AMIGOS Combined Essential Data Set Dictionary

Variable	Description	Acceptable Values List	N	Summary Statistics
Patient_Study_ID	AMIGOS Patient Study ID		900	
trt	Treatment code	A = Clomiphene B = Letrozole C = Gonadotropin	900	A = 300 (33.33%) B = 299 (33.22%) C = 301 (33.44%)
trtname	Treatment arm name	Clomiphene Citrate 50mg Kit Letrozole 2.5mg Kit Gonadotropin	900	
kitno	Kit number for Clomiphene and Letrozole treatment arms			
Age	Patient age (years) at time of randomization		900	Mean = 32.2 SD = 4.2 Range = 20.0-41.0
scrn_bmi	Body mass index (kg/m^2) at baseline		900	Mean = 26.9 SD = 6.5 Range = 16.5-52.0
scrn_waist	Waist circumference (cm) at baseline		899	Mean = 86.5 SD = 15.8 Range = 53.0-168.0
scrn_sebumtr	Sebum measurement (mcg/cm^2) at baseline		871	Mean = 90.8 SD = 48.9 Range = 1.0-273.0
scrn_sbp	Systolic blood pressure (mmHg) at baseline		900	Mean = 115.8 SD = 13.2 Range = 36.0-159.0
scrn_dbp	Diastolic blood pressure (mmHg) at baseline		900	Mean = 74.6 SD = 9.8 Range = 40.0-102.0
Bmi_male	Male BMI		865	Mean = 28.9 SD = 5.8 Range = 15.8-63.7
Hispanic	Race/ethnicity: Hispanic	0 = No 1 = Yes	900	0 = 806 (89.56%) 1 = 94 (10.44%)
White	Race/ethnicity: White	0 = No 1 = Yes	900	0 = 178 (19.78%) 1 = 722 (80.22%)
Black	Race/ethnicity: Black	0 = No 1 = Yes	900	0 = 816 (90.67%) 1 = 84 (9.33%)
Asian	Race/ethnicity: Asian	0 = No 1 = Yes	900	0 = 841 (93.44%) 1 = 59 (6.56%)

American_Indian	Race/ethnicity: American Indian or Alaskan Native	0 = No 1 = Yes	900	0 = 890 (98.89%) 1 = 10 (1.11%)
Native_hawaiian	Race/ethnicity: Native Hawaiian or other Pacific Islander	0 = No 1 = Yes	900	0 = 900 (100.00%)
Mixed_race	Race/ethnicity: Mixed race	0 = No 1 = Yes	900	0 = 875 (97.22%) 1 = 25 (2.78%)
education	Education level	1 = 8th grade or less 2 = Some high school 3 = High school graduate 4 = Some college 5 = College graduate 6 = Graduate degree	900	1 = 3 (0.33%) 2 = 15 (1.67%) 3 = 55 (6.11%) 4 = 204 (22.67%) 5 = 385 (42.78%) 6 = 238 (26.44%)
income	Household income	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	900	1 = 38 (4.22%) 2 = 114 (12.67%) 3 = 200 (22.22%) 4 = 199 (22.11%) 5 = 191 (21.22%) 6 = 158 (17.56%)
endometrial_thickness	Endometrial thickness (mm) at baseline		895	Mean = 6.7 SD = 3.2 Range = 0-20.0
left_ovarian_vol	Left ovarian volume (cm^3) at baseline		885	Mean = 8.4 SD = 8.3 Range = 0.6-127.0
left_antral_follicle	Left antral follicle count at baseline		877	Mean = 10.1 SD = 6.2 Range = 0-52.0
right_ovarian_vol	Right ovarian volume (cm^3) at baseline		887	Mean = 9.4 SD = 7.4 Range = 1.1-103.2
right_antral_follicles	Right antral follicle count at baseline		881	Mean = 10.6 SD = 6.6 Range = 0-52.0
acne_total	Acne score at baseline		899	Mean = 2.7 SD = 6.3 Range = 0-62.0
fert_qol_total	FertiQol total score at baseline		865	Mean = 77.1 SD = 12.8 Range = 26.0-100.0

