Instructions for Myelodysplastic Syndrome (MDS) Post-Infusion Form (Form 2114)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Myelodysplastic Syndrome (MDS) Post-Infusion Form.

Email comments regarding the content of the CIBMTR Forms Instruction Manual to: CIBMTRFormsManualComments@nmdp.org. Comments will be considered for future manual updates and revisions. For questions that require an immediate response, contact the CIBMTR Customer Service Center.

2114: MDS Post-HCT

This form must be completed for all recipients who are randomized to the Comprehensive Report Form (CRF) track and whose primary disease is reported on the Pre-TED Disease Classification Form (Form 2402) as "Myelodysplastic Syndrome (MDS) (50)" The Myelodysplastic Syndrome (MDS) Post-HCT Data (Form 2114) must be completed in conjunction with each Post-HCT follow-up form completed (Form 2100). 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 and the date of contact for the one-year follow up, etc.).

For recipients who had MDS that transformed to AML prior to transplant, only Form 2014 (Myelodysplastic Syndrome Pre-HCT Data) must be completed to obtain MDS data pre-HCT. Form 2114 (Myelodysplastic Syndrome Post-HCT Data) is not required for these recipients post-HCT.

Links to Sections of the Form:
Q1-72: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy
Q73-87: Post-HCT / Post-Infusion Therapy
Q88-171: Disease Detection Since the Date of Last Report
Q172-236: Disease Status at the Time of Evaluation for this Reporting Period

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. The most recent...
Q1-72: Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

Best response is based on response to the HCT or cellular therapy infusion, but does not include response to any therapy given for disease relapse or progression post-HCT or post-cellular therapy. When determining the best response to HCT or cellular therapy infusion, compare the post-HCT or post-cellular therapy disease status to the status immediately prior to the preparative regimen or infusion, regardless of time since HCT or cellular therapy. This comparison is meant to capture the best disease status in response to HCT or cellular therapy that occurred during the same reporting interval, even if a subsequent disease relapse or progression occurred during the same reporting interval. If a recipient already achieved their best response in a previous reporting interval, confirm the best response and indicate that the date was previously reported (question 5).

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 or post-cellular therapy maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

The intent of this question is to determine the best response to HCT or cellular therapy overall. This is assessed in each reporting period. When evaluating the best response, determine the disease status within the reporting period and compare it to all previous post-HCT or post-cellular therapy 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.

Any specified therapy administered post-HCT to prolong remission or for minimal residual disease, is considered part of the HCT and should be included when assessing
the recipient’s response to transplant. Treatment given post-HCT for relapsed or persistent disease is not considered part of the HCT and should be excluded when assessing the response to HCT. If treatment was given post-HCT for relapsed or persistent disease, assess the patient’s best response prior to the start of therapy. If therapy was given for reasons other than relapsed or persistent disease, assess the patient’s best response throughout the entire duration of the reporting period.

If the recipient was in remission at the start of the preparative regimen / infusion, indicate “continued complete remission” and continue with question 73.

If the recipient’s best response to HCT or cellular therapy was hematologic improvement, continue with question 2.

For all other responses, continue with question 4. See MDS Response Criteria for disease status definitions.

**Question 2: Specify the cell line examined to determine HI status (check all that apply)**

Indicate the cell line examined to determine hematologic improvement – select all that apply. To determine the cell line, review the Hematologic Improvement criteria listed in the MDS Response Criteria section of the Forms Instruction Manual.

If the cell lines examined to determine hematologic improvement included, “HI – E” continue with question 3.

If the cell lines examined to determine hematologic improvement only included, “HI – P” and / or “HI – N,” continue with question 4.

**Question 3: Specify transfusion dependence (at the time of best response)**

If the recipient’s disease status at the time of best response included hematologic improvement – erythroid, indicate the transfusion dependence at the time of best response to infusion.

Select “Non-transfused (NTD)” if the recipient received zero RBC transfusions within a period of 16 weeks prior to the date of the best response and continue with question 4.

Select “Low transfusion burden (LTB)” if the recipient had between three and seven RBC transfusion within a period of 16 weeks prior to the date of the best response in at
least two transfusion episodes with a maximum of three transfusion episodes in eight weeks and continue with question 4.

**Question 4: Was the date of best response previously reported?**
If the best response to HCT / cellular therapy was first documented during the current reporting period, report “no” and go to question 5. If the best response was achieved during a previous reporting period (and therefore reported on a previous MDS Post-Infusion Data Form), report “yes” and go to question 73.

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

**Question 5: Date assessed:**
Indicate the date the best response was achieved. Report the date of the pathological evaluation (e.g., bone marrow biopsy) or blood/serum assessment (e.g., CBC, peripheral blood smear). Enter the date the sample was collected for pathological and laboratory evaluations. This should be the earliest date when all international working group criteria for the response reported in question 1 were met.

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

**Disease Assessments at the Time of Best Response**
For reporting purposes, the definition of “at the time of best response” depends on the reporting period. See Disease Assessment Time Windows below. Only consider assessments with samples collected within the time window which corresponds to the follow-up form being completed. If assessments were performed during the reporting period, but the samples were not collected within the indicated time window, consider them not done and report “no” when completing questions 6-72.

**Table 1. Disease Assessment Time Windows**

<table>
<thead>
<tr>
<th>Follow-Up Form</th>
<th>Approximate Time Window</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 Day</td>
<td>± 15 days of date of best response (Question 6)</td>
</tr>
<tr>
<td>6 Month</td>
<td>± 15 days of date of best response (Question 6)</td>
</tr>
<tr>
<td>Annual</td>
<td>± 30 days of date of best response (Question 6)</td>
</tr>
</tbody>
</table>

**Warning:**
Questions 6-17 are answered only if the diagnosis was one of the overlap syndromes including CMMoL; JMML; aCML; MDS/MPN-RS-T; MDS/MPN, unclassifiable; if the diagnosis was other than an overlap syndrome, continue with question 18.

Questions 6-7: Did the recipient have splenomegaly? (at the time of best response)
Indicate if the recipient had splenomegaly at the time of best response. Splenomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding. Splenomegaly can also be detected by imaging techniques such as ultrasonography, CT or MRI.

Indicate “yes” if splenomegaly was present at the time of best response and report the date of assessment in question 7. Indicate “no” if splenomegaly was not present at the time of best response and continue with question 12. Indicate “unknown” if it is not possible to determine the presence or absence of splenomegaly at the time of best response and continue with question 12. Indicate “not applicable” if the question does not apply to the recipient (e.g. prior Splenectomy or congenital asplenia) and continue with question 12.

Question 8: Specify the method used to measure spleen size:
Indicate the method used to measure the spleen size, if the method selected is “physical assessment” continue with question 9. If the method selected is “ultrasound” or “CT / MRI” continue with question 10. If spleen size is measured using multiple methods, report the most accurate assessment. Ultrasound is the most specific and preferred assessment.

Question 9: Specify the spleen size in centimeters below the left costal margin
Indicate the size of the spleen in centimeters, measured below the left costal margin as assessed by physical exam then continue with question 11.

Question 10: Specify the spleen size in centimeters
Indicate the size of the spleen in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 11.

Question 11: Was this considered a disease relapse?
If the physician believes the size of the spleen indicates a disease relapse, report “yes.” If the recipient had an enlarged spleen, but the physician does not believe the finding represents disease relapse, report “no.” Continue with question 12.

Questions 12-13: Did the recipient have hepatomegaly? (at the time of best response)
Indicate if the recipient had hepatomegaly at the time of best response. Hepatomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding. Indicate “yes” if hepatomegaly was present at the time of best response and report the date of assessment in question 13. Indicate “no” if hepatomegaly was not present at the time of best response and continue with question 18. Indicate “unknown” if it is not possible to determine the presence or absence of hepatomegaly at the time of best response and continue with question 18.

**Question 14: Specify the method used to measure liver size:**
Indicate the method used to measure the liver size, if the method selected is “physical assessment” continue with question 15. If the method selected is “ultrasound” or “CT / MRI” continue with question 16. If liver size is measured using multiple methods, report the most accurate assessment. Ultrasound is the most specific and preferred assessment.

**Questions 15: Specify the liver size in centimeters below the right costal margin**
Indicate the size of the liver in centimeters, measured below the right coastal margin as assessed by physical exam then continue with question 17.

**Question 16: Specify the liver size in centimeters**
Indicate the size of the liver in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 17.

**Question 17: Was this considered a disease relapse?**
If the physician believes the size of the liver indicates a disease relapse, report “yes.” If the recipient had an enlarged liver, but the physician does not believe the finding represents disease relapse, report “no.” Continue with question 18.

**Question 18: Were molecular tests for molecular markers performed (e.g., PCR)? (at time of best response)**
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. FISH testing for molecular markers should **NOT** be reported here.

Once a marker has been identified, these methods can be repeated to detect minimal residual disease (MRD) in the recipient’s blood, bone marrow, or tissue. Molecular assessments include polymerase chain reaction (PCR) amplification to detect single specific disease markers; however, molecular methods are evolving and now include chromosomal microarray / chromosomal genomic array, Sanger sequencing, and next generation sequencing (e.g., Illumina, Roche 454, Proton / PGM, SOLiD).

