

CURRICULUM VITAE

JESUS OLIVA

Date of Birth: September 12, 1956

Place of Birth: Oriente, Cuba

Marital Status: Married, Three Children

Languages: English and Spanish (Fluent)

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EDUCATION

High School: Union Hill High School
Union City, New Jersey
1973-1975

College: Rutgers University
Newark, New Jersey
1975-1978

Certifications: ACRP/CCRC, GCP, ACLS/BLS,
OSHA Compliance, Oral Dosing Procedures,
IV Therapy/Starting & Maintaining IV's,
HIV/Aids Education, Project Management/Project 2000
EDC Certification

Current Position: Project Manager / Senior Research Coordinator
Clinical Pharmacology of Miami, Inc.
550 West 84 Street
Miami, Fl. 33014
2008 - Present

Work Experience: Project Manager / Senior Research Coordinator
Elite Research Institute
15705 NW 13th Ave
Miami, Florida 33169
2006 – 2008

Project Manager / Senior Research Coordinator
SFBC International, Inc.
11190 Biscayne Blvd
Miami, Florida 33181
2003 – 2006

Senior Research Coordinator
Clinical Pharmacology Associates
2060 N.W. 22nd Avenue
Miami, Florida 33142
1998 – 2003

Research Experience:

“Effects of Cimetidine and Probenecid on study drug renal clearance in healthy young human subjects”

“An Open-Label, Single-Dose, Parallel-Group Study to Compare the Pharmacokinetics of study drug in Subjects with Mild to Moderate Hepatic Impairment with that in Matched Healthy Control Subjects.”

“An Open, Randomized, 2-Period, Crossover, Pilot Study to Investigate the Influence of Vitamin D3 on the Oral Administration of Alendronate”

“An Open, Randomized, 3-Period, Crossover study in postmenopausal females to determine the oral Bioavailability of the 35 and 70-mg Alendronate tablets.”

“A Two-Part, Open-Label Randomized Crossover Study to Investigate the Absorption, Distribution, Metabolism, and Excretion of Single Oral and Intravenous Doses of study drug in Healthy Male Subjects”

“A 2-Part, Open, Balanced, Crossover Study in Healthy Subjects to Evaluate the Bioavailability of study drug Final market Image Tablets and Investigate the Dose Proportionality of study drug Final Market Image Tablets”

Research Experience (cont..)

“A Double-Blind, Placebo-Controlled, Double-dummy, parallel-group Study to Evaluate and Compare the Effects of 15 Days of Treatment with Oral Rofecoxib, Oral Naproxen, Oral Celecoxib or Placebo on Urinary Sodium Excretion and Other Renal Functions in Subjects 60 to 80 years of age consuming a 200mEq Sodium Diet”.

“An Open-Label, Randomized, 2-Period, Crossover Study to Examine the Influence of Timing of Meal Ingestion on the Relative Bioavailability of Study drug in Healthy Subjects”

“An Open, Randomized, Single Dose, Four Period Crossover Study to Demonstrate the Bioequivalence of Simvastatin Tablets and Encapsulated Simvastatin Tablets in Healthy Male and Female Subjects”

“An Open Label Study to Evaluate The Effect of Concomitant Chronic Administration of Topiramate or Carbamazepine on the Pharmacokinetics of Norethindrone and Estradiol (Ortho-Novum 1/35) in Healthy Non- Obese and Healthy Obese Female Subjects”

“Effects of Cimetidine and Probenecid on study drug renal clearance in healthy young human subjects”

“An Open, Randomized, 2-Period, Crossover, Pilot Study to Investigate the Influence of Vitamin D₃ on the Oral Absorption of Alendronate”

“A Double-Blind, Randomized, Placebo-Controlled, Escalating Single Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of study drug in Healthy Elderly Females, and Healthy Young Female Volunteers”

