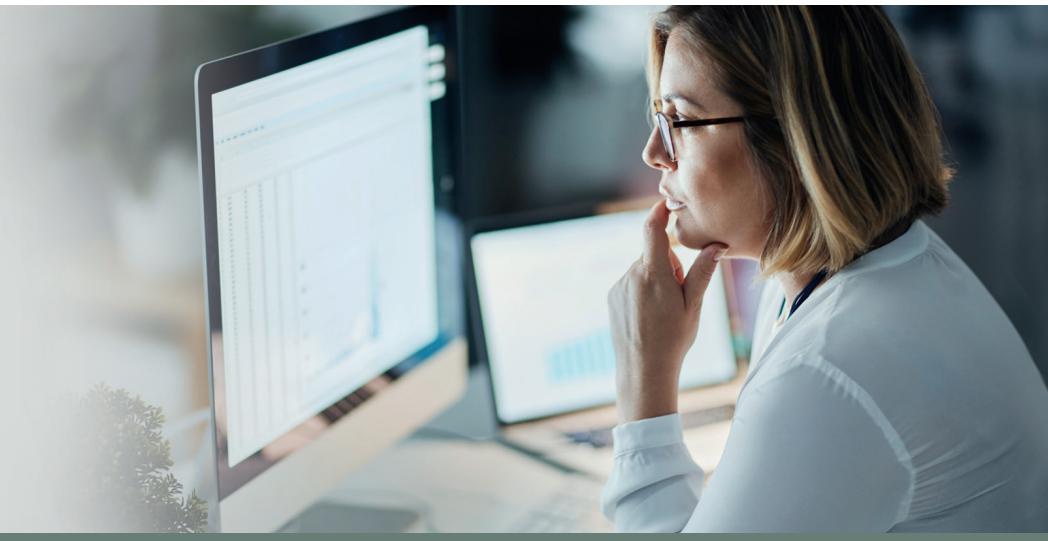
Team Approach

Expertise

Consulting



Partnering with Biotechnology Companies

NEED

- Well established pharma company required both a TQT and Multiple-Ascending Dose (MAD) protocol for a narcotic compound to advance their NDA commitments
- Drug has potential safety concerns and establishing the upper safe dose and dosing interval is complicated by ensuring subject safety

APPROACH

- Quickly enlisted a team of internal experts (cardiologist, cardiac central labs personnel, statistician, pharmacokineticist, director of cardiac safety services, protocol development team) to determine the appropriate recommendations for these two complex studies
- Recommendations collected by the protocol development team sent to the client within 2 days
- Detailed discussions immediately ensued as a result of the initial input enabling client to meet the FDA requested timelines
- Involvement of the team continued throughout the protocol development process enabling both protocols to be finalized within 3 weeks

BENEFITS

- The client was able to provide the FDA with the protocols for review and obtain approval to proceed with their Phase I program thus advancing their timelines for approval
- Comprehensive input from multi-disciplinary team facilitated quality protocol development
- Expeditious timelines for protocol development enabled a faster turnaround for regulatory approval of the protocol and thus trial initiation

See Other Case Studies

Responding to an Unexpectedly High Drop Rate

High Throughput Bioanalytical Analysis

IND Support for Asian Biotech