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XP Pharma Consulting Provides Clinical Pharmacology & PK/PD services

XP Pharma Consulting provides expert services to your drug development program through the lens of clinical pharmacology, pharmacokinetics, and pharmacometrics (modeling and simulation) to maximize the impact of each study on the overall development program in all phases of drug development.

Explore our services and let us know how we can help you.

Services and Deliverables	Pre-IND & IND	Phase 1	Phase 2	Phase 3	NDA/BLA
Population PK/PD Modeling &Simulation					
Allometric scaling					
Dose Selection and Justification					
Study design simulations					
Human exposure prediction					
Human PK/PD simulation					
Population PK analysis					
PK exposure-response (E-R) analysis					
Concentration-QT analysis and modeling					
Noncompartmental PK/PD/TK					
Noncompartmental Analysis					
Submission Ready Study Reports					
Clinical Pharmacology Strategy & Writing					
IND protocol authoring (in full or in part)					
Clinical Pharmacology plans					
Clinical study designs					
Gap Analysis/Question bases 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					

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Services and Deliverables	Pre-IND & IND	Phase 1	Phase 2	Phase 3	NDA/BLA
Pediatric dose determination for PIP and PSP					
Assess need for DDI studies					
Assess a need for a thorough QT (TQT) study					
Author TQT study waiver (in full or in part)					
Clinical Pharmacology Studies					
First-in-human (FIH)					
Single ascending dose (SAD)					
Multiple ascending doses (MAD)					
Bioequivalence and relative bioavailability					
Food effects					
Drug-drug interactions (DDIs)					
Thorough QT (TQT)					
Radio-labeled mass balance and ADMS					
PK in hepatic-impaired subjects					
PK in renal-impaired subjects					
Pediatric PK/PD bridging to adult dose study					
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					
Ad hoc PK/PD analyses					
Manuscripts, posters, conference presentation					

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