“A Double-Blind, Randomized, Placebo-Controlled, Double-Dummy, Parallel-Group Study to Evaluate and Compare the Effects of 15 Days of Treatment with Oral Etoricoxib, Oral Celecoxib, Oral Naproxen, or Placebo on Urinary Sodium Excretion, Blood Pressure, and Other Renal Functions in Subjects 60-85 Years of Age Consuming a 200-mEq Sodium diet”

“A Double-Blind Ascending Oral Dose Evaluation of Study Drug for Safety, Tolerance, and Preliminary Pharmacokinetic Profile in Healthy Subjects”

“A 2-Part, Open-Label, Randomized, Multiple, Oral-Dose, Study Comprised of 2-Crossover Periods per Part, to Investigate the Pharmacokinetic Interaction Between Simvastatin and Fenofibrate In Young Healthy Male and Female Subjects”

“A Randomized, Double-Blind, Placebo-controlled, Ascending, Oral Dose Evaluation of Study Drug for Safety, Tolerance, and a Preliminary Pharmacokinetic Profile in Healthy Subjects: Multiple Dose Administration”

Research Experience (cont..)

“An Open-Label, Randomized, Single-Dose, Four Period Crossover Study to Evaluate the Bioequivalence of Simvastatin Tablets and Encapsulated Simvastatin Tablets in Healthy Male and Female Subjects”

“A Randomized, Partially Blinded, Placebo-Controlled, 3-Period Study in Healthy Subjects to Evaluate the Effects of Diltiazem and Food on the Safety, Tolerability, and Pharmacokinetics of Single Oral Doses of Study drug”

“An Open-label Study to Investigate the Absorption, Metabolism, Excretion and Mass Balance After Oral Administration of a Single Dose of [14C]-Study Drug in Healthy Adult Male Subjects”

“A Study to Evaluate the Multiple Dose Pharmacokinetics of a Hydrocodone/Naltrexone/Acetaminophen (HXA) Combination Tablet in Healthy Subjects”

“An Open-Label Crossover Study to Evaluate the Bioequivalence of Coated Hydrocodone/Naltrexone /Acetaminophen (HXA), High and low dose Uncoated Hydrocodone/Naltrexone (HX), and Uncoated Hydrocodone (H) Tablets in Healthy Subjects”

“A Randomized, Single-Blinded, Placebo-Controlled, 2-Period, Crossover Study to Determine the Relative Bioavailability of study drug Suspension and Tablet Formulations in Healthy Male Subjects”

“An Open-Label, Randomized, 2-Period Crossover Study to Determine Definitive Bioequivalence After Administration of Single 160 mg Doses of the U.S. and UK Formulations of Fenofibrate in Healthy Adult Subjects.”

“A Phase 2, Randomized, Single-Blind, Placebo-Controlled Crossover Study to Examine the Pharmacokinetics of an Oral Drug (Acetaminophen) Administered at Various Times in Relation to Study Drug Subcutaneous Injection in Healthy Subjects”

“A Placebo- and Positive- Controlled, Parallel Designed Study of the Electrocardiographic Effects of Intravenous Study Drug in Healthy Men and Women Volunteers”

“An Evaluation of the Steady-State and Single-Dose Pharmacokinetics of Medisorb Naltrexone in Healthy Subjects”

“An Open-Label Study to Investigate the Absorption, Metabolism, Excretion, and Mass Balance of Study Drug After Oral Administration of a Single Dose of 14C-Study Drug in Healthy Adult Male Subjects”

“A Randomized, Double-Blind, Placebo-Controlled, Drug Interaction Study of Multiple Oral Doses of Study Drug with Midazolam, a Cytochrome P450 Isoenzyme 3A4 Substrate, in Healthy Volunteers”

Research Experience (cont..)

“Double Blind Randomized, Placebo-Controlled, Single dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of Study Drug Tablets in Healthy Elderly Male and Female Subjects”.

