Form 2110 R4.0: Acute Myelogenous Leukemia (AML) Post-Infusion Data

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit

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

Specify: _____

Disease Assessment at the Time of Best Response to HCT or Cellular Therapy

Questions: 1 - 40

1 What was the best response to HCT or cellular therapy since the date of the last report? (Include response to any therapy given for post-HCT / post-infusion 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) - All of the following response criteria without progression for at least four weeks: < 5% blasts in the bone marrow, no blasts with Auer rods, no extramedullary disease (e.g., central nervous system or soft tissue involvement)

○ Not in complete remission

2 Was the date of best response previously reported?

○ yes ○ no

3 Date assessed: __ __ __ __ - __ __- __ __

4 Were tests for molecular markers performed? (e.g. PCR, NGS) (at time of best response)

○ yes ○ no ○ Unknown

Specify molecular markers identified at time of best response:

5 CEBPA

○ Positive ○ Negative ○ Not Done

6 Specify CEBPA mutation

○ Biallelic (homozygous)

○ Monoallelic (heterozygous)

○ Unknown

7 FLT3 – D835 point mutation

○ Positive ○ Negative ○ Not Done

8 FLT3 – ITD mutation

○ Positive ○ Negative ○ Not Done

9 IDH1

○ Positive ○ Negative ○ Not Done

10 IDH2

○ Positive ○ Negative ○ Not Done

11 KIT

○ Positive ○ Negative ○ Not Done

12 NPM1

○ Positive ○ Negative ○ Not Done

Multiple Molecular Markers (1)

Questions: 13 - 14

13 Other molecular marker

○ Positive ○ Negative ○ Not Done

14 Specify other molecular marker: _____

15 Was the disease status assessed via flow cytometry?

○ yes ○ no

Specify tissue and results at time of best response:

16 Blood

○ yes ○ no

17 Date sample collected: __ __ __ __ - __ __- __ __

18 Was disease detected?

○ yes ○ no

19 Specify percent disease detected: _____ %

20 Bone marrow

○ yes ○ no

21 Date sample collected: __ __ __ __ - __ __- __ __

22 Was disease detected?

○ yes ○ no

23 Specify percent disease detected: _____ %

24 Were cytogenetics tested (karyotyping or FISH)? (at time of best response)

○ yes ○ no ○ Unknown

25 Were cytogenetics tested via FISH?

○ Yes ○ No

26 Results of tests

○ Abnormalities identified

○ No abnormalities

Specify cytogenetic abnormalities identified at time of best response:

27 Specify number of distinct cytogenetic abnormalities

○ One (1)

○ Two (2)

○ Three (3)

○ Four or more (4 or more)

28 Specify abnormalities (check all that apply)

☐ -5

☐ -7

☐ -17

☐ -18

☐ -X

☐ -Y

☐ +4

☐ +8

☐ +11

☐ +13

☐ +14

☐ +21

☐ +22

☐ t(3;3)

☐ t(6;9)

☐ t(8;21)

☐ t(9;11)

☐ t(9;22)

☐ t(15;17) and variants

☐ t(16;16)

☐ del(3q) / 3q-

☐ del(5q) / 5q-

☐ del(7q) / 7q-

☐ del(9q) / 9q-

☐ del(11q) / 11q-

☐ del(16q) / 16q-

☐ del(17q) / 17q-

☐ del(20q) / 20q-

☐ del(21q) / 21q-

☐ inv(3)

☐ inv(16)

☐ (11q23) any abnormality

☐ 12p any abnormality

☐ Other abnormality

29 Specify other abnormality: _____

30 Were cytogenetics tested via karyotyping?

○ Yes ○ No

31 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified at time of best response:

32 Specify number of distinct cytogenetic abnormalities

○ One (1)

○ Two (2)

○ Three (3)

○ Four or more (4 or more)

33 Specify abnormalities (check all that apply)

☐ -5

☐ -7

☐ -17

☐ -18

☐ -X

☐ -Y

☐ +4

☐ +8

☐ +11

☐ +13

☐ +14

☐ +21

☐ +22

☐ t(3;3)

☐ t(6;9)

☐ t(8;21)

☐ t(9;11)

☐ t(9;22)

☐ t(15;17) and variants

☐ t(16;16)

☐ del(3q) / 3q-

☐ del(5q) / 5q-

☐ del(7q) / 7q-

☐ del(9q) / 9q-

☐ del(11q) / 11q-

☐ del(16q) / 16q-

☐ del(17q) / 17q-

☐ del(20q) / 20q-

☐ del(21q) / 21q-

☐ inv(3)

☐ inv(16)

