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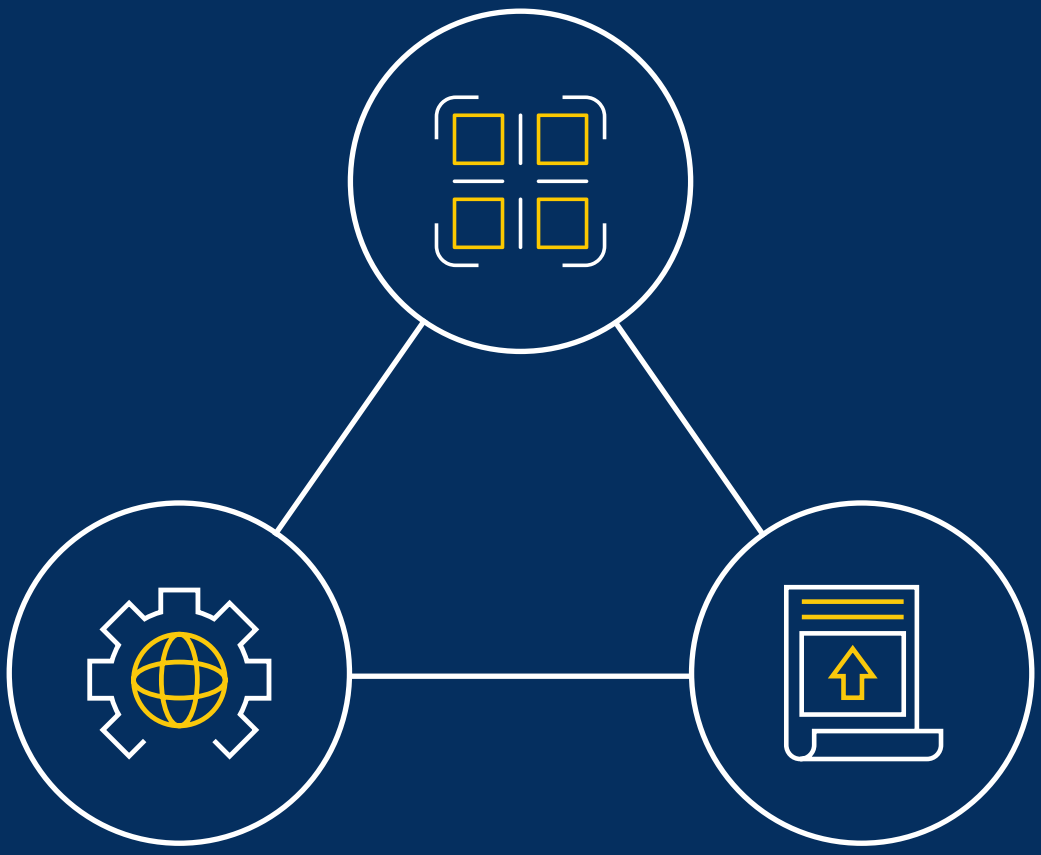
FHIR-Based ePI: A Practical Playbook for Regulatory and Labeling Teams



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Contents:

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

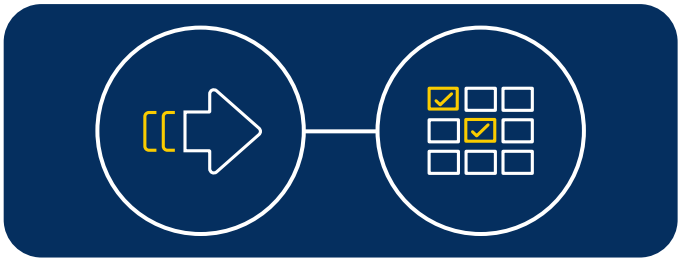
THINK: PRODUCT INFORMATION AVAILABLE ONLINE, NOT IN A BOX.

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

Challenge	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

The Impact of e-Labeling on Your Daily Work in Regulatory Affairs

The shift toward electronic labeling (e-labeling) and electronic Product Information (ePI) is no longer a distant future, it's happening now. For Regulatory Affairs teams, this transformation brings both questions and opportunities.

What Does This Mean for Regulatory Affairs Professionals?

Many professionals are asking the same practical questions about the impact of e-labeling on their workflows. Here's a breakdown of the most common concerns and what they really mean:

- **Will I have to change how I submit and manage labeling?** Yes, structured formats like XML and FHIR change how we handle, share, and submit product information.
- **Will this create more work for me?** Not necessarily, one of the biggest benefits of using structured content is that it becomes reusable and easier to maintain.
- **Will I need to learn new tools?** Possibly. But these tools are designed to automate time-consuming manual steps and improve accuracy.
- **What happens if I don't prepare now?** Delaying can mean costly, last-minute scrambles when structured labeling becomes mandatory in your region.

