BMT/Cellular Therapy Data Management Staffing

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Division of Hematologic Malignancy and Cellular Therapeutics,
The University of Kansas Cancer Center
Disclosures

- No financial disclosures
Objectives

- Provide an overview of staffing models for data management personnel
- Assist BMT administrators with developing metrics, tools for data management staffing
- Increase awareness of educational/training resources for data management staff
CIBMTR has developed an algorithm to determine which set of forms will be required for each HCT recipient.

The goal of the algorithm is to randomly select an epidemiologic sample of recipients for whom a Comprehensive Report Form (CRF) will be requested.

The algorithm includes, but is not limited to, type of HCT, product type, age of the recipient, disease, etc.

- Modified based on the CIBMTR Research Portfolio
- Your centers physicians are submitting over 100 research proposals a year to the CIBMTR

The algorithm is periodically reviewed to assess the burden of data submission for transplant centers.
TED vs CRF Randomization algorithm

- Generally, 20 to 25% of recipients selected to Comprehensive Report Forms (CRF)
- The selection percentage to Comprehensive Report Forms (CRF) may be more than 20 to 25% if
  - your center participates in the BMT-CTN and/or RCI-BMT Studies
  - your center participates CMS Research Studies
  - your center participates special CIBMTR Studies (i.e. KGF)

<table>
<thead>
<tr>
<th>KUCC Randomization Summary</th>
<th>Year</th>
<th>% Randomized to CRF</th>
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<tbody>
<tr>
<td></td>
<td>2014</td>
<td>27%</td>
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<td>2015</td>
<td>31%</td>
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<td>2016</td>
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CIBMTR – New & Revised Forms

- 2400 – Pre-TED
- 2402 – Pre-TED Disease Classification*
- 2005 – Confirmation of HLA Typing
- 2450 – Post-TED
- 2100 – CRF Follow-up Form
- 2900 – Recipient Death Form
- 2012 / 2112 – CML Disease-specific Form
- 2554 – CMS Registration*
- 2555 – CMS-MF Eligibility*
- 2556 – CMS-MF Pre-HCT Supplemental Data Form*
- 2667 – CMS-MF Post-HSCT Supplemental Data Form*

*New Form
<table>
<thead>
<tr>
<th>Effort Required per Patient for Major CIBMTR Forms (CRF track)</th>
<th>Minutes per Patient/Infusion</th>
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<td>Pre-TED (Form 2400 &amp; 2402)</td>
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<td>HSCT Infusion (Form 2006)*</td>
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<td>Infectious disease markers (Form 2004)</td>
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<td>100-day report (Form 2100)</td>
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<td>6-month report (Form 2100)</td>
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<td>1-year report (Form 2100)</td>
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<td><strong>Subtotal Minutes per Transplant</strong></td>
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<tr>
<th>TED track</th>
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<td>Pre-TED (Form 2400/2402)</td>
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<td>Post-TED (Form 2450 @ day+100)</td>
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<td>Post-TED (Form 2450 @ day+180)</td>
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<td><strong>Total Mins</strong></td>
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*TED track may also require 2005 & 2006, if Cord SCT, or participating in Sample Repository study*
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<th>201X</th>
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<th>2100 (180d)</th>
<th>2100 (1yr)</th>
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**Previously 2200 & 2300 (as of 2/1/17)**
BMT Center Analysis

- BMT center volume = 200

- If 20% selected for CRF, it will require the following:

  - Transplant:
    - Form 2000 – Baseline, Dz insert (2 forms)
    - Form 2006 – HCT infusion (per graft infused; 1 minimum)
    - Form 2005 – Confirmation of HLA typing; (2 minimum)
      [completed for both related donor, or non-NMDP facilitated MUD & recipient]
    - Form 2004 – Infectious Disease Markers [for related donor, or non-NMDP facilitated MUD & recipient]

  - Day 100
    - Form 2100 + disease insert (2 forms)

  - 6-month – Annual
    - Form 2100 + disease insert (2 forms)
CIBMTR Forms Due Report

1/2/2017: 618 Total, 235 Past Due
1/9/2017: 618 Total, 230 Past Due
1/16/2017: 622 Total, 242 Past Due
1/23/2017: 614 Total, 234 Past Due
1/30/2017: 625 Total, 235 Past Due
2/6/2017: 666 Total, 223 Past Due
2/13/2017: 700 Total, 199 Past Due
Centers must comply with the CIBMTR’s SCTOD Recipient Outcome reporting goal of 90% per trimester.

