**Form 2041 R2.0: Rheumatoid Arthritis Pre-HSCT Data**

**Center:**

**CRID:**

**Key Fields**

Sequence Number: __________________________

Date Received: __ __ __ __ - __ __-

CIBMTR Center Number: __________________________

CIBMTR Recipient ID: __________________________

Today's Date: __ __ __ __ - __ __-

Date of HSCT for which this form is being completed: __ __ __ __ - __ __-

**HSCT Type (check all that apply):**

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

**Product Type (check all that apply):**

- 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.

If this is a report of a second or subsequent transplant, check here and continue with question 80.

**Disease Assessment at Diagnosis**

<table>
<thead>
<tr>
<th>Questions</th>
<th>1 - 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What was the date of diagnosis of Rheumatoid Arthritis? __ __ __ __ - __ __- Date of diagnosis of rheumatoid arthritis unknown</td>
</tr>
<tr>
<td>2</td>
<td>Did recipient meet the American Rheumatism Association criteria for rheumatoid arthritis? (see definition)</td>
</tr>
<tr>
<td>4 or more criteria must be present to classify a patient as having rheumatoid arthritis</td>
<td></td>
</tr>
<tr>
<td>- Morning stiffness for at least 1 hour and present for at least 6 weeks</td>
<td></td>
</tr>
<tr>
<td>- Swelling of 3 or more joints for at least 6 weeks</td>
<td></td>
</tr>
<tr>
<td>- Swelling of wrist, metacarpophalangeal or proximal interphalangeal joints for 6 or more weeks</td>
<td></td>
</tr>
<tr>
<td>- Symmetric joint swelling</td>
<td></td>
</tr>
<tr>
<td>- Hand roentgenogram changes typical of rheumatoid arthritis that must include erosions or unequivocal bony decalcification</td>
<td></td>
</tr>
<tr>
<td>- Rheumatoid nodules</td>
<td></td>
</tr>
<tr>
<td>- Serum rheumatoid factor by a method positive in &lt; 5% of normals</td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>3</td>
<td>Did patient ever have positive titers of serum rheumatoid factor?</td>
</tr>
<tr>
<td>yes</td>
<td>no</td>
</tr>
</tbody>
</table>
Pre-HSCT Treatment for Rheumatoid Arthritis

Questions: 7 - 79

4 Specify titers:
   IgG  IgM  IgA  Unknown

5 Was HLA-DRB1 testing performed?
   yes  no  Unknown

6 Specify DRB1 allele: ____________________________

7 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)?
   yes  no

8 Was anti-tumor necrosis factor (TNF) given?
   yes  no  Unknown

9 Was treatment stopped?
   yes  no

10 Specify reason treatment stopped: ____________________________

11 Specify other reason: ____________________________

12 Was azathioprine given?
   yes  no  Unknown

13 Was treatment stopped?
   yes  no

14 Specify reason treatment stopped: ____________________________

15 Specify other reason: ____________________________

16 Was corticosteroids given?
   yes  no  Unknown

17 Was treatment stopped?
   yes  no

18 Specify reason treatment stopped: ____________________________

19 Specify other reason: ____________________________

20 Was cyclophosphamide given?
   yes  no  Unknown

21 Was treatment stopped?
   yes  no

22 Stopped code ____________________________

23 Specify other reason: ____________________________

24 Was cyclosporin A given?
   yes  no  Unknown
<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was treatment stopped?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify reason treatment stopped:</td>
<td></td>
</tr>
<tr>
<td>Was gold-IM given?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify other reason:</td>
<td></td>
</tr>
<tr>
<td>Was treatment stopped?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify reason treatment stopped:</td>
<td></td>
</tr>
<tr>
<td>Was gold-PO given?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify other reason:</td>
<td></td>
</tr>
<tr>
<td>Was treatment stopped?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify reason treatment stopped:</td>
<td></td>
</tr>
<tr>
<td>Was hydroxychloroquine given?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify other reason:</td>
<td></td>
</tr>
<tr>
<td>Was treatment stopped?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify reason treatment stopped:</td>
<td></td>
</tr>
<tr>
<td>Was leflunomide given?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify other reason:</td>
<td></td>
</tr>
<tr>
<td>Was treatment stopped?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify reason treatment stopped:</td>
<td></td>
</tr>
<tr>
<td>Was methotrexate given?</td>
<td>Yes/No/Unknown</td>
</tr>
<tr>
<td>Specify other reason:</td>
<td></td>
</tr>
<tr>
<td>Maximum weekly dose of methotrexate:</td>
<td>Known/Not known</td>
</tr>
</tbody>
</table>
Duration of methotrexate therapy:

50

Known  
Not known

Was minocycline given?

