**Gayathri G**

**Senior Statistical programmer**

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EXPERIENCE SUMMARY

* Sr. Statistical Programmer with 8 years of experience in design, analysis, program development

and Quality Check (QC) in Pharmaceutical and Clinical Research Organizations.

* Hands on working experienced in Phase II-III of clinical trials and various therapeutic areas including Oncology, Rare Diseases, Neurology, Immunology, Ophthalmology etc.
* Extensive working knowledge in handling complex transformations using Base/SAS, SAS/STAT, SAS/ Macros, SAS/SQL and SAS/Graphs
* Expertise in creating SDTM datasets and SDTM mapping specifications as per requirement and standards.
* Strong working knowledge in analyzing the clinical trial data and generating reports as per company standards in compliance with CDISC guidelines for Phase (I- IV) Clinical Trial studies
* Worked in creation of annotated CRF by using Adobe professional
* Experience in creation of SDTM datasets and validated those datasets
* Expertise with CDISC guidelines while producing Safety and Efficacy SDTM and ADaM Datasets, Tables, listing and Graphs.
* Experience in writing SDTM Mapping specifications and ADaM Specifications.
* Expertise in Building ADAM datasets including Complex efficacy datasets like ADRESP, ADTTE and other datasets like ADEX as per the Analyses mentioned in SAP.
* Experience in Validating the datasets and Tables by using Double programming Technique and compliance checks by using Pinnacle 21
* Good Knowledge on RECIST Criteria (1.0&1.1) and survival Analysis FDA submissions by reviewing define.xml
* Involved in FDA submissions by reviewing define.xml
* Proficient in using SAS/ODS to create ad-hoc RTF, PDF and Listing output reports
* Wrote and reviewed specifications for modifying existing Standard Macros
* Programmed Edit Checks programs to create reports for data cleaning and data validation
* Experience in creation of graphs by using PROC SGPLOT
* Good Knowledge in statistical procedures like PROC-PHREG, PROC GLM, PROC ANNOVA, PROC T-TEST, PROC LIFETEST.
* Good exposure in Developing and debugging SAS Macros that helps in re-usability of code and
* automating SAS programs.
* ● Extensively used Do loops (Do, Do While, Do until etc) and Arrays for the Derivation of
* Complex Efficacy end points using the Clinical data, date imputations,
* Worked on Medidata Rave to optimize Clinical process to ensure integrity for accurate implementation with study endpoints. Worked with Various Deliverables like DMC, IA (Interim Analysis)
* Worked extensively with Advance Analysis Actions, Calculations, Parameters, Background images, Maps, Trend Lines, Statistics, and Log Axes. Groups, hierarchies, sets to create detail level summary report and dashboard using KPI’s in TABLEAU environment to create dashboards like weekly, monthly, daily reports using tableau desktop & publish them to server
* Worked with various Deliverables like DMC, IA (Interim Analysis)
* Ability to work in a cross-platform environment that includes Windows and UNIX Operating Systems
* Excellent communication skills, good at multi-tasking and a good team player meeting timelines

SKILLS

SAS Skills SAS/BASE, SAS/STAT, SAS MACROS, SAS SQL, SAS/GRAPH

CDISC SDTM 3.2, ADaM 1.1 and Define.xml (1.0 & 2.0)

Databases Oracle Clinical, Rave, Inform, SAS clinical

Operating Systems Windows XP /7/8, Linux, UNIX, Mac

Developer Tools SAS 9.2, SAS Studio, SAS Enterprise Guide 9.4

Tools MS office, Pinnacle Enterprise 3.1.4

Languages HTML, SQL, XML.

Visualization Tools Tableau 10.3.2, QlikView, Spotfire, Power BI, DOMO, Google Analytics, Alteryx

EXPERIENCE

**Apellis Pharmaceuticals Jul 2021 – Present**

***Senior SAS Clinical Programmer***

Responsibilities:

* Developed programs for generating Safety and Efficacy Tables, Listings and Figures (TLF) as per Statistical Analysis Plan (SAP) and Mock Shells.
* Experience in creation of annotated CRF with SDTM variables.
* Created and reviewed SDTM and ADaM mapping specifications.
* Worked extensively on various SDTM domains and their SUPPQUAL and updated the Specs and Program status respectively.
* Worked on SDTM domains based associated person SDTM IG (AP).
* Worked on Trial Design Domains for early and late phase.
* Mapped current versions of MedDRA and WHODrug dictionaries with AE and CM datasets respectively.
* Mainline responsibility for working on different clinical trials data like Demographic, Adverse Event (AE), Laboratory-chemistry/Hematology/Urine analysis, Vital signs and Disposition etc.
* Developed and validated Oncology specific domains Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS).
* Involved in production of datasets and TLF’s for ISS. Generated Ad-hoc reports as per the data manager, medical writer and statistician request.
* ⮚ Extensively utilized SAS Macro facility to create datasets & TLF’s.
* Generated ADaM datasets and produced Tables, Listings and Graphs (TLG) programming based on Mockup shells
* Performed open-CDISC validation on Performed open-CDISC validation on SDTM, ADaM and Define.XML.
* Developed and validated safety and efficacy tables, listings, and figures for Summarizing clinical

trial data according to the SAP (Statistical Analysis Plan).

* Involved in FDA submissions and developed numerous Ad Hoc reports as required by medical writers and FDA.
* Worked on unblinding process for different therapeutic areas.
* Created and reviewed Define.XML and SDRG.
* Modified existing Macros as per the requirement.
* Act as POC/back up lead for small team projects in providing technical and process-related guidance to team members and leading sub-team project with minimal or no supervision.

**IQVIA Mar 2017-Jan 2021**

***Senior Statistical Programmer***

Responsibilities:

* Created SDTM datasets as per CDISC standards by analyzing Statistical Analysis Plan (SAP) and SDTM Mapping specification documents
* Working extensively on various SDTM domains and their SUPPQUAL and updated the Specs and Program status respectively
* Created and validated Oncology specific domains Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS) and their respective ADaM domains like ADRS, ADTTE, etc.
* Generated efficacy analysis outputs for Progression Free Survival (PFS), OVER ALL Survival (OS) and Change from Baseline
* Created Graphical outputs by Using Proc SGPLOT for Kaplan Meier Method for Survival Analysis
* Extensively used PROC LIFETEST with Kaplan Meier method to predict survival analysis and

study the time to events, efficacy endpoints of clinical trials

* Worked on QC, to validate peer programmers code by doing Double Programming Technique and checking SAS logs free of errors, warning and unwanted notes
* Performed compliance Checks by using Pinnacle-21
* Worked with submission team, in creation of Define.XML (metadata specifications document, datasets into transport (XPT) files)
* Involved in Reviewing SDRG and ADRG as a part of the submission
* Mentoring new joiners to help them understand SOP's, Process Manuals and other standards followed within organization
* Interacted with Biostatistician to understand the details provided in SAP shells to create accurate tables and listings

**Covance (Labcorp) Sep 2014 – Feb 2017**

***SAS Clinical Programmer/Analyst***

Responsibilities:

* Understanding of study documents and CRF annotations and been part of team in reviewing of

Protocols and Statistical Analysis Plan (SAP)

* Created SDTM domains like AE, EX, LB, CM, MH…etc based on SDTM mapping specifications and Validated them
* Created ADaM domains like ADLB, ADAE., etc based on ADaM specifications and validated them
* Worked on ADaM Dataset derivations like Treatment Emergent Adverse Event, Visit Windowing, Baseline, DType (LOCF) based on SAP
* Converting Local labs data into central labs by using Unit Conversion dataset
* Created and Validated Safety and Efficacy related analysis datasets, Summary tables, Listings and Graphs (TLG’S)
* Worked with clinical data management team for creating annotated CRF. Created SAS data sets from raw clinical data sets of clinical trials
* Extracted data from various data sources like Oracle Clinical 5.0.1 etc and converted external data into SAS raw datasets
* Developed Edit checks for different studies and in reporting those issues to the data manager in excel sheet
* Experience in importing and exporting complex internal data to and from Microsoft Excel and

Microsoft Access using PROC IMPORT and PROC EXPORT

* Produced Ad-hoc reports, listings, tables using Proc Report Validated the generated reports according to QC tracking sheet
* Working on many other Ad-hoc urgent priority tables request from other team on daily basis
* Carried out all activities according to SOPs working within the framework of the Quality

Management System and to Good Clinical Practices (GCPs)

EDUCATION

* Masters in health informatics- IUPUI
* Doctor of Pharmacy-Andhra University