# Case Study

## Literature Surveillance


**UMSai LLC**

Unique Medium for Solutions and Innovations

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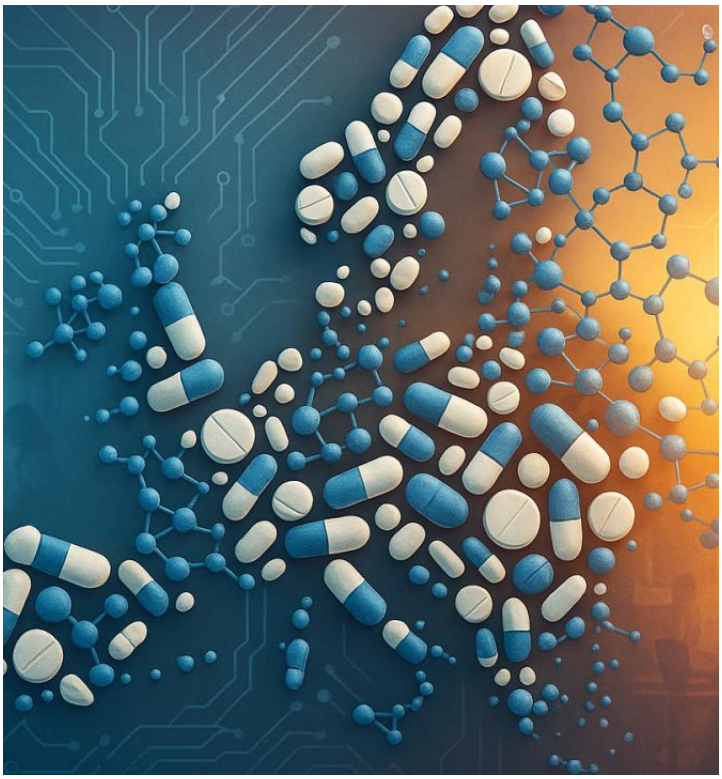
# Client Profile

*A global, research-driven pharmaceutical organization with a strong oncology portfolio required comprehensive post-marketing literature surveillance to support ongoing pharmacovigilance obligations for multiple marketed oncology therapies.*



# Business Challenge

## Marketed oncology products with unique challenges:

- High publication volume across global journals, congress abstracts, and real-world evidence sources
- Complex safety profiles, including serious and medically significant adverse events
- Regulatory expectations for robust, traceable literature surveillance and documentation
- The need to distinguish valid ICSRs from general safety signals, review articles, or non-reportable content

## Require a scalable and audit-ready process

- Comprehensive coverage of major biomedical databases
- Accurate and consistent triage of literature articles within the provded timeline.
- End-to-end traceability from literature identification through case processing decision
- Full compliance with Good Pharmacovigilance Practices (GVP) and global regulatory standards

# Solution

## Literature Surveillance

Conducted systematic and recurring searches using predefined, validated search strategies across:

- PubMed
- Embase
- MEDLINE

Searches were:

- Tailored to marketed oncology products and associated safety concepts,
- Ensuring sensitivity while minimizing noise.

## Screening and Triage

Retrieved articles were screened for:

- Presence of an identifiable patient
- Identifiable reporter
- Suspected oncology medicinal product
- Described adverse event or clinical outcome

Articles were categorized as:

- Valid ICSR
- Non-case safety information
- Not reportable / excluded with justification

## Safety System Integration

All literature receipts, including non-reportable records,

- Archived in a validated electronic safety exchange platform
- Maintained a complete audit trail.

For articles meeting ICSR validity criteria:

- Safety data were escalated and electronically routed for case processing.
- Documentation supported traceability from source identification through processing decision.

## Quality and Compliance Controls

Consistent application of triage criteria ensured alignment with:

- ICH E2A / E2D principles
- Global post-marketing pharmacovigilance requirements.

Decisions were documented clearly to support

- Inspection readiness
- Internal quality review.
- Regulatory body audits

# Outcome

The engagement delivered measurable improvements in the client's post-marketing safety operations:

- **Regulatory-compliant literature surveillance across multiple global databases**
- **Timely identification and processing of valid ICSRs related to marketed oncology therapies**
- **Enhanced traceability and audit readiness, with complete archival of all literature receipts**
- **Reduced operational burden on internal safety teams through standardized triage and escalation workflows**
- **Strengthened confidence in the client's ability to demonstrate compliance during health authority inspections**

*Overall, the project supported proactive patient safety monitoring while maintaining efficiency, consistency, and regulatory robustness within a high-complexity oncology pharmacovigilance environment*

# Contact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