

Precision Trials LLC / Arizona Wellness Center for Women

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Precision Trials and the Arizona Wellness Center for Women have been performing clinical trials in women's health care since 1987. Our facilities are located adjacent to Paradise Valley Hospital; a level 2 acute care 140-bed hospital facility located in the heart of Phoenix, Arizona. Two major freeways give easy access to our office and draw patients from a wide local area map. A sixty million dollar expansion is underway to meet the growth needs of North Phoenix and the Scottsdale community.

Precision Trials is located within the offices of the Arizona Wellness Center for Women. The medical practice is a full service Obstetric and Gynecology office that sees approximately 1000 patients per week. Our patient population includes women of all socioeconomic strata spanning adolescence thru menopause.

Services offered include prenatal care, gynecology, urinary incontinence, infertility, and gynecologic surgery. All physicians are board certified MDs, in good standing with the Board of Medical Examiners and Fellows of The American College of Obstetrics and Gynecology. All physicians are skilled gynecologic surgeons who perform advanced operative laparoscopic and hysteroscopic procedures.

Precision Trials in conjunction with the Arizona Wellness Center for Women has met or exceeded enrollment in all participated clinical trials since 1987. The majority of patients that enroll in our studies are recruited from daily patient encounters

Physicians

Steven J Wininger MD, FACOG, CPI

Valerie Sorkin-Wells MD, FACOG

Rodney Smith MD, FACOG

Nancy Harris MD, FACOG

Physician Assistants

Heather Roth, PA-C

Donna Figaro-Sheffey PA-C

Facility:

10,000 sq. feet office complex adjacent to Paradise Valley Hospital

10 fully equipped gynecology exam rooms

2 ultrasounds including transvaginal

1 external fetal monitor

1 procedure room

14 physician and support staff office rooms

Lunchroom and waiting room

High speed secure Internet on two T1 lines
Freezer –20 °Fahrenheit
Dedicated secure room for source documents and CRF's
Radiology, Dexa, EKG services available
24-hour emergency pager for study subjects
Centrifuge
Refrigerated centrifuge
2 microscopes
2 culposcopes
In-office flexible hysteroscope with video
Autoclave
Dedicated secure investigational medication room
Monitor work offices
Refrigerator
HIPAA compliant

Investigators and Support Staff

Four Board Certified MDs and Fellows of American College Of OBGYN
Two Board Certified Physician Assistant
One Nurse RNs
Four Certified Clinical Research Coordinators (CCRCs)
Two Research/Medical Assistants
ARDMS Sonographer

Patient Demographics Percent of patients that are:

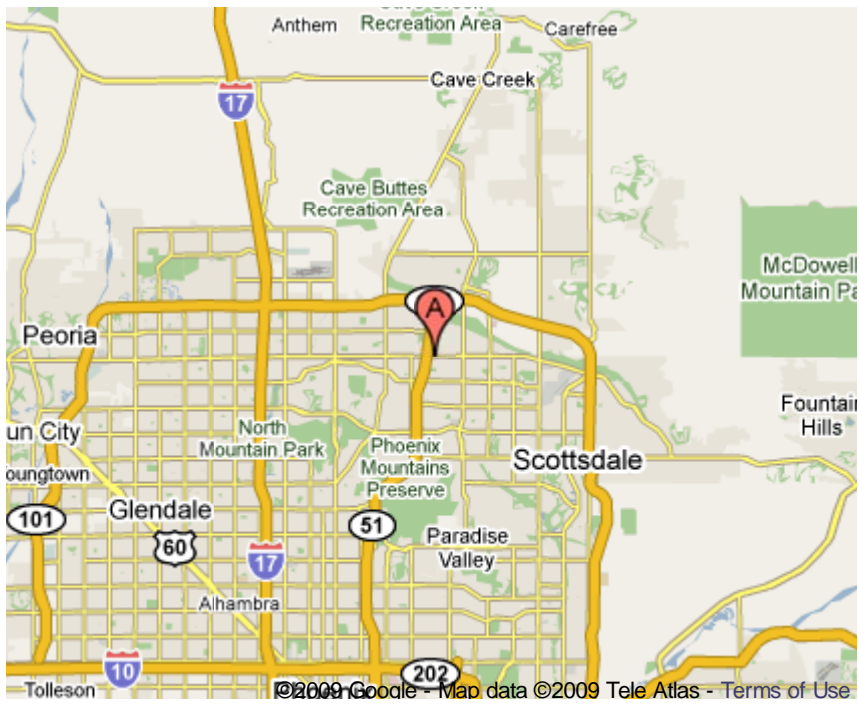
White 74%	Pediatric (birth – 12) 1%
African American 9%	Adolescent (13-17) 15%
Hispanic 14%	Reproductive Age (18-50) 55%
Asian 1%	Menopausal 29%
Native American Indian 1%	

