

Submitting a Recipient Adverse Event to NMDP Using FormsNet3SM – Quick Reference

Report all recipient serious adverse events (SAEs) that are:

- Serious infusion reaction within first 24 hours after infusion (CBU); serious infusion reaction within first 48 hours after infusion (non-CBU)
- Recipient seroconversion to, or development of, relevant communicable diseases (RCDs) within six months of infusion which are determined to be caused or potentially caused by the product. RCDs include FDA-defined: HIV 1/2, HBV, HCV, HTLV I/II, CJD, syphilis, vaccinia, WNV, and NMDP defined: Chagas.
- Recipient sepsis related to a contaminated product

An adverse event (AE) is considered “serious” if, in the view of either the investigator or NMDP, it: results in death; is a life-threatening event; or results in hospitalization or prolongation of hospitalization; persistent or significant disability; or congenital anomaly/birth defect. In addition, important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the recipient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Reporting of SAEs should occur as soon as possible, but no later than 24 hours of learning of the event for death or a life-threatening event; other SAEs should be reported within three working days.

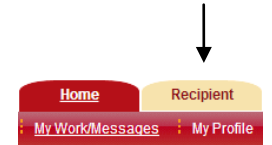
Because most or all of U.S. recipients will be receiving potentially toxic preparative therapy, significant regimen-related toxicity is anticipated. Likewise, substantial mortality and non-engraftment of a transplanted product are anticipated. This data will be captured on appropriate CIBMTR Forms. It is not necessary to report the following on the Form 3001: expected, non-serious AE; non-engraftment; complications that are attributed to the natural course of the disease; chemotherapy and/or radiation toxicity.

To log on, go to connect.nmdp.org.

- Provide your NMDP username.
Usually first initial plus up to 7 letters of your last name
- Enter your 4-digit PIN number immediately followed by the 6 digits showing in the window of the SecurID token.
- Click the link to FormsNet3SM.

- At the FormsNet3SM welcome page, log in using your username (as before) and your alpha-numeric password.

- Click on Recipient at the top of the screen



- In the “Search by Type” box, select CRID. In the “Search For” box, enter the patient’s CRID number. Click “Search.”

- With the CRID populated on the next screen, click on the icon labeled “Create Unscheduled Form.”

- Select the Form 3001 from the drop-down and click “Create Now.”

- This will open a new Form 3001 for adverse event reporting.