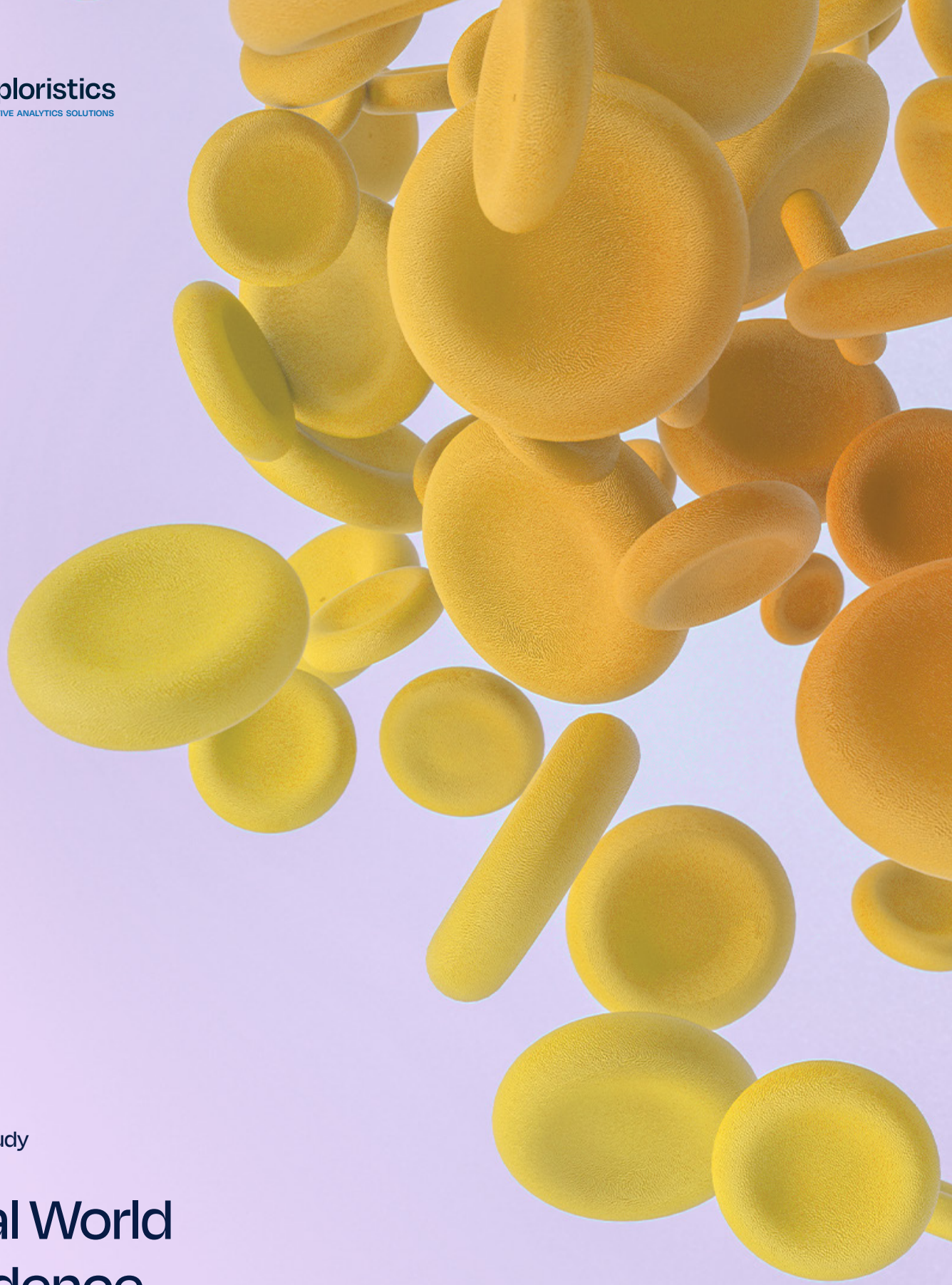
exploristics
INNOVATIVE ANALYTICS SOLUTIONS



Case Study

Real World Evidence

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

KerusCloud®

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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

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

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

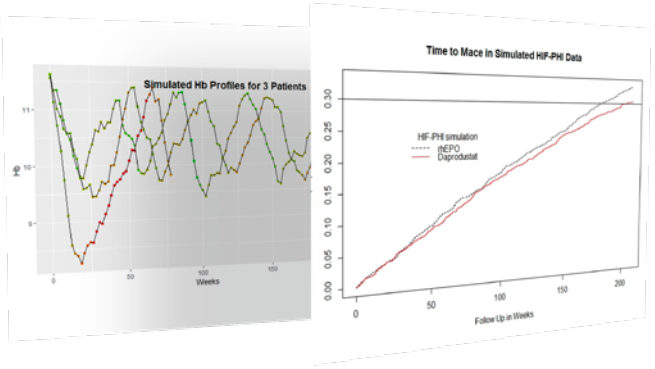
Simulating patient level outcome data to inform clinical trial design with KerusCloud

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.



- 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%.**