Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Form (A99)

Web Version: 1.0; 1.02; 12-08-16

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

1. Date event initially reported in AdvantageEDC:*(EVENTDT)* *(mm/dd/yyyy)*
2. Overall event status:*(OVSTATUS)*
   - 1 - Open
   - 2 - Closed
   - 3 - De-activated; Did Not Qualify for Expedited Reporting to Any Entity
3. Is there enough information to send to the Medical Monitor?*(INFOTOMM)* ☐ 1 - Yes ☐ 2 - No
   4. If 'Yes', date event initially sent to Medical Monitor:*(DATETOMM)* *(mm/dd/yyyy)*
   5. Indicate whether the Medical Monitor's review is complete:*(MMREVCMP)* ☐ 1 - Yes ☐ 2 - No
      6. If the Medical Monitor's review is not complete, indicate the event's review status: *(MMREVSTS)*
         - 1 - With Medical Monitor for Review
         - 2 - Pending Additional Info From Transplant Center
         - 3 - With EMMES AE Coordinator
         - 9 - Other
      7. If 'Other', specify:*(MMREVSPC)*
8. Does the event need to be reported on other Case Report Forms (CRFs)?*(OTHRCRF)* ☐ 1 - Yes ☐ 2 - No
   9. If 'Yes', specify other CRFs on which the event should be reported and whether this has been completed by the transplant center:*(OTHCRFSP)*

Reporting to DSMB

10. Does the event require expedited reporting to the DSMB?*(DSMBEX)* ☐ 1 - Yes ☐ 2 - No
    11. If 'Yes', date initial report must be circulated to the DSMB:*(DSMBIRDT)* *(mm/dd/yyyy)*
    12. If 'Yes', date initial report circulated to the DSMB:*(DSMBSNDT)* *(mm/dd/yyyy)*
13. Overall event reporting status to the DSMB:*(DSMBSTTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below
    14. If 'Other', specify:*(DSMBSTSP)*
15. DSMB report reviewer status:*(DSMBREVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other
    16. If 'Other', specify:*(DSMBROTH)*

Reporting to FDA

17. Does the event require expedited reporting to the FDA?*(FDAEX)* ☐ 1 - Yes ☐ 2 - No
    18. If 'Yes', date FDA must be notified:*(FDANOTDT)* *(mm/dd/yyyy)*
    19. If 'Yes', date initial safety report must be circulated to the FDA:*(FDAIRDT)* *(mm/dd/yyyy)*
    20. If 'Yes', date initial safety report circulated to the FDA:*(FDASNTDT)* *(mm/dd/yyyy)*
21. Overall event reporting status to the FDA:*(FDASTTS)*
    - 1 - Pending Initial Report Circulation
    - 2 - Initial Report Circulated
    - 3 - Pending Circulation of First Follow-Up Report
    - 4 - Pending Circulation of Secondary Follow-Up Report
    - 5 - Pending Circulation of Tertiary Follow-Up Report
    - *Additional Options Listed Below
    22. If 'Other', specify:*(FDASTSP)*
23. FDA report reviewer status:*(FDAREVS)*
    - 1 - With Medical Monitor for Review
    - 2 - Pending Additional Info From Transplant Center
    - 3 - With EMMES AE Coordinator
    - 9 - Other
    24. If 'Other', specify:*(FDAROTH)*

Reporting to Pharma Company #1

25. Name of pharma company #1:*(PC1NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

26. Does the event required expedited reporting to pharma company #1?*(PC1EX)*

☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

27. If 'Yes', date initial report must be circulated to pharma company #1:*(PC1IRDT)*

(mm/dd/yyyy)

28. If 'Yes', date initial report circulated to pharma company #1:*(PC1SNTDT)*

(mm/dd/yyyy)

29. Overall event reporting status to pharma company #1:*(PC1STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

30. If 'Other', specify:*(PC1STSP)*

31. Pharma company #1 report reviewer status:*(PC1REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

32. If 'Other', specify:*(PC1ROTH)*

Reporting to Pharma Company #2

33. Name of pharma company #2:*(PC2NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

34. Does the event require expedited reporting to pharma company #2?*(PC2EX)*

☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

35. If 'Yes', date initial report must be circulated to pharma company #2:*(PC2IRDT)*

(mm/dd/yyyy)

36. If 'Yes', date initial report circulated to pharma company #2:*(PC2SNTDT)*

(mm/dd/yyyy)

37. Overall event reporting status to pharma company #2:*(PC2STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

38. If 'Other', specify:*(PC2STSP)*

39. Pharma company #2 report reviewer status:*(PC2REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

40. If 'Other', specify:*(PC2ROTH)*

Reporting to Pharma Company #3

41. Name of pharma company #3:*(PC3NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

42. Does the event require expedited reporting to pharma company #3?*(PC3EX)*

☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

43. If 'Yes', date initial report must be circulated to pharma company #3:*(PC3IRDT)*

(mm/dd/yyyy)

44. If 'Yes', date initial report circulated to pharma company #3:*(PC3SNTDT)*

(mm/dd/yyyy)

45. Overall event reporting status to pharma company #3:*(PC3STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

46. If 'Other', specify:*(PC3STSP)*

47. Pharma company #3 report reviewer status:*(PC3REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

48. If 'Other', specify:*(PC3ROTH)*

Reporting to Pharma Company #4

49. Name of pharma company #4:*(PC4NAME)*

1 - Celgene
2 - Millennium
3 - Pfizer
4 - Miltenyi
5 - Novartis

50. Does the event require expedited reporting to pharma company #4?*(PC4EX)* ☐ 1 - Yes ☐ 2 - No ☐ 3 - Not Applicable

51. If 'Yes' date initial report must be circulated to pharma company #4:*(PC4IRDT)* *(mm/dd/yyyy)*

52. If 'Yes', date initial report circulated to pharma company #4:*(PC4SNTDT)* *(mm/dd/yyyy)*

53. Overall event reporting status to pharma company #4:*(PC4STTS)*

1 - Pending Initial Report Circulation
2 - Initial Report Circulated
3 - Pending Circulation of First Follow-Up Report
4 - Pending Circulation of Secondary Follow-Up Report
5 - Pending Circulation of Tertiary Follow-Up Report
*Additional Options Listed Below

54. If 'Other', specify:*(PC4STSP)*

55. Pharma company #4 report reviewer status:*(PC4REVS)*

1 - With Medical Monitor for Review
2 - Pending Additional Info From Transplant Center
3 - With EMMES AE Coordinator
9 - Other

56. If 'Other', specify:*(PC4ROTH)*

Comments:*(A99COMM)*

Additional Selection Options for A99

Overall event reporting status to the DSMB:
6 - Pending Circulation of Quaternary Follow-Up Report
7 - Closed; Reporting Complete
9 - Other

Blood and Marrow Transplant Clinical Trials Network

BMT AE Tracking Communications Form (A9C)

Web Version: 1.0; 1.01; 12-08-16

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

	Status	Communication Date	Communication Type	Contact Name	Contact Role	
Communication #1 *(A9C1RPT)* Report	*(A9C1STS)* Pending / Resolved	*(A9C1DT)* *(mm/dd/yyyy)*	*(A9C1TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C1NME)*	*(A9C1RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C1ACT)*
Communication #2 *(A9C2RPT)* Report	*(A9C2STS)* Pending / Resolved	*(A9C2DT)* *(mm/dd/yyyy)*	*(A9C2TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C2NME)*	*(A9C2RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C2ACT)*
Communication #3 *(A9C3RPT)* Report	*(A9C3STS)* Pending / Resolved	*(A9C3DT)* *(mm/dd/yyyy)*	*(A9C3TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C3NME)*	*(A9C3RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C3ACT)*
Communication #4 *(A9C4RPT)* Report	*(A9C4STS)* Pending / Resolved	*(A9C4DT)* *(mm/dd/yyyy)*	*(A9C4TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C4NME)*	*(A9C4RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C4ACT)*
Communication #5 *(A9C5RPT)* Report	*(A9C5STS)* Pending / Resolved	*(A9C5DT)* *(mm/dd/yyyy)*	*(A9C5TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C5NME)*	*(A9C5RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C5ACT)*
Communication #6 *(A9C6RPT)* Report	*(A9C6STS)* Pending / Resolved	*(A9C6DT)* *(mm/dd/yyyy)*	*(A9C6TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C6NME)*	*(A9C6RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C6ACT)*
Communication #7 *(A9C7RPT)* Report	*(A9C7STS)* Pending / Resolved	*(A9C7DT)* *(mm/dd/yyyy)*	*(A9C7TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C7NME)*	*(A9C7RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C7ACT)*
Communication #8 *(A9C8RPT)* Report	*(A9C8STS)* Pending / Resolved	*(A9C8DT)* *(mm/dd/yyyy)*	*(A9C8TYP)* 1 - Email; 2 - Telephone; 3 - Fax; 4 - In Person; 5 - Updated AdvantageEDC	*(A9C8NME)*	*(A9C8RLE)* 1 - Tx Center Coordinator; 2 - Medical Monitor; 3 - Tx Center PI/Investigator; 4 - NHLBI PO; 5 - EMMES PI/PD; *Additional Options Listed Below	*(A9C8ACT)*
Communication #9 *(A9C9RPT)* Report	*(A9C9STS)* Pending / Resolved	*(A9C9DT)* *(mm/dd/yyyy)*	*(A9C9TYP)*	*(A9C9NME)*	*(A9C9RLE)*	*(A9C9ACT)*

			1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #10*(A9C10RPT)* Report	*(A9C10STS)* Pending Resolved	*(A9C10DT)* *(mm/dd/yyyy)*	*(A9C10TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C10NME)*	*(A9C10RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C10ACT)*
Communication #11*(A9C11RPT)* Report	*(A9C11STS)* Pending Resolved	*(A9C11DT)* *(mm/dd/yyyy)*	*(A9C11TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C11NME)*	*(A9C11RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C11ACT)*
Communication #12*(A9C12RPT)* Report	*(A9C12STS)* Pending Resolved	*(A9C12DT)* *(mm/dd/yyyy)*	*(A9C12TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C12NME)*	*(A9C12RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C12ACT)*
Communication #13*(A9C13RPT)* Report	*(A9C13STS)* Pending Resolved	*(A9C13DT)* *(mm/dd/yyyy)*	*(A9C13TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C13NME)*	*(A9C13RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C13ACT)*
Communication #14*(A9C14RPT)* Report	*(A9C14STS)* Pending Resolved	*(A9C14DT)* *(mm/dd/yyyy)*	*(A9C14TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C14NME)*	*(A9C14RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C14ACT)*
Communication #15*(A9C15RPT)* Report	*(A9C15STS)* Pending Resolved	*(A9C15DT)* *(mm/dd/yyyy)*	*(A9C15TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C15NME)*	*(A9C15RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C15ACT)*
Communication #16*(A9C16RPT)* Report	*(A9C16STS)* Pending Resolved	*(A9C16DT)* *(mm/dd/yyyy)*	*(A9C16TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C16NME)*	*(A9C16RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C16ACT)*
Communication #17*(A9C17RPT)* Report	*(A9C17STS)* Pending Resolved	*(A9C17DT)* *(mm/dd/yyyy)*	*(A9C17TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C17NME)*	*(A9C17RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C17ACT)*
Communication #18*(A9C18RPT)* Report	*(A9C18STS)* Pending Resolved	*(A9C18DT)* *(mm/dd/yyyy)*	*(A9C18TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C18NME)*	*(A9C18RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C18ACT)*
Communication #19*(A9C19RPT)* Report	*(A9C19STS)* Pending Resolved	*(A9C19DT)* *(mm/dd/yyyy)*	*(A9C19TYP)*	*(A9C19NME)*	*(A9C19RLE)*	*(A9C19ACT)*

			1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC		1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	
Communication #20*(A9C20RPT)* ☐ Report	*(A9C20STS)* Pending Resolved	*(A9C20DT)* *(mm/dd/yyyy)*	*(A9C20TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C20NME)*	*(A9C20RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C20ACT)*
Communication #21*(A9C21RPT)* ☐ Report	*(A9C21STS)* Pending Resolved	*(A9C21DT)* *(mm/dd/yyyy)*	*(A9C21TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C21NME)*	*(A9C21RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C21ACT)*
Communication #22*(A9C22RPT)* ☐ Report	*(A9C22STS)* Pending Resolved	*(A9C22DT)* *(mm/dd/yyyy)*	*(A9C22TYP)* 1 - Email 2 - Telephone 3 - Fax 4 - In Person 5 - Updated AdvantageEDC	*(A9C22NME)*	*(A9C22RLE)* 1 - Tx Center Coordinator 2 - Medical Monitor 3 - Tx Center PI/Investigator 4 - NHLBI PO 5 - EMMES PI/PD *Additional Options Listed Below	*(A9C22ACT)*

Additional Selection Options for A9C

COM 1 Contact Role
6 - Pharma Rep
99 - Other

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

Web Version: 1.0; 5.00; 01-28-16

Segment *(PROTSEG)*: A
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)*: A
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)

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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)*: A
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)* 1 - Treatment of adverse event; 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event; 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event; 9 - Other

(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 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; 3.12; 06-16-16

Segment *(PROTSEG)*: A
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)	*(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)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

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

Segment *(PROTSEG)*: A
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; 10.00; 02-20-18

Segment *(PROTSEG)*: A
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?*(AMDETER)* ☐ 1 - Yes ☐ 2 - No
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

CIBMTR Recipient ID (CID)

Web Version: 1.0; 1.06; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. CRID # (CIBMTR Recipient ID):*(CRIDNM)* *(xxxxxxxxxx)*

Comments:*(CIDCOMM)*

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)* ☐ 1 - Male ☐ 2 - Female
4. Date of Birth:*(DOB)* *(mm/dd/yyyy)*
5. Ethnicity:*(ETHNIC)*
   - 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; 4.16; 06-16-17

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
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
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
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
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
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
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
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
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
1.1 - Autologous Recovery
Infection (Other than Interstitial Pneumonia)
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

Endpoint Review Form- 1202 (E07)

Web Version: 1.0; 3.00; 06-16-16

Case ID *(CASEID)*:

Site:*(EXXSITE)* *(xxxxx)*

Patient ID:*(EXXPATID)*

1. Review Date:*(REVIEWDT)* *(mm/dd/yyyy)*
2. Primary Reviewer Name:*(REVNAME)*
   - Doris Ponce
   - George Chen
   - Javier Bolanos-Meade
   - Jenna Goldberg
   - John Hansen
   - *Additional Options Listed Below
3. Case Status:*(CASESTAT)*
   - 1- Overall Complete
   - 2- Query
   - 3- Ready for Review
   - 4- Six Month Review Complete
4. Review Committee Comments:*(REVCOMM)*
5. EMMES Comments:*(EMMCOMM)*

Acute GVHD Onset Review

6. Did this case have an acute GVHD Onset Review?*(GVHDOR)* 1 - Yes 2 - No
   a. Onset Review Date:*(GVHDORDT)* *(mm/dd/yyyy)*
   b. Onset Primary Reviewer Name:*(OREVNAME)*
   - Doris Ponce
   - George Chen
   - Javier Bolanos-Meade
   - Jenna Goldberg
   - John Hansen
   - *Additional Options Listed Below

   c. Did this case have acute GVHD?*(AGVHD)* 1 - Yes 2 - No
   d. Acute GVHD onset date:*(AGVHDODT)* *(mm/dd/yyyy)*
   e. Acute GVHD grade:*(AGVHDGRD)*
   - Grade I
   - Grade II
   - Grade III
   - Grade IV

   f. Acute GVHD confidence level at onset:*(GVHDCONF)*
   - 1- Confirmed
   - 2- Probable
   - 3- Possible
   - 4- Negative

   g. Was adjudication different than site-reported data?*(GVHDRPT)* 1 - Yes 2 - No
7. Acute GVHD Onset Review Comments:*(ORCOMM)*

Reviewer Adjudicated Fields

8. Did the patient die?*(PATDIED)* 1 - Yes 2 - No
   a. Primary cause of death:*(REVCOD)*
   - 1.0 - Graft Rejection or Failure
   - 1.1 - Autologous Recovery
   - Infection (Other than Interstitial Pneumonia)
   - 1.2 - Rejection
   - 2.1 - Bacterial
   - *Additional Options Listed Below

   b. Specify other COD:*(REVCODSP)*
9. Maximum acute GVHD grade:*(MAXAGVHD)*
   - 0- Grade 0
   - 1- Grade I
   - 2- Grade II
   - 3- Grade III
   - 4- Grade IV

a. Grade II- IV acute GVHD onset date:*(AGVH24DT)* *(mm/dd/yyyy)*

b. Grade III- IV acute GVHD onset date:*(AGVH34DT)* *(mm/dd/yyyy)*

10. Chronic GVHD:*(CGVHD)* 1 - Yes 2 - No

a. Chronic GVHD onset date:*(CGVHDT)* *(mm/dd/yyyy)*

11. Overall chronic GVHD diagnosis:*(CGVHDDX)*

0 - No GVHD
1 - Late Acute GVHD
2 - Overlap Acute and Chronic GVHD
3 - Classic Chronic GVHD
9 - Unknown/Missing

12. Overall chronic GVHD severity:*(CGVHDSEV)*

1 - None
2 - Mild
3 - Moderate
4 - Severe
9 - Unknown/Missing

13. Overall chronic GVHD response:*(CGVHDRSP)*

1 - Complete Response
2 - Partial Response
3 - Unchanged/Stable
4 - Progressive
9 - Unknown/Missing

14. Graft failure:*(GFTFAIL)* 1 - Yes 2 - No

a. Date of graft failure:*(GFAILDT)* *(mm/dd/yyyy)*

15. Progression or relapse:*(PRGRLP)* 1 - Yes 2 - No

a. Date of progression or relapse:*(PRGRLPDT)* *(mm/dd/yyyy)*

16. Was the patient eligible?*(ELIGIBLE)* 1 - Yes 2 - No

a. Specify reason for ineligibility:*(ELIGIBSP)*

17. Number of Queries:*(QUERYNUM)*

00- Its A Miracle!
01
02
03
04
*Additional Options Listed Below

Number of queries indicated will determine how many queries are captured on the query form.

Comments:*(EXXCOMM)*

Additional Selection Options for E07

Primary Reviewer Name:
John Levine
Ran Reshef
Ryo Nakamura
Vincent Ho
Wael Saber
Yi-Bin Chen

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

Number of Queries:
05- Could Be Worse
06
07
08
09
10- Just Start Over

1202A (ENR)

Web Version: 1.0; 3.03; 10-16-15

Biomarkers Enrollment Form: Segment A

Inclusion Criteria

1. Patient's date of birth:*(PTNDOB)* *(mm/dd/yyyy)*
2. Patient's weight:*(PTNWGHT)* *(xxx.x)* kg
3. Date patient weight obtained:*(PTNWTDT)* *(mm/dd/yyyy)*
4. Date patient informed consent signed:*(PTNCNSDT)* *(mm/dd/yyyy)*
5. Will this be the patient's first allogeneic hematopoietic cell transplant?*(FSTALLO)* 1 - Yes 2 - No
6. Source of donor cells for the planned hematopoietic cell transplant:*(DNRSRCE)* 1 - Bone Marrow 2 - Peripheral Blood 3 - Umbilical Cord Blood
7. Type of donor for the planned hematopoietic cell transplant:*(DNRTYPE)* 1 - Related Donor 2 - Unrelated Donor
8. Patient's primary disease:*(DISTYPE)*
   - 01 - Acute Myelogenous Leukemia (AML)
   - 02 - Acute Lymphoblastic Leukemia (ALL)
   - 03 - Other Acute Leukemia
   - 04 - Chronic Myelogenous Leukemia (CML)
   - 05 - Other Leukemia
   - *Additional Options Listed Below
9. If other, specify:*(BMKOTHSP)*
10. If the patient has acute leukemia, record the disease stage:*(LEUKSTG)*
    - 1 - Primary Induction Failure
    - 2 - First Complete Remission
    - 3 - First Relapse
    - 4 - Second Complete Remission
    - 5 - Second Relapse
    - *Additional Options Listed Below
11. Did the patient consent to provide the required baseline NMDP Research Protocol samples? *(PTNMDPCS)* 1 - Yes 2 - No
12. Date NMDP Research Protocol consent signed:*(PTNMDPDT)* *(mm/dd/yyyy)*
13. Proposed start date of conditioning:*(PTNCONDT)* *(mm/dd/yyyy)*

Patients must be enrolled prior to the onset of conditioning.

Donor Information

14. If the patient is receiving a related donor transplant, did the related donor consent to provide a baseline NMDP research sample?*(RLTDDRCN)* 1 - Yes 2 - No 3 - Unknown
15. If the patient is receiving an unrelated bone marrow or peripheral blood transplant, provide the NMDP donor ID:*(NMDPID)*
16. Is the unrelated donor selected for this patient from a donor center on the approved donor center list?*(APPRDNR)* 1 - Yes 2 - No

The approved donor center list can be found on the BMT CTN SharePoint Website (https://www.bmtctnsp.net) under the 1202 Biomarkers subweb.

17. If the patient is receiving an umbilical cord blood transplant, is the patient receiving one or two UCB units?*(ONETWOCB)* 1 - One UCB Unit 2 - Two UCB Units

Enter the unique ID for each cord blood unit below. Do NOT enter the ID for the bank that the cord blood unit came from.

18. UCB #1:*(UCB1ID)*
19. UCB #2:*(UCB2ID)*

Comments:*(BMKCOMM)*

Additional Selection Options for ENR

Patient's primary disease:
06 - Myelodysplastic Disorder (MDS)
07 - Multiple Myeloma
08 - Non-Hodgkin Lymphoma
09 - Hodgkin Lymphoma
10 - Severe Aplastic Anemia
11 - Disorders of the Immune System
12 - Histiocytic Disorders
13 - Autoimmune Diseases
99 - Other Disease

If the patient has acute leukemia, record the disease stage:
6 - Third or Subsequent Complete Remission
7 - Third or Subsequent Relapse
8 - Previously Untreated

Graft Failure Form (GFL)

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

Segment *(PROTSEG)*: A

1. Did the patient experience primary or secondary graft failure?*(GRFTFAIL)* 1 - Yes 2 - No

2. Date of graft failure:*(GFTFLDT)* *(mm/dd/yyyy)*

Comments:*(GFLCMMNT)*

Acute GVHD Form (GVH)

Web Version: 1.0; 10.14; 12-09-16

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Date of staging:*(STAGEDT)* *(mm/dd/yyyy)*

   Start of GVHD Assessment Period:*(GVASSTDT)* *(mm/dd/yyyy)*

   End of GVHD Assessment Period:*(GVASENDT)* *(mm/dd/yyyy)*

   The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.

2. Immunosuppressant (prophylaxis) received:*(IMMUNORC)*
   - 0 - Prednisone
   - 1 - Cyclosporine
   - 2 - Tacrolimus
   - 3 - Not taken during assessment

3. Record most recent blood level of immunosuppressant (prophylaxis):*(TROUGHLV)* *(xxxx.x)* ng/mL

4. Record date blood sample obtained:*(TROUGHDT)* *(mm/dd/yyyy)*

Record the highest level of organ abnormalities, the etiologies contributing to the abnormalities and any biopsy results during the assessment period.

5. Skin abnormalities:*(GVHSKINA)*
   - 0 - No Rash
   - 1 - Maculopapular Rash, <25% of Body Surface
   - 2 - Maculopapular Rash, 25-50% of Body Surface
   - 3 - Generalized Erythroderma
   - 4 - Generalized Erythroderma with Bullus Formation and Desquamation

6. Skin etiologies:

GVHD			Drug Reaction			Conditioning Regimen Toxicity		
(SETGVHD)	1 - Yes	2 - No	*(SETDRGRX)*	1 - Yes	2 - No	*(SETCRTOX)*	1 - Yes	2 - No

Infection			Other		
(SETINFCT)	1 - Yes	2 - No	*(SETOTHER)*	1 - Yes	2 - No

Specify other skin etiologies:*(GVHSKNSP)*

7. Skin biopsy for GVHD:*(GVHSKINB)*
   - 1 - Positive
   - 2 - Negative
   - 3 - Equivocal
   - 4 - Not Done

8. Upper GI abnormalities:*(GVHUPGIA)*
   - 0 - No Protracted Nausea and Vomiting
   - 1 - Persistent Nausea, Vomiting or Anorexia

9. Upper intestinal tract etiologies:

GVHD			Drug Reaction			Conditioning Regimen Toxicity		
(UGIETGVH)	1 - Yes	2 - No	*(UGIETDRG)*	1 - Yes	2 - No	*(UGIETCON)*	1 - Yes	2 - No

TPN			Infection			Other		
(UGIETTPN)	1 - Yes	2 - No	*(UGIETINF)*	1 - Yes	2 - No	*(UGIETOTH)*	1 - Yes	2 - No

Specify other upper intestinal tract etiologies:*(UGIETSPC)*

10. Upper intestinal tract biopsy for GVHD:*(UGIBIORS)*
    - 1 - Positive
    - 2 - Negative
    - 3 - Equivocal
    - 4 - Not Done

11. Lower GI abnormalities:*(GVHINTA)*
    - 0 - No Diarrhea
    - 1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
    - 2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
    - 3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
    - 4 - Diarrhea >1500 mL/day or >833 mL/m^2
    - *Additional Options Listed Below

Use mL/day for adult patients and mL/m^2 for pediatric patients

12. Lower intestinal tract etiologies:

GVHD			Drug Reaction			Conditioning Regimen Toxicity		
(LGIETGVH)	1 - Yes	2 - No	*(LGIETDRG)*	1 - Yes	2 - No	*(LGIETCON)*	1 - Yes	2 - No

TPN			Infection			Other		
(LGIETTPN)	1 - Yes	2 - No	*(LGIETINF)*	1 - Yes	2 - No	*(LGIETOTH)*	1 - Yes	2 - No

Specify other lower intestinal tract etiologies:*(LGIETSPC)*

13. Lower intestinal tract biopsy for GVHD:*(LGIBIORS)*

1 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

14. Liver abnormalities:*(GVHLIVRA)*

0 - Bilirubin <2.0 mg/dL
1 - Bilirubin 2.0-3.0 mg/dL
2 - Bilirubin 3.1-6.0 mg/dL
3 - Bilirubin 6.1-15.0 mg/dL
4 - Bilirubin >15.0 mg/dL

15. Liver etiologies:

GVHD			Drug Reaction			Conditioning Regimen Toxicity			TPN		
(LIVETGVH)	1 - Yes	2 - No	*(LIVETDRG)*	1 - Yes	2 - No	*(LIVETCND)*	1 - Yes	2 - No	*(LIVETTPN)*	1 - Yes	2 - No

Infection			VOD			Other		
(LIVETINF)	1 - Yes	2 - No	*(LIVETVOD)*	1 - Yes	2 - No	*(LIVETOTH)*	1 - Yes	2 - No

Specify other liver etiologies:*(GVHLIVRS)*

16. Liver biopsy for GVHD:*(GVHLIVRB)*

1 - Positive
2 - Negative
3 - Equivocal
4 - Not Done

17. Was any treatment of GVHD modified during this assessment period?*(GVHTHERP)*

1 - Yes 2 - No

This only applies to TREATMENT for GVHD. If GVHD prophylaxis was the only modification during this assessment period, this question should be answered "2 - No".

18. If yes, specify agent name:*(GVHAGENT)*

1 - CSA
2 - FK506
3 - Topical Steroids
4 - Prednisone
5 - ATG
*Additional Options Listed Below

Specify other agent:*(GVHAGNSP)*

19. Indicate treatment modification:*(GVHTRMOD)*

1 - Started
2 - Stopped
4 - Tapered
5 - Increased

Comments:*(GVHCOMM)*

Additional Selection Options for GVH

Lower GI abnormalities:
5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

If yes, specify agent name:
6 - MMF
7 - Daclizumab
8 - Methylprednisolone
9 - Other

Acute GVHD Supplemental Form (GVS)

Web Version: 1.0; 2.03; 01-28-16

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

Date of staging:*(GVSSTGDT)* *(mm/dd/yyyy)*

Start of GVHD Assessment Period:*(GVSASTDT)* *(mm/dd/yyyy)*

End of GVHD Assessment Period:*(GVSAENDT)* *(mm/dd/yyyy)*

Guidance: *The assessment for which you are entering data must have taken place within the above dates. If the patient was not seen during the assessment period specified above, please exit the form and request an exception for this form.*

1. Record the most recent patient weight during the assessment period:*(GVSWTKG)* *(xxx.x)* kg
2. Date of weight:*(GVSWTDT)* *(mm/dd/yyyy)*
3. Has the patient received a Donor Lymphocyte Infusion (DLI)?*(GVSDLI)* 1 - Yes 2 - No 3 - Previously Reported
4. Date of most recent DLI:*(GVSDLIDT)* *(mm/dd/yyyy)*
5. Did the patient experience diarrhea during this assessment period?*(GVSDIARH)* 1 - Yes 2 - No
6. Was the volume of diarrhea obtained?*(GVSDHVLO)* 1 - Yes 2 - No

Guidance: *For diarrhea volumes, record liquid stool volume, (if available) in the following order, (1)average of 3 consecutive days if available, (2)otherwise the 3 days closest to each other, (3)otherwise average of 2 consecutive days, (4)otherwise the maximum volume from the isolated day(s) available. Formed or mostly formed stools should not be quantified or counted to the estimation of liquid stool volume.*

7. Volume of diarrhea:*(GVSDHRVL)* *(xxxx)* mL
8. Which method was used to obtain the volume of diarrhea?*(GVSDHMTH)*
   1 - 3-Day average
   2 - 2-Day average
   3 - Highest daily output

Guidance: *If this is the first time the patient has experienced diarrhea, highest daily output on the date diarrhea first appeared should be reported.*

9. If volume was not obtained, record the average number of daily diarrhea episodes: *(xx)* *(GVSDHEPI)*
10. Did the patient receive steroids during the assessment period?*(GVSSTROD)* 1 - Yes 2 - No

Guidance: *Steroids administered as 'one-time' doses for supportive care (e.g. mucositis, nausea/vomiting, premedication for blood product transfusion) should not be recorded. If patients are on different doses on alternating days, or if a patient is on twice (or more) daily dosing, the average total daily dose should be recorded. For example, if a patient is receiving 5 mg every other day the daily dose should be reported as 2.5 mg, if a patient takes 20 mg and 30 mg doses on alternating days the daily dose should be reported as 25 mg, or if a patient is on 60 mg twice daily, the daily dose should be reported as 120 mg. If the steroid was tapered during the assessment period, report the most recent dose during the assessment period.*

	Received	Dose	Started During Assessment Period	Start Date *(mm/dd/yyy)*	Reason
11. Betamethasone:	*(BETAREC)* 1 - Yes 2 - No	*(BETADOSE)* *(xx.x)* mg	*(BETASTAS)* 1 - Yes 2 - No	*(BETASDT)*	*(BETAREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
12. Beclomethasone:	*(BECLREC)* 1 - Yes 2 - No	*(BECLDOSE)* *(xxxx)* mcg	*(BECLSTAS)* 1 - Yes 2 - No	*(BECLSDT)*	*(BECLREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
13. Budesonide:	*(BUDREC)* 1 - Yes 2 - No	*(BUDDOSE)* *(xx)* mg	*(BUDSTAS)* 1 - Yes 2 - No	*(BUDSDT)*	*(BUDREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
14. Dexamethasone:	*(DEXAREC)* 1 - Yes 2 - No	*(DEXADOSE)* *(xx.x)* mg	*(DEXASTAS)* 1 - Yes 2 - No	*(DEXASDT)*	*(DEXAREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
15. Hydrocortisone:	*(HYDRREC)* 1 - Yes 2 - No	*(HYDRDOS)* *(xxx)* mg	*(HYDRSTAS)* 1 - Yes 2 - No	*(HYDRSDT)*	*(HYDRREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason

16. Methylprednisolone:	*(METHREC)* 2 - No	1 - Yes		*(METHDOS)* mg	*(xxx)*	*(METHSTAS)* 2 - No	1 - Yes		*(METHSDT)*	*(METHREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
17. Prednisone:	*(PREDREC)* 2 - No	1 - Yes		*(PREDDOS)* *(xxx.x)* mg		*(PREDSTAS)* 2 - No	1 - Yes		*(PREDSDT)*	*(PRDREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
18. Prednisolone:	*(PRLREC)* No	1 - Yes	2 -	*(PRLDOSE)* mg	*(xxx)*	*(PRLSTAS)* No	1 - Yes	2 -	*(PRLSDT)*	*(PRLREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
19. Topical Cream:	*(TOPCREC)* 2 - No	1 - Yes		*Dose is N/A*		*(TOPCSTAS)* 2 - No	1 - Yes		*(TOPCSDT)*	*(TOPCREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason
20. Other Steroid:	*(OTHREC)* No	1 - Yes	2 -	*(OTHDOSE)* *(xxx.x)* mg		*(OTHSTAS)* - No	1 - Yes	2	*(OTHDT)*	*(OTHREAS)* 1 - GVHD Prophylaxis 2 - GVHD Treatment 3 - Cytokine Storm/Engraftment Syndrome 4 - IPS 5 - Other Reason

21. Specify other reason(s):*(SPOTHRSN)*

Guidance: *If more than one steroid was provided for other reasons, specify each reason for each steroid.*

22. Specify topical cream received:*(SPTOPCRM)*

23. Specify other steroid received:*(SPOTHSTD)*

24. Were other immunosuppressive agents given?*(GVSOTIMM)* 1 - Yes 2 - No

Guidance: *All medications should be reported if given during the assessment period, whether given daily (e.g. MMF) or intermittently (e.g. anti-thymocyte globulin or etanercept). If the patient is on a study where the treatment assignment is not known, identify as experimental treatment, and list out the potential options of treatment. If the patient is receiving experimental agents, list the experimental agent. Do not report common topical therapies (e.g. steroid creams, restasis).*

Indicate all immunosuppressants received during the assessment period:

25. ALG, ALS, ATG, ATS (after day 0):*(GVSATG)* 1 - Yes 2 - No
26. Anti CD25 (Zenapax, Daclizumab, AntiTAC):*(GVSANTCD)* 1 - Yes 2 - No
27. Campath:*(GVSCAMPT)* 1 - Yes 2 - No
28. Cyclosporine (CSA):*(GVSCSA)* 1 - Yes 2 - No
29. Tacrolimus (FK506, Prograf):*(GVSTACRO)* 1 - Yes 2 - No
30. Infliximab (Remicade):*(GVSINFLX)* 1 - Yes 2 - No
31. Methotrexate (MTX):*(GVSMTX)* 1 - Yes 2 - No
32. Mycophenolate (MMF, Cellcept):*(GVSMMF)* 1 - Yes 2 - No
33. Pentostatin:*(GVSPENT)* 1 - Yes 2 - No
34. Rituximab:*(GVSRITUX)* 1 - Yes 2 - No
35. Sirolimus (Rapamycin, Rapamune):*(GVSSIRO)* 1 - Yes 2 - No
36. Experimental immunosuppressant:*(GVSEXP)* 1 - Yes 2 - No
    37. Specify experimental immunosuppressant:*(GVSEXPSP)*
    38. Is the experimental immunosuppressant part of a placebo controlled trial?*(GVSEXPLC)* 1 - Yes 2 - No
39. Etanercept:*(GVSETAN)* 1 - Yes 2 - No
    40. Indication Etanercept given for:*(GVSETREA)* 1 - GVHD 2 - IPS
41. Other immunosuppressant:*(GVSOTHER)* 1 - Yes 2 - No
    42. Specify other immunosuppressant:*(GVSOTISP)*
43. Was ECP given?*(GVSECP)* 1 - Yes 2 - No
44. Record the number of ECP treatments given during the assessment period:*(GVSECPNM)* *(xx)*

Comments:*(GVSCMMT)*

Infection Form (IFN)

Web Version: 1.0; 3.00; 06-05-17

Segment *(PROTSEG)*: A
Infection Site *(INFSITE)*:
Infection Start Date *(INFSTDT)*:

INFECTION I

1. Is Infection I a nonmicrobiologically defined infection?*(IFN1NMCR)* — 1 - Yes 2 - No
2. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection? *(IFN1PTPN)* — 1 - Yes 2 - No
3. Did the patient require mechanical ventilation?*(IFN1PTVT)* — 1 - Yes 2 - No
4. Did the patient have typhlitis?*(IFN1PTTY)* — 1 - Yes 2 - No
5. Did the patient have severe sepsis without an identified organism?*(IFN1PSEP)* — 1 - Yes 2 - No
6. Type of infection:*(IFN1TYPE)*
   B - Bacteria
   V - Viral
   F - Fungal
   P - Protozoal
   O - Other
7. Organism I:*(IFN1ORGN)*
   B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   B02 - Agrobacterium radiobacter
   B03 - Alcaligenes xylosoxidans
   B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   B05 - Bacillus (cereus, other species)
   *Additional Options Listed Below

   Specify other organism:*(IFN1OTSP)*
8. Severity of infection:*(IFN1SVRT)*
   2 - Grade 2
   3 - Grade 3
9. Was there evidence of sepsis?*(IFN1EVSP)* — 1 - Yes 2 - No
10. Was there evidence of new or worsening infiltrates at the time of the infection?*(IFN1EVIN)* — 1 - Yes 2 - No

INFECTION II

11. Is Infection II a nonmicrobiologically defined infection?*(IFN2NMCR)* — 1 - Yes 2 - No
12. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection? *(IFN2PTPN)* — 1 - Yes 2 - No
13. Did the patient require mechanical ventilation?*(IFN2PTVT)* — 1 - Yes 2 - No
14. Did the patient have typhlitis?*(IFN2PTTY)* — 1 - Yes 2 - No
15. Did the patient have severe sepsis without an identified organism?*(IFN2PSEP)* — 1 - Yes 2 - No
16. Type of infection:*(IFN2TYPE)*
   B - Bacteria
   V - Viral
   F - Fungal
   P - Protozoal
   O - Other
17. Organism II:*(IFN2ORGN)*
   B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
   B02 - Agrobacterium radiobacter
   B03 - Alcaligenes xylosoxidans
   B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
   B05 - Bacillus (cereus, other species)
   *Additional Options Listed Below

   Specify other organism:*(IFN2OTSP)*
18. Severity of infection:*(IFN2SVRT)*
   2 - Grade 2
   3 - Grade 3
19. Was there evidence of sepsis?*(IFN2EVSP)* — 1 - Yes 2 - No
20. Was there evidence of new or worsening infiltrates at the time of the infection?*(IFN2EVIN)* — 1 - Yes 2 - No

INFECTION III

21. Is Infection III a nonmicrobiologically defined infection?*(IFN3NMCR)* — 1 - Yes 2 - No
22. Did the patient have evidence of pneumonia or bronchopneumonia related to an infection? *(IFN3PTPN)* — 1 - Yes 2 - No
23. Did the patient require mechanical ventilation?*(IFN3PTVT)* — 1 - Yes 2 - No
24. Did the patient have typhlitis?*(IFN3PTTY)* — 1 - Yes 2 - No
25. Did the patient have severe sepsis without an identified organism?*(IFN3PSEP)* — 1 - Yes 2 - No
26. Type of infection:*(IFN3TYPE)*

B - Bacteria
V - Viral
F - Fungal
P - Protozoal
O - Other

27. Organism III:*(IFN3ORGN)*

B01 - Acinetobacter (baumanii, calcoaceticus, lwoffi, other species)
B02 - Agrobacterium radiobacter
B03 - Alcaligenes xylosoxidans
B04 - Anaerobic bacteria (NOS, except for Bacteroides, Clostridium)
B05 - Bacillus (cereus, other species)
*Additional Options Listed Below

Specify other organism:*(IFN3OTSP)*

28. Severity of infection:*(IFN3SVRT)*

2 - Grade 2
3 - Grade 3

29. Was there evidence of sepsis?*(IFN3EVSP)*

1 - Yes 2 - No

30. Was there evidence of new or worsening infiltrates at the time of the infection?*(IFN3EVIN)*

1 - Yes 2 - No

31. Was an agent(s) administered to treat the infection(s)?*(IFNAGTRT)*

1 - Yes 2 - No

Provide agent(s) administered for the infection(s):
Agents administered for prophylaxis should not be reported.

32. 1st agent:*(IFN1AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN1AGSP)*

33. 2nd agent:*(IFN2AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN2AGSP)*

34. 3rd agent:*(IFN3AGNT)*

abacavir (Ziagen)
acyclovir (Zovirax)
albendazole (Albenza)
amantadine (Symmetrel, Symadine)
amikacin (Amikin)
*Additional Options Listed Below

Specify other agent:*(IFN3AGSP)*

35. Were additional agents administered for the infection(s)?*(IFNADDAG)*

1 - Yes 2 - No

If yes, specify additional agents administered:*(IFNADDSP)*

Comments:*(IFNCOMM)*

Additional Selection Options for IFN

Infection Site *(INFSITE)* (key field):
01 - Blood/Buffy Coat
02 - Disseminated - Generalized, Isolated at 2 or More Distinct Sites
03 - Brain
04 - Spinal Cord
05 - Meninges and CSF
06 - Central Nervous System Unspecified
07 - Lips
08 - Tongue, Oral Cavity, and Oro-Pharynx
09 - Esophagus
10 - Stomach
11 - Gallbladder and Biliary Tree (Not Hepatitis), Pancreas
12 - Small Intestine
13 - Large Intestine
14 - Feces/Stool
15 - Peritoneum
16 - Liver
17 - Gastrointestinal Tract Unspecified
18 - Upper Airway and Nasopharynx
19 - Larynx
20 - Lower Respiratory Tract (Lung)
21 - Pleural Cavity, Pleural Fluid
22 - Sinuses
23 - Respiratory Tract Unspecified
24 - Kidneys, Renal Pelvis, Ureters and Bladder
25 - Prostate
26 - Testes
27 - Fallopian Tubes, Uterus, Cervix
28 - Vagina
29 - Genito-Urinary Tract Unspecified
30 - Genital Area
31 - Rash, Pustules, or Abscesses Not Typical of Any of the Above
32 - Skin Unspecified
33 - Woundsite
34 - Catheter Tip
35 - Eyes
36 - Ears
37 - Joints
38 - Bone Marrow
39 - Bone Cortex (Osteomyelitis)
40 - Muscle (Excluding Cardiac)
41 - Cardiac (Endocardium, Myocardium, Pericardium)
42 - Lymph Nodes
43 - Spleen
99 - Other Unspecified

Organism I:
B06 - Bacteroides (gracillis, uniformis, vulgaris, other species)
B07 - Borrelia (Lyme disease)
B08 - Branhamelia or Moraxella catarrhalis (other species)
B09 - Campylobacter (all species)
B11 - Chlamydia
B12 - Citrobacter (freundii, other species)
B13 - Clostridium (all species except difficile)
B14 - Clostridium difficile
B15 - Corynebacterium (all non-diptheria species)
B16 - Coxiella
B17 - Enterobacter
B18 - Enterococcus (all species)
B19 - Escherichia (also E. coli)
B20 - Flavimonas oryzihabitans
B21 - Flavobacterium
B22 - Fusobacterium nucleatum
B23 - Gram Negative Diplococci (NOS)
B24 - Gram Negative Rod (NOS)
B25 - Gram Positive Cocci (NOS)
B26 - Gram Positive Rod (NOS)
B27 - Haemophilus (all species including influenzae)
B28 - Helicobacter pylori
B29 - Klebsiella
B30 - Lactobacillus (bulgaricus, acidophilus, other species)
B31 - Legionella
B32 - Leptospira
B33 - Leptotrichia buccalis
B34 - Leuconostoc (all species)
B35 - Listeria
B36 - Methylobacterium
B37 - Micrococcus (NOS)
B38 - Mycobacteria (avium, bovium, haemophilum, intercellulare)
B39 - Mycoplasma
B40 - Neisseria (gonorrhoea, meningitidis, other species)
B41 - Nocardia
B42 - Pharyngeal/Respiratory Flora
B43 - Propionibacterium (acnes, avidum, granulosum, other species)
B44 - Pseudomonas (all species except cepacia and maltophilia)
B45 - Pseudomonas or Burkholderia cepacia
B46 - Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
B47 - Rhodococcus
B48 - Rickettsia
B49 - Salmonella (all species)
B50 - Serratia marcescens
B51 - Shigella
B52 - Staphylococcus (coag -)
B53 - Staphylococcus (coag +)
B54 - Staphylococcus (NOS)
B55 - Stomatococcus mucilaginosis
B56 - Streptococcus (all species except Enterococcus)
B57 - Treponema (syphilis)
B58 - Tuberculosis (NOS, AFB, acid fast bacillus, Koch bacillus)
B59 - Typical Tuberculosis (TB, Tuberculosis)
B60 - Vibrio (all species)
B99 - Other Bacteria
V01 - Herpes Simplex (HSV1, HSV2)
V02 - Herpes Zoster (Chicken pox, Varicella)
V03 - Cytomegalovirus (CMV)
V04 - Adenovirus
V05 - Enterovirus (Coxsackie, Echo, Polio)
V06 - Hepatitis A (HAV)

V07 - Hepatitis B (HBV, Australian antigen)
V08 - Hepatitis C (includes non-A and non-B, HCV)
V09 - HIV-1, HITLV-III
V10 - Influenza (Flu)
V11 - Measles (Rubeola)
V12 - Mumps
V13 - Papovavirus
V14 - Respiratory Syncytial virus (RSV)
V15 - Rubella (German Measles)
V16 - Parainfluenza
V17 - HHV-6 (Human Herpes Virus)
V18 - Epstein-Barr Virus (EBV)
V19 - Polyomavirus
V20 - Rotavirus
V21 - Rhinovirus (Common Cold)
V22 - Other Viral
P1 - Pneumoncystis (PCP)
P2 - Toxoplasma
P3 - Giardia
P4 - Cryptosporidium
P5 - Amebiasis
P6 - Echinocoocalcyst
P7 - Trichomonas (either vaginal or gingivitis)
P8 - Other Protozoal (Parasite)
O1 - Mycobacterium Tuberculosis
O2 - Other Mycobacterium
O3 - Mycoplasma
O4 - Other Organism
F01 - Candida Albicans
F02 - Candida Krusei
F03 - Candida Parasilosis
F04 - Candida Tropicalis
F05 - Torulopsis Galbrata (a subspecies of Candida)
F06 - Candida (NOS)
F07 - Asperguillus Flavus
F08 - Asperguillus Fumigatus
F09 - Asperguillus Niger
F10 - Asperguillus (NOS)
F11 - Cryptococcus Species
F12 - Fusarium Species
F13 - Mucormycosis (Zygomycetes, Rhizopus)
F14 - Yeast (NOS)
F15 - Other Fungus

1st agent:
amoxicillin / clavulanate (Augmentin)
amphotericin b (Abelcet, Amphotec, Fungizone)
ampicillin (Omnipen, Polycillin)
ampicillin / sulbactam (Unasyn)
amprenavir (Agenerase)
atovaquone (Meprone)
azithromycin (Zithromax, Z-Pack)
cefaclor (Ceclor)
cefadroxil (Duricef, Ultracef)
cefazolin (Ancef, Kefzol)
cefdinir (Omnicef)
cefepime (Maxipime)
cefixime (Suprax)
cefoperazone (Cefobid)
cefotaxime (Claforan)
cefotetan (Cefotan)
cefoxitin (Mefoxin)
cefpodoxime (Vantin)
cefprozil (Cefzil)
ceftazidime (Fortaz, Tazicef)
ceftriaxone (Rocephin)
cefuroxime (Ceftin, Kefurox, Zinacef)
cephalexin (Keflet, Keflex, Keftab)
chloramphenicol (Chloromycetin)
cidofovir (Vistide)
ciprofloxacin (Cipro)
clarithromycin (Biaxin)
clindamycin (Cleocin)
clotrimazole (Mycelex, Lotrimin)
clotrimoxazole / betamethasone (Lotrisone)
co-trimoxazole (Bactrim, Septra, Sulfamethoprim)
dapsone (DDS)
dicloxacillin (Dycill, Dynapen, Pathocil)
didanosine (Videx, ddI)
doxycycline (Vibramycin)
efavirenz (Sustiva)
erythromycin (Ery-Tab, Ilosone, Pediamycin)
erythromycin ethyl/sulfisoxazole (Pediazole)
erythromycin topical (Akne-mycin, Eryderm)
ethambutol (Myambutol)
famciclovir (Famvir)
fluconazole (Diflucan)
flucytosine (Ancobon)
foscarnet (Foscavir)
ganciclovir (Cytovene)
gatifloxacin (Tequin)
gentamicin (Garamycin, Gentacidin)
grepafloxacin (Raxar)
hepatitis a vaccine (Havrix, Vaqta)
hepatitis b vaccine (Recombivax HB, Engerix-B)
hepatitis c vaccine
imipenem / cilastatin (Primaxin)
imiquimod (Aldara)
indinavir (Crixivan)
interferon alfacon-1 (Infergen)
interferon beta-1a (Avonex)
interferon beta-1b (Betaseron)
isoniazid (INH, Lanizid, Nydrazid)
itraconazole (Sporonox)
ivermectin (Stromectol)
kanamycin (Kantrex)
ketoconazole (Nizoral)
lamivudine (Epivir, 3TC)
levofloxacin (Levaquin)
linezolid (Zyvox)
lopinavir/ritonavir (Kaletra)
mefloquine (Larium)
meropenem (Merrem I.V.)

metronidazole (Flagyl, Protostat)
minocycline (Arestin)
moxifloxacin hydrochloride (Avelox)
mupirocin (Bactroban)
nafcillin (Nallpen, Unipen)
nelfinavir (Viracept)
neomycin (Mycifradin, Myciguent)
neomycin / polymxin / hydrocortisone (Cortisporin)
nevirapine (Viramune)
nitrofurantoin (Macrobid)
nystatin (Mycostatin)
oseltamivir (Tamiflu)
oxacillin (Bactocill)
palivizumab (Synagis)
penicillin g (Bicillin)
penicillin vk (V-Cillin K, Veetids)
pentamidine (Pentam 300)
piperacillin (Pipracil)
piperacillin/tazobactam (Zosyn)
podofilox (Condylox)
polymyxin (Ak-Spore H.C., Cortisporin Ophthalmic Suspension)
PPD skin test (Mantoux Test, Tine Test)
pyrazinamide (Rifater)
pyrimethamine (Daraprim)
quinidine gluconate (Duraquin, Cardioqiuin)
quinupristin/dalfopristin (Synercid)
respiratory syncytial immune globulin (Respigam)
ribavirin (Virazole)
rifampin (Rifadin, Rimactane)
rifampin/isoniazid (Rifamate, Rimactane/INH)
rifampin/isoniazid/pyrazinamide (Rifater)
rimantadine (Flumadine)
ritonavir (Norvir)
saquinavir mesylate (Fortovase, Invirase)
stavudine (d4T, Zerit)
streptomycin (Streptomycin sulfate)
sulfamethoxazole / trimethoprim (Bactrim)
terbinafine (Lamisil)
terconazole (Terazol)
tetracycline (Achromycin)
ticarcillin / clavulanate (Ticar, Timentin)
tobramycin (Nebcin, Tobrex, TobraDex)
trimethoprim / sulfamethoxazole (Bactrim, Septra, Co-trimoxazole)
valacyclovir (Valtrex)
valganciclovir (Valcyte)
vancomycin (Vancocin)
zidovudine (AZT, Retrovir)
other

Laboratory Assessment Form - 1202 (LA9)

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

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Date of CBC sample and differential:*(LA9CBCDT)* *(mm/dd/yyyy)*

CBC

		Most Recent Value	
2. RBC:	*(LA9RBC)*	*(x.xx)*	$x10^{12}/L$
3. Hematocrit:	*(LA9HCT)*	*(xx.x)*	%
4. Hemoglobin:	*(LA9HGB)*	*(xx.x)*	g/dL
5. WBC:	*(LA9WBC)*	*(xxxxxx)*	$/mm^3$
6. Platelet Count:	*(LA9PLT)*	*(xxxxxx)*	$/mm^3$

Differential

		Most Recent Value	
7. Bands:	*(LA9BNPCT)*	*(xx)*	%
8. Segments:	*(LA9SGPCT)*	*(xx)*	%
9. Neutrophils:	*(LA9NTPCT)*	*(xxx)*	%
10. Lymphocytes:	*(LA9LPPCT)*	*(xx)*	%
11. Monocytes:	*(LA9MNPCT)*	*(xx)*	%
12. Eosinophils:	*(LA9ESPCT)*	*(xx)*	%
13. Basophils:	*(LA9BSPCT)*	*(xx)*	%
14. Blasts:	*(LA9BLPCT)*	*(xx)*	%
15. LUC:	*(LA9LCPCT)*	*(xx)*	%

Comments:*(LA9COMMT)*

Chronic GVHD Provider Survey (PCG)

Web Version: 1.0; 1.04; 06-16-16

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

Instructions:
Please score a symptom only if you know or suspect it to be *related to chronic GVHD*. Subjective symptoms are acceptable. For example, joint tightness can be scored based on subjective findings despite the absence of objective limitations.

Please score symptoms present in the *last week*. Even if they may have resolved with treatment in the past week, if they were present recently and may possibly return, please score them.

