Chronic Lymphocytic Leukemia (CLL) Pre-Infusion Data

Registry Use Only

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 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 questions 149

☐ No - Go to question 1

Disease Assessment at Diagnosis

1. What was the date of diagnosis? ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

2. Was documentation submitted to the CIBMTR (e.g. pathology report used for diagnosis)?
   ☐ Yes
   ☐ No

3. Did a histologic transformation occur at any time after CLL diagnosis?
   ☐ Yes – Go to questions 4
   ☐ No – Go to question 8

4. Date of transformation: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

5. Specify the disease classification after transformation:
   ☐ Diffuse large B-cell lymphoma (Richter syndrome) – Go to question 7 Also complete CIBMTR form 2018 - LYM
   ☐ Other disease classification – Go to question 6

6. Specify other disease classification: _______________________

7. Was documentation submitted to the CIBMTR (e.g. pathology report at transformation)?
   ☐ Yes
Autoimmune disorder(s) at diagnosis:

8. Immune hemolytic anemia
   - Yes
   - No
   - Unknown

9. Immune thrombocytopenia
   - Yes
   - No
   - Unknown

10. Other
    - Yes – Go to question 11
    - No – Go to question 12
    - Unknown – Go to question 12

11. Specify other autoimmune disorder: _______________________________________________________

12. Rai stage (at diagnosis)
    - Known – Go to question 13
    - Unknown– Go to question 14

13. What was the Rai stage? (at diagnosis)
    - Stage 0 — Low risk — lymphocytosis (> 15,000 x 10^9/L) in blood or bone marrow only without lymphadenopathy, hepatosplenomegaly, anemia or thrombocytopenia
    - Stage 1 - Intermediate risk — lymphocytosis plus enlarged lymph nodes (lymphadenopathy) without hepatosplenomegaly, anemia or thrombocytopenia
    - Stage II - Intermediate risk — lymphocytosis plus enlarged liver or spleen with or without lymphadenopathy
    - Stage III - High risk — lymphocytosis plus anemia (Hgb < 11.0 g/dL) with or without enlarged liver, spleen, or lymph nodes
    - Stage IV - High risk — lymphocytosis plus thrombocytopenia (platelet count < 100 x 10^9/L) with or without anemia or enlarged liver, spleen, or lymph nodes

14. Binet stage (at diagnosis)
15. What was the Binet stage? (at diagnosis) (Five lymphoid bearing areas are possible: axillary, cervical, inguino-femoral, liver, and spleen.)
   - Stage A — two or fewer lymphoid bearing areas enlarged, without anemia or thrombocytopenia
   - Stage B — three or more lymphoid bearing areas enlarged, without anemia or thrombocytopenia
   - Stage C — presence of anemia (Hgb < 10.0 g/dL) or thrombocytopenia (platelet count < 100 x 10^9/L)

16. Were systemic symptoms (B symptoms) present (unexplained fever > 38° C ; or night sweats; unexplained weight loss of > 10% of body weight in six months before diagnosis)?
   - Yes
   - No
   - Unknown

17. Was extranodal disease present?
   - Yes – Go to questions 18
   - No – Go to question 22

Specify site(s) of disease:

18. Central nervous system (CNS)
   - Yes
   - No

19. Lung
   - Yes
   - No

20. Other site
   - Yes – Go to question 21
   - No – Go to question 22

21. Specify other site: _______________________________________________________________

Laboratory Studies at Diagnosis

22. WBC:
23. ____ ____ ____ ____ ____ • ____
   - x 10^9/L (x 10^3/mm^3)
   - x 10^6/L

24. Hemoglobin: (untransfused)
   - Known – Go to question 25
   - Unknown – Go to question 26

   25. ____ ____ ____ ____ • ____
       - g/dL
       - g/L
       - mmol/L

26. Platelets: (untransfused)
   - Known – Go to question 27
   - Unknown – Go to question 28

   27. ____ ____ ____ ____ ____ ____
       - x 10^9/L (x 10^3/mm^3)
       - x 10^6/L