If molecular testing for molecular markers was performed at the time of best response (see Table 1), report “yes” and go to question 19.
If molecular testing for molecular markers was not performed at the time of best response, or it is unknown if testing was done, report “no” or “unknown” respectively and go to question 27.

**Question 19: Indicate if a positive molecular marker(s) was identified**

Indicate if a positive molecular marker associated with the recipient’s primary disease was identified at the time of best response.

If a positive molecular marker associated with the recipient’s primary disease was identified, select “yes” and continue with question 20.

If there were no molecular markers associated with the recipient’s primary disease identified, no positive molecular markers identified, or it is unknown whether molecular markers were identified, select “no” and continue with question 27.

**Question 20: Date sample collected**

Report the date the sample was collected for molecular testing.

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

**Questions 21-22: Specify the positive molecular marker**

Specify the positive molecular marker and continue with question 23. If a positive marker is detected, but not listed as an option, select “other molecular marker” and specify the positive molecular marker in question 22.

**Questions 23-24: Amino acid change**

Amino acid changes can be described using standard mutation nomenclature. For CIBMTR reporting purposes, only amino acid changes based on protein-level sequences, beginning with the prefix “p.,” need to be reported. See Figure 1 below for an example of an amino acid change within a molecular pathology report.

**Figure 1. Molecular disease assessment with amino acid changes documented (highlighted in yellow).**
For more information on nomenclature used for amino acid changes, visit the Human Genome Variation Society Sequence Variant Nomenclature Protein Recommendations.

For question 23, indicate if the amino acid change is “known” or “unknown” for the positive molecular marker reported in questions 21-22. If known, report the amino acid change in question 24. If unknown, continue with question 25.

Copy questions 21-24 to report more than one positive molecular marker.

**Question 25: Was this considered a disease relapse?**
Indicate if the molecular abnormalities were considered a disease relapse. Criteria for molecular relapse are established by clinical judgment and should reflect the clinical decision of the transplant physician. A recipient may be reported to have molecular relapse even in the setting of hematologic CR; criteria for complete remission are based on hematologic and pathologic characteristics and are independent of molecular markers of disease.

If the recipient has molecular abnormalities that the physician considers to be consistent with disease relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form.

If the recipient has molecular abnormalities that the physician does not consider to be consistent with molecular relapse, select “no.”

**Question 26: Was documentation submitted to the CIBMTR?**
Indicate if the molecular report is attached to support the molecular findings reported in questions 20-24. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Question 27: Was the disease status assessed via flow cytometry? (at the time of best response)**
Flow cytometry assessment is a method of analyzing peripheral blood, bone marrow, or tissue preparations for multiple unique cell characteristics; its primary clinical purpose in the setting of MDS, MPN, and leukemias is to quantify blasts in the peripheral blood or bone marrow, or to identify unique cell populations through immunophenotyping. Flow cytometry assessment may also be referred to as “MRD” or minimal residual disease testing.

Indicate if flow cytometry was performed on peripheral blood and/or bone marrow sample at the time the recipient achieved their best response post-HCT.

If flow cytometry was performed, select “yes” and continue with question 28.

If flow cytometry was not performed, the flow cytometry sample was inadequate, or it is unknown if flow cytometry was performed, select “no” and continue with question 38.
Question 28-29: Blood
Indicate if flow cytometry was performed on the peripheral blood at the time of best response. If multiple assessments were performed, report the assessment performed closest to the date of the best response.

If flow cytometry was performed on a peripheral blood sample, select “yes” and report the date the sample was collected in question 29. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.

If flow cytometry was not performed on a peripheral blood sample, select “no” and continue with question 33.

Questions 30-31: Was disease detected?
Indicate if evidence of disease was detected in the peripheral blood sample sent for flow cytometry analysis. Evidence of disease may include the presence of blasts or an immunophenotype known to characterize the patient’s disease. If flow cytometry results are consistent with evidence of disease, select “yes” and specify the percentage of disease detected (to the nearest thousandth) in the peripheral blood as documented in the flow cytometry report in question 31.

If flow cytometry results were not consistent with evidence of disease, check “no” and continue with question 33.

Question 32: Was the status considered a disease relapse?
Indicate if the peripheral blood flow cytometry results were considered consistent with disease relapse. Criteria for flow cytometric relapse are established by clinical judgment. If the recipient has abnormalities by flow cytometry that the physician considers to be consistent with flow cytometric relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 33.

If the recipient has residual disease by flow cytometry that the physician does not consider to be consistent with relapse, select “no.” Continue with question 33.

Question 33-34: Bone Marrow
Indicate if flow cytometry was performed on the bone marrow at the time of best response. If multiple assessments were performed, report the assessment performed closest to the date of the best response.

If flow cytometry was performed on a bone marrow sample, select “yes” and report the date the sample was collected in question 34. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.
If flow cytometry was not performed on a bone marrow sample, select “no” and continue with question 38.

**Questions 35-36: Was disease detected?**
Indicate if evidence of disease was detected in the bone marrow sample sent for flow cytometry analysis. Evidence of disease may include the presence of blasts or an immunophenotype known to characterize the patient’s disease. If flow cytometry results are consistent with evidence of disease, select “yes” and specify the percentage of disease detected (to the nearest thousandth) in the bone marrow as documented in the flow cytometry report in question 36.

If flow cytometry results were not consistent with evidence of disease, check “no” and continue with question 38.

**Question 37: Was the status considered a disease relapse?**
Indicate if the bone marrow flow cytometry results were considered consistent with disease relapse. Criteria for flow cytometric relapse are established by clinical judgment. If the recipient has abnormalities by flow cytometry that the physician considers to be consistent with flow cytometric relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 38.

If the recipient has residual disease by flow cytometry that the physician does not consider to be consistent with relapse, select “no.” Continue with question 38.

**Question 38: Were cytogenetics tested (karyotyping or FISH)? (at time of best response)**
Cytogenetic analysis is the study of chromosomes. Cytogenetic assessment involves testing blood or bone marrow for the presence of known chromosomal abnormalities that reflect the recipient’s disease. Testing methods include conventional chromosome analysis (karyotyping) or fluorescence in situ hybridization (FISH). For more information about cytogenetic testing and terminology, see Appendix C, Cytogenetic Assessments.

Karyotyping is performed by culturing cells (growing cells under controlled conditions) until they reach their 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 demonstrated 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. These probes are mixed with cells from the recipient’s blood or bone marrow. 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. 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.

If cytogenetic (karyotyping or FISH) studies were obtained at the time of best response (see Table 1), report “yes” and continue with question 39.

If no cytogenetic studies were obtained at the time of best response, indicate “no” and continue with question 59.

If it is not known whether any cytogenetic studies were obtained at the time of best response, indicate “unknown” and go to question 59.

**Question 39: Were cytogenetics tested via FISH?**

If FISH studies were performed at the time of best response (see Table 1), report “yes” for question 39 and go to question 40. If FISH studies were not performed, report “no” for question 39 and go to question 49. Examples of this include: no FISH study performed or FISH sample was inadequate.

**Questions 40-41: Sample source**

Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 41. Continue with question 42. If multiple sources were used to test FISH, the most preferred sample is the bone marrow.

**Question 42: Results of test**

If FISH assessments identified abnormalities associated with the recipient’s primary disease, indicate “abnormalities identified” and continue with question 43.

If FISH assessments were unremarkable, indicate “no abnormalities” and continue with question 47.

**Warning:**

Question 43 is disabled and cannot be answered at this time.

**Questions 43-46: Specify cytogenetic abnormalities (FISH)**

Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 43, then continue with question 44.

Report the number of abnormalities detected by FISH at the time of best response (see Table 1) in question 44. After indicating the number of abnormalities in question 44, select all abnormalities detected in questions 45-46.

If an abnormality is detected, but not listed as an option in question 45, select “other abnormality” and specify the abnormality in question 46. If multiple “other abnormalities” were detected, report “see attachment” in question 46 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 47: Was this considered a disease relapse?**
Indicate if the FISH results were considered consistent with disease relapse. Criteria for FISH relapse are established by clinical judgment. If the recipient has abnormalities detected by FISH that the physician considers to be consistent with relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 48.

If the recipient has residual disease by FISH that the physician does not consider to be consistent with relapse, select “no.” Continue with question 48.

**Question 48: Was documentation submitted to the CIBMTR? (e.g. FISH report)**
Indicate if the FISH report is attached to support the cytogenetic findings reported in questions 39-47. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Question 49: Were cytogenetics tested via karyotyping?**
If karyotyping studies were performed at the time of best response (see Table 1), report “yes” for question 49 and go to question 50. If karyotyping studies were not performed, report “no” for question 49 and go to question 59. Examples of this include: no karyotyping study performed or karyotyping sample was inadequate.

**Question 50-51: Sample source**
Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 51. Continue with question 52. If multiple sources were used for karyotyping analysis, the preferred sample is the bone marrow.

