CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

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: _____

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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 →

☐ No

4. Date of transformation: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

5. Specify the disease classification after transformation

☐ Diffuse large B-cell lymphoma (Richter syndrome) **– Also complete CIBMTR form 2018 - LYM**

☐ Other disease classification →

6. Specify other disease classification: _____

7. Was documentation submitted to the CIBMTR (e.g. pathology report at transformation)? ☐ Yes ☐ No

Autoimmune disorder(s) at diagnosis:

8. Immune hemolytic anemia ☐ Yes ☐ No ☐ Unknown

9. Immune thrombocytopenia ☐ Yes ☐ No ☐ Unknown

10. Other

☐ Yes →

☐ No

☐ Unknown

11. Specify other autoimmune disorder: _____

12. Rai stage (at diagnosis)

☐ Known →

☐ Unknown

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

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14. Binet stage (at diagnosis)

☐ Known → 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)

☐ Unknown

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 → **Specify site(s) of disease:**

18. Central nervous system (CNS) ☐ Yes ☐ No
19. Lung ☐ Yes ☐ No
20. Other site
    ☐ Yes → 21. Specify other site: _____
    ☐ No

☐ No

Laboratory Studies at Diagnosis

22. WBC:

☐ Known → 23. ___ ___ ___ ___ ___ ___ • ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

☐ Unknown

24. Hemoglobin: (untransfused)

☐ Known → 25. ___ ___ ___ ___ • ___ ___ ☐ g/dL ☐ g/L ☐ mmol/L

☐ Unknown

26. Platelets: (untransfused)

☐ Known → 27. ___ ___ ___ ___ ___ ___ ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

☐ Unknown

28. Lymphocytes:

☐ Known → 29. ___ ___ %

☐ Unknown

30. Prolymphocytes:

☐ Known → 31. ___ ___ %

☐ Unknown

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32. LDH:
- ☐ Known →
  - 33. ___ ___ ___ ___ ___ • ___ ___ ☐ U/L ☐ µkat/L
  - 34. Upper limit of normal for LDH: ___ ___ ___ ___ ___ • ___ ___ ☐ U/L ☐ µkat/L
- ☐ Unknown

35. Serum β2 microglobulin:
- ☐ Known →
  - 36. ___ ___ ___ • ___ ___ ___ ☐ µg/dL ☐ mg/L ☐ nmol/L
  - 37. Upper limit of normal for serum β2 microglobulin: ___ ___ ___ • ___ ___ ___ ☐ µg/dL ☐ mg/L ☐ nmol/L
- ☐ Unknown

38. Lymphocytes in bone marrow
- ☐ Known →
  - 39. ___ ___ ___ %
- ☐ Unknown

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 →
  - 42. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
  - 43. Immunoglobulin heavy chain variable (IGHV) mutation
    - ☐ Positive →
    - ☐ Negative →
      - 44. Specify method used:
        - ☐ ASO IGHV RQ-PCR
        - ☐ Consensus IGHV PCR
        - ☐ Consensus IGHV PCR using HTS
        - ☐ Nested ASO IGHV PCR
        - ☐ Other method → 45. Specify other method: _____
    - ☐ Not done
  - 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 →
    - ☐ Negative →
      - 50. Specify other molecular marker: _____
    - ☐ Not done
  - 51. Was documentation submitted to the CIBMTR? ☐ Yes ☐ No
- ☐ No
- ☐ Unknown

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Immunophenotype: (may be determined at any time after diagnosis)

52. Was flow cytometry (immunophenotyping) performed?

☐ Yes → 53–60 and 61

☐ No

☐ Unknown

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+			

57. CD38+

☐ Positive → 58. Specify percent positivity:
☐ ≥30% positivity ☐ <30% positivity

☐ Negative

☐ Not done

59.	Slg	☐ Positive	☐ Negative	☐ Not done
60.	ZAP-70 - mutated	☐ Positive	☐ Negative	☐ Not done

61. Were cytogenetics tested (karyotyping or FISH)?

☐ Yes → 62

☐ No

☐ Unknown

62. Results of tests:

☐ Abnormalities identified → Specify cytogenetic abnormalities identified at diagnosis:

☐ No evaluable metaphases

☐ No abnormalities

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 → 72. Specify other abnormality: _____

☐ No

73. Was documentation submitted to the CIBMTR (e.g. cytogenetic or FISH report)?

☐ Yes ☐ No

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CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Pre-HCT or Pre-Infusion Therapy

74. Was therapy given?
- ☐ Yes →
- ☐ No
- ☐ Unknown

Line of Therapy

75. Systemic therapy:
- ☐ Yes →
- ☐ No

76. Date therapy started
- ☐ Known →
- ☐ Unknown

77. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

78. Date therapy stopped
- ☐ Known →
- ☐ Unknown

79. Date stopped: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

80. Number of cycles
- ☐ Known →
- ☐ Unknown

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	☐ 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
103.	Rituximab (anti-CD20, Rituxan)	☐ Yes	☐ No
104.	Venetoclax	☐ Yes	☐ No
105.	Vincristine (VCR, Oncovin)	☐ Yes	☐ No

