

Data Management Closing the Data Audit Process through Follow-up

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fact FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY
OF THE UNIVERSITY OF NEBRASKA MEDICAL CENTER

25 ASBMT
American Society for Blood and Marrow Transplantation
1993-2018

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Data Management

Closing the Data Audit Process through Follow-Up

- History and Rationale:
 - FACT-CIBMTR Data Audit Collaboration
- FACT-CIBMTR Data Audit Committee
 - Processes
 - Results
 - Lessons learned
- Items to be determined

FACT – CIBMTR Data Audits

- FACT and CIBMTR have been performing independent primary on-site data audits for >20 years, with corrective action required for deficiencies
- Processes are different & have changed, yet:
 - FACT Clinical Inspectors cite programs for significant data accuracy problems
 - CIBMTR continues to find Programs with >3% critical field error rates:
 - Some programs improve with next audit; others do not
- Approximately 72% concordance:
 - Programs with >3% CER; FACT citation for data management deficiency
 - Programs with ≤3% CER; no FACT citation for data management

CIBMTR – FACT Comparative Results 2012 – 2015 N=175 Programs

	FACT CITATION	NO FACT CITATION
CIBMTR > 3.0% CER	13 (7%)	30 (17%)
CIBMTR ≤ 3.0 % CER	18 (10%)	114 (65%)

Audits Concordant = 7% + 65% = 72%
Discordant = 17% + 10% = 27%

FACT-CIBMTR Data Audit Project Background

- FACT – CIBMTR Data Audit Task Force formed (2013) assess the state of Data Auditing and to develop new, collaborative approach:
 - Facilitate improvements in data management and quality of data
 - Increase attention and potentially resources to data management through risk of more severe consequences for non-compliance
 - Reduce burden of duplicative audits for Transplant Centers
 - Allow clinical inspectors more time on-site to address other issues [e.g., clinical outcomes]
- Chair: Dr. Daniel Couriel
 - Representatives from FACT and CIBMTR

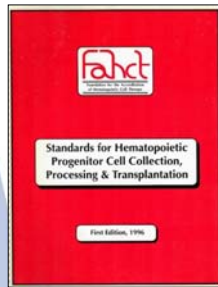
Task Force Conclusions

- Despite apparent differences, overall mission of the two organizations is the same: to improve quality patient care and outcomes in cellular therapy and transplantation
- There are strengths and weaknesses to both FACT and CIBMTR processes
- No audit system is perfect; no audit detects every error
- No Audit System can guarantee zero error rate (...to err is human...)
- No audit system can MAKE a program improve
 - Incentives and consequences matter
 - Resources matter and may be out of program control
- Collaboration has potential benefits to
 - Transplant / Cellular Therapy Programs
 - FACT
 - CIBMTR
 - Patients and public

Data Audit Task Force Conclusions

- Recommendations of Task Force:
 - Try a collaborative approach incorporating the strengths of each process and minimizes duplication
 - Add elements that increase value
- Proposal approved by both Boards: February 2015
- Data Audit Committee established
- A work in progress ...
 - Continuous study and education
 - Observation of each other's processes
 - "Soft launch" – few programs; few inspectors
 - Building trust
- Collaboration fully launched: April 2017

First Edition of the FAHCT Standards



B 4.000 DATA MANAGEMENT

- B4.100 Each Program shall keep complete and accurate patient records.
- B4.200 The records **should** include data of the type required and published by the International Bone Marrow Transplant Registry (IBMTR) or Autologous Bone Marrow Transplant Registry (ABMTR).

How to assess???

Assessment of Data Accuracy and Completeness



- Pick some data points
- Verify accuracy against source data at the Program
- Limitations:
 - It is only one Standard – must not require whole day
 - Data points must seem important to applicant & inspector
 - Should be the same data as IBMTR collects
 - Programs must know in advance which charts to prepare

FACT Assessment of Data Accuracy and Completeness 1.0

ALLOGENEIC RECIPIENT

AUTOLOGOUS RECIPIENT

Clinical on-site inspector compared data to source data
 Errors noted, reported to program, presumably corrected
 Systemic errors or many errors → B4.100 citation on inspection report
 Deficiency requires documented corrective action prior to accreditation



FACT Data Audit Process – Version 2.0

- Standard changed to “...shall...”
- Eliminated unique FACT data sheets
- Verified accuracy using copy of TED forms
- Reduced number of data points audited
- Combination of data points audited:
 - Five specified; five randomly chosen by inspector
 - Same or different for each patient, each Program; each inspector

FORM AUDITED	DATE	AUDIT DATE	COMMENTS
Personnel			
Transfusion orders			
Transfusion records			
Transfusion reactions			
Transfusion errors			