“An Open-Label, Randomized, Balanced, 2-Part Study to Establish the Bioequivalence of the Conventional Final Market Image Tablet of Rofecoxib and a Rofecoxib-ZYDIS™ Pin - Milled Wafer (Part I) and the Effect of Food on the Rofecoxib-ZYDIS™ Pin-Milled Wafer Formulation (Part II) in Healthy Subjects”

“A Double-Blind, Randomized, Placebo-Controlled Trial to Investigate the Safety, Tolerability, Biochemical Activity, and Pharmacokinetics of Multiple Oral Doses of Study Drug in Overweight Postmenopausal Females”

“Phase I Dose Escalation Study to Examine the Safety, Tolerability, and Pharmacokinetics of Orally Administered Study Drug in Healthy Male Volunteers”

“A randomized, open-label, single-dose, four-way crossover study of the effects of varying doses of ethanol on the Pharmacokinetic characteristics of 12-mg hydromorphone hydrochloride extended-release capsules(HHER) in two groups (fed and fasted) of healthy volunteers”

“An Open-Label Study to Investigate the Absorption, Metabolism, Excretion, and Mass Balance of MK-0524 After Oral Administration of a Single Dose of [14C]- Study Drug in Healthy Adult Male Subjects”

“A Double-Blind Ascending Oral Dose Evaluation of Study Drug For Safety, Tolerance, and a Preliminary Pharmacokinetic Profile in Healthy Subjects”

“A Double-Blind, Randomized, Placebo-Controlled, 3-Part Study to Investigate the Safety and Tolerability of Study Drug Administered Twice-Daily or as Escalating, Once-Daily Titrated Doses in Healthy Obese Volunteers”

“A Phase I Study in Healthy Subjects to Evaluate the Effect of Steady-State Doses of Zelpar® (Zydis® Selegiline) on Blood Pressure Responses to Tyramine”

“A Phase I, Single-Center, Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the Effect of 14-Day Treatment with Study Drug on the Single Pharmacokinetics (PK) of Atrovastatin, a Substrate for Cytochrome P450 3A4 (CYP3A4)”

“A 2-Period Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Tolerability of Study Drug in Healthy Volunteers”

Research Experience (cont..)

“An Open-Label Study to Investigate the Absorption, Metabolism, Excretion, and Mass Balance After Oral Administration of a Single Dose of [¹⁴C] Study Drug in Healthy Adult Male Subjects”

“A Randomized, Open-Label, Single-Dose, 7-Treatment, 4-Period, Incomplete Block, Crossover Study in Healthy Male Subjects to Determine the Effect of Ethanol Administration at Varying Times on the Capsules Pharmacokinetics of Hydromorphone Hydrochloride Palladone™ 12-mg “

“An Open-Label Study to Investigate the Absorption, Distribution, Metabolism, and Excretion of a Single Dose of [¹⁴C]-Study Drug in Healthy Male Subjects”

“A Randomized, Double-Blind, Placebo-Controlled, Single Site, Ascending Multiple Oral Dose Evaluation of Study Drug IR tablet for Safety and Tolerance, and a Preliminary Pharmacokinetic Profile in Healthy Subjects”

“A Randomized, Open-Label, Placebo-Controlled, 4-Period, Crossover Pilot Study to Evaluate the Pharmacokinetics and Acute Lipid Effects of Niacin in Healthy Male Subjects”

“A Double-blind, Randomized, 2-Period Crossover Study to Compare the Safety and Tolerability of a Titration of Sustained-Release Formulation Quetiapine Fumarate (SEROQUEL™) with Placebo in Healthy Volunteer”

“A Double-Blind, Randomized, Two-Period Crossover Study to Compare the Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Profiles of Study Drug and Atorvastatin Calcium Administered Alone and in Combination to Healthy Subjects Aged 18 to 45 years”

“A Phase 1, Sequential, Randomized Double-Blind, Placebo-Controlled Repeated Dose Escalation Study To Assess The Safety, Tolerability, And Pharmacokinetics of study Drug Administered Tid Or Bid To Healthy Subjects”

