

Chronic Myelogenous Leukemia (CML) Pre-Infusion Data

| Registry Use Only Sequence Number: | |
|--|---------------------------------------|
| Date Received: | |
| | |
| CIBMTR Center Number: | |
| CIBMTR Research ID: | |
| Event date:/// | |
| HCT type: (check all that apply) | geneic, unrelated Allogeneic, related |
| Product type: (check all that apply) Bone marrow | |
| ☐ PBSC | |
| ☐ Single cord blood ur | nit |
| ☐ Multiple cord blood | units |
| ☐ Other product. Spec | sify: |

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|---|--|--|--|--|
| Subsequent Transplant or Cellular Therapy | | | | |
| has not been completed for the previous transp | nsplant or cellular therapy for the same disease subtype and this baseline disease insert lant or cellular therapy (e.g. patient was on TED track for the prior HCT, prior HCT was py was not reported to the CIBMTR), begin the form at question one. | | | |
| If this is a report of a second or subsequent trai | nsplant or cellular therapy for a <u>different</u> disease, begin the form at question one. | | | |
| Is this the report of a second or subsequent transpla | ant or cellular therapy for the same disease? | | | |
| ☐ Yes - Go to question 186 | | | | |
| ☐ No - Go to question 1 | | | | |
| | | | | |
| Disease Assessment at Diagnosis | | | | |
| What was the date of diagnosis? | / | | | |
| What was the disease status? (at diagnosis) | | | | |
| Chronic phase | | | | |
| Accelerated phase - Go to question 10 | 3. Specify the chronic phase risk score used: (at diagnosis) | | | |
| ☐ Blast phase - Go to question 9 | ☐ 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: | | | |
| | 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 | | | |
| | | | | |

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| 13. | Was extramedullary disease present? Yes No Unknown | Specify site(s) of disease: 14. Central nervous system |
| Lab | oratory Studies at Diagnosis | |
| Rep | ort findings prior to any first treatment for | CML: |
| 18. | WBC: Known Unknown | 19 • |
| 21. | Hemoglobin: Known Unknown | 22 |
| 25. | Platelets: Known Unknown | 26 |
| 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:////// |

| Blasts in bone ma | 39 | te sample collected://///// |
|----------------------------------|---|--------------------------------|
| Were cytogenetics Yes No Unknown | tested (karyotyping or FISH)? | |
| | 49. Were cytogenetics tested Yes No Unknown | 50. Date sample collected://// |

| ☐ Yes ——— | 57. | Date sample collected:Y | / | / IM DD | | |
|-----------|-----|--------------------------------|-------|-------------------------|------|----------------------------------|
| Unknown | | | YYY N | IM DD | | |
| | 58. | Was BCR / ABL detected? ☐ Yes | 59. | Specify BCR / ABL break | poin | t |
| | | □ No | | ☐ p190 | | |
| | | | | ☐ p210 | | |
| | | | | ☐ p230 | | |
| | | | | ☐ Other breakpoint → 6 | 60. | Specify other breakpoint: |
| | | | | Unknown | | |
| | | | 61. | Was BCR / ABL kinase d | loma | nin mutation analysis performed? |
| | | | | ☐ Yes — → 6 | | T315I |
| | | | | □ No | | ☐ Positive |
| | | | | Unknown | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 33. | WT |
| | | | | | | Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 64. | L248V |
| | | | | | | ☐ Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 35. | G250E |
| | | | | | | Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 66. | Q252H |
| | | | | | | ☐ Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 67. | Y253F |
| | | | | | | ☐ Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |
| | | | | 6 | 88. | E255K |
| | | | | | | ☐ Positive |
| | | | | | | ☐ Negative |
| | | | | | | ☐ Not done |

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| | 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 |

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|---|--------------------|--|---|
| | | | 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 docume report) \square Ye | entation submitted to the CIBMTR? (e.g. pathology |
| re-HCT or Pre-Infusion 1 . Was therapy given? Yes | Line of Therapy | | |
| | 85. Systemic there | У | |
| | | 86 Date therapy started | |
| | □ No | 86. Date therapy started ☐ Known → 87. Date st | earted:// |
| | | Known → 87. Date st Was therapy stopped? Yes → 89. Date th | nerapy stopped bwn —➤ 90. Date stopped: |
| | | Known → 87. Date st Unknown | perapy stopped pwn → 90. Date stopped: cnown |

| | Γ | | |
|----------------------------------|---|-------------|------|
| | 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 → 111. Specify other systemic therap | oy: | |
| l l | I I No | | |
| | □ No | | |
| 112. Radiation the ☐ Yes —➤ ☐ No | | / | |
| ☐ Yes → | rapy 113. Date therapy started ☐ Known → 114. Date started: / YYYY 115. Date therapy stopped ☐ Known → 116. Date stopped: / YOOV / YOU | | |
| ☐ Yes → | rapy 113. Date therapy started | // MM DD | □ No |
| ☐ Yes → | rapy 113. Date therapy started | // MM DD | □ No |

