
**INTERNATIONAL BONE MARROW TRANSPLANT REGISTRY
AUTOLOGOUS BLOOD AND MARROW TRANSPLANT REGISTRY**

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INSTRUCTIONS FOR COMPLETING THE

**2002 CORE Insert
2002 COREFU Insert
2002 DCI Insert**

Manual for Clinical Research Professionals

Effective Date: November 10, 2003

How to use this manual....

Section 1 - General Instructions for Submitting Data to the IBMTR/ABMTR

We strongly recommend reading Section 1 ***before*** completing any of the Inserts that make up the Report Forms to get an overview of the process and some specific criteria for data submission.

Section 2 - Specific Instructions for 2002 Report Forms

Section 2 contains specific instructions for each question based on the Core Insert question numbers. There is a table in Section 3 (Appendix K) which shows the relationship of questions between 002-CORE, 002-COREFU and 002-DCI Inserts. The purpose of this section is to make as clear as possible the exact data required and, where appropriate, explain why it is requested. You are encouraged to refer to these instructions frequently when first completing the Core Insert. However, due to the rapidly developing field of hematopoietic stemcell transplantation the "rules" given in this manual are subject to change. Please check the Web site periodically for updates to the manual.

Section 3 - The IBMTR Database -- Accessing Your Own Data

Your team's previously reported data can be E-mailed to you as a file. Section 3 describes the procedure for such requests and electronic reporting via Stemsoft software. Appendices to assist in reporting are included in Section 3.

WORKING WITH THE STATISTICAL CENTER

Statistical Center personnel are available during office hours (8:00 am – 5:00 pm, CST) to answer questions about completing the Reporting Forms. You may contact the Statistical Center by:

Telephone: (414) 456-8325, or Fax: (414) 456-6530, or E-mail: ibmtr@mcw.edu.

We appreciate your calls and are happy to assist you. Most questions are answered immediately. Please feel free to contact the Statistical Center often.

The information in the database is used for summary reports and statistical analyses of transplant issues.

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SECTION 1 – GENERAL INSTRUCTIONS FOR SUBMITTING DATA TO THE IBMTR

A. Abbreviations used:

BM = Bone Marrow
DCI = Donor Cellular Infusion
EBV = Epstein-Barr Virus
HSCT = Hematopoietic Stem Cell Transplant
IT = Intrathecal
LCD = Last Contact Date
NOS = Not Otherwise Specified
PB = Peripheral Blood
PCR = Polymerase Chain Reaction
PTLD = Posttransplant Lymphoproliferative Disorder
VATS = Video Assisted Thorascopic Surgery
VOD = Veno-occlusive Disease

B. What type of Team: ‘Registering’ or ‘Research’?

If your team is a ‘Registering only’ team you will not complete the comprehensive Report Forms referred to in this manual, unless participating in a specific study. However, you may find the information in this Manual helpful for completing the Registration documents (Pre-Reg/MTED, TED, or TEDFU.) Teams who agreed to complete the comprehensive Report Forms, as indicated when submitting Pre-Reg, are known as ‘Research Teams.’

C. Your Supply of Report Forms

PAPER Report Forms (see Appendix J)

Via the internet: download from <http://www.ibmtr.org>. Use the downloaded document as a master copy and make photocopies, double-sided only! Please check back to the Web site periodically to make sure you are using the most current version available. Version dates are found on the lower right hand corner along with the Form label (e.g. 002CORE (08/03).)

- 1) You must have the current Adobe Acrobat Reader software on your PC. A link to the Adobe homepage exists on our Web site.
- 2) From www.ibmtr.org
- 3) Click on the menu far left side, “Data Collection”
- 4) Click on the drop down menu, “Report Forms”
- 5) The Forms are organized by type of Insert. Click on the Insert you wish to print.
 - Core Inserts (Core/CoreFU)
 - Graft Inserts (Allo/Auto)
 - Disease Inserts, which are further grouped by disease type. Refer to Core p2-4 for diagnosis groupings.
 - Day 100 DCI Inserts
 - DCI Disease Supplements

Tips from the webmaster for obtaining the best print quality:

Uninstall any old Acrobat Reader version/s

Check that the latest version has correctly installed on the hard drive

Close (not just “minimize”) all other software programs

Re-boot the PC just prior to opening Internet browser

Printer must support PostScript output

By mail: request via the Fax Order Form (Appendix J). We process your request within 2-3 business days. The rest is up to the U.S. and/or your country's mail service.

ELECTRONIC Report Forms

Stemsoft software/BMTbase Reports:

If your Team utilizes Stemsoft software BMTbase Reports, please submit the Report Forms via disk (see Section III). If you must print out paper copies from the software, a double-sided copy would still be required.

D. Basic reporting “rules”

- 1) Make a double-sided copy before you begin.
- 2) Use ink, any color *except black* (color is easier for data entry staff to read) *or red* (the color we use to make corrections to your data.)
- 3) Print neatly and large enough for easy reading.
- 4) Use abbreviations cautiously. If you are not certain that an abbreviation is standard worldwide, define it at first use in the Report Form.
- 5) Before entering data to an “other, specify” field please make sure it does not fit into one of the existing options. Common options are listed and may just be an alternate term for the label used by your Center. Contact us if you have questions about properly classifying data.
- 6) Although data may seem to fit in a number of places, it is recorded only in the most specific question, e.g. interstitial pneumonitis (IPn) can be caused by an infection, however there is a question just for IPn. Even if the etiology is infective, do not report it in the infection section (see section II for more on reporting IPn.) One exception is hemorrhagic cystitis. If infective, report both in the “other complications” section and in the infection section.
- 7) When completing paper copies of the Report Form, your Team number and the patient IUBMID number must appear at the top of 1 side of each page. ***Time saving tip:*** you may apply stickers, or use a stamp, for this information.
- 8) When you have deemed the Report Form complete, make a copy for your own files. Single sided Report Forms will not be accepted. Double-sided pages sent to the Registry will reduce your mailing costs and our storage costs.

- 9) Mail paper Report Forms to the address below. Do not send to the "attention" of anyone, unless specifically instructed to do so. Mail not addressed to a specific Registry staff person is opened and processed immediately.

Statistical Center
Medical College of WI
PO Box 26509
8701 Watertown Plank Road
Milwaukee WI 53226

E. Assignment of Team and Patient Identification Numbers

TEAM identification

Each team is assigned a Team Number upon receipt of the first completed Pre-Registration or TED Form.

Patient identification (IUBMID/UPN)

Institutional Unique Blood/Marrow transplant **ID**entification number (**IUBMID**) is the same as Unique Patient Number (UPN) and is assigned by your Team. Consecutive Report Form identification numbers (FORMID, ibmtrID, ALLOID, abmtrID, AUTOID) are assigned at the Statistical Center. Each transplant team is required to assign one consecutive IUBMID number to each HSCT patient. Your first patient receiving HSCT is given the number 1, the second HSCT patient is assigned number 2, etc. If your Team is a Research Team, IUBMID numbers may be assigned up to two weeks prior to the start of pretransplant conditioning.

Patients who receive at least the first dose of conditioning, but do not complete the transplant process (no infusion received) must also be given an IUBMID number and registered even though the transplant is not performed. Through random selection these patients may also be selected for a 'FORM DUE.' Notify us via MTED if a Pre-Registered patient does not receive ANY conditioning (radiation or drugs) and the transplant process is stopped or postponed

Each patient is assigned only one number. Do NOT assign a new number for subsequent transplants/infusions for any reason.

If the patient has had a prior transplant, allo or auto, at some other Center, and your Center is performing a subsequent TX/infusion you may still assign an IUBMID. Please send basic information regarding the details of the last prior transplant so that we can determine if the patient already exists in the database. If not, we will need you to submit a Pre-Reg/TED for the prior TX even though your Team did not perform it.

Patient confidentiality is an extremely important issue; as a result names/initials are no longer collected by the Registry. The IUBMID/UPN has become the primary means to identify patients for communication between the Registry and your Center. Re-numbering patients should NOT be done without explicit permission from the Registry. If for example, a patient is overlooked during the Registration process, when discovered they should be assigned the next available number. Attach a brief explanation documenting why the patient appears "out of order." Re-numbering is a very time consuming process for both your Team and the Registry. Please DO NOT re-number your patients once the numbers are assigned and submitted.

EBMT Centers: list the same number for IUBMID that you submitted to EBMT as UPN.

You may obtain a list of patients reported by your team by contacting Sharon K. Nell, Clinical Studies Coordinator, at the Statistical Center (snell@mcw.edu).

F. Reimbursement

For current reimbursement rates, please contact the Clinical Studies Coordinator, Sharon K. Nell (snell@mcw.edu).

G. Timely Submission of Report Forms

Each Report Form, whether Day 100, DCI, or Follow-up, represents a distinct block of time. Please be aware of what time period the Report Form represents before entering data to that Form. Refer to Appendix A for some sample transplant scenarios and the corresponding Report Forms to complete.

The Day 100 Report Form should be submitted as of day 100 posttransplant for living patients, or at time of death for patients who expire <day-100. The cut-off of day-100 was chosen to allow for adequate posttransplant follow-up to evaluate recovery of hematopoiesis and early transplant-related complications. Reports of living patients less than day 100 posttransplant, who have not had a subsequent reportable TX/infusion, are not acceptable and will be returned for updating. If a Report Form was not completed on day-100, and the patient has past the one-year transplant anniversary, still complete the initial Report Form as if it were day 100 and complete a Follow-up Report Form for the remainder of time. Thus, if the Report Form is being submitted two years posttransplant, submit an initial Report Form covering the first 100 days and one Follow-Up Report Form from "day 101" to the second year transplant anniversary. Please refer to Appendix A for time line diagrams representing possible transplant scenarios. Contact Diane Knutson dknutson@mcw.edu for questions regarding which Report Form to complete with what cut-off date. Be prepared to provide dates indicated on the timelines.

H. Date of Report (DOR)

The DOR should represent the date the form was deemed accurate, complete and ready to send. It has nothing to do with day 100 unless you are capable of filling out the form, checking for accuracy/ completeness and sending the form on day 100. Please check that 'date last known to be alive' or 'date of death' (page 1, Core Insert) and dates of other posttransplant entries precede DOR. All of the pieces (Core, Graft and Disease Inserts) that make up a Report Form representing a given transplant should have the same DOR even if the Inserts are not completed on the same day. The DOR should be recorded in the upper right corner of each of the Inserts for a given transplant Report Form.

If a patient receives more than one HSCT (CORE Insert p15/34) or DCI (CORE Insert p16/35), an additional 2002 version Report Form is required for each transplant/infusion. If two transplants are performed, *all information* reported for the first transplant (including date of survival) must be before the *date conditioning starts* for the second transplant (or 1 day prior to the infusion if no conditioning was used.)

Follow-Up Report Forms should be completed annually as of the latest transplant date. If more than two years of data are available for reporting, complete just *one* Follow-Up Report Form for *all* of the data (unless another reportable transplant/infusion occurred). Copy any page with more than one episode of a given complication to record the episodes separately.

I. Missing Data

If data are unknown, not tested, lost, or otherwise unavailable, please indicate as such. If no tick box option exists on the Report Form, please make a notation in the margin of paper Report Forms or on the "Report Notes" page of Stemsoft/BMTbase software. The Statistical Center must contact transplant teams regarding each unanswered or insufficiently answered question (including those that are illegible). Leaving answers blank delays processing of the Report Form, as well as reimbursement and, most importantly, delays getting complete and accurate information into the database for analysis. Any questions leading into a box with a series of 'yes/no' tick boxes must have each line completed 'yes', 'no', 'unknown', etc. Do not tick only 'yes' boxes and leave the rest blank, as the unanswered lines will be flagged as an error. Time saving tip: have another person scan completed forms for unanswered questions prior to sending.

J. Reporting Data for Patients On Double-Blind Studies

Questions in the Report Form may request information regarding specific drugs administered. If a patient is treated as part of a double-blind study such that the specific drug received is not known at the time a Report Form is submitted, please indicate the patient is "on a study." When the study is over, update the Report Form to show what was received (which drug or placebo) and forward the data as an "unrequested correction" (unless responding to an Error Report.) Patients receiving placebo will be corrected from "yes" on a study to "no, drug not received."

K. Units of Measurement

PLEASE pay careful attention to units requested and report appropriately. In general, values are requested as a concentration. If your institution records measurements in units other than those requested, please convert before entering (see Appendix F of this manual). Under NO circumstances should unit be crossed out on the Report Form and modifications made or additional boxes added. Values entered to the database are understood to be in the unit/s as printed on the Report Form. If you believe there is a unit error, please contact us and send an example from a patient chart that highlights the error.

L. Reporting Dates

All dates are to be reported as Month-Day-Year. If you are not accustomed to writing dates in that order please take care when filling in dates. A date written as 18-12-1999 is easily understood to really be December 18, unless the "2" is a typo and the date actually was October (10-18-1999) or November (11-18-1999). A date such as 05-07-1999 is not obviously July 5. That is one reason we won't make an assumption. A date written in an order other than Month-Day-Year will probably be recorded as an error.

It is also important to be careful about the chronology of the dates being reported. For example, 'date of birth' must precede 'date of diagnosis', which must precede 'date of transplant'. These three dates are often reported incorrectly, due to simple typos. For infants diagnosed in-utero, report the date of diagnosis as the date of birth. You may make a "comment" that the actual diagnosis was made in-utero. Computer checks usually detect these errors, however, clarification of questionable dates with the transplant team delays processing the Report Form, as well as reimbursement.

Be particularly careful when reporting dates for transplants that are performed at the end of a year; e.g. October to December. It is not uncommon for post-transplant events (dated January to March) to be reported as the same "year" as the pre-transplant information (the previous year).

The Inserts that make up a Report Form often divide the data collected according to what occurred at diagnosis, between diagnosis and the start of conditioning, just prior to the start of conditioning (within two weeks) and postconditioning. Copying the transplant timelines found in Appendix A, and noting important dates from the patient's record may help sort out what data belongs in which section of the Report Form.

M. Conditions Reported In Multiple Sections

When describing events, such as "abnormal pulmonary function," please only report the event in the most appropriate section, that is, where the question is most specifically asked. For example, bacterial pneumonia should be reported in the Infection Section, Q.442 CORE Insert, rather than in Qs.498 or 509, regarding "other pulmonary abnormalities", which is less specific. For this reason, we suggest you familiarize yourself with our Report Forms before completing them.

Exceptions include:

- 1) Infectious hemorrhagic cystitis will be collected in the appropriate infection question and the "other complications" section
- 2) Therapy to treat the patient's disease received within two weeks of transplant may be collected in the Disease Specific Insert and the conditioning section of the CORE Insert
- 3) Chemotherapy given to prime the patient prior to cell collection will be recorded in both the Graft and Disease Inserts.

N. Submission of NMDP Report Forms

The IBMTR has worked cooperatively with the National Marrow Donor Program to develop data collection forms that are as similar as possible. The IBMTR 2002 series Report Forms parallel NMDP Forms, e.g. Form 120, 130, 140, etc. You may submit copies of NMDP Report Forms instead of completing the entire 2002 Report Form. However, information about the donor and other items not requested by NMDP are needed by IBMTR.

To submit a copy of the NMDP Form in lieu of a 2002 IBMTR Report Form please follow these directions:

- 1) Once the patient's NMDP Form is accepted by NMDP as *error free*, make a photocopy of the completed NMDP Form with the pages double-sided.

In lieu of the CORE Insert:

- a. NMDP Form 120 – Recipient Baseline and Transplant Data
- b. NMDP Form 130 – Day 100 Form

In lieu of the Disease Insert

- c. NMDP Form 120 – Disease Specific Insert for appropriate disease.
- d. IBMTR Graft Insert (based on the tissue transplanted – no corresponding NMDP document available.)

In lieu of the Follow-up Report Form

- e. Form 140 – 6 Month to 5 Year Follow-up (as applicable)

- f. Form 150 – Greater than 5 Year Follow-up (as applicable)
 - g. Form 190 – Death Record (as applicable)
 - h. IBMTR-NMDP Supplement – not available at this time.
- 2) To the double-sided photocopy for the Registry, make any correction identified by NMDP or through your own correction process. Do NOT attach the ‘NMDP correction pages.’
 - 3) At the top of Forms 120, 130, 140, 150 and 190, clearly print the patient’s IBMTR IUBMID number.
 - 4) If the patient has a subsequent HSCT or DCI that NMDP does not collect as a separate event, but IBMTR does, you must complete a 2002 Day 100 Report Form or DCI Report Form for that subsequent HSCT/DCI. Follow-up reporting would then be based upon the date of the most recent HSCT/DCI.
 - 5) Only NMDP version May 1995 or later will be accepted
 - 6) Reimbursement for NMDP copies is less than for 2002 Report Forms. Contact Sharon Nell for current reimbursement rates.

O. Error corrections and Error Reports

To correct errors discovered by your Team, prior to identification by the Registry, please make the correction to the involved page, initial, date and circle the correction. At the top of the page write “**unrequested correction**” (as it was not requested by the Registry). Make sure your correct Team Number and patient IUBMID number appears at the top of the page, as well as any other HIPAA appropriate identifier you choose (NOT patient name), and submit via whatever method you choose.

When your Report Form is processed the Data Entry Specialist may identify errors, e.g. missing fields, date sequence errors, etc., which will be noted on Report Notes. Before the Report Form is added to the database, additional computerized data consistency checks are performed.

Periodically these errors will be compiled into an **Error Report** and sent for corrections. When a new version of the Report Form Insert is released, there may be a lag between the question numbers on the Error Report representing the new version you completed and the old version question numbers that may appear on the Report. If the question numbers on your new version Insert do not seem to match the question numbers on your Error Report, please check a copy of the version just prior to the one submitted and see if that resolved the problem. For example, if you submitted an 002-CORE Insert, you may receive an Error Report with question numbers referring to the 095-CORE Insert. We regret any inconvenience this may cause. One other explanation for questions numbers not matching up is submitting a copy of an NMDP Report Form. Our data entry staff tries to designate the Error Report questions as “NQ” for NMDP Question numbers. If there is any error on the Error Report that you do not understand, please contact us.

P. Who Follows the Patient?

If a patient transplanted at your center has another HSCT or DCI at another center, your responsibility for reporting, both Registration and Research Report Forms, ends one day prior to conditioning for HSCT or one day prior to infusion for DCI. Provide contact information at the new transplant center, so that we may request that they continue reporting where you left off.

If your center is providing follow-up care for a patient transplanted elsewhere, and your Team does not provide another HSCT or DCI, you will need to send follow-up data to the Team that did the transplant. You are not responsible for reporting directly to the Registry.

Who Can Help ???

IBMTR
ABMTR

Statistical Center

International Bone Marrow Transplant Registry
Autologous Blood & Marrow Transplant Registry

*Medical College of Wisconsin,
Post Office Box 26509,
8701 Watertown Plank Road, Report and Follow-up Forms
Milwaukee, WI U.S.A. 53226 now available online at:
Office: 414.456.8325 • Fax: 414.456.6530 • Website: www.ibmtr.org*

The logo for the Medical College of Wisconsin features a stylized book icon above the text "MEDICAL COLLEGE OF WISCONSIN".

Q. Who Can Help?

Mark Reitz, MS
Program Director/Data Operations 414-456-8137 reitzm@mcw.edu

***Reimbursement, Non-medical Registration/BMT
Clinical Trials Network/Report Form questions?***

Sharon K Nell
Clinical Studies Coordinator 414-456-8364 snell@mcw.edu

Medical Registration and Report Form questions?

Diane Jacobi Knutson, BS
Sr Research Associate 414-456-7557 dknutson@mcw.edu

***Non-medical Registration/Report Form questions,
specific study requests?***

Sarah C Mull, BS
Clinical Research Coordinator 414-456-4647 smull@mcw.edu
Amy Prentice
Clinical Research Coordinator 414-456-5776 aprecede@mcw.edu

Statistical Information requests? info-request@mcw.edu

HIPAA and Compliance issues?

Seth Ketelsen, MA
Clinical Research Coordinator 414-456-8397 sketelse@mcw.edu

Conference questions?

D'Etta Waldoch, CMP
Associate Director, Int'l Programs 414-456-8377 dettawaldoch@cs.com

Audit questions? CIBMTR-audit@mcw.edu

TED on the WEB questions? tedweb@mcw.edu

Submit Registration data? ted_data@mcw.edu

***CIBMTR Clinical Research Associates Mentoring Committee?
- Mentoring Mailing List Signup?*** www.datamanager.blogspot.com
ibmtr-crp-dm@hpi.mcw.edu

General CIBMTR questions? cibmtr@mcw.edu

Software questions (BMTted, BMTbase, BMTserve)?
Stemsoft Software Inc. 800-671-3234 support@stemcell.com

SECTION 2 – SPECIFIC INSTRUCTIONS FOR 2002 REPORT FORMS

Regarding comments written in the margin or Stemsoft ‘Report Notes’: Please try to find the most appropriate section in the Report Form to record data rather than writing notes. However, if an appropriate question is not apparent (e.g. you wish to explain why a patient is lost to follow-up) attach a sheet or use ‘Report Notes’ to provide concise information. Some patients present a challenging picture to record. If the information in this manual does not clarify how to answer a given question please consider consulting with the physician that took care of the patient at your Center, who may readily know which tick box is most appropriate. The transplant physician must sort out any conflicting information found in the patient’s chart prior to submitting the Report Form.

Use of abbreviations: According to Neil M. Davis, author of Medical Abbreviations: 24,000 Conveniences at the expense of Communications and Safety, 11th ed. “Abbreviations are a convenience, a time saver, and a way of avoiding the possibility of misspelling words. However, a price can be paid for their use. Abbreviations are sometimes not understood or are interpreted incorrectly. Their use may lengthen the time needed to train individuals in the health fields, at times delays the patient’s care, and occasionally results in patient harm.” The number of abbreviations has increased exponentially (7,000 listed in the 5th edition 1990, 15,000 in the 10th edition and 24,000 in the current, 11th edition.) Please interpret and record abbreviations carefully. If your Center has a list of commonly used abbreviations please send it to us. If not, define abbreviations at first use in each Report Form, unless you see the abbreviation used in our Report Forms.

ABBREVIATIONS

BM	= Bone Marrow
DCI	= Donor Cellular Infusion
EBV	= Epstein-Barr Virus
HSCT	= Hematopoietic Stem Cell Transplant
IT	= Intrathecal
LCD	= Last Contact Date
NOS	= Not Otherwise Specified
PB	= Peripheral Blood
PCR	= Polymerase Chain Reaction
PTLD	= Posttransplant Lymphoproliferative Disorder
VATS	= Video Assisted Thorascopic Surgery
VOD	= Veno-occlusive Disease

CORE Insert (page 1)

TEAM: Your team number is the same number used for Pre-Registration. If there are any questions regarding what your team number is please contact the Registry for assistance.

Institutional Unique Bone Marrow Transplant Identification Number (IUBMID): The IUBMID is NOT the patient's hospital or clinic number, nor is it the Registry ID. Each participating transplant team is required to assign consecutive numbers to its *consecutive stem cell transplant* patients. Thus, your first patient receiving a transplant is given number 1, the second transplant patient is assigned number 2, etc. Each patient must have a single IUBMID to be eligible for entry into the Registry database. Please do not assign a second IUBMID if a patient receives a second transplant. Use the same IUBMID for subsequent HSCT/DCI.

Numbers should be assigned at or before the time pretransplant conditioning is started. Patients who start the conditioning regimen (receive even just one dose), but who die during conditioning or choose not to proceed with the transplant, must be assigned an IUBMID and be registered even though the transplant is not performed. This system helps the Registry make certain that there is no selective reporting of cases, and helps you make certain that you have not forgotten to report a patient. If your program already has a consecutive numbering system, these numbers may be used for IUBMID's even if numbering begins with patients transplanted before January 1989. In those circumstances, the first patient on the registration form will have an IUBMID greater than 1. If your program does not currently have such a system, consecutive numbers must be assigned to all patients transplanted on or after January 1, 1989. Due to HIPAA regulations, the IUBMID must not include any letters or numbers directly identifiable with the patient (e.g. initials, medical record, social security or other identifiable numbers).

IF YOU HAVE ANY QUESTIONS
REGARDING ASSIGNMENT OF IUBMID's,
PLEASE CONTACT THE STATISTICAL CENTER (snell@mcw.edu)

To aid in handling data, your IUBMID may be modified and entered into the IBMTR database as a 6-digit number. For example, **0107** (just the consecutive number) = **000107**; **9201** (year of TX plus the consecutive number) = **920001**; **A002** = **A00002**; **IMS9** = **IMS009**, etc. This will be apparent when you receive reports back from the Registry summarizing your cases.

Registry (circle one): IBMTR = the graft source is not the recipient

ABMTR = the graft source is the recipient

Demographics*

*** If this is a report of a second (or subsequent) transplant check here complete Disease Insert and go to Q.13. If the prior transplant was autologous and the subsequent transplant is allogeneic go to Q.12.**

- 1. Date of HSCT (or first DCI) for which this form is being completed:** If there is only one infusion this question is not complicated. Report date of the first HSCT/infusion of bone marrow, blood stem cells, or other cellular therapy. Please note the order of the date: **month, day, year**. If the HSCT or DCI takes place on more than one day, the rules for “multiple infusions” for a single HSCT or DCI are as follows: HSCT – additional infusions after fourteen days may constitute a **subsequent transplant** and should be recorded on pgs 15 & 34. After completing the questions on the appropriate page it should be clear whether a subsequent initial Report Form is required. If required, a separate Pre-Registration should also be completed. DCI – additional infusions after twenty-eight days constitute a **subsequent DCI** and should be recorded on pgs 16 & 35, as well as a separate Pre-Registration and DCI Report Form. **Please note:** There are no separate Disease Inserts for DCI Report Forms. Please substitute the word “infusion” for “transplant” and complete the “date of transplant” on the Disease Insert. Also substitute the word “infusion” for “conditioning” in ‘just prior to conditioning’. (see Appendix A)
- 2. Date of Report (DOR):** The date the Report Form was deemed complete and ready to send. All dates reported within the Report Form must be no later than the Last Contact Date, which should be prior to DOR, unless your Center is able to see the patient and complete the entire report Form on the same day. The same DOR must be used on all three of the Inserts that make up a Day-100 Report Form and is entered on the upper right-hand corner of CORE Insert pg 1, Graft Insert and Disease Specific Insert. After the completing the Report Form and DOR, if sending a hard copy please send a double sided version to the Registry (see Section 1-A). Whether sending a hard copy or electronic Report Form, we suggest retaining a paper copy for your files as well.
- 3. Day 100 posttransplant:** From the date of HSCT for which this form is being completed count 100 days (approximately three months plus ten days). A quick and accurate tool for calculating d100 is a “graphic date finder/scheduler”, which may be purchased from Graphic Calculator, 234 James Street, Barrington IL 60010, <http://www.slide-chart.com/> or use the table provided in Appendix B.
- 4. Date of last actual contact (LCD) with patient to determine medical status for this report:**
Patient is alive
 - If the patient was alive up to this date without a subsequent reportable HSCT/infusion please be aware that data in this Report Form should encompass at least up to Day 100.
 - Date of last actual contact with patient to determine medical status for this report should be based upon physician contact, which includes the transplant center, referring physician, or other physician currently assuming responsibility for the patient’s care.
 - If an evaluation was not actually performed on Day 100 by the transplant center or the physician assuming the patient’s care, choose the *next later* visit as close to this date as possible.

- Information after the last contact date for this Report Form should be recorded on a Follow-up Report Form or subsequent HSCT/DCI Report Form, as applicable.
- Questions referring to “current” data should be interpreted as “current for the reporting period represented by the Report Form.”

Patient is dead

- If the patient expired prior to Day 100 answer all post-HSCT questions *up to the date of death* (e.g. it is understood that therapy is discontinued at death, but was therapy being received up to the time of death?)
- If complications were not documented prior to death but are identified at autopsy, *complete the appropriate section in the Report Form. Record the ‘date of onset’ as the date of death, because the actual date is not known.* Do not record the date of the autopsy as the date of onset (as the database will reject any dates occurring after death) and do not arbitrarily assign a date prior to death as the date of onset.
- The Report Forms represent a timeline of data and death should only be reported in only one Report Form, the last Form submitted. The LCD in that final Form will also be the date of death, even if the patient was not in a medical facility at the time, it is assumed a physician made the determination. We do not need to record the last date the transplant center had contact with the patient.

5. **Institutional protocol number:** This field is for your team to track the patient by any means you wish, as long as it is HIPPA compliant (no patient identifiers are allowed). There are no right or wrong answers to the field and it may be left blank.
6. **Patient Sex:** Check box to indicate male or female.
7. **Date of Birth:** Please note order: **month, day, year (mm/dd/yyyy)**.
8. **Ethnicity:** Indicate whether the patient is Hispanic, Latino, neither or unknown. This question was recently added due to U.S. governmental regulations. The OBM has defined ethnicity as culturally or geographically defined, and race as inherited genetic characteristics. Data collection tip: At the meeting to obtain consent for transplant, include Qs8 & 9 with the questions on pgs 37/38 on a separate sheet and ask the recipient to provide the answers.
9. **Race:** Check one box only to indicate patient race, unless patient was bi-racial, then check both (use “other, specify” if the software does not allow two entries). Report race in the groupings provided (e.g. “Caucasian: European or Western Russia”), rather than ethnic group (e.g. “German” or “Italian”). Report Maori or Noumea as ‘Asian/Pacific Islander-Oriental, not otherwise specified’. The groupings are based upon the recommendations of the National Marrow Donor Program.
10. **Race – Other, specify:** If the patient’s race cannot be classified into one of the options given, check “other” and list the “other race,” but do not specify Hispanic or Latino, as per Q8.

Disease

- 11. What was the primary disease for which HSCT was performed:** Most patients have only one diagnosis (DX) and that is what will be recorded in Q11. The sub-disease type may be recorded here or in the Disease Insert. For instances where the patient has more than one diagnosis it is imperative to report the diagnosis for which the patient is receiving the HSCT (the disease present just prior to the start of conditioning). A few common examples of concurrent/transforming diseases are:

<u>Initial DX</u>	<u>Code group</u>	<u>PreTX DX</u>	<u>Code group</u>	<u>Complete Insert:</u>
MDS	50's	New MDS subtype	50's	MDS
MDS	50's	AML*	10's	MDS: stop at AML DX. AML: entire Insert Follow-Up: AMLFU
Fanconi anemia	311	AML, ALL, or MDS	10's, 20's, or 50's	Both
LYM	100's	Different LYM subtype	100's	LYM
MYE with AMY	170's/174	MYE with AMY	170's not 174	MYE

If there is any uncertainty about which of the diagnoses to report or if the diagnosis type is deemed code 900, please fax (414-456-6530) the pathology report of each diagnosis to the Registry, and request assistance. There will be separate Manuals for the Disease Specific Inserts.

*Note: MDS patients that transform to AML any time prior to HSCT, for *reporting purposes* will remain as “transformed from MDS-AML patients”, even if according to the chart the AML appears to be under control and the physician describes the status of the MDS. If the blast count becomes >5%, report as AML relapse. These patients are analyzed as a separate group from the MDS patients and the AML patients.

