CURRICULUM VITAE

MARK DAVID SANCHEZ, MD, FACOG

2454 McMullen Booth Rd., Suite 601

Phone: (727) 796-7705

E-mail:

CURRENT POSITIONS

Reproductive Endocrinologist

IVF Medical Director

Florida Fertility Institute

Clearwater, Florida

Associate Medical Director and Investigator

Women's Medical Research Group, LLC

Clearwater, Florida

Associate Medical Director and Investigator

Florida Clinical Research Group

Clearwater, Florida

Department Chair

Obstetrics and Gynecology

Bayfront Medical Center

St. Petersburg, Florida

BIRTH DATE and PLACE

March 25, 1969, Indianapolis, IN

EDUCATION and TRAINING

1999-2002 Fellowship in Reproductive Endocrinology and Infertility

Department of Obstetrics and Gynecology
University of South Florida
Tampa, Florida

1995-1999 Obstetrics and Gynecology Residency
Department of Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

1991-1995 Doctor of Medicine
University of Florida College of Medicine
Gainesville, Florida

1989-1991 Bachelor of Science
Major: Biology
Minor: History
University of South Florida
Tampa, Florida

WORK EXPERIENCE

2002-2014 Reproductive Endocrinologist
IVF Medical Director
Florida Fertility Institute
Clearwater, Florida

2003-2014 Associate Medical Director and Investigator
Women's Medical Research Group, LLC
Clearwater, Florida

2003-2014 Associate Medical Director and Investigator
Florida Clinical Research Group
Clearwater, Florida

LICENSES, CERTIFICATIONS, AND EXAMINATIONS

1996	Florida Medical License (Active)
2005	Board Certified Reproductive Endocrinology and Infertility
2004	Board Certified American Board of Obstetrics and Gynecology
1995	Advanced Cardiac Life Support (ACLS) , Recertified YEAR (Active)
1995	Basic Life Support (BLS), Recertified YEAR (Active)

PROFESSIONAL AFFILIATIONS

American College of Obstetrics and Gynecology, Fellow

American Society for Reproductive Medicine, Full Member

American Society for Colposcopy and Cervical Pathology, Member

American Association of Gynecologic Laparoscopists, Member

Society for Reproductive Endocrinology and Infertility, Full Member

PROFESSIONAL APPOINTMENTS

2012-2014 Department Chair
Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

2012-2014 Medical Council Member
Bayfront Medical Center
St. Petersburg, Florida

2012-2014 Standards and Credential Committee
Bayfront Medical Center
St. Petersburg, Florida

2010-2012 Quality Improvement Chair
Department of Obstetrics and Gynecology
Bayfront Medical Center

St. Petersburg, Florida

2010-2012 Department Vice-Chair
Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

2001-2002 Peer Review Committee
Department of Obstetrics and Gynecology
University of South Florida
Tampa, Florida

1999-2002 Residency Selection Committee
Department of Obstetrics and Gynecology
University of South Florida
Tampa, Florida

1998-1999 Chief Administrative Resident
Department of Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

1998-1999 Residency Selection Committee
Department of Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

1997-1999 Process Improvement Team
Department of Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida

1997-1999 Quality Assurance Committee

Department of Obstetrics and Gynecology

Bayfront Medical Center

St. Petersburg, Florida

1995-1999 Medical Education Committee

Bayfront Medical Center

St. Petersburg, Florida

1995-1999 Library Committee

Bayfront Medical Center

St. Petersburg, Florida

AWARDS AND HONORS

2013 Chief Residents' Special Recognition Award, Department of Obstetrics and Gynecology,

Bayfront Medical Center

2006 Attending of the Year July 2000-June 2001, Department of Obstetrics and Gynecology,

Bayfront Medical Center

2002 Attending of the Year July 2000-June 2001, Department of Obstetrics and Gynecology,

Bayfront Medical Center

2001 Attending of the Year July 2000-June 2001, Department of Obstetrics and Gynecology,

Bayfront Medical Center

2001 Postdoctoral Grant Recipient Florida/Puerto Rico Regional, American Heart Association for paper entitled: Regulation of the High Density Lipoprotein Receptor by Estradiol

1999 Excellence in Colposcopy and the Treatment of Lower Genital Tract Disease Award, The American Society for Colposcopy and Cervical Pathology

