The Diagnostic Audit; Scanning for Errors before the FDA Does

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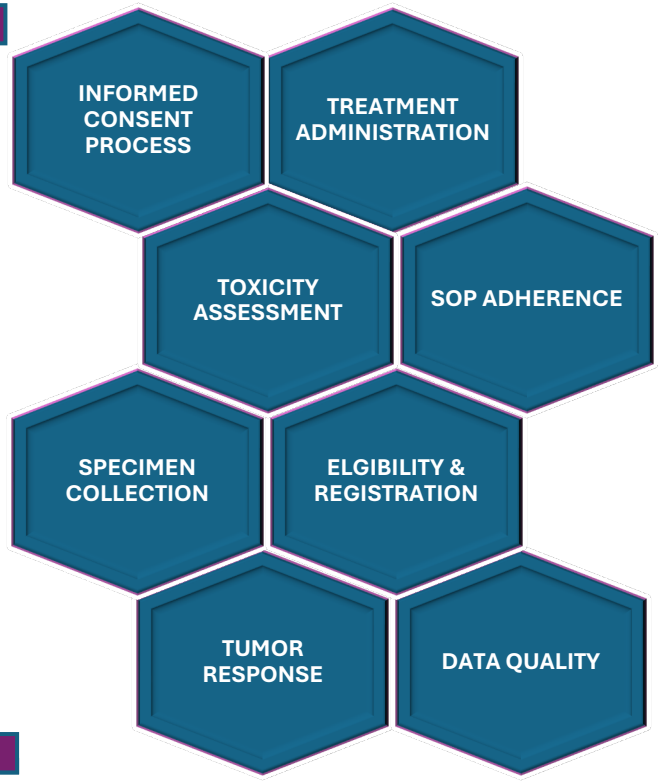
Background

The Phase I MDT Clinical Research Coordinator (CRC) team launched an internal quality-improvement initiative to strengthen audit readiness, enhance coordinator performance, and reduce documentation inconsistencies.

- We designed and implemented a standardized internal audit template and tracking spreadsheet for patient research shadow charts.
- This structured framework ensures consistent evaluation of key chart components, supports adherence to protocol requirements and departmental Standard Operating Procedures (SOPs), and provides coordinators with clear, actionable feedback.
- By establishing a uniform review process, the initiative promotes accuracy, improves documentation quality, and reinforces a culture of continuous compliance across the Phase I MDT.

Goals

- Goal #1: Maintain continuous audit readiness
- Goal #2: Provide oversite and support to Phase I CRCs
- Goal #3: Identify performance trends and areas for improvement



Methods Implemented

- Cycle 1 audits are mandatory for all CRCs to verify protocol execution, source documentation accuracy, and safety reporting practices.
- For newly onboarded CRCs, the audit period is extended through the first tumor assessment for their first five patients enrolled for additional oversight.
- The internal audit template is categorized into several key domains (noted above)
- A tracking spreadsheet was created to manage the internal audit lifecycle
- All enrolled patients are added to the tracker and weekly email notifications are distributed to the team with audit due dates

Outcomes

Focused retraining was implemented by assessing CRC adherence to protocols, departmental processes and policies. This strategic evaluation allowed for the identification of specific performance gaps, ensuring operational consistency and reinforcing the highest standards of clinical trial execution.

Lessons Learned & Future Directions

- The internal audit process provides continued support for Phase I CRCs. Standardized constructive feedback ensures the CRC competency, protocol comprehension, and adherence to institutional SOPs.
- This process was well received by the CRCs, equipping them with functional tools to execute tasks thoroughly and confidently.
- This process was also adapted by the Lung MDT CRCs.
- Continued use of this process will further the understanding of standardized methodologies and promote improvement within the ever-evolving scope of clinical trials.

Audit Temple Example

Informed Consent Process

Description	Comments	Finding(s)	OK	NA
A. Consent obtained prior to study procedures			☐	☐
B. Correct version of consent was used			☐	☐
C. Consent has required signatures, initials, and dates			☐	☐
D. Documentation of optional consent(s) presented to patient			☐	☐
E. Optional consent(s) signed, dated and filed			☐	☐
F. Consenting NTF			☐	☐
G. Oncore consenting notice			☐	☐
H. IRT/OPEN consent notice			☐	☐
I. Were errors addressed per GCP			☐	☐
J. Was re-consenting required and documented			☐	☐
K. Treatment past progression consent			☐	☐
L. Short form consent used			☐	☐
M. Full consent translated			☐	☐
N. Additional consent comments				

Conclusion

The internal audit process has successfully evolved from a compliance requirement into a vital support tool for our CRCs. By prioritizing standardized, constructive feedback, we have enabled our team to navigate the complexities of Phase I trials with increased confidence and precision. We have fostered a culture of continuous improvement and operational excellence within our team.