



Center Reference Guide



Sharing Knowledge.
Sharing Hope.

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1. PARTICIPATION IN CIBMTR RESEARCH

CIBMTR offers transplant centers two levels of participation in its research programs:

- As a Transplant Essential Data (TED level)¹ program; or
- As a Comprehensive Report Form (CRF level) program.

Each center designates its preferred reporting status; based on this, CIBMTR applies a selection algorithm (below) that assigns transplant recipient data to the appropriate data reporting track.

Form selection algorithm for CRF Programs: CIBMTR has developed an algorithm to determine which set of forms will be required for each HCT recipient. The goal of the algorithm is to randomly select an epidemiologic sample of recipients for whom a Comprehensive Report Form will be requested. The algorithm includes, but is not limited to, type of HCT, age of the recipient, disease, etc. The algorithm is periodically reviewed to assess the burden of data submission for transplant centers.

A. Transplant Essential Data (TED) centers

TED centers are required to submit the following forms:

- Unique ID Assignment (CRID) (Form 2804), due for recipient's first HCT only;
- Pre-TED (Form 2400);
- Post-TED (Form 2450);
- The HCT Infusion Form (Form 2006) is required for ALL NMDP recipients
- Infectious Disease Markers (Form 2004) (non-National Marrow Donor Program [NMDP] donors);
- Confirmation of HLA Typing (recipient and non-NMDP donors) Form 2005

B. Comprehensive Report Form (CRF) centers

Comprehensive Report Form Centers are those that have agreed to complete either Post-TED (Form 2450) forms or CRFs for their patients. Once a Pre-TED (Form 2400) is submitted for the first transplant, a selection algorithm will decide on the follow-up track for this patient.

When a center submits Comprehensive Report Forms, the following forms are included:

- Unique ID Assignment (CRID) (Form 2804), due for the recipient's first HCT only;
- Pre-TED (Form 2400), due for the recipient's first HCT only;
- HCT Infusion Form (Form 2006);
- Infectious Disease Markers (Form 2004) (non-National Marrow Donor Program [NMDP] donors);
- Confirmation of HLA Typing (recipient and non-NMDP donors) Form 2005;
- Baseline (Form 2000); Day +100 (Form 2100); 6 mo–2 yrs (Form 2200);
Annually >2 yrs (Form 2300) and appropriate disease inserts.

See Attachment B for more detail about forms submission on each track.

¹ A list of abbreviations used in this document may be found in [Attachment A](#).

C. Reimbursement

CIBMTR reimburses transplant centers for all completed CRFs, at the rates listed on the following table.

Reporting of TED level data is not reimbursed, with the exception of the Form 2006, when it is requested for data on transplant recipients who received a graft from an unrelated donor procured through the NMDP Coordinating Center (BMCC or CBCC).

Once a form is designated as “error-free” in FormsNet™2 (FormsNet™) the transplant center will be reimbursed. Any questions regarding reimbursement should be directed to Lynn Anderson 612-884-8435 or landers2@nmdp.org.

Transplant Center fee schedule		
Rate	Form number	Form Title
\$135	2000	Recipient Baseline Form with required disease form(s)
	2004	Infectious Disease Markers (non-NMDP donor or cord blood unit)
	2005	Confirmation of HLA Typing (recipient & non-NMDP donor or cord blood unit)
	2006	HCT Infusion (selected for Comprehensive Report Forms)
\$110	2100	100-day post-HCT with required disease form(s)
\$85	2200	Six-month to two-year post-HCT with required disease forms()
\$65	2300	Yearly Follow-up for greater than two years post-HCT with required disease form(s)
\$25	2006	Unrelated HCT using U.S. donor (not selected for CRF submission)
\$15	2900	Recipient Death Data

2. CENTER MEMBERSHIP INFORMATION

Following is information that centers need, along with a description of forms and processes they need to follow, to become a CIBMTR member center.

