

Case Study:

EMPOWERING EMERGING BIOTECH: MEDPACE CPU'S ROLE IN GUIDING BIOTECH THROUGH A COMPLEX SAD/MAD TRIAL

PROGRAM DESCRIPTION:

An emerging biotech with no prior Phase I experience partnered with the Medpace Clinical Pharmacology Unit (MCPU) to execute a Single Ascending Dose/Multiple Ascending Dose (SAD/MAD) clinical trial. With limited resources and expertise, the biotech relied on the MCPU's comprehensive support to navigate the complexities of early-phase clinical development.



SERVICES PROVIDED

- Protocol Review and Finalization
- Project Management
- Data Management
- Biostatistics
- Medical Writing
 - Clinical Study Report Development
- Clinical Monitoring
- Recruitment and Enrollment Support



CHALLENGES

- **Biotech Resource Constraints:** The biotech lacked dedicated medical expertise and early phase clinical trial experience, necessitating significant reliance on MCPU's expertise for protocol refinement and trial execution.
- **Protocol Inconsistencies:** The initial protocol provided by the biotech exhibited numerous inconsistencies, particularly in the dose escalation design and safety monitoring procedures, which are critical components in SAD/MAD studies. The protocol required substantial revisions to ensure it met the rigorous scientific and regulatory standards necessary for Phase I trials.
- **Complexity of Dose Escalation:** Ensuring the safe and effective design of dose escalation procedures posed challenges due to the biotech's limited experience with pharmacokinetic and pharmacodynamic assessments, as well as the need to balance safety with the exploration of therapeutic dose ranges.



THE SOLUTIONS

- **Comprehensive Protocol Review:** MCPU, including the CPU Principal Investigator and Medical Monitor, conducted an in-depth review of the protocol, providing detailed feedback on study objectives, endpoints, safety measures, and operational considerations. This process was iterative, involving streamlined communication with the biotech to refine the protocol and align it with the best practices in SAD/MAD Trials.
- **Embedded Expertise from Inception through Completion:** MCPU's Operations team offered ongoing guidance on the nuances of Phase I clinical trials, particularly regarding dose escalation strategies. The team worked closely with the biotech to educate them on the scientific and operational complexities, enabling informed decision-making throughout the trial.
- **Collaborative Model:** The partnership between the MCPU and biotech was characterized by transparent communication and a collaborative problem-solving approach. This allowed for the seamless integration of the MCPU's expertise into the trial's design and execution, ensuring that all challenges were addressed proactively.



RESULTS



Timely Recruitment and Dosing:

MCPU successfully recruited, screened, and dosed all study participants within the original timelines, overcoming the initial protocol challenges.



Coordinated Trial Execution:

All downstream activities, including data management and clinical monitoring, were completed quickly and efficiently, ensuring the trial's overall success.



Enhanced Protocol Quality:

The collaborative protocol refinement process resulted in a scientifically sound and operationally feasible study design, which contributed to the successful completion of the trial.

TRUSTED BY BIOTECH® – A PREFERRED PARTNER FOR EARLY PHASE DEVELOPMENT

The successful partnership between the emerging biotech and Medpace CPU highlights Medpace's role as a trusted, integrated research partner for emerging biotech companies. With over 30 years of experience and a focus on small to midsize biotech companies, Medpace's expertise and efficient operating model enable successful clinical trials and make MCPU a preferred partner for navigating early-phase clinical development.

