**Case Study**

**Drug Development & Regulatory Affairs**

**IND Support for Asian Biotech**

**NEED**
- Asian biotechnology company with a Central Nervous System (CNS) compound originally developed to treat a neurological disorder
- Preclinical pharmacology studies revealed potential for additional neurological indication
- Assistance requested with the preparation and filing of a new Investigational New Drug (IND)

**APPROACH**
- Reviewed original IND filing and provided a detailed gap analysis and regulatory strategy for the new indication
- Prepared and filed the new IND within an aggressive target time line
- FDA placed the clinical program on a partial clinical hold due to nonclinical data
- Developed a regulatory strategy and assisted in the design of a pivotal nonclinical toxicology study to provide conclusive data to FDA for removing the partial clinical hold
- Interacted with an academic consortium of leading Neurology experts to design and implement a novel, Phase IIa clinical proof-of-concept study, which allowed initial patient cohorts to be treated while under a partial clinical hold
- FDA removed the hold 30 days after submission of the complete response and initial safety data on the Phase IIa study

**BENEFITS**
- Leveraged existing nonclinical and Phase I safety and PK data to allow an initial proof-of-concept study as the IND-opening clinical trial
- Obtained removal of the partial clinical hold and effective FDA input into proof of concept study design allowing the client to meet all critical milestones
- Completion of the multi-site, proof-of-concept trial on time, with the positive results supportive of the new target indication
- Quality ICH-consistent Clinical Study Report prepared on time

**See Other Case Studies**
- Semen Clinical Studies
- Difficult to Recruit Population
- Bioanalytical Support of Oncology Studies