

Study Design and Conduct: Leveraging Allucent's Clinical Pharmacology Expertise

Study Design and Conduct

Allucent has extensive experience with designing, conducting, analyzing, and interpreting of data from each type of Phase 1 clinical pharmacology study needed for an individual drug development program.

While we can conduct any Phase 1 study, our focus and expertise in clinical pharmacology is our differentiator. This is about much more than just conducting one study, it's about an integrated approach to designing, conducting, analyzing, and interpreting Phase 1 studies within the context of your overall drug development program. As part of the study design phase, our senior consultants will conduct a review of your clinical pharmacology strategy to establish an understanding of existing data and how to maximize the impact of the next study on the overall plan.

Studies Supported

- First-Time-in-Human (FTIH)
- Single Ascending Dose (SAD)
- Multiple Ascending Dose (MAD)
- Food Effect
- Bioequivalence
- Drug-Drug Interaction (DDI)
- Thorough QT (TQT) Study
- Hepatic Impairment
- Renal Impairment
- Site of Absorption
- Radio-Labeled Mass Balance
- Ethnic Bridging

Services

- Clinical Pharmacology Strategy Development/Review
- Study Design and Protocol Development
- Study Startup Activities
- Data Management (eCRF, Randomization, Database Build, Edit Check, Etc.)
- Robust PK Analysis and Standalone PK Report
- Biostatistics
- Clinical Study Report (CSR)
- Study Management
- Clinical Monitoring
- Medical Monitoring
- CDISC Datasets
- Documents that are eCTD-Publishing Ready

