



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

Subsequent Infusion

If this is a report of a second or subsequent infusion for the same disease subtype and this baseline disease insert has not been completed for the previous infusion (e.g. recipient was on TED track for the prior infusion, prior infusion was autologous with no consent, prior infusion was not reported to the CIBMTR), begin the form at question two.

If this is a report of a second or subsequent infusion for a different disease, begin the form at question two.

- 1. Is this the report of a second or subsequent infusion for the same disease?
 - Yes - **Go to questions 48**
 - No - **Go to question 2**

Disease Assessment at Diagnosis

- 2. Specify hematologic autoimmune disorder(s) *(check all that apply)*
 - Cold agglutinin disease (CAD)
 - Immune neutropenia
 - Immune thrombocytopenia
 - None

- 3. Rai stage
 - Known – **Go to question 4**
 - Unknown – **Go to question 5**

- 4. What was the Rai stage?
 - Stage 0 - Low risk — lymphocytosis (> 15,000 x 10⁹/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 10⁹/L) with or without anemia or enlarged liver, spleen, or lymph nodes

- 5. 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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

6. Was extranodal disease present?
- Yes – **Go to questions 7**
 - No – **Go to question 9**
7. Specify site(s) of involvement (*extranodal disease involves sites other than the lymph nodes, spleen and thymus*) (*check all that apply*)
- Bone marrow – **Go to questions 9**
 - Central nervous system (CNS) – **Go to questions 9**
 - Lung – **Go to questions 9**
 - Other site – **Go to questions 8**
8. Specify other site: _____

Laboratory Studies at Diagnosis

9. Specify all known laboratory values (*check all that apply*)
- WBC – **Go to questions 10**
 - Hemoglobin (*untransfused*) – **Go to question 11**
 - Platelets (*untransfused*) – **Go to question 12**
 - Lymphocytes – **Go to questions 13**
 - Polymphocytes – **Go to questions 14**
 - LDH – **Go to questions 15**
 - Serum β 2 microglobulin – **Go to questions 16**
 - None – **Go to questions 18**
10. WBC: _____ • $\times 10^9/L$ ($\times 10^3/mm^3$)
 $\times 10^6/L$
11. Hemoglobin: (*untransfused*) _____ • _____ g/dL
 g/L
 mmol/L
12. Platelets: (*untransfused*) _____ $\times 10^9/L$ ($\times 10^3/mm^3$)
 $\times 10^6/L$
13. Lymphocytes: _____ %
14. Polymphocytes: _____ %

CIBMTR Center Number: _____ CIBMTR Research ID: _____

15. LDH: _____ • _____ U/L
 μ kat/L

16. Serum β 2 microglobulin: _____ • _____ μ g/dL
 mg/L
 nmol/L

17. Upper limit of normal for serum β 2 microglobulin: _____ • _____

18. Lymphocytes in bone marrow

- Known – **Go to question 19**
- Unknown – **Go to question 20**

19. Lymphocytes in bone marrow: _____ %

Molecular markers

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

- Yes – **Go to question 21**
- No – **Go to question 30**

21. Specify positive mutation(s) (*check all that apply*)

- ATM – **Go to question 28**
- BTK – **Go to question 25**
- Immunoglobulin heavy chain variable (IGHV) mutation – **Go to question 22**
- MyD88 – **Go to question 28**
- NOTCH 1 mutation – **Go to question 28**
- PLCgamma2 – **Go to question 28**
- SF3B1 mutation – **Go to question 28**
- Other molecular marker – **Go to question 27**
- None – **Go to question 28**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

22. Specify IGHV mutation (*check all that apply*)
- IGHV1-5-7 / IGHD6-19 / IGHJ4 gene rearrangement with a light chain IGKV1-39 / IGKJ1-2 gene rearrangement – **Go to question 24**
 - IGHV3-21 / IGLV3-21 – **Go to question 24**
 - IGHV4-34 / IGHD5-18 / IGHJ6 gene rearrangement and a light chain IGKV2-30 / IGKJ1-2 rearrangement – **Go to question 24**
 - IGHV4-39 / IGHD6-13 / IGHJ5 gene rearrangements – **Go to question 24**
 - Other IGHV mutation – **Go to question 23**
 - Unknown – **Go to question 27**

