

## **Post-Transplant Essential Data**

Registry Use Only Sequence Number:  Date Received:	OMB No: 0915-0310 Expiration Date: 10/31/2022  Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0310. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post-transplant, 0.85 hours per response when collected at 6 months post-transplant, 0.65 hours per response when collected at 1 and 2 years post-transplant, and 0.52 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857.
CIBMTR Center Number:	
CIBMTR Research ID:	
Event date:///	
Visit ☐ 100 day ☐ 6 months ☐ 1 year ☐ 2 y	years

IBMTR Center Number: CIBMTR Research ID:				
Sur	urvival			
1.	Date of actual contact with the recipient to determine medical status for this follow-up report:///////			
2.	<ol> <li>Specify the recipient's survival status at the date of last contact</li> <li>Alive – Answers to subsequent questions should reflect clinical status since the date of last report Go to question 7</li> <li>Dead – Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death Go to question 3</li> </ol>			
	3.	Primary cause of death Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed - Go to question 5 Acute GVHD - Go to question 5 Cytokine release syndrome - Go to question 5 Infection Infection, organism not identified - Go to question 5 Bacterial infection - Go to question 5 Fungal infection - Go to question 5 COVID-19 (SARS-GOV-2) - Go to question 5 Protozoal infection - Go to question 5 Cotopial infection - Go to question 4 Malignancy Cotopial infection - Go to question 4 Malignancy Cotopial infection - Go to question 4 Cotopial infection - Go to q		
		☐ Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed) - <i>Go to question 5</i>		

CIBMTR Center Numbe	er: CIBMTR Research ID:
	Hemorrhage
	☐ Pulmonary hemorrhage - Go to question 5
	☐ Diffuse alveolar hemorrhage (DAH) - Go to question 5
	☐ Intracranial hemorrhage - Go to question 5
	☐ Gastrointestinal hemorrhage - Go to question 5
	☐ Hemorrhagic cystitis - Go to question 5
	☐ Other hemorrhage - Go to question 4
	Vascular
	☐ Thromboembolic - Go to question 5
	☐ Disseminated intravascular coagulation (DIC) - Go to question 5
	☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)) - Go to question 5
	☐ Other vascular - Go to question 4
	Other
	☐ Accidental death - Go to question 5
	☐ Suicide - Go to question 5
	☐ Other cause - Go to question 4
	Other cause - Co to question 4
	4. Specify:
5.	Contributing cause of death (check all that apply)
	Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed  - Go to question 7
	Acute GVHD - Go to question 7
	☐ Chronic GVHD - Go to question 7
	☐ Graft rejection or failure - Go to question 7
	☐ Cytokine release syndrome - Go to question 7
	Infection
	☐ Infection, organism not identified - Go to question 7
	☐ Bacterial infection - Go to question 7
	☐ Fungal infection - Go to question 7
	☐ Viral infection - Go to question 7
	COVID-19 (SARS-CoV-2) - Go to question 7
	☐ Protozoal infection - Go to question 7
	☐ Other infection - Go to question 6
	Pulmonary  ☐ Idiopathic pneumonia syndrome (IPS) - Go to question 7
	☐ Pneumonitis due to Cytomegalovirus (CMV) - Go to question 7
	Pneumonitis due to other virus - Go to question 7
	☐ Other pulmonary syndrome (excluding pulmonary hemorrhage) - Go to question 6
	☐ Diffuse alveolar damage (without hemorrhage) - Go to question 7
	☐ Acute respiratory distress syndrome (ARDS) (other than IPS) - Go to question 7
	Organ failure (not due to GVHD or infection)
	Liver failure (not VOD) - Go to question 7

