Curriculum Vitae

Royce Morrison MD, MSEE, CPI

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Royce A Morrison MD
14 MAY 2014

Current – Clinical Research Consultancy in:

- **Translational Development**
- **Clinical Development**
- **Protocol Design**
  - **Phase I / Clinical Pharmacology**
  - **Baseline & Endpoint Integrity**
  - **Good Clinical Practice & Guidance Compliance**
  - **Participant Safety**
  - **Deviation/Violation Avoidance**
- **Preparation for IRB Submission**
- **Site Preparation / Initiation**
- **Medical Monitoring**
- **Safety Event Assessment**
- **Safety Data Assessment**
- **Data Monitoring Committee / Data Safety Monitoring Board**

Human Research Participant Protection

2013-2014 Executive Vice Chair and Board Member
Quorum Review IRB
Seattle, Washington USA

I served as Vice Chair, in-house scientific and healthcare professional Member of this highly-regarded, AAHRPP accredited independent ethical review board. The Board evaluates protocols, investigators and sites, providing oversight to ensure compliance with regulatory and ethical standards for protection of human participants in all types and phases of clinical research.

Early-Phase Clinical Research in Drug/Biologic/Vaccine Development:

2011-2012 Chief Medical Officer
Principal Investigator
Comprehensive Clinical Development

Corporate headquarters: Miramar, Florida
Office: 3615 Pacific Ave, Tacoma WA 98418

Post acquisition of Tacoma clinical pharmacology unit in March 2011, I became Chief Medical Officer of Comprehensive CD, with additional responsibilities: provide guidance to professional / investigator staff at all sites; participate in corporate integration task force and strategic decisions; facilitate harmonization of operating procedures across the organization; maintain awareness of trends in science, research methods, regulation and industry relationships; contribute to corporate executive strategic planning and leadership; further develop specialized early-phase research capabilities; expand representation to clients with the company's nationwide business development team. I continued to serve as principal investigator in clinical pharmacology research, especially cardiac safety, vaccine and radiolabeled drug studies.

2007-2011

Director of Clinical Strategy
Principal Investigator
Charles River Clinical Services
Corporate headquarters: Wilmington, Massachusetts
Office: Tacoma, WA as above

Continued as principal investigator and also represented the Phase I-II service organization in relationships with client companies, service vendors (e.g., cardiac core labs), community professionals, industry professional organizations, and industry media; participated in site management and advise on industry trends; responded to operational and regulatory issues; identified and developed necessary capabilities (e.g., cardiac safety, radiolabeled studies); wrote/reviewed/revised SOPs; wrote/edited documents and communications.

2002-2007

Director of Medical Affairs
Principal Investigator
Northwest Kinetics
Office: Tacoma, WA as above

Supervised professional staff (nurses, physician investigators). Served as Principal Investigator for >100 Phase I-II clinical research studies (subinvestigator for many more): project feasibility review; synopsis/protocol review/revision; background scientific review; protocol design and writing; development of procedural capabilities; staff training; conduct of study; management, analysis, reporting of safety signals; study report review and editing; regulatory reviews and responses;

collaboration with referring and consulting specialists. Principal Investigator in first-in-human vaccine studies for leishmaniasis, tuberculosis, Japanese Encephalitis, Venezuelan Equine Encephalitis, and a novel live-virus smallpox vaccine.

Certification

American Board of Internal Medicine

Advanced Achievement in Internal Medicine

Certified Clinical Investigator – Drug Information Association – April 2004

Certified Physician Investigator – Academy of Physicians in Clinical Research – September 2012 (through May 2015)

NIH Office of Extramural Research – certificate for web-based training "Protecting Human Research Participants" – Feb 2009

FDA Clinical Investigator Training Course – certificate Nov 2010

Principles of Clinical Pharmacology – NIH Clinical Center certificate – April 2012

Collaborative Institutional Training Initiative – CITI Good Clinical Practice Curriculum – completed most recently – August 2013

Basic and Advanced Cardiac Life Support – May 2012

Licensure

Physician & Surgeon, Washington #00014630

Education

Stanford University
MD 1973
MSEE 1969
BSEE 1968

American College of Physician Executives:
Physician in Management series

Residency

Virginia Mason Medical Center, Seattle
Internal Medicine 1975-76

University of Texas Southwestern at Dallas
Internal Medicine 1973-75

Medical Practice

1993 to 2000
Full-time Internal Medicine practice at Group Health

Cooperative of Puget Sound at central campus, emphasizing HIV/AIDS and geriatrics

Member of the GHC hospitalist team, 1996-97.
Locum tenens primary care clinic physician, 2000-04.

1976 to 1993
Private practice, primary care and consultative Internal Medicine – First Hill, Seattle
Hospital practice at major regional medical centers

1977 to 1983
Attending physician, inpatient alcoholism and drug treatment
Internal Medicine consultant to inpatient psychiatric service

1976 to 1980
Medical Officer (part-time), U.S. Public Health Service Division of Federal Employee Occupational Health.

Internet – Mediated Consumer Health Information

HealthTalk Interactive, Inc.
Seattle, WA

Led the predecessor company RxSite, with patent applications, between 1997 and 2000, to its merger and venture capitalization to form HealthTalk Interactive. As co-founder and Medical Director from 7/00 to 9/01, I was responsible for medical information in www.healthtalk.com, regulatory compliance in working with biotechnology and pharmaceutical program sponsors, liaison with patent and trademark counsel, and participation in the corporate executive team.

Consultation & Administration

2012 to Present – Proposal review, Washington Life Sciences Discovery Fund
By invitation, on the proposal review panel of this Washington State agency responsible for selectively awarding public fund grants to early-stage life science technology ventures

1985 to Present – Medicolegal Consultation
As sole/managing member of RMD Insight, LLC, I provide medical expert consultancy to attorneys in reviewing cases pertinent to professional liability or litigation, with related deposition and in-court testimony.

