

## **CHERYL M. DUGGAN, C.C.T.**

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### **PROFESSIONAL EXPERIENCE**

Ms. Duggan joined SNBL in July 2006 as the Director of Clinical Operations. Ms. Duggan is currently responsible for over 50 clinical staff and oversees the conduct and successful completion of every clinical trial performed at SNBL. Prior to SNBL, Ms. Duggan held the position of Site Director at Radiant Research in Florida where she oversaw Phase I – III clinical trials to ensure smooth daily operations. Ms. Duggan’s experience includes over 16 years of Phase I – III research and she has conducted over 200 clinical trials.

July 2006 – present

**SNBL Clinical Pharmacology Center, Inc., Maryland**

Director of Operations

February 2002 - July 2006

**Radiant Research, Inc., Georgia and Florida**

Site Director Phase I-IV

August 2000 – February 2002

**Peninsular Testing Corporation, Florida**

Director of Clinical Operations-Phase I

November 1996 – August 2000

**Clinical Studies LTD, Florida**

Clinical Research Manager, Oncology Research

Associate Director- Phase I Unit

Manager of Phase I Operation

Clinical Research Coordinator

November 1992 – August 1996

**South Florida Bioavailability Clinic, FL**

Clinic Manager-Phase I

February 1990 – November 1992

**Amerifirst Federal Savings and Loan, Florida**

Customer Service Officer

January 1986 – December 1989

**United States Army, Texas**

Aviation Systems Repairer

## **EDUCATION & TRAINING**

2005 – Present

**Bachelors of Arts**, Clayton State University, Morrow, GA

1990 - 1992

**Cardiographic Technician**, Barna College, Ft Lauderdale, FL

1984-1986

**Associate in Arts**, Broward Community College, Davie, FL

## **CERTIFICATIONS & PROFESSIONAL LICENSURE**

- Certified Cardiographic Technician (CCT)
- BLS

## **PROFESSIONAL AFFILIATIONS & MEMBERSHIPS**

- Association of Clinical Research Professionals

## **RESEARCH EXPERIENCE**

### **2009**

- A Phase 1 Double-Blind, placebo-controlled, single-center dose escalation study to evaluate the safety and tolerability and pharmacokinetics of intramuscular administration of a new oxime
- A Phase I, Double-blind Crossover Study of the Acute Tolerability of Immediate Extended Administration of Methotrexate in Normal Healthy Volunteers.
- A Longitudinal Study in healthy Adult Volunteers Aged 18 to 85 Years to Describe Antibody Levels to Antigens Expressed by Staphylococcus aureus and  $\beta$ -Hemolytic Streptococci Species, and to Describe Carriage of These Bacteria
- A Phase 2a Randomized, Double Blind, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of a Trivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine (recombinant) in Healthy Adults

### **2008**

- An open label, single dose, randomized, active controlled, two-period, two-sequence crossover pharmacokinetics study to assess the bioequivalence of the XXXX, a XXXX transdermal formulation versus Emsam 12mg/ day after a single dose in healthy volunteers.
- A phase 1 open label placebo controlled multiple dose study to evaluate the pharmacokinetics of XXXX for injection dosed twice and three times daily in healthy subjects.
- A Randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- A Phase I, Open Label, PET Study in Healthy Subjects Following a Single Oral Dose of XXXX

- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Schizophrenia.
- A placebo-controlled, ascending multiple-dose study to evaluate the safety and pharmacokinetics of XXXX in healthy subjects.
- An Open-Label Formulation Screening Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of a Single Dose and Multiple Doses of Delayed Release XXXX in Healthy Subjects.
- A randomized, open-label study to assess the effect of ketoconazole on XXXX pharmacokinetics and pharmacodynamics.
- A Randomized, Double-Blind, Sequential, Ascending Multiple Dose, Placebo Controlled, Parallel Group Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXXX in Healthy Young Male Subjects.
- A Randomized, Double-Blind, Placebo Controlled Vaccination-Challenge Study of XXXX to Determine Efficacy Against the Symptoms of Moderate to Severe *Campylobacter jejuni* Infection in Normal Healthy Volunteers.
- Single dose pharmacokinetics and safety/tolerability of two formulations of XXXX transdermal systems compared to oral XXXX in healthy volunteers
- An open-label study to assess the effect of XXXX inducers on XXXX pharmacokinetics and pharmacodynamics
- Additional cohort - A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A Three Part Study In Healthy Males and Females Assessing the Relative Bioavailability and Food Effect of Two Formulations of XXXX, the Estimated Bioavailability of XXXX, The Single and Repeat Dose Safety, Tolerability and Pharmacokinetics of Escalating Dose
- A randomized, Double-Blind, Placebo-Controlled Parallel Study to Evaluate the Effects of Estrogen on Estrogen Receptor Biomarkers in Healthy Postmenopausal Women.
- An open-label Phase I multiple dose trial to assess the safety, tolerability and efficacy of capsules containing cross-linked polyelectrolyte giving to ESRD patient.
- A 2-Period, 2-Panel, Double-Blind, Randomized, Placebo-Controlled Pilot Study of Experimental Models for the Assessment of the Perception of Potentially Injurious Heat in Household Settings After the Administration of XXXX in Healthy Subjects
- A Double-Blind, Randomized, Placebo-Controlled, 5-Arm Titration Study to Evaluate the Efficacy and Safety of XXXX When Compared With Valsartan and Olmesartan in Subjects with Essential Hypertension
- A Double-Blind, Placebo-Controlled, Randomized, Single and Multiple Rising Dose, Safety, Tolerability and Pharmacokinetic Study of XXXX When Administered to Normal Healthy Adult Volunteers
- A multiple-center, single-ascending dose, randomized, observer-blinded, placebo-controlled, study to investigate the safety, tolerability, and pharmacokinetics of XXXX following intravenous administration in individuals with allergic rhinitis.
- A Phase II Dose Finding Study with XXXX in Subjects with Recurrent Episodes of Genital Herpes
- An open label, randomized assessment of the relative bioavailability of a single dose of XXXX administered as a 15mg tablet, one 5 mg tablet or five 1 mg tablets compared with the 15 mg capsule and the effect of a high fat meal on the bioavailability of
- An open-label, dose escalating study to evaluate the safety of intravaginal oxybutynin in subjects with urge urinary incontinence

## 2007

- A placebo-controlled, ascending single-dose study to evaluate the safety and pharmacokinetics of XXXX in healthy subjects.
- An open-label, multiple-dose interaction study between XXXX and Metformin or Probenecid in healthy adult subjects.

