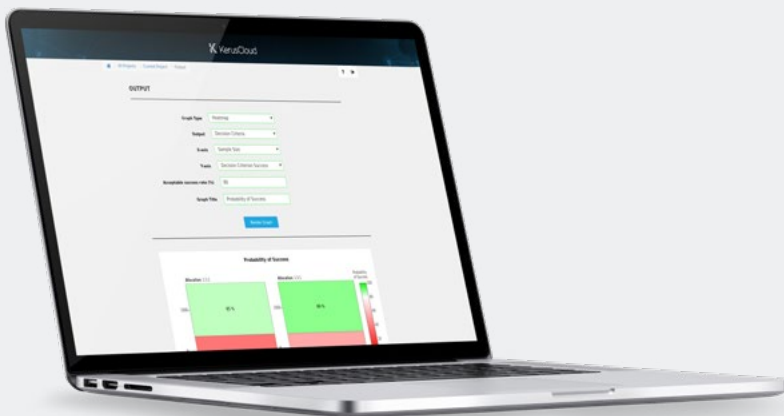


Early Phase Development

Optimising opportunity and return on investment in early phase development through the combined power of quality statistics, advanced analytics and simulation software



THE FOCUS OF EXPLORISTICS EARLY PHASE SERVICES IS TO PROVIDE CLIENTS WITH THE DATA ANALYTICS CAPABILITY TO SUPPORT TRANSLATION OF EARLY CLINICAL RESEARCH THROUGH TO PROOF OF CONCEPT (AND BEYOND).

With over 90% of experimental treatments failing to reach the market, effective clinical study planning and analysis is crucial in optimising the opportunities for success.

Our expertise in early phase studies supports effective decision-making to reduce development time, cost and risk. Good decision-making starts with good study-design; KerusCloud simulates clinical trials in silico enabling us to identify the best possible trial design. We complement this with biostatistical service experts with a track-record of delivering bespoke solutions for efficient generation of high-quality clinical evidence.

Expertise in early development

The development of investigational drugs is a complex and expensive process with many risks. The costs and timescales of clinical trials are affected by decisions that are taken as new data emerge. To leverage fullest benefit from our wide-ranging knowledge and skills, biostatisticians should be involved throughout the process from the first study design to ultimate regulatory approval.

We offer much more than number crunching. Our solutions are built around our unique KerusCloud platform which allows us to provide bespoke, end-to-end biometrics support from strategic decision support, protocol development to analysis and reporting and stakeholder engagement.

KerusCloud

KerusCloud transforms the study planning process with quick and convenient optimisation of study parameters to support the design of complex clinical research trials enabling users to:

- Simulate data with correlations and missing values reflecting real-world patients and studies
- Assess the probability of success for real-world objectives involving trade-offs between several factors
- Identify the critical study aspects impacting on the probability of success
- Compare analysis plans with selections from the comprehensive analysis suite

Key Services

Our Clinical Biostatistics Services include:

- + **Protocol Design**
Clinical study design, sample size calculations and study-start-up consultancy
- + **Randomization/Un-blinding**
Randomizations including production of emergency un-blinding envelopes
- + **Statistical Analysis Plan (SAP) and Output Shells**
Provision of the statistical content of a study to ensure timely and quality delivery
- + **Output Production**
Using our IP Library of SAS and R macros and bespoke SAS programming to increase the efficiency of output production
- + **Clinical Data Interchange Standards Consortium (CDISC)**
Using CDISC standards ensures that the data used for reporting complies with regulatory standards
- + **Production of Statistical Report/Clinical Study Report**
Our statistical and partner medical writing teams work together to produce high quality statistical and clinical study reports
- + **Strategic Decisions**
We provide quantitative methods for simulating and evaluating study and development options
- + **Interim Analyses**
Unblinded statistical support and advice for Interim Analyses to stop failing studies early or adapt appropriately in light of emerging data
- + **Exploratory Analyses**
We maximise scientific benefit by applying novel analytics to existing data sets
- + **Support for Regulatory Interactions**
We provide strategic statistical advice in preparing briefing documents and attending early scientific advice meetings
- + **Pre-Clinical Studies**
We provide support and advice for pre-clinical studies to ensure the study objective is being fulfilled

Optimise for success

Identify the right development path, optimising the number of patients required to generate robust evidence to support investment and regulatory engagement.

De-risk investment

Rapidly evaluate and test assumptions to avoid and mitigate risks.

Access the power of advanced simulation

Using our in-house KerusCloud simulation software we can identify the most efficient trial designs and development path.

Accelerate development

Combining our KerusCloud software with our early phase services you have immediate access to powerful simulations and highly-trained staff who can expedite development.

Early decision making

Our expertise in smarter study designs and success criteria allow the generation of robust clinical evidence and facilitate investment decisions.

Quality and Efficiency

By using our IP Library of SAS and R routines we can rapidly deliver high-quality analysis results at lower costs.

Therapeutic Expertise

Exploristics covers many therapeutic areas with deep mastery of:

- Oncology
- Respiratory
- Immunology
- Virology
- Diabetes
- Rare/Orphan diseases

For more information on KerusCloud or our range of services please visit us at: www.exploristics.com or email sales@exploristics.com



Exploristics Ltd. 24 Linenhall Street
Belfast, Northern Ireland BT2 8BG

find out more T +44 (0)28 9600 1996
exploristics.com | sales@exploristics.com