Office Procedures

Pregnancy and pelvic (GYN) ultrasonography including transvaginal
Leep Cervical Conization
Cryotherapy
In-office Diagnostic Hysteroscopy
Bladder catheterization
Uterine (Endometrial) biopsy
Colposcopy
Urine analysis with microscopy
Breast Cyst Aspiration
Endometrial (Uterine) Ablation
Ultrasonography, EKG

Procedures Hospital Based

Pelvic surgery including laparotomy, laparoscopy and operative hysteroscopy
Incontinence Surgery
Cesarean Delivery
Laparoscopic Hysterectomy



CURRICULM VITAE

Steven Winger, M.D. CPI

Precision Trials
3815 East Bell Road, Suite 4500
Phoenix, AZ 85032
602-931-4507

Education:

- 1980 Oberlin College/Conservatory of Music
Bachelor Degree in Music
- 1984 Post Graduate Studies
University of Massachusetts at Amherst
- 1989 Tufts University School of Medicine
Medical Doctor
Boston, MA

Postgraduate Training:

- 1989-1990 Internship, Pennsylvania Hospital
Philadelphia, PA
- 1990-1993 Resident in OB/GYN Pennsylvania Hospital
Philadelphia, PA

Professional Experience:

- 2006-present Principal Investigator/ Physician/ Medical Director
Precision Trials (formerly Arizona Wellness Center for Women
Research Department)
Phoenix, AZ
- 1998-present Obstetrics & Gynecology/Investigator/Medical Director
Arizona Wellness Center for Women
Phoenix, AZ
- 1995-1998 Obstetrics & Gynecology/Investigator
Obstetrics and Gynecology Consultants, Ltd
Phoenix, AZ

Steven Winger, MD CPI
Curriculum Vitae
Page 2

**Professional
Experience
Continued:**

1993-1995 Obstetrics & Gynecology
 Seaton Obstetrics and Gynecology
 Boston, MA

Academic Affiliations:

Assistant Professor
Tufts University School of Medicine
Boston, MA

Assistant Instructor in Obstetrics & Gynecology
University of Pennsylvania School of Medicine
Philadelphia, PA

Department Chairman in OB GYN
Paradise Valley Hospital, Phoenix, AZ

**Professional
Memberships:**

American Associates of Gynecologic Laparoscopists
American College of Obstetrics & Gynecology
Massachusetts Medical Society
Maricopa Medical Society

Hospital Appointments:

2004 Board of Directors
Paradise Valley Hospital
Phoenix, AZ

Hospitals:

Paradise Valley Hospital
Scottsdale Healthcare

Steven Winger, MD CPI
Curriculum Vitae
Page 3

Licenses/Certifications:

Arizona #23378
Massachusetts # 77483
Pennsylvania # MD044992L

Certification:

American Board of Obstetrics & Gynecology 1997
Certified Clinical Research Investigator (CCTI) ACRP 2005

Honors/Awards:

1988 – McGraw Hill Award for Outstanding Contribution and Academic Achievement
1993 - Resident Training Award, University of Pennsylvania School of Medicine
1993 - CREOG Award, Pennsylvania School of Medicine

Publications:

Prenatal Diagnosis Vol. 14:839-843 (1994)
Syndromes identified with fetuses with prenatally diagnosed cephaloceles

K. Candiotti, N. Singla, S. Winger, H. Minkowitz, J. Breitmeyer
Poster 2008. Study Results of Intravenous Acetaminophen over 48 hours for the
treatment of Postoperative Pain after Gynecologic Surgery

K. Candiotti, N Singla, S. Winger, H. Minkowitz, M Royal
Poster 2008. Study Results of Intravenous Acetaminophen over 48 hours for the
treatment of Postoperative Pain after Gynecologic Surgery

Fertility and Sterility Vol. No. 2008.
J. Simon, MD, K Reape, MD., S. Winger, MD., H. Hait MS.
Clinical Article on Synthetic Conjugates Estrogens for the treatment of Vulvovaginal
Atrophy in healthy Postmenopausal Women.

Research Experience:

A Phase III Open-Label, Single Arm Study to Assess the Safety of XXXXX Injection for
Minimal-to-Moderate Sedation in patients undergoing Minor Surgical Procedures.

Steven Wininger, MD CPI
Curriculum Vitae
Page 4

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group, Multiple-Dose study of the XXXXX Efficacy and Safety of Intravenous XXXXX versus Placebo over 48 hours for the Treatment of Postoperative Pain After Gynecologic Surgery

A Phase II, Multi-centered, Randomized, Placebo-controlled, Double-blind study of the XXXXX in pre-menopausal women with symptomatic leiomyomata

A twenty-four week, randomized, double-blind, placebo-controlled, safety and efficacy trial of XXXXX daily and, with XXXXX daily in Premenopausal women with hypoactive sexual desire disorder.