*CY17-T1 as of 2/16/17
CIBMTR Reports Submitted (CY09-CY16)

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<tr>
<th>Year</th>
<th>Monthly AVG</th>
<th>Reports Submitted</th>
<th># of FTE</th>
<th>Avg per FTE</th>
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Model for Cellular Therapy Registration

Cellular Therapy

Future

Comprehensive Data

Pre-CTED

Post CTED

CRF

Basic Level Of Data Collection

Hematopoietic Cell Transplantation

Unique ID Assignment

Form 2804/2814

Pre-TED

Post-TED

CRF

Comprehensive Data

ASBMT

American Society for Blood and Marrow Transplantation
Cellular Therapy Essential Data

Applies to all cellular therapies

Pre-CTED (Form 4000)
- Demographic data, indication, disease status prior to CT (if applicable) and therapy prior to CT

Post-CTED (Form 4100)
- Follow up infusions, patient survival and disease status, cause of death, development of malignancies, persistence of the product, development of CRS

Infusion form (Form 4006)
- Description of the product, information on manufacturing, product analysis and infusion details
Several scenarios for which we need to collect data

- Cellular therapy followed by HCT (e.g. bridge to HCT)
- Cellular therapy to cellular therapy (new indication)
- Co-infusions: HCT plus cellular therapy
- HCT followed by cellular therapy (e.g. DCI)
- Cellular therapy only

Required Reporting
Optional reporting

- Regenerative medicine
- CAR T-cells
- CTL for infection
CIBMTR Training Resources
Training and Reference

CIBMTR has developed comprehensive, secure and efficient applications to allow you to electronically submit data to CIBMTR as effortlessly as possible.

Learn more about CIBMTR training and reference services:

Center Reference Guide
Source of reference to learn about participation in CIBMTR research, center membership, access to FormsNet3℠, data manager education, mentor program, forms submission process and many useful tips and links. Information is geared toward new/existing data managers.

Manuals
Find the answers to your data submission questions by accessing the Forms Instructions Manual that includes general instructions and instructions for each form type.

FormsNet3℠
Application access and training for data submission to CIBMTR.

CRP/DM Conference Materials
Learn about educational opportunities at meetings sponsored by CIBMTR and other professional transplant groups. Access audio and visual presentations on the form submission process.

AGNIS
Training on AGNIS®, which is used to transmit data to CIBMTR directly from your center’s database.

Legacy Data and Backlog Resources
Information on making changes to legacy data.

Archived Materials/Memos
All memos distributed by CIBMTR to transplant center data management staff since launch of FormsNet2 in December 2007.
FormsNet3

The FormsNet3℠ application is a secure clinical research management system for electronic submission of outcome data to CIBMTR, in compliance with SCTOD.

Recommended Internet Browsers
In order to fully support the more modern browser features and tighter security standards developed for the FormsNet3 Application, the recommended internet browsers to use are:

- Internet Explorer 9 (Note: Windows 7 as the operating system)
- Mozilla Firefox: 14 and greater
- Google Chrome: 22 and greater
- Safari: 6 and greater
- Google Chrome Frame (plug-in to IE 8)

FormsNet3℠ Application Training
- [FormsNet3 Training Guide (PDF)](#): This practical booklet is a quick desk reference. More detailed training is in the Learning Center, with separate modules specific to the Recipient and Donor versions.
- [Query Functionality in FormsNet3](#)
Getting Started

Welcome to the CIBMTR Forms Instruction Manual. The Table of Contents on the left side of the screen is for navigational purposes; if you are on a mobile device you may find the Table on Contents on the top of the page.

General Instructions provides useful general background information for successfully completing forms.

2804/2814: CRID Assignment and Indication provides explanatory text used to generate a CIBMTR Research ID (CRID) and report the indication.

Transplant Essential Data (TED) Manuals provides explanatory text for each question found on the TED forms.

Comprehensive Baseline & Follow-up Forms Manuals provides explanatory text for each question on the Baseline, Follow-up, IDMs, HLA, and Infusion forms.

