The Cancer Genome Atlas (TCGA) **Clinical Data Reporting Form - Lung**	Barcode Internal Use Only

Tissue Source Site (TSS) Name: _____

TSS Identifier #: ☐ ☐ ☐

Tier 1 Clinical Data Definition: All of these elements (1-22) are required to "qualify" the tumor specimen for TCGA project.

1. Completed By: _____
Date: ☐☐ ☐☐ ☐☐
   M M   D D   Y Y

2. Completed By: _____
Date: ☐☐ ☐☐ ☐☐
   M M   D D   Y Y

Tier 1 Clinical Data (Page 1 of 3)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 01	TSS Unique Patient #		
1: 02	Organ of Origin – **Lung**	☐ Brain ☐ Lung ☐ 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: Lung Confirm squamous carcinoma	☐ Yes ☐ No	The description of the microscopic pattern indicating the degree of similarity between the tumor and the tissue of origin.
1:04	Gender	☐ Male ☐ 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	☐☐ / ☐☐ / ☐☐ M M D D Y Y	Date on which the patient/participant was born. (2201154)
1: 06	Reserved for Future Use	N/A	
1: 07	Tobacco smoking history indicator	☐ Current ☐ Former ☐ Never	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	☐☐ / ☐☐ / ☐☐ M M D D Y Y	The date this disease was first diagnosed. (58204)
1: 09	Neo-adjuvant (pre-operative) therapy	☐ Yes ☐ 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	☐☐ / ☐☐ / ☐☐ M M D D Y Y	The date of a surgical procedure.

Tier 1 Clinical Data (Page 2 of 3)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 11A	Tumor stage (pathological) LUNG AJCC System (Definitions are 6th edition nomenclature)	Primary Tumor (T) ☐ TX ☐ TO ☐ Tis ☐ T1 ☐ T2 ☐ T3 Regional Nodes (N) ☐ NX ☐ NO ☐ N1 ☐ N2 ☐ N3 Distant Metastasis (M) ☐ MX ☐ MO ☐ M1	
1: 11B	Stage groupings (Definitions are 6th edition nomenclature)	☐ Occult (O) ☐ I A ☐ IB ☐ IIA ☐ II B ☐ III A ☐ III B ☐ IV	
1:12	Tumor Grade For squamous of the Lung: N/A as a Tier 1 element (see q. 2.12)	NA	
1: 13	Complete Excision (RO)	☐ Yes (RO) ☐ No (R1) ☐ Unknown	RO: Surgical margins free of tumor grossly and microscopically. No evidence of residual disease following surgery. R1: Residual disease present (local, regional, or distant) New CDE to be created
1: 14	Adjuvant (Post-operative) Irradiation therapy	☐ Yes ☐ No	Yes/no indicator to ask if therapeutic application if radiation was initiated to treat disease following surgery to remove tumor and associated malignant tissue.

Tier 1 Clinical Data (Page 3 of 3)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 15	Adjuvant (Post-operative) **Chemotherapy**	☐ Yes ☐ No	Did the patient receive adjuvant chemotherapy?
1: 16	Adjuvant (Post-operative) **Immunotherapy**	☐ Yes ☐ No	Yes/no indicator that asks whether the patient has previous immunotherapy as preventive treatment for an earlier stage for this cancer.
1: 17	Adjuvant (Post-operative) **Hormonal therapy**	☐ Yes ☐ No	Yes/no/unknown indicator whether adjuvant hormone therapy was administered following surgery
1: 18	Adjuvant (Post-operative) **"Targeted" Molecular Therapy**	☐ Yes ☐ No	
1: 19	Date of first Recurrence after therapy	☐ N/A ☐☐ / ☐☐ / ☐☐ 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)	☐☐ / ☐☐ / ☐☐ 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	☐ Living ☐ Deceased	Test summary level description of patient / participant survival status
1: 22	Date of Death	☐ NA ☐☐ / ☐☐ / ☐☐ 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

TCGA Clinical Data Reporting Form - Lung	Barcode
TSS Name:_____ TSS Identifier #: ☐☐☐	Internal Use Only
TSS Unique Patient #_____	

Tissue Source Site (TSS) Name: _____

TSS Identifier #: ☐ ☐ ☐
TSS Unique Patient # _____

Tier 2 Clinical Data Definition: Desirable, but not mandatory clinical information for clinical correlation analyses.

