Flow Chart of Study Visits

	Screening Visit	Baseline Visit (Day 3)	Monthly Visit Cycle 1	Menses Visit 1	Monthly Visit Cycle 2	Menses Visit 2	Monthly Visit Cycle 3	Menses Visit 3	Monthly Visit Cycle 4	Menses Visit 4	Monthly Visit Cycle 5	Menses Visit 5 and End of Treatment Visit
Visit #	1	2	3	4	5	6	7	8	9	10	11	12
History	X	X	X		X		X		X		X	X
Full Exam	X											X
Brief Exam	X	X	X		X		X		X		X	
Serum Pregnancy Screen	X	X		X		X		X		X		X
Safety/ Eligibility Labs	X											X
Fasting Phlebotomy for Study Parameters	X	X	X		X		X		X		X	
TV U/S	X	X	X		X		X		X		X	
QOL Measures	X											X
Blood for DNA		X										
Blood for Repository		X										

Sample and Data Collection Procedures

During the participation in this study, the participants will have a total of 12 visits. They will begin with a screening visit to determine if they are eligible for study participation. Following screening they will have a baseline visit to receive their study medications. Following baseline, they will have a total of 5 monthly visits and an end of treatment visit. Below is a brief chart explaining the visits and procedures to be completed for study.

Procedures	Screen	Baseline	Midluteal MV#1-5	Menses MV#1-4	End of Treatment
Sign Consent	X				
Complete questionnaires	X				X
Urine pregnancy test	X	X	X		X
Height & BMI	X				X
Weight	X	X	X		X
Vital signs	X	X	X		X
Hip & Waist measurements	X				X
Acne score	X				X
Sebumeter score	X		X		X
Hirsutism score	X				X
Blood work for male & female hormones	X				
Blood work for progesterone	X	X	X		X
Blood work for pregnancy	X	X	X	X	X
Blood work for Safety Labs	X				X
Blood work for study DNA		X			
Blood work for central core lab	X	X	X		X
Rubella, Varicella & HIV screen	X				
Blood work for repository		X			
Complete physical exam & pap smear	X				
Transvaginal ultrasound	X	X	X		X
Sonohysterogram or Hysterosalpingogram	X				
Semen Analysis	X				
Dispensed study meds		X	X		
Collect study meds			X		
Dispense daily journals		X	X		
Collect daily journals			X		X
Assess adverse events and concomitant meds			X		X

PPCOSII Combined Essential Data Set Dictionary

Variable	Description	N	Accepted value	Summary
Patient_study_id	PPCOSII Patient Study ID	750		
trt	Treatment arm		C = Clomiphene D = Letrozole	C = 376 (50.13%) D = 374 (49.87%)
enroll_date	Date of enrollment into study	750		
scrn_ht	Height (cm) at baseline	750		Mean = 164.1 SD = 6.5 Range = 142.6-185.5
scrn_wt	Weight (kg) at baseline	750		Mean = 94.8 SD = 26.3 Range = 44.0-180.9
scrn_bmi	Body Mass Index (kg/m^2)	750		Mean = 35.1 SD = 9.3 Range = 16.7-67.5
scrn_waist	Waist circumference (cm)	748		Mean = 105.9 SD = 20.4 Range = 59.0-172.0
scrn_sebumtr	Sebum measurement (mcg/cm^2)	730		Mean = 107.7 SD = 55.5 Range = 3.0-275.0
scrn_sbp	Systolic blood pressure (mmHg) at baseline	749		Mean = 119.6 SD = 12.9 Range = 78.0-174.0
scrn_dbp	Diastolic blood pressure (mmHg) at baseline	749		Mean = 77.1 SD = 9.4 Range = 52.0-109.0
Age	Age (years)	750		Mean = 28.9 SD = 4.3 Range = 18.0-40.0
hispanic	Race/ethnicity: Hispanic	750	0 = No 1 = Yes	1 = 128/750 (17.1%)
White	Race/ethnicity: White	750	0 = No 1 = Yes	1 = 590/750 (78.7%)
Black	Race/ethnicity: Black	750	0 = No 1 = Yes	1 = 100/750 (13.3%)
Asian	Race/ethnicity: Asian	750	0 = No 1 = Yes	1 = 24/750 (3.2%)
American_Indian	Race/ethnicity: American Indian or Alaska Native	750	0 = No 1 = Yes	1 = 7/750 (0.9%)
native_hawaiian	Race/ethnicity: Native Hawaiian or other Pacific Islander	750	0 = No 1 = Yes	1 = 2/750 (0.3%)
mixed_race	Race/ethnicity: Mixed race	750	0 = No 1 = Yes	1 = 27/750 (3.6%)
left_ovary_visualized	Left ovary visualized	749	0 = No 1 = Yes	1 = 745/749 (99.5%)