August 1999 to 2003 – Medical Quality & Review Unit
For Group Health Cooperative – responsible for determining coverage of services, responding to appeals of denied coverage, for related communications with consumers and health professionals. This included participation in evaluating contract provisions, medical necessity criteria, new medical technology, and formulary provisions. Served as Medical Director 8/99 to 7/00 (part-time, while in clinical practice), then continued as a consultant thereafter.

1998 to July 2000 – Pharmacy and Therapeutics
Membership in Pharmacy and Therapeutics Committee for GHC – responsible for participating in reviews of evidence and determinations regarding formulary status of pharmaceutical and biotechnology products.

1994 to July 2000 - Guideline Development
Represented Group Health's Department of Family Practice in the multidisciplinary Depression Roadmap Steering Committee and Guideline Development Team, responsible for assessing processes of diagnosis and treatment of depressive illness, reviewing the evidence basis for those processes, creating and implementing a clinical guideline, then training mental health and primary care practitioners.

1997 - Prevention & Health Promotion
For GHC Center for Health Promotion, I served on an *ad hoc* committee to establish a GHC Central Region Wellness Center, to improve seniors' function and quality of life through educational and activity interventions supported by outcomes research.

1976 to 1993 - Medical Staff & Group Leadership
Served in Cabrini Hospital medical staff and primary care practice group leadership, and as consultant in developing primary care neighborhood clinics.

1987 to 1997 - Medical International Relations
Assisted a visiting Uzbek physician through his 1997 Seattle tenure in the United Nations Management of Change Program.

In 1987, I participated with two other Seattle physicians and our families in a Seattle-Tashkent Sister City Association Medical Exchange, traveling to Tashkent, Uzbekistan USSR to negotiate planning of the exchange, then returning to live with a physician colleague in Tashkent for 5 weeks – the first such exchange

(living with hosts, daily clinical experience, interaction with local, regional, and national USSR officials and news media) in the history of US-USSR relations. In 1988, we hosted our Soviet/Uzbek counterparts in Seattle.

Organizations

Association of Clinical Pharmacology Units
Board of Trustees, 2010 to 2013.
Drug Information Association
Chair of Special Interest Area Community in Clinical Pharmacology and Phase I; Core Committee member 2010 to present
American College of Physicians (Internal Medicine)
Northwest Association for Biomedical Research – Seattle WA
Board President, 2007-2009, then Past President, and a continuing Board member. I led through reevaluation of the organization's vision, mission, core values and strategic planning, emphasizing more focused, rigorous and professional management of this regional nonprofit organization that has achieved national impact in support of biomedical research.

Research

From 2002 to 2013, participated as Principal Investigator or Subinvestigator in review, revision, design and conduct of over 200 Phase I-III clinical research studies, with emphasis on first-in-human, cardiac safety, biologicals and vaccines.

Publications

Holzgrefe H, Ferber G, Morrison R et al. Characterization of the Human QT Interval : Novel Distribution-Based Assessment of the Repolarization Effects of Moxifloxacin. **Journal of Clinical Pharmacology. Published online June 9, 2011.** [Advised and wrote clinical background and discussion sections.]

Jamois C, Smith P, Morrison R 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 Jul;14(3):321-327.** [Complex study, challenging in logistics, collaborations for recruitment; R Morrison PI.]

von Eschen K, Morrison R et al. The candidate tuberculosis vaccine Mtb72F/AS02A: Tolerability and immunogenicity in humans. **Human**

Vaccines. 2009 Jul 27;5(7). [Report of FIH vaccine study conducted at NW Kinetics; R Morrison as protocol consultant and PI.]

Laviola M et al. Randomized study of phentolamine mesylate for reversal of local anesthesia. **J Dental Research. 2008 Jul;87(7):635-9.** [Report of Phase IIa study per protocol largely developed and written by R Morrison, conducted by NW Kinetics with local dentist investigators.]

Presentations 2009-2013

Chaired Clinical Pharmacology Community Showcase on "First-in-Human Studies: How Much Complexity is Too Much?" giving presentation on "First-in-Human Complexity and IRB Regulatory Protection" at **DIA Annual Meeting, June 2013.**

Chaired Session on "Pharmacometrics: Implications and Impact in Preclinical and Early Phase Clinical Development", giving presentation on "Opportunities to Take Advantage of Pharmacometrics" at **DIA Annual Meeting, June 2013.**

Chaired Forum on "Pharmacometric Methods: Essential for Optimal Drug Development Strategy" at **DIA Annual Meeting, June 2013.** Presentation on "The Investigators' Perspective of the Pre-study Feasibility Assessment and Dose Escalation Safety Review" at the **ACCP Annual Meeting, September 2012.**

Session Chair and presentation on "First-in-Human Challenges of Biologics and Biosimilars" at **DIA Annual Meeting, June 2012.**

Presentation of "QT Derisking With Continuous ECG Data Analysis" at **DIA Annual Meeting, June 2012**.