fsfi_total	FSFI total score at baseline		867	Mean = 29.8 SD = 5.0 Range = 4.2-36.0
Hirsutism_score	Hirsutism score at baseline		893	Mean = 7.5 SD = 5.8 Range =0-31.0
IIEF_total	IIEF total score at baseline		859	Mean = 68.1 SD = 8.1 Range = 5.0-75.0
Sf_pcs	SF 36 physical component score at baseline		857	Mean = 56.6 SD = 4.9 Range = 32.4-68.4
Sf_mcs	SF 36 mental component score at baseline		857	Mean = 53.4 SD = 6.6 Range = 23.3-71.0
fsds_total	FSDS total score at baseline		861	Mean = 5.6 SD = 7.5 Range = 0-48.0
Hx_smoke	History of smoking	0 = No 1 = Yes	900	0 = 593 (65.89%) 1 = 307 (34.11%)
smoke_current	Current smoker	0 = No 1 = Yes	900	0 = 829 (92.11%) 1 = 71 (7.89%)
smoke_quit	Quit smoking	0 = No 1 = Yes	900	0 = 664 (73.78%) 1 = 236 (26.22%)
Hx_alcohol	History of alcohol use	0 = No 1 = Yes	900	0 = 106 (11.78%) 1 = 794 (88.22%)
alchocol_current	Current alcohol user	0 = No 1 = Yes	900	0 = 237 (26.33%) 1 = 663 (73.67%)
Hx_psy_treatmnt	History of treatment from a health care professional for any psychiatric conditions	0 = No 1 = Yes	900	0 = 698 (77.56%) 1 = 202 (22.44%)
Hx_diag_infertil	Patient had a diagnosis of infertility	0 = No 1 = Yes	900	0 = 568 (63.11%) 1 = 332 (36.89%)
Hx_infertil_therapy	Patient had prior therapy for infertility	0 = No 1 = Yes	900	0 = 401 (44.56%) 1 = 499 (55.44%)
Hx_pregnant	Has the patient ever been pregnant?	0 = No 1 = Yes	900	0 = 527 (58.56%) 1 = 373 (41.44%)
Live_born	Prior live birth	0 = No 1 = Yes	900	0 = 717 (79.67%) 1 = 183 (20.33%)
pregloss	Prior pregnancy loss	0 = No 1 = Yes	900	0 = 626 (69.56%) 1 = 274 (30.44%)
parity	Parity		187	1 = 152 (81.28%)

				2 = 26 (13.90%) 3 = 8 (4.28%) 4 = 1 (0.53%)
mth_try_pregnant	Number of months the patient has been attempting conception		891	Mean = 34.7 SD = 25.7 Range = 3.0-204.0
percent_sperm_motil	Male Partner Semen Analysis: Percent sperm motility		900	Mean = 56.2 SD = 14.8 Range = 8.0-97.0
sperm_conc	Male Partner Semen Analysis: Sperm concentration (million/mL)		900	Mean = 66.4 SD = 61.8 Range = 1.8-651.0
coord_calc_tmsperm	Male Partner Semen Analysis: Coordinator calculated total motile sperm (million)		900	Mean = 107.0 SD = 128.3 Range = 2.3-1484.3
morphology	Male Partner Semen Analysis: Morphology (% Normal)		776	Mean = 12.9 SD = 14.3 Range = 0-97.0
morphology_WHO	Male Partner Semen Analysis: Morphology WHO	3 = WHO 3rd Ed 4 = WHO 4th Ed	777	3 = 163 (20.98%) 4 = 614 (79.02%)
SHG_or_HSG	Test performed for tube patency	1 = Sonohysterogram 2 = Hysterosalpingogram 3 = Others	900	1 = 281 (31.36%) 2 = 550 (61.38%) 3 = 65 (7.25%)
result_SHG	Result of test for tube patency	1 = Bilateral tube patency 2 = Right fallopian tube patent 3 = Left fallopian tube patent 4 = One patent tube unknown side (if SHG can only be **At least one Tube Patent**)	896	1 = 667 (74.44%) 2 = 43 (4.80%) 3 = 58 (6.47%) 4 = 128 (14.29%)
uncomp_birth	Having an IUP within the last three years	1=Yes	6	
TTE	Total Testosterone(ng/dL) at baseline		873	Mean = 25.3 SD = 21.6 Range = 6.0-486.2
DHEAS	DHEAS(ug/dL) at baseline		874	Mean = 131.3 SD = 65.8

