

## **ROBERT SCOTT KAUFMANN, M. D., F. A. C. P.**

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### **EDUCATION**

1982 – 1986 Medical: Morehouse School of Medicine, Atlanta, Georgia, Degree: M. D.  
1981 Undergraduate: University of Georgia, Athens, GA Degree: B. S. in Psychology

### **TRAINING**

1986 – 1987 Internship: Emory University, Atlanta, GA  
1987 – 1989 Residency: Emory University, Atlanta, GA

### **MEDICAL EXPERIENCE**

1989 – Present Physician/ Principal Investigator - Internal Medicine, The Kaufmann Clinic, Inc., Atlanta, GA  
The Kaufmann Clinic, Inc. 2001 Professional Way, Suite 220 Woodstock, GA 30188

1998 – 2009 Principal Investigator, Georgia Clinical Research, (formerly Radiant Research-Atlanta West, formerly Southeast Research Associates/Protocare), Atlanta & Austell, GA

### **CERTIFICATION AND LICENSURE**

1989 American Board of Internal Medicine, Number: 127262

**LICENSURE:** State of Georgia - Physician  
License Number: 030115

### **PROFESSIONAL AND ACADEMIC APPOINTMENTS**

1994 - Present Emory University School of Medicine-Preceptor for Nurse Practitioners  
1993 - Present Medical College of Georgia-Physician Assistant Students  
1992 - Present Emory University-Third Year Medical Students (Clinical Methods)  
1993 - Present Emory University School of Medicine, Clinical Assistant Professor of Medicine  
1990 - 1992 Emory University-Second Year Medical Students (Clinical Methods)

### **INSTITUTIONAL AFFILIATIONS**

Crawford Long Hospital of Emory University  
Piedmont Hospital

### **VOLUNTEER ORGANIZATIONS**

2000-Present Executive Board Member of the Alzheimer's Association  
2000-Present Executive Board Member of NAACP, Atlanta Chapter  
1996 Assistant Medical Officer, Atlanta Committee, for the Olympic Games/Boxing Venue  
1996 Volunteer Physicians for Atlanta Paralympic Committee

1996 American Heart Association Cardiac Arrest Event  
 1994 - Present Executive Board Member of the Carrie Steele-Pitts Home  
 1990 - Present Mercy Mobile, Volunteer Physicians

### **PROFESSIONAL ORGANIZATIONS**

1997 - 2001 Medical Director of the Mann House  
 1996 - 2000 Medical Director, Integrated Health Systems of Buckhead  
 1996 - 1997 Vice President, Crawford Long Hospital of the Emory University System of Health Care  
 1996 - 1998 Medical Director, Ansley Pavillion Nursing Home  
 1996 - 1998 Medical Director, American Medical Response  
 1994 - 1997 Medical Executive Committee, Crawford Long Hospital  
 1994 - Present Pharmacy and therapeutics Committee, Crawford Long Hospital  
 1993 - Present Southern Medical Association  
 1993 - 1998 Atlanta Clinical Society  
 1993 Emergency Care Committee, Crawford Long Hospital  
 1993 - 1994 Case Management Committee for UTI, CVA, MI, U & F Crawford Long Hospital  
 1993 - 1994 Medical Record Committee, Crawford Long Hospital  
 1992 - 1994 Governing Board Member, Brawner Hospital  
 1992 - 1994 Medical Executive Committee, Psychiatric Institute of Atlanta  
 1992 Who's Who Among Rising Young Americans  
 1990 - Present American Society of Internal Medicine  
 1990 - Present Fellow of American College of Physicians  
 1990 - Present Mamoides Society, Jewish Federation  
 1989 - 1991 Utilization Review Committee, Crawford Long Hospital  
 1989 - Present Medical Association of Atlanta  
 1989 - Present Medical Association of Georgia  
 1989 - Present American Medical Association

