

**Blood and Marrow Transplant Clinical  
Trials Network**

**Demographics (DEM)**

Web Version: 1.0; 6.00; 06-22-11

1. Name Code: (NAMECODE)

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

3. CRID # (CIBMT R Recipient ID): (CRIDNUM)

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

4. Gender: (GENDER)

 1 - Male  2 - Female

5. Date of Birth: (DOB)

6. Ethnicity: (ETHNIC)

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

7. Race: (RACE)

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

Specify race: (RACESP)

8. Secondary Race: (RACE2)

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

Specify secondary race: (RACE2SP)

Comments: (DEMCOMM1)

## Additional Selection Options for DEM

### Race:

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

**Blood and Marrow Transplant Clinical  
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**0401A (ENR)**

Web Version: 1.0; 7.01; 08-25-09

**Bexxar Enrollment Form - Segment A**

1. Record date patient informed consent signed: (CNS TDTBX)  (mm/dd/yyyy)
2. Patient's date of birth: (DOBBX)  (mm/dd/yyyy)
3. SWOG ID: (O4O1SWOG)
4. Record the proposed date of initiation of conditioning: (STCONDDT)  (mm/dd/yyyy)
5. Record the start date of mobilization: (MOBLDTBX)  (mm/dd/yyyy)
6. Record the start date of apheresis: (STAPHERE)  (mm/dd/yyyy)
7. Record the date of the most recent Rituxan administration: (LASTRTX)  (mm/dd/yyyy)

**Patient Inclusion Criteria**

8. Does the patient have persistent or recurrent REAL classification diffuse large B-cell lymphoma, composite lymphoma with > 50% diffuse large B-cell lymphoma, or medistinal B-cell lymphoma? (REALDXBX)  1 - Yes  2 - No
9. Is the patient CD20+ as demonstrated on at least one histologic specimen? (CD20BX)  1 - Yes  2 - No
10. Record the date the first CD20+ histologic specimen was obtained: (SPECDTBX)  (mm/dd/yyyy)
11. How many prior regimens of chemotherapy (including induction and salvage chemotherapies) has the patient received? (PRCHEMBX)
 

1-1 - One Prior Regimen  
 2-2 - Two Prior Regimens  
 3-3 - Three Prior Regimens
12. Indicate the patient's disease status: (DXSTATBX)
 

1-1 - Primary Induction Failure  
 2-2 - First Relapse  
 3-3 - Second Complete Remission  
 4-4 - Second Partial Response
13. Does the patient have chemosensitive disease as demonstrated by at least a partial response to induction or salvage chemotherapy? (CHEMPR)  1 - Yes  2 - No
14. What is the percentage of bone marrow involvement with lymphoma? (BM INVLBX)  (xxx) %
15. Does the patient have either no cardiac disease or AHA Class I cardiac disease? (AHACLSBX)  1 - Yes  2 - No

	Most Recent Value	ULN for Your Institution	Date of Assessment
16. LVEF:	(LVEFVLBX) <input type="text"/> (xxx) %	N/A	(LVEFDTBX) <input type="text"/> (mm/dd/yyyy)
17. Bilirubin:	(BILIVLXB) <input type="text"/> (x.x) mg/dL	N/A	(BILIDTBX) <input type="text"/> (mm/dd/yyyy)
18. ALT:	(ALTVLXB) <input type="text"/> (xxx) Units/L	(ALTULNBX) <input type="text"/> (xxx) Units/L	(ALDTBX) <input type="text"/> (mm/dd/yyyy)
19. AST:	(ASTVLXB) <input type="text"/> (xxx) Units/L	(ASTULNBX) <input type="text"/> (xxx) Units/L	(ASTDTBX) <input type="text"/> (mm/dd/yyyy)
20. Creatinine:	(CRTVLBX) <input type="text"/> (x.x) mg/dL	N/A	(CRTDTBX) <input type="text"/> (mm/dd/yyyy)
21. Creatinine Clearance:	(CRCLVLBX) <input type="text"/> (xxx) mL/min	N/A	(CRCLDTBX) <input type="text"/> (mm/dd/yyyy)
22. DLCO:	(DLCOVLBX) <input type="text"/> (xxx) %	N/A	(DLCODTBX) <input type="text"/> (mm/dd/yyyy)
23. FEV1:	(FEV1VLBX) <input type="text"/> (xxx) %	N/A	(FEV1DTBX) <input type="text"/> (mm/dd/yyyy)
24. FVC:	(FVCVLBX) <input type="text"/> (xxx) %	N/A	(FVCDTBX) <input type="text"/> (mm/dd/yyyy)

25. Indicate the patient's most recent platelet count (independent of transfusions): (PLTCNTBX)  (xxxxxx) /uL
26. Indicate the date of the most recent platelet count: (PLTDTBX)  (mm/dd/yyyy)
27. Indicate the patient's most recent ANC (independent of growth factors): (ANCBX)  (xxxxx) /mm<sup>3</sup>

28. Indicate the date of the most recent ANC: (ANCDTBX)

(mm/dd/yyyy)

### Patient Exclusion Criteria

29. Record the patient's Karnofsky performance score: (KPSBX)

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

30. Does the patient have transformed follicular lymphoma? (FOLLYMBX)

1 - Yes  2 - No

31. Does the patient have an uncontrolled bacterial, viral, or fungal infection (currently taking medication and with progression or no clinical improvement)? (INFECTBX)

1 - Yes  2 - No

32. Does the patient have a history of any malignant disease that was treated with curative intent < 5 years ago (other than DLBCL, basal cell carcinoma, or cervical cancer in situ)? (CAHXBX)

1-1 - Yes  
 2-2 - Yes, Approved by Medical Monitor  
 3-3 - No

33. Date approved by Study Chair or Medical Monitor: (CAAPRVBX)

(mm/dd/yyyy)

34. Is the patient pregnant (positive -HCG) or breastfeeding? (PREGBFBX)

1 - Yes  2 - No  3 - Not Applicable

35. Is the patient willing to use contraceptive techniques from the time of initiation of mobilization until six months post-transplant? (CNTECHBX)

1 - Yes  2 - No

36. Is the patient HIV seropositive? (HIVPOSBX)

1 - Yes  2 - No

37. Has the patient had a previous autologous or allogeneic hematopoietic stem cell transplant? (PREVTXBX)

1 - Yes  2 - No

38. Does the patient have evidence of MDS/AML or an abnormal cytogenetic analysis indicative of MDS on the pre-transplant bone marrow exam? (MDSAMLBX)

1 - Yes  2 - No

39. Has the patient had a prior severe reaction to G-CSF or Rituxan? (RXGRTXBX)

1 - Yes  2 - No

40. Has the patient received prior radioimmunotherapy? (IMMUNOBX)

1 - Yes  2 - No

41. Does the patient have known hypersensitivity to murine proteins? (KWNMURIN)

1 - Yes  2 - No

### Consent for Use of Biological Specimens for Research

42. Did the patient agree to provide blood for future research? (CNSTRSBX)

1 - Yes  2 - No

Comments: (COMMBXA)

## **Additional Selection Options for ENR**

**Record the patient's Karnofsky performance score:**

06-06 - 50 (Requires Considerable Assistance/No Active Play)

07-07 - 40 (Disabled/Able to Initiate Quiet Activities)

08-08 - 30 (Severely Disabled/Needs Assistance for Quiet Play)

09-09 - 20 (Very Sick/Limited to Very Passive Activity)

10-10 - 10 (Moribund; Completely Disabled)