☐ (11q23) any abnormality

☐ 12p any abnormality

☐ Other abnormality

34 Specify other abnormality: _____

35 Was documentation submitted to the CIBMTR? (e.g. cytogenetic or FISH report)

○ Yes ○ No

36 Was disease status assessed by other assessment?

○ Yes ○ No

37 Date assessed: __ __ __ __ - __ __- __ __

38 Specify other assessment: _____

39 Was disease detected?
yes no

40 Was the status considered a disease relapse?
yes no

Post-HCT / Post-InfusionTherapy

Questions: 41 - 50

41 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:

42 Central nervous system irradiation
yes no

43 Systemic therapy
yes no

44 Date therapy was first started
Known
Unknown
Previously reported (e.g. started in/continuing from a prior reporting period)

45 Date first started: __ __ __ __ - __ __- __ __

Specify systemic therapy given for reasons other than relapse or persistent disease:

46 Specify systemic therapy given (for reasons other than relapse or persistent disease (check all that apply)
Azacytidine (Vidaza)
All-trans retinoic acid (Tretinoin)
Decitabine (Dacogen)
Intrathecal therapy
Midostaurin
Sorafenib
Thioguanine (6-TG)
Other systemic therapy

47 Specify other systemic therapy: _____

48 Cellular therapy (e.g. donor cellular infusions (DCI),CAR T-cells)
yes **-Also complete Pre-CTED form 4000**
no

49 Other therapy
yes no

50 Specify other therapy: _____

Disease Detection Since the Date of Last Report

Questions: 51 - 103

51 Were tests for molecular markers performed? (and positive for disease) (e.g. PCR, NGS)
yes no Unknown

52 Date sample collected: __ __ __ __ - __ __- __ __

Specify molecular markers identified since the date of last report:

53 CEBPA
Positive Negative Not Done

54 Specify CEBPA mutation
Biallelic (homozygous)
Monoallelic (heterozygous)
Unknown

55 FLT3 – D835 point mutation
Positive Negative Not Done

56 FLT3 – ITD mutation
Positive Negative Not Done

57 IDH1
Positive Negative Not Done

58 IDH2
Positive Negative Not Done

59 KIT

Positive Negative Not Done

60 NPM1

Positive Negative Not Done

Multiple Molecular Markers (1) — Questions: 61 - 62

61 Other molecular marker

Positive Negative Not Done

62 Specify other molecular marker: _____

63 Was disease detected via flow cytometry?

Yes No

Specify tissue and results:

64 Blood

yes no

65 Date sample collected: __ __ __ __ - __ __- __ __

66 Specify percent disease detected: _____ %

67 Bone marrow

yes no

68 Date sample collected: __ __ __ __ - __ __- __ __

69 Specify percent disease detected: _____ %

70 Was disease detected via cytogenetics testing? (karyotyping or FISH)

Yes No Unknown

71 Were cytogenetic abnormalities identified via FISH?

Yes No

72 Date sample collected: __ __ __ __ - __ __- __ __

73 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
- ☐ t(8;21)
- ☐ t(9;11)
- ☐ t(9;22)
- ☐ t(15;17) and variants
- ☐ t(16;16)
- ☐ del(3q) / 3q-
- ☐ del(5q) / 5q-
- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

74 Specify other abnormality: _____

75 Were cytogenetic abnormalities identified via karyotyping?

○ Yes ○ No

76 Date sample collected: __ __ __ __ - __ __- __ __

77 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
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- ☐ +21
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- ☐ t(3;3)
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- ☐ del(3q) / 3q-
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- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

78 Specify other abnormality: _____

79 Was documentation submitted to the CIBMTR? (e.g. cytogenetic or FISH report)

○ Yes ○ No

80 Was disease detected by clinical / hematologic assessment?

○ Yes ○ No

81 Date assessed: __ __ __ __ - __ __- __ __

Specify site(s) of disease:

82 Central nervous system

○ Yes ○ No

83 Skin

○ yes ○ no

84 Soft tissue

○ yes ○ no

85 Other site

○ yes ○ no

86 Specify other site: _____

87 Was disease detected by other assessment?

○ Yes ○ No

88 Date assessed: __ __ __ __ - __ __- __ __

89 Specify other assessment: _____

90 Was intervention given for relapsed, persistent or progressive disease, or decreased/loss of chimerism since the date of last report?