1. Completed By: _____

   Date: ☐☐ ☐☐ ☐☐
        M M   D D   Y Y

2. Completed By: _____

   Date: ☐☐ ☐☐ ☐☐
        M M   D D   Y Y

Tier 2 Clinical Data (Page 1 of 9)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition

2: 02	Anatomic Organ Sub-Division
	a. Brain
	b. Lung
	c. Ovary
		☐ Brain ☐ N/A
		
		☐ Lung ☐R ☐Upper ☐Middle ☐Lower
		   ☐L ☐Upper ☐Lower
		
		☐ Ovary ☐ R
		   ☐ 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	☐ No: # years quit ☐☐ YRS ☐ Yes: ☐☐ Pack Yrs ☐ Not known	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 didn't smoke, expressed in number of years. (2181903) Pack years: (256448)
2: 08	Method of initial pathologic diagnosis	☐ Cytology (e.g. Peritoneal or pleural fluid) ☐ Fine needle aspiration biopsy ☐ Incision biopsy ☐ Excisional biopsy ☐ Tumor resection ☐ Other method, specify: ☐ 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**	☐ No
		☐ Yes Type:
		    ☐ External beam
		    ☐ Impants
		    ☐ Radioisotopes
		    ☐ Combinaton
		    ☐ Other
		
		Specify Source:_____
		_____
		
		Start Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		End Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		Dosage: ☐☐☐ centi-Gray / Rads
		
		         ☐☐☐ mille-curie
		
		# of fractions: ☐☐
			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)

	TCGA Clinical Data Reporting Form - Lung		Barcode
	TSS Name:_____ TSS Identifier #: ☐☐☐		Internal Use Only
	TSS Unique Patient # _____		

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 09B	Neo-adjuvant (pre-operative) **Chemotherapy**	☐ No ☐ Yes Root of administration: ☐ Oral ☐ Intravenous (IV) ☐ Intra-peritoneal (IP) ☐ IV and IP ☐ Other: Specify _____ Start Date: ☐☐ / ☐☐ / ☐☐ 　　　　　　M M　D D　Y Y End Date: ☐☐/ ☐☐/ ☐☐ 　　　　　M M　D D　Y Y # of cycles give: ☐☐ |	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)
2: 09C	Neo-adjuvant (pre-operative) **Hormone therapy**	☐ No ☐ Yes Start Date: ☐☐ /☐☐ /☐☐ 　　　　　　M M　D D　Y Y End Date: ☐☐ / ☐☐/ ☐☐ 　　　　　M M　D D　Y Y # of cycles give: ☐☐ |	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. (1515)

TCGA Clinical Data Reporting Form - Lung
TSS Name:_____ TSS Identifier #: ☐☐☐
TSS Unique Patient # _____

Barcode
Internal Use Only

Tier 2 Clinical Data (Page 3 of 9)			

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 09D	Neo-adjuvant (pre-operative) **Immunotherapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ 　　　　　 M M　 D D　 Y Y End Date: ☐☐ / ☐☐ / ☐☐ 　　　　 M M　 D D　 Y Y # of cycles give: ☐☐ <table><tr><td></td><td>Drugs used</td><td>Total dose given</td></tr><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></table>	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) Total Dosage given: Agent total cumulative dose (1515)
2: 11A	Additional information beyond AJCC manual 6th edition is included here in preparation for edition 7…: (T): Size Nodules in Ipsilateral (non-primary) lung lobe:	☐ (T) Size Recorded T): size in cm ☐☐☐ ☐ (T)size not recorded ☐ Yes ☐ No ☐ Unknown	
2: 11C	Metastasis: Plural effusion with malignant cells Distant Metastasis	☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown	
2: 11D	Vascular Invasion	☐ Negative for venous invasion ☐ Positive for venous invasion ☐ 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	☐ Negative for lymphatic invasion ☐ Positive for lymphatic invasion ☐ Unknown for lymphatic invasion	An indicator to ask if malignant cells are present on small or thin-walled vessels suggesting lymphatic involvement. (64171)
2: 12	Tumor Grade	☐ GX: Grade cannot be assessed ☐ G1: Well differentiated ☐ G2: Moderately differentiated ☐ G3: Poorly differentiated ☐ G4: Undifferentiated	Numeric value to express the degree of abnormality of cancer cells, a measure of differentiation and aggressiveness.

