Amy (Xiaoping) Zhang, M.D., Ph.D.

CEO and President

XP Pharma Consulting, LLC
11 Coventry Ln
Stoneham, MA 02180

Phone: 617-485-8693
azhang@xppharmaconsulting.com
www.xppharmaconsulting.com

EDUCATION

Ph.D.	University of Witten-Herdecke / Pharmacokinetics. Germany	1994
M.D.	Shanxi Medical University / Clinical Medicine. China	2018
M.Sc.	Shanxi University/ Pharmaceutical Chemistry & Molecular Modeling. China	1988
B.Sc.	Shanxi University / Pharmaceutical Chemistry. China	1983

OVERVIEW OF PROFESSIONAL EXPERIENCE

XP Pharma Consulting, LLC. CEO and President	2019- present
Nuventra Pharma Sciences, Inc. Sr Consultant-Clinical Pharmacology and Pharmacometrics	2019 – 2020
Alnylam Pharmaceuticals, Inc. Sr. Director – Clinical Pharmacology and Pharmacometrics	2017 – 2019
Alexion Pharmaceuticals, Inc. Director & Global Leader -Clinical Pharmacology and Pharmacometrics	2015 – 2017
Kyowa Hakko Kirin Pharma, Inc. Head of Clinical Pharmacology & Clinical Team Leader	2012 – 2015
Hoffmann-La Roche, Inc. Sr Director & Head Clinical Pharmacology – Inflammation	2001 – 2012

DRUG DEVELOPMENT EXPERIENCE SUMMARY

A clinical pharmacology expert with diverse cross-functional experience from over 23+ years of work in large pharma, biotechnology, and small pharma and an established track record of clinical and regulatory success with the pharmaceutical industry. Experience in planning, executing, and analyzing nonclinical and clinical pharmacology studies as well as experience with strategic planning and execution of entire drug development programs (from nonclinical IND enabling studies through Phase 1 to late stage studies leading to marketing registration). Conducted over 80+ international and domestic clinical trials across numerous therapeutic areas (small molecule compounds, siRNA and biologics), from Phase 1 studies through multi-national Phase 3 studies. Regulatory affairs experiences include work on multiple NDAs, INDs, IMPDs, and other regulatory documents, plus client representation at FDA meetings. Conducted 24+ population PK and PK/PD modeling simulation analysis and reporting and 74+ model independent PK and PK/PD analysis and reporting. Authored / co-authored 70+ publications in peer-reviewed journals, including 2 book chapters and 9 patents.

DETAILED PROFESSIONAL EXPERIENCE

XP Pharma Consulting, LLC. **2019 - Present**

Chief Executive Officer, President, Founder

- Worked with over 11 Clients since founding of XP Pharma Consutling LLC, offering clinical pharmacology and drug development services to industry, including strategic planning, pharmacokinetics (PK), pharmacodynamics (PD), population PK and PK/PD modeling and simulation, clinical development, and writing from IND to NDA/BLA submissions. and project management.
- Responsible for new business development, client relations, and oversight of all scientific and business activities at the company.
- Project-Based Responsibilities
  - Provide overall guidance on drug development activities for clients.
  - Conduct clinical pharmacology and PK/PD gap analyses
  - Author protocols and design studies.
  - Author INDs, NDAs, FDA briefing packets, white papers, & IMPDs, etc.
  - Author clinical study reports, Investigator Brochures, etc.
  - Represented clients at meetings with the FDA.
  - Clinical pharmacology development plans.
  - Conducted population PK and exposure-response or PK/PD analyses/reporting
  - Conducted noncompartmental PK and PK/PD analyses/reporting

Nuventra Pharma Sciences **2019 -2020**

Sr Consultant-Clinical Pharmacology and Pharmacometrics

- Consultant for clinical pharmacology and PK/PD components of clinical studies, clinical trial design and its implementation in the protocols, assessment for potential drug-drug interactions (DDIs) using in vitro data, PK/PD data analysis and interpretation, gap analysis, DDI study waiver applications, others as needed
- Consultant to eight clients: authored DDI waiver document for several DDI studies; authored/reviewed two pivotal protocols in phase 3 development; authored/reviewed clinical pharmacology plans for two small interfering RNA-lipid nanoparticle products; designed/reviewed one phase 1 first-time-in-human study in patients with a rare genetic blood disorder; authored/reviewed multiple population PK modeling analysis plans and reports; responded to numerous clinical pharmacology, PK and PD questions from clients.
- Invited frequently as ClinPharm/medical expert in business development meetings with clients by Nuventra.

Alnylam Pharmaceuticals, Inc. **2017 - 2019**

Sr. Clinical Director – Clinical Pharmacology and Pharmacometrics,

- Lead Clinical pharmacologist for the first approved RNAi therapy, Onpattrio® (Patisiran).
- Authored and reviewed regulatory documents for the patisiran NDA submission: CTD 2.7.1 and 2.7.2 and other modules, Package Insert, briefing packages for regulatory meetings, responses to questions from FDA, EMA, and PMDA.
- Designed and conducted PK exposure-response (safety and efficacy) analysis of pivotal phase 3 study and implemented analysis results in the NDA submission.
- Conducted and reviewed five NCA analysis and reports; two population PK studies, and two population PK/PD modeling analyses; authored reports.
- Authored 110+ responses to questions from the EMA, FDA, and PMDA during the NDA reviewing period for license approval of patisiran; all outstanding issues were resolved, resulting in the NDA approval

- Authored seven publications for patisiran PK, PK/PD, and E-R analysis results; wrote and delivered oral and poster presentations at international conferences for the patisiran product.

