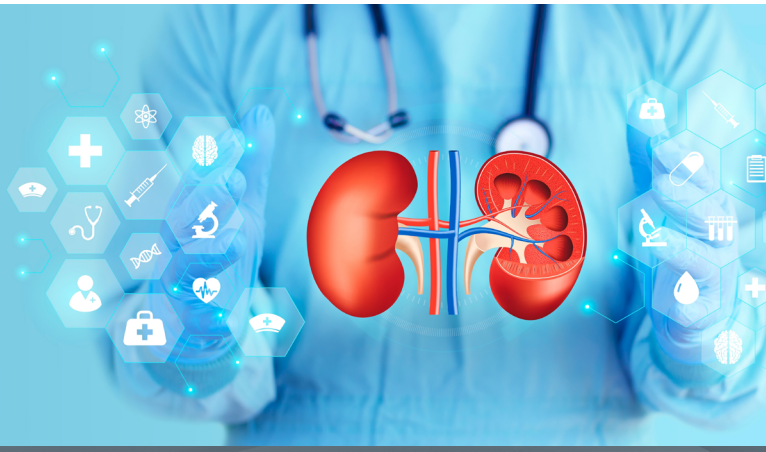
A Renal Impairment Study Evaluating Plasma and Intracellular (PBMC) Pharmacokinetics



NEED:

- A US pharmaceutical company wanted to partner with Celerion on a renal impairment study to evaluate the pharmacokinetics (PK), safety and tolerability of an investigational product in participants with renal impairment (RI)
- While typical renal impairment studies concentrate on plasma PK, the client aimed to also evaluate intracellular PK of their study drug in peripheral blood mononuclear cells (PBMCs)
- While PBMC analysis has broad application in clinical trials, it is uncommon for organ impairment studies. The requirement for collection and immediate processing of fresh blood made this particular study unique
- Results were to be compared to healthy matched control participants

APPROACH:

- Celerion identified a site with on-site capabilities to isolate PBMCs from fresh blood
- Celerion's bioanalytical team provided dedicated equipment and site staff training on PBMC isolation procedures to ensure consistency between PBMC samples collected across multiple studies for the same drug
- Throughout study conduct, Celerion provided ongoing support to the site (e.g. biweekly meetings) to optimize study conduct and PBMC sample processing
- A total of 18 participants enrolled in the study: 6 participants with moderate RI, 6 participants with severe RI, and 6 healthy matched controlled participants
- With a large database of severe and moderate RI patients, study enrollment was completed one month ahead of schedule

BENEFITS:

- By leveraging Celerion's large network of renal impairment sites, the Sponsor was able to place their study at an experienced site with access to a RI patient population as well as strong lab capabilities
- PBMCs were isolated to a high standard of quality and in consistence with the entire drug development program
- Rapid participant enrollment was completed well ahead of initial timelines

RESOURCES:

Renal/Hepatic Experience & Expertise

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

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