**Question 52: Results of test**
If karyotyping assessments identified abnormalities associated with the recipient’s primary disease, indicate “abnormalities identified” and continue with question 53.

If karyotyping assessments were unremarkable, indicate “no abnormalities” and continue with question 57.

If karyotyping assessment yielded an inadequate result, indicate “no evaluable metaphases” and continue with question 57.

**Warning:**
Question 53 is disabled and cannot be answered at this time.

**Questions 53-56: Specify cytogenetic abnormalities (karyotyping)**
Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 53, then continue with question 54.
Report the number of abnormalities detected by karyotyping at the time of best response (see Table 1) in question 54. After indicating the number of abnormalities in question 54, select all abnormalities detected in questions 55-56.

If an abnormality is detected, but not listed as an option in question 55, select “other abnormality” and specify the abnormality in question 56. If multiple “other abnormalities” were detected, report “see attachment” in question 56 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 57: Was this considered a disease relapse?**
Indicate if the karyotyping results were considered consistent with disease relapse. Criteria for karyotyping relapse are established by clinical judgment. If the recipient has abnormalities detected by karyotyping that the physician considers to be consistent with relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 58.

If the recipient has residual disease by karyotyping that the physician does not consider to be consistent with relapse, select “no.” Continue with question 58.

**Question 58: Was documentation submitted to the CIBMTR? (e.g. karyotyping report)**
Indicate if the karyotyping report is attached to support the cytogenetic findings reported in questions 50-56. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Questions 59-60: Was disease detected via bone marrow examination? (at the time of best response)**
If disease was detected via bone marrow examination at the time of best response, select “yes” for question 59 and report the date the sample was collected in question 60.

If disease was not detected or it is unknown if disease was detected via bone marrow examination at the time of best response, select “no” or “unknown” and continue with question 65.

**Questions 61-62: Blasts in the bone marrow**
Indicate wither the percentage of blasts in the bone marrow was “known” or “unknown” at the time of best response. If “known” report the percentage documented on the laboratory report in question 62. If “unknown” continue with question 63.

**Question 63: Myelofibrosis grading by WHO classification**
Fibrosis describes the replacement of bone marrow by fibrous (scar) tissue. This distinction is made on the pathology report of a bone marrow examination and the myelofibrosis grade may be documented by the pathologist.
Indicate if the myelofibrosis grading is “known” or “unknown.” If the myelofibrosis grade is documented in the pathology report, select “known,” continue with question 64. If the pathology report is not available and the grade is documented in a physician note, then this would be sufficient.

If the myelofibrosis grade is not documented on the pathology report, select “unknown,” continue with question 65.

**Question 64: Specify the grade**
Specify the Myelofibrosis grading using the WHO classification. The classification and results should be clarified in the pathology report as dictated by the pathologist or may be found in the physician note.

Select “MF-0” if the report documents scattered linear reticulin with no intersection (crossovers) corresponding to normal bone marrow.

Select “MF-1” if the report documents a loose network of reticulin with many intersections, especially in perivascular areas.

Select “MF-2” if the report documents diffuse and dense increase in reticulin with extensive intersections, occasionally with local bundles of thick fibers mostly consistent with collagen, and/or focal osteosclerosis.

Select “MF-3” if the report documents diffuse and dense increase in reticulin with extensive intersections and coarse bundles of thick fibers consistent with collagen, usually associated with osteosclerosis.

**Question 65: Was this considered a disease relapse?**
Indicate if the myelofibrosis grade by WHO classification was considered a disease relapse. Criteria for myelofibrosis relapse are established by clinical judgment. If the recipient has a myelofibrosis grade by WHO classification that the physician considers to be consistent with relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 66.

If the recipient has residual myelofibrosis that the physician does not consider to be consistent with relapse, select “no.” Continue with question 66.

**Questions 66-67: Was extramedullary disease indicative of AML detected? (e.g. myeloid sarcoma) (at the time of best response)**
Indicate if the recipient had extramedullary disease indicative of AML at the time of best response. An example of extramedullary disease would be a myeloid sarcoma. Indicate “yes” if extramedullary disease indicative of AML was present at the time of best response and report the date of assessment in question 67. Indicate “no” if extramedullary disease indicative of AML was not present at the time of best response and continue with question 68.
Questions 68-70: Was disease status assessed by other assessment? (at the time of best response)
Indicate if the recipient’s disease status was assessed by any other assessment at the time of best response. Indicate “yes” if the disease status was assessed by other assessment at the time of best response, report the date of assessment in question 69, and specify the name of the other assessment in question 70. Indicate “no” if the disease status was not assessed by other assessment at the time of best response and continue with question 73.

Question 71: Was disease detected?
If the other disease assessment indicated the presence of disease, select “yes” and continue with question 72.

If the other disease assessment did not indicate the presence of disease, select “no” and continue with question 73.

Question 72: Was this considered a disease relapse?
Indicate if the result of the other disease assessment was considered a disease relapse. Criteria for disease relapse are established by clinical judgment. If the recipient has another disease assessment that the physician considers to be consistent with relapse, select “yes.” Also report relapse or progression under the “Disease Detection Since the Date of Last Report” section of this form. Continue with question 73.

If the recipient has another disease assessment that the physician does not consider to be consistent with relapse, select “no.” Continue with question 73.

Q73-87: Post-HCT / Post-Infusion Therapy

Question 73: Was therapy given since the date of last report for reasons other than relapse or persistent disease? (include any maintenance therapy)
Indicate if the recipient received treatment post-infusion for reasons other than relapse or persistent disease during the current reporting period. Recipients generally receive a HCT / cellular therapy under a specific protocol which defines radiation and / or systemic therapy to be given prior to infusion; prophylactic medications to be administered pre- and / or post-infusion; as well as any systemic therapy, radiation, and / or other treatments to be administered post-infusion as planned (or maintenance) therapy. Planned (maintenance) therapy is given to assist in prolonging a remission. Planned therapy may be described in a research protocol or standard of care protocol. Refer to these documents (if available) when completing this section. If post-infusion therapy is given as prophylaxis or maintenance for recipients in CR, report the therapy in questions 74-87. Do not include any treatment administered as a result of relapse or persistent disease (including treatment for minimal residual disease).
If therapy was given for reasons other than relapse or persistent disease during the reporting period, report “Yes” and go to question 74. If “No,” go to question 88.

**Question 74: Systemic therapy**
Systemic therapy includes chemotherapy, immunotherapy, or targeted therapies delivered via the blood stream and distributed throughout the body. Therapy may be injected into a vein or given orally. Do not report subsequent HCT / cellular therapies in questions 74-83. If the recipient received systemic therapy during the reporting period for reasons other than relapse or persistent disease, report “Yes” and go to question 75. If not, report “No” and go to question 83.

**Questions 75-76: Date therapy started**

*Note: Form Revision Change*
If maintenance therapy was started during a prior reporting period, for which, an MDS / MPN Post-HCT Data Form Revision 3 was completed, the start date will not have been reported on that form. In this case, report the date maintenance therapy was started on the current form (MDS Post-Infusion Data Form, Revision 4) and override the validation error using the code “Verified Correct.” If the reported maintenance therapy continues into the next reporting period, the site will indicate “Previously reported” in question 75.

If the recipient started systemic therapy for reasons other than relapse or persistent disease during the reporting period, report “Known” for question 75 and indicate the date started in question 76. If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, Guidelines for Completing Forms.

If the recipient started therapy for reasons other than relapse or persistent disease in a prior reporting period and continued the therapy into the current reporting period, report “Previously reported” and go to question 77.

For recipients who start and stop therapy multiple times post-infusion, first determine whether the recipient stopped therapy for at least 30 days. If not, consider the therapy continuous. Only report a new therapy start date if all three of the below conditions are met.
- The recipient stopped all therapy given for reasons other than relapse or persistent disease during a prior reporting period; and
- The recipient restarted therapy for reasons other than relapse or persistent disease during the current reporting period; and
- Therapy was restarted at least 30 days after the therapy stop date.

**Questions 77-78: 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 78. Otherwise, report the final administration date for the therapy being reported.

If the recipient is still receiving this treatment at the end of the reporting period, report “not applicable (still receiving therapy)” and continue with 81.

If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, Guidelines for Completing Forms.

If the date therapy stopped is “Unknown,” go to question 79.

Questions 79-80: Reason therapy stopped
If the systemic therapy was stopped during the reporting period, indicate the reason it was stopped using one of the following options in question 79:

- **Toxicity (e.g. cytopenia):** The recipient developed a toxicity in response to therapy.
- **Not tolerable:** The therapy was stopped due to intolerability (adverse events)
- **Lack of response:** The course of treatment stopped due to lack of a complete response.
- **Disease progression:** The recipient’s disease progressed from HI; Requires at least one of the following in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.):
  - ≥ 50% reduction from maximum response levels in granulocytes or platelets
  - Reduction in hemoglobin by ≥ 1.5 g/dL
  - Transfusion dependence
- **Response (treatment achieved goal):** A favorable disease response was achieved and treatment was no longer required.
- **Other:** Use this option choice for any reason not included above and specify the reason in question 80.
- **Unknown:** Use this option when the reason therapy was stopped is unknown.

