2113: CLL Post-Infusion

The Chronic Lymphocytic Leukemia Post-Infusion Data Form is one of the Comprehensive Report Forms. This form captures CLL-specific post-infusion data such as: disease assessment at the time of best response to HCT or cellular therapy, laboratory studies at the time of best response to HCT or cellular therapy, post-infusion planned treatment for CLL, disease relapse or progression post-infusion, and disease status at the time of assessment for this reporting period. For an overview of CLL, refer to the instructions for the CLL Pre-Infusion Data Form.

This form must be completed for all recipients assigned to the CRF track whose disease, reported on Pre-TED Disease Classification Form (Form 2402), is chronic lymphocytic leukemia (CLL), B-cell/small lymphocytic leukemia (SLL), or prolymphocytic leukemia (PLL). If the recipient underwent a transformation to diffuse large B-cell lymphoma (Richter's transformation), only the CLL Pre-Infusion Data Form (Form 2013) must be completed. Do not complete a CLL Post-Infusion Data Form (Form 2113).

The Chronic Lymphocytic Leukemia Post-Infusion Data (Form 2113) must be completed in conjunction with each Post-Infusion Data Follow-up Form. The form is designed to capture specific data occurring within the timeframe of each reporting period (i.e., between day 0 and day 100, between day 100 and the six-month date of contact, between the date of contact for the six-month follow-up Form 2200 and one-year date of contact, etc.).

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
3/19/18	Comprehensive Disease Specific Manuals	Add	Added the following instruction for applicable post-infusion disease-specific forms where current disease status is asked (2110, 2111, 2112, 2113, 2114, 2115, 2116, 2118, 2119). *The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting period in order to complete current disease status data fields. Once a particular disease status is achieved, the*

			center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.
2/24/17	Comprehensive Disease-Specific Manuals	Modify	Updated explanations of triggers for disease inserts to refer to the primary disease reported on the Pre-TED Disease Classification Form (Form 2402) instead of the Pre-TED Form (Form 2400)
12/12/2016	2113: CLL Post-Infusion	Modify	Instructions for Revision 2 of the CLL Pre- and Post-HCT Forms were retired and instructions for Revision 3 of the CLL Pre- and Post-Infusion Forms were released.

Last modified: Mar 19, 2018

Q1-3: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

Question 1: Compared to the disease status prior to the preparative regimen, what was the best response to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent or progressive disease.)

Nodular Partial Response
Nodular partial response (nPR) is a listed disease status option on the Pre-TED Form (Form 2400 Revision 4), but not on the CLL Pre- and Post-Infusion Data Forms (Form 2013 and 2113). If the disease status meets the criteria for nPR, report the disease status as partial response (PR) on Forms 2013 (Revision 3) and 2113.

The intent of this question is to determine the best overall response to HCT / cellular therapy. This is assessed in each reporting period. When evaluating the best response, determine the disease status within the reporting period using the international working group criteria provided in the in CLL Response Criteria of the Forms Instructions Manual. Compare this response to all previous post-infusion reporting periods. If the response in the current reporting period is the best response to date, report the disease status established within this reporting period. If a better response was established in a previous reporting period, report the previously established disease status. See question 2 to indicate that this disease status was previously reported.

Include response to any post-infusion treatment planned as of Day 0. If post-infusion therapy is given as prophylaxis or maintenance for recipients in CR or as preemptive therapy for recipients with minimal residual disease, consider this “planned therapy,” even if this was not documented prior to the transplant. ***Do not include response to any treatment administered as a result of relapse, progression, or persistent disease.*** If a recipient has started treatment for relapse, progression, or persistent disease, report the best response confirmed prior to the initiation of treatment (even if this was confirmed in a prior reporting period).

Question 2: Was the date of best response previously reported?

If the best response to HCT or cellular therapy was first documented during the current reporting period, report “no” and continue with question 3. If the best response was already documented during a prior reporting period, report “yes” and skip questions 3-26.

Do not report “yes” if completing this form for the 100 Day reporting period.

Question 3: Date assessed

Report the date the best response to HCT or cellular therapy was established. This should be the earliest date when all international working group criteria for the response being reported in question 1 were met.