- An open label, randomized assessment of the relative bioavailability of a single dose of XXXX administered as a 15mg tablet, one 5 mg tablet or five 1 mg tablets compared with the 15 mg capsule and the effect of a high fat meal on the bioavailability of the 15 mg tablet.
- A phase I open-label, single ascending dose study of the safety, nasal tolerability and pharmacokinetics of XXXX intranasal granisetron delivered by XXXX in healthy volunteers.
- A phase I, double-blinded study to evaluate the safety, tolerability, and immunogenicity of Pandemic Influenza plasmid DNA vaccines administered with the XXXX needle-free System.
- A two-period, open-label, randomized, crossover study to compare the steady state bioavailability of a Hhydrocodone/Deschlorpheniramine Polistirex extended-release suspension and a Hydrocodone Bitartrate/Dexchlorpheniramine Maleate immediate-release reference formulation healthy volunteers
- An in vivo Positron Emission Tomography study of the PDE4 Enzyme Occupancy by AVE8112 using XXXX in Healthy Subjects
- Randomized, single-center, open-label, 2-way crossover, 2-arm study with 3 treatments and 2 periods lasting 7 days each, minimum 7 day washout to determine the relative bioavailability of two XXXX Transdermal systems and to assess the wear characteristics of these systems
- Blood draw to obtain the PBMC layer of cells from whole blood from MS patients
- An in vivo Positron Emission Tomography study of the XXXX in healthy subjects, in patients with Alzheimer's Disease and in patients with Schizophrenia
- A Phase I, double-blind, placebo-controlled, randomized study to assess the safety, tolerability and pharmacokinetics of single escalating doses of XXX in healthy volunteers
- An open-label, non-randomized, one sequence, multi-center study to assess the effects of an oral contraceptive on the pharmacokinetics of XXXX in healthy female subjects
- A Pilot Single-Dose Study of the pharmacokinetics of two XXXX Fentanyl Transdermal Systems Compared to XXXX in Healthy Subjects.
- A Phase 1B, randomized, placebo-controlled clinical trial to study the safety and efficacy of xxx in Hepatitis C infected patients.
- Single-dose, randomized, three-period cross over design study of the XXXX compared with the XXXX.
- A randomized, double-blind, Phase III study of the efficacy and safety to XXXX in subjects requiring NSAID treatment.
- A Randomized, Double-Blind, Multiple-Site, Placebo Controlled, Parallel Design, Clinical Study to Evaluate the Bioequivalence of XXXX Compared to XXXX in Patients with Moderate to Severe Acne Vulgaris.
- A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Repeat-Dose Study to Determine the Safety, Pharmacokinetic Effects, and Efficacy of XXXX in Patients with Hypercholesterolemia.
- A phase I study, assessing the pharmacokinetics of two formulations of Oxycodone and XXX compared with Oxycodone XXX consumed after chewing and with Oxycontin.
- A phase I study to evaluate the safety, tolerability and immunogenicity of the pandemic influenza vaccines XXXX and XXXX.
- A Phase II randomized, placebo-controlled clinical trial to study the safety and efficacy of XXXX in hepatitis C infected patients.
- Phase IIIa, 26 week, open-label, multi-center, randomized, parallel trial to investigate efficacy and safety of inhaled mealtime insulin with the XXXX plus XXXX versus XXXX in Type 2 Diabetes
- A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study Evaluating Pharmacokinetics and Safety of Anthrax Immune Globulin Intravenous (AIGIV).
- Single Dose Pharmacokinetics and Safety/Tolerability of Pramipexole Transdermal Systems Compared to Oral Pramipexole in Healthy Volunteers
- A Prospective, Multi-center Trial of XXXX Compared to Best Standard of Care in Patients with Progressive or Recurrent GBM.

- Efficacy and safety of 2 mg/day of XXXX on Sleep Maintenance Insomnia with a sub-study of the effect of XXXX on stable Type II Diabetes Mellitus: a one year, multi center, randomized, double-blind, placebo-controlled study.
- Multi-center, randomized, double-blind active controlled, parallel group study to investigate plasma folate, red blood cell folate and homocysteine levels during a 24 week oral administration of an OC containing folate compared to OC alone
- A 52-Week, Randomized, Double-Blind, Parallel-group, Multi-center, Phase IIIB Study Comparing the Long-term Safety of XXXX Actuations Twice Daily to XXXX Actuations Twice Daily in Adult and Adolescent African American Subjects with Asthma
- A 10 week Multicenter, randomized, double-blind, parallel-group, forced titration study using 24 hour ABPM to evaluate the efficacy of XXXX treatment regimen versus conventional treatment regimen with XXXX in patients with stage 2 hypertension
- A Multicenter, randomized, double-blind study to compare the efficacy and safety of patient-initiated XXXX to XXXX in immunocompetent adults with recurrent genital herpes
- A randomized, Double-Blind, Active-and Placebo-Controlled, Parallel- Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of XXXX Immediate-Release Formulation in Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease
- Analysis of protein or RNA Levels of the Glutamate Transporters, XXXX

