

CURRICULUM VITAE

NAME:

Mark Sanchez, M.D.

DATE AND PLACE OF BIRTH:

March 25, 1969, Indianapolis, IN

BUSINESS ADDRESS/PHONE:

Edward Zbella, MD, PA
DBA: Florida Fertility Institute

2454 McMullen Booth Road, Suite 601
Clearwater, FL 33759

Women's Medical Research Group, LLC
2454 McMullen Booth Road, Suite 609
Clearwater, FL 33759
(727) 724-9730
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Florida Clinical Research Group
2454 McMullen Booth Rd., Suite 610
Clearwater, FL 33759

EDUCATION:

UNDERGRADUATE:

University of South Florida
Tampa, Florida
5/89 - 4/91
Degree: B.S., Biology

GRADUATE:

University of Florida College of Medicine
Gainesville, Florida
8/91 - 5/95
Degree: Doctorate of Medicine

Internship in Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida
7/95 - 6/96

Resident in Obstetrics and Gynecology
Bayfront Medical Center
St. Petersburg, Florida
7/96 - 6/99

Fellowship in Reproductive Endocrinology
University of South Florida
Tampa, Florida
7/99 - 6/02

MEDICAL LICENSE:

Florida ME71673

**SPECIALTY BOARDS,
AWARDS AND HONORS:**

Board Certified
Reproductive Endocrinology and Infertility
2005

Board Certified, American Board of
Obstetrics and Gynecology
2004

Board Eligible
Reproductive Endocrinology and Infertility
6/2002

Bayfront Medical Center Obstetrics and Gynecology
Attending of the Year July 2000 through June 2001,
2001-2002

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

Resident Research Award for outstanding research
In endometriosis, Bayfront Medical Center
1998

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

Outstanding Leadership
University of Florida College of Medicine
1994

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

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

American Heart Association, Florida Puerto Rico Postdoctoral Grant recipient July 2001, Grant entitled:

Regulation of the High Density Lipoprotein Receptor by Estradiol
2001

Honors Convocation
University of South Florida
1990

MEMBERSHIPS:

Fellow
American College of Obstetrics and Gynecology
2004

Member,
American Society for Colposcopy and Cervical Pathology
1999

Member,
American Association of Gynecologic Laparoscopists
1999

Full Member,
Society for Reproductive Endocrinology and Infertility
1999

Full Member,
American Society for Reproductive Medicine
1999

PROFESSIONAL APPOINTMENTS:

Associate Professor
University of South Florida, Dept. OB/GYN
2019-present

Associate Program Director
Obstetrics & Gynecology Residency and
Division Director of Reproductive
Endocrinology & Infertility
Brandon Regional Hospital
2018- present

Board Member
Bayfront Health
Same Day Surgery Center
2014-2015

Medical Council Member
Bayfront Medical Center
2012- 2015

Standards & Credential Committee
Bayfront Medical Center
2012-2015

Dept. Chair, OB/GYN
Bayfront Medical Center
2012-2015

Adjunct Professor
Nova South Eastern
Physician Assistant School
2011-present

Dept OB/GYN QI Chair
Bayfront OB/GYN
2010-2012

Dept. OB/GYN Vice-Chair
Bayfront Medical Center
2010-2012

Assistant Professor
Florida State University
College of Medicine
2010-present

Clinical Assistant Professor
Florida State University
College of Medicine
2010-2016

Franchise Owner

Medi-Weightloss®
2008-2018

Reproductive Endocrinologist
Director of Oncofertility
Florida Fertility Institute, Suite 601
2006-present

Assistant Director of Reproductive
Endocrinology and Infertility
Bayfront Medical Center
2002-present

Reproductive Endocrinologist
IVF Medical Director
Florida Fertility Institute, Suite 601
2002-present

Associate Medical Director, Investigator and
Vice President
Women's Medical Research Group, Suite 609 and
Florida Clinical Research Group, Suite 610
2002-present

Instructor
University of South Florida, Dept. OB/GYN
2002-present

Peer Review Committee
University of South Florida, Dept. OB/GYN
2001-2002

Residency Selection Committee
University of South Florida, Dept. OB/GYN
1999-2002

Chief Administrative Resident
Bayfront Medical Center
1998-1999

Resident Selection Committee
Bayfront Medical Center
1998-1999

Residency Selection Committee
Bayfront Medical Center
1998-1999

Process Improvement Team
Bayfront Medical Center

1997-1999

Quality Assurance Committee
Bayfront Medical Center
1997-1999

Library Committee
Bayfront Medical Center
1995-1999

Medical Education Committee
Bayfront Medical Center
1995-1999

**RESEARCH, PUBLICATIONS,
ABSTRACTS, AND PRESENTATIONS:**

1. Incidence of Multiple Gestations in Patients with Endometriosis Undergoing IVF.
2. Tuboovarian Abscess after Saline Sonohysterography.
3. Ectopic Pregnancy in a Retained Fallopian Tube after Hemihysterectomy.
4. A Clinicopathologic Study Comparing AJCC Staging in Breast Cancer Patients.
5. Diabetic Retinopathy: An Interpretation of A,B, and C Waves in Streptozotocin Induced Diabetic Rats.
6. Saline Infusion Sonography and Your Practice; Midwinter's Conference, February 2000.
7. Effects of Dax-1 and Alien on Star promoter (In progress).
8. Genetic Regulation of the HDL-R Promoter by Estradiol, Abstract: Society for Gynecologic Investigation, Toronto 2001.
9. Estrogen Enhances the High Density Lipoprotein Receptor Through Four Estrogen Response Elements, Submitted: Endocrinology.
10. Dax-1 Represses the High Density Lipoprotein Receptor Through Interaction with Positive Regulators Sterol Regulatory Element Bindin Protein-1a and Steroidogenic Factor-1, Submitted: Endocrinology.
11. Complications of Tubal Reanastomosis, 2003 Sep; 80(3): 678

