importance of the NCI-MATCH trial

NCI-MATCH is one of several trials sponsored by the National Cancer Institute (NCI) that are investigating the strategy of precision medicine. This strategy examines the benefit of gathering genetic information about an individual’s cancer and using an agent or combination of agents to target the specific genetic abnormality. This phase II trial consists of multiple small (N = up to 35) subprotocols (treatment arms) that enroll adults with advanced solid tumors, lymphomas, and myeloma (only patients with plasmacytomas for which formalin-fixed paraffin-embedded [FFPE] or fresh biopsy tissue of the tumor will be submitted)—including up to 25% with rare cancers—whose tumors are no longer responding to standard therapy and have begun to grow. As a master protocol, or umbrella trial, NCI-MATCH can add or drop new treatments over time. The trial opened in August 2015 with 10 arms and, after scientific review, is expanded to 24 arms (as of May 2016). Additional treatment arms are in development and will open to enrollment in the upcoming months.

NCI-MATCH trial objectives

The NCI-MATCH trial is using broad-based genomic prescreening to assign patients with tumors harboring specific molecular abnormalities to relevant targeted treatments. This is a unique opportunity to collect information about:

- The prevalence of mutations, translocations, and amplifications in genes associated with cancer
- How tumors with such abnormalities respond to targeted therapy in the refractory setting

site participation

- Institutions are eligible to participate if 1) they are located in the United States; 2) they participate in the NCI National Clinical Trials Network, NCI Community Oncology Research Program (NCORP), or Minority/Underserved NCORP; and 3) they are a member of the Alliance for Clinical Trials in Oncology, Children’s Oncology Group, ECOG-ACRIN Cancer Research Group, NRG Oncology, and/or SWOG
- The NCI Central Institutional Review Board (CIRB) is the only IRB of record for participating sites until further notice. Institutions must be a member of the CIRB and use the CIRB as the IRB of record for the NCI-MATCH trial.
- The CIRB forwards regulatory approvals directly to the Cancer Trials Support Unit (CTSU) Regulatory Office on behalf of all member sites. Each participating site may check its regulatory status at www.ctsu.org> Regulatory>Site Registration> Select Protocol EAY131
- For CIRB-related questions, contact the CIRB HelpDesk at NCICIRBContact@emmes.com or leave a message at 1-888-637-3711. Inquiries are processed Monday through Friday between 8 AM and 4 PM.
- For clinical questions about a particular subprotocol, contact the appropriate NCI-MATCH subprotocol chair; the relevant contact information is included in each subprotocol document
- For eligibility questions, contact ECOG-ACRIN’s Executive and Regulatory Officers at EA.Execofficer@jimmy.harvard.edu and EA.RegOfficer@jimmy.harvard.edu
- For all other questions, please email match@jimmy.harvard.edu. Questions will be triaged to the appropriate group within the MATCH team; a follow-up email will be sent once an answer is received. The high volume of questions prevents an immediate response, especially for patient-specific inquiries. Please manage these queries locally via discussion with the treating physician, using information in the protocol.

Funding

Please visit the funding tab under the EAY131 protocol page on the CTSU website, www.ctsu.org, to view the most current funding sheet.
### First Registration Process Flow

**1** Sites must use the CIRB as the IRB of record for the NCI-MATCH trial. Site registers eligible patient into CTUS OPEN system to Screening Step 0.

**2a** Site submits biospecimens to the ECOG-ACRIN CBPF at MDACC within 48 hours of collection.

**2b** Site sends biospecimens to ECOG-ACRIN Central Biorepository and Pathology Facility (CBPF) at MD Anderson Cancer Center (MDACC) in collection kit provided.

**3a** If treatment assignment is available for selected patient, Rave® eligibility check form becomes available in Rave for selected subprotocol. 

**3b** If patient is not eligible for first treatment assignment, a reevaluation of screening results occurs for possible second treatment assignment. If second treatment assignment is available for patient, Rave eligibility check form becomes available in Rave for selected subprotocol.

Sample processing time ~14 days; treatment assignment automatically loads into Rave.

