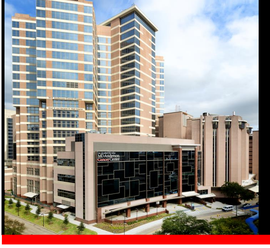

Implementation of an Audit Assessment Category Guidance System to Define Audit Deficiencies as Critical, Major or Minor

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Background

Audits conducted by MD Anderson Cancer Center (MDACC) audit team consists of reviewing and evaluating the regulatory documents and individual patient records for compliance with the study. While our audit process has been consistent, we previously did not have a standardized method to categorize the severity of each audit deficiency recorded on the audit summary report. Deficiencies are identified as any incomplete, incorrect, or missing item that does not comply with the investigational plan, institutional requirements, or federal regulations.

Goals

- Develop a systematic method to categorize audit deficiencies by degree of severity to be in line with industry and federal guidelines
- Standardize the categories to ensure each auditor uses the same grading method
- Provide a more impactful audit report for the PI, study team, and our internal Data Safety Monitoring Committee (DSMC)

Solutions and Methods

Our team developed an “Audit Assessment Category Guidance process” document that standardized categories that are used to grade the severity of each audit deficiency. The deficiencies will then be labeled as either critical, major or minor per a reference chart within the guidance document. If critical or major deficiencies are noted in the audit, the PI may also be asked to complete and return a Corrective and Preventive Action Plan (CAPA).

Audit Deficiency Categories

Informed Consent	Toxicity	Compliance	Treatment Administration
Disease Response	Eligibility	Data Quality	Regulatory Documents

Grading Scale

Critical

- Any event that adversely affects the well-being of the participant and/or study integrity. This includes any intentional misrepresentation of data.

Major

- A deviation from study procedures, practices, or schedule that is severe and/or compromises patient safety
- Impacts data integrity
- Repetitive events
- Involve multiple participants

Minor

- Minimal impact on the outcome or interpretation os the study and not described as a major deficiency

Outcomes

Since this process was initiated, Corrective and Preventive Action plans (CAPAs) for major deficiencies have been requested and completed for 28 out of the 171 protocol audits conducted, representing approximately 16% of all audits in that timeframe.

Additionally, the PI and study team are encouraged to take internal research topic educational courses for any repetitive deficiencies categorized as a ‘major’ or ‘critical’ deficiency. For internal studies with DSMC oversight, the review categories have assisted the DSMC in determining the severity of the audit.

The DSMC chair has indicated there is high value in the categories, especially for significant issues like informed consent and protocol eligibility.

Lessons Learned and Future Direction

We will continue updating this process and refining the reference chart as more data and different audit situations arise. Over the last 6 months, we began tracking additional audit metrics and trends on the number of major and critical audit deficiencies. We will use this data to better identify PIs and departments that have repetitive major findings within the same audit categories. We will also share this information with our clinical research training team so that they can assist with education needs as identified through the audit deficiencies.

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