				Range = 7.0-437.0
E2	Estradiol(pg/mL) at baseline		875	Mean = 32.9 SD = 30.9 Range = 9.0-647.6
Glucose	Fasting glucose(mg/dL) at baseline		875	Mean = 85.2 SD = 11.9 Range = 30.0-137.3
SHBG	SHBG(nmol/L) at baseline		871	Mean = 59.2 SD = 28.1 Range = 1.0-180.0
Insulin	Fasting insulin(uIU/mL) at baseline		874	Mean = 9.7 SD = 15.5 Range = 2.0-191.2
P4	Progesterone(ng/mL at baseline		873	Mean = 0.8 SD = 0.6 Range = 0.2-10.8
FSH	FSH(mIU/mL) at baseline		875	Mean = 7.0 SD = 2.7 Range = 0.2-39.9
LH	LH(mIU/mL) at baseline		871	Mean = 5.1 SD = 2.9 Range = 0.8-36.9
TSH	TSH(uIU/mL) at baseline		872	Mean = 1.9 SD = 1.0 Range = 0.0-7.2
hsCRP	hsCRP(mg/L) at baseline		872	Mean = 3.3 SD = 4.9 Range = 0.2-54.3
Prolactin	Prolaction at baseline		870	Mean = 11.6 SD = 7.2 Range = 2.5-70.1
Proinsulin	Proinsulin(pM) at baseline		870	Mean = 12.9 SD = 8.6 Range = 3.1-120.0
Androstenedione	Androstenedione(ng/mL) at baseline		865	Mean = 2.4 SD = 1.0 Range = 0.4-7.4
AMH	AMH(ng/mL) at baseline		874	Mean = 2.6 SD = 2.1 Range = 0.0-17.0
CHOLESTEROL	Total cholesterol(mg/dL) at baseline		844	Mean = 169.2 SD = 31.5 Range = 39.0-273.0

TRIGLYCERIDES	Triglycerides(mg/dL) at baseline		844	Mean = 94.8 SD = 52.4 Range = 15.0-605.0
HDL_CHOLESTEROL	HDL cholesterol(mg/dL) at baseline		844	Mean = 45.9 SD = 11.1 Range = 18.0-120.0
LDL_CHOLESTEROL	LDL cholesterol(mg/dL) at baseline		844	Mean = 109.0 SD = 33.4 Range = 2.7-400.0
ft_med_day	Date of first dose of study medication		886	
withdrawn	Has the patient been withdrawn from the study?	0 = No 1 = Yes	487	0 = 333 1 = 154
withdrawn_reason	Reason for withdrawal	1 = Unable to contact patient 2 = Medication side effects 3 = No longer interested in participating 4 = Patient non-compliant with protocol 5 = Access to clinic is difficult 6 = Moving out of the area 7 = Unable to continue study due to personal constraints 8 = Patient death 9 = Other (specify)	154	1 = 32 (20.78%) 2 = 10 (6.49%) 3 = 51 (33.12%) 4 = 10 (6.49%) 5 = 5 (3.25%) 6 = 8 (5.19%) 7 = 11 (7.14%) 8 = 0 9 = 27 (17.53%)
achieved_preg	Patient achieved pregnancy – intent to treat	0 = No 1 = Yes	900	0 = 567 (63.00%) 1 = 333 (37.00%)
preg_date	Date that patient achieved pregnancy		313	
ultrasound_num	Ultrasound number confirming pregnancy		257	
LMP	If patient achieved pregnancy, date of last menstrual period		258	
est_date_deliver	Estimated date of delivery		255	
clin_preg	Clinical pregnancy based on heart motion visualized on ultrasound	0 = No 1 = Yes	900	0 = 641 (71.22%) 1 = 259 (28.78%)

