

A task-based automated comprehensive assessment tool for clinical trial-associated workload

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Background

The accurate and efficient assessment of workload enables;

- the effective deployment of research personnel to support clinical trials
- even distribution of workload among staff
- Deploy strategies to prevent staff burnout and turnover

We have developed an objective, task-based acuity assessment tool that utilizes real-time data produced by our internally developed Clinical Trails Management Application (CTMA) to measure workload.

Goals

Our complexity assessment tool evaluates the time spent on various tasks including

- study start up
- diagnostic testing requirements
- scheduling
- treatment day visits
- safety
- modifications
- data collection, entry & queries
- monitoring/audit
- administrative tasks.

- Complexity Scale covers
 - Research Nurses
 - Data Coordinators
 - Regulatory Specialists
 - Quality Improvement & Safety Specialists
- 2,000 work hours ($\pm 10\%$) per year is the benchmark goal per full-time equivalent (FTE)
- Study and patient assignment is adjusted based on the real-time assessment of this benchmark.

Implementation

- CTMA documents trial life cycle information study start up, execution and closure
- Information is linked to each staff member to accurately measure his/her workload.
- Real-time data is analyzed by a pre-designed algorithm that will automatically calculate time spent per task category.
- The data is analyzed and made available to management, and can be drilled down to the staff, disease center, and department level.

Outcomes

- Accurately assess workload per employee based on existing patients and anticipated accruals
 - cumulative
 - completed vs anticipated
- Reassign patients or studies evenly among staff
- Reallocated FTEs within disease centers
- Use accurate task based workload assessment rather than number of open trials and accruals
- Provide real-time compliance that allows for prompt data completion
- Faster revenue realization
- Enable overall staffing and budgeting of trials
- Provides a foundation for higher level financial and efficiency analyses
- Hired schedulers to replace administrative duties of the research nurses

Future Directions

The complexity assessment can be used to assess a variety of activities based on the information compiled. Our center is conducting a comprehensive analysis of critical areas in clinical research including time to activation, cost outs, invoicing, query analysis, and regulatory tracking. Most importantly, transparent assessment of workload has resulted in increased employee satisfaction based on internal HR surveys.

Cycle/Week	v1	v2	v3	v4	v5	v6	v7	v8	v9	v10	v11
Day	1	8	15	2	8	3	4	5	6	7	8
Medical history (including eval)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
VS: weight & PS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CBC, Diff, PLT	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Chemistry W/ Na+, K+, Cl-, G	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pregnancy Test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
EKG (triplicate)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CT and/or MRI, chest x-ray or	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RECIST read by designated ra	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
confirmation imaging if neede	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
AZD1775 (oral agent, Day 1-5)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ondansetron or granisetron (o	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Dexamethasone (oral agent, D	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lipoamide (oral, at first onset	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Level 2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Level 3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Level 4	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Level 5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Data Coordinator Workload

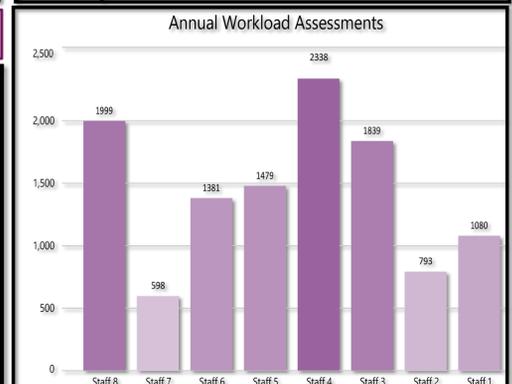
Tasks	Percent Effort
Projected Time (anticipated accruals)	34.62%
Data Entry	23.11%
Center Level Tasks	15.51%
Query	7.76%
Lab Time	5.49%
Monitoring	3.13%
Miscellaneous	3.07%
IT Issues	2.86%
Chart Prep	1.95%
Modifications	0.92%
Start Up	0.84%
Safety	0.72%

Research Nurse Workload

Tasks	Percent Effort
Projected Time (anticipated accruals)	31.41%
Center Level Tasks	25.86%
Patient Care	15.40%
Scheduling*	13.77%
Modification	3.75%
Start Up / Screening	3.15%
Miscellaneous	3.15%
Monitor/Audits	2.49%
Safety	1.03%

Regulatory Workload

Tasks	Percent Effort
Start Up	34.40%
Administrative (Documentation Compliance, Signatures, etc)	32.57%
Monitoring	15.00%
Center Level Tasks	8.17%
Monifications	5.41%
Miscellaneous	4.44%



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