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NCI-MATCH cancer trial reaches 6,000-patient tumor sequencing goal two years early

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The rapid pace of patient enrollment in the National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH or EAY131) precision medicine cancer treatment trial will result in the study reaching its goal of sequencing the tumors of 6,000 patients in June, nearly two years sooner than expected. The ECOG-ACRIN Cancer Research Group (ECOG-ACRIN), which is leading this signal-finding trial under the sponsorship of the National Cancer Institute (NCI), reports that wide-scale adoption throughout the NCI National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) caused the unprecedented rate of patient enrollment.

"NCI-MATCH's availability through more than 1,100 academic cancer centers and community hospitals reflects the broad interest in the promise of genomics, and the ability of such a study to deliver that promise to the community," said ECOG-ACRIN study co-chair Peter J. O'Dwyer, MD, University of Pennsylvania.

The more than 1,100 trial sites are all members of the research groups in the NCTN that design and lead trials focused on adult cancers: the Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, NRG Oncology, and SWOG.

"An important discovery in the patients we have tested so far shows us that every tumor gene abnormality we are studying is less common than

expected in this study population, ranging from 3.47 percent to zero," said ECOG-ACRIN study chair Keith T. Flaherty, MD, Massachusetts General Hospital Cancer Center.

"This finding adds to the ground-breaking nature of the NCI-MATCH trial, which is shedding new light on the fact that for several of the treatment arms to reach their 35-patient goal, we really need to look at tens of thousands of patients," he said.

The NCI-MATCH trial had a goal to ensure that 25 percent of patients enter with rare or uncommon cancers, defined as those other than colorectal, breast, non-small cell lung, or prostate.

"We are surprised that over 60 percent of patients came into the trial with less common types of cancer, which far surpassed our goal," said Dr. O'Dwyer. "We find it exciting that this high proportion of less common malignancies opens options for advances in these cancers."

Another contribution to the rapid accrual rate was the availability—within the trial—of tumor gene sequencing for every patient who submitted tissue for testing. The NCI provided funding to reimburse participating sites for biopsy procedures and paid for the tumor gene sequencing performed by the trial's four-laboratory network, assembled especially for this trial.

New Trial Collaborations

Tumor sequencing within the trial is capped at 6,000 patients for the purpose of determining study eligibility. For the next several weeks, patients who registered for tumor screening before the deadline of May 22, 2017, will complete the process. Then, tumor testing within the trial will come to an end.

Even though tumor gene testing will no longer be done within the trial, the trial is not ending. It continues with a new study entry process that casts a wider net for patients through collaborations with commercial and academic laboratories.

"We have found a way to move the trial toward real-world genomic analysis of tumors," said Dr. O'Dwyer. "It's becoming more common for oncologists to order genomic tumor testing to guide clinical care for our patients. This is an optimal time to align the trial with this current practice as a strategy to proactively seek out additional patients."

To complete patient enrollment to multiple treatment arms, ECOG-ACRIN is implementing collaboration agreements formed by the NCI with Caris Life Sciences and Foundation Medicine, Inc., two of the largest private-sector molecular testing laboratories. Collectively, these labs conduct sequencing for tens of thousands of people with cancer.

The collaboration agreements between the NCI and commercial labs are for Caris Life Sciences and Foundation Medicine, Inc. to notify any physician at any of the more than 1,100 clinical sites participating in NCI-MATCH when the genomic test they ordered to guide clinical care (Caris Molecular Intelligence, FoundationOne, or FoundationOne Heme) finds results that could make a patient eligible for one of several NCI-MATCH treatments.

"These new collaborations offer a paradigm shift, as the new goal for the trial is to find patients, rather than patients having to find the trial," said Dr. Flaherty. "We look forward to incorporating this trial into the independent, routine testing already being done out in the community as soon as possible."

How They Work

The new study entry process is available to physicians at any participating site who order testing directly from the commercial laboratories. For participating sites, visit the NCI website.

The labs do not specifically test patients for the NCI-MATCH trial.

These labs will look for tumor gene abnormalities being studied in NCI-MATCH as part of their normal testing procedures. When a treating physician at a site that is participating in the trial orders genomic sequencing independently (outside of the trial) to guide clinical care for his or her patients, the labs will look for trial matches in these patients. If found, the lab will include the information in the broader genomic testing report as just one potential treatment option. The oncologist can take the information into consideration when discussing treatment options with his or her patients.

If a patient registers for NCI-MATCH, the physician will evaluate them further to determine if they meet the eligibility criteria for the specific treatment arm, and if so, the patient will be able to enroll for treatment. The trial's expert panel will review every patient case, as it has done since the start of the trial.

Trial leaders chose these labs because of their capabilities in three areas:

Demonstration Project

1. A mechanism that can review tens of thousands of patient cases is necessary to identify small subsets with tumor gene abnormalities being studied in the NCI-MATCH trial. These labs are already testing a high volume of patients.

2. Trial leaders have fully vetted the commercial assays and confirmed that the comprehensive and highly-validated genomic profiles are

particularly sensitive to the tumor gene abnormalities being studied in the trial.

3. Collaboration requires that the labs provide assay results in a format that can be uploaded into MATCHbox, the trial's informatics system that generates treatment assignment information for the trial's panel of experts to review.

Two academic laboratories already involved in the trial will perform testing on their own patients, using their institutional assays. These are The University of Texas MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center.

The new study entry process will ramp up with a demonstration project focusing on 19 arms.

To help the trial adjust to the high volume of patient cases, the labs will initially report on only 19 of the 26 treatment arms still seeking patients. Each of the 19 arms addresses a tumor gene abnormality that occurred in 1.5 percent or fewer patients tested thus far. The potential for the outside labs to report on the remaining open treatment arms will be considered later in the summer once the demonstration project is complete.

To learn the status of each treatment arm, visit trials/nci-match-eay131" target="_blank">www.ecog-acrin.org/trials/nci-match-eay131

Provided by ECOG-ACRIN Cancer Research Group