Less obvious diagnosis and corresponding Disease Insert:

(30) Other Leukemia, [subtype] unknown	AML
(31) Acute undifferentiated leukemia	AML
(32) Biphenotypic, bilineage, hybrid leukemia	AML
(33) Acute mast cell leukemia	AML
(38) AML stem cell (M0, undifferentiated)	AML
(39) Other leukemia, specify	AML
(35) Hairy cell leukemia	CLL
(37) PLL Prolymphocytic leukemia	CLL
(36) Juvenile CML	JMM
(69) Chronic eosinophilic leukemia	MDS
(119) Castleman disease	LYM
***(227) PNET primitive neuroectodermal tumor	CNS
***(217) PNET peripheral neuroepithelial tumor	SAR
(900) HD + NHL simultaneously	LYM

Clinical Status Of Patient Prior To Conditioning*

***If no conditioning was used due to the diagnosis (e.g. SCID,) subsequent HSCT for engraftment problems, or when completing Disease Inserts for DCI, please substitute "just prior to HSCT/DCI" for "just prior to conditioning."**

12. **Allografts only: Patient's blood type:** Check the box that describes the combined ABO and RH type. If the first transplant was autologous and this is a subsequent allogeneic transplant please answer this Q (*even though you were instructed to skip it*).
13. **Functional status of patient prior to conditioning (Karnofsky/Lansky):** If the patient is aged 1-16 years, please use the Lansky Play-Performance Scale for Children. If performance status is not quantified in the medical record, it is acceptable to ask the responsible care provider, or interpret details recorded in the chart about energy level, work status, time spent in bed, and activities of daily living to assign a value. Please note that the following numbers are the only valid values for the performance scales: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100. Zero is not valid for this Report Form, nor are values not ending in zero, such as "85" (see Appendix D).
14. to
58. **Was there clinically significant coexisting disease or organ impairment anytime prior to conditioning?** This refers to serious pre-existing conditions unrelated to the patient's disease or treatment. Examples of significant coexisting diseases include diabetes mellitus or rheumatoid arthritis (and the transplant is not for rheumatoid arthritis). ANY history of malignancy, other than the disease for which the patient is being transplanted, should be reported (and may also be reported in the Disease Insert.) Do not report conditions that are completely resolved and unlikely to be of importance during or after the HSCT, e.g. appendectomy from 15 years ago. Please use the most specific category available. Note: version 095-Core:Q63, regarding 'history of liver disease,' has now been included in this section (see Appendix E).

Organ Function Just Prior To Conditioning

These labs create the pretransplant baseline for monitoring the clinical status of the patient postconditioning. Report the *last labs taken prior to starting* any chemotherapy or radiation *from the preparative regimen*. This may be the same day as the start of conditioning as long as the labs were drawn *before* the patient received any chemo or radiation. By providing the 'upper limit of normal' for your institution, patients can be compared by calculating the percent of upper normal during analysis. Examples of normal ranges shown in [brackets] are cited from NEJM SI Unit Conversion Guide, 1992 and may differ from your institution. *Please note the units listed and select the appropriate unit box. If the unit on your lab report is not among those listed please check Appendix F for alternate units and conversion formulas. Convert the value to a unit listed before recording the value and unit. If you have any difficulties with the conversion please contact the Registry.

59. **AST (SGOT):** (aspartate amino transferase or serum glutamic oxalic transaminase) is an enzyme measured in serum or plasma that reflect liver function and liver cell integrity. Elevated levels indicate disturbed functioning (0 - 35 U/L, 0 - 0.58 ukat/L).

60., 63., 66. &

- 69.** **Date tested:** must be prior to the date reported in Q107. The lab values ideally should be within two weeks of the start of conditioning.

61., 64. &

- 67.** **Upper limit of normal:** From the laboratory report indicate the higher value from the stated normal range.

- 62.** **Total serum bilirubin pretransplant:** Bilirubin is an orange-red pigment formed from hemoglobin during destruction of erythrocytes by the reticuloendothelial system; in the presence of liver disease or excessive destruction of red blood cells. Accumulation of bilirubin in the blood and tissues causes jaundice, a yellow appearance to the skin and/or eyes. Total bilirubin includes the direct and indirect bilirubin count. If your lab report lists direct and indirect separately, you must add them together to report the total (0.1 - 1.0 mg/dL, 2 - 18 umol/L).

- 65.** **LDH:** Lactate dehydrogenase, an enzyme that breaks down L-lactate into pyruvate, is found in the cytoplasm of almost all tissues (50 - 150 U/L, 0.82 -2.66 ukat/L). “Kat” is an abbreviation of katal, a non-S.I. unit of enzyme activity. For some diseases, high levels indicate active disease, e.g. Lymphoma, Multiple Myeloma.

- 68.** **Serum creatinine pretransplant:** Creatinine is a normal metabolic waste excreted in the urine, primarily by filtration. Since it is generally produced at a constant rate, the clearance rate and the serum level are widely used as an index of kidney function [0.6 - 1.2 mg/dL, 50 - 110 umol/L].

Hematologic Findings Just Prior to Conditioning

- 70.** **Date CBC (complete blood count):** Should be the last CBC drawn prior to the first dose of conditioning (high-dose therapy) either radiation or chemotherapy. The date may be the same as the start date of conditioning (Q107) as long as it was drawn before conditioning started. A CBC gives the number of red and white blood cells per cubic millimeter of blood. The three basic blood cell types (RBC, WBC, platelets) comprise 45% of blood; plasma or serum is the remaining 55%. In healthy people immature forms of blood cells are found in marrow but not the circulating blood. Blasts are the most immature form of blood cells. In some diseases, blasts are found circulating in blood. Values may be recorded as the quantity of cells found in a specified volume of blood; others are recorded as a percentage of the whole, known as the differential.

- 71.** **WBC:** White blood cells or leukocytes are the defense system. WBC's are subdivided into: Lymphocytes (B & T cells), Monocytes and Granulocytes. Granulocytes are further subdivided into: Neutrophils, Eosinophils & Basophils. Neutrophils = segmented neutrophils (“segs”) + banded neutrophils (bands). A lower than normal count may be due to viral infection, chemotherapy or radiation. High counts may signify bacterial infection, appendicitis, leukemia, pregnancy or stress. The normal range varies by age. ($3.2 - 9.8 \times 10^9/\text{L}$ or $10^3/\text{mm}^3$, 3200 - 9800 $\times 10^6/\text{L}$.)

WBC Differential – is a representation of white blood cell subsets as a percentage of the total WBC's (e.g. total neutrophils divided by total WBC, times 100, is the % neutrophils).

72. **Neutrophils:** Circulating WBC's responsible for the removal and destruction of bacteria and cellular debris. A "shift to the left" usually signals acute infection. Maturation occurs from promyelocytes -> myelocytes -> metamyelocytes -> bands -> neutrophils (segs, polys, PMN's [54-62%]).
73. **Lymphocytes:** Originates in lymphoid tissue (lymph nodes, spleen, thymus, submucosa of the GI and respiratory tracts). Includes B-cells that produce antibodies and immunoglobulins to recognize foreign antigens, and T-cells that destroy invaders and regulate the immune system. Normally, 25% of the total WBC count, but increase when stimulated by infection and other immune response (25-33%).
74. **Hemoglobin (HBG, Hb):** The iron carrying pigment of red blood cells and oxygen transporter (female 14.0-18.0 g/dL, 140-180 g/L; male 11.5-15.5 g/dL, 115-155 g/L).
75. **Hematocrit (Hct, Crit, PCV):** Proportion of red blood cells in whole blood, expressed as a percentage. Usually hemoglobin x 3 = hematocrit (female 33-43%; male 39-49%).
RBC Red Blood Cells – carry iron and oxygen to cells and carbon dioxide out. If an RBC transfusion was received within thirty days prior to the CBC date (Q70), report the result and tick the box for hemoglobin and hematocrit "transfused."
76. **Platelets:** The risk of hemorrhage is quite significant if the count is less than $20 \times 10^9/\text{L}$ ($130\text{-}400 \times 10^9/\text{L}$ or $10^3/\text{mm}^3$, $130000\text{-}400000} \times 10^6/\text{L}$).
Platelets – maintains homostasis by interacting with the vascular system to halt bleeding. If a platelet transfusion was received within seven days prior to the CBC date, report the result and tick the box for platelets "transfused."

77. to

81. **Does patient smoke cigarettes, or have a history of smoking cigarettes?** Information regarding smoking habits is limited to smoking within the past year and smoked prior to, but not during the past year. Smoking habits other than cigarettes are not collected. This information is often found in the admission for transplant summary.

Cigarettes/day	Packs/day	Cigarettes/day	Packs/day
1 – 2	.1	11 – 12	.6
3 – 4	.2	13 – 14	.7
5 – 6	.3	15 – 16	.8
7 – 8	.4	17 – 19	.9
9 – 10	.5		

82. **Did patient have a history of clinically significant fungal infection (documented or suspected) at any time prior to conditioning?** Tick 'yes' only if the past fungal infections could be problematic during the HSCT (e.g. a minor nail infection from many years ago was

probably not clinically significant. When in doubt consult the transplant physician as to the appropriateness of reporting).

- 83. Date of onset:** If only ‘year’ is known use June 15 for an estimated month/day. If ‘day’ is unknown, use ‘15’ to complete the date.
- 84. Organism:** Please use the organism codes for *fungal infections* found on pg 28, codes 200-260 and 503 are valid possibilities. If using code 209, 219 or 259 you must specify what the “other” fungus is. Do not use other codes to report non-fungal infections. Please see the complete list of organism codes if you are uncertain as to the category of the infection.
- 86. to**
- 87. Site(s) of fungal infection:** See Appendix G if you are uncertain about which site code to use.
- 88. Was there more than one documented or suspected fungal infection anytime prior to conditioning?** If more than one fungal organism is present, or if patient had a history of more than one significant fungal infection, please copy Qs83-87 and complete for the additional episode. Re-number as 3rd, 4th, etc.

Tests For Serological Evidence Of Prior Viral Exposure/Infection

The blood serum is checked for antigen-antibody reactions. This refers to presence of circulating antibody to, or antigens of, the organisms listed (*de novo* exposure show a > 4-fold increase in titer). If the exposure/infection was recent it usually is detected with IgM antibodies, whereas past exposure is usually detected with IgG antibodies. The patient may not be aware of having had an infection (sub-clinical infection). The measurement of antibodies is called a titer, which is the reciprocal of the highest dilution that gives a positive reaction. Initially, after infection the antibody cannot be measured (lag phase). The titer continues to rise logarithmically (log phase), then plateaus and finally declines as the antibodies are cleared from the body. The next time the antibodies are encountered the initial phases are shorter and the later phases are longer. Either a positive IgM or a positive IgG test qualifies the result as “positive” for reporting purposes.

Recipient results are collected in the Core Insert. Donor results are collected in the Graft Insert.

89. **HTLV1 antibody:** Human T-cell leukemia virus causes adult T-cell leukemia. It is also found among I.V. drug users.
90. **CMV antibody:** Cytomegalovirus: as the virus slowly multiplies the host cell (cyto-) swells (megalo-), hence the name of the virus. IgM titer <0.91 indicates absence of previous exposure to CMV. IgG titer <0.91 indicates no acute infection in three months. Infection in the previous week may give negative results. 50-90% adults test + for CMV antibody but are asymptomatic.
91. **EBV antibody:** Epstein-Barr virus causes infectious mononucleosis, 90% adults exhibit past exposure, which can trigger PTLD (posttransplant lymphoproliferative disease) in stem cell transplant patients.
92. to
93. Hepatitis B: **Anti-HBs:** “surface” means the antibody is on the outside surface of the cell and & **Anti-HBc:** “core” refers to inside the cell
94. **HBsAg:** Hepatitis B surface antigen

	Refers to	Time to infection
HBV	Hepatitis B Virus	
HBsAg	Hepatitis B surface antigen: present on the surface of the virus particle	First marker to appear ~3 weeks following infection, disappears ~6 mos later
HBcAg	Hepatitis B core antigen: associated with the core of the virus	Detected in liver cells during active viral replication
Anti-HBc	antibody to HBcAg	Antibody detectable in serum, which indicates recent infection
Anti-HBs	antibody to HBsAg	Represents past exposure to virus or vaccination

- 95. Hepatitis C Virus [HCV] antibody:** previously included in the “non-A, non-B” classification. The patient may be asymptomatic. Presence of the antibody represents exposure to Hepatitis C.
- 96. Hepatitis A Virus [HAV] antibody:** most commonly transmitted via fecal-oral transmission. Represents exposure to the virus or vaccination to Hepatitis A.
- Hepatitis** is an inflammation of the liver, which may be due to infection or other causes.
- 97. Human Immunodeficiency Virus antibody (HIV):** If patient was tested, but your institution will not release that information tick ‘Not able to release information for HIV.’

Pretransplant Antitumor and Immunosuppressive Conditioning*

***If no conditioning was used due to the diagnosis (e.g. SCID,) subsequent HSCT for engraftment problems, or completing a Disease Inserts for a DCI, please substitute "just prior to HSCT/DCI" for "just prior to conditioning" and answer all questions.**

This section collects data pertaining to the preparative regimen given for HSCT. Treatment for the patient's disease should not be reported in this section unless given within two weeks of the HSCT, which is reported in Qs139-156.

98. to

99. Was high-dose therapy (conditioning) given? Protocol requires: Choose from all outpatient, some inpatient, or all inpatient. If the protocol calls for the recipient to receive the agents as an outpatient, but the recipient becomes an inpatient during the process, report as an inpatient ("some" or "all" as applicable).

100. to

106. Was patient treated in an isolation room during the peri-transplant period: This may be done to reduce the chance of infection from sources outside the patient and may be started prior to conditioning/infusion or after. The use of an air handling system assumes a private room. Please indicate all modes of isolation in Qs101-106.

107. Date pre-transplant conditioning (radiation or drugs) was begun: If this is a traditional stem cell transplant, the purpose of the therapy reported here is to produce pancytopenia for > 1 month, requires a stem cell transplant for marrow reconstitution and produces initial complete chimerism (a.k.a. ablative therapy). Non-myeloablative (NST) transplants still utilize therapy; however, the purpose is to prevent rejection and suppress, but not eliminate the recipient's hematopoietic/immune system. Autologous hematopoietic recovery would occur within 1 month without a stem cell transplant, but with transplant initially produces mixed chimerism.

The therapy recorded here is typically part of the patient's transplant protocol. Therapy for other reasons may be given within two weeks of transplant and may impact the conditioning regimen (e.g. mobilization.) Report therapy received within two weeks of transplant here, but only therapy that is listed *per protocol for conditioning* should be considered when determining the date pre-transplant conditioning was begun.

When completing a Report Form for a subsequent transplant/infusion, do not report therapy to treat the patient's disease in this section. Only include the treatment if it is considered part of the preparative regimen for the HSCT/infusion.

This date is used to check the date sequence of all dates required to be "preconditioning" or "postconditioning," ***please make sure this date is reported accurately.*** Once the recipient receives the first dose of conditioning (radiation or chemotherapy) the patient must be Pre-Registered and if selected, a Report Form completed. For instances where the conditioning is begun, stopped and re-started, contact the Registry if in doubt about what the start date of conditioning should be. Please provide brief details of the situation.

108. to

- 109. Height and Weight – at initiation of pretransplant conditioning:** Enter values immediately prior to start of pre-transplant conditioning. Report **Actual Body Weight** (ABW), not Lean Body Weight (LBW) or Ideal Body Weight (IBW). Enter height to the nearest whole centimeter or inch; enter weight to the nearest whole kilogram or pound. Round the number up to the next whole number if the decimal is ≥ 5 , round down if the decimal value is < 5 . *Do not* modify the boxes to include decimal values.

Radiation

- 110. Was irradiation performed as part of the pretransplant conditioning regimen?** This radiation is usually begun a few days to two weeks prior to the HSCT. The purpose may be to eradicate the disease, or immunosuppress the patient. If answer is “yes”, complete Qs111-138. See Appendix F of this manual for conversion of Gy to rads.
- 111. Total body radiation (TBI):** The entire body received radiation, although certain fields (vital organs) may have been blocked or shielded.
- 112. For total dose (cGy), record total quantity of radiation administered (not the dose of each fraction).** If TBI is fractionated, the dose per fraction times number of fractions equals total dose.
- 113. Starting date:** First date TBI was administered.
- 114. Was radiation fractionated?** When the total dose is divided into smaller increments, the radiation treatment was fractionated. The purpose is to increase the loss of diseased cells as they do not recover as quickly as healthy cells. Each fraction is one treatment session.
- 115. Dose per fraction:** Dose per fraction times total number of fractions equals total dose.
- 116. The number of days fractions were given can be greater than Q117 the number of fractions given.** For example, if 2 fractions were given, 1 on Monday and 1 on Wednesday, the total number of fractions is 2, but the number of inclusive days is 3 (count: Monday, Tuesday, Wednesday). A rest day between treatments allows healthy cells to recover somewhat before the next treatment.
- 117. Enter the number of fractions (treatments) it took to complete therapy.**
- 118. to**
- 124. Was shielding used?** Shielding is done to limit the field receiving radiation, often to protect vital organs, e.g. lungs. Indicate whether shielding was used and which organs were shielded such that they received **less** than the total dose of radiation indicated (Qs119-124).

125. to

131. **Total lymphoid, total nodal (TLI, TNI):** See Qs112-117 above. Radiation fields were limited to the lymph nodes. The ‘shielding’ question was purposely omitted, as it would be ‘yes’ for all patients receiving this type of radiation.

132. to

138. **Thoraco-abdominal (TAI):** See Qs112-117 above. Radiation field was limited to this site.

139. to

148. **Was (additional) radiation given to other sites within 14 days of preparative regimen?** If another field or additional boosts to specific sites were administered, indicate in Qs140-156. The sites of CNS, gonads and spleen are common sites for which patients receive prophylactic radiation. If the radiation is to a site of residual disease in the CNS, gonads or spleen use Q149, not Qs140-148. The radiation reported in this section may have begun more than two weeks prior to the start of conditioning as long as part of it was received within two weeks of the start of conditioning. Radiation treatments completed *more than two weeks prior* to the start of conditioning should be reported in the appropriate **Disease Specific Insert only**.

149. to

156. **Site of residual tumor:** Includes localized fields for solid tumors, e.g. testicular radiation took place from April 26-29, TBI began April 30. The start of conditioning in this example is April 30 (unless chemotherapy for conditioning was also given and was prior to the start of TBI).

Drugs

157. **Was the recipient transplanted on a protocol with a conditioning regimen intended to be non-myeloablative (NST)?** Please refer to the protocol or consult with the transplant physician if you are uncertain whether the regimen was designed to be non-myeloablative. There is no published definition of ‘non-myeloablative’ at this time. At this time this question is appropriate for allogeneic transplants *only*.

158. to

289. **Were drugs given for pretransplant conditioning:** Drugs reported in this section generally should be “per protocol” and within 14 days prior to HSCT (Qs159-289.) Accurate information regarding drugs used and dosage is crucial to the evaluation of transplant regimens. Please look carefully at the patient chart and report the overall total dose (not the daily dose) of anti-tumor drugs used for pretransplant conditioning in mg and record the date the drug was first started. Convert mg/m^2 to mg before recording the answer. This conversion requires the use of the patient’s height and weight on a ‘nomogram,’ which will calculate ‘ m^2 .’ Multiply ‘ m^2 ’ times the dose in mg/m^2 to get the value in mg. There are over 45,000 websites available to assist you by searching the web with the keywords “Body Surface Area” or ask the transplant center pharmacist to show you how to perform this conversion.

When recording the value, do not modify the number of boxes nor include decimal values. If the dose includes a decimal please round down to the nearest whole number if 0.4 or less, round up if 0.5 or greater. Report the total dose that was actually received, not just what was planned. If a patient begins the conditioning process, but does not complete it, tick “yes” to any drugs listed in

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the protocol, but only record the actual doses received. If a drug was part of the protocol, but not received, report "0 mg" for that drug. A list of alternate drug names is given in Appendix H of this manual. When reporting drugs under "other, specify" please neatly print the complete drug name, do not use an abbreviation, unless the drug appears in the appendix with that abbreviation. Do not report drugs given to prevent infection, GVHD, or toxicity in this section, even if listed in the protocol.

Previous Transplant And Current Graft Information (Page 13)

- 290. Was this the first HSCT for this recipient?** Was this the first HSCT *ever*, not simply at your institution. Please complete this section carefully as documentation of more than one HSCT is extremely important in transplant studies.
- 291. Is a second HSCT planned as part of treatment protocol?** If a second HSCT is planned according to the protocol at time of first HSCT answer ‘yes’, even if the patient does not go on to receive the second HSCT. The use of the word “planned” here *does not* mean if the patient relapses we plan to re-transplant them.
- 292. Number of previous HSCT/DCI recipient has had:** Calculate the number based on transplants/infusions that are reportable to the Registry as defined on pgs 13 (see DCI calculation timeline) & 34:Q754. Note: the Registry *has no rule* that the patient must receive high-dose conditioning therapy in order for the transplant/infusion to be reportable.
- 293. Date of most recent previous HSCT/DCI:** Although *095-Core (12/98)* instructed you to complete this page for each previous transplant, complete this page only for the most recent previous transplant, as long as other prior transplants were documented in previous Report Forms. If this is the first time this patient is reported to the Registry *ever* please complete a page for each prior transplant.
- 294. to**
- 295. Was previous transplant performed at a different institution?** If ‘yes’, please provide contact information in Q295 so we may ask the appropriate transplant physician to complete the Report Form for that transplant.
- 296., 297, &**
- 299. Graft type of previous transplant:** Indicate autologous (patient’s own cells) or allogeneic (donor cells), type of donor (unrelated or related), and whether that transplant was reported to the Q297 ABMTR or Q299 IBMTR. A syngeneic donor is a genetically identical twin.
- 298. (If allogeneic) Was donor same as current?** This refers to the same donor as the HSCT/DCI immediately preceding the current HSCT.
- 300. to**
- 303. Reason for re-transplant:** If this was not the first transplant, give reason for *this* transplant. Make sure the reason is consistent with what was reported in previous Report Forms (e.g. if relapse, the disease status in the Report Form covering the time period immediately prior to this Report Form should be relapse or therapy induced remission, as applicable). Check only one answer:
- #1. *No engraftment (no hemopoietic recovery)*: This means that additional cell infusion was required because there was no recovery of granulocytes following high-dose therapy and initial infusion.
 - #2. *Partial engraftment (partial hemopoietic recovery)*: This is similar to 1 (above), but with some evidence of hematopoietic recovery deemed insufficient, or too slow, for the patient

to survive without a further stem cell infusion (ANC never $>0.5 \times 10^9/L$ for three (3) consecutive days /labs).

- #3. *Graft failure/rejection:* This is defined as loss of bone marrow function (neutrophil count falling below $0.5 \times 10^9/L$) after engraftment definitely occurred. Engraftment is defined as achieving a neutrophil count greater than $0.5 \times 10^9/L$ for three (3) consecutive labs, tested on different days. Please indicate the date bone marrow failure was documented in Q301. Of the three consecutive days, list the first date as the date of failure/rejection.
- #4. *Persistent malignancy:* The patient was transplanted with disease present and never entered a remission following the previous transplant. For acute leukemia, complete remission is defined as less than 5% blasts in a *cellular* bone marrow with the patient free of symptoms and physical findings attributable to leukemia.
- #5. *Recurrent malignancy:* This refers to relapse of the *disease for which the recipient was originally transplanted* following a previous transplant. For acute leukemia, relapse is defined as more than 5% blasts in the bone marrow or extramedullary leukemia. Please indicate the date relapse was first documented in Q302. New cancers (secondary malignancy) should be reported as below in #8.
- #6. Planned second transplant, per protocol. Prior to the current transplant, a plan was in place for a subsequent transplant/infusion, not based upon recovery, status of disease or any other assessment.
- #8. Secondary malignancy: specify diagnosis from the list on Core pgs 2-5. This should be a new cancer, not a transformation or progression of the original disease. Please make sure the details of the new malignancy have been reported to the Registry as this is of great interest for on-going studies. ***Please send a pathology report describing/ documenting the new malignancy.***
- When completing the Disease Specific Insert for the current transplant please complete the *same Disease Insert* as for the *first* transplant. ***Do not*** complete a Disease Insert for the new malignancy. The data that is required for analysis of the new malignancy has been quite specific and supplemental forms are developed at the time of those studies. All reference to disease status post-transplant should refer to the disease of the first transplant, not the new malignancy, as we must continue to track the original disease in the database
- #90. *Other:* If none of the above options apply as the reason for a subsequent transplant, please explain in Q303. If you need to use “other” contact the Registry as the reasons available are quite comprehensive.

- 304. What type of graft did the patient receive (or was planned) for the current transplant?**
Indicate #1 autologous, if the cells were obtained from the recipient; #2 allogeneic, if the cells were obtained from a donor that was not the recipient's identical twin (can be unrelated or related); and #3 syngeneic, if the donor was the recipient's genetically identical twin.

305. to

- 313. From where were the stem cells obtained?** Indicate the tissue source(s) for the current transplant. If more than one tissue was transplanted, a separate Graft Insert must be completed for each tissue type.
- 314. Did patient receive graft?** The rules of consecutive reporting require that any patient that received the first dose of conditioning be assigned an IUBMID and be Registered. For Research Teams, due to the randomness of the selection program, a Report Form may also be due, even if the patient never received the graft. If 'No', indicate the reason in Q315. If the patient is alive, briefly explain why the transplant was cancelled in Q316.

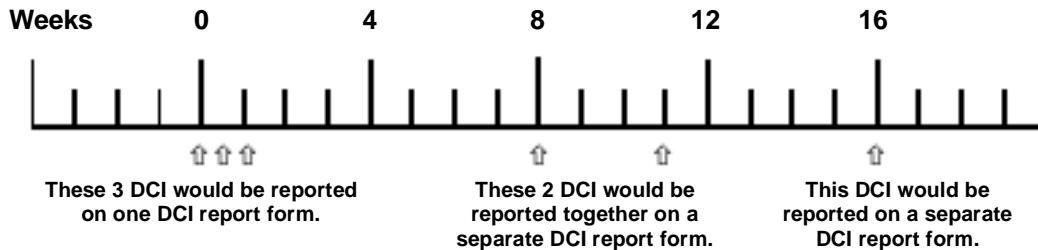
PLEASE NOTE THIS COMPLETES EVENTS OCCURRING PRIOR TO THE CONDITIONING REGIMEN. ALL DATA REPORTED IN THE REMAINING SECTIONS MUST HAVE OCCURRED AFTER THE DATE REPORTED IN Q107 (THE DATE CONDITIONING BEGAN). IF THIS IS A SUBSEQUENT TRANSPLANT/INFUSION AND *NO CONDITIONING* WAS USED, PLEASE SUBSTITUTE THE WORDS "**SUBSEQUENT TRANSPLANT/INFUSION**" FOR "CONDITIONING" AND ANSWER ALL QUESTIONS.

Post-HSCT Information

Note: All of the data in the following pages should refer to the time *after* this transplant, but not later than the last contact date required for this report as defined on pg 40. Please use the timelines in Appendix A to determine the LCD for this Report Form. Contact the Registry if you are still unclear regarding the required endpoints for this Report Form. Be prepared to list the dates and events mentioned on the timelines.

- 317. Did patient receive a subsequent HSCT after the HSCT for which this Report Form is being completed?** Any infusions given within fourteen days of the first HSC infusion should be considered multiple infusions for a single transplant event. Infusions more than fourteen days later are collected as reportable HSCT or DCI (e.g. TX2) unless it was an autologous re-infusion (“autologous rescue”) for a reason pertaining to the graft (no engraftment, partial/poor engraftment or loss of the graft/late graft failure). A timeline diagram is included on Core pg 15 to help you determine the correct, well-defined cut-off date for any additional Report Forms. Please contact us with any specific examples you wish to discuss. List the dates indicated on the timeline prior to contacting us (see Appendix A).
- 318. Has patient received (from the original donor) a subsequent DCI that requires reporting on a separate DCI Form based on the DCI Calculation Timeline (see below)?** This section refers to cellular therapy from the original donor, lymphocytes, dendritic cells, mesenchymal cells, etc. If a bag of cells saved from transplantation are now infused without a preparative regimen (no conditioning) and the reason for the infusion does **not** pertain to the prior graft (no engraftment, partial/poor engraftment or loss of the graft/late graft failure), please report as Donor Cellular Infusion. If a different donor was used, do not report here but rather use Q317 HSCT (See Appendix C). A timeline diagram is included on Core pg 16 to help you determine the correct, well-defined cut-off date for any additional Report Forms. Note: (05/03) version should list >14 days from HSCT, not >28 days [“>14 days but <100 days between HSCT & DCI”]. The diagram in the box below is correct. The rule is 14 days post HSCT; 28 days post DCI. We apologize for any confusion this typo has caused. Please contact us with any specific examples you wish to discuss. List the dates indicated on the timeline prior to contacting us.

Some patients have cellular infusions on more than one day. A single DCI form should be completed for all infusions given within a 4-week period. Separate DCI forms should be used for subsequent infusion(s) given after this 4-week period. For example:



- 319. Indicate survival status at last contact date (approximately Day 100 if no subsequent HSCT/DCI) for this Report Form:** This can be a confusing question to answer, unless you are aware of the structure of the Registry's database, in which the data is recorded as though on a timeline. If the patient had a subsequent reportable HSCT or DCI, the answer to Q319 is 'yes,' as the patient must be recorded as 'alive' in our database in order to go on to have a subsequent HSCT/DCI. If the patient did not have a subsequent HSCT/DCI, answer as of their survival status on Day 100, or if not seen by a physician (your Center or the patient's referring physician) precisely on Day 100, the next closest visit after. If you are completing this Report Form as a part of your backlog of reporting, remember you must cut-off the data as explained on the timelines. Note: the recipient's death should only be listed in the *final* Report Form/Follow-up Report Form. All other previous Report Forms/Follow-up Report Forms must indicate that the recipient was alive for the reporting period.
- 320. Did recipient have a subsequent reportable HSCT/DCI before Day 100?** Only answer this question if the recipient is alive at day 100 or had a subsequent reportable HSCT/DCI. If 'yes,' this report Form will be cut-off prior to day 100 as per the timelines on pgs 15/16. If 'no,' LCD must be at least 100 days from date of HSCT.

Hematopoietic Reconstitution Posttransplant

- 321. Has patient received hematopoietic growth factors or cytokines post conditioning?** Growth factors are proteins that stimulate the development of cells and are also known as colony stimulating factors (CSF). These agents may be given routinely to speed engraftment, as therapy for poor hematopoietic recovery posttransplant, or to enhance the anti-leukemic effect of the graft. Please report the first course only for this HSCT, Qs322-361, including the start date and indication code. Codes for the indication are found in the box at the bottom of the page. If the patient is on a study, and you do not know exactly which drug was received, report in "blinded growth factor trial." Once the study is completed, and it is revealed which patients received which drug or placebo, please remember to update the patient's data. You will see a query on Error Reports from the Registry inquiring about these data, if Q354 remains 'yes' at the time the Error Report is generated.

Alternate names: **G-CSF** = Granulocyte-Colony Stimulating Factor, filgrastim, Neupogen, Neulasta; **GM-CSF** = Granulocyte/Macrophage-Colony Stimulating Factor, sargramostim, Leukine; **Erythropoietin** = EPO, Epogen, Procrit, Darbepoietin; **Interferon-alpha** = Roferon-a, Intron-a; **Interferon-gamma** = Actimmune; **Interleukin-2** = IL-2, aldesleukin, Proleukin, KGF = Keratinocyte Growth Factor – 2.

