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

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1. Background

The 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. These 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. Currently, no validated digital tool exists to objectively quantify protocol complexity and staffing burden across oncology therapeutic areas.

2. Goals

To evaluate whether TRIALNAV OASIS^{TM}, a technology-driven workforce management platform, could deliver real-time, acuity-based workload intelligence across clinical research roles and disease departments. Objectives included: quantifying protocol complexity using a validated 0–35 acuity scale; identifying staffing inequities; and generating evidence-based staffing benchmarks to support sustainable workforce models.

3. Solutions and Methods

The TRIALNAV OASIS^{TM} pilot was deployed across 121 active and pending oncology trials (40 percent early-phase, 32 percent multi-arm, 45 percent biomarker-driven) spanning three therapeutic departments and one network location: Heme/bone marrow transplant (BMT), Sarcoma/Melanoma/Other (SMO), Genitourinary (GU), and Temple University Hospital (TUH), which managed all disease areas. Participants included 34 staff members (four research managers, 12 clinical research nurses [CRNs], six clinical research coordinators [CRCs], and 12 data coordinators [DCs]). The platform generated trial-level acuity scores reflecting protocol complexity, patient volume, data intensity, and task distribution. Following baseline assessment, portfolio redistributions were implemented: high-burden CRN assignments were rebalanced, CRC allocations normalized by complexity, and data specialist forecasting aligned to activation volume. Outcomes were evaluated at 90 days.

4. Outcomes

Acuity scoring showed 20.5 percent of trials in the high or ultra-high complexity range and 90.2 percent at moderate complexity or above. Role-stratified analysis revealed disparities undetected by headcount models. GU carried the highest combined acuity burden per FTE (809.0), 173 percent above the Heme/BMT baseline (296.95), driven by a DC load of 943.8/FTE. TUH Main, with no DC coverage despite 33 active trials, concentrated 961.0 acuity units across 2 CRN/CRC FTEs (480.5 each; 62 percent above baseline). SMO DCs carried 67 percent more acuity per FTE than RN/CRC counterparts (456.3 vs. 273.9).

At 90 days: staffing analysis time decreased 98.6% (36 hours to 30 minutes/month); trial delay risk visibility increased from 0 percent to 100 percent; staff utilization tracking expanded to full portfolio coverage; CRC workload variance normalized to ±8 percent and CRN to ±12 percent; and protocol acuity validation accuracy reached 98 percent.

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5. Lessons Learned and Future Direction

Implementation challenges included initial staff concerns regarding productivity surveillance, manual normalization of complexity inputs, and CTMS data harmonization. The pilot demonstrated that operational strain is complexity-driven rather than volume-driven and revealed five workforce management capabilities previously unavailable. Future plans include expansion to additional disease areas, embedding acuity forecasting into feasibility review, integrating with CTMS and financial systems for budget-aligned FTE modeling, and sharing anonymized benchmarks with peer NCI-designated centers to support national staffing standards.

Figure 1

Table 1 — Departmental Staffing & Trial Portfolio: Raw Data

Departmental Staffing & Trial Portfolio — Raw Data

Source data underlying all acuity burden and role-level calculations | Fox Chase Cancer Center | TRIALNAV OASIS Pilot

Department	Clinical Staff by Role: RN	CRC	DC	Total Staff per Dept	Active Trials
TUH	1	1	0	2	33
Genitourinary	5	2	5	12	38
Heme/BMT	3	1	4	8	26
SMO	3	2	3	8	24
TOTAL	12	6	12	30	121

PORTFOLIO OVERVIEW: 30 total FTEs across 3 departments; 1 network location managing 121 active trials. RN and CRC roles (18 FTEs combined) account for 60% of clinical staff. DC staff (12 FTEs) represent 40% of the workforce and carry a disproportionate acuity burden in Genitourinary (943.8/FTE). TUH Main operates with zero DC coverage despite 33 active trials.

Table 2 — Therapeutic Disease Departments-Level Acuity Burden per FTE, Stratified by Role (RN/CRC vs. DC)

Therapeutic Disease Area-Level Acuity Burden per FTE — By Role

RN/CRC Acuity/FTE = Total Acuity ÷ (RN+CRC Count) | DC Acuity/FTE = Total Acuity ÷ DC Count | Avg Combined = (RN/CRC + DC) ÷ 2 | Baseline = Heme/Transplant (lowest combined acuity)

Department	Total Acuity Load	RN / CRC Role: RN+CRC FTEs	RN/CRC Acuity / FTE	DC Role: DC FTEs	DC Acuity / FTE	Avg Combined Acuity / FTE	Relative Burden vs. Lowest Dept (Heme/Transplant)
Genitourinary	4,719.9	7	674.1	5	943.8	809.0	+173% vs. Baseline — Highest combined acuity per FTE — DC workload drives outsized burden
TUH Main	961.0	2	480.5	N/A	N/A	480.5*	+62% vs. Baseline — RN/CRC only — no DC assigned; all acuity concentrated in 2 FTEs
SMO	1,369.5	5	273.9	3	456.3	365.1	+23% vs. Baseline — Moderate burden; DC acuity/FTE notably higher than RN/CRC
Heme/BMT	1,187.8	4	296.95	4	296.95	296.95	BASELINE — Lowest combined acuity per FTE — reference point for all comparisons

KEY FINDING: Genitourinary carries the highest combined acuity per FTE (809.0) — 173% above the baseline — driven by a DC acuity load of 943.8/FTE, the highest of any role across all departments. TUH has no DC support, concentrating all 961.0 acuity units across just 2 RN/CRC FTEs (480.5 each). SMO DCs carry 67% more acuity per FTE than their RN/CRC counterparts (456.3 vs. 273.9). These role-level disparities are invisible in aggregate headcount models.

**TUH has no DC staff; combined FTE acuity reflects RN/CRC load only.*

Highest DC Acuity/FTE	Genitourinary DCs: 943.8/FTE — undetectable by headcount
TUH: No DC Coverage	All acuity on RN/CRC only — 480.5 per FTE with zero DC support
Largest Intra-Dept Role Gap	SMO: DC acuity (456.3) vs RN/CRC acuity (273.9) — 67% disparity
Lowest Combined Acuity/FTE (Baseline)	Heme/BMT: 296.95 — balanced load across 4 RN/CRC and 4 DC FTEs

Table 3 — 90-Day Summary Impact Scorecard | TRIALNAV OASIS Pilot, Fox Chase Cancer Center

90-Day Summary Impact Scorecard

TRIALNAV OASIS Pilot | Fox Chase Cancer Center | All figures verified against dataset

Key Performance Indicator	Verified Result
Protocol Acuity Validation Accuracy	98% — Exceeds ≥95% target
Staffing Analysis Time Reduction	98.6% reduction (36 hrs → 30 mins/month)
Trial Delay Risk Visibility	0% → 100% monitored — net-new capability
Staff Utilization Tracking	0% → full portfolio coverage — net-new capability
CRC Workload Variance Normalization	0% modeled → ±8% — net-new capability
CRN Workload Variance Normalization	0% modeled → ±12% — net-new capability
High-Risk Compression Identification	0% → 100% flagged — net-new capability

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