ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ___ year

Today's Date: Month / Day / 20__ Year

Infusion Date: Month / Day / 20__ Year

CIBMTR Center Number:

Initials:

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Chronic Lymphocytic Leukemia Post-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month / Day / 20__ Year

Date of HSCT for which this form is being completed: 🕮 Month / Day / Year

HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: _____

Visit: ☐ 100 day ☐ 6 month ☐ 1 year ☐ 2 years ☐ > 2 years, specify: ___

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.

Questions followed by the symbol 🕮 indicate additional information necessary to complete the question is referenced in the forms instruction manual.

Disease Assessment at the Time of Best Response to HSCT

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." 🕮

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 response to any planned post-HSCT treatment.)
   - 1 ☐ complete response (CR) — no lymphadenopathy; no organomegaly; neutrophils > 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11 g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms
   - 2 ☐ nodular partial response (nPR) — CR with persistent lymphoid nodules in the bone marrow
   - 3 ☐ partial response (PR) — ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphodenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10^9/L or 50% improvement over baseline, platelets > 100 x 10^9/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline
   - 4 ☐ stable disease — no change; not CR, PR or progressive
   - 5 ☐ progressive disease — one or more of the following: ≥ 50% increase in sum of products of 2 or more lymph nodes (1 or more nodes must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size or new heptomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10^9/L; transformation to a more aggresive histology
   - 6 ☐ not assessed
2. Date best response first began: Month / Day / 20__ Year ☐ date of best response was previously reported

Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ____ year

Today's Date: Month / Day / 20__ Year

Infusion Date: Month / Day / 20__ Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Laboratory Studies Supporting Best Response to HSCT

3. Was molecular testing / immunophenotyping performed at the time of the disease assessment for best response to HSCT reported at question 1?
   1 ☐ yes → Specify the testing method(s) used:
   2 ☐ no

4. Immunophenotyping (4 color flow cytometry)
   1 ☐ yes →
   2 ☐ no

5. Specify the date immunophenotyping was performed: Month / Day / 20__ Year

6. Was disease detected?
   1 ☐ yes
   2 ☐ no

7. Heavy chain gene rearrangement (ASO-PCR)
   1 ☐ yes →
   2 ☐ no

8. Specify the date the heavy chain gene rearrangement testing was performed: Month / Day / 20__ Year

9. Was disease detected?
   1 ☐ yes
   2 ☐ no

Post-HSCT Planned Treatment for CLL

10. Was planned treatment given per protocol since the date of the last report? (Include any maintenance therapy, but exclude any treatment for relapse / progressive disease.)
    1 ☐ yes → Specify the treatment(s) given:
    2 ☐ no

11. Chemotherapy
    1 ☐ yes
    2 ☐ no

12. Radiation
    1 ☐ yes
    2 ☐ no

13. Immune therapy / monoclonal antibody (mAb)
    1 ☐ yes →
    2 ☐ no

Specify treatment(s) given:

14. 1 ☐ yes 2 ☐ no aldesleukin (interleukin-2, IL-2)
15. 1 ☐ yes 2 ☐ no alemtuzumab (Campath)
16. 1 ☐ yes 2 ☐ no rituximab (anti-CD20, Rituxan)
17. 1 ☐ yes 2 ☐ no other mAb →
    18. Specify other mAb: _____
19. 1 ☐ yes 2 ☐ no other immune therapy →
    20. Specify immune therapy: _____

21. Other treatment
    1 ☐ yes →
    2 ☐ no
    22. Specify treatment: _____

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ ____ year

Today's Date: Month ____ Day ____ Year 20____

Infusion Date: Month ____ Day ____ Year 20____

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

Disease Relapse or Progression Post-HSCT

23. Was a disease relapse or progression detected by any method since the date of the last report?
1 ☐ yes →
2 ☐ no

24. Date disease relapse or progression was detected: Month ____ Day ____ Year 20____

25. Was molecular testing performed at the time of disease relapse or progression?
1 ☐ yes →
2 ☐ no

Specify the testing method(s) used:

26. Immunophenotyping (4 color flow cytometry)
1 ☐ yes →
2 ☐ no

27. Specify the date immunophenotyping was performed: Month ____ Day ____ Year 20____

28. Was disease detected?
1 ☐ yes
2 ☐ no

29. Heavy chain gene rearrangement (ASO-PCR)
1 ☐ yes →
2 ☐ no

30. Specify the date the heavy chain gene rearrangement testing was performed: Month ____ Day ____ Year 20____

31. Was disease detected?
1 ☐ yes
2 ☐ no

Disease Status at the Time of Assessment for This Reporting Period

32. Was molecular testing / immunophenotyping performed at the time of disease assessment reported at question 39?
1 ☐ yes →
2 ☐ no

Specify the testing method(s) used:

33. Immunophenotyping (4 color flow cytometry)
1 ☐ yes →
2 ☐ no

34. Specify the date immunophenotyping was performed: Month ____ Day ____ Year 20____

35. Was disease detected?
1 ☐ yes
2 ☐ no

36. Heavy chain gene rearrangement (ASO-PCR)
1 ☐ yes →
2 ☐ no

37. Specify the date the heavy chain gene rearrangement testing was performed: Month ____ Day ____ Year 20____

38. Was disease detected?
1 ☐ yes
2 ☐ no

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ year

Today's Date: Month Day Year

Infusion Date: Month Day Year

CIBMTR Center Number:

Initials:

CIBMTR Center Number:

CIBMTR Recipient ID:

39. What is the current disease status?
1 ☐ complete remission
2 ☐ not in complete remission

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

41. Signed: _____
Person completing form

Please print name: _____

Phone number: (_____) _____

Fax number: (_____) _____

E-mail address: _____

CIBMTR Form 2113 (CLL) v1.0 (4–4) July 2007

For internal use only: Document F00499 version 1.0 Replaces: n/a

Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).