CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Audit Guide

1 — Last update: Dec 21, 2022

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Getting Started

Welcome to the CIBMTR Audit Guide. The Table of Contents on the left side of the screen is for navigational purposes. If you are on a mobile device, you may find the Table of Contents on the top of the page.

Reference Diagram displays how to navigate with the CIBMTR Forms Instruction Manual.

Providing Feedback explains how to provide feedback and ask questions regarding the Audit Guide.

Audit Timeline shows an outline of the general audit process steps.

Before the Audit provides useful information regarding audit eligibility requirements, general information about scheduling the audit, and center requirements for hosting the auditors at your site during the audit when applicable.

During the Audit provides information generally describing the audit process.

After the Audit provides explanatory text for the processes that may occur after the audit has been completed.

Frequently Asked Questions provides answers to some frequently asked questions.

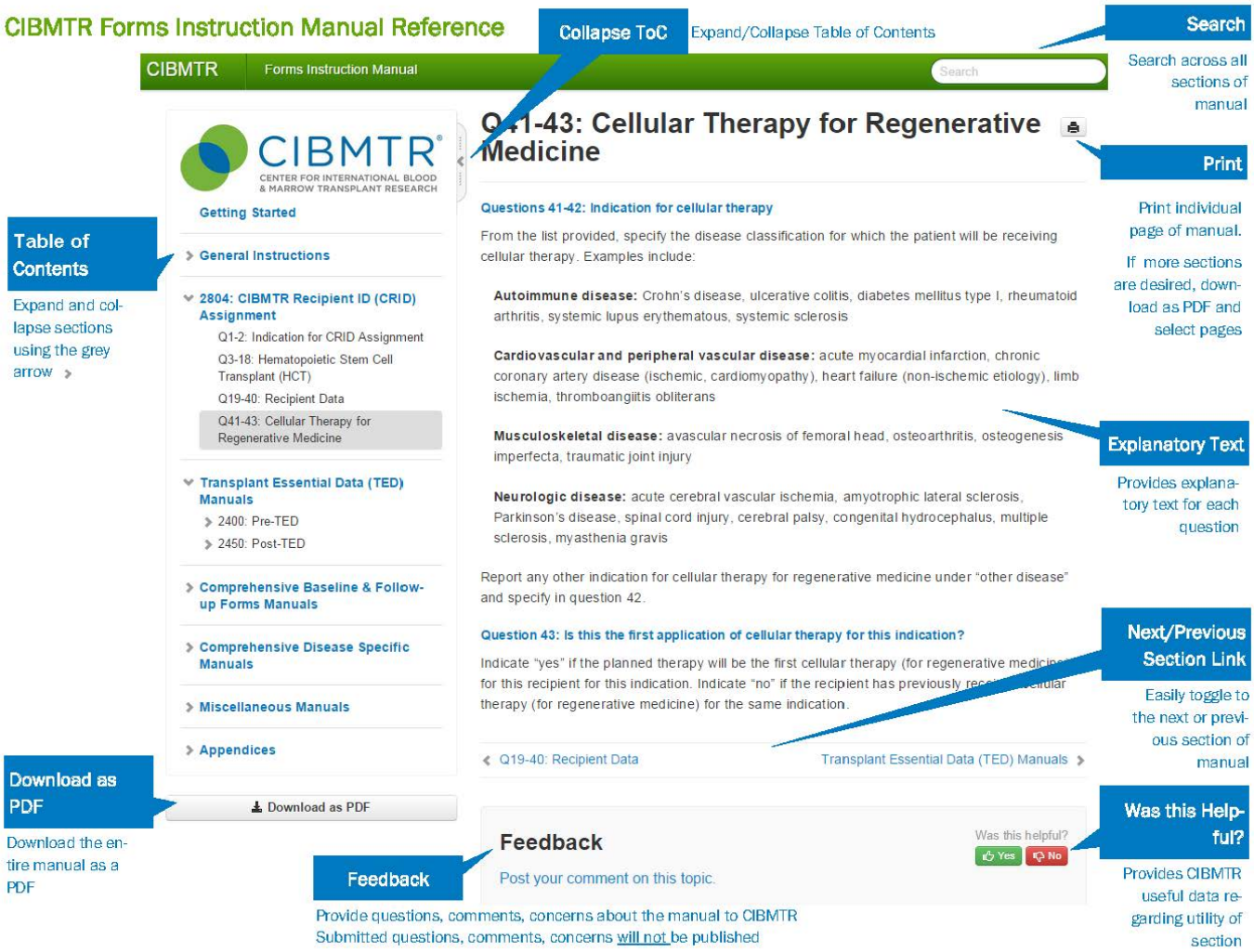
Additional Resources provides links to helpful materials.

Updates:
Sections of the Audit Guide may occasionally be updated. In addition to documenting the changes within each section, a summary of the updates to the guide can be found below. For additional information, select the appropriate section and review the updated text.

Date	Manual Section	Add/Remove/Modify	Description

Last modified: Sep 15, 2022

Reference Diagram



Click to enlarge

Last modified: Nov 15, 2017

Providing Feedback

If you have a question, comment, or concern regarding the content or how to use the Audit Guide, please contact CIBMTR Center Support here. For centers with an upcoming audit, you may contact the assigned lead auditor.