### **CLINICAL RESEARCH EXPERIENCE**

1. A dose-ranging study evaluating the efficacy, safety and tolerability of XXXX in the prophylactic treatment of migraine headache (207294)  
 Principal Investigator: Robert S. Kaufmann, MD
2. An 18-Week Randomized, Double-Blind, Multicenter, Comparator Study of Two Doses of Oral HDV-Insulin and Placebo with Background Metformin Treatment in Patients with Type 2 Diabetes Mellitus (207293)  
 Principal Investigator: Robert S. Kaufmann, MD
3. A Randomized, Double-Blind, Parallel Group, Active Controlled, Multi-center Long-term Study to Assess the Safety and Efficacy of the Beta-3 Agonist XXX(50 mg qd and 100 mg qd) in Subjects with Symptoms of Overactive Bladder (207292)  
 Principal Investigator: Robert S. Kaufmann, MD
4. A Phase III, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multicenter Study to Assess the Efficacy and Safety of the Beta-3 Agonist XXX in Subjects with Symptoms of Overactive Bladder (207291)  
 Principal Investigator: Robert S. Kaufmann, MD

5. An 8 week prospective, Multi-Center, Randomized, Double-Blind, Active Control, Parallel Group Study to Evaluate and Efficacy & Safety of XXX versus XXX in African American Patients with Stage 2 Hypertension. (207290)  
Principal Investigator: Robert S. Kaufmann, MD
6. A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety In Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing Celecoxib With Naproxen and Ibuprofen. (207340)  
Principal Investigator: Robert S. Kaufmann, MD
7. A 16 week multi-center, randomized, double-blind study to evaluate efficacy and safety of XXX combination therapy compared to patients initiated with XXX or hydrochlorothiazide monotherapy in very elderly patients with essential hypertension (207288)  
Principal Investigator: Robert S. Kaufmann, MD
8. Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Center Study Evaluating the Efficacy of XXX and Celecoxib 200 mg QD in Patients with Osteoarthritis of the Knee (207284)  
Principal Investigator: Robert S. Kaufmann, MD
9. A 16-Week, Phase 1, Multicenter, Double-Blind, Randomized, Naproxen and Ibuprofen-controlled, Parallel-Group Pharmacological study, to Assess the Effect of Naproxinod (375 mg and 750 mg, bid) compared to equimolar doses of Naproxen (250mg and 500 mg, bid) and to Ibuprofen (600mg, tid) on Arterial Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Osteoarthritis Patients with Controlled Essential Hypertension (207278)  
Principal Investigator: Robert S. Kaufmann, MD
10. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX in Black Subjects with Essential Hypertension (207271)  
Principal Investigator: Robert S. Kaufmann, MD
11. The Efficacy and Safety of XXX in the Treatment of Osteoarthritis of the Knee: Pivotal Study I (207266)  
Principal Investigator: Robert S. Kaufmann, MD
12. A rapid onset and short duration insulin secretagogue, mitiglinide, in combination with metformin versus metformin alone in patients with Type 2 diabetes mellitus: A Randomized, Double-Blind, Placebo-Controlled trial for 6 months. (207265)  
Principal Investigator: Robert S. Kaufmann, MD
13. A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Crossover Study to Evaluate the Efficacy of Trexima™ (Sumatriptan + Naproxen Sodium) versus XXX containing medications XXX for the Acute Treatment of Migraine when administered during the Moderate-Severe Pain Phase of the Migraine (Study 1 of 2) (207263)  
Principal Investigator: Robert S. Kaufmann, MD
14. A One-Year Phase 3, Open-Label Study to Evaluate the Safety and Tolerability of TAK-491 in Subjects with Essential Hypertension. (207261)  
Principal Investigator: Robert S. Kaufmann, MD

