myeloMATCH Kickoff

NCI's precision medicine umbrella trial in myeloid malignancies

(The open kickoff session will be preceded by a closed session for myeloMATCH leadership from 9 – 10 am CT.)

SATURDAY, OCTOBER 19 • 10:00-12:00 PM CT • REGENCY D (BALLROOM LEVEL)

myeloMATCH
AML | MDS
Precision Medicine in Myeloid Cancer

myeloMATCH has been activated – the MYELOMATCH screening protocol and a number of substudies are now open.

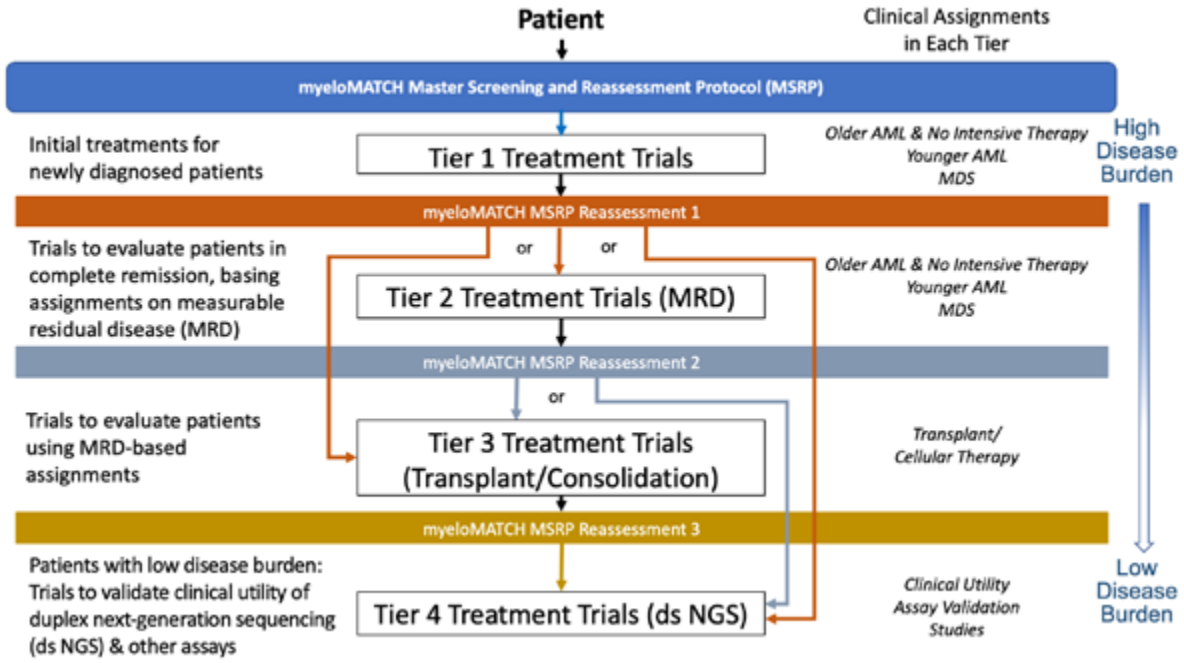
Attend the myeloMATCH Kickoff to learn more and have your questions answered!

SUBSTUDIES TO BE DISCUSSED:

MM1YA-S01 – open	**MM1OA-EA02 – open**	**MM1YA-CTG01 – open**	**MM2YA-EA01 – imminent**	**MM1MDS-A01 – imminent**

LEARN MORE ABOUT ACTIVATING AND CONDUCTING MYELOMATCH PROTOCOLS. WE'LL DISCUSS

BEACON build templates	**Funding**	**Verification team**	**Helpdesk support**	**Communication & recruitment resources**



NCI National Clinical Trials Network

MyeloMATCH MSRP Protocol Summary Sheet

MyeloMATCH, Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials

Study Chair:
Jerald Radich, M.D.

Co-Chair:
Shahanawaz Jiwani, M.D., Ph.D.

CCTG Study Champion:
Aly Karsan, M.D.