## 2006

- The Relative Bioavailability of Two Amphetamine Transdermal Systems (ATS) to xxxx 10 mg Orally Administered Capsule
- Analysis of protein or RNA Levels of the Glutamate Transporters, xxxx
- Phase I, double blind, placebo-controlled single center trial to assess the safety, tolerability and pharmacokinetics of single dose and multiple dose escalations of XXX in healthy subjects.
- A Randomized, Double-Blind, Placebo-Controlled, Forced Titration Phase IV Study Comparing XXX 80mg + XXX23mg versus XXX 160mg + XXX 25 mg Taken Orally for Eight Weeks in Patients with Stage 1 or Stage 2 Hypertension
- A Double-Blind, Multi-Center, Randomized, Placebo-Controlled Study of Safety and Efficacy of XXX 60 mg Modified Release Capsules Versus Placebo, Once Daily for 12 Weeks followed by a 9 Month, Open-Label Treatment Phase In Patients with Overactive Bladder
- A Phase III, Open Label, Multi-Center, Randomized, Parallel Group Study of the Efficacy and Safety of Fixed Combination XXX/XXX Administered Once Daily (QD) Compared to Fixed Combination XXX/XXX for 6 Weeks in Subjects with Dyslipidemia

## 2005

- 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
- A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy of XXX Influenza Vaccine in Healthy Adults 18 to 49 Years of Age
- A Non-Inferiority Comparison of XXX Influenza Virus Vaccine to a US Licensed Inactivated Split-Virion Vaccine (XXX) in Adults > 50 Years Old Living in the Community
- A Randomized Double-Blind, Multi-Center, Placebo-Controlled, Cross Over Study to determine the Consistency of Response for XXX (XXX, 8 5mg/XXX 500mg) administered during the Mild Pain Phase for the Acute Treatment of Multiple Migraine Attacks
- A Multi-center, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Efficacy of XXX in Subjects with CIAS 1 Associated Periodic Syndromes (CAPS) using both Parallel Group and Randomized Withdrawal Designs

- A Pilot Multi-Center, Double-Blind, Placebo-Controlled Comparison of Multiple Doses of Esterified Estrogens and XXX, in Combination and Alone, in Relieving Vasomotor Symptoms in Postmenopausal Women
- Phase III, Open, Randomized, Study to Compare a New Prophylactic vaccine for Japanese Encephalitis vs. XXX in healthy volunteers (comparator study)
- A Multi-Center, Placebo Controlled, Randomized, Double Blind, Subject Initiated Study of the Safety and Efficacy of a Single Topical Iontophoretic Application of XXX 5% Cream with an Open Label Conventional Therapy Treatment Arm, and a Blinded Evaluator, for the Episodic Treatment of Recurrent Herpes Labialis
- A 4-Week Randomized, Multi-center, Double-blind, Placebo-and Active- controlled, Parallel-group, Forced-titration Phase IIB Study Comparing Efficacy and Safety of Ascending Doses of XXX Prolonged Release up to 233 mg BID and XXX Prolonged Release up to 20 mg BID to XXX in Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee
- Safety of Topical Use of XXX in Humans: Determination of Clinical Responses and Serum Level of XXX

## 2004

- A Multi-Center, Open-Label Long-Term Safety Trial of XXX in the Treatment of Acne Vulgaris
- A Multiple-Dose, Dose-Escalation Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Obese Men and Women
- A Multi-Center, Active-Controlled, Double-Blind, Randomized, Sequential Escalating Dose Study to Assess Safety, Pharmacokinetics and Efficacy of 100, 150, and X mg Oral XXX Administered Monthly for Six Months in Postmenopausal Women with Low Bone Mineral Density
- An Open Label, Multiple Dose Study to Evaluate the Pharmacokinetic Drug-Drug Interaction between XXX and XXX when Given Alone or in Combination to Healthy Volunteers
- The Relative Bioavailability of Two Formulations of XXX Compared to Twice Weekly Application of XXX
- A 12 Month, Randomized, Open-Label, Multicenter, Study to Assess the Long Term Safety of XXX Alone and XXX Alone or with Optional Addition of XXX in Patients with Essential Hypertension
- A Study to Evaluate the Potential Effect of a Medium-Fat Meal on the Relative Bioavailability of Multiple Doses of XXX and XXX in Healthy Postmenopausal Women
- A 6-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study, to Assess the Efficacy and Safety of XXX and XXX in Female Patients with Dyspepsia
- Effects of XXX on Vertebral Fracture Incidence and on Invasive Breast Cancer Incidence in Postmenopausal Women with Osteoporosis or with Low Bone Density without Osteoporosis
- A Randomized, Open-Label Study Comparing the Efficacy and Safety of XXX to XXX in Patients with Pain from Osteoarthritis of the Knee
- An Open-Label, Multiple Dose, Randomized, Three-Period, Crossover Study in Healthy Volunteers to Evaluate the Pharmacokinetics of XXX and XXX when Co-Administered and Administered Alone
- A Randomized, Double-Blind, Placebo- and Positive-Controlled Phase 2A Study to Evaluate the Effect of Various Doses of XXX on Food Intake in Obese Subjects
- A Multi-Center Study to Determine the Exposure to Cigarette Smoke of Adult U.S. Smokers who Spontaneously Switched to Lower or Higher FTC Tar Delivery Cigarettes

## 2003

- A Randomized, Partly Blinded, Multi-center, Parallel Study Comparing the Efficacy and Safety of XXX at 0.5 mg QD, 1.0mg QD, 1.0mg BID, 2.0 mg BID and XXX at 400 meg BID in Adolescents (12 Years of Age and Older) and Adults with Moderate to Severe Asthma
- A Randomized, Double-Blind, Placebo Controlled Trial of XXX in Premenopausal Women with 50% to SO% Density in Brest Tissue Based on Digitized Analysis of Screening Mammography