If the reason therapy stopped isn’t listed in question 79, select “other” and report the other reason therapy stopped in question 80. Continue with question 81.

Question 81-82: Specify systemic therapy given for maintenance: (check all that apply)
Report the drug(s) given as part of this line of therapy. If multiple lines of therapy were given during the reporting period, they must be reported separately. If the drug given is not listed as an option for question 81, report “Other systemic therapy” and specify the drug in question 82.

Question 83: 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 84-85: Blinded randomized trial
Indicate whether treatment was administered as part of a blinded randomized trial. Consult the physician overseeing treatment if it is not clear whether the therapy is being given as part of a blinded randomized trial. If “yes,” report the clinicaltrials.gov number in question 85. Otherwise, go to question 86.

If the clinical trial number (NCT number) is not clearly documented, it can be looked up using the Find a Study feature on www.clinicaltrials.gov.

If the recipient is participating in a clinical trial that is not registered with clinicaltrials.gov, but is registered elsewhere, leave question 85 blank and override the validation error using the code “Unable to answer.” Also, attach documentation which displays the clinical trial number and corresponding registry to the form in FormsNet3SM. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Question 86-87: Other therapy
Indicate if the recipient received any other therapy (not already reported in questions 74-85) given for reasons other than relapse or progression as part of this line of therapy. Do not report supportive therapies (e.g., transfusions, growth factors) or a subsequent HCT in questions 86-87. If “yes,” specify all other therapies given in question 87. If “no,” go to question 88.

Copy questions 74-87 to report more than one line of therapy.

Q88-171: Disease Detection Since the Date of Last Report

Warning:
Questions 88-99 refer to overlap syndromes including CMMoL; JMML; aCML; MDS/MPN-RS-T; MDS/MPN, unclassifiable; if the diagnosis was other than an overlap syndrome, continue with question 100.

Questions 88-89: Did the recipient have splenomegaly?
Indicate if the recipient had splenomegaly indicative of disease detection since the date of the last report. Splenomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding. Splenomegaly can also be detected by imaging techniques such as ultrasonography, CT or MRI.

Indicate “yes” if splenomegaly was present and indicated disease detection since the date of the last report and report the date of assessment in question 89. Indicate “no” if
splenomegaly was not present, or if splenomegaly was not indicative of disease, since the date of the last report and continue with question 94.

Indicate “unknown” if it is not possible to determine the presence or absence of splenomegaly since the date of the last report and continue with question 94.

Indicate “not applicable” if the question does not apply to the recipient (e.g. prior Splenectomy or congenital asplenia) and continue with question 94.

**Question 90: Specify the method used to measure spleen size:**
Indicate the method used to measure the spleen size, if the method selected is “physical assessment” continue with question 91. If the method selected is “ultrasound” or “CT / MRI” continue with question 92. If spleen size is measured using multiple methods, report the most accurate assessment. Ultrasound is the most specific and preferred assessment.

**Question 91: Specify the spleen size in centimeters below the left costal margin**
Indicate the size of the spleen in centimeters, measured below the left costal margin as assessed by physical exam then continue with question 93.

**Question 92: Specify the spleen size in centimeters**
Indicate the size of the spleen in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 93.

**Question 93: Was this considered a disease relapse?**
If the physician believes the size of the spleen indicates a disease relapse, check “yes.” If the recipient had an enlarged spleen, but the physician does not believe the result represents disease relapse, check “no.” Continue with question 94.

**Questions 94-95: Did the recipient have hepatomegaly?**
Indicate if the recipient had hepatomegaly indicative of disease detection since the date of the last report. Hepatomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding.

Indicate “yes” if hepatomegaly was present and indicated disease detection since the date of the last report and report the date of assessment in question 95. Indicate “no” if hepatomegaly was not present, or if hepatomegaly was not indicative of disease, since the date of the last report and continue with question 100. Indicate “unknown” if it is not possible to determine the presence or absence of hepatomegaly since the date of the last report and continue with question 100.

**Question 96: Specify the method used to measure liver size:**
Indicate the method used to measure the liver size, if the method selected is “physical assessment” continue with question 97. If the method selected is “ultrasound” or “CT / MRI” continue with question 98. If liver size is measured using multiple methods, report
the most accurate assessment. Ultrasound is the most specific and preferred assessment.

**Questions 97: Specify the liver size in centimeters below the right costal margin**
Indicate the size of the liver in centimeters, measured below the right coastal margin as assessed by physical exam then continue with question 99.

**Question 98: Specify the liver size in centimeters**
Indicate the size of the liver in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 99.

**Question 99: Was this considered a disease relapse?**
If the physician believes the size of the liver indicates a disease relapse, check “yes.” If the recipient had an enlarged liver, but the physician does not believe the finding represents disease relapse, check “no.” Continue with question 100.

**Question 100: Were molecular tests for molecular markers performed (e.g., PCR, NGS)?**
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. FISH testing for molecular markers should NOT be reported here.

Once a marker has been identified, these methods can be repeated to detect minimal residual disease (MRD) in the recipient’s blood, bone marrow, or tissue. Molecular assessments include polymerase chain reaction (PCR) amplification to detect single specific disease markers; however, molecular methods are evolving and now include chromosomal microarray / chromosomal genomic array, Sanger sequencing, and next generation sequencing (e.g., Illumina, Roche 454, Proton / PGM, SOLiD).

If any molecular testing for molecular markers detected the recipient’s primary disease during the reporting period, report “yes” and go to question 101.

If molecular testing did not detect disease at any time during the reporting period, or it is unknown if testing was done, report “no” or “unknown” respectively and go to question 109.

**Question 101: Indicate if a positive molecular marker(s) was identified**
Indicate if a positive molecular marker associated with the recipient’s primary disease was identified during the reporting period.

If a positive molecular marker associated with the recipient’s primary disease was identified, select “yes” and continue with question 102.
If there were no molecular markers associated with the recipient’s primary disease identified, no positive molecular markers identified, or it is unknown whether molecular markers were identified, select “no” and continue with question 108.

**Question 102: Date sample collected**
Report the date the sample was collected for molecular testing.

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

**Questions 103-104: Specify the positive molecular marker**
Specify the positive molecular marker and continue with question 105. If a positive marker is detected, but not listed as an option, select “other molecular marker” and specify the positive molecular marker in question 104.

**Questions 105-106: Amino acid change**
Amino acid changes can be described using standard mutation nomenclature. For CIBMTR reporting purposes, only amino acid changes based on protein-level sequences, beginning with the prefix “p.,” need to be reported. See Figure 1 below for an example of an amino acid change within a molecular pathology report.

**Figure 1.** Molecular disease assessment with amino acid changes documented (highlighted in yellow).

For more information on nomenclature used for amino acid changes, visit the Human Genome Variation Society Sequence Variant Nomenclature Protein Recommendations.

For question 105, indicate if the amino acid change is "known "or "unknown" for the positive molecular marker reported in questions 103-104. If known, report the amino acid change in question 106. If unknown, continue with question 107.

Copy questions 103-106 to report more than one positive molecular marker.

**Question 107: Was this considered a disease relapse?**
Indicate if the molecular abnormalities were considered a disease relapse. Criteria for molecular relapse are established by clinical judgment, and should reflect the clinical decision of the transplant physician. A recipient may be reported to have molecular
relapse even in the setting of hematologic CR; criteria for complete remission are based on hematologic and pathologic characteristics and are independent of molecular markers of disease.

If the recipient has molecular abnormalities that the physician considers to be consistent with disease relapse, select “yes.”

If the recipient has molecular abnormalities that the physician does not consider to be consistent with molecular relapse, select “no.”

**Question 108: Was documentation submitted to the CIBMTR?**
Indicate if the pathology report is attached to support the molecular findings reported in questions 102-106. For further instructions on how to attach documents in FormsNet3™, refer to the Training Guide.

**Question 109: Was disease detected via flow cytometry?**
Flow cytometry assessment is a method of analyzing peripheral blood, bone marrow, or tissue preparations for multiple unique cell characteristics; its primary clinical purpose in the setting of MDS, MPN, and leukemias is to quantify blasts in the peripheral blood or bone marrow, or to identify unique cell populations through immunophenotyping. Flow cytometry assessment may also be referred to as “MRD” or minimal residual disease testing.

If disease was detected via flow cytometry, select “yes” and continue with question 110.

If disease was not detected via flow cytometry or it is unknown if disease was detected via flow cytometry, select “no” and continue with question 118.

**Question 110-112: Blood**
Indicate whether flow cytometry detected disease in a blood sample at any time during the reporting period. If “yes,” report the date the sample was collected and the percent disease detected (i.e., percent leukemic blasts) in questions 111 and 112, respectively. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.

Report “no” for question 110 and go to question 114 in either of the following cases:
- all flow cytometry assessments performed on the blood were negative for evidence of the recipient’s primary disease during the current reporting period; or
- flow cytometry testing was not performed on the blood during the reporting period.

