2018: LYM Pre-Infusion

Complete this form for recipients whose primary disease, reported on the Disease Classification Form (Form 2402), is Hodgkin Lymphoma (HL) or non-Hodgkin Lymphoma (NHL). One exception is **Waldenstrom's macroglobulinemia / lymphoplasmacytic lymphoma**, for which, a Waldenstrom's Macroglobulinemia Form (Form 2019) will be completed instead.

•

Acute Lymphoblastic Leukemia / Lymphoma

Due to the aggressive nature of precursor B- and precursor T-cell lymphoblastic lymphoma (or lymphoma/leukemia), the primary disease to report for recipients with these malignancies should be acute lymphoblastic leukemia (B- lymphoblastic leukemia/ lymphoma or early T-cell precursor lymphoblastic leukemia). If the recipient's primary disease is acute lymphoblastic lymphoma, complete an ALL Pre-Infusion Data Form (Form 2011). Do not complete a LYM Pre-Infusion Data Form (Form 2018).

Is this the report of a second or subsequent transplant or cellular therapy for the same disease?

Report "No" and go to question 1 in any of the following scenarios:

- this is the first infusion reported to the CIBMTR;
- this is the first infusion given to treat the recipient's current disease; or
- this is a second or subsequent infusion for the <u>same disease</u> and this <u>baseline disease insert was not completed for the previous transplant</u> (e.g., patient was on TED track for the prior infusion, prior infusion was autologous with no consent, etc.).

If this is a report of a second or subsequent infusion for the <u>same disease</u> and this <u>baseline lymphoma</u> <u>disease insert was completed previously</u>, report "Yes" and go to question 82.

Links to sections of form:

Q1-55: Disease Assessment at Diagnosis

Q56-68: Laboratory Studies at Diagnosis

Q69-81: Assessment of Nodal and Organ Involvement at Diagnosis

Q82-139: Disease Assessment at Transformation

Q140-152: Laboratory Studies at Transformation

Q153-165: Assessment of Nodal and Organ Involvement at Transformation

Q166-223: Pre-HCT or Pre-Infusion Therapy

Q224-233: Disease Assessment at the Failure of the 1st Line of Therapy

Q234-288: Disease Assessment at the Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

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 <u>click here</u> or reference the retired manual section on the <u>Retired Forms Manuals</u> webpage.

Date	Manual Section	Add/ Remove/ Modify	Description			
8/24/ 2020	2018: LYM Pre- Infusion	Add	Blue instruction box added above questions 180 and 188 to clarify if multiple intrathecal / intraocular therapies are given as part of a line of therapy to report each as a separate line: If a recipient receives multiple intrathecal / intraocular therapies as part of a single line of therapy, report each intrathecal / intraocular therapy as a separate line.			
7/24/ 2020	2018: LYM Pre- Infusion	Modify	Modified the instructions for completing this form for a subsequent infusion.			
6/5/ 2020	2018: LYM Pre- Infusion	Add	Provided clarification (see red text) on how to answer question 224 if therapy for DLBCL was not given between diagnosis and the start of the preparative regimen / infusion. If the recipient did not receive therapy between diagnosis of DLBCL and the start of the preparative regimen / infusion, leave question 224 blank, override the validation error using the code "unable to answer," and specify in the comments the recipient did not receive therapy for DLBCL prior to the start of the preparative regimen / infusion.			
6/5/ 2020	2018: LYM Pre- Infusion	Modify	Update the reporting instructions for question 201 (removed text is struck out and added text is in red): Indicate if the recipient received radiation to each site listed the extent of the radiation field.			
5/19/ 2020	2018: LYM Pre- Infusion	Add	Added specification that questions 62 and 146 should be answered for all Hodgkin histologies.			
4/7/ 2020	2018: LYM Pre- Infusion	Add	Added sentence after question 80-81 stating Documentation from an RN who has been trained and authorized to determine performance scores may also be used.			
4/7/2020	2018: LYM Pre- Infusion	Modify	Updated question numbers in section Q224-233: Disease Assessment at the Failure of the 1st Line of Therapy.			
3/20/ 2020	2018: LYM Pre- Infusion	Add	Added guidance in introduction to Q166-223: Pre-HCT Therapy on scenario where recipient's lymphoma histology transforms between diagnosis and start of preparative regimen.			
2/19/ 2020	2018: LYM Pre- Infusion	Add	Added information after Questions 1-2 and Questions 83-85 on double-hit or triple-hit lymphomas.			
1/25/ 2019	2018: LYM	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.			

Pre- Infusion			
Infusion	Pre-		
	Infusion		

Last modified: Aug 24, 2020

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Q1-55: Disease Assessment at Diagnosis

Question 1-2: Specify the lymphoma histology (at diagnosis)



Double-hit or triple-hit lymphomas – Rearrangements of MYC and BCL2 and/or BCL6 constitute a single category in the updated WHO classification and should be reported as "High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements" on CIBMTR forms.

If the recipient had CLL which transformed into DLBCL (Richter's transformation) or Hodgkin lymphoma (HL), report the DLBCL or HL histology in question 1 and the transformation from CLL in question 82. If a transformation did occur, also complete a CLL Pre-Infusion Data Form (Form 2013).

If the recipient has multiple types of lymphoma at diagnosis or has a transformation, report the least aggressive lymphoma histology at diagnosis (question 1) and of the most aggressive lymphoma as a transformation (questions 83-85). The occurrence of transformation and the resultant histology must be determined by a physician.

Indicate the lymphoma histology at diagnosis. Report the specific histology in question 2 if any of the options reported for question 1 are:

- Other B-cell lymphoma
- Other T-cell / NK-cell lymphoma

Question 3: Assignment of DLBCL (germinal center B-cell type vs. Activated B-cell type) subtype was based on:

Only complete question 3 if one of the following was reported as the histology at diagnosis (question 1):

- Diffuse, large B-cell lymphoma- Germinal center B-cell type
- Diffuse, large B-cell lymphoma- Activated B-cell type (non-GCB)

Otherwise, skip question 3 and go to question 4.

Report the method(s) used to confirm the histology at diagnosis. Check all that apply. If the method of diagnosis is not clear from the available documentation, report "Unknown method."

Question 4: Was documentation submitted to the CIBMTR? (e.g., path report from diagnosis

Indicate whether documents were attached to support / clarify the center's responses to questions 1-3. Attaching pathology reports at diagnosis in FormsNet3SM may prevent future data queries. For further

instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 5: Were immunohistochemical stains obtained? (at diagnosis, prior to any transformation)

Immunohistochemical staining (IHC) is a process where tissue samples are treated with antibodies and dye. The antibodies bind to specific antigens on the surfaces of the cells, allowing for the identification of those cell surface markers under microscopy. Testing is often documented in the pathology report from the tissue sample, on which, IHC was used.

Report "Yes" and go to question 6 if IHC was done at diagnosis.

If testing was not done or it is not known whether testing was performed, report "No" or "Unknown" respectively and go to question 25.

Questions 6-24: Immunohistochemical stain results

Testing may be performed on multiple sample types at diagnosis. Report testing performed on samples taken from the node / mass, if available. If IHC was not done on the node / mass or the results are not known, report testing performed on the bone marrow instead. Additionally, IHC results are documented differently across hospitals / laboratories. Consult a physician if the results are not clear.

