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

NEED:

- A US pharma company was seeking an experienced CRO to manage a renal impairment study evaluating the pharmacokinetics (PK), safety and tolerability of an investigational product (IP) in participants with severe renal impairment (RI)
- Based on statistical sample size justification, a large number of participants with severe RI (n=14) had to be enrolled, requiring multiple sites to contribute to study conduct
- As a unique aspect for impairment studies, a central lab was required because safety and pharmacodynamic biomarkers were to be evaluated after repeat dosing
- Working with a central lab, each site had to adapt their processes for lab requisites and kits
- Results were to be compared to healthy matched control participants (n=14) with normal renal function

APPROACH:

- Celerion engaged 3 experienced nephrology sites in the US, each with a large database of severely impaired patients
- Celerion supported alignment of the local site lab procedures with the central lab
- By means of real-time access to lab data, Celerion and the Sponsor could closely review lab draws and lab parameters, thus ensuring smooth study conduct and protocol adherence across sites
- Overall, recruitment of all participants (n=28) was completed in 6.5 months, which was substantially less than the 9 months scheduled for recruitment

BENEFITS:

- A large cohort of 14 patients with severe renal impairment was enrolled across 3 experienced and well-trained sites
- Sites finished recruitment well ahead of timelines
- Complicated central lab and PK lab processes were successfully navigated

RESOURCES:

Renal/Hepatic Experience & Expertise

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

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