1. A **New Center Information Form (Attachment C)** is the first form a center submits to CIBMTR to start the membership process. This provides all the contact information for both the center and for key personnel. On page 2 of the form, designate the type of transplants the center performs. If applicable, enter the center's EBMT team number, old NMDP number and old/or IBMTR/ABMTR team number (or EBMT number, see step 3 below).
2. **CIBMTR center number (CCN)**. Once the CIBMTR New Center Information Form is completed and submitted, the center will be assigned a unique CIBMTR Center number. *This is a very important number – it links all submitted data back to the center.*
3. **EBMT number**. If the center is a member of the European Group for Blood and Marrow Transplantation (EBMT), that number is provided to CIBMTR for record-keeping. EBMT centers submitting data via FormsNet™ should include their Center Identification Code number (CIC#) so that the center numbers can be cross-referenced to ensure accuracy. For more information on European centers and EBMT, please see Section 2B.
4. **Primary Contact/Data Manager**. A Primary Data Contact (PDC) is designated on the CIBMTR New Center Information online form to serve as the main contact for the center in CIBMTR's Global Contact Management (GCM) database. The PDC is the **only** person who can grant access permission to other personnel at that center, using the Center Personnel Change form found at:
<http://www.cibmtr.org/DataManagement/AdminResources/Personnel/index.html>.
To access this form, the PDC will use the same username and password as they use to enter FormsNet.
5. A **CIBMTR Center Liaison** is assigned to each center once the New Center Information Form is submitted. This person serves as that center's personal contact with CIBMTR, and will work with its data staff to help resolve any issues or answer any questions. A **campus assignment** will also be made at this same time. This campus (either Milwaukee, Wisconsin, or Minneapolis, Minnesota) is where any paper forms (if needed at some point) would be submitted.
6. A **Center Change Form** is used when a transplant center needs to change information in the CIBMTR database about their center (**Attachment D**). The first page should be filled out for all submissions, along with the appropriate additional section. The Center Change form is filled out by the Medical Director at the center. The form's four sections are:
 - Transplant type and/or reporting level changes;
 - Center splits;
 - Center mergers; and

- Participation withdrawal/center closings.
7. **Data Transmission Agreement (DTA).** Submission of a DTA allows the exchange of data (and payment for data) to take place between centers and CIBMTR. Reimbursement for report forms submitted to CIBMTR is conditional upon receipt of a completed DTA. Centers should submit their DTA to:
- NMDP Contracts Department c/o Nancy Poland,
National Marrow Donor Program
3001 Broadway St. NE, Suite 110
Minneapolis, MN 55413-1753

Further questions about DTA agreements should be directed to Nancy Poland, Sr. Manager, Contracts (Research and Clinical Trials) at 612-362-3401 or npoland@nmdp.org.

A. Institutional Review Board (IRB) Approvals

To be compliant with federal regulations for human research subject protection, transplant centers are required to obtain IRB-approved informed consent from every transplant recipient before data submitted to the Stem Cell Therapeutic Outcomes Database (SCTOD) can be used for research purposes. Informed consent also must be obtained from recipients prior to submitting blood samples to the Research Sample Repository. International centers are also required to follow the applicable laws and regulations of their country for obtaining informed consent from their transplant recipients.

NMDP and the CIBMTR have written protocols and informed consent documents for the Research Database and Research Sample Repository. The NMDP IRB has approved these protocols and consent forms. All centers must also have approval from their local IRB for the Research Database protocol. NMDP network member centers and related donor transplant centers participating in the related donor repository also need local IRB approval for the Research Sample Repository protocol.

Under 2005 federal legislation, U.S. centers are required to submit outcomes data on ***all allogeneic transplants***, related and unrelated, to CIBMTR. Data submitted without informed consent from the recipient will only be used for federally required analyses, such as the center-specific outcomes analysis. In cases where the allogeneic recipient did not provide consent, TED level data will be collected

1. Protocols and Consent Forms

The Database and Research Repository **protocols and consent forms** that must be submitted to the center's local IRB for approval are located on the CIBMTR website at: www.cibmtr.org/DataManagement/ProtocolConsent/pages/index.aspx.

Consent forms may be formatted according to each site's requirements; however, the protocols need to be submitted as written. The IRB approval letter and IRB-approved consent forms should be sent to Christina Jobe at NMDP each year after the continuing review by the local IRB. Failure to have current local IRB approval can affect a center's Continuous Process Improvement (CPI) status. Questions about the protocols or consents should be directed to Christina Jobe (cjobe@nmdp.org) at 612-627-8164.

B. European Group for Blood and Marrow Transplantation (EBMT) Centers

EBMT centers have a different process for reporting data to CIBMTR than U.S. centers. In the past, EBMT data centers electronically forwarded **MED-A** data (comparable to **TED-form data**) to CIBMTR from centers that had given their permission. Since December 2007 when the FormsNet™ application was implemented, CIBMTR has not been able to receive this electronic transfer of MED-A data. As a result, MED-A level data appear on the CIBMTR Forms Due report as being "overdue," even though a center may have submitted these data to EBMT. These MED-A "overdue" forms listed on the report can be ignored, as the data will be electronically transferred by the EBMT data center once electronic data transfer is re-established. Data submitted on the following forms will be obtained from the EBMT at that time:

- Form 2400 Pre-TED
- Form 2450 Post-TED
- Form 2455 Selective Post-TED

All other forms (2000, 2100, 2200, 2300, etc.) are CRFs, and should be submitted directly to CIBMTR, either in FormsNet™ or on paper to the center's CIBMTR Liaison.