FORM AUDITED	DATE	AUDIT DATE	COMMENTS
Personnel			
Transfusion orders			
Transfusion records			
Transfusion reactions			
Transfusion errors			



FACT Data Audit Process – Current Version 3.0

- Clinical inspector audits items from TED or MED-A forms
- Audit a minimum of 30 data points for each type of transplant
 - Five data points for each patient identified by FACT or JACIE; remainder random choice of inspector
 - Primary Disease; stem cell source; Donor type, engraftment date; survival
- Variability noted among inspectors
 - Choice of random fields, same or different for each record
 - Amount of detail recorded for FACT coordinators
 - Likelihood of citation
- Consequences of deficiency to Standard B9.1
 - Submit plan to correct data management
 - Often required follow up internal audit at interim report
 - Potential loss of accreditation

CIBMTR Audit Program Goals

- Ensure the quality and accuracy of the research database / Center-specific Outcomes Analysis
- Identify and **correct** errors
 - Critical field errors, random field errors
 - Systemic or non-systemic errors
- Implement systems / processes to help prevent errors
- Provide additional training for transplant centers

CIBMTR Audit Program - Logistics

- Generally 3-4 day audit; 2 auditors
- Four year audit cycle
- Auditors with specific initial and ongoing training and oversight of competency
- Minimum of 20 eligible recipients to qualify for audit
 - 16 recipients selected for audit, regardless of transplant center volume or reporting volume
 - Recipients eligible for audit: pre-transplant and 100-day data completed
 - TED forms and CRF forms (~6,500 data points)

FACT – CIBMTR Audit Processes

FACT

- > 60 data points
- ~ 2 hours; one inspector
- 3 year cycle
- Consequences: potential loss of accreditation and loss of insurance coverage
- Inspectors:
 - BMT physicians (Peer to peer)
 - Trained in inspecting/Standards
 - Many diverse individuals
- Goal: verify "complete and accurate data"; educate Programs / personnel
 - May define "accuracy" according to their own knowledge in the field

CIBMTR

- ~6,500 data points
- 3-4 days; 2-3 auditors
- 4 year cycle
- Consequences: data not included; scientists not allowed participation/leadership roles; possible NMDP would deny unrelated donors
- Auditors:
 - Minimum: bachelor's-prepared
 - Trained and experienced in auditing
 - Consistent; limited number of auditors
- Goals: ensure quality and accuracy of research database and SCTOD; identify & correct errors, identify preventive action; educate centers
 - Manual of Instructions to define potential answers

Collaboration Essentials - 1

- All verification of data accuracy against source data will be performed by the CIBMTR audit teams according to current procedures and schedules.
 - CAP submitted and assessed by CIBMTR; closed or further action required per CIBMTR policies and procedures
- FACT Clinical inspectors will not perform a data audit on-site.
 - Transplant programs will not prepare data sheets specifically for FACT.
 - Transplant patient logs will be required to verify transplant numbers, types of transplants, age groups, transplant sites.
 - Clinical inspectors will have access to all CIBMTR results
 - Will review data management with clinical team
 - Will focus on implementation / adequacy of corrective action plans, internal data audits, and quality improvement.
 - May have specific elements to assess at the direction of the Data Audit Committee.

STANDARDIZED FORM TO INSTRUCT

Collaboration Essentials - 2

- FACT will assess Program's data completeness and accuracy annually at the time annual report or renewal compliance application
- Each Program will submit
 - Dates of last three CIBMTR audits and results for
 - Overall Error Rate
 - Critical Field Error Rate
 - Systemic Errors
 - Random Error Rate
 - Summary report from CIBMTR
 - Any Corrective Action Plan required from most recent CIBMTR audit
 - Progress report on the implementation of the CAP, including internal data audit of effectiveness of CAP

