



Overwhelmed? Understaffed? Need help planning & executing your Clinical Pharmacology Studies?

## Introducing Certara's "Clinical Pharmacology Study Execution Team" (CP-SET)!

**A dedicated team of experts to plan studies, write protocols, oversee study conduct, analyze results, and write the clinical study reports**

*CP-SET study activities are led by functional experts with extensive experience in clinical pharmacology studies*

### CLINICAL PHARMACOLOGY DEVELOPMENT STRATEGY

- Certara has designed many clinical pharmacology programs leading to regulatory approval
- Expertise to design, guide and execute these studies, including combining studies to extract more information with fewer subjects
- Plans can be used to support First-in-Human thru label claim studies (Drug-Drug Interactions, QTc, Special Populations, etc.)
- Assess where studies can be avoided with the use of modeling & simulation

**Integrated with our industry leading modeling & simulation capabilities**

#### FIH TO POC

- SAD/MAD
- Food Effect
- Ethnic differences
- Cardiac Safety
- Absolute/Relative bioavailability and formulation studies
- Drug Metabolizing Enzyme Probes or Genotyping
- Early Metabolic Profile
- First-in-Patient

#### NDA ENABLING (SUPPORT PRODUCT)

- Drug-Drug Interactions (DDI)
- Thorough QT (TQT) or concentration-QT analyses
- Radiolabeled AME
- Bioequivalence (BE)
- PK or PK/PD Special Populations
  - Hepatic & Renal Impaired
  - Pediatrics/Geriatrics
  - Maternal

### CLINICAL OPERATIONS SUPPORT WITHIN CP-SET

- Ability to oversee a clinical study in collaboration with a Sponsor or oversee the Sponsor's preferred CRO on behalf of a Sponsor
- Collaborate with Sponsor or selected CRO early to coordinate timelines, expectations, and feedback

#### Coverage includes

- Study design and Start Up Activities
- Identification of sites/ CPUs and ongoing study oversight
- Protocol, study specific manuals and clinical study report writing & electronic submission
- Pharmacometrics, data management, and biostatistical analysis



**To find out more about how Certara's CP Set can help:**  
Email Alberto Bryan - [Alberto.Bryan@Certara.com](mailto:Alberto.Bryan@Certara.com)

**LEARN MORE AT: [CERTARA.COM/CLINICAL-PHARMACOLOGY-SET-OFFERING/](https://www.certara.com/clinical-pharmacology-set-offering/)**

## About Certara

Certara accelerates medicines using proprietary biosimulation software and technology to transform traditional drug discovery and development. Its clients include 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

For more information, visit [www.certara.com](https://www.certara.com).