Inclusion / Exclusion Criteria

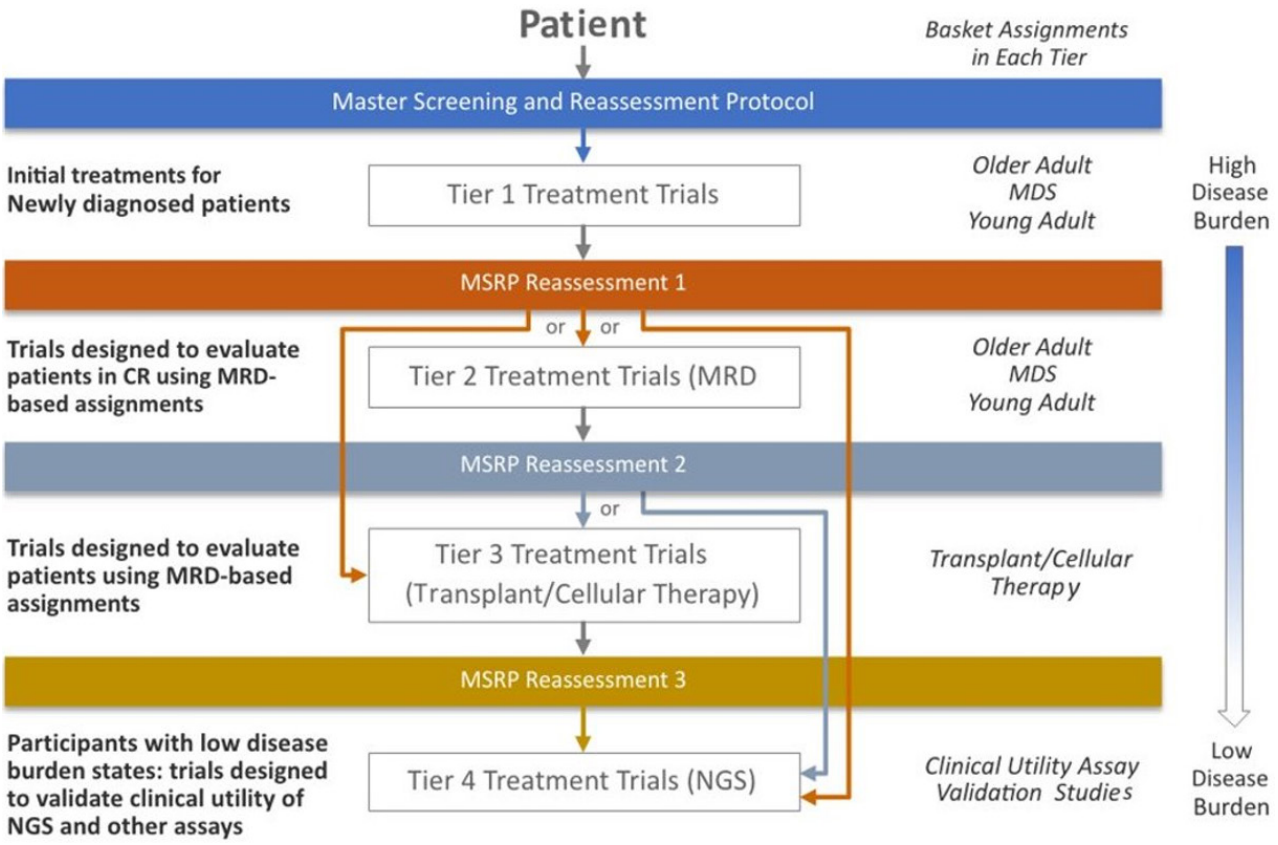
See Section 5 of the Protocol for Complete Eligibility Criteria

