Chronic Myelogenous Leukemia (CML)
Pre-Infusion Data

Registry Use Only
Sequence Number:

Date Received:

CIBMTR Center Number: _____ _____ _____ _____
CIBMTR Research ID: _____ _____ _____ _____ _____ _____ _____
Event date: __ __ __ / __ / __
YYYY MM DD

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 different 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 - Go to question 186
☐ No - Go to question 1

Disease Assessment at Diagnosis

1. What was the date of diagnosis? __ __ __ __ / __ __ / __ __
   YYYY  MM  DD

2. What was the disease status? (at diagnosis)
   ☐ Chronic phase
   ☐ Accelerated phase - Go to question 10
   ☐ Blast phase - Go to question 9

3. Specify the chronic phase risk score used: (at diagnosis)
   ☐ EUTOS - Go to question 4
   ☐ Hasford - Go to question 5
   ☐ Sokal - Go to question 6
   ☐ Other - Go to question 7
   ☐ Unknown - Go to question 12

   In the treating provider’s opinion, specify the risk score:
   4. Specify the EUTOS score: ____  ____ - Go to question 12
   5. Specify the Hasford score: ____  ____  ____  ____ - Go to question 12
   6. Specify the Sokal score: __ . ____ - Go to question 12
   7. Specify other chronic phase score: ____  ____  ____  ____
   8. Specify other chronic phase risk score used:
      ____________________________ - Go to question 12

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 11. Specify other criteria:______________________________
    ☐ Unknown

12. Specify the spleen size: ____ ____ centimeters below left lower costal margin
13. Was extramedullary disease present?

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Specify site(s) of disease:

14. Central nervous system
   - Yes
   - No

15. Granulocytic sarcoma
   - Yes
   - No

16. Other site
   - Yes
   - No
   - Specify other site: ____________________________

Laboratory Studies at Diagnosis

Report findings prior to any first treatment for CML:

18. WBC:

   - Known
   - Unknown

19. ___ ___ ___ ___ • ___ □ x 10⁹/L (x 10³/mm³) □ x 10⁶/L

20. Date sample collected: __ __ / __ / __ YYYY  MM  DD

21. Hemoglobin:

   - Known
   - Unknown

22. ___ ___ ___ • ___ □ g/dL □ g/L □ mmol/L

23. Date sample collected: __ __ / __ / __ YYYY  MM  DD

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

25. Platelets:

   - Known
   - Unknown

26. ___ ___ ___ ___ ___ ___ • ___ □ x 10⁹/L (x 10³/mm³) □ x 10⁶/L

27. Date sample collected: __ __ / __ / __ YYYY  MM  DD

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

29. Eosinophils:

   - Known
   - Unknown

30. ___ ___ %

31. Date sample collected: __ __ / __ / __ YYYY  MM  DD

32. Basophils:

   - Known
   - Unknown

33. ___ ___ %

34. Date sample collected: __ __ / __ / __ YYYY  MM  DD

35. Blasts in blood:

   - Known
   - Unknown

36. ___ ___ %

37. Date sample collected: __ __ / __ / __ YYYY  MM  DD
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<th>Question</th>
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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

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
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<td>69. E255V</td>
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<td>70. D276G</td>
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<td>72. V299L</td>
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<td>73. F317L</td>
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<td>76. L384M</td>
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<td>77. H396P</td>
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<td>78. H396R</td>
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84. Was therapy given?  
☐ Yes  ☐ No

85. Systemic therapy  
☐ Yes  ☐ No

86. Date therapy started  
☐ Known  ☐ Unknown

87. Date started: __ __ __ __ / __ __ / __ __  YYYY MM DD

88. Was therapy stopped?  
☐ Yes  ☐ No

89. Date therapy stopped  
☐ Known  90. Date stopped:  ☐ Unknown  YYYY MM DD

91. Specify reason therapy stopped:  
☐ Toxicity  ☐ Not tolerable  ☐ Lack of response  ☐ Disease progression  ☐ Other  92. Specify other reason:  ☐ Unknown
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  ☐ Yes  ☐ No
☒ Known  ☐ Unknown
114. Date started: ___ / ___ / ___
YYYY   MM   DD

115. Date therapy stopped  ☐ Yes  ☐ No
☒ Known  ☐ Unknown
116. Date stopped: ___ / ___ / ___
YYYY   MM   DD

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: _______________________

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Therapy response:

123. WBC
☐ Known
☐ Unknown

124. ___ ___ ___ ___ ___ • ___ x 10^9/L (x 10^3/mm^3)
☐ x 10^9/L

125. Date sample collected: ___ ___ ___ / ___ / ___
YYYY MM DD

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

127. Basophils
☐ Known
☐ Unknown

128. ___ ___ %

129. Platelets
☐ Known
☐ Unknown

130. ___ ___ ___ ___ ___ ___ ___ x 10^9/L (x 10^3/mm^3)
☐ x 10^9/L

131. Date sample collected: ___ ___ ___ / ___ / ___
YYYY MM DD

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: ___ ___ ___ / ___ / ___
YYYY MM DD

136. Results of test
☐ 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)
141. Were cytogenetics tested via FISH?
☐ Yes
☐ No
☐ Unknown

142. Date sample collected: __  __  __  __ / __  __ / __  __

143. Results of test
☐ 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

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 >10⁴])
   ☐ 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
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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) - Go to question 181
☐ Chronic phase - Go to question 181
☐ Accelerated phase - Go to question 183
☐ Blast phase - Go to question 182

181. Specify level of best response:
☐ No cytogenetic response (No CyR) - Go to question 183
☐ Minimal cytogenetic response - Go to question 183
☐ Minor cytogenetic response - Go to question 183
☐ Partial cytogenetic response (PCyR) - Go to question 183
☐ Complete cytogenetic response (CCyR) - Go to question 183
☐ Major molecular remission (MMR) - Go to question 183
☐ Complete molecular remission (CMR) - Go to question 183

182. Specify blast phase phenotype
☐ Lymphoid ☐ Myeloid ☐ Mixed phenotype ☐ Unknown

183. Date assessed: ___ __ __ / __ __ __ YY MM DD

184. Did disease relapse/progress following this line of therapy?
☐ Yes ☐ No

185. Date of relapse / progression: ___ __ __ / __ __ __ YY MM DD

Copy questions 85 - 185 if needed for multiple lines of therapy

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

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

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 test
- [ ] 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 → 213. Specify other abnormality:
☐ No

214. Was documentation submitted to the CIBMTR?
☐ Yes ☐ No

215. Were cytogenetics tested via FISH?
☐ Yes → 216. Date sample collected: ___ ___/___/___
☐ No
☐ Unknown

216. Date sample collected: ___ ___/___/___

217. Results of test
☐ Abnormalities identified → Specify cytogenetic abnormalities identified at last evaluation prior to preparative regimen / infusion:
☐ No evaluable metaphases
☐ No abnormalities

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

219. Other abnormality
☐ Yes → 220. Specify other abnormality:
☐ No

221. Was documentation submitted to the CIBMTR?
☐ Yes ☐ No

222. Were tests for molecular markers performed (e.g. PCR)?
☐ Yes → 223. Date sample collected: ___ ___/___/___
☐ No
☐ Unknown

223. Date sample collected: ___ ___/___/___

224. Was BCR / ABL detected:
☐ Yes
☐ No - Go to question 227, then skip to question 252

225. Specify level of detection:
☐ ≤ 0.1 %
☐ > 0.1 %
☐ ≥ 3-log reduction from standardized baseline
☐ < 3-log reduction from standardized baseline

226. Other abnormality ☐ 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  229. Specify other breakpoint: __________
   ☐ Unknown

230. Was BCR / ABL kinase domain mutation analysis performed?
   ☐ Yes  231. T315I  ☐ Positive  ☐ Negative  ☐ Not done  ☐ No  ☐ Unknown

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
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
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**

253. What was the disease status?
☐ Complete hematologic response (CHR) - Go to question 254
☐ Chronic phase - Go to question 254
☐ Accelerated phase - Go to question 256
☐ Blast phase - Go to question 255

254. Specify level of response:
☐ No cytogenetic response (No CyR) - Go to question 256
☐ Minimal cytogenetic response - Go to question 256
☐ Minor cytogenetic response - Go to question 256
☐ Partial cytogenetic response (PCyR) - Go to question 256
☐ Complete cytogenetic response (CCyR) - Go to question 256
☐ Major molecular remission (MMR) - Go to question 256
☐ Complete molecular remission (CMR) - Go to question 256

255. Specify blast phase phenotype
☐ Lymphoid
☐ Myeloid
☐ Mixed phenotype
☐ Unknown

256. Date assessed: ___ ___ ___ __ __ / __ __ / __  ___

YYYY          MM        DD