23. Specify other IGHV mutation: _____

24. Percentage of cells (IGHV) mutation: ___ %

25. Specify BTK mutation (*check all that apply*)
- C481S - **Go to question 27**
 - Other – **Go to question 26**
 - Unknown – **Go to question 27**

26. Specify other BTK mutation: _____

27. Specify other molecular marker: _____

28. P53 / TP53 mutation
- Positive
 - Negative
 - Not done

29. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the molecular marker report*)
- Yes
 - No

Flow cytometry (immunophenotyping)

30. Was flow cytometry performed? (*minimum 4-color flow*) (*immunophenotyping*)
- Yes - **Go to question 31**
 - No - **Go to question 34**

31. Specify positive immunophenotyping (*check all that apply*)
- CD5+ – **Go to question 33**

CIBMTR Center Number: _____

CIBMTR Research ID: _____

- CD19+ – **Go to question 33**
- CD20+ – **Go to question 33**
- CD23+ – **Go to question 33**
- CD38+ – **Go to question 32**
- CD200+ – **Go to question 33**
- Slg – **Go to question 33**
- ZAP-70 – mutated – **Go to question 33**
- None – **Go to question 34**

32. Specify percent positivity (*CD38+*)

- ≥30% positivity
- <30% positivity

33. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the flow cytometry report*)

- Yes
- No

Cytogenetics

34. Were cytogenetics tested? (*FISH or karyotyping*)

- Yes – **Go to question 35**
- No – **Go to question 48**

35. Were cytogenetics tested via FISH?

- Yes – **Go to question 36**
- No – **Go to question 40**

36. Results of tests

- Abnormalities identified – **Go to questions 37**
- No abnormalities – **Go to question 40**

37. International System for Human Cytogenetic Nomenclature (ISCN) compatible string:

_____105

38. Specify cytogenetic abnormalities (*check all that apply*)

Trisomy

+12, MDM2 – **Go to question 40**

Translocation

t(11;14), IGH-CCND1– **Go to question 40**

Any other translocation of 14 – **Go to question 40**

Deletion

del(11q) / 11q–, ATM – **Go to question 40**

del(13q) / 13q–, D13S319 or LSI13q34 – **Go to question 40**

del(17p) / 17p–, P53 – **Go to question 40**

Other

Any chromosome 6 abnormalities – **Go to question 40**

Any chromosome 8 abnormalities – **Go to question 40**

BCL2 rearrangement – **Go to question 40**

BCL6 rearrangement – **Go to question 40**

CyclinD1 – **Go to question 40**

Other abnormality – **Go to question 39**

39. Specify other abnormality: _____

40. Were cytogenetics tested via karyotyping?

Yes – **Go to question 41**

No – **Go to question 47**

41. What type of cytogenetic karyotype was performed?

Stimulated karyotype

Unstimulated karyotype

42. Results of tests

Abnormalities identified – **Go to questions 43**

No evaluable metaphases – **Go to question 47**

No abnormalities – **Go to question 47**

43. International System for Human Cytogenetic Nomenclature (ISCN) compatible string:

44. Specify number of cytogenetic abnormalities

< 3

3 – 5

CIBMTR Center Number: _____ CIBMTR Research ID: _____

> 5

45. Specify cytogenetic abnormalities (*check all that apply*)

Trisomy

+12 – **Go to question 47**

Translocation

t(11;14) – **Go to question 47**

Any other translocation of 14 – **Go to question 47**

Deletion

del(11q) / 11q– – **Go to question 47**

del(13q) / 13q– – **Go to question 47**

del(17p) / 17p– – **Go to question 47**

Other

Any chromosome 6 abnormalities – **Go to question 47**

Any chromosome 8 abnormalities – **Go to question 47**

Other abnormality – **Go to question 46**

46. Specify other abnormality: _____

47. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the cytogenetics FISH / karyotyping report*)

Yes

No

Pre-Infusion Therapy

48. Was therapy given?

Yes – **Go to question 49**

No – **Go to question 105**

Unknown – **Go to question 105**

Copy and complete questions 49 – 104 if needed for multiple lines of therapy.