- Must be suspected to have previously untreated acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). Participants with AML cannot have a history of previously treated myeloproliferative neoplasms (MPN) or MDS.
- Must be ≥ 18 years of age and must have Zubrod PS evaluation within 28 days prior to registration.
- Must not have received prior anti-cancer therapy for AML or MDS. Note: Hydroxyurea to control the white blood cell count (WBC) is allowed. Note: Prior erythroid stimulating agent (ESA) is not considered prior therapy for the purposes of eligibility. Participants must not be currently receiving any cytarabine-containing therapy other than up to 1 g/m^2 of cytarabine, which is allowed for urgent cytoreduction.
- Must not have a prior or concurrent malignancy that requires concurrent anti-cancer therapy. Note: active hormonal therapy is allowed.
- Participants are allowed prior use of hydroxyurea, all-trans retinoic acid (ATRA), BCR-ABL directed tyrosine kinase inhibitor, erythropoiesis- stimulating agent, thrombopoietin receptor agonist and lenalidomide, with a maximum limit of 1 month of exposure. Note: Participants receiving hydroxyurea prior to treatment sub-study or TAP assignment must agree to discontinue hydroxyurea within 24 hours before beginning sub-study or TAP treatment.
- Must agree to have translational medicine specimens submitted per Section 15.2.
- Must be offered the opportunity to participate in specimen banking as outlined in Section 15.3.
- Must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines.

NCI National Clinical Trials Network

MyeloMATCH MSRP

Schema



Legend: There are five clinical baskets within myeloMATCH, as follows: younger AML basket (18-59 years of age), older AML basket (60 years of age and older) (and unfit AML of any age), MDS basket, transplant/consolidation basket, and Duplex-Sequencing (DS) basket.
The baskets are contained in tiers as shown.

SWOG CANCER RESEARCH NETWORK

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

THIS PROTOCOL SUMMARY SHEET IS INTENDED TO BE USED AS A REFERENCE TOOL *ONLY* AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL.

Clinical trial summary

myeloMATCH
AML | MDS
Precision Medicine in Myeloid Cancer

Testing for Biomarkers to Match People with Myeloid Cancer to myeloMATCH Clinical Trials for Treatment

What is the purpose of this clinical trial?

This trial is the first step in joining a large research study called myeloMATCH. In myeloMATCH, researchers will conduct many different clinical trials for people with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

This trial is a screening study. It uses biomarker testing to tell the study doctors if they can match you with a myeloMATCH clinical trial for cancer treatment.

A **biomarker** (sometimes called a marker) is anything about the body that can be measured. In cancer care, specific proteins, genes, and abnormal changes in genes can be important biomarkers. Testing for certain markers can give doctors more information about each patient's cancer and how to treat it.

The biomarker testing you receive in myeloMATCH has been approved only for use in clinical trials. The tests have not been approved yet for general use outside of the myeloMATCH study.

This trial is set up to find out:

- If you have biomarkers that specific drugs can target in myeloMATCH treatment clinical trials
- How well the process of biomarker testing works to match patients with trials for cancer treatment

Why is this trial important?

Research about cancer biomarkers has led to new treatments that target specific markers. In recent years, targeted drugs have improved treatment options for people with myeloid (blood) cancers.

As new targeted drugs are developed and tested, they are often first only available to patients in clinical trials. The myeloMATCH study is designed to help people access new drugs in clinical trials at all stages of treatment. It will also test recently available drugs to compare them to existing treatments. It aims to speed up the pace of developing targeted treatments for myeloid cancers. The study is also a chance to improve how new cancer treatments are developed in the future.

Who can be in this trial?

This trial is for adults, age 18 or older, with AML or MDS.

This trial is for people who:

- Have not started treatment yet for AML or MDS

This trial is not for people who:

- Will need treatment for another cancer while they start treatment for AML or MDS

Talk with your doctor to learn more about who can join this study.

What can I expect during the trial?

If you join this study, researchers will test your bone marrow and blood for specific biomarkers. It will take about 3 days to get your biomarker test results.

If there is a treatment trial that matches your biomarkers, you can choose whether to join that trial.

- You may choose to receive standard treatment instead.
- Talk with your doctor and ask any questions you need to make the right choice for you.

Biomarkers can change. While you are in the study, you can have more biomarker testing to see if your markers match with other myeloMATCH treatment trials.

How long will I be in the trial?

You may stay in myeloMATCH through all stages of your treatment. Even if you receive standard treatments, the researchers will follow how you are doing for 10 years.

Are there costs? Will I get paid?

Biomarker testing is provided free in this study. You will not be paid for joining the study.

Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT05564390**
- For a list of trial locations, visit swog.org/NCI-myeloMATCH

Key information This trial is for adults 18 years or older being

Protocol number: MYELOMATCH

Full trial title: MYELOMATCH, Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI myeloMATCH Clinical Trials

NCT number: NCT05564390

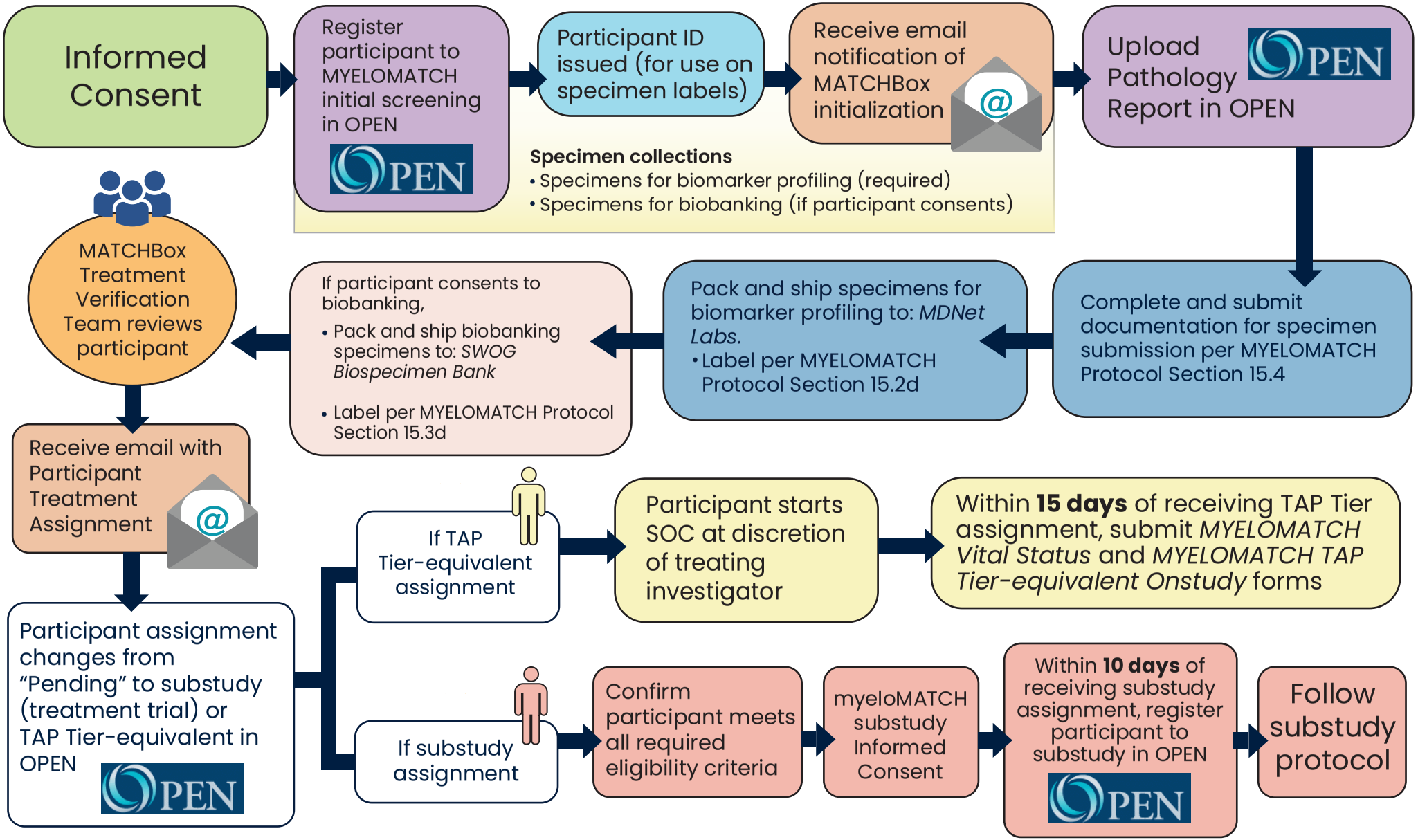
Trial sponsor: SWOG Cancer Research Network

Publishing date: June 2, 2024

Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.