52

yes  
no  
Unknown

Was treatment stopped?

53

yes  
no

Specify reason treatment stopped:

54

Specify other reason:

55

Was penicillamine given?

56

yes  
no  
Unknown

Was treatment stopped?

57

yes  
no

Specify reason treatment stopped:

58

Specify other reason:

59

Was rituximab given?

60

yes  
no  
Unknown

Was treatment stopped?

61

yes  
no

Specify reason treatment stopped:

62

Specify other reason:

63

Was sulfasalazine given?

64

yes  
no  
Unknown

Was treatment stopped?

65

yes  
no

Specify reason treatment stopped:

66

Specify other reason:

67

Other treatment

68

yes  
no  
Unknown

Specify other treatment:

69

Was treatment stopped?

70

yes  
no

Specify reason treatment stopped:

71

Specify other reason:

72
Did the recipient stop receiving disease-modifying drugs (e.g., cyclophosphamide, methotrexate, etc.) or anti-TNF regimen (not NSAIDS) prior to mobilization for stem cell collection (or high-dose therapy if mobilization was not done)?

- [ ] yes
- [ ] no
- [ ] Unknown

Specify the date that the recipient last received disease-modifying drugs or anti-TNF regimen:

- [ ] ____________________

Date recipient last received disease-modifying drugs or anti-TNF regimen unknown

Was the recipient receiving non-steroidal anti-inflammatory drugs (NSAIDS) within 4 weeks of mobilization for stem cell collection (or high-dose therapy if mobilization was not done)?

- [ ] yes
- [ ] no
- [ ] Unknown

Were the NSAIDS discontinued prior to mobilization?

- [ ] yes
- [ ] no
- [ ] Unknown

Specify the date NSAIDS were stopped:

- [ ] ____________________

Date NSAIDS were stopped unknown

Specify the reason for stopping:

- [ ] ____________________

Pre-Mobilization Evaluation

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 152.

Date of evaluation prior to mobilization for stem cell collection:

- [ ] ____________________

Specify the number of painful/tender joints prior to mobilization: (Eular/ACR 28 joint count; Fuchs and Pincus, Arthritis Rheum, 1994, 37:470.)

Joints included in 28 joint count are bilateral shoulders, elbows, wrists, MCPs, PIPs and knees.)

- [ ] ____________________

Number of painful/tender joints unknown

Specify the number of swollen/effused joints prior to mobilization: (Eular/ACR 28 joint count; Fuchs and Pincus, Arthritis Rheum, 1994, 37:470.)

Joints included in 28 joint count are bilateral shoulders, elbows, wrists, MCPs, PIPs and knees.)

- [ ] ____________________

Number of swollen/effused joints unknown

Was morning stiffness present just prior to mobilization?

- [ ] yes
- [ ] no
- [ ] Unknown

Specify duration:

- [ ] ____________________ Hours ____________________ Minutes

Were extra-articular manifestations of RA present just prior to mobilization?

- [ ] yes
- [ ] no
- [ ] Unknown

Were nodules present?

- [ ] yes
- [ ] no

Were other manifestations present?

- [ ] yes
- [ ] no

Specify:

- [ ] ____________________

Laboratory Studies Prior to Mobilization for Stem Cell Collection

Specify any of the following laboratory values were elevated prior to mobilization:

Antinuclear antibody (ANA) titers

- [ ] yes
- [ ] no
- [ ] Unknown
<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C-reactive protein</strong></td>
<td></td>
<td>yes</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Erythrocyte sedimentation rate (ESR)</strong></td>
<td></td>
<td>yes</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Serum rheumatoid factor (RF) titers</strong></td>
<td></td>
<td>yes</td>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Date CBC tested:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WBC:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Segs:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Bands:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Lymphocytes:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Monocytes:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Eosinophils:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Basophils:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Hemoglobin:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
<tr>
<td><strong>Hematocrit:</strong></td>
<td></td>
<td>Known</td>
<td>Not known</td>
</tr>
</tbody>
</table>