1999 Excellence in Endoscopic Procedures, The American Association of Gynecologic Laparoscopists

1999 Outstanding Research in Women's Health, Organon Resident Research Award

1998 Outstanding Research in Endometriosis, Resident Research Award, Bayfront Medical Center

1994 Outstanding Leadership, University of Florida, College of Medicine

1993 Recipient, Minority Affairs Dean's Scholarship, University of Florida, College of Medicine

1990 Academic Excellence Honors Convocation, University of South Florida

PEER-REVIEWED PUBLICATIONS

1. Beltsos AN, **Sanchez MD**, Doody KJ, Bush MR, Domar AD, Collins MG. Patients' administration preferences: progesterone vaginal insert (Endometrin(R)) compared to intramuscular progesterone for Luteal phase support. Reprod Health. 2014 Nov 11;11(1):78.

2. Hirth R, Zbella E, **Sanchez M**, Prieto J. Microtubal reanastomosis: success rates as compared to in vitro fertilization. J Reprod Med. 2010 Mar-Apr;55(3-4):161-5.

3. Lopez D, **Sanchez MD**, Shea-Eaton W, McLean MP. Estrogen activates the high-density lipoprotein receptor gene via binding to estrogren response elements and interaction with sterol regulatory element binding protein-1A. Endocrinology. 2002 Jun;143(6):2155-68.

4. Lopez D, Shea-Eaton W, **Sanchez MD**, McLean MP. DAX-1 represses the high-density lipoprotein receptor through interaction with positive regulators sterol regulatory element-binding protein-1a and steroidgenic factor-1. Endocrinology. 2001 Dec; 142(12):5097-106.

ABSTRACTS

1. S. Tubens, **M. Sanchez**, E. Zbella, J. Steele.Pregnancy: tubooclusive vs. standard ligation reversal. Fertility and Sterility Vol. 100, Issue 3, Supplement, Page S173

CLINICAL RESEARCH TRIALS

Ongoing Clinical Studies

Sponsor: Nora Therapeutics, Inc
Protocol: NT-03
Title: A Randomized, Double-Blind, Multi-Center, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Doses of NT100 Following In Vitro-Fertilization (IVF) in Women with a History of Repeated IVF Failure (Thrive-IVF)
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: NovaDigm Therapeutics, Inc
Protocol: NDV3A-003
Title: A Phase 1b/2a, Multi-center, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Safety, Tolerability, Immunogenicity and Efficacy in Preventing Vulvovaginal Candidiasis in Subjects with Recurrent Vulvovaginal Candidiasis Following Administration of a Single Dose of NDV-3A Vaccine, NDV-3 Vaccine or Placebo
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Abbott Laboratories
Protocol: M12-665
Title: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Elagolix in Subjects with Moderate to Severe Endometriosis-Associated Pain
Site PI: Mark Sanchez, M.D.
Role: Principal Investigator

Sponsor: Repros Therapeutics, Inc.
Protocol: ZPE-202
Title: A Phase 2, Multi-Center, Three –Arm, Parrallel Designed, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of 6 and 12 mg Proellex® (Telapristone Acetate) Administered Orally in the Treatment of Premenopausal Women with Endometriosis Confirmed Within the Last Five Years and Who are Currently Using Narcotic For Control of Symptomatic Pain
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Repros Therapeutics, Inc.
Protocol: ZA-301 ext.
Title: An Open Label, 6 Month Phase III Extension Study of Enclomiphene Citrate in the Treatment of Men with Secondary Hypogonadism
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2013