Granulopoiesis

The definition of ANC engraftment is under review. Note that there is one change already between 095 and 002 versions. If labs are not tested on consecutive days, it is appropriate to use 3 consecutive labs, tested on different days. We are in the process of reviewing if it is still statistically important to use three or whether that number can be reduced. We will inform you when a decision has been made.

362. Is/Was there evidence of hematopoietic recovery following the initial hematopoietic cell infusion?

ANC refers to the Absolute Neutrophil Count, a subset of the granulocytes, demonstrated in peripheral blood (CBC). Commonly reported units are $500/\text{mm}^3 = 0.5 \times 10^9/\text{L}$. Engraftment is defined as achieving $> 0.5 \times 10^9/\text{L}$ neutrophils ("segmented neutrophils + band neutrophils", or "segs & bands") for three (3) consecutive days, e.g., WBC $5,400/\text{mm}^3$ with 70% segs + 3% bands = $0.73 \times 5.4 = 3.942 \times 10^9/\text{L}$ ANC.

Differential: the relative number of each type of cell (red, white and platelets) in the sample. Typically expressed as a percentage. Do not report the values from a differential. If the absolute neutrophil count is not given, the differential will have to be converted as follows:

Calculating the *absolute count* from a *differential*:

(% neutrophils times total WBC) divided by 100 = absolute neutrophils.

If the segs and bands are reported individually, add them together before doing the calculation.

Traditionally, the definition of neutrophil engraftment required selecting the first date of three consecutive days in which the patient's ANC was $\geq 500/\text{mm}^3$ ($0.5 \times 10^9/\text{L}$). For various reasons it may not be possible to obtain daily lab values. Under those circumstances you may report neutrophil engraftment based upon *three consecutive lab values that are more than a day apart as long as the counts show a continual increase, not counts going up and down. Select one of the five options below that best describes the patient's neutrophil recovery

Opt 1 Yes, ANC $\geq 500/\text{mm}^3$ achieved and sustained for *three consecutive lab values with no subsequent decline.

363. Date ANC $> 500/\text{mm}^3$ ($0.5 \times 10^9/\text{L}$) first of three consecutive lab values*: The format is MM/DD/YYYY. Please report the first date unsupported counts reached designated levels and were maintained for *three consecutive labs. ***Unsupported*** refers to no unirradiated granulocyte transfusions or "boosts" from the donor. The counts may be achieved while on growth factors, but please be sure to record the latter in Q321, if it is the first course. If patient was not tested daily you may report the results from three consecutive labs providing the recovery is shown to be representative (counts were continually going up, not going up and down).

Opt 2 Yes, ANC $\geq 500/\text{mm}^3$ achieved and sustained for three consecutive lab values with subsequent decline in ANC to $< 500/\text{mm}^3$ ($0.5 \times 10^9/\text{L}$) for greater than 3 days.

364. Date ANC $> 500/\text{mm}^3$ ($0.5 \times 10^9/\text{L}$) First of three consecutive lab values: Same as Opt 1, Q363.

365. Date of decline in ANC to <500/mm³ (0.5 x 10⁹/L) for greater than three lab values*:

Graft failure is defined as a decline in ANC to <500/mm³ (0.5x10⁹/L) for three consecutive days/labs. It may be due to drugs, infection (especially CMV), GVHD and other etiologies. List the first date from the three days/labs <500/mm³ (0.5x10⁹/L).

366. to

- 367.** Report **WBC & % Neutrophils** from the CBC data on the first date of the decline (Q365).

368. to

- 371.** Report a subsequent recovery here, as long as it was not achieved by a reportable subsequent transplant/infusion, which must be reported on a Subsequent Report Form (see pgs 15 & 16). The same rules regarding three consecutive lab values tested on different days applies here as well.

Opts 3 &

- 4** No, ANC ≥500/mm³ was not achieved and there [was no evidence of recurrent disease] or [was documented persistent disease] in the bone marrow.

If unsupported counts never reached designated levels, or were not maintained for three (3) consecutive labs*, check Opt 3 if there was no evidence of the disease for which the patient was transplanted in the bone marrow or option Opt 4 if there was. Opts 3 and 4 refer only to presence of the patient's disease in the marrow (or blood), not disease present in extramedullary sites.

- Opt 7* ANC never dropped below 500/mm³ at any time post conditioning.

May be applicable if the patient was transplanted for an Immune Deficiency or the conditioning regimen was non-myeloablative. If the count drops below **500/mm³** for just 1 reading you may not use this option.

SPECIAL SITUATIONS

Recording engraftment for patients receiving an autologous rescue (see pg 34:Q754 for definition):

Patient engrafted and lost the graft:

Use Q362:Opt 2. If the patient engrafted from the auto rescue, copy Q362 and complete separately for the auto rescue recovery.

Patient never engrafted:

Use Q362:Opt 3 or 4 if the auto rescue also failed, or Opt 1 or 2, as applicable, if engraftment was achieved from the auto rescue. The date recorded in Q363 or Q364 will be later than the date in Q753.

Megakaryopoiesis

Report the *initial platelet recovery* in this section. The date achieved must be at least seven days following the last platelet transfusion and the first date of three consecutive lab reports that show that level was achieved and maintained. If there is more than 30 days between the consecutive lab results documenting platelets below and above the threshold tick the box “date estimated” as the actual recovery date may have been earlier. You must report platelet recovery data according to these rules so that your Center’s data is recorded in the same manner as every other Center.

372.,

374. Was a platelet count of $\geq 20 \times 10^9/L$ achieved? ... $\geq 50 \times 10^9/L$ achieved? See above.

373.,

375. First date of three consecutive labs at or above $20 \times 10^9/L$? ... $50 \times 10^9/L$. See above

Current Hematologic Findings

376. Date of most recent CBC results: “Most recent” refers to “most recent for this reporting period”. The CBC result reported should be the same as the last contact date reported on CORE pg 1 or before. Later results will be collected on a Follow-up Report Form or subsequent HSCT/DCI Day-100 Report Form as applicable.

See Qs71-76 for more detailed information on the cell types reported on a CBC.

*Please note the units listed and select the appropriate unit box. If the unit on your lab report is not among those listed please check Appendix F for alternate units and conversion formulas. Convert the value to a unit listed before recording the value and unit. If you have any difficulties with the conversion please consult your lab. Contact the Registry if you are unable to resolve conversion problems, be prepared to send an example of the document you are obtaining CBC data from.

377. WBC:

378. % Neutrophils = (actual # neutrophils divided by total WBC) x 100
include segs (segmented neutrophils) and bands (band neutrophils).

379. % Lymphocytes = (actual # lymphocytes divided by total WBC) x 100

380. to

381. If an RBC transfusion was received within thirty days prior to the CBC date, report the result and tick the box for hemoglobin and hematocrit “transfused.”

382. If a platelet transfusion was received within seven days prior to the CBC date, report the result and tick the box for platelets “transfused.”

Graft-vs-Host Disease Prophylaxis

Graft versus host disease (GVHD) is an immunological phenomenon resulting from the reaction of donor immune cells against major or minor histocompatibility antigens of the recipient. The donor cell primarily responsible is the T-lymphocyte, which also explains why GVHD almost never occurs in autologous transplants. The severity of GVHD is determined primarily by the degree of genetic disparity between the donor and the patient; in part by the age of the patient/recipient, and the type of therapy given posttransplant to prevent GVHD (GVHD prophylaxis).

GVHD can be classified into acute or chronic on the basis of its time to onset following transplant, and other clinical and histological (biopsy or post-mortem) features.

Acute GVHD usually begins between 10 and 40 days after HSCT but can appear earlier or later. It occurs in 20-40% of non-T-cell depleted HLA identical sibling transplants. The rate is higher for transplants from mismatched family donors and unrelated donors. The organs usually affected are the skin, gut or liver although other sites (e.g. conjunctiva) may be involved.

The usual methods of preventing or modifying acute GVHD are removal of T-cells (T-depletion) from the donor marrow/blood prior to infusion and/or immune suppressive drugs given post-transplant to inhibit T-lymphocyte (T-cells) activation and proliferation, and/or bind tumor necrosis factor (TNF).

- 383. Was specific therapy used post conditioning to prevent or induce acute GVHD, or promote engraftment (other than growth factors reported in Q321)?** Check 'Yes' or 'No' as appropriate. The therapy requested in this question is considered prophylactic, and refers to something that is done as a preventive measure. It typically is done to all patients as outlined in their treatment protocol. Recipients of transplants from an identical twin usually do not receive GVHD prophylaxis. If GVHD prophylaxis is used for an identical twin transplant, please provide an explanation.

***Please note:** 002-Core specifies *posttransplant*; however agents given for GVHD prophylaxis postconditioning, but pretransplant should also be record in Q383. Do not report agents started *after* the development of Acute GVHD in this section.

- 384. ALS, ALG, ATS, ATG:** These are all abbreviations for serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. They are usually prepared from animals immunized against human lymphocytes. (ALS/G = Anti-Lymphocyte Serum/Globulin, ATS/G = Anti-Thymocyte Serum/Globulin.) **Q385** Also report the animal source, **Q386** list the "other" animal.

- 387. Corticosteroids:** (e.g. dexamethasone, hydrocortisone, methylprednisolone, prednisone/prednisolone.) Usually combined with cyclosporine when used for prophylaxis. Only systemic steroids are listed here. If topical steroids are used prophylactically, report in Qs408-409 and provide an explanation regarding how the site for topical application was selected.

388. **Cyclosporine:** Cyclosporine is usually given for ≥ 3 months. CSA, CYA, sandimmune, Neoral.
389. **ECP** (extra-corporeal photopheresis): Recipient's blood is exposed to ultraviolet light (outside their body), and re-infused.
390. **FK-506** (Tacrolimus, Prograf): inhibits T-cells.
391. to
399. **In vivo anti T-lymphocyte monoclonal antibody:** These are antibody preparations infused *in the patient* following transplant. Specify antibody used in Q392 Anti-CD25, Q393 list the specific anti-CD25 agent used: Zenapax; Daclizumab, AntiTAC; Q394 Campath-1G, 1H, 1M, anti-CD52; Q395 Etanercept, Anti-TNF, Enbrel; Q396 Infliximab, Remicade; Q397 OKT3, Orthoclone; Q398 "other" agent not listed above, and Q399 specify the "other" agent. If used *in vitro* to remove donor T-cells, report on the Graft Insert only.
400. **In vivo immunotoxin, specify:** antibody joined to a toxin. Q401 list the immunotoxin.
402. **Methotrexate:** This agent is usually given for a "short course" when combined with cyclosporine or for a "long course" (about 100 days) when used alone.
403. **Mycophenolate mofetil** (MMF, Cellcept): inhibits the de novo pathway of guanosine nucleotide synthesis without incorporation into DNA.
404. **Sirolimus** (Rapamycin, Rapamune): inhibits T-cells.
405. **Ursodiol (Actigall):** Suppresses synthesis and secretion of cholesterol from the liver and absorption in the intestines.
406. **Blinded randomized trial:** Q407 specify agent being studied. Once the trial is over, inform the Registry which arm of the trial the patient participated in.
- 408-
409. **Other agents:** (e.g., Xomazyme, Tresperimus) Do not report T-cell depletion here; report on the Graft Insert only. Do not report agents to prevent infection here; report in Qs569-598 only..

Acute Graft-vs-Host Disease

- 410. Did acute GVHD (aGVHD) occur?** Check ‘yes’ or ‘no’ as appropriate. Biopsy of affected organs allows for more precise diagnosis as to the presence or absence of GVHD. However, ***overall grading remains clinical*** and is based on the criteria proposed by Thomas et al, N Engl J Med 1975 (see Appendix I of this manual.)
- 411. Maximum overall grade:** Please note: this scale is based on ***clinical evidence*** (physician observation), not histology. If there is a difference in the clinical grade recorded by the physician and a histologic report, use the data from the clinical documentation by the physician, noting the difference as a ‘Report Note’ if you wish. Use criteria in Appendix I of this manual to calculate whether mild to severe (Grade I to Grade IV). The score given should correlate with the details given in Qs415-422.
- 412. Diagnosis was based on:** Histological evidence may be from a biopsy or post-mortem. The purpose is to confirm the clinical evidence as recorded by the physician. Note: the overall grade is based on a ***clinical*** system, not histology. Clinical evidence: If no histology was available, then diagnosis was clinical only.
- 413. Date of onset:** Is expected to be within the first 90 days post-transplant. A late donor buffy coat (DCI) given for failure of engraftment or relapse can trigger aGVHD, that is one of the reasons to separate the reporting of these infusions. If aGVHD begins after d-100 please attach documentation.
- 414. Is aGVHD still present at last contact date for this report?** If the patient died with acute GVHD, check ‘yes.’ If acute GVHD progresses to chronic GVHD, check Opt 2. If aGVHD resolved as of the last contact date reported on CORE pg 1 check ‘no’. If present at time of death, consider whether it was a contributing cause of death.
- 415-**
- 422. Maximum severity of organ involvement attributed to aGVHD was scored as follows:** Use Appendix I of this manual for staging individual organ involvement. Stages given must be compatible with the overall grade given in Q411.
- 423-**
- 468. Specific therapy was used to treat aGVHD:** This section is for agents used after the appearance of acute GVHD. Agents administered as prophylaxis and continued would be indicated here as Opt 1. Drugs started for the purpose of treating aGVHD would be recorded as Opt 2. If the dose was increased for the purpose of treatment after onset of acute GVHD indicate as Opt 3. Do not use Opt 3 if dose increase was strictly related to toxicity monitoring.
- For a description of these agents see Qs384-409 in this manual. “Systemic” refers to the drug given by mouth, IM or IV; “Topical” means it was applied to the skin, eye drops or inhalation therapy.
- 467. Other agents:** Many alternate methods are being used in combination with the above. Examples include PUVA (Psoralen and Ultra-Violet A).

Chronic Graft-vs-Host Disease

Chronic Graft-vs-Host Disease: Chronic GVHD can occur following acute GVHD or *de novo* (without prior evidence of aGVHD) and affects 25-50% of long-term survivors of allogeneic transplants. It usually develops after day 100, but has been documented as occurring as early as day 60 and as late as day 400 posttransplant. The mechanism of tissue damage differs from acute GVHD and a greater variety of organs are affected. There is a simple staging system for grading severity as limited or extensive.

- 470. Has patient developed clinical chronic GVHD?** Check response as applicable.
- 471. Date of onset:** Report the date of clinical diagnosis recorded in the patient's medical record, or if not recorded, you may use the date of histologic confirmation. The date of diagnosis is not necessarily the same as the date of symptoms onset. Between patient visits the symptoms of GVHD may change from those of acute GVHD to chronic. When the exact date of this progression is not known the "100 day rule" is often applied for the purpose of calculating intervals for statistical analysis. The rule assigns the end date of acute GVHD to 99 days from the date of transplant, and the onset of chronic to day 100. It is only applied when actual dates are not known. You do not need to apply the rule and report the estimated date, as there is a tick box in the next question for progression from acute GVHD and date of progression is not known.
- If this is a Follow-Up Report Form and the patient had chronic GVHD that resolved for at least 30 days, but has reactivated ("flair"); report the new episode and list the new date of onset.
- 472. Onset of chronic GVHD was:** If acute GVHD was present and unresolved at the time of chronic GVHD diagnosis, check Opt 1 – 'Progressive' ('Date unknown' in Q471 may be checked if a clear date of progression is not discernable). If acute is resolved for seven days or more before onset of chronic GVHD, check Opt 2 – 'Interrupted'. Only check Opt 3 – 'De novo' if Q410:Opt 0 – 'No' was checked.
- 473. Karnofsky/Lansky score at diagnosis of chronic GVHD:** See Appendix D. If performance status is not quantified in the medical record, it is acceptable to ask the responsible care provider or interpret details recorded in the chart about energy level, work status, time spent in bed, and activities of daily living to assign a value.
- 474. Platelet count at diagnosis of chronic GVHD:** This is the count closest to the date entered in Q471. A low platelet count predicts increased mortality from GVHD. Values from within 14 days +/- are acceptable, although the value closest to the date of diagnosis should be recorded.
- 475. Total serum bilirubin at diagnosis of chronic GVHD:** Total bilirubin includes the direct and indirect bilirubin count [0.1-1.0 mg/dL, 2-18 umol/L]. Values from within 14 days +/- are acceptable, although the value closest to the date of diagnosis should be recorded.
- 476. Diagnosis based on:** Histological evidence: If biopsy or post-mortem evidence was found please indicate. Code "yes" for histologic evidence if specific biopsy results are "consistent with cGVHD" even if another diagnosis is also mentioned. If no histology was available, then the diagnosis was clinical only.

477. Maximum grade of chronic GVHD: Please make certain that the information provided in Qs479-528 on individual organ involvement corresponds. If there is a discrepancy between what is noted in the medical record and the definitions listed, record what is in the medical record and provide documentation. Although according to strict criteria, patients must have at least skin and/or liver involvement to be considered “extensive”, involvement of any other target organ has generally also met the definition. For example, a patient with only eye involvement or only mouth involvement would still be considered “extensive.” Note that patients with limited chronic GVHD can ONLY have skin and/or liver involvement since other manifestations make them “extensive.”

Reporting Stage of Chronic GVHD (Blood 1981; 57:267)

Limited: Localized skin involvement resembling localized scleroderma with or without liver involvement; no other organ involvement.

Extensive: Generalized skin and/or multiple organ involvement.

478. Overall severity: This subjective assessment of severity, should be made by the clinician overseeing the patient’s care.

Mild: signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (steroids.)

Moderate: signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy defined as steroids.

Severe: signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy.

If severity is not recorded in medical record, it is acceptable to interpret it if sufficient details about manifestations, functional impairment, current therapy and response to therapy are available in the record.

Indicate organ involvement with chronic GVHD from list below: There is no published staging system for organ involvement with chronic GVHD. Report as ‘Absent’, ‘Present’, or ‘Unknown (if present)’. The organ involvement designations of “mild”, “moderate”, and “severe” are no longer collected by the Registry.

479. to

488. Skin/Hair: Ranges from skin discolorization to severe scarring and tightness.

Subclinical: biopsy findings only.

Rash

Scleroderma (morphoea): thickening of the skin, which may cause loss of suppleness.

Lichenoid skin changes: whitish lacy patches.

Dyspigmentation: change in color of skin. Usually erythema (redness) or vitiligo (loss of skin color.)

Alopecia: scalp hair loss (baldness.)

%BSA: body surface area involved of the most prominent component (e.g. 50% rash, 10% Dyspigmentation, report 50%).

For Other cutaneous involvement not classifiable above, specify the “other.”

489. to

493. **Eyes:** Patients often have dry eyes and corneal ulcers due to keratoconjunctivitis sicca.

Dry eyes

Schirmer's test: a measure of tear production, decreased wetting <5mm. Part of sicca syndrome (with dry mouth.)

Corneal erosion/conjunctivitis: ulcers on the cornea, usually quite painful, or inflammation of thin membrane covering the eye and inner lids.

For Other ocular involvement not classifiable above, specify the "other."

494. to

497. **Mouth:** Refers to white plaques, scarring and ulcers occurring in the mouth and throat.

Lichenoid changes: whitish lacy patches, usually appear first on inner cheeks, but can involve roof of mouth, gums, and/or tongue.

Mucositis/ulcers: similar to cold sores but they can involve any part of the mouth, important not to confuse with herpes simplex infections.

Other oral involvement not classifiable above, specify the "other."

498. to

500. **Lung:** This ranges from mild impairment on pulmonary function tests to the severe disorder.

Bronchiolitis Obliterans (BO, BOOP, "small airway disease"): literally, scarring of the small airways. Usually diagnosed by lung biopsy or pulmonary function tests (showing obstruction of airflow.) Symptoms include poor exercise tolerance, shortness of breath (SOB.) Also record in Qs673-681.

For "Other" pulmonary involvement not classified above, specify the "other." Please include all related pulmonary disorders here. Report IPn in Qs646-671 only.

501. to

507. **G.I (gastrointestinal) tract:**

Esophageal: May have difficulty swallowing (dysphagia), pain when swallowing (odynophagia), narrowing of esophagus (esophageal web), poor motility (food doesn't move down esophagus normally.)

Chronic nausea/vomiting: either nausea or vomiting that occurs on at least 25% of days (1 out of 4 weeks) or occurs frequently enough to interfere with functioning and lifestyle.

Chronic diarrhea: occurs on at least 25% of days (1 out of 4 weeks) or occurs frequently enough to interfere with functioning and lifestyle. This may occur due to thickening of the intestinal wall.

Malabsorption: inability to digest or absorb the nutrients from food. Diagnosed with specific tests measuring fecal fat, xylose uptake or vitamin level.

Abdominal pain/cramps

For Other GI involvement not classifiable above, specify the "other."

508. to

509. **Liver:** Liver involvement may be manifested by elevation in any of the liver function tests (bilirubin particularly the direct component), alkaline phosphatase, GGT, SGOT [AST], SGPT [ALT].) Liver biopsy may show obliteration of bile ducts (canalicular) or cirrhosis. Record all types of liver abnormalities, clinical or histological, here. Report infective hepatitis in Qs622-629 only.

510. to

512. GU Tract: Genitourinary tract.

Vaginitis/stricture: Pain, ulceration, inflammation, eventually scarring/ narrowing of the vaginal opening can occur.

For Other GU involvement not classifiable above, specify the “other.”

513. to

518. Musculoskeletal: refers to pain, contractures and/or joint deformities.

Arthritis: inflammation of joints.

Contractures: loss of joint mobility due to skin changes.

Myositis: inflammation of muscles.

Myasthenia: weakness of muscles.

For Other joint involvement not classifiable above, specify the “other.”

519. to

523. Hematologic: involving the blood system.

Thrombocytopenia: decreased platelet count (<100,000.)

Eosinophilia: elevation in percent eosinophils in blood (>5% of upper limit normal for your institution.)

Autoantibodies: any abnormal antibody against the patient’s normal bodily tissue (for example, antinuclear antibody [ANA], red cell autoantibodies [if directed against patient’s own blood type].)

Other hematologic involvement not classifiable above, specify the “other.”

524. to

528. Other:

Serositis: inflammation of a serous membrane, specify the site.

Weight loss.

For Other “other” involvement not classifiable above, provide details. Please consider whether any of the above categories can be used before recording organ involvement here.

529. Specific therapy was used to treat chronic GVHD: Most of the agents listed here are the same as in Qs424-469. Please refer to Qs384-409 in this manual for explanation of those drugs. As with acute GVHD, include agents that were started as prophylaxis against GVHD and were continued after the onset of chronic GVHD. If dose was increased for the purpose of treatment, as opposed to modifications for toxicity levels, check ‘yes, dose increased’.

Additional Drugs

533. Azathioprine: (Imuran) Sometimes used at low doses in combination with other treatments.
Inhibits purine synthesis in cells.

538. Etretinate: Synthetic derivative of vitamin A.

540. Hydroxychloroquine (Plaquenil): commonly used as an anti-malarial drug; inhibits transcription of DNA to RNA.

550. **Lamprene** (Clofazimine): anti-inflammatory properties.
552. **Pentostatin:** Inhibits adenosine deaminase which blocks DNA, and some RNA, synthesis.
553. **PUVA** (Psorelen and UVA)
555. **Thalidomide**
559. **Other drug, Q560 specify:** e.g. Cyclophosphamide: Sometimes used at low doses in combination with other treatments. Do not confuse with high-dose cyclophosphamide given for pretransplant conditioning.
561. **Is patient still receiving immuno-suppressive agents (including PUVA) to treat/prevent cGVHD?** Although symptoms may not be present the patient may still be receiving treatment or be slowly tapered off medication (usually Corticosteroids, cyclosporine, tacrolimus or other agents). Do not include any local or topical therapies. Also, exclude therapies targeted at functional deficits only (physical therapy, oxygen, etc.). If all therapy has ceased tick ‘no’ and provide the date of last therapy, if known. The date, Q562, can be estimated if the precise date is not known and it is noted as such.
563. **Are symptoms of chronic GVHD still present (or present at time of death)?** Refers to *as of the cut-off for this Report Form*, approximately 100 days from transplant. Defined as evidence of active disease. Do not include fixed deficits once chronic cGVHD resolves, e.g. dry eyes, shortness of breath, weight loss, etc. which can persist once chronic GVHD has resolved because of permanent damage to those organs. Only check ‘no’ if patient has no symptoms and has discontinued all medications to treat chronic GVHD (see Qs529-560). If present at death, please consider carefully if it was a contributing cause of death.

Other Treatment and Clinical Status After Start of Conditioning

Transfusions

- 564.** **Were transfusions given at any time after the start of conditioning to 60 days post-HSCT or LCD, whichever comes sooner?** Total number of transfusions given: do not include transfusions given prior to conditioning. Count units from the first date of conditioning to Day 60 posttransplant/infusion. The number of transfusions received posttransplant is important for studying the costs related to transplant, as well as patient recovery. As it can be time consuming to count transfusion slips, consider contacting the blood bank to inquire if these data can be provided to you from their computerized system.
- 565.** **RBC:** Count each transfusion (e.g. two units RBC's = 2).
- 566.** **Single donor platelets:** Count each transfusion (e.g. five single donor transfusions = 5).
- 567.** **Random donor platelets:** Count each donor (e.g. six donors required per single transfusion = 6).
- 568.** **Irradiated granulocyte infusions:** Irradiation destroys stem cells and T-cells. This is not the same as a graft infusion or Donor Leukocyte (Lymphocyte) Infusion.

Infectious Complications

- 569.** **Did patient receive any of the following agents for infection prophylaxis after the start of conditioning?** This section is to record agents given to prevent infection and are typically given per protocol to all patients after the start of conditioning. Do not record *treatment* of documented/suspected infection/fever here. See generic vs. trade drug names listed below.
- 570.** **Systemic antibacterial antibiotics:** These agents may be given IV (e.g. ceftazadime) or orally (e.g. ciprofloxacin).
- 571.** **Non-absorbable oral antibiotics:** The main purpose is to sterilize the gastrointestinal tract, e.g. Colymycin S, colistin sulfate, polymixin E, Mycifradin, Neobiotic, neomycin, Aerosporin, polymixin B.
- 572.** **Polyclonal IV gamma globulin (e.g., IVIG, not ATG):** e.g. Cytogam Gammagard, Gamastan, Gammimune N, Gammar, Iveegam, Polygam, Sandoglobulin, Venoglobulin.
- 573.** **CMV/hyperimmune gamma globulin**
- 574. to**
- 583.** **Prophylaxis against fungal infection:** Indicate any agents given. If oral amphotericin-B is administered, please report in Qs582-583. Also, any newer or less commonly used agents should be specified in "other" Qs582-583, e.g. clotrimazole, Canesten, Lotrimin, Mycelex, ketoconazole, Nizoral, nystatin, Mycostatin, Nadostine, Nilstat.

584. to

590. Prophylaxis against viral infection: Check responses as appropriate.

591. to

596. Prophylaxis against pneumocystis infection: This organism commonly causes interstitial pneumonitis in immunocompromised patients and therefore prophylaxis is sometimes used for prolonged periods pre- and posttransplant. Indicate route of administration for Pentamidine Qs592 or 593.

597. to

598. Other, specify: Please determine that drugs listed here are not known by another name listed above before recording as "other."

599. Did patient develop clinically significant infection after the start of conditioning? Please report only clinically important infections. Do not report results of surveillance cultures in which only normal flora are identified and the patient is asymptomatic. Do not re-list *persistence* of organisms at a site already reported. Whenever there are more infections than spaces to report them (>2 per category), please photocopy pg 27 or use Stemssoft "Report Notes", and continue labeling appropriately (e.g. Bacterial, third, 18 [site], 132 [organism], mm/dd/yyyy; Viral, third, 41, 303, mm/dd/yyyy). Do not report infections in other sections of the Report Form, except hemorrhagic cystitis (Q719); if the etiology is infective, also report in this section.

600. to

644. Bacterial, Fungal, Viral, Parasitic, and Other: Report each of these under the following categories

Site: Indicate site of infection (e.g. lung, urinary tract, upper respiratory site, etc.). Try to avoid the use of non-specific site codes (3, 10, 30, 40, 50, 60) as these are too vague for use in analysis. If that is the only information available please include clinical syndrome, e.g. pneumonia, meningitis, pharyngitis, etc. with site (See Appendix G of this manual for list of typical sites).

Organism: Record the organism as reported on microbiology, lab report, or other physician documentation. If an organism is suspected but not proved, report using codes 501-505 as applicable. If the source of the infection is not determined use code 509

Bacterial infections: *Atypical bacteria* are collected separately from other more common types of bacteria (100-119 & 501.) *Typical bacteria* are code 120-198 & 502. If more than one typical bacterial organism is found in a single site include all the organisms in the one listing, do not record each separately, either write the code in the margin or use 'Report Notes.'

Fungal infections: note the inclusion of Pneumocystis (formerly found under parasites). The most commonly found fungal infections are Candida (C. albicans, C. tropicalis, C. glabrata*, C. parapsilosis, C. krusei), Aspergillus (A. fumigatus), Fusarium sp., and Zygomycetes. *Also known as Torulopsis glabrata (fungal codes 200-260 & 503).

Viral infections: caused by exposure to a new virus or reactivation of a dormant virus already present in the body. The most common viral infections are due to HSV (Herpes simplex), VZV (Varicella zoster, shingles), and CMV (Cytomegalovirus). If the site of CMV is the lung, please check whether patient had IPN (interstitial pneumonitis) rather than CMV pneumonia. IPN is a

very serious posttransplant complication for SCT patients and is recorded in Q646 only (viral 301-329 & 504).

Parasitic infections: are fairly rare. Toxoplasma gondii is often transmitted through the handling of a cat litter box. Giardia and Cryptosporidium can be found in contaminated water (protozoal 402-409 & 505).

Date of onset: Enter the month, day and year infection was diagnosed.

Fever of undetermined origin: Defined as *any fever (> 38°C) not associated with documented/suspected infection in a specific site* are no longer collected by the Registry as the occurrence is too common for analysis.

- 645. Did patient develop more than 2 infections of any category post-DCI?** Note: if greater than two infections in a given organism category occurred, do not report in the “other, specify” field. Tick the box at the bottom of the page, copy pg 27 (or list on Report Notes) and re-number as 3rd, 4th, etc.

Pulmonary Function

- 646. Has patient developed interstitial pneumonitis (IPn or ARDS)?** Interstitial pneumonitis (IPn) is defined as nonbacterial pneumonia characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray. DO NOT REPORT BACTERIAL PNEUMONIA IN THIS SECTION, report in Q600. Patients who develop IPn generally also have ARDS, which has been combined with this question; therefore, do NOT report ARDS in “other” pulmonary complications.
- 647. Has the patient had prior episode(s) of IPn?** Check ‘no’ if this is the first documented episode of IPn. As this is primarily a postTX complication, if the Report Form you are completing is for TX1, we anticipate this to be ‘no,’ except in the most unusual of circumstances. If TX1 and ‘yes’, provide an explanation to avoid a later query.
- 648. Total number of prior episodes since first HSCT?** If the patient had a prior episode, recovered, and now has a new episode of IPn, the number of prior episodes is “1.”
- 649. Date of onset:** This will usually be the date a chest x-ray confirmed the diagnosis. For a subsequent episode provide the new diagnosis date.
- 650. Were diagnostic tests *other than radiographic studies* done?** Indicate all diagnostic tests performed to establish the diagnosis and determine the etiology (cause) of IPn.
- 651. Brochoalveolar lavage (BAL)** A solution is injected into the lung through a bronchoscope and aspirated back out. It is evaluated for evidence of infective organisms, malignancy, etc.
- 652. Transbronchial biopsy**
- 653. Open lung biopsy, Video Assisted Thorascopic Surgery (VATS)**

654. Autopsy Only tick ‘yes’ if the patient is being reported as deceased in this reporting period and an autopsy was performed.