Tier 2 Clinical Data (Page 4 of 9)			
Tier #	**Data Element**	**Entry Alternatives**	caBIG Definition
2: 13	Tumor Margins	N/A	Some tumors may have additional specifics in the definitions of margin involved with tumor

2: 14	Neo-adjuvant (pre-operative) **Irradiation therapy**	☐ No
		☐ Yes Type:
		     ☐ External beam
		     ☐ Impants
		     ☐ Radioisotopes
		     ☐ Combinaton
		     ☐ Other
		
		Specify Source:_____
		_____
		
		Start Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		End Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		Dosage: ☐☐☐☐ centi-Gray / Rads
		         ☐☐☐ mille-curie
		# of fractions: ☐☐
			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)

2: 15	Adjuvant (Post-operative) **Chemotherapy**	☐ No
		☐ Yes
		
		Root of administration:
		☐ Oral
		☐ Intravenous (IV)
		☐ Intra-peritoneal (IP)
		☐ IV and IP
		☐ Other: Specify
		     _____
		
		Start Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		
		End Date: ☐☐ / ☐☐ / ☐☐
		         M M D D Y Y
		
		# of cycles give: ☐☐
		
		|
			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)

	TCGA Clinical Data Reporting Form - Lung TSS Name:_____ TSS Identifier #: ☐☐☐ TSS Unique Patient # _____		Barcode Internal Use Only

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 16	Adjuvant (Post-operative) **Immunotherapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y End Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y # of cycles give: ☐☐ <table><tr><td></td><td>Drugs used</td><td>Total dose given</td></tr><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></table>	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)
2: 17	Adjuvant (Post-Operative) **Hormone therapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y End Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y # of cycles give: ☐☐ <table><tr><td></td><td>Drugs used</td><td>Total dose given</td></tr><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></table>	
2: 18	Adjuvant (Post-operative) **Targeted** Molecular Therapy	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y End Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y Specify: _____ _____ _____	

	TCGA Clinical Data Reporting Form - Lung TSS Name:_____ TSS Identifier #: ☐☐☐ TSS Unique Patient # _____	Barcode Internal Use Only

Tier 2 Clinical Data (Page 6 of 9)

Tier #	Data Element	Entry Alternatives	caBIG Definition

2: 21	Vital Status
	 A. Living
	
	 B. Dead
		☐ Living
		   ☐ Tumor Free
		   ☐ With Tumor
		   ☐ Unknown Tumor Status
		
		☐ Dead
		   ☐ Tumor Free
		   ☐ With Tumor
		   ☐ 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	☐ American Indian or Alaska Native *(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)* ☐ Asian *(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)* ☐ White *(A person having origins in any of the original peoples of Europe, the Middle East, or North Africa)* ☐ Black or African American *(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.")* ☐ Native Hawaiian or other Pacific Islander *(A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands)* ☐ Not Reported *(Not provided or available)* ☐ Unknown *(Could not be determined or unsure)*	Race (2192199)
	Ethnicity	☐ Not Hispanic or Latino *(A person not meeting the definition for Hispanic or Latino)* ☐ Hispanic or Latino *(A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race)* ☐ Not reported *(Not provided or available)* ☐ Unknown *(Could not be determined or unsure)*	Ethnicity (2192217)

	TCGA Clinical Data Reporting Form - Lung TSS Name:_____ TSS Identifier #: ☐☐☐ TSS Unique Patient # _____	Barcode Internal Use Only

