

Rockaway, NJ Sr. Clinical Study Programmer Recruitment Summary

The Senior Clinical Study Programmer, an integral member of the data management group, is accountable for the timely production of clinical database structures, clinical data logic checks, clinical data extraction, external data loading, dictionary version update (MedDRA, WHOdrug) programs and tools and the conversion of clinical views to extraction data-sets for multiple uses.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the U.S. and Western European pharmaceuticals market. It is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. We have established strong franchises in women's healthcare and dermatology through our marketing techniques and specialty sales forces. We believe that our proven product development capabilities, coupled with our ability to execute acquisitions and inlicensing transactions and develop partnerships will enable us to sustain and grow our business.

The individual will be responsible for the following activities:

- Responsible for the design, development, and implementation of electronic case report forms (eCRF), eCRF behaviors, validation and derivation procedures, and complex data logic checks/programs
- Evaluates and implement changes to eCRF/database programming as a result of study change requests or UAT findings
- Presents eCRF update options to study management team
- Develops, tests, and reviews extraction programs, based on user requirements, for reporting and statistical analysis
- Design(development), create (production) and work with IT to validate new studies in Oracle Clinical; this includes data object configuration, and validation documentation
- Integrate protocol and charter requirements with internal business practices to draft Data Quality Specifications
- Review study documentation, translate study design parameters into Oracle Clinical data objects
- Develop validation and derivation procedures that satisfy constraints of study data quality plans
- Manage validation and deployment of new studies
- Plan and manage the update and re-validation of amended studies
- Integral member of Data Management liaise with Project Teams

- Document activities and work according to SOPs. Write clearly and accurately.
- Liaise with Data Managers of vendors to set standards and manage the electronic transfer of clinical data from the vendor to WC

Qualifications

- Bachelor's Degree in Bioinformatics, Computer Science or a related field or equivalent experience.
- Experience handling biomedical data using programming languages such as PL/SQL, C++, SAS, and OC/RDC systems.
- Demonstrated knowledge of programming in Oracle Clinical, Oracle RDC, including creation of Custom Functions
- Minimum of five years experience in data management programming, with focus in Oracle Clinical
- Experience in a regulated environment, specifically pharmaceutical (21 CFR Part 11)
- Strong interpersonal and communication skills; capable of production technical support, training users and writing documentation
- In depth knowledge of data management processes and responsibilities
- Clinical data knowledge and experience in the pharmaceutical industry is required
- Knowledge and experience programming to follow CDISC study data tabulation model (SDTM), and complex data logic checks/programs

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Candidates must be authorized to be employed in the United States. Candidates should be willing and able to travel as necessary. Candidates must be organized and have excellent oral presentation and communication skills. Candidates must also successfully pass a drug test and background check.

Warner Chilcott realizes that our success as an organization is dependant upon our people. We seek aggressive, success oriented and adaptable associates. Please apply at jobs@wcrx.com and reference "Sr Clinical Study Programmer" in the subject.