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CONTRACTING ORGANIZATION: Medical College of Wisconsin  
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## TABLE OF CONTENTS

Grant Number: DAMD17-95-1-5002  
Database of Autotransplants for Breast Cancer

Front Cover .....	1
SF298 Report Documentation Page .....	2
Foreword .....	3
Table of Contents .....	4
Introduction .....	5
Body .....	5-13
Conclusions .....	13

### Appendices

Appendix 1	ABMTR Report Forms
Appendix 2	1996 Data Management Sessions
Appendix 3	ABMTR Audit Schema
Appendix 4	Graphics
Appendix 5	Survey of Transplant Activity 1991-1995
Appendix 6	Publications on Breast Cancer
Appendix 7	ABMTR Newsletter, including 1996 IBMTR/ABMTR Summary Slides
Appendix 8	Presentations on Breast Cancer
Appendix 9	ABMTR Participating Centers and ABMTR Breast Cancer Working Committee Members

## INTRODUCTION

Use of high-dose therapy with autologous blood or bone marrow hematopoietic support (autotransplants) to treat breast cancer is increasing rapidly. According to data reported to the Autologous Blood and Marrow Transplant Registry - North America (ABMTR), breast cancer was the most common indication for allogeneic or autologous blood or marrow transplantation in 1995 (Appendix 4; Figure 2). The ABMTR maintains a large database of clinical information on persons receiving autotransplants. This database has the potential to provide important information relevant to breast cancer treatment. The purpose of the work funded in this contract was 1.) to enhance the existing ABMTR database so that important unresolved issues in use of autotransplants to treat breast cancer could be addressed and to provide accurate information on autotransplants to women with breast cancer; and, 2.) to develop and make available appropriate biostatistical models for analyzing this database. Considerable progress was made during the first year of this contract including development of revised data collection forms, planning an institutional survey, evaluation of statistical models, direct provision of data to patients and clinicians, presentation of data to national societies and organizations involved in planning breast cancer research, and planning of a registry World Wide Web site with information related to autotransplants for breast cancer. Progress continued in the second year of the project including development of software for distributed data entry, initiation and near-completion of the institutional survey planned in Year 1, provision of general transplant and breast cancer information on the World Wide Web, development of a comprehensive review of autotransplants in breast cancer soon to be put on the World Wide Web, and continued work on appropriate statistical models. Progress in each of the Technical Objectives outlined in our contract proposal is outlined below.

## PROGRESS IN ACHIEVING TECHNICAL OBJECTIVES

1.0 *Develop and enhance an observational database for autotransplants in breast cancer, including demographic, clinical, treatment, financial, and outcome data.*

### 1.1 Data collection

Data collection during for 1994-1996 is summarized in Table 1.1.

Table 1.1

<u>Dates</u>	<u>Core Data</u>	<u>Comprehensive Data</u>
7/94 - 6/95	1,900	637
7/95 - 6/96	1,575	958
<b>TOTAL</b>	<b>3,945</b>	<b>1,595</b>

The ABMTR now has core data for 8,065 and comprehensive data for 2,694 recipients of autotransplants for breast cancer.

Data collection instruments (Report Forms) were revised during the first year of this contract and distributed in August 1995 (Appendix 1). Report Form enhancements included fields for: 1.) income, occupation, educational level, and place of residence of autotransplant recipients; 2.) source and mode of payment for transplant procedure (insurer, fixed fee versus fee for service); 3.) inpatient versus outpatient setting for high-dose treatment; 4.) total number of hospital days in the first 100 days posttransplant; 5.) reason for using bone marrow versus peripheral blood stem cells for hematopoietic support; 6.) additional details regarding prior treatment for breast cancer; 7.) graft procurement procedures. Additionally the forms were made clearer, incorporating more detailed explanations for data required, and formatted so that data entry could be done directly from the Forms without an intermediate coding step. During the second year of the Contract, data entry software was modified to accommodate the new Forms (data entry screens now mirror Report Forms) and data submitted on the previous Forms were converted to the new format. Additionally, we obtained supplemental data for patients previously registered. It was not deemed feasible, based on discussions with data managers at participating hospitals, to obtain socioeconomic information on all previously reported patients but additional data on organ involvement, prior treatment, other disease-related variables and posttransplant secondary cancers were provided for about 2,000 patients. The result of these enhancements is a database with greater capabilities to address multiple issues relevant to breast cancer treatment.

## 1.2 Uniform Reporting of Data

During the second year of this contract, work began on a revised Data Manual to accompany the new Report Forms. The new manual gives comprehensive explanations of data requested on current forms with examples and suggestions for data sources. Anticipated date of completion is February 1, 1997.

In January 1996, the ABMTR conducted a two-day training session for data managers, in conjunction with the ABMTR Annual Meeting in Keystone, Colorado. The program, attendance list and evaluations for this session are included in Appendix 2. The ABMTR awarded 49 travel grants to partially offset expenses of those attending this session. Revised Report Forms and data collection software were reviewed at this session. Evaluation of the session by the participants indicated a high level of satisfaction with the topics covered and training provided.

## 1.3 Data Review and Entry

Revised Report Forms have several advantages for the data review and entry process. Forms now minimize open-ended and text-field responses which make completion easier and faster, and provide more precise responses. The new format also eliminates most of the need for coding prior to computer entry, making the data entry process more accurate and efficient. In the second year of this contract, data entry tasks were shifted from an outside contractor to the Statistical Center, where data are now entered by trained Data Entry Assistants who also code the limited number of free text fields. Prior to this, forms were coded by Statistical Center personnel and coding sheets sent out for computer entry.

As noted in Section 1.1, data entry screens now mimic Reporting Forms, which also facilitates accurate data entry. During the second year of the contract, we continued our work with StemCell Technologies to develop software for distributed data entry. Approximately 100 centers have purchased StemSoft and about 15 now use StemSoft programs to enter data and generate (paper) ABMTR forms. More are expected to start using the software for reporting during the next six months. Software to directly convert data entered with StemSoft software to a computerized format appropriate for incorporation in the ABMTR database is being developed in cooperation with StemCell and tested at the ABMTR Statistical Center. Further modifications are required before this software can be widely implemented but, once implemented, it will allow data entry to be done completely at transplant centers, submitted on disk and incorporated into the ABMTR database after appropriate error, consistency and virus checks. This will result in substantial savings in effort and cost by the Statistical Center, allowing us to keep pace with rapidly increasing volumes without substantially increasing data management costs. During the next contract year, the Statistical Center will increase its efforts to implement more extensive error checks into the data entry programs so that centers can correct errors and resolve inconsistencies before data are submitted. Processing paper forms will still be done for those centers who do not purchase StemSoft software. We are still considering the benefits of a bar coding system for tracking Report Forms though the move to a paperless system, even if not adopted by all centers, will substantially decrease the number of paper forms to be tracked. Other options for managing paper forms include scanning and digitizing those images. Images would be reviewed visually on a large screen PC to verify any spots where the software was unsure of the correct interpretation of digits.

#### 1.4 Data validation

An Audit Schema was developed and approved in 1995 (Appendix 3). The plan was to audit 20 randomly selected centers yearly. We actually audited 23 in the past year. The list of centers audited in the past year is shown below.

<u>Date</u>	<u>Institution</u>	<u>Team Leader</u>
December, 1995	Toronto Hospital	Keating
April, 1996	Univ. of Wisconsin - Madison	Longo
May, 1996	Medical College of Wisconsin, Milwaukee	Burns
May, 1996	Montefiore Hospital, Pittsburgh	Ball
June, 1996	Johns Hopkins, Baltimore	Miller
July, 1996	Univ. of Minnesota, Minneapolis	McGlave
July, 1996	Case Western Reserve University	Lazarus
July, 1996	Univ. of Nebraska, Omaha	Armitage
July, 1996	Children's Hosp, Cincinnati	Harris
August, 1996	Hosp for Sick Children, Toronto	Calderwood
August, 1996	Duke University	Kurtzburg
September, 1996	University of Oklahoma	Confer
September, 1996	St. Judes Hospital, Memphis	Brenner
September, 1996	Baylor University, Dallas	Fay
September, 1996	Dana Farber Cancer Institute, Boston	Elias
September, 1996	Royal Victoria Hospital, Montreal	Langleben
September, 1996	Vancouver Hospital	Barnett
September, 1996	St. Louis University	Petruska
October, 1996	NE Ontario Cancer Institute, Sudbury	Gluck
October, 1996	Emory Clinic, Atlanta	Yaeger
November, 1996	Baptist Hospital, Miami	Kalman
November, 1996	H.L. Moffitt Cancer Center, Tampa	Elfenbein
November, 1996	Univ. of Alabama, Birmingham	Vaughan

Results of audits indicate a high level of accuracy in data reporting.

#### 1.5 Computer Capabilities

The color printer purchased in Year 1 is being used to produce high quality graphics for educational and scientific materials (Appendix 4).

During the second year of the contact, the Statistical Center switched from a manual to a computerized log-in system that includes checking key fields on Report Forms against previously submitted Registration Data. During this contract year, many centers started to provide registration data on disk rather than paper. Statistical Center personnel are working on conversion programs to accommodate multiple data formats. As noted above, the move toward replacing paper with paperless systems for registering and reporting data has made the proposed implementation of a bar code system for tracking reports less

urgent. Accordingly we have requested that the funds originally designated for such a system be reassigned to purchase computers for Data Entry Assistants who log in cases and directly enter data from Report Forms and programmers who are developing, testing and implementing software for distributed data entry.

2.0 ***Identify institutional characteristics of centers performing autotransplants for breast cancer in the United States and Canada, including academic affiliation, patient volume, physician training, staff/patient ratio.***

The institutional survey designed in Year 1 was distributed in early 1996. To date, 124 U.S. centers have provided data for the survey (Appendix 5). Identification of new centers and additional requests for data from non-responding centers continue. Analysis is proceeding.

3.0 ***Evaluate and develop statistical models and software for effectively analyzing transplant data.***

Statistical Center faculty have been exploring several aspects of statistical analysis of transplant data. These include the following:

3.1 Estimating the survival function in the proportional hazards regression model: A study of small sample size properties

Dr. John Klein and Prof. Per Andersen (Dept. of Biostatistics, University of Copenhagen) have studied the small sample properties of four asymptotic equivalent estimators of the survival function one obtains from a Cox regression analysis. Included in the study is the performance of the statistics as point estimators as well as their small sample behavior in finding confidence intervals for the survival function.

3.2 Statistical challenges in comparing transplant and non-transplant therapy

Drs. John Klein and Mei-Jie Zhang are studying techniques for improved inference in bone marrow transplant studies. One problem faced when comparing survival under alternative technologies is that the initial reference time origin may be different for each technology. For example, when comparing bone marrow transplants to conventional chemotherapy the clock for transplant starts at transplant while for chemotherapy it may start at some other landmark event. Some adjustment for the different time scales must be made. A study of various approaches found that a left-truncated Cox regression technique provided the optimal means of estimating covariate effects.

### 3.3 Effects of model misspecification in estimating covariate effects in survival analysis for small sample sizes

Dr. Klein and Drs. Li (University of Pittsburgh) and Moeschberger (Ohio State University) have compared the small sample performance of the Cox regression model as compared to the parametric models available in most statistical packages when the Cox model holds as well as when the assumption of proportional hazards is violated. The study shows that the Cox model is very robust to model misspecification while the other models are not.

### 3.4 The use of additive hazard regression models in analyzing bone marrow transplant data

Dr. Klein and Ms. Alicia Howell have developed a user friendly SAS macro to fit Aalen's additive regression model to right censored data. This program has been used to study relative performance of the additive and proportional hazards models.

### 3.5 Confidence regions for the times where two survival curves are different.

Profs. Klein and Zhang have developed a procedure for finding confidence regions for the times at which two treatments have different survival functions. The confidence regions can be based on either a proportional hazards or additive hazards model. They allow for adjustment for other fixed covariates.

### 3.6 Comparison of tests for center effects.

Drs. Klein, Zhang and Per Andersen (University of Copenhagen) have completed an extensive Monte Carlo study of methods of testing for the presence of a center effect in a Cox regression analysis. They compared the performance of a fixed covariate approach to modeling the center effect to a score test for a random center. The study found that the fixed effect test rejects the hypothesis of no center effect too often when there is no center effect and that this test requires much larger sample sizes not to be anti-conservative. The random effects test works quite well for small samples and has quite good power to detect either fixed or random group effects. The study also examined the effect of ignoring a center effect on the fixed covariates of interest. The manuscript which describes these results is currently being prepared.

### 3.7 The use of Frailty (random effect) models in survival analysis

Frailty models are used in survival analysis to either model unobserved heterogeneity or to model shared unobserved random effects between group members (e.g. siblings). For the univariate case Prof. Klein and Prof. Niels Keiding and Per Andersen (University of Copenhagen) have studied the effects of ignoring the frailty when there is a random effect. They found that when the extra homogeneity is ignored the regression coefficients tend to be too small. This effect is somewhat abated if an accelerated failure time model is used in the estimation rather than the proportional hazards model. For the multivariate

frailty problem Dr. Klein and his students are writing user friendly SAS macros to implement the semi-parametric gamma, inverse Gaussian and positive stable frailty models. Estimation in these models is based on recent theoretical work by Drs. Klein and Andersen that estimates the regression coefficients using a modified EM algorithm and which has led to an improved estimator of standard error of the model parameters. Dr. Klein and Laud (MCW Biostatistics) have implemented a fully Bayesian approach to the semi-parametric gamma frailty problem. They are now extending this approach to other frailty models. This Bayesian approach finds the posterior by using a Monte Carlo Markov chain approach. Profs. Klein and Zhang are investigating an alternative frailty model for the accelerated failure time class of models which leads to a multivariate log normal distribution in each group. They are developing an algorithm for estimation of parameters based on a censored sample from this multivariate log normal model.

### 3.8 Analyzing longitudinal data

Profs. Zhang and Scheike (Biostatistics Dept., University of Copenhagen) are studying the model identification problem of the regression analysis for longitudinal data with counting process measurement times. Prof. Thomas Scheike studied parametric and nonparametric regression function for longitudinal data. The goodness-of-fit test for model selection is under study.

### 3.9 Multistate modeling of transplant data

Multistate models are used in survival analysis to model complex experiments where a patient may experience a number of intermediate events prior to their eventual death or treatment failure. Often each of the events is modeled separately and their effects on each other are inferred on an ad hoc basis. Prof. Klein with Prof. Keiding (University of Copenhagen) and Chun-Lin Qian (The American College of Radiology) have examined techniques for synthesizing the many intermediate analyses into a coherent set of summary predictive probabilities. Ongoing work with Klein, Zhang and Keiding is looking at the problem of modeling serial measurements such as blood transfusions in a complex survival experiment such as a bone marrow transplant.

## 4.0 ***Provide access to data and biostatistical support for clinical studies related to autotransplants in breast cancer.***

During the first year of this contract, the ABMTR Working Committee completed its first review of use and outcome of autotransplants for breast cancer. This manuscript is now in press in the *Journal of Clinical Oncology* (Appendix 6). Work is nearly complete on an in-depth analysis of prognostic factors for outcome after autotransplants for metastatic breast cancer and a manuscript will be drafted within the next few months. Other studies in progress are:



- 4.1. Comparison of autotransplant with conventional chemotherapy for metastatic breast cancer. This analysis uses autotransplant data from the ABMTR and chemotherapy data from the Cancer and Leukemia Group (PI: Don Berry [CALGB], David Hurd [ABMTR]) This latter study will benefit directly from some the statistical work described in section 3.0 and the additional clinical data now available.
- 4.2. Assessment of variation in costs of autotransplants for breast cancer among institutions. (PI: Charles Bennett, Northwestern University). This study will benefit from the socioeconomic and resource utilization data now collected on Report Forms.
- 4.3. Analysis of prognostic factors for survival after autotransplants for Stage II, III breast cancer. (PI: Karen Antman, Columbia University). This study will benefit from the additional clinical data now available.
- 4.4. Determination of second cancer risk after autotransplants for breast cancer. (PI: Mary Horowitz) Increased surveillance for second cancers was part of several efforts at supplemental data collection.

All of these studies are enhanced by the improved data collection, entry and management funded by this contract and by the greater level of detail now available on transplant recipients.

5.0 ***Disseminate information regarding autotransplants for breast cancer to patients, physicians and others involved in care of women with breast cancer.***

The ABMTR database is a unique resource of information regarding use and outcome of transplants, containing data not readily available in the medical literature. Summary statistics on the use and outcome of autotransplants for breast cancer were included in the November 1996 issue of the ABMTR Newsletter (Appendix 7), which is widely distributed to transplant and oncology centers. An updated version of these data are also available on-line at the IBMTR/ABMTR homepage on the World Wide Web (address: [www.biostat.mcw.edu/IBMTR](http://www.biostat.mcw.edu/IBMTR); Appendix 7).

There were 22 presentations of ABMTR data related to use and/or outcome of autotransplants for breast cancer during the second contract year (Appendix 8). Notable among these was a presentation on the low risk of transplant-related mortality after autotransplants for breast cancer made by Dr. Horowitz at a meeting of the Blue Cross and Blue Shield Medical Advisory Panel in February, 1996.

Additionally during the second contract year, the ABMTR, through its Information Resource program (partially funded by this contract) provided information regarding use and outcome of autotransplants for breast cancer in response to about 200 specific requests from physicians, patients and health-related agencies or companies. Data provided in response to these requests often included survival and other outcome data not

readily available in the medical literature. This represents an increase of 300% over the previous calendar year.

In addition to the IBMTR/ABMTR homepage, and in cooperation with the National Marrow Donor Program and the American Society of Blood and Marrow Transplantation, the ABMTR is establishing a World Wide Web site with comprehensive information on the role of transplantation in treating a variety of cancers. A comprehensive review of the role of high-dose chemotherapy in treating breast cancer will be among the first three topics to be made available. Information will be provided at both physician and patient levels, with an extensive bibliography that will be updated periodically, and with links to other relevant Web sites providing information on transplantation and cancer.

### **CONCLUSIONS AND FUTURE PLANS**

This contract continues to facilitate numerous enhancements to the ABMTR database and Statistical Center. It is already elevating the quality of information available for studies and for health care providers and consumers. By completion of the four-year term of this award, we are confident that the infrastructure enhancements will lead to numerous high-quality investigations.



# APPENDICES

Grant No. DAMD17-95-1-5002

## “Database of Autotransplants for Breast Cancer”

- Appendix 1 ABMTR Report Forms
- Appendix 2 1996 Data Management Sessions
- Appendix 3 ABMTR Audit Schema
- Appendix 4 Graphics
- Appendix 5 Survey of Transplant Activity 1991-1995
- Appendix 6 Publications on Breast Cancer
- Appendix 7 ABMTR Newsletter, including 1996 IBMTR/ABMTR Summary Slides
- Appendix 8 Presentations on Breast Cancer
- Appendix 9 ABMTR Participating Centers and ABMTR Breast Cancer Working Committee Members

Submitted to: U.S. Army Medical Research and Material Command

December 1, 1996

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Autologous Blood & Marrow Transplant Registry - North America  
Medical College of Wisconsin  
8701 Watertown Plank Road • P.O. Box 26509  
Milwaukee, WI 53226 USA



**CORE FORM**

TEAM     IUBMID

(Institutional Unique Blood or Marrow Transplant Identification Number)

Date of transplant for which this form is being completed:


Month Day Year

**FOR REGISTRY USE ONLY:**  
 I.D.  -      -        
 Date received:

Registry: **IBMTR** **ABMTR** (circle one)

Date of report:

Month Day Year

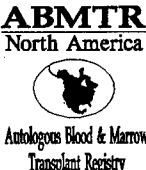


**IBMTR**  
International Bone Marrow Transplant Registry

Series 095 Reporting Forms

**IBMTR/ABMTR**

Statistical Center ♦ Medical College of Wisconsin  
 P.O. Box 26509 ♦ 8701 Watertown Plank Road ♦ Milwaukee, WI 53226  
 Telephone: 414-456-8325 ♦ Fax: 414-266-8471



**ABMTR**  
North America  
Autologous Blood & Marrow Transplant Registry

**Demographics**

**\* If this is a report of a second (or subsequent) transplant check here  and go to Q.20**

1. Institutional protocol number (if applicable):

2. Was patient enrolled in cooperative group (eg. CALGB, CCSG, EBMT, ECOG, EORTC, MRC, NSABP, POG, SWOG, etc.) study at any time or reported to the NMDP or EBMT? (include transplant and non-transplant studies)

- 1  Yes
- 0  No
- 8  Unknown

<b>Study 1:</b>	3. Group _____	4. Study No. _____	5. Patient No. _____
<b>Study 2:</b>	6. Group _____	7. Study No. _____	8. Patient No. _____
<b>Study 3:</b>	9. Group _____	10. Study No. _____	11. Patient No. _____

12. Sex: 1  Male 2  Female

13. Race: (If patient's parents are from two separate groups of the following, check both)

<p><b>Caucasian/White</b></p> <p>11 <input type="checkbox"/> European or Western Russia</p> <p>12 <input type="checkbox"/> Middle East or North Coast of Africa</p> <p>10 <input type="checkbox"/> White, not otherwise specified</p> <p><b>Black</b></p> <p>21 <input type="checkbox"/> African American</p> <p>22 <input type="checkbox"/> African Black (both parents born in Africa)</p> <p>23 <input type="checkbox"/> Caribbean Black</p> <p>24 <input type="checkbox"/> South or Central American Black</p> <p>20 <input type="checkbox"/> Black, not otherwise specified</p>	<p><b>Asian/Pacific Islander</b></p> <p>31 <input type="checkbox"/> Asian Indian</p> <p>32 <input type="checkbox"/> Filipino</p> <p>33 <input type="checkbox"/> Hawaiian (Polynesian)</p> <p>34 <input type="checkbox"/> Japanese</p> <p>35 <input type="checkbox"/> Korean</p> <p>36 <input type="checkbox"/> Northern Chinese</p> <p>37 <input type="checkbox"/> Southeast Asian/Southern Chinese</p> <p>30 <input type="checkbox"/> Oriental, not otherwise specified</p> <p><b>Hispanic</b></p> <p>41 <input type="checkbox"/> Caribbean Hispanic</p> <p>42 <input type="checkbox"/> Mexican or Southwestern USA Hispanic</p>	<p>43 <input type="checkbox"/> South or Central American Hispanic</p> <p>40 <input type="checkbox"/> Hispanic, not otherwise specified</p> <p><b>Native American</b></p> <p>51 <input type="checkbox"/> Native Alaskan/Eskimo/Aleut</p> <p>52 <input type="checkbox"/> American Indian</p> <p>50 <input type="checkbox"/> Native American, not otherwise specified</p> <p><b>Other</b></p> <p>90 <input type="checkbox"/> Other, specify: _____</p> <p>88 <input type="checkbox"/> Unknown</p>
--	---	--

14. Date of birth:

Month Day Year

TEAM

IUBMID

### Disease

15. What was the primary disease for which transplant was performed?  
 (Appropriate Insert must be submitted with this form)

10  Acute myelogenous leukemia (AML or ANLL)

- 11  M1, myeloblastic
- 12  M2, myelocytic
- 13  M3, promyelocytic (APML, APL)
- 14  M4, myelomonocytic
- 15  M5, monocytic
- 16  M6, erythroblastic
- 17  M7, megakaryoblastic
- 18  Granulocytic sarcoma
- 19  Other, specify: \_\_\_\_\_

10  Unknown

Complete Insert I and continue with Question 17 on Page 5

30  Other leukemia

34  Chronic lymphocytic leukemia (CLL)

Complete Insert IV and continue with Question 17 on Page 5

- 31  Acute undifferentiated leukemia
- 32  Biphenotypic, bilineage or hybrid leukemia
- 33  Acute mast cell leukemia
- 35  Hairy cell leukemia
- 36  Juvenile CML (no evidence of Philadelphia chromosome or BCR/ABL)
- 37  Prolymphocytic leukemia (PLL)
- 38  M0, stem cell
- 39  Other, specify: \_\_\_\_\_

30  Unknown

Continue with Question 16 on Page 5

20  Acute lymphoblastic leukemia (ALL)

- 21  Mature B-cell (L3)
- 22  T-cell
- 23  Null cell (early Pre-B)
- 24  cALLa (includes Pre-B)
- 29  Other, specify: \_\_\_\_\_

20  Unknown

Complete Insert II and continue with Question 17 on Page 5

50  Myelodysplastic/myeloproliferative disorders (please classify all preleukemias)

(If patient has transformed to AML, complete Insert I and indicate AML as the primary disease)

- 51  Refractory anemia (RA)
- 52  Refractory anemia with excess blasts (RAEB)
- 53  Refractory anemia with excess blasts in transformation (RAEBT)
- 54  Chronic myelomonocytic leukemia (CMML)
- 55  Acquired idiopathic sideroblastic anemia (RARS)
- 56  Paroxysmal nocturnal hemoglobinuria (PNH)
- 57  Polycythemia vera
- 58  Essential or primary thrombocythemia
- 59  Myelofibrosis with myeloid metaplasia
- 60  Other myelofibrosis or myelosclerosis
- 69  Other myelodysplasia or myeloproliferative disorder, specify: \_\_\_\_\_

50  Unknown

Complete Insert V and continue with Question 17 on Page 5

40  Chronic myelogenous leukemia (CML)

- 41  Ph<sup>1</sup> +; BCR/ABL +
- 42  Ph<sup>1</sup> +; BCR/ABL -
- 43  Ph<sup>1</sup> +; BCR/ABL unknown
- 44  Ph<sup>1</sup> -; BCR/ABL +
- 45  Ph<sup>1</sup> -; BCR/ABL -
- 46  Ph<sup>1</sup> -; BCR/ABL unknown
- 47  Ph<sup>1</sup> unknown; BCR/ABL +
- 48  Ph<sup>1</sup> unknown; BCR/ABL -
- 49  Other, specify: \_\_\_\_\_

40  Ph<sup>1</sup> unknown; BCR/ABL unknown

Complete Insert III and continue with Question 17 on Page 5

TEAM     IUBMID

100  Non-Hodgkin lymphoma

- 101  Small cell lymphocytic
- 102  Follicular, predominantly small cleaved cell
- 103  Follicular, mixed, small cleaved and large cell
- 104  Follicular, predominantly large cell
- 105  Diffuse, small cleaved cell
- 106  Diffuse, mixed, small and large cell
- 107  Diffuse, large cell
- 108  Large cell, immunoblastic
- 109  Lymphoblastic
- 110  Small noncleaved cell, unclassified
- 111  Small noncleaved cell, Burkitt
- 112  Small noncleaved cell, non-Burkitt
- 113  Mycosis fungoides
- 114  Histiocytic
- 115  Mantle cell/intermediate differentiation
- 116  Composite, specify: \_\_\_\_\_
- 117  Large cell anaplastic lymphoma, Ki1 positive
- 118  Primary CNS lymphoma
- 119  Other non-Hodgkin lymphoma, specify: \_\_\_\_\_
- 100  Non-Hodgkin lymphoma, unknown

*Complete Insert VI and continue with Question 17 on Page 5*

150  Hodgkin lymphoma

- 151  Lymphocyte predominant
- 152  Nodular sclerosis
- 153  Mixed cellularity
- 154  Lymphocyte depleted
- 159  Other Hodgkin lymphoma, specify: \_\_\_\_\_
- 150  Hodgkin lymphoma, unknown

*Complete Insert VI and continue with Question 17 on Page 5*

170  Multiple myeloma/Plasma cell disorder

- 171  Multiple myeloma
- 172  Plasma cell leukemia
- 173  Waldenstrom macroglobulinemia
- 174  Amyloidosis
- 175  Solitary plasmacytoma
- 179  Other, specify: \_\_\_\_\_

*Continue with Question 16 on Page 5*

200  Other malignancies

- 250  Breast cancer
- Complete Insert VIII and continue with Question 17 on Page 5*
- 201  Head & neck cancer
- 202  Lung cancer, small cell
- 203  Lung cancer, non-small cell
- 239  Lung, not otherwise specified
- 204  Mediastinal neoplasm, specify: \_\_\_\_\_
- 205  GI tract cancer
- 206  Pancreatic cancer
- 207  Hepatobiliary cancer
- 208  Kidney & urinary tract cancer
- 209  Prostate cancer
- 210  Testicular cancer
- 211  External genitalia cancer
- 212  Cervical cancer
- 213  Uterine cancer
- 214  Ovarian (epithelial) cancer
- 215  Vaginal cancer
- 216  Sarcoma unspecified
- 217  Soft tissue sarcoma
- 218  Bone sarcoma (not Ewing)
- 219  Melanoma
- 220  Central nervous system tumor
- 221  Wilm tumor
- 222  Neuroblastoma
- 223  Retinoblastoma
- 224  Ewing sarcoma
- 269  Other malignancy, specify: \_\_\_\_\_

*Continue with Question 16 on Page 5*

300  Severe aplastic anemia

- 301  Idiopathic
- 302  Secondary to hepatitis
- 303  Secondary to toxin/other drug
- 304  Amegakaryocytosis (not congenital)
- 309  Other, specify: \_\_\_\_\_

*Complete Insert IX and continue with Question 17 on Page 5*

310  Inherited abnormalities of erythrocyte differentiation or function

- 311  Fanconi anemia
- 312  Diamond-Blackfan anemia (pure red cell aplasia)
- 319  Other, specify: \_\_\_\_\_

*Complete Insert IX and continue with Question 17 on Page 5*

*(If patient has developed leukemia, complete Insert for appropriate leukemia diagnosis)*

TEAM

IUBMID

310  Inherited abnormalities of erythrocyte differentiation or function, *continued*

- 350  Thalassemia major ( $\beta$  thalassemia), unspecified
- 351  Type A Thalassemia major
- 352  Type B+ Thalassemia major
- 353  Type B0 Thalassemia major
- 354  Type BE Thalassemia major
- 355  Sickle Thalassemia major
- 356  Sickle cell anemia
- 359  Other hemoglobinopathy, specify: \_\_\_\_\_

310  Unknown

*Complete Insert XI and continue with Question 17 on Page 5*

400  SCID and other disorders of the immune system

- 401  ADA deficiency severe combined immunodeficiency (SCID)
- 402  Absence of T and B cells SCID
- 403  Absence of T, normal B cell SCID
- 404  Omenn syndrome
- 405  Reticular dysgenesis
- 406  Bare lymphocyte syndrome
- 419  SCID other, specify: \_\_\_\_\_

- 451  Ataxia telangiectasia
- 452  HIV infection
- 454  DiGeorge anomaly
- 455  Chronic granulomatous disease
- 456  Chediak-Higashi syndrome
- 457  Common variable immunodeficiency
- 458  X-linked lymphoproliferative syndrome
- 459  Leukocyte adhesion deficiencies, including GP180, CD-18, LFA and WBC adhesion deficiencies
- 460  Kostmann agranulocytosis (congenital neutropenia)
- 461  Neutrophil actin deficiency
- 462  Cartilage-hair hypoplasia
- 470  Combined immunodeficiency disease (CID), unspecified
- 474  CID other, specify: \_\_\_\_\_
- 479  Other immunodeficiencies, specify: \_\_\_\_\_

*Complete Insert XII and continue with Question 17 on Page 5*

453  Wiskott Aldrich syndrome

*Complete Insert XIII and continue with Question 17 on Page 5*

500  Inherited abnormalities of platelets

- 501  Amegakaryocytosis/ congenital thrombocytopenia
- 502  Glanzmann thrombasthenia
- 509  Other, specify: \_\_\_\_\_

*Continue with Question 16 on Page 5*

520  Inherited disorders of metabolism

521  Osteopetrosis (malignant infantile osteopetrosis)

*Complete Insert XV and continue with Question 17 on Page 5*

- 522  Lesch-Nyhan Mucopolysaccharidosis
  - 531  Hurler syndrome (IH)
  - 532  Scheie syndrome (IS)
  - 533  Hunter syndrome (II)
  - 534  Sanfilippo (III)
  - 535  Morquio (IV)
  - 536  Maroteaux-Lamy (VI)
  - 537   $\beta$ -glucuronidase deficiency (VII)
  - 538  Mucopolysaccharidosis (V)
  - 539  Other mucopolysaccharidosis, specify: \_\_\_\_\_
- 530  Mucopolysaccharidosis, not otherwise specified

Mucolipidoses

- 541  Gaucher disease
- 542  Metachromatic leukodystrophy
- 543  Adrenoleukodystrophy
- 544  Krabbe disease (globoid leukodystrophy)
- 545  Neiman-Pick disease
- 546  I-cell disease
- 547  Wolman disease
- 548  Glucose storage disease
- 549  Lysosomal storage disease
- 559  Other mucolipidoses, specify: \_\_\_\_\_

- 540  Mucolipidoses, not otherwise specified
- 529  Other specific inherited metabolic disorders, specify: \_\_\_\_\_

520  Unknown

*Complete Insert XIV and continue with Question 17 on Page 5*

570  Histiocytic disorders

- 571  Familial erythrophagocytic lymphohistiocytosis (FEL, Familial hemophagocytic lymphohistiocytosis)
- 572  Histiocytosis-X
- 573  Hemophagocytosis
- 574  Malignant histiocytosis
- 579  Other, specify: \_\_\_\_\_
- 570  Unknown

*Continue with Question 16 on Page 5*

900  Other

Specify: \_\_\_\_\_

*Continue with Question 16 on Page 5*

TEAM

IUBMID

### Clinical Status of Patient Prior to Conditioning

16. Date of diagnosis of primary disease:        
 (complete only if a disease-specific  
 Insert is not required) Month Day Year

17. **Allografts only:** Patient's blood type:
- |  |  |   |                                     |
|--|--|---|-------------------------------------|
| 1 <input type="checkbox"/> A Positive  | 5 <input type="checkbox"/> A Negative  | 9 <input type="checkbox"/> A Rh unknown   | 88 <input type="checkbox"/> Unknown |
| 2 <input type="checkbox"/> B Positive  | 6 <input type="checkbox"/> B Negative  | 10 <input type="checkbox"/> B Rh unknown  |                                     |
| 3 <input type="checkbox"/> AB Positive | 7 <input type="checkbox"/> AB Negative | 11 <input type="checkbox"/> AB Rh unknown |                                     |
| 4 <input type="checkbox"/> O Positive  | 8 <input type="checkbox"/> O Negative  | 12 <input type="checkbox"/> O Rh unknown  |                                     |

18. Has patient ever been pregnant?  
 1  Yes ————— 19. Number of pregnancies:    
 0  No  
 8  Unknown  
 7  Not applicable (patient is male, or a female child)

20. Did patient receive blood transfusions at any time prior to conditioning?  
 1  Yes ————— 21. Give number (best estimate) of donor exposures:  
 0  No  
 8  Unknown

1 <input type="checkbox"/> 1 - 5	5 <input type="checkbox"/> 31 - 40
2 <input type="checkbox"/> 6 - 10	6 <input type="checkbox"/> 41 - 50
3 <input type="checkbox"/> 11 - 20	7 <input type="checkbox"/> > 50
4 <input type="checkbox"/> 21 - 30	8 <input type="checkbox"/> Unknown

22. What was the functional status of patient prior to conditioning?  
 If the patient is 16 years of age or older, complete the Karnofsky Scale. If patient is younger than 16 years of age, complete the Lansky Scale. Rate activity of patient immediately prior to initiation of conditioning.

**Karnofsky Scale (age ≥16 yrs)**  
 Select the phrase in the Karnofsky Scale which best describes the activity status of the patient:

**Able to carry on normal activity; no special care is needed.**

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort

**Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.**

- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care

**Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.**

- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

**Lansky Scale (age <16 yrs)**  
 Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the patient:

**Normal range.**

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active

**Mild to moderate restriction.**

- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play

**Moderate to severe restriction.**

- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (i.e., TV)
- 10 Completely disabled, not even passive play



TEAM

IUBMID

23. Was there clinically significant coexisting disease or organ impairment prior to conditioning?

- 1  Yes  
0  No

What were the diagnoses?  
Yes No

24. 1  0  Significant hemorrhage (e.g. CNS or GI), specify site(s):  
\_\_\_\_\_

Cardiovascular

25. 1  0  Coronary artery disease

26. 1  0  Hypertension

27. 1  0  Other cardiac disease, specify: \_\_\_\_\_

Endocrine

28. 1  0  Diabetes mellitus

29. 1  0  Thyroid disease

30. 1  0  Other endocrine disease, specify: \_\_\_\_\_

CNS

31. 1  0  Seizure disorder

32. 1  0  Other CNS disease, specify: \_\_\_\_\_

Pulmonary

33. 1  0  Asthma

34. 1  0  Other pulmonary disease, specify: \_\_\_\_\_

35. 1  0  Genitourinary disease, specify: \_\_\_\_\_

36. 1  0  Gastrointestinal disease, specify: \_\_\_\_\_

37. 1  0  Hematologic disease, specify: \_\_\_\_\_

Chromosomal

38. 1  0  Fanconi anemia

39. 1  0  Down syndrome

40. 1  0  Other chromosomal disorders, specify: \_\_\_\_\_

41. 1  0  History of other malignancy, specify: \_\_\_\_\_

42. 1  0  Neonatal GVHD

Autoimmune disease

43. 1  0  Rheumatoid arthritis

44. 1  0  Systemic lupus erythematosus

45. 1  0  Multiple sclerosis

46. 1  0  Polyarteritis nodosa

47. 1  0  Psoriasis

48. 1  0  Other autoimmune disease, specify: \_\_\_\_\_

49. 1  0  Other, specify: \_\_\_\_\_

TEAM  IUBMID

**Organ Function Prior to Conditioning**

Provide values for patient's liver function just prior to conditioning:

		Date tested:	
		Month    Day    Year	What is the upper limit of normal for your institution?
50. AST (SGOT)	<input type="text"/> <input type="text"/> <input type="text"/> . U/L	51. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	52. <input type="text"/> <input type="text"/> <input type="text"/> . U/L
53. ALT (SGPT)	<input type="text"/> <input type="text"/> <input type="text"/> . U/L	54. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	55. <input type="text"/> <input type="text"/> <input type="text"/> . U/L
56. Total serum bilirubin	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	58. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	59. <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>

57. Unit of measurement for bilirubin:  
 1  mg/dL    2  μmol/L

60. LDH  . U/L      61.         62.  . U/L

63. Did patient have known clinical liver disease (eg. viral hepatitis) at any time prior to conditioning?

1  Yes  
 0  No

	Yes	No	Unknown	
64.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Hepatitis B
65.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Hepatitis A
66.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Hepatitis C
67.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Drug toxicity
68.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Other, specify: _____
69. Date of onset:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="checkbox"/> Date Unknown	
	Month    Year			

70. What was patient's serum creatinine prior to conditioning?  .

72.     
 Date tested:    Month    Day    Year

71. Unit of measurement for creatinine:  
 1  mg/dL    2  μmol/L

73. Patient smokes cigarettes, or has in the past:

1  Yes  
 0  No  
 8  Unknown

74. Average number of packs per day:  .

75. Number of years:

TEAM     IUBMID

76. Was clinically important infection(s) present or being treated within one week prior to conditioning?  
*Note: Report later infections on page 30 of this report.*

- 1  Yes  
 0  No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism were involved, list one site of infection and organism on the first line, second site and/or organism on second line.

		Site		Organism	
77. <input type="checkbox"/> Bacterial	<u>Typical</u>	First	78. <input type="text"/> <input type="text"/>	79. _____	
		Second	80. <input type="text"/> <input type="text"/>	81. _____	
	<u>Atypical</u>	First	83. <input type="text"/> <input type="text"/>	84. <b>B</b> <input type="text"/> <input type="text"/> <input type="text"/>	
		Second	85. <input type="text"/> <input type="text"/>	86. <b>B</b> <input type="text"/> <input type="text"/> <input type="text"/>	
87. Other atypical bacterium, specify: _____					
88. <input type="checkbox"/> Fungal		First	89. <input type="text"/> <input type="text"/>	90. <b>F</b> <input type="text"/> <input type="text"/> <input type="text"/>	
		Second	91. <input type="text"/> <input type="text"/>	92. <b>F</b> <input type="text"/> <input type="text"/> <input type="text"/>	
	93. Other fungus, specify: _____				
	94. <input type="checkbox"/> Viral		First	95. <input type="text"/> <input type="text"/>	96. <b>V</b> <input type="text"/> <input type="text"/> <input type="text"/>
Second			97. <input type="text"/> <input type="text"/>	98. <b>V</b> <input type="text"/> <input type="text"/> <input type="text"/>	
99. Other virus, specify: _____					
100. <input type="checkbox"/> Parasitic			First	101. <input type="text"/> <input type="text"/>	102. <b>P</b> <input type="text"/> <input type="text"/> <input type="text"/>
	Second		103. <input type="text"/> <input type="text"/>	104. <b>P</b> <input type="text"/> <input type="text"/> <input type="text"/>	
	105. Other parasite, specify: _____				
	106. <input type="checkbox"/> No organism identified	First	107. <input type="text"/> <input type="text"/>	108. <b>0509</b>	
Second		109. <input type="text"/> <input type="text"/>	110. <b>0509</b>		

TEAM IUBMID **Codes for Common Sites of Infection**

01	Blood/buffy coat	40	<u>Genito-Urinary Tract unspecified</u>
02	Disseminated – generalized, isolated at 3 or more distinct sites	41	Kidneys, renal pelvis, ureters and bladder
03	<u>Central Nervous System unspecified</u>	42	Prostate
04	Brain	43	Testes
05	Spinal cord	44	Fallopian tubes, uterus, cervix
06	Meninges and CSF	45	Vagina
10	<u>Gastrointestinal Tract unspecified</u>	50	<u>Skin unspecified</u>
11	Lips	51	Genital area
12	Tongue, oral cavity and oro-pharynx	52	Cellulitis
13	Esophagus	53	Herpes Zoster
14	Stomach	54	Rash, pustules or abscesses not typical of any of the above
15	Gallbladder and biliary tree (not hepatitis), pancreas	60	Central venous catheter, not otherwise specified
16	Small intestine	61	Catheter insertion site
17	Large intestine	62	Catheter tip
18	Feces/stool	70	Eyes
19	Peritoneum	75	Ear
20	Liver	80	<u>Other unspecified</u>
30	<u>Respiratory unspecified</u>	81	Joints
31	Upper airway and nasopharynx	82	Bone marrow
32	Laryngitis/larynx	83	Bone cortex (osteomyelitis)
33	Lower respiratory tract (lung)	84	Muscle (excluding cardiac)
34	Pleural cavity, pleural fluid	85	Cardiac (endocardium, myocardium, pericardium)
35	Sinuses	86	Lymph nodes
		87	Spleen

**Codes for Commonly Reported Organisms****1. Bacteria**

(Indicate code for atypical bacteria;  
list bacterium for non-atypical bacteria.)

100	Atypical bacteria, not otherwise specified
101	Coxiella
102	Legionella
103	Leptospira
104	Listeria
105	Mycoplasma
106	Nocardia
107	Rickettsia
110	Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
111	Typical tuberculosis (TB, Tuberculosis)
112	Mycobacteria (avium, bovis, intracellulare)
113	Chlamydia
119	Other atypical bacteria, specify

**2. Fungal Infections**

200	Candida, not otherwise specified
201	Candida albicans
202	Candida krusei
203	Candida parapsilosis
204	Candida tropicalis
205	Torulopsis glabrata (a subspecies of candida)
209	Candida, other
210	Aspergillus, not otherwise specified
211	Aspergillus flavus
212	Aspergillus fumigatus
213	Aspergillus niger
219	Aspergillus, other
220	Cryptococcus species
230	Fusarium species
240	Mucormycosis (zygomycetes, rhizopus)
250	Yeast, not otherwise specified
259	Other fungus, specify

**3. Viral Infections**

301	Herpes Simplex (HSV1, HSV2)
302	Herpes Zoster (Chicken pox, Varicella)
303	Cytomegalovirus (CMV)
304	Adenovirus
305	Enterovirus (Coxsackie, Echo, Polio)
306	Hepatitis A (HAV)
307	Hepatitis B (HBV, Australian antigen)
308	Hepatitis C (HCV)
309	HIV-1 (HTLV-III)
310	Influenza
311	Measles (Rubeola)
312	Mumps
313	Papovavirus
314	Respiratory syncytial virus (RSV)
315	Rubella (German Measles)
316	Parainfluenza
317	Human herpesvirus-6 (HHV-6)
318	Epstein-Barr virus (EBV)
319	Polyomavirus
320	Rotavirus
321	Rhinovirus
329	Other viral, specify

**4. Parasite Infections**

401	Pneumocystis (PCP)
402	Toxoplasma
403	Giardia
404	Cryptosporidium
409	Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

**5. Other Infections**

509	No organism identified
-----	------------------------

TEAM  IUBMID

112. Did patient have a history of clinically important fungal infection at any time prior to conditioning for transplant?

- 1  Yes  
0  No

<p>113. Date of onset: <input type="text"/><input type="text"/> <input type="text"/><input type="text"/> Month Year</p> <p>Select site(s) from list on previous page: 115. <input type="text"/><input type="text"/> 116. <input type="text"/><input type="text"/> Other, specify: _____</p>	<p>114. Select organism from list on previous page: <b>F</b> <input type="text"/><input type="text"/><input type="text"/><input type="text"/> If other, specify: _____</p>
---	--

### Tests for Serological Evidence of Prior Viral Exposure / Infection

	Positive	Negative	Inconclusive	Not Tested
117. HTLV1 antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
118. Toxoplasma antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
119. Cytomegalovirus antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
120. Epstein-Barr antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
121. Hepatitis B surface and/or core antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
122. Hepatitis B surface antigen	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
123. Hepatitis C antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
124. Hepatitis A antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
125. Human Immunodeficiency Virus (HIV) antibody	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
	7 <input type="checkbox"/> Not able to release information for HIV			

### High-Dose Therapy (Pretransplant Conditioning)

126. Was patient given high-dose therapy (conditioning) as an inpatient?

- 1  Yes  
0  No, given as outpatient  
7  No high dose therapy given

127. Was patient treated in an isolation room during the peri-transplant period?

- 1  Yes  
0  No

Please specify:	
<u>Yes</u>	<u>No</u>
128. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Conventional private room
129. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Laminar air flow room
130. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	HEPA filtered room
131. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Positive pressure
132. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Other, specify: _____

133. Date pretransplant conditioning (radiation or drugs) was begun:     
Month Day Year

134. Height at initiation of pretransplant conditioning (without shoes):  cm

135. Weight at initiation of pretransplant conditioning (without shoes):  kg

TEAM

IUBMID

136. Was irradiation performed as part of the pretransplant conditioning regimen? 1  Yes 0  No — **Go to Q. 182**

137. Source of x-ray therapy:

1  Linear accelerator 2  <sup>60</sup>Co 7  Other, specify: \_\_\_\_\_

138. Maximum energy:     MV (million volts)

139. Calculated mid-line dose-rate during irradiation:   .  cGy (rad)/min

What was the radiation field?

