4001: Pre-Cellular Therapy Baseline Data

This form must be completed for all recipients of cellular therapy (non-HCT), including post-HCT DCI infusions, selected for CRF reporting level. It will be completed in conjunction with the Pre-Cellular Therapy Essential Data (Pre-CTED) (4000) form. For more information on TED and CRF level reporting, click here

The Pre-Cellular Therapy Baseline Data (4001) form will come due after the Pre-CTED (4000) form has been completed if the infusion is selected for CRF reporting level. This form captures pre-infusion data such as: setting for the infusion, lymphodepleting therapy details, toxicity prophylaxis, and socioeconomic information. The Baseline Form is due within 30 days after infusion.

Links to sections of form:

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
11/6/ 2023	4001: Pre-Cellular Therapy Baseline Data	Add	Add blue box at top of section: If drugs given for toxicity prophylaxis were started at the time of cell therapy infusion, including after day zero, they should be reported in this section.
7/28/ 2023	4001: Pre-Cellular Therapy Baseline Data	Add	Version 1 of the 4001: Pre-Cellular Therapy Baseline Data section of the Forms Instruction Manual released. Version 1 corresponds to revision 1 of the form 4001.

Last modified: Nov 06, 2023

Q1-4: Product Identification

Question 1: In what setting is this cell therapy product infusion being planned?

Indicate if this cell therapy product infusion will be administered as an **Inpatient** or **Outpatient** procedure.

Question 2: Is a subsequent HCT part of the overall treatment protocol?

This question intends to capture instances where the cellular therapy is administered in association with an HCT, either planned or dependent upon the response to the cellular therapy. It is not intended to capture an HCT given prior to this cellular therapy infusion. If, at the time of the current infusion, a subsequent HCT is planned according to the protocol, check **Yes** even if the recipient does not receive the planned subsequent HCT. The word “planned” should not be interpreted as: if the recipient relapses, then the “plan” is to perform a subsequent HCT. If a subsequent HCT is not planned as part of the overall treatment protocol, select **No**.

Question 3: Specify the HCT type:

Specify the type of the subsequent HCT that is planned as part of the overall treatment protocol.

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

Allogeneic product is from a donor who is not the recipient, either related or unrelated to the recipient.

Question 4: Specify the circumstances which the subsequent HCT will be performed:

Specify the reason for which the subsequent HCT will be performed as **Regardless of response to cellular therapy**, **Only if the patient responds to cellular therapy**, or **Only if the patient fails to respond or has an incomplete response**.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2023

Q5-10: Lymphodepleting Therapy Prior to Cellular Therapy

Bridging therapy is a new terminology and is defined as any treatment that is given after the leukapheresis, during the period of cell manufacturing, with the goal of controlling the disease until the cellular product is ready to be infused. Do not report bridging therapy in this section. Bridging therapy, therapy given after leukapheresis up until the initiation of lymphodepleting chemotherapy for the purpose of disease control or management, should be reported on the disease specific form as a line of therapy, if applicable.

Question 5: Height at start of lymphodepleting therapy:

Report the recipient's actual height just prior to the start of the lymphodepleting therapy. The intent of this question is to determine the height used when calculating lymphodepleting therapy drug doses. This height is usually documented on the infusion orders or admitting orders. Report height to the nearest whole centimeter or inch (round up if 0.5 or greater).

Question 6: Weight at start of lymphodepleting therapy:

Report the recipient's actual body weight just prior to the start of the lymphodepleting therapy. The intent of this question is to report the actual weight at the time the lymphodepleting therapy starts (which may be different than the weight used to determine lymphodepleting therapy doses). This weight is usually documented on the infusion orders or admitting orders. Report weight to the nearest tenth of a kilogram or pound. Do not report adjusted body weight, lean body weight, or ideal body weight.

Questions 7-8: Specify lymphodepleting drugs

The form lists each drug by the generic name.

For each lymphodepleting drug administered, check the box to indicate the drug was given as part of the lymphodepleting therapy used prior to the cellular therapy infusion.

Select **Other drug** and specify the drug name in question 8 only if the lymphodepleting drug is not listed as an option. If more than one "other" drug is prescribed, each "other" drug should be reported in a separate instance. List the generic name of the drug in the space provided and attach a copy of the source document using the attachment feature in FormsNet3^{SM}.

Question 9: Total prescribed dose:

Report the ***total*** **prescribed dose** of each drug in mg/m^2 as stated in the protocol. **Do not report the prescribed *daily* dose**. Report the drug doses to the nearest tenth.

Question 10: Date started:

Report the date (YYYY-MM-DD) the drug was first administered. If the exact date is unknown, review the General Instructions, General Guidelines for Completing Forms for more information on reporting partial and unknown dates.

> ✻ Copy and complete *Specify lymphodepleting drugs*, *total prescribed dose*, and *Date started* to report all drugs given as lymphodepleting therapy.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2023

Q11-14: Toxicity Prophylaxis

If drugs given for toxicity prophylaxis were started at the time of cell therapy infusion, including after day zero, they should be reported in this section .

Question 11-12: Therapy given for the prevention of CRS: (prophylactic therapy)

Presently, CRS prophylaxis is not routinely performed. However, practices related to CRS are evolving rapidly and some programs have considered using drugs like tocilizumab preemptively in patients with high risk to develop serious CRS. If therapy was given for the prevention of CRS check all that apply from the list of the drugs given. If **Other therapy** is selected, specify the therapy.

If more than one **Other** drug is prescribed, report each **Other** drug in the specify field. List the generic name of the drug in the space provided and attach a copy of the source document using the attachment feature in FormsNet3^{SM}.

