Case Study — Supporting Funding Rounds

How trial design simulation supports successful funding rounds

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 small Biotech was developing new treatments for respiratory syncytial virus (RSV), a highly contagious virus that is a common cause of respiratory illness in immunocompromised individuals and bronchiolitis in infants under 2 years. Following completion of an observational study on viral load and immune mediator levels in nasal mucosa lining fluid over the course of RSV infection, the sponsor was seeking to design several early phase studies as part of a developmental program evaluating the efficacy of its pipeline of candidate RSV therapeutics.

The Approach

To ensure the best use of resources across the RSV program, MMS provided biostatistics support with the Statistical Consulting team optimizing the design of these studies using ground-breaking simulation software, KerusCloud®. To derisk the constituent studies, Statistical Consulting:

- Developed an RSV simulation framework in KerusCloud® using data sourced from the literature and results from completed studies in RSV.
- Integrated the multiple sources of information about RSV and treatment effects to create a data repository within KerusCloud® that recorded emerging knowledge relating to the treatment of RSV and mitigation strategies for key risks.
- Used KerusCloud® to quantify the ability to detect differential treatment effects in each study and in patient subgroups as well as in alternative design scenarios.

MMS Holdings Inc. 6880 Commerce Blvd. Canton, MI 48187, USA
Find out more: info@mmsholdings.com or mmsholdings.com

The Results

Study simulation in KerusCloud® provided quantitative evidence that enabled the sponsor to:

- **Identify the key factors for study success**
- **Optimize study designs within the program to:**
  - deal with the seasonal nature of RSV infection
  - reduce the time required for the trials from 3 years to 1 year

The Impact

For this sponsor, trial design simulation with KerusCloud® helped to:

- Increase the probability of program success.
- Dramatically drive down study timelines, risks, and costs.
- Provide evidence which was used to support raising US$30 million in a subsequent financing round.

"With MMS, we are cultivating an important partnership that grows as we develop our RSV program across multiple studies. The KerusCloud® platform has proved to be a core part of our decisionmaking as it allows us to prospectively tailor study designs as new information becomes available."

Chief Medical Officer, Biotech, UK

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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