Form 2112 R3.0: Chronic Myelogenous Leukemia (CML) Post-Infusion Data

Center: CRID:

Key Fields

Questions: -

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

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

Questions: 1 - 63

Best response is based on response to the HCT or cellular therapy, but does NOT include response to any therapy given for disease relapse or progression post-HCT / post-infusion. When determining the best response, compare the post-HCT / post-infusion disease to the status immediately prior to the preparative regimen or cellular therapy, regardless of time since HCT or infusion. This comparison is meant to capture the BEST disease status in response to HCT or cellular therapy 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 "yes" to indicate "date previously reported."

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 maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- ○ Complete hematologic response (CHR)
- ○ Chronic phase
- ○ Accelerated phase
- ○ Blast phase

2 Specify level of best response

- ○ No cytogenetic response (No CyR)
- ○ Minimal cytogenetic response
- ○ Minor cytogenetic response
- ○ Partial cytogenetic response (PCyR)
- ○ Complete cytogenetic response (CCyR)
- ○ Major molecular remission (MMR)
- ○ Complete molecular remission (CMR)

3 Specify blast phase phenotype

○ Lymphoid ○ Myeloid ○ Mixed phenotype ○ Unknown

4 Was the date of best response previously reported?

○ yes ○ no

5 Date assessed: __ __ __ __ - __ __- __ __

Laboratory studies supporting best response (including planned therapy):

6 WBC

○ Known ○ Unknown

7 _____

- ○ x 10^9/L (x 10^3/mm^3)
- ○ x 10^6/L

8 Date sample collected: __ __ __ __ - __ __- __ __

9 Were immature cells (i.e., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood?

○ Yes ○ No ○ Unknown

10 Basophils

○ Known ○ Unknown

11 _____ %

12 Platelets

○ Known ○ Unknown

13 _____ ○ x 10^9/L (x 10^3/mm^3)

○ x 10^6/L

14 Date sample collected: __ __ __ __ - __ __- __ __

15 Were platelets transfused ≤ 7 days before date of test?

○ Yes ○ No

16 Were cytogenetics tested (karyotyping or FISH)?

○ yes ○ no ○ Unknown

17 Were cytogenetics tested via karyotyping?

○ Yes ○ No ○ Unknown

18 Date sample collected: __ __ __ __ - __ __- __ __

19 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified:

20 _____ % Ph+ metaphases (t(9;22)(q34;q11) and variants)

21 Other abnormality

○ yes ○ no

22 Specify other abnormality: _____

23 Was documentation submitted to the CIBMTR?

○ Yes ○ No

24 Were cytogenetics tested via FISH?

○ yes ○ no ○ Unknown

25 Date sample collected: __ __ __ __ - __ __- __ __

26 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified:

27 _____ % Ph+ metaphases (t(9;22)(q34;q11) and variants)

28 Other abnormality

○ yes ○ no

29 Specify other abnormality: _____

30 Was documentation submitted to the CIBMTR?

○ Yes ○ No

31 Were tests for molecular markers performed (e.g. PCR)?

○ yes ○ no ○ Unknown

32 Date sample collected: __ __ __ __ - __ __- __ __

33 Was BCR / ABL detected?

○ Yes ○ No

34 Specify level of detection

○ ≤ 0.1 %

○ > 0.1 %

○ ≥ 3-log reduction from standardized baseline

○ < 3-log reduction from standardized baseline

35 Was BCR/ABL level of detection reported on the standardized International Scale (IS)?

○ Yes ○ No

36 Were 2 consecutive tests performed? (quantitative and/or nested; of adequate quality [sensitivity > 10^4])

○ Yes ○ No

37 Specify BCR / ABL breakpoint

○ p190 ○ p210 ○ p230 ○ Other breakpoint ○ Unknown

38 Specify other breakpoint: _____

39 Was BCR / ABL kinase domain mutation analysis performed?

○ Yes ○ No ○ Unknown

40 T315I

○ Positive ○ Negative ○ Not done

41 WT
Positive Negative Not done

42 L248V
Positive Negative Not done

43 G250E
Positive Negative Not done

44 Q252H
Positive Negative Not done

45 Y253F
Positive Negative Not done

46 E255K
Positive Negative Not done

47 E255V
Positive Negative Not done

48 D276G
Positive Negative Not done

49 E279K
Positive Negative Not done

50 V299L
Positive Negative Not done

51 F317L
Positive Negative Not done

52 M351T
Positive Negative Not done

53 F359V
Positive Negative Not done

54 L384M
Positive Negative Not done

55 H396P
Positive Negative Not done

56 H396R
Positive Negative Not done

57 G398R
Positive Negative Not done

58 F486S
Positive Negative Not done

59 Other mutation
Positive Negative Not done

60 Specify other mutation: _____

61 Was documentation submitted to the CIBMTR? (e.g. pathology report)
Yes No

62 Spleen size
Known
Unknown
Not applicable (splenectomy)

63 Specify the spleen size: _____ centimeters below left lower costal margin

Post-HCT / Post-Infusion Planned Therapy

Questions: 64 - 99

64 Was therapy given since the date of the last report for reasons other than relapse or progressive disease? (Include any maintenance and consolidation therapy.)
yes no