Sponsor: Agility Clinical
Protocol: TET2013-001A
Title: A Multicenter, 26-Week, Prospective, Observational Study In Adult Patients With Prediabetes Assessing The Impact Of The PreDx Test On Patient Treatment And Outcomes In Community-Based Clinical Practices
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Teva Pharmaceuticals Industries, Ltd.
Protocol: 71036006
Title: Randomized, Investigator-Blind, Placebo-Controlled, Parallel Design, Multiple-Site Study Comparing TEVA Pharmaceuticals Estradiol Vaginal Tablets with Vagifem® (Estradiol) Vaginal Tablets (Novo Nordisk) in the Treatment of Atrophic Vaginitis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Warner Chilcott, LLC
Protocol: PR-08112
Title: A Randomized, Multicenter, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of WC3011 in Postmenopausal Women with Dyspareunia
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Warner Chilcott, LLC
Protocol: PR-05812
Title: A Randomized, Multicenter, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of WC3011 in Postmenopausal Women.
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Repros Therapeutics Inc.
Protocol: ZA-301
Title: A Randomized, Double Blind, Placebo Controlled Multi Center Phase III Study to Evaluate Normalization of Morning Testosterone Levels in Overweight Men with Acquired Hypogonadotropic Hypogonadism and Normal Sperm Concentration
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Repros Therapeutics Inc.
Protocol: ZA-300
Title: An Open-Label, Escalating Dose, 6-Month Phase *III Safety Study of Enclomiphene Citrate in the Treatment Of Men with Secondary Hypogonadism*
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Medicis Pharmaceutical Corp
Protocol: MP-1601-01
Title: A Phase III, Multi-Center, Randomized, Doubl Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Product 55394 in the Treatment of (BV) Bacterial Vaginosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: EMD Serono, Inc.
Protocol: 26109
Title: A phase IV, multi-center, randomized, double- blind, clinical trial to confirm the efficacy of the 75 IU dose of Luveris vs. placebo when administered with follitropin alfa for induction of follicular development and pregnancy in hypogonadotropic hypogonadal women with profound LH deficiency, as defined by a baseline LH level <1.2 IU/L
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2012

Sponsor: EMD Serono Inc.
Protocol: EMR200497-001
Title: Exploratory, Non-Interventional Study to Identify and Validate Biomarkers in Follicular Fluid, Cumulus or Granulose Cells or Embryo Culture Medium for Prediction of Implantation and Pregnancy Outcome of Assisted Reproductive Technology Cycle
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Gene Security Network, Inc.
Protocol: GSN-IVF006-D3
Title: A Multi-Center, Randomized, Open-Label Study to Evaluate the Implantation and Pregnancy Rates Following 24 Chromosome Aneuploidy Screening With Parental Support in Patients Undergoing (IVF)
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FE 999906 CS12

Title: A Multicenter, Randomized, Open-Label, Parallel-Group Study Comparing the Combination of Menopur® and Bravelle® with Menopur® Alone in Subjects Undergoing Assisted Reproductive Technology (ART)
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Warner Chilcott, LLC
Protocol: PR-04509
Title: A Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of WC3011 (estradiol vaginal gel) in the Treatment of Symptoms of Vulvovaginal Atrophy in Postmenopausal Women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Warner Chilcott, LLC
Protocol: PR-04409
Title: A Randomized, Double-Blind, Vehicle-Controlled Study of the Safety and Efficacy of WC3011 (estradiol vaginal gel) in the Treatment of Symptoms of Vulvovaginal Atrophy in Postmenopausal Women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Novartis Pharmaceuticals Corp.
Protocol: CBGS649A2202
Title: A double blind, randomized, controlled, multicenter, efficacy and safety study of oral BGS649 vs. placebo (each co-administered with a combined oral contraceptive) assessing pain response in patients with refractory endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Amag Pharmaceuticals, Inc.
Protocol: AMAG-FER-IDA-303
Title: A Phase III, Open-Label Extension Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Alere, Inc.
Protocol: STE-0134
Title: Clinical Evaluation of Triage® hCG in Whole Blood and Plasma (device) GOAL
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Amag Pharmaceuticals, Inc.
Protocol: AMAG-FER-IDA-301
Title: A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Teva Pharmaceuticals Industries, Ltd
Protocol: DSG-PPS-303
Title: A Multicenter, Open Label Study to Evaluate the Efficacy and Safety of a Combination Oral Contraceptive Regimen (DR-102) for the Prevention of Pregnancy in Women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Duramed Research, Inc.
Protocol: DR-105-202
Title: A multicenter, open-label, randomized, controlled study to compare the effects on bone mineral density of DR-105 and a 28-Day cycle oral contraceptive regimen in healthy, postmenarchal, adolescent females
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2011

