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EDUCATION

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

OVERVIEW OF PROFESSIONAL EXPERIENCE

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

DRUG DEVELOPMENT EXPERIENCE SUMMARY

A clinical pharmacology and pharmacokinetic expert with diverse cross functional experience from over 20 years of work in large pharma and biotechnology companies and an established track record of clinical and regulatory success. Experience in planning, executing, and analyzing clinical pharmacology and clinical studies of entire drug development programs (Phase 1 to late stage studies leading to marketing registration and phase 4 post approval commitment studies).Conducted 60+ international and domestic clinical trials across numerous therapeutic areas (oncology, rare genetic diseases, neurology, rheumatology, infectious disease, and inflammation.) with various modules (small molecules, large molecules (mAB and peptide), and oligonucleotide). Regulatory affairs experiences include work on multiple NDAs/BLAs, INDs, IMPDs, MAAs, and other regulatory documents, plus client representation at FDA and EMA meetings including advisory board meetings and EU hearings. Authored / co-authored 70+ publications in peer reviewed journals including 2 book chapters and 5 patents.

DETAILED PROFESSIONAL EXPERIENCE

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

CEO and President

- As both CEO and president of the XP Pharma Consulting LLC (www.xppharmaconsulting.com), efforts include both company and project-based responsibilities. Focus on quality and effective/efficient consulting services.
- Sr. Consultant at Nuventra Pharma Sciences (https://www.nuventra.com/)
- Provides consultation services in all phases of drug development for clinical pharmacology and the associated disciplines (pharmacokinetics [PK], pharmacodynamics[PD], modeling and simulation):
    - Ssingle and multiple ascending dose study in healthy subjects or patient population
    - Proof of concept study
    - PK/PD bridging for new route of administration or new formulation
    - Clinical development strategy-clinical development plans
    - Phase 2 and 3 trials design and PK/PD sampling strategy
    - Drug-drug interaction study
    - Special population studies (hepatic or renal impairment)
    - Radio labelled mass balance study
    - Bioequivalence study for small molecule or biologics
    - Non-compartmental and compartmental pharmacokinetic (PK) data analysis
    - Population PK and PK/PD modelling and simulation
    - Post approval commitment PK/PD study in pediatric patients and other population
    - Manuscripts, meeting abstracts, and posters
    - Clinical pharmacology section of regulatory documents (e.g., CTD/NDA/MAA, USPI, SmPC, briefing documents; Investigator's brochure, EU label variations, pediatric investigational plans, breakthrough designation, etc)
    - Gap analysis and waivers

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

Sr. Clinical Director – Clinical Pharmacology and Pharmacometrics

- Overall Responsibilities:
    - Responsible for all day-to-day aspect of 8 patisiran clinical trials
    - Responsible for strategic planning, implementation, and execution of clinical pharmacology plans (NDA submissions, study designs, authoring protocols, CSR publications, modelling/simulation, cross-functional team interactions, medical affair, etc.)
- Scientific Leadership:
    - Identified clinical pharmacology gaps for patisiran NDA filing package
    - Authored clinical pharmacology sections of 2 pivotal Phase 3 CSRs, briefing packages, and other regulatory documents
    - Authored patisiran CTD 2.7.1 (Summary of Biopharmaceutics) and 2.7.2 (Summary of Clinical Pharmacology) and co-authored other module 2 CTDs

- Designed and conducted comparability analyses between trial formulation and to-be-marketed formulation
- Conducted/directed NCA PK and population PK/PD and disease progression modelling analyses, and integrated these results in the NDA submission package
- Authored 110+ responses to questions from the EMA, FDA, and PMDA during NDA reviewing period; all outstanding issues were resolved with outcome of approvals
- Authored/co-authored 7 publications for 2 novel RNAi therapeutic trial results and 7 oral/poster presentations in international conferences

- Project Management:
  - Organized and managed 4 cross-functional working groups for outstanding issues identified as gaps, and implemented working group outcomes in the patisiran NDA filing package
  - Formed and managed cross-functional team members for drafting responses to the cross-functional issues raised by EMA and PMDA reviewers for patisiran NDA
  - Managed clinical pharmacology sub-team (NCA, PK/PD modelling, and DMPK) for ad hoc analyses authoring responses to numerous questions from PMDA for patisiran NDA

