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Excellence, Experience & Ethics

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Pharmaceutical Research Experience Summary

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Summary Data:

Total Number of Studies:	**33**
Principal Investigator:	17
Sub-Investigator:	16
Category Count:	
Menopause:	12
Osteoporosis Prevention:	4
Female Contraception	5
Osteoporosis Treatment:	3
Endometriosis:	3
Polycystic Ovarian Syndrome:	2
Premenstrual Dysphoric Disorder	1
Hypertension	1
General Gynecology	2

Phase I:	0
Phase II:	4
Phase III:	27
Phase IV:	2

Detailed Summary:

Category	Investigator Type	Affiliation*	Description	Start Date	Study Number
Menopause	Principal Investigator	SMR	*Ortho-McNeail Pharmaceuticals, Inc. (CAPSS-300):* The effect of Ditropan XL® on vasomoror symptoms in healthy post-menopausal women: A double-blind placebo controlled pilot study.	3/04	#33
General Gynecology	Principal Investigator	SMR	*Barrier Therapeutics (BT0300C1-300-USA):* A multi-center, randomized, double-blind, comparative, safety and efficacy study of a single dose of 400 mg itraconazole given as two 200 mg film-coated tablets versus a single dose of 150 mg fluconazole given as a single tablet in the treatment of vaginal candidiasis.	3/04	#32

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Female Contraception	Principal Investigator	SMR	*Wyeth Research (0858A2-314-NA):* A phase III, multi-center study to evaluate the teturn to spontaneous menses for subjects receiving prior treatment with a continuous daily regimen of levonorgestrel and ethinyl estradiol for oral contraception.	2/04	#31
General Gynecology	Principal Investigator	SMR	*Galen (08102.1):* An open label, randomized study of the efficacy and safety of an intravaginal ring delivering metronidazole compared to commercially available metronidazole oral tablets in the treatment of bacterial vaginosis.	6/03	#30
Female Contraception	Principal Investigator	SMR	*Wyeth Research (0858A2-313-NA):* A phase III, multi-center, open-label study to evaluate the safety and efficacy of levonorgestrel 90 ug and ethinyl estradiol 20 ug in a continuous daily regimen for oral contraception.	2/03	#29
Endometriosis	Principal Investigator	SMR	*TAP Pharmaceutical Products Inc. (M02-408):* A phase II, 12-month, open-label extension study to evaluate the safety of J867 (5 mg QD) in subjects with endometriosis.	1/03	#28
Endometriosis	Principal Investigator	SMR	*TAP Pharmaceutical Products Inc. (M01-398/306143):* A phase II, 3-month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 (0.5, 1.5 and 5 mg QD) versus placebo in subjects with endometriosis.	8/02	#27
Menopause	Sub-Investigator	ICSL/CNS	*Galen (00501.0):* A multi-center, double-blind, placebo-controlled, randomized study to determine efficacy in the relief of hot flushes in women receiving oral estradiol acetate tablets.	1/01	#26
Menopause	Sub-Investigator	ICSL/CNS	*Organon, Inc. (32972):* A multinational, multi-center, randomized, double-blind, parallel group, active controlled, comparative trial to assess the endometrial histological profile following treatment with tibolone (Org OD 14) versus conjugated estrogen (CE) plus medroxyprogesterone acetate (MPA) in postmenopausal women.	1/01	#25
Osteoporosis	Principal Investigator	ICSL/CNS/ SMR	*Endeavor Pharmaceuticals (ENDV-01-001):* A multi-center, double-blind, placebo-controlled study to evaluate the safety and efficacy of three doses of synthetic 10-component conjugated estrogens (CE10 0.3 mg, 0.45 and 0.625 mg modified release tablets) compared with placebo in hysterectomized postmenopausal women for the prevention of osteoporosis.	4/01	#24
Osteoporosis	Principal Investigator	ICSL/CNS/ SMR	*Wyeth-Ayerst Research (3068A1-300-US):* A multi-center, double-blind, randomized, placebo- and Raloxifene-controlled study to assess safety and efficacy of TSE-424 in the prevention of postmenopausal osteoporosis.	8/01	#23
Hypertension	Sub-Investigator	ICSL/CNS	*Berlex Laboratories, Inc. (305140):* A multi-center, double-blind, randomized, placebo-controlled study to evaluate the effect of a continuous-combined HRT preparation containing 1 mg estradiol and 3 mg drospirenone on blood pressure in mildly hypertensive postmenopausal women.	10/01	#22
PMDD	Sub-Investigator	ICSL/CNS	*Berlex Laboratories Inc. (304049):* A multi-center, double blind, randomized, placebo-controlled, parallel group study to evaluate the efficacy of a monophasic oral contraceptive preparation containing Drospirenone 3 mg Ethinyl Estradiol 20 ug (as Beta-Cyclodextrin Clathrate) in the treatment of premenstrual dysphoric disorder (PMDD).	10/01	#21
PCOS	Principal Investigator	ICSL/CNS	*Insmed Pharmaceuticals Research (INS1-PO-19):* A randomized, double-blinded, placebo controlled, dose-ranging study to assess the effect of INS-1 on Insulin and Ovarian Androgen production in Obese Women with Polycystic Ovary Syndrome (PCOS). This study will also examine the effects of INS-1 on plasma lipids, blood pressure and appetite as well as follow the safety of the drug.	2001	#20
Menopause	Principal Investigator	ICSL	*Endeavor Pharmaceuticals (GA326):* A randomized, double-blinded, dose-ranging, parallel-group study to compare the safety and efficacy of synthetic 10-component conjugated estrogens (CE10) (0.3, 0.625 and 1.25 mg modified release) with placebo in postmenopausal women suffering from moderate to severe vasomotor symptoms.	8/00	#19

