



## Instructions for Recipient Baseline Data (Form 2000 – Revision 4)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Recipient Baseline Data Form.

E-mail comments regarding the content of the CIBMTR Forms Instruction Manual to: [CIBMTRFormsManualComments@nmdp.org](mailto:CIBMTRFormsManualComments@nmdp.org). Comments will be considered for future manual updates and revisions. For questions that require an immediate response, please contact your transplant center’s CIBMTR CRC.

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## Recipient Baseline Data

A transplant center designated as a *Comprehensive Report Form* center will submit data on the Pre-TED Form, followed by either the Post-TED Form or the Comprehensive Report Forms. The type of follow-up form used for a specific recipient is determined by the CIBMTR’s form selection algorithm (see General Instructions, [Center Type and Data Collection Forms](#)).

The Baseline Form is one of the Comprehensive Report Forms. This form captures pre-HCT data such as: recipient demographics, organ function and hematologic status, preparative regimen, and socioeconomic information. The Baseline Form is due within 60 days after HCT.

For recipients receiving a subsequent HCT, the recipient will remain on the original follow-up form track (TED or Comprehensive Report Forms) assigned by the form

selection algorithm, except for situations where the recipient has enrolled into a study requiring comprehensive report forms. For recipients assigned to Comprehensive Report Forms by the form selection algorithm, centers will submit an additional Pre-TED form.

## Key Fields

Accuracy of the Key Fields is essential for ensuring that:

- Data are being reported for the correct recipient.
- Outcomes data accurately reflects appropriate transplant type and product for each transplant center.
- Data are being shared with the correct donor center, cord blood bank, cooperative registry, or other agency.

The Key Fields precede the form body and are automatically populated in the FormsNet3<sup>SM</sup> application based on information provided on the CRID Assignment Form 2804. If errors are noted in the key fields, correct Form 2804 and then review it for accuracy. After Form 2804 has been corrected, verify data has been updated on all completed forms. If the data has not been updated automatically, centers will need to reprocess the completed forms to correct the key field data. If errors are noted in key fields for second or subsequent transplants, contact your CRC to make any necessary corrections to the transplant or product type. Transplant and product type will not be automatically populated on product or donor specific forms (Forms 2004, 2005, and 2006) and will need to be manually reported.

## Recipient Demographics

### Questions 1-2: Country of primary residence: (check only one)

Select the recipient's country of residence. If "other" is chosen, continue with question 2 and specify the country. If the recipient's country of primary residence is the United States of America, continue with question 3. If the recipient's country of primary residence is not the United States, continue with question 4.

### Question 3: State of residence of recipient (for residents of USA)

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

### Question 4: Race

Indicate the race of the recipient. If this recipient has reported that they are more than one race, you may indicate each race by adding an additional instance in the FormsNet application. The race groups provided are specific to the United States. If the recipient declines to provide this information, select "not reported."

For *non-U.S.* centers, select “not reported” if the rules/regulations of your country prohibit the collection or reporting of race data (or due to lack of documentation). If race data is reported, it may be necessary to consult with the recipient to select the race group(s) with which they most closely identify.

For more information regarding race, see [Appendix I](#).

**Question 5: Race Detail**

Indicate the detailed race of the recipient. If this recipient has reported that they are more than one detailed race, you may indicate each detailed race by adding an additional instance in the FormsNet application.

For more information regarding race, see [Appendix I](#).

**Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)**

**Question 6: Specify blood type: (for allogeneic HCTs only)**

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

**Question 7: Specify Rh factor: (for allogeneic HCTs only)**

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

**Question 8: Does the recipient have a history of smoking cigarettes?**

The intent of this question is to determine the recipient’s history of smoking cigarettes only. Do not report the use of cigars, pipe tobacco, chewing tobacco, or other drugs. The recipient’s smoking history is usually documented on the transplant admission summary.

Indicate whether the recipient has a history of smoking cigarettes. If “yes,” continue with question 9. If “no” or “unknown” continue with question 15.

**Question 9: Has the recipient smoked cigarettes within the past year?**

Indicate if the recipient has a history of smoking cigarettes within the year prior to HCT.

**Question 10: Has the recipient smoked cigarettes prior to but not during the past year?**

Indicate if the recipient smoked cigarettes prior to, but not during, the year prior to HCT. The intention of this question is to ascertain if the recipient has smoked cigarettes in the past, but not within the year prior to transplant. Indicate “yes” if the recipient has smoked cigarettes, but not during the past year leading up to transplant. Indicate “no” if

the recipient has a history of smoking that continued into the year prior to transplant. Select “unknown” if it is not known if the recipient smoked cigarettes prior to, but not during, the past year.

**Questions 11-12: Number of years:**

Indicate if the number of years the recipient smoked cigarettes is “known” or “unknown.” If “known,” report the total number of years the recipient smoked cigarettes, rounded to the nearest year, in question 12. If “unknown,” continue to question 13.

**Questions 13-14: Average number of packs per day:**

Indicate if the number of packs per day is “known” or “unknown.” If known, report the average number of packs per day the recipient smoked/smokes in question 14. See the conversion chart below to calculate the number of packs per day from a reported cigarette(s) per day history. See the example below to calculate packs per day from a reported pack-year history. If this information is not documented, select “unknown” and continue with question 15.

