PharmaSoft

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- DRUG SAFETY
- REGULATORY EXCELLENCE
- SMART TECHNOLOGY
- STRONG PARTNERSHIPS
- DATA DRIVEN INSIGHTS

Case Study #3

Evolving a Pharmacovigilance Partnership Through Changing Working Models

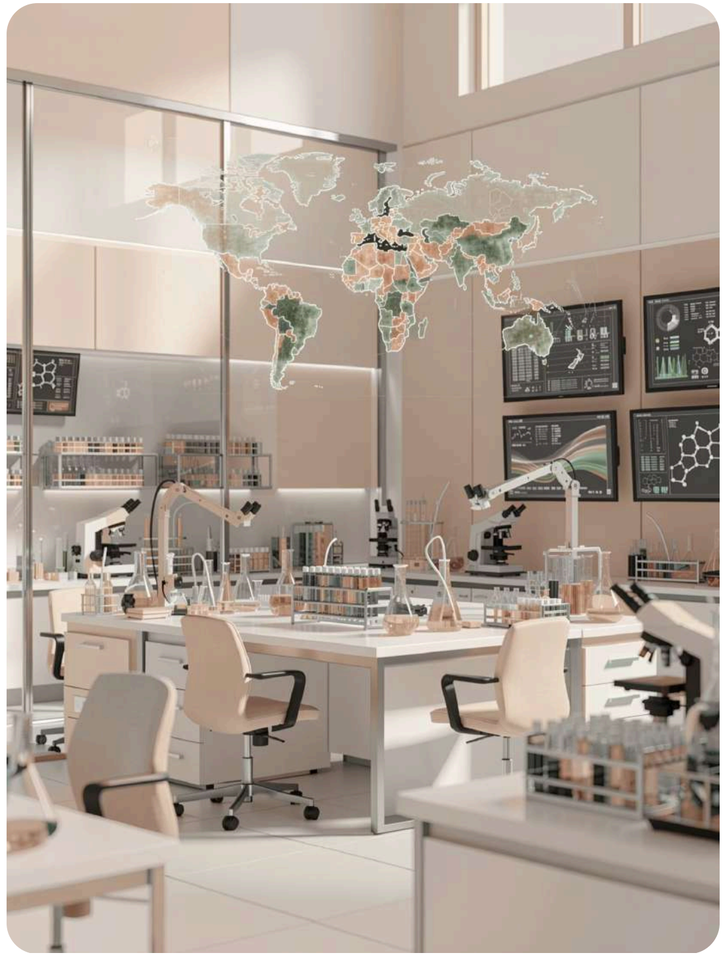
Smarter today, Safer tomorrow.

PharmaSoft

CASE STUDY | TÜRKIYE & INTERNATIONAL MARKETS | 2016 – PRESENT

Evolving a Pharmacovigilance Partnership Through Changing Working Models

How PharmaSoft delivered sustained pharmacovigilance continuity across multiple operating models. From external support to full departmental responsibility and back to a managed structure aligned with updated local regulations.



Client Context

The Foundation, The Shift & The Continuity

A pharmaceutical company with sustained pharmacovigilance requirements in Türkiye and ongoing obligations across multiple international export markets. The partnership with PharmaSoft has spanned over a decade and multiple structural transitions.

Early 2016

Partnership Began

External support model operated with PharmaSEARCH & PharmaBASE

2017

Full PV Department

PharmaSoft assumed responsibility as the client's pharmacovigilance department

2024

Model Restructured

Transitioned to a managed external support model in accordance with the updated local guideline

10+

Years of Continuity

Uninterrupted pharmacovigilance operations across all model transitions

The Challenge

External Support in a Complex Environment

The collaboration began in 2016 under an external support structure. At that stage, the client's QPPV and deputy QPPV roles were maintained internally, while PharmaSoft provided external pharmacovigilance services and database support through its own specialized platforms.

Operational Complexity

The client needed structured pharmacovigilance coverage in Türkiye while simultaneously managing compliance obligations tied to international export market activities.