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Audit Timeline

Before the Audit

12 weeks before the audit
- Receive general audit and auditor information
- Receive and complete pre-audit questionnaire

8 weeks before the audit
- Recipients are selected for audit and forms are locked in FormsNet.
- Receive the CIBMTR Audit Recipient list and request for copies of IRB regulatory documents
- **Request access to electronic medical record (EMR) and recipient medical records**
- For onsite audits, arrange workspace for the auditors
- Attend Pre-Audit Call #1

4 weeks before the audit
- Attend Pre-Audit Call #2

1-2 weeks before the audit
- Ensure proper access has been granted to the EMR
- Determine if all applicable paper records have arrived and are complete

During the Audit

Audit Start
- Be available during the pre-specified time to meet auditors and participate in the Opening Meeting
- Describe layout of the records and ensure proper EMR access

General auditing time
- Check-in with auditors / attend check-in meetings
- Be available to answer questions and provide troubleshooting help for medical records navigation.
- Review recipient level summary findings, as time allows
- Utilize audit as a training opportunity and ask questions

Audit End
- Participate in the Closing Meeting

After the Audit

Friday of the audit week
- Auditors will ensure all recipient level summary findings have been provided by the EOD Friday of the audit week

Following Wednesday post-audit
- Obtain physician clarification to auditor questions and missing documents requests, as applicable
- Respond to recipient level summary findings on the VDR by due date, understanding the auditors may have additional questions and requests throughout the post-audit process

8-12 weeks post-audit
- Once all follow-up has been completed, sign and date the Recipient List and return to lead auditor
- Receive the Audit Report, Corrective Action Plan Checklist (if applicable), and Data Change Summary

- Review the Data Change Summary and return to lead auditor once signed by medical director

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Before the Audit

In this section:

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Audit Eligibility

Center Eligibility

A transplant center is eligible for an audit after performing a minimum of 20 transplants (any combination of related or unrelated allogeneic and autologous). From the completed transplants, 16 eligible transplant events are selected for audit. Once a recipient is determined to be eligible for audit, forms submitted without errors in FormsNet will be audited. US-based centers who have not performed 20 transplants will be deferred from the audit process until they have reached their 20th transplant.

Currently, the CIBMTR audits non-US-based centers whose medical records are primarily documented in English and whose staff speaks English. In addition to the above listed eligibility criteria, we will also identify whether the non-US center has utilized a donor or product from the US. If not, we may not conduct an audit at the center even if they meet all other eligibility criteria.

Recipient Eligibility

For a recipient to be eligible for audit, one of the following form combinations must be submitted error-free (in CMP status) to FormsNet:

- Pre-Transplant Essential Data (TED) (2400) Form, Disease Classification (2402) Form, and 100 Day Post-TED (2450) Form
- Pre-Transplant Essential Data (TED) (2400) Form, Disease Classification (2402) Form, Recipient Baseline (2000) Form, and 100 Day Post-Infusion Follow-up (2100) Form

Form Eligibility

Forms that are in complete status at the time recipients are randomly selected for audit (approximately six to eight weeks prior to the audit date) are eligible. Once a recipient is selected for audit, all forms to be audit will be locked in FormsNet and no changes will be allowed to be made by the center. The following forms may be audited:

- Pre- and Post-Transplant Essential Data (Forms 2400, 2402 and 2450)
- Baseline Data (Form 2000)
- Post-Infusion Follow-up (Form 2100)
- Six Month to Two Year Follow-Up (Form 2200 – retired)
- Greater than Two Year Follow-Up (Form 2300 — retired)
- Death Data (Form 2900)
- All corresponding disease, infectious disease markers, HLA typing, infection, and infusion inserts

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Cellular Therapy Audit Information

Starting in FY20, centers scheduled for an HCT audit that have submitted CAR-T infusions will also have a Cellular Therapy audit performed as part of the HCT audit process. Up to eight CAR-T infusions will be randomly selected for audit. The Cellular Therapy audit results will not impact HCT audit results. A separate CT audit report will be provided with the final CIBMTR Audit Report.

Forms that are in complete status at the time recipients are randomly selected for audit (approximately six to eight weeks prior to the audit date) are eligible. The following forms may be audited:

- Cellular Therapy Essential Data Pre-Infusion (4000) Form
- Disease Classification (2402) Form
- Cellular Therapy Product (4003) Form
- Cellular Therapy Infusion (4006) Form
- Death Data (Form 2900)
- All corresponding disease, HLA typing, and infection forms

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Scheduling an Audit

When a center is eligible for audit for the next audit year1, the CIBMTR will send a notice of the upcoming audit to the center and start the process of scheduling the audit in mid to late spring. The transplant center's primary contact and Medical Director will be notified of the upcoming audit and asked to finalize the dates of the audit.

Audits are most commonly performed over 4 days (Monday – Thursday). Audits typically include two auditors; however, additional auditors may be present if a Cellular Therapy Audit is also occurring, due to training, etc. The audit may be performed onsite or via remote access to the electronic medical record (EMR).