Comprehensive Disease Specific Manuals provides explanatory text and additional information for disease indications requiring CIBMTR reporting.

Cellular Therapy Manuals provides explanatory text for completing pre-infusion, infusion, and post-infusion forms.

Infection & Miscellaneous Manuals provides explanatory text for manuals such as the Hepatitis Serology, VOD / SOS, and Myelofibrosis CMS Study forms.

Appendices provide additional information beyond the scope of the other manuals.
eLearning Modules

The following courses are located in the Learning Center

HLA Series

- *Introduction to HLA* – Describes HLA and the factors that may affect HLA matching. (17:04 minutes)
- *HLA Reporting (Form 2005)* – Includes form revisions and reporting HLA typing. (12 minutes)
- *HLA for the Rest of Us* – If you have little to no knowledge of HLA and biology, this fun session is for you. Simple terms are used to describe what HLA is, why it matters, and how to communicate HLA to donors, patients, and the general public. (17 minutes)
- *Basic Biology of HLA* – Explore protein functions and why matching is so important. (11:54 minutes)
- *Advanced Biology of HLA* – Look at protein types, peptides, and immune responses. (16:33 minutes)

Disease Specific Series

- Form 2016 / 2116 Plasma Cell Disorders (20 minutes)
- Form 2018 / 2118 Lymphoma (20 minutes)
- Basics of Multiple Myeloma 1 (20 minutes)
- Basics of Multiple Myeloma 2 (30 minutes)
- MDS & MPN Reporting (30 minutes)

General Information

- Data Back to Center (DBtC) Overview – (10 minutes)
- Research Sample Submission – Instruction for network center staff who handle the collection of donor and recipient blood samples and submission to the CIBMTR Research Repository. (11 minutes)

Essential Form Series

- Baseline Form 2000
- Cellular Therapy Forms, Introduction and Submission – A high level overview of the CIBMTR Cellular Therapy data collection forms, and training for the data manager to know when to complete each one. (10 minutes)
- CRID 2804
- Form 2400 Pre-TED Module 1 (25 minutes)
- Form 2400 Pre-TED Module 2 (10 minutes)
- Indication for CRIB Assignment (Form 2814)
- Infusion Data (Form 2006) Reporting Overview
- Reporting Preparative Regimen on Pre-TED (Form 2400) and Baseline (Form 2000)
Additional CIBMTR Resources

- Data management Mentorship web page
- CIBMTR Training e-mail group

Need Help?

Email CIBMTR Training with any questions: cibmtrtraining@nmdp.org.
Polling Question

Would you be interested in taking staffing-related surveys in the future including future iterations of the BMT/Cellular Therapy Data Management survey? (CHOOSE ONE)

1. Yes
2. No
3. Maybe

Poll Results
Polling Question

Is there a time of year when you would prefer to take this survey? (CHOOSE ONE)

1. Winter
2. Spring
3. Summer
4. Autumn
5. Doesn’t matter

Poll Results
Polling Question

What is the best mode to communicate that a survey is available to take? *(CHOOSE ALL THAT APPLY)*

1. Email from the NMDP
2. Email from the ASBMT
3. Email from the CIBMTR
4. Notification on the ASBMT website
5. Notification via listserv (Administrative Directors, Quality)

Poll Results
Polling Question

What information is the **MOST valuable** to you from a BMT/Cellular Therapy Data Management coordination survey? *(CHOOSE ONE)*

1. Metrics regarding how the # of data management FTEs to support the CIBMTR report forms requirements.

2. Information about training materials, resources and/or reference materials – e.g. manuals and powerpoint presentations from Tandem meetings, etc.

3. Talking points to share with hospital administration when seeking support for our BMT Program.

4. None – I have a firm grasp of the data management role and feel efforts should be focused on additional staffing roles.

Poll Results
Polling Question

Will your BMT data management staff be responsible for submitting cellular therapy forms to the CIBMTR for all applicable cellular therapies performed at your center? (i.e. our BMT data managers will be solely responsible for submitting this information, and not additional staffing.) (CHOOSE ONE)

1. Yes
2. No
3. Undecided

Poll Results
Data Management Survey URL

- For those interested in completing the BMT/Cellular Therapy data management survey, please access the survey via the CIBMTR’s Data Management web page:

  http://sgiz.mobi/s3/BMTCA
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