

Rajesh Iyer

Principal Statistical Programmer

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SUMMARY

Principal Statistical Programmer with 12 years in pharmaceutical and CRO programming, leading submission work for 3 approved drugs. Directs teams of up to 10 programmers on SDTM, ADaM and TLF deliverables built to CDISC standards in Base SAS and SAS/STAT, and owns FDA submissions packages that follow ICH guidelines.

EXPERIENCE

Principal Statistical Programmer

01/2021 - Present

Triangle Park Biopharma Services

Morrisville, NC

Full-service CRO biometrics group of 350 staff.

- Lead programming for 3 sponsor programs, directing 10 programmers across 14 studies and 2 FDA submissions.
- Deliver SDTM, ADaM, define.xml and reviewer's guides for an NDA approved in 2024 with no data standards findings.
- Design a SAS macro and SAS/GRAPH reporting library adopted by 4 delivery teams, cutting TLF build time by 35%.
- Establish programming plans, spec reviews and QC standards that follow CDISC standards and ICH guidelines.

Senior Statistical Programmer

03/2016 - 12/2020

Neuse River Pharmaceuticals

Durham, NC

Pharmaceutical company with a cardiometabolic and drug development pipeline.

- Programmed an integrated safety database in Base SAS from 22 studies for a drug development program.
- Pulled Oracle Clinical data with SAS/ACCESS and automated 30 daily data transfers.
- Mentored 5 programmers on ADaM design and validation.

Statistical Programmer

07/2014 - 02/2016

Cary Clinical Data Group

Cary, NC

- Validated 200 TLFs per study and wrote SAS/STAT efficacy models for 6 trials.
- Created SDTM mapping specifications for 10 legacy oncology studies.
- Automated listing checks in Base SAS for 4 data safety monitoring reviews.

SKILLS

- | | | |
|-------------|-------------------|-------------------|
| • Base SAS | • SAS/ACCESS | • FDA Submissions |
| • SAS/STAT | • SDTM | • ICH Guidelines |
| • SAS/GRAPH | • ADaM | |
| • SAS Macro | • CDISC Standards | |

EDUCATION

Master of Science

05/2014

North Carolina State University

Raleigh, NC

Statistics

CERTIFICATES

SAS Certified Professional: Advanced Programming Using SAS 9.4

02/2018

SAS