THE DIFFERENCE IS IN THE DATA®

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Case Study

Re-evaluating design of an initiated trial

De-risking once a study has initiated, adapting to new information

KerusCloud® is a revolutionary simulation-guided study design tool that ensures clinical trials are designed effectively to collect the right data, in the right patients, in the right way. Its use supports evidence-based design decisions to extensively de-risk real clinical studies, reducing development time, costs and patient burden.

The Challenge

A sponsor was running a clinical trial to examine the effect on an inflammatory biomarker of interest in patients treated with an investigative treatment versus placebo. Following initiation of the trial, two things changed:

- It emerged that the treatment effect was potentially larger than originally expected at the study design and planning stage. This meant that the original sample size was probably conservative.
- During recruitment, the COVID-19 pandemic occurred making the planned sample size difficult to achieve.

Therefore, the sponsor wished to re-evaluate the probability of success (PoS) for the study if it was adapted to include fewer patients than initially planned.

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The Approach

The MMS Strategic Consulting team carried out additional literature searches to obtain relevant background information on the clinical biomarker of interest to inform the strategy for simulation. This identified two critical design assumptions that were not considered at the initial design stage:

- **Assumption 1:** correlation between baseline and post dose biomarker value
- **Assumption 2:** truncation of biomarker data due to values outside lab range.

KerusCloud® quantified the Probability of Success (PoS) of multiple design and efficacy 'what if' scenarios, going beyond the original sample size calculations to consider:

- A range of assumed expected effect sizes (including larger than originally planned)
- A range of assumed correlations between baseline and post dose (given the true underlying value was unknown)
- Different recruitment design decisions between 60% and 100% of the planned sample size

The Results

KerusCloud® identified a previously hidden risk; the importance of the baseline to post dose correlation. Simulated scenarios indicated that this correlation was a key driver of success, and the study as originally planned was underpowered if the correlation was below 0.9.

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The Impact

KerusCloud® identified:

- the importance of the baseline to post dose correlation in this study, enabling mitigation for this risk to be put in place through a blinded ongoing review of the data.
- a viable design with an improved recruitment/risk profile relative to the original sample size calculation.

Why MMS?

Expertise In Early Development

The development of investigational drugs is a complex and expensive process with many risks. Our teams have extensive experience supporting and de-risking clinical development with their in-depth statistics and modelling expertise. Our study planning, statistical analysis and programming services add value to early stage development programs by ensuring they deliver the robust evidence needed for incisive, informed decision-making.

Innovative Software

KerusCloud® allows multiple study uncertainties to be explored simultaneously, in minutes, within a virtual environment. Study outcomes are visualized with an interactive heatmap where detailed results help identify the pros and cons of different design options. This allows the key drivers of study success to be pinpointed rapidly so that the best design and analysis approach can be selected, first time.

Diverse information and data types inform the simulations 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 'what if' study scenarios questions.

KerusCloud® provides exceptional advanced analytical insights able to deliver the smarter studies needed to address today's complex clinical research challenges.

Let's talk!

If you'd like to discuss this case study further or learn more on how our technology enabled services can support your development project, please visit our website: mmsholdings.com

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