Twelve weeks prior to the audit, an email will be sent with general audit and auditor information. This email will also include a link to a pre-audit questionnaire. The primary contact should complete and return the pre-audit questionnaire.

Eight weeks prior to the audit, recipients will be selected for audit. All forms in complete status for each recipient selected for audit will be locked at this time. The lead auditor will provide the site's primary contact with a list of the 16 transplant events that have been selected for audit. A list of eight cellular therapy events will be included if a Cellular Therapy Audit is also being performed. As a reminder, the auditors will need full read-only access to the EMR to complete the audit. As this process can sometimes be lengthy, any required consents / documents for medical record access should be sent directly to the auditors as soon as possible to avoid any issues with conducting the audit. At this time, the first of two pre-audits will be scheduled. In the first call, EMR access will be discussed along with any documentation that needs to be completed to grant access. In addition, an overview of the audit process will be provided along with a summary of the audit week and any required meeting times for the opening meeting, daily check-ins, prior corrective action plan review and the closing meeting. There will also be an opportunity to have any questions regarding the audit week answered.

Approximately four weeks prior to the audit, during the second pre-audit call, EMR access will be confirmed, and the schedule of the audit week will be finalized. An audit agenda will then be created and sent to the center following the call, along with invites for each meeting. See Meeting Time Requirements for additional information.

[1] The audit year corresponds to the fiscal year (October 1 – September 30).

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Medical Records/EMR

The auditors require access to a recipient's entire medical record. The Office of the General Counsel, United States Department of Health and Human Services has determined, with the concurrence of the Office of Civil Rights, that the CIBMTR meets the Privacy Rule's definition of a public health authority (PHA) and is authorized by law to collect the information necessary to fulfill the legislated mandate to collect data needed to assess outcomes of hematopoietic stem cell therapy. It is therefore not a "covered entity" under HIPAA. Additionally, transplant centers fitting the definition of covered entities may disclose certain individually identifiable health information to the CIBMTR under 45 CRF 164.512 (Privacy Rule), which allows for the disclosure of an individual's protected health information without the individual's written consent or authorization when such a disclosure is made to a PHA that is authorized by law to collect information for the purpose of preventing or controlling disease, injury, or disability.

In addition, the Data Transmission Agreement, signed by all transplant centers, agrees to provide CIBMTR access to all records used during completion of CIBMTR data collection forms. This agreement is a useful resource when ensuring necessary access to medical records is provided to auditors.

All charts (inpatient, outpatient and/or clinic, and stem cell processing) should be available at one site. The following recommendations should be considered when preparing recipient medical records for audit:

- All security access paperwork for either electronic or paper access should be completed prior to audit.
- EMR access must allow for full view of the medical record (i.e., a single PDF of the entire chart ***cannot*** be used for auditing). If the recipient data is stored in multiple applications, the auditors will need access to each system. When EMR access is granted, the site should verify that the auditors have full access to all information in a usable format before the auditors' arrival at the site.
- If records are stored outside of the EMR (i.e., stem cell lab documentation), these records must be available for review during the audit.
- If the auditors are not granted access to the EMR, all notes, labs, tests, etc. will need to be printed for their review. The printed documentation should be organized into separate categories chronologically (i.e., progress notes, pathology reports, labs, etc.).
- Forms will be locked for audit, preventing editing or changes being made by the transplant center. Error correction forms (ECFs) do not need to be completed for forms locked for audit. The auditors will make necessary changes based on reviewed documentation. Following the audit, if the transplant center wishes to make additional changes, an ECF and supporting documentation can be submitted to CIBMTR Center Support for review.

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Space Requirements (on-site audits)

Auditors will typically be on-site four days and require a workspace each day. Ensure the following accommodations are provided throughout the duration of the audit:

- Desk or table to use as workspace.
- Electrical outlets near workspace for each auditor.
- Computers to access EMR (if applicable) for each auditor.
- Space availability 8:00am to 6:00pm each day, with potential to work later.
- Additional accommodations, such as meals, do not need to be provided for the auditors.

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Meeting Time Requirements

Before the audit, the site's primary contact should ensure that appropriate staff have made time in their schedules to be available at particular times during the audit. The auditors are able to work independently for the majority of the audit, however interaction with the data management staff is necessary at the following times:

- The opening meeting will be held on the first day of the audit and is most applicable to those the auditors will be working closely with throughout the audit week (i.e., data management staff). The opening meeting takes approximately 30 minutes to complete and will be followed by a brief tour of the recipient charts and workspace if on-site. The lead auditor will send a meeting invite to the primary data manager who can then forward the invite to applicable staff members. During this meeting, the audit process, purpose, and goals, summary emails (see below), the role of the data manager during the audit, and the audit follow-up process will be reviewed.

- Throughout the audit, the data manager should be available to assist with locating missing documentation or answering auditor questions.

- For remote audits, daily check-ins will be scheduled for approximately 30 minutes. These meetings provide an opportunity for staff to ask questions regarding the summary emails, discuss recipient-specific scenarios, manual instructions, and ask questions outside the scope of the audit.

