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FACT and CIBMTR Data Audit Collaboration: What Every FACT Accredited Center Needs to Know

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FACT accredited transplant centers have a important responsibility to maintain accurate data and data audits to improve quality and clinical outcomes in hematopoietic stem cell transplantation and cellular therapies. Since other oversight organizations also require data auditing operations, transplant centers were in the difficult position of having to set up duplicative data audits and reporting mechanisms. Recognizing this burden on transplant centers, FACT and CIBMTR (Center for International Blood and Marrow Transplant Research) formed a collaboration to address reducing this burden of duplicative data audits and reporting for transplant centers in 2013. The following outlines the history, features, and operation of the collaborative Data Audit Plan.

The Foundation for the Accreditation of Cellular Therapy (FACT) was founded in 1995 by the ASTCT (formerly ASBMT) and ISCT to promote quality medical and laboratory practice in hematopoietic transplantation. FACT published the first edition of Standards for Hematopoietic Progenitor Cell Collection, Processing, and Transplantation in 1996, which detailed the important requirement for accredited clinical programs to keep complete and accurate data, based on the firm assumption that only with accurate data could the clinical program assess practices and improve outcomes. Compliance with this standard was assessed by clinical inspectors comparing selected data points submitted to FACT against source documents on-site. The CIBMTR (Center for International Blood and Marrow Transplant Research) also was an important member of the world wide cellular therapy quality community, which collaborated with the global scientific community and a large network of transplant centers to facilitate observational and interventional research through its extensive clinical outcomes research database and statistical expertise. Ongoing data audits are required by transplant centers submitting data to the CIBMTR to ensure to accuracy and completeness of the research database, to identify systemic and non-systemic errors, make corrections, and providing training to data management staff.

The Task Force Creation

For over 20 years FACT and CIBMTR performed independent on-site data audits, each separately requiring corrective actions for deficiencies. Despite this attention to data accuracy, FACT clinical inspectors continued to cite programs for significant data accuracy problems, and CIBMTR identified

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programs with critical field error rates (CER) >3.0%. Some programs demonstrated improvement at the time of the subsequent audit or inspection and others did not. To address this problem,the FACT-CIBMTR Data Audit Task Force, chaired by Dr. Daniel Couriel, was formed in 2013 to assess the state of data auditing and to develop a new collaborative approach to facilitate improvements in data management and quality of data while reducing the burden of duplicative audits for Transplant Centers.

The Task Force initially evaluated results of FACT inspections and CIBMTR data audits and concluded that, despite apparent differences in methodology, in general, the two organizations identified data accuracy issues in the same Clinical Programs. When comparing the two organizations' results, 72% concordance* was observed for the last cycle of inspections and audits.

		FACT	
		Citation	No Citation
CIBMTR	>3.0% CER	13 (7%)*	30 (17%)
	≤ 3.0 % CER	18 (10%)	114 (65%)*

Strengths and weaknesses were identified in both FACT and CIBMTR processes; however, no audit system can detect every error or force a program to improve. The Task Force recommended development of a collaboration incorporating the strength of each process to minimize duplication, improve data quality, and increase attention and resources to data management through more significant consequences. This collaboration would be beneficial to the transplant and cellular therapy programs, FACT, CIBMTR, and patients and the public.

Data Audit Committee

Following approval of a collaboration by both Boards in February 2015, the FACT-CIBMTR Data Audit Committee was established to develop and implement a collaborative process. Dr. Phyllis Warkentin, FACT Chief Medical Officer, and Dr. Bronwen Shaw, CIBMTR Associate Chief Scientific Director and Associate Center Director, co-chair the committee. The committee members include representatives from CIBMTR, FACT clinical inspectors, and program data managers. The committee began meeting monthly in the fall of 2016 and studied each other's processes to determine the path forward. The following table illustrates the differences identified and unique aspects of the two processes.

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	FACT	CIBMTR
Data points	>60	>4,000
Time/auditors	~ 2 hours; one inspector	2-4 days; 1-3 auditors
Cycle	3 years	4 years
Consequences	Potential loss of accreditation and loss of insurance coverage	Data not included; scientists not allowed participation/leadership roles; possible NMDP would deny unrelated donors
Auditors	Clinical Inspectors:	CIBMTR Staff Auditors
	• BMT physicians (peer to peer)	• Minimum: bachelor's-prepared
	• Trained and experienced in BMT, inspecting/Standards	• Trained and experienced in auditing
	• Many diverse individuals	• Consistent; limited number of auditors
Goal	Verify "complete and accurate data" and educate programs and personnel	Ensure quality and accuracy of research database and Stem Cells Therapeutic Outcomes Data Base (SCTOD); identify and correct errors, identify preventive action; educate centers and personnel
	• May define accuracy according to their own knowledge in the field	• Forms Instruction Manual to define potential answers

The collaborative Data Audit Plan, which started in early 2017, has the following principal features:

- CIBMTR on-site data audit is the sole source of outside data audit results to verify compliance of the Program with FACT Standards and CIBMTR benchmarks. Programs submit CIBMTR results to FACT and do not have to prepare data sheets specifically for FACT. FACT clinical inspectors do not perform on-site data audits, but do assess implementation of corrective action.
- Programs with >3% CER or systemic errors continue to be required to submit a corrective action plan (CAP) to CIBMTR.
- Programs with >3% CER also submit the CAP to the FACT-CIBMTR Data Audit Committee. To ensure continued compliance with FACT standards and implementation of CAP, programs are required to submit annual updates to FACT for review by the Data Audit Committee.