Report the date the sample was collected for pathologic evaluation (e.g., bone marrow biopsy) or blood/serum assessment (e.g., CBC, peripheral blood smear). If no pathologic, radiographic, or laboratory assessments were performed to establish the best response, report the office visit in which the physician clinically evaluated the response to HCT or cellular therapy.

If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, General Guidelines for Completing Forms.

Section Updates:

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

Q4-26: Disease Assessment at the Time of Best Response

Question 4-5: Were tests for molecular markers performed (e.g. PCR)?

Molecular markers for disease refer to specific genetic sequences which are believed to be associated with the recipient's primary disease. Testing for these sequences is often performed using PCR based methods; however, lower sensitivity testing, including FISH, may also be used to detect molecular markers. Once a marker has been identified, these methods can be repeated to detect minimal residual disease (MRD) in the recipient's blood, marrow, or tissue.

If testing for molecular markers was performed at the time of best response, report "yes" and indicate the sample collection date in question 5. If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, General Guidelines for Completing Forms.

If no molecular marker testing was performed or it is unknown if testing was done, report "no" or "unknown" respectively and skip questions 5-13.

Question 6-13: Specify results

For each molecular marker in questions 6-12, report whether testing was "positive," "negative," or "not done." If tests identified a molecular marker other than those listed in questions 6-11, report the result in question 12 and specify the marker in question 13.

If multiple "other molecular markers" were tested at the time of best response, report "see attachment" in question 13 and attach the final reports for any other markers which were tested. For further instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide. In this scenario, report "positive" in question 12 if any of the "other molecular markers" were detected.

Question 14-15: Was the disease status assessed via flow cytometry (minimum 4 color flow) (immunophenotyping)?

Flow cytometry (immunophenotyping) is a technique that can be performed on blood, bone marrow, or tissue preparations where cell surface markers can be detected on cellular material.

If flow cytometry (immunophenotyping) was performed at the time of best response, report "yes" and indicate the sample collection date in question 15. If the exact date is not known, use the process described for reporting partial or unknown dates in General Instructions, General Guidelines for Completing Forms.

If flow cytometry (immunophenotyping) was not performed, report "no" and skip questions 15-16.

Question 16: Was disease detected?

Indicate whether disease was detected by flow cytometry. If this is not clear from the laboratory report,

consult with a physician and have them document whether evidence of disease is present.

Question 17: Was the disease status assessed via cytogenetic testing (karyotyping or FISH)?

Cytogenetic analysis is the study of chromosomes. Cytogenetic assessment involves testing blood or bone marrow for the presence of a known chromosomal abnormality which reflects the recipient's disease. Testing methods you may see include conventional chromosome analysis (karyotyping) or fluorescence in situ hybridization (FISH). For more information about cytogenetic testing and terminology, see Appendix C.

Karyotyping is performed by culturing cells (growing cells under controlled conditions) until they reach the dividing phase. Techniques are then performed to visualize the chromosomes during cell division so that various bands and reconfigurations can be seen. Banding pattern differentiation and chromosomal reconfiguration demonstrate evidence of disease.

FISH is a sensitive technique that assesses a large number of cells. This technique uses special probes that recognize and bind to fragments of DNA commonly found in CLL. These probes are mixed with cells from the recipient's blood. A fluorescent "tag" is then used to visualize the binding of the probe to the diseased cells. Additionally, the FISH probe panel should reflect the patient's current disease; FISH may be used as surveillance for changes associated with post-therapy malignancy.

FISH testing for sex chromosomes after sex-mismatched allogeneic HCT should not be considered a disease assessment as the purpose is to determine donor chimerism.
If cytogenetic (karyotyping or FISH) studies were obtained at the time of best response, report "yes" and continue with question 18.

If cytogenetic studies were attempted at the time of best response, but there were not adequate cells (metaphases), report "no," and skip questions 18-26.

If no cytogenetic studies were obtained at the time of best response, indicate "no" and skip questions 18-26.

Question 18-19: Was the disease status assessed via FISH?

If FISH studies were performed at the time of best response to HCT or cellular therapy, report "yes" and indicate the sample collection date in question 19. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If FISH studies were not performed, indicate "no" and skip questions 19-20. Examples of this include: no FISH study performed or FISH sample was inadequate.

Question 20: Was disease detected?

Indicate whether disease was detected by FISH. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 21-22: Was the disease status assessed via karyotyping?