- As applicable, a meeting to discuss the center's prior Corrective Action Plan (CAP) will also be scheduled to occur for approximately 30 minutes. This meeting is intended to review the corrective action assigned following the prior audit, the implementation of the corrective action plan, and any other improvement efforts implemented by the center. Staffing or reporting changes will also be discussed, as applicable.

- On the fourth day of the audit (Thursday), a closing meeting will be held to review high-level findings from the audit and reporting instructions, provide training, and answer questions. This meeting lasts approximately one hour. Final audit error rates and results will not be available at this time and will be sent in the final audit report. The lead auditor will send a meeting invite to the primary data manager who can then forward the invite to applicable staff members. The closing meeting is most appropriate for individuals who complete the CIBMTR forms; however, the medical director and other center staff are more than welcomed to attend. If the medical director wishes to attend the closing meeting but is unavailable due to scheduling conflicts, the auditors can meet with medical director separately, to briefly discuss the findings, if requested.

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During the Audit

In this section:

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Audit Logistics

The Primary Contact for the CIBMTR data audit will have the following responsibilities during the audit:

- For on-site audits, meet auditors on arrival. Orient them to the workspace and recipient charts.
- Attend check-in meetings as determined by the auditors and data management staff.
- Be available to answer questions and retrieve additional documentation if needed.
- Ensure a transplant physician is available for occasional questions best addressed by a physician (availability via e-mail is appropriate).
- Ask questions! The entire audit is an opportunity for education about CIBMTR reporting.

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Audit Process

Compare Source Documents to Submitted Data

The auditors compare recipient data entered into FormsNet with data in the recipient medical record and other appropriate source documents (e.g., HSC processing records). If a discrepancy is found between the data reported to the CIBMTR and the source document or if the data was not submitted in accordance with the CIBMTR Forms Instruction Manual, the auditors correct the originally reported data.
The auditors categorize the discrepant data into one of three groups: audit errors, missing documentation errors, and non-audit changes.

Critical versus Random Fields

Not all fields on the form will be audited. Two types of fields are selected for audit: critical fields and random fields.

- **Critical fields** are those data fields that have been identified as being essential to the accurate completion of outcomes analyses. These fields will be audited for each recipient, though may differ based on disease and transplant type.
- **Random fields** are additional data fields added to the audit to increase the validity of the audit. The random fields may differ between recipients.

Error types

- **Audit errors** are assigned when data in the medical record differs from what was reported, data found in the medical record was not reported, or the data was reported not in accordance with the CIBMTR Forms Instruction Manual. Auditors make all data corrections in the Research Database, and the transplant center is provided with a record of each change made to forms.
- **Missing documentation** errors are assigned when data cannot be verified by a source document at the time of audit. Attempts are made during and post-audit to acquire the missing documentation. For more information, see Recipient Level Summary Findings and Post-Audit Follow-up sections below.
- **Non-audit changes** do not count towards audit error rates. Fields not selected for audit may be reviewed and updated as necessary. Changes made to these types of fields will be classified as “non-audit changes.” Non-audit changes may also be made in critical or random fields for situations where it is not appropriate to assign audit or missing documentation errors.

Consent Form Review

In addition to auditing CIBMTR forms, consent forms are audited for proper completion. The consent forms audited are dependent on the type of transplant. For additional information about Consent Forms, review information located in the Protocols and Consents section of the CIBMTR website.

When reviewing the consent forms, the following criteria are used:

- All pages of the consent form are present.
- The consent form has been signed and dated by the recipient (or parent/guardian).
- All blanks on the consent form are completed. This includes any space designated for printed names,

health care provider signatures and dates, checkboxes, initials, witness lines (if applicable, etc.).
- The correct version of the consent form has been signed (e.g., Autologous Recipient or Allogeneic Recipient) and that the recipient signed the current approved version of the consent form available at the time of consent.
- The consent form was signed within the IRB approval period. If the date range is not on the consent form itself, accompanying IRB correspondence is reviewed.

If any issues are found on a recipient's consent form, corrective action is necessary to address each issue.

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Recipient Level Summary Findings

Recipient level summary findings will be uploaded to the Virtual Data Room (VDR) in real-time following review of each record. The purpose is to provide a high-level overview of changes identified during the audit to provide training and increased transparency in the audit process. It will also include areas requiring physician-level clarification and requests for missing documentation. It does not include a list of every change identified.

The summaries will be uploaded as Microsoft Word documents and can be distributed internally to data management staff as needed. The center will be notified via email when each summary findings is ready for review. Responses should be provided directly within the document, and additional documentation can be uploaded to the VDR.

The due date to review and respond to the findings is approximately two weeks post-audit and will be provided by the lead auditor. Although not required, it is encouraged to review the summary findings in real-time if possible.

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After the Audit

In this section:

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Post-Audit Follow-up

The center will review and respond to all recipient level summary findings by the assigned due date within the Virtual Data Room. This may include answering general questions, responding to inquiries where the auditors are seeking physician-level clarification, and providing any missing documentation requests.

Within approximately two to six weeks post-audit, each auditor will review the site responses based on their availability and the audit schedule. The site will be notified when there are additional follow-up questions and/or requests. Once all outstanding queries are resolved, the data manager will be notified to sign / date the Audit Recipient List indicating audit follow-up is complete.