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

- Overall Responsibilities:
  - Responsible for design of clinical studies from Phase 1 to 3 to ensure NDA success
  - Responsible for managing internal and external resources for PK and PK/PD analyses including modelling/simulation
  - Responsible for authoring PK reports and clinical pharmacology sections of the clinical protocol, CSRs and regulatory documents (pre-IND, IND, IB, IMPD, IND Annual Update, and NDA/BLA documents)

- Scientific Leadership:
  - Contributed to 3 clinical trials for samalizumab in treatment of CLL, AML, and advanced solid tumours; authored PK/PD components of the protocols, CSRs, and other documents
  - Contributed to proof-of concept study for SBC-103 for treatment of pediatric patients with MPSIIIB; conducted 2 interim PK/PD analyses to support Go/No-Go milestones
  - Conducted allometric scaling for dose recommendation to support Phase 3 protocol design including all age groups since birth for patients with MPSIIIB
  - Accomplished 2 patents, 5 publications and 7 conference presentations

- Project Management:
  - Directed and managed external CRO for population PK and PK/PD modeling analyses and clinical trial simulations

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

- Overall Responsibilities:

  - As clinical team leader, reresponsible for overall success of 2 clinical projects: burosumab (KRN23) for treatment of X-linked hypophosphatemia (XLH) and CEP-37250/KHK2804 for treatment of solid tumour; responsible for monitoring overall study integrity, review, interpretation, and communication of safety, PK/PD and efficacy data to internal team external Key Opinion Leaders (KOLs)
  - As head of clinical pharmacology, responsible for management of clinical pharmacology group and support 8 products with a total of 18 clinical trials from Phase 1 to 3 in multiple disease areas (oncology, CNS, inflammation, nephrology, rare genetic disorder)
- Scientific Leadership:
  - Managed and lead burosumab clinical team: authored clinical development plan (CDP) for adults and pediatric population in collaboration with KOLs and regulatory experts; completed multiple clinical trials, data analysis and reporting (phase 1 SAD, Phase 2 MAD trials and long-term extension study of phase 1 MAD study in patients with X-linked Hypophosphatemia; authored 4 burosumab publications and 13 oral/ poster presentations with KOLs; contributed out-license phase 3 trial to an external partner.
  - Authored clinical development plan for CEP-37250/KHK2804 with KOLs; directed study team for a phase 2 study in advanced solid tumour; completed dose-escalation (3+3 design) in Part I of the protocol and identified colangiocarcinoma for expansion cohort in Part II.
  - Lead team to support 4 clinical trials for an anti-CCR4 antibody for the treatment of hematological malignancies; analyzed interim data and identified potential issues; proposed risk mitigation strategy that was implemented; performed population PK and PK/PD analyses for 4 Japan studies; authored Clinical Pharmacology Plan for NDA submission
  - Contributed to the study design and protocol authoring for 3 immuno-oncology studies using check point inhibitors in treatment of solid tumors.
  - Performed preclinical to clinical translation for 5 Phase 1 POC studies in 5 different types of malignancies; contributed to pre-IND, study design and protocol authoring; completed PK/PD data analyses and interpretation; authored study reports; managed external consultants for modelling and trial simulation; responded to health authority questions; participated in discussion with regulatory agencies.
  - Supported Phase 3 trial of istradefylline in the treatment of Parkinson's disease with population PK and PK/PD component; lead study teams for vendor selection, design, execution and completion of 2 clinical pharmacology studies: a drug-drug interaction study and a special population study in hepatic impaired subjects; outlined NDA submission plan.

- Project /People Management:
  - Managed 2 medical monitors (MDs), 2 bioanalytical monitors (MSc and PhD), 2 clinical pharmacologists and 3 external expert consultants, including expert in modelling and simulation (PhDs).
  - Contributed to CRO selection for clinical trials, initiated numerous work orders under master service agreement and master consulting agreement, and managed budget.

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

- Held various progressively advanced positions: hired as Clinical Science Specialist in 2001; promoted to Associate Clinical Director/Clinical Pharmacologist in 2005; promoted to Clinical

Director/Sr. Clinical Pharmacologist in 2008; and appointed as head of Clinical Pharmacology-inflammation in 2008.

