2400: Pre-TED

The Pre-TED Form is now required for all transplants, including subsequent transplants on the comprehensive report form track.

All transplant centers participating in the CIBMTR must submit a Pre-TED (2400) Form for each allogeneic (related or unrelated) hematopoietic cell transplant (HCT). The Pre-TED is a requirement of the SCTOD for all United States transplant centers when either the stem cell donation or the transplant occurs within the United States. For more information regarding the SCTOD, see General Instructions, Stem Cell Therapeutics Outcomes Database.

Although data regarding recipients receiving autologous HCTs are not required to be submitted as part of the C.W. Bill Young Transplant Program, the CIBMTR is highly committed to collecting data on these recipients for research studies. Centers choosing to report autologous data to the CIBMTR must report on all autologous transplants performed at their center. For more information regarding data reporting for autologous HCT, review HCT in the Data Management Guide.

The Pre-TED may be submitted to the CIBMTR up to two weeks prior to the start of the recipient's preparative regimen (see *Helpful Hint* below).

Helpful Hint:
In order to avoid having to make changes to the HCT date, complete the data for the Pre-TED (in FormsNet3^{SM} or on paper), but do not submit the form until the first dose of the preparative regimen is given.

Consent Status and Baseline Forms
There has been a change to the functionality of submitting the Pre-Transplant Essential Data (2400), Pre-Transplant Essential Data Disease Classification (2402), and Pre-Cellular Therapy Essential Data (4000) forms. If a consent status has not yet been reported for a recipient, the edit form icon will appear disabled (see Figure 1 below). When the user hovers over the icon, it will display that consent has not yet been reported for that recipient (see Figure 2 below). The user should go to the Consent Tool (see Navigation to the Consent Tool) and document the recipient's consent status in order to enable the edit icon and allow for completion of the form.

Figure 1. Disabled Edit Form Icon

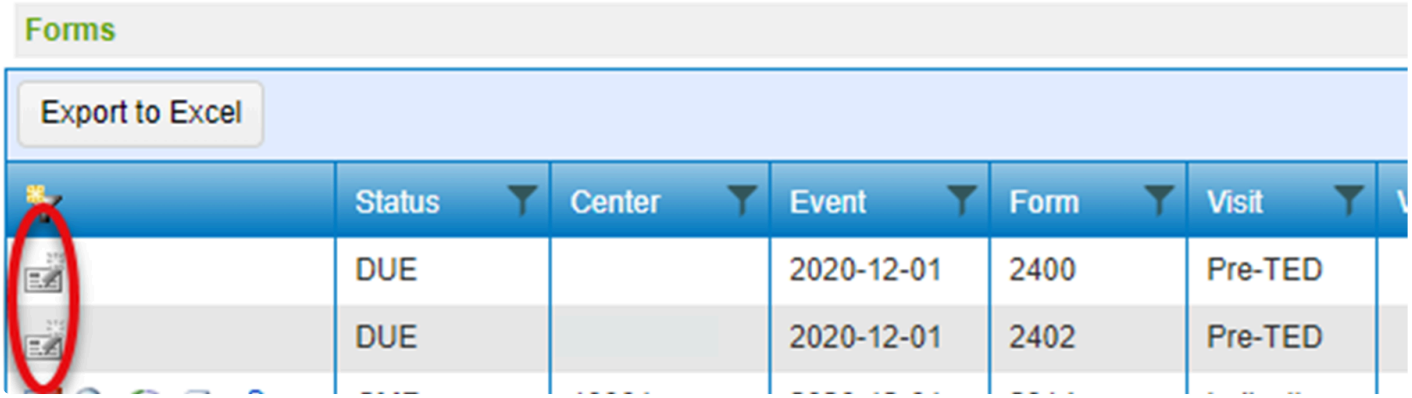
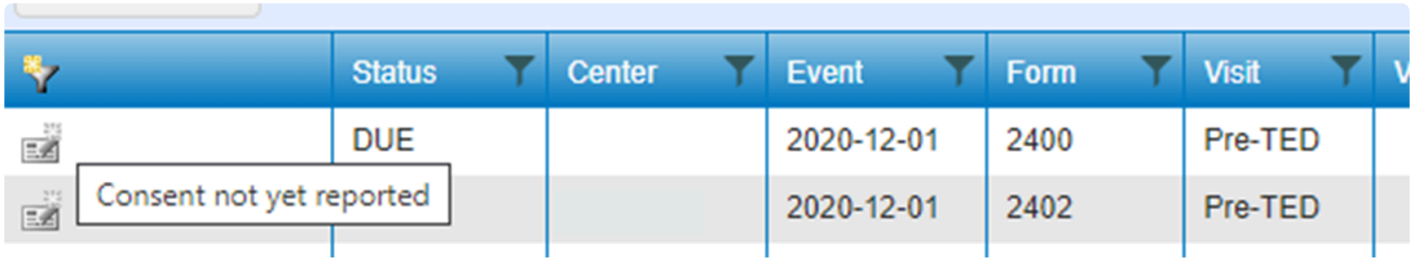


Figure 2. Hovered Text, Consent Not Yet Reported



For recipients receiving a subsequent HCT:
Transplant centers must submit a Pre-TED for all subsequent HCTs; this includes recipients assigned to the TED Forms **and** the Comprehensive Report Forms by the form selection algorithm.

For the majority of subsequent HCTs, the recipient will remain on the original follow-up form track assigned by the form selection algorithm. For more information regarding center type and the form selection algorithm, see Section 1 in the Center Reference Guide. A recipient may need to change tracks if enrolled on a study that requires comprehensive forms.

For recipients of multiple transplants, transplant centers are not granted access to the new Pre-TED Form in FormsNet3 until the Post-TED (Form 2450) or Post-Infusion Data Form (Form 2100) from the previous transplant has been completed.

Transplant centers can use the FormsNet3 application to determine if a Pre-TED is due by either: 1) accessing the Forms Due Report, or 2) entering the recipient's unique ID (CRID) in the Patient Forms Due field.

Links to Sections of the Form:
Q1 – 21: Recipient Information
Q22 – 41: Hematopoietic Cellular Transplant (HCT) and Cellular Therapy
Q42 – 80: Donor Information
Q81 – 86: Clinical Status of Recipient Prior to the Preparative Regimen
Q87 – 119: Comorbid Conditions
Q120 – 134: Pre-HCT Preparative Regimen
Q135 – 139: Additional Drugs Given in the Peri-Transplant Period

Q140 – 142: GVHD Prophylaxis
Q143 – 145: Post-HCT Disease Therapy Planned as of Day 0
Q146: Prior Exposure: Potential Study Eligibility
Q147 – 157: COVID-19 (SARS-CoV-2) Impact on Hematopoietic Cell Transplantation

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

If you need to reference the historical Manual Change History for this form, please click here or reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/ Remove/ Modify	Description
7/25/ 2025	2400: Pre-TED	Add	Recipient Research Repository Consent and Prior Infusion blue box added in Q12: ***Recipient Research Repository Consent and Prior Infusions****: The recipient consent to the Research Repository question should only be answered for the recipient's first allogeneic transplant. If the recipient has had prior autologous or cellular therapy infusions, and this infusion is the first allogeneic, please override the error message. If the recipient has had prior allogeneic infusion(s), please leave this question blank.*
7/25/ 2025	2400: Pre-TED	Modify	Instruction updated on how to answer Q135 – 139 when peri-transplant drugs were not given: *For each agent listed, indicate whether the drug was administered during the peri-transplant period to prevent transplant-related complications or facilitate engraftment, and any additional question(s) for each drug administered.* • ***ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin, ATS (Anti-Thymocyte Serum)****: Serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized against human lymphocytes. Report the total dose prescribed pre and post infusion and the animal source. If* ***Other*** *is selected, specify the source.* • ***Alemtuzumab (Campath)****: Antibody preparations that are infused in the recipient. Report the total dose prescribed pre and postinfusion to the nearest tenth and specify the units of measurement.* • ***Defibrotide****: Antithrombotic agent used to prevent veno occlusive disease.* • ***KGF (keratinocyte growth factor)****: Alternate names: palifermin, Kepivance. KGF acts to stimulate the growth of cells that line the surface of the mouth and intestinal tract. KGF may also be given to treat oral mucositis or as GVHD prophylaxis.*

			• ***Ursodiol**: A naturally occurring bile acid used to dissolve small gall stones and to increase bile flow in patients with primary biliary cirrhosis.* *If the recipient did not receive any of the drugs listed above, ~~leave these questions blank and override the error as 'verified correct'~~ select **None**.*
7/25/2025	2400: Pre-TED	Add	Instructions updated in Q71: *Indicate if the related donor signed an IRB-approved consent form to donate research blood samples to the CIBMTR. This question should only be answered if this is the recipient's first allogeneic transplant.*
7/25/2025	2400: Pre-TED	Add	Instructions updated in Q73: *There are a select number of transplant centers participating in the Related Sample Repository. If your center is one of the participating centers, and the donor provided a research sample, select **Yes** and provide the donor's sample ID for the current infusion. The ID number is located on the bar code that is attached to the sample tube. If the donor did not provide a research sample, select **No**.*
7/25/2025	2400: Pre-TED	Add	Instructions updated in Q14: *There are a select number of transplant center participating in the Related Specimen Repository. If your center is one of the participating centers, and the recipient provided a research sample, select **Yes** and provide the recipient's sample ID in Research sample recipient ID for the current infusion. The ID number is located on the bar code that is attached to the sample tube.*
7/25/2025	2400: Pre-TED	Add	Instructions updated on when Q12 comes due for subsequent transplants: *The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donors or cord blood units. Related allogeneic recipients and/or donors will participate at selected transplant centers. The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cellular transplantation. Studies in which these data may be used include* • *Improving the understanding of tissue matching for hematopoietic cellular donors and recipients.* • *Determining and evaluating the factors that affect transplant outcomes.* • *Studying the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types).* *Indicate if the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR. If **Yes (recipient consented)**, continue with _Date form signed. If **No (recipient declined)**, **Not approached**, or **Not applicable** (center not*

			participating), continue with Is the recipient participating in a clinical trial. *For subsequent allogeneic transplants, this question is disabled, and blood samples are not submitted as consent and blood sample collection is only required for the first allogeneic transplant.*
4/19/2025	2400: Pre-TED	Add	Gene therapy examples 6 and 7 added to Q75: ***Example 6 (single product):*** *a single mobilization event, even when collected over several days* ***Example 7 (single product):*** *A recipient may require multiple mobilizations, and possibly multiple manufacturing steps, for the final product intended for infusion. It should be considered a single gene therapy product, regardless of how many mobilizations or steps required for manufacturing.*
7/26/2024	2400: Pre-TED	Add	Orca Bio Products and Donor Information blue box added above Q42
7/26/2024	2400: Pre-TED	Remove	Omidubicel and Orca-T Products blue box updated above Q42, 45, 47, 75, an 76 to clarify the instruction is only applicable for Omidubicel
7/26/2024	2400: Pre-TED	Modify	Due to June 2024 monthly maintenance release, instructions updated on when Q12 comes due to subsequent transplants: *The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donors or cord blood units. Related allogeneic recipients and/or donors will participate at selected transplant centers. The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cellular transplantation. Studies in which these data may be used include* • *Improving the understanding of tissue matching for hematopoietic cellular donors and recipients.* • *Determining and evaluating the factors that affect transplant outcomes.* • *Studying the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types).* *Indicate if the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR. If* ***Yes (recipient consented)****, continue with Date form signed. If* ***No (recipient declined)****,* ***Not approached****, or* ***Not applicable (center not participating)****, continue with Is the recipient participating in a clinical trial. For subsequent transplant, this question is disabled and blood samples are not submitted.* ~~*for subsequent transplants; however, this question is asked for subsequent transplants. If the recipient previously consented to submit research blood samples to NMDP / CIBMTR, select* ***Yes (recipient consented)****.*~~

4/19/2024	2400: Pre-TED	Remove	Instructions reporting weight prior to prep updated in Q121: *Report the recipient's body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the weight used to calculate the preparative regimen drug doses. This weight may also be the same weight reported on the Recipient Baseline (2000) Form, if applicable. Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight. Even if the recipient does not receive a preparative regimen, the weight is still required.*
4/19/2024	2400: Pre-TED	Modify	The Diagnosis of COVID-19 After the Start of the Preparative Regimen blue box removed and the COVID-19 Infection red box added above Q87 to clarify these questions are now disabled.
4/19/2024	2400: Pre-TED	Modify	The COVID-19 Vaccine red box updated above Q90 to clarify these questions are now disabled.
4/15/2024	2400: Pre-TED	Remove	Instructions reporting weight prior to prep updated in Q121 due to missing a sentence with the previous 4/3/2024 update: *Report the recipient's body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the weight used to calculate the preparative regimen drug doses. This weight may also be the same weight reported on the Recipient Baseline (2000) Form, if applicable. Report weight to the nearest tenth of a kilogram or pound. ~~Do not report adjusted body weight, lean body weight, or ideal body weight.~~ Even if the recipient does not receive a preparative regimen, the weight is still required.*
4/4/2024	2400: Pre-TED	Add	Plasma vs Serum Samples blue box added above Q106
4/3/2024	2400: Pre-TED	Modify	Instructions for reporting the weight prior to prep were updated in Q121: *Report the recipient's ~~actual~~ body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the ~~actual~~ weight used to calculate the preparative regimen drug doses. This may be the same weight reported on the Recipient Baseline (2000) Form. ~~at the time the preparative regimen starts (which may be different than the weight used to determine preparative regimen doses). This weight is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders.~~ Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight.*
3/13/2024	2400: Pre-TED	Modify	The red warning box above Q147 updated to clarify this section is now disabled and will be updated with the next revision of the Pre-TED (2400) form.
3/8/	2400: Pre-	Add	Omidubicel and Orca-T Products blue box added above Q76: ***Omidubicel and***

2024	TED		***Orca-T Products**: If the product is Omidubicel, report the number of products intended to achieve hematopoietic engraftment as **two** and complete two HCT Product and Infusion (2006) forms. If the product is Orca-T, report the number of products intended to achieve hematopoietic engraftment as **one** and complete one HCT Product and Infusion (2006) forms and two Cellular Therapy Product (4003) forms.*
3/8/2024	2400: Pre-TED	Add	Omidubicel and Orca-T Products blue box added above Q75: ***Omidubicel and Orca-T Products**: If the product is Omidubicel, report the number of products from the donor as **two**. If the product is Orca-T, report the number of products from the donor as **three**.*
3/8/2024	2400: Pre-TED	Add	Omidubicel and Orca-T Products blue box added above Q47: ***Omidubicel and Orca-T Products**: If the product is Omidubicel or Orca-T, report **No**, the product was not genetically modified.*
3/8/2024	2400: Pre-TED	Add	Omidubicel and Orca-T Products blue box added above Q45: ***Omidubicel and Orca-T Products**: If the product is Omidubicel, report the product type as **CBU**. If the product is Orca-T, report the product type as **BM**.*
3/8/2024	2400: Pre-TED	Add	Omidubicel and Orca-T Products blue box added above Q42: ***Omidubicel and Orca-T Products**: If the product is Omidubicel or Orca-T, select **No** for multiple donors.*
2/21/2024	2400: Pre-TED	Add	ATG / Campath blue note box added above Q106
12/4/2023	2400: Pre-TED	Remove	Removed the Cord Blood Units and Ex-vivo Expansion blue box: ~~***Cord Blood Units and Ex-vivo Expansion** If the product is a cord blood unit that was ex-vivo expansion was performed, select **Other product** and specify 'ex-vivo cord blood unit' along with the method of expansion (examples of expansion methods include, but are not limited to, with omidubicel, with UM171, or on mesenchymal stem cells).*~~
10/25/2023	2400: Pre-TED	Modify	Navigation instructions updated: *Continue with Specify number of products infused from this donor ~~What agents were used to mobilize the autologous recipient for this HCT~~ if the donor type is autologous.*
8/28/2023	2400: Comorbid Conditions:	Remove	Condensed comorbidity instructions listed in Q100 and 101 Appendix J
8/6/2023	2400: Pre-TED	Add	The Canadian Cancer Trials Group red warning box was above Q16: ***Canadian Cancer Trials Group** Do not report Canadian Cancer Trials Group (CCTG) trials.*
7/28/2023	2400: Pre-TED	Add	Instructions updated in Q79 – 80 on how to report product name due to specific products being added to the form: *Report the name of the product. If the name is not listed, select **Other name** and specify the gene therapy product name.*

