

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

From Static Scores to Strategic Staffing: Evolution of the ASCO Framework Into the PACT Near-Real-Time Workload Model

J. Shaub, X. Liu, C. Sowers, J. Liao, D. Shank, M. Joshi

Penn State Cancer Institute

1. Background

Accurately assessing clinical trial workload is essential for sustainable staffing and high-quality trial conduct. While the American Society of Clinical Oncology (ASCO) Clinical Trial Workload Assessment Tool provided a foundational framework, it often overlooks the administrative burdens of eligibility verification, multidisciplinary coordination intensity, and the varying staff capacity based on tenure.

2. Goals

The Penn State Cancer Institute (PSCI) developed the Penn State Assessment of Clinical Trials (PACT) method to:

- Engineer an operationally nuanced scoring system reflecting modern trial complexity.
- Quantify near-real-time workload across three roles: clinical research coordinator (CRC), clinical research associate (CRA), and data manager (DM) and stratified by four experience levels: L1 (0-6 months), L2 (6-18 months), L3 (18-36 months), and L4 (36+ months).
- Utilize dynamic data visualization to guide trial reallocation and justify FTE expansion.

3. Solutions and Methods

The PACT model evolves the ASCO framework by focusing on operational bottlenecks. Key advancements include:

- **Administrative Sophistication:** Replaced randomization metrics with eligibility confirmation (local Primary Investigator (PI) versus sponsor-required), acknowledging screening and verification as the primary labor burden.
- **Refined Metrics:** Increased the threshold for level four coordination to four or more ancillary departments and removed agent-delivery distinctions to focus on toxicity and data volume.
- **The PACT Formula:** Developed a dynamic calculation weighing active and pending cases by protocol intensity while capturing survival follow-up as a constant +1. For each trial on a given day: $\text{Daily Per-Trial Workload} = \text{PACT Score} \times (\text{Active} + \text{Pending Cases}) + \text{Follow-up Cases}$.
- A staff member's total daily workload was determined by summing the scores of all trials assigned to them. Distribution was categorized by role and experience level using box plots (Figure 1).
- **Automated Visualization:** A near-real-time Power Business Intelligence (BI) dashboard integrates the clinical trial management system (OnCore) data with overnight refreshes, providing leadership with an objective, data-driven tool for immediate workload oversight.

4. Outcomes

Analysis of eight months of longitudinal data from 14 staff members established role-specific capacity benchmarks (Figure 1):

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- Data Managers (DM): Demonstrated clear scalability. L1 DMs averaged a workload score of 46.58, while L4 DMs managed a mean of 87.56, representing an 88 percent increase in handled complexity.
- Patient-Facing Staff (CRC/CRA): Capacity peaked at L3 with a mean score of 92.97. L4 staff averaged 51.99; this dip reflects a strategic departmental shift toward senior staff managing higher-intensity protocols with lower accrual volume while mentoring junior staff.
- Operational Impact: Leadership utilizes these tenure-based benchmarks to assign protocols to staff currently below their experience-level median, preventing burnout and ensuring equitable distribution.

5. Lessons Learned and Future Directions

The PACT model relies on rigorous data hygiene within OnCore. To ensure accuracy, PSCI implemented new standard workflows: CRCs and CRAs must remove themselves from the “On Study” tab once a subject enters survival follow-up, and DMs must update the PACT score to one when all subjects reach the survival follow-up phase. Future directions include automating ramp-up expectations for new hires within the dashboard to further refine capacity forecasting.

Feature	ASCO 2019 (Baseline)	PSCI PACT (Sophisticated Model)	Rationale
Primary Metric	Randomization steps	Eligibility Confirmation	Captures primary labor bottleneck
Complexity Trigger	2+ ancillary departments	4+ ancillary departments	Refined high-intensity granularity
Agent Delivery	Oral vs. IV distinction	Toxicity & Data-Centric	Focuses on monitoring burden
Staff Benchmarking	Aggregate volume	Tenure-Based Levels	Links capacity to professional growth
Data Update	Manual/Static	Near-Real-Time	Automated via Power BI & OnCore

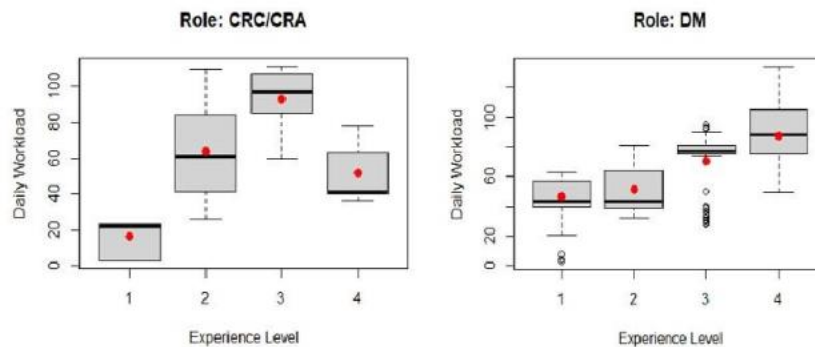


Figure 1. PSCI PACT Framework Evolution and Capacity Benchmarks.

Top: Comparative analysis of the legacy ASCO 2019 framework versus the evolved PACT model.

Bottom: Box-and-whisker plots illustrating the interquartile range, median, and mean (red dots) of daily workload scores for 14 staff members over eight-month period. Notably, Level 4 patient-facing workload reflects adjustments for increased mentorship and administrative responsibilities.