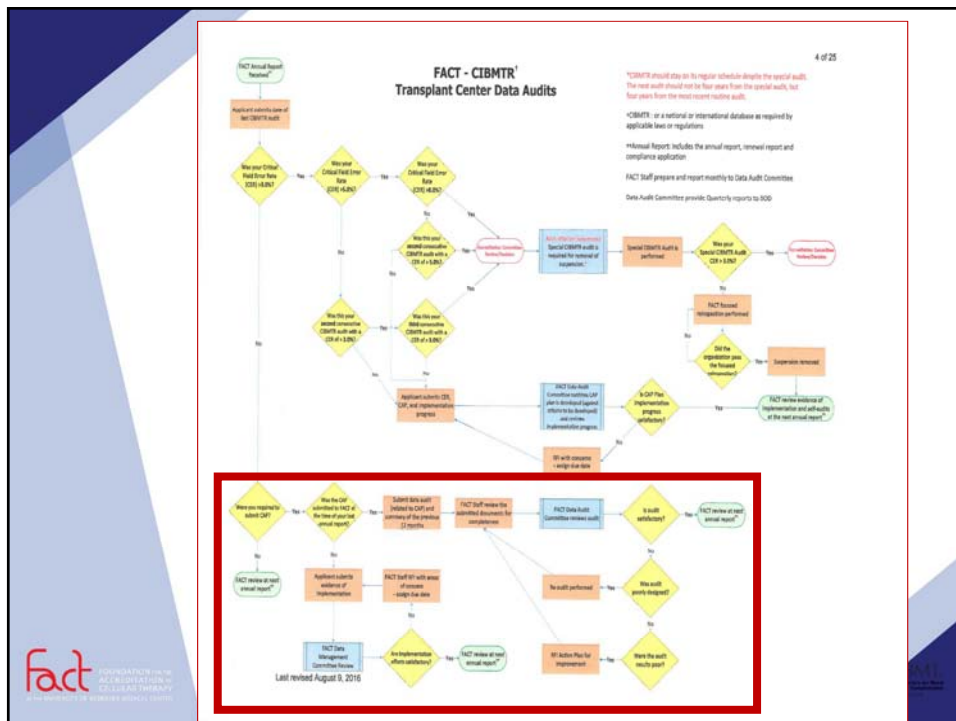
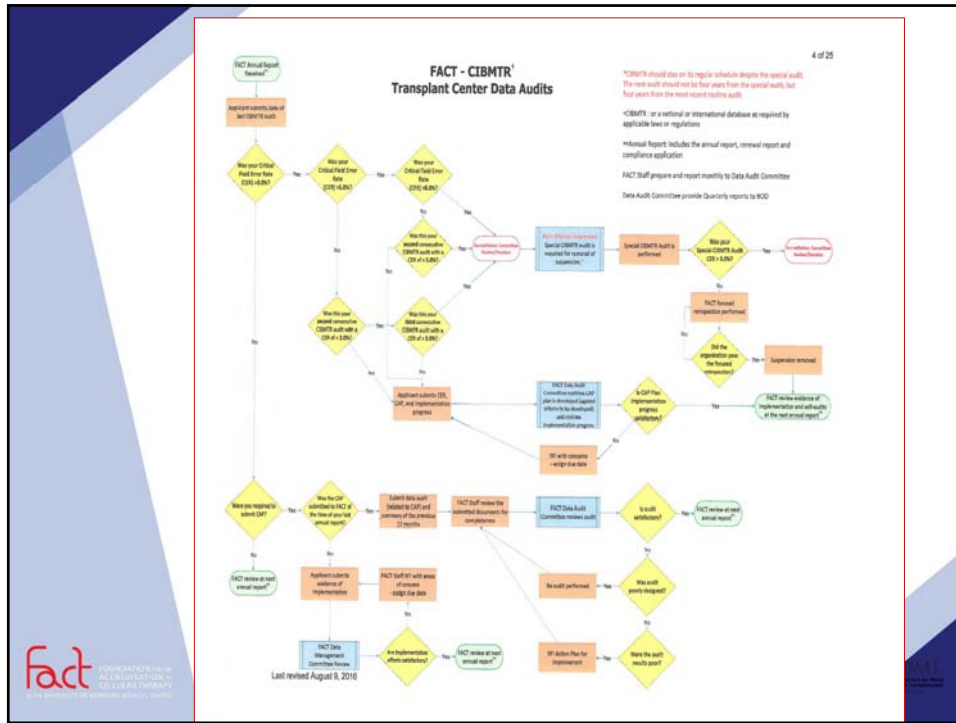
Collaboration Essentials - 3

