



**March 1, 2017**  
**FACT and CIBMTR Begin**  
**Collaboration on Data Audits**

You are preparing for the next visit of FACT inspectors to your transplant facility. Imagine not having to:

- prepare clinical data sheets or download CIBMTR pre- and post-Transplant Essential Data (TED) forms
- prepare “shadow charts” or flag primary source data for the inspectors
- assist the inspectors as they complete an audit of specific data points

This isn’t imaginary. It is a reality that should make life a little easier for both transplant programs and inspectors because of a collaboration between the Foundation for the Accreditation of Cellular Therapy (FACT) and the Center for International Blood and Marrow Transplant Research (CIBMTR). Beginning March 1, 2017, the two organizations are coordinating their efforts to avoid duplicate data audits.

The purpose of the collaboration is to reduce redundant activity and to enhance quality improvements in data management.

**Significant Change**

FACT and CIBMTR have been conducting independent on-site data audits for over 20 years, with both programs requiring Corrective Action Plans (CAP) when deficiencies were identified. A recent study by the two organizations found a high degree of concurrence in their audit results. Some transplant programs consistently perform well in data audits for both FACT and CIBMTR, while others have significant data accuracy problems.

In the new collaboration, all verification of data accuracy will be performed by CIBMTR auditors according to their current practices during their regularly scheduled on-site visits every four years. Transplant centers should expect no change in the CIBMTR data audit process or frequency. Each CIBMTR center has an assigned liaison who will continue to assist that program in its process improvement as in the past. The CIBMTR audit results and Continuous Process Improvement (CPI) reports will be provided to FACT.

The significant change is that FACT inspections will no longer include verification of clinical data against source data. FACT clinical inspectors will have access to CIBMTR data audit results, CAPs, and reports, allowing them to spend more time assessing clinical operations, the adequacy and implementation of corrective action plans, internal audits, and quality improvement. Inspectors will use all of this information to determine if a program meets the FACT Standards related to data management.

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In addition, a joint FACT-CIBMTR Data Audit Committee will review implementation, adequacy, and effectiveness of corrective action plans with the goal of providing education and assistance to programs throughout the accreditation cycle to achieve quality improvement in data management. At the time of accreditation renewal, the FACT Accreditation Committee will assess the completeness and accuracy of a program's data management based on the clinical inspector's report and the report of the FACT-CIBMTR Data Audit Committee. Additional information regarding the new collaborative data audit process is available for your review. See [frequently asked questions](#).

## **Quality Enhancement**

"Accurate and complete clinical records are an important component of quality care and an important factor in accreditation decisions," said Phyllis Warkentin, MD, FACT Medical Director. "Repeated failure to meet targets and to demonstrate improvement in data management can adversely affect a program's accreditation."

"The collaboration between CIBMTR and FACT eliminates redundant efforts for transplant programs," said Bronwen Shaw, MD, PhD, CIBMTR Senior Scientific Director. "The collaboration also locks into the strengths of both agencies. The CIBMTR auditors are able to review a larger number of data points during an audit, and FACT inspectors can focus on important peer-to-peer physician interaction for the evaluation of clinical and laboratory programs."

FACT will also use CIBMTR data audits to identify commendable practices in data management. "When reviewing transplant program performance, the inspectors and the FACT Accreditation Committee see programs that always seem to do well," Dr. Warkentin said. "Identifying the factors that contribute to superior performance can be useful to other programs that are struggling to meet their data management targets. We will describe those factors and provide examples in our education programs."

The new collaboration takes effect with applications and renewals submitted after March 1, 2017. FACT accreditation applications and renewals currently under way are not affected.