Tier 2 Clinical Data (Page 7 of 9)

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 00B	Patient Performance Status Scale	☐ Not Recorded a. Karnofsky Score ☐ 100　asymptomatic ☐ 80-90　symptomatic by fully ambulatory ☐ 60-70　symptomatic but in bed less then 50% of day ☐ 40-50　symptomatic, in bed more than 50% of the day, but not bed ridden ☐ 20-30　bed ridden b. Eastern Cancer Oncology Group (ECOG) ☐ 0　asymptomatic ☐ 1　symptomatic by fully ambulatory ☐ 2　symptomatic but in bed less then 50% of day ☐ 3　symptomatic, in bed more than 50% of the day, but not bed ridden ☐ 4　bed ridden	Performance status scale, representing the functional capabilities of a person. (2003853)
2: 00C	Second Surgery for tumor recurrence or progression	☐ None Local site procedure ☐ No　☐☐ / ☐☐ / ☐☐ ☐ Yes　M M　D D　Y Y Lymph Node procedure ☐ No　☐☐ / ☐☐ / ☐☐ ☐ Yes　M M　D D　Y Y Metastasis procedure ☐ No　☐☐ / ☐☐ / ☐☐ ☐ 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**	☐ No ☐ Yes　　Type: 　　　☐ External beam 　　　☐ Impants 　　　☐ Radioisotopes 　　　☐ Combinaton 　　　☐ Other Specify Source:_____ _____ Start Date: ☐☐ / ☐☐ / ☐☐ 　　　　　　M M　D D　Y Y End Date: ☐☐ / ☐☐ / ☐☐ 　　　　　M M　D D　Y Y Dosage: ☐☐☐☐ centi-Gray / Rads 　　　　☐☐☐ mille-curie # of fractions: ☐☐	**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)

	TCGA Clinical Data Reporting Form - Lung TSS Name:_____ TSS Identifier #: ☐☐☐ TSS Unique Patient # _____	Barcode Internal Use Only

Tier #	Data Element	Entry Alternatives	caBIG Definition
2: 00E	Additional treatment for tumor recurrence/ progression **Chemotherapy**	☐ No ☐ Yes Root of administration: ☐ Oral ☐ Intravenous (IV) ☐ Intra-peritoneal (IP) ☐ IV and IP ☐ Other: Specify _____ Start Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y End Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y # of cycles give: ☐☐ |	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)
2:00F	Additional treatment of tumor recurrence/progression **Immunotherapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y End Date: ☐☐ / ☐☐ / ☐☐ M M D D Y Y # of cycles give: ☐☐ |	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 ther 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)

Tier 2 Clinical Data (Page 9 of 9)

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 00G	Additional treatment for tumor recurrence/ progression **Hormone therapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ 　　　　　　 M M 　 D D 　 Y Y End Date: ☐☐ / ☐☐ / ☐☐ 　　　　　 M M 　 D D 　 Y Y # of cycles give: ☐☐ |	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 ther return of a disease after a period of remission or new disease. (2759828) **Start Date**: Date that additional hormonal therapy began after the recurrence or progression of disease. (2759830) **Stop Date**: Date that additional hormonal therapy ended for the recurrence or progression of disease. (2759832) **# 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. (2759834) Total dose given: Agent total cumulative dose (1515)
2: 00H	Additional treatment of tumor recurrence/progression **Targeted molecular therapy**	☐ No ☐ Yes Start Date: ☐☐ / ☐☐ / ☐☐ 　　　　　　 M M 　 D D 　 Y Y End Date: ☐☐ / ☐☐ / ☐☐ 　　　　　 M M 　 D D 　 Y Y # of cycles give: ☐☐ |	Drugs used	Total dose given | |1|　|　| |2|　|　| |3|　|　|	Definitions and descriptions as previously described.

Comments:

_____
_____
_____

_____ 　 _____ 　 ☐☐ / ☐☐ / ☐☐

Principal Investigator Signature 　　 Print Name 　　　　　　 M M 　 D D 　 Y Y