

GOG 250 NCTN DATA ARCHIVE

October 7, 2019

Data as of: December 19, 2013

Notes

- 1 Randomized Phase III Trial of Gemcitabine Plus Docetaxel Plus Bevacizumab or Placebo As First-Line Treatment for Metastatic Uterine Leiomyosarcoma: An NRG Oncology/Gynecologic Oncology Group Study.
- 2 doi: 10.1200/JCO.2014.58.3781
- 3 PMID: 25713428
- 4 Clinical trial information: NCT01012297.
- 5 Data submission information: NCT01012297-D1
- 6 Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Var 1	Type	Label
patid_blind	Character	Patient ID

36 character string

Var 2	Type	Label
nrxn	Numeric	Randomized Treatment Assignment

Value	Label
1	GD+Plac
2	GD+Bev

Var 3	Type	Label
racen	Numeric	Race (Levels combined for patient privacy)

Value	Label
1	White
2	African American
3	Asian/American Indian/unspecified

Var 4	Type	Label
age	Numeric	Age Rounded to the Year.

Continuous Variable

Var 5	Type	Label
perfxn	Numeric	Performance Status (Levels combined for patient privacy)

Value	Label
0	0:Asymptomatic
1	1 or 2: Fully Ambulatory or in bed <50%

Var 6	Type	Label
prhmynn	Numeric	Prior Hormone Therapy

Value	Label
1	Yes
2	No

Var 7	Type	Label
prradynn	Numeric	Prior Pelvic Radiation Therapy

Value	Label
1	Yes
2	No

Var 8	Type	Label
Qcourses	Numeric	Number of treatment courses recieved. Patients indicating no treatment were included in the intent to treat analysis.

Continuous Variable

Var 9	Type	Label
AEEExcluded	Numeric	1:Patients excluded from AE reporting

Value	Label
0	Include
1	Exclude

Var 10	Type	Label
Neutropenia	Numeric	Max Grade: Neutropenia

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3
4	4

Var 11	Type	Label
Thrombocyt	Numeric	Max Grade: Thrombocytopenia

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3
4	4

Var 12	Type	Label
Anemia	Numeric	Max Grade: Anemia

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3

Var 13	Type	Label
Hypertens	Numeric	Max Grade: Hypertension

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3

Var 14	Type	Label
Thromboemb	Numeric	Max Grade: Thromboembolic

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3
4	4

Var 15	Type	Label
Lymphedema	Numeric	Max Grade: Lymphadema

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2

Var 16	Type	Label
GI_Hemorr	Numeric	Max Grade: GI Hemorrhage (Due to data cleaning, the AE data may contain slight discrepancies from that reported in Table 2 of the publication.)

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3

Var 17	Type	Label
Fistula	Numeric	Max Grade: Fistula

Value	Label
.	Excluded from AE Analyses
0	0
3	3

Var 18	Type	Label
GI_Any	Numeric	Max Grade: Any GI

Value	Label
.	Excluded from AE Analyses
0	0
1	1
2	2
3	3
4	4

Var 19	Type	Label
respxn	Numeric	Best Response

Value	Label
1	Complete response
2	Partial response
3	Stable disease
4	Increase disease
6	Not evaluable

Var 20	Type	Label
objresp	Numeric	Objective Response (CR+PR)

Value	Label
0	CR/PR
1	Non Resp

Var 21	Type	Label
MH_stable	Numeric	24 patients who elected to stop study treatment for reasons other than toxicity or disease progression.

Value	Label
0	Other
1	Elected to Stop Tx Early

Var 22	Type	Label
MH_time	Numeric	Months from Withdrawal to Recurrence/Death among 24 patients who elected to stop study treatment for reasons other than toxicity or disease progression.

Continuous Variable

Var 23	Type	Label
MH_stat	Numeric	Event status among 24 patients who elected to stop study treatment for reasons other than toxicity or disease progression.

Value	Label
.	Excluded from this analysis patient set
1	Censored
2	Event

Var 24	Type	Label
pfstat	Numeric	Progression Free Survival Status

Value	Label
1	Censored
2	Event

Var 25	Type	Label
pfstime	Numeric	Time (months) to documentation of disease progression, death or the last CT Scan

Continuous Variable

Var 26	Type	Label
pfstimeint	Numeric	PFS Time Interval (Weeks- per protocol)

Value	Label
0.1	0.1
8	8
16	16
20	20
24	24
30	30
36	36
44	44
52	52
65	65
78	78
91	91
104	104

Var 27	Type	Label
respdur	Numeric	Response Duration. Months from response to recurrence or last followup. For Stable Disease, start date is the 1st CT scan. For Increasing Dis or 1st CT Scan not evaluable, RESPDUR=0.

Continuous Variable

Var 28	Type	Label
survstat	Numeric	Overall Survival Status (Due to data cleaning, the OS data may contain slight discrepancies from that reported in the publication.)

Value	Label
1	Censored
2	Event

Var 29	Type	Label
survtime	Numeric	Time (months) to death or last followup (Due to data cleaning, the OS data may contain slight discrepancies from that reported in the publication.)

Continuous Variable