**NOTE: Conversion into packs per day**

Cigarettes/Day	=	Packs/Day
1-2		0.1
3-4		0.2
5-6		0.3
7-8		0.4
9-10		0.5
11-12		0.6
13-14		0.7
15-16		0.8
17-19		0.9

**If the progress notes the recipient’s smoking history in pack-years:**

**Definition:**

Pack-year history = number of packs per day X number of years.

1 pack per day for 20 years = 20 pack-year history

½ packs per day for 20 years = 10 pack-year history

**Conversion Example:**

Progress Note: Recipient has smoked for 20 years and has a 40 pack-year history.

40 (pack-year history)/20 (years) = 2 packs per day

Report “average number of packs per day” as 2

## Organ Function Prior to the Preparative Regimen (Conditioning)

**Questions 15-38: Provide last laboratory values recorded for recipient's organ function (testing done within 30 days prior to the start of the preparative regimen).**

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

For each organ function test below, indicate if the value is "known" or "unknown" prior to the start of the preparative regimen. Indicate the values for each test. If necessary, convert values so they can be reported in the units of measurement available on the form.

**AST (SGOT):** Aspartate aminotransferase, or serum glutamic oxalic transaminase, is an enzyme measured in serum or plasma that reflects liver function and liver cell integrity. Elevated levels of AST may indicate liver damage.

**Total serum bilirubin:** Bilirubin is a pigment that is formed from the breakdown of hemoglobin in red blood cells. Serum bilirubin is a test of liver function that reflects the ability of the liver to take up, process, and secrete bilirubin. Total bilirubin includes the direct (conjugated) and indirect (unconjugated) bilirubin values. If your laboratory reports direct and indirect separately, add the two together to report the total serum bilirubin.

**LDH:** Lactate dehydrogenase is an enzyme found in the cytoplasm of almost all tissues, which converts L-lactate into pyruvate, or pyruvate into L-lactate depending on the oxygen level. For some diseases, high levels indicate active disease (e.g., lymphoma and multiple myeloma).

**Serum creatinine:** Creatinine is a normal metabolic waste that is primarily filtered from the blood by the kidneys and then excreted in the urine. Since it is generally produced at a constant rate, the clearance rate and the serum level are widely used as indicators of kidney function.

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

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

**Date sample collected:**

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

**Upper limit of normal for your institution:**

Report the upper limit of normal for each assessment result. Normal values may vary by laboratory, so it is important to report the upper limit of normal for each assessment.

## **Hematologic Findings Prior to the Preparative Regimen (Conditioning)**

**Question 39: Date CBC tested: (testing within 30 days of start of preparative regimen)**

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

**Questions 40-54: Provide last laboratory values recorded just prior to preparative regimen:**

For each value below, indicate if the result was “known” or “unknown” prior to the start of the preparative regimen. Indicate the units for each test, taking care to convert them to a unit available on the form, if necessary.

**WBC:** The white blood cell count is a value that represents all of the white blood cells in the blood. If the count is too high or too low, the ability to fight infection may be impaired.

**Neutrophils:** Neutrophils are a subtype of white blood cell that fights infection. The value on the laboratory report may be a percentage or an absolute value. If an absolute value is reported, divide it by the white blood cell count for a percentage. Neutrophils are also known as polymorphonuclear leukocytes (PMNs).

**Lymphocytes:** Lymphocytes are another subtype of white blood cell that fights infection. The value on the laboratory report may be a percentage of

an absolute value. If an absolute value is reported, divide it by the white blood cell count for a percentage.

**Hemoglobin:** Hemoglobin is a molecule in red blood cells that delivers oxygen to tissues throughout the body. A low hemoglobin count is considered “anemia” and blood transfusions or growth factors may be required to increase the hemoglobin level. Also indicate if the recipient received a red blood cell transfusion within 30 days prior to testing.

**Hematocrit:** The hematocrit is the percentage (sometimes displayed as a proportion) of red blood cells relative to the total blood volume. A low hematocrit may require red blood cell transfusions or growth factors. Indicate if the recipient received a red blood cell transfusion within 30 days prior to testing.

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

## Infection

### **Question 55: Did the recipient have a history of clinically significant fungal infection (documented or suspected) at any time prior to the preparative regimen?**

Fungal infections play a major role in the clinical outcome of a transplant recipient. The intent of this question is to identify serious fungal infection(s) that might have an effect on the outcome of the HCT. For the purposes of this manual, the term “clinically significant” refers to conditions that are treated at the time of pre-HCT evaluation, or that have affected the recipient’s medical history, that might cause complications post-HCT.

Examples of fungal infections include, but are not limited to the following: invasive aspergillosis (infection codes 210-213, 219), zygomycosis (infection code 240) and other molds (infection codes 230, 240, 242, 261), invasive candidiasis (infection codes 200-209), cryptococcosis (infection code 220), endemic mycosis (infection code 241), other yeasts (infection code 250), and pneumocystis (PCP/PJP) (infection code 260). Include any fungal abscesses of the lungs, sinuses, liver, or spleen.

#### **NOTE:**

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

If the recipient has a history of clinically significant fungal infection at **any time** prior to this HCT event, check “yes” and continue with question 56. For a subsequent HCT,

report any documented significant fungal infections in the recipient's medical history, between the start of the preparative regimen of the previous HCT to just prior to the preparative regimen for the current HCT.

If the recipient does not have a history of clinically significant fungal infection at any time prior to this HCT event, check "no" and continue with question 64.  
For assistance with reporting fungal infections, consult with a transplant physician.

