

*Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress*

## **Supporting IIT Research Through the Lens of [ClinicalTrials.gov](https://www.clinicaltrials.gov) Registration and Results Reporting Requirements**

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### **1. Background**

Registration and results reporting on [www.clinicaltrials.gov](https://www.clinicaltrials.gov) for Applicable Clinical Trials (ACTs) is a common administrative challenge most large institutions face. At our institution, ClinicalTrials.gov support was historically decentralized, requiring all regulatory staff to maintain specialized knowledge while balancing competing responsibilities. This approach resulted in inconsistent oversight and variable familiarity with reporting requirements, creating challenges in maintaining consistent compliance across the portfolio.

### **2. Goals**

The primary goal of this project was to increase compliance with ClinicalTrials.gov registration and results reporting requirements by establishing a centralized and sustainable support model within the Clinical Trials Office (CTO). Additional objectives included reducing administrative burden on regulatory staff, improving communication across stakeholders, and creating consistent oversight for all ACTs within the scope of management in the CTO.

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

The Regulatory Operations Manager identified this gap in oversight for overdue results on ACTs. To address identified gaps in oversight and compliance, a dedicated ClinicalTrials.gov Specialist position was created within the CTO. The role centralized responsibility for ClinicalTrials.gov activities under a single subject matter expert with dedicated time and focused expertise. The ClinicalTrials.gov Specialist provides ongoing oversight for registration, results reporting, and record maintenance throughout the life cycle of the trial, while supporting education and guidance for investigators, regulatory coordinators, statisticians, and data managers.

Responsibilities include review of study records, coordination of data collection and entry, response to Protocol Registration and Results System (PRS) comments, and facilitation of communication between stakeholders. The ClinicalTrials.gov Specialist maintains oversight of approximately 260 clinical trial records within the ClinicalTrials.gov system across the entire CTO portfolio. Establishing a collaborative culture across study teams, regulatory staff, and leadership was essential to successful implementation. Leadership support enabled timely communication and access to information needed to complete the records. This reinforces the shared accountability for ClinicalTrials.gov compliance.

### **4. Outcomes**

Since implementation of the ClinicalTrials.gov Specialist role in early 2025, all outstanding records were resolved in just over six months. Centralized oversight improved collaboration with investigators and statistical teams, leading to earlier discussion of outcome measure definitions and results reporting expectations. Increased engagement and education across stakeholders improved organizational understanding of ClinicalTrials.gov requirements and streamlined communication. Consolidating specialized expertise into a single role reduced administrative burden for regulatory staff and created a more consistent approach to compliance oversight.

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## **5. Lessons Learned and Future Directions**

<http://www.clinicaltrials.gov/> expertise improved efficiency and strengthened collaboration. However, early investigator engagement remains essential for long-term success. Future efforts will focus on assessing ClinicalTrials.gov requirements during study feasibility review to engage investigators earlier in protocol development. Early review of outcome measures, data collection planning, and reporting expectations are expected to improve protocol alignment with ClinicalTrials.gov requirements, streamline registration and reduce downstream revisions. Embedding ClinicalTrials.gov considerations earlier in the study development will support sustained compliance and operational efficiency across the trial lifecycle.