SINTAYEHU GEBRETEKLE

Data Scientist | Clinical SAS Programmer | R Programmer

SAS Certified Base Programmer for SAS 9 and SAS Certified Advanced Programmer for SAS 9 with 10+ years of experience and master's degree in Biostatistics.

Experience as a Clinical SAS Programmer in Pharma/CROs and extensively involved in programming of ADAM Datasets, Tables, Listings and Graphs.

Maintained QC checklist, Data Issue log, Analysis Dataset Specification Document, Programming Plan, QC Plan documents specific for each study.

Excellent experience in SAS/BASE, SAS/MACRO, SAS/STAT, SAS/GRAPH, SAS/ODS, SAS/ENTERPRISE GUIDE and SAS/SQL in Windows and UNIX platforms.

Experience in RStudio in producing Excel, RTF, HTML and PDF formatted files and qc'ing ADAM datasets using RStudio.

Involved in the production and validation of analysis datasets produced both internally and also oversighting experience with major CRO companies.

Experience in handling multiple tasks independently in a dynamic and good experience working in a team comprised of various professions.

PROFESSIONAL EXPERIENCE

Present – 2018

Principal Statistical Programmer

GlaxoSmithKline Inc. — Collegeville, PA

- Provide Statistical Programming support using CDISC standards. Primarily working with SDTM but also involved in macro creation and writing generic programs.
- Created specifications and program mapping of complex SDTM domains from internal Clinical Data Management System (CDMS) and client specifications, including the specification/mapping of custom domains, supplemental qualifier (SUPPQUAL) domains.
- Created SAS programs to generate tables, listings and figures for inclusion in Clinical Study Reports, annual safety reports as requested.
- Prepared Analysis Datasets (ADaM) based on the standards of Analysis Data Model Implementation Guide ADaM Implementation Guide.
- Perform quality control on analysis datasets and tables, figures and listings programs and outputs developed by other programmers and Biostatisticians.
- Provide input to statistical analysis plan, table shells, data integration plans and verify all programs and documentations are archived.
- Created annual clinical trial safety reports for adverse events observed during clinical trials which will be submitted to health authorities. These reports are Development Safety Update Report (DSUR) and Periodic Benefit-Risk Evaluation Report (PBRER).
- R advocate within the organization, exploring the development of internal R packages and used R-shiny to create validation application for Adverse Event and Laboratory reports.
- Set-up R environment and the R packages for reading the input SAS datasets and processing the data to generate ADSL datasets by using tidyverse, diplyr and admiral package.

CONTACT

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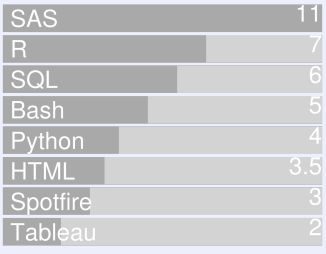
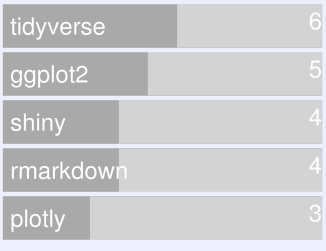
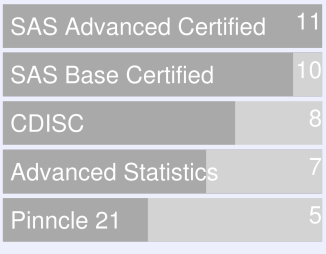
SOFTWARE SKILLS



R SKILLS



CERTIFICATIONS



*Made w/ **pagedown**.*
*Source code: **Github repo**.*
Last updated on 2022-06-15.

