

Experts in clinical trial reporting
and statistical programming

Shafi
Consultancy

At Shafi Consultancy, we know statistical programming inside out.

In today's fast-paced drug development environment, it's vital that pharmaceutical sponsors make the most of their valuable clinical trial data. At Shafi Consultancy, we offer a suite of statistical programming products and services to help pharmaceutical sponsors extract insight from their data efficiently, accurately, and reliably.

The Shafi Consultancy Difference

- Our leadership team and expert teams of programmers have decades of experience in creating efficient clinical analytics solutions.
- We invest in standardised programs and efficient macros to produce work more quickly and cost-effectively while retaining industry-leading quality.
- Our low staff turnover ensures exceptional knowledge retention, and we always aim to retain the same team for clients.
- A streamlined customer-focused project delivery process ensures Quality by Design.
- We design our templates and documents to minimise the time for review and mitigate the client oversight burden.
- Our longstanding track record of excellence in specialist NONMEM and CDISC programming enables us to navigate the challenges of these often-complex deliverables.
- We maintain a 'bench' of programmers to allow us additional flexibility and capacity for fast turn-around projects.

Our Services

Clinical Trial Reporting Services

Our services are underpinned by our efficient macros and applications and include:

- Programming and validation of Tables, Listings, Figures and Analysis Datasets
- Independent QC, double programming
- Data quality and consistency checking
- Template programs and analysis macros
- Statistical support

CDISC Services

Our experts have detailed domain knowledge of CDISC requirements across therapeutic areas. CDISC services include:

- Generation and validation of CDASH, SDTM and ADaM standard datasets or conversion of legacy data
- Implementation of client-specific CDISC standards in their environment
- Complete generation of regulatory specifications required for submission such as Define.XML and Data Review Guides

NONMEM Programming Services

We have delivered specialist NONMEM services for over two decades and understand the specific challenges of navigating their complex workflows. Our services are underpinned by standard macros and processes to increase efficiency, and deliverables include:

- Template specifications to ensure consistency and quality across studies, and save time
- Creation of NONMEM and datasets, summary tables, and patient profiles
- Reports on all covariates, including a summary of issues
- Traceability reports and summary tables

METALYTICS

Clinical Trial Reporting Application

Metalytics is an application designed by programmers for programmers using metadata-generated automation to streamline clinical trial reporting. Available as a standalone enterprise application or as part of a services package, Metalytics enables sponsors and CROs to:

- Improve efficiency and accuracy for programming tasks
- Ensure oversight of global resources and workflows
- Maintain traceability
- Implement standards management

Metalytics underpins many of our services offerings enabling us to deliver quality at speed.

Our Work

Shafi Consultancy works with a portfolio of clients worldwide, including pharmaceutical companies, biotechnology companies, and CROs. Our work spans from strategic consultancy advising on processes and development of metadata-driven solutions to ongoing engagements providing a virtual extended team to sponsors and CROs alike for clinical trial reporting, CDISC, and NONMEM services.

What our Clients Say

> *Shafi Consultancy analysed a very large and complex database for us, a task that we consider challenging enough to justify Shafi's inclusion as second author of the resultant publication.*
>
> Roche

> *Shafi Consultancy did some very complex and important data transformations for us for high profile multiple trials. They managed the communications between the functions as well as the validation of the programming during these very tight timelines.*
>
> Boehringer Ingelheim

Our credentials

Shafi Consultancy was founded in 2001. With established presences in the UK and Bangladesh, the majority of our team have advanced degrees in Statistics or related disciplines and have become recognised as thought leaders in statistical programming and trusted partners to the industry. Team members regularly share their insights at PhUSE events and other industry conferences.

To learn more, visit **www.shaficonsultancy.com** or contact us at **info@shaficonsultancy.com** to arrange an exploratory discussion.