

# PHARMACOVIGILANCE



Outlined below are the key responsibilities of Pharmacovigilance team:

Phase	Activities Performed
Start up	<p><b>Protocol Review:</b> Ensure protocol includes correct safety procedures and reporting steps</p> <p><b>Safety Plan Development:</b> Create Safety Management Plan detailing Adverse Event (AE) and Serious Adverse Event (SAE) handling</p> <p><b>Reporting Requirements:</b> Define suspected unexpected serious adverse reaction (SUSAR) reporting timelines and methods to regulators and ethics committees</p> <p><b>Database Setup:</b> Build safety database to track Adverse Events and safety data</p> <p><b>Training:</b> Train site staff to identify, document and report AEs and SAEs accurately</p>
During Study	<p><b>Case Processing:</b> Receive, code and medically review AE cases for accuracy and completeness</p>

	<p><b>Expedited SUSAR Reporting:</b> Support timely submission of SUSARs to regulatory authorities</p> <p><b>Maintain Safety Database:</b> Enter, update and securely store Adverse Event and safety data</p> <p><b>Trend Analysis:</b> Monitor safety data to identify emerging risks or trends</p> <p><b>Aggregate Reporting (DSUR):</b> Prepare and submit annual Development Safety Update Reports (DSUR) summarizing cumulative safety data</p> <p><b>Support DSMB/DMC Safety Outputs:</b> Provide safety data and analyses for Data and Safety Monitoring Boards or Committees review</p> <p><b>Communicate Safety Issue:</b> Notify stakeholders promptly about new or critical safety concerns</p>
<b>Study Closure</b>	<p><b>SAE Reconciliation:</b> Verify and align SAE data across safety and clinical databases</p> <p><b>Archival:</b> Securely archive SUSARs and safety reports for compliance and future reference</p> <p><b>Final DSUR:</b> Compile and submit final DSUR with cumulative safety data</p> <p><b>Database Closure:</b> Lock and close the safety database</p> <p><b>Safety Data Transfer:</b> Transfer safety data to post-marketing system, if applicable for ongoing monitoring</p>

Thus, the pharmacovigilance department ensures participant safety during a clinical trial by monitoring, evaluating and reporting adverse events. They serve as safety gatekeepers—monitoring risks, guiding investigators and ensuring safety data is properly documented and reported to regulators

## Primary Technology / Tools used by Medical Affairs and Pharmacovigilance:

- J Review portal is a clinical data review and analytics tool used by Medical Affairs teams to analyze, visualize, and report on clinical trial data for safety, efficacy, and risk monitoring
- Argus Safety is a widely used pharmacovigilance software to manage drug safety data. It supports the collection, processing, analysis, and reporting of adverse event cases for both clinical trials and post-marketing surveillance
- Aris G (ARISg) is a leading pharmacovigilance and clinical safety software system used to manage and report adverse drug reactions, support

regulatory compliance, automate workflows and handle safety data for drugs,  
vaccines,  
biologics and devices effectively