CIBMTR is working to restore electronic data transfer from EBMT, but such systems are not yet available. CIBMTR acknowledges it is a burden for centers to submit MED-A level follow-up data to both EBMT and CIBMTR, and intends to collect these follow-up data from EBMT once the two systems are reconnected. We encourage all centers to maintain timely follow-up with the EBMT.

Because of large differences in data elements and format between **MED-B data** and CIBMTR **CRF data**, there is not an "electronic pathway" for these data to be transferred from EBMT to CIBMTR. Therefore, CIBMTR plans to continue to request follow-up wherever possible for patients for whom it has CRF data. Follow-up for these patients can be submitted to CIBMTR on paper forms or electronically via FormsNet™. ***These patients also appear on Forms Due reports, and CIBMTR would like centers to respond to requests for follow-up CRF data.***

At CIBMTR, we understand that the current Forms Due Report is not optimal for EBMT centers, and apologize for this inconvenience. We appreciate your patience as we work to restore smooth electronic data transmission between the EBMT and CIBMTR databases. Feel free to contact your CIBMTR Center Liaison if you have additional questions about the Forms Due reports.

3. CIBMTR ACCESS

A. FormsNet™2.0

FormsNet™ is CIBMTR's Web-based application for submission of outcomes data. This system allows transplant centers to electronically submit TED or CRF data to CIBMTR. FormsNet™ includes real-time error validation and override capabilities, and access to the Forms Due Report.

CIBMTR takes security of electronic and paper medical information seriously. Substantial security procedures are in place to maintain the integrity and confidentiality of data submitted to CIBMTR. These security procedures apply to the FormsNet™ application. All users need to obtain a SecurID®, which helps maintain proof of identity for all system users.

The transplant center's PDC need to log into FormsNet™ and activate other employee accounts before the employee will be able to use the application. The PDC can request new or replacement SecurID® tokens at:

www.cibmtr.org/DataManagement/AdminResources/Personnel/Pages/index.aspx.

After the request is complete, it will be necessary for the Primary Contact/Data Manager to activate the new user in FormsNet™ under the Maintenance tab.

1. FormsNet™ training

Training in the proper use of FormsNet™ is very important. It is recommended that each user complete the appropriate training module(s) before attempting to log into the application. All teams should continue to submit paper forms until their access to FormsNet™ is established.

The training portion of the CIBMTR website is located at:

<http://www.cibmtr.org/DataManagement/TrainingReference/index.html>. All revised CIBMTR forms are available for submission using FormsNet™.

Users can contact the NMDP Service Desk at servicedesk@nmdp.org for help with technical problems, and their Center Liaison with all other questions. They should be prepared to provide their center's five-digit CCN number when making inquiries.

2. SecurID® Log-In

The SecurID® system is one of the important security features built into FormsNet™, and is used as a second form of identity authentication. PDCs can expect to receive SecurID® tokens via FedEx approximately six to eight weeks after their center's application is received.

The NMDP Help Desk will contact the PDC under separate cover with the user's SecurID® PIN number, FormsNet™ User ID and Password. A SecurID® is a small physical token that displays a six digit number. This number changes every 60 seconds and is in sync with a server at NMDP. The user should log into FormsNet™ at least once every 30 days in order to keep the two

synchronized. If the token gets out of sync, the user should contact the NMDP Help Desk and they can re-synchronize the token with the server during the phone call.

Initially, only a few people at each center may be assigned a SecurID® token for FormsNet™ access. These tokens ***must not be shared*** between individuals. They remain the property of NMDP. Report lost or stolen tokens to NMDP immediately at 612-362-3411 (1-800-526-7809) or by email to servicedesk@nmdp.org. Centers are asked to return the tokens to the NMDP Help Desk if a staff member leaves the organization. The help desk address is:

ATTN: Service Desk
National Marrow Donor Program
3001 Broadway St. N.E.
Broadway Ridge, Suite 100
Minneapolis, MN 55413

4. TRAINING AND REFERENCE

CIBMTR provides substantial education related to its data collection tools, FormsNet™, data quality audit procedures and general processes. A wide variety of training resources are available to new centers, Center Directors, Primary Contacts, and Data Managers. A prime resource for in-person instruction and for new personnel to talk with others is attendance at educational sessions held twice per year: at the BMT Tandem Meetings in February and at the NMDP Council meeting in November.

