Strategic Pharmacovigilance Enablement in Oncology Drug Development

AWINSA
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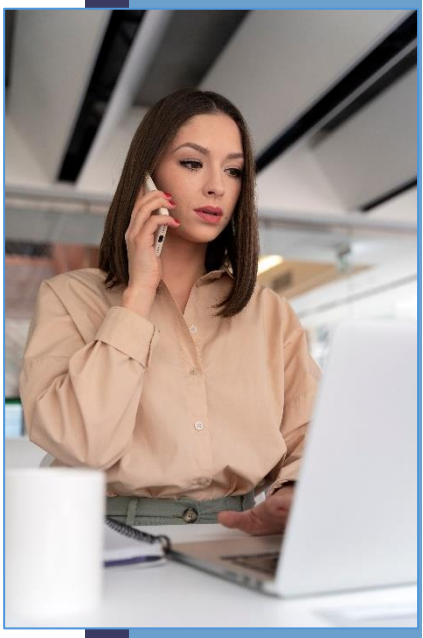
Background

The development and commercialization of oncology drugs present exceptionally complex pharmacovigilance (PV) challenges. Oncology products are often associated with serious and potentially life-threatening adverse events, requiring meticulous monitoring of patient safety data across diverse populations and multiple geographies. The involvement of multiple clinical research organizations (CROs), global regulatory submissions, and a broad indication landscape further compound these challenges.

A US-based pharmaceutical biotechnology company was developing a key oncology molecule targeting a specific mutation, with multiple clinical trials running simultaneously across different solid tumor indications. The same investigational product served as the foundation for each trial, but each indication was being pursued as a separate clinical program — with different CROs managing the respective studies. As the program expanded across more than 45 countries, the complexity of managing concurrent safety data streams, regulatory timelines, multi-CRO reconciliation, and harmonized signal detection grew substantially. This case study explores how AWINSA Life Sciences stepped in to consolidate and transform the company's pharmacovigilance operations, ensuring global regulatory compliance across all active programs.

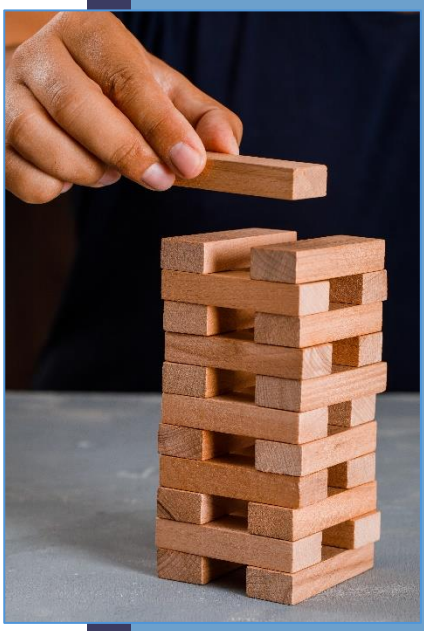
Business Challenge

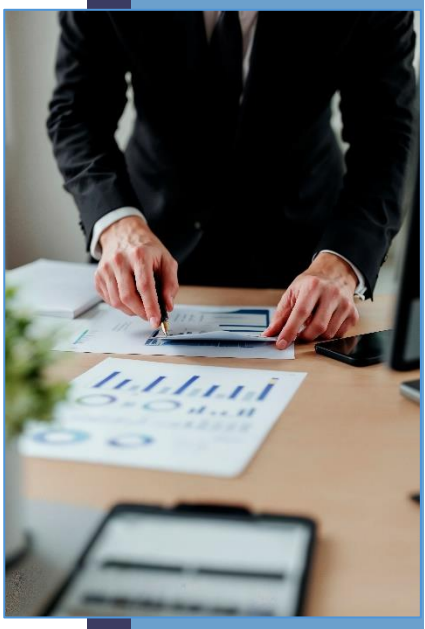
- The biotechnology company's rapid expansion across multiple geographies, combined with the complexity of running parallel clinical trials for multiple solid tumor indications using the same molecule, created an increasingly unmanageable pharmacovigilance workload. Different CROs were managing individual indication-specific trials, each with its own safety data flows and reporting obligations — while the underlying molecule and its initiation-phase work remained shared. The need to transition all PV activities from this fragmented multi-CRO model to a single, unified partner was both operationally critical and strategically urgent.



