XP PHARMA CONSULTING

Your Trusted Partner in Clinical Pharmacology, Pharmacokinetics, Pharmacometrics Services from pre-IND to NDA/BLA Registration.

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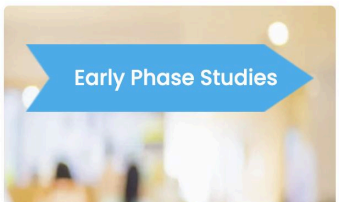
About Us

XP Pharma Consulting is a specialized service provider offering expert Clinical Pharmacology and PK/PD consulting to pharmaceutical and biotechnology companies. The firm is led by Dr. Xiaoping (Amy) Zhang (pictured on the right), a seasoned industry leader with 25 years of experience and an exceptional academic background that includes an MD, PhD, and MSc in mathematics and modeling. This unique combination of clinical, quantitative, and translational expertise positions her to deliver the highest level of scientific and regulatory insight to clients. Dr. Zhang has held key roles at leading pharmaceutical companies and CROs, including Roche and Allucent

XP Pharma Consulting provides independent, objective, and highly specialized support in Clinical Pharmacology, pharmacokinetics (PK), pharmacodynamics (PD), and PK/PD modeling and simulation (pharmacometrics). Our mission is simple: to deliver regulatory-submission-ready analyses, reports, and strategy that accelerate drug development and increase the probability of program success. Every project is led by senior scientific experts with decades of experience across U.S. and EU regulatory pathways, Clinical Pharmacology, PK/PD modeling, translational science, and Model-Informed Drug Development (MIDD).

Services

By Drug Development Stages:



By Service Areas:

Clinical Pharmacology Studies

Protocol design, PK/PD integration, and study oversight for small and large molecules.

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Noncompartmental PK Analysis

Robust PK analysis supporting dose justification and submission-ready documentation.

LEARN MORE

Pharmacometrics

Model-informed drug development to optimize dose for clinical responses.

LEARN MORE

Clinical Pharmacology Strategy & Writing

End-to-end strategy development and regulatory writing for IND/NDA/BLA submissions.

LEARN MORE

Clinical Pharmacology Studies

Clinical pharmacology studies are necessary to characterize your drug's pharmacokinetics (PK) and pharmacodynamics (PD) properties and for dosing instructions on the label. XP Pharma Consulting works with you to identify the necessary clinical pharmacology studies based on available nonclinical, DMPK, pharmacokinetic, pharmacodynamic, clinical data, and industry standards. We are confident in our recommendations to ensure you have what you need to achieve regulatory success for your drug development and registration. XP Pharma Consulting has extensive experience in clinical pharmacology plan, study design, protocol authoring, PK/PD data analysis, study monitoring, and study reporting for various clinical pharmacology study types.

- First-in-human (FIH)
- Single ascending dose (SAD)
- Multiple ascending doses (MAD)
- Proof-of-Concept
- Bioequivalence
- Relative bioavailability
- Food effects
- Drug-drug interactions (DDI)
- Thorough QT/QTc (TQT)
- Pediatric PK/PD bridging
- PK in hepatic-impaired subjects
- PK in renal-impaired subjects
- Radio-labeled mass balance
- Large Registrational Safety and Efficacy, to establish population PK and exposure-response (PK/PD)
- Pediatric and Elderly

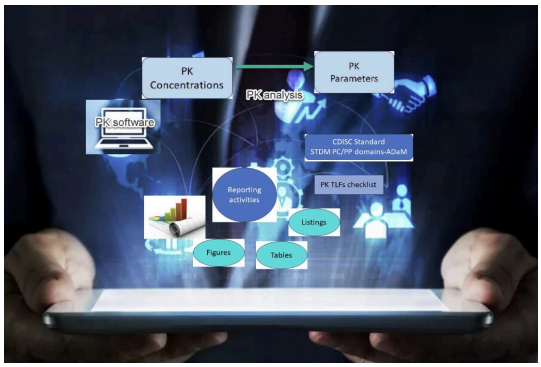
Clinical Pharmacology Strategy and Writing

Clinical pharmacology presents many challenges along the development milestones to successful market approval. A streamlined clinical pharmacology strategy based on your drug's class-specific properties is essential for efficiency and cost savings. XP Parma Consulting has intensive experience setting the strategy roadmap and helping you advance your drug development milestones. Our subject matter experts prepare regulatory documents specific to clinical pharmacology, modeling, and simulation (M&S), and dose justification across the development spectrum from pre-IND to registration. We deliver high-quality written deliverables and submission-ready documents to facilitate drug development.