**Question 56: Did the recipient have more than one fungal infection (documented or suspected) at any time prior to the preparative regimen?**

Indicate if the recipient had more than one fungal infection at any time prior to the preparative regimen.

If the infection was due to yeast, and recurred in  $\leq 14$  days, it is considered a single incident and should **not** be reported multiple times.

If the infection was due to mold, and recurred in  $\leq 90$  days, it is considered a single incident and should **not** be reported multiple times.

**Question 57: Date of onset:**

Enter the date of onset of the fungal infection. For suspected fungal infections, enter the date of a radiology test or date treatment was started as the date of onset.

**Question 58-59: Select organism from list below:**

From the list of "Codes for Commonly Reported Fungal Organisms," select the code corresponding to the identified or suspected fungus. Report the code in the boxes provided. If the specific organism is not listed, use the "other, specify" code 209 - candida, 219 - aspergillus, or 259 - fungus and report the name of the organism in the space provided for question 59.

**A Fungal Infection Form (F2046) must be completed for the following organisms:**

- 211 *Aspergillus flavus*
- 212 *Aspergillus fumigatus*
- 213 *Aspergillus niger*
- 219 Other *Aspergillus*, specify
- 210 *Aspergillus*, NOS
- 230 *Fusarium* species
- 240 *Zygomycetes*, NOS
- 241 *Mucormycosis*
- 242 *Rhizopus*

**Question 60-62: Select site(s) from list below:**

From the list of “Codes for Common Sites of Infection,” select the code corresponding to the site of the infection. If more than one site was involved, report the codes for up to three affected sites.

If three or more sites were infected with the same fungal organism, enter code 2 (Disseminated - generalized, isolated at 3 or more distinct sites).

**NOTE: Disseminated Infections**

The CIBMTR acknowledges that a discrepancy exists between the CIBMTR definition (3 or more sites) and the BMT CTN definition (2 or more sites) for disseminated infections.

**Question 63: Was this fungal infection active within 2 weeks prior to the preparative regimen?**

Indicate if the fungal infection was active within the two weeks prior to the start of the preparative regimen.

For suspected fungal infections, select “yes” if the recipient received fungal treatment (not prophylaxis) and/or had a finding on an x-ray or CT scan consistent with a suspected fungal infection within 2 weeks prior to the preparative regimen.

**Questions 64-75: Testing for evidence of prior viral exposure/infection:**

For each of the tests below, indicate if the results of the test were “reactive” or “not reactive.” If the test was performed but the results were not clearly reactive or non-reactive, report the results as “inconclusive.” “Not done” indicates that the test was not performed.

**NOTE: Serologic Tests**

Serologic tests should be completed during the **pre-HCT work-up phase**, or **approximately one month** prior to the start of the preparative regimen.

Exception: If a recipient has a documented history of a reactive CMV test at any time prior to transplant, the CMV test might not be repeated during the pre-HCT work-up phase. In this case, it is acceptable to report a CMV test from greater than one month prior to the start of the preparative regimen.

If a recipient tests positive for Hepatitis B core antibody (Anti HBc), Hepatitis B surface antigen (HBsAg), Hepatitis B DNA, Hepatitis C antibody (Anti HCV), and/or Hepatitis C NAT serologic tests, also complete the HEP Form (2047).

If a recipient tests positive for HIV antibody or HIV NAT serologic tests, also complete the HIV Form (2048).

**HTLV1 antibody:** Human T-Lymphotropic virus I/II (HTLV I/II) is a retrovirus in the same class as HIV. HTLV I/II is associated with certain

leukemias and lymphomas, as well as demyelinating diseases such as multiple sclerosis.

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

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

- Most laboratory reports indicate a positive result as *reactive*, and a negative result as *non-reactive*. Occasionally, laboratory reports show a specific antibody titer. In this case, the laboratory result must be compared to the reported standards to determine the reactive or non-reactive result.
- If the laboratory reports a CMV IgM antibody only, not total IgG/IgM or CMV IgG antibody, report the result as “not done.”
- **Recipients < 6 months:** If the recipient is less than 6 months old, report any positive CMV antibody results as “inconclusive” due to the presence of maternal antibodies. However, in infants less than 6 months old, positive CMV PCR results indicate a CMV infection and the results may be reported as “reactive.”
- **Exposure to IVIG:** Exposure to IVIG may result in a false positive CMV antibody result. If the recipient has been exposed to IVIG leading up to HCT (within 3-6 months), indicate the CMV antibody results using the following guidelines:
  - If the recipient had a non-reactive CMV antibody result prior to IVIG therapy and then routine CMV PCR results showed no copies of CMV, the CMV antibody may be reported as “non-reactive,” even if the CMV antibody became reactive *during* IVIG treatment.
  - If CMV PCR results quantified copies of CMV DNA (e.g., was positive) during IVIG treatment, the results may be reported as “reactive.”

- If the recipient did not have a CMV antibody test prior to the initiation of IVIG, but had a positive antibody test during the IVIG therapy, report “inconclusive.”
- “Not done” should be reported if no CMV antibody tests were done prior to the initiation of IVIG therapy, even if CMV PCR testing was negative during IVIG treatment (because CMV PCR only detects active infection, not prior exposure).
- For other situations, if the laboratory reports CMV testing by PCR (DNA detection) but no CMV antibody testing is done during the pre-transplant work-up or within one month prior to transplant, report the result as “not done.” CMV testing by PCR is used to detect the presence of the CMV virus and does not test for prior exposure.

