

SUKALPO SAHA

R and Shiny Developer with 6.5+ years of working experience in the pharmaceutical industry.

Developing production ready R packages/Shiny applications which enable interactive exploration of statistical analysis results to support medical writing and/or publishing of the clinical study reports, planned analysis, and other ad hoc result exploration. Core developer of the R package(s) enabling creation of company standard **ADaM data sets, tables and figures**.

Familiar with **CDISC Standards** including **SDTM** and **ADaM**. Also having experience in various aspects of Risk Based Quality Management (RBQM) eg. Quality Tolerance Limits and Statistical Monitoring.

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

2023-
Present



Principal Statistical Data Scientist

📍 Mumbai, IN

- Maintainer for 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 to create Pfizer Specific ADaM data sets and TLFs.
- Contributed in development of an 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.

2021
|
2022



Senior Programmer

📍 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.

CONTACT INFO

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PROGRAMMING LANGUAGES

R
Shiny
SAS
JMP
Python

DOMAIN KNOWLEDGE

Statistics
Statistical Modeling
CDISC Standards
Good Clinical Practice
Tables and Figures

2017
|
2021



Business Process Lead (Team Lead)

📍 Mumbai, IN

- Team lead for the Centralized Statistical Monitoring and Quality Tolerance Limit (QTL) team consisting of a group of 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.
- Developed a Shiny application for understanding the impact of Covid-19 on Clinical data quality based on important parameters such as Adverse Events, Protocol Deviations, Missing Visits etc



EDUCATION

2017



University of Hyderabad

M.Sc in Statistics

📍 Hyderabad, IN

Specialization: Bio Statistics, Operations Research

Class: First

2015



University of Calcutta

B.Sc in Statistics

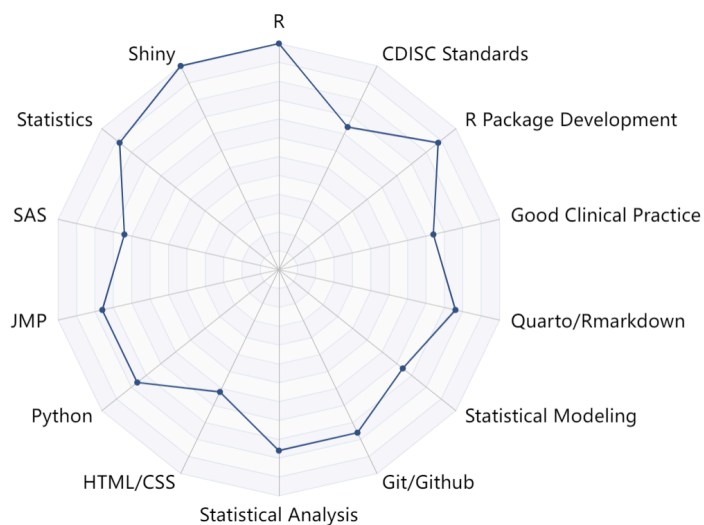
📍 Kolkata, IN

Major: Statistics

Minors: Economics, Mathematics

Class: First

SKILLS OVERVIEW



PUBLICATIONS/PRESENTATIONS

- 2020 • **Utilizing a Bayesian Hierarchical Model to Design Quality Into a Clinical Trial**
[Poster](#) for DIA Global Annual Meeting 📍 Virtual
- 2023 • **Clinical Visual Analytics for Review and Submission**
[Presentation](#) for PHUSE SDE India 📍 Chennai, IN
- 2023 • **Creating Climate Crisis: Indian Case**
[Article](#) for Indian Researcher-A Bi-annual Interdisciplinary Journal 📍 Mumbai, IN