Form 2141 R2.0: Rheumatoid Arthritis Post-HSCT Data

<table>
<thead>
<tr>
<th>Key Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence Number:</td>
</tr>
<tr>
<td>Date Received:</td>
</tr>
<tr>
<td>CIBMTR Center Number:</td>
</tr>
<tr>
<td>CIBMTR Recipient ID:</td>
</tr>
<tr>
<td>Today's Date:</td>
</tr>
<tr>
<td>Date of HSCT for which this form is being completed:</td>
</tr>
<tr>
<td>HSCT Type (check all that apply):</td>
</tr>
<tr>
<td>- Autologous</td>
</tr>
<tr>
<td>- Allogeneic, unrelated</td>
</tr>
<tr>
<td>- Allogeneic, related</td>
</tr>
<tr>
<td>- Syngeneic (identical twin)</td>
</tr>
<tr>
<td>Product Type (check all that apply):</td>
</tr>
<tr>
<td>- Marrow</td>
</tr>
<tr>
<td>- PBSC</td>
</tr>
<tr>
<td>- Cord blood</td>
</tr>
<tr>
<td>- Other product</td>
</tr>
<tr>
<td>Specify:</td>
</tr>
<tr>
<td>Visit:</td>
</tr>
<tr>
<td>- 100 day</td>
</tr>
<tr>
<td>- 6 months</td>
</tr>
<tr>
<td>- 1 year</td>
</tr>
<tr>
<td>- 2 years</td>
</tr>
<tr>
<td>- &gt; 2 years,</td>
</tr>
<tr>
<td>Specify:</td>
</tr>
</tbody>
</table>

**Disease Assessment at the Time of Best Response to HSCT**

Questions: 1 - 5

1. Specify the date the recipient was evaluated for this report: __ __ __ __ - __ __- __ __
Specify the percent of clinical improvement at the time of best response since HSCT compared to the evaluation just prior to mobilization, according to American College of Rheumatology (ACR) criteria:


Requires 20%* or more improvement in tender and swollen joints plus 20%* or more improvement in 3 of following 6 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)
- Disease in remission

Specify the date of disease progression:

Specify the date of maximal improvement:

Specify the date of disease remission:

Did the recipient receive any treatment for RA since the date of the last report?

- Yes
- No
- Unknown

Was anti CD20 / rituximab therapy given?

- Yes
- No
- Unknown

Reason for therapy:

- Planned per protocol
- Continued from prior to HSCT
- Relapse / progression of RA
- Other reason
- Reason unknown

Specify:

Date therapy started:

Currently receiving?

- Yes
- No
12. Was anti-tumor necrosis factor (TNF) therapy given?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

13. Reason for therapy:
   - [ ] 1 Planned per protocol
   - [ ] 2 Continued from prior to HSCT
   - [ ] 3 Relapse / progression of RA
   - [ ] 4 other reason
   - [ ] 5 Reason unknown

14. Specify: __________________________

15. Date therapy started: __ __ __ __  -  __ __

16. Currently receiving?
   - [ ] yes
   - [ ] no

17. Was azathioprine therapy given?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

18. Reason for therapy:
   - [ ] 1 Planned per protocol
   - [ ] 2 Continued from prior to HSCT
   - [ ] 3 Relapse / progression of RA
   - [ ] 4 other reason
   - [ ] 5 Reason unknown

19. Specify: __________________________

20. Date therapy started: __ __ __ __  -  __ __

21. Currently receiving?
   - [ ] yes
   - [ ] no

22. Was corticosteroid therapy given?
   - [ ] yes
   - [ ] no
   - [ ] Unknown

23. Reason for therapy:
   - [ ] 1 Planned per protocol
   - [ ] 2 Continued from prior to HSCT
   - [ ] 3 Relapse / progression of RA
   - [ ] 4 other reason
   - [ ] 5 Reason unknown
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 Specify:</td>
<td></td>
</tr>
<tr>
<td>25 Date therapy started:</td>
<td>__ __ __ __ - __ __- __ __</td>
</tr>
<tr>
<td>26 Currently receiving?</td>
<td>yes no</td>
</tr>
<tr>
<td>27 Cyclophosphamide</td>
<td>yes no Unknown</td>
</tr>
</tbody>
</table>
| 28 Reason for therapy: | 1 Planned per protocol  
2 Continued from prior to HSCT  
3 Relapse / progression of RA  
4 other reason  
5 Reason unknown |
| 29 Specify: | |
| 30 Date therapy started: | __ __ __ __ - __ __- __ __ |
| 31 Currently receiving? | yes no |
| 32 Was cyclosporine A therapy given? | yes no Unknown |
| 33 Reason for therapy: | 1 Planned per protocol  
2 Continued from prior to HSCT  
3 Relapse / progression of RA  
4 other reason  
5 Reason unknown |
| 34 Specify: | |
| 35 Date therapy started: | __ __ __ __ - __ __- __ __ |
| 36 Currently receiving? | yes no |
| 37 Was gold-IM therapy given? | yes no Unknown |
38 Reason for therapy code
   1 Planned per protocol
   2 Continued from prior to HSCT
   3 Relapse / progression of RA
   4 other reason
   5 Reason unknown