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

**Anti-EBV (Epstein-Barr virus antibody):** Epstein-Barr Virus (EBV) is a common virus of the herpes family. It can cause infectious mononucleosis, but in most cases is asymptomatic. EBV establishes a lifelong dormant infection in some cells of the body’s immune system. Serious post-transplant complications related to EBV include EBV viremia (reactivation) and post-transplant lymphoproliferative disease (PTLD).

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” or “not done.”

**Hepatitis B surface antibody:** Hepatitis B is caused by the hepatitis B virus (HBV). Infection with this virus can cause scarring of the liver, liver failure, liver cancer, and even death. Hepatitis B is spread through infected blood and other body fluids. Acute hepatitis B infection does not usually require treatment because most adults clear the infection. Treatment of chronic infection may be necessary to reduce the risk of cirrhosis and liver cancer.

The hepatitis B surface antibody test reveals the presence of hepatitis B antibodies, indicating previous exposure to HBV (or successful vaccination), but the virus is no longer present and the person cannot pass on the virus.

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

A Hepatitis insert (Form 2047) is **not** required for a positive result.

**Anti-HBc (hepatitis B core antibody):** The enzyme-linked immunosorbent assay (ELISA) technique tests for the antibody directed against the hepatitis B virus core proteins. The hepatitis B core antibody test can indicate previous HBV infection. Currently there is no licensed confirmatory test for Anti-HBc. If the screening test is reactive, a second Anti-HBc test is performed using a different manufacturer's test kit.

Indicate the test result documented on the laboratory report as either "reactive," "non-reactive," or "not done."

**If the result is "positive," a Hepatitis insert (Form 2047) is also required.**

**HBsAg (hepatitis B surface antigen):** The ELISA or enzyme immunoassay (EIA) techniques test for the presence of proteins produced by the hepatitis B virus. Confirmatory testing is done using a neutralization test. The first marker appears approximately three weeks following infection, and disappears approximately six months later.

Indicate the test result documented on the laboratory report as either "reactive," "non-reactive," or "not done."

**If the result is "positive," a Hepatitis insert (Form 2047) is also required.**

**Hepatitis B – DNA:** The HBV DNA test is more sensitive than regular serologic tests, and is often used in conjunction with those tests to monitor patients with chronic HBV infections.

Indicate the test result documented on the laboratory report as either "positive," "negative," "inconclusive," or "not done."

**If the result is "positive," a Hepatitis insert (Form 2047) is also required.**

**Anti-HCV (hepatitis C antibody):** Hepatitis C is a serious infection caused by the hepatitis C virus (HCV), which attacks the liver and may cause life-long infection. HCV is considered the most serious hepatitis infection because of its significant long-term health consequences. The infection is often asymptomatic, but once established, chronic infection can cause inflammation of the liver. This condition can progress to fibrosis and cirrhosis. In some cases, those with cirrhosis will go on to develop liver failure or liver cancer. Presence of the antibody in the blood represents exposure to HCV, which is most often spread by blood-to-blood contact. No vaccine against HCV is available.

The ELISA technique tests for antibodies to the HCV. Confirmatory testing is done using the recombinant immunoblot assay (RIBA) test. These tests can determine past exposure to HCV, but not current viral load.

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

**If the result is “positive,” a Hepatitis insert (Form 2047) is also required.**

**Hepatitis C – NAT:** Nucleic acid testing (NAT) is a combination PCR test that detects the presence of viral genes (HCV RNA) rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

**If the result is “positive,” a Hepatitis insert (Form 2047) is also required.**

**Hepatitis A Antibody:** Hepatitis A is an acute infectious disease of the liver caused by the hepatitis A virus (HAV). HAV is often transmitted via contaminated food and drinking water, and is prevalent in developing countries and areas with poor hygiene standards. Hepatitis A may cause influenza-like symptoms, but is often asymptomatic. There is a highly effective HAV vaccine available that can provide protection for up to 20 years.

A total antibody test (which detects both IgM and IgG antibodies) detects both current and previous infection with HAV and will also be positive after receiving the hepatitis A vaccine.

If the laboratory reports a HAV IgM antibody only, not total IgG/IgM or HAV IgG antibody alone; report the result as “not done.”

Indicate the test result documented on the laboratory report as either “reactive,” “non-reactive,” “inconclusive,” or “not done.”

A Hepatitis insert (Form 2047) is **not** required for a positive result.

**HIV antibody:** HIV infection is caused by exposure to one of two viruses: HIV-1 or HIV-2. HIV-2 is less virulent and has a longer incubation period than HIV-1. Both types of HIV progressively destroy lymphocytes, which are an important part of the body’s immune defense. HIV can lead to acquired immunodeficiency syndrome (AIDS), a condition in which the immune system begins to fail, leading to life-threatening opportunistic

infections. Infection with HIV occurs by the transfer of bodily fluids and is present as both free virus particles and virus within infected immune cells.

HIV antibody testing is done using combination ELISA which detects antibodies to the HIV-1 and HIV-2 viruses. HIV-1 is confirmed by Western Blot, which detects specific proteins using gel electrophoresis. There is currently no licensed confirmatory test for HIV-2. If the screening test is reactive, HIV-2 is confirmed by specific ELISA.

