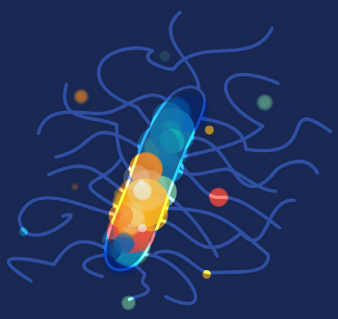
Case Study:

INNOVATIVE STRATEGIES FOR ADAPTIVE CLINICAL TRIALS IN REFRACTORY LUNG INFECTION AND INFECTIOUS DISEASES



Phase II portion of a pivotal Phase II/III study for the treatment of refractory lung infection

>170	>110	6
PATIENTS	SITES	COUNTRIES

Services: *Full-service Medpace trial, including wholly owned Central Lab and Core Lab services using ClinTrak IRT, ePRO, and EDC.*

CHALLENGES

- Site selection and enrollment started slow – emerging from COVID-19 pandemic, US sites were not able to find patients under initial restrictive protocol I/E, so enrollment into Phase II was longer than anticipated.
- European countries were originally planned to join the study, but due to EMEA feedback, the region was abandoned and eventually the study pivoted to APAC countries instead.
- Due to the different randomization scheme ratio between Phase II and III, both Investigators and potential patients were reluctant to enroll into Phase II and wanted to wait for Phase III.
- When Japan, South Korea, and Australia were opened for enrollment, they were very successful and the enrollment rate improved considerably, leading to the issue of enrolling too quickly and a bottleneck of data coming in. The Sponsor had to put the study on an enrollment pause to allow the Phase II analysis to get further along to plan next steps for the remaining Phase III subjects, which sites found frustrating and caused negative feedback and concern, including:
  - Subjects and Investigators expressed concerns over safety although the Sponsor assured there were none.
  - Many sites in start-up refused to continue with activities until the hold was lifted.
  - Many active sites asked to be closed or expressed high frustration that potential patients could not be screened or those that had screened couldn't be enrolled.

THE SOLUTIONS

Clarity: Released multiple protocol amendments to aid in improving Phase II enrollment after challenges raised by sites to find viable patients who qualify.

Preparation: Detailed study plans and risk analyses were formulated early in the study planning process to plot out the different data cuts and their associated activities (monitoring, data cleaning, PK analysis, etc.).

Adaptability: After receiving the challenging feedback from one region (EUR), the study team worked together quickly to initiate feasibility in the new region (APAC) and select and activate sites quickly.

Communication: Sponsor and Medpace team provided close, frequent communication with the sites regarding study changes.

Availability: Sponsor and Medpace team ensured availability to meet with Investigators.

RESULTS

- Site engagement increased, and new sites/Investigators requested to take part in the study.
- Recruitment completed ahead of schedule.
- Successful set-up of labs, securing endpoint data.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.