myeloMATCH: Initial Screening and Registration Workflow



ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY | Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer | NCI National Clinical Trials Network | NCI Community Oncology Research Program | ECOGACRIN cancer research group | SWOG CANCER RESEARCH NETWORK

myeloMATCH: myeloid Malignancies Molecular Analysis for Therapy CHoice

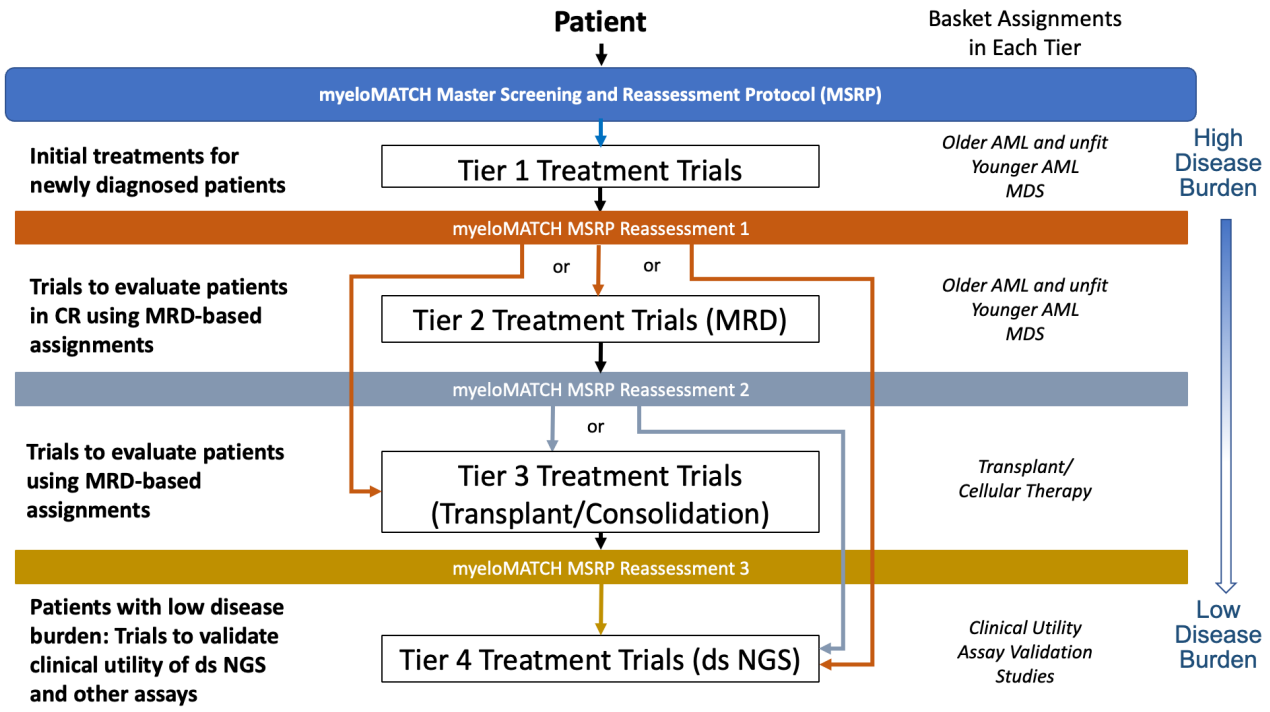
A precision medicine trial for people newly diagnosed with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS)

myeloMATCH offers a portfolio of substudies (typically phase 2) to treat patients sequentially from diagnosis throughout their treatment journey. Participants are screened – at no cost to them – under a Master Screening and Reassessment Protocol (MYELOMATCH, *aka* MSRP). They may then "match" to a substudy based on clinical, cytogenetic, and molecular features. Treatment studies include:

- A therapy targeted to their mutational profile *or*
- A novel combination without a target-specific drug

If no appropriate substudy is available, myeloMATCH participants will be followed on the Tier Advancement Pathway while receiving standard-of-care treatment chosen by their physician.