7/28/2023	2400: Pre-TED	Add	Updated instructions in Q17-18 to clarify RCI-BMT is now known as CIBMTR CRO Services: *Select the study sponsor of the clinical trial the recipient is participating in. If the participant is enrolled in multiple studies, even if from the same sponsor, report each study separately. If the study sponsor is reported as* ***BMT-CTN****,* ***CIBMTR CRO Services*** *(formerly RCI-BMT), or PIDTC, continue with Study ID Number.*
7/28/2023	2400: Pre-TED	Add	Clarified in Q19 response options will remain the same, even though the RCI-BMT has been updated to CIBMTR CRO Services: *Enter the* ***BMT-CTN****,* ***RCI-BMT****, or* ***PIDTC*** *study ID number of the recipient. Although the RCI-BMT study sponsor name has been updated to CIBMTR CRO Services, existing study ID options will remain listed as RCI-BMT. The new title CIBMTR CRO Services will be used as new studies are added to the option list.*
7/19/2023	2400: Pre-TED	Modify	Updated instructions on what relapse date to report when the reason for subsequent HCT is recurrent primary disease in Q31-35: ***Recurrent primary disease:*** *Additional stem cells are required because of relapse primary disease (i.e., complete remission was achieved pre- or post-transplant, but the disease relapsed following the previous transplant). If the reason is recurrent primary disease, continue with Date of relapse and report the relapse date. If multiple relapses have occurred since the previous infusion, report the date of the most recent relapse. ~~Ensure that the date of recurrent primary disease matches the relapse/progression date reported on the previous transplant's appropriate follow-up form.~~*
7/19/2023	2400: Pre-TED	Add	Therapy Clinical Trials red warning box added above Q16: ***Therapy Clinical Trials*** *Do not report clinical trials for induction / consolidation / salvage therapy (excluding clinical trials sponsored by COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC), blood / tissue sample collection, or any trial the recipient is enrolled post-HCT.*
7/19/2023	2400: Pre-TED	Modify	Clarified which clinical trials should be reported in Q16: *For the infusion being reported on this form, indicate if the recipient is a registered participant of a ~~key treatment~~ clinical trial ~~pre or post infusion~~* ***regardless of if that sponsor uses CIBMTR forms to capture outcomes data****. Only clinical trials relating to the HCT intervention and are known and consented at the time of HCT should be reported. This includes trials related to, but not limited to, the graft source, GVHD prophylaxis, or the preparative regimen. ~~Examples of pre-infusion key treatment clinical trials include cooperative group initial treatment trials (i.e., Alliance, ECOG-ACRIN, SWOG, and COG), cooperative group relapse treatment trials, and transplant trials.~~* *Report any clinical trial, including upfront or relapse chemotherapy, only if the sponsor is COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC* *~~If the recipient is a registered participant of key treatment clinical trials and enrolled post-infusion, the Pre-TED (2400) should be updated to reflect the post-~~*

			~~*infusion trials. Examples of post-infusion key treatment clinical trials include the Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) and MAGIC consortium.*~~
7/19/2023	2400: Pre-TED	Modify	Clinical trials blue box updated above Q16: ***Clinical Trials*** *As of the April 2023 release,* ~~*pre or post infusion key treatment*~~ *clinical trials* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data*** ~~*should*~~ *are now reported on the Pre-TED (2400) Form,* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data****. Review the instructions below for additional information on key treatment clinical trials. Corporate / industry trials or investigator-initiated trials should be reported under Other.*
5/1/2023	2400: Pre-TED	Add	Clinical trials blue box added above Q16: ***Clinical Trials*** *As of the April 2023 release, and pre- or post-infusion key treatment clinical trials should now be reported on the Pre-TED (2400) Form,* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data****. Review the instructions below for additional information on key treatment clinical trials. Corporate / industry trials or investigator-initiated trials should be reported under* ***Other****.*
5/1/2023	2400: Pre-TED	Modify	Instructions for reporting clinical trials updated as part of the Spring 2023 release: *Indicate if the recipient is a registered participant of a key treatment clinical trial pre- or post-infusion. Examples of pre-infusion key treatment clinical trials include cooperative group initial treatment trials (i.e., Alliance, ECOG-ACRIN, SWOG, and COG), cooperative group relapse treatment trials, and transplant trials* ~~*with BMT-CTN, RCI-BMT, USIDNET, COG, PedAL and/or another clinical trial sponsor that uses CIBMTR forms to capture outcomes data*~~*. If the recipient is a registered participant of key treatment clinical trials and enrolled post-infusion, the Pre-TED (2400) should be updated to reflect the post-infusion trials. Examples of post-infusion key treatment clinical trials include the Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) and MAGIC consortium. Sponsors include but are not limited to, BMT-CTN, RCI-BMT, USIDNET, COG, and PedAL. Report corporate / industry trials or investigator-initiated trials as an* ***Other*** *clinical trial sponsor.* • **BMT-CTN:** Blood and Marrow Transplant Clinical Trials Network • **RCI-BMT:** Resource for Clinical Investigation in Blood and Marrow Transplant • **PIDTC:** Primary Immune Deficiency Treatment Consortium • **USIDNET:** United States Immunodeficiency Network • **COG:** Children's Oncology Group • **PedAL:** LLS PedAL • ***Other:*** *Corporate / industry or investigator initiated* ~~*The* ***Other sponsor*** *option should rarely be used. Do not report any transplant center specific clinical trials or investigator-initiated trials the recipient is participating at the transplant center. If the recipient is participating in a clinical trial but does not use CIBMTR form to*~~

			~~*capture outcomes data and does not fit in one of the specified options listed, contact CIBMTR Customer Support.*~~ *If the recipient is not participating in a clinical trial, select* ***No****. Submit a ticket through CIBMTR Center Support when there are questions on reporting clinical trials.*
5/1/ 2023	2400: Pre-TED	Add	Peri-transplant time frame defined: *Drugs may be given during the peri-transplant (before and after infusion). period to prevent transplant-related complications, such as liver injuries or to facilitate engraftment. For each agent listed, indicate whether the drug was administered during the peri-transplant period to prevent transplant-related complications or facilitate engraftment, and any additional question(s) for each drug administered.* • ***ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin, ATS (Anti-Thymocyte Serum)***: *Serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized against human lymphocytes. Report the total dose prescribed pre- and post-infusion and the animal source. If* ***Other*** *is selected, specify the source.* • ***Alemtuzumab (Campath)***: *Antibody preparations that are infused in the recipient. Report the total dose prescribed pre- and post-infusion to the nearest tenth and specify the units of measurement.*
5/1/ 2023	2400: Pre-TED	Add	Cord Blood Units and Ex-vivo Expansion blue box added add to Q45: ***Cord Blood Units and Ex-vivo Expansion*** *If the product is a cord blood unit that was ex-vivo expansion was performed, select* ***Other product*** *and specify 'ex-vivo cord blood unit' along with the method of expansion (examples of expansion methods include, but are not limited to, with omidubicel, with UM171, or on mesenchymal stem cells).*
2/15/ 2023	2400: Pre-TED	Remove	Instructions for reporting the height prior to prep were updated: *Report the recipient's height just prior to the start of the preparative regimen. The intent of this question is to determine the height used when calculating preparative regimen drug doses. This height is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders.* ~~*Report height to the nearest whole centimeter or inch (round up if 0.5 or greater).*~~
10/ 20/ 2022	2400: Pre-TED	Add	Instructions for Q17 – 18 updated to include PedAL option: *If the study sponsor is reported as USIDNET, COG, or PedAL continue with Subject ID.*
10/ 20/ 2022	2400: Pre-TED	Add	Instructions for Q16 updated to include PedAL option: *Indicate if the recipient is a registered participant with BMT-CTN, RCI-BMT, USIDNET, COG, PedAL and/ or another clinical trial sponsor that uses CIBMTR forms to capture outcomes data.* • **BMT-CTN:** Blood and Marrow Transplant Clinical Trials Network

			• **RCI-BMT:** Resource for Clinical Investigation in Blood and Marrow Transplant • **PIDTC:** Primary Immune Deficiency Treatment Consortium • **USIDNET:** United States Immunodeficiency Network • **COG:** Children's Oncology Group • **PedAL:** LLS PedAL
10/18/2022	2400: Pre-TED	Add	Clarification added on how to answer Q135 – 139 when peri-transplant drugs were not given: *If the recipient did not receive any of the drugs listed above, leave these questions blank and override the error as 'verified correct.'*
9/23/2022	2400: Pre-TED	Modify	Version 9 of the 2400: Pre-TED section of the Forms Instruction Manual released. Version 9 corresponds to revision 10 of the Form 2400.

Last modified: Jul 28, 2025

Q1 – 21: Recipient Information

Question 1: Date of Birth

The date of birth is automatically populated based on the value reported in the CRID Assignment tool in FormsNet3. Verify that the date of birth is correct. If an error is noted, correct the CRID Assignment tool and verify that the date of birth has been updated on the Pre-TED Form.

Question 2: Sex

The recipient's sex is automatically populated based on the value reported in the CRID Assignment tool in FormsNet3^{SM}. Verify that the recipient's sex is correct. If an error is noted, correct the CRID Assignment tool and verify that the recipient's sex has been updated on the Pre-TED Form.

Question 3: Ethnicity

The recipient's ethnicity is automatically populated based on the value reported in the CRID Assignment tool in FormsNet3^{SM}. Verify that the recipient's ethnicity is correct. If an error is noted, correct the CRID Assignment tool and verify that the recipient's ethnicity has been updated on the Pre-TED Form.

Question 4: Race

The recipient's race is automatically populated based on the value reported in the CRID Assignment tool in FormsNet3^{SM}. Verify that the recipient's race is correct. If an error is noted, correct the CRID Assignment tool and verify that the recipient's race has been updated on the Pre-TED Form.

Question 5: Race Detail

The recipient's race detail is automatically populated based on the value reported in the CRID Assignment tool in FormsNet3^{SM}. Verify that the recipient's race detail is correct. If an error is noted, correct the CRID Assignment tool and verify that the recipient's race detail has been updated on the Pre-TED Form.

Question 6: Country of primary residence

Select the recipient's country of residence.

- If the recipient's country of primary residence is **Brazil**, continue with *State of residence of recipient (for residents of Brazil)*.
- If the recipient's country of primary residence is **Canada**, continue with *Providence or territory of residence of recipient (for residents of Canada)*.
- If the recipient's country of primary residence is the **United States**, continue with *State of residence of recipient (for residents of USA)*.
- If the recipient's country of primary residence is not Brazil, Canada, or the United States, continue with *NMDP Recipient ID (RID)*.

Question 7: State of residence of recipient (for residents of Brazil)

If **Brazil** was selected as the recipient's primary country of residence, enter the recipient's state of permanent residence at the time of transplant.

Question 8: Providence or territory of residence of recipients (for residents of Canada)

If **Canada** was selected as the recipient's primary country of residence, enter the recipient's providence or territory of permanent residence at the time of transplant.

Question 9: State of residence of recipients (for residents of USA)

If the **United States** was selected as the recipient's primary country of residence, enter the recipient's state of permanent residence at the time of transplant.

Question 10. NMDP Recipient ID (RID)

The NMDP RID is automatically populated based on the value reported on the CRID Assignment Form (2804). Verify that the NMDP RID is correct. If an error is noted, correct Form 2804 and verify that the NMDP RID has been updated on the Pre-TED Form.

Question 11: ZIP or postal code for place of recipient's residence (USA recipients only)

Enter the five-digit ZIP code in which the recipient resides. Only five digits are required; however, if the ZIP+4 (nine digit) code is available, please report it in this field. The zip or postal code is required for USA residents.

The postal code is optional for Canadian residents. The question can be answered or left blank without error for Canadian residents.

> **Recipient Research Repository Consent and Prior Infusions**
> This question The recipient consent to the Research Repository question should only be answered for the recipient's first allogeneic transplant. If the recipient has had prior autologous or cellular therapy infusions, and this infusion is the first allogeneic, please override the error message. If the recipient has had prior allogeneic infusion(s), please leave this question blank.

Question 12: Has the recipient signed an IRB / ethics committee (or similar body) – approved consent form to donate research blood samples to the NMDP / CIBMTR? (for allogeneic HCTs only)

The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donors or cord blood units. Related allogeneic recipients and/or donors will participate at selected transplant centers.

The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cellular transplantation.

Studies in which these data may be used include

- Improving the understanding of tissue matching for hematopoietic cellular donors and recipients.
- Determining and evaluating the factors that affect transplant outcomes.
- Studying the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types).

Indicate if the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR. If **Yes (recipient consented)**, continue with *Date form signed*. If **No (recipient declined)**, **Not approached**, or **Not applicable** (center not participating), continue with *Is the recipient participating in a clinical trial*.

For subsequent allogeneic transplants, this question is disabled, and blood samples are not submitted as consent and blood sample collection is only required for the first allogeneic transplant.

Question 13: Date form was signed

Report the date the research sample consent form was signed by the recipient. Do not report the date that the witness or health care professional signed the consent form.

Questions 14 – 15: Did the recipient submit a research sample to the NMDP / CIBMTR repository? (Related donors only)

There are a select number of transplant center participating in the Related Specimen Repository. If your center is one of the participating centers, and the recipient provided a research sample, select **Yes** and provide the recipient's sample ID in *Research sample recipient ID* for the current infusion. The ID number is located on the bar code that is attached to the sample tube.

If the recipient did not provide a research sample, select **No**.

Clinical Trials
As of the April 2023 release, and pre- or post-infusion key treatment clinical trials should now be reported on the Pre-TED (2400) Form, **regardless of if the sponsor uses CIBMTR forms to capture outcomes data**. Review the instructions below for additional information on key treatment clinical trials. Corporate / industry trials or investigator-initiated trials should be reported under **Other**.

Therapy Clinical Trials
Do not report clinical trials for induction / consolidation / salvage therapy (excluding clinical trials sponsored by COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC), blood / tissue sample collection, or any trial the recipient is enrolled post-HCT.

Canadian Cancer Trials Group
Do not report Canadian Cancer Trials Group (CCTG) trials.

Question 16: Is the recipient participating in a clinical trial?

For the infusion being reported on this form, indicate if the recipient is a registered participant of a clinical trial **regardless of if that sponsor uses CIBMTR forms to capture outcomes data**. Only clinical trials relating to the HCT intervention and are known and consented at the time of HCT should be reported. This includes trials related to, but not limited to, the graft source, GVHD prophylaxis, or the preparative regimen.

Report any clinical trial, including upfront or relapse chemotherapy, only if the sponsor is COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC.

Sponsors include but are not limited to, BMT-CTN, CIBMTR CRO Services (formerly RCI-BMT), USIDNET, COG, and PedAL. Report corporate / industry trials or investigator-initiated trials as an **Other** clinical trial sponsor.

- **BMT-CTN:** Blood and Marrow Transplant Clinical Trials Network
- **CIBMTR CRO Services:** Resource for Clinical Investigation in Blood and Marrow Transplant
- **PIDTC:** Primary Immune Deficiency Treatment Consortium
- **USIDNET:** United States Immunodeficiency Network
- **COG:** Children's Oncology Group
- **PedAL:** LLS PedAL
- **Other:** Corporate / industry or investigator initiated

If the recipient is not participating in a clinical trial, select **No**.

Submit a ticket through CIBMTR Center Support when there are questions on reporting clinical trials.

Reporting Participation in More Than One Study
FormsNet3℠ application: Complete the *Study Sponsor, Study ID Number, Subject ID, and Specify the ClinicalTrials.gov identification number* questions for each study the recipient is participating in by adding an additional instance in the FormsNet3℠ application.
Paper form submission: Copy the *Study Sponsor, Study ID Number, Subject ID, and Specify the ClinicalTrials.gov identification number* questions and complete for each study in which the recipient is participating.
If the participant is enrolled in multiple studies, even if from the same sponsor, report each study separately.

Questions 17 – 18: Study Sponsor

Select the study sponsor of the clinical trial the recipient is participating in. If the participant is enrolled in multiple studies, even if from the same sponsor, report each study separately.

If the study sponsor is reported as **BMT-CTN**, **CIBMTR CRO Services** (formerly RCI-BMT), or **PIDTC**, continue with *Study ID Number*.

If the study sponsor is reported as **USIDNET**, **COG**, or **PedAL,** continue with *Subject ID*.

If **Other sponsor** is reported, specify the study sponsor and continue with *Subject ID*.

Question 19: Study ID Number

Enter the **BMT-CTN**, **RCI-BMT**, or **PIDTC** study ID number of the recipient.

Although the **RCI-BMT** study sponsor name was updated to **CIBMTR CRO Services**, existing study ID options will remain listed as RCI-BMT. The new title **CIBMTR CRO Services** will be used as new studies are added to the option list.

Question 20: Subject ID

Enter the recipient's **USIDNET, COG**, or **Other sponsor** subject ID.

If the recipient is participating in a BMT-CTN study and the EMMES ID is known, enter it here.

If the recipient is participating in a CIBMTR CRO Services (formerly RCI-BMT study), enter the Subject ID given at the time of successful enrollment.

Recipients enrolled in CIBMTR's CMS studies should leave the subject ID blank.

Question 21: Specify the ClinicalTrials.gov identification number

All clinical trials are required to be registered on the clinicaltrials.gov website and will have an associated identification number.