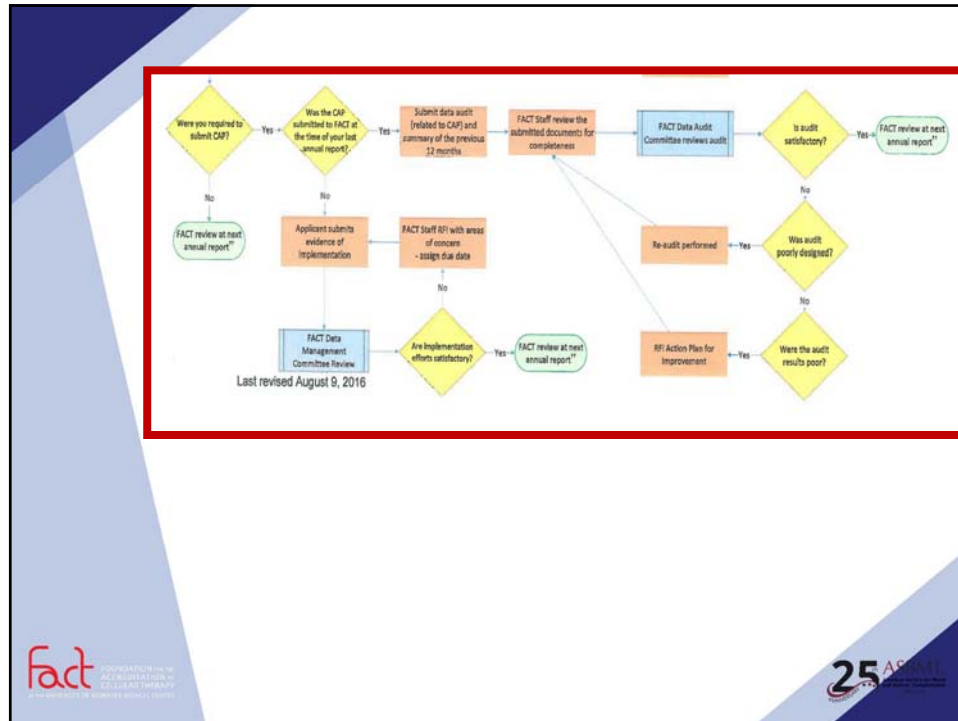
- FACT and CIBMTR will use the same criteria for “acceptable performance” or assignment of consequences:
 - > 8% CER X 1 audit
 - > 5% CER X 2 consecutive audits
 - > 3% CER X 3 consecutive audits [3% of 6,500 = 195 errors]
- FACT consequences will be phased in, allowing programs already not performing well to improve
 - Consequences may include loss of accreditation
- FACT will assess timeliness and completeness of data by CPI reports from CIBMTR indicating “in good standing”.
 - Consequences will follow designation of “not in good standing”

Collaboration Essentials - 4

VALUE – ADDED ELEMENTS:

- FACT-CIBMTR Data Audit Committee will review ALL data management information submitted to FACT
- Committee will independently assess adequacy of CAP, timely implementation and documentation of CAP, adequacy and results of internal audits, and effectiveness of CAP.
 - Standardized data collection tools have been developed
 - When new FACT Accreditation Portal is launched, these data will automatically be required with each submission of a compliance or renewal application or annual report.
- Continuous process rather than every 3-4 years – more opportunity to educate, make adjustments
- Increased scrutiny over adequacy of CAP and of implementation, timeliness, follow up audits
- Additional tools to assist programs struggling with making improvements. Webpage: resources, examples, tips
- Increased pressure on institutions to provide needed resources
- Hope to publish commendable practices







Programs Not Audited by CIBMTR

- CIBMTR does not audit Centers that are too small [< 20 transplants per cycle] or non-reporting programs
- Standard B9.1 is not going away
- Until there is a better plan, there will be an on-site data audit by Clinical Inspector similar to, but more comprehensive than what has been done in the past
 - Alternatives being considered:
 - Larger data set
 - Additional inspector (Quality Manager) to perform more comprehensive data audit
 - Require submission to CIBMTR
 - Other

FACT-CIBMTR Data Audit Committee

**Co-Chairs: Phyllis I. Warkentin, MD
Bronwen Shaw, MD, PhD**



- Debra Christianson
- Patricia Steinert
- Daniel Couriel, MD
- William Tse, MD
- Shakila Khan, MD
- David Vesole, MD
- Roberta King
- John Wagner, MD
- Carlos Ramos, MD
- Victoria Whalen
- Vandana Rangnekar
- Heather Conway
- Sharon Robison
- Linda Miller

