

Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Participant ID

Variable # 1 Usage Notes: none

Sas Name: ID

Categories: Study: Administration Sas Label: Participant ID

Centrally adjudicated total breast cancer

Variable # 2 Usage Notes: none

Sas Name: BRSTC

Categories:

Values Ν % 97.4% No 16,178 Yes 2.6% 430

16,608

Medical History: Breast Sas Label: Central adj total breast cancer

Medical History: Cancer Outcome: Adjudicated

Days from randomization to total breast cancer

Variable # 3 Usage Notes: none

Sas Name: BRSTCDY

Sas Name: INSITU

No

Sas Name: INSITUDY

Ν

84

Categories: Medical History: Breast Sas Label: Days from rand to total breast cancer

Std Dev Ν Min Max Mean 430 3026 1241.1070 647.58724 Medical History: Cancer Outcome: Adjudicated

Centrally adjudicated in situ breast cancer

Sas Label: Central adj in situ breast cancer

Variable # 4 Usage Notes: In situ breast cancer occuring on or after the same date as an

invasive breast cancer was not counted since reporting of such

events was not required by the study protocol.

Survival type analyses using in situ breast cancer as the **Values** N %

endpoint should consider censoring the survival time at the date

of invasive breast cancer if it occurred.

Yes 84 0.5% Categories: Medical History: Breast

16,524

16,608

Mean

1263.6310

99.5%

Std Dev

641.84083

Medical History: Cancer Outcome: Adjudicated

Days from randomization to in situ breast cancer

Max

2602

Sas Label: Days from rand to in situ breast cancer

Min

94

Variable # 5 Usage Notes: In situ breast cancer occuring on or after the same date as an

invasive breast cancer was not counted since reporting of such

events was not required by the study protocol.

Survival type analyses using in situ breast cancer as the

endpoint should consider censoring the survival time at the date

of invasive breast cancer if it occurred.

Categories: Medical History: Breast

Medical History: Cancer

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

In situ breast cancer diagnostic confirmat status

In situ breast cancer diagnostic confirmation status

Variable # 6

Sas Name: INSDIAG

Sas Label: In situ breast diagnostic conf status

Values % Ν Positive histology (pathology) 84 0.5% Positive exfoliative cytology, no 0.0% 0 positive histology Positive histology (pathology), 0 0.0% distant metastatic site only Positive microscopic confirmation, 0 0.0% method not specified Positive laboratory test/marker 0 0.0% study Direct visualization without 0 0.0% microscopic confirmation Radiography & other image 0 0.0% technique w/o microscopic confirm Clinical diagnosis only (other than 0 0.0% 5, 6, or 7) Unknown if microscopically 0 0.0% confirmed Missing 16,524

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

16,524 99.5% 16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

In situ breast cancer histology

Variable # 7

Sas Name: INSHIST

Sas Label: In situ breast cancer histology

Jas L	aber. In situ breast cancer histology		
Values	s	N	%
8000	Neoplasm, malignant	0	0.0%
8010	Carcinoma	0	0.0%
8020	Carcinoma, undifferentiated, NOS	0	0.0%
8022	Pleomorphic carcinoma	0	0.0%
8032	Spindle cell	0	0.0%
8050	Papillary	0	0.0%
8070	Squamous cell	0	0.0%
8140	Adenocarcinoma, NOS	0	0.0%
8200	Adenoid cystic	0	0.0%
8201	Cribriform	13	0.1%
8210	Adenocarcinoma in adenomatous polyp	0	0.0%
8211	Tubular	0	0.0%
8230	Solid	16	0.1%
8240	Carcinoid tumor, NOS	0	0.0%
8246	Neuroendocrine	0	0.0%
8261	Adenocarcinoma in villous adenoma	0	0.0%
8263	Adenocarcinoma in tubulovillous adenoma	0	0.0%
8310	Clear cell	0	0.0%
8380	Endometrioid	0	0.0%
8401	Apocrine	1	0.0%
8441	Serous, NOS	0	0.0%
8442	Serous, borderline malignancy	0	0.0%
8450	Papillocystic	0	0.0%
8460	Papillary, serous	0	0.0%
8462	Papillary, serous, borderline malignancy	0	0.0%
8472	Mucinous tumor of low malignant potential	0	0.0%
8480	Colloid (mucinous)	0	0.0%
8481	Mucin-secreting	0	0.0%
8490	Signet ring cell	0	0.0%
8500	Ductal	15	0.1%
8501	Comedo	18	0.1%
8503	Intraductal papillary with or without invasion	3	0.0%
8504	Intracystic	0	0.0%
8510	Medullary	0	0.0%
8512	Medullary with lymphoid stroma	0	0.0%
8520	Lobular	5	0.0%
8522	Ductal and lobular	4	0.0%
8530	Inflammatory	0	0.0%
8540	Pagets	0	0.0%
8541	Pagets and infiltrating ductal	0	0.0%
8543	Pagets and intraductal	0	0.0%

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

In situ breast cancer histology

Values	3	N	%
8560	Squamous cell and adenocarcinoma mixed	0	0.0%
8570	Adenocarcinoma with squamous metaplasia	0	0.0%
8571	Adenocarcinoma with cartilaginous metaplasia	0	0.0%
8572	Adenocarcinoma with spindle cell metaplasia	0	0.0%
8930	Stromal sarcoma	0	0.0%
8950	Mixed mullerian	0	0.0%
8980	Carcinosarcoma, NOS	0	0.0%
9020	Phyllodes malignant tumor	0	0.0%
9070	Embryonal	0	0.0%
9999	Other	0	0.0%
	Missing	16,533	99.5%

16,608

In situ breast cancer grade

Variable # 8

Sas Name: INSGRADE

Sas Label: In situ breast cancer grade

Valu	ies	N	%
1	Well differentiated	3	0.0%
2	Moderately differentiated	25	0.2%
3	Poorly differentiated	32	0.2%
4	Anaplastic	0	0.0%
9	Unknown	24	0.1%
	Missing	16,524	99.5%

16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

In situ breast cancer tumor size (mm)

Variable # 9

Sas Name: INSSIZE

Sas Label: In situ breast cancer tumor size, mm

Value	s	N	%
0	No tumor found/No primary mass	0	0.0%
1	Microscopic focus or foci	10	0.1%
2	Mammogram diagnosis only, tumor not clinically palpable	2	0.0%
3	<=3 mm	5	0.0%
4		4	0.0%
5		6	0.0%
6		3	0.0%
7		4	0.0%
8		3	0.0%
10		2	0.0%
11		1	0.0%
12		2	0.0%
13		2	0.0%
15		6	0.0%
17		1	0.0%
20		4	0.0%
25		2	0.0%
40		1	0.0%
100		1	0.0%
	Missing	16,549	99.6%

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

In situ breast cancer tumor size (cm)

Variable # 10

Sas Name: INSSIZECM

Sas Label: In situ breast cancer tumor size, cm

 N
 Min
 Max
 Mean
 Std Dev

 42
 .4
 10
 1.36667
 1.55401

16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Centrally adjudicated invasive breast cancer