Report the identification number – do not include the letters "NCT," preceding the digits.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q12	7/25/ 2025	Add	Recipient Research Repository Consent and Prior Infusion blue box added: ***Recipient Research Repository Consent and Prior Infusions****: The recipient consent to the Research Repository question should only be answered for the recipient's first allogeneic transplant. If the recipient has had prior autologous or cellular therapy infusions, and this infusion is the first allogeneic, please override the error message. If the*	Due to change in FormsNet3^{SM} validation

			recipient has had prior allogeneic infusion(s), please leave this question blank.	
Q12	7/25/ 2025	Add	Instructions updated on when this question comes due for subsequent transplants: *The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donors or cord blood units. Related allogeneic recipients and/or donors will participate at selected transplant centers. The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cellular transplantation. Studies in which these data may be used include* • *Improving the understanding of tissue matching for hematopoietic cellular donors and recipients.* • *Determining and evaluating the factors that affect transplant outcomes.* • *Studying the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types).* *Indicate if the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR. If* ***Yes (recipient consented)****, continue with _Date form signed. If* ***No (recipient declined)****,* ***Not approached****, or* ***Not applicable*** *(center not participating), continue with Is the recipient participating in a clinical trial.* *For subsequent allogeneic transplants, this question is disabled, and blood samples are not submitted as consent and blood sample collection is only required for the first allogeneic transplant.*	Due to change in FormsNet3^{SM} validation
Q12	7/26/ 2024	Modify	Instructions updated on when this question comes due to subsequent transplants: *The Research Sample Repository contains blood samples from unrelated recipients and/or their adult volunteer donors or cord blood units. Related allogeneic recipients and/or donors will participate at selected transplant centers. The primary objective of the Research Repository is to make blood samples available for research studies related to histocompatibility and hematopoietic cellular transplantation. Studies in which these data may be used include* • *Improving the understanding of tissue matching for hematopoietic cellular donors and recipients.*	Due to change in FN3 validation with the June 2024 monthly maintenance release

			• *Determining and evaluating the factors that affect transplant outcomes.* • *Studying the distribution of HLA tissue types in different populations (e.g., study tissue typing differences between different racial and ethnic populations to help develop methods to improve tissue matching between donors and recipients, including testing of rare HLA types).* *Indicate if the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR. If* ***Yes (recipient consented)****, continue with Date form signed. If* ***No (recipient declined)****,* ***Not approached****, or* ***Not applicable (center not participating)****, continue with Is the recipient participating in a clinical trial. For subsequent transplant, this question is disabled and blood samples are not submitted. ~~for subsequent transplants; however, this question is asked for subsequent transplants. If the recipient previously consented to submit research blood samples to NMDP / CIBMTR, select~~* ***~~Yes (recipient consented)~~****.*	
Q14 – 15	7/25/ 2025	Add	Instructions updated: *There are a select number of transplant center participating in the Related Specimen Repository. If your center is one of the participating centers, and the recipient provided a research sample, select* ***Yes*** *and provide the recipient's sample ID in Research sample recipient ID for the current infusion. The ID number is located on the bar code that is attached to the sample tube.*	Updated for clarification
Q16	7/19/ 2023	Add	Added the Canadian Cancer Trials Group red warning box: ***Canadian Cancer Trials Group*** *Do not report Canadian Cancer Trials Group (CCTG) trials.*	Updated for clarification
Q16	7/19/ 2023	Modify	Clarified which clinical trials should be reported: *For the infusion being reported on this form, indicate if the recipient is a registered participant of a ~~key treatment~~ clinical trial ~~pre or post infusion~~* ***regardless of if that sponsor uses CIBMTR forms to capture outcomes data****. Only clinical trials relating to the HCT intervention and are known and consented at the time of HCT should be reported. This includes trials related to, but not limited to, the graft source, GVHD prophylaxis, or the preparative regimen. ~~Examples of pre-infusion key treatment clinical trials include cooperative group initial treatment trials (i.e., Alliance, ECOG-ACRIN, SWOG, and COG), cooperative~~*	Updated for clarification

			~~*group relapse treatment trials, and transplant trials.*~~ *Report any clinical trial, including upfront or relapse chemotherapy, only if the sponsor is COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC* ~~*If the recipient is a registered participant of key treatment clinical trials and enrolled post-infusion, the Pre-TED (2400) should be updated to reflect the post-infusion trials. Examples of post-infusion key treatment clinical trials include the Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) and MAGIC consortium.*~~	
Q16	7/19/ 2023	Add	Therapy Clinical Trials red warning box added above Q16: ***Therapy Clinical Trials*** *Do not report clinical trials for induction / consolidation / salvage therapy (excluding clinical trials sponsored by COG or if the recipient is enrolled on the PedAL study, COG APAL2020SC), blood / tissue sample collection, or any trial the recipient is enrolled post-HCT.*	Added for clarification
Q16	7/19/ 2023	Modify	Clinical trials blue box updated above Q16: ***Clinical Trials*** *As of the April 2023 release,* ~~*pre or post infusion key treatment*~~ *clinical trials* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data*** ~~*should*~~ *are now reported on the Pre-TED (2400) Form,* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data****. Review the instructions below for additional information on key treatment clinical trials. Corporate / industry trials or investigator-initiated trials should be reported under Other.*	Updated for clarification
Q16	5/1/ 2023	Add	Clinical trials blue box added above Q16: ***Clinical Trials*** *As of the April 2023 release, and pre- or post-infusion key treatment clinical trials should now be reported on the Pre-TED (2400) Form,* ***regardless of if the sponsor uses CIBMTR forms to capture outcomes data****. Review the instructions below for additional information on key treatment clinical trials. Corporate / industry trials or investigator-initiated trials should be reported under* ***Other****.*	All key treatment clinical trials should now be reported as part of the Spring (April) 2023 quarterly release
Q16	5/1/ 2023	Modify	Instructions for reporting clinical trials updated as part of the Spring 2023 release: *Indicate if the recipient is a registered participant of a key treatment clinical trial pre- or post-infusion. Examples of pre-infusion key treatment clinical trials include cooperative group initial treatment trials (i.e., Alliance, ECOG-ACRIN, SWOG, and COG), cooperative group relapse treatment trials, and transplant trials* ~~*with BMT-CTN, RCI-BMT,*~~	All key treatment clinical trials should now be reported as part of the Spring (April)

			~~*USIDNET, COG, PedAL and/or another clinical trial sponsor that uses CIBMTR forms to capture outcomes data*~~. *If the recipient is a registered participant of key treatment clinical trials and enrolled post-infusion, the Pre-TED (2400) should be updated to reflect the post-infusion trials. Examples of post-infusion key treatment clinical trials include the Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) and MAGIC consortium. Sponsors include but are not limited to, BMT-CTN, RCI-BMT, USIDNET, COG, and PedAL. Report corporate / industry trials or investigator-initiated trials as an* ***Other*** *clinical trial sponsor.* • **BMT-CTN:** Blood and Marrow Transplant Clinical Trials Network • **RCI-BMT:** Resource for Clinical Investigation in Blood and Marrow Transplant • **PIDTC:** Primary Immune Deficiency Treatment Consortium • **USIDNET:** United States Immunodeficiency Network • **COG:** Children's Oncology Group • **PedAL:** LLS PedAL • ***Other:*** *Corporate / industry or investigator initiated* ~~*The* ***Other sponsor*** *option should rarely be used. Do not report any transplant center specific clinical trials or investigator-initiated trials the recipient is participating at the transplant center. If the recipient is participating in a clinical trial but does not use CIBMTR form to capture outcomes data and does not fit in one of the specified options listed, contact CIBMTR Customer Support.*~~ *If the recipient is not participating in a clinical trial, select* ***No****. Submit a ticket through CIBMTR Center Support when there are questions on reporting clinical trials.*	2023 quarterly release
Q16	10/20/ 2022	Add	Instructions updated to include PedAL option: *Indicate if the recipient is a registered participant with BMT-CTN, RCI-BMT, USIDNET, COG, PedAL and/or another clinical trial sponsor that uses CIBMTR forms to capture outcomes data.* • **BMT-CTN:** Blood and Marrow Transplant Clinical Trials Network • **RCI-BMT:** Resource for Clinical Investigation in Blood and Marrow Transplant • **PIDTC:** Primary Immune Deficiency Treatment Consortium • **USIDNET:** United States Immunodeficiency Network	Instructions missed in new manual version

			• **COG:** Children's Oncology Group • **PedAL:** LLS PedAL	
Q17 – 18	7/28/ 2023	Modify	Updated instructions to clarify RCI-BMT is now known as CIBMTR CRO Services: *Select the study sponsor of the clinical trial the recipient is participating in. If the participant is enrolled in multiple studies, even if from the same sponsor, report each study separately. If the study sponsor is reported as **BMT-CTN**, **CIBMTR CRO Services** (formerly RCI-BMT), or PIDTC, continue with Study ID Number.*	Due to changes with Summer 2023 Quarterly Release
Q17 – 18	10/20/ 2022	Add	Instructions updated to include PedAL option: *If the study sponsor is reported as USIDNET, COG, or PedAL continue with Subject ID.*	Instructions missed in new manual version
Q19	7/28/ 2023	Add	Clarified response options will remain the same, even though the RCI-BMT has been updated to CIBMTR CRO Services: *Enter the **BMT-CTN**, **RCI-BMT**, or **PIDTC** study ID number of the recipient. Although the RCI-BMT study sponsor name has been updated to CIBMTR CRO Services, existing study ID options will remain listed as RCI-BMT. The new title CIBMTR CRO Services will be used as new studies are added to the option list.*	Instructions missed in new manual version

Last modified: Jul 28, 2025

Q22 – 41: Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

Question 22: Is a subsequent HCT planned as part of the overall treatment protocol (not as a reaction to post-HCT disease assessment) (For autologous HCTs only)

If, at the time of the current HCT, a second (tandem transplant) or subsequent HCT is planned according to the protocol, check **Yes** even if the recipient does not receive the planned subsequent HCT. The word "planned" should not be interpreted as: if the recipient relapses, then the "plan" is to perform a subsequent HCT.

Question 23: Specify subsequent HCT planned

Indicate whether the planned subsequent HCT is **Autologous** or **Allogeneic**.

Question 24: Has the recipient ever had a prior HCT?

Include all HCTs in the recipient's history, even if the transplants were not performed at your center. The intent is to capture the full picture of the recipient's treatment / transplant history.

If the recipient never had a prior HCT, report **No**.

Question 25: Specify the number of prior HCTs

Enter the number of prior HCTs for the recipient. An HCT event is defined as an infusion of mobilized peripheral blood stem cells (PBSC), bone marrow, or cord blood. For more information on how to distinguish infusion types [example: HCT versus donor cellular infusion (DCI)], see Appendix D.

For recipients who have received a previous HCT (prior to the HCT for which this form is being completed), the following are examples of how to calculate the number of prior HCTs.

Example 1: A recipient was previously transplanted under a protocol that included an infusion of cells over multiple days: day 0, day +1 and day +2. This series of infusions is considered one HCT event (as opposed to three HCT events) and should be counted as *HCT Event #1*.

After receiving the infusion, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent HCT including a preparative regimen. This HCT is *HCT Event #2*. One prior HCT should be reported.

Example 2: A recipient previously received an allogeneic HCT (*HCT Event #1*). Then, due to delayed neutrophil recovery, the recipient received additional cryopreserved allogeneic mobilized PBSC from the original donor, without a preparative regimen (i.e., "boost" – *HCT Event #2*).

After receiving the boost, the recipient had relapse of disease. The recipient is scheduled to receive a subsequent allogeneic HCT with preparative regimen (HCT Event #3). Two prior HCTs should be reported.

Example 3: A recipient previously received an autologous HCT (*HCT Event #1*). Then due to delayed neutrophil recovery, the recipient received additional cryopreserved autologous cells without a preparative regimen (i.e., "boost" which is not counted as an HCT event because the intent of the autologous infusion is to treat the graft failure).

The boost is successful, but a few years later the recipient develops a new malignancy. The recipient is scheduled to receive a subsequent autologous HCT with preparative regimen (*HCT Event #2*). One prior HCT should be reported.

If the allogeneic recipient receives an infusion due to poor graft response, count the infusion as a subsequent HCT. The exception to this is "autologous rescue." Autologous rescue **should not be** counted as a separate HCT and the data collection forms will not start over (i.e., the forms will continue from the previous HCT).

Prior HCTs reported to the CIBMTR
If **Unknown** is selected for *Were all prior HCTs reported to the CIBMTR, Date of prior HCT, Was the prior HCT performed at a different institution, Specify the institution that performed the last HCT, and What was the HPC source for the prior HCT* questions can still be answered to report information regarding prior HCTs; however, these questions are not required to be completed.

Question 26: Were all prior HCTs reported to the CIBMTR?

This should include any / all HCTs not performed at your center. If the recipient is a transfer patient, you will be able to see all past HCT dates in the Recipient Information Grid in FormsNet3^{SM}. Contact CIBMTR Customer Support if there are questions.

If **Yes** or **Unknown**, continue with *Reason for current HCT*.

Reporting Prior HCTs
FormsNet3^{SM} application: Complete the *Date of prior HCT, Was the prior HCT performed at a different institution, Specify the institution that performed the last HCT*, and *What was the HPC source for the prior HCT* questions to report all prior HCTs that have not yet been reported to the CIBMTR by adding an additional instance in the FormsNet3SM application.
Paper form submission: Copy the *Date of prior HCT, Was the prior HCT performed at a different institution, Specify the institution that performed the last HCT*, and *What was the HPC source for the prior HCT* questions and complete for the prior HCT that has not yet been reported to the CIBMTR.

Question 27: Date of prior HCT

Report the date (YYYY-MM-DD) of the prior HCT being reported in this instance. If the exact date is unknown and must be estimated, check the **Date estimated** box.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 28: Was the prior HCT performed at a different institution?

Indicate if the prior HCT being reported in this instance was performed at another institution. If the prior HCT was not performed at a different institution, select **No**.

Question 29: Specify the institution that performed the HCT

Report the name, city, state, and country of the institution where the recipient's prior HCT being reported in this instance was performed. These data are used to identify and link the recipient's existence in the database and, if necessary, obtain data from the other institution where the previous infusion was administered

Question 30: What was the HPC source for the prior HCT? (check all that apply)

Report the cell source(s) for the prior HCT being reported in this instance.

An **Autologous** product has cells collected from the recipient for his / her own use.

An unrelated donor (**Allogeneic, unrelated**) is a donor who shares no known ancestry with the recipients. Include adoptive parents / children or stepparents / children.

A related donor (**Allogeneic, related**) is a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-sibling, etc.

Questions 31 – 35: Reason for current HCT

Indicate the reason for the current HCT (check only one). If this was a subsequent transplant, verify that this answer is consistent with the reason for the subsequent transplant reported on the previous series of report forms.

- **Graft failure / insufficient hematopoietic recovery:** Additional stem cells are required because there wasn't any ANC recovery following HCT (primary graft failure), the hematopoietic recovery indefinitely declined after the initial hematopoietic recovery (secondary graft failure), or hematopoietic recovery was deemed insufficient or too slow for survival following previous high-dose therapy and HCT. If the reason is graft failure after initial recovery or insufficient hematopoietic recovery, also report the date of graft failure / rejection.
    - If autologous cells are infused for this reason, this is considered an autologous rescue; in this case, reporting will continue under the prior HCT date and a new Pre-TED form is not required.
    - If allogeneic cells are infused, this would be considered a subsequent HCT, and a new Pre-TED is required, and reporting would start over.
- **Persistent primary disease:** Additional stem cells are required because of the persistent presence of disease pre- and post-transplant (i.e., complete remission was never achieved following the previous

transplant).

- **Recurrent primary disease:** Additional stem cells are required because of relapse primary disease (i.e., complete remission was achieved pre- or post-transplant, but the disease relapsed following the previous transplant). If the reason is recurrent primary disease, continue with *Date of relapse* and report the relapse date. If multiple relapses have occurred since the previous infusion, report the date of the most recent relapse.
- **Planned subsequent HCT, per protocol:** Additional stem cells are given as defined by the protocol for a subsequent transplant/infusion. This includes all planned subsequent transplants (including triple or quadruple transplants). This transplant is not based upon recovery, disease status, or any other assessment.
- **New malignancy (including PTLD and EBV lymphoma):** Additional stem cells are required because the recipient has developed a new malignancy. This does not include a transformation or progression of the original malignancy for which the recipient was transplanted. If the reason is a new malignancy, continue with *Date of secondary malignancy* and report the diagnosis date of the new malignancy. In addition, attach a copy of the pathology report using the "Add Attachment" feature in FormsNet3^{SM}. Ensure that the date of diagnosis for the new malignancy matches the date of diagnosis for the new malignancy reported on the previous transplant's appropriate follow-up form.
- **Insufficient chimerism:** In the case of a stable, mixed donor chimerism, the infusion of additional cells (usually lymphocytes and not mobilized stem cells) is typically classified as a DCI. Verify with the transplant physician that the cells given should be reported as a subsequent transplant and that stable, mixed chimerism is the reason for the transplant. However, in the case of declining chimerism – when the percentage of donor cells is sequentially decreasing on several studies, indicating possible impending graft failure – additional stem cells are required. Usually, the donor chimerism has fallen below 30-50%.
- **Other:** If additional stem cells are given for a reason other than the options listed, select **Other** and specify in *Specify other reason*.