Panel discussant – "21st Century CPU – The Future of Clinical Pharmacology Units and Early Phase Clinical Research" at **Association of Clinical Pharmacology Units Annual Meeting, at NIH Natcher Conference Center, April 2012.**

Session chair and presentation "ECG Interpretation and Documentation in Clinical Trials" for **DIA 2011 Annual Meeting. June 2011.**

Planning group, session chair and presentation "First-in-Human: Reducing Risk" for DIA (Drug Information Association) workshop titled **Nonclinical and Clinical Strategies in First-in-Human Dosing of Large and Small Molecules. April 2011.**

Holzgrefe H and Morrison R. Blinded Identification of Clinical QT Prolongation with Moxifloxacin Employing Distribution-based QT Analysis. **Poster presentation #1056548 to Society of Toxicology 2011 Annual Meeting, March 2011.**

Workshop Co-chair for Cardiovascular Risk Assessment in Early Phase Studies; presentation "ECG Risks – Acquiring and Analyzing Data" **CBI 5th Annual Cardiovascular Risk Assessment Summit., January 2011.**

Morrison R, Wikler MA, Rock JA, Morganroth J. Poster presentation "Single-center, Triple blind, Triple-dummy, Randomized, Single-dose, Four-way Crossover Phase I Study to Define the ECG Effects of Zabofloxacin Using a Clinical and Supratherapeutic Dose Compared to Placebo and Moxifloxacin (a positive control) in Healthy Adult Male and Female Subjects: A Thorough ECG Trial." **2010 International Conference on Antimicrobial Agents and Chemotherapy. September 2010.**

Session Chair for Phase I Clinical Safety: Subjects and Signals; presentation "Biologics: Safety and Signals" **DIA Annual Meeting, June 2010.**

University of Washington School of Pharmacy Biomedical Regulatory Affairs program, presented "Biosimilars and Clinical Trials – What are the Issues?" **Biosimilars Conference; March 2010.**

Charles River Webinar "When Drugs Have Heart Attacks." **June 2009.**

Academic Honors

National Science Foundation Graduate Fellow
Phi Beta Kappa – Stanford U
Tau Beta Pi Engineering Honor Society – Stanford U
BSEE "with Great Distinction," Stanford U

Languages

Strong aptitude and excellent pronunciation
French – basic conversational level
Russian – independent tourist level

Community

Seattle Pro Musica
Member (& 4 yrs Board Member) – 1993 to 2010

St. Martin de Porres Winter Shelter

Transportation and overnight presence / supervision at shelter site, winter months – 2004 to 2012

References

Available on request.

Investigator Research Experience (2006-2011; 2012 studies not listed)

A Phase 1, double-blind, adjuvant and placebo-controlled, dose-escalating study to evaluate the safety, tolerability and immunogenicity of the recombinant three-antigen XXX XXX XXX when administered in three subcutaneous doses to healthy adults.

A double-blind, randomized, placebo-controlled, multiple-dose study to evaluate the safety, tolerance and pharmacokinetic profile of an initial dose of 600mg of XXX, followed by a cohort at either 300, 600 or 900mg dose of XXX in healthy male subjects.

A Phase 1 study of XXX in elderly subjects.

A placebo-controlled, ascending, multiple-dose study to evaluate the safety, pharmacokinetics and pharmacodynamics of XXX in Type 2 Diabetic subjects.

A double-blind, vehicle-controlled, single-dose escalation study to assess the safety, tolerability and pharmacokinetics of topical XXX(XXX) in healthy volunteers.

An open-label, randomized, two-period cross-over study to estimate the effect of particle size on the relative bioavailability of single oral 200mg doses of XXX in healthy subjects.

An open-label, two-period, three-way cross-over study to evaluate the pharmacokinetics of 300mg, 150mg and 90mg doses of XXX in healthy volunteers previously exposed to XXX.

A dose-ranging, single center, double-blind, randomized, placebo-controlled study of the safety and efficacy of a single injection of XXX in the mandibular region of healthy subjects.

A randomized, two-period cross-over study to evaluate the effects of food on the pharmacokinetic profile of a single dose of two different XXX formulations in comparison with 500mg XXX extended release tablet in healthy male volunteers.

XXX: A single dose pharmacokinetic assessment in adolescents following an intravenous infusion.

An open-label, one-sequence cross-over study to assess the pharmacodynamic and pharmacokinetic interaction of XXX with XXX in healthy adult subjects.

A Phase 2, double-blind, placebo-controlled, randomized, parallel-group study of the safety and toleration of XXX and XXX administered concomitantly for six weeks to subjects with controlled hypertension.

A randomized, double-blind, placebo-controlled, period balanced, two-part, three-period cross-over drug interaction study of XXX (10mg and 20mg) and XXX (0.4mg) in healthy males aged 45 to 75 to evaluate changes in blood pressure.

A dose-ranging, single-center, double-blind, randomized, placebo-controlled study of the safety and efficacy of a single injection of XXX in the maxillary region of healthy subjects.

A double-blind, randomized, placebo-controlled study of the efficacy and safety of XXX in dental patients.

An ascending, multiple-dose safety and tolerance study of XXX in healthy adult male subjects.

A double-blind, vehicle-controlled, single-dose study to assess the safety, tolerability, and efficacy of topical XXX (XXX) in patients with post-therapeutic neuralgia.

A multi-center, double-blind, randomized, placebo-controlled, multiple-dose safety and tolerance study of XXX in male subjects with or without erectile dysfunction.

A multiple-dose, parallel-group, open-label study of the pharmacokinetics of XXX and XXX in Blacks, Hispanics and Caucasians infected with chronic Hepatitis C.

A study to assess the safety, tolerability and immunogenicity of XXX Smallpox vaccine in adults without previous smallpox vaccination: A randomized, double-blind, fixed dose, Phase 3 comparison between XXX and ZZZ Smallpox vaccines.

A multiple-dose pharmacokinetic study of XXX (XXX) in healthy adolescents with Attention Deficit Hyperactivity Disorder (ADHD).

A Phase 1, open-label, dose-escalation study to evaluate the safety and immunogenicity of the recombinant Mycobacterium Tuberculosis vaccine, XXX with XXX adjuvant, when administered intramuscularly to healthy purified protein derivative negative adults.

A Phase 1 study of the safety and pharmacokinetics of repeated-dose XXX (XXX) and single-dose of XXX after separate and concomitant administration to healthy adult volunteers.

