Regulatory Strategy

Scientific Input

Regulatory Operations

Proof-of-Concept Efficacy Clinical Study

NEED

- Approached by Japanese pharmaceutical company with an antiviral product intended to treat and prevent influenza, seeking approval for proof-of-concept (PoC) efficacy clinical study
- Assistance required for interactions with European agency to ensure efficient review of protocol and general clinical development plan

See Other Case Studies

Semen Clinical Studies

Difficult to Recruit Population

Bioanalytical Support of Oncology Studies

APPROACH

- Reviewed non-clinical data and non-clinical development program
- Prepared briefing package for scientific advice meeting with national European agency
- Liaised with European agency and ensured timely submissions for scientific advice meeting
- Coordinated European agency meeting with the client and managed all oral and written communications between the Japanese client and European agency

BENEFITS

- Extensive review of all submission information from the Celerion team enabled on-time and effective input from a European agency on the timing and acceptability of a proof-of-concept efficacy study, and acceptability of development plan allowed quick and immediate go-ahead decision for the client