Variable # 11

Sas Name: INVASIVE

Sas Label: Central adj invasive breast cancer

 Values
 N
 %

 0
 No
 16,259
 97.9%

 1
 Yes
 349
 2.1%

 16,608
 16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Days from randomization to invasive breast cancer

Variable # 12

Sas Name: INVADY

Sas Label: Days from rand to invasive breast cancer

 N
 Min
 Max
 Mean
 Std Dev

 349
 16
 3026
 1234.5903
 649.4604

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer diagnostic confirmat status

Invasive breast cancer diagnostic confirmation status

Variable # 13
Sas Name: INVDIAG

Sas Label: Invasive breast cancer diagnostic conf status

Values % Positive histology (pathology) 347 2.1% Positive exfoliative cytology, no 0 0.0% positive histology Positive histology (pathology), 0.0% 1 distant metastatic site only Positive microscopic confirmation, 0 0.0% method not specified Positive laboratory test/marker 0 0.0% study Direct visualization without 0 0.0% microscopic confirmation Radiography & other image 0 0.0% technique w/o microscopic confirm Clinical diagnosis only (other than 0 0.0% 5, 6, or 7) Unknown if microscopically 0 0.0% confirmed Missing 16,260 97.9%

16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer histology

Variable # 14

Sas Name: INVHIST

Sas Label: Invasive breast cancer histology

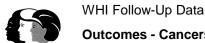
abel: Invasive breast cancer histology		
\$	N	%
Neoplasm, malignant	0	0.0%
Carcinoma	0	0.0%
Carcinoma, undifferentiated, NOS	0	0.0%
Pleomorphic carcinoma	1	0.0%
Spindle cell	0	0.0%
Papillary	1	0.0%
Squamous cell	0	0.0%
Adenocarcinoma, NOS	2	0.0%
Adenoid cystic	0	0.0%
Cribriform	4	0.0%
Adenocarcinoma in adenomatous polyp	0	0.0%
Tubular	14	0.1%
Solid	0	0.0%
Carcinoid tumor, NOS	0	0.0%
Neuroendocrine	0	0.0%
Adenocarcinoma in villous adenoma	0	0.0%
Adenocarcinoma in tubulovillous adenoma	0	0.0%
Clear cell	0	0.0%
Endometrioid	0	0.0%
Apocrine	2	0.0%
Serous, NOS	0	0.0%
Serous, borderline malignancy	0	0.0%
Papillocystic	0	0.0%
Papillary, serous	0	0.0%
Papillary, serous, borderline malignancy	0	0.0%
Mucinous tumor of low malignant potential	0	0.0%
		0.1%
		0.0%
		0.0%
		1.3%
		0.0%
Intraductal papillary with or without invasion	1	0.0%
Intracystic	0	0.0%
Medullary	1	0.0%
Medullary with lymphoid stroma	0	0.0%
Lobular	32	0.2%
Ductal and lobular	48	0.3%
Inflammatory	0	0.0%
Pagets	1	0.0%
Pagets and infiltrating ductal	1	0.0%
Pagets and intraductal	2	0.0%
	Neoplasm, malignant Carcinoma Carcinoma, undifferentiated, NOS Pleomorphic carcinoma Spindle cell Papillary Squamous cell Adenocarcinoma, NOS Adenoid cystic Cribriform Adenocarcinoma in adenomatous polyp Tubular Solid Carcinoid tumor, NOS Neuroendocrine Adenocarcinoma in villous adenoma Adenocarcinoma in tubulovillous adenoma Clear cell Endometrioid Apocrine Serous, NOS Serous, borderline malignancy Papillary, serous Papillary, serous Papillary, serous, borderline malignancy Mucinous tumor of low malignant potential Colloid (mucinous) Mucin-secreting Signet ring cell Ductal Comedo Intraductal papillary with or without invasion Intracystic Medullary Medullary Medullary with lymphoid stroma Lobular Ductal and lobular Inflammatory Pagets Pagets and infiltrating ductal	Neoplasm, malignant 0 Carcinoma 0 Carcinoma, undifferentiated, NOS 0 Pleomorphic carcinoma 1 Spindle cell 0 Papillary 1 Squamous cell 0 Adenocarcinoma, NOS 2 Adenoid cystic 0 Cribriform 4 Adenocarcinoma in adenomatous polyp Tubular 14 Solid 0 Carcinoid tumor, NOS 0 Neuroendocrine 0 Adenocarcinoma in villous adenoma Adenocarcinoma in tubulovillous adenoma Adenocarcinoma in tubulovillous adenoma Clear cell 0 Endometrioid 0 Apocrine 2 Serous, NOS 0 Serous, borderline malignancy 0 Papillary, serous 0 Papillary, serous, borderline malignancy 0 Mucinous tumor of low malignant potential 1 Colloid (mucinous) 18 Mucin-secreting 0 Signet ring cell 1 Ductal 218 Comedo 0 Intraductal papillary with or without invasion 1 Intracystic 0 Medullary 1 Medullary 1 Medullary with lymphoid stroma 0 Lobular 32 Ductal and lobular 48 Inflammatory 0 Pagets 1 Pagets and infiltrating ductal 1

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer histology

Values	5	N	%
8560	Squamous cell and adenocarcinoma mixed	0	0.0%
8570	Adenocarcinoma with squamous metaplasia	0	0.0%
8571	Adenocarcinoma with cartilaginous metaplasia	0	0.0%
8572	Adenocarcinoma with spindle cell metaplasia	0	0.0%
8930	Stromal sarcoma	0	0.0%
8950	Mixed mullerian	0	0.0%
8980	Carcinosarcoma, NOS	0	0.0%
9020	Phyllodes malignant tumor	1	0.0%
9070	Embryonal	0	0.0%
9999	Other	0	0.0%
	Missing	16,260	97.9%

16,608

16,608

Invasive breast cancer histology categorized

Recoding as per Chlebowski RT et al. JAMA 2003; 289: 3243-3253

Variable # 15

Sas Name: INVHISTC

Sas Label: Invasive breast cancer histology categorized and

recoded

Values		N	%
1	Ductal only	220	1.3%
2	Lobular only	32	0.2%
3	Invasive ductal and invasive lobular	23	0.1%
4	Tubular	14	0.1%
5	Medullary	0	0.0%
6	Inflammatory	0	0.0%
7	Phyllodes malignant tumor	0	0.0%
8	Comedo	0	0.0%
9	Cribriform	0	0.0%
10	Solid	0	0.0%
11	Other	35	0.2%
3.1	Invasive ductal and LCIS	10	0.1%
3.2	Invasive lobular and DCIS	4	0.0%
3.3	Invasive ductal with lobular features	6	0.0%
3.4	Invasive lobular with ductal features	2	0.0%
3.5	Invasive carcinoma with ductal and lobular features	2	0.0%
	Missing	16,260	97.9%

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer grade

Variable # 16

Sas Name: INVGRADE

Sas Label: Invasive breast cancer grade

% **Values** Ν 0.4% Well differentiated 67 Moderately differentiated 132 0.8% Poorly differentiated 93 0.6% 0 0.0% Anaplastic Unknown 0.3% 56 Missing 16,260 97.9% 16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer laterality: Not paired