- Overall Responsibilities:
  - Responsible for authoring clinical pharmacology plans co-authoring CDPs
  - Approve clinical study protocol, reports and regulatory documents
  - Responsible for design, execution and reporting of clinical pharmacology studies
  - Responsible for Clinical Pharmacology sections of phase 2 and 3 trials
  - Responsible for Clinical Pharmacology parts of NDA/BLA submissions
  - Management and mentoring responsibility for Clinical Pharmacology group and fellows
- Scientific Leadership for Clinical Pharmacology Studies:
  - Directed and completed /contributed 7 drug-drug interaction 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. (see Publication list).
  - Directed and completed 3 through 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 administration 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 doses in healthy subjects (see Publication list)
  - Directed 4 special population studies: (1) effect of 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; and (4) tocilizumab post-approval commitment PK /PD study in sJIA patients < 2 years of age.
  - Contributed to the completion of 3 SAD and MAD studies: (1) a randomized double blind, positive controlled 14-day multiple-ascending dose study to investigate 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, memory impairment and Alzheimer's disease) in healthy subjects
  - Directed and completed 1 mass balance study including ADME and metabolic profiling of in healthy male subjects with ^{14}C-labeled pamapimod (see Publication list)
  - Directed and completed 3 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 pre-filled syringe and auto-injector.
- Scientific Leadership for Phase 1 to 2 Proof-of-Concept Studies:

- Contributed to clinical pharmacology sections of 6 phase 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-2 positive 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 enfuvirtide Phase 3 trial for BLA
  - Analyzed PK/PD data and authored reports for tocilizumab Phase 3 trials for BLA
  - Authored PK/PD sections of protocol and CSR for 2 pivotal Phase 3 studies conducted in sJIA and pJIA for tocilizumab BLA filings in two indications
  - Contributed to study design, conduct and reporting of 2 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
  - Patents for SC dose/regimen and study design for tocilizumab Phase 3 studies in sJIA and pJIA pediatric patient population
- Scientific Leadership for Due-Diligence for in License Opportunity:
  - Alectinib project: Evaluated preclinical and phase 1 clinical data of alectinib in patients with NSCLC, authored due diligence report and clinical pharmacology plan and
- 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 3 tocilizumab BLA submission and approvals (RA, sJIA, and pJIA) in EU, US, and global; authored CTD 2.7.2 and attended pre-BLA meetings in EU and US; responded to list of CHMP questions during 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 3 pediatric investigational plans (PIP) for rituximab and tocilizumab
- Scientific Leadership for PK/PD Modelling and Simulation:
  - Conducted population PK and exposure-analysis using NONMEM 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 enfuvirtide PK
  - Managed internal resources for population PK and PK/PD modeling of tocilizumab in sJIA and pJIA patient population for respective BLA submission
- Scientific Leadership for Clinical Pharmacology Study Methods:
  - First leading scientist to bring disease-drug-drug interaction data and concepts to FDA and authored 1 CPT paper and 1 book chapter (see Publication list)

  - First time demonstrated that period correction of the QTc of moxifloxacin with multiple predose baseline ECGs is the least variable of 4 methods tested which eliminated time-matched baseline measurements (see Publication list)
- Project/People Management:
  - Managed four Clinical Science Specialists (Pharm D, MSc, BSc), one Associate director (Pharm D) and one administrative assistant (BSc) (set up performance goals, provide feedback throughout the year, propose bonus, salary raise and promotion)
  - Initiated many clinical Pharmacology studies (either heathy volunteers or patients) and managed cross functional teams (clinical operation, statistics, safety and preclinical) for plan, execution and reporting of the clinical trials

Academic Positions **1988 - 2000**

Assistant Professor and /or Research Fellow

- Responsible for research and mentoring graduate students at following schools:
  - Texas Tech University, Amarillo, TX, USA (1999-2000, 1 year)
  - University of Kansas, Lawrence, KS, USA (1995-1997, 2 years)
  - University of Erlangen-Nurnberg, Erlangen, Germany (1994-1995, 1 year)
  - Shanxi University, Taiyuan, Shanxi, China (1988-1991, 3 years)