A double-blind, randomized, multi-center, two-part, parallel-group, dose-ranging study of twice daily and once-daily (RR) XXX in the treatment of subjects with Chronic Obstructive Pulmonary Disorder (COPD).

An open-label, multi-center, protocol providing prgylated inteferon XXX (XXX) as mono-therapy or in combination with XXX (XXX) for patients with chronic Hepatitis C who have participated in previous XXX protocols.

A single-blind, repeat dose, placebo-controlled, parallel-group study to assess the effects of age and gender on the pharmacokinetics of XXX in relatively healthy subjects.

A Phase 1, two-way cross-over study to assess the effect of multiple oral doses of XXX on the pharmacokinetics and pharmacodynamics of XXX following multiple oral doses of XXX.

A randomized, open-label, single oral dose, four-period cross-over study to estimate the relative bioavailability and dose proportionality of XXX modified release tablet versus the immediate release capsule followed by repeat oral dosing to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX modified release tablet in healthy subjects.

A randomized, open-label, period-balanced, cross-over study with two parallel groups conducted in healthy subjects to assess the pharmacokinetics and pharmacodynamics of a XXX modified release tablet formulation of XXX.

A Phase 1 study of the safety and pharmacokinetics of steady state XXX (XXX) and the steady state XXX after separate and concomitant administration to healthy adult volunteers.

A study to evaluate the effect of XXX 2-XXX (XXX) on ATP levels in circulating B cells.

A comparison of the pharmacokinetics of XXX in nanoparticle tablets and improved classical capsules V26 and the effect of food on the pharmacokinetics of XXX in nanoparticle tablets.

An open-label, exploratory study to compare the single-dose pharmacokinetics of a glucokinase activator (XXX or XXX) administered alone and concomitantly with XXX or XXX in Type 2 Diabetic patients.

A comparison of three new tablet formulations of XXX with the improved classical capsules ZZZ under standard dietary conditions.
A randomized, double-blind, placebo-controlled, multiple-dose, parallel-group study of the safety, tolerability, pharmacokinetic and pharmacodynamic effects of XXX administered daily for twenty-eight days in healthy, post-menopausal women with moderate to severe hot flashes.

A Phase 1, randomized, double-blind, placebo-controlled, single-center, sequential dose escalation study to evaluate the response of multiple doses of intravenous XXX on 48-hour XXX pH and pharmacokinetic measurements.

A study to evaluate the effect of co-administration of boosted XXX (co-administration with low dose ritonavir) and methadone on the pharmacokinetics and pharmacodynamics of methadone and the pharmacokinetics of XXX and XXX in opiate dependent patients on stable methadone maintenance.

An open-label, single-dose study to evaluate the excretion of XXX into the breast milk of lactating healthy women.

A Phase 1, randomized, cross-over, fed/fasted, single-dose study of the safety, tolerability and pharmacokinetics of oral XXX in healthy adult subjects.

A Phase 1, randomized, open-label, four-period cross-over, multiple-dose single-center study to evaluate the pharmacokinetics, pharmacodynamics and safety following administration of 60mg, 90mg and 120mg oral doses of a modified release formulation of XXX and 30mg oral doses of XXX in healthy subjects.

A study to evaluate the effect of repeated, once-daily XXX capsules (400MG/M2/Day) on the single dose pharmacokinetics of XXX tablets in healthy subjects.

A Phase 1, randomized, open-label, four-arm, two-period, two-by-two, cross-over, drug interaction study to assess steady-state plasma XXX and XXX pharmacokinetics following administration of XXX 700mg BID + RTV 100mg BID + XXX 300mg QD, XXX 700mg BID + RTV 100mg BID, and XXX 300mg QD, + RTV 100mg QD in healthy adult subjects.

A double-blind, placebo-controlled, dose-escalation study of the safety, pharmacokinetics and pharmacodynamics of a single subcutaneous dose of XXX administered to healthy human subjects.

A comparison of the bioavailability of XXX acid formulations relative to that from the micronized XXX capsule formulation.

A twelve-week, parallel-group, double-blind, randomized, placebo-controlled, multi-center, dose-ranging study to evaluate the efficacy, safety and tolerability of XXX (2.5mg, 7.5mg, 15mg, 30mg and 45mg) administered orally, once daily, as mono-therapy in subjects with Type 2 Diabetes Mellitus who are drug naïve, treated with diet & exercise, or prior oral anti-diabetic mono-therapy, followed by a twelve week active treatment extension.

A Phase 2A, randomized, double-blind, placebo and positive-controlled trial to determine the effect of XXX on food intake and eight week safety.

A Phase 1, clinical trial to evaluate the safety and immunogenicity of an XXX immunotherapeutic vaccine in healthy adult subjects.

A Phase 1, randomized, open-label, two-period, two-sequence, drug-drug interaction study comparing steady state plasma XXX pharmacokinetics following co-administration of XXX 700mg + XXX 100mg twice daily (BID) and XXX 150mg every other day (QOD) and following administration of XXX 300mg once daily (QD) in healthy adult subjects.

A Phase 1, single-blind, controlled, randomized study of the safety, tolerability and immunogenicity of XXX XXX B XXX XXX +/-XXX when administered at a 0, 2, 6 or a 0, 1, 2, 6-month dose schedule in healthy adults.

A single-blind, placebo-controlled, randomized, three-way, single-dose cross-over study to evaluate the effect of food on the bioavailability of XXX healthy adult subjects.

An open-label, single-dose, three-session, partially-randomized cross-over study to assess morning and evening dosing of XXX MR capsules in healthy adult subjects.

A Phase 1, randomized cross-over, fed/fasted single-dose study of the safety, tolerability and pharmacokinetics of two oral sustained release formulations of XXX in healthy adult subjects.

