Data Dictionary for SWOG S0230 Clinical Dataset

Column	Variable Name	Type	Variable description	Code	Code definition
1	patid	Num	Patient identifier		Number
2	txg	Char	Allocated treatment	Goserelin	Goserelin
				Standard	Standard
3	coopgrp	Char	Cooperative group	CALGB	CALGB
				ECOG	ECOG
				IBCSG	IBCSG
				SWOG	SWOG
4	age	Num	Patient age at randomization		Number
5	agen	Num	Patient age at randomization (stratification factor) Note: there were some stratification errors, where patient age does not match age stratification	0	< 40 years old
				1	≥ 40 years old
6	raceg	Char	Race	A	Asian
				B	Black
				N	Native American
				W	White
				" "	Missing data (Data on race were not available at many of the sites outside the United States; for patients at those sites, data are missing)
7	hispanic*	Num	Hispanic ethnicity	1	Hispanic
				0	Not Hispanic
				" "	Missing data (Data on ethnicity were not available at many of the sites outside the United States; for patients at those sites, data are missing)
8	chemo	Char	Type of planned chemotherapy regimen	3-4, A	3-4 weeks of anthracycline-based chemotherapy
				3-4, NA	3-4 weeks of non-anthracycline-based chemotherapy

Column	Variable Name	Type	Variable description	Code	Code definition
				6-8, A	6-8 weeks of anthracycline-based chemotherapy
				6-8, NA	6-8 weeks of non-anthracycline-based chemotherapy
9	ajcct	Char	Cancer stage	1	Stage I
				2	Stage II
				3A	Stage IIIA
				“ ”	Missing data
10	reason_inel	Char	Reason patient was not eligible	DNSTST	Did not submit baseline pathological test results or reports
				DNSPSF	Did not submit prestudy forms
				INSUFF	Had baseline pathological tests or reports with insufficient information
				NOPROT	Had no plans for protocol prescribed therapy
				INCSTG	Was in incorrect stage
				NA	Patient was eligible
11	reason_noteval	Char	Reason patient could not be evaluated for primary analysis	HYST	Underwent hysterectomy
				OOPH	Underwent oophorectomy
				WITH	Withdrew consent
				NA	Patient was evaluable for primary analysis or was ineligible
12	reason_noof	Char	Reason patient could not be evaluated for 2-year ovarian failure endpoint	DIED	Died
				LTF	Were lost to follow-up
				FSH	Were missing 2-yr data on FSH levels
				FSHMENS	Were missing 2-yr data on FSH levels and menstrual status
				NA	Patient was evaluable for ovarian failure
13	menopause	Num	Menopausal status at randomisation	1	Pre-menopausal

Column	Variable Name	Type	Variable description	Code	Code definition
14	exclude	Num	Primary analysis indicator variable	0	Patient was eligible and evaluable for primary analysis
				1	Patient was not eligible and evaluable for primary analysis
15	erstat	Num	Summary of Estrogen Receptor (ER) status of primary tumour	1	ER negative
16	pgrstat	Num	Summary of Progesterone Receptor (PR) status of primary tumour	1	PGR-negative
17	her2stat	Num	HER2 status	0	Negative
				1	Positive
				“ ”	Missing data
18	pof	Num	Did the patient develop premature ovarian failure (POF) according to study definition?	0	Patient did not develop POF at 2 years after registration
				1	Patient did develop POF at 2 years after registration
				9	NA (patient not evaluable for 2-year ovarian failure endpoint)
				“ ”	Missing data
19	ovardys_1	Num	Did the patient develop ovarian dysfunction at year 1 according to study definition?	0	Patient did not develop ovarian dysfunction at 1 year after registration
				1	Patient developed ovarian dysfunction at 1 year after registration
				“ ”	Missing data
20	ovardys_2	Num	Did the patient develop ovarian dysfunction at year 2 according to study definition?	0	Patient did not develop ovarian dysfunction at 2 years after registration
				1	Patient developed ovarian dysfunction at 2 years after registration
				“ ”	Missing data
21	attempt_pregnancy	Num	Did the patient try to become pregnant?	0	No
				1	Yes
				“ ”	Missing data