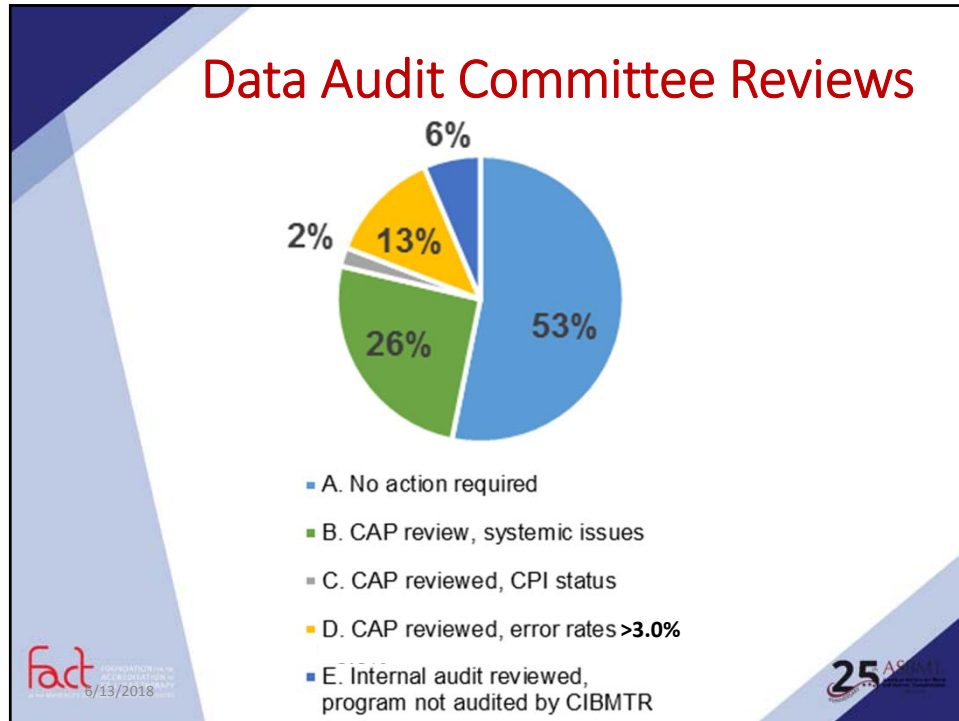



Data Audit Accomplishments

April 2017-January 2018, Committee reviewed CIBMTR results of 94 Programs

Group	Critical Field Error Rates	CPI status	Systemic issue identified	Corrective Action Plan required (CAP)	Number of programs reviewed
A	≤3.0%	Passed	No	No	50
B	≤3.0%	Passed	Yes	Yes	24
C	≤3.0%	Failed	No	Yes	2
D	>3.0%	Passed	Yes	Yes	12
E	No CIBMTR Audits	Passed	NA	NA	6
TOTAL					94

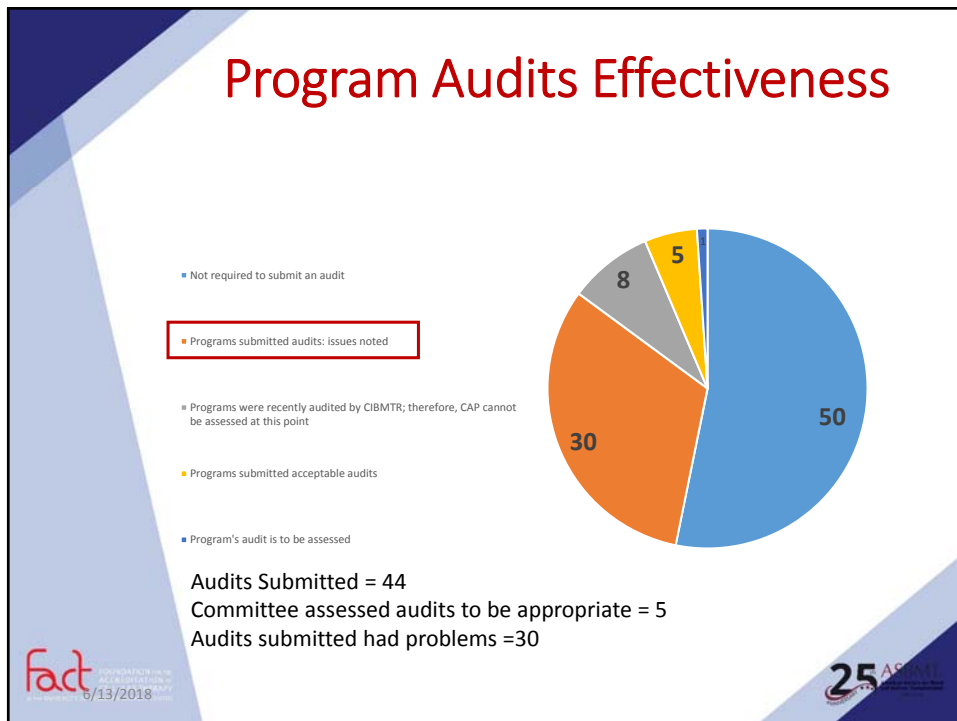
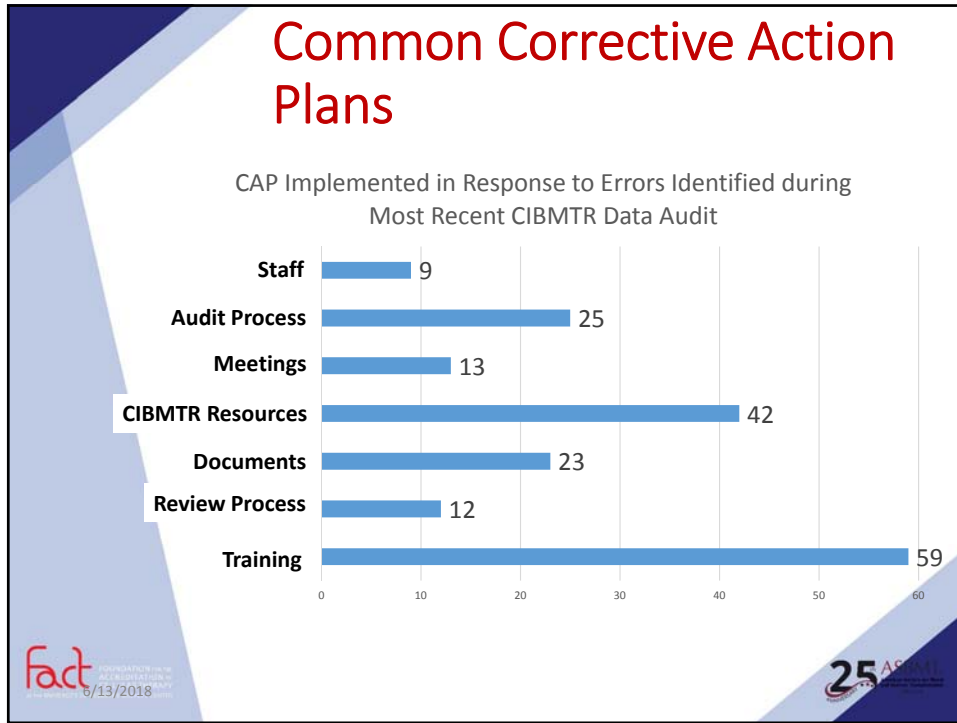