If multiple flow cytometry assessments performed on blood samples were positive for disease, report the date / results of the earliest positive assessment performed during the reporting period.
Question 113: Was this considered a disease relapse?
Indicate if the peripheral blood flow cytometry results were considered consistent with disease relapse. Criteria for flow cytometric relapse are established by clinical judgment. If the recipient has abnormalities by flow cytometry that the physician considers to be consistent with flow cytometric relapse, select “yes.” Continue with question 114.

If the recipient has residual disease by flow cytometry that the physician does not consider to be consistent with relapse, select “no.” Continue with question 114.

Question 114-116: Bone Marrow
Indicate whether flow cytometry detected disease in a bone marrow at any time during the reporting period. If “yes,” report the date the sample was collected and the percent disease detected (i.e., percent leukemic blasts) in questions 115 and 116, respectively. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.

Report “no” for question 114 and go to question 118 in either of the following cases:
- all flow cytometry assessments performed on the bone marrow were negative for evidence of the recipient’s primary disease during the current reporting period; or
- flow cytometry testing was not performed on the bone marrow during the reporting period.

If multiple flow cytometry assessments performed on bone marrow were positive for disease, report the date / results of the earliest positive assessment performed during the reporting period.

Questions 117: Was this considered disease relapse?
Indicate if the bone marrow flow cytometry results were considered consistent with disease relapse. Criteria for flow cytometric relapse are established by clinical judgment. If the recipient has abnormalities by flow cytometry that the physician considers to be consistent with flow cytometric relapse, select “yes.” Continue with question 118.

If the recipient has residual disease by flow cytometry that the physician does not consider to be consistent with relapse, select “no.” Continue with question 118.

Question 118: Was disease detected 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 known chromosomal abnormalities that reflect the recipient’s disease. Testing methods include conventional chromosome analysis (karyotyping) or fluorescence in situ hybridization (FISH). For more information about cytogenetic testing and terminology, see Appendix C, Cytogenetic Assessments.
Karyotyping is performed by culturing cells (growing cells under controlled conditions) until they reach their 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 demonstrated 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. These probes are mixed with cells from the recipient’s blood or bone marrow. 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. 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.

If cytogenetic testing detected the recipient’s primary disease at any time during the reporting period, report “yes” and go to question 119. If all cytogenetic testing was negative for evidence of the recipient’s primary disease during the current reporting period, report “no” and go to question 137. Report “Unknown” for question 118 and go to question 137 in any of the following cases:

- cytogenetic testing was not performed during the reporting period; or
- cytogenetic testing was attempted, but no assessments could be performed during the reporting period (e.g., insufficient sample); or
- it cannot be determined whether cytogenetic testing was performed during the reporting period.

**Question 119: Were cytogenetic abnormalities identified via FISH?**
Indicate whether FISH studies detected disease at any time during the reporting period. If “yes” go to question 120.

Report “no” for question 119 and go to question 128 in any of the following cases:

- FISH testing was not performed during the reporting period; or
- FISH testing was performed during the reporting period but no abnormalities associated with the recipient’s primary disease were detected
- FISH testing was attempted, but no assessments could be performed during the reporting period (e.g., insufficient sample); or
- it cannot be determined whether FISH testing was performed during the reporting period.

**Questions 120-121: Sample source**
Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 121. If multiple sources were used to test FISH, the most preferred sample is the bone marrow.

If multiple FISH assessments were positive for disease, report the date / results of the earliest positive assessment performed during the reporting period.

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

**Warning:**
Question 122 is disabled and cannot be answered at this time.

**Questions 122-125: Specify cytogenetic abnormalities (FISH)**
Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 122, then continue with question 123.

Report the number of abnormalities detected by FISH in question 123. After indicating the number of abnormalities in question 123, select all abnormalities detected in questions 124-125.

If an abnormality is detected, but not listed as an option in question 124, select “other abnormality” and specify the abnormality in question 125. If multiple “other abnormalities” were detected, report “see attachment” in question 125 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 126: Was this considered a disease relapse?**
Indicate if the FISH results were considered consistent with disease relapse. Criteria for FISH relapse are established by clinical judgment. If the recipient has abnormalities detected by FISH that the physician considers to be consistent with relapse, select “yes.” Continue with question 127.

If the recipient has residual disease by FISH that the physician does not consider to be consistent with relapse, select “no.” Continue with question 127.

**Question 127: Was documentation submitted to the CIBMTR? (e.g. FISH report)**
Indicate if the FISH report is attached to support the cytogenetic findings reported in questions 122-126. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Question 128: were cytogenetic abnormalities identified via karyotyping?**
Indicate whether karyotyping studies detected disease at any time during the reporting period. If “yes” go to question 129.

Report “no” for question 128 and go to question 137 in any of the following cases:
• karyotyping was not performed during the reporting period; or
• karyotyping was performed during the reporting period but no abnormalities associated with the recipient’s primary disease were detected
• karyotyping was attempted, but no assessments could be performed during the reporting period (e.g., insufficient sample); or
• it cannot be determined whether karyotyping was performed during the reporting period.

Questions 129-130: Sample source
Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 130. If multiple sources were used for karyotyping analysis, the preferred sample is the bone marrow.

If multiple karyotyping assessments were positive for disease, report the date / results of the earliest positive assessment performed during the reporting period.

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

Warning:
Question 131 is disabled and cannot be answered at this time.

Questions 131-134: Specify cytogenetic abnormalities (karyotyping)
Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 131, then continue with question 132.

Report the number of abnormalities detected by karyotyping in question 132. After indicating the number of abnormalities in question 132, select all abnormalities detected in questions 133-134.

If an abnormality is detected, but not listed as an option in question 133, select “other abnormality” and specify the abnormality in question 134. If multiple “other abnormalities” were detected, report “see attachment” in question 134 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 135: Was this considered a disease relapse?
Indicate if the karyotyping results were considered consistent with disease relapse. Criteria for karyotype relapse are established by clinical judgment. If the recipient has abnormalities detected by karyotyping that the physician considers to be consistent with relapse, select “yes.” Continue with question 136.

If the recipient has residual disease by karyotyping that the physician does not consider to be consistent with relapse, select “no.” Continue with question 136.
Question 136: Was documentation submitted to the CIBMTR? (e.g. karyotyping report)
Indicate if the karyotyping report is attached to support the cytogenetic findings reported in questions 131-134. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Questions 137-138: Was disease detected via bone marrow examination?
If a bone marrow biopsy detected disease during the reporting period, report “yes” for question 137 and report the date of the positive assessment in question 138. Continue with question 139.

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

If multiple bone marrow biopsies detected disease, report the date of the earliest positive assessment performed during the reporting period.

If bone marrow biopsies did not detect disease at any time during the reporting period, or it is unknown if any bone marrow biopsies were done, report “no” or “unknown” respectively and go to question 144.

Questions 139-140: Blasts in the bone marrow
Indicate whether the percentage of blasts in the bone marrow was “known” or “unknown.” If “known” report the percentage documented on the laboratory report in question 140. If “unknown” continue with question 141.

Question 141: Myelofibrosis grading by WHO classification
Fibrosis describes the replacement of bone marrow by fibrous (scar) tissue. This distinction is made on the pathology report of a bone marrow examination and the myelofibrosis grade may be documented by the pathologist.

Indicate if the myelofibrosis grading is “known” or “unknown.” If the myelofibrosis grade is documented in the pathology report, select “known,” continue with question 142. If the pathology report is not available and the grade is documented in a physician note, then this would be sufficient.

If the myelofibrosis grade is not documented on the pathology report, select “unknown,” continue with question 143.

Question 142: Specify the grade
Specify the Myelofibrosis grading using the WHO classification. The classification and results should be clarified in the pathology report as dictated by the pathologist or may be found in a physician note if the BM path report is not available.

Select “MF-0” if the report documents scattered linear reticulin with no intersection (crossovers) corresponding to normal bone marrow.
Select “MF-1” if the report documents a loose network of reticulin with many intersections, especially in perivascular areas.

Select “MF-2” if the report documents diffuse and dense increase in reticulin with extensive intersections, occasionally with local bundles of thick fibers mostly consistent with collagen, and/or focal osteosclerosis.

Select “MF-3” if the report documents diffuse and dense increase in reticulin with extensive intersections and coarse bundles of thick fibers consistent with collagen, usually associated with osteosclerosis.

**Question 143: Was this considered a disease relapse?**
Indicate if the myelofibrosis grade by WHO classification was considered a disease relapse. Criteria for myelofibrosis relapse are established by clinical judgment. If the recipient has a myelofibrosis grade by WHO classification that the physician considers to be consistent with relapse, select “yes.” Continue with question 144. If the recipient has residual myelofibrosis that the physician does not consider to be consistent with relapse, select “no.” Continue with question 144.

**Questions 144-145: Was extramedullary disease indicative of AML detected? (e.g. myeloid sarcoma)**
Indicate if the recipient had extramedullary disease indicative of AML during the reporting period. An example of extramedullary disease would be a myeloid sarcoma. Indicate “yes” if extramedullary disease indicative of AML was present and report the date of assessment in question 145. Indicate “no” if extramedullary disease indicative of AML was not present during the reporting period and continue with question 148.