Female Contraception	Sub-Investigator	ICSL	*Organon Inc. (147-001):* A randomized, open-label, comparative, multi-center trial to evaluate the contraceptive efficacy, cycle control, safety and acceptability of a monophasic oral contraceptive containing 200 ug ORG 30659 and 20 ug ethinyl estradiol compared to a monophasic oral contraceptive containing 100 ug levonorgestrel and 20 ug ethinyl estradiol.	2000	#18
Menopause	Sub-Investigator	ICSL	*Novavax Pharmaceuticals, Inc. (E99-1):* Evaluation of daily dose of Estrasorb 7.5 mg compared to placebo in the treatment of symptomatic postmenopausal women.	1/00	#17
Endometriosis	Principal Investigator	ICSL	*PRAECIS Pharmaceuticals, Inc. (149-99-02):* The FASTER Study (First Abarelix-Depot Study for Treating Endometriosis Pain Rapidly) A multi-center, double-blind, randomized study to evaluate the safety profile of Abarelix-Depot in women with endometriosis. In addition, this study will also compare the effectiveness of Abarelix-Depot to Lupron® Depot 3.75 mg. for treating endometriosis-associated pain. The study will also evaluate how rapid the medications take affect, quality of life issues, changes in interpersonal relationships while on the study medications, health resource utilization issues, changes in bone mineral density and the number and severity of adverse drug reactions.	1999	#16
Osteoporosis	Sub-Investigator	MS/ICSL	*Berlex Laboratories (96041B):* A multi-center, double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of two doses of estradiol given by continuous transdermal administration in the prevention of osteoporosis in hysterectomized postmenopausal women. This study will also evaluate biochemical markers of bone metabolism.	7/99	#15
PCOS	Principal Investigator	MS/ICSL	*Insmed Pharmaceuticals, Inc (INS - /10):* A multi-center, double-blind, randomized, placebo-controlled, dose-ranging study to assess the effect of INS-1 on insulin and ovarian androgen production in obese women with polycystic ovary syndrome (PCOS).	9/98	#14
Menopause	Sub-Investigator	MS/ICSL	*Merk KGaA Pharmaceuticals, Inc. (EMD 90171-002):* A multi-center dose-finding study comparing the efficacy of EMD 90 171, a once-a-week estradiol-levonorgestrel combination transdermal patch with placebo in the treatment of vasomotor symptoms associated with menopause, type and incidence of vaginal bleeding and changes in endometrial histology.	6/98	#13
Menopause	Sub-Investigator	MS/ICSL	*Parke-Davis Pharmaceutical Research (376-401):* A randomized, double-blinded, placebo controlled, parallel group, multi-center study assessing the safety and protective effect on the endometrium of four dosage combinations of Norethindrone Acetate plus Ethinyl estradiol in the post-menopausal patient. This study is unusual in that it also compares the above regiment directly to Prempro, a commonly prescribed form of HRT. Changes in bone mineral density, lipids and the incidence of vaginal bleeding as well as changes in endometrial histology will be followed.	9/98	#12
Female Contraception	Sub-Investigator	MS/ICSL	*Otho-McNeil Pharmaceutical (CAPSS-066):* A randomized, open-label, multi-center, comparative Phase IV study of reproductive age women to compare the safety of Ortho Tri-Cyclen (norgestimate and ethinyl estradiol) and Alesse (levonorgestrel and ethinyl estradiol) on cycle control, lipids, coagulation and androgen profiles.	1/98	#11
Menopause	Sub-Investigator	MS/ICSL	*Berlex Laboratories, Inc. (96097):* A double-blind, randomized, multi-center comparison of continuous oral Estradiol-Drospirenone combinations and continuos oral estradiol examining the effects on the endometrium, systemic symptoms and bleeding patterns of postmenopausal women.	1/98	#10
Osteoporosis	Principal Investigator	MS/ICSL	*Novo Nordisk Pharmaceuticals, Inc. (LEV/PD/16):* A double-blind, randomized, placebo controlled parallel-group, multi-center dose comparison study contrasting the efficacy and safety of levormeloxifene in the treatment of postmenopausal osteoporosis and the prevention of vertebral compression fractures.	1/98	#9

