

Rupali Ponkshe

Core Competencies

15+ years of industry experience. Core competencies include Project Planning and Execution, Project Management, Risk Management, Study Specific Customization, Site Management, Site Monitoring, IP Management, Clinical Supplies Management, Quality Control, Safety Management, Project Tracking, SOP Development and Review, Line Management, Training, Personnel File Review, Staff Recruitment and Annual Appraisals

Educational Background

Post Graduation in Life Sciences (With specialization in **Biochemistry**) - G. S. Medical College and King Edward VII Memorial Hospital (**Mumbai University**) – 2001

Bachelor of Science (**Chemistry** Majors) – D.G.Ruparel College of Arts, Science and Commerce (**Mumbai University**) - 1999

Job Details

Working on Learning Management System (LMS)	July 2025 – Present
Visiting Faculty at Institute of Clinical Research (India) - (ICRI)	19 th October 2022 – 30 th October 2024
Senior Manager – Clinical Operations	30 th November 2006 – March 2021
Project Manager- Clinical Operations	October 2005 – 29 th November 2006
Clinical Research Associate	December 2001 – September 2005
Data Manager	September 2001 – December 2003

- Worked with **DiagnoSearch Life Sciences Pvt. Ltd.** (formerly known as iGATE Clinical Research) from September 2001 to March 2021
- Was on sabbatical from July 2017 to March 2021

Therapeutic Area(s) / Indication(s)

- **Endocrinology:** Type I and Type II Diabetes Mellitus
- **Infections:** CMV disease in solid organ transplant recipients, Hepatitis C
- **Oncology:** Postmenopausal women with Advanced Breast Cancer, Non-muscle invasive bladder cancer, Anaplastic Thyroid Carcinoma, mCRC and NSCLC
- **Vaccine:** Rabies - Human / Clinical Pharmacology, Post –exposure Prophylaxis, Potential Exposure
- **Cardiovascular** - Atrial Flutter or Atrial Fibrillation post Coronary Artery Bypass Graft Surgery (CABG) and/or Valvular Surgery, Stage 2 Hypertension
- **Electrolyte Imbalance** - Euvolemic Hyponatremia
- **Central Nervous System** - Moderate to late-stage Parkinson's disease, Dementia associated with cerebrovascular disease

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- **Respiratory** - Bronchial Asthma
- **Urology** - Erectile Dysfunction

Responsibilities Handled

Senior Manager

- Support Director Operations in **interviewing & recruiting** well-qualified staff
- **Manage** the Clinical Operations group, including staff **training** and **development**
- Support **Business Development activities**: Participate in proposal development including project budgets, lead operational and project management presentation during bid defense with support of business development and Director Operations
- **Revenue and Change Order process**: Forecast revenue for the study in coordination with the assigned Project Manager and Director Operations. Supervise change order process initiated by assigned Project Manager
- Provide the clinical operations team with **technical expertise and direction** on activities involved with planning, conducting, and reporting of clinical trial data and **oversee activities of the cross-functional teams** (i.e. Central Laboratory/ Data Management) in achieving trial execution timelines
- Execution of **Risk Management** throughout the project life cycle in collaboration with project team & cross functional leads (as applicable)
- **Supervise** Clinical Trial Execution and provide direction regarding implementation of the activities needed to meet critical milestones
- Support Director Operations in **assigning resources** to studies considering their experience & current work load
- Participate in **SOP review process** and provide recommendations. Update existing SOPs / Develop new SOPs based on the recommendations received
- Develop **SOP training material / assessment questionnaire**
- Ensure team is **trained on the latest SOPs** and have completed all applicable assessments
- Ensure reporting team members **adhere to current policies/ procedures and applicable guidelines**
- Perform **annual review of Training material and Personnel File** for all resources
- Define **Key Performance Indicators** along with Director Operations for all designations within Clinical Operations
- **Performance Management** by providing inputs in setting yearly objectives, reviewing progress, and define developmental needs of staff
- Provide frequent reinforcement or **feedback** to staff and work closely with team
- **Investigator database development**: Set up performance indicators, compile feedback across studies & support Director Operations & project managers in Investigator Site Selection decisions

Other Activities Handled

- Customization and implementation of validated **CTMS** within organization. Development of user manual and training the staff on the same

