

Outlined below are the key responsibilities of Regulatory Affairs team:

Phase	Activities Phase Performed
Start up	<p>Regulatory Strategy Development: Define submission pathways e.g. Investigational New Drug (IND), Clinical Trial Application (CTA) based on region and product type</p> <p>Document Submission: Prepare and submit all required documents for Investigational New Drug (IND) or Clinical Trial Application (CTA) approval</p> <p>Regulatory Approval: Respond to queries and secure approvals from regulatory authorities</p> <p>Import/Export License: Obtain all necessary regulatory licenses to enable the cross-border shipment of investigational products, specimens</p> <p>Trial Registration: Register the clinical trial in the appropriate trial registry, as applicable, before enrolling the first participant in the study. E.g. Clinical Trials Registry – India (CTRI)</p>
During Study	<p>Ongoing Submissions: Submit ongoing protocol amendments, safety updates and reports to regulatory authorities</p> <p>Regulatory Insights: Stay updated on evolving regulations and guidelines</p> <p>Audits and Inspections: Maintain audit and inspection readiness through organized documentation and routine internal reviews</p>
Study Closure	<p>End of Study Notification: Notify regulatory authorities of trial completion or early termination</p> <p>Clinical Study Report (CSR) Submission: Submit final Clinical Study Report summarizing trial outcomes</p> <p>Archival: Keep essential documents secure, compliant and ready for audits or future use</p> <p>Potential marketing authorization: Assist in preparing data and documentation for marketing authorization applications (MAAs) or New Drug Applications (NDAs)</p>

Thus, Regulatory Affairs team ensures regulatory compliance and smooth coordination with authorities throughout the clinical trial lifecycle

Primary Technology / Tools used by Regulatory Affairs:

- **E-submission portals** that facilitate secure regulatory filings to authorities e.g. SUGAM Portal (India-specific) for online regulatory filings with Central Drugs Standard Control Organization (CDSCO)
- **Electronic Common Technical Document (eCTD) software** is a specialized tool used by regulatory teams to compile, manage, and electronically submit drug approval documents to health authorities in a globally standardized format
- **Regulatory Information Management (RIM) systems** are software platforms that help manage regulatory activities, documents and submissions across the product lifecycle