Beat AML Master Trial: *A Groundbreaking Clinical Trial for Acute Myeloid Leukemia Patients*

What is the Beat AML Master Trial?

The Leukemia & Lymphoma Society (LLS) is leading this groundbreaking precision medicine approach to improve cancer treatment. This Master Trial will take place at multiple academic research institutions and involve many researchers, drug companies, a company that provides genetic analysis, and a clinical research organization. LLS's goal is to test a number of investigational drugs in development to speed up approval and increase effectiveness of treatments for patients diagnosed with AML.

The five centers initially participating in this trial are:

- Memorial Sloan Kettering Cancer Center in New York
- The Ohio State University Comprehensive Cancer Center in Ohio
- OHSU Knight Cancer Institute in Oregon
- Dana-Farber Cancer Institute in Massachusetts
- Massachusetts General Hospital Cancer Center in Massachusetts

More centers will be available soon.

To participate in this study, a patient must be newly diagnosed with AML and be 60 years or older.

Why is this study being done?

There has been no change in the standard of care for patients with AML in 40 years. LLS is undertaking this unique collaborative approach to develop better individualized treatments for patients diagnosed with AML.

How is this study being done?

Newly diagnosed AML patients will be asked to consent to provide a bone marrow biopsy which will be quickly sent for genomic screening. The screening takes up to seven days. The patient will be assigned to a specific treatment arm of the trial based on the results of the screening.

If a patient does not have a genetic marker that would place him or her onto a specific arm of the trial, the study will offer therapy with a different investigational AML agent that has shown broad activity against AML. Every patient who enters the trial will receive an option for treatment.

How long does the study last?

Patients in the trial will participate in three phases. The first phase includes the seven-day genomic screening. The second phase is the treatment, which will vary depending on which arm the patient is placed in. The third phase includes a follow-up period of 28 days or longer after treatment is over. The total duration may last from one to two years.

How is the Beat AML Master Trial different from other AML trials?

This trial is designed to speed up the process of finding better treatments for AML. A typical clinical trial only studies one drug or one combination of drugs. This trial will begin with four different treatments, each being tested in one of several arms of the trial based on a particular genetic mutation. In doing so, the trial is designed to understand multiple drugs and their effectiveness in treating patients diagnosed with AML.

Further, this trial is only open to newly diagnosed, untreated patients. Most AML clinical trials are for relapsed or refractory patients.

This Beat AML Master Trial has the potential to stand as a model for future cancer clinical trials.

Trial Access and Participation

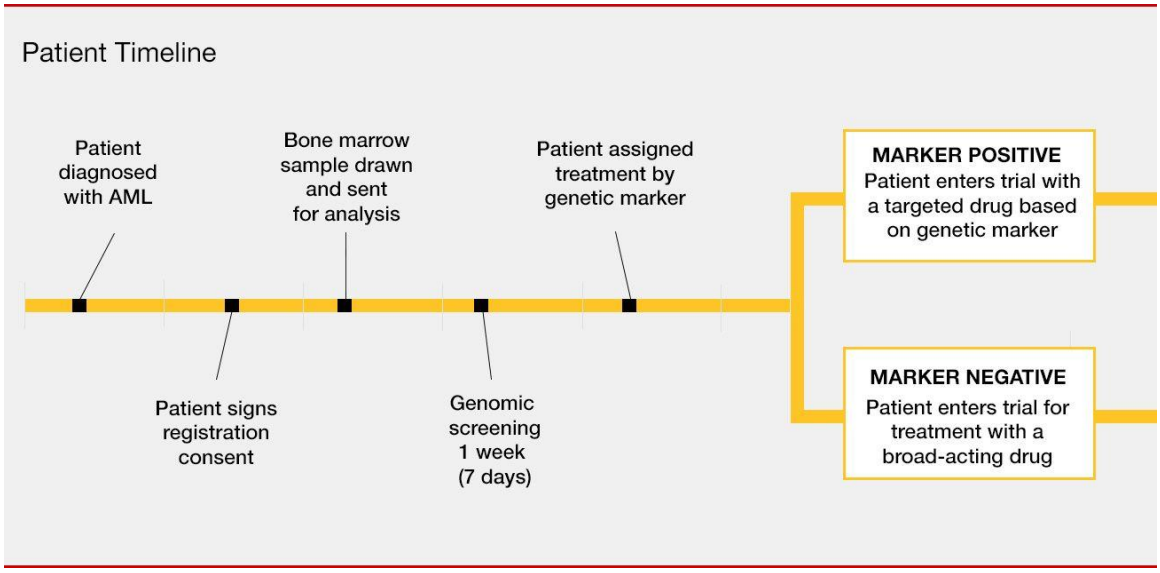
Clinical trials are an essential step in the development and approval of a new drug. Only five percent of U.S. patients participate in cancer clinical trials so a concerted education and awareness effort – to health care practitioners and patients and their caregivers – will be a major component of the Beat AML initiative.

