

Enrollment Form Cervical (CESC)

Instructions: The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient (“Date of Initial Pathologic Diagnosis” and “Date of Last Contact” on this form).

Questions regarding this form should be directed to the Tissue Source Site’s primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the “Unknown” and “Not Evaluated” answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____ TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By (Interviewer Name in OpenClinica): _____ Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. <i>Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy). Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
2	Is this a prospective tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
3	Is this a retrospective tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528

Patient Information

#	Data Element	Entry Alternatives	Working Instructions
4	Date of Birth	____/____/____ (month) (day) (year)	Provide the date the patient was born. 2896950 (month), 2896952 (day), 2896954 (year) <i>Note: The day of Birth is not required.</i>
5	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient’s date of birth. 3008233 <i>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
6	Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Provide the patient’s gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
7	Menopause Status <i>(at time of diagnosis)</i>	<input type="checkbox"/> Premenopausal <i><6 months since LMP AND no prior bilateral oophorectomy AND not on estrogen replacement</i> <input type="checkbox"/> Perimenopausal <i>6-12 months since last menstrual period</i> <input type="checkbox"/> Postmenopausal <i>Prior bilateral oophorectomy OR >12 months since LMP with no prior oophorectomy</i> <input type="checkbox"/> Indeterminate or Unknown <input type="checkbox"/> Not Evaluated	Using the patient's medical records, indicate menopause status at the time the patient was diagnosed with the malignancy submitted for TCGA. 2957270
8	Height <i>(at time of diagnosis)</i>	_____(cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 649
9	Weight <i>(at time of diagnosis)</i>	_____(kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651
10	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 in 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 the far Europe, the Middle East, or North Africa.</i> <input type="checkbox"/> Black or African American <i>A person having origins in any of 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 Evaluated <i>Not provided or available.</i> <input type="checkbox"/> Unknown <i>Could not be determined or unsure.</i>	Provide the patient's race using the defined categories. 2192199
11	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino: <i>A person not meeting the definition of 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 Evaluated <i>Not provided or available.</i> <input type="checkbox"/> Unknown <i>Could not be determined or unsure.</i>	Provide the patient's ethnicity using the defined categories. 2192217

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#	Data Element	Entry Alternatives	Working Instructions
12	History of Prior Malignancy	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736</p> <p>If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA.</p> <p>If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.</p>
13	History of Neo-adjuvant Treatment for Sample Submitted for TCGA	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737</p> <p>Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.</p>
14	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	<p>Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550</p>
15	Vital Status (at date of last contact)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	<p>Indicate whether the patient was living or deceased at the date of last contact. 2939553</p>
16	Date of Last Contact	____ / ____ / ____ (month) (day) (year)	<p>If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (month), 2897022 (day), 2897024 (year)</p> <p><i>Note: Do not answer if patient is deceased. The day of Last Contact is not required.</i></p>
17	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	<p>Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273</p> <p>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</p>
18	Date of Death	____ / ____ / ____ (month) (day) (year)	<p>If the patient is deceased, provide the month of death. 2897026, (month) 2897028 (day), 2897030 (year)</p> <p><i>Note: The day of Death is not required.</i></p>
19	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	<p>Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475</p> <p>Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</p>
20	Cause of Death	<input type="checkbox"/> Cervical cancer <input type="checkbox"/> Other cause(s), specify <input type="checkbox"/> Unknown	<p>Indicate the patient's cause of death. 2554674</p>
21	Other Cause of Death	_____	<p>If the patient's cause of death was not included in the provided list, specify the patient's cause(s) of death. 2004150</p>
History of Pregnancies and Contraceptive Use			
22	Use of Hormonal Contraceptives	<input type="checkbox"/> Current User <input type="checkbox"/> Former User <input type="checkbox"/> Never Used <input type="checkbox"/> Unknown	<p>Indicate whether the patient has used or is currently using hormonal contraceptives. 3104217</p>