Report "Positive," "Negative," or "Unknown" for each marker based on the IHC results at diagnosis. If the report documents "dim" for a specific marker, report this as "Positive." Report "Unknown" for markers which were not tested or were tested, but the results are not known.

If "Positive" is reported for any of the markers listed below, indicate whether the percent of cells positive for this marker (as determined by IHC) is known. If so, report the percent of cells positive for the specified marker.

- BCL-2
- BCL-6
- C-MYC
- Ki-67

If the percent is documented as **a range**, report the average. If the percent is documented as **less than a specified percent**, report the percent specified minus one (e.g., report < 10% as 9%). If the percent is documented as **more than a specified percent**, report the percent specified plus one. (e.g., report > 90% as 91%).

Question 25: Were cytogenetics tested (karyotyping or FISH)?

Cytogenetics is the study of chromosomes. This assessment involves testing blood or bone marrow for known chromosomal abnormalities that reflect the recipient's disease. For more information about

cytogenetic testing and terminology, see <u>Appendix C. Cytogenetic Assessments</u>. Indicate whether cytogenetic studies were performed at diagnosis. Do not report any testing performed after treatment was started for the disease histology specified in question 1.

If cytogenetic studies were obtained at diagnosis, report "Yes" and go to question 26.

If cytogenetic studies were not obtained at diagnosis or it is not known whether chromosome studies were performed, report "No" or "Unknown" respectively and go to question 56.

Question 26-27: Were cytogenetics tested via FISH?

If FISH studies were performed at diagnosis, report "Yes" for question 26 and indicate whether clonal abnormalities were detected in question 27.

If FISH studies were not performed at this time point, report "No" for question 26 and go to question 51. Examples include: no FISH study performed or FISH sample was inadequate.

See Appendix C, Cytogenetic Assessments, for assistance interpreting FISH results.

Question 28-49: Specify cytogenetic abnormalities (FISH)

For each abnormality:

Report "Yes" if FISH testing detected the abnormality at diagnosis.

Report "No" if FISH testing for the abnormality was done at diagnosis and was negative.

Report "**Not done**" if FISH testing for the abnormality was not included or could not be successfully performed (e.g., inadequate sample) at diagnosis.

If a clonal abnormality is detected, but cannot be reported in questions 28-47, report "Yes" for question 48 and specify the abnormality in question 49. If multiple "other abnormalities" were detected, report "see attachment" in question 49 and attach the final report(s) for any other abnormalities detected. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Question 50: Was documentation submitted to the CIBMTR? (e.g., FISH report)

Indicate if a FISH testing report is attached to support the findings reported in questions 26-49. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 51-52: Were cytogenetics tested via karyotyping?

If karyotyping was performed at diagnosis, report "Yes" for question 51 and indicate whether clonal abnormalities were detected in question 52.

If karyotyping was not performed at this time point, report "No" for question 51 and go to question 56. Examples include: no karyotyping performed or karyotyping sample was inadequate.

See Appendix C, Cytogenetic Assessments, for assistance interpreting karyotype results.

Question 53-54: Specify cytogenetic abnormalities (karyotyping)

Check any abnormalities detected by karyotyping at diagnosis. If karyotyping detected an abnormality that is not specified in question 53, check "Other abnormality" and report the abnormality in question 54. If multiple "other abnormalities" were detected at diagnosis, report "see attachment" for question 54 and attach the karyotyping report to the form. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 55: Was documentation submitted to the CIBMTR?

Indicate if a karyotyping report is attached to support the findings reported in questions 51-54. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Last modified: Feb 19, 2020

Q56-68: Laboratory Studies at Diagnosis

Questions 56-68 will be enabled / disabled in FormsNet3SM based on the histology reported in question 1. Reporting instructions for specific questions are provided at the bottom of this page for reference.

All values reported in questions 56-68 must reflect testing performed prior to any treatment for the histology specified in question 1. If testing was not performed near the time of diagnosis (within approximately 30 days) and prior to the initiation of treatment, the center should report "Unknown" for that value.

For each laboratory study, indicate whether the test result was "Known" or "Unknown" at the time of diagnosis. If "Known," report the result and the unit of measure. If "Known" is reported for LDH (question 66), also specify the upper limit of normal and corresponding unit of measure in question 68.

Laboratory Studies Enabling / Disabling Rules

Question 56-57 (WBC): Only answer for mantle cell lymphoma and Hodgkin lymphoma (all histologies). Question 58-59 (hemoglobin): Only answer for follicular lymphoma (all histologies) and Hodgkin lymphoma (all histologies).

Question 60-61 (absolute lymphocyte count): Only answer for Hodgkin lymphoma (all histologies).

Question 62-63 (lymphocytes): Answer for all Hodgkin histologies.

Question 64-65 (serum albumin): Only answered for Hodgkin lymphoma (all histologies).

Question 66-68 (LDH): Answered for all histologies.

Last modified: May 19, 2020

Q69-81: Assessment of Nodal and Organ Involvement at Diagnosis

All values reported in questions 69-81 must reflect testing / evaluations performed prior to any treatment for the histology specified in question 1. If testing / evaluation was not done near the time of diagnosis (within approximately 30 days) and prior to the initiation of treatment, the center should report "Unknown" for that value.

Question 69-70: Was a PET (or PET/CT) scan performed?

Positron Emission Tomography (PET) is a type of nuclear medicine imaging in which a patient receives a small amount of radioactively labeled sugar. Because cancer cells absorb sugar more avidly than other cells of the body, the radioactively labeled sugar accumulates in these areas and reveals tumors as bright spots. A PET/CT combines the results of the PET scan along with the results of a CT (computed tomography) scan.

If a PET (or PET/CT) scan was performed at diagnosis, report "Yes" for question 69 and specify whether the scan was positive for lymphoma in question 70. Consult a physician to confirm how complete question 70 if the scan report is unclear.

If a PET or (PET/CT) scan was not performed at diagnosis, report "No" for question 69 and go to question 71.

Question 71: Did the recipient have known nodal involvement?

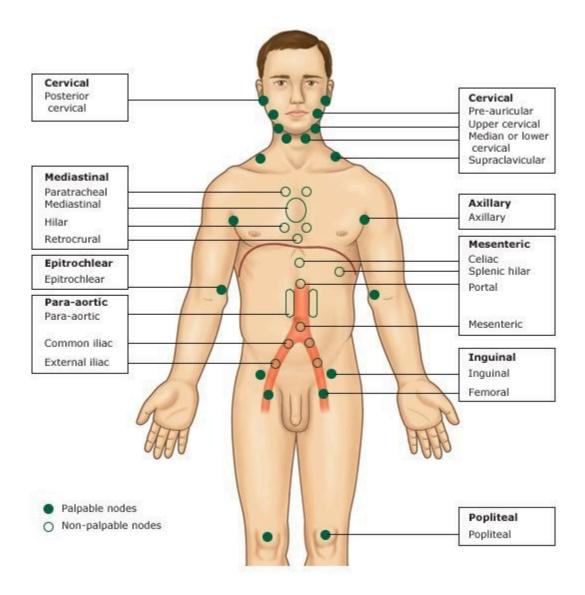
Nodal involvement may be assessed by a physician palpating lymph nodes, pathology from a lymph node biopsy, or radiological assessment (e.g., PET or CT imaging). Report "Yes" and go to question 72 if nodal involvement was detected by any of these methods. Otherwise, report "No" and go to question 75.