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- Involved in the conduct of the **Annual GCP Refresher trainings** for the team / organization
- Involved in defining criteria for qualification and performance indicators for Clinical Operations **Vendors** whose services are critical to quality
- Involved in the development of organizational SOPs relevant to **Observational Study**
- Support team in handling **audits & regulatory inspections**
- **IP and Ancillary Supplies Management:** Import of IP, storage at required temperature and its distribution to sites with necessary documentation / tracking. Procurement of ancillary supplies from applicable vendor(s), storage and distribution to sites with the necessary documentation / tracking, coordinate annual calibration of the instrument(s) used

Project Manager

- **Plan & supervise execution** of end-to-end activities (Protocol Review to Study Closure) and ensure **compliance** to the study protocol, applicable SOPs, guidelines/ regulatory requirements
- **Primary Liaison** to Sponsor
- Establish scope of work, timelines, resources, communication flow for study, amongst project team & cross functional leads as well as with sponsor & stakeholders, through **Kick of Meeting**
- Review / customization of **core study documents** (Protocol, ICF, CRF)
- Development of **study specific plans/ tools** (Monitoring plan, communication plan)
- **Resource management** (delegate responsibilities, training, mentorship)
- **Vendor Management** (e.g. translating agency): Maintain tracking with necessary documentation (e.g. Vendor Contract Agreement), review and approve vendor invoices
- **Site Management & Monitoring:** Oversee activities related to study and site feasibilities, investigator site selection & approval, budget & contract finalization, site readiness (infrastructure and site staff), site staff training (conduct Investigator meetings & site initiation visits, approve training tools), setting up monitoring & SDV expectations, ensure compliance to monitoring plan, review and approve site visit reports & ensure timely closure of open action(s), ensure archival of the study documents at the end of the study
- Approve **travel plans & expense reports** for study teams
- Raise study Invoices at a defined frequency. Perform monthly financial review with the support from the departments involved in the study. Check for any Out-of-Scope activities and initiate change Order process
- **Analyse data listings/ Study Trackers** (Screen failure and drop out listing, Protocol Deviation listing, data entry and query reports, safety listings, laboratory data, IWRS data, site visits open action list) to identify any trends including training needs
- **Regulatory Oversight:** Coordinating the regulatory process which involves approvals, licences, review of ethics committee documentation, deviation documentation
- **Trial Master File Management:** Finalize TMF structures to be maintained for the study, define process for collating documents from all stakeholders (internal and external), define review plan & perform TMF review to ensure the files are audit/inspection/archival ready

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- **Safety Management:** Review safety reporting requirements, provide inputs on safety management plan, track compliance to safety reporting notifications to regulatory & Ethics committee by Sponsor/Sponsor Representative & Sites

Global Project Manager

Regions involved: Mexico, Philippines, Poland, Hungary, Thailand, Russia

Review of study protocol, review of responses received from sites during feasibility process, shortlisting sites for qualification visit, review of Site Qualification Visit reports

Clinical Research Associate

Project File/s set-up, maintenance including archival, Obtaining documents from Investigators (CVs, Delegation of Authority, Laboratory Normal Ranges/certification, Ethics Committee documents), Investigator Meeting Preparation (Travel Arrangements, Preparation of Presentations/ Workshops), Site monitoring (100 % Source Data Verification, ICF review, verifying Protocol, ICH – GCP compliance), Site Management – (Documentation, EC approvals, Site Training), Investigational Product Management (Accountability, Inventory), SAE Management (SAE Reporting to Sponsor/EC/Regulatory, coordination with the site and sponsor and reconciliation with Source Data), Generating Site Visit Reports (Site Qualification, Initiation, Monitoring, Special visit, Close Out), Data retrieval and query resolution, Project Tracking (Enrolment, CRFs, DCFs, SAEs, deviations), Supply Management (CRFs , Patient Diaries, ICFs, Glucometers etc.)

Data Manager

CRF Designing, Creating Edit Check Specifications, Define CRF filling guidelines, Data Cleaning, SAE Reconciliation and Database Lock

Personal Details

Date of Birth: 26 th December 1978	Gender: Female
Marital Status: Married	Nationality: Indian
Permanent Address: E/5, Kalpana, 2 nd Floor, Tilak Nagar, V.P.Road, Girgaon, Mumbai - 400004	
Contact No:	Residence No.: 022 – 40153831 Mobile No.: +91-9820918610

I solemnly declare that all the above information is correct to the best of my knowledge and belief

Signature: _____

Date: _____