Alexion Pharmaceuticals, Inc. **2015 - 2017**
Clinical Pharmacology Director / Global Clinical Pharmacology Team Leader

- Responsible for the design, execution, and completion of clinical pharmacology, PK, and PK/PD of phases 1 to 3 clinical trials for successful NDA/BLA submissions
- Contributed to the study design, protocols, and PK/PD sections of clinical study reports for three clinical trials for samalizumab in cancer patients and three clinical trials for a recombinant human N-acetyl-α-D-glucosaminidase in children with mucopolysaccharidosis IIIB (MPSIII); conducted and reviewed PK and PK/PD analyses, including modelling and trial simulation analyses for these clinical trials.
- Conducted allometric scaling for dose recommendations and protocol design for the phase 3 study in patients with MPSIII.
- Filed two patents authored five publications and delivered seven conference presentations.
- Conducted and analysed PK/PD data for due diligence of two in-license opportunities.

Kyowa Hakko Kirin Pharma, Inc. **2012 - 2015**
Clinical Development Team Leader / Head of Clinical Pharmacology

- Responsible for leading clinical teams to overall success for two clinical projects: burosumab and CEP-37250/KHK2804; monitoring overall study integrity and GCP compliance; reviewing, interpreting, and communicating safety, PK/PD, and efficacy results to investigators and FDA. Delivered oral or poster presentations at conferences.
- Responsible for the management of clinical pharmacology group and consultants (MD, PhD, and MSc); supported PK/PD components of 18 clinical trials (phase 1 to 3) of eight products in five disease areas (oncology, CNS, inflammation, nephrology, and rare genetic disorders).
- Authored and reviewed burosumab clinical development plans (CDP) for adults and pediatric patients; completed three phases 1 and 2 clinical trials in patients with X-linked hypophosphatemia, including PK/PD, safety, and efficacy data analyses, and clinical study reports; authored four publications and delivered 13 oral/poster presentations.
- Authored clinical pharmacology plan for mogamulizumab from phase 1 through NDA submission; contributed to pivotal clinical trials; analyzed/reviewed population PK and population PK and PK/PD analyses and reports for four studies; and contributed to the successful NDA approval.
- Authored clinical pharmacology plan for istradefylline from phase 1 through NDA submission; contributed to pivotal clinical trials; analyzed/reviewed population PK and population PK and PK/PD analyses; led clinical pharmacology study team for vendor selection, design, execution, and completion of two clinical pharmacology studies (drug-drug interaction study with rifampin and a special population study in hepatically impaired subjects); and contributed to the successful NDA approval of istradefylline.
- Conducted preclinical to clinical PK/PD translation for five Phase 1 POC studies in five different types of malignancies; contributed to preparation of IND, study design, and protocol authoring; completed PK/PD data analyses and interpretation; authored study reports; managed external consultants for modeling and trial simulations; responded to health authority questions; participated in discussion on the clinical pharmacology plans with regulatory agencies.
- Authored ten publications and delivered six conference presentations.

Hoffmann-La Roche, Inc. **2001 - 2012**
Sr. Director / Head Clinical Pharmacology – Inflammation

- Overall Responsibilities:
  - Responsible for authoring clinical pharmacology plans and co-authoring CDPs, clinical study protocols and reports, and regulatory documents
  - Responsible for design, execution, and reporting of clinical pharmacology studies
  - Responsible for the Clinical Pharmacology sections of phase 2 and 3 trials
  - Responsible for the Clinical Pharmacology sections of NDA/BLA submissions
  - Management and mentoring responsibility for the Clinical Pharmacology group and fellows
- Scientific Leadership for Clinical Pharmacology Studies:
  - Directed and completed seven drug-drug interaction (DDI) studies:
    (1) Pittsburgh cocktail study for enfuvirtide using a five-drug cocktail in HIV-1 patients; (2) DDI study between enfuvirtide and ritonavir or ritonavir-boosted saquinavir in HIV-1 patients;
    (3) DDI study of ritonavir-boosted saquinavir in combination with rifabutin in healthy subjects;
    (4) DDI study of enzyme-inducing effect of rifampicin on PK of enfuvirtide;
    (5) DDI study of tocilizumab with MTX and simvastatin in RA patients;
    (6) DDI study of tocilizumab in combination with oral contraceptive in RA patients,
    (7) DDI study of pamapimod and methotrexate in patients with RA.
  - Directed and completed three thorough QT/QTc studies:
    (1) effect of saquinavir-boosted by ritonavir at the therapeutic dose, and at a supra-therapeutic dose, on the QT/QTc interval after multiple-dose administrations in healthy subjects;
    (2) effect of pamapimod at a projected therapeutic dose and a supra-therapeutic dose level on the QT/QTc Interval after a single dose in healthy volunteers;
    (3) tocilizumab effect on QT interval following single doses in healthy subjects at therapeutic and supratherapeutic dose levels in healthy subjects
  - Directed four special population studies:
    (1) effect of the moderate liver impairment on the PK of saquinavir after administration of saquinavir/ritonavir 1000/100 mg BID;
    (2) phase I/II PK and safety study of saquinavir soft gelatin capsules and pediatric pellet formulations in combination with nucleoside antiretroviral agents, with or without nelfinavir, in HIV-infected infants and children;
    (3) enfuvirtide post-approval commitment PK study in HIV-1 infected infants <2 years of age;
    (4) tocilizumab post-approval commitment PK/PD study in sJIA patients <2 years of age.
  - Contributed to the completion of three SAD and MAD studies:
    (1) a randomized double-blind, positive controlled 14-day multiple ascending-dose study to investigate the safety, tolerability, and PK of saquinavir boosted with ritonavir in healthy subjects;
    (2 &3) SAD (EIH) and MAD studies conducted for MEM1414 (phosphodiesterase-4 inhibitor) in healthy subjects.
  - Directed and completed one mass-balance study including ADME and metabolic profiling of in healthy male subjects with ^{14}C-labeled pamapimod.
  - Directed and completed three bioavailability, bioequivalence, and PK/PD formulation bridging studies:
    (1) study to investigate the influence of subcutaneous (SC) injection sites (abdomen, thigh, and arm) on the steady-state PK of enfuvirtide in HIV-1 infected patients;
    (2) tocilizumab PK/PD dose bridging for SC and intravenous (IV) study in RA patients;
    (3) bioequivalence study of tocilizumab SC injection using prefilled syringe and auto-injector.
- Scientific Leadership for Phase 1 to 2 Proof-of-Concept Studies:
  - Contributed to clinical pharmacology sections of six phases 1/2 POC studies:
    (1) pamapimod Phase 2 POC study in RA patients;
    (2) GC33 phase 2 dose-range study in patients with advanced or metastatic hepatocellular carcinoma (HCC) in combination therapy with sorafenib;
    (3) based on DMPK properties of MDM2 (p53-MDM2 Interaction Inhibitor), performed trial simulation using Time-Dependent CYP450 Inhibition Mechanism Based Feedback Model and proposed continual