	lusive disease (VOD) / sinusoidal obstruction syndrome (SOS) - Go to question 7
	y failure - Go to question 7
	ervous system (CNS) failure - Go to question 7
l <u> </u>	ure - Go to question 7
☐ Gastroint	estinal (GI) failure (not liver) - Go to question 7
☐ Multiple o	rgan failure - Go to question 6
☐ Other org	an failure - Go to question 6
Malignancy	
☐ New mali	gnancy (post-HCT or post-cellular therapy) - Go to question 7
☐ Prior mali which the	gnancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for HCT or cellular therapy was performed) - <b>Go to question 7</b>
Hemorrhage	
☐ Pulmonar	y hemorrhage - Go to question 7
☐ Diffuse al	veolar hemorrhage (DAH) - Go to question 7
☐ Intracrani	al hemorrhage - Go to question 7
Gastroint	estinal hemorrhage - Go to question 7
_	agic cystitis - Go to question 7
☐ Other her	norrhage - Go to question 6
Vascular	
☐ Thromboo	embolic - Go to question 7
_	ated intravascular coagulation (DIC) - Go to question 7
(HUS)) -	ic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome Go to question 7
☐ Other vas	cular - Go to question 6
Other	
☐ Accidenta	l death - Go to question 7
	Go to question 7
☐ Other cau	ise - Go to question 6
	6. Specify:

	GIBMTR Center Number: CIBMTR Research ID: CIBMTR Research ID:			
Subsequent Transplant				
7.	7. Did the recipient receive a subsequent HCT since the date of last report?			
	☐ Yes → No	s. Date of subsequent HCT:////		
		. What was the indication for subsequent HCT?		
		Graft failure / insufficient hematopoietic recovery – Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		Persistent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		Recurrent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		☐ Planned subsequent HCT, per protocol – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		□ New malignancy (including PTLD and EBV lymphoma) – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		☐ Insufficient chimerism – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 11		
		☐ Other – Complete a Pre-TED Form 2400 for the subsequent HCT - Go to question 10		
		10. Specify other indication:		
		44. Course of UCCs (shooth off that oright)		
		11. Source of HSCs (check all that apply)  Allogeneic, related  Allogeneic, unrelated  Autologous		
12.	2. Has the recipient received a cellular therapy since the date of last report? (e.g. CAR-T, DCI)  Yes – Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000  No  13. Date of cellular therapy:////			
Initia	al ANC Recover	у		
14.	14. Was there evidence of initial hematopoietic recovery?  ☐ Yes (ANC ≥ 500/mm³ achieved and sustained for 3 lab values) - Go to question 15  ☐ No (ANC ≥ 500/mm³ was not achieved) - Go to question 16  ☐ Not applicable (ANC never dropped below 500/mm³ at any time after the start of the preparative regimen) - Go to question 16  ☐ Previously reported (Recipient's initial hematopoietic recovery was recorded on a previous report) - Go to question 16  15. Date ANC ≥ 500/mm³ (first of 3 lab values):///			
16.	Did late graft fa	ilure occur? Yes No		

JBMTR Center Number:	CIBINITR Research ID:
Initial Platelet Recovery	
(Optional for Non-U.S. Centers)	
	ever dropped below 20 x 10°/L - Go to question 19  /L was achieved and reported previously - Go to question 19  18. Date platelets ≥ 20 x 10°/L://///
	YYYY MM DD
Graft vs. Host Disease	
	e recipient's HCT or cellular therapy, report all graft-versus-host disease occurring in this reporting used, continue to Liver Toxicity Prophylaxis, question 45.
19. Did acute GVHD develop since the	date of last report?
☐ Yes ———	20. Date of acute GVHD diagnosis: / / <b>Go to question 22</b>
∐ No □ Unknown	YYYY MM DD
21. Did acute GVHD persist since the c	late of last report?
<ul> <li>☐ Yes - Go to question 29</li> <li>☐ No - Go to question 37</li> </ul>	
☐ Unknown - Go to question 37	
	e of acute GVHD at diagnosis:
	on ≤ 50% of skin, no liver or gut involvement
	on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea or vomiting bin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
<u> </u>	eralized erythroderma with bullous formation, or bilirubin >15 mg/dL
	cable (acute GVHD present but cannot be graded)
	, ,
List the stage for each organ at diagnosis of acute GVHD:	
23. Skin	
☐ Stage 0 – no rash, no rash attributable to acute GVHD	
l	maculopapular rash, < 25% of body surface
	maculopapular rash, 25-50% of body surface
	generalized erythroderma, > 50% of body surface
	generalized erythroderma with bullae formation and/or desquamation
	nal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)
(pediatric	
l	diarrhea 500-1000 mL/day (adult), or 10-19.9 mL/kg/day (pediatric)
l	diarrhea 1001-1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)
	diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
│	severe abdominal pain, with or without ileus, and/or grossly bloody stool

