Form 2111 R4.0: Acute Lymphoblastic Leukemia (ALL) 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 - 34

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 transplanted 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 BCR / ABL

○ Positive ○ Negative ○ Not Done

6 TEL-AML / AML1

○ Positive ○ Negative ○ Not Done

Additional molecular markers (1)

Questions: 7 - 8

7 Other molecular marker

○ Positive ○ Negative ○ Not Done

8 Specify other molecular marker: _____

9 Was the disease status assessed via flow cytometry?

○ yes ○ no

Specify tissue and results at time of best response:

10 Blood

○ yes ○ no

11 Date sample collected: __ __ __ __ - __ __- __ __

12 Was disease detected?

○ yes ○ no

13 Specify percent disease detected: _____

14 Bone marrow

○ yes ○ no

15 Date sample collected: __ __ __ __ - __ __- __ __

16 Was disease detected?

○ yes ○ no

17 Specify percent disease detected: _____

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

○ yes ○ no ○ Unknown

19 Were cytogenetics tested via FISH?

○ Yes ○ No

20 Results of tests

○ Abnormalities identified

○ No abnormalities

Specify cytogenetic abnormalities identified at time of best response:

21 Specify number of distinct cytogenetic abnormalities

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

22 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

23 Specify other abnormality: _____

24 Were cytogenetics tested via karyotyping?

○ Yes ○ No

25 Results of tests

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

Specify cytogenetic abnormalities identified at time of best response:

26 Specify number of distinct cytogenetic abnormalities

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

27 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

28 Specify other abnormality: _____

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

○ Yes ○ No

30 Was disease status assessed by other assessment?

○ Yes ○ No

31 Date assessed: __ __ __ __ - __ __- __ __

32 Specify other assessment: _____

33 Was disease detected?

○ yes ○ no

34 Was the status considered a disease relapse?

○ yes ○ no

Post-HCT / Post-Infusion Therapy

Questions: 35 - 47

35 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:

36 Central nervous system irradiation

○ yes ○ no

Specify CNS irradiation:

37 Cranial

○ yes ○ no

38 Craniospinal

○ Yes ○ No

39 Intrathecal therapy

○ yes ○ no

40 Systemic therapy

○ yes ○ no

41 Date therapy (maintenance) was first started post-HCT / post-infusion

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

42 Date started: __ __ __ __ - __ __- __ __

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

43 Specify systemic therapy given (for reasons other than relapse or persistent disease) (check all that apply)

- ☐ Blinatumomab (Blincyto)
- ☐ Chemotherapy
- ☐ Dasatinib (Sprycel)
- ☐ Imatinib (Gleevec)
- ☐ Inotuzumab (CMC-544)
- ☐ Nilotinib (AMN107, Tasigna)
- ☐ Obinutuzumab (Gazyva)
- ☐ Ponatinib (Iclusig)
- ☐ Rituximab (Rituxan, MabThera)
- ☐ Other systemic therapy

44 Specify other systemic therapy: _____

45 Cellular therapy (e.g. CAR T-cells, DCI)

- ○ yes **-Also complete CIBMTR Form 4000**
- ○ no

46 Other therapy

- ○ yes ○ no

47 Specify other therapy: _____

Disease Detection Since the Date of Last Report

Questions: 48 - 94

Indicate if disease was detected since the date of last report – including relapsed disease, persistent disease, and minimal residual disease.

48 Were tests for molecular markers performed? (and positive for disease) (e.g. PCR, NGS)

- ○ yes ○ no ○ Unknown

49 Date sample collected: __ __ __ __ - __ __- __ __

50 BCR / ABL

- ○ Positive ○ Negative ○ Not Done

51 TEL-AML / AML1

- ○ Positive ○ Negative ○ Not Done

Other molecular marker (1)

Questions: 52 - 53

52 Other molecular marker

- ○ Positive ○ Negative ○ Not Done

53 Specify other molecular marker: _____

54 Was disease detected via flow cytometry?

- ○ Yes ○ No

Specify results since the date of the last report:

55 Blood

- ○ yes ○ no

56 Date sample collected: __ __ __ __ - __ __- __ __

57 Specify percent disease detected: _____

58 Bone marrow

- ○ yes ○ no

59 Date sample collected: __ __ __ __ - __ __- __ __

60 Specify percent disease detected: _____

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

- ○ Yes ○ No ○ Unknown

62 Were cytogenetic abnormalities identified via FISH?

- ○ Yes ○ No

63 Date sample collected: __ __ __ __ - __ __- __ __

64 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

65 Specify other abnormality: _____

66 Were cytogenetic abnormalities identified via karyotyping?

○ Yes ○ No

67 Date sample collected: __ __ __ __ - __ __- __ __

68 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

69 Specify other abnormality: _____

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

○ Yes ○ No

71 Was disease detected by clinical / hematologic assessment?

○ Yes ○ No

72 Date assessed: __ __ __ __ - __ __- __ __

Specify site(s) of disease:

73 Central nervous system

○ Yes ○ No

74 Skin

○ yes ○ no

75 Soft tissue

○ yes ○ no

76 Other site (s)

○ yes ○ no

77 Specify other site: (s) _____

78 Was disease detected by other assessment?

○ Yes ○ No

79 Date assessed: __ __ __ __ - __ __- __ __

80 Specify other assessment: _____

81 Was intervention given for relapsed disease, persistent disease, or minimal residual disease? (since the date of the last report)

○ Yes ○ No

Intervention given (1)	Questions: 82 - 94

82 Specify reason for which therapy was given

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

83 Central nervous system irradiation

○ yes ○ no

84 Intrathecal therapy
- yes
- no

85 Systemic therapy
- yes
- no

86 Date therapy was first started post-HCT/post-infusion
- Known
- Unknown
- Previously reported (e.g. started in a prior reporting period/continued from prior reporting period)

87 Date started: __ __ __ __ - __ __- __ __

88 Specify systemic therapy given (check all that apply)
- Blinatumomab (Blincyto)
- Chemotherapy
- Dasatinib (Sprycel)
- Imatinib (Gleevec)
- Inotuzumab
- Nilotinib (AMN107, Tasigna)
- Ponatinib (Iclusig)
- Rituximab (Rituxan, MabThera)
- Other systemic therapy

89 Specify other systemic therapy: _____

90 Cellular therapy (e.g. CAR T-cells, DCI)
- yes **-Also complete CIBMTR Form 4000**
- no

91 Subsequent HCT
- yes
- no

92 Accelerated withdrawal of immunosuppression in response to disease assessment
- Yes
- No

93 Other therapy
- yes
- no

94 Specify other therapy: _____

Disease Status at the Time of Evaluation for This Reporting Period

Questions: 95 - 130

95 Does the current disease status reflect the disease detected in this reporting period (as captured in questions 47-81), without subsequent therapy?
- Yes
- No
- Not Applicable (disease not assessed in the reporting period)

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

96 Were tests for molecular markers performed? (e.g. PCR, NGS)
- yes
- no
- Unknown

Specify molecular markers:

97 BCR / ABL
- Positive
- Negative
- Not Done

98 TEL-AML / AML1
- Positive
- Negative
- Not Done

Additional Molecular Marker (1)

Questions: 99 - 100

99 Other molecular marker
- Positive
- Negative
- Not Done

100 Specify other molecular marker: _____

101 Was the disease status assessed via flow cytometry?
- yes
- no

Specify tissue and results:

102 Blood
- yes
- no

103 Date sample collected: __ __ __ __ - __ __- __ __

104 Was disease detected?

○ yes ○ no

105 Specify percent disease detected: _____

106 Bone marrow

○ yes ○ no

107 Date sample collected: __ __ __ __ - __ __- __ __

108 Was disease detected?

○ yes ○ no

109 Specify percent disease detected: _____

110 Were cytogenetics tested? (karyotyping or FISH)

○ yes ○ no ○ Unknown

111 Were cytogenetics tested via FISH?

○ Yes ○ No

112 Results of tests

○ Abnormalities identified

○ No abnormalities

Specify cytogenetic abnormalities identified

113 Specify number of distinct cytogenetic abnormalities

○ One (1)

○ Two (2)

○ Three (3)

○ Four or more (4 or more)

114 Specify abnormalities (check all that apply)

☐ -7

☐ +4

☐ +8

☐ +17

☐ +21

☐ t(1;19)

☐ t(2;8)

☐ t(4;11)

☐ t(5;14)

☐ t(8;14)

☐ t(8;22)

☐ t(9;22)

☐ t(10;14)

☐ t(11;14)

☐ t(12;21)

☐ del(6q) / 6q-

☐ del(9p) / 9p-

☐ del(12p) / 12p-

☐ add(14q)

☐ (11q23) any abnormality

☐ 9p any abnormality

☐ 12p any abnormality

☐ Hyperdiploid (> 50)

☐ Hypodiploid (< 45)

☐ iAMP21

☐ Other abnormality

115 Specify other abnormality: _____

116 Were cytogenetics tested via karyotyping?

○ Yes ○ No

117 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified:

118 Specify number of distinct cytogenetic abnormalities

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

119 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

120 Specify other abnormality: _____

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

○ Yes ○ No

122 Was disease status assessed by clinical / hematologic assessment?

○ yes ○ no

123 Date assessed: __ __ __ __ - __ __- __ __

124 Was disease detected?

○ yes ○ no

125 Was disease status assessed by other assessment?

○ Yes ○ No

126 Date assessed: __ __ __ __ - __ __- __ __

127 Specify other assessment: _____

128 Was disease detected?

○ yes ○ no

129 What is the current disease status?

- ○ 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

130 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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