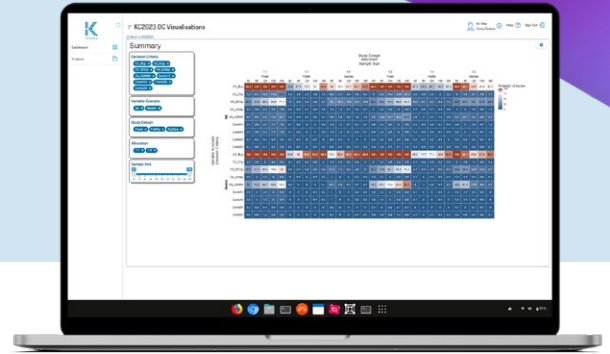


KerusCloud® 2023 Release

Exceptional simulation-guided
clinical study design.



Over 90% of clinical studies fail during development. Ensure your clinical studies achieve meaningful statistical and clinical outcomes. Build in more success upfront with **KerusCloud**: the fast, flexible simulation platform that delivers smarter study design.

With **KerusCloud** clinical trials are designed effectively from the outset to collect the **right data**, in the **right patients**, in the **right way**. Its use delivers quantitative insights that support evidence-based decisions to de-risk studies by design. This powerful prospective approach has already been shown to increase study success three-fold, while reducing patient burden, development costs and timelines.

Simulation with **KerusCloud** during clinical protocol development allows multiple study design and analysis approaches to be explored simultaneously, in minutes, within a secure virtual environment. Study outcomes are visualised using an intuitive interactive heatmap where detailed quantitative results help research teams to rapidly identify the pros and cons of different design options. This allows the key drivers of study success to be pinpointed so the best design and analysis approach can be selected, first time.

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 diverse information and data types to inform the simulations it generates with sources including the scientific literature, disease registries, historical trials and real-world data. These data are captured in the platform as synthetic data sets, avoiding privacy constraints, and used to build virtual patient populations to answer multiple 'what if' study scenarios questions.

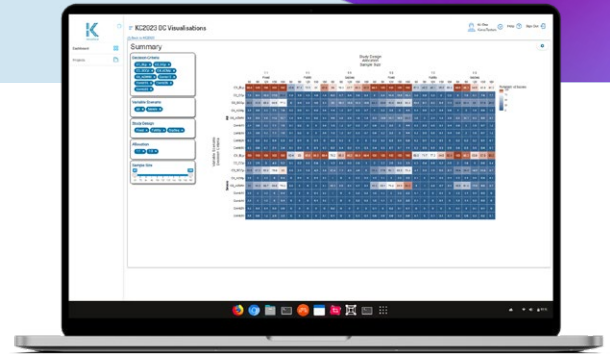
Delivering simple sample sizes but also much more, KerusCloud's synthetic data-based simulations are uniquely informative. They best represent the complexity found in real studies by accurately mimicking the quirks found in real patient-level data, like missingness. Therefore, **KerusCloud** provides exceptional advanced analytical insights able to deliver the smarter studies needed to address today's complex clinical research challenges.

KerusCloud is available as Software as a Service (SaaS) and can be licensed either for direct use with wrap-around on-boarding support or as part of an integrated **Statistical Consultancy** services package. Access to simulation can be regularly updated to suit your growing needs with our simple KerusCredits system.

On purchase of a KerusCloud license you can:

- + **Build** Identify and integrate information from a wide range of data sources supported by our **Data Science** team to build realistic synthetic patient populations.
- + **Simulate** Sample virtual populations and generate high numbers of study simulations in minutes for multiple 'what if' study scenarios of interest.
- + **Visualise** View and share scenario outcomes with quantitated Probability of Success values using the interactive heatmap.
- + **Analyse** Explore the pros and cons of multiple fixed and adaptive study designs, analysis and estimand strategies by applying different statistical analyses and decision criteria.
- + **Optimise** Pinpoint the best study designs and data analysis methods for your development asset guided by the Probability of Success values calculated for each approach.

Features & Benefits



Building on KerusCloud's exceptional capabilities, the Spring 2023 release offers three new and improved innovative simulation-guided design features:

✓ **NEW ANALYSIS FEATURE**

Bayesian posterior probabilities

for greater flexibility in defining study success criteria.

Benefit Simulated studies can be assessed according to a wider range of success criteria, ensuring a more flexible and realistic decision framework for early-stage studies.

✓ **NEW ANALYSIS FEATURE**

Repeated measures

across multiple time points.

Benefit Repeated measures across several time points per subject in a study can now be included into decision-making, so studies can be designed and implemented with fewer patients.

✓ **IMPROVED & UNIQUE ANALYSIS FEATURE**

Enhanced estimand strategies

to ensure proper handling of intercurrent events.

Benefit Estimands describe what is to be measured in a study. Consideration of estimands is now recommended by the **FDA** and the **EMA** when drafting a clinical study protocol. KerusCloud is the only platform that implements the new Regulatory guidelines, **ICH E9**, as part of clinical trial design. This ensures the best estimand strategy for more successful regulatory interactions.

With these exceptional new features, the KerusCloud Spring 2023 release offers cost-effective state-of-the-art cloud-based simulation for developers of any size. Delivering fast, flexible data-driven decision-making during clinical trial design, KerusCloud can revolutionise how you design your clinical studies. Use the Spring 2023 release 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.

So, discover the benefits of exceptional simulation-guided design when selecting the right approach for your healthcare asset.

Book a one-to-one demonstration and discover KerusCloud.