A two-part, randomized, open-label, single-dose, period-balanced cross-over study conducted in healthy subjects to assess the pharmacokinetics of modified release tablet formulations of XXX.

A randomized, open-label, single oral dose, five-period cross-over study to estimate the relative bioavailability and dose proportionality of XXX modified release tablet versus the ZZZ formulation tablet followed by a repeat oral dosing session to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX modified release tablet in healthy subjects.

A single-blind, randomized (with respect to placebo), placebo-controlled, three-period cross-over, dose-rising study to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses of XXX, A Calcium Sensing Receptor Antagonist, in healthy adult male subjects.

A single-blind, randomized, placebo-controlled, dose-escalation, three-period cross-over study to assess the safety, tolerability and pharmacokinetics of single oral doses of XXX in healthy adult subjects.

A Phase 1, open-label, single-dose, pharmacokinetic trial of three different dose levels of XXX tablets in healthy males.

A Phase 1, open-label, parallel-group study to assess the effect of moderate hepatic impairment (Child-Pugh B Classification) on the pharmacokinetics and safety of XXX (XXX) in cigarette smokers and non-smokers following administration of 40mg XXX once daily for fourteen days.

An open-label, non-randomized, two-period, sequential, drug-interaction study to evaluate the potential pharmacokinetic interaction between multiple doses of XXX and a single dose of XXX administered intravenously as a 30-minute infusion to healthy subjects.

An open-label, randomized, incomplete block, three-period cross-over study to estimate the effect of formulation on the relative bioavailability of single dose oral 100mg XXX in healthy adult subjects.

A six-month, randomized, double-blind, placebo and positive-controlled Phase 2B study to evaluate the effect of various doses of XXX on weight loss in obese subjects.

A non-randomized, open-label, two-session study to evaluate the effects of steady-state XXX on the pharmacokinetics and pharmacodynamics of warfarin and to determine the effects of steady-state warfarin on the pharmacokinetics and pharmacodynamics of XXX in healthy subjects.

A randomized, open-label, single-dose, three-period cross-over study to determine the pharmacokinetics of the potential drug interaction between XXX and ibuprofen.

An open-label study to evaluate the pharmacokinetics of an oral contraceptive containing norethisterone and ethinylestradiol when co-administered with XXX in healthy adult female subjects.

An open-label, sequential study of the effects of rifampin administration on XXX pharmacokinetics and pharmacodynamics.

A randomized, open-label, single-dose, four-treatment, four-period cross-over study in healthy subjects to assess the relative bioavailability of XXX XXX XXX (XXX) 10mg capsules + XXX XXX XXX XXX (XXX) 8mg capsules and XXX 10mg tablets under a variety of tamper conditions compared to XXX 10mg & XXX 8mg and XXX 10mg tablets administered orally intact and 10mg XXX and 8mg XXX oral solutions.

A Phase 1 study to evaluate the safety and pharmacokinetics of XXX following single and multiple doses in healthy adult subjects.

A pilot, bioavailability study comparing the current XXX capsule formulation with new tablet formulations in both fasted and fed states.

A study to evaluate the effect of XXX on the pharmacokinetics of a combined oral contraceptive in healthy female subjects.

An open-label, randomized, three-way crossover study to evaluate the potential for and extent of pharmacokinetic interactions between XXX (the combination of XXX and XXX XXX XXX) and XXX (XXX) when administered alone and together in healthy male volunteers.

A Phase 1, single-center, open-label, randomized, two-period, two-sequence cross-over study to assess the effect of a high-fat meal on the pharmacokinetics and safety of XXX (XXX) in non-smoking, normal, healthy, male volunteers following single-dose administration of 40mg XXX.

A study to evaluate the safety, tolerability and immunogenicity of the Venezuelan Equine Encephalitis (VEE) Attenuated Live-Virus Vaccine XXX in XXX-naïve healthy volunteers after single-dose subcutaneous administration.

An eight-period, replicate design, randomized cross-over study of XXX ER in healthy adult male subjects to evaluate the bioequivalence of 500 and 1000mg tablets.

A Phase 1, randomized, double-blind, placebo-controlled, multiple-ascending dose study to assess the safety/tolerability, bioavailability, pharmacokinetics and pharmacodynamics of XXX administered intravenously as a bolus or subcutaneously in healthy, middle-aged, non-obese, male and female volunteers.

A multi-center, randomized, double-blind, placebo-controlled, two-period cross-over, single-dose finding study to assess the efficacy and safety of controlled release XXX in patients with gastroesophageal reflux disease.

A randomized, double-blind, placebo-controlled, single-dose cross-over study to evaluate the safety, pharmacodynamics and pharmacokinetics of XXX in patients with Type 2 Diabetes Mellitus.

A multi-center, randomized, double-blind, Phase 3 study of the comparative immunogenicity, safety and tolerability of two Japanese Encephalitis Vaccines (XXX-XX and XX-XXX).

A single-blind, randomized (with respect to placebo), placebo-controlled, dose-rising, three-period cross-over study to investigate the safety, tolerability, pharmacokinetics and preliminary

pharmacodynamics of single oral doses of two multi-particulate formulations of XXX (oral XXX) in healthy adult subjects.

A dose-rising oral formulation study to assess the safety, pharmacokinetics and pharmacodynamics of XXX enteric coated (XXX-L) bilayer tablet in healthy adult subjects.

A randomized, double-blind, placebo-controlled, sequential-group, ascending single dose study of the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX administered subcutaneously and intravenously to asthma subjects.

A randomized, placebo-controlled, cross-over study to evaluate the safety, tolerability and pharmacokinetics of single escalating oral doses of XXX in healthy volunteers.

A placebo-controlled, single-dose, multi-dose and combination pilot drug study of intravenous injection(s) of XXX administered to healthy human subjects.