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FE-992026 CS40
Title: A Multi-centre, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial to Demonstrate the Efficacy and Safety of Desmopressin Orally Disintegrating Tablet for the Treatment of Nocturia in Adult Females
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FE-992026 CS41
Title: A Multi-centre, Randomised, Double-blind, Placebo-controlled, Parallel-group Trial with an Open-label Extension to Demonstrate the Efficacy and Safety of Desmopressin Orally Disintegrating Tablets for the Treatment of Nocturia in Adult Males
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Noven Pharmaceuticals, Inc.
Protocol: N30-004
Title: A phase 3, twenty four week, multicenter, double- blind, randomized, placebo-controlled, efficacy and safety study of Mesafem (Paroxetine Mesylate) capsules in the treatment of Vasomotor symptoms associated with menopause.
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: PRA International
Protocol: 17P-ES-003
Title: A phase IIIb, multi-center, randomized, double blind study of hydroxyprogesterone caproate injection, 250 mg/ml, versus vehicle for the prevention of preterm birth in women with a previous singleton spontaneous preterm delivery
Site PI: Mark Sanchez, M.D.
Role: Principal Investigator

Sponsor: Serenity Pharmaceuticals Corp.
Protocol: SPC-SER120-OLI-200903
Title: A phase III open-label extension study to investigate the safety of SER120 nasal spray formulations in patients with nocturia completing study SPC-SER120-DB1-200901 or Study SPC-SER120-DB2-200902
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Teva Pharmaceuticals Industries, Ltd
Protocol: DR-103-301

Title: *A multicenter, open-label study to evaluate the efficacy and safety of a combination oral contraceptive regimen (DR-103) for the prevention of pregnancy in women*
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Bayer HealthCare
Protocol: 91556
Title: Multi-center, double-blind, double-dummy, randomized, parallel-group study to evaluate cycle control, bleeding pattern, pressure, lipid and carbohydrate metabolism of the transdermal contraceptive patch vs. an oral comparator containing 20µg ethinylestradiol and 100µg levonorgestrel in a 21day regimen for 7 cycles in 400 women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Bayer HealthCare
Protocol: 13108
Title: A multicenter, randomized, double-blind, active-controlled, parallel group, 2-arm study to show superiority of the oral contraceptive SH T00658ID over Ortho Tri-Cyclen Lo on hormone withdrawal associated symptoms after 6 cycles of treatment
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2010

Sponsor: Luitpold Pharmaceuticals, Inc.
Protocol: 1VIT09031
Title: A multicenter, randomized, active controlled *study to investigate the efficacy and safety of Intravenous Ferric Carboxymaltose (FCM) in Patients with Iron Deficiency Anemia (IDA)*
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Depomed, Inc.
Protocol: 81-0064
Title: A phase 3, multicenter, randomized, double-blind placebo controlled study to investigate the safety efficacy of Gabapentin Extended Release (G-ER) tablets in the treatment of vasomotor symptoms in postmenopausal women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: 2009-02
Title: A randomized assessor-blinded, multi-center study investigating the efficacy, safety and tolerability of “Day before” PicoPrep™ for oral administration versus Halflytlely® for colon cleansing in preparation for colonoscopy
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FE992026 CS31
Title: A multi-center Extension Study Investigating the Long Term Efficacy and Safety of a Fast-Dissolving (“Melt”) Formulation of Desmopressin for the treatment of Nocturia in Adults
Site PI: Edward Zbella, M.D., CPI

Role: Sub-Investigator

Sponsor: Neurocrine Biosciences, Inc.
Protocol: NBI-56418-0702
Title: A Phase II, Randomized, Double-Blind, Placebo Controlled Study to Assess the Efficacy and safety of nbi-56418 in Subjects with Endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Neurocrine Biosciences, Inc.
Protocol: NBI-56418-0901
Title: A phase II, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of NBI-56418 Na in subjects with Endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Serenity Pharmaceuticals Corp.
Protocol: SPC-SER120-DB1-200901
Title: A Phase III randomized, double-blind, placebo control, multicenter study to investigate the efficacy and safety of SER120 nasal spray formulation in patients with Nocturia
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FPI MEN 2008-05
Title: A multi-center, randomized, open-label evaluation of MENOPUR versus Follistim in polycystic Ovarian Syndrome (PCOS) patients
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Wyeth Pharmaceuticals, Inc.
Protocol: 3151A2-3353-NA
Title: A Double blind, Randomized, Placebo-Controlled Study assessing the safety and efficacy of DVS SR for the treatment of Vasomotor symptoms associated with menopause
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Bayer HealthCare
Protocol: 310523
Title: A double-blind, Randomized, Multicenter Study to Investigate the Endometrial Safety of a Continuous, Combined, Oral Estrogen/Progestin Preparation (0.5 mg 17ß-estradiol [E2] / 0.25 mg drospirenone [DRSP]) and to Compare the Bleeding Pattern of Subjects treated with 1.0 mg E2 / .5 mg norethisterone acetate (NETA) when used for hormone therapy (HT) for 1 year in Post-Menopausal Women.
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: GlaxoSmithKline Biologicals
Protocol: 107682 (HPV-018)
Title: A phase IIIb, randomized, open, multi-center study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' HPV-16/18 LI/AS04 vaccine co-administered intramuscularly with GlaxoSmithKline Biologicals Boostrix vaccine and/or Sanofi-Aventis' Menactra vaccine according to different dose schedule combinations as compared to the administration of