2018 | 2015

Sr.Statistical Programmer

Bristol-Myers Squibb — Lawrenceville, NJ

- Worked with in the Clinical Pharmacology and Pharmacometrics (CPP) group in the department of Discovery Medicine and Clinical Pharmacology to ensure all SAS programming activities are performed according to standard operating procedures.
- Write SAS programs to handle ADaM datasets both for safety and efficacy domains for Oncology trials, and programming to pool analysis datasets across multiple clinical datasets.
- Experience in the development of ADaM datasets and dataset specifications in line with sponsor standards and CDISC implementation guides for ADaM and SDTM.
- Worked with PRA Health Sciences (CRO) team to identify appropriate source data databases, and to extract and process this data to create analysis data sets, Safety Tables, Safety listings, and Plasma Concentration Graphs for clinical study team and Biostatistical review team.
- Design and maintain SAS macros for the preparation and validation of NONMEM datasets for PK and PK/PD analysis data sets for Pharmacokinetics analysis in generating AUC, Half-life, T-max, C-min, and C-max.
- Use Spotfire to visualize data for various Oncology trials and visualization of data in order to explore the clinical data for safety, tolerability and pharmacokinetics.
- Assisted progrmming for ISS and ISE integrated summary of safety tables and listings submission for the FDA.

2015 | 2014

Sr.SAS Programmer

Social & Scientific Systems, Inc. — Silver spring, MD

- Experience in manipulating large and complex CMS data by applying data extraction and data management techniques using SAS Enterprise Guide, identifying trends and patterns in data, and applying relevant analytical methods.
- Process large health care inpatient and Outpatient data for Health Services Cost Review Commission (HSCRC) in maintaining and updating SAS server dataset for enrollment, encounters and Fee-For-Service beneficiaries.
- Created tables and graphs to generate study reports for the collected requirement from the statisticians referring to the Statistical Analysis Plan (SAP).
- Process large health care data files (Medicare/Medicaid claims data) for institutional and non-institutional data types for the Maryland Health Care Commission (MHCC) project.
- Pool data from the Chronic Data Warehouse to document enrollment and costs associated with Medicare Fee-For-Service patients and compare growth rate of between Maryland and nation.
- Provide input to tableau for report visualization to develop and maintains dashboards of key performance metrics.

2014 | 2013

SAS Data Reporting

Mayo Clinic — Rochester, Minnesota

- Produces various routine and ad hoc reports for internal and external clients in evaluating a wide array of data types, including case review, medical and prescription drug claims, and eligibility data.
- Work with internal development teams to create algorithms designed to detect members with Medicare or other Commercial insurance, and to realize cost saving is met for new and existing clients.
- Worked on large, complex data files such as claims data, health tradition datasets linking and integrating data from disparate databases, and transforming raw data coming from complex ASCII files into finished reports using SAS infile, data_null, and DDE techniques.
- Transformed company old software Monarch report creation system into customized SAS reporting application using advanced features of PROC REPORT compute blocks, SAS templates, stored and compiled SAS autoexec macros.
- Automated the whole task of reporting from data extraction to sending attached e-mails, a recurring report that would have required hundreds of employee hours to produce over its lifespan, now takes no time at all.
- Write SAS utility macros that greatly helped the report automation process by reducing programming effort, increase efficiency and decrease the chances of making mistakes in manual processes.
- Provides guidance and work leadership to less-experienced programmers, and also supervisory responsibilities.

2012 | 2011

Clinical SAS Programmer

Nor Consult, LLC — Seattle, Washington

- Contributed to computer programming in clinical trial project and provided programming support for clinical trial data reporting and CDSIC SDTM regulatory submissions.
- Write Macro Program to extract data from clinical database to SAS datasets and create validation tracking spreadsheet to help communicate with sponsors.
- Develop the validation plan for the SDTM datasets for the submission and validate the datasets by parallel programming.
- Generated Safety Analysis Datasets, Tables and Listings related to Demographics, Adverse Events, Lab, Vitals, Concomitant, Drug Administration, and Medical History.
- Extensively used Statistical procedures like ANOVA, MIXED, GLM, NPAR1WAY, FREQ, UNIVARIATE, PHREG, and LIFETEST to generated descriptive statistics and Inferential Statistics (p-value, LS Means, Odds Ratio).
- Expertise in producing the customized graphs by employing SAS/GRAPH procedures PROC GPLOT, PROC GCHART and PROC GREPLAY to generate statistical graphs such as Kaplan-Meier plots, PK graphs and Mean Score graphs.
- Collaborate with Biostatistician, Data Manager, and Clinical Research Associates to identify and address data issues, inconsistencies, and data entry errors.

EDUCATION

MSc in Biostatistics

University Of Hasselt — Hasselt, Belgium

BSc in Applied Statistics

Addis Ababa University — Addis Ababa, Ethiopia