> It's about delivering the right content to the right people at the right time. That's where structured e-labeling adds real value.

How Daily Workflows Are Changing

The e-labeling transition is more than a technical update; it's a workflow shift. Let's look at how things used to work, and what's changing now.

BEFORE E-LABELING:

- Multiple versions of printed labels floating between departments
- Manual updates that were time-consuming and error-prone
- Long approval cycles and repeated proofing steps

WITH E-LABELING:

- A single structured source of truth across regions and teams
- Faster updates through modular content and automation
- Less back-and-forth between departments and reduced risk of inconsistencies

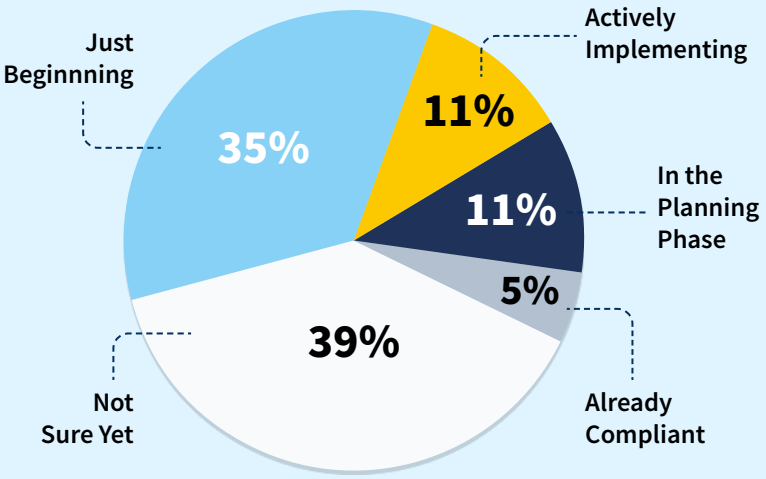
WE ASKED REGULATORY PROFESSIONALS:

Where does your organization currently stand in the e-labeling adoption process?

Data Breakdown:

- **39%** Not sure yet
- **35%** Just beginning
- **11%** Planning phase
- **11%** Actively implementing
- **5%** Already compliant

Only 5% are compliant - most are just starting out. You're not behind. But now is the time to act.



Results from 2025 RAPS Webinar on ePI

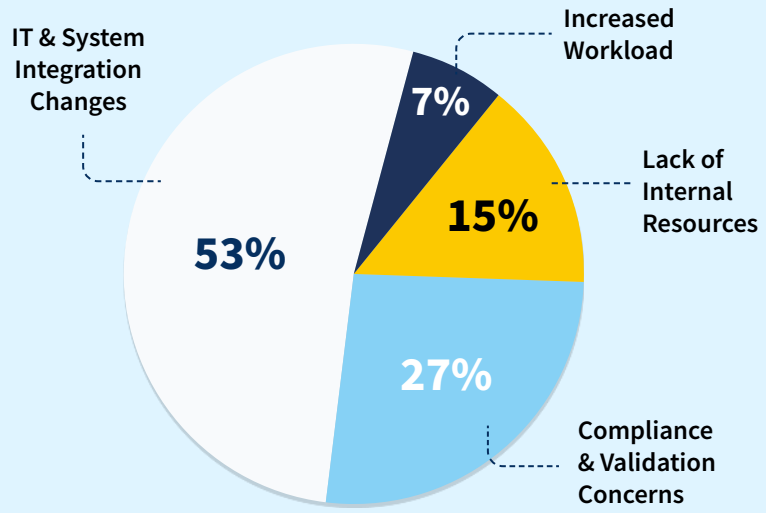
WE ASKED REGULATORY PROFESSIONALS:

What is your biggest perceived barrier to implementing e-labeling?

Data Breakdown:

- **53%** IT & Integration
- **27%** Compliance Concerns
- **15%** Internal Resources
- **7%** Increased Workload

Technology is the #1 concern - but it's also the most solvable with the right toolset.



Results from 2025 RAPS Webinar on ePI

Top Challenges Faced by Regulatory Affairs Teams

1. Version control nightmares

Outdated or conflicting documents create compliance risk. Structured formats reduce this by providing one up-to-date source.

2. Increasing submission complexity

With regional differences in e-labeling formats (e.g. FHIR vs. PharmaLedger ePI), global compliance is more demanding than ever.

3. New forms of collaboration

Structured labeling requires stronger coordination with IT, labeling, and data teams—not just Regulatory.

4. Unclear implementation timelines

Authorities like EMA, US FDA, and Jordan FDA are already supporting FHIR—but adoption timelines vary.

5. A change in how we think about labeling

We're no longer designing for paper. ePI may appear differently depending on the user's device, platform, or health system.

6. The silver linings

Structured e-labeling can actually support faster implementation of safety updates, regulatory variations, and cross-functional alignment.