Question 72-73: Specify total number of nodal regions involved

Lymph node regions or groups occur above and below the diaphragm. Nodal regions include cervical (neck), axillary (underarm), mediastinal (thoracic), mesenteric (abdominal), para-aortic (pelvic), inguinal (groin), epitrochlear (inside of arm just above elbow), and popliteal (back of knee). Indicate the total number of nodal regions with evidence of lymphoma involvement. Refer to Graphic 1 below for identification of nodal areas and specific nodes within each area.

Complete question 72 if the histology at diagnosis (question 1) was not follicular lymphoma. Otherwise, complete question 73.

Graphic 1. Nodal Areas¹



Question 74: Specify the size of the largest nodal mass

Report the size of the largest known nodal mass as measured in centimeters. If the mass is given in three dimensions (for example: $3 \text{ cm } \times 5 \text{ cm } \times 4 \text{ cm}$), report the longest two dimensions.

Question 75: Was there any known extranodal or splenic involvement? (at diagnosis, prior to any transformation)

Extranodal refers to the presentation of lymphoma outside of the lymph nodes. Common areas of extranodal involvement may include bone, gastrointestinal tract, and skin. Splenic involvement in lymphoma is also common. It is usually evidenced by enlargement of the spleen (splenomegaly). Splenic or other extranodal involvement is most often detected by imaging techniques or pathological findings.

If extranodal or splenic involvement was identified, indicate "Yes" and go to guestion 76.

If there was no evidence of extranodal or splenic involvement or it is not known, report "No" or "Unknown"

respectively and go to question 78.

Questions 76-77: Specify site(s) of involvement:

Check each site with known lymphomatous involvement. If an involved site was documented, but is not listed as an option for question 76, check "Other site" and report all other sites of lymphomatous involvement in question 77.

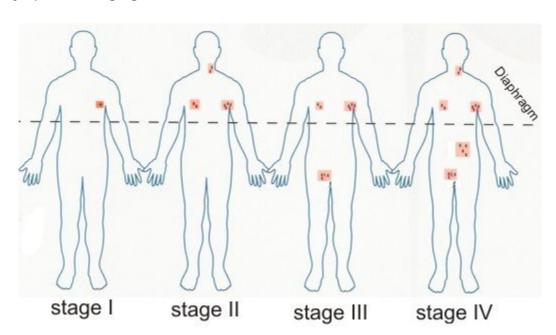
Question 78: Stage of organ involvement: (at diagnosis)

Use the staging criteria below to indicate the organ involvement at diagnosis. If staging at diagnosis is not available or unknown, select "Unknown."

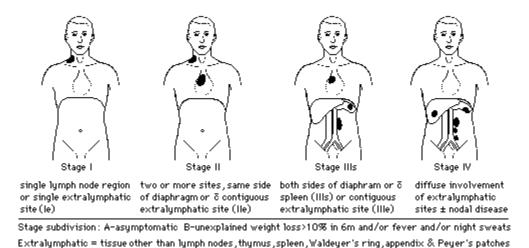
Table 1. Lymphoma Staging

Stage	Description				
Stage I	Involvement of a single lymph node region or of a single extralymphatic organ or site				
Stage II	Involvement of two or more lymph node regions on same side of diaphragm, or localized involvement of an extralymphatic organ or site, and one or more lymph node regions on same side of diaphragm				
Stage III	Involvement of lymph node regions on both sides of diaphragm, which may also be accompanied by localized involvement of extralymphatic organ or site, the spleen, or both				
Stage IV	Diffuse or disseminated involvement of one or more extralymphatic organs in tissues with or without associated lymph node enlargement/involvement				

Graphic 2. Lymphoma Staging²



Graphic 3. Staging Classification³



Question 79: Were systemic symptoms (B symptoms) present?

Systemic symptoms, also known as "B" symptoms, are defined as follows:

- unexplained fever > 38° C (100.4°F)
- · night sweats
- unexplained weight loss of > 10% of body weight over 6 months

Evidence of systemic symptoms is significant because it may indicate the presence of disease in parts of the body not identified using standard testing methods. The presence or absence of systemic symptoms may be indicated in the staging (e.g., II-B or II-A).

If there was evidence of systemic symptoms at diagnosis, select "Yes". Otherwise, select "No."

If documentation is not clear or is not available to determine if systemic symptoms were present at diagnosis or prior to first therapy, select "Unknown."

Question 80-81: ECOG score (at diagnosis)

Recipient performance status is a critical data field that has been determined to be essential for all outcome-based studies. If a performance score is not documented in the source documentation (e.g., inpatient progress note, physician's clinic note), data management professionals should not assign a performance score based on analysis of available documents. Rather, a physician should provide documentation of the performance score. Documentation from an RN who has been trained and authorized to determine performance scores may also be used.

If the performance score has been documented using Karnofsky or Lansky scales, refer to Appendix L: Karnofsky / Lansky Performance Status for assistance converting the score to the ECOG scale.

Report whether the recipient's ECOG score at diagnosis is known in question 80. If "Known," report the score in question 81. Otherwise, go to question 82.

Last modified: Apr 07, 2020

¹ "Lymphadenopathy." Web log post. Horses and Zebras. Morning Report at Toronto General Hospital, 20 July 2010. Accessed on 9/22/2013 at http://morningreporttgh.blogspot.com/2010/07/lymphadenopathy.html

² "Staging Lymphomas." Patients Against Lymphoma. 05 May 2013. Accessed on 9/22/2013 at http://www.lymphomation.org/stage.htm.

³ "Ann Arbor" Staging Classification," "Lymphoma: Clinical- Hodgkin's Lymphoma." Pathology Tool. University of Virginia Medical School. 02 May 2012. Accessed 9/22/2013 at http://www.med-ed.virginia.edu/courses/path/innes/wcd/hodgclinic.cfm.

Q82-139: Disease Assessment at **Transformation**

Question 82: Is the lymphoma histology reported at diagnosis a transformation from CLL?

CLL may evolve to a more aggressive diffuse large B-cell lymphoma (DLBCL). This is commonly referred to as Richter's syndrome or Richter's transformation. Note, CLL may also transform to Hodgkin lymphoma.

If recipient's lymphoma histology at diagnosis (question 1) is transformation from CLL, report "Yes" and go to question 166. Also, complete a CLL Pre-Infusion Data Form (Form 2013). Otherwise, report "No" and go to question 83.

Question 83-85: Did the recipient transform to a different lymphoma histology between diagnosis and the start of the preparative regimen / infusion? (not CLL)



Double-hit or triple-hit lymphomas – Rearrangements of MYC and BCL2 and/or BCL6 constitute a single category in the updated WHO classification and should be reported as "High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements" on CIBMTR forms.