reassessment method (CRM) for dose escalation in Phase 1 MAD study in patients with advanced solid tumors;
(4) epothilone D in combination with herceptin in patients with HER-2positive advanced or metastatic breast cancer;
(5) epothilone D in patients with stage IIIB or stage IV NSCLC;
(6) epothilone D as second-line treatment for patients with advanced or metastatic refractory colorectal cancer.

- Scientific Leadership Phase 3 Pivotal Studies:
  - Analyzed PK/PD data and authored PK/PD reports for the enfuvirtide Phase 3 trial for BLA filing
  - Analyzed PK/PD data and authored reports for tocilizumab Phase 3 trials for BLA filing
  - Authored PK/PD sections of protocol and CSR for two pivotal phase 3 studies conducted in sJIA and pJIA for tocilizumab BLA filings for two indications
  - Contributed to study design, conduct, and reporting of two pivotal Phase 3 studies (SUMMACTA and BREVACTA), using tocilizumab SC formulation for sBLA
  - Patent for SC dose/regimen and study design for tocilizumab phase 3 trials
  - Inventor for 7 patents for SC dose/regimen and study design for tocilizumab phase 3 studies in sJIA and pJIA pediatric patient population
- Scientific Leadership for NDA/BLA Submission:
  - Co-authored CTD filing documents (2.7.1, 2.7.2) for the enfuvirtide and supported responses to questions from regulatory agencies; received Roche Olympiad award for the recognition of outstanding and innovative contributions
  - Direct contribution to three tocilizumab BLA submissions and approvals (RA, sJIA, and pJIA) in EU, US, and globally; authored CTD 2.7.2 and attended pre-BLA meetings in EU and US; responded to list of CHMP questions during the review period; prepared and attended FDA advisory board meeting and EU hearing
  - Authored CTD 2.7.2 for rituximab BLA submission for treatment of ANCA-associated vasculitis; responded to questions from CHMP and FDA questions during review period; prepared slides for FDA advisory board meeting
  - Contributed to three pediatric investigational plans (PIP) for rituximab and tocilizumab
- Scientific Leadership for PK/PD Modelling and Simulation:
  - Conducted population PK and exposure-analysis using Nonlinear Mixed Effect Modeling (NONMEM) technique for enfuvirtide in pediatric patients and authored reports/publications
  - Contributed to the population PK and PK/PD modeling analyses of enfuvirtide in adult HIV patients and co-authored reports and publications
  - Developed Inverse Gaussian Density Model describing the enfuvirtide PK profile following subcutaneous administration.
  - Contributed to population PK and PK/PD modeling of tocilizumab in systemic juvenile rheumatoid arthritis (sJIA) and polyarticular systemic juvenile rheumatoid arthritis (pJIA) patient populations for the respective BLA submissions and approvals.
- Scientific Leadership for Clinical Pharmacology Study Methods:
  - First leading scientist to bring disease-drug-drug interaction data and concepts to FDA and authored one Clinical Pharmacology and Therapeutics paper and one book chapter.
  - First time demonstration that the period correction of the QTc of moxifloxacin with multiple predose baseline ECGs is the least variable of the four methods tested, which eliminated time-matched baseline measurements
- Scientific Leadership for Due-Diligence for in License Opportunity:
  - Alectinib project: Evaluated preclinical and phase 1 clinical data for alectinib in patients with NSCLC; authored due diligence report and clinical pharmacology plan
- Project/People Management:

- Managed four Clinical Science Specialists (Pharm D, MSc, BSc), one Associate director (Pharm D), and one administrative assistant (BSc) (established performance goals, provided feedback throughout the year on proposed bonuses, salary raises, and promotions)
- Initiated 22 clinical Pharmacology studies (either healthy volunteers or patients) and managed cross-functional teams (clinical operation, statistics, safety, and preclinical) for planning, execution, and reporting of the clinical trials).
- Authored 34 publications and delivered 15 conference presentations.

