

When Should You Incorporate CPMS?

Clinical pharmacology modeling and simulation data is a pivotal segment of drug development, and it is common practice to incorporate CPMS later in clinical development. However, integrating CPMS earlier can bring tremendous benefits.

When does incorporating CPMS improve the drug development process?

- ▶ Study design (particularly Phase 1)
- ▶ Optimal dose and dose regimen selection (First in Human through later phase)
- ▶ Pharmacokinetics (PK), Pharmacodynamics (PD) and Population PK/PD analysis
- ▶ Exposure-response analysis
- ▶ Drug interactions
- ▶ Physiological based pharmacokinetic
- ▶ Concentration-QT analysis
- ▶ 505(b)2 bridging strategies
- ▶ Generics, Bioavailability, and Bioequivalence
- ▶ Special patient populations
- ▶ Pre-IND, EOP2, or other regulatory meetings

CPMS tools help to improve the benefit-risk profile for a given product through optimal dose selection, inform the clinical trial design, and streamline drug development by avoiding unnecessary studies.

Use CPMS early and often!