2450: Post-TED

Transplant centers participating in the CIBMTR must submit a Post-TED Form for recipients who meet any of the following criteria:

- Recipient receives a transplant at a United States center designated as a *TED-only* center.
- Recipient receives a transplant at a United States center designated as *Comprehensive Report Form* center but has been assigned to the TED track by the Form Selection Algorithm.
- Recipient receives an allogeneic transplant at a United States center designated as *Comprehensive Report Form* center but has not consented to participate in research.
- Recipient receives a transplant at an international center, has consented to participate in research, and has been assigned to the TED track by the Form Selection Algorithm.

The Post-TED fulfills the requirements of the SCTOD for recipients meeting any of the above criteria. For more information regarding the SCTOD, see General Instructions, Stem Cell Therapeutics Outcomes Database.

For more information, including information on the TED and Comprehensive Report Form Selection Algorithm, see Section 1 in the Center Reference Guide.

The Post-TED must be completed at the following time points: 100 days, six months, and annually post-HCT. These forms should be completed as closely to these time points as possible. The structure of the TED Forms is such that each form should fit on a timeline with distinct start and stop dates that do not overlap any other forms, except in the case of a subsequent HCT.

✻ If the Post-TED form is being completed for a six-month or annual evaluation, the answers to all questions should reflect the clinical status of the recipient **since the last report**.

Subsequent HCT
If a recipient receives a subsequent HCT between Post-TED time points (100 day, six months, annually), the TED form sequence will start over again with another Pre-TED.

However, if the recipient receives an autologous HCT as a result of a poor graft or graft failure, the TED form sequence **will not** start over again. Generally, this type of infusion (autologous rescue) is used to treat the recipient's poor graft response, rather than to treat the recipient's disease.

Contact the CIBMTR Customer Service Center if the subsequent Pre-TED does not come due automatically.

✻ If the recipient received a subsequent transplant (excluding an autologous rescue), the answers to all questions should reflect the clinical status of the recipient the day prior to the start of the preparative regimen or, if no preparative regimen was given, the answers to all questions should reflect the clinical status of the recipient the day prior to HCT infusion.

Non-Malignant Diseases

If the HCT being reported was given to treat a non-malignant disease (as reported on the Pre-TED Disease Classification Form {Form 2402}), do not complete the following sections of the Post-TED Form:

- Q66 – 87: Disease Assessment at the Time of Best Response to HCT
- Q89 – 97: Post-HCT Therapy
- Q98 – 108: Relapse or Progression Post-HCT
- Q109 – 111: Current Disease Status

Lost to Follow-Up

Occasionally, centers may lose contact with recipients for a variety of reasons, including the recipient's moving, changing physicians, or death. If contact with a recipient appears lost, please consider calling the recipient at home or work, sending a letter, communicating with the treating or referring physician, or contacting the hospital billing department. If no documentation exists and several unsuccessful attempts have been made to contact the recipient, they are considered lost to follow-up and the form may be marked as such using the Lost to Follow-Up tool in FormsNet3^{SM} for each reporting period in which no contact exists.

Links to Sections in Manual:

Q1 – 2: Survival
Q3: Subsequent Transplant
Q4 – 6: Initial ANC Recovery
Q7 – 8: Initial Platelet Recovery
Q9 – 34: Graft-Versus-Host Disease
Q35 – 37: Liver Toxicity Prophylaxis
Q38 – 39: Veno-occlusive disease (VOD) / Sinusoidal obstruction syndrome (SOS)
Q40 – 46: Infection
Q47: New Malignancy, Lymphoproliferative or Myeloproliferative Disorder
Q48 – 65: Chimerism Studies
Q66 – 88: Disease Assessment at the Time of Best Response to HCT
Q89 – 97: Post-HCT Therapy
Q98 – 108: Relapse or Progression Post-HCT
Q109 – 111: Current Disease Status

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

7/26/2024	2450: Post-TED	Modify	Version 7 of the 2450: Post-TED section of the Forms Instruction Manual released. Version 7 corresponds to revision 8 of the Form 2450.

Last modified: Jul 29, 2024

Q1 – 2: Survival

The date of actual contact with the recipient to determine medical status for this follow-up report is based on a medical evaluation conducted by a clinician with responsibility for the recipient's care. Report the date of the medical evaluation performed closest to the designated time period of the form (e.g., Day+100, 6 months, or annual follow-up visit). Time windows are provided to guide selection of dates for reporting purposes. Recipients are not always seen within the time windows used for reporting follow-up dates, and some discretion is therefore required when determining which date to report. If the recipient is not seen within the time windows, report the date closest to the date of contact within reason.

If the Post-TED Form reports a subsequent infusion (transplant or genetically modified cellular therapy), report the date of latest follow-up as the day prior to the start of the preparative regimen / systemic therapy. If no preparative regimen or conditioning / systemic therapy was given, report the day prior to infusion as the date of contact.

No Documentation of Contact Date
The contact date data field cannot be left blank and is required to be reported. In cases where the recipient passed away and there is no documentation to report the date of death, the guidelines for reporting estimated dates must be used.

Reporting Latest Follow-Up
When reporting the date of latest follow-up prior to a subsequent infusion (HCT or cellular therapy), report the date specified above regardless of whether there is actual patient contact on the date. This is an exception to the standard date of follow-up reporting to ensure all dates are captured within the sequence of forms.

Reporting the 1-Year Date of Contact
If this form is being completed for the 1-year reporting period, ensure the reported contact date is > Day 365. Review the **1-Year Date of Contact** instructions below for additional information.

Reporting Contact Dates Reporting Instruction Overview
Review the Contact Dates Reporting Instruction Overview for additional information on reporting contact dates for recipient death, subsequent infusions, and various contact date reporting examples.

Question 1: Date of actual contact with the recipient to determine medical status for this follow-up report

Enter the date of actual contact with recipient to determine medical status for this follow-up report. Acceptable evaluations include those from the transplant center, referring physician, or other physician

currently assuming responsibility for the recipient's care. Please capture a physician evaluation that falls within the appropriate range, if possible, rather than other types of patient contact that may be closer to the actual time point. If an evaluation was not performed at Day+100, at 6 months, or on the HCT anniversary, choose the date of the visit closest to the actual time point.

If the recipient has not been seen by a clinician during the reporting period but the survival status is known, complete the Survival Tool referenced in the CIBMTR Data Management Guide, found here.

In general, the date of contact should be reported as close to the 100-day, 6 month, or annual anniversary to transplant as possible. Report the date of actual contact with the recipient to evaluate medical status for the reporting period. In the absence of contact with a clinician, other types of contact may include a documented phone call with the recipient, a laboratory evaluation, or any other documented recipient interaction on the date reported. If there was no contact on the exact time point, choose the date of contact closest to the actual time point. Below, the guidelines show an ideal approximate range for reporting each post-transplant time point:

Time Point	Approximate Range
100 days	+/- 15 days (Day 85-115)
6 months	+/- 30 days (Day 150-210)
1 year	+ 60 days (Day 366 – 425)
Annual reporting 2+ years	+/- 30 days (Months 23-25, 35-37, etc.)

Recipients are not always seen within the approximate ranges and some discretion is required when determining the date of contact to report. In that case, report the date closest to the date of contact within reason. The examples below assume that efforts were undertaken to retrieve outside medical records from the primary care provider, but no documentation was received.

Date of Contact & Death

In the case of recipient death, the date of death should be reported as the date of contact regardless of the time until the ideal date of contact. The date of death should be reported no matter where the death took place (inpatient at the transplant facility, at an outside hospital, in a hospice setting, or within the recipient's home).

If the death occurred at an outside location and records of death are not available, the dictated date of death within a physician note may be reported. If the progress notes detailing the circumstances of death are available, request these records. These records are useful for completing required follow-up data fields and the cause of death data fields on this form. If the exact date of death is not known, use the processed described for reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Date of Contact & Subsequent Infusion

If the recipient has a subsequent infusion (HCT or cellular therapy), the date of contact will depend on the

type of subsequent infusion. If the subsequent infusion is an HCT or genetically modified cellular therapy (e.g. CAR-T), report the date of contact as the day before the preparative regimen / lymphodepleting therapy begins for the subsequent infusion. If no preparative regimen / lymphodepleting therapy is given, report the date of contact as the day before the subsequent infusion. In these cases, actual contact on that day is **not** required, and the day prior to the initiation of the preparative regimen (or infusion, if no preparative regimen / lymphodepleting therapy) should be reported. This allows every day to be covered by a reporting period but prevents overlap between infusion events. If the subsequent infusion is a non-genetically modified (e.g. DLI) cellular therapy infusion, report the date of contact as appropriate to the reporting period.

Review the Contact Dates Reporting Instruction Overview for additional information on reporting contact dates for recipient death, subsequent infusions, and various contact date reporting examples.

Specify the Survival Status
If the survival status is reported as **Dead**, the Recipient Death Data (2900) form will come due. It is encouraged to complete Recipient Death Data (2900) form along with the Post-TED (2450) form, when applicable.

Question 2: Specify the recipient's survival status at the date of last contact

Indicate the clinical status of the recipient on the date of actual contact for follow-up evaluation.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q3: Subsequent Infusion

Question 3: Did the recipient receive a subsequent infusion?

Indicate if the recipient received a subsequent infusion during the reporting period. Subsequent infusions include transplant, cellular therapy, gene therapy, DLI, and 'boost' (autologous or allogeneic).

If **Yes**, complete the Indication for CIBMTR Data Reporting (2814).

For more information on infusion types, review Appendix D: How to Distinguish Infusion Types.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q4 – 6: Initial ANC Recovery

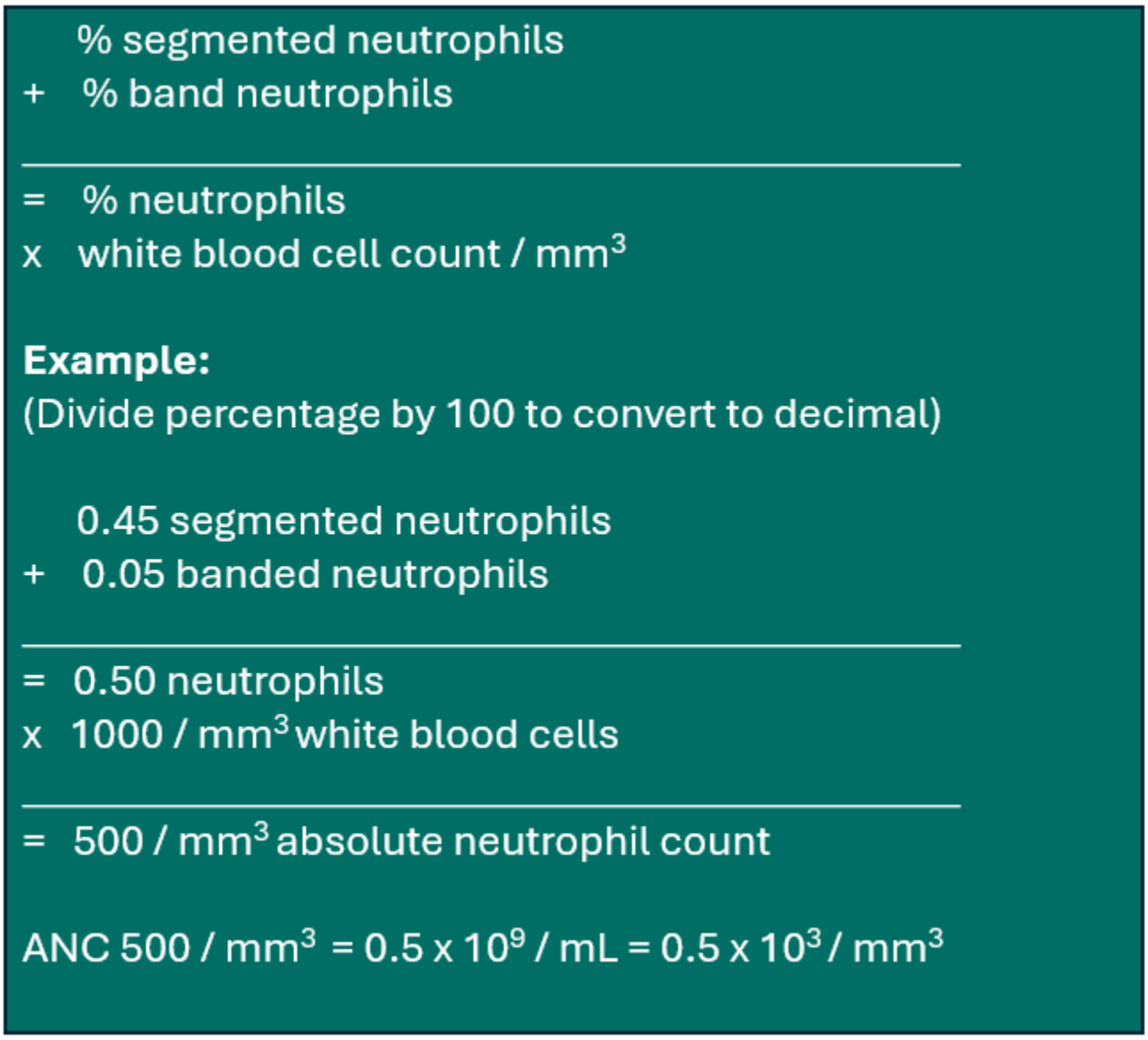
Initial ANC Recovery
The Initial ANC Recovery questions can only be completed on the 100-day, 6-month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods. *Did late graft failure occurr* must be answered on all follow-up forms.

Initial ANC Recovery
Recovery, as reported in this section, does not distinguish between allogeneic engraftment (blood and stem cells of donor origin) and autologous engraftment (blood and stem cells of host origin). To demonstrate *engraftment* for allogeneic recipients, particularly non-myeloablative or reduced intensity approaches, chimerism tests must be done. These measure the quantity of donor cells relative to the quantity of host (recipient) cells. While ANC usually represents donor cells in allogeneic HCT, it cannot be proven without chimerism studies.

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

ANC recovery is defined as an absolute neutrophil count (ANC) of ≥ 0.5×10^9/L ($500/mm^3$) for three consecutive laboratory values obtained on different days. Date of ANC recovery is the date of the first of three consecutive laboratory values where the ANC is ≥ 0.5×10^9/L. At some institutions, the laboratory reports display the ANC value once there are sufficient white blood cells to perform a differential count. At other institutions, the laboratory reports do not display the ANC, and it must be calculated from the white blood cell count (WBC) and the percent of segmented and band neutrophils (if the differential was performed on a machine, the percent neutrophils will include both segmented and band neutrophils). If the laboratory report displays an automated ANC value of exactly 0.5, the actual ANC value should be calculated from the manual differential if available. The calculated value from the manual differential will determine ANC recovery. If your institution's laboratory reports do not display the ANC value, use the following calculation to determine the ANC:

Calculating Absolute Neutrophil Count (ANC)[1]



[1] Traditionally, the definition of ANC recovery required selecting the first date of three consecutive days in which the recipient's ANC was ≥ 0.5×10^9/L (500/mm^3). For various reasons it may not be possible to obtain daily laboratory values. Under those circumstances, report ANC recovery based upon three consecutive laboratory values (drawn more than a day apart) as long as the ANC remains ≥ 0.5×10^9/L (500/mm^3).

