A Typical Organogram of Clinical Research Organization

Clinical Research

- Clinical Operations
  - Clinical Operations Manager
  - Project Manager
  - Clinical Team Leader
  - Senior Clinical Research Associate
  - Clinical Research Associate
  - CTA/Inhouse CRA

- Data Management
  - Head-Data Management
  - Lead Data Manager
  - Assistant Data Manager

- Pharmacovigilance
  - Head-Pharmacovigilance
  - Pharmacovigilance Physician
  - Safety Expert

- Medical Writing
  - Medical Writer
  - Executives
  - Lead Biostatistician

- Biostatistics
  - Head-Biostatistics
  - Lead Biostatistician

- Business Development
  - Business Development Manager
  - Executive

- Quality Assurance
  - Head- QA
  - Lead Auditor

- Regulatory Affairs
  - Head-Regulatory Affairs
  - Manager

- Medical Affairs
  - Medical Advisor
  - Executive

- Business Development
  - Executive

- Biostatistics
  - SAS Programmer
  - Validation Expert
  - Trainee/QA Analyst

- Quality Assurance
  - QA Executive
  - QA trainee/Assistant

- Regulatory Affairs
  - Assistant Manager
  - Executive

- Medical Affairs
  - Executive

- Business Development
  - Executive

- Pharmacovigilance
  - Medical Monitor

- Medical Writing
  - Medical Writer

- Clinical Operations
  - Lead Data Manager

- Data Management
  - Head-Data Management

- Clinical Research
  - Clinical Research

- Clinical Team Leader
  - Clinical Team Leader

- Senior Clinical Research Associate
  - Senior Clinical Research Associate

- Clinical Research Associate
  - Clinical Research Associate

- CTA/Inhouse CRA
  - CTA/Inhouse CRA

- Pharmacovigilance
  - Pharmacovigilance

- Medical Writing
  - Medical Writing

- Biostatistics
  - Biostatistics

- Business Development
  - Business Development

- Quality Assurance
  - Quality Assurance

- Regulatory Affairs
  - Regulatory Affairs

- Medical Affairs
  - Medical Affairs
Key Functions in Clinical Operations

• Project Management.
• Managing and coordination of study conduct
• Monitoring and tracking of project milestones to ensure that the project runs within timelines.
• Participation as appropriate to CORE TEAMS to expedite the feasibility and conduct of global trials
• Ensuring that the regulatory and EC’s submission are of acceptable quality
• Support Investigator as and when required (e.g. Finalisation of Investigator agreements and contracts; Finalisation of Protocols/CRFs)
Key Functions in Data Management

• Data Entry
• Database creation, Updation, Validation and lock
• Data QC and QA
• DCF generation
• Coordination with Operations team to resolve queries
• CDM software Training, validation.
Key Functions in Business Development

• Promotion and Business Development activities for the organization through networking, meetings etc.
• Maintain a central list of clients and contacts for which local business development can be targeted
• Attending local/International conferences/exhibitions as a means of exposure
Key Functions in Quality Assurance

• Facilitate audits which are conducted by clients locally within the country
• Ensure that all staff within the country has a complete and current training record
• Facilitate the auditing of suppliers and vendors used by company within the country
• Ensure that all GCP compliance issues with sites or elsewhere are raised to the Director of Quality Assurance and the Director of Medical Affairs
• Maintaining version control of SOPs to ensure that all staff are following the correct and up to date SOPs
Key Functions in Pharmacovigilance

• Collect, follow-up, transmit all local adverse events (AEs), and pregnancy cases, to Global Pharmacovigilance.
• Process cases in accordance with Global and Local Pharmacovigilance procedures.
• Answer queries and requests from Global Pharmacovigilance.
• Answer ADR and ADR case processing questions from local Regulatory Authorities and Health Care Professionals.
• Submit the reportable ADRs, (local & foreign) to the local Regulatory Authorities according to the national regulations and answer any subsequent questions in collaboration with the Global Pharmacovigilance.
Key Functions in Pharmacovigilance

• Assist the Director Pharmacovigilance in developing and maintaining the local Pharmacovigilance SOPs and Work Practice Documents.

• Provide input into labeling changes to the Regulatory Affairs Department.

• To identify all local safety observational studies (Post-Authorization Safety Studies), in conjunction with Regulatory Affairs.
Key Functions in Regulatory Affairs

• Submission to Regulatory Authorities of the parent country and other markets as well.,

• Participates in supporting and promoting current electronic initiatives in moving the company forward with electronic submissions and electronic archives.

• Ensures that regulatory documents comply with the relevant guidelines for content and format and that the content of the document is accurate and reflects information/data in the source documentation.

• Identifies and records issues that require resolution prior to finalization and liaises with responsible author to resolve issues.
Key Functions in Regulatory Affairs

• Assists authors in the completion and compilation of regulatory documents to ensure all components are provided and presented in the correct format.

• May provide training to functional group contributors on regulatory document content and format.
Key Functions in Medical Writing

- Clinical Study Protocol Writing
- Clinical Research Standard Operating Procedure Writing
- Clinical Research Report Writing
- Clinical Research Abstract and Excerpt Writing
- Writing Case Reports Forms
- Documentation for Regulatory Submission
- Technical Documentation for Clinical Trials
- e-learning Modules Writing
- Writing Medical Cases
- Managing SAEs during clinical trials
- Closely associated with regulatory department in preparing narratives for submission.
Key Functions in Medical Affairs

• Develop Scientific medical content (Medical Writing) for all Projects, meeting the international quality standards
• Providing Medico-Marketing inputs for new product development and launches
• Preparation of training manuals and product monographs
• Participate in CMEs for doctors.