Peripheral meetings held in conjunction with the BMT Tandem Meetings include the Clinical Research Professionals/Data Management Conference, BMT CTN Steering Committee, Coordinator and Investigator Sessions, FACT Training Workshops, BMT Center Administrative Directors, BMT Pharmacists, Transplant Nurses, Pediatric BMT, Advanced Practice Professionals, Clinical Practice Forum, and BMT Center Medical Directors Conference. Up-to-date information about upcoming meetings can be found on the CIBMTR (www.cibmtr.org) and ASBMT (www.asbmt.org) websites.

A. Data Manager Education

Self-study packets for new CRPs, Webcasts, conference calls and individual sessions are provided by data management staff at all training sessions.

In addition, CIBMTR newsletters (www.cibmtr.org/ReferenceCenter/Newsletters/Pages/index.aspx) include articles addressing data reporting issues. Key presentations at the CRP Data Management meetings are video-recorded and made available on the CIBMTR website. Topics include descriptions of CIBMTR policy changes, procedures and data forms, reviews of the HCT process, pertinent diseases, HCT-specific medical terminology, hematology, histocompatibility and immunology, and good clinical practices for documentation, time management and resource allocation.

All training modules available on the cibmtr.org website are in the process of being updated. There is currently a pre-TED manual and a TED manual, and others are being developed. Please check the website at www.cibmtr.org/DataManagement/TrainingReference/Pages/index.aspx for updates.

B. Mentor Program

Thanks to the efforts of many dedicated CIBMTR Clinical Research Professionals from transplant centers in several countries, there is a website devoted to issues faced by data managers in collecting and reporting data to CIBMTR and to improving their effectiveness:

www.datamanager.blogspot.com. This site includes the following:

- Answers to frequently (and not so frequently) asked questions about HCT and CIBMTR;
- Opportunities for experienced professional mentors to assist new or inexperienced data managers with specific challenges;

- Help for data managers preparing for audits with practical tips from the personal experiences of other data managers;
- Many useful internal and external links to related Websites, e.g. online medical dictionary and a helping-hand guide for data managers.

C. Tips from the Network

Following are suggestions from experienced CRPs/Data Managers about organizing workflow. Some may work for you and some may not. Note that most of these suggestions are based on paper forms submission – if your center submits forms electronically, you may need to adapt them.

- Put patient’s name on a calendar (electronic or paper) for the dates when each report is due. Choose the time point that works best for your team:
 - When the infusion is scheduled or when the patient is admitted;
 - When the monthly report comes out;
 - When the Continuous Process Improvement (CPI) trimester begins;
 When the calendar reminder pops up, complete everything that you can and then make note of what you still need and check for it regularly. For instance, when an infusion is scheduled, complete as much information as you already know on the Baseline form. This will help you get forms submitted with contact dates closest to the standard reporting periods (100-day, 6-month, annual).
- An alternate suggestion is to keep a file for each patient and for each month and place the patient’s file in the month file when the next form is due.
- Pick a day each week to work on forms. Minimize other distractions on that day.
- For transplant recipients who received a graft from an unrelated donor procured through the NMDP Coordinating Center, “Search Forms” will not show up in FormsNet™. They are part of a different CPI phase. When you are setting up your calendar or files for a patient, print out a Form 22, complete the key fields and give them to the search coordinators. Print 180/183/184 or mark it on your calendar. These have a narrow window of completion time, so timely submission is vital.
- Keep up on events with your inpatients and watch for re-admissions. Print or note what information you can, so you will have it available when it is time to fill in the form.
- Play with the online tools that are provided. If they don’t work for you, make your own tracking system. A few hours of organizing can save significant time.
- Keep a list in a visible area and mark off forms when they are completed. Watching the list get shorter and looking at what you’ve already accomplished can be very motivating.
- Have someone else on the team review your paper forms for mistakes (check boxes missed, values left blank) before you submit them. If you do not have anyone available, wait a day or two and then scan the form again yourself. FormsNet™ will perform this

check for you if you are entering the data electronically, but you probably still should review the data to be sure it is keyed correctly before you submit the form.

- Sort by what works for you. For example, generate lists by form type (Baselines, 100-days, etc.) and work on them that way.
- Don't hesitate to call or email your liaison.

