

Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Web Version: 1.0; 4.07; 10-16-15

Segment (PROTSEG):

Date of Admission (ADMITDT):

1. Date of discharge: (DISCHDT)

(mm/dd/yyyy)

2. Patient discharge status: (DISCPTST)

1 - Alive 2 - Dead

If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis: (PHSPREAS)

01 - GVHD
02 - Relapse/Progression
03 - Graft Failure
04 - Infection
05 - Fungal Infection
*Additional Options Listed Below

*Specify organ: (ADM4SPEC)

**Specify other: (ADM1SPEC)

4. Record secondary discharge diagnoses:

a. GVHD: (REASGVHD)

1 - Contributory 2 - Noncontributory

b. Relapse/progression: (REASRLPS)

1 - Contributory 2 - Noncontributory

c. Graft failure: (REASGF)

1 - Contributory 2 - Noncontributory

d. Infection: (REASINF)

1 - Contributory 2 - Noncontributory

e. Fever: (REASFVR)

1 - Contributory 2 - Noncontributory

f. Seizure: (REASSZR)

1 - Contributory 2 - Noncontributory

g. Bleeding/hemorrhage: (REASGIBL)

1 - Contributory 2 - Noncontributory

h. Diarrhea: (REASDRH)

1 - Contributory 2 - Noncontributory

i. Nausea/vomiting: (REASNV)

1 - Contributory 2 - Noncontributory

j. Organ failure: (REASORGF)

1 - Contributory 2 - Noncontributory

Specify organ: (ADM3SPEC)

k. Trauma: (REASTRAM)

1 - Contributory 2 - Noncontributory

l. Psychiatric: (REASPSYC)

1 - Contributory 2 - Noncontributory

m. Secondary malignancy: (REASMALG)

1 - Contributory 2 - Noncontributory

n. Scheduled procedure/treatment: (REASPROC)

1 - Contributory 2 - Noncontributory

o. Thrombosis/thrombus/embolism: (REASTRMB)

1 - Contributory 2 - Noncontributory

p. Other: (REASOTHR)

1 - Contributory 2 - Noncontributory

Specify other: (ADM2SPEC)

5. Record re-admission institution: (ADMCENTR)

1 - Original Transplant Center
2 - Other Transplant Center
3 - Other Hospital

Comments: (ADMCOMM1)

Additional Selection Options for ADM

Record PRIMARY discharge diagnosis:

- 06 - Non-Fungal Infection
- 07 - Fever
- 08 - Seizure
- 09 - Bleeding/Hemorrhage
- 10 - Diarrhea
- 11 - Nausea/Vomiting
- 12 - Organ Failure (specify organ)*
- 13 - Trauma
- 14 - Psychiatric
- 15 - Secondary Malignancy
- 16 - Transplant
- 17 - Scheduled Procedure/Treatment
- 18 - Thrombosis/Thrombus/Embolism
- 99 - Other (specify)**

**Blood and Marrow Transplant Clinical
Trials Network**

Adverse Event Form (AE1)

Web Version: 1.0; 4.00; 10-16-15

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

1. Report activation status:(AVSTATUS)

- 1 - Keep report active
- 2 - Deactivate - Report filed in error
- 3 - Deactivate - Key field error
- 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 - Mild
- 2 - Moderate
- 3 - Severe
- 4 - Life Threatening
- 5 - Fatal



6. What is the relationship to study therapy/intervention:(AVRELAT)

- 1 - Unrelated
- 2 - Unlikely
- 3 - Possible
- 4 - Probable
- 5 - Definite

7. Is there an alternative etiology:(AVETIOL)

- 0 - None Apparent
- 1 - Study Disease
- 2 - Other Pre-Existing Disease or Condition
- 3 - Accident, Trauma, or External Factors
- 4 - Concurrent Illness/Condition (Not Pre-Existing)

8. What is the effect on study therapy/intervention schedule:(AVEFFECT)

- 1 - No Change - Completed
- 2 - No Change - Ongoing
- 3 - Dose Modified
- 4 - Temporarily Stopped
- 5 - Permanently Stopped

9. Record the most severe outcome of the event:(AVOUTCOM)

- 1 - Resolved, No Residual Effects
- 2 - Resolved with Sequelae
- 3 - Persistent Condition
- 4 - Resolved by Death



10. Record the date of resolution:(AVRESDT)

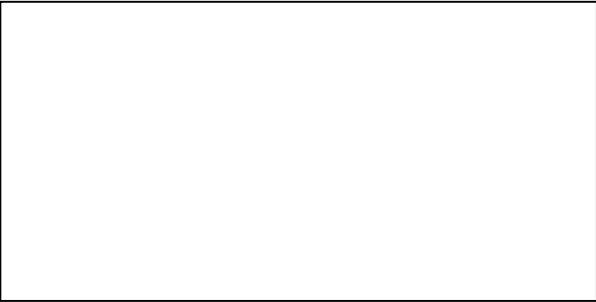
(mm/dd/yyyy)

11. Was this event associated with:(AVASSOCI)

- 0 - None of the Following
- 1 - Death
- 2 - Life-Threatening Event
- 3 - Disability
- 4 - Congenital Anomaly
- *Additional Options Listed Below



Comments:(AE1COMM)



Additional Selection Options for AE1

Was this event associated with:

5 - Required Intervention to Prevent Permanent Impairment or Damage

6 - Hospitalization (Initial or Prolonged)

9 - Other SAE

**Blood and Marrow Transplant Clinical
Trials Network**

AE Summary Form (AE2)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:(AVSTAT_A)

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

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions?(SEMEDHXS)

1 - Yes 2 - No

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) (mm/dd/yyyy)

5. Authorized submitter:(SEASUBBY)

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

**Blood and Marrow Transplant Clinical
Trials Network**

AE Therapy Form (AE3)