clin_preg_date	Clinical pregnancy date		258	
preg_single	Patient had a singleton pregnancy	0 = No 1 = Yes	900	0 = 692 (76.89%) 1 = 208 (23.11%)
preg_twin	Patient had a twin pregnancy	0 = No 1 = Yes	900	0 = 859 (95.44%) 1 = 41 (4.56%)
preg_triple	Patient had a triplet pregnancy	0 = No 1 = Yes	900	0 = 890 (98.89%) 1 = 10 (1.11%)
loss	Patient had a pregnancy loss	0 = No 1 = Yes	900	0 = 792 (88.00%) 1 = 108 (12.00%)
loss_num	Pregnancy loss number		108	1 = 105 (97.22%) 2 = 3 (2.78%)
baby	Pregnancy loss for which baby	A = Baby A B = Baby B C = Baby C	108	A = 97 (89.81%) B = 7 (6.48%) C = 4 (3.70%)
wk_loss	Week of pregnancy loss		108	
biochemical	Biochemical miscarriage	0 = No 1 = Yes	104	0 = 75 (72.12%) 1 = 29 (27.88%)
spontaneous	Spontaneous abortion/Miscarriage	0 = No 1 = Yes	107	0 = 58 (54.21%) 1 = 49 (45.79%)
induced	Induced abortion	0 = No 1 = Yes	108	0 = 106 (98.15%) 1 = 2 (1.85%)
sel_reduct	Selective reduction	0 = No 1 = Yes	106	0 = 104 (98.11%) 1 = 2 (1.89%)
ectopic	Ectopic pregnancy	0 = No 1 = Yes	108	0 = 87 (80.56%) 1 = 21 (19.44%)
ectopic_loc_specify	Specify location of ectopic pregnancy		9	
heterotopic	Heterotopic gestation	0 = No 1 = Yes	108	0 = 108
pul	Pregnancy of unknown location	0 = No 1 = Yes	3	1 = 3
live_birth	Patient had a live birth	0 = No 1 = Yes	900	0 = 677 (75.22%) 1 = 223 (24.78%)
single_live_birth	Singleton live birth	0 = No 1 = Yes	900	0 = 720 (80.00%) 1 = 180 (20.00%)
twin_live_birth	Twin live birth	0 = No 1 = Yes	900	0 = 863 (95.89%) 1 = 37 (4.11%)
triple_live_birth	Triplet live birth	0 = No 1 = Yes	900	0 = 894 (99.33%) 1 = 6 (0.67%)
ave_birth_weight	Average birth weight (grams)		219	Mean = 3044.0 SD = 716.1

				Range = 226.8-4507.6
ave_hosp_days	Average days in hospital		24	Mean = 26.4 SD = 26.0 Range = 5.0-125.0
birth_order	Infant birth order	1 = First infant 2 = Second infant 3 = Third infant	224	1 = 181 (80.80%) 2 = 37 (16.52%) 3 = 6 (2.68%)
ega	Estimated gestational age (weeks)		223	Mean = 37.8 SD = 2.9 Range = 21.0-42.0
date_delivery	Date of infant delivery		224	
infant_gender	Gender of infant	F = Female M = Male	224	F = 118 (52.68%) M = 106 (47.32%)
infant_lbs	Infant birth weight: lbs		219	Mean = 6.2 SD = 1.6 Range = 0-9.0
infant_oz	Infant birth weight: oz		220	Mean = 7.9 SD = 4.6 Range = 0-16.0
birth_defect	Infant born with any birth defects	0 = No 1 = Yes	222	0 = 215 1 = 7
birth_defect1	Specify birth defect		7	
nicu	Infant NICU admission	0 = No 1 = Yes	222	0 = 183 1 = 39
compl_after_delivery	Neonatal complication after delivery	0 = No 1 = Yes	219	0 = 163 1 = 56
sae_congenital	Neonatal complication: Congenital malformations	1 = Yes	9	1 = 9
ic_hemo	Neonatal complication: Intracranial hemorrhage	0 = No 1 = Yes	1	1 = 1
rds	Neonatal complication: Respiratory distress	0 = No 1 = Yes	56	0 = 40 1 = 16
jaundice	Neonatal complication: Jaundice	0 = No 1 = Yes	56	0 = 16 1 = 40
neonatal_hosp	Neonatal complication:	0 = No 1 = Yes	57	0 = 32 1 = 25

