Beat AML Master Trial®

A groundbreaking collaborative clinical trial targeting acute myeloid leukemia
What is the Beat AML Master Trial®?

The Leukemia & Lymphoma Society (LLS) is leading the Beat AML Master Trial, a groundbreaking collaborative clinical trial testing several novel targeted therapies for patients with acute myeloid leukemia (AML). AML is one of the deadliest blood cancers and the most commonly diagnosed form of leukemia in adults.

Why is this study being done?

There have been few advances in AML treatment in 40 years. Standard treatment has historically been intensive chemotherapy followed by a stem cell transplant once a patient is in remission. With today’s therapies, only one in four AML patients survives five years after diagnosis.

In the United States, AML takes the lives of more than 10,000 people each year. AML generally affects adults 60 years and older. These older patients cannot tolerate standard chemotherapy – it is simply too toxic. To address this unmet urgent medical need, LLS is leading the offensive against AML through a collaborative precision medicine approach.

Who is involved?

LLS is leading the Beat AML Master Trial and is the first nonprofit cancer organization to sponsor a clinical trial. The trial is open at multiple academic research institutions across the country, where several investigational targeted therapies are being tested.

The U.S. Food and Drug Administration (FDA) granted LLS permission to run the trial and worked closely with LLS to develop the trial protocol. Three world-renowned blood cancer scientists lead the clinical trial: Brian Druker, MD, The Knight Cancer Institute at Oregon Health & Science University; John Byrd, MD, The Ohio State University Comprehensive Cancer Center; and Ross Levine, MD, Memorial Sloan Kettering Cancer Center. Many other prominent researchers lead each arm of the trial at their institutions.

This is the first collaborative clinical trial in a blood cancer and involves multiple medical institutions, drug companies, and the FDA, all of whom have committed to working collaboratively to drive this master clinical trial forward.

There have been few advances in treatment for AML in 40 years and LLS aims to change that through a precision medicine approach. AML is extremely complicated to treat because it is not a single disease, but a group of more than 10 different major subtypes and other rare mutations. With advances in genomics, we can now identify and target specific types of AML. This precision medicine approach is the key to new therapies for patients.

With the Beat AML Master Trial, newly diagnosed patients who are 60 years of age or older are screened for genetic changes or mutations driving the disease. This "genomic screening" process takes up to seven days. A patient is then assigned to a therapy based on their genetic profile. If a patient does not have a genetic marker for a specific treatment, they will receive a broad-acting therapy. Every patient who enters the trial receives an option for treatment.
Why is LLS convening the Beat AML Master Trial®?

As the voice for blood cancer patients, LLS is uniquely qualified to lead this unprecedented clinical trial collaboration. This is because LLS is:

» **Patient-focused:** LLS exists to find cures and ensure that patients have access to the best available treatments.

» **A Trusted Convener:** LLS serves as a catalyst for collaboration among clinicians, researchers, companies and regulators.

» **A Leader in AML:** LLS has unparalleled expertise and dedicates 26% of research funds to AML every year.

The Beat AML Master Trial demonstrates LLS’s ability to convene the medical and research communities to think and act boldly in the quest for new and better treatments for blood cancer patients, and supports its goal to accelerate the rate at which precisely targeted breakthrough therapies reach the patients who urgently need them.

Findings will help inform future clinical trials and treatment options for AML, and the unique collaborative approach of the Beat AML Master Trial will stand as a model for future cancer clinical trials.

How many patients will take part in the Beat AML Master Trial?

LLS expects up to 500 patients to enroll in the trial.

Where can I learn more about the Beat AML Master Trial?

For detailed information, go to our website: [www.lls.org/beataml](http://www.lls.org/beataml).