

Fast Facts

Molecular Analysis for Combination Therapy Choice(ComboMATCH)

Eligibility Criteria Screening

1. Patient must have measurable disease.
2. Patient must have an ECOG performance status between 0-2.

OR

Patient must have Lansky performance status of $\geq 50\%$ or Karnofsky performance status of $\geq 50\%$.

3. Patient must be deemed potentially eligible for a ComboMATCH Treatment Trial as assessed by the enrolling provider.
4. All patients must have sequencing results available from ctDNA or tumor tissue testing from an NCI credentialed Designated Laboratory (DL). If both results are available, then both CLIA reports must be submitted.
5. Patients must have locally advanced or advanced histologically documented solid tumors requiring therapy and meet one of the following criteria:

- Patients must have progressed on at least one line of standard systemic therapy.

OR

- Patients whose disease has no standard treatment that has been shown to prolong overall survival.

6. Patient must meet one of the following requirements:

- i. Patients 18 years and older who have tumor amenable to minimal risk image-guided or direct vision biopsy and must be willing and able to undergo a tumor biopsy to obtain samples for research if the patient is to enroll in a ComboMATCH treatment trial. For patients who are enrolled by ctDNA AND do not have tissue that can be collected, the fresh tissue biopsy requirement is waived. However, a request for archival tissue collected within 1 year of study is required.

OR

- ii. Patients 18 years and older who do not have disease that is biopsiable at minimal risk to the patient must confirm availability of an archival tumor tissue specimen for submission for research if the patient enrolls to a ComboMATCH Treatment Trial. This tumor tissue must meet the following criteria:

- Tissue must have been collected within 12 months prior to registration to the EAY191 Registration Trial
- Formalin-fixed paraffin-embedded tumor tissue block(s) or slides must be available (see Section [5.3](#)).

OR

- iii. Patients under 18 years old must confirm willingness to submit an archival tumor tissue specimen, if available, for research if patient enrolls to a ComboMATCH Treatment Trial. This tumor tissue must meet the following criteria:

- Formalin-fixed paraffin-embedded tumor tissue block(s) or slides (see Section

5.3).

NOTE: See specific ComboMATCH Treatment Trial protocol for tissue collection and management instructions.

Performance of the mandatory research biopsy or submission of pre-trial FFPE and collection and submission of the blood specimens for the integrated studies will be performed under the consent authority of the specific treatment trial protocol to which the patient is registered. No procedures to collect specimens for research only are to be performed for patients registered to the EAY191 Registration Trial only.

NOTE: Each ComboMATCH Treatment Trial contains specific eligibility criteria. If patient is found to not be eligible for the assigned ComboMATCH Treatment Trial, indication of ineligibility will trigger re-evaluation and potential assignment to another Treatment Trial.

Schema

