

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Today's Date:

Infusion Date:

CIBMTR Center Number:

Visit: 100 day 6 month year

Initials:

Form 2113 R2.0: Chronic Lymphocytic Leukemia Post-HSCT Data

Center: _____ CRID: _____

Key Fields

Registry Use Only:

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number _____

CIBMTR Recipient ID: _____

Today's Date: ____-____-____

Date of HSCT for which this form is being completed: ____-____-____

HSCT type: (check all that apply)

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product type: (check all that apply)

- Marrow
- PBSC
- Cord blood
- Other product

Specify: _____

Visit:

- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years,

Specify: _____

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Form 2113 R2.0: Chronic Lymphocytic Leukemia Post-HSCT Data

Center: _____ CRID: _____

Disease Assessment at the Time of Best Response to HSCT Questions: 1 - 2

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.)

- complete response (CR) - no lymphadenopathy; no organomegaly; neutrophils $> 1.5 \times 10^9/L$; platelets $> 100 \times 10^9/L$; hemoglobin $> 11g/dL$; lymphocytes $< 4 \times 10^9/L$; bone marrow $< 30\%$ lymphocytes; absence of constitutional symptoms
- nodular partial response (NPR) - complete response with persistent lymphoid nodules in bone marrow
- partial response (PR)- $\geq 50\%$ decrease in peripheral blood lymphocyte count from pretreatment value; $\geq 50\%$ reduction in lymphadenopathy if present pretreatment; $\geq 50\%$ reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils $\geq 1.5 \times 10^9/L$ or 50% improvement over baseline, platelets $> 100 \times 10^9/L$ or 50% improvement over baseline, hemoglobin $> 11.0 g/dL$ or 50% improvement over baseline
- stable disease (SD) - no change; not complete response; partial response; nor progressive disease
- progressive disease (Prog) - one or more of the following: $\geq 50\%$ increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; $\geq 50\%$ increase in liver or spleen size, or new hepatomegaly or splenomegaly; $\geq 50\%$ increase in absolute lymphocyte count to $\geq 5 \times 10^9/L$; transformation to a more aggressive histology
- untreated - no chemotherapy given in the 6 months prior to HSCT
- Not assessed

2 date of best response was previously reported

Date best response first began: ____ - ____ - ____

Laboratory Studies Supporting Best Response to HSCT Questions: 3 - 9

3 Was molecular testing/immunophenotyping performed at the time of the disease assessment for best response to HSCT reported at question 1?

yes no

Specify the testing method(s) used:

4 Immunophenotyping (4 color flow cytometry)

yes no

5 Specify the date immunophenotyping was performed: ____ - ____ - ____

6 Was disease detected?

yes no

7 Heavy chain gene rearrangement (ASO-PCR)

yes no

8 Specify the date the heavy chain gene rearrangement testing was performed: ____ - ____ - ____

9 Was disease detected?

yes no

Post-HSCT Planned Treatment for CLL Questions: 10 - 22

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.)

yes no

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Form 2113 R2.0: Chronic Lymphocytic Leukemia Post-HSCT Data

Center: _____ CRID: _____

Specify the treatment(s) given:

11 Chemotherapy

yes no

12 Radiation

yes no

13 Immune therapy/monoclonal antibody (mAb)

yes no

Specify treatment(s) given:

14 aldesleukin (interleukin-2, IL-2)

yes no

15 Alemtuzumab (Campath)

yes no

16 Rituximab (anti-CD20, Rituxan)

yes no

17 other mAb

yes no

18 Specify other mAb: _____

19 Other immune therapy

yes no

20 Specify immune therapy: _____

21 Other treatment

yes no

22 Specify treatment: _____

Disease Relapse or Progression Post-HSCT

Questions: 23 - 31

23 Was a disease relapse or progression detected by any method since the date of the last report?

yes no

24 Date disease relapse or progression was detected: ____ - ____ - ____

25 Was molecular testing performed at the time of disease relapse or progression?

yes no

Specify the testing method(s) used:

26 Immunophenotyping (4 color flow cytometry)

yes no

27 Specify the date immunophenotyping was performed: ____ - ____ - ____

28 Was disease detected?

yes no

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Month	Day	20	Year	Month	Day	20	Year		

Form 2113 R2.0: Chronic Lymphocytic Leukemia Post-HSCT Data

Center: _____ CRID: _____

29 Heavy chain gene rearrangement (ASO-PCR)

yes no

30 Specify the date the heavy chain gene rearrangement testing was performed: _____ - ____ - ____

31 Was disease detected?

yes no

Disease Status at the Time of Assessment for This Reporting Period

Questions: 32 - 40

32 Was molecular testing/immunophenotyping performed at the time of disease assessment reported at question 39?

yes no

Specify the testing method(s) used:

33 Immunophenotyping (4 color flow cytometry)

yes no

34 Specify the date immunophenotyping was performed: _____ - ____ - ____

35 Was disease detected?

yes no

36 Heavy chain gene rearrangement (ASO-PCR)

yes no

37 Specify the date the heavy chain gene rearrangement testing was performed: _____ - ____ - ____

38 Was disease detected?

yes no

39 What is the current disease status?

complete remission

Not in complete remission

40 Date the current disease status was established in this reporting period: _____ - ____ - ____

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

E-mail address: _____

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