28. Lymphocytes:
   - Known – Go to question 29
   - Unknown – Go to question 30

   29. ____ ____ %

30. Prolymphocytes:
   - Known – Go to question 31
   - Unknown – Go to question 32

   31. ____ ____ %

32. LDH:
   - Known – Go to question 33
   - Unknown – Go to question 35

   33. ____ ____ ____ ____ • ____ ____
       - U/L
34. Upper limit of normal for LDH: ___ ___ ___ ___ • ___ ___ □ μkat/L
   □ U/L

35. Serum β₂ microglobulin:
   □ Known – Go to question 36
   □ Unknown – Go to question 38

36. ___ ___ ___ • ___ ___ □ μg/dL
   □ mg/L
   □ nmol/L

37. Upper limit of normal for serum β₂ microglobulin: ___ ___ ___ • ___ ___ ___ □ μg/dL
   □ mg/L
   □ nmol/L

38. Lymphocytes in bone marrow:
   □ Known – Go to question 39
   □ Unknown – Go to question 40

39. ___ ___ ___ %

40. Leukemia cell type: (may be determined at any time after diagnosis)
   □ B-cell
   □ T-cell
   □ Unknown

41. Were tests for molecular markers performed (e.g. PCR)?
   □ Yes – Go to question 42
   □ No – Go to question 52
   □ Unknown – Go to question 52

42. Date sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___

43. Immunoglobulin heavy chain variable (IGHV) mutation
   □ Positive – Go to question 44
   □ Negative – Go to question 44
44. Specify method used:
   - ASO IGHV RQ-PCR – Go to question 46
   - Consensus IGHV PCR – Go to question 46
   - Consensus IGHV PCR using HTS – Go to question 46
   - Nested ASO IGHV PCR – Go to question 46
   - Other method – Go to question 45

45. Specify other method: _____________________________

46. NOTCH 1 mutation
   - Positive
   - Negative
   - Not done

47. P53 mutation
   - Positive
   - Negative
   - Not done

48. SF3B1 mutation
   - Positive
   - Negative
   - Not done

49. Other molecular marker
   - Positive – Go to question 50
   - Negative – Go to question 50
   - Not done – Go to question 51

50. Specify other molecular marker: _____________________________

51. Was documentation submitted to the CIBMTR?
   - Yes
   - No
**Immunophenotype:**

52. Was flow cytometry (immunophenotyping) performed?
   - ☐ Yes - Go to question 53
   - ☐ No - Go to question 61
   - ☐ Unknown – Go to question 61

53. CD5+
   - ☐ Positive
   - ☐ Negative
   - ☐ Not done

54. CD19+
   - ☐ Positive
   - ☐ Negative
   - ☐ Not done

55. CD20+
   - ☐ Positive
   - ☐ Negative
   - ☐ Not done

56. CD23+
   - ☐ Positive
   - ☐ Negative
   - ☐ Not done

57. CD38+
   - ☐ Positive – Go to question 58
   - ☐ Negative – Go to question 59
   - ☐ Not done – Go to question 59

58. Specify percent positivity:
   - ☐ ≥30% positivity
   - ☐ <30% positivity
59. Slg
   □ Positive
   □ Negative
   □ Not done

60. ZAP-70 - mutated
   □ Positive
   □ Negative
   □ Not done

61. Were cytogenetics tested (karyotyping or FISH)?
   □ Yes – Go to question 62
   □ No – Go to question 74
   □ Unknown – Go to question 74

62. Results of tests:
   □ Abnormalities identified – Go to questions 63
   □ No evaluable metaphases – Go to question 74
   □ No abnormalities – Go to question 74

   Specify cytogenetic abnormalities identified at diagnosis:

   Trisomy

63. +12
   □ Yes
   □ No

   Translocation

64. t(11;14)
   □ Yes
   □ No

65. Any other translocation of 14
   □ Yes
   □ No
Deletion

66. del(11q) / 11q–
   □ Yes
   □ No

67. del(13q) / 13q–
   □ Yes
   □ No

68. del(17p) / 17p–
   □ Yes
   □ No

Other

69. Chromosome 6 abnormalities
   □ Yes
   □ No

70. Chromosome 8 abnormalities
   □ Yes
   □ No

71. Other abnormality
   □ Yes – Go to question 72
   □ No – Go to question 73

72. Specify other abnormality: ___________________________________________________

73. Was documentation submitted to the CIBMTR (e.g. cytogenetic or FISH report)?
   □ Yes
   □ No

Pre-HCT or Pre-Infusion Therapy
74. Was therapy given?
   □ Yes – *Go to question 75*
   □ No – *Go to question 149*
   □ Unknown – *Go to question 149*