HPV vaccine, Boostrix or Menactra alone in healthy female subjects aged 11-18 years
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2009

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FPI MEN 2008-04
Title: A multi-center, randomized, open-label evaluation of MENOPUR versus FOLLISTIM in GnRH antagonist cycles
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Luitpold Pharmaceuticals, Inc.
Protocol: IVIT07017
Title: A multi-center, Randomized, Controlled Study to Investigate the Safety and Tolerability of Intravenous Ferric Carboxymaltose (FCM) vs. Standard Medical Care Testing Iron Deficiency Anemia in Heavy Uterine Bleeding and Postpartum Patients
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Bayer HealthCare
Protocol: 311642
Title: A multi-center, Open-Label, Single-Arm Study to assess the Efficacy and Safety of the Oral Contraceptive SH TOO186D (0.02 mg ethinyl estradiol as betaex clathrate and 3 mg drospirenone) in a flexible extended regimen in 1356 healthy females for 1 Year
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Proctor & Gamble Co.
Protocol: 2007004
Title: A Randomized, Double-blind, Placebo-Controlled, Multi-center, 52-Week Study to Evaluate the Endometrial Safety of Transdermal Testosterone (300mcg/day) in Naturally Post-Menopausal Women with Hypoactive Sexual Desire Disorder
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Duramed Research, Inc.
Protocol: DR-PGN-302
Title: A Phase III, Single-Blind, Randomized Study to Compare DR-2011 to a Progesterone Vaginal Gel for luteal Phase Supplementation for InVitro Fertilization
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Duramed Research, Inc.
Protocol: DR-ENJ-401
Title: A Phase IIII, Multi-center, Randomized, Double-blind, Placebo-controlled Study to evaluate the effects of SCE-B on Nocturnal Vasomotor Symptoms in Postmenopausal Women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: KV Pharmaceuticals Co.
Protocol: CBC-302-602-622467
Title: Randomized, Double-blind, Parallel-Group Study Evaluating the Safety and Efficacy of of Clindamycin/Butoconazole Vaginal Cream in the treatment of mixed Bacterial Vaginosis/Vulvovaginal Candiadiasis Infections
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: KV Pharmaceuticals Co.
Protocol: LDC-201-601-669020
Title: A Phase II, 18-week, Double-blind, Placebo-Controlled, Multi-center Study Evaluating the *Safety and Efficacy of Lidocaine/Diphenhydramine Combination Cream in the treatment of Vulvar Vestibulitis Syndrome*
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: KV Pharmaceuticals Co.
Protocol: DZ2-201-601-725036
Title: A phase II clinical study evaluating the safety and efficacy of two regimens of Danazol administered intravaginally for three months in women with moderate-to-severe pain associated with endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Neurocrine Bionsciences, Inc.
Protocol: NBI-56418-0603
Title: A Phase II, Randomized, Double-Blind, Active Controlled Study to Assess the Safety and efficacy of NBI-56418 in Subjects with Endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: EMD Serono, Inc.
Protocol: 25550
Title: A phase II, prospective, randomized, double-blind, multi-center, dose finding, comparative study for the evaluation of the aromatase inhibitor anastrozole (Multiple-Dose) versus Clomiphene Citrate in stimulating follicular growth and ovulation in infertile women with ovulatory dysfunction
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2008

