UCSF Helen Diller Family Comprehensive Cancer Center

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

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BACKGROUND

The UCSF 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% 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.

GOALS

- The primary goal of the newly-implemented AIR process is to ensure that 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.

SOLUTIONS AND METHODS

- After each review, the DSMC Data and Safety Auditors (DSA) provides the study team with a MVR and AIR within one month. The AIR response is due within 8 weeks. Up to two additional 1-month extensions for extenuating circumstances may be granted with approval by the DSMC. In studies requiring approval for dose escalation or expansion, only the significant items require completion prior to approval of Dose Escalation. 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 performed until all action items are resolved. DSMC determines if any remediation action is required to ensure completion of the report. The remediation action may include one of the following: postponement in dose escalation approval, accrual hold, or a change in the overall outcome of the report to a more significant finding with resulting IRB submission and requirement for a CAPA due to the DSMC within 10 business days.
- 95 MVRs were completed by DSMC in 2023. The completion rate, extension rate, and median time to completion were measured for MVRs before and after implementation of the AIR process.

OUTCOMES

The AIR process has contributed to a **29.0%** decrease in median time to completion of MVR action items within the 8-week completion date and a meaningful 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.

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RESULTS

Metrics for Completion of Action Item Reports

Year	MVRs	AIRs Completed	AIRs > 1st Ext	AIRs > 2nd Ext	AIRs completed late	AIRs Pending	Median Time Completion (days)
Jan – May 2023	38	NA	NA	NA	NA	16 (42%)	104.5 (21-306 days)
June – December 2023	57	24 (42%)	16 (28%)	5 (9%)	4 (9%)	8 (14%)	55.0 (7 - 150 days)