16.1.4 Curricula Vitae of Investigator(s)

celerion
Translating Science to Medicine

621 Rose Street
Lincoln, NE 68502

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Allen Hunt, MD

Curriculum Vitae

Education:

1988	Lincoln Medical Education Foundation Lincoln, Nebraska Family Medicine Residency Training
1985	University of Nebraska Medical Center Omaha, Nebraska Medical Doctor, Bachelor of Science in Medicine
1981	University of Nebraska – Lincoln Lincoln, Nebraska Life Sciences Major

Experience:

Sept-2017 – Present	Principal Investigator Celerion Lincoln, Nebraska
Jul-2004 – Jul-2017	Urgent Care Physician The Physician Network Lincoln, Nebraska
May-2011 – Current	Medical Director Southlake Village Rehabilitation & Care Center Lincoln, Nebraska
Jul-1990 – Oct-2001	Family Practice with Obstetrics and Emergency Room Physician, Chief of Staff Cherry County Hospital and Clinic Valentine, Nebraska
Jul-1988 – Jul-2004	Family Practice with Obstetrics and Emergency Room Physician Cherry County Hospital and Clinic Valentine, Nebraska

Signature: (b) (6) Date: 28 Sep 2018

Sep-2018

Continuing Education:

2017 – Present	Documentation of training completed is available for inspection upon request.

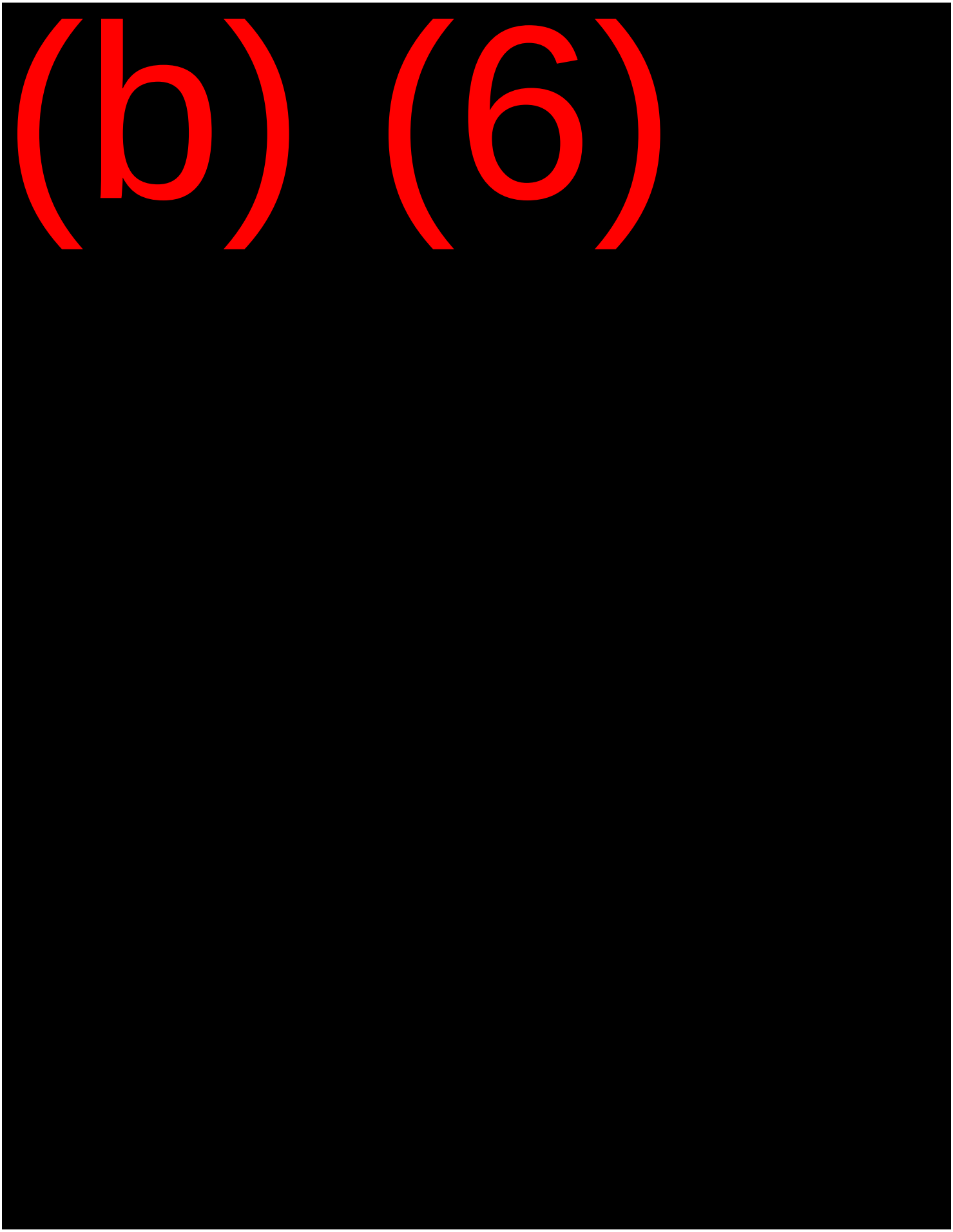
Professional Licenses:

Nebraska Physician License (b) (6)

American Board of Family Medicine Certification— Renewed 2014

Professional Societies and Other Organizations:

AAFP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State of Nebraska
Department of Health and Human Services
Division of Public Health
License #:
Expiration:
Status:

celerion
Translating Science to Medicine

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Tempe, AZ 85283

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Philip Mathew, M.D.

Curriculum Vitae

Education:

1999	University of Medicine & Dentistry of New Jersey New Brunswick, New Jersey Infectious Diseases Fellowship
1997	University of Medicine & Dentistry of New Jersey New Brunswick, New Jersey Internal Medicine Internship and Residency
1991	Christian Medical College / Dr. MGR Medical University Vellore, India MD, General Medicine
1985	Calicut Medical College / Calicut University Calicut, India Bachelor of Medicine and Surgery (MBBS)

Experience:

Dec-2018 – Present	Principal Investigator II Celerion Tempe, Arizona
Dec-2017 – Dec-2018	Principal Investigator II Celerion Lincoln, Nebraska
Dec-2016 – Nov-2017	Physician Comprehensive Health Care Network Toronto, Ontario, Canada
Jul-2016 – Nov-2016	Medical Director and Principal Investigator Inflamax Research Toronto, Ontario, Canada

Signature: (b) (6) Date: 10 DEC 2018

Dec-2018

Experience (Continued):

Dec-2012 – Jul-2016	Medical Director and Principal Investigator Lambda Therapeutic Research Inc. Toronto, Ontario, Canada
Feb-2010 – Nov-2012	Vice President, Medical and Scientific Affairs & Co-Investigator Lambda Therapeutic Research Limited, Ahmedabad, Gujarat, India
May-2008 – Feb-2010	Consultant India Clinical Epidemiology Network Chennai, Tamil Nadu, India
Dec-2007 – Apr-2008	Director Strategic Development PPD India Pvt. Ltd. Mumbai, Maharashtra, India
Oct-2004 – Nov-2007	Associate Medical Director Covance Inc, Princeton, New Jersey, USA
Apr-2002 – Oct-2004	Medical Director & Principal Investigator, MDS Pharma Services /Sankyo Clinical Pharmacology Unit, Neptune, New Jersey, USA
Oct-2000 – Feb-2002	Attending Physician Robert Wood Johnson University Hospital New Brunswick, New Jersey, USA
May-1991 – Apr-1992	Consultant Physician Church of South India Mission Hospital Tirur, Kerala, India

Continuing Education:

2017 – Present	Documentation of training completed is available for inspection upon request
Current	ACLS (Advanced Cardiovascular Life Support) Certification
Current	American Board of Internal Medicine
2017	Certified Principal Investigator (ACRP)

Professional Licenses:

Arizona Medical Board License (b) (6)

Nebraska Physician License (b) (6)

New Jersey Physician License (b) (6)

College of Physicians and Surgeons of Ontario, Canada (b) (6)
Restricted to Internal Medicine as Qualified (Principal) Investigator

Tamil Nadu, India State Medical License (b) (6)

Professional Societies and Other Organizations:

Association of Clinical Research Professionals

American College of Physicians

College of Physicians and Surgeons of Ontario

Publications:

1. Rolston DDK, Mathew P and Mathan VI. Food based solutions are a viable alternative to glucose electrolyte solutions for oral rehydration in acute diarrhea - studies in a rat model of secretory diarrhea. Transactions of the Royal Society of Tropical Medicine and Hygiene (1990) 84:156-159.

2. Mathew P. Study of cardiac function in young diabetics. Dr MGR Medical University, Madras, Tamil Nadu, India, March 1991. (MD Thesis)

3. Mathew P, John L, Jose J and Krishnaswamy S. Assessment of left ventricular diastolic function in young diabetics: a two dimensional echo-Doppler study. Indian Heart Journal (1992) 44(1): 29-32.

4. John JF and Mathew P. More bad news: even orange juice is a risk for salmonellosis! (Commentary). Infectious Disease Alert (1998) 18 (6): 43-44.

5. Alcid DV and Mathew P. Colony Stimulating Factors in the Therapeutic Approach to Sepsis. Current Infectious Disease Reports (1999) 1(3): 218-223.

6. Mathew P, Kuo Y-H, Vazirani B, Eng, RHK, and Weinstein MP. Utility of sputum AFB smear examination for discontinuing tuberculosis isolation. Journal of Clinical Microbiology (2002) 40 (9): 3482-3484.