Sponsor: Sanofi-Aventis
Protocol: DR16271
Title: A placebo controlled randomized, 12-week, dose-ranging, double-blind study versus placebo using tolterodine as a study calibrator to evaluate efficacy and safety of ssr240600C in women with overactive bladder including urge urinary incontinence
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: GlaxoSmithKline Biologicals
Protocol: 208141/040
Title: A double-blind, randomized, controlled study to evaluate the immunogenecity and safety of GlaxoSmithKline Biologicals' herpes simplex candidate vaccine (gD2-AS04) in healthy HSV seronegative and seropositive female subjects aged 10-17 years
Site PI: Edward Zbella, M.D., CPI

Role: Sub-Investigator

Sponsor: Quintiles, Inc.
Protocol: DUB 308960
Title: A multi-center, double-blind, randomized, parallel-group, placebo-controlled, 7 cycle duration (196 days), phase 3 of oral treatment of dysfunctional uterine bleeding
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Takeda Pharmaceuticals USA, Inc.
Protocol: 1547-851B
Title: A randomized, placebo-controlled phase II study of multiple dosing regimens of intravaginally administered 851B Gel for the treatment of cervical high risk HPV infection
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Solvay Pharmaceuticals, Inc
Protocol: S1684002
Title: Evaluation of safety and efficacy of Prometrium capsules in induction of secretory conversion of endometrium and withdrawl bleeding in subjects with secondary amenorrhea
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2007

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: FE992026-CS31
Title: A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multi-Center Study Investigating the Efficacy and Safety of a Fast-Dissolving ("Melt") Formulation of Desmopressin for the treatment of Nocturia in Adults
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Symbollon Pharmaceuticals, Inc
Protocol: SYM-CL-005
Title: A phase III, multi-center, randomized, double-blind, placebo-controlled study of IoGen for the treatment of moderate or severe, periodic breast pain associated with symptomatic fibrocystic breast disease in otherwise healthy, euthyroid, pre-menopausal women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Cytokine PharmaSciences, Inc
Protocol: Miso-Obs-004
Title: A multi-center, randomized, double-blind phase III study of the efficacy and safety of the Misoprostol vaginal insert (MVI) compared to Cervidil for women requiring cervical ripening and induction of labor
Site PI: Mark Sanchez, M.D.
Role: Principal Investigator

Sponsor: Solvay Pharmaceuticals, Inc
Protocol: S0302108
Title: A multi-center validation study of the daily log of sexual activities (DLSA) in postmenopausal women

Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Duramed Research, Inc.
Protocol: DR-CEN-302
Title: A randomized, multi-center, double-blind, placebo-controlled trial to compare the effects of 12 weeks of treatment with DR-2041 vaginal cream vs. placebo vaginal cream on vulvovaginal atrophy in healthy postmenopausal women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Duramed Research, Inc.
Protocol: DR-DZL-201
Title: A phase II, multi-center, double-blind, randomized, placebo-controlled study to evaluate two doses of a Danazol vaginal ring for the management of moderate to severe endometriosis-related non-menstrual pelvic pain
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Wyeth Pharmaceuticals, Inc.
Protocol: 3142A2-203-WW
Title: A double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of 75 MG and 150 MG doses of ERB-041 on the reduction of symptoms associated with endometriosis during treatment and post treatment in reproductive-aged women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Wyeth Pharmaceuticals, Inc.
Protocol: 3115A1-305-US
Title: A double-blind, randomized, placebo-controlled, efficacy and safety study of bazeoxifene/conjugated estrogens combinations for treatment of vasomotor symptoms associated with menopause
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Neurocrine Biosciences, Inc.
Protocol: NBI-56418-0504
Title: A phase II, randomized, double-blind, placebo-controlled twice-daily dosing study of NBI 56418 in endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Solvay Pharmaceuticals, Inc.
Protocol: SO202112
Title: A multi-center, double-blind, placebo-controlled comparison of multiple doses of esterified estrogens and methyltesttosterone, in combination and alone, in relieving vasomotor symptoms on postmenopausal women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2006

Sponsor: GlaxoSmithKline Biologicals
Protocol: NKB105022
Title: A twelve-week randomized, double-blind, placebo-controlled, parallel group, forced titration, proof of concept study to assess the efficacy safety and tolerability as well as the pharmacokinetic profile of 60 mg and 120 mg of

