A Concierge Support Model for ClinicalTrials.gov Compliance in Investigator-Initiated Trials

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Background

ClinicalTrials.gov administration and compliance present ongoing challenges in supporting investigator-initiated research at large institutions.
Historically, these responsibilities were decentralized to study-assigned regulatory coordinators, who balanced competing priorities and often lacked dedicated time or specialized expertise in registration, maintenance, and results reporting.
This approach led to inconsistent oversight and variable understanding of requirements, complicating efforts to maintain compliance across the portfolio.

Project Goals

Increase compliance with ClinicalTrials.gov registration and results reporting requirements through implementation of a centralized, sustainable support model within the Clinical Trials Office (CTO).

Additional objectives:
- Reduce administrative burden on regulatory staff
- Improve communication and shared understanding across stakeholders
- Establish consistent oversight for all applicable clinical trials (ACTs) managed within the CTO

Methods & Solutions

Methods:
- Gap in CT.gov oversight for overdue ACT results identified
- Dedicated ClinicalTrials.gov Specialist role established within the CTO

Solution: Concierge Support Model
- Centralized CT.gov responsibilities under a dedicated subject matter expert
- Provided structured, cross-functional support to study teams
- Delivered key services including:
  - QA review
  - Data coordination and entry
  - Reviewer response management
  - Stakeholder communication
  - Stakeholder education

Outcomes

- Oversight centralized across ~260 studies within the CTO portfolio to Concierge Support Model
- All outstanding ClinicalTrials.gov records resolved within ~6 months
- Improved cross-functional collaboration and earlier alignment on reporting expectations
- Increased stakeholder understanding of ClinicalTrials.gov requirements and streamlined communication
- Reduced administrative burden and improved consistency in compliance oversight

Key Takeaways
- All previously overdue ClinicalTrials.gov records were resolved within six months of implementing the model.
- Using a centralized, concierge support model was instrumental supporting high/extreme support needs trials

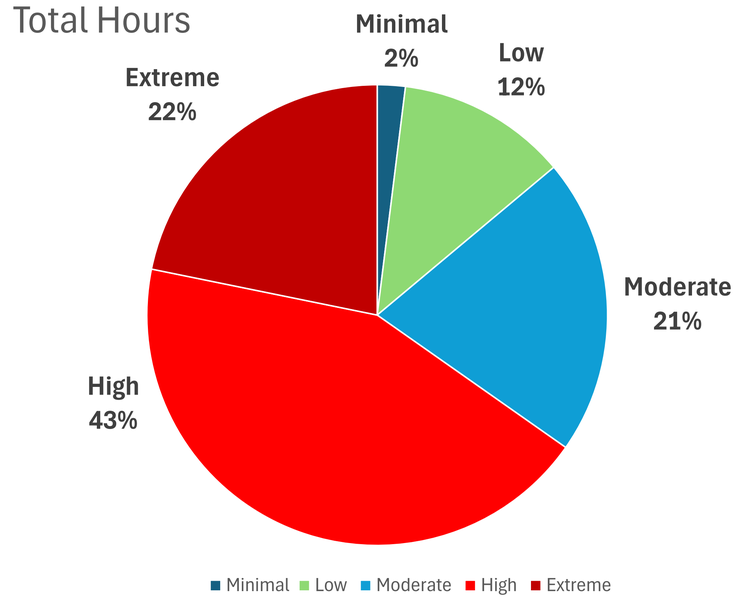
Future Directions
- Integrate a review of ClinicalTrials.gov requirements earlier in study feasibility and protocol development
- Align outcomes and data collection with reporting requirements to reduce downstream revisions

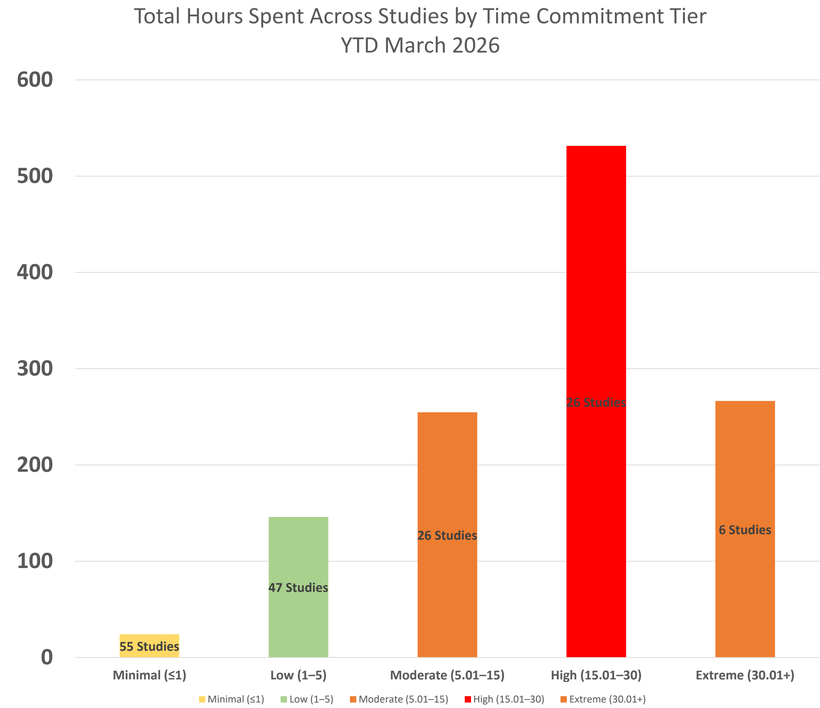
Effort Reported – Data Visualization

Support Time Analysis (Effort Tracking Data, YTD March 2025–2026)
Support Categories:
Minimal, Low, Moderate, High, Extreme

Support Category & Ranges:
- Minimal = 55 studies (<1 hr)
- Low = 47 studies (1–5 hrs)
- Moderate = 26 (5–15 hrs)
- High = 26 (15–30 hrs)
- Extreme = 6 (>30 hrs)

Key Findings:
- High-support studies (n=26) accounted for 43% of total time
- Moderate (n=26) and Extreme (n=6) required similar total time despite different volumes
- A small subset (n=6) required disproportionately high levels of support





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