Academic Positions

Assistant Professor or Research Fellow **1988-2000**

- Texas Tech University, Amarillo, TX, USA (1999-2000)
- University of Kansas, Lawrence, KS, USA (1995-1997)
- University of Erlangen-Nurnberg, Erlangen, Germany (1994-1995)
- Shanxi University, Taiyuan, Shanxi, China (1988-1991)

POST GRADUATE EDUCATION

- IntiQuan Webinar Series: Efficient Support of Model Informed Drug Development (MIDD) in R. M1.1 Models (5-11-2021) M1.2 Simulations made Easy, M1.3 Parameter Representation and Sampling, and M1.4 Models. Instructor: Dr. Henning Schmidt (IntiQuan GmbH, Basel, Switzerland). May 11, 13, 18 and 20. 2021
- Basic Population PK Modeling-Seamless Use of NONMEM and/or MONOLIX through R. IntiQuan Webinar. Instructor: Dr. Henning Schmidt (IntiQuan GmbH, Basel, Switzerland). June 9, 2020.
- Population PK/PD modeling Workshop for Intermediate and Advanced Features of NONMEM 7. Instructors: Drs. Robert J. Bauer and Brian Sadler. Vice president Pharmacometrics. ICON Development Solutions. Columbia, Maryland. January 2022, Sept 29-20. 2021. April 7 to 9, 2015
- Modeling Biologics with Targeted-Mediated Disposition. Instructors: Drs. Leonid Gibiansky and Ekaterina Gibiansky. QuantPharm LLC. March 4, 2016. San Francisco, CA
- ASoP Workshop: Population Pharmacometrics Modeling with Monolix. Somerset, NJ. Instructor: Marc Lavielle. Research Director at Inria Saclay, France. May 17-18, 2012.
- PK/PD modeling on continuous and categorical data in NONMEM7. Instructor: Dr. Mats Karlsson. Professor in Pharmacometrics (Department of Pharmacy, Uppsala University, Sweden). Morristown, NJ. June 13 to 15, 2010.

CLINICAL PHARMACOLOGY EXPERIENCE

- Development of comprehensive clinical pharmacology development plans and strategies
- Strong knowledge of PK and PD concepts and modelling analyses from industry experience and completion of advanced PK/PD modelling courses
- Scientific and strategic contributions to study design, protocols, reports, and other documents
- Scientific contributions to the analysis of data
- Clinical operations management/development/investigator's meetings
- Project and vendor selection and management
- Represent clients during clinical pharmacology interactions with regulatory agencies
- Clinical team leadership roles for cross-functional teams
- NDA/BLA submission experiences in various disease areas and response to questions

CLINICAL STUDY EXPERIENCE

- First-time-in-human

- Single (SAD) and multiple-dose studies (MAD)
- Bioavailability & Bioequivalence
- Food effect study
- Drug-drug interactions and disease-drug-drug interactions for inflammation
- Special populations (hepatic and renal impaired, and elderly, etc.)
- Thorough QT/QTc in healthy subjects
- PK/PD bridging study from IV infusion to SC injection in patients
- Postmarketing commitment safety, PK and PD study in pediatric patients
- Radiolabeled studies for mass balance and ADME characterization
- Proof of Concept Phase 2 studies
- PK and PD assessments in Phase 2 and 3 studies

PHARMACOKINETICS EXPERIENCE

- Hand-on in use of Phoenix WinNonlin software for NCA and modeling analysis
- Developed SOP for NCA analysis for 3 companies
- Experiences in interpretation of PK for various molecules (small molecule, larger monoclonal antibody, small interfering RNA encapsulated in lipid nanoparticles)
- Expert in interpretation of PK parameters in relation to drug effect on PD, safety and efficacy
- Inventor for inverse Gaussian density function model in describing absorption of SC injected enfuvirtide (see Publication)
- Knowledge in applying traditional PK analysis to cell kinetic analysis for gene therapies

PHARMACOMETRICS EXPERIENCE

- Experience in PK and PK/PD modelling analysis at various stage of development
- Provided scientific guidance to population PK, PK/PD, and disease progression modelling analyses
- Directed internal and external resources for extensive modelling analyses by pooling data for NDAs
- Integrated PK, PK/PD modelling analysis results in the NDA submission packages

PROGRAMMING EXPERIENCE

- Eexperiences in NONMEM model coding for population PK and PK/PD modelling
- Experiences in IQR Tools-IntiQuan GmBH for population PK and PK/PD modelling
- Experiences in PK and PK/PD graphic displays and data management with R coding
- Experiences in IQnca Tools- IntiQuan GmBH for noncompartmental PK analysis

NONCLINICAL EXPERIENCE

- Experiences in the translation of preclinical data package to the first-in-human trial design and doses
- Gap analysis for IND package to ensure a high probability of acceptance
- Knowledge in bioanalytical PK, PD, and immunogenicity guidance documents
- Knowledge in what bioanalytical info is needed for clinical study protocol, reports, and CTD
- Experiences in reporting immunogenicity data (standalone reports or integrated reports in CTD)

REGULATORY AFFAIRS EXPERIENCE

- Direct contributions to 7 NDAs/BLAs and 5 sBLAs

- Contributed to approval of 8 drugs in US and global markets (Enfuvirtide, Tocilizumab (RA, sJIA and pJIA), Rituximab, Patisiran, Istradefylline, Mogamulizumab, Alectinib , and Burosumab)
- Direct contributions to 30+ IND amendments and IND Annual reports
- Participated in meetings with FDA and EU agencies (face-to-face and teleconferences):, including Scientific Advice, End of Phase 2 , Pre-NDA/BLA, EMA Oral Explanation, and FDA Advisory Committee.
- Authored CTD 2.7.1 and 2.7.2 and Investigational Medicinal Product Dossier authoring.
- Authored responses to numerous challenging questions from EMA, FDA and PMDA during NDA/MAA review periods and supported timely approval or action for all products.