12. University Fertility Associates website development, www.universityfertilityassociates.com
13. Microtubal Reanastomosis: Success Rates as Compared to in Vitro Fertilization: J. Reprod. Med 161-165, 2010
14. Efficacy of Vaginal Progesterone Insert (Endometrin ®) Compared to Intramuscular Progesterone in Oil for Luteal support in PCOS Patients 2011 Sept; FP 1137, ASRM11. Infertility. Beltsos
15. Patients' administration preference: progesterone vaginal insert (Endometrin ®) compared to intramuscular progesterone for Luteal phase support. Repro Health. 2014 Nov 11;11(1): 78. [Epub ahead of Print]
16. Risk of Post Tubal Pain Syndrome following Hysteroscopic Sterilization Versus Traditional Tubal Ligation: Neal Trulock, DO, Richard Bravo, DO; Jessica Young, MD, Camille Imbo, MD, Luke Ying, MD, Scott Greenberg, DO, Edward Zbella, MD, Mark Sanchez, MD/HCA
17. Increased Occurrence of Twin and Vert Pre-Term Birth in Patients Undergoing In Vitro Fertilization (IVF) Using Frozen Donor Oocytes; Luke Y. Ying, MD, James Baron, MD, Mark D. Sanchez, MD, Ying Ying, MD.
18. Preimplantation Genetic Testing (PGT) and Frozen Embryo Transfer (FET) Synergistically Decreased Pre-Term Delivery in Patients Undergoing In Vitro Fertilization (IVF); Luke Y. Ying, MD, Mark D. Sanchez, MD, James Baron, MD, Ying Ying, MD.
19. Increased occurrence of twin and very pre-term births in patients undergoing in vitro fertilization (IVF) using frozen donor oocytes; Luke Y. Ying, MD, James Baron, MD, Mark D. Sanchez, MD, Ying Ying, Ph.D.
20. Preimplantation genetic testing (PGT) and frozen embryo transfer (FET) synergistically decreased pre-term delivery in patients undergoing in vitro fertilization (IVF); Luke Y. Ying, MD, James Baron, MD, Mark D. Sanchez, MD, Ying Ying, Ph.D. 2019

CLINICAL RESEARCH STUDIES:

1. **STUDY 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.
- PROTOCOL:** M01-398
- COMPLETION YEAR:** 2004
- SPONSOR:** TAP Laboratories

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

2. **STUDY 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.
PROTOCOL: M02-408, Extension of M01-398
COMPLETION YEAR: 2005
SPONSOR: TAP Laboratories
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
3. **STUDY 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.
PROTOCOL: M01-390
COMPLETION YEAR: 2004
SPONSOR: TAP Laboratories
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
4. **STUDY 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.
PROTOCOL: M01-391, extension of M01-390
COMPLETION YEAR: 2005
SPONSOR: TAP Laboratories
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
5. **STUDY TITLE:** An open label study of the contraceptive efficacy and safety of Triphasic Norethindrone Acetate 1 mg / Ethinyl Estradiol 0.005, 0.030, and 0.035 mg oral tablets administered for 24 days of a 28-day cycle.
PROTOCOL: PR 10503
COMPLETION YEAR: 2005
SPONSOR: Warner Chilcott
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

6. **STUDY TITLE:** A phase III, continuation study to evaluate the safety of Asoprisinil beyond 2 years in subjects with uterine leiomyomata.
- PROTOCOL:** A-FB04-078
- COMPLETION YEAR:** 2006
- SPONSOR:** TAP
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
7. **STUDY TITLE:** A safety and efficacy study of N O-Carboxymethylchitosan (NOCC) when used for reduction of postoperative adhesion development in women undergoing laparoscopy.
- PROTOCOL:** Chito-03
- COMPLETION YEAR:** 2004
- SPONSOR:** Chitogenics, Inc.
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
8. **STUDY TITLE:** The efficacy of Eszopiclone 3 mg compared to placebo in the treatment of insomnia secondary to perimenopause or menopause.
- PROTOCOL:** 190-054
- COMPLETION YEAR:** 2005
- SPONSOR:** Sepracor
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
9. **STUDY TITLE:** Evaluation of safety and efficacy of Prometrium capsules in induction of secretory conversion of endometrium and withdrawal bleeding in subjects with secondary amenorrhea.
- PROTOCOL:** S1684002
- COMPLETION YEAR:** 2008
- SPONSOR:** Solvay Pharmaceuticals, Inc
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
10. **STUDY TITLE:** Efficacy study comparing 0.9 g and 1.25 g EstroGel 0.03% doses with placebo in the treatment of vasomotor symptoms and vulvar and vaginal atrophy associated with menopause.
- PROTOCOL:** S1664003
- COMPLETION YEAR:** 2005