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#	Data Element	Entry Alternatives	Working Instructions														
23	Total Number of Pregnancies	_____	Provide the total number of times the patient conceived and became pregnant. This should include all of the pregnancies under the question "Number of Pregnancies by Outcome Type" and current pregnancies. 2005341														
24	Number of Pregnancies by Outcome Type <i>(Complete all that apply)</i>	<table border="1"> <thead> <tr> <th>Pregnancy Type</th> <th>Number of Pregnancies</th> </tr> </thead> <tbody> <tr> <td>Live Birth <i>(single or multiple births)</i></td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Miscarriage</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Induced Abortion</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Ectopic Pregnancy</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Stillbirth <i>(early fetal death)</i></td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Unknown</td> <td style="text-align: center;">_____</td> </tr> </tbody> </table>	Pregnancy Type	Number of Pregnancies	Live Birth <i>(single or multiple births)</i>	_____	Miscarriage	_____	Induced Abortion	_____	Ectopic Pregnancy	_____	Stillbirth <i>(early fetal death)</i>	_____	Unknown	_____	Provide the number of times the patient had successful pregnancies that resulted in the live birth of at least one child. 2005342
		Pregnancy Type	Number of Pregnancies														
		Live Birth <i>(single or multiple births)</i>	_____														
		Miscarriage	_____														
		Induced Abortion	_____														
		Ectopic Pregnancy	_____														
Stillbirth <i>(early fetal death)</i>	_____																
Unknown	_____																
Provide the number of times the patient conceived and became pregnant, but did not carry fetus to term due to natural occurrences or problems during the pregnancy. 2180637																	
Provide the number of times the patient conceived and became pregnant, but did not carry fetus to term due to medical intervention to end the pregnancy. 2180648																	
Provide the number of times the patient conceived and became pregnant, but did not carry the fetus to term due to an ectopic pregnancy. 2261915																	
Indicate the number of times the patient conceived and became pregnant, but the pregnancy ended with stillbirth. 2183304																	
Provide the number of times the patient was known to be pregnant, but the outcome of the pregnancy was unknown. 3012573																	
25	Pregnant at Time of Diagnosis	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the patient was pregnant at the time of initial diagnosis. 3012573														
Smoking History																	
26	Tobacco smoking history indicator	<input type="checkbox"/> Lifelong non-smoker (<100 cigarettes smoked in lifetime) <input type="checkbox"/> Current smoker (includes daily and non-daily smokers) <input type="checkbox"/> Current reformed smoker (duration not specified) <input type="checkbox"/> Current reformed smoker for > 15 years <input type="checkbox"/> Current reformed smoker for <= 15 years <input type="checkbox"/> Smoking History not Documented	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories. If the patient is a lifelong non-smoker, skip the additional smoking questions. 2181650														
27	Age of onset tobacco smoking	___ ___ Years of Age	Provide the age in years when the patient began smoking cigarettes. 2178045 If the patient is a lifelong non-smoker, do not answer this question.														
28	Year of quitting tobacco smoking	___ ___ ___ ___ (YYYY)	Provide the year the patient quit smoking. 2228610 If the patient is a lifelong non-smoker or if the patient has not quit smoking, do not answer this question.														
29	Number of Pack Years Smoked	___ ___ Years	Provide the number of pack years the patient smoked. This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if a patient smoked 5 cigarettes per day times 10 years divided by 20, the patient would have 2.5 pack years (e.g. 5 x 10 / 20=2.5). 2955385 If the patient is a lifelong non-smoker, do not answer this question.														
History of Immunosuppressive Disease																	

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#	Data Element	Entry Alternatives	Working Instructions
30	History of Immunosuppressive Disease (Check all that apply)	<input type="checkbox"/> HIV <input type="checkbox"/> Organ Transplant <input type="checkbox"/> Chronic Systemic Steroid Use <input type="checkbox"/> Unknown <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Other, specify	If the patient has had any history of immunosuppressive disease(s), provide the patient's medical history. If the patient's disease is not provided in the list, select "other" and provide the specific disease in the following question. 3151446
31	Other Immunosuppressive Disease	_____	Specify any history of immunosuppressive disease that is not included in the list provided. 3151449

