SUKALPO SAHA

R and Shiny Developer with 6.5+ years of experience in the Pharmaceutical Industry

Developing production ready R packages and Shiny applications which enable creation of company standard ADaM data sets, TLFs, and interactive exploration of statistical analysis results, to support medical writing and/or publishing of the clinical study reports, planned analysis, and any other ad hoc result.

Passionate about innovating, modernizing statistical programming and reporting using open-source tools and technologies (R/Python); building web applications with cutting edge UI/UX and data visualizations.



Present-2023



Principal Statistical Data Scientist

- Maintaining the admiralvaccine R package (Vaccine extension of admiral) within the pharmaverse group
- of packages · Co-developer of the admiralpeds R package (admiral package extension for pediatric trials).
- · Contributing in development of the R package(s) to create Pfizer Specific ADaM data sets and TLFs.
- · Contributed in developing the R Shiny Web application cvars wrapped as an R package to

generate interactive forest and volcano plots for for adverse event and FDA Medical Queries (FMQs) analysis outputs for inclusion in submissions to the

- · Create/maintain customized CI/CD pipelines for R packages using Github Actions.
- Training/mentoring associate/junior programmers and data scientists in developing R packages and Shiny applications.

2022 2021



Senior Programmer (R & Shiny)

- Work with clinical programmers/statistical analysts and other internal customers to understand business review, writing unit tests, end-to-end tests, and requirements and industry regulations.
- · Design, create, maintain, and develop standard tools and applications for internal customers.
- · Provide scalable, secure, and modern UI/UX when required.

Bangalore, IN

Mumbai IN

- · Provide high quality and efficient code, perform code sharing of best practices.
- · Hands-on with clinical trial data to create appropriate and high-quality tools.
- · Deliver documentation and training material for standard tools and applications.

2021 2017



Business Process Lead (Team Lead)

- Team lead for the Centralized Statistical Monitoring and Quality Tolerance Limit (QTL) team consisting a group 10-12 Statisticians/Statistical Programmers.
- · Co-developer of the in-house R package used in QTL Analysis (based on Bayesian Hierarchical Model) for Key Risk Indicators i.e. Adverse Events, Serious Adverse Events, Ongoing, Baseline Protocol Deviations and also Study specific parameters.

Mumbai, IN

- Developed a Shiny application to trigger the QTL Reports quarterly for each study.
- · Helped study teams set up and implement QTLs in their respective studies, and take actions in case of a breach
- · Created a Shiny application to monitor the impact of Covid-19 on Clinical data quality based on Adverse Events, Protocol Deviations, Missing Visits etc.



Contact

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Programming Languages

Shiny SAS **JMP** Python

Domain Knowledge

Statistical Analysis **Data Analytics** CDISC Standards Good Clinical Practice Tables and Figures

Languages

English Bengali Hindi



2017



Specialization: Biostatistics, Operations Research

Class: First

2015



B.Sc in Statistics

♥ Kolkata, IN

♥ Hyderabad, IN

Major: Statistics

Minors: Economics, Mathematics

Class: First

☐ SKILLS OVERVIEW



2023

2020

PUBLICATIONS/PRESENTATIONS

Clinical Visual Analytics for Review and Submission

Presentation for PHUSE SDE India

♥ Chennai, IN

Utilizing a Bayesian Hierarchical Model to Design Quality Into a Clinical Trial
 Poster for DIA Global Annual Meeting

Virtual