Implementing a Metrics-Based and Automated Approach to Clinical Trial Audit Prioritization

Madison Hayes, BS, Mihir Wanchoo, MHA, MBBS, David Castro, PhD, Christina Burgin, BA

Oregon Health & Science University – Knight Cancer Institute

Background:

- The OHSU Knight Cancer Institute Data and Safety Monitoring Committee (DSMC) has the authority to audit any cancer-related study per the institutional Data and Safety Monitoring Plan (DSMP). The focus tends to be on investigator-initiated studies without external oversight. Historically, the Knight Clinical Research Auditor was charged with prioritizing studies for audit, under DSMC oversight. The auditor manually reviewed study activity and considered historical/institutional knowledge to guide recommendations. This led to an unintentional over-prioritization of high-risk studies as well as ongoing concern about missing potential studies for audit. A system was necessary to reduce the auditor's administrative burden and reduce bias by establishing metrics-based conditions to prioritize studies for audit.

Goals:

- Automate audit prioritization utilizing metrics-based and objective criteria
- Reduce bias in selecting studies for audit
- Remove 'institutional knowledge' component for audit prioritization
- Execute institutional DSMP's mission to oversee all risk-levels of clinical trials

Solutions and Methods:

Design a tracker to capture data needed for audit prioritization

- Accrual rate
- Audit history
- NCI research category
- Other factors (e.g., PI/team experience, prior audit findings)

Define data rules; create dashboard to stratify the data meaningfully

- Initial audit watch list and active auditing portfolio differentiated
- High, moderate, and low priority buckets defined
- Data rules defined using tracker columns and program thresholds

Table 1. Data-Driven Rules for Establishing Audit Priority (using 'Initial Audit Watchlist' as an Example)

Higher Priority for Audit

Definition:

- High-risk studies with at least 1 enrollment and no history of audit
- Moderate-risk, treatment studies with at least 1 enrollment and no history of audit
- Moderate-risk studies (other than treatment) with one or more ++ audit priority risk factors, at least 1 enrollment, and no history of audit

Studies to include in this sub-section:

- 'DSMC-defined Audit Condition' = 'Initial after 1-3 OHSU subjects consent' **AND**
- 'Risk per DSMP' = 'High' and 'Current Total # Consented' is equal to or greater than '1' **OR**
- 'Risk per DSMP' = 'Moderate' and 'NCI Trial Type' = 'Treatment' and 'Current Total # Consented ' is equal to or greater than '1' **OR**
- 'Risk per DSMP' = 'Moderate' and 'NCI Trial Type' is anything other than 'Treatment' and 'DSMC Audit Priority Risk Factors' include any containing '++' and 'Current Total # Consented' is equal to or greater than '1'

Moderate Priority for Audit

Definition:

- Moderate-risk studies (other than treatment) without any ++ audit priority risk factors, at least 1 enrollment, and no history of audit
- Low-risk studies with one or more ++ audit priority risk factors, at least 1 enrollment, and no history of audit

Studies to include in this sub-section:

- 'DSMC-defined Audit Condition' = 'Initial after 1-3 OHSU subjects consent' **AND**
- 'Risk per DSMP' = 'Moderate' and 'NCI Trial Type' is anything other than 'Treatment' and 'DSMC Audit Priority Risk Factors' are either blank or otherwise do not include any containing '++' and 'Current Total # Consented' is equal to or greater than '1' **OR**
- 'Risk per DSMP' = 'Low' and 'DSMC Audit Priority Risk Factors' include any containing '++' and 'Current Total # Consented ' is equal to or greater than '1'

Lower Priority for Audit

Definition:

- Studies of any risk level or trial type, with zero enrollments to date, and no history of prior audit

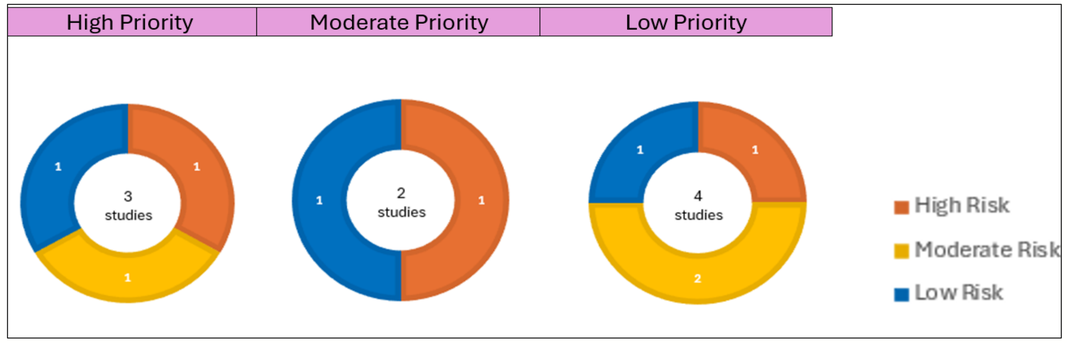
Studies to include in this sub-section:

- 'DSMC-defined Audit Condition' = 'Initial after 1-3 OHSU subjects consent' **AND**
- Regardless of risk level or trial type, if 'Current Total # Consented' = '0'

Outcomes:

- The dashboard was implemented in July 2024, and we have since noticed a shift towards a more representative distribution of audit activity across the portfolio: 43% of the studies audited were high-risk, 29% moderate-risk, and 29% low-risk, all the while ensuring that high-risk studies were appropriately weighted for priority. This distribution has had the added benefit of resulting in a greater variety of disease teams exposed to the audit process and its inherent learning opportunities.
- The implementation has also eased the administrative burden of audit prioritization, resulting in a fully automated system. This highlights the strategic use of study level attributes and domain knowledge to diversify which studies are audited and to ensure the audit requirements of the DSMP are executed.
- The dashboard has increased the committee's confidence that studies are being appropriately prioritized for audit and that all studies in our portfolio are accounted for.

Table 2. Example Distribution of Audits by Study Risk Level, Stratified by Priority Grouping



NOTE: The full dashboard contains confidential information; these charts are a sampling to demonstrate the distribution of audits per the rules outlined in **Table 1**.

Lessons Learned:

- Once established, a metrics-based data tracking system greatly enhances administrative efficiency and the ability to summarize complex information in meaningful ways.

Future Directions:

- Continue to refine audit risk factors
- Continue to assess potentially pertinent data to collect which can further enhance the process