

The Cancer Genome Atlas (TCGA) Clinical Data Reporting Form - Ovarian	Barcode Internal Use Only
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Tissue Source Site(TSS) Name: _____ TSS Identifier #: <input type="text"/> <input type="text"/> <input type="text"/>	1. Completed By: _____ Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y 2. Completed By: _____ Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y
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Tier 1 Clinical Data (Page 1 of 3)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 01	TSSI Unique Patient #		
1: 02	Organ of Origin – Ovary	<input type="checkbox"/> Brain <input type="checkbox"/> Lung <input type="checkbox"/> Ovary	Whole organ level. Text term for originating or primary anatomic site of the disease/condition under investigation or review. (2735776)
1: 03	Histological Type: Ovarian (Serous carcinoma)	<input type="checkbox"/> Yes <input type="checkbox"/> No	The description of the microscopic pattern indicating the degree of similarity between the tumor and the tissue of origin.
1:04	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis on their social roles. [Explanatory Comment 1: Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc. (2200604)
1: 05	Date of Birth	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	Date on which the patient/participant was born. (2201154)
1: 06	Reserved for Future Use		
1: 07	Tobacco smoking history indicator (Ovary-GBM: N/A)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Text indicator to represent a person’s tobacco smoking, the act of puffing and/or inhaling smoke from a lit tobacco cigarette, cigar, or pipe. (2436233)
1: 08	Date of initial pathologic diagnosis	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	The date this disease was first diagnosed. (58204)
1: 09	Neo-adjuvant (pre-operative) therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No	Therapy includes any of the following: Radiation/ Chemo/ Immuno/ Hormonal Therapy. The yes/no indicator to ask whether any treatment was given the patient prior to surgery.
1: 10	Date of Surgical Resection	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	The date of a surgical procedure.

Tier 1 Clinical Data (Page 3 of 3)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 17	Adjuvant (Post-operative) Hormonal therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No	Yes/no/unknown indicator whether adjuvant hormone therapy was administered following surgery
1: 18	Adjuvant (Post-operative) "Targeted" Molecular Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No	
1: 19	Date of first Recurrence after therapy	<input type="checkbox"/> N/A <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	The date when the return or spread of cancer was first diagnosed.
1: 20	Date of last contact (clinical evaluation)	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	The date of the last successful contact with the patient, family member, or caregiver to establish responses for 1:21 and 1:22 below
1: 21	Vital Status	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Test summary level description of patient / participant survival status
1: 22	Date of Death	<input type="checkbox"/> NA <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y	The actual date of a patients/participants death

Comments:

Principal Investigator Signature

Print Name

/ /
M M D D Y Y

 The Cancer Genome Atlas (TCGA) Clinical Data Reporting Form	Barcode Internal Use Only
Tissue Source Site(TSS) Name: _____ TSS Identifier #: <input type="text"/> <input type="text"/> <input type="text"/> TSS Unique Patient #: _____ Tier 2 Clinical Data Definition: Desirable, but not mandatory clinical information for clinical correlation analyses.	1. Completed By: _____ Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y 2. Completed By: _____ Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y

Tier 2 Clinical Data (Page 1 of 10)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 02	Anatomic Organ Sub-Division a. Brain b. Lung c. Ovary	<input type="checkbox"/> Brain <input type="checkbox"/> N/A <input type="checkbox"/> Lung <input type="checkbox"/> R <input type="checkbox"/> Upper <input type="checkbox"/> Middle <input type="checkbox"/> Lower <input type="checkbox"/> L <input type="checkbox"/> Upper <input type="checkbox"/> Lower <input type="checkbox"/> Ovary <input type="checkbox"/> R <input type="checkbox"/> L	Anatomic organ: Text term for originating of primary anatomic site of the disease/condition under investigation or review. (2735776) For tumors in paired organs, designates the side on which was obtained (2007875)
2: 07	Tobacco current use	<input type="checkbox"/> No: # years quit <input type="text"/> <input type="text"/> YRS <input type="checkbox"/> Yes: <input type="text"/> <input type="text"/> Pack Yrs	Pack years: The number of packs (of cigarettes) smoked per day times the number of years smoked (2546448) No. years quit: Total time period during when an individual did not smoke, expressed in number of years. (2181903) Pack years: (256448)
2: 08	Method of initial pathologic diagnosis	<input type="checkbox"/> Cytology (e.g. Peritoneal or pleural fluid) <input type="checkbox"/> Fine needle aspiration biopsy <input type="checkbox"/> Incision biopsy <input type="checkbox"/> Excisional biopsy <input type="checkbox"/> Tumor resection <input type="checkbox"/> Other method, specify: <input type="checkbox"/> Unknown	Method: Name of the procedure used to secure tissue for the original pathologic diagnosis. (2757941) Other method: Test to describe a method used to secure tissue for an original pathologic diagnosis that is different from other methods. (2757948)
2: 09A	Neo-adjuvant (pre-operative) Irradiation therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Type: <input type="checkbox"/> External beam <input type="checkbox"/> Impants <input type="checkbox"/> Radioisotopes <input type="checkbox"/> Combinaton <input type="checkbox"/> Other Specify Source: _____ <hr/> Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y Dosage: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> centi-Gray / Rads <input type="text"/> <input type="text"/> <input type="text"/> mille-curie # of fractions: <input type="text"/> <input type="text"/>	Name of the neo-adjuvant radiation therapy type administered preoperatively to an individual (2757957) Other type: Name of neo-adjuvant radiation therapy type administered preoperatively that is different from other identified types (2757964) Start date: Date neo-adjuvant preoperative radiation therapy began. (2759142) Stop date: Date neo-adjuvant preoperative radiation therapy ended. (2759144) Dosage: Text description of the total dose of radiation therapy administered to an individual expressed as a dosage amount and unit of measure (UOM). (2721441) Fractions: The total number of radiation therapy sessions (fractions) which the patient has completed to receive the required radiation dose to primary treatment fields. (61465)

