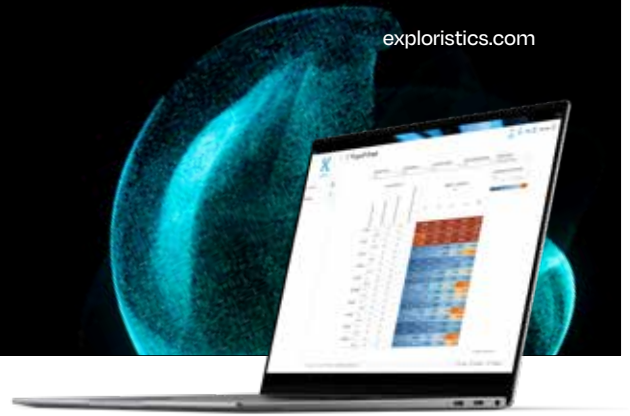




Discover KerusCloud, the essential simulation and biostatistics tool optimizing clinical study design and analysis strategies for success.



KerusCloud is a next generation clinical trial simulation software that is the future of study planning. This uniquely powerful new platform supports earlier engagement by statisticians in the clinical protocol development process, delivering key insights to drive strategy through evidence-based design and analysis.

KerusCloud Revolutionize study design with advanced statistical modelling and simulation



Leveraging the combined power of statistical modelling, simulation, and cloud computing, **KerusCloud** generates and evaluates the performance of thousands of realistic **studies in parallel, in silico, in minutes**. It is the only statistical software that assesses multiple aspects of clinical protocol design simultaneously to ensure studies achieve statistically

and clinically meaningful outcomes. **KerusCloud** transforms the development process by going beyond traditional statistics support for study design. With **KerusCloud**, statisticians can be involved from the earliest stages of clinical protocol planning, ensuring that projects are **de-risked** and driven by **evidence-based decision-making** from **inception to completion**.

Leveraging the Power of Statistics

KerusCloud Making an Impact

× 3
PROBABILITY OF
DEVELOPMENT SUCCESS

Increase the probability of success three-fold for a development programme

+ 41%
PROBABILITY OF
STUDY SUCCESS

Increase the probability of success by over 41% for a precision medicine study

- 4
YEARS FROM TOTAL
DEVELOPMENT TIME

Decrease development time by 4 years for a clinical study

KerusCloud supports a multi-dimensional optimization process where pinpointing the right combination of design features can dramatically increase study success. Without adding cost, KerusCloud has already helped organisations to:

-\$20m
USDG ON A
SINGLE STUDY

Save US \$20M on a single study

-100%
WASTAGE OF UNNECESSARY
PROGRAMMES

Identify an extensive development programme for termination that had little chance of success

Diverse and complex data-handling

KerusCloud is a highly versatile platform, handling not only the diverse and complex data collected routinely in clinical research but also new data types from emerging digital technologies, facilitating their integration into clinical development and precision medicine approaches. Therefore, KerusCloud supports the crucial role of statisticians in ensuring clinical project teams can harness the growing variety of data sources now available to better understand the often-complicated inter-relationships between risk factors, outcomes and treatment effects when designing a study.

Augmenting statistical expertise

By using KerusCloud statisticians can expand on

their own expertise with further unique, data-driven, insights into the optimal design and analysis strategy to ensure that the only best approach is selected, giving development programmes the greatest chance of success.

Enabling earlier statistical input

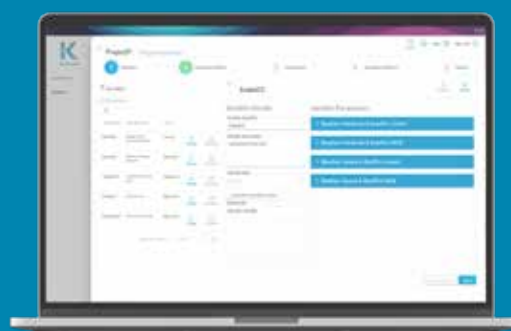
KerusCloud enables statisticians to collaborate much earlier in the planning of individual studies or of development programmes. This is supported by a key strength of the software, the ability to construct scenarios where there are multiple sources of uncertainty that are likely to impact the outcome. With KerusCloud, statisticians can evaluate and implement strategies that minimise the risks from the outset.



By supporting early biostatistics engagement, KerusCloud builds a stronger statistical foundation for any study.



KerusCloud Heatmap Analysis



KerusCloud Virtual Population Construction

KerusCloud an exceptional tool

KerusCloud provides statisticians with an exceptional *in silico* tool with which they can:

- ✓ **Rapidly construct complex simulations** to generate results that support project timescales.
- ✓ **Influence more decisions** on important study factors: **right study population characteristics, sample size, sampling schedule, study power, stratification, multiple endpoints** and **observation time, analysis strategy** and **decision criteria**.
- ✓ **Overcome challenges** with **implementing new methodologies** and **generating simulation code**.

KerusCloud a unique approach

KerusCloud offers a unique approach, generating **virtual patient populations** that are the most realistic representation of data collected in modern trials. It can model variables based on any data type and statistical distribution, as well as the correlation between variables. This innovation is the result of years of research and development on copulas for generating complex multivariate data that ensure the properties of the marginal distributions as well as the

correlation structure is maintained. Consequently, **KerusCloud** can generate complex data comprising:

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

Using this highly realistic virtual data and its intensive processing power, **KerusCloud** can run **thousands** of Monte Carlo simulations in **minutes** to evaluate the probability of success of many, varied study designs and analysis options to achieve study or programme objectives. These utilise the comprehensive library of design, analysis and decision tools available with the platform. Flexible and user-friendly, **KerusCloud** also offers the option of exporting patient level data or the results into other packages for further analysis.

KerusCloud for maximising value

KerusCloud can be used in a wide range of applications and is particularly useful for maximising the evidence generated at important transition points during clinical development, such as proof of concept or commit to late stage development. It adds significant value as standalone tool or as a precursor to existing design tools as it can efficiently narrow the potential options available.

For informed drug development strategies, the role of the statistician has never been more important. Add KerusCloud to your design toolbox to transform clinical trials.

KerusCloud: Why design a study without it?