Transformation may occur when a slow-growing lymphoma with an indolent clinical history changes to a more aggressive lymphoma. An example of a common transformation would include follicular lymphoma evolving to a diffuse large B-cell lymphoma (DLBCL).

If the recipient has multiple types of lymphoma at diagnosis or has a transformation, report the least aggressive lymphoma histology at diagnosis (question 1) and the most aggressive lymphoma as a transformation (questions 83-85). The occurrence of transformation and the resultant histology must be determined by a physician.

If the recipient's lymphoma histology transformed between diagnosis and the start of the preparative regimen (or date of infusion if no preparative regimen), report "Yes" for question 83 and specify the histology at transformation in question 84. Report the specific histology in question 85 if any of the following options were reported for question 84:

- Other B-cell lymphoma
- Other T-cell / NK-cell lymphoma

If a transformation did not occur after or concurrently with diagnosis, indicate "No" for question 83 and go to question 166.

Question 87: Was the date of transformation the same as the date of diagnosis?

If a concurrent diagnosis (multiple histologies) has occurred, it is not necessary to repeat the diagnosis information in the transformation section of the report.

Report "Yes" and go to question 166 if the transformation was identified at the time of the original lymphoma diagnosis.

Report "No" and go to question 88 if the transformation was identified after the date of the original lymphoma diagnosis.

Question 88: Date of transformation:

Report the date the transformation was diagnosed. Enter the date the sample was collected for examination. If the date of transformation was determined at an outside center, and no documentation of a pathological or laboratory assessment is available, a dictated date within a physician note may be reported.

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.

Question 89: Were immunohistochemical stains obtained? (at transformation)

See <u>question 5</u> for a description of immunohistochemical stains (IHC).

Report "Yes" and go to question 90 if IHC was done at transformation.

If testing was not done or it is not known whether testing was performed, report "No" or "Unknown" respectively and go to question 109.

Questions 90-108: Immunohistochemical stain results

Testing may be performed on multiple sample types at transformation. Report testing performed on samples taken from the node / mass, if available. If IHC was not done on the node / mass or the results are not known, report testing performed on the bone marrow instead. Additionally, IHC results are documented differently across hospitals / laboratories. Consult a physician if the results are not clear.

Report "Positive," "Negative," or "Unknown" for each marker based on the IHC results at transformation. If the report documents "dim" for a specific marker, report this as "Positive." Report "Unknown" for markers which were not tested or were tested, but the results are not known.

If "Positive" is reported for any of the markers listed below, also indicate if the percent of cells positive for this marker (as determined by IHC) is known. If so, report the percent of cells positive for the specified marker.

- BCL-6
- C-MYC
- Ki-67

If the percent is documented as **a range**, report the average. If the percent is documented as **less than a specified percent**, report the percent specified minus one (e.g., report <10% as 9%). If the percent is documented as **more than a specified percent**, report the percent specified plus one. (e.g., report >90% as 91%).

Question 109: Were cytogenetics tested (karyotyping or FISH)?

Cytogenetics is the study of chromosomes. This assessment involves testing blood or bone marrow for known chromosomal abnormalities that reflect the recipient's disease. For more information about cytogenetic testing and terminology, see Appendix C, Cytogenetic Assessments. Indicate whether cytogenetic studies were performed at transformation.

If cytogenetic studies were obtained at transformation, report "Yes" and go to question 110.

If cytogenetic studies were not obtained at this time point or it is not known whether chromosome studies were performed, report "No" or "Unknown" respectively and go to question 140.

Question 110-111: Were cytogenetics tested via FISH?

If FISH studies were performed at transformation, report "Yes" for question 110 and indicate whether clonal abnormalities were detected in question 111.

If FISH studies were not performed at this time point, report "No" for question 110 and go to question 135. Examples include: no FISH study performed or FISH sample was inadequate.

Question 112-133: Specify cytogenetic abnormalities (FISH)

For each abnormality:

Report "**Yes**" if FISH testing detected the abnormality at transformation.

Report "No" if FISH testing for the abnormality was done at transformation and was negative.

Report "**Not done**" if FISH testing for the abnormality was not attempted or could not be successfully performed (e.g., inadequate sample) at transformation.

If a clonal abnormality is detected, but cannot be reported in questions 112-131, report "Yes" for question 132 and specify the abnormality in question 133. If multiple "other abnormalities" were detected, report "see attachment" in question 133 and attach the final report(s) for any other abnormalities detected. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 134: Was documentation submitted to the CIBMTR? (e.g., FISH report)

Indicate if a FISH testing report is attached to support the findings reported in questions 110-133. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 135-136: Were cytogenetics tested via karyotyping?

If karyotyping was performed at transformation, report "Yes" for question 135 and indicate whether clonal abnormalities were detected in question 136.

If karyotyping was not performed at this time point, report "No" for question 135 and go to question 140. Examples include: no karyotyping performed or karyotyping sample was inadequate.

Question 137-138: Specify cytogenetic abnormalities (karyotyping)

Check any abnormalities detected by karyotyping at transformation. If karyotyping detected an abnormality that is not specified in question 137, check "Other abnormality" and report the abnormality in question 138. If multiple "other abnormalities" were detected at transformation, report "see attachment" for question 138 and attach the karyotyping report to the form. For further instructions on how to attach documents inFormsNet3SM, refer to the <u>Training Guide</u>.

Refer to Appendix C, Cytogenetic Assessments for assistance interpreting karyotyping results.

Question 139: Was documentation submitted to the CIBMTR?

Indicate if a karyotyping report is attached to support the findings reported in questions 135-139. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Last modified: Feb 19, 2020

Q140-152: Laboratory Studies at Transformation

Questions 140-152 will be enabled / disabled in FormsNet3SM based on the histology reported in question 84. Reporting instructions for specific questions are provided at the bottom of this page for reference.

All values reported in questions 140-152 must reflect testing performed prior to any treatment for the histology specified in question 84. If testing was not performed near the time of transformation (within approximately 30 days) and prior to the initiation of treatment, the center should report "Unknown" for that value.

For each laboratory study, indicate whether the test result was "Known" or "Unknown" at the time of transformation. If "Known," report the result and the unit of measure. If "Known" is reported for LDH (question 150), also specify the upper limit of normal and corresponding unit of measure in question 152.

Laboratory Studies Enabling / Disabling Rules

Question 140-141 (WBC): Only answer for mantle cell lymphoma and Hodgkin lymphoma (all histologies).

Question 142-143 (hemoglobin): Only answer for follicular lymphoma (all histologies) and Hodgkin lymphoma (all histologies).

Question 144-145 (absolute lymphocyte count): Only answer for Hodgkin lymphoma (all histologies).

Question 146-147 (lymphocytes): Answer for all Hodgkin histologies.

Question 148-149 (serum albumin): Only answered for Hodgkin lymphoma (all histologies).

Question 150-152 (LDH): Answered for all histologies.

Last modified: May 19, 2020

Q153-165: Assessment of Nodal and Organ Involvement at Transformation

All values reported in questions 153-165 must reflect testing / evaluations performed prior to any treatment for the histology specified in question 84. If testing / evaluation was not done near the time of transformation (within approximately 30 days) and prior to the initiation of treatment, the center should report "Unknown" for that value.