Line of Therapy

49. Systemic therapy

Yes – **Go to questions 50**

No – **Go to question 61**

50. Date therapy started

CIBMTR Center Number: _____ CIBMTR Research ID: _____

YYYY MM DD

76. Specify positive mutation(s) *(check all that apply)*

- ATM – **Go to question 83**
- BTK – **Go to question 80**
- Immunoglobulin heavy chain variable (IGHV) mutation – **Go to question 77**
- MyD88 – **Go to question 83**
- NOTCH 1 mutation – **Go to question 83**
- PLCgamma2 – **Go to question 83**
- SF3B1 mutation – **Go to question 83**
- Other molecular marker – **Go to question 82**
- None – **Go to question 83**

77. Specify IGHV mutation *(check all that apply)*

- IGHV1-5-7 / IGHD6-19 / IGHJ4 gene rearrangement with a light chain IGKV1-39 / IGKJ1-2 gene rearrangement – **Go to question 79**
- IGHV3-21 / IGLV3-21 – **Go to question 79**
- IGHV4-34 / IGHD5-18 / IGHJ6 gene rearrangement and a light chain IGKV2-30 / IGKJ1-2 rearrangement – **Go to question 79**
- IGHV4-39 / IGHD6-13 / IGHJ5 gene rearrangements – **Go to question 79**
- Other IGHV mutation – **Go to question 78**
- Unknown – **Go to question 82**

78. Specify other IGHV mutation: _____

79. Percentage of cells (IGHV) mutation: ___ %

80. Specify BTK mutation *(check all that apply)*

- C481S - **Go to question 82**
- Other – **Go to question 81**
- Unknown – **Go to question 82**

81. Specify other BTK mutation: _____

82. Specify other molecular marker: _____

83. P53 / TP53 mutation

- Positive
- Negative
- Not done

CIBMTR Center Number: _____ CIBMTR Research ID: _____

84. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the molecular marker report*)
- Yes
 - No

Flow cytometry (immunophenotyping)

85. Was the disease status assessed via flow cytometry? (*minimum 4-color flow*) (*immunophenotyping*)
- Yes - **Go to question 86**
 - No - **Go to question 89**
86. Date sample collected: _____
- YYYY MM DD
87. Was disease detected?
- Yes
 - No
88. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the flow cytometry report*)
- Yes
 - No

Cytogenetics

89. Was the disease status assessed via cytogenetic testing? (*FISH or karyotyping*)
- Yes - **Go to questions 90**
 - No - **Go to question 105**
90. Were cytogenetics tested via FISH?
- Yes – **Go to question 91**
 - No – **Go to question 95**
91. Results of tests
- Abnormalities identified – **Go to questions 92**
 - No abnormalities – **Go to question 95**
92. International System for Human Cytogenetic Nomenclature (ISCN) compatible string: _____
93. Specify cytogenetic abnormalities (*check all that apply*)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

Trisomy

- +12, MDM2 – **Go to questions 95**

Translocation

- t(11;14), IGH-CCND1– **Go to questions 95**
- Any other translocation of 14 – **Go to questions 95**

Deletion

- del(11q) / 11q–, ATM – **Go to questions 95**
- del(13q) / 13q–, D13S319 / LSI13q34 – **Go to questions 95**
- del(17p) / 17p–, P53 – **Go to questions 95**

Other

- Any chromosome 6 abnormalities – **Go to questions 95**
- Any chromosome 8 abnormalities – **Go to questions 95**
- BCL2 rearrangement – **Go to questions 95**
- BCL6 rearrangement – **Go to questions 95**
- CyclinD1 – **Go to questions 95**
- Other abnormality – **Go to question 94**

94. Specify other abnormality: _____

95. Were cytogenetics tested via karyotyping?

- Yes – **Go to question 96**
- No – **Go to question 102**

96. What type of cytogenetic karyotype was performed?

- Stimulated karyotype
- Unstimulated karyotype

97. Results of tests

- Abnormalities identified – **Go to questions 98**
- No evaluable metaphases – **Go to question 102**
- No abnormalities – **Go to question 102**

98. International System for Human Cytogenetic Nomenclature (ISCN) compatible string: _____

99. Specify number of cytogenetic abnormalities

- < 3
- 3 – 5
- > 5

CIBMTR Center Number: _____ CIBMTR Research ID: _____

107. Was extranodal disease present?

- Yes – **Go to questions 108**
- No – **Go to question 110**

108. Specify site(s) of involvement (*extranodal disease involves sites other than the lymph nodes, spleen, and thymus*) (*check all that apply*)

