IMPLEMENTING PRECISION CANCER TRIAL MATCHING: A PROSPECTIVE PRAGMATIC TRIAL TO IDENTIFY BARRIERS TO AUTOMATING CLINICAL TRIAL MATCHING

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Clinical trial enrollment is an arduous process and requires active involvement and heavy maintenance efforts by providers, trial investigators, or other clinical staff. Setting up automated processes triggers to perform a reflex clinical trial matching can kick-start the process without requiring human intervention. We present here the results from a pragmatic study that was conducted at Vanderbilt-Ingram Cancer Center (VICC) using ordering of an NGS test as a automated trigger to perform clinical trial matching for oncology patients. The goal of this study was to understand the obstacles to clinical trial enrollment at VICC and steps in the enrollment process that can be automated for a faster, efficient, and more streamlined end-to-end clinical trial matching workflow.

INTRODUCTION

Approximately 40% of cancer-related clinical trials terminate prematurely5, resulting in an immense loss of time, money, and human effort. Since successful trial accrual is paramount to drug discovery, efforts to address this challenge are needed urgently. Informatics tools can improve accruals and facilitate workflows to dramatically enhance the outcomes of the clinical trial enrollment process. Without the support of automated systems for supporting the entire breadth of the clinical trial enrollment workflow, it is only possible to make incremental improvements to the efficiency of the accrual process.

There are two aspects of information about clinical trials that need to be collected and reported accurately for improving accrual—(i) recruiting status–related information (e.g., overall recruitment status, cohort status, slot availability, etc.), and (ii) patient eligibility–related information (clinical details, disease status, prior treatments, and other inclusionary/exclusionary criteria). A single clinical trial may have many enrollment sites. Although clinical trial recruitment status for each of these sites is currently publicly available through the National Library of Medicines6 and National Cancer Institute’s Clinical Trial Reporting Program7, there can be a delay of about 5 months for recruitment updates at local sites to reflect on these resources8. This could result in inaccurate trial matches and misdirected enrollment efforts. Further, for studies with multiple cohorts or arms such as early phase studies and multi-disease trials, there is an additional burden of keeping track of slot availability as well as the recruiting status of individual cohorts/arms. A consolidated version of this information for all participating sites is not currently available from any commercial or publicly available resource. Patient eligibility–related information is part of a detailed patient data model and has been discussed in more detail elsewhere.

METHODS

Using a clinical trial matching service developed in collaboration with GenomOncology, we used the receipt of sequencing test results as a process trigger to perform reflex clinical trial matching on all patients with solid cancers (Fig. 1). Providers were randomized to receive clinical trial recommendations. An automated data query from our clinical trial management system allowed daily updates to the recruiting statuses for all open trials enhancing accuracy of trial results.

METHODS

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Fig. 1. Overall Study Design. Providers were randomized in this pragmatic study to either receive precision clinical trial enrollment (PCTE) recommendations or not.

RESULTS

Prescreening was performed on 149 patients in two phases of the study. The first phase of the study was conducted in a delayed prospective fashion, while the second phase of the study was done in a real-time prospective fashion. The results presented here are from the delayed prospective part of the study. Trial recommendations were marked by the intervention providers as: (i) will consider treatment, (ii) will consider treatment in future, and (iii) not clinically appropriate.

- 88% of  the trials that initially matched to the patient based on diagnosis and biomarkers were eventually found to be false matches
- Only 12% (n=87) of the initially identified trials were found to be actual matches.
- 72% of the false matches were attributed to inaccurate open/close status of trial cohorts as well as limited slot availability on trials.
- 46% of the trial suggestions were acknowledged by providers as appropriate current or next line treatments for patients, while 16% were deemed inappropriate due to a change in patient’s disease state or change in the patient’s care provider. No provider response was received on 36% of the recommendations.

CONCLUSIONS

It is not possible to make substantial improvements to the clinical trial enrollment workflow without building infrastructure and processes to maintain accurate status of the trial arms/cohorts and information about slot availability. Such efforts can drastically reduce the burden of manual work needed to prescreen and enroll patients to trials.

As of now, there are no private or public databases that contain reliable information about cohort level recruiting statuses. Update of such efforts by national cancer institute (NCI) or national library of medicine (NLM) has the potential to radically change the accuracy of clinical trial matching services and can be beneficial to the entire oncology community.

REFERENCES

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