SPONSOR: Solvay
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

11. STUDY 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.

PROTOCOL: A6121002
COMPLETION YEAR: 2006
SPONSOR: Pfizer
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

12. STUDY 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).

PROTOCOL: 2004-02 (IVF)
COMPLETION YEAR: 2006
SPONSOR: Ferring Pharmaceutical
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

13. STUDY 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.

PROTOCOL: Pulsatile GnRH 2004-05 (IV Pump)
COMPLETION YEAR: 2006
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

14. STUDY 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
- PROTOCOL:** MM 17385
COMPLETION YEAR: 2006
SPONSOR: Roche
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
15. **STUDY TITLE:** A multi-center, double-blind, placebo-controlled comparison of multiple doses of esterified estrogens and Methyltestosterone, in combination and alone, in relieving vasomotor symptoms on postmenopausal women.
- PROTOCOL:** SO202112
COMPLETION YEAR: 2007
SPONSOR: Solvay Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
16. **STUDY 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.
- PROTOCOL:** KV05-601-622467
COMPLETION YEAR: 2006
SPONSOR: KV Pharmaceutical Co.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
17. **STUDY 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.
- PROTOCOL:** 3142A2-200-US
COMPLETION YEAR: 2006
SPONSOR: Wyeth
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
18. **STUDY TITLE:** A phase II, randomized, double-blind, placebo-controlled study of NBI-56418 in endometriosis.
- PROTOCOL:** NBI-56418-0501
COMPLETION YEAR: 2006
SPONSOR: Neurocrine Biosciences
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

19. **STUDY TITLE:** A phase II, randomized, double-blind, placebo-controlled twice-daily dosing study of NBI-56418 in endometriosis.
- PROTOCOL:** NBI-56418-0504
- COMPLETION YEAR:** 2007
- SPONSOR:** Neurocrine Biosciences
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
20. **STUDY TITLE:** A double-blind, randomized, placebo-controlled, efficacy and safety study of Bazeoxifene/conjugated Estrogens combinations for treatment of vasomotor symptoms associated with menopause.
- PROTOCOL:** 3115A1-305-US
- COMPLETION YEAR:** 2007
- SPONSOR:** Wyeth
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
21. **STUDY 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.
- PROTOCOL:** 3142A2-203-WW
- COMPLETION YEAR:** 2007
- SPONSOR:** Wyeth
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
22. **STUDY TITLE:** A randomized, placebo-controlled phase II study of multiple dosing regimens of intra vaginally administered 851B Gel for the treatment of cervical high risk HPV infection.
- PROTOCOL:** 1547-851B
- COMPLETION YEAR:** 2008
- SPONSOR:** Takeda
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
23. **STUDY TITLE:** A phase II, multicenter, 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.

PROTOCOL: DR-DZL-201
COMPLETION YEAR: 2007
SPONSOR: Duramed
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

24. STUDY 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.

PROTOCOL: 25550
COMPLETION YEAR: 2009
SPONSOR: Serono
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

25. STUDY 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.

PROTOCOL: 26109
COMPLETION YEAR: 2013
SPONSOR: Serono
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

26. STUDY 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.

PROTOCOL: DR-CEN-302
COMPLETION YEAR: 2007
SPONSOR: Duramed

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

27. **STUDY TITLE:** A multi-center validation study of the daily log of sexual activities (DLSA) in postmenopausal women.
PROTOCOL: S0302108
COMPLETION YEAR: 2007
SPONSOR: Solvay Pharmaceuticals, Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

28. **STUDY 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 to Valacyclovir 500 mg B.I.D. X 3 days in immunocompetent adults with recurrent genital herpes.
PROTOCOL: CFAM810A2308
COMPLETION YEAR: 2006
SPONSOR: Novartis
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

29. **STUDY 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.
PROTOCOL: NKB105022
COMPLETION YEAR: 2006
SPONSOR: GlaxoSmithKline
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

30. **STUDY TITLE:** A multi-center, double-blind, randomized, parallel-group, placebo-controlled, 7 cycle duration (196 days), phase 3 study of oral Estradiol Valerate/Dienogest tablets for the treatment of dysfunctional uterine bleeding.
PROTOCOL: DUB 308960
COMPLETION YEAR: 2008
SPONSOR: Quintiles
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

- 31. STUDY TITLE:** A phase II, randomized, double-blind, active controlled study to assess the safety and efficacy of NBI-56418 in subjects with endometriosis.
- PROTOCOL:** NBI-56418-0603
- COMPLETION YEAR:** 2009
- SPONSOR:** Neurocrine
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
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- 32. STUDY 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.
- PROTOCOL:** Miso-Obs-004
- COMPLETION YEAR:** 2007
- SPONSOR:** Cytokine PharmaSciences, Inc
- PRINCIPAL INVESTIGATOR:** Mark Sanchez, MD
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- 33. STUDY TITLE:** A phase II clinical study evaluating the safety and efficacy of two regimens of Danazol administered intra vaginally for three months in women with moderate-to-severe pain associated with endometriosis
- PROTOCOL:** DZ2-201-601-725036
- COMPLETION YEAR:** 2009
- SPONSOR:** KV Pharmaceutical
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
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- 34. STUDY 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 Glaxo SmithKline Biologicals Boostrix vaccine and/or Sanofi-Aventis' Menactra vaccine according to different dose schedule combinations as compare to the administered of HPV vaccine, Boostrix or Menactra alone in healthy female subjects 11-18 yr.
- PROTOCOL:** 107682 (HPV-018)
- COMPLETION YEAR:** 2010
- SPONSOR:** GlaxoSmithKline

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

35. STUDY TITLE: A double-blind, randomized, controlled study to evaluate the immunogenicity and safety of GlaxoSmithKline Biologicals' herpes simplex candidate vaccine (gD2-AS04) in healthy HSV seronegative and seropositive female subjects aged 10-17 years.