Question 153-154: Was a PET (or PET/CT) scan performed?

See the instructions for <u>questions 69-70</u> for a description of PET scans.

If a PET (or PET/CT) scan was performed at transformation, report "Yes" for question 153 and specify whether the scan was positive for lymphoma in question 154. Consult a physician to confirm how complete question 154 if the scan report is unclear.

If a PET or (PET/CT) scan was not performed at transformation, report "No" for question 153 and go to question 155.

Question 155: Did the recipient have known nodal involvement?

Nodal involvement may be assessed by a physician palpating lymph nodes, pathology from a lymph node biopsy, or radiological assessment (e.g., PET or CT imaging). Report "Yes" and go to question 156 if nodal involvement was detected by any of these methods. Otherwise, report "No" and go to question 159.

Questions 156-157: Specify total number of nodal regions involved

See the instructions for <u>questions 72-73</u> for general information regarding nodal involvement.

Complete question 156 if the histology at transformation (question 84) was not follicular lymphoma. Otherwise, complete question 157.

Question 158: Specify the size of the largest nodal mass

Report the size of the largest known nodal mass as measured in centimeters. If the mass is given in three dimensions (for example: $3 \text{ cm } \times 5 \text{ cm } \times 4 \text{ cm}$), report the longest two dimensions.

Question 159: Was there any known extranodal or splenic involvement? (at transformation)

Refer to the instructions for <u>question 75</u> for a description of extranodal and splenic involvement.

If extranodal or splenic involvement was identified, indicate "Yes" and continue with question 160.

If there was no evidence of extranodal or splenic involvement or it is not known, report "No" or "Unknown"

respectively and go to question 162.

Questions 160-161: Specify site(s) of involvement:

Check each site with known lymphomatous involvement. If an involved site was documented, but is not listed as an option for question 160, check "Other site" and report all other sites of lymphomatous involvement in question 161.

Question 162: Stage of organ involvement: (at transformation)

Refer to <u>Table 1</u> as well as <u>Graphics 2 and 3</u> for information regarding organ involvement / staging. Indicate the stage of organ involvement at transformation. If this information is not available or not known, select "Unknown."

Question 163: Were systemic symptoms (B symptoms) present?

See the instructions for <u>question 79</u> for a description of systemic symptoms. Indicate whether systemic symptoms were present at transformation. If documentation is not clear or is not available, select "Unknown."

Question 164-165: ECOG score (at transformation)

See the instructions for <u>questions 80-81</u> for more information about reporting ECOG scores. Indicate whether the recipient's ECOG score at transformation is known in question 164. If "Known," report the score in question 165. Otherwise, go to question 166.

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Q166-223: Pre-HCT Therapy

The FormsNet3SM application allows questions 167-233 to be reported multiple times. Complete these questions for each line of therapy administered on or after the date of diagnosis of lymphoma and prior to the start of the preparative regimen (or prior to infusion if no preparative regimen was given). When submitting the paper version of the form for more than one line of therapy, copy the "Pre-HCT or Pre-Infusion Therapy" section and complete a copy of the section for each line of therapy administered.

If this is a subsequent infusion and the 2018 was completed for the previous infusion, lines of therapy do not need to be reported in duplication on the subsequent 2018. Please report from post previous infusion to time of preparative regimen (or infusion) for the current HCT or cellular therapy. If no 2018 was completed previously, all lines of therapy from original diagnosis to current preparative regimen (or infusion) will have to be completed.



If the recipient's lymphoma histology transformed between diagnosis and the start of the preparative regimen, all therapy administered from diagnosis (of the original lymphoma) until the start of the preparative regimen should be reported.

A single line of therapy refers to any agents administered during the same time period with the same intent (induction, consolidation, etc.). If a recipient's disease status changes resulting in a change to treatment, a new line of therapy should be reported. Additionally, if therapy is changed because a favorable disease response was not achieved, a new line of therapy should be reported.

Question 166: Was therapy given?

Indicate if the recipient received treatment for their primary disease between diagnosis and the start of the preparative regimen (or infusion if no preparative regimen was given). This includes systemic chemotherapy, immunotherapy, intrathecal therapy, radiation therapy, surgery, and cellular therapies. Do not report a prior HCT in questions 166-223. If therapy was given to treat lymphoma during the time frame indicated above, report "Yes" and go to question 167. If reporting "No" or "Unknown," go to question 233.

Question 167: Systemic therapy

Systemic therapy is delivered via the blood stream and distributed throughout the body. Therapy may be injected into a vein / central line or given orally. Do not report intrathecal therapy as systemic therapy. If systemic therapy was administered as part of the line of therapy being reported, report "Yes" and go to guestion 168. If not, report "No" and go to guestion 180.

Question 168-169: Date therapy started

Indicate whether the therapy start date is "Known" or "Unknown." If the therapy start date is known, report the date the recipient began this line of therapy in question 169. If the start date is partially known (e.g., the

recipient started in mid-July 2010), use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms</u>.

If the date therapy started is "Unknown," go to question 170.

Question 170-171: Date therapy stopped

Indicate if therapy stop date is "Known" or "Unknown." If the therapy is being given in cycles, report the date the recipient **started the last cycle** for this line of therapy in question 171. Otherwise, report the final administration date for the therapy being reported. If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms</u>.

If the date therapy stopped is "Unknown," go to question 172.

Question 172-173: Number of cycles

Systemic therapy is usually administered in cycles with rest periods in-between. This enables cancer cells to be attacked at vulnerable times and provides healthy cells adequate time to recover from the damage sustained during therapy. A cycle can last one or more days and can repeat weekly, bi-weekly, or monthly. A single systemic therapy course may consist of multiple cycles.

Indicate whether the number of cycles is "Known" or "Unknown." If "Known," enter the number of cycles the recipient received in question 173. If "Unknown," go to question 174.

If therapy is not being administered in cycles (e.g., daily chemotherapy), report "Unknown" for question 172 and go to question 174.

Question 174-175: Was a standard drug regimen given?

Systemic chemotherapy / immunotherapy may involve administration of multiple drugs / agents during the line of therapy. Rather than reporting each drug separately, standard combination regimens should be reported using the options in question 175 when available. Review the regimen options provided in question 175. If the recipient's line of therapy included one of the regimens listed, report "Yes" for question 174 and indicate the regimen that was given in question 175. If the recipient did not receive one of the standard regimens provided in question 175 as part of the line of therapy being reported, indicate "No" for question 174 and go to question 176.

Only one regimen may be reported for question 175. Generally, each regimen should be reported as a separate line of therapy. If the recipient received a regimen specified in question 175 as well as additional systemic therapy drugs as part of the line of therapy being reported, indicate the standard regimen in question 175 and report the additional drugs in questions 176-178.

The BEACOPP regimen may be reported as standard or escalated dosing. The center should choose the

option most consistent with their treatment guidelines. If it is not clear which option to report, consult the transplant physician.

If none of the standard regimens specified in question 175 were given as part of the line of therapy being reported, indicate "No" for question 174 and go to question 176.

Question 176-178: Were systemic drugs given?