Systemic Errors

- Definition: Critical field error rate >3% OR ≤ 3%, systemic error exists when >10% of total CER occur in a single data reporting field.
- 36 programs had systemic errors identified
 - 24 with CER ≤ 3%; 12 with CER >3%
 - Corrective Action Plans required and reviewed
 - Most common Data Areas cited for systemic errors:
 - **DISEASE STATUS AND LATEST DISEASE ASSESSMENT – 77%**
[e.g.,: disease status at TX; best response; relapse indicators; method of disease assessment [molecular, flow, cytogenetics]]
 - **HCT Product and Infusion – 22%**
[e.g.,: type of product; cell counts; thaw and infusion times]
 - **GVHD – 14%**
[e.g.,: GVHD indicator, organ involvement; grade, diagnosis date, prophylaxis, treatment]

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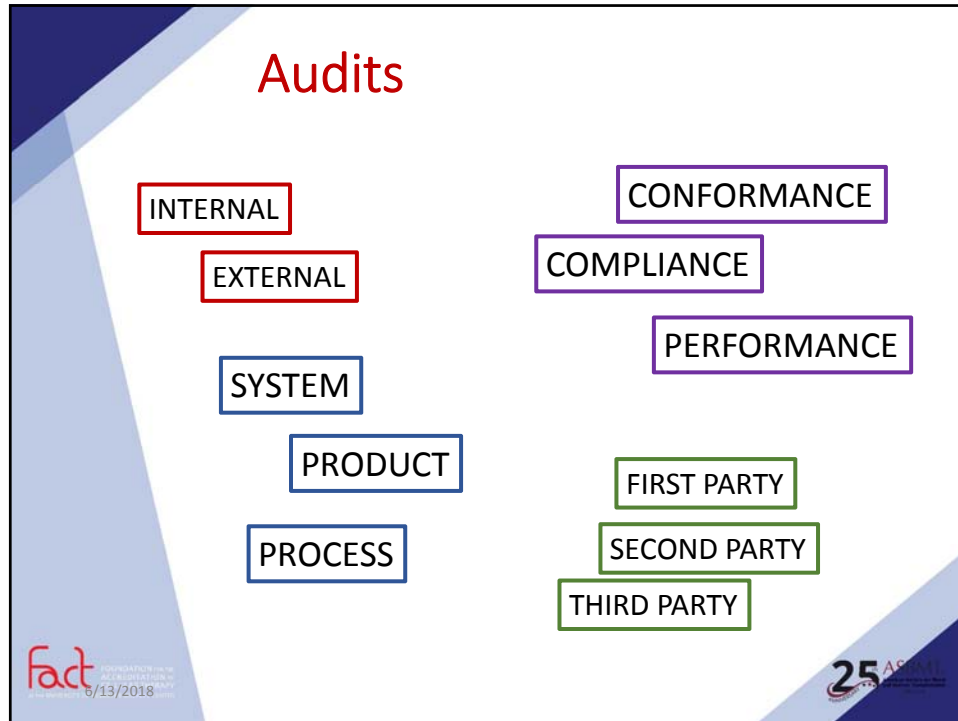


