Category: Training, Career Development, and Staff Retention - Work in progress

The Impact of Action Item Reports (AIR) on Response to Findings From Routine Monitoring Visits

J. McAdams, M. Gawliu, K. Kelley

UCSF Helen Diller Family Comprehensive Cancer Center

1. Background

The University of California at San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center (HDFCCC) Data and Safety Monitoring Committee (DSMC) is responsible for ensuring safety and data integrity for all cancer related clinical research trials conducted at UCSF. The DSMC utilizes a risk-based process for the review of institutional studies, with all patients enrolled on high-risk studies monitored through the Dose Limiting Toxicity (DLT) period, and 20 percent of participants enrolled on moderate and low-risk trials audited on an annual basis. After each review, the study team is provided with a Monitoring Visit Report (MVR) which provides an overview of findings from each review. In June 2023, our team implemented an Action Item Report (AIR) to standardize the required timelines for study teams to respond to MVR findings along with a remediation process. We describe here the AIR process and results of implementation since June 2023.

2. Goals

Timely and thorough response to auditing and monitoring findings is required for data integrity and participant safety, as well as audit and inspection readiness. The primary goal of the newly implemented AIR process is to ensure that these findings are mitigated in a standardized timeframe after receipt of the MVR for all institutional trials conducted across UCSF HDFCCC Site Committees. A secondary goal is to define a clear remediation plan for the study teams unable to comply with the AIR timelines.

3. Solutions and Methods

After each review, the DSMC Data and Safety Auditors (DSA) provides the study team with an MVR and AIR within 20 business days. The AIR response is due within 8 weeks. Up to 2 additional 1-month extensions for extenuating circumstances may be granted with approval by the DSMC. For the AIR in a study requiring approval for dose escalation or expansion, only the significant items require completion prior to approval of the Dose Escalation Report. The remainder of the action items require completion within the standard AIR 8-week timeline.

If the AIR has not been completed within the 8-week timeline (or after two 4-week extensions, if granted) the assigned DSA will let the study team know that future monitoring will not be granted until all follow-up action items are resolved. Additionally, the DSMC will determine if any remediation action is required to ensure the completion of this report. The remediation action may include postponement in dose escalation approval, accrual hold, or a change in the overall outcome of the report to a more significant finding with resulting Institutional Review Board (IRB) submission and requirement for a Corrective and Preventative Action Plan (CAPA) due to the DSMC within 10 business days.

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4. Outcomes

Year	Total MVRs	AIRs Completed in 8 weeks' timeline	AIRs completed after 1st extension	AIRs completed after 2nd extension	AIRs completed past the 2nd extension	Pending late MVR responses	Median time to response to MVR findings (days)
Jan – May 2023	38	NA	NA	NA	NA	16 (42%)	104.5 (21 - 306)
June 2023 – present*	57	24 (42%)	16 (28%)	5 (9%)	4** (9%)	8*** (14%)	55.0 (7 - 150)

*29Feb2024

**Dose Escalation Approvals delayed until AIRs were completed.

***Minor edits required for most AIRs. Pending remediation action for others.

5. Lessons Learned and Future Directions

The implementation of the AIR process has contributed to a 29.0 percent decrease in median time to completion of MVR action items within the 8-week completion date and a significant improvement in the median time for the response to the MVR findings of 49.5 days. The AIR process has been facilitated by sending reminders to study team and study teams' awareness of consequences of delayed mitigation of MVR action items.

We are improving our monitoring processes with feedback from study teams and discussions within our team, along with benchmarking with other comprehensive cancer centers.