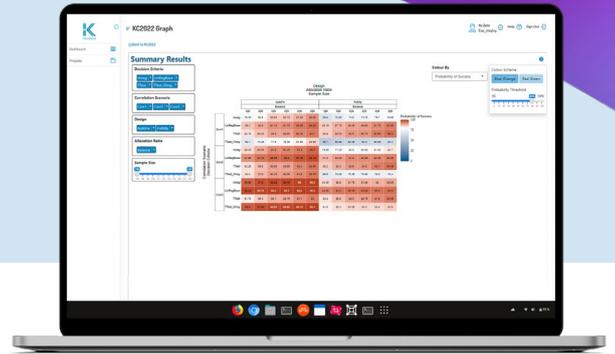


# KerusCloud

Discover the power of next-generation cloud-based study simulation with KerusCloud, for fast, flexible, quantitative decision-making and a more data driven approach to designing clinical studies.



Over 90% of clinical studies fail during development. Ensure your clinical studies achieve meaningful outcomes, statistically and clinically. Build in success upfront with **KerusCloud** – the fast, flexible simulation platform that fully optimises clinical study design and analysis strategies.

Secure and user-friendly, **KerusCloud** supports rapid optimisation of study design and analysis approaches to drive more development success in real-time, first time. Investing just a few hours to evaluate the best study approaches *in silico* with **KerusCloud** during protocol development delivers uniquely informative data-driven insights for incisive, quantitative decision-making, de-risking projects to ensure cost-effective and successful studies long-term.

Leveraging the scalable processing power of cloud computing, **KerusCloud** handles the diverse and complex data now routinely collected in clinical research with ease. It can draw on a wide variety of data types to create highly realistic virtual patient populations to inform true-to-life simulated studies exploring the impact of multiple correlated study variables, designs and analysis strategies *in silico*, in minutes

Much more than just a sample size calculator, **KerusCloud** allows key study characteristics such as target population and study duration to be assessed, and automatically quantifies the outcomes of the simulated study scenarios it generates in terms of probability of success (POS). This provides robust data that can be used by clinical development teams to support selection of the study design and analysis approach most likely to meet project needs, increasing the efficiency and de-risking the process of delivering tomorrow's precision medicines.

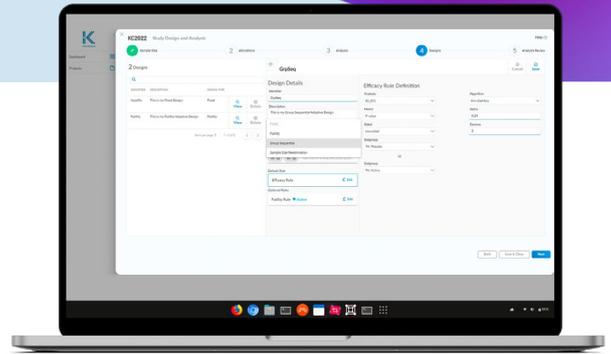
Using **KerusCloud** to design clinical studies and trials supports more collaborative decision-making communicating complex statistical insights, simply and intuitively, with its state-of-the-art, easy-to-read heatmap. Project information can be shared across the platform between development team members and easily exported for further auditing and review, archiving the scenarios and data used to make key design and analysis decisions.

Available as Software as a Service (SaaS) and accessed via a web-browser, **KerusCloud** can be licensed for direct use by your statistics team or as part of an integrated services package. User access can be regularly updated to suit your growing needs with our simple KerusCredits system.

## On purchase of a KerusCloud license you can:

- + **Build** Integrate existing and emerging knowledge and data sources from the literature, clinical trial data, real-world data and expert opinion to build realistic synthetic patient populations.
- + **Simulate** Sample these virtual populations to generate highly realistic study simulations in minutes for high numbers of scenarios.
- + **Analyse** Explore multiple fixed and adaptive study designs, analysis and decision-making strategies by applying different statistical analyses and decision criteria.
- + **Optimise** Evaluate the suitability of different trial designs and data analysis methods guided by the quantified POS for each approach.
- + **Visualise** View and share simulated outcomes with POS values using the interactive heatmap to quickly identify the design and analysis strategy most likely to deliver success.

