

CURRICULUM VITAE

NAME: Jeffrey Kenneth Kingsley DO, MBA, MS, CPI, FACRP

EDUCATION AND TRAINING:

08/09-05/11 Master of Business Administration
Emory University, Atlanta, GA

07/02-06/04 Family Medicine Residency
Columbus Regional Medical Center, Columbus, GA

07/01-06/02 Family Medicine Internship
Columbus Regional Medical Center, Columbus, GA

09/97-06/01 Doctor of Osteopathic Medicine
Philadelphia College of Osteopathic Medicine, Philadelphia, PA

01/96-05/97 Master of Science, Biochemistry
University of Scranton, Scranton, PA

09/87-12/96 Bachelor of Science, Biology, Chemistry, History, Cultural Anthropology
University of Scranton, Scranton, PA

BOARD CERTIFICATIONS AND FELLOWSHIPS:

2016 Fellow- Association of Clinical Research Professionals

2009 Certified Principal Investigator – NCCA Accredited - Academy of Clinical Research Professionals

2009 Fellow – American Academy of Family Practice

2004 Diplomate - American Academy of Family Practice

MEDICAL LICENSURES:

Active Georgia

CURRENT BUSINESS AND MEDICAL PRACTICES:

2005-present President and CEO; Institute for the Advancement of Clinical Trials DBA IACT Health

- Purchased SERRG, Inc Apr 2016
- Purchased Gwinnett Biomedical Research Dec 2015
800 Talbotton Rd, Columbus, GA 31904

President and CEO; Southeast Regional Research Group, Inc. and affiliate companies

2005-2013 SERRG Columbus- 5210 Armour Road, Suites 200 & 400, Columbus, GA 31904

2006-2013 SERRG Savannah- 6709 Waters Ave, Savannah, GA 31406

2008-Present SERRG Rincon- 131 Silverwood Centre Suite 100, Rincon, GA 31326

2011-2013 SERRG Augusta- 1208 George C. Wilson Dr., Augusta, GA 30909

2011-2013 SERRG Aiken- 953 Dougherty Rd Suite B, Aiken, SC 29803

2013-Present SERRG Savannah- 4849 Paulsen St., Suite 101, Savannah, GA 31405

2013-Present-Columbus Regional Research Institute-

- 800 Talbotton Rd Columbus, GA 31904
- Purchased Southern Diabetes Foundation March 2014; 2425 Brookstone Centre Parkway Columbus, GA 31904
- Purchased Allergy Center at Brookstone Research May 2015; 1220 Brookstone Centre Parkway Columbus, GA 31904
- 710 Center St. Columbus, GA 31901
- 1800 10th Avenue, Columbus, GA 31901

2015-Present-Gwinnett Biomedical Research- 555 Old Norcross Rd. Suite 250, Lawrenceville, GA 30046

2008-present President and CEO; LIF Investments, LLC, Columbus, GA 31904

FACULTY and ACADEMIC APPOINTMENTS:

- 2015-present Clinical Assistant Professor
Department of Family Medicine
School of Medicine – Columbus campus, Columbus, GA
Mercer University
- 2008-2010 President; Association for the Behavioral Sciences in Medical Education
Burton, MI
- 2004-2006 Associate Faculty
Family Medicine Residency Program
Columbus Regional Healthcare System, Columbus, GA

HOSPITAL AFFILIATIONS:

- 2013-present Midtown Medical Center
710 Center St., Columbus, GA 31901
- 2014-present Family Medicine Center
1800 10th Ave Suite 100, Columbus, GA 31901
- 2012-present St. Francis Hospital
2122 Manchester Expressway, Columbus, GA 31904

