

KerusCloud

CASE STUDY

Simulating patient level outcome data to inform clinical trial design based on RWE, clinical trial and literature data

KerusCloud is a ground-breaking new clinical study design and analytics software platform which delivers smarter real-time studies for today's clinical research challenges.

Using powerful cloud-based processing, KerusCloud can handle the diverse and complex data now collected routinely, to deliver advanced analytics which simplify the study planning and decision-making process.

With unique second-generation study simulation capabilities, KerusCloud provides exceptional support in developing robust evidence packages for drug approval.



The Challenge

- 1 GSK are conducting a phase III programme for a novel treatment for anaemia associated with chronic kidney disease in dialysis patients.
- 2 The comparator arm for this study is recombinant human erythropoietin, the current standard of care.
- 3 Both treatments modulate the Haemoglobin (Hb) levels.
- 4 Low and/or very high levels of Hb are both associated with an increased risk of major adverse cardiac events (MACE).
- 5 Baseline risk factors (older age, Diabetes, prior MI, HF, stroke) are also known to increase risk of MACE.
- 6 The complex relationship of varying risks over time in different risk groups at baseline may lead to uncertainty for accurate outcome prediction.

Simulating patient level outcome data to inform clinical trial design with KerusCloud

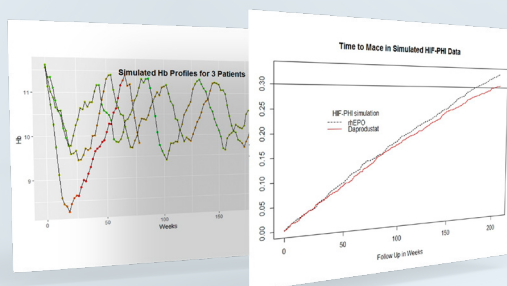
The Approach

Subject level data was simulated using KerusCloud with input data derived from multiple sources including literature, real world data and clinical trial data.

A range of study design and analysis options were evaluated for their ability to detect differences in treatment for time to MACE. Design options included studies that were enriched for high risk patients. Additional analysis options included standard cox regression models, adjusted models and time variant models.

Various metrics were derived from 1000 simulated studies including probability of success, study duration and sample size.

KerusCloud generated realistic data which could be used to better evaluate treatment effects under different scenarios.



Studies enriched with high-risk patients resulted in smaller sample size or duration.

The analysis approach had minimal impact on study power when Hb levels were well controlled.

The Impact

This study demonstrated successfully the feasibility for KerusCloud in a situation where there are **multiple sources of uncertainty**.

It showed that KerusCloud could utilize **real world data** to optimize the design and analysis options *in silico*.

The simulations showed the ability of design and analysis options to evaluate treatment effects under **different conditions** and these confirmed the validity of assumptions for the actual study.

KerusCloud also enabled the evaluation of alternative approaches such as the enriched study design which **reduced study duration and sample size by as much as 30%**.

Testimonial

“The feasibility study simulating patient level data to inform clinical trial design and outcome based on Real World, trial and literature data was successful. The KERUS platform simulated complex data under a variety of scenarios including time varying component, confirming clinical trial assumptions in the process.”

Director, Real World Evidence and Epidemiology, GSK

KerusCloud

Generate Robust Evidence

Develop strong evidence packages to support regulatory engagement or investment, increasing the value of development pipelines.

Optimise Studies for Success

Identify the right development path, optimising the number of patients required to generate the evidence needed to reduce approval timelines, costs and the risk of failure.

Accelerate Development

Accelerate access to novel treatments through better targeting of patient population and selection of outcome measures.

De-Risk Investment

Rapidly evaluate and test the impact of key assumptions to de-risk investment.

Transform Study Planning

KerusCloud transforms study planning with quick and convenient optimisation of study parameters to support the design of complex clinical research trials so you can:

- Simulate data with correlations and missing values reflecting real-world patients and studies
- Assess the probability of success for real-world objectives involving trade-offs between several factors
- Identify the critical study aspects impacting on the probability of success
- Compare analysis plans with selections from the comprehensive analysis suite



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