Web Version: 1.0; 4.05; 10-16-15

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

1. Report activation status:(AVSTAT_B)

| |
|---|
| 1 - Keep report active 2 - Deactivate - Report filed in error 3 - Deactivate - Key field error 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 | Date Study Product First Started (mm/dd/yyyy) | Date Study Product Last Taken (mm/dd/yyyy) | Reason for Use |
|--|--|---|--|--|---|----------------|
| (SPNAME1) | (SP1DOSE) | (SP1ROUTE) | (SP1SCHED) | (SP1STDT) | (SP1SPDT) | (SP1REASO) |
| (SPNAME2) | (SP2DOSE) | (SP2ROUTE) | (SP2SCHED) | (SP2STDT) | (SP2SPDT) | (SP2REASO) |
| (SPNAME3) | (SP3DOSE) | (SP3ROUTE) | (SP3SCHED) | (SP3STDT) | (SP3SPDT) | (SP3REASO) |
| (SPNAME4) | (SP4DOSE) | (SP4ROUTE) | (SP4SCHED) | (SP4STDT) | (SP4SPDT) | (SP4REASO) |
| (SPNAME5) | (SP5DOSE) | (SP5ROUTE) | (SP5SCHED) | (SP5STDT) | (SP5SPDT) | (SP5REASO) |

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 | Indication |
|------------|----------------------------|---------------------------|-----------------------|---|
| (CONMED1) | (CM1STDT) | (CM1SPDT) | (CM1DOSE) | (CM1INDIC) 1 - Treatment of adverse event 9 - Other |
| (CONMED2) | (CM2STDT) | (CM2SPDT) | (CM2DOSE) | (CM2INDIC) 1 - Treatment of adverse event 9 - Other |
| (CONMED3) | (CM3STDT) | (CM3SPDT) | (CM3DOSE) | (CM3INDIC) 1 - Treatment of adverse event 9 - Other |
| (CONMED4) | (CM4STDT) | (CM4SPDT) | (CM4DOSE) | (CM4INDIC) 1 - Treatment of adverse event 9 - Other |
| (CONMED5) | (CM5STDT) | (CM5SPDT) | (CM5DOSE) | (CM5INDIC) |

| | | | | |
|------------|------------|------------|------------|--|
| | | | | <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED6) | (CM6STDT) | (CM6SPDT) | (CM6DOSE) | <input type="checkbox"/> (CM6INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED7) | (CM7STDT) | (CM7SPDT) | (CM7DOSE) | <input type="checkbox"/> (CM7INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED8) | (CM8STDT) | (CM8SPDT) | (CM8DOSE) | <input type="checkbox"/> (CM8INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED9) | (CM9STDT) | (CM9SPDT) | (CM9DOSE) | <input type="checkbox"/> (CM9INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED10) | (CM10STDT) | (CM10SPDT) | (CM10DOSE) | <input type="checkbox"/> (CM10INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED11) | (CM11STDT) | (CM11SPDT) | (CM11DOSE) | <input type="checkbox"/> (CM11INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED12) | (CM12STDT) | (CM12SPDT) | (CM12DOSE) | <input type="checkbox"/> (CM12INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED13) | (CM13STDT) | (CM13SPDT) | (CM13DOSE) | <input type="checkbox"/> (CM13INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED14) | (CM14STDT) | (CM14SPDT) | (CM14DOSE) | <input type="checkbox"/> (CM14INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED15) | (CM15STDT) | (CM15SPDT) | (CM15DOSE) | <input type="checkbox"/> (CM15INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED16) | (CM16STDT) | (CM16SPDT) | (CM16DOSE) | <input type="checkbox"/> (CM16INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED17) | (CM17STDT) | (CM17SPDT) | (CM17DOSE) | <input type="checkbox"/> (CM17INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED18) | (CM18STDT) | (CM18SPDT) | (CM18DOSE) | <input type="checkbox"/> (CM18INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED19) | (CM19STDT) | (CM19SPDT) | (CM19DOSE) | <input type="checkbox"/> (CM19INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |
| (CONMED20) | (CM20STDT) | (CM20SPDT) | (CM20DOSE) | <input type="checkbox"/> (CM20INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other |

| | | | | |
|------------|------------|------------|------------|---|
| (CONMED21) | (CM21STDT) | (CM21SPDT) | (CM21DOSE) | (CM21INDI) 1 - Treatment of adverse event 9 - Other |
| (CONMED22) | (CM22STDT) | (CM22SPDT) | (CM22DOSE) | (CM22INDI) 1 - Treatment of adverse event 9 - Other |
| (CONMED23) | (CM23STDT) | (CM23SPDT) | (CM23DOSE) | (CM23INDI) 1 - Treatment of adverse event 9 - Other |
| (CONMED24) | (CM24STDT) | (CM24SPDT) | (CM24DOSE) | (CM24INDI) 1 - Treatment of adverse event 9 - Other |
| (CONMED25) | (CM25STDT) | (CM25SPDT) | (CM25DOSE) | (CM25INDI) 1 - Treatment of adverse event 9 - Other |

Comments:(AE3COMM)

**Blood and Marrow Transplant Clinical
Trials Network**

AE Laboratory/Diagnostics Form (AE4)

Web Version: 1.0; 3.11; 10-16-15

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

1. Report activation status:(AVSTAT_C)

| |
|---|
| 1 - Keep report active 2 - Deactivate - Report filed in error 3 - Deactivate - Key field error 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 grid below.

