Unexpected, Grade 3-5 Adverse Event Form (AE1)

Segment (PROTSEG):
Date of Onset (ADVDATE):
Event description (ADVENT):

1. Report activation status: (AVSTATUS)
   - 1-1 - Keep report active
   - 2-2 - Deactivate - Report filed in error
   - 3-3 - Deactivate - Key field error
   - 9-9 - Deactivate - Other reason
   If Other, specify reason for deactivation: (AESPEC1)

2. Record date transplant center became aware of the event: (AVAWARET)

3. Indicate weight at time of the event: (AVWGHTKG)

4. Was this event expected or anticipated? (AVEXPECT)
   - 1 - Yes
   - 2 - No

5. Record the severity of event: (AVEVENT)
   - 1-1 - Mild
   - 2-2 - Moderate
   - 3-3 - Severe
   - 4-4 - Life Threatening
   - 5-5 - Fatal

6. What is the relationship to study therapy/intervention: (AVRELAT)
   - 1-1 - Unrelated
   - 2-2 - Unlikely
   - 3-3 - Possible
   - 4-4 - Probable
   - 5-5 - Definite

7. Is there an alternative etiology: (AVETIOL)
   - 0-0 - None Apparent
   - 1-1 - Study Disease
   - 2-2 - Other Pre-Existing Disease or Condition
   - 3-3 - Accident, Trauma, or External Factors
   - 4-4 - Concurrent Illness/Condition (Not Pre-Existing)

8. What is the effect on study therapy/intervention schedule: (AVEFFECT)
   - 1-1 - No Change - Completed
   - 2-2 - No Change - Ongoing
   - 3-3 - Dose Modified
   - 4-4 - Temporarily Stopped
   - 5-5 - Permanently Stopped

9. Record the most severe outcome of the event: (AVOUTCOM)
   - 1-1 - Resolved, No Residual Effects
   - 2-2 - Resolved with Sequelae
   - 3-3 - Persistent Condition
   - 4-4 - Resolved by Death

10. Record the date of resolution: (AVRESDT)

11. Was this event associated with: (AVASSOCI)
   - 0-0 - None of the Following
   - 1-1 - Death
   - 2-2 - Life-Threatening Event
   - 3-3 - Disability
   - 4-4 - Congenital Anomaly
   *Additional Options Listed Below

Comments: (AE1COMM)
Additional Selection Options for AE1

Was this event associated with:
5-5 - Required Intervention to Prevent Permanent Impairment or Damage
6-6 - Hospitalization (Initial or Prolonged)
9-9 - Other SAE
Summary Form - Unexpected, Grade 3-5 Adverse Event (AE2)

Segment (PROTSEG):
Date of Onset (ADVDATE):
Event description (ADVENT):

1. Report activation status: (AVSTAT_A)

   1-1 - Keep report active
   2-2 - Deactivate - Report filed in error
   3-3 - Deactivate - Key field error
   9-9 - Deactivate - Other reason

Relevant Past Medical History
2. Does the patient have any relevant history, including pre-existing medical conditions? (SEMEDHXS)
   If Yes, include any relevant history, including preexisting medical conditions below.

   (SEMEDHX)

3. Event Summary
   Include clinical history of event, associated signs and symptoms, alternative etiologies being considered and medical management below.

   (SESUMM)

4. Initial submitter: (SEISUBBY)

   Name: ____________________________
   Date: (SEISUBDT) __/__/yyyy

5. Authorized submitter: (SEASUBBY)

   Name: ____________________________
   Date: (SEASUBDT) __/__/yyyy

**Therapy Form - Unexpected, Grade 3-5 Adverse Event (AE3)**

**Segment (PROTSEG):**
Date of Onset (ADVDATE): 
Event description (ADVENT):

1. Report activation status: (AVSTAT_B)

<table>
<thead>
<tr>
<th>Study Product Name</th>
<th>Dose of Study Product(s) at SAE Onset</th>
<th>Route of Study Product(s) at SAE Onset</th>
<th>Schedule of Study Product(s) at SAE Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SPNAME1)</td>
<td>(SP1DOSE)</td>
<td>(SP1ROUTE)</td>
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<td>(SPNAME5)</td>
<td>(SP5DOSE)</td>
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**Concomitant Medications**
3. Was the patient taking any concomitant medications? (RCVCONMD)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>Stop Date (mm/dd/yyyy)</th>
<th>Dose, Route, Schedule</th>
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<tbody>
<tr>
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<td>(CM25SPDT)</td>
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</table>

