SUMMARY OF ROLE The Biostatistician is responsible for intermediate-level statistical analyses and programming for clinical trials and/or research projects. The Biostatistician will provide statistical support for the production and review of both derived analysis datasets and statistical outputs, and assist in the development of statistical analysis plans. This position will assist in trial design and data management review and consultation.

A Biostatistician II role requires elevated statistical programming skills, among others.

ESSENTIAL DUTIES
- Assist with the preparation of statistical analysis plans; independently generate descriptive and basic test statistics, analyze basic data requests, and generate statistical modeling results
- Contribute to the design and validation of analysis data sets, programs, and statistical output products (e.g., tables, listings, figures, etc.)
- Document analyses, create summaries/reports, and present results in written and verbal form
- Participate in most statistical aspects of a clinical trial/project, with consultation or assistance when needed
- Attend applicable internal project team meetings and teleconferences
- May design analysis data set specifications through writing own code, find errors, correct, and validate output and results

KNOWLEDGE, SKILLS and ABILITIES
- Familiarity with basic statistical methods that apply to Phase I-IV clinical trials
- High proficiency with full Microsoft applications; strong aptitude for SAS and/or SPSS programming skills preferred
- Strong spoken and written communication skills to include grammatical/technical writing; fluency in English
- Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE
- Bachelor’s degree in biostatistics and 2 years’ related experience/advanced education, or
- Master’s degree or PhD in biostatistics and 0–2 years’ related experience preferred
- Some clinical experience is required

TRAVEL and PHYSICAL REQUIREMENTS
- Travel can range from 0 to 10%

CAREER PATHWAYS
- Biostatistician 2
- Biostatistician 3
- Senior Biostatistician
- Principal Biostatistician Role
- Manager
Clinical Research Technician

Job Title(s): Research Technician, Clinical Research Technician  
Department: Clinical Research Unit  
Organization Type: Site-based  
Status/Salary: Exempt and Hourly (Range $32,000–$58,500)

SUMMARY OF ROLE

The Clinical Research Technician supports ongoing clinical research processes by following protocol requirements.

ESSENTIAL DUTIES

• Carry out major experimental protocol events, such as EKGs, phlebotomy, urine collection, standard measurements, vital signs, and blood pressures
• Set up and monitor data collection equipment
• Follow universal/standard precautions and maintain clean and safe work and subject areas; report unsafe work areas to appropriate leadership
• May serve as a lead worker

KNOWLEDGE, SKILLS and ABILITIES

• Knowledge of applicable laboratory procedures, tests, techniques, and terminology
• Ability to maintain the safety and wellbeing of participants at all times
• Strong spoken and written communication skills; fluency in English
• Strong interpersonal, collaborative, and time management abilities
• Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE

• High school diploma with 2 years’ clinical research experience, or
• Associate’s degree with no experience, or
• Bachelor’s degree preferred

TRAVEL and PHYSICAL REQUIREMENTS

• Travel can range from 0 to 10% depending on protocol requirements

CAREER PATHWAYS

Foundational role that leads to many others within contract research organization (CRO) industry, including:

→ In-house clinical research associate or clinical research associate
→ Clinical research coordinator
→ Data research coordinator
→ Clinical research specialist
SUMMARY OF ROLE The Clinical Research Associate is responsible for assigned aspects of clinical monitoring and site management in accordance with applicable Standard Operating Procedures (SOPs) and the International Conference on Harmonisation's (ICH) guidelines for Good Clinical Practice (GCP). Site visits are conducted to assess protocol and regulatory compliance, data reliability, and the proper care and treatment of test subjects. The Clinical Research Associate represents the organization in a professional and collegial manner.

ESSENTIAL DUTIES

• Ensure compliance with standard protocol and regulatory and ICH GCP obligations in assigned aspects of clinical site monitoring, such as site initiation, routine monitoring, maintenance of study files, study close out, and retrieval of study materials

• Complete on-site and remote monitoring activities in compliance with the Clinical Monitoring Plan, including source document verification, as required

• Ensure the integrity of data and that the study is conducted in compliance with approved protocol, GCP, applicable regulations, and internal SOPs

• Perform key risk assessment and management responsibilities throughout the project, including key risk indicator and site health analysis, site process evaluation, and project escalation

• Participate in audit preparation and follow-up activities, as needed

• Verify the protection of study participants by informed consent procedures and protocol requirements that follow appropriate regulations

• Verify proper management and accountability of Investigational Product

• Write and submit reports of investigational site findings and update applicable tracking systems, as required; escalate observed deficiencies and issues as appropriate

