

STEPHAN A. BART SR., M.D.

PROFESSIONAL EXPERIENCE

June 2006 - Present

SNBL Clinical Pharmacology Center, Inc., Maryland

Medical Director

- Administrative functions entailed in medical directorship
- Function as the Principal Investigator for Clinical Research Studies.
- Adherence to Good Clinical Practices (GCP), and SNBL-CPC's Standard Operating Procedures (SOPs).
- Administers Informed Consent, explains protocol procedures and discusses study details to participant
- Conduct Physical Exams in study participants.
- Monitors and documents all participant's adverse events, medical condition and response to study medications and treatments.
- Ensures that all protocol guidelines are met.
- Administers study medications.
- Lead all staff members involved in the participant's care.
- Arranges for additional pre/post laboratory work or procedures as needed.
- Manage research physician staff and extenders to include RN's, CCRC's, and RA's.

June 2005 - June 2006

Blair Medical Associates, Pennsylvania

Medical Director Clinical Research, Medical Director Urgent Care
Facilities

- Began development of Phase I capabilities
- Directed phase II –IV research studies
- Directed Urgent Care Unit
- Responded to emergency situations

July 2001 - June 2005

Radiant Research, Florida

Medical Director of Clinical Research

- Directed phase I – III research facility
- Managed staff of physicians and physician extenders
- Interfaced with pharmaceutical companies and regulatory authorities

July 1995 – Present

Steven A. Bart Sr. MD, Florida

Physician, Family Medicine

- President, American Family Practice Associates
- Multi-physician, full scope, primary care practice

**EDUCATION &
TRAINING**

1993 – 1995

Residency, Department of Family Medicine, University of South Florida, Bay Front Medical Center

1992 – 1993

Internship, Department of Family Medicine, University of South Florida, Bay Front Medical Center

1991 – 1992

Post Graduate Elective Courses, University of Pittsburgh

1988 – 1992

Doctor of Medicine, Rush Medical College, Chicago, IL

1984 – 1988

Bachelor of Science, Northeastern Illinois University, Chicago, IL

1979 – 1981

Research Assistant Neuropharmacology, University of Illinois, Chicago, IL

**CERTIFICATIONS
&
PROFESSIONAL
LICENSURE**

- Certified Physician Investigator
- Diplomat, American Board of Family Practice
- Diplomat, American Board of Medical Examiners
- Licensed State of Maryland: Physician
- Licensed State of Pennsylvania: Physician
- Licensed State of Florida: Physician
- BLS
- ACLS
- PALS
- NLS

**PROFESSIONAL
AFFILIATIONS
&
MEMBERSHIPS**

- American Medical Association
- American Academy of Family Practitioners
- AAFP International Family Practice Association
- Florida Wellcare Alliance
- Association of Clinical Research Professionals
- Drug Information Association

RESEARCH EXPERIENCE

- Co-Author Infantile Chinese Restaurant Syndrome
- Phase III, Community Acquired Pneumonia
- Phase III, Treatment of Community Acquired Pneumonia
- Phase III, Hypertension in patients with low renin levels
- Phase III, Mild to Moderate essential hypertension
- Phase III, Respiratory effectiveness Trial
- Phase III, BMS, Lipid lowering efficacy and safety of XXX alone and in combination with XXX in subjects with mixed dyslipidemia
- Phase III, 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, 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
- Phase I, Randomized, Double-Blind, Placebo-Controlled, Parallel- Group, Fixed-dose, Multi-center Study of Weight- Reducing Effect and Safety of XXX in Obese Patients with or without Comorbidities
- 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 Phase I, 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
- Phase I, 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, 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
- Phase I, 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 up 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
- A Randomized, Partly Blinded, Multi-center, Parallel Study Comparing the Efficacy and Safety of XXX at 0.5mg QD, 1,0 mg QD, 1.0 mg BID, 2.0 mg BID and XXX at 400 mcg BID in Adolescents (12 Years of Age and Older) and Adults with Moderate to Severe Asthma
- Phase I, A Randomized, Double-Blind, Placebo Controlled Trial of XXX in Premenopausal Women with 50% to 80% Density in breast Tissue Based on Digitized Analysis of Screening Mammography
- XXX Excellence in Therapeutic Response and Activity Assessing Symptom Relief in Urinary Tract Infections
- A Multi-center, Randomized, Double-Blind, Parallel-Group, Placebo-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, Multi-factorial, 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 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
- Phase I, Randomized, Blinded, Placebo-controlled, Single-dose Study to Evaluate the Pharmacokinetics and Pharmacodynamics of XXX in Healthy Postmenopausal Women
- Phase I, A Replicate Design, Double-blind, Randomized, Placebo Controlled Tolerance and Pharmacokinetics Study of XXX in Normal, Healthy Volunteers
- Phase II, Pharmacokinetics and Bioavailability Comparison of Immediate Release and Enteric Coated XXX - A Double-Blind, Single Dose Crossover Phase I Study in Normal Volunteers
- A Multi-Center, Open-Label Long-Term Safety Trial of XXX in the Treatment of Acne Vulgaris
- Phase I, A Multiple-Dose, Dose-Escalation Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of XXX in Healthy Obese Men and Women
- Phase I, 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
- Phase I, 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
- Phase II, The Relative Bioavailability of Two Formulations of XXX Compared to Twice Weekly Application of XXX
- A 12 Month, Randomized, Open-Label, Multi-center, Study to Assess the Long Term Safety of XXX Alone and XXX Atone or with Optional Addition of XXX in Patients with Essential Hypertension
- Phase I, 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
- Phase I, 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 IIA 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
- 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
- Phase I, Safety of Topical Use of XXX in Humans: Determination of Clinical Responses and Serum Level of XXX