Key challenges included

- **CRO Consolidation and Transition:**
  - The company had multiple CROs simultaneously managing clinical trials for different oncology indications of the same molecule. Transitioning all pharmacovigilance activities from this distributed multi-CRO structure to a single partner required meticulous planning to preserve data integrity, avoid regulatory gaps, and harmonize differing processes across vendors.
- **High Volume and Backlog of Safety Cases:**
  - The concurrent clinical trial activity across multiple indications resulted in a significant backlog of individual case safety reports (ICSRs). Unprocessed and pending cases posed a direct risk to compliance timelines and the company's ability to meet regulatory submission deadlines.
- **Multi-Country Regulatory Submissions:**
  - With ongoing clinical trials spanning more than 45 countries across multiple indication programs, the company faced the daunting task of managing distinct regulatory requirements, submission formats, and timelines across multiple health authorities simultaneously.
- **Signal Detection Across Multiple Solid Tumor Indications:**
  - Running parallel trials in different oncology indications required robust signal detection and evaluation processes capable of identifying emerging safety trends across distinct patient populations and tumor types, each with its own risk profile.
- **Compliance Audit Readiness:**
  - Impending audits by regulatory authorities and business partners necessitated that all PV processes, SOPs, and documentation be current, complete, and inspection-ready at all times.
- **Business Partner Reconciliation:**
  - With multiple CROs involved across indication-specific programs, reconciliation of safety data was fragmented and inconsistent, leading to potential data gaps and reporting discrepancies across the portfolio.

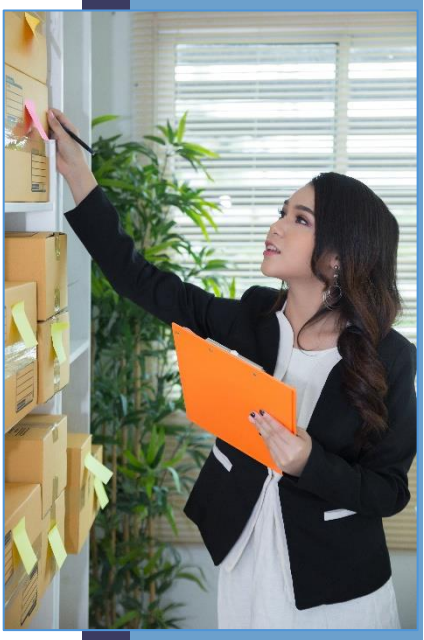




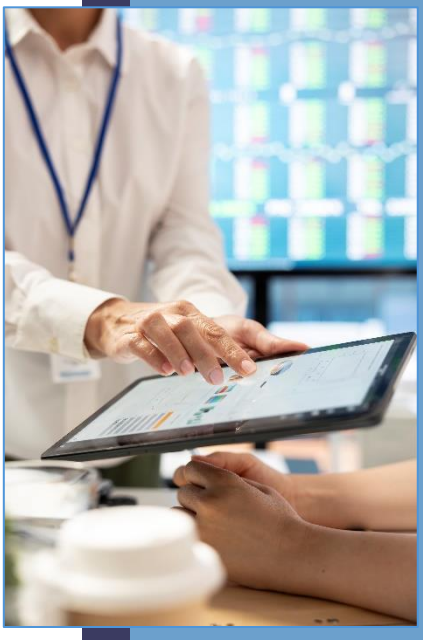
Business Solution

AWINSA Life Sciences was selected as the single, unified pharmacovigilance partner to replace the fragmented multi-CRO model. AWINSA developed a comprehensive, phased transition strategy designed to consolidate all ongoing PV activities under one roof, ensure continuity of operations, eliminate existing backlogs, and build a scalable, audit-ready PV infrastructure capable of supporting the company's ambitious global oncology growth plan.

- **Strategic PV Transition Planning:**
    - AWINSA conducted a thorough gap assessment across all incumbent CRO arrangements, mapping each indication-specific trial's safety data flows, ongoing case inventory, and regulatory submission status. A detailed transition roadmap was developed for each CRO handover, covering data migration protocols, system access, staff onboarding, and structured knowledge transfer. Clear milestones and escalation pathways were established to ensure seamless handovers without disruption to ongoing regulatory submissions.