7. Jones MR, Baker BA, Mathew P. Effect of colesevelam HCl on single-dose fenofibrate pharmacokinetics. Clin Pharmacokinetic. (2004) 43(13):943-50

8. Marier JF, Guilbaud R, Kambhampati SRP, Mathew P, Moberly J, Lee J and Salazar DE. The Effect of AST-120 on the Single-Dose Pharmacokinetics of Losartan and Losartan Acid (E-3174) in Healthy Subjects. J Clin Pharmacol. 2006 Mar;46(3):310-20.

9. Patel S; Chauhan V; Mandal J, Shah S; Patel K, Saptarshi D, Maheshwari K, Jha PK, Kale P, Patel K and Mathew P. Single-dose, Two-way Crossover, Bioequivalence Study of Mycophenolate Mofetil 500 mg Tablet Under Fasting Conditions in Healthy Male Subjects. Clin Ther. 2011 Mar; 33(3):378-90.

Poster Presentations and Abstracts:

1. Rolston DDK, Mathew P and VI Mathan. WHO Oral Rehydration Solution utilization by rural communities in southern India: suggestions for alternative strategies. (Abstract). Gastroenterology (1988) 94(5): 4383.

2. Mathew P, Vazirani B, Kuo YH, Eng RK, Smith SM and Weinstein MP. Discontinuing TB Isolation - Are 3 Negative Sputum Smears Necessary? 39th Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, Sept. 25, 1999.

3. Mathew P, Vazirani B, Kuo YH, Jain M, John JF. Barriers to implementation of the prediction rule for community acquired pneumonia. 37th Infectious Diseases Society of America Annual Meeting. Philadelphia, Nov. 19, 1999 and Clinical Infectious Diseases (1999) 29 (4): 1052 (Abstract)

4. Mathew P, Vazirani B, Kuo YH and John JF. Validation of an expert system for management of HIV occupational postexposure prophylaxis. 7th Conference on Retroviruses and Opportunistic Infections. San Francisco, Feb. 1, 2000.

5. Mathew P, Vazirani B, Magadia R, O'Malley K, Brown I. Efficacy of ritonavir plus indinavir containing HAART regimens in highly protease inhibitor experienced HIV positive indigent patients. 9th International Congress on Infectious Diseases, Buenos Aires, Argentina, April 12, 2000.

6. Vazirani B, Mathew P Kuo YH and John JF. Use Of Rapid HIV Testing In Conjunction With A World Wide Web Enabled Expert System For Managing Occupational Post Exposure Prophylaxis (PEP). 38th Infectious Diseases Society of America Annual Meeting, New Orleans, Sept. 7, 2000.

7. Mathew P, U Chaudhari, Y Gaffar, LT Dooley, YH Kuo, DG Baker and AB Gottlieb. Comparison of the National Psoriasis Foundation Psoriasis Score with Psoriasis Area and Severity Index. 62nd Annual Meeting, Society for Investigative Dermatology May 2001, Washington, DC.

8. Mathew P, Vazirani B, Kuo YH, A Wilson, John JF, RHK Eng. Relationship between Survival and Experience with Antiretroviral Therapy (ART) of a Veterans Administration HIV Cohort in NJ. 39th Infectious Diseases Society of America Annual Meeting, San

Francisco, Oct. 27th 2001 and Clinical Infectious Diseases (2000) 33 (7): 1212 (Abstract)

9. Mathew P, Tracewell W, Cuddy T, Salazar D. The Pharmacokinetic Interaction of Pitavastatin with Fenofibrate or Gemfibrozil in Healthy Volunteers. 105th Annual Meeting, American Society for Clinical Pharmacology and Therapeutics (ASCPT), Mar 2004, Miami, FL.

10. Walker JR, Triscari J, Dmuchowski CF; Mathew P; Izumi T; Samata N; and Salazar, DE. Single and Multiple Dose Pharmacokinetics and Pharmacodynamics of Rivoglitazone (CS-011) in Healthy Male Subjects. 35th Annual Meeting of the American College of Clinical Pharmacology, Sep 2006, Boston, MA

11. MA. Walker JR, Dmuchowski CF, Izumi T; Samata N, Mathew P and Salazar, DE. The Steady-State Pharmacokinetics of Rivoglitazone (Cs-011) Are Not Affected By Coadminstration of the Potent Cyp3A4 Inhibitor Itraconazole. 36th Annual Meeting of the American College of Clinical Pharmacology, Mar 2007, Anaheim, CA

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HIGH POINT CLINICAL TRIALS CENTER
EMPLOYEE CURRICULUM VITAE

Melanie Fein, MD, CPI, DABFM			
Fein	Melanie		
Surname	First Name	Middle Initial	
Study Site Affiliation (PI, Coordinator, etc.):	Medical Director and Principal Investigator		
Medical License Jurisdiction:	North Carolina License - current Florida License - current		
Professional Mailing Address:	High Point Clinical Trials Center 4160 Mendenhall Oaks Parkway, Suite 105 High Point, NC 27265	Study Center Address:	High Point Clinical Trials Center 4160 Mendenhall Oaks Parkway, Suite 105 High Point, NC 27265
Telephone:	(b) (6)	e-mail:	(b) (6)@highpointctc.com
Alternate Telephone:	(b) (6)	Fax:	(b) (6)

Education

Degree / Certification	Institution	Date (Most Recent First)
Physician Investigator Certification	Association of Clinical Research Professionals	2006 - Present
Board Certification	American Board of Family Medicine	Valid until 2023
MD	University of Witwatersrand Medical School Johannesburg, South Africa	1982

Work History

Current and Previous Relevant Positions Including Academic Appointments (most current date first)

Role / Title	Company/Institution	Date (Most Recent First)
Medical Director	High Point Clinical Trials Center High Point, North Carolina	March 2018 - Current
Medical Director/Principal Investigator	Covance Clinical Research Daytona Beach, Florida	July 2015 – December 2017
Research Consultant	Melanie Fein, MD Plantation, Florida	July 2014 – July 2015
Medical Director / Principal Investigator	High Point Clinical Trials Center High Point, North Carolina	October 2010 - July 2014
Medical Director	Comprehensive Phase One Fort Myers, Florida	2008 - 2010

HIGH POINT CLINICAL TRIALS CENTER
EMPLOYEE CURRICULUM VITAE

Work History		
Current and Previous Relevant Positions Including Academic Appointments (most current date first)		
Principal Investigator	Comprehensive Phase One Fort Myers, Florida	2007 - 2010
Sub Investigator	Comprehensive Phase One Miramar, FL	2004 - 2007

Relevant Clinical and/or Research Experience

Expertise includes:

- Participating as an Investigator in the conduct of over 300 early phase trials in multiple therapeutic areas, in healthy and special populations.
- Studies included First In Man, MAD, SAD, DDI, Food Effect, BE, QTC, oral, IV, subcutaneous, inhalational topical patch studies
- Writing of functional SOPS
- Assessment of protocols for feasibility
- Liaison with Pharmaceutical Companies, Medical Writers, Project Managers, Data Managers, IRBs, CRAs
- Creating and review of content of generic and protocol specific documents.
- Implementation and supervision of high quality efficient systems and process improvements for clinical trial
- Design and implementation of training programs for clinical trial departments and Investigators
- Implementation of Quality Control systems
- Business Development
- Organization of community recruitment programs
- Liaison with community physicians and improving community awareness of clinical trials.
- Member of review committees for review of SOPs, Company Policies and Procedures, Root Cause Analysis and CAPA Plans, Streamlining of research procedures
- Created and Organized "Research University" a training program offering staff a didactic overview of clinical trails
- Supervision of summer intern programs

RESEARCH TRIAL EXPERIENCE:

1. Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Safety and Pharmacokinetics of XXX in Subjects with Type 2 Diabetes Mellitis
2. A Randomized, Double-Blind, Placebo-Controlled, Multiple Dose, Parallel Group Study of the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of XXX-XXX Administered for Twenty-One Days in Healthy, Estrogen-Treated, Postmenopausal Women
3. Phase 1, Open, Randomized, 2-way Crossover Pivotal Bioequivalence Study Comparing XXX Tablets Made with Drug Substance Manufactured Using A Wet Granulation Process Compared with a Roller Compaction Process
4. A Phase 1, Open-Label, Randomized, Two-Way Crossover, Single-Dose XXX, Multiple-Dose XXX Study to Estimate the effects of Steady State XXX on the Single-dose Pharmacokinetics of XXX in Healthy Adult
5. A Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy, Safety, and Pharmacokinetics of XXX, a Progesterone Receptor Modulator, in the Inhibition of Ovulation in Healthy Women
6. A Randomized, Open-Labeled Absolute Bioavailability Study of XXX

