CDDP Colorectal (CRC)

Instructions: The Enrollment Form should be completed for each CDDP 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 CDDP 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

	ned. This could be because ested was never disclosed.		ne patient or the TSS knows that the information
Γissu	e Source Site (TSS):	TSS Identifier:	TSS Unique Patient Identifier:
Comp	leted By (Interviewer Nam	e in OpenClinica):	Completed Date:
Gen	eral Information		
#	Data Element	Entry Alternatives	Working Instructions
Coll	ection Information		
1*	Is this a prospective tissue collection?	□ Yes □ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of CDDP, the tissue has been collected prospectively. 3088492
2*	Is this a retrospective tissue collection?	□ Yes □ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the CDDP contract was executed, the tissue has been collected retrospectively. 3088528
	ient Information		
Den	nographics		
3*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
4*	Date of Birth	Marsh Day V	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
5	Patient Height (at time of diagnosis)	(cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for CDDP. 649
6	Patient Weight (at time of diagnosis)	(kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for CDDP. 651
7*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander: ☐ Not Reported ☐ Unknown	Provide the patient's race using the defined categories. 2192199 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 in 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 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.

#	Data Element	Entry Alternatives	Working Instructions
8	Ethnicity	□ Not Hispanic or Latino: □ Hispanic or Latino: □ Not Reported □ Unknown	Provide the patient's ethnicity using the defined categories. 2192217 Not Hispanic or Latino: A person not meeting the definition of 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.
Med	lical/Health History		
9*	Has the patient had any prior cancer diagnosed?	 □ None □ History of Prior Malignancy □ History of Synchronous / Bilateral Malignancy □ Both History of Synchronous / Bilateral and Prior Malignancy 	Indicate whether the patient has a history of malignancies. If the patient has any history, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for CDDP. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from CDDP. If the patient has any history of prior malignancies, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for CDDP. If the patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types.
10	Did the patient have a history of synchronous colon/rectal tumor(s) at the time of tissue collection?	☐ Yes ☐ No	Indicate whether the patient had a history of colon/rectal cancer at the time the CDDP tumor was procured. 2185953
11	Did the patient have a history of colon polyps at the time of tissue collection?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a history of colon polyps at the time the CDDP tumor was procured. 3107197
12	Were colon polyps present at the time of tissue collection?	☐ Yes ☐ No	Indicate whether the patient had colon polyps present at the time the CDDP tumor was procured. 64184
13	Number First Degree Relative Relatives with a History of Colon/ Rectal Cancer?	□ 0 □ 3 □ 3 □ > 3 □ 2 □ Unknown	Indicate the number of first degree relatives (parent, sibling and/or child) associated with a diagnosis of colon or rectal cancer. 3107205
14	Tobacco Smoking Status at Time of Diagnosis	 □ Lifelong Non-smoker (<100 cigarettes smoked in Lifetime) □ Current smoker (includes daily smokers and non-daily smokers or occasional smokers) □ Current reformed smoker for > 15 years (greater than 15 years) □ Current reformed smoker for ≤15 years (less than or equal to 15 years) □ Current reformed smoker, duration not specified □ Smoking History not Documented 	Indicate the patient's current smoking status or smoking history as self-reported by the patient. 2181650
15	Tobacco Smoking Year of Onset		If the patient is a current or reformed smoker, indicate the year in which the patient began smoking. 2228604
16	Tobacco Smoking Year of Quitting		If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
17	Number Pack Years Smoked at Time of Diagnosis		Indicate the lifetime tobacco exposure of the patient. Number of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by 20. 2955385