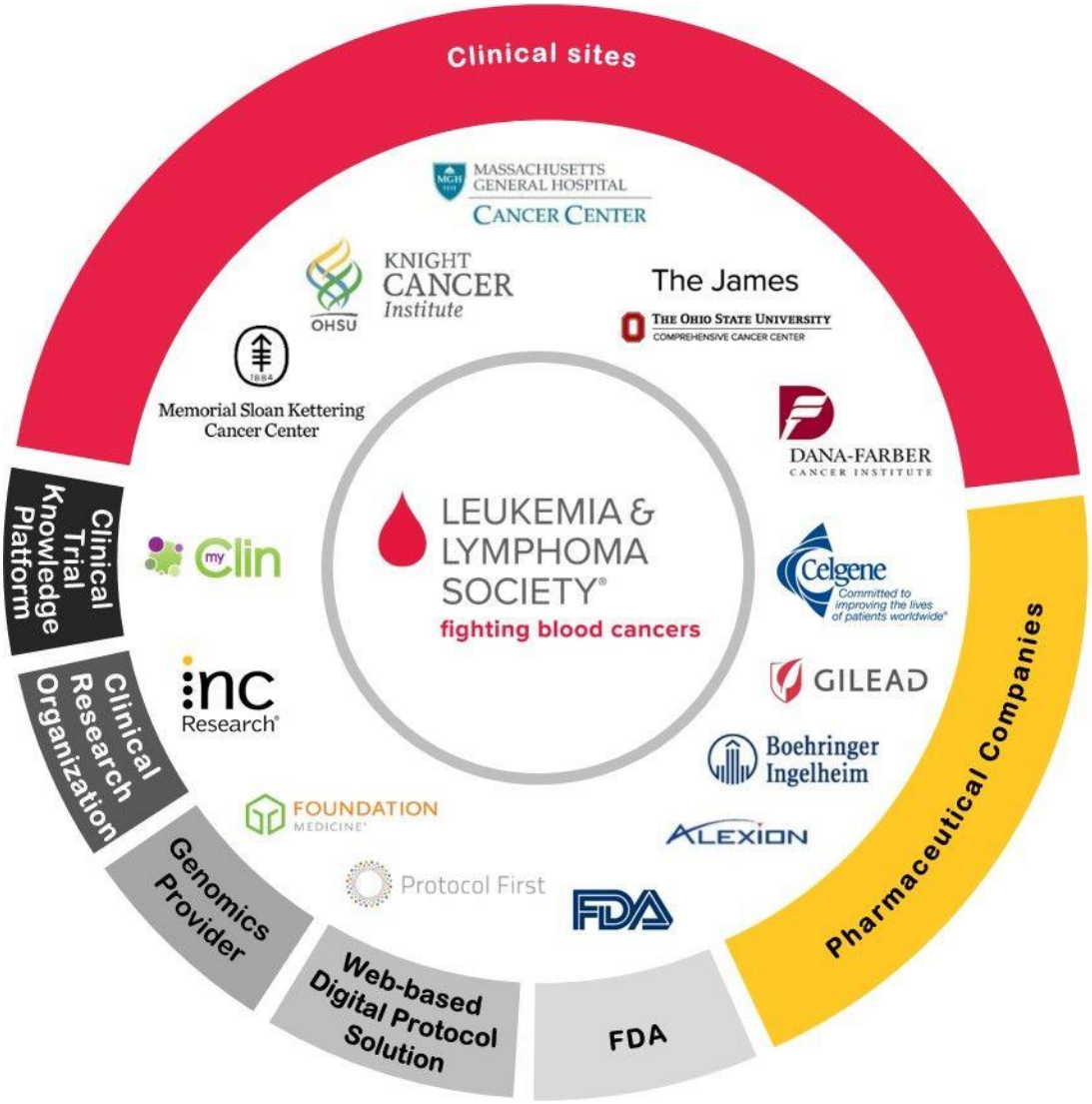
A Model for Future Trials

LLS is sponsoring the trial and holds the Investigational New Drug (IND) for all of the agents. This frees multiple pharmaceutical companies to participate by providing their drugs for the trial. The trial will be centralized via a clinical research organization and a single genomic provider. The protocol is designed to facilitate a collaborative, fast-acting clinical trial consortium that represents an attractive venue for testing new agents moving forward. This Master Trial has the potential to stand as a model for future cancer clinical trials.

How many patients will take part in this trial?

LLS is looking for 500+ patients for this trial.


Patient Timeline
Patient diagnosed with AML
Patient signs registration consent
Bone marrow sample drawn and sent for analysis
Genomic screening 1 week (7 days)
Patient assigned treatment by genetic marker
MARKER POSITIVE
Patient enters trial with a targeted drug based on genetic marker
MARKER NEGATIVE
Patient enters trial for treatment with a broad-acting drug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FDA
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Genomics Provider
Clinical Research Organization
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CANCER CENTER
KNIGHT CANCER Institute
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