Disease Assessment at the Time of Best Response to HSCT

1. Compared to the disease status prior to the preparative regimen, what was the best response to HSCT since the date of the last report? (Include any therapy planned as of Day 0, but exclude any change in therapy in response to disease assessment.)

   1. complete remission (CR) — requires all of the following, maintained for ≥ 4 weeks:
      • bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines
      • peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000 / mm³ without myeloid growth factor support; platelets ≥ 100,000 / mm³ without thrombopoietic support; 0% blasts
   2. hematologic improvement (HI) — requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy:
      • HI-E — hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in the previous 8 weeks
      • HI-P — for pre-treatment platelet count of > 20,000 / mm³, platelet absolute increase of ≥ 30,000 / mm³; for pre-treatment platelet count of < 20,000 / mm³, platelet absolute increase of ≥ 20,000 / mm³ and ≥ 100% from pre-treatment level
      • HI-N — neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm³
   3. no response (NR) / stable disease (SD) — does not meet the criteria for at least HI, but no evidence of disease progression
   4. progression from hematologic improvement (prog 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
   5. relapse from complete remission (rel from CR) — requires at least one of the following:
      • return to pre-treatment bone marrow blast percentage
      • decrease of ≥ 50% from maximum response levels in granulocytes or platelets
      • transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy
   6. progression to AML — ≥ 20% blasts in the bone marrow

Best response is based on response to the HSCT, but does NOT include response to any therapy given for disease relapse or progression post-HSCT. When determining the best response to HSCT, compare the post-HSCT disease status to the status immediately prior to the preparative regimen, regardless of time since HSCT. This comparison is meant to capture the BEST disease status in response to HSCT that occurred in the 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 check the box to indicate “date previously reported.”

To be completed in conjunction with a Form 2100 – 100 Days Post-HSCT Data, Form 2200 – Six Months to Two Years Post-HSCT Data, or Form 2300 – Yearly Follow-Up for Greater Than Two Years Post-HSCT Data. Information reported here should reflect the date of last contact as reported in the post-HSCT data collection form, or immediately prior to death.
2. Date best response first began: [ ] date of best response was previously reported

Relapse or Progression Post-HSCT
3. Was a disease relapse or progression detected by any method since the date of the last report?
   1. ☐ yes
   2. ☐ no

4. Date the disease relapse or progression was established in this reporting period:

Most Recent Laboratory Studies
5. Was the bone marrow examined (post-HSCT) since the date of the last report?
   1. ☐ yes
   2. ☐ no

6. Date of bone marrow exam:
   Month 20 Day 20 Year

7. Blasts in marrow:
   1. ☐ known
   2. ☐ not known

8. Did the recipient have myelofibrosis since the date of the last report?
   1. ☐ yes
   2. ☐ no

9. Specify the status of marrow fibrosis since the date of the last report:
   1. ☐ unchanged / more severe
   2. ☐ improved
   3. ☐ resolved
   4. ☐ unknown

10. Is a copy of the bone marrow lab report attached?
    1. ☐ yes
    2. ☐ no

Disease Status at the Time of Assessment for this Reporting Period
11. What is the current disease status?
    1. ☐ complete remission
    2. ☐ not in complete remission

12. Date the current disease status was established in this reporting period:
   Month 20 Day 20 Year

13. Signed: ____________________________
    Person completing form

    Please print name: ____________________________
    Phone: (__________) ____________________________
    Fax: (__________) ____________________________
    E-mail address: ____________________________