

## CASE STUDY

# Precision Pharmacovigilance

## in Primary Membranous Nephropathy (PMN)

End-to-End Safety Oversight for a Global Phase 3 Clinical Programme



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### Introduction

Primary Membranous Nephropathy (PMN) is a rare autoimmune kidney disease and one of the leading causes of nephrotic syndrome in adults. The disease is characterised by immune mediated injury to the glomerular filtration barrier, resulting in significant proteinuria, hypoalbuminaemia, oedema, and, in some patients, progressive decline in renal function. For clinical development programmes in PMN, pharmacovigilance presents unique challenges. Manifestations of the underlying disease often overlap with potential treatment emergent adverse events, making accurate safety assessment particularly complex. Distinguishing disease progression from drug related safety signals requires a combination of therapeutic expertise, rigorous medical review, and robust operational processes.

A biopharmaceutical company conducting a global Phase 3 clinical programme in adult PMN patients required a pharmacovigilance partner capable of delivering comprehensive safety oversight across multiple countries. The programme involved extensive clinical and laboratory safety monitoring, complex regulatory reporting requirements, and the need for continuous evaluation of renal safety outcomes throughout the study lifecycle.

## Business Challenge

- The programme presented several interconnected pharmacovigilance challenges.
- First, the underlying disease itself created substantial complexity for safety evaluation. Changes in renal function, fluctuations in disease activity, and associated clinical events required careful medical assessment to differentiate disease related findings from potential treatment related adverse reactions.
- Second, the global nature of the study required coordinated safety management across multiple countries, investigators, and stakeholders while maintaining consistent regulatory compliance and data quality standards.
- Third, the large volume of clinical and laboratory safety information generated throughout the programme demanded robust processes for data review, reconciliation, and reporting to ensure the integrity of the overall safety dataset.
- The sponsor required a pharmacovigilance partner capable of integrating therapeutic expertise, operational excellence, and global regulatory oversight within a single safety framework.



## Business Solution

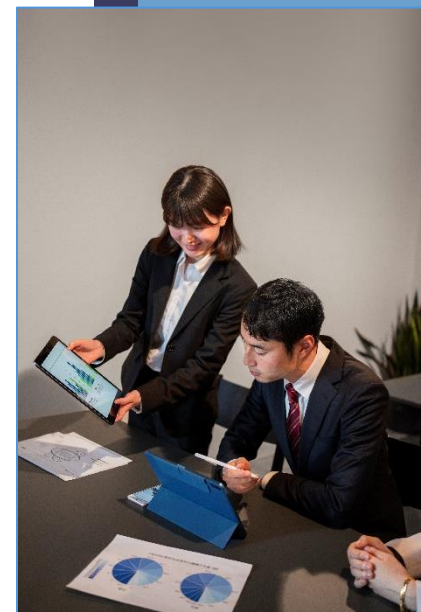
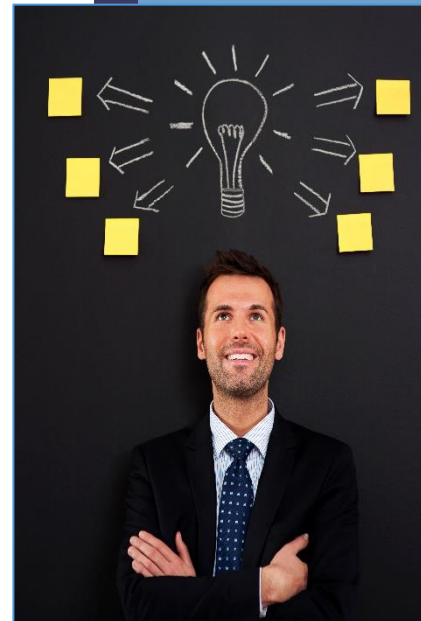
- AWINSA was selected as the dedicated pharmacovigilance partner for the programme, providing end to end safety support through a centralised governance model. A tailored pharmacovigilance framework was developed to address the specific needs of a complex renal disease study while ensuring compliance across all participating regions.