Preparing for FHIR-based ePI:
How TVT Supports your ePI Journey

Getting e-labeling right means making sure your XML content is exactly what was approved.

No formatting tweaks, no manual comparisons, no room for error. That's where content verification steps in. But not just any tool will do. Here are 5 essential capabilities to look for in a solution that's built to handle structured content and strict compliance:

The 5 Essential Capabilities

1. NATIVE SUPPORT FOR FHIR XML

- Your Content Verification Solution should ingest and compare FHIR XML as-is.
- Avoid manual XML transformation or formatting hacks.
- **TVT Advantage:** Supports structured XML directly, preserving tags, hierarchy, and metadata. No workarounds needed.

2. HIGH-PRECISION COMPARISON AT SCALE

- FHIR documents contain nested structures and sensitive content (e.g., dosage, safety)
- You need detailed deviation detection at the character level.
- **TVT Advantage:** Detects even the tiniest deviation in complex structured layouts.

3. COMPLIANCE-DRIVEN DESIGN

- Accuracy alone isn't enough—it must align with regulatory expectations.
- FHIR-based labeling must meet strict standards for safety, efficacy, and traceability.
- **TVT Advantage:** Audit-ready out of the box - built for the world's most regulated teams.

4. ROLE-BASED, WORKFLOW-READY

- Regulatory Affairs and labeling teams need intuitive tools, not dev platforms.
- Proofreading should fit your current process, not force a new one.
- **TVT Advantage:** Built for non-technical users. Works with your existing labeling and regulatory workflows.

5. FUTURE-PROOF SCALABILITY

- FHIR is part of a broader digital shift—your solution must adapt.
- Think beyond today's needs: will it scale to multilingual content, medical device UDI, or evolving health data formats?
- **TVT Advantage:** One platform for every format, file, and future need.

How TVT Supports You

- ✓ Supports FHIR XML and other structured .xml content out-of-the-box
- ✓ Automatically compares structured content and tags
- ✓ Flags critical deviations, even across multilingual ePI
- ✓ Integrates with document, artwork and labeling systems
- ✓ Proven in pharma and med device labeling environments
- ✓ HTML compliance: Instantly run a comparison between the original approved file and the HTML version, including embedded image support for accurate online text and images
- ✓ Direct URL loading: Simply copy/paste the URL of the HTML version into TVT and compare the content on this page to the original approved copy.
- ✓ 1D and 2D Barcode hyperlink support: Open hyperlinks embedded in barcodes directly from within TVT to check the link is working and correct.

> Whether you're piloting an ePI project or preparing for full FHIR adoption, the right proofreading tool can make all the difference. TVT helps you get it right—first time, every time.

Your e-labeling Readiness Checklist

Here are the key steps Regulatory, Labeling, and Quality teams should take now to get ahead:

- [ ] Understand the basics of structured e-labeling formats: XML, FHIR, ePI
- [ ] Identify which regulatory bodies in your markets are mandating or piloting structured ePI
- [ ] Start internal conversations with IT and labeling teams
- [ ] Assess your current tools—can they handle structured data?
- [ ] Build out your strategy before it becomes a fire drill
- [ ] Test the tools you may need (XML editors, ePI validation platforms, automated proofreading tools like TVT) to ensure compatibility and scalability

> "FHIR makes content machine-readable and usable across many different platforms and applications. It's not just about labeling, it's about improving the flow of product information across the whole healthcare ecosystem."

MIKE BAIRD
Director of Product Management, Schlafender Hase

Final Thoughts

e-Labeling isn't just a regulatory requirement, it's an opportunity to modernize and future-proof your work. It may seem like a challenge at first, but with the right preparation, Regulatory Affairs teams can lead the shift to faster, smarter, and safer product information.

And the earlier you start, the smoother that shift will be.

Book a Demo With Our Team

Bonus Content! On-Demand Webinar:

The Future of Labeling is Already Here

REGULATORY AFFAIRS PROFESSIONALS SOCIETY

E-labeling is no longer a future concept. Regulatory authorities across the globe, including the EMA, FDA, and MHRA, are moving forward with digital product information initiatives. Structured ePI is fast becoming the new standard.

But what does this mean for your day-to-day work in Regulatory Affairs?

How will it affect your submission timelines, content workflows, or labeling reviews?

This playbook walks you through the shift to structured e-labeling using FHIR XML—from definitions to compliance best practices. And to help you get started, we've included insights from our on-demand webinar.

Gain practical guidance on what's changing and how to prepare:

- What's driving the global push to e-labeling
- How key markets (EU, US, UK) are progressing
- What to expect in your own labeling and submission workflows
- Real-world example: How Rote Liste supports structured ePI conversion

Watch the Webinar

Ready to Bunny-Proof Your FHIR ePI Process?

Book a Demo

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