

Navigating Paediatric Complexity: Integrated PV and Medical Monitoring for a Large GI Clinical Study

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Background

Gastrointestinal disorders in infants and young children represent a significant and underserved area of paediatric medicine. Conditions such as functional constipation, dysbiosis, and gut microbiome imbalance carry a high burden of symptom variability and caregiver-reported outcomes, making clinical safety surveillance particularly demanding. The complexity of assessing AEs in a non-verbal or pre-verbal population where safety data depends entirely on caregiver observation and reporting creates a distinct challenge not encountered in adult trials.

A US-based biotechnology company initiated a large Phase III clinical study of an investigational probiotic/pharmaceutical product in approximately 400 infants and young children across multiple countries. The study was designed to evaluate GI tolerability and safety as primary endpoints, with stool consistency and frequency as key measures assessed using validated caregiver-reported tools. AWINSA Life Sciences was engaged as the integrated clinical trial safety and pharmacovigilance partner across all sites and regulatory jurisdictions.

Business Challenge

The paediatric population introduces unique complexities for safety monitoring. AE assessment relied entirely on caregiver-reported stool consistency, frequency, and tolerability data, requiring careful training and quality control to ensure reliable and consistent capture across all sites. Distinguishing study product-related GI events from normal developmental GI variability in infants demanded a paediatric-specific medical review framework. Managing concurrent ICSR and DSUR submissions across multiple regulatory jurisdictions required a centralized tracking and submission system. Variable investigator experience with paediatric GI trials required structured site training and ongoing performance monitoring to maintain data quality and caregiver engagement throughout the study.

Business Solution

AWINSA Life Sciences was appointed as the integrated pharmacovigilance and medical monitoring partner to address these challenges. A structured project plan was developed to consolidate all PV and medical monitoring activities under AWINSA, with a phased ramp-up designed to manage increasing case volumes, ensure regulatory continuity, and build resilience for a high-frequency caregiver-reported AE environment. AWINSA deployed a safety team with paediatric GI expertise structured around seven operational pillars.

1. Integrated Safety Monitoring:

AWINSA deployed dedicated paediatric safety physicians providing continuous medical review with age-appropriate AE triage criteria, supported by a real-time dashboard tracking AE and SAE volumes, caregiver query status, and submission timelines across all participating countries.

2. SAE Case Processing, Follow-Up Management and DSUR Writing:

AWINSA managed end-to-end AE and SAE case processing including medical coding using paediatric-appropriate MedDRA terms, narrative documentation capturing caregiver-reported GI events, and safety database entry within defined timelines. A structured follow-up tracking system ensured proactive retrieval of outstanding safety information from sites and caregivers, keeping cases complete and submission-ready. All DSURs were authored by AWINSA in line with ICH E2F requirements and submitted to applicable health authorities on schedule.

3. Global Regulatory Submissions:

AWINSA implemented a centralized country-specific ICSR and DSUR tracking system with automated deadline alerts, maintaining 100% submission compliance and managing all health authority queries including those specific to paediatric GI safety with accurate, timely responses.

4. Caregiver-Reported Outcome (CRO) Data Quality Management:

AWINSA established a dedicated data quality framework for caregiver-reported stool consistency and frequency data, incorporating validated scoring tools. Standardized guidance was provided to caregivers and site staff to ensure consistent, reliable recording of GI events throughout the study, with systematic reconciliation of reported outcomes against the safety database within required timelines.



5. Signal Detection and DSMB Support:

AWINSA applied a paediatric GI-specific signal detection methodology, accounting for the high background rate of normal GI variability in infants and young children, to reliably distinguish product-attributable signals from developmental GI patterns. All DSMB safety packages including GI tolerability trend analyses and benefit-risk summaries were delivered on time for every review cycle.

6. Site Training and Performance:

AWINSA trained site staff across all participating countries on paediatric-appropriate AE assessment, caregiver interview techniques, and stool diary completion standards, and implemented a site-level performance scorecard to track data quality adherence and drive early corrective action across all regions.

