Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Optimizing Clinical Trial Reporting: A Metrics-Driven Analysis of CTRP & ClinicalTrials.gov

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1. Background
The Clinical Trials Reporting Program (CTRP) is a centralized database for reporting National Cancer Institute (NCI) funded interventional clinical trials. It helps identify research gaps, prioritize new trials, standardize and streamline data access, and ensure compliance with NCI reporting requirements. CTRP also facilitates reporting to ClinicalTrials.gov and supports cancer research efforts.

NCI's Center for Biomedical Informatics and Information Technology (CBIIT) collaborates with the Coordinating Center for Clinical Trials to manage CTRP by maintaining data integrity, ensuring regulatory compliance, overseeing technical architecture, and integrating data from various sources.

To ensure that the OHSU Knight Cancer Institute (KCI) complies with federal regulations, our Research Administration (RA) staff must keep the trials up to date in the CTRP and ClinicalTrials.gov databases.

2. Goals
Ensure accurate, complete, and timely clinical trial reporting by monitoring compliance, evaluating reporting efficiency, enhancing transparency, and tracking performance trends for continuous improvement.

3. Solutions and Methods
Our team utilized Smartsheet (SS) to track our both our interventional and observational investigator-initiated trials (IITs). Team members log each action item (action) into the SS trackers to ensure visibility, real-time updates, task assignments, and detailed commenting to track the progress of each action. The team members classify each action by type and track the status until the action is complete. The SS data is then imported into Tableau, a data visualization software product, to support analytical assessments on a monthly basis.

4. Outcomes
There are 292 Interventional (INT) and 121 Observational (OBS) IITs at the KCI. The number of actions across both Interventional and Observational IITs are presented in Figure 1.

The total number of actions across both types of trials is represented below in Figure 2.

The average length of each action was calculated for INT trials and OBS trials (Figure 3). The trend of INT actions taking longer than the same type of action for an OBS trial is due to the involvement of study teams to review and provide edits if necessary to the Verification and Amendment actions.

5. Learned and Future Directions
By starting the tracking process of actions, it has allowed the RA team to conduct an analysis of workflows, bandwidth, and pain points provides valuable insights into operational efficiency and areas for improvement. By examining the amounts of AIs based on trial type, action type, and average time to completion, it will allow the RA team to help coordinate the clinical trial infrastructure of the KCI to identify redundancies, streamline processes, and enhance productivity across the KCI. Assessing

bandwidth helps determine whether clinical research management teams have the capacity to meet demands or if additional resources (either from the administration or from study teams) should be added and incorporated.

Identifying pain points allows for targeted interventions to address bottlenecks, improve average time to completion, and enhance overall performance. Ultimately, this analysis will lead to data-driven decision-making, optimized resource management, and a more agile and responsive KCI RA team.

Figure

Figure 1. Number of Actions from both INT and OBS IITs

	2020	2021	2022	2023	2024
Total AIs	228	285	287	310	395

Figure 2. Number of Categorized Actions Across Years from both INT and OBS IITs

	2020	2021	2022	2023	2024
New Registration	47	66	29	43	36
Amendment	92	78	83	111	106
Update*					47
Verification	86	133	167	145	199
Results**	3	8	8	10	10

* 2024 was first year to separate verifications from Updates

** Results are only from INT studies