**Note:**
- The date format is not specified in the document. It could be interpreted as either **Month Day Year** or **Month Day Month**.
- The units for Hemoglobin are not clearly stated. It could be **g/dL**, **g/L**, or **mmol/L**.
- The units for WBC are **x 10^9/L** or **x 10^6/mm^3**.
- The context of the form suggests it is related to **Rheumatoid Arthritis Pre-HSCT Data**.
<table>
<thead>
<tr>
<th>Question</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>111</td>
<td>%</td>
</tr>
<tr>
<td>112 Platelets:</td>
<td>Known</td>
</tr>
<tr>
<td>113</td>
<td>$x \times 10^9/L$ (x $10^3/mm^3$)</td>
</tr>
<tr>
<td>114 Creatinine:</td>
<td>Known</td>
</tr>
<tr>
<td>115</td>
<td>mg/dL</td>
</tr>
<tr>
<td>116 Alkaline phosphatase:</td>
<td>Known</td>
</tr>
<tr>
<td>117</td>
<td>U/L</td>
</tr>
<tr>
<td>118 AST:</td>
<td>Known</td>
</tr>
<tr>
<td>119</td>
<td>U/L</td>
</tr>
<tr>
<td>120 ALT:</td>
<td>Known</td>
</tr>
<tr>
<td>121</td>
<td>U/L</td>
</tr>
<tr>
<td>122 Total bilirubin:</td>
<td>Known</td>
</tr>
<tr>
<td>123</td>
<td>mg/dL</td>
</tr>
<tr>
<td>124 Albumin:</td>
<td>Known</td>
</tr>
<tr>
<td>125</td>
<td>g/dL</td>
</tr>
<tr>
<td>126 Were radiographic bone erosions present prior to mobilization?</td>
<td>yes</td>
</tr>
</tbody>
</table>

**Recipient Pain Self-Assessment**

Specify the recipient’s assessment of pain level experienced due to disease in the 2 weeks prior to mobilization:

- **Recipient's pain assessment:**
- **Worst possible pain score:**
- **Best possible pain score:**
### Recipient Disability Self-Assessment

**Questions: 130 - 151**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 Did the recipient complete an SF-36 Health Survey prior to mobilization?</td>
<td>yes, no, unknown</td>
<td></td>
</tr>
<tr>
<td>131 How is the score reported?</td>
<td>transformed score (range 0-100), raw score, unknown</td>
<td></td>
</tr>
<tr>
<td>132 Specify the following scale scores:</td>
<td>Physical Functioning score unknown</td>
<td></td>
</tr>
<tr>
<td>133 Role Functioning-Physical:</td>
<td>Role functioning-physical score unknown</td>
<td></td>
</tr>
<tr>
<td>134 Role Functioning-Emotional:</td>
<td>Role functioning-emotional score unknown</td>
<td></td>
</tr>
<tr>
<td>135 Social Functioning:</td>
<td>Social functioning score unknown</td>
<td></td>
</tr>
<tr>
<td>136 Bodily Pain:</td>
<td>Bodily pain score unknown</td>
<td></td>
</tr>
<tr>
<td>137 Mental Health:</td>
<td>Mental health score unknown</td>
<td></td>
</tr>
<tr>
<td>138 Vitality:</td>
<td>Vitality score unknown</td>
<td></td>
</tr>
<tr>
<td>139 General Health:</td>
<td>General health score unknown</td>
<td></td>
</tr>
<tr>
<td>140 Did the recipient complete a Health Assessment Questionnaire (HAQ) prior to mobilization?</td>
<td>yes, no, unknown</td>
<td></td>
</tr>
<tr>
<td>141 Recipient's score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>142 Worst possible function score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>143 Best possible function score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>144 Did the recipient complete a Global Assessment of Functioning of his/her own health prior to mobilization?</td>
<td>yes, no, unknown</td>
<td></td>
</tr>
<tr>
<td>145 Recipient-rated Global Assessment score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>146 Worst possible score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>147 Best possible score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>148 Did the physician complete a Global Assessment of Functioning of the recipient's health prior to mobilization?</td>
<td>yes, no, unknown</td>
<td></td>
</tr>
<tr>
<td>149 Physician-rated Global Assessment score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>145 Worst possible score:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 Best possible score:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Evaluation Prior to the Preparative Regimen (High-Dose Therapy)

**Questions: 152 - 165**

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 the signature lines.
152 Was an assessment performed after mobilization and prior to starting conditioning (high-dose therapy?)

| yes | no |
---|---|

153 Date of evaluation prior to the preparative regimen: __ __ __ __ - __ __

154 Specify the number of painful / tender joints prior to the preparative regimen: (Eular/ACR 28 joint count; Fuchs and Pincus, Arthritis Rheum, 1994, 37:470. Joints included in 28 joint count are bilateral shoulders, elbows, wrists, MCPs, PIPs and knees.)

