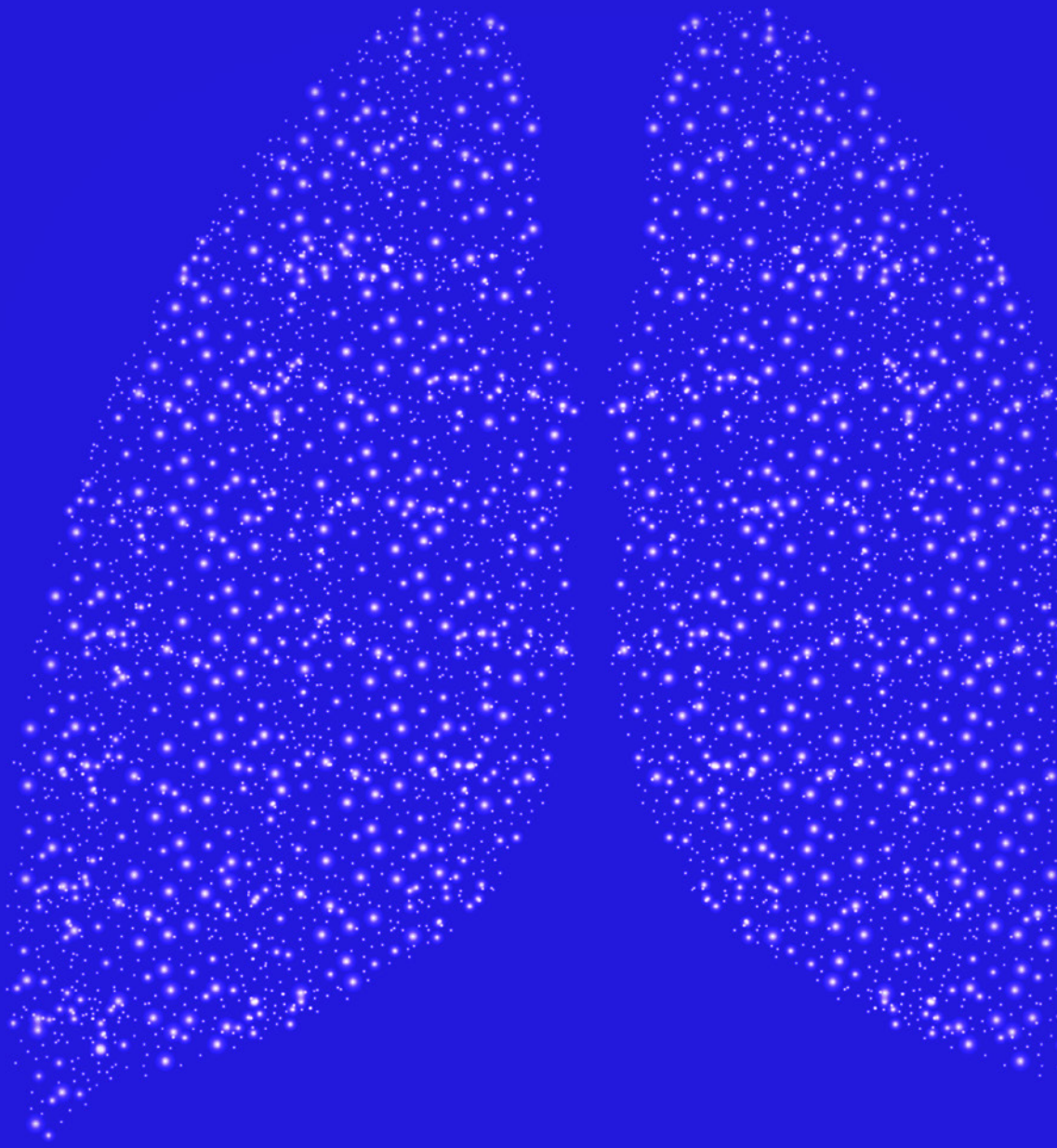
exploristics
INNOVATIVE ANALYTICS SOLUTIONS



Case Study

Early Phase RSV Study

Generating robust clinical evidence for an RSV development programme using Early Phase Services.

Over 90% of treatments undergoing trials currently fail to reach the market. Effective study planning and analysis is essential to reduce these failure rates and maximise the chances of a successful treatment development programme.

Exploristics' Early Phase Services provides key support in the translation of early clinical research through to proof of concept with innovative integrated data analytics solutions. Our expertise at this crucial stage of a development programme can transform effective decision-making to increase the overall success rate, reducing development time, cost and risk.

Good decision-making starts with good study-design. Our Early Phase Services facilitate this with the use of our ground-breaking new clinical study design and analytics platform, **KerusCloud**. **KerusCloud** provides unique second-generation simulation of clinical trials, examining *in silico* the effect of multiple variables and uncertainties in the clinical trial to identify the best possible trial design and analysis plan.