25.	Upper intestinal tract	
	Stage 0 – no persistent nausea or v	
	☐ Stage 1 – persistent nausea or vom	iting
26.	Liver	
	☐ Stage 0 – no liver acute GVHD / bill	irubin < 2.0 mg/dL (< 34 μmol/L)
	☐ Stage 1 – bilirubin 2.0-3.0 mg/dL (3	4-52 μmol/L)
	☐ Stage 2 – bilirubin 3.1-6.0 mg/dL (5	3-103 μmol/L)
	☐ Stage 3 – bilirubin 6.1-15.0 mg/dL (	104-256 μmol/L)
	☐ Stage 4 – bilirubin > 15.0 mg/dL (>	256 μmol/L)
27.	Other site(s) involved with acute GVHD	
	☐ Yes — → No	28. Specify other site(s):
Sp	ecify the maximum overall grade and	organ staging of acute GVHD since the date of last report:
29.	Maximum overall grade of acute GVHD	
	☐ I - Rash on ≤ 50% of skin, no liver o	or gut involvement
	☐ II - Rash on > 50% of skin, bilirubin	2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea or vomiting
		ge 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
	_	bullous formation, or bilirubin >15 mg/dL
	☐ Not applicable (acute GVHD preser	nt but cannot be graded)
		30. Date maximum overall grade of acute GVHD:
		— <u></u>
31.	Skin	
	☐ Stage 0 – no rash, no rash attributa	ble to acute GVHD
	☐ Stage 1 – maculopapular rash, < 25	5% of body surface
	☐ Stage 2 – maculopapular rash, 25–	50% of body surface
	☐ Stage 3 – generalized erythroderma	a, > 50% of body surface
	☐ Stage 4 – generalized erythroderma	a with bullae formation and/or desquamation
32.	Lower intestinal tract (use mL/day for a	dult recipients and mL/kg/day for pediatric recipients)
	☐ Stage 0 – no diarrhea, no diarrhea (pediatric)	attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/da
	☐ Stage 1 – diarrhea 500 - 1000 mL/d	lay (adult), or 10 - 19.9 mL/kg/day (pediatric)
	☐ Stage 2 – diarrhea 1001 - 1500 mL	/day (adult), or 20 - 30 mL/kg/day (pediatric)
	☐ Stage 3 – diarrhea > 1500 mL/day (	(adult), or > 30 mL/kg/day (pediatric)
	☐ Stage 4 – severe abdominal pain, w	vith or without ileus, and/or grossly bloody stool
33.	Upper intestinal tract	
I	☐ Stage 0 – no persistent nausea or v	vomiting
	9	

CIBMTR Center Number:	CIBMTR Research ID:
☐ Stage 1 – b ☐ Stage 2 – b ☐ Stage 3 – b ☐ Stage 4 – b	No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)  bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)  bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)  bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)  bilirubin > 15.0 mg/dL (> 256 µmol/L)  avolved with acute GVHD  36. Specify other site(s):
37. Did chronic GVHD develop since the d ☐ Yes  ☐ No ☐ Unknown	date of last report?  38. Date of chronic GVHD diagnosis:/// Date estimated  YYYY
39. Did chronic GVHD persist since the data and the since the data are	Specify the maximum grade of chronic GVHD since the date of last report:  40. Maximum grade of chronic GVHD (according to best clinical judgment)    Mild   Moderate   Severe   Unknown  41. Specify if chronic GVHD was limited or extensive   Limited – localized skin involvement and/or liver dysfunction   Extensive – one or more of the following:   generalized skin involvement; or,   liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,   involvement of eye: Schirmer's test with < 5 mm wetting; or   involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or   involvement of any other target organ  42. Date of maximum grade of chronic GVHD:
43. Is the recipient still taking systemic stekg/day for children)  ☐ Yes ☐ No ☐ Not applica	eroids? (Do not report steroids for adrenal insufficiency, or steroid dose ≤10 mg/day for adults, <0.1 mg/
44. Is the recipient still taking (non-steroic ☐ Yes ☐ No ☐ Not applica	d) immunosuppressive agents (including PUVA) for GVHD?

