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

Jessica Cardin[1], David Castro[1], Lara Fournier[1], and Mindy Roberts[1]
[1]OHSU Knight Cancer Institute

BACKGROUND

The National Cancer Institute (NCI) Clinical Trials Reporting Program (CTRP) is a centralized database for reporting on trials that are in some part funded by the NCI (either directly or indirectly). 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.

GOALS

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

SOLUTIONS AND METHODS

Our team utilized Smartsheet® (SS) to track our interventional and observational investigator-initiated trials (IITs). Team members log each action item (AI) 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 with leadership on a monthly basis.

FIGURES AND DIAGRAMS

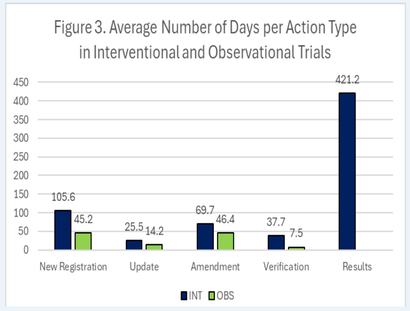
Figure 1. Number of Actions from both INT and OBS IITs

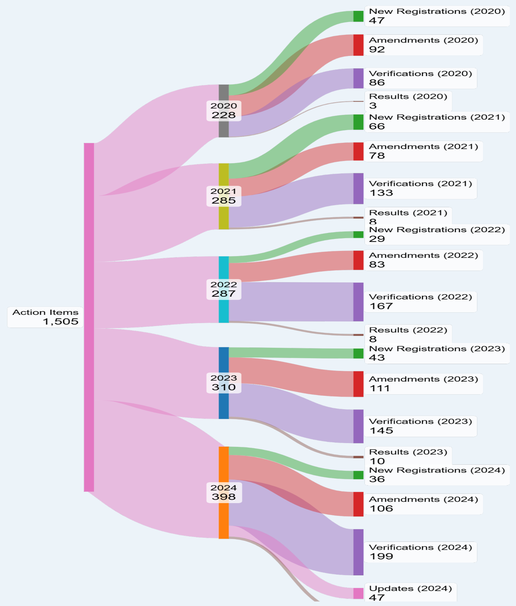
	2020	2021	2022	2023	2024
Total AIs	228	285	287	310	395

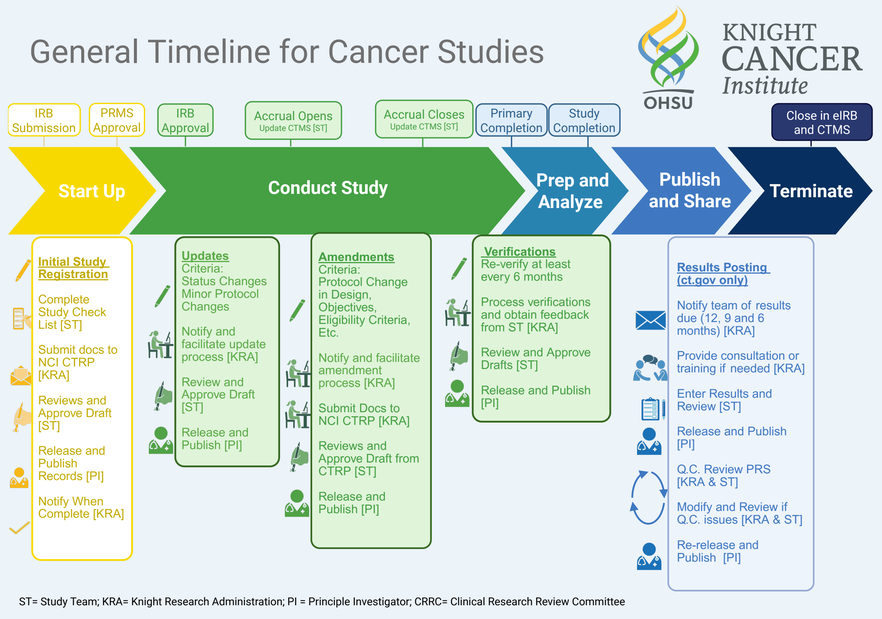
Figure 2. Number of Categorized Actions Across Years from both INT and OBS IITs

	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







ST= Study Team; KRA= Knight Research Administration; PI = Principle Investigator; CRRC= Clinical Research Review Committee

OUTCOMES

There are 292 Interventional (INT) and 121 Observational (OBS) IITs at the KCI. The number of actions are across both Interventional and Observational IITs from January 2020 - December of 2024 are presented in Figure 1. This includes studies that are actively enrolling, closed to accrual, administratively complete and and results phase.

The total number of items broken out by action item type are represented 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 can be attributed to 2 factors; 1) increase in complexity and 2) the involvement of study teams to review and provide edits if necessary to the Verification and Amendment actions.

This has created a framework to identify potential gaps in training for study teams and areas to increase efficiency. For example, the interval of time between reminder emails has been decreased to maximize responsiveness from study teams.

FUTURE DIRECTIONS

By starting the tracking process of actions, it has allowed the KCI RA team to conduct an analysis of workflows, bandwidth, and pain points, providing 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.