A Randomized, Multi-center, Double-Blind, Placebo-Controlled Trial, to demonstrate the safety and efficacy of Daily XXXXX and XXXXX daily for the treatment of vasomotor symptoms in postmenopausal women.

A 12 month, Open Label, Multi-center Study to Evaluate the safety of XXXXX Formulation administered three times daily for women with heavy menstrual bleeding associated with menorrhagia.

A multi-center, randomized, double-blind phase III study of the efficacy and safety of XXXXX compared to XXXXX for women requiring cervical ripening and induction of labor.

A phase 3, randomized, double blind, dose-controlled study to assess the efficacy and safety of XXXXX injection for minimal-to-moderate sedation in patients undergoing flexible Bronchoscopy.

A multi-center, double-blind, randomized, placebo-controlled study of XXXXX in the treatment of High-Grade cervical intraepithelial lesions of the uterine cervix.

A Phase II, multi-center, double-blind, randomized, placebo-controlled study to evaluate induction of Withdrawal bleeding after administration of XXXXX in women with secondary amenorrhea.

A phase II b multi-centered, double-blind, placebo-controlled, parallel-group, dose-ranging study evaluating the efficacy and safety of XXXXX for the treatment of moderate to severe vasomotor symptoms associated with menopause.

A Randomized, multi-center, double-blind, placebo-controlled trial to compare the effects of 12 weeks of treatment with XXXXX vs. XXXXX on vulvovaginal atrophy in healthy post menopausal women.

Steven Winger, MD CPI
Curriculum Vitae
Page 5

A phase II, multi-center, double-blind, randomized, placebo-controlled study to evaluate two doses of XXXXX for the management of moderate to severe endometriosis related non-menstrual pelvic pain.

A Pilot clinical study to evaluate the efficacy of XXXXX in the treatment of the signs and symptoms of atrophic Vaginitis.

Evaluating the Safety and Efficacy of XXXX in the treatment of Vaginal Atrophy in Postmenopausal Women

Evaluating the Safety & Efficacy of XXXX, vaginal cream compared with Metro Gel vaginal cream for the treatment of Bacterial Vaginosis

Evaluating the Safety & Efficacy of XXX, combination pack in bedtime versus daytime administration

Evaluating the Safety & Efficacy of XXXX, vaginal ointment, plus XXXX external vulvar cream of XXX, vaginal cream in the Treatment of Vulvovaginal candidiasis.

Evaluate the Treatment of Women with Menorrhagia with Intrauterine XXXX Ablation

Evaluate the dosing optimization study of XXXX for Endometriosis

Evaluate the Safety & Efficacy of Triphasic Oral Contraception

Evaluating the Safety & Efficacy in a double-blinded study of XXXX versus Placebo in Subjects with Endometriosis

Evaluating the Safety & Efficacy of XXXX estrogen combination in Postmenopausal Women

Evaluating XXXX for Contraceptive use

Evaluating XXX in Women using XXXX to Depo-Provera for Contraception

Evaluate the Safety & Efficacy of XXXX in the ovulatory, endocrine and metabolic abnormalities of Women with Polycystic Ovary Syndrome

Evaluation of XXXX vs hysterectomy in Safety & Efficacy trial for Permanent Female Sterilization

Steven Wininger, MD CPI
Curriculum Vitae
Page 6

A Multicenter, Randomized, Double-Blind, Study to Evaluate the Safety And Efficacy of XXXX versus XXXX versus Placebo in Women Diagnosed with Overactive Bladder Who Have Symptoms of Predominant or Pure Urge Incontinence

A Randomized, Multicenter, Double-Blind, Placebo-Controlled Trial to Demonstrate the Safety and Efficacy of XXXX for the Treatment of Vasomotor Symptoms in Postmenopausal Women

A Randomized, Multicenter, Double-Blind, Placebo-Controlled Trial to Compare the Efficacy and Safety of XXXX vs. XXXX Vulvovaginal Atrophy in Healthy Postmenopausal Women

A Randomized, Multicenter, Double-Blind, Placebo Controlled Trial to Evaluate the Efficacy and Safety of XXXX for the Treatment of Vulvovaginal Atrophy in Healthy Postmenopausal Women

A Phase II, Multicenter, Double-Blind, Randomized, Placebo Controlled Study to Evaluate Induction of Withdrawal Bleeding After Administration of XXXX in Women with Secondary Amenorrhea

A Randomized, MultiCenter, Double-Blind Study to Evaluate the Efficacy of XXXX Compared to Conventional Oral Contraceptive Therapy for the Treatment of Cyclic Pelvic Pain in Women

A Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of an XXXX for the Prevention of Pregnancy in Women