In the rare event there are items for which documentation cannot be located following the audit and summary findings review, any missing documentation issues will be detailed in the Corrective Action Plan. At that time, if the source documentation still cannot be located, the data will be removed from the FormsNet database after the Corrective Action Plan, signed by medical director, is returned to the CIBMTR.

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Data Entry

The center will be provided with a record of all data changes made via the Data Change Summary, included with the final Audit Report. The Data Change Summary should be reviewed by the center, signed by the medical director acknowledging the changes made to the database as part of the audit, and returned to the lead auditor. The auditors will make all data corrections to the database, and the audited forms will remain locked after the audit. Following the audit, if the transplant center wishes to make additional changes, an ECF and supporting documentation can be submitted to CIBMTR Center Support for review.

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Passing Criteria

The CIBMTR has established an acceptable error rate of less than or equal to 3% in critical data fields. Critical fields have been identified as being essential for outcome analyses. Therefore, it is imperative that these data fields are reported accurately. Based on the center's critical field error rate, a center will: 1) pass, 2) pass with required corrective action, or 3) fail with required corrective action. See the "Corrective Action" section for more information on this subject.

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Audit Report

Transplant centers will receive a detailed audit report evaluating the results of the audit. The report is sent to the site Medical Director, primary data management audit contact, and CIBMTR leadership. The report includes:

- A statement of whether the center passed the audit, passed the audit with corrective action, or failed the audit. Passing the audit requires a critical data field error rate less than or equal to 3%.
- An overall, critical, and random data field error rate & error rates by form.
- A data management discussion section reviewing grouped critical field errors, termed “reporting areas.” Examples of reporting areas include disease status pre- and post-transplant data fields, HCT product and infusion data fields, disease status, acute and/or chronic GVHD data fields.
- A comparison to the center’s previous audit, if applicable.
- A section that itemizes and discusses any issues on IRB-approved CIBMTR Research Database or Research Sample Repository consent forms.

A summary of all changes made to the database as a result of the audit (Data Change Summary) will be sent with the audit report.

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Data Review Process

The Audit Program has developed a formal post-audit process for inquiries regarding data changes made during the audit. Following the audit, in addition to the final CIBMTR Audit Report, the center is sent a data change summary to summarize all changes made to the FormsNet3 database as a result of the audit. If a center has questions or concerns regarding a specific audited data field change, the review process is initiated.

If a center requests changes to data fields reviewed and changed as part of the audit, the center submits their questions and concerns along with any applicable source documentation regarding the data changes. This information is then reviewed by the audit team. If the changes reviewed result in data field changes and a change to the originally calculated error rates, a summary letter describing the data changes and new error rates are sent to the center along with a detailed explanation about why the change was made. In the case where a center's pass/fail status is changed based on the data review, an amended audit report is also produced and sent to the center.

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Corrective Action and Audit Completion

Centers may be required to submit a Corrective Action Plan (CAP) in response to errors identified during the audit. The submission of a CAP will be requested to address any of the following concerns:

- A critical field error rate greater than 3.0%
- Systemic errors are identified in a single reporting area, even if the critical field error rate is less than or equal to 3.0%
- Issues with CIBMTR Research Database or Research Sample Repository consent forms
- Outstanding missing documentation

If systemic issues are identified, corrective action will be required to address the issue on all submitted recipients, not just those identified during the audit.

A Corrective Action Plan checklist which details the issue, the requested corrective action, and signature lines for data management staff and the Medical Director are included with the audit report. Data management staff should submit a written plan to address each item on the Corrective Action Plan Checklist, collaborating with data management staff colleagues and Medical Director in a timely manner. Once returned, the CAP is reviewed and evaluated to ensure that each item was addressed appropriately. As part of the FACT/CIBMTR collaboration, FACT inspectors will evaluate successful implementation of CIBMTR corrective action requirements.

Once each of the items on the Corrective Action Plan checklist has been addressed, the audit process is considered complete and a certificate of completion is sent to the transplant center. If a CAP is unsatisfactory, auditors will request additional information from the site. The effectiveness of any corrective actions will be evaluated during the next audit.

If no corrective action is required, the transplant center will receive an audit completion certificate when the report is sent.

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Audit Consequences

High quality data provides the foundation for CIBMTR research. To further support the collection of quality data, CIBMTR implemented consequences for centers that have particularly high error rates or that consistently fail to meet data quality standards. Effective **October 1, 2020**, audit consequences will be applied when a center has **two** consecutive audits resulting in a Critical Field Error Rate >3%. The first audits applied to the new policy are audits performed on or after October 1, 2016. The updated policy eliminates the critical field error rate tiers and reduces the number of consecutively failed audits to two for the implementation of audit consequences.

Audit Consequences

Implementation of audit consequences at a center is carefully considered by CIBMTR Leadership and is approved by the Chair of the CIBMTR Advisory Committee. The nature and extent of the audit errors are taken into consideration as well as the potential impact on the quality of research data and reporting functions of the CIBMTR.