140. Total Body Radiation 1  Yes 0  No

141. Total dose:     cGy

Prescription point:  
Yes No

142. 1  0  Midline umbilicus

143. 1  0  Other, specify: \_\_\_\_\_

Patient orientation:  
Yes No

144. 1  0  AP/PA

145. 1  0  Other, specify: \_\_\_\_\_

Method of dose verification:  
Yes No

146. 1  0  Phantom

147. 1  0  Diodes on patient

148. 1  0  Other, specify: \_\_\_\_\_

149. Starting date:   /   /    
Month Day Year

150. Was radiation fractionated?  
1  Yes  
0  No  
8  Unknown

151. Dose per fraction:     cGy

152. Number of days:

153. Total number of fractions:

154. Was shielding used?  
1  Yes  
0  No  
8  Unknown

Yes No

155. 1  0  Lungs

156. 1  0  Eyes

157. 1  0  Liver

158. 1  0  Kidney

159. 1  0  Other, specify: \_\_\_\_\_

Radiation field data continued on next page

TEAM

IUBMID

160. Total lymphoid or nodal regions 1  Yes  
0  No

161. Total dose:     cGy 162. Starting date:     
Month Day Year

163. Was radiation fractionated?  
1  Yes  
0  No  
8  Unknown

164. Dose per fraction:     cGy

165. Number of days:

166. Total number of fractions:

167. Thoraco-abdominal region 1  Yes  
0  No

168. Total dose:     cGy 169. Starting date:     
Month Day Year

170. Was radiation fractionated?  
1  Yes  
0  No  
8  Unknown

171. Dose per fraction:     cGy

172. Number of days:

173. Total number of fractions:

174. Other radiation field 1  Yes  
0  No

175. Specify field: \_\_\_\_\_  
176. Total dose:     cGy 177. Starting date:     
Month Day Year

178. Was radiation fractionated?  
1  Yes  
0  No  
8  Unknown

179. Dose per fraction:     cGy

180. Number of days:

181. Total number of fractions:

TEAM     IUBMID

182. Was (additional) radiation given to other sites?

1  Yes  
0  No

183. Was CNS irradiation performed?

1  Yes — 184.     cGy  
0  No Dose:

185. Date started:     
Month Day Year

186. Was gonadal irradiation performed?

1  Yes — 187.     cGy  
0  No Dose:

188. Date started:     
Month Day Year

189. Was splenic irradiation performed?

1  Yes — 190.     cGy  
0  No Dose:

191. Date started:     
Month Day Year

192. Other site, specify: \_\_\_\_\_

1  Yes — 193.     cGy  
0  No Dose:

194. Date started:     
Month Day Year

195. Were drugs given for pretransplant conditioning? 1  Yes 0  No — Go to Q. 361

196. Date started:     
Month Day Year

	Drug Given		Total dose (in mg) pre-marrow infusion (not daily dose)	Number of doses	Continuous infusion		Number of days
	No	Yes			Yes	No	
197. ALG, ALS, ATG, ATS	0 <input type="checkbox"/>	1 <input type="checkbox"/>	198. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	199. <input type="text"/>	200. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	201. <input type="text"/>
202. Anthracycline	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes						
203. Daunomycin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	204. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	205. <input type="text"/>	206. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	207. <input type="text"/>
208. Doxorubicin (Adriamycin)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	209. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	210. <input type="text"/>	211. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	212. <input type="text"/>
213. Idarubicin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	214. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	215. <input type="text"/>	216. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	217. <input type="text"/>
218. Rubidazone	0 <input type="checkbox"/>	1 <input type="checkbox"/>	219. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	220. <input type="text"/>	221. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	222. <input type="text"/>
223. Other anthra- cycline, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	224. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	225. <input type="text"/>	226. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	227. <input type="text"/>
228. Bleomycin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	229. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	230. <input type="text"/>	231. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	232. <input type="text"/>
233. Busulfan (myleran)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	234. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	235. <input type="text"/>	236. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	237. <input type="text"/>
238. Carboplatin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	239. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	240. <input type="text"/>	241. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	242. <input type="text"/>
243. Cisplatin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	244. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	245. <input type="text"/>	246. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	247. <input type="text"/>

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TEAM

IUBMID

248. Corticosteroids	Drug Given		Total dose (in mg) pre-marrow infusion	Number of doses	Continuous infusion		Number of days
	No	Yes			Yes	No	
249. Methylprednisolone (Solumedrol)	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes						
1 <input type="checkbox"/> Yes	250. <input type="checkbox"/> Oral <input type="checkbox"/> IV		251. <input type="checkbox"/>	252. <input type="checkbox"/>	253. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	254. <input type="checkbox"/>	
0 <input type="checkbox"/> No							
255. Prednisone	0 <input type="checkbox"/>	1 <input type="checkbox"/>	256. <input type="checkbox"/>	257. <input type="checkbox"/>	258. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	259. <input type="checkbox"/>	
260. Dexamethasone	0 <input type="checkbox"/>	1 <input type="checkbox"/>	261. <input type="checkbox"/>	262. <input type="checkbox"/>	263. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	264. <input type="checkbox"/>	
265. Other cortico- steroids, specify:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	266. <input type="checkbox"/>	267. <input type="checkbox"/>	268. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	269. <input type="checkbox"/>	
270. Cyclophosphamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	271. <input type="checkbox"/>	272. <input type="checkbox"/>	273. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	274. <input type="checkbox"/>	
275. Cytarabine (Ara-C)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	276. <input type="checkbox"/>	277. <input type="checkbox"/>	278. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	279. <input type="checkbox"/>	
280. Etoposide (VP16)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	281. <input type="checkbox"/>	282. <input type="checkbox"/>	283. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	284. <input type="checkbox"/>	
285. Ifosfamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	286. <input type="checkbox"/>	287. <input type="checkbox"/>	288. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	289. <input type="checkbox"/>	
290. Intrathecal chemotherapy	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes						
291. Cytarabine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	292. <input type="checkbox"/>	293. <input type="checkbox"/>		294. <input type="checkbox"/>	
295. Methotrexate	0 <input type="checkbox"/>	1 <input type="checkbox"/>	296. <input type="checkbox"/>	297. <input type="checkbox"/>		298. <input type="checkbox"/>	
299. Other, specify:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	300. <input type="checkbox"/>	301. <input type="checkbox"/>		302. <input type="checkbox"/>	
303. Melphalan (L-PAM)	1 <input type="checkbox"/> Yes						
0 <input type="checkbox"/> No	304. <input type="checkbox"/> Oral <input type="checkbox"/> IV		305. <input type="checkbox"/>	306. <input type="checkbox"/>	307. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	308. <input type="checkbox"/>	
309. Mitoxantrone	0 <input type="checkbox"/>	1 <input type="checkbox"/>	310. <input type="checkbox"/>	311. <input type="checkbox"/>	312. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	313. <input type="checkbox"/>	
314. Monoclonal antibody	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes						
315. Radionuclide- tagged Mab, specify:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	316. <input type="checkbox"/>	317. <input type="checkbox"/>	318. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	319. <input type="checkbox"/>	
320. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	321. <input type="checkbox"/>	322. <input type="checkbox"/>	323. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	324. <input type="checkbox"/>	
325. Other Mab, specify:	0 <input type="checkbox"/>	1 <input type="checkbox"/>	326. <input type="checkbox"/>	327. <input type="checkbox"/>	328. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	329. <input type="checkbox"/>	

Continued on next page

TEAM

IUBMID

	Drug Given		Total dose (in mg) pre-marrow infusion	Number of doses	Continuous infusion		Number of days
	No	Yes			Yes	No	
<b>330. Nitrosourea</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes						
331. BCNU	<input type="checkbox"/>	<input type="checkbox"/>	332. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	333. <input type="text"/>	334. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	335. <input type="text"/>
336. CCNU	<input type="checkbox"/>	<input type="checkbox"/>	337. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	338. <input type="text"/>	239. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	340. <input type="text"/>
341. Other nitrosourea, specify:  _____	<input type="checkbox"/>	<input type="checkbox"/>	342. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	343. <input type="text"/>	344. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	345. <input type="text"/>
Paclitaxel (Taxol)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="text"/>
346. Teniposide (VM26)	<input type="checkbox"/>	<input type="checkbox"/>	347. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	348. <input type="text"/>	349. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	350. <input type="text"/>
351. Thiotepa	<input type="checkbox"/>	<input type="checkbox"/>	352. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	353. <input type="text"/>	354. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	355. <input type="text"/>
356. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	357. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	358. <input type="text"/>	359. <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	360. <input type="text"/>

361. Was this the first transplant for this recipient?

Yes  
 No

362. Is a second transplant planned as part of treatment protocol?

Yes  
 No

Go to Q. 384

363. Number of previous transplants recipient has had:

(if more than 1 previous transplant, photocopy Q.364-383 and answer for each previous transplant)

Continued on next page

TEAM

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364. Date of previous transplant:     
Month Day Year

365. Graft type of previous transplant:

1  Autologous

Yes No  
366. 1  0  Bone marrow  
367. 1  0  Peripheral blood  
368. 1  0  Other, specify: \_\_\_\_\_  
369. Was this transplant reported to the ABMTR – North America?  
1  Yes — ABMTR I.D.   
0  No  
8  Unknown

2  Allogeneic, unrelated donor

370. Same donor as current transplant? 1  Yes 0  No  
Yes No Yes No  
371. 1  0  Bone marrow 374. 1  0  Fetal tissue  
372. 1  0  Peripheral blood 375. 1  0  Other, specify: \_\_\_\_\_  
373. 1  0  Cord blood  
376. Was this transplant reported to the IBMTR?  
1  Yes — IBMTR I.D.   
0  No  
8  Unknown

3  Allogeneic, related donor

377. Same donor as current transplant? 1  Yes 0  No  
Yes No Yes No  
378. 1  0  Bone marrow 380. 1  0  Cord blood  
379. 1  0  Peripheral blood 381. 1  0  Other, specify: \_\_\_\_\_  
382. Was this transplant reported to the IBMTR?  
1  Yes — IBMTR I.D.   
0  No  
8  Unknown

383. Reason for re-transplant:

- 1  No engraftment
- 2  Partial engraftment
- 3  Graft failure/rejection
- 4  Persistent malignancy
- 5  Recurrent malignancy
- 6  Planned second transplant, per protocol
- 7  Other, specify: \_\_\_\_\_

384. What type of graft did patient receive for the current transplant?

- 1  Autologous
- 2  Allogeneic
- 3  Syngeneic

Complete INSERT ALLOBM

385. From where were stem cells obtained?

- 1  Bone marrow — Complete INSERT AUTOBM
- 2  Blood — Complete INSERT AUTOPB
- 3  Bone marrow & Blood — Complete INSERTS AUTOBM & AUTOPB

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### Posttransplant Information

Provide information for first 100 days after transplant **OR** until start of conditioning (high-dose therapy) for second or subsequent transplant if started < 100 days after initial transplant **OR** until infusion of cells for second transplant without conditioning if done < 100 days after initial transplant **OR** until donor leukocyte infusion done to treat relapse, infection, or lymphoproliferative disorder or graft failure if done < 100 days after initial transplant **OR** until time of death if death occurred < 100 days after transplant. If this form is being completed more than 100 days after transplant, provide data to 100 days on this form. Provide data for course after 100 days on a follow-up form. **IF YOU HAVE ANY QUESTIONS ABOUT HOW TO COMPLETE THIS SECTION OF THE FORM, PLEASE CONTACT THE STATISTICAL CENTER.**

386. Date of last actual contact with patient to determine medical status for this report:        
Month Day Year

387. Did patient die prior to day 100 after this transplant?

- 1  Yes – Answers to subsequent questions should reflect clinical status immediately prior to death
- 0  No – Answers to subsequent questions should reflect clinical status on day of actual contact for this follow-up examination (approximately 100 days posttransplant)

388. Did patient receive a subsequent blood or marrow infusion after the transplant for which this report is being completed? (other than peripheral blood leukocytes or T-lymphocytes from original allogeneic donor)

- 1  Yes
- 0  No

Answers to the following questions should reflect clinical status immediately prior to start of conditioning for subsequent infusion. **A separate report covering the subsequent transplant must be submitted.**

389. Date of subsequent infusion:        
Month Day Year

390. Reason for subsequent infusion:

- 1  No engraftment
- 2  Partial engraftment
- 3  Late graft failure
- 4  Persistent malignancy
- 5  Relapse
- 6  Planned second transplant, per protocol
- 7  Other, specify: \_\_\_\_\_

391. Type of graft:

- 1  Allogeneic, related
- 2  Allogeneic, unrelated
- 3  Autologous

Donor:

- 1  Same donor
- 2  Different donor
- 3  Not applicable, initial transplant was autologous

Source of cells:

392. 1  Fresh  
2  Cryopreserved

393. Check all that apply:

- 1  Yes 0  No Bone marrow
- 1  Yes 0  No Peripheral blood
- 1  Yes 0  No Cord blood
- 1  Yes 0  No Fetal tissue
- 1  Yes 0  No Other, specify: \_\_\_\_\_

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395. **Allografts only:** Has patient received an infusion of peripheral blood leukocytes or T-lymphocytes from the original donor?

- 1  Yes  
0  No

396. Date first infusion given:     
Month Day Year

397. Patient weight within 2 weeks of first infusion:   kg

398. Total number of infusions:

399. Total dose of mononuclear cells given:    .  x 10<sup>10</sup>

400. Were cells manipulated prior to infusion?

- 1  Yes  
0  No

401. Indicate method:

- 1  T-cell depletion  
2  CD34 selection  
7  Other, specify: \_\_\_\_\_

402. Indication for the infusion(s) of donor cells:

- 1  Prophylaxis against B-cell lymphoproliferative disorder (or viral infection)  
2  Prophylaxis against relapse

- 3  Treatment of relapse  
4  Treatment of B-cell lymphoproliferative disorder  
5  Treatment of viral infection, specify: \_\_\_\_\_  
6  Graft failure  
7  Other, specify: \_\_\_\_\_

*If answers 3 – 7 were selected, then answers to following questions should reflect clinical status immediately prior to infusion.  
**This is considered a transplant and a separate report covering this infusion and post-infusion events must be submitted.***

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### Hematopoietic Reconstitution Posttransplant

403. Has patient received hematopoietic growth factors or cytokines posttransplant? 1  Yes 0  No

Specify agents given as planned therapy to promote engraftment:

<u>Per Protocol:</u>	Yes No		<u>Date Started</u>			<u>Date Stopped</u>				
			Month	Day	Year	Month	Day	Year		
G-CSF	404.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	405.	<input type="text"/>	<input type="text"/>	<input type="text"/>	406.	<input type="text"/>	<input type="text"/>	<input type="text"/>
GM-CSF	407.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	408.	<input type="text"/>	<input type="text"/>	<input type="text"/>	409.	<input type="text"/>	<input type="text"/>	<input type="text"/>
Interleukin-3	410.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	411.	<input type="text"/>	<input type="text"/>	<input type="text"/>	412.	<input type="text"/>	<input type="text"/>	<input type="text"/>
Interleukin-6	413.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	414.	<input type="text"/>	<input type="text"/>	<input type="text"/>	415.	<input type="text"/>	<input type="text"/>	<input type="text"/>
PIXY-321	416.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	417.	<input type="text"/>	<input type="text"/>	<input type="text"/>	418.	<input type="text"/>	<input type="text"/>	<input type="text"/>
Stem Cell Factor (SCF)	419.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	420.	<input type="text"/>	<input type="text"/>	<input type="text"/>	421.	<input type="text"/>	<input type="text"/>	<input type="text"/>
Blinded growth factor trial, specify agent(s) being studied:	422.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	423.	<input type="text"/>	<input type="text"/>	<input type="text"/>	424.	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other, specify:	425.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	426.	<input type="text"/>	<input type="text"/>	<input type="text"/>	427.	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Coding for Indication of Therapy (below)**  
 1. Intervention for delay/decline in Absolute Neutrophil Count (ANC)  
 2. Intervention for delay/decline in platelets  
 3. Intervention for delay/decline in both ANC and platelets  
 4. Intervention for delay/decline in red blood cell counts  
 5. Anti-leukemic or tumor agent to prevent relapse  
 6. Anti-leukemic or tumor agent to treat relapse  
 7. Other indication

Specify additional agents given:

	Yes No		<u>Date Started</u>			<u>Date Stopped</u>			<u>Indication</u>			
			Month	Day	Year	Month	Day	Year				
G-CSF	428.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	429.	<input type="text"/>	<input type="text"/>	<input type="text"/>	430.	<input type="text"/>	<input type="text"/>	<input type="text"/>	431.	<input type="checkbox"/>
GM-CSF	432.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	433.	<input type="text"/>	<input type="text"/>	<input type="text"/>	434.	<input type="text"/>	<input type="text"/>	<input type="text"/>	435.	<input type="checkbox"/>
Erythropoietin	436.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	437.	<input type="text"/>	<input type="text"/>	<input type="text"/>	438.	<input type="text"/>	<input type="text"/>	<input type="text"/>	439.	<input type="checkbox"/>
Thrombopoietin	440.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	441.	<input type="text"/>	<input type="text"/>	<input type="text"/>	442.	<input type="text"/>	<input type="text"/>	<input type="text"/>	443.	<input type="checkbox"/>
Interleukin-2	444.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	445.	<input type="text"/>	<input type="text"/>	<input type="text"/>	446.	<input type="text"/>	<input type="text"/>	<input type="text"/>	447.	<input type="checkbox"/>
Interleukin-3	448.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	449.	<input type="text"/>	<input type="text"/>	<input type="text"/>	450.	<input type="text"/>	<input type="text"/>	<input type="text"/>	451.	<input type="checkbox"/>
Interleukin-6	452.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	453.	<input type="text"/>	<input type="text"/>	<input type="text"/>	454.	<input type="text"/>	<input type="text"/>	<input type="text"/>	455.	<input type="checkbox"/>
PIXY-321	456.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	457.	<input type="text"/>	<input type="text"/>	<input type="text"/>	458.	<input type="text"/>	<input type="text"/>	<input type="text"/>	459.	<input type="checkbox"/>
Stem Cell Factor (SCF)	460.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	461.	<input type="text"/>	<input type="text"/>	<input type="text"/>	462.	<input type="text"/>	<input type="text"/>	<input type="text"/>	463.	<input type="checkbox"/>
Interferon-alpha	464.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	465.	<input type="text"/>	<input type="text"/>	<input type="text"/>	466.	<input type="text"/>	<input type="text"/>	<input type="text"/>	467.	<input type="checkbox"/>
Interferon-gamma	468.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	469.	<input type="text"/>	<input type="text"/>	<input type="text"/>	470.	<input type="text"/>	<input type="text"/>	<input type="text"/>	471.	<input type="checkbox"/>
Blinded growth factor trial, specify agent(s) being studied:	472.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	473.	<input type="text"/>	<input type="text"/>	<input type="text"/>	474.	<input type="text"/>	<input type="text"/>	<input type="text"/>	475.	<input type="checkbox"/>
Other, specify:	476.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	477.	<input type="text"/>	<input type="text"/>	<input type="text"/>	478.	<input type="text"/>	<input type="text"/>	<input type="text"/>	479.	<input type="checkbox"/>

TEAM

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480. Did patient receive other courses of growth factors or cytokines posttransplant?

- 1  Yes — Photocopy Q. 428–479 and answer for each additional course given.  
0  No  
8  Unknown

### Granulopoiesis

481. Is (was) there evidence of hematopoietic recovery following the initial bone marrow infusion? (check only one)

<p>1 <input type="checkbox"/> Yes,  ANC <math>\geq 500/\text{mm}^3</math> achieved and sustained for 3 consecutive days</p>	<p>482. Date ANC <math>\geq 500/\text{mm}^3</math>:  (First of 3 consecutive days) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</p> <p>483. Was ANC <math>\geq 1000/\text{mm}^3</math> achieved and sustained for 3 consecutive days? 1 <input type="checkbox"/> Yes — <span style="border: 1px solid black; padding: 2px;">484. Date achieved: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Date unknown Month Day Year (first of 3 consecutive days)</span> 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown</p> <p style="text-align: center;"><span style="border: 1px solid black; border-radius: 10px; padding: 2px;">Go to Q. 512</span></p>
<p>2 <input type="checkbox"/> Yes,  ANC <math>\geq 500/\text{mm}^3</math> for 3 consecutive days with subsequent decline in ANC to <math>&lt;500/\text{mm}^3</math> for greater than 3 days</p>	<p>485. Date ANC <math>\geq 500/\text{mm}^3</math>:  (First of 3 consecutive days) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</p> <p>486. Was ANC <math>\geq 1000/\text{mm}^3</math> achieved and sustained for 3 consecutive days? 1 <input type="checkbox"/> Yes — <span style="border: 1px solid black; padding: 2px;">487. Date achieved: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Date unknown Month Day Year (first of 3 consecutive days)</span> 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown</p> <p>488. Date of decline in ANC to <math>&lt; 500/\text{mm}^3</math> for greater than 3 days:  (First of 3 days that ANC declined) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</p> <p>489. Did patient recover and maintain ANC <math>\geq 500/\text{mm}^3</math> following the decline? 1 <input type="checkbox"/> Yes — <span style="border: 1px solid black; padding: 2px;">490. Date of ANC recovery: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</span> 0 <input type="checkbox"/> No</p> <p style="text-align: center;"><span style="border: 1px solid black; border-radius: 10px; padding: 2px;">Go to Q. 491</span></p>
<p>3 <input type="checkbox"/> No, ANC <math>\geq 500/\text{mm}^3</math> was not achieved and there was no evidence of recurrent disease in the bone marrow</p>	<p><span style="border: 1px solid black; border-radius: 10px; padding: 2px;">Go to Q. 491</span></p>
<p>4 <input type="checkbox"/> No, ANC <math>\geq 500/\text{mm}^3</math> was not achieved and there was documented persistent disease in the bone marrow posttransplant</p>	<p><span style="border: 1px solid black; border-radius: 10px; padding: 2px;">Go to Q. 491</span></p>

TEAM

IUBMID

Suspected etiology of failure to achieve ANC  $\geq 500/\text{mm}^3$  or of a decline in ANC:

**491. Persistent disease or relapse:**

- 1  Yes
- 0  No
- 8  Unknown

**492. Graft versus host disease:**

- 1  Yes
- 0  No
- 8  Unknown

**493. Immune-mediated rejection:**

- 1  Yes
- 0  No
- 8  Unknown

**494. Non-viral infection:**

- 1  Yes
- 0  No
- 8  Unknown

**495. Suspected viral infection:**

- 1  Yes
- 0  No
- 8  Unknown

Virus suspected:

- |             | <u>Yes</u>                 | <u>No</u>                  |                                  |
|-------------|----------------------------|----------------------------|----------------------------------|
| <b>496.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Cytomegalovirus (CMV)            |
| <b>497.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Human Herpes Virus Type 6 (HHV6) |
| <b>498.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Herpes Simplex Virus (HSV)       |
| <b>499.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Varicella                        |
| <b>500.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____         |

**501. Documented viral infection:**

- 1  Yes
- 0  No
- 8  Unknown

Virus involved:

- |             | <u>Yes</u>                 | <u>No</u>                  |                                  |
|-------------|----------------------------|----------------------------|----------------------------------|
| <b>502.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Cytomegalovirus (CMV)            |
| <b>503.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Human Herpes Virus Type 6 (HHV6) |
| <b>504.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Herpes Simplex Virus (HSV)       |
| <b>505.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Varicella                        |
| <b>506.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____         |

**507. Drugs:**

- 1  Yes
- 0  No
- 8  Unknown

- |             | <u>Yes</u>                 | <u>No</u>                  |   |
|-------------|----------------------------|----------------------------|---|
| <b>508.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Ganciclovir                                       |
| <b>509.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bactrim, Septra,<br>Trimethoprim-sulfamethoxazole |
| <b>510.</b> | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____                          |

**511. Etiology undetermined:**

- 1  Yes
- 0  No



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### Megakaryopoiesis

The following questions relate to initial platelet recovery. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory results.

512. Was a platelet count of  $\geq 20 \times 10^9/L$  achieved?

1  Yes

0  No

8  Unknown

Go to Q. 518

513. Date platelets  $\geq 20 \times 10^9/L$ :

Date unknown

Month Day Year

514. Was a platelet count of  $\geq 50 \times 10^9/L$  achieved?

1  Yes

0  No

8  Unknown

Go to Q. 518

515. Date platelets  $\geq 50 \times 10^9/L$ :

Date unknown

Month Day Year

516. Was a platelet count of  $\geq 100 \times 10^9/L$  achieved?

1  Yes

0  No

8  Unknown

517. Date platelets  $\geq 100 \times 10^9/L$ :

Date unknown

Month Day Year

518. Was patient ever platelet transfusion independent?

1  Yes

0  No

8  Unknown

7  Not applicable  
(never dependent)

519. Date of last (most recent) platelet transfusion\*:

Date unknown

Month Day Year

*\* If patient was platelet transfusion independent for  $\geq 14$  days but subsequently experienced a decline in platelet count and required platelet transfusions, record date of last platelet transfusion before decline in counts. If patient has not required platelet transfusions since initial date of recovery, record date of last platelet transfusion.*

520. Is patient now receiving platelet transfusions?

1  Yes

0  No

8  Unknown

### Erythropoiesis

521. Has patient received red blood cell (RBC) transfusions within 20 days of the day of last contact?

1  Yes

0  No

522. Date of last (most recent) RBC transfusion\*:

Date unknown

Month Day Year

*\* If patient was RBC transfusion independent for  $\geq 1$  month but subsequently experienced a decline in RBC count and required RBC transfusions, record date of last RBC transfusion before decline in counts. If patient has not required RBC transfusions since initial date of recovery, record date of last RBC transfusion.*

523. Is patient now receiving RBC transfusions?

1  Yes

0  No

8  Unknown

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**Current Hematologic Findings**

Date of most recent CBC:          
 Month Day Year

**Actual CBC results:**

WBC:    .  x 10<sup>9</sup>/L  
 Neutrophils:   %  
 Lymphocytes:   %  
 Hemoglobin:     .    Transfused  
 Hematocrit:   %  Transfused  
 Platelets:   x 10<sup>9</sup>/L  Transfused

Specify units for hemoglobin:  g/dL  
 g/L  
 mmol/L

**Acute Graft-vs-Host Disease (GVHD)**

**524. Was specific therapy used posttransplant to prevent or induce acute GVHD, or promote engraftment?**

- 1  Yes
- 0  No
- 8  Unknown

For each agent listed below indicate whether or not it was used to prevent or induce acute GVHD:

	Yes	No	
525.	<input type="checkbox"/>	<input type="checkbox"/>	Methotrexate
526.	<input type="checkbox"/>	<input type="checkbox"/>	Cyclosporine
527.	<input type="checkbox"/>	<input type="checkbox"/>	FK 506 (Tacrolimus)
528.	<input type="checkbox"/>	<input type="checkbox"/>	Corticosteroids
529.	<input type="checkbox"/>	<input type="checkbox"/>	ALS, ALG, ATS, ATG
530.	<input type="checkbox"/>	<input type="checkbox"/>	Azathioprine
531.	<input type="checkbox"/>	<input type="checkbox"/>	Cyclophosphamide
532.	<input type="checkbox"/>	<input type="checkbox"/>	In vivo anti T-lymphocyte monoclonal antibody
538.	<input type="checkbox"/>	<input type="checkbox"/>	In vivo immunotoxin, specify: _____
539.	<input type="checkbox"/>	<input type="checkbox"/>	Blinded randomized trial; specify agent being studied: _____
540.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

Allografts:  
Go to Q. 541

Autografts:  
Go to Q. 680

	Yes	No	
533.	<input type="checkbox"/>	<input type="checkbox"/>	Anti IL-2
534.	<input type="checkbox"/>	<input type="checkbox"/>	Anti CD 25
535.	<input type="checkbox"/>	<input type="checkbox"/>	Campath
536.	<input type="checkbox"/>	<input type="checkbox"/>	OKT3
537.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

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541. Did acute GVHD occur?

- 1  Yes  
 0  No  
 8  Unknown Go to Q. 593

542. Maximum overall grade: 1  I 2  II 3  III 4  IV

What was diagnosis based on?

543. Histologic evidence:

- 1  Yes  
 0  No

548. Clinical evidence:

- 1  Yes  
 0  No

Sites:

- |      | Yes                        | No                         |                       |
|------|----------------------------|----------------------------|-----------------------|
| 544. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Skin                  |
| 545. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Gut                   |
| 546. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Liver                 |
| 547. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____ |

549. Date of onset:            
 Month Day Year

550. Was acute GVHD still present at time of this report?

- 1  Yes  
 0  No  
 2  Progressed to chronic GVHD  
 8  Unknown

List the maximum severity of organ involvement attributed to acute GVHD:

- |  | <u>Stage 0</u>   | <u>Stage 1</u>  | <u>Stage 2</u>   | <u>Stage 3</u>  | <u>Stage 4</u>   |
|--|--|---|--|---|--|
| 551. Skin:   | 1 <input type="checkbox"/> No rash   | 2 <input type="checkbox"/> Maculopapular rash, <25% of body surface                         | 3 <input type="checkbox"/> Maculopapular rash, 25–50% of body surface                        | 4 <input type="checkbox"/> Generalized erythroderma                             | 5 <input type="checkbox"/> Generalized erythroderma with bullae formation and desquamation |
| 552. Intestinal tract (use ml/day for adult patients and ml/m <sup>2</sup> /day for pediatric patients): | 0 <input type="checkbox"/> No diarrhea<br>1 <input type="checkbox"/> Diarrhea ≤500 ml/day or <280 ml/m <sup>2</sup> /day | 2 <input type="checkbox"/> Diarrhea >500 but ≤1000 ml/day or 280–555 ml/m <sup>2</sup> /day | 3 <input type="checkbox"/> Diarrhea >1000 but ≤1500 ml/day or 556–833 ml/m <sup>2</sup> /day | 4 <input type="checkbox"/> Diarrhea >1500 ml/day or >833 ml/m <sup>2</sup> /day | 5 <input type="checkbox"/> Severe abdominal pain, with or without ileus                    |
| 553. Liver:  | 1 <input type="checkbox"/> Bilirubin <2.0 mg/dL  | 2 <input type="checkbox"/> Bilirubin 2.0–3.0 mg/dL  | 3 <input type="checkbox"/> Bilirubin 3.1–6.0 mg/dL   | 4 <input type="checkbox"/> Bilirubin 6.1–15.0 mg/dL                             | 5 <input type="checkbox"/> Bilirubin >15.0 mg/dL   |

554. Other organ involvement?

- 1  Yes  
 0  No

- |      | Yes                        | No                         |                       |
|------|----------------------------|----------------------------|-----------------------|
| 555. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Upper GI tract        |
| 556. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Lung                  |
| 557. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____ |

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558. Was specific therapy used to **treat** acute GVHD? 1  Yes 0  No —

For each agent listed below indicate whether or not it was used to **treat** acute GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking?	
					Yes	No
559. Methotrexate	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	560. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
561. Cyclosporine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	562. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
563. FK 506 (Tacrolimus)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	564. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
565. Systemic Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	566. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
567. Topical Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	568. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
569. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	570. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
571. Azathioprine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	572. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
573. Cyclophosphamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	574. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
575. Thalidomide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	576. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

In vivo anti-T-lymphocyte monoclonal antibody:

577. Anti IL-2	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	578. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
579. Anti CD 25	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	580. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
581. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	582. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
583. OKT3	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	584. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
585. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	586. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
587. In vivo immunotoxin, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	588. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
589. Blinded randomized trial; specify agent being studied: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	590. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
591. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	592. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

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### Chronic Graft-vs-Host Disease (GVHD)

593. Has patient developed clinical chronic GVHD?

1  Yes  
0  No  
8  Unknown

Go to Q. 680

594. Date of onset:        
Month Day Year

595. Progressed from acute GVHD?  
1  Yes  
0  No

596. Karnofsky/Lansky score (see page 5) at diagnosis of chronic GVHD:

597. Platelet count at diagnosis of chronic GVHD:       .  x 10<sup>9</sup>/L

598. Total serum bilirubin at diagnosis of chronic GVHD:    .

599. Unit of measurement for bilirubin:  
1  mg/dL  
2  μmol/L

What was diagnosis based on?

600. Histologic evidence:  
1  Yes  
0  No

609. Clinical evidence:  
1  Yes  
0  No

Sites:

	Yes	No	
601.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Skin
602.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Gut
603.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Liver
604.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Buccal mucosa/lip
605.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Conjunctiva
606.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lung
607.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Muscle
608.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

610. Maximum grade of chronic GVHD:  
1  Limited (*Localized skin involvement and/or hepatic dysfunction due to chronic GVHD*)  
2  Extensive (*Generalized skin involvement; or localized skin involvement and/or hepatic dysfunction due to chronic GVHD, plus:*  
*-Liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,*  
*-Involvement of eye: Schirmer's test with < 5 mm wetting; or,*  
*-Involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or,*  
*-Involvement of any other target organ)*

611. Overall severity: 1  Mild 2  Moderate 3  Severe

Continued on next page

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Indicate organ involvement with chronic GVHD from list below:

		Yes	No	
Skin/Hair:	612.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Subclinical (biopsy findings only)
	613.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Rash
	614.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Scleroderma
	615.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Dyspigmentation
	616.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Contractures
	617.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Alopecia
	618.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other skin/hair involvement, specify: _____
Eyes:	619.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Dry eyes
	620.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Corneal erosion/conjunctivitis
	621.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other eye involvement, specify: _____
Mouth:	622.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lichenoid changes
	623.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Mucositis/ulcers
	624.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other mouth involvement, specify: _____
Lung:	625.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Bronchiolitis obliterans
	626.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other lung involvement, specify: _____
GI Tract:	627.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Esophageal involvement
	628.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Chronic nausea/vomiting
	629.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Chronic diarrhea
	630.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Malabsorption
	631.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other GI tract involvement, specify: _____
Liver:	632.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Liver involvement, specify: _____
GU Tract:	633.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Vaginitis/stricture
	634.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other GU involvement, specify: _____
Musculoskeletal:	635.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Arthritis
	636.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Myositis
	637.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Myasthenia
	638.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other musculoskeletal involvement, specify: _____
Hematologic:	639.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Thrombocytopenia
	640.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Eosinophilia
	641.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Autoantibodies
	642.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other hematologic involvement, specify: _____
Other:	643.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Specify: _____

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644. Was specific therapy used to treat chronic GVHD? 1  Yes 0  No — Go to Q. 679

For each agent listed below indicate whether or not it was used to treat chronic GVHD

	No. drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking?	
					Yes	No
645. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	646. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
647. Azathioprine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	648. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
649. Cyclosporine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	650. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
651. FK 506 (Tacrolimus)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	652. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
653. Systemic Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	654. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
655. Topical Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	656. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
657. Cyclo- phosphamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	658. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
659. Thalidomide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	660. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
In vivo anti-T-lymphocyte monoclonal antibody						
661. Anti IL-2	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	662. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
663. Anti CD 25	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	664. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
665. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	666. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
667. OKT3	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	668. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
669. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	670. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
671. In vivo immunotoxin, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	672. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
673. Blinded randomized trial; specify agent being studied: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	674. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
675. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	676. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

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677. Is patient still receiving treatment for chronic GVHD?

1  Yes

0  No

678. Date last treatment was administered:

Month Day Year

679. Is chronic GVHD still present?

1  Yes

0  No

2  No symptoms, but patient still receiving treatment

### Other Treatment and Clinical Status After Start of Conditioning

680. Were transfusions given at any time after the start of conditioning to present?

1  Yes

0  No

	Yes	No	
681.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Did patient receive only CMV-negative blood products?
682.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Were blood products filtered to remove leukocytes?
683.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Were all transfusions irradiated?
684.	Number of RBC transfusions in first 60 days:		<input type="text"/> <input type="text"/> <input type="text"/> units
685.	Number of platelet transfusions in first 60 days:		<input type="text"/> <input type="text"/> <input type="text"/> units

686. Did patient receive any of the following agents for infection prophylaxis after start of conditioning?

1  Yes

0  No

	Yes	No	
	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Systemic antibacterial antibiotics
	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Nonabsorbable antibiotics
687.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Polyclonal IV gamma globulin (not ATG)
688.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CMV/hyperimmune gamma globulin
689.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	IV amphotericin
690.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Fluconazole
691.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Itraconazole
692.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other systemic antifungal agent, specify: _____
693.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Acyclovir
694.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Ganciclovir (DHPG)
695.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Foscarnet
696.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other antiviral agent, specify: _____
697.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Trimethoprim-sulfamethoxazole (Bactrim/Septra)
698.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Pentamidine inhaled
699.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Pentamidine IV
700.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Dapsone
701.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other pneumocystis prophylaxis, specify: _____
702.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____



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703. Did patient develop clinically significant infection after start of conditioning? 1  Yes 0  No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism was involved, list one site of infection and organism on the first line; second site and/or organism on second line.

		Site	Organism	Date of Onset			Did infection resolve?	
				Month	Day	Year	Yes	No
704. <input type="checkbox"/> Bacterial	<u>Typical</u>	First 705. <input type="text"/>	706. _____	707. <input type="text"/>	<input type="text"/>	<input type="text"/>	708. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 709. <input type="text"/>	710. _____	711. <input type="text"/>	<input type="text"/>	<input type="text"/>	712. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	<u>Atypical</u>	First 716. <input type="text"/>	717. B <input type="text"/>	718. <input type="text"/>	<input type="text"/>	<input type="text"/>	719. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 720. <input type="text"/>	721. B <input type="text"/>	722. <input type="text"/>	<input type="text"/>	<input type="text"/>	723. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
724. Other atypical bacterium, specify: _____								
727. <input type="checkbox"/> Fungal		First 728. <input type="text"/>	729. F <input type="text"/>	730. <input type="text"/>	<input type="text"/>	<input type="text"/>	731. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 732. <input type="text"/>	733. F <input type="text"/>	734. <input type="text"/>	<input type="text"/>	<input type="text"/>	735. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
736. Other fungus, specify: _____								
739. <input type="checkbox"/> Viral		First 740. <input type="text"/>	741. V <input type="text"/>	742. <input type="text"/>	<input type="text"/>	<input type="text"/>	743. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 744. <input type="text"/>	745. V <input type="text"/>	746. <input type="text"/>	<input type="text"/>	<input type="text"/>	747. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
748. Other virus, specify: _____								
751. <input type="checkbox"/> Parasitic		First 752. <input type="text"/>	753. P <input type="text"/>	754. <input type="text"/>	<input type="text"/>	<input type="text"/>	755. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 756. <input type="text"/>	757. P <input type="text"/>	758. <input type="text"/>	<input type="text"/>	<input type="text"/>	759. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
760. Other parasite, specify: _____								
763. <input type="checkbox"/> No organism identified		First 764. <input type="text"/>	765. O 5 0 9	766. <input type="text"/>	<input type="text"/>	<input type="text"/>	767. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 768. <input type="text"/>	769. O 5 0 9	770. <input type="text"/>	<input type="text"/>	<input type="text"/>	771. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	

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### Codes for Common Sites of Infection

01	Blood/buffy coat	40	<u>Genito-Urinary Tract unspecified</u>
02	Disseminated – generalized, isolated at 3 or more distinct sites	41	Kidneys, renal pelvis, ureters and bladder
03	<u>Central Nervous System unspecified</u>	42	Prostate
04	Brain	43	Testes
05	Spinal cord	44	Fallopian tubes, uterus, cervix
06	Meninges and CSF	45	Vagina
10	<u>Gastrointestinal Tract unspecified</u>	50	<u>Skin unspecified</u>
11	Lips	51	Genital area
12	Tongue, oral cavity and oro-pharynx	52	Cellulitis
13	Esophagus	53	Herpes Zoster
14	Stomach	54	Rash, pustules or abscesses not typical of any of the above
15	Gallbladder and biliary tree (not hepatitis), pancreas	60	Central venous catheter, not otherwise specified
16	Small intestine	61	Catheter insertion site
17	Large intestine	62	Catheter tip
18	Feces/stool	70	Eyes
19	Peritoneum	75	Ear
20	Liver	80	<u>Other unspecified</u>
30	<u>Respiratory unspecified</u>	81	Joints
31	Upper airway and nasopharynx	82	Bone marrow
32	Laryngitis/larynx	83	Bone cortex (osteomyelitis)
33	Lower respiratory tract (lung)	84	Muscle (excluding cardiac)
34	Pleural cavity, pleural fluid	85	Cardiac (endocardium, myocardium, pericardium)
35	Sinuses	86	Lymph nodes
		87	Spleen

### Codes for Commonly Reported Organisms

#### 1. Bacteria

(Indicate code for atypical bacteria;  
list bacterium for non-atypical bacteria.)

100	Atypical bacteria, not otherwise specified
101	Coxiella
102	Legionella
103	Leptospira
104	Listeria
105	Mycoplasma
106	Nocardia
107	Rickettsia
110	Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
111	Typical tuberculosis (TB, Tuberculosis)
112	Mycobacteria (avium, bovis, intracellulare)
113	Chlamydia
119	Other atypical bacteria, specify

#### 2. Fungal Infections

200	Candida, not otherwise specified
201	Candida albicans
202	Candida krusei
203	Candida parapsilosis
204	Candida tropicalis
205	Torulopsis glabrata (a subspecies of candida)
209	Candida, other
210	Aspergillus, not otherwise specified
211	Aspergillus flavus
212	Aspergillus fumigatus
213	Aspergillus niger
219	Aspergillus, other
220	Cryptococcus species
230	Fusarium species
240	Mucormycosis (zygomycetes, rhizopus)
250	Yeast, not otherwise specified
259	Other fungus, specify

#### 3. Viral Infections

301	Herpes Simplex (HSV1, HSV2)
302	Herpes Zoster (Chicken pox, Varicella)
303	Cytomegalovirus (CMV)
304	Adenovirus
305	Enterovirus (Coxsackie, Echo, Polio)
306	Hepatitis A (HAV)
307	Hepatitis B (HBV, Australian antigen)
308	Hepatitis C (HCV)
309	HIV-1 (HTLV-III)
310	Influenza
311	Measles (Rubeola)
312	Mumps
313	Papovavirus
314	Respiratory syncytial virus (RSV)
315	Rubella (German Measles)
316	Parainfluenza
317	Human herpesvirus-6 (HHV-6)
318	Epstein-Barr virus (EBV)
319	Polyomavirus
320	Rotavirus
321	Rhinovirus
329	Other viral, specify

#### 4. Parasite Infections

401	Pneumocystis (PCP)
402	Toxoplasma
403	Giardia
404	Cryptosporidium
409	Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

#### 5. Other Infections

509	No organism identified
-----	------------------------

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**Pulmonary function**

775. Has patient developed interstitial pneumonitis (IPn)?

*Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload.*

- 1  Yes
- 0  No

776. How many episodes of IPn occurred?

*Note: If more than one episode of IPn, photocopy this page and complete Q. 775 – 795 for subsequent episode(s).*

777. Date of onset of IPn:     
Month Day Year

778. Were diagnostic tests other than radiographic studies done?

- 1  Yes
- 0  No

Diagnosis was evaluated by:

	Yes	No	
779.	<input type="checkbox"/>	<input type="checkbox"/>	Bronchoalveolar lavage
780.	<input type="checkbox"/>	<input type="checkbox"/>	Transbronchial biopsy
781.	<input type="checkbox"/>	<input type="checkbox"/>	Open lung biopsy
782.	<input type="checkbox"/>	<input type="checkbox"/>	Autopsy
783.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

784. Was an organism isolated?

- 1  Yes
- 0  No (idiopathic, or no organism isolated)

Etiology:

	Yes	No	
785.	<input type="checkbox"/>	<input type="checkbox"/>	Pneumocystis carinii
786.	<input type="checkbox"/>	<input type="checkbox"/>	Aspergillus
787.	<input type="checkbox"/>	<input type="checkbox"/>	Candida toxoplasma
788.	<input type="checkbox"/>	<input type="checkbox"/>	Respiratory syncytial virus
789.	<input type="checkbox"/>	<input type="checkbox"/>	Cytomegalovirus
790.	<input type="checkbox"/>	<input type="checkbox"/>	Herpes simplex
791.	<input type="checkbox"/>	<input type="checkbox"/>	Adenovirus
792.	<input type="checkbox"/>	<input type="checkbox"/>	Human herpes virus 6
793.	<input type="checkbox"/>	<input type="checkbox"/>	Other virus, specify: _____
794.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

795. Has interstitial pneumonitis resolved?

- 1  Yes
- 0  No
- 8  Unknown

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796. Did patient develop pulmonary abnormalities other than interstitial pneumonitis after start of conditioning?

