Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Electronic Record Systems for Clinical Programs: Transplant Outcomes Database

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COMM-PAS-009
ELECTRONIC RECORD SYSTEMS FOR CLINICAL PROGRAMS: TRANSPLANT OUTCOMES DATABASE

1 PURPOSE

1.1 This procedure outlines how to execute statistical analyses that describe post-transplant outcomes for the Duke University Adult and Pediatric Blood and Marrow Transplant (APBMT) programs using statistical software developed by the program staff.

2 INTRODUCTION

2.1 Outcomes for APBMT patients are monitored periodically, including results of the analyses that are executed by the software described in this procedure. Data for these analyses is derived from the Adult Blood and Marrow Transplant (ABMT) and Pediatric Blood and Marrow Transplant (PBMT) databases.

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure applies to the development, modification, maintenance or application of the Transplant Outcomes Database.

3.2 All personnel involved in the development, maintenance, and use of the Transplant Outcomes Database are responsible for ensuring the requirements of this procedure are met.

4 DEFINITIONS/ACRONYMS

4.1 ABMT – Adult Blood and Marrow Transplant

4.2 PBMT – Pediatric Blood and Marrow Transplant

4.3 APBMT – Adult and Pediatric Blood and Marrow Transplant

4.4 SAS – Statistical Analysis System, SAS Institute, Cary, NC. http://www.sas.com

4.5 GitLab – A cloud-based hosting service for the management of Git repositories. https://about.gitlab.com/

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 The Transplant Outcomes Database consists of the following components.

8.1.1 A single data file listing outcomes after hematopoietic cell transplantation or cell therapy in the ABMT program. This data file is derived from the ABMT database.

8.1.2 A single data file listing outcomes after hematopoietic cell transplantation or cell therapy in the PBMT program. This data file is derived from the PBMT database.

8.1.3 Statistical report template

8.1.3.1 This document describes the report that is to be produced from the data files above.

8.1.3.2 This document serves as the requirements document for the Transplant Outcomes Database and was developed collaboratively by the APBMT program statistician and medical directors

8.1.4 Statistical software programs

8.1.4.1 These programs produce the analyses described in the Statistical Report Shell.

8.1.4.2 Programs are written using the SAS System (SAS Institute, Cary, NC)

8.1.5 Validation test scripts

8.1.5.1 These test scripts are used to validate the results of the statistical software programs described above.

8.1.5.2 Test scripts are developed based on the requirements described in the statistical report template.

8.1.6 The GitLab Server

8.1.6.1 Git is a source code revision control system that tracks changes to the statistical software programs, data files used to produce those programs, and the results output by those programs.

8.1.6.2 GitLab is a Git-based fully integrated platform for software development.

8.1.6.3 The ABMT and PBMT data files, statistical report template, SAS software programs, and validation test scripts are stored virtually in GitLab.

8.2 The Transplant Outcomes Database is used by the APBMT program statistician and designated statistical staff to produce reports on a routine basis in accordance with the schedule proscribed by the associated medical directors.

8.3 Each time reports are produced using the Transplant Outcomes Database the complete set of data, program code, and results are stored permanently in GitLab.

8.4 Development requirements and function

8.4.1 Requirements for the Transplant Outcomes Database were developed collaboratively between the APBMT program statistician and the APBMT medical directors.

8.4.2 The original requirements document is stored in GitLab.

8.5 Maintenance of data accuracy, integrity, identity, and confidentiality

8.5.1 De-identified data are provided for analysis from the ABMT and PBMT databases.

8.5.2 Data files are stored temporarily, while executing analyses, on shared drives on the Duke network, which are behind the Duke firewall and encrypted.

8.5.3 Data files, program code, and results are stored permanently in GitLab, which is also located on a server behind the Duke firewall.

8.6 Assurance of Training.

8.6.1 All statistical staff involved in the execution of analyses using the Transplant Outcomes Database have a Masters or PhD degree in biostatistics or a related field and have received the necessary academic training required to understand the analytical methodology that the Transplant Outcomes Database uses.

8.6.2 The APBMT program Statistician or their designee is in charge of training individual statistical staff members on the proper use of the system as described in this SOP.

8.6.3 When training is complete statistical staff are given access to the GitLab server. Having a GitLab account shall serve as documentation of completed training on the Transplant Outcomes Database.

8.7 Access

8.7.1 The GitLab server containing the program code and data files associated with Transplant Outcomes Database is password protected.

8.7.2 Access is controlled by the APBMT program statistician or their designee.

8.8 Record entry, review of data, record verification, and record revision

8.8.1 Analyses are executed using pre-written statistical programs and data derived from the APBMT and PBMT databases. One designated statistician executes the analyses and another reviews the results for correctness. Program code, data, and results are then committed to GitLab where they are maintained permanently. Future modification of the programs, data, or results--if any is required--is tracked by the GitLab software.

8.9 Record Ownership

8.9.1 The APBMT statistician is ultimately responsible for the correct use of the Transplant Outcomes Database.

8.10 Record Protection and Retrieval

8.10.1 Data, programs, and results are retrievable at any time by authorized users of the GitLab system.

8.10.2 There will be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.

8.10.3 Data, programs, and results stored in GitLab can be readily retrieved in human-readable format by designated staff with access to GitLab.

8.10.4 The APBMT program Statistician or their designee controls access to GitLab. Only trained statistical staff (see Section 8.6) and APBMT medical directors have access to GitLab.

8.11 Alternative Systems for "downtime"

8.11.1 The statistical analyses conducted through the Transplant Outcomes Database are not feasibly conducted without the aid of computer software and therefore there is no alternative system in case of downtime.

8.12 System Backup

8.12.1 The GitLab server is backed up on a schedule defined by the APBMT program statistician.

8.13 Unique Identifiers

8.13.1 Unique Identifiers in this system are those assigned by the CIBMTR for tracking transplant outcomes at the patient level.

8.13.2 The identifiers alone do not provide access to PHI, however the data files and program code that processes records that include these identifiers are stored in a protected manner as described in Section 8.5 of this SOP.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-044 Approaches to Validation

9.2 COMM-PAS-008 Electronic Record Systems for Clinical Programs

10 REFERENCES

10.1 N/A

11 REVISION HISTORY

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