Where Would You Rather Be?

Tandem

Minneapolis
Form Revisions
Retired Disease Forms

- Ovarian cancer (Forms 2023/2123)
- Rheumatoid Arthritis (Forms 2041/2141)
- Breast Cancer (Forms 2020/2120)
- Juvenile Idiopathic Arthritis (Forms 2042/2142)
- Systemic Lupus Erythematosus (Forms 2045/2145)
- Renal Cell Carcinoma (Forms 2027/2127)

Retired in January 2017
Forms Released in January 2017

Pre-TED Form 2400 has been split into 2 forms

- Form 2400 – Pre-TED (Part A)
- Form 2402 – Pre-TED Disease Classification (Part B)

This change was made to create a more flexible form

- Make updates to diseases more frequently in order to collect the most relevant data
- Lessen impact to users
Forms Released in January 2017

- Post-TED Form 2450 replaced the previous Forms 2450, 2451 (Chimerism Studies) & 2455 (Selective Post-Transplant Essential Data)
- CRF Follow-Up Form 2100 R4 replaced the previous Forms 2100, 2200 & 2300
  - Collects data at 100 days, 6 months & annually
- Visit ID will enable and disable certain fields that are only applicable at specific time points
Overview of TED Changes

Pre-TED

- AML and ALL subtypes have been updated with the newest WHO classifications
- Date of original MDS diagnosis will now be captured if the disease transformed to AML

Post-TED

- Cause of death options harmonized with F2900
- Subsequent transplant questions harmonized with F2100
- Recovery questions reformatted to harmonize with F2100
- Acute GVHD: Overall grade and organ stage at diagnosis added
## Overview of CRF Changes

<table>
<thead>
<tr>
<th>Chimerism</th>
<th>Acute GVHD</th>
<th>Chronic GVHD</th>
<th>Infection prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2 former sections have been merged into one</td>
<td>• Overall grade and organ stages are now captured at diagnosis, prophylaxis and treatment drugs have been updated</td>
<td>• NIH criteria is now captured at diagnosis of cGVHD</td>
<td>• Reformatted to capture the drug in each group that the patient received first and closest to the start of the preparative regimen, rather than any drugs given for prophylaxis</td>
</tr>
</tbody>
</table>
DCI Data Collection – Major Change

DCI Data has been removed from the CRF Follow-Up Forms and Post-TED

DCI reporting will be collected on the Cellular Therapy data collection forms (Forms 4000, 4006 & 4100)
# Future Form Revisions

## TED/CRF
- 2402 - Pre-TED – Disease Classification Section (Part B)
- 2400 - Pre-TED (Part A)
- 2000 - Baseline
- 2006 - HCT Infusion
- 2008 - HCT Canceled or Delayed

## Disease Forms
- 2046/2146 - Fungal Infection (FNG)
- New infection form – CMV/EBV/ADV/HHV-6
- New infection form – Respiratory Virus
- 2010/2110 - Acute Myelogenous Leukemia (AML)
- 2011/2111 - Acute Lymphoblastic Leukemia (ALL)
- 2018/2118 Hodgkin and Non-Hodgkin Lymphoma (LYM)

## Cellular Therapies
- 4000 - Pre-CTED
- 4006 - CT Infusion
- 4100 - Post-CTED
Participated in Forms Revisions

- Christine Gibson
- Connie Nelson
- Elizabeth Roberts
- Emmanuelle Polge
- Erin Coster-Mullen
- Gloria Rhyne
- Lisa Stoppenhagen
- Maria Kempner
- Meredith West
- Noemi Feliciano
- Becca Hulme
- Samantha McCormick
- Staci Williamson
- Tatiana Ochoa
- Theresa Amatucci
- Theresa Scoggins
- Yolanda Clay
Cellular Therapies
Pilot Study Update

Centers Participating

- Memorial Sloan Kettering Cancer Center
- Baylor College of Medicine Center for Cell and Gene Therapy
- Stanford Health Care
- Fred Hutchinson Cancer Research Center
- MD Anderson
- Abramson Cancer Center University of Pennsylvania Medical Center
- H. Lee Moffitt Cancer Center and Research Institute
- Duke University Medical Center

Number of forms submitted

- 216 forms (from both pilot/non-pilot centers)
October 2016 Cellular Therapy Forum

- October marked the 2nd annual CIBMTR Cellular Therapy Registry Forum
- Attendees from across the country representing the cellular therapy community, industry and regulatory groups
Day One of the Forum

Provided an overview of the cellular therapy world and where it is headed

Presentations from multiple centers on their practices

Updates from industry representatives such as Kite Pharma and Atara Biotherapeutics

Outline of the work being done by the FDA and FACT around cellular therapies
Day Two of Forum – Data Managers