Variable	Description	N	Accepted value	Summary
left_ovarian_vol	Left ovarian volume (cm^3)	743		Mean = 11.6 SD = 6.3 Range = 0.8-50.4
left_morphology	Left ovary morphology	744	1 = Normal 2 = PCOS	
left_antral_follicle	Left antral follicle size	729		Mean = 23.3 SD = 15.2 Range = 0.0-119.0
left_cysts_visualized	Left ovarian cysts visualized	745	0 = No 1 = Yes	1 = 78/745 (10.5%)
left_cysts_ge10mm	Left cysts ≥10mm	745		Mean = 0.1 SD = 0.3 Range = 0.0-2.0
right_ovary_visualized	Right ovary visualized	749	0 = No 1 = Yes	1 = 741/749 (98.9%)
right_ovarian_vol	Right ovarian volume (cm^3)	739		Mean = 12.6 SD = 7.4 Range = 0.3-76.5
right_morphology	Right ovary morphology	740	1 = Normal 2 = PCOS	
right_antral_follicles	Right antral follicle size	730		Mean = 23.5 SD = 14.4 Range = 0.0-111.0
right_cysts_visualized	Right ovarian cysts visualized	741	0 = No 1 = Yes	1 = 71/741 (9.6%)
right_cysts_ge10mm	Right cysts ≥10mm	741		Mean = 0.1 SD = 0.3 Range = 0.0-2.0
TTE_scrn	Testosterone value at screening	748		Mean = 55.0 SD = 28.8 Range = 4.0-233.6
E2_scrn	Estradiol (pg/mL) at screening	748		Mean = 55.2 SD = 36.8 Range = 7.8-442.6
SHBG_scrn	SHBG (nmol/L) at screening	748		Mean = 33.9 SD = 23.1 Range = 6.6-180.0
IGF1_scrn	IGF1 (ng/mL) at screening	748		Mean = 181.7 SD = 69.7 Range = 46.8-555.0
Insulin_scrn	Fasting insulin (µU/mL) at screening	748		Mean = 19.3 SD = 27.0 Range = 2.0-535.3
P4_scrn	Progesterone (ng/mL) at screening	748		Mean = 1.5 SD = 3.1 Range = 0.1-28.4

Variable	Description	N	Accepted value	Summary
FSH_scrn	FSH (mIU/mL) at screening	748		Mean = 6.2 SD = 3.1 Range = 0.1-63.0
LH_scrn	LH (mIU/mL) at screening	748		Mean = 11.1 SD = 8.5 Range = 0.2-93.3
Glucose_scrn	Fasting glucose (mg/dL) at screening	748		Mean = 86.0 SD = 12.6 Range = 30.7-187.1
TSH_scrn	TSH (IU/mL) at screening	748		Mean = 2.1 SD = 3.0 Range = 0.0- 78.1
hsCRP_scrn	hsCRP (mg/L) at screening	748		Mean = 6.4 SD = 7.0 Range = 0.2-48.5
AMH_scrn	AMH (ng/mL) at screening	748		Mean = 8.0 SD = 7.0 Range = 0.2-62.8
androstenedione_scrn	Androstenedione (ng/mL) at screening	748		Mean = 4.2 SD = 1.7 Range = 0.6-14.5
Proinsulin_scrn	Proinsulin (pM) at screening	748		Mean = 18.0 SD = 14.4 Range = 3.1-127.9
CHOLESTEROL_scrn	Total cholesterol (mg/dL) at screening	748		Mean = 177.9 SD = 36.6 Range = 51.0-311.0
TRIGLYCERIDES_scrn	Triglycerides (mg/dL) at screening	748		Mean = 116.5 SD = 57.8 Range = 25.0-446.0
HDL_CHOLESTEROL_scrn	HDL cholesterol (mg/dL) at screening	748		Mean = 37.9 SD = 10.7 Range = 8.0-76.0
LDL_CHOLESTEROL_scrn	LDL cholesterol (mg/dL) at screening	748		Mean = 121.0 SD = 33.2 Range = 34.0-400.0
FAI_scrn	Calculated Free Androgen Index at screening	748		Mean = 7.8 SD = 5.9 Range = 0.2-49.5
lh_fsh_scrn	LH to FSH ratio at screening	748		Mean = 2.2 SD = 6.7 Range = 0.2-154.4
Homa_scrn	HOMA score at screening	748		Mean = 4.4 SD = 9.1 Range = 0.2-217.2
Quiki_scrn	Quiki at screening	748		Mean = 5.0

