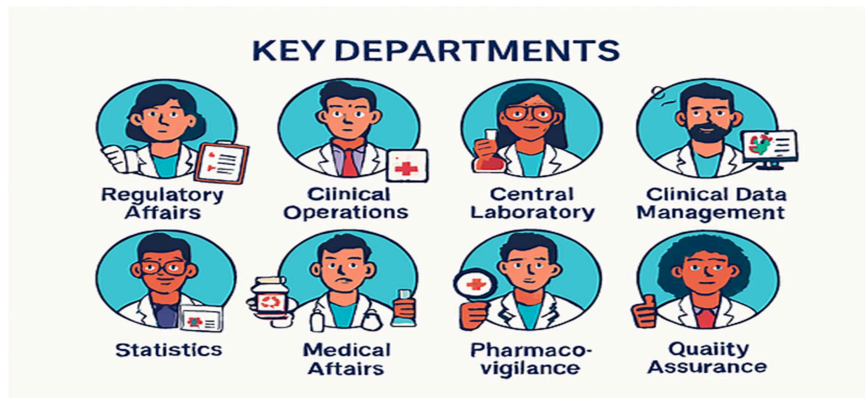


Key Departments and Their Roles in a Clinical Trial



Introduction:

Clinical trials need teamwork among several special departments, each with an important role. This teamwork helps make sure the trial's results are reliable and the process is safe for everyone involved. Every department focuses on a specific part, such as securing regulatory approval prior to trial initiation, managing day-to-day activities, handling and analyzing biological samples collected from participants across different trial sites, ensuring participant safety, collecting, validating and analyzing data and checking quality.

Together, the departments of the Sponsor and/or Clinical Research Organisation collaborate closely to ensure clinical trials are conducted with integrity, safety and scientific accuracy. Their teamwork helps maintain high standards and follows all rules, which supports the development and approval of new treatments that benefit patient care.

This module will guide you through the various departments involved in a clinical trial and provide a clear overview of their key roles and responsibilities. Each department performs its tasks as per departmental standard operating procedures and fulfills its roles in compliance with regulations and company policies.

For clarity, the roles and responsibilities of each department are grouped into three stages : Start up Phase, During Study Phase and Study Closure Phase. This classification helps provide a clear understanding of duties at each stage of the clinical trial.