



Chronic Lymphocytic Leukemia (CLL) 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: _____

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

No

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 ($> 15,000 \times 10^9/L$) 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 $< 100 \times 10^9/L$) with or without anemia or enlarged liver, spleen, or lymph nodes

14. Binet stage (at diagnosis)

CIBMTR Center Number: _____

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- Known – **Go to question 15**
- Unknown – **Go to question 16**

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 10⁹/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:

CIBMTR Form 2013 R3 (page 4 of 24). Form released November 2016. Form Last Updated November 2016.

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CIBMTR Center Number: _____

CIBMTR Research ID: _____

Known – **Go to question 23**

Unknown – **Go to question 24**

23. _____ • _____
 x 10⁹/L (x 10³/mm³)
 x 10⁶/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 10⁹/L (x 10³/mm³)
 x 10⁶/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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

$\mu\text{kat/L}$

34. Upper limit of normal for LDH: _____ • _____ U/L
 $\mu\text{kat/L}$

35. Serum β_2 microglobulin:

Known – **Go to question 36**

Unknown– **Go to question 38**

36. _____ • _____ $\mu\text{g/dL}$
 mg/L
 nmol/L

37. Upper limit of normal for serum β_2 microglobulin: _____ • _____ $\mu\text{g/dL}$
 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**

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Not done– **Go to question 46**

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

No

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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: _____ — _____ — _____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

YYYY

MM

DD

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: _____

YYYY

MM

DD

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 $\geq 1.5 \times 10^9/L$; platelets $> 100 \times 10^9/L$; hemoglobin > 11.0 g/dL; lymphocytes $< 4 \times 10^9/L$; bone marrow $< 30\%$ lymphocytes; absence of constitutional symptoms – **Go to question 123**

Partial remission (PR) — $\geq 50\%$ decrease in peripheral blood lymphocyte count from pretreatment value; $\geq 50\%$ reduction in lymphadenopathy if present pretreatment; $\geq 50\%$ reduction in liver and spleen size if enlarged pretreatment; one or more of the following: neutrophils $\geq 1.5 \times 10^9/L$ or 50% improvement over baseline, platelets $> 100 \times 10^9/L$ or 50% improvement over baseline, hemoglobin > 11.0 g/dL or 50% improvement over baseline – **Go to question 123**

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- 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 10⁹/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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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.

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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. Polymphocytes:

Known – **Go to question 157**

Unknown – **Go to question 158**

157. _____ %

158. Serum β_2 microglobulin:

Known – **Go to question 159**

Unknown – **Go to question 161**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Not done

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**

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Unknown – **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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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 $\geq 1.5 \times 10^9/L$; platelets $> 100 \times 10^9/L$; hemoglobin > 11.0 g/dL; lymphocytes $< 4 \times 10^9/L$; bone marrow $< 30\%$ lymphocytes; absence of constitutional symptoms – **Go to question 193**

Partial remission (PR) — $\geq 50\%$ decrease in peripheral blood lymphocyte count from pretreatment value; $\geq 50\%$ reduction in lymphadenopathy if present pretreatment; $\geq 50\%$ reduction in liver and spleen size if

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enlarged pretreatment; one or more of the following: neutrophils $\geq 1.5 \times 10^9/L$ or 50% improvement over baseline, platelets $> 100 \times 10^9/L$ or 50% improvement over baseline, hemoglobin $> 11.0 \text{ g/dL}$ 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: $\geq 50\%$ increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be $\geq 2 \text{ cm}$) or new nodes; $\geq 50\%$ increase in liver or spleen size, or new hepatomegaly or splenomegaly; $\geq 50\%$ increase in absolute lymphocyte count to $\geq 5 \times 10^9/L$; 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