Consultancy

Custom Planning

Regulatory Strategy

Customized Program Plan for Opening IND Study

NEED

Virtual US Biotech Company developing a central nervous system (CNS) – targeted compound completed an initial Single Ascending Dose (SAD) study in the EU with limited preclinical data package and single dose patient study in Asia. Client required integrated program management of outsourced program to address regulatory gaps required for opening their US Investigational New Drug (IND) study designed to support further patient studies

APPROACH

- Integrated project team led by Celerion program director that assisted the client with planning the drug development program and designed/managed all outsourced studies within and external to Celerion, including subcontractor qualification.
- Provided regulatory guidance, facilitated PreIND meeting with the FDA, and prepared IND documentation and subsequently coordinated the Scientific Advisory Board meetings.

BENEFITS

- In Vitro drug-drug interaction elucidation of parent and metabolite
- Develop and validate human plasma assays for parent and metabolite
- Radioisotope tagging of parent compound
- Human ADME study for parent and metabolite analysis

OUTCOMES

Preclinical work and IND submitted within challenging investor-driven timelines: involved complex program management with vendors, client representatives and external consultants.

- Alignment of Celerion and client enabled the senior management to focus on investors
- Successful initiation of the opening IND healthy normal food effect study
- Successful initial study allowed for Phase II program initiation in patients

See Other Case Studies

Semen Clinical Studies

Difficult to Recruit Population

Bioanalytical Support of Oncology Studies