Performance Status and Measure of Success

32	Performance Status: Eastern Cooperative 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 the day <input type="checkbox"/> 3 - Symptomatic and in bed more than 50% of the day <input type="checkbox"/> 4 - Bedridden	Using the patient's medical records, provide the ECOG performance status score at the time provided in the following question. 88
33	Performance Status: Timing	<input type="checkbox"/> Preoperative <input type="checkbox"/> Pre-adjuvant therapy <input type="checkbox"/> Post-adjuvant therapy <input type="checkbox"/> Other, specify	Indicate the time point of the documented ECOG performance score provided above. 2792763
34	Other Performance Status Scale: Timing	_____	If the status of the patient during the last documented ECOG performance score was not included in the provided list, specify the patient's status. 3151756
35	Date of Performance Status	____/____/____ (month) (day) (year)	Provide the date of the last documented ECOG performance score. 3121370 (month), 3121372 (day), 3121374 (year) <i>Note: The day of Performance Status is not required.</i>
36	Measure of success of outcome <i>at the completion of initial first course treatment (including surgery)</i>	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> Complete Response <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable (Treatment Ongoing)	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. 2786727

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
Pathologic Diagnosis Information			
37	Primary Site of Disease	<input type="checkbox"/> Cervix	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
38	Histological Subtype	<input type="checkbox"/> Cervical Squamous Cell Carcinoma <input type="checkbox"/> Endocervical type of Adenocarcinoma <input type="checkbox"/> Endocervical Adenocarcinoma of the Usual Type <input type="checkbox"/> Mucin-depleted Adenocarcinoma <input type="checkbox"/> Endometrioid Adenocarcinoma of Endocervix <input type="checkbox"/> Mucinous Adenocarcinoma of Endocervical Type <input type="checkbox"/> Adenosquamous Carcinoma	Using the patient's pathology/laboratory report, select the histology of the tumor submitted for TCGA. 3081934
39	Keratinization in Squamous Cell Carcinoma	<input type="checkbox"/> Keratinizing squamous cell carcinoma <input type="checkbox"/> Non-keratinizing squamous cell carcinoma	If the patient had squamous cell carcinoma, indicate whether the tumor has any keratinizing squamous cell carcinoma using the patient's pathology/laboratory report. Keratinizing tumors have at least one well-formed keratin pearl. All other patterns are non-keratinizing. 3151599

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#	Data Element	Entry Alternatives	Working Instructions
40	Tumor Grade	<input type="checkbox"/> G1 Well Differentiated <input type="checkbox"/> G2 Moderately Differentiated <input type="checkbox"/> G3 Poorly Differentiated <input type="checkbox"/> G4 Undifferentiated <input type="checkbox"/> GX Grade cannot be assessed	Using the patient's pathology/laboratory report, select the tumor grade. 2785839
41	Date of Initial Pathologic Diagnosis	____/____/____ (month) (day) (year)	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (month), 2896958 (day), 2896960 (year) <i>Note: The day of Initial Pathologic Diagnosis is not required.</i>
42	Age at Initial Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
43	Method of Initial Pathologic Diagnosis	<input type="checkbox"/> Cytology <input type="checkbox"/> Biopsy (cervical, CT-guided or other) <input type="checkbox"/> Cone biopsy/ LEEP <input type="checkbox"/> Lymph node sampling or dissection <input type="checkbox"/> Other, specify	Provide the procedure used to initially diagnose the patient. 2757941 Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.
44	Other Method of Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
45	If hysterectomy was performed, what type was it?	<input type="checkbox"/> Hysterectomy not performed <input type="checkbox"/> Simple <input type="checkbox"/> Radical (modified or not modified) <input type="checkbox"/> Other, specify	Indicate whether a hysterectomy was performed at diagnosis. If a hysterectomy was performed, indicate the type. 2647164
46	Other Type of Hysterectomy	_____	If the type of hysterectomy performed was not included in the list provided, please provide the type of hysterectomy performed. 3151506
47	If hysterectomy was performed, were there involved pathologic margins?	<input type="checkbox"/> Macroscopic parametrial involvement <input type="checkbox"/> Microscopic parametrial involvement <input type="checkbox"/> Positive bladder margin <input type="checkbox"/> Positive vaginal margin <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify	If a hysterectomy was performed, provide the patient's margin involvement after surgery. 3151541
48	Other Involved Pathologic Margins	_____	If the margin involvement was not included in the provided list, describe the pathologic margins. 3151544
49	Pelvic Extension Comment	_____	Using the patient's pathology/laboratory report, provide comments regarding any tumor extension to the pelvic wall. 3151605
50	Pathologic Lymphovascular Invasion	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Unknown	Using the patient's pathology/laboratory report, indicate the presence or absents of pathologic lymphovascular invasion. 2008052
51	Corpus Involvement	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Unknown	The corpus uteri is the part of the uterus above the isthmus, comprising about two thirds of the non-pregnant organ. To have a connection by participation or association or use; sharing in an activity or process. 3151610
Lymph Node Status			
52	Were Lymph Nodes Examined at the Time of Primary Resection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
53	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
54	Number of Lymph Nodes Positive by H&E	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy.

