Reporting Disease Assessments
Navigating the revised Post-TED (2450)

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Objectives

1. Review changes to the Post-TED disease assessment sections
2. Overview of disease assessments
3. Review reporting instructions
4. Case Studies
Previous versions of Post-TED

Malignant Disease Evaluation

Relapse or Progression

Additional Treatment

Method of Latest Disease Assessment
Revised Version of Post-TED (r4)

- Disease Assessment at the time of Best Response
- Post HCT Therapy
- Relapse or Progression
- Current Disease Status
Disease Assessments

• Molecular (e.g. PCR)
• Flow Cytometry
• Cytogenetic
  – Karyotyping
  – FISH
• Radiological (e.g. PET, MRI, CT)
• Clinical/Hematologic
# Disease Assessments

## Examples of Clinical/Hematologic Assessments

<table>
<thead>
<tr>
<th>CBC</th>
<th>Physician examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor marker labs</td>
<td>BM biopsy</td>
</tr>
<tr>
<td>Myeloma labs (SPEP, UPEP, Free Light Chains)</td>
<td></td>
</tr>
</tbody>
</table>
Disease Assessments

79. Was the disease status assessed by molecular testing (e.g. PCR)?
   [ ] Yes  [ ] No  [ ] Not applicable

80. Date assessed: ___ ___ ___ / ___ ___ / ___
   YYYY MM DD

81. Was disease detected?  [ ] Yes  [ ] No
Disease response criteria

- CIBMTR captures disease response based on criteria established by international working groups

- Criteria are available in the Pre-TED disease classification (2402) instructions section of the CIBMTR Data Management manual
Disease Assessment at the time of Best Response

Questions 75-97
Reporting Guidelines

• Captures the recipient’s best response to the planned course of HCT

• Treatment post-HCT
  – Maintenance or consolidation—response IS captured
  – For relapsed, persistent or progressive disease—response PRIOR to relapse/progression is captured
Reporting Guidelines

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- [ ] Continued complete remission (CCR) - Go to question 98
- [ ] Complete remission (CR) - Go to question 77
- [ ] Not in complete remission - Go to question 76
- [ ] Not evaluated - Go to question 98
In CR at time of HCT

- Day 100
  - Continued Complete Remission

- 6 months
  - Complete Remission (best response previously reported)

- 1 year
  - Never in Complete Remission
    - No additional therapy or maintenance/consolidation therapy started
    - Treatment started for persistent or progressive disease

Not in CR at time of HCT

- Not Evaluated
In CR at time of HCT

Day 100

6 months

1 year

Continued Complete Remission

Complete Remission (best response previously reported)

Never in Complete Remission

No additional therapy OR maintenance/consolidation therapy started

Treatment started for persistent or progressive disease

Not Evaluated

Not in CR at time of HCT
Continued Complete Remission

- Use this option if the recipient meets disease response criteria for CR prior to the start of preparative regimen
- Post-HCT: CCR for all reporting periods even if relapse post-transplant
In CR at time of HCT

Not in CR at time of HCT

Day 100

6 months

1 year

Continued Complete Remission

Complete Remission (best response previously reported)

Complete Remission

Never in Complete Remission

No additional therapy OR maintenance/consolidation therapy started

Treatment started for persistent or progressive disease

Not Evaluated
Complete Remission

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - Go to question 98
- Complete remission (CR) - Go to question 77
- Not in complete remission - Go to question 76
- Not evaluated - Go to question 98

- If a recipient was not in CR at the time of HCT but met the criteria for CR post HCT
  – Excludes any additional therapy given for relapse/progressive disease
Date of Best Response

77. Was the date of best response previously reported?
   □ Yes - Go to question 98
   □ No

78. Date assessed: __ __ ____ / __ __ / __ __

• CR achieved in a prior reporting period?
  – If so, select “Yes” and skip to Post-HCT Therapy section

• If Day 100 or CR has not been reported yet, select “no” and report the date CR was achieved in Q78
Disease Assessment Questions

• Complete these fields based on assessments performed at the time the recipient achieved CR

Specify the method(s) used to assess the disease status at the time of best response:

79. Was the disease status assessed by molecular testing (e.g. PCR)?
   - □ Yes
   - □ No
   - □ Not applicable

80. Date assessed: ___ ___ ___ / ___ ___ ___

81. Was disease detected? □ Yes □ No

82. Was the disease status assessed via flow cytometry?
   - □ Yes
   - □ No
   - □ Not applicable

83. Date assessed: ___ ___ ___ / ___ ___ ___

84. Was disease detected? □ Yes □ No
Disease Assessment Questions

- Complete these fields based on assessments performed at the time the recipient achieved CR

### Disease Assessment Time Windows

<table>
<thead>
<tr>
<th>Follow-Up Form</th>
<th>Approximate Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 Day</td>
<td>+/- 15 days of date of best response (question 78)</td>
</tr>
<tr>
<td>6 Month</td>
<td>+/- 15 days of date of best response (question 78)</td>
</tr>
<tr>
<td>Annual</td>
<td>+/- 30 days of date of best response (question 78)</td>
</tr>
</tbody>
</table>
In CR at time of HCT

Not in CR at time of HCT

Day 100

6 months

1 year

Continued Complete Remission

Complete Remission (best response previously reported)

Never in Complete Remission

No additional therapy OR maintenance/consolidation therapy started

Treatment started for persistent or progressive disease

Complete Remission

Never in Complete Remission

Not Evaluated
**Not in Complete Remission**

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

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- [ ] Continued complete remission (CCR) - *Go to question 98*
- [ ] Complete remission (CR) - *Go to question 77*
- [ ] Not in complete remission - *Go to question 76*
- [ ] Not evaluated - *Go to question 98*
Not in Complete Remission

- If a recipient does not meet the criteria for CR in the reporting period and the recipient has not received any therapy post-transplant, select “Not in complete remission.”
- If the recipient does not meet the criteria for CR in the reporting period and the recipient has started maintenance or consolidation therapy, select “Not in complete remission.”
Disease status if not in CR

76. Specify disease status if not in complete remission:
- Disease detected - Go to question 79
- No disease detected but incomplete evaluation to establish CR - Go to question 79

- Indicate if disease was detected, or if no disease was detected but the criteria for CR was not met due to incomplete evaluations to establish CR
Disease Assessments

• Purpose of the disease assessment section is to capture the latest disease assessments

Specify the method(s) used to assess the disease status at the time of best response:

79. Was the disease status assessed by molecular testing (e.g. PCR)?
   - Yes
   - No
   - Not applicable

80. Date assessed: __/__/__

81. Was disease detected?  Yes  No

82. Was the disease status assessed via flow cytometry?
   - Yes
   - No
   - Not applicable

83. Date assessed: __/__/__

84. Was disease detected?  Yes  No
In CR at time of HCT

Day 100

6 months

1 year

Continued Complete Remission

Complete Remission (best response previously reported)

Never in Complete Remission

Not in CR at time of HCT

No additional therapy OR maintenance/consolidation therapy started

Treatment started for persistent or progressive disease

Not Evaluated
Not in Complete Remission – with treatment

- If a recipient did not meet the criteria for CR and started treatment for relapse, persistent or progressive disease, select “Not in Complete Remission”
Not in Complete Remission – with treatment

76. Specify disease status if not in complete remission:
   - Disease detected - Go to question 79
   - No disease detected but incomplete evaluation to establish CR - Go to question 79

• Indicate if disease was detected, or if no disease was detected but the criteria for CR was not met due to incomplete evaluations to establish CR
Disease Assessment

- Was testing by each method performed prior to initiation of treatment for relapse, persistent, progressive disease?

Specify the method(s) used to assess the disease status at the time of best response:

79. Was the disease status assessed by molecular testing (e.g. PCR)?
   - [ ] Yes
   - [ ] No
   - [ ] Not applicable

   80. Date assessed: ___ / ___ / ___

   81. Was disease detected?  [ ] Yes  [ ] No

82. Was the disease status assessed via flow cytometry?
   - [ ] Yes
   - [ ] No
   - [ ] Not applicable

   83. Date assessed: ___ / ___ / ___

   84. Was disease detected?  [ ] Yes  [ ] No
In CR at time of HCT

Day 100

Continuous Complete Remission

Complete Remission (best response previously reported)

