



CIBMTR[™]

CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

Dear Colleagues:

Please review and reply to this one time Amnesty Plan to reduce your CIBMTR data backlog by February 1, 2008, by faxing or mailing the enclosed Response Form.

The Stem Cell Therapeutics Outcomes Database (SCTOD) of the C.W. Bill Young Transplantation Program launch has brought significant changes for transplant centers, including the adoption of the NMDP's Continuous Process Improvement (CPI) for Forms Submission, which assesses and maintains standards for timely and accurate completion of required forms. As of December 3, 2007, this program now includes all new CIBMTR forms. To help you prospectively focus on data submission for the CIBMTR, we developed a plan to alleviate your burden of historic un-submitted data. The plan does NOT affect any cases involving NMDP facilitated HCTs. The research value of data already submitted to the CIBMTR will be preserved. The Amnesty Plan is a one time program that will NOT be repeated.

As of December 3, 2007, the CIBMTR began to apply CPI to related donor and autologous transplants in addition to the existing NMDP program for unrelated transplants. The CPI program will be phased in gradually over the ensuing 18 months, including an expectation that requested legacy data will be submitted for patients transplanted before December 2007 by then and maintained in a timely fashion thereafter.

All data, especially Comprehensive Report Form data submitted to the CIBMTR are essential to our research objectives as determined by participating scientific investigators. Complete, accurate and timely data results in complete, accurate and timely studies. Similarly, long-term follow-up is essential to research on late effects and to avoid biased outcome reporting

Most affected by this plan are your "backlogged" comprehensive research forms. The remainder of this document and attached spreadsheet outline the implementation details. Note: The attached "Forms Due" spreadsheet references the old CIBMTR form names, however please use the comparable new CIBMTR forms when submitting this data. The "forms due" status of these patients will also be conveyed in FormsNet[™] 2. It is important to note that Post-TED Forms will be due for recipients where research forms will no longer be requested.

As of December 3, 2007, you should have begun using the new Forms located at http://www.cibmtr.org/DATA/data_idx.html. Forms (including StemSoft submissions) already in process prior to that date will be accepted until January 31, 2008. After that date all outdated forms will not be processed and will be returned to you.

We appreciate your commitment to the CIBMTR and look forward to achieving our collective research and data reporting objectives. Following your review of the attached plan and spreadsheet, complete the attached response form as soon as possible. If you have questions, please contact Sharon Meiers by email at snell@mcw.edu or Jeanne Dobratz by email at jdobratz@mcw.edu.

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Medical College of Wisconsin
P.O. Box 26509, 8701 Watertown Plank Road
Milwaukee, WI 53226 USA
(414) 456-8325

3001 Broadway St. N.E. Suite 110
Minneapolis, MN 55413-1753 USA
(612) 884-8600



CIBMTRTM

CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH

Response Form

Acknowledgement of CIBMTR plans to revise data collection procedures for backlogged forms

Center Name:

Center Medical Director:

Center Number:

We have read and understand the attached revised data collection procedures. We agree with this plan, and will adjust our data submission accordingly. We understand that this plan will apply retrospectively to patients transplanted before December 3, 2007, and that all data requested prospectively by CIBMTR will be monitored by the Continuous Process Improvement Plan to maintain accurate and timely submission.

Signature of Center Medical Director (required):

Date:

Signature of Center lead Data Professional:

Date:

Please save a copy of this form, and return the original by mail or fax to:

CIBMTR
Attn Sharon Meiers
Medical College of Wisconsin
PO Box 26509
8701 W. Watertown Plank Road
Milwaukee, WI 53226

Fax 414-456-6165

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Medical College of Wisconsin
P.O. Box 26509, 8701 Watertown Plank Road
Milwaukee, WI 53226 USA
(414) 456-8325

3001 Broadway St. N.E. Suite 110
Minneapolis, MN 55413-1753 USA
(612) 884-8600



Submission Guidelines for Unsubmitted CIBMTR Forms:

1. CIBMTR will drop requests for all comprehensive Report Forms (RF) that have been requested for HCTs executed before December 3, 2007 except for the following:
 - a. Cases enrolled in CTN studies
 - b. Cases and controls in the Amgen KGF study
 - c. CIBMTR specific study request
 - d. Second HCT, or any subsequent HCT, where the first HCT was submitted on a Report Form.
2. CIBMTR will drop requests for all comprehensive Report Form Follow-ups (RFFU) except for the following:
 - a. CTN cases must maintain current RFFU and annually thereafter.
 - b. Patients in an active CIBMTR Study where follow-up has been requested must maintain current RFFU and annually thereafter.
 - c. Cases with multiple transplants, where first HCT was submitted on a Report Form must maintain current RFFU and annually thereafter.
 - d. Cases where a RF was submitted, or is still being requested, for an HCT that occurred in 1998 and thereafter must maintain current RFFU and annually thereafter.
3. CIBMTR requests that all comprehensive RFFU exempted in item 2 will have TED level follow-up (previously TEDFU now post-TED forms) submitted and maintained annually thereafter.
4. All CTN Teams, Registration or Research, are requested to meet these Registration track (TED level) data rules.
 - a. Pre-register all cases for both CTN and non-CTN patients from 2003 and thereafter.
 - b. Cases transplanted before 1998 and selected for the registration track only, a SELECTIVE TED FU must be maintained and annually thereafter. The SELECTIVE TED FU consists of the following fields:
 1. Death indicator
 2. Date of death
 3. Date of last contact
 4. New malignancy indicator and type
 5. Date of new malignancy
 6. Cause of death
 - c. Cases transplanted in 1998 or thereafter, a complete Post-TED must be maintained and annually thereafter.

