celerion
Translating Science to Medicine

Product Labeling Studies

Celerion collaborates with pharmaceutical companies seeking market approval for new drugs and product labeling studies are a key component. We proactively create efficient and cost-effective packages of product labeling studies that form the basis for specific labeling claims in your drug applications (Figure1). Most importantly:

- For speed and accuracy of your data, Celerion global clinics and bioanalytical laboratories share SOPs, data capture and analysis systems
- Working with Celerion for your early clinical development, our scientists apply their knowledge of your drug in executing all studies
- Celerion has the capacity to manage many studies simultaneously to ensure your submission timelines are not compromised

Figure 1. Different types and features of product labeling clinical pharmacology studies

Study Type	Typical Study Design Elements	Typical Duration of Clinical Conduct	Comments
Drug-Driving Interactions*	• 1-way or 2-way crossover • 2,3,4 arm parallel • Fixed sequence	1-3 months	• Common co-administered drugs • Warfarin, Digoxin – low TI • Drugs that reflect activity of certain drug metabolizing enzymes of transport proteins where in vitro studies suggest that the new drug candidate may interact • Strong inhibitors or inducers of key elimination pathways for new drug candidate
Hepatic Insufficiency	• 2,3,4 arm parallel • Adaptive (staged)	6-12 months	• Mild, moderate and severely impaired as measured by Child-Pugh score
Renal Insufficiency	• 2,3,4 arm parallel • Adaptive (staged)	6-12 months	• Mild, moderate and severely impaired as measured by estimated GFR or creatine clearance • During and between hemodialysis
Absorption, Distribution, Metabolism, Excretion (ADME)	• Single dose of radiolabeled drug (traditional dose ~100 microCuries; microtracer dose <500 nanoCuries)	2 weeks conduct 1-4 months sample analysis	• Usually healthy young male participants • Sometimes can only be done in patient populations (e.g. oncology) which might require microtracer approach in hospital setting with conduct covering 1-2 patients at a time
Thorough QT (TQT)	• 3,4-way crossover • 3,4 arm parallel • Parallel with nested crossover	2-6 months	• Moxifloxicin is usual positive control • Highly automated digital ECG analysis now supported by regluators
Market-Image Bioequivalence	• 2-way crossover • Parallel (rare)	1-2 months	• Compare bioavailability of product from commercial production batch versus product used in pivotal clinical trials
Definitive Food Effect	• 2,3 way crossover (fasting, low fat and/or high fat meal)	1-2 months	• For orally delivered drugs where earlier studies indicated a potentially clinically significant food effect
Ethnic Bridging PK Studies	• Parallel need to relate clinical data collected in one population to use in another defined population	1-4 months (depends on availability of suitable participants)	• Justified by known polymorphic differences among different ethnic or genetic populations in expression of proteins involved in metabolism, transport or effect.
PK in Special Patient Populations	• Single dose or repeated dose as justified by intended clinical use	1-12 months (depends on availability of suitable participants)	• Pediatric, Adolescents, Elderly/Aged, Disease Situations • Pressure by regulators for data in pediatric patients - conduct presents ethical challenges
Population PK or PK/PD Analysis	• Sparse sampling from patients enrolled in pivotal efficacy and safety studies	Duration of phase III program	• Effect of Disease, Age, BMI, Gender, Genetics, Ethnicity on contributing to intersubject variability PK parameters • Population PK model often set up from Phase I and II PK studies