Comments: (AE3COMM)
**Laboratory/Diagnostics Form - Unexpected, Grade 3-5 Adverse Event (AE4)**

Segment (PROTSEG):
Date of Onset (ADVDATE):
Event description (ADVENT):

1. Report activation status: (AVSTAT_C)

1-1 - Keep report active  
2-2 - Deactivate - Report filed in error  
3-3 - Deactivate - Key field error  
9-9 - Deactivate - Other reason

---

**Laboratory Test Results**

2. Were relevant laboratory tests performed? (LABTSTPF)

If Yes, record the relevant laboratory test results in the grid below.

<table>
<thead>
<tr>
<th>Test</th>
<th>Collection Date (mm/dd/yyyy)</th>
<th>Result (Include units)</th>
<th>Site Normal Range (Include units)</th>
</tr>
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<tbody>
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</tbody>
</table>

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**Diagnostic Tests (EX: MR, CT Scan, Ultrasound)**

3. Were relevant diagnostic tests performed? (DXSTPF)

If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

<table>
<thead>
<tr>
<th>Test</th>
<th>Date Performed (mm/dd/yyyy)</th>
<th>Results/Comments</th>
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**Protocol: 0101 - Fungal Prophylaxis - Segment 0 (01010)**

Blood and Marrow Transplant
Clinical Trials Network
Review Form - Unexpected, Grade 3-5 Adverse Event (AE5)

Segment (PROTSEG):
Date of Onset (ADVDATE):
Event description (ADVENT):

1. Report activation status: (AVSTAT_D)
   1-1 - Keep report active
   2-2 - Deactivate - Report filed in error
   3-3 - Deactivate - Key field error
   9-9 - Deactivate - Other reason

2. Reviewed: (AEREVIEW)
   1 - Yes
   2 - No

3. Reviewed by: (ARFREVBY)

4. Review date: (ARFREVDT) (mm/dd/yyyy)

5. Comment 1 - For Distribution: (ARCM1DIS)

6. Comment 2 - All Other Reviewers/Data Coordinating Center (ARCM2ALL)
Medical Monitor Reviewer Form - Unexpected, Grade 3-5 Adverse Event (AE6)

Segment (PROTSEG):
Date of Onset (ADVDATE):
Event description (ADVENT):

1. Adverse event status: (AVSTAT_E)

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? (AMDETER)

3. Does this require expedited reporting to the DSMB? (AMEXPDSM)

4. Do you recommend unblinding the patient? (AMUNBLIN)

5. Do you recommend the patient be withdrawn from further protocol therapy? (AMWITHDR)

6. Is the review complete? (AMREVDNE)

   7. If No, what additional information is required: (AMREVINF)

8. Medical Monitor event description: (AMMMEVDS)

Comments: (AE6COMM)
Demographics (DEM)

1. Name Code: (NAMECODE)

2. IUBMID # (if available): (IUBMID)

3. CRID # (CIBMTR Recipient ID): (CRIDNUM) (xxxxxxxxxx)

Do NOT use IUBMID/UPN numbers in the CRID field.