Variable	Description	N	Accepted value	Summary
				SD = 0.4 Range = 3.8-6.1
acne_total	Acne score at screening	749		Mean = 8.7 SD = 16.1 Range = 0.0-180.0
Hirsutism_score	F-G score at screening	749		Mean = 17.0 SD = 8.5 Range = 0.0- 41.0
fert_qol_total	Total FertiQOL score	733		Mean = 72.3 SD = 14.8 Range = 16.7-97.9
fert_emotion	FertiQOL: Emotional	731		Mean = 59.6 SD= 22.4 Range= 0.0-100.0
fert_mind	FertiQOL: Mind/body	732		Mean= 74.4 SD= 18.5 Range= 4.2-100.0
fert_relation	FertiQOL: Relational	733		Mean= 80.1 SD= 14.6 Range= 20.8-100.0
fert_social	FertiQOL: Social	731		Mean = 75.3 SD = 17.6 Range = 8.3-100.0
fsfi_total	Total score of FSFI	737		Mean = 29.9 SD = 4.6 Range = 6.0-36.8
fsfi_low	FSFI: Sexual dysfunction	737	0 = No 1 = Yes	 1 = 149/737 (20.2%)
IIEF_total	Total score of IIEF	708		Mean = 69.3 SD = 6.1 Range = 25.0-75.0
maintain_often	During intercourse, how often able to maintain erection after penetration	708	0 = Did not attempt intercourse 1 = Almost never/never 2 = A few times 3 = Sometimes 4 = Most times 5 = Almost always/always	Mean = 4.8 SD = 0.6 Range = 0.0-5.0
Hx_heart_disease	History of heart disease	750	0 = No 1 = Yes	 1= 14/750(1.9%)
Hx_resp_disease	History of respiratory system disease	750	0 = No 1 = Yes	 1= 105/750(14.0%)
Hx_cns_disease	History of brain or nervous system	750	0 = No	

Variable	Description	N	Accepted value	Summary
	disease		1 = Yes	1= 83/750(11.1%)
Hx_heent_disease	History of head, eyes, ear, nose or throat disease	750	0 = No 1 = Yes	1= 70/750(9.3%)
Hx_GI_disease	History of gastrointestinal system disease	750	0 = No 1 = Yes	1= 108/750(14.4%)
Hx_muscle_disease	History of muscle, joint or bone disease	750	0 = No 1 = Yes	1= 75/750(10.0%)
Hx_HTN	History of high blood pressure	750	0=No 1=Yes	1= 42/750(5.6%)
HTN_med	Blood pressure medication	43	0=No 1=Yes	1= 31/43(72.1%)
Hx_smoke	Patient has history of smoking	750	0=No 1=Yes	1= 317/750(42.3%)
smoke_current	Current smoker	750	0=No 1=Yes	1= 111/750(14.8%)
smoke_per_day	Cigarettes smoked per day	317		Mean= 1.2 SD= 0.4 Range= 1.0- 4.0
smoke_quit	Quit smoking	750	0=No 1=Yes	1= 206/750(27.5%)
Hx_alcohol	Patient has history of alcohol use	750	0=No 1=Yes	1= 658/750(87.7%)
alchocol_current	Currently drinking alcohol	750	0=No 1=Yes	1= 472/750(62.9%)
alcohol_freq	How often do you drink alcohol?	492	1 = 1-2 times per year 2 = 1-2 times per month 3 = 1-2 days per week 4 = 3-6 days per week 5 = Everyday	Mean= 1.9 SD= 0.8 Range= 1.0- 5.0
alcohol_drink	On the days you drink, how many drinks on average do you consume?	491	1 = 1 drink 2 = 2-4 drinks 3 = 5-7 drinks 4 = 8 or more drinks	Mean= 1.7 SD= 0.6 Range= 1.0- 4.0
Hx_psy_treatmnt	Patient has history of psychiatric disorder	750	0=No 1=Yes	1= 194/750(25.9%)
mth_try_pregnant	How long has the patient been attempting conception (months)?	715		Mean= 41.7 SD= 37.8 Range= 0.0- 264.0
Hx_pregnant	History of prior pregnancy	750	0=No 1=Yes	1= 273/750(36.4%)
Hx_preg_num	Number of prior pregnancies patient	309		Mean= 1.4