655. Other

656. Specify the “other” method of testing.

657. Was an organism isolated? The most common organisms to cause IPn are CMV and PCP. If no infectious organism was identified despite evaluation, please indicate ‘no’ (idiopathic, or no organism isolated). IPn may be caused by chemotherapy and/or radiotherapy received pretransplant and occasionally due to acute GVHD.

658. to

670. Etiology: By definition, this cannot be a bacterium. If bacterial pneumonia is documented simultaneously with IPn, report the bacterial pneumonia in Q600, do NOT report in Q669.

Note: If IPn did not resolve and the patient died, list as a cause of death on pg 36.

Non-infectious Complications

Posttransplant infections should not be reported on pgs 30-31; only on pg 27 of Core Insert. Do not leave items blank; if data are “unknown”, please indicate. When describing events such as the occurrence of interstitial pneumonia (IPn), please report in the appropriate and most specific section of the Report Form only. For example, IPn would be reported in Q646, which asks specifically for IPn information.

672. Did patient develop non-infectious pulmonary abnormalities other than interstitial pneumonitis/ARDS postconditioning? Record any pulmonary complications other than infections and IPn/ARDS in this section.

673. Did patient develop bronchiolitis obliterans? (BO/BOOP- bronchiolitis obliterans organizing pneumonia)? If patient has a concurrent diagnosis of chronic GVHD BOOP (pg 24:Q498) also report the episode here.

674. Date of onset of BOOP: mm/dd/yyyy

675. Were diagnostic tests done?

676. to

681. Indicate all diagnostic tests performed to establish the diagnosis and determine the etiology (cause) of BOOP. See Qs651-656 above for an explanation.

682. Did patient develop pulmonary hemorrhage? Including Diffuse Alveolar Hemorrhage (DAH) which is blood leaking through the lungs. It is more common in auto TX, especially if TBI used.

683. Date of onset of pulmonary hemorrhage: mm/dd/yyyy

684. Were diagnostic tests done?

685. to

690. Indicate all **diagnostic tests** performed to establish the diagnosis and determine the etiology (cause) of pulmonary hemorrhage. See Qs651-656 above for an explanation.

691. Did patient develop other non-infectious pulmonary abnormalities?

692. If 'yes', specify: e.g. pleural effusion of uncertain etiology. If specifying ARDS, please investigate whether patient also had IPn and if 'yes', report *only* in Q646.

Liver Function

(See Qs59-65 For Explanations Of Liver Function Tests.)

693. Did patient develop non-infectious liver toxicity after conditioning (excluding GVHD)?

694. What was **date of onset**: mm/dd/yyyy. VOD typically occurs within three weeks of transplant.

Etiology

695. to

697. **Unknown:** Etiology of non-infectious liver toxicity was not determined or not documented in patient's record.

695. **Hepatic veno-occlusive disease (VOD):** can be caused by chemo/radiotherapy. Consists of endothelial damage, micro thrombosis of the hepatic venules and sinusoidal fibrosis. It is more common in allogeneic transplants than autologous and typically occurs within 3 weeks of transplant. Indicate how diagnosis was made in Qs699-713. In the absence of a histological diagnosis, patients must fulfill the criteria below for a diagnosis of VOD.

CLINICAL CRITERIA FOR VENO-OCCLUSIVE DISEASE OF LIVER

Patients reported as having veno-occlusive disease of liver based on clinical signs and symptoms

only must have two or more of the following with no other identifiable cause for liver disease:

1. Jaundice (bilirubin \geq 2 mg/dL or $>$ 34 μ mol/L)
2. Hepatomegaly with right upper quadrant pain
3. Ascites and/or weight gain ($>5\%$ over baseline, as generally accepted)

References: McDonald GB, et al. Hepatology 1984; 4:116-122
Jones RJ, et al. Transplantation 1987; 778-783

696. **Cirrhosis:** degenerative disease in which fibrous tissue forms and the lobes become filled with fat.
697. **Other liver abnormalities** developed: Q698. Describe liver abnormalities not reported in other sections. Do not include hepatic infections here; report those on pg 27. Do not report GVHD here.

699. to

713. Indicate all **diagnostic tests** performed to establish the diagnosis and determine the etiology (cause) of non-infectious liver toxicity.

Other Complications

714. Did patient *develop* any **other non-infectious clinically significant organ impairment or disorder** after conditioning? Do not re-report conditions that existed pretransplant (Qs14-58.) Determine ‘clinical significance’ by reading MD notes corresponding to lab and test reports. Generally, if the complication is being treated, or there is consideration of treatment, it is clinically significant. Complications that occur to virtually all patients are not clinically significant, e.g. mild-moderate mucositis.
715. **Renal failure severe enough to warrant dialysis?** If ‘yes’, Q716 received dialysis? Report whether dialysis was ordered or recommended after the start of conditioning and, if so, whether the patient received the treatment.
717. Posttransplant microangiopathy/thrombotic thrombocytopenia purpura (**TTP**), hemolytic uremic syndrome (**HUS**) or similar syndrome (e.g. **Evan syndrome**.) Features include: microangiopathic hemolysis, thrombocytopenia ($<50 \times 10^9/L$), LDH $>2x$ lab upper range, serum creatinine $>2\text{mg/dL}$ or $>50\%$ rise over baseline, neurological changes, bilirubin $>2x$ upper range, and/or pulmonary involvement.
718. **Depression.**
719. **Hemorrhagic cystitis:** developed. Hemorrhagic cystitis is characterized by: bleeding and inflammation of the bladder wall. It may result from chemotherapy, radiation and/or some viral infections. Report only cases with macroscopic (visible to the naked eye) or gross (massive) hematuria (WHO Grades III and IV hemorrhagic cystitis). If the etiology is infective, also report on pg 27. This is one of the exceptions to only reporting a complication in one place.
720. **Seizures:** Sudden involuntary muscle contractions due to the hyperexcitation of neurons.
721. **Avascular necrosis:** Localized tissue death due to inadequate oxygen to the cells. Also maybe called coagulation necrosis or ischemic necrosis.
722. **Cataracts:** Loss of transparency in the lens of the eye.

- 723. Gonadal dysfunction:** Females – symptoms of menopause including amenorrhea; Males – impotence.
- 724. Hypothyroidism:** Decreased activity of the thyroid gland due to various causes.
- 725. Growth hormone deficiency/growth disturbance**
- 726. Myocardial infarction:** An obstruction in the coronary artery resulting in damage /necrosis to the cardiac muscle; a.k.a. M.I., heart attack. Do not check ‘Yes’ if simply part of the death process.
- 727. Other, specify:** Do not report complications already reported elsewhere in the Form, e.g. liver complications. If ‘yes’, specify: e.g. interstitial nephritis, nephrotic syndrome, etc.
- Eye complications: Non-infectious eye complications (e.g. retinopathy due to radiotherapy or retinal hemorrhages due to thrombocytopenia) may occur posttransplant and should be recorded here. Infectious complications, e.g. CMV retinitis, should be reported on pg 27 under the appropriate organism group.
- Bone abnormalities: Degenerative changes in the absence of infection (e.g. aseptic necrosis or osteoporosis) should be reported here. Infectious complications, e.g. osteomyelitis, should be reported on pg 27 under the appropriate organism group.
- This question should be completed infrequently as we have provided for most all expected complications. If it seems you are completing this question with the same complication for virtually all your patients, please contact us to see if the complication is better suited to another section of the Report Form. Typical complications occurring to virtually all patients, are not collected by the Registry, e.g. Grades I-III mucositis (inflammation of the lining of the mouth), nausea & vomiting.
- ### New Malignancy
- 729. Did a new malignancy lymphoproliferative or myeloproliferative disorder appear?** Please be sure to differentiate between disease that has relapsed and a *de novo* (“first time”) malignant process diagnosed posttransplant. Do not report a history of a malignancy diagnosed before the first transplant and now relapsed. Pre-existing history of malignancy should be reported pg 7:Qs17-18. Report all new cancers including skin cancers (basal, squamous, melanoma,) new leukemia, myelodysplasia, solid tumor and lymphoproliferative disorders.
- 730. Did more than one new malignancy develop?** Although this is unlikely in the first one hundred days posttransplant, the question is repeated on the Follow-up Insert and through time the patient may develop more than one new malignancy.
- 731. Has more than 1 new malignancy been diagnosed during this reporting period?** As the etiology of new malignancy posttransplant is of great interest, precise detail of reporting is important. Only check ‘yes’ if the patient has more than one new malignancy diagnosed posttransplant and it was not reported on any prior Report Forms.

732. **Date of diagnosis:** Should be the date of the pathology report confirming the new malignancy.
733. **Origin of (the malignant) cells:** Indicate host, donor or unknown (not tested).
734. to
745. **Diagnosis:** Please provide complete information regarding the histological diagnosis, **site/s** of disease, **histologic type** and **behavior**. Include the method used to make the diagnosis (e.g. lymph node biopsy), and any ancillary information available. Cytogenetic abnormalities that appear posttransplant, but are known to be associated with the pretransplant diagnosis should be reported as relapse of the disease and not in Q734. For breast cancer found in the contralateral breast, please report as “relapse of breast cancer” as that is where we will look for these patients at the time of any studies. Note: PTLD (posttransplant lymphoproliferative disorder) is collected in Q739, not “other” (Q742).
746. **Is a pathology/autopsy report or other documentation available?** If ‘yes’, make a copy with all patient/institutional identifiers removed except Team, IUBMID and patient birth date; attach the copy and reference Q729.

Note: If a subsequent transplant is performed for the new malignancy, continue to complete the Disease Insert for the original diagnosis, not the Disease Insert for the new malignancy. While this may not “seem right” it has to do with our research question, which is did the (first) transplant work (eradicate the patient’s disease?). If a new malignancy occurs, then research question might be, what caused the new malignancy, but unfortunately it is not how did the patient’s new malignancy respond to HSCT/DCI, at least not at this time. If we are able to conduct a study on the treatment of the new malignancy we will probably need a very specialized Disease Insert for that purpose. Please do not use your valuable time completing a Disease Insert for the new malignancy that we cannot utilize at this time.

Survival and Functional Status

- 747. Was patient discharged from hospital after transplant?** Check ‘No’ if not discharged, expired prior to discharge, or was transferred to rehabilitation or intermediate recovery center and is still there at the time of last contact for the reporting period included in this Report Form.
- 748. Date of first discharge from hospital after transplant:** mm/dd/yyyy. Should not be the same date as date of death unless patient coincidentally was discharged, left the hospital and expired the same day.
- 749. Autograft only:** Total number of **inpatient days** from day 0 to day 60, including readmits after initial discharge as long as <d60.
- 750. Allograft only:** Total number of **inpatient days** from day 0 to day 100, including readmits after initial discharge as long as <d100.
- 751. Was patient alive on the day of last contact** (refer to pg 1 for date)? If ‘yes’, complete Functional Status Posttransplant in Q752. If ‘no’, go to Q764. Note: cannot be ‘no’ if patient received a subsequent reportable HSCT or DCI after this HSCT.
- 752. Karnofsky performance score:** If the patient is aged 1-16 years, please use the Lansky Performance Scale for Children. If performance status is not quantified in the medical record, it is acceptable to ask the responsible care provider, or interpret details recorded in the chart about energy level, work status, time spent in bed, and activities of daily living to assign a value. Please note that the following numbers are the only valid values for the Karnofsky scale: 10, 20, 30, 40, 50, 60, 70, 80, 90, 100. Zero is not valid, nor are numbers such as “85” (see Appendix D).

Subsequent HSCT

- 753. Date of subsequent transplant:** This date must be greater than 14 days after the HSCT date given in Q1, and greater than the last contact date, Q4, unless this is an autologous rescue (see definition in Q754.) Only this date or Q760 can be later than the LCD. To determine if the transplant is reportable see the next question.

- 754. Reason for subsequent HSCT:** Please make sure the reason is consistent with other data reported (e.g. if relapse we expect to see a posttransplant relapse reported in the Disease Insert for this Report Form.)

In the event the patient does not engraft, or engrafts but loses the graft, an “autologous rescue” may be performed. These are cells collected from the patient prior to transplant and held in reserve to keep the patient alive in the event there are problems with the graft. If a Report Form is required for this patient, the auto rescue will be recorded in Qs753-759.

- 755. Type of graft:** Check the appropriate option and Q757 ‘donor,’ if allogeneic HSCT.

- 758. Was the subsequent HSCT performed at a different institution?** If ‘yes’, please supply contact information Q759, as we will ask them to complete the Report Form for that transplant.

Subsequent DCI

To analyze what is the best schedule of DCI, this treatment must be reported according to the rules outlined on p1 & 2 of 002-DCI. Please adhere to the cut-off dates for reporting DCI.

- 760. Date first subsequent DCI given:** List the date of the first reportable DCI. Must be more than 14 days from HSCT (Q1) see timelines on pg 16. This date will be later than the last contact date in Q4. Only this date or Q753 can be later than the LCD.
- 761. to**
- 762. Was infusion performed at a different institution?** If 'yes', please supply contact information in Q762, as we will ask them to complete the Day-100 DCI Report Form for the infusion.
- 763. If patient received a DCI >14 days post-HSCT, was any therapy given to treat the patient's disease between this HSCT and the next reportable DCI?** If 'yes', complete a DCI Disease Supplement and submit with the next Day 100 DCI Report Form. If you are uncertain as to the purpose of drugs or radiation given to the patient, please ask the transplant physician for clarification. Do not make assumptions about treatment as to whether it is conditioning for a subsequent HSCT or treatment for the patient's disease.

Death Information

- 764. Date of death:** Indicate date of death. If exact date is not known, please provide an estimate and note that it is an “* estimate.” Please read the instructions regarding which Report Forms must be completed for a given patient’s course of treatment, report death only in the *final* Report Form or *final* Follow-up Report Form.
- 765. Cause of death (COD):** Only one primary cause of death may be specified. If relevant, multiple contributing causes may be listed. If the COD is truly not known, indicate as such. DO not report the final event, “cardiac arrest”, as the primary COD.

765-

770. Primary and contributing cause of death

Codes:

- 10 Graft failure/rejection:** Includes failure of marrow to achieve an ANC $0.5 \times 10^9/L$ (no engraftment or partial engraftment) or loss of graft as defined in Qs364-367. May also be recorded as bone marrow failure or aplasia (note: patient’s transplanted for a disease other than Aplastic Anemia the term “aplasia” does not necessarily refer to the patient developing SAA.) Also provide details on pg 18.
- 20 Unclassified infection:** Clinical evidence of infection that contributed to death, where no bacterial, viral, fungal or protozoal organism could be confirmed; details should be recorded on pg 27 using code 509 or if organism was suspected, but not documented use code 501-505.
- 21 Bacterial infection:** Provide details of fatal bacterial infection/s pg 27.
- 22 Fungal infection:** Fatal fungal infections other than IPn; provide details pg 27.
- 23 Viral infection:** Fatal viral infections other than IPn; provide details pg 27.
- 24 Parasitic/Protozoal infection:** Fatal parasitic infections other than IPn; provide details pg 27.
- 30 Interstitial Pneumonia, idiopathic:** IPn is defined as nonbacterial pneumonia characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload. If the etiology was not determined, indicate as idiopathic. If IPn is a cause of death, provide details on pg 29. Any other form of pneumonia should be indicated on pg 27 if infective, or pg 30 if not.
- 31 IPN-CMV:** Etiology of IPn was Cytomegalovirus.
- 32 IPN-Other Virus:** Etiology of IPn was a virus, not CMV.
- 33 IPN-PCP:** Etiology of IPn was Pneumocystis carinii pneumonia.
- 34 IPN-Fungal:** Etiology of IPn was fungal.
- 39 IPn-Other, specify:** Etiology of IPn was none of the above. Specify the “other” etiology on the line provided.
- 40 Adult respiratory distress syndrome (ARDS):** This diagnosis may be appropriate if the patient died due to hypoxia with diffuse interstitial lung infiltrates but was not

considered to have interstitial pneumonia (IPn) and did not have left ventricular failure, intravenous fluid overload or chronic lung disease [capillary leak of the lungs.] Report details on pg 30. “Aspiration of vomitus” is recorded as ARDS.

- 50 Acute GVHD:** Provide details of acute GVHD on pgs 21-22.
- 60 Chronic GVHD:** Provide details of chronic GVHD on pgs 23-25.
- 70 Persistence or recurrence of underlying disease for which patient was transplanted:** For DX code 300-309 use code “10”, not “70”. Be sure the Disease Insert reflects the presence of disease posttransplant.
- 80 Organ failure,** not otherwise specified: Describe what is known on pgs 30-31.
- 81 Liver** (not VOD): Include all cases of liver failure **other than** those due to veno-occlusive disease or GVHD. Corresponding information should be recorded in Qs693-713.
- 82 (Hepatic) Veno-Occlusive Disease:** If biopsy evidence is not available, criteria for clinical diagnosis are described at Qs700-704. Corresponding details should be entered in Qs693-713.
- 83 Cardiac** (cardiomyopathy): This as primary COD should be fairly rare. Use only if the physician states this as the primary COD, the disease for which the patient received the transplant was not present and no other causes could be determined, record in Qs726-728, as appropriate.
- 84 Pulmonary:** Lung failure not from IPn, ARDS, or infection, includes bronchiolitis obliterans organizing pneumonia (BOOP), or radiation pneumonia. Corresponding details should be entered in Qs673-681 or 691-692.
- 85 CNS** (Central Nervous System): anoxic brain damage; includes brain, and spinal column. Record in Qs720 or 727-728.
- 86 Renal:** Renal failure, nephrotic syndromes. Record in Qs715-716
- 87 G.I.** (Gastrointestinal, not liver): includes all of the organs of the G.I. tract from the mouth to the colon (e.g. peritonitis secondary to small bowel perforation). Record in Qs727-728.
- 88 Multiple organ failure:** more than one organ system and if none can be determined more significant than the other’s, specify which organs (use code numbers) on the line provided. Record each complication in the appropriate posttransplant organ section.
- 89 Other organ failure:** Should be rare; use for organ failure not fitting #s80-88. Specify the “other” organ on the line provided.
- 90 New malignancy:** Must be diagnosed after the first transplant was performed, if prior, use code 140. Please be sure that the new malignancy differs from the malignant disease for which the transplant was performed (e.g. *de novo* leukemia, AML diagnosed many years after a transplant for ALL). Provide details on pg 32.
- 100 Hemorrhage,** not otherwise specified. Provide details in Qs727-728.
- 101 Pulmonary hemorrhage:** Provide details in Qs682-690.

- 102 Intracranial hemorrhage:** Provide details in Qs727-728
- 103 Gastrointestinal hemorrhage:** e.g. peptic ulcer disease, provide details Qs727-728.
- 104 Hemorrhagic cystitis:** Provide details Q719, and if infective etiology, pg 27.
- 109 Other hemorrhage, specify.** Provide details in Qs727-728 and specify the “other” site of hemorrhage on the lines provided (e.g. thrombocytopenia/anemia).
- 110 Accidental death**
- 115 Suicide**
- 120 Vascular, not otherwise specified:** Use this code if “vascular” is all that is known and record in Qs727-728.
- 121 Thromboembolic:** clumps of platelets creating a blockage, e.g. pulmonary emboli.
- 122 Disseminated intravascular coagulation:** This is a hematological syndrome with low platelet count, low serum fibrinogen and prolonged coagulation times. Also record in Qs727-728.
- 123 Thrombotic thrombocytopenic purpura (TTP):** Characterized by thrombocytopenia, hemolytic anemia, and neurologic abnormalities, record pg 31:Q717.
- 129 Other vascular, specify:** Record in Qs727-728 and specify the “other” vascular complication on the lines provided (e.g. cerebrovascular event).
- 130 In utero death** (in utero transplants only)
- 140 Prior malignancy:** Malignancy that existed prior to the diagnosis for which the transplant was performed as reported on p7:Qs17-18.
- 900 Other:** Please carefully consider whether the cause of death can be classified into one of the categories provided above. If this is not possible, then indicate and provide details on “Report Notes” (e.g. hypercalcemia, diabetes). Also report in Qs727-728.
- 771. Was cause of death confirmed by autopsy?** If an autopsy was performed and the results are available, check ‘yes’, if not, check ‘pending’. **Q772** Please include a copy of the report or send when it becomes available and check the appropriate box. On the report, be sure to note your Team number, patient IUBMID number and “pg 36, Q771.”

Confidential/Socioeconomic Information

These data are collected to study the availability of transplant among various groups. One way to collect this information is to photocopy pgs 37-38 and request the patient complete the pages at the time of signing the consent for transplant forms. A note of explanation should be attached so the patient understands the significance of answering the questions. The patient may check ‘unknown’ for data they do not wish to share. All questions should be answered “at the time of transplant.”

- 773. Patient's state of residence (US only):** Use the postal state abbreviations, which can be found in U.S. telephone directories or several directories exist on the Internet.
- 774. Country of residence (check only one):** Report the country in which the patient's home is located.
- 775. Patient is ≥18 years old:** Age at time of transplant. If patient is <18 years old on the day of transplant, skip to Q778.
- 776. Patient's marital status:** ≥18 years old, at time of transplant (check only one).
- 777. Highest grade patient finished in school:** ≥18 years old, at time of transplant (check only one).

Type of health insurance:

At time of transplant (answer each type)

- 778.** None
- 779.** Medicaid - public assistance
- 780.** Medicare - US only
- 781.** Disability insurance
- 782.** HMO - Health Maintenance Organization
- 783.** Individual Health Insurance - generally purchased by the recipient (or family)
- 784.** Group Health Insurance - recipient participates in a group plan, generally through an employer
- 785.** National Health Insurance - non-US, generally provided through the government
- 786.** VA/Military - Veterans Administration or through military service
- 787.** Other - specify insurance not included in the list above.

- 788. Type of fee reimbursement - U.S. patients only** (check only one):
Fee for service - charges accrue as services and supplies are used.
Capitation - charges accrue up to a limit (a "cap").
Other - specify reimbursement that cannot be classified above.
- 789. Occupation:** If age ≥ 18 years old: which category best describes the patient's current or last known job if unemployed or retired (if Q775 is 'no' leave Q789 blank).
- 790. Yearly income of patient/family before taxes:** *U.S. patients only* include income of all members of the patient's household, before taxes are subtracted. If amount is not precisely known please provide best estimate (check only one).

Log of Appended Documents

Whether the Report Form is completed on paper or with StemSoft software any pages photocopied and attached from the patient's medical, **must have all identifiers covered** (blinded) before the copy is made. This is due to recent patient privacy regulations (HIPAA) enacted in the U.S. Identifiers include names (patient, physician, hospital personnel, etc.), locations (addresses, hospital/clinic names), or numbers (medical record, telephone, etc.). Please do not inadvertently cover dates!

On HLA typing reports please re-label the "recipient", "donor", recipient's "mother" and "father" as applicable. Do not submit HLA typing for other persons who were not selected as the donor. Do not submit HLA typing for parents who are not birth parents (e.g. adoptive parents, a step-parent, or parent who do not know they are not the birth parent, etc.)

After blinding please record the attachment on this page, also note the Form type, page and question number on the copy. *Include your Team number and the patient IUBMID number for identification with that patient's Report Form.* These attachments may help keep future communication to a minimum as potentially questionable data will have a copy of the source document available for review. The attachments do not need to be in English. You may also attach a written interpretation if you feel it would be helpful. Please contact the Registry if you have any questions about attachments.

791. Number of attached documents: Please be sure the number listed here matches the number of attachments.

792. to

796. Date of Document: If the date of the document doesn't appear on the page submitted you may hand write the date at the top (e.g. Patient summary letter pg 2 of 3, 23Jul03).

Type of Document: Indicate the type of document and which Insert of the Report Form the document is submitted for.

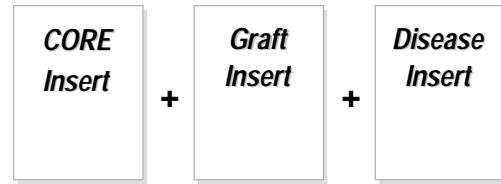
Document Referenced To: Include the page and question number from the Insert. Please double check that the time frame of the document matches the time frame from the Report Form. This section also alerts us to extra copied pages of the Report Form for multiple episodes of events.

Day-100 CORE Insert Institutional Information (page 40)

Date of Report: The date the Report Form was deemed complete and ready to send. All dates reported within the Report Form must be no later than this date. This must correspond with the date entered on the upper right-hand corner of the Core Insert pg 1, Graft Insert and Disease Specific Insert.

- i. **Signed:** The person who actually completed the form should sign and then *legibly print* their name
- ii. **Name of Doctor for Correspondence:** Enter name of physician to whom questions regarding this Report should be directed. This may be a different person than indicated in Question vi. If *copies* of correspondence should be sent to the Clinical Researcher/Data Manager, please indicate. Report name and address of institution where transplant was performed.
- iii.,
- iv. **Telephone/FAX Number:** Indicate telephone and (if available) FAX number(s) for Physician (and others) listed in Question ii.
- v. **Make Reimbursement Check Payable to:** List the name that should appear on the reimbursement check. If a physician or data manager in the United States is directly reimbursed, it is necessary to furnish his/her social security number for tax-reporting purposes. Payment for the Report Forms is contingent on the availability of funds that have been obtained from sources external to the Medical College of Wisconsin for purposes of these payments.
- vi. **Physician's Initials to Indicate Consent of Patient/Authorized family member-guardian:** Individual patient/family consent is NOT required by the IBMTR/ABMTR in order for data to be submitted per Medical College of Wisconsin IRB review, although many institutions now obtain consent. In order for data to be used and disclosed by the IBMTR/ABMTR, a signed Data Use Agreement must be on file with the registry. For more information or to request a copy of the IBMTR/ABMTR Data Use Agreement, please contact the registry at 414-456-8325 or ibmtr@mcw.edu
- vii. **Determining the cut-off for this Day-100 Report Form** (Note: all three parts should have the same Date of Report and date of HSCT/DCI). Please make sure you use the most current version of the Report Form by occasionally checking online at <http://www.ibmtr.org>. A complete Report Form consists of the following three parts:
 - 1 A (white) CORE Insert
 - 2 A tissue appropriate Graft-specific Insert (ALLOBM, ALLOPB, ALLOCB [blue], AUTOBM or AUTOPB [pink].)
 - 3 An appropriate [ivory] Disease-specific Insert

Report Form =



viii. As defined on pgs 15 & 16, was a reportable HSCT or DCI performed?

- ix.** ‘Yes’ - Was conditioning given for subsequent transplant? If ‘yes’, cut-off for this Report Form is one day prior to conditioning start date. If ‘no’, cut-off for this Report Form is one day prior to the subsequent infusion.
- x.** Enter date 100 days from this transplant. A graphic date finder/scheduler or computer calculation will be most accurate. For a quick estimate, add 3 months plus 10 days from the Date of Transplant, or use the Table in Appendix B.
- xi.** Was patient alive on Day 100 for this Report Form? If the patient was alive up to this date without a subsequent reportable transplant/infusion please be aware that data in this Report Form should encompass at least up to Day 100. If an evaluation was not actually performed on this date by your physicians or a referring physician, choose the next later visit as close to this date as possible. Information after the LCD for this Report Form should be recorded on a Follow-up Report Form or subsequent transplant Report Form, as applicable. If the patient expired prior to Day 100 answer all post-transplant questions *up to the date of death* (e.g. it is understood that therapy is discontinued at death, was therapy being received up to the time of death?) If complications were not documented prior to death but are identified at autopsy, record the date of onset as *the date of death and complete the appropriate section in the Report Form*.

Extra Questions CoreFU Insert

7. to

17. **Collect information on quality of life posttransplant.** These questions were intentionally deleted from the Day-100 Report Form as most patients did not return to school or work in the first 100 days, thus the information is collected in the Core Follow-Up only. If the patient did return to work or school in less than 100 days, report in the first Follow-Up completed after the Day-100 Report Form. If the patient expires during the reporting period represented by the Follow-Up, skip Qs7-17. These patients would be excluded from a quality of life study.
7. **Does patient (age >6 years) currently attend school?** For analysis, school age is defined as >6 years old, which is the age most children are required to attend school. If the child is less than 6, but attends school, you may answer Q7 'Yes' and complete Qs8 & 9. Include home schooling as 'yes'.
8. **Specify patient student status:** Anything less than the full schedule should be reported as part-time.
9. **Date returned to school:** Report a return to school only after it occurs; do not report the intention to return to school.
10. **Has patient resumed all household activities?** Subjective. Has the patient returned to the activities they were capable of prior to TX? Or in the case of children, age appropriate activities.
11. **Date activities resumed:** Date must be within the reporting period.
12. **Was patient employed outside the home prior to current illness?** If the patient is a child (<18 years old) check that option. If patient is <18 and was employed prior to the current illness, check 'yes'. Between diagnosis and the transplant, if patient was not working or if retired and not working, check 'No'.
13. **Has patient returned to work?** Report a return to work only after it occurs; do not report the intention to return to work.
14. **'Yes' Date returned to work:** Date must be within the reporting period.
15. **'No' Is patient able to work, but not employed?** There are many reasons a patient may be able to work but is not employed. It could be any reason from being imposed by the physician to the patient just does not want to work.
16. **Is patient now employed?** Report working patients who were not employed prior to the current illness here.

- 17. Date work began:** Date must be within the reporting period.
- 20. Did patient achieve an initial hematopoietic recovery (ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values*) since last report?** Most patients will have already recovered their ANC (engraftment) by day 100; therefore, this question reads as it does.
- Engraftment: please review Core Q362 for definitions of achieving ANC engraftment and selecting the date to list on the Report Form.
- Opt 1 ‘Yes’ – indicates the patient did not achieve 500 ANC in the initial transplant Report Form but has now. This assumes no further HSCT (except autologous rescue) or DCI, in which case a new HSCT/DCI Report Form should have been completed for that TX/infusion. Q21 Date – see Core Q362 for date parameters.
- Opt 2 ‘No, patient’s initial hematopoietic recovery was recorded on a previous report’ – Double check the copy of the transplant Report Form or Follow-Up Report Form prior to this Follow-Up Report Form to verify the data was previously submitted.
- Opt 3 ‘No, patient has never achieved an ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values* and there is no evidence of recurrent disease’ – in the bone marrow.
- Opt 4 ‘No, patient has never achieved an ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values* and there was documented persistent malignant disease posttransplant’ – in the bone marrow. Persistent malignant disease in the bone marrow will have an effect on engraftment. This is an important distinction for analyzing failure of ANC recovery.
- 52. Was acute GVHD still present at time of last report?** Double check the copy of the transplant Report Form or Follow-Up Report Form prior to this Follow-Up Insert to verify acute GVHD had not resolved or progressed to chronic GVHD as of the LCD of the last Report Form. If the patient had acute GVHD, but it resolved or progressed to chronic on or before the LCD of the last report check ‘no’. If ‘yes’ answer Qs54-112 for the time period represented by the Follow-Up Insert.
- 113. Was chronic GVHD present at time of last report?** Double check the copy of the transplant Report Form or Follow-Up Report Form prior to this Follow-Up Insert to verify chronic GVHD had begun and was not resolved as of the LCD of the last Report Form. If the patient had chronic GVHD, but it resolved on or before the LCD of the last report check ‘no’. If ‘yes’ answer Qs121-207 for the time period represented by the Follow-Up Insert.
- 319. Has the patient or partner become pregnant since last report?** We are collecting the fertility of the transplant recipient in this question. If their partner became pregnant, but it had nothing to do with the recipient, check ‘no’.
- 320. to**
- 322. Options include:** Fathered a child with cryopreserved sperm, fathered a child naturally, had a live birth.