“A Double-Blind, Randomized, Parallel-Group Study to Define the ECG Effects of Study Drug Using a Clinical and a Supratherapeutic Dose Compared to Placebo and Moxifloxacin (a Positive Control) Compared to Placebo in Non-Smoking, Healthy, Male and Female Subjects: A Thorough QTc Study”

“Effect of Food on Oral Bioavailability of Study Drug in Healthy Male Volunteers”

“A Double-Blind, Randomized, Placebo-Controlled, Multiple Ascending Dose Study of Study Drug, a 5-HT₄ Agonist, in Healthy Female Subjects”

Research Experience (cont..)

“Drug-Interaction Study to Evaluate the Effect of Co-Administered Antacid on the Pharmacokinetics of Study Drug”

“A Randomized, Double Blind, Placebo Controlled, Escalating, Single Oral Dose, Safety, Tolerability and Pharmacokinetic Study in Healthy Male Subjects”

“A Phase I, Open-Label, Crossover Study to Assess the Pharmacokinetic Interaction of Caperitide and Lisinopril In Healthy Adult Volunteers”

“A Single Center, Placebo-Controlled, Single-Blind, Rising Dose Tolerance Evaluation of Single Intravenous Dose of Study Drug in Healthy Normal Volunteers”.

“Comparison of Pharmacokinetics if 40 mg/day Oral Study Drug for Five Days to Pharmacokinetics of 40 mg/day Intravenous Study Drug for Four Days in Healthy Subjects”+

“Safety and Tolerability of 2-O, 3-O, Desulfated Heparin (ODSH) when administered as a Bolus with Continuous Infusion for 3 days in Normal Healthy Male and Female Volunteers”

“A Phase I, Randomized Single-Blind Study to Determine the Relative Pharmacokinetics of Two Regimens of Study Administered Orally to Normal, Healthy Male and Female Subjects”

“A Randomized, Double-Blind, Placebo-Controlled, Ascending Single-Dose Study of the Safety, Tolerability and Pharmacokinetics of Orally Administered Study Drug”

“A Phase I, Double-blind, Randomized, Placebo-controlled, Single Escalating Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Study Drug Administered Orally to Young Healthy Male and Female Subjects”

“A Randomized, Double-Blind, Placebo-Controlled, Single Escalating Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Study Drug when Administered as a 30 Minute I.V. Infusion to Healthy Volunteers”

“An Open-Label, Randomized, 2-Part, Single-Dose Crossover Study in Healthy Male Subjects to Assess the Impact of Food and Multiple Capsule Units on the Relative Bioavailability of Study Drug”

“An Open Label, Pilot Study to Assess the Reproducibility of Platelet Aggregation and Bleeding Time Tests to Monitor the Effect of 650 mg Aspirin and 75 mg Clopidogrel on Platelet Function in Healthy Volunteers”

Research Experience (cont..)

“A Randomized, Double-Blind, Placebo-Controlled, Sequential, Ascending, Single and Multiple Loading and Maintenance Dose, Safety, Tolerability, and Pharmacokinetic Study of Study Drug Mono-Salt Following Oral Administration to Healthy Subjects”

“An Open-Label Study to Evaluate the Effect of Study Drug on Cytochrome P450 Enzyme in Healthy Subjects Using a “Cocktail” of Tolbutamide, Omeprazole, Midazolam, Dextrometorphane, and Caffeine as In Vivo Probe”

“A Two-Tier Randomized, Double-Blind, Placebo-and Moxifloxacin-Controlled, Parallel Design Study to Evaluate the Influence of Study Drug on Cardiac Repolarization Pharmacodynamics (QTC Interval) Following Infusion of Repeated Intravenous Doses to Healthy Subjects”

“A Single-Dose, Dose Escalation Study to Assess the Safety, Pharmacokinetic, and Pharmacodynamics of Subcutaneous Study Drug in Subjects with Stage 2 to 4 Chronic Kidney Disease”

