Registration for Treatment Assignment Based on Genetic Testing

WHY consider participating in this study?

- Research studies are an important way to test the effectiveness of new therapies and approaches for treating cancer.
- The usual approach (i.e., the standard treatment most people receive after a diagnosis of cancer) involves surgery, radiation, and/or chemotherapy.
- ComboMATCH/EAY191 will help determine if you are eligible to participate in a trial testing new combinations of anti-cancer drugs, based on the characteristics of your tumor. The drug combinations have shown evidence that they may be more effective than single-drug therapy in treating some cancers.
  - If you participate in ComboMATCH, you could be matched to a specific treatment trial based on the genetic makeup of your tumor. If you are matched, you will be offered the treatment prescribed in that study, which may involve one or more of the standard treatments.
  - ComboMATCH is being done to help see whether a combination of drugs based on your tumor’s genetic characteristics will be a better treatment than the usual approach.

WHAT does this study involve?

- All ComboMATCH participants are required to have, or previously have had, a sample of their tumor tested by a ComboMATCH-designated laboratory, and the results must show that you are able to join the study.
- If your tumor has a genetic change or mutation that is targeted by one or more of the drugs used in ComboMATCH, you will be asked to participate in a treatment trial, and a sample of your tumor, if available, will be sent to the ComboMATCH study central laboratory.
  - For patients aged 18 or older: if your tumor can be biopsied with minimal risk and you have matched to a treatment trial, you will need to have a new biopsy prior to starting treatment. If your tumor can't be biopsied, you must have tissue available from a previous biopsy that can be used for the study.
  - For patients younger than 18 years old, you will be asked if you are willing to:
    » Submit previously biopsied tissue, if available, or
    » Have a new optional biopsy for research purposes, if the biopsy can be performed at minimal risk.
  - The results will be compared to the results that were provided from the ComboMATCH-designated laboratory.

WHO will take part in this study?

- Approximately 2900 people will take part in this study. Participants must have cancer that has spread to nearby tissue or lymph nodes (locally advanced) or to other places in the body (advanced) that has gotten worse after standard treatment; ComboMATCH is also for patients with a type of advanced cancer for which no standard treatment exists.
- You can decide to stop taking part in this study at any time, even after you have enrolled.

WHAT are the costs of taking part in this study?

- You and/or your insurance plan will need to pay for some or all of the costs of medical care you get as part of this study. Please check with your insurance company to find out what they will pay for.
- You will not pay for:
  - the costs of the genetic test performed on the submitted tissue
  - any other research studies done on the submitted tissue samples
  - the cost of shipping the samples to the central lab
- If you are eligible to get study drug(s) on a treatment trial, any costs of being in the study will be discussed along with details of your treatment.
**HOW does ComboMATCH work?**

Your tumor is tested by a ComboMATCH-designated lab and the lab notifies your doctor that you may be eligible for treatment on ComboMATCH. You will stop any treatment for your cancer that you may be taking.

**ComboMATCH Study Registration**
You agree to take part in ComboMATCH. Your test results are sent by the ComboMATCH-designated lab for central review.*

*Note: The screening steps can take 1–2 weeks.*

**Off Study**
Tumor does not have a genetic change targeted by a study drug or you are not able to have the study drug for other reasons.

The central review of the designated lab’s test results confirms your tumor has a genetic change targeted by study drugs.

You agree to take part in a ComboMATCH treatment trial, and it is determined by your doctor that you are eligible to take part in that treatment trial.

You will undergo a new biopsy prior to receiving treatment if you are ≥ 18 years and have biopsiable disease that can be done with minimal risk OR

If you do not have biopsiable disease or are < 18 years old, you must be willing to submit tissue, when available, for use by the study.

**ComboMATCH Treatment Trial**
You will receive study drugs until/if your cancer gets worse or if you develop serious side effects.

After completion of the ComboMATCH treatment trial, you may be asked for a biopsy (optional) and blood (optional) to help understand why the tumor grew.

*It is possible that, even though your tumor has a mutation that is targeted by one of the treatment trials in ComboMATCH, you will not be able to enroll in that treatment trial. Some reasons for this include:
- The treatment trial is “full”—it has registered all the needed patients.
- You do not qualify for the study for other reasons, such as previous drugs you took for your cancer, or your physical condition.

**IF you would like to know more**

- About the ComboMATCH/EAY191 study, talk with your doctor, or:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org) and search EAY191, then select the link to EAY191.
    - For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
    - For a current list of the ComboMATCH treatment trials: visit [ecog-acrin.org/treatment-trials/](http://ecog-acrin.org/treatment-trials/)
  - Call the NCI Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- About clinical trials:
  - General cancer information: visit the NCI website at [www.cancer.gov](http://www.cancer.gov)
- About ECOG-ACRIN:
  - Visit [www.ecog-acrin.org](http://www.ecog-acrin.org)
  - For a list of patient resources and links to patient advocacy groups, visit [https://ecog-acrin.org/patients/resources](https://ecog-acrin.org/patients/resources)

ComboMATCH is a large precision medicine initiative with a coordinated set of clinical trials evaluating novel drug combinations. Its patient registration trial is being led by the ECOG-ACRIN Cancer Research Group and National Cancer Institute; treatment trials are being led by the Alliance for Clinical Trials in Oncology, Children’s Oncology Group, ECOG-ACRIN, NRG Oncology, and SWOG Cancer Research Network.