

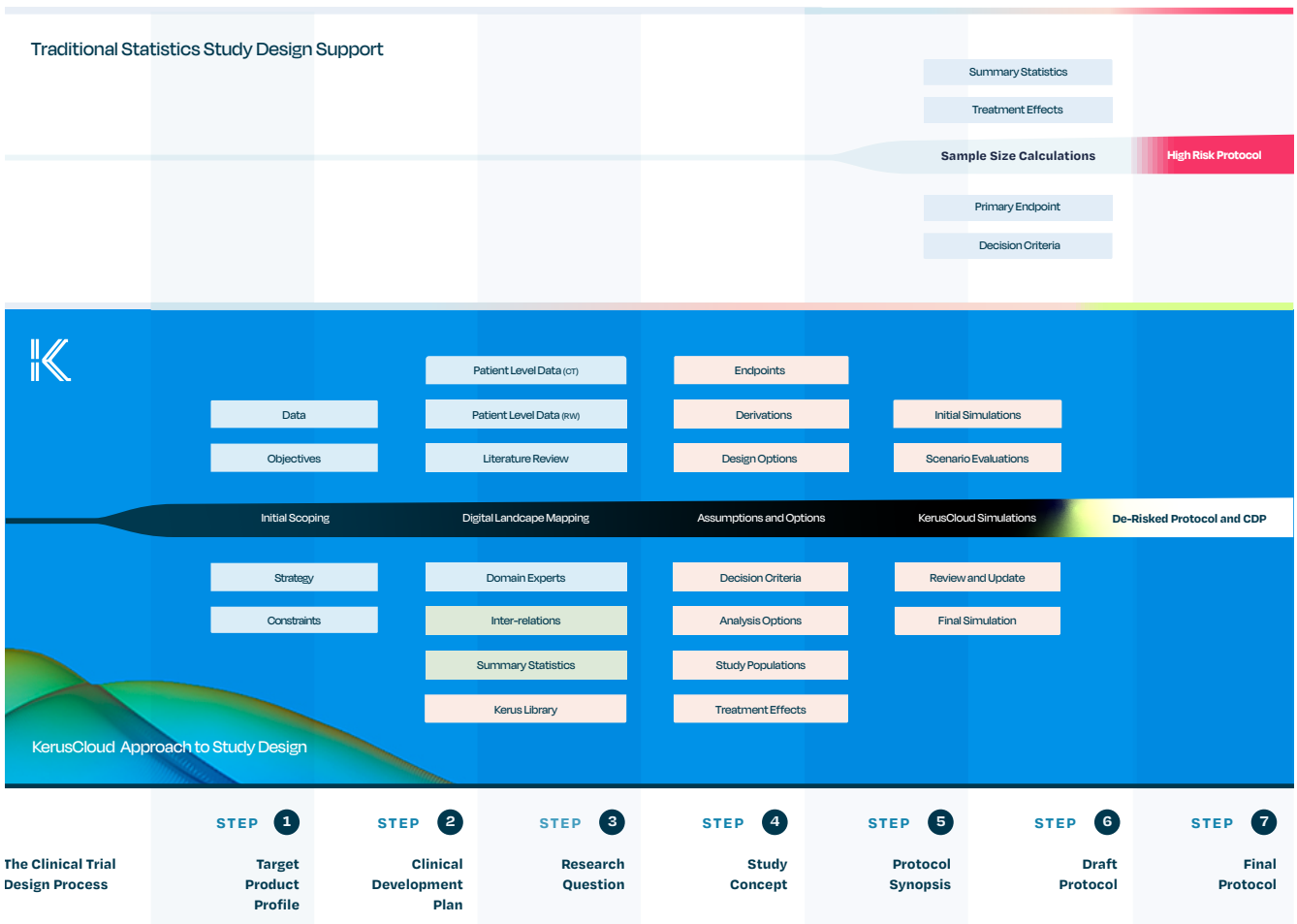
# KerusCloud

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 delivers rapid, data-driven insights for more quantitative and collaborative decision-making. Its use de-risks clinical projects by fully optimizing them for success. This uniquely powerful platform supports earlier engagement by statisticians in the clinical protocol development process, helping them to share key insights across all stakeholders to drive strategy through evidence-based design and analysis.

## KerusCloud Revolutionize study design with advanced statistical modelling and simulation



Designed by statisticians with in-depth experience in clinical development, **KerusCloud** transforms study design and planning by going beyond simplistic traditional statistics approaches which often fail to account for the trade-offs between design features and the sources of uncertainty

in real studies. With **KerusCloud**, study design and analysis strategies can be fully optimised prospectively in just a few hours to ensure that real studies can achieve statistically and clinically meaningful outcomes.

## Leveraging the Power of Statistics

### KerusCloud Making an Impact

**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:

3x

Probability of **Development** Success

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

41%

Probability of **Precision Medicine Study** Success

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

-4

Years Removed from the **Development Time**

Decrease development time **by 4 years** for a clinical study.

+20m

USD Saved on a **Single Study**

Save **\$20M** on a single study.

### Augmenting statistical expertise

**KerusCloud** supports statisticians in influencing study design at every phase of clinical development, ensuring that projects are de-risked and driven by evidence-based decision-making from inception to completion. By using **KerusCloud**, statisticians can expand on their own expertise with further unique, data-driven, insights into the optimal design and analysis strategy so that the best approach is selected to give development programmes the greatest chance of success.