15. A Phase 3, 53 Weeks Study on Analgesic Efficacy and Safety of XXX: 26-Week, Randomized, Parallel-Group, Double-Blind, Placebo (13 Weeks)- and Naproxen (26 Weeks)- Controlled, Multicenter Study of XXX (375 mg bid and 750 mg bid) with a 26-Week Naproxen-Controlled Safety Follow-up in Subjects with Osteoarthritis of the Knee, and a 1-Week Post-treatment Safety Follow-up. (207260)  
Principal Investigator: Robert S. Kaufmann, MD
16. A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Two Doses of XXX Sustained Release (SR)/XXX Sustained Release (SR) and Placebo in Obese Subjects (207256)  
Principal Investigator: Robert S. Kaufmann, MD
17. A Phase II, Multicenter, Randomized, Double-Mask, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intramuscular XXX in Subjects with Uncomplicated Acute Influenza (207255)  
Principal Investigator: Robert S. Kaufmann, MD
18. A Phase III Randomized, Evaluator-Blind, Parallel Group Study of the Safety and Efficacy of XXX Tablets, XXX Capsules and Placebo in the Treatment of Onychomycosis of the Toenail (207252)  
Principal Investigator: Robert S. Kaufmann, MD
19. A randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and tolerability of TREXIMA™ (sumatriptan succinate/naproxen sodium) for a single moderate or severe headache in adults diagnosed with probable migraine without aura (207094)  
Principal Investigator: Robert S. Kaufmann, MD
20. Multicenter, randomized, double-blind titration study to evaluate and compare the efficacy and safety of XXX added on to XXX40 mg versus up titration to XXX 80 mg in Hypercholesterolemic patients at high risk for coronary heart disease not adequately controlled on XXX 40 mg. (207089)  
Principal Investigator: Robert S. Kaufmann, MD
21. A Phase II, Randomized, Double-Blind, Placebo-controlled, Proof of Concept, Efficacy and Safety Study of XXX and Naproxen in Treating the Signs and Symptoms of Osteoarthritis of the Knee (206910)  
Principal Investigator: Robert S. Kaufmann, MD
22. A Parallel, Randomized, Open-Label, Multi-Center, 52-Week Follow-up Study of XXXX (375 mg bid and 750 mg bid) in Subjects with Osteoarthritis of the Knee (Follow-up of the 13-Week, Double-Blind, Parallel, Randomized Placebo- and Naproxen-Controlled XXXX Efficacy and Safety Study. (206886)  
Principal Investigator: Robert S. Kaufmann, MD
23. A Phase 2, Double-Blind, Randomized, Placebo-Controlled Dose-Ranging Study of the Efficacy, Safety and Tolerability of XXX in Subjects With Mild to Moderate Uncomplicated Essential Hypertension (206865)  
Principal Investigator: Robert S. Kaufmann, MD.
24. Patient outcome with education, drug therapy, and support (POETS): A multicenter, open label randomized study to evaluate depressed subjects treated with Venlafaxine™ extended

release vs Venlafaxine™ extended plus the dialog time to talk program in a primary care setting. (206762)