Question 36: Has the recipient ever had a prior cellular therapy? (do not include DLIs)

Include all cellular therapy infusions, except DLIs, in the recipient's history, even if the infusions were not performed at your center. The intent is to capture the full picture of the recipient's treatment history.

> **Prior cellular therapy reported to the CIBMTR**
> If **Unknown** is selected for *Were all prior cellular therapies reported to the CIBMTR, Date of the prior cellular therapy, Was the cellular therapy performed at a different institution, Specify the institution that performed the cellular therapy*, and *Specify the source(s) for the prior cellular therapy* questions can be answered to report information regarding prior cellular therapies; however, these questions are not required to be completed.

Question 37: Were all prior cellular therapies reported to the CIBMTR?

This should include all cellular therapy infusions (except for DLIs) not performed at your center. If the recipient is a transfer patient, you will be able to see all past infusion dates in the Recipient Information Grid

in FormsNet3^{SM}. Contact the CIBMTR Customer Support if there are questions.

If **Yes**, all prior cellular therapies were reported to the CIBMTR or **Unknown**, continue with the Donor Information section.

Reporting Multiple Prior Cellular Therapies

FormsNet3^{SM} application: Complete the *Date of the prior cellular therapy, Was the cellular therapy performed at a different institution, Specify the institution that performed the cellular therapy*, and *Specify the source(s) for the prior cellular therapy* questions to report all prior cellular therapies that have not yet been reported to the CIBMTR by adding an additional instance in the FormsNet3SM application.

Paper form submission: Copy the *Date of the prior cellular therapy, Was the cellular therapy performed at a different institution, Specify the institution that performed the cellular therapy*, and *Specify the source(s) for the prior cellular therapy* questions and complete for prior cellular therapy that has not yet been reported to the CIBMTR

Question 38: Date of the prior cellular therapy

Report the date (YYYY-MM-DD) of the prior cellular therapy being reported in this instance.

For information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 39: Was the cellular therapy performed at a different institution?

Indicate if the prior cellular therapy being reported in this instance was performed at another institution. If the prior cellular therapy was not performed at a different institution, select **No**.

Question 40: Specify the institution that performed the cellular therapy

Report the name, city, state, and country of the institution where the recipient's prior cellular therapy being reported in this instance was performed. These data are used to identify and link the recipient's existence in the database and, if necessary, obtain data from the other institution where the previous treatment was administered.

Question 41: Specify the source(s) for the prior cellular therapy (check all that apply)

Indicate the cell source(s) for the prior cellular therapy being reported in this instance. If the product is "off the self" or a "third party donor" product obtained from pharmaceutical companies or other corporate entities, donor type should still be identified.

An **Autologous** product has cells collected from the recipient for his / her own use.

An unrelated donor (**Allogeneic, unrelated**) is a donor who shares no known ancestry with the recipient. Include adoptive parents / children or stepparents / children.

A related donor (**Allogeneic, related**) is a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q31 – 35	7/19/ 2023	Modify	Updated instructions on what relapse date to report when the reason for subsequent HCT is recurrent primary disease: ***Recurrent primary disease:*** *Additional stem cells are required because of relapse primary disease (i.e., complete remission was achieved pre- or post-transplant, but the disease relapsed following the previous transplant). If the reason is recurrent primary disease, continue with Date of relapse and report the relapse date. If multiple relapses have occurred since the previous infusion, report the date of the most recent relapse. ~~Ensure that the date of recurrent primary disease matches the relapse/progression date reported on the previous transplant's appropriate follow-up form.~~*	Updated for consistency / accuracy

Last modified: Jul 19, 2023

Q42 – 80: Donor Information

Orca Bio Products and Donor Information
Refer to the Orca Bio Reporting Guide, located on the CIBMTR Portal, to determine how to report donor information for Orca Bio products.

Omidubicel Product
If the product is Omidubicel, select **No** for multiple donors.

Question 42: Multiple donors?

Indicate if cells from multiple different donors (multiple CBUs, combinations of other products from different donors) are to be used for this HCT.

For example, supplemental infusions should be included when determining if multiple donors were used for this HCT event. An infusion of supplemental cells is often given in conjunction with a preparative regimen for HCT. A supplemental infusion is defined as an infusion of cells given prior to clinical day 0 (of an HCT) for any reason other than to produce engraftment

For more information on supplemental infusions, see Appendix D.

If multiple donors were not used, select **No**.

Question 43: Specify number of donors

Report the number of donors used for this HCT. Note that this value should never be “1,” since multiple donors were reported in the prior question.

Reporting More Than One Donor
FormsNet3^{SM} application: Complete the donor specific question (questions 44 – 80) to report all prior cellular therapies that have not yet been reported to the CIBMTR by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy the donor specific question (questions 44 – 80) and complete for prior cellular therapy that has not yet been reported to the CIBMTR

Question 44: Specify donor

Indicate the donor type for this product .

An **Autologous** product has cells collected from the recipient for his / her own use.

An unrelated donor (**Allogeneic, unrelated**) is a donor who shares no known ancestry with the recipient. Include adoptive parents / children or stepparents / children.

A related donor (**Allogeneic, related**) is a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

Omidubicel Product
If the product is Omidubicel, report the product type as **CBU**.

Questions 45 – 46: Specify product type (check all that apply)

Select from the list of product type(s) for the donor being reported in this instance.

Specify Product Type
Previous CIBMTR forms required two instances to be entered in the donor section when a single donor donated multiple products. **This is no longer required**. Report all product collected from a single donor in the same instance of the donor section.

If **Other product** is indicated, specify the product type. If your center has a protocol where using “other products” is common, consistently report the same text in the specify field so that the “like” products can be grouped together. Do not report the cell type (i.e., CD3+ cells), report the product type.

Omidubicel Product
If the product is Omidubicel, report **No**, the product was not genetically modified.

Question 47: Is the product genetically modified?

Genetically modified products include any product where the cells are manipulated via either:

- Gene transfer: a process by which copies of a gene are inserted into living cells in order to induce synthesis of the gene’s product; or
- Transduction: a process by which foreign DNA is introduced into a cell by a virus or viral vector

These techniques alter its gene expression through the insertion of different genes or editing of genes. If more than one product is being infused, indicate if any of the products are genetically modified.

If the infusion is a gene therapy, select **Yes**.

Continue with *Specify the related donor type* if the donor type is a related donor (allogeneic, related).

Continue with *Specify unrelated donor type* if the donor type is an unrelated donor (allogeneic, unrelated).

Continue with *Specify number of products infused from this donor* if the donor type is autologous.

Question 48: Specify the related donor type

Indicate the relationship and match between the recipient and the related donor being reported in this instance. When determining the donor's match / mismatched relationship to the recipient, only consider HLA-A, B, C, and DRB1.

Syngeneic:
Includes: Monozygotic (identical) twins. Occurs when a single egg is fertilized to form one zygote, which then divides into two separate embryos.
Does not include: Other types of twins or HLA-identical siblings (see below).

Continue with *Did NMDP facilitate the procurement, collection, or transportation of the product*.

HLA-identical sibling:
Includes: Non-monozygotic (dizygotic, fraternal, non-identical) twins. Occurs when two eggs are fertilized by two different sperm cells at the same time. This category also includes siblings who aren't twins but have identical HLA types. The recipient and donor with be allele level matched at HLA-A, B, C, and DRB1.
Does not include: Half-siblings (report as **HLA-matched other relatives** if their HLA typing is a match, or **HLA-mismatched relative** if it does not match).

Continue with *Did NMDP facilitate the procurement, collection, or transportation of the product*.

HLA-matched other relative:
Includes: All blood-related relatives, other than siblings, who are HLA matched (e.g., parents, aunts, uncles, children, cousins, half-siblings). The recipient and donor will be allele level matched HLA-A, B, C, and DRB1.
Does not include: Adoptive parents / children or stepparents / children who are HLA matched.

Continue with *Specify the biological relationship of the donor to the recipient*.

HLA-mismatched relative:
Includes: Siblings who are not HLA-identical and all other blood-related relatives who have at least one HLA mismatch (mismatch can be at the antigen or allele level) (e.g., parents, aunts, uncles, children, cousins, half-siblings). The recipient and donor will be antigen or allele level mismatched at 1 or more loci (HLA-A, B, C, or DRB1).
Does not include: Adoptive parents / children or stepparents / children.

This is the option that should be used for haploidentical transplants.

Continue with *Specify the biological relationship of the donor to the recipient*.

Questions 49 – 50: Specify the biological relationship of the donor to the recipient

Indicate the relationship between the recipient and the related donor being reported in this instance. If the

donor is **Other biological relative**, specify the donor's relationship to the recipient.

Question 51: Degree of mismatch (related donors only)

If the donor being reported in this instance is an HLA-mismatched relative, indicate the degree of mismatch as either **HLA-mismatched 1 allele** or **HLA-mismatched ≥ 2 alleles (does include haploidentical donor)**.

Haploidentical means that one half of the HLA type matches the recipient. This type of HLA mismatch is common between blood-related parents and children. When determining the donor's matched/mismatched relationship to the recipient, only consider HLA-A, B, C and DRB1.

Question 52: Specify unrelated donor type

Indicate the unrelated donor type. When determining the donor's match/mismatched relationship to the recipient, only consider HLA-A, B, C, and DRB1.

Question 53: Did NMDP / Be The Match facilitate the procurement, collection, or transportation of the product?

Determine if the NMDP (previously known as NMDP or Be The Match) facilitated the procurement, collection, and / or transportation of the product (i.e., the product from the donor being reported in this instance is an NMDP product or a non-NMDP product). Examples of non-NMDP donor registries include but are not limited to St. Louis Cord Blood Bank, Anthony Nolan, and StemCyte International Cord Blood Center. This information is included on the product label, the paperwork accompanying the product, and within the NMDP search/product documentation.

If the documentation is unclear if NMDP facilitated the procurement, collection, and / or transportation of the product, seek clarification from the transplant coordinator.

If the recipient received a product facilitated by NMDP select **Yes** and then either report the NMDP cord blood unit ID or the GRID. Additionally, ensure the NMDP RID is reported on the CRID Assignment (2804) Form. For products facilitated by NMDP, the Registry or UCB Bank ID question will be disabled, and the Infectious Disease Markers (2004) and HLA Typing (2005) forms will not come due.

Below is a list of donor registries who were once "non-NMDP" registries but may now be an "NMDP-facilitated" registry:

- Matchis Foundation 71 (Netherlands)
- Hadassah Medical Organization 72 (Israel)
- Knochenmarkspenderzentrale – Dusseldorf 114 (Germany)
- The Tobias Registry of Swedish Bone Marrow Donors 119 (Sweden)
- The Norwegian Bone Marrow Donor Registry 120 (Norway)
- Welsh Bone Marrow Donor Registry 131 (Wales)
- British Bone Marrow Registry 134 (United Kingdom)
- Anthony Nolan 135 (United Kingdom)

- ZKRD 136 (Germany)

Question 54: Was this donor used for any prior HCTs? (for this recipient)

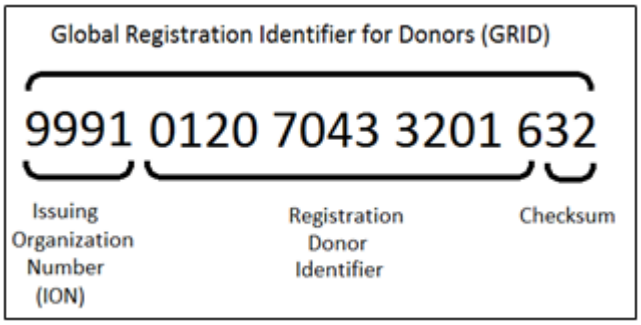
Indicate if the current donor for this HCT was used for any prior HCTs for this recipient. If this is the recipient's first HCT, select **No**.

If this is an autologous infusion, select **No**.

Question 55: Global Registration Identifier for Donors (GRID)

The Global Registration Identifier for Donors (GRID) was developed by the WMDA to ensure secure, reliable and unambiguous assignment of donors. The GRID standard is a 19-character donor identifier composed of three elements: Issuing Organization Number (ION), Registration Donor Identifier, and Checksum (shown below). This standard will ensure each donor ID is globally unique and will reduce the risk of misidentification of donors or their donations.

GRID
The GRID has its own section on the Pre-TED (2400) form. Therefore, only the 19-character donor identifier needs to be reported. This is essential for proper donor linking and, if done incorrectly, will result in queries being placed on the form.



https://www.wmda.info/professionals/optimising-search-match-connect/why-global-identifier/

GRIDs from DKMS
If you are receiving a GRID from the DKMS registry, the eighth character is being reported as the letter "O" however, this character should be the number "0". When entering a GRID from the DKMS ensure that the eighth character reported is the number "0".

If the product is not NMDP facilitated (PBSC or marrow product), indicate the GRID number and continue with *Registry or UCB Bank ID*.

If the product is NMDP facilitated (PBSC or marrow product), indicate the GRID number and continue with *Donor CMV-antibodies (IgG or Total)*.

NMDP cord blood unit ID

Report the NMDP Donor ID (e.g., 0000-0000-0). This ID is unique for each donor and is assigned by NMDP. This information is included on the product label, the paperwork accompanying the product, and within the NMDP search / product documentation.

Question 57: Registry donor ID (not applicable for related donors)

Report the non-NMDP unrelated donor ID. Examples of non-NMDP donor registries include Australia Bone Marrow Donor Registry and REDOME. This ID may be located on the product label, the paperwork accompanying the product, and registry-specific search / product documentation.

Question 58: Non-NMDP cord blood unit ID (include related and autologous CBUs)

Report the non-NMDP cord blood unit ID. Examples of non-NMDP donor registries include St. Louis Cord Blood Bank and StemCyte International Cord Blood Center. This ID is often located on the product label, the paperwork accompanying the product, and registry-specific search / product documentation.

Note that some cord blood banks can ship their units either through the NMDP or directly to the transplant center. Carefully review the accompanying documentation to determine which is appropriate for your unit. You may wish to consult with your center's Transplant Coordinator, as he or she will have insight as to how the product was acquired.

Question 59: Is the CBU ID also the ISBT DIN number?

Report Yes if the non-NMDP CBU ID is the same as the International Society of Blood Transfusion (ISBT) Donation Identification Number (DIN) and continue with question 61. If the product has an ISBT label on it, the ISBT DIN number is in the upper-left-hand corner and consists of a letter followed by 12 numbers, two sideways numbers, and a letter in a box. Example below:

Please find additional information regarding the ISBT DIN numbers and traceability here. For example, you may see a barcode with an alphanumeric string below it.

If the CBU ID is not the same as the ISBT DIN number, or it is not known, select **No**.

Question 60: Specify the ISBT DIN number:

Report the ISBT DIN number using the letter, 12 digits, 2 sideways numbers, and the letter in the box.

Registry Code(s)
FormsNet3 application: Select the appropriate registry code from the drop down directory.
Paper form submission: Use the CIBMTR Hematopoietic Stem Cell Transplant (HCT)

Infusion (2006) form to determine the registry's appropriate match code. **Enter the match code listed in brackets**.

Question 61: Registry or UCB Bank ID

Specify the registry used to obtain the adult donor or umbilical cord blood unit and continue with question 68. The Bone Marrow Donors Worldwide (BMDW) codes have been adopted to avoid submitting the entire name and address of the donor registry. Some common banks that do not list with BMDW have been added to the FormsNet list, including St Louis Cord Blood Bank (SLCBB) and Viacord (VIAC).

The registry code for NMDP donors is USA1 and for NMDP cord units is U1CB.

If the donor was found through DKMS, report the registry that facilitated the HCT. Some registries may be listed more than once with BMDW (one way for marrow/PBSC products and differently for cord blood products). Ensure that the appropriate code for the product was selected because distribution of data depends on the code.

If the registry code cannot be determined using the BMDW website, select **Other registry**.

Question 62: Specify other Registry or UCB Bank

If the BMDW website does not list a match code for the adult donor registry or cord blood bank, provide the registry's official name in *Specify other Registry or UCB Bank*.

Ensure the registry entered is not already listed in the pull-down list for *Registry or UCB Bank ID* question. For example, NMDP adult donors, NMDP cords, and New York Cord Bank each have their own entries above in the registry or UCB Bank ID drop down menu.

Questions 63 – 64: Donor date of birth

Report if the donor's / infant's date of birth is **Known** or **Unknown**. If the donor's / infant's date of birth is **Known**, report the date of birth (YYYY-MM-DD).