If karyotyping (conventional cytogenetic) studies were performed at time of best response to HCT or cellular therapy, report “yes” and indicate the date sample collection date in question 22. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If karyotyping was not performed, report “no” and skip questions 22-23. Examples of this include: no karyotyping was performed or karyotyping culture failed.

Question 23: Was disease detected?

Indicate whether disease was detected by conventional cytogenetics (karyotyping). If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 24-25: Was the disease status assessed by clinical/hematologic assessment?

Clinical and hematologic assessments are the least sensitive methods of establish a patient’s disease status. Examples include: pathologic evaluation (e.g., bone marrow biopsy), radiographic examination (e.g., X-ray, CT scan, MRI scan, PET scan), and laboratory assessment (e.g., CBC, peripheral blood smear), in addition to clinician evaluation and physical examination.

Indicate whether clinical and/or hematologic assessments were performed at the time the best response. If “yes,” report the date of assessment in question 25. The date reported should be that of the most-disease specific assessment performed at the time of best response (question 3). When determining the most disease-specific assessment, only consider studies which have previously or currently show evidence of disease. If all assessments are negative, report the date of the most sensitive test performed (e.g., report a bone marrow biopsy rather than a CBC) within the appropriate time period. If assessments are positive for disease, report the first assessment confirming the best response (question 1). If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If no clinical and/or hematologic assessments were performed during this time period, report “no” and skip questions 25-26. This option should rarely be reported given the inclusion of physician assessments.

Question 26: Was disease detected?

Indicate whether disease was detected by clinical/hematologic assessment. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Section Updates:

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

Q27-42: Post-HCT / Post-Infusion Planned Therapy

Question 27: Was therapy given since the date of last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy.)

Indicate if the recipient received treatment post-Infusion for reasons other than relapse, progressive, or persistent disease (excluding minimal residual disease (MRD)) during the current reporting period. Recipients are generally transplanted under a specific protocol that defines radiation and/or systemic therapy the recipient is intended to receive as a preparative regimen prior to the HCT or cellular therapy; infection and GVHD prophylaxis to be administered pre- and/or post-HCT; as well as any systemic therapy, radiation, and/or other treatments to be administered post-HCT or cellular therapy as planned (or maintenance) therapy. Planned (maintenance or consolidation) therapy is given to assist in prolonging a remission. Planned therapy may be described in a research protocol or standard of care protocol and these should be referred to when completing this section. If post-transplant therapy is given as prophylaxis or maintenance for recipients in CR, or as preemptive therapy for recipients with minimal residual disease, consider this “planned therapy,” even if this was not documented prior to the transplant. For example, if a physician decides to put the recipient on rituximab maintenance therapy post-HCT or cellular therapy, even if it the intent wasn’t documented prior to transplant, report it in this section of the form. ***Do not include any treatment administered as a result of relapse, progression, or persistent disease (excluding MRD).***

If planned therapy, including therapy given for maintenance or consolidation, was given during the reporting period, report “yes” continue with question 28. If “no” or “unknown,” continue skip questions 28-42.

Question 28: Systemic therapy

Systemic therapy is delivered via the blood stream and distributed throughout the body. Therapy may be injected into a vein or given orally. Common systemic therapies used to treat CLL include chemotherapy and monoclonal antibodies.

Report “yes” if systemic therapy was given as planned treatment post-HCT or cellular therapy (including maintenance and consolidation treatments) during the reporting period and continue with question 29.

If systemic therapy was not given as planned therapy during the reporting period, report “no and skip questions 29-38.

Question 29: Chemotherapy

Indicate whether chemotherapy was given as planned treatment post-HCT or cellular therapy (including maintenance and consolidation treatments) during the reporting period. Do not report immune therapy / monoclonal antibodies (e.g., rituximab) as these treatments will be captured in questions 30-38.

Questions 30-38: Immune therapy/monoclonal antibody (mAb)

Indicate whether immune therapy/monoclonal antibody (mAb) was given as planned treatment post-HCT or

cellular therapy (including maintenance and consolidation treatments) during the reporting period.

If “yes,” report the treatment(s) given using questions 31-38. If the recipient received a monoclonal antibody which is not listed, report “Other mAb” for question 35 and specify any other monoclonal antibodies given in question 36. If the recipient received an immune therapy which is not listed, report “yes” in question 37 and specify the other immune therapy in question 38.