- XXX Excellence in Therapeutic Response and Activity Assessing Syriptom Relief in Urinary Tract Infections
- A Multi-center, Randomized, Double-Blind, Parallel-Group, Placbo Control, Clinical Evaluation of XXX in Combination with XXX compared to XXX Plus Placebo for 24 Weeks in Subjects with Type 2
- Diabetes Mellitus who are Inadequately Controlled on Non-TZD Oral Monotherapy
- A Open-Label, Randomized Study of the Efficacy and Safety of an XXX Compared to Commercially Available Metronidazole Oral Tablets in the Treatment of Bacterial Vaginosis
- A Randomized, Double-Blind, Multi-center, Multifactorial, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of XXX and XXX combined and Alone in Hypertensive Patients
- A Phase III, Randomized, Multi-center, XXX and Placebo-Controlled Study Assessing the Safety and Efficacy of Oral XXX in Subjects with Gout
- A Phase III, Open-Label Study to Assess the Long-Term Safety of Oral XXX in Subjects with Gout
- Substituting XXX for a XXX VS. a Third Oral Agent as Add-On Therapy in Patients Failing a Thiazolidinedione and Sulfonylurea for Glucophage Combination: A Multi-center, Controlled, Randomized, Open Label Study
- Randomized, Blinded, Placebo-controlled, Single-dose Study to Evaluate the Pharmacokinetics and Pharmacodynamics of XXX in Healthy Postmenopausal Women
- Replicate Design, Double-blind, Randomized, Placebo Controlled Tolerance and Pharmacokinetics Study of XXX in Normal, Healthy Volunteers
- Pharmacokinetics and Bioavailability Comparison of Immediate Release and Enteric Coated XXX — A Double-Blind, Single Dose Crossover Phase I Study in Normal Volunteers

## 2002

- BMS, Lipid Lowering Efficacy and Safety of XXX alone and in combination with xxx in subjects with mixed Dyslipidemia
- A 16-Week, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose, Parallel Group, Multi-center Study with a Withdrawal Phase to Investigate the Safety and Efficacy of xxx in Female Patients with Constipation-Predominant Irritable Bowel Syndrome
- Phase III, 1 2-Month, Double Blind, Randomized, Parallel Group, Placebo Controlled, Efficacy and Safety Study of xxx in Overweight and Obese Subjects with a 12-Month Open-Label Extension Phase
- A Two-Part, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Clinical Trial of xxx in Patients with Moderate to Severe Plaque Psoriasis
- A Phase IIB Randomized, Double-Blind, Placebo-Controlled Study of The Effect Of xxx Rheumatoid Arthritis (RA) Patients With Active Disease Despite Receiving xxx or xxx
- A Phase II study on Analgesic Efficacy, Safety, and Tolerability of xxx: a six week, randomized, double-blind, placebo-controlled, dose-finding, multi-center study comparing xxx with xxx and with xxx in subjects with osteoarthritis of the knee
- A Phase I, Double-blind, Placebo-controlled Study Evaluating the Safety, Pharmacokinetics, and Pharmacodynamics of Single and Multiple Subcutaneous Administrations of Human Monoclonal Antibody to Human xxx in Patients with Rheumatoid Arthritis
- A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study of xxx in Type 2 Diabetic Patients
- Phase III Study: A Long Term Safety and Efficacy Study of xxx in Subjects with Acne Vulgaris
- A Randomized, Double Blind, Placebo Controlled Study to Evaluate the Safety and Activity of xxx in Patients with Active Rheumatoid Arthritis
- A Double-Blind, Parallel, Placebo-Controlled, Randomized, 2-Segment Study to Assess the Safety, Tolerability, and Pharmacokinetics of xxx in Patients with Rheumatoid Arthritis
- Analgesic Efficacy of xxx versus xxx in Opioid Naïve, Chronic Pain Patients

- An Evaluation of the Ability of xxx to Reduce the Daily xxx Requirement and Limit the Escalation of the Daily xxx Dose in Order to Maintain the Same Degree of Pain Control over three months in Chronic Pain Patients with Osteoarthritis
- A Multi-center Dose Randomized Double-Blind Placebo-Controlled Study of the Human xxx Monoclonal Antibody xxx Administered in Patients with Active Rheumatoid Arthritis
- Multi-Center Continuation Study of the Human xxx Antibody xxx Administered as a Subcutaneous Injection in Patients with Rheumatoid Arthritis
- Clinical Protocol for a Double-Blind, Randomized Three Arm, Two Period, Crossover Study to Compare xxx, and xxx in Patients with Osteoarthritis of the Hip or Knee.
- A Phase I, Double-blind, Placebo-controlled Study Evaluating the Safety and Pharmacology of Single Subcutaneous Administrations of Human Monoclonal Antibody to xxx in Subjects with Moderate to Severe Psoriasis Vulgaris
- A Phase II, Randomized, Triple-Blind, Placebo-Controlled, Short-Term, Dose-Response Study to Examine the Effect on Glucose Control and Tolerability of xxx given Two Times a Day in Subjects With Type 2 Diabetes Mellitus
- A randomized, double blind, placebo controlled, period balanced, two part, three period cross over drug interaction study of xxx and xxx in healthy males aged 45 to 75 to evaluate changes in blood pressure
- A Phase III Randomized, Multi-center Study Comparing the Safety and Efficacy of xxx versus xxx in Subjects with Gout
- A Phase II, Double-Blind, Placebo-Controlled, Nerve Sorbitol Effect, Dose Ranging, Safety, and Pharmacokinetic Study of xxx Administered for tip to 26 Weeks in Patients with Diabetic Neuropathy
- A Multi-center, Double-Blind, Randomized, Parallel Study Comparing the Efficacy and Safety of xxx, xxx, and Placebo in Subjects with Perennial Allergic Rhinitis
- A Double-Blind, Multi-Center, Randomized, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of xxx added to Existing xxx Treatment in Patients with Mild to Moderate Hypertension
- A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke
- A Multi-center, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of an Oral Contraceptive Preparation, Containing xxx for 6 Treatment Cycles in Women with Mild to Moderate Acne Vulgaris
- A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of xxx in Patients with Osteoarthritis or Rheumatoid Arthritis