D. CIBMTR.ORG website

The CIBMTR website at www.cibmtr.org includes many resources for helping new data managers. Available information includes:

- **Administrative Resources**
www.cibmtr.org/DataManagement/AdminResources/Pages/index.aspx
- **Center Membership**
www.cibmtr.org/DataManagement/CenterMembership/Pages/index.aspx
- **Contact a Liaison**
www.cibmtr.org/DataManagement/ContactLiaison/Pages/index.aspx
- **Data Collection Forms**
www.cibmtr.org/DataManagement/DataCollectionForms/Pages/index.aspx
- **Protocols and Consent Forms**
www.cibmtr.org/DataManagement/ProtocolConsent/Pages/index.aspx
- **Training and Reference**
www.cibmtr.org/DataManagement/TrainingReference/Pages/index.aspx

E. Other Helpful Websites

- **AGNIS**
www.agnis.net
<http://bioinformatics.nmdp.org/>
- **Blood & Marrow Transplant Information Network (BMT InfoNet)**
www.bmtinfonet.org
- **Bone Marrow Donors Worldwide (registry codes):**
www.bmdw.org/index.php?id=addresses_members&no_cache=1
- **Cord Blood Licensure information from NMDP**
www.marrows.org/cblicensure
- **Foundation for the Accreditation of Cellular Therapy (FACT)**
<http://factwebsite.org>
- **FormsNet™ and Traxis applications**
<https://connect.nmdp.org>

- **Good Clinical Practices (GCPs):** International ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects (International Conference on Harmonization Document):
www.fda.gov/cder/guidance/959fnl.pdf
- **Lab Conversions**
www.unit-conversion.info/volume.html
www.globalrph.com/conv_si.htm
www.lymphomation.org/testsimmunoglobulins.htm
www.unc.edu/~rowlett/units/scales/clinical_data.html
- **Mentors and website goals**
www.datamanager.blogspot.com
- **National Cancer Institute (NCI)**
www.cancer.gov
- **National Marrow Donor Program (NMDP)**
www.marrow.org
www.marrow.org/md (Physicians' Resource Center)
www.marrow.org/patient (Patient Resource Center)
- **NMDP Service Desk**
www.servicedesk@nmdp.org
- **Social Security Death Index**
<http://ssdi.rootsweb.ancestry.com>

5. ATTACHMENTS

Attachment A: Abbreviations

AE	adverse event	CTAC	Clinical Trials Advisory Committee
AGNIS	A Growable Network Information System	CVDR	Center Volume Data Report
aGVHD	acute graft-versus-host disease	CY	cyclophosphamide
ALL	acute lymphoblastic leukemia	DBtC	Data Back to Centers
AML	acute myelogenous leukemia	DFS	disease-free survival
AP	accelerated phase	DLBCL	diffuse large B-cell lymphoma
APL	acute promyelocytic leukemia	DLI	donor leukocyte infusion
ASBMT	American Society for Blood and Marrow Transplantation	DM	data management
ATG	antilymphocyte globulin	DSA	donor-directed specific allo-antibodies
BM	bone marrow	DSS	Durie-Salmon Scoring System
BMCC	Bone Marrow Coordinating Center	DUA	Data Use Agreement
BMI	Body Mass Index	EBMT	European Group for Blood & Marrow Transplantation
BMT	blood and marrow transplantation	EDSS	Extended Disability Severity Score
BMT CTN	Blood and Marrow Transplant Clinical Trials Network	ESRD	end stage renal disease
BO	bronchiolitis obliterans	FA	Fanconi anemia
BP	blast phase	FACT	Foundation for Accreditation of Cellular Therapy
Bu	busulfan	FAQ	frequently-asked questions
BuCy	busulfan/cytoxan	FDA	Food and Drug Administration
CAC	Consumer Advocacy Committee	GCM	Global Contact Management
caDSR	Cancer Data Standards Registry	GCP	Good Clinical Practice
CBCC	Cord Blood Coordinating Center	GVHD	graft-versus-host disease
CDE	Common Data Elements	GVL	graft-versus-leukemia
cGVHD	chronic graft-versus-host disease	GVT	graft-versus-tumor
CIBMTR	Center for International Blood and Marrow Transplant Research	HCT	hematopoietic (stem) cell transplantation
CIC	Center Identification Code	HD	Hodgkin disease
CIT	CIBMTR Information Technology	HIPAA	Health Insurance Portability & Accountability Act
CLL	chronic lymphocytic leukemia	HLA	human leukocyte antigen
CML	chronic myelogenous leukemia	HLH	hemophagocytic lymphohistiocytosis
CMV	cytomegalovirus	HRSA	Health Resources and Service Administration
CNS	central nervous system	IBMTR	International Bone Marrow Transplant Registry
COG	Children's Oncology Group	IHWG	International Histocompatibility Working Group
CP	chronic phase	IM	imatinib mesylate
CPI	Continuous Process Improvement	IPSS	International Prognostic Scoring System
CR1	first complete remission	IRB	Institutional Review Board
CR2	second complete remission	IRG	immune response gene
CRC	Clinical Research Coordinator	ISS	International Staging System
CRF	Comprehensive Report Form	IV	intravenous
CRID	CIBMTR Recipient Identification Number		
CRP	Clinical Research Professional		
CSA	cyclosporine		
CSV	comma separated value		