PROTOCOL: 208141/040
COMPLETION YEAR: 2008
SPONSOR: GlaxoSmithKline Biologicals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

36. STUDY 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.

PROTOCOL: SYM-CL-005
COMPLETION YEAR: 2007
SPONSOR: Symbollon Pharmaceuticals, Inc
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

37. STUDY 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.

PROTOCOL: FE992026-CS31
COMPLETION YEAR: 2007
SPONSOR: Ferring
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

38. STUDY 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.

PROTOCOL: LDC-201-601-669020
COMPLETION YEAR: 2009
SPONSOR: KV Pharmaceuticals

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

39. STUDY TITLE: Randomized, double-blind, parallel-group study evaluating the safety and efficacy of Clindamycin/Butoconazole vaginal cream in the treatment of mixed bacterial vaginosis/ vulvovaginal candidiasis infections.
PROTOCOL: CBC-302-602-622467
COMPLETION YEAR: 2009
SPONSOR: KV Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

40. STUDY TITLE: A phase III, multi-center, randomized, double-blind, placebo-controlled study to evaluate the effects of SCE-B on nocturnal vasomotor symptoms in postmenopausal women.
PROTOCOL: DR-ENJ-401
COMPLETION YEAR: 2009
SPONSOR: Duramed Research
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

41. STUDY TITLE: A phase III, single-blind, randomized study to compare DR-2011 to a Progesterone vaginal gel for luteal phase supplementation for In Vitro Fertilization.
PROTOCOL: DR-PGN-302
COMPLETION YEAR: 2009
SPONSOR: Duramed Research
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator.

42. STUDY TITLE: A double-blind, randomized, multicenter study to investigate the endometrial safety of a continuous, combined, oral Estrogen/Progestin Preparation (0.5 mg 17 β -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 postmenopausal women.

PROTOCOL: 310523
COMPLETION YEAR: 2010
SPONSOR: Bayer
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

43. **STUDY 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.

PROTOCOL: 2007004
COMPLETION YEAR: 2009
SPONSOR: Proctor and Gamble
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

44. **STUDY TITLE:** A phase II, randomized, double-blind, placebo controlled study to assess the efficacy and safety of NBI-56418 in subjects with endometriosis.

PROTOCOL: NBI-56418-0702
COMPLETION YEAR: 2010
SPONSOR: Neurocrine Biosciences
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

45. **STUDY 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.

PROTOCOL: FE992026 CS31
COMPLETION YEAR: 2010
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

46. **STUDY 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.

PROTOCOL: 311642
COMPLETION YEAR: 2009

- SPONSOR:** Bayer
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
47. **STUDY 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.
- PROTOCOL:** DR16271
COMPLETION YEAR: 2008
SPONSOR: Sanofi-Aventis
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
48. **STUDY 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.
- PROTOCOL:** IVIT07017
COMPLETION YEAR: 2009
SPONSOR: Luitpold
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
49. **STUDY 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.
- PROTOCOL:** 13108
COMPLETION YEAR: 2011
SPONSOR: Bayer
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
50. **STUDY 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.

PROTOCOL: 3151A2-3353-NA
COMPLETION YEAR: 2010
SPONSOR: Wyeth
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

51. STUDY TITLE: A multi-center, randomized, open-label evaluation of MENOPUR versus Follistim in polycystic ovarian syndrome (PCOS) patients.

PROTOCOL: FPI MEN 2008-05
COMPLETION YEAR: 2010
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Mark Sanchez, M.D.

52. STUDY 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

PROTOCOL: 91556
COMPLETION YEAR: 2011
SPONSOR: Bayer HealthCare
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

53. STUDY 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, post-medarchal, adolescent females

PROTOCOL: DR-105-202
COMPLETION YEAR: 2012
SPONSOR: Duramed
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

- 54. STUDY 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.
- PROTOCOL:** DR-103-301
- COMPLETION YEAR:** 2011
- SPONSOR:** Teva
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 55. STUDY 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
- PROTOCOL:** SPC-SER120-DB1-200901
- COMPLETION YEAR:** 2010
- SPONSOR:** Serenity Pharmaceuticals
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 56. STUDY 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
- PROTOCOL:** SPC-SER120-OLI-200903
- COMPLETION YEAR:** 2011
- SPONSOR:** Serenity
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 57. STUDY TITLE:** A phase II, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of NBI-56418 Na in subjects with endometriosis.
- PROTOCOL:** NBI-56418-0901
- COMPLETION YEAR:** 2010
- SPONSOR:** Neurocrine Biosciences
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 58. STUDY TITLE:** A multi-center, randomized, open-label evaluation