If “no,” skip questions 31-38.

Question 39: Radiation

Radiation therapy utilizes high-energy x-rays, gamma rays, electron beams, or proton beams to kill cancer cells. For CLL, radiation therapy may be used to kill cells which have invaded other tissues and lymph nodes. Radiation therapy may be given in conjunction with systemic chemotherapy or as a separate line of therapy.

Report “yes” if the recipient received radiation as planned therapy post-HCT or cellular therapy (including maintenance and consolidation treatments) during the reporting period. If not, report “no.”

Question 40: Cellular therapy

Cellular therapy treatment strategies include isolation and transfer of specific stem cell populations, administration of effector cells (e.g., cytotoxic T-cells), induction of mature cells to become pluripotent cells, and reprogramming of mature cells (e.g., CAR T-cells).

Report “yes” if the recipient received cellular therapy as planned therapy post-HCT (including maintenance and consolidation treatments) during the reporting period. If not, report “no.”

Question 41-42: Other therapy

Indicate if the recipient received any other treatment as planned therapy post-HCT (including maintenance and consolidation treatments). If “yes,” specify the type of treatment administered using question 42. If “no,” skip question 42.

Section Updates:

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

Q43-88: Disease Relapse or Progression Post-HCT / Post-Infusion

Question 43: Was a disease relapse or progression detected since the date of last report?

Refer to the international working group criteria provided in CLL Response Criteria section of the Forms Instructions Manual for more information on how to determine recurrence or progression of disease. If the recipient met the criteria for relapse or progression during the reporting period, report “yes” and continue with question 44. Do not report persistent disease in this section of the form.

If the recipient’s disease did not relapse or progress during the reporting period, report “no” and skip questions 44-54. Questions 44-52 are meant to capture the recipient’s molecular, immunophenotypic, and cytogenetic status at the time of hematologic relapse / progression. Therefore, these questions will only be completed if the recipient has met the criteria for clinical/hematologic relapse or progression during the reporting period.

Question 44-45: Was a disease relapse or progression detected by molecular testing (e.g. PCR)?

If relapse or progression was identified by molecular testing, report “yes” and indicate the sample collection date in question 45. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

Only consider testing performed via molecular methods (e.g., PCR or other methods of equal or greater sensitivity) when completing question 44. Do not consider lower sensitivity testing such as FISH, flow cytometry, karyotyping, or clinical/hematologic methods.

If relapse or progression was not identified by molecular testing, report “no” and skip question 45.

Question 46-47: Was a disease relapse or progression detected via flow cytometry?

If relapse or progression was identified by flow cytometry (immunophenotyping), report “yes” and indicate the sample collection date in question 47. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If relapse or progression was not detected by flow cytometry, report “no” and skip question 47.

Question 48: Was a disease relapse or progression detected by cytogenetic testing (karyotyping or FISH)?

Indicate if cytogenetic studies (karyotyping or FISH) were obtained at the time of hematologic relapse / progression. If either of these methods detected relapse / progression, report “yes” and continue with question 49. If “no,” skip questions 49-52.

Question 49-50: Was a disease relapse or progression detected via FISH?

If FISH studies identified disease relapse or progression, report “yes” and indicate the date of sample collection in question 50. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If FISH studies did not identify disease relapse or progression, report “no” and skip question 50. Examples of this include: no FISH studies performed or FISH sample was inadequate.

Question 51-52: Was a disease relapse or progression detected via karyotyping?

If conventional cytogenetics identified disease relapse or progression, indicate “yes” and report the date of sample collection in question 52. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If conventional cytogenetics did not identify disease relapse or progression, report “no” and skip question 52. Examples of this include: no conventional cytogenetics performed or conventional cytogenetic culture failed.

Question 53-54: Was a disease relapse or progression detected by clinical/hematologic assessment?

Clinical and hematologic assessments are the least sensitive methods of establishing a patient’s disease status. Examples of those include: pathologic evaluation (e.g., bone marrow biopsy), radiographic examination (e.g., X-ray, CT scan, MRI scan, PET scan), and laboratory assessment (e.g., CBC, peripheral blood smear), in addition to clinician evaluation and physical examination.

