Form 2402 R3.0: Disease Classification

Center: CRID:

Key Fields

OMB No: 0915-0310

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Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Primary Disease for HCT / Cellular Therapy

Questions: 1 - 2

1 Date of diagnosis of primary disease for HCT / cellular therapy: __ __ __ __ - __ __- __ __

2 What was the primary disease for which the HCT / cellular therapy was performed?

- ○ Acute myelogenous leukemia (AML or ANLL) (10)
- ○ Acute lymphoblastic leukemia (ALL) (20)
- ○ Acute leukemia of ambiguous lineage and other myeloid neoplasms (80)
- ○ Chronic myelogenous leukemia (CML) (40)
- ○ Myelodysplastic (MDS) / myeloproliferative (MPN) diseases (50) (Please classify all preleukemias) (If recipient has transformed to AML, indicate AML as the primary disease)
- ○ Other leukemia (30) (includes CLL)
- ○ Hodgkin lymphoma (150)
- ○ Non-Hodgkin lymphoma (100)
- ○ Multiple myeloma / plasma cell disorder (PCD) (170)
- ○ Solid tumors (200)
- ○ Severe aplastic anemia (300) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease)
- ○ Inherited abnormalities of erythrocyte differentiation or function (310)
- ○ Disorders of the immune system (400)
- ○ Inherited abnormalities of platelets (500)
- ○ Inherited disorders of metabolism (520)
- ○ Histiocytic disorders (570)
- ○ Autoimmune diseases (600)
- ○ Other disease (900)

Acute Myelogenous Leukemia (AML)

Questions: 3 - 89

3 Specify the AML classification _____

4 Did AML transform from MDS or MPN?

- ○ yes **- Also complete MDS Disease Classification questions**
- ○ no

5 Is the disease (AML) therapy related?

- ○ yes ○ no ○ Unknown

6 Did the recipient have a predisposing condition?

- ○ yes ○ no ○ Unknown

7 Specify condition

- ○ Bloom syndrome
- ○ Down syndrome
- ○ Fanconi anemia
- ○ Dyskeratosis congenita
- ○ Other condition

8 Specify other condition: _____

Labs at diagnosis

9 Were cytogenetics tested (karyotyping or FISH)? (at diagnosis)

- ○ yes ○ no ○ Unknown

10 Were cytogenetics tested via FISH? (at diagnosis)

- ○ Yes ○ No

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11 Results of tests

- ○ Abnormalities identified
- ○ No abnormalities

Specify cytogenetic abnormalities identified at diagnosis:

12 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

13 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
- ☐ t(8;21)
- ☐ t(9;11)
- ☐ t(9;22)
- ☐ t(15;17) and variants
- ☐ t(16;16)
- ☐ del(3q) / 3q-
- ☐ del(5q) / 5q-
- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

14 Specify other abnormality: _____

15 Were cytogenetics tested via karyotyping? (at diagnosis)

○ Yes ○ No

16 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

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Specify cytogenetic abnormalities identified at diagnosis:

17 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

18 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
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- ☐ t(9;11)
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- ☐ t(15;17) and variants
- ☐ t(16;16)
- ☐ del(3q) / 3q-
- ☐ del(5q) / 5q-
- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

19 Specify other abnormality: _____

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

○ Yes ○ No

21 Were tests for molecular markers performed? (e.g. PCR, NGS) (at diagnosis)

○ yes ○ no ○ Unknown

Specify molecular markers identified at diagnosis:

22 CEBPA

○ Positive ○ Negative ○ Not Done

23 Specify CEBPA mutation

- ○ Biallelic (homozygous)
- ○ Monoallelic (heterozygous)
- ○ Unknown

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24 FLT3 – D835 point mutation
Positive Negative Not Done

25 FLT3 – ITD mutation
Positive Negative Not Done

26 FLT3 - ITD allelic ratio
Known Unknown

27 Specify FLT3 - ITD allelic ratio: _____

28 IDH1
Positive Negative Not Done

29 IDH2
Positive Negative Not Done

30 KIT
Positive Negative Not Done

31 NPM1
Positive Negative Not Done

Other Molecular Marker (1) — Questions: 32 - 33

32 Other molecular marker
Positive Negative Not Done

33 Specify other molecular marker: _____

Labs between diagnosis and last evaluation:

