Completed By:

Follow-Up: Neuroblastoma



HC

Form Notes: A Follow-Up Form should be completed for each HCMI case upon notice of model establishment and molecular characterization success from Leidos. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2		2003301	Provide the patient's ID2 (this ID will only be used
2	ID3		5845012	by IMS for internal quality control). Provide the HCMI-specific anonymized ID (ID3).
Z	103		5845012	Provide the HCIVII-specific anonymized ID (ID3).
3	Index date	Initial pathologic diagnosis	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial
		 Sample procurement First patient visit 		pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and
				use it for all interval calculations.
	Patient Status			
4	Number of days from index date to date of last follow-up		3008273	Provide the number of days from the index date to the last date of follow-up with the patient or last contact with the medical record.
5	Vital status	 Alive Dead Lost to follow-up 	5	Indicate whether the patient is alive, dead, or lost to follow-up at the date of last contact. Note: If the patient is deceased, continue to Question 6, otherwise skip to Question 8.
6	Number of days from index date to date of death		3165475	Provide the number of days from the index date to the date of death.
7	Cause of death	 Related to this cancer Non-cancer related Related to another cancer Other (specify) Unknown 	2554674	Indicate the patient's cause of death.
7a	Other cause of death		4783275	If the cause of death is not included in the provided list, specify the cause of death.
8	Disease status at follow-up	 No evidence of disease Stable disease Progressive disease Unknown 	2188290	Provide the last known state of the patient's tumor up to the point of current follow-up data submission.
Treatment	Information		-	·
9	Was surgery performed as part of the primary disease treatment plan?	□ Yes □ No □ Unknown	2978013	Indicate whether surgery was performed to treat the primary tumor. Note: If the patient did not receive surgical treatment, skip to Question 11.
10	Number of days from index date to date of surgical treatment		3008335	Provide the number of days from the index date to the date of surgical treatment.
11	Was systemic adjuvant therapy administered?	□ Yes □ No □ Unknown	3397567	Indicate whether the patient received systemic adjuvant pharmaceutical therapy. Note: If the patient did have systemic adjuvant therapy, the Pharmaceutical Supplemental Form should be completed.
12	Was adjuvant radiation therapy administered?	□ Yes □ No □ Unknown	2005312	Indicate whether the patient had adjuvant radiation therapy. Note: If the patient had adjuvant radiation therapy, the Radiation Supplemental Form should be completed.

Follow-Up: Neuroblastoma

Tissue Source Site (TSS) Name: _____ Completed By: _____

_____HCMI Identifier (ID3): __ Completion Date (MM/DD/YYYY): _



Pharmaceutical Supplemental Form

Form Notes: A Pharmaceutical Supplemental Form should be completed for each HCMI case for which the patient received adjuvant pharmaceutical therapy. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	Was cytotoxic		5628399	Indicate whether the patient received cytotoxic
	chemotherapy	□ Yes		chemotherapy.
	administered?	🗆 No		Note: If cytotoxic chemotherapy was
		Unknown		administered, proceed to the "Cytotoxic
				Chemotherapy" section, Questions 2-5.
2	Was		3057655	Indicate whether the patient received
	immunotherapy			immunotherapy.
	(cellular and	□ Yes		Note: If immunotherapy was administered,
	immune			proceed to the "Immunotherapy" section,
	checkpoint)	□ Unknown		Questions 6-9.
	administered?			
3	Was targeted		2785850	Indicate whether the patient received targeted
	therapy (small			therapy.
	molecule	□ Yes		Note: If targeted therapy was administered,
	inhibitors and	□ No		proceed to the "Targeted Therapy" section,
	targeted	🗖 Unknown		Questions 10-13.
	antibodies)			
	administered?			
Cytotoxic C	hemotherapy			l
2	Chemotherapeutic	Busulfan and Melphalan	2853873	Select the chemotherapeutic used for therapy.
	administered	Carboplatin		Note: Questions 2-5 are repeatable as needed to
		□ Cis-retinoic acid		capture each individual chemotherapeutic
		□ Cisplatin		administered.
		Cyclophosphamide		If the chemotherapeutic is not included in the
		,		provided list, proceed to Question 2a, otherwise,
				skip to Question 3.
		Etoposide		
		Ifosfamide		
		Topotecan		
		Vincristine		
		Vincristine, actinomycin-D,		
		cyclophosphamide (VAC)		
		Vincristine, doxorubicin,		
		cyclophosphamide, ifosfamide,		
		etoposide (VDC/IE)		
		□ Vincristine, actinomycin-D,		
		cyclophosphamide, vincristine,		
		irinotecan (VAC/VI)		
		□ Ifosfamide, carboplatin, etoposide (ICE)		
		Vincristine, irinotecan, temozolomide		
		(VIT)		
		High-dose methotrexate, doxorubicin,		
		cisplatin (MAP)		
		Other (specify)		
2a	Other		2514640	If the adjuvant therapy is not included in the
	chemotherapeutic			provided list, specify adjuvant therapy.
3	Days from index		5102411	Provide the number of days from the index date
	date to start of			to the date of initiation of treatment with
	pharmaceutical			adjuvant pharmaceutical therapy.
	treatment		1	