SCIENTIFIC MEDICAL WRITINGEXPERIENCE

- Authored 80+ full protocols, protocol amendments, and concept protocols for studies in different therapeutic areas including the following: analgesia, anesthesia, cardiovascular, central nervous system, hematology, infectious disease, metabolic and endocrine disorders, oncology, pediatrics, pulmonary, rare genetic diseases, and rheumatology
- Authored 62+ Clinical Study Reports (Lead or contributing author).
- Authored 74+ PK & PD reports
- Authored 14+ population PK and 10+ population PK/PD reports
- Authored 70+ publications in peer-reviewed journals.

INTERNATIONAL DRUG DEVELOPMENT EXPERIENCE

- Knowledge and experiences in PMDA requirements and structure for NDAs in Japan
- Direct experiences in the development of Japan approved drugs in EU and US
- NDA/BLA submission and responses to questions for from Switzerland, Canada and Japan

HONORS&AWARDS

- 2 Shooting Star Awards for the successful launch of Onpattro® (patisiran) in Canada and Japan (including submissions and responses to questions from FDA, EMEA and PDMA). Alnylam Pharmaceuticals, Inc., Cambridge, MA. 2019.
- Outstanding Scientific Contribution Award. The 21st SAPA-NE Scientific Symposium for Next generation of Gene and Cell Therapy. Oral Presentation: Onpattro® (Patisiran): The First Approved RNAi Therapeutics. Nov 3, 2018. Boston, MA.
- Special Recognition for "Delivered tangible results, behaviors, and values, and future potential". Alnylam Pharmaceuticals, Inc., Cambridge, MA. 2018.
- Steller Supernova Award for Passion for Excellence. Alnylam Pharmaceuticals, Inc., New. Cambridge, MA. 2017.Stellar All-Star Award for Sense of Urgency supporting Patisiran Filing Working Group, Alnylam Pharmaceuticals Inc., Cambridge, MA. 2017.
- Oscar Award for the best synopsis entitled "A Multicenter, Dose-Escalation, Phase 1 Study of Samalizumab to Evaluate the Pharmacokinetics, Safety, and Tolerability in Patients with Advanced Cancer" (ClinicalTrials.gov Identifier: NCT02987504). Alexion Pharmaceuticals Inc., New Haven, CT. March 2017.
- Alexion Innovator's Award for scientific contribution to the treatment of a rare genetic disorder (mucopolysaccharidosis type IIIB) using enzyme replacement therapy. Alexion Pharmaceuticals, Inc., New Haven, CT. December 2016.
- Presidential Award for Outstanding Achievement in Significant Clarification and Clinical Understanding of Human Monoclonal anti-FGF23 Antibody (KRN23) in Treating Adults with X-Linked

Hypophosphatemia. 2014 European Society of Paediatric Endocrinology Annual Meeting. Dublin, Ireland.

- Presidential Award for Innovative Clinical Research on human monoclonal anti-FGF23 antibody (KRN23) to patients with X-linked hypophosphatemia. Annual Meeting for American Society of Bone and Mineral Research. Baltimore, Maryland. 2013.
- Presidential Award for the Outstanding Poster and Abstract for development of Inverse Gaussian pharmacokinetics model for subcutaneous administration of enfuvirtide in treating HIV patients. Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics. Washington DC, April 2-5, 2003.
- Pharmaceuticals Olympiad Gold Award for Innovation, Speed, and Growth Applied to the Team Approval of Enfuvirtide in EU and US, Hoffmann-La Roche, Inc., Nutley, NJ. 2003.
- First Prize for Best Student of Class 1983 at Shanxi University, Taiyuan, China.

