

## **Identification of Barriers to Accrual in a Comprehensive Cancer Center**

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### **1. Background**

Accrual to interventional therapeutic clinical trials is at the heart of any cancer center's research mission. While decreases in accrual noted since 2020 have been attributed to the coronavirus pandemic and limited clinical research staff, underlying structural issues in trial implementation, study availability and diversity, trial populations and trial sponsorship may also be significant yet often overlooked contributors to the overall decline in clinical trial accrual.

### **2. Goals**

To review decreases in interventional therapeutic trial accrual over the last 10 years compared to the previous 17 years. We hypothesize that a decreased number of patients (pts) accrued per open trial has driven an overall decrease in accrual. Identifying the underlying factors that has led to this decrease in number of pts accrued per trial will improve the clinical trial portfolio.

### **3. Solutions and Methods**

We analyzed interventional therapeutic trial data from 1996-2023 at The Ohio State University James Comprehensive Cancer Center. We identified 2236 trials and 24273 interventional therapeutic accruals over this time frame. Information regarding phase of trial, funding source, sponsorship and principal investigators was extracted.

### **4. Outcomes**

Overall therapeutic trial accrual increased annually from <100 prior to 1999 to 1663 therapeutic accruals in 2012. The number of new trials opened in any given year as well as the number of trials open for accrual at any given time increased concurrently, matching our center growth. From 2012 to 2023, accruals to trials have decreased by almost 50 percent, despite continued center growth. The number of new trial openings and trials open for accrual at any given time did not experience a similar decline but continued to increase until pandemic limitations occurred in 2020-2021. When looking at individual trials, the average number of pts enrolled on a clinical trial for the span of 1996-2023 was 10.6 pts/trial. This number peaked at 19.6 pts/trial in 2012 and decreased to 6.98 pts/trial in 2023, its lowest value since 1999. Since 1999 the overall breakdown of clinical trials by phase has not significantly changed, approximately 24 percent Phase I, 7 percent Phase I/II, 41 percent phase II, 24 percent phase III, and 4 percent other (phase II/III, expanded access, phase IV, compassionate use). Overall accrual by phase was not significantly different over time. When separated by sponsor type, average accrual per trial is highest for externally peer-reviewed trials (NCI/ECTCN) and institutional investigator-initiated trials (average 14.7 and 23.7 pts per trial, respectively), while industry sponsored trials have the lowest average accrual per trial (8.1 pts/trial). Prior to 2012, accrual to industry-sponsored clinical trials had never exceeded 50 percent of overall accrual while after 2012 it has never been below 50 percent of total accrual.

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

The composition of our clinical trial portfolio and accrual patterns based on sponsor type has significantly changed from 1996-2023. Increased reliance on industry-sponsored trials has led to lower overall accrual without decreasing overall trial numbers. To counteract this phenomenon, we must

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increase our efficiencies and timelines with industry-sponsored trials and expand our portfolio of IITs, NCI/ECTCN, and LAPS/NCTN trials.

Figure