Audit Issues in 30 Submissions

- **Audit Design Deficiencies**
 - Data audited was not in the reporting area with systemic errors **14**
 - Audit acceptance error rate higher than 3% CIBMTR expected accuracy rate **5**
 - Small sample size **6**
 - Old data / Follow up not timely **4**
 - Scope unclear **4**
 - Audit fields not defined **13**
- **Audit Performance Deficiencies**
 - No evidence cause of error was investigated **11**
 - No summation or evaluation of data **22**
 - Only summary submitted **3**
 - No data submitted
 - Only data table submitted **6**
- **Report Deficiencies**
 - Various documentation practices, no signatures, date

Audit Report: Minimal Requirements

- Audit Plan
- Date audit performed
- Audit Scope
- Fields audited: number of fields, which fields. May attach a table of raw data to the report
- Findings and recommendations, including explanation of any deviations from expected scope or method and of any data not included in the analysis
- Summary:
 - Assessment/evaluation of results
 - Identify underlying cause(s) of errors
 - Define corrective and preventive action
- Follow up, including timeline. Verify correction
- Signatures and comments
- Documentation of where results were reviewed
- Quality meeting presentation, if applicable. Include meeting minutes and attendance.



Audits

- **AUDIT:** a systematic, independent, documented process for obtaining relevant evidence and evaluating it objectively to determine the extent to which the criteria have been fulfilled. [ISO 19011]
- Many ways to classify: by method, by purpose or scope, by process, product, system, management, quality; by auditor (internal / external)
- Performed by someone knowledgeable to understand but not responsible for the activity being audited
- Four phases:
 - Preparation: define scope, prepare checklists of data to collect, define time
 - Performance: data-gathering
 - Reporting: communication of results; include correct and clear data, evaluation of results, conclusions, corrective action or preventive action may be requested
 - Follow-up: prescribe requirements

Logos for fact and 25 ASQ are visible in the bottom corners.

Audit Tips

- Choose data points in area of reporting in which problems have been encountered
 - When audits demonstrate 100% accuracy over time, rotate to other data points.
- Read and follow the data management instruction manual
- Take advantage of training opportunities
- If program is passing all CIBMTR data audit requirements, perform internal audits of new or revised forms when issued, data points where instructions for completion have changed, or choose data points from areas where most programs struggle.
- Set acceptance criteria higher than CIBMTR
- Be certain to audit work by all personnel

DATA MANAGEMENT INSPECTOR TOOL

Program			
FACT ID			
Error rates for the last three (3) CIBMTR Data Audits	[Insert date here]	[Insert date here]	[Insert date here]
Critical Field Error Rate (CER)			
Random Field Error Rate			
Overall Field Error Rate			
Systemic CAP identified?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
CIBMTR auditor comments	[Enter auditor comments]		
CPI	[Enter date here]	[Enter date here]	[Enter date here]
In Good Standing:			
1. Current IRB documents on file with CIBMTR	Good Standing <input type="checkbox"/>	Good Standing <input type="checkbox"/>	Good Standing <input type="checkbox"/>
2. Met consecutive reporting requirements for HCT transplants	Not in Good Standing <input type="checkbox"/>	Not in Good Standing <input type="checkbox"/>	Not in Good Standing <input type="checkbox"/>
3. Completed 90% of the required forms			
Comments			
Corrective actions	[From Corrective Action Plans]		
FACT-CIBMTR Data Audit Committee determination of adequacy of CAP and implementation progress	[Enter committee comments]		
Internal audit on data accuracy required?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Additional information, recommendations, and comments by FACT-CIBMTR Data Audit Committee	[Enter committee comments]		
Description of program's progress on CAP implementation	[Enter inspector comments]		
Additional information provided to inspector as requested by FACT-CIBMTR Data Audit Committee	[Enter inspector comments]		
Commendable practices	[Enter inspector comments regarding commendable practices here for those programs showing improved scores or consistently scoring at a commendable level, if applicable]		