Tracking the date of ANC recovery may not always be straightforward. In some cases the ANC may fluctuate for a period of time before the recipient fully recovers. In other cases the ANC may remain above 0.5×10^9/L for several days immediately post-HCT and then fall below 0.5×10^9/L. Do not begin counting ANC values of ≥ 0.5×10^9/L towards recovery until the ANC has dropped to the lowest level (nadir) post-HCT. If the recipient was transplanted using a non-myeloablative (NST) or reduced intensity (RIC) regimen, or was transplanted for an immunodeficiency (e.g., SCID, WAS), the recipient's ANC may never drop below 0.5×10^9/L. If this is the case, an ANC recovery date will not be reported, and the "never below" option should be chosen. However, if the recipient's ANC drops below 0.5×10^9/L for even one day, this should be considered the nadir and "never below" should not be chosen. See the following example for more

information regarding tracking the date of ANC recovery.

Tracking ANC Recovery

Transplant Date = May 6

Date	WBC	%Neutrophils	ANC	
May 7	900	0.6	540	
May 8	850	0.59	502	
May 9	720	0.7	504	
May 10	300	0.45	135	
May 11	15	No differential	—	
May 12	30	No differential	—	
May 13	50	No differential	—	
May 14	250	0.4	100	
May 15	800	0.7	560	*Date of first recovery: ANC ≥ 0.5×10^9/L*
May 16	1050	0.8	840	
May 17	1000	0.7	700	
May 18	1800	0.6	1080	
May 19	2000	0.55	1100	
May 20	2500	0.53	1325	
May 21	2250	0.43	968	
May 22	1500	0.45	675	

Question 4: Was there evidence of initial hematopoietic recovery?

Indicate whether or not there was evidence of **initial** ANC recovery following this HCT.

Check only **one** response:

- If **Yes** if ANC ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L) achieved and sustained for 3 laboratory values.
- If **No** if ANC ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L) was not achieved.
- Check **Not applicable** if the recipient's ANC never dropped below 0.5 × 10^9/L at any time post-HCT. This option is only applicable in the 100-day reporting period.
- Check **Previously reported** if this is the 6-month or annual follow-up, and the initial ANC recovery has already been reported.

Not Applicable and Previously Reported
When **Not applicable** is reported for 100-day reporting period, for all future reporting periods, select **Previously reported**.

Question 5: Date ANC ≥ 500/mm^3 (first of 3 lab values)

Enter the **first** date of the three consecutive laboratory values obtained on different days where the ANC was ≥ 500/mm^3 (or ≥ 0.5 × 10^9/L). For an example of tracking ANC recovery, see the Tracking ANC Recovery example above.

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

Question 6: Did late graft failure occur?

Late (or secondary) graft failure is defined when the recipient meets criteria for initial engraftment but subsequently develops loss of a previously functioning graft by development of at least two lines of cytopenia. Late graft failure is more often associated with allogeneic HCT than with autologous HCT. Some possible causes for late graft failure include graft rejection related to residual host immunity, persistent or progressive disease, low donor cell yield, medication side-effect, infection or GvHD.[2]

If the recipient meets the criteria of graft failure, check **Yes**.

[2] Appelbaum, F. R., & Thomas, E. D. (2009). Thomas' Hematopoietic Cell Transplantation: Stem Cell Transplantation (4th ed.). Chichester, UK: Wiley-Blackwell.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Aug 27, 2024

Q7 – 8: Initial Platelet Recovery

Initial Platelet Recovery
The Initial Platelet Recovery section can only be completed on the 100-day, 6 month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

Optional for Non-U.S. Centers

The following questions refer to **initial** platelet recovery following the HCT for which this form is being completed. All dates should reflect **no platelet transfusions administered for seven consecutive days.**

Report the date of the first of three consecutive laboratory values ≥ 20 × 10^9/L obtained on different days, as shown in the Reporting Platelet Recovery example below. Note that platelet recovery may take place well after the recipient has returned to the referring physician for care. It is essential that information and laboratory values be obtained from the referring physician.

Transfusions temporarily increase blood cell counts. When the data is later used for analysis, it is important to be able to distinguish between a recipient whose own body was creating the cells and a recipient who required transfusions to support the counts.

The following example illustrates the procedure to follow for reporting platelet recovery.

Reporting Platelet Recovery

	Transfusion										
Day	**0**	1	2	3	4	5	6	**7**	8	9	10
Platelet Count	**10,000**	35,000	30,000	25,000	10,000	15,000	19,000	**23,000**	25,000	40,000	50,000
Date	**1/1/2008**	1/2/ 2008	1/3/ 2008	1/4/ 2008	1/5/ 2008	1/6/ 2008	1/7/ 2008	**1/8/ 2008**	1/9/ 2008	1/10/ 2008	1/11/ 2008
								1st of 3			

Report **1/8/08** as date platelet count ≥ 20 × 10^9/L

Question 7: Was an initial platelet count ≥ 20 × 10^9/L achieved?

Indicate whether or not there was evidence of initial platelet recovery following this HCT.

Check only one response:

- Select **Yes** if platelet count ≥ 20 × 10^9/ L was achieved and sustained for 3 consecutive laboratory values, obtained on different days without platelet transfusions administered in the previous 7 days
- Select **No** if platelet count was not ≥ 20 × 10^9 / L or if platelet transfusions were administered in the previous 7 days.
- Check **Not applicable**, if the recipient's platelets never dropped below 20 × 10^9/L at any time post-HCT and a platelet transfusion was never required. If the recipient's platelet count drops below 20 × 10^9/L and/or the recipient received a platelet transfusion even once, do not use this option. This option is only applicable in the 100-day reporting period.
- Check **Previously reported** if this is the six-month or annual follow-up, and initial platelet recovery has already been reported on a previous form.

Not Applicable and Previously Reported
Not applicable and Previously reported options: When **Not applicable** is reported for 100-day reporting period, for all future reporting periods, select **Previously reported**.

Question 8: Date platelet ≥ 20 × 10^9/L

Enter the **first** date of three consecutive laboratory values obtained on different days where the platelet count was ≥ 20 × 10^9/L. Ensure that no platelet transfusions were administered for seven days immediately preceding this date. Include day seven, as shown in the Reporting Platelet Recovery example above, when determining the recovery date.

Reporting Estimated Dates
If a recipient is not seen within a month after their last platelet transfusion, an estimated date may be reported. In this case, the date seven days after the last platelet transfusion may be reported (see example A below). However, if the recipient is seen within a month of the last platelet transfusion, an estimated date should not be reported.

If three laboratory values were not obtained on consecutive days, but a sequential rise of ≥ 20 × 10^9/L is demonstrated, follow the examples below when determining an estimated date.

Reporting Scenarios:

A. The recipient is being seen in the outpatient clinic and receives a platelet transfusion on January 1. The platelet count is 22 × 10^9/L on January 2, 24 × 10^9/L on January 3, and 28 × 10^9/L on January 4. The

recipient does not come into the clinic for evaluation until one month later. The recipient has not received any more platelet transfusions and the platelet count is well above 20 × 10^9/L. Report January 8 (day seven post-platelet transfusion) for the date of platelet recovery.

B. The recipient is being seen in the outpatient clinic and receives a platelet transfusion on January 1. The platelet count is ≥ 20 × 10^9/L on January 2, January 3, and January 4. The recipient is then discharged back to their primary care physician. The transplant center receives a follow-up note from the primary care physician that states “recipient recovered their platelets in January of 2011.” Report an estimated date of recovery using the guidelines available in General Instructions, General Guidelines for Completing Forms.

For more information regarding reporting 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)
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Last modified: Jul 29, 2024

Q9 – 34: Graft versus Host Disease (Allogeneic Only)

Autologous Infusions
If this was an autologous infusion, continue with the Liver Toxicity Prophylaxis section of the form. The graft-versus-host disease section should only be completed for allogeneic infusions.

Graft versus Host Disease (**GVHD**) is an immunological phenomenon resulting from the reaction of donor immune cells against major or minor histocompatibility antigens of the recipient. GVHD is primarily caused by donor-derived T-cells. Very rarely, GVHD may occur due to autologous reactivity (autologous GVHD), third party transfusions, or with identical twin transplantation.

Factors influencing the severity of GVHD are related to three main categories: 1) donor or graft, 2) recipient, and 3) treatment. The most influential donor/graft factor is the degree of genetic disparity between the donor and the recipient (HLA match), but other risk factors include female donor to male recipient, donor parity, older donors, and T-cell dose. The occurrence of acute GVHD becomes a risk factor for the development of chronic GVHD. Recipient age and prior infections are also factors.

In the past, GVHD was classified as acute or chronic based on its time to diagnosis following transplant, and other clinical and histological (biopsy or post-mortem) features. Today, there has been increased recognition that acute and chronic GVHD are not dependent upon time since HCT, so determination of acute or chronic should rest on clinical and histologic features. **However, organ staging and overall grade should only be calculated from the clinical picture, not histology.** Acute GVHD usually begins between 10 and 40 days after HCT but can appear earlier or later. The organs most commonly affected by acute GVHD are the skin, gut, or liver. Other sites, such as the lung, may be involved.

Acute / Chronic GVHD
If acute GVHD is diagnosed prior to chronic GVHD, report the diagnosis information, maximum severity of any symptoms, and treatment administered up to the date of diagnosis of chronic GVHD in the acute GVHD section of the form. Do not include any signs, symptoms, or treatment occurring on or after the onset of chronic GVHD when completing the acute GVHD section.
Report any new or persistent acute GVHD symptoms occurring on or after the onset of chronic GVHD only in the chronic GVHD section. If chronic GVHD was diagnosed in a prior reporting period, report **No** for questions *Did acute GVHD develop* and *Did acute GVHD persist* in each subsequent reporting period. See reporting scenarios included in the *Did acute GVHD develop* question.

Transaminitis
Previously, if the recipient only had transaminitis related to acute GVHD, this would have

been reported as “stage 0” liver GVHD with and overall grade of “not applicable.” However, as of July 2021, isolated transaminitis should not be reported as acute GVHD. In this scenario, report **No**, acute GVHD did not develop or persist. If the recipient has transaminitis and other organs involved (i.e., skin rash), then report **Yes**, acute GVHD developed or persisted but do not report there was liver involvement.

Question 9: Did acute GVHD develop since the date of last report?

Did acute GVHD develop since the date of last report and *Did acute GVHD persist since the date of last report* questions on the Post-TED Form are meant to capture whether the recipient had active symptoms of acute GVHD during the reporting period. If the recipient had active acute GVHD during the reporting period, either *Did acute GVHD develop since the date of last report* or *Did acute GVHD persist since the date of last report* must be answered **Yes** unless there has been a prior / concurrent diagnosis of chronic GVHD (see Acute / Chronic GVHD note box above). There will not be a situation where **Yes** is reported for both *Did acute GVHD develop since the date of last report* and *Did acute GVHD persist since the date of last report* questions. If this question is answered **Yes** and a diagnosis date has been reported, the question *Did acute GVHD persist since the date of last report* will be disabled in FormsNet3^{SM}. Centers should report **Yes** for this question to indicate the recipient developed acute GVHD in the following scenarios:

- Acute GVHD is diagnosed for the first time during the reporting period.
- An acute GVHD flare is diagnosed during the current reporting period and **all** the following conditions are met:
  - The recipient’s prior acute GVHD symptoms did **not** persist from the prior reporting period into the beginning of the current reporting period.
  - The flare is diagnosed after **at least 30 days** without any active acute GVHD symptoms.
  - The recipient was not diagnosed with chronic GVHD on or before the date of the flare (see Acute / Chronic GVHD note box above).

If the recipient does have active acute GVHD during the reporting period, but does not match either of the scenarios above, the center will likely need to report **No** for this question and **Yes** for the question, *Did acute GVHD persist since the date of last report*. *Did acute GVHD persist since the date of last report*, is intended to capture acute GVHD which has continued from a prior reporting period. This includes any flares which do not meet the above conditions. The intent of classifying GVHD episodes as newly developed or persistent is to avoid having centers re-report diagnosis information which has been captured on a prior form. Refer to the Acute GVHD Diagnosis Scenarios below to see examples of how to answer *Did acute GVHD develop since the date of last report* and *Did acute GVHD persist since the date of last report* questions.

Report **No** for *Did acute GVHD develop since the date of last report* and *Did acute GVHD persist since the date of last report* if the recipient had no active acute GVHD symptoms during the reporting period **OR** all acute GVHD signs / symptoms during the reporting period occurred after a diagnosis of chronic GVHD (see Acute / Chronic GVHD note box above).

Indicate **Unknown** if there is no information about the recipient’s GVHD status for the reporting period. This

option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

If chronic GVHD has been diagnosed in a prior reporting period, report **No** for *Did acute GVHD develop since the date of last report* and *Did acute GVHD persist since the date of last report*. Any new or persistent acute GVHD symptoms occurring after the onset of chronic GVHD must be reported in the chronic GVHD section of the form. Do not include any signs, symptoms, or treatment occurring on or after the onset of chronic GVHD when completing the acute GVHD section. This instruction has been provided in the Acute / Chronic GVHD note box above.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 10: Date of acute GVHD diagnosis

Report the date of clinical diagnosis of acute GVHD. The clinical diagnosis date may not necessarily be the date the symptoms began (example: the recipient developed a rash one week prior to the physician clinically diagnosing acute skin GVHD). If the clinical diagnosis is documented, but the diagnosis date is unclear, obtain documentation from the primary physician confirming the clinical diagnosis date.

If the recipient developed more than one episode of acute GVHD in the same reporting period, report the date of onset of the first episode of acute GVHD.

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

> **Persistent GVHD and Day 100 Reporting Period**
> Previously, reporting **Yes** for *Did acute GVHD persist since the date of last report* was not an applicable option for the Day 100 reporting period. However, if there was a prior infusion, the recipient developed acute GVHD in the last reporting period of the previous infusion *and* acute GVHD persisted into the Day 100 reporting period of the current infusion, report **Yes**, acute GVHD persisted since the date of last report.

Question 11: Did acute GVHD persist since the date of last report?

This question will only be enabled in FormsNet3^{SM} if the center has reported **No** for the question *Did acute GVHD develop since the date of last report* and, therefore, has not reported a date of diagnosis. If prompted to answer this question, report **Yes** if acute GVHD was diagnosed in a prior reporting period and **any** of the following conditions are met:

- The recipient's acute GVHD symptoms have been active since diagnosis and continue to be active during the current reporting period (i.e., no period of resolution or quiescence since diagnosis).
- The recipient's acute GVHD symptoms had resolved before the first day of the current reporting period, but a flare occurred **within 30 days** of symptom resolution / quiescence.
- The recipient was not diagnosed with chronic GVHD on or before the date of the flare (see Acute /

Chronic GVHD note box above).

Report **No** for *Did acute GVHD develop since the date of last report* and *Did acute GVHD persist since the date of last report* questions if the recipient had no active acute GVHD symptoms during the reporting period **OR** all acute GVHD signs / symptoms during the reporting period occurred after a diagnosis of chronic GVHD (see Acute / Chronic GVHD note box above).

