|  |  |
| --- | --- |
| **audit title** | Transplant Essential Data Forms Data Accuracy Audit |
| **division** |  |
| **division contact** |  |
| **audit date(s)** |  |
| **responses required by** | 30 business days from the date submitted to Auditee[[1]](#footnote-1)7 business days from the date submitted to Auditee (for Critical Observations) |
| **auditors** |  |
| **sops reviewed** |  |
| **audit objective** | To review the accuracy of information submitted to the CIBMTR data registry via FormsNet”.  |
| **audit scope** | Selected clinical data points, both as mandated during FACT inspection and randomly chosen by auditor, in the completed CIBMTR data collection forms (from pre-transplant to 100 days) and related source documentation for 10 allogeneic and 5 autologous transplants identified for upcoming FACT inspection.  |
| **audit criteria** | FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing & Administration (current edition)CIBMTR Data Management Manual  |
| **personnel interviewed** |  |

*This report contains information from a confidential compliance audit. It is the recipient’s responsibility to ensure that it is not copied or distributed. Under no circumstances should this document be stored or archived in files open to regulatory agency inspections. The original report will be archived as part of Quality Management files.*

**Audit Results**

**Overall Audit Grade:** The audit reflected <NNN> Observations that include <N> nonconformity issues, classified as follows (see the Audit Observations section below for details):

|  |  |
| --- | --- |
| **rating** | **number of observations** |
| **Nonconformities** | **Critical** | <N> |
| **Major** | <N> |
| **Minor** | <N> |
| **Process Improvement Opportunities** | <N> |
| **Good and Best Practices** | <N> |

**Overall Comments:**

1. Source documentation, when requested, was located by the auditee for <NNN> data elements reviewed on the CIBMTR forms provided.

**Overall Recommendations:
Instructions for Audit Response:**

Please provide a written response to each observation listed in the tables below. To fully address the observations, it is necessary to investigate and determine the root cause of each nonconformity and include a corrective and preventive action plan for each finding with proposed completion dates.

Note:

* Critical and Major audit observations require an investigation to include root cause analysis and appropriate corrective actions and preventive actions (CAPA) to address the root causes.
* Minor audit observations only require appropriate corrective action (root cause analysis and preventive action are optional).

Provide the proposed action plan to the lead auditor for preliminary review to ensure that appropriate corrective and preventive actions will be taken.

As CAPA activities are completed, the auditee provides, to the lead auditor, objective evidence of completion for each action implemented.

Corrective Actions – Action taken to correct the cause(s) of a detected nonconformity or other undesirable situation.
Preventive Actions – Action taken to prevent recurrence or eliminate the cause of a potential nonconformity or other undesirable situation.

If there are questions and/or concerns, please contact the lead auditor, <NAME> (name@email.com)

**Report Distribution**

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| **name of recipient** | **title / job function** |
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| Auditor File (Original) |

**Documents Reviewed and Copied**

| **document title** | **attachment designation(if copied / attached to report)** |
| --- | --- |
| CIBMTR forms and associated source documentation from the official patient health record: * ALLO <CRID> Pre TED R1
* ALLO <CRID> Pre TED R2
* AUTO <CRID> Post TED R1
* AUTO <CRID> Pre TED R1
* UALLO ALLO <CRID> Pre TED R2
* UALLO ALLO <CRID> 100 Day R3…
 |  |

**List of Abbreviations and Acronyms**

**CIBMTR = Center for International Blood & Marrow Transplant Research**

**FACT = Foundation for the Accreditation of Cellular Therapy**

**SOP = Standard Operating Procedure**

The signatures below indicate that the audit report has been reviewed and approved for distribution to the Auditee.

|  |  |
| --- | --- |
| **lead auditor signature** | **date** |
| **title** |

|  |  |
| --- | --- |
| **quality manager review and approval signature** | **date** |
| **title** |

|  |  |
| --- | --- |
| **program director approval signature** | **date** |
| **title**  |