Reviewed CIBMTR’s cellular therapy data collection initiative

Reviewed the cellular therapy data collection forms in detail

Gathered suggestions for the first revisions of the cellular therapy forms (Tentatively planned for summer 2017)
Participated in the Forum

- Gabby Rondon
- Romelia May
- Molly Maloy
- Ryan Hillgruber
- Erin Coster-Mullen
- Linda Elder
- Jessie Barnum
- Jen Baker
- Julie Chen
- Kathy Cunningham
- Elena Labovitis
Queries
Query (QRY) Status Code

• Query (QRY) status is for a previously submitted form that has errors and/or queries on it
• QRY, as part of the query functionality, will represent a form needing to be reviewed by the center
Pending (PND)

- PND represents a form awaiting review from CIBMTR
Process Overview

- CIBMTR staff initiates queries on completed forms when needed

- The center reviews each queried form question and works to resolve them

- The resolution submitted by the center is reviewed

- Once answers are approved, the form goes back to CMP status
Finding and Reviewing a Query

1. Navigate to the Center Forms Due page & search for forms in QRY status
2. Choose edit form
3. Collapse all sections
4. Search for and click the bubble to review the query
Reasons for Queries

• Each query will have a comment category put on by CIBMTR
Guidelines

1. This new functionality relies upon data managers searching for forms in QRY status

2. Try to check for new queries every week

3. Fewer emails will mean less reminders
   - Try to complete requests within the normal two week span
   - Take advantage of the “last update date” in the center forms due grid
Training
Training Releases in 2016

• Query Functionality
• eDBtC
• Research Sample Submission
• CPA
• MDS & MPN Reporting
• Multiple Myeloma – Part 1
• Multiple Myeloma – Part 2
NEW Online Training Webpage

• Replaces location of eLearning training modules that were in the NMDP Learning Center
• Accessible from cibmtr.org
• No account set-up
• Start eLearning by providing your name, email address and CCN

Online Training

Educational opportunities are continually being developed as part of our commitment to improving data quality and providing resources for data managers for data reporting to the CIBMTR. CIBMTR Training has implemented eLearning for easily accessible training which is available whenever needed (24/7). Here is our Course Menu:

Application Series

FormsNet3 Recipient Application Training (20 minutes)
FormsNet3 is the system we use to collect and store Recipient transplant data. The purpose of this training module is to familiarize the new user with FormsNet3 features and functionality. Access the eLearning here.

eDRBC Data Sharing (30 minutes)
The eDRBC application gives your center self-service access to comprehensive report form (CRF) and Transplant Essential Data (TED). This training shows how to set filters and use this enhanced version which replaces the original DRBC data retrieval application. Access the eLearning here.

Query Functionality (10 minutes)
CIBMTR staff have the ability to place a query directly on certain questions in FormsNet3 which allows the data manager to see immediately where queries need to be resolved. This training will demonstrate through video how to respond to an active query, ultimately saving time in the
Please Take My Survey
Clinical Research Professionals and Data Managers Surveys

• Clint Divine & Marie Matlack
• Last survey was done late 2008/early 2009
• Collect data to help answer questions that centers are asking
  – What is the ideal number of staff to complete CIBMTR forms?
  – How does my program compare to other centers for staffing, time needed to complete forms, etc.?
Administrative Tasks
CIBMTR Center Maintenance

We use SurveyGizmo as a tool to collect information about you and your centers.

We try to keep the surveys short and to pre-populate whenever possible to cut down on the amount of typing the respondent needs to do.

Usually just about your contact information - almost never a need to look things up.

Most surveys do not involve open-ended questions so they are quick to fill out.
Center Staff List Cleanup

- Center reports have been sent to current U.S. center primary contacts asking for any changes or additions.
- We would like to get a response to our survey so we can make necessary changes.
  - The link to the survey is on the top of the staff list report page.
- See who CIBMTR has on the list as data management staff at your center.
  - Is the list correct? Is anyone missing or extra?
  - Is the information we have correct vis-à-vis names and e-mails?
  - We will need that information in the near future to do our contact detail information cleanup.
- Non U.S. centers will be getting their reports soon.
Coming Soon!

Individual Contact Information Update

- Request for contact update from CIBMTR Center Maintenance to each person on the data management team at centers will be coming this spring
- A pre-populated survey showing what data we have now
- Corrections/changes can be submitted by completing the survey
A survey recently went out to all U.S. medical directors about current CIBMTR Portal application access. The survey asks:

- Is the current default access that staff has to CIBMTR Portal applications acceptable?
- What changes to staff access to the CIBMTR Portal applications would the medical director like us to make?

Based on the survey response, CIBMTR Portal application access will remain the same, or be modified (which could mean either expanded access would be granted or current access changed).
Questions