34 Were cytogenetics tested (karyotyping or FISH)? (between diagnosis and last evaluation)
yes no Unknown

35 Were cytogenetics tested via FISH? (between diagnosis and last evaluation)
Yes No

36 Results of tests
Abnormalities identified
No abnormalities

Specify cytogenetic abnormalities identified between diagnosis and last evaluation:

37 Specify number of distinct cytogenetic abnormalities
One (1)
Two (2)
Three (3)
Four or more (4 or more)

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38 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
- ☐ t(8;21)
- ☐ t(9;11)
- ☐ t(9;22)
- ☐ t(15;17) and variants
- ☐ t(16;16)
- ☐ del(3q) / 3q-
- ☐ del(5q) / 5q-
- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

39 Specify other abnormality: _____

40 Were cytogenetics tested via karyotyping? (between diagnosis and last evaluation)

○ Yes ○ No

41 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified between diagnosis and last evaluation:

42 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

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43 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
- ☐ t(3;3)
- ☐ t(6;9)
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- ☐ del(5q) / 5q-
- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

44 Specify other abnormality: _____

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

○ Yes ○ No

46 Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis and last evaluation)

○ yes ○ no ○ Unknown

Specify molecular markers identified between diagnosis and last evaluation:

47 CEBPA

○ Positive ○ Negative ○ Not Done

48 Specify CEBPA mutation

- ○ Biallelic (homozygous)
- ○ Monoallelic (heterozygous)
- ○ Unknown

49 FLT3 – D835 point mutation

○ Positive ○ Negative ○ Not Done

50 FLT3 – ITD mutation

○ Positive ○ Negative ○ Not Done

51 FLT3 - ITD allelic ratio

○ Known ○ Unknown

52 Specify FLT3 - ITD allelic ratio: _____

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53 IDH1

Positive Negative Not Done

54 IDH2

Positive Negative Not Done

55 KIT

Positive Negative Not Done

56 NPM1

Positive Negative Not Done

Other Molecular Marker (1) **Questions: 57 - 58**

57 Other molecular marker

Positive Negative Not Done

58 Specify other molecular marker: _____

Labs at last evaluation:

59 Were cytogenetics tested (karyotyping or FISH)? (at last evaluation)

yes no Unknown

60 Were cytogenetics tested via FISH? (at last evaluation)

Yes No

61 Results of tests

Abnormalities identified

No abnormalities

Specify cytogenetic abnormalities identified at last evaluation:

62 Specify number of distinct cytogenetic abnormalities

One (1)

Two (2)

Three (3)

Four or more (4 or more)

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63 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
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- ☐ del(7q) / 7q-
- ☐ del(9q) / 9q-
- ☐ del(11q) / 11q-
- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

64 Specify other abnormality: _____

65 Were cytogenetics tested via karyotyping? (at last evaluation)

○ Yes ○ No

66 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified at last evaluation:

67 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

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68 Specify abnormalities (check all that apply)

- ☐ -5
- ☐ -7
- ☐ -17
- ☐ -18
- ☐ -X
- ☐ -Y
- ☐ +4
- ☐ +8
- ☐ +11
- ☐ +13
- ☐ +14
- ☐ +21
- ☐ +22
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- ☐ del(16q) / 16q-
- ☐ del(17q) / 17q-
- ☐ del(20q) / 20q-
- ☐ del(21q) / 21q-
- ☐ inv(3)
- ☐ inv(16)
- ☐ (11q23) any abnormality
- ☐ 12p any abnormality
- ☐ Other abnormality

69 Specify other abnormality: _____

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

○ Yes ○ No

71 Were tests for molecular markers performed? (e.g. PCR, NGS) (at last evaluation)

○ yes ○ no ○ Unknown

Specify molecular markers identified at last evaluation:

72 CEBPA

○ Positive ○ Negative ○ Not Done

73 Specify CEBPA mutation

- ○ Biallelic (homozygous)
- ○ Monoallelic (heterozygous)
- ○ Unknown

74 FLT3 – D835 point mutation

○ Positive ○ Negative ○ Not Done

75 FLT3 – ITD mutation

○ Positive ○ Negative ○ Not Done

76 FLT3 - ITD allelic ratio

○ Known ○ Unknown

77 Specify FLT3 - ITD allelic ratio: _____

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78 IDH1

Positive Negative Not Done

79 IDH2

Positive Negative Not Done

80 KIT

Positive Negative Not Done

81 NPM1

Positive Negative Not Done

Other Molecular Marker (1) — Questions: 82 - 83

82 Other molecular marker

Positive Negative Not Done

83 Specify other molecular marker: _____

CNS Leukemia

84 Did the recipient have central nervous system leukemia at any time prior to the start of the preparative regimen / infusion?

yes no Unknown

Status at transplantation:

85 What was the disease status (based on hematological test results)?

- Primary induction failure
- 1st complete remission (no previous bone marrow or extramedullary relapse) (include CRi)
- 2nd complete remission
- ≥3rd complete remission
- 1st relapse
- 2nd relapse
- ≥3rd relapse
- No treatment

86 How many cycles of induction therapy were required to achieve 1st complete remission? (includes CRi)

1 2 ≥ 3

87 Was the recipient in remission by flow cytometry?

Yes No Unknown Not applicable

88 Date of most recent relapse: __ __ __ __ - __ __- __ __

89 Date assessed: __ __ __ __ - __ __- __ __

Acute Lymphoblastic Leukemia (ALL) — Questions: 90 - 151

90 Specify ALL classification _____

91 Did the recipient have a predisposing condition?

yes no Unknown

92 Specify condition

- Aplastic anemia **- Also complete CIBMTR Form 2028 - APL**
- Bloom syndrome
- Down syndrome
- Fanconi anemia **- Also complete CIBMTR Form 2029 - FAN**
- Other condition

93 Specify other condition: _____

94 Were tyrosine kinase inhibitors given for therapy at any time prior to the start of the preparative regimen / infusion? (e.g. imatinib mesylate, dasatinib, etc.)

yes no

Laboratory studies at diagnosis:

95 Were cytogenetics tested (karyotyping or FISH)? (at diagnosis)

yes no Unknown

96 Were cytogenetics tested via FISH? (at diagnosis)

Yes No

97 Results of tests

- Abnormalities identified
- No abnormalities

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Specify cytogenetic abnormalities identified at diagnosis:

98 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

99 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

100 Specify other abnormality: _____

101 Were cytogenetics tested via karyotyping? (at diagnosis)

○ Yes ○ No

102 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified at diagnosis:

103 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

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104 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

105 Specify other abnormality: _____

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

○ Yes ○ No

107 Were tests for molecular markers performed? (e.g. PCR, NGS) (at diagnosis)

○ yes ○ no ○ Unknown

Specify molecular markers identified at diagnosis:

108 BCR / ABL

○ Positive ○ Negative ○ Not Done

109 TEL-AML / AML1

○ Positive ○ Negative ○ Not Done

Other Molecular Marker (1) **Questions: 110 - 111**

110 Other molecular marker

○ Positive ○ Negative ○ Not Done

111 Specify other molecular marker: _____

Laboratory studies between diagnosis and last evaluation:

112 Were cytogenetics tested (karyotyping or FISH)? (between diagnosis and last evaluation)

○ yes ○ no ○ Unknown

113 Were cytogenetics tested via FISH? (between diagnosis and last evaluation)

○ Yes ○ No

114 Results of tests

- ○ Abnormalities identified
- ○ No abnormalities

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Specify cytogenetic abnormalities identified between diagnosis and last evaluation:

115 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

116 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

117 Specify other abnormality: _____

118 Were cytogenetics tested via karyotyping? (between diagnosis and last evaluation)

○ Yes ○ No

119 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified between diagnosis and last evaluation:

120 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

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121 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

122 Specify other abnormality: _____

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

○ Yes ○ No

124 Were tests for molecular markers performed? (e.g. PCR, NGS) (between diagnosis and last evaluation)

○ yes ○ no ○ Unknown

Specify molecular markers identified between diagnosis and last evaluation:

125 BCR / ABL

○ Positive ○ Negative ○ Not Done

126 TEL-AML / AML1

○ Positive ○ Negative ○ Not Done

Other Molecular Marker (1) **Questions: 127 - 128**

127 Other molecular marker

○ Positive ○ Negative ○ Not Done

128 Specify other molecular marker: _____

Laboratory studies at last evaluation:

129 Were cytogenetics tested (karyotyping or FISH)? (at last evaluation)

○ yes ○ no ○ Unknown

130 Were cytogenetics tested via FISH? (at last evaluation)

○ Yes ○ No

131 Results of tests

- ○ Abnormalities identified
- ○ No abnormalities

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Specify cytogenetic abnormalities identified at last evaluation:

132 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

133 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

134 Specify other abnormality: _____

135 Were cytogenetics tested via karyotyping? (at last evaluation)

○ Yes ○ No

136 Results of tests

- ○ Abnormalities identified
- ○ No evaluable metaphases
- ○ No abnormalities

Specify cytogenetic abnormalities identified at last evaluation:

137 Specify number of distinct cytogenetic abnormalities

- ○ One (1)
- ○ Two (2)
- ○ Three (3)
- ○ Four or more (4 or more)

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138 Specify abnormalities (check all that apply)

- ☐ -7
- ☐ +4
- ☐ +8
- ☐ +17
- ☐ +21
- ☐ t(1;19)
- ☐ t(2;8)
- ☐ t(4;11)
- ☐ t(5;14)
- ☐ t(8;14)
- ☐ t(8;22)
- ☐ t(9;22)
- ☐ t(10;14)
- ☐ t(11;14)
- ☐ t(12;21)
- ☐ del(6q) / 6q-
- ☐ del(9p) / 9p-
- ☐ del(12p) / 12p-
- ☐ add(14q)
- ☐ (11q23) any abnormality
- ☐ 9p any abnormality
- ☐ 12p any abnormality
- ☐ Hyperdiploid (> 50)
- ☐ Hypodiploid (< 45)
- ☐ iAMP21
- ☐ Other abnormality

139 Specify other abnormality: _____

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

○ Yes ○ No

141 Were tests for molecular markers performed? (e.g. PCR, NGS) (at last evaluation)

○ yes ○ no ○ Unknown

Specify molecular markers identified at last evaluation:

142 BCR / ABL

○ Positive ○ Negative ○ Not Done

143 TEL-AML / AML1

○ Positive ○ Negative ○ Not Done

Other Molecular Marker (1) **Questions: 144 - 145**

144 Other molecular marker

○ Positive ○ Negative ○ Not Done

145 Specify other molecular marker: _____

CNS Leukemia

146 Did the recipient have central nervous system leukemia at any time prior to the start of the preparative regimen / infusion?

○ yes ○ no ○ Unknown

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Status at transplantation:

147 What was the disease status (based on hematological test results)?

- Primary induction failure
- 1st complete remission (no previous marrow or extramedullary relapse) (include CRi)
- 2nd complete remission
- ≥3rd complete remission
- 1st relapse
- 2nd relapse
- ≥3rd relapse
- No treatment

148 How many cycles of induction therapy were required to achieve 1st complete remission? (include CRi)

1 2 ≥ 3

149 Was the recipient in remission by flow cytometry?

Yes No Unknown Not applicable

150 Date of most recent relapse: __ __ __ __ - __ __- __ __

151 Date assessed: __ __ __ __ - __ __- __ __

Acute Leukemias of Ambiguous Lineage and Other Myeloid Neoplasms

Questions: 152 - 155

152 Specify acute leukemias of ambiguous lineage and other myeloid neoplasm classification

- Blastic plasmacytoid dendritic cell neoplasm (296)
- Acute undifferentiated leukemia (31)
- Mixed phenotype acute leukemia (MPAL) with t(9;22)(q34.1;q11.2); BCR-ABL1 (84)
- Mixed phenotype acute leukemia with t(v; 11q23.3); KMT2A rearranged (85)
- Mixed phenotype acute leukemia, B/myeloid, NOS (86)
- Mixed phenotype acute leukemia, T/myeloid, NOS (87)
- Other acute leukemia of ambiguous lineage or myeloid neoplasm (88)