SOCIETIES AND PROFESSIONAL ACTIVITIES:**POSITIONS:**

- 2017-present ACRP; Member, Fellowship Committee
- 2016-present Chair, Board of Trustees; Association of Clinical Research Professionals
- 2016-2017 Fellowship Program Working Group
- 2016-present B2B Advisory Group; Association of Clinical Research Professionals
- 2015-present Governance Committee, Finance Committee, Executive Committee, & Conference Planning Committee; Association of Clinical Research Professionals
- 2013-2015 Treasurer; Association of Clinical Research Professionals and Academy of Physicians in Clinical Research
- 2013-2015 Chair, Finance Committee; Association of Clinical Research Professionals and Academy of Physicians in Clinical Research
- 2012 Leadership Georgia
- 2010-2012 Global Planning Committee; Association of Clinical Research Professionals and Academy of Pharmaceutical Physician Investigators
- 2010-2012 Nominations Committee; Academy of Pharmaceutical Physician Investigators
- 2009-2012 Awards and Recognition Committee; Association of Clinical Research Professionals
- 2009-2010 Marketing and Communications Committee; Association of Clinical Research Professionals
- 2008-2015 Healthcare Committee; Columbus Chamber of Commerce
- 2008-2010 Education Committee; Georgia Academy of Family Physicians
- 2004-2006 Associate Director, Family Medicine Residency Program
Medical Director, Family Medicine Center
Medical Director, Regional Urgent Care Center
Columbus Regional Healthcare System

MEMBERSHIPS:

- Association of Clinical Research Professionals (ACRP) 2005-present
Association of Physicians in Clinical Research (APCR) 2005-2015

EDITORIAL REVIEW:

- Annals of Behavioral Science and Medical Education; 2009-2012

PRESENTATIONS:

- May 2017 **The New & Changing Role of Study Site Personnel & Site Monitors: Managing Through the Disruption Phase**; 4th Annual ACRP Executive Summit; Seattle, WA
- April 2017 **Financial Management from the Investigator Site Perspective**; Trial Financial Management Summit; Philadelphia, PA
- March 2017 **Keynote: A Career in Clinical Research**; TIEGA; Columbus, GA
- December 2016 **Incorporate the Site Perspective to Improve Partnerships in Clinical Quality**; 13th Clinical Performance Metrics Summit; Philadelphia, PA
- April 2016 **An Idea Whose Time Has Come: Next Steps in the Professionalization of Clinical Research**; ACRP 2016 Meeting & Expo; Atlanta, GA
- April 2015 **Design the Future of Our Profession as a Profession**; ACRP 2015 Global Conference & Exhibition; Salt Lake City, UT
- April 2014 **Design the Future of Our Profession as a Profession**; ACRP 2014 Global Conference & Exhibition; San Antonio, TX
- September 2013 **The Investigator POV: What Disruption is Needed to Achieve Better Relationships**; Disruptive Innovations Conference; Boston, MA
- May 2012 **Clinical Research for Medical Professionals**; Philadelphia College of Osteopathic Medicine Georgia Campus; Atlanta, GA
- February 2011 **The New FDA Paradigm; ABSSSI**; Presented at the XXX meeting of investigators; Scottsdale, AZ
- November 2008 **The Privilege of Prescription**; Presented at the Georgia Osteopathic Medical Association; Atlanta, Georgia
- October 2008 **Improving Patient Understanding of Medical Communications via Teach-Back and Appropriate Handouts**; Presented at the 38th Annual Conference of the Association for the Behavioral Sciences in Medical Education; San Diego, California
- October 2006 **The Need for a Mental-Physical Co-Morbidity Science**; Presented at the 36th Annual Conference of the Association for the Behavioral Sciences in Medical Education; Annapolis, Maryland
- October 2004 **Developing Resilience, Balance, and Sensitivity: A Time-Limited Exercise for Residents and Medical Students**; Presented at the 34th Annual Conference of the Association for the Behavioral Sciences in Medical Education; Vail, Colorado

PUBLICATIONS:

Peer-reviewed journal articles:

- 2016-Present Chair Column. Clinical Researcher; Standing Column
- August 2016 Kingsley J. August 2016. Measurements, Metrics, and KPIs: Achieving a Balanced Scorecard. *Clinical Researcher*, 30 (4): 12-15.
- April 2016 Kingsley J. April 2016. The Evolving Role of the PI. *Clinical Researcher*, 30 (2): 48-49.
- February 2015 Hinkley TL, Kingsley J, and Ziemba S. February 2015. Clinical Research as a Profession: Are We There Yet?. *Clinical Researcher*, 29: 24-27.
- Oct 2014 - present Kingsley J. PI Corner. *Clinical Researcher*; standing column.
- October 2014 O'Riordan W, Mehra P, Manos P, Kingsley J, Lawrence L, Cammarata S. 2015. A randomized phase 2 study comparing two doses of delafloxacin with tigecycline in adults with complicated skin and skin-structure infections. *Int J Infect Dis* 30:67-73.
- November 2012 Stryjewski M, Potgieter P, Yu-Ping L, Barriere S, Churukian A, Kingsley J, Corey GR, and for the TD-1792 Investigators Group. November 2012. TD-1792 versus Vancomycin for Treatment of Complicated Skin and Skin Structure Infections. *Antimicrob. Agents Chemother.*; 56:5476-5483 published ahead of print 6 August 2012 doi:10.1128/AAC.00712-12.
- June 2012 Senn, C. and Kingsley, J. (2012). Case Study: Commentaries on Harassment and Confidentiality. *Annals of Behavioral Science and Medical Education*, 18, 44-48.

- September 2009 Efficacy and Safety of Torezolid Phosphate (TR-701) in a Dose-Ranging Phase 2 Randomized, Double-Blind Study in Patients with Severe Complicated Skin and Skin Structure Infections (cSSSI)
- October 2008 Senn, C. and Kingsley, J. K. *Improving Patient Understanding of Medical Communications via Teach-Back and Appropriate Handouts*. Paper presented at the 38th annual Association for the Behavioral Sciences and Medical Education conference, San Diego, CA.

CONSULTANCIES:

Research Protocol Design:

- 2011-2012 Trius Therapeutics
 2010 Furiex Pharmaceuticals
 2009 RibX Pharmaceuticals
 2008 CVRx Inc.

Research Expert Opinion and Consultancy:

- 2014 Nabriva Therapeutics
 2015 Melinta Therapeutics

Clinical Study Report to FDA:

- 2014 Achaogen, Inc.

Research Law Expert Opinion:

- 2015 Simha S.

BOARD of DIRECTOR POSITIONS:

- 2011-present Association of Clinical Research Professionals (ACRP)
 2013-2015 Academy of Physicians in Clinical Research (APCR)
 2005-2012 Association for the Behavioral Sciences in Medical Education
 2005-present Institute for the Advancement of Clinical Trials, (purchased SERRG Inc.)
 2005-present Columbus Regional Research Institute (formerly Southeast Regional Research Group, Inc.)
 2006-present SERRG Savannah Inc.

SIGNIFICANT AWARDS:

- 2015 Georgia Small Business Rock Star; Georgia Department of Economic Development and the Georgia Economic Developers Association
 2012 American Psychological Association's Psychologically Healthy Workplace, Georgia
 2011 Emory University's Goizueta Business School honors; Beta Gamma Sigma
 2009 PharmaVoice 100 of the Most Inspiring People
 2009 Georgia Trend's Top 10 Best Places to Work in the State of Georgia
 2008 Hometown Hero, Columbus GA Chamber of Commerce

TEACHING SERVICE:

Undergraduate Student Teaching:

- 2008-present Externship preceptor and research mentor; One month annually

Medical Student Teaching:

- 2015-present Integrative Readings in Clinical Medicine Faculty; 3rd and 4th year medical students; Mercer School of Medicine
 2008-present Elective Preceptor in Clinical Research; 3rd and 4th year medical students for one month rotations; approximately 3 students per year
 2004-2006 Preceptor in Family Medicine; 3rd and 4th year medical students rotating monthly

Resident Teaching:

2008-present Elective Preceptor in Clinical Research; one month rotations; approximately 3 residents per year
2004-2006 Associate Faculty in Family Medicine; Full time

RESEARCH EXPERIENCE:

Principal Investigator

Allergan

A Multicenter, Randomized, Open-Label Extension Study to Evaluate the Long Term Safety and Tolerability of Oral Ubrogepant in the Acute Treatment of Migraine With or Without Aura

Allergan

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Single Attack Study to Evaluate the Efficacy, Safety and Tolerability of Oral Ubrogepant in the Acute Treatment of Migraine

AZ

Double-blind, Randomized, Placebo-controlled, Parallel-group, Phase IV Study to Evaluate the Effect of Acclidinium Bromide on Long-term Cardiovascular Safety and COPD Exacerbations in Patients with Moderate to Very Severe COPD (ASCENT COPD)

Northrop Grumman

Evaluation of the CytoRADx System as a Biodosimeter for Special Human Populations

Pearl

A Randomized, Double-Blind, Multi-Center, Parallel Group Study to Assess the Efficacy and Safety of PT010 Relative to PT003 and PT009 on COPD Exacerbations over a 52-Week Treatment Period in Subjects with Moderate to Very Severe COPD

Purdue

A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled and Active-controlled, Parallel-group Study Evaluating the Analgesic Efficacy and Safety of VM902A in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee

Regeneron

An Open-Label Study of Dupilumab in Patients with Atopic Dermatitis Who Participated in Previous Dupilumab Clinical Trials

Debiopharm

A Phase 2, Randomized, Double Blind, Multi-Center Study of Safety, Tolerability, and Efficacy of DEBIO1450 vs Vancomycin/Linezolid in the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Due to Staphylococci spp.

Roche

A Phase II, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of lebrikizumab in patients with chronic obstructive pulmonary disease and a history of exacerbations

MicuRx

A Phase 2, Multicenter, Randomized, Double-blind Study to Evaluate the Safety and Efficacy of MRX-I Versus Linezolid in Adult Patients with Acute Bacterial Skin and Skin Structure Infection

Takeda

A phase 3, randomized, double blind, multicenter, placebo controlled study to evaluate the efficacy and safety of febuxostat 40 mg, XR, 80 mg XR, 40 mg IR and 80 mg IR in subjects with gout.

Fidia

A multi-center, parallel, double-blind, randomized, placebo-controlled study to evaluate the safety and effectiveness of HYMOVIS, a new viscoelastic hydrogel, for the treatment of osteoarthritis of the knee

Vertex

A Phase 2b, Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter Study of 2 Dose Levels of VX 787 Administered as Monotherapy and One Dose Level of VX-787 Administered in Combination With Oseltamivir for the Treatment of Acute Uncomplicated Seasonal Influenza A in Adult Subjects

GSK

A Phase III, 52 week, randomized, double blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease

Pfizer

A randomized, double blind, placebo- and active-controlled, 4 week, multi-centre, parallel group study assessing the analgesic effect, safety and tolerability of PF-06372865 in subjects with chronic lower back pain using naproxen as positive control

Durata

A Phase 3b, Double-Blind, Multicenter, Randomized Study to Compare the Efficacy and Safety of Single Dose Dalbavancin to a Two Dose Regimen of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections

Smallpox

A randomized, double-blind, placebo-controlled Phase III trial to evaluate immunogenicity and safety of three consecutive production lots of IMVAMUNE® (MVA-BN) smallpox vaccine in healthy, vaccine-naïve subjects.

Pfizer

A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Randomized-Withdrawal Study to Evaluate the Efficacy and Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at 30 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients With Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time

Pearl

A Randomized, Double-Blind, (Test Products and Placebo), Chronic Dosing (24 Weeks), Placebo-Controlled, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of PT003, PT005, and PT001 in Subjects With Moderate to Very Severe COPD, Compared With

Placebo and Spiriva® Handihaler® (Tiotropium Bromide 18 µg, Open-Label) as an Active Control

GSK

A Safety and Efficacy Study of Inhaled Fluticasone Propionate/Salmeterol Combination versus Inhaled Fluticasone Propionate in the Treatment of Adolescent and Adult Subjects with Persistent Asthma