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Medical College of Wisconsin
P.O. Box 26509, 8701 Watertown Plank Road
Milwaukee, WI 53226 USA
(414) 456-8325

3001 Broadway St. N.E. Suite 110
Minneapolis, MN 55413-1753 USA
(612) 884-8600



- d. Those patients that were pre-registered and on the registration track (e.g. not selected for report forms) that have not had a 100 day MTED submitted will not be required to submit an MTED. These cases will only require an ongoing annual Post-TED that covers the entire time since HCT. If any of the following conditions exist, then a Post-TED and an ongoing annual Post-TED will be required:
 - i. If the HCT was not performed
 - ii. The date of the HCT changed from the date submitted on the pre-registration.
5. All non-CTN Teams, Registration or Research, are requested to meet these Registration track (TED level) data rules, at a minimum.
 - a. As of December 3, 2007, please submit a Pre-TED for all cases. Any transplants that occurred prior to this date and were not pre-registered will not need a Pre-TED submitted.
 - b. Cases transplanted before 1998 and were selected for the registration track only, a SELECTIVE TED FU must be maintained and annually thereafter. The SELECTIVE TED consists of the following fields:
 1. Death indicator
 2. Date of death
 3. Date of last contact
 4. New malignancy indicator and type
 5. Date of new malignancy
 6. Cause of death
 - c. Cases transplanted in 1998 or thereafter, a complete Post-TED must be maintained and annually thereafter.
 - d. For Research teams only: Those patients that were pre-registered and on the registration track that have not had a 100 day MTED submitted will not be required to submit an MTED. These cases will only require an ongoing annual Post-TED that covers the entire time since HCT. If any of the following conditions exist, then a Post-TED and an ongoing annual Post-TED will be required:
 - i. If the HCT was not performed
 - ii. The date of the HCT changed from the date submitted on the pre-registration.

CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Medical College of Wisconsin
P.O. Box 26509, 8701 Watertown Plank Road
Milwaukee, WI 53226 USA
(414) 456-8325

3001 Broadway St. N.E. Suite 110
Minneapolis, MN 55413-1753 USA
(612) 884-8600

FAQ's from Centers: How to Read Amnesty Plan Spreadsheet?

Q: What do the headings on the Amnesty Plan Spreadsheet mean?

A:

Reason Request: This column provides some insight as to why a Report Form is selected as being due. For the Report Forms that you have due marked "SeqReq", the reason they are due is because they are for a subsequent transplant in which the first transplant had a Report Form previously submitted. If the column is marked with "Study," "KGF," or "CTN," that patient has been previously selected for a CIBMTR study, the KGF study, or is in a CTN protocol. These items are discussed more in the submission guidelines #1 & 2 of the amnesty letter.

Report Form Request: Utilizing the new forms, you will need to submit the baseline Form 2000 + disease specific insert + (INF + IDM + HLA when applicable) and 100 day report Form 2100 + disease specific insert as well as ongoing annual report form follow-up

Report Form FU Due: Denotes all patients who have a Follow Up Report Form that is currently due for the legacy data. The Report Form currently due will be available for data entry in FormsNet.

Report Form FU Will Due: Denotes all Follow Up Report Forms that will be due and will display as being due in FormsNet in the future.

TEDFU Request: This means that a Post-TED is due or will be due.

Selective TEDFU Request: A Selective Post-TED will be requested annually after completion of the first Selective Post-TED.

Q: Why do some of the patients listed on the spreadsheet have a Unique ID assigned, but no IUBMID?

A: Most likely the patient had multiple transplants and the IUBMID number is only listed for the first transplant.

Q: Why do some of my patients listed on the spreadsheet not have a Unique ID assigned?

A: If a pre-registration was received by the CIBMTR from October 8, 2007-January 31, 2008 a Unique ID wasn't assigned. Teams will receive the Unique ID's soon from their team liaison.

Q: I've already submitted a form that you are requesting. Do I need to submit it again?

A: Most of the amnesty plan spreadsheets were run on 12/11/2007, so if anything was received around that time or after, it isn't accurately reflected on the spreadsheet. Contact your team liaison with specific forms you are concerned about.

Q: I have completed a report form that has now been exempted by the Amnesty Plan. Should I still submit it?

A: The team should not submit the report form. They should complete the form that is being requested now. If a team does decide to submit a Report Form, they can be reimbursed for it, but only with the expectation that they will continue to send Report Form Follow Up (not post-TED) in the future to assure the value of that patient for research uses.

Q: I have submitted a TEDFU form recently and now you are requesting it again?

A: The 'TEDFU Request' column indicates patients that are both currently due and will be due. Please reference the last contact date we have on file to see if the form is currently due or will be due.

Q: I recently submitted a report form/TEDFU form on a patient and the spreadsheet says that the patient will be due?

A: Teams are now responsible to submit follow up forms on the anniversary date of the transplant. We will no longer reference the last contact date or when the last form was received to determine when the next form is due. Requesting follow up on the anniversary date is something that the NMDP has done previously and something that we need to do going forward as we implement CPI.

Q: I've reported a patient lost to follow up in the past, do I still need to submit the form that is being requested?

A: The team still needs to submit the Lost to Follow Up Declaration. The Lost to Follow Up Declaration will need to be submitted annually for the patient. If the patient is located through a CIBMTR search, they will then need to complete the form that is being requested.

Q: How soon do I need to submit these forms?

A: The forms need to be submitted over the next 12 months as we begin to phase in the CPI process.