| Test | Collection Date (mm/dd/yyyy) | Result (Include units) | Site Normal Range (Include units) | Lab Value Previous to this SAE (Include units) | Collection Date for Previous Lab (mm/dd/yyyy) |
|------------|---------------------------------|---------------------------|---|--|---|
| (ADLTST1) | (ADL1CD) | (ADL1RES) | (ADL1NORG) | (ADL1PRVL) | (ADL1PCD) |
| (ADLTST2) | (ADL2CD) | (ADL2RES) | (ADL2NORG) | (ADL2PRVL) | (ADL2PCD) |
| (ADLTST3) | (ADL3CD) | (ADL3RES) | (ADL3NORG) | (ADL3PRVL) | (ADL3PCD) |
| (ADLTST4) | (ADL4CD) | (ADL4RES) | (ADL4NORG) | (ADL4PRVL) | (ADL4PCD) |
| (ADLTST5) | (ADL5CD) | (ADL5RES) | (ADL5NORG) | (ADL5PRVL) | (ADL5PCD) |
| (ADLTST6) | (ADL6CD) | (ADL6RES) | (ADL6NORG) | (ADL6PRVL) | (ADL6PCD) |
| (ADLTST7) | (ADL7CD) | (ADL7RES) | (ADL7NORG) | (ADL7PRVL) | (ADL7PCD) |
| (ADLTST8) | (ADL8CD) | (ADL8RES) | (ADL8NORG) | (ADL8PRVL) | (ADL8PCD) |
| (ADLTST9) | (ADL9CD) | (ADL9RES) | (ADL9NORG) | (ADL9PRVL) | (ADL9PCD) |
| (ADLTST10) | (ADL10CD) | (ADL10RES) | (ADL10NRG) | (ADL10PVL) | (ADL10PCD) |

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

3. Were relevant diagnostic tests performed?(DXSTPF)

1 - Yes 2 - No

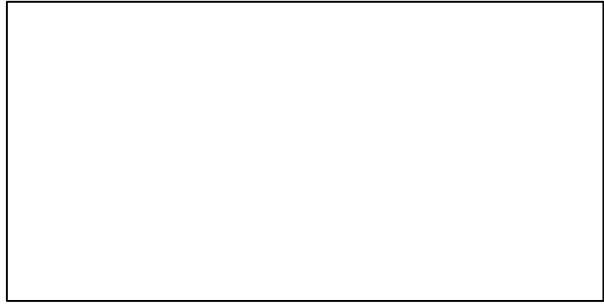
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

| Test | Date Performed (mm/dd/yyyy) | Results/Comments |
|------|--------------------------------|------------------|
| | | |

| | | |
|-------------------------------|---------------------------------|---------------------------------|
| (ADDTS1) <input type="text"/> | (AD1DTDAT) <input type="text"/> | (AD1DTRES) <input type="text"/> |
| (ADDTS2) <input type="text"/> | (AD2DTDAT) <input type="text"/> | (AD2DTRES) <input type="text"/> |
| (ADDTS3) <input type="text"/> | (AD3DTDAT) <input type="text"/> | (AD3DTRES) <input type="text"/> |
| (ADDTS4) <input type="text"/> | (AD4DTDAT) <input type="text"/> | (AD4DTRES) <input type="text"/> |
| (ADDTS5) <input type="text"/> | (AD5DTDAT) <input type="text"/> | (AD5DTRES) <input type="text"/> |

| | | |
|--------------------------------|----------------------------------|----------------------|
| (ADDTS6) <input type="text"/> | (AD6DTDAT) <input type="text"/> | <input type="text"/> |
| (ADDTS7) <input type="text"/> | (AD7DTDAT) <input type="text"/> | <input type="text"/> |
| (ADDTS8) <input type="text"/> | (AD8DTDAT) <input type="text"/> | <input type="text"/> |
| (ADDTS9) <input type="text"/> | (AD9DTDAT) <input type="text"/> | <input type="text"/> |
| (ADDTS10) <input type="text"/> | (AD10DTDAT) <input type="text"/> | <input type="text"/> |

Comments:(AE4COMM)



**Blood and Marrow Transplant Clinical
Trials Network**

AE Review Form (AE5)

Web Version: 1.0; 3.12; 10-16-15

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

1. Report activation status:(AVSTAT_D)

- 1 - Keep report active
- 2 - Deactivate - Report filed in error
- 3 - Deactivate - Key field error
- 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)

**Blood and Marrow Transplant Clinical
Trials Network**

AE Medical Monitor Reviewer Form (AE6)

Web Version: 1.0; 7.00; 10-16-15

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

1. Adverse event status:(AVSTAT_E)

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

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? 1 - Yes 2 - No
(AMDETER)

3. Does this require expedited reporting to the DSMB?(AMEXPDSM) 1 - Yes 2 - No

4. Do you recommend the patient be withdrawn from further protocol therapy?
(AMWITHDR) 1 - Yes 2 - No

5. Is the review complete?(AMREVDNE) 1 - Yes 2 - No

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

7. Medical Monitor event description:(AMMMEVDS)

8. Medical Monitor CTCAE grade of event:(CTCAEGRD)

- 1 - Grade 1
- 2 - Grade 2
- 3 - Grade 3
- 4 - Grade 4
- 5 - Grade 5

Comments:(AE6COMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Baseline Form - 0902 (BL6)

Web Version: 1.0; 3.04; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Pre-transplant Status

1. Patient's primary diagnosis pre-transplant: (BLPRMDG)

- 01 - Acute Myelogenous Leukemia (AML or ANLL)
- 02 - Acute Lymphoblastic Leukemia (ALL)
- 03 - Other Acute Leukemia
- 04 - Chronic Myelogenous Leukemia (CML)
- 05 - Other Leukemia
- *Additional Options Listed Below

2. If Acute Leukemia, record the disease status pre-transplant: (BLACL)

- 1 - Primary Induction Failure
- 2 - First Complete Remission
- 3 - First Relapse
- 4 - Second Complete Remission
- 5 - Second Relapse
- *Additional Options Listed Below

3. If CML, record the disease status pre-transplant: (BLCML)

- 01 - First Chronic Phase
- 02 - Hematologic Complete Remission
- 03 - Accelerated Phase
- 04 - Blast Crisis
- 05 - Second or Greater Chronic Phase

4. If Other Leukemia, specify primary diagnosis pre-transplant: (BLOTHLEU)

5. If Other Leukemia, record the disease status pre-transplant: (BLOTLEUS)

6. If MDS/MPS, record the disease status pre-transplant: (BLMDS)

- 1 - Refractory Anemia
- 2 - Refractory Anemia with Ringed Sideroblasts
- 3 - Refractory Cytopenia with Multilineage Dysplasia
- 4 - Refractory Cytopenia with Multilineage Dysplasia and Ringed Sideroblasts
- 5 - Refractory Anemia with Excess Blasts - 1 (5-10% blasts)
- *Additional Options Listed Below

7. If Multiple Myeloma/PCD, record the disease status pre-transplant: (BLMYELOM)

- 01 - Stringent Complete Response (sCR)
- 02 - Complete Response (CR)
- 03 - Near Complete Response (nCR)
- 04 - Very Good Partial Response (VGPR)
- 05 - Partial Response (PR)
- *Additional Options Listed Below

8. If Lymphoma, record the disease status pre-transplant: (BLL YMPHO)

- 01 - Disease Untreated
- 02 - Primary Induction Failure - Resistant
- 03 - Primary Induction Failure - Sensitive
- 04 - Primary Induction Failure - Sensitivity Unknown
- 05 - 1st Complete Remission
- *Additional Options Listed Below

9. If Other Disease, specify primary diagnosis pre-transplant: (BLOTHPRE)

10. If Other Disease, record the disease status pre-transplant: (BLOTDXST)

Indicate the agents used for the patient's conditioning regimen.

11. Cyclophosphamide: (BLCYCLOS)

1 - Yes 2 - No

12. TBI (Total Body Irradiation): (BLTBI)

1 - Yes 2 - No

13. Busulfan: (BLBULSUL)

1 - Yes 2 - No

14. Fludarabine: (BLFLUDAR)

1 - Yes 2 - No

15. Melphalan: (BLMELPHA)

1 - Yes 2 - No

16. ATG (thymoglobulin): (BLATG)

1 - Yes 2 - No

17. Other agent: (BLOTHCON)

1 - Yes 2 - No

If Other agent, specify:(*BLOTCNSP*)

18. What is the patient's Karnofsky score?(*BLKARNF*)

01 - 100 (Normal; No Complaints/Fully Active)
02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
05 - 60 (Requires Occasional Assistance/Minimal Active Play)
*Additional Options Listed Below

19. Date of Karnofsky score:(*BLKARNDT*)

(mm/dd/yyyy)

20. Patient's weight:(*BLWEIGHT*)

(xxx.x) kg OR (*BLWTLB*) (xxx) lbs

21. Date patient's weight assessed:(*BLWTD*)

(mm/dd/yyyy)

22. Patient's height:(*BLHEIGHT*)

(xxx.xx) cm OR (*BLHTIN*) (xx.xx) in

23. Date patient's height assessed:(*BLHTDT*)

(mm/dd/yyyy)

Interventions

24. Did the patient have the baseline intervention?(*BLINTVN*)

1 - Yes 2 - No

25. Date of baseline intervention:(*BLINTDT*)

(mm/dd/yyyy)

26. Did the patient's transplant occur more than two weeks after the baseline intervention training?(*BLXPINT*)

1 - Yes 2 - No

27. Did the patient have a baseline booster contact?(*BLBSTR*)

1 - Yes 2 - No

28. Date of baseline booster contact:(*BLBSTRDT*)

(mm/dd/yyyy)

Comments:(*BLCOMM*)

Additional Selection Options for BL6

Patient's primary diagnosis pre-transplant:

- 06 - Myelodysplastic (MDS)/ Myeloproliferative (MPS) Disorders
- 07 - Multiple Myeloma/ Plasma Cell Disorder (PCD)
- 08 - Non-Hodgkin Lymphoma
- 09 - Hodgkin Lymphoma
- 10 - Solid Tumors
- 11 - Severe Aplastic Anemia
- 12 - Inherited Abnormalities of Erythrocyte Differentiation or Function
- 13 - Disorders of the Immune System
- 14 - Inherited Abnormalities of Platelets
- 15 - Inherited Disorders of Metabolism
- 16 - Histiocytic Disorders
- 17 - Autoimmune Disorders
- 99 - Other Disease

If Acute Leukemia, record the disease status pre-transplant:

- 6 - Third or Subsequent Complete Remission
- 7 - Third or Subsequent Relapse
- 8 - Previously Untreated

If MDS/MPS, record the disease status pre-transplant:

- 6 - Refractory Anemia with Excess Blasts - 2 (10-20% blasts)
- 7 - Myelodysplastic Syndrome, Unclassified
- 8 - MDS Associated with Isolated Del(5q)
- 9 - Chronic Myelomonocytic Leukemia

If Multiple Myeloma/PCD, record the disease status pre-transplant:

- 06 - Stable Disease (SD)
- 07 - Progressive Disease
- 08 - Relapse from CR

If Lymphoma, record the disease status pre-transplant:

- 06 - 2nd Complete Remission
- 07 - 3rd or Subsequent Complete Remission
- 08 - 1st Complete Remission Undetermined
- 09 - 2nd Complete Remission Undetermined
- 10 - 3rd or Subsequent Complete Remission Undetermined
- 11 - 1st Relapse - Untreated
- 12 - 1st Relapse - Resistant
- 13 - 1st Relapse - Sensitive
- 14 - 1st Relapse - Sensitivity Unknown
- 15 - 2nd Relapse - Untreated
- 16 - 2nd Relapse - Resistant
- 17 - 2nd Relapse - Sensitive
- 18 - 2nd Relapse - Sensitivity Unknown
- 19 - 3rd or Subsequent Relapse - Untreated
- 20 - 3rd or Subsequent Relapse - Resistant
- 21 - 3rd or Subsequent Relapse - Sensitive
- 22 - 3rd Relapse or Greater - Sensitivity Unknown

What is the patient's Karnofsky score?

- 06 - 50 (Requires Considerable Assistance/No Active Play)
- 07 - 40 (Disabled/Able to Initiate Quiet Activities)
- 08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)
- 09 - 20 (Very Sick/Limited to Very Passive Activity)
- 10 - 10 (Moribund; Completely Disabled)

**Blood and Marrow Transplant Clinical
Trials Network**

Cancer and Treatment Distress - 0902 (CTX)

Web Version: 1.0; 2.00; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Date of Assessment (CTXDATAS)

/ / (mm/dd/yyyy)

Below are thoughts many people have during or after treatment. Some of the events below may distress or worry you, even if they have not happened.

For each statement, please circle how much **distress or worry** (such as feeling upset, tense, sad, frustrated) it caused you in the **PAST WEEK**.

WHETHER OR NOT THE EVENT HAS OCCURRED, rate how much **DISTRESS** or **WORRY** it caused you in the **PAST WEEK**:

| | None | Mild | Moderate | Severe | Not Answered |
|---|--|----------------------------|----------------------------|----------------------------|-----------------------------|
| 1. Medical problems. | (CTXMEDPR) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 2. Not being able to do what I used to do. | (CTXNOTDO) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 3. Long term effects of treatment. | (CTXLNGTM) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 4. Dealing with the medical system. | (CTXMEDSY) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 5. Wondering about the emotional toll on my family or other caregivers. | (CTXEMOT) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 6. Changes in my appearance. | (CTXCHAPP) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 7. Dealing with insurance. | (CTXINSUR) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 8. Not knowing what the future will bring. | (CTXFUTUR) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 9. Getting information when I need it. | (CTXINFOR) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 10. Thinking about possible things that could go wrong. | (CTXWRONG) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 11. Feeling tired or worn out. | (CTXTIRED) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 12. The family having to help out more than in the past. | (CTXFAMILY) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 13. My hair thinning or falling out. | (CTXHAIR) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 14. Wondering how to support myself and the family financially. | (CTXSUPRT) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 15. Losing "myself" in all the changes. | (CTXSELF) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 16. Thinking about the possibility of relapse. | (CTXRELPS) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 17. Communicating with medical people. | (CTXCMMED) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 18. Being a burden to other people. | (CTXBRDN) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 19. Thoughts about the possibility of dying. | (CTXPSDIE) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 20. The cost of my treatment. | (CTXTRCST) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 21. Not feeling as masculine or feminine as I used to feel. | (CTXMSFEM) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 22. Not having my usual energy. | (CTXNONRG) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |

In the PAST WEEK, how much did your **DISTRESS** or **WORRY** INTERFERE with:

| | Interfered Not at all | Interfered A Little | Interfered Moderately | Interfered A Lot | Not Answered |
|-------------------------|---------------------------------------|----------------------------|------------------------------|----------------------------|-----------------------------|
| 23. General activities. | (CTXGNACT) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 24. Work. | (CTXWORK) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 25. Sleep. | (CTXSLEEP) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |

| | | | | | |
|----------------------------------|---------------------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 26. Enjoyment of life. | (CTXENJLF) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |
| 27. Relations with other people. | (CTXRELPP) <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 88 |

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Comments:(CTXCOMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Demographics (DEM)

Web Version: 1.0; 6.02; 12-02-15

1. Name Code:(*NAMECODE*)

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

3. Gender:(*GENDER*)

4. Date of Birth:(*DOB*)

5. Ethnicity:(*ETHNIC*)

1 - Male 2 - Female
 (mm/dd/yyyy)

- 1- Hispanic or Latino
- 2- Not Hispanic or Latino
- 8- Unknown
- 9- Not Answered

6. Race:(*RACE*)

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

Specify race:(*RACESP*)

7. Secondary Race:(*RACE2*)

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

Specify secondary race:(*RACE2SP*)

Comments:(*DEMCOMM1*)

Additional Selection Options for DEM

Race:

15 - South or Central American

16 - Eastern European

17 - Northern European

18 - Western European

81 - White Caribbean

82 - North Coast of Africa

83 - Middle Eastern

Black

20 - Black (Not Otherwise Specified)

21 - African American

22 - African Black (Both Parents Born in Africa)

23 - Caribbean Black

24 - South or Central American Black

29 - Black, Other Specify

Asian

30 - Asian (Not Otherwise Specified)

31 - Indian/South Asian

32 - Filipino (Pilipino)

34 - Japanese

35 - Korean

36 - Chinese

37 - Other Southeast Asian

38 - Vietnamese

American Indian or Alaska Native

50 - Native American (Not Otherwise Specified)

51 - Native Alaskan/Eskimo/Aleut

52 - American Indian (Not Otherwise Specified)

53 - North American Indian

54 - South or Central American Indian

55 - Caribbean Indian

Native Hawaiian or Other Pacific Islander

60 - Native Pacific Islander (Not Otherwise Specified)

61 - Guamanian

62 - Hawaiian

63 - Samoan

Other

88 - Unknown

90 - Other, Specify

99 - Not Answered

**Blood and Marrow Transplant Clinical
Trials Network**

Death Form (DTH)

Web Version: 1.0; 4.14; 11-05-15

1. Record date of death: (DTHDT)

(mm/dd/yyyy)

2. Was an autopsy performed? (AUTPERF)

1 - Yes 2 - No

If yes, attach de-identified autopsy report or death summary to the form below.

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

3. Primary cause of death: (CZDTHPRM)

1.0 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
1.1 - Autologous Recovery
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below



Specify other: (DTHSPEC1)

4. Secondary cause of death: (SCNDCZ1)

1.0 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
1.1 - Autologous Recovery
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other: (DTHSPEC2)

5. Secondary cause of death: (SCNDCZ2)

1.0 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
1.1 - Autologous Recovery
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other: (DTHSPEC3)

6. Secondary cause of death: (SCNDCZ3)

1.0 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
1.1 - Autologous Recovery
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other: (DTHSPEC4)

7. Secondary cause of death: (SCNDCZ4)

1.0 - Graft Rejection or Failure
Infection (Other than Interstitial Pneumonia)
1.1 - Autologous Recovery
1.2 - Rejection
2.1 - Bacterial
*Additional Options Listed Below

Specify other: (DTHSPEC5)

Comments: (DTCMMNTS)

Additional Selection Options for DTH

Primary cause of death:

- 2.2 - Fungal
- 2.3 - Viral
- 2.4 - Protozoal
- 2.5 - Other, Specify Below
- 2.9 - Organism Not Identified
- Interstitial Pneumonia
- 3.1 - Viral, CMV
- 3.2 - Viral, Other
- 3.3 - Pneumocystis
- 3.4 - Other, Specify Below
- 3.9 - Idiopathic
- 4.0 - Adult Respiratory Distress Syndrome
- 5.0 - Acute GVHD
- 6.0 - Chronic GVHD
- 7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
- 7.1 - Persistent Disease
- Organ Failure (Not Due to GVHD or Infection)
- 8.1 - Liver
- 8.2 - Cardiac (Cardiomyopathy)
- 8.3 - Pulmonary
- 8.4 - CNS
- 8.5 - Renal
- 8.6 - Other, Specify Below
- 8.7 - Multiple Organ Failure, Specify Below
- 8.8 - Secondary Graft Failure
- 9.0 - Secondary Malignancy
- 9.1 - EBV
- 9.2 - Other, Specify Below
- Hemorrhage
- 10.1 - Pulmonary
- 10.2 - Intracranial
- 10.3 - Gastrointestinal
- 10.4 - Hemorrhage Not Specified
- 10.5 - Other, Specify Below
- Vascular
- 11.1 - Thromboembolic
- 11.2 - Disseminated Intravascular Coagulation (DIC)
- 11.3 - Gastrointestinal
- 11.4 - Thrombotic Thrombocytopenic Purpura
- 11.5 - Vascular Not Specified
- 11.9 - Other, Specify Below
- 12.0 - Accidental Death
- 13.0 - Other, Specify Below

**Blood and Marrow Transplant Clinical
Trials Network**

0902B (ENR)

Web Version: 1.0; 2.00; 05-09-11

1. Select the type of transplant procedure planned within 6 weeks:(*TXTYPESB*)

- 1 - Autologous / Syngeneic
- 2 - Myeloablative Allogeneic
- 3 - Reduced Intensity / Non-Myeloablative Allogeneic

Verify that the patient completed all items on the baseline questionnaires before proceeding with enrollment in Segment B.

2. Has the participant completed all baseline questionnaires?(*QUESTESB*)

- 1 - Yes 2 - No

Comments:(*COMMESB*)

**Blood and Marrow Transplant Clinical
Trials Network**

Follow Up Status Form - 0902 (FU9)

Web Version: 1.0; 3.00; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

1. Date of last contact:(FU9LCTDT) (mm/dd/yyyy)

Since the date of the last visit indicate if any of the following have occurred:

2. Has the patient died?(FU9DIEED) 1 - Yes 2 - No

If Yes, a Death Form must be submitted.

3. Date of patient death:(FU9DTHDT) (mm/dd/yyyy)

4. Has the patient been hospitalized?(FU9HOSPT) 1 - Yes 2 - No

If Yes, a Re-Admission Form must be submitted.

5. Date of hospitalization:(FU9HOSDT) (mm/dd/yyyy)

6. Has the patient experienced any Unexpected, Grade 3-5 Adverse Events, which are possibly, probably, or definitely associated with participation in the study? (FU9UAE) 1 - Yes 2 - No

If Yes, an Unexpected, Grade 3-5 Adverse Event Form must be submitted.

7. Date of onset of Unexpected, Grade 3-5 Adverse Event, which is possibly, probably or definitely associated with participation in the study: (FU9UAEDT) (mm/dd/yyyy)

8. Has the patient had a Day 30 booster intervention?(FU930BST) 1 - Yes 2 - No

9. Type of contact:(FU930SP)
10. Date of Day 30 booster intervention:(FU930DT) (mm/dd/yyyy)

11. If No, indicate reason for missed booster intervention:(FU930NO)

12. Has the patient had a Day 60 booster intervention?(FU960BST) 1 - Yes 2 - No

13. Type of contact:(FU960SP)
14. Date of Day 60 booster intervention:(FU960DT) (mm/dd/yyyy)

15. If No, indicate reason for missed booster intervention:(FU960NO)

16. What was the method of data collection for the patient's Day 30 assessments? (FU930DAT)
1 - Self-administered
2 - Interviewer-administered

17. What was the method of data collection for the patient's Day 60 assessments? (FU960DAT)
1 - Self-administered
2 - Interviewer-administered

18. What was the method of data collection for the patient's Day 100 assessments? (FU9100SP)
1 - Self-administered
2 - Interviewer-administered

19. What was the method of data collection for the patient's Day 180 assessments? (FU9180SP)
1 - Self-administered
2 - Interviewer-administered

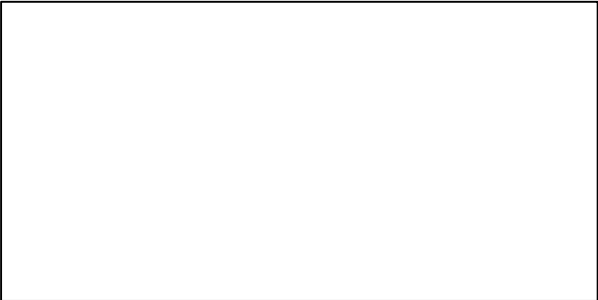
20. Has the patient received a second transplant?(FU9XTWO) 1 - Yes 2 - No

21. Date of second transplant:(FU9XTDT) (mm/dd/yyyy)

22. Has the patient experienced a relapse?(FU9RELPS) 1 - Yes 2 - No

23. Date of relapse:(FU9RLPDT) (mm/dd/yyyy)

Comments:(FU9COMM)



**Blood and Marrow Transplant Clinical
Trials Network**

Intervention Credibility- 0902 (INT)

Web Version: 1.0; 1.02; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Date of Assessment (INTDT)

 (mm/dd/yyyy)

1. How effective do you think the program you received as part of the study will be in improving your quality of life during and after your transplant?