7. Open Labeled, Randomized, Three-Way Crossover Study to Evaluate the Exposure of XXX From Commercial XXX®
8. A Study of the Effect of Erythromycin on the Pharmacokinetics of XXX and XXX-N-Oxide
9. An Open-Label, Parallel-group Study to Evaluate the Pharmacokinetics After Administration of Multiple 5-mg Doses of XXX to Patients with Type 2 Diabetes and Healthy, Matched Control Subjects
10. A Single-Center, Randomized, Single-Blind, Placebo-Controlled, Dose-Escalation Study to Determine the Safety and Pharmacokinetics of Single Oral Doses of XXX in Healthy Adult Subjects
11. A Double-Blind, Placebo Controlled, Cross Over Study to Assess the Pharmacokinetic/Pharmacodynamic Drug-Drug Interaction with XXX and XXX in Patients with Type 2 Diabetes
12. A Double Blind, Randomized, Placebo Controlled, Sequential Panel, Single Rising Oral Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Postmenopausal Female Subjects and Women of Non – Childbearing Potential
13. A 2 Part Crossover Study to Evaluate the Pharmacokinetics After Administration of Single Doses of The Extended Release and Immediate Release Formulations and the Effect of Food on the Matrix and Multiparticulate Extended –Release Formulations of XXX in Healthy Adult Subjects
14. The Safety, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Normal Renal Function or Mild, Moderate or Severe Renal Impairment.
15. The Comparative Bioequivalence of Reformulated versus Investigational XXX Extended Release/XXX Immediate –Release Combination (NS) Tablets Administered as a Single 2000/40mg Dose To Healthy Volunteers
16. A Single Blind, Randomized, Placebo Controlled, Partially –Balanced, Eight –Treatment, Four Period Crossover Study To Evaluate the Pharmacokinetics After Administration of Single Doses of the Extended-Release and Immediate Release Formulations of XXX in Healthy Adult Subjects
17. A Randomized, Double-Blind, Placebo-Controlled, 2-Panel, Single Intravenous Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Elderly Male and Female Subjects
18. A 2 Part, Double Blind, Randomized, Placebo Controlled, Alternating Panel, Single-Rising Dose Study To Assess The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of a 2 Hour Intravenous Infusion of L-001298185 in Health Adult Male Subjects
19. A Double-Blind, Randomized, Parallel Group Study of Two Long Acting Crystalline Recombinant hGH Formulations XXX and XXX in Normal Healthy Adults To Determine Pharmacokinetics, Pharmocodynamics and Drug Safety
20. A Partially-Blinded, 3-Part Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of XXX Following Administration of a Probe Optimized Liquid Filled Capsule Formulation in Healthy Male Subjects
21. A Double-Blind, Placebo Controlled, Randomized, Single Oral Dose Study to Determine the Safety, Tolerability and Pharmacokinetics/Pharmacodynamics of XXX in Healthy Elderly Subjects
22. A Double-Blind, Randomized, Placebo-Controlled, Sequential-Panel, Single-Rising-Dose and 2-Period Crossover Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Patients with Type 2 Diabetes
23. A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Study to Access the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Efficacy of XXX in Healthy Postmenopausal Women
24. A Randomized, Placebo-Controlled, Double-Blind, Double-Dummy, Four-Period Crossover Study to Assess the Effects of Concomitant Administration of Single Oral Doses of XXX and XXX Alone and in Combination on XXX Concentrations in Healthy Adult Subjects
25. A Single-Blind, Randomized, Three-Period Crossover Study of the Bioequivalence of Three Different Formulations of XXX in Overweight and Obese Subjects
26. A Double-Blind, Randomized, Parallel Group Study of XXX Formulations (XXX) in Normal Healthy Adults to Determine Pharmacokinetics, Pharmacodynamics, and Drug Safety
27. A Phase I, Open Label, Non-randomized Two Component Pharmacokinetic and Safety Study of XXXs, *XXX* (XXX) In Healthy Volunteers: (A) Single Dose and (B) Multiple Dose
28. A Phase I, Open Label Food Effect and Safety Study of XXX (XXX) In Healthy Volunteers
29. A Single-Blinded, Randomized, Placebo-Controlled, Sequential-Parallel, Escalating Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Subcutaneous Injections of XXX in Healthy Volunteers

30. A Single-Blinded Randomized, Placebo-Controlled, Staggered-Parallel, Escalating-Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of subcutaneous injections of XXX in Subjects with Type 2 Diabetes Mellitus
31. A Randomized, Double-Blind, Parallel Group, Multi-Center, Vehicle-Controlled, Multiple-Dose, Combined Phase 1Phase2 Trial of XXX Applied Topically to Scalp of Subjects With Oily Skin
32. A Phase 1, Open Label Study of the Pharmacokinetics of Multiple Doses of XXX and Single Doses of Oral XXX in Rheumatoid Arthritis Subjects
33. A Randomized, Double Blind, Placebo-Controlled, Multiple-Dose, Parallel-Group Study of the Safety Tolerability, Pharmacokinetics, and Pharmacodynamics Effects of XXX Administered Daily for Twenty-Eight Days in Healthy Postmenopausal Women with Moderate to Severe Hot Flushes
34. A Double-Blind, 2-Part, Randomized, Placebo-Controlled, 2-Period, Crossover Study to Assess the Effect of XXX on the Pharmacokinetics of XXX after Concomitant Administration for 10 days in Healthy Adult Subjects
35. A Double Blind, Placebo Controlled, Randomized, Single Oral Rising Dose Study To Determine The safety, Tolerability and Pharmacokinetics of XXX in Healthy Elderly Men and Women
36. A Phase 1, Open Label, Multiple Dose Study To Evaluate The Pharmacokinetics, Lipid Effects, Safety and Tolerability of The Fixed Combination of XXX/XXX Administered To Subjects With Mild and Moderate Renal Impairment and Normal Renal Function
37. A Randomized, Open Label, Three Period, Cross-Over Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Two New XXX 100mg and 150mg Modified Release Formulations In Patients With Type 2 Diabetes
38. Open-label, Randomized, single-dose, four-way crossover study to evaluate the oral bioavailability of four controlled release (XX) tablet formulations of XX mg (XX) XXX relative to The immediate release (XX) formulation in healthy adult smokers
39. A Single-Blind, Randomized, Placebo-Controlled, 2-Period Crossover Pilot Study to Evaluate the Variability of Baseline QTc Interval With and Without XXX in Healthy Subjects
40. A Double-Blind, Randomized, Placebo-Controlled, Double-Dummy, 4-Period, Single-Dose Crossover Study to Assess the Effect of XXX on QTc Interval in Healthy Volunteers
41. A Pilot Study to Investigate Biomarkers of Skin XXX following Short-Term XXX Administration in Healthy Postmenopausal Women
42. An Open Label, 4-Period, Crossover Study To Investigate The Pharmacokinetics of a Single Oral Dose of XXX Pediatric and Adult Formulations In Healthy Adults
43. An Open Label, 4-Period, Crossover Study To Investigate The Pharmacokinetics of a Single Oral Dose of XXX Pediatric and Adult Formulations In Healthy Adults
44. A Double-Blind, Placebo-Controlled Study to Investigate the Effect of XXX on Oral XXX Pharmacokinetics in Rheumatoid Arthritis Patients.
45. A Randomized, Double-Blind, Placebo-Controlled, 2-Period Study to Evaluate the Influence of XXX on a Single Dose of XXX in Healthy Male Subjects
46. A Bioequivalence and Relative Bioavailability Study In Healthy Volunteers of Lovastatin and Niacin in XXX Tablet Formulations
47. A study of the Effects of XXX and XXX on the 24-Hour serum and Urine Potassium Level Profiles in Patients with Mild to Moderate Renal Insufficiency and Hypertension
48. An Exploratory Open-Label, Two-Way Crossover Study to Evaluate The Effect of A Single Oral Dose Of XXX on The Pharmacokinetics, Safety Tolerability and Pharmacodynamics of A Single Oral Dose of XXX In Healthy Male Subjects
49. An Open-Label, 2-Part Pilot Study to Compare the Pharmacokinetics of the XXX and XX Components of a Probe Formulation of XXX With That of XXX and XXX Tablets
50. A Comparative Bioequivalence of Coated versus Uncoated, Reformulated, XXX mg XX Extended-Release Tablets Administered as a Single XXX mg Dose to Healthy Volunteers
51. A Double-Blind, Placebo-Controlled, Once-Weekly, Multiple-Dose Study to Investigate the Safety, Tolerability, Plasma Concentration Profile and Effects on Biochemical Markers of Bone Reabsorption of XXX in Healthy Postmenopausal Female Subjects

52. An Open-Label, Single Dose, Randomized Study in Healthy Male Subjects to Explore the Relative Oral Bioavailability of XXX Administered as a Tablet Under Fed and Fasting Conditions Versus Oral Solution Taken in Fed and Fasting Conditions
53. A Single-Dose Bioequivalence and Food Effect Study of the Reformulated and Commercial Extended Release Capsules of XXX
54. A Double-Blind, Randomized, Placebo-Controlled, 2-Part Study to Assess the Safety, Tolerability, and Pharmacokinetics of Single and Multiple Doses of XXX Administered With a Meal in Young Healthy Male Subjects
55. An Open-Label, Randomized, Balanced, Crossover Pilot Study to Assess the Effect of Storage Conditions on the Pharmacokinetics of a Probe Formulation of Extended Release XXX and to Compare with the Pharmacokinetics of XXX
56. A Study of the Effects of XXX Alone and in Combination with XXX or XXX on the 24-Hour Serum and Urine Potassium Level Profiles in Patients with Mild to Moderate Renal Insufficiency and Mild to Moderate Hypertension
57. Evaluation of the Urinary Calcium, Bone Biomarkers, Cardiovascular Safety, and Pharmacokinetics Between Morning and Evening Administration of XXX For Two Weeks in Postmenopausal Women
58. A Single-Blind, Randomized, Balanced, Crossover Pilot Study to Compare the Pharmacokinetics of 3 Probe Formulations of Extended Release XXX With XXX and XXX
59. An Open Label, Randomized, Multiple Dose, 3-Way Crossover Study of XXX Inhalation Solution and XXX (XXX) in Subjects with Mild to Moderate Chronic Obstructive Pulmonary Disease (COPD)
60. A Randomized, Open-Label, Three period, Cross-over Study to Evaluate the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of two new XXX XX mg and XX mg Modified Release Formulations in Patients with Type 2 Diabetes
61. An Open-Label, Randomized, Two-Part, Two-Period Crossover Study to Demonstrate the Definitive Bioequivalence After Administration of the Final Market Image (FMI) of XXX/XXX XX/XX mg and XX/XXX mg Fixed-Dose Combination (FDC) Tablet and Concomitant Administration of XX-mg Doses of XXX and XX- or XX-mg Doses of XXX as Individual XXX Healthy Adult Subjects
62. A Multi Center, Randomized, Double-Blind, Parallel-Design Study to Evaluate the XXX Efficacy of 2 Formulations of XXX Compared to XXX
63. A Double-Blind, Placebo-Controlled, Randomized, Multiple-Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of XXX in Diabetic Subjects
64. An Open-Label, Randomized, Balanced, 2-Period, Crossover, Multiple-Dose, Study to Compare the Steady-State Exposure of XXX Following the Administration of XXX Tablets to that Following XXX (XXX®) Tablets in Healthy Middle-Age and Elderly Subjects
65. An Open-Label, 2-Period, Crossover, Single-Dose Study to Evaluate the Effects of XXX® on the Pharmacokinetics of XXX in Healthy Subjects
66. A Single-Blind, Randomized, Balanced, Crossover Pilot Study to Compare the Pharmacokinetics of Two Probe Formulations of Extended Release XXX with XXX®
67. A Single-Blind, 2-Period Crossover, Study to Evaluate the Pharmacokinetic Interaction of Multiple Doses of XXX and XXX® in Healthy Subjects
68. A Double Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of a Single Oral Dose of XXX in Healthy Elderly Male, Elderly Female and Young Female Volunteers
69. A Randomized, Double-Blind, Placebo-Controlled, 2-Period Study to Evaluate the Influence of XXX on a Single Dose of XXX in Healthy Male Subjects
70. A Randomized, Double-Blind, Placebo-Controlled, Single Oral Dose Study to Assess the Pharmacokinetics of XXX in Healthy Middle-Aged and Elderly Females
71. An Ascending Multiple-Dose Study of the Safety, Pharmacokinetics, and Pharmacodynamics of XXX Administered Orally to Healthy, Cycling Women
72. A Multiple Escalating, Oral Dose Study to Investigate the Safety. Tolerance, Pharmacokinetics, and Pharmacodynamics of XXX Capsules in Healthy Volunteers
73. A Study of the Effect of XXX Administration on the Single-Dose Pharmacokinetics of XXX and XXXX-N-Oxide
74. A Pilot, Open-Label, Randomized, 4-Period, 4-Treatment, Relative Bioavailability Trial of XXX Chewable Formulations in Healthy Volunteers