Teva

A 12-Week Dose-ranging Study to Evaluate the Efficacy and Safety of Fp Spiromax® (Fluticasone Propionate Inhalation Powder) Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Severe Persistent Asthma Uncontrolled on High dose Inhaled Corticosteroid Therapy

Teva

A 12-Week Dose-ranging Study to Evaluate the Efficacy and Safety of Fp Spiromax® (Fluticasone Propionate Inhalation Powder) Administered Twice Daily compared with Placebo in Adolescent and Adult Subjects with Persistent Asthma Uncontrolled on Non-steroidal Therapy

Salix

A study to assess repeat treatment efficacy and safety of rifaximin 550 mg tid in subjects with irritable bowel syndrome with diarrhea (IBS-d)

GSK

A Phase II Multicenter, Parallel Group, Randomized, Dose Ranging Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Following 12 Weeks of Oral Administration of GSK2336805 With Pegylated Interferon and Ribavirin in Treatment-Naïve Subjects with Chronic Genotype 1 or 4 Hepatitis C Infection

Durata Pharmaceuticals

A phase 3, randomized, double-blind, double-dummy study to compare the efficacy and safety of dalbavancin to a comparator regimen (vancomycin and linezolid) for the treatment of acute bacterial skin and skin structure infections

Affinium

A Phase 2, Open-Label, Multi-Center Study of Safety, Tolerability, and Efficacy of AFN-12520000 in the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) Due to Staphylococci

Boehringer Ingelheim

A phase III, randomised, double-blind and placebo-controlled study of once daily BI 201335 for 24 weeks in combination with pegylated interferon-a and ribavirin in patients who fail to a prior PegIFN / RBV treatment with genotype 1 chronic hepatitis C infection.

Boehringer Ingelheim

A phase III, open-label study of once daily BI 201335 240 mg for 24 weeks in combination with pegylated interferon-a (PegIFN) and ribavirin (RBV) in patients with genotype 1 chronic hepatitis C infection who failed a prior PegIFN / RBV treatment

Durata Pharmaceuticals

A phase III, randomized, double-blind, double-dummy study to compare the efficacy and safety of XXXX to a comparator regimen (Vancomycin and Linezolid) for the treatment of acute bacterial skin and skin structure infections

Boehringer Ingelheim

A phase III, randomized, double-blind and placebo-controlled study of once daily XXXX for 12 or 24 weeks in combination with pegylated interferon-a and ribavirin in treatment naïve patients with genotype 1 chronic hepatitis C infection

Rib-X Pharmaceuticals, Inc.

A Phase 2 exploratory study of objective endpoints in subjects with acute bacterial skin and skin structure infections treated with Delafloxacin, Vancomycin, or Linezolid

Exscel

A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular outcomes after treatment with Exenatide once weekly in patients with Type 2 Diabetes Mellitus.

Trius Therapeutics

A Phase 3 Randomized, Double-Blind, Multicenter Study Comparing the Efficacy and Safety of 6-Day Oral TR-701 Free Acid and 10-Day Oral Linezolid for the Treatment of Acute Bacterial Skin and Skin Structure Infections

Boehringer Ingelheim

A randomised, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 µg and 5 µg Tiotropium Inhalation Solution delivered by the Respimat® Inhaler with Tiotropium inhalation capsulF3 in subjects with COPD

Daiichi Sankyo

A phase 3, randomized, double-blind, double-dummy, parallel-group, multi-center, multi-national study for the evaluation of efficacy and safety of (LMW) Heparin/Edoxaban versus (LMW) Heparin/Warfarin in subjects with symptomatic deep-vein thrombosis and/or pulmonary embolism

Sepracor Inc.

A Large Simple Safety Study of Arformoterol Tartrate Inhalation Solution in Subjects with Chronic Obstructive Pulmonary Disease (COPD)

Furiex

A randomized, controlled, double-blind, double-dummy, multicenter Phase 2 study of the efficacy/tolerability and efficacy of JNJ-32729463 compared with Linezolid (Zyvox) for the treatment of complicated skin and skin structure infection

Achaogen

A double-blind, randomized, comparator-controlled study to assess the safety, efficacy, and pharmacodynamics of two durations of XXXX injection administered intravenously in patients with complicated urinary tract infections or acute pyelonephritis

Forest

A long-term, randomized, double-blind study of the safety, tolerability and efficacy of XXXX at two dosage levels when administered to patients with moderate to severe stable chronic obstructive pulmonary disease.