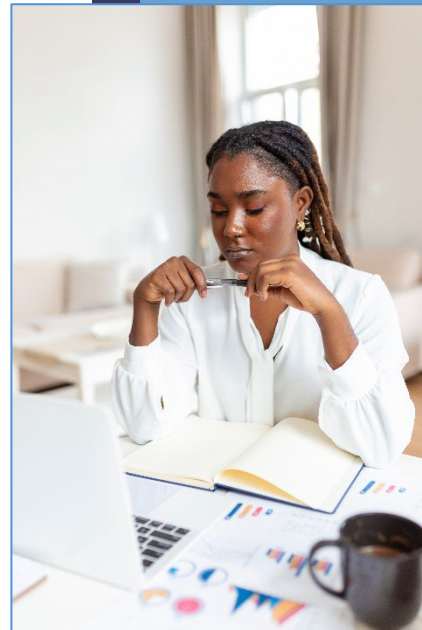
7. Medical Monitoring:

AWINSA provided dedicated medical monitoring support throughout the study. This encompassed ongoing medical review of individual patient data and listings to identify clinically significant findings, safety-efficacy medical review of cumulative data to support DSMB packages, and protocol deviation review with medical input to assess clinical relevance and patient impact. A qualified medical monitor was available on-call to provide site teams with real-time medical guidance on AE assessment, caregiver-reported GI events, and patient management queries ensuring that safety decisions at site level were always supported by expert medical oversight.

Result

AWINSA's seven-pillar safety and medical monitoring strategy delivered consistent, high-quality performance across all trial safety and regulatory obligations. By combining paediatric specialist medical oversight, medical monitoring, caregiver-reported data quality management, centralized regulatory submissions, indication-specific signal detection, structured site management, and rigorous AE/SAE case processing, AWINSA ensured full compliance, data integrity, and patient safety throughout the study duration.

- Zero late regulatory submissions across all participating countries for the full trial duration.
- 100% of caregiver-reported AE data reviewed and reconciled within mandated timelines across all study sites.
- GI safety signal transparency maintained and clearly presented at every DSMB review cycle.
- Protocol deviations reduced by 75% following site training and caregiver data quality scorecard implementation.
- No significant findings from any internal or regulatory audit during the trial period.

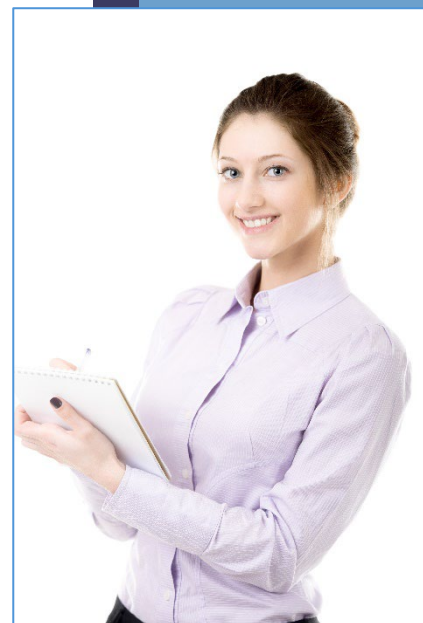


Conclusion

This partnership established AWINSA as the client's preferred end-to-end pharmacovigilance and medical monitoring partner, covering clinical trial safety, medical monitoring, post-marketing surveillance, aggregate reporting, and literature monitoring. The collaboration enabled the client to confidently advance their paediatric GI program, pursue label expansions, and engage health authorities with a robust safety data package, supported by a scalable, compliance-driven PV infrastructure. AWINSA's ability to navigate the unique demands of paediatric safety surveillance and medical monitoring while maintaining the highest regulatory standards demonstrates its capability as a long-term partner in the paediatric and GI therapeutic space.

WHO WE ARE

AWINSA Life Sciences is a specialized pharmacovigilance and clinical safety organization delivering end-to-end PV services across the full drug development lifecycle, from first-in-human trials to post-marketing surveillance. Our teams bring deep scientific expertise, regulatory intelligence, and therapeutic area knowledge to every engagement, ensuring safety data is interpreted with precision and reported with integrity. With a proven track record across complex global programs, AWINSA partners with pharmaceutical and biotechnology companies to safeguard patient safety, meet regulatory expectations, and support confident, evidence-based benefit-risk decisions at every stage of a product's lifecycle.



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