*Line of Therapy*

75. Systemic therapy:
   □ Yes – *Go to questions 76*
   □ No – *Go to question 109*

76. Date therapy started
   □ Known - *Go to question 77*
   □ Unknown - *Go to question 78*

77. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___
      YYYY       MM       DD

78. Date therapy stopped
   □ Known - *Go to question 79*
   □ Unknown - *Go to question 80*

79. Date stopped: ___ ___ ___ ___ — ___ ___ — ___ ___
      YYYY       MM       DD

80. Number of cycles
   □ Known - *Go to question 81*
   □ Unknown - *Go to question 82*

81. Number of cycles: ___ ___

82. Alemtuzumab (Campath)
   □ Yes
   □ No

83. Bendamustine
   □ Yes
   □ No
84. Chlorambucil (Leukeran)
   □ Yes
   □ No

85. Cladribine (2-CdA, Leustatin)
   □ Yes
   □ No

86. Corticosteroids
   □ Yes
   □ No

87. Cyclophosphamide (Cytoxan)
   □ Yes
   □ No

88. Cytarabine (Ara-C)
   □ Yes
   □ No

89. Doxorubicin (Adriamycin)
   □ Yes
   □ No

90. Etoposide (VP-16, VePesid)
   □ Yes
   □ No

91. Fludarabine (Fludara)
   □ Yes
   □ No

92. Gemcitabine (Gemzar)
   □ Yes
   □ No

93. Ibrutinib (Imbruvica)
   □ Yes
94. Idelalisib (Zydelig)
   - [ ] Yes
   - [ ] No

95. Ifosfamide (Ifex)
   - [ ] Yes
   - [ ] No

96. Lenalidomide (Revlimid)
   - [ ] Yes
   - [ ] No

97. Nelarabine
   - [ ] Yes
   - [ ] No

98. Nitrogen mustard (mustine)
   - [ ] Yes
   - [ ] No

99. Obinutuzumab
   - [ ] Yes
   - [ ] No

100. Oblimersen
    - [ ] Yes
    - [ ] No

101. Ofatumumab (Arzerra, HuMax-CD20)
    - [ ] Yes
    - [ ] No

102. Pentostatin (Nipent)
    - [ ] Yes
    - [ ] No
103. Rituximab (anti-CD20, Rituxan)
   - Yes
   - No

104. Venetoclax
   - Yes
   - No

105. Vincristine (VCR, Oncovin)
   - Yes
   - No

106. Other systemic therapy
   - Yes – Go to question 107
   - No – Go to question 108

107. Specify other systemic therapy: _______________________________________________

108. Was this line of therapy given for stem cell mobilization (priming)?
   - Yes
   - No

109. Radiation therapy:
   - Yes – Go to question 110
   - No – Go to question 117

110. Date therapy started
   - Known – Go to question 111
   - Unknown - Go to question 112

   111. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___
       YYYY  MM  DD

112. Date therapy stopped
   - Known – Go to question 113
   - Unknown – Go to question 114

   113. Date stopped: ___ ___ ___ ___ — ___ ___ — ___ ___
Specify site(s) of radiation therapy:

114. Mediastinum
   □ Yes
   □ No

115. Other site
   □ Yes – Go to question 116
   □ No – Go to question 117

   116. Specify other site: ______________________________________________________

117. Surgery:
   □ Yes – Go to question 118
   □ No – Go to question 122

   118. Date of surgery: ___ ___ ___ ___ — ___ ___ — ___ ___

119. Splenectomy
   □ Yes
   □ No

120. Other site
   □ Yes – Go to question 121
   □ No – Go to question 122

   121. Specify other site: ______________________________________________________

122. Best response to line of therapy
   □ Complete remission (CR) — no lymphadenopathy; no organomegaly; neutrophils ≥ 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11.0 g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms – Go to question 123