39 Specify: ____________________________

40 Date therapy started __ __ __ __ - __ __- __ __

41 Currently receiving?
   yes [ ] no [ ]

42 Was gold-PO therapy given?
   yes [ ] no [ ] Unknown [ ]

43 Reason for therapy:
   1 Planned per protocol
   2 Continued from prior to HSCT
   3 Relapse / progression of RA
   4 other reason
   5 Reason unknown

44 Specify: ____________________________

45 Date therapy started: __ __ __ __ - __ __- __ __

46 Currently receiving?
   yes [ ] no [ ]

47 Was hydroxychloroquine therapy given?
   yes [ ] no [ ] Unknown [ ]

48 Reason for therapy:
   1 Planned per protocol
   2 Continued from prior to HSCT
   3 Relapse / progression of RA
   4 other reason
   5 Reason unknown

49 Specify: ____________________________

50 Date therapy started: __ __ __ __ - __ __- __ __
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
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<tbody>
<tr>
<td>51 Currently receiving?</td>
<td>yes  no</td>
</tr>
<tr>
<td>52 Was leflunomide therapy given?</td>
<td>yes  no  Unknown</td>
</tr>
<tr>
<td>53 Reason for therapy:</td>
<td>1 Planned per protocol</td>
</tr>
<tr>
<td></td>
<td>2 Continued from prior to HSCT</td>
</tr>
<tr>
<td></td>
<td>3 Relapse / progression of RA</td>
</tr>
<tr>
<td></td>
<td>4 other reason</td>
</tr>
<tr>
<td></td>
<td>5 Reason unknown</td>
</tr>
<tr>
<td>54 Specify:</td>
<td></td>
</tr>
</tbody>
</table>
| 55 Date therapy started:                                              | __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ ____
Reason for therapy:

1. Planned per protocol
2. Continued from prior to HSCT
3. Relapse / progression of RA
4. Other reason
5. Reason unknown

Specify:

Date therapy started: __ __ __ __ - __ __- __ __

Currently receiving?

Yes  No  Unknown

Was penicillamine therapy given?

Yes  No  Unknown

Reason for therapy:

1. Planned per protocol
2. Continued from prior to HSCT
3. Relapse / progression of RA
4. Other reason
5. Reason unknown

Specify:

Date therapy started: __ __ __ __ - __ __- __ __

Currently receiving?

Yes  No

Was sulfasalazine therapy given?

Yes  No  Unknown

Reason for therapy:

1. Planned per protocol
2. Continued from prior to HSCT
3. Relapse / progression of RA
4. Other reason
5. Reason unknown

Specify:

Date therapy started: __ __ __ __ - __ __- __ __
76 Currently receiving?
   yes  no

77 Was any other treatment given?
   yes  no  Unknown

78 Specify other treatment: __________________________

79 Reason for therapy:
   1 Planned per protocol
   2 Continued from prior to HSCT
   3 Relapse / progression of RA
   4 other reason
   5 Reason unknown

80 Specify: __________________________

81 Date therapy started: ___ __ ___ - ___ __ - ___ __

82 Currently receiving?
   yes  no

Disease Status at the Time of Evaluation for This Reporting Period

83 Specify the percent of clinical improvement at this current evaluation compared to the evaluation just prior to mobilization, according to American College of Rheumatology (ACR) criteria:


Requires 20%* or more improvement in tender and swollen joints plus 20%* or more improvement in 3 of following 6 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% adn 70% improvement levels, respectively.

   disease is worse
   no improvement
   20% improvement (ACR20)
   50% improvement (ACR50)
   70% improvement (ACR70)
   disease in remission