4. Gender: (GENDER) 1 - Male  2 - Female

5. Date of Birth: (DOB) (mm/dd/yyyy)

6. Ethnicity: (ETHNIC) 1-1- Hispanic or Latino 2-2- Not Hispanic or Latino 8-8- Unknown 9-9- Not Answered

7. Race: (RACE) Specify race: (RACESP)

-White 10-10 - White (Not Otherwise Specified) 11-11 - European (Not Otherwise Specified) 13-13 - Mediterranean 14-14 - White North American *Additional Options Listed Below

8. Secondary Race: (RACE2) Specify secondary race: (RACE2SP)

-White 10-10 - White (Not Otherwise Specified) 11-11 - European (Not Otherwise Specified) 13-13 - Mediterranean 14-14 - White North American *Additional Options Listed Below

Comments: (DEMCMM1)

http://test.emmes.com/wfb/zkau/view/gndq/z_nd_73/2

9/18/2009
### Additional Selection Options for DEM

**Race:**
- 15-15 - South or Central American
- 16-16 - Eastern European
- 17-17 - Northern European
- 18-18 - Western European
- 81-81 - White Caribbean
- 82-82 - North Coast of Africa
- 83-83 - Middle Eastern
- -Black
  - 20-20 - Black (Not Otherwise Specified)
  - 21-21 - African American
  - 22-22 - African Black (Both Parents Born in Africa)
  - 23-23 - Caribbean Black
  - 24-24 - South or Central American Black
  - 29-29 - Black, Other Specify
- -Black
  - 20-20 - Black (Not Otherwise Specified)
  - 21-21 - African American
  - 22-22 - African Black (Both Parents Born in Africa)
  - 23-23 - Caribbean Black
  - 24-24 - South or Central American Black
  - 29-29 - Black, Other Specify
- -Asian
  - 30-30 - Asian (Not Otherwise Specified)
  - 31-31 - Indian/South Asian
  - 32-32 - Filipino (Pilipino)
  - 34-34 - Japanese
  - 35-35 - Korean
  - 36-36 - Chinese
  - 37-37 - Other Southeast Asian
  - 38-38 - Vietnamese
  - -American Indian or Alaska Native
  - 50-50 - Native American (Not Otherwise Specified)
  - 51-51 - Native Alaskan/Eskimo/Aleut
  - 52-52 - American Indian (Not Otherwise Specified)
  - 53-53 - North American Indian
  - 54-54 - South or Central American Indian
  - 55-55 - Caribbean Indian
  - -Native Hawaiian or Other Pacific Islander
  - 60-60 - Native Pacific Islander (Not Otherwise Specified)
  - 61-61 - Guamanian
  - 62-62 - Hawaiian
  - 63-63 - Samoan
  - -Other
  - 88-88 - Unknown
  - 90-90 - Other, Specify
  - 99-99 - Not Answered
Death Form (DTH)

1. Record date of death: (DTHDT)  (mm/dd/yyyy)

2. Was an autopsy performed? (AUTPERF)
   □ 1 - Yes  □ 2 - No
   If yes, submit autopsy report to DCC

Enter appropriate cause of death code below. List in order of decreasing severity.

3. Primary cause of death: (CZDTHPRM)
   1.0-1.0 - Graft Rejection or Failure
   - Infection (Other than Interstitial Pneumonia)
   1.1-1.1 - Autologous Recovery
   1.2-1.2 - Rejection
   2.1-2.1 - Bacterial
   *Additional Options Listed Below
   Specify other: (DTHSPEC1)

4. Secondary cause of death: (SCNDCZ1)
   1.0-1.0 - Graft Rejection or Failure
   - Infection (Other than Interstitial Pneumonia)
   1.1-1.1 - Autologous Recovery
   1.2-1.2 - Rejection
   2.1-2.1 - Bacterial
   *Additional Options Listed Below
   Specify other: (DTHSPEC2)

5. Secondary cause of death: (SCNDCZ2)
   1.0-1.0 - Graft Rejection or Failure
   - Infection (Other than Interstitial Pneumonia)
   1.1-1.1 - Autologous Recovery
   1.2-1.2 - Rejection
   2.1-2.1 - Bacterial
   *Additional Options Listed Below
   Specify other: (DTHSPEC3)

6. Secondary cause of death: (SCNDCZ3)
   1.0-1.0 - Graft Rejection or Failure
   - Infection (Other than Interstitial Pneumonia)
   1.1-1.1 - Autologous Recovery
   1.2-1.2 - Rejection
   2.1-2.1 - Bacterial
   *Additional Options Listed Below
   Specify other: (DTHSPEC4)