Questions 176-178 are intended to capture systemic therapy drugs / agents not already reported in questions 174-175. If part or all of the recipient's regimen can be reported in questions 174-175, report them in those questions and do not report them again in questions 176-178. If all systemic therapy drugs given as part of the line of therapy being reported were included in the regimen indicated in question 175, report "No" for question 176 and go to 179.

If the recipient received systemic chemotherapy drugs not already reported in questions 174-175 as part of the line of therapy being reported, report "Yes" for question 176 and specify the chemotherapy drug(s) in questions 177-178. Otherwise, report "No" for question 176 and go to question 179.

If the center needs to report a systemic chemotherapy drug (or drugs) in question 177, but it is not listed as an option, report "Other systemic therapy" and use question 178 to specify any drugs not already reported. Only report systemic chemotherapy drugs in questions 176-178.

Question 179: Was this line of therapy given for stem cell mobilization (priming)?

Report "Yes" if this line of therapy was given for stem cell priming. For example, R-ICE (rituximab, ifosfamide, carboplatin, and etoposide) may be used in a lymphoma patient to collect their peripheral blood stem cells (PBSCs) as they recover their white blood count. Report "No" if this line of therapy was not given for stem cell priming.



Multiple intrathecal therapies: If a recipient receives multiple intrathecal therapies as part of a single line of therapy, report each intrathecal therapy as a separate line.

Question 180: Intrathecal therapy

Intrathecal therapy refers to chemotherapy administered via lumbar puncture to treat or prevent leukemic blasts in the central nervous system. Report "Yes" and go to question 181 if intrathecal therapy was given as part of the line of therapy being reported. Report "No" and go to question 188 if intrathecal therapy was not given as part of the line of therapy being reported.

Question 181: Reason for intrathecal therapy

Intrathecal therapy may be given to prevent disease in the central nervous system. It may also be given as treatment once disease has been detected. Indicate the reason intrathecal therapy was given. Report "Unknown" if the reason cannot be determined.

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Question 182-183: Date therapy started

Indicate whether the therapy start date is "Known" or "Unknown." If the therapy start date is known, report the date the recipient began this line of therapy in question 183. If the start date is partially known (e.g., the recipient started in mid-July 2010), use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date therapy started is "Unknown," go to question 184.

Question 184-185: Date therapy stopped

Indicate if therapy stop date is "Known" or "Unknown." If "Known," report the final administration date in question 185. If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date therapy stopped is "Unknown," go to question 186.

Question 186-187: Specify intrathecal therapy

Indicate the drug given as intrathecal therapy during the line of therapy being reported. If the drug is not listed as an option in question 186, report "Other intrathecal therapy" and specify the drug in question 187.



Multiple intraocular therapies: If a recipient receives multiple intraocular therapies as part of a single line of therapy, report each intraocular therapy as a separate line.

Question 188: Intraocular therapy

Intraocular therapy refers to chemotherapy administered via injection to the eye. Report "Yes" and go to question 189 if intraocular therapy was given as part of the line of therapy being reported. Report "No" and go to question 196 if intraocular therapy was not given as part of the line of therapy being reported.

Question 189: Reason for intraocular therapy

Intraocular therapy may be given to prevent disease in the eye. It may also be given as treatment once disease has been detected. Indicate the reason intraocular therapy was given. Report "Unknown" if the reason cannot be determined.

Question 190-191: Date therapy started

Indicate whether the therapy start date is "Known" or "Unknown." If the therapy start date is known, report the date the recipient began this line of therapy in question 191. If the start date is partially known (e.g., the recipient started in mid-July 2010), use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date therapy started is "Unknown," go to question 192.

Question 192-193: Date therapy stopped

Indicate if therapy stop date is "Known" or "Unknown." If "Known," report the final administration date in question 193. If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms</u>.

If the date therapy stopped is "Unknown," go to question 194.

Question 194-195 Specify intraocular therapy

Indicate the drug given as intraocular therapy during the line of therapy being reported. If the drug is not listed as an option in question 194, report "Other intraocular therapy" and specify the drug in question 195.

Question 196: Radiation therapy

Radiation therapy utilizes high-energy x-rays, gamma rays, electron beams, or proton beams to kill cancer cells. 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.

If radiation therapy was given during or adjacent to administration of systemic therapy, report them together as single line of therapy on the form (i.e., one copy of questions 167-223). Otherwise, capture the radiation treatment as a separate line of therapy.

If the recipient received radiation therapy as part of the line of therapy being reported, report "Yes" and go to question 197. If not, report "No" and go to question 209.

Question 197-198: Date therapy started

Indicate whether the therapy start date is "Known" or "Unknown." If the therapy start date is known, report the date the recipient began this line of therapy in question 198. If the start date is partially known (e.g., the recipient started in mid-July 2010), use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date therapy started is "Unknown," go to question 199.

Question 199-200: Date therapy stopped

Indicate if therapy stop date is "Known" or "Unknown." If "Known," report the final administration date in question 200. If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date therapy stopped is "Unknown," go to question 201.

Question 201: What was the extent of the radiation field?

Indicate the extent of the radiation field.

Question 202-203: Specify site(s) of radiation therapy

Report all sites of radiation therapy administered between the start and stop dates reported in questions 197-200. If "Other site" is reported, specify all other sites in question 203.

Question 204: Dose per fraction:

Enter the dose per fraction in either grays (Gy) or centigrays (cGy).

Question 205: Total number of fractions:

Enter the total number of fractions (treatments) of radiation that were administered. The recipient may receive more than one fraction per day (hyperfractionation).

Question 206: Total dose: (dose per fraction X total number of fractions)

Enter the total dose of radiation given. If radiation was given as a single dose, the amount of radiation delivered in the single dose constitutes the total dose. If the radiation was given in fractionated doses, multiply the total number of fractions by the dose per fraction to determine the total dose. Enter the total dose of radiation in either grays (Gy) or centigrays (cGy).

Example:

Radiation Order: TBI, 200 cGy/day for three days (3 doses)

Total dose: 200 cGy x 3 doses = 600 cGy

Report "Total Dose" as: 600 cGy

The dose per fraction (question 204) multiplied by the total number of fractions (question 205) must be equal to the total dose reported in question 206.

Question 207-208: Specify technique

Indicate the technique used to deliver radiation therapy. If the technique was not "Electron beam" or "Proton," report "Other" and specify the technique in question 208.

Question 209: Surgery

If the recipient underwent surgical treatment for lymphoma as part of the line of therapy being reported, indicate "Yes" and go to question 210. If the recipient did not undergo surgical treatment, report "No" and go to question 215.

Do not report the initial diagnostic biopsy, even if surgery was required, as pre-HCT therapy.

Question 210-211: Date of surgery

Indicate whether the surgery date is "Known" or "Unknown." If the date is known, report it in question 211. If the date is partially known (e.g., the recipient started in mid-July 2010), use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If the date is "Unknown," go to question 212.

Question 212-214: Specify site(s) of surgery:

Indicate the site(s) of the surgery. Report "Yes or "No" for "Splenectomy" and for "Other site." If "Other site" is selected, specify all other sites in question 214

Question 215: Photopheresis

Photopheresis involves removing blood from the body, exposing it to psoralen and ultraviolet light, and then reinfusing it. Indicate whether photopheresis was administered as part of the line of therapy being reported.

