DukeMedicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-014

DOCUMENT TITLE:

Data Management

DOCUMENT NOTES:

Document Information

Revision: 03	**Vault:** ABMT-General-rel
Status: Release	**Document Type:** General

Date Information

Creation Date: 23 Jul 2018	**Release Date:** 21 Mar 2019
Effective Date: 21 Mar 2019	**Expiration Date:**

Control Information

Author: JLF29	**Owner:** JLF29
Previous Number: ABMT-GEN-014 Rev 02	**Change Number:** ABMT-CCR-206, ABMT-CCI

ABMT-GEN-014
DATA MANAGEMENT

1 PURPOSE

1.1 The Adult Blood and Marrow Transplant (ABMT) Database is a Microsoft Access application that provides for the data entry, querying, and reporting of patient and donor information for the Adult Blood and Marrow Transplant Program at Duke. The data contained includes, but is not limited to, patient/donor demographics, transplant information, referring physicians, scheduling of upcoming admissions, diagnoses, reinfusion, procedures, notes and follow-ups, and toxicity. The application is a supplementary data management tool and does not function as the patient electronic medical record.

2 INTRODUCTION

2.1 ABMT Database

2.1.1 There are various queries and reports available to the users ranging from basic data reporting to more complex data analysis. Knowledgeable users can also create their own queries and reports. The database sends information to other systems such as Press Ganey, who administers patient satisfaction surveys.

3 SCOPE AND RESPONSIBILITIES

3.1 Use is restricted to authorized personnel only. Users must first have access to the ABMT shared drive via the Cancer Center and then they must be on the list of approved users in order to use the application. In addition, the database keeps an audit trail of what changes the users make to the data and when they are made.

3.2 Data entry is limited to the data management staff. Training of data staff is completed after a 90 day orientation, which included, but is not limited to, the review of program data management SOPs and one on one mentoring with an experienced data manager. A data management competency checklist has been developed.

4 DEFINITIONS/ACRONYMS

4.1 ABMT Adult Blood and Marrow Transplant

4.2 CIBMTR Center for International Blood and Marrow Transplant Research

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Computer

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 To ensure data accuracy and integrity, a process to audit data has been developed. This process includes a triple check system of eligibility criteria, disease response, and other Center for International Blood and Marrow Transplant Research (CIBMTR) data points and the information is entered directly into Formsnet3. The Clinical Research Coordinator/designee will audit 20% of the TED forms and 30% of the research track per trimester with 100% accuracy. Physician note templates have also been developed to ensure documentation in the physician note captures all reporting data points.

8.2 The Clinical Program will collect all data necessary to complete the transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.

8.3 The Clinical Program will submit the data specified in 8.2 to a national or internal database if required by applicable laws and regulations.

8.4 The Clinical Program will submit the data specified in 8.2 for allogenic and autologous transplants to a national or internal database.

8.5 The Clinical Program will collect data specified in 8.2 for all patients for at least one (1) year following administration of a cellular therapy or immune effector product.

8.6 The data management staff will participate in continuing education annually.

9 RELATED DOCUMENTS/FORMS

9.1 N/A

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	J. Frith	8.1 Updated CIBMTR data points and the information is entered directly into Formsnet3. The Clinical Research Coordinator/designee will audit 20% of the TED forms and 30% of the research track per trimester with 100% accuracy. 8.2 Added to ensure the Clinical Program collects all data necessary to complete the transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT. 8.3 The Clinical Program will submit the data specified in 8.2 to a national or internal database if required by applicable laws and regulations.

Revision No.	Author	Description of Change(s)
		8.4 The Clinical Program will submit the data specified in 8.2 for allogenic and autologous transplants to a national or internal database. 8.5 The Clinical Program will collect data specified in 8.2 for all patients for at least one (1) year following administration of a cellular product. 8.6 The data management staff will participate in continuing education annually.

Signature Manifest

Document Number: ABMT-GEN-014 **Revision:** 03
Title: Data Management

All dates and times are in Eastern Time.

ABMT-GEN-014 Data Management

Author

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		05 Mar 2019, 10:06:02 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		05 Mar 2019, 01:35:28 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		06 Mar 2019, 11:22:28 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		06 Mar 2019, 01:26:11 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		07 Mar 2019, 10:30:40 AM	Approved