

# 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  
|  
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  
|  
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

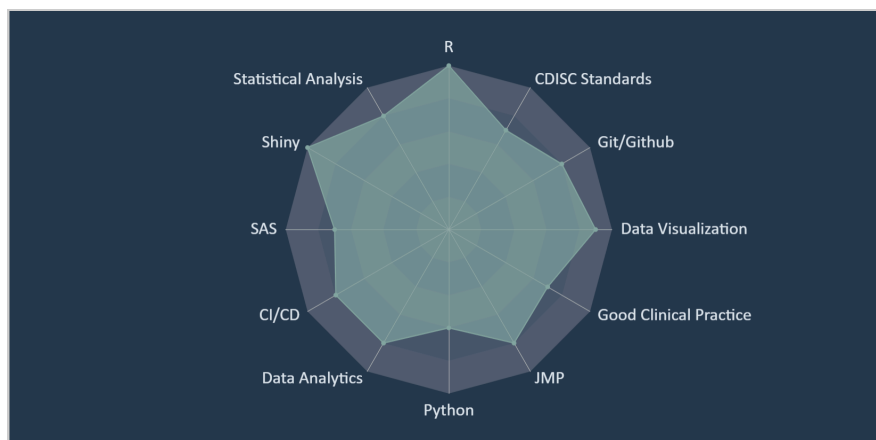
Kolkata, IN

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