153 Specify other acute leukemia of ambiguous lineage or myeloid neoplasm: _____

Status at transplantation:

154 What was the disease status (based on hematological test results)?

- Primary induction failure
- 1st complete remission (no previous marrow or extramedullary relapse)
- 2nd complete remission
- ≥3rd complete remission
- 1st relapse
- 2nd relapse
- ≥3rd relapse
- No treatment

155 Date assessed: __ __ __ __ - __ __- __ __

Chronic Myelogenous Leukemia (CML)

Questions: 156 - 166

156 Was therapy given prior to this HCT?

yes no

157 Combination chemotherapy

yes no

158 Hydroxyurea (Droxia, Hydrea)

yes no

159 Tyrosine kinase inhibitor (e.g. imatinib mesylate, dasatinib, nilotinib)

yes no

160 Interferon-α (Intron, Roferon) (includes PEG)

yes no

161 Other therapy

yes no

162 Specify other therapy: _____

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163 What was the disease status?

- Complete hematologic response (CHR)
- Chronic phase
- Accelerated phase
- Blast phase

164 Specify level of response

- No cytogenetic response (No CyR)
- Minimal cytogenetic response
- Minor cytogenetic response
- Partial cytogenetic response (PCyR)
- Complete cytogenetic response (CCyR)
- Major molecular remission (MMR)
- Complete molecular remission (CMR)

165 Number

1st 2nd 3rd or higher

166 Date assessed: __ __ __ __ - __ __ - __ __

Myelodysplastic (MDS) / Myeloproliferative (MPN) Diseases

Questions: 167 - 260

167 What was the MDS / MPN subtype at diagnosis? **- If transformed to AML, indicate AML as primary disease; also complete AML Disease Classification questions** _____

168 Was the disease (MDS/MPN) therapy related?

yes no Unknown

169 Did the recipient have a predisposing condition?

yes no Unknown

170 Specify condition

Aplastic Anemia Bloom syndrome Down syndrome Fanconi anemia Other condition

171 Specify other condition: _____

Laboratory studies at diagnosis of MDS:

172 WBC

Known Unknown

173 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

174 Hemoglobin

Known Unknown

175 _____ g/dL g/L mmol/L

176 Was RBC transfused ≤ 30 days before date of test?

Yes No

177 Platelets

Known Unknown

178 _____

- x 10^9/L (x 10^3/mm^3)
- x 10^6/L

179 Were platelets transfused ≤ 7 days before date of test?

Yes No

180 Neutrophils

Known Unknown

181 _____ %

182 Blasts in bone marrow

Known Unknown

183 _____ %

184 Were cytogenetics tested (karyotyping or FISH)?

yes no Unknown

185 Results of tests

- Abnormalities identified
- No evaluable metaphases
- No abnormalities

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Specify abnormalities identified at diagnosis:

186 Specify number of distinct cytogenetic abnormalities

- One (1)
- Two (2)
- Three (3)
- Four or more (4 or more)

Monosomy

187 –5
yes no

188 -7
yes no

189 –13
yes no

190 –20
yes no

191 –Y
yes no

Trisomy

192 +8
yes no

193 +19
yes no

Translocation

194 t(1;3)
yes no

195 t(2;11)
yes no

196 t(3;3)
yes no

197 t(3;21)
yes no

198 t(6;9)
yes no

199 t(11;16)
yes no

Deletion

200 del(3q) / 3q–
yes no

201 del(5q) / 5q-
yes no

202 del(7q) / 7q–
yes no

203 del(9q) / 9q–
yes no

204 del(11q) / 11q–
yes no

205 del(12p) / 12p–
yes no

206 del(13q) / 13q-
yes no

207 del(20q) / 20q–
yes no

Inversion

208 inv(3)
yes no

Other

209 i17q
yes no

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210 Other abnormality

yes no

211 Specify other abnormality: _____

212 Did the recipient progress or transform to a different MDS / MPN subtype between diagnosis and the start of the preparative regimen?

