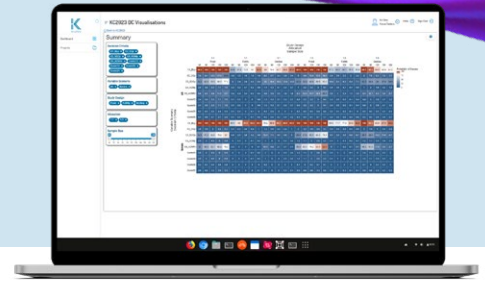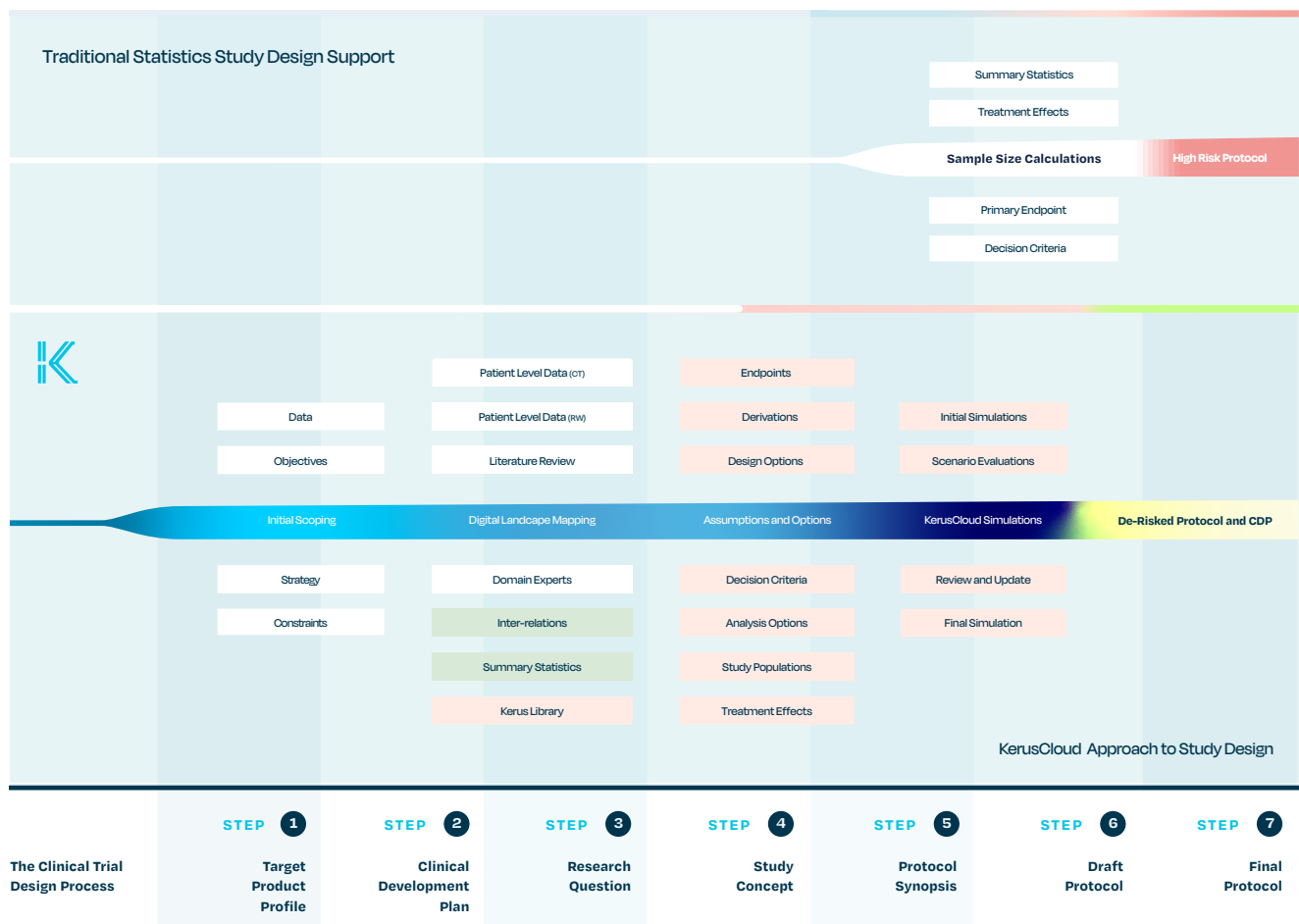# KerusCloud® 2023 Release

Discover study simulation with KerusCloud,
for a more data-driven approach to clinical study design.

KerusCloud is an exceptional study simulation software that delivers quantitative insights on study design for more data-driven and collaborative decision-making. Its use extensively de-risks studies upfront by optimising them for success.

