Blood and Marrow Transplant
Clinical Trials Network

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

Web Version: 1.0; 3.01; 06-17-09

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: *(AVAWARDT)* *(mm/dd/yyyy)*
3. Indicate weight at time of the event: *(AVWGHTKG)* *(xxx.x)* kg
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)* *(mm/dd/yyyy)*
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

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Summary Form - Unexpected, Grade 3-5 Adverse Event (AE2)

Web Version: 1.0; 3.00; 06-17-09

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.

☐ 1- Yes ☐ 2 - No

(SEMEDHX)

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

(SESUMM)

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4. Initial submitter: *(SEISUBBY)*

Name:
Date: *(SEISUBDT)* *(mm/dd/yyyy)*

5. Authorized submitter: *(SEASUBBY)*

Name:
Date: *(SEASUBDT)* *(mm/dd/yyyy)*

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

Web Version: 1.0; 3.00; 06-17-09

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

1. Report activation status: *(AVSTAT_B)*

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

Study Product/Suspect Medication Data

2. Was the patient receiving any study products/suspect medications? *(RCVSP)* ☐ 1- Yes ☐ 2 - No

If Yes, list the study product/suspect medications the subject was taking in the grid below.

Study Product Name (Note: If blinded, indicate as such)	Dose of Study Product(s) at SAE Onset	Route of Study Product(s) at SAE Onset	Schedule of Study Product(s) at SAE Onset
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*

Concomitant Medications

3. Was the patient taking any concomitant medications? *(RCVCONMD)* ☐ 1- Yes ☐ 2 - No

If Yes, list the concomitant medications the patient was taking up to 1 month prior to SAE onset in the grid below.

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*

(CONMED6)	(CM6STDT)	(CM6SPDT)	(CM6DOSE)
(CONMED7)	(CM7STDT)	(CM7SPDT)	(CM7DOSE)
(CONMED8)	(CM8STDT)	(CM8SPDT)	(CM8DOSE)
(CONMED9)	(CM9STDT)	(CM9SPDT)	(CM9DOSE)
(CONMED10)	(CM10STDT)	(CM10SPDT)	(CM10DOSE)
(CONMED11)	(CM11STDT)	(CM11SPDT)	(CM11DOSE)
(CONMED12)	(CM12STDT)	(CM12SPDT)	(CM12DOSE)
(CONMED13)	(CM13STDT)	(CM13SPDT)	(CM13DOSE)
(CONMED14)	(CM14STDT)	(CM14SPDT)	(CM14DOSE)
(CONMED15)	(CM15STDT)	(CM15SPDT)	(CM15DOSE)
(CONMED16)	(CM16STDT)	(CM16SPDT)	(CM16DOSE)
(CONMED17)	(CM17STDT)	(CM17SPDT)	(CM17DOSE)
(CONMED18)	(CM18STDT)	(CM18SPDT)	(CM18DOSE)
(CONMED19)	(CM19STDT)	(CM19SPDT)	(CM19DOSE)
(CONMED20)	(CM20STDT)	(CM20SPDT)	(CM20DOSE)
(CONMED21)	(CM21STDT)	(CM21SPDT)	(CM21DOSE)
(CONMED22)	(CM22STDT)	(CM22SPDT)	(CM22DOSE)
(CONMED23)	(CM23STDT)	(CM23SPDT)	(CM23DOSE)

(CONMED24)	*(CM24STDT)*	*(CM24SPDT)*	*(CM24DOSE)*
(CONMED25)	*(CM25STDT)*	*(CM25SPDT)*	*(CM25DOSE)*

Comments: *(AE3COMM)*

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Laboratory/Diagnostics Form - Unexpected, Grade 3-5 Adverse Event (AE4)

Web Version: 1.0; 3.00; 06-23-09

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)* ☐ 1- Yes ☐ 2 - No

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

Test	Collection Date *(mm/dd/yyyy)*	Result (Include units)	Site Normal Range (Include units)
(ADLTST1)	*(ADL1CD)*	*(ADL1RES)*	*(ADL1NORG)*
(ADLTST2)	*(ADL2CD)*	*(ADL2RES)*	*(ADL2NORG)*
(ADLTST3)	*(ADL3CD)*	*(ADL3RES)*	*(ADL3NORG)*
(ADLTST4)	*(ADL4CD)*	*(ADL4RES)*	*(ADL4NORG)*
(ADLTST5)	*(ADL5CD)*	*(ADL5RES)*	*(ADL5NORG)*
(ADLTST6)	*(ADL6CD)*	*(ADL6RES)*	*(ADL6NORG)*
(ADLTST7)	*(ADL7CD)*	*(ADL7RES)*	*(ADL7NORG)*
(ADLTST8)	*(ADL8CD)*	*(ADL8RES)*	*(ADL8NORG)*
(ADLTST9)	*(ADL9CD)*	*(ADL9RES)*	*(ADL9NORG)*
(ADLTST10)	*(ADL10CD)*	*(ADL10RES)*	*(ADL10NRG)*

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

3. Were relevant diagnostic tests performed? *(DXSTPF)* ☐ 1- Yes ☐ 2 - No

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

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments
(ADDTS1)	*(AD1DTDAT)*	*(AD1DTRES)*
(ADDTS2)	*(AD2DTDAT)*	*(AD2DTRES)*

(ADDTS3)	*(AD3DTDAT)*	*(AD3DTRES)*
(ADDTS4)	*(AD4DTDAT)*	*(AD4DTRES)*
(ADDTS5)	*(AD5DTDAT)*	*(AD5DTRES)*
(ADDTS6)	*(AD6DTDAT)*	*(AD6DTRES)*
(ADDTS7)	*(AD7DTDAT)*	*(AD7DTRES)*
(ADDTS8)	*(AD8DTDAT)*	*(AD8DTRES)*
(ADDTS9)	*(AD9DTDAT)*	*(AD9DTRES)*
(ADDTS10)	*(AD10DTDT)*	*(AD10DTRS)*

Comments: *(AE4COMM)*

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Review Form - Unexpected, Grade 3-5 Adverse Event (AE5)

Web Version: 1.0; 3.00; 06-17-09

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)*

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Medical Monitor Reviewer Form - Unexpected, Grade 3-5 Adverse Event (AE6)

Web Version: 1.0; 4.00; 08-10-09

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

1. Adverse event status: *(AVSTAT_E)*

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1- Yes ☐ 2 - No
3. Does this require expedited reporting to the DSMB? *(AMEXPDSM)* ☐ 1- Yes ☐ 2 - No
4. Do you recommend unblinding the patient? *(AMUNBLIN)* ☐ 1- Yes ☐ 2 - No
5. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1- Yes ☐ 2 - No
6. Is the review complete? *(AMREVDNE)* ☐ 1- Yes ☐ 2 - No

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

8. Medical Monitor event description: *(AMMMEVDS)*

Comments: *(AE6COMM)*

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Demographics (DEM)

Web Version: 1.0; 5.00; 06-10-09

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)*

-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

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

-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

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

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
-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

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Death Form (DTH)

Web Version: 1.0; 4.00; 04-20-09

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:
2.2-2.2 - 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

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01010 (ENR)

Web Version: 1.0; 4.00; 06-26-09

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- Yes ☐ 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? *(PSTGMFT)* ☐ 1- Yes ☐ 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- Yes ☐ 2 - No

Comments: *(COMMENR0)*

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Termination Form (TRM)

Web Version: 1.0; 5.00; 04-20-09

Segment *(PROTSEG)*:

1. Date of termination: *(TRMDATE)* *(mm/dd/yyyy)*

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