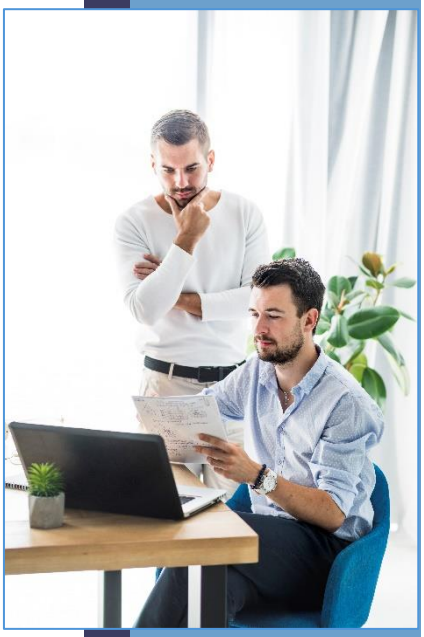


- **Structured Data Migration:**
    - AWINSA executed carefully planned migrations of all historical case data, ongoing ICSRs, and safety documentation from each of the predecessor CROs' systems. Data integrity checks and validation protocols were implemented at every stage to ensure accuracy and completeness. A dedicated reconciliation plan was established to identify and resolve discrepancies arising from different data standards across the outgoing CROs. Stakeholder Collaboration and Training:
- **Prioritized Case Management:**
    - Upon assuming consolidated responsibility, AWINSA implemented a case prioritization framework based on regulatory sensitivity, signal potential, and submission urgency across all active indication programs. Serious adverse events and cases approaching submission deadlines were triaged immediately. Over a two-and-a-half month period, the existing backlog of cases was systematically cleared while new incoming cases were processed within agreed service level agreements (SLAs).



- **Global Regulatory Submissions Management:**
    - AWINSA assumed ownership of regulatory submissions across more than 45 countries, covering all active clinical programs. A centralized submission tracker based on regulatory submission matrix was established to provide real-time visibility into submission status across all regions and indications. Submissions were aligned with local regulatory requirements, including those of the FDA, EMA, PMDA, and other national health authorities.
- **Signal Detection and Medical Review:**
    - A structured, indication-aware signal detection program was implemented to continuously monitor safety data from all clinical trials. Regular Quality and Medical review meetings were instituted to assess emerging signals, update the risk management framework, and ensure consistent medical interpretation of safety data across the solid tumor indications being studied.

- **Compliance and SOP Optimization:**
    - AWINSA's subject matter experts conducted a comprehensive review and revision of all existing Standard Operating Procedures (SOPs), work instructions, and data entry manuals. Documentation was harmonized across programs and updated to reflect current regulatory guidance and internal best practices, significantly enhancing audit readiness. A continuous process improvement framework was established to adapt processes to changing regulatory requirements.
- **Business Partner Reconciliation:**
    - Comprehensive reconciliation plans were developed and implemented with all outgoing clinical CROs and remaining business partners to align safety data, resolve discrepancies, and ensure consistent ICSR reporting. Safety Data Exchange Agreements (SDEAs) were reviewed, updated, and operationalized with each partner to clearly define roles, responsibilities, and reporting timelines.



Results

AWINSA's strategic and systematic approach enabled the biotechnology company to achieve full regulatory compliance, restore operational efficiency, and build a robust PV infrastructure capable of supporting its expanding global oncology portfolio across all active indication programs. Key outcomes included:

- **Successful Multi-CRO Consolidation:**
    - All pharmacovigilance activities were seamlessly consolidated from multiple incumbent CROs to AWINSA, with no loss of data integrity and no regulatory submission gaps during any handover. The structured data migrations ensured continuity of safety monitoring across all active indication programs throughout.
- **Elimination of Case Backlogs:**
    - The backlog of ICSRs across all programs was fully cleared within the planned transition timeframe. A real-time case management dashboard provided complete visibility over case volumes, processing status, and submission timelines, ensuring no further accumulation of backlogged cases.
- **Global Regulatory Compliance Achieved:**
    - All pending and ongoing regulatory submissions across more than 45 countries were brought into compliance. The company received no regulatory non-compliance notices following the transition, reflecting the effectiveness of AWINSA's submission management approach.
- **Streamlined Processes and Reduced Cycle Times:**
    - The implementation of optimized workflows, automation tools, and advanced PV technology significantly reduced case processing cycle times. Efficiency gains allowed the team to handle increased volumes without a proportional increase in resources.

- **Enhanced Signal Monitoring Across Indications:**
    - The structured, indication-aware signal detection program enabled early identification and evaluation of safety trends across all active solid tumor programs, supporting informed benefit-risk decision-making and proactive regulatory communication.
- **Audit-Ready Documentation:**
    - Revised SOPs, updated work instructions, and comprehensive audit trails ensured that the company was fully prepared for regulatory inspections and internal audits. This documentation framework instilled confidence among the company's leadership and regulatory stakeholders.
- **Scalable Capacity for Future Growth:**
    - With AWINSA's scalable resource model in place, the company was well-positioned to expand its clinical program, pursue new Marketing Authorization Holder (MAH) approvals in additional territories, and continue development across multiple oncology indications.
- **Robust Safety Profiles:**
    - Facilitated early identification of safety signals, ensuring proactive risk management

Conslusion

This partnership underscores AWINSA's capability to manage complex, multi-CRO pharmacovigilance consolidations in oncology — from distributed multi-vendor transitions and data migrations to global regulatory submissions and cross-indication signal management. The biotechnology company can now confidently advance its oncology pipeline, supported by a reliable, scalable, and compliance-driven pharmacovigilance partner.

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