

# Your trusted partner for biostatistics. Delivering statistical insights clients can trust.

Exploristics provides comprehensive statistical analysis and programming capabilities from the preclinical stage to commercialisation and beyond.



**We have the adaptability and breadth of experience to rapidly respond to the changing needs of our clients, whether we're working with an early stage company or augmenting in-house staff in a major pharmaceutical company.**

We support both exploratory and regulatory projects with our flexible and robust processes. We work to standards that are appropriate for the study, including compliance with ICH and GCP guidelines and according to clients' specification.

We adopt a client-centred approach, partnering closely with customers to understand their needs and to ensure we provide them with insights and expertise that help them make the right decisions as early as possible.

## Study Design

Our aim is to deliver smarter studies by providing expert input at the protocol development stage. By quantifying and controlling for sources of uncertainty, we ensure studies generate robust clinical evidence. Our proprietary software, KerusCloud, is a simulation platform that generates realistic virtual studies and evaluates the probability of success *in silico*. KerusCloud is particularly valuable in complex studies where there are multiple design options and sources of uncertainty. Our approach transforms the study planning process with rapid and convenient optimisation of study parameters, including the identification of the best design and analysis strategy.

## Data Management and Validation

Exploristics offer data management services that are 21 CFR compliant and in line with industry standards. We work in collaboration with our clients to design study specific case report forms for the collection of data. We create and test study databases ready for data entry, perform data validation, query resolution, quality control and transfer of data. In addition, we can process, clean, transform and integrate external data sources.

## Analysis and Reporting

We work with clients to provide a comprehensive bespoke analysis plan covering all processes that translate raw data into statistical outputs that lead to actionable decisions. We support primary, secondary and exploratory analyses as well as ad hoc consultancy. Our integrated analysis strategies result in a more complete understanding of the data and give greater insight into development options.

# Biostatistics Services

**Exploristics have extensive experience in drug discovery and clinical development within the pharmaceutical industry and we pride ourselves on offering bespoke high-level biostatistics service to all clients, big or small.**

Exploristics offer the exceptional ability to create greater insights through data exploration. Our staff have the mindset and culture that enables innovative thinking whilst at the same time understanding the importance of rigour and quality in clinical statistics. We have long-standing relationships with

many life sciences organisations including top ten global Pharmaceutical Companies as well as those developing Diagnostics and Medical Devices. Our comprehensive IP library of SAS and R macros allows us to accurately and efficiently repeat standard analyses. In addition, we have unrivalled experience in developing and applying advanced analytics to provide personalised solutions for a wide range of problems including data validation, handling missing data, subgroup analysis, inferential statistics, Bayesian methods, complex modelling (multivariate, predictive, longitudinal, non-linear) and visualisation.

## Biostatistics Services

**Exploristics provide end-to-end support for all biostatistics activities including:**

- ✓ Full service or independent bio-statistical and programming support
- ✓ Support for meetings with regulatory authorities
- ✓ High-level strategic support
- ✓ Protocol and statistical analysis plan development
- ✓ Study Design (Sample size / Power Calculations)
- ✓ Interim analyses and Data Monitoring Boards
- ✓ Preparation of integrated summaries of safety and efficacy for regulatory submissions
- ✓ Randomisation services
- ✓ Production of tables, listings and/or graphs
- ✓ Input to publications
- ✓ Data Management and Validation

## Studies Supported

**Exploristics provides analysis support for the following study types:**

- ✓ Randomised Controlled Trials
- ✓ Precision Medicine
- ✓ Biomarker discovery and development
- ✓ Multi-platform biomarker studies
- ✓ Real World Evidence
- ✓ Pre-clinical studies
- ✓ Translational / Experimental medicine
- ✓ Diagnostics & Medical devices
- ✓ Bioequivalence
- ✓ Observational Studies
- ✓ Pragmatic trials
- ✓ Exploratory studies including ad hoc analyses, retrospective analyses and pooled data
- ✓ Meta-Analysis and Meta-Regression
- ✓ Integration of disparate data sources

*Exploristics: an essential partner in data driven decision-making for accelerated development.*

# Biostatistics Services

## Providing expert insight to early clinical development

The early phases of clinical development are crucial and pose unique challenges in time and cost. Our approach is to work closely with our clients to design smarter studies and conduct meaningful data analysis that provide reliable insights based on robust regulatory compliant data.

## Delivering evidence of value

Exploristics integrates with the client's team to design clinical trials that can be successfully executed with confidence, at lower risk, in shorter timelines and are able to generate greater value for stakeholders.

## Accelerated development using simulation

KerusCloud, our unique clinical trials simulation platform enables the rapid valuation of assumptions, accelerating development, delivering robust evidence packages to support investment and regulatory engagement.

## Experienced team

The Exploristics team is comprised of highly skilled, innovative data analysis experts. With many years' experience in the pharmaceutical industry and academia, our team have a broad knowledge of drug discovery and clinical development.

## Delivering practical solutions

Our Teams are dedicated to working closely with our clients to deliver decision-making information with realistic and actionable solutions for their clinical research needs.

## Wide range of expertise

With the knowledge and experience of the Exploristics team we can provide a deeper level of understanding in early stage development, precision (stratified) medicine and a wide range of therapeutic areas.