JACIE	Joint Accreditation Committee of ISCT & EBMT	PI	Principal Investigator
KGF	Kepivance	PLL	prolymphocytic leukemia
KIR	killer-cell immunoglobulin-like receptors	PTLD	post-transplant lymphoproliferative disorder
KPS	Karnofsky Performance Score	QOL	quality of life
LAD	leukocyte adhesion deficiency	RCC	renal cell cancer
LCH	Langerhans cell histiocytosis	RCI	Resource for Clinical Investigations in Blood and Marrow Transplantation
LEL	low expression loci	BMT	Bone Marrow Transplantation
LFS	leukemia-free survival	RF	Report Form
MA	myeloablative	RFI	Request for Information
MCW	Medical College of Wisconsin	RI	reduced intensity
MDS	myelodysplastic syndrome	RIC	reduced intensity conditioning
mHAg	minor histocompatibility antigens	RR	relative risk
MM	multiple myeloma	RTX	rituximab
mmRD	mismatched related donor	RUCA	Rural Urban Commuting Area
MS	multiple sclerosis	SAA	severe aplastic anemia
MSD	matched sibling donor	SAE	severe adverse event
MSP	Minneapolis	SCD	sickle cell disease
MTX	methotrexate	SCID	severe combined immunodeficiency
NCBI	National Cord Blood Institute	SCTOD	Stem Cell Therapeutic Outcomes Database
NCI	National Cancer Institute	SEER	Surveillance Epidemiology and End Results
NHL	Non-Hodgkin lymphoma	SES	Socioeconomic status
NHLBI	National Heart, Lung and Blood Institute	SLL	small lymphocytic leukemia
NIAID	National Institute of Allergy and Infectious Disease	SM	secretory myeloma
NIH	National Institutes of Health	SNP	single nucleotide polymorphism
NIMA	Non-inherited maternal antigens	t-AML	transformed-acute myeloid leukemia
NK	Natural killer	TBI	total body irradiation
NMA	Non-myeloablative	TED	Transplant Essential Data
NMDP	National Marrow Donor Program	TGFB1	transforming Growth Factor beta 1
Non-SCC	Non-squamous cell carcinoma	t-MDS	transformed myelodysplastic syndrome
NSM	Non-secretory myeloma	TNF	tumor necrosis factor
OIT	Office of Information Technology	TRM	transplant related mortality
OPA	Office of Patient Advocacy	UCBT	umbilical cord blood transplantation
OS	Overall survival	UML	Unified Modeling Language
PB	Peripheral blood	URD	unrelated donor
PBMTC	Pediatric Blood and Marrow Transplant Consortium	VOD	veno-occlusive disease
PBPC	peripheral blood progenitor cells	VRE	vancomycin resistant enterococcus
PBSC	peripheral blood stem cells	WBC	white blood count
PDC	Primary Data Contact	WMDA	World Marrow Donor Association
PFS	progression-free survival		
PHA	Public Health Authority		