- 1  Yes  
0  No

797. Did patient develop Acute Respiratory Distress Syndrome (ARDS)?

- 1  Yes  
0  No

798. Date of onset of ARDS:

Month Day Year

799. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | Yes                        | No                         |                        |
|------|----------------------------|----------------------------|------------------------|
| 800. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 801. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 802. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 803. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 804. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

805. Did patient develop bronchiolitis obliterans?

- 1  Yes  
0  No

806. Date of onset:

Month Day Year

807. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | Yes                        | No                         |                        |
|------|----------------------------|----------------------------|------------------------|
| 808. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 809. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 810. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 811. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 812. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

813. Did patient develop pulmonary hemorrhage?

- 1  Yes  
0  No

814. Date of onset:

Month Day Year

815. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | Yes                        | No                         |                        |
|------|----------------------------|----------------------------|------------------------|
| 816. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 817. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 818. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 819. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 820. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

821. Did patient develop other non-infectious pulmonary abnormalities?

- 1  Yes  
0  No

822. Specify: \_\_\_\_\_

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**Liver function**

823. Patient's maximum total bilirubin in the first 100 days posttransplant:

.

824. Unit of measurement for bilirubin:

• 1  mg/dL 2   $\mu$ mol/L

825. Date of maximum total bilirubin in the first 100 days posttransplant:

Month Day Year

826. Patient's bilirubin on day of last contact: (Refer to Q. 386, page 17 for date)

.

827. Unit of measurement for bilirubin:

1  mg/dL 2   $\mu$ mol/L

828. Did patient develop any of the following clinical signs/symptoms of abnormal liver function?

1  Yes

0  No

	<u>Yes</u>	<u>No</u>	
829.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Jaundice
830.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hepatomegaly
831.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Right upper quadrant pain
832.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Ascites
833.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Weight gain (>5%)
834.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

835. Did patient develop non-infectious liver toxicity after conditioning?

1  Yes

0  No

836. What was the date of onset?	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year
Etiology:			
	<u>Yes</u>	<u>No</u>	
837.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Veno-occlusive disease
838.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
839.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Unknown
Diagnosis was based on:			
	<u>Yes</u>	<u>No</u>	
840.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Clinical signs and symptoms (see Q. 828)
841.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Elevated liver enzymes
842.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Biopsy
843.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Autopsy
844.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Ultrasonography
845.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Doppler
846.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
847. Has liver toxicity resolved?			
	1 <input type="checkbox"/>	Yes	
	0 <input type="checkbox"/>	No	

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848. Did patient develop any other non-infectious clinically significant organ impairment or disorder after conditioning?

1  Yes  
0  No

	<u>Yes</u>	<u>No</u>																					
849.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Renal failure requiring dialysis																				
850.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	TTP/HUS or similar syndrome																				
851.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hemorrhage, specify site:																				
<table border="1"><thead><tr><th></th><th><u>Yes</u></th><th><u>No</u></th><th></th></tr></thead><tbody><tr><td>852.</td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>CNS</td></tr><tr><td>853.</td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Upper GI tract</td></tr><tr><td>854.</td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Lower GI tract</td></tr><tr><td>855.</td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Other, specify: _____</td></tr></tbody></table>					<u>Yes</u>	<u>No</u>		852.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CNS	853.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Upper GI tract	854.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lower GI tract	855.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
	<u>Yes</u>	<u>No</u>																					
852.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CNS																				
853.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Upper GI tract																				
854.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lower GI tract																				
855.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____																				
856.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hemorrhagic cystitis																				
857.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Seizures																				
858.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Cataracts																				
859.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Avascular necrosis																				
860.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hypothyroidism																				
861.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Gonadal dysfunction																				
862.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Growth hormone deficiency/growth disturbance																				
863.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____																				

864. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear? (If more than one new malignancy developed, copy this page and complete for each new cancer)

1  Yes  
0  No

865. Date of diagnosis:	<input type="text"/>	<input type="text"/>	<input type="text"/>	866. Origin of cells:	1 <input type="checkbox"/> Host	8 <input type="checkbox"/> Unknown														
	Month	Day	Year		2 <input type="checkbox"/> Donor	7 <input type="checkbox"/> Not tested														
Diagnosis ( <i>send copy of pathology report/other documentation</i> ):																				
	<u>Yes</u>	<u>No</u>																		
867.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Clonal cytogenetic abnormality without leukemia or MDS																	
868.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Acute myeloid leukemia																	
869.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other leukemia, specify: _____																	
870.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Myelodysplasia																	
871.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lymphoma or lymphoproliferative disease																	
<table border="1"><tr><td>872. EBV positive?</td><td>1 <input type="checkbox"/> Yes</td><td>0 <input type="checkbox"/> No</td><td>8 <input type="checkbox"/> Unknown</td></tr></table>							872. EBV positive?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No	8 <input type="checkbox"/> Unknown										
872. EBV positive?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No	8 <input type="checkbox"/> Unknown																	
873.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hodgkin disease																	
875.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other cancer																	
<table border="1"><tr><td>876. Primary site:</td><td>_____</td></tr><tr><td>877. Histologic type:</td><td>_____</td></tr><tr><td>878. Behavior:</td><td></td></tr><tr><td>1 <input type="checkbox"/></td><td>Benign</td></tr><tr><td>2 <input type="checkbox"/></td><td>In situ</td></tr><tr><td>3 <input type="checkbox"/></td><td>Malignant/invasive</td></tr><tr><td>8 <input type="checkbox"/></td><td>Unknown</td></tr></table>							876. Primary site:	_____	877. Histologic type:	_____	878. Behavior:		1 <input type="checkbox"/>	Benign	2 <input type="checkbox"/>	In situ	3 <input type="checkbox"/>	Malignant/invasive	8 <input type="checkbox"/>	Unknown
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878. Behavior:																				
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2 <input type="checkbox"/>	In situ																			
3 <input type="checkbox"/>	Malignant/invasive																			
8 <input type="checkbox"/>	Unknown																			

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### Survival and Functional Status

879. Was patient discharged from hospital after transplant?

- 1  Yes
- 0  No
- 7  Not applicable, high-dose therapy given as outpatient

880. Date of first discharge from hospital after transplant:     
Month Day Year

881. **Autografts only:** Total number inpatient days in first 60 days after start of high-dose therapy:

882. **Allografts only:** Total number inpatient days in first 100 days after start of high-dose therapy:

883. Was patient alive on the day of last contact? (Refer to Q. 386, page 17 for date):

- 1  Yes
- 0  No

884. If the patient is 16 years of age or older, complete the Karnofsky Scale. If the patient is younger than 16 years of age, complete the Lansky Scale.

Go to Q. 895

#### Karnofsky Scale (age ≥16 yrs)

Select the phrase in the Karnofsky Scale which best describes the activity status of the patient:

**Able to carry on normal activity; no special care is needed.**

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort

**Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.**

- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care

**Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.**

- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

#### Lansky Scale (age <16 yrs)

Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the patient:

**Normal range.**

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active

**Mild to moderate restriction.**

- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play

**Moderate to severe restriction.**

- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (i.e., TV)
- 10 Completely disabled, not even passive play

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(If patient is alive, answer Q. 885–894; if dead, skip to Q. 895)

885. Patient (age  $\geq$  6 years) currently attends school:

- 1  Yes  
0  No

886. 1  Part-time 2  Full-time 8  Unknown, whether part-time or full-time

887. Date returned to school:      
Month Year

888. Patient was employed outside the home prior to current illness:

- 1  Yes  
0  No

889. Patient has returned to work:

- 1  Yes  
0  No

890. Date returned to work:      
Month Year

891. Patient able to work but is not employed:

- 1  Yes  
0  No

892. Patient has resumed all household activities:

- 1  Yes  
0  No

893. Date resumed all activities:      
Month Year

894. Patient is a student:

- 1  Yes  
0  No



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### Death Information

895. Date of death:          
                                   Month      Day      Year

Cause(s) of death:

<p>Enter appropriate cause of death below. If a code number for "Other, specify" is entered, write the cause in the space provided.</p> <p>896. Primary: <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>Contributing or secondary causes:</p> <p>897. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>898. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>899. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>900. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>901. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><b>Cause of Death Codes</b></td> </tr> <tr> <td>10 Graft rejection or failure</td> </tr> <tr> <td>Infection (other than interstitial pneumonia)</td> </tr> <tr> <td>20 Infection, organism not identified</td> </tr> <tr> <td>21 Bacterial</td> </tr> <tr> <td>22 Fungal</td> </tr> <tr> <td>23 Viral</td> </tr> <tr> <td>24 Protozoal</td> </tr> <tr> <td>29 Other infection, specify</td> </tr> <tr> <td>Interstitial pneumonia</td> </tr> <tr> <td>30 IPn, idiopathic</td> </tr> <tr> <td>31 Cytomegalovirus (CMV)</td> </tr> <tr> <td>32 Viral, other</td> </tr> <tr> <td>33 Pneumocystis (PCP)</td> </tr> <tr> <td>34 Fungal</td> </tr> <tr> <td>39 Other IPn, specify</td> </tr> <tr> <td>40 Adult Respiratory Distress Syndrome, ARDS (other than IPN)</td> </tr> <tr> <td>50 Acute GVHD</td> </tr> <tr> <td>60 Chronic GVHD</td> </tr> <tr> <td>70 Recurrence or persistence of primary disease</td> </tr> <tr> <td><i>NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.</i></td> </tr> <tr> <td>Organ failure (not due to GVHD or infection)</td> </tr> <tr> <td>80 Organ failure, not otherwise specified</td> </tr> <tr> <td>81 Liver (not VOD)</td> </tr> <tr> <td>82 VOD</td> </tr> <tr> <td>83 Cardiac (Cardiomyopathy)</td> </tr> <tr> <td>84 Pulmonary</td> </tr> <tr> <td>85 CNS</td> </tr> <tr> <td>86 Renal</td> </tr> <tr> <td>89 Other organ failure, specify</td> </tr> <tr> <td>90 Secondary malignancy</td> </tr> <tr> <td>100 Hemorrhage</td> </tr> <tr> <td>110 Accidental death</td> </tr> <tr> <td>900 Other, specify</td> </tr> </table>	<b>Cause of Death Codes</b>	10 Graft rejection or failure	Infection (other than interstitial pneumonia)	20 Infection, organism not identified	21 Bacterial	22 Fungal	23 Viral	24 Protozoal	29 Other infection, specify	Interstitial pneumonia	30 IPn, idiopathic	31 Cytomegalovirus (CMV)	32 Viral, other	33 Pneumocystis (PCP)	34 Fungal	39 Other IPn, specify	40 Adult Respiratory Distress Syndrome, ARDS (other than IPN)	50 Acute GVHD	60 Chronic GVHD	70 Recurrence or persistence of primary disease	<i>NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.</i>	Organ failure (not due to GVHD or infection)	80 Organ failure, not otherwise specified	81 Liver (not VOD)	82 VOD	83 Cardiac (Cardiomyopathy)	84 Pulmonary	85 CNS	86 Renal	89 Other organ failure, specify	90 Secondary malignancy	100 Hemorrhage	110 Accidental death	900 Other, specify
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110 Accidental death																																			
900 Other, specify																																			

902. Was cause of death confirmed by autopsy?

- 1  Yes
- 0  No
- 8  Unknown
- 6  Pending

**Send copy of autopsy report when available**

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**FOR REGISTRY USE ONLY:**

I.D.  -  -

Date received:

Registry: IBMTR ABMTR (circle one)

**Confidential/Socioeconomic Information**

903. Patient's First Name:

904. Patient's Last Name:

905. Patient's state of residence (US only):

906. Zip code for place of patient's residence (US only):  -

907. Country of residence (if non-US):

908. Does patient have a US Social Security Number or Canadian Social Insurance Number?

- 1  Yes
- 0  No
- 8  Unknown
- 7  Not applicable

909. Social Security or Social Insurance Number:

910. (For patients  $\geq 18$  years of age) What is patient's marital status? (check one)

- 1  Single, never married
- 2  Married
- 3  Separated
- 4  Divorced
- 5  Widowed
- 8  Unknown

911. (For patients  $\geq 18$  years of age) What is the highest grade patient finished in school?

- 1  1 - 8 grades
- 2  9 - 11 grades
- 3  High School graduate
- 4  Some college
- 5  Junior college degree
- 6  College degree (BA/BS)
- 7  Some post-college work
- 8  Advanced degree
- 88  Unknown

TEAM

IUBMID

912. What type of health insurance does patient have? (check all that apply)

- 0  No Insurance
- 1  Medicaid
- 2  Medicare (US)
- 3  Disability Insurance
- 4  HMO
- 5  Individual Health Insurance
- 6  Group Health Insurance
- 7  National Health Insurance (non-US)
- 8  V.A./Military
- 9  Other, specify: \_\_\_\_\_

913. (U.S. patients only) Type of fee reimbursement:

- 1  Fee for service
- 2  Capitation
- 7  Other, specify: \_\_\_\_\_
- 8  Unknown

914. Which category best describes patient's occupation?

*If not currently employed, which best describes patient's LAST job? (check only one)*

- 1  Professional, Technical, & Related Occupations (teacher/professor, nurse, lawyer, physician or engineer)
- 2  Manager, Administrator or Proprietor (sales manager, real estate agent, or postmaster)
- 3  Clerical & Related Occupations (secretary, clerk, or mail carrier)
- 4  Sales Occupation (salesperson, demonstrator, agent or broker)
- 5  Service Occupation (police, cook or hairdresser)
- 6  Skilled crafts & Related Occupations (carpenter, repairer or telephone line worker)
- 7  Equipment or Vehicle Operator & Related Occupations (driver, railroad brakeman, or sewer worker)
- 8  Laborer (helper, longshoreman or warehouse worker)
- 9  Farmer (owner, manager, operator, or tenant)
- 10  Member of the military
- 11  Homemaker
- 90  Other, please describe: \_\_\_\_\_
- 88  Unknown

915. (US patients only) What is patient's yearly income, earned by all family members living in household, before taxes? (check one)

- 1  Less than \$5,000
- 2  \$ 5,000 – \$9,999
- 3  \$10,000 – \$19,999
- 4  \$20,000 – \$29,999
- 5  \$30,000 – \$39,999
- 6  \$40,000 – \$49,999
- 7  \$50,000 – \$59,999
- 8  \$60,000 – \$79,999
- 9  \$80,000 and over
- 88  Unknown

# INSTITUTIONAL INFORMATION

TEAM

IUBMID

(Institutional Unique Blood or Marrow Transplant Identification Number)

Date of transplant for which this form is being completed:     
Month Day Year

## FOR REGISTRY USE ONLY:

I.D. --

Date received:

Registry: IBMTR ABMTR (circle one)

Date of report:     
Month Day Year

1. Signed: \_\_\_\_\_ /

Person completing this form / Please print name

2. Date form completed:     
Month Day Year

3. Name of doctor for correspondence: \_\_\_\_\_

Institution: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone:

Extension:

Fax:

4. Make reimbursement check payable to: \_\_\_\_\_

5. Patient or authorized family member/guardian is aware of, and has consented to, the fact that this case is being entered into the Registry database:

\_\_\_\_\_ (physician's initials).

6. A complete report of transplant consists of the following three forms.

Check when complete:

- A (white) CORE FORM
- An appropriate (blue or pink) graft-specific insert (Insert ALLOBM, AUTOPB, or AUTOBM)
- An appropriate (ivory) disease-specific insert (Inserts I through XVI)

**INSERT AUTOBM**

**FOR REGISTRY USE ONLY:**

I.D. --

Date received:

TEAM

IUBMID

(Institutional Unique Blood or Marrow Transplant Identification Number)

Registry: *IBMTR* *ABMTR* (circle one)

Date of transplant for which this form is being completed:

Month Day Year

Date of report:

Month Day Year

**Autologous Bone Marrow Collection and Processing**

1. Date of bone marrow harvest:

Month Day Year

1.2 Did patient receive treatment prior to harvesting to enhance bone marrow collection?

1  Yes

0  No

What treatment did patient receive?

1.3 Chemotherapy:

1  Yes

0  No

1.4 Growth factors:

1  Yes

0  No

	Yes	No	
1.5	1 <input type="checkbox"/>	0 <input type="checkbox"/>	G-CSF
1.6	1 <input type="checkbox"/>	0 <input type="checkbox"/>	GM-CSF
1.7	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

1.8 1  Yes 0  No Other, specify: \_\_\_\_\_

2. For leukemia/lymphoma patients only:

What was disease state at time of harvest?

1  First remission

2  Second remission

3  Third remission

4  First relapse

5  Second relapse

7  Other, specify: \_\_\_\_\_

3. Date of remission:     
Month Day Year

TEAM

IUBMID

4. Was bone marrow cryopreserved?

- 1  Yes  
0  No

5. Cryopreservative was:

1  DMSO

2  Hydroxyethylstarch

7  Other, specify: \_\_\_\_\_

Indicate whether or not tumor involvement of bone marrow or circulating cells was detected prior to transplant by each of the indicated methods:

	<u>Detected in circulating cells*</u>			<u>Detected in bone marrow, prior to harvest*</u>			<u>Detected in harvested bone marrow (before purging)</u>		
	<u>Yes</u>	<u>No</u>	<u>Not Tested</u>	<u>Yes</u>	<u>No</u>	<u>Not Tested</u>	<u>Yes</u>	<u>No</u>	<u>Not Tested</u>
Routine histopathology	6. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	7. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	8. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Polymerase chain reaction (PCR)	9. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	10. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	11. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Other molecular technique	12. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	13. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	14. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Immunohistochemistry	15. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	16. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	17. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Cell culture technique	18. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	19. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	20. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Other, specify: _____	21. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	22. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	23. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>

\* Refers to detection of tumor cells in circulation or bone marrow in the interval between last chemotherapy and harvest.

24. Was bone marrow treated to remove malignant cells (purged)?

- 1  Yes  
0  No

Which of the following were used for purging?

	<u>Yes</u>	<u>No</u>	
25.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Monoclonal antibody, specify: _____
26.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	4-hydroperoxycyclophosphamide (4HC)
27.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Mafofamide
28.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other drug, specify: _____
29.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Elutriation
30.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Immunomagnetic column
31.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Toxin, specify: _____
32.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Positive stem cell selection (other than preparation of mononuclear fraction) Specify method: _____
33.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

*continued on next page*

TEAM

IUBMID

Indicate whether or not tumor involvement of harvested bone marrow was detected after purging by each of the indicated methods:

- |     | Yes                        | No                         | Not Tested                 |                                 |
|-----|----------------------------|----------------------------|----------------------------|---------------------------------|
| 34. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Routine histopathology          |
| 35. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Polymerase chain reaction (PCR) |
| 36. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Other molecular technique       |
| 37. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Immunohistochemistry            |
| 38. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Cell culture technique          |
| 39. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Other, specify: _____           |

40. Were cells (or a portion of cells) expanded ex vivo prior to infusion?

- 1  Yes  
0  No

41. Days of expansion culture:

Growth factors used:

- |     | Yes                        | No                         |                       |
|-----|----------------------------|----------------------------|-----------------------|
| 42. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | G-CSF                 |
| 43. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | GM-CSF                |
| 44. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-2                  |
| 45. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-3                  |
| 46. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-6                  |
| 47. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | SCF                   |
| 48. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Thrombopoietin        |
| 49. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | M-CSF                 |
| 50. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | PIXY 321              |
| 51. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____ |

52. Number of nucleated cells pre-expansion:    .  x 10<sup>10</sup>

53. Number of nucleated cells post-expansion:    .  x 10<sup>10</sup>

54. Total number of nucleated cells infused:    .  x 10<sup>10</sup>

55. Total number of mononucleated cells infused:    .  x 10<sup>10</sup>

56. Were bone marrow progenitor assays done?

- 1  Yes  
0  No

57. Number of CD34+ cells infused:    .  x 10<sup>7</sup> -8  Unknown

**INSERT AUTO PB**

**FOR REGISTRY USE ONLY:**  
I.D. -  
Date received: \_\_\_\_\_

TEAM  IUBMID

*(Institutional Unique Blood or Marrow Transplant Identification Number)*

Registry: **IBMTR** **ABMTR** (circle one)

Date of transplant for which this form is being completed:     
Month Day Year

Date of report:     
Month Day Year

### Autologous Blood Collection and Processing

1. What was the reason for using blood rather than bone marrow for hematopoietic reconstitution?

- 1  All patients receive peripheral blood cells, per protocol
- 2  Bone marrow involvement with tumor
- 3  Prior radiation to pelvis
- 4  Inadequate bone marrow cellularity
- 7  Other, specify: \_\_\_\_\_

2. Date of first stem cell collection:     
Month Day Year

3. Date of last stem cell collection:     
Month Day Year

4. Number of collections:

5. Did patient receive treatment prior to harvesting to enhance stem cell collection?

- 1  Yes
- 0  No

What treatment did patient receive?

6. Chemotherapy:  
1  Yes  
0  No

7. Growth factors:

	Yes	No	
8.	<input type="checkbox"/>	<input type="checkbox"/>	G-CSF
9.	<input type="checkbox"/>	<input type="checkbox"/>	GM-CSF
10.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

11. 1  Yes 0  No Other, specify: \_\_\_\_\_



TEAM

IUBMID

**12. For leukemia/lymphoma patients only:**

What was disease state at time of stem cell collections?

1 <input type="checkbox"/> First remission	Date of remission: <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year
2 <input type="checkbox"/> Second remission	
3 <input type="checkbox"/> Third remission	
4 <input type="checkbox"/> First relapse	
5 <input type="checkbox"/> Second relapse	
7 <input type="checkbox"/> Other, specify: _____	

**13. Were cells cryopreserved?**

- 1  Yes  
0  No

**14. Cryopreservative was:**

- 1  DMSO  
2  Hydroxyethylstarch  
7  Other, specify: \_\_\_\_\_

Indicate whether or not tumor involvement of bone marrow or circulating cells was detected prior to transplant by each of the indicated methods:

	<u>Detected in circulating cells*</u>			<u>Detected in bone marrow, prior to harvest*</u>			<u>Detected in harvested cells (before purging)</u>		
	Yes	No	Not Tested	Yes	No	Not Tested	Yes	No	Not Tested
Routine histopathology	15. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	16. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	17. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Polymerase chain reaction (PCR)	18. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	19. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	20. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Other molecular technique	21. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	22. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	23. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Immunohistochemistry	24. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	25. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	26. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Cell culture technique	27. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	28. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	29. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>
Other, specify: _____	30. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	31. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>	32. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>

\* Refers to detection of tumor cells in circulation or bone marrow in the interval between last chemotherapy and stem cell collection.

TEAM

IUBMID

33. Were cells treated to remove malignant cells (purged)? 1  Yes 0  No

Which of the following were used for purging?

- |     | <u>Yes</u>                 | <u>No</u>                  |  |
|-----|----------------------------|----------------------------|--|
| 34. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Monoclonal antibody, specify: _____  |
| 35. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 4-hydroperoxycyclophosphamide (4HC)  |
| 36. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Mafosfamide  |
| 37. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other drug, specify: _____   |
| 38. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Elutriation  |
| 39. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Immunomagnetic column  |
| 40. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Toxin, specify: _____  |
| 41. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Positive stem cell selection (other than preparation of mononuclear fraction)<br>Specify method: _____ |
| 42. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

Indicate whether or not tumor cells were detected in the graft after purging by each of the indicated methods:

- |     | <u>Yes</u>                 | <u>No</u>                  | <u>Not Tested</u>          |                                 |
|-----|----------------------------|----------------------------|----------------------------|---------------------------------|
| 43. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Routine histopathology          |
| 44. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Polymerase chain reaction (PCR) |
| 45. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Other molecular technique       |
| 46. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Immunohistochemistry            |
| 47. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Cell culture technique          |
| 48. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 7 <input type="checkbox"/> | Other, specify: _____           |

49. Were cells expanded ex vivo prior to infusion?

1  Yes  
0  No

50. Days of expansion culture:

Growth factors used:

- |     | <u>Yes</u>                 | <u>No</u>                  |                       |
|-----|----------------------------|----------------------------|-----------------------|
| 51. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | G-CSF                 |
| 52. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | GM-CSF                |
| 53. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-2                  |
| 54. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-3                  |
| 55. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | IL-6                  |
| 56. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | SCF                   |
| 57. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Thrombopoietin        |
| 58. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | M-CSF                 |
| 59. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | PIXY 321              |
| 60. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____ |

61. Number of nucleated cells pre-expansion:    .  x 10<sup>10</sup>

62. Number of nucleated cells post-expansion:    .  x 10<sup>10</sup>

TEAM

IUBMID

63. Total number of nucleated cells infused:    .  x 10<sup>10</sup>

64. Total number of mononucleated cells infused:    .  x 10<sup>10</sup>

65. Were progenitor cell assays done?

1  Yes

0  No

66. Number of CD34+ cells infused:    .  x 10<sup>7</sup> -8  Unknown

**INSERT VIII**  
**Breast Cancer**

**FOR REGISTRY USE ONLY:**  
I.D. -  
Date received: \_\_\_\_\_

TEAM  IUBMID

(Institutional Unique Blood or Marrow  
Transplant Identification Number)

Registry: **IBMTR**    **ABMTR**    (circle one)

Date of transplant for which  
this form is being completed:        
Month      Day      Year

Date of report:        
Month      Day      Year

**Pretransplant Information**

**\* If this is a report of a second (or subsequent) transplant, check here  and go to Q.168**

1. Date of pathologic diagnosis of breast cancer:       
**Append copy of pathology report if available.**    Month      Year

2. Stage of breast cancer at diagnosis:

- 0 In situ  
 1 I - T<sub>1</sub>N<sub>0</sub>M<sub>0</sub>  
 2 II - T<sub>0,1</sub>N<sub>1</sub>M<sub>0</sub> or T<sub>2</sub>N<sub>0,1</sub>M<sub>0</sub> or T<sub>3</sub>N<sub>0</sub>M<sub>0</sub>  
 3 IIIA - T<sub>0-2</sub>N<sub>2</sub>M<sub>0</sub> or T<sub>3</sub>N<sub>1-2</sub>M<sub>0</sub>  
 4 IIIB - T<sub>4</sub>N<sub>Any</sub>M<sub>0</sub>, T<sub>Any</sub>N<sub>3</sub>M<sub>0</sub>, Inflammatory  
 5 IV - T<sub>Any</sub>N<sub>Any</sub>M<sub>1</sub>  
 8 Unknown

*If transplant was done after  
occurrence of a second primary  
breast cancer, report staging and  
treatment [Q.1-75] of each primary  
separately by copying pages 1-4.*

3. Breast cancer histology at diagnosis:

- 1 Invasive/infiltrating ductal  
 2 Invasive lobular  
 3 Inflammatory  
 4 Other, specify: \_\_\_\_\_  
 8 Unknown

4. Location of breast cancer at diagnosis:

- 1 Right breast  
 2 Left breast  
 3 Bilateral

5. Menopausal status at diagnosis:

- 1 Premenopausal  
 2 Postmenopausal  
 7 Not applicable, male patient  
 8 Unknown

6. Age at menopause:  years

7. Did patient have a history of prior cancer (other than breast cancer)?

- 1 Yes  
 0 No

8. Cite prior disease:  
 1 Hodgkin lymphoma  
 2 Non-Hodgkin lymphoma  
 7 Other, specify: \_\_\_\_\_

9. Date of diagnosis of prior cancer:    
Month      Year

TEAM

IUBMID

10. Were metastases (other than ipsilateral axillary lymph nodes) present at diagnosis?

- 1  Yes
- 0  No

	<u>Yes</u>	<u>No</u>	<u>Unknown</u>	
11.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Bone
12.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Bone marrow
13.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Lung
14.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Liver
15.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Skin
16.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Chest wall
17.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Other lymph nodes, specify site: _____
18.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Other, specify: _____

19. Did patient receive neoadjuvant treatment (includes chemotherapy, hormones and/or radiation) prior to definitive surgery?

- 1  Yes
- 0  No

Go to Q. 38

### Neoadjuvant Treatment

Size of primary tumor (largest diameter before neoadjuvant treatment)

20. Was tumor multicentric?

- 1  Yes
- 0  No
- 8  Unknown

Give size of largest tumor in Q. 21 – 22

21. Clinical size:   cm    -7  Not measurable    -8  Unknown

22. Radiographic size:   cm    -7  Not measurable    -8  Unknown

23. Did patient receive neoadjuvant chemotherapy?

- 1  Yes
- 0  No

Specify chemotherapy:

	<u>Yes</u>	<u>No</u>	
24.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Adriamycin alone
25.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CAF
26.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CMF
27.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	AFM
28.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
29.	Number of cycles: <input type="text"/>		

30. Did patient receive neoadjuvant hormone therapy?

- 1  Yes
- 0  No

Specify hormones:

	<u>Yes</u>	<u>No</u>	
31.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Tamoxifen
32.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
33.	Duration of pre-surgical treatment was: <input type="text"/> <input type="text"/> . <input type="text"/> mos.		

Continued on next page

TEAM

IUBMID

34. Did patient receive neoadjuvant radiation therapy?

- 1  Yes  
0  No

35. Specify radiation field: \_\_\_\_\_

36. Total dose:  cGy (rads)

37. Best clinical response (at time of surgery) to neoadjuvant treatment:

- 1  Complete response  
2  Partial response  
3  Stable disease  
4  Progressive disease  
8  Not evaluable, specify why not evaluable: \_\_\_\_\_

38. Did patient have surgery as part of initial management (include surgery done after neoadjuvant treatment)?

- 1  Yes  
0  No

39. Type of surgery was:

- 1  Mastectomy  
2  Lumpectomy  
7  Other, specify: \_\_\_\_\_

Size of primary tumor at time of definitive surgery; or, if surgery was not done, prior to initial non-surgical treatment

40. Was tumor multicentric?

- 1  Yes  
0  No

Give size of largest tumor in Q.41 – 43

41. Clinical size:  cm -8  Unknown

42. Radiographic size:  cm -8  Unknown

43. Pathologic size:  cm -8  Unknown

44. How many axillary nodes were examined?  -8  Unknown

45. How many axillary nodes were positive for breast cancer?  -8  Unknown

46. Were estrogen receptor assays done?

- 1  Yes  
0  No  
8  Unknown

47. Results:

- 1  Positive 3  Borderline  
2  Negative 8  Unknown

48. Actual value if available (specify units):

49. Units:

- 1  fmol/mg  
7  Other, specify: \_\_\_\_\_

50. Were progesterone receptor assays done?

- 1  Yes  
0  No  
8  Unknown

51. Results:

- 1  Positive 3  Borderline  
2  Negative 8  Unknown

52. Actual value if available (specify units):

53. Units:

- 1  fmol/mg  
7  Other, specify: \_\_\_\_\_

TEAM

IUBMID

54. Did patient receive radiation, chemotherapy and/or hormone treatment (excluding neoadjuvant) after definitive surgery as part of initial management?

- 1  Yes  
0  No

55. Did patient receive radiation treatment?

- 1  Yes  
0  No

Radiation field:

Yes No

56. 1  0  local/regional

57. 1  0  sites of distant metastatic disease

58. 1  0  Other, specify: \_\_\_\_\_

59. Total dose:     cGy (rads)

60. Did patient receive hormones?

- 1  Yes  
0  No

Specify hormones:

Yes No

61. 1  0  Tamoxifen

62. 1  0  Other, specify: \_\_\_\_\_

63. Date started:      
Month Year

64. Date ended:      
Month Year

65. Did patient receive chemotherapy?

- 1  Yes  
0  No

66. Reason for chemotherapy:

1  Adjuvant

2  For metastatic disease — [Go to Q.79](#)

Chemotherapy given:

Yes No

67. 1  0  CMF

68. 1  0  CAF

69. 1  0  Adriamycin-containing regimen

70. 1  0  Taxol alone

71. 1  0  Taxol plus other drugs

72. 1  0  Other chemotherapy, specify:  
\_\_\_\_\_

73. Number of cycles:   -s  Unknown

74. Date started:      
Month Year

75. Date ended:      
Month Year

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76. Did breast cancer recur?

1  Yes  
0  No

77. Date:      
Month Year

78. Site(s): \_\_\_\_\_

79. Did patient receive treatment for persistent, recurrent or metastatic disease? 1  Yes 0  No

Regimen	Date Started	Date Stopped	Number cycles (chemotherapy)	Total dose (radiation)	Non-bone Response (see below)	Bone Response (see below)	Date Relapse/Progression
1st	80. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	81. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	82. <input type="text"/> <input type="text"/>	83. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cGy (rads)	84. <input type="checkbox"/>	85. <input type="checkbox"/>	86. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year
Treatment, specify all drugs given:							
Yes No							
87. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Adriamycin	91. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Methotrexate	94. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Thiotepa		
88. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cytosar	92. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Mitoxantrone	95. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Vinblastine		
89. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cisplatin	93. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Taxol	96. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Other, specify:	_____	
90. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	5-fluorouracil (5-FU)						
2nd	97. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	98. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	99. <input type="text"/> <input type="text"/>	100. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cGy (rads)	101. <input type="checkbox"/>	102. <input type="checkbox"/>	103. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year
Treatment, specify all drugs given:							
Yes No							
104. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Adriamycin	108. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Methotrexate	111. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Thiotepa		
105. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cytosar	109. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Mitoxantrone	112. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Vinblastine		
106. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cisplatin	110. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Taxol	113. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Other, specify:	_____	
107. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	5-fluorouracil (5-FU)						
3rd	114. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	115. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	116. <input type="text"/> <input type="text"/>	117. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cGy (rads)	118. <input type="checkbox"/>	119. <input type="checkbox"/>	120. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year
Treatment, specify all drugs given:							
Yes No							
121. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Adriamycin	125. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Methotrexate	128. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Thiotepa		
122. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cytosar	126. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Mitoxantrone	129. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Vinblastine		
123. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Cisplatin	127. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Taxol	130. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	Other, specify:	_____	
124. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	5-fluorouracil (5-FU)						

**Non-bone response codes:**  
 1 = CR  
 2 = PR  
 3 = stable disease  
 4 = progressive disease

**Bone response codes:**  
 1 = no prior bone disease  
 2 = symptomatic improvement, no progression  
 3 = symptomatic and radiographic (not bone scan only) improvement  
 4 = no response  
 5 = progressive disease  
 6 = not evaluable (radiographic data not available)

Continued on next page



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Regimen	Date Started	Date Stopped	Number cycles (chemotherapy)	Total dose (radiation)	Non-bone Response (see below)	Bone Response (see below)	Date Relapse/Progression																																												
4th	131. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	132. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	133. <input type="text"/> <input type="text"/>	134. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cGy (rads)	135. <input type="text"/>	136. <input type="text"/>	137. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year																																												
Treatment, specify all drugs given:																																																			
<table border="0"> <tr> <td><u>Yes</u></td> <td><u>No</u></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>138. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Adriamycin</td> <td>142. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Methotrexate</td> <td>145. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Thiotepa</td> </tr> <tr> <td>139. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Cytoxan</td> <td>143. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Mitoxantrone</td> <td>146. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Vinblastine</td> </tr> <tr> <td>140. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Cis-platin</td> <td>144. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Taxol</td> <td>147. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>Other, specify: _____</td> </tr> <tr> <td>141. 1 <input type="checkbox"/></td> <td>0 <input type="checkbox"/></td> <td>5-fluorouracil (5-FU)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>								<u>Yes</u>	<u>No</u>							138. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Adriamycin	142. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Methotrexate	145. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Thiotepa	139. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Cytoxan	143. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Mitoxantrone	146. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Vinblastine	140. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Cis-platin	144. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Taxol	147. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____	141. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	5-fluorouracil (5-FU)						
<u>Yes</u>	<u>No</u>																																																		
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5th	148. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	149. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year	150. <input type="text"/> <input type="text"/>	151. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> cGy (rads)	152. <input type="text"/>	153. <input type="text"/>	154. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Year																																												
Treatment, specify all drugs given:																																																			
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<u>Yes</u>	<u>No</u>																																																		
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4 = progressive disease				4 = no response																																															
				5 = progressive disease																																															
				6 = not evaluable (radiographic data not available)																																															

What was the total dose of anthracyclines prior to start of high-dose therapy (conditioning)?

165. Doxorubicin:    mg/m<sup>2</sup> -8  Unknown -7  Not given  
(Adriamycin)
166. Mitoxantrone:    mg/m<sup>2</sup> -8  Unknown -7  Not given
167. Other anthracycline,    mg/m<sup>2</sup> -8  Unknown -7  Not given  
specify: \_\_\_\_\_

TEAM

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168. Was bone marrow biopsy done prior to high-dose conditioning?

- 1  Yes
- 0  No

169. Date of most recent biopsy

Month      Day      Year

170. Was breast cancer present?

- 1  Yes
- 0  No

How was it detected?

		<u>Yes</u>	<u>No</u>	<u>Not tested</u>	
171.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Routine histopathology
172.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		PCR (polymerase chain reaction)
173.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Other molecular technique
174.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Immunohistochemistry
175.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Cell culture technique
176.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Other, specify: _____

177. Did patient ever have bone marrow involvement with breast cancer other than involvement indicated in Q.168?

- 1  Yes
- 0  No

How was it detected?

		<u>Yes</u>	<u>No</u>	<u>Not tested</u>	
178.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Routine histopathology
179.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		PCR (polymerase chain reaction)
180.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Other molecular technique
181.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Immunohistochemistry
182.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Cell culture technique
183.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	7 <input type="checkbox"/>		Other, specify: _____

184. What was status of disease immediately prior to start of conditioning?

- 1  Complete response - no evidence of disease
- 2  Complete response with exception of bone scan abnormalities of unknown significance
- 3  Partial response
- 4  Stable
- 5  Progressive disease

Indicate all sites of disease involvement:

	<u>At any time between diagnosis and transplant</u>			<u>Immediately prior to start of conditioning</u>		
	<u>Yes</u>	<u>No</u>	<u>Unknown</u>	<u>Yes</u>	<u>No</u>	<u>Unknown</u>
Breast	185.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	185.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Chest wall	186.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	186.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Bone - symptomatic	187.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	187.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Bone - radiographic	188.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	188.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Axillary lymph nodes	189.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	189.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Other lymph nodes	190.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	190.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Brain	191.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	191.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Lung	192.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	192.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Pleura	193.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	193.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Liver	194.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	194.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Skin	195.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	195.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
Other, specify:	196.1. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	196.2. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>

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197. What was sensitivity of breast cancer to chemotherapy prior to conditioning? (*Response to last chemotherapy given prior to transplant; chemotherapy must include  $\geq 2$  cycles treatment given  $\leq 6$  months prior to transplant*)

- 1  Sensitive:  $\geq 50\%$  reduction in bidimensional diameter of all disease sites with no new sites of disease
- 2  Resistant:  $< 50\%$  reduction in diameter of all disease sites or development of new disease sites
- 3  Untreated
- 8  Unknown

### Outcome

198. What was patient's best response to transplant excluding planned posttransplant treatment?

- 1  Complete response: complete disappearance of all known disease for  $\geq 4$  weeks
- 2  Complete response with persistent bone scan/x-ray abnormalities of unknown significance
- 3  Partial response:  $\geq 50\%$  reduction in greatest diameter of all sites of known disease and no new sites of disease for  $\geq 4$  weeks
- 4  No response:  $< 50\%$  reduction in greatest diameter of all sites of known disease and no new sites of disease
- 5  Progressive disease: increase in size of sites of known disease or new sites of disease
- 6  Not evaluable, toxic death
- 7  Not evaluable, other reason, specify: \_\_\_\_\_

199. Was planned treatment (treatment before progressive disease) given posttransplant?

- 1  Yes
- 0  No

Go to Q.207

200. Was disease restaged prior to planned posttransplant treatment?

- 1  Yes
- 0  No

Specify treatment given whether restaged or not:

- |      | Yes                        | No                         |                                   |
|------|----------------------------|----------------------------|-----------------------------------|
| 201. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Chemotherapy, specify: _____      |
| 202. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Hormone therapy, specify: _____   |
| 203. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Radiation therapy, specify: _____ |
| 204. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Immune therapy, specify: _____    |
| 205. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____             |

206. What was patient's best response to transplant including planned posttransplant treatment?

- 1  Complete response: complete disappearance of all known disease for  $\geq 4$  weeks
- 2  Complete response with persistent bone scan/x-ray abnormalities of unknown significance
- 3  Partial response:  $\geq 50\%$  reduction in greatest diameter of all sites of known disease and no new sites of disease for  $\geq 4$  weeks
- 4  No response:  $< 50\%$  reduction in greatest diameter of all sites of known disease and no new sites of disease
- 5  Progressive disease: increase in size of sites of known disease or new sites of disease
- 6  Not evaluable, toxic death
- 7  Not evaluable, other reason, specify: \_\_\_\_\_

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**207. Status of breast cancer: (at time of this report or at time of death)**

- 1  Free of breast cancer; no recurrence posttransplant
- 2  Free of breast cancer except for persistent scan abnormalities of unknown significance, no recurrence posttransplant
- 3  Persistent breast cancer without progression (*never achieved complete response*)
- 4  Progressive disease (*never achieved complete response*)

Date of progression       Site(s): \_\_\_\_\_  
 Month Day Year

- 5  Recurrent disease (relapse after complete response)

Date of recurrence       Site(s): \_\_\_\_\_  
 Month Day Year

- 6  Free of breast cancer after posttransplant recurrence

Date of recurrence       Site(s): \_\_\_\_\_  
 Month Day Year

- 7  Not evaluable; explain: \_\_\_\_\_

**First site(s) of progression/recurrence:**

	<u>Yes</u>	<u>No</u>	
208.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lymph node
209.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Bone marrow
210.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CNS
211.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Liver
212.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lung
213.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Local
214.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Contralateral breast
215.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

216. Date status established:        
 Month Day Year

**FOLLOW-UP CORE FORM**


**FOR REGISTRY USE ONLY:**  
 I.D. --  
 Date received:

TEAM  IUBMID   
 (Institutional Unique Blood or Marrow Transplant Identification Number)

Registry: **IBMTR** **ABMTR** (circle one)

Date of transplant for which this form is being completed:     
 Month Day Year


Date of report:     
 Month Day Year



**IBMTR**  
International Bone Marrow Transplant Registry

**IBMTR/ABMTR**

Series 095 Reporting Forms



**ABMTR**  
North America  
Autologous Blood & Marrow Transplant Registry

**Follow-up Information**

For living patients, submit follow-up data every 12 months from date of transplant. If patient died since last report, indicate findings present at time of death. For patients lost to follow-up since last report, submit last known information. If another transplant was done since last report, provide information only until date of conditioning for subsequent transplant. If patient received peripheral blood leukocytes from original allogeneic donor since last report to treat relapse, lymphoproliferative disorder, viral infection or graft failure, provide information only until date of infusion (see Q. 33 of this report).

1. Date of last report:     
 Month Day Year
2. Patient birthdate:     
 Month Day Year
3. Date of last actual contact with patient to determine medical status for this report:     
 Month Day Year

**Survival and Functional Status**

4. Was patient alive on the day of last contact?

- 1  Yes  
 0  No ——— Go to Q. 15

5. If the patient is 16 years of age or older, complete the Karnofsky Scale. If the patient is younger than 16 years of age, complete the Lansky Scale.

Karnofsky Scale (age ≥16 yrs)	Lansky Scale (age <16 yrs)
<p>Select phrase which best describes activity status:</p> <p><b>Able to carry on normal activity; no special care is needed.</b></p> <p><input type="checkbox"/> 100 Normal; no complaints; no evidence of disease</p> <p><input type="checkbox"/> 90 Able to carry on normal activity</p> <p><input type="checkbox"/> 80 Normal activity with effort</p> <p><b>Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.</b></p> <p><input type="checkbox"/> 70 Cares for self; unable to carry on normal activity or to do active work</p> <p><input type="checkbox"/> 60 Requires occasional assistance but is able to care for most needs</p> <p><input type="checkbox"/> 50 Requires considerable assistance and frequent medical care</p> <p><b>Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.</b></p> <p><input type="checkbox"/> 40 Disabled; requires special care and assistance</p> <p><input type="checkbox"/> 30 Severely disabled; hospitalization indicated, although death not imminent</p> <p><input type="checkbox"/> 20 Very sick; hospitalization necessary</p> <p><input type="checkbox"/> 10 Moribund; fatal process progressing rapidly</p>	<p>Select phrase which best describes the activity status:</p> <p><b>Normal range.</b></p> <p><input type="checkbox"/> 100 Fully active</p> <p><input type="checkbox"/> 90 Minor restriction in physically strenuous play</p> <p><input type="checkbox"/> 80 Restricted in strenuous play, tires more easily, otherwise active</p> <p><b>Mild to moderate restriction.</b></p> <p><input type="checkbox"/> 70 Both greater restrictions of, and less time spent in, active play</p> <p><input type="checkbox"/> 60 Ambulatory up to 50% of time, limited active play with assistance/supervision</p> <p><input type="checkbox"/> 50 Considerable assistance required for any active play; fully able to engage in quiet play</p> <p><b>Moderate to severe restriction.</b></p> <p><input type="checkbox"/> 40 Able to initiate quiet activities</p> <p><input type="checkbox"/> 30 Needs considerable assistance for quiet activity</p> <p><input type="checkbox"/> 20 Limited to very passive activity initiated by others (i.e., TV)</p> <p><input type="checkbox"/> 10 Completely disabled, not even passive play</p>

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6. Patient currently attends school:

1  Yes  
0  No

7. 1  Part-time 2  Full-time 8  Unknown whether part-time or full-time

8. Date returned to school:     or  Reported previously  
Month Year

9. Patient was employed outside the home prior to current illness:

1  Yes  
0  No

10. Patient has been employed outside the home since transplant:

1  Yes  
0  No

11. Date returned to work:     or  Reported previously  
Month Year

12. Patient able to work but is not employed:  
1  Yes  
0  No

13. Patient has resumed all household activities:

1  Yes  
0  No

14. Approximate date resumed all activities:     or  Reported previously  
Month Year

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15. Did patient receive a blood or marrow infusion since the date of last report?  
(other than peripheral blood leukocytes or T-lymphocytes from original allogeneic donor)

- 1  Yes  
0  No

16. Date of subsequent infusion:        
Month Day Year

17. Reason for subsequent infusion:

- 1  No engraftment  
2  Partial engraftment  
3  Late graft failure  
4  Persistent malignancy  
5  Relapse  
6  Planned second transplant, per protocol  
7  Other, specify: \_\_\_\_\_

18. Type of graft:

- 1  Allogeneic, related  
2  Allogeneic, unrelated  
3  Autologous

19. Donor

- 1  Same donor  
2  Different donor  
3  Not applicable,  
initial transplant  
was autologous

Source of cells:

- |     | Yes                        | No                         |                       |
|-----|----------------------------|----------------------------|-----------------------|
| 20. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Cryopreserved         |
| 21. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bone marrow           |
| 22. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Peripheral blood      |
| 23. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Umbilical cord blood  |
| 24. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Fetal tissue          |
| 25. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____ |

Answers to all questions in this report should reflect clinical status immediately prior to start of conditioning for subsequent infusion. A separate report covering the subsequent transplant must be submitted.