#	Data Element	Entry Alternatives		Working Instructions
18	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) at Time of Diagnosis	□ 0 □ 1 □ 2 □ 3 □ 4 □ Not Evaluated □ Unknown		Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient. 88 1: Asymptomatic 1: Symptomatic, but fully ambulatory 2: Symptomatic, in bed less than 50% of day 3: Symptomatic, in bed more than 50% of day, but not bed-ridden 4: Bed-ridden
19	Performance Status Score: Karnofsky Score At Time of Diagnosis	□ 100 □ 90 □ 80 □ 70 □ 60 □ 50 □ 40 □ 30 □ 20 □ 10 □ 0 □ Not Evaluated □ Unknown		Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient. 2003853 100: Normal, no complaints; no evidence of disease 90: Able to carry on normal activity; minor signs or symptoms of disease 80: Normal activity with effort; some signs or symptoms of disease 70: Cares for self; unable to carry on normal activity or to do active work 60: Requires occasional assistance; but is able to care for most of his/her needs 50: Requires considerable assistance and frequent medical care 40: Disabled; requires special care 30: Severely disabled 20: Very sick; requiring hospitalization 10: Moribund; fatal processes progressing rapidly 0: Dead Not Evaluated Unknown
	OP Tumor Information			
Ana	tomic Information	<u> </u>		Using the patient's pathology/laboratory report, select the
20*	Primary Site of Disease	□ Colon		anatomic site of disease of the tumor submitted for CDDP. 3427536
21	Region of Tumor	☐ Colon, NOS ☐ Cecum ☐ Sigmoid Colon ☐ Splenic Flexure	☐ Ascending Colon ☐ Hepatic Flexure ☐ Descending Colon ☐ Transverse Colon	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for CDDP. 3108203
Pati	hologic Information			
22*	Histological Subtype	☐ Colon Adenocarcinoma ☐ Colon Mucinous Adeno		Indicate the histologic subtype of the malignant sample submitted. 3081934
23*	Date of Initial Pathological Diagnosis	 Month Day	- <u></u> <u></u> Year	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted. 2896956 (month), 2896958(day), 2896960 (year)
24	Method of Initial Pathologic Diagnosis	☐ Right Hemicolectomy ☐ Left Hemicolectomy ☐ Transverse Colectomy ☐ Sigmoid Colectomy ☐ Total Colectomy ☐ Pan-Procto Colectomy ☐ Low Anterior Colon Re ☐ Other Surgical Resection	esection	Provide the procedure used to initially diagnose the patient. This is the method used on the date provided above. 2757941
25	Non-nodal Tumor Deposits (TD) in Resected Specimen	☐ Yes ☐ No ☐ Unknown		Indicate the pathologic presence of tumor deposits in the pericolic fat or in adjacent mesentery away from the leading edge of the tumor submitted to CDDP. 3107051
26	Circumferential Resection Margin (CRM) (also known as radial surgical clearance)		(mm)	Indicate the measured length (mm) between a malignant lesion of the colon and the nearest radial (or circumferential) border of tissue removed during surgery for the tumor submitted to CDDP. 64202
27	Vascular Invasion Present	☐ Yes ☐ No		Indicate if large vessel or venous invasion was pathologically present in the tumor specimen submitted to CDDP. 64358

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#	Data Element	Entry Alternat	tives		Working Instructions		
28	Lymphatic Invasion Present	☐ Yes ☐ No ☐ Unknown			Indicate if malignant cells are pathologically present in small or thin walled vessels suggesting lymphatic involvement in the tumor submitted to CDDP. 64171		
29	Perineural Invasion Present	☐ Yes ☐ No ☐ Unknown			Indicate if perineural invasion or infiltration of tumor or cancer is pathologically present in tumor submitted to CDDP. $\underline{64181}$		
30	Residual Tumor	□ RX □ R0	□ R1 □ R2 □ Not Evaluat	ted	Using the patient's pathology/laboratory report, select the tissue margin status at time of surgical resection for the tumor submitted for CDDP. 2608702		
31	Were Lymph Nodes Examined at the time of Primary Presentation?	☐ Yes ☐ No			Indicate whether any lymph nodes were examined at the time of the primary resection for the tumor submitted to CDDP.		

