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APBMT Transplant Essential Data (TED) Form Audit JA10

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APBMT Transplant Essential Data (TED) Form Audit

1 PURPOSE

1.1 To provide guidance for conducting internal transplant essential data (TED) form audit for the Adult and Pediatric Blood and Marrow Transplant (APBMT) programs.

1.2 To standardize the internal TED form audit process and to ensure that the APBMT programs comply with the Center for International Blood and Marrow Transplant Research (CIBMTR) and the Foundation for the Accreditation of Cellular Therapy (FACT) requirements.

2 INTRODUCTION

2.1 Self-assessment to identify, correct and prevent data quality issues are crucial for maintenance of a complete and accurate data.

2.2 The APBMT programs are expected to comply with Applicable Law and the rules of the relevant registry(ies) in regard to data collection and maintenance.

3 SCOPE AND RESPONSIBILITIES

3.1 This JA applies to the internal TED form audit led by the Quality Systems Unit (QSU).

3.2 This JA applies to the trained APBMT subject matter experts (SME) who assist the QSU in conducting the internal TED form audit.

3.3 This JA applies to the QSU personnel who leads the internal TED form audit activities, approves the audit result, and leads the audit closure activities.

3.4 This JA applies to the APBMT data management personnel and data analysts who assist the QSU with selection of the audited transplants and assist the audited APBMT programs with the statistical analysis to assess and evaluate the audit results.

3.5 This JA applies to the APBMT program directors and QSU management who review the audit results, determine the appropriate corrective action(s), and approve the audit report.

4 DEFINITIONS/ACRONYMS

4.1	APBMT	Adult and Pediatric Blood and Marrow Transplant
4.2	CAPA	Corrective and Preventive Actions
4.3	CIBMTR	Center for International Blood and Marrow Transplant Research
4.4	FACT	Foundation for the Accreditation of Cellular Therapy
4.5	JA	Job Aid

4.6 QSU Quality Systems Unit

4.7 SME Subject Matter Expert

4.8 TED Transplant Essential Data

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Computer access to the CIBMTR database, the electronic health record and other data sources.

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 The annual QSU internal TED form audit will be led by the QSU and conducted by the trained APBMT SMEs (auditor). The auditor should not have oversight of his/her own work.

8.2 The established goals of the internal TED form audit are as following:

8.2.1 Overall error rate ≤ 3%

8.2.2 Critical field error rate ≤ 2%

8.2.3 No identified systemic issue(s)

8.3 The audit score will be assessed as following:

8.3.1 Pass

8.3.1.1 If the overall error rate ≤ 3% and the critical field error rate ≤ 2%, and there is no evidence indicating the presence of any systemic issue(s), the audit result will be scored as "Pass".

8.3.2 Pass, with required corrective and preventive actions (CAPA)

8.3.2.1 If the overall error rate ≤ 3% and the critical field error rate ≤ 2%, but there is evidence indicating the presence of certain systemic issue(s), the audit result will be scored as "Pass, with required CAPA".

8.3.2.2 If the overall error rate ≤ 3% and the critical field error rate is > 2% but ≤3%, the audit result will be scored as "Pass, with required CAPA", regardless of the evidence of the presence of any systemic issue(s).

8.3.3 Fail, with required CAPA

8.3.3.1 If the overall error rate > 3% and/or the critical field error rate > 3%, the audit result will be scored as "Fail, with

required CAPA" regardless of the evidence of the presence of any systemic issue(s).

8.4 The audit can be conducted more frequently than once a year based on the audit score.

8.4.1 When the audit score is "Fail", follow-up audit should be performed to assess the effectiveness of the corrective actions and demonstrate improvement in the area where the original deficiency occurred.

8.4.2 The audit date, audit time period and the number of transplants audited for the follow-up audit will be determined by the QSU management based on the audit results.

8.5 The audit period (i.e., date range) of the annual QSU TED form audit will include the transplants performed during a 12-month period since the last audit.

8.5.1 Audit periods for each program will be as follows:

8.5.1.1 ABMT: September 1 – August 31

8.5.1.2 PBMT: August 1 – July 31

8.5.2 If the program has been determined that the audit needs to be conducted more frequently than once a year, the audit period will be adjusted accordingly as determined by the QSU.

8.6 Data for Ten (10) patients who received transplants during the defined 12-month period for each program will be randomly selected by the program data analyst for the annual QSU TED form audit. To be eligible for audit, transplant associated 100 Day Post-TED form must be submitted to the outcome registry.

8.7 The audit will be conducted against the source documentation defined by each program.

8.8 The current list of TED forms is attached to this JA (see Appendix I) for reference. However, the auditor should verify the attached list with the most current list on the CIBMTR website (www.cibmtr.org) prior to the audit. If there is any discrepancy, the auditor should use the list on the CIBMTR website as the primary source.