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26. *Allografts only:* Has patient received an infusion of peripheral blood leukocytes or T-lymphocytes from the original donor since date of last report?

- 1  Yes  
0  No

27. Date first infusion given:        
Month Day Year

28. Patient weight within 2 weeks of first infusion:     .  kg

29. Total number of infusions:

30. Total dose of mononuclear cells infused:     .  x 10<sup>10</sup>

31. Were cells manipulated prior to infusion?

- 1  Yes  
0  No

32. Indicate method:

Yes		No	
1 <input type="checkbox"/>	0 <input type="checkbox"/>	1 <input type="checkbox"/>	0 <input type="checkbox"/>
T-cell depletion			
1 <input type="checkbox"/>	0 <input type="checkbox"/>	1 <input type="checkbox"/>	0 <input type="checkbox"/>
CD34 selection			
1 <input type="checkbox"/>	0 <input type="checkbox"/>	1 <input type="checkbox"/>	0 <input type="checkbox"/>
Other, specify: _____			

33. Indication for the infusion(s) of donor cells:

- 1  Prophylaxis against B-cell lymphoproliferative disorder or viral infection  
2  Prophylaxis against relapse

- 3  Treatment of relapse  
4  Treatment of B-cell lymphoproliferative disorder  
5  Treatment of viral infection, specify: \_\_\_\_\_  
6  Graft failure  
7  Other, specify: \_\_\_\_\_

*If answers 3 – 7 were selected, then answers to all questions in this report should reflect clinical status immediately prior to infusion. This is considered a transplant and a separate report covering this infusion and post-infusion events must be submitted.*



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## Hematopoietic Reconstitution

34. Has patient received hematopoietic growth factors or cytokines since last report?

1  Yes    0  No

**Coding for Indication of Therapy (below)**

1. Intervention for delay/decline in Absolute Neutrophil Count (ANC)
2. Intervention for delay/decline in platelets
3. Intervention for delay/decline in both ANC and platelets
4. Intervention for delay/decline in red blood cell counts
5. Anti-leukemic or tumor agent to prevent relapse
6. Anti-leukemic or tumor agent to treat relapse
7. Other indication

Specify agents given:

			Date Started			Date Stopped			Indication			
	Yes	No	Month	Day	Year	Month	Day	Year				
G-CSF	35.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	36.	<input type="text"/>	<input type="text"/>	<input type="text"/>	37.	<input type="text"/>	<input type="text"/>	<input type="text"/>	38.	<input type="checkbox"/>
GM-CSF	39.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	40.	<input type="text"/>	<input type="text"/>	<input type="text"/>	41.	<input type="text"/>	<input type="text"/>	<input type="text"/>	42.	<input type="checkbox"/>
Erythropoietin	43.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	44.	<input type="text"/>	<input type="text"/>	<input type="text"/>	45.	<input type="text"/>	<input type="text"/>	<input type="text"/>	46.	<input type="checkbox"/>
Thrombopoietin	47.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	48.	<input type="text"/>	<input type="text"/>	<input type="text"/>	49.	<input type="text"/>	<input type="text"/>	<input type="text"/>	50.	<input type="checkbox"/>
Interleukin-2	51.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	52.	<input type="text"/>	<input type="text"/>	<input type="text"/>	53.	<input type="text"/>	<input type="text"/>	<input type="text"/>	54.	<input type="checkbox"/>
Interleukin-3	55.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	56.	<input type="text"/>	<input type="text"/>	<input type="text"/>	57.	<input type="text"/>	<input type="text"/>	<input type="text"/>	58.	<input type="checkbox"/>
Interleukin-6	59.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	60.	<input type="text"/>	<input type="text"/>	<input type="text"/>	61.	<input type="text"/>	<input type="text"/>	<input type="text"/>	62.	<input type="checkbox"/>
PIXY-321	63.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	64.	<input type="text"/>	<input type="text"/>	<input type="text"/>	65.	<input type="text"/>	<input type="text"/>	<input type="text"/>	66.	<input type="checkbox"/>
Stem Cell Factor (SCF)	67.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	68.	<input type="text"/>	<input type="text"/>	<input type="text"/>	69.	<input type="text"/>	<input type="text"/>	<input type="text"/>	70.	<input type="checkbox"/>
Interferon-alpha	71.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	72.	<input type="text"/>	<input type="text"/>	<input type="text"/>	73.	<input type="text"/>	<input type="text"/>	<input type="text"/>	74.	<input type="checkbox"/>
Interferon-gamma	75.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	76.	<input type="text"/>	<input type="text"/>	<input type="text"/>	77.	<input type="text"/>	<input type="text"/>	<input type="text"/>	78.	<input type="checkbox"/>
Blinded growth factor trial, specify agent(s) being studied:	79.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	80.	<input type="text"/>	<input type="text"/>	<input type="text"/>	81.	<input type="text"/>	<input type="text"/>	<input type="text"/>	82.	<input type="checkbox"/>
Other, specify:	83.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	84.	<input type="text"/>	<input type="text"/>	<input type="text"/>	85.	<input type="text"/>	<input type="text"/>	<input type="text"/>	86.	<input type="checkbox"/>

87. Did patient receive other courses of growth factors or cytokines since last report?

1  Yes

0  No

8  Unknown

*Photocopy Q.35-86 and answer for each additional course given.*

**NOTE:** A new course includes starting a new agent, restarting a previously administered agent for a new indication or restarting a previously administered agent for the same indication but  $\geq 30$  days after discontinuing the agent.

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## Granulopoiesis

88. Did patient achieve an initial hematopoietic recovery ( $ANC \geq 500/mm^3$  for 3 consecutive days) since last report?

1  Yes

89. Date  $ANC \geq 500/mm^3$ :     Date unknown  
(First of 3 consecutive days) Month Day Year

90. Was  $ANC \geq 1000/mm^3$  achieved and sustained for 3 consecutive days?

1  Yes

0  No

91. Date achieved:     Date unknown  
(first of 3 consecutive days) Month Day Year

Go to Q. 92

2  No, patient's initial hematopoietic recovery was recorded on a previous report

Go to Q. 92

3  No, patient has never achieved an  $ANC \geq 500/mm^3$  for three consecutive days and there is no evidence of recurrent disease

Go to Q. 96

4  No, patient has never achieved an  $ANC \geq 500/mm^3$  for three consecutive days and there was documented persistent malignant disease posttransplant

Go to Q. 96

92. Following initial hematopoietic recovery ( $ANC \geq 500/mm^3$  for three consecutive days) did the patient experience a subsequent decline in  $ANC$  to  $< 500/mm^3$  for greater than three days since last report?

1  Yes

0  No

Go to Q. 117

93. Date of decline in  $ANC$  to  $< 500/mm^3$  for greater than 3 days:     
(First of 3 days that  $ANC$  declined) Month Day Year

Date unknown

94. Did patient recover and maintain  $ANC \geq 500/mm^3$  following the decline?

1  Yes

0  No

95. Date of  $ANC$  recovery:     Date unknown  
Month Day Year

Go to Q. 96

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Suspected etiology of failure to achieve ANC > 500/mm<sup>3</sup> or of a decline in ANC:

96. Persistent disease or relapse:

- 1  Yes
- 0  No
- 8  Unknown

97. Graft versus host disease:

- 1  Yes
- 0  No
- 8  Unknown

98. Immune-mediated rejection:

- 1  Yes
- 0  No
- 8  Unknown

99. Non-viral infection:

- 1  Yes
- 0  No
- 8  Unknown

100. Suspected viral infection:

- 1  Yes
- 0  No
- 8  Unknown

Virus suspected:

- |      | <u>Yes</u>                 | <u>No</u>                  |                                  |
|------|----------------------------|----------------------------|----------------------------------|
| 101. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Cytomegalovirus (CMV)            |
| 102. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Human Herpes Virus Type 6 (HHV6) |
| 103. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Herpes Simplex Virus (HSV)       |
| 104. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Varicella                        |
| 105. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____         |

106. Documented viral infection:

- 1  Yes
- 0  No
- 8  Unknown

Virus involved:

- |      | <u>Yes</u>                 | <u>No</u>                  |                                  |
|------|----------------------------|----------------------------|----------------------------------|
| 107. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Cytomegalovirus (CMV)            |
| 108. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Human Herpes Virus Type 6 (HHV6) |
| 109. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Herpes Simplex Virus (HSV)       |
| 110. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Varicella                        |
| 111. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____         |

112. Drugs:

- 1  Yes
- 0  No
- 8  Unknown

- |      | <u>Yes</u>                 | <u>No</u>                  |   |
|------|----------------------------|----------------------------|---|
| 113. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Ganciclovir                                       |
| 114. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bactrim, Septra,<br>Trimethoprim-sulfamethoxazole |
| 115. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify:<br>_____                          |

116. Etiology undetermined:

- 1  Yes
- 0  No

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### Megakaryopoiesis

The following questions relate to initial platelet recovery. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory results.

117. Did recipient achieve an initial platelet count of  $\geq 20 \times 10^9/L$  since last report?

- 1  Yes ————— **Go to Q. 118**
- 2  No, recipient achieved a platelet count of  $\geq 20 \times 10^9/L$  but  $< 50 \times 10^9/L$  prior to last report ————— **Go to Q. 119**
- 3  No, recipient achieved a platelet count of  $\geq 50 \times 10^9/L$  but  $< 100 \times 10^9/L$  prior to last report ————— **Go to Q. 121**
- 4  No, recipient achieved a platelet count of  $\geq 100 \times 10^9/L$  prior to last report ————— **Go to Q. 125**
- 0  No, recipient never achieved a platelet count of  $\geq 20 \times 10^9/L$  ————— **Go to Q. 123**

118. Date platelets  $\geq 20 \times 10^9/L$ :     Date unknown  
Month Day Year

119. Was a platelet count of  $\geq 50 \times 10^9/L$  achieved?

- 1  Yes —————
  - 0  No ————— **Go to Q. 123**
  - 8  Unknown —————
120. Date platelets  $\geq 50 \times 10^9/L$ :     Date unknown  
Month Day Year

121. Was a platelet count of  $\geq 100 \times 10^9/L$  achieved?

- 1  Yes —————
  - 0  No —————
  - 8  Unknown —————
122. Date platelets  $\geq 100 \times 10^9/L$ :     Date unknown  
Month Day Year

123. Was recipient ever platelet transfusion independent?

- 1  Yes —————
  - 0  No —————
124. Date of the last platelet transfusion:\*
- Date unknown  
Month Day Year
- \*If recipient was platelet transfusion independent for  $\geq 14$  days but subsequently experienced a decline in platelet count and required platelet transfusions, record date of last platelet transfusion before decline in counts. If recipient has not required platelet transfusions since initial platelet recovery record date of last platelet transfusion.

Go to Q. 125 if platelet count of  $\geq 20 \times 10^9/L$  achieved; otherwise go to Q. 133

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125. After initial recovery to platelet count  $\geq 20 \times 10^9/L$  did the platelet count decline to  $< 20 \times 10^9/L$  for 3 consecutive laboratory values or decline to  $< 20 \times 10^9/L$  for one laboratory value and the recipient received a platelet transfusion?

1  Yes

2  No

Go to Q. 159 if platelet count of  $\geq 100 \times 10^9/L$  achieved, otherwise go to Q. 133

126. Date of the first day that platelet count declined below  $20 \times 10^9/L$ :

Month

Day

Year

Date unknown

127. Has platelet count recovered?

1  Yes

0  No

Go to Q. 133

The following date questions relate to **subsequent** platelet recovery following a decline of platelet count to below  $20 \times 10^9/L$ . All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory values.

128. Was a platelet count of  $\geq 20 \times 10^9/L$  achieved?

1  Yes

0  No

Go to Q. 131

129. Was a platelet count of  $\geq 50 \times 10^9/L$  achieved?

1  Yes

0  No

Go to Q. 131

130. Was a platelet count of  $\geq 100 \times 10^9/L$  achieved?

1  Yes

0  No

131. Was patient ever transfusion independent following recovery from decline?

1  Yes

0  No

132. Date of the last platelet transfusion (following recovery from decline):

Month

Day

Year

Date unknown

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Suspected etiology of failure to achieve a platelet count  $\geq 100 \times 10^9/L$  or decline in platelet count to  $< 20 \times 10^9/L$ :

<b>133. Persistent disease or relapse:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown	<b>134. Graft versus host disease:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown																								
<b>135. Non-viral infection:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown																									
<b>136. Immune-mediated:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown	<b>Immune mediated etiology:</b> <table border="1"><thead><tr><th></th><th>Yes</th><th>No</th><th></th></tr></thead><tbody><tr><td><b>137.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Cellular</td></tr><tr><td><b>138.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Antibody</td></tr><tr><td><b>139.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Third party engraftment</td></tr><tr><td><b>140.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Unknown</td></tr></tbody></table>		Yes	No		<b>137.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Cellular	<b>138.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Antibody	<b>139.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Third party engraftment	<b>140.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Unknown				
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	Yes	No																							
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	Yes	No																							
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<b>151.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Varicella																						
<b>152.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____																						
<b>153. Drugs:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown	<b>Therapy:</b> <table border="1"><thead><tr><th></th><th>Yes</th><th>No</th><th></th></tr></thead><tbody><tr><td><b>154.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Ganciclovir</td></tr><tr><td><b>155.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Bactrim, Septra, Trimethoprim-sulfamethoxazole</td></tr><tr><td><b>156.</b></td><td>1 <input type="checkbox"/></td><td>0 <input type="checkbox"/></td><td>Other, specify: _____</td></tr></tbody></table>		Yes	No		<b>154.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Ganciclovir	<b>155.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Bactrim, Septra, Trimethoprim-sulfamethoxazole	<b>156.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____								
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<b>156.</b>	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____																						
<b>157. Veno-occlusive disease (VOD):</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown																									
<b>158. Etiology undetermined:</b> 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No																									

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## Erythropoiesis

159. Has patient received red blood cell (RBC) transfusions since last report?

- 1  Yes  
0  No

160. Date of last RBC transfusion: \*     Date unknown  
Month Day Year

*\* If patient was RBC transfusion independent for  $\geq 1$  month but subsequently experienced a decline in RBC count and required RBC transfusions, record date of last RBC transfusion before decline in counts. If patient has not required RBC transfusions since initial date of recovery, record date of last RBC transfusion.*

### Current Hematologic Findings

161. Date of most recent CBC:     
Month Day Year

#### Actual CBC results:

162. WBC  .  x 10<sup>9</sup>/L
163. Neutrophils  %
164. Lymphocytes  %
165. Hemoglobin  .  g/dL  Transfused
166. Hematocrit  %  Transfused
167. Platelets  x 10<sup>9</sup>/L  Transfused

168. Were chimerism studies performed since last report?

- 1  Yes —
- 0  No —

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**Autotransplants only  
Chimerism Studies**

*(Provide date(s), method(s) and other information for all chimerism studies performed since date of last report)*

Date	Method (See Valid List Below)	Cell Type (See Valid List Below)	Number of Cells Examined (Total Cells)		Number of Donor Cells	Number of Host Cells	Number of Unknown Origin (third party) Cells	Percent Donor Cells		Percent Host Cells		Percent Unknown Origin (third party) Cells	
			Month	Year				Quant.	*Non- Quant.	Quant.	*Non- Quant.	Quant.	*Non- Quant.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**Valid Cell Types**  
(Insert number in box above to indicate cell type used)

- 1 - Bone Marrow (BM)
- 2 - Peripheral Blood Mononuclear Cells (PBMC)
- 3 - T-Cells
- 4 - B-Cells
- 5 - Red Cells
- 6 - Monocytes
- 7 - Neutrophils
- 8 - Other, specify: \_\_\_\_\_

**Valid Method Codes**  
(Insert number in box above to indicate method used)

- 1 - Standard Cytogenetics
- 2 - Fluorescent In situ Hybridization (FISH)
- 3 - Restriction Fragment-length polymorphisms (RFLP)
- 4 - Polymerase Chain Reaction (PCR)
- 5 - HLA Serotyping
- 6 - VNTR
- 7 - Other, specify: \_\_\_\_\_

\* If performed by non-quantitative method, indicate the presence of donor, host or third party cells by (+)



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### Graft-vs-Host Disease (GVHD)

169. Was specific therapy used since last report to prevent or induce GVHD, or promote engraftment?

- 1  Yes
- 0  No
- 8  Unknown

Allografts:  
Go to Q. 186

Autografts:  
Go to Q. 326

For each agent listed below indicate whether or not it was used to prevent or induce GVHD since last report:

	Yes	No		Yes	No	
170.	<input type="checkbox"/>	<input type="checkbox"/>	Methotrexate	178.	<input type="checkbox"/>	Anti IL-2
171.	<input type="checkbox"/>	<input type="checkbox"/>	Cyclosporine	179.	<input type="checkbox"/>	Anti CD 25
172.	<input type="checkbox"/>	<input type="checkbox"/>	FK 506 (Tacrolimus)	180.	<input type="checkbox"/>	Campath
173.	<input type="checkbox"/>	<input type="checkbox"/>	Corticosteroids	181.	<input type="checkbox"/>	OKT3
174.	<input type="checkbox"/>	<input type="checkbox"/>	ALS, ALG, ATS, ATG	182.	<input type="checkbox"/>	Other, specify: _____
175.	<input type="checkbox"/>	<input type="checkbox"/>	Azathioprine			
176.	<input type="checkbox"/>	<input type="checkbox"/>	Cyclophosphamide			
177.	<input type="checkbox"/>	<input type="checkbox"/>	In vivo anti T-lymphocyte monoclonal antibody: _____			
183.	<input type="checkbox"/>	<input type="checkbox"/>	In vivo immunotoxin, specify: _____			
184.	<input type="checkbox"/>	<input type="checkbox"/>	Blinded randomized trial; specify agent being studied: _____			
185.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____			

186. Was acute GVHD present at time of last report?

- 1  Yes — **Go to Q. 195**
- 0  No

187. Did acute GVHD develop since date of last report?

- 1  Yes
- 0  No
- 8  Unknown

**Go to Q. 238**

188. Date of onset:     
Month Day Year

What was diagnosis based on?

189. Histologic evidence:

- 1  Yes
- 0  No

Sites:

	Yes	No	
190.	<input type="checkbox"/>	<input type="checkbox"/>	Skin
191.	<input type="checkbox"/>	<input type="checkbox"/>	Gut
192.	<input type="checkbox"/>	<input type="checkbox"/>	Liver
193.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

194. Clinical evidence:

- 1  Yes
- 0  No

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195. Maximum overall grade since last report: 1  I 2  II 3  III 4  IV

List the maximum severity of organ involvement attributed to acute GVHD:

<u>Stage 0</u>	<u>Stage 1</u>	<u>Stage 2</u>	<u>Stage 3</u>	<u>Stage 4</u>
196. Skin:				
1 <input type="checkbox"/> No rash	2 <input type="checkbox"/> Maculopapular rash, <25% of body surface	3 <input type="checkbox"/> Maculopapular rash, 25-50% of body surface	4 <input type="checkbox"/> Generalized erythroderma	5 <input type="checkbox"/> Generalized erythroderma with bullae formation and desquamation

197. Intestinal tract (use ml/day for adult patients and ml/m<sup>2</sup>/day for pediatric patients):

0 <input type="checkbox"/> No diarrhea	2 <input type="checkbox"/> Diarrhea >500 but ≤1000 ml/day or 280-555 ml/m <sup>2</sup> /day	3 <input type="checkbox"/> Diarrhea >1000 but ≤1500 ml/day or 556-833 ml/m <sup>2</sup> /day	4 <input type="checkbox"/> Diarrhea >1500 ml/day or >833 ml/m <sup>2</sup> /day	5 <input type="checkbox"/> Severe abdominal pain, with or without ileus
1 <input type="checkbox"/> Diarrhea ≤500 ml/day or <280 ml/m <sup>2</sup> /day				

198. Liver:

1 <input type="checkbox"/> Bilirubin <2.0 mg/dL	2 <input type="checkbox"/> Bilirubin 2.0-3.0 mg/dL	3 <input type="checkbox"/> Bilirubin 3.1-6.0 mg/dL	4 <input type="checkbox"/> Bilirubin 6.1-15.0 mg/dL	5 <input type="checkbox"/> Bilirubin >15.0 mg/dL
---	--	--	---	--

199. Other organ involvement?

1  Yes  
0  No

	<u>Yes</u>	<u>No</u>	
200.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Upper GI tract
201.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lung
202.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

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203. Was specific therapy used to **treat** acute GVHD since last report? 1  Yes 0  No

For each agent listed below indicate whether or not it was used to **treat** acute GVHD

	No. drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking?	
					Yes	No
204. Methotrexate	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	205. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
206. Cyclosporine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	207. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
208. FK 506 (Tacrolimus)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	209. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
210. Systemic Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	211. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
212. Topical Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	213. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
214. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	215. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
216. Azathioprine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	217. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
218. Cyclophosphamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	219. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
220. Thalidomide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	221. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

In vivo anti-T-lymphocyte monoclonal antibody:

222. Anti IL-2	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	223. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
224. Anti CD 25	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	225. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
226. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	227. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
228. OKT3	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	229. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
230. Other, antibody specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	231. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
232. In vivo immunotoxin, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	233. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
234. Blinded randomized trial; specify agent(s) being studied: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	235. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
236. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	237. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

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238. Was chronic GVHD present at time of last report?

- 1  Yes
- 0  No

239. Chronic GVHD is still present or was present at time of death:

- 1  Yes — Go to Q. 256
- 0  No

240. Did clinical chronic GVHD develop since date of last report?

- 1  Yes
- 0  No
- 8  Unknown

Go to Q. 326

241. Date of onset:  /  /   
Month Day Year

242. Progressed from acute GVHD?

- 1  Yes
- 0  No

243. Karnofsky/Lansky score (see page 1) at diagnosis of chronic GVHD:

244. Platelet count at diagnosis of chronic GVHD:  .  x 10<sup>9</sup>/L

245. Total serum bilirubin at diagnosis of chronic GVHD:  .

Unit of measurement for bilirubin:

- 1  mg/dL
- 2  μmol/L

What was diagnosis based on?

246. Histologic evidence:

- 1  Yes
- 0  No

255. Clinical evidence:

- 1  Yes
- 0  No

Sites:		
	Yes No	
247.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Skin
248.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Gut
249.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Liver
250.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Buccal mucosa/lip
251.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Conjunctiva
252.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Lung
253.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Muscle
254.	1 <input type="checkbox"/> 0 <input type="checkbox"/>	Other, specify: _____

Continued on next page

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**256. Maximum grade of chronic GVHD:**

- 1  Limited (*Localized skin involvement and/or hepatic dysfunction due to chronic GVHD*)
- 2  Extensive (*Generalized skin involvement; or localized skin involvement and/or hepatic dysfunction due to chronic GVHD, plus:*
  - Liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
  - Involvement of eye: Schirmer's test with < 5 mm wetting; or,
  - Involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or,
  - Involvement of any other target organ)

**257. Overall severity:** 1  Mild 2  Moderate 3  Severe

Indicate organ involvement with chronic GVHD from list below:

- |                  |      | Yes                      | No                       |   |
|------------------|------|--------------------------|--------------------------|---|
| Skin/Hair:       | 258. | <input type="checkbox"/> | <input type="checkbox"/> | Subclinical (biopsy findings only)                |
|                  | 259. | <input type="checkbox"/> | <input type="checkbox"/> | Rash  |
|                  | 260. | <input type="checkbox"/> | <input type="checkbox"/> | Scleroderma                                       |
|                  | 261. | <input type="checkbox"/> | <input type="checkbox"/> | Dyspigmentation                                   |
|                  | 262. | <input type="checkbox"/> | <input type="checkbox"/> | Contractures                                      |
|                  | 263. | <input type="checkbox"/> | <input type="checkbox"/> | Alopecia  |
|                  | 264. | <input type="checkbox"/> | <input type="checkbox"/> | Other skin/hair involvement, specify: _____       |
| Eyes:            | 265. | <input type="checkbox"/> | <input type="checkbox"/> | Dry eyes  |
|                  | 266. | <input type="checkbox"/> | <input type="checkbox"/> | Corneal erosion/conjunctivitis                    |
|                  | 267. | <input type="checkbox"/> | <input type="checkbox"/> | Other eye involvement, specify: _____             |
| Mouth:           | 268. | <input type="checkbox"/> | <input type="checkbox"/> | Lichenoid changes                                 |
|                  | 269. | <input type="checkbox"/> | <input type="checkbox"/> | Mucositis/ulcers                                  |
|                  | 270. | <input type="checkbox"/> | <input type="checkbox"/> | Other mouth involvement, specify: _____           |
| Lung:            | 271. | <input type="checkbox"/> | <input type="checkbox"/> | Bronchiolitis obliterans                          |
|                  | 272. | <input type="checkbox"/> | <input type="checkbox"/> | Other lung involvement, specify: _____            |
| GI Tract:        | 273. | <input type="checkbox"/> | <input type="checkbox"/> | Esophageal involvement                            |
|                  | 274. | <input type="checkbox"/> | <input type="checkbox"/> | Chronic nausea/vomiting                           |
|                  | 275. | <input type="checkbox"/> | <input type="checkbox"/> | Chronic diarrhea                                  |
|                  | 276. | <input type="checkbox"/> | <input type="checkbox"/> | Malabsorption                                     |
|                  | 277. | <input type="checkbox"/> | <input type="checkbox"/> | Other GI tract involvement, specify: _____        |
| Liver:           | 278. | <input type="checkbox"/> | <input type="checkbox"/> | Liver involvement, specify: _____                 |
| GU Tract:        | 279. | <input type="checkbox"/> | <input type="checkbox"/> | Vaginitis/stricture                               |
|                  | 280. | <input type="checkbox"/> | <input type="checkbox"/> | Other GU involvement, specify: _____              |
| Musculoskeletal: | 281. | <input type="checkbox"/> | <input type="checkbox"/> | Arthritis   |
|                  | 282. | <input type="checkbox"/> | <input type="checkbox"/> | Myositis  |
|                  | 283. | <input type="checkbox"/> | <input type="checkbox"/> | Myasthenia  |
|                  | 284. | <input type="checkbox"/> | <input type="checkbox"/> | Other musculoskeletal involvement, specify: _____ |
| Hematologic:     | 285. | <input type="checkbox"/> | <input type="checkbox"/> | Thrombocytopenia                                  |
|                  | 286. | <input type="checkbox"/> | <input type="checkbox"/> | Eosinophilia                                      |
|                  | 287. | <input type="checkbox"/> | <input type="checkbox"/> | Autoantibodies                                    |
|                  | 288. | <input type="checkbox"/> | <input type="checkbox"/> | Other hematologic involvement, specify: _____     |
| Other:           | 289. | <input type="checkbox"/> | <input type="checkbox"/> | Specify: _____                                    |

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290. Was specific therapy used to treat chronic GVHD since last report? 1  Yes 0  No Go to Q. 325

For each agent listed below indicate whether or not it was used to treat chronic GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking?	
					Yes	No
291. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	292. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
293. Azathioprine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	294. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
295. Cyclosporine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	296. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
297. FK 506 (Tacrolimus)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	298. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
299. Systemic Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	300. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
301. Topical Corticosteroids	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	302. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
303. Cyclo- phosphamide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	304. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
305. Thalidomide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	306. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

In vivo anti-T-lymphocyte monoclonal antibody

307. Anti IL-2	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	308. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
309. Anti CD 25	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	310. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
311. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	312. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
313. OKT3	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	314. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
315. Other, antibody specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	316. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
317. In vivo immunotoxin, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	318. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
319. Blinded randomized trial; specify agent(s) being studied: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	320. 1 <input type="checkbox"/>	0 <input type="checkbox"/>
321. Other, specify: _____	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	322. 1 <input type="checkbox"/>	0 <input type="checkbox"/>

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323. Is patient still receiving treatment for chronic GVHD?

1  Yes

0  No

324. Date last treatment was administered:

Month

Day

Year

325. Is chronic GVHD still present?

1  Yes

0  No

8  No symptoms, but patient still receiving treatment

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326. Did patient develop clinically significant infection since date of last report? 1  Yes 0  No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism was involved, list one site of infection and organism on the first line; second site and/or organism on second line.

		Site	Organism	Date of Onset			Did infection resolve?	
				Month	Day	Year	Yes	No
327. <input type="checkbox"/> Bacterial	<u>Typical</u>	First 328. <input type="text"/>	329. _____	330. <input type="text"/>	<input type="text"/>	<input type="text"/>	331. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 332. <input type="text"/>	333. _____	334. <input type="text"/>	<input type="text"/>	<input type="text"/>	335. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	336. Other bacterium, specify: _____							
346. <input type="checkbox"/> Fungal	<u>Atypical</u>	First 337. <input type="text"/>	338. B <input type="text"/>	339. <input type="text"/>	<input type="text"/>	<input type="text"/>	340. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 341. <input type="text"/>	342. B <input type="text"/>	343. <input type="text"/>	<input type="text"/>	<input type="text"/>	344. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	345. Other atypical bacterium, specify: _____							
346. <input type="checkbox"/> Fungal		First 347. <input type="text"/>	348. F <input type="text"/>	349. <input type="text"/>	<input type="text"/>	<input type="text"/>	350. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 351. <input type="text"/>	352. F <input type="text"/>	353. <input type="text"/>	<input type="text"/>	<input type="text"/>	354. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	355. Other fungus, specify: _____							
356. <input type="checkbox"/> Viral		First 357. <input type="text"/>	358. V <input type="text"/>	359. <input type="text"/>	<input type="text"/>	<input type="text"/>	360. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 361. <input type="text"/>	362. V <input type="text"/>	363. <input type="text"/>	<input type="text"/>	<input type="text"/>	364. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	365. Other virus, specify: _____							
366. <input type="checkbox"/> Parasitic		First 367. <input type="text"/>	368. P <input type="text"/>	369. <input type="text"/>	<input type="text"/>	<input type="text"/>	370. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 371. <input type="text"/>	372. P <input type="text"/>	373. <input type="text"/>	<input type="text"/>	<input type="text"/>	374. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
	375. Other parasite, specify: _____							
376. <input type="checkbox"/> No organism identified		First 377. <input type="text"/>	378. O 5 0 9	379. <input type="text"/>	<input type="text"/>	<input type="text"/>	380. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	
		Second 381. <input type="text"/>	382. O 5 0 9	383. <input type="text"/>	<input type="text"/>	<input type="text"/>	384. 1 <input type="checkbox"/> 0 <input type="checkbox"/>	



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### Codes for Common Sites of Infection

- |   |  |
|---|--|
| 01 Blood/buffy coat   | 40 <u>Genito-Urinary Tract unspecified</u>                     |
| 02 Disseminated – generalized, isolated at 3 or more distinct sites | 41 Kidneys, renal pelvis, ureters and bladder                  |
| 03 <u>Central Nervous System unspecified</u>                        | 42 Prostate  |
| 04 Brain  | 43 Testes  |
| 05 Spinal cord  | 44 Fallopian tubes, uterus, cervix                             |
| 06 Meninges and CSF   | 45 Vagina  |
| 10 <u>Gastrointestinal Tract unspecified</u>                        | 50 <u>Skin unspecified</u>                                     |
| 11 Lips   | 51 Genital area  |
| 12 Tongue, oral cavity and oro-pharynx                              | 52 Cellulitis  |
| 13 Esophagus  | 53 Herpes Zoster   |
| 14 Stomach  | 54 Rash, pustules or abscesses not typical of any of the above |
| 15 Gallbladder and biliary tree (not hepatitis), pancreas           | 60 Central venous catheter, not otherwise specified            |
| 16 Small intestine  | 61 Catheter insertion site                                     |
| 17 Large intestine  | 62 Catheter tip  |
| 18 Feces/stool  | 70 Eyes  |
| 19 Peritoneum   | 75 Ear   |
| 20 Liver  | 80 <u>Other unspecified</u>                                    |
| 30 <u>Respiratory unspecified</u>                                   | 81 Joints  |
| 31 Upper airway and nasopharynx                                     | 82 Bone marrow   |
| 32 Laryngitis/larynx  | 83 Bone cortex (osteomyelitis)                                 |
| 33 Lower respiratory tract (lung)                                   | 84 Muscle (excluding cardiac)                                  |
| 34 Pleural cavity, pleural fluid                                    | 85 Cardiac (endocardium, myocardium, pericardium)              |
| 35 Sinuses  | 86 Lymph nodes   |
|   | 87 Spleen  |

### Codes for Commonly Reported Organisms

#### 1. Bacteria

(Indicate code for atypical bacteria; list bacterium for non-atypical bacteria.)

- 100 Atypical bacteria, not otherwise specified
- 101 Coxiella
- 102 Legionella
- 103 Leptospira
- 104 Listeria
- 105 Mycoplasma
- 106 Nocardia
- 107 Rickettsia
- 110 Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
- 111 Typical tuberculosis (TB, Tuberculosis)
- 112 Mycobacteria (avium, bovis, intracellulare)
- 113 Chlamydia
- 119 Atypical bacteria – other, specify

#### 2. Fungal Infections

- 200 Candida, not otherwise specified
- 201 Candida albicans
- 202 Candida krusei
- 203 Candida parapsilosis
- 204 Candida tropicalis
- 205 Torulopsis glabrata (a subspecies of candida)
- 209 Candida, other
- 210 Aspergillus, not otherwise specified
- 211 Aspergillus flavus
- 212 Aspergillus fumigatus
- 213 Aspergillus niger
- 219 Aspergillus, other
- 220 Cryptococcus species
- 230 Fusarium species
- 240 Mucormycosis (zygomycetes, rhizopus)
- 250 Yeast, not otherwise specified
- 259 Other fungus, specify

#### 3. Viral Infections

- 301 Herpes Simplex (HSV1, HSV2)
- 302 Herpes Zoster (Chicken pox, Varicella)
- 303 Cytomegalovirus (CMV)
- 304 Adenovirus
- 305 Enterovirus (Coxsackie, Echo, Polio)
- 306 Hepatitis A (HAV)
- 307 Hepatitis B (HBV, Australian antigen)
- 308 Hepatitis C (HCV)
- 309 HIV-1 (HTLV-III)
- 310 Influenza
- 311 Measles (Rubeola)
- 312 Mumps
- 313 Papovavirus
- 314 Respiratory syncytial virus (RSV)
- 315 Rubella (German Measles)
- 316 Parainfluenza
- 317 Human herpesvirus-6 (HHV-6)
- 318 Epstein-Barr virus (EBV)
- 319 Polyomavirus
- 320 Rotavirus
- 321 Rhinovirus
- 329 Other Viral, specify

#### 4. Parasite Infections

- 401 Pneumocystis (PCP)
- 402 Toxoplasma
- 403 Giardia
- 404 Cryptosporidium
- 409 Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

#### 5. Other Infections

- 509 No organism identified

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### Pulmonary function

385. Has patient developed interstitial pneumonitis (IPn) since date of last report?

1  Yes

0  No

*Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload.*

386. How many episodes of IPn occurred since date of last report?

*Note: If more than one episode of IPn, photocopy this page and complete Q. 385 – 406 for subsequent episode(s).*

387. Date of onset of IPn:

Month Day Year

388. Were diagnostic tests other than radiographic studies done?

1  Yes

0  No

Diagnosis was evaluated by:

	Yes	No	
389.	<input type="checkbox"/>	<input type="checkbox"/>	Bronchoalveolar lavage
390.	<input type="checkbox"/>	<input type="checkbox"/>	Transbronchial biopsy
391.	<input type="checkbox"/>	<input type="checkbox"/>	Open lung biopsy
392.	<input type="checkbox"/>	<input type="checkbox"/>	Autopsy
393.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

394. Was an organism isolated?

1  Yes

0  No (idiopathic, or no organism isolated)

Etiology:

	Yes	No	
395.	<input type="checkbox"/>	<input type="checkbox"/>	Pneumocystis carinii
396.	<input type="checkbox"/>	<input type="checkbox"/>	Aspergillus
397.	<input type="checkbox"/>	<input type="checkbox"/>	Candida
398.	<input type="checkbox"/>	<input type="checkbox"/>	Toxoplasma
399.	<input type="checkbox"/>	<input type="checkbox"/>	Respiratory syncytial virus
400.	<input type="checkbox"/>	<input type="checkbox"/>	Cytomegalovirus
401.	<input type="checkbox"/>	<input type="checkbox"/>	Herpes simplex
402.	<input type="checkbox"/>	<input type="checkbox"/>	Adenovirus
403.	<input type="checkbox"/>	<input type="checkbox"/>	Human herpes virus 6
404.	<input type="checkbox"/>	<input type="checkbox"/>	Other virus, specify: _____
405.	<input type="checkbox"/>	<input type="checkbox"/>	Other, specify: _____

406. Has interstitial pneumonitis resolved?

1  Yes

0  No

8  Unknown

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407. Did patient develop pulmonary abnormalities other than interstitial pneumonitis since date of last report?

- 1  Yes  
0  No

408. Did patient develop Acute Respiratory Distress Syndrome (ARDS) since last report?

- 1  Yes  
0  No

409. Date of onset of ARDS:     
Month Day Year

410. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | <u>Yes</u>                 | <u>No</u>                  |                        |
|------|----------------------------|----------------------------|------------------------|
| 411. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 412. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 413. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 414. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 415. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

416. Did patient develop bronchiolitis obliterans since last report?

- 1  Yes  
0  No

417. Date of onset:     
Month Day Year

418. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | <u>Yes</u>                 | <u>No</u>                  |                        |
|------|----------------------------|----------------------------|------------------------|
| 419. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 420. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 421. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 422. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 423. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

424. Did patient develop pulmonary hemorrhage since last report?

- 1  Yes  
0  No

425. Date of onset:     
Month Day Year

426. Were diagnostic tests done?

- 1  Yes  
0  No

Diagnosis was evaluated by:

- |      | <u>Yes</u>                 | <u>No</u>                  |                        |
|------|----------------------------|----------------------------|------------------------|
| 427. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Bronchoalveolar lavage |
| 428. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Transbronchial biopsy  |
| 429. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Open lung biopsy       |
| 430. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Autopsy                |
| 431. | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | Other, specify: _____  |

432. Did patient develop other non-infectious pulmonary abnormalities since last report?

- 1  Yes  
0  No

433. Specify: \_\_\_\_\_

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**Liver function**

434. Did patient develop non-infectious liver toxicity since last report?

- 1  Yes
- 0  No

435. What was the date of onset?        
Month Day Year

Etiology:

	Yes	No	
436.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Veno-occlusive disease
437.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
438.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Unknown

439. Has liver toxicity resolved?

- 1  Yes
- 0  No
- 8  Unknown

440. Did patient develop any other non-infectious clinically significant organ impairment or disorder since last report?

- 1  Yes
- 0  No

	Yes	No	
441.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Renal failure requiring dialysis
442.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	TTP/HUS or similar syndrome
443.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hemorrhage, specify site:
			444. 1 <input type="checkbox"/> 0 <input type="checkbox"/> CNS
			445. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Upper GI tract
			446. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Lower GI tract
			447. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Other, specify: _____
448.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hemorrhagic cystitis
449.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Seizures
450.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Cataracts
451.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Avascular necrosis
452.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hypothyroidism
453.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Gonadal dysfunction
454.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Growth hormone deficiency/growth disturbance
455.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

TEAM

IUBMID

456. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear since last report? (If more than one new malignancy developed, copy this page and complete for each new cancer)

1  Yes  
0  No

457. Date of diagnosis:        
Month Day Year

458. Origin of cells:  
1  Host 8  Unknown  
2  Donor 7  Not tested

Diagnosis (send copy of pathology report/other documentation):

Yes No

459. 1  0  Clonal cytogenetic abnormality without leukemia or MDS  
460. 1  0  Acute myeloid leukemia  
461. 1  0  Other leukemia, specify: \_\_\_\_\_  
462. 1  0  Myelodysplasia  
463. 1  0  Lymphoma or lymphoproliferative disease

464. EBV positive? 1  Yes 0  No 8  Unknown

465. 1  0  Hodgkin disease

466. 1  0  Other cancer

467. Primary site: \_\_\_\_\_

468. Histologic type: \_\_\_\_\_

469. Behavior:

- 1  Benign  
2  In situ  
3  Malignant/invasive  
8  Unknown

TEAM

IUBMID

### Death Information

470. Date of death:          
                                     Month      Day      Year

Cause(s) of death:

<p>Enter appropriate cause of death below. If a code number for "Other, specify" is entered, write the cause in the space provided.</p> <p>471. Primary: <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>Contributing or secondary causes:</p> <p>472. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>473. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>474. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>475. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p> <p>476. <input type="text"/> <input type="text"/> <input type="text"/> Specify: _____</p>	<p style="text-align: center;"><b>Cause of Death Codes</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">10 Graft rejection or failure</td> </tr> <tr> <td style="padding: 2px;">20 Infection (other than interstitial pneumonia)</td> </tr> <tr> <td style="padding: 2px;">21 Bacterial</td> </tr> <tr> <td style="padding: 2px;">22 Fungal</td> </tr> <tr> <td style="padding: 2px;">23 Viral</td> </tr> <tr> <td style="padding: 2px;">24 Protozoal</td> </tr> <tr> <td style="padding: 2px;">25 Infection, organism not identified</td> </tr> <tr> <td style="padding: 2px;">29 Other infection, specify</td> </tr> <tr> <td style="padding: 2px;">30 Interstitial pneumonia</td> </tr> <tr> <td style="padding: 2px;">31 Viral, CMV</td> </tr> <tr> <td style="padding: 2px;">32 Viral, other</td> </tr> <tr> <td style="padding: 2px;">33 Pneumocystis</td> </tr> <tr> <td style="padding: 2px;">34 Fungus</td> </tr> <tr> <td style="padding: 2px;">39 Other IPn, specify</td> </tr> <tr> <td style="padding: 2px;">40 Adult Respiratory Distress Syndrome</td> </tr> <tr> <td style="padding: 2px;">50 Acute GVHD</td> </tr> <tr> <td style="padding: 2px;">60 Chronic GVHD</td> </tr> <tr> <td style="padding: 2px;">70 Recurrence or persistence of primary disease</td> </tr> <tr> <td style="padding: 2px;"><i>NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.</i></td> </tr> <tr> <td style="padding: 2px;">80 Organ failure (not due to GVHD or infection)</td> </tr> <tr> <td style="padding: 2px;">81 Liver</td> </tr> <tr> <td style="padding: 2px;">82 VOD</td> </tr> <tr> <td style="padding: 2px;">83 Cardiac (Cardiomyopathy)</td> </tr> <tr> <td style="padding: 2px;">84 Pulmonary</td> </tr> <tr> <td style="padding: 2px;">85 CNS</td> </tr> <tr> <td style="padding: 2px;">86 Renal</td> </tr> <tr> <td style="padding: 2px;">89 Other organ failure, specify</td> </tr> <tr> <td style="padding: 2px;">90 Secondary malignancy</td> </tr> <tr> <td style="padding: 2px;">100 Hemorrhage</td> </tr> <tr> <td style="padding: 2px;">110 Accidental death</td> </tr> <tr> <td style="padding: 2px;">900 Other, specify</td> </tr> </table>	10 Graft rejection or failure	20 Infection (other than interstitial pneumonia)	21 Bacterial	22 Fungal	23 Viral	24 Protozoal	25 Infection, organism not identified	29 Other infection, specify	30 Interstitial pneumonia	31 Viral, CMV	32 Viral, other	33 Pneumocystis	34 Fungus	39 Other IPn, specify	40 Adult Respiratory Distress Syndrome	50 Acute GVHD	60 Chronic GVHD	70 Recurrence or persistence of primary disease	<i>NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.</i>	80 Organ failure (not due to GVHD or infection)	81 Liver	82 VOD	83 Cardiac (Cardiomyopathy)	84 Pulmonary	85 CNS	86 Renal	89 Other organ failure, specify	90 Secondary malignancy	100 Hemorrhage	110 Accidental death	900 Other, specify
10 Graft rejection or failure																																
20 Infection (other than interstitial pneumonia)																																
21 Bacterial																																
22 Fungal																																
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24 Protozoal																																
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84 Pulmonary																																
85 CNS																																
86 Renal																																
89 Other organ failure, specify																																
90 Secondary malignancy																																
100 Hemorrhage																																
110 Accidental death																																
900 Other, specify																																

477. Was cause of death confirmed by autopsy?

- 1  Yes
- 0  No
- 8  Unknown
- 6  Pending

Send copy of autopsy report when available



**FOLLOW-UP: INSERT VIII**  
**Breast Cancer**

**FOR REGISTRY USE ONLY:**

I.D.  -  -

Date received: \_\_\_\_\_

TEAM

IUBMID   
*(Institutional Unique Blood or Marrow Transplant Identification Number)*

Registry: *IBMTR* *ABMTR* (circle one)

Date of transplant for which this form is being completed:     
Month Day Year

Date of report:     
Month Day Year

**Follow-up Information**

**\* Report data for date of last contact as reported in Q.3 of Follow-up Core Form or immediately prior to death.**

1. Was planned post transplant treatment (treatment before progressive disease) given since date of last report?

- 1  Yes  
0  No

**Go to Q.9**

2. Was disease restaged prior to planned posttransplant treatment?

1  Yes  
0  No

Specify treatment given whether restaged or not:

	<u>Yes</u>	<u>No</u>	
3.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Chemotherapy, specify: _____
4.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hormone therapy, specify: _____
5.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Radiation therapy, specify: _____
6.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Immune therapy, specify: _____
7.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

8. Specify best response to transplant including planned posttransplant treatment:

- 1  Complete response (*complete disappearance of all known disease for  $\geq 4$  weeks*)
- 2  Complete response with persistent bone scan or x-ray abnormalities of unknown significance
- 3  Partial response ( *$\geq 50\%$  reduction in greatest diameter of all sites of known disease and no new sites of disease for  $\geq 4$  weeks*)
- 4  No response: *< 50% reduction in greatest diameter of all sites of known disease and no new sites of disease*
- 5  Progressive disease: *increase in size of sites of known disease or new sites of disease*  
Specify site(s) of persistent/new disease: \_\_\_\_\_
- 6  Not evaluable, toxic death
- 7  Not evaluable, other reason, specify: \_\_\_\_\_



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9. Most recent status of breast cancer: (for patients who died, report status at time of death)

- 1  Free of breast cancer; no recurrence posttransplant
- 2  Free of breast cancer except for persistent scan abnormalities of unknown significance, no recurrence posttransplant
- 3  Persistent breast cancer without progression (never achieved CR or PR)
- 4  Progressive disease (never achieved CR or PR)

Date of progression    Site(s): \_\_\_\_\_  
Month Day Year

- 5  Recurrent disease (relapse after complete remission)

Date of progression    Site(s): \_\_\_\_\_  
Month Day Year

- 6  Free of breast cancer after posttransplant recurrence

Date of recurrence    Site(s): \_\_\_\_\_  
Month Day Year

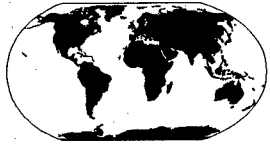
- 7  Not evaluable; explain: \_\_\_\_\_

10. Date current status established     
Month Day Year

First site(s) of progression/recurrence:

	Yes	No	
11.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lymph node
12.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Bone marrow
13.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	CNS
14.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Liver
15.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lung
15.2	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Local (chest wall)
15.3	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Contralateral breast
16.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

**IBMTR**



International Bone Marrow  
Transplant Registry

**Working Committee Meetings  
&  
Data Management Workshops**

**ABMTR**

North America



Autologous Blood & Marrow  
Transplant Registry



**Keystone Resort, Colorado**

**January 13-15, 1996**

*immediately preceding the  
Keystone Symposium on "Blood Cell & Bone Marrow Transplants"  
Keystone, January 15-21, 1996*

  
MEDICAL  
COLLEGE  
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Ortho Biotech \* Pfizer, Inc. \* Pharmacia \* Roche Laboratories \* Sandoz Oncology  
StemCell Technologies, Inc. \* Systemix \* Wyeth-Ayerst Laboratories

*Special air and ground transportation packages available*

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IBMTR

Working Committee Meetings

&

ABMTR

Data Management Workshops

January 13-15, 1996 \* Keystone, Colorado

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**Program Goals & Objectives**

- ◆ The 1996 joint meeting of the IBMTR and ABMTR will be held in Keystone, Colorado immediately preceding the Keystone Symposium on "Blood Cell & Bone Marrow Transplants". Participants may take advantage of the opportunity to attend both meetings, efficiently utilizing valuable travel funds.
- ◆ **All participating IBMTR and ABMTR team members are encouraged to attend.**  
We hope to have all contributing teams represented at this year's Meeting.
- ◆ Current data on use and outcome of blood and bone marrow transplants will be presented.
- ◆ All participants are invited to attend and contribute to meetings of IBMTR and ABMTR Working Committees in their areas of interest and expertise. Committees will discuss Registry analyses currently in progress and directions for future research. See Registration Form and Agenda for Committee listings.
- ◆ Data Managers and Research Nurses are encouraged to attend interactive Data Management Workshops. The newly revised IBMTR/ABMTR Reporting Forms, designed in collaboration with the US National Marrow Donor Program (NMDP), will be reviewed in detail. StemCell Technologies, Inc. will demonstrate StemSoft software for the newly revised IBMTR/ABMTR Forms and an interrelated statistical analysis package. IBMTR/ABMTR Registration Procedures will be reviewed.
- ◆ Approaches to use and analysis of clinical transplant data will be presented.