Extra Questions DCI Insert

3. **Total number of previous reportable HSCT/DCI patient has had:** Please follow these rules for counting:

HSCT: cells given <14 days from the first HSCT infusion count as one HSCT.

DCI: cells given <28 days from first DCI infusion count as one DCI.

8. to

15. These questions were designed to uniformly collect procedures which will be sorted as HSCT or DCI. It is important for the sake of accurate analysis to answer the questions and complete the Day-100 or DCI Report Form as defined on pg 2.

16. **Indication for this DCI (*check only one*):** if more than one applies, please ask the physician that performed the DCI to determine a single response. You may make a margin comment if necessary. Note: decreasing chimerism may suggest the patient is losing the graft after NST, but boosting the patient with donor T-cell is subtly different than an “empty marrow” (graft failure) after an ablative transplant.

85. to

101. Duration of Aplasia Post-DCI section:

Measuring the effect of the DCI is different from measuring HSCT engraftment, as the recipient may have an ANC count above $500/\text{mm}^3$ ($0.5 \times 10^9/\text{L}$) Please follow these two requirements for selecting the date ANC 500 was achieved or platelet levels are achieved:

ANC date should be the first date of three consecutive lab values tested on different days. The labs may also be consecutive days, but if they are not tested on consecutive days, use what is available.

Platelet date/s: Recipient should not have any platelet transfusions in the 7 days prior to the date selected for achieving $20 \times 10^9/\text{L}$ or $50 \times 10^9/\text{L}$. The date should be the first of three consecutive lab values tested on different days. The labs may also be consecutive days, but if they are not tested on consecutive days, use what is available.

109, &

135. These questions are similar, but note the time frame is different.

SECTION 3 - THE DATABASE: ACCESSING YOUR OWN DATA

We often get requests from centers that would like to get an electronic copy of the Report Forms they have submitted so that they can put the information from old Report Forms into the BMTbase Reports database from StemSoft Software, Inc. We do provide extraction of the tables in our Report Form database, but the format is quite complex and you will probably need to work with StemSoft Software, Inc. to have this data transferred to a BMTbase Reports database, for which they charge a fee. We can provide documentation on the format and coding of the extracted file so it may also be used by programmers at your center for purposes other than populating the BMTbase Reports database.

If you wish to receive an extraction of the Report Form data submitted by your center, please provide a written request on the letterhead stationery of your institution. This request should specify whether you are requesting data on allogeneic or autologous transplants, be signed by the Center Administrator and be mailed or faxed to the Registry, attention: Claudia Abel, Data Coordinator. Most requests are accommodated within 2-3 weeks.

Included in the data set are your team's actual data, as well as IBMTR database format and coding documentation. Each patient is entered as a single case. After accessing a particular case, information is available on any of that patient's transplants or follow-up reports via multiple record types. A table at the beginning of the document identifies various record types used to house the data, and points out those records which may occur more than once per patient to accommodate reports of multiple transplants and follow-ups.

Note: the data is primary numbers. Any descriptions written in specify fields, or in the margins, were recorded as code (a number) if an appropriate question existed in which to capture the information.

The following instructions for sending Report Form data to the IBMTR/ABMTR on diskette come directly from the BMTbase Export Help for version 2.5, 2.6 and 3.0 BMTbase Export, copied with permission for the convenience of our StemSoft BMTbase users. The IBMTR is not responsible for keeping them up-to-date with new version of StemSoft software. If there are any questions about this process, please contact StemSoft Software Inc at support@stemsoft.com or 800/671-3234.

Exporting BMTbase Reports Data to Registry Formatted Files

Using BMTbase Export, you can submit your BMTbase Reports patient data to the IBMTR/ABMTR on diskette. These diskettes will not be returned to you by the IBMTR. The IBMTR has requested that data managers do not submit more than one diskette of BMTbase Reports Form data per month, unless requested to do so for a patient in a priority study. Over one hundred Report Forms will fit on a single diskette. To conserve diskette usage, do not send each Report Form on an individual diskette.

To submit your BMTbase Reports patient data to the IBMTR/ABMTR on diskette:

1. In the **Export From** section, click **BMTbase Reports**.
Your default BMTbase Reports database folder will appear.
 2. In the **Export To** section, click **Formatted Files for Submission to Registry**.
Your default Registry Formatted Files folder will appear.
You can set this to your a:\ to save the files directly to a floppy diskette.
- Note:** Always confirm your **Export From** and **Export To** paths. If a path is incorrect, click **Browse** and select the correct folder, or edit your default values.
3. Click **Next**.
The **BMTbase Export – Reports to Registry** screen will appear.
 4. In the patients and reports list, select the reports you wish to submit to the Registry using one of the following methods:
 - To export only those reports that have not previously been exported, click **Non-Exported**.
 - To export only those reports that you have marked as Completed in the BMTbase Reports Completed check box, click **Completed**. (You must manually tick the Completed check box on each completed report in BMTbase Reports. Reports are not marked as completed automatically.)
 - To export one or more individual reports, highlight the reports in the list.
 5. Click **Export**.
The export progress bar is displayed, and then a list of the Registry Formatted Files that have been created is displayed in the **Files Created** dialog box.
 6. In the **Files Created** dialog box, click **OK**.
The **Exporting Complete** dialog box will appear.
 7. In the **Exporting Complete** dialog box, click **OK**.
 8. Click **Print List** and print the **selected** reports.
 9. You must **Exit** BMTbase Export to removing the diskette to complete the creation of the Registry Formatted Files.

- 10.** Send the diskette to the Registry along with a copy of the patient list you printed. If you saved the files to a folder, copy them onto a diskette and send to the Registry.

Note from IBMTR staff: Before sending a disk to the Registry, right click on the Windows 'Start' button and click 'Explore'. Highlight your floppy disk drive to verify that files were actually written to the diskette. If the disk is empty, contact StemSoft Software Inc. at support@stemsoft.com for further instructions.

Print options define Export options:

BMTbase Export uses the print options in your BMTbase Reports database for its export options. To change or check these options, click the print button in BMTbase Reports. The Print Options are on the right. If you change them, click Cancel to avoid actually printing anything. The Print Options will still be changed.

Range of reports:

To select a range of reports, select the first report in the range, hold down SHIFT and select the last report in the range.

Display order:

You can change the order in which reports are displayed in the list by clicking on a column heading.

Cancel function:

If Cancel is clicked during the export process, it will continue until it has completed the export of the current report and will not undo the export of any reports whose export process was completed.

Checking the file on the disk:

Look at the extension (three letters of the filename after the dot.)

- .IAR = IBMTR/ABMTR Report and is the correct format for exporting a Report Form.
- .TED = export format for Registration data.
- .ZIP = database backup file, do not send these or a file with any other extension.

Correctly formatted export files are ASCII text file and can be viewed using the Word Pad accessory in Windows. If you wish to view the contents of the export file you can do the following:

Locate and highlight the file in the Windows Explorer
Hold down the shift key while **right**-clicking the mouse
Choose 'Open with ...' from the menu
Choose 'Word Pad' from the list of programs

The contents of the file is not very interesting to look at, just a lot of numbers, but you should be able to identify your center number and the patient's IUBMID on the first line.

Error Reports:

We will send electronically, Error Reports generated for Registration documents received electronically. You may make corrections, highlighting them in red, and return the Error Report electronically. Error Reports for Report Forms are not sent electronically at this time. Please continue to return these by fax or traditional mail.

APPENDIX A

Timelines For Reporting Data

What is a Report Form? In 1995 IBMTR adopted a modular style report form, in cooperation with the National Marrow Donor Program (NMDP), so as to be able to accept copies of NMDP Report Forms in lieu of the IBMTR/ABMTR Report Forms for Teams who submit data to both registries. The RF consists of three distinct Inserts:

Core Insert: one for every HSCT, which collects clinical status of the patient pre- and postHSCT in addition to the actual transplant procedures outlined in the patient's protocol.

Graft Insert: one for each tissue infused for that HSCT. Usually only one Graft Insert is required, but if the patient received more than one product, e.g. marrow (BM) and peripheral blood (PB), two Graft Inserts would be completed, one for each product.

Disease Insert: typically only one Disease Insert is completed and it is the disease for which the transplant is performed, although there are a few exceptions:

MDS that transforms to AML prior to the first HSCT requires both MDS and AML Inserts.

Fanconi Anemia with concurrent MDS/AML prior to the first HSCT requires FAN and MDS or AML as applicable.

MYE and AMY, complete only MYE.

Note: In the past the Core Insert had been referred to as a "Core Form", but that term is no longer used as there was a lot of confusion as to whether it only referred to what is now called the Core Insert or the entire Day 100 RF. Please do not use the term "Core Form".

Figure 1:

Upper left corner depicts a **Day 100 Report Form (RF)**. This document is cut-off with the day 100 (d100) visit. If the patient is not seen on d100, the next closest visit *after* d100 should be used, e.g.

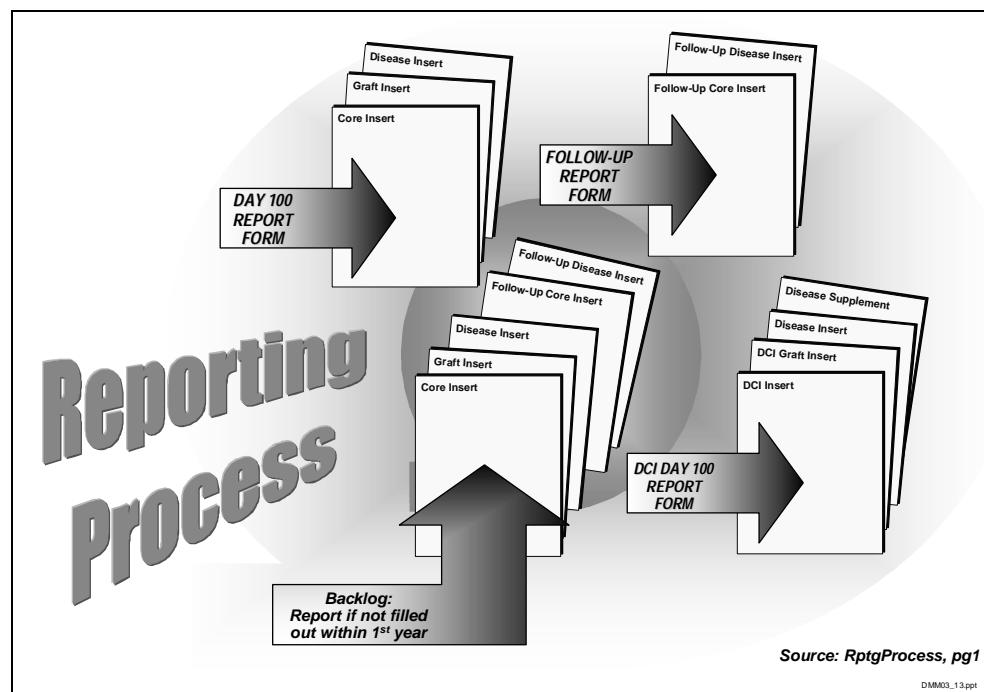


Figure 1. "Reporting Process" timeline

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patient seen on d99 and d104, use d104. Your transplant Team does not have to be the one to perform the d100 assessment, it can be done by a referring physician, or any physician that the patient is presently being followed by. If the patient dies prior to d100, the RF will cut-off as of the date of death. All questions should be answered “up to the time of death”, e.g. is patient still receiving treatment? It is assumed treatment is discontinued at death, but was the patient receiving treatment up to the time of death?

Continuing across to the upper right corner, there is a **Follow-Up Report Form (FURF)**. This report begins the day after the d100 assessment and ends on the HSCT anniversary visit. One FURF is completed each year thereafter, unless the patient receives a subsequent HSCT or DCI. Common scenarios are depicted in later Timelines.

Lower left corner shows what should be completed if the patient’s HSCT occurred more than two years ago (**Backlog**). The Day 100 RF is still cut-off as stated previously, on d100. Only one FURF should be completed for the remaining time, assuming no subsequent HSCT or DCI occurred (Fig 3). See later timelines for those scenarios (Fig 7, 9, 11, 13).

Lower right corner is a **DCI Report Form**. The DCI Insert is analogous to the Core Insert, DCIG is the appropriate Graft Insert, the Disease Insert is the same as the one completed for HSCT #1, and a Disease Supplement is completed only if the Disease Insert did not collect treatment for the patient’s disease between the previous HSCT/DCI and the current one.

Figure 2

Each RF, FURF and DCI entered to the database has a distinct start and end date, and could be placed onto a timeline. That is why it is important to be aware of what the correct start and end date is for each

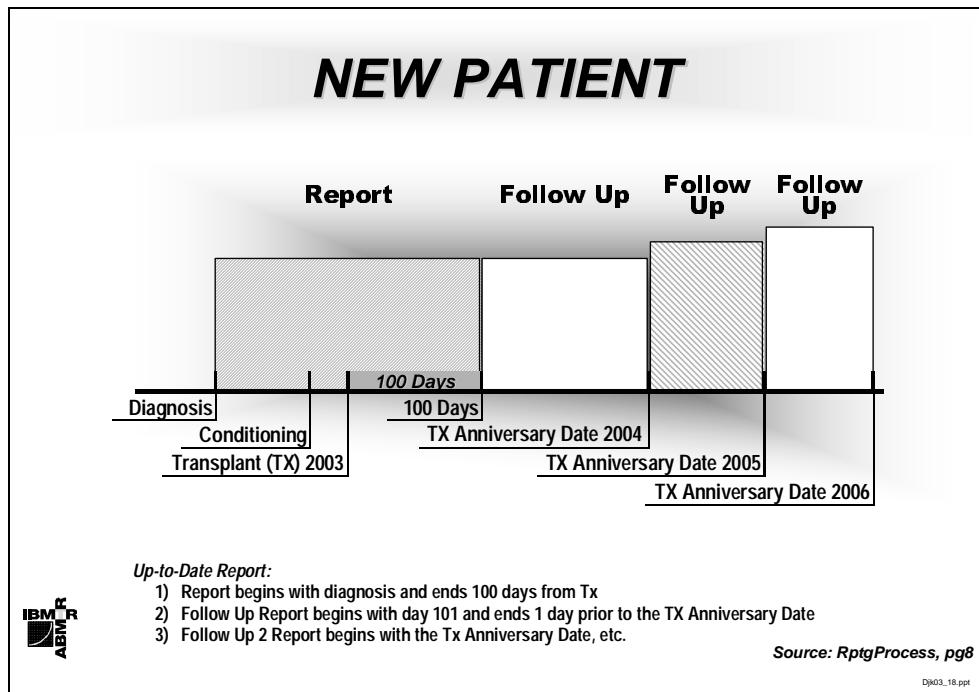


Figure 2. “Up to date reporting” timeline

document. The database is organized much like a filing cabinet. The various RFs are sorted into “folders,” one for each HSCT or DCI. When a complication occurs after a subsequent HSCT or DCI, but is reported in the first HSCT RF, it is like placing the page with the complication in the wrong file folder. When reporting current patients, the timelines included in 002-Core Insert (p15/16) and 002-DCI

Insert (p5/6) are designed to help you determine what is the appropriate cut-off date for each document when a subsequent HSCT/DCI occurs. It may be helpful photocopy these diagrams as templates and actually write the significant dates on them. As you go through the patient's chart you will then know into which document the various pieces of data belong. If all of the data is neatly organized in the patient's chart, you might not need to do this, but rarely is every single piece of paper exactly where it is supposed to be at all times. And most of us cannot keep all of the significant dates for each patient in our head (nor should you try!) If the patient has no additional HSCT or DCI, and the reporting period is kept current, the reporting will look like this:

Figure 3

If the patient has no additional HSCT or DCI, and it is more than one year post HSCT, reporting looks like this:

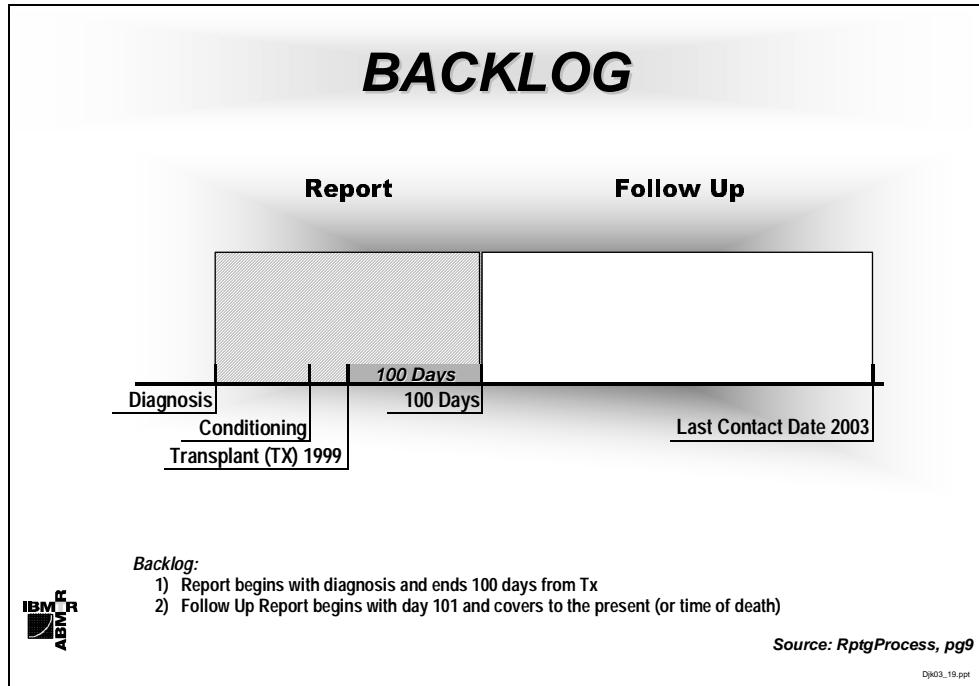


Figure 3. "Backlog reporting" timeline

The additional timelines in this appendix are for patients that have already had an initial HSCT RF completed and/or FURF and then have a subsequent HSCT or DCI. You must be aware of the Last Contact Date (LCD) reported to IBMTR on the last RF submitted to know when reporting resumes and whether a FURF is required prior to the subsequent HSCT or DCI RF (one almost always is.) When the data is analyzed the interval between significant events is usually part of the study. Unless all points in time are correctly recorded in the database, the interval to significant events may be missing or incorrectly represented.

If the patient already has the first HSCT RF and possibly one or more FURFs submitted, and then reporting stopped for a while but now the patient had another HSCT or DCI, it is important to begin

reporting from the LCD of the last RF/FURF submitted. Typically, one more FURF from that LCD to one day before conditioning for HSCT or one day prior to DCI, is needed. Do not skip this FURF, if required, as quite often this is the document that captures the reason for the subsequent HSCT/DCI (Figure 4/Figure 5)

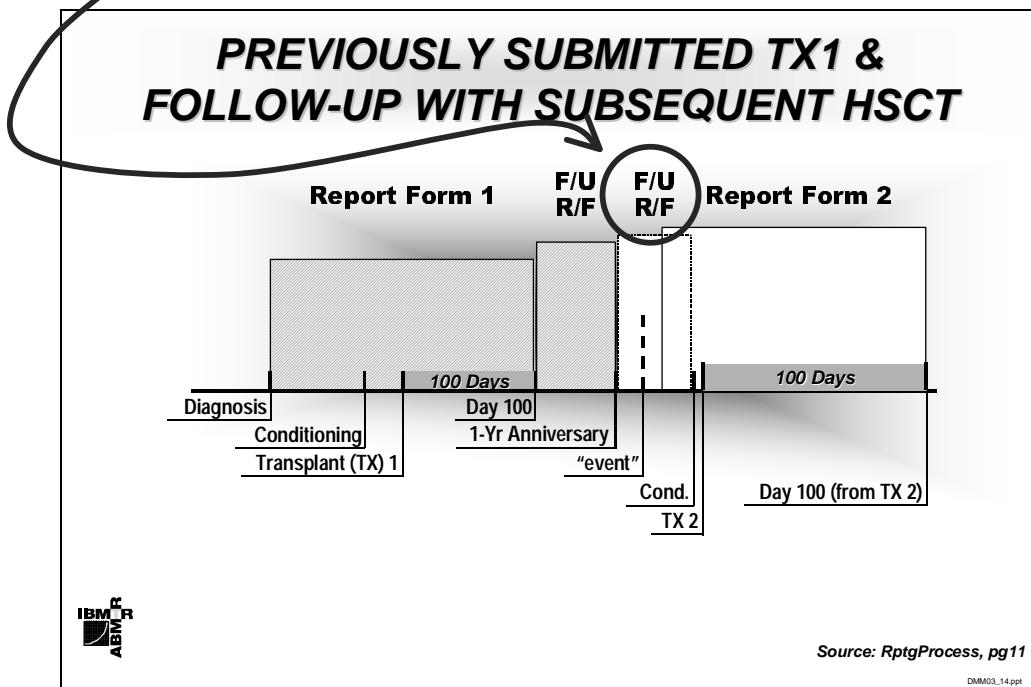


Figure 4. Previous submission and subsequent HSCT

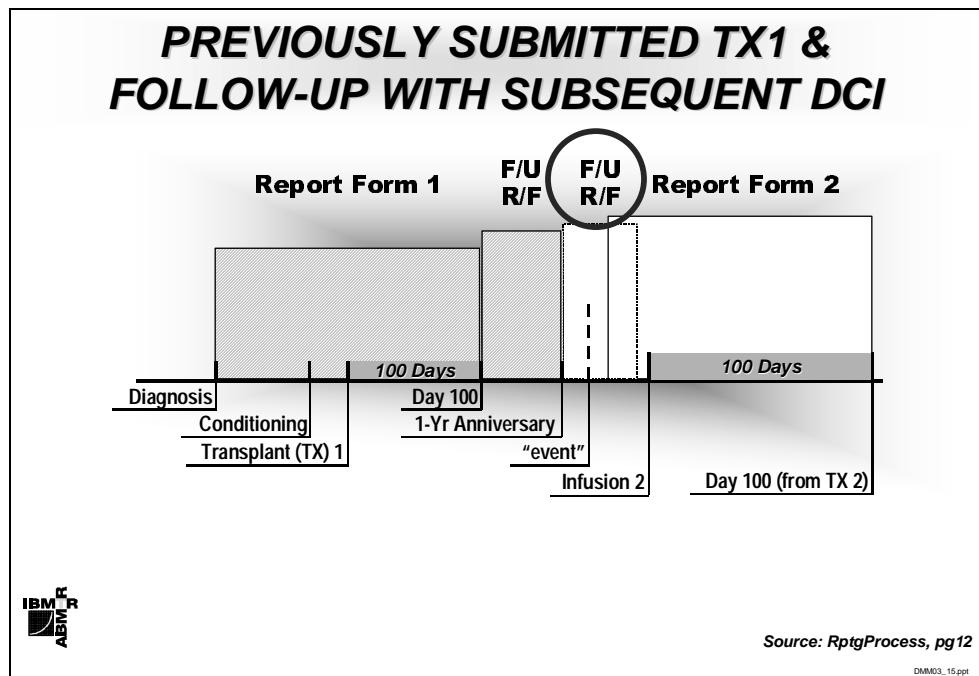


Figure 5. Previous submission and subsequent DCI

Figures 6-13

The first two divisions between Figs 6-13 are whether the subsequent HSCT/DCI was less than 100 days from the one currently being completed or more than 100 days apart. Then you may notice the HSCT and DCI diagrams are almost identical, except HSCT shows the start of conditioning (Figs. 6, 7, 10, 11) and DCI's (Figs 8, 9, 12, 13) never use conditioning. There may be times when HSCTs do not use conditioning, but are still HSCTs and not DCIs. If the patient is transplanted for a disease in which they do not have an immune system strong enough to mount a response to the Allogeneic graft, no conditioning may be used, e.g. Immunodeficiency Diseases. If the patient has had a transplant and did not engraft, additional *donor stem cells* may be infused, again without conditioning. These should still be reported as HSCT and not DCI simply because no conditioning was used. When completing the Day 100 RF for an HSCT without conditioning, any question qualified by the phrase "just prior to conditioning" or "after the start of conditioning" should be read as "just prior to subsequent infusion" or "after/post infusion." Do not leave the questions blank just because "conditioning" is mentioned and the patient didn't have any. If you do not know what conditioning is or are unsure whether the patient received a subsequent HSCT or if it was a DCI, your best resource is the physician that transplanted the patient or your transplant Team Leader. If a doctor is unavailable to you, you may contact IBMTR and we will try to help you sort out the events. Conflicting data in the patient's chart must be sorted out by a physician or other qualified person at your Center.

What's the difference between multiple infusions and subsequent transplants or DCI's? Some patients receive more than one infusion within a single HSCT or single DCI. In order to sort out if any combination or schedule is better, some rules were created to categorize what was being done. The purpose of the rules is to collect what happened in a systematic fashion. There are other possible ideas for collecting the data, but this is how the system is set up for now:

- Any infusions given within 14 days of the first infusion for an HSCT will be counted as one single transplant with multiple infusions. If a Report Form is required, you will complete one Core Insert and one Disease Insert, but you must complete separate Graft Inserts for different tissues or separately answer Graft Insert questions pertaining to the handling of the graft and quantity of cells infused for each day of infusion for the same tissue.
- Typically engraftment has occurred by d14, if not, intervention is generally taken and should be reflected as a separate HSCT (unless it is an autologous rescue: 002-Core p34:Q754).
- DCIs were given the cut-off of twenty-eight days. Any infusions less than 28 days from the first are considered multiple infusions for a single DCI, anything after must be reported separately.
- Any time conditioning is used, that HSCT must be reported separately, regardless of how much time has lapsed.

These timelines can be linked together as needed to figure out when to start and stop reporting in any given document. For example, a patient has HSCT-1, d50 allo HSCT-2 for poor engraftment, d125 first DCI (counts as DCI RF #3) for declining chimerism, d180 DCI-2 for relapse (count as DCI RF #4), the following documents would be used:

Day 100 RF #1 from diagnosis of disease to d49 (fig 6).

Day 100 RF #2 from patient status evaluation just prior to HSCT-2 through d100 from HSCT-2 and FURF from d101-d124 (fig 9).

DCI RF #3 from patient status evaluation just prior to DCI-1 through d100 from DCI-1 and FURF from d101 after DCI-1 through d179 from DCI-1 (fig 13).

DCI RF #4 from patient status evaluation just prior to DCI-2 through d100 from DCI-2.

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As long as patient survives, continue FURF on the anniversary of DCI-2 (RF #4).

Please note the 002-Core Insert version was 05/03 unfortunately contained a misprint on pg 16. Inside the box at Q318, the title of the top timeline shows “>28 Days.” It should read “>14 days.” Also, the 002DCI Insert pg 5:Q40 should read “<100 Days,” not “>14 Days but.”