| Thomas | | |
|---------|---|--|
| | response: | |
| | C Known ——————————————————————————————————— | ■ 124 • x 10 ⁹ /L (x 10 ³ /mm ³) □ x 10 ⁶ /L 125. Date sample collected: / / / DD |
| | | 126. Were immature cells (i.e., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood? Yes No Known |
| | ophils Known ——————————————————————————————————— | 128% |
| | elets Known ——————————————————————————————————— | 130 |
| | | 131. Date sample collected://///// |
| 133. We | re cytogenetics tested (kar | ☐ Yes ☐ No yotyping or FISH)? |
| | Yes — | ytogenetics tested via karyotyping? |
| | No Unknown ☐ Yes ☐ No ☐ Unk | 135. Date sample collected://///// |
| | | ☐ No evaluable metaphases ☐ No abnormalities Specify cytogenetic abnormalities identified following this line of therapy: |
| | | 137% Ph+ metaphases (t(9;22) (q34;q11) and variants) |
| | | |
| | | |

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| 138. Other abnormality Yes |
| Yes No 148. Were tests for molecular markers performed (e.g. PCR)? Yes Yes Yes No 149. Date sample collected://////// |
| |

| AFO Mes DODIARI lavel of detection |
|--|
| 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 adequat 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 mutatic analysis performed? |
| ☐ Yes ☐ No ☐ Unknown ▼ |
| 157. T315I |
| Positive |
| ☐ Negative ☐ Not done |
| I Not dolle |
| 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 |
| | 407 1/0001 |
| | 167. V299L ☐ Positive |
| | ☐ Negative |
| | ☐ Not done |
| | |
| | 168. F317L ☐ Positive |
| | |
| | ☐ Negative ☐ Not done |
| | |
| | 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: |
| | |
| | |
| | |
| 17 | Was documentation submitted to the CIBMTR? (e.g. pathology report) |
| | ☐ Yes ☐ No |
| 179 Specify the spleen | ize: centimeters below left lower costal margin |
| 179. Specify the spieeri | ize certuirieteis pelow lett lower Costal Hargin |
| | |

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| | 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 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:///////// |
| | ast Evaluation Prior to the Start of the Preparative Regimen / Infusion |
| 186. Specify the spleen siz 187. Was extramedullary d ☐ Yes ———— | isease present? |
| ☐ Yes ☐ No ☐ Unknown | Specify site(s) of disease: 188. Central nervous system |
| | |

| Laboratory Studies at Las | Evaluation Prior to the Start of the Preparative Regimen / Infusion |
|--|--|
| 192. Were immature cells (i | ., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood? Unknown |
| 193. Eosinophils: | 194 % 195. Date sample collected://// |
| 196. Basophils: | 197 % 198. Date sample collected://// |
| 199. Blasts in blood: Known Unknown | 200 % 201. Date sample collected:/// |
| 202. Blasts in bone marrow: | 203 % 204. Date sample collected:/// |
| 205. What was the status of Absent Mild Moderate Severe Unknown | 206. Date sample collected://// |
| 207. Were cytogenetics test ☐ Yes → ☐ ☐ No ☐ Unknown | 208. Were cytogenetics tested via karyotyping? Yes |

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| | 215. Were cytogenet | 211% Ph+ metaphases (t(9;22) (q34;q11) and variants) 212. Other abnormality Yes → 213. Specify other No abnormality: 214. Was documentation submitted to the CIBMTR? Yes No |
| | ☐ Yes → ☐ No ☐ Unknown | 216. Date sample collected: |
| 222. Were tests for molecu ☐ Yes → ☐ No | lar markers performed (e | llected: / / |
| ☐ Unknown | 224. Was BCR / ABL | detected: question 227, then skip to question 252 225. Specify level of detection: |

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| | 227. Were 2 consecutive tests performed? (quantitative and / or nested; of adequate quality [sensitivity >104]) |
| | ☐ Yes ☐ No 228. Specify BCR / ABL breakpoint ☐ p190 ☐ p210 ☐ p230 ☐ Other breakpoint → 229. Specify other breakpoint: ☐ Unknown ☐ Unknown 230. Was BCR / ABL kinase domain mutation analysis performed? ☐ Yes → 231. T315I |
| | ☐ No ☐ Positive ☐ Unknown ☐ 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 |

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| | | |
| | | ☐ 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 |

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| | 248. G398R |
| Disease Status at the Last E 253. What was the disease st Complete hematolog Chronic phase - Go Accelerated phase - | gic response (CHR) - Go to question 254 to question 254 Go to question 256 |
| | 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 Specify blast phase phenotype Lymphoid |
| 256. Date assessed: | ☐ Myeloid ☐ Mixed phenotype ☐ Unknown |

| CIBMTR Center Number: | CIBMTR Recipient ID: |
|-----------------------|----------------------|
| First Name: | |
| Last Name: | |
| E-mail address: | |
| Date:/ / / DD | |
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