yes no

213 Specify the MDS / MPN classification after transformation:

_____

214 Specify the date of the most recent transformation: __ __ __ __ - __ __- __ __

215 Date of MDS diagnosis: __ __ __ __ - __ __- __ __

Laboratory studies at last evaluation prior to the start of the preparative regimen:

216 WBC

Known Unknown

217 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

218 Hemoglobin

Known Unknown

219 _____ g/dL g/L mmol/L

220 Was RBC transfused ≤ 30 days before date of test?

Yes No

221 Platelets

Known Unknown

222 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

223 Were platelets transfused ≤ 7 days before date of test?

Yes No

224 Neutrophils

Known Unknown

225 _____ %

226 Blasts in bone marrow

Known Unknown

227 _____ %

228 Were cytogenetics tested (karyotyping or FISH)?

yes no Unknown

229 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified at last evaluation prior to the start of the preparative regimen:

230 Specify number of distinct cytogenetic abnormalities

One (1)

Two (2)

Three (3)

Four or more (4 or more)

Monosomy

231 –5

yes no

232 -7

yes no

233 –13

yes no

234 –20

yes no

235 –Y

yes no

Trisomy

236 +8

yes no

237 +19

yes no

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Translocation

238 t(1;3)
yes no

239 t(2;11)
yes no

240 t(3;3)
yes no

241 t(3;21)
yes no

242 t(6;9)
yes no

243 t(11;16)
yes no

Deletion

244 del(3q) / 3q–
yes no

245 del(5q) / 5q-
yes no

246 del(7q) / 7q–
yes no

247 del(9q) / 9q–
yes no

248 del(11q) / 11q–
yes no

249 del(12p) / 12p–
yes no

250 del(13q) / 13q-
yes no

251 del(20q) / 20q–
yes no

Inversion

252 inv(3)
yes no

Other

253 i17q
yes no

254 Other abnormality
yes no

255 Specify other abnormality: _____

Status at transplantation:

256 What was the disease status?

- Complete remission (CR) – requires all of the following, maintained for ≥ 4 weeks: * bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines * peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000/mm^3 without myeloid growth factor support; platelets ≥ 100 x 10^9/L without thrombopoietic support; 0% blasts
- Hematologic improvement (HI) – requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks * HI-P – for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-treatment level * HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500/mm^3
- No response (NR) / stable disease (SD) – does not meet the criteria for at least HI, but no evidence of disease progression
- Progression from hematologic improvement (Prog from HI) – requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL *transfusion dependence
- Relapse from complete remission (Rel from CR) – requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy
- Not assessed

257 Specify the cell line examined to determine HI status

- HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks
- HI-P – for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-treatment level
- HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500/mm^3

258 Date of progression: __ __ __ __ - __ __- __ __

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259 Date of relapse: __ __ __ __ - __ __- __ __

260 Date assessed: __ __ __ __ - __ __- __ __

Other Leukemia (OL) — Questions: 261 - 267

261 Specify the other leukemia classification _____

262 Specify other leukemia: _____

263 Was any 17p abnormality detected?

- ○ yes ○ no

264 Did a histologic transformation to diffuse large B-cell lymphoma (Richter syndrome) occur at any time after CLL diagnosis?

- ○ yes **- Also complete NHL Disease Classification questions**
- ○ no

Status at transplantation:

265 What was the disease status? (Atypical CML)

- ○ Primary induction failure
- ○ 1st complete remission (no previous bone marrow or extramedullary relapse)
- ○ 2nd complete remission
- ○ ≥3rd complete remission
- ○ 1st relapse
- ○ 2nd relapse
- ○ ≥3rd relapse
- ○ No treatment

266 What was the disease status? (CLL, PLL, Hairy cell leukemia)

- ○ Complete remission (CR)
- ○ Partial remission (PR)
- ○ Stable disease (SD)
- ○ Progressive disease (Prog)
- ○ Untreated
- ○ Not assessed