Principal Investigator: Robert S. Kaufmann, MD

25. A Phase III, multi-center, randomized, double-blind, placebo-controlled, parallel group trial of fourteen day treatment with XXXX 15 mg once a day in frequent heartburn (206687)  
Principal Investigator: Robert S. Kaufmann, MD
26. A randomized, double-blind, active-controlled, vehicle-controlled, subject initiated study comparing efficacy and safety of XXX versus acyclovir cream for treatment of recurrent herpes simplex labialis (206690)  
Principal Investigator: Robert S. Kaufmann, MD
27. A double-blind, randomized, parallel-group, dose ranging, multicenter study to evaluate the efficacy and safety of 2.5, 10, 35, and 50 mg XXX once daily, using 100 mg XXX once daily as calibrator, for 12 months treatment, in patients with mild to moderate hypertension (206248)  
Principal Investigator: Robert S. Kaufmann, MD
28. A Long-Term, Open-Label, Safety Extension Study of the Combination of Fenofibric Acid and Statin Therapy for Subjects with Mixed Dyslipidemia (206221)  
Principal Investigator: Robert S. Kaufmann, MD
29. A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXX and XXX Combination Therapy to XXX and XXX Monotherapy in Subjects with Mixed Dyslipidemia 205743  
Principal Investigator: Robert S. Kaufmann, MD
30. A Phase 3 study of the Analgesic Efficacy and Safety of XXX: a Parallel, Randomized, Double-Blind, 13-week Placebo- and Naproxen-Controlled, Multicenter Study of XXX (375 mg bid and 750 mg bid) in Patients with Osteoarthritis of the Knee (205708)  
Principal Investigator: Robert S. Kaufmann, MD
31. A randomized, double-blind, multi-center, placebo-controlled, cross-over study to determine the consistency of response for XXX administered during the mild pain phase for the acute treatment of multiple migraine attacks (205603)  
Principal Investigator: Robert S. Kaufmann, MD
32. Randomized, double-blind trial of XXX 350 mg and 250 mg tablets compared to placebo in patients with Acute, Painful Musculoskeletal Spasm of the Lower Back (#205717)  
Principal Investigator: Robert S. Kaufmann, MD
33. An open-label, randomized study evaluating the long-term effects of XXX versus XXX as monotherapy or in combination with XXX or XXX for the treatment of patients with hypertension (#206108)  
Principal Investigator: Robert S. Kaufmann, MD
34. An 8-week randomized, double-blind, parallel group, multi-center, placebo and active controlled dose escalation study to evaluate the efficacy and safety of XXX (150 mg and 300 mg) administered alone and in combination with XXX (160 mg and 320 mg) in patients with

hypertension (205280)

Principal Investigator: Robert S. Kaufmann, MD

35. A placebo-controlled, randomized, double-blind, Fixed-Dose, at-home study to evaluate the efficacy and safety of intranasally administered XXX in Subjects with Erectile Dysfunction and Diabetes Mellitus (#205337)  
Principal Investigator: Robert S. Kaufmann, MD
36. A placebo-controlled, randomized, double-blind, fixed-dose, at-home study to evaluate the Efficacy and Safety of intranasally Administered XXX in Subjects with Erectile Dysfunction (#203781)  
Principal Investigator: Robert S. Kaufmann, MD.
37. A randomized, multicenter, double-blind, placebo-controlled study to assess the safety and efficacy of XXX in subjects with muscle strain. (#205117)  
Principal Investigator: Robert S. Kaufmann, MD
38. An 8-week, multi-center, randomized, double-blind, placebo-controlled, parallel group trial of XXX Sodium Gel 1% in patients with primary osteoarthritis of the hand. (#205017)  
Principal Investigator: Robert S. Kaufmann, MD
39. A randomized, double-blind, placebo controlled, parallel-group study of the efficacy, safety and tolerability of XXX in patients with generalized anxiety disorder. (#205059)  
Principal Investigator: Robert S. Kaufmann, MD
40. A Double-blind, Randomized, Placebo- and Active-controlled, Forced Titration Study Evaluating the effects of XXX on Blood Pressure and Heart Rate in African American Patients with Hypertension. (#204693)  
Principal Investigator: Robert S. Kaufmann, MD
41. A 13-week, multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel group trial of XXX in patients with primary hip osteoarthritis using XXX as a positive control. (#203505)  
Principal Investigator: Robert S. Kaufmann, MD
42. The Efficacy and Safety of XXXX Combination Therapy as First Line Treatment for Severe Hypertension (#204322)  
Principal Investigator: Robert S. Kaufmann, M.D.
43. The Efficacy and Safety of XXXX Combination Therapy as First Line Treatment for Patients with Moderate Hypertension (#204428)  
Principal Investigator: Robert S. Kaufmann, MD
44. An uncontrolled long-term safety trial of XXXX, 1% in patients with O.A. of the Knee (#204830)  
Principal Investigator: Robert S. Kaufmann, MD
45. A Randomized, Double-blind, Parallel Group, Placebo-controlled, Single-attack Evaluation of the Efficacy and Tolerability of XXXX Tablets vs Placebo When Administered During the Mild Pain Phase of a Migraine. (#204736)  
Principal Investigator: Robert S. Kaufmann, MD

