# Clinical Research Modules

| Study Design | Study Start Up | Operational Management | Budget & Vendor Management | Risk, Safety & Ethics |
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| Contracts | Study Start Up | Risk based monitoring | Participant Concierge Services | Diversity, Equity, Inclusion |
| Feasibility | Ethics/IRB | Safety Reporting Requirements (Site) | Stakeholder Management | Vigilance for fraud, misconduct and errors |
| Regulatory | TMF set up | Regulatory Reporting for Pharmacovigilance | CRO Oversight | Critical Thinking, Root Cause Analysis, and CAPAs |
| Design of Clinical Trials | Site Initiation Visits | Management of IMP | Study Finances | Good Governance |
| Protocols (design and application) | Ethical participant identification and engagement | Clinical Laboratories | Budget and Vendor Management | Risk Management |
| Roles and Responsibilities of Clinical Research stakeholders | Informed Consent | Monitoring Visits | | Understanding and Improving The Participant Journey and Experience |
| Writing effective SOPs | | Accompanied Field Visits | | |
| CRF (design and application) | | Site Close out Visits | | |
| Essential Records | | Clinical Trial Data Collection | | |
| Understanding Structure and Content of Clinical Study Reports | | Clinical Trial Data Management | | |
| Drug Safety and Development | | Dealing with Data Queries | | |
| Research and Statistics | | Decentralised trials | | |
| Medical Devices | | Central Monitoring | | |
| Regulatory Compliance | | Advanced Monitoring Skills | | |
| | | Lead CRA Skills | | |
| | | Oncology Trials | | |
| | | Site Development and Sustaining Quality | | |
| | | Audits and Inspections | | |
| | | Inspection Readiness | | |