(INTEFFECT) 0 1 2 3 4 5 6

Not at all Effective

Extremely Effective

2. How skillful and knowledgeable do you consider the person who explained the program to you?

(INTSKILL) 0 1 2 3 4 5 6

Not at all Skillful

Extremely Skillful

3. How important do you think it is that we make this program available to other transplant patients?

(INTIMPT) 0 1 2 3 4 5 6

Not at all Important

Extremely Important

Comments:(INTCOMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Leisure Score Index- 0902 (LSI)

Web Version: 1.0; 3.00; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Date of Assessment (LSIDT)

(mm/dd/yyyy)

Please report the frequency, average duration, and exertion level of any exercise OVER THE PAST WEEK in the spaces below.

A. STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING)

Examples: running, jogging, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes.

Did you do any strenuous exercise over THE PAST WEEK?

(LSISEWK) 1 - No 2 - Yes 88 - Not Answered

1. What was the **frequency** of strenuous exercise?(LSSEFRQ)

(xxx) times

2. What was the average **duration** of strenuous exercise?(LSSE DUR)

(xxx) minutes

3. What was the **exertion** level?(LSSELVL)

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

B. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION)

Examples: fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing.

Did you do any moderate exercise over THE PAST WEEK?

(LSIMEWK) 1 - No 2 - Yes 88 - Not Answered

4. What was the **frequency** of moderate exercise?(LSIMEFRQ)

(xxx) times

5. What was the average **duration** of moderate exercise?(LSIMEDUR)

(xxx) minutes

6. What was the **exertion** level?(LSIMELVL)

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

C. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION)

Examples: easy walking, yoga, bowling, shuffleboard, horseshoes, golf.

Did you do any mild exercise over THE PAST WEEK?

(LSIMLWK) 1 - No 2 - Yes 88 - Not Answered

7. What was the **frequency** of mild exercise?(LSIMLFRQ)

(xxx) times

8. What was the average **duration** of mild exercise? (LSIMLDUR)

(xxx) minutes

9. What was the **exertion** level?(LSIMLLVL)

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

Additional Selection Options for LSI

What was the exertion level?

11 light

12

13 somewhat hard

14

15 hard (heavy)

16

17 very hard

18

19 extremely hard

20 maximal exertion

**Blood and Marrow Transplant Clinical
Trials Network**

Pittsburgh Sleep Quality Index - 0902 (PSQ)

Web Version: 1.0; 1.01; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Date of Assessment (PSQASTDT) (mm/dd/yyyy)

The following questions relate to your usual sleep habits during the **PAST WEEK ONLY**. Your answers should indicate the most accurate reply for the majority of days and nights in the past week. Please answer all questions.

1. During the past week, when have you usually gone to bed at night?

USUAL BED TIME (PSQBEDTM)

(hh.mm) (PSQBAMP)

2. During the past week, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES (PSQSLPMN)

(xxx) minutes

3. During the past week, when have you usually gotten up in the morning?

USUAL GETTING UP TIME (PSQGUPTM)

(hh.mm) (PSQGAMP)

4. During the past week, how many hours of actual sleep did you get a night? (This may be different than the number of hours you spend in bed.)

HOURS OF SLEEP PER NIGHT (PSQSLPNH)

(xx) Hours (PSQSLPNM) (xx) minutes

For each of the remaining questions, check the best response. Please answer all questions.

5. During the past week, how often have you had trouble sleeping because you cannot get to sleep within 30 minutes? (PSQSL30M)

- 1 - Not at all
- 2 - A few (1-2) times
- 3 - Several (3-5) times
- 4 - Every night or almost every night
- 9 - Not answered

6. During the past week, how would you rate your sleep quality overall? (PSQSLOQ)

- 1 - Very Good
- 2 - Fairly Good
- 3 - Fairly Bad
- 4 - Very Bad
- 9 - Not answered

7. During the past week, how often have you taken medicine (prescribed or "over the counter") to help you sleep? (PSQSLAID)

- 1 - Not at all
- 2 - A few (1-2) times
- 3 - Several (3-5) times
- 4 - Every night or almost every night
- 9 - Not answered

Comments: (PSQCMNTS)

**Blood and Marrow Transplant Clinical
Trials Network**

Intervention Recording Form - 0902 (REC)

Web Version: 1.0; 1.00; 10-16-15

Date Form Entered (DATENTER):

1. Name of BMT CTN 0902 interventionist: (RECNAME)

2. Date intervention was recorded: (RECINTDT)

 (mm/dd/yyyy)

3. Indicate the patient's intervention arm: (RECARM)

| |
|--|
| 1 - Exercise Intervention |
| 2 - Stress Management Intervention |
| 3 - Combination of Exercise and Stress Management Intervention |
| 4 - Standard of Care Intervention |

4. Indicate the intervention recording number: (RECNUMBR)

 (xxx)

Comments: (RECCOMM)

**Blood and Marrow Transplant Clinical
Trials Network**

SF-36v2 Health Survey- Acute (SFA)

Web Version: 1.0; 1.01; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please select the choice that best describes your answer.

Date of assessment: (SFADATE)

(mm/dd/yyyy)

1. In general, would you say your health is: (SFGENHLT)

1 - Excellent
2 - Very Good
3 - Good
4 - Fair
5 - Poor
*Additional Options Listed Below

2. Compared to one week ago, how would you rate your health in general now? (SFCOMPWK)

1 - Much better than one week ago
2 - Somewhat better now than one week ago
3 - About the same as one week ago
4 - Somewhat worse than one week ago
5 - Much worse than one week ago
*Additional Options Listed Below

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Activities

Amount of Limitation

a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFVIGOR)

b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFMODERA)

c. Lifting or carrying groceries

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFGROCRY)

d. Climbing several flights of stairs

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFCLIMBS)

e. Climbing one flight of stairs

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SF1CLIMB)

f. Bending, kneeling, or stooping

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFBEND)

g. Walking more than a mile

- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

(SFWALKM)

h. Walking several hundred yards

- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

(SFWALKSH)

i. Walking one hundred yards

- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

(SFWALK1H)

j. Bathing or dressing yourself

- 1 - Yes, limited a lot
- 2 - Yes, limited a little
- 3 - No, not limited at all
- 9 - Subject did not complete

