Category: Trial Recruitment and Study Conduct - Work in progress

Evaluating Independent Tumor Measurement Treatment Response Vendors - and Why We Chose to Stay In-House

E. Waalkes, K. Allen, P. Koya, N. Chowdhury, B. Bodin, A. Joshi, J. Mehnert, B. Pothuri

Laura & Isaac Perlmutter Cancer Center at NYU Langone Health

1. Background

Cancer centers utilize various tools to assess tumor measurements and response, including radiology scan reports reviewed by investigator, independent dedicated in-house trained radiologists, and external vendors. Prior to Fall 2023, NYU relied on investigators to complete response forms based on scan reports. This led to a large number of discrepancies such as, missing lesion measurements (40 percent), incomplete dimension measurements (29 percent), discrepancies in previous measurements (22 percent), and typos (9 percent) (n=35). Overall, 55 percent (n=64) of reports had some issue that required study team to follow up with radiology team, within our two-group sample. Additionally, delays in resolution were experienced, with an average of two (n=35, min= 1, max= 6) emails needed to address the discrepancies due to lack of a dedicated team. In 2022, NYU CTO began exploring alternative approaches such as engaging independent reviewers to reduce bias in treatment effect estimation delegated to investigators.[1]

2. Goals

We sought to ensure accurate and efficient tumor measurements at each time point. In order to accomplish this, we explored options of external vendors as well as establishing a core group of dedicated in-house radiologists, while also considering cost. We also wanted to implement a solution that allows for treatment response assessment independent of the treating investigator, to reduce bias. Given that progression free survival (PFS) and objective response rates are common primary endpoints of trials, having accurate and highly quality data for tumor response is critical.

3. Solutions and Methods

Various external companies were evaluated based on factors such as annual and per time-point fees, turnaround time, and communication channels. Concurrently, a new radiology team with expertise in oncology clinical trials was hired, and after consulting with the new leadership regarding overall cost and support, the decision was made to keep workflow in-house as it was most expedient. The implementation of this decision as of November 2023 has been a multistep project. Specifically, unique orders in the electronic medical record (EMR), which prompt the radiology team to read a specified scan (either ongoing or prior) per tumor guidelines and email a detailed report to the study team.

4. Outcomes

Since Fall of 2023, we assigned our in-house independent radiologists to complete tumor assessment forms with the aim of reducing bias in the interpretation process and improving data quality. In the initial stages of this transition, we have already observed a decrease in discrepancies in reports, down to 15 percent (n= 34) from 55 percent. Having a well-trained dedicated team has also led to reduction in communications required when addressing any discrepancies, only once among five patients. Another positive, is retaining funding within our institution.

5. Lessons Learned and Future Directions

Having dedicated radiologists with expertise in oncology clinical trials has improved reporting efficiency and data quality. The future goal of this project is to transition the radiology team from the current

practice of emailing the study team the assessments to having them upload the worksheet directly to the EMR. Clinical Research Nurses have begun taking an active role in entering scan orders, further aiming to reduce discrepancies.

References:

1. Zettler, Marjorie E., Choo H. Lee, F. Lee, Ajeet Gajra, and Bruce A. Feinberg. "Assessment of Objective Response Rate (ORR) by Investigator versus Blinded Independent Central Review in Pivotal Trials of Drugs Approved for Solid Tumor Indications." *Journal of Clinical Oncology 39*, no. 15 (2021). Accessed January 23, 2024. https://doi.org/10.1200/JCO.2021.39.15_suppl.e13570.

Figure

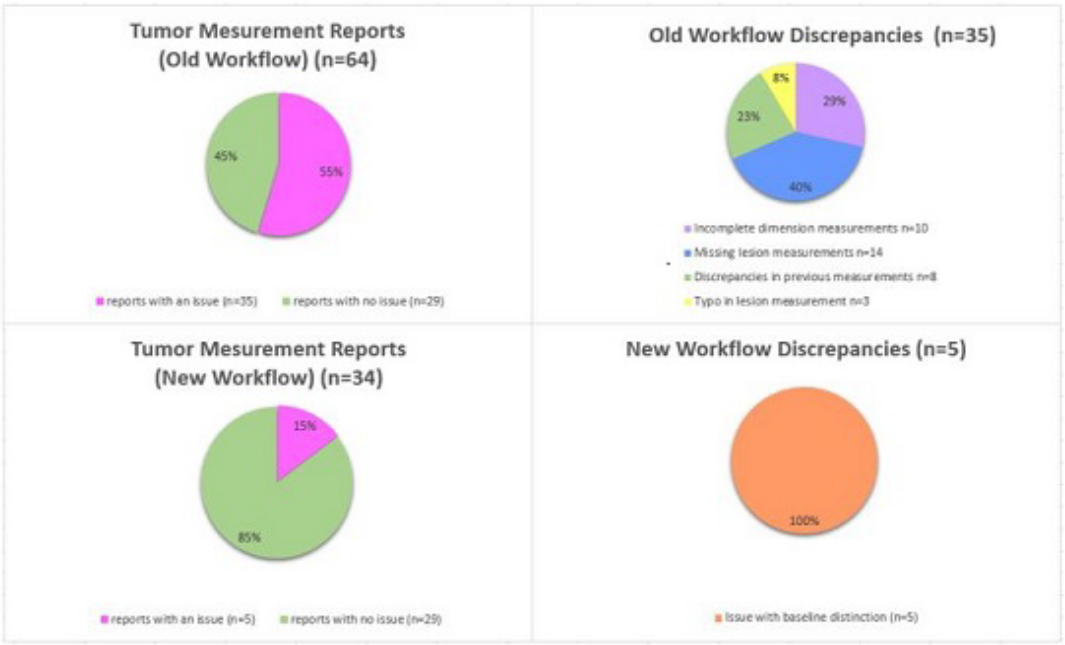

Figure 1: Reduction in Discrepancies in New Workflow and Type of Discrepancies Seen. In the old workflow, 55% (n=64) of reports had some issue requiring follow up. Issues included: missing lesion measurements (40%), incomplete dimension measurements (29%), discrepancies in previous measurements (22%), and typos (9%) (n=35). With implementation of new workflow, issues requiring follow up reduced to 15% (n=34), all of which (100%, n=5) were due to a baseline distinction error, which we aim to eliminate with new EMR order.