8.9 The audited TED forms for each patient may differ depending on the number and type of the transplants and the audited program. It's the auditor's responsibility to determine which TED forms for each transplant should be included in the audit.

8.9.1 The audited TED forms for each patient (identified by CRID) should include all forms due during the audit period.

8.9.2 If a patient received more than one transplant, forms associated with all transplants that were due during the audit period should be audited.

8.10 The critical fields should be regularly reviewed and updated based on the most current revisions of the forms. For a complete list of current critical fields, the auditor and the data analyst should visit the CIBMTR website.

8.11 The audit results and the associated assessment and evaluation, including the statistical analysis, root cause analysis and corrective action(s), if applicable, should be documented on the template attached to this JA (see Appendix II).

8.12 An acceptable audit report contains the following elements:

8.12.1 Audit title

8.12.2 Audit type (e.g., Annual QSU audit, Follow-up audit)

8.12.3 Audit program

8.12.4 Date audit is assigned (includes name and title of QSU representative who assigned the audit)

8.12.5 Name and title of SME(s) assigned to complete the audit

8.12.6 Audit period (date range)

8.12.7 Date audit started and completed

8.12.8 Audit score

8.12.9 Audit scope

8.12.10 Audit purpose and plan (includes the audited transplants and the goal of the audit)

8.12.11 Findings and recommendations

8.12.12 Summary (includes assessment/evaluation of results, root cause analysis, CAPA, if applicable)

8.12.13 Timeline for follow-up, if applicable

8.12.14 Signatures and comments

8.12.15 Documented staff review and date of review

8.12.16 Quality meeting results presentation date, if required

8.13 The audit results, including the statistical analysis, should be reviewed and approved by the QSU representative who leads the audit activities followed by the QSU Director. The approved audit report will be distributed to the management of the audited program.

8.14 It is the responsibility of the management of the audited program to evaluate the findings and recommendations, identify the underlying cause of the errors, determine the appropriate CAPA(s) and responses to the audit, formally document the CAPA(s) in the MasterControl system, including a timeline for associated CAPA(s), and sign the audit report.

8.15 Audit Closure:

8.15.1 The lead QSU representative will verify the items below:

8.15.1.1 Audit results have been reviewed by the audited program staff.

8.15.1.2 Audit results have been presented at the quality meeting.

8.15.1.3 Appropriate CAPA(s) have been initiated in the MasterControl system.

8.15.2 Once the verification is complete, the lead QSU representative will sign the report and submit the report to QSU director for final approval.

8.15.2.1 Once the report is signed by the QSU director, the audit is considered closed.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-039 Quality Systems Unit Audit

10 REFERENCES

10.1 FACT-JACIE Accreditation Manual

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	B. Shen	New Document

APPENDIX I – LIST of TED FORMS

Form Number*	Form Title*
2003	Gene Therapy Product
2004	Infectious Disease Markers
2005	Confirmation of HLA Typing
2006	Hematopoietic Stem Cell Transplant (HCT) Infusion
2400	Pre-Transplant Essential Data
2402	Pre-Transplant Essential Data: Disease Classification
2450	Post-Transplant Essential Data
2800	Log of Appended Documents

*The auditor should verify this list with the most current list on the CIBMTR website (www.cibmtr.org)

APPENDIX II – TEMPLATE for TED FORM AUDIT REPORT

(See Next Page for Template for the Annual QSU TED Form Audit Report)

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APBMT Program TED Form Audit

SECTION I

The QSU will complete the fields located in Section I.

Program/Facility:		
Audit Type:		
Date Audit Assigned:		
Audit Assigned By:	**Name:**	**Title:**
Audit Assigned To:	**Name:**	**Title:**
Audit Period:		
Audit Date:	**Date Started:**	**Date Completed:**
Audit Score:		

Audit Scope:	

Audit Purpose/Plan:	

SECTION II

*The audited program's SMEs will complete below table Part A&B for each patient (CRID#) they are assigned to audit. Multiple transplants for the same patient will be documented on the separate table. Below table will be replicated by the SMEs or the QSU Lead Representative based on the total number of transplants audited. All TED forms due in Formsnet for all transplants performed for the patient during the defined audit period should be reviewed. Diagnosis codes and data type should be determined using the most current information found on www.cibmtr.org, with careful attention paid to form version, which can be found at the top of the form while it is open in view mode. Data category is the header that the question falls under while the form is open in view mode in Formsnet (ie, Chimerism, Comorbidities, GVHD, etc.). Time period is the period that the form applies to in relation to the transplant (Pre-TED, infusion, 100 days, etc.). Items with * are optional for the ABMT program. The auditor will make the correction(s) upon discovery of the error(s) and provide recommendations as needed. The QSU Lead Representative will complete Part C once the verification of the completion of the correction(s), where appropriate, is done.*