GW679769 administered once daily vs. placebo in women with overactive bladder
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Novartis AG
Protocol: CFAM810A2308
Title: A multi-center, randomized, double-blind study to compare the efficacy and safety of patient-initiated Famciclovir 1000 mg B.I.D. X 1 day toValacyclovir 500 mg B.I.D. X 3 days in immunocompetent adults with recurrent genital herpes
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Neurocrine Biosciences, Inc.
Protocol: NBI-56418-0501
Title: A phase II, randomized, double-blind, placebo-controlled study of NBI-56418 in endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Wyeth Pharmaceuticals, Inc.
Protocol: 3142A2-200-US
Title: A double-blind randomized, placebo-controlled dose-ranging study of the effects of ERB-041 in the reduction of symptoms associated with endometriosis in reproductive aged women
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: KV Pharmaceutical Co.
Protocol: KV05-601-622467
Title: A randomized, double-blind, placebo-controlled, parallel-group study comparing Clindamycin Phosphate 2% Butoconazole Nitrate 2% combination vaginal cream with Clindesse, Gynazole-1, and placebo
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Roche
Protocol: MM 17385
Title: Randomized, double-blind, double-dummy, parallel group, multi-center study to compare the efficacy and safety of once-monthly oral administration of 150 mg ibandronate with once-weekly oral administration of 70 mg alendronate in postmenopausal osteoporosis-non-inferiority trial
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceuticals, Inc.
Protocol: Pulsatile GnRH 2004-05 (IV Pump)
Title: A multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of three dosage strengths of Pulsatile GnRH administered intravenously or subcutaneously via portable infusion pump compared to oral treatment with Clomiphene Citrate in anovulatory or oligoovulatory infertile females
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Ferring Pharmaceutical, Inc.
Protocol: 2004-02 (IVF)

Title: A multi-center, randomized, open-label, parallel group study of vaginal micronized progesterone tablet (Endometrium) compared to Crinone 8% vaginal gel in female patients undergoing in-vitro fertilization (IVF)
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Pfizer, Inc.
Protocol: A6121002
Title: A multi-center, double-phase, randomized, Double blind, placebo controlled study evaluating the effect of Tolterodine ER on urgency urinary incontinence, urgency, frequency, sexual quality of life and sexual function in women with overactive bladder
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: TAP Laboratories
Protocol: A-FB04-078
Title: A Phase III, Continuation Study to Evaluate the Safety of Asoprisinil Beyond 2 years in Subjects with Uterine Leiomyomata
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2005

Sponsor: Solvay Pharmaceuticals, Inc.
Protocol: S1664003
Title: Efficacy Study Comparing 0.9g and 1.25g EstroGel 0.03% Doses with Placebo in the treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Associated with Menopause
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Sepracor, Inc.
Protocol: 190-054
Title: The Efficacy of Eszopiclone 3 mg Compared to Placebo in the treatment of Insomnia Secondary to Perimenopause or Menopause
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: Warner Chilcott, LLC
Protocol: PR 10503
Title: An Open Label Study of the Contraceptive Efficacy and Safety of Triphasic Norethindrone acetate 1mg/Ethinyl Estradiol 0.005mg, 0.030mg and 0.035mg Oral Tablets Administered for 24 Days of a 28-day Cycle
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: TAP Laboratories
Protocol: M01-391, extension of M01-390
Title: A phase III, 12 month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 versus placebo in subjects with uterine leiomyomata
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: TAP Laboratories
Protocol: M02-408, Extension of M01-398

Title: A phase II, 3 month, randomized, double-blind study to evaluate the efficacy and safety of two doses of J867 versus placebo in subjects with uterine leiomyomata
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Clinical Studies Completed in 2004

Sponsor: Chitogenics, Inc.
Protocol: Chito-03
Title: A safety and efficacy study of N, O-Carboxymethylchitosan (NOCC) when used for reduction of postoperative adhesion development in women undergoing laparoscopy
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: TAP Laboratories
Protocol: M01-390
Title: A phase III, 12 month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 versus placebo in subjects with uterine leiomyomata
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator

Sponsor: TAP Laboratories
Protocol: M01-398
Title: A phase II, 6 month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 versus placebo in subjects with endometriosis
Site PI: Edward Zbella, M.D., CPI
Role: Sub-Investigator