For Domestic and International Centers Reporting Transplants with US Donors:

Center Specific Survival Analysis (CSA) Reporting:

- Center Specific Survival Analysis (CSA) is performed to meet federal requirements of the Stem Cell Transplant Outcomes Database (SCTOD). The CSA predominantly uses pre-transplant variables, and the survival outcome. Center's data will not be included in the Center Specific Outcomes. Implementation of this audit consequence will result in the center's data being excluded from the calculation of the center's expected performance. Additionally, these centers will be identified on the Center Specific Outcomes webpage as a center that has not met data quality requirements (relevant only to US centers).

Research Studies:

- Data may be quarantined from observational research activities; however, continued involvement in prospective studies will be evaluated

Transplant Essential Data and Comprehensive Report Form Reporting:

- If the center is a case report form (CRF) reporting center, the center may be changed to a Transplant Essential Data (TED) reporting only center.

CIBMTR Leadership Roles

- Participation in CIBMTR leadership roles or membership in CIBMTR administrative committees may be denied.

Access to Unrelated Donors

- If the center is a National Marrow Donor Program (NMDP) center, access to NMDP donors may only be allowed if an accepted corrective action plan (CAP) to improve data quality has been submitted, and CPI is up-to-date or has an approved CAP.

For International Centers Not Reporting Transplants with US Donors: **CIBMTR membership may be terminated**.

Removal of Audit Consequences

If any of the audit consequences outlined above are applied to a center, they will remain in place until the center passes the next regularly scheduled CIBMTR data quality audit in four years. Centers can request an interim audit at the site's expense; however, the interim audit cannot be conducted until the site has successfully implemented the corrective action plan (CAP), which was agreed at the time consequences were applied, and sufficient data has been submitted to assess the effectiveness of the CAP. In order for the center's CSA data to be released from consequences the interim audit must include data from the current CSA three-year window applicable at the time the interim audit is performed. In addition, systemic errors identified in CSA data fields as a result of the audit must be corrected for all patients included in the current CSA three-year window.

For centers audited in FY2020, the previous audit consequences policy (effective June 1, 2015) will apply to the audit. Please contact the CIBMTR Audit Team for more information.

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FACT/CIBMTR Collaboration

Beginning in 2017, FACT and CIBMTR have launched a collaborative program of data auditing, designed to reduce duplicative efforts, enhance quality improvement efforts, and provide support to accredited programs. The essential elements of the collaboration are:

- FACT clinical inspectors will no longer perform a data audit at the on-site FACT inspection. This will eliminate the need for data sheets to be prepped only for FACT inspectors and allow the clinical inspector to focus on adequacy of corrective actions and quality improvement.
- All verification of the accuracy of data against source data will be done by the CIBMTR audit teams on site according to their current practices and schedules. The current CIBMTR process will not change.
- The FACT-CIBMTR Data Audit Committee will review CIBMTR audit reports and corrective action plans to assess compliance with Standards, implementation of effective corrective action, and improvements.
- Timeliness and completeness of data submission will also be assessed by the Committee using CPI reports from CIBMTR indication “in good standing”.

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Frequently Asked Questions

In this section:

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General

Which forms are eligible for audit?

See “Form Eligibility” on the Audit Eligibility page.

Are auditors evaluating CPI status?

No. Auditors only evaluate forms that have been submitted as complete to the CIBMTR. However, if a center is struggling with CPI compliance, please contact CIBMTR Center Support for assistance.

Someone else completed the forms you selected for audit; can you review more of the forms that I completed? Why am I being held accountable for someone else’s work?

All transplants that were performed since the date of the last audit are eligible for audit regardless of any staff changes that have occurred. One of the goals of the audit is to ensure the quality and accuracy of the entire CIBMTR research database.

Forms are randomly selected for audit and, typically, transplants selected for audit are usually distributed across the entire four-year audit cycle to establish an error rate for all of the center’s data in the time period.

If there are concerns about the center’s data quality, we suggest the center conduct an internal audit of their data to identify the scope of the issue and develop a plan to proactively update the data, prior to any official audit from the CIBMTR.

Where can I find my previous audit results?

The audit report from the previous audit was emailed to the medical director and primary contact at the time of the previous audit. All prior audit results are also located under the center’s audit folder on the CIBMTR Portal. If you do not have access to the CIBMTR Portal or the “Audit Tab” on the portal, please submit a ticket to CIBMTR Center Support.

Will you be reviewing every data field on every form?

No. Two types of fields are selected for audit: critical fields and random fields.

Critical fields are those data fields that have been identified as being essential to the accurate completion of outcomes analyses. These fields will be audited for each recipient, though may differ based on disease and transplant type.

Random fields are additional data fields added to the audit to increase the validity of the audit error rates. At least thirty random fields will be selected per recipient. The random fields that are selected will differ between recipients.

Fields not selected for audit are visible to auditors and may be updated as necessary, though will not count in the error rates. Changes made to these types of fields are called “non-audit changes.”

Are you able to tell me what fields are considered critical?

Critical Field lists for all audited are located on the “Audit Tab” of the CIBMTR Portal.

If you do not have access to the CIBMTR Portal or the “Audit Tab” on the portal, please submit a ticket to CIBMTR Center Support.

Are you able to tell me which random fields you will be auditing?

