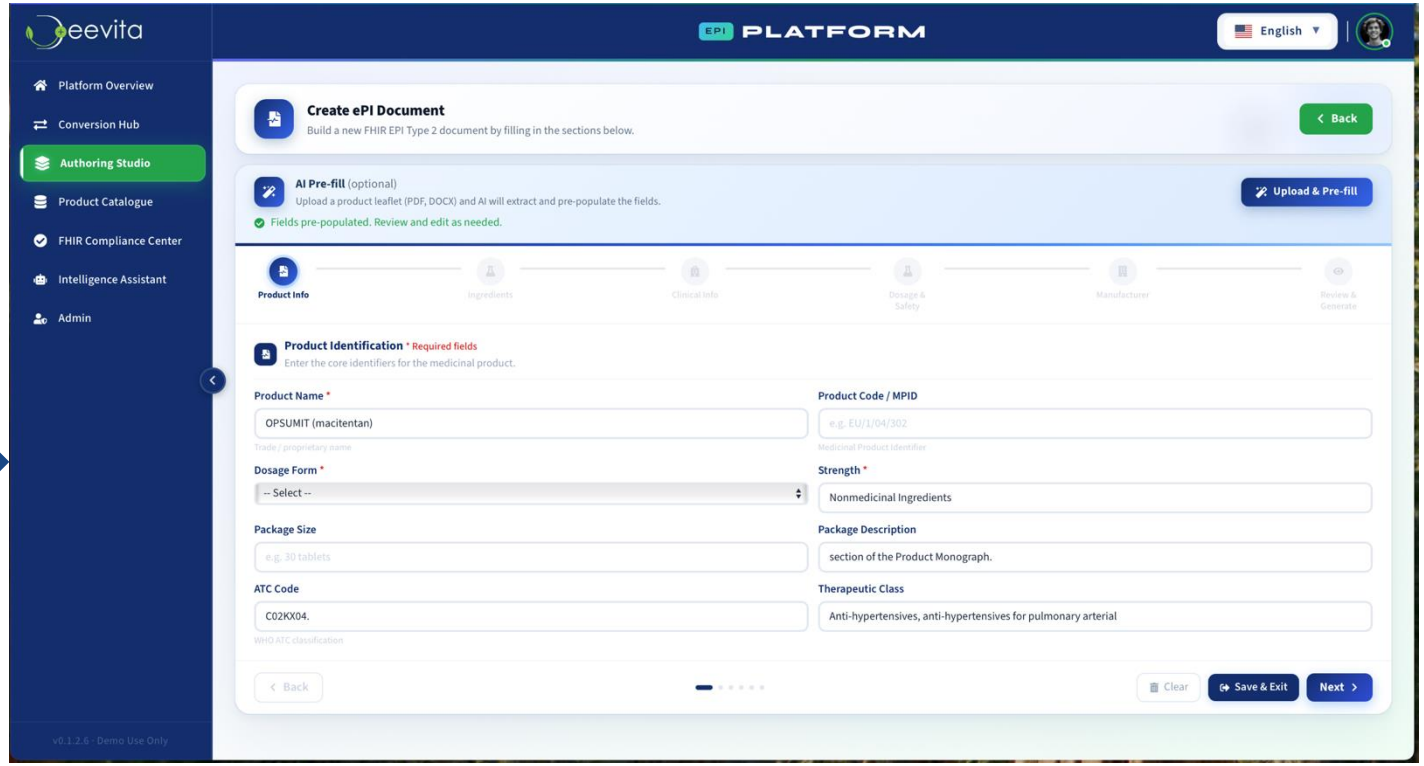


DEEVITA EPI Platform – EPI Authoring Studio



Manage all EPI creations in One Place

AI-Powered New ePI (FHIR) creation



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