

Quality | Experience | Value | Expertise



veeda biometrics

Veeda Biometrics

Veeda Biometrics; a division of Veeda Clinical Research with offices in Belgium, France, India, and the U.S.; has over 20 years of experience in all phases and designs of clinical research, spanning across various therapeutic areas. Veeda Biometrics is specialized in providing high quality data management, statistics, and report writing services in accordance with regulatory standards.

Veeda Biometrics is in an unparalleled position to meet both the regional and global needs of clients and deliver a unique service offering combining the quality and experience of the West with the intellectual ability and tireless work ethic of the East at Eastern prices.

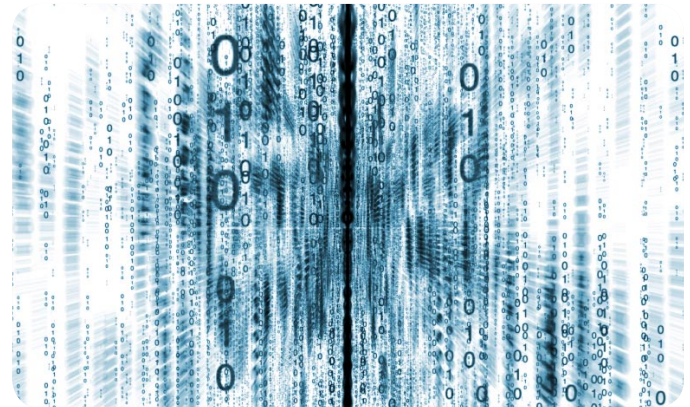
All services and systems are tailored to fit the various clinical trial needs of clients, from individual stand-alone services to outsourcing of large studies, and are governed by well defined SOPs which are compliant with regulatory requirements such as ICH/GCP and FDA 21 CFR Part 11.

Through the close collaboration with other Veeda Clinical Research departments, Veeda Biometrics has gained extensive experience in early phase clinical development, including oncology, and can make use of the knowledge and experience of Veeda CR's pharmacology

experts. Involvement in Phase I and II studies, from initial planning to report writing, provided a sound insight in pharmacokinetic and pharmacodynamic processes in various domains.

The services offered by Veeda Biometrics group include

- Clinical Data Management
- Statistical Analysis and Programming
- Medical Writing



Services: Clinical Data Management

The clinical data management team is involved in all aspects of the clinical trial process, from development of the protocol till report writing. Veeda has implemented industry recognized and accepted data management systems which enables to deliver high-quality outputs with confidence. Veeda provides direct, on-line access to a project-specific database allowing on-screen generation of various reports, set according to the customer's requirements. The broad experience of the European group, both in all stages of development and in all therapeutic areas, is an added value across all the phases.

The Veeda team has extensive data management experience across a broad range of therapeutic areas, using both paper and EDC systems. Data Management applies quality norms and procedures to complete complex clinical programs successfully. Veeda's expert trained resources work with customers internally and externally to ensure each study is accomplished using the efficient technologies available.

Clinical Data Management Services include

- CRF Design
- Database Design (Paper/EDC)
- Data Entry /Data Validation
- Data Coding
- SAE Reconciliation
- Medical Review
- Protocol Violations
- Data Mapping (CDISC)



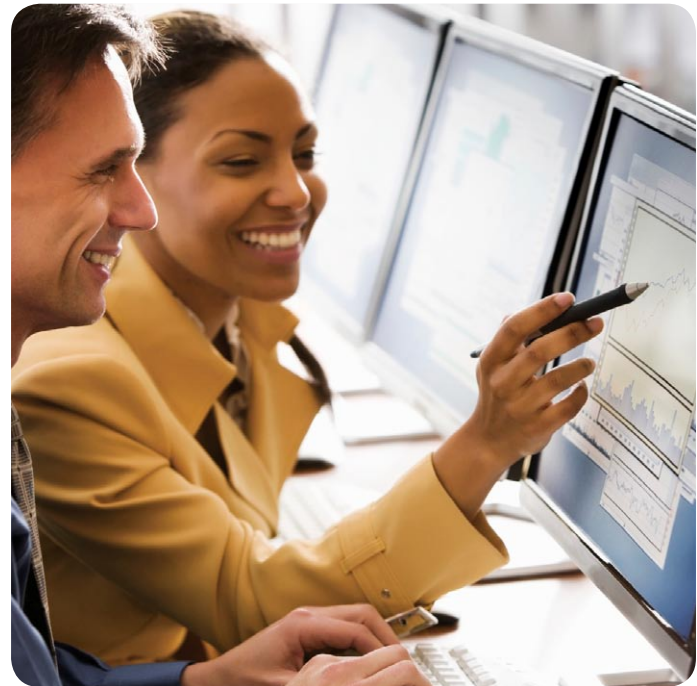
Services: Statistical Analysis and Programming

Veeda has been involved in the analysis of data from all stages of clinical development with a variety of designs and statistical hypotheses including interim analyses using adaptive, sequential, and sample size adjustment designs.

The Veeda Biometrics staff has also been involved in Independent Data Monitoring Committees to assist in the decision-making process or to offer statistical support independent from the sponsor.

Statistical Analysis and Programming Services include

- Sample Size Calculation
- Study Design
- Randomization
- Statistical Analysis Plan
- TFL Programming
- Statistical Analysis
- Statistical Report



Services: Medical Writing



Clinical study reports are produced by the medical writer, in collaboration with the medical team and the project statistician, ensuring a complete and accurate representation of all aspects of the study and its results, while respecting tight timelines.

The integrated clinical reports are prepared according to ICH E3 guidelines and format, or according to the sponsor's specific format. The final documents can be published compliant to the requirements for an eCTD submission.

Support is provided for preparing abstracts, posters and manuscripts.

Medical Writing Services include

- Protocol
- Clinical Study Report
- PSUR
- ISE/ISS
- Abstract
- Poster

Systems Used at Veeda Biometrics

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- **Clintrial:** For Data Entry and Data Management
- **EDC:** Experience with a range of different eCRF systems. Veeda partners with various EDC vendors to provide Screen design, Flow design, determining the validation checks, Testing etc.
- **SAS:** For Statistical Analysis and Data Management
- **Online Data Access:** Access to the clinical database is provided through a web portal VeedaLink. The secure web portal contains a library of standard reports as well as functionalities to provide customized reports as per the study requirements.
- **WinNonlin:** For Statistical Analysis of PK/PD data.

All systems at Veeda are CFR 21 part 11 compliant.



Why Veeda Biometrics?

Veeda Biometrics has unmatched expertise in conducting global clinical trials for pharmaceutical, biotechnology, and medical device companies. The sponsor receives accurate data in the required global standard format with high quality deliverables and cost savings that only India can offer.

Apart from experience in robust Project Management which integrates all the Biometrics services (Data Management, Statistical Analysis and Medical Writing), Veeda adds the value of its experience in providing Biometrics support in various European languages.

Strong quality assurance permeates the culture, service and operating philosophy of Veeda. While continuously reviewing SOPs and working practices to identify areas that can be developed to improve service, Veeda Biometrics ensures synergy across its various units.

In the past 5 years, Veeda Biometrics has

- Completed more than 200 studies
- Worked with 8 of the Top 10 Bio-Pharmaceutical companies
- Worked on all phases of drug development
- Experience in EDC / Paper studies
- Processed data from over 115,000 subjects
- Handled over 1 million CRF pages
- Participated in rescue studies

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