Invasive breast cancer - Laterality: Not a paired site

Variable # 17

Sas Name: INVNOPAIR

Sas Label: Invasive breast cancer - not a paired site

 Values
 N
 %

 0
 No
 0
 0.0%

 1
 Yes
 0
 0.0%

 .
 Missing
 16,608
 100.0%

16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer laterality: Right

Invasive breast cancer - Laterality: Right: origin of primary

Variable # 18

Sas Name: INVRIGHT

Sas Label: Invasive breast cancer - right origin of primary

 Values
 N
 %

 0
 No
 0
 0.0%

 1
 Yes
 174
 1.0%

 .
 Missing
 16,434
 99.0%

 16.608
 16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer laterality: Left

Invasive breast cancer - Laterality: Left: origin of primary

Variable # 19

Sas Name: INVLEFT

Sas Label: Invasive breast cancer - left origin of primary

 Values
 N
 %

 0
 No
 0
 0.0%

 1
 Yes
 175
 1.1%

 .
 Missing
 16,433
 98.9%

 16,608
 16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer laterality: One side

Invasive breast cancer - Laterality: Only one side involved, right or left origin unspecified.

Variable # 20

Sas Name: INVONESIDE

Sas Label: Invasive breast cancer - only one side involved (left or

right unspec)

Values		N	%
0	No	0	0.0%
1	Yes	0	0.0%
	Missing	16,608	100.0%

Usage Notes: none

Medical History: Breast Categories:

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer laterality: Bilateral

Invasive breast cancer - Laterality: Bilateral involvement, lateral origin unknown: stated to be single primary.

16,608

Variable # 21

Sas Name: INVBILAT

Sas Label: Invasive breast cancer - bilateral: lateral origin

unknown/single primary

Valu	es	N	%
0	No	0	0.0%
1	Yes	0	0.0%
	Missing	16,608	100.0%

16,608

Usage Notes: none

Categories: Medical History: Breast

> Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer laterality: Paired

Invasive breast cancer - Laterality: Paired site, but no information concerning laterality; midline tumor

Variable # 22 Usage Notes: none

Sas Name: INVPAIRED

Sas Label: Invasive breast cancer - paired site: no lateral

info/midline tumor

Valu	ues	N	%	
0	No	0	0.0%	
1	Yes	1	0.0%	
	Missing	16,607	100.0%	

Medical History: Breast Categories:

Medical History: Cancer Outcome: Adjudicated

16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer tumor size (mm)

Variable # 23

Sas Name: INVSIZE

Sas Label: Invasive breast cancer tumor size, mm

Sas Label: Invasive breast cancer tumor size, mm			
Values	.	N	%
0	No tumor found/No primary mass	1	0.0%
1	Microscopic focus or foci	17	0.1%
2	Mammogram diagnosis only, tumor not clinically palpable	0	0.0%
3	<=3 mm	6	0.0%
4		12	0.1%
5		16	0.1%
6		10	0.1%
7		16	0.1%
8		13	0.1%
9		16	0.1%
10		25	0.2%
11		13	0.1%
12		17	0.1%
13		13	0.1%
14		3	0.0%
15		33	0.2%
16		5	0.0%
17		4	0.0%
18		7	0.0%
19		6	0.0%
20		26	0.2%
21		1	0.0%
22		8	0.0%
23		5	0.0%
24		2	0.0%
25		11	0.1%
26		1	0.0%
27		1	0.0%
29		1	0.0%
30		8	0.0%
32		1	0.0%
34		2	0.0%
35		3	0.0%
36		1	0.0%
38		1	0.0%
40		6	0.0%
42		3	0.0%
45		1	0.0%
47		1	0.0%
50		2	0.0%
55		1	0.0%
60		1	0.0%
85		1	0.0%
3.5		1	0.0%
		•	3.370

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Invasive breast cancer tumor size (mm)

Values	N	%
8.5	1	0.0%
. Missing	16,285	98.1%
	16,608	

Invasive breast cancer tumor size (cm)

Variable # 24

Sas Name: INVSIZECM

Sas Label: Invasive breast cancer tumor size, cm

 N
 Min
 Max
 Mean
 Std Dev

 298
 .4
 8.5
 1.59782
 1.07018

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer lymph node involvement

Variable # 25

Sas Name: INVINVLV

Sas Label: Invasive breast cancer lymph node involvement

% **Values** 261 1.6% No lymph node involvement 7 0.0% <=0.2 cm (micrometastasis) 0.2 cm - 2 cm (no extension 6 0.0% beyond capsule) <2 cm (extension beyond capsule) 6 0.0% >=2 cm 2 0.0% Fixed/Matted ipsilateral axillary 12 0.1% Axillary/Regional, NOS 36 0.2% Internal mammary, ipsilateral 0 0.0% 0.0% Distant 2 Unknown 0 0.0% Missing 16,276 98.0%

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer number lymph nodes examined

16,608

Invasive breast cancer number of lymph nodes examined

Sas Name: INVNLYMPH

Variable # 26

Sas Label: Invasive breast cancer number of lymph nodes

examined

 N
 Min
 Max
 Mean
 Std Dev

 334
 0
 36
 10.53293
 7.84672

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

File Date: 04/06/2006 Structure: One row per participant Data File: ocan_ep_fu_pub Population: E+P participants

Invasive breast cancer number positive lymph nodes

Invasive breast cancer number of positive lymph nodes

Variable # 27

Sas Name: INVPLYMPH

Sas Label: Invasive breast cancer number of + lymph nodes

Ν Std Dev Min Max Mean 307 0 15 .55049 1.6108 Usage Notes: none

Medical History: Breast Categories:

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer SEER stage

Variable # 28

Sas Name: INVSTAGE

Sas Label: Invasive breast cancer SEER stage

Values Ν % In situ 0 0.0% Localized 1.6% 268 Regional 68 0.4% Distant 5 0.0% Unknown 0 0.0% Missing 16,267 97.9% Usage Notes: none

Categories: Medical History: Breast

> Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer estrogen receptor assay

Variable # 29

Sas Name: INVERASSAY

Sas Label: Invasive breast cancer ER assay

Values N % Positive 270 1.6% Negative 39 0.2% Borderline 0 0.0% Ordered/Results not available 19 0.1% Unknown/Not done 19 0.1% Missing 16,261 97.9%

16,608

16,608

Usage Notes: none

Medical History: Breast Categories:

Medical History: Cancer Outcome: Adjudicated

Invasive breast cancer progesterone receptor assay

Variable # 30

Sas Name: INVPRASSAY

Sas Label: Invasive breast cancer PR assay

Values Ν % Positive 221 1.3% Negative 82 0.5% 0.0% Borderline 2 Ordered/Results not available 19 0.1% Unknown/Not done 0.1% 23 Missing 16,261 97.9% 16,608

Usage Notes: none

Categories: Medical History: Breast

Medical History: Cancer Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Centrally adjudicated total colorectal cancer

Variable # 31

Sas Name: COLOTOT

Sas Label: Central adj total colorectal cancer

Values Ν % No 16,486 99.3% Yes 122 0.7% 16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Days from randomization to total colorectal cancer