Questions 65 – 66: Donor age

Report if the donor's / infant's age is **Known** or **Unknown**. If the donor's/infant's age is **Known**, report the donor's/infant's age at the time of product collection. Report the age in months if the donor is less than 1 year old, otherwise report the age in years.

Question 67: Donor sex

Indicate the donor's biological sex as **Male** or **Female**. For cord blood units, report the infant's sex.

Question 68: Specify blood type (donor) (non-NMDP allogeneic donors only)

Indicate the donors' blood type as **A**, **B**, **AB**, or **O**. Blood type is an important characteristic in allogeneic

transplant because products may require manipulation to minimize the risk of immune reaction due to incompatibility.

Question 69: Specify Rh factor (donor) (non-NMDP allogeneic donors only)

Indicate the donor's Rh (rhesus) factor. The Rh factor is an important characteristic in allogeneic transplant because product may require manipulation to minimize the risk of immune reaction due to incompatibility.

Question 70: Donor CMV-antibodies (IgG or Total) (Allogeneic HCTs only)

CMV is a common virus that infects 50-80% of adults worldwide and is transmitted from person to person through bodily fluids. The virus that causes CMV is part of the herpes virus family and, like other herpes viruses, CMV may be dormant for a period of time before the virus is activated in the host. CMV infections are usually harmless in a healthy immune system and typically cause only mild symptoms, if any. However, if a person's immune system is seriously weakened (as in an immunosuppressed stem cell recipient) the virus can have serious consequences such as pneumonia, liver failure, and even death.

Most laboratory reports indicate a positive result as *reactive*, and a negative result as *non-reactive*. Occasionally, laboratory reports show a specific antibody titer. In this case, compare the laboratory result to the reported standards to determine if the result was reactive or non-reactive.

If the laboratory reports the results as "inconclusive" or "equivocal," select **Indeterminant**.

If the laboratory reports a CMV IgM antibody only, not total IgG/IgM or CMV IgG antibody; report the result as **Not done**.

If the laboratory reports CMV testing by PCR (DNA detection), report the result as **Not done**. CMV testing by PCR is used to detect the presence of the CMV virus and does not test for prior exposure.

Indicate the test result documented on the laboratory report as either **Reactive**, **Non-reactive**, **Indeterminant**, **Not done**, or **Not applicable (cord blood unit)**.

Question 71: Has the donor signed and IRB / ethics committee (or similar body) approved consent form to donate research blood samples to the NMDP / CIBMTR? (Related donors only)

Indicate if the related donor signed an IRB-approved consent form to donate research blood samples to the CIBMTR. This question should only be answered if this is the recipient's first allogeneic transplant.

Questions 72: Date form signed

Report the date (YYYY-MM-DD) the research sample consent form was signed by the related donor. Do not report the date that the witness or healthcare professional signed the consent form.

Questions 73 – 74: Did the donor submit a research sample to the NMDP / CIBMTR repository? (Related donors only)

There are a select number of transplant centers participating in the Related Sample Repository. If your

center is one of the participating centers, and the donor provided a research sample, select **Yes** and provide the donor's sample ID for the current infusion. The ID number is located on the bar code that is attached to the sample tube.

If the donor did not provide a research sample, select **No**.

Omidubicel Product
If the product is Omidubicel, report the number of products from the donor as **two**.

Question 75: Specify number of products infused from this donor

Report the number of products infused from the donor being reported for this infusion. See below for examples of HCT versus gene therapy products..

HCT
Single Product: CIBMTR defines a single product (i.e., cellular product) as **cells collected from a single donor using the same mobilization cycle and collection method regardless of the number of collection days.**

Example 1 (multiple bags): A G-CSF stimulated donor had two PBSC collections on subsequent days. The products collected over the two days were divided into four bags. Although the product is contained in multiple bags, this collection is considered a single product, as there was no change in mobilization technique or collection method.

Example 2 (change in mobilization): A G-CSF stimulated donor had a PBSC collection, but the cell count was poor. Plerixafor (Mozobil) was added as part of the mobilization and the donor was re-collected the following day. As the change in mobilization occurred during the same mobilization cycle, these collections are considered a single product.

Multiple Products: For the purposes of this manual, the CIBMTR defines multiple products as cells collected using more than one mobilization technique and / or collection method.

Example 3 (multiple collection methods): A G-CSF-stimulated donor had a PBSC collection and the product was cryopreserved. One month later the donor had a marrow collection; both products were infused at the time of transplant. Each collection is considered a separate product because different collection methods were used. The number of products infused from this donor is two.

Example 4 (re-mobilization): A G-CSF-stimulated donor had a PBSC collection, but the cell count was poor. No further collections were attempted and a week later the donor was re-mobilized with G-CSF and a second PBSC collection was performed. Each collection is considered a separate product due to the re-mobilization of the donor.

Example 5 (two different product types): A cord blood unit is infused at the same time as marrow. Each product type is considered a separate product. The number of products infused is two.

Gene therapy
p(. **Example 6 (single product):** a single mobilization event, even when collected over several days

Example 7 (single product): A recipient may require multiple mobilizations, and possibly multiple manufacturing steps, for the final product intended for infusion. It should be considered a single gene therapy product, regardless of how many mobilizations or steps required for manufacturing.

Omidubicel Product
If the product is Omidubicel, report the number of products intended to achieve hematopoietic engraftment as **two** and complete two HCT Product and Infusion (2006) forms.

Question 76: Specify the number of these product intended to achieve hematopoietic engraftment

If infusions of additional cells (not intended to product engraftment) were given as a supplemental infusion either prior to the HCT being reported (i.e., prior to clinical Day 0) or shortly after the HCT being reported, the cells must be reported as a product on the Pre-TED Form (2400) form and on a separate Cellular Therapy Product (4003) form.

If additional cells were infused post-HCT, for any reason other than a subsequent HCT or a supplemental infusion as part of the HCT, they should be reported as cellular therapy on the appropriate follow-up form. Reporting the additional cells (given pre-HCT and not intended to produce engraftment) on the Form 4003 is the only mechanism the CIBMTR has in place to collect this data and ensure that the quality assurance data is reported to the cord blood banks, if applicable.

Report the number of products administered to achieve hematopoietic engraftment.

What agents were used to mobilize the autologous recipient for this HCT: The following mobilization questions are for autologous HCT recipients only. If other than autologous, continue with *Name of product*.

Questions 77 – 78: What agents were used to mobilize the autologous recipient for this HCT? (check all that apply)

Report if any of the following agents listed were used in the mobilization event(s).

- **G-CSF:** granulocyte colony-stimulating factor, filgrastim, Neupogen®
- **Pegylated G-CSF:** pegfilgrastim, Neulasta®
- **Perlixafor:** Mozobil®
- **Combined with chemotherapy:** Systemic therapies used to enhance the stem cell product may include cyclophosphamide or ICE chemotherapy (Ifosfamide, carboplatin, and etoposide) with or without rituximab.
- **Anti-CD20:** rituximab, Rituxan®

- **Other agent**: If an agent was used but not listed above, select Other agent and specify.

Questions 79 – 80: Name of product (gene therapy recipients)

Report the name of the product. If the name is not listed, select **Other name** and specify the gene therapy product name.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
75	4/18/25	Modify	Examples of single vs multiple products have been updated to include gene therapy examples. See added example 6 & 7	The definition of a gene therapy product has been updated
Q42	7/26/ 2024	Add	Orca Bio Products and Donor Information blue box added above Q42: ***Orca Bio Products and Donor Information****: Refer to the Orca Bio Reporting Guide, located on the CIBMTR Portal , to determine how to report donor information for Orca Bio products.*	Orca Bio Reporting Guide now available
Q42	7/26/ 2024	Remove	Omidubicel and Orca-T Products blue box updated above Q42 to clarify instructions are only applicable for Omidubicel: ***Omidubicel ~~and Orca-T~~ Product-s-****: If the product is Omidubicel ~~or Orca-T~~, select **No** for multiple donors.*	Orca Bio Reporting Guide now available
Q42	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q42: ***Omidubicel and Orca-T Products****: If the product is Omidubicel or Orca-T, select **No** for multiple donors.*	Added for product specific reporting
Q45	7/26/ 2024	Remove	Omidubicel and Orca-T Products blue box updated above Q45 to clarify instructions are only applicable for Omidubicel: ***Omidubicel ~~and Orca-T~~ Product-s-****: If the product is Omidubicel, report the product type as **CBU**. ~~If the product is Orca-T, report the product type as **BM**~~.*	Orca Bio Reporting Guide now available
Q45	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q45: ***Omidubicel and Orca-T Products****: If the product is Omidubicel, report the product type as **CBU**. If the product is Orca-T, report the product type as **BM**.*	Added for product specific reporting

Q45	12/4/ 2023	Remove	Removed the Cord Blood Units and Ex-vivo Expansion blue box: ~~***Cord Blood Units and Ex-vivo Expansion*** *~~If the product is a cord blood unit that was ex-vivo expansion was performed, select~~ ***Other product*** *~~and specify 'ex-vivo cord blood unit' along with the method of expansion (examples of expansion methods include, but are not limited to, with Omidubicel, with UM171, or on mesenchymal stem cells).~~*	Due to CIBMTR Cord Blood Quality Reports requirements
Q45	5/1/ 2023	Add	Cord Blood Units and Ex-vivo Expansion blue box added: ***Cord Blood Units and Ex-vivo Expansion*** *If the product is a cord blood unit that was ex-vivo expansion was performed, select* ***Other product*** *and specify 'ex-vivo cord blood unit' along with the method of expansion (examples of expansion methods include, but are not limited to, with Omidubicel, with UM171, or on mesenchymal stem cells.*	Instructions added to explain how to report ex-vivo expansion of CBUs
Q47	7/26/ 2024	Remove	Omidubicel and Orca-T Products blue box updated above Q47 to clarify instructions are only applicable for Omidubicel: ***Omidubicel ~~and Orca-T~~ Product-s-****: If the product is Omidubicel ~~or Orca-T~~, report* ***No****, the product was not genetically modified.*	Orca Bio Reporting Guide now available
Q47	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q47: ***Omidubicel and Orca-T Products****: If the product is Omidubicel or Orca-T, report* ***No****, the product was not genetically modified.*	Added for product specific reporting
Q47	10/25/ 2023	Modify	Navigation instructions updated: *Continue with Specify number of products infused from this donor ~~What agents were used to mobilize the autologous recipient for this HCT~~ if the donor type is autologous.*	Incorrect 'go-to' navigation
Q71	7/25/ 2025	Add	Instructions updated: *Indicate if the related donor signed an IRB-approved consent form to donate research blood samples to the CIBMTR. This question should only be answered if this is the recipient's first allogeneic transplant.*	Update for clarification.
Q73 – 74	7/25/ 2025	Add	Instructions updated: _There are a select number of transplant centers participating in the Related Sample Repository. If your center is one of the participating centers, and the donor provided a research sample, select **Yes** and provide the donor's sample ID for the current infusion. The ID number is located on the bar code that is attached to the sample tube. If the donor did not provide a research sample, select **No**.	Updated for clarification
Q75	4/19/ 2025	Add	Gene therapy examples 6 and 7 added: ***Example 6 (single product):*** *a single mobilization event, even when collected*	Added for product

			over several days ***Example 7 (single product):*** *A recipient may require multiple mobilizations, and possibly multiple manufacturing steps, for the final product intended for infusion. It should be considered a single gene therapy product, regardless of how many mobilizations or steps required for manufacturing.*	specific reporting
Q75	7/26/ 2024	Remove	Omidubicel and Orca-T Products blue box updated above Q75 to clarify instructions are only applicable for Omidubicel: ***Omidubicel and ~~Orca-T~~ Product-s-****: If the product is Omidubicel, report the number of products from the donor as* ***two****.* ~~*If the product is Orca-T, report the number of products from the donor as* ***three****.*~~	Orca Bio Reporting Guide now available
Q75	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q75: ***Omidubicel and Orca-T Products****: If the product is Omidubicel, report the number of products from the donor as* ***two****. If the product is Orca-T, report the number of products from the donor as* ***three****.*	Added for product specific reporting
Q76	7/26/ 2024	Remove	Omidubicel ~~and Orca-T~~ Product-s- blue box added above Q76 to clarify instructions are only applicable for Omidubicel: ***Omidubicel and ~~Orca-T~~ Product-s-****: If the product is Omidubicel, report the number of products intended to achieve hematopoietic engraftment as* ***two*** *and complete two HCT Product and Infusion (2006) forms.* ~~*If the product is Orca-T, report the number of products intended to achieve hematopoietic engraftment as* ***one*** *and complete one HCT Product and Infusion (2006) forms and two Cellular Therapy Product (4003) forms.*~~	Orca Bio Reporting Guide now available
Q76	3/8/ 2024	Add	Omidubicel and Orca-T Products blue box added above Q76: ***Omidubicel and Orca-T Products****: If the product is Omidubicel, report the number of products intended to achieve hematopoietic engraftment as* ***two*** *and complete two HCT Product and Infusion (2006) forms. If the product is Orca-T, report the number of products intended to achieve hematopoietic engraftment as* ***one*** *and complete one HCT Product and Infusion (2006) forms and two Cellular Therapy Product (4003) forms.*	Added for product specific reporting
Q79-80	7/28/ 2023	Add	Instructions updated on how to report product name due to specific products being added to the form: *Report the name of the product. If the name is not listed, select* ***Other name*** *and specify the gene therapy product name.*	Due to Summer 2023 Quarterly Release –

				additional response options added

Last modified: Jul 28, 2025

Q81 – 86: Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Question 81: What scale was used to determine the recipient's functional status?

The CIBMTR uses the Karnofsky / Lansky scale to determine the functional status of the recipient immediately prior to the start of the preparative regimen. The Karnofsky Scale is designed for recipients aged 16 years and older and is not appropriate for children under the age of 16. The Lansky Scale is designed for recipients one year old to less than 16 years old.

If the recipient is less than one year old, leave the *Performance score questions* blank.

Questions 82 – 83: Performance score prior to the start of the preparative regimen

Recipient performance status is a critical data field that has been determined to be essential for all outcome-based studies. The CIBMTR uses the Karnofsky / Lansky scale to determine the functional status of the recipient immediately prior to the start of the preparative regimen. For the purposes of this manual, the term "immediately prior" represents the **pre-HCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen. In cases where the pre-transplant work-up occurs in months prior to transplant (i.e., the pre-transplant workup occurs more than one month prior to transplant), a documented performance score may be submitted ***if*** the recipient does not have a score closer to the start of the preparative regimen, the recipient receives no additional treatment after the date of assessment, and the recipient's status does not clearly decline.

Select the appropriate performance scale, Karnofsky or Lansky, based on the recipient's age. Using this scale, select the score (10-100) that best represents the recipient's activity status immediately prior to the start of the preparative regimen. For an example of the Karnofsky / Lansky scale, see Appendix L.

If a Karnofsky / Lansky score is not documented in the source documentation (e.g., inpatient progress note, physician's clinic note), data management professionals **should not** assign a performance score based on analysis of available documents. Rather, a physician or mid-level health care provider (NPs and PAs) should provide documentation of the performance score. Documentation from an RN who has been trained and authorized to determine performance scores may also be used.

The CIBMTR recognizes that some transplant centers prefer to collect and use the ECOG performance score as opposed to the Karnofsky / Lansky score. Although the ECOG and Karnofsky / Lansky performance score systems are based on similar principles, the scales are not the same. For example, the Karnofsky / Lansky scale is described in 11 categories, whereas the ECOG performance status is reported in six categories. Due to the overlap between the two systems, an ECOG score of "one" can represent either "80" or "90" on the Karnofsky/Lansky scale. For centers that collect only an ECOG performance score, CIBMTR will make the following accommodations when auditing the source data:

- Centers collecting ECOG scores should do so using standard practices to ensure accuracy.
- For the purposes of CIBMTR reporting, conversion of ECOG to Karnofsky / Lansky should follow a

standard and consistent practice. This practice should be clear and reproducible.

For more information regarding converting an EGOG score to a Karnofsky / Lansky score, see Appendix L.

Question 84: Specify blood type (of recipient): (For allogeneic HCTs only)

Indicate the recipient's blood type as **A, B, AB**, or **O**. Blood type is an important characteristic in allogeneic transplant because products may require manipulation to minimize the risk of immune reaction due to incompatibility.

Question 85: Specify Rh factor (of recipient): (For allogeneic HCTs only)

Indicate the recipient's Rh (rhesus) factor. The Rh factor is an important characteristic in allogeneic transplant because products may require manipulation to minimize the risk of immune reaction due to incompatibility.