Specify therapy given:

65 Systemic therapy
yes no

Specify systemic therapy given:

66 Bosutinib (Bosulif)
Yes No

67 Was the date therapy was first started previously reported? (post-HCT)
Yes No

68 Date started: __ __ __ __ - __ __- __ __

69 Was this therapy still being given at the date of last contact?

Yes No

70 Date stopped: __ __ __ __ - __ __- __ __

71 Dasatinib (Sprycel)

yes no

72 Was the date therapy was first started previously reported? (post-HCT)

Yes No

73 Date started: __ __ __ __ - __ __- __ __

74 Was this therapy still being given at the date of last contact?

Yes No

75 Date stopped: __ __ __ __ - __ __- __ __

76 Imatinib (Gleevec)

yes no

77 Was the date therapy was first started previously reported? (post-HCT)

Yes No

78 Date started: __ __ __ __ - __ __- __ __

79 Was this therapy still being given at the date of last contact?

Yes No

80 Date stopped: __ __ __ __ - __ __- __ __

81 Nilotinib (AMN107, Tasigna)

yes no

82 Was the date therapy was first started previously reported? (post-HCT)

Yes No

83 Date started: __ __ __ __ - __ __- __ __

84 Was this therapy still being given at the date of last contact?

Yes No

85 Date stopped: __ __ __ __ - __ __- __ __

86 Ponatinib (Iclusig)

Yes No

87 Was the date therapy was first started previously reported? (post-HCT)

Yes No

88 Date started: __ __ __ __ - __ __- __ __

89 Was this therapy still being given at the date of last contact?

Yes No

90 Date stopped: __ __ __ __ - __ __- __ __

91 Other systemic therapy

yes no

92 Specify other systemic therapy: _____

93 Was the date therapy was first started previously reported? (post-HCT)

Yes No

94 Date started: __ __ __ __ - __ __- __ __

95 Was this therapy still being given at the date of last contact?

Yes No

96 Date stopped: __ __ __ __ - __ __- __ __

97 Cellular therapy

yes **- Also complete form 4000**

no

98 Other therapy

yes no

99 Specify other therapy: _____

Disease Relapse or Progression Post-HCT / Post-Infusion

Questions: 100 - 109

Report relapse or progression since the date of last report:

100 Was a disease relapse or progression detected by molecular testing (e.g. PCR)?

yes no

101 Date sample collected: __ __ __ __ - __ __- __ __

102 Was a disease relapse or progression detected by cytogenetic testing (karyotyping or FISH)?

yes no

103 Was a disease relapse or progression detected via karyotyping?

Yes No

104 Date sample collected: __ __ __ __ - __ __- __ __

105 Was a disease relapse or progression detected via FISH?

yes no

106 Date sample collected: __ __ __ __ - __ __- __ __

107 Was a disease relapse or progression detected by clinical / hematologic assessment?

yes no

108 Date assessed: __ __ __ __ - __ __- __ __

109 Specify CML phase

Chronic phase Accelerated phase Blast phase

Post-HCT / Post-Infusion Therapy

Questions: 110 - 194

110 Was any therapy given for relapse or progressive disease since the date of last report?

yes no

Specify therapy given:

111 Systemic therapy

yes no

112 Was the date therapy was first started previously reported? (post-HCT)

Yes No

113 Date first started: __ __ __ __ - __ __- __ __

114 Bosutinib (Bosulif)

Yes No

115 Busulfan (Busulfex, Myleran)

Yes No

116 Cytarabine (Ara-C)

yes no

117 Dasatinib (Sprycel)

yes no

118 Daunorubicin (Cerubidine)

yes no

119 Homoharringtonine (HHT)

Yes No

120 Hydroxyurea (Droxia, Hydrea)

yes no

121 Idarubicin (Idamycin)

yes no

122 Imatinib (Gleevec)

yes no

123 Interferon-α (Intron, Roferon) (includes PEG)

yes no

124 Nilotinib (AMN107, Tasigna)

yes no

125 Ponatinib (Iclusig)

Yes No

126 Other systemic therapy

yes no

127 Specify other systemic therapy: _____

128 Withdrawal of immunosuppression

Yes No

129 Cellular therapy

yes no

130 Subsequent HCT

yes no

131 Other therapy

yes no

132 Specify other therapy: _____

Therapy response:

133 WBC

Known Unknown

134 _____
- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

135 Date sample collected: __ __ __ __ - __ __- __ __

136 Were immature cells (i.e., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood?
- Yes
- No
- Unknown

137 Basophils
- Known
- Unknown

138 _____ %

139 Platelets
- Known
- Unknown

140 _____
- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

141 Date sample collected: __ __ __ __ - __ __- __ __

142 Were platelets transfused ≤ 7 days before date of test?
- Yes
- No

143 Were cytogenetics tested (karyotyping or FISH)?
- yes
- no
- Unknown

144 Were cytogenetics tested via karyotyping?
- Yes
- No
- Unknown

145 Date sample collected: __ __ __ __ - __ __- __ __

146 Results of tests
- Abnormalities identified
- No evaluable metaphases
- No abnormalities

Specify cytogenetic abnormalities identified following this line of therapy:

147 _____ % Ph+ metaphases (t(9;22)(q34;q11) and variants)

148 Other abnormality
- yes
- no

149 Specify other abnormality: _____

150 Was documentation submitted to the CIBMTR?
- Yes
- No

151 Were cytogenetics tested via FISH?
- yes
- no
- Unknown

152 Date sample collected: __ __ __ __ - __ __- __ __

153 Results of tests
- Abnormalities identified
- No evaluable metaphases
- No abnormalities

Specify cytogenetic abnormalities identified following this line of therapy:

154 _____ % Ph+ metaphases (t(9;22)(q34;q11) and variants)

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- Yes
- No

158 Were tests for molecular markers performed (e.g. PCR)?
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- no
- Unknown

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160 Was BCR / ABL detected?
- Yes
- No

161 Specify level of detection
- ≤ 0.1 %
- > 0.1 %
- ≥ 3-log reduction from standardized baseline
- < 3-log reduction from standardized baseline

162 Was BCR/ABL level of detection reported on the standardized International Scale (IS)?
- Yes
- No

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Center: CRID:

163 Were 2 consecutive tests performed? (quantitative and/or nested; of adequate quality [sensitivity > 10^4])

Yes No

164 Specify BCR / ABL breakpoint

p190 p210 p230 Other breakpoint Unknown

165 Specify other breakpoint: _____

166 Was BCR / ABL kinase domain mutation analysis performed?

Yes No Unknown

167 T315I

Positive Negative Not done

168 WT

Positive Negative Not done

169 L248V

Positive Negative Not done

170 G250E

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171 Q252H

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172 Y253F

Positive Negative Not done

173 E255K

Positive Negative Not done

174 E255V

Positive Negative Not done

175 D276G

Positive Negative Not done

176 E279K

Positive Negative Not done

177 V299L

Positive Negative Not done

178 F317L

Positive Negative Not done

179 M351T

Positive Negative Not done

180 F359V

Positive Negative Not done

181 L384M

Positive Negative Not done

182 H396P

Positive Negative Not done

183 H396R

Positive Negative Not done

184 G398R

Positive Negative Not done

185 F486S

Positive Negative Not done

186 Other mutation

Positive Negative Not done

187 Specify other mutation: _____

188 Was documentation submitted to the CIBMTR? (e.g. pathology report)

Yes No

189 Spleen size

Known

Unknown

Not applicable (splenectomy)

190 Specify the spleen size: _____ centimeters below left lower costal margin

Form 2112 R3.0: Chronic Myelogenous Leukemia (CML) Post-Infusion Data

Center: CRID:

191 What was the best response to therapy?

- Complete hematologic response (CHR)
- Chronic phase
- Accelerated phase
- Blast phase

192 Specify level of best response

- No cytogenetic response (No CyR)
- Minimal cytogenetic response
- Minor cytogenetic response
- Partial cytogenetic response (PCyR)
- Complete cytogenetic response (CCyR)
- Major molecular remission (MMR)
- Complete molecular remission (CMR)

193 Specify blast phase phenotype

Lymphoid Myeloid Mixed phenotype Unknown

194 Date assessed: __ __ __ __ - __ __- __ __

Disease Status at Time of Evaluation for this Reporting Period

Questions: 195 - 198

195 What was the disease status?

- Complete hematologic response (CHR)
- Chronic phase
- Accelerated phase
- Blast phase

196 Specify level of response

- No cytogenetic response (No CyR)
- Minimal cytogenetic response
- Minor cytogenetic response
- Partial cytogenetic response (PCyR)
- Complete cytogenetic response (CCyR)
- Major molecular remission (MMR)
- Complete molecular remission (CMR)

197 Specify blast phase phenotype

Lymphoid Myeloid Mixed phenotype Unknown

198 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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