Strategic Consulting

Statistical Strategies for Disrupted Clinical Trials

How to adjust, evaluate and mitigate study designs.

Unexpected disruption to clinical trials, such as that seen in the global COVID-19 pandemic, can have a devastating impact on patients and healthcare systems and cause numerous unforeseen challenges for developers of medicines, medical diagnostics and devices. At Exploristics, we offer a unique package of statistical expertise and tools to address issues arising from the current situation, helping healthcare and life sciences organisations overcome the challenge and getting trials back on track.

Common study issues arising from disruption include

- Poor patient retention
- Cancelled or suspended screening and enrolment
- Delayed recruitment
- Paused site activation
- Low levels of persistence and adherence to treatment
- Missed visits
- Incomplete, imperfect data
- Unexpected bias that impacts certain patient groups

However, despite the serious impact of these issues on ongoing development programmes, some can be resolved or mitigated with strategic statistical input and reassessment of current trial design and analysis approaches.

Statistical Services Adjusting for Disruption

Exploristics' experienced team of statisticians and programmers are well-placed to identify and tackle a wide range of study design and analysis issues. Our biostatistics services offer a comprehensive range of strategic support including:

- Ensuring optimal amendments to the Protocol and Statistical Analysis Plans
- Identifying the right analysis and evidence generation strategy for sparse or missing data and sources of uncertainty
- Evaluating the impact of patterns of missing data and unexpected variability on the likelihood of success
- Assessing the utility of existing data given the sources of bias and uncertainty
- Predicting the likelihood of success given current data and uncertainty
- Re-evaluating the development strategy
- Providing evidence to support investment decisions

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KerusCloud Study Simulation Software for Re-Optimizing Trials

KerusCloud redefining study success

In addition to providing strategic biostatistics support, Exploristics can tackle issues arising from study disruption with our unique next generation study simulation software platform, **KerusCloud**. **KerusCloud** enables the rapid design of smarter, more successful trials as well as re-evaluation of ongoing design and analysis approaches.

As the only statistical software that assesses multiple aspects of clinical trial design simultaneously, **KerusCloud** ensures that studies achieve statistically and clinically meaningful outcomes.

Harnessing statistical modelling, simulation, and cloud computing, **KerusCloud** can generate and evaluate thousands of realistic studies in parallel, *in silico*, in minutes. This fast and efficient approach enables evidence-based decision-making to drive study design so that real studies are fully optimised for the best chance of success. **KerusCloud** is also highly versatile, handling diverse and complex multidimensional data to model realistic scenarios associated with study disruption such missing and noisy data.

KerusCloud an adaptive tool

KerusCloud is an exceptionally flexible and effective tool for re-evaluating study options *in silico* to:

- Rapidly construct complex simulations to generate results that account for patterns of missing data
- Re-evaluate key study factors such as: right study population characteristics, sample size, sampling schedule, study power, stratification, endpoint(s) and observation time, analysis strategy and decision criteria
- Identify strategies that overcome the challenges of bias, inconsistency and sources of uncertainty

KerusCloud a unique approach

KerusCloud provides a uniquely targeted statistical approach to addressing trial disruption. Its unique power lies in its ability to generate virtual patient populations that are the most realistic representation of data collected in modern trials. **KerusCloud** can model variables based on any data type and statistical distribution, as well as the correlation between variables. It can also introduce missingness and noise in the data to create a realistic representation of clinical trial datasets. As a result, **KerusCloud** can generate complex virtual data comprising:

- Common features such as subgroups and strata, risk factors/covariates, multiple outcomes
- Special features including derived variables, missing data, truncation and censoring

Virtual data generated within **KerusCloud** can realistically mimic that from disrupted trials and be used to generate thousands of study simulations within minutes. This provides an unrivalled opportunity for multiple study design and analysis options to be re-evaluated rapidly, so that approaches can be adjusted and objectives can still be achieved.

So, don't let unexpected disruption to your clinical trial stall your development programme. Use Exploristics and **KerusCloud** to identify the best way forward.