Question 86: Recipient CMV-antibodies (IgG or Total)

Report the cytomegalovirus (CMV) status of the recipient immediately prior to the start of the preparative regimen. For the purposes of this manual, the term "immediately prior" represents the **pre-HCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen. An exception to this definition would apply to a recipient with a documented history of a "reactive" CMV test result. In this case, the CMV test may not be repeated during the pre-HCT work-up phase. Therefore, a timeframe of greater than one month prior to the start of the preparative regimen is acceptable. In cases where the pre-transplant work-up occurs in months prior to transplant (i.e., the pre-transplant workup occurs more than one month prior to transplant), a CMV assessment may be submitted if the recipient does not have an assessment closer to the start of the preparative regimen.

CMV is a common virus that infects 50-80% of adults worldwide and is transmitted from person to person through bodily fluids. The virus that causes CMV is part of the herpes virus family and, like other herpes viruses, CMV may be dormant for a period of time before the virus is activated in the host. CMV infections are usually harmless in a healthy immune system and typically cause only mild symptoms, if any. However, if a person's immune system is seriously weakened (as in an immunosuppressed stem cell recipient) the virus can have serious consequences such as pneumonia, liver failure, and even death.

Most laboratory reports indicate a positive result as *reactive*, and a negative result as *non-reactive*. Occasionally, laboratory reports show a specific antibody titer. In this case, compare the laboratory result to the reported standards to determine if the result was reactive or non-reactive.

If the laboratory reports a CMV IgM antibody only, not total IgG/IgM or CMV IgG antibody, report the result as **Not done**.

If the laboratory reports the results as "inconclusive" or "equivocal," select **Indeterminant**.

Indicate the test result documented on the laboratory report as either **Reactive**, **Non-reactive**, **Indeterminant**, or **Not done**.

Additional Considerations:

- **Recipients < 6 months:** If the recipient is less than 6 months old, report any positive CMV antibody results as “not done” due to the presence of maternal antibodies. However, in infants greater than 6 months old, positive CMV PCR results indicate a CMV infection and the results may be reported as “reactive.”
- **Exposure to IVIG:** Exposure to IVIG may result in a false positive CMV antibody result. If the recipient has been exposed to IVIG leading up to HCT (within 3-6 months), indicate the CMV antibody results using the following guidelines:
    - If the recipient had a non-reactive CMV antibody result prior to IVIG therapy and then routine CMV PCR results showed no copies of CMV, the CMV antibody may be reported as “non-reactive,” even if the CMV antibody became reactive during IVIG treatment.
    - If CMV PCR results quantified copies of CMV DNA (i.e., was positive) during IVIG treatment, the results may be reported as “reactive.”
    - If the recipient did not have a CMV antibody test prior to the initiation of IVIG, but had a positive antibody test during the IVIG therapy, report “not done.”
    - “Not done” should be reported if no CMV antibody tests were done prior to the initiation of IVIG therapy, even if CMV PCR testing was negative during IVIG treatment (because CMV PCR only detects active infection, not prior exposure).
- **Documented history of “reactive” CMV:** In cases where a recipient has a documented history of a “reactive” CMV test and does not have a history of IVIG or blood transfusions from a CMV positive donor, “reactive” should be reported for the CMV status even if the CMV test is repeated during the pre-HCT work-up phase and is “non-reactive”.
- **CMV testing by PCR:** If the laboratory reports CMV testing by PCR (DNA detection) but no CMV antibody testing is done during the pre-transplant work-up or within one month prior to transplant, report the result as “not done.” CMV testing by PCR is used to detect the presence of the CMV virus and does not test for prior exposure.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Sep 23, 2022

Q87 – 119: Comorbid Conditions

COVID-19 Infection
The COVID-19 infection questions are disabled as of April 2024.

Question 87: Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of the preparative regimen / infusion?

SARS-CoV-2 is a novel virus belonging to the coronavirus (CoV) family that emerged in December 2019. The disease caused by this new CoV is known as COVID-19 (coronavirus disease 2019). The new virus is highly contagious and was officially declared a pandemic in March 2020. Transmission is believed to be from person to person through respiratory droplets from coughing and sneezing. Testing for COVID-19 is generally performed on specimens collected from a nasal swab or sputum sample.

Indicate whether or not the patient has ever had a known COVID-19 (SARS-CoV-2) infection, based on a positive test result, at any time prior to the start of the preparative regimen or infusion (if no preparative regimen was given).

If the patient has had a documented COVID-19 (SARS-CoV-2) infection, report **Yes**.

If the patient has not had a documented COVID-19 (SARS-CoV-2) infection, report **No**.

If this is a subsequent infusion and the documented COVID-19 (SARS-CoV-2) infection was already reported on previous forms, report **No**.

Possible Reporting Scenarios:

An infection **should not** be reported if:

- A recipient has a positive antibody result. They do not have a history of positive COVID diagnostic results (PCR or antigen).
- The recipient was symptomatic and treated, but COVID-19 diagnostic testing was not performed and / or COVID diagnostic testing was performed and negative.

An infection **should** be reported if:

- A recipient has a positive COVID diagnostic result (PCR or antigen). No treatment was given and/or recipient was asymptomatic.

Question 88: Did the patient require hospitalization for management for COVID-19 (SARS-CoV-2) infection?

Report **Yes** if the recipient was admitted to the hospital for management of their COVID-19 (SARS-CoV-2)

infection. This includes any regular hospital or intensive care unit (ICU) admissions. Otherwise, report **No**.

Question 89: Was mechanical ventilation used for COVID-19 (SARS-CoV-2) infection?

The clinical spectrum of COVID-19 varies from asymptomatic or paucisymptomatic forms to clinical conditions characterized by respiratory failure that necessitates mechanical ventilation and support in an intensive care unit (ICU). Mechanical ventilation may impact the recipient's pulmonary function post-infusion. Indicate **Yes** or **No** if the recipient was placed on mechanical ventilation for COVID-19.

> **COVID-19 Vaccine**
> The COVID-19 vaccine questions are disabled as of April 2024.

Question 90: Was a vaccine for COVID-19 (SARS-CoV-2) received?

Indicate if the recipient received a vaccine for COVID-19 (one dose without a planned second dose, first dose with planned second dose, second dose, third dose, and / or booster dose) at any time prior to the start of the preparative regimen / infusion.

If the recipient did not receive a vaccine for COVID-19 or it is not known if the recipient received a vaccine, select **No** or **Unknown**, respectively.

If this is a subsequent infusion and all vaccine doses have already been reported on previous forms, select **No**.

If this is a subsequent infusion and some, but not all vaccine doses have already been reported on previous forms select **Yes** and only report the vaccine doses not previously reported.

> **Reporting Multiple COVID-19 Vaccine Doses**
> **FormsNet3^{SM} application**: Complete the *Specify vaccine type and Select dose(s) received* questions to report all COVID-19 vaccine doses received prior to the start of the preparative regimen / infusion by adding an additional instance in the FormsNet3SM application. A separate instance should be added for each dose.
> **Paper form submission**: Copy the *Specify vaccine type and Select dose(s) received* questions and complete report all COVID-19 vaccine doses received prior to the start of the preparative regimen / infusion. A separate instance should be completed for each dose

Questions 91 – 92: Specify vaccine type

For the reported dose, specify the vaccine brand the recipient received. If the vaccine brand is not listed, select **Other type** and specify. If the vaccine brand is unknown, leave the field blank and override the error as 'unknown.'

Third dose versus Booster dose
To determine between a third dose and a booster dose, seek clinician clarification, as needed, using the guidelines listed below:
Third dose: An additional primary dose required for recipients who did not build enough protection from their primary vaccine series, typically for immunocompromised individuals
Booster dose: Administered to recipients who have enough protection after completing their primary vaccine series but then protection decreases over time
Primary vaccine series:
- Two doses of Pfizer-BioNTech or Moderna
- One dose of Johnson & Johnson's Janssen

Questions 93 – 94: Select dose(s) received

For the reported dose, specify the vaccine dose the recipient received prior to the start of the preparative regimen / infusion and report the date when the dose was received.

Select **One dose (without planned second dose)** if the recipient received a single dose, without the plans of receiving the second dose and report the date of administration.

Select **First dose (with planned second dose)** if the recipient received their first dose, with plans for receiving the second dose and report the date of administration.

Select **Second dose** if this is the recipient's planned second dose of the vaccine and report the date of administration.

Refer to the blue instructional box above for additional information regarding third and booster doses.

If the exact date is not known, use the process described in the General Instructions, Guidelines for Completing Forms and select **Date estimated**.

Question 95: Is there a history of mechanical ventilation (excluding COVID-19 (SARS-CoV-2)?

A history of mechanical ventilation may impact the recipient's pulmonary function post-HCT. Mechanical ventilation is any assisted ventilation on behalf of the recipient. Mechanical ventilation can occur as both an endotracheal tube and ventilator, or as a BIPAP machine with a tight fitting mask in continuous use. The one exception to BIPAP is CPAP used for sleep apnea, which generally involves overnight use only for patients with documented sleep apnea. Therefore, **do not** report a CPAP used for sleep apnea, as it does not have the same implications as other forms of mechanical ventilation.

Indications for mechanical ventilation include, but are not limited to:

- Apnea with respiratory arrest (excludes sleep apnea)
- Acute lung injury
- Vital capacity < 15 mL/kg
- Chronic obstructive pulmonary disease (COPD)

- Clinical deterioration
- Respiratory muscle fatigue
- Obtundation or coma
- Hypotension
- Tachypnea or bradypnea

If the recipient was placed on mechanical ventilation at any time prior to this HCT event (excluding mechanical ventilation during surgery) check **Yes**. If the recipient does not have a history of mechanical ventilation, check **No**.

Question 96: Is there a history of invasive fungal infection?

Fungal infections play a major role in the clinical outcome of transplant recipients. If the recipient has a history of proven, suspected, or documented invasive fungal infection at any time prior to this HCT, check **Yes**. If the recipient has not had a history of a proven, suspected, or documented invasive fungal infection, check **No**. For a subsequent HCT, report any documented significant fungal infections in the recipient's medical history, starting with the preparative regimen of the previous HCT to the time prior to the preparative regimen for the current HCT.

Examples of invasive fungal infections include, but are not limited to invasive aspergillosis, zygomycosis and other molds, invasive candidiasis, cryptococcosis, endemic mycosis, other yeasts, and pneumocystosis.

Non-invasive fungal infections such as thrush and nail fungus should not be reported.

For assistance with reporting fungal infections, consult a transplant physician.

Questions 97 – 98: Glomerular filtration rate (GFR) before start of the preparative regiment (pediatric only)

The glomerular filtration rate (GFR) estimates how much blood passes through the glomeruli each minute and is used to check how well the kidneys are working. Indicate if the GFR is **Known** or **Unknown**. If the GFR is **Known**, indicate the value for this test.

Testing may be performed multiple times within the pre-transplant work-up period; report the most recent laboratory value obtained. Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn *before* any radiation or systemic therapy was administered.

If the GFR is reported as a range, report the average of the range.

If the GFR is reported as either "< X" or "> X," report the value as X – 1 or X + 1, respectively.

If the actual GFR result is not available, an estimated GFR may be reported, using the GFR calculator *or* the GFR may be calculated using either the bedside Schwartz or cystatin C-based equations..

Question 99: Does the recipient have a known complex congenital heart disease? (corrected or uncorrected (excluding simple ASD, VSD, or PDA repair) (pediatric only)

The intent of this question is to determine the pediatric recipient's history of any known complex congenital heart disease (corrected or uncorrected). Exceptions for reporting would be any simple ASD, VSD, or PDA repair. Indicate **Yes** if the recipient has known complex congenital heart disease, or **No** if they do not.

> **Comorbidities**
> Prior to answering *Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)* question, review the list of co-existing disease(s) and/or organ impairments listed in Appendix J.

Question 100: Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)? (Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.)

The criteria for reporting comorbidities is based on Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.

Report **Yes** if the recipient has a documented history and / or current diagnosis of any of the conditions listed in Appendix J: Reporting Comorbidities

Report all comorbidities including those that are considered complications of the primary disease for transplant. See examples below.

- A patient with sickle cell had a stroke prior to HCT, the comorbidity to report would be "cerebrovascular disease".
- A toddler with Hurler Syndrome has cardiomyopathy, cardiac valvular disease and an ejection fraction of 45%, the comorbidities to report would be "cardiac" & "heart valve disease".

The intent of this question is to identify serious pre-existing conditions that may have an effect on the outcome of the HCT. For the purposes of this manual, the term "clinically significant" refers to conditions that are being treated at the time of pre-HCT evaluation or are in the recipient's medical history and could cause complications post-HCT. Conditions listed in the recipient's medical history that have been resolved (e.g., appendectomy), and/or that would not pose a concern during or after the HCT should not be reported.

Additionally, for the purposes of this manual, the term "at the time of patient assessment" is defined as the pre-HCT evaluation period prior to the start of the preparative regimen. If the recipient does not have a documented history of clinically significant disease(s) or organ impairment(s), check **No**.

For information regarding reporting clinically significant co-existing disease or organ impairment, see Appendix J: Reporting Comorbidities.

Question 101: Specify co-existing disease or organ impairments (check all that apply)

Select each clinically significant co-existing disease or organ impairment for this recipient. The definitions for each of the categories are taken from Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.

The physician performing the recipient's pre-HCT evaluation may use the HCT Co-Morbidity Index (HCT-CI) to document co-morbid conditions. For detailed information on what should and shouldn't be reported for each category see Appendix J: Reporting Comorbidities.

Question 102: Was the recipient on dialysis immediately prior to start of preparative regimen?

Indicate if the recipient was dialysis, hemodialysis, or peritoneal dialysis dependent within approximately one month prior to the start of the preparative regimen.

Questions 103 – 105: Specify prior malignancy (check all that apply)

Specify the recipient's prior solid tumor(s) and / or hematologic malignancy(ies).

If **Other skin malignancy** is selected, specify the skin malignancy.

If **Other prior hematologic malignancy** is selected, specify the hematologic malignancy.

If **Other prior solid tumor** is selected, specify the solid tumor.

Laboratory Values Prior to Start of Preparative Regimen
Report the laboratory values prior to the start of the preparative regimen using the results measured within four weeks prior to the start of the preparative regimen. If the assessment was performed multiple times, report the closest value to the start of the preparative regimen. The following are considered biomarkers according to the augmented HCT comorbidity index.

ATG / Campath
If ATG / Campath was given prior to the preparative regimen, use the following guidelines to determine which lab values to report:
- If there are more than two days between when ATG / Campath ended and the drugs listed in the preparative regimen began, report the most recent lab values prior to the drugs listed in the preparative regimen.
- If there are two days or less between when ATG / Campath ended and the drugs listed in the preparative regimen began, report the most recent lab values prior to starting ATG / Campath.

Plasma vs Serum Samples

It is acceptable to report chemistry laboratory results based on plasma sample analysis in instances where serum sample analysis is not conducted or if it is not a standard practice at your center, even if the question text states 'serum.'

Questions 106 – 115: Provide last laboratory values recorded within four weeks prior to the start of the preparative regimen

These questions are intended to determine the clinical status of the recipient prior to the start of the preparative regimen for stem cell transplantation. Testing may be performed multiple times prior to the start of the preparative regimen; report the most recent laboratory value obtained for each specific test. Laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn **before** any radiation or systemic therapy was administered.

For each assessment below, indicate if the result was **Known** or **Unknown** prior to the start of the preparative regimen. Indicate the value for each test. If necessary, convert values so they can be reported in the units of measurement available on the form.

Serum ferritin: Ferritin is a protein that stores, transports, and release iron. Iron is toxic to cells, so it is stored within the ferritin protein for use. Ferritin that is too low might be indicative of iron deficiency related anemia. Ferritin that is too high might be indicative of iron overload. It is tracked for some diseases, such as hemaophagocytic lymphohistiocytosis.

Date Sample Collected: Report the date the sample was collected. This date should be before the date of the start of the preparative regimen; however, laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn before any radiation or systemic therapy was administered.

Upper Limit of Normal for your Institution: Report the upper limit of normal. Normal values may vary by laboratory, so it is important to report the upper limit of normal for each assessment.

Serum albumin: Serum albumin is a protein found in the blood. Levels are most often reported on a chemistry panel but may occasionally be found in a separate liver function test report.

Date Sample Collected: Report the date the sample was collected. This date should be before the date of the start of the preparative regimen; however, laboratory values obtained on the first day of the preparative regimen may be reported as long as the blood was drawn before any radiation or systemic therapy was administered.

Platelets: Platelet are formed elements within the blood that help with coagulation. A low platelet count, call thrombocytopenia, may lead to easy bleed or bruising. Thrombocytopenia may require platelet transfusions. Indicate if the recipient received a platelet transfusion within 7 days prior to testing.

Reporting More Than One Prior Solid Organ Transplant

FormsNet3^{SM} application: Complete *Specify organ and Year of prior solid organ transplant questions* for each solid organ transplant by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy *Specify organ and Year of prior solid organ transplant* questions and complete for each solid organ transplant.

Questions 116 – 118: Did the recipient have a prior solid organ transplant?