- of MENOPUR versus FOLLISTIM in GnRH antagonist cycles.
PROTOCOL: FPI MEN 2008-04
COMPLETION YEAR: 2009
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
59. **STUDY 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.
- PROTOCOL:** 17P-ES-003
COMPLETION YEAR: 2011
SPONSOR: PRA International
PRINCIPAL INVESTIGATOR: Mark Sanchez, M.D.
60. **STUDY 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.
- PROTOCOL:** 2009-02
COMPLETION YEAR: 2010
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Harry Sperber, MD
POSITION HELD: Sub-Investigator
61. **STUDY 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.
- PROTOCOL:** 81-0064
COMPLETION YEAR: 2010
SPONSOR: Depomed, Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
62. **STUDY 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)
- PROTOCOL:** 1VIT09031
COMPLETION YEAR: 2010
SPONSOR: Luitpold
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

- POSITION HELD:** Sub-Investigator
- 63. STUDY 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.
- PROTOCOL:** N30-004
- COMPLETION YEAR:** 2011
- SPONSOR:** Noven Pharmaceuticals
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 64. STUDY TITLE:** A multi-centre, randomized, 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
- PROTOCOL:** FE-992026 CS41
- COMPLETION YEAR:** 2011
- SPONSOR:** Ferring Pharmaceuticals
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 65. STUDY 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
- PROTOCOL:** FE-992026 CS40
- COMPLETION YEAR:** 2011
- SPONSOR:** Ferring Pharmaceuticals
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub-Investigator
- 66. STUDY 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
- PROTOCOL:** DSG-PPS-303
- COMPLETION YEAR:** 2012

- SPONSOR:** Teva Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
67. **STUDY TITLE:** A phase III, randomized, double-blind, placebo-controlled trial of Ferumoxytol for the treatment of iron deficiency anemia
PROTOCOL: AMAG-FER-IDA-301
COMPLETION YEAR: 2012
SPONSOR: Amag Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
68. **STUDY TITLE:** Clinical evaluation of Triage® hCG in whole blood and plasma (device) GOAL
PROTOCOL: STE-0134
COMPLETION YEAR: 2012
SPONSOR: Alere San Diego Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
69. **STUDY TITLE:** A phase III, open-label extension trial of the safety and efficacy of Ferumoxytol for the episodic treatment of iron deficiency anemia
PROTOCOL: AMAG-FER-IDA-303
COMPLETION YEAR: 2012
SPONSOR: Amag Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
70. **STUDY 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
PROTOCOL: CBGS649A2202
COMPLETION YEAR: 2012
SPONSOR: Novartis Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
71. **STUDY 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
PROTOCOL: PR-04409
COMPLETION YEAR: 2012
SPONSOR: Warner Chilcott
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
72. **STUDY 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
PROTOCOL: PR-04509
COMPLETION YEAR: 2012
SPONSOR: Warner Chilcott
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
73. **STUDY 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)
PROTOCOL: FE 999906 CS12
COMPLETION YEAR: 2012
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
74. **STUDY 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)
PROTOCOL: GSN-IVF006-D3
COMPLETION YEAR: 2012
SPONSOR: Gene Security Network
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
75. **STUDY TITLE:** Exploratory, non-interventional study to identify

and validate biomarkers in follicular fluid, cumulus or granulosa cells or embryo culture medium for prediction of implantation and pregnancy outcome of assisted reproductive technology cycle
EMR200497-001

PROTOCOL:
COMPLETION YEAR: 2012
SPONSOR: EMD Serono Inc. USA
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

76. **STUDY TITLE:** A phase III, multi-center, randomized, double blind, vehicle-controlled study to evaluate the safety and efficacy of product 55394 in the treatment of (BV) bacterial vaginosis

PROTOCOL: MP-1601-01
COMPLETION YEAR: 2013
SPONSOR: Medicis Pharmaceutical Corp.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

77. **STUDY TITLE:** An open-label, escalating dose, 6-month phase III safety study of Enclomiphene Citrate in the treatment of men with secondary hypogonadism

PROTOCOL: ZA-300
COMPLETION YEAR: 2013
SPONSOR: Repros Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

78. **STUDY 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
PROTOCOL: ZA-301
COMPLETION YEAR: 2013
SPONSOR: Repros Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

79. **STUDY TITLE:** An open Label, 6- month phase III extension study of Enclomiphene Citrate in the treatment of men with secondary hypogonadism

PROTOCOL: ZA-301 ext.
COMPLETION YEAR: 2013
SPONSOR: Repros Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

- 80. STUDY 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 narcotics for control of symptomatic pain
- PROTOCOL:** ZPE-202
COMPLETION YEAR: 2014
SPONSOR: Repros Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
- 81. STUDY 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
- PROTOCOL:** M12-665
COMPLETION YEAR: 2015
SPONSOR: Abbott Laboratories
PRINCIPAL INVESTIGATOR: Mark Sanchez, M.D.
- 82. STUDY TITLE:** A randomized, multicenter, double-blind, vehicle-controlled study to evaluate the safety and efficacy of WC3011 in postmenopausal women.
- PROTOCOL:** PR-05812
COMPLETION YEAR: 2013
SPONSOR: Warner Chilcott, LLC
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
- 83. STUDY TITLE:** A randomized, multicenter, double-blind, vehicle-controlled study to evaluate the safety and efficacy of WC3011 in postmenopausal women with dyspareunia.
- PROTOCOL:** PR-08112
COMPLETION YEAR: 2013