Indicate **Unknown** if there is no information about the recipient's GVHD status for the reporting period. This option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

Question 12: Overall grade of acute GVHD at diagnosis

Indicate the overall grade of acute GVHD at the time of diagnosis. For reporting purposes, "at diagnosis" is defined as the period between onset of signs / symptoms and the initiation of therapy to treat GVHD (topical or systemic). The acute GVHD grading scale is based on **clinical evidence** (physician observation), not histology. Pathology reports sometimes list a histologic grade of GVHD. Do not report the histologic grade. GVHD scoring and grading is based on *clinical* severity, not histologic severity. Biopsy of affected organs allows for more precise diagnosis as to the presence or absence of GVHD. However, **overall grading remains clinical** and is based on the criteria published by Przepiorka et al., *Bone Marrow Transplant* 1995; 15(6):825-8, see the GVHD Grading and Staging table below.

GVHD Grading and Staging Criteria
The CIBMTR will continue to collect overall grade of acute GVHD data based on the Przepiorka et al. criteria. New methods of grading acute GVHD, such as the MAGIC consortium criteria[7], can be used internally at sites; however, all data reported to the CIBMTR should be consistent with the Przepiorka et al. criteria.

[7] Harris AC, Young R, Devine S, et al. International, Multicenter Standardization of Acute Graft-versus-Host Disease Clinical Data Collection: A Report from the Mount Sinai Acute GVHD International Consortium. Biol Blood Marrow Transplant. 2015;22(1):4–10. doi:10.1016/j.bbmt.2015.09.001

If acute GVHD was present but the grade at diagnosis was not documented and it cannot be determined from the grading and staging table, report **Not applicable**.

Examples may include:

- Any other organ involvement without skin, liver, or gut symptoms attributable to GVHD
- Lower intestinal tract involvement where the stage cannot be determined in select scenarios (see lower intestinal tract involvement description below)

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Upper GI GVHD
If the recipient only has upper GI GVHD during the reporting period, report this as overall grade II. This may differ from prior instructions regarding how to report upper GI GVHD.

GVHD Grading and Staging

Stage	Skin	Liver	Gut
1	Rash on <25% of skin[1]	Bilirubin 2-3 mg/dl[2]	Diarrhea > 500 ml/day[3] or persistent nausea[4] *Pediatric*: 280-555 ml/m^2/day or 10-19.9 mL/kg/day
2	Rash on 25-50% of skin	Bilirubin 3-6 mg/dl	Diarrhea >1000 ml/day *Pediatric*: 556-833 ml/m^2/day or 20-30 mL/kg/day
3	Rash on >50% of skin	Bilirubin 6-15 mg/dl	Diarrhea >1500 ml/day *Pediatric*: >833 ml/m^2/day or > 30 mL/kg/day
4	Generalized erythroderma with bullous formation	Bilirubin >15 mg/dl	Severe abdominal pain, with or without ileus, and / or grossly bloody stool
Grade[5]			
I	Stage 1-2	None	None
II	Stage 3	Stage 1	Stage 1
III	—	Stage 2-3	Stages 2-4
IV[6]	Stage 4	Stage 4	—

[1] Use “Rule of Nines” (Percent Body Surfaces table) or burn chart to determine extent of rash.

[2] Range given as total bilirubin. Downgrade one stage if an additional cause of elevated bilirubin has been documented.

[3] Volume of diarrhea applies to adults. For pediatric patients, the volume of diarrhea should be based on body surface area. Downgrade one stage if an additional cause of diarrhea has been documented.

[4] Persistent nausea with or without histologic evidence of GVHD in the stomach or duodenum.

[5] Criteria for grading given as minimum degree of organ involvement required to confer that grade.

[6] Grade IV may also include lesser organ involvement with an extreme decrease in performance status

Questions 13 – 18: List the stage for each organ at diagnosis of acute GVHD

Report the stage of each organ at diagnosis. For reporting purposes, “at diagnosis” is defined as the period between onset of signs / symptoms and the initiation of therapy to treat GVHD (topical or systemic).

Skin: Select the stage that reflects the body surface area involved with a maculopapular rash attributed to acute GVHD at the time of acute GVHD diagnosis or flare in the reporting period. See the Percent Body Surfaces table below to determine the percent of body surface area involved with a rash. Do not report ongoing rash not attributed to acute GVHD at the time of acute GVHD diagnosis or flare.

Percent Body Surfaces

Body Area	Percent	Total Percentage
Each Arm	9%	18%
Each Leg	18%	36%
Chest & Abdomen	18%	18%
Back	18%	18%
Head	9%	9%
Pubis	1%	1%

Lower GI GVHD and Stool Output Not Documented
If diarrhea is attributed to acute GVHD during the reporting period, but the volume of stool output is not documented, leave the lower GI stage data field blank, override the FormsNet3 error as “not documented,” and specify the volume of stool output was not documented. In this case, report **Not applicable** for the overall grade unless stage 4 acute skin GVHD, stage 4 acute liver GVHD, or an extreme decrease in performance status *or* stage 2 or 3 acute liver GVHD was also documented at the time point being reported (*at diagnosis or maximum grade during the current reporting period*.

Lower intestinal tract (use mL/day for adult recipients and mL/m^2/day for pediatric recipients): Select the stage that reflects the volume of diarrhea attributed to acute GVHD at the time of acute GVHD diagnosis or flare in the reporting period. Use mL/day for adult recipients and mL/m^2/day for pediatric recipients. Input and output records may be useful in determining the volume of diarrhea. Do not report diarrhea ongoing but not attributed to acute GVHD at the time of acute GVHD diagnosis or flare.

Upper intestinal tract: Select the stage that reflects the presence of persistent nausea or vomiting attributed to acute GVHD at the time of acute GVHD diagnosis or flare in the reporting period. Do not report nausea or vomiting ongoing but not attributed to acute GVHD at the time of acute GVHD diagnosis or flare.

Liver: Select the stage that reflects the bilirubin level attributed to acute GVHD at the time of acute GVHD diagnosis or flare in the reporting period. Do not report hyperbilirubinemia ongoing but not attributed to acute GVHD at the time of acute GVHD diagnosis or flare.

Other site(s) involved with acute GVHD: Indicate whether acute GVHD affected an organ other than skin, upper GI, lower GI, or liver manifesting with hyperbilirubinemia. Report only other organ involvement at the time of acute GVHD diagnosis or flare in the reporting period. Do not report symptoms ongoing but not attributed to acute GVHD at the time of acute GVHD diagnosis or flare. Specify the other organ system involvement.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 19: Maximum Overall Grade of Acute GVHD

Indicate the overall maximum grade of acute GVHD since the date of the last report. Grading is based on **clinical evidence** (physician observation), not histology. Pathology reports sometimes list a histologic grade of GVHD. Do not report the histologic grade. GVHD scoring and grading is based on *clinical* severity, not histologic severity. Biopsy of affected organs allows for more precise diagnosis as to the presence or absence of GVHD. However, **overall grading remains clinical** and is based on the criteria published by Przepiorka et al., *Bone Marrow Transplant* 1995; 15(6):825-8; see the GVHD Grading and Staging table above.

If chronic GVHD was diagnosed during the reporting period, report the maximum severity of acute GVHD prior to the onset of chronic GVHD.

Report the recipient's maximum acute GVHD grade in the reporting period; **this may differ from the grade at diagnosis or may be the same.** If acute GVHD was present, but the maximum grade was not documented and it cannot be determined from the grading and staging table, report **Not applicable**.

Examples may include:

- Any other organ involvement without skin, liver, or gut symptoms attributable to GVHD
- Lower intestinal tract involvement where the stage cannot be determined in select scenarios (see lower intestinal tract involvement description above)

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

> **Upper GI GVHD**
> If the recipient only has upper GI GVHD during the reporting period, report this as overall grade II. This may differ from prior instructions regarding how to report upper GI GVHD.

Question 20: First date of maximum overall grade of acute GVHD

Report the first date of maximum acute GVHD involvement, based on clinical grade. If the recipient had

multiple instances in which their GVHD reached the same maximum grade, report the earliest date, regardless of any variation in the organ staging.

If **Not applicable** was reported for *Maximum overall grade of acute GVHD*, this question must be left blank.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

> **Maximum Organ Staging**
> Due to further clarification provided, the instructions for reporting the maximum organ staging were updated with the Fall 2023 Quarterly Release. The intent of the maximum organ staging questions is to capture the maximum stage of each organ involved with acute GVHD in the reporting period; not at the time of the maximum overall grade, despite what the question text states. The question text will be revised with the next revision of the Post-TED (2450) Form.

Questions 21 – 26: List the stage for each organ at the time of maximum overall grade of acute GVHD

Report the maximum acute GVHD stage of each organ involved in the reporting period. The maximum staging does not need to be at the time when the maximum overall grade occurred. Refer to the GVHD Grading and Staging Table above for staging guidelines. Also, review example E above for further information.

Skin: Select the maximum stage that reflects the body surface area involved with a maculopapular rash attributed to acute GVHD in the reporting period. See the Percent Body Surfaces table below to determine the percent of body surface area involved with a rash. Do not report ongoing rash not attributed to acute GVHD at the time of maximum overall grade of acute GVHD.

Percent Body Surfaces

Body Area	Percent	Total Percentage
Each Arm	9%	18%
Each Leg	18%	36%
Chest & Abdomen	18%	18%
Back	18%	18%
Head	9%	9%
Pubis	1%	1%

Lower intestinal tract (use mL/day for adult recipients and mL/m^2/day for pediatric recipients): Select the maximum stage that reflects the volume of diarrhea attributed to acute GVHD in the reporting period. Use mL/day for adult recipients and mL/m^2/day for pediatric recipients. Input and output records

may be useful in determining the volume of diarrhea. Do not report diarrhea ongoing but not attributed to acute GVHD at the time of maximum overall grade of acute GVHD.

Report an overall grade of IV if stage 4 acute skin GVHD, stage 4 acute liver GVHD, or an extreme decrease in performance status is documented at the time point being reported (see GVHD Staging and Grading Table). Report overall grade III if stage 2-3 liver involvement is documented at the time point being reported and there is no evidence of grade IV GVHD.

Upper intestinal tract: Select the maximum stage that reflects the presence of persistent nausea or vomiting attributed to acute GVHD in the reporting period. Do not report nausea or vomiting ongoing but not attributed to acute GVHD at the time of maximum overall grade of acute GVHD.

Liver: Select the maximum stage that reflects the bilirubin level attributed to acute in the reporting period. Do not report hyperbilirubinemia ongoing but not attributed to acute GVHD at the time of maximum overall grade of acute GVHD.

Other site(s) involved with acute GVHD: Indicate whether acute GVHD affected an organ other than skin, upper GI, lower GI, or liver manifesting with hyperbilirubinemia. Report only other organ involvement at the time of maximum overall grade of acute GVHD in the reporting period. Do not report symptoms ongoing but not attributed to acute GVHD at the time of maximum overall grade of acute GVHD. Specify the other organ system involvement.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 27: Did chronic GVHD develop since the date of last report?

Indicate whether a new clinical diagnosis of chronic GVHD was documented during the reporting period. If chronic GVHD was diagnosed during the reporting period, report **Yes**.

If the recipient had a flare of chronic GVHD occurring after at least a 30-day period of symptom quiescence, report **Yes**. Report **No** if symptoms resolve or become quiescent prior to the date of last report and then flare within 30 days. This should be reported as persistent chronic GVHD which is captured in the question *Did chronic GVHD persist since the date of last report*.

Report **No** if chronic GVHD was not clinically diagnosed – initially or as a flare – in the reporting period; this includes instances where chronic GVHD persists from a prior reporting period.

Indicate **Unknown** if there is no information about the recipient's GVHD status for the reporting period. This option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 28: Date of chronic GVHD diagnosis

Report the date of clinical diagnosis of chronic GVHD. The clinical diagnosis date may not necessarily be

the date the symptoms began (example: the recipient developed shortness of breath one month prior to the clinical diagnosis of pulmonary chronic GVHD). If the clinical diagnosis is documented, but the diagnosis date is unclear, obtain documentation from the primary physician confirming the clinical diagnosis date.

If the recipient developed more than one episode of chronic GVHD in the same reporting period, report the date of onset of the first episode of chronic GVHD.

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

> **Persistent GVHD and Day 100 Reporting Period**
> Previously, reporting **Yes** for *Did chronic GVHD persist since the date of last report* was not an applicable option for the Day 100 reporting period. However, if there was a prior infusion, the recipient developed chronic GVHD in the last reporting period of the previous infusion *and* chronic GVHD persisted into the Day 100 reporting period of the current infusion, report **Yes**, chronic GVHD persisted since the date of last report.

Question 29: Did chronic GVHD persist since the date of last report?

Indicate whether chronic GVHD was clinically diagnosed during a previous reporting period and persisted, with active symptoms, into the present reporting period. Do not report quiescent or inactive chronic GVHD, or a prior history of GVHD. If **Yes**, questions concerning chronic GVHD at the time of diagnosis will be skipped. See instructions above on reporting a chronic GVHD flare.

If the recipient has no active symptoms during the reporting period, report **No**.

Indicate **Unknown** if there is no information about the recipient's GVHD status for the reporting period. This option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

Question 30: Maximum grade of Chronic GVHD (according to best clinical judgement)

Report the maximum chronic GVHD involvement, based on the opinion of the clinician (i.e., clinical grade), since the date of the last report. The intent of this question is to capture the maximum grade based on the best clinical judgment. If both the global severity score and the score based on the clinician's opinion is documented, report the clinician score. If the maximum clinical grade is not documented, request documentation from the recipient's primary care provider.

Guidelines on how to report the maximum grade of chronic GVHD are outlined below:

- **Mild**: Signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (e.g., corticosteroids and/or cyclosporine or FK 506)
- **Moderate**: Signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (e.g., corticosteroids and/or

cyclosporine or FK 506)
- **Severe**: Signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

Indicate **Unknown** if there is no information about the recipient's GVHD status for the reporting period. This option should be used sparingly and only when no judgment can be made about the presence or absence of GVHD in the reporting period.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Organ Scoring of Chronic GVHD

Organ	Score 0	Score 1	Score 2	Score 3
Skin % BSA[1]	No BSA involved	1-18% BSA	19-50% BSA	>50% BSA
Skin Features	No sclerotic features	N/A	Superficial sclerotic features, but not "hidebound"	Deep sclerotic features; "hidebound;" impaired mobility; ulceration
Mouth	No symptoms	Mild symptoms **with** disease signs but not limiting oral intake significantly	Moderate symptoms with disease signs **with** partial limitation of oral intake	Severe symptoms with disease signs **with** major limitation of oral intake
Eyes	No symptoms	Mild dry eye symptoms not affecting ADL (requirement of lubricant drops ≤ 3x/day)	Moderate dry eye symptoms partially affecting ADL (requiring lubricant drops > 3x/day or punctal plugs) **WITHOUT** new vision impairment due to keratoconjunctivitis sicca (KCS)	Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) **OR** unable to work because of ocular symptoms **OR** loss of vision due to keratoconjunctivitis sicca (KCS)
GI Tract	No symptoms	Symptoms without significant weight loss (< 5%)	Symptoms associated with mild to moderate weight loss (5-15%) within 3 months **OR** moderate diarrhea without significant interference with daily living	Symptoms associated with significant weight loss (> 15%) within 3 months, requires nutritional supplement for most calorie needs **OR** esophageal dilation **OR** severe diarrhea with significant interference with daily living.
Liver	Normal total	Normal total bilirubin with	Elevated total bilirubin but ≤ 3 mg / dL or ALT > 5 x ULN	Elevated total bilirubin > 3 mg / dL

	bilirubin and ALT or AP < 3 x ULN	ALT ≥ 3 to 5 x ULN or AP ≥ 3 x ULN		
Lungs Symptom Score:	No symptoms	Mild symptoms (SOB after climbing one flight of steps)	Moderate symptoms (SOB after walking on flat ground)	Severe symptoms (SOB at rests; requires O2)
Lungs Lung Score:	FEV1 ≥ 80%	FEV1 60-79%	FEV1 40-59%	FEV1 ≤ 39%
Joints and Fascia	No symptoms	Mild tightness of arms or legs, normal or mild decreased range of motion **AND** not affecting ADL	Tightness of arms or legs **OR** joint contractures, erythema thought to be due to fasciitis, moderate decrease of range of motion **AND** mild to moderate limitation of ADL	Contractures **WITH** significant decrease of range of motion **AND** significant limitation of ADL (unable to tie shoes, button shirts, dress self, etc.)
Genital Tract[2]	No signs	Mild signs and females with or without discomfort on exam	Moderate signs and may have signs of discomfort on exam	Severe signs with or without symptoms
Other Features[3]	No GVHD	Mild	Moderate	Severe

NIH Consensus Criteria, 2014

[1] Features to be scored by BSA: Maculopapular rash, lichen planus-like features, sclerotic features, papulosquamous lesions or ichthyosis, keratosis pilaris-like GVHD.