75. An Oral, Rising Multiple-Dose Tolerance Study of XXX Capsules in Healthy Volunteers
76. A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Safety and Pharmacokinetics of XXX in Subjects with Type 2 Diabetes Mellitus
77. A Double-Blind, 2-Part, Randomized, Placebo-Controlled, 2-Period, Crossover Study to Assess the Effect of XXX on the Pharmacokinetics of XXX after Concomitant Administration for X days in Healthy Adult Subjects
78. A Randomized, Double-blind, Placebo-controlled, Rising Single and Multiple Dose Study to Investigate Safety, Tolerability and Pharmacokinetics of XXX in Healthy Adult Volunteers
79. A Single-Dose Bioequivalence and Food Effect Study of the Reformulated and Commercial Extended Release Capsules of XXX and XXX
80. An Open-Label, 6-Way Cross-Over, XXX Concentration Evaluation Study in Healthy Volunteers
81. Phase I, Open Label, Drug-Drug Interaction Study in Healthy Subjects to Investigate the Effect of XXX on the Plasma Pharmacokinetics of XXX
82. A Phase I, Open Label, Single Arm,, Drug-Drug Interaction Study in Healthy Subjects to Investigate the Effects of XXX/XXX and XXX/XXX/XXX Combination on the Plasma Pharmacokinetics of XXX
83. A Pharmacokinetic Comparison of Single Doses of 3 mg and 5 mg XXX (XXX) and 10 mg XXX in Normal Healthy Volunteers
84. A Randomized, Double- Blind, Placebo –Controlled, 4-Period Study Crossover To Compare the Flushing Symptoms Associated with XXX With Two Extended Release XXX Formulations and XXX in Healthy Subjects
85. A Randomized, Double-Blind, Placebo-Controlled, Multiple Oral Dose Study To Assess the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Middle-Aged and Elderly Females
86. A Double- Blind, Randomized, Placebo-Controlled, Rising Single Oral Dose Study To Evaluate The Safety, Tolerability, and Pharmacokinetics of XXX Capsules in Healthy Male Subjects
87. An Open Label, Three Way Crossover Drug Interaction Study to Determine the Effect of Naproxen and Acetylsalicyclic Acid on the Pharmacokinetics of an Immediate –Release Capsule of XXX in Healthy Subjects
88. A Phase1, Open Label Trial in 16 Healthy Subjects To Investigate The Effect Of Single Dose and Steady State XXX On The Pharmacokinetics of XXX
89. An Open Label, Two Way Crossover, Drug Interaction Study To Determine the Effect of Probenecid on The Pharmacokinetics of an Immediate Release Capsule of XXX in Healthy Subjects
90. A Randomized, Open Label, Placebo- Controlled, Repeat Dose Study To Assess the Pharmacokinetics and Pharmacodynamics of 5micrograms XXX Administered Subcutaneously Twice Daily For 7 Days in Healthy Normal Volunteers and In Subjects With Type Two Diabetes Mellitus
91. A Two-Panel, Two Period, Double Blind Study of the Safety, Tolerability and Pharmacokinetics of XXX Following Oral Administration in Patients During and Between Acute Migraine Attacks
92. A Randomized, Placebo-Controlled, 3 Period Study to Evaluate the Effects of Ketoconazole and Food on the Single-Dose Pharmacokinetics of XXX in Healthy Young Subjects
93. A Double –Blind, Placebo-Controlled, Sequential- Panel, Rising Multiple Oral Dose Study to Investigate the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Elderly Male and Female Subjects
94. A Double-Blind, Randomized, Placebo-Controlled Study To Evaluate the Safety, Tolerability and Pharmacokinetics of A Single Oral Dose of XXX in Healthy Elderly Male and Female Volunteers
95. A Double-Blind, Placebo Controlled, Multiple-Dose Study to Investigate the Safety, Tolerability and Plasma Concentration Profile of XXX in Healthy Elderly Male and Female Volunteers
96. A Randomized 2 Part Study To Assess Safety and Tolerability of Supratherapeutic Doses Of XXX To Assess The Effect of XXX on QTc Interval In Healthy Males
97. A Double-Blind, Randomized, Placebo Controlled, Double Dummy, 4 Arm, Single Dose Parallel Study To Assess the Effect of XXX on QTc Interval in Healthy Volunteers
98. A Double Blind Randomized, 6 Period Crossover, Pilot Study to Compare the Effects of Dosing Time, Food and Aspirin on the Flushing Symptoms Associated With 2000mg XXX in Healthy Subjects
99. A Double-Blind, Placebo –Controlled, Randomized, Parallel-Group Study to Compare the Effects of XXX on the Flushing Symptoms Associated with 1g XXX in Healthy Subjects

100. An Open Label, Randomized, Balanced, Crossover Pilot Study to Compare the Pharmacokinetics of a Probe Formulation of Extended Release XXX and XXX
101. A Double-Blind, Placebo-Controlled, Randomized, Parallel Group Study to Compare the Effects of XXX on the Flushing Symptoms Associated With 1 g NIASPAN in Healthy Subjects
102. A 2-Period, Open Label Study To Assess The Effects of Caloric Restriction on Protein Catabolism in Postmenopausal Women and Older Men
103. A Randomized, Placebo-Controlled, Double Blind, Double Dummy, Four Period Crossover Study To Assess the Effects of Concomitant Administration of XXX and XXX Alone and in Combination on Post Meal Incretin Hormone Concentrations in Healthy Adult Subjects
104. An Open Label, Randomized, Two Part, Two Period Crossover Study To Demonstrate The Definitive Bioequivalence After Administration of The Final Market Image of XXX 50/500mg and 50/100mg Fixed –Dose Combination Tablet and Concomitant Administration of 50mg Doses of XXX and 500 or 1000 mg Doses of XXX as Individual Tablets To Healthy Adult Subjects
105. A Double Blind, Placebo Controlled, Sequential-Panel, Rising-Multiple-Oral-Dose Study To Investigate the Safety, Tolerability, and Pharmacokinetics of XXX in Healthy Elderly Male and Female Subjects
106. A Randomized, Open Label, Placebo- Controlled, Repeat Dose Study To Assess the Pharmacokinetics and Pharmacodynamics of 5micrograms XXX Administered Subcutaneously Twice Daily For 7 Days in Healthy Normal Volunteers and In Subjects With Type Two Diabetes Mellitus
107. An Open Label, Single-Dose, 2-Period, Crossover Study to Evaluate The Comparative Bioavailability of XXX Tablets and Liquid Filled Capsules In Young Healthy Male Volunteers
108. A Phase 1, Open Label, Non Randomized Two Component Pharmacokinetic and Safety Study of FTS in Healthy Volunteers: Single Dose and B Multiple Dose
109. A Randomized, Single-Blind, Placebo-controlled, Dose-Rising Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Pharmacodynamics of Single and Repeat Oral Doses of XXX in Healthy Postmenopausal Women.
110. A Randomized, Double Blind, Placebo Controlled, Two Way Crossover Study of XXX Transdermal System (TDS) In Healthy Elderly Volunteers
111. The comparative Bioavailability of a XXX and XXX Combination versus XXX and XXX.
112. A Phase 1, Randomized, Double Blind, Placebo Controlled, Ascending-Dose Study Evaluating the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX Administered Once Daily With and Without Calcium and Vit D Supplementation for Two Weeks in Healthy Postmenopausal Female Subjects
113. A Phase 1, Randomized, Placebo Controlled, Sequential Parallel Group, Multiple Dose Escalation Trial To Evaluate the Safety, Tolerability, Pharmacokinetics And Pharmacodynamics of 28 Days of Administration of XXX Tablets To Subjects With Type 2 Diabetes Mellitus
114. An Open Label Randomized, 2 Period Crossover Study To Evaluate the Effect of Multiple Doses of XXX on the Single Dose Pharmacokinetics of XXX in Healthy Adult Subjects
115. A Randomized, Double Blind, Double Dummy, Placebo Controlled, 2 Period Crossover Study In Healthy Subjects To Evaluate the Relative Flushing Response Induced by 500 and 1000 mg Doses of XXX
116. A Double-Blind, Randomized, Placebo-Controlled, Single Rising Dose, Sequential Panel and Double Dummy, Two Period Crossover Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Patients With Type Two Diabetes.
117. A Single Blinded, Randomized, Placebo Controlled, Staggered-Parallel Escalating Dose Study To Investigate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Subcutaneous Injections of XXX in Subjects With Type 2 Diabetes Mellitus
118. A Single Blind, Placebo Controlled, Partially Balanced, Eight Treatment, Four Period Crossover Study to Evaluate the Pharmacokinetics After Administration of Single Doses of The Extended Release and Immediate Release Formulations of XXX in Healthy Adult Subjects
119. A Phase One, Single Dose, Partially Blinded, Active Controlled, Crossover Study of The Pharmacokinetics and Tolerability of 2 Doses (200 and 300ug) Of XXX Nasal Spray Compared With XXX In Healthy Human Subjects