The results of HIV assessments are often kept in confidence and may not be reportable to anyone other than the patient and their physician. If HIV testing was done, but the results are not available, select “not reported.”

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” “not done,” or “not reported.”

**If the result is “positive,” an HIV insert (Form 2048) is also required.**

**HIV – NAT:** Nucleic acid testing (NAT) is a PCR test that detects the presence of viral genes rather than antigens or antibodies. This test allows earlier detection and provides more sensitivity than previously used tests.

The results of HIV assessments are often kept in confidence and may not be reportable to anyone other than the patient and their physician. If HIV testing was done, but the results are not available, select “not reported.”

Indicate the test result documented on the laboratory report as either “positive,” “negative,” “inconclusive,” “not done,” or “not reported.”

**If the result is “positive,” an HIV insert (Form 2048) is also required.**

## Pre-HCT Preparative Regimen (Conditioning)

### **Question 76: Was a pre-HCT preparative regimen given?**

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

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

- Primary diagnosis of an immune deficiency.

- Subsequent allogeneic HCT due to loss of, or poor, neutrophil engraftment.

If a preparative regimen was given, select “yes” and continue with question 77. If a preparative regimen was not given, select “no” and continue with question 248.

**Question 77: Specify protocol intent: (check only one)**

Indicate whether “all agents given as outpatient,” “some, but not all, agents given as inpatient,” or “all agents given as inpatient.” Agents are defined as systemic therapy drugs or radiation therapy.

**Question 78: Date pre-HCT preparative regimen (irradiation or drugs) began:**

**NOTE: Date Pre-HCT Preparative Regimen Began**

Additional radiation and/or intrathecal chemotherapy start dates may be prior to the date the preparative regimen began. Report additional radiation in questions 87-104 and additional intrathecal chemotherapy in questions 177-190.

**Example:**

*Radiation Order:* TBI, 200 cGy/day April 15-17, 2009

CNS Radiation, 200 cGy/day April 1-3, 2009

*Report “Additional Radiation date started”:* April 1, 2009

*Report “Date pre-HCT preparative regimen began” as:* April 15, 2009

Enter the date the preparative regimen began. Use the earliest date from questions 82, (radiation), or 109-176 and 193-241 (systemic therapy). All dates reported in the preparative regimen section must be equal to or after the date reported for this question.

**Question 79: Was irradiation performed as part of the pre-HCT preparative regimen?**

If irradiation was performed as part of the preparative regimen, check “yes” and continue with question 80. If irradiation was not performed, check “no” and continue with question 87. Irradiation performed as previous treatment should not be reported in this section, but as previous treatment on the appropriate Disease Specific Form or in question 87, if applicable (radiation given within 14 days of the pre-HCT preparative regimen).

**Question 80: What was the radiation field?**

Indicate if the recipient received irradiation to “total body,” “total body by tomotherapy,” “total lymphoid or nodal regions,” or “thoraco-abdominal region.” This information is often available on the radiation oncology summary.

**Question 81: Total dose: (dose per fraction X total number of fractions)**

Enter the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the

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dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy).

**Example:**

**Radiation Order:** TBI, 200 cGy/day for three days (3 doses)

**Total dose:** 200 cGy x 3 doses = 600 cGy

**Report “Total Dose” as:** 600 cGy

**Question 82: Date started:**

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

**Question 83: Was the radiation fractionated?**

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

If the radiation was fractionated, check “yes” and continue with question 84. If the radiation was not fractionated, check “no” and continue with question 87.

**Question 84: Dose per fraction:**

Enter the dose per fraction in either grays (Gy) or centigrays (cGy).

The dose per fraction multiplied by the total number of fractions (question 86) must be equal to the total dose reported in question 81.

**Question 85: Number of days: (include “rest” days)**

Enter the total number of days radiation therapy was delivered including any days of rest between days when therapy was administered. The number of days radiation was administered can be greater than the number of fractions.

**Example:**

**Radiation Order:** TBI, 200 cGy/day every other day (Mon-Wed-Fri) x 3 doses

**Total dose:** 200 cGy x 3 doses = 600 cGy

**Report “Number of days” as:** 5

**Question 86: Total number of fractions:**

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

The total number of fractions multiplied by the dose per fraction (question 84) must be equal to the total dose reported in question 81.

**Question 87: Was additional radiation given to other sites within 14 days of the pre-HCT preparative regimen?**

**NOTE: Additional Radiation**

Additional radiation start dates may be **prior** to the date the preparative regimen began.

If additional radiation began **more than** 14 days prior to the start of preparative regimen, but at least one dose was **received within** 14 days prior to the preparative regimen, report the actual start date of the additional radiation in this section, even if the start date is more than 14 days prior to the start of the preparative regimen.

Radiation treatments **completed** more than 14 days prior to the start of the preparative regimen should be reported on the appropriate Disease Specific Form in the treatment section.

In this section, report any sites that received a “radiation boost.” Boosts are often given to smaller sites that may have residual malignant cells or to areas that were shielded (ex. chest wall or lung). Include any radiation boosts that were administered **within 14 days** prior to the preparative regimen start date.

**Questions 88-104: Specify radiation field:**

Indicate if the recipient received radiation to each site listed. For each site that received additional radiation, indicate the dose, units, and start date.

