Sahitya G

SAS Programmer II - PRA Health Sciences

Dallas, TX 75204
sahityag4_euh@indeedemail.com - 571-266-7718

WORK EXPERIENCE

SAS Programmer II

PRA Health Sciences -

2015-01 - Present

Responsibilities:
* Reviewed Protocols, Case Report Forms (CRF), and Statistical Analysis Plans (SAP) for clinical trials.
* Collaborated with Biostatisticians and team mates to develop analysis data sets, tables, figures and listings.
* Extensively worked on validation of SDTM and ADaM datasets using double programming.
* Mapped legacy data in SDTM format and created analysis datasets based on ADaM standards.
* Reviewed open CDISC report, Reviewer's Guide and eSUB packages (SDTM/ADaM).
* Validated and Developed Analysis datasets as per ADaM specifications, tables, listings and graphs as per mockups in SAP.
* Generated various Efficacy and Safety Listings, Tables and graphs for several studies.
* Involved in creating the data definition table and SAS transport files for submission as part of the final report to the FDA.
* Managing data issue tracker and coordinating with CDM Lead, Programming Lead and Biostatistician for queries related to clinical study data, analysis, report generation and final delivery.
* Involved in creating ADaM's and ADSL datasets.
* Producing Top line efficacy results and creating analysis dataset for these efficacy results as per the specifications of client.
* Prepared analysis datasets from excel files using Import Techniques for PK analysis.
* Developed several Ad-hoc reports as per client requests.
* Experience in producing RTF, PDF, HTML formatted files using SAS ODS facility.
* Ensure overall consistency of a project including macro definitions, debugging programs, and documentation.

Environment: SAS EG, Base SAS, SAS Proc, SAS Macros, SAS ODS, Oracle, SAS Graphs, Gplot.

SAS Programmer

Accenture -

2014-05 - 2014-12

Responsibilities:
* Analyzed clinical trial data and generated Tables, Listings and Graphs using MACRO, GRAPH and SQL.
* Extensively worked on ad-hoc reports.
* Review clinical study protocol, Case Report Form (CRF), SDTM specification, ADaM specification and annotate eCRF according to SDTM variables.
* Performed quality checks on the existing table, listing and figures, tested and debugged SAS programs against data.

* Create SAS programs for SDTM mapping of raw datasets.
* Programmed Datasets and Created TLF's.
* Compare data structures, formats and variables using Proc Compare.
* SAS Macros were used extensively in analysis of standard clinical data and generated reports, graphs, listings, summaries, tables.
* Collaborated with statisticians and data management team to generate and resolve queries.
* Developed, modified SAS programs and supported lead programmer in electronic submission.
* Formatted HTML and RTF reports, using SAS - output delivery system (ODS).

Environment: SAS 9.2, Base SAS, SAS Macros, SAS ODS, SAS Proc, UNIX, Excel, SAS Graphs, Gplot.

Clinical Analyst

Medreich Limited -

2011-08 - 2013-12

Responsibilities:
* Responsible for extracting, cleaning, manipulating, transferring and managing clinical data from the database and create SAS data sets.
* Understand study documents (Protocol, eCRF, Annotated CRF and SAP).
* Knowledge and understanding on Bioavailability, Bioequivalence and Biowaiver studies.
* Worked with clinical data management team for creating annotated CRF.
* Preparing new datasets from raw data files and modify existing datasets using SET, MERGE, SORT, FORMATS, FUNCTIONS and CONDITIONAL STATEMENTS, if required.
* Involved in writing SAS codes to extract and validate clean data to analyse clinical data (validation, analysis and report generation).
* Involved in development, validation, testing and enhancement of SAS programs to generate TFLs based on SAP.
* Created reports in different formats like RTF, PDF and HTML using SAS output delivery systems (ODS).
* Debugging and correcting the syntax and semantic errors in the code.
* Participated in study specific meetings, attended project team meetings, worked closely with the cross functional team to meet the timelines.

Environment: SAS 9, Base SAS, SAS ODS, UNIX, SAS/ACCESS, EXCEL/ACCESS.

EDUCATION

Bachelor's in Pharmacy

MGR Medical University - Chennai, Tamil Nadu

2007 - 2011

SKILLS

CONDITIONAL RANDOM FIELD, CRF, DATASETS, HTML, ODS

ADDITIONAL INFORMATION

CORE COMPETENCIES:

* Qualified Professional with Base SAS certification backed by Master's Degree in Pharmaceutics, accented with the latest trends and techniques of the field, determined to carve a successful and satisfying career.
* Implemented CDISC standards, manage CDISC database for several studies by strong understanding of CDISC SDTM models and experience in converting data to SDTM datasets.
* Expertise in creation of SDTM and ADaM specifications for Phases I, II and III studies.
* Provided analytical support to the statisticians by performing SDTM and ADaM in the production of Clinical Study Reports and verify the final reports against the generated reports.
* Created and validated Table, Listings, and Figures by using ADaM datasets.
* Extensive Knowledge of Statistical Analysis Plan (SAP), Standard Operating Procedures (SOP), Protocols of Clinical trials and CRF forms.
* Conversant with cGLP, cGMP, ICH, GCP, FDA guidelines.
* Possess extensive knowledge of SAS software with a comprehensive understanding of its contents like SAS/BASE, SAS/MACRO, SAS/STAT, SAS/GRAPH, SAS/ODS, SAS/SQL, etc.
* Data Management skills like merging, handling missing values, reading raw data sets, creating data structures, handling programming errors, accessing and managing data, appending, concatenating, interleaving of datasets.
* Extensive knowledge on procedures like PROC REPORT, PROC FREQ, PROC MEANS, PROC UNIVARIATE, PROC TRANSPOSE, PROC TABULATE, PROC FORMAT and PROC SORT.
* Usage of SAS/MACRO for creating Macro variables, Macro programs and Auto call macro library to modify existing SAS programs for ease of modification while maintaining consistency of results.
* Hands on experience in importing techniques like SQL pass through facility, SAS Access, SAS Connect and expert in implementing SAS functions and applications for data cleaning, programming, reporting, and documentation.
* Expertise in analysis of Visit Windowing, Missing data handling using LOCF, BOCF, WOCF concepts and created analysis files specifications for various therapeutic areas.
* Experience with Data Validation, designing Edit check programs and parallel development of tables & listings for project level programs.
* Experience in usage of Pinnacle 21 validation process and global regulatory submission as per CDISC standards.
* High proficiency in creating output files in a variety of formats including EXCEL, RTF, HTML, PDF using SAS/ODS and SAS/EXPORT for reporting and ad-hoc reports for presentation.
* Experience in creating tables and listings for Integrated Summaries of Safety (ISS) and Efficacy (ISE) as per the specifications.
* Highly motivated, positive and goal oriented with analytical approach and conceptualization.

TECHNICAL EXPERTISE:
Statistical Tools: SASv9.0/9.1/9.2, SAS/BASE, SAS/STAT, SAS/SQL, SAS/ODS, SAS/MACRO, SAS/GRAPH, SAS/ACCESS, SAS/CONNECT, SAS/ETL
Programming Languages: C, HTML, SQL
Operating System: Windows XP/ NT/2000/2003/2008/Windows 7, UNIX
Databases: Oracle Clinical, MS SQL Server, Medidata Rave, Inform, MS Access
Office Tools: MS office (Word, Excel, Power point)