## 1999

- A Double-Blind, Randomized, Parallel-Group, Two-Arm, Placebo-Controlled, Multi-center Evaluation of xxx Anti-Idiotypic Antibody in the Management of Patients with Stage IV Colon or Rectal Carcinomas Receiving xxx Plus xxx
- A Phase II Study of the Efficacy and Tolerability of xxx in Patients with Metastatic Colorectal or Pancreatic Cancer
- Phase III Randomized Study of RFS 2000 (xxx) verses xxx xxx in Chemonaive Pancreatic Cancer Patients
- Phase III Randomized Study of RFS 2000 (xxx) versus xxx (xxx) in Pancreatic Cancer Patients that have Progressive Disease following Gemcitabine HC1 Treatment
- Phase III Study of FRS 2000 (xxx) Versus Most Appropriate Therapy in Refractory Pancreatic Cancer Patients
- A Phase II Study of the Efficacy and Tolerability of xxx in the Treatment of Metastatic Breast Cancer
- A Randomized, Double-Blind, Placebo Controlled, Phase III Study of The Matrix Metalloprotease Inhibitor AG3340 in Combination with xxx and xxx with Provision for Subsequent Change in Therapy in Patients Having Metastatic, Hormone-Refractory Prostate Cancer

- A Randomized, Double-Blind, Placebo Controlled, Phase III Study of The Matrix Metalloprotease Inhibitor AG3340 in Combination with xxx and xxx in patients having Metastatic or Recurrent Non-Small Cell Lung Cancer
- Phase III Study of xxx Plus xxx versus xxx in Patients with Unresectable, Locally Recurrent or Metastatic Breast Cancer
- A Double-Blind, Randomized, Multi-center Trial Comparing the Efficacy and Tolerability of 250mg of xxxTM (xxx) with 20mg of xxxTM (xxx) in Postmenopausal Women with Advanced Breast Cancer
- A Multiple-Dose Study of the Pharmacokinetics of xxxxl xxxx (xxxx®) in Patients with Moderately to Severely Impaired Renal Function and in Subjects with Normal Renal Function.
- A Multiple Ascending Dose Pharmacokinetic and Safety Study of xxx in Healthy, Post-Menopausal Women.
- Comparison of Once-Daily xxxx and Once-Daily xxxx Insulin Treatment in Type 2 Diabetic Patients: A Multi-Center, Open-label, Randomized, Parallel Study.
- The Comparative Bioequivalence Of xxxx® 750mg and XXXXTM 750 Mg Core Tablets Manufactured at two Sites.
- A Single-Blind, Placebo Controlled Crossover Study to Evaluate the Safety, Tolerability and Effects of Multiple Doses of xxxx given by the Subcutaneous Route to subjects having Type 2 Diabetes Mellitus.
- The Pharmacokinetics and Pharmacodynamics of xxxx Oral Syrup in Healthy Young and Elderly Adults.
- An Open Label Study of the Safety of xxxx® [Iron Sucrose Injection] in Patients with Anaphylactoid Reactions to Iron Dextran.
- A Single-Blind, Rising Dose, Placebo Controlled study to evaluate the safety, tolerability and effects of multiple doses of xxxx given by the subcutaneous route to subjects with Type 2 Diabetes Mellitus.
- Bioavailability and Dose Proportionality of xxxxTM Tablets in Healthy Female Volunteers.
- An Ascending Dose Pharmacokinetic and Safety Study of xxxx in Healthy, Post-Menopausal Women.

## 1998

- A Phase II/III, Open Label Study of the Safety and Efficacy of xxxx® [Iron Sucrose Injection] in Patients with Dialysis-Associated Anemia.
- A Study to Evaluate the Time-Dependency of Food Effect on the Pharmacokinetics of xxx x-MG Tablet.
- Study of xxx® xxx Performance in Actual Home Environments of Subjects with Diabetes Mellitus.
- A Randomized Open-Label Three Treatment Crossover Pharmacokinetic Study in Healthy Male Volunteer to Assess the Dose Proportionality of Three Registration Lots of a New Formulation of xxxx Under Fasted Conditions.
- The Evaluation of the Single Dose Fasting Pharmacokinetics of Two Formulations of xxxx Capsules vs. xxxx® ER Capsules in Healthy Volunteers — A Pilot Study.
- The Evaluation of the Wear Properties of xxxx xxxx vs. xxxx xxxx® in Healthy Volunteers
- A Home-Simulated Study of xxxx® xxxx Function Over a 39-Hour Time Period in Subjects with Diabetes Mellitus.
- A Phase I Study to assess the Bioavailability of xxxx Tablets (5mg) relative to Solution. Pharmacokinetics of xxxx in subjects with Normal or Impaired Renal Function.
- Study of xxxx© Monitor Performance in Actual Home Environments in Subjects with Diabetes Mellitus.
- A Home-Simulated Study of xxxx® xxxx Function Over a 38-Hour Time Period in Subjects with Diabetes Mellitus.

