



Biostatistics Services

GVK BIO provides a complete range of development services to help clients progress their research programs through Clinical Research phases.

GVK BIO's Clinical Biostatistics team offers statistical analysis for Phase II-IIIb trials. Our biostatisticians provide insight into trial design, develop complex statistical analysis plans and assist Sponsors through-out the regulatory filing process.

Our experienced group of biostatisticians and programmers dedicate themselves to a project from inception to completion. We can serve as statistics experts for your trial or liaise with your company's internal statistics team to achieve your goals.

Services Offered

- Statistical Inputs for Protocol Preparation
- Sample Size Calculation
- Randomization and Unblinding Procedures
- Statistical Analysis Plan SAS Programming using SAS® 9.1.3
- Validation of Biostatistical Programs and Outputs
- Statistical Report Writing
- Interim Analysis
- PK/PD Analysis
- Inputs to Clinical Study Reports

Business Model

Functional Outsourcing

In this flexible business model, sponsors can choose GVK BIO Biostatistics team as their virtual Biostatistics department. The Clinical and Data Management leads within the sponsor organization liaise with our Biostatistics leads for full service statistical support.

Full Service Outsourcing

As regulatory submissions require cross functional synergy between clinical operations, biostatistics, data management, and medical writing, GVK BIO offers integrated end-to-end services in these functions as a one-stop shop.

Transactional Outsourcing

We offer Biostatistics services for standalone deliverables such as Sample Size Calculation, Statistical Analysis Plan, Interim Analysis and other services listed in this brochure. These services are offered as a package of comprehensive support in all phases of clinical trials, as well as for preclinical studies in animals.

Protocol ID: _____
Version: Draft

Table 34.1:
Subject disposition
safety population

| Disposition Reason | Arm A | |
|--------------------------------------|----------|----------|
| | N=74 | n(%) |
| Treated with study drug | 74 | 100 |
| Completed treatment period | | |
| Completed follow-up | | |
| Early termination from study | 65(87.8) | 98(90.7) |
| Adverse event /Serious Adverse event | 15(20.3) | 10(9.3) |
| Treatment failure | 5(6.8) | 2(1.9) |
| Consent withdrawn | | |
| Lost to follow-up | 2(4.3) | 1(1.1) |
| Non-compliance | | |
| Protocol Violation | 1(1.4) | 0(0.0) |
| Positive Pregnancy Test | 1(1.4) | 0(0.0) |
| Other | 0(0.0) | 0(0.0) |

Denominator of the percentage is the total number of subjects in the column.

Standards, Adaptability and Flexibility

Our Biostatistics team is adept at handling changes in client requirements and quick to adapt to the needs of the client, striving for satisfaction without compromising on quality or timelines.

- Can work in accordance with client's SOPs
- Collaboratively work with other CRO/Consultants' statistician/ programmers
- Can work with ease with client's SAP and analysis standards
- Programming standards to meet client requirements
- Timely response for any additional or new requests
- Adaptable to changing needs during the course of the study
- Sound understanding of SDTM, ADaM and CDISC standards
- Our team is up to date with the latest statistical techniques accepted by regulatory authorities such as USFDA, EMEA and DCGI

Team Expertise

- Our Head of Biostatistics has extensive domain expertise, having spent over 14 years designing, managing and analyzing data from health-related research projects. She has worked across multiple healthcare related domains. She has many scientific publications in renowned journals to her credit
- The team comprises of best-of-breed talent drawn from research institutes and the CRO industry, with 3 to 14 years of experience in clinical trials. The team members have experience in working across multiple therapeutic areas and have been extensively trained in ICH-GCP
- Our biostatisticians and SAS programmers hold doctorate / postgraduate degrees in Biostatistics. All SAS programmers have Base SAS certification
- Our biostatisticians are well versed with epidemiological measures and advanced biostatistics analysis methods (Artificial Neural Networks, Classification & Regression Trees, Generalized Estimating Equation (GEE) models, Survival Analysis)

Domain Expertise

- HIV/AIDS
- Oncology
- Tuberculosis
- Leprosy
- Ophthalmology
- Pediatrics
- Malaria
- Diabetes
- Hepatitis
- Cardiology
- Multiple Sclerosis
- Dermatology
- Renal Impairment
- Psychiatry
- Quality of Life
- Sociological Studies
- PK / PD studies

Quality and Compliance

GVK BIO's Biostatistics facility and systems are 21 CFR Part 11 compliant. Our working procedures are governed by SOPs and are routinely audited by our Quality Assurance team to ensure compliance.

About GVK BIO

GVK Biosciences (GVK BIO) is Asia's leading Discovery Research and Development organization. GVK BIO provides a broad spectrum of services, stand-alone and integrated, across the R&D value chain.

Services

- Chemistry Services
- Process R&D and Custom Synthesis
- Biology
- Informatics
- Clinical Research
- Clinical Pharmacology

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