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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
4	Days from index date to last known date of pharmaceutical		65167	Provide the number of days from the index date to the last known date of pharmaceutical treatment.
5	treatment Is the patient still receiving treatment?	Yes No Unknown	6379568	Indicate whether the patient is still undergoing treatment.
Immunothe	rapy			
6	Immunotherapy administered	DinutuximabOther (specify)	6010528	Select the immunotherapy administered. Note: Questions 6-9 are repeatable as needed to capture each individual immunotherapy administered. If the immunotherapy is not included in the provided list, proceed to Question 6a, otherwise, skip to Question 7.
6a	Other immunotherapy		2953828	If the immunotherapy is not included in the provided list, specify the therapy.
7	Days from index date to start of immunotherapy treatment		5102411	Provide the number of days from the index date to the date of the initiation of treatment with immunotherapy.
8	Days from index date to last known date of immunotherapy treatment		65167	Provide the number of days from the index date to the last known date of immunotherapy treatment.
9	Is the patient still receiving treatment?	Yes No Unknown	6379568	Indicate whether the patient is still undergoing treatment.
Targeted Th				
10	Targeted therapy administered	 ALK inhibitor MIBG Other (specify) 	6010389	Select the targeted therapy administered. Note: Questions 10-13 are repeatable as needed to capture each individual targeted therapy administered. If the targeted therapy is not included in the provided list, proceed to Question 10a, otherwise, skip to Question 11.
10a	Other targeted therapy		4308476	If the targeted therapy is not included in the provided list, specify the therapy.
11	Days from index date to start of targeted therapy treatment		5102411	Provide the number of days from the index date to the date of initiation of treatment with targeted therapy.
12	Days from index date to last known date of targeted therapy treatment		65167	Provide the number of days from the index date to the last known date of targeted therapy treatment.
13	Is the patient still receiving treatment?	Yes No Unknown	6379568	Indicate whether the patient is still undergoing treatment.

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Tissue Source Site (TSS) Name: _____ Completed By: _____

_____ HCMI Identifier (ID3): _ Completion Date (MM/DD/YYYY): _



Radiation Supplemental Form

Form Notes: A Radiation Supplemental Form should be completed for each HCMI case for which the patient received adjuvant radiation therapy. All information provided on this form should include activity from the "Date of Last Contact" provided on the HCMI Enrollment Form to the most recent date of contact with the patient or the patient's medical record.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	Radiation therapy	2D conventional	3028890	Provide the type of adjuvant radiation therapy
	administered type	3D conformal		that was administered to the patient, if not
		Brachytherapy HDR		collected on the enrollment form for this patient.
		Brachytherapy LDR		Note: If the radiation therapy type is not
				included in the provided list, proceed to
		Proton Beam		Question 1a, otherwise, skip to Question 2.
		Stereotactic Body RT		
		Stereotactic Radiosurgery		
		Other (specify)		
		Unspecified		
1a	Other radiation		3028890	If the radiation therapy type is not included in the
	therapy			provided list, specify the type.
2	Days from index		5102411	Provide the number of days from the index date
	date to start of			to the date of treatment with adjuvant post-
	adjuvant radiation			operative radiation therapy.
	therapy treatment			
3	Days from index		65167	Provide the number of days from the index date
	date to last known			to the last known date of radiation therapy
	date of adjuvant			treatment.
	radiation therapy			
	treatment			
4	Is the patient still	□ Yes	6379568	Indicate whether the patient is still undergoing
	receiving	□ No		treatment.
	treatment?	Unknown		