Variable # 32

Sas Name: COLOTOTDY

Sas Label: Days from rand to total colorectal cancer

Ν 122

Min	Max	Mean	Std Dev
13	2664	1118 6721	653 9332

Usage Notes: none

Categories:

Medical History: Cancer Medical History: Colorectal

Outcome: Adjudicated

Centrally adjudicated colon cancer

Variable # 33

Sas Name: COLON

Sas Label: Central adj colon cancer

Values

Ν 99.4% No 16,512 Yes 96 0.6%

16,608

Usage Notes: none

Categories: Medical History: Cancer

> Medical History: Colorectal Outcome: Adjudicated

Days from randomization to colon cancer

Variable # 34

Sas Name: COLONDY

Sas Label: Days from rand to colon cancer

Ν

Std Dev Min Max Mean 96 2547 1071.8021 642.3407 13

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Colorectal Outcome: Adjudicated

Centrally adjudicated rectal cancer

Variable # 35

Sas Name: RECTAL

Sas Label: Central adj rectal cancer

Values

% Ν No 16,589 99.9% Yes 0.1% 19

16,608

Usage Notes: none

Categories:

Medical History: Cancer Medical History: Colorectal

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Days from randomization to rectal cancer

Variable # 36 Usage Notes: none

Sas Name: RECTDY

Sas Label: Days from rand to rectal cancer

Std Dev Mean Min Max 19 77 2664 1336.6842 687.70868

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Centrally adjudicated invasive colorectal cancer

Variable # 37 Usage Notes: none

Sas Name: INVCOLO

Sas Label: Central adj invasive colorectal cancer

% **Values** N Nο 99.3% 16,493 Yes 0.7% 115

16,608

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Days from rand to invasive colorectal cancer

Days from randomization to invasive colorectal cancer

Variable # 38 Usage Notes: none

Sas Name: INVCOLDY

Yes

Sas Name: COLLOCDY

Sas Label: Days from rand to invasive colorectal cancer

Ν Min Max Mean Std Dev 115 2664 1115.5652 654.42466 13

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Centrally adj localized invasive colorectal cancer

Centrally adjudicated localized invasive colorectal cancer

Variable # 39 Usage Notes: none

Sas Name: COLLOCAL

Medical History: Cancer Categories: Sas Label: Centrally adj localized invasive colorectal cancer Medical History: Colorectal

46

Outcome: Adjudicated **Values** % Ν No 16.562 99.7%

0.3%

16,608

Days from rand to localize invasive colorec cancer

Days from randomization to localized invasive colorectal cancer

Variable # 40 Usage Notes: none

Medical History: Cancer Categories: Sas Label: Days from rand to localized invasive colorectal cancer

Medical History: Colorectal Outcome: Adjudicated

Ν Min Mean Std Dev Max 662.40162 46 13 2547 1203.0870

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Central adj invasive colorectal cancer detectable

Centrally adjudicated invasive colorectal cancer detectable by sigmoidoscopy

Variable # 41

Sas Name: COLDETCT

Sas Label: Central adj invasive colorectal cancer detectable by

sigmoidoscopy

 Values
 N
 %

 0
 No
 16,541
 99.6%

 1
 Yes
 67
 0.4%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Days from rand to invasiv colorectal cancer detect

Days from randomization to invasive colorectal cancer detectable by sigmoidoscopy

Variable # 42 Usage Notes: none

Sas Name: COLDETCTDY

Sas Label: Days from rand to invasive colorectal cancer detectable

by sigmoidoscopy

 N
 Min
 Max
 Mean
 Std Dev

 67
 13
 2547
 1083.8508
 677.05732

G

Categories: Medical History: Cancer

Medical History: Colorectal

Outcome: Adjudicated

Central adj invasive colorectal cancer not detect

Centrally adjudicated invasive colorectal cancer not detectable by sigmoidoscopy

Variable # 43 Usage Notes: none

Sas Name: COLNODTCT

Sas Label: Central adj invasive colorectal cancer not detectable by

sigmoidoscopy

Valu	ues	N	%
0	No	16,561	99.7%
1	Yes	47	0.3%

16,608

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Days from rand to invas colorec cancer not detect

Days from randomization to invasive colorectal cancer not detectable by sigmoidoscopy

Variable # 44 Usage Notes: none

Sas Name: COLNODTCTDY

Sas Label: Days from rand to invasive colorectal cancer not

detectable by sigmoidoscopy

 N
 Min
 Max
 Mean
 Std Dev

 47
 27
 2664
 1170.7021
 627.97421

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Centrally adj regional invasive colorectal cancer

Centrally adjudicated regional/metastatic invasive colorectal cancer

Sas Name: COLREGMET

Variable # 45

Sas Label: Central adj regional/metastatic invasive colorectal

Values Ν % 99.6% No 16,542 Yes 66 0.4%

16,608

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Colorectal Outcome: Adjudicated

Days from rand to regional invas colorectal cancer

Days from randomization to regional/metastatic invasive colorectal cancer

Variable # 46 Usage Notes: none

Sas Name: COLREGMETDY

Sas Label: Days from rand to regional/metastatic invasive colorectal

Ν Min Max Mean Std Dev 66 27 2664 1037.7879 639.67729

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer site

Sas Label: Colorectal cancer site

Variable # 47 Usage Notes: none

Sas Name: COLSITE

Medical History: Cancer Categories: Medical History: Colorectal

Outcome: Adjudicated

Values % Ν 18 0.6% Colon 93 19 Rectosigmoid junction 6 0.0% 20 Rectum 0.1% 23 Missing 16,486 99.3%

16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Colorectal cancer sub-site

Variable # 48

Sas Name: COLICD

Sas Label: Colorectal cancer sub-site

Value	S	N	%
18	Cecum	24	0.1%
18.2	Ascending colon	20	0.1%
18.3	Hepatic flexure of colon	4	0.0%
18.4	Transverse colon	7	0.0%
18.5	Splenic flexure	5	0.0%
18.6	Descending colon	7	0.0%
18.7	Sigmoid colon	24	0.1%
18.8	Overlapping lesion	0	0.0%
18.9	Unknown	1	0.0%
19.9	Rectosigmoid junction	7	0.0%
20.9	Rectum	23	0.1%
	Missing	16,486	99.3%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Colorectal cancer histology

