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CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Chronic Myelogenous Leukemia (CML) Post-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month Day Year 2 0

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.

Post-HSCT Planned Treatment for CML

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

2. Donor cellular infusions (e.g., DLI)
   - 1 ☐ yes
   - 2 ☐ no

3. Interferon α
   - 1 ☐ yes →
     - 4. Date interferon α started: Month Day Year
     - 5. Date interferon α stopped: Month Day Year
   - 2 ☐ no

6. Intrathecal drugs
   - 1 ☐ yes
   - 2 ☐ no

7. Tyrosine kinase inhibitors
   - 1 ☐ yes →
     - Specify tyrosine kinase inhibitors given:
       - 8. 1 ☐ yes 2 ☐ no dasatinib (Sprycel)
       - 9. 1 ☐ yes 2 ☐ no imatinib (Gleevec)
       - 10. 1 ☐ yes 2 ☐ no nilotinib (AMN107, Tasigna)
   - 2 ☐ no

11. Other treatment
    - 1 ☐ yes →
      - 12. Specify other treatment: _____
    - 2 ☐ no

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

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Disease Assessment at the Time of Best Response to the HSCT

13. Was a complete remission (CR) ever achieved in response to the HSCT? (Include any therapy planned as of Day 0, but exclude any change in therapy in response to a disease assessment.)
    - 1 ☐ disease was in remission at the time of the preparative regimen
    - 2 ☐ yes, post-HSCT CR was achieved →
    - 3 ☐ no, CR was never achieved post-HSCT

14. Specify the date complete remission was achieved: | | Month | | | Day | | | | Year |

15. Was the date and disease assessment method for this CR previously reported?
    - 1 ☐ yes → **Continue with question 23**
    - 2 ☐ no

Laboratory Studies Supporting Best Response (Including Planned Therapy)

16. Did molecular testing confirm the presence of the complete remission?
    - 1 ☐ yes →
    - 2 ☐ no
    - 3 ☐ not tested

17. Specify the date the molecular CR was determined: | | Month | | | Day | | | | Year |

18. Did cytogenetic testing confirm the presence of the complete remission?
    - 1 ☐ yes →
    - 2 ☐ no
    - 3 ☐ not tested

19. Was FISH used to determine cytogenetic CR status?
    - 1 ☐ yes →
    - 2 ☐ no

20. Specify the date the cytogenetic CR was determined via FISH: | | Month | | | Day | | | | Year |

21. Were conventional cytogenetics used to determine cytogenetic CR status?
    - 1 ☐ yes →
    - 2 ☐ no

22. Specify the date the cytogenetic CR was determined via conventional cytogenetics: | | Month | | | Day | | | | Year |

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Disease Relapse and/or Progression Post-HSCT

23. Has the disease relapsed or progressed since the date of the last report?

1 ☐ yes → Specify the method(s) used to assess the disease relapse: *(report all concurrent assessments)*

2 ☐ no

If disease status is CR or persistent disease without progression, continue with question 40.

24. Molecular assessment

1 ☐ yes →

2 ☐ no

25. Date of the molecular assessment:

Month | Day | 2 0 | | Year

26. Was there evidence of disease?

1 ☐ yes →

2 ☐ no

27. Was the status considered a disease relapse or progression?

1 ☐ yes

2 ☐ no

28. Cytogenetic assessment

1 ☐ yes →

2 ☐ no

29. Was the disease relapse / progression assessed via FISH?

1 ☐ yes →

2 ☐ no

30. Date of FISH test:

Month | Day | 2 0 | | Year

31. Was there evidence of disease?

1 ☐ yes →

2 ☐ no

32. Was the status considered a disease relapse or progression?

1 ☐ yes

2 ☐ no

33. Was the disease relapse / progression assessed via conventional cytogenetics?

1 ☐ yes →

2 ☐ no

34. Date of conventional cytogenetic test:

Month | Day | 2 0 | | Year

35. Was there evidence of disease?

1 ☐ yes →

2 ☐ no

36. Was the status considered a disease relapse or progression?

1 ☐ yes

2 ☐ no

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37. Clinical / hematologic assessment
    1 ☐ yes → 38. Date of the clinical / hematologic assessment: Month | | Day | | 2 0 | | Year
    2 ☐ no
    39. Was there evidence of disease?
        1 ☐ yes
        2 ☐ no