- Gap analyses and mitigation strategy
- Due diligence (asset evaluation)
- Clinical pharmacology plans
- Clinical study designs
- Clinical Study protocols (in full or in part)
- Clinical Study reports and/or standalone PK report
- Regulation document preparations (PK/PD)
- Clinical development plans (in full or in part) and reviews
- Responses to regulatory questions (in full or in part) and reviews

- Comparator PK/PD data analyses
- Regulatory meeting representations
- Dose rationale and justification
- PK/PD design in the study protocols
- Inclusion/exclusion criteria
- Assessment of Drug-drug interaction (DDI) potential
- Assessment of Drug-drug interaction (DDI) potential
- Drug-drug interaction (DDI) waiver justifications
- Assessment of risk for QT prolongation potential
- Thorough QT ((TQT) waiver justification
- Pediatric drug development and dose determination

Noncompartmental PK Analysis (NCA)



Noncompartmental pharmacokinetics (PK) analysis (NCA) is a standard method for calculating PK parameters. It is indispensable for characterizing PK within a single study and making time-critical dose selection decisions. XP Pharma Consulting has extensive experience supporting end-to-end pharmacokinetics for clinical studies. We can help you with PK study design, data transfer, NCA analysis with validated software tools, and TLFs (Tables, Listings, and figures) to display results aligned with the PK analysis plan, results interpretation, and high-quality reporting. We ensure you get the most out of your data, setting your program up for success. We offer following NCA services:

- NCA analysis with validated software tools
- PK/PD design in the study protocols
- Analysis plans
- PK/PD sampling in schedule of assessments
- NCA analysis plan as part of study protocol or standalone

- NCA analysis results (tables, listings and figures)
- PK-dose proportionality
- NCA analysis results interpretation
- NCA PK exposure-response analysis
- Submission ready reports

Pharmacometrics

Regulatory agencies are responsible for approving all new drugs and ensuring that all available drugs on the market are effective and safe for human use. Understanding the safety and effectiveness of any drug depends, in large part, on pharmacokinetics (PK), pharmacodynamics (PD), PK/PD modeling and simulation (M&S). Because regulatory authorities increasingly emphasize M&S analyses and the wealth of information they provide, it is essential to consider M&S to advance your drug development program.

XP Pharma Consulting has expertise in M&S analysis and reporting. We can work with you to optimize dose and regimen, improve the probability of success, and ensure ideal labeling, prescribing, and an optimal patient experience. We offer following services:

- Population PK analysis
- PK exposure-response (E-R) analysis
- Concentration-QT analysis and modeling
- Dose selection and justification
- NONMEM data set preparation
- Identify intrinsic and extrinsic factors impacting PK exposure
- Dose simulations for different populations and formulations
- Submission-ready authoring report authoring

Effective Organization
XP Pharma's flexible structure allows us to customize our services to suit our clients' needs. Our consultants can work as an extension of your team and/or to provide support for your complex projects that require broader experience and expertise.

A Step Above
The broad scope of XP Pharma's experience combined with effective internal procedures put us a step above our competitors. We ensure:

- Focused expertise in regulatory clinical pharmacology, translational science, small molecule, and biologics development
- Clients' needs are matched to the most qualified consultant.
- Detailed attention to each client and to every detail
- Client projects are never left stagnant; timelines are established and met

Testimonials from Pharma Customers

Population PK/PD Modeling & Simulation

XP Pharma played a significant role in supporting the early clinical development programs. Their PK assessments, modeling & simulation offered important information to determine safe and optimal dosing regimens for our Phase 1 and Phase 2 clinical trials.

Executive Director – Clinical Development

Clinical Pharmacology Studies

XP Pharma Consulting's knowledge of FDA requirements around clinical pharmacology (drug-drug interaction studies, CYP450 interaction studies) has helped us to design our clinical pharmacology plans effectively by allowing us to incorporate NDA-required studies optimally.

Executive Director – Clinical Development

Leading Edge Pharmacology Support

XP Pharma provided leading-edge clinical pharmacology advice and services that led to several successful IND approvals. They have assisted us on translational research programs at the pre-IND to IND stage using PK/PD modeling and simulation.

Director – Clinical Development

Clinical Pharmacology Strategy and Writing

XP Pharma can manage all aspects of clinical pharmacology projects. XP Pharma assessed DDI potential, risk of QT prolongation potential, designed clinical pharmacology studies, and authored TQT waiver applications, CTD 2.7.2 and CTD 2.7.2, and responses to regulatory question.

Sr. Director – Clinical Pharmacology

Contact Us Today To Discuss How We Can Help

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