If clinical and/or hematologic assessments identified disease relapse or progression, report “yes” and indicate the date of assessment in question 54. Enter the date of the clinical/hematologic disease assessment that documented disease relapse or progression. Report the date disease was detected by radiographic examination (e.g., CT, MRI, PET, or PET/CT scans), bone marrow examination, peripheral blood assessment, or clinical assessment. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If clinical and/or hematologic assessments did not identify disease relapse or progression, report “no” and skip question 54.

Question 55: Was any therapy given for relapse or progressive disease since the date of last report?

Therapy for Persistent Disease
Report treatment for persistent disease (excluding MRD) in questions 55-88. Do not include therapy which has already been reported in questions 27-42 (planned therapy including maintenance and consolidation) unless the treatment is continued after the recipient’s disease has relapsed or progressed.

Systemic therapy, radiation, and/or other treatments may be administered for relapse or progressive disease. Indicate if the recipient received treatment post-infusion for relapse or progressive disease since the date of last report.

Question 56: Date started

Enter the date the recipient first received treatment for relapse, progressive, or persistent (excluding MRD) disease during the current reporting period. If the therapy reported in this section is continued from a prior reporting period, leave question 56 blank and override the validation error using the code “Unable to Answer.” If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

Question 57: Systemic therapy

Systemic therapy is delivered via the blood stream and distributed throughout the body. Therapy may be injected into a vein or given orally. Common systemic therapies used to treat CLL include chemotherapy and monoclonal antibodies.

Report “yes” if systemic therapy was given for relapsed, progressive, or persistent (excluding MRD) disease during the reporting period and continue with question 58.

If systemic therapy was not given for relapsed, progressive, or persistent (excluding MRD) disease during the reporting period, report “no and skip questions 58-83.

Questions 58-83: Specify systemic therapy

Report “yes” or “no” for each chemotherapy and immunotherapy drug listed on the form. If the recipient received a chemotherapy treatment that is not listed, report “yes” for “other treatment” and specify the treatment in question 83. Report the generic name of the agent, not the name brand.

Question 84: Radiation therapy

Radiation therapy utilizes high-energy x-rays, gamma rays, electron beams, or proton beams to kill cancer cells. For CLL, radiation therapy may be used to kill cells that have invaded other tissues and lymph nodes. Radiation therapy may be given in conjunction with systemic chemotherapy or as a separate line of therapy.

Report “yes” if the recipient was given treatment for relapsed, progressive, or persistent (excluding MRD) disease during the reporting period. If not, report “no.”

Question 85: Cellular therapy

Cellular therapy treatment strategies include isolation and transfer of specific stem cell populations, administration of effector cells (e.g., cytotoxic T-cells), induction of mature cells to become pluripotent cells, and reprogramming of mature cells (e.g., CAR T-cells).

Report “yes” if the recipient received cellular therapy as treatment for relapsed, progressive, or persistent

(excluding MRD) disease during the reporting period. If not, report “no.”

Question 86: Withdrawal of immunosuppression

Immunosuppressive medications may be tapered or entirely withdrawn in order to promote a graft vs leukemia effect in the setting of relapsed, progressive, or persistent (excluding MRD) disease post-HCT.

If immunosuppression is reduced or stopped during the reporting period in order to treat disease, report “yes.” If not, report “no.”

Questions 87-88: Other therapy

Indicate if the recipient received any other treatment for relapsed, progressive, or persistent (excluding MRD) disease during the reporting period. If “yes,” specify the type of treatment administered using question 88. If “no,” skip question 88.

Section Updates:

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

Q89-113: Disease Status at the Time of Evaluation for This Reporting Period

Question 89-90: Were tests for molecular markers performed (e.g. PCR)?

If testing for molecular markers was performed during the reporting period, report “yes” and report the sample collection date of the most recent testing performed during the reporting period in question 90. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If testing for molecular markers was not performed during the reporting period, report “no” or “unknown” and continue with question 99.

For more information on testing for molecular markers, refer to the instructions for questions 4-5.

Questions 91-98: Specify results

For each molecular marker in questions 91-97, report whether the most recent testing performed during the reporting period was “positive,” “negative,” or “not done.” If tests identified a molecular marker other than those listed in questions 91-96, report the result in question 97 and specify the marker in question 98.

If multiple “other molecular markers” were tested at the time of evaluation for this reporting period, report “see attachment” in question 98 and attach the final reports for any other markers which were tested. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Question 99-100: Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?

