

Assessment of Academic Effort for Clinical Trials Among Oncology Faculty

The James



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Background and Goals

There is no data on how many hours academic physicians spend managing clinical trials and caring for study patients.

Hypothesis: Providing care through clinical trials requires twice as much time as standard of care.

Primary objective: To determine the actual time needed to complete all clinical trial protocol good clinical practice (GCP) requirements over 1 week.

Solutions and Methods

Eligibility criteria: Practicing oncologist faculty who are PIs on >3 OSUCCC cancer clinical trials and treat >3 study patients per month

- Participants were surveyed via REDCap for 7 days
- Participants timed all clinical research activities
- Descriptive statistics were used to assess responses
 - Surveys with >50% missing data were eliminated
 - Surveys with >50% collected data, data was normalized to 7 days for regulatory, monitoring, and data analysis tasks, but not for the tasks that should only happen when research participants are seen in clinic.

Outcomes

Time Spent on Clinical Research, n=23

Task Category	Mean Time (min.)	95% CI
Regulatory	474	338-610
Clinical	413	224-602
Monitoring	110	50-170
Data Analysis	243	98-348
Translational Activities	245	81-409
Other	60	60-60
TOTAL - Minutes per week	1545	851-2199
TOTAL - Hours per week	25.75	14.2-36.65

- 80 PIs were eligible, with 29% answering the survey
- 3 PIs had <3 days of data, inaccurate data, or did not see patients and were removed from the analysis.
- Responders were medical oncologists (17) and gynecologic oncologists (3).

Range of clinical research activities per week:
305 - 3240 minutes per week

Median of clinical research activities per week:
1500 minutes (25 hours).

- Large variations can be explained by differences of clinical research involvement.

Outcomes (cont.)

Mean number of emails addressing clinical trial questions per week per PI: 121 (95% CI: 89-153)

Mean number of hours spent on all clinical trial duties: 25 hours per week.

Lessons and Future Directions

The time required for clinical research exceeds the time devoted to such activities on faculty contracts.

- Clinical research activities occupy about a 60% FTE equivalent of the participants' time
- Given the clinical research mission of NCI-designated cancer centers, time must be protected to ensure that progress is made in the care of cancer patients.
- Payments received for clinical trial activities are grossly underestimated.
 - A reassessment of dollars attributed to PI tasks should be done and the actual time spent on clinical trials should be paid for through budgeting and contracting.
 - This is a limited study at a single institution. We are currently expanding this pilot study to additional cancer centers to gain insight and confirm our pilot study data.

Join the study here: go.osu.edu/CTAT



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