

About Us

XP Pharma Consulting is a service provider that specializes in:

- Clinical pharmacology
- Pharmacokinetics
- Pharmacometrics
- Regulatory strategy
- Translational science

Clinical Study and PK/PD

- Allometric scaling
- Clinical study design
- Protocol writing
- PK/PD sampling design
- Non-compartmental PK analysis (NCA) with validated software
- Submission ready reports

Regulatory Strategy & Writing

- Gap analysis
- Clinical pharmacology plan
- TQT study waiver
- Regulatory representation
- Integrated risk assessment for QT/QTc prolongation
- Pediatric dose selection

NDA/BLA Submission

- Author clinical pharmacology and biopharmaceutical modules
- Integrated analysis for PK, PD and dose-response and immunogenicity
- Responses questions
- Label negotiation

Contact Us

Amy Zhang, MD, PhD
CEO and President
Phone: 781.507.5713
services@xp-pharmaconsulting.com
Web: xp-pharmaconsulting.com



Population PK Modeling

- Population PK modeling with NONMEM
- Covariates evaluation
- Exposure-response analysis
- Dose selection
- Trial simulation
- Concentration modeling analysis and risk prediction

Clinical Pharmacology Studies



- Single ascending dose study
- Multiple ascending dose study
- Bioequivalence study
- Drug-drug interaction
- Pediatric bridging study
- PK/PD bridging study

- Hepatic impairment study
- Renal impairment study
- Proof of concept study
- Thorough QT/QTc study
- Mass balance study
- Food effect study