Column	Variable Name	Type	Variable description	Code	Code definition
22	achieve_pregnancy	Num	Did the patient achieve pregnancy?	0	No
				1	Yes
				“ ”	Missing data
23	numdeliver	Num	Did the patient have >= 1 live delivery?	0	No
				1	Yes
				“ ”	Missing data
24	deliver_ongoing	Num	Does the patient have >= 1 delivery or ongoing pregnancy?	0	No
				1	Yes
				“ ”	Missing data
25	livebirth	Num	Number of babies born		Number
				“ ”	Missing data
26	currpreg	Num	Ongoing pregnancy at last report	0	No
				1	Yes (patient was pregnant at last report)
				“ ”	Missing data
27	miscar	Num	Number of miscarriages		Number
				“ ”	Missing data
28	electerm	Num	Number of elective terminations		Number
				“ ”	Missing data
29	deliver_comp	Num	Number of deliveries with complications		Number
				“ ”	Missing data
30	dfsind	Num	Recurrence indicator	0	No recurrence
				1	Recurrence
31	dfstim	Num	Time to recurrence in years		Number
32	surind	Num	Survival indicator	0	Patient was alive at last contact (censor)
				1	Patient died; last contact was date of death (event)
33	surtim	Num	Survival time, in years, from randomization until date of last contact (if alive) or date of death		Number
34	pregtime	Num	Time (in years) to pregnancy, death, or last contact if alive and not pregnant at last contact		Number
				“ ”	Missing data
35	pregind	Num	Pregnancy indicator	0	Censor
				1	Pregnancy

Column	Variable Name	Type	Variable description	Code	Code definition
				2	Death
				“ ”	Missing data
36	ovarfail_2a	Num	Ovarian failure at 2 years, with deaths counted as treatment failures	0	Patient did not have treatment failure
				1	Patient had treatment failure
				“ ”	Missing data
37	ovarfail_2b	Num	Ovarian failure at 2 years, with death, hysterectomy, or oophorectomy counted as treatment failure	0	Patient did not have treatment failure
				1	Patient had treatment failure
				“ ”	Missing data
38	ovarfailsens_2	Num	Ovarian failure at 2 years, with either amenorrhea or postmenopausal FSH counted as treatment failure	0	Patient did not have treatment failure
				1	Patient had treatment failure
				“ ”	Missing data
39	tot_ovarfailsens	Num	Ovarian failure at year 1 or year 2: failure defined as amenorrhea in the 6 months prior to year 2, or FSH at year 2 in the postmenopausal range; or, if those data were missing, amenorrhea in the 6 months prior to year 1, or FSH at year 1 in the postmenopausal range	0	Patient did not have treatment failure
				1	Patient had treatment failure
				“ ”	Missing data
40	second_primary	Char	Site of any second malignancy (except for breast cancer) during follow-up		Text (verbatim from site)
				NA	Patient had no evidence of non-breast cancer second primary
41	clintox	Num	Evaluable for toxicities	0	Patient was not evaluable for toxicities
				1	Patient was evaluable for toxicities
				9	NA (patient was not included in the primary analysis, exclude=1)
42	diarrhea_max	Num	Maximum CTCAE grade of diarrhea while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4

Column	Variable Name	Type	Variable description	Code	Code definition
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
43	fatigue_max	Num	Maximum CTCAE grade of fatigue while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
44	hotflash_max	Num	Maximum CTCAE grade of hot flashes while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
45	menses_max	Num	Maximum CTCAE grade of irregular menses while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
46	libido_max	Num	Maximum CTCAE grade of decreased libido while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)