Tier 2 Clinical Data (Page 2 of 10)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition												
2: 09B	Neo-adjuvant (pre-operative) Chemotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Root of administration: <input type="checkbox"/> Oral <input type="checkbox"/> Intravenous (IV) <input type="checkbox"/> Intra-peritoneal (IP) <input type="checkbox"/> IV and IP <input type="checkbox"/> Other: Specify _____ Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Start Date: The date on which prior neo-adjuvant chemotherapy treatment started. (62690) Stop Date: The total number of cycles (courses) administered to the patient of a protocol specified drug or therapy agent. (62590) Drug Used: Name of a neo-adjuvant agent administered to an individual. (2758212) Total Dosage given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															
2: 09C	Neo-adjuvant (pre-operative) Hormone therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Start Date: the start date of neo-adjuvant hormone therapy. (2199659) Stop Date: The date neo-adjuvant hormonal therapy ended. (2199665) Drugs Used: Name of the neo-adjuvant hormonal prior therapy agent administered to an individual. (2758641) # of cycles: The total number of cycles (courses) administered to the patient f a protocol specified drug of therapy agent. (62590) Total dose given: Agent total cumulative dose. (1515)
	Drugs used	Total dose given													
1															
2															
3															

	TCGA Clinical Data Reporting Form - Ovary TSS Name: _____ TSS Identifier #: <input type="text"/> <input type="text"/> <input type="text"/> TSS Unique Patient # _____	Barcode Internal Use Only
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Tier 2 Clinical Data (Page 3 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition												
2: 09D	Neo-adjuvant (pre-operative) Immunotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <div style="text-align: center;">M M D D Y Y</div> End Date: <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <div style="text-align: center;">M M D D Y Y</div> # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">2</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">3</td> <td></td> <td></td> </tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Start Date: Date that neo-adjuvant immunotherapy began. (2758923) Stop Date: Date that neo-adjuvant immunotherapy ended. (2759147) Drug Used: Name of a neo-adjuvant immunotherapy agent administered to an individual. (2759151) # of cycles: The total number of cycles (courses) administered to the patient f a protocol specified drug of therapy agent. (62590) Total Dosage given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															
2: 11A	Definition of Tumor Spread (FIGO)	<input type="checkbox"/> I: Tumor limited to ovaries (one or both) <input type="checkbox"/> IA: Tumor limited to one ovary: capsule intact, no tumor on ovarian surface. No malignant cells in ascites or peritoneas washings. <input type="checkbox"/> IB: Tumor limited to both ovaries; capsules intact, no tumor on ovarian surface. No malignant cells in ascites or peritoneal washings. <input type="checkbox"/> IC: Tumor limited to one or both ovaries with any of the following: capsule ruptured, tumor on ovarian surface, malignant cells in ascites or peritoneal washings. <input type="checkbox"/> II: Tumor involves one or both ovaries with pelvic extension. <input type="checkbox"/> IIA: Extension and/or implants on uterus and/or tube(s). No malignant cells in ascites or peritoneal washings. <input type="checkbox"/> IIB: Extension to other pelvic tissues. No malignant cells in ascites or peritoneal washings. <input type="checkbox"/> IIC: Pelvic extension (2a or 2b) with malignant cells in ascites or peritoneal washings. <input type="checkbox"/> III: Tumor involves one or both ovaries with microscopically confirmed peritoneal metastasis outside the pelvis and/or regional lymph node metastasis. <input type="checkbox"/> IIIA: Microscopic peritoneal metastasis beyond pelvis <input type="checkbox"/> IIIB: Macroscopic peritoneal metastasis beyond pelvis 2cm or less in greatest dimension. <input type="checkbox"/> IIIC: Feritoneal metastasis beyond pelvis more than 2cm in greatest dimension and/or regional lymph node metastasis. <input type="checkbox"/> IV: Distant metastasis (excludes peritoneal metastasis)													

	TCGA Clinical Data Reporting Form - Ovary TSS Name: _____ TSS Identifier #: <input type="text"/> <input type="text"/> <input type="text"/> TSS Unique Patient # _____	Barcode Internal Use Only
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Tier 1 Clinical Data (Page 4 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 11B	Number of regional lymph nodes examined microscopically	<input type="checkbox"/> <input type="checkbox"/> # examined <input type="checkbox"/> <input type="checkbox"/> # positive for tumor <input type="checkbox"/> <input type="checkbox"/> Examined, but # unknown = 98 <input type="checkbox"/> <input type="checkbox"/> Unknown if lymph nodes were examined (NX..99)	Indicator: Text term to signify the presence of microscopic disease in regional lymph nod(s) (2759195) Number: Numeric count of regional lymph nodes with microscopic disease involvement. (2759157)
2: 11C	Metastasis Definition	See 2.11A above	
2: 11D	Vascular Invasion	<input type="checkbox"/> Negative for venous invasion <input type="checkbox"/> Positive for venous invasion <input type="checkbox"/> Unknown for venous invasion	An indicator to ask if large vessel or venous invasion was detected by surgery or presence in tumor specimen. (64358 information to be derived from pathology reports (CDE # 64358)
2: 11E	Lymphatic Invasion	<input type="checkbox"/> Negative for lymphatic invasion <input type="checkbox"/> Positive for lymphatic invasion <input type="checkbox"/> Unknown for lymphatic invasion	An indicator to ask if malignant cells are present on small or thin-walled vessels suggesting lymphatic involvement. (64171)
2: 13	Tumor Residual Disease: ovary (For largest remaining Nodule)	<input type="checkbox"/> None <input type="checkbox"/> 1-10 mm <input type="checkbox"/> 11-20 mm <input type="checkbox"/> >20 mm	New CDE Required

Tier 2 Clinical Data (Page 5 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition												
2: 14	Adjuvant (Post-operative) Irradiation therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Type: <input type="checkbox"/> External beam <input type="checkbox"/> Impants <input type="checkbox"/> Radioisotopes <input type="checkbox"/> Combinaton <input type="checkbox"/> Other Specify Source: _____ Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y Dosage: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> centi-Gray / Rads <input type="text"/> <input type="text"/> <input type="text"/> mille-curie # of fractions: <input type="text"/> <input type="text"/>	CDE Definition (Type) Name of the neo-adjuvant radiation therapy type administered preoperatively to an individual (2757957) Other Type: Name of the neo-adjuvant radiation therapy type administered preoperatively that is different from other identified types (2757964) Start Date: Date neo-adjuvant preoperative radiation therapy began. (2759142) Stop Date: Date neo-adjuvant preoperative radiation therapy ended. (2759144) Dosage: Text description of the total dose of radiation therapy administered to an individual expressed as a dosage amount and unit of measure (UOM). (2721441) Fractions: The total number of radiation therapy sessions (fractions) which the patient has completed to receive the required radiation dose to primary treatment fields. (61465)												
2: 15	Adjuvant (Post-operative) Chemotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Root of administration: <input type="checkbox"/> Oral <input type="checkbox"/> Intravenous (IV) <input type="checkbox"/> Intra-peritoneal (IP) <input type="checkbox"/> IV and IP <input type="checkbox"/> Other Specify _____ Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">2</td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;">3</td> <td></td> <td></td> </tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Start Date: the start date for previous chemotherapy administered as preventive treatment for an earlier stage of this cancer. (2285) Stop Date: the end date for previous chemotherapy administered as preventive treatment for an earlier stage of this cancer. (2287) # of Cycles: The total number of cycles (courses) administered to the patient of a protocol specified drug or therapy agent. (62590) Drug Used: the name of the agent or regimen of adjuvant Cytotoxic chemotherapy that was administered. (2464267) Total Dose given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															