MYELOMATCH Master Screening and Reassessment Protocol Schema



myeloMATCH (NCT05564390), sponsored by the National Cancer Institute, is a precision medicine initiative for people with myeloid malignancies. The screening protocol is led by SWOG Cancer Research Network, and treatment sub-studies are led by the Alliance for Clinical Trials in Oncology, Canadian Cancer Trials Group, ECOG-ACRIN Cancer Research Group, and SWOG.

SWOG Cancer Research Network · ECOG-ACRIN cancer research group · NCI National Clinical Trials Network · NCI Community Oncology Research Program · Alliance for Clinical Trials in Oncology · Canadian Cancer Trials Group · Groupe canadien des essais sur le cancer

Clinical trial summary (MM1YA-S01)

Testing New Treatments for People with High-Risk Acute Myeloid Leukemia (AML) Who Have Not Started Treatment

What is the purpose of this clinical trial?

Patients are matched with this clinical trial based on their biomarker test results in the myeloMATCH study. This treatment trial is for adults (ages 18-59) with high-risk AML who have not started treatment yet. Doctors consider AML high risk if it has certain biomarkers that can make it harder to treat.

Treatment plans for AML often involve several phases of treatment. The first phase aims to get rid of as many leukemia cells as possible. It helps make it easier for further treatment to keep the cancer under control.

Usually, the first treatment patients receive for AML is a combination of 2 chemotherapy drugs, daunorubicin and cytarabine.

The purpose of this study is to learn if other options for first treatment may work better for people with high-risk AML. The study doctors will test 4 new treatments and compare them to the usual chemotherapy.

There is evidence that the 4 new treatments being tested in this trial are safe, and any of them may be better than the usual chemotherapy at getting rid of leukemia cells.

This trial is set up to find out:

- If the study treatments are better than the usual chemotherapy at getting rid of leukemia cells in adults with high-risk AML
- What side effects patients have from the study treatments

Why is this trial important?

Knowing AML is high-risk gives doctors more information about the cancer and how to treat it. People with high-risk AML may benefit from a different approach to treatment. Improving options for people in the first phase of treatment could make further phases of treatment more successful.

Who can be in this trial?

This trial is for adults ages 18-59 with high-risk AML.

This trial is for people who:

- Had biomarker testing as part of the myeloMATCH study

This trial is not for people who:

- Already started treatment for AML
- Have signs or symptoms of disease that make it hard to do many daily activities (for example, if your symptoms often keep you in bed, the study may not be right for you)
- Are pregnant

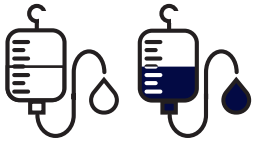
Talk with your doctor to learn more about who can join this study.

What treatments will I get?

A computer will randomly assign you to one of 5 treatment groups.You may be assigned to receive the usual chemotherapy or one of 4 study treatments.

Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.

Group 1: **Daunorubicin and cytarabine** (usual chemotherapy)



- This treatment is approved by the Food and Drug Administration (FDA) for treating newly diagnosed AML.
- This treatment is sometimes called "7+3".

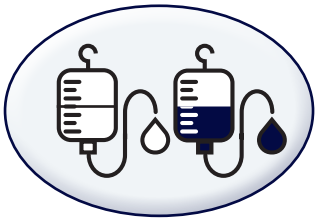
Group 2: Daunorubicin and cytarabine + venetoclax

- Adds a targeted drug called venetoclax to the usual chemotherapy
- **Venetoclax** is called a targeted drug because it "targets" a certain protein in cancer cells. The drug may help the body use its normal process to get rid of cancer cells.

Group 3: Azacitidine + venetoclax

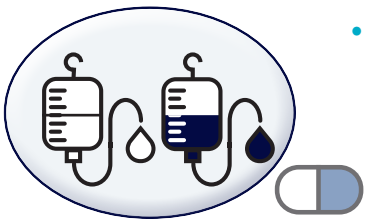
- Combines a chemotherapy drug called azacitidine with venetoclax
- Azacitidine is used for treating other types of blood cancers.

Group 4: Daunorubicin and cytarabine liposome



- Uses the usual chemo drugs but in a different form called a liposome
- A **liposome** is a way of preparing drugs. Liposomes are like tiny bubbles made of fat. In this form, it is easier for the body to absorb the drugs and allows more of the drugs to reach the cancer cells.

