KerusCloud

Case Study

Identifying
Best Strategy

Identifying the best overall strategy for study
designs and drug development pathways.

KerusCloud®

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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 selecting the best overall strategy for a study or drug development path.
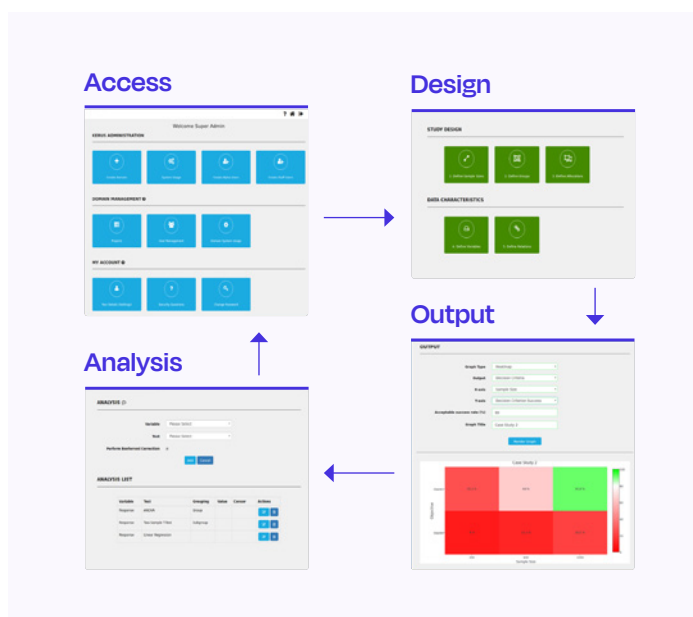
In collaboration with NICE, MIT and NEWDIGS, Exploristics examined how the MAPPS concept could be applied in development, evaluating the benefits and risks of a treatment, and the commercial impact of this on the treatment.

Evaluating and selecting best development strategy with KerusCloud:

The Challenge

EU and US regulators are interested in enabling early access to novel treatments for patients with severe unmet need. In the EU, the Medicines Adaptive Pathways for Patients (MAPPs) is an initiative looking at ways to enable early access such as:

- Flexible development and access pathways within the current regulatory framework that balance early patient access, public health and societal benefits.

- Early authorization of a product focused on a well-defined and targeted population with a clear safety and efficacy profile.

Testimonial

❝ Adaptive Pathways integration of staged approvals with real world evidence poses many issues regarding patient safety, patient access, developer incentives and payer affordability. The Exploristics team worked seamlessly with a joint MIT and IMI ADAPT-SMART team to create a case study that quantified not just a single study but an entire adaptive clinical development plan of multiple trials for dual approvals. The work was done in only a few months, demonstrating improved patient safety and increased population benefit inducing further support for adaptive pathways policies.

Mark Trusheim, **NEWDIGS Strategic Director, MIT Center for Biomedical Innovation**, USA

Selecting the best study strategy or development path with KerusCloud

The Approach

Information on a marketed treatment for relapsing Multiple Sclerosis (MS) was used to provide realistic data for a case study on MAPPS.

Exploristics designed an alternative MAPP development plan from the perspective of the forward-looking team to:

➕ Identify a higher benefit moderate & severe (M&S) sub-population for early authorization and real-world evidence collection

➕ Continue to develop the All-comers indication with no launch delay

KerusCloud simulated drug development scenarios using information and assumptions from the approved drug. This used therapeutic and study

conduct information derived from public sources, additional information from the MS literature. The outputs were used for commercial forecasting.
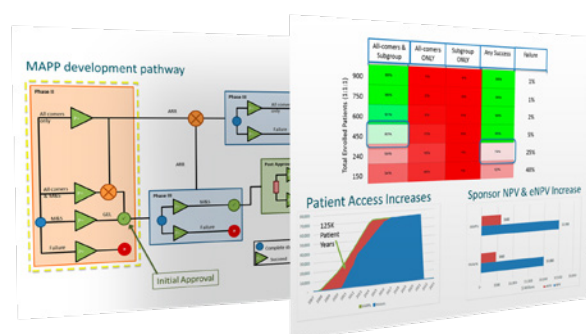

Figure 1: The outputs and commercial forecast

The Impact

The case study broadly supported the MAPPs approach with **KerusCloud** demonstrating that:

➕ **The MAPPs design would provide sufficient evidence for approval in a larger Phase II trial.**

➕ **The Phase II trial would need to randomize 450 patients rather than 240 in the original design.**

➕ **Initial approval would be in 5 rather than 8 years.**

➕ **The MAPPs approach can provide access for patients up to 3 years earlier.**

➕ **MAPPs was beneficial for developer and payer economics.**

Quantified sample-sizes and probability of success values from **KerusCloud** enabled financial modelling of the impact of MAPPs for Patients, Payers and Sponsors. This indicated an **increased** expected Net Present Value (eNPV) of **$600M** rather than **$460M** for sponsor.