**NEWTON-RAY UKWUOMA**

xxxx, NJ 08536. Newtray2002@yahoo.co (301)-820-8033

**SUMMARY**

* A clinical research professional with 5 years of experience in clinical data management. Extensive project management skills and proven ability to manage clinical data with several data management and electronic data capture (EDC) systems.
* Experience in managing projects from start-up to close-out. Hands on expertise on end-to-end aspect of Data Management (CRF Design, DB build/Validation, Edit Checks, UAT, Data Management Plans, Study execution – SAE/Lab Recon, EDC cleaning, Listing review, Medical Coding and Close out activities – DB transfer and DB lock).
* Experience in the EDC systems (Oracle9i, MediData, Oracle Clinical, eTMF, CTMS)
* Knowledge of FDA/ICH guidelines and industry standard practices regarding the management of clinical trial data.
* Successfully led multiple clinical studies which involved reviewing, programming and testing.
* Collaborated with the Technical designing team, Validation team, Study lead team to create a robust clinical database
* Participated in all study meetings, reviewed client specifications and programs. Made sure deliverables are meeting expected quality.
* Coordinated with the other Database Programmers to ensure that all jobs are carried out and timelines are met.
* Experience in implementation of Best Practices, use of Microsoft Visio Professional for Process flowcharts etc.
* Proven track record ofmanaging and delivering successful clean locked databases.

**Business/Technical Skill:**

eCRF Design, Edit Check Programming, Custom Function Programming, Derivation, Report Setup, ALS Upload, PDF Generation, Study startup activities, Drug Development Cycle, excel VBA, MS SQL

**Professional experience**

**xxxxxxxxxx, NJ Jul. 2017– Present**

**Clinical Data Manager/Database Developer**

* Designed/created and tested clinical databases including forms, folders, matrices, data dictionaries, unit
* dictionaries, edit checks, derivations, C# custom functions on Medidata Rave.
* Reviewed programmed edit checks
* Tracked study progress and issued periodic status reports
* Updated database to correct errors
* Provide mentorship and training to new database developers/study builders (Oracle Clinical and Medidata Rave
* 5.6.4)
* Create customized study reports and data listings for clinical review (Oracle Clinical)
* Working within the Standard Operating Procedure (SOP) system, including departmental
* Provide computer and program support on all levels for the Clinical Study group
* Prepare files for FDA audits
* Reviewing and processing clinical trial data to ensure the accuracy and consistency of clinical databases.

**xxxxxxxxxxxxxxxxxx, NJ Aug. 2015– June2017**

**Clinical Data Manager**

* Perform all Data Management activities from study start-up to data lock for both in-house and outsourced studies.
* Participate in study planning and execution by contributing to protocol review; case report form (CRF) development.
* Create and maintain data management documents such as data management plan (DMP), CRF completion guidelines, edit check specifications, data review guidelines, data dictionary, critical variables list, and annotated CRFs.
* Perform data listing review and clean-up. Reconcile data from different data resources. Provide high quality data for final analysis.

**EDUCATION**

**Towson University, Towson, Maryland**

Bachelor of Science (Business Administration-Marketing)

**Certifications**

RAVE SDBE - DATA MANAGERS FOR RAVE EDC  
RAVE EDC SDBE FOR DATA VALIDATIONS