

ERROR CORRECTION FORM

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Systemic Sclerosis Pre-HSCT Data

Registry Use Only

Sequence Number:

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Date of HSCT for which this form is being completed:

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HSCT type: autologous allogeneic, unrelated allogeneic, related syngeneic (identical twin)

Product type: marrow PBSC cord blood other product, specify: _____

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

Questions followed by the symbol indicate additional information necessary to complete the question is referenced in the forms instruction manual.

If this is a report of a second or subsequent transplant, check here and continue with question 157.

Disease Assessment at Diagnosis

1. What was the date of diagnosis of Systemic Sclerosis (SSc)?

2. What was the extent of cutaneous systemic sclerosis at diagnosis?
- 1 limited (cutaneous thickening distal (but not proximal) to elbows or knees)
 - 2 diffuse
 - 3 unknown

Laboratory Studies at Diagnosis

Report findings prior to any first treatment for systemic sclerosis.

3. Date CBC tested:

4. WBC: known not known

Specify units:

- 1 x 10⁹/L (x 10³/mm³)
- 2 x 10⁶/L

5. Hemoglobin: known not known

- 1 g/dL
- 2 g/L
- 3 mmol/L

6. Hematocrit: known not known

%

Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

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7. Platelets:

- 1 known →

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- 2 not known

Specify units:

- 1 $\times 10^9/L$ ($\times 10^3/mm^3$)
- 2 $\times 10^6/L$

8. Serum creatinine:

- 1 known →

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|--|--|
- 2 not known

- 1 mg/dL
- 2 $\mu mol/L$
- 3 mmol/L

9. Creatinine clearance:

- 1 known →

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- 2 not known

- 1 mL/min
- 2 mL/sec

10. Creatinine phosphokinase:

- 1 known →

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- 2 not known

- 1 U/L
- 2 $\mu kat/L$

11. Blood urea nitrogen:

- 1 known →

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|--|
- 2 not known

- 1 mg/dL
- 2 mmol/L

12. Was there evidence of hematuria at diagnosis?

- 1 yes, present
- 2 no, absent
- 3 unknown

13. Was there evidence of proteinuria at diagnosis?

- 1 yes, present
- 2 no, absent
- 3 unknown

14. Thyroid stimulating hormone (TSH):

- 1 known →

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- 2 not known

- 1 mU/L
- 2 $\mu U/mL$

15. Was any testing for autoantibodies performed at diagnosis?

- 1 yes →
- 2 no
- 3 unknown

Specify the test results for the following autoantibodies:

16. Anti-centromere: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
17. Anti-DNA topoisomerase I (Scl-70): 1 positive 2 negative 3 inconclusive 4 not tested / unknown
18. Anti-nuclear: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
19. Anti-SS-A: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
20. Anti-SS-B: 1 positive 2 negative 3 inconclusive 4 not tested / unknown

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Pre-HSCT Treatment for Systemic Lupus Erythematosus

21. Did the recipient receive any disease-modifying treatments between the time of diagnosis and prior to mobilization for stem cell collection (or high-dose therapy if mobilization was not done)?

1 yes → **Continue with table below**

2 no → **Continue with question 73**

| Treatment Given? | Treatment Stopped? | Stopped Code | Codes for Treatment Stopped |
|------------------|--------------------|--------------|--|
| | | | 1 Failure 2 Toxicity 3 Other reason 4 Reason unknown |

22. Antithymocyte globulin (ATG) / antilymphocyte globulin (ALG)

1 yes → 23. 1 yes → 24.

 25. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

26. Cyclophosphamide (CTX, Cytoxan, Neosar)

1 yes → 27. 1 yes → 28.

 29. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

30. Cyclosporine (CsA, Neoral, Sandimmune)

1 yes → 31. 1 yes → 32.

 33. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

34. D-penicillamine (penicillamine, Cuprimine, Depen)

1 yes → 35. 1 yes → 36.