### 1. Integrated Safety Monitoring:

- Dedicated safety physicians provided ongoing medical review and assessment of adverse events and serious adverse events throughout the programme. Clinical evaluations incorporated review of renal function trends, laboratory findings, and disease activity indicators to support accurate interpretation of safety events.
- Longitudinal assessment of patient level data enabled differentiation between disease progression and potential treatment emergent safety signals, ensuring appropriate characterisation of the investigational product's safety profile.
- A real time safety oversight framework supported continuous monitoring of case volumes, reporting metrics, and emerging safety trends across participating sites.

### 2. End to End Case Processing and Regulatory Reporting:

- AWINSA managed the complete adverse event lifecycle, including case intake, medical review, MedDRA coding, quality control, database management, follow up activities, and expedited reporting.
- A structured follow up process ensured timely collection of outstanding clinical information, laboratory results, and outcome data, supporting the completeness and accuracy of the safety database.



- Periodic aggregate safety reports were authored and managed in accordance with applicable regulatory requirements throughout the duration of the programme.

### 3. Global Regulatory Compliance Management:

- A centralised regulatory tracking system was implemented to manage reporting obligations across participating countries. Automated workflows and compliance monitoring ensured timely submission of all expedited and periodic safety reports.
- Health authority and sponsor safety queries were addressed through scientifically robust and evidence based responses, supporting ongoing regulatory interactions and programme milestones.

### 4. Safety Data Quality and Reconciliation:

- Given the extensive volume of clinical and laboratory information generated during the programme, AWINSA established a comprehensive data quality framework to support consistency, traceability, and accuracy.
- Routine reconciliation activities were conducted between safety, clinical, and laboratory datasets to ensure alignment of critical safety information and readiness for regulatory review.
- Standardised processes and oversight mechanisms helped maintain data integrity throughout the study lifecycle.

### 5. Signal Detection and Aggregate Safety Review:

- AWINSA implemented a structured signal management process incorporating medical review, trend analysis, cumulative safety assessment, and periodic evaluation of emerging risks.
- Signal detection activities were performed within the context of the disease's natural history, enabling more meaningful interpretation of renal safety findings and supporting ongoing benefit risk evaluation.
- Safety observations and emerging trends were incorporated into aggregate reporting activities, ensuring continuous visibility of the evolving safety profile throughout clinical development.

### 6. Site Oversight and Performance Management:

- A structured site oversight programme was established to promote consistent adverse event reporting, protocol compliance, and documentation quality across participating sites.
- Targeted training initiatives, ongoing communication, and performance monitoring supported continuous improvement in reporting quality and operational efficiency.

## Results

- AWINSA successfully delivered comprehensive pharmacovigilance support throughout the clinical programme, ensuring uninterrupted safety surveillance and regulatory compliance across all participating regions.
- Key outcomes included:



- Timely submission of all expedited and aggregate safety reports throughout the duration of the programme.
- Consistent review, reconciliation, and management of clinical and laboratory safety data within established timelines.
- Effective identification and evaluation of emerging safety trends through ongoing medical review and signal management activities.
- Improved site level compliance following implementation of targeted oversight and training initiatives.
- Successful support of sponsor audits and regulatory inspections with no critical pharmacovigilance findings.
- Delivery of a high quality, submission ready safety dataset supporting continued programme advancement and regulatory interactions.
- Ongoing medical evaluation of renal safety events, contributing to accurate characterisation of the investigational product's safety profile throughout development.



## Conclusion

- This engagement demonstrates the value of specialised pharmacovigilance expertise in complex renal disease programmes. By combining therapeutic understanding, medical oversight, operational excellence, and global regulatory support, AWINSA delivered a comprehensive safety solution that enabled the sponsor to maintain patient safety, regulatory compliance, and data integrity throughout clinical development.
- The programme highlights AWINSA's ability to serve as a trusted long term pharmacovigilance partner for sponsors conducting clinical research in rare and scientifically complex therapeutic areas, where meaningful safety assessment requires both deep medical expertise and flawless operational execution.



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