

Form 2110 R3.0: Acute Myelogenous Leukemia (AML) Post-HCT Data

Center: _____

CRID: _____

Key Fields

Sequence Number: _____

Date Received: ____ - ____ - ____

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

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

HCT type: (check all that apply)

- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product type: (check all that apply)

- Bone marrow
- PBSC
- Single cord blood unit
- Multiple cord blood units
- Other product

Specify: _____

Visit

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

Specify: _____

Disease Assessment at the Time of Best Response to HCT

Questions: 1 - 20

1 Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report?

(Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) -For patients transplant in CR
- Complete remission (CR) -A treatment response where all of the following criteria are met for at least four weeks: <5% blasts in the bone marrow, normal maturation of all cellular components in the bone marrow (myeloid, erythroid, and megacaryocytic lineages), no blasts with Auer rods, no extramedullary disease (e.g., central nervous system or soft tissue involvement), ANC of >1,000/ μ L, Platelets \geq 100,000/ μ L
- Not in complete remission

2 Was the date of best response previously reported?

- yes
- no

3 Date assessed: ____ - ____ - ____

4 Was the disease status assessed by molecular testing (e.g. PCR)?

- yes
- no

5 Date assessed: ____ - ____ - ____

6 Was disease detected?

- yes
- no

7 Was the status considered a disease relapse?

- yes
- no

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8 Was the disease status assessed via flow cytometry?

yes no

9 Date assessed: ____-____-____

10 Was disease detected?

yes no

11 Was the status considered a disease relapse?

yes no

12 Was the disease status assessed by cytogenetic testing (conventional or FISH)?

yes no

13 Was the disease status assessed via FISH?

yes no

14 Date assessed: ____-____-____

15 Was disease detected?

yes no

16 Was the status considered a disease relapse?

yes no

17 Was the disease status assessed via conventional cytogenetics?

yes no

18 Date assessed: ____-____-____

19 Was disease detected?

yes no

20 Was the status considered a disease relapse?

yes no

Post-HCT Therapy

Questions: 21 - 43

21 Was therapy given since the date of the last report for reasons other than relapse or persistent disease?

(Include any maintenance and consolidation therapy)

yes no

Specify therapy given:

22 Central nervous system irradiation

yes no

23 Systemic therapy

yes no

Specify systemic therapy given:

24 Azacytidine (Vidaza)

yes no

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25 All-trans retinoic acid (Tretinoin)

yes no

26 Arsenic

yes no

27 Clofarabine

yes no

28 Cytarabine (Ara-C)

yes no

29 Daunorubicin (Cerubidine)

yes no

30 Decitabine (Dacogen)

yes no

31 Doxorubicin (Adriamycin)

yes no

32 Etoposide (VP-16, VePesid)

yes no

33 Gemtuzumab (Mylotarg)

yes no

34 Idarubicin (Idamycin)

yes no

35 Intrathecal therapy

yes no

36 Mitoxantrone (Novantrone)

yes no

37 Sorafenib

yes no

38 Thioguanine (6-TG)

yes no

39 Other systemic therapy

yes no

40 Specify other systemic therapy: _____

41 Donor cellular infusions

yes no

42 Other therapy

yes no

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43 Specify other therapy: _____

Disease Relapse Post-HCT

Questions: 44 - 85

44 Was a disease relapse detected by molecular testing (e.g. PCR)?

yes no

45 Date assessed: _____ - ____ - ____

46 Was a disease relapse detected via flow cytometry?

yes no

47 Date assessed: _____ - ____ - ____

48 Was a disease relapse detected by cytogenetic testing (conventional or FISH)?

yes no

49 Was a disease relapse detected via FISH?

yes no

50 Date assessed: _____ - ____ - ____

51 Was a disease relapse detected via conventional cytogenetics?

yes no

52 Date assessed: _____ - ____ - ____

53 Was a disease relapse detected by clinical / hematologic assessment?

yes no

54 Date assessed: _____ - ____ - ____

Specify site(s) of disease relapse:

55 Blood

yes no

Specify site(s) of disease relapse:

56 Bone marrow

yes no

57 Central nervous system

yes no

58 Skin

yes no

59 Soft tissue

yes no

60 Other site(s)

yes no

61 Specify other site(s): _____

62 Was any therapy given for relapsed disease since the date of the last report?

yes no

63 Central nervous system irradiation

yes no

64 Systemic therapy

yes no

Specify systemic therapy given:

65 Azacytidine (Vidaza)

yes no

66 All-trans retinoic acid (Tretinoin)

yes no

67 Arsenic

yes no

68 Clofarabine

yes no

69 Cytarabine (Ara - C) \leq 10 g/m²/cycle

yes no

70 Cytarabine (Ara - C) $>$ 10 g/m²/cycle

yes no

71 Daunorubicin (Cerubidine)

yes no

72 Decitabine (Dacogen)

yes no

73 Etoposide (VP-16, VePesid)

yes no

74 Gemtuzumab (Mylotarg)

yes no

75 Idarubicin (Idamycin)

yes no

76 Intrathecal therapy

yes no

77 Mitoxantrone (Novantrone)

yes no

78 Sorafenib

yes no

79 Thioguanine (6-TG)

yes no

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80 Other systemic therapy

yes no

81 Specify other systemic therapy: _____

82 Donor cellular infusions

yes no

83 Subsequent HCT

yes no

84 Other therapy

yes no

85 Specify other therapy: _____

Disease Status at the Time of Evaluation for this Reporting Period

Questions: 86 - 109

86 Was the disease status assessed since the date of the last report?

yes no

87 Does the disease assessment reflect the relapsed disease in this reporting period (as captured in questions 44-61), without subsequent therapy?

yes no

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

88 Was the disease status assessed by molecular testing (e.g. PCR)?

yes no

89 Date assessed: ____ - ____ - ____

90 Was disease detected?

yes no

91 Was the status considered a disease relapse?

yes no

92 Was the disease status assessed via flow cytometry?

yes no

93 Date assessed: ____ - ____ - ____

94 Was disease detected?

yes no

95 Was the status considered a disease relapse?

yes no

96 Was the disease status assessed by cytogenetic testing (conventional or FISH)?

yes no

97 Was the disease status assessed via FISH?

yes no

98 Date assessed: ____ - ____ - ____

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99 Was disease detected?

yes no

100 Was the status considered a disease relapse?

yes no

101 Was the disease status assessed via conventional cytogenetics?

yes no

102 Date assessed: ____ - ____ - ____

103 Was disease detected?

yes no

104 Was the status considered a disease relapse?

yes no

105 Was the disease status assessed by clinical / hematologic assessment?

yes no

106 Date assessed: ____ - ____ - ____

107 Was disease detected?

yes no

108 What is the current disease status?

- Complete -A treatment response where all of the following criteria are met for at least four weeks: <5% blasts in the bone marrow, normal maturation of remission (CR) all cellular components in the bone marrow (myeloid, erythroid, and megakaryocytic lineages), no blasts with Auer rods, no extramedullary disease (e.g., central nervous system or soft tissue involvement), ANC of >1,000/ μ L, Platelets \geq 100,000/ μ L
- Not in complete remission

109 Date assessed: ____ - ____ - ____

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____