Attachment B: Forms Submission Process

CIBMTR Forms Submission Process		
<ul style="list-style-type: none"> Center submits CRID Assignment Form (Form 2804) CRID generated <ul style="list-style-type: none"> If autologous recipient declines consent for research participation, stop here² Pre-TED (Form 2400) is added to Forms Due list Center completes and submits Pre-TED CRF Track: Pre-TED data is processed through the selection algorithm resulting in CRF or TED track. Follow appropriate track below TED Track: Follow TED track below 		
	CRF Track³	TED Track
1	<ul style="list-style-type: none"> Forms 2004 and 2005 due for each non-NMDP allogeneic donor Form 2005 due for each non-NMDP allogeneic recipient Form 2006 added for all products 	<ul style="list-style-type: none"> Forms 2004 and 2005 will be added if participating in related specimen repository and for all non-NMDP cord blood units Form 2006 due for all NMDP products and all cord blood units
2	Baseline and Follow-up Forms added to Forms Due list	Post-TED Follow-up Form 2450 added to Forms Due list
3	Center completes Baseline form after infusion	Center completes Post-TED Forms at appropriate time points ³
4	Center completes CRF Follow-up Forms at appropriate time points ⁴	Is recipient alive? If yes, go to Step 5. If no, go to Recipient Death Table
5	Follow-up Form entered	Did recipient have a subsequent transplant? If yes, go to Step 6. If no, go to Step 3
6	Is recipient alive? If yes, go to Step 7. If no, go to Recipient Death Table	Subsequent transplant is reported on the next available follow-up form
7	Did recipient have subsequent transplant? If yes, go to Step 8. If no, continue reporting at next time point (Step 4).	Future time points will be deleted for prior transplant from FormsNet when the form reporting the subsequent transplant is error free.
8	Future time points will be deleted for prior transplant from FormsNet when the form reporting the subsequent transplant is error free. Go to Step 2 for subsequent transplant	Center completes and submits Pre-TED (Form 2400) for subsequent transplant. Go to Step 2.
Recipient Death Table		
Death Form 2900 is completed to report the recipient's death.* If a follow-up form is received and reports the recipient's death, and a form 2900 has not been submitted, one will be made due on the Forms Due list.		The recipient's death is reported on the Post TED.

*** Complete the Death Form 2900 even if autopsy is pending. Another Death Form will be requested to confirm Cause of Death if autopsy was pending.**

² If your center has chosen to submit autologous forms without consent, follow the TED track.

³ Recipient has the option to withdraw consent at any time. If this happens, your Center Liaison can move this transplant record to the TED Track.

⁴ 100 days, 6 months, annually

Attachment C: New Center Information Form Sample

CIBMTR NEW CENTER INFORMATION FORM

Please complete this form and return via e-mail to mammi@nmdp.org, or if you prefer, fax it to 612-627-5895, Attention: Monique Ammi. If there are any questions, please do not hesitate to contact us.

CENTER INFORMATION			
Complete name of center:			
Department:			
Division:			
Center address line one:			
Center address line two:			
City:		State/Province:	
Zip/Postal Code:		Country:	
Main Phone:		Center website:	
Main Fax:		Center e-mail:	
If applicable, NMDP TC number:		Was this center ever a member of IBMTR? <input type="checkbox"/> Yes <input type="checkbox"/> No	
		If applicable, IBMTR number:	
Is this center affiliated with any current or former CIBMTR center? <input type="checkbox"/> Yes <input type="checkbox"/> No		If yes, center number or name(s):	
BMT-CTN member? <input type="checkbox"/> Yes <input type="checkbox"/> No		If yes, how does the center participate? <input type="checkbox"/> Core center <input type="checkbox"/> Affiliate center <input type="checkbox"/> PBMTTC center	
Is the center affiliated with any of the following U.S. NCI Cancer Cooperative Groups? Please check Yes or No for each.		CALGB: <input type="checkbox"/> Yes <input type="checkbox"/> No	ECOG: <input type="checkbox"/> Yes <input type="checkbox"/> No
		SWOG: <input type="checkbox"/> Yes <input type="checkbox"/> No	COG: <input type="checkbox"/> Yes <input type="checkbox"/> No
Is the center a member of the Canadian Blood and Marrow Transplantation Group (CBMTG)? <input type="checkbox"/> Yes <input type="checkbox"/> No			
EBMT member? <input type="checkbox"/> Yes <input type="checkbox"/> No		If yes, EBMT team number:	Forms currently submitted to: <input type="checkbox"/> EBMT <input type="checkbox"/> CIBMTR <input type="checkbox"/> both
TRANSPLANT TYPES AND REPORTING LEVELS			
<p>The CIBMTR offers two levels of participation – as a Transplant Essential Data (TED level) Program or as a Comprehensive Report Form (CRF level) Program.</p> <p>Please review the requirements for each level and choose the program your center would like to pursue.</p> <p>Transplant Essential Data (TED) only centers receive all CIBMTR general mailings, including the newsletter and summary slides, pay member rates for attending CIBMTR's annual meeting, and may serve on CIBMTR Working Committees. No forms reimbursement for TED forms.</p> <p>Comprehensive Report Form (CRF) centers receive all the benefits of TED only centers, plus members may chair CIBMTR Working Committees, may be members of the Executive Committee, and have voting privileges. Centers are reimbursed for submitting Report Forms.</p>			
PATIENT AND TRANSPLANT TYPE INFORMATION			
Patient type(s): <input type="checkbox"/> Pediatric <input type="checkbox"/> Adult <input type="checkbox"/> Both	Transplant types: Allogeneic, unrelated: <input type="checkbox"/> Performed <input type="checkbox"/> Not performed Allogeneic, related: <input type="checkbox"/> Performed <input type="checkbox"/> Not performed Autologous: <input type="checkbox"/> Performed <input type="checkbox"/> Not performed		Reporting levels: <input type="checkbox"/> CRF <input type="checkbox"/> TED Only <input type="checkbox"/> Will not report* <input type="checkbox"/> CRF <input type="checkbox"/> TED Only <input type="checkbox"/> Will not report* <input type="checkbox"/> CRF <input type="checkbox"/> TED Only <input type="checkbox"/> Will not report
*See note below.			
<p><i>* U.S. law requires that U.S. centers performing related or unrelated allogeneic transplants must report outcomes data to a national registry. The minimum reporting level is TED forms. CIBMTR administers this data collection. International centers performing transplants using unrelated donor products from the U.S. should also report outcomes.</i></p> <p><i>*Those international centers locating donors through the NMDP (including cord blood) must report data on allogeneic-unrelated transplants for those patients.</i></p>			

