

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

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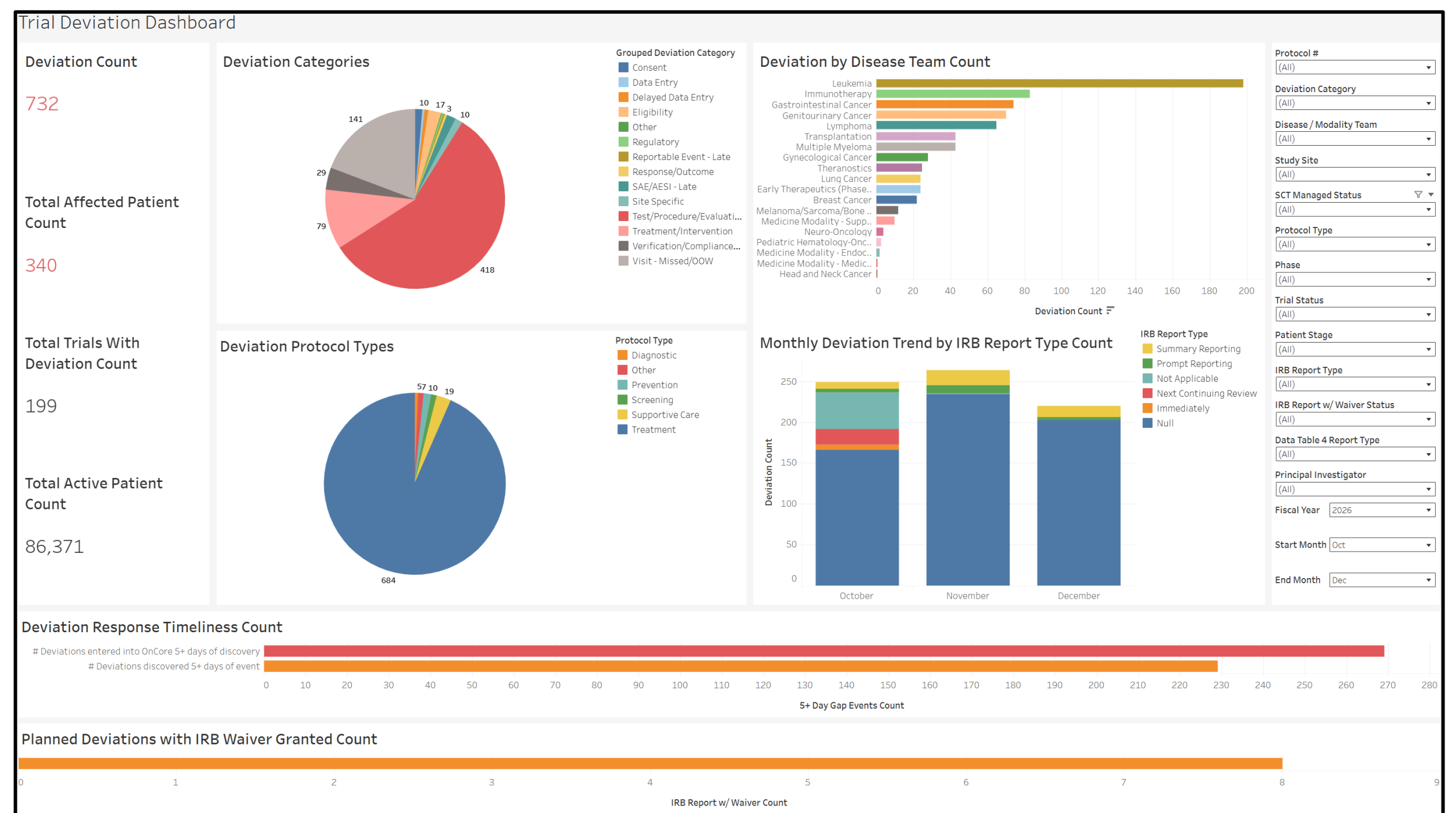
## BACKGROUND

Rapid 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.

Establishing systemwide oversight strengthens trial safety, supports data quality/reliability, and facilitates the expansion of trial access.

## DEVIATION DASHBOARD EXAMPLE



## GOALS

This initiative aims to:

- Enhance leadership's ability to identify deviations and emerging trends
- Strengthen patient safety
- Support broader trial access
- Reduce downstream operational and financial burdens

## SOLUTIONS AND METHODS

Multiple panel interviews were conducted with stakeholders of varying backgrounds, from clinical research 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.

The live data were subsequently visualized in Tableau to display deviation category prevalence, affected/total patient ratios, deviation counts by disease team, response timeliness, IRB reporting types, and monthly trends.

To accommodate stakeholder needs, the dashboard was designed for flexibility through filtering features automated calculations that allow users to view trends by site, disease team, protocol ID, protocol phase, and additional variables.

While phase II is still undergoing refinement, the dashboard is already being utilized by system leadership to guide the development, implementation, and tracking of remedy initiatives.

## OUTCOMES

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

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

## LESSONS LEARNED AND FUTURE DIRECTION

Building the deviation dashboard posed unique challenges, as it was the first system-wide tool to centralize sensitive deviation data across all locations. As 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.