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#	Data Element	Entry Alternatives	Working Instructions
	light microscopy		3086388
55	Number of Lymph Nodes Positive by IHC Keratin Staining only	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383
56	Pathologic Positive Lymph Node Location(s) (Check all that apply)	<input type="checkbox"/> Pelvic (external iliac, internal iliac, obturator) <input type="checkbox"/> Common iliac <input type="checkbox"/> Paraaortic <input type="checkbox"/> Supraclavicular <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify	Using the patient's pathology/laboratory report, provide the location(s) of any positive lymph nodes. 3151519
57	Other Positive Lymph Node	_____	If the location of positive lymph nodes was not included in the list provide, please provide the location of positive lymph nodes. 3151522

AJCC Staging

58	AJCC Cancer Staging Edition	<input type="checkbox"/> 1 st Edition (1978-1983) <input type="checkbox"/> 2 nd Edition (1984-1988) <input type="checkbox"/> 3 rd Edition (1989-1992) <input type="checkbox"/> 4 th Edition (1993-1997) <input type="checkbox"/> 5 th Edition (1998-2002) <input type="checkbox"/> 6 th Edition (2003-2009) <input type="checkbox"/> 7 th Edition (2010-present)	Please select the AJCC Cancer Staging Edition used to answer the following questions. 2722309																					
59	Pathologic Spread: Primary Tumor (pT)	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> TX</td> <td><input type="checkbox"/> T1b</td> <td><input type="checkbox"/> T2a2</td> </tr> <tr> <td><input type="checkbox"/> T0</td> <td><input type="checkbox"/> T1b1</td> <td><input type="checkbox"/> T2b</td> </tr> <tr> <td><input type="checkbox"/> Tis</td> <td><input type="checkbox"/> T1b2</td> <td><input type="checkbox"/> T3</td> </tr> <tr> <td><input type="checkbox"/> T1</td> <td><input type="checkbox"/> T2</td> <td><input type="checkbox"/> T3a</td> </tr> <tr> <td><input type="checkbox"/> T1a</td> <td><input type="checkbox"/> T2a</td> <td><input type="checkbox"/> T3b</td> </tr> <tr> <td><input type="checkbox"/> T1a1</td> <td><input type="checkbox"/> T2a1</td> <td><input type="checkbox"/> T4</td> </tr> <tr> <td><input type="checkbox"/> T1a2</td> <td></td> <td></td> </tr> </table>	<input type="checkbox"/> TX	<input type="checkbox"/> T1b	<input type="checkbox"/> T2a2	<input type="checkbox"/> T0	<input type="checkbox"/> T1b1	<input type="checkbox"/> T2b	<input type="checkbox"/> Tis	<input type="checkbox"/> T1b2	<input type="checkbox"/> T3	<input type="checkbox"/> T1	<input type="checkbox"/> T2	<input type="checkbox"/> T3a	<input type="checkbox"/> T1a	<input type="checkbox"/> T2a	<input type="checkbox"/> T3b	<input type="checkbox"/> T1a1	<input type="checkbox"/> T2a1	<input type="checkbox"/> T4	<input type="checkbox"/> T1a2			Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3045435
<input type="checkbox"/> TX	<input type="checkbox"/> T1b	<input type="checkbox"/> T2a2																						