**Audit Observations**

| **observation number** | 1 | **classification** | Clinical Documentation and Registry Reporting | **rating** | Compliant |
| --- | --- | --- | --- | --- | --- |
| **observation**see audit results above.  |
| **citations / requirements**None |
| **examples**Not applicable |
| **recommendations**Re-audit annually |
| **responsible party:**  |
| **response (to be completed by auditee or responsible party*)*** |
| **investigation results (provide root cause for critical and major nonconformities)**<No response required.> |
| **corrective actions (required for critical, major, and minor nonconformities)** |
| **no.** | **action** | **deliverable** | **person responsible** | **target completion date** | **date completed(date/ initials)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **preventive actions (required for critical and major nonconformities)** |
| **no.** | **action** | **deliverable** | **person responsible** | **target completion date** | **date completed (date/ initials)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **response completed by:** | **date** |
| **observation number** | 1 | **classification** |  | **rating** |  |
| **response acceptance - to be completed by lead auditor** |
| Does the investigation and response address the observation adequately?[ ]  Yes [ ]  No (return form to the responsible party for additional investigation)Will the corrective actions cause any negative effects to other processes?[ ]  Yes (return form to responsible party to address potential negative affects) [ ]  NoWill the corrective actions cause any negative effects to other documents?[ ]  Yes (return form to responsible party to address potential negative affects) [ ]  NoWill the corrective actions cause any negative effects to other groups?[ ]  Yes (return form to responsible party to address potential negative affects) [ ]  No |
| **response acceptance completed by:** | **date** |
| **objective evidence verification (describe actions taken to evaluate effectiveness)** |
| **finding status**[ ]  **Complete** (actions completed and verified to be effective)[ ]  **Ineffective** (actions completed but subsequent issues noted) – return to responsible party for additional investigation and actions (use another form if necessary). |
| **verification performed by:** | **date** |

**Process Improvement Opportunities (formal response not required)**

|  |  |
| --- | --- |
| **item number** | **process improvement opportunities** |
| 1 |  |
| 2 |  |

**Good and Best Practices (no response required)**

|  |  |
| --- | --- |
| **item number** | **good and best practices** |
| 1 |  |
|  |  |

|  |
| --- |
|  **FORM 2100**  |
|  **DAY 100**  |  CRID:  | HSCT Date:  | Data Coordinator: |
|  Transplant Type: |  Product Type: | Disease Category:**\*** |
| 🞏 Auto🞏 Allo / MUD/MMUD🞏 Allo/MSD/MRD/ Syn/Haplo🞏 Allo / Cord | 🞏 HPC-A🞏 HPC-M🞏 HPC-C – Single🞏 HPC-C– Multiple | 🞏 Plasma Cell Disorder🞏 Acute Leukemia🞏 Other Leukemia🞏 Lymphoma | 🞏 MDS/MPS🞏 CML/CLL🞏 Anemia🞏 Other Malignancies Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Critical Fields- CIBMTR/FACT\* | Yes | No | N/A | **Source Documentation** |
| **In-house Records** | **Outside Records** | **Reviewed by**  |
|  | Contact *Date* / Date of Follow-Up |  |  |  |  |  |  |
|  | Engraftment Indicator / Date |  |  |  |  |  |  |
|  | ANC Subsequent Decline |  |  |  |  |  |  |
|  | Second Infusion Indicator/Date  |  |  |  |  |  |  |
|  | Acute GVHD Indicator/Date of Onset/Skin/Gut/Liver/Other/Maximum Grade |  |  |  |  |  |  |
|  | Chronic GVHD Indicator/Date of Onset/Onset Code/Maximum Grade/Organ Involvement/Present on Date of Contact  |  |  |  |  |  |  |
|  | Immunosuppressant Therapy Indicator |  |  |  |  |  |  |
|  | New Malignancy, Lymphoproliferative or Myeloproliferative Disorder |  |  |  |  |  |  |
|  | Karnofsky/Lansky Performance Score  |  |  |  |  |  |  |
|  | Death Indicator  |  |  |  |  |  |  |
|  | \*Remission Assessment Post-BMT |  |  |  |  |  |  |
|  | \*Assessment Date Post- BMT  |  |  |  |  |  |  |
|  | \*Relapse/Disease Progression Post-BMT |  |  |  |  |  |  |
|  | \*Method of Latest Disease Assessment  |  |  |  |  |  |  |
|  | \*Cause of Death  |  |  |  |  |  |  |
| Notes:  |  |
| Corrective Action Required:  | # of Critical Fields :* Audited <NN>
* Correctly Reported <NN>
* Correction Required: <NN>
* Error Rate: <NN>%
 |
|  |
|  |
|  |
| Auditor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Acceptable forms of Documentation:**