CIBMTR Center Number: CIBMTR Research ID: CIBMTR Research ID:			
Liver Toxicity Prophylaxis			
45. Was specific therapy used to prevent liver toxicity?    Yes			
48. Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?    Yes			
Infection			
50. Did the recipient develop COVID-19  Yes  No  Copy and complete questions 50 - 51	(SARS-CoV-2) since the date of last report?  51. Date of diagnosis://  YYYY MM DD  to report more than one infection.		
	or Myeloproliferative Disease / Disorder		
Report new malignancies that are different than the disease / disorder for which HCT was performed. Do not include relapse, progression or transformation of the same disease subtype.  52. Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)    Yes			

IBMTR Center Number:	CIBMTR Research ID:
	Breast cancer - Go to question 56 Central nervous system (CNS) malignancy (e.g. glioblastoma, astrocytoma) - Go to question 56 Central nervous system (CNS) malignancy (e.g. colon, rectum, stomach, pancreas, intestine) - Go to question 56 Cenitourinary malignancy (e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix) - Go to question 56 Cenitourinary malignancy - Go to question 56 Celanoma - Go to question 5
	- Go to question 56
	55. Is the tumor EBV positive?
57. Was	of diagnosis://MMDD  documentation submitted to the CIBMTR? (e.g. pathology / autopsy report or other documentation)  des No  the new malignancy donor / cell product derived?  fes  59. Was documentation submitted to the CIBMTR? (e.g. cell origin evaluation (VNTR, cytogenetics, FISH))  lot done Yes No
Chimerism Studies (Cord Bloo	d Units, Beta Thalassemia, and Sickle Cell Disease Only)
halassemia or sickle cell disea different primary disease, conf 60. Were chimerism studies per	sm studies from allogeneic HCTs using cord blood units or for recipients whose primary disease is beta ase. If this was an autologous HCT, or an allogeneic HCT using a bone marrow or PBSC product, or a tinue to disease assessment.  If or med since the date of last report?
☐ Yes ☐ No - Go to question 80	61. Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)  □ Yes □ No
	62. Were chimerism studies assessed for more than one donor / multiple donors?
Provide date(s), method(s) and	other information for all chimerism studies performed since the date of last report.
NMDP cord blood unit ID:	
6 Non-NMDP cord blood unit	

CIBM	R Center Number: CIBMTR Research ID:
67.	Global Registration Identifiers for Donors (GRID):
68.	Date of birth: (donor / infant)//// OR - Age: (donor/infant)
	69. Sex (Donor / infant)
70.	Date sample collected://////
71.	Method  Karyotyping for XX/XY  Fluorescent in situ hybridization (FISH) for XX/XY  Restriction fragment-length polymorphisms (RFLP)  VNTR or STR, micro or mini satellite (Also include AFLP)  Other  72. Specify:
73.	Cell source Bone marrow Peripheral blood
74.	Cell type  Unsorted / whole - Go to question 76  Red blood cells - Go to question 78  Hematopoietic progenitor cells (CD34+ cells) - Go to question 78  Total mononuclear cells (lymphs & monos) - Go to question 78  T-cells (includes CD3+, CD4+, and/or CD8+) - Go to question 78  B-cells (includes CD19+ or CD20+) - Go to question 78  Granulocytes (includes CD33+ myeloid cells) - Go to question 78  NK cells (CD56+) - Go to question 78  Other  75. Specify:
76.	otal cells examined:
	lumber of donor cells: Go to question 78
78.	Vere donor cells detected?  Yes 79. Percent donor cells:%
Сор	and complete questions 63 - 79 for multiple chimerism studies.
Disc	ise Assessment at the Time of Best Response to HCT
80.	Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report?  Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)  Continued complete remission (CCR) – For patients transplanted in CR - Go to question 103  Complete remission (CR) - Go to question 82  Not in complete remission - Go to question 81  Not evaluated - Go to question 103

CIBMTR Center Number:	CIBMTR Resea	arch ID:
☐ Disease det☐ No disease	e status if not in complete remission sected - Go to question 84 detected but incomplete evaluation to establish f best response previously reported? question 101  83. Date assessed://////	h CR - Go to question 84  L
		☐ Not applicable ▼

