Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

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

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1. 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.

2. 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

3. Solutions and Methods

A Smartsheet tracker was designed to capture data needed for audit prioritization, e.g., accrual rate, audit history, NCI research category, and risk factors, such as PI and team experience level, and prior audit findings. Once data was compiled, a dashboard was created to visualize the data in meaningful ways. The most critical step in designing the dashboard was to define the data rules that would categorize studies into high, moderate, and low priority 'buckets.' For example, a study meeting any of the following combined criteria would be considered high priority for audit: high-risk study with at least one enrollment and no history of audit; moderate-risk treatment study with at least one enrollment and no history of audit; moderate-risk non-treatment study with at least one audit risk factor, at least one enrollment and no history of audit. Once the dashboard was designed, scenario testing was performed to ensure rules were appropriate and accurately reflect the inputted data.

4. 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 percent of the studies audited were high-risk, 29 percent moderate-risk, and 29 percent 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 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 confidence that DSMC is appropriately prioritizing studies for audit and that all studies in our portfolio are accounted for.

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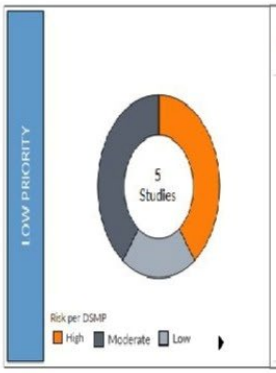
5. Lessons Learned and Future Directions

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 include refining audit risk factors and continual assessment of potentially pertinent data to collect which can further enhance the process.

Figure



IRB#	PI	IRB Long Title	PHASE	NCI Research Category	NCI Trial Type	Risk per DSMP	DSMC Audit Priority Risk Factors	Audit Notes/To-Do	DSMC-defined Audit Condition[MANUAL]	Date Open to Enrollment	Total # Consented/ Target Enrollments	Date Last Subject Enrolled	# New Subjects Consented since Previous DSMC Audit	Date of Previous Knight DSMC Audit	# Subject Consented at Prev Knight DS..	Scope Previous DSMC Audit	Time Since Last Audit (Mo)
			Phase 4	Interventional	Diagnostic	Low	Null	Null	Per Knight DSMC RBM	10/4/2023	48/0	1/13/2025	48	3/5/2024	Null	Initial QA	11.9
			Phase 1	Interventional	Treatment	High	Null	Null	Per Knight DSMC RBM	7/3/2022	17/0	6/28/2024	14	12/6/2023	5	Initial QA	15.6
			Phase 2	Interventional	Treatment	Modera..	Null	2023 Audit: Next per RBM	Per Knight DSMC RBM	5/19/2021	43/72	2/13/2024	35	9/21/2023	8	Initial QA	17.5
			Phase 1	Interventional	Treatment	High	Null	Null	Per Knight DSMC RBM	12/11/2019	22/24	8/1/2024	15	5/17/2024	7	Routine	9.5
			Phase 2	Interventional	Treatment	Modera..	Null	Recent mod closed enrollmen..	Per Knight DSMC RBM	5/11/2020	12/120	11/22/20..	9	8/29/2024	9	n/a - Ext ernal Ov ersight	6.1