CRP/DM Tandem CIBMTR Hot Topics
Marie Matlack
February 11, 2015
HOT TOPICS
Radiation Injury Treatment Network (RITN)

Provides comprehensive evaluation and treatment for victims of radiation exposure or other marrow toxic injuries
Radiation Injury Treatment Network (RITN)

National Marrow Donor Program (NMDP)

American Society for Blood and Marrow Transplantation (ASBMT)

US Navy
Radiation Injury Treatment Network (RITN)

- Affiliated with the National Marrow Donor Program
- Network Composition
  - 72 total centers
    - 59 Medical Centers
    - Stem Cell Donor Centers
    - 7 Cord Blood Banks
RITN Goals

To develop treatment guidelines for managing hematologic toxicity among victims of radiation exposure

To educate health care professionals about pertinent aspects of radiation exposure management

To help coordinate the medical response to radiation events

To provide comprehensive evaluation and treatment for victims at participating centers
How does RITN affect you?

- New forms (November release)
  - Form 5000: RITN Baseline Form
  - Form 5001: RITN Follow-Up Form
  - Form 5002: Contact Form
- Updates to FormsNet
- Changes to the CRID (2804) Form (May release)
CRID Assignment Form (2804)

• Split into 2 forms
• Only collect enough details needed to create a CRID (e.g. name, date of birth, etc.).
• Collect institution-specific IDs, and other outcomes registry IDs
**CIBMTR Research ID Assignment Form**

**Key Fields**

- **CIBMTR Center Number:** (Select Center)

**Demographics**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. First name:</strong> (patient)</td>
<td></td>
</tr>
<tr>
<td><strong>2. Last name:</strong> (patient)</td>
<td></td>
</tr>
<tr>
<td><strong>3. Date of birth:</strong> YYYY-MM-DD</td>
<td></td>
</tr>
<tr>
<td><strong>4. Location of birth:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>5. Country:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>6. City:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>7. Sex:</strong></td>
<td>Male</td>
</tr>
<tr>
<td><strong>8. Social Security number:</strong> (not applicable for non-U.S. citizens)</td>
<td>DDD-XX-XXXX</td>
</tr>
<tr>
<td><strong>9. Patient's mother's maiden name:</strong> (optional for non-U.S. centers)</td>
<td>One hundred characters allowed</td>
</tr>
<tr>
<td><strong>Specify additional IDs assigned to this patient:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>10. Recipient NMDP ID:</strong></td>
<td>Seven characters allowed</td>
</tr>
<tr>
<td><strong>11. Recipient ID:</strong></td>
<td>Four characters allowed</td>
</tr>
<tr>
<td><strong>12. Team ID:</strong> (former CIBMTR #)</td>
<td>Four characters allowed</td>
</tr>
<tr>
<td><strong>13. Institution-specific subject ID:</strong></td>
<td>Fifteen characters allowed</td>
</tr>
</tbody>
</table>

Indicate all outcomes registries the patient's data is being reported to, and specify the subject ID.
Indicate all outcomes registries the patient’s data is being reported to, and specify the subject ID:

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
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<td>Specify outcomes registry:</td>
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<tr>
<td>15</td>
<td>EBMT Code (CIC): Five characters allowed</td>
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<tr>
<td>16</td>
<td>Specify other outcomes registry:</td>
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<tr>
<td>17</td>
<td>Recipient outcomes registry ID:</td>
</tr>
</tbody>
</table>

First Name: 

Last Name: qatest15

Email address: qatest15@nmdp.org

Date: 2015-02-05

CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program®/Be The Match® and the Medical College of Wisconsin.
Indication Form (2814)

- Captures why the CRID was created
- Completed when a CRID is created
  Completed when the indication changes
- Form will be included in CPI
Form 2814 R1.0: Indication for CRID Assignment

<table>
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<tr>
<th>Key Fields</th>
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<tr>
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<tr>
<td>Date Received: YYYY-MM-DD</td>
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<tr>
<td>CIBMTR Center Number: 10091</td>
</tr>
<tr>
<td>CIBMTR Research ID: 0003863612</td>
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<table>
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<tr>
<th>Indication Questions: 1 - 1</th>
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<tr>
<td>1. What is the indication for CIBMTR Research ID (CRID) assignment?</td>
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<tr>
<td>- HCT</td>
</tr>
<tr>
<td>- Cellular therapy (non-HCT)</td>
</tr>
<tr>
<td>- Marrow toxic injury</td>
</tr>
<tr>
<td>- Non-cellular therapy (e.g., chemotherapy, immunotherapy, etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hematopoietic Cellular Transplant (HCT) Questions: 2 - 5</th>
</tr>
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<tbody>
<tr>
<td>Specify the planned cell source(s) for this HCT:</td>
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<tr>
<td>2. Autologous:</td>
</tr>
<tr>
<td>- yes</td>
</tr>
<tr>
<td>- no</td>
</tr>
<tr>
<td>3. Allogeneic, unrelated:</td>
</tr>
<tr>
<td>- yes</td>
</tr>
<tr>
<td>- no</td>
</tr>
<tr>
<td>4. Allogeneic, related:</td>
</tr>
<tr>
<td>- yes</td>
</tr>
<tr>
<td>- no</td>
</tr>
<tr>
<td>5. Planned HCT date: YYYY-MM-DD</td>
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</table>

<table>
<thead>
<tr>
<th>Cellular Therapy Questions: 6 - 8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
Form 2814 R1.0: Indication for CRID Assignment

**Cellular Therapy**

- Planned infusion date: [YYYY-MM-DD]