84 Specify the date of disease progression: ___ __ ___ - ___ __ - ___ __

85 Specify the date of maximal improvement: ___ __ ___ - ___ __ - ___ __

86 Specify the date of disease remission: ___ __ ___ - ___ __ - ___ __
Specify the following criteria for clinical remission in rheumatoid arthritis, according to criteria of the American College of Rheumatology (ACR): (Pinals et al, Arthritis Rheum, 1981, 24:1308.) 5 or more of the criteria must be fulfilled for at least 2 consecutive months. No alternative explanation may be invoked to account for the failure to meet a particular requirement. For instance, in the presence of knee pain, which might be related to degenerative arthritis, a point for “no joint pain” may not be awarded. Exclusions: clinical manifestations of active vasculitis, pericarditis, pleuritis or myositis, and unexplained recent weight loss or fever attributable to rheumatoid arthritis will prohibit a designation of complete clinical remission.

87 Duration of morning stiffness not exceeding 15 minutes
   yes  [ ]  no  [ ]  Unknown  [ ]

88 No fatigue
   yes  [ ]  no  [ ]  Unknown  [ ]

89 No joint pain (by history)
   yes  [ ]  no  [ ]  Unknown  [ ]

90 No joint tenderness or pain on motion
   yes  [ ]  no  [ ]  Unknown  [ ]

91 No soft tissue swelling in joints or tendon sheaths
   yes  [ ]  no  [ ]  Unknown  [ ]

92 Erythrocyte sedimentation rate (Westergren method) <30 mm/hr (female) or <20 mm/hr (male)
   yes  [ ]  no  [ ]  Unknown  [ ]

93 Date of assessment for the current disease evaluation: __ __ __ __ __ __ __ __

94 Number of painful / tender joints unknown
   (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.)
   Specify the number of painful / tender joints since the date of the last report: __________________________

95 Number of swollen / effused joints unknown
   (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.)
   Specify the number of swollen / effused joints since the date of the last report: __________________________

96 Was morning stiffness present since the date of the last report?
   yes  [ ]  no  [ ]  Unknown  [ ]

97 Specify duration: __________________________  duration unknown

98 Were extra-articular manifestations of RA present since the date of the last report?
   yes  [ ]  no  [ ]  Unknown  [ ]

99 Were nodules present?
   yes  [ ]  no  [ ]

100 Were other manifestations present?
    yes  [ ]  no  [ ]
Specify if any of the following laboratory values were elevated since the date of the last report:

102 Antinuclear antibody (ANA) titers
   yes  no  Unknown

103 C-reactive protein
   yes  no  Unknown

104 Erythrocyte sedimentation rate (ESR)
   yes  no  Unknown

105 Serum rheumatoid factor (RF) titers
   yes  no  Unknown

Specify the recipient's assessment of pain level experienced due to disease within one week prior to the date of the current evaluation:

106 Recipient's pain assessment:

107 Worst possible pain score:

108 Best possible pain score:

Specify the following scale scores:

111 Physical Functioning:  Physical functioning score unknown

112 Role Functioning-Physical:
   Role functioning-physical score unknown

113 Role Functioning-Emotional:
   Role functioning-emotional score unknown

114 Social Functioning:
   Social functioning score unknown

115 Bodily Pain:
   Bodily pain score unknown

116 Mental Health:
   Mental health score unknown

117 Vitality:
   Vitality score unknown

118 General Health:
   General health score unknown

119 Did the recipient complete a Health Assessment Questionnaire (HAQ) since the date of the last report?
   yes  no  Unknown

120 Recipient's score:

121 Worst possible function score:

122 Best possible function score:
### Form 2141 R2.0: Rheumatoid Arthritis Post-HSCT Data

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>123 Did the recipient complete a Global Assessment of Functioning of his/her own health since the date of the last report?</td>
<td>yes, no, Unknown</td>
</tr>
<tr>
<td>124 Recipient-rated Global Assessment score</td>
<td></td>
</tr>
<tr>
<td>125 Worst possible score:</td>
<td></td>
</tr>
<tr>
<td>126 Best possible score:</td>
<td></td>
</tr>
<tr>
<td>127 Did the physician complete a Global Assessment of Functioning of the recipient's health since the date of the last report?</td>
<td>yes, no, Unknown</td>
</tr>
<tr>
<td>128 Physician-rated Global Assessment score:</td>
<td></td>
</tr>
<tr>
<td>129 Worst possible score:</td>
<td></td>
</tr>
<tr>
<td>130 Best possible score:</td>
<td></td>
</tr>
</tbody>
</table>

First Name: ____________________  Last Name: ____________________
Phone number: ____________________  Fax number: ____________________
E-mail address: ____________________