A Hepatic Impairment Study for a Drug with a Long Half-Life; Aggressive Enrollment Timelines at a European Site

NEED:

- A US biotech company seeking a CRO to support a hepatic impairment (HI) study to evaluate the pharmacokinetics (PK), safety and tolerability of an investigational product (IP) in participants with severe HI and healthy matched controls
- The HI study was part of the critical path of development of the study drug
- The IP had a long half-life and, in line with FDA requirements, PK sampling timepoints had to cover a relatively long timeframe to adequately capture full exposure to the study drug
- Multiple US sites declined participation because of the long IP half-life, as that would complicate patient recruitment

APPROACH:

- Celerion's extensive site network includes several sites in Europe
- The European site readily facilitated regulatory and ethical submission allowing for timely IP release by a Qualified Person and delivery to site
- Upon regulatory and ethics approval, the European site instantly initiated recruitment and enrollment of participants with severe HI
- The Last Patient Last Visit (LPLV) date was completed within 3 months

BENEFITS:

- A highly motivated, European site with good relationships with national regulatory authorities and an ethical committee effectuated extremely rapid conduct of an HI study
- The large database of HI patients at the European site facilitated rapid recruitment of participants with severe HI and healthy matched controls
- Despite the IP's long half-life and the tight timelines for the HI study, study conduct was completed in less than 3 months

RESOURCES:

Renal/Hepatic Experience & Expertise

Navigating Enrollment & Central Lab Challenges in a Large PK Study with Severe Renal Impairment

A Renal Impairment Study Evaluating Plasma and Intracellular (PBMC) Pharmacokinetics (PK)