Sanofi-Aventis

A randomized, double-blind, assessor-blind, non-inferiority study comparing the efficacy and safety of once-weekly subcutaneous XXXX with oral adjusted-dose warfarin in the prevention of stroke and systemic thromboembolic events in patients with atrial fibrillation

BioCryst

A phase II, multicenter, randomized, placebo-controlled, study to evaluate the efficacy and safety of XXXX in subjects with uncomplicated acute influenza

Pozen

Study evaluating the efficacy of XXX and celecoxib 200 mg QD in patients with osteoarthritis of the knee

CVRx Inc.

XXXX Pivotal Trial: XXXX Baroreflex Hypertension Therapy System

Affymax Inc.

A Phase 3, randomized, active-controlled, open-label, multi-center, study of the safety and efficacy of XXXX injection for the correction of anemia in patients with Chronic Renal Failure (CRF) not on dialysis and not on Erythropoiesis Stimulating Agent (ESA) treatment.

Pfizer

Gastrointestinal (GI) randomized event and safety open-label NSAID Study (GI Reasons): A randomized, Open-label, blinded-endpoint, parallel-group trial of GI safety of XXXX compared with non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in Osteoarthritis patients

Bayer and Johnson & Johnson

A prospective, randomized, double-blind, double-dummy, parallel-group, multi-center, event-driven, non-inferiority study comparing the efficacy and safety of once-daily oral XXXX with adjusted-dose Warfarin for the prevention of stroke and non-CNS systemic embolism in subjects with non-vascular atrial fibrillation

Replidyne Inc.

Determination of etiology and susceptibility if bacterial pathogens causing Impetigo and other uncomplicated skin infections in the USA

ALTANA Pharma AG

Effect of XXXX on exacerbation rate in patients with COPD: A 52 week, double-blind study with 500mcg XXXX once daily versus placebo

Amgen

Trial to reduce cardiovascular events with Aranesp Therapy (TREAT)

Sub-Investigator

CoLucid

An Open-label, Long-term, Safety Study of LAsmiDitan (100 mg and 200 mg) in the Acute Treatment of Migraine (GLADIATOR)

Genentech

A phase III randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of lebrikizumab in adult patients with mild to moderate asthma

BMS

A Randomized, Double-Blind, Placebo-Controlled Parallel Arm Study to Evaluate the Safety, Tolerability, and Effect on Atrial Fibrillation Burden of BMS-919373 in Patients with Paroxysmal Atrial Fibrillation

Regeneron

A randomized, Double-blind, Placebo-Controlled Study to Demonstrate the Efficacy and Long Term Safety of Dupilumab in Adult Patients with Moderate to Severe Atopic Dermatitis (AD)

Pfizer

A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study To Evaluate Safety and Efficacy of PF 04965842 in Patients with Moderate to Severe Psoriasis

Sanofi

Long-term safety and tolerability of REGN727/SAR236553 in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study

Asubio

A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-group Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of ASB17061 Capsules in Adult Subjects with Atopic Dermatitis

Ferring

A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period

Cubist

A multicenter, randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain

Pfizer

A randomized double blind placebo controlled parallel Group study of the efficacy and safety of pregabalin (bid) in Subjects with post-traumatic peripheral neuropathic pain

NexBio

Randomized, double-blind, placebo-controlled Phase 2B study on safety and therapeutic efficacy of DAS181 in adult subjects with naturally acquired influenza

Cubist

A multicenter, randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term safety and tolerability of cb-5945 for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain

Cempra

A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Oral Solithromycin (CEM-101) Compared to Oral Moxifloxacin in the Treatment of Adult Patients with Community-Acquired Bacterial Pneumonia