**Participants Will Benefit From Attending by:**

- ◆ Participating in discussions of current and future IBMTR and ABMTR analyses, learning the advantages and limitations of using Registry data to address issues in transplantation
- ◆ Participating in Plenary Sessions addressing important scientific issues in blood and marrow transplantation
- ◆ Lending expertise to IBMTR and ABMTR Working Committees
- ◆ Meeting and interacting with Statistical Center staff
- ◆ Obtaining up-to-date statistics of IBMTR and ABMTR data.

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IBMTR

Working Committee Meetings

&

ABMTR

Data Management Workshops

January 13-15, 1996 \* Keystone, Colorado

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Scientific Program

The IBMTR/ABMTR Meeting will provide a forum for members to discuss current blood and marrow research activities and plan future studies that address critical and timely issues in transplantation.

IBMTR & ABMTR Working Committees

Working Committees allow involvement of all participating centers in IBMTR and ABMTR studies. All teams are invited to send one or more representatives to participate. Senior and junior faculty members are encouraged to register for Committees in specific areas of interest and/or expertise.

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**IBMTR**

- Acute Leukemia
- Chronic Myelogenous Leukemia
- CLL/Lymphoma/Multiple Myeloma
- Long-term Complications/Second Cancers
- GVHD/GVL/Immune Reconstitution
- Aplastic Anemia/Fanconi Anemia
- Metabolic Disease/Immune Deficiencies
- Histocompatibility/Alternative Donors & Stem Cell Sources

**ABMTR**

- Leukemia
  - Lymphoma
  - Breast Cancer
  - Multiple Myeloma
  - Pediatric Cancers
- 

Data Management Workshops

Data managers and research nurses will find topics of interest and direct communication with on-site Statistical Staff members leading informal participatory workshops on two tracks.

- ▶ **Track I** features fundamental concepts for IBMTR/ABMTR data managers attending the Data Management Workshops for the first time.
- ▶ **Track II** designed for more experienced data management and nursing professionals, features special topics related to clinical research.

Both tracks will provide discussion of the many recent changes in IBMTR/ABMTR Registration and Reporting procedures. Additionally, StemCell Technologies, Inc., will demonstrate their StemSoft software for the newly revised IBMTR/ABMTR Forms and their interrelated statistical analysis package.

"Hands-on" training with StemSoft is available on Sunday, January 14th for those who preregister with StemCell Technologies, Inc.

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IBMTR

Working Committee Meetings  
&  
Data Management Workshops

ABMTR

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## More About IBMTR/ABMTR Data Management Workshops

IBMTR/ABMTR Data Management Workshops, primarily designed for Data Managers and Nurses, are conducted in an informal setting, and provide for open discussion between Statistical Center staff and meeting participants. The program includes brief overview presentations by Statistical Center personnel and others followed by roundtable discussions among members of collaborating bone marrow transplant centers. This series of Data Management Workshops will feature an emphasis on issues related to allo- and autotransplants for leukemia, lymphoma and breast cancer. Key Statistical Center staff members will be on hand to answer your questions:

Mary M. Horowitz, MD, MS, Scientific Director  
John P. Klein, PhD, Statistical Director  
Philip A. Rowlings, MD, Associate Scientific Director  
Kathleen A. Sobocinski, Associate Statistical Director  
Jakob Passweg, MD, Research/Clinical Fellow  
D'Etta Waldoch Koser, Associate Director-International Programs  
Barbara A. McGary, Information Systems Manager  
Sharon K. Nell, Senior Communications Coordinator  
Diane J. Knutson, Systems Coordinator

NOTE: Data Managers with questions requiring individual training sessions may contact Diane J. Knutson at 414/ 456-8325 at the Statistical Center for an appointment. Diane will be available at Keystone after the Data Management Workshops from Sunday, January 14 through Tuesday, January 16, 1996.

## Hands-on Training: IBMTR/ABMTR Data Management with StemSoft

Mr. Gerry Racine from StemCell Technologies, Inc., will lead participants through this informative seminar and provide valuable advice for using StemSoft data entry software for completing the newly revised IBMTR/ABMTR registration and reporting forms, and their statistical analysis package.

The Statistical Center has worked closely with StemCell Technologies, Inc. in software development. Programs are currently available in WINDOWS (IBM-compatible) format. Workshop participants will be provided with an IBM-compatible PC during hands-on training.

Due to the technical nature of this full-day seminar, it is necessary to preregister. Please contact Violet Molnar at StemCell Technologies, Inc. in Vancouver, BC by telephone at: 604/ 877-0713 or by fax: 604/ 877-0704, to register for the Sunday seminar.

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Saturday, January 13

**IBMTR/ABMTR Data Management Workshops**

Track I: Fundamentals of Data Management

Track II: Special Topics Related to Clinical Research

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**TRACK I**

**TRACK II**

9:30 - 11:00AM

**Workshop I-A**

**Orientation/ Overview**

- Barbara McGary

**Tips for Completing Registration Forms**

- Sharon Nell

**Tips for Completing Reporting Forms**

- Diane Knutson

**Workshop II-A**

**StemSoft: Introductory Demonstration**

- Gerry Racine

**Retrieving Your Data**

- Barbara McGary

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11:15 - 12:45PM

**Workshop I-B**

**StemSoft Introductory Demonstration**

- Gerry Racine

**Retrieving Your Data**

- Barbara McGary

**Workshop II-B**

**The Evolution of BMT**

- Betsy Stein, Clinical Research Manager

Marrow Transplant Program

Baylor University Medical Center

Dallas, TX

Roundtable discussions to follow

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12:45 - 2:30PM

**Lunch Break**

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2:45 - 4:00PM

**Workshop I-C**

**Hands-on Case Completion I**

(Core & Graft Inserts)

**Hands-on Case Completion II**

(Disease-specific Inserts)

- Diane Knutson

- Claudia Kabler-Babbitt

Clinical Studies Coordinator

BMT Program

Medical College of Wisconsin

Milwaukee, WI

**Workshop II-C**

**What Do We Do With All Those Data?**

(Introductory Statistics)

- Kathleen A Sobocinski

Roundtable discussions to follow

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Sunday, January 14

**StemCell Technologies, Inc. Hands-on Training**

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9:00 - 5:30PM

**IBMTR/ABMTR Data Management using updated StemSoft software\***

\* requires preregistration

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Sunday, January 14

Working Committees & Plenary Session

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TENTATIVE PROGRAM

8:00AM	<i>Registration/Information Desk</i>	<i>Foyer</i>
9:00 - 10:15AM	<i>Simultaneous Working Committee Meetings</i> <b>IBMTR - Acute Leukemia</b> Chair: Daniel Weisdorf      Statistician: Mei-Jie Zhang <b>IBMTR - Long-term Complications/Second Cancers</b> Chair: Gérard Socié      Statistician: Kathleen A Sobocinski	
10:15 - 10:40AM	<i>Coffee Break &amp; Exhibits</i>	<i>Exhibit Area</i>
10:40 - 12:00N	<i>Simultaneous Working Committee Meetings</i> <b>ABMTR - Pediatric Cancers</b> Chair: Bruce Camitta      Statistician: Corey Pelz <b>IBMTR - GVHD/GVL, Immune Reconstitution</b> Chair: A John Barrett      Statistician: John P Klein	
12:00 - 4:30PM	<i>Afternoon Recreation Break</i>	
12:00 - 2:00PM	<b>IBMTR Executive Committee</b>	<i>Star Slide Boardroom</i>
4:00PM-	<i>Reception - Pasta Buffet &amp; Beverages</i>	<i>Exhibit Area</i>
4:30 - 6:30PM	<i>Scientific Plenary Sessions</i> "Introduction"      Mary M Horowitz "ABMTR Update"      James O Armitage "IBMTR Update"      Robert Peter Gale "Recent Studies"      Study Chairs •      Autotransplants for Breast Cancer •      Allogeneic Transplants -vs- Autotransplants for AML •      Purging in Autotransplants for AML •      The Role of Laminar Air Flow/HEPA Filtration in Allogeneic BMT <b>KEYNOTE SPEAKER</b> TBA	
6:30 - 8:00PM	<i>Simultaneous Working Committee Meetings</i> <b>ABMTR - Breast Cancer</b> Chair: Karen Antman      Statistician: Corey Pelz <b>IBMTR - Aplastic Anemia/Fanconi Anemia</b> Chair: Jill Hows      Statistician: Kathleen A Sobocinski	
8:00 - 8:30PM	<i>Coffee Break &amp; Exhibits</i>	<i>Exhibit Area</i>

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Monday, January 15

Working Committee Meetings

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TENTATIVE PROGRAM

7:00AM -	<i>Registration/Information Desk</i>	<i>Foyer</i>
8:00 - 9:20AM	<i>Simultaneous Working Committee Meetings</i> <b>ABMTR - Multiple Myeloma</b> Chair: Sundar Jagannath                      Statistician: John P. Klein <b>IBMTR - Metabolic Disorders &amp; Immune Deficiencies</b> Chair: Alexandra Filipovich                      Statistician: Corey Pelz	
9:20 - 9:35AM	<i>Coffee Break &amp; Exhibits</i>	<i>Exhibit Area</i>
9:35 - 10:50AM	<i>Simultaneous Working Committee Meetings</i> <b>ABMTR - Lymphoma</b> Co-Chairs: Hillard Lazarus (HD); Julie Vose (NHL) Statistician: Kathleen A. Sobocinski <b>IBMTR - Chronic Myelogenous Leukemia</b> Chair: Phillip McGlave                      Statistician: Mei-Jie Zhang	
10:50 - 11:05AM	<i>Coffee Break &amp; Exhibits</i>	<i>Exhibit Area</i>
11:05 - 12:30AM	<i>Simultaneous Working Committee Meetings</i> <b>ABMTR - Leukemia</b> Co-Chairs: Armand Keating (AML); Daniel Weisdorf (ALL); Richard Champlin (CLL) Statistician: John Klein <b>IBMTR - CLL/Lymphoma/Multiple Myeloma</b> Chair: TBA                      Statistician: Kathleen A. Sobocinski	
12:30 - 2:00PM	<b>ABMTR Executive Committee</b>	<i>Star Slide Boardroom</i>
2:00 - 3:30PM	<i>Working Committee Meeting</i> <b>IBMTR - Histocompatibility, Alternative Donors &amp; Stem Cell Sources</b> Chair: Richard Champlin                      Statistician: John P Klein	

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## Register Today!

### No Registration Fees for IBMTR/ABMTR Participating Team Members

Questions?

Contact D'Etta Waldoch Koser at IBMTR Statistical Center \* 414/ 456-8377 \* FAX: 414/ 266-8471

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### General Information

All members of more than 400 IBMTR- and ABMTR-participating bone marrow transplant centers, representing more than 50 countries, are invited to attend the Working Committee Meetings and Data Management Workshops in Keystone, Colorado. The Data Management Workshops will start on Saturday, January 13; IBMTR and ABMTR Working Committee Meetings will begin on Sunday, January 14 and continue on Monday, January 15 at Keystone Resort. All IBMTR and ABMTR Working Committee members should plan to attend

▶ **Working Committee Meetings Are Open to All Meeting Participants**

We enthusiastically welcome attendance by senior and junior faculty members, nursing staff and data managers and hope to have each contributing team represented. Non-members are also welcome to take advantage of this opportunity to learn about Statistical Center activities and participate in the scientific program.

### Meeting Venue

Keystone Resort has become a favorite venue for many members of the international blood and marrow transplant community over the years. Those who have attended meetings previously at Keystone look forward to returning each year to meet with their colleagues in this familiar and information setting.

Keystone is located approximately 75 miles west of Denver, Colorado, via Route I-70.

In addition to providing the perfect setting for the IBMTR and ABMTR Meetings, Keystone Resort offers lodging, recreational activities, dining, child care facilities and more!

### Meeting Registration

▶ **Registration is easy by fax! Do it today!**

There are no registration fees for participating IBMTR and/or ABMTR team members.

Please fax the enclosed Registration Form to the Statistical Center today. Don't forget to indicate which Working Committee Meetings you expect to attend. Confirmation for registered participants will be returned by fax.

### To join the IBMTR and/or ABMTR contact the Statistical Center

c/o Ms. Sharon Nell  
Senior Communications Coordinator  
414/ 456-8325 \* FAX: 414/ 266-8471  
IBMTR/ABMTR Statistical Center  
Medical College of Wisconsin  
8701 Watertown Plank Road  
Milwaukee, WI 53226 USA

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**Register today!**

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## **Continuing Medical Education**

The Medical College of Wisconsin (MCW) is accredited by the U.S. Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. MCW designates this continuing medical education (CME) activity for 19 credit hours in Category I of the Physician's Recognition Award of the American Medical Association for the IBMTR Meeting.

The Medical College of Wisconsin, accredited by the Council on the Continuing Education Unit, certifies that this program meets the criteria for 1.90 Continuing Education Units (CEU).

Participants requesting CME or CEU credit should check the appropriate box on the enclosed Registration Form, and include social security number.

### ***CME/CEU Disclosure***

The IBMTR is committed to providing unbiased, balanced and objective educational and scientific programs. In accordance with ACCME guidelines, all IBMTR Meeting speakers were asked to provide relevant disclosure statements, which are on file at the Medical College of Wisconsin Continuing Medical Education office.

## **High Altitude Warning**

Keystone Resort is located 9,300 feet above sea level. If you have any health problems which may be complicated by high altitude, please consult with your physician before registering for the IBMTR/ABMTR Meetings.

## **Discounted Lift Tickets**

Group-rate lift tickets will be available for IBMTR/ABMTR Meeting Participants at \$32 per person per day. Lift tickets are good at Keystone, Breckenridge, North Peak and Arapahoe Basin and The Outback.



### ***Questions May Be Directed to:***

D'Etta Waldoch Koser, CMP  
Associate Director-International Programs  
IBMTR/ABMTR Statistical Center, Medical College of Wisconsin  
8701 Watertown Plank Road, Milwaukee, WI 53226 USA  
telephone: 414/456-8377 -or- fax: 414/266-8471

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IBMTR

Working Committee Meetings

&

ABMTR

Data Management Workshops

January 13-15, 1996 \* Keystone, Colorado

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Hotel Accommodations

A limited number of rooms at Keystone Lodge, The Inn, and a variety of 1- and 2-bedroom condominiums are available for Friday, January 12 through Sunday, January 14 for those attending only the IBMTR/ABMTR Meetings. Keystone Resort will make every attempt to accommodate individual requests.

- ▶ **Complete the enclosed Housing Form and return it to Keystone Group Reservations prior to December 1, 1995.**
- ▶ **Those planning to spend the weekend with the IBMTR/ABMTR and attend the Keystone Symposia must complete the official Symposia Housing Form, along with the IBMTR/ABMTR Housing Form.**
- ▶ **Questions about Housing? Contact the Keystone Group Reservations Office:  
PO Box 38, Keystone, Colorado 80435, USA  
Telephone: 970/468-2316 or 800/258-0437  
FAX: 970/468-4543**

GROUP NAME: **IBMTR/ABMTR**  
GROUP DATES: **January 12-15, 1996**

GROUP CODE: **CA0CIBT**  
CUT-OFF DATE: **December 1, 1995**

You must indicate a major credit card number for a one-night deposit (as directed on the official Housing Form). Reservations will not be held without a deposit. Housing confirmation will be sent directly from Keystone Resort. Reservations made after the cutoff date may not be available at the discounted Meeting rate. Keystone Resort tends to have a 100% occupancy rate each year during the Martin Luther King Holiday Weekend (January 12-14). It may be impossible to accommodate last minute or walk-in requests.

KEYSTONE'S CANCELLATION POLICY IS INDICATED ON THE HOUSING FORM AND WILL BE STRICTLY ENFORCED.

Meeting participants from US institutions which are exempt from their own state sales tax must provide Keystone Resort with a photocopy of the tax exempt certificate, and complete the enclosed State of Colorado Sales and Use Tax Registration Form.

**Keystone Resort IBMTR/ABMTR "Group Discount" Room Rates**

<u>Keystone Lodge</u>	<u>The Inn</u>	<u>Village Condo Suites</u>	<u>Resort Condo Suites</u>
\$145 single	\$128 single	\$158 studio (up to 2 ppl)	\$170 1-bdrm (up to 2 ppl)
\$160 double	\$138 double	\$178 1-bdrm (up to 2 ppl)	\$255 2-bdrm (up to 4 ppl)
		\$275 2-bdrm (up to 4 ppl)	

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Register *today!*

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## Group Travel Assistance



### Air Transportation

Special air transportation packages are available through "Meetings & Incentives", independent specialists in medical conferences, worldwide. Discounts are provided on super saver, full coach or first class for IBMTR/ABMTR meeting participants and accompanying persons.

Reservations may be made through "Meetings & Incentives" by calling:

800/ 776-3582 x 107 -or- 414/ 835-3553 x 107

or faxing: 414/ 835-3569

Monday through Friday 8:30am - 5:00pm US Central Time

Please identify yourself as an IBMTR/ABMTR Keystone Meeting participant. Discounted tickets are limited in availability and carry penalties once issued. Wherever possible, seat assignments and boarding cards will be issued per your preference.

### Ground Transportation

#### *Hertz*

Hertz is the official car rental company for the IBMTR/ABMTR Meeting in Keystone. Special discount meeting rates start from a daily Sub-Compact rate at \$28.99 and a weekly Sub-Compact rate at \$102.99. Four-wheel drive vehicles are available for mountain driving, starting at \$53.99 daily, \$219.99 weekly. These rates are guaranteed and available one week before through one week after the meeting dates, subject to car availability, and include unlimited free mileage. In addition, at the time of reservation, when using the Hertz exclusive meeting ID number: CV#17321, Hertz will automatically compare the guaranteed meeting rates to other Hertz published rates to give you the best comparable rate available.

- ▶ For reservations, call Hertz at 800/ 654-2240 and refer to CV#17321, or call your travel agent.

When booking through the toll-free number, please identify yourself by the above CV number or identify yourself as an IBMTR/ABMTR Keystone Meeting participant. Standard rental conditions and qualifications apply, including minimum rental age. Check with your Hertz representative for other details.



#### **CAUTION:**

*Weather at the airport is not a good indication of driving conditions in the mountains. Before heading west on I-70, check the local forecast and road conditions. Inexperienced drivers and those not familiar with driving in winter conditions may wish to use a transportation service, such as Resort Express.*

#### *Resort Express*

A regularly scheduled shuttle service is available to meet you at the Denver International Airport and deliver you to the Keystone Lodge, with 16 daily departures. It is strongly recommended that reservations be made in advance.

- ▶ For more information, call Resort Express 800/334-7433 or 303/468-7600  
Round-trip \$64 One-way \$32  
Mention the "IBMTR/ABMTR Meeting at Keystone" to obtain discount fares.

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**IBMTR & ABMTR**  
Working Committee Meetings & Data Management Workshops  
Keystone, Colorado \* January 13-15, 1996

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*featuring:*

**Scientific Program**

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**Working Committee Meetings**

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**Data Management Workshops**



*Scientific Organizing Committee:*

Mary M. Horowitz  
James O. Armitage  
Robert Peter Gale

**Exhibits & Sponsorship**

A limited amount of space is available for exhibiting. If you are interested in a table top exhibit, or in sponsoring a luncheon or coffee break, please contact:

Ms. Susan Ladwig  
Assistant Director of Development, IBMTR/ABMTR  
414/ 456-8325, fax: 414/ 266-8471

**IBMTR/ABMTR Data Management Workshops  
January 13, 1996 Keystone, Colorado  
Program Evaluation Summary**

	<b>Poor</b>	<b>Fair</b>	<b>Good</b>	<b>Very Good</b>	<b>Excellent</b>
<b>Overall Program</b>					
Topics	0/24	0/24	8/24	11/24	5/24
Speakers	0/22	0/22	7/22	10/22	5/22
Slides/Hand-outs	0/23	2/23	5/23	10/23	6/23
<b>Data Management Sessions - Track I</b>					
Workshop IA	0/19	1/19	1/19	11/19	6/19
Workshop IB	0/14	1/14	2/14	5/14	6/14
Workshop IC	0/18	1/18	2/18	9/18	6/18
<b>Data Management Sessions - Track II</b>					
Workshop IIA	0/7	0/7	3/7	3/7	1/7
Workshop IIB	0/8	0/8	3/8	2/8	3/8
Workshop IIC	0/11	1/11	2/11	4/11	4/11

NOTE: Some participants did not provide answers for all questions.

**COMMENTS**

Data Management Sessions - Track I:

“I learned a lot and feel much more comfortable.”

“Very informative.”

“I appreciated very much the information I received...”

Data Management Sessions - Track II:

“Very good introductory talk...”

“well-prepared and good presentation...”

“Terrific presentation, great presentation, well-done...”

## DATA MANAGEMENT PARTICIPANTS AT 1996 KEYSTONE MEETINGS

Manuel Abecasis  
Instituto Portugues Oncologia, Lisboa, Portugal

Sue Anderson  
Saint Francis Hospital, Tulsa, OK

Carmin Apollo  
Washington University, St. Louis, MO

Mark Arneson  
Arlington Cancer Center, Arlington, TX

\*Susan Bach, RN  
Cancer and Blood Institute of Desert, Rancho Mirage, CA

\*Odette Biron, RN  
St. Sacrement, Quebec City, CANADA

Loreen Bonnar  
Health Sciences Centre, Winnipeg, CANADA

\*Beth A Bonvillain  
University of Arkansas, Little Rock, AR

\*Daphne A Brockington, HRA  
Bone Marrow Transplant Program of British Columbia, Vancouver, BC CANADA

\*Christopher Buzzard  
The Western Pennsylvania Hospital, Pittsburgh, PA

\*Lorraine Cambria  
North Shore Hem/Onc Associates, Port Jefferson Station, NY

Fernando Campilal, MD  
Instituto Portugues Oncologia, Porto, Portugal

Jeannette Cassar  
Childrens Hospital of Orange County, Orange, CA

\*Jean Chieppa  
St. Charles & Mather Hospital, New York, NY

Gary Choban  
Western Pennsylvania Hospital, PA

Sonja J Classen, RN  
P/SL Medical Center, Denver, CO

\*Sue Corringham, RN  
UCSD Cancer Center, San Diego, CA

\*Elizabeth Cox  
Indiana University Medical Center, Indianapolis

Lorraine Cumbria, RN  
North Shore Hem/Onc Associates, New York

\*Christine DeFrancisco  
UCSD Cancer Center, San Diego, CA

Susan De Vivo  
St. Joseph Hospital & Medical Center

Robert Deves  
BMT Unit, Budapest, Hungary

Patricio di Donato  
Childrens Hospital of Orange County, Orange, CA

Kathy Dillon  
Riverview Cancer Center, New Jersey

Rebecca Eisen  
BMT Program of Atlantic Canada/VG Hospital, Halifax, Nova Scotia, CANADA

William Flescher  
University of Rochester, Rochester, NY

\*Laurie Ann Ford, RRA, BS  
Roswell Park Cancer Institute, Buffalo, NY

Emily Fisher  
Wilford Hall Medical Center, Lackland AFB, TX

Susan E Gerard  
Northeastern Ontario Regional Cancer Centre, CANADA

\*Esther Gorelik, RN  
University of Pittsburgh, Pittsburgh, PA

\*Alison N Greenwald, BS  
Jewish Hospital Cincinnati, Cincinnati, OH

Martha Rolland Grinton  
Hospital for Sick Children, Toronto, Ontario, CANADA

Amy Hairston  
Northwestern University, Evanston, IL

\*Susan C Hale, RN  
University of Utah, Salt Lake City, UT

Mary Hamielec, RN  
University of Wisconsin, Madison, WI

\*Josephine Stephenson Hinds, PhD  
USC/Norris Cancer Hospital, Los Angeles, CA

\*Norine E Huneke  
Mayo Clinic Rochester, Rochester, MN

\*Debra Ishihara-Wong, RN  
The Queen's Medical Center, Honolulu, HI

\*Traci H Iwasaki  
The Queen's Medical Center, Honolulu, HI

Michelle Jensen  
Georgetown University, Washington, DC

Mary Kay Johnston, RN  
Abbott Northwestern Hospital-VPCI, Minneapolis, MN

\*Terry Wayne Jones, BS  
Emory University Hospital, Atlanta, GA

\*Michele Joseph  
Hopital du Saint Sacrement, Quebec, CANADA

Twila Jukes  
University of Kansas Medical Center, KS

Claudia Kabler-Babbitt  
Medical College of Wisconsin/Froedtert East Hospital, Milwaukee, WI

\*Caren Kauderer  
Sutter Memorial Hospital, Sacramento, CA

\*Kristen R Kemp, BSN, OCN  
St Lukes Medical Center, Milwaukee, WI

Dong-Wook Kim, MD  
St. Marys Hospital, Seoul, Korea

\*Terry M Koski, RN  
Northeastern Ontario Regional Cancer Center, CANADA

\*Lori E Kronish, RN  
H.Lee Moffitt Cancer Center, Tampa, FL

\*Lorriann Langreck  
Marshfield Clinic, Marshfield, WI

Jong Lee  
St. Mary's Hospital, Seoul, Korea

\*Susan B Lerchie, RN  
LSU Medical Center-Shreveport, Shreveport, LA

Margaret Lewis  
University of Texas Health Sciences Center, San Antonio, TX

Kathy M Lindgren  
RMCC/P/SLMC, Denver, CO



\*Kathy A Loper, MT(ASCP)  
LSU Medical Center-Shreveport, Shreveport, LA

Nadeem Mariza  
MD Anderson Cancer Center, Houston, TX

\*Jan M McCrae, RN  
Toronto General Hospital, Toronto, Ontario CANADA

\*Beverly Jane McGloin, BA  
University Hospital of Cleveland, Cleveland, OH

\*Wendy K McIntyre, RN  
St Louis University Health Sciences Center, St Louis, MO

Tom Miller  
Rocky Mountain Cancer Center, Denver, CO

Pamela Monroe, RN  
Washoe Medical Center

\*Mary E Morris, RN  
University of Nebraska Medical Center, Omaha, NE

\*Lolly Naslund, RRA,CTR  
VirginiaPiper Cancer Institute/Abbott NW Hospital, Minneapolis, MN

\*Sheryl L Oliversen, RN  
So Texas Cancer Institute, San Antonio, TX

\*Barbara Phlaum  
Cancer & Blood Institute of the Desert, Rancho Mirage, CA

\*Jene L Pierson  
University of Nebraska Medical Center, Omaha, NE

\*Carlene Porter  
Rush Presbyterian St Lukes Medical Center, Chicago, IL

David Rice  
University of Kentucky, Lexington, KY

\*Colleen M Rivera, RN  
St Joseph Hospital, Orange, CA

Shari Rottman  
Childrens Hospital of Denver, CO

Jean Sabatos  
St. Josephs Medical Center

\*Ruth Santucci Beale, RN  
Sutter Memorial Hospital, Sacramento, CA

\*Galina Sapozhnikova  
University Hospitals of Cleveland, Cleveland, OH

Louis Schweichler  
Arlington Cancer Center, Arlington, TX

\*Chris Scott  
University of North Carolina, Chapel Hill, NC

\*Linda M Simpson, CTR  
Hoag Memorial Hospital, Newport Beach, CA

\*Paula J Smith, Data Coordinator  
Bowman Gray School of Medicine, Winston Salem, NC

\*Betsy A Stein, CCRC  
Baylor University Medical Center, Dallas, TX

\*Mary C Swinney, RN  
Methodist of IN, Inc, Indianapolis, IN

\*Rosalie S Sziarto, RN  
Northside Hospital, Atlanta, GA

\*Nancy Tainer  
University Hospitals of Cleveland, Cleveland, OH

Miki Takahashi  
Tokai University, Japan

Nita Takeuchi  
BC Childrens Hospital, Vancouver, BC, CANADA

Dixon Terry  
Arkansas Cancer Research Center, Little Rock, AR

Mark R Tindall  
Emory University Hospital, Atlanta, GA

Zutaka Tokuda, MD  
Tokai University, Japan

\*Renee A Vadeboncoeur, RN  
University of Utah, Salt Lake City, UT

Marlies Van Hoef, MD  
Sunnyvale, CA

Twillia Westercamp, RN  
Truman Medical Center

Michael Wierman, MD  
St. Vincent Hospital, Indianapolis, IN

\*Diana D Wilson  
Case Western Reserve Univ, Cleveland, OH

\*Rita Winter  
Via Christi Regional Medical Center, Wichita, KS

\*received grant for partial travel expenses

**ABMTR**  
North America



Autologous Blood & Marrow  
Transplant Registry

AUDIT PROGRAM FOR CENTERS  
PARTICIPATING IN THE ABMTR-North America

I. Objectives

To verify consecutive case reporting and accuracy of reported data as compared to institutional medical records.

II. Audit Operations

Participating institutions are at risk of being audited once every three years. Each year, one third of institutions contributing reports to the ABMTR are notified that they may be audited in the ensuing 12 months. From that list, 20 institutions are selected at random. For each of the 20, an Advisory Committee member near the institution is identified and three convenient times chosen for the audit. Auditors are asked to sign a waiver indicating they have no political, financial or other conflict of interest with the team to be audited prior to notifying the team leader of the identity of the auditor. If the team leader perceives that there may be a bias on the part of the selected auditor, team leaders are given one week to request another auditor. If none is available from among Advisory Committee members in the immediate vicinity, a member of the Statistical Center will perform the audit. The institution to be audited is notified and a final date agreed upon. Three weeks prior to the date of audit, the institution is notified of ten cases selected at random from among its contributions during the preceding five years. The audited institution is expected to have medical records and all necessary supporting information gathered and available at the time of the audit for each of these ten cases.

III. Verification of Consecutive Reporting

Cases reported to the ABMTR by the audited team for one year in the five years prior to the audit will be compared by the auditor to institutional records of all transplants performed, to verify that all eligible cases were reported. The auditor will verify that records of the transplant program confirm reporting.

IV. Verification of Accurate Reporting

At the time of the audit, the auditor selects five of the ten available cases for detailed review. For these five cases, specific items reported on ABMTR data collection forms are compared with data in the institutional medical record. Deficits and discrepancies are documented by question number and discrepancy, using a form-specific checklist prepared by the ABMTR Statistical Center and the Executive Committee.

## ABMTR AUDIT PROGRAM

page 2

### V. Assistance with the Audit

The data manager and/or transplant coordinator of the audited institution will function as an assistant to the Advisory Committee member performing the audit. The assistant locates information required in the medical record (based on information provided by the Statistical Center) prior to the time of the on-site audit to expedite retrieval and verification by the auditor. The assistant also provides documentation of consecutive patients transplanted at the time of the audit.

### VI. Analysis of Audits

The Auditor is responsible for preparing an analysis of the audit to include consideration of the following:

1. Questionable or falsified reporting forms, that is, reporting forms submitted to the ABMTR describing patients who are not documented by a medical record;
2. Misinterpretation of instructions or questions such that incorrect answers are submitted;
3. Discrepancies between data found in the medical record and on the ABMTR reporting form;
4. Failure to provide required follow-up.

Audit analyses are done using a form provided by the Statistical Center. Analyses are submitted to the Audit Committee within 30 days of completing the audit.

### VII. Review of Audits

The Audit Committee will review each Audit Analysis and prepare an Audit Report to be sent to the audited institution and the Executive Committee within 30 days of receiving the Audit Analysis. This report may contain recommendations for improvement in local data management. Institutions that the Audit Committee considers suspect for fraud, biased reporting and/or serious deficiencies in data management are referred to the Executive Committee for further action.

VIII. Audit Summaries

The Audit Committee prepares an annual report of all audits for the ABMTR Executive Committee. The Executive Committee is responsible for summarizing these reports for ABMTR annual progress reports and the annual meeting of the ABMTR Advisory Committee.

IX. Consequences of Fraudulent, Non-consecutive and/or Inaccurate Reporting

As noted above, institutions with serious deficiencies are referred to the Executive Committee for action. Instances in which fraud is suspected may result in additional requests for documentation and additional audits. If fraud is documented, the institution is denied further participation in ABMTR activities and all data previously reported to the ABMTR removed from the ABMTR database. In the event of failure to report consecutive cases, an institution is given 120 days to rectify the deficiency by reporting all omitted cases and is subject to re-audit in 12 months. Failure to remedy the deficiency results in suspension and removal of all data previously reported by the offending institution from the database. Serious inaccuracies in data reported to the IBMTR are brought to the attention of the offending institution with recommendations for remedial action. The institution is subject to re-audit within 12 months. Whether previously reported cases are deleted from the ABMTR database is at the discretion of the Executive Committee after consideration of audit findings.

Figure 1

# ANNUAL NUMBER OF BLOOD AND MARROW TRANSPLANTS WORLDWIDE 1970-1995

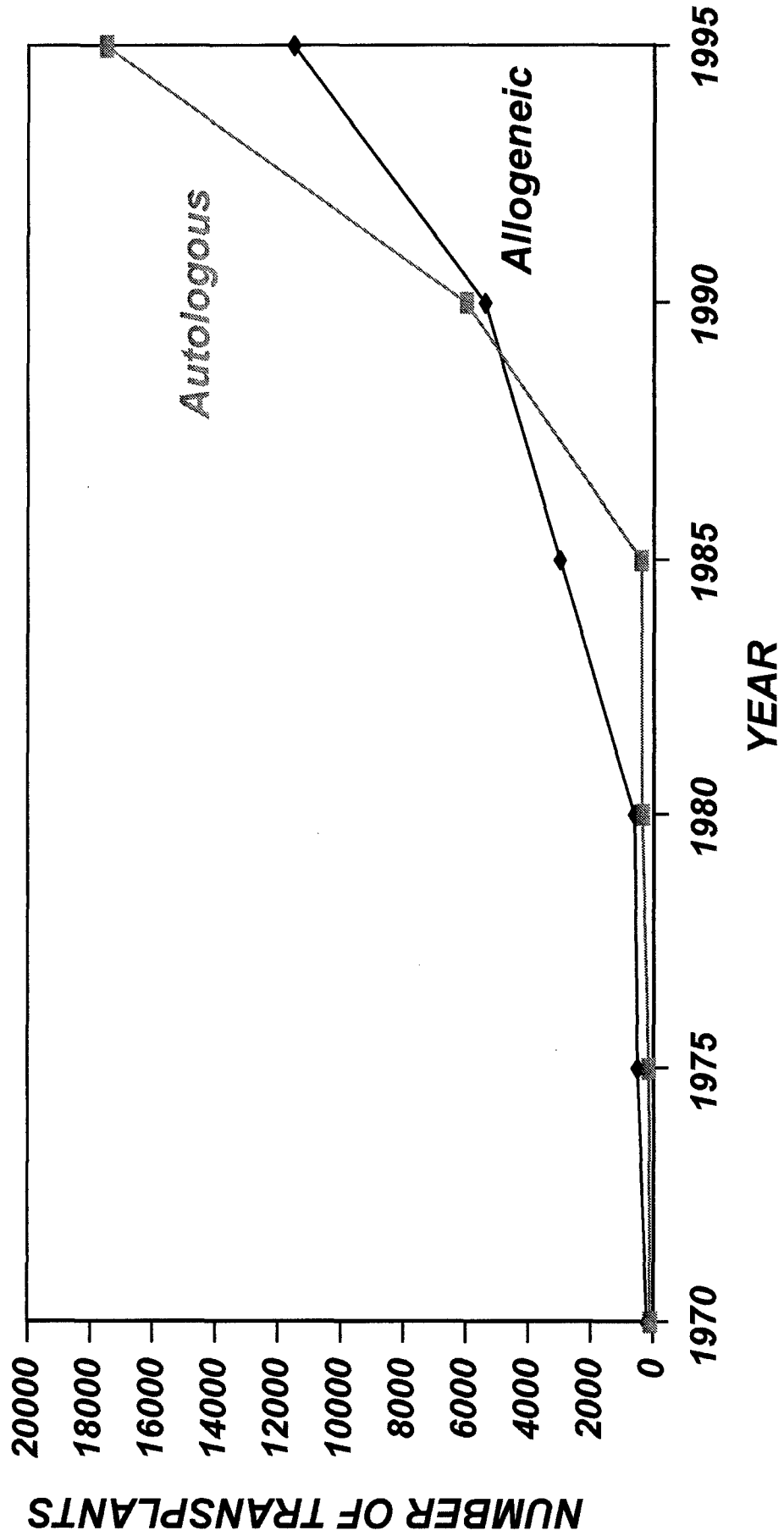


Figure 2

# INDICATIONS FOR BLOOD AND MARROW TRANSPLANTATION IN NORTH AMERICA 1995

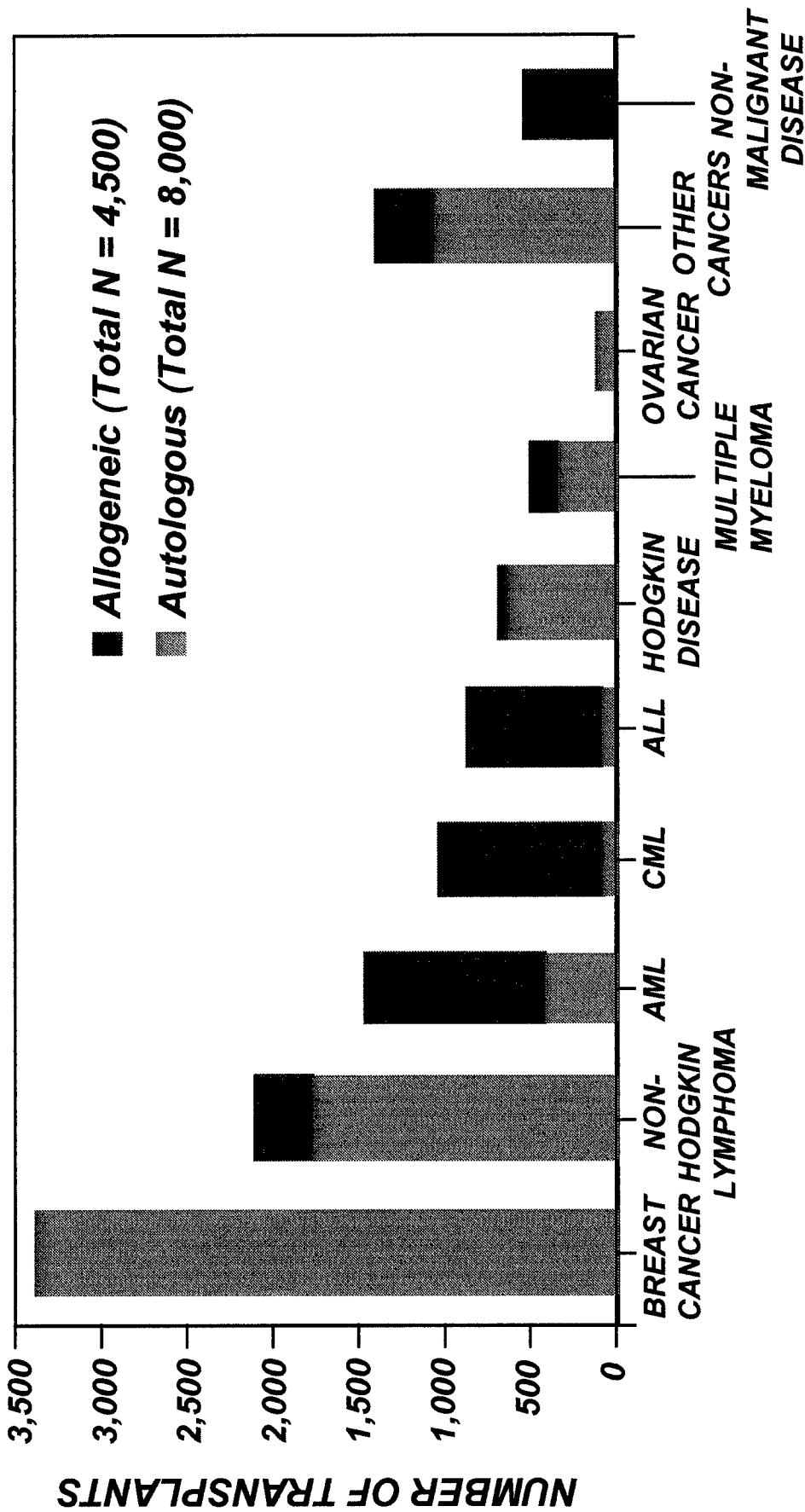
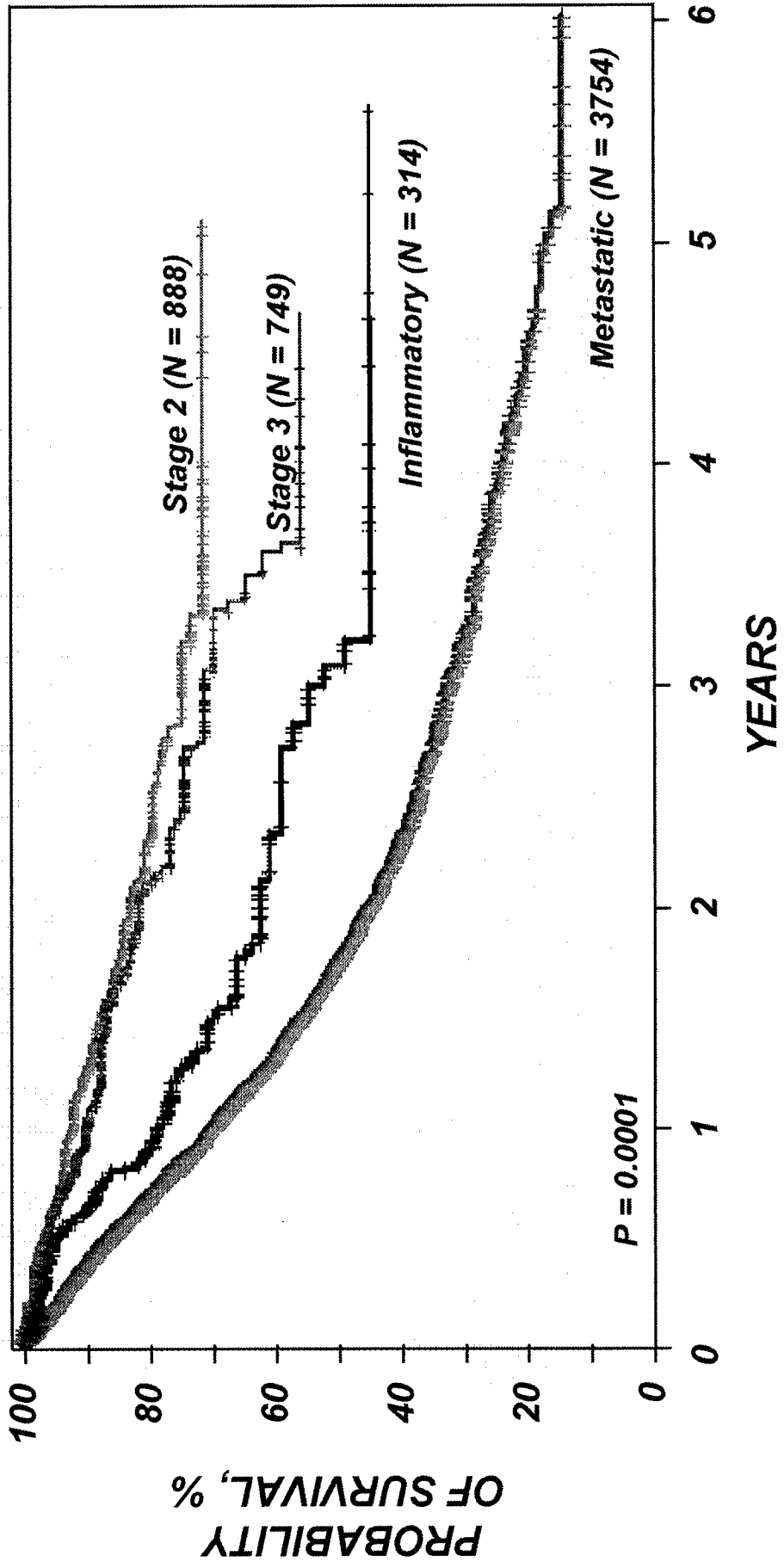


