



## 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 Tapsivo'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



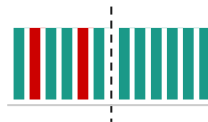
Replaced disparate forms and eliminated ambiguity over the primary record of submission.

### 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**

---

[www.tepsivo.com](https://www.tepsivo.com)

[contact@tepsivo.com](mailto:contact@tepsivo.com)

+358 402 204 698