### Biopsy Collection

- Sites are encouraged to meet with their affiliated surgeons and interventional radiologists to make proactive site plans to allow for rapid scheduling of biopsies (ie, block one slot per week on the interventional radiology schedule) to ensure that biopsies are completed as soon as possible
- Percutaneous biopsies will be performed on patients with solid tumors or lymphomas, or myeloma plasmacytomas. Multiple myeloma patients only able to submit bone marrow aspirates for screening are ineligible
- Patients may undergo up to 2 different MATCH treatments following each biopsy; those ineligible for Step 1 treatment may be eligible to have their screening results rerun through MATCHbox
- Maximum number of potential biopsies = 5
  - Step 0: Patient is initially screened and undergoes biopsy 1 (for all patients enrolled) or FFPE tumor tissue (metastatic tissue preferred) is submitted from a prior procedure
    - If the biopsy does not contain enough tumor tissue for analysis, a second biopsy may be part of this initial screening step. Potential biopsy 2
  - Step 1: Patient has an actionable mutation and is assigned and re-consented to a subprotocol. Patients who progress are allowed to have a rebiopsy
  - Step 2: Patient has a biopsy. Potential biopsy 3
    - If the biopsy does not contain enough tumor tissue for analysis, a second biopsy may be part of this screening step. Potential biopsy 4
  - Step 4: Patient progresses and a biopsy is collected for research to understand the mechanisms of resistance. Potential biopsy 5
- Please contact the NCI-MATCH EAY131 Call Center, 844-744-2420, for questions regarding specimen collection and results
## Important Tips for Successful Enrollment

- Patients must meet eligibility criteria for screening, and as necessary for each relevant subprotocol
- For any issues related to patient enrollment on Screening Step 0, contact the CTSU HelpDesk at 1-888-823-5923 or ctsucontact@westat.com. CTSU responds to inquiries within one business day
- Contact the NCI-MATCH Pathology Coordinator at the ECOG-ACRIN Central Biorepository and Pathology Facility at MDACC at 1-844-744-2420, 1-713-745-4440 international, or eacbpf@mdanderson.org for questions regarding the following:
  - Instructions for submitting biospecimens
  - Potential anticipated problems
  - Not receiving a notification of candidate treatment within 14 days of specimen submission

## Contact Information

**ECOG-ACRIN Study Chair**  
Keith T. Flaherty, MD  
EA Deputy Chair of Biomarker Sciences  
*Massachusetts General Hospital*  
Cancer Center  
617-724-4800  
kflaherty@partners.org

**NCI Study Chair**  
Alice P. Chen, MD  
*Developmental Therapeutics Clinic*  
DCTD/NCI  
301-496-4291  
chenali@mail.nih.gov

**ECOG-ACRIN Study Co-Chair**  
Peter J. O’Dwyer, MD  
EA Chair of Gastrointestinal Cancer Committee  
*University of Pennsylvania*  
215-662-7606  
peter.odwyer@uphs.upenn.edu

**NCI Study Co-Chair**  
Barbara A. Conley, MD  
Associate Director  
*Cancer Diagnosis Program*  
240-276-6505  
conleyba@mail.nih.gov

**ECOG-ACRIN Laboratory Lead**  
Stanley R. Hamilton, MD  
EA Deputy Chair of Laboratory Sciences  
*MD Anderson Cancer Center*  
713-792-2040  
shamilto@mdanderson.org

**NCI Laboratory Lead**  
Mickey Williams, PhD  
Director of the Molecular Characterization Laboratory  
*Frederick National Laboratory for Cancer Research*  
301-228-4654  
mickey.williams@nih.gov

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### For More Information

To learn more about this study or to download a copy of this brochure, visit the ECOG-ACRIN website at [www.ecog-acrin.org/nci-match-eay131](http://www.ecog-acrin.org/nci-match-eay131). Additional information about this trial is posted on the National Cancer Institute (NCI) website at [www.cancer.gov/nci-match](http://www.cancer.gov/nci-match).

This study is co-developed by the NCI, part of the National Institutes of Health, and the ECOG-ACRIN Cancer Research Group, part of the NCI National Clinical Trials Network (NCTN). It is being led by ECOG-ACRIN. To learn more about the NCTN, visit [www.cancer.gov/nctn](http://www.cancer.gov/nctn).
1 Image submission requirements: see protocol section 11 for submission instructions.
2 For multiple myeloma patients (excluding plasmacytoma), a bone marrow aspirate is required.
3 Patients may be eligible to be reconsidered for treatment.
4 For patients who have consented to undergo the research biopsy, register to step 8.
5 aMOIs = actionable mutations of interest.