Form 2012 R3.0: Chronic Myelogenous Leukemia (CML) Pre-Infusion Data

Center: CRID:

Key Fields

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: _____

Subsequent Transplant or Cellular Therapy

If this is a report of a second or subsequent transplant or cellular therapy for the same disease subtype and this baseline disease insert has not been completed for the previous transplant or cellular therapy (e.g. patient was on TED track for the prior HCT, prior HCT was autologous with no consent, prior cellular therapy was not reported to the CIBMTR), begin the form at question one.

If this is a report of a second or subsequent transplant or cellular therapy for a <u>different</u> disease, begin the form at question one.

Is this the report of a second or subsequent transplant or cellular therapy for the same disease?

○ Yes ○ No

Disease Assessment at Diagnosis

Questions: 1 - 17

1 What was the date of diagnosis? __ __ __ __ - __ __- __ __

2 What was the disease status? (at diagnosis)

○ Chronic phase ○ Accelerated phase ○ Blast phase

3 Specify the chronic phase risk score used (at diagnosis)

○ EUTOS ○ Hasford ○ Sokal ○ Other ○ Unknown

In the treating provider's opinion, specify the risk score:

4 Specify the EUTOS score: _____

5 Specify the Hasford score: _____

6 Specify the Sokal score: _____

7 Specify other chronic phase score: _____

8 Specify other chronic phase risk score used: _____

9 Specify blast phase phenotype

○ Lymphoid ○ Myeloid ○ Mixed phenotype ○ Unknown

10 Specify the criteria used to establish accelerated phase or blast phase

- ○ World Health Organization (WHO)
- ○ International Bone Marrow Transplant Registry (IBMTR)
- ○ Sokal
- ○ MD Anderson
- ○ European Leukemia Net
- ○ Other
- ○ Unknown

11 Specify other criteria: _____

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

13 Was extramedullary disease present?

○ yes ○ no ○ Unknown

Specify site(s) of disease:

14 Central nervous system

○ yes ○ no

15 Granulocytic sarcoma

○ Yes ○ No

Center: CRID:

16 Other site
○ yes ○ no

17 Specify other site: _____

Laboratory Studies at Diagnosis

Questions: 18 - 83

Report findings prior to any first treatment for CML:

18 WBC
○ Known ○ Unknown

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

20 Date sample collected: __ __ __ __ - __ __- __ __

21 Hemoglobin
○ Known ○ Unknown

22 _____ ○ g/dL ○ g/L ○ mmol/L

23 Date sample collected: __ __ __ __ - __ __- __ __

24 Was RBC transfused ≤ 30 days before date of test?
○ Yes ○ No

25 Platelets
○ Known ○ Unknown

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

27 Date sample collected: __ __ __ __ - __ __- __ __

28 Were platelets transfused ≤ 7 days before date of test?
○ Yes ○ No

29 Eosinophils
○ Known ○ Unknown

30 _____ %

31 Date sample collected: __ __ __ __ - __ __- __ __

32 Basophils
○ Known ○ Unknown

33 _____ %

34 Date sample collected: __ __ __ __ - __ __- __ __

35 Blasts in blood
○ Known ○ Unknown

36 _____ %

37 Date sample collected: __ __ __ __ - __ __- __ __

38 Blasts in bone marrow
○ Known ○ Unknown

39 _____ %

40 Date sample collected: __ __ __ __ - __ __- __ __

41 Were cytogenetics tested (karyotyping or FISH)?
○ yes ○ no ○ Unknown

42 Were cytogenetics tested via karyotyping?
○ Yes ○ No ○ Unknown

43 Date sample collected: __ __ __ __ - __ __- __ __

44 Results of tests
○ Abnormalities identified
○ No evaluable metaphases
○ No abnormalities

Specify cytogenetic abnormalities identified at diagnosis:

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

46 Other abnormality
○ yes ○ no

47 Specify other abnormality: _____

48 Was documentation submitted to the CIBMTR?
○ Yes ○ No

49 Were cytogenetics tested via FISH?
○ yes ○ no ○ Unknown

50 Date sample collected: __ __ __ __ - __ __- __ __

51 Results of tests

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

Specify cytogenetic abnormalities identified at diagnosis:

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

53 Other abnormality

○ yes ○ no

54 Specify other abnormality: _____

55 Was documentation submitted to the CIBMTR?

○ Yes ○ No

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

○ yes ○ no ○ Unknown

57 Date sample collected: __ __ __ __ - __ __- __ __

58 Was BCR / ABL detected?

○ Yes ○ No

59 Specify BCR / ABL breakpoint

○ p190 ○ p210 ○ p230 ○ Other breakpoint ○ Unknown

60 Specify other breakpoint: _____

61 Was BCR / ABL kinase domain mutation analysis performed?

○ Yes ○ No ○ Unknown

62 T315I

○ Positive ○ Negative ○ Not done

63 WT

○ Positive ○ Negative ○ Not done

64 L248V

○ Positive ○ Negative ○ Not done

65 G250E

○ Positive ○ Negative ○ Not done

66 Q252H

○ Positive ○ Negative ○ Not done

67 Y253F

○ Positive ○ Negative ○ Not done

68 E255K

○ Positive ○ Negative ○ Not done

69 E255V

○ Positive ○ Negative ○ Not done

70 D276G

○ Positive ○ Negative ○ Not done

71 E279K

○ Positive ○ Negative ○ Not done

72 V299L

○ Positive ○ Negative ○ Not done

73 F317L

○ Positive ○ Negative ○ Not done

74 M351T

○ Positive ○ Negative ○ Not done

75 F359V

○ Positive ○ Negative ○ Not done

76 L384M

○ Positive ○ Negative ○ Not done

77 H396P

○ Positive ○ Negative ○ Not done

78 H396R

○ Positive ○ Negative ○ Not done

79 G398R

○ Positive ○ Negative ○ Not done

80 F486S

Positive Negative Not done

81 Other mutation

Positive Negative Not done

82 Specify other mutation: _____

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

Yes No

Pre-HCT or Pre-Infusion Therapy

Questions: 84 - 185

84 Was therapy given?

yes no

Line of Therapy (1)

Questions: 85 - 185

85 Systemic therapy

yes no

86 Date therapy started

Known Unknown

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

88 Was therapy stopped?

Yes No

89 Date therapy stopped

Known Unknown

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

91 Specify reason therapy stopped

Toxicity Not tolerable Lack of response Disease progression Other Unknown

92 Specify other reason: _____

93 Bosutinib (Bosulif)

Yes No

94 Busulfan (Busulfex, Myleran)

Yes No

95 Corticosteroids

yes no

96 Cyclophosphamide (Cytoxan)

yes no

97 Cytarabine (Ara-C)

yes no

98 Dasatinib (Sprycel)

yes no

99 Daunorubicin (Cerubidine)

yes no

100 Doxorubicin (Adriamycin)

yes no

101 Homoharringtonine (HHT)

Yes No

102 Hydroxyurea (Droxia, Hydrea)

yes no

103 Idarubicin (Idamycin)

yes no

104 Imatinib (Gleevec)

yes no

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

yes no

106 Methotrexate (MTX) (Amethopterin)

yes no

107 Nilotinib (AMN107, Tasigna)

yes no

108 Ponatinib (Iclusig)

Yes No

109 Vincristine (VCR, Oncovin)
- ○ yes ○ no

110 Other systemic therapy
- ○ yes ○ no

111 Specify other systemic therapy: _____

112 Radiation therapy
- ○ yes ○ no

113 Date therapy started
- ○ Known ○ Unknown

114 Date started: __ __ __ __ - __ __- __ __

115 Date therapy stopped
- ○ Known ○ Unknown

116 Date stopped: __ __ __ __ - __ __- __ __

Specify site(s) of radiation therapy:

117 Spleen
- ○ yes ○ no

118 Other site(s)
- ○ yes ○ no

119 Specify other site(s): _____

120 Splenectomy
- ○ yes ○ no

121 Other therapy
- ○ yes ○ no

122 Specify other therapy: _____

Therapy response:

123 WBC
- ○ Known ○ Unknown

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

125 Date sample collected: __ __ __ __ - __ __- __ __

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

127 Basophils
- ○ Known ○ Unknown

128 _____ %

129 Platelets
- ○ Known ○ Unknown

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

131 Date sample collected: __ __ __ __ - __ __- __ __

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

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

134 Were cytogenetics tested via karyotyping?
- ○ Yes ○ No ○ Unknown

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

136 Results of tests
- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified following this line of therapy:

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

138 Other abnormality
- ○ yes ○ no

139 Specify other abnormality: _____

140 Was documentation submitted to the CIBMTR?
- ○ Yes ○ No

141 Were cytogenetics tested via FISH?

○ yes ○ no ○ Unknown

142 Date sample collected: __ __ __ __ - __ __- __ __

143 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified following this line of therapy:

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

145 Other abnormality

○ yes ○ no

146 Specify other abnormality: _____

147 Was documentation submitted to the CIBMTR?

○ Yes ○ No

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

○ yes ○ no ○ Unknown

149 Date sample collected: __ __ __ __ - __ __- __ __

150 Was BCR / ABL detected?

○ Yes ○ No

151 Specify level of detection

○ ≤ 0.1 %

○ > 0.1 %

○ ≥ 3-log reduction from standardized baseline

○ < 3-log reduction from standardized baseline

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

○ Yes ○ No

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

○ Yes ○ No

154 Specify BCR / ABL breakpoint

○ p190 ○ p210 ○ p230 ○ Other breakpoint ○ Unknown

155 Specify other breakpoint: _____

156 Was BCR / ABL kinase domain mutation analysis performed?

○ Yes ○ No ○ Unknown

157 T315I

○ Positive ○ Negative ○ Not done

158 WT

○ Positive ○ Negative ○ Not done

159 L248V

○ Positive ○ Negative ○ Not done

160 G250E

○ Positive ○ Negative ○ Not done

161 Q252H

○ Positive ○ Negative ○ Not done

162 Y253F

○ Positive ○ Negative ○ Not done

163 E255K

○ Positive ○ Negative ○ Not done

164 E255V

○ Positive ○ Negative ○ Not done

165 D276G

○ Positive ○ Negative ○ Not done

166 E279K

○ Positive ○ Negative ○ Not done

167 V299L

○ Positive ○ Negative ○ Not done

168 F317L

○ Positive ○ Negative ○ Not done

Center: CRID:

169 M351T
Positive Negative Not done

170 F359V
Positive Negative Not done

171 L384M
Positive Negative Not done

172 H396P
Positive Negative Not done

173 H396R
Positive Negative Not done

174 G398R
Positive Negative Not done

175 F486S
Positive Negative Not done

176 Other mutation
Positive Negative Not done

177 Specify other mutation: _____

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

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

180 Best response to line of therapy
- Complete hematologic response (CHR)
- Chronic phase
- Accelerated phase
- Blast phase

181 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)

182 Specify blast phase phenotype
Lymphoid Myeloid Mixed phenotype Unknown

183 Date assessed: __ __ __ __ - __ __- __ __

184 Did disease relapse/progress following this line of therapy?
yes no

185 Date of relapse/progression: __ __ __ __ - __ __- __ __

Disease Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions: 186 - 191

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

187 Was extramedullary disease present?
yes no Unknown

Specify site(s) of disease:

188 Central nervous system
yes no

189 Granulocytic sarcoma
Yes No

190 Other site
yes no

191 Specify other site: _____

Laboratory Studies at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions: 192 - 252

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

193 Eosinophils

○ Known ○ Unknown

194 _____ %

195 Date sample collected: __ __ __ __ - __ __- __ __

196 Basophils

○ Known ○ Unknown

197 _____ %

198 Date sample collected: __ __ __ __ - __ __- __ __

199 Blasts in blood

○ Known ○ Unknown

200 _____ %

201 Date sample collected: __ __ __ __ - __ __- __ __

202 Blasts in bone marrow

○ Known ○ Unknown

203 _____ %

204 Date sample collected: __ __ __ __ - __ __- __ __

205 What was the status of bone marrow fibrosis prior to the preparative regimen / infusion?

○ Absent ○ Mild ○ Moderate ○ Severe ○ Unknown

206 Date sample collected: __ __ __ __ - __ __- __ __

207 Were cytogenetics tested (karyotyping or FISH)?

○ yes ○ no ○ Unknown

208 Were cytogenetics tested via karyotyping?

○ Yes ○ No ○ Unknown

209 Date sample collected: __ __ __ __ - __ __- __ __

210 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified at last evaluation prior to preparative regimen / infusion:

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

212 Other abnormality

○ yes ○ no

213 Specify other abnormality: _____

214 Was documentation submitted to the CIBMTR?

○ Yes ○ No

215 Were cytogenetics tested via FISH?

○ yes ○ no ○ Unknown

216 Date sample collected: __ __ __ __ - __ __- __ __

217 Results of tests

○ Abnormalities identified

○ No evaluable metaphases

○ No abnormalities

Specify cytogenetic abnormalities identified at last evaluation prior to preparative regimen / infusion:

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

219 Other abnormality

○ yes ○ no

220 Specify other abnormality: _____

221 Was documentation submitted to the CIBMTR?

○ Yes ○ No

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

○ yes ○ no ○ Unknown

223 Date sample collected: __ __ __ __ - __ __- __ __

224 Was BCR / ABL detected?

○ Yes ○ No

225 Specify level of detection

○ ≤ 0.1 %

○ > 0.1 %

○ ≥ 3-log reduction from standardized baseline

○ < 3-log reduction from standardized baseline

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

Yes No

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

Yes No

228 Specify BCR / ABL breakpoint

p190 p210 p230 Other breakpoint Unknown

229 Specify other breakpoint: _____

230 Was BCR / ABL kinase domain mutation analysis performed?

Yes No Unknown

231 T315I

Positive Negative Not done

232 WT

Positive Negative Not done

233 L248V

Positive Negative Not done

234 G250E

Positive Negative Not done

235 Q252H

Positive Negative Not done

236 Y253F

Positive Negative Not done

237 E255K

Positive Negative Not done

238 E255V

Positive Negative Not done

239 D276G

Positive Negative Not done

240 E279K

Positive Negative Not done

241 V299L

Positive Negative Not done

242 F317L

Positive Negative Not done

243 M351T

Positive Negative Not done

244 F359V

Positive Negative Not done

245 L384M

Positive Negative Not done

246 H396P

Positive Negative Not done

247 H396R

Positive Negative Not done

248 G398R

Positive Negative Not done

249 F486S

Positive Negative Not done

250 Other mutation

Positive Negative Not done

251 Specify other mutation: _____

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

Yes No

Disease Status at the Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

Questions: 253 - 256

Form 2012 R3.0: Chronic Myelogenous Leukemia (CML) Pre-Infusion Data

Center: CRID:

253 What was the disease status?

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

254 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)

255 Specify blast phase phenotype

Lymphoid Myeloid Mixed phenotype Unknown

256 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

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