   □ Partial remission (PR) — ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10^9/L or 50% improvement over baseline, platelets > 100 x 10^9/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline – Go to question 123
☐ Stable disease (SD) — no change; not complete remission, partial remission, nor progressive disease — Go to question 123

☐ Progressive disease (Prog) — one or more of the following: ≥ 50% increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size, or new hepatomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10^9/L; transformation to a more aggressive histology — Go to question 123

☐ Not assessed — Go to question 149

☐ Unknown — Go to question 149

123. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___ YYYY MM DD

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

☐ Yes — Go to question 125

☐ No — Go to question 134

☐ Unknown — Go to question 134

125. Date sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___

126. Immunoglobulin heavy chain variable (IGHV) mutation

☐ Positive — Go to question 127

☐ Negative— Go to question 127

☐ Not done— Go to question 129

127. Specify method used:

☐ ASO IGHV RQ-PCR — Go to question 129

☐ Consensus IGHV PCR — Go to question 129

☐ Consensus IGHV PCR using HTS — Go to question 129

☐ Nested ASO IGHV PCR — Go to question 129

☐ Other method — Go to question 128

128. Specify other method: _____________________________

129. NOTCH 1 mutation

☐ Positive

☐ Negative

☐ Not done
130. P53 mutation
   □ Positive
   □ Negative
   □ Not done

131. SF3B1 mutation
   □ Positive
   □ Negative
   □ Not done

132. Other molecular marker
   □ Positive – Go to question 133
   □ Negative – Go to question 133
   □ Not done – Go to question 134

133. Specify other molecular marker: ________________________________

134. Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?
   □ Yes - Go to question 135
   □ No - Go to question 137

135. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
       YYYY MM DD

136. Was disease detected?
   □ Yes
   □ No

137. Was the disease status assessed via cytogenetic testing (karyotyping or FISH)?
   □ Yes - Go to questions 138
   □ No - Go to question 144

138. Was the disease status assessed via FISH?
   □ Yes – Go to question 139
   □ No – Go to question 141
139. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

140. Was disease detected?
    □ Yes
    □ No

141. Was the disease status assessed via karyotyping?
    □ Yes – Go to question 142
    □ No – Go to question 144

142. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___

143. Was disease detected?
    □ Yes
    □ No

144. Was the disease status assessed by clinical / hematologic assessment?
    □ Yes - Go to question 145
    □ No - Go to question 147

145. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

146. Was disease detected?
    □ Yes
    □ No

147. Did disease relapse/progress following this line of therapy?
    □ Yes – Go to question 148
    □ No – Go to question 149

148. Date of relapse/progression: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

Copy questions 75 – 148 if needed for multiple lines of therapy.
Disease Assessment at Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

149. Did the recipient have known nodal involvement?
   ☐ Yes – Go to questions 150
   ☐ No – Go to question 151

150. Specify the size of the largest nodal mass: ___ ___ cm x ___ ___ cm

151. Was extranodal disease present?
   ☐ Yes – Go to questions 152
   ☐ No – Go to question 156

Specify site(s) of involvement:

152. Central nervous system (CNS)
   ☐ Yes
   ☐ No

153. Lung
   ☐ Yes
   ☐ No

154. Other site
   ☐ Yes – Go to question 155
   ☐ No – Go to question 156

155. Specify other site: _______________________________________________________________

156. Prolymphocytes:
   ☐ Known – Go to question 157
   ☐ Unknown – Go to question 158

157. ___ ___ %

158. Serum β₂ microglobulin:
   ☐ Known – Go to question 159
   ☐ Unknown– Go to question 161
159. ___ ___ ___ • ___ ___ ___
   □ µg/dL
   □ mg/L
   □ nmol/L

160. Upper limit of normal for serum β2 microglobulin: ___ ___ ___ ___ ___ • __ __ __ __________
   □ µg/dL
   □ mg/L
   □ nmol/L

