

January 2019 Forms Instruction Manual Updates

In case you missed them, here are the changes made to the Forms Instruction Manual during the month of January. Check the "[Getting Started](#)" page of the Forms Instruction Manual for a list of the most recent updates. Updates made after March 2015 are always available for reference in the "[Historical Manual Updates](#)" section.

Date	Manual Section	Add/Remove/Modify	Description
1/17/19	4000: Cellular Therapy Essential Data Pre- Infusion	Remove	Removed the following blue note box instruction (struck out below) for questions 250 to 252 functional status. Functional status should be reported for every indication These questions are for malignant disease indications or relapsed, persistent or progressive disease only.
1/17/19	4100: Cellular Therapy Essential Data Follow- Up	Modify	Added (in red below) clarification on how hypogammaglobulinemia is documented: Report the date (YYYY-MM-DD) in question 126 when the hypogammaglobulinemia was documented by either a physician/health care provider or determined by lab results. <i>If the hypogammaglobulinemia continues from a prior reporting period, report the original diagnosis date as the onset date and override the error.</i> <i>Example 1. The recipient developed hypogammaglobulinemia at day +22 which was reported on the 4100 day 100 form. The lab results continue to show IgG levels < 600 mg/dl during the 6 month reporting period. Report the original diagnosis date on the 4100 6 month form and override the error.</i>
			Added examples (in red below) in question 33 on when to use "previously reported" option: If a new malignancy is reported, please complete the Subsequent Neoplasms Form 3500 to answer questions specific to the new malignancy. The option of 'Previously reported' should only be used if the same new malignancy instance has already been reported on a F3500. <i>See examples below.</i> If there is a question regarding use of this option, please contact your CIBMTR CRC. <i>Example 1. Recipient develops a new malignancy at day +68. It is reported at the time the 100-day form 4100 is completed. Question 33 should be answered as 'yes' and the form 3500 should be completed to report all new malignancy information.</i> <i>Example 2. Recipient develops a new</i>

1/24/19	4100: Cellular Therapy Essential Data Follow- Up	Modify	<i>malignancy at day +68 and had received a commercial CAR-T product. Per protocol, the new malignancy should be reported at the time of knowledge of the new malignancy. The form 3500 should be created as an unscheduled form in FormsNet3 and completed in a timely manner. No other new malignancy develops during the 100-day reporting period. When the 100-day form 4100 is completed, question 33 should be answered as 'previously reported'. Example 3. Recipient develops a new malignancy at day +68 and had received a commercial CAR-T product. Per protocol, the new malignancy should be reported at the time of knowledge of the new malignancy. The form 3500 should be created as an unscheduled form in FormsNet3 and completed in a timely manner. Another new malignancy develops at day +100. It is decided to report the 2nd new malignancy on the 100-day form 4100 since it is due. Question 33 should be answered as 'yes' to create another form 3500.</i>
1/25/19	2018: LYM Pre-Infusion	Modify	Version 4 of the 2018: Lymphoma Pre-Infusion Data section of the Forms Instruction Manual released. Version 4 corresponds to revision 5 of the Form 2018.
1/25/19	2900: Recipient Death	Modify	Version 3 of the 2900: Recipient Death section of the Forms Instructions Manual released. Version 3 corresponds to revision 4 of the Form 2900.
1/25/19	4003: Cellular Therapy Product	Modify	Version 2 of the 4003: Cellular Therapy Product section of the Forms Instruction Manual released. Version 2 corresponds to revision 2 of the Form 4003.

Questions, feedback, or requests may be submitted directly on the manual website using the Feedback Feature at the bottom of each page. For more information on how to submit feedback, [click here](#).