• Manage essential documents as required by local regulations and ICH GCP before, during, and after a clinical study; assist with resolution of investigational site/data queries

KNOWLEDGE, SKILLS and ABILITIES

• General knowledge of regulatory requirements & GCP

• Ability to multi-task and deal with shifting priorities

• High proficiency with full Microsoft applications

• Strong spoken and written communication skills; fluency in English

• Strong interpersonal, collaborative, and time management abilities

• Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE

• Bachelor’s degree in a life science-related field, a registered nurse (RN) certification, or equivalent

• 2 years’ experience in a clinical trials research environment required

• Valid driver’s license required

TRAVEL and PHYSICAL REQUIREMENTS

• Travel can range from 60% to 85%

CAREER PATHWAYS

Foundational role that leads to many others within CRO industry, including:

▷ Clinical research associate 2 ▷ senior/principal clinical research associate

▷ Clinical trial/team lead/manager (CTM); project management

▷ Quality control/quality analytics (QC/QA)

▷ Data analytics, data management, safety
Clinical Research Coordinator

Job Title(s): Clinical Research Coordinator, Clinical Research Specialist, Coordinator–Research, Clinical Studies Coordinator, Medical Research Associate

Department: Clinical Operations or Project Management

Organization Type: Contract Research Organization (CRO)-based and Site-based

Status/Salary: Exempt and Salaried or Non-Exempt and Hourly (Range $56,000–$85,000)

SUMMARY OF ROLE

The Clinical Research Coordinator is responsible for the support and coordination of all aspects of clinical research including subject screening and recruitment, regulatory maintenance, data collection, and data management activities. These positions manage protocols to ensure the safety of patients and quality of clinical trial data.

Some Clinical Research Coordinator positions are more senior and may have increased responsibilities for patient care, protocol design, implementation, and training junior staff. These senior positions require additional experience and/or education.

ESSENTIAL DUTIES

- Develop or assist in the development of protocol-specific systems and documents including process flows, training manuals, and Standard Operating Procedures (SOPs); order supplies and equipment
- Recruit, screen, schedule, consent, and collect adverse events information for participants in a variety of studies; maintain documentation, including consent
- Perform technical procedures on clinical subjects under the direction of the principal investigator or their designee; collect, prepare, process, maintain, and ship collected samples
- Maintain appropriate patient records, as necessary, including charting the condition of the patient and determining their continued eligibility in the study
- Assist in providing patient education on the benefits and risks of participating in a clinical trial
- Assist with or develop data collection documents and instruments
- Review and document trends, problems encountered, patient adverse events, and subject progress

KNOWLEDGE, SKILLS and ABILITIES

- Understanding of medical terminology
- General knowledge of regulatory requirements & Good Clinical Practices (GCP)
- Data evaluation skills
- Ability to multi-task and deal with shifting priorities
- High proficiency with full Microsoft applications
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; extremely accurate and detail-oriented

EDUCATION and EXPERIENCE

- Associate’s degree in related field and 2 years’ experience in a medical and/or research setting, or
- Bachelor’s degree in related field and 0–1 year of experience in a medical and/or research setting
- Phlebotomy and/or venipuncture experience preferred
- Dual roles involving patient care may prefer a Bachelor of Science Degree in Nursing

TRAVEL and PHYSICAL REQUIREMENTS

- Travel can range from 0 to 10%

CAREER PATHWAYS

- Clinical research coordinator 2 → clinical research coordinator 3
- Clinical research associate path

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Data Research Coordinator

Job Title(s): Data Technician, Clinical Data Associate, Clinical Research Associate Assistant, Assistant Project Coordinator, Data Coordinator, Research Data Abstractor

Department: Biometrics, Clinical Research

Organization Type: Contract Research Organization (CRO)-based and Site-based

Status/Salary: Non-Exempt and Hourly (Range $40,000–$60,000)

SUMMARY OF ROLE
The site-based Data Research Coordinator is responsible for clinical data review and query generation, resolution, and reconciliation to support the delivery of clinical data. Under general supervision, the position may also perform administrative and coordinative work directed toward the design, implementation, evaluation, and review of the assigned project(s).

ESSENTIAL DUTIES
• Enter study data into appropriate database and perform review of discrepancy output and validation listings
• Review and respond to queries to address problematic data identified during data review activities; apply proper correction/modification
• Apply quality control procedures and ensure data quality standards are achieved
• Create, update, track, and maintain study-specific trial management files, tools, and systems
• Maintain awareness of contract and scope of work for assigned project(s)
• Assist local team members with administrative activities as required, including filing, document maintenance, and ordering and maintaining adequate supplies for project
• Track site performance metrics (e.g., patient screening, enrollment, retention, etc.)