- Indication for cellular therapy:
  - Autoimmune disease (600)
  - Cardio and peripheral vascular disease (700)
  - Musculoskeletal disease (720)
  - Neurologic disease (730)
  - Other disease (900)

- Specify other indication for cellular therapy: [One hundred characters allowed]

**Marrow Toxic Injury**

- Event date: [YYYY-MM-DD]

**Non-Cellular Therapy**

- Specify the disease for which non-cellular therapy was given:
  - MDS
  - Other disease

- Specify other disease: [One hundred characters allowed]

- Enrollment date: [YYYY-MM-DD] (date of consent)

- First Name:
- Last Name:

- E-mail address:

- Date:
CPI – Autologous HCT

January 2015

- Monitor autologous forms submission with the earliest complete date of December 3, 2007 through August 31, 2014

May 2015

- To meet CPI “good standing” criteria, 75% of the autologous forms with the earliest complete date of December 3, 2007 through December 31, 2014 must be submitted and completed

September 2015

- To meet CPI “good standing” criteria, 90% of the autologous forms with the earliest complete date of December 3, 2007 through April 30, 2015 must be submitted and completed
Registering Patients

• Crucial for Center Volumes Data Report and Transplant Center Specific Analysis
  – bloodcell.transplant.hrsa.gov
  – BeTheMatch.org
  – cibmtr.org

• Consecutive Reporting
  – Integrity of database
### My Work

#### Recipient Tasks

<table>
<thead>
<tr>
<th>Status</th>
<th>CRID</th>
<th>NMDP RID</th>
<th>IUBMID/Team</th>
<th>Event</th>
<th>Form</th>
<th>Visit</th>
<th>Group</th>
<th>Sequence</th>
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CIBMTR® (Center for International Blood and Marrow Transplant Research) is a research collaboration between the National Marrow Donor Program®/Be The Match® and the Medical College of Wisconsin.
"Work in Progress"
Outstanding Forms Due

• Met CPI (>90% but <100%)
• Need to submit outstanding forms
• Missing Forms Impact:
  – Transplant Center Specific Analysis
  – Center Volumes Data Report
  – Observational Studies
  – BMT-CTN Clinical Trials
  – KGF Study
  – CMS MDS study
  – Quality Assurance Reports
Print Icon on Form Track Row

<table>
<thead>
<tr>
<th>Status</th>
<th>NMDP RID</th>
<th>U8MID/Team</th>
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<th>Event</th>
<th>Form</th>
<th>Visit</th>
<th>Group</th>
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<th>Earliest</th>
<th>Due</th>
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</table>
Printing from Processing Page
Log of Appended Documents

Instructions for Log of Appended Documents
(Form 2800 – Revision 2)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Log of Appended Documents Form.

E-mail comments regarding the content of the CIBMTR Forms Instruction Manual to: CIBMTRFormsManualComments@nmdp.org. Comments will be considered for future manual updates and revisions. For questions that require an immediate response, please contact your transplant center’s CIBMTR-CRC.
Forms Instructions Manual

Future move to online, interactive manual management system

Features

- Interactive
- Searchable across manual sections
- Print individual pages or entire manual (or save as PDF)
- Cross browser (chrome, IE, Firefox), cross platform (computer, tablet, phone) support
- More timely updates
Additional information to come.

Roll out to include:
• eBlast
• Newsletter update
• “one sheet” reference
• eLearning Module

This is a development screenshot. Final manual may appear different.
Who is my center’s CRC?
As a transplant center administrator or data manager, you play a critical role in advancing hematopoietic cell transplantation through complete, accurate and timely data submission to CIBMTR. Your efforts are key in supporting the research that has led to increased survival and an enriched quality of life for thousands of patients.

Learn more about CIBMTR data submission and resources available to your center:

**Center Administrators**
- Center membership
- Administrative resources

**Data Managers**
- Data collection forms
- Training and reference
Contact a Clinical Research Coordinator (CRC)

A transplant center is assigned to either the Minneapolis or Milwaukee campus of CIBMTR for purposes of data submission and support. Each transplant center is also assigned a CRC from its assigned CIBMTR campus. CRCs answer questions not covered in the Data Management Manual or on this Web site, and provide additional assistance answering complicated questions.

CRCs also provide assistance with Continuous Process Improvement (CPI) compliance, study queries and data submission questions.

Information regarding your transplant center's CRC can be found by clicking: Look up your CRC.

To view PDF documents you will need Adobe Reader.
Identify your CRC by Center

Please enter your 5-digit CIBMTR Center Number here:

CCN

The CIBMTR center number (CCN) in the box above helps the system to match your center with your center's clinical research coordinator (CRC). It will need to be entered before you can continue.

Are you having trouble finding your center number?

- Yes, I need to look it up.
- No, I have it.

Next

0%
Identify your CRC by Center

Your center's CRC and contact information:

- Name: Drea Benoit
- E-mail: anbenoit@mcw.edu
- Phone: 414-805-0657
- Fax: 414-805-0714

Would you like this information e-mailed to you?

- No, this was all I needed.
- Yes, send it to me!
We hope this CRC lookup tool worked well for you.

If you have any comments you would like to share, contact us at cibmtr-centermaintenance@ndmp.org.

Thank you!
The CIBMTR Center Maintenance Team

Join the CIBMTR Training mailing list to get the monthly Data Managers Training Newsletter and breaking news about FormsNet3!

Scan the QR code above with a mobile device or go to the sign up form:
Click to sign up!
Opportunities

- Daily Evaluations
- Tandem Program Evaluations
- How else to participate or provide feedback?
- Contact CRC
- Mentor
- Forms Development
- Training Development