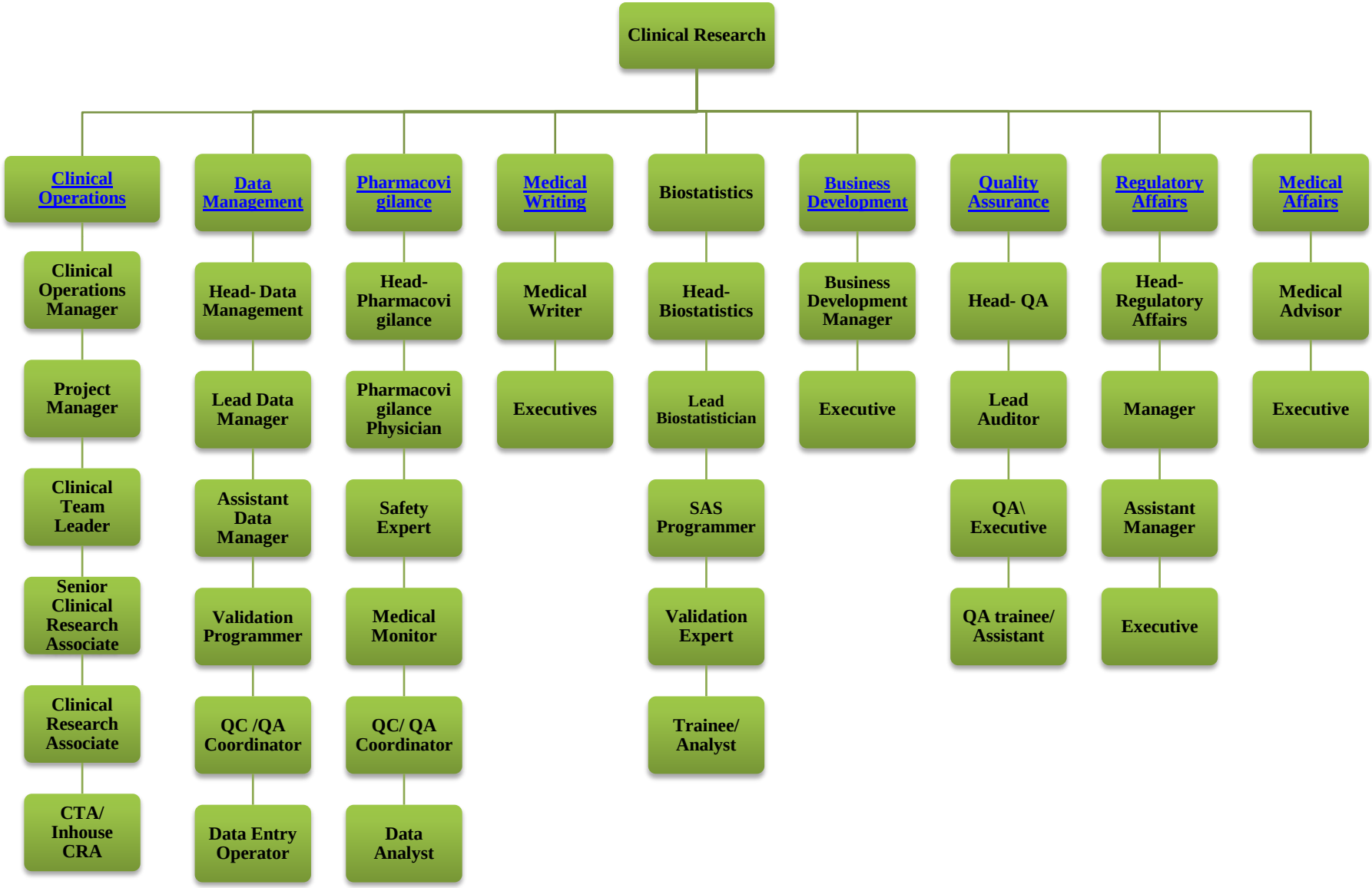
A Typical Organogram of Clinical Research Organization



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)

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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.

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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

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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

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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.

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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.

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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.

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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.

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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.

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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.

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