Category: Quality Assurance – Work in Progress

Improving System-Wide Deviation Identification and Targeted Reduction Through a Live Monitoring Dashboard

W. Huang, N. Cassim, A. Hammond

City of Hope Comprehensive Cancer Center

1. Background

Rapid, systematic identification of clinical trial deviations is essential to maintaining the safety, integrity, and reliability of oncological research. Deviations, whether related to dosing, eligibility, assessments, or operational processes, can introduce patient risk, compromise data quality, and threaten regulatory compliance. Because oncology studies involve complex and tightly regulated procedures, even minor deviations can elevate risk or undermine study credibility. Establishing systemwide oversight strengthens trial safety and supports high-quality, reliable data.

City of Hope (CoH) Comprehensive Cancer Center conducts advanced cancer research across its Southern California, Atlanta, Chicago, and Phoenix sites, with a commitment to expanding access to quality clinical trials. To support this effort, the clinical trial deviation dashboard was developed in September 2025 to provide leadership with real-time, systemwide visibility into protocol deviations. The dashboard centralizes data, highlights trends, and enables timely identification of operational gaps, ultimately driving improvements in patient safety, compliance, and research performance.

2. Goals

This initiative aims to enhance leadership's ability to identify deviations and emerging trends, thereby strengthening patient safety, supporting broader trial access, and reducing downstream operational and financial burdens.

3. Solutions and Methods

Multiple panel interviews were first conducted with stakeholders of varying backgrounds, from clinical to operations. Raw deviation data were then extracted from OnCore, including key variables such as deviation category, disease team, study site, patient count, trial status, and occurrence/report dates. These data were subsequently visualized in Tableau to display deviation category prevalence, affected/total patient ratios, deviation counts by disease team, response timeliness, Institutional Review Board (IRB) reporting types, and monthly trends. To accommodate varying stakeholder needs, the dashboard also includes flexible filtering features that allow users to view trends by site, disease team, protocol identification, protocol phase, and additional variables. Although still under refinement, the dashboard is already being used by leadership to guide the development and implementation of remedy initiatives.

4. Outcomes

Since its inception, the clinical trial operations leadership has noted the following achievements:

- Increased transparency on deviation trends across varying levels of leadership and clinical trial departments
- Use of machine learning to identify top deviation-reduction opportunities
- Collaboration with site research team to operationalize and implement high-impact remedy initiatives
- Favorable feedback from IRB, Data Safety Monitoring Committee, and medical director executive committees, with emerging use cases for ongoing meetings

5. Lessons Learned and Future Directions

Building the deviation dashboard posed unique challenges, as it was the first system-wide tool to centralize sensitive deviation data across all sites. Because framing was essential to supporting appropriate use and interpretation, the dashboard underwent a staged rollout that emphasized quality improvement rather than oversight. Early piloting also revealed the diverse needs of clinical, operational, regulatory, and leadership users, prompting development of a highly adaptive and modular platform capable of serving multiple perspectives.

Future efforts will focus on strengthening this modularity and increasing stakeholder engagement as the dashboard becomes further integrated into deviation reduction initiatives. As the tool matures, teams plan to leverage its analytics to support targeted deviation-reduction strategies and monitor performance to improve overall trial quality and patient safety.