SPONSOR: Warner Chilcott, LLC
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

84. STUDY 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

PROTOCOL: 71036006
COMPLETION YEAR: 2013
SPONSOR: Teva Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

85. STUDY 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

PROTOCOL: NDV3A-003
COMPLETION YEAR: 2016
SPONSOR: NovaDigm Therapeutics, Inc
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

86. STUDY TITLE: A multicenter, 26-week, prospective, observational study in adult patients with prediabetes assessing the impact of the Pre Dx test on patient treatment and outcomes in community-based clinical practices

PROTOCOL: TET2013-001A
COMPLETION YEAR: 2013
SPONSOR: Agility Clinical
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator

87. STUDY 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)
PROTOCOL: NT-03
COMPLETION YEAR: 2014
SPONSOR: Nora Therapeutics, Inc
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub-Investigator
- 88. STUDY TITLE:** Extension study to evaluate the long-term safety and efficacy of Elagolix in subjects with moderate to severe endometriosis associated pain
PROTOCOL: M12-667 (Ext to M12-665)
COMPLETION YEAR: 2016
SPONSOR: Abbvie
PRINCIPAL INVESTIGATOR: Mark Sanchez, M.D.
- 89. STUDY TITLE:** A phase III investigator-and assessor-blinded 1:1 randomized, parallel-group multicenter study to compare efficacy and safety of Two r-hFSH formulations (AFOLIA pen vs. Gonal-f® RFF) in normal ovulatory women 35-42 years of age undergoing in vitro fertilization (IVF)
PROTOCOL: FIN-3002
COMPLETION YEAR: 2016
SPONSOR: Finox AG
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 90. STUDY TITLE:** A phase 2, multi-center, prospective, randomized, double-blind, placebo-controlled study to evaluate the effectiveness and safety of SYM-1219 for the Treatment of women with bacterial vaginosis
PROTOCOL: SYM-1219-201
COMPLETION YEAR: 2014
SPONSOR: Symbiomix Therapeutics
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 91. STUDY TITLE:** A randomized, placebo-controlled, parallel group, multicenter study to evaluate the efficacy and

- safety of Ulipristal Acetate for the intermittent treatment of abnormal uterine bleeding associated with leiomyomas
- PROTOCOL:** UL1208
COMPLETION YEAR: 2017
SPONSOR: Watson Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
92. **STUDY TITLE:** A multicenter, double-blind, randomized, placebo-controlled study evaluating two doses of subcutaneous Pulsatile GnRH administered via OmniPod Pump for ovulation induction in female subjects with primary amenorrhea with hypogonadotropic hypogonadism
- PROTOCOL:** 000070
COMPLETION YEAR: 2018
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
93. **STUDY TITLE:** A phase 3, open-label, non- randomized, clinical trial to evaluate the efficacy and safety of FE 999303 (Testosterone Gel) in adult hypogonadal males
- PROTOCOL:** 000127
COMPLETION YEAR: 2015
SPONSOR: Ferring Pharmaceuticals
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
94. **STUDY TITLE:** Phase 3, multi-center, prospective, open-label study to evaluate the safety of a single dose of SYM-1219, a granule formulation containing 2 grams of Secnidazole for the treatment of women and postmenarchal adolescent girls with bacterial vaginosis
- PROTOCOL:** SYM-1219-350
COMPLETION YEAR: 2016
SPONSOR: Symbiomix Therapeutics, LLC
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

95. **STUDY TITLE:** Prospective collection of specimen for the development of vaginal bacteria and vaginal candida assays
PROTOCOL: PLN-03012
COMPLETION YEAR: 2016
SPONSOR: Hologic, INC
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
96. **STUDY TITLE:** A randomized, assessor-blind trial comparing MENOPUR® (menotropins for injection) and recombinant FSH (Follicle Stimulating Hormone) in a GnRH Antagonist cycle with single-blastocyst transfer in a high responder subject population
PROTOCOL: 000205
COMPLETION YEAR: 2017
SPONSOR: Ferring
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
97. **STUDY TITLE:** Multi-center, open-label, single-arm study to assess the safety and contraceptive efficacy of a Levonorgestrel-containing intravaginal ring during a treatment period of one year in healthy women 18 to 35 years of age
PROTOCOL: BAY-98-7196 / 16803
COMPLETION YEAR: 2016
SPONSOR: Bayer HealthCare AG, (Germany)
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
98. **STUDY TITLE:** Multi-center clinical feasibility evaluation of the access AMH Assay to measure AMH as an aid in the prediction of poor ovarian response to controlled ovarian stimulation
PROTOCOL: AMH-01-14
COMPLETION YEAR: 2016
SPONSOR: Beckman Coulter
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