Number of painful / tender joints unknown

155 Specify the number of swollen / effused joints prior to the preparative regimen: (Eular/ACR 28 joint count; Fuchs and Pincus, Arthritis Rheum, 1994, 37:470. Joints included in 28 joint count are bilateral shoulders, elbows, wrists, MCPs, PIPs and knees.)

Number of swollen / effused joints unknown

156 Was morning stiffness present just prior to the preparative regimen?

| yes | no | Unknown |
---|---|---|

157 Specify duration: __________________________ Hours __________________________ Minutes

158 Were extra-articular manifestations of RA present just prior to the preparative regimen?

| yes | no | Unknown |
---|---|---|

159 Were nodules present?

| yes | no |
---|---|

160 Were other manifestations present?

| yes | no |
---|---|

161 Specify: __________________________

Specify if any of the following signs / symptoms were elevated prior to the preparative regimen:

162 Antinuclear antibody (ANA) titers

| yes | no | Unknown |
---|---|---|

163 C-reactive protein

| yes | no | Unknown |
---|---|---|

164 Erythrocyte sedimentation rate (ESR)

| yes | no | Unknown |
---|---|---|

165 Serum rheumatoid factor (RF) titers

| yes | no | Unknown |
---|---|---|

Laboratory Values Prior to the Preparative Regimen

Questions: 166 - 171

166 Date tested: (testing done within 30 days of start of preparative regimen) __ __ __ __ - __ __

167 Alkaline phosphatase:

| Known | Not known |
---|---|

168 __________________________ U/L µkat/L

169 Albumin:

| Known | Not known |
---|---|
170. \[ \text{g/dL} \] \[ \text{g/L} \]

171. Were radiographic bone erosions present prior to the preparative regimen?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

### Recipient Pain Self-Assessment

Questions: 172 - 174

Specify the recipient's assessment of pain level experienced due to disease in the 2 weeks prior to the preparative regimen

172. Recipient's pain assessment: ________________

173. Worst possible pain score: ________________

174. Best possible pain score: ________________

### Recipient Disability Self-Assessment

Questions: 175 - 197

Specify the following scale scores:

175. Did the recipient complete an SF-36 Health Survey prior to the preparative regimen?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

176. How is the score reported?

- Transformed score (range 0-100)
- Raw score
- Unknown

177. Physical Functioning: ________________  Physical functioning score unknown

178. Role Functioning-Physical: ________________  Role functioning-physical score unknown

179. Role Functioning-Emotional: ________________  Role functioning-emotional score unknown

180. Social Functioning: ________________  Social functioning score unknown

181. Bodily Pain: ________________  Bodily pain score unknown

182. Mental Health: ________________  Mental health score unknown

183. Vitality: ________________  Vitality score unknown

184. General Health: ________________  General health score unknown

185. Did the recipient complete a Health Assessment Questionnaire (HAQ) prior to the preparative regimen?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

186. Recipient's score: ________________

187. Worst possible function score: ________________

188. Best possible function score: ________________

189. Did the recipient complete a Global Assessment of Functioning of his/her own health prior to the preparative regimen?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

190. Recipient-rated Global Assessment score: ________________

191. Worst possible score: ________________

192. Best possible score: ________________
193 Did the physician complete a Global Assessment of Functioning of the recipient's health prior to the preparative regimen?

- [ ] yes
- [ ] no
- [ ] Unknown

194 Physician-rated Global Assessment score: ____________________________

195 Worst possible score: ____________________________

196 Best possible score: ____________________________

197 Specify the recipient's percent of clinical improvement compared to the evaluation just prior to mobilization, according to the criteria of the American College of Rheumatology (ACR) (see definition):


Requires 20%* or more improvement in tender and swollen joint count plus 20%* or more improvement in 3 of the following 5 criteria:

- Patient pain assessment
- Patient global assessment
- Physician global assessment
- Patient self-assessed disability
- Acute-phase reactant (ESR or CRP)
- Remission

*Substitute 50% or 70% for 50% and 70% improvement levels, respectively.

- [ ] disease is worse
- [ ] no improvement
- [ ] 20% improvement (ACR20)
- [ ] 50% improvement (ACR50)
- [ ] 70% improvement (ACR70)
- [ ] remission
- [ ] not applicable, not mobilized
- [ ] Unknown