CRID #											
	Transplant date	**Transplant Type (Auto/Allo)**	**Diagnosis Code***	**Malignant Disease* (Y/N)**	**Form**	**Form Version**	**Time Period**	**Form Initially Completed By (Name)**	**Date Form Submitted**	**Date Audited**	**Audited By (Name)**
Part A											

	Were errors discovered on the forms?			☐ No, continue to audit next patient						
				☐ Yes, complete Part B for each question in error						
Part B **☐ N/A**	**Form with Data Error**	**Question # with Data Error**	**Data Type (Critical /Random)**	**Data Category***	**Data Point in Error (Describe)**	**Reason for Error**	**Correct Data**	**Data Corrected in Formsnet? (Y/N)**	**Date Corrected**	**Corrected By (Name)**

Comment (*includes recommendation from the auditor***):**	
Part C	*Completed by Lead QSU Representative:* **Corrections completed (***where appropriate***)?** **☐ Yes ☐ No ☐ N/A** **Initials/Date:**

SECTION III

The audited program's SME will complete the fields located in Section III. Attachment can be added to this section as needed.

Frequency of Errors by Form and Field Type (Required):

Name of Form Audited	Number of Forms Audited (#)	Critical Data Fields			Random Data Fields			Overall Data Fields		
		Errors (#)	Fields Audited (#)	Error Rate (%)	Errors (#)	Fields Audited (#)	Error Rate (%)	Errors (#)	Fields Audited (#)	Error Rate (%)

Systemic Issue(s) Identified: *(if applicable)*	

Recommendations: *(if applicable)*	

Comment:	

SECTION IV

The audited program' SME, QSU Lead Representative and QSU Director will sign indicating that the observations above in Section II are accurate, the appropriate immediate corrections have been made and approved, audit results in Section III have been reviewed and the audit score is appropriate. Once signed, the report will be distributed to the audited program's management for completion of Section V.

APBMT SME	**Signature:**	**Date:**	**Comment:**
QSU Lead Representative	**Signature:**	**Date:**	**Comment:**
QSU Director	**Signature:**	**Date:**	**Comment:**

SECTION V

This section will be completed by the audited program's management. The management of the audited program will review the adult results listed in Section II and Section III and complete below Summary, including the assessment and evaluation of the audit results and identifying the underlying cause of the errors (5 why root cause analysis tool recommended), and determining the appropriate CAPA(s), where appropriate. The management of the audited program will define the timeline for CAPA follow-up, if applicable. Attachment can be added to this section as needed.

Summary:	

Timeline for CAPA follow-up: *(if applicable)*	

Comment:	

SECTION VI

The Clinical Program Director and the BMT Quality Committee Chair for the audited program will sign indicating that the audit results listed in Section II and Section III, the Audit Summary and the Timeline for CAPA Follow-up listed in Section V have been reviewed and no concerns are noted. Once signed, the report will be sent back to QSU for completion of Section VII.

Clinical Program Director	**Signature:**	**Date:**	**Comment:**
BMT Quality Committee Chair	**Signature:**	**Date:**	**Comment:**

SECTION VII

This section will be completed by the QSU. The lead QSU representative will verify if the audit results and summary, including the appropriate CAPA(s), have been reviewed and documented by the audited program staff. Additionally, the lead QSU representative will verify if audit results have been presented at the quality meeting and will verify that CAPA (s) have been initiated, as appropriate.

Documented Staff Review	**Presence of the Documentation**	**Lead QSU Representative Initials/Date**
Documentation in Place	☐ **Yes** ☐ **No**	
Staff Review Date:		

Results Presented at the Quality Meeting	**Presence of the Documentation**	**Lead QSU Representative Initials/Date**
Documentation in Place	☐ **Yes** ☐ **No**	
Name of the Quality Meeting		
Presentation Date:		

CAPA Number	**Initiated in the MasterControl System?**	**Lead QSU Representative Initials/Date**
	☐ **Yes** ☐ **No**	
	☐ **Yes** ☐ **No**	

SECTION VIII

Once the Lead QSU representative has verified that the audit results have been reviewed by the audited program staff, the audit results have been presented at the quality meeting, the appropriate CAPA(s) have been initiated in the MasterControl system, the Lead Auditor and QSU Director will sign below to close the audit.

QSU Lead Representative	**Signature:**	**Date:**
QSU Director	**Signature:**	**Date:**

Signature Manifest

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Author

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		10 Oct 2022, 04:41:26 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		10 Oct 2022, 05:01:22 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Isabel Storch De Gracia (IMS19)		13 Oct 2022, 12:29:25 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		18 Oct 2022, 05:34:53 PM	Approved