KerusCloud Revolutionise study design with advanced statistical modelling and simulation

Traditional Statistics Study Design Support

Summary Statistics

Treatment Effects

Sample Size Calculations — High Risk Protocol

Primary Endpoint

Decision Criteria

	Patient Level Data (CT)	Endpoints	
Data	Patient Level Data (RW)	Derivations	Initial Simulations
Objectives	Literature Review	Design Options	Scenario Evaluations
Initial Scoping	Digital Landcape Mapping	Assumptions and Options	KerusCloud Simulations — De-Risked Protocol and CDP
Strategy	Domain Experts	Decision Criteria	Review and Update
Constraints	Inter-relations	Analysis Options	Final Simulation
	Summary Statistics	Study Populations	
	Kerus Library	Treatment Effects	

KerusCloud Approach to Study Design

The Clinical Trial Design Process	STEP 1 Target Product Profile	STEP 2 Clinical Development Plan	STEP 3 Research Question	STEP 4 Study Concept	STEP 5 Protocol Synopsis	STEP 6 Draft Protocol	STEP 7 Final Protocol

Designed by statisticians, for statisticians, **KerusCloud** transforms clinical study planning by going beyond simplistic traditional sample size approaches using analytical or parametric methods. These simplistic approaches often fail to account for the trade-offs and complexities between design features and the sources of uncertainty, and don't include the data quirks found in real studies. With **KerusCloud**, multiple design and analysis strategies can be explored in a virtual environment to ensure that the best approach is chosen for real studies to achieve statistically and clinically meaningful outcomes.

Leveraging the Power of Statistics
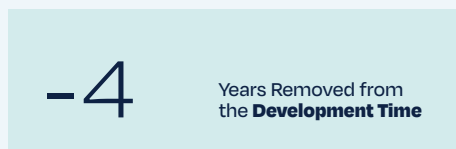
KerusCloud
Making an Impact

KerusCloud supports a multi-dimensional optimisation 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
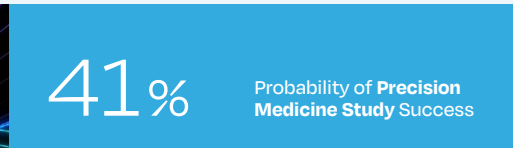
Increase the probability of success **by over 41% for a precision medicine study.**

−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.

Enabling earlier statistical input

KerusCloud maximises the impact of statisticians by offering a quantitative tool that can be used to assess, visualise and communicate the best study design approaches at an early stage of protocol development. Generating realistic in silico trials, **KerusCloud** quantifies the probability of success for simulated studies so the impact of multiple controllable and uncontrollable factors can be compared. Results are captured in an interactive heatmap so key design insights can be identified and shared with research teams.
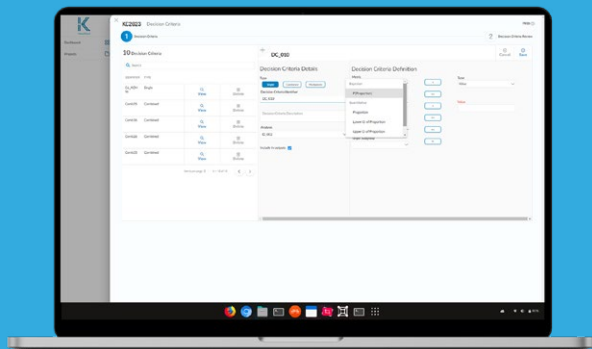
Handling diverse and complex data

KerusCloud handles the diverse and complex data now collected routinely in clinical research. It can incorporate data from sources including the scientific literature, disease registries, historical trials and real-world data. With KerusCloud, statisticians ensure research teams can harness a wider range of information to better understand the complicated inter-relationships between risk factors, outcomes and treatment effects when designing a study.
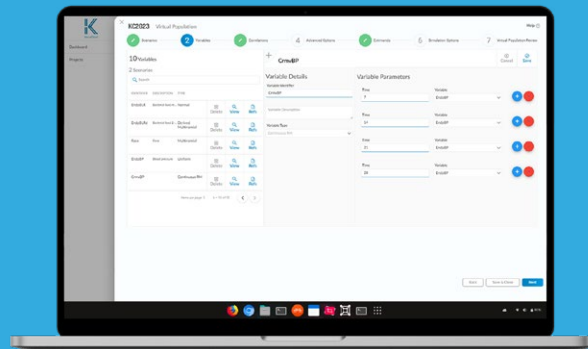
Exceptionally realistic simulation

In **KerusCloud**, real summary and subject-level data can be used to create synthetic virtual patient populations which inform realistic simulated 'what if' study scenarios. It can model variables based on any data type and statistical distribution, as well as the correlation between variables. Consequently, **KerusCloud** can generate complex synthetic data comprising:

- Common features such as subgroups and strata, risk factors/covariates, multiple outcomes.