[2] Scoring is based on severity of the signs instead of symptoms, based on limited available data and the opinions of experts. Female or male genital GVHD is not scored if a practitioner is unable to examine the patient.

[3] May include ascites, pericardial effusion, pleural effusion(s), nephrotic syndrome, myasthenia gravis, peripheral neuropathy, polymyositis, weight loss without GI symptoms, eosinophilia > 500/µL, platelets < 100,000/µL, others.

Question 31: Date of maximum grade of chronic GVHD

Report the date of maximum chronic GVHD involvement, based on clinical grade, during the current

reporting period. If the recipient had multiple instances in which their GVHD reached the same maximum grade, report the earliest date.

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

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 32: Specify if chronic GVHD was limited or extensive

The grading system for chronic GVHD is divided into two categories: limited and extensive. Definitions are based on Sullivan KM, *Blood* 1981; 57:267.

Report **Limited** if chronic GVHD includes only localized skin involvement and / or liver dysfunction. Report **Extensive** if **any** of the following symptoms are attributed to chronic GVHD:

- Generalized skin involvement and / or liver dysfunction
- Liver histology showing chronic aggressive hepatitis, bridging necrosis, or cirrhosis
- Involvement of the eye: Schirmer's test with <5 mm wetting, or
- Involvement of the salivary glands or oral mucosa demonstrated on labial biopsy (labial biopsy not required), or
- Involvement of any other target organ

The intent of this question is to capture if chronic GVHD was limited or extensive throughout the entire reporting period and is not dependent on the maximum grade and date of chronic GVHD. If the criteria to report extensive was met at any time in the reporting period, report **Extensive**.

Question 33: Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, ≤10 mg/day for adults, <0.1 mg/kg/day for children)

Steroids and Non-Steroid Immunosuppression for GVHD
GVHD treatment questions will only be completed if the center has reported **Yes** acute and/ or chronic GVHD develop or persisted since the date of last report. If **No** has been reported, then the GVHD treatment questions will be left blank.

Corticosteroids
Corticosteroids are captured differently depending on whether they are used topically or systemically. Use the following guidelines when determining how to report corticosteroids used to treat acute GVHD:
Topical Creams for Skin: Do not report topical ointments or creams used to treat skin GVHD including corticosteroid creams such as Triamcinolone or Hydrocortisone.
Other Topical Treatments: Certain corticosteroid treatments are inhaled or ingested but are not absorbed and are therefore considered topical. Examples include beclomethasone and budesonide. Do not consider these medications when answering the question regarding

systemic steroids.
Systemic Treatments: Systemic administration of corticosteroids, including use of prednisone and dexamethasone, should be reported in the question regarding systemic steroids.

Indicate whether the recipient is still taking systemic steroids to treat or prevent GVHD on the date of contact. Refer to the guidelines included in the question text if the recipient is taking low dose steroids or steroids for adrenal insufficiency.

Indicate **Not applicable** in any of the following scenarios:

- The recipient has never received systemic steroids (> 10 mg / day for adults or ≥ 0.1 mg / kg / day for children) to treat or prevent GVHD.
- This form is being completed for a subsequent HCT and the recipient has never received systemic steroids (> 10 mg / day for adults or ≥ 0.1 mg / kg / day for children) to treat or prevent GVHD since the start of the preparative regimen for the most recent infusion (or since the date of the most recent infusion if no preparative regimen is given).
- The recipient stopped taking systemic steroids (> 10 mg / day for adults or ≥ 0.1 mg / kg / day for children) to treat or prevent GVHD in a previous reporting period and did not restart systemic steroids (> 10 mg / day for adults or ≥ 0.1 mg / kg / day for children) during the current reporting period.

Indicate **Unknown** if there is no information to determine if the recipient is still taking systemic steroids. This option should be used sparingly and only when no judgment can be made about the recipient still receiving treatment for GVHD on the date of contact.

If the recipient has died prior to the discontinuation of systemic steroids used to treat or prevent acute and / or chronic GVHD, select **Yes**.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Question 34: Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

Steroids and Non-Steroid Immunosuppression for GVHD
GVHD treatment questions will only be completed if the center has reported **Yes**, acute and/ or chronic GVHD develop or persisted since the date of last report. If **No**,has been reported, then the GVHD treatment questions will be left blank.

Indicate whether the recipient is still taking systemic non-steroidal immunosuppressive agents (including PUVA) to treat or prevent acute and / or chronic GVHD on the date of contact. Descriptions of many immunosuppressive agents are included below. Only report systemic non-steroidal immunosuppressive agents and not topical non-steroids immunosuppressive agents, such as Restasis and or Protopic.

If the recipient did not receive systemic non-steroidal immunosuppressive agents to treat or prevent acute and / or chronic GVHD during the reporting period, report **Not applicable**.

Indicate **Not applicable** in any of the following scenarios:

- The recipient has never received systemic non-steroidal immunosuppressive agents (including PUVA) to treat or prevent GVHD.
- This form is being completed for a subsequent HCT and the recipient has never received systemic non-steroidal immunosuppressive agents (including PUVA) to treat or prevent GVHD since the start of the preparative regimen for the most recent infusion (or since the date of the most recent infusion if no preparative regimen was given).
- The recipient stopped systemic taking non-steroidal immunosuppressive agents (including PUVA) to treat or prevent GVHD in a previous reporting period and did not restart non-steroidal immunosuppressive agents (including PUVA) during the current reporting period.
- The recipient only received *topical* non-steroidal immunosuppressive agents (i.e., systemic non-steroidal immunosuppressive agents were never administered).

Indicate **Unknown** if there is no information to determine if the recipient is still taking non-steroidal immunosuppressive agents. This option should be used sparingly and only when no judgment can be made about the recipient still receiving treatment for GVHD in the reporting period.

Review the GVHD Reporting Instruction Overview for various GVHD reporting examples.

Section Updates:

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

Last modified: Jul 29, 2024

Q35 – 37: Liver Toxicity Prophylaxis

> **Liver Toxicity Prophylaxis**
> Liver Toxicity Prophylaxis section can only be completed on the 100 day and 6-month follow-up forms. These questions will be skipped for all subsequent reporting periods.

Question 35: Was specific therapy used to prevent liver toxicity?

Liver toxicities in transplant patients may be related to drugs / treatments, infection, GVHD, iron overload, cirrhosis, or sinusoidal obstructive syndrome (SOS) / veno-occlusive disease (VOD). Agents such as ursodiol may be given as prophylaxis against one or more of these transplant-related liver injuries. Agents given to prevent liver toxicity will generally be started prior to or during the conditioning regimen and may be continued well after transplant.

Indicate whether the recipient received any therapy intended to prevent liver toxicity during the current reporting period. For the Day 100 reporting period, this includes any therapy given during the conditioning regimen. Report only agents given to prevent liver toxicities, not those given to treat a diagnosed liver injury or toxicity. If liver toxicity prophylaxis was given, report **Yes**. If liver toxicity prophylaxis was not given during the reporting period, report **No**.

Questions 36 – 37: Specify therapy (check all that apply)

Select the agent(s) given during the reporting period to prevent liver toxicity, including therapy given during the conditioning regimen. Only report agents given to prevent liver toxicities, not those given to treat a diagnosed liver injury or toxicity. If **Other** therapy is reported, specify agent(s).

Section Updates:

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

Last modified: Jul 29, 2024

Q38 – 39: Veno-occlusive disease (VOD) / Sinusoidal obstruction syndrome (SOS)

Veno-occlusvie disease (VOD) / Sinusoidal obstruction syndrome (SOS) occurs following injury to the hepatic venous endothelium, resulting in hepatic venous outflow obstruction due to occlusion of the hepatic venules and sinusoids. This typically results in a distinctive triad of clinical signs including hepatomegaly with right upper quadrant tenderness, third space fluid retention (e.g., ascites), and jaundice with a cholestatic picture. For more information on VOD / SOS including diagnostic criteria, refer to the VOD / SOS section of the Forms Instructions Manual.

Questions 38 – 39: Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?

Indicate whether VOD / SOS was diagnosed during the reporting period. If **Yes**, report the date of diagnosis. If VOD / SOS persisted from the prior reporting period, indicate **No**.

For more information regarding reporting 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)
.	.	.	.	.

Last modified: Jul 29, 2024

Q40 – 46: Infection

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

Combined Follow-Up
In scenarios where both HCT and cellular therapy forms are being completed, duplicate questions will exist between the Cellular Therapy Essential Data Follow-Up (4100) form and the Post-HCT Data (2100) or Post-Transplant Essential Data (2450) form. To reduce the reporting burden, duplicate questions, including infection, on the Post-Transplant Essential Data (2450) form are disabled when there is a cellular therapy and an HCT.

Reporting Multiple COVID-19 Infections
FormsNet3^{SM} application: Complete the development of COVID-19 questions to report multiple COVID-19 infections by adding an additional instance in the FormsNet3^{SM} application. A separate instance should be added for each infection.
Paper form submission: Copy the development of COVID-19 questions and complete to report multiple COVID-19 infections occurring in the current reporting period. A separate instance should be completed for each infection.

Diagnosis of COVID-19 after the start of the preparative regimen: Any COVID-19 infections diagnosed after the start of the preparative regimen should be reported in the development of COVID-19 questions on the Post-TED (2450) form. Effective November 18, 2022, the Respiratory Virus Post-Infusion Data (2149) form for transplants on the TED track will no longer be required. Additionally, an unscheduled Respiratory Virus Post-Infusion (2149) form cannot be created for these recipients.

Reporting COVID-19 Reinfection
There have been cases of recipients recovering from COVID-19 infection, only to later test positive again. For CIBMTR purposes, a new COVID-19 infection should be reported when a recipient tests positive again >21 days from resolution (resolution defined as no signs or symptoms of infection, or a negative diagnostic test).

Questions 40 – 41: Did the recipient develop COVID-19 (SARS-CoV-2) since the date of last report?

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 .

As a result of the global COVID-19 pandemic, the U.S. Food and Drug Administration granted Sherlock Biosciences an emergency use of authorization (EUA) for its COVID-19 diagnostic assay, CRISPR. Although still in its infancy in real-life application, positive results by this method should be reported, even if tandem testing by other method(s) (i.e., PCR) indicate a negative result. If the CRISPR results are unclear, seek physician clarification.

Indicate whether or not the recipient has ever had a known COVID-19 (SARS-CoV-2) infection, based on a positive test result, at any time during the current reporting period.

If the recipient has had a documented COVID-19 (SARS-CoV-2) infection, report **Yes** and then specify the first date of the pathological diagnosis.

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

Possible Reporting Scenarios:

Do NOT report an infection in the following scenarios:

- A recipient only has a positive antibody result
- The recipient was symptomatic and treated, but COVID-19 diagnostic testing was not performed and / or COVID-19 diagnostic testing was performed and negative

DO report an infection in the following scenarios:

- A recipient has a positive COVID-19 diagnostic result (PCR or antigen) regardless of if treatment was given or if the recipient was asymptomatic
- A recipient has a positive antibody result *and* a positive COVID-10 diagnostic test (PCR or antigen)

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

Question 42: 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) within the current reporting period.

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.

Revaccination Post – Infusion

When vaccines are given post-infusion, the physician should make the determination on whether the doses are part of the primary series of vaccines, third primary dose, boosters, or revaccination. If a recipient receives a new course of COVID-19 vaccines following infusion as revaccination, report the vaccines as a new series. The most up to date CDC COVID-19 vaccine information for immunocompromised people can be found here.

COVID-19 Vaccine Doses

FormsNet3^{SM} application: Complete the COVID-19 vaccine questions to report all COVID-19 vaccine doses received in the current reporting period by adding an additional instance in the FormsNet3SM application. A separate instance should be added for each dose.

Paper form submission: Copy the COVID-19 vaccine questions and complete report all COVID-19 vaccine doses received in the current reporting period. A separate instance should be completed for each dose

Questions 43 – 44: Specify vaccine brand

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 45- 46: Select dose(s) received

For the reported dose, specify the vaccine dose the recipient in the current reporting period and specify 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**.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q47: New Malignancy, Lymphoproliferative or Myeloproliferative Disorder

Combined Follow-Up
In scenarios where a cellular therapy was given after an HCT and this form is now being completed based on the subsequent cellular therapy date, these questions do not apply and are disabled.

Question 47. Did a new malignancy, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)

Indicate whether a new or secondary malignancy, lymphoproliferative disorder, or myeloproliferative disorder has developed. Do not report recurrence, progression, or transformation of the recipient's primary disease (disease for which the transplant was performed), or relapse of a prior malignancy.

New malignancies, lymphoproliferative disorders, or myeloproliferative disorders include but are not limited to:

- Skin cancers (basal, squamous, melanoma)
- New leukemia
- New myelodysplasia
- Solid tumors
- PTLD (post-transplant lymphoproliferative disorder) (report as NHL)

The following should **not** be reported as new malignancy:

- Recurrence of primary disease (report as relapse or disease progression)
- Relapse of malignancy from recipient's pre-HCT medical history
- Breast cancer found in other (i.e., opposite) breast (report as relapse)
- Post-HCT cytogenetic abnormalities associated with the pre-HCT diagnosis (report as relapse)
- Transformation of MDS to AML post-HCT (report as disease progression)

Post-Transplant Lymphoproliferative Disorder (PTLD)
PTLD should be reported as a new malignancy if it was confirmed via a biopsy (treatment not required) or suspected to be PTLD and treated.