46. A Randomized, Double-Blind, Placebo-Controlled Study Evaluating XXXX Extended Release (3900 mg/day) in the Treatment of Osteoarthritis of the Hip or Knee. (#203319)  
Principal Investigator: Robert S. Kaufmann, MD
  
47. A prospective, multinational, multicenter, double-blind, randomized, active-controlled trial to compare the effects of XXXX to XXXX and XXXX combined on the reduction of cardiovascular morbidity and mortality in patients with high risk hypertension – ACCOMPLISH (Avoiding Cardiovascular Events through Combination Therapy in Patients Living with Systolic Hypertension) (#202832)  
Principal Investigator: Robert S. Kaufmann, MD
  
48. A 12 week randomized double-blind multicenter vehicle controlled parallel group study to assess the efficacy and safety of XXXX for the relief of signs and symptoms in patients with O.A. of the knee. (#204458)  
Principal Investigator: Robert S. Kaufmann, MD
  
49. A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of XXXX in Patients 18 - 70 Years of Age with Symptoms of Overactive Bladder (#203870)  
Principal Investigator: Robert S. Kaufmann, MD
  
50. A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of XXXX in Patients with Osteoarthritis or Rheumatoid Arthritis (#201465)  
Principal Investigator: Robert S. Kaufmann, MD
  
51. A phase III open label study randomized allopurinol-controlled study to assess the long term safety of XXXX in subjects with gout (#202413)  
Principal Investigator: Robert S. Kaufmann, MD
  
52. The Efficacy and Safety of XXXX Combination Therapy as First Line Treatment for Severe Hypertension (#204322)  
Principal Investigator: Robert S. Kaufmann, MD.
  
53. The Safety, Tolerability, and Immunogenicity of XXXX Smallpox Vaccine in Adults Without Previous Smallpox Vaccination. A Randomized, Double-Blind, Fixed Dose, Phase 3 Comparison Between XXXX 2000 and XXXX Smallpox Vaccine. (#201873)  
Sub-Investigator: Robert S. Kaufmann, M.D.
  
54. The Safety, Tolerability, and Immunogenicity of XXXX Smallpox Vaccine in Adults with Previous Smallpox Vaccination. A Randomized, Double-Blind, Fixed Dose, Phase 3 Comparison Between XXXX and XXXX Smallpox Vaccines. (#203095)  
Sub-Investigator: Robert S. Kaufmann, M.D.
  
55. A 26 –week, Double-Blind, Randomized, Multi-Center, Phase IIIB, Parallel Group Study to Compare the Efficacy and Safety of XXXX (40mg) with XXXX (80mg) in Subjects with Hypercholesterolaemia and Coronary Heart Disease or CHD Risk Equivalents (#202322)  
Principal Investigator: Robert S. Kaufmann, M.D.