- A Randomized, Double-Blind, Placebo-Controlled, Three-Period Crossover Study to Compare the Pharmacodynamic Effects of xxxx, xxxx and xxxx in Type 2 Diabetic Subjects in the Event of a Missed Lunch Time Meal and Missed Dose of xxxx.
- A Double-Blind, Randomized, Placebo-Controlled, Ascending, MultiDose, Safety and Tolerance Study of xxxx in Healthy, Postmenopausal Women.
- Assessment of Renal Effects of xxxx Alone or in Combination with xxxx or Continuous Combined xxxx Replacement Therapy.
- A Single Dose, Open Label, Parallel Group Study to Determine the Pharmacokinetics of xxxx in NIDDM Subjects with Severe Renal Insufficiency Compared with Age, Sex, Height and Weight-Matched Healthy Subjects.
- A Randomized, Single Dose, Parallel, Blinded Study to Characterize the Pharmacokinetics and Pharmacokinetic-Pharmacodynamic Relationship of xxxx use during Hemodialysis in Patients with Chronic Renal Failure.
- A Randomized, Partially-Blinded, Placebo-Controlled, Fixed Sequence Study to Examine the Safety, Tolerability, Biochemical Activity, and Pharmacokinetics of Combinations of xxxx and xxxx.
- Phase I Open Study to Compare the Bioavailability of Two Tablet Formulations of xxxx After Single Dose Administration to Healthy, Postmenopausal, and Female Subjects.
- A Pilot Study of the Comparative Bioavailability of a xxxx and xxxx Combination Tablet versus Coadministration of xxxx and xxxx.
- A Pharmacokinetic Drug Interaction Study of xxxx and xxxx in Healthy Young Subjects.
- Study of xxxx Function as Compared to Capillary Blood Samples Measured on A xxxx over a Time Period in Subjects with xxxx.
- A Multi-center, Randomized, Double-Blind, xxxx and Placebo-Controlled, Study of xxxx in the Treatment of Mild to Moderate Hypertension.
- Phase I, Open-Label, Crossover Study to Determine the Bioequivalence of xxxx to xxxx in Healthy Subjects.
- A Double-Blind, Placebo-Controlled, Safety and Tolerance Study of Ascending Single Oral Doses of xxxx in Healthy Post-Menopausal Women.
- A Single-dose, Open Label, Bioequivalence Study Comparing xxxx as an Oral Solution with xxxx as a Tablet in Human Volunteers.
- A Multi-center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate xxxx in Patients with Possible or Probable Alzheimer's Disease of Mild to Moderate Severity.
- A 2-Period, Balanced, Multiple-Dose, Crossover Study in Healthy Young Subjects to Establish the Bioequivalence of Tablet and Encapsulated Tablet Formulations of xxxx.
- Evaluation of the Effect of xxxx on the Pharmacokinetics of a Single Oral Dose of xxxx in Healthy Postmenopausal Women.
- An Open-Label Study of the Effects of Diurnal Variation on the Pharmacokinetic Disposition of a Single-Dose of xxxx in Healthy Volunteers.
- A Single Dose, Pharmacokinetic Study of xxxx in Young and Elderly Subjects.
- A Pharmacokinetic and Tolerability Evaluation of Continuous Subcutaneous Infusions of xxxx with the xxxx a Standard Infusion Pump and xxxx Controlled-Release Tablets (xxxx).
- A Phase II, open-label, crossover, comparative pharmacokinetic study in male and female patients administered with a single oral dose of xxxx both during a moderate to severe migraine attack and outside a migraine attack.
- The Comparative Bioequivalence of Two xxxx Batches Manufactured at Two Different Sites Representing Two Different Batch Sizes.

## 1997

- The Comparative Bioequivalence of Two xxxx Batches Manufactured at Two Different Sites Representing Two Different Batch Sizes.
- The Single-Dose Bioequivalence of an Extended-Release xxxx Formulation Relative to xxxx

- A Partially Open-Label, Three-Part, Randomized, Crossover Study to Investigate the Influence of Altered xxxx Activity on xxxx Pharmacokinetics and of xxxx on xxxx Activity in Healthy Subjects. Investigation of the Pharmacokinetic Effect of Multiple Doses of xxxx on a Single Oral Dose of xxxx.
- Investigation of the Pharmacokinetic Effect of Multiple Doses of xxxx on a Single Oral Dose of xxxx.
- Phase I Open-Label, Crossover Study to Determine the Bioequivalence of xxxx to xxxx and xxxx in Healthy Subjects.
- Investigation of the Safety and Single Dose Pharmacokinetics of xxxx in Elderly Postmenopausal Women.
- Phase I, Double-Blind, Placebo Controlled Evaluation of the Safety, Toleration, Pharmacokinetics of xxxx in Healthy, Elderly Volunteers.
- A Single-Dose, Relative Bioavailability Study of a 7-Day, xxxx at Three Different Application Sites in Healthy, 1-lysterectomized, Post-menopausal Women.
- The Single-Dose Bioavailability of Three Extended-Release xxxx-xxxxxxx Formulations of Different Excipient Ratios, Relative to xxxx.
- Study of the Potential Pharmacokinetic Interaction between xxxx and xxxx.
- A Multi-Center, Randomized, Double Blind Study in Normal Healthy Subjects to Evaluate the Efficacy and Safety of Both a Two Dose, One Month Regimen of xxxx and a Three Dose, Six Month Regimen of xxxx Compared to a Standard Three Dose, Six Month Regimen of xxxx.
- A Pilot Four-Way Crossover, Single-Dose, Open-Labeled, Bioequivalence Study of xxxx Tablets in Normal Healthy Male Volunteers with and without food.
- A Phase II Study to Evaluate Safety, Efficacy and Pharmacokinetics of a Single Dose and Multiple Doses of xxxx with xxxx in Healthy Subjects.
- The Effect of Oral Calcium Supplements on the Absorption Pharmacokinetics of xxxx in Healthy Post-Menopausal Women.
- A Multiple-Dose, Pharmacokinetic Study of xxxx, and xxxx/xxxx Combination Transdermal Delivery System Administered in a Sequential Dosing Regimen in Healthy, Postmenopausal Women.
- Investigation of the Relative Bioavailability of Two Different Tablet Formulations of xxxx in Healthy Post-Menopausal Women.
- Pharmacokinetics and Safety of xxxx in Normal Healthy Volunteers. A Double-Blind, Placebo-Controlled, Ascending Dose Study.
- A Multi-center, Double-Blind, Placebo-Controlled, Randomized, Parallel Group Study to Evaluate the Safety and Absorption Profile of a Single Oral Dose of xxxx in Migraine Patients During an Attack.
- A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-center Dose-Range-Finding Study to Assess the Efficacy, Tolerability and Safety of xxxx (Administered as a Single Dose) in the Treatment of Acute Migraine.
- A Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Assess the Cardiovascular Safety of xxxx in Patients Suffering From an Acute Migraine Episode.
- A Randomized, Comparative, Multi-center, Safety and Contraceptive Efficacy Study of Two xxxx/xxxx Regimens, and One xxxx/xxxx Regimen (xxxx) and xxxx.
- A Randomized, Crossover, Pharmacokinetic/Pharmacodynamic Study of xxxx TDS 25 rig/hr Single Dose to Determine the Relative Bioavailability from Different Body Regions in Healthy Adult Volunteers.
- A Single Dose, Four-Treatment, Pharmacokinetic/Pharmacodynamic Comparison Study of Two Once-A-Day Controlled-Release xxxx Tablet Formulations and xxxx Tablets in Fasted Normal Volunteers.