Report "Yes" if the recipient received photophoresis as part of the line of therapy being reported. If not, report "no".

Question 216: 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 part of the line of therapy being reported. If not, report "No."

Question 217: Best response to line of therapy by CT (radiographic) criteria:

Indicate the best response to the line of therapy using the international working group radiographic criteria provided in <u>LYM Response Criteria</u> section of the Forms Instruction Manual. If the recipient had palpable disease on a physical exam, those results can be reported in the CT (radiographic) criteria. Report "Not assessed" if no applicable assessments were performed after the line of therapy being reported and prior to the initiation of any new therapy.

Question 218: Date assessed

Report the date of the CT scan used to determine the response reported in question 217. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms</u>.

Question 219: Best response to line of therapy by PET (metabolic) criteria:

Indicate the best response to the line of therapy using the international working group metabolic criteria provided in <u>LYM Response Criteria</u> section of the Forms Instruction Manual. Report "Not assessed" if a PET scan was not performed after the line of therapy being reported and prior to the initiation of any new therapy.

Question 220: Date assessed

Report the date of the PET scan used to determine the response reported in question 220. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

Question 221: Was this line of therapy maintenance / consolidation?

Report "Yes" if this line of therapy was being given for maintenance or consolidation. Report "No" if this line of therapy was not given for maintenance or consolidation. See below for general definitions.

Consolidation: Once a recipient has achieved a hematologic CR (1st, 2nd, 3rd or greater), they may receive several additional lines of therapy as part of a protocol or to eliminate known minimal residual disease.

Maintenance: Following induction and consolidation, a recipient may receive low dose chemotherapy over an extended period of time to maintain a CR. Maintenance therapy is usually given as a single drug taken in the outpatient setting when the recipient has no known evidence of disease.

Question 222-223: Did disease relapse / progression occur following this line of therapy?

Refer to the international working group criteria provided in LYM Response Criteria section of the Forms Instructions Manual for more information on how to determine recurrence / progression of disease. Report "Yes" if the recipient met the criteria (radiographic or metabolic) for relapse after starting this line of therapy and prior to starting a subsequent line of therapy. If "Yes" is reported, indicate the date of relapse / progression in question 223. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

Report "No" if the recipient's disease did not relapse or progress following this line of therapy. Also, report "No" if the relapse / progression occurred after beginning a subsequent line of therapy. This episode of relapse / progression will be captured in the instance (i.e., copy) of questions 166-223 completed for the subsequent line of therapy. If "No" is reported, go to question 224.

If this is the last line of therapy administered prior to infusion, only report "Yes" if relapse occurred prior to infusion. Relapse occurring after the infusion date will be reported on the HL/NHL Post-Infusion Data Form (Form 2118).

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Q224-233: Disease Assessment at the Failure of the 1st Line of Therapy (DLBCL only)

Questions 224-233 will only be answered if the primary disease was reported as diffuse large B-cell lymphoma (DLBCL) either at transformation (question 84) or at diagnosis (question 1) if no transformation occurred. This includes the following DLBCL subtypes: cell of origin unknown, germinal center B-cell type, and activated B-cell type (non-GCB). If the recipient's primary disease was not DLBCL, skip questions 224-233 and go to question 234.

Question 224: Did recipient achieve a CR after 1st line of therapy?

Refer to the international working group criteria provided in LYM Response Criteria section of the Forms Instruction Manual. Report "Yes" and go to question 234 if the recipient achieved a CR (radiographic or metabolic) in response to their first line of therapy. CR must be achieved prior to the initiation a second line of therapy (or transplant) in order to report "Yes." If the recipient did not achieve a CR in response to their first line of therapy, report "No" and go to question 225.

If the recipient did not receive therapy between diagnosis of DLBCL and the start of the preparative regimen / infusion, leave question 224 blank, override the validation error using the code "unable to answer," and specify in the comments the recipient did not receive therapy for DLBCL prior to the start of the preparative regimen / infusion.



Questions 225-233

Complete questions 225-233 based on testing / evaluations performed between the end of the first line of therapy and the start of the second line of therapy. If a second line of therapy was not given prior to transplant, complete these questions based on testing performed between the end of the first line of therapy and the start of the preparative regimen (or infusion if no preparative regimen was given). If multiple tests were performed during this time frame, report the most recent testing.

Question 225-227: LDH

Indicate whether the recipient's LDH value was "Known" or "Unknown" during the time frame specified above. If "Known," report the test result and corresponding units in question 226. Also, report the upper limit of normal and corresponding units for the test.

Question 228: Stage of organ involvement: (at 1st relapse / progression)

Use the staging criteria in Table 1 to determine the stage of organ involvement during the time frame specified above. Also refer to Graphic 2 and Graphic 3 for examples. If staging at this time point is not available or unknown, select "Unknown."

Question 229-230: ECOG score (at failure of 1st line of therapy)

See the instructions for <u>questions 80-81</u> for more information about reporting ECOG scores. Indicate whether the recipient's ECOG score during the time frame specified above is known. If "Known," report the score in question 230. Otherwise, go to question 231.

Question 231: Did the recipient have known extranodal involvement?

Extranodal refers to the presentation of lymphoma outside of the lymph nodes. Common areas of extranodal involvement may include bone, gastrointestinal tract, and skin. Splenic involvement in lymphoma is also common. It is usually evidenced by enlargement of the spleen (splenomegaly). Splenic or other extranodal involvement is most often detected by imaging techniques or pathological findings.

If extranodal involvement was identified, report "Yes" and go to question 232.

If there was no evidence of extranodal involvement or it is not known, report "No" or "Unknown" respectively and go to question 234.

Questions 232 – 233: Specify site(s) of involvement: (check all that apply)

Check each site with known lymphomatous involvement. If an involved site was documented but is not listed as an option for question 232, check "Other site" and report all other sites of lymphomatous involvement in question 233.

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Q234-288: Disease Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

All values reported in questions 234-288 must reflect the most recent testing prior to the start of the preparative regimen (or infusion if not preparative regimen was given). Do not report testing performed during a line of therapy reported in questions 167-223. If testing was not performed near the start of the preparative regimen / infusion (within approximately 30 days) and after the most recent line of therapy (if applicable), the center should report "Unknown" for that value.

Question 234: Were cytogenetics tested (karyotyping or FISH)?

If cytogenetic studies were obtained at the last evaluation prior to the start of the preparative regimen / infusion, report "Yes" and go to question 235.

If cytogenetic studies were not obtained at the last evaluation prior to the start of the preparative regimen / infusion or it is not known whether studies were obtained, report "No" or "Unknown" respectively and go to question 265.

For more information about cytogenetic testing and terminology, see <u>Appendix C, Cytogenetic Assessments</u>.

Question 235-236: Were cytogenetics tested via FISH?

If FISH studies were performed at the last evaluation prior to the start of the preparative regimen / infusion, report "Yes" for question 235 and indicate whether clonal abnormalities were detected in question 236.