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#	Data Element	Entry Alterna	itives		Working Instructions	
42	Regional Lymph Nodes: Clinical (cN)	□ NX □ N0 □ N1 □ N1a	□ N1b □ N1c □ N2	□ N2a □ N2b □ N3	Using the patient's medical record, select the code for the clinical N (nodal) as defined by the American Joint Committee on Cancer (AJCC). 3440330	
43	Distant Metastasis: Clinical (M)	□ MX □ M0 □ M1		M1a M1b	Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical M (metastasis) as defined by the American Joint Committee on Cancer (AJCC). 3440331	
44	Overall Stage: Clinical	□ Stage I □ Stage IA □ Stage IB	□ Stage II □ Stage IIA □ Stage IIB		Using the patient's pathology/laboratory report, in conjunction with the patient's medical record select the stage as defined by the American Joint Committee on Cancer (AJCC). 3440332	
45	Preoperative / Pretreatment CEA Level			(ng/ml)	Provide the carcinoembryonic antigen or CEA level (ng/ml) prior to the resection of tumor submitted to CDDP. 2716510	
Mol	ecular/Genomic Informat	tion				
46	Microsatellite Instability (Abnormal at >33% loci tested)	☐ Yes ☐ No ☐ Unknown			Indicate whether microsatellite instability was present in more than 33% of loci tested in the tumor submitted to CDDP. 3123142	
47	Number of Loci Tested				If microsatellite instability was identified, indicate the number of loci tested to detect recessive mutations in the tumor submitted to CDDP. 3107127	
50	Number of Abnormal Loci				Indicate the number of loci found to be abnormal during testing to detect microsatellite instability in the tumor submitted to CDDP. 3107129	
51	Was Loss of Expression of Mismatch Repair Proteins Tested (by IHC)?	☐ Yes ☐ No ☐ Unknown			Indicate if testing was performed to identify any loss of expression in mismatch repair proteins tested by immunohistochemistry (IHC). 3123153 Note: If not performed, skip to the KRAS gene questions.	
52	Loss of Expression of mismatch Repair Proteins by IHC	MLH1 MSH2 PMS2 MSH6	Expressed □ □ □ □ □	Not Expressed	Indicate if any loss of expression of mismatch repair proteins by immunohistochemistry (IHC) is expressed for each of the listed genes. $\underline{3105496}$	
53	KRAS Gene Analysis Performed	☐ Yes ☐ No ☐ Unknown			Indicate if KRAS gene analysis was performed on the tumor submitted for CDDP. Note: If not performed, skip to BRAF gene questions. 3123147	
54	Mutation Found (KRAS)	☐ Yes ☐ No			If KRAS Gene Analysis was performed, indicate if KRAS Mutation was found. 2932340	
55	If KRAS Mutation Identified, What Codon?	□ 12 □ 61		13 Other	If KRAS mutation was identified, indicate the specific codon. 3124509	
56	BRAF Gene Analysis Performed?	☐ Yes ☐ No ☐ Unknown			Indicate if BRAF gene analysis was performed on tumor submitted for CDDP. 3123151	
57	BRAF Gene Analysis Results	□ Normal □ Abnormal			If BRAF gene analysis was performed, indicate the result. 3107189	
Tre	atment Information					

#	Data Element	Entry Alternatives	Working Instructions
58*	History of Neo-adjuvant Treatment for Sample Submitted for CDDP	 □ None □ Radiation prior to sample procurement* □ Pharmaceutical treatment prior to sample procurement* □ Both pharmaceutical treatment and radiation prior to sample procurement* 	Indicate whether the patient received therapy for this cancer prior to the sample procurement of the tumor submitted for CDDP. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. 3382737 *Systemic therapy and certain localized therapies (those administered to the same site as the CDDP submitted tissue) given prior to the procurement of the sample submitted for CDDP are exclusionary.
59*	Adjuvant (Post- Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy <u>for the tumor submitted.</u> 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
60*	Adjuvant (Post- Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy <i>for the tumor submitted</i> . 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
61	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and/or adjuvant therapies)	□Progressive Disease □Complete Response □Stable Disease □Not Applicable □Partial Response □Unknown	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 2786727
Sur	vival Information		
62*	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
63	Date of Last Contact	Month Day Year	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) Do not answer if patient is deceased.
64	Date of Death	Month Day Year	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
65*	Tumor Status (at time of last contact or death)	☐ Tumor free ☐ With tumor ☐ Unknown Tumor Status	Indicate whether the patient was tumor/disease free (i.e. free of the malignancy that yielded the sample submitted for the CDDP study) at the date of last contact or death. 2759550
New	Tumor Event Informati	on Complete the section below if the patient had a new	
		submission of the Enrollment Form. If the patient of indicate this in the question below, and the remain	did not have a new tumor event (or if the TSS does not know) ader of this section can be skipped.
66*	New Tumor Event After Initial Treatment?	□ Yes □ No □ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment for the tumor submitted to CDDP. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
67	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)
68	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence or a distant metastasis of the tissue submitted for CDDP; or a new primary tumor. 3119721
69	Anatomic Site of New Tumor Event	□ Bone □ Retroperitoneum □ Lung □ Lymph Node(s) □ Liver □ Other, specify	Indicate the site of this new tumor event. 3108271

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#	Data Element	Entry Alternatives	Working Instructions
70	Other Anatomic 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
71	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy with Histologic Confirmation ☐ Convincing Imaging (i.e. CT, PET, MRI) ☐ Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose tumor recurrence or relapse. 2786205
72	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question. 3427611
73	Additional Treatment of New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
74	Additional Treatment of New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

	Pharmaceutical Therapy	□ Unknown	<u>3427616</u>
	his form.		e Source Site is unable to provide the dates requested ovide time intervals as a substitute for requested dates on this form.
#	Question	Entry Alternatives	Working Instructions
i	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	□ Yes □ No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e. biopsy or resection). 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.
ii	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	days	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
iii	Age at Initial Diagnosis		Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657
iv	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	days	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 Do not answer this question if the patient is deceased.
v	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	days	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
vi	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	days	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

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