<input type="checkbox"/> T0	<input type="checkbox"/> T1b1	<input type="checkbox"/> T2b																						
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<input type="checkbox"/> T1a2																								
60	Pathologic Spread: Regional Nodes (pN)	<input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3203106																					
61	Pathologic Distant Spread: Distant Metastasis (M)	<input type="checkbox"/> MX <input type="checkbox"/> M0 <input type="checkbox"/> M1	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3045439																					
62	FIGO Staging System (Publication Date Used for Staging)	<input type="checkbox"/> 1988 <input type="checkbox"/> 1995 <input type="checkbox"/> 2009	Using the patient's pathology/laboratory report, provide the FIGO staging system used to stage the patient. 3114049																					
63	FIGO Stage	<table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Stage I</td> <td><input type="checkbox"/> Stage IIA1</td> </tr> <tr> <td><input type="checkbox"/> Stage IA</td> <td><input type="checkbox"/> Stage IIA2</td> </tr> <tr> <td><input type="checkbox"/> Stage IA1</td> <td><input type="checkbox"/> Stage IIB</td> </tr> <tr> <td><input type="checkbox"/> Stage IA2</td> <td><input type="checkbox"/> Stage III</td> </tr> <tr> <td><input type="checkbox"/> Stage IB</td> <td><input type="checkbox"/> Stage IIIA</td> </tr> <tr> <td><input type="checkbox"/> Stage IB1</td> <td><input type="checkbox"/> Stage IIIB</td> </tr> <tr> <td><input type="checkbox"/> Stage IB2</td> <td><input type="checkbox"/> Stage IV</td> </tr> <tr> <td><input type="checkbox"/> Stage II</td> <td><input type="checkbox"/> Stage IVA</td> </tr> <tr> <td><input type="checkbox"/> Stage IIA</td> <td><input type="checkbox"/> Stage IVB</td> </tr> </table>	<input type="checkbox"/> Stage I	<input type="checkbox"/> Stage IIA1	<input type="checkbox"/> Stage IA	<input type="checkbox"/> Stage IIA2	<input type="checkbox"/> Stage IA1	<input type="checkbox"/> Stage IIB	<input type="checkbox"/> Stage IA2	<input type="checkbox"/> Stage III	<input type="checkbox"/> Stage IB	<input type="checkbox"/> Stage IIIA	<input type="checkbox"/> Stage IB1	<input type="checkbox"/> Stage IIIB	<input type="checkbox"/> Stage IB2	<input type="checkbox"/> Stage IV	<input type="checkbox"/> Stage II	<input type="checkbox"/> Stage IVA	<input type="checkbox"/> Stage IIA	<input type="checkbox"/> Stage IVB	Using the patient's pathology/laboratory report, provide the FIGO stage given to the patient at the time of diagnosis. 3225684			
<input type="checkbox"/> Stage I	<input type="checkbox"/> Stage IIA1																							
<input type="checkbox"/> Stage IA	<input type="checkbox"/> Stage IIA2																							
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<input type="checkbox"/> Stage IIA	<input type="checkbox"/> Stage IVB																							