Recurrent Skin Cancers
For most malignancies, do not report recurrence, progression or transformation of the recipient's primary disease (disease for which the transplant was performed) or relapse of a

prior malignancy in the “New Malignancy” section.
For example, a recipient had a basal cell skin cancer diagnosed on the neck four months post-HCT and six months later had another basal cell located on the nose. The lesion on the nose is not considered a metastasis from the neck, but a new discrete lesion. These discrete episodes should be reported as **Basal cell skin malignancy** on the Post-TED forms.

If a new malignancy, lymphoproliferative disorder, or myeloproliferative disorder was diagnosed during the reporting period, report **Yes** and complete the Subsequent Neoplasms (3500) Form, which will come due.

The **Previously reported** option should only be used if the same malignancy has already been reported on a Subsequent Neoplasms (3500) form that was made do on demand. See examples below. If it is unclear whether or not to use this option, contact CIBMTR Center Support if there are questions.

Example 1. A recipient developed a new malignancy at Day +68 and is reported at the time the Day 100 Post-Infusion Follow-up (2450) form is completed. In this scenario, report Yes, the recipient developed a new malignancy, and a Subsequent Neoplasms (3500) form will be completed to report the new malignancy information. For all future reporting periods, select **No**.

Example 2. A recipient developed a new malignancy during the seven-year reporting period and the transplant center decided to create the Subsequent Neoplasms (3500) form as an unscheduled form in FormsNet3SM to report the new malignancy information immediately since a Post-Infusion Follow-Up for seven-year reporting period will not come due. When the eight-year Post-Infusion Follow-Up (2450) form is completed, **Previously reported**, will be reported since a prior Subsequent Neoplasms (3500) form has already been submitted for the new malignancy.

Example 3. A recipient was diagnosed with basal cell skin cancer on the neck in the one-year reporting period and two months later, within the same reporting period, there was a diagnosis of basal cell located on the nose. The lesion on the nose is not considered a metastasis from the neck, but a new discreet lesion. Report **Yes**, there was a new malignancy on the Post-HCT Follow-Up (2450), and a single Subsequent Neoplasms (3500) form will come due to report one of the basal cell malignancies. Create a second Subsequent Neoplasms (3500) form to report the other basal cell malignancy as these are discreet episodes.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q48 – 65: Chimerism Studies (Cord Blood Units, Beta Thalassemia, and Sickle Cell Disease Only)

Chimerism Studies
This section relates to chimerism studies from allogeneic HCTs using cord blood units, or for allogeneic HCT recipients whose primary disease is beta thalassemia or sickle cell disease only. If this was an autologous HCT, an allogeneic HCT using a bone marrow or PBSC product, and / or allogeneic HCT recipient whose primary disease for transplant was not beta thalassemia or sickle cell disease, continue to the disease assessment section.

Chimerism Studies
Chimerism study questions can only be completed on the 100-day, 6-month, 1 year, and 2 year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Chimerism studies are performed to determine the percent of blood or marrow cells post-transplant that are produced from donor hematopoietic stem cells and the percent that are produced from host (recipient) hematopoietic stem cells. Different types of blood cells and a variety of laboratory tests can be used to determine if a chimera (presence of both donor- and host-derived cells) exists. If cytogenetic testing was performed to look for disease markers, and the donor and recipient are different sexes, the test may also be used to determine if a chimera exists. If the donor and recipient are of the same sex, cytogenetic testing using the common staining technique, known as giemsa banding (G-banding), cannot be used to determine if there is a chimera. However, quinicrine banding (Q-banding) can be used to identify if the cells are of donor origin or not in a same-sex transplant, as this staining technique highlights inherited chromosome polymorphisms on certain human chromosomes including 3, 4, 13, 15, 21, 22, and Y. This is not a commonly used staining technique and is only helpful when the polymorphism is documented pre-HCT.

Failed Chimerism Studies
If chimerism studies were attempted, but no evaluable results were obtained, do not report the test.
When a multi-donor chimerism exists and includes a donor (or donors) from a previous HCT, report as a multi-donor chimerism though there may only be one donor for the current transplant.

Questions 48 – 49: Were chimerism studies performed since the date of last report?

Indicate whether chimerism studies were performed within the reporting period. If **Yes**, indicate whether documentation was submitted to CIBMTR (e.g., chimerism laboratory reports).

If chimerism studies were not performed within the reporting period, select **No**.

Question 50: Were chimerism studies assessed for more than one donor / multiple donors?

Indicate whether this HCT included product(s) from multiple donors. When a multi-donor chimerism exists and includes a donor or donors from a previous HCT, report as a multi-donor chimerism even though there may only be one donor for the current transplant.

Reporting Multiple Chimerism Studies:
FormsNet3^{SM} application: Complete the chimerism-specific questions for each chimerism study by adding an additional instance in the FormsNet3^{SM} application.
Paper form submission: Copy the chimerism-specific questions for each chimerism study since the date of last report.

Questions 51 – 65: Provide date(s), method(s) and other information for all chimerism studies performed since the date of last report

When reporting chimerism studies for multiple donors, there should be one instance for each donor for each chimerism test results. For haplo cords, (i.e., haplo donor PBSC and CBU), there should be an instance for both the CBU and the PBSC.

Transplant centers may perform frequent chimerism studies. If there is a need to reduce the number of chimerism study results reported due to volume, ensure that the following are reported at a minimum:

- Studies performed on or at approximately Day+28
- Most recent studies performed prior to the date of contact, particularly for Day+100
- Most recent studies performed prior to and after an intervention (such as a donor cellular infusion)
- The first result to show complete / 100% donor chimerism

Chimerism – Single Donor

Data Field	Description
51. Global Registration Identifiers for Donors (GRID)	The GRID standard (ICCBBA ST-015) is a 19-character donor identifier used to ensure that each donor ID is globally unique. For more information about the GRID, see the Pre-TED (2400) Forms Instruction Manual
52. NMDP cord blood unit ID	If the donor or one of the donors was an NMDP cord blood unit, enter the 9 digit NMDP cord blood unit ID.
53. Registry donor ID	If the donor or one of the donors was a non-NMDP unrelated PBSC or marrow donor, enter the registry donor ID.
54. Non-	If the donor or one of the donors was a non-NMDP cord blood unit, enter the non-NMDP registry

NMDP cord blood unit ID	donor ID.
55. Donor date of birth or age	If the donor was related or the cord blood unit was related or supplied by a non-NMDP registry, provide the date of birth, if known; if date of birth is not known, provide the donor's age at donation.
56. Sex	If the donor was related or the cord blood unit was related or supplied by a non-NMDP registry, provide the biological sex.
57. Date sample collected	Enter the date the sample was collected for the chimerism test.
58 – 59. Method	Report the test method used for the reported chimerism study. Cytogenetic testing methods include karyotyping and fluorescent in situ hybridization (FISH). Cytogenetic methods are only valid for sex mismatched transplants with the exception of quinicrine banding. VNTR / STR is one of the most common molecular methods for assessing chimerism. See the Chimerism Methods table below for additional details on chimerism testing methods.
60. Cell source	Report whether the specimen taken for chimerism testing was from a **Bone marrow** or **Peripheral blood** source.
61 – 62. Cell type	Indicate the cell type tested. If the specimen was not sorted for a specific cell line, indicate **Unsorted / whole**. See the Chimerism Cell Types table below for additional details on cell markers unique to certain cell lines.
63. Total cells examined	Cytogenetic testing methods include karyotyping and fluorescent in situ hybridization (FISH), each of which examines a specific and relatively low number of cells – generally 15 to 200, depending on specimen and test method. If a cytogenetic method was used, enter the total number of cells that were examined. If a non-cytogenetic test was used, leave these boxes blank.
64. Number of donor cells	Cytogenetic methods, karyotyping and FISH, examine a specific and relatively low number of cells – generally 15 to 200, depending on specimen and test method. If a cytogenetic method was used, enter the total number of cells that were examined and found to be of donor origin. If a non-cytogenetic test was used, leave these boxes blank.
65. Percent donor cells	Molecular testing methods include VNTR / STR, RFLP, and AFLP. Report the percentage of donor cells identified by molecular testing. If the test result did not detect any recipient cell population within the sensitivity of the assay, report 100% donor cells. If the test detected recipient cells, but indicated donor cells "> n%," report "n + 1" percent donor cells. If the test detected donor cells but indicated donor cells "< n%," report "n – 1" percent donor cells.

Chimerism Methods

Method	Description

Karyotyping for XX / XY	Cells are grown in culture, stained, and examined under a microscope to identify the **number** of cells matching the sex of the donor. This method is only valid when donor and recipient are sex mismatched.
Fluorescent in situ hybridization (FISH) for XX / XY	Cells are exposed to fluorescent DNA probes which attach to X and Y chromosomes. A microscope is used to identify the *number *of cells matching the sex of the donor. This method is only valid when donor and recipient are sex mismatched. *Do not report FISH testing for disease-specific abnormalities in the chimerism section of the Post-TED.*
Restricted fragment length polymorphisms (RFLP)	A restriction fragment is a portion of DNA which has been cut out by an enzyme. RFLP testing begins by isolating DNA from the sample. Enzymes are used to cut the DNA at specific loci resulting in many unique restriction fragments. The fragments are separated according to size by electrophoresis. The unique pattern of separation is used to identify the **percent** donor DNA present in the sample.
Variable number tandem repeat (VNTR), micro- or minisatellite	VNTR refers to a portion of DNA containing a repeating sequence of base pairs (micro- or minisatellite). The number of times a micro- or minisatellite repeats within specific loci can differ between individuals. These differences are used to distinguish donor DNA from recipient DNA. VNTR testing involves obtaining samples from the recipient and donor prior to transplant. Specific loci are compared to determine which loci contain VNTRs unique to the donor. After transplant, DNA is isolated from recipient samples. Donor-specific VNTRs are amplified by PCR techniques. The sample is then analyzed to determine the **percent** donor DNA present.
Small tandem repeat (STR), micro- or minisatellite	STR also refers to a portion of DNA containing a repeating sequence of base pairs (micro- or minisatellite). The number of times a micro- or minisatellite repeats within specific loci can differ between individuals. These differences are used to distinguish donor DNA from recipient DNA. STR testing involves obtaining samples from the recipient and donor prior to transplant. Specific loci are compared to determine which loci contain STRs unique to the donor. After transplant, DNA is isolated from recipient samples. Donor-specific STRs are amplified by PCR techniques. The sample is then analyzed to determine the **percent** donor DNA present.
Amplified fragment length polymorphisms (AFLP)	A restriction fragment is a portion of DNA which has been cut out by an enzyme. AFLP testing begins by isolating DNA from the sample. Enzymes are used to cut the DNA at specific loci resulting in many unique restriction fragments. Many restrictions fragments are amplified using PCR techniques. The fragments are separated according to size by electrophoresis. The unique pattern of separation is used to identify the **percent** donor DNA present in the sample. *Report AFLP testing using the VNTR/STR method option on the 2450 form.*

Chimerism Cell Types

Cell Type	Description
Unsorted / whole	The peripheral blood or bone marrow sample has not been sorted or selected for a certain cell line.

Red blood cells	Also known as RBCs or erythrocytes; carry the CD235a cell marker
Hematopoietic progenitor cells	Includes CD34+ cells
Total mononuclear cells	Total mononuclear cells would be a specimen containing only and both lymphocytes and monocytes
T cells	Includes CD3+, CD4+, and / or CD8+ cells
B cells	Includes CD19+ or CD20+ cells
Granulocytes	Also known as polymorphonuclear leukocytes (PMNs, PMLs) and includes neutrophils, eosinophils, and basophils. Includes CD33+ cells
NK cells	Includes CD56+ cells
Other, specify	Use this option to report cell types that do not fit in a category above.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q66- 88: Disease Assessment at the Time of Best Response to Infusion

Malignant Diseases Only
Only complete Disease Assessment at the Time of Best Response to Infusion questions if the HCT being reported was given to treat a malignant disease. If the HCT being reported was given to treat a non-malignant disease, leave these questions blank. FormsNet3^{SM} should enable / disable this section based on the primary disease reported on the Pre-TED Disease Classification Form (Form 2402). Contact the CIBMTR Customer Support if you believe FormsNet3^{SM} is incorrectly enabling / disabling these fields.

Combined Follow-Up
In scenarios where both HCT and cellular therapy forms are being completed and a disease specific form is being completed for the cellular therapy, disease assessment at time of best response is not reported on this form and these questions are disabled. It will be captured on the corresponding disease form.

This section collects the data known as “best response to transplant.” **The purpose of this section is to report the recipient’s best response to the planned course of the HCT.** This includes response to any therapy given for post-HCT maintenance or consolidation and does not include response to treatment given for relapsed, progressive or persistent disease. The best response is often achieved in the first 100 days. However, for some diseases such as multiple myeloma and CLL, the best response to HCT may take longer.

If the recipient relapses / progresses post-HCT and receives therapy for the disease relapse/progression, the response to that additional therapy should not be reported in this section. The best response prior to the relapse / progression should be reported. For subsequent reporting periods where the best response prior to the start of unplanned therapy was reported, if a CR was achieved prior to relapse / progression, the date of best response will be reported as **Previously reported**. If a CR was not achieved prior to relapse / progression, the best response will be reported as **Not evaluated**. Refer to the best response to infusion questions below for more information.

Reporting Complete Remission (CR) Post-HCT
Complete remission (CR) criteria vary by disease and are outlined in the CIBMTR Forms Instructions Manual. Please refer to the appropriate disease response criteria section of the Forms Instructions Manual and review the criteria to report CR.

Tandem Transplants: For recipients receiving a tandem transplant, the best response to the prior transplant (i.e., HCT #1 of the tandem) depends on the pre-transplant disease status.

- If the recipient was in complete remission at the time of HCT #1, report the best response to transplant as “Continued complete remission (CCR)”.
- If the recipient was not in complete remission at the time of HCT #1, and ***no*** disease assessments (including labs and / or physician’s exams) occurred in the reporting period, between HCT #1 and HCT #2 of their tandem transplant, report **Not evaluated**. However, ensure the best response to transplant and the current disease status are reported consistently
- If the recipient was not in complete remission at the time of HCT #1, and achieved complete remission prior to HCT #2 of their tandem transplant, report **Complete remission**, the date which complete remission was achieved
- If the recipient was not in complete remission at the time of HCT #1 and did not achieve complete remission in response to HCT #1 and prior to HCT #2 of their tandem transplant, report **Not in complete remission (NCR)**

Question 66: Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

If the recipient was already in CR at the start of the preparative regimen, check **Continued complete remission (CCR)**.

> **Continued Complete Remission (CCR)**
> Continued Complete Remission (CCR) should be reported for all patients who were already in CR at the start of the preparative regimen.

If the recipient achieved CR post-HCT (excluding unplanned therapy), check **Complete remission (CR)**.

If the recipient has not achieved a post-HCT CR to date, check **Not in complete remission**.

If the recipient’s disease status was not evaluated post-HCT, check **Not evaluated**. This option is **not** commonly used, as this would indicate that no tests (radiological, laboratory, or a clinical assessment) were performed to assess the CR status at **any time** during the reporting period.

If the recipient never achieved a post-transplant complete response and started unplanned therapy, given for relapsed, persistent, or progressive disease, in a previous reporting period, indicate “not evaluated.”