KNOWLEDGE, SKILLS and ABILITIES
• Knowledge of clinical data and Good Clinical Practices; knowledge of medical terminology
• High proficiency with full Microsoft applications; relational database management software systems experience
• Strong spoken and written communication skills; fluency in English
• Strong interpersonal, collaborative, and time management abilities
• Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE
• Bachelor’s degree in a life science-related field preferred
• 0–2 years’ experience in a data management, medical, and/or research setting

TRAVEL and PHYSICAL REQUIREMENTS
• Travel can range from 0 to 10%

CAREER PATHWAYS
• Data manager
• Clinical research coordinator
• Project assistant

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**SUMMARY OF ROLE** The Financial Analyst contributes to the achievement of financial and project objectives through accurate and timely reporting of revenue and costs. The Financial Analyst prepares, reconciles, analyzes, and reports revenue, contracts, projects, and associated metrics for assigned projects and contracts. This position interfaces with management on requests for financial information and addressing compliance issues, while ensuring that all reporting activities are accurate and prepared within established timelines.

**ESSENTIAL DUTIES**

- Perform project analysis using different sources of information to support the financial decision-making process
- Identify and highlight potential issues related to project financial risks that impact profitability
- Monitor the overall health of assigned projects, including, but not limited to, revenues, gross profit, receivables, and unbilled amounts, as well as project close-outs and reconciliations
- Make appropriate recommendations that will positively impact operational effectiveness
- Prepare special reports and financial studies for management and provide findings and variances to plan
- Provide required financial reports within required deadlines, as requested

**KNOWLEDGE, SKILLS and ABILITIES**

- Solid understanding of accounting/financial principles and regulations/legal requirements
- Ability to handle sensitive information and make sound recommendations
- High proficiency with full Microsoft applications; proficiency with accounting software packages
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented

**EDUCATION and EXPERIENCE**

- Bachelor’s degree or its international equivalent in accounting, finance, or business administration
- 0–2 years’ related experience
- Pharmaceutical or contract research organization (CRO) experience preferred

**TRAVEL and PHYSICAL REQUIREMENTS**

- Travel can range from 0 to 10%

**CAREER PATHWAYS**

- Senior financial analyst
- Assistant project management
- Business proposals/contracts
### SUMMARY OF ROLE
The In-house Clinical Research Associate is responsible for the assigned aspects of clinical monitoring and site management that can be accomplished remotely in accordance with applicable Standard Operating Procedures (SOPs) and the International Conference on Harmonisation’s (ICH) guidelines for Good Clinical Practice (GCP).

### ESSENTIAL DUTIES
- Liaise with management staff to ensure compliance with standard protocol and regulatory and ICH GCP obligations in assigned aspects of clinical site monitoring
- Collect documents, review data points/findings from electronic data capture (EDC) and file review
- Review and appropriately escalate site key risk/performance/quality indicators; provide trial status reports to project management, as required
- Write, follow, and resolve clinical queries and issues
- Assist with investigator recruitment activities utilizing phone scripts, questionnaires, study site materials, and other tools for evaluating investigative sites
- Document site management contacts according to the monitoring plan
- Assist in ensuring audit ready files; contribute to company, client, and federal/local regulatory requirements/audit responses, as needed

### KNOWLEDGE, SKILLS and ABILITIES
- General knowledge of regulatory requirements & GCP
- Ability to multi-task and deal with shifting priorities
- Data evaluation skills
- High proficiency with full Microsoft applications
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; highly accurate and detail-oriented

### EDUCATION and EXPERIENCE
- Bachelor’s degree in a life science-related field, a registered nurse (RN) certification, or equivalent
- 1+ year of experience in clinical research trial environment preferred

### TRAVEL and PHYSICAL REQUIREMENTS
- Travel can range from 0 to 10%

### CAREER PATHWAYS
Foundational role that leads to many others within CRO industry, including:
- Clinical research associate pathway
- Data management
- Site start-up

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Nurse Consultant

Job Title(s): Consultant Nurse, Nurse
Department: Medical Communications, PVG (pharmacovigilance)
Organization Type: Contract Research Organization (CRO)-based or Site-based
Status/Salary: Exempt and Salaried or 1099 Consultant (Range $53,500–$86,500)

SUMMARY OF ROLE
The Nurse Consultant is a full-time role that provides expert medical information that is delivered with a high level of customer service to a variety of audiences, both internal and external.

