Optimizing Clinical Research Workforce Efficiency Through Technology-Driven Workload Assessment: an NCI-Designated Comprehensive Cancer Center TRIALNAV OASIS Pilot

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Background

Operational complexity of modern oncology clinical trials has significantly increased workload demands across multidisciplinary research teams.

Protocols increasingly incorporate biomarker-driven eligibility, intensive safety monitoring, real-world data integration, and decentralized procedures.

Requirements extend beyond traditional role boundaries, contributing to role strain, inefficiencies in trial activation and conduct, and potential risks to data integrity and patient experience.

No validated digital tool exists to objectively quantify protocol complexity and staff burden across oncology therapeutic areas.

Goals

To evaluate the TRIALNAV OASIS™ platform, a technology-driven workforce management tool designed to explore real-time, acuity-based workload intelligence across clinical research roles and disease departments.

Objectives: 1) to quantifying protocol complexity using a validated 0–35 acuity scale; **2)** to identify staffing inequities across four therapeutic areas; and **3)** to generate evidence-based staffing benchmarks to support sustainable workforce models.

Methods & Solutions

- TRIALNAV OASIS™ pilot was applied to 121 oncology trials across four (4) therapeutic areas.
- 34 research staff involved, generating acuity scores based on trial complexity and workload.
- Baseline assessment, workload redistribution strategies implemented and evaluated 90 days later.

Outcomes

Trial & Staff Characteristics

121	34	4	0 – 35
Total Trials	Staff Participants	Departments	Validated Acuity Scale

*Trials = Active and Pending

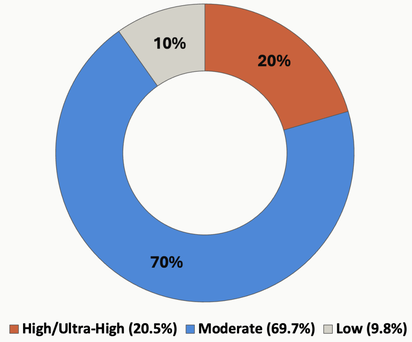
40% Early-phase trials	32% Multi-arm design
45% Biomarker-driven	4 Research managers

12 CRNs	6 CRCs	12 DCs	4 Managers

CRNs=Clinical Research Nurses; CRCs=Clinical Research Coordinators; DCs=Data Coordinators

Trial Complexity Distribution

Acuity scoring across 121 active and pending oncology trials

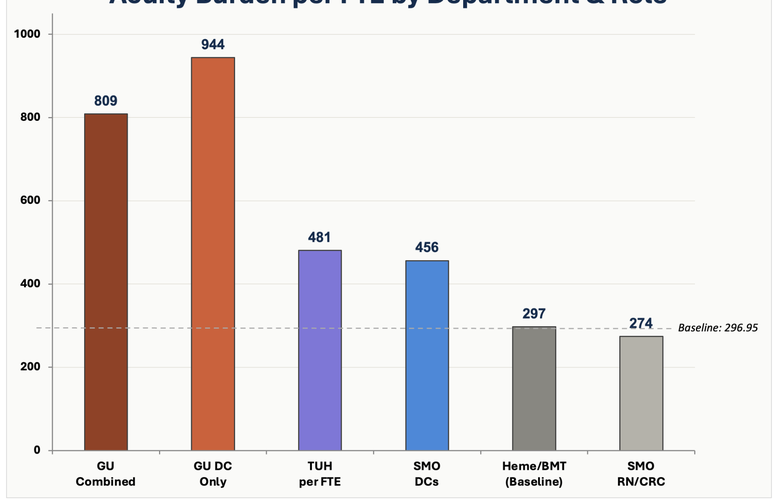


20.5%
High/Ultra-High Complexity
1 in 5 trials — invisible to headcount models

69.7%
Moderate complexity
Largest tier; still requires acuity weighting

9.8%
Low complexity
Only 1 in 10 trials is genuinely low-burden

Acuity Burden per FTE by Department & Role



Outcomes contd.

90-Day Outcomes

Post-redistribution results across all four departments and three staff role categories

Before: 36 hrs/month	Before: 0%	Before: partial
30 min	100%	Full
Staffing analysis time per month	Trial delay risk visibility	Staff utilization tracking coverage
−98.6%	+100 percentage pts	Full portfolio

Before: untracked	Before: untracked	Target: ≥95%
±8%	±12%	98%
CRC workload variance	CRN workload variance	Protocol acuity validation accuracy
Normalized	Normalized	Exceeded target

CRC Workload Variance
Before: untracked/unknown
±8%
After — normalized variance at 90 days

CRN Workload Variance
Before: untracked/unknown
±12%
After — normalized variance at 90 days

Protocol acuity validation accuracy
98%
Achieved — exceeded ≥95% target
Target: ≥95%
+3 pp above target
Validation accuracy exceeded the pre-specified benchmark, confirming the platform's acuity scoring reliability across all four departments.

1 Acuity scoring revealed hidden complexity
20.5% of trials in high/ultra-high tier — invisible to headcount models. 90.2% at moderate or above.

2 Structural gaps made visible
GU burdened at 173% above baseline. TUH concentrated 961 acuity units across 2 FTEs with zero DC coverage.

3 Role-stratified disparities detected
SMO DCs carried 67% more acuity per FTE than RN/CRC peers — undetectable without role-level scoring.

4 Massive efficiency gain
Staffing analysis time fell 98.6% — from 36 hours to 30 minutes per month — at 90 days post-deployment.

5 Full visibility and normalized variance
Trial delay risk visibility: 0% → 100%. CRC variance: ±8%. CRN variance: ±12%. Accuracy: 98% (target ≥95%).

Lessons Learned & Future Considerations

Challenges included staff concerns about productivity monitoring, manual data normalization, and CTMS integration.

Pilot showed that complexity, not volume, drives operational strain and identified five new workforce management capabilities.

Future plans involve expanding to more disease areas, incorporating acuity forecasting, integrating with CTMS and financial systems, and sharing anonymized benchmarks with peer centers.