Variable	Description	N	Accepted value	Summary
	has had			SD= 1.1 Range= 0.0- 8.0
education	Education level	750	1 = 8th grade or less 2 = Some high school 3 = High school graduate 4 = Some college 5 = College graduate 6 = Graduate degree	
income	Household income	750	1 = <$25,000 2 = $25,000 to $49,999 3 = $50,000 to $74,999 4 = $75,000 to $100,000 5 = >$100,000 6 = Wish to not answer	
prior_live_born	Prior live birth	750	0=No 1=Yes	1= 148/750(19.7%)
prior_pregloss	Prior pregnancy loss	750	0=No 1=Yes	1= 174/750(23.2%)
pcos_qol_total	Total score of PCOS	733		Mean= 3.9 SD= 1.2 Range= 1.2- 6.9
pcos_emotion	PCOS: Emotions	733		Mean= 4.5 SD= 1.3 Range= 1.1- 7.0
pcos_hair	PCOS: Body hair	733		Mean= 4.1 SD= 1.8 Range= 1.0- 7.0
pcos_weight	PCOS: Weight	733		Mean= 3.3 SD= 1.9 Range= 1.0- 7.0
pcos_infert	PCOS: Infertility problems	733		Mean= 2.9 SD= 1.4 Range= 1.0- 7.0
pcos_mens	PCOS: Menstrual problems	733		Mean= 4.1 SD= 1.1 Range= 1.0- 7.0
sf_pcs	SF-36 physical component score	729		Mean= 53.5

Variable	Description	N	Accepted value	Summary
				SD= 6.4 Range= 31.3- 70.6
sf_mcs	SF-36 mental component score	729		Mean= 49.5 SD= 9.5 Range= 8.5- 69.7
fsds_total	Total score of FSDS	736		Mean= 6.8 SD= 8.6 Range= 0.0- 44.0
trouble_asleep	Has trouble falling asleep	738		Mean= 2.6 SD= 1.1 Range= 1.0- 5.0
sleepy	Feels excessively sleepy during the day	737		Mean= 2.5 SD= 1.1 Range= 1.0- 5.0
ever_snored	Have you ever snored?		0=No 1=Yes 8=unknown	
snore_yes	Has snored at night	738	0=No 1=Yes	1= 466/738(63.1%)
snoreno	Does not snore at night	738	0=No 1=Yes	1= 189/738(25.6%)
snoreuk	Snoring at night unknown	738	0=No 1=Yes	1= 83/738(11.2%)
Stop_breathing	Have you ever stopped breathing during sleep?		0=No 1=Yes 8=unknown	
breath_yes	Has ever stopped breathing during sleep	727	0=No 1=Yes	1= 45/727(6.2%)
breathno	Has never stopped breathing during sleep	727	0=No 1=Yes	1= 498/727(68.5%)
breathuk	Ever stopped breathing during sleep unknown	727	0=No 1=Yes	1= 184/727(25.3%)
prime_maj_depress	Major depressive syndrome	739	0=No 1=Yes	1= 27/739(3.7%)
prime_oth_depress	Other depressive syndrome	739	0=No 1=Yes	1= 38/739(5.1%)
prime_panic	Panic syndrome	739	0=No 1=Yes	1= 14/739(1.9%)
prime_oth_anxity	Other anxiety syndrome	734	0=No 1=Yes	1= 20/734(2.7%)
cyst_vol_left	Left cyst volume	70		Mean= 4.1 SD= 5.3 Range= 0.5- 33.6
cyst_vol_right	Right cyst volume	62		Mean= 4.5 SD= 6.2 Range= 0.0- 30.4