Tests Performed

64	Date of FED-PET or PET / CT	____ / ____ / _____ (month) (day) (year)	If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the month of the FED-PET or PET/CT. 3151498 (month), 3151499 (day), 3151500 (year)
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65	Cervix SUV Results	_____	If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the cervix standardized uptake value (SUV). 3151615																												
66	FED-PET or PET / CT Results <i>(Check all that apply)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%;">Anatomic Site</th> <th style="width: 10%;">Present</th> <th style="width: 10%;">Absent</th> <th style="width: 10%;">Unknown</th> </tr> </thead> <tbody> <tr><td>Pelvic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Paraortic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Supraclavicular Nodes</td><td></td><td></td><td></td></tr> <tr><td>Parametrium</td><td></td><td></td><td></td></tr> <tr><td>Bladder</td><td></td><td></td><td></td></tr> <tr><td>Extra-Pelvic Metastatic Disease</td><td></td><td></td><td></td></tr> </tbody> </table>	Anatomic Site	Present	Absent	Unknown	Pelvic Nodes				Paraortic Nodes				Supraclavicular Nodes				Parametrium				Bladder				Extra-Pelvic Metastatic Disease				If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the results for each applicable anatomic site. 3151497
Anatomic Site	Present	Absent	Unknown																												
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67	Date of MRI	____ / ____ / ____ (month) (day) (year)	If the patient's medical records indicate the patient had an MRI, provide the date of the MRI. 3151491 (month), 3151492 (day), 3151493 (year)																												
68	MRI Results <i>(Check all that apply)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%;">Anatomic Site</th> <th style="width: 10%;">Present</th> <th style="width: 10%;">Absent</th> <th style="width: 10%;">Unknown</th> </tr> </thead> <tbody> <tr><td>Pelvic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Paraortic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Supraclavicular Nodes</td><td></td><td></td><td></td></tr> <tr><td>Parametrium</td><td></td><td></td><td></td></tr> <tr><td>Bladder</td><td></td><td></td><td></td></tr> <tr><td>Extra-Pelvic Metastatic Disease</td><td></td><td></td><td></td></tr> </tbody> </table>	Anatomic Site	Present	Absent	Unknown	Pelvic Nodes				Paraortic Nodes				Supraclavicular Nodes				Parametrium				Bladder				Extra-Pelvic Metastatic Disease				If the patient's medical records indicate the patient had a MRI, provide the results for each applicable anatomic site. 3151441
Anatomic Site	Present	Absent	Unknown																												
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Parametrium																															
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Extra-Pelvic Metastatic Disease																															
69	Date of CT	____ / ____ / ____ (month) (day) (year)	If the patient's medical records indicate the patient had an MRI, provide the date of the MRI. 3151134 (month), 3151132 (day), 3151133 (year)																												
70	CT Results <i>(Check all that apply)</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 35%;">Anatomic Site</th> <th style="width: 10%;">Present</th> <th style="width: 10%;">Absent</th> <th style="width: 10%;">Unknown</th> </tr> </thead> <tbody> <tr><td>Pelvic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Paraortic Nodes</td><td></td><td></td><td></td></tr> <tr><td>Supraclavicular Nodes</td><td></td><td></td><td></td></tr> <tr><td>Parametrium</td><td></td><td></td><td></td></tr> <tr><td>Bladder</td><td></td><td></td><td></td></tr> <tr><td>Extra-Pelvic Metastatic Disease</td><td></td><td></td><td></td></tr> </tbody> </table>	Anatomic Site	Present	Absent	Unknown	Pelvic Nodes				Paraortic Nodes				Supraclavicular Nodes				Parametrium				Bladder				Extra-Pelvic Metastatic Disease				If the patient's medical records indicate the patient had a CT, provide the results for each applicable anatomic site. 3151439
Anatomic Site	Present	Absent	Unknown																												
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Paraortic Nodes																															
Supraclavicular Nodes																															
Parametrium																															
Bladder																															
Extra-Pelvic Metastatic Disease																															
71	HPV <i>(List all types)</i>	<input type="checkbox"/> HPV 16 <input type="checkbox"/> HPV 18 <input type="checkbox"/> Other HPV Type <input type="checkbox"/> None	If the patient's medical records indicate human papillomavirus (HPV), provide the HPV type. 2922649																												
72	Other HPV Type(s)	_____	If the patient's medical records indicate human papillomavirus (HPV) and the type is not included in the provided list, please describe the HPV type. 3166168																												
73	Method of HPV Typing	<input type="checkbox"/> PCR <input type="checkbox"/> Qiagen-digene #C2 <input type="checkbox"/> Roche - linear array <input type="checkbox"/> Other (please specify)	Indicate the method used for HPV typing. 3151457																												
74	Other Method of HPV Typing	_____	If the method used for HPV typing is not included in the provided list, please describe the method used. 3151460																												
75	PCR Primer Pairs	<input type="checkbox"/> MY09/MY11 <input type="checkbox"/> PGMY09/PGMY11 <input type="checkbox"/> Roche - linear array <input type="checkbox"/> SPF10-LiPA <input type="checkbox"/> GP5+/GP6+ <input type="checkbox"/> Other (please specify)	Indicate the PCR primer pairs used. 3151487																												

