Appendix O: Cellular Therapy Critical 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 CIBMTR website.

Field	Form(s)
Primary Disease for CT	
Date of Diagnosis	2402
Primary disease for which the CT was performed, including classification / subtype	2402
Predisposing condition	2402
Prior HCT or CT	2011, 4000
Indication for CT	4000
Infusion date	Appears on multiple CIBMTR forms
Laboratory studies, cytogenetic abnormalities, molecular markers, and immunohistochemical stains assessed at diagnosis	2011, 2018, 2402
Laboratory studies, cytogenetic abnormalities, and molecular markers, assessed in-between diagnosis and start of systemic therapy	2402
Laboratory studies, cytogenetic abnormalities, molecular markers, immunohistochemical stains, and flow cytometry assessed prior to CT	2011, 2018, 2402
Histologic transformation (date of transformation and disease classification	2018
Product and Infusion Data	
Is this the first application of cellular therapy (non-HCT)?	4000
Did NMDP/Be the Match facilitate the procurement, collection, or transportation of the product?	4000
Date of infusion	4006, 4100
Product name	4000, 4003, 4006, 4100
Product cell type	4000, 4003
Genetic modification of product	4000
Product identification (including cell product ID, batch number, lot number)	4000, 4006
Cell counts (total number of cells administered, lymphocytes (unselected) administered),	4006

CD4+ lymphocytes administered, CD8+ lymphocytes administered, natural killer cells (NK cells) administered)	
Total volume infused	4006
Total number of products infused	4000, 4003
Concomitant therapy	4006
Where was the cellular therapy product manufactured / processed? (pharmaceutical / biotech company)	4003
In what setting is this cell therapy product infusion being planned?	4000
Consent	
IRB-approved consent for submitting research	4000
Participation in a cellular therapy clinical trial (study sponsor, sponsor name, etc.)	4000
Clinical status of recipient	
Karnofsky / Lansky score	4000
ECOG score	2018
Dialysis immediately prior to the start of the preparative regimen	4000
Prior malignancy	4000
Comorbidities	4000
Systemic Therapy Prior to CT and Lines of Therapy	
Lymphodepleting therapy prior to infusion (drug, dose, date started)	4000
GVHD	
Acute GVHD developed	4100
Chronic GVHD developed / persisted	4100
Date of maximum overall grade of chronic GVHD	4100
Post-CT Disease Therapy	
Subsequent transplant / cellular therapy	4100, 2111
Therapy / intervention given in reporting period	2111, 2118
Disease Status	
Disease status at diagnosis and prior to systemic therapy including remission status	2402
Laboratory studies prior to preparative regimen (monocyte, blasts, etc.)	2011
Best response to CT and date best response first began	2111, 2118
Best response: Clinical / hematologic assessment	2111, 2118
Best response and disease assessment at the time of evaluation: Molecular, flow, cytogenetic, FISH, and cytogenetics	2111, 2118
Disease detected by clinical / hematologic assessments	2111

Current disease status and date assessed	2111, 2118
Recipient Status	
Date of actual contact with recipient	4100
Survival status	4100
Pregnant at any time in reporting period (recipient or recipient's female partner)	4100
Date of death and cause of death	4100, 2900
Peripheral Blood Count Recovery	
Evidence of initial hematopoietic recovery and date	4100
ANC subsequent decline after recovery	4100
Platelet recovery ≥ 20 × 109/L	4100
Infection	
Development of clinically significant infection since date of last report	4100
Organism, infection site, date of diagnosis	4100
Toxicities	
Cytokine Release Syndrome (CRS) (diagnosis date, therapy, symptoms, resolution)	4100
Neurotoxicity (date of onset, symptoms, resolution, therapy, CARTOX-10 / ICE score)	4100
Hypogammaglobulinemia (date of onset, therapy, resolution)	4100
Tumor lysis syndrome (date of onset and grade	4100
Other toxicity (date of onset)	4100
Development of grade 3 or 4 organ toxicity	4100
C-reactive protein level	4100
Other	
New malignancy, myelodysplastic, myeloproliferative disease or disorder	4100

Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. In addition to documenting the changes within each manual section, the most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

Date	Manual Section	Add/Remove/ Modify	Description
8/10/ 2020	Appendix O: Cellular Therapy Critical Fields	Add	***Appendix O: Cellular Therapy Critical Fields*** released.

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