TRAINING

- Certificate of attendance for "Modeling Biologics with targeted-Mediated Disposition" training course. Instructors: Drs. Leonid Gibiansky and Ekaterina Gibiansky. March 4, 2016. San Francisco, CA
- Population PK/PD modeling Workshop for Intermediate and Advanced Features of NONMEM 7. April 7-9 2015. Instructors: Robert J. Bauer and Brian Sadler. Maryland. 2015
- Population Modeling Methodology using Phoenix NLME. Pharsight Co. King of Prussia, PA, US. 2012
- ASoP Workshop: Population Pharmacometrics Modeling with Monolix. Somerset, NJ. Instructor: Marc Lavielle. May 17-18, 2012
- PK/PD modeling on continuous and categorical data in NONMEM7. Instructor: Prof. Dr. Mats Karlsson from Uppsala University, Sweden. Morristown, NJ. June 13 to 15, 2010

ADDITIONAL PROFESSIONAL ACTIVITIES

- American Society of Clinical Pharmacology and Therapeutics (ASCPT), member
- American Society of Clinical Oncology (ASCO), member
- American Society of Pharmacometrics (ASoP), member

HONORS & AWARDS

- Shooting Star Awards (two) for successful launch of Onpattro in Canada and Japan (including submissions and responses to questions). Alnylam Pharmaceuticals, Inc. 2019

- Outstanding Scientific Contribution Award for presentation of clinical data on first ever approved RNAi therapeutic in hATTR patients. 2018 SAPA-NE Symposium
- Special Recognition for "delivered tangible results, behaviors and values, and future potential". Alnylam Pharmaceuticals, Inc, 2018
- Steller Supernova Award for Passion for Excellence. Alnylam Pharmaceuticals Inc. 2017
- Stellar All-Star Award for Sense of Urgency supporting Patisiran Filing Working Group, Alnylam Pharmaceuticals Inc. 2017
- Oscar Award for the best synopsis of Samalizumab. Alexion Pharmaceuticals Inc. March 2016
- Alexion innovator's award for scientific contribution to the area of MPSIIIB treatment using enzyme replacement therapy. Alexion Pharmaceuticals, Inc. 2016
- President Award for Outstanding Achievements and Novel Results from a state of the art study resulting in significant clarification of our scientific or clinical understanding. 2014 European Society of Pediatric Endocrinology Annual Meeting (ESPE). Dublin, Ireland, 2014
- President award for the innovative clinical research. Annual Meeting for American Society of Bone and Mineral Research (ASBMR). Maryland. 2013
- President award for the Outstanding Poster and Abstract. American Society of Clinical Pharmacology and Therapeutics (ASCPT). 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. 2003
- First Prize and Best Student Award at Shanxi University, China, 1983 and 1988

CLINICAL PHARMACOLOGY EXPERIENCE

- Development of comprehensive clinical pharmacology development plans and strategies
- Strong knowledge of PK and PD concepts and modeling analyses from industry experience and completion of an advanced PK/PD modeling courses (See Training)
- Scientific and strategic contributions to study design, protocols, reports, and other documents
- Scientific contributions to 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
- Post marketing 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

- Hands-on experience in PK and PK-PD modeling analysis at various stage of development (allometric scaling, dose prediction, safety margin prediction, clinical trial design, etc)
- Provided scientific guidance to population PK, PK/PD and disease progression modeling analyses
- Directed internal and external resources for large modeling analyses by pooling data for NDAs
- Integrated PK, PK/PD modeling analysis results in the NDA submission packages

NONCLINICAL EXPERIENCE

- Experiences in translation of preclinical data package to the first in human trial design and doses 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 report in CTD)

REGULATORY AFFAIRS EXPERIENCE

- Participated in meetings with FDA and EU agencies (face-to-face and teleconferences): Scientific Advice Meetings, End of Phase 2 Meetings, Pre-NDA/BLA Submission Meetings, EMA Oral Explanation, and FDA Advisory Committee Meeting.
- CTD structure/requirement understanding and gap identification for NDA/BLA submission
- 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 numerous full protocols, protocol amendments, and concept protocols for studies in different therapeutic areas
- Authored numerous Clinical Study Reports (Lead or contributing author).
- Authored numerous PK & PD reports or contributions to CSRs
- Authored 7 CTD modules (Lead or contributing author)
- Authored 70+ peer-reviewed clinical manuscripts
- Authored 5 patents and associated drawings

