Appendix M: HCT Critical Data Fields

The following list of data fields have been identified as being critical to accurate outcome analyses. These fields are audited for each recipient selected for audit. The table below is a summary of many of the critical data points grouped by data field type. Critical fields are regularly reviewed and updated; therefore, the list below includes the critical fields for the most current revisions of the forms. Since the audit process reviews data reported over four years (including older form revisions), critical fields reviewed as part of the audit may differ from the summary below. For a complete list of current data collection forms (including form numbers and names) visit the <u>CIBMTR website</u>.

Field	Form(s)
Demographics Data	
Recipient Date of Birth	2400
Recipient Race and Ethnicity	2400
Product and Infusion Data	
Infusion date	Appears on multiple CIBMTR forms
Previous transplants	2010 – 2045 (comprehensive disease specific pre-transplant forms), 2055, 2400
Infusion times	2006
Total volume infused	2006
Entire volume of product infused (what happened to the reserved)	2006
Adverse events associated with infusion	2006
HCT product type	Appears on multiple CIBMTR forms
Donor identification	2006
Pre-collection therapy	2006
Consent	
IRB-approved consent for submitting research	2400
IRB-approved consent to donate research blood samples	2400
Product Manipulation and Analysis	
Product manipulation and thaw	2006, 2400
Methods of manipulation	2006
Product thaw information	2006
Tumor cells detected in recipient or product prior to HCT (autologous HCT)	2006

Selected product analysis data including timepoint, volume, and certain cell counts	2006
Clinical Status of Recipient	
Karnofsky / Lansky score	2100, 2400
Recipient blood type	2000
Hematologic findings prior to preparative regimen	2000
CMV	2000
Disease specific staging	2013, 2016
Pre-HCT Preparative Regimen and Line	s of Therapy
Preparative regimen prescribed	2000, 2400
Classify recipient's prescribed preparative regimen	2000, 2400
Date preparative regimen began	2000, 2400
Preparative regimen drugs	2000, 2400
Irradiation performed	2000
Pharmacokinetics performed to determine dosing	2000
Pre-HCT or pre-infusion therapy	Appears on multiple pre-HCT CIBMTR forms
GVHD	
Select GVHD prophylaxis drugs	2400
Acute and chronic GVHD develop / persist	2100, 2450
Grading, staging, onset, and extent of GVHD, including dates	2100, 2450
Preventative therapy used after preparative regimen	2100
Recipient still receiving therapy at date of contact	2100, 2450
Post-HCT Disease Therapy	
Additional post-HCT therapy planned	2400
Subsequent transplant / cellular therapy	2100, 2400, 2450
Therapy / intervention given in reporting	2110-2145 (comprehensive disease
period	specific post-transplant forms), 2450
Primary Disease for HCT	specific post-transplant forms), 2450

Primary disease for which the HCT was performed, including classification / subtype Predisposing condition / therapy related Laboratory studies, cytogenetic abnormalities, molecular markers, immunohistochemical stains, and flow cytometry assessed prior to HCT Histologic transformation (date of transformaton and disease classification) Disease Status Disease status at diagnosis and prior to preparative regimen including remission status Laboratory studies prior to preparative regimen (monocyte, blasts, etc.) Disease status at day 30 Clinical / hematologic, molecular, flow, and cytogenetic relapse or progression including pertinent dates Best response to HCT and date best response (Clinical / hematologic assessment at the time of evaluation: Molecular, flow, cytogenetic, FISH, and cytogenetic, FISH, and cytogenetic, FISH, and cytogenetic, FISH, and cytogenetic of evaluation: Molecular, flow, cytogenetic, FISH, and cytogenetic assessed Survival Date of actual contact and survival status Date of death and cause of death ANC Recovery Evidence of initial hematopoietic recovery and date ANC subsequent decline after recovery Diagnosis of new malignancy, lymphoproliferative or myeloproliferative 2010-2045, 2402 2010-2045, 2402 2010-2045 2010-204		
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Evidence of initial hematopoietic recovery and date ANC subsequent decline after recovery Other Diagnosis of new malignancy, 2100, 2450	Date of death and cause of death	2100, 2450, 2900
recovery and date ANC subsequent decline after recovery Other Diagnosis of new malignancy, 2100, 2450	ANC Recovery	
Other Diagnosis of new malignancy, 2100, 2450	·	2100, 2450
Diagnosis of new malignancy, 2100, 2450	ANC subsequent decline after recovery	2100
	Other	
		2100, 2450

disease / disorder, development of VOD / SOS	
Solid organ transplant in reporting period	2100
Who is being tested for IDMs/HLA	2004, 2005, 2047
History of infection at any time prior to start of preparative regimen	2039

<u>Appendix M – Critical Data Fields</u>

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