 37. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

38. Methotrexate (MTX, Folex)

1 yes → 39. 1 yes → 40.

 41. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown
 42. Specify the maximum weekly dose:

 mg dose unknown
 43. Specify the duration of therapy:

 1 weeks duration unknown
 2 months

44. Mycophenolate mofetil (MMF, CellCept)

1 yes → 45. 1 yes → 46.

 47. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

48. Non-steroidal anti-inflammatory drugs (NSAIDS)

1 yes → 49. 1 yes → 50.

 51. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

52. Phototherapy

1 yes → 53. 1 yes → 54.

 55. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

56. Prednisone (Intenol, Sterapred) or equivalent

1 yes → 57. 1 yes → 58.

 59. If code 3, specify other reason: _____
 2 no → 2 no
 3 unknown

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60. Prostanoids / prostaglandin analogs

- | | | | |
|------------------------------------|--------------------------------------|------------------------------|--|
| 1 <input type="checkbox"/> yes → | 61. 1 <input type="checkbox"/> yes → | 62. <input type="checkbox"/> | 63. If code 3, specify other reason: _____ |
| 2 <input type="checkbox"/> no | 2 <input type="checkbox"/> no | | |
| 3 <input type="checkbox"/> unknown | | | |

64. Tacrolimus (FK 506, Prograf)

- | | | | |
|------------------------------------|--------------------------------------|------------------------------|--|
| 1 <input type="checkbox"/> yes → | 65. 1 <input type="checkbox"/> yes → | 66. <input type="checkbox"/> | 67. If code 3, specify other reason: _____ |
| 2 <input type="checkbox"/> no | 2 <input type="checkbox"/> no | | |
| 3 <input type="checkbox"/> unknown | | | |

68. Other treatment

- | | | | |
|------------------------------------|--------------------------------------|------------------------------|--|
| 1 <input type="checkbox"/> yes → | 69. 1 <input type="checkbox"/> yes → | 70. <input type="checkbox"/> | 71. If code 3, specify other reason: _____ |
| 2 <input type="checkbox"/> no | 2 <input type="checkbox"/> no | | |
| 3 <input type="checkbox"/> unknown | 72. Specify other treatment: _____ | | |

Disease Assessment Prior to Mobilization Therapy for Stem Cell Collection

Information for this section should come from the most recent evaluation prior to the initiation of mobilization therapy (≤ 4 weeks prior to mobilization for stem cell collection). If the recipient did not receive mobilization therapy, check here and continue with question 157.

73. Date of evaluation prior to mobilization for stem cell collection:

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| Month | Day | Year | | | |

74. What was the extent of cutaneous systemic sclerosis prior to mobilization for stem cell collection?

- 1 limited (cutaneous thickening distal (but not proximal) to elbows or knees)
- 2 diffuse
- 3 unknown

Specify skin thickness for the following sites as determined by clinical palpation performed prior to mobilization for stem cell collection: *Clements P, Lachenbruch P, Seibold J, White B, Weiner S, Martin R, et al. Inter and intraobserver variability of total skin thickness score (modified Rodnan TSS) in systemic sclerosis. J Rheumatol 1995; 22:1281-1285.*

| Anatomic Area | Modified Rodnan Skin Thickness Score (MRSS) | | | | * Severe = inability to pinch skin into a fold |
|----------------------------|---|------------------------------------|------------------------------------|------------------------------------|--|
| | normal | mild | moderate | severe * | |
| 75. Face | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 76. Anterior chest | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 77. Abdomen | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 78. Upper arm – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 79. Upper arm – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 80. Forearms – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 81. Forearms – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 82. Dorsum of hand – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 83. Dorsum of hand – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 84. Fingers – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 85. Fingers – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 86. Thigh – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 87. Thigh – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 88. Lower leg – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 89. Lower leg – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 90. Dorsum of foot – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |
| 91. Dorsum of foot – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | |

92. Total modified Rodnan Skin Score: (add scores from questions 75–91)

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Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

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Specify the following clinical findings prior to mobilization for stem cell collection:

93. Changes in skin pigmentation:

- 1 present
2 absent
3 unknown

94. Raynaud's phenomenon:

- 1 present
2 absent
3 unknown

95. Painful digital ulcers:

- 1 present
2 absent
3 unknown

96. Specify number of digital ulcers:

| | | | |
|--|--|--|--|
| | | | |
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97. Gut dysmotility:

- 1 present
2 absent
3 unknown

98. Malabsorption:

- 1 present
2 absent
3 unknown

99. Weight loss > 10% of body weight:

- 1 present
2 absent
3 unknown

100. Muscle weakness:

- 1 present
2 absent
3 unknown

101. Joint tenderness:

- 1 present
2 absent
3 unknown

102. Specify number of joints affected:

| | | | |
|--|--|--|--|
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103. Tendon friction rubs:

- 1 present
2 absent
3 unknown

104. Specify number of sites affected:

| | | | |
|--|--|--|--|
| | | | |
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105. Contractures:

- 1 present
2 absent
3 unknown

Laboratory Studies Prior to Mobilization Therapy for Stem Cell Collection

106. Date CBC tested:

| | | | | | | | |
|-------|-----|------|--|---|---|--|--|
| | | | | 2 | 0 | | |
| Month | Day | Year | | | | | |

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107. WBC:

1 known →

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2 not known

Specify units:

- 1 x 10⁹/L (x 10³/mm³)
2 x 10⁶/L

108. Hemoglobin:

1 known →

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2 not known

- 1 g/dL
2 g/L
3 mmol/L

109. Hematocrit:

1 known →

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2 not known

110. Platelets:

1 known →

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 1 x 10⁹/L (x 10³/mm³)

2 not known 2 x 10⁶/L

111. Serum creatinine:

1 known →

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2 not known

1 mg/dL
2 μmol/L
3 mmol/L

112. Creatinine clearance:

1 known →

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2 not known

1 mL/min
2 mL/sec

113. Creatinine phosphokinase:

1 known →

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2 not known

1 U/L
2 μkat/L

114. Blood urea nitrogen:

1 known →

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2 not known

1 mg/dL
2 mmol/L

115. Was there evidence of hematuria prior to mobilization therapy for stem cell collection?

- 1 yes, present
2 no, absent
3 unknown

116. Was there evidence of proteinuria prior to mobilization therapy for stem cell collection?

- 1 yes, present
2 no, absent
3 unknown

117. Thyroid stimulating hormone (TSH):

1 known →

| | | | | | | | | | | | | | | | | | | | |
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2 not known

1 mU/L
2 μU/mL

118. Was any testing for autoantibodies performed prior to mobilization therapy for stem cell collection?

- 1 yes →

| | | | | | | | | | | | | | | | | | | | |
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- 2 no
- 3 unknown

Specify the test results for the following autoantibodies:

119. Anti-centromere: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
120. Anti-DNA topoisomerase I (Scl-70): 1 positive 2 negative 3 inconclusive 4 not tested / unknown
121. Anti-nuclear: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
122. Anti-SS-A: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
123. Anti-SS-B: 1 positive 2 negative 3 inconclusive 4 not tested / unknown

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

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Infusion Date:

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CIBMTR Center Number:

CIBMTR Recipient ID:

Specify the results of the following pulmonary function tests performed prior to mobilization therapy for stem cell collection:

124. Was dyspnea present on exertion?

- 1 yes
2 no
3 unknown

125. Vital capacity (VC):

- 1 known → . % (predicted value)
2 not known

126. Was the actual VC value in the normal range (≥ 80% of predicted value)?

- 1 yes
2 no

127. D_LCO:

- 1 known → . % (predicted value)
2 not known

128. Was the actual D_LCO value in the normal range (≥ 80% of predicted value)?

- 1 yes
2 no

129. D_LCO corrected for hemoglobin:

- 1 known → . % (predicted value)
2 not known

130. Was the D_LCO value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?

- 1 yes
2 no

131. Was oxygen desaturation present on exercise testing?

- 1 yes
2 no
3 unknown

132. Was ground glass appearance present on chest x-ray?

- 1 yes
2 no
3 unknown

133. Was a high resolution chest CT scan performed?

- 1 yes →
2 no
3 unknown

134. Was ground glass appearance present on CT scan?

- 1 yes
2 no
3 unknown

135. Was bronchoalveolar lavage (BAL) performed?

- 1 yes →
2 no
3 unknown

136. Was alveolitis present?

- 1 yes
2 no

137. Specify the highest percentage of neutrophils present in the segments tested: %

138. Was pulmonary artery hypertension present?

- 1 yes →
2 no
3 unknown

139. Specify the mean pulmonary artery pressure (PAP) level:

- 1 known → mm/Hg
2 unknown

140. Specify the method used to examine the PAP level:

- 1 echocardiogram
2 catheterization

ERROR CORRECTION FORM

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141. Was systemic hypertension present that required treatment?

- 1 yes
- 2 no
- 3 unknown

Specify treatment(s) given for hypertension:

142. ACE inhibitor

- 1 yes
- 2 no

143. Other antihypertensive therapy

- 1 yes
- 2 no

144. Specify antihypertensive therapy: _____

145. Specify the duration of antihypertensive therapy:

| | | |
|--|--|--|
| | | |
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 months

146. Was arrhythmia present that required treatment?

- 1 yes
- 2 no
- 3 unknown

147. Was an echocardiogram performed prior to mobilization therapy for stem cell collection?

- 1 yes
- 2 no
- 3 unknown

148. Was pericardial effusion present?

- 1 yes
- 2 no
- 3 unknown

149. Specify the size of the area of accumulated excess fluid:

- 1 small
- 2 moderate
- 3 large

150. Specify the left ventricular ejection fraction:

- 1 known
- 2 not known

| | | |
|--|--|---|
| | | % |
|--|--|---|

151. Was a multiple gate acquisition scan (MUGA test / nuclear ventriculography) performed prior to mobilization therapy for stem cell collection?

- 1 yes
- 2 no
- 3 unknown

152. Specify the left ventricular ejection fraction:

| | | |
|--|--|--|
| | | |
|--|--|--|

 %

153. Did the recipient complete a modified Health Assessment Questionnaire (HAQ) for Scleroderma prior to mobilization therapy for stem cell collection?

Steen VD, Medsger Jr. TA. The value of the Health Assessment Questionnaire and special patient-generated scales to demonstrate change in systemic sclerosis patients over time. Arthritis Rheum 1997; 40 (11): 1984-1991.

- 1 yes
- 2 no
- 3 unknown

154. Recipient's score:

| | | |
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| | | |
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155. Worst possible score:

| | | |
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156. Best possible score:

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ERROR CORRECTION FORM

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Most Recent Disease Assessment Prior to the Start of the Preparative Regimen

Information for this section should come from the most recent evaluation performed ≤ 2 weeks prior to the preparative regimen. If the recipient was not evaluated prior to the preparative regimen, check here and continue with question 236.

157. Date of evaluation prior to the preparative regimen:

| | | | | | |
|-------|-----|------|---|--|--|
| | | 2 | 0 | | |
| Month | Day | Year | | | |

158. What was the extent of cutaneous systemic sclerosis prior to the start of the preparative regimen?

- 1 limited (cutaneous thickening distal (but not proximal) to elbows or knees)
- 2 diffuse
- 3 unknown