- Investigation of the Relative Bioavailability of Two Different Tablet Formulations of xxxx in Healthy Post-Menopausal Women.
- A Multiple-Dose, Pharmacokinetic Study of a 3 V2 Day 17-xxxx/xxxx-Only and a 3 V2 Day 1 713-xxxx/xxxx Combination Transdermal Delivery System Administered in a Sequential Dosing Regimen in Healthy, Postmenopausal Women.

## 1996

- A Single-Dose, Comparative, Bioavailability Study of a Single Combination-Tablet Formulation (0.625mg/i 0mg) vs a xxxx Tablet (0.625mg) and a xxxx Capsule (1 0mg) Administered Concomitantly.
- A Double-Blind, Placebo-Controlled, Randomized, Parallel Group Evaluation of the Efficacy of xxxx, xxxx, and xxxx in the Prevention of Nausea and Emesis Induced by xxxx.
- A Single Dose, Four-Treatment, Pharmacokinetic/Pharmacodynamic Comparison Study of Two Once-A-Day Controlled-Release 200mg xxxx Tablet Formulations and xxxx 100mg Tablets in Fasted Normal Volunteers.
- A Randomized, Crossover, Pharmacokinetic/Pharmacodynamic Study of xxxx 25 JLg/hr Single Dose to Determine the Relative Bioavailability From Different Body Regions In Healthy Adult Volunteers.
- Pharmacokinetics and Safety of xxxx in Normal Healthy Volunteers. A Double-Blind, Placebo-Controlled, Ascending Dose Study.

## 1995

- A Double-Blind, Placebo-Controlled, Two-Panel and Multiple Oral Dose Studies of xxxx in the Healthy Elderly (with Extension).
- A Comparison of Bioavailability of Three xxxx Controlled-Release Tablet Formulation with and Immediate Release Tablet Formulation.
- A Study Evaluating the Drug Interaction Potential of xxxx and xxxx.
- Phase I Study to Determine the Bioequivalence of a Commercial Dosage Formulation of xxxx in Healthy Male Subjects.
- Phase I Observer-Blind, Placebo-Controlled, Parallel Group Study Evaluating the Effect of xxxx on the Steady State Pharmacokinetics of xxxx in Healthy Subjects.
- Study to Determine the Bioequivalence of a Sugar-Coated Tablet Formulation Containing 50mcg xxxx and 30mcg xxxx Relative to the Wyeth-Ayerst Manufactured Sugar-Coated xxxx Tablets Containing the Same Amounts of xxxx and xxxx.
- Two Week, Multi-center, Double-Blind, Parallel Placebo and xxxx (10, 30, 100mcg qid) Study of Plasma Glucose Profiles and Pharmacokinetics in Subjects with Juvenile-Onset Diabetes Mellitus.
- A Comparative Bioavailability Study of a xxxx Tablet (0.625mg) and a xxxx Encapsulated Tablet (2.5mg) Administered Concomitantly vs a Single Combination Tablet Formulation.
- A Double-Blind, Placebo-Controlled, Two-Way Crossover Study to Evaluate the Action of xxxx in Glyburide Treated Adult Volunteers with Insulin Dependent Diabetes Mellitus.
- Multiple Dose Interaction Study of xxxx (50mg qd) with xxxx (50 and 100mg qd) or xxxx (20 and 30mg qd) in Healthy Adult Volunteers.
- Study to Assess the Potential Interaction of xxxx and xxxx in Healthy Male Volunteers.

## 1994

- To Determine the Concentrations of xxxx and xxxx in Sural Nerve Tissue in Relation to Plasma Concentrations of xxxx and xxxx After Dosing to Steady State with xxxx in Male and Female Patients Diagnosed with Either Non-Insulin Dependent or Insulin Dependent Diabetes Mellitus.
- A Comparative Multiple Dose Pharmacokinetic/Pharmacodynamic Study of xxxx and xxxx in Mild to Moderate Hypertensive Subjects.
- A Double-Blind, Randomized, Placebo-Controlled, 4 Period Crossover Pharmacodynamic and Safety Study of xxxx in Normal Subjects.