The Platform Advantage

All services were delivered through **PharmaSEARCH** and **PharmaBASE**, PharmaSoft's own dedicated platforms, ensuring a structured and purpose-built environment from day one, rather than relying on generic infrastructure.

Phase 1 (2016)

External Support Model

The partnership launched as a structured external support arrangement. PharmaSoft provided full pharmacovigilance services while the client retained internal QPPV roles, establishing a solid operational foundation.

PHARMABASE

Dedicated pharmacovigilance database platform enabling structured case management, compliance tracking, and signal documentation from the outset of the partnership.

PharmaSEARCH

Literature monitoring and safety intelligence platform providing ongoing surveillance of the published scientific literature for relevant safety data.

Regulatory Compliance

Pharmacovigilance activities aligned with Türkiye local requirements, supporting the client's QPPV and deputy QPPV roles with expert operational backing.

International Scope

Support for pharmacovigilance obligations in export markets ensured compliance across multiple country-specific reporting requirements from the start.

Phase 2 (2017)

PharmaSoft as PV Department

As the collaboration deepened, the client required full operational ownership rather than supplementary support. In 2017, PharmaSoft assumed the role of the client's pharmacovigilance department, taking on end-to-end responsibility under a dedicated local service package.

Local PV Operations

Ongoing PV management in Türkiye, fully aligned with local regulatory expectations and authority requirements throughout the duration of the engagement.

Case & Compliance Support

Database-based individual case safety report (ICSR) management and compliance monitoring delivered through **PharmaBASE**, ensuring audit-ready records at all times.

Safety Intelligence

Continuous literature monitoring and emerging safety signal detection through **PharmaSEARCH**, supporting proactive risk management obligations.

International Reporting

Preparation of pharmacovigilance reports for multiple international markets, addressing country-specific formats and submission timelines for export market compliance.

Inspection & Audit Readiness

Sustained inspection-ready posture supporting the client through authority inspections in Türkiye and providing assistance during overseas audits and external audit processes.

Inspections & Audits

Supporting Inspections and Audits

Pharmacovigilance inspections and external audits demand thorough documentation, operational consistency, and expert readiness. PharmaSoft provided hands-on support throughout these high-stakes processes both locally and internationally.

Türkiye Authority Inspections

PharmaSoft supported the client through **successful authority inspections** conducted by Turkish regulatory authorities, ensuring documentation integrity, procedural compliance, and responsive engagement with inspectors throughout each assessment.