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76	Other PCR Primer Pairs	_____	If the PCR primer pairs used are not included in the provided list, please describe the PCR primer pairs used. 3151490
77	Squamous Cellular Carcinoma Antigen (SCCA) Tumor Marke	_____ µg/µL	Provide the patient's squamous cellular carcinoma antigen (SCCA) tumor marker results. 3151234
78	Date of SCCA Performed	____/____/____ (month) (day) (year)	Provide the date SCCA was performed. 3151235 (month), 3151236 (day), 3151237 (year)

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions
79	Adjuvant (Post-Operative) Radiation Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
80	Adjuvant (Post-Operative) Pharmaceutical Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.

Radiation Therapy (Brachytherapy and External Radiation)

81	If patient did not complete radiation, provide the primary reason why it was not given or not completed.	<input type="checkbox"/> Adverse event/complications <input type="checkbox"/> Scheduling problems <input type="checkbox"/> Participant refusal <input type="checkbox"/> Not done per treating physicians discretion <input type="checkbox"/> Other, specify <input type="checkbox"/> Unknown	If the patient did not receive radiation indicate the reason treatment was not administered. 2733266
82	Other Reason Radiation Not Given or Not Completed	_____	If the reason the patient did not receive radiation is not included in the provided list, specify the reason. 2733267
83	If patient received brachytherapy, indicate the type.	<input type="checkbox"/> LDR <input type="checkbox"/> HDR <input type="checkbox"/> Other, specify	If the patient received brachytherapy, indicate the type administered. If the patient did not receive brachytherapy, skip all related questions. 2966127
84	Other Type of Brachytherapy	_____	If the type of brachytherapy the patient received is not included in the provided list, specify the type administered. 3150976
85	If patient received brachytherapy, provide the total dose to point A.	_____ cGy	Indicate the total dose (cGy) of brachytherapy to point A the patient received. 3151100
86	If patient received external radiation provide type of external radiation	<input type="checkbox"/> 3D Conformal <input type="checkbox"/> IMRT <input type="checkbox"/> External Beam <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify	If the patient received external radiation, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 61468
87	Other Type of External Radiation	_____	If the type of external radiation the patient received is not included in the provided list, specify the type administered. 2195477
88	Total Dose to Pelvis/Pelvic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to pelvis/pelvic nodes. 3006
89	Total Dose to Paraaortic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to paraaortic nodes. 3151106

Concurrent Chemotherapy

Enrollment Form Cervical (CESC)