Variable	Description	N	Accepted value	Summary
clomi_only	Clomiphene Citrate only	750	0=No 1=Yes	1= 344/750(45.9%)
letroz_only	Letrozole only	750	0=No 1=Yes	1= 4/750(0.5%)
clomi_letroz	Letrozole and Clomiphene Citrate	750	0=No 1=Yes	1= 20/750(2.7%)
No_drug	No drug used (neither letrozole nor clomiphene)	750	0=No 1=Yes	1= 382/750(50.9%)
alcohcur_not	No current alcohol use	750	0=No 1=Yes	1= 186/750(24.8%)
left_not_visu	Left ovary not visualized	749	0=No 1=Yes	1= 4/749(0.5%)
right_not_visu	Right ovary not visualized	749	0=No 1=Yes	1= 8/749(1.1%)
right_left_not_visu	Neither ovary visualized	749	0=No 1=Yes	1= 1/749(0.1%)
left_normal	Left: Normal	738	0=No 1=Yes	1= 91/738(12.3%)
left_pcos	Left: PCOS	738	0=No 1=Yes	1= 627/738(85.0%)
left_hthecotic	Left: Hyperthecotic	738	0=No 1=Yes	1= 20/738(2.7%)
right_normal	Right: Normal	736	0=No 1=Yes	1= 77/736(10.5%)
right_pcos	Right: PCOS	736	0=No 1=Yes	1= 646/736(87.8%)
right_hthecotic	Right: Hyperthecotic	736	0=No 1=Yes	1= 13/736(1.8%)
both_neither	Both ovaries: Neither ovary polycystic	729	0=No 1=Yes	1= 41/729(5.6%)
pcos_normal	Both ovaries: Polycystic/normal combination	729	0=No 1=Yes	1= 85/729(11.7%)
pcos_pcos	Both ovaries: Both polycystic	729	0=No 1=Yes	1= 603/729(82.7%)
pcos_morph	Has PCOS morphology	743	0=No 1=Yes	1= 703/743(94.6%)
waist_ms	Elevated waist circumference	748	0=No 1=Yes	1= 577/748(77.1%)
bp_ms	Elevated blood pressure	750	0=No 1=Yes	1= 114/750(15.2%)
glucose_ms	Elevated fasting glucose	748	0=No 1=Yes	1= 64/748(8.6%)
TRIG_ms	Elevated triglycerides	748	0=No 1=Yes	1= 186/748(24.9%)
hdl_ms	Reduced HDL cholesterol	748	0=No 1=Yes	1= 642/748(85.8%)

Variable	Description	N	Accepted value	Summary
ms_3	Having 3, 4 or 5 components-metabolic syndrome	747	0=No 1=Yes	1= 254/747(34.0%)
highSchool	High school graduate or less	750	0=No 1=Yes	1= 173/750(23.1%)
college	College graduate or some college	750	0=No 1=Yes	1= 491/750(65.5%)
graduate	Graduate degree	750	0=No 1=Yes	1= 86/750(11.5%)
ft_ovu_cycle	First ovulation cycle	619		Mean= 1.7 SD= 1.0 Range= 0.0- 5.0
ovulation	Ovulated	750	0=No 1=Yes	1= 619/750(82.5%)
ovu_total	Total ovulation cycle	619		Mean= 2.5 SD= 1.3 Range= 1.0- 5.0
achieved_preg	Achieved pregnancy	750	0=No 1=Yes	1= 257/750(34.3%)
date_1st_dose_study_med	Date of first dose of study medication	714		
preg_time	Date of first positive pregnancy test	248		
time_to_preg	Time to get pregnant (days)	235		Mean= 88.7 SD= 46.1 Range= 21.0- 225.0
withdrawn	Withdrawn from study	750	0=No 1=Yes	1= 158/750(21.1%)
heart_motion_visualized_a	Fetal heart motion visualized a	198	0=No 1=Yes	1= 198/198(100.0%)
heart_motion_visualized_b	Fetal heart motion visualized b	10	0=No 1=Yes	1= 10/10(100.0%)
est_date_deliver	Estimated date of delivery	198		
clin_preg	Clinical pregnancy based on heart motion visualized on ultrasound	750	0=No 1=Yes	1= 198/750(26.4%)
single_preg	Singleton clinical pregnancy	750	0=No 1=Yes	1= 188/750(25.1%)
twin_preg	Twin clinical pregnancy	750	0=No 1=Yes	1= 10/750(1.3%)
loss_num	Pregnancy loss number	79	0=No 1=Yes	1= 79/79(100.0%)
wk_loss	Week of pregnancy loss	78		Mean= 7.1 SD= 3.5 Range= 3.0- 22.0
biochemical	Biochemical miscarriage	79	0=No 1=Yes	1= 26/79(32.9%)
spontaneous	Spontaneous abortion/Miscarriage	79	0=No 1=Yes	1= 44/79(55.7%)