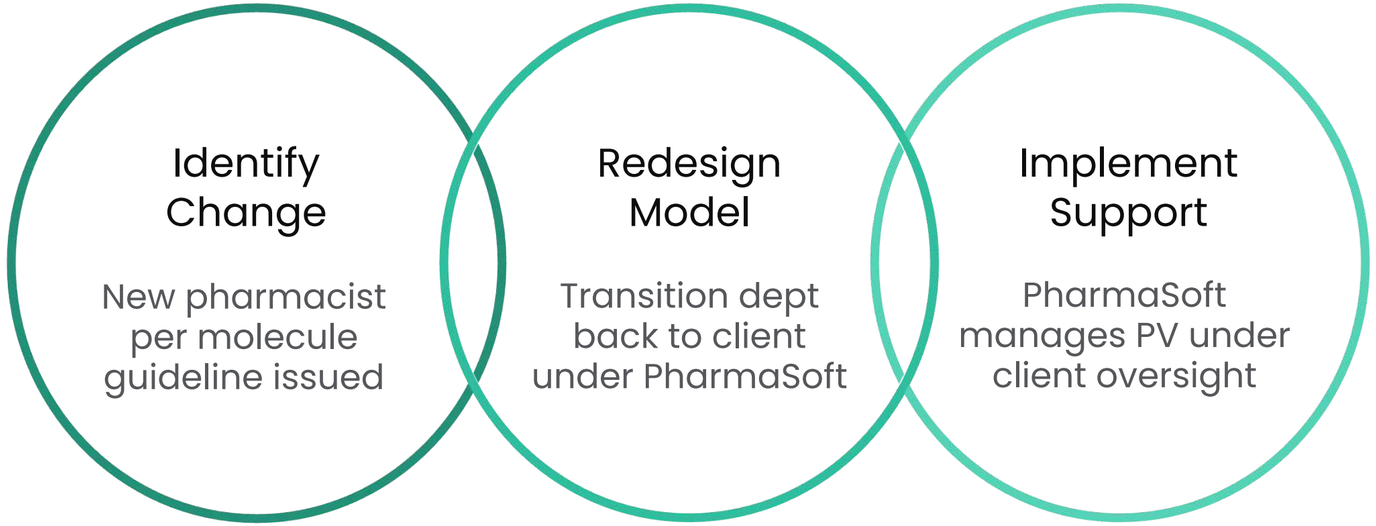
Overseas Audits & Inspections

Beyond Türkiye, the client's international footprint created audit exposure across export markets. PharmaSoft provided targeted support during these overseas inspection and audit processes, drawing on its experience with country-specific pharmacovigilance expectations and international reporting standards.

Regulatory Change

The 2024 Regulatory Change

A significant update to the local regulatory framework introduced a **pharmacist-per-molecule requirement**, fundamentally changing the structural requirements for pharmacovigilance organization in Türkiye. This required a deliberate and controlled adaptation of the existing operating model.



Rather than treating this as a disruption, PharmaSoft worked alongside the client to interpret the new requirements, redesign the operational structure, and execute the transition in a way that preserved continuity and maintained full compliance with the updated guideline.

Phase 3 (2024)

Managed External Support Model

Under the redesigned structure, the pharmacovigilance department was formally transitioned back into the client's internal organization, satisfying the new regulatory requirement, while the actual conduct of pharmacovigilance responsibilities continued to be carried out by PharmaSoft on the client's behalf and under the client's direct supervision.

Internal Department Structure

The client holds the formal pharmacovigilance department, fulfilling the pharmacist per molecule requirement under the new local guideline.

PharmaSoft Execution

Pharmacovigilance activities continue to be performed by PharmaSoft, preserving institutional knowledge, operational expertise, and process continuity without interruption.

Client Supervision

Oversight and strategic control remain with the client, ensuring accountability while benefiting from PharmaSoft's established pharmacovigilance infrastructure and experience.

Partnership Timeline

The **10+ year** collaboration has passed through three distinct operating models, each tailored to the client's evolving regulatory environment and business needs, with PharmaSoft ensuring continuity across every transition.

2016

External Support Model

PharmaSEARCH & PharmaBASE deployed. Client retains internal QPPV roles. Full external PV services initiated.

2017

Full PV Department

PharmaSoft becomes the client's pharmacovigilance department. Local service package active. International reporting begins.

2017–2024

Sustained Operations

Ongoing PV management, inspection support, international market reporting, and overseas audit assistance across multiple markets.

2024 - Present

Managed External Support

New local guideline triggers controlled restructuring. Department returns to client; PharmaSoft continues PV execution under client oversight.

Key Takeaway

One Partnership

A single, trusted pharmacovigilance partner serving the client across nearly a decade, removing the risk and cost of repeated transitions between service providers.

Multiple Operating Models

From external support, to full departmental responsibility, to a managed external structure, each model was designed around the client's regulatory and operational reality.

Sustained PV Continuity

Pharmacovigilance operations in Türkiye, international reporting, and inspection readiness were maintained without interruption through every structural transition.

Since 2016, PharmaSoft has supported this client through multiple pharmacovigilance operating models, from external support to full departmental responsibility and later to a managed external support structure aligned with updated local regulations, all while maintaining continuity across Türkiye operations, international reporting needs, and inspection readiness.

PharmaSoft

Complex processes need the right partner.

Let Us Take Care!

Pharmacovigilance | Regulatory Affairs | Digital Solutions

+90 216 326 77 12

info@pharmasoft.com.tr