#	Data Element	Entry Alternatives	Working Instructions
90	Was chemotherapy given concurrent to radiation after tissue procurement?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received chemotherapy concurrent to radiation treatment after tissue procurement. 2539220
91	If patient did not complete chemotherapy concurrent to radiation, provide the primary reason why it was not given or not completed.	<input type="checkbox"/> Adverse event/complications <input type="checkbox"/> Scheduling problems <input type="checkbox"/> Participant refusal <input type="checkbox"/> Not done per treating physicians discretion <input type="checkbox"/> Other, specify <input type="checkbox"/> Unknown	If the patient did not receive chemotherapy concurrent to radiation treatment indicate the reason treatment was not administered. 3151120
92	Other Reason Chemotherapy Not Given concurrent to Radiation	_____	If the reason the patient did not receive chemotherapy concurrent to radiation treatment is not included in the provided list, specify the reason. 3151824
93	If patient received concurrent chemotherapy, indicate type of concurrent chemotherapy. <i>(Check all that apply)</i>	<input type="checkbox"/> Cisplatin <input type="checkbox"/> Carboplatin <input type="checkbox"/> Other, specify	If the patient received chemotherapy concurrent to radiation treatment, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 2007212
94	Other Type of Concurrent Chemotherapy	_____	If the type of chemotherapy given concurrent to radiation treatment is not included in the provided list, specify the type administered. 2426129
95	Concurrent Chemotherapy Dose	_____	Indicate the dose of the concurrent chemotherapy the patient received. Include the unit of measure. 3166172 and 3065815
96	Concurrent Chemotherapy Frequency	<input type="checkbox"/> Every hour <input type="checkbox"/> 5 times daily <input type="checkbox"/> 4 times daily <input type="checkbox"/> 3 times daily <input type="checkbox"/> 2 times daily <input type="checkbox"/> Every 24 hours <input type="checkbox"/> Every other day <input type="checkbox"/> Twice a week <input type="checkbox"/> Once weekly	Indicate the frequency the concurrent chemotherapy was received. 2179580
97	Concurrent Chemotherapy Number of Total Doses	_____	Indicate the total number of doses the patient received the concurrent chemotherapy. 2180805

New Tumor Event Information Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.

#	Data Element	Entry Alternatives	Working Instructions
98	New Tumor Event After Initial Treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
99	Type of New Tumor Event	<input type="checkbox"/> Locoregional recurrence <input type="checkbox"/> Distant Metastasis <input type="checkbox"/> New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
100	Site of New Tumor Event	<input type="checkbox"/> Cervix <input type="checkbox"/> Head & Neck <input type="checkbox"/> Lung <input type="checkbox"/> Vulvar <input type="checkbox"/> Anus <input type="checkbox"/> Other, specify <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable	If the patient had a new tumor event, provide the site of this tumor. 3108271
101	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033

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#	Data Element	Entry Alternatives	Working Instructions
<u>102</u>	Date of New Tumor Event	____/____/____ (month) (day) (year)	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (month), 3104042 (day), 3104046 (year)
<u>103</u>	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
<u>104</u>	Method of Pathologic Diagnosis for New Tumor Event	<input type="checkbox"/> Cytology <input type="checkbox"/> Tumor Resection <input type="checkbox"/> Other, specify _____	Indicate the method used to pathologically diagnose the new tumor event. 3151113
<u>105</u>	Other Method of Pathologic Diagnosis for New Tumor Event	_____	If the pathologic method used to diagnose the new tumor event is not included in the provided list, specify the method used. 3151116
<u>106</u>	Additional Surgery for New Tumor Event	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
<u>107</u>	Date of Additional Surgery for New Tumor Event	____/____/____ (month) (day) (year)	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (month), 3427613 (day), 3427614 (year)
<u>108</u>	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (loco-regional). 3008335 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
<u>109</u>	Residual Tumor After surgery for New Tumor Event	<input type="checkbox"/> RX: The presence of residual tumor or margin status cannot be assessed. <input type="checkbox"/> R0: No residual tumor and negative microscopic margins in resected specimen. <input type="checkbox"/> R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. <input type="checkbox"/> R2: Macroscopic residual tumor. Grossly visible residual disease.	Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. 3104061
<u>110</u>	Additional treatment for New Tumor Event: Radiation Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
<u>111</u>	Additional treatment for New Tumor Event: Pharmaceutical Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Principal Investigator or Designee Signature

Print Name

 ____/____/_____
Date