120. A Phase 1, Double – Blind, Placebo Controlled, Two Way Crossover Study To Assess The Effect of Multiple Oral Doses of XXX on the Pharmacokinetics of XXX Following a Single Intravenous Dose of XXX
121. An Open Label, Three Way Crossover, Drug Interaction Study To Determine The Effect of XXX and XXX on The Pharmacokinetics of An Immediate Release Capsule of XXX In Healthy Subjects.
122. A Randomized, Multi Center, Double-Blind, Placebo Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in patients with Primary Hypercholesterolemia or Mixed Hyperlipidemia
123. A Double-Blind, Randomized, Placebo-Controlled, Single Rising Dose, Sequential Panel, Two Period Crossover Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Patients With Type Two Diabetes
124. A Double Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of a Single Oral Dose of XXX in Healthy Elderly Male, Elderly Female and Young Female Volunteers.
125. A Partially-Blinded, 4-Part Study to Assess the Safety, Pharmacokinetics, and Pharmacodynamics of XXX Following Administration of a Probe Optimized Liquid Filled Capsule Formulation in Healthy Male Subjects
126. Multi-Center, Double –Blind, Double Dummy, Placebo-Controlled, Parallel Panel Study To Assess the Safety, Tolerability and Glucose Lowering Efficacy of XXX in Patients With Type 2 Diabetes Mellitus
127. A Randomized, Placebo Controlled, 2 Period, Crossover Study To Evaluate The Effect of XXX on Oral Contraceptive Pharmacokinetics in Healthy Female Subjects
128. A Partially –Blinded, Partially-Crossover, Randomized, 5 Part Study To Assess The Safety, Tolerability and Pharmacokinetics of XXX Following Administration of Probe Formulations In Healthy Subjects.
129. A Phase 1, Open Label, Single Dose, Randomized, Three –Way Crossover Study To Evaluate The Relative Bioavailability Of Combination Formulation Versus Co- Administration of XXX and XXX In Healthy Subjects
130. A Clinical Evaluation for the XXX Needle-Free Injection Device When Giving ID, SC and IM Injections
131. A randomized, Placebo Controlled, 2Period, Crossover Study to Evaluate the Effect of XXX on Oral Contraceptive Pharmacokinetics in Healthy Female Subjects
132. A Double Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Two Single Doses of XXX in Healthy Young Male, Elderly Male and Elderly Female Subjects
133. A Multi- Center, Double Blind, Double Dummy, Placebo Controlled, Parallel Panel Study to Assess the Safety, Tolerability and Glucose Lowering Efficacy of XXX in Patients with Type 2 Diabetes XXX
134. An Open Label, Single Dose Study to Investigate the Pharmacokinetics, Safety and Tolerability of XXX in Patients With Moderate Hepatic Insufficiency.
135. A Phase 1 Randomized Single Dose Five Period Crossover Study To Evaluate the Intra Subject Variability of a XXX Extended Release (ER) Tablet Formulation Under Fasted Conditions and The Effect of Food on XXX Extended Release (ER) and Immediate Release (IR) XXX Tablet Formulations Administered Orally To Healthy Male Subjects Under Fed and Fasted Conditions
136. A Study To Evaluate the Single Dose Pharmacokinetics of XXX in Black, Hispanic and Caucasian Healthy Subjects
137. A Study Of The Safety of XXX in Elderly Subjects.
138. An Ascending Single Dose, Randomized Study of The Safety, Tolerability and Pharmacokinetic Profile of XXX In Healthy Subjects.
139. A Randomized, Double Blind, Placebo Controlled, Escalating, Multiple Dose Study To Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX when Administered as a 30 minute IV Infusion To Healthy Volunteers.
140. A Partially Blinded, Partially Crossover, Randomized 5-Part Study to Assess The Safety, Tolerability and Pharmacokinetics of XXX Following Administration of Probe Formulations In Healthy Subjects
141. A Randomized, Double Blind, Placebo Controlled, Single Dose, Dose Escalation Study Of The Safety and Pharmacokinetics Of An Oral Formulation of XXX in Healthy Adult Subjects.
142. A Double Blind, Randomized, Placebo-Controlled, Multiple Dose Study To Assess Safety, Tolerability and Multiple-Dose Pharmacokinetics of a Supratherapeutic Dosing Regimen of XXX in Healthy Male and Female Volunteers.
143. Effects of XXX On Adrenal Function, Luteinizing Hormone and Testosterone Levels In Healthy Male Volunteers.
144. An Open Label Non Randomized, Pharmacokinetic and Safety Study of Multiple Oral Doses of XXX in Subjects with Renal Impairment.

145. A Phase 1, Randomized, Single Dose, Four Period, Crossover Study In Healthy Male Subjects To Evaluate The Intra Subject Variability and the Effect of Food on an Oral XXX Extended Release Tablet Formulation and The Relative Bioavailability of An Oral XXX ER Tablet Formulation Versus and Oral Immediate Release (IR) XXX Tablet Formulation.
146. A Phase 1, Randomized, Single Dose, Five Period, Crossover Study In Healthy Subjects To Evaluate the Intra- Subject Variability of a XXX Extended Release (ER) Tablet Formulation Under Fasted Conditions and the Effect of Food on A XXX (ER) Tablet Formulation and an Aqueous Solution of XXX Administered Orally Under Fed and Fasted Conditions.
147. A Randomized, Double Blind, Placebo Controlled Multiple Dose, Phase 1/11 Study To Evaluate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Effect of 5 Weekly Administrations of XXX As An Adjunct Therapy To XXX In Patients With Type Two Diabetes
148. A Randomized, Double Blind, Placebo Controlled, Sequential Cohort Study To Assess Safety, Tolerance, Pharmacokinetics and Pharmacodynamics of Repeat Doses of XXX In Healthy Volunteers and Patients With Type 2 Diabetes
149. A Double- Blind Placebo Controlled, Multiple Oral Dose Study To Investigate The Safety, Tolerability and Pharmacokinetics of XXX In Healthy Elderly Male and Female Subjects.
150. A Partially- Blinded, Partially Crossover, Randomized, 7 Part Study to Assess Safety, Tolerability and Pharmacokinetics of XXX Following Administration of Probe Formulations in Healthy Subjects
151. A Randomized, Placebo Controlled, 2 Period Crossover Study To Evaluate The Effect of XXX on Oral Contraceptive Pharmacokinetics in Healthy Female Subjects.
152. 153. A Randomized, Double Blind, 2 Period, Crossover Study to Evaluate Effects of XXX and XXX on Prostoglandin Metabolism in Healthy Subjects.
153. An Open Label, Randomized, 2-Period, Crossover Study to Establish the Definitive Bioequivalence of XXX and XXX of 2 Sources of XXX Tablets.
154. A Randomized, Double-Blind, Placebo Controlled, Single Oral Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Elderly Subjects.
155. A Randomized, Double-Blind, Placebo Controlled, Double Dummy, Multiple –Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Endpoints of XXX in Healthy Older Men.
156. A Double Blind, Placebo Controlled, Positive- Controlled, Randomized, Crossover Study To Assess The Effect of XXX at a Projected Therapeutic Dose and a Supra- Therapeutic Dose Level on QT/QTc Interval After a Single Dose In Healthy Volunteers.
157. A Double Blind, Randomized, Placebo Controlled, Single Rising Oral Dose Study To Assess the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Postmenopausal Female Subjects and Women Of Non-Childbearing Potential.
158. An Open Label, Randomized, 3 Period Crossover Study To Evaluate the Comparative Bioavailability of 3 Formulations of XXX Administered Orally as Single Doses in Healthy Subjects.
159. A Double Blind, Placebo – Controlled, Multiple Oral Dose Study to Investigate the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Elderly Male Subjects
160. The Pharmacokinetics and Safety of a Single Dose of XXX With and Without Food in Healthy Volunteers.
161. 162. An Open Label, Randomized, Multi Site Study To Assess the Pharmacokinetics of Single Subcutaneous Injections of 16mg and 64mg of XXX Administered at Three Different Injection Sites In Adult Male and Female Subjects With Type 2 Diabetes and of Single Subcutaneous Injections of 16mg and 64mg of XXX Administered in the Abdomen of Healthy Normal Volunteers
162. A Double Blind, Randomized, Placebo –Controlled, Sequential Panel, Single – Rising Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Healthy Young Adult Male Subjects.
163. An Open Label, Single Dose, Randomized, Crossover, 2 part Study To Assess the Pharmacokinetics of XXX Following Administration of Hot Melt Extruded Tablet and Liquid Filled Capsule Formulations in Healthy Subjects
164. A 2 part, Open Label, Pilot Study to Compare the Pharmacokinetics of the XXX, XXX Acid and XXX Components of 2 Probe Formulations of XXX With That of XXX and XXX Tablets
165. A Phase 1, Randomized, Single Blind, Placebo Controlled, Multiple Ascending Dose Tolerance Trial of XXX ER Tablets in Healthy Adult Subjects In The Fasted State
166. A Randomized, Double Blind, Placebo Controlled Study Of The Safety And Tolerability of XXX following Multiple Dose Administration of XXX Modified Release Capsules In Healthy Older Volunteers.

