

## 3500: Subsequent Neoplasms

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This form must be completed when a new malignancy is reported on a Cellular Therapy Essential Data Follow-Up Form (Form 4100). Reported new malignancies should be different than the disease / disorder for which cellular therapy was performed. Do not include relapse, progression or transformation of the same disease subtype.

New malignancies, lymphoproliferative disorders, and 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 lymphoma or lymphoproliferative disease

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-cellular therapy medical history
- Breast cancer found in other (i.e., opposite) breast (report as relapse)
- Post-cellular therapy cytogenetic abnormalities associated with the pre-cellular therapy diagnosis (report as relapse)

A separate form 3500 must be submitted to report each new malignancy diagnosed since the date of last report. Reporting a new malignancy / disorder on a Form 4100 will make one Form 3500 due. If more than one new malignancy occurs during a reporting period, the Form 3500 can be made due on demand. Contact your CIBMTR CRC with any questions.

The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

Links to sections of the form:

[Q1-23: New Malignancy, Lymphoproliferative or Myeloproliferative Disease/ Disorder](#)

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.

<b>Date</b>	<b>Manual Section</b>	<b>Add/ Remove/ Modify</b>	<b>Description</b>
1/ 30/ 18	3500: Subsequent Neoplasms	Add	Version 1 of the 3500: Subsequent Neoplasms section of the Forms Instruction Manual released. Version 1 corresponds to revision 1 of the Form 3500.

*Last modified: Jan 30, 2018*

# Q1-23: New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

\* The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

## Questions 1-3: Specify the new malignancy:

Indicate which new malignancy / disorder was diagnosed during the reporting period. If the new malignancy / disorder is not found in the list, select 'other new malignancy' and specify in question 2. Report the date of diagnosis in question 3, using the pathologic diagnosis date. If the original assessment confirming diagnosis is not available, report the date of diagnosis indicated in the progress notes.

For more information regarding reporting partial or unknown dates, see General Instructions, [General Guidelines for Completing Forms](#).

## Question 4 & 5: Was the new malignancy donor / cell product derived?

Indicate whether the new malignancy originated from the donor / cell product. If "yes," indicate whether documentation was submitted to CIBMTR (e.g., cell origin evaluation (VNTR, cytogenetics, FISH)) in question 5.

For further instructions on how to attach documents in FormsNet3<sup>SM</sup>, refer to the [Training Guide](#).

## Question 6: Was documentation submitted to the CIBMTR? (e.g. pathology report, autopsy report)

Indicate whether documentation of the new malignancy, lymphoproliferative disorder, or myeloproliferative disorder was submitted to CIBMTR (e.g., pathology report, autopsy report).

For further instructions on how to attach documents in FormsNet3<sup>SM</sup>, refer to the [Training Guide](#).

## Post-Transplant Lymphoproliferative Disorder

! Questions 7-23 can only be answered if post-transplant lymphoproliferative disorder is selected in question 1.

## Question 7: Was there EBV reactivation in the blood?

If reactivation in the blood was confirmed during the reporting period, report "yes" and continue with question 8. If reactivation did not occur during the reporting period report "no" and continue with question 13.

Indicate “unknown” if no EBV testing was performed during the reporting period and continue with question 13.

### **Question 8-12: How was EBV reactivation diagnosed?**

Indicate the method of detection for EBV reactivation.

If reactivation was diagnosed by “qualitative PCR of blood,” continue with question 13.

If the diagnosis was made by “quantitative PCR of blood,” report the number of copies detected in question 10. Also, indicate whether repeat testing was performed during the reporting period in question 11. If repeat testing was performed, report the results of the most recent test performed during the reporting period in question 12.

If the diagnosis was made by “other method,” specify the method of detection in question 9 and then continue with question 13.

### **Question 13: Was there lymphomatous involvement? (e.g., a mass)**

Indicate whether a mass or other lymphomatous involvement was detected during the reporting period. If there was lymphomatous involvement was confirmed during the reporting period, report “yes” and continue with question 14. If lymphomatous involvement was not confirmed during the reporting period, report “no” and continue with question 22.

### **Question 14-21: Specify sites of PTLD involvement:**

For each site listed, indicate whether there was post-transplant lymphoproliferative disorder (PTLD) involvement. Sites may be identified by radiographic or pathologic methods. If there was PTLD involvement at a site not listed, report “other site” in question 20 and specify in question 21.

### **Question 22 & 23: Was PTLD confirmed by biopsy?**

Indicate whether PTLD was confirmed by a biopsy. If PTLD was confirmed by a biopsy, report “yes” and indicate whether documentation was submitted to CIBMTR (e.g., pathology report) in question 23. If a biopsy did not confirm the diagnosis of PTLD, report “no”.

For further instructions on how to attach documents in FormsNet3<sup>SM</sup>, refer to the [Training Guide](#).

### **Section Updates:**

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (If applicable)
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*Last modified: Dec 22, 2020*