

NCT02446600 NRG-GY004 D1 NCTN/NCORP Data Archive

Olaparib With or Without Cediranib Versus Platinum-Based Chemotherapy in Recurrent Platinum-Sensitive Ovarian Cancer (NRG-GY004): A Randomized, Open-Label, Phase III Trial

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Dataset ID: NCT02446600-D1

This dataset contains the data from the treatment comparison between olaparib with or without cediranib versus platinum-based Chemotherapy in women diagnosed with platinum-sensitive ovarian cancer. NCT02446600-D2 contains the quality of life (QOL) data.

These Data can be used to approximate the 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).

Seq	Name	Type	Label
1	upi	char	Universal Patient ID

Seq	Name	Type	Label
2	pregimens	char	Number of Prior Anti-cancer Regimens

Values
1
2
3 or more

Seq	Name	Type	Label
3	pfstime_2	num	Months at risk of first progression or death (PFS)

Seq	Name	Type	Label
4	pfstat_2	char	PFS Status

Values

<i>Values</i>
Alive without progression
Died or progressed

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
5	pfstime_3	num	PFS duration (months) censored at initiation of maintenance therapy (Sensitivity analysis)

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
6	pfstat_3	char	PFS Status censored at initiation of maintenance therapy (Sensitivity analysis)

<i>Values</i>
Alive without progression
Died or progressed

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
7	survtime	num	Survival duration from study enrollment in months

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
8	survstat	char	Survival Status

<i>Values</i>
Alive
Died

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
9	whyoff	char	Reason stopped study regimen

Values
Receiving study treatment
Completed planned treatment
Disease progression
Adverse Event
Death
Patient Withdrew
Bowel Obstruction
Other Reason
Did not initiate treatment

Seq	Name	Type	Label
10	Initrx	char	Initiated assigned study treatment

Values
No
Yes

Seq	Name	Type	Label
11	tx_ass	char	Randomly Assigned Treatment Group

Values
Chemotherapy
Olaparib
Olaparib+Cediranib

Seq	Name	Type	Label
12	tx_selx	char	Chemotherapy regimen

Values

<i>Values</i>
Crb+Tax
Crb+Gem
Crb+PLD
Olap
Olap+Ced

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
13	perf	char	Performance Status

<i>Values</i>
0
1
2

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
14	agecat	char	Age Group (Years)

<i>Values</i>
40 - 44
45 - 49
50 - 54
55 - 59
60 - 64
65 - 69
< 40
>= 70

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
15	celltyp	char	Histology

<i>Values</i>
Serous adenoca.
Endometrioid adenoca.
Mixed adenoca.
Other/not specified

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
16	site	char	Primary Disease Site

<i>Values</i>
Ovary
Fallopian Tube
Peritoneum

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
17	BRCA_status	char	gBRCA1/2 Mutation Status

<i>Values</i>
No
Yes

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
18	Racecat	char	Race

<i>Values</i>
Black or African American
Other/Not Specified
White

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
19	Ethncat	char	Ethnicity

<i>Values</i>
Hispanic or Latino
Not Hispanic or Latino
Not Specified

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
20	resp	char	Best unconfirmed response

<i>Values</i>
No response
Not evaluable
Response

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
21	rxdtb	char	Possible treatment related death

<i>Values</i>
No
Yes

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
22	prior_PFI	char	Prior Platinum-Free Interval (months)

<i>Values</i>
PFI > 12

<i>Values</i>
PFI > 6 and PFI <= 12

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
23	prior_AA	char	Prior Anti-angiogenic Therapy

<i>Values</i>
No
Yes

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
24	Constipation	char	Max CTC Grade Constipation

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
25	Dyspnea	char	Max CTC Grade Dyspnea

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
26	Fatigue	char	Max CTC Grade Fatigue

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
27	Headache	char	Max CTC Grade Headache

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
28	Nausea	char	Max CTC Grade Nausea

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
29	Neutrophil_count_decreased	char	Max CTC Grade Neutrophil count decreased

<i>Values</i>
No such AE reported
1 or 2

<i>Values</i>
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
30	Peripheral_sensory_neuropathy	char	Max CTC Grade Peripheral Sensory Neuropathy

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
31	Diarrhea	char	Max CTC Grade Diarrhea

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
32	Anorexia	char	Max CTC Grade Anorexia

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
33	Hypertension	char	Max CTC Grade Hypertension

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
34	Hypothyroidism	char	Max CTC Grade Hypothyroidism

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
35	Mucositis_oral	char	Max CTC Grade Mucositis oral

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
36	Platelet_count_decreased	char	Max CTC Grade Platelet count decreased

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
37	Urinary_tract_infection	char	Max CTC Grade Urinary Tract Infection

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
38	White_blood_cell_decreased	char	Max CTC Grade White blood cell decreased

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
39	Weight_loss	char	Max CTC Grade Weight loss

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
40	Vomiting	char	Max CTC Grade Vomiting

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
41	Abdominal_pain	char	Max CTC Grade Abdominal pain

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
42	Dizziness	char	Max CTC Grade Dizziness

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
43	Anemia	char	Max CTC Grade Anemia

<i>Values</i>
No such AE reported
1 or 2
3
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
44	Hyperglycemia	char	Max CTC Grade Hyperglycemia

<i>Values</i>
No such AE reported
1 or 2
3

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
45	Creatinine_increased	char	Max CTC Grade Creatinine increased

<i>Values</i>
No such AE reported
1 or 2
4

<i>Seq</i>	<i>Name</i>	<i>Type</i>	<i>Label</i>
46	cycmod	char	First Cycle Dose Modified for AE

Values

Not Applicable

1 to 3

4 to 6

7 to 9

10 to 12

No modification
