

	AUDIT PLAN AND REPORT
	AUDIT NUMBER: AUD-YYYY-EXT-001

AUDIT TITLE	Transplant Essential Data Forms Data Accuracy Audit
DIVISION	
DIVISION CONTACT	
AUDIT DATE(S)	
RESPONSES REQUIRED BY	30 business days from the date submitted to Auditee ¹ 7 business days from the date submitted to Auditee (for Critical Observations)
AUDITORS	
SOPS REVIEWED	
AUDIT OBJECTIVE	To review the accuracy of information submitted to the CIBMTR data registry via FormsNet [®] .
AUDIT SCOPE	Selected clinical data points, both as mandated during FACT inspection and randomly chosen by auditor, in the completed CIBMTR data collection forms (from pre-transplant to 100 days) and related source documentation for 10 allogeneic and 5 autologous transplants identified for upcoming FACT inspection.
AUDIT CRITERIA	FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing & Administration (current edition) CIBMTR Data Management Manual http://www.cibmtr.org/datamanagement/datacollectionforms/pages/index.aspx
PERSONNEL INTERVIEWED	

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