A Multicenter, Randomized, Double Blind, Placebo-controlled, Dose-ranging, Parallel Group Phase II Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of XXXX When Administered with XXXX for the Prevention of Post-operative Nausea and Vomiting (PONV) and Post-discharge Nausea and Vomiting (PDNV) in Female Subjects with Known Risk Factors for PONV Who are Undergoing Surgical Procedures Associated with an Increased Emetogenic Risk

A Randomized, Double-Blind, Multicenter, Parallel Group, Balanced, Stratified, Phase 3 Study to Evaluate the Efficacy and the Safety of XXXX Following Elective Abdominal or Gynecological Laparoscopic Surgery

Comparison of the Safety and Efficacy of XXXX in the Treatment of Iron Deficiency Anemia Secondary to Heavy Uterine Bleeding”

Steven Winger, MD CPI
Curriculum Vitae
Page 7

Comparison of the Safety and Efficacy of XXXX in Subjects who Display Postpartum Anemia

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of XXXXX in Endometriosis

A Phase II, Randomized, Double-Blind, Placebo-Controlled Twice-Daily Dosing Study of XXXX in Endometriosis

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of XXXX Breast Disease in Otherwise Healthy, Premenopausal Women

A 12-Month, Open Label, Multicenter Study to Evaluate the Safety of XXXX During the Menstrual Cycle in Women with Heavy Menstrual Bleeding Associated with Menorrhagia

A Double Blind, Randomized, Placebo Controlled, Efficacy and Safety of XXXX for the Treatment of Vasomotor Symptoms Associated with Menopause.

An Open-Label Study of the Safety and Efficacy of a New Low Dose Oral Contraceptive Containing XXXXX.

An Open Label Study of the Contraceptive Efficacy of an Extended Regimen of XXXXX and XXXXX.

A Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of an Extended Cycle, Low Dose, Combination Oral Contraceptive Regimen XXXXX During the Seven Day Interval Between Each 84-Day Cycle of Combination Therapy For the Prevention of Pregnancy in Women

A Double-Blind, Randomized, Placebo-Controlled, Efficacy and Safety Study of XXXXX Combinations for Treatment of Vasomotor Symptoms associated with Menopause

Whole Blood Collection Protocol for XXXXX Clinical Trial in Women with Ovarian Tumors

A Phase II, 18-Week, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of XXXXX Combination Cream Compared with XXXXX Placebo Creams in the Treatment of Vulvar Vestibulitis Syndrome

Steven Winger, MD CPI
Curriculum Vitae
Page 8

A Phase II, Randomized, Double-Blind, Active-Controlled Study to Assess the Safety and Efficacy of XXXXX in Subjects with Endometriosis

A twelve month, open-label, safety trial of XXXXX daily in women with Hypoactive Sexual Desire Disorder.

A randomized, double-blind, placebo-controlled, multi-center, 52 week study to evaluate the endometrial safety of XXXXX in naturally postmenopausal women with hypoactive sexual desire disorder.

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group, Multiple-Dose Study of the Analgesic Efficacy and Safety of Intravenous XXXXX Versus Placebo over 48 hours for the Treatment of Postoperative pain after Gynecologic Surgery

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group, Repeated-Dose Study of the Analgesic Efficacy and Safety of Intravenous Acetaminophen versus Placebo for the Treatment of Postoperative Pain after Laparoscopic Surgery

A multi-center, open-label, randomized study to assess the safety and contraceptive efficacy of two doses of the ultra low dose XXXXX contraceptive intrauterine system for a maximum of 3 years in women 18 to 35 years of age

A multi-center, randomized, controlled study to investigate the safety and tolerability of XXXXX vs. standard medical care in treating Iron Deficiency Anemia in Heavy Uterine Bleeding and Post Partum patients.

Multi-center clinical study to determine the effectiveness and safety of HEDA in the screening of women for breast cancer

A Phase II single dose, blinded prospective study to investigate the efficacy, safety and Pharmacokinetics profile of the XXXXX in women following abdominal hysterectomy.

A Phase II clinical study evaluating the safety and efficacy of two regimens of XXXXX administered intravaginally for three months in women with moderate to severe pain associated with endometriosis.

Randomized, double-blind, parallel-group study evaluating the safety and efficacy of XXXXX in the treatment of mixed bacterial vaginosis/vulvovaginal candidiasis infections.

Steven Wininger, MD CPI
Curriculum Vitae
Page 8

A Phase III, Randomized, Double-blind, Placebo-controlled, Multi-center, Efficacy and Safety Study of XXXXX creams in the treatment of External Genital Warts.

Evaluation of the XXXXX HPV Test and the Linear Array High Risk HPV Genotyping Test for the Detection of High-Grade Cervical disease in Women Undergoing Routine Cervical Cancer Screening Using Cervical Samples Prepared With the Cobas x 421 Instrument

Updated: July 2008