If multiple assessments detected extramedullary disease indicative of AML during the reporting period, report the date of the earliest positive assessment performed during the reporting period.

**Questions 146-147: Specify site(s) of disease (check all that apply)**
Select each site where extramedullary disease indicative of AML was detected on the date reported in question 145. If extramedullary disease indicative of AML was detected at a site not specified in question 146, report “other site” and specify all other sites where extramedullary disease indicative of AML have been identified in question 147.

**Questions 148-150: Was disease detected by other assessment?**
Indicate if disease was detected by any other assessment during the reporting period. Indicate “yes” if disease was detected by other assessment during the reporting period, report the date of assessment in question 149, and specify the name of the other assessment in question 150. Indicate “no” if disease was not detected by any other during the reporting period and continue with question 152.
Question 151: Was this considered a disease relapse?
Indicate if the result of the other disease assessment was considered a disease relapse. Criteria for disease relapse are established by clinical judgment. If the recipient has another disease assessment that the physician considers to be consistent with relapse, select “yes.” Continue with question 152.

Question 152: Was intervention given for minimal residual disease, persistent disease, relapsed disease, decreased/loss of chimerism, or progression to AML since the date of the last report?
Indicate if the recipient received treatment post-infusion for minimal residual disease, persistent disease, relapsed disease, decreased/loss of chimerism, or progression to AML since the date of last report. If “Yes,” go to question 153. If “No,” go to question 172. See question 153 for definitions each of these indications for treatment.

Question 153: Specify reason for which intervention was given
Select all indications for which treatment was administered during the reporting period. See below for definitions of each indication.

- **Minimal Residual Disease:** Recipient is in hematologic CR, but has evidence of disease by more sensitive assessments including molecular, flow cytometry or cytogenetic methods.

- **Persistent Disease:** The recipient was in primary induction failure or relapse at the time of infusion and has not achieved a hematologic CR post-infusion.

- **Relapsed Disease:** The recipient was in CR at the time of infusion or the recipient achieved a CR post-infusion. In either case, treatment is administered for a relapse which occurred post-infusion.

- **Decreased / Loss of Chimerism:** If the recipient’s chimerism decreased or was being lost during the reporting period, treatment is administered to recover the lost chimerism.

- **Progression to AML:** If an examination demonstrated ≥20% blasts in the blood or bone marrow during the reporting period, this is a progression to AML and treatment would be administered in order to treat this progression.

Question 154: Systemic therapy
Systemic therapy includes chemotherapy, immunotherapy, or targeted therapies delivered via the blood stream and distributed throughout the body. Therapy may be injected into a vein or given orally. Do not report subsequent HCT / cellular therapies in questions 154-162. If the recipient received systemic therapy during the reporting period to treat minimal residual disease, persistent disease, relapsed disease, decreased/loss of chimerism, or progression to AML, report “yes” and go to question 155. If not, report “no” and go to question 163.
Questions 155-156: Date therapy was first started

Note: Form Revision Change
If therapy was started during a prior reporting period, for which, an MDS Post-HCT Data Form Revision 3 was completed, the start date will not have been reported on that form. In this case, report the date maintenance therapy was started on the current form (MDS Post-Infusion Data Form, Revision 4) and override the validation error using the code “Verified Correct.” If the reported therapy continues into the next reporting period, the site will indicate “Previously reported” in question 155.

Indicate if the therapy start date is “Known” or “Unknown” in question 155. If “Known” indicate the start date in question 156. If the date therapy first started is “Unknown” go to question 157 If the exact date is not known, use the process for reporting partial or unknown dates as described in the General Instructions, Guidelines for Completing Forms.

If the recipient started therapy in a prior reporting period to treat minimal residual disease, persistent disease, relapsed disease, decreased/loss of chimerism, or progression to AML, and continued the therapy into the current reporting period, report “Previously reported” and go to question 157.

For recipients who start and stop therapy multiple times post-infusion, first determine whether the recipient stopped therapy for at least 30 days. If not, consider the therapy continuous. Only report a new therapy start date if all three of the below conditions are met.

1. The recipient stopped all therapy given for treatment; and
2. The recipient restarted therapy for treatment during the current reporting period; and
3. Therapy was restarted at least 30 days after the therapy stop date.

Questions 157-158: 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 158. Otherwise, report the final administration date for the therapy being reported.

If the recipient is still receiving this treatment at the end of the reporting period, report “not applicable (still receiving therapy)” and continue with 161.

If the stop date is partially known, use the process for reporting partial or unknown dates as described in the General Instructions, Guidelines for Completing Forms.

If the date therapy stopped is “Unknown,” go to question 159.

Questions 159-160: Reason therapy stopped
If the systemic therapy was stopped during the reporting period, indicate the reason it was stopped in question 159. If the reason therapy stopped isn’t listed in question 159,
select “other” and report the other reason therapy stopped in question 160. Continue with question 161.

**Question 161-162: Specify systemic therapy given for maintenance: (check all that apply)**
Report the drug(s) given as part of this line of therapy. If multiple lines of therapy were given during the reporting period, they must be reported separately. If the drug given is not listed as an option for question 161, report “Other systemic therapy” and specify the drug in question 162.

**Question 163-164: Supportive Treatment**
Supportive treatment is given to patients with MDS to treat the symptoms of their disease. If supportive treatment was given as part of this line of therapy, report “yes” for question 163. Select all supportive treatments administered as part of this line of therapy in question 164.

If supportive treatment was not given as part of this line of therapy, report “no” for question 163 and continue with question 165.

**Question 165: 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 166: Subsequent HCT**
If the recipient received a subsequent HCT to treat minimal residual disease, persistent disease, relapsed disease, decreased/loss of chimerism, or progression to AML, report “yes.” If not, report “no.”

If a subsequent HCT was performed during the reporting period, ensure this was reported on the Post-infusion Data (2100 or 4100) forms as well. Reporting a subsequent HCT given to treat the recipient’s primary disease will prompt a new Pre-TED (2400) form to come due in FormsNet3SM.

**Question 167: Accelerated withdrawal of immunosuppression in response to disease assessment**
Immunosuppressive medications may be tapered or entirely withdrawn in order to promote a graft vs leukemia effect in the setting of relapsed, progressive, persistent disease or decreased/loss of chimerism. If immunosuppression is reduced or stopped during the reporting period in order to treat disease, report “yes.” If not, report “no.”

**Question 168-169: Blinded randomized trial**
Indicate whether treatment was administered as part of a blinded randomized trial. Consult the physician overseeing treatment if it is not clear whether the therapy is being given as part of a blinded randomized trial. If “yes,” report the clinicaltrials.gov number in question 169. Otherwise, go to question 170.

If the clinical trial number (NCT number) is not clearly documented, it can be looked up using the Find a Study feature on www.clinicaltrials.gov.

If the recipient is participating in a clinical trial that is not registered with clinicaltrials.gov, but is registered elsewhere, leave question 169 blank and override the validation error using the code “Unable to answer.” Also, attach documentation which displays the clinical trial number and corresponding registry to the form in FormsNet3SM. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Question 170-171: Other therapy**
Indicate if the recipient received any other therapy (not already reported in questions 154-169) given for minimal residual disease, persistent disease, relapsed disease, decreased / loss of chimerism, or progression to AML. Do not report supportive therapies (e.g., transfusions, growth factors) or a subsequent HCT in questions 170-171, as they should already have been reported above. If “yes,” specify all other therapies given in question 171. If “no,” go to question 172.

**Q172-238: Disease Status at the Time of Evaluation for this Reporting Period**

**Question 172: Does the current disease status reflect the disease detected in this reporting period section (as captured in questions 89-152), without subsequent therapy?**
This section of the form is intended to capture the most recent disease assessments performed in the reporting period. The most recent disease assessments may have already been reported in questions 88-151 (Disease Detection Since the Date of Last Report) and, if that is the case, it is not necessary to report those same disease assessments in questions 172-232 (Disease Status at the Time of Evaluation for this Reporting Period). Refer to the instructions below to determine how to complete this section of the form. Reporting scenarios have also been provided below.

Report “Yes” for question 172 and go to question 233 in any of the following scenarios:
- the most recent disease assessments in the reporting period have already been reported in questions 88-151 (Disease Detection Since the Date of Last Report)
- if assessments were reported in questions 88-151 (Disease Detection Since the Date of Last Report) and no therapy was given to treat disease between the date(s) of the reported assessments and the date of contact for this reporting period.

Report “No” for question 172 and go to question 173 in any of the following scenarios:
• disease was not detected by any method of assessment during the reporting period; or
• disease was detected by at least one method of assessment during the reporting period (reported in questions 88-151), but the most recent assessments have not yet been reported on the form.

Report “Not applicable” for question 172 and submit the form if the disease was not assessed during the reporting period. This option should not commonly be used as it would indicate that the recipient did not have any disease evaluations, including a physical exam by their primary care provider, performed during the reporting period.

Submit a ticket through the CIBMTR Customer Service Center if there are questions regarding whether a visit or test should be reported as a disease assessment.