161. Lymphocytes in bone marrow:
   □ Known – Go to question 162
   □ Unknown – Go to question 163

162. ___ ___ ___ %

163. Were tests for molecular markers performed (e.g. PCR)?
   □ Yes – Go to question 164
   □ No – Go to question 174
   □ Unknown – Go to question 174

164. Date sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___

165. Immunoglobulin heavy chain variable (IGHV) mutation
   □ Positive – Go to question 166
   □ Negative – Go to question 168
   □ Not done – Go to question 168

166. Specify method used:
   □ ASO IGHV RQ-PCR – Go to question 168
   □ Consensus IGHV PCR – Go to question 168
   □ Consensus IGHV PCR using HTS – Go to question 168
   □ Nested ASO IGHV PCR – Go to question 168
   □ Other method – Go to question 167

167. Specify other method: _____________________

168. NOTCH 1 mutation
   □ Positive
   □ Negative
169. P53 mutation
   - Positive
   - Negative
   - Not done

170. SF3B1 mutation
   - Positive
   - Negative
   - Not done

171. Other molecular marker
   - Positive – Go to question 172
   - Negative – Go to question 172
   - Not done – Go to question 173

172. Specify other molecular marker:

173. Was documentation submitted to the CIBMTR?
   - Yes
   - No

174. Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?
   - Yes - Go to question 175
   - No - Go to question 177

175. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
     YYYY          MM      DD

176. Was disease detected?
   - Yes
   - No

177. Were cytogenetics tested (karyotyping or FISH)?
   - Yes - Go to question 178
   - No – Go to question 189
178. Results of tests:

☐ Abnormalities identified – Go to questions 179
☐ No evaluable metaphases – Go to question 189
☐ No abnormalities – Go to question 189

Specify cytogenetic abnormalities detected at last evaluation prior to the start of the preparative regimen / infusion:

Trisomy

179. +12

☐ Yes
☐ No

Translocation

180. t(11;14)

☐ Yes
☐ No

181. Any other translocation of 14

☐ Yes
☐ No

Deletion

182. del(11q) / 11q–

☐ Yes
☐ No

183. del(13q) / 13q–

☐ Yes
☐ No

184. del(17p) / 17p–

☐ Yes
☐ No
Other

185. Chromosome 6 abnormalities
   □ Yes
   □ No

186. Chromosome 8 abnormalities
   □ Yes
   □ No

187. Other abnormality
   □ Yes – Go to question 188
   □ No – Go to question 189

   188. Specify other abnormality: ___________________________________________________

189. Was the disease status assessed by clinical / hematologic assessment?
   □ Yes - Go to question 190
   □ No - Go to question 192

   190. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
        YYYY            MM     DD

   191. Was disease detected?
       □ Yes
       □ No

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

192. What was the disease status?
    □ Complete remission (CR) — no lymphadenopathy; no organomegaly; neutrophils ≥ 1.5 x 10^9/L; platelets > 100 x 10^9/L; hemoglobin > 11.0 g/dL; lymphocytes < 4 x 10^9/L; bone marrow < 30% lymphocytes; absence of constitutional symptoms – Go to question 193
    □ Partial remission (PR) — ≥ 50% decrease in peripheral blood lymphocyte count from pretreatment value; ≥ 50% reduction in lymphadenopathy if present pretreatment; ≥ 50% reduction in liver and spleen size if
enlarged pretreatment; one or more of the following: neutrophils ≥ 1.5 x 10⁹/L or 50% improvement over baseline, platelets > 100 x 10⁹/L or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline – **Go to question 193**

☐ Stable disease (SD) — no change; not complete remission, partial remission, nor progressive disease – **Go to question 193**

☐ Progressive disease (Prog) — one or more of the following: ≥ 50% increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes; ≥ 50% increase in liver or spleen size, or new hepatomegaly or splenomegaly; ≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10⁹/L; transformation to a more aggressive histology – **Go to question 193**

☐ Untreated — no chemotherapy given in the 6 months prior to HCT – **Go to question 193**

☐ Not assessed – **Go to First Name**

193. Date assessed: _____ _____ — _____ — _____

    YYYY    MM    DD