Attachment D: Center Change Form Sample

CIBMTR CENTER CHANGE FORM

This form is for use by **current** CIBMTR centers; to become a **new** CIBMTR center, please complete the [CIBMTR New Center Information Form](#).

Please complete this page and applicable section(s) of this form and return it via e-mail to mammi@nmdp.org. **All requests for center changes must be made with the knowledge and consent of the center's Medical Director.** For this form, e-mails originating from the Medical Director's e-mail account will be considered signed. If it is impossible to submit the form electronically, please fax it to 612-627-5895, Attention: Monique Ammi.

GENERAL CENTER INFORMATION		TYPE OF CHANGE
CIBMTR center number(s):	Date of request:	Transplant type/reporting level change <input type="checkbox"/> Center splitting <input type="checkbox"/> Center merging <input type="checkbox"/> Withdrawal from participation <input type="checkbox"/> Center closing <input type="checkbox"/> Other, please explain below. <input type="checkbox"/>
Center name:	<h1>Sample</h1>	
Submitting Medical Director:		
Medical Director's e-mail:		
If applicable, old IBMTR team number:		
BMT-CTN member? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, how does the center participate? <input type="checkbox"/> Core center <input type="checkbox"/> Affiliate center <input type="checkbox"/> PBMTC center		
Is the center affiliated with any of the following U.S. NCI Cancer Cooperative Groups? <input type="checkbox"/> Yes <input type="checkbox"/> No Please check Yes or No for each.		CALGB: <input type="checkbox"/> Yes <input type="checkbox"/> No ECOG: <input type="checkbox"/> Yes <input type="checkbox"/> No SWOG: <input type="checkbox"/> Yes <input type="checkbox"/> No COG: <input type="checkbox"/> Yes <input type="checkbox"/> No
Is the center a member of the Canadian Blood and Marrow Transplantation Group (CBMTG)? <input type="checkbox"/> Yes <input type="checkbox"/> No		
EBMT member? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, EBMT team number: _____		Forms currently submitted to: <input type="checkbox"/> EBMT <input type="checkbox"/> CIBMTR <input type="checkbox"/> both
PLEASE PROVIDE ADDITIONAL INFORMATION AND, IF APPLICABLE, AN EXPLANATION IF "OTHER" WAS SELECTED AS THE TYPE OF CHANGE:		

TRANSPLANT TYPE AND/OR REPORTING LEVEL CHANGES SECTION A	CENTER SPLITS SECTION B	CENTER MERGERS SECTION C	PARTICIPATION WITHDRAWAL & CENTER CLOSINGS SECTION D
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NOTE: Only the first page and the applicable section(s) of the form need to be completed; all other sections may be skipped.
All submitted forms subject to review and approval by CIBMTR Leadership.

** U.S. law requires that U.S. centers performing related or unrelated allogeneic transplants must report outcomes data to a national registry. The minimum reporting level is TED forms. CIBMTR administers this data collection. International centers performing transplants using unrelated donor products from the U.S. should also report outcomes.*

**Those international centers locating donors through the NMDP (including cord blood) must report data on allogeneic-unrelated transplants for those patients.*