

JOB DESCRIPTION: RESEARCH FELLOW

Position:	Research Fellow	Department:	Cancer Care Programme
Reports To:	Arnie Purushotham	Organisation:	Tata Trusts

PRIMARY RESPONSIBILITIES

A) Overall

- To support design, delivery and analysis of public health research, clinical trials and research studies for India region
- Actively contribute to the development of clinical research knowledge in India including healthcare system, regulatory requirements, site capabilities, etc.
- Key interface for study sites for India
- Identify critical risks that may delay timelines and proactively develop plans (in partnership with Principal Investigator to ensure that risks are alleviated/controlled and timelines are met
- Provide reports on trial activities in India and progress updates/changes on development programs to appropriate stakeholders in a timely manner
- Ensure high quality standard in the conduct of the studies in India. Overall project management of day-to-day activities for the research project, including coordination across multiple sites
- QA/ QC (quality control) for the project
- Contribute to publications of high quality research (Literature research, systematic review, preparation of abstracts, articles, papers, manuscripts etc.)
- Be able to write grant applications to secure funding for research

B) Study Preparation

- Submission of protocols for scientific, ethical and regulatory approvals (IRB, HMSC, CTIRI etc) and applications for funding for the studies, coordinate local review and approval process across study sites.
- Create clinical trial manuals, case report forms, training manuals etc.
- Develop budget for the project
- Prepares a Study Monitoring Plan, after discussion with Investigator.
- Prepare the draft Clinical Study Agreements (CSA) and coordinate with Legal and sites for approvals.
- Coordinate and facilitate logistic planning and strategy for study training meetings for the Sites.
- Ensure proper and adequate training on studies to the team.
- Coordinate with Translator for translations of ICD and related documents in local languages.

C) Study Conduct

- Plan and execute co-monitoring activities and other Quality management initiatives along with Investigators.
- Review all monitoring visit reports and ensure all issues are reported or closed, as applicable.
- Ensure that monitoring activities are conducted as per Study Monitoring Plan.
- Ensure proper conduct of study initiation visits, routine monitoring visits and close-out activities and coordinate the provision of essential documents (e.g. trial report) for such activities, in collaboration with Investigator.
- Data collection coordination of data collection across multiple sites.
- Processing of Invoices as per the CSA agreements.

Experience and Skill sets:

1. Master of Public Health (MPH) or Master of Science (M Sc) in Clinical Research
2. 3-5 years of experience after MPH/ M. Sc. in Clinical Research, in the field of public health research/ clinical research and trial management is mandatory
3. Well versed in methodologies of clinical research
4. Experience in medical statistics will be desirable
5. Ability to manage a team
6. Ability to handle and coordinate multiple projects at a time
7. Good interpersonal skills
8. Good communication skills, both spoken and written