

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



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.

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