Shirisha Namasani, M.Sc.Botany
Statistical Programmer
Email:Sirisha.namasani@gmail.com
Phone: 7993566121

Areas of Expertise: Clinical Research, SAS Programming, CDISC SDTM, CDISC ADaM , TLF's, GCP, CRF- Annotation

Summary

- Experience in CDISC standards and Models such as Study Data Tabulation Model, Analysis Dataset Model.
- Familiar with standard dictionaries such as MedDRA and WHO Drug dictionaries.
- Experience Working closely with cross functional teams in achieving timelines and deliverables with highest quality.
- Experience in creating annotated CRF, .XPT files
- Have good Knowledge in creating TLFs from ADaMs/Derived data based on the mock-shells/TLF specification.
- Knowledge in understanding of clinical trial Protocol, SAP (Statistical Analysis Plan), and CRF (Case report Form).
- Have knowledge about Clinical data management and clinical trial process.
- Effectively communicate within team and be proactive in team meetings.

Professional Experience

- ❖ Associate Stat Programming at Aston Carter , Bengaluru
  For IQVIA , Bengaluru   *Mar 2023 – Sep 2023*

- Extensively using of BASE SAS, Macros, SQL, Statistical Procedures for Data management, data validation, data analysis and Reporting.
- Preparing new Datasets from raw data files using Import Techniques and modified existing datasets using Set, Merge, Sort, and Update, Formats, Functions, and conditional statements.
- Creating analysis data sets and performed statistical analysis on raw data to achieve safety and efficacy objectives of the study using SAS procedures like Proc Means, Proc Freq, Proc Sort etc.
- Generating of SDTM Datasets as per Implementation guide and Specifications
- Preparing of mapping specifications of raw datasets to CDISC SDTM Standards
- Creating of ADAM datasets like ADSL and BDS structured domains
- Validating derived datasets and other coded programs using PROC COMPARE.
- Creating and validating of datasets according of CDISC SDTM standards following specifications document.
- Converting the datasets into transport (.XPT) for e-submission to FDA
- Performing quality check on SAS programs/outputs created by another Statistician/SAS Programmer
- Preparing, maintaining, and archiving of SAS programming documentation and collaborate in establishing and maintaining SOPs related to SAS programming.
- Worked on SDTM Mapping Specifications, programming SDTM datasets using the annotated CRF's and SDTM Implementation Guide .
- Validated SDTM datasets from raw datasets as per the Specification document.
- Worked on ADaM specifications for safety analysis datasets ADSL, ADAE, etc.
- Generated ADaM datasets from SDTM datasets as per the ADaM spec's and the SAP.

❖ Statistical Programmer
   Clinsoft Technologies Pvt Ltd, Hyderabad   *Feb 2021 – Dec 2022*

- Created datasets in SDTM (3.2) standards from raw datasets.
- Modified existing datasets using Set, Sort, Merge, Formats, Functions, Conditional statements and procedures.
- Mapping the received data from CRF into CDISC SDTM standards.
- Performed CDISC mapping for current trials and classified data into domains such as Demographics (DM), Disposition (DS), Medical History (MH), Concomitant Medications (CM), Exposure (EX) and Adverse Events (AE) etc.
- Generated Tables as per the Mock shell given in the Statistical Analysis Plan (SAP).
- Generated safety tables, which also involved in analysing data and generating Reports.
- Involved in the development of tables like Summary of Disposition, Summary of Demographics, Summary of Concomitant Medications.
- Formatted RTF reports using SAS/ODS (Output Delivery System).
- Involved in multiple projects and interacted with other Programmers, statisticians and data managers to analyse data.
- Created Macros to optimise the code for Demographics and baseline characteristics.
- Created reports using the PROC REPORT for the submission as per the FDA regulations and company standards.

Education

- M.Sc (Botany) , Satavahana University, India , 2022

Certifications

- SAS certified specialist base programming using SAS 9.4
- Certificate number - 2ZV7H2ECBJF4Q13M
- Certification Url : https://www.certmetrics.com/SAS/public/verification.aspx

Personal Details

- Full Name: Namasani Shirisha
- Date of Birth: 20Aug1998
- Address: Shivaji nagar Godavarikhani (505209)
- Linkedin profile: https://www.linkedin.com/in/shirisha-namasani-1a69471b0

Declaration

I hereby declare that the information given above is genuine to the best of my knowledge & if you give an opportunity to work in your organization, I will put my best efforts.

(Shirisha)