Category: Trial Recruitment & Study Conduct (IIT) – Work in progress

Piloting a Standardized Prescreening Process: Lessons Learned

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1. Background
Prescreening patients for potential clinical trial eligibility can maximize the success of trial enrollment and help reduce the incidence of screen failures. At the University of Arizona Cancer Center (UACC), a standardized prescreening process was piloted in March 2023. Prior to implementation, prescreening for clinical trial eligibility was not documented nor performed consistently across disease groups within the Clinical Trials Office (CTO). With this pilot, each clinical research team (CRT) followed a standard process for reviewing new and existing patients clinical trial eligibility and for entering data in the Oncore Pre-Screening database.

2. Goals
The goal of piloting a standardized prescreening process was to increase accrual to clinical trials and to help identify gaps in clinical trials portfolios. The pilot also aimed to assess the feasibility of utilizing existing staff to collect and document prescreening data rather than creating additional full-time equivalents (FTEs).

3. Solutions and Methods
Prior to implementation, a waiver of protected health information (PHI) was obtained from the institutional review board (IRB) for all open trials. A workflow was documented describing the process for obtaining and entering pre-screening patient information in the Oncore database. A designated coordinator from each CRT and all principal investigators (PIs) were trained to review new and existing patients scheduled for clinic visits. The PIs provided the following information on each patient for subsequent entry into Oncore:

- Was there a trial available for the patient?
- Was the subject consented?
- Was the subject eligible?
- Did the subject go on study?

Reasons were included for why patients were not consented, eligible or enrolled. Demographic information including race and ethnicity was also recorded. A custom report was created in Oncore to export the database to excel for review of data utility, consistency, and accuracy. Clinical Research Coordinators (CRCs) recorded time spent prescreening in the effort tracking console in Oncore.

4. Outcomes
Review of data collected between March 1, 2023, and February 1, 2024, showed 2,651 patients were prescreened for potential eligibility for clinical trials, while 146 (5.5 percent) were enrolled on a clinical trial. Total annual accrual and screen fail rates for the calendar year (CY) prior to implementation (CY 2022) were compared to those after implementation (CY2023). There was no statistically significant difference in accrual or screen fail rates between 2022 and 2023 ($p=.62$). Additionally, effort-tracking data showed nearly 900 staff hours were attributed to prescreening over the nearly one-year period.

	CY 2022	CY 2023
Total accruals	197	195
Screen fail rate	34.3%	36.3%

5. Lessons Learned and Future Directions

The significant amount of time and effort invested by CTO staff in this pilot prescreening process did not show a return on investment in terms of accrual. Despite efforts to standardize the process, the decentralization of data collection and entry lead to inconsistencies that prevented the ability to identify gaps in research portfolios. If we were to continue this process, we would dedicate 1-2 FTEs and mandate collection of data in a systematic manner to ensure gaps in trial portfolios were being filled. Despite the lack of increase in accrual, the pilot project did help create a culture of prescreening among investigators with greater focus on tailoring trial portfolios to the patient population.