# AMAREX JOB DESCRIPTION

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| Position Title: Clinical Research Associate (CRA) | Department: Clinical Operations |
| Reporting Requirements: Reports to Sr. Vice President, Clinical Operations or Project Manager as Designated | Supervisory Responsibilities: None |
| Travel Requirements: > 70% | |

## POSITON SUMMARY

The Clinical Research Associate performs monitoring visits to ensure compliance with ICH-GCP guidelines, local regulations, corporate SOPs and project-specific requirements.

Key Duties and Responsibilities:

- Independently oversee and manage multiple sites within one or more protocols to assure compliance with protocols, project plans, and Good Clinical Practices (GCPs).
- Conduct on-site visits as required; pre-study, initiation, interim, and close-out visits and prepare visit reports.
- Oversee site study start-up procedures, including IRB submissions and contract/budget negotiations
- Serve as primary point of contact for site questions related to study conduct issues and study progress.
- Prepare study manuals, informed consent documents, regulatory binders, source document templates, and other study materials.
- Participate in project team meetings and communicate, in a timely and effective manner, with the appropriate internal or external individuals involved in the project.
- Recommend processes that lead to timely and successful placement, completion and/or resolution of project tasks
- Assure that regulatory and other required documents are complete and accurate, and are maintained and approved in accordance with required regulations, guidelines, and SOPs.
- Review source documents and case report form data to assure timely, accurate, and quality data retrieval.
- Interface with study team to resolve data queries in a timely manner.
- Contact and manage study vendors.
- Participate in the training and mentoring of CTAs, as requested.

## REQUIRED EDUCATION AND EXPERIENCE

- BA/BS in nursing, biological sciences or related field.
- One year of clinical trial monitoring experience with a CRO, pharmaceutical or biotech firm.
- Working knowledge of Good Clinical Practices (GCPs).
- Recognized CRA certification (ACRP or SoCRA) a plus.
- Proficient in Microsoft Office software.
- Ability to work effectively both independently and in a team environment.
- Ability to organize and prioritize work in order to meet demanding timelines.
- Strong problem solving, interpersonal and communication skills.
- Willing to travel extensively to meet corporate and project goals.
- Other duties as assigned.