

# Case Study

## Signal Management



# UMSai LLC

Unique Medium for Solutions  
and Innovations

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# Client Profile

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*A US-based biotechnology company with a diversified early-stage clinical portfolio spanning oncology, autoimmune disorders, and additional therapeutic areas was actively conducting multiple Phase I trials. As pipeline activity accelerated, pharmacovigilance activities were being executed at the program level without a centralized governance structure, standardized operating procedures, or a formalized signal management framework.*

*Recognizing the increasing regulatory expectations associated with a growing and multi-asset portfolio, the organization required the establishment of a centralized, scalable, and inspection-ready pharmacovigilance infrastructure. The objective was to implement a compliant, harmonized safety framework that would ensure consistent oversight across programs while supporting sustainable growth and future clinical advancement.*

# Business Challenge

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Absence of a formally established system and documented, standardized operating procedures.

No structured signal management framework or defined safety governance model to support proactive risk identification and escalation.

Lack of a formal Safety Management Team (SMT) structure or recurring safety review forums to ensure consistent oversight.

Fragmented and program-specific safety data review processes, creating inconsistency in decision-making and documentation.

# Solution



## SOP and Process Development

Authored and implemented core PV procedures, including:

- Signal Detection and Management
- Safety Data Review and Medical Monitoring Interface
- Aggregate Safety Reporting (DSUR)
- Safety Issue Escalation and Communication
- Cross-functional Safety Governance and Meeting Management
- Literature and External Safety Surveillance (as applicable)

All procedures were designed to be **scalable for future Phase II/III expansion.**

## PV System Design and Governance

- Designed and implemented a **fit-for-purpose PV operating model** aligned with ICH E2A, E2F, E2E, and GVP expectations
- Developed key governance documents:
  - ❖ Safety Management Team (SMT) Charter
  - ❖ Signal Review / Safety Review Charter
  - ❖ Roles and Responsibilities (RACI) across Clinical, Medical, Regulatory, and PV
- Established a **risk-based escalation pathway** for emerging safety issues and potential signals

# Solution



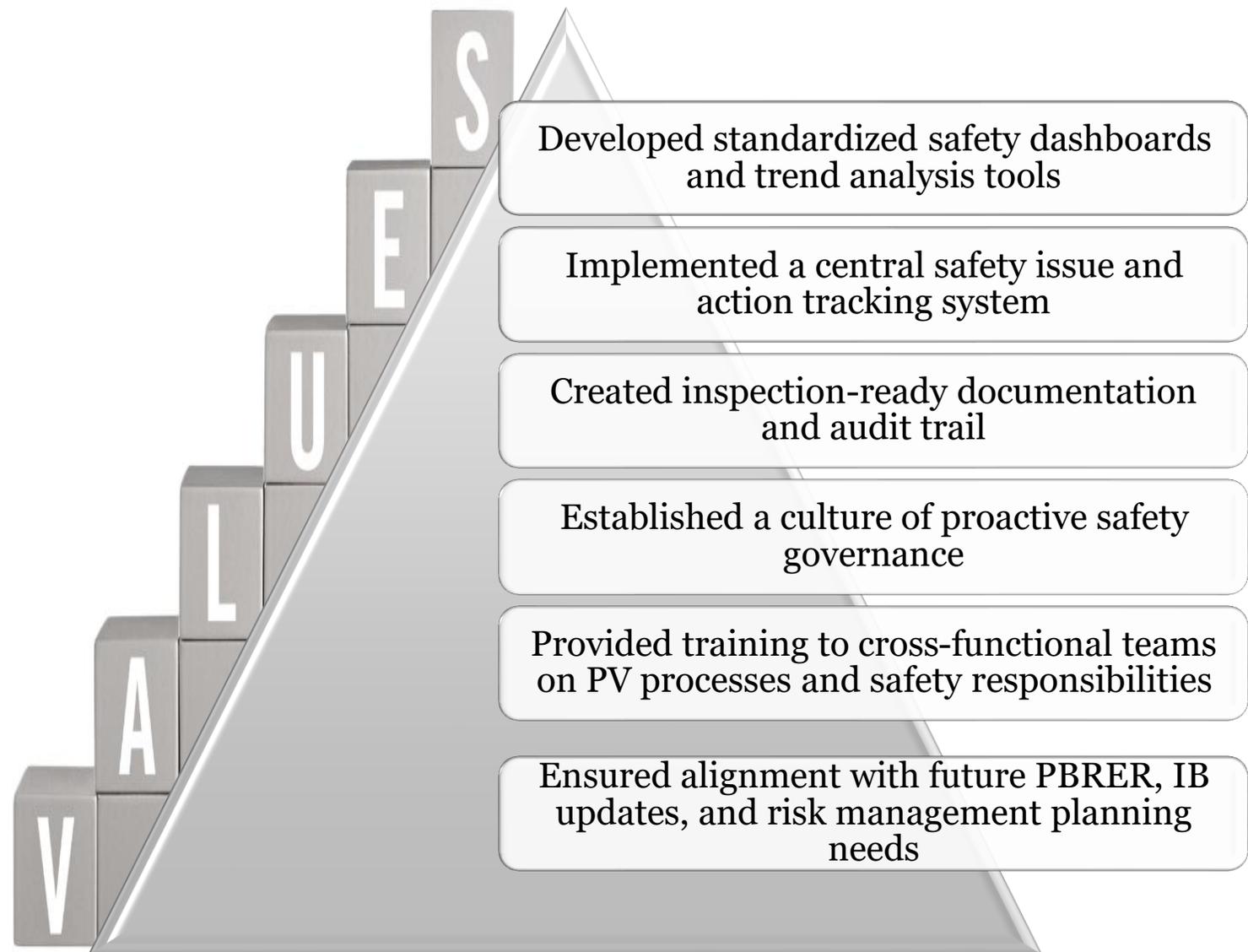
## Signal Management Framework

- Established structured **signal detection and evaluation processes** using:
  - ❖ Clinical trial SAE trend analysis
  - ❖ Case series review
  - ❖ Medical and scientific evaluation
- Developed:
  - ❖ Signal tracking log
  - ❖ Validation and prioritization criteria
  - ❖ Documentation templates for signal evaluation
- Enabled proactive identification and discussion of emerging safety trends.

## Safety Management Team (SMT) Structure

- Designed the **Safety Management Team meeting framework**, including:
  - ❖ Meeting frequency and agenda structure
  - ❖ Standardized safety data review packages (line listings, trends, summaries)
  - ❖ Signal and risk discussion workflows
  - ❖ Decision documentation and action tracking
- Facilitated cross-functional collaboration among:
  - ❖ Clinical Development
  - ❖ Medical Monitoring
  - ❖ Regulatory Affairs
  - ❖ Biostatistics (as needed)

# Additional Value



**Engagement Type:** *PV System Setup & Scientific Leadership*  
**Therapeutic Area:** *Early Clinical Development (Phase I)*

# Outcome

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**Successfully implemented a compliant and scalable PV system for early clinical development**



**Enabled structured signal detection and risk oversight**



**Improved cross-functional transparency and decision-making**



**Reduced regulatory and inspection risk**



**Positioned the organization for seamless transition into later-phase development**

# Contact

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