An open-label, randomized cross-over study of the effects of food (Standard FDA high-fat breakfast) on XXX pharmacokinetics in normal subjects following administration of 60mg oral XXX tablets.

A randomized, cross-over, single-dose pharmacokinetic study assessing two oral sustained release formulations of XXX and pharmacokinetics after evening dosing in healthy adult subjects.
A randomized open-label, single-dose, four-period cross-over study to evaluate the relative bioavailability of four formulations of XXX compared to XXX and to compare over-encapsulated XXX to XXX.

A Phase 1, randomized cross-over study to evaluate the bioequivalence of two liquid formulations of XXX in healthy volunteers: Liquid XXX 1000ug/mL and Liquid XXX 500ug/mL.

A pilot study to evaluate the effectiveness of the XXX XXX XXX (XXX) to induce an involuntary cough that confirms urinary leakage in female subjects who give a history of mild stress urinary incontinence.

A double-blind, randomized, placebo-controlled, three-period cross-over study to explore the additive effect of Aspirin to XXX on flushing symptoms in healthy subjects.

An open-label, randomized cross-over study to evaluate the effects of a standard meal and high fat meal on the pharmacokinetics of XXX follow single oral doses or enteric coated tablet formulations and an enteric coated bead formulation in healthy volunteers.

A two-part, open-label, randomized cross-over study to evaluate the bioequivalence of the 70 g XXX final market combination tablet to a 70mg XXX marketed tablet and the relative bioavailability of XXX.

An open-label, randomized, four-period, single-dose cross-over study to evaluate the effect of food on the bioavailability of XXX.

An open-label, randomized, two-period, parallel-group study to evaluate the potential pharmacokinetic interaction of co-administered XXX and XXX in healthy subjects.

An open-label study to evaluate the effects of multiple doses of XXX on the steady-state pharmacokinetics, safety and tolerability of XXX in healthy male and female adult subjects.

A randomized, open-label, single-dose, four-period cross-over study to determine the effects of alcohol on the pharmacokinetics of XXX.

A pilot, sequential, open-label, multiple-dose, relative bioavailability study of XXX following oral administration as a 150mg jet-milled tablet formulation compared to the current 60mg clinical tablet formulation in healthy male and female subjects.

A Phase 1b, comparative, bioavailability study following oral, sublingual and subcutaneous administration of XXX in healthy adult subjects.

A randomized, double-blind, placebo-controlled, ascending multiple-dose study of the safety, pharmacokinetics and antiviral activity of XXX in subjects with chronic Hepatitis C virus infection.

A multiple-center, open-label, randomized, six-sequence, three-way cross-over study to investigate the potential pharmacokinetics interaction between XXX and XXX in Type 2 Diabetic patients.

A pharmacokinetic study of XXX in cerebral spinal fluid among healthy adult males following intravenous administration.

A two-part, randomized, placebo-controlled study to investigate the safety, pharmacokinetics and pharmacodynamics of single oral doses of the XXX receptor agonist, XXX and the effect of XXX on cardiac conductions as compared to placebo and single oral doses of XXX in healthy adult subjects.

A double-blind, placebo-controlled parallel study of the safety and tolerability of XXX in healthy subjects for twelve weeks on an outpatient basis.

A pilot, single-dose, two-period, two-treatment, two-sequence cross-over, bioequivalency study of XXX 8mg tablets under fasting conditions.

A randomized, open-label, period-balanced, cross-over study to assess the pharmacokinetics and pharmacodynamics of modified release tablet formulations of XXX 500mg in healthy subjects.

A single-dose, two-period, replicate design, pilot pharmacokinetic study of XXX 750mg/5mL suspension in healthy subjects.

A randomized, double-blind, placebo-controlled, multiple-ascending dose, intravenous infusion, Phase 1 study to evaluate the safety, tolerability and pharmacokinetics of XXX XX in healthy subjects.

A Phase 1, double-blind, randomized, placebo-controlled, dose escalation study of the safety, tolerability and pharmacokinetics of oral XXX in healthy adult subjects.

A randomized, single-blind, four-period cross-over study examining the single dose pharmacokinetics of XXX, XXX and combination tablet dosing in fasting and fed healthy volunteers.

A multi-center, double-blind, double-dummy, placebo-controlled, parallel-panel study to assess the safety, tolerability and efficacy of XXX in Type 2 Diabetic patients.

An ascending single dose study of the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX administered orally to healthy subjects.

A Phase 1, pilot, dose-ranging, pharmacokinetic study to evaluate the effect of a range of XXX doses on the pharmacokinetics of XXX.

An open-label, two-part study to evaluate a) the relative bioavailability of three formulations of oral XXX b) the relative bioavailability of testosterone administered alone and with approximate steady-state concentrations of XXX in Lupon-induced hypo-gonadal men and c) safety, tolerability and pharmacokinetics of testosterone co-administered with XXX for seven days in Lupron-induced hypo-gonadal men.

A double-blind, Phase 1b, multi-dose tolerability and pharmacokinetic study of XXX.

A Phase 1 study to determine the relative bioavailability of various formulations of XXX boosted with Ritonavir.

An open-label, drug-drug interaction study between XXX and an oral contraceptive containing norgestimate and ethinyl estradiol in healthy women.

A Phase 1, open-label, randomized, pharmacokinetic, drug interaction study of XXX/r and Antacid or XXX.

A Phase 1, randomized, double-blind, placebo-controlled, single-ascending dose and multiple-ascending dose study to assess the safety and tolerability of aerosolized XXX in healthy adult volunteers.

A rising single-dose, safety, tolerability and pharmacokinetic study of XXX in healthy subjects.

A study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of XXX after multiple subcutaneous doses in patients with Type 2 Diabetes Mellitus.