56. A Randomized, Double-Blind, Placebo-Controlled Study Evaluating XXXX Extended Release (3900 mg/day) in the Treatment of Osteoarthritis of the Hip or Knee. (#203399)  
Principal Investigator: Robert S. Kaufmann, M.D.
57. A Randomized, Controlled Study of XXXX (250 mcg and 500 mcg) versus Placebo in XXXX Randomized, Controlled Study of XXXX (250 mcg and 500 mcg) versus Placebo in Patients with Asthma. (#203122)  
Principal Investigator: Robert S. Kaufmann, M.D.
58. A Phase IIIB, Multi-Center, Double-Blind Clinical Study to Evaluate the Safety and Tolerability of XXXX, Ultra-Lo Following a Run-In of XXXX Extended Regimen Oral Contraceptive Therapy. (#201784)  
Principal Investigator: Robert S. Kaufmann, M.D.
59. Symptom Specific Effectiveness of XXXX 4 mg in Patients with Symptoms of Overactive Bladder (OAB) in a Primary Care Setting. A Phase IV, Open –Label, Single Arm, Non-Randomized Trial in Adult Patients with OAB. (#203272)  
Principal Investigator: Robert S. Kaufmann, M.D.
60. A Prospective, Multi-national, Multi-Center, Double-Blind, Randomized, Active-Controlled Trial to Compare the Effects of XXXX to XXXX and XXXX Combined on the Reduction of Cardiovascular Morbidity and Mortality in Patients with High Risk Hypertension. (#202832)  
Principal Investigator: Robert S. Kaufmann, M.D.
61. An Open-Label, Long-Term, Phase 3 Trial of the Safety and Efficacy of XXXX in Male Subjects with Erectile Dysfunction. (#203292)  
Principal Investigator: Robert S. Kaufmann, M.D.
62. A Randomized, Placebo-Controlled, Double-Blind Parallel Design Phase 3 Bridging Trial of the Efficacy and Safety of XXXX 300mcg in Male Subjects with Erectile Dysfunction.  
Principal Investigator: Robert S. Kaufmann, M.D.
63. A Multi-Center, Randomized, Double-Blind, Double-Dummy Comparative Trial of XXXX Versus XXXX Extended Release for the Treatment of Mild to Moderate Community-Acquired Pneumonia in Adults. (#201623)  
Principal Investigator: Robert S. Kaufmann, M.D.
64. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXX in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties (#4889x1)  
Principal Investigator: Robert S. Kaufmann, M.D.
65. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties (#4889)  
Principal Investigator: Robert S. Kaufmann, M.D.
66. A Randomized, Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of XXXX vs. XXXX in the Treatment of Acute Gouty Arthritis  
Principal Investigator: Robert S. Kaufmann, M.D. (#4778)



67. A Phase III Randomized, Multicenter Study Comparing the Safety and Efficacy of XXXX versus XXXX in Subjects with Gout (#4630)  
Principal Investigator: Robert S. Kaufmann, M.D.
68. A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of XXXX in Patients with Osteoarthritis or Rheumatoid Arthritis  
Principal Investigator: Robert S. Kaufmann, M.D. (#4536)
69. A randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and tolerability of oral XXXX 25mg, 50mg, and 100mg tablets for a single moderate or severe headache in adults diagnosed with migrainous disorder (IHS 1.7)  
Principal Investigator: Robert S. Kaufmann, M.D. (#4488)
70. An Open-Label, Parallel Design, Twelve Month Phase 3 Trial of the Safety and Efficacy of XXXX in Male Patients with Erectile Dysfunction (#4453)  
Principal Investigator: Robert S. Kaufmann, M.D.
71. A Randomized, Placebo-Controlled, Double-Blind, Parallel Design Phase 3 Trial Of The Efficacy And Safety Of XXXX In Male Patients With Erectile Dysfunction (#4357)  
Principal Investigator: Robert S. Kaufmann, M.D.
72. A Randomized, Double-Blind, Placebo-Controlled, Single-Attack, Parallel-Group Evaluation of the Efficacy of XXXX 50mg Tablets versus Placebo in the Treatment of Self-Described and/or Physician-Diagnosed Sinus Headaches that Meet International Headache Society (IHS) Criteria for Migraine Headache (#4147)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: April 2002
73. Systolic and Pulse Pressure Hemodynamic Improvement By Restoring Elasticity: The SAPPHIRE Study (#3783)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2001
74. A Phase III, Double-Blind, Randomized, Placebo Controlled Study of XXXX in Severely Obese Subjects (#3696a1)  
Principal Investigator: Robert S. Kaufmann, M.D.
75. A Randomized, Double-Blind, Placebo-Controlled, Forced Titration Study of Ascending Doses of XXXX, XXXX and XXXX in Patients with Essential Hypertension (#3668)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: July 2002
76. Double-Blind, Placebo and Active Controlled Study of Sustained Release XXXX In Subjects with Symptoms of Overactive Bladder of Urgency, Frequency and Urinary Incontinence (#3641)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2001
77. The Efficacy and Safety of 5 Days Oral XXXX Versus 10 Days Oral XXXX in the Treatment of Acute Exacerbation of Chronic Bronchitis (AECB) (#3628)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: June 2002
78. An Open-Label Continuation Trial of XXXX (Topical Gel Formulation of XXXX and XXXX) in Male ED Patients Who Previously Participated in XXXX (#3601x1)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: March 2002