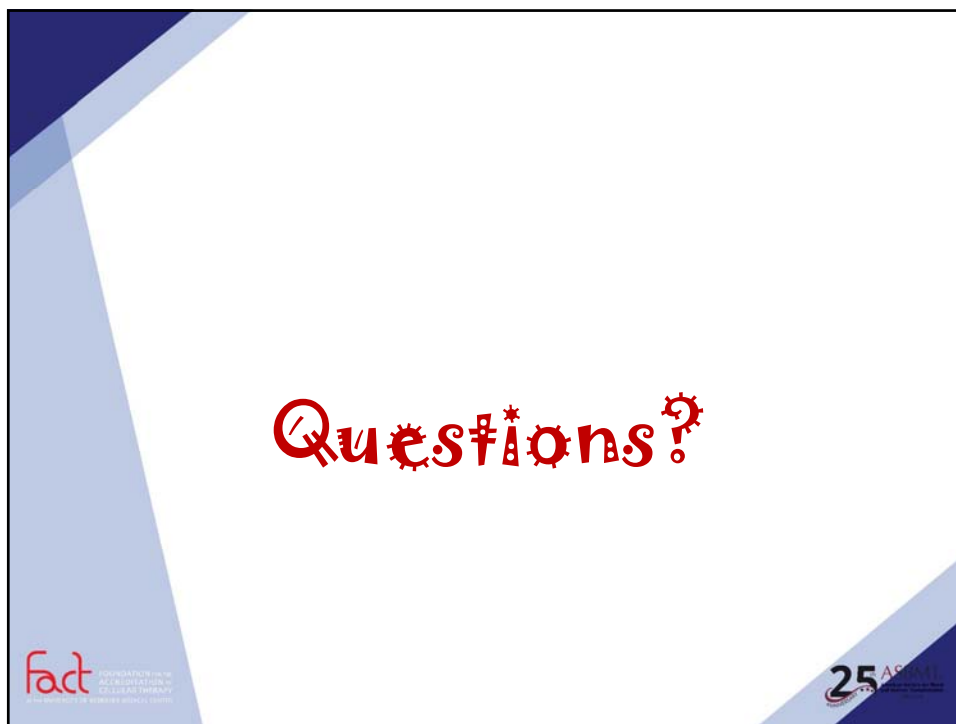
Program Status

CRITERIA	Number of Programs
Three audits in a row with >3.0% CER	2
Two audits in a row with >5.0% CER	1
Two audits in a row with >3.0% CER	5

Nature and timing of FACT consequences to be determined

A Work in Progress...

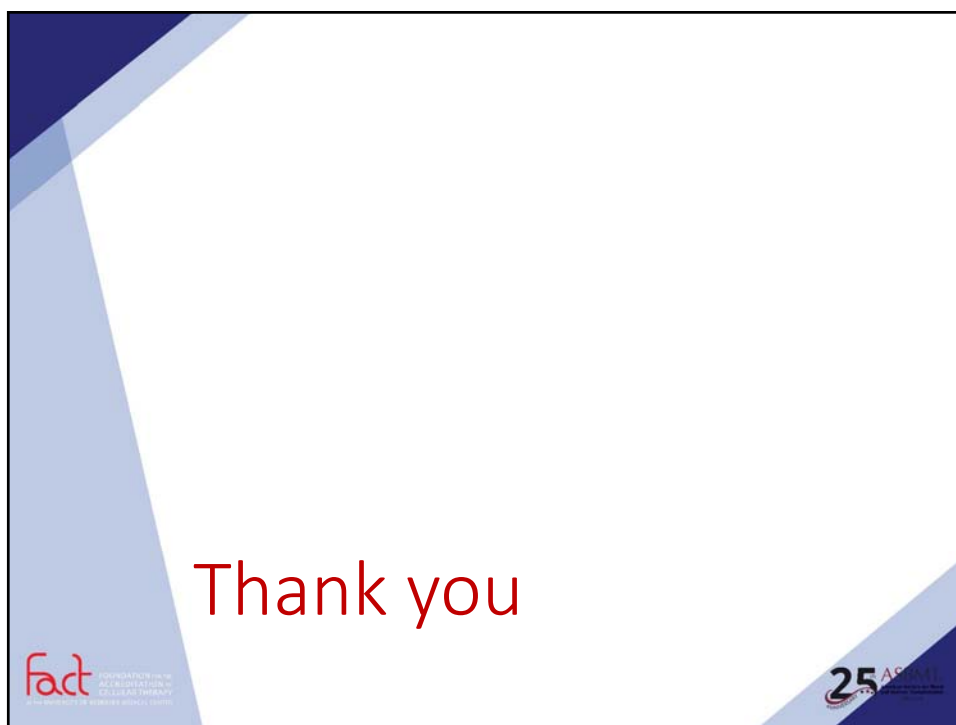
- Remaining issues:
 - Programs that do not report to or are not audited by to CIBMTR – need a process to address data (International Programs with FACT accreditation; small Programs)
 - Small number of accredited programs
 - Several alternatives – report to CIBMTR; additional on-site audit with accreditation ...
 - Criteria for improvement
 - Define measurements of Process success
 - Timeline to suspend accreditation
 - Other details...



Questions?

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COLLEGE STUDENT DRUG AND
ALCOHOL PROBLEMS

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Thank you

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