106. Other systemic therapy
- ☐ Yes →
- ☐ No

107. Specify other systemic therapy: _____

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

109. Radiation therapy:
☐ Yes →
☐ No

110. Date therapy started
☐ Known →
☐ Unknown

111. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

112. Date therapy stopped
☐ Known →
☐ Unknown

113. Date stopped: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Specify site(s) of radiation therapy:

114. Mediastinum ☐ Yes ☐ No

115. Other site
☐ Yes →
☐ No

116. Specify other site: _____

117. Surgery:
☐ Yes →
☐ No

118. Date of surgery: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

119. Splenectomy ☐ Yes ☐ No

120. Other site
☐ Yes →
☐ No

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***

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123. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

124. Were tests for molecular markers performed (e.g. PCR)?
- ☐ Yes →
- ☐ No
- ☐ Unknown

125. Date sample collected: __ __ __ __ / __ __ / __ __
YYYY MM DD

126. Immunoglobulin heavy chain variable (IGHV) mutation
- ☐ Positive →
- ☐ Negative →
- ☐ Not done

127. Specify method used:
- ☐ ASO IGHV RQ-PCR
- ☐ Consensus IGHV PCR
- ☐ Consensus IGHV PCR using HTS
- ☐ Nested ASO IGHV PCR
- ☐ Other method →

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 →
- ☐ Negative →
- ☐ Not done

133. Specify other molecular marker:
_____

134. Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?
- ☐ Yes →
- ☐ No

135. Date sample collected: __ __ __ __ / __ __ / __ __
YYYY MM DD

136. Was disease detected? ☐ Yes ☐ No

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137. Was the disease status assessed via cytogenetic testing (karyotyping or FISH)?
- ☐ Yes →
- ☐ No

138. Was the disease status assessed via FISH?
- ☐ Yes →
- ☐ No

139. Date sample collected:
__ __ __ __ / __ __ / __ __
YYYY MM DD

140. Was disease detected?
☐ Yes ☐ No

141. Was the disease status assessed via karyotyping?
- ☐ Yes →
- ☐ No

142. Date sample collected:
__ __ __ __ / __ __ / __ __
YYYY MM DD

143. Was disease detected?
☐ Yes ☐ No

144. Was the disease status assessed by clinical / hematologic assessment?
- ☐ Yes →
- ☐ No

145. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

146. Was disease detected? ☐ Yes ☐ No

147. Did disease relapse/progress following this line of therapy?
- ☐ Yes →
- ☐ No

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 →
- ☐ No

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

151. Was extranodal disease present?
- ☐ Yes →
- ☐ No

Specify site(s) of involvement:

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

153. Lung ☐ Yes ☐ No

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154. Other site
- ☐ Yes → 155. Specify other site: _____
- ☐ No

156. Prolymphocytes
- ☐ Known → 157. ___ ___ %
- ☐ Unknown

158. Serum β2 microglobulin:
- ☐ Known →
  159. ___ ___ ___ • ___ ___ ___ ☐ µg/dL ☐ mg/L ☐ nmol/L
  160. Upper limit of normal for serum β2 microglobulin: ___ ___ ___ ___ ___ • ___ ___
  ☐ µg/dL ☐ mg/L ☐ nmol/L
- ☐ Unknown

161. Lymphocytes in bone marrow:
- ☐ Known → 162. ___ ___ ___ %
- ☐ Unknown

163. Were tests for molecular markers performed (e.g. PCR)?
- ☐ Yes →
  164. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
  165. Immunoglobulin heavy chain variable (IGHV) mutation
  - ☐ Positive →
    166. Specify method used:
    - ☐ ASO IGHV RQ-PCR
    - ☐ Consensus IGHV PCR
    - ☐ Consensus IGHV PCR using HTS
    - ☐ Nested ASO IGHV PCR
    - ☐ Other method → 167. Specify other method: _____
  - ☐ Negative
  - ☐ Not done

  168. NOTCH 1 mutation ☐ Positive ☐ Negative ☐ Not done
  169. P53 mutation ☐ Positive ☐ Negative ☐ Not done
  170. SF3B1 mutation ☐ Positive ☐ Negative ☐ Not done
  171. Other molecular marker
  - ☐ Positive →
  - ☐ Negative → 172. Specify other molecular marker: _____
  - ☐ Not done

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

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174. Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?

☐ Yes → 175. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

176. Was disease detected? ☐ Yes ☐ No

☐ No

177. Were cytogenetics tested (karyotyping or FISH)?

☐ Yes → 178. Results of tests:

- ☐ Abnormalities identified →

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 → 188. Specify other abnormality: _____

☐ No

- ☐ No evaluable metaphases
- ☐ No abnormalities

☐ No

☐ Unknown

189. Was the disease status assessed by clinical / hematologic assessment?

☐ Yes → 190. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

191. Was disease detected? ☐ Yes ☐ No

☐ No

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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 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 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 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

First Name: _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __
YYYY MM DD

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