

Contact

www.linkedin.com/in/tushar-nikumbh-107a38a4 (LinkedIn)

Top Skills

SAS

Data Management

Analysis

Languages

English (Professional Working)

Hindi

Marathi

Tushar Nikumbh

Principal Biostatistician at IQVIA

Mumbai, Maharashtra, India

Summary

Experienced Biostatistician with a demonstrated history of working in the CRO & Pharmaceutical industry. Skilled in Statistics, CDISC Standards, Clinical Trials, SAS Programming, Good Clinical Practice (GCP), and Biostatistics. Strong research professional with a Master's Degree focused in M.Sc Statistics from North Maharashtra University, Jalgaon.

- Worked on Phase I to III clinical trials on different therapeutic area (Dyslipidemia (Phase II and III), Hypertension (Phase III), Rheumatoid Arthritis (Phase III), Malaria (Phase II), Nutritional (Phase II), Oncology (Phase I) and Inflammation (Phase I)).

Currently working on Inflammation and oncology trials having indication Multiple Myeloma and Solid Tumors.

- Experience on IB (Investigation Brochure), DSUR (Development Update Safety Report), Interim, Primary and Final Analysis of clinical trials.

- Writing Statistical Analysis Plan (SAP) and Preparing Mock shells.

- Experienced in reviewing of outputs before sending to client.

- Experienced in Protocol, SAP, TFL shell, CRF, DMP, etc....

- Efficacy programming using SAS and R software.

Experience

IQVIA Asia Pacific

Principal Biostatistician

August 2024 - Present (1 year 6 months)

Thane, Maharashtra, India

Role & Responsibilities:

- Working as an independent statistician to drive the study and provide end to end statistical support to one of the major FSE project.
- Reviewing protocol and providing inputs during study planning activity.
- Reviewing CRF, DMP and other documents requires in study start up activity.
- Writing Statistical analysis plan (SAP) for late phase studies (For Multiple sclerosis and Immunology).

- Preparing mock TLF's for analysis.
- Reviewing analysis dataset specification
- TFLs and ADAM review/QC of studies to ensure quality
- Reviewing SAP and mock TLF's for analysis.
- Performing and providing support on safety and efficacy programing on need basis
- Working with statistical programing team for TFLs deliverables and timeline.
- Need to regularly connect with cross function teams (CDM, Safety, PK...etc) for study updates.
- Working with client statistician and medics team to help them addressing research and scientific questions by providing stats support

ICON plc

Senior Biostatistician II

January 2023 - August 2024 (1 year 8 months)

Bengaluru, Karnataka, India

Role & Responsibilities:

- Developing and Reviewing of statistical analysis plan (SAP)
- Preparing mock shell TLF's
- Review of statistical outputs (TLF's) to ensure quality
- Review and QC of efficacy and safety ADaM datasets
- Supported to programming team for efficacy and safety logic and programing as per SAP and protocol
- Developing efficacy TFLs outputs

IQVIA Asia Pacific

4 years 9 months

Biostatistician II

May 2021 - January 2023 (1 year 9 months)

Thane, Maharashtra, India

Biostatistician I

May 2018 - May 2021 (3 years 1 month)

Thane, Maharashtra, India

Role & Responsibilities:

- Working as an independent statistician to drive the study and provide end to end statistical support to one of the major FSE project.
- Reviewing protocol and providing inputs during study planning activity.
- Reviewing CRF, DMP and other documents requires in study start up activity.

- Writing Statistical analysis plan (SAP) for phase I studies (For oncology and inflammation therapeutic area).
- Preparing mock TLF's for analysis.
- Reviewing analysis dataset specification
- TFLs and ADAM review/QC of studies to ensure quality
- Reviewing SAP and mock TLF's for analysis.
- Performing and providing support on safety and efficacy programing on need basis
- Working with statistical programing team for TFLs deliverables and timeline.
- Need to regularly connect with cross function teams (CDM, Safety, PK...etc) for study updates.
- Working with client statistician and medics team to help them addressing research and scientific questions by providing stats support

CYTEL STATISTICAL SOFTWARE & SERVICES PRIVATE LIMITED

Associate - Biostatistician

November 2017 - April 2018 (6 months)

Navi Mumbai, Maharashtra, India

- Working as an independent statistician to drive the study and provide end to end statistical support to one of the major FSE project.
- Completed the client specific trainings and SOPs.
- Drafted the SAP for one nutritional trial.

Cognizant

Jr. Analyst -Biostat and Reporting

May 2016 - October 2017 (1 year 6 months)

Mumbai Area, India

Role & Responsibilities:

- Review of statistical analysis plan and mock shell TLF's
- Preparing mock shell TLF's
- Review of statistical outputs (TLF's) to ensure quality
- Review and QC of efficacy and safety ADaM datasets
- Supported to programming team for efficacy and safety logic and programing as per SAP and protocol
- Developing efficacy TFLs outputs
- Raw data review and cleaning

Ipca Laboratories Limited

Biostatistician

November 2014 - May 2016 (1 year 7 months)

Mumbai Area, India

Job Description:-

- 1) Estimate sample size for clinical studies and BE studies.
- 2) Preparation of tables, listing and graphs using SAS.
- 3) Preparation of SAP for clinical study.
- 4) Analysis of Data using SAS software.
- 5) Preparing e- CRF database in SAS Pheedit 3.01 and data management plans.
- 6) Preparing SAS program for clinical studies.
- 7) Preparation, execution, reporting and documentation of final statistical analyses.

Education

North Maharashtra University

Master's degree, Statistics · (2012 - 2014)

North Maharashtra University

Bachelor's degree, Statistics · (2009 - 2012)