Figure 3

# PROBABILITY OF SURVIVAL AFTER AUTOTRANSPLANTS FOR BREAST CANCER 1989-1995





**U.S. CENTERS RESPONDING TO INSTITUTIONAL SURVEY****ALABAMA**

Brookwood Medical Center, Birmingham  
University of Alabama at Huntsville, Huntsville  
University of South Alabama, Mobile

**ARIZONA**

University of Arizona Health Sciences Center, Tucson

**CALIFORNIA**

Alta Bates Medical Center, Comprehensive Cancer Center, Berkeley  
University of California, San Diego, La Jolla  
University of California, Irvine, Newport Beach  
Children's Hospital of Orange County (CHOC), Orange  
St. Joseph Hospital, Orange  
Sutter Memorial Hospital, Sacramento  
University of California, Davis Cancer Center, Sacramento  
Children's Hospital of San Diego, San Diego  
University of San Diego, San Diego  
University of California - San Francisco, Moffitt Hospital, San Francisco  
John Muir Hospital, Walnut Creek  
Westlake Comprehensive Cancer Center, Westlake Village

**COLORADO**

Presbyterian-St. Luke's Medical Center, Denver

**CONNECTICUT**

Yale University School of Medicine / New Haven Hospital, New Haven  
Bennett Cancer Center, Stamford

**DELAWARE**

Medical Center of Delaware / Christiana Hospital, Newark

**FLORIDA**

Impact Center of Clearwater, Clearwater  
Bone Marrow Stem Cell Institute of Florida, Ft. Lauderdale  
Impact Center of South Broward, Ft. Lauderdale  
University of Florida, J. Hillis Miller Health Center, Gainesville  
Baptist Regional Cancer Center, Jacksonville  
Mayo Clinic Jacksonville/St. Luke's Hospital, Jacksonville  
Baptist Hospital of Miami, Miami  
All Children's Hospital, St. Petersburg  
H. Lee Moffitt Cancer Center & Research Institute, Tampa

**GEORGIA**

Egleston Hospital for Children at Emory University, Atlanta  
Emory University Hospital / The Emory Clinic, Atlanta

**IOWA**

University of Iowa Hospital & Clinics, Iowa City

**ILLINOIS**

Children's Memorial Medical Center, Chicago

University of Chicago Medical Center, Chicago

Loyola University Cancer Center, Maywood

Lutheran General Hospital / University of Chicago, Park Ridge

**INDIANA**

Impact Center of Ft. Wayne / Ft. Wayne Medical Oncology-Hematology, Ft. Wayne

Methodist Hospital of Indiana, Indianapolis

St. Vincent Hospital & Health Care Center, Indianapolis

**KANSAS**

Children's Mercy Hospital, Kansas City

University of Kansas Medical Center, Kansas City

St. Francis Hospital, Wichita

**KENTUCKY**

Kosair Children's Hospital, Louisville

**LOUISIANA**

Mary Bird Perkins Cancer Center, Baton Rouge

Children's Hospital, New Orleans / Louisiana State University, New Orleans

Tulane University Medical Center / Tulane Cancer Center, New Orleans

Louisiana State University Medical Center-Shreveport, Shreveport

**MASSACHUSETTS**

Beth Israel Health Care Charles C. Shapiro Cancer Center, Boston

Brigham & Women's Hospital, Boston

Children's Hospital of Boston / Dana-Farber Cancer Institute, Boston

Dana-Farber Cancer Institute, Boston

Massachusetts General - MGH East, Boston

Massachusetts General Hospital, Boston

Cancer Center of Boston, Plymouth

Baystate Medical Center / Tufts University School of Medicine, Springfield

Medical Center of Central Massachusetts, Worcester

University of Massachusetts Medical Center, Worcester

**MARYLAND**

University of Maryland Cancer Center, Baltimore

Holy Cross Hospital, Silver Spring

**MAINE**

Maine Medical Center, South Portland

**MICHIGAN**

Henry Ford Hospital, Detroit

**MINNESOTA**

Abbott Northwestern Hospital, Minneapolis  
University of Minnesota Hospital & Clinics, Minneapolis  
Mayo Clinic & Foundation, Rochester  
Methodist Hospital & Park Nicollet Cancer Center, St. Louis Park

**MISSOURI**

Mid America Medical Consultants, Kansas City  
Barnes Hospital / Washington University Medical Center, St. Louis  
Cardinal Glennon Children's Hospital, St. Louis  
St. Louis Children's Hospital / Washington University School of Medicine, St. Louis

**NORTH CAROLINA**

University of North Carolina, Chapel Hill  
North Carolina Baptist Hospital/Bowman Gray School of Medicine, Winston-Salem

**NEBRASKA**

Immanuel Cancer Center, Omaha  
University of Nebraska Medical Center, Omaha

**NEW HAMPSHIRE**

Dartmouth-Hitchcock Medical Center, Lebanon

**NEW JERSEY**

St. Joseph's Hospital & Medical Center, Paterson  
Riverview Medical Center, Red Bank

**NEVADA**

Washoe Regional Cancer Center / University of Nevada School of Medicine, Reno

**NEW YORK**

Albany Medical Center, Albany  
Montefiore Medical Center, Bronx  
Schneider Children's Hospital, New Hyde Park  
Columbia Presbyterian Medical Center, New York  
Mount Sinai Medical Center, New York  
St. Charles & John T. Mather Hospital / North Shore Stem Cells, Port Jefferson Station  
University Hospital-SUNY Health Sciences Center, Syracuse

**OHIO**

Children's Hospital Medical Center, Cincinnati  
Jewish Hospital of Cincinnati, Cincinnati  
Rainbow Babies and Children's Hospital / University Hospitals of Cleveland, Cleveland  
A.G. James Cancer Hospital & Research Institute / Ohio State University Hospitals, Columbus  
Columbus Children's Hospital, Columbus  
Miami Valley Hospital, Dayton

**OKLAHOMA**

University of Oklahoma Health Sciences Center, Oklahoma City  
St. Francis Hospital, Tulsa

**PENNSYLVANIA**

Fox Cancer Center, Philadelphia  
Temple University Comprehensive Cancer Center, Philadelphia  
Thomas Jefferson University Hospital, Philadelphia  
University of Pennsylvania Hospital, Philadelphia  
Children's Hospital of Pittsburgh, Pittsburgh  
Shadyside Hospital, Pittsburgh  
Western Pennsylvania Cancer Institute, Pittsburgh

**SOUTH CAROLINA**

Medical University of South Carolina / Hollings Cancer Center, Charleston  
Richland Memorial Hospital / University of South Carolina, Columbia

**TENNESSEE**

Methodist Hospital Central, Memphis  
St. Jude's Children's Research Hospital, Memphis

**TEXAS**

Southwest Regional Cancer Center, Austin  
Baylor University Medical Center, Dallas  
Children's Medical Center of Dallas, Dallas  
Cook-Fort Worth Children's Medical Center, Fort Worth  
Harris Methodist Oncology Program, Fort Worth  
Texas Children's Hospital, Houston  
Audie L. Murphy Memorial Veterans Hospital, San Antonio  
Wilford Hall Medical Center, San Antonio

**UTAH**

Intermountain Health Care, Inc., LDS Hospital, Salt Lake City  
Oncology Clinical Trials Office, Salt Lake Clinic, Salt Lake City  
University of Utah Medical Center, Salt Lake City

**VERMONT**

Fletcher Allen Health Care / UHC Campus, Burlington

**WASHINGTON**

Seattle Department of Veterans Affairs Medical Center, Seattle

**WASHINGTON, DC**

Georgetown University Medical Center  
Pasquerilla Healthcare / Vincent T. Lombardi Cancer Research Center  
Walter Reed Army Medical Center

**WISCONSIN**

University of Wisconsin Hospital & Clinics, Madison

Marshfield Clinic, Marshfield

Medical College of Wisconsin, Froedtert East Hospital, Milwaukee

St. Luke's Medical Center, Milwaukee

**WEST VIRGINIA**

West Virginia University Hospitals, Morgantown

**IBMTR**



International Bone Marrow  
Transplant Registry

**IBMTR/ABMTR**

**ABMTR**  
North America



Autologous Blood & Marrow  
Transplant Registry

## Survey of Transplant Activity 1991-1995

Name of Institution: \_\_\_\_\_

Director of Transplant Program: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Country: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

FAX Number: \_\_\_\_\_

e-mail Address: \_\_\_\_\_

Transplant Coordinators: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Person completing this form: \_\_\_\_\_

Date completed:        
Month Day Year



REGISTRY USE ONLY

Four empty boxes for registry use.

IBMTR



International Bone Marrow Transplant Registry

IBMTR/ABMTR

ABMTR

North America



Autologous Blood & Marrow Transplant Registry

## Survey of Transplant Activity 1991-1995

During the years 1991 through 1995, were any of the following done at your transplant center?

- |   | <u>Yes</u>                 | <u>No</u>                  | <u>Don't Know</u>          |
|---|----------------------------|----------------------------|----------------------------|
| 1. <b>Autologous</b> bone marrow transplantation          | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 8 <input type="checkbox"/> |
| 2. <b>Autologous</b> peripheral stem cell transplantation | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 8 <input type="checkbox"/> |
| 3. <b>Allogeneic</b> bone marrow transplantation          | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 8 <input type="checkbox"/> |
| 4. <b>Allogeneic</b> peripheral stem cell transplantation | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 8 <input type="checkbox"/> |
| 5. <b>Cord blood</b> transplantation                      | 1 <input type="checkbox"/> | 0 <input type="checkbox"/> | 8 <input type="checkbox"/> |

6. Number of cord blood transplants in 1995:

7. Is your center/unit primarily:

- 1  Community \_\_\_\_\_
- 2  Academic
- 3  Other, SPECIFY: \_\_\_\_\_

8. Is your center/unit affiliated with an academic center?

- 1  Yes, specify: \_\_\_\_\_
- 0  No

9. What is the total number of beds at your hospital?

- 1  <100
- 2  100-199
- 3  200-299
- 4  300-399
- 5  400-499
- 6  ≥500
- 8  Don't know

10. Does your hospital treat only cancer patients?

- 1  Yes
- 0  No

11. Does your center have dedicated transplant beds?

- 1  Yes
- 0  No

12. Number of dedicated transplant beds:



13. How many separate bone marrow and/or peripheral stem cell transplant units (or teams) are physically located at your center? [NOTE: Separate units/teams are defined as units with separate administrative and clinical personnel.]

- 1  One unit  
 0  More than one unit

14. Would you describe your transplant unit as primarily:

1  Pediatric      2  Adult      3  Combined

15. Number of units:

How would you characterize or distinguish each of these units (eg. breast cancer, autologous, etc.)?

16. Unit 1: \_\_\_\_\_ Contact person: \_\_\_\_\_

17. Unit 2: \_\_\_\_\_ Contact person: \_\_\_\_\_

18. Unit 3: \_\_\_\_\_ Contact person: \_\_\_\_\_

19. Unit 4: \_\_\_\_\_ Contact person: \_\_\_\_\_

20. Unit 5: \_\_\_\_\_ Contact person: \_\_\_\_\_

Would you describe these transplant units as primarily pediatric, adult or combined units?

	<u>Pediatric</u>	<u>Adult</u>	<u>Combined</u>
21. Unit 1:	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
22. Unit 2:	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
23. Unit 3:	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
24. Unit 4:	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
25. Unit 5:	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>

26. If your center has more than one transplant unit, please indicate whether responses to the following questions in this survey pertain to all units or one unit.

1  All units  
 2  One unit

27. Indicate which unit (as numbered in Questions 7-14):

1  Unit 1  
 2  Unit 2  
 3  Unit 3  
 4  Unit 4  
 5  Unit 5

28. If you answered "yes" to question 1 and/or 2, when did your center/unit first perform autologous bone marrow and/or peripheral stem cell transplants?      19

29. If you answered "yes" to question 3, 4, or 5, when did your center/unit first perform allogeneic, related donor bone marrow and/or peripheral stem cell and/or cord blood transplants?      19

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30. If you answered "yes" to question 3, 4 and/or 5, when did your center/unit first perform allogeneic, unrelated donor bone marrow and/or peripheral stem cell and/or cord blood transplants?

19   OR -7  do not perform unrelated donor transplants

31. Do medical students or physicians in postgraduate training work on your transplant unit?

- 1  Yes
- 0  No

32. Does your center/unit treat patients only on clinical study protocols, only off-protocol or both?

- 1  Only on clinical study protocols
- 2  Only off-protocol
- 3  Both on and off-protocol

33. Does your center/unit perform any chemotherapy followed by stem cell reinfusion that is entirely on an outpatient basis?

- 1  Yes
- 0  No
- 8  Don't know

34. For how many of the patients who received a transplant at your center/unit in 1995 was pretransplant conditioning (high dose therapy) administered entirely on an outpatient basis?

Does your center/unit regularly perform:

	<u>Yes</u>	<u>No</u>	<u>Don't Know</u>
35. Chemical purging to remove tumor cells from autografts	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
36. Gene therapy studies	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
37. Negative selection with monoclonal antibodies	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
38. Positive selection with CD34 monoclonal antibodies	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
39. Ex vivo expansion of marrow-derived cells	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
40. Ex vivo expansion of blood-derived cells	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
41. T-cell depletion	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>

42. Which one of the following agents are primarily used for priming or mobilization for autologous peripheral stem cell collection at your center/unit? (CHECK ONE)

- 1  G-CSF alone
- 2  G-CSF plus some chemotherapeutic agent
- 3  GM-CSF alone
- 4  GM-CSF plus some chemotherapeutic agent
- 5  A chemotherapeutic agent alone
- 6  Other agent or combination of agents, PLEASE SPECIFY: \_\_\_\_\_
- 7  None

--	--	--	--

43. Which one of the following agents are primarily used for priming or mobilization for allogeneic peripheral stem cell collection at your center/unit? (CHECK ONE)

- 1  G-CSF alone
- 2  G-CSF plus some chemotherapeutic agent
- 3  GM-CSF alone
- 4  GM-CSF plus some chemotherapeutic agent
- 5  A chemotherapeutic agent alone
- 6  Other agent or combination of agents, PLEASE SPECIFY: \_\_\_\_\_
- 7  None

44. Do you currently have a computerized system for capturing and analyzing clinical data on your transplant patients? (Do not include systems used primarily for billing purposes unless specifically designed to be suitable for clinical studies.)

- 1  Yes
- 0  No

45. Type of computer used:

- 1  IBM-compatible PC
- 2  Macintosh
- 3  Workstation
- 4  Mainframe

46. Database used:

- 1  FoxPro
- 2  dBase
- 3  Paradox
- 4  Sybase
- 5  Oracle
- 6  Stem Soft
- 7  Other, specify: \_\_\_\_\_

47. (U.S. and Canada only) What is the average nurse/patient ratio on your inpatient allogeneic transplant unit?

- 1  1:2
- 2  1:3
- 3  1:4
- 4  <1:4
- 8  Don't know

48. (U.S. and Canada only) What is the average nurse/patient ratio on your inpatient autologous transplant unit?

- 1  1:2
- 2  1:3
- 3  1:4
- 4  <1:4
- 8  Don't know

**(U.S. only)** As best you can, please estimate what percent of autologous transplants at your center/unit are paid by the following mechanisms:

- 49. Negotiated fixed price (eg. as with managed care)    %
- 50. Traditional fee-for-service    %
- 51. Discounted fee-for-service    %
- 52. Hospital-absorbed cost for indigent patient    %

**(U.S. only)** As best you can, please estimate what percent of allogeneic transplants at your center/unit are paid by the following mechanisms:

- 53. Negotiated fixed price (eg. as with managed care)    %
- 54. Traditional fee-for-service    %
- 55. Discounted fee-for-service    %
- 56. Hospital-absorbed cost for indigent patient    %

57. **(U.S. only)** Do any of the bone marrow and/or peripheral stem cell transplants performed at your center/unit involve a commercial enterprise such as Response Technologies, Caremark, Salick, and/or TOPA in any way?

- 1  Yes
- 0  No

With which particular commercial enterprises is your center/unit involved as part of its transplant program?

	<u>Yes</u>	<u>No</u>	
58.	<input type="checkbox"/>	<input type="checkbox"/>	Response Technologies
59.	<input type="checkbox"/>	<input type="checkbox"/>	Caremark
60.	<input type="checkbox"/>	<input type="checkbox"/>	Salick
61.	<input type="checkbox"/>	<input type="checkbox"/>	TOPA
62.	<input type="checkbox"/>	<input type="checkbox"/>	Other, SPECIFY: _____

63. For what percent of the transplants performed at your center/unit do these organizations play some role?    %

<b>REGISTRY USE ONLY</b>				

Is your center/unit a member of (CHECK ALL THAT APPLY):

- Yes No
64. 1  0  International Bone Marrow Transplant Registry (IBMTR) — 65. Team Number
66. 1  0  Autologous Blood & Marrow Transplant Registry of North America (ABMTR) — 67. Team Number
68. 1  0  European Blood and Marrow Transplant Group (EBMTG)
69. 1  0  National Marrow Donor Program (NMDP)
70. 1  0  Cooperative clinical trials group(s), specify: \_\_\_\_\_

<u>Yes</u>	<u>No</u>		<u>Yes</u>	<u>No</u>	
71. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	EORTC	78. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	NSABP
72. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	MRC	79. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	NCCOG
73. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	ECOG	80. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	RTOG
74. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	CALGB	81. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
75. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	SWOG	82. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
76. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	POG	83. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____
77. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	CCSG	84. 1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other, specify: _____

**On the following tables, please provide the number of transplants done in each year (1991-1995) by disease and graft type.**

TABLE 1 - 1991

DONOR SOURCE, No. of transplants done in 1991

INDICATION	Autologous			Allogeneic								
	BM only	PB only	BM + PB	Total	HLA-identical sibling		Family		Twin		Unrelated	
					BM	PB	BM	PB	BM	PB	BM	PB
Acute myeloid leukemia 1st complete remission												
not 1st complete remission												
Acute lymphoblastic leukemia 1st complete remission												
not 1st complete remission												
Chronic myeloid leukemia 1st chronic phase												
not 1st chronic phase												
Myelodysplastic syndrome												
Chronic lymphocytic leukemia												
Multiple myeloma												
Hodgkin's lymphoma												
Non Hodgkin lymphoma												
Neuroblastoma												
Glioma												
Soft tissue sarcoma												
Germinal tumors												
Breast cancer stage 2												
Breast cancer stage 3												
Breast, inflammatory												
Breast, metastatic												
Ewing												
Lung cancer												
Other solids tumors												
Severe aplastic anemia												
Fanconi Anemia												
Thalassemia												
SCID												
Inborn errors												
Auto immune disease												
Others												
TOTAL												

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE:

TABLE 2 - 1992

DONOR SOURCE, No. of transplants done in 1992

INDICATION	Autologous			Allogeneic								
	BM only	PB only	BM + PB	Total	Family			Unrelated		PB	Total	
					HLA-identical sibling		Twin	BM	BM			
	BM	PB	BM	PB	BM	PB				BM	PB	
Acute myeloid leukemia 1st complete remission												
not 1st complete remission												
Acute lymphoblastic leukemia 1st complete remission												
not 1st complete remission												
Chronic myeloid leukemia 1st chronic phase												
not 1st chronic phase												
Myelodysplastic syndrome												
Chronic lymphocytic leukemia												
Multiple myeloma												
Hodgkin's lymphoma												
Non Hodgkin lymphoma												
Neuroblastoma												
Glioma												
Soft tissue sarcoma												
Germinal tumors												
Breast cancer stage 2												
Breast cancer stage 3												
Breast, inflammatory												
Breast, metastatic												
Ewing												
Lung cancer												
Other solids tumors												
Severe aplastic anemia												
Fanconi Anemia												
Thalassemia												
SCID												
Inborn errors												
Auto immune disease												
Others												
TOTAL												

REGISTRY USE:

BM: bone marrow; PB: peripheral blood progenitor cells

TABLE 3 - 1993 DONOR SOURCE, No. of transplants done in 1993

INDICATION	Autologous			Allogeneic							Total		
	BM only	PB only	BM + PB	HLA-identical sibling		Family			Unrelated				
				BM	PB	BM	PB	BM	PB	BM		PB	
													Twin
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast inflammatory													
Breast metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE:



TABLE 4 - 1994 DONOR SOURCE, No. of transplants done in 1994

INDICATION	Autologous			Allogeneic												
	BM only	PB only	BM + PB	Total	Family				Unrelated							
					HLA-identical sibling		Other		Twin		BM		PB			
	BM	PB	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	BM	PB	Total	
Acute myeloid leukemia 1st complete remission																
not 1st complete remission																
Acute lymphoblastic leukemia 1st complete remission																
not 1st complete remission																
Chronic myeloid leukemia 1st chronic phase																
not 1st chronic phase																
Myelodysplastic syndrome																
Chronic lymphocytic leukemia																
Multiple myeloma																
Hodgkin's lymphoma																
Non Hodgkin lymphoma																
Neuroblastoma																
Glioma																
Soft tissue sarcoma																
Germinal tumors																
Breast cancer stage 2																
Breast cancer stage 3																
Breast inflammatory																
Breast metastatic																
Ewing																
Lung cancer																
Other solids tumors																
Severe aplastic anemia																
Fanconi Anemia																
Thalassemia																
SCID																
Inborn errors																
Auto immune disease																
Others																
TOTAL																

REGISTRY USE:

BM: bone marrow; PB: peripheral blood progenitor cells

TABLE 5 - 1995

DONOR SOURCE, No. of transplants done in 1995

INDICATION	Autologous			Allogeneic											
	BM only	PB only	BM + PB	Total	Family			Unrelated							
					HLA-identical sibling		Other		Twin		BM	PB	Total		
					BM	PB	BM	PB	BM	PB					
Acute myeloid leukemia 1st complete remission															
Acute myeloid leukemia not 1st complete remission															
Acute lymphoblastic leukemia 1st complete remission															
Acute lymphoblastic leukemia not 1st complete remission															
Chronic myeloid leukemia 1st chronic phase															
Chronic myeloid leukemia not 1st chronic phase															
Myelodysplastic syndrome															
Chronic lymphocytic leukemia															
Multiple myeloma															
Hodgkin's lymphoma															
Non Hodgkin lymphoma															
Neuroblastoma															
Glioma															
Soft tissue sarcoma															
Germinal tumors															
Breast cancer stage 2															
Breast cancer stage 3															
Breast, inflammatory															
Breast, metastatic															
Ewing															
Lung cancer															
Other solids tumors															
Severe aplastic anemia															
Fanconi Anemia															
Thalassemia															
SCID															
Inborn errors															
Auto immune disease															
Others															
TOTAL															

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE:

**HIGH-DOSE CHEMOTHERAPY WITH AUTOLOGOUS HEMATOPOIETIC  
STEM CELL SUPPORT FOR BREAST CANCER IN NORTH AMERICA**

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Running Head: Autotransplants for Breast Cancer in North America

## ABSTRACT

Purpose: Identify trends in high-dose therapy with autologous hematopoietic stem cell support (autotransplants) for patients with breast cancer from 1989 to 1995.

Patients and Methods: Analysis of observational database of the Autologous Blood and Marrow Transplant Registry of North America (ABMTR). Data on 19,291 autotransplants between 1989 and June 30, 1995 were reviewed; 5,886 were performed for breast cancer. Patients received high-dose chemotherapy (with or without radiation therapy) with autologous hematopoietic stem cell support. Main outcome measures were progression-free survival (PFS) and survival from time of autotransplant.

Results: Use of autotransplants for breast cancer increased six-fold between 1989 and 1995. After 1992, breast cancer was the most common indication for autotransplant. Significant trends included increasing use for locally advanced (stages 2 and 3) rather than metastatic (stage 4) disease ( $p < 0.00001$ ) and use of blood- rather than bone marrow-derived cells ( $p < 0.00001$ ). Treatment-related mortality decreased substantially from 22% in 1989 to 5% in 1995 ( $p < 0.0001$ ).

Three-year probabilities of PFS (95% confidence intervals) were 65 (59-71)% for women with stage 2 breast cancer and 60 (53-67)% for those with stage 3 breast cancer. Three-year probabilities of survival were 74 (68-80)% and 70 (63-77)% for stage 2 and 3 breast cancer, respectively among women with stage 4 breast cancer, three-year probabilities of PFS and survival were 7 (4-10)% and 16 (12-20)%, respectively, for those with stable or progressive disease after conventional dose chemotherapy; 13 (9-17)% and 29 (25-33)% for those with a partial response to conventional chemotherapy, and 32 (27-37)% and 46 (42-50)% for those with a complete response to conventional chemotherapy. Eleven percent of women with stage 2 or 3 disease and fewer than 1% of those with stage 4 disease participated in national cooperative

group randomized trials.

Conclusions: Autotransplants are increasingly used to treat breast cancer and are now the most common indication for transplant. Treatment-related mortality has decreased substantially.

Three-year survival is better in women with stage 2 and 3 versus stage 4 disease and in those responding to pretransplant chemotherapy.

## INTRODUCTION

Breast cancer is the most common cancer and the second most common cause of cancer deaths in American women.<sup>1</sup> Survival of women with breast cancer correlates with extent of disease. Ten-year survival is 65-80% for women with disease confined to the breast.<sup>2-4</sup> Ten-year survival rates are 35-65% for those with 1-3 involved axillary lymph nodes, 30-40% for those with 4-9 involved axillary nodes and 15-30% in those with >9 involved axillary nodes.<sup>5-7</sup> Recurrent disease tends to develop earlier in patients with multiple involved nodes and relapse risk persists for at least 20 years after mastectomy. Women with metastatic breast cancer have a median survival of about two years and a 2-5% probability of five-year disease-free survival.<sup>8-11</sup>

Intensive therapy (chemotherapy with or without radiation therapy) with autologous hematopoietic stem cell support (autotransplant) is increasingly used to treat breast cancer in women at high risk of persistent or recurrent disease. However, most reports of autotransplants include relatively few subjects and there are likely to be substantial reporting biases. One small randomized study of women with metastatic breast cancer shows a statistically significant advantage in both survival and disease-free survival for high-dose chemotherapy with bone marrow transplant versus conventional dose chemotherapy.<sup>12</sup> Here we report results of autotransplants in more than 5800 consecutive women receiving autotransplants at over 130 centers between 1989 and 1995.



## METHODS

**Patients:** The Autologous Blood and Marrow Transplant Registry of North America (ABMTR) is a voluntary organization of more than 170 transplant institutions in the United States, Canada, and Central and South America that report data on consecutive autotransplants to a Statistical Center at the Medical College of Wisconsin. An autotransplant is defined as treatment with a sufficiently high dose of chemotherapy to require autologous bone marrow or blood-derived hematopoietic stem cell support. The Statistical Center also collects data for allogeneic bone marrow transplants (allotransplants) from centers participating in the International Bone Marrow Transplant Registry, a similar but independent organization of allotransplant centers worldwide.

The ABMTR began data collection in 1992. Data were collected retrospectively for patients receiving autotransplants between 1989 and 1992 and prospectively thereafter. Participating centers register core information on consecutive autotransplants for all disease indications. Based on data collected in the Center for Disease Control Hospital Surveys<sup>13,14</sup>, about half of North American autotransplants for all diseases were registered with the ABMTR during the study period. A list of participating centers is shown in Appendix 1. Registration data from consecutive women with breast cancer receiving an autotransplant at ABMTR centers between January 1989 and June 30, 1995 were the subject of this analysis.

Data regarding disease type, age, gender and posttransplant survival were requested for all patients. Questions regarding pretransplant disease stage and chemotherapy-responsiveness, date of diagnosis, graft type (bone marrow and/or blood-derived stem cells), high-dose conditioning regimen and posttransplant disease progression were added to registration forms more recently. Although an attempt was made to collect this information for previously registered patients, these data are not available for all patients. Patients with primary (stages 2, 3 and inflammatory) and

metastatic breast cancer were considered separately in the analysis. The ABMTR requests data on progression or death in registered patients at six month intervals.

**Statistical Methods:** Comparisons of patient and treatment characteristics over time used chi-square test for categorical and Kruskal-Wallis test for continuous variables.<sup>15</sup> Probabilities of 100-day mortality, progression-free survival (PFS) and overall survival were calculated using the Kaplan-Meier product limit estimate.<sup>16</sup> Comparisons of 100-day mortality, PFS and survival between groups used the log rank test.<sup>17</sup>

## RESULTS

Between January 1, 1989 and June 30th, 1995, 19,291 patients receiving high-dose therapy with autologous hematopoietic stem cell support were reported to the ABMTR. Of these, 5,886 (31%) were for breast cancer. Between 1989 and 1995, autotransplants for breast cancer increased from 16% to 40% ( $P < 0.00001$ ) of all autotransplants reported (Figure 1, Table 1). Numbers of autotransplants for breast cancer exceeded those for Hodgkin disease and non-Hodgkin lymphoma after 1992. Breast cancer was the most common indication for stem cell transplants of all types in 1993-94 (Figure 1).

Numbers of patients reported per year, age at transplant, pretransplant disease stage, source of stem cells, and treatment-related mortality are shown in Table 1. The distribution of disease stage at transplantation changed from 7% local and 93% metastatic disease in 1989 to about 50% local and 50% metastatic disease in 1995 ( $P < 0.00001$ ). This is reflected in the interval from diagnosis to transplant which decreased over the study period. By 1995, 57% of transplants for breast cancer were done within one year of diagnosis.

Use of blood-derived cells alone or in combination with bone marrow increased from 19% to

90% ( $P < 0.00001$ ) in these six years. Various preparatory regimens were used with only the combination of cyclophosphamide, thiotepa and carboplatin (CTCb) used in more than 25% of all patients. An important finding was decreasing 100-day mortality, from 22% in 1989 to 5% in 1995 ( $P < 0.00001$ ).

### **High-Risk Primary Breast Cancer**

Characteristics of women receiving autotransplants for Stage 2, 3 and inflammatory breast cancer are shown in Table 2. Eleven percent were treated as part of randomized cooperative group trials. While most patients had stage 2 or 3 breast cancer and 10 or more involved axillary nodes, some transplants were done for inflammatory breast cancer (17%) or for women with <10 axillary nodes involved (28%). Kaplan-Meier estimates of survival and PFS by disease stage are shown in Figure 2; three-year probabilities are listed in Table 3.

### **Metastatic Breast Cancer**

Characteristics of women receiving autotransplants for metastatic breast cancer are shown in Table 4. Fewer than 1% were treated on randomized cooperative group trials. Most patients had chemotherapy-sensitive disease (complete or partial response prior to transplant) and either visceral or bone disease. Median survival was 19 months (Figure 2). Three-year PFS and survival probabilities are shown in Table 3. Women with a complete response to chemotherapy pretransplant had superior survival and PFS to those with either a partial response or resistant disease (Figure 3).

## Second Malignancies

Data regarding second malignancies were available for 2,045 women. There were 13 cancers reported: 4 myelodysplastic syndromes, 2 endometrial carcinomas, 1 ovarian carcinoma, 1 squamous cell carcinoma, 1 transitional cell carcinoma of the bladder, 1 Hurthle cell tumor of the thyroid, 1 lung carcinoma, 1 glioblastoma, and 1 cervical cancer.

## DISCUSSION

These data indicate several interesting aspects of autotransplants for breast cancer. First, the annual frequency of autotransplants has increased substantially, from fewer than 300 reported to the ABMTR in 1989 to about 1,500 presently. Second, an increasing proportion are for women with locally advanced disease: <10% in 1989 versus about 50% presently. As a correlate, the interval from diagnosis to transplant has decreased substantially; <20% of transplants were done within 1 year of diagnosis in 1989 versus >50% presently. A third trend is increasing use of blood- rather than marrow-derived grafts: 14% in 1989 versus >70% presently. Finally, treatment-related mortality also decreased substantially, from >20% in 1989 versus 5% presently. This probably reflects several factors including selection of patients with less advanced disease and better performance status.

Women with locally advanced (stage 2 and 3) breast cancer receiving autotransplants differ from the general population of women presenting with breast cancer. Median age was 44 years and more than 70% had >9 involved lymph nodes. These data contrast with typical women with breast cancer whose median age is about 60, of whom about 5% have >9 involved lymph nodes.<sup>6,7</sup> These differences reflect the substantial selection factors for transplant and underscore the importance of comparing autotransplants and chemotherapy in comparable subjects. A Toronto

study reported that 28% of patients referred for one randomized trial of high versus lower dose therapy were ineligible because of occult metastatic disease identified by the required pre-transplant evaluation.<sup>18</sup> Thus, differences observed between transplanted patients and patients receiving conventional dose chemotherapy in historical data bases may result from selection of patients without occult metastases.

Women with metastatic (stage 4) disease receiving autotransplants were also somewhat atypical. Median age was 44 years and 58% had cancers with estrogen receptors. About 28% had a complete response to chemotherapy, but 24% had disease progression. These data contrast with typical women with stage 4 breast cancer whose median age is about 60 years, of whom about 60-70% have cancers with estrogen receptors. These differences again underscore the importance of comparing autotransplants and chemotherapy in comparable subjects.

Nevertheless, one small randomized study shows a statistically significant advantage in both survival and disease-free survival for high-dose chemotherapy with bone marrow transplant versus conventional dose chemotherapy.<sup>12</sup>

Results of autotransplants correlated with disease stage. Women with stage 2 or 3 disease had better PFS and survival than those with stage 4 disease. There was, however, no difference in PFS or survival between women with stage 2 versus 3 disease. Among women with metastatic (stage 4) disease, those with a complete response to pretransplant chemotherapy did better than those with a partial response. The latter did better than those with stable disease or progression. Women with tumors unresponsive to lower dose treatment are unlikely to achieve long term disease-free survival after autotransplant.

The correlation between stage and chemotherapy response and outcome is not surprising. Similar results are reported for conventional treatments. Better transplant outcome in "better"

subjects does not mean that transplants should be performed earlier or indicate whether transplants are better than conventional therapy. These questions are best addressed in prospective studies, several of which are underway (Table 5). However, randomized trials, one of which has been reported<sup>12</sup>, and those listed in Table 5, are not designed to answer other important questions such as relative efficacy of various high-dose regimens, supportive care technologies, or even patient, disease and treatment-related factors important for transplant outcome. The ABMTR is an important resource for addressing such issues. Data collected by the Centers for Disease Control hospital survey<sup>13,14</sup> suggest that about half of all autotransplants in North America are reported to the ABMTR. We believe reporting of autotransplants for breast cancer is similar, making available a substantial and likely representative proportion of cases for study. Registry audits ensure that this sample is unselected and that data are accurate. Registry data will be critical for extrapolating results of randomized trials, which tend to be applied in restricted populations, to other patients and in evaluating the impact of preparative regimens, demographic factors and prior treatment and other variables. Thus registry data provide an important observational database with which to monitor trends and assess new technology and will complement data from randomized trials.

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## FIGURE LEGENDS

- Figure 1: Numbers of allotransplants (hematopoietic stem cells collected from a donor) and autotransplants by year by disease for most common indications.
- Figure 2: Kaplan-Meier estimates of progression-free survival (PFS) (2a) and survival (2b) after autotransplants for primary (stage 2, 3 or inflammatory) and metastatic breast cancer.
- Figure 3. Kaplan-Meier estimates of progression-free survival (PFS) (3a) and survival (3b) after autotransplant for metastatic breast cancer by responsiveness to chemotherapy pretransplant. CR=complete response to conventional dose chemotherapy pretransplant, PR=partial response and Resistant=stable or progressive disease pretransplant.

Table 1. Autotransplants for breast cancer registered with the ABMTR.

	1989	1990	1991	1992	1993	1994	1995	P-value
Number (N)	272	342	683	1069	1189	1513	818	
Percent of all autotransplants registered:	16%	16%	25%	33%	33%	39%	40%	<0.00001
Autotransplants for breast cancer:								
Number of centers reporting	34	45	66	85	99	105	101	
Median transplants/center	3 (1-58)	5 (1-44)	6 (1-44)	7 (1-71)	6 (1-59)	8 (1-86)	5 (1-63)	0.005
Stage immediately prior to high-dose chemotherapy and autotransplant:								
N evaluable <sup>a</sup>	213	313	650	1005	1088	1404	721	<0.00001
Local disease <sup>b</sup>	7%	16%	23%	34%	31%	39%	49%	
Metastatic	93%	83%	77%	65%	68%	60%	50%	
Other <sup>c</sup>	<1%	1%	<1%	1%	1%	1%	1%	
Age								
N evaluable	272	341	678	1059	1123	1461	817	<0.00001
Median (range) yrs	41 (23-64)	42 (24-66)	44 (22-72)	44 (25-65)	45 (24-66)	45 (22-69)	45 (22-71)	
Interval, diagnosis to transplant								
N evaluable	237	299	614	960	1106	1392	774	<0.00001
<1 yr	18%	24%	31%	44%	42%	49%	57%	
1-2 yrs	28%	19%	16%	14%	12%	13%	10%	
>2 yrs	54%	57%	53%	42%	46%	38%	33%	

Table 1, continued

Graft type													
N evaluable	162	215	474	813	1189	1447	760	<0.00001					
BM	81%	79%	58%	42%	30%	19%	10%						
BM + PBSC	5%	7%	22%	33%	30%	25%	18%						
PBSC	14%	14%	20%	25%	40%	56%	72%						
Conditioning regimen													
N evaluable	140	183	423	735	870	1174	587	<0.00001					
CBP	7%	4%	11%	13%	9%	14%	6%						
CT	25%	22%	23%	23%	21%	21%	21%						
CTCb	18%	16%	15%	28%	37%	39%	44%						
CTM	6%	2%	6%	4%	4%	2%	1%						
ICE	3%	10%	8%	7%	6%	4%	4%						
CTHu	8%	4%	5%	4%	3%	3%	4%						
CEP	3%	3%	5%	3%	2%	1%	2%						
Other	30%	37%	27%	18%	18%	16%	18%						
100-day mortality													
N evaluable	265	340	679	1034	1153	1366	784	<0.00001					
%	22%	15%	11%	6%	6%	4%	5%						

<sup>a</sup>Information for all variables not available for all patients; registration forms were revised in 1992 and 1993 to capture additional information.

<sup>b</sup>Local disease = stage 2, 3 and inflammatory breast cancer

<sup>c</sup>Patients with locally persistent or recurrent disease post conventional therapy.

Abbreviations: BM, bone marrow; PBSC, peripheral blood stem cells; C, cyclophosphamide; B, BCNU; P, cisplatin; T, thiotepa; Cb, carboplatin; M, mitoxantrone; I, ifosfamide; E, etoposide; Hu, hydroxyurea

Table 2. Autotransplants for Stage 2, 3 or inflammatory breast cancer.

	N evaluable <sup>a</sup>	N	(%) <sup>b</sup> (range) <sup>c</sup>
Number registered	1,747		---
Age, years (median)	1,731	44	(22-69) y
Stage pretransplant	1,613 <sup>d</sup>		
2		750	(46%)
3		603	(37%)
Inflammatory		260	(17%)
Months from diagnosis to transplant	1,636	7	(2-16)
Number of nodes positive	542		
< 10		150	(28%)
≥ 10		392	(72%)
ER receptor positive	479	298	(62%)
Principal adjuvant chemotherapy			
CAF	491	314	(64%)
Graft type	1,527		
BM		502	(32%)
BM + PBSC		450	(30%)
PBSC		555	(38%)
High-dose chemotherapy regimen used:	1,370		
CT		432	(32%)
CTCb		403	(29%)
CBP		220	(16%)
CTM		52	(4%)
ICE		78	(6%)
CEP		26	(2%)
Other		156	(11%)
100-day mortality (%)	1,668		(3%)

<sup>a</sup>Information for all variables not available for all patients. Registration forms were revised in 1992 and 1993 to capture additional information.

<sup>b</sup>For categorical variables

<sup>c</sup>For continuous variables

<sup>d</sup>134 additional patients stage 2 versus 3 versus inflammatory not specified

Abbreviations: ER, estrogen receptor; C, cyclophosphamide; A, doxorubicin (Adriamycin); F, fluorouracil; BM, bone marrow; PBSC, peripheral blood stem cells; B, carmustine (BCNU); P, cisplatin, T, thiotepa; Cb, carboplatin; M, mitoxantrone; E, etoposide; Hu, hydroxyurea

Table 3. Three-year Kaplan-Meier estimates of progression-free (PFS) and overall survival after autotransplants for breast cancer.

Stage	PFS	95 % CI	Survival	95 % CI
2 2 to 5 cm or involved lymph nodes	65%	59-71%	74%	68-80%
3 > 5 cm or fixed to the chest wall	60%	53-67%	70%	63-77%
Inflammatory	42%	31-53%	52%	40-64%
4 Metastatic	18%	16-20%	30%	28-32%
Response to chemotherapy:				
In complete remission	32%	27-37%	46%	40-52%
In partial remission	13%	9-17%	29%	25-33%
Not responding	7%	4-10%	16%	12-20%

Table 4. Autotransplants for metastatic breast cancer.

	N evaluable <sup>a</sup>	N	(%) <sup>b</sup> (range) <sup>c</sup>
Number registered	3451		
Age, years (median)	3398	44	(22-72) y
Sensitivity to chemotherapy pretransplant	3411		
Complete or partial response		2134	(63%)
Stable or progressive disease		595	(17%)
Undetermined		682	(20%)
Sites of metastatic disease	1212		
Viscera (no CNS) <sup>d</sup>		593	(49%)
Bone or bone marrow ± soft tissue <sup>e</sup>		328	(27%)
Soft tissue alone		273	(23%)
CNS <sup>f</sup>		18	(1%)
ER receptor positive	1203	700	(58%)
Interval, diagnosis to transplant	3298		
< 1 yr		687	(21%)
1-2 yrs		568	(17%)
> 2 yrs		2038	(62%)
Graft type	3018		
BM		993	(33%)
PBSC		1373	(46%)
BM + PBSC		652	(21%)



Table 4, continued

Conditioning regimen	2522	
CTCb	899	(36%)
CT	416	(17%)
ICE	132	(5%)
CTHu	146	(6%)
CTM	71	(3%)
CBP	202	(8%)
CEP	60	(2%)
Other	596	(23%)
100-day mortality (%)	3395	(10%)

a Information for all variables not available for all patients. Registration forms were revised in 1992 and 1993 to capture additional information.

b For categorical variables

c For continuous variables

d Includes patients with or without bone, bone marrow, or soft tissue involvement

e Excludes patients with visceral or CNS involvement

f Includes patients with or without visceral, bone, bone marrow, or soft tissue involvement

Abbreviations: CNS, central nervous system; ER, estrogen receptor; BM, bone marrow; PBSC, peripheral blood stem cells; C, cyclophosphamide; B, carmustine (BCNU); P, cisplatin, T, thiotepa; Cb, carboplatin; M, mitoxantrone; E, etoposide; Hu, hydroxyurea

Table 5. Ongoing randomized trials of autotransplants in breast cancer by stage.