Akros

A Phase 2, Randomized, Double-blind, Double-dummy, Placebo and Active-controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy and Safety of JTT-851 in Patients with Type 2 Diabetes Mellitus

Collegium

A Phase 3, Multi-Center, Randomized, Double-blind, Placebo-Controlled, Safety, Tolerability, and Efficacy Study of Oxycodone DETERx™ Versus Placebo in Opioid-Experienced and Opioid-Naive Subjects with Moderate-to-Severe Chronic Low Back Pain

Orexigen

A multicenter randomized double-blind placebo controlled study assessing the occurrence of Major Adverse Cardiovascular Events (MACE) in overweight and obese subjects with Cardiovascular risk factors receiving Naltrexone SR/ Bupropion SR

Amgen

A Randomized, Double-Blind, Placebo-Controlled Study to Explore Dose Effect and Frequency of Administration of AMG 151 in Subjects with Type 2 Diabetes Mellitus

Purdue

A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain

Purdue

An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Nonmalignant and Nonneuropathic Pain.

Ventrus

A phase 3, randomized, double-blind, placebo-controlled, parallel-treatment group, multicenter efficacy and safety study of intra-anal application of ifersanserin (10 mg) as a 0.5% ointment in subjects with symptomatic internal hemorrhoids

Purdue

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioids

Astra Zeneca

An Open-Label 52-week Study to Assess the Long-Term Safety of NKTR-118 in Opioid-Induced Constipation (OIC) in Patients with Non-malignancy-related Pain

Sucampo

A Multicenter, Randomized, Placebo-controlled, Double-blinded study of the Efficacy and Safety of Lubiprostone in Subjects with Opioid-induced Bowel Dysfunction

Alcon Research, Ltd.

Safety and Efficacy Evaluation of Topical Moxidex Otic Solution in the Treatment of Acute Otitis Media with Otorrhea in Tympanostomy Tubes

Trygg Pharma Inc.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Phase III Study to Assess Efficacy and Safety of AKR-963 Therapy in Subjects with Severe Hypertriglyceridemia

Furiex Pharmaceuticals, Inc.

A Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Irritable Bowel Syndrome with Diarrhea

Cempra Pharmaceuticals

A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Oral CEM-101 Compared to Oral Levofloxacin in the Treatment of Patients with Community-Acquired Bacterial Pneumonia

Nabriva

A phase 2, multi-center, randomized, double-blind study comparing the safety and efficacy of two doses of XXXX versus vancomycin in patients with complicated skin and skin structure infections

Biocryst

A phase III, open label, randomized study of the antiviral activity, safety, and tolerability of intravenous XXXX in adult and adolescent hospitalized subjects with confirmed or suspected influenza infection

Novexel

A multicenter, investigator-blinded, randomized, comparative study to evaluate the efficacy and safety of XXXX versus oral linezolid in the treatment of acute bacterial skin and skin structure infections

GlaxoSmithKline

A randomized, double-blind, double dummy, comparative, multicenter study to assess the safety and efficacy of topical XXXX versus oral linezolid in the treatment of secondarily-infected traumatic lesions and impetigo due to Methicillin-resistant staphylococcus aureus

Cempra

An adaptive design, randomized, double-blind, multi-center study to evaluate the safety and efficacy of XXXX compared to linezolid in the treatment of acute bacterial skin structure infections

Roche

A phase IV registry in the evaluation of influenza strains seasonally

Paratek

A Randomized, Evaluator-Blinded, Phase 3 Study to Compare the Safety and Efficacy of XXXX with Linezolid in the Treatment of Adults with Complicated Skin and Skin Structure Infection

Cosmo

Efficacy and safety of new oral XXXX extended release tablet formulations in patients with mild or moderate, active ulcerative colitis

Millennium

A study of the induction and maintenance of clinical response and remission by XXXX in patients with moderate to severe ulcerative colitis

Millennium

A study of the induction and maintenance of clinical response and remission by XXXX in patients with moderate to severe Crohn's Disease