Never in Complete Remission

No additional therapy OR maintenance/consolidation therapy started

Treatment started for persistent or progressive disease

Not in CR at time of HCT

6 months

1 year

Not Evaluated
Not Evaluated

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - Go to question 98
- Complete remission (CR) - Go to question 77
- Not in complete remission - Go to question 76
- Not evaluated - Go to question 98

- Disease response not evaluated
  - This option is not commonly used
- If recipient started therapy for relapsed, persistent or progressive disease in a previous reporting period

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TRAINING & DEVELOPMENT 30
Current Disease Status

Questions 235-238
Current Disease Status

- This is a new section on the Post-TED forms
- Captures disease status at last evaluation in reporting period
Current Disease Status

• Includes response to any therapy given for maintenance or consolidation and/or relapse, persistent or progressive disease

• “Not evaluated” will rarely be selected
  – This would indicate that no tests (radiological, laboratory, or a clinical assessment) were performed to assess the CR status at any time during the reporting period
Current Disease Status

- Latest clinical/hematologic assessment consistent with the disease status reported in Q235.
Case Studies
## Case Study #1

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease</strong></td>
<td>Acute megakaryoblastic leukemia (M7)</td>
</tr>
<tr>
<td><strong>Karyotype</strong></td>
<td>Trisomy 19, Trisomy 20</td>
</tr>
<tr>
<td><strong>FISH</strong></td>
<td>Not done</td>
</tr>
<tr>
<td><strong>Flow cytometry</strong></td>
<td>20% megakaryoblasts detected</td>
</tr>
<tr>
<td><strong>Molecular</strong></td>
<td>No abnormalities detected (BCR/ABL, JAK2, FLT3-D835 point mutation, FLT3-ITD mutation, NPM1)</td>
</tr>
</tbody>
</table>
## Case Study #1

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Status</th>
</tr>
</thead>
</table>
| **Pre-HCT** | • Disease status: PIF  
• Day 0: 10/24/2016 |
| **Day 100** | • Day 30 (11/23/16): Persistent disease  
• **Day 60 (12/23/16): CR achieved**  
• Day 100 (1/30/17): Continued CR |
| **6 month** | • Continued CR |
# Case Study #1

<table>
<thead>
<tr>
<th>Date</th>
<th>Disease Assessments</th>
<th>Bone Marrow Aspirate</th>
<th>Karyotype</th>
<th>FISH</th>
<th>Flow cytometry</th>
<th>Molecular</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/23/16</td>
<td>Persistent disease</td>
<td>46 XX</td>
<td>Not done</td>
<td>No increase in megakaryoblasts</td>
<td>Not done</td>
<td></td>
</tr>
<tr>
<td>12/23/16</td>
<td>NED</td>
<td>Not done (insufficient cells)</td>
<td>Not done</td>
<td>No increase in megakaryoblasts</td>
<td>Not done</td>
<td></td>
</tr>
<tr>
<td>1/30/17</td>
<td>NED</td>
<td>46 XX</td>
<td>Not done</td>
<td>No increase in megakaryoblasts</td>
<td>Not done</td>
<td></td>
</tr>
<tr>
<td>2/1/17</td>
<td>Day 100 Date of Contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/17/17</td>
<td>NED</td>
<td>46 XX</td>
<td>Not done</td>
<td>Not done</td>
<td>Not done</td>
<td></td>
</tr>
<tr>
<td>4/19/17</td>
<td>6 month Date of Contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Case Study #1

• What is the recipient’s best response to transplant at Day 100?

<table>
<thead>
<tr>
<th>Disease Assessment at the Time of Best Response to HCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)</td>
</tr>
<tr>
<td>☐ Continued complete remission (CCR) - Go to question 98</td>
</tr>
<tr>
<td>☐ Complete remission (CR) - Go to question 77</td>
</tr>
<tr>
<td>☐ Not in complete remission - Go to question 76</td>
</tr>
<tr>
<td>☐ Not evaluated - Go to question 98</td>
</tr>
</tbody>
</table>
Case Study #1

- Best response to transplant is “Complete Remission”
Case Study #1

- What assessments would be reported in the Disease Assessment section?