7. Secondary cause of death: (SCNDCZ4)
   1.0-1.0 - Graft Rejection or Failure
   - Infection (Other than Interstitial Pneumonia)
   1.1-1.1 - Autologous Recovery
   1.2-1.2 - Rejection
   2.1-2.1 - Bacterial
   *Additional Options Listed Below
   Specify other: (DTHSPEC5)

Comments: (DTCMMNTS)
Additional Selection Options for DTH

Primary cause of death:
2.2.2 - Fungal
2.3.2.3 - Viral
2.4.2.4 - Protozoal
2.5.2.5 - Other, Specify Below
2.9.2.9 - Organism Not Identified
-Interstitial Pneumonia
3.1.3.1 - Viral, CMV
3.2.3.2 - Viral, Other
3.3.3.3 - Pneumocystis
3.4.3.4 - Other, Specify Below
3.9.3.9 - Idiopathic
4.0.4.0 - Adult Respiratory Distress Syndrome
5.0.5.0 - Acute GVHD
6.0.6.0 - Chronic GVHD
7.0.7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1.7.1 - Persistent Disease
-Organ Failure (Not Due to GVHD or Infection)
8.1.8.1 - Liver
8.2.8.2 - Cardiac (Cardiomyopathy)
8.3.8.3 - Pulmonary
8.4.8.4 - CNS
8.5.8.5 - Renal
8.6.8.6 - Other, Specify Below
8.7.8.7 - Multiple Organ Failure, Specify Below
8.8.8.8 - Secondary Graft Failure
9.0.9.0 - Secondary Malignancy
9.1-9.1 - EBV
9.2-9.2 - Other, Specify Below
-Hemorrhage
10.1-10.1 - Pulmonary
10.2-10.2 - Intracranial
10.3-10.3 - Gastrointestinal
10.4-10.4 - Hemorrhage Not Specified
10.5-10.5 - Other, Specify Below
-Vascular
11.1-11.1 - Thromboembolic
11.2-11.2 - Disseminated Intravascular Coagulation (DIC)
11.3-11.3 - Gastrointestinal
11.4-11.4 - Thrombotic Thrombocytopenic Purpura
11.5-11.5 - Vascular Not Specified
11.9-11.9 - Other, Specify Below
12.0-12.0 - Accidental Death
13.0-13.0 - Other, Specify Below
01010 (ENR)

1. Record date informed consent form signed: (CNSNTDT0) (mm/dd/yyyy)
2. Will fungal prophylaxis be suspended prior to the initiation of the conditioning regimen? (FNGLPRPH)
   1-1 - Yes
   2-2 - No
   3-3 - Not Applicable

Consent for Biological Samples

Pre-Transplant:
3. Did the patient give consent to have a sample of blood taken pre-transplant for future research and testing? (PREFUTRT)
   1-1 - Yes
   2-2 - No

Post-Transplant:
4. Did the patient give consent to have samples of blood taken post-transplant each time samples are taken for the GM assay for future research and testing? (PSTGMF)
   1-1 - Yes
   2-2 - No

5. Did the patient give consent to have samples of tissue and fluid taken post-transplant for future research and testing? (PSTTSUFL)
   1-1 - Yes
   2-2 - No

Comments: (COMMENR0)
Termination Form (TRM)

Segment (PROTSEG):

1. Date of termination: (TRMDATE)  

2. Record reason for termination: (TRMRSN1)
   - 01-01 - Death
   - 02-02 - Fungal Infection
   - 03-03 - Uncontrolled Infection (Other than Fungal Infection)
   - 04-04 - Disease Stage
   - 05-05 - Ineligible ALT Value
   *Additional Options Listed Below

   If Death, a Death form must be submitted.

Specify other termination reason: (TRMSPEC1)

Comments: (TRMCOMM)
Additional Selection Options for TRM

Record reason for termination:

06-06 - Inadequate Organ Function
07-07 - Patient Became Pregnant
08-08 - Patient Refused/Withdrew Consent
09-09 - Other, Specify