If FISH studies were not performed at the last evaluation prior to the start of the preparative regimen / infusion, report "No" for question 235 and go to question 260. Examples include: no FISH study performed or FISH sample was inadequate.

Question 237-258: Specify cytogenetic abnormalities (FISH)

Results reported in questions 237-258 must reflect testing performed at the last evaluation prior to the start of the preparative regimen / infusion.

For each abnormality:

Report "Yes" if FISH testing detected the abnormality.

Report "No" if FISH testing for the abnormality was done and was negative.

Report "**Not done**" if FISH testing for the abnormality was not attempted or could not be successfully performed (e.g., inadequate sample).

If a clonal abnormality is detected, but cannot be reported in questions 237-258, report "Yes" for question 257 and specify the abnormality in question 258. If multiple "other abnormalities" were detected, report "see attachment" in question 258 and attach the final report(s) for any other abnormalities detected. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 259: Was documentation submitted to the CIBMTR? (e.g., FISH report)

Indicate if a FISH testing report is attached to support the findings reported in questions 235-258. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 260-261: Were cytogenetics tested via karyotyping?

If karyotyping was performed at the last evaluation prior to the start of the preparative regimen / infusion, report "Yes" for question 260 and indicate whether clonal abnormalities were detected in question 261.

If karyotyping was not performed at the last evaluation prior to the start of the preparative regimen / infusion, report "No" for question 260 and go to question 265. Examples include: no karyotyping performed or karyotyping sample was inadequate.

Question 262-263: Specify cytogenetic abnormalities (karyotyping)

Results reported in questions 262-263 must reflect testing performed at the last evaluation prior to the start of the preparative regimen / infusion.

Check any abnormalities detected by karyotyping. If karyotyping detected an abnormality that is not specified in question 262, check "Other abnormality" and report the abnormality in question 263. If multiple "other abnormalities" were detected, report "see attachment" for question 263 and attach the karyotyping report to the form. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training</u> Guide.

Refer to Appendix C, Cytogenetic Assessments for assistance interpreting karyotyping results.

Question 264: Was documentation submitted to the CIBMTR?

Indicate if a karyotyping report is attached to support the findings reported in questions 260-263. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 265-266: Hemoglobin

Questions 265-266 will only be answered if the primary disease was follicular lymphoma (all histologies) and Hodgkin lymphoma (all histologies) either at transformation (question 84) or at diagnosis (question 1) if no transformation occurred.

Indicate whether the hemoglobin in the peripheral blood is "Known" or "Unknown" at the last evaluation prior

to the start of the preparative regimen / infusion. If "Known," report the laboratory value and unit of measure in question 266. If the hemoglobin at the last evaluation prior to the start of the preparative regimen / infusion is not known, report "Unknown" and go to question 267.

Question 267-268: Absolute lymphocyte count

Questions 267-268 will only be answered if the primary disease was reported as Hodgkin lymphoma (all histologies) either at transformation (question 84) or at diagnosis (question 1) if no transformation occurred.

Indicate whether the absolute lymphocyte count in the peripheral blood is "Known" or "Unknown" at the last evaluation prior to the start of the preparative regimen / infusion. If "Known," report the laboratory value and unit of measure in question 268. If the absolute lymphocyte count at the last evaluation prior to the start of the preparative regimen / infusion is not known, report "Unknown" and go to question 269.

Question 269: Was minimal residual disease (MRD) assessed during the pre-HCT or pre-infusion evaluation?

Minimal residual disease assessments include flow cytometry, PCR, and next generation sequencing. If testing was performed by any of these three methods on blood, bone marrow, or any other specimen at the last evaluation prior to the preparative regimen / infusion, report "Yes" and go to question 270. If testing by these methods was not done or it is not known whether testing was performed, report "No" or "Unknown" respectively and go to question 283.

Question 270-273: Flow cytometry

Indicate the result of flow cytometry testing performed at the last evaluation prior to the start of the preparative regimen / infusion. If testing was "Positive," report the sample source in questions 271-272. Also, report the date the sample was collected in question 273. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms.</u>

If all flow cytometry testing was negative or testing was not done at the last evaluation prior to the start of the preparative regimen, report "Negative" or "Not done" respectively for question 270 and go to question 274.

Question 274-277: PCR

Indicate the result of PCR testing performed at the last evaluation prior to the start of the preparative regimen / infusion. If testing was performed for multiple disease markers and any of the test results were positive, report "Positive" for question 273. If testing was "Positive," report the sample source in questions 275-276. Also, report the date the sample was collected in question 277. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, <u>General Guidelines for Completing Forms</u>.

If all PCR testing was negative or testing not done at the last evaluation prior to the start of the preparative

regimen, report "Negative" or "Not done" respectively for question 274 and go to question 278.

Question 278-281: Next generation sequencing (NGS, 3rd gen)

Indicate the result of next generation sequencing (NGS, 3rd gen) testing performed at the last evaluation prior to the start of the preparative regimen / infusion. If testing was performed for multiple disease markers and any of the test results were positive, report "Positive" for question 278. If testing was "Positive," report the sample source in questions 279-280. Also, report the date the sample was collected in question 281. If the date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, General Guidelines for Completing Forms.

If all next generation sequencing testing was negative or testing was not done at the last evaluation prior to the start of the preparative regimen, report "Negative" or "Not done" respectively for question 278 and go to question 282.

Question 282: Was documentation submitted to the CIBMTR?

Indicate if documentation is attached to support the findings reported in questions 269-280. For further instructions on how to attach documents in FormsNet3SM, refer to the <u>Training Guide</u>.

Question 283: Did the recipient have known nodal involvement?

Nodal involvement may be assessed by a physician palpating lymph nodes, pathology from a lymph node biopsy, or radiological assessment (e.g., PET or CT imaging). Report "Yes" if nodal involvement was detected by any of these methods. Otherwise, report "No" and go to question 286.

Questions 284: Specify total number of nodal regions involved (follicular only)

Question 284 will only be answered if the primary disease was follicular lymphoma (all histologies) either at transformation (question 84) or at diagnosis (question 1) if no transformation occurred.

Refer to <u>questions 72-73</u> for instructions on how to assess and report nodal involvement. Report the total number of nodal regions identified at the last evaluation prior to the start of the preparative regimen / infusion.

Questions 285: Specify the size of the largest nodal mass

Report the size of the largest known nodal mass as measured in centimeters. If the mass is given in three dimensions (for example: 3 cm x 4 cm), report the longest two dimensions.

Question 286: Was there any known extranodal or splenic involvement? (at last evaluation)

Refer to <u>question 75</u> for a description of extranodal and splenic involvement. If extranodal or splenic involvement was identified at the last evaluation prior to the start of the preparative regimen / infusion, indicate "Yes" and continue with question 287.

If there was no evidence of extranodal or splenic involvement at the last evaluation prior to the start of the preparative regimen / infusion or it is not known, report "No" or "Unknown" respectively and submit the form.

Questions 287-288: Specify site(s) of involvement:

Check each site with known lymphomatous involvement at the last evaluation prior to the start of the preparative regimen. If an involved site was documented, but is not listed as an option for question 287, check "Other site" and report all other sites of lymphomatous involvement in question 288.

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