167. Study of The Effect of Concomitant Administration of XXX on the PK of XXX In Healthy Subjects
168. Pharmacokinetic Evaluation of Various Controlled Release XXX Formulations Relative to Immediate Release Formulation. (A Single Center, Open Label, Single Dose, Randomized, Four Treatment, Four Period, 4 Sequence Crossover Study In Healthy Male Subjects)
169. A Randomized, Double Blind, Placebo- Controlled, Sequential Multiple Ascending Dose Study of the Safety and Pharmacokinetics of XXX Acetate in Healthy Adult Volunteers.
170. A Double- Blind, Randomized, Placebo Controlled Multiple Dose Crossover Study to Evaluate the Safety and Efficacy of XXX In Healthy Male Volunteers.
171. A Randomized, Double Blind, Placebo Controlled Multiple Dose, Phase 1/11 Study To Evaluate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Effect of 5 Weekly Administrations (Q1W) Of XXX As An Adjunct Therapy To XXX In Patients With Type 2 Diabetes XXX
172. Re-Dosing Study From A 2 Way Crossover, Bioequivalence Study Of XXX 120mg Tablet and XXX Administered As 1x 120mg Tablet In Healthy Subjects Under Fasting Conditions.
173. A Randomized, Double Blind, Placebo Controlled, 2 Period Crossover Study to Evaluate the Effect of Single Dose Administration of XXX 40mg on Oral Contraceptive Pharmacokinetics in Healthy Female Subjects
174. A Double Blind, Randomized, Placebo Controlled, Single Dose Study To Evaluate the Safety, Tolerability and Pharmacokinetics of XXX in Healthy Elderly Male and Elderly Female Volunteers.
175. A Placebo-Controlled, Randomized, Double-Blind, Phase I Study to Investigate the Safety, Tolerability and Pharmacokinetics of Single Oral Doses of XXX in Healthy Young Male, Healthy Young Female, Healthy Elderly Male and Healthy Elderly Female Subjects.
176. A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel Group Study Evaluating the Efficacy and Safety of XXX-XXX Administered Daily for Four Weeks in Subjects with Low HDL-C Levels
177. A Randomized, Open-Label, 3-Period Crossover Study to Evaluate the Pharmacokinetics of XXX and XXX (XXX™) After Administration of Single Doses of the XXX/XXX Fixed-Dose Combination Tablet Probe Formulations or Co-administration of Corresponding Doses of XXX and XXX as Individual Tablets
178. An Open-Label, Randomized, 2-Period, Single-Dose Crossover Study in Healthy Subjects to Investigate the Influence of Formulation on the Pharmacokinetics of XX-XXX in Healthy Subjects
179. An Open-label, Multiple-dose, Randomized, Two-period Crossover Study to Assess Bioequivalence of the 300 mcg/day XXX Reduced-size Patch (14 cm2) Relative to the XXX Reference Patch (28 cm2) in Healthy Postmenopausal Women
180. A Phase I, Cross-Over, Randomized, Single Dose, Bioequivalence Study of the Pharmacokinetics and Safety of XXX 20 mg in Fasted and Fed, Normal, Healthy Volunteer
181. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Repeat-Dose Study to Determine the Safety, Pharmacokinetic Effects, and Efficacy of XXX in Patients with Hypercholesterolemia.
182. A double blind, randomized, placebo-controlled study of the safety and pharmacokinetics of repeated oral doses of XXX, administered either QD (0.15, 0.5 and 1 mg) or BID (0.5 or 1mg) for 14 days to elderly male and female subjects
183. An Open-Label, Randomized, Partially Fixed-Sequence, 3-Period Crossover Study to Assess the Pharmacokinetics After Administration of the XXX and XXX Formulations and the Food-Effect on the XXX Formulation of XX-XXX in Patients with Type 2 Diabetes
184. A Randomized, Open-Label, 2-Period Crossover Study to Evaluate the Effect of Food on the Pharmacokinetics of XXX and XXX (XXX™) After Administration of Single Doses of the XXX/XXX Fixed-Dose Combination Tablet Probe Formulations (Part 2)
185. A Phase I, Multicenter, Randomized, Placebo-Controlled Study to Assess the Relative Effect of XXX Surface Area of Administration XXX and Payload on the Immunogenicity of a XXX Administered by Particle Mediated XXX Delivery to Healthy Adults.
186. A Randomized Open-label, Single-dose, Four-period Crossover Study to Assess the Influence of a High-fat Meal on the Relative Bioavailability of a 35 mg XXX-XXX Formulation of XXX Compared to the Same 35 mg XXX-XXX Formulation Under Fasted Conditions and a 35 mg XXX-XXX Formulation Administered Fasted or 30 Minutes Prior to a High-Fat Meal in Postmenopausal Women

187. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multiple-Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Efficacy of XXX and XXX in Healthy Postmenopausal Women.
188. An Open-Label, Randomized, Two-Period Crossover Definitive Bioequivalence Study with the FMI XXX/XXX FDC Tablet and Co-Administration of XXX and XXX Individual Tablets After Consumption of a High-Fat Meal in Healthy Adult Subjects.
189. A Randomized, Double-Blind, Placebo-Controlled, Double-Dummy, Multiple-Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Endpoints of XXX in Healthy Older Men.
190. A Two Treatment, Two-Period, Randomized Single-Dose Crossover Study of the Bioequivalence of XXX Sodium Phosphate and XXX Acetate Injectable Suspension Compared to XXX in Healthy Subjects.
191. An Open-Label, Four-Period, Randomized, Crossover Pilot Study to Evaluate the Bioequivalence of Three Extended-Release Test Tablet Formulations of XXX (54mg) Compared to an Equivalent Dose of a Commercially Available Reference drug Product (XXX® 54 mg. XXX) in Normal Human Subjects Under Fed Conditions.
192. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multiple-Dose Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Efficacy of XXX and XXX in Healthy Postmenopausal Women.
193. An Open-Label, Single Center, Non-Randomized Pharmacokinetic Study to Evaluate Safety of and Systemic Exposure to Multiple Applications of XXX Cream in Subjects with Actinic Keratoses of the Face and/or Balding Scalp.
194. A 3-Way cross-over, randomized, placebo-controlled, double-blind, multicenter study to assess pharmacologic effects of a 7-day exposure to XXX 15 mg o.d. and XXX 4 mg o.d. on cardiovascular parameters in healthy subjects 50 years of age and older.
195. A Phase I Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Study the Safety, Tolerability, and Pharmacokinetics of a Single Oral Dose of XXX in Healthy Elderly Male, Elderly Female, Young Female, and Young Obese Male Subjects.
196. Randomized, Open-Label, 4 -Period Replicate Crossover, Bioequivalence Study of XXX 1% And XXX ® 1% (XXX) Following A2 x 5 Gram Dose in Hypogonadal Male Volunteers
197. A Phase I Randomized Clinical Trial to Study the Definitive Bioequivalence of 2 Formulations of XXX in Healthy Young Adults.
198. A Randomized, Partially-blinded, Single-rising-dose, Multicenter, Parallel-design, Phase I, Tolerability and Pharmacokinetics Study of XXX Formulations Compared to a XXX Formulations in Normal Healthy Women Between the Ages of 40-70.
199. A Phase I Study to Evaluate the Definitive Bioequivalence of XXX with Marketed Products
200. Open label, 2-period Crossover, Multiple-dose Study to Determine the Effect of Gastric pH on the Relative Bioavailability of the XXX Oral Tablet Formulation in Healthy Volunteers
201. An Open label, 2-period cross-over, multiple-dose study to determine the effect of ethanol on the relative bioavailability of the XXX oral tablet formulation in healthy volunteers
202. Open-label, single-dose, randomized sequence, 3-period cross-over, study to determine the effects of food on the relative bioavailability of the XXX oral tablet formulation in healthy volunteer
203. Randomized, Partially-blinded, Single-rising-Dose, Multicenter, Parallel-design, Phase I, Tolerability, and Pharmacokinetic Study of XXX Formulations Compared to a XXX Formulation in Normal Healthy Women Between the Ages of 40-70
204. A Multi-center, Randomized, Double-Blind, Two-treatment, Two-period, Two-sequence, Crossover Study to Assess the Bioequivalence of the Phase III and Commercial XXX Formulations in Healthy Male and Female Subjects
205. A Multiple Dose Clinical Trial to Study the Safety, Tolerability, Pharmacodynamics, and Pharmacokinetics of XXX (type 2 diabetics)
206. A Double–Blind, Randomized Placebo Controlled, Sequential Cohort Study to Evaluate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Multiple Oral Daily Doses of XXX in Subjects with Type 2 Diabetes Mellitus
207. A Multi Center Randomized, Double Blinded, Multiple Ascending Dose, Placebo Controlled, Parallel Group, 3 Part Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX Administered Once Weekly For 4 Weeks in Patients With Type 2 Diabetes Mellitus On Stable Doses Of Metformin
208. A Study to Assess the Pharmacokinetics of XXX and XXX After Administration of Single Doses Of XXX/XXX Fixed Dose Combination (FDC) Tablet Probe Formulation.
209. A Placebo Controlled Multiple Dose Study To Evaluate The Pharmacokinetics and Pharmacodynamics of XXX in Subjects With Type 2 Diabetes.