An open-label, fixed-sequence, two-period cross-over, multiple-drug interaction study to evaluate the potential pharmacokinetic interaction of co-administered XXX and XXX, XXX, caffeine and XXX in healthy subjects.

A Phase 1 study to determine the relative bioavailability of a test formulation at two doses of XXX boosted with XXX.

An open-label study to evaluate the impact of XXX fixed dose XXX combinations on the relative bioavailability of the individual dutasteride and testosterone components.

An open-label, randomized, two-period cross-over, drug interaction study to evaluate the potential pharmacokinetic interaction between multiple doses of XXX and a single dose of XXX administered orally to healthy subjects.

A Phase 3b, observer-blind, randomized, multi-center study with two parallel-groups to compare the immunogenicity of XXX biological XXX vaccine versus XXX vaccine when administered intramuscularly according to a three-dose schedule in healthy adult females 18-45 years of age.

A safety assessment following administration of XXX to healthy volunteers.

A dose-optimization study evaluating the safety and immunogenicity of four doses of XXX in normal volunteers.

A randomized, open-label, two-period cross-over study to evaluate the bioequivalence of two formulations of XXX in healthy adult subjects.

A two-part, open-label, pilot study to compare the pharmacokinetics of the XXX, XXX, and XXX with that of XXX and XXX tablets.

A Phase 1, multiple-dose, pharmacokinetic drug interaction study of XXX and dose-reduced XXX.

A Phase 3, multi-center, randomized double-blind, placebo-controlled, parallel-group trial of fourteen day treatment with XXX 15mg or 30mg once a day in frequent nighttime heartburn.

A Phase 1, multiple-dose pharmacokinetic drug interaction study of XXX and XXX.

A two-part, open-label, cross-over study to assess the pharmacokinetics of XXX following single oral doses of various modified release formulations and a solution in healthy adult subjects and to determine the effect of a high fat meal on the PK of a formulation of interest.

A randomized, double-blind, active and placebo-controlled, parallel-group safety study assessing simulated driving performance in XXX treated patients with restless leg syndrome.

A cross-over study to evaluate the effect of XXX on intraocular pressure in healthy volunteers.

A randomized, double-blind, placebo-controlled, parallel-group study to assess two intravenous dosing regimens of XXX in healthy subjects.

A Phase 1, healthy volunteer dose and route finding study for XXX.

A randomized, double-blind, placebo-controlled, dose-escalation study designed to investigate the safety, tolerability, pharmacokinetics and antiviral activity of short-term multiple dosing with a novel anti-Hepatitis C virus drug in subjects with chronic Hepatitis C genotype 1 infection as a combination first-in-man/proof-of-concept trial.

A Phase 1, randomized, double-blind, placebo-controlled, single-ascending dose and multiple-ascending dose study to assess the safety and tolerability of aerosolized XXX in healthy adult male volunteers.

A double-blind, randomized, parallel-group trial to define the electrocardiographic effects of XXX using a therapeutic and a supra-therapeutic dose compared with placebo and XXX (A single- blinded, positive-control) in healthy male subjects: A thorough ECG trial.

A randomized, placebo-controlled, sequential, dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of intravenous XXX in healthy adult male and female volunteers.

A Phase 1, randomized, open-label, parallel-design, inpatient/outpatient study to assess the bioequivalence of a single-dose subcutaneous administration of XXX delivered by the XXX auto-injector or a needle and syringe in healthy subjects.

A randomized, double-blind, placebo and active-controlled, four-period cross-over study to evaluate the effect of XXX on cardiac repolarization by thorough analysis of QTc effect in healthy adult subjects.

An open-label, multi-center, randomized, cross-over study in subjects with relapsing forms of multiple sclerosis comparing the pharmacokinetic properties of the XXX produced by the current commercial process and XXX produced by the high titer process.

A Phase 1, randomized, placebo-controlled, double-blind study of the safety, reactogenicity and immunogenicity of a recombinant XXX Influenza A Vaccine candidate (XXX) in healthy adults.

A Phase 1, healthy volunteer, dose and route finding study for XXX (XXX) blood collection.

A multi-center, randomized, double-blind, active-controlled, parallel-group study to investigate plasma folate, red blood cell folate and XXX levels during a 24-week oral administration of an OC containing folate compared to OC alone.

A bioequivalence study assessing the pharmacokinetics following single-dose administration of XXX manufactured at XXX and XXX manufacturing sites.

A randomized, double-blind, multiple-dose, placebo-controlled investigation of XXX.

A Phase 1, double-blind, randomized, placebo-controlled clinical trial to study the safety, efficacy and mechanism of action of XXX and XXX in patients with Type 2 Diabetes Mellitus who have inadequate glycemic control on diet and exercise.

A single-dose, randomized, open-label, cross-over, pilot pharmacokinetic study of four prototype once-a-day formulations of XXX XX 1000 mg tablets and current twice-a-day formulation of XXX XX 1000 mg tablet in healthy adult male subjects.

A thorough Phase 1 XX/QTc study for XXX.

A randomized, observer-blind, placebo-controlled study to assess the safety and immunogenicity of intramuscular inactivated influenza X/XXX vaccine administered with and without a dose-sparing adjuvant patch in healthy adults.

An open-label, Phase 1 study in healthy adult subjects to examine the drug-drug interaction between XXX and XXX and XXX and XXX.

XXX applied to fingers versus YYY, applied to the chest: A pharmacokinetic comparison in normal subjects.

A Phase 1, randomized, open-label, parallel-design, inpatient/outpatient study to assess the absolute bioavailability of single-dose of XXX in healthy subjects after SC administration.

A randomized, parallel study assessing the safety, tolerability and pharmacokinetics of oral XXX-XXX and warfarin when given alone and with XXX to healthy adult subjects.

A single-dose, two-period, two-treatment, two-way cross-over, bioequivalency study of XXX XXX 2.5mg capsules under fed conditions.