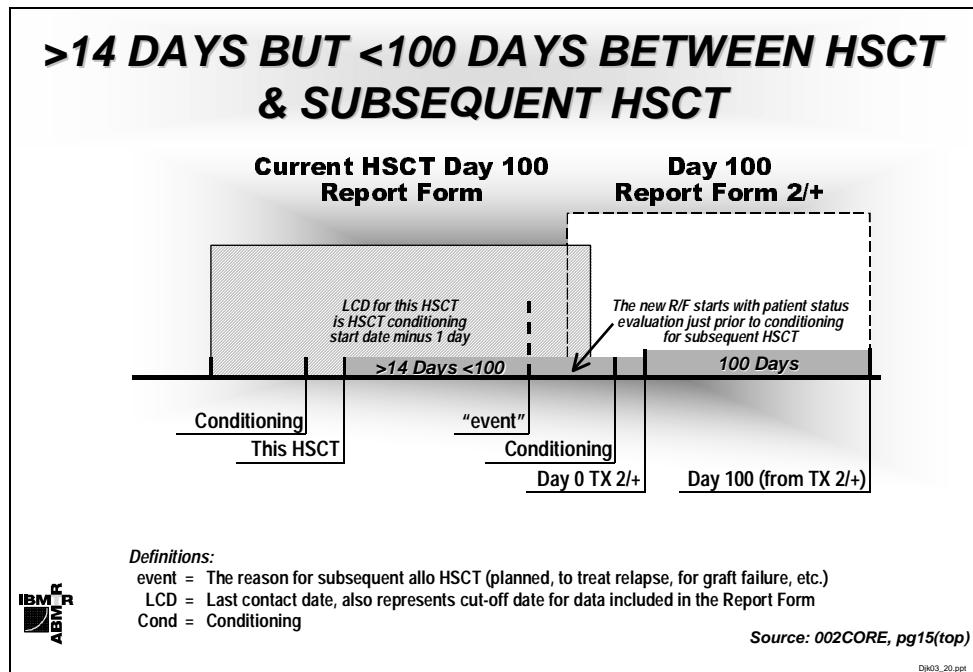


Figure 6. 002-CORE, top of pg 15

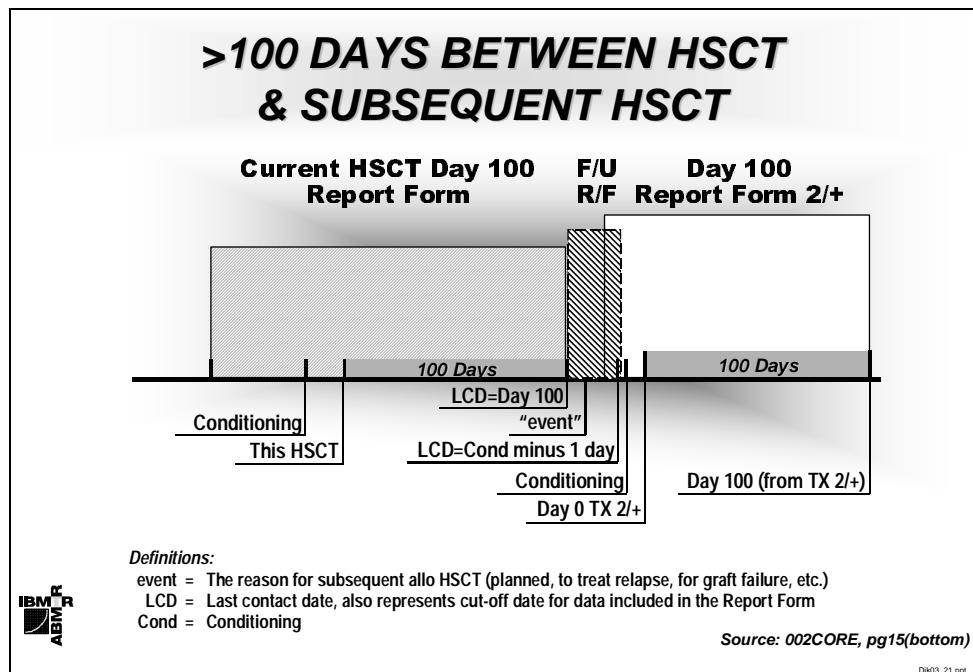
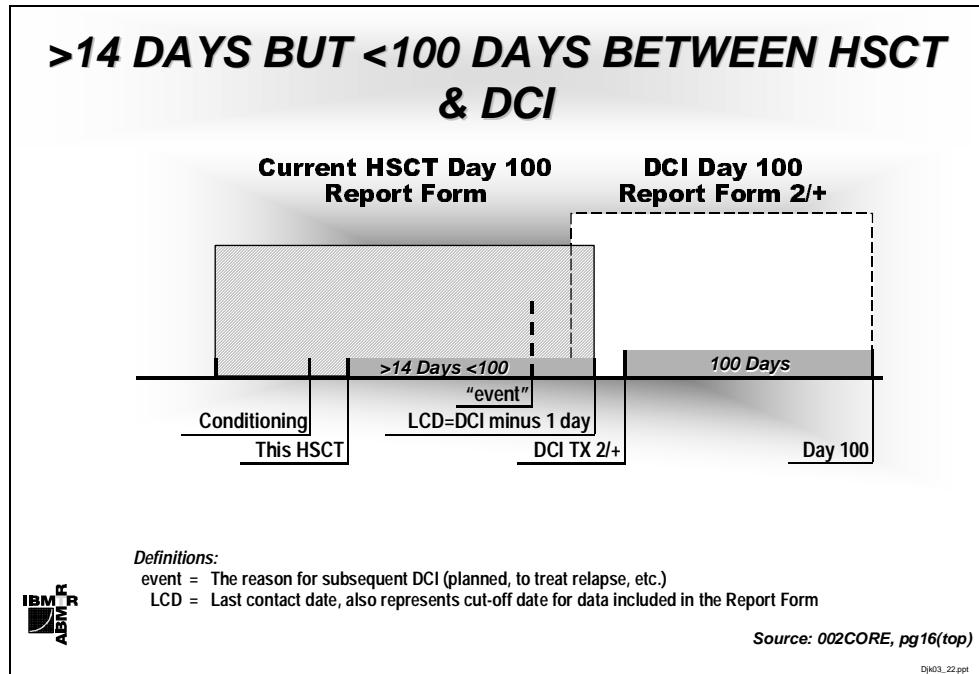
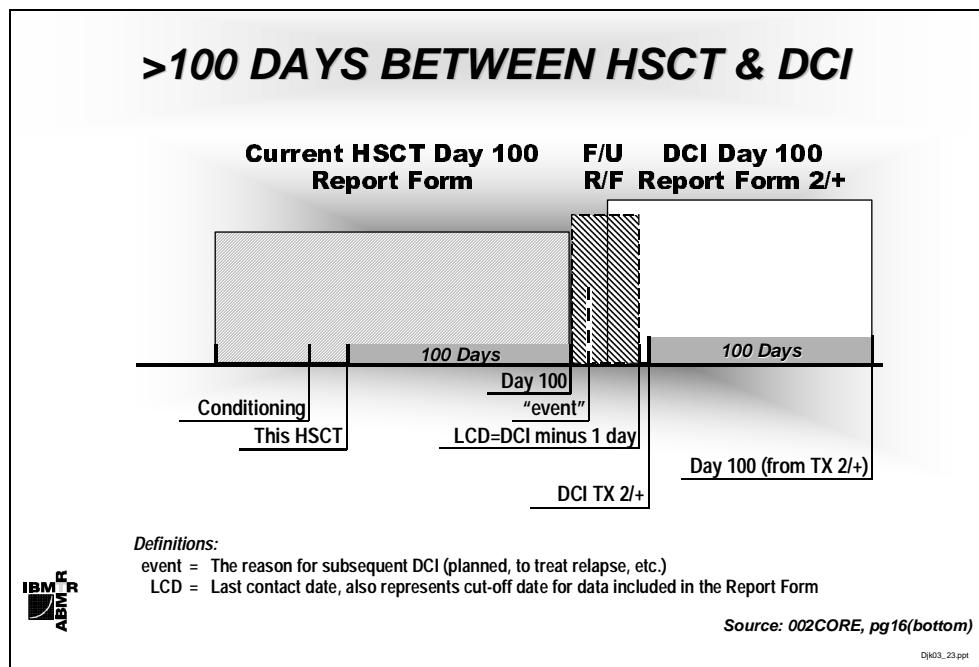


Figure 7. 002-CORE, bottom of pg 15

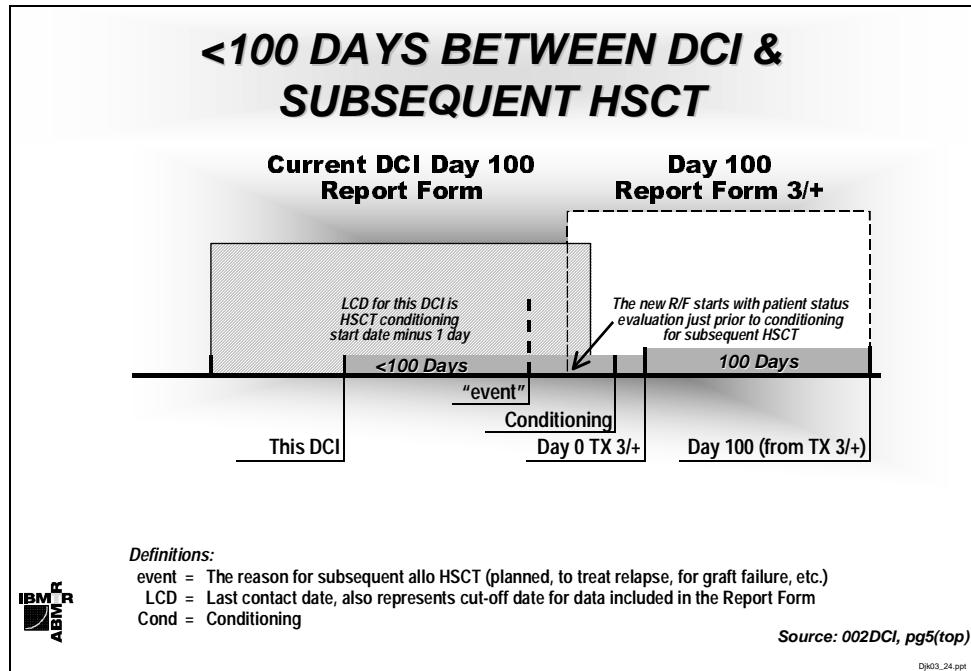
**Figure 8. 002-CORE, top of pg 16**

Please note the 002-Core Insert (05/03) unfortunately contained a misprint on pg 16. Inside the box at Q318, the title of the top timeline shows “>28 Days.” It should read “>14 days” as shown in Fig 8.

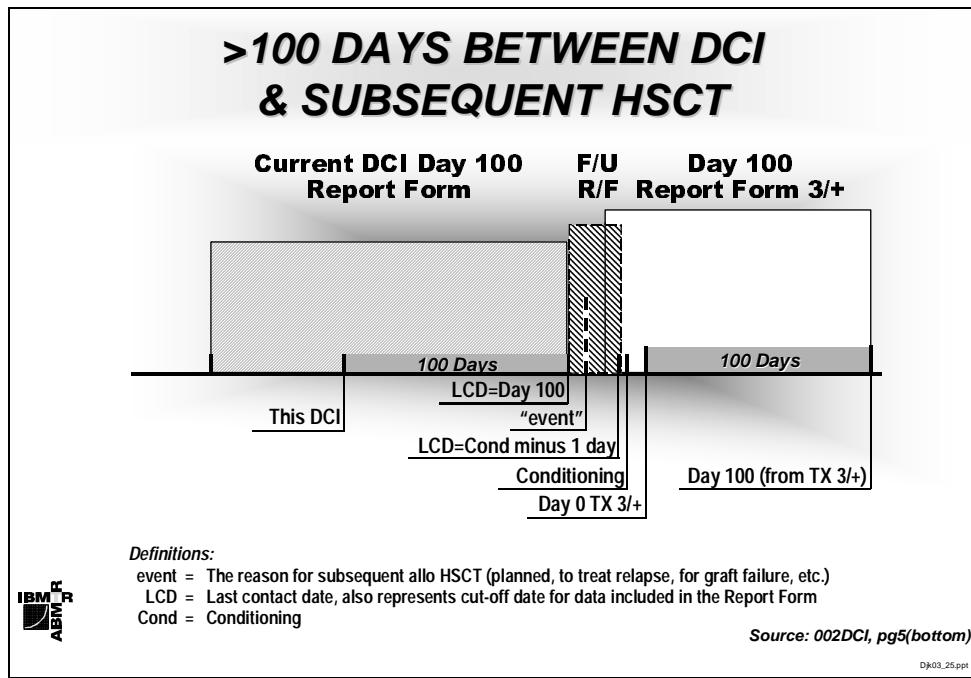
**Figure 9. 002-CORE, bottom of pg 16**

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**Figure 10. 002-DCI, top of pg 5**

Please note the 002DCI Insert (05/03) unfortunately contained a misprint on pg 5:Q40. It should read “<100 Days,” not “>14 Days but” as in Fig 10.

**Figure 11. 002-DCI, bottom of pg 5**

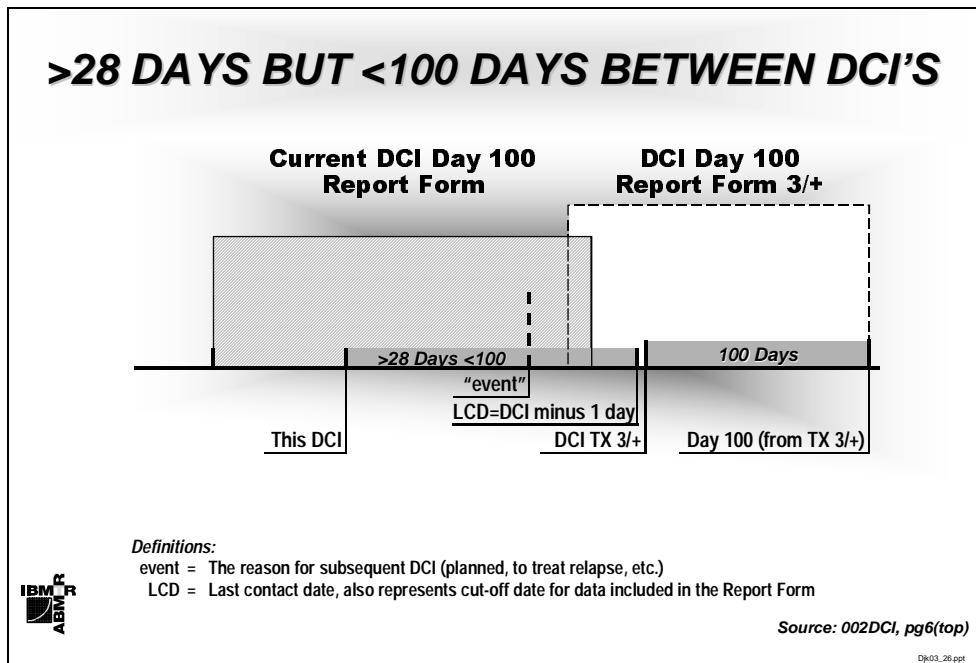
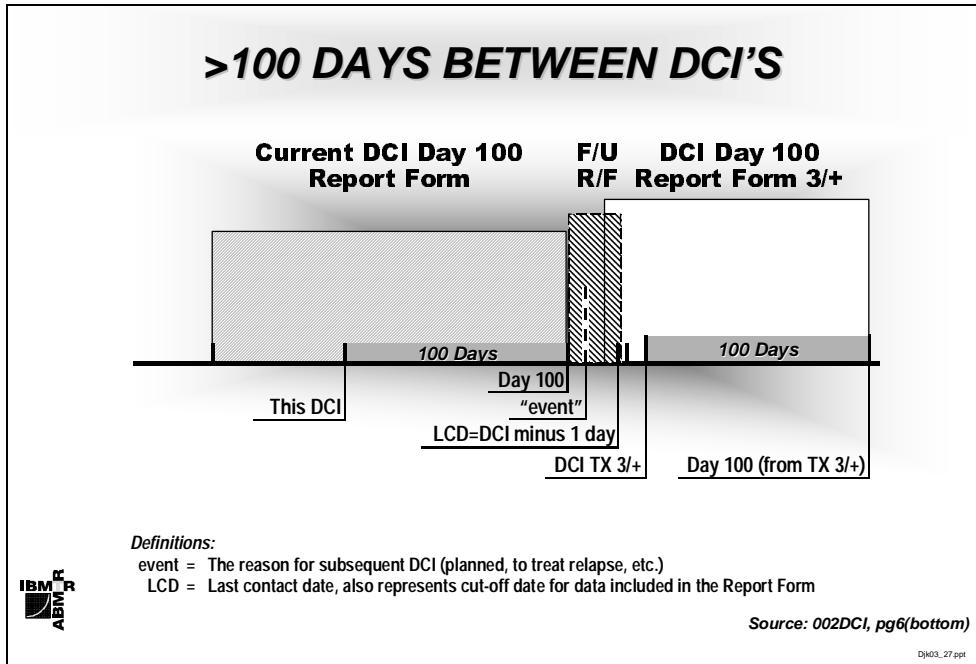
**Figure 12. 002-DCI, top of pg 6****Figure 13. 002-DCI, bottom of pg 6**

Figure 14 and 15 are samples of how you can use the timelines for a particular patient and write out their transplant story to show what the cut-off dates should be to assist you as you go through the patient's chart.

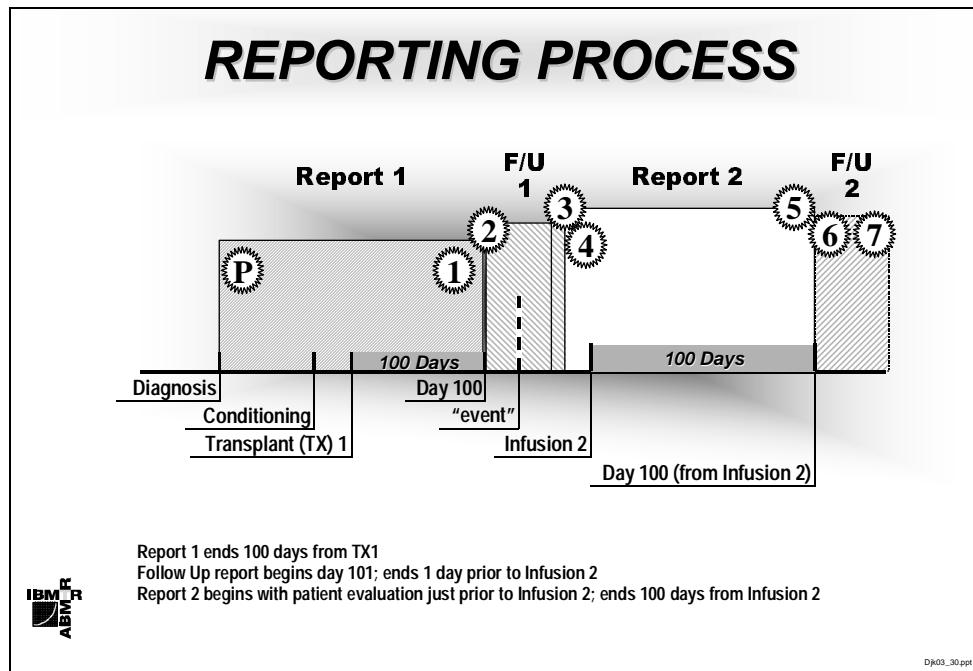


Figure 14. Reporting Process Diagram 1

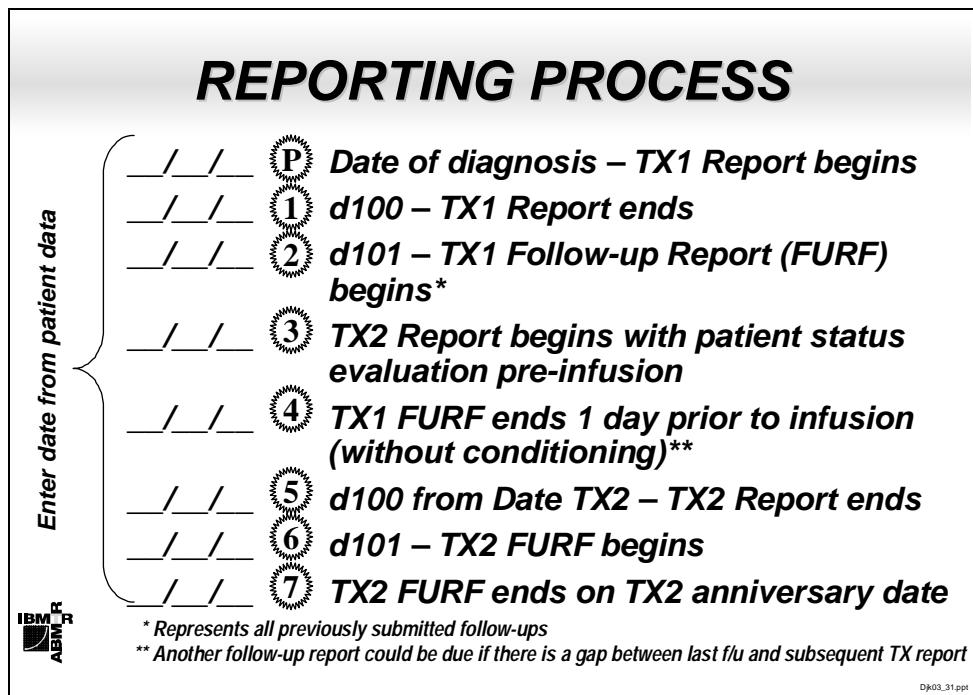


Figure 15. Reporting Process Diagram 2

APPENDIX B

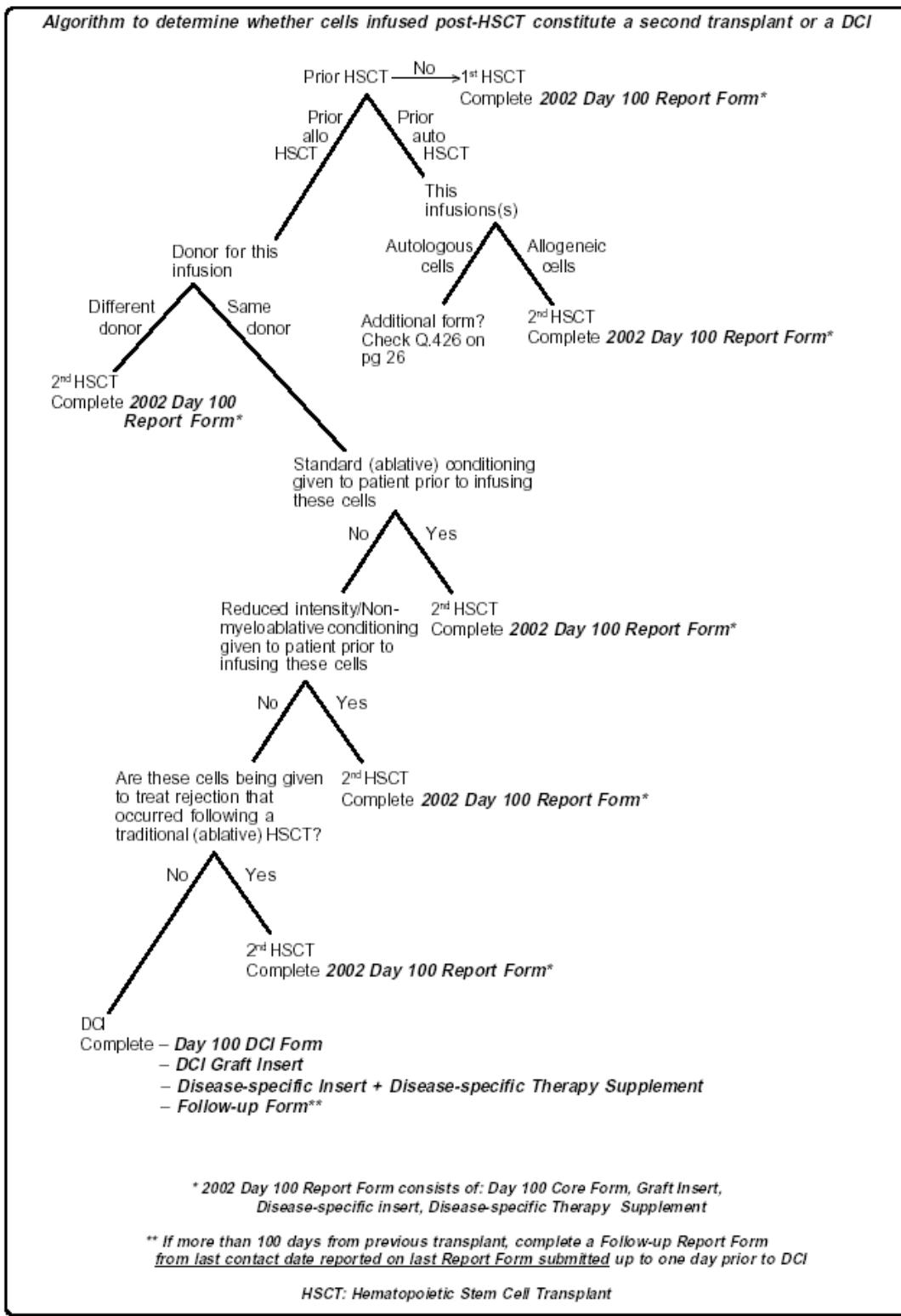
Calculating Day 100

Select the day of the transplant (column 1), move over to the month of transplant, that is Day 100.

TX Day	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	4/11	5/12	6/09	7/10	8/09	9/09	10/09	11/09	12/10	1/09	2/09	3/11
2	4/12	5/13	6/10	7/11	8/10	9/10	10/10	11/10	12/11	1/10	2/10	3/12
3	4/13	5/14	6/11	7/12	8/11	9/11	10/11	11/11	12/12	1/11	2/11	3/13
4	4/14	5/15	6/12	7/13	8/12	9/12	10/12	11/12	12/13	1/12	2/12	3/14
5	4/15	5/16	6/13	7/14	8/13	9/13	10/13	11/13	12/14	1/13	2/13	3/15
6	4/16	5/17	6/14	7/15	8/14	9/14	10/14	11/14	12/15	1/14	2/14	3/16
7	4/17	5/18	6/15	7/16	8/15	9/15	10/15	11/15	12/16	1/15	2/15	3/17
8	4/18	5/19	6/16	7/17	8/16	9/16	10/16	11/16	12/17	1/16	2/16	3/18
9	4/19	5/20	6/17	7/18	8/17	9/17	10/17	11/17	12/18	1/17	2/17	3/19
10	4/20	5/21	6/18	7/19	8/18	9/18	10/18	11/18	12/19	1/18	2/18	3/20
11	4/21	5/22	6/19	7/20	8/19	9/19	10/19	11/19	12/20	1/19	2/19	3/21
12	4/22	5/23	6/20	7/21	8/20	9/20	10/20	11/20	12/21	1/20	2/20	3/22
13	4/23	5/24	6/21	7/22	8/21	9/21	10/21	11/21	12/22	1/21	2/21	3/23
14	4/24	5/25	6/22	7/23	8/22	9/22	10/22	11/22	12/23	1/22	2/22	3/24
15	4/25	5/26	6/23	7/24	8/23	9/23	10/23	11/23	12/24	1/23	2/23	3/25
16	4/26	5/27	6/24	7/25	8/24	9/24	10/24	11/24	12/25	1/24	2/24	3/26
17	4/27	5/28	6/25	7/26	8/25	9/25	10/25	11/25	12/26	1/25	2/25	3/27
18	4/28	5/29	6/26	7/27	8/26	9/26	10/26	11/26	12/27	1/26	2/26	3/28
19	4/29	5/30	6/27	7/28	8/27	9/27	10/27	11/27	12/28	1/27	2/27	3/29
20	4/30	5/31	6/28	7/29	8/28	9/28	10/28	11/28	12/29	1/28	2/28	3/30
21	5/01	6/01	6/29	7/30	8/29	9/29	10/29	11/29	12/30	1/29	3/01	3/31
22	5/02	6/02	6/30	7/31	8/30	9/30	10/30	11/30	12/31	1/30	3/02	4/01
23	5/03	6/03	7/01	8/01	8/31	10/01	10/31	12/01	1/01	1/31	3/03	4/02
24	5/04	6/04	7/02	8/02	9/01	10/02	11/01	12/02	1/02	2/01	3/04	4/03
25	5/05	6/05	7/03	8/03	9/02	10/03	11/02	12/03	1/03	2/02	3/05	4/04
26	5/06	6/06	7/04	8/04	9/03	10/04	11/03	12/04	1/04	2/03	3/06	4/05
27	5/07	6/07	7/05	8/05	9/04	10/05	11/04	12/05	1/05	2/04	3/07	4/06
28	5/08	6/08	7/06	8/06	9/05	10/06	11/05	12/06	1/06	2/05	3/08	4/07
29	5/09	X	7/07	8/07	9/06	10/07	11/06	12/07	1/07	2/06	3/09	4/08
30	5/10	X	7/08	8/08	9/07	10/08	11/07	12/08	1/08	2/07	3/10	4/09
31	5/11	X	7/09	X	9/08	X	11/08	12/09	X	2/08	X	4/10

APPENDIX C

002-DCI Algorithm



8. Did patient receive prior HSCT or DCI?

Yes

No

Stop!
Complete
Day 100
Report
Form*
only

9. Was prior HSCT/DCI performed at this institution?

Yes

No

10. Indicate where performed:

Name: _____

City: _____ State: _____

Country: _____

11. Indicate donor cell type for last previous HSCT/DCI (*check only one*):

Autologous

Allogeneic,
unrelated
donor

Allogeneic,
related/
syngeneic
donor

12. For current infusion, graft is (*check only one*):

Allogeneic cells **Stop!**
Complete Day 100 Report Form* only

Autologous cells **Stop!**
See Q.504 to determine if additional
Day 100 Report Form* is due

13. Was the same donor used for the current infusion?

Yes

No

Stop!
Complete
Day 100
Report
Form*
only

14. Conditioning (standard or reduced intensity/non-myeloablative) given to patient prior to infusing these cells?

Yes

No

Stop!
Complete Day 100 Report Form* only

15. Are these cells being given to treat graft failure that occurred following a traditional (ablative) HSCT?

Yes

No

Stop!
Complete Day 100 Report Form* only

Continue!
Complete Day 100 DCI Report Form**

Source: 002-DCI Insert, pg 2

APPENDIX D

Functional Status Of Patient

In describing the pretransplant and posttransplant clinical condition of patients ≥ 16 years of age, please use the ***Karnofsky scale for Rating Activity Status*** as shown below:

- A.** Able to carry on normal activity; no special care needed
 - 100% = Normal; no complaints; no evidence of disease
 - 90% = Able to carry on normal activity
 - 80% = Normal activity with effort
- B.** Unable to work; able to live at home, care for most personal needs; varying amount of assistance is needed
 - 70% = Cares for self; unable to carry on normal activity or to do active work
 - 60% = Requires occasional assistance but is able to care for most needs
 - 50% = Requires considerable assistance and frequent medical care
- C.** Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly
 - 40% = Disabled; requires special care and assistance
 - 30% = Severely disabled; hospitalization indicated, although death not imminent
 - 20% = Very sick; hospitalization necessary
 - 10% = Moribund; fatal process progressing rapidly
 - 0% = Dead

In describing pretransplant and posttransplant clinical condition of children, aged 1-16 years, please use the ***Lansky Play-Performance scale for Children*** as shown below:

- A.** Normal range
 - 100% = Fully active
 - 90% = Minor restriction in physically strenuous play
 - 80% = Restricted in strenuous play, tires more easily, otherwise active
- B.** Mild to moderate restriction
 - 70% = Both greater restriction of, and less time spent in, active play
 - 60% = Ambulatory up to 50% of time, limited active play with assistance/supervision
 - 50% = Considerable assistance required for any active play; able to engage in quiet play
- C.** Moderate to severe restriction
 - 40% = Able to initiate quiet activities
 - 30% = Needs considerable assistance for quiet activity
 - 20% = Limited to very passive activity initiated by other (e.g. TV)
 - 10% = Completely disabled, not even passive play
 - 0% = Unresponsive, coma

APPENDIX E

Coexisting disease categories

Autoimmune: See list of diagnoses 2002 Day 100 CORE Insert pg 5, Q.8

Cardiovascular: *Other, specify:* coronary thrombosis, myocardopathy, Wolff-Parkinson-White.

Chromosomal: *Other, specify:* Klinefelter syndrome, Turner syndrome.

CNS/Psychiatric: epilepsy = seizure disorder

Other, specify: autonomic – cranial & spinal nerves, blindness, brain, cerebral palsy, coma, confusion, delirium, encephalitis, encephalopathy, facial palsy, Horner syndrome, hydrocephalus, leukoencephalopathy, memory disturbances, neuropathy, papilledema, paraplegia, paralysis, paresis, polyneuropathy, post herpetic neuralgia, retinopathy, spinal cord. Bipolar, manic depression, psychosis, suicidal.

Endocrine:

Thyroid disease: cretinism/infants, elevated TSH (thyroid stimulating syndrome), goiter, grave disease, hashimoto disease, hyperthyroidism, hypothyroidism, m. basedow, myxedema/adults, thyrotoxicosis.

Other, specify: adrenal, cushing syndrome, hormonal, hyperglycemia, hyperparathyroidism, hypoparathyroidism, pancreas, pituitary, SIADH (syndrome of inappropriate antidiuretic hormone.)

Gastrointestinal: *Other, specify:* cholelithiasis (gallstones), Crohn disease, peptic ulcer, ulcerative colitis.

Genitourinary: *Other, specify:* cystitis, nephritis, urinary bleeding.

Hematologic: *Other, specify:* cold – A1HA antibodies, ITP (idiopathic thrombocytopenic purpura), MAHA (Microangiopathic Hemolytic Anemia), TTP/HUS, sickle cell anemia, drepanocytosis, thalassemia, thrombosis.

Liver: *Other, specify:* alcohol (ETOH), bacterial endo/exo-toxin, Bilharzia, Gaucher disease, Gilbert disease, hemochromotosis, hemosiderosis, iron load, non-viral hepatitis.

Pulmonary: *Other, specify:* bronchiolitis, chronic bronchitis, COPD (chronic obstructive pulmonary disease), emphysema, pulmonary fibrosis.

Other: *Other, specify:* Gonadal – amenorrhea, FSH (follicle stimulating hormone), gynecomastia, menorrhagia, ovary, testis. Growth – acromegaly, dwarfism, gigantism, growth retardation.

Musculoskeletal: arthritis, avascular necrosis, osteoarthritis. Neonatal GVHD. Skin: pityriasis versicolor, psoriasis.

APPENDIX F

Methods for converting units of measure

Exponents:

$$\begin{aligned}10 &= 1 \\10^2 &= 100 \\10^3 &= 1000 \\10^6 &= 1,000,000\end{aligned}$$

$$1.5 \times 10^3 = 150 \times 10 = 1500$$

When converting from a “smaller” exponent number to a “larger” exponent the actual value gets smaller (e.g. $1944 \times 10^6 = 0.1944 \times 10^{10} = .19 \times 10^{10} = .2 \times 10^{10}$ (depending on the number of decimal boxes available for reporting.)