### Diverse and complex data-handling

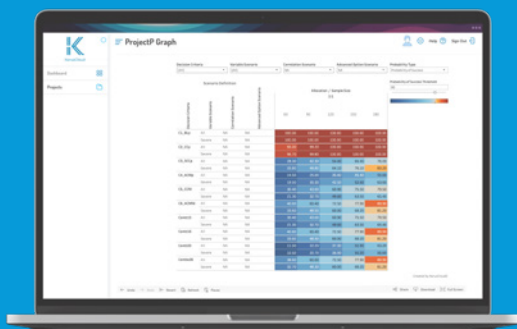
A highly versatile platform, **KerusCloud** can handle not only the diverse and complex data collected routinely in clinical research but also new data types from emerging digital technologies, facilitating their integration into clinical development and precision medicine approaches. Its use supports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

### Enabling earlier statistical input

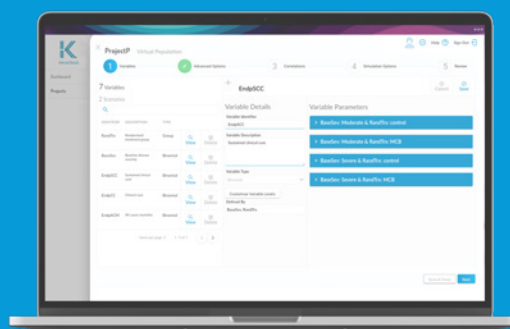
**KerusCloud** enables statisticians to collaborate much earlier in the planning of individual studies or of development programmes. This is supported by a key strength of the software, the ability to construct scenarios where there are multiple sources of uncertainty that are likely to impact the outcome.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

### Sharing key insights on design

Data from a variety of sources can be incorporated into **KerusCloud** where they are used to create synthetic datasets or virtual patient populations which inform the generation of highly realistic study scenarios for evaluation in parallel, *in silico*, in minutes. Capturing this complex multi-dimensional information both quantitatively and visually in a heatmap, **KerusCloud** can be used by statisticians to share key insights across project teams on the study design features that drive success.



**KerusCloud** Interactive Heatmap Analysis



**KerusCloud** Virtual Population Construction

## KerusCloud an exceptional tool

As a SaaS platform with no need for installation or maintenance, **KerusCloud** provides statisticians with a uniquely powerful and easy to use *in silico* tool with which they can:

- ✓ **Rapidly construct complex simulations** to generate results that support project timescale.
- ✓ **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**.
- ✓ Communicate complex statistical information across stakeholders to help direct design and analysis strategies.

## 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:

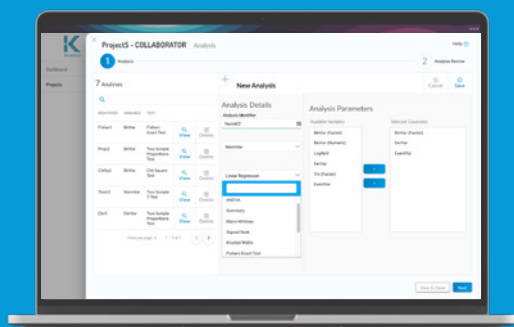
- ✓ **Common features** such as **subgroups and strata, risk factors/covariates, multiple outcomes**
- ✓ **Special features** including **derived variables, missing data, truncation** and **censoring**

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.

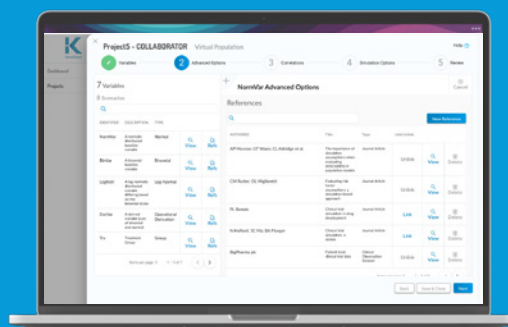
## KerusCloud a new release

Building on its core capabilities, the **KerusCloud** Spring 2021 release now offers a range of new innovative features including:

- ✓ **An expanded analysis library of statistical tests** including regression analysis, survival analysis and additional tests for proportions and derived variables



**NEW KerusCloud Advanced Analysis Library**



**NEW KerusCloud Metadata Repository?**

so that the performance of all commonly applied analysis strategies can be assessed to identify the optimal approach, control for sources of bias and evaluate alternative designs, such as the application of historical controls.

- ✓ **Enhanced synthetic data for even more realistic study simulations**, including time-to-event data with flexible censoring distributions, so virtual population datasets more closely represent actual data generated in real-world studies.
- ✓ **A meta data repository to keep track of integrated data sources** so that assumptions are linked to the original data sources for greater transparency and ease of auditing and review.
- ✓ **A new administration portal for tighter control over platform usage and costs** with managed user access and more flexible allocation of KerusCredits so that you only pay for what you use.
- ✓ **Robust collaboration and sharing tools ideal for distributed teams** providing everyone access to the same virtual population data and simulation project.
- ✓ **Enhanced scalability, robustness and security** delivering enterprise grade protection for rapid

construction of complex study scenarios in real time whilst data is kept safe with best-in-class security features including multi-factor authentication, data encryption and disaster recovery to give you complete peace of mind.

### 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.

### KerusCloud for maximising impact

**KerusCloud** maximises the impact of statisticians offering a unique rapid quantitative tool with which to assess, visualise and communicate the best approaches across project teams early on in protocol development. With consistently high attrition rates in clinical trials, the role of the statistician has never been more important for informed drug development strategies. So, discover and share a more data-driven approach to clinical study optimisation. **Add KerusCloud to your design toolbox today and transform clinical trial success.**