INTERNATIONAL DRUG DEVELOPMENT EXPERIENCE

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

PROGRAMMING EXPERIENCE

- Experiences in user defined PK and PK/PD modeling with WinNonlin coding

  Experiences in PK and PK/PD modelling with NONMEM control stream
- Experiences in PK and PK/PD graphic displays with R coding

REGULATORY SUBMISSIONS FOR APPROVED PRODUCTS

- Direct contributions to 7 NDAs/BLAs and several sBLAs: patisiran (hATTR amyloidosis polyneuropathy), tocilizumab (RA), tocilizumab (sJIA), tocilizumab (pJIA), rituximab (ANCA associated vasculitis), enfuvirtide (HIV-1), burosumab (X-Linked Hypophosphatemia)
- Strategy contributions to CDP and clinical studies resulting in 1 NDA and 1 BLA approval: mogamulizumab (cutaneous T-cell lymphoma) and alectinib (non-small cell lung cancer)

SELECTED PUBLICATIONS

- 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.
- Zhang, X, Goel V, et al. Pharmacokinetics of patisiran, the first approved RNA interference (RNAi) therapy, in patients with hereditary transthyretin-mediated amyloidosis. *J Clinical Pharmacology*. 2019 Nov 27. doi: 10.1002/jcph.1553. [Epub ahead of print]
- 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 Clinical Pharmacology.* Published ahead of print. https://doi.org/10.1002/jcph.1480; July 19, 2019.
- Judge,D.P., Zhang, X. et al. Phase 3 multicenter study of revusiran in patients with hereditary transthyretin-mediated (hATTR) amyloidosis with cardiomyopathy (ENDEAVOUR). *Cardiovascular Drugs and Therapy*. 2020.
- 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. *Clinical Pharmacology and Therapeutics*, 105(S1);E-009;S31;2019.
- Zhang X, Goel V, Robbie G. Pharmacokinetics of patisiran in patients with hereditary transthyretin-mediated amyloidosis. *Journal of Neuromuscular Diseases*. 5: S280; Abstract 568; 2018.
- Goel, V, Zhang, X. et al. Population pharmacokinetics (PK) of patisiran in healthy volunteers and in patients. *J. of Neuromuscular Diseases.*5: S251.Abstract 567; 2018.
- 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. *European Journal of Neurology*. 25 (Suppl. 2); Abstract EPR2142; 460; 2018.
- 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. *European Journal of Neurology*. 25 (Suppl. 2); Abstract EPR1139; 354; 2018.
- Zhang, X, Goel, V, Robbie, G. Pharmacokinetics of patisiran in patients with hereditary transthyretin-mediated amyloidosis. *J. Neuromuscular. Disease.* 5, S280. Abstract 568; 2018.
- 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*. 7(1):227;2019.
- Mukai, M., Zhang X., et al. Effects of rifampin on the pharmacokinetics of a single dose of istradefylline in healthy subjects. *J. of Clinical Pharmacology*. 58(2); 193-201;2018.
- 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 Clinical Pharmacology*. 56(2): 176-185;2016.

- Ruppe MD, 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*. 5:158–162;2016.
- 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 Clinical Pharmacology.* 57(4):459-468;2017.
- 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. *Molecular Genetics and Metabolism*. 126(2);131-138;2019.
- 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 Pharmacology*.56(4):429-38;2016.
- 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*. 11(3):317-27; 2016.
- 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*. 125(2): 1883-1889; 2015.
- Imel EA, Zhang X, et al. Prolonged correction of serum phosphorus in adults with X-linked hypophosphatemia using monthly doses of KRN23. *J Clin Endocrinol Metab.* 100(7):2565-73, 2015.
- Carpenter TO, Zhang X, et al. Randomized trial of the anti-FGF23 antibody KRN23 in X-linked hypophosphatemia. *J Clin Invest*. 124(4):1587-97. 2014.
- 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*. 52(1):27-38; 2014.
- Carpenter TO, 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*. 28 (Suppl 1); 2013
- Zhang X, Carpenter TO, 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*. 28 (Suppl 1); 2013.
- 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. of Clin Pharmacol &Ther*. 51(8); 620-630; 2013.
- Zhang X, Chen YC, and Terao K. Clinical pharmacology of tocilizumab for the treatment of polyarticular-course juvenile idiopathic arthritis. *Expert Rev. Clin. Pharmacol.* 10(5):471-482;2017.

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