> **Example 1:** A recipient with neuroblastoma is not in complete remission prior to transplant, in the 100-day reporting period the recipient receives a tandem transplant. Between HCT 1 and HCT 2 the only disease assessment performed was a clinical evaluation. In this case either option would be appropriate to answer for the best response: “Not evaluated” or “Not in complete remission (NCR)” and “no disease detected but incomplete evaluation to establish CR”.

Question 67: Specify disease status if not in complete remission

For recipients **Not in complete remission**, indicate whether clinical evidence of disease persisted on

disease-specific assessments within the reporting period. If the most recent assessments have shown resolution of disease, but not all assessments required to report complete remission have been completed, indicate **No disease detected but incomplete evaluation to establish CR**. This option is also appropriate for scenarios in which the recipient has not previously achieved a post-HCT CR but does not have any disease assessments performed within the reporting period. If the most recent radiological or clinical / hematological assessment detects disease, indicate **Disease detected**. Persistence of abnormalities by molecular, cytogenetic, or flow cytometry assessments does not constitute 'disease detected' and should not be reported as disease detected for this question.

Example 2: A recipient with multiple myeloma goes to transplant in VGPR, without a bone marrow showing < 5% plasma cells completed prior to transplant. Post-transplant serum and urine electrophoreses and immunofixations are negative. However, no bone marrow biopsy is performed within the 100-day reporting period. In this case, "not in complete remission" should be selected for the best response, and "no disease detected by incomplete evaluation to establish CR" for specifying the disease status if not in complete remission data field.

Example 3: A recipient with AML goes to transplant in primary induction failure. Post-transplant, they recover their counts, but had circulating blasts noted on differential. They expire due to persistent disease with their last CBC performed on their date of death showing circulating blasts. In this case, "not in complete remission" should be selected for the best response to HCT, and "disease detected" for specifying the disease status if not in complete remission data field.

Example 4: Similar to example 2, a recipient with AML goes to transplant in primary induction failure. They expire on D+11 due to infection and had not engrafted as of that date. Their last CBC showed a WBC of 0.5×10^9/L with no blasts detected on their differential. A bone marrow biopsy was not performed between transplant and the date of death. In this case, "not in complete remission" should be selected for the best response to HCT, and "no disease detected by incomplete evaluation to establish CR" for specifying the disease status if not in complete remission data field.

Question 68: Was the date of best response previously reported?

Indicate whether complete remission was reported in a previously reporting period. This question does not apply if the best response is **Not in complete remission**.

Question 69: Date assessed

Report the date complete remission was achieved. This date should fall after transplant but before or on the date of contact for the current reporting period. This should reflect the date of specimen collection or imaging for the latest assessment required to fulfill complete remission criteria for the recipient's transplant disease.

Disease Assessment at Time of Best Response

The disease assessment questions (i.e., molecular, flow cytometry, cytogenetic, radiologic and clinical / hematologic assessments) refer to disease assessments performed at the time of best response (*Date*

assessed). The following guidelines should be used to determine whether testing was performed at the time of best response:

If the recipient's best response is **Not in Complete Remission**, report the latest assessment performed during the reporting period. If the recipient never achieved a CR and started treatment for progressive disease (excluding treatment for minimal residual disease), report the most recent assessments prior to progression. Review example E and F below.

If the recipient' best response is **Complete Remission**, report testing performed closest to the date of best response (*Date assessed*) and within the time windows in the Disease Assessment Time Windows table.

Disease Assessment Time Windows

Follow-Up Form	Approximate Range
100 Day	+/- 15 days of date of best response (*Date assessed*)
6 Month	+/- 15 days of date of best response (*Date assessed*)
Annual	+/- 30 days of date of best response (*Date assessed*)

Disease Assessment Reporting Scenarios:

A. A recipient receives a transplant on 1/1/2015 for multiple myeloma in partial remission. Prior to HCT, FISH testing detects an IGH rearrangement associated with the recipient's primary disease. During the 100 day reporting period, the recipient achieves a very good partial remission. FISH testing is only performed on 2/1/2015 is positive for the previously detected IGH rearrangement. The 100 day date of contact is 4/15/2015. In this case, the center would report the recipient was "Not in Complete Remission" on the 100 Day Post-TED Form. The center would report FISH testing was performed on 2/1/2015. When the best response is "Not in Complete Remission" report the most recent testing performed during the reporting period (assuming treatment was not started for relapsed, progressive, or persistent disease during the reporting period – see Scenario B).

B. A recipient receives a transplant on 1/1/2015 for multiple myeloma in partial remission. Prior to HCT, FISH testing detects an IGH rearrangement associated with the recipient's primary disease. During the 100 day reporting period, the recipient has disease progression and starts treatment on 3/1/2015. FISH testing is performed on 2/1/2015 and 3/15/2015. Both tests are positive for the previously detected IGH rearrangement. The 100 day date of contact is 4/15/2015. In this case, the center would report the recipient was "Not in Complete Remission" on the 100 Day Post-TED Form. The center would report FISH testing was performed on 2/1/2015. When the best response is "Not in Complete Remission" report the most recent testing performed during the reporting period and prior to treatment for relapsed, progressive or persistent disease.

Note: For all subsequent reporting periods, the center would report "Not Evaluated" for the best response to HCT and skip to the Post-HCT Therapy section of the form. If treatment was started in a prior reporting period, the center is not able to report, and assessments performed during the reporting

period and prior to treatment

C. A recipient receives a transplant on 1/1/2015 for AML in primary induction failure. Prior to HCT, molecular testing confirms the recipient's disease is FLT3 positive. On 2/1/2015, the recipient achieves a hematologic remission, but FLT3 is not tested at that time. Later, on 2/10/2015, molecular testing is performed and confirms the recipient is FLT3 negative. In this case, the center would report the recipient achieved a CR on 2/1/2015 on the 100 Day Post-TED Form. The center would report molecular testing was performed at the time of best response as testing was done within 15 days of 2/1/2015.

D. A recipient receives a transplant on 1/1/2015 for AML in primary induction failure. Prior to HCT, molecular testing confirms the recipient's disease is FLT3 positive. On 2/1/2015, the recipient achieves a hematologic remission, but FLT3 is not tested at that time. Later, on 3/1/2015, molecular testing is performed and confirms the recipient is FLT3 negative. In this case, the center would report the recipient achieved a CR on 2/1/2015 on the 100 Day Post-TED Form. The center would report no molecular testing was performed at the time of best response as testing was not done within 15 days of 2/1/2015.

E. A recipient receives a transplant on 1/1/2015 for NHL in stable disease. During the 100 Day reporting period, a PET / CT was performed on Day 60, confirming stable disease but then on Day 95, another PET / CT was performed and showed progression. As a result, therapy for progression began on Day 100. The best response to HCT for the Day 100 reporting period would be reported as "Not in complete remission – disease detected" and report "Yes," radiologic assessments were performed with the Day 60 PET / CT as this is the most recent scan prior to progression.

F. A recipient receives a transplant on 1/1/2020 for IgA Kappa Multiple Myeloma in stable disease. During the 100 Day reporting period, the first set of myeloma labs on Day 29, 1/30/2020, show progressive disease. Myeloma labs repeated on Day 60 and Day 100 also showed disease progression. As a result, therapy is planned to be given, starting in the 6-month reporting period, on Day 110. The best response to HCT for the Day 100 reporting period would be reported as "Not in complete remission – disease detected" and report "Yes," clinical / hematologic assessments were performed with the Day 100 myeloma labs, as this is the most recent testing in the reporting period. In cases where the first assessment post-HCT shows progression, report the last assessment prior to the start of treatment. If treatment doesn't start until the next reporting period, report the last assessment in the current reporting period.

Molecular

The molecular testing questions are intended to capture **molecular abnormalities** identified by **molecular methods**. Additional testing methods, such as FISH, may identify molecular marker results but should **not** be reported in the molecular section of the Post-TED (2450) Form. Abnormalities identified by karyotyping, FISH, or microarray should only be reported in the cytogenetic section of the Post-TED (2450) Form.

Question 70: Was the disease status assessed by molecular testing (e.g. PCR)?

Molecular assessment involves determining whether a molecular marker for the disease exists in the blood

or bone marrow. Molecular assessment is the most sensitive method of detection and can indicate known genetic abnormalities associated with the disease for which the HCT was performed. Molecular assessments include polymerase chain reaction (PCR) amplification to detect single specific disease markers; however, molecular methods are evolving and now include Sanger sequencing and next generation sequencing (e.g., Illumina, Roche 454, Proton / PGM, SOLiD). Molecular marker results identified by FISH or chromosomal microarray assessments should not be reported as molecular testing.

Report **Not applicable** if molecular studies were never performed or have never shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if molecular studies were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any progression or treatment for persistent / progressive disease, excluding treatment for minimal residual disease). Report **No** if assessments were not performed, prior to any progression or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient's best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows listed in the *Disease Assessments Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 71: Date assessed

If the best response is **Complete remission**, report the date of testing performed nearest to the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable.

If the best response is **Not in complete remission**, report the date of the most recent testing performed during the reporting period and prior to progression or treatment for persistent disease, if applicable.

Report the date of specimen collection for molecular disease assessment. If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms for information about reporting partial or unknown dates.

Question 72: Was disease detected?

Report whether the recipient's primary disease was detected by molecular testing on the date reported. This question may be reported as **Yes** even when **Not in complete remission – no disease detected but incomplete evaluation to establish CR** is reported as the best response. In order to be considered positive for disease, the assay must detect a number of copies of the molecular marker exceeding the threshold for sensitivity of the assay, for a quantitative study. However, do note that presence of only a single marker among numerous tested is sufficient to indicate disease detected.

Flow Cytometry

Question 73: Was the disease status assessed via flow cytometry?

Flow cytometry is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be quantified on cellular material. This allows for the detection of abnormal cell populations for some diseases.

Report **Not applicable** if flow cytometry was never performed or have never shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if flow cytometry studies were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any progression or treatment for persistent / progressive disease, excluding treatment for minimal residual disease). Report **No** if assessments were not performed, prior to any progression or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient's best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows listed in the *Disease Assessments Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 74: Date assessed

If the best response is **Complete remission**, report the date of testing performed nearest to the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable.

If the best response is **Not in complete remission**, report the date of the most recent testing performed during the reporting period and prior to progression or treatment for persistent disease, if applicable.

Report the date of specimen collection for flow cytometry assessment. If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 75: Was disease detected?

Report whether the recipient's primary disease was detected by flow cytometry on the date reported in question 93. Report **Yes** if an abnormal cell population associated with the recipient's primary transplant disease was detected regardless of the sensitivity of the flow cytometry panel performed; this means an abnormal cell population detected by MRD flow cytometry would be reported in the same way as an abnormal cell population detected by a standard flow cytometry assay. This question may be reported **Yes** even when **Not in complete remission – no disease detected but incomplete evaluation to establish**

CR is reported as the best response.

Cytogenetic Testing (Karyotyping or FISH)

Question 76: Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?

Cytogenetic studies involve the study of chromosomes, typically through one of two methods: karyotyping or fluorescence in situ hybridization (FISH). Blood, bone marrow, or tissue preparations may be tested by either of these two methods. Karyotyping is both less sensitive and less specific than FISH testing; FISH studies identify only abnormalities detectable by the employed probe set and cannot provide information about the presence or absence of chromosomal abnormalities or markers outside the specific probe set utilized.

Report **Not applicable** if cytogenetic studies were never performed or have never shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if cytogenetic studies were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any progression or treatment for persistent / progressive disease, excluding treatment for minimal residual disease). Report **No** if assessments were not performed, prior to progression or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient's best response is **Complete Remission**, report Yes if disease assessments were performed within the time windows listed in the *Disease Assessments Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 77: Was the disease status assessed via FISH?

FISH XX/XY probe sets are not considered relevant to disease assessment and should not be reported in the disease assessment section.

Chromosomal microarrays / chromosomal genomic arrays should be reported as FISH assessments.

Report **Not applicable** if FISH studies were never performed or have never shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if FISH studies were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any progression or treatment for persistent / progressive disease, excluding treatment for minimal residual disease). Report **No** if assessments were not performed, prior to any progression or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient's best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows listed in the *Disease Assessments Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 78: Date assessed

If the best response is **Complete remission**, report the date of testing performed nearest the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable.

If the best response is **Not in complete remission**, report the date of the most recent testing performed during the reporting period and prior to progression or treatment for progressive disease, if applicable.

Report the date of specimen collection for FISH assessment. If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 79: Was disease detected?

Report whether the recipient's primary disease was detected by FISH testing on the date reported. This question may be reported as **Yes** even when **Not in complete remission – no disease detected but incomplete evaluation to establish CR** is reported as the best response.

Question 80: Was the disease status assessed via karyotyping?

Report **Not applicable** if karyotyping was never performed or hasnever shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if karyotyping studies were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any relapse, progression or treatment for persistent disease, (excluding treatment for minimal residual disease). Report **No** if assessments were not performed, prior to any relapse, progression, or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient' best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows in the Disease Assessments Time Windows table above. If testing was not performed within the applicable time window, report **No**.

Question 81: Date assessed

If the best response is **Complete remission**, report the date of testing performed nearest the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable.

If the best response is **Not in complete remission**, report the date of the most recent testing performed during the reporting period and prior to progression or treatment for persistent disease, if applicable.

Report the date of specimen collection for karyotyping. If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 82: Was disease detected?

Report whether the recipient's primary disease was detected by karyotyping on the date reported. Do not include clinically insignificant polymorphism, or chromosomal abnormalities of no known significance, as disease detected; this includes anomalies such as age-dependent loss of the chromosome Y. This question may be reported as **Yes** even when **Not in complete remission – no disease detected but incomplete evaluation to establish CR** is reported as the best response.

Radiologic

Question 83: Was the disease status assessed by radiological assessment (e.g. PET, MRI, CT)

Radiologic assessments are imaging techniques used to assess disease response to transplant, typically for lymphomas or solid tumors, though valuable in some less common presentations of disease, such as leukemia cutis. Imaging techniques used to evaluate disease response typically include PET, CT, or MIBG, but may include x-ray, skeletal survey, or ultrasound in some cases.

Report **Not applicable** if radiological assessments were never performed or have never shown abnormalities associated with the recipient's primary transplant disease.

Once an assessment is positive for disease, **Not applicable** will never be an appropriate response.

Report **No** if radiological assessments were positive for disease in the past but not performed during the current reporting period.

If the recipient's best response is **Not in Complete Remission**, report **Yes** if assessments were performed, prior to any progression or treatment for persistent / progressive disease, excluding treatment for minimal residual disease). Report No if assessments were not performed, prior to any progression or treatment for persistent disease (excluding treatment for minimal residual disease).

If the recipient's best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows listed in the *Disease Assessments Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 84: Date assessed

If the best response is **Complete remission**, report the date of the assessment performed nearest the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable.

This date may match the date CR was achieved reported in *Date assessed* for the best response for recipients with lymphomas, solid tumors, or other diseases with imaging criteria for reporting CR.

If the best response is **Not in complete remission – no disease detected but incomplete evaluation to establish CR**, report the last assessment performed in the reporting period and prior to progression or treatment for persistent / progressive disease, if applicable.