- A Placebo-Controlled Trial to Assess the Safety, Tolerance and Pharmacokinetics of Ascending Oral Doses of xxxx in Patient/Volunteers to Explore the Safety and Kinetic Profile of xxxx in Subjects with Ischaemic Heart Disease on Single and Multiple Dosing.
- Double-Blind, Randomized Dose Acceleration Efficacy and Tolerance Study of xxxx vs Placebo in Patients with Mild to Moderate Primary Hypertension.
- A Double-Blind, Multiple Dose, Randomized, Placebo-Controlled, Parallel Group Hemodynamic Drug Interaction Study Between xxxx and xxxx in Male Patients with Essential Hypertension.
- The Effect of Grapefruit Juice on the Pharmacokinetic of xxxx in Normal Volunteers.
- Bioequivalence Study of 4mg xxxx Tablets and Capsules.
- Determination of Bioequivalence Under Fasted Conditions of xxxx Tablets Manufactured by Searle at Two Sites.
- A Comparative of Bioequivalence Study of xxxx 2 x 25mg Tablets Ground and Encapsulated vs xxxx 2 x 25mg Tablets in Healthy Men.
- A Randomized, Open Label, Cross-Over Study Comparing the Pharmacokinetic Properties of Liquid and Lyophilized xxxx Given both Intravenously and Subcutaneously to Normal Healthy Male Volunteers.

### 1993

- A Multiple Dose Study to Determine the Interaction xxxx with xxxx in Young Healthy Males.
- A Single Dose Bioequivalency Study of Two Lots 20mg xxxx Research Tablets and One Lot 20mg xxxx Commercial Tablet in Young Healthy Males.
- An Open Label, Interaction Study Between a Single Dose of xxxx and Multiple Dose of xxxx on the Cardiac Function and Pharmacokinetic Profile in Healthy Adult Male Volunteers.
- A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Safety, Tolerance and Pharmacokinetic Study of xxxx Administered as an Oral Solution in Adult Mild to Moderate Hypertensive Patients for Two Weeks.
- Study of the Effect of Food on the Pharmacokinetics of xxxx (0.625mg) Tablets and xxxx (2.5mg) Tablets Administered Concomitantly in Healthy Postmenopausal Female Subjects.
- Oral Safety, Toleration and the Dose Proportionality of xxxx at Steady State in Male and Female Patients Diagnosed with Non Insulin Dependent Diabetes Mellitus.

### 1992

- Oral Safety, Toleration and the Dose Proportionality of xxxx at Steady State in Male and Female Patients Diagnosed with Insulin Dependent Diabetes Mellitus.
- Bioavailability Interaction of xxxx After Co-Administration with xxxx and xxxx in Normal Healthy Males.
- Ascending Single Dose Safety, Tolerance and Preliminary Pharmacokinetic Study of xxxx Capsules in Normal Male Subjects.
- A Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose Safety, Tolerance, and Pharmacokinetic Study of xxxx Administered as an Oral 300mg Solution in Adult Mild to Moderate Hypertensive Patients for Two Weeks.
- A Multiple Dose Bioequivalency Study of the 20mg xxxx Commercial Tablets (Vacaville) vs the 20mg xxxx Research Tablet (Mountainview) in Subjects with Non Insulin Dependent Diabetes Mellitus.
- A Single Center, Randomized, Open, Parallel, Placebo-Controlled Efficiency Study of Trough Serum Potassium Level with 40meq xxxx in Single or Divided Doses in Hypertensive Patients Predisposed to Diuretic Induced Hypokalemia.
- Evaluation of the Pharmacokinetics of a Single 2 x 60mg Dose of xxxx in Subjects with Varying Degrees of Renal Impairment.
- A Pharmacokinetics Evaluation of xxxx and xxxx Administration in Postmenopausal Females.
- A Controlled Clinical Trial Comparing xxxx 10-12.5 and xxxx 10-25 (xxxx/xxxx) to each of the Monocomponents and Placebo on the Treatment of Mild to Moderate Essential Hypertension.

- A Four-Way Cross-Over, Replicate Design, Pharmacokinetic Comparison of Marketed Sustained Release xxxx Products Under Steady State Conditions in Young, Healthy Male Volunteers.
- Pharmacokinetics and Tolerance of xxxx Tablets in a Two-Way Cross-Over Comparison of Morning vs Evening Administration.
- Single Rising Dose Pharmacokinetics/Toleration Study of xxxx Formulation in Healthy Male Volunteers.
- A Study Evaluating the Interaction Potential of xxxx and xxxx Following Multiple Dosing.
- A Pharmacokinetic Study evaluating the Interaction Potential of xxxx and xxxx.
- Phase I Study to Assess the Affect of Concomitant xxxx Therapy on the Plasma Concentrations and Electrocardiogram Effects of xxxx.
- Follow-up Study on the Effect of Renal Impairment on xxxx Pharmacokinetics.
- A Pharmacokinetic Study Evaluating the Interaction Potential of xxxx 2 x 60mg qd and xxxx 500mg qid Following Multiple Dosing.
- Pilot multiple Dose Pharmacokinetics/Toleration Study of xxxx Formulation in J-Healthy Male Volunteers.
- Bioequivalence Study of 3 Lots of xxxx Tablets.
- A Placebo-Controlled, Double-Blind, Parallel Group, Cardiac Safety and Pharmacokinetic Study of Ascending Doses of xxxx in Healthy Male Volunteers.
- An Open-Label, Replicate Design, Randomized, Four-Way Cross-Over Pharmacokinetic and Pharmacodynamic Comparison of Single and Multiple Dose xxxx vs Generic Extend Release xxxx.