

Chronic Myelogenous Leukemia (CML) Pre-Infusion Data

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

Cibivitr Center Number:	
Subsequent Transplant or Cellular Therapy	
has not been completed for the previous transpla	splant or cellular therapy for the same disease subtype and this baseline disease insert ant or cellular therapy (e.g. patient was on TED track for the prior HCT, prior HCT was you was not reported to the CIBMTR), begin the form at question one.
If this is a report of a second or subsequent trans	splant or cellular therapy for a <u>different</u> disease, begin the form at question one.
Is this the report of a second or subsequent transplat Yes - Go to question 186 No - Go to question 1	nt or cellular therapy for the same disease?
Disease Assessment at Diagnosis	
What was the date of diagnosis?	_//
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 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 7. Specify the Sokal score: Go to question 12 7. Specify other chronic phase score: Go to question 12 7. 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 b	pelow left lower costal margin

CIBM	TR Center Number:	CIBMTR Recipient ID:
13.	Was extramedullary disease present?	
	☐ Yes — → No ☐ Unknown	Specify site(s) of disease: 14. Central nervous system
Lab	oratory Studies at Diagnosis	
	ort findings prior to any first treatment for	CML:
18.	WBC: Known Unknown	19 •
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
29.	Eosinophils: Known Unknown	30 % 31. Date sample collected:////
32.	Basophils:	33 % 34. Date sample collected:////
35.	Blasts in blood: Known Unknown	36 % 37. Date sample collected:///

8. Blasts in bone marrow: Known Unknown	39 % 40. Date sample collected:///
Unknown Yes No Unknow	genetics tested via karyotyping? 43. Date sample collected://// 44. Results of test
	CIBMTR? Yes No

☐ Yes — ☐ No ☐ Unknown		Date sample collected:	<u></u>	MM DD		
	58.	Was BCR / ABL detected? Yes No	59.	Specify BCR / ABL brought p190 p210 p230 Other breakpoint Unknown		Specify other breakpoint:
			61.	Was BCR / ABL kinas	e doma	ain mutation analysis performed?
				☐ Yes — → No ☐ Unknown	► 62.	T315I ☐ Positive ☐ Negative ☐ Not done
					63.	WT Positive
						☐ Negative
					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 Negative Negative Negative Negative Not done	
☐ 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	

IBMTR Center Number:			CIBMTR Recipient ID:
			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
re-HCT or Pre-Infusion 1	⁻ herapy		
. Was therapy given? ☐ Yes ———	Line of Therapy		
□ No	85. Systemic there	ару	
	☐ Yes → ☐ No	86. Date therap	
		☐ Known	I 87 Date started: / /
		88. Was therap	y stopped?
		☐ Yes —	89. Date therapy stopped Known → 90. Date stopped: Unknown — TYYYY MM DD
			91. Specify reason therapy stopped: Toxicity Not tolerable
			☐ Lack of response

	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
		☐ Yes	□ No
	104. Imatinib (Gleevec)	☐ Yes	
	105. Interferon-α (Intron, Roferon) (includes PEG)	☐ Yes	□ No
	106. Methotrexate (MTX) (Amethopterin)		- 1
	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 the	ару:	
	□ No		
_	ation therapy 113. Date therapy started Known 114. Date started: YYYY	_//	
	115. Date therapy stopped ☐ Known → 116. Date stopped:	//	
	Specify site(s) of radiation therapy:		
	117. Spleen 118. Other site(s) ☐ Yes → 119. Specify other site(s): ☐ No	☐ Yes	□ No
120. Sple	nectomy Yes No		
	es —> 122. Specify other therapy:		

CIBMTR Recipient ID: ___ __ __ __ __ __ __ __ ___

CIBMTR Center Number: ___ __ __ __

CIBMTR Center Number:		CIBMTR Recipient ID:
	Therapy response:	
	123. WBC Known Unknown	124 • \ x 10 ⁹ /L (x 10 ³ /mm ³) \[x 10 ⁶ /L 125. Date sample collected: \ / / / \text{MM} \ DD 126. Were immature cells (i.e., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood?
	127. Basophils ☐ Known — ☐ Unknown	Yes No Known 128. %
	129. Platelets Known Unknown	130
	133. Were cytogenetics tested (ka	cytogenetics tested via karyotyping? 135. Date sample collected:///

CIBMTR Center Number:	CIBMTR Recipient ID:
	138. Other abnormality Yes
	146. Specify other abnormality: 147. Was documentation submitted to the CIBMTR? Yes No No Yes No No Unknown No Specify evel of detection No Specify level of detection No Specify evel of detection No Specify evel of detection Specify evel of det

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 >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
	☐ Negative
	☐ Net done
	166. E279K
	Positive
	☐ Negative
	☐ Not done
	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
178. Was	documentation submitted to the CIBMTR? (e.g. pathology report)
470 0 11 11	
179. Specify the spleen size:	centimeters below left lower costal margin

	CIBMTR Recipient ID:	
	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:///////	
	Copy questions 85 - 185 if needed for multiple lines of therapy	
	Last Evaluation Prior to the Start of the Preparative Regimen / Infusion ze: centimeters below left lower costal margin disease present?	
☐ Yes ———— ☐ No ☐ Unknown	Specify site(s) of disease: 188. Central nervous system 189. Granulocytic sarcoma 190. Other site	

Laboratory Studies at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion			
`.	., myelocytes, promyelocytes or myeloblasts) noted on the WBC differential from the peripheral blood? Unknown		
193. Eosinophils:	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			
207. Were cytogenetics teste ☐ Yes ☐ No ☐ Unknown	208. Were cytogenetics tested via karyotyping? Yes		

IBMTR Center Number:		CIBMTR Recipient ID:
	215. Were cytogenet ☐ Yes → ☐ No ☐ Unknown	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 ics tested via FISH? 216. Date sample collected: YYYY / / / DD 217. Results of test Abnormalities identified 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 → 220. Specify other No abnormality: 221. Was documentation submitted to the CIBMTR? Yes No
222. Were tests for molecu	lar markers performed (e	.g. PCR)?
☐ Yes — → No ☐ Unknown	223. Date sample co	llected:///
	224. Was BCR / ABL	detected: 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

CIBMTR Center Number:	CIBMTR	Recipient ID:
	quality [sensitivity >104	sts performed? (quantitative and / or nested; of adequate
	☐ Yes ☐ No	
	228. Specify BCR / ABL bre	akpoint
	☐ p190	
	☐ p210	
	☐ p230	
	☐ Other breakpoint —	➤ 229. Specify other breakpoint:
	☐ 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

CIBMTR Center Number:	CIBMTR Recipient ID:	
		☐ Positive
		☐ Negative
		☐ Not done
	220	D276G
	239.	□ Positive
		I 1
		☐ Negative ☐ Not done
	240.	E279K
		Positive
		☐ Negative
		☐ Not done
	241	V299L
	241.	☐ 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
	040	
	240.	H396P
		☐ Positive
		☐ Negative ☐ Not done
	247.	H396R
		Positive
		☐ Negative
		☐ Not done

	248. G398R	Specify other mutation:
Disease Status at the Last E	emitted to the CIBMTR? (e.g. pathology report) Yes No Evaluation Prior to the Start of the Preparative Regimen / Infusion tatus? pic response (CHR) - Go to question 254	
☐ Chronic phase - Go ☐ Accelerated phase -	to question 254	
☐ 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	

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