Sanofi-Aventis

Study comparing the efficacy and safety of XXXX with enoxaparin for the prevention of Venous Thromboembolism in patients undergoing major abdominal surgery

Centocor

Study to Evaluate the Efficacy and Safety of XXXX in Subjects with Moderately to Severely Active Crohn's Disease Previously Treated with TNF Antagonist Therapy

Roche

A study, to evaluate the effects of XXXX on cardiovascular (CV) risk in stable CHD patients, with a documented recent Acute Coronary Syndrome (ACS)

Trius

A study comparing the safety, tolerance, and efficacy of 2 doses of XXX in patients with complicated skin and skin structure infections

Cogentus

A study of XXXX compared with clopidogrel to reduce upper gastrointestinal events including bleeding and symptomatic ulcer disease

Pfizer and Bristol Myers-Squibb

A Safety and Efficacy Trial evaluating the use of XXXX for the Extended Treatment of Deep Vein Thrombosis and Pulmonary Embolism

Rib-X

A randomized, double-blind, multicenter study of the safety and efficacy of RX-3341 compared with Tigecycline for the treatment of complicated skin and skin structure infections

Bristol-Myers-Squibb

XXXX Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or are Unsuitable for Vitamin K Antagonist Treatment: A Randomized Double Blind Trial

Astellas

Study to Assess the Safety and Efficacy of XXXX in Subjects with Symptoms of Overactive Bladder

Rib-X

A Phase 2, Multicenter, Randomized, Open-Label, Comparative Study to Evaluate the Safety and Efficacy of XXXX versus Linezolid in the Outpatient Treatment of Adult Patients with Uncomplicated Skin and Skin Structure Infections

Proctor & Gamble Pharmaceuticals

A multi-center, Investigator-blinded, randomized, 12-month, parallel group, non-inferiority study to compare the efficacy of 1.6 to 2.4g XXXX therapy QD versus divided dose (BID) in the maintenance of remission of ulcerative colitis

Cerexa Inc.

A Phase 2, multi-center, randomized, open-label, comparative study to evaluate the safety and efficacy of XXXX versus Linezolid in the outpatient treatment of adult patients with uncomplicated skin and skin structure infection

Genentech Inc.

An open-label, prospective study of the safety of XXXX in combination with other disease-modifying anti-rheumatic drugs in subjects with active Rheumatoid Arthritis

Cerexa Inc.

A Phase 3 multi-center, randomized, double-blind, comparative study to evaluate the safety and efficacy of XXXX versus Vancomycin plus Aztreonam in adult subjects with cSSSI

Cubist Pharmaceuticals

A Phase 2 multi-center, randomized, semi-single blind study to compare the efficacy and safety of high dose, short duration XXXX with that of conventional therapy in the treatment of patients with cSSSI due to gram-positive bacteria

Theravance Inc.

A Phase 2, randomized, double-blind study of intravenous XXXX versus Vancomycin for treatment of complicated gram-positive skin and skin structure infections

Salix Pharmaceuticals

A double-blind, randomized, controlled trial of XXXX compared to Vancomycin for the treatment of Clostridium Difficile associated diarrhea

Theravance Inc.

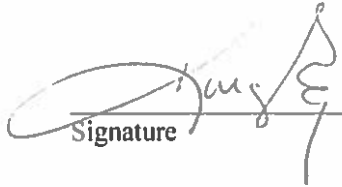
A Phase 3, randomized, double-blind, multi-national trial of intravenous XXXX versus Vancomycin for treatment of complicated gram-positive skin and skin structure infections with a focus on patients with infections due to Methicillin-resistant *Staphylococcus Aureus*

Aventis Pharmaceuticals

A multi-national, multi-center, randomized, double-blind study in areas of high pneumococcal resistance comparing the clinical efficacy and health outcomes of outpatients with mild to moderate Community-Acquired Pneumonia (CAP) treated with either XXXX once daily for 7 days or XXXX once daily for 5 days

PROFESSIONAL SKILLS AND INTERESTS:

Entrepreneurship, Data analysis, Leadership, Business strategy

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Signature

19 Sept 2017
_____ Date