Reviewed By/Date:	**Approved By/Date**:
Name, Title	Name, Title

1. Job Summary

The CRA performs and coordinates all aspects of clinical monitoring and site management in accordance with ICH Good Clinical Practices, FDA guidelines, ISO standards, local regulations, and CRS SOPs. Both on-site and remote monitoring techniques may be used based upon project-specific requirements. The CRA conducts site visits to assess protocol and regulatory compliance and manages required documentation. The CRA is responsible for ensuring that data will successfully pass international quality assurance audits. The CRA develops and maintains collaborative relationships with investigational sites. The CRA works closely with project management functions to identify and escalate risks of patient safety and data integrity to clients during a study. The CRA often works remotely from their home office.

2. Duties, Activities, and Responsibilities

2.1. Assisting with the conduct of feasibilities with investigational sites and documenting results.
2.2. Conducting site qualification, initiation, interim monitoring and close-out visits.
2.3. Participating in co-monitoring and remote visits when needed.
2.4. Documenting results of visits in monitoring reports for review and finalization.
2.5. Motivating investigational sites to close queries and action items.
2.6. Escalating deviations, breaches, and suspected data integrity issues to project management.
2.7. Facilitating IRB submissions and renewals when needed.
2.8. Maintaining contact with research site personnel over the life of a trial, including staffing changes and handling training or retraining.
2.9. Managing in-house work assigned by project management.
2.10. Contributing to study plans, site trackers, reports, and routine meetings.
2.11. Preparing expense reports with adherence to CRS or client's Travel Policy.
2.12. Ensuring consistent use of study tools and training materials and compliance with standard processes, policies and procedures.
2.13. Collecting and reviewing Essential Documents.
2.14. Assisting Quality Assurance with CAPAs, SOP revisions, audits, and inspections.
2.15. Additional tasks not described within to meet company requirements and client milestones.

3. Education and Experience

3.1. A Bachelor's degree or equivalent in a life sciences, nursing, or related discipline.
3.2. Ideally five years of clinical research experience with three years as a clinical research associate.
3.3. Alternatively, equivalent combination of education, training and experience in a life science environment with work in clinical trials.

4. Knowledge, Skills, and Abilities

4.1. Continuous learning and training on ICH GCP, FDA, ISO, and international regulatory positions and updates.
4.2. Proficiency in Word, PowerPoint, Excel, and Outlook.
4.3. Excellent professional written and verbal communication skills.
4.4. Excellent time management skills and attention to details.
4.5. Proven ability to be flexible and adaptable.
4.6. Ability to maintain relationships for repeat business.

4.7. Ability to write and modify SOPs, CAPAs, work instructions, forms, and templates.
4.8. Valid driver's license.
4.9. Demonstrated understanding of medical terminology and knowledge in therapeutic areas.