If flow cytometry (immunophenotyping) was performed during the reporting period, report “yes” and indicate the sample collection date of the most recent testing performed during the reporting period in question 100. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If flow cytometry (immunophenotyping) was not performed during the reporting period, report “no” and skip questions 100-101.

For more information on reporting flow cytometry, refer to the instructions for questions 14-15.

Question 101: Was disease detected?

Indicate whether disease was detected by the most recent flow cytometry assessment performed during the reporting period. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 102: Was the disease status assessed by cytogenetic (karyotyping or FISH)?

Indicate whether cytogenetic studies (karyotyping or FISH) were obtained during the reporting period. If cytogenetic studies were obtained, report “yes” and continue with question 103. If not, report “no” and skip questions 103-108.

For more information on reporting karyotyping and FISH studies, refer to the instructions for question 17.

Question 103-104: Was the disease status assessed via FISH?

If FISH studies were performed during the reporting period, report “yes” and indicate the sample collection date of the most recent testing performed during the reporting period in question 104. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If FISH studies were not performed, report “no” and skip questions 104-105. Examples of this include: no FISH study performed or FISH sample was inadequate.

Question 105: Was disease detected?

Indicate whether disease was detected by the most recent FISH study performed during the reporting period. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 106-107: Was the disease status assessed via karyotyping?

If conventional cytogenetic studies were obtained during the reporting period, report “yes” and report the sample collection date of the most recent testing performed during the reporting period in question 107. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If conventional cytogenetic studies were not performed, report “no” and continue with question 109. Examples of this include: no conventional cytogenetics performed or conventional cytogenetic culture failed.

Question 108: Was disease detected?

Indicate whether disease was detected by the most recent karyotyping study performed during the reporting period. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 109-110: Was the disease status assessed by clinical/hematologic assessment?

Indicate whether any clinical and/or hematologic assessments were performed during the reporting period. If “yes,” report the date of assessment in question 110. The date reported should be that of the most-disease specific assessment performed within approximately 30 days of the date of contact (reported on the Post-Infusion Data Form). When determining the most disease-specific assessment, only consider studies which have previously or currently show evidence of disease. If all assessments are negative, report the date of

the most sensitive test performed (e.g., report a bone marrow biopsy rather than a CBC) within the appropriate time period. If assessments are positive for disease, report the most recent positive assessment. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If no clinical and/or hematologic assessments were performed during this time period, report “no” and skip questions 110-111. This option should rarely be reported given the inclusion of physician assessments.

For more information on reporting clinical/hematologic assessments, refer to the instructions for questions 24-25.

Question 111: Was disease detected?

Indicate whether disease was detected by clinical/hematologic assessment on the date reported in question 110. If the findings are unclear, consult with a physician and have them document whether evidence of disease is present.

Question 112: What is the current disease status?

Nodular Partial Response
Nodular partial response (nPR) is a listed disease status option on the Pre-TED Form (Form 2400 Revision 4), but not on the CLL Pre- and Post-Infusion Data Forms (Form 2013 and 2113). If the disease status meets the criteria for nPR, report the disease status as partial response (PR) on Forms 2013 (Revision 3) and 2113 (Revision 3).

Report the recipient’s disease status at the time of evaluation for this reporting period. Ensure the disease status is consistent with the international working group criteria provided in the in CLL Response Criteria section of the Forms Instructions Manual. If the disease was not assessed, report “not assessed” and go to “First Name.” This option should rarely be used given the inclusion of physician assessments as disease evaluations.

The center does not need to repeat all disease-specific assessments (biopsies, scans, labs) each reporting period in order to complete current disease status data fields. Once a particular disease status is achieved, the center can continue reporting that disease status (based on labs / clinical assessments) until there is evidence of relapse / progression.

Question 113: Date assessed

The date reported should be that of the most-disease specific clinical / hematologic assessment performed within approximately 30 days of the date of contact (reported on the Post-Infusion Data Form). When determining the most disease-specific assessment, only consider studies which have previously or currently show evidence of disease. If all assessments are negative, report the date of the most sensitive test performed (e.g., report a bone marrow biopsy rather than a CBC) within the appropriate time period. If assessments are positive for disease, report the most recent positive assessment. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions,

General Guidelines for Completing Forms.

Section Updates:

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