79. A Randomized, Double-Blind, Placebo-Controlled, Dose Finding Study of XXXX (Topical Gel Formulation of XXXX and XXXX) for the Treatment of Male Erectile Dysfunction in an At-Home Setting (#3601)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2001
80. A Randomized, Double-Blind, Placebo-Controlled and Open-Label Twelve Month Study of the Safety of XXXX in Adult Subjects with Insomnia (#3572a1)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: September 2002
81. A Randomized, Multicenter, Double-Blind, Placebo Controlled Study of the Iontophoretic Administration of XXXX in the Treatment of patients with Epicondylitis (#3499a1)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: June 2001
82. Prospective, Randomized, Double-Blind Study Comparing XXXX with XXXX in the Treatment of Patients with Acute, Uncomplicated Lower Urinary Tract Infections (#3473)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: April 2002
83. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Lipid-Altering Efficacy, Safety, and Tolerability of XXXX When Added to Ongoing Therapy with an HMG-CoA Reductase Inhibitor (XXXX) in Patients with Primary Hypercholesterolemia, Known Heart Disease or Multiple Cardiovascular Risk Factors .(#3452)  
Principal Investigator: Robert S. Kaufmann, M.D Completed: September 2002
84. Prospective, Randomized, Double-Blind Study Comparing XXXX with XXXX in the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis (#3405a1)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2001
85. An Open-Label, Randomized, Rater-Blinded Study to Compare Rate of Remission in Patients with Major Depressive Disorder Treated with XXXX Versus Selective Serotonin Reuptake Inhibitors Using Treatment Algorithms (#3368)  
Principal Investigator: Robert S. Kaufmann, M.D.
86. Phase III Study: Comparative Study of the Safety and Efficacy of Two Oral Doses of XXXX for the Treatment of Community-Acquired Pneumonia (#3366)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: February 2002
87. XXXX Cardiovascular Treatment Assessment Versus XXXX (#3268)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2001
88. Phase III Study: A Comparative Study of the Safety and Efficacy of XXXX and XXXX for the Treatment of Subjects with Acute Bacterial Exacerbation of Chronic Bronchitis  
Principal Investigator: Robert S. Kaufmann, M.D. (#2986a2) Completed: February 2002
89. A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multicenter, Flexible Dose Study to Evaluate the Efficacy and Safety of XXXX in Males with Erectile Dysfunction and Arterial Hypertension Who Are Taking Multiple Antihypertensive Treatment (#2770)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: December 2000
90. A Double-Blind, Randomized, Placebo-Controlled Trial of a Tablet Formulation of XXXX in the Treatment of Viral Respiratory Infection in Adults (#2732)  
Principal Investigator: Robert S. Kaufmann, M.D. Completed: August 2001