○ Yes ○ No

Intervention Given (1) — Questions: 91 - 103

91 Specify reason for which intervention was given

- ○ Minimal residual disease
- ○ Persistent disease
- ○ Relapsed disase

92 Central nervous system irradiation

○ yes ○ no

93 Intrathecal therapy

○ yes ○ no

94 Systemic therapy

○ yes ○ no

95 Date therapy was first started

- ○ Known
- ○ Unknown
- ○ Previously reported (e.g. started in a prior reporting period/continued from prior reporting period)

96 Date first started: __ __ __ __ - __ __- __ __

97 Specify systemic therapy given (check all that apply)

- ☐ Azacytidine (Vidaza)
- ☐ All-trans retinoic acid (Tretinoin)
- ☐ Arsenic
- ☐ Cladribine (2-CDA, Leustatin)
- ☐ Clofarabine
- ☐ Cytarabine (Ara - C) ≤ 10 g/m2/cycle
- ☐ cytarabine (Ara - C) > 10 g/m2/cycle
- ☐ Daunorubicin (Cerubidine)
- ☐ Decitabine (Dacogen)
- ☐ Etoposide (VP-16, VePesid)
- ☐ Fludarabine (Fludara)
- ☐ Gemtuzumab (Mylotarg)
- ☐ Idarubicin (Idamycin)
- ☐ Midostaurin
- ☐ Mitoxantrone (Novantrone)
- ☐ Sorafenib
- ☐ Thioguanine (6-TG)
- ☐ Other systemic therapy

98 Specify other systemic therapy: _____

99 Cellular therapy (e.g. donor cellular infusions (DCI), CAR T-cells)

- ○ yes **-Also complete Pre-CTED form 4000**
- ○ no

100 Subsequent HCT

- ○ yes **-Also complete Pre-TED form 2400**
- ○ no

101 Accelerated withdrawal of immunosuppression in response to disease assessment

○ Yes ○ No

102 Other therapy

○ yes ○ no

103 Specify other therapy: _____

Disease Status at the Time of Evaluation for this Reporting Period — Questions: 104 - 145

104 Does the disease status reflect the disease detected in this reporting period section without subsequent therapy? (as captured in questions 51-89)

○ Yes ○ No ○ Not Applicable

Specify the method(s) used to assess the disease status at the time of evaluation for this reporting period:

105 Were tests for molecular markers performed? (e.g. PCR, NGS)

○ yes ○ no ○ Unknown

Specify molecular markers identified:

106 CEBPA

○ Positive ○ Negative ○ Not Done

107 Specify CEBPA mutation

○ Biallelic (homozygous)

○ Monoallelic (heterozygous)

○ Unknown

108 FLT3 – D835 point mutation

○ Positive ○ Negative ○ Not Done

109 FLT3 – ITD mutation

○ Positive ○ Negative ○ Not Done

110 IDH1

○ Positive ○ Negative ○ Not Done

111 IDH2

○ Positive ○ Negative ○ Not Done

112 KIT

○ Positive ○ Negative ○ Not Done

113 NPM1

○ Positive ○ Negative ○ Not Done

Current Molecular Marker (1) **Questions: 114 - 115**

114 Other molecular marker

○ Positive ○ Negative ○ Not Done

115 Specify other molecular marker: _____

116 Was the disease status assessed via flow cytometry?

○ yes ○ no

Specify tissue and results at the time of evaluation for this reporting period:

117 Blood

○ yes ○ no

118 Date sample collected: __ __ __ __ - __ __- __ __

119 Was disease detected?

○ yes ○ no

120 Specify percent disease detected: _____ %

121 Bone marrow

○ yes ○ no

122 Date sample collected: __ __ __ __ - __ __- __ __

123 Was disease detected?

○ yes ○ no

124 Specify percent disease detected: _____ %

125 Were cytogenetics tested? (karyotyping or FISH)

○ yes ○ no ○ Unknown

126 Were cytogenetics tested via FISH?

○ yes ○ no ○ Unknown

127 Results of tests

○ Abnormalities identified

○ No abnormalities

Center: CRID:

Specify cytogenetic abnormalities identified:

128 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

129 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
- ☐ t(8;21)
- ☐ t(9;11)
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- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

130 Specify other abnormality: _____

131 Were cytogenetics tested via karyotyping?

○ Yes ○ No ○ Unknown

132 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified:

133 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

134 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
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- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

135 Specify other abnormality: _____

136 Was documentation submitted to the CIBMTR? (e.g. cytogenetic or FISH report)

○ Yes ○ No

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

○ yes ○ no

138 Date assessed: __ __ __ __ - __ __- __ __

139 Was disease detected?

○ yes ○ no

140 Was disease status assessed by other assessment?

○ Yes ○ No

141 Date assessed: __ __ __ __ - __ __- __ __

142 Specify other assessment: _____

143 Was disease detected?

○ yes ○ no

144 What is the current disease status?

- ○ Complete remission (CR)
- ○ Not in complete remission

145 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __