

# BLOOD AND MARROW TRANSPLANT CLINICAL TRIALS NETWORK PROTOCOL #0401 Bexxar

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## 1. Introduction

This documents the final study data files delivered to the Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC) of the National Heart, Lung and Blood Institute (NHLBI) for the **Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Protocol 0401 Bexxar** study conducted from 2006 to 2009 and coordinated by the Emmes Corporation. The study is titled “Phase III Rituxan/BEAM vs. Bexxar/BEAM With Autologous Hematopoietic Stem Cell Transplantation (ASCT) for Persistent or Relapsed Chemotherapy Sensitive Diffuse Large B-cell Non-Hodgkin's Lymphoma (BMT CTN #0401)” and is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under NCT00329030. The study is fully documented by the BMT CTN Protocol and by the BMT CTN Manual of Procedures (MOP). The present files contain the data files from the BMT CTN Data and Coordinating Center (DCC) data system. The data and all of its accompanying documentation, including this specification document are uploaded to the specified website per NHLBI.

## 2. Specifications of Final Data Sets

- BMT CTN0401\_Final Data Submission to NHLBI BioLINCC\_ Documentation.doc  
This document serves as a readme file to describe the data submission package.
  
- a. Reference to necessary study documents
  - BMTCTN0401\_Protocol\_FinalVersion.pdf  
This is the Version 8.0 of the protocol, which was the final official version of the study protocol.
  - BMTCTN0401\_Protocol\_FirstVersion\_SummaryofChanges.pdf  
This includes the first version of the protocol along with summary of changes for each version.
  - BMTCTN0401\_CaseReportForms\_FinalVersion.pdf  
This is the final version of the annotated Case Report Forms that were used to collect data.
  - BMTCTN0401\_PrimaryPublication.pdf  
This is the primary manuscript officially published for the study.
  - Documentation for Outcomes Dataset.doc  
This is the documentation for the outcome dataset. Since the outcome dataset has no corresponding annotated Case Report Form, this serves as the detailed description for each variable in this outcome dataset, which may include data coding conventions, algorithms to calculate outcome variables,

adjudications by the study Endpoint Review Committee and some data variables that may be retrieved from CIBMTR data source.

- BMT CTN Admin Manual of Procedures.pdf

This is the most recent version, version 11.0 of the BMT CTN Admin MOP.

- BMT CTN Technical Manual of Procedures.pdf

This is the most recent version, version 3.0 of the BMT CTN Technical MOP.

- BMT-0401\_BioLINCC\_Publication\_Review.docx

This is an analysis done by BioLINCC of the replicability of the tables in the Primary Outcome Paper based on the publication data included in this submission. The results section includes feedback from the DCC.

#### b. List of final datasets delivered

- Set 1 – data lock for the primary publication

This set 1 includes all data at the data lock for the primary publication. A complete list of all the SAS data files are in the below table. The .sas file includes all the formats that can be applied to all the related data variables in the alphabetical order to the SAS data files. The Data Dictionary gives the labels/format assignments for the variables within each SAS data file.

- 17 datasets in BMTCTN0401\_SASdata\_PrimaryPublication
- Format for SASdata\_PrimaryPublication.sas
- Data\_Dictionary\_publication\_data.pdf

- Set 2 – final data lock for study close-out

This set 2 follows the similar structure as set 1, and includes all data at the data lock for the final data lock for study close-out. There may be minor difference between the data in this set and set 1, mainly due to data updates after the primary publication (e.g. data for some secondary endpoints may not be available at the data lock for the primary publication, some data may be corrected after an on-site data audit etc.) For future analysis, we recommend set 2 data files should be used. Set 1 can be referred to re-generate the results as published in the primary paper.

- 17 datasets in BMTCTN0401\_SASdata\_FinalDataLock
- Format for SASdata\_FinalDataLock.sas

- Data\_Dictionary\_final\_data.pdf

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
<b><i>Clinical Forms (in alphabetical order)</i></b>			
ADM	Re-Admission/ Hospitalization Form	ADM1SPEC ADM2SPEC ADM3SPEC ADM4SPEC Comments: ADMCOMM1	Subject IDs PROJID and PATID replaced with randomized ID RANDID ADMITDT recoded to days since randomization -> ADMITDT_DAYS Q1: DISCHDT recoded to days since randomization -> DISCHDT_DAYS

AE	Adverse Event Form AE1, AE2, AE3, AE4, AE5, AE6	<p>AE1 form AESPEC1 Comments: AE1COMM</p> <p>AE2 form AVSTAT_A SEMEDHX SESUMM SEISUBBY SEISUBDT SEASUBBY SEASUBDT</p> <p>AE3 form AVSTAT_B All variables related to Study Product 2-5 All variables related to Concomitant Medications 4-25. Comments: AE3COMM</p> <p>AE4 form AVSTAT_C All Variables Related to Lab Tests 2-10 All Variables Related to Diagnostic Tests 2-10 Comments: AE4COMM</p> <p>AE5 form AVSTAT_D AEREVIEW ARFREVBY ARFREVDT ARCM1DIS ARCM2ALL</p> <p>AE6 form AVSTAT_E AMREVINP Comments: AE6COMM</p>	<p>The series of AE forms are combined in one dataset. Subject IDs PROJID and PATID replaced with randomized ID RANDID ADVDATE recoded to days since randomization -&gt; ADVDATE_DAYS AE1 Q2: AVAWARDT recoded to days since randomization -&gt; AVAWARDT_DAYS AE1 Q3: AVWGHTKG top coded at 127 AE1 Q10: AVRESDT recoded to days since randomization -&gt; AVRESDT_DAYS AE3 Q2: SP1STDT recoded to days since randomization -&gt; SP1STDT_DAYS AE3 Q2: SP1SPDT recoded to days since randomization -&gt; SP1SPDT_DAYS AE3 Q3: CM1STDT recoded to days since randomization -&gt; CM1STDT_DAYS AE3 Q3: CM1SPDT recoded to days since randomization -&gt; SM1SPDT_DAYS AE3 Q3: CM2STDT recoded to days since randomization -&gt; CM2STDT_DAYS AE3 Q3: CM2SPDT recoded to days since randomization -&gt; CM2SPDT_DAYS AE3 Q3: CM3STDT recoded to days since randomization -&gt; CM3STDT_DAYS AE3 Q3: CM3SPDT recoded to days since randomization -&gt; CM3SPDT_DAYS AE4 Q2: ADL1CD recoded to days since randomization -&gt; ADL1CD_DAYS</p>
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Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
			AE4 Q2: ADL1PCD recoded to days since randomization -> ADL1PCD_DAYS AE4 Q3: AD1DTDAT recoded to days since randomization -> AD1DTDAT_DAYS
CLR	Consolidative Localized Radiation Therapy Form	Comments: CLRCOMM	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q1: SIT1DATE recoded to days since randomization -> SIT1DATE_DAYS Q1: SIT2DATE recoded to days since randomization -> SIT2DATE_DAYS Q1: SIT3DATE recoded to days since randomization -> SIT3DATE_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
CND	Conditioning Regimen Form	Comments: COMMCND	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q2: BSURFDT recoded to days since randomization -> BSURFDT_DAYS Q3: FSTRXDT recoded to days since randomization -> FSTRXDT_DAYS Q5: SECRTXDT recoded to days since randomization -> SECRTXDT_DAYS Q6: BXRDDT recoded to days since randomization -> BXRDDT_DAYS Q7: BXRTDT recoded to days since randomization -> BXRTDT_DAYS Q8: BCNUDT recoded to days since randomization -> BCNUDT_DAYS Q10: VPSTDT recoded to days since randomization -> VPSTDT_DAYS Q11: VPENDDT recoded to days since randomization -> VPENDDT_DAYS Q13: CYSTDT recoded to days since randomization -> CYSTDT_DAYS Q14: CYENDDT recoded to days since randomization -> CYENDDT_DAYS Q15: MELPHDT recoded to days since randomization -> MELPHDT_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
CYM	Cytoreductive Therapy/Mobilization Regimen Form	Comments: COMMCYM	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q1: PWEIGHT top coded at 127 Q2: WEIGHDT recoded to days since randomization -> WEIGHDT_DAYS Q4: PBSADT recoded to days since randomization -> PBSADT_DAYS Q5: LTRTXDT recoded to days since randomization -> LTRTXDT_DAYS Q10: RTX1ADDT recoded to days since randomization -> RTX1ADDT_DAYS Q11: RTX2ADDT recoded to days since randomization -> RTX2ADDT_DAYS Q12: RTX3ADDT recoded to days since randomization -> RTX3ADDT_DAYS Q15: CHEMDT recoded to days since randomization -> CHEMDT_DAYS Q17: GCSFSDT recoded to days since randomization -> GCSFSDT_DAYS Q18: GCSFEDT recoded to days since randomization -> GCSFEDT_DAYS Q20: GRWTDT recoded to days since randomization -> GRWTDT_DAYS Q7: APHESTDT recoded to days since randomization -> APHESTDT_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
DEM	Demographics Form	NAMECODE IUBMID CRIDNUM RACESP RACE2SP DOB Comments: DEMCOMM1	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q7: RACE recoded to only WHITE, BLACK, UNKNOWN, OTHER, or NOT ANSWERED Q8: RACE2 recoded to only WHITE, BLACK, UNKNOWN, OTHER, or NOT ANSWERED Q5: Created new variable "Age at Enrollment" (AGE_AT_ENRLMNT)
DTH	Death Form	DTHSPEC1 DTHSPEC2 SCNDCZ2 DTHSPEC3 SCNDCZ3 DTHSPEC4 SCNDCZ4 DTHSPEC5 Comments: DTCMMNTS	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q1: DTHDT recoded to days since randomization -> DTHDT_DAYS

ENRA	Enrollment Form for Screening	ENRLDATE CNSTDTBX DOBBX O4O1SWOG CAAPRVBX Comments: COMMBXA	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q4: STCONDDT recoded to days since randomization -> STCONDDT_DAYS Q5: MOBLDTBXDT recoded to days since randomization -> MOBLDTBXDT_DAYS Q6: STAPHERE recoded to days since randomization -> STAPHERE_DAYS Q7: LASTRTX recoded to days since randomization -> LASTRTX_DAYS Q10: SPECDTBX recoded to days since randomization -> SPECDTBX_DAYS Q16: LVEFDTBX recoded to days since randomization -> LVEFDTBX_DAYS Q17: BILIDTBX recoded to days since randomization -> BILIDTBX_DAYS Q18: ALDDTBX recoded to days since randomization -> ALDDTBX_DAYS Q19: ASTDTBX recoded to days since randomization -> ASTDTBX_DAYS Q20: CRTDTBX recoded to days since randomization -> CRTDTBX_DAYS Q21: CRCLDTBX recoded to days since randomization -> CRCLDTBX_DAYS Q22: DLCODTBX recoded to days since randomization -> DLCODTBX_DAYS Q23: FEV1DTBX recoded to days since randomization -> FEV1DTBX_DAYS Q24: FVCDTBX recoded to days since randomization -> FVCDTBX_DAYS
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Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
			Q26: PLTDTBX recoded to days since randomization -> PLTDTBX_DAYS Q28: ANCDTBX recoded to days since randomization -> ANCDTBX_DAYS Q2: Created new variable "Age at Enrollment" (AGE_AT_ENRLMNTX)
ENRB	Enrollment Form for Randomization	SITE Comments: COMMBXB	Subject IDs PROJID and PATID replaced with randomized ID RANDID
FUS	Follow Up Status Form	Comments: FUS1COMM	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q1: LASTCTDT recoded to days since randomization -> LASTCTDT_DAYS Q3: DEATHDT recoded to days since randomization -> DEATHDT_DAYS Q5: RELAPSDT recoded to days since randomization -> RELAPSDT_DAYS Q7: TREATDT recoded to days since randomization -> TREATDT_DAYS Q15: INFDT recoded to days since randomization -> INFDT_DAYS Q17: HOSPTLDT recoded to days since randomization -> HOSPTLDT_DAYS Q19: DATRANSP recoded to days since randomization -> DATRANSP_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
IMR	Immune Reconstitution/Lab Form	Comments: COMMIMR	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q2: ANCDT1IR recoded to days since randomization -> ANCDT1IR_DAYS Q2: ANCDT2IR recoded to days since randomization -> ANCDT2IR_DAYS Q4: ANCRCNTD recoded to days since randomization -> ANCRCNTD_DAYS Q6: PLTDT1IR recoded to days since randomization -> PLTDT1IR_DAYS Q6: PLTDT2IR recoded to days since randomization -> PLTDT2IR_DAYS Q8: PLTRCNTD recoded to days since randomization -> PLTRCNTD_DAYS Q10: HEMGDTIR recoded to days since randomization -> HEMGDTIR_DAYS Q12: DTFCIMR recoded to days since randomization -> DTFCIMR_DAYS Q24: DTQIIMR recoded to days since randomization -> DTQIIMR_DAYS Q28: DTPTCLL recoded to days since randomization -> DTPTCLL_DAYS
INF	Infection Form	CERTNTY1 ORGN02 INFSPEC2 CERTNTY2 ORGN03 INFSPEC3 CERTNTY3 INFSPEC4 Comments: INFCOM	Subject IDs PROJID and PATID replaced with randomized ID RANDID INFSTDT recoded to days since randomization -> INFSTDT_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
MUC	Immune Reconstitution Form	Comments: MUCCOMM	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q2: MUCSTRDT recoded to days since randomization -> MUCSTRDT_DAYS Q3: MUCENDDT recoded to days since randomization -> MUCENDDT_DAYS Q4: MUC1DATE recoded to days since randomization -> MUC1DATE_DAYS Q18: MUC2DATE recoded to days since randomization -> MUC2DATE_DAYS
PRE	Progression/Relapse Form	Comments: PRECOMM	Subject IDs PROJID and PATID replaced with randomized ID RANDID PRREL PDT recoded to days since randomization -> PRREL PDT_DAYS Q5: DTAPPLES recoded to days since randomization -> DTAPPLES_DAYS Q7: DTSPDINC recoded to days since randomization -> DTSPDINC_DAYS Q9: DTINCDIA recoded to days since randomization -> DTINCDIA_DAYS Q11: DATINCRE recoded to days since randomization -> DATINCRE_DAYS

TX6	Toxicity Form	Comments: TX6COMM	<p>Subject IDs PROJID and PATID replaced with randomized ID RANDID</p> <p>Q1: TX6EVLDT recoded to days since randomization -&gt; TX6EVLDT_DAYS</p> <p>Q32: TX6RBCDT recoded to days since randomization -&gt; TX6RBCDT_DAYS</p> <p>Q33: TX6HCTDT recoded to days since randomization -&gt; TX6HCTDT_DAYS</p> <p>Q34: TX6HMGDT recoded to days since randomization -&gt; TX6HMGDT_DAYS</p> <p>Q35: TX6WBCDT recoded to days since randomization -&gt; TX6WBCDT_DAYS</p> <p>Q36: TX6PLTDT recoded to days since randomization -&gt; TX6PLTDT_DAYS</p> <p>Q37: TX6NETDT recoded to days since randomization -&gt; TX6NETDT_DAYS</p> <p>Q38: TX6LYMDT recoded to days since randomization -&gt; TX6LYMDT_DAYS</p> <p>Q39: TX6CRTDT recoded to days since randomization -&gt; TX6CRTDT_DAYS</p> <p>Q40: TX6BIRDT recoded to days since randomization -&gt; TX6BIRDT_DAYS</p> <p>Q41: TX6ALTDT recoded to days since randomization -&gt; TX6ALTDT_DAYS</p> <p>Q42: TX6ASTDT recoded to days since randomization -&gt; TX6ASTDT_DAYS</p> <p>Q43: TX6ALPDT recoded to days since randomization -&gt; TX6ALPDT_DAYS</p> <p>Q44: TX6LDHDT recoded to days since randomization -&gt; TX6LDHDT_DAYS</p>
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Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
			Q45: TX6DLCDT recoded to days since randomization -> TX6DLCDT_DAYS Q46: TX6FEVDT recoded to days since randomization -> TX6FEVDT_DAYS Q47: TX6FVCDT recoded to days since randomization -> TX6FVCDT_DAYS Q48: TX6OXYDT recoded to days since randomization -> TX6OXYDT_DAYS
TXP	Transplant Form	T_IUBMID TXPCRID Comments: COMMTXP1	Subject IDs PROJID and PATID replaced with randomized ID RANDID Q1: TXDTPXP recoded to days since randomization -> TXDTPXP_DAYS

