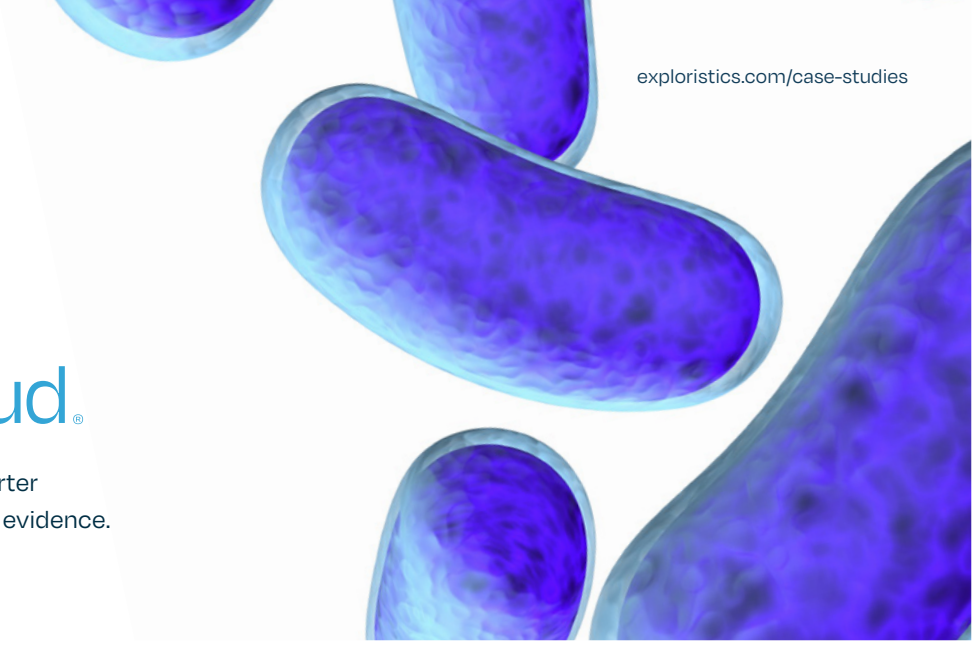
exploristics
INNOVATIVE ANALYTICS SOLUTIONS

Case Study

Enabling Early Approval

Enabling early approval through a smarter approach to generating robust clinical evidence.

KerusCloud®



KerusCloud®

Enabling early approval through a smarter approach to generating robust clinical evidence.

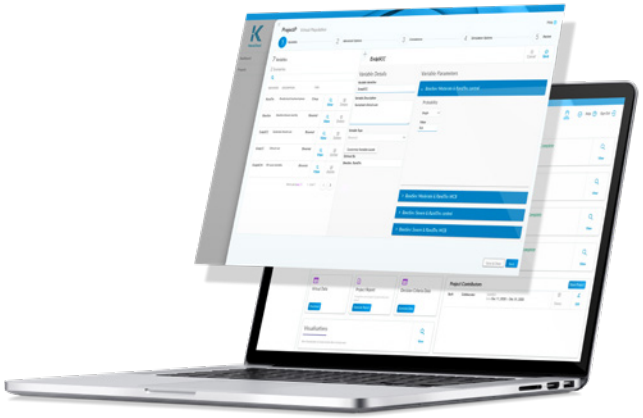
KerusCloud is a ground-breaking new clinical study design and analytics software platform which delivers smarter real-time studies for today's clinical research challenges.

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

- C. difficile (CDI) is the most common single organism causing healthcare associated infections. In vulnerable patients, CDI infections have high mortality rates, ~30% for severe CDI and ~40% in elderly patients, yet there is currently no available approved treatment.
- A new antibacterial treatment for CDI was developed by a small company with limited resources which was seeking early access for patients via the breakthrough therapy initiative in the US and the medicines adaptive pathways for patients (MAPPs) in the EU.
- A previous study assessment indicated that the development programme for this new antibacterial agent would need ~1000 patients. This development plan was impractical and could not be executed.
- How could evidence be generated to support rapid marketing authorisation?



Testimonial

"The **KerusCloud** simulation tool is very powerful! The simulations for our pivotal trials showed us a suitable and straight forward path to reach marketing approval with a smaller number of patients and quicker compared to our original plans. Discussions with statistic experts from CROs, investigators and key opinion leaders confirmed the approach.

CEO, Small Biotech, Germany

Evidence for approval with **KerusCloud**

The Approach

KerusCloud used information from published scientific literature and experts to simulate hundreds of studies to determine the best strategy for generating an evidence package for rapid approval.

This included collecting data on multiple correlated endpoints comprising clinical and pharmacodynamic measurements. The impact of study design parameters on outcomes could then be assessed rapidly *in silico.*

Design options and simulated evidence were presented to the FDA and EMA. Regulators could then give scientific advice on how best to proceed.

The Results

The Impact

KerusCloud helped to deliver a new antibacterial treatment option to patients that will save lives by:

- **Identifying the best design and endpoints for the study.**
- **Showing that an initial evidence package could be generated using 180 patients rather than 1000.**
- **Potentially saving the sponsor £18M andreducing the time to market by 3-5 years.**
- **Providing evidence that Regulators agreed would likely be sufficient for approval.**