(SFBATHNG)

4. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Physical Work Limitations

Amount of Time

a. Cut down on the amount of time you spent on work or other activities

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFPHTIME)

b. Accomplished less than you would like

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFPHACCM)

c. Were limited in the kind of work or other activities

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFPHLIMIT)

d. Had difficulty performing the work or other activities (for example, it took extra effort)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFPHDIFF)

5. During the past week, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Emotional Work Limitations

Amount of Time

a. Cut down on the amount of time you spent on work or other activities

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFEPTIME)

b. Accomplished less than you would like

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFEPACCM)

c. Did work or other activities less carefully than usual

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFEP CARE)

6. During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?(SFHLTHEX)

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely
- *Additional Options Listed Below

7. How much bodily pain have you had during the past week?(SFBODYPN)

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- *Additional Options Listed Below

8. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?(SFPAININ)

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely
- *Additional Options Listed Below

9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week:

a. Did you feel full of life?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFFLFULL)

b. Have you been very nervous?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFFLNERV)

c. Have you felt so down in the dumps that nothing could cheer you up?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFFLDOWN)

d. Have you felt calm and peaceful?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

(SFFLCALM)

e. Did you have a lot of energy?

(SFFLENRG)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

f. Have you felt downhearted and depressed?

(SFFLDEPR)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

g. Did you feel worn out?

(SFFLWORN)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

h. Have you been happy?

(SFFLHPPY)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

i. Did you feel tired?

(SFFLTIRE)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

10. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?(SFHLTHAM)

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time
- *Additional Options Listed Below

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people(SFSICKER)

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

b. I am as healthy as anybody I know(SFHEALTH)

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

c. I expect my health to get worse(SFWORSE)

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

d. My health is excellent(SFEXCLNT)

- 1 - Definitely true
- 2 - Mostly true
- 3 - Don't know
- 4 - Mostly false
- 5 - Definitely false
- *Additional Options Listed Below

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The following questions also ask for your views about your health. For each question, please select the option that best describes your answer.

12. How much nausea have you had during the past week?(SFNAUSEA)

- 1 - None
- 2 - Very mild
- 3 - Moderate
- 4 - Severe
- 5 - Very Severe
- *Additional Options Listed Below

13. During the past week, how much did nausea interfere with your normal work (including both work outside the home and housework)? Select one.(SFNAUSIN)

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely
- *Additional Options Listed Below

Comments:(SFACOMM)

Additional Selection Options for SFA

In general, would you say your health is:

9 - Subject did not complete

Compared to one week ago, how would you rate your health in general now?

9 - Subject did not complete

Physical Time Cut Down

9 - Subject did not complete

During the past week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

9 - Subject did not complete

How much bodily pain have you had during the past week?

6 - Very severe

9 - Subject did not complete

During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

9 - Subject did not complete

I seem to get sick a little easier than other people

9 - Subject did not complete

How much nausea have you had during the past week?

9 - Subject did not complete

**Blood and Marrow Transplant Clinical
Trials Network**

Stages of Change Form for Exercise - 0902 (SOC)

Web Version: 1.0; 2.00; 10-16-15

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of Assessment (*SOC DT*)

(mm/dd/yyyy)

Regular exercise is any *planned* physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Such activity should be performed 3-5 times per week for at least 20-30 minutes per session.

Question:

1. Do you exercise regularly according to that definition? (*SOCEXREG*)

- 1 - Yes, I have been for MORE than 3 months.
 - 2 - Yes, I have been for LESS than 3 months.
 - 3 - No, but I intend to in the next 30 days.
 - 4 - No, but I intend to in the next 3 months.
 - 5 - No, and I do NOT intend to in the next 3 months.
- *Additional Options Listed Below

Comments: (*SOC COMM*)

Additional Selection Options for SOC

Do you exercise regularly according to that definition?

88 - Not Answered

**Blood and Marrow Transplant Clinical
Trials Network**

Stress Reduction Checklist - 0902 (SRC)

Web Version: 1.0; 2.00; 10-16-15

Segment (PROTSEG):

Visit Number (VISNO):

Date of Assessment (SRCDT)

(mm/dd/yyyy)

In the **PAST WEEK**, have you done any of the following to relieve stress?

1. Practiced deep breathing:(SRCDPBRT)

1 - No 2 - Yes 88 - Not Answered

IF YES, how often?(SRCDPBRY)

(xxx) times

2. Listened to relaxation audio tapes:(SRCRLXAT)

1 - No 2 - Yes 88 - Not Answered

IF YES, how often?(SRCRLXY)

(xxx) times

3. Practiced relaxation on your own:(SRCRLXOW)

1 - No 2 - Yes 88 - Not Answered

IF YES, how often?(SRCRLXOY)

(xxx) times

4. Watched videos/DVDs about managing stress:(SRCVDDVD)

1 - No 2 - Yes 88 - Not Answered

IF YES, how often?(SRCVDDVY)

(xxx) times

5. Told yourself things to help you cope:(SRCCOPE)

1 - No 2 - Yes 88 - Not Answered

IF YES, how often?(SRCCOPEY)

(xxx) times

Comments:(SRCCOMM)

**Blood and Marrow Transplant Clinical
Trials Network**

Transplant Form (TXP)

Web Version: 1.0; 15.00; 11-05-15

Segment (PROTSEG):

Visit Number (VISNO):

1. Record date of initiation of conditioning regimen:(CONDNGDT)

(mm/dd/yyyy)

2. Record date of hematopoietic stem cell infusion:(TXDTP)

(mm/dd/yyyy)

3. Record the patient's pre-transplant CMV antibody (IgG) status:(CMVSTAT)

1 - Positive 2 - Negative

4. IUBMD for this patient (if available):(T_IUBMD)

Comments:(COMMTXP1)