Question 13-14: Therapy given for the prevention of neurotoxicity (ICANS: (prophylactic therapy))

For neurotoxicity, anti-epileptic drugs are often prescribed to prevent seizures. The intent of this question to separate the use of these drugs from prevention to treatment of seizure, which is captured in F4100. Additionally and similar to CRS, practices are evolving rapidly, and other drugs might be used to prevent neurotoxicity among patients with high risk for serious manifestations of this complication. If therapy was given for the prevention of neurotoxicity, check all that apply from the list of the drugs given. If **Other therapy** is selected, specify the therapy.

If more than one **Other** drug is prescribed, report each **Other** drug in the specify field. List the generic name of the drug in the space provided and attach a copy of the source document using the attachment feature in FormsNet3^{SM}.

Section Updates:

Question Number	Date of Change	Add/ Remove/ Modify	Description	Reasoning (If applicable)
11-14	11/6/ 2023	Add	Add blue box at top of section: If drugs given for toxicity prophylaxis were started at the time of cell therapy infusion, including after day zero, they should be reported in this section.	Added for clarification

Last modified: Nov 06, 2023

Q15-33: Hematologic Findings Prior to Lymphodepleting Therapy

✻ The following questions will only be answered if the recipient received lymphodepleting therapy as reported on the Pre-CTED (4000) form.

✻ Current hematologic findings data collection has been split between TED and CRF level reporting. TED level reporting will capture only LDH values. All other lab values will be captured on the Pre-Cellular Therapy Baseline Data (4001) form if the infusion is selected for CRF level reporting.

Question 15: Date complete blood count (CBC) sample drawn:

These questions are intended to determine the clinical status of the recipient prior to the start of lymphodepleting therapy for cellular therapy. Testing may be performed multiple times within the pre-infusion work-up time period; report the most recent CBC obtained. Laboratory values obtained on the first day of the lymphodepleting therapy may be reported as long as the blood was drawn before any lymphodepleting therapy was administered.

If no lymphodepleting therapy is given, report most recent CBC result prior to the infusion.

Questions 16-24: Complete blood count results available: (check all that apply)

For each cell type listed, checking the box will indicate a result is available. Provide the most recent laboratory values from the CBC on the date reported in the prior question.

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.

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 obtaining the blood sample.

If a hematocrit value is reported, also indicate if the recipient received a red blood cell transfusion within 30 days prior to the date of the CBC reported in question 22.

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.

If a platelet value is reported, also indicate if the recipient received a platelet transfusion within 7 days prior to the date of the CBC reported in question 24.

Question 25: Did the recipient receive any growth factors <7 days before the start of systemic therapy?

Indicate if the recipient received any growth factor (e.g., GCS-F) within 7 days prior to the start of systemic therapy (i.e. lymphodepleting therapy). If no systemic therapy was given, indicate if the recipient received any growth factor (e.g., GCS-F) within 7 days prior to the infusion. In the event of a long acting growth factor (e.g., pegfilgrastim (Neulasta®), please answer this question as **Yes** if the recipient received it within 14 days prior.

Question 26-27: Total serum ferritin:

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

Date Sample Collected: Testing may be performed multiple times within the pre- infusion work-up time period; report the most recent total serum ferritin value obtained within 30 days of the start of lymphodepleting therapy. Laboratory values obtained on the first day of the lymphodepleting therapy may be reported as long as the blood was drawn before any lymphodepleting therapy was administered.

Question 28-31: C-reactive protein:

Testing may be performed multiple times within the pre- infusion work-up time period; report the most recent C-reactive protein value obtained within 30 days of the start of lymphodepleting therapy. Laboratory values obtained on the first day of the lymphodepleting therapy may be reported as long as the blood was drawn before any lymphodepleting therapy was administered.

Indicate whether the C-reactive protein result was **Known** or **Unknown** prior to the start of lymphodepleting therapy. If **Known**, report the date (MM-DD-YYYY) of the test, report the result and the unit of measure, and specify the upper limit of normal.

Question 32-33: 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.

Testing may be performed multiple times within the pre- infusion work-up time period; report the most recent serum creatinine value obtained. Laboratory values obtained on the first day of the lymphodepleting therapy may be reported as long as the blood was drawn before any lymphodepleting therapy was administered.

Report the result and the unit of measure and report the date (MM-DD-YYYY) of the test.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2023

Q34-47: Socioeconomic Information

> ! This section will be answered for US recipients only

Question 34: Is the recipient an adult (18 years of age of 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.

Question 35: 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 36-37: 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.

The **Other** 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 38: What is the recipient's most recent work status? (Within the last year)

> ✻ The question on the form currently refers to the recipient's current or most recent work status with the last year; 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 within the last year. 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**, specify **Full time**, **Part time**, or **Unknown**.

Question 39: 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 40: 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 41-44: Is the recipient covered by health insurance?

Indicate if the recipient has health insurance, and report the recipient’s source of health insurance as of the date of HCT. If the recipient carries more than one source, check for all that apply. If the recipient has a government health insurance that is not listed, select **Other government program** and specify the government health insurance program. If the recipient has a health insurance that is not listed, select **Other health insurance coverage** and specify the health insurance.

! Question 45-47 will be **disabled** in FormsNet3^{SM} and will **not** be answered

Question 45: 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**.

Question 46: Number of people living in the household

Specify the total number of people who are living in the recipient’s household. Include those who are both

older and younger than the age of 18.

Question 47: Number of people living in the household under the age of 18

Specify the number of people who are under the age of 18 living in the recipient's household.

Section Updates:

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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Last modified: Jul 29, 2023