- 99. STUDY TITLE:** A phase 3, randomized, double-blind, placebo-controlled multicenter study to evaluate the efficacy and safety of Ospemifene in patients with moderate to severe vaginal dryness, a symptom of vulvovaginal atrophy (VVA) due to menopause
- PROTOCOL:** 1517I0231
- COMPLETION YEAR:** 2017
- SPONSOR:** Shionogi INC
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 100. STUDY TITLE:** A multi-centre, observation study to validate the professional clinical Alere Clearview hCG Easy pregnancy test (“hCG Easy”)
- PROTOCOL:** ASD-10-002
- COMPLETION YEAR:** 2016
- SPONSOR:** Alere
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 101. STUDY TITLE:** A phase III study to evaluate the efficacy and safety of Elagolix in combination with Estradiol/ Norethindrone Acetate for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women
- PROTOCOL:** M12-815
- COMPLETION YEAR:** 2018
- SPONSOR:** Abvie
- PRINCIPAL INVESTIGATOR:** Mark Sanchez, MD
- 102. STUDY TITLE:** A prospective, non-interventional, multicenter, clinical study to evaluate the efficacy of the Diafert G-CSF ELISA as an adjunct to morphological assessment in predicting embryos’ potential to develop to the blastocyst stage
- PROTOCOL:** DFT-MD- 05
- COMPLETION YEAR:** 2017
- SPONSOR:** Forest/Actavis/Allegan
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 103. STUDY TITLE:** A phase 2, randomized, multicenter, double-blind, vehicle-controlled study to evaluate safety and efficacy of three doses of Estradiol vaginal capsule in postmenopausal women with vulvovaginal Atrophy
- PROTOCOL:** EVC-MD-01
- COMPLETION YEAR:** 2016

- SPONSOR:** Allergan
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 104. STUDY TITLE:** A randomized, double-blind, placebo-controlled, phase 2b dose-ranging study to assess the efficacy and safety of OBE2109 in subjects with endometriosis associated pain
- PROTOCOL:** 15-OBE2109-001
COMPLETION YEAR: 2020
SPONSOR: OBSEVA
PRINCIPAL INVESTIGATOR: Mark Sanchez, M.D
- 105. STUDY TITLE:** A phase 2, open-label, multicenter, randomized, active-controlled study of the safety and tolerability of two formulations of CD101 compared to Fluconazole for the treatment of moderate to severe episodes of acute vulvovaginal candidiasis
- PROTOCOL:** CD101.TP.2.01
COMPLETION YEAR: 2017
SPONSOR: Cidara Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 106. STUDY TITLE:** A non-interventional extension study to investigate vulvovaginal candidiasis recurrence and candida colonization following a phase 2 randomized, active-controlled study of two formulations of CD101 compared to Fluconazole for the treatment of moderate to severe episodes of acute vulvovaginal candidiasis
- PROTOCOL:** CD101.TP.2.02
COMPLETION YEAR: 2017
SPONSOR: Cidara Therapeutics Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 107. STUDY TITLE:** A multicenter, open-label, single-arm study to evaluate the contraceptive efficacy and safety of a combined oral contraceptive containing 15 g Estetrol and 3 mg Drospirenone
- PROTOCOL:** MIT-Es0001-C302
COMPLETION YEAR: 2019
SPONSOR: Estetra SPRL
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

- 108. STUDY TITLE:** A prospective, randomized, placebo-controlled phase III study of VGX-3100, (HPV16 E6/E7, HPV18 E6/E7 DNA Vaccine) delivered IM followed by electroporation (EP) with Collectra® - 5P for the treatment of biopsy-proven CIN 2 or CIN 3 associated with HPV 16 or 18
- PROTOCOL:** HPV-301
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Invio Pharmaceuticals, Inc.
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 109. STUDY TITLE:** A blood test for patients prescribed a laboratory test for syphilis
- PROTOCOL:** FDI-72
- COMPLETION YEAR:** 2016
- SPONSOR:** Fujirebio Diagnostics, Inc
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 110. STUDY TITLE:** Multi-center clinical evaluation of the access AMH assay to measure AMH as an aid in the prediction of poor ovarian response to controlled ovarian stimulation
- PROTOCOL:** AMH-02-16
- COMPLETION YEAR:** 2018
- SPONSOR:** Beckman Coulter
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 111. STUDY TITLE:** A 12-week, phase 2 randomized, double-blind, placebo-controlled study to assess the efficacy safety and tolerability of Gemcabene in subjects with severe hypertriglyceridemia (INDIGO-1)
- PROTOCOL:** GEM-401
- COMPLETION YEAR:** 2017
- SPONSOR:** Gemphire
- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
- POSITION HELD:** Sub Investigator
- 112. STUDY TITLE:** Extension study to evaluate the efficacy and safety of Elagolix in premenopausal women with heavy menstrual bleeding associated with uterine fibroids
- PROTOCOL:** M12-816

COMPLETION YEAR: 2018
SPONSOR: Abbott Laboratories
PRINCIPAL INVESTIGATOR: Mark Sanchez, MD

