Measuring the Impact of Multiple Strategies to Increase Enrollment in Molecular Targeted Trials

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BACKGROUND

Optimal patient enrollment in cancer clinical trials is increasingly hindered by molecular inclusion criteria that define rare populations. Additionally, patients may undergo internal molecular testing (IMT) or external molecular testing (EMT) through third-party vendors such as Foundation One or Tempus at various points in their care. While EMT results are uploaded into the Electronic Medical Records (EMR), extracting meaningful insights remains a significant challenge.

Although AI-driven clinical trial matching tools hold promise in addressing these barriers, many available solutions are currently more aspirational than functional. As a result, our organization has paused requests for applications (RFAs) for these tools until more robust published data demonstrate their effectiveness.

In the interim, given the complexities of trial design and data silos, we have implemented multiple strategies to enhance enrollment in molecularly targeted trials and systematically evaluated their impact.

OBJECTIVE

Given the complexity of trial design, data silos, and the absence of effective AI-driven clinical trial matching tools, we implemented four strategies to enhance enrollment in molecularly targeted trials and systematically evaluated their impact. Our analysis focused on protocols requiring more than 26 distinct rare genomic variants for eligibility.

SOLUTION IMPLEMENTED

Strategy 1- Matching based on External Molecular Testing (EMT)
We partnered with Tempus to increase enrollment to rare mutation trials. Ordering providers that had a patient identified as having an applicable mutation who resided within 50 miles from our center or were receiving treatment at pre-specified clinical sites received a written notification regarding the potential trial eligibility. Additional outreach, including reasons for not pursuing the trial was conducted.

SOLUTION IMPLEMENTED (CONTINUED)

Strategy 2 – Matching based on Internal Molecular Testing (IMT)
We partnered with our internal Clinical Research Informatics (CRI) team to develop an algorithm that would identify potentially eligible patients with internal molecular testing (IMT) and other select criteria (i.e., age, prior treatments, last visit, etc.).

Strategy 3 – Integration of trial eligibility into standard of care pathways
We partnered with our hospital to integrate specific clinical trials into our electronic standard of care pathways (Clinpath) that clinicians need to utilize for documenting any change in therapy and compliance with peer reviewed standards of care.

Strategy 4 – Clinical Research Staff Manual Pre-Screening
We implemented a manual process where our Clinical Research Coordinators (CRCs) pre-screened patients who presented to clinic on a weekly basis. All new patients or patients who progressed and needed a new treatment plan recommendation were flagged and manually screened by review of EMR for molecular targeted trial eligibility.

RESULTS

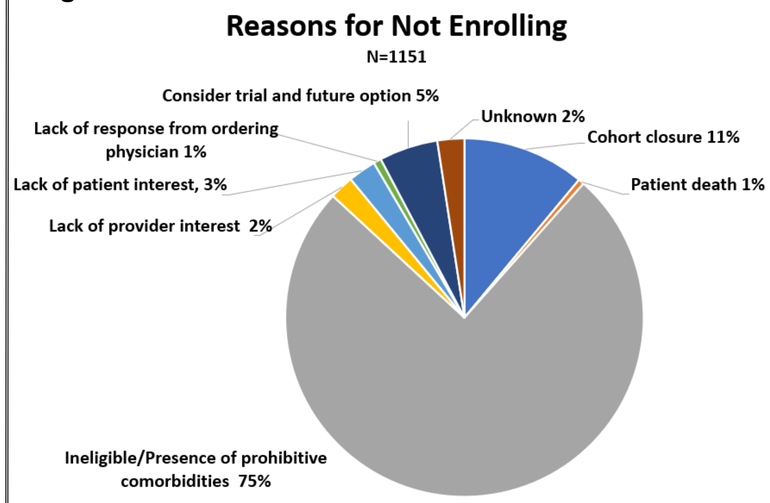
A total of 1,208 patients were identified and pre-screened across the 4 strategies and 57 patients were enrolled as a result (Table 1). The primary factor leading to non-enrollment was clinical situations precluding trial participation. Other factors comprised unresponsiveness from healthcare providers, lack of interest from the patient, and the dynamic nature of the trials, including cohort closures and protocol amendments that revised the eligibility criteria (Figure 1).

Table 1

	# Patients Identified/Pre-Screened	# Patients Consented	# of Patients Enrolled	% of Patients Enrolled w/ Genomic Variants
Strategy 1	38	0	0	0%
Strategy 2	157	1	1	0.6%
Strategy 3	850	29	23	2.7%
Strategy 4	163	89	33	20.2%
Total	1,208	119	57	4.7%

RESULTS (CONTINUED)

Figure 1



LESSONS LEARNED & FUTURE DIRECTIONS

The four strategies represented independent approaches to augmenting enrollment in molecularly targeted trials. The relatively low enrollment conversion rate underscores the persistent challenges associated with recruiting participants for rare disease trials. To effectively increase enrollment in these trials, a comprehensive approach that incorporates multiple strategies is necessary. These strategies require an investment in specialized oncology bioinformatics personnel, the establishment of a robust data warehouse, and dedicated clinical research staff.

Future directions include enhancing the data warehouse to obtain access to IMT and EMT results uniformly, training additional research staff to perform manual pre-screening, and increasing the number of trials and the number of physicians using the integrated pathways tool. Lastly, we will continue to assess potential AI-driven clinical trial matching solutions and look for published studies that demonstrate their impact on improving enrollment.