If the best response is **Not in complete remission – disease detected**, report the most recent radiological testing performed in the reporting period that detects disease and prior to progression or treatment for persistent disease, if applicable. If disease was not detected by this method report the date of the most recent radiological testing performed **and** prior to progression or treatment for persistent disease, if applicable.

If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 85: Was disease detected?

Report whether the recipient's primary disease was detected by radiologic assessment on the reported date.

Clinical / Hematologic

> **Reporting 'No' for Clinical / Hematologic Assessments**
> The **No** option should rarely be used as this would indicate *no* clinical / hematologic assessments (including labs and physician's exams) were not performed at the time of best response.

Question 86: Was the disease status assessed by clinical / hematologic assessment?

Clinical / hematologic disease assessments are the least sensitive method of disease detection. Examples include circulating blasts in the bloodstream for AML, and enlargement of a malignant mass for lymphoma or a solid tumor on physical examination. Every recipient who has an evaluation by a physician has a "clinical" assessment. Do not include radiologic or imaging assessments when answering this question.

If the recipient's best response is **Not in Complete Remission**, report **Yes** If assessments were performed prior to progression or treatment for persistent disease, (excluding treatment for minimal residual disease). Report **No** If assessments were not performed prior to progression or treatment for persistent disease, (excluding treatment for minimal residual disease).

If the recipient' best response is **Complete Remission**, report **Yes** if disease assessments were performed within the time windows in the *Disease Assessment Time Windows* table above. If testing was not performed within the applicable time window, report **No**.

Question 87: Date assessed

If the best response is **Complete remission**, report the date of the assessment performed nearest the date of best response (within the time windows listed in the *Disease Assessments Time Windows* table above) and prior to relapse or progression, if applicable. This will likely match the date CR reported in Date assessed for the best response, since complete remission criteria generally require clinical or hematologic assessment to confirm.

If the best response is **Not in complete remission – no disease detected but incomplete evaluation to establish CR**, report the last assessment performed in the reporting period and prior to progression or treatment for persistent disease, if applicable.

If the best response is **Not in complete remission – disease detected**, report the most recent assessment performed in the reporting period that detects disease and prior to progression or treatment for persistent disease, if applicable. If disease was not detected by this method report the date of the most recent assessment performed **and** prior to progression or treatment for persistent disease, if applicable.

If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Question 88: Was disease detected?

Report whether clinical / hematologic abnormalities associated with the primary disease were detected. In general, if the clinical / hematologic assessment date is the same as the reported *Date assessed* for the best response, for recipients achieving complete remission in the reporting period, the answer to this question should be **No**.

Section Updates:

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

Last modified: Jul 29, 2024

Q89 – 97: Post-Infusion Therapy

Malignant Diseases Only
Only complete the *Therapy for reasons other than relapse, persistent, or progressive disease* questions if the HCT being reported was given to treat a malignant disease. If the HCT being reported was given to treat a non-malignant disease, leave the *Therapy for reasons other than relapse, persistent, or progressive disease* questions blank.
FormsNet3^{SM} should enable / disable this section based on the primary disease reported on the Pre-TED Disease Classification Form (2402) Form. Contact the CIBMTR Customer Service Center if you believe FormsNet3^{SM} is incorrectly enabling / disabling these fields.

Combined Follow-Up
In scenarios where both HCT and cellular therapy forms are being completed and a disease specific form is being completed for the cellular therapy, post-infusion therapy is not reported on this form and these questions are disabled. It will be captured on the corresponding disease form.

Report therapy given since the date of last report for reasons other than relapse, persistent, or progressive disease. This may include maintenance and consolidation therapy as well as treatment for minimal residual disease. Do not report any therapy given for relapse, persistent, or progressive disease.

Question 89: Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include maintenance and consolidation therapy)

Indicate whether therapy was given during the reporting period for maintenance or consolidation; this therapy may have been specifically planned as part of the original transplant protocol or determined after transplant. Do not include therapy given for relapse, persistent, or progressive disease. Any post-transplant therapy included as part of the initial transplant protocol should be reported in this area of the form.

Question 90: Specify Therapy (check all that apply)

Indicate which therapies were given since the date of the last report for reasons other than relapse, persistent, or progressive disease.

Systemic therapy: refers to a delivery mechanism where a therapeutic agent is delivered orally or intravenously, enters the bloodstream, and is distributed throughout the body. Indicate whether systemic therapy was given during the reporting period for reasons other than relapse, persistent, or progressive disease and report the systemic therapy given.

Radiation: Radiation therapy uses high-energy radiation to kill cancer cells. External beam radiation is one of the more frequently used types of radiation. In this method, a beam of radiation is delivered to a specific part of the body, such as the mediastinum. Radiation may be planned if bulky disease was present just prior to transplant for a recipient with lymphoma or a solid tumor. Indicate whether radiation therapy was given

during the reporting period for reasons other than relapse, persistent, or progressive disease.

Cellular therapy: Cellular therapy refers to the infusion of human or animal derived cells, which may or may not be modified or processed to achieve a specific composition. Examples include CAR T-cell, NK cell, and mesenchymal cell infusions as well as donor cellular infusions. Select this option if the recipient received any form of cellular therapy for reasons other than relapse, persistent, or progressive disease or decreasing / loss of donor chimerism; hematopoietic cell transplantation should not be reported as cellular therapy. Indicate whether a cellular therapy was infused during the reporting period for reasons other than relapse, persistent, or progressive disease .

Blinded randomized trial: A blinded, randomized trial refers to a research treatment protocol in which the participant is assigned to the control arm or investigational group, and the researcher or clinician is not informed whether the subject is receiving the placebo or standard of care versus the investigational therapy. This makes it impossible to report agents or therapies the recipient is receiving. Indicate whether the recipient is receiving therapy on a randomized, blinded clinical trial during the reporting period for reasons other than relapse, persistent, or progressive disease

Other therapy: Indicate whether the recipient received additional therapy for reasons other than relapsed, persistent, or progressive disease which does not fit into the previous categories. Examples may include intrathecal therapy or surgery. Specify the other therapy.

Questions 91 – 92: Specify systemic therapy (check all that apply)

Systemic therapy agents and treatment regimens vary based on disease, prognosis, and protocol. Treatment may consistent of one or multiple drugs, and may be given in an inpatient or outpatient setting; additionally, drugs may be administered on a single day, over consecutive days, or continuously.

Form options are arranged alphabetically. Indicate which systemic therapy agents were administered during the current reporting period for reasons other than relapse, persistent, or progressive disease. If the recipient received a therapeutic agent that is not listed, select **Other systemic therapy** and specify the therapy.

> ! **Steroids Administered Post-HCT**
> Previously, steroids given for reasons other than relapsed, persistent, or progressive disease were reported in the **Other systemic therapy** section of the Post-TED (2450) Form. We no longer capture steroids (e.g. dexamethasone) on our Post-TED (2450) Form and they **should not** be reported here.

Question 93: Specify other therapy

Specify other therapy the recipient received additional therapy for reasons other than relapsed, persistent, or progressive disease which does not fit into the previous form categories. Examples may include intrathecal therapy or surgery.

Questions 94 – 95: Did a fecal microbiota transplant (FMT) occur since the date of last report?

Fecal microbiota transplant (FMT) is a procedure where fecal matter is collected from a pre-screened donor and transferred to a recipient by the oral or rectal route (i.e., by nasogastric tube or enema) in order to restore intestinal microbial flora.

Indicate **Yes** if the recipient received a FMT in the current reporting period. If **Yes**, report the date of the FMT. If multiple FMTs occurred during the reporting period, report the date of the first procedure.

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

If a FMT did not occur or it is not known if one occurred during the current reporting period, select **No**.

Questions 96 – 97: Specify indication for the FMT

Specify the indication for the FMT. If the indication is not listed, select Other and specify.

Section Updates:

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

Last modified: Jul 29, 2024

Q98 – 108: Relapse or Progression Post-Infusion

Malignant Diseases Only
Only complete the relapse or progression post-infusion questions if the HCT being reported was given to treat a malignant disease. If the HCT being reported was given to treat a non-malignant disease, leave these questions blank. Intervention for relapsed, persistent, or progressive disease questions must be completed regardless of disease type.
FormsNet3^{SM} should enable / disable this section based on the primary disease reported on the Pre-TED Disease Classification (2402) Form. Contact the CIBMTR Center Support if you believe FormsNet3^{SM} is incorrectly enabling / disabling these fields.

Report if the recipient has experienced a clinical/hematologic relapse or progression post-HCT. If the relapse or progression was detected in a previous reporting period indicate that and continue on. If the first clinical/hematologic relapse occurred since the date of the last report, indicate the date it was first detected in this reporting period.

Combined Follow-Up
In scenarios where both HCT and cellular therapy forms are being completed and a disease specific form is being completed for the cellular therapy, relapse or progression post-infusion is not reported on this form and these questions are disabled. It will be captured on the corresponding disease form.

Question 98: Did the recipient experience a clinical / hematologic relapse or progression post-HCT?

Clinical / hematologic assessment is the least sensitive method of disease detection. Examples include circulating blasts in the bloodstream for AML, or enlargement of a malignant mass for lymphoma or a solid tumor. Every recipient who has an evaluation by a physician has a “clinical” assessment. Include radiographic evidence of relapse or progression as clinical/hematologic relapse or progression. Disease specific criteria for establishing relapse or progression are published as part of the CIBMTR Forms Instructions Manual. If the recipient dies, and the relapse or progression of disease is discovered by autopsy, the date of assessment should be reported as the date of death, not the autopsy date.

If clinical / hematologic evidence of relapse / progressive disease was found at any time post-transplant, check **Yes**.

If clinical / hematologic evidence of relapse / progressive disease was not found at any time post-transplant, check **No**.

Question 99: Was the date of clinical / hematologic relapse or progression previously reported?

Only the date of first clinical / hematologic relapse or progression post-transplant needs to be reported.

Therefore, if the recipient experienced clinical / hematologic relapse or progression in a prior reporting period and it was reported on the prior form, report **Yes**. If this is the report of first instance of clinical/ hematologic relapse or progression, indicate **No**.

Question 100: Date first seen

Indicate the date relapse/progressive disease was determined by clinical / hematological evaluation. If exact date is not known, refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

> **Combined Follow-Up**
> In scenarios where both HCT and cellular therapy forms are being completed and a disease specific form is being completed for the cellular therapy, intervention is not reported on this form and these questions are disabled. It will be captured on the corresponding disease form.

Question 101: Was intervention given for relapsed, persistent or progressive disease since the date of last report?

Indicate whether therapy was given during the reporting period for persistent or relapsed / progressive disease. Do not include therapy given for maintenance or planned post-transplant consolidation. Any post-transplant therapy included as part of the initial transplant protocol should not be reported in this area of the form.

If treatment for relapse / progression started after the reporting period in which relapse / progression was first reported in, the *intervention for relapse / persistent / progressive disease* data fields are disabled and relapse / progression treatment is not captured.

See the *Intervention reporting scenarios* provided below for further clarification.

Question 102: Specify reason for which intervention was given

Indicate whether therapy was given for persistent or relapsed / progressive disease. If therapy continued from a prior reporting period and a new therapy was started for a different reason during the current reporting period, report the reason the new therapy was started. See the *Intervention reporting scenarios* provided below for further clarification.

Question 103: Specify the method(s) of detection for which intervention was given (check all that apply)

Indicate the methods detecting the reason for which therapy for persistent disease or relapsed / progressive disease was given (as reported above). Indicate all methods of disease assessment in which disease was detected; given that the assessment was performed prior to the start of the intervention(s) and was consistent with the rationale reported above. There may be some cases for which an assessment by a particular method was last performed in the prior reporting period but was still consistent with the justification reported; in this case, the method of disease assessment should be indicated.

For example, in the 100-day reporting period, the last cytogenetic assessment detected a new abnormality associated with the recipient's primary transplant disease. In this case, monosomy 7 was identified on a peripheral blood sample for a recipient transplanted for AML in CR1 with normal cytogenetics prior to transplant. In the 6-month reporting period, relapse was detected in the bone marrow morphology (clinical assessment) and concurrent flow cytometry (flow cytometry) and therapy was initiated for relapsed / progressive disease. In this case, each of these methods should be indicated on the Post-TED (2450) Form in the 6-month reporting period.

If multiple therapies were given during the reporting period for different reasons (e.g., the recipient initially receives treatment for persistent disease and subsequently receives different treatment for progressive disease during the same reporting period), indicate any methods of detection confirming the reason above. See the *Intervention reporting scenarios* provided below for further clarification.

If assessment by that method was not performed or was performed and not consistent with the reason for which intervention was given reported above, do not indicate it in this question.

See below for definitions and examples of each method of detection:

- **Clinical / hematologic:** Clinical / hematologic assessment is the least sensitive method of disease detection. Examples include circulating blasts in the bloodstream for AML, or enlargement of a malignant mass for lymphoma or a solid tumor. Every recipient who has an evaluation by a physician has a "clinical" assessment. Examples of clinical/hematologic assessments include: bone marrow biopsy / morphologic evaluation, complete blood count, serum protein electrophoresis, etc.
- **Radiologic (e.g., PET, MRI, CT):** Radiologic assessments are imaging techniques used to assess disease response. Imaging techniques used to evaluate disease response typically include PET, CT, or MIBG, but may include x-ray, skeletal survey, or ultrasound in some cases.
- **Cytogenetic:** Cytogenetic studies involve the study of chromosomes, typically through one of two methods: karyotyping or fluorescence in situ hybridization (FISH). Blood, bone marrow, or tissue preparations may be tested by either of these two methods. Karyotyping is both less sensitive and less specific than FISH testing; FISH studies identify only abnormalities detectable by the employed probe set and cannot provide information about the presence or absence of chromosomal abnormalities or markers outside the specific probe set utilized.
- **Flow cytometry:** Flow cytometry is a technique that can be performed on blood, marrow, or tissue preparations where the cell surface markers can be quantified on cellular material. This allows for the detection of abnormal cell populations for some diseases. Flow cytometry may also be referred to as immunophenotyping.
- **Disease specific molecular marker:** Molecular assessment involves determining whether a molecular marker for the disease exists in the blood or bone marrow. Molecular assessment is the most sensitive method of detection and can indicate known genetic abnormalities associated with the disease for which the HCT was performed.

Question 104: Date intervention started

Report the date therapy was started for the reason specified above; if multiple instances, cycles, or lines of therapy are administered, report the date of the first treatment. If treatment was started in a prior reporting

period and continues into the current reporting period, report the original therapy start date (prior to the start of the current reporting period) and override the validation error in FormsNet3^{SM} using the code “verified correct.” If therapy was stopped in a prior reporting period and restarted (or a new therapy was started) during the current reporting period, report the earliest date treatment was administered during the current reporting period. See the *Intervention reporting scenarios* provided below for further clarification.

Intervention Reporting Scenarios

A. A recipient with NHL in complete remission at the time of HCT has a relapse during the 100 day reporting period. Relapse was detected by a PET scan and a lymph node biopsy. Following these assessments, rituximab was started on 5/1/2016. The disease did not respond to this therapy prompting a switch to brentuximab on 6/1/2016. The 100 Day date of contact is 6/15/2016.