267 Date assessed: __ __ __ __ - __ __- __ __

Hodgkin and Non-Hodgkin Lymphoma — Questions: 268 - 285

268 Specify the lymphoma histology (at infusion) _____

269 Specify other lymphoma histology: _____

270 Assignment of DLBCL (germinal center B-cell type vs. activated B-cell type) subtype was based on

- ○ Immunohistochemistry (e.g. Han's algorithm)
- ○ Gene expression profile
- ○ Unknown method

271 Is the lymphoma histology reported at transplant a transformation from CLL?

- ○ yes ○ no

272 Was any 17p abnormality detected?

- ○ yes ○ no

273 Is the lymphoma histology reported at transplant a transformation from a different lymphoma histology? (Not CLL)

- ○ Yes ○ No

274 Specify the original lymphoma histology (prior to transformation) _____

275 Specify other lymphoma histology: _____

276 Date of original lymphoma diagnosis: __ __ __ __ - __ __- __ __ **(report the date of diagnosis of original lymphoma subtype)**

277 Was a PET (or PET/CT) scan performed? (at last evaluation prior to the start of the preparative regimen / infusion)

- ○ yes ○ no

278 Was the PET (or PET/CT) scan positive for lymphoma involvement at any disease site?

- ○ yes ○ no

279 Date of PET scan

- ○ Known ○ Unknown

280 Date of PET (or PET/CT) scan: __ __ __ __ - __ __- __ __

281 Deauville (five-point) score of the PET (or PET/CT) scan

- ○ Known ○ Unknown

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282 Scale

- 1 - no uptake or residual uptake
- 2 - slight uptake, but below blood pool (mediastinum)
- 3 - uptake above mediastinal, but below or equal to uptake in the liver
- 4 - uptake slightly to moderately higher than liver
- 5 - markedly increased uptake or any new lesions

Status at transplantation / infusion:

283 What was the disease status? _____

284 Total number of lines of therapy received

1 line 2 lines 3+ lines

285 Date assessed: __ __ __ __ - __ __- __ __

Multiple Myeloma / Plasma Cell Disorder (PCD)

Questions: 286 - 317

286 Specify the multiple myeloma/plasma cell disorder (PCD) classification _____

287 Specify other plasma cell disorder: _____

288 Light chain

kappa lambda

289 What was the Durie-Salmon staging? (at diagnosis)

- Stage I (All of the following: Hgb > 10g/dL; serum calcium normal or <10.5 mg/dL; bone x-ray normal bone structure (scale 0), or solitary bone plasmacytoma only; low M-component production rates IgG< 5g/dL, IgA < 3g/dL; urine light chain M-component on electrophoresis <4 g/24h)
- Stage II (Fitting neither Stage I or III)
- Stage III (One or more of the following: Hgb < 8.5 g/dL; serum calcium > 12 mg/dL; advanced lytic bone lesions (scale 3); high M-component production rates IgG > 7g/dL, IgA > 5 g/dL; Bence Jones protein > 12g/24h)
- Unknown

290 What was the Durie-Salmon sub classification? (at diagnosis)

- A - relatively normal renal function (serum creatinine < 2.0 mg/dL)
- B - abnormal renal function (serum creatinine ≥ 2.0 mg/dL)

I.S.S.:

291 Serum β2-microglobulin: _____ µg/dL mg/L nmol/L

292 Serum albumin: _____ g/dL g/L

293 Stage

- 1 (β2 -mic < 3.5, S. albumin ≥3.5)
- 2 (Not fitting stage 1 or 3)
- 3 (β2-mic ≥ 5.5; S. albumin -)

294 Were cytogenetics tested (karyotyping or FISH)?

yes no Unknown

295 Results of tests

- Abnormalities identified
- No evaluable metaphases
- No abnormalities

Specify cytogenetic abnormalities identified at any time prior to the start of the preparative regimen:

Trisomy

296 +3

yes no

297 +5

yes no

298 +7

yes no

299 +9

yes no

300 +11

yes no

301 +15

yes no

302 +19

yes no

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Translocation

303 t(4;14)
yes no

304 t(6;14)
yes no

305 t(11;14)
yes no

306 t(14;16)
yes no

307 t(14;20)
yes no

Deletion

308 del(13q) / 13q-
yes no

309 del (17p) / 17p-
yes no

Other

310 Hyperdiploid (>50)
yes no

311 Hypodiploid (<46)
yes no

312 Any abnormality at 1q
yes no

313 Any abnormality at 1p
yes no

314 Other abnormality
yes no

315 Specify other abnormality: _____

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Status at transplantation:

316 What was the disease status?

- Stringent complete remission (sCR) - CR as defined, plus: normal free light chain ratio, and absence of clonal cells in the bone marrow by immunohistochemistry of immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based upon the K/λ ratio. An abnormal K/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is K/λ of > 4:1 or < 1:2.) sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.
- Complete remission (CR) - negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and < 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed). CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.
- Near complete remission (nCR) - serum and urine M-protein detectable by immunoelectrophoresis (IFE), but not on electrophoresis (negative SPEP & UPEP); < 5% plasma cells in bone marrow. nCR requires two consecutive assessments made at any time before the initiation of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy nCR requirements.
- Very good partial remission (VGPR) - serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.
- Partial remission (PR) - ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours. If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL. Urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline. PR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.
- Stable disease (SD) - not meeting the criteria for CR, VGPR, PR or PD. SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements.
- Progressive disease (PD) - requires any one or more of the following: Increase of ≥ 25% from baseline in: serum M-component and/or (absolute increase ≥ 0.5 g/dL) (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL). Urine M-component and/or (absolute increase ≥ 200 mg/24 hours) for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels (absolute increase > 10 mg/dL). Bone marrow plasma cell percentage (absolute percentage ≥ 10%) (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas. Development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder. PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy.
- Relapse from CR (Rel) (untreated) - requires one or more of the following: reappearance of serum or urine M-protein by immunofixation or electrophoresis development of ≥ 5% plasma cells in the bone marrow (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia). Rel requires two consecutive assessments made at any time before classification as relapse, and/or the institution of any new therapy.
- Unknown
- Not applicable (Amyloidosis with no evidence of myeloma)

317 Date assessed: __ __ __ __ - __ __- __ __

Solid Tumors

Questions: 318 - 319

318 Specify the solid tumor classification _____

319 Specify other solid tumor: _____

Severe Aplastic Anemia

Questions: 320 - 321

320 Specify the severe aplastic anemia classification _____

321 Specify other acquired cytopenic syndrome: _____

Inherited Abnormalities of Erythrocyte Differentiation or Function

Questions: 322 - 324

322 Specify the inherited abnormalities of erythrocyte differentiation or function classification _____

323 Specify other constitutional anemia: _____

324 Specify other hemoglobinopathy: _____

Disorders of the Immune System

Questions: 325 - 327

325 Specify disorder of immune system classification _____

326 Specify other SCID: _____

327 Specify other immunodeficiency: _____

Inherited Abnormalities of Platelets

Questions: 328 - 329

328 Specify inherited abnormalities of platelets classification

- Congenital amegakaryocytosis / congenital thrombocytopenia (501)
- Glanzmann thrombasthenia (502)
- Other inherited platelet abnormality (509)

329 Specify other inherited platelet abnormality: _____

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Form 2402 R3.0: Disease Classification

Center: CRID:

Inherited Disorders of Metabolism

Questions: 330 - 331

330 Specify inherited disorders of metabolism classification _____

331 Specify other inherited metabolic disorder: _____

Histiocytic Disorders

Questions: 332 - 333

332 Specify histiocytic disorder classification _____

333 Specify other histiocytic disorder: _____

Autoimmune Diseases

Questions: 334 - 341

334 Specify autoimmune disease classification _____

335 Specify other arthritis: _____

336 Specify other juvenile idiopathic arthritis (JIA): _____

337 Specify other connective tissue disease: _____

338 Specify other vasculitis: _____

339 Specify other autoimmune neurological disorder: _____

340 Specify other autoimmune cytopenia: _____

341 Specify other autoimmune bowel disorder: _____

Other Disease

Questions: 342 - 342

342 Specify other disease: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __

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