Tier 2 Clinical Data (Page 6 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition												
2: 16	Adjuvant (Post-operative) Immunotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Start Date: The start date for previous immunotherapy administered as preventive treatment for an earlier stage of this cancer. (2293) Stop Date: The end date for previous immunotherapy administered as preventive treatment for an earlier stage of this cancer. (2295) Drug Used: Name of a adjuvant immunotherapy agent administered to an individual.[Manually-curated] (2759176) # of Cycles: The total number of cycles (courses) administered to the patient of a protocol specified drug or therapy agent. (62590) Total Dose given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															
2: 17	Adjuvant (Post-Operative) Hormonal therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Subha and Peter to curate
	Drugs used	Total dose given													
1															
2															
3															
2: 18	Adjuvant (Post-operative) Targeted Molecular Therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y Specify: _____ _____ _____	Subha and Peter to curate												

TCGA Clinical Data Reporting Form - Ovary TSS Name: _____ TSS Identifier #: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> TSS Unique Patient # _____		Barcode Internal Use Only	
Tier 2 Clinical Data (Page 7 of 10)			
Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 21	Vital Status A. Living B. Dead	<input type="checkbox"/> Living <input type="checkbox"/> Tumor Free <input type="checkbox"/> With Tumor <input type="checkbox"/> Unknown Tumor Status <input type="checkbox"/> Dead <input type="checkbox"/> Tumor Free <input type="checkbox"/> With Tumor <input type="checkbox"/> Unknown Tumor Status	The state or condition of an individual's neoplasm at a particular point in time. (2759550) The state or condition of an individual's neoplasm at a particular point in time. (2759550)
2: 00A	Race	<input type="checkbox"/> American Indian or Alaska Native (<i>A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment</i>) <input type="checkbox"/> Asian (<i>A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam</i>) <input type="checkbox"/> White (<i>A person having origins in any of the original peoples of Europe, the Middle East, or North Africa</i>) <input type="checkbox"/> Black or African American (<i>A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."</i>) <input type="checkbox"/> Native Hawaiian or other Pacific Islander (<i>A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands</i>) <input type="checkbox"/> Not Reported (<i>Not provided or available</i>) <input type="checkbox"/> Unknown (<i>Could not be determined or unsure</i>)	Race (2192199)
	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino (<i>A person not meeting the definition for Hispanic or Latino</i>) <input type="checkbox"/> Hispanic or Latino (<i>A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race</i>) <input type="checkbox"/> Not reported (<i>Not provided or available</i>) <input type="checkbox"/> Unknown (<i>Could not be determined or unsure</i>)	Ethnicity (2192217)

Tier 2 Clinical Data (Page 8 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 00B	Performance Status Scale	<input type="checkbox"/> Not Recorded Karnofsky Score <input type="checkbox"/> 100 asymptomatic <input type="checkbox"/> 80-90 symptomatic but fully ambulatory <input type="checkbox"/> 60-70 symptomatic but in bed less than 50% of day <input type="checkbox"/> 40-50 symptomatic, in bed more than 50% of the day, but not bed ridden <input type="checkbox"/> 20-30 bed ridden Eastern Cancer Oncology Group (ECOG) <input type="checkbox"/> 0 asymptomatic <input type="checkbox"/> 1 symptomatic but fully ambulatory <input type="checkbox"/> 2 symptomatic but in bed less than 50% of day <input type="checkbox"/> 3 symptomatic, in bed more than 50% of the day, but not bed ridden <input type="checkbox"/> 4 bed ridden	Performance status scale, representing the functional capabilities of a person. (2003853)
2: 00C	Second Surgery for tumor recurrence or progression	<input type="checkbox"/> None Local site procedure <input type="checkbox"/> No <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="checkbox"/> Yes M M D D Y Y Lymph Node procedure <input type="checkbox"/> No <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="checkbox"/> Yes M M D D Y Y Metastasis procedure <input type="checkbox"/> No <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="checkbox"/> Yes M M D D Y Y	Indicator: The yes/no/unknown indicator that asks whether the recurrence was treated by surgery. (2199761) Procedure: Name of the second surgical procedure performed for recurrent or progressive disease. (2759612) Date: Date of the second surgical procedure performed for recurrent or progressive disease. (2759616)
2: 00D	Additional treatment of tumor recurrence/progression Irradiation therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Type: <input type="checkbox"/> External beam <input type="checkbox"/> Impants <input type="checkbox"/> Radioisotopes <input type="checkbox"/> Combinaton <input type="checkbox"/> Other Specify Source: _____ Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y Dosage: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> centi-Gray / Rads <input type="text"/> <input type="text"/> <input type="text"/> mille-curie # of fractions: <input type="text"/> <input type="text"/>	Indicator: the yes/no indicator related to the additional administration of the use of high-energy radiation from x-rays, gamma rays, neutrons, and other sources to kill cancer cells and shrink tumors after the return of a disease. (2650648) Type: Particular kind of radiation therapy administered after the recurrence or progression of disease. (2759630) Start Date: Date that additional radiation therapy began after the recurrence or progression of disease. (2759632) Stop Date: Date that additional radiation therapy ended for the recurrence or progression of disease. (2759634) Dosage: Text description of the total dose of radiation therapy administered to an individual expressed as a dosage amount and unit of measure (UOM). (2721441) Fractions: The total number of radiation therapy sessions (fractions) which the patient has completed to receive the required radiation dose to primary treatment fields. (61465)