Eligible Stage	Study Sponsor	Standard Initial Therapy	High-dose Regimen	Control
<b>Stage 2</b>				
Number of involved lymph nodes				
≥ 4	Milan/Italy	None	HDS	E x 3, CMF x 6
≥ 4	Inter-Scandinavian	CEF x 4	CTCb	CEF x 4
≥ 4	Italian	CEF x 4	CEL	CEF x 2
≥ 4	Dutch	CEF x 4	CTCb	CEF x 1
4-9	Duke	AF	CBP	no more therapy vs. CBP alone
≥ 6	ICG (Manchester)	CE x 4	CTCb	CE x 4
≥ 8	SFGM/FNCCC	CEF x 4	CMitoxL	no further therapy
≥ 10 or > 4 high risk	IBCSG		CE x 3	AC or EC x 4, then CMF x 3
≥ 10	CALGB	CAF x 4	CBP	conventional dose CBP
≥ 10	German Multicenter	CE x 4	CTMitox	CMF x 3
≥ 10	ECOG	CAF x 4	CT	no further therapy
<b>Stage 3</b>				
	Milan/Italy	None	HDS	E x 3, then CMF x 6
	SFGM/FNCCC	Chemo x 4	CMitoxL	conventional chemotherapy
	IBCSG		CE x 3	AC or EC x 4, then CMF x 3
	CALGB	A x 4	CTCb	continuous CMF x 16 weeks
	German Multicenter	CE x 4	CTMitox	CMF x 3
<b>Stage 4</b>				
	Duke (CRs only)	AFM x 4	CBP	CBP at relapse
	Duke (bone only)	AFM x 4, radiation	CBP	CBP at relapse
	Phila Intergroup	CAF x 6	CTCb	CMF x 2 years
	SFGM/FNCCC	Chemo x 4	CMitoxL	conventional chemotherapy

Legend: ICG, International Collaborative Group (Manchester), SFGM, Societe Francaise de Greffe du Muelle; FNCCC; Federation Nationale des Centres de Lulte Centra le Cancer; CALGB, Cancer and Leukemia Group B; ECOG, Eastern cooperative oncology group; SWOG, Southwest Oncology Group; IBCSG International breast Cancer Study Group; C, cyclophosphamide; E, epirubicin; A, doxorubicin (Adriamycin); F 5-fluorouracil; Cb, carboplatin; M, methotrexate; P, cisplatin; L, melphalan; Mitox, mitoxantrone; T, thiotepa; HDS high-dose sequential therapy

Appendix 1. Institutions reporting breast cancer cases to the ABMTR.

<u>Country, Institution</u>	<u>City</u>
<u>Argentina</u>	
Alexander Fleming Institute	Buenos Aires
Centro de Internacion e Investigation	Buenos Aires
Hospital Privado de Oncologia	Buenos Aires
Navy Hospital "Pedro Mallo"	Buenos Aires
Hospital Privado de Cordoba	Cordoba
<u>Austria</u>	
Donauspital	Vienna
<u>Brazil</u>	
Hospital de Clinicas	Curitiba
Hospital Nossa Senhora das Gracias	Curitiba
<u>Canada</u>	
University of Calgary	Calgary
Royal Victoria Hospital	Montreal
Sacré Coeur Hospital	Montreal
Northeastern Ontario Regional Cancer Centre	Sudbury
Toronto Hospital	Toronto
Vancouver General Hospital	Vancouver
Manitoba Cancer Treatment Center	Winnipeg

**Cuba**

Hermanos Ameijeiras Hospital Havana

**Mexico**

Institute Nacional de Cancerologia Mexico City

Centro de Hematologia y Medicina Interna Puebla

**Russia**

Petrov Research Institute of Oncology St. Petersburg

**United States**

Presbyterian Health Care Services Albuquerque

University of Michigan Medical Center Ann Arbor

Arlington Cancer Center Arlington

Emory Clinic Atlanta

Southwest Regional Cancer Center Austin

Johns Hopkins Hospital Baltimore

University of Maryland Cancer Center Baltimore

Mary Bird Perkins Cancer Center Baton Rouge

Alta Bates Hospital Berkeley

University of Alabama at Birmingham Birmingham

Dana-Farber Cancer Institute Boston

Montefiore Medical Center Bronx

Roswell Park Cancer Institute Buffalo

University of North Carolina Chapel Hill Chapel Hill

Medical University of South Carolina Charleston

University of Virginia Medical Center	Charlottesville
Rush Presbyterian/St. Luke's Medical Center	Chicago
University of Chicago Medical Center	Chicago
Jewish Hospital of Cincinnati	Cincinnati
University Hospital Cincinnati	Cincinnati
Case Western Reserve University Hospital	Cleveland
Cleveland Clinic Foundation	Cleveland
University of South Carolina	Columbia
Ohio State University Hospital	Columbus
Baylor University Medical Center	Dallas
Miami Valley Hospital	Dayton
Presbyterian/St. Luke's Hospital	Denver
Wayne State University	Detroit
City of Hope National Medical Center	Duarte
University of Connecticut Health Center	Farmington
Bone Marrow & Stem Cell Institute of Florida	Fort Lauderdale
Harris Methodist Oncology Program	Fort Worth
University of Florida, Shands Hospital	Gainesville
East Carolina University School of Medicine	Greenville
Hackensack Medical Center	Hackensack
Hinsdale Hematology-Oncology Associates	Hinsdale
Queen's Cancer Center	Honolulu
St. Francis Medical Center	Honolulu

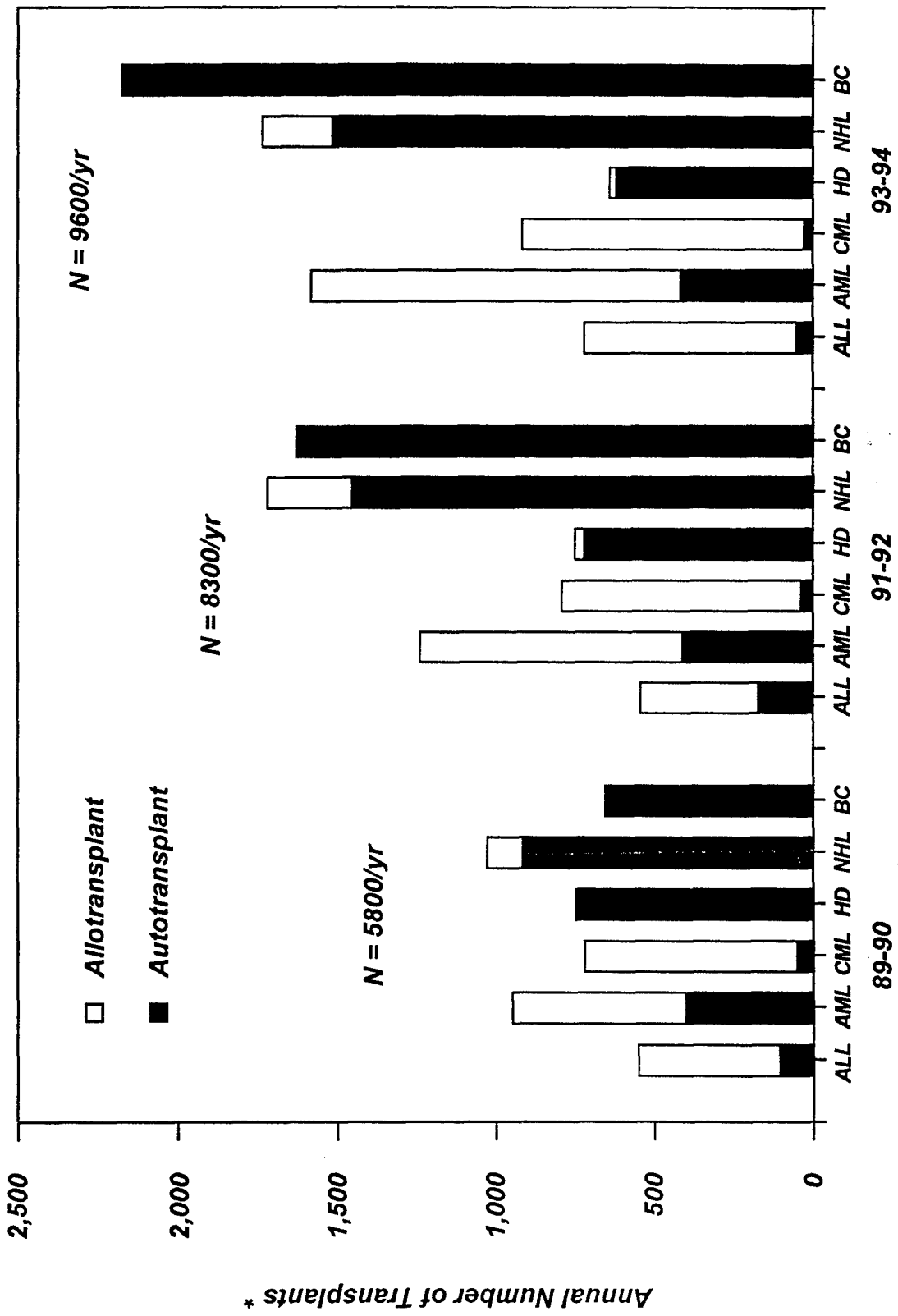
Baylor College of Medicine	Houston
M.D. Anderson Cancer Center	Houston
Indiana University Hospital & Outpatient Center	Indianapolis
Methodist Hospital of Indiana	Indianapolis
St. Vincent Hospital & Health Care Ctr.	Indianapolis
Baptist Regional Cancer Center	Jacksonville
University of Kansas Medical Center	Kansas City
Scripps Clinic & Research Foundation	La Jolla
Dartmouth-Hitchcock Medical Center	Lebanon
University of Kentucky Medical Center	Lexington
University of Arkansas for Health Sciences	Little Rock
UCLA Center for Health Sciences	Los Angeles
USC/Norris Cancer Hospital	Los Angeles
James Graham Brown Cancer Center	Louisville
University of Wisconsin	Madison
North Shore University Hospital	Manhasset
Marshfield Clinic	Marshfield
Loyola University Medical Center	Maywood
Methodist Hospital Central	Memphis
Baptist Hospital of Miami	Miami
Froedtert East Hospital	Milwaukee
St. Luke's Medical Center	Milwaukee
Abbott Northwestern Hospital	Minneapolis

University of Minnesota	Minneapolis
West Virginia University	Morgantown
Vanderbilt University Medical Center	Nashville
Columbia Presbyterian Medical Center	New York
Mount Sinai Medical Center	New York
Medical Center of Delaware	Newark
Hoag Cancer Center	Newport Beach
University of Oklahoma Health Sciences Center	Oklahoma City
University of Nebraska Medical Center	Omaha
Saint Joseph Hospital	Orange
Lutheran General Hospital	Park Ridge
Hematology Associates	Peoria
Hahnemann University Hospital	Philadelphia
Temple University Comprehensive Cancer Center	Philadelphia
University of Pennsylvania Hospital	Philadelphia
Shadyside Hospital	Pittsburgh
University of Pittsburgh	Pittsburgh
Cancer Center of Boston	Plymouth
St. Charles & John T. Mather Hospital	Port Jefferson Station
Oregon Health Sciences Univ.	Portland
Roger Williams Medical Center	Providence
Cancer & Blood Institute of the Desert	Rancho Mirage
Washow Regional Cancer Center	Reno

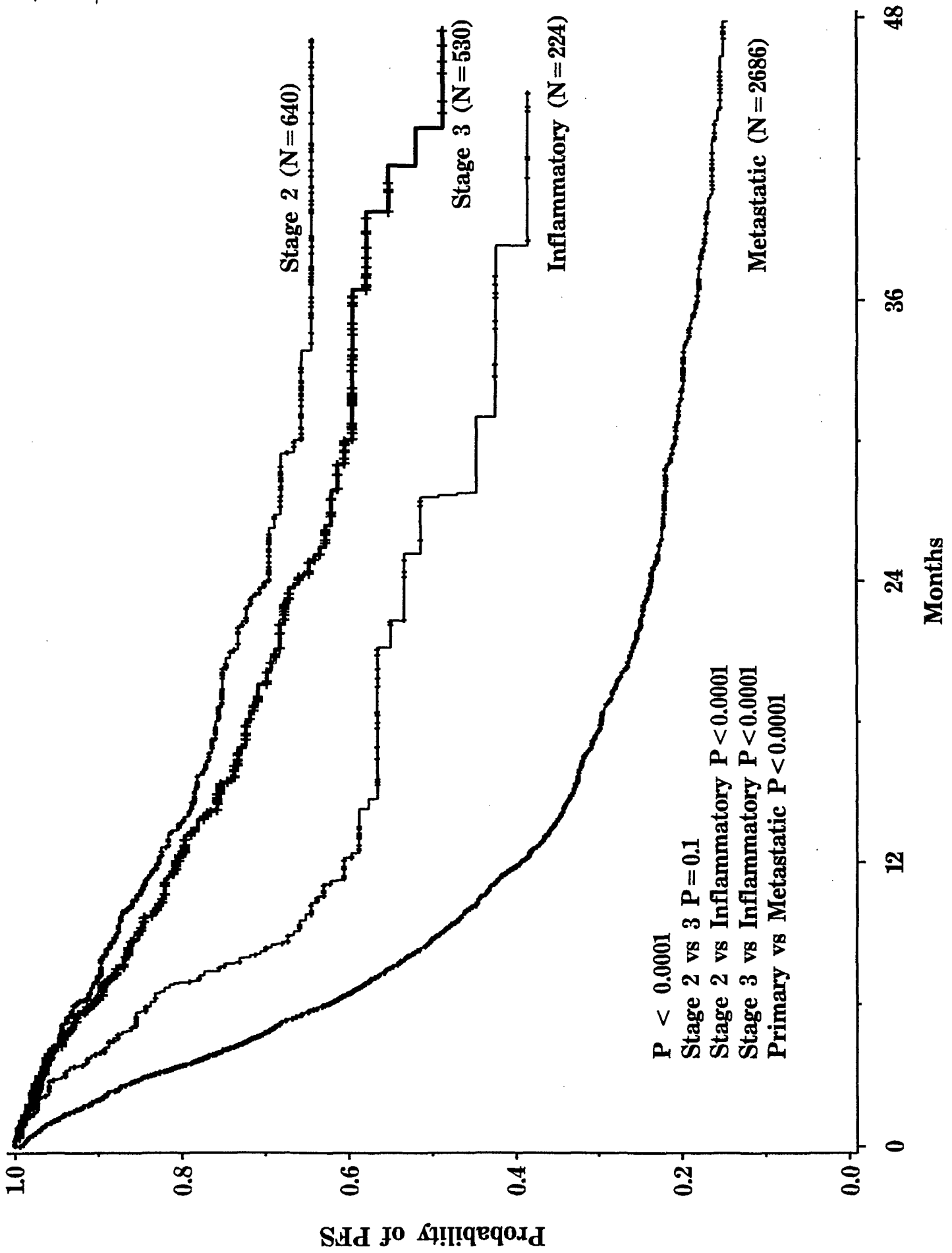
Mayo Clinic Rochester	Rochester
University of Rochester	Rochester
Sutter Memorial Hospital	Sacramento
University of California Davis Cancer Center	Sacramento
Latter Day Saints Hospital	Salt Lake City
University of Utah Medical Center	Salt Lake City
South Texas Cancer Institute	San Antonio
University of Texas Health Sciences Center	San Antonio
University of CA, San Diego	San Diego
University of CA, San Francisco Medical Center	San Francisco
Mayo Clinic Scottsdale	Scottsdale
LSU Medical Center-Shreveport	Shreveport
Memorial Medical Center	Springfield
Tufts University School of Medicine	Springfield
Methodist Hospital/Nicollet Cancer Center	St. Louis Park
St. Louis University Medical Center	St. Louis
Bennett Cancer Center	Stamford
Stanford University Hospital	Stanford
SUNY-Health Science Center	Syracuse
H. Lee Moffitt Cancer Center	Tampa
Arizona Cancer Center	Tucson
St. Francis Hospital	Tulsa
New York Medical College	Valhalla

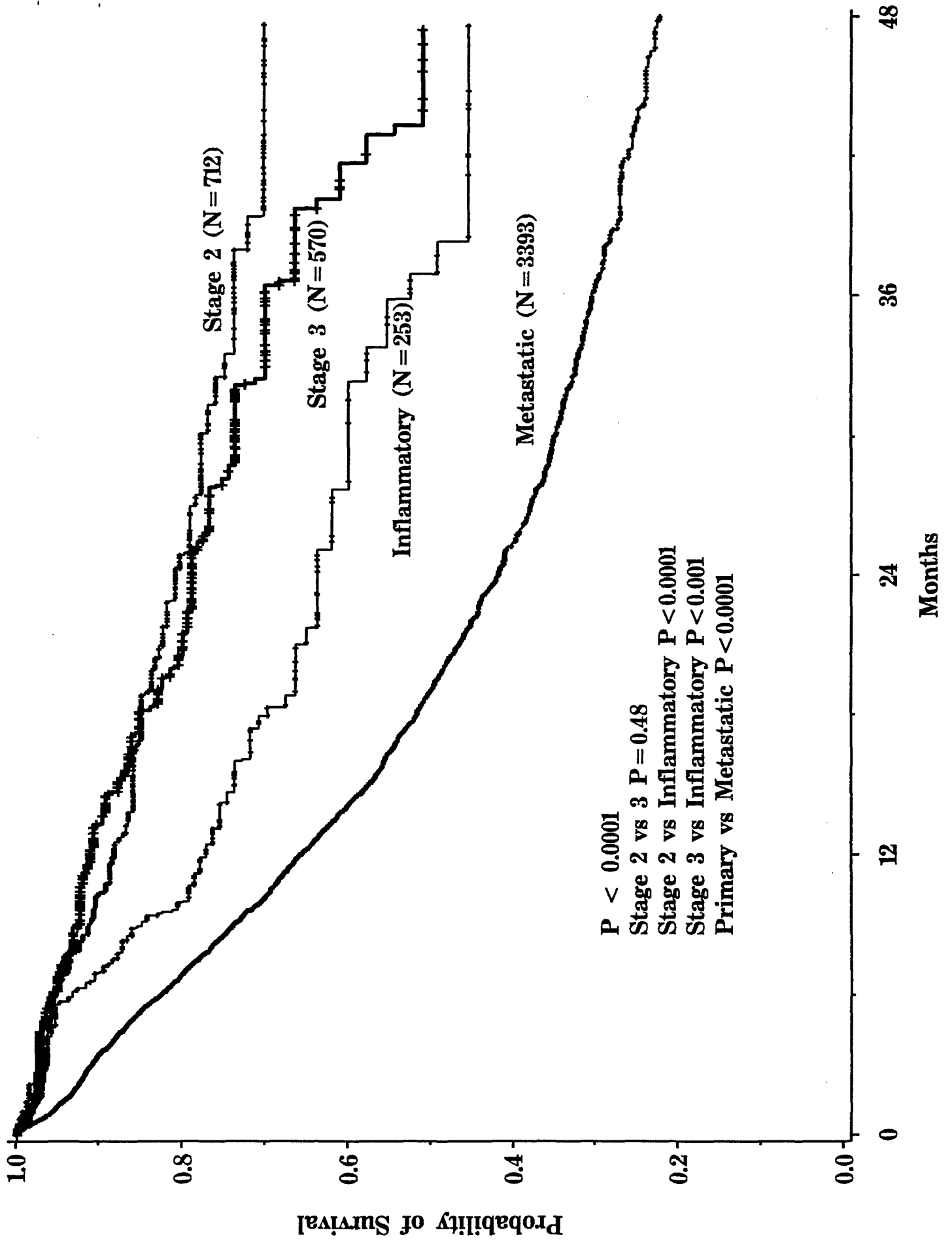


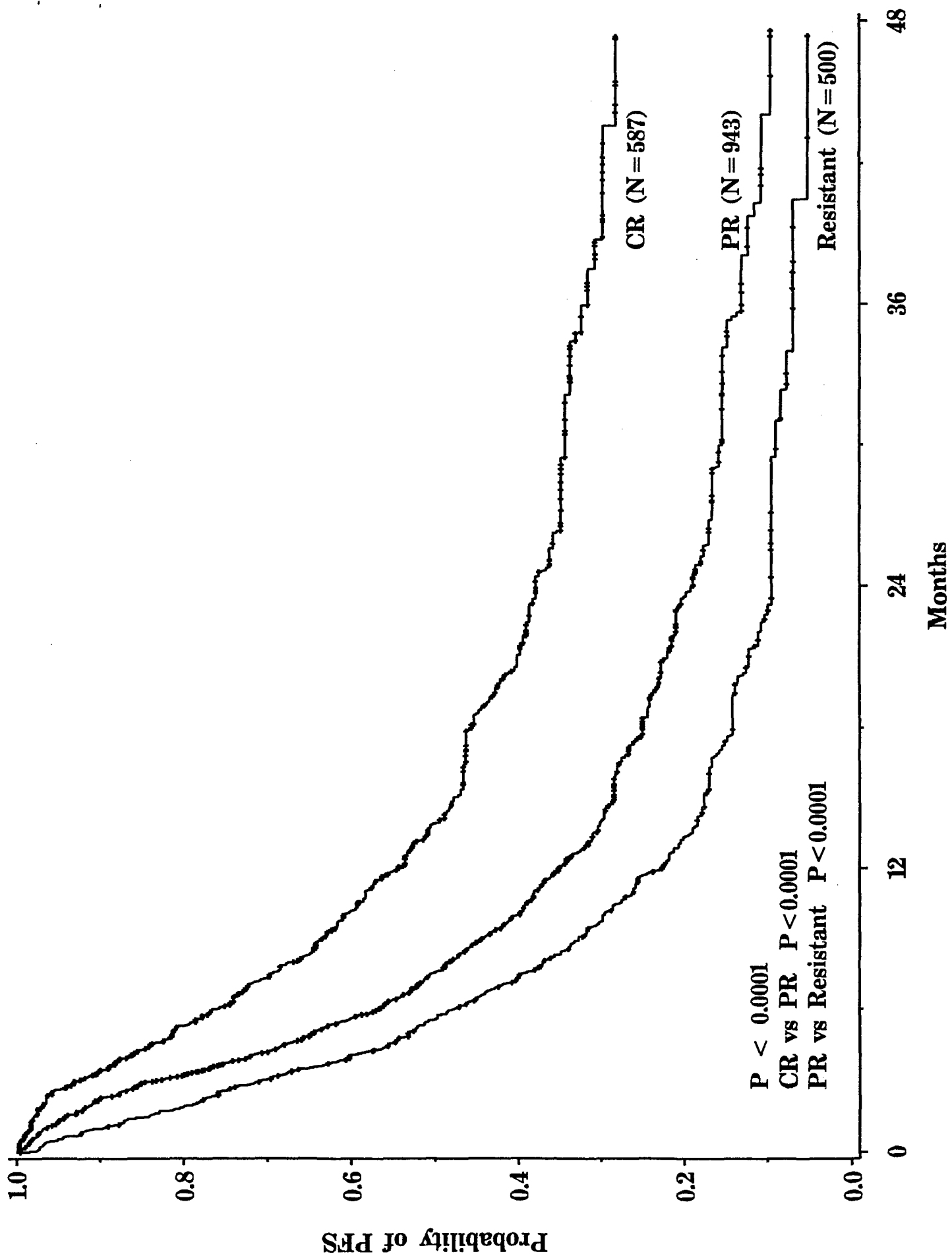
George Washington University Medical Ctr.	Washington, D.C.
Walter Reed Army Medical Center	Washington, D.C.
Westlake Comprehensive Cancer Center	Westlake Village
St. Francis Hospital	Wichita
Wake Forest University	Winston-Salem
University of Massachusetts Medical Center	Worcester



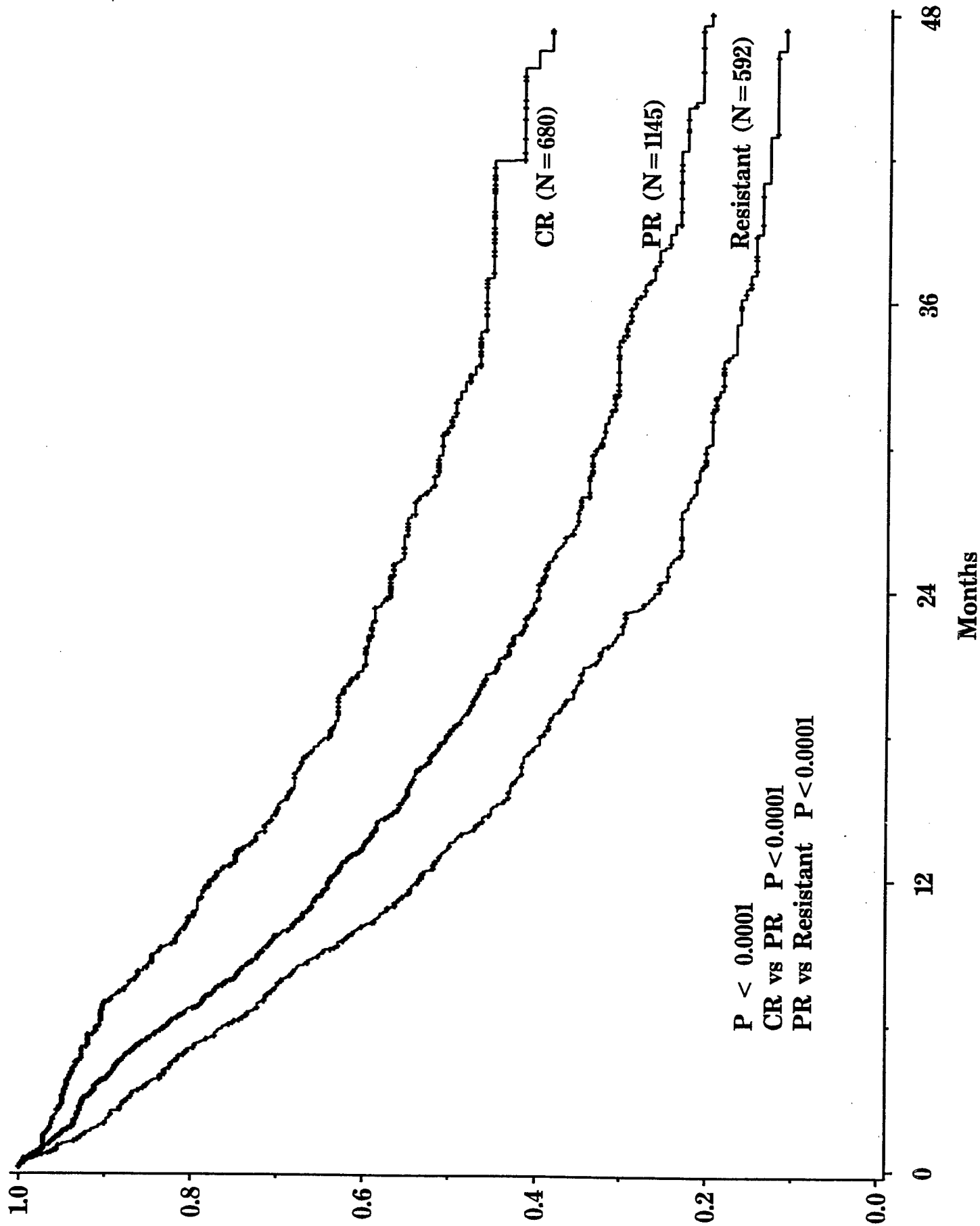
\* Average number of transplants done yearly in each 2-year period







Probability of Survival





## Autologous Blood &amp; Marrow Transplant Registry—North America

**ABMTR NEWSLETTER**

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The IBMTR/ABMTR Statistical Center introduces a new logo. The new look reflects the cooperation between the IBMTR & ABMTR and our optimism for continuing progress in blood and marrow transplantation.

**Contents:**

Message from the Scientific Advisory Committee Chair .....	2
Message from the Scientific Director .....	3
IBMTR Member Profile: Patrick J. Stiff, MD .....	5
Special 1996 Summary Slide Section .....	6-12
Statistical Methods for Analyzing Transplant Outcome .....	13
Recent Scientific Reports from the IBMTR/ABMTR .....	14
Foundation and Corporate Support of the IBMTR/ABMTR .....	15
Statistical Center Personnel .....	16
IBMTR Advisory Committee Listing .....	16

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**ABMTR INITIATES STUDY OF AUTOTRANSPLANTS FOR ADVANCED OVARIAN CANCER**

By Patrick J. Stiff, MD

Loyola University Medical Center, Maywood, Illinois

Despite recent improvements in conventional therapy of advanced ovarian carcinoma, the mortality rate remains 65% at 5 years and few women are cured<sup>1-4</sup>. Although initial response rates are high, drug resistance develops rapidly. Response rates with conventional salvage therapy are only 10-40% with responses lasting an average of 6 months.

**Dose Intensity and Ovarian Cancer**

Considerable data on dose-intensity in ovarian cancer treatment suggest that high-dose therapy may improve outcome<sup>5-7</sup>. *In vitro* studies demonstrate a favorable dose-response relationship for platinum, other alkylating agents and mitoxantrone, and additive or synergistic cytotoxicity with drug combinations<sup>8-12</sup>. Early transplant trials indicate that intensifying

platinum-based chemotherapy to doses to approximately 5 times conventional levels increases response rates<sup>13-15</sup>. Patterns of response appear similar to those observed with high-dose therapy for lymphoma, testicular cancer and, possibly, breast cancer.

**Relapsed/Refractory Ovarian Cancer**

Early autotransplant trials usually included patients failing 2 prior regimens, with platinum-resistance (tumor progression during or within 6 months of achieving remission with platinum-based therapy). Responses varied from 55-75%, with substantial numbers of clinical complete remissions. Remission durations were short, usually 5-7 months. However, 10-15% of women had long-term remissions suggesting the possibility of cure.

*(Continued on page 4)*

**SPECIAL ISSUE**  
**REPORT ON STATE OF THE ART IN BLOOD AND MARROW TRANSPLANTATION**  
**WITH GUIDE TO IBMTR/ABMTR SUMMARY SLIDES**  
*(see pages 6-12)*

**SCIENCE, SUNSHINE AND SCOTTSDALE ON THE AGENDA FOR 1997 ANNUAL IBMTR/ABMTR PARTICIPANTS' MEETING**

By D'Etta Waldoch Koser, CMP, Associate Director, International Programs, IBMTR/ABMTR

The IBMTR/ABMTR Annual Meeting is scheduled for February 22-25 at the Radisson Resort Scottsdale. A full program of Scientific Sessions addressing the basic and clinical science of blood and marrow transplantation, Working Committee meetings and Data Management training is planned. CME credits are available.

• **Deadline for abstract submission extended to December 15.** Abstract Forms are available through the Statistical Center. \$500 will be awarded to the abstract using the most innovative techniques for clinical research, with special attention given to studies benefitting from

use of Registry data. Poster Sessions will be combined with a light dinner buffet each evening.

- **Housing is limited;** fax your Room Reservation Form to the Radisson Resort Scottsdale *today* to take advantage of special discounted guest room rates during peak season.
- Watch for "Provisional Program Update." Enclosed in that mailing are Northwest Airlines "Association Dollars Off Certificates" for discounted airfares for IBMTR/ABMTR meeting participants (some restrictions apply).

*(Continued on page 14)*

**Message from  
the Scientific  
Advisory  
Committee  
Chair**

James O. Armitage, MD,  
Chair, Scientific Advisory  
Committee

**New ABMTR Studies Evaluate Growing Use  
of Autologous Transplantation**

The Autologous Blood & Marrow Transplant Registry – North America (ABMTR) continues to grow. Currently, 188 participating centers in the United States, Canada, Mexico and South America provide data to the Registry. More than 100 physicians from these centers volunteer their time to serve on one or more ABMTR Working Committees, to plan and conduct studies using these data.

ABMTR centers registered about 7,000 new patients in 1995. The total number of transplants available for study exceeds 23,000. The distribution of diseases treated by those transplants is shown below.

Approximately two-thirds of transplants were for lymphoma (Hodgkin or non-Hodgkin) or breast cancer. However, more than 400 transplants each

for neuroblastoma, ovarian cancer and testicular cancer were registered. Additionally, over 2,000 transplants for acute leukemia and over 1,000 for multiple myeloma are available for study. The Registry provides a unique resource for studying the impact of this complicated therapy on the management of patients with these disorders.

This issue of the *Newsletter* focuses on research being done in the use of high-dose therapy and transplantation to manage patients with ovarian cancer. However, this is just one of numerous ongoing studies that are possible only because of the participation of physicians and their transplant teams.

On behalf of the Registry, I want to express thanks to all those whose efforts are making this project a success.

photo for  
position  
only

ABMTR Advisory  
Committee Chair,  
James O. Armitage, MD,  
is Professor and  
Chairman, Department of  
Medicine, University of  
Nebraska Medical Center,  
Omaha.

Dr. Armitage is also  
current President of the  
American Society for  
Clinical Oncology.

**Distribution of autotransplants performed between  
1989 and 1995, registered with the ABMTR by 188  
centers in North and South America**

Disease	Numbers, %
Breast cancer	7646 (33)
Non-Hodgkin lymphoma	5789 (25)
Hodgkin lymphoma	2992 (13)
Acute myelogenous leukemia	1965 (9)
Acute lymphoblastic leukemia	511 (2)
Chronic myelogenous leukemia	205 (1)
Multiple myeloma	1192 (5)
Neuroblastoma	579 (3)
Ovarian cancer	440 (2)
Testicular cancer	406 (2)
Brain tumor	272 (1)
Lung cancer	129 (<1)
Bone sarcoma	118 (<1)
Other cancer	813 (3)
<b>Total</b>	<b>23,057</b>



## Five IBMTR/ABMTR Studies to be Presented at the American Society of Hematology Meetings in December

The IBMTR/ABMTR Statistical Center is coordinating more than 50 transplant-related studies, addressing a wide range of issues. Current projects include comparison of unrelated donor and autologous transplants for leukemia, determining risk factors for second cancers after allogeneic and autologous transplants, and identifying prognostic factors in autotransplants for breast cancer, among many others. These studies are possible because of data contributed by hundreds of transplant centers, 20 years of statistical expertise in analyzing transplant data and active involvement of investigators from IBMTR and ABMTR institutions.

IBMTR/ABMTR studies to be presented at the annual meeting of the American Society of Hematology (ASH), December 6-10, 1996 include:

**Effect of Prior Interferon Therapy on Outcome of HLA-Identical Sibling Bone Marrow Transplant for Chronic Myelogenous Leukemia (CML) in First Chronic Phase; to be presented by Mary M. Horowitz (platform session).** This study of 882 transplants for CML indicates that treatment with  $\alpha$ -interferon pretransplant does not adversely affect outcome of HLA-identical sibling transplants. Analysis of additional data regarding pretransplant interferon dose and response is in progress and will be available in early December.

**Solid Cancers after Bone Marrow Transplantation; to be presented by Rochelle E. Curtis (platform session).** This study was done in collaboration with the Fred Hutchinson Cancer Center and the Radiation Epidemiology Branch of the National Cancer Institute. It found that bone marrow transplant recipients have an increased risk of developing solid cancers at specific sites. A trend toward increasing risk with time posttransplant as well as greater risk among younger patients underscores the need for lifelong surveillance of transplant recipients.

**Long-term Survival and Analysis of Late Causes of Death after Allogeneic Bone Marrow Transplantation; to be presented by Gérard Socié (platform session).** Patient, disease, and transplant characteristics were analyzed for their association with late death in 5,773 patients alive and disease-free  $\geq 2$  years posttransplant. The data suggest that graft-versus-host disease (GVHD) and relapse contribute to late as well as early posttransplant mortality and suggest the need for long-term follow-up of transplant recipients.

**Effects of G- and GM-CSF on Outcomes Following HLA-Identical Sibling Bone Marrow Transplants for Early Leukemia; to be presented by Kerry Atkinson (poster session).** The study analyzed patients receiving HLA-identical sibling bone

marrow transplants for acute leukemia in complete remission and CML in first chronic phase. Preliminary analysis comparing patients receiving G- or GM-CSF with patients not receiving growth factors showed shorter time to neutrophil recovery with growth factors. There was no increase in relapse risk in any disease. Acute GVHD was not increased but there was increased risk of chronic GVHD in older patients receiving G- or GM-CSF.

**A Decision Analysis of Unrelated Donor Transplantation for CML; to be presented by Stephanie J. Lee (platform session).** This study uses data from the IBMTR and the National Marrow Donor Program, analyzed by Dr. Stephanie Lee (Dana-Farber Cancer Institute, Boston). Timing of unrelated transplants for CML in chronic phase was studied using a Markov model, incorporating the competing risks of death from CML and bone marrow transplantation, risks of chronic GVHD and adjustments for quality of life posttransplant and risk aversion. The study found a benefit of *early* transplantation that was greatest for younger persons, but evident even for patients  $>40$  years of age.

An important new area of study for the ABMTR is highlighted in this *Newsletter*: autotransplants for ovarian cancer. Patrick Stiff, Chair of the Ovarian Working Committee, reviews recent studies suggesting a role for high-dose therapy in advanced ovarian cancer (cover story). A short questionnaire was recently distributed to obtain additional data on women with ovarian cancer registered with the ABMTR. This study will provide important information on posttransplant outcomes and prognostic factors in a large number of women. We urge your participation.

Another important function of the Statistical Center is to provide yearly overviews of transplant outcomes. This issue of the *Newsletter* provides an interpretation guide for our 1996 **Summary Slides on State-of-the-Art in Blood and Marrow Transplantation.** The slides will be sent to all IBMTR/ABMTR Participating Teams and to IBMTR/ABMTR Corporate Members in January.

Thank you for your participation in the research programs of the IBMTR and ABMTR. With your collaboration, we are able to continue our important work to improve the success of blood and marrow transplantation.

## Message from the Scientific Director

Mary M. Horowitz,  
MD, MS  
Scientific Director

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only

Mary M. Horowitz,  
MD, MS is  
Scientific Director  
of the IBMTR/ABMTR  
and  
Professor of  
Medicine at the Medical  
College of Wisconsin

A survey of U.S. programs with active autotransplant protocols for ovarian carcinoma was conducted in 1992<sup>16</sup>. Eleven centers reported 153 patients of whom 146 received transplants for relapsed or refractory disease. Among 61 women with platinum-resistant tumors, 51% had partial and 34%, complete responses. Among 37 with platinum-sensitive disease, 14% had partial and 73%, complete responses. Median progression free survival (PFS) in the entire group was 6 months. 14% of women were disease-free 1 year after treatment.

A trial at Loyola University (Chicago) also found an association between platinum-sensitivity and transplant outcome<sup>17</sup>. Among 30 women receiving high-dose mitoxantrone, carboplatinum and cyclophosphamide, median PFS was 10.1 months for 10 with platinum-sensitive disease versus 5.1 months for 20 with platinum-resistance ( $p=.03$ ). 80% of those with platinum-sensitive disease were alive 18 months posttransplant. A recent (unpublished) update of 34 patients with platinum-sensitive disease <1 cm in diameter at time of transplant showed median PFS of 19 months and overall survival of 30 months. These data, when compared to historical results in relapsed ovarian cancer, suggest that autotransplants may be superior to conventional therapy for patients with platinum-sensitive tumors, though one must be cautious in interpreting single-arm studies of patients referred for transplant.

#### **Persistent Disease at Second-Look Laparotomy**

Several pilot studies of autotransplants in women with persistent ovarian cancer at second-look laparotomy are reported. Dauplat et al. described 14 such patients (12 with microscopic disease) receiving a single course of high-dose melphalan<sup>18</sup>. Three-year PFS and survival were 33% and 64%. A recently published update demonstrated median PFS of 27 months in 31 women<sup>19</sup>. Of 19 women reported by Viens et al., 3 of 10 with disease <2 cm in diameter and 6 of 9 with pathologic complete remissions were alive and disease-free at a median follow-up of 22 months after high-dose therapy<sup>20</sup>. Among 87 women receiving autotransplants after second-look laparotomy reported by Extra et al., median survival after transplant was 47 months<sup>21</sup>. Sixty-five (76%) of these had suboptimal stage III and IV disease, a group with, historically, only about 2 years

survival after conventional-dose platinum and cyclophosphamide. These data suggested better response with autotransplants and also demonstrated its safety. The fatal toxicity rate was only 1.1%.

The Southwest Oncology Group is currently conducting a randomized trial comparing two transplant regimens for patients with <3 cm disease at second-look laparotomy to verify safety and efficacy of autotransplants in this setting.

#### **Initial Management of Ovarian Cancer**

Several studies report results of high-dose chemotherapy after induction chemotherapy for advanced ovarian cancer. Benedetti-Panici et al. treated 35 women presenting with Stage III or IV disease with

*To facilitate the ABMTR study of ovarian cancer, a request for additional data was recently sent to participating transplant centers. We encourage you to submit this brief supplemental form as quickly as possible. Additionally, a new form is being developed to prospectively capture data on autotransplants for ovarian cancer. Analyses of these data will be important for designing future clinical trials and improving outcome of transplants for ovarian cancer.*

2-4 cycles of standard chemotherapy followed by either high-dose cisplatin, carboplatinum and etoposide or carboplatinum, etoposide and melphalan stem cell rescue<sup>22</sup>. Among 24 women completing all therapy, 10 (42%) had a pathologic complete response. Seven remain in remission more than 3 years posttransplant.

Fennelly et al. treated 16 patients (10 suboptimally debulked) with high-dose cyclophosphamide and Taxol with cytokine support only for 2 cycles followed by 4 courses of carboplatinum and cyclophosphamide and blood stem cell rescue<sup>23</sup>. Five (38%) women had a negative second-look laparotomy. This may or may not be better than achievable with Taxol and cisplatinum at conventional doses.

#### **The Next Step**

While these data are encouraging, the true role of autotransplants in management of advanced ovarian cancer is still uncertain. Randomized trials are needed. Under the auspices of the National Cancer Institute (NCI), one such trial will soon start in the U.S. Cooperative Groups (GOG164). In this study, after initial surgery, women with Stage III ovarian cancer will receive 4-6 cycles of a platinum-based regimen followed by second-look laparotomy. Those with low tumor burden (microscopic disease for optimal Stage III, <1 cm for suboptimal Stage III) will be randomized to either six cycles of carboplatin and Taxol or a single cycle of high-dose carboplatin, mitoxantrone and cyclophosphamide<sup>17</sup> and a blood stem cell transplant.

#### **Role of the ABMTR**

Little is known about which patients are most likely to benefit from high-dose therapy. The influence of timing, platinum-sensitivity, tumor bulk, histology and grade, high-dose chemotherapy regimen, and multiple cycles of moderate-dose chemotherapy are all important issues. Neither the currently planned randomized nor single institution Phase II trials can address all of these satisfactorily. The ABMTR, by accumulating data on hundreds of autotransplants for ovarian cancer, is uniquely suited to these issues. Thanks to a generous educational grant from Amgen, Inc., an ABMTR study of autotransplants for ovarian cancer was recently initiated. This study will define the survival rate after autotransplants in a large group of women, identify prognostic factors for transplant outcome and suggest the most successful transplant strategies.

To facilitate the ABMTR study of ovarian cancer, a request for additional data was recently sent to participating transplant centers. We encourage you to submit this brief supplemental form as quickly as possible. Additionally, a new form is being developed to prospectively capture data on autotransplants for ovarian cancer. Analyses of these data will be important for designing future clinical trials and improving outcome of autotransplants for ovarian cancer.

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(Continued on next page)

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### ABMTR MEMBER PROFILE: PATRICK J. STIFF, MD

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position  
only

**Patrick J. Stiff, MD** is Associate Professor of Medicine and Director of the Bone Marrow Transplant Program at the Loyola University Stritch School of Medicine in Maywood, Illinois. Dr. Stiff is a member of the ABMTR Scientific Advisory Committee and chair of the Ovarian Cancer Committee. He is nationally recognized for his pioneering work in autotransplants for ovarian cancer.

After receiving his medical degree in 1975 from Loyola University, Dr. Stiff completed a fellowship in medical oncology at Memorial Sloan-Kettering Cancer Center in New York. In 1981, he was appointed Assistant Professor and Director of Bone Marrow Transplantation Services at Southern Illinois University School

of Medicine in Springfield, Illinois where he was named Faculty Member of the Year in 1985. He joined the Department of Hematology/Oncology at Loyola in 1986.

Dr. Stiff is a member of many scientific and medical organizations. Among these are the Gynecologic Oncology Executive Committee, Leukemia Committee and Lymphoma Committee of the Southwest Oncology Group and Board of Directors of the International Society for Hematotherapy and Graft Engineering. Dr. Stiff is also a member of the State of Illinois Medical Advisory Committee, serving on the Subcommittee on Transplantation. Dr. Stiff has authored or co-authored over 30 articles in scientific journals as well as many book chapters.

Through Dr. Stiff's efforts the ABMTR has developed a data collection form for ovarian cancer and initiated the first ABMTR analysis of autotransplants in ovarian cancer.

# 1996 SUMMARY SLIDES SHOW CURRENT USE AND OUTCOME OF BLOOD AND MARROW TRANSPLANTATION

By Philip A. Rowlings, MD, MS  
*IBMTR/ABMTR Assistant Scientific Director*

Since 1972 the IBMTR has collected data from over 300 transplant centers, worldwide. The IBMTR database includes information for about 40% of allogeneic bone marrow transplants done between 1970 and 1995. In 1991, the ABMTR began collecting data on autotransplants from centers in North and South America. More than 180 autotransplant centers now contribute data to the ABMTR. The ABMTR database includes information for about 50% of autotransplants done in North America between 1989 and 1995.