- Bone marrow – **Go to questions 110**
- Central nervous system (CNS) – **Go to questions 110**
- Lung – **Go to questions 110**
- Other site – **Go to questions 109**

109. Specify other site: _____

110. Was lymphadenopathy present?

- Yes
- No

111. Polymphocytes

- Known – **Go to question 112**
- Unknown – **Go to question 113**

112. Polymphocytes: _____ %

113. Serum β 2 microglobulin

- Known – **Go to question 114**
- Unknown – **Go to question 116**

114. Serum β 2 microglobulin: _____ • _____ μ g/dL

mg/L

nmol/L

115. Upper limit of normal for serum β 2 microglobulin: _____ • _____

116. Lymphocytes in bone marrow

- Known – **Go to question 117**
- Unknown – **Go to question 118**

117. Lymphocytes in bone marrow: _____ %

Molecular markers

CIBMTR Center Number: _____ CIBMTR Research ID: _____

136. Sample source

- Blood
- Bone marrow

137. Was disease or measurable residual disease detected?

- Yes
- No

138. Specify the sensitivity of test for MRD (*i.e level of detection*)

- 10^{-4}
- 10^{-5}
- 10^{-6}
- Unknown

139. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the flow cytometry report*)

- Yes
- No

Cytogenetics

140. Were cytogenetics tested? (*FISH or karyotyping*)

- Yes – **Go to question 141**
- No – **Go to question 154**

141. Were cytogenetics tested via FISH?

- Yes – **Go to question 142**
- No – **Go to question 146**

142. Results of tests

- Abnormalities identified – **Go to questions 143**
- No abnormalities – **Go to question 146**

143. International System for Human Cytogenetic Nomenclature (ISCN) compatible string:

144. Specify cytogenetic abnormalities (*check all that apply*)

Trisomy

- +12, MDM2 – **Go to question 146**

Translocation

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- t(11;14), IGH-CCND1 – **Go to question 146**
- Any other translocation of 14 – **Go to question 146**

Deletion

- del(11q) / 11q–, ATM – **Go to question 146**
- del(13q) / 13q–, D13S319 or LSI13q34 – **Go to question 146**
- del(17p) / 17p–, P53 – **Go to question 146**

Other

- Any chromosome 6 abnormalities – **Go to question 146**
- Any chromosome 8 abnormalities – **Go to question 146**
- BCL2 rearrangement – **Go to question 146**
- BCL6 rearrangement – **Go to question 146**
- CyclinD1 – **Go to question 146**
- Other abnormality – **Go to question 145**

145. Specify other abnormality: _____

146. Were cytogenetics tested via karyotyping?

- Yes – **Go to question 147**
- No – **Go to question 153**

147. What type of cytogenetic karyotype was performed?

- Stimulated karyotype
- Unstimulated karyotype

148. Results of tests

- Abnormalities identified – **Go to questions 149**
- No evaluable metaphases – **Go to question 153**
- No abnormalities – **Go to question 153**

149. International System for Human Cytogenetic Nomenclature (ISCN) compatible string:

150. Specify number of cytogenetic abnormalities

- < 3
- 3 – 5
- > 5

151. Specify cytogenetic abnormalities (*check all that apply*)

Trisomy

CIBMTR Center Number: _____ CIBMTR Research ID: _____

+12 – **Go to question 153**

Translocation

t(11;14) – **Go to question 153**

Any other translocation of 14 – **Go to question 153**

Deletion

del(11q) / 11q- – **Go to question 153**

del(13q) / 13q- – **Go to question 153**

del(17p) / 17p- – **Go to question 153**

Other

Any chromosome 6 abnormalities – **Go to question 153**

Any chromosome 8 abnormalities – **Go to question 153**

Other abnormality – **Go to question 152**

152. Specify other abnormality: _____

153. Was documentation submitted to the CIBMTR? (*CIBMTR strongly encourages attaching the cytogenetics FISH / karyotyping*)

Yes

No

154. Hypogammaglobulinemia

Yes

No

Not applicable (*IgG is not assessed*)