Summary of revised CTMB Guidelines (version August 2017)

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Alliance Fall 2017 Group Meeting

Objectives

- Discuss how the CTMB Guideline revisions will effect the audit process
- Discuss how the revisions may effect audit outcomes

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CHANGES TO THE AUDIT PROCESS

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Changes to the audit process

Single Site Audit Committee (SSAC)

An initiative between the CTMB & CTSU for sites that are subject to audit by ≥1 Network Group:

- Multi-Group Audits (MGAs) will be arranged by the CTSU designated facilitator
- 2-3 Network Groups would audit at the same time (as feasible for each site)
- Currently subject to site/NCORP agreement

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Changes to the audit process

MGAs (con't)

1) Intended to promote more efficient auditing practices

2) Sites selected for MGAs are based on parameters related to enrollment numbers (currently medium to low accruing sites), Network Group audit schedules, expected audit duration, and other attributes such as re-audit, first time audit, etc.

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Changes to the audit process

Rave

- Auditors will review CRFs in Rave and will electronically record Source Data Verification (SDV) directly into each Rave case.

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GUIDELINE REVISIONS MAY EFFECT THE AUDIT OUTCOME

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Changes that may effect audit outcome

- Mandatory audit of registration trials
- Addition of DTL (delegation task log) review for registration trials during regulatory compliance audit
- Addition of **Critical** deficiency to current deficiency rating scale
- Limited audit review of Pharmacy/Drug Accountability

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Mandatory audit of registration trials

- At least 1 case from each NCI code will be chosen for audit from each registration trial

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Algorithm for number of cases in Patient Case Review

1) 10% Tx cases from auditing Group or credited to Group through enrollment
2) 10% advanced imaging studies/embedded advanced imaging
3) 10% DCP cancer control/prevention
4) At least 1 case, per NCI code, from enrollment to each registration trial

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Mandatory audit of registration trials

- DTL will be reviewed during the regulatory compliance audit
- DTL review will receive a rating of Acceptable, ANFU, or UN rating (just as with IRB/ICC)

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Addition of Critical Deficiency

Three levels of deficiencies for each audit component

- Critical
- Major
- Lesser

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Critical Deficiencies

Definition:

Any condition, practice, process or pattern that adversely affect the rights, safety or well-being of the patient/study participant and/or the quality and integrity of the data; includes serious violation of safeguards in place to ensure *safety of a patient/study participant* and/or manipulation and *intentional misrepresentation of data*.

[Examples: 1) Patient did not sign & date a consent form prior to enrollment; 2) Any finding suspected to be fraudulent.]

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Major Deficiencies

Definition:

A variance from protocol-specified procedures or practices that *makes the resulting data questionable*.

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Lesser Deficiencies

Definition:

Finding does not have impact on the outcome or interpretation of the study and is not described as above as a major deficiency.

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CTMB Guideline Revision re: Audit Component Ratings

- Any one Critical Deficiency rating will result in an UNACCEPTABLE audit component rating

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Limited Review Pharmacy Audit

- During on-site audits, when no drugs are supplied for that audit timeline, review for security, storage, authorized prescribers only, and temperature monitoring will still be conducted.

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Resources

- Link to CTMB Guidance
- https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm

- Note: Alliance P&Ps soon to be revised according to guideline changes

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Thank you!
Questions?

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