Using these data, the Statistical Center

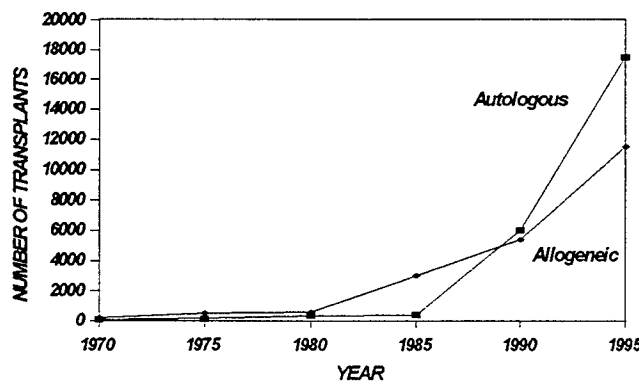
periodically prepares and distributes slides summarizing current use and outcome of allogeneic and autologous hematopoietic stem cell transplants. **This year's Summary Slides, made possible by a generous educational grant from Bristol-Myers Oncology, are described below.**

**Slide 1:** Use of blood and marrow transplants continues to increase. We estimate 12,000 allogeneic and 18,000 autologous transplants were done in 1995, worldwide.

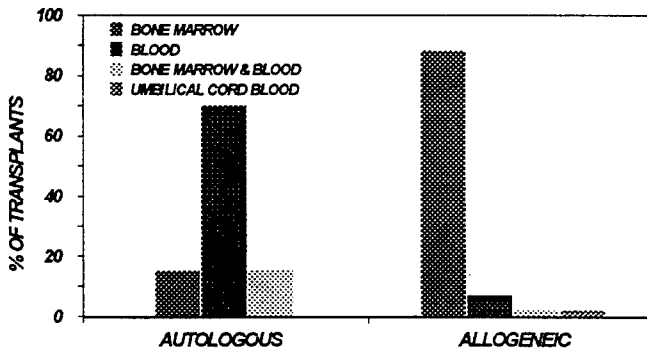
**Slide 2:** Most autotransplants use hematopoietic progenitor cells collected from

blood. Fewer than 20% are done with bone marrow alone. In contrast, over 90% of allografts use bone marrow. Despite recent interest in collecting allogeneic cells from peripheral blood or umbilical cord blood, few such transplants have yet been done.

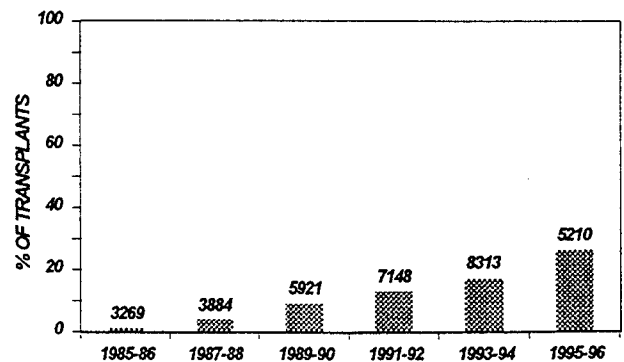
**Slide 3:** Most allogeneic transplants are from HLA-identical sibling donors. However, only about 30% of transplant candidates have such a donor. Increasing availability of HLA-typed volunteers through large national and international registries has enabled increasing use of unrelated donors for bone marrow transplants. Transplants



Slide 1. Annual Number of Blood and Marrow Transplants Worldwide, 1970-1995



Slide 2. Stem Cell Sources, 1995



Slide 3. Percent of Allogeneic Transplants from Unrelated Donors

from unrelated donors now account for about 25% of allogeneic transplants.

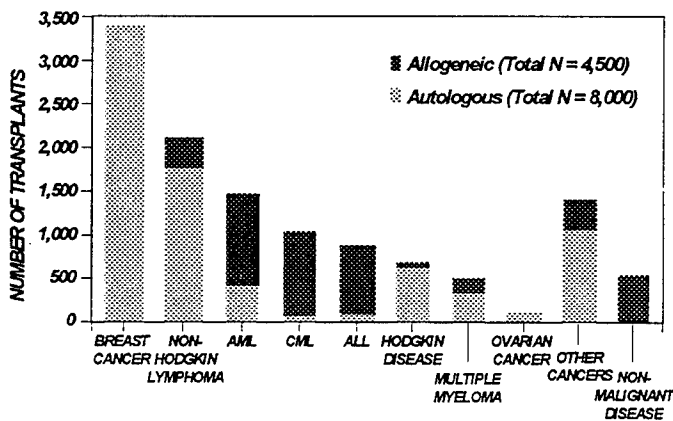
**Slide 4:** The most common indications for allogeneic and autologous transplants differ. Among cases reported to the IBMTR/ABMTR, 74% of allogeneic transplants are for leukemia or preleukemia: 22% for chronic myelogenous leukemia (CML), 23% for acute myelogenous leukemia (AML), 19% for acute lymphoblastic leukemia (ALL), 7% for myelodysplastic syndromes and 3% for other leukemias. Ten percent are for other cancers including non-Hodgkin lymphoma (6%), multiple myeloma (3%), and Hodgkin disease (<1%). The remainder are for aplastic

anemia (7%), immune deficiencies (2%), inherited disorders of metabolism (1%) and other non-malignant disorders (6%). Autotransplants are used to treat cancer. The most common indications for autotransplants in North America in 1995 were breast cancer (42%), non-Hodgkin lymphoma (23%), Hodgkin disease (9%), multiple myeloma (8%), AML (6%), ovarian cancer (2%), ALL (1%), CML (1%), with 8% for a variety of other cancers. The most striking recent change in autotransplant use is the dramatic increase in autotransplants for breast cancer. In 1989, about 15% of autotransplants in North America were for breast cancer while in 1995, over 40% were

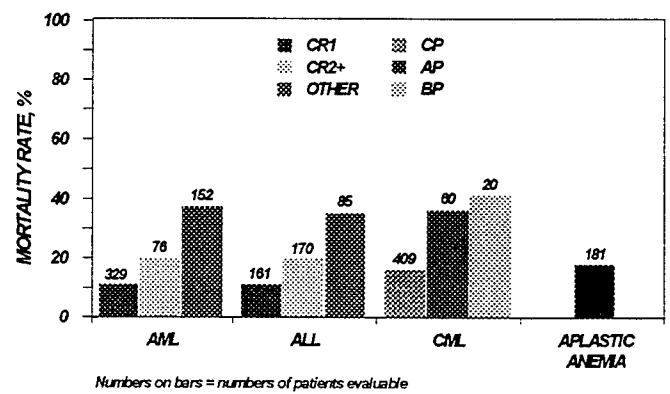
for breast cancer.

**Slide 5:** 100-day mortality is often used as a gauge of procedure-related toxicity. Allogeneic transplants are associated with high risks of graft-versus-host disease (GVHD), infections and liver toxicity, resulting in relatively high early mortality. Among HLA-identical transplants done in 1995 and reported to the IBMTR, 100-day mortality rates range from about 10% for persons with acute leukemia in first remission to almost 40% for those with advanced leukemia. Progressive leukemia

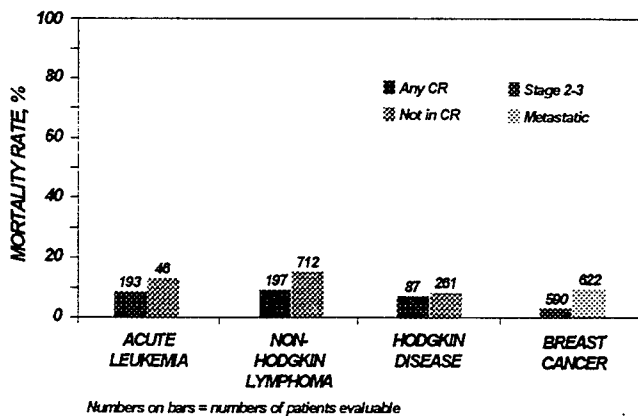
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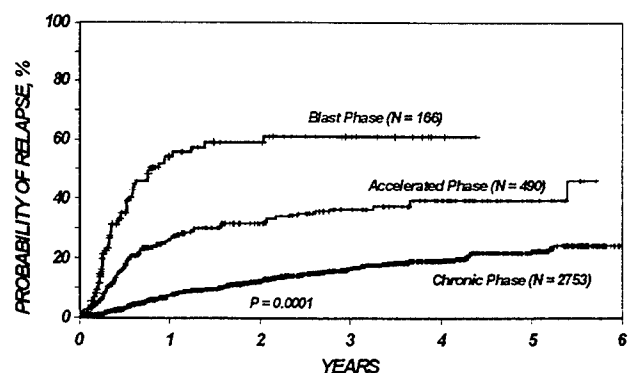
Slide 4. Indications for Blood and Marrow Transplantation in North America, 1995



Slide 5. 100-Day Mortality after HLA-identical Sibling Transplants, 1995



Slide 6. 100-Day Mortality after Autotransplants, 1995



Slide 7. Probability of Relapse after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995

contributes to the early mortality rates among patients transplanted with advanced disease.

**Slide 6:** Early mortality is generally lower after auto- than allotransplants. Among autotransplants done in 1995 and reported to the ABMTR, 100-day mortality ranges from <5% in women with Stage 2-3 breast cancer to about 15% in persons with advanced lymphoma.

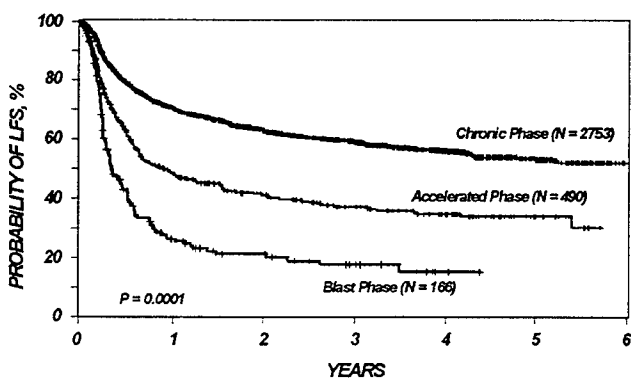
**Slides 7, 8:** CML is the most frequent indication for allogeneic bone marrow transplantation. Among 3,409 recipients of HLA-identical sibling transplants done

between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse (95% confidence interval) were  $16 \pm 2\%$  for 2,753 transplants done in first chronic phase,  $36 \pm 6\%$  for 490 in accelerated phase, and  $61 \pm 11\%$  for 166 in blast phase. 3-year probabilities of leukemia-free survival (LFS) were  $59 \pm 2\%$ ,  $37 \pm 5\%$  and  $17 \pm 7\%$ , respectively.

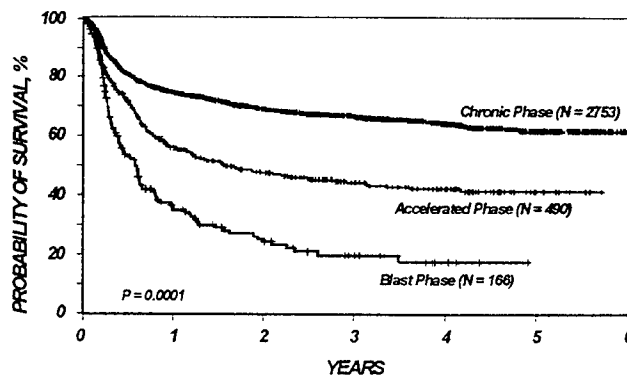
**Slide 9:** Persons relapsing after an HLA-identical sibling transplant for CML often survive for long intervals with conventional treatment. Many achieve durable hematologic and cytogenetic remissions with infusion of donor lymphocytes.

Consequently, 3-year survival rates after transplants are somewhat higher than LFS rates:  $66 \pm 2\%$  in chronic phase,  $44 \pm 5\%$  in accelerated phase, and  $19 \pm 7\%$  in blast phase.

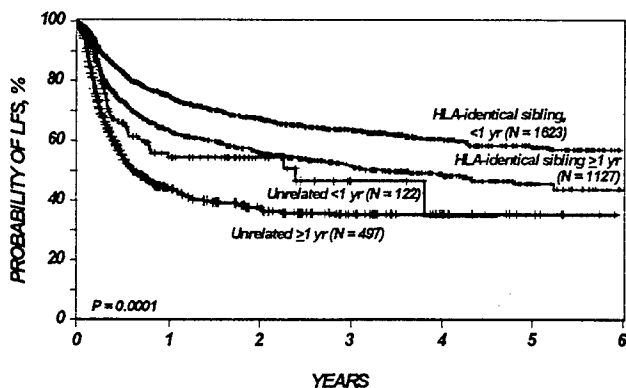
**Slide 10:** Only about 30% of persons with CML have an HLA-identical sibling donor. Unrelated donor transplants can cure CML but are associated with higher risks of GVHD and transplant-related mortality. Additionally, unrelated donor transplants are often delayed because of the time required to identify a donor and reluctance to risk the high transplant-related mortality. Delaying transplantation may adversely



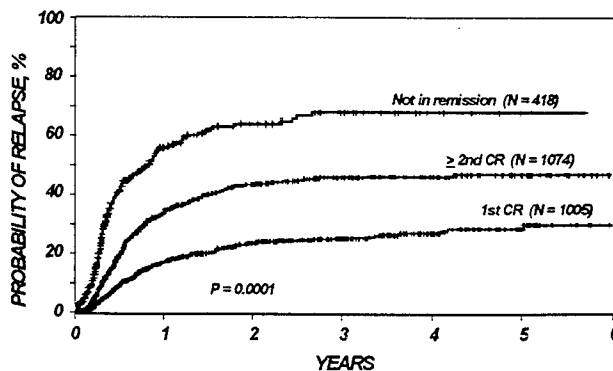
**Slide 8. Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995**



**Slide 9. Probability of Survival after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995**



**Slide 10. Probability of LFS after BMT for Chronic Myelogenous Leukemia in Chronic Phase, by Donor Type and Time to Transplant**



**Slide 11. Probability of Relapse after HLA-identical Sibling BMT for Acute Lymphoblastic Leukemia 1989-1995**

affect outcome. Slide 10 shows LFS after 1,623 HLA-identical sibling transplants done <1 year after diagnosis of CML ( $64 \pm 3\%$  at 3 years), 1,127 HLA-identical sibling transplants done a year or more after diagnosis ( $51 \pm 3\%$ ), 122 unrelated donor transplants done <1 year after diagnosis ( $47 \pm 13\%$ ), and 497 unrelated donor transplants done a year or more after diagnosis ( $35 \pm 5\%$ ). Outcome of unrelated donor transplantation may be affected by factors other than interval between diagnosis and transplant such as donor-recipient histocompatibility, recipient age and others.

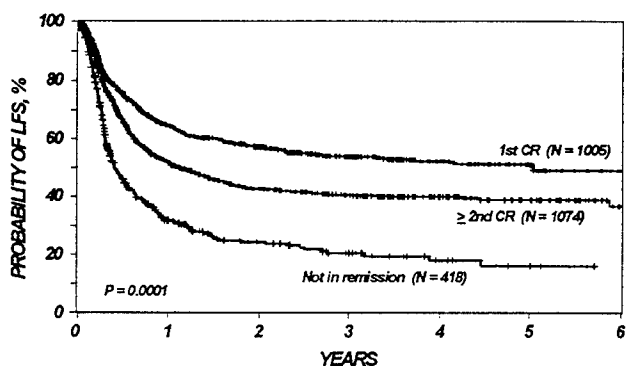
Slides 11, 12: Most patients with ALL are

cured with conventional chemotherapy. Consequently, bone marrow transplants are generally reserved for patients failing conventional therapy, i.e., in relapse or second or subsequent remission, or patients in first remission with prognostic factors predicting a high risk of failure with conventional therapy. The most frequent indications for transplants in first remission are older age, high leukocyte count at diagnosis, Ph<sup>1</sup> and other chromosome abnormalities and difficulty obtaining a first remission. Among 2,497 recipients of HLA-identical sibling transplants between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse were  $25 \pm 4\%$  for 1,005

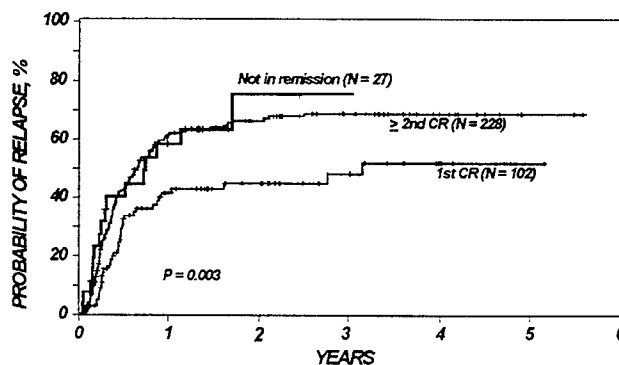
transplants done in first remission,  $46 \pm 4\%$  for 1,074 in second or subsequent remission, and  $68 \pm 7\%$  for 418 done in relapse. 3-year probabilities of LFS were  $54 \pm 4\%$ ,  $40 \pm 13\%$  and  $20 \pm 5\%$ , respectively.

Slides 13, 14: Among 357 recipients of autotransplants for ALL done between 1989 and 1995, reported to the ABMTR, 3-year probabilities of relapse were  $49 \pm 14\%$  for 102 transplants done in first remission,  $70 \pm 7\%$  for 228 done in second or subsequent remission, and  $76 \pm 24\%$  for 27 done in relapse. 3-year probabilities of LFS were  $43 \pm 12\%$ ,  $25 \pm 6\%$  and  $17 \pm 17\%$ , respectively.

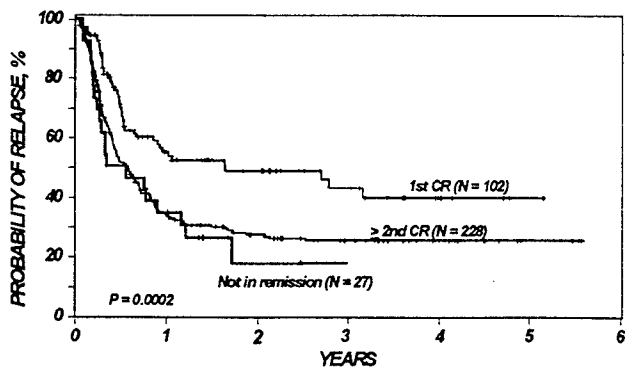
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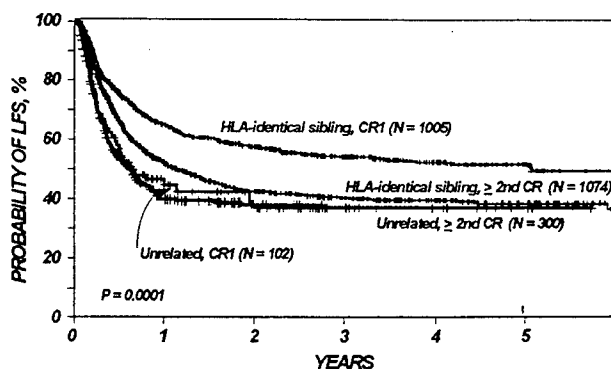
Slide 12. Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Acute Lymphoblastic Leukemia, 1989-1995



Slide 13. Probability of Relapse after Autotransplants for Acute Lymphoblastic Leukemia, 1989-1995



Slide 14. Probability of Leukemia-free Survival after Autotransplants for Acute Lymphoblastic Leukemia, 1989-1995



Slide 15. Probability of Leukemia-free Survival after Allogeneic BMT for Acute Lymphoblastic Leukemia, 1989-1995

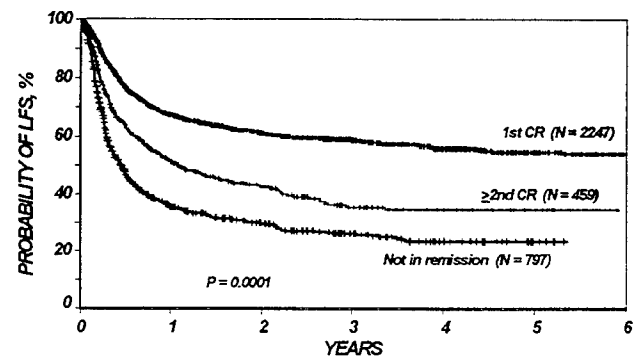
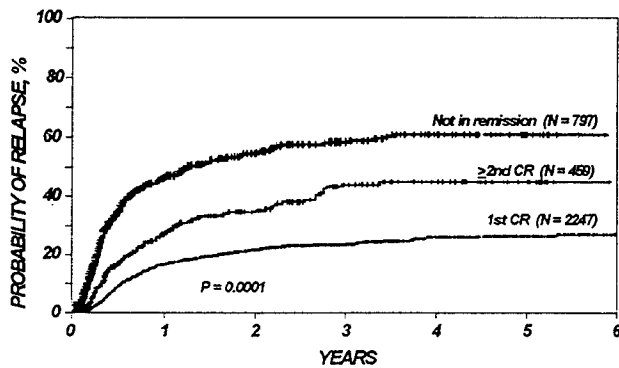
**Slide 15:** Although associated with higher transplant-related mortality, unrelated donor transplants may be considered for patients with ALL unlikely to be cured with chemotherapy. Among 102 recipients of unrelated donor transplants for ALL in first remission reported to the IBMTR, 3-year LFS was  $37 \pm 14\%$ ; among 300 receiving unrelated donor transplants in second or subsequent remission, LFS was  $36 \pm 6\%$ . Among patients transplanted in second remission, there was no difference in LFS between HLA-identical sibling and unrelated donor transplants, since higher GVHD rates were offset by lower relapse rates after unrelated donor transplants.

**Slides 16, 17:** As in ALL, results of HLA-identical sibling transplants for AML correlate with remission state. Among 3,503 recipients of HLA-identical sibling transplants done between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse were  $24 \pm 2\%$  for 2,247 transplants done in first remission,  $45 \pm 8\%$  for 459 in second or subsequent remission and  $57 \pm 5\%$  for 979 done in relapse. 3-year probabilities of LFS were  $59 \pm 2\%$ ,  $35 \pm 5\%$  and  $26 \pm 4\%$ , respectively.

**Slides 18, 19:** Among recipients of auto-transplants for AML between 1989 and 1995, reported to the ABMTR, 3-year probabilities

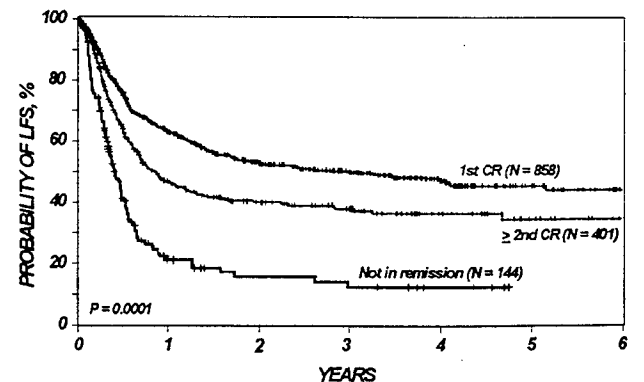
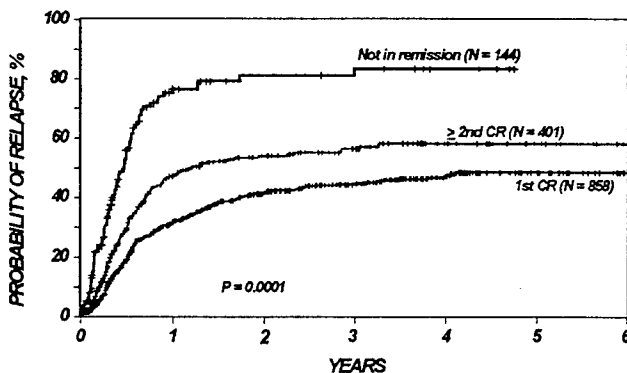
of relapse were  $44 \pm 4\%$  for 858 transplants done in first remission,  $56 \pm 6\%$  for 401 in second or subsequent remission and  $83 \pm 8\%$  for 144 done in relapse. 3-year probabilities of LFS were  $50 \pm 4\%$ ,  $38 \pm 5\%$  and  $12 \pm 7\%$ , respectively.

**Slide 20:** As in ALL, unrelated donor transplants may be considered for some patients with AML lacking an HLA-identical sibling donor. Among 208 patients receiving unrelated donor transplants for AML between 1989 and 1995, reported to the IBMTR, the 3-year probability of LFS was  $57 \pm 13\%$  for 87 receiving a transplant in first remission and  $25 \pm 12\%$  for 121



**Slide 16. Probability of Relapse after HLA-identical Sibling BMT for Acute Myelogenous Leukemia, 1989-1995**

**Slide 17. Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Acute Myelogenous Leukemia, 1989-1995**



**Slide 18. Probability of Relapse after Autotransplants for Acute Myelogenous Leukemia, 1989-1995**

**Slide 19. Probability of Leukemia-free Survival after Autotransplants for Acute Myelogenous Leukemia, 1989-1995**



receiving a transplant in second or subsequent remission.

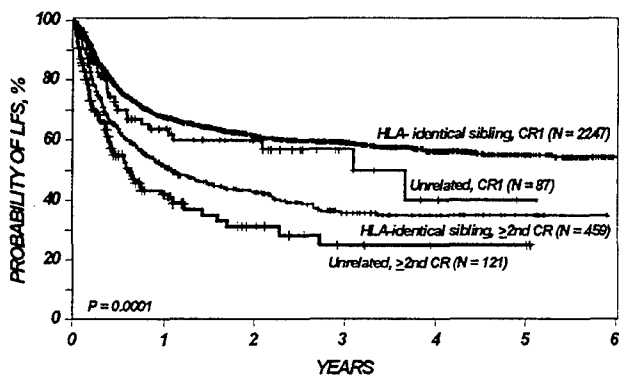
**Slide 21:** Bone marrow transplantation is the treatment of choice for young patients with aplastic anemia who have an HLA-identical sibling. 3-year probabilities of survival after 1,477 HLA-identical sibling transplants between 1989 and 1995, reported to the IBMTR, were  $73 \pm 4\%$  for patients <20 years of age and  $61 \pm 5\%$  for those older. Results were not as good in 200 recipients of unrelated donor transplants:  $41 \pm 10\%$  in 136 patients <20 years and  $40 \pm 13\%$  in 64 older patients.

**Slide 22:** Most patients with Hodgkin disease are cured with conventional chemotherapy. However, for the 20-30% failing conventional therapy, autotransplants are effective salvage therapy. Among 993 autotransplants between 1989 and 1995, reported to the ABMTR, 3-year probabilities of survival were  $86 \pm 12\%$  for 49 patients transplanted in first remission,  $60 \pm 6\%$  for 463 transplanted in first relapse, and  $76 \pm 8\%$  for 224 transplanted in second or subsequent remission and  $49 \pm 9\%$  for 257 patients never in remission.

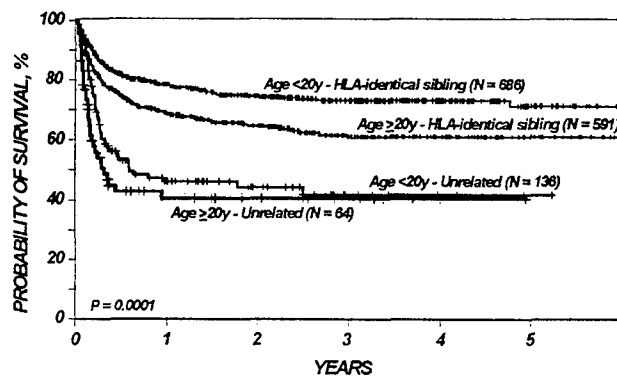
**Slide 23, 24:** Autotransplants are also commonly used for non-Hodgkin lymphoma.

Among 407 patients receiving autotransplants for low-grade lymphoma, 3-year probabilities of survival were  $83 \pm 14\%$  for 64 patients transplanted in first remission,  $67 \pm 11\%$  for 159 in first relapse,  $65 \pm 16\%$  for 64 in second remission and  $52 \pm 16\%$  for 120 never achieving remission with standard chemotherapy. Among 1,413 patients receiving autotransplants for intermediate grade or immunoblastic lymphoma, 3-year probabilities of survival were  $68 \pm 10\%$  for 143 patients in first remission,  $45 \pm 5\%$  for 594 in first relapse,  $60 \pm 8\%$  for 250 in second remission and  $40 \pm 7\%$  for 426 never

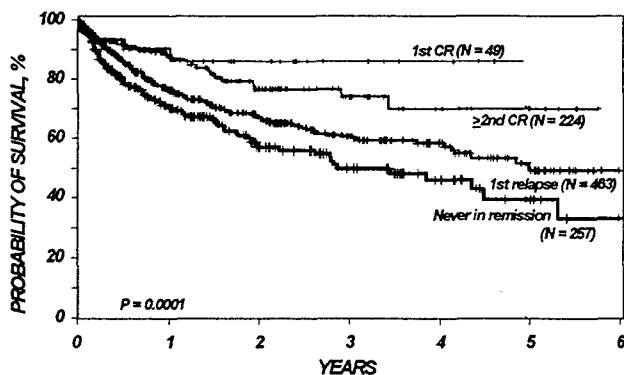
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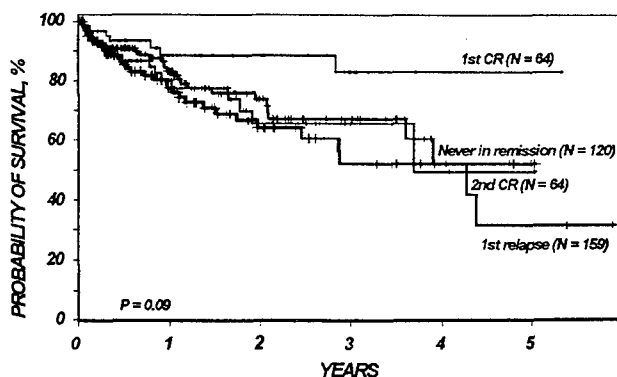
Slide 20. Probability of Leukemia-free Survival after Allogeneic BMT for Acute Myelogenous Leukemia, 1989-1995



Slide 21. Probability of Survival after HLA-identical Sibling and Unrelated BMT for Severe Aplastic Anemia, 1989-1995



Slide 22. Probability of Survival after Autotransplants for Hodgkin Disease, 1989-1995



Slide 23. Probability of Survival after Autotransplants for Low-Grade Non-Hodgkin Lymphoma, 1989-1995

achieving remission with conventional chemotherapy. Most failures after autotransplants for non-Hodgkin lymphoma are due to relapse.

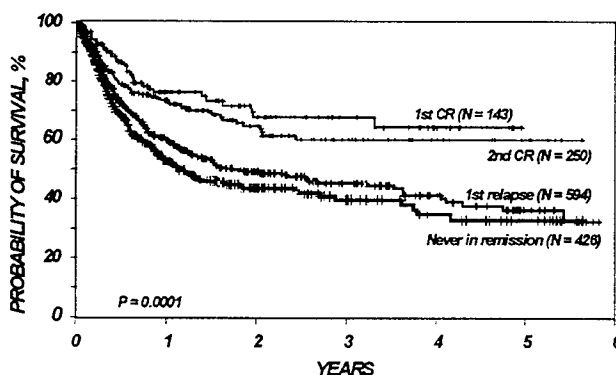
*Slide 25, 26:* Breast cancer is the most frequent indication for autotransplants in North America. Among 5,705 women receiving autotransplants for breast cancer between 1989 and 1995 and reported to the ABMTR, 3-year probabilities of survival were  $74 \pm 6\%$  in 888 women with Stage 2 disease,  $70 \pm 7\%$  in 749 women with Stage 3 disease,  $51 \pm 11\%$  in 314 women with inflammatory breast cancer and  $31 \pm 2\%$  in 3,754 women with metastatic breast cancer.

Outcome in metastatic breast cancer is significantly better for women achieving a complete response with conventional therapy prior to transplant. Among the 3,220 women transplanted for metastatic disease in whom pretransplant response to chemotherapy was known, 3-year survival was  $45 \pm 5\%$  in 901 with a complete response,  $27 \pm 4\%$  in 1,557 with a partial response and  $17 \pm 4\%$  in 762 women with resistant disease.

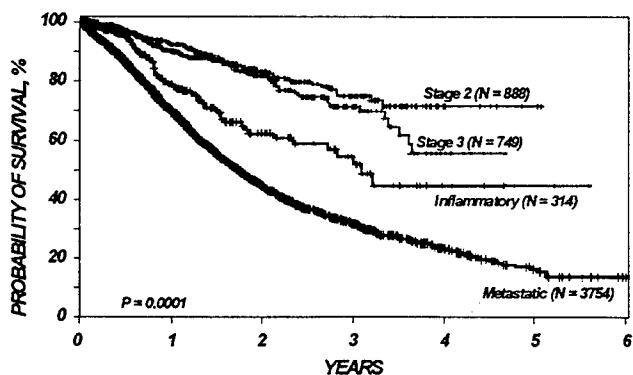
Two sets of slides will be sent to participating teams of the IBMTR/ABMTR free of charge. Teams may purchase additional sets for \$50.00.

If your budget does not permit this purchase, limited educational grants are available through the Statistical Center.

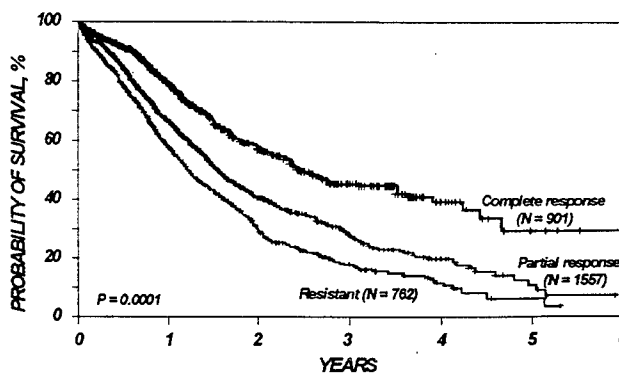
If you have any questions about our new slides, please call Melodee L. Nugent, MA at (414) 456-8325.



Slide 24. Probability of Survival after Autotransplants for Intermediate Grade or Immunoblastic Non-Hodgkin Lymphoma, 1989-1995



Slide 25. Probability of Survival after Autotransplants for Breast Cancer, 1989-1995



Slide 26. Probability of Survival after Autotransplants for Metastatic Breast Cancer by Pretransplant Chemosensitivity, 1989-1995

## STATISTICAL METHODS FOR ANALYZING TRANSPLANT OUTCOME

Transplant outcome depends on complex interactions among patient characteristics, disease biology and treatment. A statistical tool frequently used by the Statistical Center to study those interactions is regression analysis. Regression analyses examine the relationship between a set of factors (independent or explanatory variables) and an outcome (dependent or response variable). Explanatory variables may be patient and disease characteristics like age and disease stage and/or treatment strategies like conditioning regimen and growth factor use.

There are many techniques for regression analysis. The technique used for a specific study is determined by the outcome or response variable of interest. If the outcome is a continuous variable, e.g., days of hospitalization after high-dose therapy, linear regression is commonly used. Linear regression models consider the mean of the response variable as a linear function (sum) of a set of explanatory variables plus some measurement error. For example, a person's days in the hospital might be predicted by the sum of age, disease and growth factor use, each multiplied by an appropriate factor determined in the regression analysis.

For binary (yes/no) data (e.g., 100-day mortality), logistic regression is the most common approach. Logistic regression models the logarithm of the odds of an event occurring (yes response) as a linear function of the explanatory variables. The odds of an event occurring is the ratio of the probability of the event occurring divided by the probability of the event not occurring. When the independent variable is also binary, the logistic model also estimates the odds ratio for the independent variable. This gives a measure of how much more likely it is that an event will occur in an individual with a certain characteristic as compared to an individual without the characteristic. Logistic regression is available in many statistical packages. A good introductory book on this technique is Kleinbaum's *Logistic Regression: A Self Learning Text*, Springers Series on Statistics in the Health Sciences, 1994. Logistic regression techniques are also used to analyze matched-pairs data and analyze data where the response has more than two characteristics.

Most transplant studies focus on outcomes that involve time, e.g., time to engraftment, time to graft-versus-host disease (GVHD), time to disease recurrence, and time to death. The outcome measure has two aspects: whether or not the event occurs

and the time at which it occurs. An important issue in these studies is that patients analyzed may be followed for different lengths of time (either because of entering the study at different times or loss to follow-up) or may die from another cause before the event occurs. These patients are *censored*. Whether they would have developed the event of interest with longer follow-up is unknown. For these situations, the technique most commonly used is *Cox or proportional hazards* regression.

Cox regression models the hazard rate of the time to occurrence of an event (hazard rate is the chance the event occurs at a given time for patients who have yet to experience the event). It assumes that for an individual with a given set of characteristics (explanatory variables), the hazard rate at any point in time can be obtained by multiplying a baseline hazard rate by the exponential of a linear function of the independent variables. It is called a proportional hazards model since individuals with distinct values of the independent covariates have hazard rates that are proportional at all points in time. The ratio of the hazard rates for such individuals is called the relative risk and gives a measure of how much more quickly individuals with one set of risk factors experience the event than individuals with some other set of risk factors. Cox regression is available in some of the standard statistical packages such as SAS and BMDP. It allows for the handling of censored data (data where some individuals do not experience the event) in a natural way. A good introductory reference on this techniques is the book by Kleinbaum on *Survival Analysis: A Self Learning Text*, Springers Series on Statistics in the Health Sciences, 1996.

Selection of the appropriate statistical model is crucial to avoid bias and maximize power to detect important relationships between explanatory and response variables. All models make some assumptions about these relationships (e.g., the assumption of proportionality for Cox models). Failure to check or meet these assumptions can produce misleading results. Though regression techniques are widely available in statistical packages, they should be used with guidance of persons with the statistical background to assure appropriate models are used correctly.

By  
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position  
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IBMTR/ABMTR Biostatisticians  
(left-right): Kathleen A. Sobocinski,  
MA; John P. Klein, PhD; Mei-Jie  
Zhang, PhD

## RECENT SCIENTIFIC REPORTS FROM THE IBMTR/ABMTR

Gale RP, Horowitz MM, Rees JKH, Gray RG, Oken MM, Estey EH, Kim KM, Zhang MJ, Ash RC, Atkinson K, Champlin RE, Dicke KA, Gajewski JL, Goldman JM, Helbig W, Henslee-Downey PJ, Hinterberger W, Jacobsen N, Keating A, Klein JP, Marmont AM, Prentice HG, Reiffers J, Rimm AA, Rowlings PA, Sobocinski KA, Speck B, Wingard JR, Bortin MM. **Chemotherapy versus transplants for acute myelogenous leukemia in second remission.** *Leukemia*, 10:13-19, 1996.

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REPRINTS AVAILABLE ON REQUEST

### Annual Meeting...(continued from page 1)

- Assistance with flights to Sky Harbor International Airport in Phoenix is available through Meetings & Incentives ☎ (414) 835-3553 ext.126 or (800) 776-3582 ext.126.
- Sky Harbor Airport is an easy 20 minute drive to the Radisson Resort Scottsdale. Special rental discounts available through Hertz—the official car rental company: ☎ (800) 654-2240; refer to CV#17584.

IBMTR/ABMTR Working Committee meetings are open to those interested in *actively* participating in ongoing and future Registry studies. All Working Committee members should plan to attend.

Fifty \$500 grants were recently awarded to persons registered for the Data Management Workshops on Saturday, February 22. Grant funds were provided by the US Department of the Army for teams submitting breast cancer data to the ABMTR. The Data

Management Workshops are designed specifically for clinical research associates, data managers, nurses and others interested in data management. Fundamentals of Registry data management and special topics related to clinical research will be covered.

StemCell Technologies, Inc. will offer "hands-on" training for StemSoft data entry software on Sunday, February 23. Call Violet Molnar in Vancouver, BC at ☎ (604) 877-0713 to register. The fee for this additional session is US \$300.

All members of IBMTR and ABMTR-North America participating bone marrow transplant teams are encouraged to attend. We hope to have each team represented at the 1997 Meeting.

Detailed meeting brochures available, please contact: D'Etta Waldoch Koser, CMP, at the Statistical Center; ☎ (414) 456-8377, fax: (414) 266-8471, or email: [ibmtrdvwk@hp04.biostat.mcw.edu](mailto:ibmtrdvwk@hp04.biostat.mcw.edu)

## FOUNDATION AND CORPORATE SUPPORT OF THE IBMTR/ABMTR

All of us at the IBMTR/ABMTR Statistical Center thank the many contributors who have joined our international collaboration for research in blood and marrow transplantation. Private support for the Registries continues to be vitally important since federal grants cover only 60 percent of the Statistical Center's budget. We gratefully acknowledge the support of the Medical College of Wisconsin; the National Cancer Institute; the National Institute of Allergy and Infectious Disease; the National Heart, Lung and Blood Institute; the Department of Defense; and the generosity of the following foundations and corporations:

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Several corporations have joined the newly established IBMTR/ABMTR Corporate Membership Program (see above listing). The annual membership program provides member organizations with informational materials on blood and bone marrow transplantation developed by the IBMTR/ABMTR Information Resource Service.

The program includes subscriptions to the *Statistical Center Report on Survival Statistics for Blood and Marrow Transplants*, *IBMTR and ABMTR Newsletters*, the worldwide *IBMTR/ABMTR Directory of Bone Marrow Transplant Teams*, and the *IBMTR/ABMTR Summary Slides on State-of-the-Art in Blood and Marrow Transplantation* as well as invitations to our meetings and educational forums and access to the IBMTR/ABMTR databases for simple analyses. These resources are useful for marketing managers, medical directors, research directors, product managers, case managers or transplant coordinators.

For additional information on the Corporate Membership Program, please contact Susan Ladwig, Associate Director of Development ☎ (414) 456-8363, Fax: (414) 266-8471.

By  
**Susan Ladwig,**  
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P.A. Rowlings: Prognostic factors in autotransplants for metastatic breast cancer

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1996 IBMTR/ABMTR Participants' Meeting

K. Antman: Autotransplants for breast cancer

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M.M. Horowitz: Analyzing transplant outcomes: comparison with other therapies

J.O. Armitage: Do autotransplants uniquely cure cancer?

R.P. Gale: How do autotransplants cure cancer?

K. Antman: Breast cancer workshop

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February 1996

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M.M. Horowitz: Outcomes of autologous transplants for breast cancer

Chicago, USA

March 1996

4th International Symposium on Blood Cell Transplantation

K.A. Antman: Blood cell transplants for breast cancer

Adelaide, South Australia

Association of Cancer Executives

R.O. Dillman: Update on autologous BMT

Philadelphia, USA

22nd Annual Meeting of the European Group for Blood & Marrow Transplantation Vienna, Austria  
M.M. Horowitz: Challenges in using observational data to compare transplant and non-transplant treatment

April 1996

First South American Transplantation Meeting Buenos Aires, Argentina  
P.A. Rowlings: Autotransplant for metastatic breast cancer

May 1996

American Society of Clinical Oncology Philadelphia, USA  
J.K. Erban: Effect of legislation mandating coverage for BMT for breast cancer

Experimental and Clinical Approaches in Oncology: Approaching the 21st Century Teaneck, USA  
M.M. Horowitz: Use of blood and marrow transplant in cancer treatment

Societat Catalana de Hematologia Barcelona, Spain  
A. Julia: Indications of transplantation

June 1996

Advances in Haematology London, UK  
M.M. Horowitz: Use of blood and marrow transplantation in cancer treatment

August 1996

8th International Symposium on Autologous Marrow and Blood Transplantation Arlington, USA  
P.A. Rowlings: ABMTR results  
P.A. Rowlings: Clinical studies in metastatic disease

September 1996

Meeting of the American Academy of Insurance Medicine Kansas City, USA  
M.M. Horowitz: Outcome of blood and marrow transplantation

October 1996

Oncology Nursing Conference 1996 Santo Domingo, Dominican Republic  
C. Meneghetti: High dose chemotherapy and autologous BMT for breast cancer treatment

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Memorial Medical Center	Springfield	United States
Cardinal Glennon Children's Hospital	St. Louis	United States
St. Louis Children's Hospital	St. Louis	United States
St. Louis University Medical Center	St. Louis	United States
Methodist Hospital/Nicollet Cancer Center	St. Louis Park	United States
All Children's Hospital	St. Petersburg	United States
Petrov Res. Inst. of Oncology	St. Petersburg	Russia
Bennett Cancer Center	Stamford	United States
Stanford University Hospital	Stanford	United States
Northeastern Ontario Regional Cancer Centre	Sudbury	Canada
SUNY-Health Science Center	Syracuse	United States
H. Lee Moffitt Cancer Center	Tampa	United States
Scott & White Clinic	Temple	United States
Toronto General Hospital	Toronto	Canada
Arizona Cancer Center	Tucson	United States

St. Francis Hospital	Tulsa	United States
New York Medical College	Valhalla	United States
British Columbia's Children's Hospital	Vancouver	Canada
Vancouver General Hospital	Vancouver	Canada
Donauspital	Vienna	Austria
Georgetown University Medical Center	Washington, DC	United States
George Washington University Medical Ctr.	Washington, DC	United States
Walter Reed Army Medical Center	Washington, DC	United States
Westlake Comprehensive Cancer Center	Westlake Village	United States
St. Francis Hospital	Wichita	United States
Manitoba Cancer Treatment Center	Winnipeg	Canada
Wake Forest University	Winston-Salem	United States
University of Massachusetts Medical Center	Worcester	United States



## ABMTR Breast Cancer Working Committee

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Karen Antman, MD

Columbia University, New York

ABMTR Statistician: Sandy Murphy, MS

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*Rec'd  
11/1/2000*



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US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
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FORT DETRICK, MARYLAND 21702-5012

REPLY TO  
ATTENTION OF:

MCMR-RMI-S (70-1y)

4 Jan 00

MEMORANDUM FOR Administrator, Defense Technical Information  
Center, ATTN: DTIC-OCA, 8725 John J. Kingman  
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SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for the attached Grants. Request the limited distribution statements for Accession Document Numbers listed be changed to "Approved for public release; distribution unlimited." This report should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by email at Judy.Pawlus@amedd.army.mil.

FOR THE COMMANDER:

*Phylis Rinehart*  
PHYLIS M. RINEHART  
Deputy Chief of Staff for  
Information Management

*' 95-1-5002 AD-B 224 543*

*completed 1-3-00 an*