1. White Blood Cell (WBC) and Platelet Counts

$$\begin{aligned}10^9/\text{L} &= 1000 \text{ cells/mm}^3 = \text{K/mm}^3 \\10^3/\text{mm}^3 &= 10^3/\mu\text{L}\end{aligned}$$

Therefore, to convert counts in cells/mm³ (μL) to acceptable units, divide by 1000.

$$\text{e.g. WBC } 4,600 \text{ cells/mm}^3 (\mu\text{L}) = 4.6 \times 10^9/\text{L}$$

$$\text{Platelets } 240,000 \text{ cells/mm}^3 (\mu\text{L}) = 240 \times 10^9/\text{L}$$

2. Hemoglobin

$$1 \text{ g/dL} = 10 \text{ g/L}$$

There are 10 deciliters (dL) per liter (L) therefore results in g/L must be divided by 10

$$\text{e.g. Hb } 120 \text{ g/L} = 12 \text{ g/dL}$$

3. Radiation Doses

$$\begin{aligned}1 \text{ Gy} &= 100 \text{ Rads} \\100 \text{ cGy} &= 100 \text{ Rads} \\100 \text{ cGy} &= 1 \text{ Gy} \\1 \text{ cGy} &= 1 \text{ Rad}\end{aligned}$$

Therefore to convert rads or cGy to Gy, divide by 100

$$\text{e.g. } 858 \text{ rads} = 858 \text{ cGy} = 8.58 \text{ Gy}$$

4. Albumin

$$1 \text{ g/dL} = 10 \text{ g/L}$$

Therefore to convert albumin from g/L to g/dL, divide by 10

$$\text{e.g. } 35 \text{ g/L} = 3.5 \text{ g/dL}$$

5. Height and Weight

$$\begin{aligned}\text{HEIGHT } 1 \text{ foot} &= 30.7 \text{ centimeters} \\1 \text{ inch} &= 2.540 \text{ centimeters}\end{aligned}$$

$$\text{e.g. } 5'10'' = (5 \times 30.7) + (10 \times 2.540) = 153.5 + 25.4 = 178.9 \text{ cm}$$

$$\text{WEIGHT } \text{lbs} \times .4536 = \text{kilograms}$$

$$\text{e.g. } 160 \text{ lbs} = 160 \times .4536 = 72.6 \text{ kg}$$

BSA: there are ~46K websites to assist you.

Here is one of them:

<http://www.halls.md/body-surface-area/bsa.htm>

6. Creatinine

To convert $\mu\text{mol/L}$ to mg/dL multiply by 0.0113

$$\text{e.g. } 100\mu\text{mol/L} = 100 \times 0.0113 = 1.1 \text{ mg/dL}$$

7. Unit conversions

LFT's:

$$\begin{aligned}\text{U/L } \text{U/L} &= \text{NU/dL} \\\text{ukat/L} &\div 0.016\end{aligned}$$

APPENDIX G**Sites of infection: commonly used terms/definitions**

Blood or **Buffy Coat**: sepsis, septicemia, bacteremia, viremia, blood through the catheter line. Do not include positive cultures from samples of the infused product.

Disseminated (3 or more anatomically separate areas; specify predominant sites of infection if possible)

Central nervous system (CNS): *describe the clinical syndrome.*

Brain: Frontal (etc.) Lobes, cerebellum, encephalitis.

Spinal Cord: lumbar puncture, myelopathy, nerves, nerve roots, C1-8, T1-12, L1-5 (not for VZV.)

Meninges/CSF (cerebral spinal fluid): meningitis.

Gastrointestinal: *describe the clinical syndrome if:* bowel, enteric, GIT, gut, GI tract, gastroenteritis, intestines.

Lips: cold sore, HSV of the lips.

Oral cavity: buccal, gingivitis, mouth, mucositis, oral thrush (Candida), oro-pharynx, pharyngitis, saliva, stomatitis, throat, tongue.

Esophagus: esophagitis.

Stomach: gastritis, gastric biopsy.

Gallbladder/Biliary tree/Pancreas (not hepatitis): biliary fluid, cholecystitis, cholangitis.

Small intestine: duodenum, ileum, jejunum, small bowel.

Large intestine: appendix, cecum, colitis, colon, diverticular abscess, diverticulitis, enterocolitis, pericolic abscess, perirectal, sigmoid, typhlitis.

Feces/Stool. * “fecal flora” is NOT clinically significant.

Peritoneum: ascitic fluid, peritonitis.

Liver: hepatic abscess, hepatitis.

Respiratory *describe the clinical syndrome if:* bronchitis, endotracheal (ET) tube aspirates, expectoration, URTI (upper Respiratory Tract Infection.)

Upper airway (not sinuses): nares, nasopharynx, nose, post nasal space, rhinitis.

Larynx: laryngitis

Lower respiratory tract: lungs, BAL, LLL, LUL, RLL, RML, RUL, alveolae, bronchopneumonia, hilar, hilum, lingula, lobar pneumonia, sputum associated with pneumonia, trachea, tracheal aspirate. Bronchial brushings/washings, but only if not associated with IPN (interstitial pneumonitis).

Pleural: biopsy, cavity, effusions, fluid.

Sinuses: antral washout, ethmoid, frontal, mastoid, maxillary, paranasal, sinusitis, sphenoid.

Genito-Urinary Tract *describe the clinical syndrome if:* GU, NSU (non-specific urethritis)

UTI (Urinary Tract Infection): bladder, cystitis, kidney, mid-stream urine (MSU), mid-stream void (MSV), perinephric, pyelonephritis, renal abscess, renal pelvis, ureters urine.

Prostate: prostatitis.

Testes: epididymitis, orchiditis.

Female reproductive tract: endometritis, fallopian tubes, salpingitis, uterus

Vagina: vaginitis, vaginal thrush (Candida.)

Skin: *describe the clinical syndrome if:* chest wall, wound

Genital area: balanitis, genital herpes/ulcers/warts, groin, labia, penis, perianal, perineum, scrotum.

Cellulitis: diffuse inflammation of the skin, may lead to ulceration and abscess formation.

Herpes Zoster of the skin: small blisters in a characteristic distribution, C1-8, T1-12, L1-5 in reference to VZV, shingles, trigeminal herpes, Varicella zoster virus (VZV), Zoster.

Abscess, pustules, or rash not typical of any of the above: exfoliation, Herpes Simplex (HSV) of the skin, scabies, scalded skin syndrome.

Central Venous Line/Catheter: *describe the clinical syndrome if:* Broviac, CVC, CVL, Hickman, intravenous, long term indwelling, portacath, quimon, quinton.

Catheter Insertion/Exit Site

Catheter Tip

Eye/s: conjunctiva, conjunctivitis, cornea, corneal ulcers, episclera, episcleritis, intra-ocular, keratitis, orbit, retina, retinitis, sclera, scleritis, anterior or posterior chambers (e.g. vitreous humor.)

Ear/s: external auditory meatus, glue ear, inner ear, labyrinthitis, middle ear, otitis externa, otitis media, outer ear canal.

Joints: septic arthritis

Bone marrow: not osteomyelitis.

Bone cortex: osteomyelitis.

Muscle (not cardiac/heart): myositis.

Cardiac: heart muscle/values, endocardium/itis, myocardium/itis, pericardium/itis

Lymph nodes: lymphadenitis, swollen glands.

Spleen: splenic abscess..

Other: clot, dental, teeth, flu, parotid gland, septic shock

APPENDIX H

Drug List reproduced with permission from NMDP

Drug List

<u>ALPHABETIZED LISTING</u>	<u>CATEGORY</u>	<u>OTHER NAMES FOR THIS DRUG</u>
5+2	AML INDUCTION REGIMEN	
6-mercaptopurine	ANTINEOPLASTIC	cytarabine, daunorubicin
6-MP	ANTINEOPLASTIC	mercaptopurine
6-Thioguanine	ANTINEOPLASTIC	mercaptopurine
7+3	AML INDUCTION REGIMEN	6-Thioguanine, Lanvis (CAN), TG cytarabine with daunorubicin or idarubicin or mitoxantrone
8 in 1	BRAIN TUMORS REGIMEN (pediatrics)	methylprednisolone, vincristine, methyl-CCNU, procarbazine, hydroxyurea, cisplatin, cyclophosphamide or dacarbazine
Abelcet	ANTIFUNGAL	amphotericin
ABV	KAPOSI'S SARCOMA REGIMEN	doxorubicin, bleomycin, vinblastine
ABVD	HODGKIN'S LYMPHOMA REGIMEN	doxorubicin, bleomycin, vinblastine, decarbazine
AC	BREAST CANCER REGIMEN	doxorubicin, cyclophosphamide
AC	SARCOMA REGIMEN	doxorubicin, cisplatin
ACe	BREAST CANCER (metastatic or recurrent) REGIMEN	cyclophosphamide, doxorubicin
ACNU	ANTINEOPLASTIC	nitrosourea
Actimmune	BIOLOGICAL RESPONSE MODIFIERS	interferon gamma
acyclovir	ANTIVIRAL	Avirax, Zovirax
ADIC	SARCOMA REGIMEN	doxorubicin, dacarbazine
Adriamycin	ANTINEOPLASTIC	doxorubicin
Adriblastin	ANTINEOPLASTIC	doxorubicin
Aeroseb-Dex	TOPICAL CORTICOSTEROIDS	dexamethosone
Aeroseb-HC	TOPICAL CORTICOSTEROIDS	hydrocortisone
Alexan	ANTINEOPLASTIC	cytarabine
Alfernon F	BIOLOGICAL RESPONSE MODIFIERS	interferon alpha
Alkeran	ANTINEOPLASTIC	melphalan
Amethopterin	ANTINEOPLASTIC	methotrexate
amphotericin	ANTIFUNGAL	Abelcet, Fungizone
Ancoban	ANTIFUNGAL	flucytosine
anti-CD5/ricin	IMMUNOTOXIN	Xomazyme
AP	OVARIAN, ENDOMETRIAL CANCER REGIMEN	doxorubicin, cisplatin
Arabinosylcytosine	ANTINEOPLASTIC	cytarabine
Arabitin	ANTINEOPLASTIC	cytarabine
Ara-C	ANTINEOPLASTIC	cytarabine
Aracytine	ANTINEOPLASTIC	cytarabine
Aristopan	TOPICAL CORTICOSTEROIDS	triamicinolone
Artistocort A	TOPICAL CORTICOSTEROIDS	triamicinolone
asparaginase (L-asparaginase)	ANTINEOPLASTIC	colaspase, Elspar, Kidrolase (CAN)
ATG/ALG	IMMUNOSUPPRESSIVES	ATGAM
ATGAM	IMMUNOSUPPRESSIVES	ATG/ALG
Avirax	ANTIVIRAL	acyclovir
azathioprine	IMMUNOSUPPRESSIVES	Imuran
BACOP	NON-HODGKIN'S LYMPHOMA REGIMEN	Bleomycin, doxorubicin, cyclophosphamide, vincristine, prednisone

**ALPHABETIZED
LISTING**

	CATEGORY
Bactrim	ANTI-INFECTIVE / ANTIBACTERIAL / ANTIPROTOZOAL
Basiliximab	MONOCLONAL ANTIBODIES
BCNY or BICNY	ANTINEOPLASTIC HODGKIN'S LYMPHOMA INDUCTION REGIMEN
BCVPP	SYSTEMIC CORTICOSTEROIDS
beclomethazone	SYSTEMIC CORTICOSTEROIDS
Beclovant	SYSTEMIC CORTICOSTEROIDS
Beconase	SYSTEMIC CORTICOSTEROIDS
Belustine	ANTINEOPLASTIC
BEP	TESTICULAR CANCER REGIMENT
BHAS-behenoyl	ANTINEOPLASTIC
BiCNU	ANTINEOPLASTIC
BIP	CERVICAL CANCER REGIMENT
Blenoxane	ANTINEOPLASTIC / ANTIBIOTIC
bleomycin	ANTINEOPLASTIC / ANTIBIOTIC
Blephamide Liquifilm	TOPICAL CORTICOSTEROIDS
BLM	ANTINEOPLASTIC / ANTIBIOTIC
BOMP	CERVICAL CANCER REGIMENT
busulfan	ANTINEOPLASTIC
CAE	LUNG CANCER REGIMENT
CAF	BREAST CANCER, METASTATIC DISEASE REGIMENT
CAL-G	ALL REGIMENT
cam IG, cam T, campath IM	MONOCLONAL ANTIBODIES
CAMP	LUNG CANCER REGIMENT NON-SMALL CELL CARCINOMA OF THE LUNG REGIMENT
CAP	ANTINEOPLASTIC
Carmustine	SMALL CELL LUNG CANCER REGIMENT
CAV	SMALL CELL LUNG CANCER REGIMENT
CAVE	OVARION CANCER REGIMENT
CC	ANTINEOPLASTIC
CCNU	ANTINEOPLASTIC
CCNU or CeeNU	ANTINEOPLASTIC
CDDP	PEDIATRIC BRAIN TUMORS REGIMENT
CDDP/VP	ANTINEOPLASTIC
CeeNu	ANTI-INFECTIVE / ANTIBIOTIC
ceftazidime	IMMUNOSUPPRESSIVES
CellCept	ANTI-INFECTIVE / ANTIBIOTIC
Ceptaz	ANTINEOPLASTIC
Cerubidine	SMALL CELL LUNG CANCER REGIMENT ADENOCARCINOMA, HEAD AND NECK CANCER REGIMENT
CEV	HEAD AND NECK CANCER REGIMENT
CF	BREAST CANCER REGIMENT
CF	OVARION CANCER REGIMENT
CFM (CNF/FNC)	HODGKIN'S LYMPHOMA REGIMENT
CHAP	
ChiVPP	

OTHER NAMES FOR THIS DRUG

Trimethoprim/sulfamethoxazole (TMP/SMX)
Simulect
nitrosourea
carmustine, cyclophosphamide, vinblastine, procarbazine, prednisone
Beclovant, Beconase, Vancanase
beclomethasone
beclomethasone
nitrosourea
bleomycin, etoposide, cisplatin
cytarabine
nitrosourea
bleomycin, ofosfamide, cisplatin, mesna
bleomycin
Blenoxane, BLM
prednisolone acetate
bleomycin
bleomycin, vincristine, cisplatin, mitomycin
Myleran
cyclophosphamide, doxorubicin, etoposide
cyclophosphamide, doxorubicin, fluorouracil asparaginase or pegaspargase, cyclophosphamide, daunorubicin, vincristine, prednisone
cyclophosphamide, doxorubicin, methotrexate, procarbazine
cyclophosphamide, doxorubicin, cisplatin
nitrosourea
cyclophosphamide, doxorubicin, vincristine
cyclophosphamide, doxorubicin, vincristine, etoposide
cisplatin, cyclophosphamide
lomustine
nitrosourea
cisplatin
cisplatin, etoposide
lomustine
Ceptaz, Fortaz, Tazicef, Tazidime
Mycophenolate Mofetil (MMF)
ceftazidime
daunorubicin
cyclophosphamide, etoposide IV, etoposide PO, vincristine
cisplatin, fluorouracil
carboplatin, fluorouracil
cyclophosphamide, fluorouracil, mitoxantrone
cyclophosphamide, altretamine, doxorubicin, cisplatin
chlorambucil, vinblastine, procarbazine, prednisone

ALPHABETIZED LISTING**CATEGORY**

ChiVPP/EVA	HODGKIN'S LYMPHOMA REGIMEN
chlorambucil	ANTINEOPLASTIC
CHOP	NON-HODGKIN'S LYMPHOMA REGIMEN
CHOP-BLEO	NON-HODGKIN'S LYMPHOMA REGIMEN
Ciloxin (CAN)	ANTI-INFECTIVE / ANTIBACTERIAL
Cipro, Cipro IV	ANTI-INFECTIVE / ANTIBACTERIAL
ciprofloxacin hydrochloride	ANTI-INFECTIVE / ANTIBACTERIAL
CISCA	BLADDER CANCER REGIMEN
CISCA/VBiv	GERM CELL TUMORS, ADVANCED REGIMEN
cisplatin	ANTINEOPLASTIC
C-Kit Ligand	BIOLOGICAL RESPONSE MODIFIERS
cladribine	ANTINEOPLASTIC
clotrimazole	ANTIFUNGAL
CMF	BREAST CANCER (metastatic or recurrent) REGIMEN
CMFP	BREAST CANCER, METASTATIC DISEASE REGIMEN
CMFVP	BREAST CANCER (metastatic or recurrent) REGIMEN
CMV	BLADDER CANCER REGIMEN
COB	HEAD AND NECK CANCER REGIMEN
CODE	SMALL CELL LUNG CANCER REGIMEN
colaspase	ANTINEOPLASTIC
COMLA	NON-HODGKIN'S LYMPHOMA REGIMEN
COMP	HODGKIN'S LYMPHOMA REGIMEN (pediatrics)
COP	NON-HODGKIN'S LYMPHOMA REGIMEN
COP-BLAM	NON-HODGKIN'S LYMPHOMA REGIMEN
COPE	SMALL CELL LUNG CANCER REGIMEN
COPP	HODGKIN'S LYMPHOMA REGIMEN (pediatrics)
COPP or "C" MOPP	NON-HODGKIN'S LYMPHOMA REGIMEN
cortisone	SYSTEMIC CORTICOSTEROIDS
cortisone	TOPICAL CORTICOSTEROIDS
Cortisporin cream	TOPICAL CORTICOSTEROIDS
Cortisporin cream/ointment	TOPICAL CORTICOSTEROIDS
Cortone	SYSTEMIC CORTICOSTEROIDS
CP	CHRONIC LYMPHOCYTIC LEUKEMIA REGIMEN
CP	REGIMEN
CSA or CYA (cyclosporine)	OVARION CANCER REGIMEN
CT	IMMUNOSUPPRESSIVES
CVD	OVARION CANCER REGIMEN
	MALIGNANT MELANOMA REGIMEN

OTHER NAMES FOR THIS DRUG

chlorambucil, vinblastine, procarbazine, prednisone, etoposide, doxorubicin
Leukeran
cyclophosphamide, doxorubicin, vincristine, prednisone
bleomycin, cyclophosphamide, doxorubicin, vincristine, prednisone
ciprofloxacin hydrochloride
ciprofloxacin hydrochloride
Ciloxin (CAN), Cipro, Cipro IV
cyclophosphamide, doxorubicin, cisplatin
cyclophosphamide, doxorubicin, cisplatin, vinblastine
CDDP, Platinol, Platinol-AQ
stem cell factor (SCF)
Leustatin
Lotrimin, Mycelex
cyclophosphamide, methotrexate, fluorouracil
cyclophosphamide, methotrexate, fluorouracil, prednisone
CMF, vincristine, prednisone
cisplatin, methotrexate, vinblastine
cisplatin, vincristine, bleomycin
cisplatin, vincristine, doxorubicin, etoposide
asparaginase (L-asparaginase)
cyclophosphamide, vincristine, methotrexate, calcium leucovorin rescue, cytarabine
cyclophosphamide, vincristine, methotrexate, prednisone
cyclophosphamide, vincristine, prednisone
cyclophosphamide, vincristine, prednisone, bleomycin, doxorubicin, procarbazine
cyclophosphamide, vincristine, cisplatin, etoposide
cyclophosphamide, vincristine, procarbazine, prednisone
cyclophosphamide, vincristine, procarbazine, prednisone
Cortone
Cortisporin cream
cortisone
hydrocortisone
cortisone
chlorambucil, prednisone
cyclophosphamide, cisplatin
Neoral, Sandimmune
cisplatin, paclitaxel
cisplatin, vinblastine, dacarbazine

ALPHABETIZED LISTING

	CATEGORY
CVI (VIC)	LUNG CANCER REGIMEN
CVP	NON-HODGKIN'S LYMPHOMA REGIMEN
CVPP	HODGKIN'S LYMPHOMA REGIMEN
CY-VA-DIC cyclophosphamide (CTX) cyclosporine (CSA or CYA)	SOFT TISSUE SARCOMAS, ADULT SARCOMAS REGIMEN
cytarabine	ANTINEOPLASTIC
Cytosar-U	IMMUNOSUPPRESSIVES
Cytosine arabinoside	ANTINEOPLASTIC
Cytovene	ANTIVIRAL
Cytoxan (CTX)	ANTINEOPLASTIC
D-3+7	AML INDUCTION REGIMEN
DA	AML INDUCTION REGIMEN (pediatrics)
dacarbazine	ANTINEOPLASTIC
Daclizumab	MONOCLONAL ANTIBODIES
DAL	AML INDUCTION REGIMEN (pediatrics)
Dalalone	SYSTEMIC CORTICOSTEROIDS
DAT	AML INDUCTION REGIMEN (pediatrics)
Daunoblastin	ANTINEOPLASTIC
Daunomycin	ANTINEOPLASTIC
daunorubicin	ANTINEOPLASTIC
DAV	AML INDUCTION REGIMEN (pediatrics)
DCT (DAT, TAD)	AML INDUCTION REGIMEN
Decadron	SYSTEMIC CORTICOSTEROIDS
Deltasone	SYSTEMIC CORTICOSTEROIDS
Depo-medrol	SYSTEMIC CORTICOSTEROIDS
desoximetasone	TOPICAL CORTICOSTEROIDS
DEX	MULTIPLE MYELOMA REGIMEN
dexamethasone	SYSTEMIC CORTICOSTEROIDS
dexamethosone	TOPICAL CORTICOSTEROIDS
DHPAP	HODGKIN'S LYMPHOMA REGIMEN
DHPG (ganciclovir)	ANTIVIRAL
DI	SOFT TISSUE SARCOMA REGIMEN
Diflucan	ANTIFUNGAL
Doxil	ANTINEOPLASTIC
doxorubicin	ANTINEOPLASTIC
DTIC	ANTINEOPLASTIC
DTIC-Dome	ANTINEOPLASTIC
DVP	ALL INDUCTION REGIMEN
EAP	GASTRIC, SMALL BOWEL CANCER REGIMEN
EC	SMALL CELL LUNG CANCER REGIMEN
EDAP	MULTIPLE MYELOMA REGIMEN
EFP	GASTRIC, SMALL BOWEL CANCER REGIMEN
ELF	GASTRIC CANCER REGIMEN
Elspar	ANTINEOPLASTIC

OTHER NAMES FOR THIS DRUG

carboplatin, etoposide, ifosfamide, mesna
cyclophosphamide, vincristine, prednisone
lomustine, vinblastine, procarbazine, prednisone
cyclophosphamide, vincristine, doxorubicin, dacarbazine
Cytoxan (CTX), Endoxan, Neosar
Sandimmune, Neoral
Alexan, Ara-C, Arabinosylcytosine, Arabitin, Aracytine, BHAS-behenoyl, Cytosar-U, Cytosine arabinoside, Erpalfa, Iretin, Udicil
cytarabine
cytarabine
ganciclovir/DHPG
cyclophosphamide
daunorubicin, cytarabine
daunorubicin, cytarabine
DTIC, DTIC-Dome, imidazole carboxamide
Zenapax
cytarabine, daunorubicin, asparaginase
dexamethasone
daunorubicin, cytarabine, 6-thioguanine
daunorubicin
daunorubicin
Cerubidine, Daunomycin, Daunoblastin, Rubidomycin
daunorubicin, cytarabine, etoposide
daunorubicin, cytarabine, thioguanine
dexamethasone
prednisone
methylprednisolone
Topicort
dexamethasone
Dalalone, Decadron, Hexadrol
Aeroseb-Dex, TobraDex
dexamethasone, cisplatin, cytarabine
Cytovene, Vitraser
doxorubicin, ifosfamide, mesna
fluconazole
doxorubicin
Adriamycin, Adriblastin, Doxil, Farmiblastina, Hydrocyldaunorubicin, Rubex
dacarbazine
dacarbazine
daunorubicin, vincristine, prednisone
etoposide, doxorubicin, cisplatin
etoposide, carboplatin
etoposide, dexamethasone, cytarabine, cisplatin
etoposide, fluorouracil, cisplatin
etoposide, leucovorin, fluorouracil
asparaginase (L-asparaginase)

ALPHABETIZED LISTING

	CATEGORY
EMA 86	ALL INDUCTION REGIMEN
Endoxan	ANTINEOPLASTIC
EP	ADENOCARCINOMA REGIMEN
Epipodophylotoxin	ANTINEOPLASTIC
Epojen	BIOLOGICAL RESPONSE MODIFIERS
Erpalfa	ANTINEOPLASTIC
erythropoietin (Epoetin Alfa)	BIOLOGICAL RESPONSE MODIFIERS
ESHAP	NON-HODGKIN'S LYMPHOMA REGIMEN
Etopophos	ANTINEOPLASTIC
etoposide	ANTINEOPLASTIC
EVA	HODGKIN'S LYMPHOMA REGIMEN BREAST CANCER, METASTATIC DISEASE REGIMEN
FAC	GASTRIC CARCINOMA, ADENOCARCINOMA REGIMEN
FAM	ANTIVIRAL
famciclovir	GASTRIC CANCER REGIMEN
FAMe	GASTRIC CANCER REGIMEN
FAMTX	ANTIVIRAL
Famvir	GASTRIC CANCER REGIMEN
FAP	ANTINEOPLASTIC
Farmiblastina	COLORECTAL CANCER REGIMEN
F-CL (FU/LV)	LUNG CANCER REGIMEN
FED	BIOLOGICAL RESPONSE MODIFIERS
filgrastim (G-CSF)	IMMUNOSUPPRESSIVES
FK506 (tacrolimus)	PROSTATE CANCER REGIMEN
FL	COLORECTAL CANCER REGIMEN
Fle	ANTI-INFECTIVE / ANTIBACTERIAL
Floxin	ANTIFUNGAL
fluconazole	ANTIFUNGAL
flucytosine	ANTINEOPLASTIC
fludarabine	ANTINEOPLASTIC
Fludara	ANTINEOPLASTIC
Fortaz	ANTI-INFECTIVE / ANTIBIOTIC
foscarnet	ANTIVIRAL
Foscavir	ANTIFUNGAL
Fungizone	ANTIFUNGAL
FZ	PROSTATE CANCER REGIMEN
Gamastan	IMMUNE SERUM
Gamimune N	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
Gammaguard	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
Gammer - IV	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
ganciclovir (DHPG)	ANTIVIRAL
G-CSF (filgrastim)	BIOLOGICAL RESPONSE MODIFIERS
gemcitabine	ANTINEOPLASTIC
Gemzar	ANTINEOPLASTIC
GM-CSF (sargramostim)	BIOLOGICAL RESPONSE MODIFIERS

OTHER NAMES FOR THIS DRUG

cytarabine, etoposide, mitoxantrone
cyclophosphamide
etoposide, cisplatin
etoposide
erythropoietin (epoetin alfa)
cytarabine
Epogen, Procrit
etoposide, cisplatin, cytarabine, methylprednisolone
etoposide
Epipodophylotoxin, Etopophos, VePesid, Vetoposide, VP-16-213, VP-16
etoposide, vinblastine, doxorubicin
fluorouracil, doxorubicin, cyclophosphamide
fluorouracil, doxorubicin, mitomycin
Famvir
fluouracil, doxorubicin, semustine
fluouracil, doxorubicin, methotrexate, leucovorin
famciclovir
fluouracil, doxorubicin, cisplatin
doxorubicin
fluouracil, leucovorin
fluouracil, etoposide, cisplatin
Neupogen
Prograf
flutamide, leuprolide acetate or leuprolide depot
fluouracil, levamisole
ofloxacin
Diflucan
Ancoban
Fludara
fludarabine
ceftazidime
Foscavir
foscarnet
amphotericin
flutamide, goserelin acetate
polyclonal IV gamma globulin (IGIV)
Cytovene, Vitrasert
Neupogen
Gemzar
gemcitabine
Leukine

**ALPHABETIZED
LISTING**

	CATEGORY
HDMTX	SARCOMA REGIMEN
Hexadrol	SYSTEMIC CORTICOSTEROIDS
HiDAC	AML CONSOLIDATION REGIMEN
HN2	ANTINEOPLASTIC
Hycamtin	ANTINEOPLASTIC
Hydrea	ANTINEOPLASTIC
hydrocortisone	TOPICAL CORTICOSTEROIDS
Hydrocyldaunorubicin	ANTINEOPLASTIC
hydroxyurea	ANTINEOPLASTIC
I-3+7	AML INDUCTION REGIMEN
Idamycin	ANTINEOPLASTIC
Idamycin	ANTINEOPLASTIC
idarubicin	ANTINEOPLASTIC
idarubicin	ANTINEOPLASTIC
IE	SARCOMA REGIMEN
Ifex	ANTINEOPLASTIC
ifosfamide	ANTINEOPLASTIC
IfoVP	SaRCOMA REGIMEN (pediatrics)
IGIV (polyclonal IV gamma globulin)	IMMUNE SERUM
imidazole	ANTINEOPLASTIC
carboxamide	IMMUNOSUPPRESSIVES
Imuran	BIOLOGICAL RESPONSE MODIFIERS
interferon alpha	BIOLOGICAL RESPONSE MODIFIERS
interferon gamma	BIOLOGICAL RESPONSE MODIFIERS
interleukin-2 (IL-2), interleukin-3 (IL-3)	BIOLOGICAL RESPONSE MODIFIERS
intravenous immune globulin (IVIG)	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
Intron	BIOLOGICAL RESPONSE MODIFIERS
Iretin	ANTINEOPLASTIC
itraconazole	ANTIFUNGAL
Iveegam	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
ketoconazole	GLOBULIN
Kidrolase (CAN)	ANTIFUNGAL
Lanvis (CAN)	ANTINEOPLASTIC
LCR	ANTINEOPLASTIC
Leukeran	ANTINEOPLASTIC
Leukine (sargramostim)	BIOLOGICAL RESPONSE MODIFIERS
Leustatin	ANTINEOPLASTIC
Levaquin	ANTI-INFECTIVE / ANTIBACTERIAL
levofloxacin	ANTI-INFECTIVE / ANTIBACTERIAL
Litalir	ANTINEOPLASTIC
lomustine	ANTINEOPLASTIC
Lotrimin	ANTIFUNGAL
L-PAM	ANTINEOPLASTIC
L-Phenylaline mustard	ANTINEOPLASTIC
L-sarcolysin	ANTINEOPLASTIC
M-2	MULTIPLE MYELOMA REGIMEN
M-3+7	AML INDUCTION REGIMEN
MACOP-8	NON-HODGKIN'S LYMPHOMA REGIMEN
MAID	SARCOMA REGIMEN

OTHER NAMES FOR THIS DRUG

methotrexate, leucovorin
dexamethasone
cytarabine
mechlorethamine
topotecan hydrochloride
hydroxyurea
Aeroseb-HC, Cortisporin cream/ointment
doxorubicin
Hydrea, Latalir, OncoCarbide
idarubicin, cytarabine
idarubicin
idarubicin
Idamycin
Idamycin
ifosfamide, etoposide, mesna
ifosfamide
Ifex
ifosfamide, etoposide, mesna
Gammimune N, Gammaguard, Gammar - IV, Gamastan, Iveegam, Polygam, Sandoglobulin, Venoglobulin - I
dacarbazine
azathioprine
Alfernon F, Intron, Roferan
Actimmune
interferon alpha
cytarabine
Sporonox
polyclonal IV gamma globulin (IGIV)
Nizoral
asparaginase (L-asparaginase)
6-Thioguanine, Lanvis (CAN), TG
vincristine
chlorambucil
GM-CSF
cladribine
levofloxacin
Levaquin
hydroxyurea
CCNU, CeeNu
clotrimazole
melphalan
melphalan
melphalan
vincristine, carmustine, cyclophosphamide, melphalan, prednisone
mitoxantrone, cytarabine
methotrexate, calcium leucovorin rescue, doxorubicin, cyclophosphamide, vincristine, bleomycin, prednisone mesna, doxorubicin, ifosfamide, dacarbazine