**Warning:**
Questions 173-182 refer to overlap syndromes including CMMoL; JMML; aCML; MDS/MPN-RS-T; MDS/MPN, unclassifiable; if the diagnosis was other than an overlap syndrome, continue with question 184.

**Questions 173-174: Did the recipient have splenomegaly? (at the time of evaluation for this reporting period)**
Indicate if the recipient had splenomegaly at the time of evaluation for this reporting period. Splenomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding. Splenomegaly can also be detected by imaging techniques such as ultrasonography, CT or MRI.

Indicate “yes” if splenomegaly was present at the time of evaluation for this reporting period and report the date of assessment in question 174.

Indicate “no” if splenomegaly was not present at the time of evaluation for this reporting period and continue with question 178.

Indicate “unknown” if it is not possible to determine the presence or absence of splenomegaly at the time of evaluation for this reporting period and continue with question 178.

Indicate “not applicable” if the question does not apply to the recipient (e.g. prior Splenectomy or congenital asplenia) and continue with question 178.

**Question 175: Specify the method used to measure spleen size:**
Indicate the method used to measure the spleen size, if the method selected is “physical assessment” continue with question 176. If the method selected is “ultrasound” or “CT / MRI” continue with question 177. If spleen size is measured using multiple methods, report the most accurate assessment. Ultrasound is the most specific and preferred assessment.
Question 176: Specify the spleen size in centimeters below the left costal margin
Indicate the size of the spleen in centimeters, measured below the left costal margin as assessed by physical exam then continue with question 178.

Question 177: Specify the spleen size in centimeters
Indicate the size of the spleen in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 178.

Questions 178-179: Did the recipient have hepatomegaly? (at the time of evaluation for this reporting period)
Indicate if the recipient had hepatomegaly at the time of evaluation for this reporting period. Hepatomegaly is often documented during the physician’s physical assessment of the patient and represents an abnormal finding.

Indicate “yes” if hepatomegaly was present at the time of evaluation for this reporting period and report the date of assessment in question 179.

Indicate “no” if hepatomegaly was not present at the time of evaluation for this reporting period and continue with question 183.

Indicate “unknown” if it is not possible to determine the presence or absence of hepatomegaly at the time of evaluation for this reporting period and continue with question 183.

Question 180: Specify the method used to measure liver size:
Indicate the method used to measure the liver size, if the method selected is “physical assessment” continue with question 181. If the method selected is “ultrasound” or “CT / MRI” continue with question 182. If liver size is measured using multiple methods, report the most accurate assessment. Ultrasound is the most specific and preferred assessment.

Questions 181: Specify the liver size in centimeters below the right costal margin
Indicate the size of the liver in centimeters, measured below the right costal margin as assessed by physical exam then continue with question 183.

Question 182: Specify the liver size in centimeters
Indicate the size of the liver in centimeters, as assessed by imaging (ultrasound, CT / MRI) then continue with question 183.

Question 183: Were molecular tests for molecular markers performed (e.g., PCR)? (at time of evaluation for this reporting period)
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. FISH testing for molecular markers should NOT be reported here.

Once a marker has been identified, these methods can be repeated to detect minimal residual disease (MRD) in the recipient’s blood, bone marrow, or tissue. Molecular assessments include polymerase chain reaction (PCR) amplification to detect single specific disease markers; however, molecular methods are evolving and now include chromosomal microarray / chromosomal genomic array, Sanger sequencing, and next generation sequencing (e.g., Illumina, Roche 454, Proton / PGM, SOLiD).

If molecular testing for molecular markers was performed at the time of evaluation for this reporting period, report “yes” and go to question 184.

If molecular testing for molecular markers was not performed at the time of evaluation for this reporting period, or it is unknown if testing was done, report “no” or “unknown” respectively and go to question 191.

**Question 184: Indicate if a positive molecular marker(s) was identified**

Indicate if a positive molecular marker associated with the recipient’s primary disease was identified at the time of evaluation for this reporting period.

If a positive molecular marker associated with the recipient’s primary disease was identified at the time of evaluation for this reporting period, select “yes” and continue with question 185.

If there were no molecular markers associated with the recipient’s primary disease identified, no positive molecular markers identified, or it is unknown whether molecular markers were identified, select “no” and continue with question 190.

**Question 185: Date sample collected**

Report the date the sample was collected for molecular testing.

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

**Questions 186-187: Specify the positive molecular marker**

Specify the positive molecular marker and continue with question 188. If a positive marker is detected, but not listed as an option, select “other molecular marker” and specify the positive molecular marker in question 187.

**Questions 188-189: Amino acid change**

Amino acid changes can be described using standard mutation nomenclature. For CIBMTR reporting purposes, only amino acid changes based on protein-level sequences, beginning with the prefix “p.,” need to be reported. See Figure 1 below for an example of an amino acid change within a molecular pathology report.
Figure 1. Molecular disease assessment with amino acid changes documented (highlighted in yellow).

For more information on nomenclature used for amino acid changes, visit the Human Genome Variation Society Sequence Variant Nomenclature Protein Recommendations.

For question 188, indicate if the amino acid change is “known” or “unknown” for the positive molecular marker reported in questions 186-187. If known, report the amino acid change in question 189. If unknown, continue with question 190.

Copy questions 186-189 to report more than one positive molecular marker.

Question 190: Was documentation submitted to the CIBMTR?
Indicate if the pathology report is attached to support the molecular findings reported in questions 186-189. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Question 191: Was the disease status assessed via flow cytometry? (at the time evaluation for this reporting period)
Flow cytometry assessment is a method of analyzing peripheral blood, bone marrow, or tissue preparations for multiple unique cell characteristics; its primary clinical purpose in the setting of MDS, MPN, and leukemias is to quantify blasts in the peripheral blood or bone marrow, or to identify unique cell populations through immunophenotyping. Flow cytometry assessment may also be referred to as “MRD” or minimal residual disease testing.

Indicate if flow cytometry was performed on peripheral blood and/or bone marrow sample at the time of evaluation for this reporting period.

If flow cytometry was performed, select “yes” and continue with question 192.

If flow cytometry was not performed, flow cytometry sample was inadequate, or it is unknown if flow cytometry was performed, select “no” and continue with question 200.

Question 192-193: Blood
Indicate if flow cytometry was performed on the peripheral blood at the time of evaluation for this reporting period. If multiple assessments were performed, report the assessment performed closest to the date of contact.

If flow cytometry was performed on a peripheral blood sample, select “yes” and report the date the sample was collected in question 193. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.

If flow cytometry was not performed on a peripheral blood sample, select “no” and continue with question 196.

**Questions 194-195: Was disease detected?**
Indicate if evidence of disease was detected in the peripheral blood sample sent for flow cytometry analysis. Evidence of disease may include the presence of blasts or an immunophenotype known to characterize the patient’s disease. If flow cytometry results are consistent with evidence of disease, select “yes” and specify the percentage of disease detected (to the nearest thousandth) in the peripheral blood as documented in the flow cytometry report in question 195.

If flow cytometry results were not consistent with evidence of disease, check “no” and continue with question 196.

**Question 196-197: Bone Marrow**
Indicate if flow cytometry was performed on the bone marrow at the time of evaluation for this reporting period. If multiple assessments were performed, report the assessment performed closest to the date of contact.

If flow cytometry was performed on a bone sample, select “yes” and report the date the sample was collected in question 197. If the exact date is not known, use the process for reporting partial or unknown dates as described in General Instructions, Guidelines for Completing Forms.

If flow cytometry was not performed on a bone marrow sample, select “no” and continue with question 200.

**Questions 198-199: Was disease detected?**
Indicate if evidence of disease was detected in the bone marrow sample sent for flow cytometry analysis. Evidence of disease may include the presence of blasts or an immunophenotype known to characterize the patient’s disease. If flow cytometry results are consistent with evidence of disease, select “yes” and specify the percentage of disease detected (to the nearest thousandth) in the peripheral blood as documented in the flow cytometry report in question 199.

If flow cytometry results were not consistent with evidence of disease, check “no” and continue with question 200.
Question 200: Were cytogenetics tested (karyotyping or FISH)? (at time of evaluation for this reporting period)

Cytogenetic analysis is the study of chromosomes. Cytogenetic assessment involves testing blood or bone marrow for the presence of known chromosomal abnormalities that reflect the recipient’s disease. Testing methods include conventional chromosome analysis (karyotyping) or fluorescence in situ hybridization (FISH). For more information about cytogenetic testing and terminology, see Appendix C, Cytogenetic Assessments.

Karyotyping is performed by culturing cells (growing cells under controlled conditions) until they reach their 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 demonstrated evidence of disease.

FISH is a sensitive technique that assesses large numbers of cells. This technique uses special probes that recognize and bind to fragments of DNA. These probes are mixed with cells from the recipient’s blood or bone marrow. 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. 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.

If cytogenetic (karyotyping or FISH) studies were obtained at the time of evaluation for this reporting period, report “yes” and continue with question 201.

If no cytogenetic studies were obtained at the time of evaluation for this reporting period, indicate “no” and continue with question 219.