Variable	Description	N	Accepted value	Summary
induced	Induced abortion	79	0=No 1=Yes	1= 0/79(0.0%)
ectopic	Ectopic pregnancy	79	0=No 1=Yes	1= 7/79(8.9%)
heterotopic	Heterotopic gestation	79	0=No 1=Yes	1= 1/79(1.3%)
pul	Pregnancy of unknown location	79	0=No 1=Yes	1= 2/79(2.5%)
loss_12wks	Pregnancy loss in the first 12 weeks	74	0=No 1=Yes	1= 74/74(100.0%)
preg_loss_13to20wks	Pregnancy loss during 13 to 20 weeks gestation	5	0=No 1=Yes	1= 5/5(100.0%)
birth_order	Infant birth order	177		Mean= 1.1 SD= 0.2 Range= 1.0- 2.0
ega	Estimated gestational age (weeks)	177		Mean= 37.9 SD= 3.5 Range= 21.0- 42.0
date_delivery	Date of infant delivery	177		.
infant_lbs	Infant birth weight, lbs	174		Mean= 6.6 SD= 1.5 Range= 1.0- 10.0
infant_oz	Infant birth weight, oz	174		Mean= 7.7 SD= 4.6 Range= 0.0- 16.0
birth_defect	Infant birth defect	177	0=No 1=Yes	1= 6/177(3.4%)
live_birth	Patient had a live birth	750	0=No 1=Yes	1= 175/750(23.3%)
compl_after_delivery	Complication after delivery	750	0=No 1=Yes	1= 54/750(7.2%)
rds	Respiratory distress	54	0=No 1=Yes	1= 9/54(16.7%)
jaundice	Jaundice	54	0=No 1=Yes	1= 44/54(81.5%)
neonatal_infection	Neonatal infection	54	0=No 1=Yes	1= 4/54(7.4%)
neonatal_hosp	Neonatal hospitalization	54	0=No 1=Yes	1= 8/54(14.8%)
other_compl_after_delivery	Other complication after delivery	54	0=No 1=Yes	1= 9/54(16.7%)
single_live_birth	Singleton live birth	750	0=No 1=Yes	1= 166/750(22.1%)
twin_live_birth	Twin live birth	750	0=No 1=Yes	1= 9/750(1.2%)

Variable	Description	N	Accepted value	Summary
ave_birth_weight	Average birth weight	173		Mean=3231.3 SD= 679.7 Range= 481.9-4734.4
pre_term_labor	Pre-term labor	180	0=No 1=Yes	1= 26/180(14.4%)
pre_eclampsia1	Pre-eclampsia	181	0=No 1=Yes	1= 32/181(17.7%)
hyperemesis	Hyperemesis	180	0=No 1=Yes	1= 13/180(7.2%)
gest_dm	Gestational diabetes	179	0=No 1=Yes	1= 40/179(22.3%)
iugr	Intrauterine growth restriction	178	0=No 1=Yes	1= 7/178(3.9%)
incomp_cervix	Incompetent cervix	177	0=No 1=Yes	1= 14/177(7.9%)
premature_rupture	Premature rupture of membranes	180	0=No 1=Yes	1= 15/180(8.3%)
other_compl_dur_preg	Other complication during pregnancy	178	0=No 1=Yes	1= 23/178(12.9%)
comp_dur_preg	Complication during pregnancy	750	0=No 1=Yes	1= 90/750(12.0%)
sae	Serious Adverse Event	750	0=No 1=Yes	1= 41/750(5.5%)
ran_liveb_dur	Days between randomization and delivery date	175		Mean= 340.8 SD= 55.8 Range= 182.0- 474.0
preg_dur2	Pregnancy duration	175		Mean = 38.1 SD = 3.6 Range = 20.9-44.9
bmi_eot	BMI at end of study	709		Mean = 35.5 SD = 9.2 Range = 16.7-63.6
sebumeter_eot	Sebum measurement at end of study	696		Mean = 100.8 SD = 54.2 Range = 1.0-273.0
systolic_eot	Systolic blood pressure at end of study	708		Mean = 119.1 SD = 13.5 Range = 78.0-177.0
diastolic_eot	Diastolic blood pressure at end of study	708		Mean = 76.6 SD = 10.1 Range = 46.0-112.0
hirsu_eot	F-G score at end of study	576		Mean = 16.5 SD = 8.1 Range = 0.0-41.0
endometrial_thickness_scrn	Endometrial thickness at screening	745		Mean = 6.7 SD = 3.0