	Neonatal hospitalization >3 days			
hosp_days	Number of days of neonatal hospitalization		24	
iugr	Neonatal complication: Intrauterine growth restriction	0 = No 1 = Yes	900	0 = 890 (98.89%) 1 = 10 (1.11%)
pre_eclampsia1	Preeclampsia	0 = No 1 = Yes	900	0 = 874 (97.11%) 1 = 26 (2.89%)
placental_abn	Placental abnormality	0 = No 1 = Yes	900	0 = 876 (97.33%) 1 = 24 (2.67%)
placenta_abrup	Placental abnormality: Placenta abruption	0 = No 1 = Yes	24	0 = 24
placenta_accreta	Placental abnormality: Placenta accreta	0 = No 1 = Yes	24	0 = 24
placenta_previa	Placental abnormality: Placenta previa	0 = No 1 = Yes	24	0 = 13 1 = 11
placenta_other	Placental abnormality: Other	0 = No 1 = Yes	24	0 = 10 1 = 14
placenta_other_specify	Placental abnormality: Other, specify		14	
SAE	Serious adverse event	1 = Yes	48	1 = 48
SAE_Type	Specify serious adverse event		48	
sae_num	Serious adverse event number		48	1 = 43 2 = 5
mul_preg	Multiple pregnancy	0 = No 1 = Yes	900	0 = 849 1 = 51
mul_live_birth	Multiple live births	0 = No 1 = Yes	900	0 = 857 1 = 43
trt_2	Treatment code 2	AC = Clomiphene and Gonadotropin B = Letrozole	900	AC = 601 (66.78%) B = 299 (33.22%)
bmi_c	BMI Categories	1 = BMI < 25 2 = BMI 25 - <30 3 = BMI ≥ 30	900	1 = 433 (48.11%) 2 = 226 (25.11%) 3 = 241 (26.78%)
concept_up	Patient achieved pregnancy and had a clinical pregnancy or a pregnancy loss	0 = No 1 = Yes	900	0 = 569 (63.22%) 1 = 331 (36.78%)

preg_dur2	Pregnancy duration		222	Mean = 38.1 SD = 2.7 Range = 23.0-45.1
time_to_preg	Time to pregnancy (Number of days between day of first dose of study medication and pregnancy date)		312	Mean = 65.2 SD = 48.9 Range = 19.0-247.0
time_to_clin_preg	Time to clinical pregnancy (Number of days between day of first dose of study medication to clinical pregnancy date)		256	Mean = 88.3 SD = 52.6 Range = 34.0-271.0
time_to_live_birth	Time to live birth (Number of days between day of first dose of study medication to date of delivery)		222	Mean = 307.3 SD = 55.5 Range = 188.0-496.0
single_congenital	Singleton, congenital malformations	0 = No 1 = Yes	900	0 = 893 1 = 7
twin_congenital	Twins, congenital malformations	0 = No 1 = Yes	900	0 = 899 1 = 1
triple_congenital	Triplets, congenital malformations	0 = No 1 = Yes	900	0 = 899 1 = 1
single_nicu	Singleton, NICU admission	0 = No 1 = Yes	900	0 = 883 1 = 17
twin_nicu	Twins, NICU admission	0 = No 1 = Yes	900	0 = 885 1 = 15
triple_nicu	Triplets, NICU admission	0 = No 1 = Yes	900	0 = 893 1 = 7
Single_neo	Any Neonatal complications for singleton	0 = No 1 = Yes	900	1 = 39
Twin_neo	Any Neonatal complications for twins	0 = No 1 = Yes	900	1 = 15
Triple_neo	Any Neonatal complications for triplets	0 = No 1 = Yes	900	1 = 4

Neo_all	Any Neonatal complications	0 = No 1 = Yes	900	1 = 58
congenital_all	Any congenital malformations	0 = No 1 = Yes	900	1 = 8