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FHIR ePI 101:
A beginners guide to electronic labeling

What Is e-Labeling?

Global term for "electronic labeling"

Can refer to anything digital (PDFs, web pages, XML)

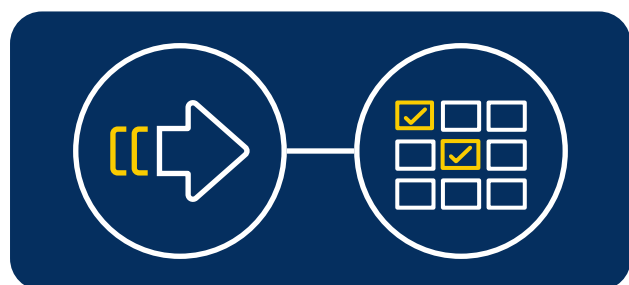A digital alternative to printed leaflets and paper labels

Think: product information available online, not in a box.

Glossary of terms

- **e-Labeling** – Any form of digital labeling (PDF or XML)

- **ePI** – Electronic Product Information (always structured, XML-based)

- **FHIR®** – Fast Healthcare Interoperability Resources

  - A global standard for structuring and exchanging health data (including ePI)

  - Uses XML and/or JSON

  - Developed by Health Level 7 (HL7)

  - Built for easy integration into digital health systems, apps, and platforms

XML e-Labeling Formats in Use

- **HL7 FHIR**

- **PharmaLedger™ ePI (PLA)**

- **GS1 XML**

- **DITA XML**

How do these initiatives work together?

- **e-Labeling** is the **umbrella term.**

- **ePI** is a type of structured eLabeling.

- **FHIR** is a **data format standard** used for ePI.

Structured vs. Unstructured e-Labeling

	Unstructured e-Labeling	Structured e-Labeling
Definition	Label content is presented as traditional documents (e.g., PDFs, Word files) without underlying data structure.	Label content is encoded in a standardized, machine-readable format (e.g., XML, HL7 SPL).
Purpose	Mainly intended for human reading, not easily usable by machines or automated systems.	Enables systems (like regulatory portals) to automatically search, validate, and reuse information.
Benefits or Drawbacks	Difficult to extract data for reuse, prone to manual errors, and harder to update consistently across systems.	Supports multilingual updates, improves patient safety, and reduces errors in submissions and product data management.

Side-by-Side Feature Comparison: Structured vs. Unstructured

	PDF eLabeling (Unstructured)	XML eLabeling (Structured)
Searchable	❌ Hard To Search	✔ Instantly Searchable
Updatable	❌ Manual Updates	✔ Updates In Real Time
Translatable	❌ Not Machine- Friendly	✔ Supports Auto-translation
Interoperable	❌ Low Interoperability	✔ Built For Digital Systems

Why e-Labeling is Becoming the Standard

Accessibility for
patients & professionals

Updatability
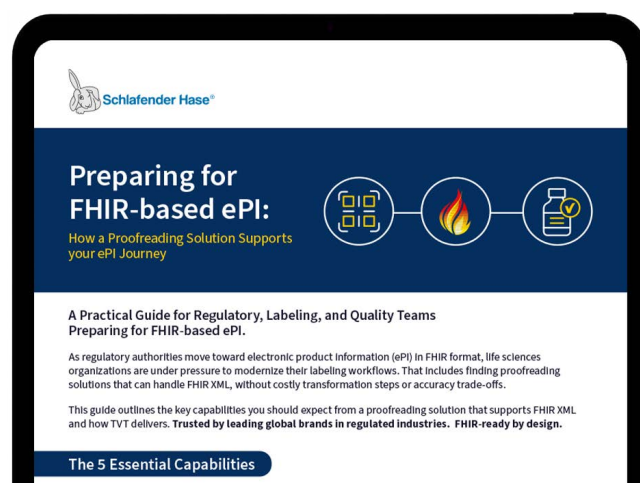in real time

Adaptability across
regions & languages

Environmental impact
reduces paper waste

The Future of Product Information: Global FHIR ePI Adoption Snapshot

Authority	Country/ Region	Status
EMA	EU	Pilot/ Implementation
MHRA	UK	Exploratory
HSA	Singapore	Pilot
TGA	Australia	Planning
FDA	USA	Exploratory
Health Canada	Canada	Early Evaluation

Start Your FHIR ePI Prep Today

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Preparing for FHIR-based ePI:
How a Proofreading Solution Supports your ePI Journey

A Practical Guide for Regulatory, Labeling, and Quality Teams Preparing for FHIR-based ePI.

As regulatory authorities move toward electronic product information (ePI) in FHIR format, life sciences organizations are under pressure to modernize their labeling workflows. That includes finding proofreading solutions that can handle FHIR XML, without costly transformation steps or accuracy trade-offs.

This guide outlines the key capabilities you should expect from a proofreading solution that supports FHIR XML and how TVT delivers. **Trusted by leading global brands in regulated industries. FHIR-ready by design.**

The 5 Essential Capabilities