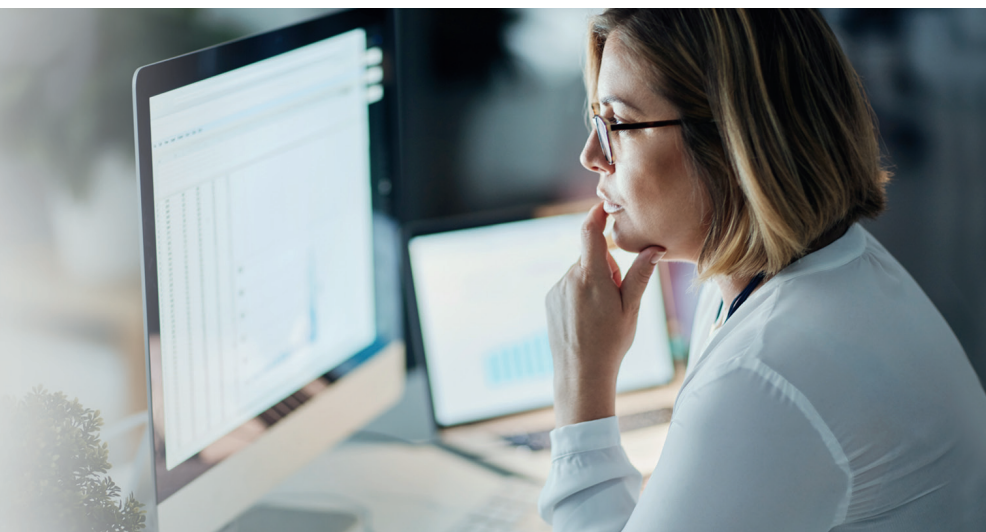


Team Approach

Expertise

Consulting



Partnering with Large Pharmaceutical Companies

NEED

- The client required a study protocol incorporating a single ascending and multiple ascending design for a novel compound
- Key objective was to find the maximum tolerated dose and a suitable supra therapeutic dose for future investigations, one being a TQT study

APPROACH

- Advised the client on several critical issues to ensure their protocol met the safety standards for such a design, these included staggered dosing requirements, escalation criteria between ascending doses, and required stopping criteria
- Informed the client immediately to incorporate intensive electrocardiogram (ECG) monitoring due to the potential cardiac issues related to the drug. The analysis of the data would greatly assist in the design of their future TQT study

BENEFITS

- Effectively designed the study protocol using the clients' template and following their specific Standard Operating Procedures (SOPs) for document review and updating procedures
- In-house knowledge and experience ensured the study protocol was developed within 3 weeks
- Novel study design saved at least 4 weeks over traditional study designs

See Other Case Studies

[Responding to an Unexpectedly High Drop Rate](#)

[High Throughput Bioanalytical Analysis](#)

[IND Support for Asian Biotech](#)