Variable	Description	N	Accepted value	Summary
				Range = 1.0-24.0
tot_cyst_scrn	Total number of measured follicles/cysts at screening	750		Mean = 0.2 SD = 0.5 Range = 0.0-3.0
tot_folli_scrn	Total antral follicle count at screening	719		Mean = 46.9 SD = 27.9 Range = 0.0-211.0
tot_volume_scrn	Total ovarian volume at screening	735		Mean = 24.0 SD = 11.4 Range = 1.3-96.9
endometrial_thickness_eot	Endometrial thickness at end of study	708		Mean = 9.6 SD = 3.3 Range = 1.0-25.0
tot_cyst_eot	Total number of measured follicles/cysts at end of treatment visit or last visit before pregnancy	709		Mean = 0.9 SD = 1.0 Range = 0.0-8.0
tot_folli_eot	Total antral follicle count at end of treatment visit or last visit before pregnancy	663		Mean = 43.1 SD = 24.9 Range = 0.0-181.0
tot_volume_eot	Total ovarian volume at end of treatment visit or last visit before pregnancy	691		Mean = 35.9 SD = 28.7 Range = 2.7-504.4
Testosterone_eot	Testosterone value at end of treatment visit or last visit before pregnancy	707		Mean = 59.0 SD = 35.5 Range = 9.0-284.3
dheas_eot	DHEAS at end of study	705		Mean = 165.3 SD = 87.9 Range = 7.0-577.0
e2_eot	Estradiol at end of study	707		Mean = 86.1 SD = 83.8 Range = 6.7-823.1
glucose_eot	Glucose at end of study	707		Mean = 89.2 SD = 15.9 Range = 46.7-210.8
shbg_eot	SHBG at end of study	705		Mean = 39.7 SD = 28.1 Range = 5.9-266.0
IGF1_eot	IGF1 at end of study	699		Mean = 166.0 SD = 75.9 Range = 25.0-563.0
insulin_eot	Insulin at end of study	704		Mean = 25.9 SD = 32.3 Range = 2.0-335.0
p4_eot	Progesterone at end of study	707		Mean = 13.6 SD = 21.6 Range = 0.1-145.6

Variable	Description	N	Accepted value	Summary
fsh_eot	FSH at end of study	704		Mean = 4.7 SD = 2.7 Range = 0.2-46.9
lh_eot	LH at end of study	704		Mean = 8.8 SD = 6.8 Range = 0.1-65.7
amh_eot	AMH at end of study	706		Mean = 7.9 SD = 6.9 Range = 0.1-72.5
proinsulin_eot	Proinsulin at end of study	707		Mean = 29.1 SD = 43.1 Range = 3.1-780.0
Androstenedione_eot	Androstenedione at end of study	706		Mean = 4.3 SD = 1.8 Range = 0.6-14.9
FAI_eot	FAI at end of study	705		Mean = 7.6 SD = 7.5 Range = 0.4-85.4
Homa_eot	HOMA score at end of study	704		Mean = 6.3 SD = 10.9 Range = 0.3-158.2
Quiki_eot	Quiki at end of study	704		Mean = 4.9 SD = 0.2 Range = 4.2-5.9

PPCOS II: Variable Dictionary for Samples

Variable	Description
Current_Label	Current Label
BSI_ID	BSI ID
Material_Type	Material Type
Study_Id	Study Id
Volume	Volume
Volume_Unit	Volume Unit
NA_Concentration	Nucleic acid concentration
trt	Treatment arm: C-Clomiphene; D-Letrozole
scrn_ht	Height at screening (cm)
scrn_wt	Weight at screening (kg)
scrn_bmi	BMI at screeing
scrn_waist	Waist at screening (cm)
age	Age
Oligomen	Does the patient have chronic oligomenorrhea?
hyperandrogen	Does the patient have hyperandrogenemia or hirsutism or polycystic ovaries on ultrasound?
good_health	Is the patient in good general health and off of all current medications which may confound response to the study medications?
age18_40	Is the patient =18 and =40 years of age at time of consent?
seek_preg	Does the patient want to seek pregnancy actively during the study period of 20 weeks?
male_consent	Did the male partner provide consent for participation in this study?
sperm_concen	Does the male partner have a sperm concentration of 14million/mL in at least one ejaculation with at least some motile sperm?
inter_course	Do the patient and the male partner agree to have regular intercourse?
patent_tube	Does the patient have at least one patent fallopian tube and a normal uterine cavity?
steriliz	Does the patient and male partner report NO to any previous sterilization procedures?
current_pregnant	Is the patient currently pregnant?
contracep	Does the patient take oral contraceptives, depo progestins, or hormonal implants?
hyper_prolact	Does the patient have hyperprolactemia?
_1_hydroxy_deficien	Does the patient have known 21-hydroxylase deficiency or other enzyme deficiency leading to the phenotype of congenital adrenal hyperplasia?
menopaus	Does the patient have menopausal levels of FSH?
thyroid_disease	Does the patient have uncontrolled thyroid disease?

diabetes	Does the patient have Type I or II diabetes?
liver_disease	Does the patient have liver disease?
renal_disease	Does the patient have renal disease?
anemia	Does the patient have significant anemia?
DVT	Does the patient have a history of deep venous thrombosis, pulmonary embolus, or cerebrovascular accident?
heart_disease	Does the patient have a pre-existing heart disease that is a contraindication to pregnancy?
HTN	Does the patient have untreated poorly controlled hypertension?
cancer	Does the patient have a history of or suspected cervical carcinoma, endometrial carcinoma, or breast carcinoma?
alcohol_abuse	Does the patient have a current history of alcohol abuse?
other_study	Is the patient simultaneously enrolled in another competing study?
meds	Is the patient using medication known to affect reproductive function or metabolism?
adrenal_tumor	Does the patient have a suspected adrenal or ovarian tumor secreting androgens?
cushing	Does the patient have suspected Cushing's syndrome?
bariatrc	Has the patient undergone a bariatric surgery procedure in the past 12 months and are in a period of acute weight loss or have been advised against pregnancy by their bariatric surgeon?