Effective Date:
November 10, 2003

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ALPHABETIZED LISTING

	CATEGORY
Matulane	ANTINEOPLASTIC
m-BACOD	NON-HODGKIN'S LYMPHOMA REGIMEN
M-BACOD	NON-HODGKIN'S LYMPHOMA REGIMEN
m-BACOS	NON-HODGKIN'S LYMPHOMA REGIMEN
MBC	HEAD AND NECK CANCER REGIMEN
MC	AML CONSOLIDATION REGIMEN
MCCNU or MeCCNU	ANTINEOPLASTIC
mechlorethamine	ANTINEOPLASTIC
Medrol	SYSTEMIC CORTICOSTEROIDS
melphalan	ANTINEOPLASTIC
mercaptopurine	ANTINEOPLASTIC
methotrexate	ANTINEOPLASTIC
methylprednisolone	SYSTEMIC CORTICOSTEROIDS
MF	BREAST CANCER REGIMEN
MICE (ICE)	SARCOMA, LUNG CANCER REGIMEN
MIH	ANTINEOPLASTIC
MINE-EISHAP	HODGKIN'S LYMPHOMA REGIMEN
mini-BEAM	HODGKIN'S LYMPHOMA REGIMEN
mitoxantrone	ANTINEOPLASTIC
MIV	NON-HODGKIN'S LYMPHOMA REGIMEN
MM	ALL MAINTENANCE REGIMEN
MMF (Mycophenolate Mofetil)	IMMUNOSUPPRESSIVES
MOP	PEDIATRIC BRAIN TUMORS REGIMEN
MOPP	HODGKIN'S LYMPHOMA REGIMEN
MOPP/ABV Hybrid	HODGKIN'S LYMPHOMA REGIMEN
MOPP/ABVD	HODGKIN'S LYMPHOMA REGIMEN
MP	MULTIPLE MYELOMA REGIMEN
MTXCP-PDAdr	OSTEOSARCOMA REGIMEN (pediatrics)
Mustargen	ANTINEOPLASTIC
MV	AML INDUCTION REGIMEN
MV	BREAST CANCER REGIMEN
M-VAC	TRANSITIONAL CELL CARCINOMA (BLADDER) REGIMEN
MVP	LUNG CANCER REGIMEN
MVPP	HODGKIN'S LYMPHOMA REGIMEN
Mycelex	ANTIFUNGAL
Mycophenolate Mofetil (MMF)	IMMUNOSUPPRESSIVES
Mycostatin	ANTIFUNGAL
Myleran	ANTINEOPLASTIC
Natulan (CAN)	ANTINEOPLASTIC
Navelbine	ANTINEOPLASTIC
NebuPent	ANTI-INFECTIVE / ANTIPROTOZOAL
Neoral	IMMUNOSUPPRESSIVES
Neosar	ANTINEOPLASTIC

OTHER NAMES FOR THIS DRUG

procarbazine	
bleomycin, doxorubicin, cyclophosphamide, vincristine, dexamethasone, methotrexate, calcium leucororin rescue	
bleomycin, doxorubicin, cyclophosphamide, vincristine, dexamethasone, methotrexate, calcium leucovorin rescue	
doxorubicin, vincristine, bleomycin, cyclophosphamide, methotrexate, calcium leucovorin rescue	
methylprednisolone	
methotrexate, bleomycin, cisplatin	
mitoxantrone, cytarabine	
nitrosourea	
HN2, Mustargen, nitrogen mustard	
methylprednisolone	
L-PAM, Alkeran, L-sarcolysin, L-Phenylaline mustard	
6-mercaptopurine, 6-MP, Purinethol	
Amethopterin	
Depo-medrol, Medrol, Solu-medrol	
methotrexate, fluorouracil, leucovorin	
mesna, ifosfamide, carboplatin, etoposide	
procarbazine	
etoposide, ifosfamide, mesna, mitoxantrone	
carmustine, cytarabine, etoposide, melphalan	
Novantrone	
etoposide, ifosfamide, mesna, mitoxantrone	
mercaptopurine, methotrexate	
CellCept	
MOPP without prednisone	
mechlorethamine (nitrogen mustard), vincristine, procarbazine, prednisone	
mechlorethamine (nitrogen mustard), vincristine, prednisone, procarbazine, doxorubicin, vinblastine, bleomycin, hydrocortisone	
alternate MOPP and ABVD regimens	
melphalan, prednisone	
methotrexate, leucovorin, cisplatin, doxorubicin	
mechlorethamine	
mitoxantrone, etoposide	
mitomycin, vinblastine	
methotrexate, vinblastine, doxorubicin, cisplatin	
mitomycin, vinblastin, cisplatin	
mechlorethamine (nitrogen mustard), vinblastine, procarbazine, prednisone	
clotrimazole	
CellCept	
nystatin	
busulfan	
procarbazine	
vinorelbine	
pentamidine	
cyclosporine (CYA, CSA)	
cyclophosphamide	

**ALPHABETIZED
LISTING**

Neumega
(?oprelvikin)
Neupogen (filgrastim)
NFL
nitrogen mustard

nitrosourea
Nizoral
N-methylhydrazine
Novantrone
NOVP
nystatin
Ocuflox
ofloxacin
OKT3
Oncaspar
OncoCarbide
Oncovin Vincasar PFS
OPA
OPPA
oprelvikin?
(Neumega)
Orthoclone
PAC
paclitaxel
PC
PCV
pegasparagase
PEG-L
Pentacarinat
Pentam - 300
pentamidine
peptichem

PFL
Platinol
Platinol-AQ
Pneumopenet
POC
polyclonal IV gamma globulin (IGIV)

Polygam
Prednicen-M21
prednisolone acetate
prednisone
Prednisone
Primosoll
procabazine
Procrit
Prograf
Proloprim

ProMACE

CATEGORY

BIOLOGICAL RESPONSE MODIFIERS
BIOLOGICAL RESPONSE MODIFIERS
BREAST CANCER REGIMEN
ANTINEOPLASTIC

ANTINEOPLASTIC
ANTIFUNGAL
ANTINEOPLASTIC
ANTINEOPLASTIC
HODGKIN'S LYMPHOMA REGIMEN
ANTIFUNGAL
ANTI-INFECTIVE / ANTIBACTERIAL
ANTI-INFECTIVE / ANTIBACTERIAL
MONOCLONAL ANTIBODIES
ANTINEOPLASTIC
ANTINEOPLASTIC
ANTINEOPLASTIC
HODGKIN'S LYMPHOMA REGIMEN (pediatrics)
HODGKIN'S LYMPHOMA REGIMEN

BIOLOGICAL RESPONSE MODIFIERS
MONOCLONAL ANTIBODIES
OVARIAN, ENDOMETRIAL CANCER REGIMEN
ANTINEOPLASTIC
LUNG CANCER REGIMEN
BRAIN TUMOR REGIMEN
ANTINEOPLASTIC
ANTINEOPLASTIC
ANTI-INFECTIVE / ANTIPROTOZOAL
ANTI-INFECTIVE / ANTIPROTOZOAL
ANTI-INFECTIVE / ANTIPROTOZOAL
MONOCLONAL ANTIBODIES
HEAD AND NECK, GASTRIC CANCER
REGIMEN
ANTINEOPLASTIC
ANTINEOPLASTIC
ANTI-INFECTIVE / ANTIPROTOZOAL
BRAIN TUMOR REGIMEN (pediatrics)

IMMUNE SERUM
IMMUNE SERUM / POLYCLONAL GAMMA
GLOBULIN
SYSTEMIC CORTICOSTEROIDS
TOPICAL CORTICOSTEROIDS
SYSTEMIC CORTICOSTEROIDS
SYSTEMIC CORTICOSTEROIDS
ANTI-INFECTIVE / ANTIBACTERIAL
ANTINEOPLASTIC
BIOLOGICAL RESPONSE MODIFIERS
IMMUNOSUPPRESSIVES
ANTI-INFECTIVE / ANTIBACTERIAL /
ANTIPROTOZOAL

HODGKIN'S LYMPHOMA REGIMEN

OTHER NAMES FOR THIS DRUG

like G-CSF
G-CSF
mitoxantrone, fluorouracil, leucovorin
mechlorethamine
Belustine, Carmustine, ACNU, BCNY or BICNY,
CCNU or CeeNU, MCCNU or MeCCNU
ketoconazole
procabazine
mitoxantrone
mitoxantrone, vincristine, vinblastine, prednisone
Mycostatin
ofloxacin
Floxin, Ocuflox
Orthoclone
pegasparagase
hydroxyurea
vincristine
vincristine, prednisone, doxorubicin
vincristine, procabazine, prednisone, doxorubicin

like G-CSF
OKT3
cisplatin, doxorubicin, cyclophosphamide
Taxol
paclitaxell, carboplatin
lomustine, procabazine, vincristine
Oncaspar, PEG-L
pegasparagase
pentamidine
pentamidine
NebuPent, Pneumopenet, Pentacarinat, Pentam - 300

cisplatin, fluorouracil, leucovorin
cisplatin
cisplatin
pentamidine
prednisone, methyl-CCNU, vincristine
Gammimune N, Gammaguard, Gammar - IV, Gamastan,
Iveegam, Polygam, Sandoglobulin, Venoglobulin - I

polyclonal IV gamma globulin (IGIV)
prednisone
Blephamide Liquifilm
Deltasone, Prednisone, Prednicen-M21, Sterapred
prednisone
trimethoprim/sulfamethoxazole (TMP/SMX)
Matulane, MIH, N-methylhydrazine, Natulan (CAN)
erythropoietin (epoetin alfa)
FK506 (tacrolimus)

trimethoprim/sulfamethoxazole (TMP/SMX)
cyclophosphamide, doxorubicin, etoposide, leucovorin,
methotrexate, prednisone

**ALPHABETIZED
LISTING****CATEGORY**

ProMACE/cytaBOM	NON-HODGKIN'S LYMPHOMA REGIMEN
ProMACE/MOPP	NON-HODGKIN'S LYMPHOMA REGIMEN
Purinethol	ANTINEOPLASTIC
PVB	TESTICULAR CARCINOMA,
PVDA	ADENOCARCINOMA REGIMEN
PVP-16	ALL INDUCTION REGIMEN (pediatrics)
Rapamune	LUNG CANCER REGIMEN
Rapamycin	IMMUNOSUPPRESSIVES
Rituxan	IMMUNOSUPPRESSIVES
Roferan	MONOCLONAL ANTIBODIES
Rubex	BIOLOGICAL RESPONSE MODIFIERS
Rubidomycin	ANTINEOPLASTIC
Sandimmune	ANTINEOPLASTIC
Sandoglobulin	IMMUNOSUPPRESSIVES
sargramostim (GM-CSF)	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
SCF (stem cell factor)	BIOLOGICAL RESPONSE MODIFIERS
Septra	BIOLOGICAL RESPONSE MODIFIERS
Simulect	ANTI-INFECTIVE / ANTIBACTERIAL /
Sirolimus	ANTIPROTOZOAL
Solu-medrol	MONOCLONAL ANTIBODIES
Sporonox	IMMUNOSUPPRESSIVES
Stanford V	SYSTEMIC CORTICOSTEROIDS
stem cell factor (SCF)	ANTI-INFECTIVE / ANTIBACTERIAL /
Sterapred	ANTIPROTOZOAL
Sulfatrim	ANTINEOPLASTIC
tacrolimus (FK506)	IMMUNOSUPPRESSIVES
Taxol	ANTINEOPLASTIC
Tazicef	ANTI-INFECTIVE / ANTIBIOTIC
Tazidime	ANTI-INFECTIVE / ANTIBIOTIC
tenoposide	ANTINEOPLASTIC
TESPA	ANTINEOPLASTIC
TG	ANTINEOPLASTIC
thalidomide	IMMUNOSUPPRESSIVES
thioguanine	ANTINEOPLASTIC
Thioplex	ANTINEOPLASTIC
thiotepa	ANTINEOPLASTIC
thrombopoietin	BIOLOGICAL RESPONSE MODIFIERS
TMP/SMX	
(trimethoprim/sulfame thoxazole)	ANTI-INFECTIVE / ANTIPROTOZOAL
TobraDex	TOPICAL CORTICOSTEROIDS
Topicort	TOPICAL CORTICOSTEROIDS
topotecan	
hydrochloride	ANTINEOPLASTIC
triamcinolone	TOPICAL CORTICOSTEROIDS
Triethylenethiophosph	ANTINEOPLASTIC

OTHER NAMES FOR THIS DRUG

cyclophosphamide, doxorubicin, etoposide, prednisone, cytarabine, bleomycin, vincristine, methotrexate, calcium leucovorin rescue
prednisone, methotrexate, calcium leucovorin rescue, doxorubicin, cyclophosphamide, etoposide mercaptopurine
cisplatin, vinblastine, bleomycin
prednisone, vincristine, daunorubicin, L-asparaginase
cisplatin, etoposide
Rapamycin, Sirolimus
Rapamune, Sirolimus
radioactive isotope
interferon alpha
doxorubicin
daunorubicin
cyclosporine (CSA)
polyclonal IV gamma globulin (IGIV)
Leukine
C-Kit Ligand
trimethoprim/sulfamethoxazole (TMP/SMX)
Basiliximab
Rapamycin, Rapamune
methylprednisolone
itraconazole
mechlorethamine, doxorubicin, vinblastine, vincristine, bleomycin, etoposide, prednisone
C-Kit Ligand
prednisone
trimethoprim/sulfamethoxazole (TMP/SMX)
Progaf
paclitaxel
ceftazidime
ceftazidime
VM26, VEHEM, Vumon
thiotepa
6-Thioguanine, Lanvis (CAN), TG
6-Thioguanine, Lanvis (CAN), TG
thiotepa
triethylenethiophosphoramide, TESPA, TSPA, Thioplex
Bactrim, Primosol, Proloprim, Septra, sulfatrim, Trimpe
dexamethosone
desoximetasone
Hycamtin
Artistocort A, Aristopan
thiotepa

**ALPHABETIZED
LISTING**

	CATEGORY
oramide	ANTI-INFECTIVE / ANTIPROTOZOAL
trimethoprim/sulfamet hoxazole (TMP/SMX)	ANTI-INFECTIVE / ANTIBACTERIAL / ANTIPROTOZOAL
Trimpex	ANTINEOPLASTIC
TSPA	ANTINEOPLASTIC
Udical	SOFT TISSUE SARCOMAS REGIMEN
VAC Pulse	SOFT TISSUE SARCOMAS REGIMEN
VAC Standard	SARCOMA REGIMEN (pediatrics)
VACAdr-IfoVP	ALL INDUCTION REGIMEN
VAD	REFRACTORY MULTIPLE MYELOMA REGIMEN
VAD	SARCOMA REGIMEN (pediatrics)
VAdrC	SYSTEMIC CORTICOSTEROIDS
Vancanase	ANTI-INFECTIVE / ANTIBACTERIAL
Vancocin	ANTI-INFECTIVE / ANTIBACTERIAL
Vancoled	ANTI-INFECTIVE / ANTIBACTERIAL
vancomycin	AML INDUCTION REGIMEN (pediatrics)
VAPA	BREAST CANCER REGIMEN
VATH	MULTIPLE MYELOMA REGIMEN
VBAP	LUNG CANCER REGIMEN
VC	MULTIPLE MYELOMA REGIMEN
VCAP	ANTINEOPLASTIC
VCR	ALL INDUCTION REGIMEN (pediatric)
VDA	MALIGNANT MELANOMA REGIMEN
VDP	ANTINEOPLASTIC
VEHEM	ANTINEOPLASTIC
Velban	ANTINEOPLASTIC
Velbe (CAN)	IMMUNE SERUM / POLYCLONAL GAMMA GLOBULIN
Venoglobulin-I	ANTINEOPLASTIC
VePesid	ANTINEOPLASTIC
Vetoposide	ANTINEOPLASTIC
vinblastine	ANTINEOPLASTIC
vincristine	ANTINEOPLASTIC
vinorelbine	ANTINEOPLASTIC
VIP	TESTICULAR CANCER REGIMEN
VIP-1	LUNG CANCER REGIMEN
VIP-2	LUNG CANCER REGIMEN
Vitrasert	ANTIVIRAL
VLB	ANTINEOPLASTIC
VM26	ANTINEOPLASTIC
VMI	BREAST CANCER REGIMEN
VP-16	ANTINEOPLASTIC
VP-16-213	ANTINEOPLASTIC
VPA	ALL INDUCTION REGIMEN (pediatrics)
V-TAD	AML INDUCTION REGIMEN
Vumon	ANTINEOPLASTIC
Xomazyme	IMMUNOTOXIN
Zenapax	MONOCLONAL ANTIBODIES
Zovirax	ANTIVIRAL
	ALL INDUCTION REGIMEN
	ALL INDUCTION REGIMEN
	BIOLOGICAL RESPONSE MODIFIERS
	BIOLOGICAL RESPONSE MODIFIERS

OTHER NAMES FOR THIS DRUG

Bactrim, Primosol, Proloprim, Septra, sulfatrim, Trimpex
trimethoprim/sulfamethoxazole (TMP/SMX)
thiotepa
cytarabine
vincristine, dactinomycin, cyclophosphamide
vincristine, dactinomycin, cyclophoshamide
vincristine, dactinomycin, doxorubicin, cyclophosphamide, ifosfamide, etoposide
vincristine, doxorubicin, dexamethasone
vincristine, doxorubicin, dexamethasone
vincristine, doxorubicin, cyclophosphamide beclomethasone
vancomycin
vancomycin
Vancocin, Vancoled
vincristine, doxorubicin, prednisone, cytarabine
vinblastine, doxorubicin, thiotapec, fluoxymesterone
vincristine, carmustine, doxorubicin, prednisone
vinorelbine, cisplatin
vincristine, cyclophosphamide, doxorubicin, prednisone
vincristine
asparaginase, daunorubicin, vincristine
vinblastine, dacarbazine, cisplatin
tenoposide
vinblastine
vinblastine
polyclonal IV gamma globulin (IGIV)
etoposide
etoposide
Velban, Velbe (CAN), VLB
LCR, Oncovin Vincasar PFS, VCR
Navelbine
vinblastine or etoposide,, ifosfamide, cisplatin, mesna
ifosfamide, mesna, cisplatin, etoposide
ifosfamide, mesna, cisplatin, etoposide
ganciclovir/DHPG
vinblastine
tenoposide
mitomycin, vinblastine
etoposide
etoposide
vincristine, daunorubicin, L-asparaginase
cytarabine, daunorubicin, etoposide, thioguanine
tenoposide
anti-CD5/ricin
Daclizumab
acyclovir
L-asparaginase
pegaspargase
interleukin-2 (IL-2)
interleukin-3 (IL-3)

**ALPHABETIZED
LISTING**

CATEGORY

IMMUNOSUPPRESSIVES
MONOCLONAL ANTIBODIES
MONOCLONAL ANTIBODIES
MONOCLONAL ANTIBODIES
MONOCLONAL ANTIBODIES

OTHER NAMES FOR THIS DRUG

thalidomide
cam IG
cam T
campath IM
peptichem

APPENDIX I

Criteria for Acute Graft-vs-Host Disease

Clinical staging of acute graft-versus-host disease according to organ involvement.

Stage	Skin	Liver	Intestinal Tract
0	No rash	Bilirubin ≤ 2.0 mg/dL ≤ 34 µmol/L	Diarrhea ≤ 500 ml/day or ≤ 280 ml/m ² /day
+	Maculopapular rash <25% of body surface	Bilirubin 2.0 - 3.0 mg/dL 34 - 52 µmol/L	Diarrhea >500 but ≤ 1000 ml/day or 280-555 ml/m ² /day
++	Maculopapular rash 25-50% of body surface	Bilirubin 3.1 - 6.0 mg/dL 53 - 103 µmol/L	Diarrhea >1000 but ≤ 1500 ml/day or 556-833 ml/m ² /day
+++	Generalized erythroderma	Bilirubin 6.1 - 15.0 mg/dL 104 - 256 µmol/L	Diarrhea >1500 ml/day or >833 ml/m ² /day
++++	Generalized erythroderma with bullous formation and desquamation	Bilirubin > 15.0 mg/dL > 256 µmol/L	Severe abdominal pain with or without ileus

Clinical grading of severity of acute graft-versus-host disease

Grade	Degree of Organ Involvement
I	+ to ++ skin rash; [and] no gut involvement; [and] no liver involvement; [and] no decrease in clinical performance
II	+ to +++ skin rash; [or] + gut involvement [and/or] + liver involvement); [and] mild decrease in clinical performance
III	++ to +++ skin rash; [and/or] ++ to +++ gut involvement [and/or] ++ to +++; liver involvement); [and] marked decrease in clinical performance
IV	Similar to Grade III with ++ to +++; organ involvement and extreme decrease in clinical performance

Source: Thomas et al, N Engl J Med 1975;292,832.

Effective Date:
November 10, 2003

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APPENDIX J Fax Order Form



ORDER FORM FOR IBMTR/ABMTR REPORT FORMS

Complete and fax this form to **414-456-6530 Attn: Statistical Center**
Please note! All documents are accessible online at: <http://www.ibmtr.org>

FORM TYPE	DESCRIPTION OF FORMS	FORM NUMBER & # NEEDED	MOST RECENT
Report Insert	Core Insert & Follow-up	002-CORE_____ 002-COREFU_____	8/03
DCI Report	Donor Cellular Infusion (DCI) Insert	002-DCI_____	8/03
Other Core Insert	In Utero Core Insert	095-UCR_____	<i>not available at this time</i>
Graft Insert	AUTOBM	002-ABM_____	5/03
Graft Insert	AUTOPB	002-APB_____	5/03
Graft Insert	ALLOBM	002-DBM_____	8/03
Graft Insert	ALLOPB	002-DPB_____	8/03
Graft Insert	ALLOCB	002-ACB_____	5/03
DCI Graft Insert	ALLODCI	002-DCIG_____	5/03
DCI Supplement	Amyloidosis	DCI-AMY_____	9/03
DCI Supplement	Breast Cancer	DCI-BC_____	9/03
DCI Supplement	Chronic Lymphocytic Leukemia	DCI-CLL_____	9/03
DCI Supplement	Hodgkin and Non-Hodgkin Lymphoma	DCI-LYM_____	9/03
DCI Supplement	Juvenile Myelomonocytic Leukemia (JMML or JCML)	DCI-JMM_____	9/03
DCI Supplement	Langerhans Cell Histiocytosis (LCH)	DCI-LCH_____	9/03
DCI Supplement	Multiple Myeloma/Plasma Cell Leukemia	DCI-MYE_____	9/03
DCI Supplement	Myelodysplasia/Myeloproliferative Disorders	DCI-MDS_____	9/03
DCI Supplement	Neuroblastoma	DCI-NEU_____	9/03
DCI Supplement	Sarcoma	DCI-SAR_____	9/03
DCI Supplement	Testicular Cancer/Germ Cell Tumors	DCI-TC_____	9/03
DCI Supplement	Waldenstrom's Macroglobulinemia	DCI-MAC_____	9/03
Registration	Transplant Essential Data (<i>Registering Team only</i>) First Report: 100 Days Post Transplant	TED-01_____	7/02
Registration	Pre-Registration (<i>Research Team only</i>)	PreReg_____	1/03
Registration	Transplant Essential Data (<i>Research Team only</i>) Modified 100 Day Report for Preregistered Patients	M TED_____	7/02
Registration	Transplant Essential Data (<i>Registering & Research Teams</i>) Follow-up Report: 1 Yr Post Transplant & Annually ...	TEDFU-01_____	7/02

Ship to: NAME _____
 ADDRESS _____
 PHONE # _____ TEAM # _____



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FORM TYPE	DESCRIPTION OF FORMS	FORM NUMBER & # NEEDED	MOST RECENT	
Disease-Specific Insert I	Acute Myelogenous Leukemia	095-AML _____	12/95	
		095-AMLFU _____	9/95	
Disease-Specific Insert II	Acute Lymphoblastic Leukemia	095-ALL _____	12/95	
		095-ALLFU _____	9/95	
Disease-Specific Insert III	Chronic Myelogenous Leukemia.....	095-CML _____	2/97	
Disease-Specific Insert III	Chronic Myelogenous Leukemia Follow-up	095-CMLFU _____	9/95	
Disease-Specific Insert IV	Chronic Lymphocytic Leukemia & Follow-up	095-CLL _____	095-CLLFU _____	7/99
Disease-Specific Insert V	Myelodysplastic/Myeloproliferative Disorders	095-MDS _____	095-MDSFU _____	9/95
			8/96	
Disease-Specific Insert VI	Hodgkin and Non-Hodgkin Lymphoma	095-LYM _____	4/98	
		095-LYMFU _____	10/98	
Disease-Specific Insert VII	Multiple Myeloma/Plasma Cell Leukemia & Follow-up	095-MYE _____	095-MYEFU _____	11/99
Disease-Specific Insert VIII	Breast Cancer & Follow-up	095-BC _____	7/96	
		095-BCFU _____	10/96	
Disease-Specific Insert IX	Aplastic Anemia (Blackfan) & Follow-up	095-APL _____	9/95	
		095-APLFU _____	12/95	
Disease-Specific Insert X	Fanconi Anemia/Constitutional Anemia & Follow-up	095-FAN _____	095-FANFU _____	6/98
			not available at this time	
Disease-Specific Insert XI	Thalassemia & Follow-up	095-THAL _____		
Disease-Specific Insert XII	Immune Deficiency & Follow-up	095-ID _____	8/96	
		095-IDFU _____	9/95	
Disease-Specific Insert XIII	Wiskott-Aldrich Syndrome (WAS) & Follow-up	095-WAS _____	12/96	
		095-WASFU _____	10/96	
Disease-Specific Insert XIV	Sickle Cell Anemia & Follow-up	095-SCA _____	095-SCAFU _____	4/02
Disease-Specific Insert XV	Osteopetrosis & Follow-up	095-OST _____	095-OSTFU _____	8/00
Disease-Specific Insert XVI	Ovarian Cancer & Follow-up	095-OV _____	095-OVFU _____	2/00
Disease-Specific Insert XVII	Neuroblastoma & Follow-up	095-NEU _____	095-NEUFU _____	6/98
Disease-Specific Insert XVIII	Central Nervous System Tumor & Follow-up	095-CNS _____	095-CNSFU _____	5/99
Disease-Specific Insert XIX	Chediak-Higashi Syndrome & Follow-up	095-CHS _____	4/98	
		095-CHSFU _____	5/98	
Disease-Specific Insert XX	Small Cell Lung Cancer & Follow-up	095-SCL _____	095-SCLFU _____	10/98
Disease-Specific Insert XXI	Multiple Sclerosis Disease & Follow-up	095-MS _____	095-MSFU _____	3/00
Disease-Specific Insert XXII	Rheumatoid Arthritis Disease & Follow-up	095-RA _____	095-RAFU _____	3/00
Disease-Specific Insert XXIII	Systemic Lupus Erythematosus (SLE) & Follow-up	095-SLE _____	095-SLEFU _____	3/00
Disease-Specific Insert XXIV	Systemic Sclerosis (SSc) & Follow-up	095-SSC _____	095-SSCFU _____	3/00
Disease-Specific Insert XXV	Amyloidosis & Follow-up	095-AMY _____	095-AMYFU _____	3/00
Disease-Specific Insert XXVI	Waldenstrom's Macroglobulinemia & Follow-up	095-MAC _____	095-MACFU _____	1/00
Disease-Specific Insert XXVII	Langerhans Cell Histiocytosis (LCH) & Follow-up	095-LCH _____	095-LCHFU _____	1/01
Disease-Specific Insert XXVIII	Juvenile Idiopathic Arthritis (JIA) & Follow-up	095-JRA _____	095-JRAFU _____	3/00
Disease-Specific Insert XXIX	Immune Cytopenias (IC) & Follow-up	095-IC _____	not available at this time	
Disease-Specific Insert XXX	Immune Myopathies (IM) & Follow-up	095-IM _____	not available at this time	
Disease-Specific Insert XXXI	Sarcoma & Follow-up	095-SAR _____	095-SARFU _____	4/00
Disease-Specific Insert XXXII	Testicular Cancer & Follow-up	095-TC _____	095-TCFU _____	6/00
Disease-Specific Insert XXXIII	Juvenile Myelomonocytic Leukemia (JMML & JCML) & Follow-up	095-JMM _____	095-JMMFU _____	8/01
Disease-Specific Insert XXXIV	Mucopolysaccharidosis & Follow-up	095-MUC _____	095-MUCFU _____	4/01
Disease-Specific Insert XXXV	Leukodystrophies & Follow-up	095-LDS _____	095-LDSFU _____	4/01
Disease-Specific Insert XXXVI	Renal Carcinoma & Follow-up	095-RC _____	095-RCFU _____	4/02

Ship to: NAME _____
 ADDRESS _____
 PHONE # _____ TEAM # _____

Questions in common between CoreFU, Core and DCI Inserts

Question	Core Insert Q#	CoreFU Q#	DCI Q#
Date HSCT or DCI	1	1	1
Date of Report	2	2	2
Recipient DOB	7	3	7
Last Contact Date	4	4	6
Karnofsky Preconditioning/DCI	13	-	29
Recipient height & weight	108, 109	-	30, 31
Preconditioning/DCI labs	59-61, 62-64, 68-69	-	32-34, 35-37, 38-39
Alive on LCD?	751	5	501
Karnofsky post TX	752	6	502
QOL work/school	-	7-17	-
Subsequent HSCT	317	18	40
Subsequent DCI	318	19	41
Report Form Cut-off date	319, 320	-	42,43
Growth factors/cytokines	321-361	-	44-84
Duration of aplasia postDCI	-	-	85-87
Granulopoiesis	362	20	88
Date 500	363, 364	21	89
Decline <500?	362, #2	22	-
Date ANC <500	365	23	-
Recover ANC >500	368-371	24-27	-
Platelets <20, <50	-	-	90, 93, 96, 99
Megakaryopoiesis 20	372, 373	28, 29	92 or 95
Megakaryopoiesis 50	374, 375	30, 31	98 or 101
CBC	376-382	32-38	102-108
Chimerism	Allo Graft Insert	39-51	DCI Graft Insert
GVHD proph 1 week prior	-	-	109-134
GVHD proph started/con't.	383-409	-	135-160
aGVHD in last RF?	-	52-53	-
aGVHD	410-469	53-112	161-220
cGVHD in last RF?	-	113	-
cGVHD	470-563	114-207	221-314
Transfusions	564-568	-	315-319
Infection prophylaxis	569-598	-	320-349
Significant infections	599-645	208-254	350-396
IPn/ARDS	646-671	255-280	397-422
Non-inf. pulmonary comps	672-692	281-301	423-443
Non-inf. liver comps	693-713/ 695, 696	Cirrhosis 315, VOD 316	444-464
Non-inf. other comps	714-728	302-318	465-479
Conception	-	319-322	-
New malignancy	729-746	323-340	480-497
Discharge, In-patient days	747-750	-	498-500
Subsequent HSCT	753-759	341-347	503-509
Subsequent DCI	760-763	348-351	510-513
Death	764-772	352-360	514-522
Log of appended documents	791-796	361-366	523-528
Institutional Information	i-xi	i-x	i.-xi