“A Single-Center, Randomized, Open-Label, Two-Way Crossover, Single-Dose Study Comparing the Systemic Exposure of Theophylline 300-MG Extended-Release Tablets Manufactured at Two Different Sites in Healthy Volunteers”

“A Randomized, Placebo-Controlled, Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacodynamics, and Steady State Pharmacokinetic of Repeat Oral Doses of Study Drug in Subjects with Borderline high to high LDL Cholesterol Levels”

“A Single Dose Pharmacokinetic Study of Study Drug in Healthy Subjects and Subjects with Mild to Severe Impaired Renal function”

“A Two-Period, Randomized, Open-Label, Parallel Group, Multiple-Probe Drug Interaction Study to Determine the Effects of Study Drug on the Metabolism of CYP450 Probe Substrates in Healthy Postmenopausal Female Subjects”

“A Single-Center, Randomized, Open-Label, Parallel-Group, Oral Bioavailability and Exploratory Tolerability Study Comparing Study Drug Immediate Release Formulation with Study Drug Modified (Delayed) Release Formulation in Healthy Human Volunteers”

“An Open-Label, Partially Randomized, Interaction Study to Evaluate the Effects of Study Drug on the Pharmacokinetics of Rosuvastatin and Atorvastatin or the Effects of Ketoconazole on Study Drug in Healthy Postmenopausal Female Subjects”

“A Randomized, Double-Blind, Placebo-Controlled, Sequential, Ascending, Single-Dose, Safety, Tolerability, and Pharmacokinetic Study of Study Drug following Oral Administration to Healthy Subjects”

Research Experience (cont..)

“An Open-Label, Single-Dose, Parallel-Group Study to Assess the Pharmacokinetics of Study Drug (5 mg) in Healthy Subjects and Subjects With Varying Degrees of Hepatic Impairment”

“ A Phase I Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Study the Safety, Efficacy, and Mechanism of Action of Sitagliptin and Pioglitazone in patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Diet and Exercise”

“A Randomized, Double-Blind, Crossover Study to Compare the Effects of Exenatide and Sitagliptin on Postprandial Glucose in Subjects with Type 2 Diabetes Mellitus”

“A Randomized, Placebo-Controlled, Single-Dose, Crossover Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of Study Drug in Subjects with Type 2 Diabetes”

“A Single-Center, Randomized, Open-Label, Parallel-Group, Multiple-Dose Study of the Drug-Drug Interaction Between Study Drug and Ketoconazole in Healthy Subjects”

“A Randomized, Open-Label, Three-Way Crossover, Single-Dose Bioequivalence, and Food-Effect Study of the Clinical Formulation and the To-Be-Marketed Modified-Release Formulation of Study Drug in Healthy Subjects”

“A Phase I, Open-Label, Parallel Group, Multiple-Dose Study to Evaluate the Pharmacokinetics, Safety, and Toleration of Study Drug Administered to Subjects with Severely Impaired and Normal Renal Function”

“Evaluation of the Extrapulmonary Effects of Mometasone Furoate from a Combination MDI Formulation Versus Fluticasone Propionate From a Fluticasone Propionate/Salmeterol Combination Comparator on HPA-Axis Function”

“A Single-Center, Randomized, Open-Label, Parallel-Group, Single-Dose Study Assessing the Effects of Food and Gender on the Pharmacokinetics of Study Drug After Oral Administration of Study Drug 2-mg Tablet in Healthy Volunteers.

“ A Randomized, Double-Blind, Double-Dummy, Parallel Group, Factorial Design Trial to Assess the Efficacy and Safety of up to Six Weeks Treatment with 20mg, 40mg, or 80mg QD Doses of Carvedilol Controlled Release Formulation (COREG CR) or 10mg, 20mg, or 40mg QD doses of Lisinopril (Zestril) or a Combination of One of the Doses of Each Medication”