100 Day Post-TED Form:

Was intervention given for relapsed, persistent or progressive disease since the date of last report: Report “Yes” to indicate therapy was given for relapsed disease during this reporting period.
Specify reason for which intervention was given: Report “Relapsed / progressive disease.”
Specify the method(s) of detection for which intervention was given: Check the boxes to indicate that disease was detected by both clinical/hematologic (lymph node biopsy) and radiological (PET Scan) assessments. All other methods of detection must be left blank.
Date intervention started: Report “5/1/2016” to reflect the date of the first treatment given for relapsed disease.
Specify therapy: Report both rituximab and brentuximab as treatments for relapsed disease given during the reporting period.

B. A recipient with multiple myeloma in VGPR at the time of HCT was started on maintenance lenalidomide during the six month reporting period. Later in the reporting period, progression was detected by serum protein electrophoresis on 9/15/2014 and so the recipient stopped lenalidomide and started bortezomib as well as dexamethasone on 9/20/2014 The recipient continued bortezomib and dexamethasone treatment into the one year reporting period.

Six Month Post-TED Form:

Was intervention given for relapsed, persistent or progressive disease since the date of last report: Report “Yes” to indicate therapy was given for progressive disease during this reporting period.
Specify reason for which intervention was given: Report “Relapsed / progressive disease.”
Specify the method(s) of detection for which intervention was given: Check the box to indicate that disease was detected by clinical/hematologic (serum protein electrophoresis) assessment. All other methods of detection must be left blank.
Date intervention started: Report “9/20/2014” to reflect the date of the first treatment given for progressive disease.
Specify therapy: Report bortezomib as treatment for progressive disease given during the reporting period. Dexamethasone is no longer captured on the Post-TED (2450) Form. The lenalidomide therapy

should not be reported in this section of the form. This medication was given as maintenance therapy and will therefore be reported under Post-HCT Therapy.

One Year Post-TED Form:

Intervention given for relapse, persistent, or progressive disease questions: These questions will be disabled in FormsNet3. Starting with Revision 5 of the Post-TED 2450, therapy given for relapsed or progressive disease will only be captured in the reporting period in which treatment first started.

C. A recipient with multiple myeloma in PR at the time of HCT was started on lenalidomide during 100 day reporting period (started 3/15/2012) due to persistent disease (detected by serum electrophoresis testing). This treatment was not planned and was given due to an unsatisfactory disease response to HCT. Thirty days after lenalidomide was started, a karyotype assessment confirmed persistent cytogenetic abnormalities present in a bone marrow sample. Lenalidomide was continued into the six month reporting period, during which, there was disease progression (detected by serum electrophoresis). Lenalidomide was stopped and carfilzomib was started on 5/30/2012. By the end of the six month reporting period, the recipient achieved a complete remission in response to carfilzomib and was switched to a lower maintenance dose of carfilzomib which was continued into the one year reporting period.

100 Day Post-TED Form:

Was intervention given for relapsed, persistent or progressive disease since the date of last report: Report “Yes” to indicate therapy was given for persistent disease during this reporting period.
Specify reason for which intervention was given: Report “Persistent disease.”
Specify the method(s) of detection for which intervention was given: Check the box to indicate that disease was detected by clinical/hematologic (serum protein electrophoresis) assessment. All other methods of detection must be left blank. The karyotype test would not be reported as a method of detection since it was performed after treatment was started and, therefore, did not inform the decision to start lenalidomide.
Date intervention started: Report “3/15/2012” to reflect the date of the first treatment for persistent disease.
Specify therapy: Report lenalidomide as the only treatment given during the reporting period.

Six Month Post-TED Form:

Was intervention given for relapsed, persistent or progressive disease since the date of last report: Report “Yes” to indicate therapy was given for persistent and progressive disease during this reporting period.
Specify reason for which intervention was given: Report “relapsed / progressive disease.” If therapy continued from a prior reporting period and a new therapy was started for a different reason during the current reporting period, report the reason the new therapy was started.
Specify the method(s) of detection for which intervention was given: Check the box to indicate that disease was detected by clinical/hematologic (serum protein electrophoresis) assessment. All other methods of detection must be left blank.
Date intervention started: Report “5/30/2012” to reflect the date of the first treatment for progressive

disease.
Specify therapy: Report the lenalidomide and carfilzomib as treatments received during the reporting period

One Year Post-TED Form:

Was intervention given for relapsed, persistent or progressive disease since the date of last report: Report “No” to indicate therapy was not given for persistent or relapsed / progressive disease during this reporting period. The lower dose carfilzomib given as maintenance (to keep the recipient in CR) must be reported in the Post-HCT Therapy Section of the Post-TED Form. Reporting “No” will disable questions the remaining *intervention for relapse, persistent, or progressive disease* questions.

Question 105: Specify therapy (check all that apply)

Indicate which therapies were given since the date of the last report for relapsed, persistent, or progressive disease.

Systemic therapy: refers to a delivery mechanism where a therapeutic agent is delivered orally or intravenously, enters the bloodstream, and is distributed throughout the body. Indicate whether systemic therapy was given during the reporting period for relapsed, persistent, or progressive disease and report the systemic therapy.

Radiation: Radiation therapy uses high-energy radiation to kill cancer cells. External beam radiation is one of the more frequently used types of radiation. In this method, a beam of radiation is delivered to a specific part of the body, such as the mediastinum. Radiation may be planned if bulky disease was present just prior to transplant for a recipient with lymphoma or a solid tumor. Indicate whether radiation therapy was given during the reporting period for relapsed, persistent, or progressive disease.

Cellular therapy: Cellular therapy refers to the infusion of human or animal derived cells, which may or may not be modified or processed to achieve a specific composition. Examples include CAR T-cell, NK cell, and mesenchymal cell infusions as well as donor cellular infusions. Select this option if the recipient received any form of cellular therapy for relapse, persistent, or progressive disease; hematopoietic cell transplantation should not be reported as cellular therapy. Indicate whether a cellular therapy was infused during the reporting period for relapsed, persistent, or progressive disease.

Blinded randomized trial: A blinded, randomized trial refers to a research treatment protocol in which the participant is assigned to the control arm or investigational group, and the researcher or clinician is not informed whether the subject is receiving the placebo or standard of care versus the investigational therapy. This makes it impossible to report agents or therapies the recipient is receiving. Indicate whether the recipient is receiving therapy on a randomized, blinded clinical trial during the reporting period for relapsed, persistent, or progressive disease.

Other therapy: Indicate whether the recipient received additional therapy for relapsed, persistent, or progressive disease which does not fit into the previous categories. Examples may include intrathecal therapy or surgery. Specify the other therapy given.

Questions 106 – 107: Specify systemic therapy (check all that apply)

Systemic therapy agents and treatment regimens vary based on disease, prognosis, and protocol. Treatment may consistent of one or multiple drugs and may be given in an inpatient or outpatient setting; additionally, drugs may be administered on a single day, over consecutive days, or continuously.

Form options are arranged alphabetically. Indicate which systemic therapy agents were administered during the current reporting period for relapse, persistent, or progressive disease. If the recipient received a chemotherapy agent that is not listed (e.g. cyclophosphamide), **Chemotherapy** should be selected. If the recipient received a therapeutic agent, other than chemotherapy, that is not listed, select **Other systemic therapy** and specify the systemic therapy.

> ! **Steroids Administered Post-HCT**
> Previously, steroids given for relapsed, persistent, or progressive disease were reported in the “other systemic therapy” section of the Post-TED (2450) Form. We no longer capture steroids (e.g. dexamethasone) on our Post-TED (2450) Form and they **should not** be reported here.

Question 108: Specify other therapy

Specify other therapy the recipient received additional therapy for reasons other than relapsed, persistent, or progressive disease which does not fit into the previous form categories. Examples may include intrathecal therapy or surgery.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2024

Q109 – 111: Current Disease Status

Malignant Diseases Only
Only complete the *Current Disease Status* section if the HCT being reported was given to treat a malignant disease. If the HCT being reported was given to treat a non-malignant disease, leave these questions blank. FormsNet3^{SM} should enable / disable this section based on the primary disease reported on the Pre-TED Disease Classification (2402) Form. Contact the CIBMTR Center Support if you believe FormsNet3^{SM} is incorrectly enabling / disabling these fields.

Combined Follow-Up
In scenarios where both HCT and cellular therapy forms are being completed and a disease specific form is being completed for the cellular therapy, current disease status is not reported on this form and these questions are disabled. It will be captured on the corresponding disease form.

Tandem Transplants: For recipients receiving a tandem transplant, the current disease status prior to HCT #2 of the tandem depends on the pre-transplant disease status and the best response to the prior transplant (i.e., HCT #1 of the tandem).

- If the recipient was in complete remission at the time of HCT #1 or achieved complete remission prior to HCT #2 of their tandem transplant, the current disease status should be reported as “Complete remission (CR)” (given there is no evidence of relapse / progression disease based on labs / clinical assessments between the tandem HCTs).
- If the recipient was not in complete remission or did not achieve complete remission in response to HCT #1 prior to HCT #2 of their tandem transplant, either “Not in complete remission (NCR)” or “Not evaluated” would be appropriate options; however, ensure the best response to transplant and the current diseases status are answered consistently

Question 109: What is the current disease status?

Indicate the disease status of the primary transplant disease as of the last evaluation in the reporting period. Complete remission (CR) criteria vary by disease and are outlined in the CIBMTR Forms Instructions Manual. If the recipient achieves CR or continues in CR at the time of last evaluation in the reporting period, indicate **Complete remission (CR)**. If the recipient is not in CR due to presence of disease on last evaluation in the reporting period or an incomplete evaluation that does not allow for reporting CR, indicate **Not in complete remission**. If the recipient’s disease status was not evaluated post-HCT, check **Not evaluated** and submit the form. This option is **not** commonly used, as this would indicate that **no tests** (radiological, laboratory, or a clinical assessment) were performed to assess the CR status at **any time** during the reporting period.

The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting

period in order to complete current disease status data fields. Once a particular disease status is achieved, the center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.

Example 1: A recipient with neuroblastoma is not in complete remission prior to transplant, in the 100-day reporting period the recipient receives a tandem transplant. Between HCT 1 and HCT 2 the only disease assessment performed was a clinical evaluation. In this case either option would be appropriate to answer for the current disease status: “Not evaluated” or “Not in complete remission (NCR)” and “no disease detected but incomplete evaluation to establish CR.”. However, we want to ensure the best response and the current disease status are consistent.

Example 2: A recipient with neuroblastoma is in complete remission prior to transplant, in the 100-day reporting period the recipient receives a tandem transplant. Between HCT 1 and HCT 2 the only disease assessment performed was a clinical evaluation in which the clinician did not mention progressive or relapsed disease. In this case “Complete remission (CR)” should be reported for the current disease status.

Question 110: Specify disease status if not in complete remission

Disease status criteria are generally based upon clinical assessment confirming ongoing presence or absence of disease. However, there are also situations in which an evaluation may have been performed but be incomplete and not have all testing required in order to meet the criteria for reporting complete remission (CR).

For recipients **Not in complete remission**, indicate whether clinical evidence of disease persisted on disease-specific assessments within the reporting period. If all assessments have shown resolution of disease, but not all assessments required to report complete remission have been completed, indicate **No disease detected but incomplete evaluation to establish CR**. This option is also appropriate for scenarios in which the recipient has not previously achieved a post-HCT CR but does not have any disease assessments performed within the reporting period. Indicate **Disease detected** if disease persists by any method of radiological or clinical assessment; persistence of abnormalities by molecular, cytogenetic, or flow cytometry assessments does not constitute “disease detected.”

Example 1: A recipient with multiple myeloma goes to transplant in VGPR, without a bone marrow showing < 5% blasts completed prior to transplant. Post-transplant serum and urine electrophoreses and immunofixations are negative. However, no bone marrow biopsy is performed within the 100-day reporting period. In this case, “not in complete remission” should be selected for question the current disease status, and “no disease detected by incomplete evaluation to establish CR” for the specify disease status if not in complete remission question.

Example 2: A recipient with AML goes to transplant in primary induction failure. Post-transplant, they recover their counts, but had circulating blasts noted on differential. They expire due to persistent disease with their last CBC performed on their date of death showing circulating blasts. In this case, “not in complete remission” should be selected for the current disease status, and “disease detected” for the specify disease status if not in complete remission question.

Example 3: Similar to example 2, a recipient with AML goes to transplant in primary induction failure. They expire on D+11 due to infection and had not engrafted as of that date. Their last CBC showed a WBC of 0.5 × 109/L with no blasts detected on their differential. A bone marrow biopsy was not performed between transplant and the date of death. In this case, “not in complete remission” should be selected for the current disease status, and “no disease detected by incomplete evaluation to establish CR” for the specify disease status if not in complete remission question.

Question 111 Date of assessment of current disease status

Report the date of latest clinical / hematologic assessment for the current disease status using the guidelines below:

Report the date of the clinical / hematologic assessment using the guidelines below:

- If the current disease status is **Complete remission**, report the date of the most disease specific clinical / hematologic or radiologic assessment performed within approximately 30 days of the contact date.
- If the current disease status is **Not in complete remission – disease detected**, report the most recent clinical / hematologic or radiologic assessment performed in the reporting period that detects disease.
- If the current disease status is **Not in complete remission – no disease detected but incomplete evaluation to establish CR**, report the last clinical / hematologic or radiologic assessment performed in the reporting period.
- If there are no disease-specific assessments within the reporting period, report the latest assessment in which the recipient was clinically assessed by a physician or midlevel clinician. In this scenario, this date does not need to be consistent with the disease status reported current disease status.

Refer to General Instructions, General Guidelines for Completing Forms, for information about reporting partial or unknown dates.

Example 1: The current disease status for a recipient with non-Hodgkin’s lymphoma is “complete remission.” A PET scan was performed 3 months prior to the contact date showing no evidence of disease and a physician’s exam was performed on the contact date. In this case, the physician’s exam performed on the contact date should be reported as the current disease assessment date since this is the most disease specific clinical / hematologic assessment performed within 30 days of the contact date.

Example 2: For a recipient with neuroblastoma, the current disease status is “not in complete remission – disease detected” since disease was still present on the last PET scan. The PET scan was performed 7 months prior to the contact date and a physician’s exam was performed on the contact date – disease cannot be detected by the physician’s exam. The date of the PET scan should be reported as the current disease assessment date since this is the most disease specific clinical / hematologic assessment showing evidence of disease.

Example 3: The bone marrow biopsy performed for a recipient with AML still showed > 5% blasts in the bone marrow and therefore, the current disease status is reported as “not in complete remission – disease

detected." The bone marrow biopsy was performed 6 months prior to the contact date and a CBC was performed 2 weeks prior to the contact date – the CBC showed > 5% blasts in the blood. In this scenario, the current disease assessment date should be reported as the date of the CBC as this is the most recent disease specific clinical / hematologic assessment showing evidence of disease.

Example 4: A recipient with multiple myeloma had a bone marrow biopsy performed 2 weeks prior to the contact date which showed < 5% plasma cells; however, the last set of myeloma labs performed in the prior reporting period still showed evidence of disease; these labs were not repeated in the current reporting period. On the contact date, a physician's exam was performed. The current disease status is "not in CR – no disease detected but incomplete evaluation to establish CR" and the current disease assessment date should be reported as the date of the physician's exam as this is the last clinical / hematologic assessment performed in the reporting period.

Section Updates:

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