Category: Quality Assurance – Work in Progress

Improving Rapid Event Reporting Compliance Through a Real-Time Monitoring Dashboard

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1. Background

Timely rapid event reporting in oncology clinical trials is crucial for safe, compliant and credible research. Rapid events, especially serious adverse events (SAEs), can pose risk to patient safety and must be reported to study sponsors within the protocol prescribed time frame. Utilization of a dashboard that captures rapid event reporting timeliness across clinical trials can increase visibility into timely reporting for leadership teams, as well as strengthen patient safety monitoring and compliance.

City of Hope (CoH) Comprehensive Cancer Center conducts advanced clinical research across its national network of sites in Southern California, Atlanta, Chicago, and Phoenix, with a focus on expanding clinical trials across all locations.

The rapid event reporting dashboard was developed in January 2026 to give leadership systemwide oversight of reporting timeliness and to help drive improvements in safety, compliance, and operational performance.

2. Goals

The dashboard is designed to enhance leadership oversight of rapid event reporting timeliness in clinical trials, strengthening patient safety, ensuring regulatory compliance, and minimizing downstream operational and financial impacts.

3. Solutions and Methods

Rapid event reporting data was pulled from OnCore, capturing key metrics such as event discovery date, sponsor notification date, event management group, and additional attributes. The data was analyzed and visualized in Tableau to illustrate reporting timeliness, measuring the time from discovery to sponsor notification, as well as outstanding follow-up reporting, the proportion of events reported outside required windows, and trends by management group. The dashboard includes flexible filtering capabilities, allowing users to view performance by site, fiscal year, management group, and other variables. While still being refined as teams continue entering data, the dashboard is being used by leadership to monitor reporting performance and strengthen compliance across CoH.

4. Outcomes

Since the inception of the dashboard in January 2026, the clinical trials quality assurance (QA) leadership has noted the following achievements:

- Created transparency across portfolios as it relates to volume and staff workload
- Identified and advised documentation gaps in rapid event reporting to improve data entry and quality

- Improved working instructions for staff to capture additional data to enhance timeliness monitoring
- Instituted quarterly internal audits focused on rapid event reporting to ensure accuracy of data captured in OnCore and source records
- Presented dashboards to IRB and DSMC Executive Committee's with favorable feedback and potential uses for committee meetings

5. Lessons Learned and Future Directions

The development of the rapid event reporting dashboard encountered challenges before reaching current state. Early iterations revealed gaps in the capturing of timeliness metrics, prompting QA teams to revise work instructions and adjust workflows to ensure key fields were consistently recorded. As new data requirements represent a shift from long-standing practices, teams are still adapting and working to improve data entry completeness, so the dashboard accurately reflects reporting timeliness.

Looking ahead, efforts will focus on increasing consistent entry of timeliness fields to enhance accuracy and utility of the dashboard. As data quality strengthens, teams plan to conduct deeper analyses of rapid events to identify root causes of reporting delays and develop targeted solutions to improve overall compliance.