ESSENTIAL DUTIES
- Research and respond to inquiries and documents according to applicable guidelines
- Identify and record adverse events and product complaints, and provide clinical trial information
- May provide technical expertise and guidance in assessing, developing, and implementing educational research
- Provide after-hours on-call support, as needed (e.g., on-call pager coverage)

KNOWLEDGE, SKILLS and ABILITIES
- Previous experience that provides the knowledge, skills, and abilities to perform the job
- Knowledge of policies and procedures including client products, Standard Operating Procedures, protocols, Good Clinical Practices, and all applicable regulatory requirements
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE
- Associate’s degree and Nursing Diploma plus 2 years’ nursing experience, or
- Bachelor of Science in Nursing plus 0 to 2 years’ nursing experience
- Possession of a current North Carolina license to practice as a registered nurse (RN)

TRAVEL and PHYSICAL REQUIREMENTS
- Travel can range from 0 to 10%

CAREER PATHWAYS
- Medical science liaison, pharmacovigilance, quality assurance/quality control, regulatory
- Study start-up

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SUMMARY OF ROLE
The Project Assistant and Clinical Trial Assistant are junior roles responsible for administrative tasks—both simple and complex—in support of project or department goals. These positions work with team members to ensure that projects and assignments are completed in accordance with contract, customer, and/or organizational expectations.

Project Coordinators, Associates, and Specialists are more senior positions that assume additional responsibilities such as Trial Master File updates and overall document and regulatory management. These positions may also train junior staff and have increased responsibilities for project team support in the areas of initiation, planning, execution, control, and/or closure.

ESSENTIAL DUTIES
- Responsible for the coordination and completion of simple and complex administrative tasks in support of project or department management, such as file creation and maintenance, phone coverage, and the creation of status reports, presentations, and graphics
- Coordinate, attend, and participate in project meetings; prepare and distribute meeting minutes and action items
- Regularly facilitate team communication and liaise with sponsors, investigate sites, and third-party contractors, as requested
- May update or coordinate updates to Trial Master File
- May provide support for quality assurance activities, including preparation for audits and internal review, preparation of documentation, and resolution on actionable issues
- May create and track budgets, and assist in the preparation of work order requests

KNOWLEDGE, SKILLS and ABILITIES
- High proficiency with full Microsoft applications
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE
- Associate’s degree in related field and 2 years’ experience in a medical and/or research setting, or
- Bachelor’s degree in related field and 0–1 year of experience in a medical and/or research setting

TRAVEL and PHYSICAL REQUIREMENTS
- Travel can range from 0 to 10%

CAREER PATHWAYS
- Project management
- In-house clinical research associate (CRA) → CRA pathway
- Remote monitor
- Clinical research coordinator
- Regulatory specialist
SUMMARY OF ROLE The Safety Assistant performs a variety of safety monitoring duties within the department. Responsible for assisting with the smooth function of the pharmacovigilance department to ensure all adverse events are processed to the required standard and submitted to the client and regulatory agencies (if applicable) within agreed upon timelines. The Safety Assistant must adhere to all data protection guidelines, the Health Insurance Portability and Accountability Act (HIPAA), Good Clinical Practices (GCPs), regulatory guidelines, and study procedures.

ESSENTIAL DUTIES
• Manage all adverse event and endpoint source documentation in accordance with Standard Operating Procedure (SOP) specifications; escalate issues to management, as needed
• Scan received documents for unrequested personal identifiers and initiates appropriate actions to protect data privacy
• Perform file creation, tracking, retention, and maintenance—both paper and electronic; maintain industry reference documentation
• Assist in the preparation of safety-related meetings and prepare minutes
• Provide simple and complex administrative support, such as the appropriate distribution of incoming paperwork/inquiries and assisting in production of queries of safety data for clients

KNOWLEDGE, SKILLS and ABILITIES
• Medical terminology knowledge strongly preferred
• Ability to multi-task and deal with shifting priorities
• High proficiency with full Microsoft applications; database experience
• Strong spoken and written communication skills; fluency in English
• Strong interpersonal, collaborative, and time management abilities
• Excellent organizational skills; accurate and detail-oriented

EDUCATION and EXPERIENCE
• Associate's Degree in Nursing plus 1-2 years' experience, or
• Bachelor's degree in a life science-related field and 1+ year of related safety experience preferred

TRAVEL and PHYSICAL REQUIREMENTS
• Travel can range from 0 to 10%

CAREER PATHWAYS
▷ Safety manager 1 ▷ safety manager 2 ▷ senior safety manager
▷ Regulatory, post-marketing surveillance