PPCOSII Repository Summary

Material Type	Treatment		Age (yrs)			Screening BMI (kg/m2)			Total
	Clomiphene	Letrozole	0-25	26-30	>30	0-30	30.1-40	>40	
Blood Clot (by Samples)	292	306	120	262	216	191	220	187	598
Blood Clot (by Patients)	292	305	120	262	215	191	220	186	597
Blood Spot (by Samples)	313	323	133	274	229	197	237	202	636
Blood Spot (by Patients)	313	322	132	274	229	197	236	202	635
DNA (by Samples)	1079	1110	445	932	812	700	783	706	2189
DNA (by Patients)	265	277	109	231	202	174	195	173	542
Serum (by Samples)	2663	2775	1104	2426	1908	1717	1983	1738	5438
Serum (by Patients)	293	306	123	265	211	189	220	190	599
Whole Blood (by Samples)	298	306	119	263	222	193	222	189	604
Whole Blood (by Patients)	298	305	119	263	221	193	221	189	603

PPCOS II Core Lab Results Summary
Number of pateints (Range of test results)

Items	Testosterone	DHEAS	Estradiol	Glucose	SHBG	IGF1	Insulin	Progesterone	FSH	LH	TSH	hsCRP	AMH	Anti_TPO	Proinsulin	Androstenedione	Cholesterol	Triglycerides	HDL_Cholesterol	LDL_Cholesterol
Screening	748 (4.0 to 233.6)	748 (8.5 to 550.0)	748 (7.8 to 442.6)	748 (30.7 to 187.1)	748 (6.6 to 180.0)	748 (46.8 to 555.0)	748 (2.0 to 535.3)	748 (0.1 to 28.4)	748 (0.1 to 63.0)	748 (0.2 to 93.3)	748 (0 to 78.1)	748 (0.2 to 48.5)	748 (0.2 to 62.8)	747 (10.0 to 1000.0)	748 (3.1 to 127.9)	748 (0.6 to 14.5)	748 (51.0 to 311.0)	748 (25.0 to 446.0)	748 (8.0 to 76.0)	748 (34.0 to 400.0)
End of Treatment (EOT)	589 (9.0 to 443.2)	588 (7.0 to 570.0)	590 (6.7 to 3777.1)	589 (37.0 to 210.8)	589 (0.2 to 388.0)	588 (25.0 to 563.0)	588 (2.0 to 318.0)	590 (0.1 to 684.1)	588 (0.1 to 46.9)	588 (0.1 to 45.3)			590 (0.1 to 72.5)		590 (3.1 to 780.0)	590 (0.6 to 24.9)				
Last study visit before pregnancy or EOT for those who did not achieve pregnancy	707 (9.0 to 284.3)	705 (7.0 to 577.0)	707 (6.7 to 823.1)	707 (46.7 to 210.8)	705 (5.9 to 266.0)	699 (25.0 to 563.0)	704 (2.0 to 335.0)	707 (0.1 to 145.6)	704 (0.2 to 46.9)	704 (0.1 to 65.7)			706 (0.1 to 72.5)		707 (3.1 to 780.0)	706 (0.6 to 14.9)				
Monthly Visit (MV)																				
MV1	695	694	695	695	694	694	674	694	694	694			617		596	693				
MV2	558	105	555	88	582	96	106	578	97	97			113		603	546				
MV3	477	90	478	72	500	81	90	495	83	83			90		520	472				
MV4	400	78	396	65	410	69	78	411	70	70			78		429	391				
MV5	310	83	311	74	313	79	83	318	80	80			80		331	305				
Range of MV1-5	6.1 to 433.0	7.4 to 598.0	7.0 to 1810.5	45.5 to 169.1	5.5 to 266.0	25.0 to 485.0	2.0 to 335.0	0.2 to 145.6	0.2 to 35.5	0.1 to 78.8			0.2 to 76.0		3.1 to 449.1	0.7 to 24.0				