

## Assessment of Academic Effort for Clinical Trials Among Oncology Faculty

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### 1. Background

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

### 2. Goals

We hypothesized that providing care through clinical trials requires twice as much time as standard of care. The primary objective was to determine the actual time needed to complete all clinical trial protocol good clinical practice (GCP) requirements over one week.

### 3. Solutions and Methods

Practicing oncologist faculty who are investigators (PIs) on  $\geq 3$  OSUCCC cancer clinical trials and treat  $\geq 3$  study patients per month were eligible to participate in this single-center, IRB-exempt, prospective pilot study of time spent on clinical research. Participants, who provided electronic informed consent, were surveyed via RedCAP surveys for seven days. Descriptive statistics were used to assess survey responses. Surveys with  $>50$  percent missing data were eliminated; for those with  $>50$  percent collected data, data was normalized to seven days for regulatory, monitoring, and data analysis tasks (see Table), but not for the tasks that should only happen when research participants are seen in clinic. Participants timed all clinical research activities.

### 4. Outcomes

Eighty PIs were eligible to participate, with 29 percent ( $n=23$ ) answering the survey. Three had less than three 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). The mean number of emails addressing clinical trial questions received per week per PI was 121 (95 percent CI: 89-153). The mean number of hours spent on all clinical trial duties was 25 hours per week.

#### Time Spent on Clinical Research

Task Category	Mean Time (minutes)	95% CR
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
<b>TOTAL - Minutes per week</b>	<b>1545</b>	<b>851 - 2199</b>
<b>TOTAL - Hours per week</b>	<b>25.75</b>	<b>14.2 - 36.65</b>

The range of clinical research activities varies by physician, from 305 - 3240 minutes per week with a median of 1500 minutes (25 hours). There are large variations between participants, but these can easily be explained by their level of clinical research involvement.

## **5. Lessons Learned and Future Directions**

The time required for clinical research exceeds the time devoted to such activities on faculty contracts. If this time were to be accounted as a full-time equivalent percentage, with the customary average of 40 hours worked per week, clinical research activities occupy about 60 percent of the 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. Further, 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, but it opens the conversation regarding investigators' efforts to advance the clinical research mission. We are currently expanding this pilot study to additional cancer centers to gain insight and confirm our pilot study data.