**Question 105: Were drugs given for pre-HCT preparative regimen?**

**NOTE: Preparative Regimen: Drugs**

The following questions refer to the drug therapy that was **actually given** as part of the preparative regimen versus the *prescribed* drug therapy that was reported on the Pre-TED. In this section, include any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease **within 14 days prior** to the start date of the preparative regimen.

Do not include drugs that are intended to offset the side effects of the systemic therapy (e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).

Occasionally, protocols list drugs that may be given before and after day 0. If the drugs are given before and after day 0, only the doses given before day 0 should be quantified in the preparative regimen section. The doses given after day 0 should be reported on the **Post-HCT Disease Specific form** (if applicable on that form) or **GVHD Prophylaxis section of the 100 Day Post-HCT Data Form (Form 2100)**. For example, if bortezomib or rituximab is given on Days -2, +1, +4, and +7, report the day -2 dose in the preparative regimen section, and the post-transplant doses as planned post-HCT therapy on the disease insert.

ATG or alemtuzumab (Campath) given for GVHD prophylaxis prior to Day 0 should be reported in the preparative regimen section of the Baseline Form. If ATG, alemtuzumab, or cyclophosphamide is given after Day 0 for GVHD prophylaxis, it should be reported in the acute GVHD prophylaxis section on the 100 Day Post-HCT Data form.

The form lists each drug by the generic name. The form also lists some drugs by broad categories, with specific drugs listed individually. For example, anthracycline is listed as the broad drug category, followed by the specific drugs of daunorubicin, doxorubicin, and idarubicin.

If the recipient received drugs as part of the preparative regimen, select “yes” and continue with question 106. If the recipient did not receive drugs as part of the preparative regimen, check “no” and continue with question 248. Ensure that the drugs being given correspond appropriately with the Pre-TED (Form 2400).

**Question 106: Dosing body weight used for pre-HCT preparative regimen (adjusted body weight):**

Report the recipient’s dosing (adjusted) body weight calculated by the pharmacy/physician to determine the total dose of the drugs given as part of the preparative regimen. The dosing body weight is usually documented on the transplant preparative regimen chemotherapy orders.

If different dosing body weights were used for the calculation of drug doses (for example, the dose for cyclophosphamide was calculated with the recipient’s adjusted body weight and the fludarabine was calculated using the recipient’s actual weight), leave this field blank, override the error, and submit a Log of Appended Documents (2800) showing the different weights and drug calculations.

**Questions 107-242: Specify preparative regimen drugs:**

For each drug listed, indicate whether or not it was given as part of the preparative regimen. Report the total dose of each drug that was actually given. **Do not report the prescribed dose or the daily dose.** The pharmacy record or Medication Administration Record (MAR) should be used for determining the exact total doses given.

Some drugs used as part of the preparative regimen are administered with guidance of serum pharmacokinetic testing to determine the recipient’s metabolism of the drug. This allows for individual “customization” of the drug dosing to optimize the desired effect and minimize the toxicity. Depending upon when the drug used to monitor drug levels is administered, it can be reported in one of two different ways on the CIBMTR Pre-TED (2400) and Baseline (2000) forms.

A common example of this situation occurs in the use of busulfan. In some cases, a “test dose” of the drug is given before the actual preparative regimen is started, and this dose is used for acquiring drug levels that are used to adjust the dose that will be used in the preparative regimen. In other situations, the first dose of the drug is given in the usual fashion as part of the preparative regimen. After this first dose, serum drug levels

are drawn and sent to a reference lab. The drug is continued at the starting dose until the lab results are reported and adjustment is made to later doses.

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

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

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

- a. On the Pre-TED (2400) form, the total prescribed dose per protocol would NOT include the test dose.
  - b. On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first therapeutic dose was administered. The actual dose received would NOT include the test dose.
2. The first dose of therapeutic dosing is used for monitoring.
    - **Example:** A patient with MDS received an allogeneic HCT from an unrelated donor; busulfan and fludarabine were used as the preparative regimen. She was admitted to the hospital 7 days before her HCT, and received a dose of busulfan at 0.8 mg/kg IV at 6:00 AM. Serum samples were drawn every 30 minutes until the next dose of Busulfan at 0.8 mg/kg IV was given at 12:00 noon. Her blood was sent to a reference lab, and she continued to receive busulfan every 6 hours. On day -6, the lab called with her drug levels, and it was determined that the current dose was correct. No adjustment was made, and she completed all 16 doses of busulfan. Since the dose of busulfan (0.8 mg/kg) that was used for drug testing was ALSO her first dose of the preparative regimen, it should be included in the amount of drug that was given for preparative regimen.

If the first dose of the preparative regimen was used to determine pharmacokinetics, the following should be reported:

- a. On the Pre-TED (2400) form, the total prescribed dose per protocol would include the dose used for monitoring.
- b. On the Baseline (2000) form, the start date of the chemotherapy agent should be reported as the date the first dose was administered. The actual dose received would include the dose used for monitoring.

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

Drug doses must be reported in whole numbers. If the total dose includes a decimal, round to the nearest whole number (round up if 0.5 or greater). For paper submission, do not modify the number of boxes or include decimal values.

The “other, specify” category should only be used if the drug is not one of the listed options. If more than one “other” drug is prescribed, list the generic name of the drugs in the space provided and attach a copy of the source document using the Log of Appended Documents (Form 2800).