PUBLICATIONS

- Yamashita, T., Zhang, X., et al. Patisiran, an RNAi therapeutic for patients with hereditary transthyretin-mediated amyloidosis: Sub-analysis in Japanese patients from the APOLLO study. *Neurol Clin Neurosci*. 2020;8:251–260.
- Judge, D. P., Zhang, X., et al. Phase 3 multicenter study of revusiran in patients with hereditary transthyretin-mediated (hATTR) amyloidosis with cardiomyopathy (ENDEAVOUR). *Cardiovas Drugs Ther*. 2020;34(3):357-370. doi: 0.1007/s10557-019-06919-4.
- Zhang, X., Goel, V., et al. Pharmacokinetics of patisiran, the first approved RNA interference (RNAi) therapy, in patients with hereditary transthyretin-mediated amyloidosis. *J Clin Pharmacol*. 2020;60(5):573–585.
- Zhang, X., Goel, V., et al. "Patisiran pharmacokinetics, pharmacodynamics, and exposure–response analyses in the phase 3 APOLLO trial, in patients with hereditary transthyretin-mediated (hATTR) amyloidosis. *J Clin Pharmacol.* 2020;60(1):37-49.
- Zhang, X., Sweetser, M. Results from APOLLO phase 3 study of patisiran, the first approved RNAi therapeutic, in hereditary ATTR (hATTR) amyloidosis patients with polyneuropathy. *Clin Pharmacol Ther.* 2019;105(S1);E-009;S31.
- Zhang, X., Goel, V., Robbie, G. Pharmacokinetics of patisiran in patients with hereditary transthyretin-mediated amyloidosis. *J Neuromuscul Dis*. 2018;5:S280; Abstract 568.
- Zhang, X., Brennan, B. Disease-drug-drug interaction assessments for tocilizumab – a monoclonal antibody against interleukin-6 receptor to treat patients with rheumatoid arthritis. In: Drug-Drug Interaction for Therapeutic Proteins (H. Zhou and B. Meibohm, eds.), ISBN 978-1-118-03216-9. WILEY Wiley-Blackwell Publisher. 2013.
- Goel, V., Zhang, X., et al. Population pharmacokinetics (PK) of patisiran in healthy volunteers and in patients. *J Neuromuscul Dis.* 2018;5:S251.Abstract 567.
- Zhang, X., et al. Patisiran-LNP pharmacokinetics (PK), pharmacodynamics (PD), and exposure-response (E-R) relationship in patients with hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy. *Eur J Neurol*. 2018;25 (Suppl. 2); Abstract EPR2142; 460.
- Goel, V., Zhang, X., et al. Population pharmacokinetic (PK)/pharmacodynamic (PD) model of serum transthyretin (TTR) following patisiran-LNP administration in healthy volunteers and patients with hereditary TTR-mediated (hATTR) amyloidosis with polyneuropathy. *Eur J Neurol*. 2018;25 (Suppl. 2); Abstract EPR1139; 354.
- Zhang, X., Goel, V., Robbie, G. Pharmacokinetics of patisiran in patients with hereditary transthyretin-mediated amyloidosis. *J Neuromuscul Dis.* 2018;5, S280. Abstract 568.
- Mahadevan, D., Zhang, X., et al. Phase I study of samalizumab in chronic lymphocytic leukemia and multiple myeloma: Blockade of the immune checkpoint CD200. *J Immunother Cancer*. 2019;7(1):227.

- Mukai, M., Zhang, X., et al. Effects of rifampin on the pharmacokinetics of a single dose of istradefylline in healthy subjects. *J Clin Pharmacol*. 2018;58(2): 93-201.
- Zhang, X., Imel, E. A., et al. Population pharmacokinetic and pharmacodynamic analyses from a 4-Month intra-dose escalation and its subsequent 12-month dose titration studies for a human monoclonal anti-FGF23 antibody (KRN23) in adults with X-linked hypophosphatemia. *J Clin Pharmacol*. 2016;56(2):176-185.
- Ruppe, M. D., Zhang, X., et al. Effect of four monthly doses of a human monoclonal anti-FGF23 antibody (KRN23) on quality of life in X-linked hypophosphatemia. *Bone Reports*. 2016;5:158–162.
- Abdallah, H., Zhang, X., et al. Pharmacokinetic and pharmacodynamic analysis of subcutaneous tocilizumab in patients with rheumatoid arthritis from two randomized controlled trials: SUMMACTA and BREVACTA. *J Clin Pharmacol*. 2017;57(4):459-468.
- Whitley, C. B., Zhang, X. Results of the phase 1/2, open-label clinical study of intravenous recombinant human N-acetyl-α-D-Glucosaminidase (SBC-103) in children with mucopolysaccharidosis IIIB. *Mol Genet Metab*. 2019;126(2);131-138.
- Zhang, X., Chen, Y-C,, and Terao, K. Clinical pharmacology of tocilizumab for the treatment of polyarticular-course juvenile idiopathic arthritis. *Expert Rev Clin Pharmacol.* 2017;10(5):471-482.
- Zhang, X., Peyret, T., et al. Population pharmacokinetic and pharmacodynamic analyses from a 4-month intra-dose escalation and its subsequent 12-month dose titration studies for a human monoclonal anti-FGF23 antibody (KRN23) in adults with X-linked hypophosphatemia. *J Clin Pharmacol*. 2016;56(4):429-38.
- Sarantopoulos, J., Zhang, X., et al. Phase 1 Study of monotherapy with KHK2866, an anti-heparin-binding epidermal growth factor-like growth factor monoclonal antibody, in patients with advanced cancer. *Targeted Oncology*. 2016;11(3):317-27.
- Duvic, M., Zhang, X., et al. Phase I/II study of mogamulizumab (KW-0761), a defucosylated anti-CCR4 antibody, in previously treated patients with cutaneous or peripheral T-cell lymphoma. *Blood*. 2015;125(2):1883-1889.
- Imel, E. A., Zhang, X., et al. Prolonged correction of serum phosphorus in adults with X-linked hypophosphatemia using monthly doses of KRN23. *J Clin Endocrinol Metab.* 2015;100(7):2565-73.
- Carpenter, T. O., Zhang, X., et al. Randomized trial of the anti-FGF23 antibody KRN23 in X-linked hypophosphatemia. *J Clin Invest*. 2014;124(4):1587-97.
- Zhang, X., Rowell, L., et al. Assessment of disease-drug-drug interaction between single-dose tocilizumab and oral contraceptives in women with active rheumatoid arthritis. *Int J Clin Pharmacol Ther*. 2014;52(1):27-38.
- Carpenter, T. O., Zhang, X., et al. A First-In-Human, randomized, double-blind, placebo-controlled, single-dose study of a human monoclonal anti-FGF23 antibody (KRN23) in X-linked hypophosphatemia. *J Bone Miner Res*. 2013;28 (Suppl 1)
- Zhang, X., Carpenter, T.O., et al. Pharmacokinetics and pharmacodynamics of a human monoclonal anti-FGF23 antibody (KRN23) after single-dose administration to patients with X-linked hypophosphatemia. *J Bone Miner Res*. 2013;28 (Suppl 1).
- Zhang, X., Chen, Y-C., et al. Clinical study to investigate pharmacokinetics, pharmacodynamics, efficacy, and safety of tocilizumab after subcutaneous administration weekly or every 2 weeks in patients with rheumatoid arthritis. *Int J Clin Pharmacol Ther*. 2013;51(8); 620-630.
- Zhang, X., Georgy, A., Rowell, L. An Open-label, single-center study investigating pharmacokinetics and pharmacodynamics of tocilizumab, a humanized anti–interleukin-6 receptor monoclonal antibody, following single-dose administration by subcutaneous and intravenous routes to healthy subjects. *Int J Clin Pharmacol Ther*. 2013;51(6);443-455
- Morcos, P., Zhang, X. Pharmacokinetics and Pharmacodynamics of single subcutaneous doses of tocilizumab administered with or without rHuPH20 in healthy volunteers. *Int J Clin Pharmacol Ther*. 2013;51(7); 537-548.