Specify skin thickness for the following sites as determined by clinical palpation performed prior to the start of the preparative regimen: *Clements P, Lachenbruch P, Seibold J, White B, Weiner S, Martin R, et al. Inter and intraobserver variability of total skin thickness score (modified Rodnan TSS) in systemic sclerosis. J Rheumatol 1995; 22:1281-1285.*

| Anatomic Area | Modified Rodnan Skin Thickness Score (MRSS) | | | | * Severe = inability to pinch skin into a fold | | |
|--|---|------------------------------------|------------------------------------|------------------------------------|--|--|--|
| | normal | mild | moderate | severe * | | | |
| 159. Face | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 160. Anterior chest | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 161. Abdomen | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 162. Upper arm – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 163. Upper arm – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 164. Forearms – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 165. Forearms – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 166. Dorsum of hand – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 167. Dorsum of hand – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 168. Fingers – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 169. Fingers – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 170. Thigh – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 171. Thigh – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 172. Lower leg – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 173. Lower leg – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 174. Dorsum of foot – left | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 175. Dorsum of foot – right | 1 <input type="checkbox"/> score 0 | 2 <input type="checkbox"/> score 1 | 3 <input type="checkbox"/> score 2 | 4 <input type="checkbox"/> score 3 | | | |
| 176. Total modified Rodnan Skin Score: (add scores from questions 159–175) | | | | | <table border="1" style="width: 40px; height: 20px;"> <tr> <td></td><td></td> </tr> </table> | | |
| | | | | | | | |

Specify the following clinical findings prior to the start of the preparative regimen:

177. Changes in skin pigmentation:

- 1 present
- 2 absent
- 3 unknown

178. Raynaud's phenomenon:

- 1 present
- 2 absent
- 3 unknown

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

Month Day

20

Year

Infusion Date:

Month Day

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Year

CIBMTR Center Number:

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179. Painful digital ulcers:

- 1 present
2 absent
3 unknown

180. Specify number of digital ulcers:

181. Gut dysmotility:

- 1 present
2 absent
3 unknown

182. Malabsorption:

- 1 present
2 absent
3 unknown

183. Weight loss > 10% of body weight:

- 1 present
2 absent
3 unknown

184. Muscle weakness:

- 1 present
2 absent
3 unknown

185. Joint tenderness:

- 1 present
2 absent
3 unknown

186. Specify number of joints affected:

187. Tendon friction rubs:

- 1 present
2 absent
3 unknown

188. Specify number of sites affected:

189. Contractures:

- 1 present
2 absent
3 unknown

Laboratory Studies Prior to the Start of the Preparative Regimen

190. Date laboratory studies were performed:

Month Day

20

Year

191. Creatinine clearance:

- 1 known
2 not known

- 1 mL/min
2 mL/sec

192. Creatinine phosphokinase:

- 1 known
2 not known

- 1 U/L
2 μ kat/L

193. Blood urea nitrogen:

- 1 known
2 not known

- 1 mg/dL
2 mmol/L

ERROR CORRECTION FORM

Sequence Number:

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194. Was there evidence of hematuria prior to the start of the preparative regimen?

- 1 yes, present
- 2 no, absent
- 3 unknown

195. Was there evidence of proteinuria prior to the start of the preparative regimen?

- 1 yes, present
- 2 no, absent
- 3 unknown

196. Thyroid stimulating hormone (TSH):

- 1 known →

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 1 mU/L
- 2 not known 2 μU/mL

197. Was any testing for autoantibodies performed prior to the start of the preparative regimen?

- 1 yes →
- 2 no
- 3 unknown

Specify the test results for the following autoantibodies:

198. Anti-centromere: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
199. Anti-DNA topoisomerase I (Scl-70): 1 positive 2 negative 3 inconclusive 4 not tested / unknown
200. Anti-nuclear: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
201. Anti-SS-A: 1 positive 2 negative 3 inconclusive 4 not tested / unknown
202. Anti-SS-B: 1 positive 2 negative 3 inconclusive 4 not tested / unknown

Specify the results of the following pulmonary function tests performed prior to the start of the preparative regimen:

203. Was dyspnea present on exertion?

- 1 yes
- 2 no
- 3 unknown

204. Vital capacity (VC):

- 1 known →

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 % (predicted value)
- 2 not known

205. Was the actual VC value in the normal range (≥ 80% of predicted value)?

- 1 yes
- 2 no

206. D_LCO:

- 1 known →

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 % (predicted value)
- 2 not known

207. Was the actual D_LCO value in the normal range (≥ 80% of predicted value)?

- 1 yes
- 2 no

208. D_LCO corrected for hemoglobin:

- 1 known →

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 % (predicted value)
- 2 not known

209. Was the D_LCO value (corrected for hemoglobin) in the normal range (≥ 80% of predicted value)?

- 1 yes
- 2 no

210. Was oxygen desaturation present on exercise testing?

- 1 yes
- 2 no
- 3 unknown

211. Was ground glass appearance present on chest x-ray?

- 1 yes
- 2 no
- 3 unknown

ERROR CORRECTION FORM

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212. Was a high resolution chest CT scan performed?

- 1 yes
2 no
3 unknown

213. Was ground glass appearance present on CT scan?

- 1 yes
2 no
3 unknown

214. Was bronchoalveolar lavage (BAL) performed?

- 1 yes
2 no
3 unknown

215. Was alveolitis present?

- 1 yes
2 no

216. Specify the highest percentage of neutrophils present in the segments tested:

| | | | | | | | |
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 %

217. Was pulmonary artery hypertension present?

- 1 yes
2 no
3 unknown

218. Specify the mean pulmonary artery pressure (PAP) level:

- 1 known →

| | | | |
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 mm/Hg
2 unknown

219. Specify the method used to examine the PAP level:

- 1 echocardiogram
2 catheterization

220. Was systemic hypertension present that required treatment?

- 1 yes
2 no
3 unknown

Specify treatment(s) given for hypertension:

221. ACE inhibitor

- 1 yes
2 no

222. Other antihypertensive therapy

- 1 yes →
2 no

223. Specify antihypertensive therapy: _____

224. Specify the duration of antihypertensive therapy:

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 months

225. Was arrhythmia present that required treatment?

- 1 yes
2 no
3 unknown

226. Was an echocardiogram performed prior to the start of the preparative regimen?

- 1 yes
2 no
3 unknown

227. Was pericardial effusion present?

- 1 yes →
2 no
3 unknown

228. Specify the size of the area of accumulated excess fluid:

- 1 small
2 moderate
3 large

229. Specify the left ventricular ejection fraction:

- 1 known →

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 %
2 not known

ERROR CORRECTION FORM

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230. Was a multiple gate acquisition scan (MUGA test / nuclear ventriculography) performed prior to the start of the preparative regimen?

1 yes

2 no

3 unknown

231. Specify the left ventricular ejection fraction: %

Functional Assessment Prior to the Start of the Preparative Regimen

232. Did the recipient complete a modified Health Assessment Questionnaire (HAQ) for Scleroderma prior to the start of the preparative regimen?

Steen VD, Medsger Jr. TA. The value of the Health Assessment Questionnaire and special patient-generated scales to demonstrate change in systemic sclerosis patients over time. Arthritis Rheum 1997; 40 (11): 1984-1991.

1 yes

2 no

3 unknown

233. Recipient's score:

234. Worst possible score:

235. Best possible score:

Specify the site(s) of disease involvement which were included in the primary indication(s) to proceed with HSCT:

236. 1 yes 2 no 3 unknown Gastrointestinal (GI) tract

237. 1 yes 2 no 3 unknown Heart

238. 1 yes 2 no 3 unknown Lungs

239. 1 yes 2 no 3 unknown Severe functional impairment

240. 1 yes 2 no 3 unknown Skin

241. 1 yes 2 no 3 unknown Other site of disease → 242. Specify site of disease: _____

243. Signed: _____

Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____