Variable # 49

Sas Name: COLHIST

Sas Label: Colorectal cancer histology

Sas La	bel: Colorectal cancer histology		
Values		N	%
8000	Neoplasm, malignant	1	0.0%
8010	Carcinoma	0	0.0%
8020	Carcinoma, undifferentiated, NOS	0	0.0%
8022	Pleomorphic carcinoma	0	0.0%
8032	Spindle cell	0	0.0%
8050	Papillary	0	0.0%
8070	Squamous cell	1	0.0%
8140	Adenocarcinoma, NOS	74	0.4%
8200	Adenoid cystic	0	0.0%
8201	Cribriform	0	0.0%
8210	Adenocarcinoma in adenomatous polyp	9	0.1%
8211	Tubular	0	0.0%
8230	Solid	0	0.0%
8240	Carcinoid tumor, NOS	2	0.0%
8246	Neuroendocrine	0	0.0%
8261	Adenocarcinoma in villous adenoma	3	0.0%
8263	Adenocarcinoma in tubulovillous adenoma	17	0.1%
8310	Clear cell	0	0.0%
8380	Endometrioid	0	0.0%
8401	Apocrine	0	0.0%
8441	Serous, NOS	0	0.0%
8442	Serous, borderline malignancy	0	0.0%
8450	Papillocystic	0	0.0%
8460	Papillary, serous	0	0.0%
8462	Papillary, serous, borderline malignancy	0	0.0%
8472	Mucinous tumor of low malignant potential	0	0.0%
8480	Colloid (mucinous)	10	0.1%
8481	Mucin-secreting	4	0.0%
8490	Signet ring cell	1	0.0%
8500	Ductal	0	0.0%
8501	Comedo	0	0.0%
8503	Intraductal papillary with or without invasion	0	0.0%
8504	Intracystic	0	0.0%
8510	Medullary	0	0.0%
8512	Medullary with lymphoid stroma	0	0.0%
8520	Lobular	0	0.0%
8522	Ductal and lobular	0	0.0%
8530	Inflammatory	0	0.0%
8540	Pagets	0	0.0%
8541	Pagets and infiltrating ductal	0	0.0%
8543	Pagets and intraductal	0	0.0%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Colorectal cancer histology

Values	5	N	%
8560	Squamous cell and adenocarcinoma mixed	0	0.0%
8570	Adenocarcinoma with squamous metaplasia	0	0.0%
8571	Adenocarcinoma with cartilaginous metaplasia	0	0.0%
8572	Adenocarcinoma with spindle cell metaplasia	0	0.0%
8930	Stromal sarcoma	0	0.0%
8950	Mixed mullerian	0	0.0%
8980	Carcinosarcoma, NOS	0	0.0%
9020	Phyllodes malignant tumor	0	0.0%
9070	Embryonal	0	0.0%
9999	Other	0	0.0%
-	Missing	16,486	99.3%

16,608

Colorectal cancer tumor behavior

Variable # 50

Sas Name: COLBEHAV

Sas Label: Colorectal cancer tumor behavior

Valu	ies	N	%
1	Borderline	0	0.0%
2	In situ	4	0.0%
3	Invasive	118	0.7%
	Missing	16,486	99.3%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer grade

Variable # 51

Sas Name: COLGRADE

Sas Label: Colorectal cancer grade

Valu	es	N	%
1	Well differentiated	7	0.0%
2	Moderately differentiated	75	0.5%
3	Poorly differentiated	21	0.1%
4	Anaplastic	2	0.0%
9	Unknown	0	0.0%
	Missing	16,503	99.4%
		16,608	

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer tumor size (cm)

Variable # 52

Sas Name: COLSIZE

Sas Label: Colorectal cancer tumor size, cm

Std Dev Ν Min Max Mean 90 .1 16 4.38444 2.5447 Usage Notes: none

Medical History: Cancer Categories:

Medical History: Colorectal Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Colorectal cancer lymph node involvement

Variable # 53

Sas Name: COLINVLV

Sas Label: Colorectal cancer lymph node involvement

Valu	es	N	%
0	No lymph node involvement	71	0.4%
1	<=0.2 cm (micrometastasis)	20	0.1%
2	0.2 cm - 2 cm (no extension beyond capsule)	0	0.0%
3	<2 cm (extension beyond capsule)	22	0.1%
4	>=2 cm	0	0.0%
5	Fixed/Matted ipsilateral axillary	0	0.0%
6	Axillary/Regional, NOS	0	0.0%
7	Internal mammary, ipsilateral	1	0.0%
8	Distant	0	0.0%
9	Unknown	0	0.0%
	Missing	16,494	99.3%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer number lymph nodes examined

16.608

Colorectal cancer number of lymph nodes examined

Sas Name: COLNLYMPH

Variable # 54

Sas Label: Colorectal cancer number of lymph nodes examined

 N
 Min
 Max
 Mean
 Std Dev

 115
 0
 61
 10.73043
 9.60201

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer number of positive lymph nodes

Variable # 55

Sas Name: COLPLYMPH

Sas Label: Colorectal cancer number of + lymph nodes

 N
 Min
 Max
 Mean
 Std Dev

 103
 0
 14
 1.61165
 2.95798

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

Colorectal cancer SEER stage

Variable # 56

Sas Name: COLSTAGE

Sas Label: Colorectal cancer SEER stage

Values Ν % In situ 4 0.0% Localized 49 0.3% 53 0.3% Regional 0.1% Distant 13 0 Unknown 0.0% Missing 16,489 99.3%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Colorectal Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Centrally adjudicated endometrial cancer

Variable # 57

Sas Name: ENDOCA

Sas Label: Central adj endometrial cancer

Values Ν % 99.7% No 16,550 Yes 58 0.3% Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

16,608

Days from randomization to endometrial cancer

Variable # 58

Sas Name: ENDOCADY

Sas Label: Days from rand to endometrial cancer

Ν 58

Min Mean Std Dev Max 111 2909 1242.0172 661.08604 Usage Notes: none

Categories:

Medical History: Cancer Medical History: Reproductive

Outcome: Adjudicated

Centrally adj epithelial endometrial cancer

Centrally adjudicated epithelial endometrial cancer

Variable # 59

Sas Name: EPIENDOCA

Sas Label: Central adj epithelial endometrial cancer

Values Ν % No 16,555 99.7% Yes 0.3% 53

16,608

Usage Notes: none

Categories:

Medical History: Cancer Medical History: Reproductive

Outcome: Adjudicated

Days from rand to epithelial endometrial cancer

Days from randomization to epithelial endometrial cancer

Variable # 60

Sas Name: EPIENDOCADY

Sas Label: Days from rand to epithelial endometrial cancer

Ν

Std Dev Min Mean Max 53 111 2909 1271.2453 655.39398 Usage Notes: none

Categories:

Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Endometrial cancer histology