- Zhang, X., Hsu, J., et al. Pharmacokinetics (PK) and pharmacodynamics (PD) of tocilizumab (TCZ) in polyarticular course juvenile idiopathic arthritis (pcJIA). *Clin Pharmacol Ther*. 2013;93 (Suppl 1): S88 (PIII-60).
- Zhang, X., Morcos, P., Terao, K. Clinical Pharmacology of Tocilizumab for the Treatment of Patients With Systemic Juvenile Idiopathic Arthritis. *Expert Rev Clin Pharmacol*. 2013;6(2), 123–137
- Zhang, X., Chen, Y-C., et al. A Clinical study to investigate pharmacokinetics, pharmacodynamics, efficacy, and safety of tocilizumab after subcutaneous administration weekly or every two weeks in patients with rheumatoid arthritis. *Clin Pharmacol Ther*. 2012;91 (Suppl 1): S117 (PIII-60).
- Zhang, X., Chen, Y-C., et al. A Clinical study to investigate pharmacokinetics, pharmacodynamics, efficacy, and safety of tocilizumab after subcutaneous administration weekly or every two weeks in patients with rheumatoid arthritis. *Clin Pharmacol Ther*. 2012; 91 (Suppl 1): S117 (PIII-60).
- Zhang, X., Peck, R. Clinical pharmacology of tocilizumab for the treatment of patients with rheumatoid arthritis. *Expert Rev Clin Pharmacol*. 2011;4(5):539–558.
- Zhang, X., et al: Pharmacokinetics (PK) and pharmacodynamics (PD) of tocilizumab in patients with systemic juvenile rheumatoid arthritis: 12-week data from the phase 3 Tender trial. *Ann Rheum Dis*. 2010;69 (Suppl 3):641
- Zhang X., et al: Pharmacokinetics and pharmacodynamics of tocilizumab in systemic juvenile idiopathic arthritis. *Ann Rheum Dis*. 2010;70 (Suppl 3):409.
- Schmitt, C., Kuhn, B., Zhang, X., Kivitz, A., Grange, S. Tocilizumab has no clinically relevant effects on methotrexate pharmacokinetics in patients with rheumatoid arthritis. *Int J Clin Pharmacol Ther*. 2011;30(3):218-223
- Zhang, X., Schmitt, C., et al. Disease-drug interaction studies of tocilizumab with cytochrome P450 substrates in vitro and in vivo. *Clin Pharmacol Ther*. 2009;85 (supplement 1):S59.
- Schmitt, C., Kuhn, B., Zhang, X., Kivitz, A. J., Grange, S. Disease-drug-drug interaction involving tocilizumab and simvastatin in patients with rheumatoid arthritis. *Clin Pharmacol Ther*. 2011;89(5):735-740.
- Grange, S., Schmitt, C., Banken, L,, Kuhn, B., Zhang, X. Thorough QT/QTc study of tocilizumab after single-dose administration at therapeutic and supratherapeutic doses in healthy subjects. *Int J Clin Pharmacol Ther*. 2011;49(11):648-55.
- Zhang, X., et al. Pharmacokinetics and pharmacodynamics of tocilizumab in systemic juvenile idiopathic arthritis. *Clin Pharmacol Ther*. 2011;89, S36–S37.
- Zhang, X., Jordan, P., et al. Thorough QT/QTc study of ritonavir-boosted saquinavir following multiple-dose administration of therapeutic and supratherapeutic doses in healthy participants. *J Clin Pharmacol*. 2012;52(4):520-529.
- Zhang, X., Fettner, S., et al. Pharmacokinetic interaction study of ritonavir-boosted saquinavir in combination with rifabutin in healthy subjects. *Antimicrob Agents Chemother*. 2011;55(2):680–687.
- Zhang, X., Fettner, S., et al. Metabolism and excretion of a novel p38 MAP kinase inhibitor pamapimod in healthy male subjects. I*nt. J Clin Pharmacol Ther,* 2011;49(6): 345-352.
- Zhang, X., Huang, Y., et al. A Proof-of-concept and drug-drug interaction study of pamapimod, a novel p38 MAP kinase inhibitor, with methotrexate in patients with rheumatoid arthritis. *J. Clin Pharmacol*. 2010;50(9):1031-8.
- Zhang, X., Silkey, M., Schumacher, M., Wang, L., Raval, H., Caulfield, J. P. Period correction of the QTc of moxifloxacin with multiple predose baseline ECGs is the least variable of 4 methods tested. *J Clin Pharmacol.* 2009;49(5):534-9.
- Jamois, C., Zhang, X., et al. Effect of saquinavir/ritonavir (1000/100 mg bid) on the pharmacokinetics of methadone in opiate-dependent HIV-negative patients on stable methadone maintenance therapy. *Addiction Biology*. 2009;14(3):321-327.
- Kaeser, K., Zhang, X., et al. Drug-drug interaction study of ketoconazole and ritonavir-boosted saquinavir. *Antimicrob Agents Chemother*. 2009;53(2):609–614.