<table>
<thead>
<tr>
<th>Date</th>
<th>Bone Marrow Aspirate</th>
<th>Karyotype</th>
<th>FISH</th>
<th>Flow cytometry</th>
<th>Molecular</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/23/16</td>
<td>Persistent disease</td>
<td>46 XX</td>
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<td>Not done</td>
</tr>
<tr>
<td>12/23/16</td>
<td>NED</td>
<td>Not done (insufficient cells)</td>
<td>Not done</td>
<td>No increase in megakaryoblasts</td>
<td>Not done</td>
</tr>
<tr>
<td>1/30/17</td>
<td>NED</td>
<td>46 XX</td>
<td>Not done</td>
<td>No increase in megakaryoblasts</td>
<td>Not done</td>
</tr>
<tr>
<td>2/1/17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Day 100 Date of Contact</td>
</tr>
</tbody>
</table>
Case Study #1

77. Was the date of best response previously reported?
   - Yes - Go to question 98
   - No

78. Date assessed: \[2016/12/23\]

Specify the method(s) used to assess the disease status at the time of best response:

79. Was the disease status assessed by molecular testing (e.g. PCR)?
   - Yes
   - No
   - Not applicable

80. Date assessed: \[YYYY/MM/DD\]

81. Was disease detected?
   - Yes
   - No
Case Study #1

82. Was the disease status assessed via flow cytometry?
   - Yes
   - No
   - Not applicable

83. Date assessed: 2016 /12/23

84. Was disease detected?  
   - Yes
   - No

85. Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?
   - Yes
   - No
   - Not applicable

86. Was the disease status assessed via FISH?
   - Yes
   - No
   - Not applicable

87. Date assessed:
   - YYYY / MM / DD

88. Was disease detected?  
   - Yes
   - No
Case Study #1

92. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)
   - [ ] Yes
   - [ ] No
   - [X] Not applicable

93. Date assessed: __ __ __ / __ __ / __

YYYY MM DD

94. Was disease detected?  [ ] Yes  [ ] No

95. Was the disease status assessed by clinical / hematologic assessment?
   - [X] Yes
   - [ ] No
   - [ ] Not applicable

96. Date assessed: __ __ __ / __ __ / __

YYYY MM DD

97. Was disease detected?  [ ] Yes  [X] No
Case Study #1

• What should be reported as the best response to transplant in the 6 month and annual reporting periods?

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - Go to question 98
- Complete remission (CR) - Go to question 77
- Not in complete remission - Go to question 76
- Not evaluated - Go to question 98

TRAINING & DEVELOPMENT
Case Study #1

- Best response to transplant is “Complete Remission” and the best response was previously reported.
Case Study #2

Pre-HCT

- Recipient with multiple myeloma
- Disease status: PR

Day 100

- Day 30: Myeloma labs show persistent disease
- Day 60: Myeloma labs show progression
- **Day 65: Treatment started for progressive disease**
- Day 90: Myeloma labs show stable disease
Case Study #2

- What is the recipient’s best response to transplant at Day 100?

Disease Assessment at the Time of Best Response to HCT

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - Go to question 98
- Complete remission (CR) - Go to question 77
- Not in complete remission - Go to question 76
- Not evaluated - Go to question 98
Case Study #2

• Best response to transplant is “Not in Complete Remission”

Disease Assessment at the Time of Best Response to HCT

- 75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)
  - [ ] Continued complete remission (CCR) - Go to question 98
  - [ ] Complete remission (CR) - Go to question 77
  - [x] Not in complete remission - Go to question 76
  - [ ] Not evaluated - Go to question 98
Case Study #2

• What assessments would be reported in the Disease Assessment section:

  • Day 30: Myeloma labs show persistent disease
  • Day 60: Myeloma labs show progression
  • Day 65: Treatment started for progressive disease
  • Day 90: Myeloma labs show stable disease
Case Study #2

Day 100

• Day 30: Myeloma labs show persistent disease
• Day 60: Myeloma labs show progression
• Day 65: Treatment started for progressive disease
• Day 90: Myeloma labs show stable disease
Case Study #2

- What should be reported as the best response to transplant in the 6 month and annual reporting periods?

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

75. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- [ ] Continued complete remission (CCR) - Go to question 98
- [ ] Complete remission (CR) - Go to question 77
- [ ] Not in complete remission - Go to question 76
- [ ] Not evaluated - Go to question 98
Case Study #2

• Report “Not Evaluated”
Questions?