91. A Randomized, Double-Blind Study to Compare the Durability of Glucose Lowering and Preservation of Pancreatic Beta-Cell Function of XXXX, Compared to XXXX or XXXX/XXXX in Patients with Drug Naïve, Recently Diagnosed Type 2 Diabetes Mellitus ( $\leq$  2 Years) (#2550)  
Principal Investigator: Robert S. Kaufmann, M.D.                      Completed: May 2002
92. Long-Term, Open Label, Safety and Tolerability Study of XXXX in Subjects with Primary Hypercholesterolemia (#2524x1)  
Principal Investigator: Robert S. Kaufmann, M.D.                      Completed: December 2002
93. A Six Week Trial of XXXX as Empirical Therapy in Female Subjects with Symptoms of Diarrhea Predominant Irritable Bowel Syndrome  
Principal Investigator: Robert S. Kaufmann, M.D.
94. Clinical Protocol for a Double-Blind, Randomized, Parallel Group Comparison Study of the Safety of XXXX vs. XXXX in Hypertensive Patients with Peripheral Osteoarthritis Taking Antihypertensive Medications  
Principal Investigator: Robert S. Kaufmann, M.D.
95. Prospective, Randomized, Double-Blind, Multi-Center Comparison of the Safety and Efficacy of XXXX Versus XXXX for Seven Days in the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis  
Principal Investigator: Robert S. Kaufmann, M.D.
96. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Study to Investigate the Efficacy and Safety of Inhaled XXXX in the Treatment of Symptomatic Influenza A and B Viral Infections in Subjects Aged  $\geq$ 65 Years  
Principal Investigator: Robert S. Kaufmann, M.D.
97. A Randomized, Double-Blind, Double-Dummy, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Oral XXXX Versus Oral XXXX in the Treatment of Adults with Bacterial Community Acquired Pneumonia  
Principal Investigator: Robert S. Kaufmann, M.D.
98. A Randomized, Double-Blind, Double-Dummy, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Oral XXXX Versus Oral XXXX in the Treatment of Acute Exacerbation of Chronic Bronchitis  
Principal Investigator: Robert S. Kaufmann, M.D.
99. A Phase III Double-Blind Efficacy and Safety Study of One Dose of XXXX Compared to Placebo in Subjects with Primary Hypercholesterolemia  
Principal Investigator: Robert S. Kaufmann, M.D.
100. A Randomized, Placebo-Controlled, Parallel Group (with Subject Option for Treatment Switch), Double-Blind Study (with Open Label Treatment Extension) to Evaluate the Efficacy and Safety of XXXX in Black Americans with Erectile Dysfunction  
Principal Investigator: Robert S. Kaufmann, M.D.

101. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Study to Investigate the Efficacy and Safety of Inhaled XXXX in the Treatment of Influenza in Patients 12 Years or Over Diagnosed with Asthma or Chronic Obstructive Pulmonary Disease  
Principal Investigator: Robert S. Kaufmann, M.D.
102. A Clinical Study To Evaluate The Bioequivalence Of Two Formulations Of XXXX XXXX Cream In The Treatment Of Tinea Pedis (Athlete's Foot)  
Principal Investigator: Robert S. Kaufmann, M.D.
103. Prospective, Randomized, Double-Blind, Multi-Center Comparison of the Safety and Efficacy of XXXX Versus XXXX in the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis  
Principal Investigator: Robert S. Kaufmann, M.D.
104. A Double-Blind, Placebo-Controlled, Randomized Trial to Determine the Effects of a Range of Doses of XXXX Oral Dose Form (Biphasic Tablet) Administered Either Once or Twice a Day in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercise  
Principal Investigator: Robert S. Kaufmann, M.D.
105. A Study of the Relative Clinical Efficacy of Two XXXX Vaginal Ointment Products: A Bioequivalence Study  
Principal Investigator: Robert S. Kaufmann, M.D.
106. A Randomized, Double-Blind, Double-Dummy, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Oral XXXX Versus Oral XXXX in the Treatment of Bacterial Community Acquired Pneumonia (CAP) in Adults  
Principal Investigator: Robert S. Kaufmann, M.D.
107. A Randomized, Double-Blind, Placebo-Controlled 12-Week Extension Study to Assess the Safety and Tolerability of XXXX in Patients with Non-Cancer- Related Pain and Opioid-Induced Constipation (OIC)  
Principal Investigator: Robert S. Kaufmann, MD
108. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)  
Principal Investigator: Robert S. Kaufmann, MD
109. A Multi-Center Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXXX and XXXX in Subjects with Gout and Cardiovascular Comorbidities.  
Principal Investigator: Robert S. Kaufmann, MD
110. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Long-Term XXXX Treatment for the Prevention of Gout Flares.  
Principal Investigator: Robert S. Kaufmann, MD