Variable # 61

Sas Name: ENHIST

Sas La	bel: Endometrial cancer histology		
Values	•	N	%
8000	Neoplasm, malignant	0	0.0%
8010	Carcinoma	0	0.0%
8020	Carcinoma, undifferentiated, NOS	0	0.0%
8022	Pleomorphic carcinoma	0	0.0%
8032	Spindle cell	0	0.0%
8050	Papillary	0	0.0%
8070	Squamous cell	1	0.0%
8140	Adenocarcinoma, NOS	17	0.1%
8200	Adenoid cystic	0	0.0%
8201	Cribriform	0	0.0%
8210	Adenocarcinoma in adenomatous polyp	0	0.0%
8211	Tubular	0	0.0%
8230	Solid	0	0.0%
8240	Carcinoid tumor, NOS	0	0.0%
8246	Neuroendocrine	0	0.0%
8261	Adenocarcinoma in villous adenoma	0	0.0%
8263	Adenocarcinoma in tubulovillous adenoma	0	0.0%
8310	Clear cell	1	0.0%
8380	Endometrioid	28	0.2%
8401	Apocrine	0	0.0%
8441	Serous, NOS	0	0.0%
8442	Serous, borderline malignancy	0	0.0%
8450	Papillocystic	0	0.0%
8460	Papillary, serous	1	0.0%
8462	Papillary, serous, borderline malignancy	0	0.0%
8472	Mucinous tumor of low malignant potential	0	0.0%
8480	Colloid (mucinous)	2	0.0%
8481	Mucin-secreting	0	0.0%
8490	Signet ring cell	0	0.0%
8500	Ductal	0	0.0%
8501	Comedo	0	0.0%
8503	Intraductal papillary with or without invasion	0	0.0%
8504	Intracystic	0	0.0%
8510	Medullary	0	0.0%
8512	Medullary with lymphoid stroma	0	0.0%
8520	Lobular	0	0.0%
8522	Ductal and lobular	0	0.0%
8530	Inflammatory	0	0.0%
8540	Pagets	0	0.0%
8541	Pagets and infiltrating ductal	0	0.0%
8543	Pagets and intraductal	0	0.0%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Endometrial cancer histology

Values	8	N	%
8560	Squamous cell and adenocarcinoma mixed	0	0.0%
8570	Adenocarcinoma with squamous metaplasia	3	0.0%
8571	Adenocarcinoma with cartilaginous metaplasia	0	0.0%
8572	Adenocarcinoma with spindle cell metaplasia	0	0.0%
8930	Stromal sarcoma	2	0.0%
8950	Mixed mullerian	2	0.0%
8980	Carcinosarcoma, NOS	1	0.0%
9020	Phyllodes malignant tumor	0	0.0%
9070	Embryonal	0	0.0%
9999	Other	0	0.0%
	Missing	16,550	99.7%

16,608

Endometrial cancer tumor behavior

Variable # 62

Sas Name: ENBEHAVIOR

Sas Label: Endometrial cancer tumor behavior

Valu	ies	N	%
1	Borderline	0	0.0%
2	In situ	0	0.0%
3	Invasive	58	0.3%
	Missing	16,550	99.7%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

Endometrial cancer tumor grade

Variable # 63

Sas Name: ENGRADE

Sas Label: Endometrial cancer tumor grade

Valu	es	N	%
1	Well differentiated	15	0.1%
2	Moderately differentiated	25	0.2%
3	Poorly differentiated	12	0.1%
4	Anaplastic	6	0.0%
9	Unknown	0	0.0%
	Missing	16,550	99.7%
		16,608	

Usage Notes: none

Categories:

Medical History: Cancer Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Endometrial cancer tumor size (mm)

Variable # 64

Sas Name: ENSIZE

Sas Label: Endometrial cancer tumor size

Values		N	%
0	No tumor found/No primary mass	0	0.0%
1	Microscopic focus or foci	1	0.0%
2	Mammogram diagnosis only, tumor not clinically palpable	0	0.0%
3	<=3 mm	0	0.0%
5		1	0.0%
10		1	0.0%
15		5	0.0%
16		1	0.0%
20		2	0.0%
23		1	0.0%
25		1	0.0%
26		1	0.0%
30		6	0.0%
35		1	0.0%
36		1	0.0%
40		1	0.0%
45		1	0.0%
75		1	0.0%
	Missing	16.583	99.8%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

Endometrial cancer lymph node involvement

16,608

Variable # 65

Sas Name: ENLNODES

Sas Label: Endometrial cancer lymph node involvement

Values		N	%
0	No lymph node involvement	55	0.3%
1	<=0.2 cm (micrometastasis)	2	0.0%
2	0.2 cm - 2 cm (no extension beyond capsule)	0	0.0%
3	<2 cm (extension beyond capsule)	0	0.0%
4	>=2 cm	0	0.0%
5	Fixed/Matted ipsilateral axillary	0	0.0%
6	Axillary/Regional, NOS	0	0.0%
7	Internal mammary, ipsilateral	0	0.0%
8	Distant	0	0.0%
9	Unknown	1	0.0%
	Missing	16,550	99.7%
		16,608	

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Endometrial cancer number lymph nodes examined

Endometrial cancer number of lymph nodes examined

Sas Name: ENLYMPHVE

Variable # 66

Sas Label: Endometrial cancer number of lymph nodes examined

Std Dev Ν Min Max Mean 53 0 7.75472 12.14006 Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive Outcome: Adjudicated

Endometrial cancer number of positive lymph nodes

Variable # 67 Usage Notes: none

Sas Name: ENLYMPNUM

Sas Name: ENSTAGE

Sas Label: Endometrial cancer number of positive lymph nodes

Std Dev Ν Min Max Mean 30 .26667 1.28475 0

Medical History: Cancer Categories:

Medical History: Reproductive Outcome: Adjudicated

Endometrial cancer SEER stage

Variable # 68 Usage Notes: none

Sas Label: Endometrial cancer SEER stage

Values N % 0.0% 0 In situ Localized 49 0.3% Regional 9 0.1% Distant 0 0.0% Unknown 0 0.0% 16,550 99.7% Missing

16,608

Medical History: Cancer Categories:

Medical History: Reproductive Outcome: Adjudicated

Centrally adjudicated ovarian cancer

Variable # 69 Usage Notes: none

Sas Name: OVCA

Sas Name: OVCADY

Min

Ν

Sas Label: Central adj ovarian cancer

Values N % No 16,572 99.8% Yes 36 0.2% 16,608

Medical History: Cancer Categories:

Medical History: Reproductive

Outcome: Adjudicated

Days from randomization to ovarian cancer

Variable # 70 Usage Notes: none

Mean

Categories: Medical History: Cancer Sas Label: Days from rand to ovarian cancer

Std Dev

Medical History: Reproductive Outcome: Adjudicated

36 79 644.57332 2302 1121.0833

Max

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Centrally adjudicated invasive ovarian cancer

Variable # 71

Sas Name: OVCAINV

Sas Label: Central adj invasive ovarian cancer

Values N % No 99.8% 16,576 Yes 32 0.2% 16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

Days from randomization to invasive ovarian cancer

Sas Name: OVCAINVDY

Variable # 72

Sas Label: Days from rand to invasive ovarian cancer

Ν Min Mean Std Dev Max 32 79 2302 1056.4063 623.41991 Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive

Outcome: Adjudicated

Centrally adj epithelial invasive ovarian cancer

Centrally adjudicated epithelial invasive ovarian cancer

Variable # 73

Sas Name: EPIINVOV

Sas Label: Central adj epithelial invasive ovarian cancer

Values Ν % No 16,578 99.8% Yes 30 0.2% 16,608

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive Outcome: Adjudicated

Days from rand to epithelial invas ovarian cancer

Days from randomization to epithelial invasive ovarian cancer

Sas Name: EPIINVOVDY

Variable # 74

Sas Label: Days from rand to epithelial invasive ovarian cancer

Std Dev Ν Min Mean Max 30 79 2302 1067.7667 629.2928 Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive

Outcome: Adjudicated

Central adj ovarian cancer w/ low malignant potent

Centrally adjudicated ovarian cancer with low malignant potential

Variable # 75

Sas Name: OVCALMP

Sas Label: Central adj ovarian cancer w/ low malignant potential

Values 100.0% No 16,604 Yes 0.0% Usage Notes: none

Categories:

Medical History: Cancer Medical History: Reproductive

Outcome: Adjudicated

16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Days from rand to ovarian cancer w/ low malignant

Days from randomization to ovarian cancer with low malignant potential

,

Sas Name: OVCALMPDY

Variable # 76

Sas Label: Days from rand to ovarian cancer w/ low malignant

potential

 N
 Min
 Max
 Mean
 Std Dev

 4
 741
 2219
 1638.5
 655.4014

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Ovarian cancer histology

Variable # 77

Sas Name: OVHIST

Sas Label: Ovarian cancer histology

Sas La	abel: Ovarian cancer histology		
Values	s	N	%
8000	Neoplasm, malignant	0	0.0%
8010	Carcinoma	4	0.0%
8020	Carcinoma, undifferentiated, NOS	1	0.0%
8022	Pleomorphic carcinoma	0	0.0%
8032	Spindle cell	0	0.0%
8050	Papillary	0	0.0%
8070	Squamous cell	0	0.0%
8140	Adenocarcinoma, NOS	2	0.0%
8200	Adenoid cystic	0	0.0%
8201	Cribriform	0	0.0%
8210	Adenocarcinoma in adenomatous polyp	0	0.0%
8211	Tubular	0	0.0%
8230	Solid	0	0.0%
8240	Carcinoid tumor, NOS	0	0.0%
8246	Neuroendocrine	0	0.0%
8261	Adenocarcinoma in villous adenoma	0	0.0%
8263	Adenocarcinoma in tubulovillous adenoma	0	0.0%
8310	Clear cell	3	0.0%
8380	Endometrioid	2	0.0%
8401	Apocrine	0	0.0%
8441	Serous, NOS	2	0.0%
8442	Serous, borderline malignancy	1	0.0%
8450	Papillocystic	1	0.0%
8460	Papillary, serous	15	0.1%
8462	Papillary, serous, borderline malignancy	1	0.0%
8472	Mucinous tumor of low malignant potential	2	0.0%
8480	Colloid (mucinous)	0	0.0%
8481	Mucin-secreting	0	0.0%
8490	Signet ring cell	0	0.0%
8500	Ductal	0	0.0%
8501	Comedo	0	0.0%
8503	Intraductal papillary with or without invasion	0	0.0%
8504	Intracystic	0	0.0%
8510	Medullary	0	0.0%
8512	Medullary with lymphoid stroma	0	0.0%
8520	Lobular	0	0.0%
8522	Ductal and lobular	0	0.0%
8530	Inflammatory	0	0.0%
8540	Pagets	0	0.0%
8541	Pagets and infiltrating ductal	0	0.0%
8543	Pagets and intraductal	0	0.0%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Ovarian cancer histology

Values	.	N	%
8560	Squamous cell and adenocarcinoma mixed	0	0.0%
8570	Adenocarcinoma with squamous metaplasia	0	0.0%
8571	Adenocarcinoma with cartilaginous 0 metaplasia		0.0%
8572	Adenocarcinoma with spindle cell 0 metaplasia		0.0%
8930	Stromal sarcoma	0	0.0%
8950	Mixed mullerian	1	0.0%
8980	Carcinosarcoma, NOS	osarcoma, NOS 0	
9020	Phyllodes malignant tumor	0	0.0%
9070	Embryonal 1		0.0%
9999	Other	0	0.0%
	Missing	16,572	99.8%

16,608

Ovarian cancer tumor behavior

Variable # 78

Sas Name: OVBEHAV

Sas Label: Ovarian cancer tumor behavior

Values Ν % 0.0% Borderline 4 In situ 0.0% 0 Invasive 32 0.2% Missing 99.8% 16,572

16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

Ovarian cancer tumor grade

Moderately differentiated

Poorly differentiated

Anaplastic

Unknown

Sas Name: OVGRADE

Variable # 79 Usage Notes: none

Categories:

6

14

3

0

Medical History: Cancer Medical History: Reproductive Sas Label: Ovarian cancer tumor grade

> 0.0% 0.1%

> 0.0%

0.0% 99.9%

Outcome: Adjudicated **Values** Ν % 0.0% Well differentiated 0

Missing 16,585 16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Ovarian cancer laterality

Variable # 80

Sas Name: OVLATERAL

Sas Label: Ovarian cancer laterality

% **Values** Ν 0.0% Not a paired site 0 10 Right: origin of primary 0.1% 0.0% Left: origin of primary 6 Only one side involved, right or left 0 0.0% origin unspecified Bilateral involvement, lateral origin 17 0.1% unknown/single primary 3 0.0% Paired site, no info concerning laterality; midline tumor Missing 16,572 99.8% Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

16,608

Ovarian cancer tumor size (mm)

Variable # 81
Sas Name: OVSIZE

Sas Label: Ovarian cancer tumor size

Values Ν % No tumor found/No primary mass 0 0.0% Microscopic focus or foci 0 0.0% Mammogram diagnosis only, tumor 0 0.0% not clinically palpable <=3 mm 0 0.0% 1 0.0% 15 0.0% 1 60 0.0% 1 100 1 0.0% 100.0% Missing 16,604 16,608

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Ovarian cancer lymph node involvement

Variable # 82

Sas Name: OVLNODES

Sas Label: Ovarian cancer lymph node involvement

Values		N	%
0	No lymph node involvement	21	0.1%
1	<=0.2 cm (micrometastasis)	1	0.0%
2	0.2 cm - 2 cm (no extension beyond capsule)	2	0.0%
3	<2 cm (extension beyond capsule)	0	0.0%
4	>=2 cm	0	0.0%
5	Fixed/Matted ipsilateral axillary	0	0.0%
6	Axillary/Regional, NOS	0	0.0%
7	Internal mammary, ipsilateral	3	0.0%
8	Distant	0	0.0%
9	Unknown	9	0.1%
	Missing	16,572	99.8%

Usage Notes: none

Categories: Medical History: Cancer

Medical History: Reproductive Outcome: Adjudicated

16,608

Variable # 83

Sas Name: OVLYMPHVE

Sas Label: Ovarian cancer number of lymph nodes examined

Ovarian cancer number of lymph nodes examined

Std Dev Min Max Mean 33 4.45455 6.61953 0 23

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive Outcome: Adjudicated

Ovarian cancer number of positive lymph nodes

Variable # 84

Sas Name: OVLYMPNUM

Sas Label: Ovarian cancer number of positive lymph nodes

Std Dev Min Max Mean .94591 19 0 4 .31579

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive

Outcome: Adjudicated

Ovarian cancer SEER stage

Variable # 85

Sas Name: OVSTAGE

Sas Label: Ovarian cancer SEER stage

Values Ν % In situ 0 0.0% Localized 7 0.0% 0.0% Regional 7 Distant 21 0.1% 0 0.0% Unknown Missing 16,573 99.8%

16,608

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Reproductive

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Locally adjudicated bladder cancer