Indicate if the recipient had a prior solid organ transplant. If **Yes**, specify the organ transplant.

If **Other organ** is reported, specify the organ.

If the recipient did not receive a prior solid organ transplant or it is not known, report **No**.

Question 119: Year of prior solid organ transplant

If a recipient received a solid organ transplant during the reporting period, report the date of the solid organ transplant.

For more information regarding partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q87	4/19/ 2024	Modify	The Diagnosis of COVID-19 After the Start of the Preparative Regimen blue box removed and the COVID-19 Infection red box added to clarify these questions are now disabled.	Due to disabling of questions with the Spring 2024 release
Q90	4/19/ 2024	Modify	The COVID-19 Vaccine red box updated to clarify these questions are now disabled.	Due to disabling of questions with the Spring 2024 release
Q100	8/28/ 2023	Remove	Removed the Hepatic and Renal Comorbidities blue box from Q100:~~*Hepatic and Renal Comorbidities In addition to the guidelines listed on the Pre-TED form, include the following*~~	All comorbidity information

			~~*time-specific guidelines when reporting hepatic and renal comorbidities*~~ ~~*Hepatic Comorbidity: The assessment of liver function tests (ALT, AST and/or Total Bilirubin) has to include at least 2 values per test on two different days within a period extending between day -24 and the start of the systemic therapy regimen/ lymphodepleting therapy. If no therapy was given, then it would be day -24 and the cellular therapy infusion date. If only a single value was reported in this time period, use the most recent test performed between days -40 & -25 as the second value. When determining the severity of the hepatic comorbidity, the value closest to the start of the systemic therapy regimen/ lymphodepleting therapy should be used. If the liver function test values closest to the start of the preparative regimen do not meet the criteria specified above, a hepatic comorbidity should not be reported.*~~ ~~*Renal (Moderate/Severe) Comorbidity: Serum creatinine > 2 mg/dL or > 177 µmol/L, as detected in at least two lab values on two different days within a period extending between day -24 and the start of the systemic therapy regimen/lymphodepleting therapy. If no systemic therapy was given, then it would be day -24 and the cellular therapy infusion date. If only a single value was reported in this time period, use the most recent test performed between days -40 & -25 as the second value. If the serum creatinine value closest to the start of the systemic therapy regimen/lymphodepleting therapy did not meet the criteria specified above, a renal (moderate/severe) comorbidity should not be reported.*~~	has been consolidated to Appendix J
Q100	8/28/ 2023	Remove	Removed the ‘documented medical history from Q100:‘~~*Documented Medical History*~~ ~~*-Arrhythmia that has required specific antiarrhythmic treatment*~~ ~~*-Cardiac*~~ ~~*-Cerebrovascular disease*~~ ~~*-Inflammatory bowel disease*~~ ~~*-Peptic ulcer*~~ ~~*-Rheumatologic*~~ ~~*-Prior malignancy, requiring treatment*~~ ~~*Current Diagnosis at the Time of Pre-Infusion Evaluation*~~ ~~*-Diabetes*~~ ~~*-Heart valve disease*~~ ~~*-Hepatic, mild*~~ ~~*-Hepatic, moderate/severe*~~ ~~*-Infection*~~	All comorbidity information has been consolidated to Appendix J

			~~-Obesity~~ ~~-Psychiatric disturbance~~ ~~-Pulmonary, moderate~~ ~~-Pulmonary, severe~~ ~~-Renal, moderate/severe~~ ~~2Ejection fraction (EF) ≤ 50% should be reported only if present on most recent test~~ ~~3Excluding asymptomatic mitral valve prolapse~~ ~~4Including any history of hepatitis B or hepatitis C infection~~ ~~5If the PFT lists both a "control" FEV1 and a "post-dilator" FEV1, the "control" FEV1 should be used to determine if a pulmonary comorbidity is present.~~ ~~6Including renal transplantation at any time in the patient's history~~	
Q101	8/28/ 2023	Remove	Removed each specific comorbidity and it's criteria	All comorbidity information has been consolidated to Appendix J
Q106	4/4/ 2024	Add	Plasma vs Serum Samples blue box added	Added for clarification
Q106	2/21/ 2024	Add	ATG / Campath blue box added	Added for clarification

Last modified: Apr 21, 2024

Q120 – 134: Pre-HCT Preparative Regimen (Conditioning)

Question 120: Height at initiation of pre-HCT preparative regimen

Report the recipient's height just prior to the start of the preparative regimen. The intent of this question is to determine the height used when calculating preparative regimen drug doses. This height is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders.

Even if the recipient does not receive a preparative regimen, the height is still required.

Question 121: Actual weight at initiation of pre-HCT preparative regimen

Report the recipient's body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the weight used to calculate the preparative regimen drug doses. This weight may also be the same weight reported on the Recipient Baseline (2000) Form, if applicable. Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight.

Even if the recipient does not receive a preparative regimen, the weight is still required.

> **MIBG Therapy:** MIBG therapy given for recipients with neuroblastoma is no longer considered preparative regimen and should not be reported.

Question 122: Was a pre-HCT preparative regimen prescribed?

Recipients are generally transplanted under a specific protocol that defines the radiation and/or systemic therapy the recipient is intended to receive as a preparative regimen. This protocol, which may be either a research protocol or standard of care protocol, should be referred to when completing this section.

However, there are instances when a preparative regimen is not given. Examples may include, but are not limited to:

- Primary diagnosis of an immune deficiency.
- Subsequent allogeneic HCT due to loss of, or poor, neutrophil engraftment.

If a preparative regimen is prescribed per protocol, check **Yes**. If a preparative regimen is not prescribed, check **No**.

For more information regarding the recipient's preparative regimen, consult a transplant physician or contact CIBMTR Center Support.

Question 123: Classify the recipient's prescribed preparative regimen

Myeloablative pre-transplant conditioning destroys bone marrow cells using high-dose radiation and/or systemic therapy. It is used to eliminate the recipient's immune system and to leave space in the bone marrow niche for the donated cells. A myeloablative regimen is sometimes used for recipients with non-malignant diseases who require HCT for marrow reconstitution (i.e., immunodeficiencies) or to produce a complete donor chimerism.

Non-myeloablative stem cell transplant (**NMA** or **NST**) and reduced-intensity conditioning (**RIC**) preparative regimens generally use lower doses of radiation and/or systemic therapy to prevent graft rejection and to suppress the recipient's hematopoietic immune system, but not eliminate it completely. Non-myeloablative protocols rely on the immune cells of the donor to destroy the disease (called graft versus tumor or GVT effect), and typically produces mixed chimerism. NST is a common treatment option for recipients who are older or who have other health problems, as the lower radiation and/or systemic therapy doses are easier for the recipient to tolerate.

In general, RIC includes any regimen that does not meet the criteria for either myeloablative or non-myeloablative regimens.

The determination of the intent of the regimen should be based on the center's protocol or the opinion of the physician overseeing the care of the recipient. However, if the intent is not specified, the regimen intensity may be reported based on the CIBMTR operational guidelines below.

Table 1. Examples of Myeloablative, Reduced Intensity, and Non-Myeloablative Regimens

Myeloablative Regimens	Reduced Intensity and Non-Myeloablative Regimens
• TBI > 500 cGy (single) or > 800 cGy (fractionated) • Cyclophosphamide + TBI (> 500 cGy (single) or > 800 cGy (fractionated)) • Cyclophosphamide + Etoposide + TBI (> 500 cGy (single) or > 800 cGy (fractionated)) • Busulfan > 7.2 mg/kg IV or >9.0mg/kg orally • Busulfan >300 mg/m2 IV or >375 mg/m^2 orally • Busulfan (> 7.2 mg/kg IV or >9.0mg/kg orally) + Cyclophosphamide • Busulfan (>7.2 mg/kg IV or >9.0 mg/kg orally) + Melphalan >150 mg/m^2 • Melphalan >150 mg/m^2 • Thiotepa ≥ 10 mg/kg • Treosulfan > 30,000 mg/m^2 or > 30 g/m^2	• TBI ≤ 500 cGy (single) or ≤ 800 cGy (fractionated) • ATG + Cyclophosphamide • BEAM (Carmustine [BCNU], Etoposide, Cytarabine [Ara-C], Melphalan) • Busulfan ≤ 7.2 mg/kg IV or ≤ 9.0mg/kg orally • Busulfan ≤ 300 mg/m^2 IV or ≤ 375 mg/m^2 orally • Melphalan ≤ 150 mg/m^2 • Fludarabine + Cytarabine • Fludarabine + Cyclophosphamide • Fludarabine + TBI ≤ 500 cGy (single) or ≤ 800 cGy (fractionated) • Thiotepa < 10 mg/kg • Treosulfan ≤ 30,000 mg/m^2 or ≤ 30 g/m^2 • Etoposide + Cyclophosphamide

> **Preparative Regimen – Intensity**
> These values represent the total prescribed doses. For example, if a recipient is scheduled to receive Melphalan 100 mg/m^2 for two days (200 mg/m^2), the regimen would be myeloablative because the total prescribed dose is > 150 mg/m^2.

Indicate whether the intent of the preparative regimen was **Myeloablative** (to produce marrow ablation or pancytopenia), **Non-myeloablative**, or **Reduced intensity**.

Question 124: Was irradiation planned as part of the pre-HCT preparative regimen?

If irradiation is planned as part of the preparative regimen, check **Yes**. If irradiation is not planned, check **No**.

Irradiation performed as previous treatment should not be reported in this section. Report irradiation performed as previous treatment on the appropriate Disease Specific Form. Additionally, “radiation boosts,” often given to smaller sites that may have residual malignant cells or to areas that were shielded (i.e., chest wall or lung), should not be reported in this section. Report irradiation boosts administered on the applicable Recipient Baseline Data (2000) Form.

Question 125: What was the prescribed radiation field?

Indicate if the planned irradiation was to **Total body**, **Total body by intensity-modulated radiation therapy (IMRT)**, **Total lymphoid or nodal regions**, or **Thoracoabdominal region**.

Question 126: Total prescribed dose

Enter the total dose of radiation prescribed. If radiation was prescribed as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was prescribed in fractionated doses, multiply the dose per fraction by the total number of fractions to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy).

Example:
Radiation Order: TBI, 200 cGy/day for three days (3 doses)
Total dose: 200 cGy x 3 doses = 600 cGy
Report “Total Dose” as: 600 cGy

Question 127: Date started

Enter the date the single dose or first fraction of radiation was administered.

Question 128: Was the radiation fractionated?

Radiation is either delivered as a single dose or in several treatments (fractions). Radiation is fractionated to increase the loss of diseased cells, as they do not recover as quickly as disease-free cells.

Indicate if the radiation was fractionated. If the radiation was not fractionated, check **No**.

Question 129: Total number of fractions

Enter the total number of fractions (treatments) of radiation that were administered. The recipient may receive more than one fraction per day (hyperfractionation).

The total number of fractions multiplied by the dose per fraction must be equal to the total dose reported above.

Reporting Multiple Drugs for Preparative Regimen
FormsNet3^{SM} application: Complete the drug-specific preparative regimen questions for each drug given as part of the preparative regimen by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy the drug-specific preparative regimen questions and complete for each drug given as part of the preparative regimen.

Questions 130 – 131: Drug

Preparative Regimen – Drugs
The following questions report the **prescribed** drug therapy that was part of the preparative regimen. Do not report the dose that was actually given. If the recipient has comprehensive report forms due, the actual dose given will be reported on the Recipient Baseline Form (Form 2000). **Do not include drugs that are intended to offset the side effects of the chemotherapy** (e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).

Drugs After Transplant
Occasionally, protocols list drugs that may be given before and after transplant. If the drugs are planned to be given before and after transplant, only the doses given before transplant should be quantified in the preparative regimen section. The doses given after transplant should be reported in the **Post-HCT Disease Therapy Planned as of Day 0** or **GVHD Prophylaxis** section. For example, if bortezomib or rituximab is planned to be given on Days -2, +1, +4, and +7, report the Day -2 dose in the preparative regimen section, and the post-transplant doses as planned post-HCT therapy.

Drugs during the Peri-Transplant Period
ATG, alemtuzumab (Campath), defibrotide, KGF, and ursodiol may be given during the peri-transplant period. Previously, if these drugs were administered prior to Day 0, they were reported in the preparative regimen section of the Pre-TED (2400) Form. However, the Pre-TED (2400) Form has been updated – if these drugs were administered prior to Day 0, report them in the Additional Drugs Given in the Peri-Transplant Period section, not in the Pre-HCT Preparative Regimen (Conditioning) section.

The form lists each drug by the generic name. The following website provides the trade names under which generic drugs are manufactured: http://www.rxlist.com/script/main/hp.asp.

The **Other drug** category should be used only if the drug is not one of the listed options. If an "other" drug is prescribed, list the name of the drug. Include any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease within 21 days prior to the start of the preparative regimen. Do not report additional sites of radiation (e.g., cranial boost) in the "other" drug category. If the recipient is assigned to the Comprehensive Report Forms by the form selection algorithm, the additional sites of radiation will be reported on the Recipient Baseline Form (Form 2000). If the recipient is assigned to TED Forms by the form track selection algorithm, the additional sites of radiation will not be reported.

If the Pre-TED is being completed for a subsequent HCT, do not report therapy that was given to treat the recipient's disease (between the previous and current planned HCTs) in the preparative regimen section.

If there is a change to the chemotherapy preparative regimen (e.g., from busulfan + fludarabine to melphalan + fludarabine) after the Form 2400 has been submitted, return to the Pre-TED (2400) form and make this correction directly in FormsNet3^{SM} to ensure that the chemotherapy reported reflects the actual chemotherapy regimen given.

Question 132: Total prescribed dose

Report the ***total*** **dose** of each drug as **prescribed** in the preparative regimen section of the HCT protocol. **Do not report the prescribed *daily* dose**. Report the drug doses to the nearest tenth. For paper submission, do not modify the number of boxes or include decimal values. The pharmacy record or Medication Administration Record (MAR) should be used for determining the date the drug was started.

Report the dose units as either "mg/m^2," "mg/kg," "AUC (mg x h/L)," "AUC (µmol x min/L)," or "CSS (ng/mL)." If the total prescribed dose is reported in a unit other than those listed, convert the dose to the appropriate unit. See the example below or consult with a transplant pharmacist for the appropriate conversion. If drug doses cannot be converted to the unit listed (e.g., Campath), leave the unit field blank, override the error (using "unable to answer"), and attach a copy of the source document to the Pre-TED using the attachment feature in FormsNet3.

Calculating Total Drug Doses
Drug doses are calculated either by recipient weight in kilograms (kg) or recipient body surface area (BSA) in m^2. The HCT protocol will specify "x mg/kg" or "x mg/m^2" and the total number of doses to be administered.
For example, if the protocol requires cyclophosphamide at 60 mg/kg x 2 days (i.e., 2 doses), the "total prescribed dose" should be reported as "120 mg/kg."

Pharmacokinetic testing can be used to determine whether the drug concentration in the bloodstream is appropriate to the dose given. This reflects the speed of absorption and elimination of the drug. These tests are usually performed using the first dose of systemic therapy, or a test dose, where multiple samples are

drawn at specific time points following the first dose. The samples are sent to a laboratory that performs the testing to determine the drug concentration. If carboplatin was prescribed, indicate if pharmacokinetic testing was performed to determine the preparative regimen dosing. If it is not known whether or not this testing was performed, consult a transplant physician.

A common example of this situation occurs in the use of busulfan. When pharmacokinetic (pK) testing is performed, the ordered busulfan dose can be calculated from either the *AUC dose* or *daily AUC*. If an *AUC dose* is documented, this can be multiplied by the number of ordered doses in order to calculate the ordered busulfan dose. When a *daily AUC* is documented, this can be multiplied by the number of days in order to calculate the ordered busulfan dose. See the example below for more information.

Example – Calculating the ordered dose of Busulfan using *AUC dose*: The AUC dose in the example below is 2842 uMol x Min, which was prescribed for a total of 5 doses. The total ordered dose of Busulfan in this scenario should be reported as 14,210 uMol x Min.

Description	Result	Units
Area Under the Curve(AUC)	2842 for Dose #1	uMol x Min
AUC Target	Cumulative 21924	uMol x Min
AUC Estimated Average Exposure	[See comments]	uMol x Min
Clearance Rate	5.45	ml/min/kg
Recommended Dosing Type	Q24	
Dose recommended starts at dose #	2	
Dose recommended ends at dose #	5 [See comments]	

In some cases, a “test dose” of the drug is given before the actual preparative regimen is started, and this dose is used for acquiring drug levels that are used to adjust the dose that will be used in the preparative regimen. In other situations, the first dose of the drug is given in the usual fashion as part of the preparative regimen. After this first dose, serum drug levels are drawn and sent to a reference lab. The drug is continued at the starting dose until the lab results are reported and adjustment is made to later doses.