Post-HSCT Treatment for CML

40. Was any treatment given in response to a disease assessment (i.e., persistent, relapsed or progressice disease) since the date of the last report?
    1 ☐ yes → Specify treatment(s) for persistent or recurrent CML:
    2 ☐ no

41. Systemic therapy
    1 ☐ yes → Specify chemotherapy drug(s) given for persistent or recurrent CML:
    2 ☐ no

42. 1 ☐ yes 2 ☐ no anagrelide (Agrylin)
43. 1 ☐ yes 2 ☐ no busulfan
44. 1 ☐ yes 2 ☐ no cytarabine (Ara-C)
45. 1 ☐ yes 2 ☐ no dasatinib (Sprycel)
46. 1 ☐ yes 2 ☐ no homoharringtonine (HHT)
47. 1 ☐ yes 2 ☐ no hydroxyurea (Droxia, Hydrea)
48. 1 ☐ yes 2 ☐ no idarubicin (Idamycin)
49. 1 ☐ yes 2 ☐ no imatinib (Gleevec)
50. 1 ☐ yes 2 ☐ no interferon α (Referon α)
51. 1 ☐ yes 2 ☐ no nilotinib (AMN107, Tasigna)
52. 1 ☐ yes 2 ☐ no other systemic agent → 53. Specify other systemic agent: _____

54. Donor cellular infusions (e.g., DLI)
    1 ☐ yes
    2 ☐ no

55. Subsequent HSCT
    1 ☐ yes
    2 ☐ no

56. Withdrawal of immunosuppression
    1 ☐ yes
    2 ☐ no

57. Other treatment
    1 ☐ yes → 58. Specify other treatment: _____
    2 ☐ no

59. Specify the degree of disease response to treatment(s):
    1 ☐ hematologic response
    2 ☐ cytogenetic response →
    3 ☐ molecular response

    60. Specify the Philadelphia chromosome positive metaphases:
        1 ☐ known → | | | | %
        2 ☐ not known

61. Date disease response established: Month | | Day | | 2 0 | | Year

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Disease Status at the Time of Assessment for This Reporting Period

62. Was the disease status assessed since the date of the last report?
    - 1 ☐ yes →
    - 2 ☐ no

Specify the method(s) used to assess the disease status:

63. Current molecular assessment
    - 1 ☐ yes →
    - 2 ☐ no

64. Date of the molecular assessment:
    Month | Day | 2 0 Year

65. Was there evidence of disease?
    - 1 ☐ yes →
    - 2 ☐ no

66. Was the status considered a disease relapse, progression, or persistent disease?
    - 1 ☐ yes
    - 2 ☐ no

67. Current cytogenetic assessment
    - 1 ☐ yes →
    - 2 ☐ no

68. Was the disease status assessed via FISH?
    - 1 ☐ yes →
    - 2 ☐ no

69. Date of FISH test:
    Month | Day | 2 0 Year

70. Was there evidence of disease?
    - 1 ☐ yes →
    - 2 ☐ no

71. Was the status considered a disease relapse, progression, or persistent disease?
    - 1 ☐ yes
    - 2 ☐ no

72. Was the disease status assessed via conventional cytogenetics?
    - 1 ☐ yes →
    - 2 ☐ no

73. Date of conventional cytogenetic test:
    Month | Day | 2 0 Year

74. Was there evidence of disease?
    - 1 ☐ yes →
    - 2 ☐ no

75. Was the status considered a disease relapse, progression, or persistent disease?
    - 1 ☐ yes
    - 2 ☐ no

76. Current clinical / hematologic assessment
    - 1 ☐ yes →
    - 2 ☐ no

77. Date of the clinical / hematologic assessment:
    Month | Day | 2 0 Year

78. Was the status considered a relapse, progression, or persistent disease?
    - 1 ☐ yes
    - 2 ☐ no

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

80. Date the current disease status was established in this reporting period: | | | | | 2 | 0 | | |
    Month Day Year

81. Signed: _____
    Person completing form

    Please print name: _____

    Phone number: (_____) _____

    Fax number: (_____) _____

    E-mail address: _____

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