# JOB DESCRIPTION

**Position:** CRA

**Reports to:** Associate Director or above

**Responsibilities Overview:**

The Clinical Research Associate (CRA) will support efforts to plan, monitor and execute clinical research project(s) and is specifically accountable for completing activities assigned to ensure appropriate sponsor oversight of sites and monitors as directed by the Clinical Research Manager and in accordance with Conatus' SOPs, Regulatory regulations/guidelines and project requirements. CRAs will collaborate with personnel within clinical operations and across functions and should be able to work proficiently by having a solid understanding of site level activities and have a solid knowledge of the clinical research process.

**Tasks and Responsibilities:**

Leadership

- Takes ownership of assigned tasks that support the project and oversight of sites, monitors and CROs.
- Raises issues impacting timelines, quality or budget, finds solutions and makes recommendations.

Project Related Planning, Management and Execution

- Support site activation activities by working with sites and/or monitors/CRO to ensure follow-up is completed within project and regulatory timelines, including confirmation of IRB submissions, review or development of ICF templates, review of country/site specific ICFs, review of regulatory documents prepared by the CTA.
- Responsible for reviewing or developing site-level Study Documents (e.g. reference manuals, Laboratory manuals, CRF Completion Guidelines, forms, etc.) under the direction of a senior team member
- Responsible for reviewing and understanding the content of site-level project plans, including the monitoring plan for any assigned projects, drug accountability and reconciliation plans
- Oversee site level drug accountability processes with sites, monitors/CRO and Internal team members.
- Supports the CTAs to maintain the TMF.
- Meet project and department metrics in accordance with assigned tasks.
- Other duties as assigned (e.g. assist other departments with ad hoc assignments related to cross study data review, clinical research study document review, and review vendor scopes of work)

Site Management

- Participate in site selection activities including conduct of site selection visits, and reviewing recommendations from vendors as needed.
- Conduct monitoring or co-monitoring visits (e.g. qualification visits (SQV), site initiation visits (SIV), interim monitoring visits (IMV), close-out visits (COV)) and demonstrate independence and proficiency in all types of visits
- Execute on monitoring oversight plan by reviewing monitoring reports, track and raise issues, and follow-up on outstanding issue with sites.

Vendor Management

- Participate in day to day management of vendors in regards to their services to sites as requested

Communication and Coordination

- Effectively communicates to internal and external study team members, as appropriate, to ensure adequate distribution of information and coordination of activities
- Participates in cross functional team work for assigned study team(s)
- May organize and run internal meetings for process issues

**Preferred educational background and skill required:**

- Bachelor's degree or licensed certified health care training or equivalent combination of education and experience
  - Minimum of 2-3 years in the clinical research industry with relevant experience (e.g. clinical trial administration, monitoring)
- Experience in and/or exposure to site monitoring (e.g. site selection, site initiation, interim monitoring and closeout visits) and/or site management activities
- Experience creating form documents, and contributing to review of procedures
- Experience with electronic data capture, a plus

**Knowledge, Skills and Attributes:**

- Basic understanding and demonstrated application of clinical development guidelines, applicable regulatory authority requirements and guidances (e.g. ICH-GCP, FDA guidelines, US CFRs, EU Directive etc.), and Conatus Standard Operating Procedures
- Knowledge of requirements related to clinical monitoring and ability to learn and understand applicable medical/therapeutic area knowledge and medical terminology
- Basic understanding and appreciation of clinical research/development, including medical and therapeutic areas, phases and medical terminology
- Effective communication skills (listening, oral, and written) and can communicate in English language (oral, written)
- Sound interpersonal and negotiation skills, is flexible and adapts to changing situations
- Organized and proficient at multi-tasking with strong attention to detail