No. Random fields differ between recipients. Therefore, it would be very difficult to provide a list of all random fields prior to the audit. Most non-critical data fields are eligible for selection as random fields on forms selected for audit. This increases the reliability and validity of the audit.

How are recipients selected for audit?

For previously audited centers, 16 transplant events are randomly selected from all the transplants that have been submitted to the CIBMTR research database since the date of the last audit for those centers that have been audited previously. For those centers that have never been audited by the CIBMTR, any reported transplants occurring since December 3, 2007, will be eligible for audit.

Audited transplants can include any combination of allogeneic (related and unrelated) and autologous transplants. In addition, if a recipient has had more than one transplant, each transplant that meets the eligibility criteria may be audited.

Will I still be able to complete new forms for this recipient, even though they are being audited?

Yes. Only forms selected for audit will be locked. Any forms that were not completed prior to forms being locked for audit will still be available for completion. Any new forms submitted as complete between the time forms are locked for audit and the actual audit will not be reviewed during the audit.

Will autologous patients be audited?

Only autologous patients who have signed an IRB or ethics committee approved research database consent form to submit data to the CIBMTR will be audited. During the audit, if auditors discover that an autologous patient never consented to the research database, the auditors will not audit that patient and update the consent status accordingly.

What if we cannot get electronic record access for the auditors?

If your center uses an electronic medical record (EMR), it is expected that CIBMTR auditors will have full read-only access to the EMR. It is recommended the auditor's access mirrors the same access as the center's data management staff. Access in the form of pdfs from the medical record will not be sufficient for audit purposes.

Obtaining access to the complete record is vital for completing the audit in a timely and accurate manner. The data transmission agreement (DTA) that exists between the CIBMTR and all centers that submit data is typically sufficient to attain access to the EMR for auditors. Additionally, the auditors will provide additional information, sign confidentiality agreements, and complete training necessary to obtain access to a center's EMR.

If a center is not able to provide access to the EMR, the recipient's **entire** medical record must be printed from the EMR for auditor review. Once printed, the medical record should be organized into categories chronologically (progress notes, labs, pathology, MARs, chemotherapy orders, platelet transfusions, etc.). This method is not recommended.

Are shadow charts okay for the auditors to use? Are shadow or floor charts needed for the auditors?

If your site keeps research or shadow charts, they are frequently a helpful outline of the patient's pre and post- transplant course. However, the auditors require full access to the recipients' entire medical record.

Shadow charts are not a satisfactory substitution for medical record access. They are also not a requirement for the audit.

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Before The Audit

What are the date ranges for the patients to be audited?

Any recipient that received a transplant after the date of your last audit will be eligible for audit.

For those centers that have never been audited by the CIBMTR, all transplants since December 3, 2007 or the start date of data entry to the research database (if after the 2007 date) will be eligible for audit.

When will the forms be locked?

The forms that are selected for audit are locked approximately eight weeks prior to the audit.

When will you send me the recipients to be audited?

The list of recipients to be audited will be sent to the primary contact immediately after the forms are locked, eight weeks prior to the audit.

Should ECFs be made for the recipients being audited?

No. Do not create ECFs after the forms are locked prior to the audit. The auditors will review the forms on-site and will make any necessary changes at that time. If, following the audit, changes are identified that need to be made to locked forms, please submit error correction forms (ECFs) with the changes and supporting documentation to CIBMTR Center Support.

When will I know who the auditors will be?

The auditors' names and contact information will be sent twelve weeks prior to the audit.

What materials do you need us to pull from the Stem Cell Laboratory? If we have the cell counts in the EMR, will that be enough?

The entire stem cell processing record is needed to effectively audit the HCT Infusion Form (Form 2006). This form collects processing information, adverse events, manipulation, donor information, and cell counts; the stem cell processing laboratory's records are the best source documents for verifying these data fields.

Are you familiar with common medical record systems?

The auditors have experience with many electronic medical record systems from major vendors, although configurations of the systems do vary from center to center. When the auditors arrive on site, they will ask for a brief tour of the medical record from data management staff regarding the location of key source documentation.

Do you need access to any/all of the medical records for the entire audit (including lab charts)?

Yes. The auditors should have access to all medical records for the entire audit. If stem cell product

records cannot be removed from the stem cell processing lab, the auditors may schedule a time to visit the stem cell processing lab and review those records.

Are the auditors willing to complete training or sign confidentiality agreements to get access to my site's medical records?

Yes. The auditors will provide additional information, sign confidentiality agreements, and complete short, remote training required to obtain access to a site's EMR. Please send any training or confidentiality agreements to the auditors as soon as possible to ensure ample time for completion prior to the audit.

If medical records are at two different sites, will the auditors be traveling to both sites or do you require records to be at one site?

To the extent possible, efforts should be made to ensure that the records are at one site. One exception is the stem cell processing records, which sometimes may not be removed from the stem cell processing lab. In this case, the auditors may schedule a time to visit the stem cell processing lab and review those records.

What sort of room requirements are there?

The room should have enough space for two to three auditors. The room should have electrical outlets for the auditors' computers.

Can the auditors use only one computer (if electronic records)?

