



Adverse Event Follow-up Form Instructions

Note: This form is used to report new information on a previously reported Adverse Event. Do not use this form for the original adverse event submission. It is helpful to have access to information from the original submission for completion of this form.

Key Field: Sequence Number: This field will be auto-populated by the system. Make note of the sequence number in any external tracking mechanism you have to easily locate the form again.

Key Field: Date Received: This field will be auto-populated by the system as the date the form is first processed.

Recipient Information

Question 1: Adverse Event Group ID:

The Adverse Event Group ID is the way the system distinguishes which Adverse Event goes with which Adverse Event Follow-up Form. The Group ID for the original Adverse Event can be found in the Recipient Forms grid.

Enter the Adverse Event Group ID for the corresponding original Adverse Event.

Question 2: CIBMTR Recipient ID (CRID):

The CRID is a lifelong ID assigned by the CIBMTR to each recipient. The CRID is generated using the CIBMTR Unique ID Assignment Form (Form 2804), and must be completed for all HSCT recipients.

Question 3: NMDP Recipient ID (RID): *(if applicable)*

Enter the NMDP-generated Recipient ID number (RID). This number should be in XXX-XXX-X format. This is the recipient identification number you use with the NMDP's search department, among others. The RID must be entered without dashes. This is an optional field.

Question 4: CIBMTR Center Number (CCN):

Enter your center's five-digit CIBMTR center number. This number should appear at the top of the FormsNetTM2 screen next to your site name when you are logged in. If you

are unfamiliar with this number, ask your center's data manager who completes the CIBMTR data collection forms.

Adverse Event Follow-up Information

Question 5: Product type received by recipient:

Enter the product type the recipient received. If the recipient has had more than one transplant, enter the product type that is associated with the Adverse Event originally reported for which this follow-up form is being completed.

This question will be checked against the answer provided on the Adverse Event Form 3001 and an error will appear if they do not match.

Question 6: Does this adverse event now meet the regulatory definition of a serious adverse event when it previously did not?

Compare the adverse event status at the time of this report to the status of the adverse event at last report. Review the definition of a serious adverse event and select response.

If the adverse event has worsened from non-serious to serious, select "Yes" and go to question 7.

If the adverse event was not serious at last report and remains non-serious, select "No" and go to question 9.

If the adverse event has been previously reported as serious, select "Not applicable" and go to question 9.

Questions 7-8: Serious adverse event outcome: and Specify other serious adverse event outcome:

Select serious adverse event outcome if the response to question 6 is "Yes".

If "Other" is selected in question 7, specify other serious adverse event outcome in question 8.

Question 9: Has the assessment of relatedness between this adverse event and the product changed?

Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response to indicate if there has been a change in relatedness between the adverse event and the product.

If "Yes" is selected, answer question 10.

If "No" is selected, continue to question 11.

Question 10: What is the relationship between the reported adverse event and the product?

Attribution is based on the nature of the event versus the scientific plausibility that the event was related to the medical treatment, the temporal relationship between the event and the treatment, and the potential for alternative explanations (underlying disease, other meds, etc). Select response for the relationship between the adverse event and the product if the response to question 9 is "Yes". If there was more than one cord blood unit infused please specify the relatedness for each unit in the event description.

Definitely Related: The adverse event is **clearly related** to the test product; a re-challenge confirms the association (not required or desirable in some circumstances but provides strong evidence when it happens).

Probably Related: The adverse event is **temporally associated and plausibly related** to the product/procedure but there are also potential alternative explanations, though the alternatives are not likely.

Possibly Related: The adverse event **may be related**, scientifically plausible, but there are also alternative explanations.

Unlikely Related: The adverse event is **doubtfully related**.

Not Related: The adverse event is **clearly not related**. The adverse event is most plausibly explained by the subject's underlying medical condition or their concomitant therapy, or the adverse event has no plausible relationship to study treatment, or the adverse event has no plausible biological relationship to the study treatment.

Question 11: Has the assessment of a possible, probable, or definite product-related disease transmission changed?

Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response to indicate if this assessment has changed.

If "Yes" is selected, answer question 12.

If "No" is selected, continue to question 13.

Question 12: Is this adverse event a possible, probable, or definite disease transmission caused by the product?

Select response for the question of disease transmission if the response to question 11 is "Yes".

Question 13: Has the CTCAE assessment for this adverse event changed?

Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response.

If "Yes" is selected, answer questions 14-16.

If “No” is selected, continue to question 17.

Question 14: CTCAE Primary Category:

Select the primary CTCAE category of the adverse event from the dropdown that best matches the adverse event at the time of this report if the response to question 13 is “Yes”.

Question 15: CTCAE Primary Event:

Select the primary CTCAE event for the adverse event at the time of this report from the dropdown if the response to question 13 is “Yes”.

Question 16: CTCAE Grade (most severe):

Select the most severe CTCAE Grade for the adverse event from the onset of the event to the time of this follow-up report if the response to question 13 is “Yes”.

Question 17: Has the assessment of expectedness for this adverse event changed?

Compare the adverse event status at the time of this report to the status of the adverse event at last report and select response.

If “Yes” is selected, answer question 18.

If “No” is selected, continue to question 19.

Question 18: Does this adverse event meet the regulatory definition of “unexpected”?

Review the definition of unexpected provided on the form within the FormsNet 2 system and select response if the response to question 17 is “Yes”.

Question 19: Event description update since previous report of this adverse event:

Enter a description of the adverse event update. Include details since the last report. Specifically include any details that change / alter the event pertaining to the nature, seriousness, relatedness, or severity of the event. The previously reported description does not need to be repeated.

Question 20: Additional relevant medical clinical findings (e.g., pre-existing conditions, lab results, concomitant medications, procedures, etc.): *(optional)*

Enter any other relevant findings that have not been collected elsewhere on the form or with the original submission. Include any subject details that are used to determine seriousness and relatedness of the event. This question is optional.

Questions 21-23: Has this adverse event resolved at the time of this report? and Date of resolution: and Type of resolution:

Select response for adverse event resolution at the time the form is being completed.

If “Yes” is selected in question 21, then enter the date of resolution and the type of resolution.

Question 24: Additional comments: (optional)

Enter any additional comments on the adverse event. This question is optional.

Person Completing Form

First Name: and Last Name:

The First Name and Last Name of the person logged in to complete the form will be populated by the system. There is no action required by the user. These questions will populate each time the form is opened and saved.

Date:

This question will be populated by the system each time the form is opened and saved. There is no action required by the user.

Preferred method of contact: (phone number or email address)

Enter information for the best way to contact the person completing the form. This information will be used if there are questions on the form or the adverse event that is being reported.

NMDP Review Section

Questions 29-36: To Be Completed By NMDP/CIBMTR Reviewer ONLY

This section will be completed by NMDP/CIBMTR. Do not enter any information into this section. The form cannot be processed if any of the fields have been completed.

Queries Review and Form Processing

Once the Preferred method of contact field has been completed, proceed to the Queries Review page. Answer any queries and process the form. The “Process” button will submit the form and display a form process page. The “Process/Next” button will submit the current form and will open a new Form 3003 for entry.

When Form 3003 is processed by a user at the transplant center and there are no errors, the form will go to ‘Review’ status. NMDP will review your submission and document the results of the review on the same form. Once the form has been reviewed by NMDP/CIBMTR the form will go to ‘Complete’ status.

In the event the form is in 'Complete' status and data is changed by the center and the form is saved or processed, the information contained in the review section will be removed by the system.