210. A Double Blinded, Randomized, Placebo and Active Controlled Crossover Study To Evaluate The Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Subjects With Type 11 Diabetes
211. A Multi Center, Double Blind, Double Dummy, Active Controlled, Parallel Design Study To Assess The Efficacy, Safety and Pharmakokinetics of Risedronate Upon Multiple Dose Administration In Post Menopausal Women
212. A Single – Dose Study To Assess the Pharmacokinetics of XXX and XXX
213. A Study To Assess The Pharmacokinetics of XXX and XXX After Administration of Single Doses Of XXX/XXX Fixed Dose Combination (FDC) Tablet Probe Formulation
214. Evaluation of the Effect Of Showering On The Absorption Of Testosterone Following Application Of A Single Dose XXX 4mg Testosterone Transdermal System In Hypogonadal Males
215. A Multiple Dose Pharmacokinetic and Comparative Bioavailability Study Of Testosterone Absorption After Administration of 5mg Testosterone Gel XXX To The Upper Arms/Shoulders Using Application Site Rotation Or A Combination Of Application Sites In Hypogonadal Males
216. A Double Blind Placebo Controlled Randomized Parallel Group Multi-Center Study To Evaluate The Multiple Dose Pharmacokinetic and Pharmacodynamic Characteristics Of XXX In Subjects With Type 2 Diabetes Mellitus
217. A randomized, double-blind, placebo-controlled, Phase I, multiple-dose escalation study to evaluate the safety, tolerability and pharmacokinetics of orally-administered XXX capsules in healthy overweight or obese volunteers
218. Development of Biomarkers of Effect from Chronic Tobacco Usage: A Clinical Study Examining Metabolic Profiling, Inflammation, and Oxidative Stress
219. An open-label, escalating-dose trial to evaluate the safety, tolerability, and pharmacokinetics of orally administered XXX tablets in healthy volunteers
220. A Randomized, Double-Blind, Placebo-Controlled, Phase I, Single-Ascending-Dose Trial to Evaluate the Safety, Tolerability, and Pharmacokinetics of Orally Administered XXX Capsules in Healthy Male Volunteers
221. An open-label, escalating-dose trial to evaluate the safety, tolerability, and pharmacokinetics of orally administered XXX tablets in healthy volunteers.
222. An open-label, escalating-dose trial to evaluate the safety, tolerability, and pharmacokinetics of orally administered XXX tablets in healthy volunteers.
223. A prospective, double-blind, randomized, placebo-controlled, multiple-dose study to assess the safety and tolerability of 4 doses of XXX for 28 days in subjects with Type 2 diabetes not well controlled on metformin.
224. A randomized, double-blind, multiple-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally administered XXX capsules in obese subjects with moderate dyslipidemia.
225. A double-blind, randomized, placebo-controlled, Phase I, multiple-dose escalation study to evaluate the safety, tolerability, and pharmacokinetics of orally-administered XXX in subjects with mild cognitive impairment or a diagnosis of mild Alzheimer's disease
226. A randomized, double-blind, placebo-controlled study evaluating the safety and tolerability of XXX capsules in overweight or obese subjects taking a selective serotonin reuptake inhibitor or serotonin norepinephrine reuptake inhibitor
227. A randomized, double-blind, placebo-controlled, Phase I, multiple-ascending-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally-administered XXX capsules in healthy subjects
228. An open-label, single dose escalation study to evaluate the pharmacokinetics of XXX new tablet formulation in healthy volunteers.
229. An open-label, single dose study to evaluate the pharmacokinetics of XXX tablet formulation at doses of 35mg and 50mg, once a day in healthy male volunteers.
230. A double-blind, randomized, placebo-controlled, Phase I study of 2 escalating, single subcutaneous doses to evaluate the safety, tolerability, immunogenicity, and pharmacokinetics of XXX in subjects with Alzheimer's disease with mild cognitive impairment.
231. An open-label, Phase I, multiple-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally-administered XXX capsules in healthy subjects.
232. A Phase I, open label, randomized dose, 3-period, crossover study to evaluate the single-dose pharmacokinetics of two XXX tablet formulations at doses of 35mg and 50mg and one XXX capsule formulation at dose of 50mg, once a day in healthy male volunteers.

233. A single-blinded, randomized, three-way cross-over, single dose study to assess the safety and tolerability of 3 doses of XXX in subjects with type 2 diabetes on a stable dose of metformin.
234. A Phase 1, open label, randomized, crossover study to evaluate the multi-dose pharmacokinetics of XXX 50mg tablet formulation and XXX 50mg capsule formulation once a day in healthy male volunteers.
235. An open-label, Phase I, dose titration study to evaluate the safety and tolerability or orally-administered XXX capsules in healthy older study participants.
236. A 26 week randomized, double-blind, placebo-controlled Phase 2 study to evaluate the safety and efficacy of various doses of XXX on weight loss in overweight or obese subjects
237. Randomized, Open-Label, 4-Period Replicate Crossover, Bioequivalence Study of XXX (X)% and XXX (X)% (XXX) Following a X Grams Dose in Hypogonadal Male Volunteers
238. Randomized, Open-Label, 4-Period Replicate Crossover, Bioequivalence Study of Testosterone Gel (X)% and XXX® Testosterone Gel (X)% Following a X.X Grams Dose in Hypogonadal Male Volunteers
239. An open label, single dose, crossover study to evaluate the pharmacokinetics of tablet X formulation of XXX in healthy, volunteers
240. A randomized, single-blind, placebo-controlled, crossover, Phase I, single-ascending dose trial to evaluate the safety, tolerability and pharmacokinetics of orally administered xxx in healthy subjects
241. A randomized, placebo-controlled, single-blind, crossover, phase I, single-ascending-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally-administered HPP737 in healthy subjects.
242. A Phase 1, Single-Dose Escalation and 4-week Multiple-Dose Escalation Study of the Safety and Pharmacokinetics of XXX in Healthy Volunteers
243. A Phase 1, Placebo-Controlled, randomized trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple IV doses of XXXX in obese hyperlipidemic adult subjects with and without type 2 diabetes mellitus on a background of Atorvastatin
244. A phase 1 placebo-controlled trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple escalating oral doses of XXXX in adult patients with type 2 diabetes mellitus (T2DM) on stable doses of metformin
245. A randomized, placebo-controlled, investigator- and subject-blind, sponsor open, parallel, phase I, multiple-ascending-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally-administered XXX in healthy subjects
246. Methods for *In Vitro* Evaluation of Biomarkers of Tobacco Effect
247. A randomized, investigator- and subject-blind, placebo-controlled, phase I, single-ascending-dose trial to evaluate the safety, tolerability and pharmacokinetics of orally-administered XXXXXX in healthy subjects
248. A phase 1B, randomized, double-blind, active comparator controlled, 3-period, cross-over study to characterize pharmacodynamics and tolerability of two dosing regimens of XX-XXXXXXXX in adults with type 2 diabetes mellitus inadequately controlled on metformin
249. A randomized, investigator- and subject-blind, sponsor open, placebo-controlled, phase 1, multiple-ascending-dose trial to evaluate the safety, tolerability and pharmacokinetics of XXXXXX administered orally for 10 days in healthy overweight or obese subjects
250. Comparison of the XXXXXXXX Analog, XXXXXXXXX, to once-weekly Exenatide and to placebo in patients with type 2 diabetes
251. Phase 1, open-label, randomized, parallel, single dose study to evaluate the pharmacokinetics of a 5mg formulation of XXX under fed and fasted conditions in healthy volunteers
252. A Multi- Center Single Ascending Dose Tolerability And Safety Study Of Placebo and XXX Administered By Subcutaneous Injection In Healthy Volunteer Subjects
253. A Phase 1 Open Label, Randomized Three Period, Two Way Crossover Study In Healthy Subjects To Evaluate The Bioavailability Of A Test XXX Oral Suspension Relative To The Reference Capsule Formulation And To Assess The Effect Of Food On The Bioavailability Of XXX From The Oral Suspension
254. A Study to Evaluate The Relative Bioavailability Of XXX 250mg/ml Administered via Subcutaneous Injection to arm vs Intramuscular Injection To The Gluteus Maximis In Healthy Postmenopausal Female Adult Subjects
255. Vaccination Response Following Administration Of XXX To Healthy Subjects