Female Contraception	Principal Investigator	MS/ICSL	*Organon Pharmaceuticals, Inc. (068003):* An open-label, non-comparative, multi-center study to evaluate the contraceptive efficacy, cycle control and safety of a single-compartment ethylene-vinyl-acetate copolymer etoroestrel/ethinyl estradiol impregnated vaginal ring.	1/98	#8
Menopause	Sub-Investigator	MS/ICSL	*Wyeth-Ayerst Research (0802D1-324-US):* A randomized, double-blind, placebo and active-controlled, parallel, multi-center study to assess the safety and efficacy of a 3½ day transdermal patch containing 17 beta-estradiol/ norethindrone acetate on the relief of menopausal vasomotor symptoms and the reduction of endometrial hyperplasia.	1/98	#7
Menopause	Sub-Investigator	MS/ICSL	*Organon Pharmaceuticals, Inc. (010201):* A double-blind, randomized, parallel-group, multi-center, placebo-controlled study to evaluate the efficacy and safety of Tibolone in the treatment of moderate to severe vasomotor symptoms and atrophic conditions associated with menopause.	9/97	#6
Osteoporosis	Sub-Investigator	MS/ICSL	*Lilly Research Laboratories (H3S-MC-GGHD):* A double-blind, randomized, parallel-group, multi-center comparing Raloxifene HCl, continuous co	1/96	#5
Menopause	Principal Investigator	MS/ICSL	*Wyeth-Ayerst Research (0802E1-316-US):* A randomized, double-blind, placebo-controlled, parallel, multi-center to assess the efficacy and safety of three strengths of a 7-day 17 beta-estradiol transdermal system for relief of menopausal vasomotor symptoms.	1/96	#4
Osteoporosis	Sub-Investigator	MS	*Novo Nordisk Pharmaceuticals, Inc. (KLUM/PD/11/USA):* A double-blind, randomized, parallel-group, multi-center, placebo-controlled, dose comparison study contrasting the efficacy and safety in the prevention of postmenopausal osteoporosis with 1 mg. of 17 beta-estradiol in combination with varying dosages of norethindrone acetate.	9/94	#3
Osteoporosis	Sub-Investigator	MS	*Proctor and Gamble (RHN 009193-A):* A multi-center, randomized, double-blind, placebo-controlled, parallel group study to determine efficacy and safety of risedronate in the treatment of osteoporosis in women	1994	#2
Menopause	Principal Investigator	MS	*Novo Nordisk Pharmaceuticals (KLIM/PD17/USA):* A double-blind, randomized, parallel-group, multi-center, dose-finding study comparing the efficacy and safety of 1 mg 17 beta-estradiol in combination with low doses of norethindrone acetate with that of 1 mg. 17 beta-estradiol alone on the endometrium in postmenopausal women.	1994	#1

* Legend:

SMR: Specialists In Medical Research, Inc.
12670 World Plaza Lane, Building 62, Suite 2
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CNS: Comprehensive NeuroScience, Inc.
12751 New Brittany Blvd., Suite 501
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ICSL: Innovative Clinical Solutions, Ltd.
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MS: Medical Studies, Florida
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(Medical Studies changed its name to ICSL in 1999)

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