



# 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

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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)

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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 10<sup>9</sup>/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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Known – **Go to question 23**

Unknown – **Go to question 24**

23. \_\_\_\_\_ • \_\_\_\_\_  
 x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/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<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)  
 x 10<sup>6</sup>/L

28. Lymphocytes:

Known – **Go to question 29**

Unknown – **Go to question 30**

29. \_\_\_\_\_ %

30. Polymphocytes:

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  $\beta_2$  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  $\beta_2$  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**

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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

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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



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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

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### 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

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- 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

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84. Chlorambucil (Leukeran)

Yes

No

85. Cladribine (2-CdA, Leustatin)

Yes

No

86. Corticosteroids

Yes

No

87. Cyclophosphamide (Cytosan)

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

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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



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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 ≥  $5 \times 10^9/L$ ; 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



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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**



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**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  $\beta_2$  microglobulin:

Known – **Go to question 159**

Unknown – **Go to question 161**

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159. \_\_\_\_\_ • \_\_\_\_\_
- µg/dL
  - mg/L
  - nmol/L

160. Upper limit of normal for serum β<sub>2</sub> 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

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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**

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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

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**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  $> 11.0$  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  $\geq 2$  lymph nodes ( $\geq 1$  node must be  $\geq 2$  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