- Zhang, X., Lin, T., et al. Population pharmacokinetics of enfuvirtide in HIV-1-infected pediatric patients over 48 weeks of treatment. *J Clin Pharmacol.* 2007;47(4):510-7.
- Patel, I. H., Zhang, X., Nieforth, K., Salgo, M., Buss, N. Pharmacokinetics, pharmacodynamics and drug Interaction potential of enfuvirtide. *Clin Pharmacokinet*. 2005;44(2):175-86.
- Mould, D. R., Zhang, X., Nieforth, K., et al. Population pharmacokinetics and exposure-response relationship of enfuvirtide in treatment-experienced human immunodeficiency virus type 1-infected patients. *Clin Pharmacol Ther*. 2005;77(6):515-28.
- Ruxrungtham, K., Zhang, X., et al. Lack of Interaction between enfuvirtide and ritonavir or ritonavir-boosted saquinavir in HIV-1-infected patients. *J Clin Pharmacol*. 2004;44(7):793-803.
- Zhang, X., Lalezari, J. P., et al. Assessment of drug-drug interaction potential of enfuvirtide in human immunodeficiency virus type 1-infected patients. *Clin Pharmacol Ther*. 2004;75(6):558-68.
- Boyd, M. A., Zhang, X., et al. Lack of enzyme-inducing effect of rifampicin on the pharmacokinetics of enfuvirtide. *J Clin Pharmacol*. 2003;43(12):1382-91.
- Lalezari, J. P, Patel, I. H., Zhang, X., et al. Influence of subcutaneous injection site on the steady-state pharmacokinetics of enfuvirtide (T-20) in HIV-1-infected patients. *J Clin Virol.* 2003;28(2):217-22.
- Zhang, X., Nieforth, K., et al. Pharmacokinetics of plasma enfuvirtide after subcutaneous administration to patients with immunodeficiency virus: Inverse Gaussian Density absorption and 2-compartment disposition. *Clin Pharmacol Ther*. 2002;72(1):10-19.

P A T E N T S

- Zhang, X., Terao, K., Jahreis, A. M., Bao, M. Subcutaneously Administered Anti-IL-6 Receptor Antibody. Assigned to Hoffmann-La Roche Inc, Genentech Inc., and Chugai Seiyaku Kabushiki Kaisha. Pub. No.: US 2021/0228597 A1. Pub. Date: Jul. 29, 2021.
- Zhang, X., Terao, K. Subcutaneously Administered Anti-IL-6 Receptor Antibody. Assigned to Hoffmann-La Roche Inc and Chugai Seiyaku Kabushiki Kaisha. Patent No.: US 10,874,677 B2 Date of Patent: Dec. 29, 2020.
- Zhang, X., Terao, K., Harari, O. A. Subcutaneously Administered Anti-IL-6 Receptor Antibody for treatment of Juvenile idiopathic Arthritis. Assigned to Hoffmann-La Roche Inc and Chugai Seiyaku Kabushiki Kaisha. Patent No. US 10,231,981 B2. Date of Patent: Mar. 19, 2019.
- Zhang, X., Pan, W. J. "Method of Treating Acute Myeloid Leukemia (AML) with combinations of anti-CD200 antibodies, cytarabine, and daunorubicin". International Publication No.: WO 2018/075 408 A1. International Publication Date: 26 April 2018.
- Zhang, X., Pan, W. J. "Method of Treating Solid tumor with anti-CD200 antibodies". Assigned to Alexion Pharmaceuticals Inc. International Publication No.: WO 2018/102594 A1. International Publication Date: 07 June 2018.
- Zhang, X., Terao, K, Harari, O. A. Subcutaneously Administered Anti-IL-6 Receptor Antibody for treatment of Juvenile idiopathic Arthritis. Assigned to Hoffmann-La Roche Inc and Chugai Seiyaku Kabushiki Kaisha. Patent No.: US 9,750,752 B2. Date of Patent: Sept 5, 2017.
- Zhang, X., Terao, K., Jahreis, A. Subcutaneously Administered Anti-IL-6 Receptor Antibody for treatment of Systemic Sclerosis. Assigned to Hoffmann-La Roche Inc., Genentech Inc., and Chugai Seiyaku Kabushiki Kaisha. Patent No. US 9,539,263 B2. Date of patent: Jan. 10, 2017
- Zhang, X., Terao, K., Harari, O. A. Subcutaneously Administered Anti-IL-6 Receptor Antibody. Assigned to Hoffmann-La Roche Inc and Chugai Pharmaceutical Inc. Pub. No.: US 2014/0056883 A1. Pub. Date: Feb. 27, 2014
- Zhang, X., Bao, M., Jahres, M. A, Terao K. US Patent. "Subcutaneously Administered Anti-IL-6 Receptor Antibody. Assigned to Hoffmann-La Roche Inc, Genentech Inc. Patent No. 8,580,264 B2. Nov 12, 2013.