No. Auditors must audit records concurrently in order to finish the audit in a timely manner and therefore will need access to electronic records at the same time on two computers unless the EMR is able to accessed from the auditors' computers.

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During the Audit

What time will the auditors be arriving? What is the tentative agenda?

After the second pre-audit call approximately four weeks prior to the audit (where the audit logistics are discussed), a tentative agenda will be provided to the center for reference.

The auditors will typically arrive in the late morning or early afternoon on the first scheduled day of the audit. When the auditors arrive, they will conduct a brief introductory meeting to review the audit process and the layout of the week. They will then ask for a brief tour of the medical record, where data management staff may show them where to find certain source documentation in the medical record (e.g. progress notes, laboratory values, stem cell processing records, transfusion records, etc.).

For remote audits, daily check-ins will be scheduled to occur throughout the audit week between data management staff and auditors. This may occur once or twice per day for approximately 30 minutes, depending on site preference and staff availability. These are intended to provide an opportunity for the data management staff to ask questions regarding summary findings, discuss recipient-specific scenarios, and forms instruction manuals.

On the final day of the audit, the auditors will conduct a closing meeting with data management staff that will last approximately one hour.

Will a data manager (or other staff person) need to be with the auditors during the time of the audit?

No, but there should be a communication process set-up during the introductory meeting for questions/ troubleshooting; in addition, they should plan on checking in with the auditors every few hours.

Who needs to be present the week of the audit?

Data management staff should be present to answer any questions the auditors may have and to capitalize on learning opportunities provided during the audit. A transplant physician, not necessarily the Medical Director, should be available to answer any clinical question via email (they do not need to be present for the audit, unless that is their preference).

Does the physician/Medical Director need to be present during the audit time?

The Medical Director does not need to be present during the audit time. However, a transplant physician, not necessarily the Medical Director, should be available to answer any clinical question via email (they do not need to be present for the audit, unless that is their preference). While not required, the Medical Director may choose to attend the audit opening and closing meetings, where the auditors provide a summary of the audit process and initial observations.

What hours will the auditors work?

The auditors typically work from 8:00 am to 6:00 pm, however they may request to work additional hours.

Should I provide food for the auditors?

While we appreciate the gesture of providing food for the auditors, it is not a requirement.

Lunch: In order to provide a brief break from the audit, the auditors will typically utilize a cafeteria or other facility available onsite. If there is not a suitable eating facility available onsite, a list of restaurants near the center that provide quick lunch opportunities would be appreciated.

Snacks/Beverages: The auditors will typically provide their own snacks and beverages as needed throughout the day. Again, they may utilize a cafeteria/gift shop or vending machines as needed.

A list of available options and a map or directions to any of these places would be helpful and can be provided during the introductory meeting.

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After the Audit

When will I receive the audit results?

An audit report containing results will be sent to the Medical Director and primary audit contact approximately eight to twelve weeks after the audit.

What will happen if I fail the audit?

All centers that fail an audit with a critical field error rate >3% will be required to complete a corrective action plan. Centers that have a significantly high error rate or consistently fail to meet data quality standards will have audit consequences applied. For more information regarding audit consequences, please see the Audit Consequences page.

When will my forms be unlocked?

The forms that were audited will remain locked in the FormsNet database after the audit. Any changes made as a result of the audit will be entered into the FormsNet database by the auditors. A summary of the changes made in the FormsNet database will be sent along with the audit report.

Forms that were not audited due to time constraints will be unlocked following the audit.

Can we make/request changes to the audited (locked) forms?

If, following the audit, changes are identified that need to be made to locked forms, please submit error correction forms (ECFs) with supporting documentation to CIBMTR Center Support.

What if I need more time to complete a CAP?

CAP extensions are given on a case-by-case basis. If an extension is needed, contact the lead auditor to arrange a CAP due date extension.

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Additional Resources

Please see the list below of additional resources:

- **CIBMTR Forms Instruction Manual**: The Forms Instructions Manual is a comprehensive reference document to help centers complete the Transplant Essential Data (TED) Forms and the Comprehensive Report Forms and submit them to CIBMTR.
- **CIBMTR Portal**:
  - **Training and eLearning tab**: Provides comprehensive information and training materials for data management professionals regarding data submission requirements of CIBMTR and field knowledge.
  - **Audit tab**: View and download prior Audit Reports, Audit Completion Certificates, CAP items, and anything else relevant to past CIBMTR audits. Provides audit resources including disease trackers, critical fields, and additional internal audit tools.
- **TCT Presentations**: The Clinical Research Professionals/Data Management Conference provides training and educational opportunities to data management staff responsible for completing and submitting recipient data to the CIBMTR. Meeting topics, PowerPoints, and recordings from prior conferences may be reviewed
- **Data Management Guide**: Contains information on center participation and data submission to the CIBMTR and serves as a resource for individuals seeking guidance about forms due, data quality, and the functions of CIBMTR research data processing.
- **CIBMTR Center Support**: A ServiceNow application used by centers to request support from CIBMTR regarding technical issues, clinical data reporting questions, and any other CIBMTR data related queries. This can also be used to contact the CIBMTR Audit team with questions regarding the audit process, past audit reports, portal access, etc.

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