256. A Four Period Open Label Randomized Crossover Study to Evaluate the Pharmacokinetic Properties Of A single Dose Once Daily XXX Extended Release Prototype Formulation In Healthy Volunteers In Both Fed And Fasted Conditions
257. A Randomized Open Label Single Dose Parallel Group Study to Assess the Pharmacokinetic Bioequivalence of XXX in a Prefilled Syringe vs XXX DP in an Auto Injector In Healthy Male and Female Subjects
258. A Two Period Double Bind Randomized Placebo Controlled Cross Over Study to Evaluate the Efficacy and Tolerability of XXX in Subjects with Nocturnal Leg Cramps
259. A Phase 1 Study of The Safety of Levodopa and Pharmacokinetics Following Single Dose Administration of XXX Inhalation Powder) In Smoking and Non-Smoking Adults
260. A Phase 1 Open Label Study to Evaluate the Relative Bioavailability of Two Formulations of XXX and to Assess the Effect of Food on XXX Pharmacokinetics In Healthy Subjects
261. A Bioequivalent Study Comparing XXX Capsule and Tablet Formulations and Effect of Food on XXX Tablet Pharmacokinetics In Healthy Subjects
262. The Effect of Food on The Bioavailability of XXX in Healthy Subjects
263. A Single Ascending Dose Study for The Evaluation of the Effects of XXX on the QT/corrected QT interval In Healthy Subjects and Pilot Relative Availability
264. PK and PD of XXX in Healthy Subjects Following Subcutaneous Administration of XXX Solution in a Prefilled Syringe or an Autoinjector
265. Relative Bioavailability and the Effect of Food on The Bioavailability of XXX in Healthy Subjects
266. A Phase 1 Open Label Randomized Two Period Two Sequence Crossover Study to Evaluate the Effect of XXX on the PK Profile of Pitavastatin A Sensitive OATPIB Substrate In Healthy Male and Female Subjects
267. Effects of Nutritive Protein Supplement on Healthy Men Undergoing Unilateral Knee Immobilization
268. A Phase 2b/3 Multicenter Randomized Double-Blind Placebo Controlled Parallel Group Study to Evaluate the Efficacy Safety and Tolerability of Two Doses of XXX in Subjects with Lactose Intolerance
269. A Phase 1 Study Comparing Once Daily vs Twice Daily Dosing of XXX in Healthy Volunteers
270. A Repeat Dose to Evaluate the PK of XXX Applied Topically as A Gel in Healthy Subjects
271. A Randomized Open Label Parallel Group Study of the PK Safety and Tolerability of a Single IM Injection of XXX Produced By 2 Different Cell Lines in Healthy Adult Subjects
272. A Phase 1 First in Human Open Label Study Of The Safety and PK Of Single Ascending Doses of XXX (Inhalation Powder) In Healthy Adults
273. A Prospective Randomized Open Label Nonreplicate Crossover Study To Compare The Bioavailability Of A Tablet Formulation of XXX To A Capsule Formulation Of XXX In Healthy Volunteer Subjects
274. A Phase 1 Open Label Randomized Two Part Study To Evaluate The PK Exposure of a Once Daily XXX Formulation Relative to the Twice Daily Reference Immediate Release Tablet and the Effect of Food on the QD XXX Formulation In Healthy Subjects
275. A Multipart Randomized Single and Multi-Dose Study In Healthy Volunteers To Assess The PK and Tolerability of New XXX Formulations Compared With XX
276. A Phase 1 Open Label Randomized Three Period Two Way Crossover Study In Healthy Subjects To Evaluate The Bioavailability Of A Test XXX Oral Suspension Relative To The Reference Capsule Formulation And To Assess The Effect Of Food On The Bioavailability Of XXX From The Oral Suspension
277. A Phase 1 Open Label Randomized Three Period Two Sequence Crossover Study In Healthy Subjects To Evaluate The Bioavailability Of A Test Dose XXX Oral Suspension Relative To The Reference Capsule Formulation And To Assess The Effect Of Food On The Bioavailability Of The XXX Oral Suspension
278. A Randomized, Open Label, Single Dose, Parallel Group Study To Assess the PK Bioequivalence of XXX DP in a Pre filled Syringe vs XXX DP in an Autoinjector In Healthy Male and Female Subjects
279. A Two Part Two Period Per Part, Double Blind, Randomized, Placebo Controlled, Cross-Over Study To Evaluate The Efficacy and Tolerability of XXX In Subjects With Nocturnal Leg Cramps
280. The Effect Of Food On The Bioavailability of XXX in Healthy Subjects

281. A Phase 1, Three Part, Open Label, Randomized Study To Evaluate The PK of One Or More Prototype Once Daily XXX Formulations Compared to The Reference 40mg Twice Daily Immediate Release Formulation In Healthy Adult Male Subjects
282. A 4 Part Phase 1 Study To Evaluate The Effect of XXX On The PK of Mldazolam
283. A Randomized Open Label 2 Part, 2 Arm, Parallel Group Single Dose Multi-Center Study In Healthy Subjects To Investigate the Comparability Of PK of XXX Administered Subcutaneously By A Prefilled Syringe With Needle Safety Device Or Auto Injector
284. Effect of XXX On The PK of Rosuvastatin in Caucasian Healthy Subjects
285. A Phase 1 Open Label Randomized Two Period Two Sequence Crossover Study To Evaluate The Effect Of XXX On the PK Profile of Pitavastatin A Sensitive OATIB Substrate In Healthy Male Subjects
286. A randomized, single center, open-label, three-period cross-over study to investigate the relative bioavailability of two new oral suspension formulations of XX (10 x 10 mg dispersible tablets reconstituted in water) of XXX in comparison to XXX 2 x 5O mg capsules (2 x SO mg) following a single oral dose of 100 mg in healthy adult volunteers
287. A repeat dose maximum use study to evaluate the PK of XXX applied topically as a gel to subjects with hyperhidrosis
288. A Phase 1 Open-label Study To Evaluate The Relative Bioavailability of Two Formulations of XXX and to assess The Effect Of Food on XXX
289. A Phase 1 Study To Evaluate The PK Interaction Potential Between XXX and an Oral Contraceptive Regimen In Healthy Female Subjects
290. A Phase 1, Open Label, Randomized, Two Part Study To Evaluate The PK Exposure Of A Once Daily XXX Formulation Relative to The Twice Daily Reference Immediate Release Tablet and The Effect Of Food on The QD XXX Formulation In Healthy Subjects
291. Randomized Double Blind, Placebo Controlled Study To Evaluate The Safety, Tolerability, PK and PD of Ascending Doses of XXX for 4 weeks In Patients With Osteoarthritis
292. A 4-part phase 1 study to evaluate the effect of XXX ON THE PK of Midazolam, Rosuvastatin and Simvastatin and the Effect of Itraconazole on the PK of XXX
293. Effect of Age on the PK Safety and Tolerability of XXX in Healthy Volunteers
294. Multiple Ascending Dose Safety Tolerability PK and Drug Drug Interaction Study of XXX
295. A Randomized Double Blind Four Period Crossover Study To Evaluate Cardiovascular Effect of Single Oral Doses of XXX When Coadministered With Single Oral Doses of XX In Healthy Subjects Pl Effect Of XXX On Heart Rate and Blood Pressure In Healthy Subjects Receiving Oral Doses of Propanolol
296. A Phase 1 Randomized Three-Way Crossover Study To Evaluate The Single Dose PK, Safety and Tolerability of XXX and XX when administered alone and concomitantly in Healthy Volunteers
297. A Phase 1, Open Label Non-Randomized, Fixed Sequence Composite Study To Evaluate the Effects of Probenecid, Rifampin and Verapamil on the PK and PD of XXX in Healthy Subjects
298. A Phase 1, Open Label Randomized Two Period Two Treatment Crossover Study To Evaluate The Effect of XXX on the PK of Digoxin In Healthy Subjects
299. A Phase 1, Open Label Single Dose Study In Healthy Subjects To Evaluate the Relative PK and Bioavailability of The Same Once Daily XXX Formulation By Two Different Manufacturers
300. A Phase 1, Four Part, Fixed Sequence Open Label Study To Evaluate The Effect Of Multiple Doses of XXX On The PK of
301. Omeprazole, Midazolam, Warfarin, Rosuvastatin, Metformin, Digoxin and XX In Healthy Adult Subjects
302. A Randomized Three Period Open Label Crossover Study To Investigate The Relative Bioavailability Of Two New Oral Suspension Formulations of XXX Dispersible Tablets reconstituted in water in comparison to XXX HMPC capsules in healthy volunteers
303. A Randomized Double Blind Single Dose Parallel Group Phase 1 Comparative PK Trial To Support The Comparability Evaluation of Manufacturing Sites For Commercial XXX
304. A Safety and Tolerability Study of 2ml Autoinjector Compared to A Prefilled Syringe For Manual Use In Healthy Subjects

305. A Single Center Randomized Cross Over Study To Assess Nicotine Exposure from and the Subjective Effects of XX Electronic Cigarettes Compared To Combustible Cigarettes, Nicotine Gum and an Electronic Cigarette Comparator In Healthy Adult Smokers
306. A Single Center Randomized Cross Over Study to Assess Nicotine Exposure from and the Subjective Effects of XXX Compared to Combustible Cigarettes and Nicotine Gum in Healthy Adult Smokers
307. A Single Center randomized cross over study to assess nicotine exposure from and the subjective effects of XXX electronic cigarettes compared to combustible cigarettes nicotine inhaler and a comparator electronic cigarette in healthy adult smokers
308. A randomized parallel group open label study to assess biomarkers of tobacco exposure and potential harm during a 60 day controlled switch to XX or XXX compared to continued use of combustible cigarettes or tobaccocessation

HIGH POINT
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EMPLOYEE CURRICULUM VITAE

Additional Information

LICENSES/CERTIFICATES:

- NCML #(b) (6) - Current
- FLML (b) (6) - Current
- DEA License - Current
- Good Clinical Practices (GCP) Certification
- Advanced Cardiovascular Life Support (ACLS) Certification
- Basic Life Support (BLS) and AED Certification
- OSHA
- CSSRS

BOARD CERTIFICATIONS:
American Board of Family Medicine - 2023

PUBLICATION
Pharmacokinetics of Imiquimod 3.75% cream applied daily for 3 weeks to actinic keratoses on the face and/or balding scalp.

PROFESSIONAL AFFILIATIONS
ACRP
American Academy Of Family Practice
North Carolina Medical Society
Greensboro Medical Society
SOCRA

CONFERENCES 2014-2017

- ADA
- DIA
- ACRP
- SOCRA

(b) (6) 27 MAR 2018

Signature Date