A single-dose, two-period, two-treatment, two-way cross-over, bioequivalency study of XXX XXX 2.5mg capsules under fasted conditions.

A Phase 1, single-center, open-label study to evaluate the effects of multiple-dose, oral administration of 40mg/day XXX on the single-dose pharmacokinetics of XXX 0.4mg in normal healthy male subjects.

A randomized, open-label, period cross-over study in healthy subjects to determine the effect of particle size on the pharmacokinetics of a single 15mg dose of XXX.

A Phase 1, single-dose, open-label study to determine the pharmacokinetics, safety and tolerability of XXX in healthy subjects at the extremes of body weight.

A randomized, open-label, single-dose, cross-over study to demonstrate the bioequivalence of the final fixed dose combination (FDC) formulation to the individual components (XXX XX & XXX) employed in the Phase 3 Factorial study.

A double-blind, randomized, parallel trial to investigate the ECG effects of XX-XXX using a clinical and a supra-therapeutic dose compared to placebo and XXX (A positive control) in healthy men and women: A Thorough ECG Trial.

A multi-center, two-part, randomized, double-blind, placebo-controlled, multiple-dose study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of XX-XXX on postprandial plasma glucose concentrations after daily administration of XX-XX before each meal (q.a.c.) in subjects with Type 2 Diabetes being treated with basal insulin.

A pilot study of the effect of steady state XXX exposures on the QT/QTc interval in healthy subjects.

An open-label, single-dose study of the mass balance and metabolic disposition of orally administered XXX-labeled XXX in healthy male subjects.

A single-center, triple-blind, triple-dummy, randomized, single dose, four-way cross-over trial to define the ECG effects of XXX using a clinical and supra-therapeutic dose compared to placebo and XXX (A positive control) in healthy men and women: A thorough ECG trial.

An open-label, randomized, three-period cross-over study to evaluate XXX and XXX pharmacokinetics for a XXX (XXX XXX/XXX sodium) tablet followed by XXX (XXX XXX) injection 4mg administered using the XXX XXX system and a XXX tablet followed by XXX (XXX XXX) injection 6mg administered using the XXX system compared with an XXX tablet 100mg followed by an XXX tablet 100mg.

A Phase 1, open-label study in healthy subjects to evaluate the cardiovascular safety, general safety, tolerability and pharmacokinetics of single subcutaneous doses of 0.5 and 2.0mg/kg XXX.

A study to evaluate the pharmacokinetics of the XXX-coated XXX free base formulation of XXX and its metabolites in healthy volunteers.

A protocol to collect human complement (either through collection of serum or plasma) from healthy young adults.

A Phase 1, open-label, randomized, cross-over clinical trial in healthy normal volunteers to evaluate the bioequivalence of XXX inhalation powder administered using the XXX inhaler compared to a ZZZ inhaler, and dose equivalence of XXX inhalation of two doses versus one dose using the YYY inhaler.

A multi-center, randomized, double-blind, placebo-controlled, parallel-group, repeated-dose study to evaluate the efficacy, safety, tolerability and pharmacokinetics of three different dosing regimens of inhaled XXX in patients with persistent asthma.

An open-label, randomized, up-titration study to assess the effect of urine sample handling procedures on the safety results of urine obtained from healthy subjects receiving repeat doses of XXX/XXX.

A Proof of Principle study to investigate the pharmacokinetic profiles of sustained release and standard XXX formulations.

An open-label, single-period, Phase 1 study to evaluate the pharmacokinetics, excretion balance and metabolism of [14C]-XXX in healthy adult male subjects.

A Phase 1, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of escalating, multiple, oral doses of XXX in treatment naïve subjects with chronic genotype 1 Hepatitis C virus infection.

An open-label study to characterize the absorption, distribution, metabolism and elimination of a single oral 14C labeled dose of XXX in subjects with BRAF mutant solid tumors.

An open-label, mass-balance study to investigate the absorption, distribution, metabolism and elimination of a single oral dose of XXX inhibitor [14C] XXX in male subjects with solid tumors.

A determination of the absolute bioavailability of XXX following a single oral dose co-administered with an intravenous radiolabelled micro-dose of XXX in subjects with solid tumors.

A determination of the absolute bioavailability of XXX following a single oral dose co-administered with an intravenous radiolabelled micro-tracer of XXX in subjects with BRAF mutant solid tumors.

A double-blind, randomized, placebo-controlled, multiple-dose ranging study evaluating the safety, tolerability, pharmacokinetics and antiviral activity of XXX in treatment naïve subjects with chronic Hepatitis C virus infection.

A single-center, randomized, cross-over pharmacokinetic study to assess the influence of simultaneous XXX and p-glycoprotein inhibition on XXX pharmacokinetics, following single dose oral administration of 5 mg XXX to healthy volunteers.

An open-label, one-sequence, two-period, cross-over study to evaluate the effect of XXX on the pharmacokinetics of five XXX substrates, cocktail (caffeine (1A2), warfarin + Vitamin K (2C9), omeprazole (2C19), dextromethorphan (2D6), midazolam (3A4) in healthy subjects.

A Phase 1, open-label, drug-drug interaction and food effect study of XXX in healthy subjects.
A randomized, double-blind, placebo-controlled, single-ascending dose study to explore the safety, tolerability, pharmacokinetics and pharmacodynamics of parenterally administered XXX in healthy subjects without and with insulin resistance.

An open-label, dose-proportionality, bioavailability and dose-titration investigation of the pharmacokinetics, metabolism, efficacy and safety of two testosterone XXX systems in hypo-gonadal men.

A Phase 1, open-label, fixed-sequence, drug-drug interaction study to evaluate the effects of single doses of XXX XXX and XXX on the pharmacokinetics of XXX in healthy subjects.