- 113. STUDY TITLE:** An international phase, 3 randomized, double-blind, placebo- controlled efficacy and safety study to evaluate Relugolix co-administered with and without low-dose estradiol and Norethindrone Acetate in women with heavy menstrual bleeding associated with uterine fibroids
- PROTOCOL:** MVT-601-3001
COMPLETION YEAR: 2020
SPONSOR: Myovant Sciences GmbH
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 114. STUDY TITLE:** A phase 3, multicenter, randomized, double-blind, placebo-controlled study investigating the efficacy and safety of daily oral administration of OB2109 alone and in combination with add-back therapy for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women
- PROTOCOL:** 16-OBE2109-008
COMPLETION YEAR: 2019
SPONSOR: ObsEva S.A.
PRINCIPAL INVESTIGATOR: Mark Sanchez, MD
- 115. STUDY TITLE:** An open-label, parallel-group, randomized, multicenter study to assess the safety and efficacy of Vilaprisan in subjects with uterine fibroids versus standard of care.
- PROTOCOL:** BAY1002670 / 16953
COMPLETION YEAR: Ongoing
SPONSOR: Non-US Territory Bayer AG
PRINCIPAL INVESTIGATOR: Mark Sanchez, MD
- 116. STUDY TITLE:** A randomized, double-blind, placebo-controlled, response-adaptive dose-finding trial investigating the efficacy, safety and tolerability of oral doses of FE 201836, with Desmopressin orally disintegrating tablet as a benchmark, during 12 weeks of treatment for Nocturia due to nocturnal polyuria in adults
- PROTOCOL:** 000233

COMPLETION YEAR: 2020
SPONSOR: Ferring US
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

117. STUDY TITLE: A randomized, open-label, comparative trial comparing the incidence of hypophosphatemia in relation to treatment with iron isomaltoside and ferric Carboxymaltose in subjects with iron deficiency anemia

PROTOCOL: IDA-04
COMPLETION YEAR: 2018
SPONSOR: Pharmacosmos A/S
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

118. STUDY TITLE: A randomized, double-blind, placebo-controlled study to assess the efficacy of MT-8554 on the frequency and severity of vasomotor symptoms in postmenopausal women

PROTOCOL: MT-8554-A01& A02 ext.
COMPLETION YEAR: 2019
SPONSOR: Mitsubishi Tanab Pharma Development America
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

119. STUDY TITLE: A Prospective, Multi-Center, Non-Comparative Trial of the Clinical Safety of the Progesterone Vaginal Ring in Women Undergoing Assisted Reproductive Technology (ART) Procedures

PROTOCOL: 000293
COMPLETION YEAR: 2019
SPONSOR: Ferring
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator

120. STUDY TITLE: A Phase 2a, Proof of Concept, Randomized, Double-blind, Placebo-controlled Clinical Trial, to Evaluate the Efficacy and Safety of MK-7264 in Women with Moderate to Severe Endometriosis-related Pain

PROTOCOL: MK7264-034
COMPLETION YEAR: Ongoing
SPONSOR: Merck
PRINCIPAL INVESTIGATOR: Mark Sanchez, MD

- 121. STUDY TITLE:** A randomized, parallel-group, double-blind and placebo controlled, multicenter study to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids
- PROTOCOL:** BAY 1002670 / 15790
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Non-US Territory Bayer AG
- PRINCIPAL INVESTIGATOR:** Mark Sanchez, MD
- 122. STUDY TITLE:** A randomized, double-blind, placebo-controlled, parallel groups, multicenter trial investigating the efficacy and safety of FE 999049 in controlled ovarian stimulation in women aged 18-34 years undergoing assisted reproductive technology
- PROTOCOL:** 00001
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Ferring
- PRINCIPAL INVESTIGATOR:** Edward Zbella, MD
- POSITION HELD:** Sub Investigator
- 123. STUDY TITLE:** A randomized, double-blind, placebo-controlled, parallel groups, multicenter trial investigating the efficacy and safety of FE 999049 in controlled ovarian stimulation in women aged 34- 42 years undergoing assisted reproductive technology
- PROTOCOL:** 00002
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Ferring
- PRINCIPAL INVESTIGATOR:** Edward Zbella, MD
- POSITION HELD:** Sub Investigator
- 124. STUDY TITLE:** Prospective Collection of Anti-Mullerian Hormone (AMH) for Assessing Ovarian Reserve Prior to Infertility Therapy
- PROTOCOL:** FD-191
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Fujirebio

- PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 125. STUDY TITLE:** A Randomized, Blinded, Standard-Controlled Study to Evaluate the Safety and Efficacy of Ohana In-Vitro Fertilization (IVF) Sperm Preparation Kit OHB-035 on IVF
PROTOCOL: OHANA-IVF-001
COMPLETION YEAR: Ongoing
SPONSOR: Ohana
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 126. STUDY TITLE:** A Multicenter, Observational Cohort Study of Women receiving Standard of Care (SOC) for the Treatment of Pelvic Pain Attributable to Suspected or Confirmed Endometriosis
PROTOCOL: P16-836
COMPLETION YEAR: Ongoing
SPONSOR: Abbvie
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator
- 127. STUDY TITLE:** A Phase 3b Study to Evaluate the Safety and Efficacy of Elagolix in Combination with Combined Oral Contraceptives in Premenopausal Women with Documented Endometriosis and Associated Moderate to Severe Pain
PROTOCOL: M18-969
COMPLETION YEAR: Ongoing
SPONSOR: Abbvie
PRINCIPAL INVESTIGATOR: Mark Sanchez, MD
- 128. STUDY TITLE:** ADVIA Centaur AMH Ovarian Reserve Specimen Collection Protocol
PROTOCOL: CA-Centaur-201905.PRO
COMPLETION YEAR: Ongoing
SPONSOR: Siemens Healthcare Diagnostics
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.
POSITION HELD: Sub Investigator