## Features & Benefits



Building on KerusCloud's exceptional capabilities, the Spring 2022 release now offers new innovative features to support fully optimised design of clinical studies including:

### NEW STUDY DESIGN FEATURE

#### Adaptive designs

for the evaluation of Futility, Group Sequential and Sample Size Re-estimation studies.

**Benefit** Compare fixed versus different adaptive design types to identify the optimal study design to address project needs.

### NEW ANALYSIS FEATURE

#### Extended analysis options

with a broader range of commonly applied statistical tests including the Cochran-Mantel-Haenszel test (CMH) for stratifying variables, Poisson Regression Analysis with Dispersion, and ANOVA tests with optional adjustment methods such as Tukey, Sidak and Bonferroni.

**Benefit** Assess the performance of different analysis strategies to pinpoint the optimum approach, control for sources of bias and evaluate alternative options.

### NEW ANALYSIS FEATURE

#### Additional decision criteria

to quantify and define study success such as multiplicity adjustments to p-values and odds ratio for Logistic regression.

**Benefit** Improve decision-making with a wider choice of methods for controlling false positive rates in both exploratory and regulatory studies.

### NEW ANALYSIS FEATURE

#### Powerful evaluation of estimands, imputation and analysis strategies

for more realistic simulated study scenarios.

**Benefit** Generate study scenarios that closely mimic data quirks such as missingness and the intercurrent events found in real studies as well as strategies to deal with intercurrent events for more accurate quantitation of the probability of study success.

### NEW DATA INPUT FEATURE

#### Integrated data model builder (DMB)

allowing direct automated input of patient level data in the form of summary data models into the KerusCloud platform.

**Benefit** Faster and more robust generation of virtual populations.

### NEW INTERFACE DESIGN FEATURE

#### Streamlined interface with error-free entry of study assumptions

for an improved user experience.

**Benefit** More intuitive workflow and input data validation to prevent errors when entering study variables for more robust virtual population setup.

*Book a free one-to-one software demonstration today to discover a more data-driven approach to clinical study optimisation. Discover KerusCloud.*

## Features & Benefits

The Spring 2022 release of KerusCloud's also includes the following new features:

✓ **NEW VISUALISATION FEATURE**

### Enhanced heatmap

available in two colour palettes to ensure full visual accessibility and provide more information on simulated scenario performance.

**Benefit** More detailed visual breakdown of analysis and adaptive design data to facilitate study design decision-making.

✓ **NEW OUTPUT FEATURE**

### Detailed downloadable PDF reports

ideal for distributed teams to share key project information including virtual population models, study designs, analyses, decision criteria and a bibliography of references used for data sourcing.

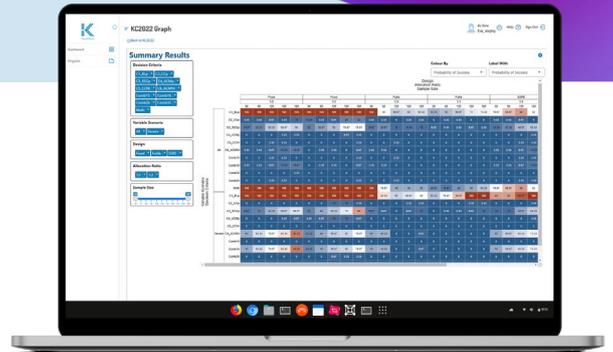
**Benefit** Greater transparency and engagement across projects teams with a sharable record of evaluated approaches to ease auditing and review.

✓ **NEW SECURITY FEATURE**

### Improved robustness and security protocols

including external penetration testing and a new project share acceptance feature for enterprise grade protection.

**Benefit** Best-in-class security ensures enhanced user privacy, and that data stays safe for complete peace of mind.



Revolutionise how you design clinical studies to build in more success upfront. Use the new and innovative features of KerusCloud Spring 2022 to:

- **Improve study success rates** with fully optimised study design for more efficient clinical development.
- **Identify the best endpoints and target populations** to de-risk projects, saving significant time and costs.
- **Develop more robust evidence packages** to support investment and regulatory engagement helping you to hit the fast-track to approval.

**KerusCloud** is now available with full wraparound statistical support as part of your SaaS package. Our experienced statisticians can help implement KerusCloud quickly offering software onboarding, data integration, population building, generation of design and analysis options and scenario evaluation.

*Book a free one-to-one software demonstration today to discover a more data-driven approach to clinical study optimisation. Discover KerusCloud.*