Chronic Lymphocytic Leukemia (CLL)
Pre-Infusion Data

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: ____________________

Registry Use Only
Sequence Number:
Date Received:
# 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: __  __  __  __ / __  __ / __  __
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?
4. Date of transformation: __  __  __  __ / __  __ / __  __
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
14. Binet stage (at diagnosis)
- [ ] Known
- [ ] Unknown

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
- [ ] No

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

19. Lung
- [ ] Yes
- [ ] No

20. Other site
- [ ] Yes
- [ ] No

21. Specify other site:
______________________________

22. WBC:
- [ ] Known
- [ ] Unknown

23. ____________ x 10^9/L (x 10^3/mm^3)  x 10^6/L

24. Hemoglobin: (untransfused)
- [ ] Known
- [ ] Unknown

25. ____________ • __________ g/dL  g/L  mmol/L

26. Platelets: (untransfused)
- [ ] Known
- [ ] Unknown

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

28. Lymphocytes:
- [ ] Known
- [ ] Unknown

29. __ __ %

30. Prolymphocytes:
- [ ] Known
- [ ] Unknown

31. __ __ %
32. LDH:
☐ Known
☐ Unknown

33. ____ ____ • ____ __ U/L µkat/L

34. Upper limit of normal for LDH: ____ ____ • ____ __ U/L µkat/L

35. Serum β2 microglobulin:
☐ Known
☐ Unknown

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
☐ Unknown

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
☐ No
☐ Unknown

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

43. Immunoglobulin heavy chain variable (IGHV) mutation
☐ Positive
☐ Negative
☐ Not done

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:
_____________________________

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
☐ Not done

50. Specify other molecular marker:
_____________________________

51. Was documentation submitted to the CIBMTR?
☐ Yes
☐ No
### Immunophenotype: (may be determined at any time after diagnosis)

52. Was flow cytometry (immunophenotyping) performed?
- [ ] Yes
- [ ] 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+  
   - [ ] Positive
   - [ ] Negative
   - [ ] Not done

58. Specify percent positivity:  
   - [ ] ≥30% positivity
   - [ ] <30% positivity

59. Slg  
   - [ ] Positive
   - [ ] Negative
   - [ ] Not done

60. ZAP-70 - mutated  
   - [ ] Positive
   - [ ] Negative
   - [ ] Not done

### Cytogenetics

61. Were cytogenetics tested (karyotyping or FISH)?
- [ ] Yes
- [ ] No
- [ ] Unknown

62. Results of tests:  
   - [ ] Abnormalities identified
   - [ ] No evaluable metaphases
   - [ ] No abnormalities

**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  
   - [ ] No

72. Specify other abnormality:
   ______________________________

73. Was documentation submitted to the CIBMTR (e.g. cytogenetic or FISH report)?
- [ ] Yes
- [ ] No
74. Was therapy given?
- [ ] Yes
- [ ] No
- [ ] Unknown

**Pre-HCT or Pre-Infusion Therapy**

<table>
<thead>
<tr>
<th>Line of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>75. Systemic therapy:</strong></td>
</tr>
<tr>
<td>- [ ] Yes</td>
</tr>
<tr>
<td>- [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date therapy started</th>
</tr>
</thead>
<tbody>
<tr>
<td>- [ ] Known</td>
</tr>
<tr>
<td>- [ ] Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date therapy stopped</th>
</tr>
</thead>
<tbody>
<tr>
<td>- [ ] Known</td>
</tr>
<tr>
<td>- [ ] Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>- [ ] Known</td>
</tr>
<tr>
<td>- [ ] Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>76. Date therapy started</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYYY-MM-DD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>77. Date started: YYYY-MM-DD</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>78. Date therapy stopped</th>
</tr>
</thead>
<tbody>
<tr>
<td>YYYY-MM-DD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>79. Date stopped: YYYY-MM-DD</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>80. Number of cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>___ ___</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>81. Number of cycles: ___ ___</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>82. Alemtuzumab (Campath)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>83. Bendamustine</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>84. Chlorambucil (Leukeran)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>85. Cladribine (2-CdA, Leustatin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>86. Corticosteroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>87. Cyclophosphamide (Cytoxan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>88. Cytarabine (Ara-C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>89. Doxorubicin (Adriamycin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>90. Etoposide (VP-16, VePesid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>91. Fludarabine (Fludara)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>92. Gemcitabine (Gemzar)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>93. Ibrutinib (Imbruvica)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>94. Idelalisib (Zydelig)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>95. Ifosfamide (Ifex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>96. Lenalidomide (Revlimid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>97. Nelarabine</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>98. Nitrogen mustard (mustine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>99. Obinutuzumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>100. Obrimersen</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>101. Ofatumumab (Arzerra, HuMax-CD20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>102. Pentostatin (Nipent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>103. Rituximab (anti-CD20, Rituixan)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>104. Venetoclax</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>105. Vincristine (VCR, Oncovin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>106. Other systemic therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

| 107. Specify other systemic therapy: ____________________ |
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
### 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

---

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>137. Was the disease status assessed via cyogenetic testing (karyotyping or FISH)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>138. Was the disease status assessed via FISH?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>139. Date sample collected:</td>
<td>YYYY / MM / DD</td>
<td></td>
</tr>
<tr>
<td>140. Was disease detected?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>141. Was the disease status assessed via karyotyping?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>142. Date sample collected:</td>
<td>YYYY / MM / DD</td>
<td></td>
</tr>
<tr>
<td>143. Was disease detected?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>144. Was the disease status assessed by clinical / hematologic assessment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>145. Date assessed:</td>
<td>YYYY / MM / DD</td>
<td></td>
</tr>
<tr>
<td>146. Was disease detected?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>147. Did disease relapse/progress following this line of therapy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>148. Date of relapse/progression:</td>
<td>YYYY / MM / DD</td>
<td></td>
</tr>
</tbody>
</table>

Copy questions 75-148 if needed for multiple lines of therapy.
174. Was the disease status assessed via flow cytometry (minimum 4-color flow) (immunophenotyping)?
☐ Yes
☐ No

175. Date sample collected: __ __ __ __ / __ __ / __ __

176. Was disease detected?
☐ Yes
☐ No

177. Were cytogenetics tested (karyotyping or FISH)?
☐ Yes
☐ No
☐ Unknown

178. Results of tests:
☐ Abnormalities identified
☐ No evaluable metaphases
☐ No abnormalities

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
      ________________________________

189. Was the disease status assessed by clinical / hematologic assessment?
☐ Yes
☐ No

190. Date assessed: __ __ __ __ / __ __ / __ __

191. Was disease detected?
☐ Yes
☐ No
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

First Name: ____________________________________________________

Last Name: ____________________________________________________

E-mail address: ________________________________________________

Date: __ __ __ __/ __ __/ __ __

YYYY MM DD