Variable # 86 Usage Notes: none

Sas Name: BLADDER

Sas Label: Local adj bladder cancer

Values Ν % No 16,577 99.8% Yes 31 0.2%

16,608

Categories: Medical History: Cancer

Outcome: Adjudicated

Days from randomization to bladder cancer

Variable # 87 Usage Notes: none

Sas Name: BLADDERDY

Sas Label: Days from rand to bladder cancer

Medical History: Cancer Categories: Outcome: Adjudicated

Ν Min Mean Std Dev Max 31 1260.8387 680.07005

Locally adjudicated kidney cancer

Variable # 88 Usage Notes: none

Sas Name: KIDNEY

Sas Label: Local adj kidney cancer

Values Ν % 99.9% No 16,589 Yes 19 0.1%

16,608

Medical History: Cancer Categories:

Outcome: Adjudicated

Days from randomization to kidney cancer

Variable # 89 Usage Notes: none

Sas Name: KIDNEYDY

Sas Label: Days from rand to kidney cancer

Medical History: Cancer Categories:

Outcome: Adjudicated

Std Dev Ν Min Max Mean 19 65 2785 1218.9474 791.76711

Locally adjudicated leukemia

Locally adjudicated leukemia [hematopoietic and reticuloendothelial systems (includes blood; excludes multiple myeloma)]

Variable # 90 Usage Notes: none

Sas Name: LEUK

Sas Label: Local adj leukemia

Categories: Medical History: Cancer Outcome: Adjudicated

Values % Ν No 16,591 99.9% Yes 17 0.1%

16,608

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Days from randomization to leukemia

Days from randomization to leukemia [hematopoietic and reticuloendothelial systems (includes blood; excludes multiple myeloma)]

Variable # 91

Sas Name: LEUKDY

Sas Label: Days from rand to leukemia

Usage Notes: none

Categories: Medical History: Cancer

Outcome: Adjudicated

N	Min	Max	Mean	Std Dev
17	182	2090	1063	581.81473

Locally adjudicated lung (bronchus) cancer

Variable # 92

Sas Name: LUNG

Sas Label: Local adj lung cancer

Usage Notes: none

Categories:

Medical History: Cancer Outcome: Adjudicated

Values Ν % 16,483 99.2% No Yes 125 0.8%

Days from randomization to lung (bronchus) cancer

Variable # 93

Sas Name: LUNGDY

Sas Label: Days from rand to lung cancer

Usage Notes: none

Categories:

Medical History: Cancer Outcome: Adjudicated

%

Min Max Mean Std Dev 125 72 2770 1235.296 694.32744

Locally adjudicated lymphoma, non-Hodgkin's diseas

Locally adjudicated lymphoma, non-Hodgkin's disease

Variable # 94

Sas Name: LYMPHNH

Sas Label: Local adj lymphoma/non-Hodgkins cancer

Values

No 16.572 99.8% Yes 36 0.2%

16.608

Ν

16,608

Usage Notes: none

Categories:

Medical History: Cancer

Outcome: Adjudicated

Days from rand to lymphoma, non-Hodgkin's disease

Days from randomization to lymphoma, non-Hodgkin's diseas

Variable # 95

36

Sas Name: LYMPHNHDY

Sas Label: Days from rand to lymphoma/non-Hodgkins cancer

Ν Min Mean Std Dev Max 190 620.91667 2490 1156.4167

Usage Notes: none

Categories:

Medical History: Cancer

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Locally adjudicated melanoma of the skin

Variable # 96 Sas Name: MEL

Sas Label: Local adj melanoma of the skin cancer

Values Ν % No 99.6% 16,547 Yes 61 0.4% 16,608

Usage Notes: none

Categories: Medical History: Cancer

Outcome: Adjudicated

Days from randomization to melanoma of the skin

Variable # 97

Sas Name: MELDY

Sas Label: Days from rand to melanoma of the skin cancer

Ν Min Max Mean Std Dev 61 18 2847 1197.4590 693.32774 Usage Notes: none

Medical History: Cancer Categories:

Outcome: Adjudicated

Locally adjudicated multiple myeloma

Variable # 98

Sas Name: MULT

Sas Label: Local adj multiple myeloma cancer

Values N 99.9% No 16,585 Yes 23 0.1%

16,608

Usage Notes: none

Categories: Medical History: Cancer

Outcome: Adjudicated

Days from randomization to multiple myeloma

Variable # 99

Sas Name: MULTDY

Sas Label: Days from rand to multiple myeloma cancer

Medical History: Cancer Categories:

Outcome: Adjudicated

Std Dev Ν Min Max Mean 23 68 2684 1239.6522 677.66193

Locally adjudicated pancreas cancer

Variable # 100

Sas Name: PANC

Sas Label: Local adj pancreas cancer

Values % Ν No 16,590 99.9% Yes 0.1% 18 16,608

Usage Notes: none

Usage Notes: none

Medical History: Cancer Categories:

Outcome: Adjudicated

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Outcomes - Cancers (Forms 122, 130)

Data File: ocan_ep_fu_pub File Date: 04/06/2006 Structure: One row per participant Population: E+P participants

Days from randomization to pancreas cancer

Variable # 101 Usage Notes: none

Sas Name: PANCDY

Sas Label: Days from rand to pancreas cancer

Std Dev Mean N Min Max 18 92 2169 1068.3889 536.20432

Categories: Medical History: Cancer

Outcome: Adjudicated

Locally adjudicated thyroid cancer

Variable # 102 Usage Notes: none

Sas Name: THY

Yes

Sas Label: Local adj thyroid cancer

% **Values** Ν Nο 16,592 99.9%

> 16 16,608

0.1%

Categories: Medical History: Cancer

Medical History: Thyroid Outcome: Adjudicated

Days from randomizaiton to thyroid cancer

Variable # 103

Sas Name: THYDY

Sas Label: Days from rand to thyroid cancer

Std Dev Min Mean Ν Max 38 613.86794 16 2252 1408.875

Usage Notes: none

Medical History: Cancer Categories:

Medical History: Thyroid Outcome: Adjudicated

Locally adjudicated other cancer

Locally adjudicated other cancer (e.g. accessory sinuses, adrenal gland, anus, appendix, biliary tract, bone, brain, CNS, cervical, connective soft tissue, endocrine gland, esophagus, eye, other genital organ, larynx, liver, lymph node, Hodgkin's, mouth, palate, parotid gland, peripheral nerve, pyriform sinus, respiratory, salivary gland, stomach, tongue, urinary organ, non-endometrial, or other/unknown site)

Variable # 104 Usage Notes: none

Sas Name: LOTHCA

Sas Label: Local adj other cancer

Values N % 99.5% No 16,517 Yes 91 0.5%

Categories: Medical History: Cancer

Outcome: Adjudicated

Days from randomization to other cancer

Variable # 105 Usage Notes: none

16,608

Sas Name: LOTHCADY

Sas Label: Days from rand to other cancer

Std Dev Ν Min Max Mean 675.43996 91 32 2942 1094.2857

Categories: Medical History: Cancer

Outcome: Adjudicated

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