This facility, combined with our analysis andreporting capabilities, means that Exploristics delivers exceptional solutions that enable the development of robust evidence packages for early stage research.

The Challenge

Respiratory syncytial virus (RSV) is a common and highly contagious virus that infects the respiratory tract. It is a common cause of respiratory illness in immunocompromised individuals and bronchiolitis in infants under 2 years. Patients with underlying conditions infected with RSV can develop serious complications yet there is currently no effective vaccine for this virus and treatment options are limited.

To address this high unmet medical need, new anti-infective agents, including a treatment for RSV, are being developed by the small biopharmaceutical company Pulmocide. These novel agents are being designed to treat common acute and chronic respiratory tract infections associated with serious complications and devastating effects on patients' quality of life.

Pulmocide's development plan for RSV treatment consists of multiple studies including a first-time-in-patient study, a challenge study and proof of concept studies in adults and infants with RSV. Given the lack of available data on some aspects of RSV, there are multiple sources of uncertainty relating to how best to investigate the efficacy and safety of a novel treatment. Consequently, several significant risks may impact the operational conduct of the studies as well as the likelihood of demonstrating safety and efficacy.

Can the integrated solutions provided by our Early Phase Services help de-risk this early development programme for RSV treatments?

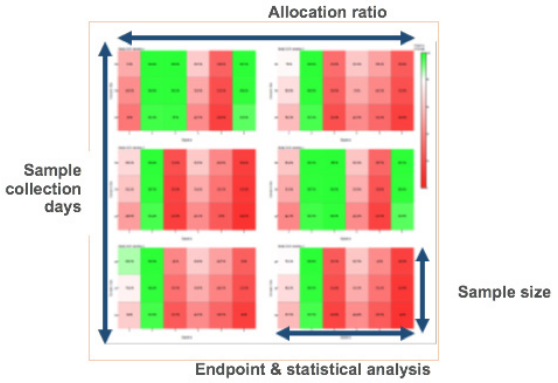


Figure 1: A **KerusCloud** heatmap displaying the impact of five study factors simultaneously to select the best design option.

Testimonial

"With Exploristics, we are cultivating an important partnership that grows as we develop our RSV programme across multiple studies. They offer highly skilled people who are a pleasure to work with. They are very responsive and are able to quickly react to ad hoc requests facilitated by a nimble contracting process. The **KerusCloud** platform has proved to be a core part of our decision-making as it allows us to prospectively tailor study designs as new information becomes available.

Chief Medical Officer, **Pulmocide**, UK

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Early Phase Services support efficient generation of clinical evidence for early stage research

The Approach

Exploristics' Early Phase Services provided key support in examining the optimal controllable study design features and impact of operational aspects of the RSV studies. Exploristics provided end-to-end statistics supportfor the RSV programme covering:

- Study Design with **KerusCloud**
- Study protocol review and input; production of statistical analysis plan
- Production and validation of analysis ready (AR) datasets
- Reporting of Tables, Figures and Listings (TFLs)

In the design phase, an RSV simulation framework was developed in **KerusCloud** using natural history data and results from completed studies in RSV. **KerusCloud** quantified the ability of studies to detect differential treatment effects in the study overall and in patient subgroups as well as in alternative design scenarios. As new data on other anti-RSV compounds were published, the results were incorporated into **KerusCloud** and designs were re-evaluated and updated, enabling design options to be ruled in or out. Once the study design was finalized, Exploristics collaborated with the study team to implement the study. Our integrated approach also increased the efficiency of the analysis and reporting: the simulated data was used to prospectively develop customized reporting algorithms in advance of the study data being available whilst the knowledge accumulated during the design phase facilitated greater understanding of customer and patient needs.

The Impact

KerusCloud integrated multiple sources of information about RSV and treatment effects so that the data repository within KerusCloud created a record of the emerging knowledge relating to the treatment of RSV and mitigation strategies for key risks.

- **The simulation results identified key factors for study success and optimized study designs to deal with the seasonal nature of infection**
- **Use of the integrated design and analysis solutions provided by Early Phase Services enhanced the chances of studies succeeding and reduced the risks, costs and duration of the Pulmocide's RSV programme.**
- **Exploristics developed analysis and reporting code prior to availability of actual study data to reduce study timelines.**

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KerusCloud®

Discover the power of cloud-based simulation.

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.

Expertise In Early Development

The development of investigational drugs is a complex and expensive process with many risks. The costs and timescales of clinical trials are affected by decisions that are taken as new data emerge. To leverage fullest benefit from our wide-ranging knowledge and skills, biostatisticians should be involved throughout the process from the first study design to ultimate regulatory approval. We offer comprehensive early stage biostatistics support. Our solutions are built around our unique **KerusCloud** platform which allows us to provide bespoke, end-to-end biometrics support from strategic decision-making and protocol development to analysis, reporting and stakeholder engagement.