Drugs given for prophylaxis of infection, GVHD, or organ toxicity should not be reported in this section. Report these drugs on the 100 Day Follow-up Form (2100).

If the Baseline is completed for a subsequent HCT, do not report therapy that was given to treat the recipient’s disease (between the previous and current planned HCTs) in the preparative regimen section. Report this therapy on the appropriate Disease Specific Form.

**Question 243: Were pharmacokinetics performed to determine preparative drug dosing?**

Pharmacokinetic testing can be used to determine whether the drug concentration in the bloodstream is appropriate to the dose given. This reflects the speed of absorption and elimination of the drug. These tests are usually performed with a test dose prior to the preparative regimen, or performed after the first dose of systemic therapy, where multiple samples are drawn at specific time points following the first dose. The samples are sent to a laboratory that performs the testing to determine the drug concentration. Pharmacokinetic evaluation of busulfan dosing, as in the examples shown above, is common. If it is not known whether or not this testing was performed, consult with a transplant physician.

Indicate if pharmacokinetics were performed to determine preparative regimen drug dosing. If “yes,” continue with question 244. If “no,” continue with question 248.

**Questions 244-247: Specify drugs:**

Indicate which drug(s) were pharmacokinetically tested. If “other” is chosen, specify the drug in question 247.

## Socioeconomic Information

**Question 248: Is the recipient an adult (18 years of age or older) or emancipated minor?**

Indicate if the recipient is 18 years of age or older, or if under 18, has been declared an emancipated minor by law. An emancipated minor is a child who has been granted the status of adulthood by a court order or other formal arrangement.

If “yes,” continue with question 249. If “no,” continue with question 250.

**Question 249: Specify the recipient’s marital status:**

Report the recipient’s marital status as of the date of HCT. If the recipient is in a same-sex partnership, but they are not legally married in their state, report “married or living with a partner.”

**Questions 250-251: Specify the category which best describes the recipient’s current occupation: (if the recipient is not currently employed, check the box which best describes his/her last job.)**

Report the recipient’s occupation category prior to illness.

If the recipient is unemployed, select the option that best describes his/her most recent job.

If the recipient is “under school age,” select this option, and continue with question 253.

The “other, specify” category should only be used if the recipient’s occupation does not fit into one of the broad occupation categories listed. Please review the text associated with each answer to ensure that the occupation is being reported within the correct category. One common oversight is the reporting of “other” when the recipient’s occupation actually fits best in the “Professional, technical, or related occupation” category.

**Question 252: What is the recipient’s current or most recent work status prior to illness?**

**NOTE:**

The question on the form currently refers to the recipient’s current or most recent work status prior to the illness; however, the intent of the question is to capture the recipient’s *most recent work status prior to the start of the preparative regimen.*

Report the recipient's most recent work status prior to the preparative regimen. This refers to the employment status at the time in which they were no longer able to work due to the illness or due to preparation for their transplant. If the recipient is on medical leave other than medical disability (such as short-term or long-term medical leave), report their employment status prior to the start of their leave. If they are on medical disability, select "medical disability."

**Example 1.**

Patient was diagnosed with AML and had been working a full-time job. The patient was on a medical leave as the AML treatment prevented them from returning to work prior to the HCT. The correct option to choose would be "Full time."

**Example 2.**

Patient was diagnosed with Multiple Myeloma and had been working a full-time job. Due to treatment related side effects, the patient had to reduce their hours and only work part-time. The correct option to choose would be "Part time, due to illness" & not "Full time". Full time would not be chosen because the most recent status of their employment was part time. Full time would have been chosen had the recipient stopped working and was on a medical leave from their employer due to their illness.

**Example 3.**

Patient was diagnosed with Non-Hodgkin's Lymphoma and worked part time during her treatment. Following initial therapy, the recipient began working full time. After the recipient's retirement, her annual scan showed relapse, treatment began again and the recipient proceeded to transplant. "Retired" would be reported on the form.

If the recipient's occupation was reported as "student" in question 250, specify "full time," "part time," or "unknown" in question 252.

**Question 253: What is the highest educational grade the recipient completed?**

Report the recipient's highest completed educational level as of the date of HCT. If the recipient is a student who is currently in the middle of a school year, indicate the previous education level completed.

**Question 254: Is the recipient currently in school, or was enrolled prior to illness?**

Indicate if the recipient is a current student, or was a student prior to illness.

**Question 255: Is the recipient covered by health insurance?**

Indicate if the recipient has health insurance.

If "yes," continue with question 256. If "no," continue with question 264.

**Questions 256-263: Specify type of health insurance:**

Report the recipient's source of health insurance as of the date of HCT. If the recipient carries more than one source, select "yes" for all that apply. For each option, select "yes" or "no" and do not leave any options blank. U.S.-based, government-sponsored health insurance should be reported in question(s) 256 and/or 257. Non-U.S.-based, government-sponsored health insurance (such as the National Health Service in the United Kingdom) should be reported in question 258. If the recipient has a health insurance that is not listed, select "yes" for "other" and specify the health insurance in question 263.

**Question 264: Specify the recipient's combined household gross annual income: (include earnings by all family members living in the household, before taxes.) (For U.S. residents only)**

Indicate the sum of the before-tax annual incomes for all family members living in the recipient's household. If the recipient decides not to provide this information, select "recipient declines to provide this information." If annual income is only known for some of the income earners in the house or if it is not known what the household's gross annual income is, select "unknown."

