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## Summary of CIBMTR On-Site Data Audit Program

### Audit Cycle

- Each domestic and international center will be audited once within a four-year audit cycle. Transplant centers will be assigned to one of the years in the four-year audit cycle.
- To be eligible for an on-site audit a transplant center must have completed a minimum of 20 HSCTs. This can be any combination of allogeneic related and unrelated, and autologous HSCT.
- A new center's first audit will occur in the year following the accrual of the center's 20<sup>th</sup> recipient.

### Recipient Selection and Eligibility Requirements

- A maximum number of HSCTs will be audited at each center. If a center has performed more than the maximum number of HSCTs, the recipients will be randomly selected for audit.
- A recipient is eligible for audit if the TED form or the required Comprehensive Report Forms have been submitted to the CIBMTR. Each form must be considered complete and designated as "error-free" in the FormsNet<sup>TM</sup>2 application.
- Recipients will be selected only once for audit.

### Forms and Data Fields

- All TED and Comprehensive Report Form-level data will be subject to the data audit.
- Data fields that have been identified as being essential to the accurate completion of outcome analyses will be audited for each recipient. Additional data fields may be added to the audit to increase the validity of the audit error rates.

### Methodology

- Auditors will compare the data submitted to the research database with the data in the recipient's medical record.
- Discrepancies will be categorized into one of four groups: missing documentation, omission, interpretation, and non-audit errors.

- Errors will be reviewed with the data coordinator.
- The auditors will make all data corrections to the database and the transplant center will be provided with a record of all changes made to the TED Forms and/or Comprehensive Report Forms.

### **Audit Analysis and Reports**

- Transplant centers will receive a detailed audit report evaluating the results of the audit.
- Centers may be required to submit a Corrective Action Plan following the audit in response to errors identified during the audit.