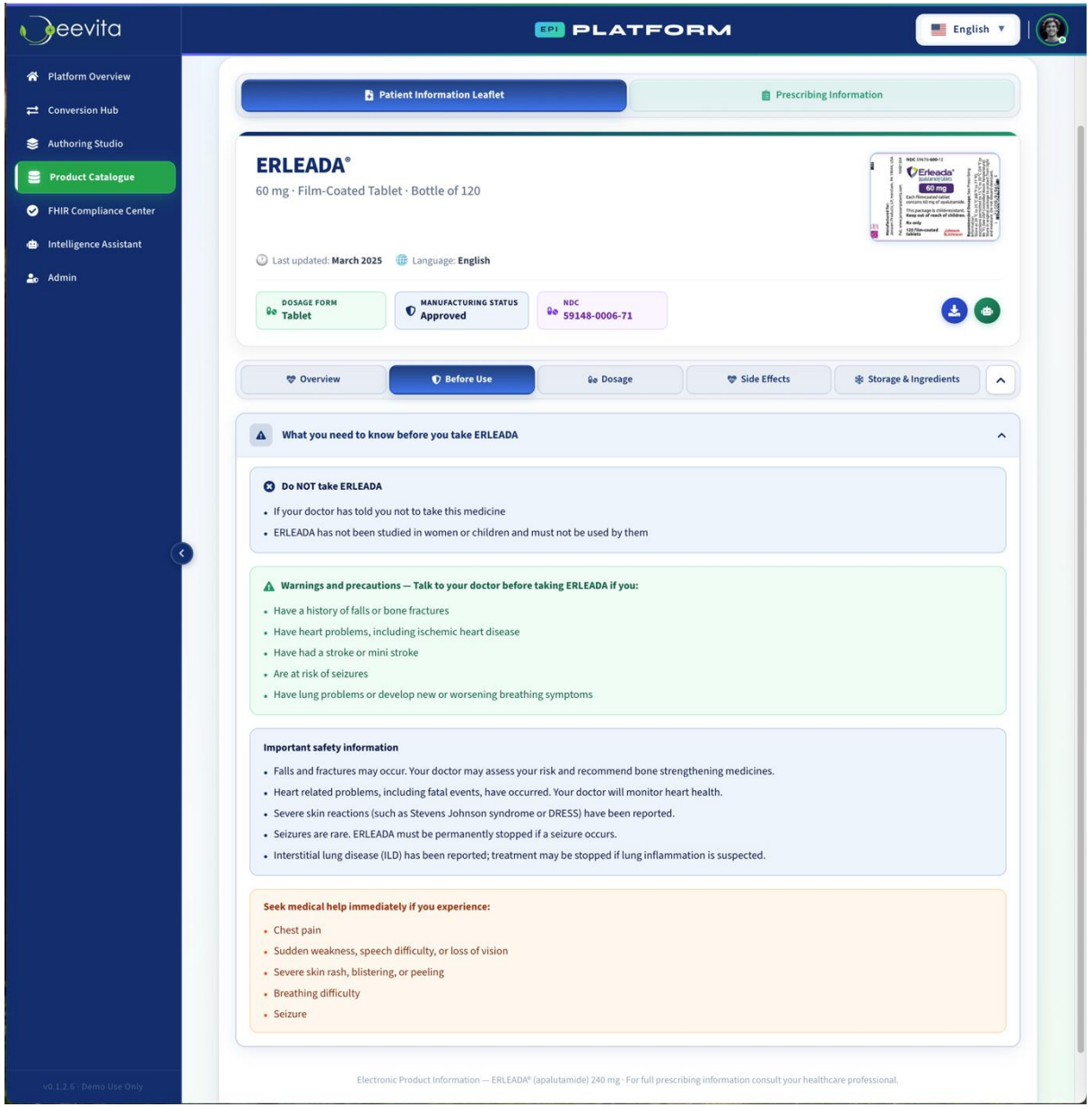
DEEVITA EPI Platform – Patient Leaflet (from FHIR)



Thank you !

EPI IG

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

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