

## **From Backlog to Zero: a Governance Redesign That Eliminated Year-End Monitoring Deferrals and Strengthened Institutional Oversight**

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### **1. Background**

Timely completion of study monitoring reviews is critical for regulatory compliance, audit readiness, and effective oversight. Prior to intervention, monitoring deferrals occurred across multiple years, with 5 of 50 reviews (ten percent) deferred in 2021 and escalating to 18 of 69 required reviews (26 percent) deferred in 2022. This recurring and worsening backlog reflected reactive scheduling practices, limited workload visibility, and insufficient real-time performance tracking, creating avoidable compliance risk and reducing institutional oversight transparency.

### **2. Goals**

To eliminate year-end monitoring backlog, improve workload transparency, and ensure proactive, timely oversight of all studies without adding staffing resources.

### **3. Solutions and Methods**

Beginning January 2023, we implemented a structured, data-driven governance framework:

1. Quarterly Workload Planning: Annual monitoring reviews were assigned by quarter at the start of the year, replacing ad hoc scheduling, ensuring balanced workload distribution.
2. Monthly Performance Tracking: Metrics were reviewed in quality assurance (QA) meetings, including total studies due, completed reviews, and outstanding assignments, to maintain team-wide transparency.  
In addition, study status was reviewed monthly to determine whether monitoring remained required based on activity level, accrual status, or closure. This ensured monitoring resources were aligned with active oversight needs.
3. Early Risk Escalation: Quarterly progress assessments enabled proactive workload redistribution before delays accumulated.

The intervention was implemented without increasing staffing levels or requiring structural reorganization.

### **4. Outcomes**

Monitoring deferrals were observed prior to intervention:

- 2021: 50 studies reviewed; five deferred (10 percent)
- 2022: 69 studies reviewed; 18 deferred (26 percent)

*Category: Quality Assurance – Completed Project*

Following implementation of the governance redesign in 2023, sustained elimination of year-end backlog was achieved:

- 2023: 75 studies monitored; zero deferred (0 percent)
- 2024: 74 studies monitored; zero deferred (0 percent)
- 2025: 74 studies monitored; one deferred (1.4 percent)

Compared to 26 percent deferral in 2022, this represents a  $\geq 94$  percent reduction in backlog over three years. Importantly, these outcomes were maintained despite QA staffing transitions in 2023, during which two quality monitors departed and two new staff were onboarded. Full-year completion was achieved even with increased monitoring volume in 2023, demonstrating structural durability and sustainability.

**5. Lessons Learned and Future Directions**

Structured quarterly planning combined with real-time performance tracking is a low-cost, scalable strategy to eliminate backlog, improve oversight timeliness, and strengthen institutional governance. Sustained success despite staffing changes highlights the framework's resilience.

Future directions include integrating dashboards to further visualize workload distribution and exploring risk-based prioritization for even greater operational efficiency.