August 31, 2016

TO: Program Directors, Quality Managers, Data Managers
FACT-accredited Hematopoietic Cell Therapy Programs

NEW: FACT / CIBMTR Joint Data Audit Program

FACT and CIBMTR are pleased to announce our long-awaited collaborative program of data auditing, designed to reduce duplicative efforts, enhance quality improvement efforts, and provide support to accredited programs. In this collaboration, the joint FACT-CIBMTR Data Audit Committee acknowledges the importance of complete and accurate data for self-assessment in individual hematopoietic cell therapy programs, for research and outcome reporting, and for compliance with FACT-JACIE Standards. This letter is an introduction to the expected initial processes. Additional details will be available later this year through newsletters from each organization.

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 prepared 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 indicating “in good standing”.

On-site, clinical FACT inspectors will have access to this information and CIBMTR reports. The expectation is that clinical inspectors will look at documentation of internal data audits and implementation of corrective action plans (CAP). Where data management is outstanding and there are no corrective action plans to review, the on-site inspectors may ask to see these commendable practices that have resulted in exemplary data management.

Over the years, both FACT inspectors and CIBMTR auditors have continued to observe some programs and personnel who struggle with data accuracy and completeness. We hope that intensified support between inspections, increased emphasis on implementation of CAPs and follow up to document continuous improvement will assist programs in data management improvement. We also hope the expertise in commendable practices in data management can be more widely shared and adopted where problems are being encountered. Ultimately, successful FACT accreditation will depend on satisfactory progress through these stages.

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The following pages contain answers to some frequently asked questions and a timeline. There are still some details to be finalized, however, do not hesitate to contact Heather Conway, Quality Manager in the FACT office or either of us if you have concerns or questions.

We look forward to this new collaboration.

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Bronwen Shaw, MD, PhD; CIBMTR

Co-chairs, FACT-CIBMTR Data Audit Committee

C: FACT Accreditation Coordinators
CIBMTR Data Auditors

FACT-CIBMTR DATA AUDIT COMMITTEE: FREQUENTLY ASKED QUESTIONS

1. When will this start?

The new data audit program will be phased in starting late fall, 2016. Programs submitting an Annual Report or Renewal Application to FACT after this time will find new questions related to this program on those reports. Programs that have already submitted renewal applications will notice there is no change in the upcoming inspection. There may be some overlap in processes as reports and applications are not always received in an orderly manner.

2. How does this help my program?

FACT-accredited programs will no longer have to prepare data sheets for review by the on-site FACT inspector and will not have a data audit at the on-site FACT inspection. Programs will have the opportunity for enhanced review of corrective action plans and assistance with self-audits and other follow up to ensure compliance and improvements are made following any CIBMTR audit. Programs with outstanding Data Management will have the opportunity to share their expertise with their colleagues in webinars, writing, or other educations forums and be recognized for their accomplishments. On-site clinical inspectors will review internal quality management activities that support improvement in data management. Commendable practices in Data Management will be available to programs and persons to adopt as appropriate to their setting.

3. What will this cost us?

There is no added cost to accredited programs for this program.

4. How will the FACT inspectors be trained?

Over the next months, webinar presentations and written materials will be made available to current FACT inspectors. FACT Staff will observe portions of a CIBMTR audit to gain understanding and assist in training. This collaborative program will also be covered at the FACT Inspector Training at Tandem Meetings in February 2107. FACT Coordinators will be trained and will work with each program and inspector to ensure needed information is available.

5. If we have had difficulty with our CIBMTR audits, will we lose our accreditation next year?

Not immediately. Initially, centers will be given a grace period to show improvement in critical field and random error rates. During this time, programs will be expected to learn from prior difficult audits, design appropriate investigations, implement effective corrective actions, and follow up to ensure that improvements are sustained. This new process is designed to help you identify the issues that may be barriers to improvement and to develop strategies to be successful. When this process has been fully implemented, FACT-accredited programs will be required to remain in good standing with the CIBMTR data audit program.

6. How will the FACT and CIBMTR schedules change to accommodate this program?

There will not be a change in either FACT or CIBMTR schedules for on-site visits. CIBMTR audits will remain every four years as scheduled (unless you request and pay for an interim special audit). You will respond to these audits to the principal auditor as usual and according to the time frames defined by CIBMTR. FACT will receive information from you annually, and will manage the processes on an on-going basis, depending on the needs of the program. FACT on-site inspections will continue to occur every three years.

7. Will the CIBMTR auditors know this is happening?

Yes. This process is intended to be completely transparent. Over the next several months, educational presentations will be available for CIBMTR staff related to FACT-JACIE Standards, FACT accreditation process, and this data management collaboration. The committee charged with implementation of this program is a combined FACT-CIBMTR committee, with representation from both organizations.

8. If we submit a corrective action plan to CIBMTR related to consent issues, will FACT review these also?

No. While FACT does have Standards related to informed consent, the consent issues managed by CIBMTR are outside the scope of this data project.

9. If we fail a CIBMTR audit, will we have to request and pay for a special interim audit?

Not necessarily. This option is open to you, however, there will be other mechanisms defined through which you should be able to demonstrate appropriate implementation of corrective action and improvements in data management.

10. Will we still have to submit a patient accrual list to FACT?

Yes. The patient list is used in many ways by the FACT staff to document new patient numbers, pediatric and adult recipients, and types of transplants.

11. What happens if I disagree with the CIBMTR audit results?

There is no change in the processes available through CIBMTR to appeal or further discuss the results, either individually or cumulatively. FACT will not intervene in these processes.

12. To whom should questions be addressed?

Specifically related to this collaborative process, questions will be handled by Heather Conway, FACT Quality Manager. Questions may be triaged to FACT Medical Director or Accreditation Coordinator or to CIBMTR as needed and appropriate.