- Special features including derived variables, missing data, truncation and censoring.

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KerusCloud®

NEW **KerusCloud** *Bayesian Posterior Probabilities*

NEW **KerusCloud** *Assess Repeated Measures*

Informing more design decisions

KerusCloud enables statisticians to play a greater role in design decisions by providing a powerful tool with which they can:

- Rapidly construct complex simulations to generate results that support project timescale.

- Influence more decisions on important study factors such as the right study population characteristics, sample size, sampling schedule, study power/Probability of Success (PoS), stratification, endpoints, analysis strategy and decision criteria.

- Overcome challenges with implementing new methods and generating simulation code, with no need to code.

- Communicate complex statistical information across stakeholders to help direct design and analysis strategies.

Maximising evidence for key stages

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 either as a standalone platform or as a precursor to existing design tools to efficiently narrow potential approach options.

KerusCloud Spring 2023 release

Building on core adaptive and fixed design capabilities, the Spring 2023 release now offers new innovative features so you can:

- **Explore Bayesian Posterior Probabilities**
  For applicable analysis types, new posterior probabilities metrics are available providing an additional way to define decision criteria and give users more flexibility on defining meaningful study success criteria.

- **Evaluate Complex Estimands Conditions**
  More complex estimand conditions can be created and applied to variables in response to a wider range of events to specify how data should be handled in response to each condition. KerusCloud is the only platform that implements new Regulatory guidelines, **ICH E9**, as part of clinical trial design. This ensures the best estimand strategy for more successful regulatory interactions.

- **Assess Repeated Measures**
  New repeated measures variables are now available so information for multiple time points per subject in a study can be considered. Mixed Models have been added so users can define repeated measures analysis to account for this.

![exploristics]
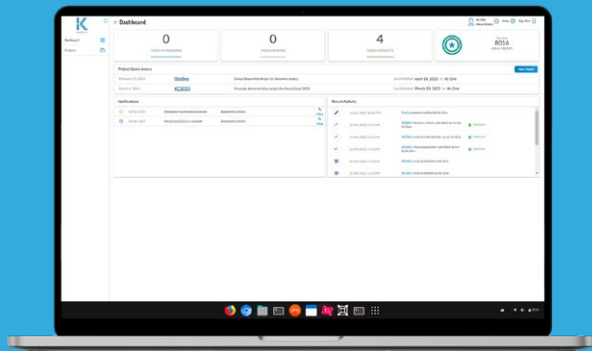
NEW **KerusCloud** *Live Notifications*
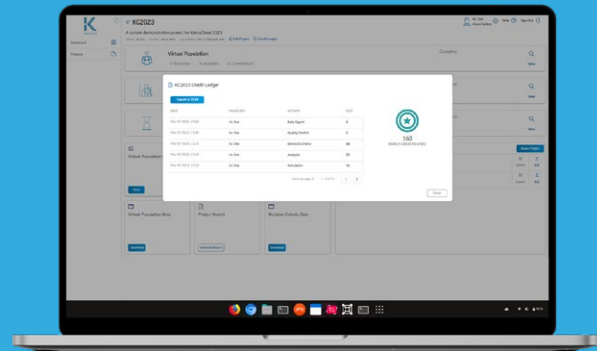
NEW **KerusCloud** *Usage History*

● **Apply Estimands in the Context of Repeated Measures**
Estimand conditions can be created and defined using repeated measures variables. Two new estimand strategies specific to repeated measures variable types have been added: Linear Interpolation and Last Observation Carried Forward. These make use of time information to work out how data should be handled when estimands are applied.

For direct users from Spring 2023 KerusCloud also offers:

● **Visualisation of Virtual Population QC**
Quality Control (QC) checks can be run and visualised for virtual populations. This allows comparison of user-requested variable parameters and correlations to the characteristics observed in the simulated virtual population data.

● **Live Notifications**
Regular notifications of important information such as new features or scheduled maintenance are now available for more effective planning and platform use. Recent edits to project tasks can also be tracked across projects.

● **KerusCredit Usage History**
KerusCredit usage for a project can be viewed in a new Credit Ledger. This information is displayed with a list of submitted project tasks indicating date, which user requested the task, the task type and the KerusCredit cost and can be exported for review in .xlsx format.

So, discover and share a more data-driven approach to optimising clinical study design with the Spring 2023 KerusCloud release.

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

✕ exploristics

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