



Outlined below are the key responsibilities of Medical Affairs team:

Phase	Activities Performed
Start up	<p>Protocol Development: Design protocol with clear objectives, safety measures and regulatory compliance</p> <p>Document Review: Review Investigator's Brochure, Informed Consent Form and Case Report Form for medical accuracy and patient safety</p> <p>Safety Monitoring and Risk Planning: Plan safety tracking and risk management strategies</p> <p>Training: Provide scientific training to internal staff and investigators for proper study conduct</p> <p>Support Regulatory/Ethics Committee Submission: Prepare and review scientific and safety documents to support regulatory and ethics committee approvals</p>
During Study	<p>Eligibility Review: Assess eligibility for protocol adherence and participant safety</p> <p>Data Review: Evaluate Case Report Form, laboratory data and deviations for safety, integrity and clinical relevance</p> <p>Respond to Site Queries: Provide timely clinical clarifications and protocol guidance</p> <p>Medical Review of Serious Adverse Event (SAE) Narratives: Review SAE</p>

	<p>narratives for causality, significance and reporting needs</p> <p>Attend Safety Review Meetings: Participate in safety meetings to discuss risks and support ongoing safety assessments</p> <p>Protocol Amendments: Provide clinical input to ensure scientific and ethical alignment</p> <p>Interim Analysis: Review interim data to assess efficacy and safety trends for informed study decisions</p>
Study Closure	<p>Final data review: Check all clinical data for accuracy, completeness and consistency before database lock</p> <p>Safety evaluation: Analyze safety data to confirm participant well-being and identify any final safety signals</p> <p>Contribute to Clinical Study Report: Provide scientific input for the Clinical Study Report summarizing trial results</p> <p>Input to publications/presentation: Help prepare scientific papers and presentations based on the trial data</p>

Thus, the Medical Affairs team supports clinical trials by providing scientific guidance in trial design, ensuring patient safety, reviewing clinical data, training trial sites, addressing medical queries, participating in safety and data reviews, assisting with protocol changes and data analysis and contributing to final reporting and publication to ensure accurate and ethical trial outcomes