Tier 2 Clinical Data (Page 9 of 10)

Tier #	Data Element	Entry Alternatives	caBIG Definition												
2: 00E	Additional treatment of tumor recurrence/ progression Chemotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Root of administration: <input type="checkbox"/> Oral <input type="checkbox"/> Intravenous (IV) <input type="checkbox"/> Intra-peritoneal (IP) <input type="checkbox"/> IV and IP <input type="checkbox"/> Other: Specify _____ Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Indicator: the yes/no indicator related to the additional administration of chemotherapy after the return of a disease after a period of remission. (2650626) Start Date: Date that additional chemotherapy ended for the recurrence of progression of disease. (2759815) Drugs: Name of the additional chemotherapy agent administered to an individual after disease recurrence or progression. (2759817) # of cycles: the total number of cycles (courses) administered to he patient of a protocol specified drug or therapy agent. (62590) Total dose given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															
2:00F	Additional treatment of tumor recurrence/progression Immunotherapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td>1</td><td></td><td></td></tr> <tr><td>2</td><td></td><td></td></tr> <tr><td>3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			Indicator: the yes/no indicator related to the additional administration of various treatment modalities that produce the desired therapeutic effect by means of change of hormone/hormones level after the return of a disease after a period of remission or new disease. (2650646) Start Date: Date that additional hormonal therapy began after the recurrence or progression of disease. (2759819) Stop Date: Date that additional hormonal therapy ended for the recurrence or progression of disease. (2759821) # of Cycles: The total number of cycles (courses) administered to the patient of a protocol specified drug or therapy agent. (62590) Drugs Used: Name of the additional hormonal agent administered to an individual after disease recurrence or progression. (2759823) Total dose given: Agent total cumulative dose (1515)
	Drugs used	Total dose given													
1															
2															
3															

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Tier #	Data Element Label	Entry Alternatives	caBIG Definition												
2: 00G	Additional treatment of tumor recurrence/ progression Hormone therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">1</td><td></td><td></td></tr> <tr><td style="text-align: center;">2</td><td></td><td></td></tr> <tr><td style="text-align: center;">3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			<p>Indicator: the yes/no indicator for the administration of additional immunotherapy to an individual following recurrence or progression of disease. (2650646)</p> <p>Start Date: Date that additional immunotherapy began after the recurrence or progression of disease. (2759819)</p> <p>Stop Date: Date that additional immunotherapy ended for the recurrence or progression of disease. (2759821)</p> <p># of Cycles: The total number of cycles (courses) administered to the patient of a protocol specified drug or therapy agent. (62590)</p> <p>Drugs Used: Name of the additional hormonal agent administered to an individual after disease recurrence or progression. (2759823)</p> <p>Total dose given: Agent total cumulative dose (1515)</p>
	Drugs used	Total dose given													
1															
2															
3															
2: 00H	Additional treatment of tumor recurrence/progression Targeted molecular therapy	<input type="checkbox"/> No <input type="checkbox"/> Yes Start Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y End Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M D D Y Y # of cycles give: <input type="text"/> <input type="text"/> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 45%;">Drugs used</th> <th style="width: 50%;">Total dose given</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">1</td><td></td><td></td></tr> <tr><td style="text-align: center;">2</td><td></td><td></td></tr> <tr><td style="text-align: center;">3</td><td></td><td></td></tr> </tbody> </table>		Drugs used	Total dose given	1			2			3			<p>Definitions and descriptions as previously described.</p>
	Drugs used	Total dose given													
1															
2															
3															

Comments:

Principal Investigator Signature

Print Name

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