

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.

EXPERIENCE

Present-
2023



Principal Statistical Data Scientist

Mumbai, IN

- 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 adverse event and FDA Medical Queries (FMQs) analysis outputs for inclusion in submissions to the FDA.
- 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
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2021



Senior Programmer (R & Shiny)

Bangalore, IN

- Work with clinical programmers/statistical analysts and other internal customers to understand business 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.

- Provide high quality and efficient code, perform code review, writing unit tests, end-to-end tests, and 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
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2017



Business Process Lead (Team Lead)

Mumbai, IN

- 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.

- 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

R
Shiny
SAS
JMP
Python

Domain Knowledge

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

Languages

English
Bengali
Hindi

EDUCATION

2017



University of Hyderabad

M.Sc in Statistics

Hyderabad, IN

Specialization: Biostatistics, Operations Research

Class: First

2015



University of Calcutta

B.Sc in Statistics

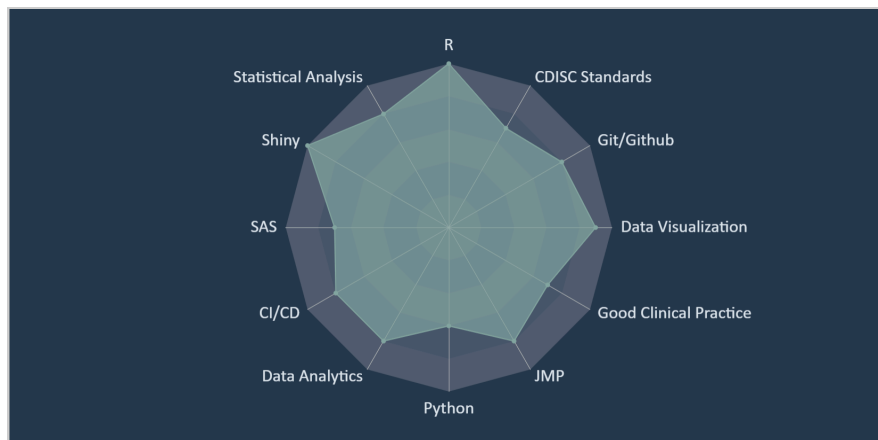
Kolkata, IN

Major: Statistics

Minors: Economics, Mathematics

Class: First

SKILLS OVERVIEW



PUBLICATIONS/PRESENTATIONS

2023

Clinical Visual Analytics for Review and Submission

[Presentation](#) for PHUSE SDE India

Chennai, IN

2020

Utilizing a Bayesian Hierarchical Model to Design Quality Into a Clinical Trial

[Poster](#) for DIA Global Annual Meeting

Virtual