Job Description for Clinical Research Associate **Version 4.0; November 2020**

Summary: The Clinical Research Associate (CRA) is responsible for clinical monitoring activities as part of a clinical trial team. The CRA serves as liaison between the Project Manager (PM), Clinical Trial Assistants (CTAs), Clinical Trial Specialists (CTSs) and clinical trial sites. They are integral in the documentation capture process ensuring all information is secured and accurate at both site and CRO levels.

Reports to: Chief Operating Officer (COO)

Primary Responsibilities:

- Travel to clinical trial sites to provide clinical monitoring throughout the lifecycle of a pharmaceutical or device study from feasibility determination to close-out
- Supervises on-site conduct of clinical studies acting as liaison between Project Manager and site personnel
- Ensures quality execution of clinical trial by verifying materials, subject safety and data integrity, ensuring every trial is always “audit ready”
- Verifies integrity of Investigator Site Files ensuring compliance and completeness of documentation at the site level
- Report development to ensure proper documentation of site visits and study conduct
- Communicates action items and/or pending issues to the Principal Investigator and site staff for timely resolution

Clinical Monitoring

- Assesses protocol adherence and implementation at sites throughout the conduct of a clinical trial
- Ensures compliance with subject Informed Consent process
- Verifies receipt, handling, accounting, storage, and availability of Investigational Product (IP)
- Verifies compliance and quality of collected data through site visits and ongoing query management
- Ensure compliance with procedures related to Serious Adverse Events (SAEs) and Pregnancies
- Verifies investigator records and checks for consistency with Trial Master File and Investigator Site Files
- In cooperation with PM, CTA and CTS, ensures timely collection of documentation from trial sites

Reporting

- Develops timely reports for submission and approval throughout the lifecycle of the clinical trial
- Ensures completeness and accuracy of reports, as well as site visit letters and other forms of documentation
- Timely submission of expense and other administrative reports (i.e., time tracking)

Qualifications

- A Bachelor’s Degree in biomedical sciences, pharmacy, pharmacology, nursing or a related discipline and/or a minimum of two years’ experience as a CRA; combination of relevant experience and education acceptable
- Excellent oral and written communication skills
- Excellent interpersonal skills
- Ability to work independently
- Ability to travel extensively (i.e., up to 4 days per work week)
- Detail-oriented and highly organized

- At least two years' experience working in clinical trials from study start-up to closeout
- Knowledge and proficient use of CTMS, EDC, project management software, and other technology-based programs (including Microsoft Office programs)
- Knowledge of applicable clinical research regulatory requirements (i.e., GCP and ICH Guidelines)
- Mindset of superior customer service for sponsors and sites

Employee Signature	Date
Supervisor Signature	Date