
Case study #7

Automating safety reporting
in a large-scale patient support program

tepsivo

Collaboration overview

In 2025, we were asked to secure a high-volume, multi-vendor safety reporting for our large biosimilars client.

The customer required a compliant, efficient, and user-friendly solution to manage Adverse Event (AE) and Product Quality Complaint (PQC) reporting across its Patient Support Program (PSP).

Scale:

5

Products / Programs

Client:

LARGE

biosimilars company

Total budget:

€ 250K

per year

Delivery time:

4 weeks

1st production-ready
version

Key challenges

1

High user and report volume

Supporting a significant and growing user base including **hundreds of users**.

Initial estimate: weekly report volumes nearing **1,000 reports per week**.

Multi-vendor coordination

Integrating reporting from numerous PSP vendors, each requiring a streamlined and standardized process.

2

Canadian bilingual requirements

Ensuring full compliance and usability in both English / French, from data entry to final report generation.

3

Data integrity and compliance

Maintaining GxP-critical compliance, ensuring data accuracy in follow-up reports, and preventing post-submission edits.

4

Our solution

Tepsivo deployed a validated, GxP-critical application, replacing the generic safety form with a bespoke **"Adverse Event and Product Quality Complaint (AE & PQC) Report"** form tailored for the client's patient safety program. The solution focused on three core pillars.

Core pillar 1

automation

Architecture designed to remove any need for manual interventions.

Focus on data integrity and extra features (follow-up auto population, bilingual translation / localization).

Core pillar 2

user management

Scalable. Multi-vendor.
Easy-to-control.

Core pillar 3

compliance

Fully traceable, efficient reporting ecosystem ready for audits.

Client priority is rigorous access governance to ensure continuous adherence to GxP standards.

Pillar 1

Core Automation and Data Integrity

Automated reporting and tracking

No manual intervention:

The entire data sending process had to be fully automated, with no manual intervention required.

Primary transmission: Data and source documents were required to be sent automatically via XML if the Partner gateway was configured.

Fallback transmission: If the gateway was unavailable, the data and documents had to be sent via Email to a designated mailbox using a PDF form. The PDF form's format was kept consistent with the manual process.

API connection: Data entry via API connection was required and enabled.

Response handling: The platform supports auto-forwarding of partner response and automatic acknowledgement tracking.

Reconciliation: Reconciliation reports are automatically generated and sent to the data exchange partners.

Follow-up auto population

The system was enhanced to automatically populate key fields in follow-up reports. The final scope is auto-populated, yet modifiable according to the customer requirements.

Tepsivo Platform for PSP Safety Reporting supports full localization in French, with Automatic Translation.

The system automatically detects and translates French free-text entries to English (for processing), retaining the original French for review.

Bilingual translation and localization

Bilingual user interface:
Users can choose their preferred language.

Manual review workflow: A dedicated workflow allows Business Admin users to review and approve French translations, providing a human oversight mechanism and a possibility to improve the translations.

Pillar 2

Scalable User Management and Access Control

Designed for large user volumes

Tepsivo Platform for PSP Safety Reporting supports many external users across multiple organizations, with simplified onboarding via **Self-Registration** or **Admin-Added** process.

Delegated administration

Customer-defined roles, including **Reporter** and **Vendor Admin**, allow Vendor Admins to manage user accounts (add, edit, deactivate) within their respective organizations.

Pillar 3

Compliance Roster

Access to the safety reporting platform is governed by Tepsivo's formal IT process for **Security and Access Controls**.

Access Roster is continuously maintained within the application for GxP compliance.

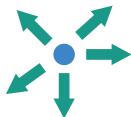
The outcome:

Streamlined, compliant and traceable reporting.

The Tepsivo solution provided the client with a single, controlled submission channel which delivers not only full compliance, but also significantly accelerates operations.

We summarize the most important implications on the next page 

Single source of truth



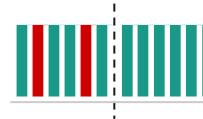
Replaced disparate forms and eliminated ambiguity over the primary record of submission.

Faster reporting process



Automated data transmission (XML / email / API) and follow-up population eliminate need for manual intervention.

Enhanced compliance



The AE & PQC record is locked after submission for PSP users (Reporter and Vendor Admin roles). This prevents accidental post-hoc edits and ensures complete data immutability for GxP compliance.

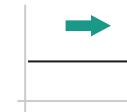
The safety reporting platform is delivered with a comprehensive, continuously updated validation package.

Full bilingual capability



Robust French-to-English translation capabilities and comfort of a fully French-localized user interface.

Continuous operation guarantee



A detailed Business Continuity Plan (BCP) was established to ensure manual workarounds for scenarios like system unavailability.

It's your turn now.

Contact us and we will establish a truly modern,
100% compliant safety reporting system for you too.

tepsivo

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