|  |  |
| --- | --- |
| **Recipient Identification** | **Acceptable Source** |
| **Unique ID** | **Assigned by the CIBMTR** |
| **Date of HCST** | **Stem Cell Transplant Infusion Record** |
| **Transplant Type**  | **Stem Cell Transplant Infusion Record** |
| **Product Type**  | **Stem Cell Transplant Infusion Record** |
| **Contact Date/Date of Follow-up** | **Lab Report and Progress Note** |
| **Engraftment Indicator**  | **Lab Report Calculations** |
| **ANC Subsequent Decline** | **Lab Reports** |
| **Second Infusion Indicator/Date**  | **Lack of second infusion record** |
| **Acute GVHD Indicator/Date of Onset/Skin/Gut/Liver/Other/Maximum Grade** | **Physician Progress Note** |
| **Chronic GVHD Indicator/Date of Onset/Onset Code/Maximum Grade/Organ Involvement/Present on Date of Contact** | **Physician Progress Note** |
| **Immunosuppressant Therapy**  | **Physician Progress Note** |
| **New Malignancy, Lymphoproliferative or Myeloablative Disorder**  | **Physician Progress Note** |
| **Karnofsky/Lansky Performance Score** | **Physician Progress Note** |
| **Death Indicator**  | **Physician Progress Note** |

|  |
| --- |
|  **FORM 2400 Pre-TED** |
|  Pre- TED | CRID:  | HSCT Date: | Data Coordinator: |
|  Transplant Type: |  Product Type: |  Disease Category:**\*** |
| * Auto
* Allo / MUD/MMUD
* Allo/MSD/MRD/Syn/Haplo
* Allo / Cord
 | * HPC-A
* HPC-M
* HPC-C– single
* HPC-C – multiple
 | * Plasma Cell Disorder
* Acute Leukemia
* Other Leukemia
* Lymphoma
 | * MDS/MPS
* CML/CLL
* Anemia
* Other Malignancies

Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Critical Fields-CIBMTR  | Yes | No | N/A | **Source Documentation** |
| **In-house Records** | **Outside Records** | **Reviewed by** |
|  | Disease Stage  |  |  |  |  |  |  |
|  | Patient Date of Birth |  |  |  |  |  |  |
|  | Patient CMV Status |  |  |  |  |  |  |
|  | Patient Race  |  |  |  |  |  |  |
|  | Karnofsky/Lansky Performance Score |  |  |  |  |  |  |
|  | Prep. Regimen Drugs Indicator \*reported as prescribed doses |  |  |  |  |  |  |
|  | Radiation Indicator/TBI/TBI Dose/Unit of Measure |  |  |  |  |  |  |
|  | Non-Myeloablative/Reduced Intensity (allo only)  |  |  |  |  |  |  |
|  | Ex-Vivo Graft Manipulation |  |  |  |  |  |  |
|  | Disease Status Pre-HSCT  |  |  |  |  |  |  |
|  | Cytogenetic Remission Pre-HSCT |  |  |  |  |  |  |
|  | Molecular Remission Pre-HSCT |  |  |  |  |  |  |
|  | Database Consent □ Repository Consent □\*all checkboxes and required signatures must be complete |  |  |  |  |  |  |
| Notes:  |  |
| Corrective Action Required:  | # of Critical Fields :* Audited <NN>
* Correctly Reported <NN>
* Correction Required: <NN>
* Error Rate: <NN>%
 |
|  |
|  |
|  |
| Auditor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Acceptable forms of Documentation:**

|  |  |
| --- | --- |
| Recipient Identification | Acceptable Source |
| Unique ID | **Assigned by the CIBMTR** |
| Date of HCST |  |
| Transplant Type  |  |
| Product Type  |  |
| Disease Category |  |
| Disease Stage |  |
| Patient Date of Birth  |  |
| Patient CMV Status  |  |
| Patient Race  |  |
| Karnofsky/Lansky Performance Score  |  |
| Prep. Regimen Drugs Indicator  |  |
| Radiation Indicator/TBI/TBI Dose/Unit of Measure |  |
| Non-Myeloablative/Reduced Intensity(allo only) |  |
| Ex-Vivo Graft Manipulation |  |
| Disease Status Pre-HSCT |  |
| Cytogenetic Remission Pre-HSCT |  |
| Molecular Remission Pre-HSCT  |  |
| Database Consent /Repository Consent  |  |

1. Only acknowledgement of receipt is required when there are no citations or requirements resulting from the audit. [↑](#footnote-ref-1)