**Signature Lines:**

The FormsNet3<sup>SM</sup> application will automatically populate the signature data fields, including name and email address of person completing the form and date upon submission of the form.

## Manual Change History

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.1	11/21/2013	Remove	A typo was removed from the text of question 4: removed the word “centers” before the last line of the first paragraph
2.1	11/21/2013	Add	Added “Revision 4” to title of document
2.2	02/07/2014	Modify	Modified the explanatory text of question 10 to read:  <i>Indicate if the recipient smoked cigarettes prior to, but not during, the year prior to HCT. The intention of this question is to ascertain if the recipient has smoked cigarettes in the past, but not within the year prior to transplant. Indicate “yes” if the recipient has smoked cigarettes, but not during the past year leading up to transplant. Indicate “no” if the recipient has a history of smoking that continued into the year prior to transplant. <del>or never smoked cigarettes except during the year prior to transplant.</del> Select “unknown” if it is not known if the recipient smoked cigarettes prior to, but not during, the past year.</i>
2.3	06/01/2014	Modify	Updated formatting to match CIBMTR brand standards

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.3	06/01/2014	Modify	<p>The explanatory text regarding the preparative regimen drugs was changed to reflect operational reporting standards when drugs are given both pre- and post-transplant:</p> <p><b>NOTE: Preparative Regimen: Drugs</b>  <i>The following questions refer to the drug therapy that was <b>actually given</b> as part of the preparative regimen versus the prescribed drug therapy that was reported on the Pre-TED. In this section, include any intrathecal drugs the recipient received for prophylaxis or treatment of CNS disease <b>within 14 days prior</b> to the start date of the preparative regimen.</i></p> <p><i>Do not include drugs that are intended to offset the side effects of the systemic therapy (e.g., corticosteroids for nausea, MESNA for hemorrhagic cystitis, etc.).</i></p> <p><i>Occasionally, protocols list drugs that may be given before and after day 0. If the drugs are given before and after day 0, only the doses given before day 0 should be quantified in the preparative regimen section. The doses given after day 0 should be reported on the <b>Post-HCT Disease Specific form</b> (if applicable on that form) or <b>GVHD Prophylaxis section of the 100 Day Post-HCT Data Form (Form 2100)</b>. For example, if bortezomib or rituximab is given on Days -2, +1, +4, and +7, report the day -2 dose in the preparative regimen section, and the post-transplant doses as planned post-HCT therapy on the disease insert.</i></p> <p><i>ATG or alemtuzumab (Campath) given for GVHD prophylaxis prior to Day 0 should be reported in the preparative regimen section of the Baseline Form. If ATG, alemtuzumab, or cyclophosphamide is given after Day 0 for GVHD prophylaxis, it should be reported in the acute GVHD prophylaxis section on the 100 Day Post-HCT Data form.</i></p> <p><i>The form lists each drug by the generic name. The form also lists some drugs by broad categories, with specific drugs listed individually. For example, anthracycline is listed as the broad drug category, followed by the specific drugs of daunorubicin, doxorubicin, and idarubicin.</i></p>

Version Number	Date of Change	Type of Change (Add / Remove / Modify)	Description of Change
2.3	06/01/2014	Remove	<p>The text box regarding ATG and campath in the preparative section was removed, because it was a duplicate.</p> <p><b>NOTE: ATG or Campath given as GVHD prophylaxis</b>  <del>Report ATG (antithymocyte globulin) or Campath (alemtuzumab) given before Day 0 in the preparative regimen section (questions 107-111).</del>  <del>Report ATG or Campath given after the HCT on Day 0 in the GVHD prophylaxis section on the 100 Day Follow-up Form (2100).</del></p>
2.4	06/13/2014	Modify	<p>Modified and added explanatory text to question 252:</p> <p><b>Note:</b>  <i>The question on the form currently refers to the recipient's current or most recent work status prior to the illness; however, the intent of the question is to capture the recipient's most recent work status prior to the start of the preparative regimen.</i></p> <p><i>Report the recipient's most recent work status <del>as of the date of HCT.</del> prior to the preparative regimen. This refers to the employment status at the time in which they were no longer able to work due to the illness or due to preparation for their transplant. If the recipient is on medical leave other than medical disability (such as short-term or long-term medical leave), report their employment status prior to the start of their leave. If they are on medical disability, select "medical disability."</i></p> <p><b>Example 1.</b>  <i>Patient was diagnosed with AML and had been working a full-time job. The patient was on a medical leave as the AML treatment prevented them from returning to work prior to the HCT. The correct option to choose would be "Full time."</i></p> <p><b>Example 2.</b>  <i>Patient was diagnosed with Multiple Myeloma and had been working a full-time job. Due to treatment related side effects, the patient had to reduce their hours and only work part-time. The correct option to choose would be "Part time, due to illness" &amp; not "Full time". Full time would not be chosen because</i></p>

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			<p><i>the most recent status of their employment was part time. Full time would have been chosen had the recipient stopped working and was on a medical leave from their employer due to their illness.</i></p> <p><b>Example 3.</b> <i>Patient was diagnosed with Non-Hodgkin's Lymphoma and worked part time during her treatment. Following initial therapy, the recipient began working full time. After the recipient's retirement, her annual scan showed relapse, treatment began again and the recipient proceeded to transplant. "Retired" would be reported on the form.</i></p>
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