Clinical Pharmacology Consulting

XP Pharma Consulting provides comprehensive clinical pharmacology consulting and PK/PD services that enhance, facilitate, and shorten your drug development time and maximize the impact of each study in all phases of your drug development program. Explore our services and let us know how we can help you or where, in your development, submission, and/or approval process, we can provide additional expertise.

SERVICES AND DELIVERABLES	Pre-IND & IND	Phase 1	Phase 2	Phase 3	NDA/BLA
Population PK/PD Modeling & Simulation					
Allometric scaling and human PK prediction					
Dose selection and justification					
Study design and human PK/PD simulations					
Population PK analysis					
PK exposure-response (E-R) analysis					
Concentration-QT analysis and modeling					
Noncompartmental PK/PD/TK					
Noncompartmental analysis and TLFs					
Submission-ready PK/PD study reports					
Clinical Pharmacology Strategy & Writing					
IND protocol authoring (in full or in part)					
Clinical pharmacology plans					
Clinical study designs					
Gap Analysis/Question-based review					
Study protocols (in full or in part) and reviews					
Study reports (in full or in part) and reviews					
Regulation documents preparation (PK/PD)					
Regulatory meeting representation					
Comparator PK/PD data analysis					
Pediatric dose determination for PIP and iPSP					

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SERVICES AND DELIVERABLES	Pre-IND & IND	Phase 1	Phase 2	Phase 3	NDA/BLA
Assess DDI potential based on in vitro study data					
Integrated assessment for risk of QT-prolongation potential and author report					
Author TQT study waiver document					
Regulatory meeting representation					
Clinical Pharmacology Studies					
Single ascending dose (SAD)					
Multiple ascending doses (MAD)					
Bioequivalence and relative bioavailability					
Food effects					
Drug-drug interactions					
Thorough QT (TQT)					
Radio-labeled mass balance and ADME					
PK in hepatic-impaired subjects					
PK in renally-impaired subjects					
Regulatory Strategy & Writing					
Integrated PK and PK/PD analyses and reports					
NDA/BLA (CTD modules 2.7.1 and 2.7.2)					
PK and PD sections of the label					
Integrated immunogenicity analyses					
Responses to questions in the review period					
Regulatory representation					
Manuscripts, posters, conference presentation					

Abbreviations: ADME= absorption, distribution, metabolism and excretion; BLA=biological license application: DDI=drug-drug interaction; E-R=exposure-response; MAD= multiple ascending dose study; NDA=new drug application; PIP= pediatric investigational plan; iPSP = initial pediatric study plan; IND= investigational new drug application; PK=Pharmacokinetics; PD=Pharmacodynamics; SAD-single ascending dose study; TK=toxicokinetics; TLFs=tables, listings, and figures.