When a drug is used for the preparative regimen where pharmacokinetics will be tested, it is important to distinguish whether the testing will be done with a “test dose” before beginning the preparative regimen or using the first dose of the preparative regimen. The reporting of the dosing for the CIBMTR forms depends upon this distinction. This helps distinguish whether the dose is part of the therapeutic regimen, or not.

1. A test dose was given **> 24 hours** prior to the intended therapeutic dosing.
    - **Example:** A patient with AML underwent allogeneic HCT from a sibling; busulfan and cyclophosphamide were used as the preparative regimen. The patient presented to clinic 9 days before the HCT, where a dose of busulfan at 0.5 mg/kg was given intravenously. Blood samples were drawn for the next 6 hours, after which the patient left the clinic. His samples were sent to a lab, results were returned the next day, and an adjusted dose of busulfan was calculated. He returned to the hospital 6 days before HCT, and began to receive busulfan at the adjusted dose intravenously for 4 days, followed by cyclophosphamide, and proceeded to receive his cells. Since he received 0.5 mg/kg as a “test dose,” this would not be reported in his total preparative regimen dose.

If a test dose was given, where the dose was distinct from the therapeutic dosing preparative regimen (often 1-2 or more days prior to the initiation of regular dosing), the following should be reported:

- On the Pre-TED (2400) form, the total prescribed dose per protocol would NOT include the test dose.
- On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first therapeutic dose was administered. The actual dose received would NOT include the test dose.

2. The first dose of therapeutic dosing is used for monitoring.
   - **Example:** A patient with MDS received an allogeneic HCT from an unrelated donor; busulfan and fludarabine were used as the preparative regimen. She was admitted to the hospital 7 days before her HCT, and received a dose of busulfan at 0.8 mg/kg IV at 6:00 AM. Serum samples were drawn every 30 minutes until the next dose of Busulfan at 0.8 mg/kg IV was given at 12:00 noon. Her blood was sent to a reference lab, and she continued to receive busulfan every 6 hours. On day -6, the lab called with her drug levels, and it was determined that the current dose was correct. No adjustment was made, and she completed all 16 doses of busulfan. Since the dose of busulfan (0.8 mg/kg) that was used for drug testing was ALSO her first dose of the preparative regimen, it should be included in the amount of drug that was given for preparative regimen. The total prescribed dose per protocol should be reported as “13 mg/kg.” (0.8 mg/kg x 16 doses = 12.8 mg/kg rounded to 13 mg/kg).
     If the first dose of the preparative regimen was used to determine pharmacokinetics, the following should be reported:
     - On the Pre-TED (2400) form, the total prescribed dose per protocol would include the dose used for monitoring.
     - On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first dose was administered. The actual dose received would include the dose used for monitoring.

Test doses must be reported consistently at your center. Since most centers follow a consistent approach to pharmacokinetic testing, it should be straightforward for the center to adopt a consistent approach to the reporting of test doses.

Question 133: Date started

Enter the date when the first dose of the preparative regimen drug was administered. The pharmacy record or Medication Administration Record (MAR) should be used for determining the date the drug was started.

Question 134: Specify administration (busulfan only)

Report the busulfan administration route as either **Oral**, **IV**, or **Both**.

Section Updates:

Report the recipient’s actual body weight just prior to the start of the preparative regimen. The intent of this question is to report the actual weight at the time the preparative regimen starts (which may be different

than the weight used to determine preparative regimen doses). This weight is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders. Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight.

Even if the recipient does not receive a preparative regimen, the weight is still required.

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q120	2/15/ 2023	Remove	Instructions for reporting the height prior to prep were updated: *Report the recipient's height just prior to the start of the preparative regimen. The intent of this question is to determine the height used when calculating preparative regimen drug doses. This height is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders. ~~Report height to the nearest whole centimeter or inch (round up if 0.5 or greater).~~*	Due to change in form revision
Q121	4/19/ 2024	Remove	Instructions reporting weight prior to prep updated: *Report the recipient's body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the weight used to calculate the preparative regimen drug doses. This weight may also be the same weight reported on the Recipient Baseline (2000) Form, if applicable. Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight. Even if the recipient does not receive a preparative regimen, the weight is still required.*	Sentenced incorrectly removed
Q121	4/15/ 2024	Remove	Instructions reporting weight prior to prep updated: *Report the recipient's body weight just prior to the start of the preparative regimen as documented on the transplant (for radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the weight used to calculate the preparative regimen drug doses. This weight may also be the same weight reported on the Recipient Baseline (2000) Form, if applicable. Report weight to the nearest tenth of a kilogram or pound. ~~Do not report adjusted body weight, lean body weight, or ideal body weight.~~ Even if the recipient does not receive a preparative regimen, the weight is still required.*	Sentenced missed when instructions were updated on 4/3/2024
Q121	4/3/ 2024	Modify	Instructions for reporting the weight prior to prep were updated: *Report the recipient's ~~actual~~ body weight just prior to the start of the preparative regimen as documented on the transplant (for*	Incorrect instructions

			radiation and/or systemic therapy) or admitting orders. The intent of this question is to report the ~~actual~~ weight used to calculate the preparative regimen drug doses. This may be the same weight reported on the Recipient Baseline (2000) Form. ~~at the time the preparative regimen starts (which may be different than the weight used to determine preparative regimen doses). This weight is usually documented on the transplant orders (for radiation and/or systemic therapy) or admitting orders.~~ Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight.	

Last modified: Apr 21, 2024

Q135 – 139: Additional Drugs Given in the Peri-Transplant Period

Drugs may be given during the peri-transplant (before and after infusion) period to prevent transplant-related complications, such as liver injuries or to facilitate engraftment.

Questions 135 – 139: Drugs

For each agent listed, indicate whether the drug was administered during the peri-transplant period to prevent transplant-related complications or facilitate engraftment, and any additional question(s) for each drug administered.

- **ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin, ATS (Anti-Thymocyte Serum)**: Serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized against human lymphocytes. Report the total dose *prescribed* pre- and post-infusion and the animal source. If **Other** is selected, specify the source.
- **Alemtuzumab (Campath)**: Antibody preparations that are infused in the recipient. Report the total dose *prescribed* pre- and post-infusion to the nearest tenth and specify the units of measurement.
- **Defibrotide**: Antithrombotic agent used to prevent veno-occlusive disease.
- **KGF (keratinocyte growth factor)**: Alternate names: palifermin, Kepivance. KGF acts to stimulate the growth of cells that line the surface of the mouth and intestinal tract. KGF may also be given to treat oral mucositis or as GVHD prophylaxis.
- **Ursodiol**: A naturally occurring bile acid used to dissolve small gall stones and to increase bile flow in patients with primary biliary cirrhosis.

If the recipient did not receive any of the drugs listed above, select **None**.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q135 – 139	7/25/ 2025	Modify	Instruction updated on how to answer question when peri-transplant drugs were not given: *For each agent listed, indicate whether the drug was administered during the peri-transplant period to prevent transplant-related complications or facilitate engraftment, and any additional question(s) for each drug administered.* • ***ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin, ATS (Anti-Thymocyte Serum)****: Serum or*	Outdated instructions

			gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized against human lymphocytes. Report the total dose prescribed pre and post infusion and the animal source. If ***Other*** *is selected, specify the source.* • ***Alemtuzumab (Campath)****: Antibody preparations that are infused in the recipient. Report the total dose prescribed pre and postinfusion to the nearest tenth and specify the units of measurement.* • ***Defibrotide****: Antithrombotic agent used to prevent veno occlusive disease.* • ***KGF (keratinocyte growth factor)****: Alternate names: palifermin, Kepivance. KGF acts to stimulate the growth of cells that line the surface of the mouth and intestinal tract. KGF may also be given to treat oral mucositis or as GVHD prophylaxis.* • ***Ursodiol****: A naturally occurring bile acid used to dissolve small gall stones and to increase bile flow in patients with primary biliary cirrhosis.* _If the recipient did not receive any of the drugs listed above, ~~leave these questions blank and override the error as 'verified correct'~~ select **None**.	
Q135 – 139	10/18/ 2022	Add	Clarification added on how to answer these questions when peri-transplant drugs were not given: *If the recipient did not receive any of the drugs listed above, leave these questions blank and override the error as 'verified correct.'*	Added for clarification
Q135 – 139	5/1/ 2023	Add	Peri-transplant time frame defined: *Drugs may be given during the peri-transplant (before and after infusion). period to prevent transplant-related complications, such as liver injuries or to facilitate engraftment. For each agent listed, indicate whether the drug was administered during the peri-transplant period to prevent transplant-related complications or facilitate engraftment, and any additional question(s) for each drug administered.* • ***ALG (Anti-Lymphocyte Globulin), ALS (Anti-Lymphocyte Serum), ATG (Anti-Thymocyte Globulin, ATS (Anti-Thymocyte Serum)****: Serum or gamma globulin preparations containing polyclonal immunoglobulins directed against lymphocytes. These drugs are usually prepared from animals immunized against human lymphocytes. Report the total dose prescribed pre- and post-infusion and the animal source. If* ***Other*** *is selected, specify the source.*	Added for clarification

			• ***Alemtuzumab (Campath)***: *Antibody preparations that are infused in the recipient. Report the total dose prescribed pre- and post-infusion to the nearest tenth and specify the units of measurement.*	

Last modified: Jul 28, 2025

Q140 – 142: GVHD Prophylaxis

! The following GVHD prophylaxis questions are to be completed for allogeneic HCTs only. Autologous HCTs continue with the Post-HCT Therapy Planned as of Day 0 section.

* If ATG or Campath were ordered for GVHD prophylaxis prior to or after Day 0, report these drugs in the Additional Drugs Given in the Peri-Transplant Period section of the Pre-TED. Do not report these drugs in the GVHD Prophylaxis section.

Question 140: Was GVHD prophylaxis planned?

After allogeneic HCT, specific immunosuppressive therapy may be administered to prevent GVHD or to immunosuppress the host marrow, thereby promoting engraftment of the donor stem cells. Most transplant centers have specific GVHD prophylaxis protocols and graft rejection protocols. **Planned** agents a recipient receives as a result of these protocols should be included in this section. This answer does not have to match what is reported on the Post-Infusion Follow-Up (2100) Form.

Indicate if GVHD prophylaxis was planned at the time of transplant. If GVHD prophylaxis was not planned at the time of transplant, check **No**.

Questions 141 – 142: Specify drugs / intervention (check all that apply)

The prophylactic drug options listed on the form are intended to be administered in a **systemic or oral form**. If the recipient received one of the listed drugs in a topical form, select the “other agent” option and specify the drug.

! **Product Manipulation for GVHD Prophylaxis**
In *Specify drugs / intervention* questions, be sure to report any product manipulation done for GVHD Prophylaxis. Product manipulation is not captured anywhere else on this revision of the Pre-TED (2400) Form and any manipulation done for GVHD Prophylaxis should be reported here. An example of product manipulation for GVHD prophylaxis is T-cell depletion.

The Pre-TED Form lists the generic chemotherapy drug names. The following website provides the trade names under which generic drugs are manufactured: http://www.rxlist.com/script/main/hp.asp

If GVHD prophylaxis is used for a syngeneic (monozygotic or identical twin) or autologous HCT, attach a copy of the source document using the attachment feature in FormsNet3^{SM}.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Sep 23, 2022

Q143 – 145: Planned Post-HCT Disease Therapy Planned as of Day 0

Question 143: Is additional post-HCT therapy planned?

If additional post-HCT therapy is planned according to the protocol or standard of care, check **Yes** even if the recipient does not receive the planned therapy. The word “planned” should not be interpreted as: *if the recipient relapses, then the “plan” is to treat with additional therapy*. If additional post-HCT therapy is not planned per protocol, check **No** and submit the form.

Planned Post-HCT Therapy
The following post-HCT planned therapy questions are optional for non-U.S. centers.

Questions 144 – 145: Specify post-HCT therapy planned (check all that apply)

Indicate if the options listed on the form are intended to be part of the post-HCT planned therapy according to the protocol or standard of care. Select **Other therapy** for other planned therapies and specify the other therapy.

Examples of when the **Unknown** option would be used include inclusion in a treatment protocol where a trial drug is used and randomized, or if post-HCT therapy is planned, but the specific therapy intended for use is not known pre-HCT.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Sep 23, 2022

Q146: Prior Exposure: Potential Study Eligibility

Question 146: Specify if the recipient received any of the following (at any time prior to HCT / infusion) (check all that apply)

Indicate if any of the following agents were administered to the patient prior to HCT / infusion:

- **Blinatumomab**: A monoclonal antibody used to treat B-cell acute lymphoblastic leukemia (ALL)
- **Gemtuzumab ozogamicin**: An antibody-drug conjugate used to treat CD33 positive acute myeloid leukemia (AML)
- **Inotuzumab ozogamicin**: An antibody-drug conjugate used to treat B-cell acute lymphoblastic leukemia (ALL)
- **Adienne Tepadina®.**: A specific brand of thiotepa, an alkylating agent used in the conditioning regimen to treat myeloma, lymphomas, acute leukemia and other malignant and non-malignant
- **Mogamulizumab**: A monoclonal antibody used to treat mycosis fungoides or Sezary syndrome (types of cutaneous T-cell lymphoma). It is also being studied in the treatment of other types of cancer

If the recipient did not receive any of the agents listed above select **None of the above**.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
.	.	.	.	.

Last modified: Sep 23, 2022

Q147 – 157: COVID-19 (SARS-CoV-2) Impact on Hematopoietic Cell Transplantation (HCT)

COVD-19 Impact on HCT Questions Disabled
This section is disabled and will be updated with the next Pre-TED (2400) form.

Question 147: Was the HCT impacted for a reason related to the COVID-19 (SARS-CoV-2) pandemic? (Examples of applicable impacts include changes to the original HCT date, donor, product type, preparative regimen, and GVHD prophylaxis) (Does not apply if infected by COVID-19 (SARS-CoV-2))

Indicate if the HCT was impacted for any reason related to the COVD-19 pandemic. Examples include changes to the original HCT date, donor, product type, preparative regimen, and / or GVHD prophylaxis.

For example, the initial plan was to use myeloablative conditioning but changed to reduced intensity to minimize transfusion needs or the preferred stem cell source was marrow but changed to peripheral blood for more rapid count recovery.

Do not include here if the HCT was impacted due to the recipient being infected by COVID-19 (i.e., the HCT was delayed due to the recipient having COVID-19 or there was a change in the original planned preparative regimen due to the recipient having a history of COVID-19). Information about COVID-19 infection of the recipient is captured above in the Comorbid Conditions section.

If the HCT was not impacted for a reason related to COVID-19, report **No** and submit the form.

Questions 148 – 149: Is the HCT date different than the originally intended HCT date?

Indicate if the current HCT date is different than the originally planned HCT date. If **Yes**, report the original HCT date (YYYY-MM-DD). If the exact date is unknown, use the guidelines for reporting estimated dates and check the **Date estimated** box.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 150 – 151: Is the donor different than the originally intended donor?

Indicate if the current donor for HCT is different than the originally intended donor. If Yes, specify the originally intended donor.

- **Unrelated donor**: A donor who shares no known ancestry with the recipients. Include adoptive parents / children or stepparents / children.
- **Syngeneic**: Monozygotic (identical) twins. Does not include other types of twins or HLA-identical siblings (see below).
- **HLA-identical sibling**: Non-monozygotic (dizygotic, fraternal, non-identical) twins. Does not include

half-siblings (report as HLA-matched other relatives if their HLA typing is a match, or HLA-mismatched relative if it does not match).

- **HLA-matched other relative**: All blood-related relatives, other than siblings, who are HLA matched (e.g., parents, aunts, uncles, children, cousins, half-siblings). Does not include adoptive parents / children or stepparents / children who are HLA matched.
- **HLA-mismatched relative**: Siblings who are not HLA-identical and all other blood-related relatives who have at least one HLA mismatch (mismatch can be at the antigen or allele level) (e.g., parents, aunts, uncles, children, cousins, half-siblings). Does not include adoptive parents / children or stepparents / children.

Questions 152 – 154: Is the product type (bone marrow, PBSC, cord blood unit) different than the originally intended product type?

Indicate if the current product type of HCT is different than the originally intended product type. If **Yes**, specify the originally intended product type. If **Other product** is selected, specify the product.

Question 155: Was the current product thawed from a cryopreserved state prior to infusion?

Indicate if the current product for HCT was thawed from a cryopreserved state prior to infusion.

Question 156: Did the preparative regimen change from the original plan?

Indicate if the current preparative regimen changed from the original plan. This includes changes in the preparative regimen drugs.

Question 157: Did the GVHD prophylaxis change from the original plan?

Indicate if the current GVHD prophylaxis changed from the original plan.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
Q147	3/13/ 2024	Modify	The red warning box above Q147 updated to clarify this section is now disabled and will be updated with the next revision of the Pre-TED (2400) form.	Due to change in FormsNet3^{SM} validation

Last modified: Mar 13, 2024