If it is not known whether any cytogenetic studies were obtained at the time of evaluation for this reporting period, indicate “unknown” and go to question 219.

Question 201: Were cytogenetics tested via FISH?

If FISH studies were performed at the time of evaluation for this reporting period, report “yes” for question 201 and go to question 202. If FISH studies were not performed, report “no” for question 201 and go to question 210. Examples of this include: no FISH study performed or FISH sample was inadequate.

Question 202-203: Sample source

Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 203. Continue with question 204. If multiple sources were used to test FISH, the preferred sample is the bone marrow.
Question 204: Results of test
If FISH assessments identified abnormalities associated with the recipient’s primary disease, indicate “abnormalities identified” and continue with question 205.

If FISH assessments were unremarkable, indicate “no abnormalities” and continue with question 209.

Warning:
Question 205 is disabled and cannot be answered at this time.

Questions 205-208: Specify cytogenetic abnormalities (FISH)
Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 205, then continue with question 206.

Report the number of abnormalities detected by FISH at the time of evaluation for this reporting period in question 206. After indicating the number of abnormalities in question 206, select all abnormalities detected in questions 207-208.

If an abnormality is detected, but not listed as an option in question 207, select “other abnormality” and specify the abnormality in question 208. If multiple “other abnormalities” were detected, report “see attachment” in question 208 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 209: Was documentation submitted to the CIBMTR? (e.g. FISH report)
Indicate if the FISH report is attached to support the cytogenetic findings reported in questions 203-208. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Question 210: Were cytogenetics tested via karyotyping?
If karyotyping studies were performed at the time of evaluation for this reporting period, report “yes” for question 210 and go to question 211. If karyotyping studies were not performed, report “no” for question 210 and go to question 219. Examples of this include: no karyotyping study performed or karyotyping sample was inadequate.

Questions 211-212: Sample source
Indicate if the sample was from “bone marrow” or “peripheral blood” and report the date the sample was collected in question 212. Continue with question 213. If multiple sources were used for karyotyping analysis, the preferred sample is the bone marrow.

Question 213: Results of test
If karyotyping assessments identified abnormalities associated with the recipient’s primary disease, indicate “abnormalities identified” and continue with question 214.
If karyotyping assessments were unremarkable, indicate “no abnormalities” and continue with question 218.

If karyotyping assessment yielded an inadequate result, indicate “no evaluable metaphases” and continue with question 218.

**Warning:**
Question 214 is disabled and cannot be answered at this time.

**Questions 214-217: Specify cytogenetic abnormalities (karyotyping)**
Report the International System for Human Cytogenetic Nomenclature (ISCN) compatible string, if applicable, in question 214, then continue with question 215.

Report the number of abnormalities detected by karyotyping at the time of evaluation for this reporting period in question 215. After indicating the number of abnormalities in question 215, select all abnormalities detected in questions 216-217.

If an abnormality is detected, but not listed as an option in question 216, select “other abnormality” and specify the abnormality in question 217. If multiple “other abnormalities” were detected, report “see attachment” in question 217 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 218: Was documentation submitted to the CIBMTR? (e.g. karyotyping report)**
Indicate if the karyotyping report is attached to support the cytogenetic findings reported in questions 212-217. For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

**Questions 219-220: Was disease detected via bone marrow examination? (at the time of evaluation for this reporting period)**
If a bone marrow biopsy was performed at the time of evaluation for this reporting period, report “yes” for question 219 and report the date of the assessment in question 220. Continue with question 221.

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

If multiple bone marrow biopsies were performed during the reporting period, report the date of the assessment performed closest to the date of contact.

If bone marrow biopsies were not performed at any time during the reporting period, or it is unknown if any bone marrow biopsies were done, report “no” or “unknown” respectively and go to question 225.

**Questions 221-222: Blasts in the bone marrow**
Indicate whether the percentage of blasts in the bone marrow was “known” or “unknown” at the time of evaluation for this reporting period. If “known” report the percentage documented on the laboratory report in question 222. If “unknown” continue with question 223.

**Question 223: Myelofibrosis grading by WHO classification**

Fibrosis describes the replacement of bone marrow by fibrous (scar) tissue. This distinction is made on the pathology report of a bone marrow examination and the myelofibrosis grade may be documented by the pathologist.

Indicate if the myelofibrosis grading is “known” or “unknown.” If the myelofibrosis grade is documented in the pathology report, select “known,” continue with question 224. If the pathology report is not available and the grade is documented in a physician note, then this would be sufficient.

If the myelofibrosis grade is not documented on the pathology report, select “unknown,” continue with question 225.

**Question 224: Specify the grade**

Specify the Myelofibrosis grading using the WHO classification. The classification and results should be clarified in the pathology report as dictated by the pathologist or documented in a physician note if the pathology report is not available.

Select “MF-0” if the report documents scattered linear reticulin with no intersection (crossovers) corresponding to normal bone marrow.

Select “MF-1” if the report documents a loose network of reticulin with many intersections, especially in perivascular areas.

Select “MF-2” if the report documents diffuse and dense increase in reticulin with extensive intersections, occasionally with local bundles of thick fibers mostly consistent with collagen, and/or focal osteosclerosis.

Select “MF-3” if the report documents diffuse and dense increase in reticulin with extensive intersections and coarse bundles of thick fibers consistent with collagen, usually associated with osteosclerosis.

**Questions 225-226: Was extramedullary disease indicative of AML detected? (e.g. myeloid sarcoma) (at the time of evaluation for this reporting period)**

Indicate if the recipient had extramedullary disease indicative of AML at the time of evaluation for this reporting period. An example of extramedullary disease would be a myeloid sarcoma. Indicate “yes” if extramedullary disease indicative of AML was present at the time of evaluation for this reporting period and report the date of assessment in question 226. Indicate “no” if extramedullary disease indicative of AML was not present at the time of evaluation for this reporting period and continue with question 229.
Questions 227-228: Specify site(s) of disease (check all that apply)
Select each site where extramedullary disease indicative of AML was detected on the date reported in question 226. If extramedullary disease indicative of AML was detected at a site not specified in question 227, report “other site” and specify all other sites where extramedullary disease indicative of AML have been identified in question 228.

Questions 229-231: Was disease status assessed by other assessment? (at the time of evaluation for this reporting period)
Indicate if the recipient’s disease status was assessed by any other assessment at the time of evaluation for this reporting period. Indicate “yes” if the disease status was assessed by other assessment at the time of evaluation for this reporting period, report the date of assessment in question 230, and specify the name of the other assessment in question 231. Indicate “no” if the disease status was not assessed by other assessment at the time of best response and continue with question 233.

Question 232: Was disease detected?
If the other disease assessment indicated the presence of disease, select “yes” and continue with question 233.

If the other disease assessment did not indicate the presence of disease, select “no” and continue with question 233.

Question 233: What is the current disease status?
Report the disease status at the time of evaluation for this reporting period. Some judgment is required when evaluating if the recipient meets all specified CR criteria, specifically ANC and platelet criteria. If the recipient does not meet these parameters, the underlying cause should be assessed. If the cause for a low ANC or a low platelet count is related to MDS, the disease status should not be reported as “complete remission.” If the cause for not meeting one of these parameters is due to something other than underlying hematologic disease, such as renal insufficiency, hemolysis, or drug-related causes, the disease status may still be reported as “complete remission.”

If the recipient’s current disease status was hematologic improvement, continue with question 234.

For all other disease statuses, continue with question 236. See MDS Response Criteria for disease status definitions.

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 234: Specify the cell line examined to determine HI status (check all that apply)
Indicate the cell line examined to determine hematologic improvement. To determine the cell line, review the Hematologic Improvement criteria listed in the MDS Response Criteria section of the Forms Instruction Manual.

If the cell lines examined to determine hematologic improvement included, “HI – E” continue with question 235.

If the cell lines examined to determine hematologic improvement only included, “HI – P” and / or “HI – N,” continue with question 236.

Question 235: Specify transfusion dependence
If the recipient’s current disease status included hematologic improvement – erythroid, indicate the transfusion dependence at the time of evaluation for this reporting period.

Select “Non-transfused (NTD)” if the recipient received zero RBC transfusions within a period of 16 weeks prior to the contact date and continue with question 236.

Select “Low transfusion burden (LTB)” if the recipient had between three and seven RBC transfusions within a period of 16 weeks prior to the contact date in at least two transfusion episodes with a maximum of three transfusion episodes in eight weeks and continue with question 236.

Question 236: Date assessed:
Enter the date of the most recent assessment establishing disease status within the reporting period. The date reported should be that of the most disease-specific assessment within a reasonable timeframe of the date of contact (approximately 30 days). Clinical and hematologic assessments include pathological evaluation (e.g., bone marrow biopsy), radiographic examination (e.g., X-ray, CT scan, MRI scan, PET scan), laboratory assessment (e.g., CBC, peripheral blood smear), and clinician evaluation and physical examination. Enter the date the sample was collected for pathological and laboratory evaluations, the date the imaging took place for radiographic assessments, or the date of physical examination.

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