1. Date of visit:*(PCGDATE)* *(mm/dd/yyyy)*

	0	1	2	3
Skin Score	*(PCGSKIN)* No Symptoms	<18% BSA with disease signs but NO sclerotic features	19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)	>50% BSA OR deep sclerotic feats. hidebound OR impaired mobility, ulceration or severe pruritis
Mouth Score	*(PCGMOUTH)* No Symptoms	Mild symptoms with disease signs but not limiting oral intake significantly	Moderate symptoms with signs with **partial** limitation of oral intake	Severe symptoms with disease signs on examination with **major** limitation of oral intake
GI Tract Score	*(PCGGITRC)* No symptoms	Symptoms: dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea with weight loss (<5%)	Symptoms associated with mild to moderate weight loss (5-15%)	Symptoms with significant weight loss >15%, requires nutritional supplements OR esophageal dilation
Eye Score	*(PCGEYE)* No symptoms	Mild dry eye not affecting ADL OR asymptomatic signs of kerato-conjunctivitis sicca	Moderate dry eye partially affecting ADL WITHOUT vision impairment	Severe dry eye symptoms significantly affecting ADL OR unable to work OR loss of vision
Joint and Fascia Score	*(PCGJOINT)* No symptoms	Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL	Tightness of arms or legs OR joint contractures, erythema due to fasciitis, moderate decrease in ROM	Contracture WITH significant decrease of ROM AND significant limitation of ADL
Genital Tract Score (score even if no GYN exam; score required for men, too) *(PCGNOEXM)* **No GYN Exam**	*(PCGGNITL)* No symptoms	Symptomatic, mild distinct signs on exam and no effect on coitus, minimal discomfort w/ GYN exam	Symptomatic, distinct signs on exam and mild dyspareunia or discomfort w/ GYN exam	Symptomatic, advanced signs, severe pain with coitus or inability to insert vaginal spectrum
Lung Score	*(PCGLUNG)* No symptoms	Mild symptoms (shortness of breath after climbing one flight of steps)	Moderate symptoms (shortness of breath after walking on flat ground)	Severe symptoms (shortness of breath at rest; requiring oxygen)

Please rate the severity of this person's chronic GVHD

on this scale *(PCGSEV1)* 1 - None 2 - Mild 3 - Moderate 4 - Severe

and on this scale *(PCGSEV2)* 0 - cGVHD symptoms are not at all severe 1 2 3 4 5 6 7 8 9 10 - cGVHD symptoms are most severe possible

Is an erythematous or maculopapular rash present?*(PCGRASH)* 1 - Yes 2 - No

Does the patient have nausea, vomiting or diarrhea?*(PCGVOMIT)* 1 - Yes 2 - No

Liver score to be completed using most recent LFTs from within +/- 2 weeks of the assessment

	0	1	2	3
Liver Score *(PCGLIVER)*	Normal LFTs	Elevated bilirubin, alkaline phosphatase, AST or ALT < 2x ULN	Bilirubin > 3 mg/dl or bilirubin, AST or ALT 2-5x ULN	Bilirubin, AST or ALT > 5x ULN

Date LFT sample obtained:*(PCGLFTDT)* *(mm/dd/yyyy)*

PFT values from within one month of the assessment

% FEV1*(PCGFEV1)* *(xxx)* % Date of FEV1*(PCGFEVDT)* *(mm/dd/yyyy)* *(PCGFEVND)* Not Done

% DLCOc*(PCGDLCO)* *(xxx)* % Date of DLCOc*(PCGDLCDT)* *(mm/dd/yyyy)* *(PCGDLCND)* Not Done

Comments:*(PCGCOMM)*

Endpoint Review Query Form- 1202 (Q07)

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

Case ID *(CASEID)*:

Site:*(QXXSITE)*

Patient ID:*(QXXPATID)*

Number of Queries Indicated:*(QRYNUM)*

Queries

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT01) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT01)* *(mm/dd/yyyy)*	*(QDESC01)*	*(QRSPDT01)* *(mm/dd/yyyy)*	*(QRSPNS01)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT02) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT02)* *(mm/dd/yyyy)*	*(QDESC02)*	*(QRSPDT02)* *(mm/dd/yyyy)*	*(QRSPNS02)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT03) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT03)* *(mm/dd/yyyy)*	*(QDESC03)*	*(QRSPDT03)* *(mm/dd/yyyy)*	*(QRSPNS03)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT04) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT04)* *(mm/dd/yyyy)*	*(QDESC04)*	*(QRSPDT04)* *(mm/dd/yyyy)*	*(QRSPNS04)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT05) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT05)* *(mm/dd/yyyy)*	*(QDESC05)*	*(QRSPDT05)* *(mm/dd/yyyy)*	*(QRSPNS05)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT06) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT06)* *(mm/dd/yyyy)*	*(QDESC06)*	*(QRSPDT06)* *(mm/dd/yyyy)*	*(QRSPNS06)*
Query Status	**Date Query Sent**	**Query**	**Date Response Received**	**Query Response**
(QSTAT07) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT07)* *(mm/dd/yyyy)*	*(QDESC07)*	*(QRSPDT07)* *(mm/dd/yyyy)*	*(QRSPNS07)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT08) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT08)* *(mm/dd/yyyy)*	*(QDESC08)*	*(QRSPDT08)* *(mm/dd/yyyy)*	*(QRSPNS08)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT09) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT09)* *(mm/dd/yyyy)*	*(QDESC09)*	*(QRSPDT09)* *(mm/dd/yyyy)*	*(QRSPNS09)*

Query Status	Date Query Sent	Query	Date Response Received	Query Response
(QSTAT10) 1- Resolved 2- Not Yet Sent To Site 3- Pending Site Response 4- Never Resolved	*(QSNTDT10)* *(mm/dd/yyyy)*	*(QDESC10)*	*(QRSPDT10)* *(mm/dd/yyyy)*	*(QRSPNS10)*

Relapse Form - 1202 (RLS)

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

Segment *(PROTSEG)*: A

1. Did the patient relapse or experience progression of the disease for which HCT was performed? *(RELPSE)* 1 - Yes 2 - No

2. Date of relapse or progression:*(RELPSEDT)* *(mm/dd/yyyy)*

Comments:*(RLSCOMM)*

Specimen Acquisition Form - 1202 (SA9)

Web Version: 1.0; 2.03; 10-16-15

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Was a whole blood sample collected for proteomic studies?*(PROTSMP)*	1 - Yes	2 - No
2. Date whole blood sample was collected:*(PROTSMDT)*		*(mm/dd/yyyy)*
3. Were whole blood samples collected in PAXgene tubes for gene expression studies?*(PAXGENE)*	1 - Yes	2 - No
4. Date PAXgene sample was collected:*(PAXGNDT)*		*(mm/dd/yyyy)*
5. Was a whole blood sample collected in a CytoChex tube for immunophenotyping?*(CYTOCHEX)*	1 - Yes	2 - No
6. Date CytoChex sample was collected:*(CYTCHXDT)*		*(mm/dd/yyyy)*
7. Were the recipient pre-conditioning NMDP Research Samples collected?*(RCNMDPSM)*	1 - Yes	2 - No
8. Date NMDP recipient sample was collected:*(RCNMDPDT)*		*(mm/dd/yyyy)*
9. NMDP recipient sample ID:*(RECSMPID)*		(XXX-XXX-X)
10. Were the related donor pre-donation NMDP Research Samples collected?*(RLDNRSMP)*	1 - Yes	2 - No
11. Date NMDP related donor sample was collected:*(RLDNRDT)*		*(mm/dd/yyyy)*
12. NMDP related donor sample ID:*(DNRSMPID)*		(XXXX-XXXX-X)

Comments:*(SA9COMM)*

Termination Form (TER)

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

1. Date of Termination:*(TERMDT)* *(mm/dd/yyyy)*

2. Reason for Termination:*(TERMRSN)*

01 - Patient No Longer Receiving Transplant
02 - Patient No Longer Meets Inclusion/Exclusion Criteria
03 - Patient Refused/Withdrew Consent
04 - Donor Refused/Withdrew Consent
05 - Insurance Denied
*Additional Options Listed Below

If "Other", specify:*(TERMSP)*

3. Date Termination Approved by BMT CTN:*(TERMAPDT)* *(mm/dd/yyyy)*

Termination must be reviewed and approved by the EMMES protocol coordinator prior to form submission.

Comments:*(TERMCOMM)*

Additional Selection Options for TER

Reason for Termination:
06 - Patient Became Pregnant
99 - Other, Specify

Transplant Form (TXP)

Web Version: 1.0; 18.00; 08-09-18

Segment *(PROTSEG)*: A
Visit Number *(VISNO)*:

1. Record date of initiation of conditioning regimen:*(CONDNGDT)* *(mm/dd/yyyy)*
2. Record date of hematopoietic stem cell infusion:*(TXDTTXP)* *(mm/dd/yyyy)*
3. Record the patient's pre-transplant CMV antibody (IgG) status:*(CMVSTAT)* 1 - Positive 2 - Negative
4. IUBMID for this patient (if available):*(T_IUBMID)*

Comments:*(COMMTXP1)*