Column	Variable Name	Type	Variable description	Code	Code definition
47	agitation_max	Num	Maximum CTCAE grade of agitation while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
48	anxiety_max	Num	Maximum CTCAE grade of anxiety while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
49	depression_max	Num	Maximum CTCAE grade of depression while on study	0	No event while on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
50	jointpain_max	Num	Maximum CTCAE grade of joint pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
51	musclepain_max	Num	Maximum CTCAE grade of muscle pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2

Column	Variable Name	Type	Variable description	Code	Code definition
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
52	headache_max	Num	Maximum CTCAE grade of headache while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
53	sweating_max	Num	Maximum CTCAE grade of sweating while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
54	thrombo_max	Num	Maximum CTCAE grade of thromboembolic event while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
55	vaginaldryness_max	Num	Maximum CTCAE grade of vaginal dryness while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4

Column	Variable Name	Type	Variable description	Code	Code definition
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
56	ataxia_max	Num	Maximum CTCAE grade of ataxia while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
57	dehydration_max	Num	Maximum CTCAE grade of dehydration while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
58	drymouth_max	Num	Maximum CTCAE grade of dry mouth while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
59	edemalimb_max	Num	Maximum CTCAE grade of limb edema while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)

Column	Variable Name	Type	Variable description	Code	Code definition
60	fracture_max	Num	Maximum CTCAE grade of fracture while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
61	abdomenpain_max	Num	Maximum CTCAE grade of abdomen pain while on study	0	No event while on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
62	uterushem_max	Num	Maximum CTCAE grade of uterus hemorrhage while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
63	hyperglycemia_max	Num	Maximum CTCAE grade of hyperglycemia while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
64	hypertension_max	Num	Maximum CTCAE grade of hypertension while on study	0	No event on study
				1	Grade 1
				2	Grade 2

Column	Variable Name	Type	Variable description	Code	Code definition
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
65	sterility_max	Num	Maximum CTCAE grade of infertility/sterility while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
66	insomnia_max	Num	Maximum CTCAE grade of insomnia while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
67	chestwall_max	Num	Maximum CTCAE grade of chest wall pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
68	throat_max	Num	Maximum CTCAE grade of throat pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4

Column	Variable Name	Type	Variable description	Code	Code definition
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
69	mucositis_max	Num	Maximum CTCAE grade of mucositis while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
70	bonepain_max	Num	Maximum CTCAE grade of bone pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
71	nausea_max	Num	Maximum CTCAE grade of nausea while on study	0	No event while on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
72	otherneuro_max	Num	Maximum CTCAE grade of neurology – other AE while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)

Column	Variable Name	Type	Variable description	Code	Code definition
73	neuropathy_max	Num	Maximum CTCAE grade of neuropathy while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
74	osteoporosis_max	Num	Maximum CTCAE grade of osteoporosis while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
75	platelets_max	Num	Maximum CTCAE grade of platelets while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
76	rash_max	Num	Maximum CTCAE grade of rash while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
77	vaginf_max	Num	Maximum CTCAE grade of vaginal infection while on study	0	No event on study
				1	Grade 1
				2	Grade 2

Column	Variable Name	Type	Variable description	Code	Code definition
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
78	breastpain_max	Num	Maximum CTCAE grade of breast pain while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)
79	vomiting_max	Num	Maximum CTCAE grade of vomiting while on study	0	No event on study
				1	Grade 1
				2	Grade 2
				3	Grade 3
				4	Grade 4
				9	NA (patient was not included in the primary analysis or was not evaluable for toxicities)

*Note: Table 1 in the primary publication for this study (Moore et al., New England Journal of Medicine, 2015) contains two errors. Hispanic and non-Hispanic counts were reversed in the “All Eligible Patients: Chemotherapy Alone” and in the “Patients with 2-Yr Data on Ovarian Failure: Overall” columns. The archived dataset associated with this data dictionary will provide the correct counts.