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- A program's CIBMTR audit result (specifically the critical field error rate) determines the initial documents required at the time of submission, as described in the table below.

Programs' (CER)	Systemic Errors	Documents required for submission to FACT, annually*
<2.0%	No	• CIBMTR Audit Results Report
	Yes	• CIBMTR Audit Results Report • Internal data accuracy audit
≥2.0% through ≤3.0%	No	• CIBMTR Audit Results Report • Internal data accuracy audit
	Yes	• CIBMTR Audit Results Report • Internal data accuracy audit
>3.0%	Yes	• CIBMTR Audit Results Report • CAP from most recent CIBMTR data audit • Implementation progress of CAP • Internal data accuracy audit
Not Audited by CIBMTR	NA	• Corrective actions from most recent internal audit • Implementation progress of corrective actions • Follow-up internal data accuracy audit • Reporting every 6 months, as needed

*Requirements as of November 2019

The Data Audit Committee began review of program submissions in April 2017 and found programs' corrective action plans frequently included increased training for data management staff, use of CIBMTR resources, collaboration with other departments (e.g., Processing Facility), regular meetings between data management staff and physicians, improvements in the internal audit processes, implementation or revision of policies and SOPs, and need for additional staff. Initially, over 50% of audit reports submitted were determined deficient in design, performance, or report elements. Common issues with audit reports were: goal of audit was not defined, insufficient number of data fields were audited, systemic areas previously identified as problematic were not included in the internal audit, lack of assessment of the underlying cause of errors, and audit results not shared with others in the Program. In an effort to assist programs with internal audits and data audit process improvements, the Data Audit Committee developed the Data Management Resource Center in July 2018. The resource center provides information on CIBMTR resources, FACT educational resources, guidelines for data management submissions, and examples (audit templates, audit reports, and a FACT Standard B9 response report template).

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Clinical inspectors who no longer have to perform their own on-site data audits have access to all CIBMTR results and review the data management process with the program's clinical team. With direction from the Data Audit Committee, clinical inspectors focus on implementation and adequacy of corrective action plans, internal data audits and quality improvement. The Data Audit Committee reviews the clinical inspector's comments and suggestions, and any additional information the program has submitted, to determine compliance with Standard B9 and make recommendations to the FACT Cellular Therapy Accreditation Committee. Clinical inspectors are encouraged to look for and report commendable data management practices observed on-site.

In October 2019, CIBMTR and FACT released updated consequences related to failure to meet Data Audit benchmarks. FACT's Data Audit Policy was implemented, including the following points:

- Compliance with FACT data accuracy standards requires passing a CIBMTR data audit.
- CIBMTR data audits on or after October 1, 2016 apply to this policy.
- Each accredited clinical program was notified of its status and given guidance for required actions.
- Consequences of failing CIBMTR data audit may now affect FACT accreditation:
    - First failing audit: programs are placed on probation. Probation is a period of time during which a program has not met defined benchmark criteria. The program is still accredited, but is at risk of losing FACT accreditation if additional requirements as specified by the Data Audit Committee are not met.
    - Data Audit Committee requirements during this time are harmonized with the CIBMTR Milestone Reporting requirements and are designed specifically to assist the Program to make necessary changes to improve data quality.
    - Following a second consecutive CIBMTR Audit failure, FACT accreditation may be suspended.
- Programs not audited by CIBMTR are required to submit data audit reports to FACT every six (6) months.

Process Improvements

The FACT-CIBMTR Data Audit Committee continues to assess the collaborative data audit process to identify process improvements. FACT's Quality Management Series Module 9 related to Auditing is a direct result of the committee's determination that the audit process was deficient for many programs.

The committee has recommended that future FACT compliance applications include submission of an internal audit report of their choosing (in addition to the data accuracy audit report submitted under Standard B9.1) for review prior to the on-site inspection. The intent is to improve the program's overall quality management processes. Auditing is a critical process for programs to evaluate whether approved processes have been properly implemented and followed and to assess the effectiveness of

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corrective and preventive actions. Thus it is critical that internal auditing is performed well and that the results are reported clearly as appropriate to facilitate quality improvement. Increased review of these processes is intended to assist programs in these activities.

Programs that do not report to or are not audited by CIBMTR (e.g., international FACT-accredited programs not operating in English; small programs) need a process to address data management and accuracy. There are several alternatives for these programs: report to CIBMTR; additional on-site audit with accreditation or use of CIBMTR's remote auditing or centralized data audit process (in the pilot phase). This applies to a small number of FACT accredited programs but must be assessed to ensure data accuracy.

Programs with critical field error rates >3.0% are frequently required to submit Milestone Reports to CIMBTR and separately to the FACT-CIBMTR Data Audit Committee. The Milestone Report review process is being evaluated to better integrate these reviews and provide programs a singular response with expectations that incorporate comments and suggestions from all key stakeholders.

Over the past three years, both FACT and CIBMTR have observed some programs and personnel who struggle with data accuracy and completeness. We hope that the intensified support between inspections, increased emphasis on implementation of CAPs and follow up have assisted and will continue to assist programs in data management improvement.