	97. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)    Yes
consolidation thera 103. Was therapy gi	en since the date of last report to prevent relapse or progressive disease. This may include maintenance and apy. Do not report any therapy given for relapsed, persistent, or progressive disease.  Ven since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any and consolidation therapy.)
☐ Yes → ☐ No	104. Systemic therapy (check all that apply)  Blinded randomized trial - Go to question 108 Cellular therapy - Go to question 108 Radiation - Go to question 105 Other therapy - Go to question 107  105. Specify systemic therapy (check all that apply) Alemtuzumab (Campath) Azacytidine (Vidaza) Blinatumomab Bortezomib (Velcade) Bosutinib Carfilzomib Chemotherapy Dasatinib (Sprycel) Decitabine (Dacogen) Gentuzumab (Mylotarg, anti-CD33) Gilteritinib Intuinib Intuinid Intu

CIDIVITA Center Nu	ımber: CIBMTR Research ID:
	Midostaurin   Nilotinib (AMN107, Tasigna)   Nivolumab   Pembrolizumab   Pomalidomide   Quizartinib   Rituximab (Rituxan, MabThera)   Sorafenib   Sunitinib   Thalidomide (Thalomid)   Other systemic therapy   106. Specify other systemic therapy:
in a previous repor indicate the date it	ent has experienced a clinical/hematologic relapse or progression post-HCT. If the relapse or progression was detected ting period indicate that and continue on. If the first clinical/hematologic relapse occurred since the date of last report, was first detected in this reporting period.  In experience a clinical/hematologic relapse or progression post-HCT?
☐ Yes ———	109. Was the date of the first clinical/hematologic relapse or progression previously reported?  Yes (only valid >day 100) - Go to question 119  No  110. Date first seen:////
	apsed disease, persistent disease, or progressive disease on given for relapsed, persistent or progressive disease since the date of last report?
☐ Yes → ☐ No	112. Specify reason for which intervention was given  Persistent disease Relapsed / progressive disease  113. Specify the method(s) of detection for which intervention was given (check all that apply) Clinical/hematologic Cytogenetic Disease specific molecular marker Flow cytometry Radiological (e.g. PET, MRI, CT)

114.	Date intervention started://///
	Specify therapy (check all that apply)
	Systemic therapy - Go to question 116
	☐ Radiation - Go to question 119
	Cellular therapy - Go to question 119
	☐ Blinded randomized trial - Go to question 119
	☐ Other therapy - Go to question 118
	Other therapy - Go to question 116
	116. Specify systemic therapy (check all that apply)
	☐ Alemtuzumab (Campath)
	☐ Azacytidine (Vidaza)
	☐ Blinatumomab
	☐ Bortezomib (Velcade)
	Bosutinib
	☐ Carfilzomib
	☐ Chemotherapy
	☐ Dasatinib (Sprycel)
	☐ Decitabine (Dacogen)
	☐ Gemtuzumab (Mylotarg, anti-CD33)
	Gilteritinib
	☐ Ibrutinib
	☐ Imatinib mesylate (Gleevec)
	☐ Ixazomib
	☐ Lenalidomide (Revlimid)
	Lestaurtinib
	☐ Midostaurin
	☐ Nilotinib (AMN107, Tasigna)
	☐ Nivolumab
	Pembrolizumab
	Pomalidomide
	Quizartinib
	Rituximab (Rituxan, MabThera)
	Sorafenib
	Sunitinib
	☐ Thalidomide (Thalomid)
	Other systemic therapy ———— 117. Specify other systemic therapy:
	440.0 7 11 11
	118. Specify other therapy:

CIBMTR Center Number: CIBMTR Research ID:
Current Disease Status
119. What is the current disease status?  Complete remission (CR) - Go to question 121  Not in complete remission - Go to question 120  Not evaluated - Go to signature line
120. Specify disease status if not in complete remission  ☐ Disease detected ☐ No disease detected but incomplete evaluation to establish CR  121. Date of most recent disease assessment  ☐ Known → ☐ Unknown ☐ 122. Date of most recent disease assessment:///////
First Name:
Last Name:
E-mail address:
Date:YYYY / _MM / _DD