Dataset Name	Case Report Form or Data Source	Notes/Comments	
		Fields Removed (due to no data, text response or other reasons)	Fields Recoded, adjudication, or other notes
<b>Analysis Dataset</b>			
OUTCOMES	This dataset has no corresponding Case Report Form and it includes the Endpoint Review Committee (ERC) adjudicated outcomes, the computed variables and selected data retrieved from Center for International Blood and Marrow Transplant Research (CIBMTR) if applicable.	<ul style="list-style-type: none"> <li>• This OUTCOMES dataset includes the most important data fields for the primary analysis and is made up of 3 parts: (1) All the ERC data, which means the ERC adjudicated the study outcomes for the patients e.g. the Disease response at Day 100. (2) All the coded variables, which means they are not the directly-collected data by CRFs, e.g. computed days for survival analysis, computed age, computed covariates for the multivariate analyses etc. (3) Data from CIBMTR, e.g. date of diagnosis, long-term follow up on survival post-transplant.</li> <li>• The original data submitted by the transplant centers in CRFs (such as DEM, DTH, TXP etc.) are still included in this data submission (as listed above individually) for reference and completeness, but analyses should use this outcome data that were adjudicated by ERC if the data fields in OUTCOMES is different from the site-reported raw data. The primary manuscript used this OUTCOMES data to publish the study results.</li> <li>• A detailed documentation is provided with this data submission to add more specifics for each variable in this OUTCOMES database. Please refer as needed.</li> </ul>	

Note: All the data files can be linked by the randomized subject ID (RANDID).

Below is the forms submission schedule for reference. For example, some forms such as toxicity are assessed at multiple times per protocol schedule so each data point will have a record in the data set for each patient; while some forms are event-driven forms such as death, which means, only those with event will have a corresponding record in the dataset.

### BMT CTN PROTOCOL #0401 Forms Submission Schedule

Form	Prior to Conditioning	Day -7	Day 0	Day 7	Day 14	Day 21	Day 28	Day 56	Day 100	Day 180	Day 365	Day 730
Enrollment Segment A	X											
Enrollment Segment B	X											
Cytoreductive Therapy/ Mobilization Regimen	X											
Transplant			X									
Conditioning Regimen			X									
Toxicity	X	X					X	X	X	X	X	X
Mucositis				X	X	X						
Consolidative Localization Radiation Therapy									X			
Immune Reconstitution/Lab	X						X		X		X	X
Follow-up Status							X	X	X	X	X	X
Infection			Submit at time of infection									
Relapse			Submit at time of relapse									
Re-admission			Submit at time of re-admission									
Unexpected, Grade 3-5 Adverse Event			Submit at onset of unexpected, grade 3-5 adverse event									
CIBMTR Day 100 Report <sup>1</sup>									X			
CIBMTR Follow-up <sup>2,3</sup>											X	X

Notes:

<sup>1</sup> includes Core, Disease and Graft Inserts

<sup>2</sup> Includes Core and Disease Follow-up Forms

<sup>3</sup> IBMTR Follow-up Form should be submitted yearly through Year 5 post-transplant

### 3. **List of Major Publications**

Primary publication

- Vose JM, Carter S, Burns LJ, Ayala E, Press O, Moskowitz CH, Stadtmauer EA, Mineshi S, Ambinder RF, Fenske TS, Horowitz MM, Fisher RI, Tomblyn M. Phase III randomized study of rituximab/carmustine, etoposide, cytarabine, melphalan (BEAM) compared with 131-Iodine tositumomab/BEAM with autologous stem cell transplantation for relapsed diffuse large B-cell lymphoma: results from the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) 0401 trial. *Journal of Clinical Oncology*. 2013 May 1; 31(13):1662-1668. Epub 2013 Mar 11.