Group 5: Daunorubicin and cytarabine liposome + venetoclax



- Adds venetoclax to the liposome form of the usual chemo drugs

The Food and Drug Administration (FDA) has not yet approved the drug combinations being tested in this study for newly diagnosed AML. Venetoclax, azacitidine, and the daunorubicin and cytarabine liposome are approved separately for treating other types of AML.

How long will I be in the trial?

The treatment you receive in this study may last up to 8 weeks.

After you finish treatment in the study, your doctor will continue to follow your condition. You will have follow-up clinic visits or phone calls until you have been in the study for a total of 5 years.

After treatment in this treatment trial, you may have the option to join another myeloMATCH treatment trial.

Are there costs? Will I get paid?

Venetoclax and the daunorubicin and cytarabine liposome are provided free in this study.

As part of the myeloMATCH study, biomarker lab testing in this treatment trial is also provided free.

Check with your health care provider and insurance provider to find out what costs will and won't be covered in this study. You will not be paid for joining the study.

Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT05554406**
- For a list of trial locations, visit swog.org/NCI-MM1YA-S01

Key information

This trial is for adults 18 years or older being

Protocol number: MM1YA-S01

Full trial title: Protocol MM1YA-S01, A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients Aged 59 or Younger Who Are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH; A myeloMATCH Clinical Trial

NCT number: NCT05554406

Trial sponsor: SWOG Cancer Research Network

Publishing date: July 31, 2024

myeloMATCH
AML | MDS
Precision Medicine in Myeloid Cancer

Thank you!

When you join a clinical trial,
you're moving cancer medicine and patient care forward.

MM1OA-EA02 Study

Do you have acute myeloid leukemia (AML) and are age 60 or older?

If so, you may be able to participate in this study of a potential new treatment.

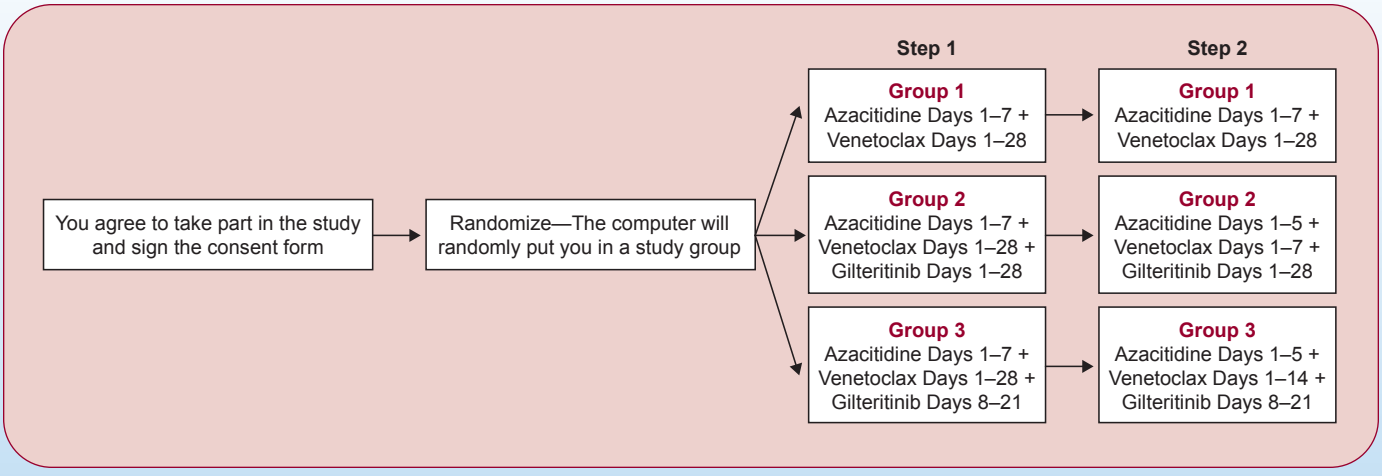
Venetoclax and Hypomethylating Agent (HMA) Treatment of Older and Unfit Adults with FLT3 Mutated AML

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 get for AML) is treatment with chemotherapy and other drugs. Sometimes, combinations of these treatments are used.
- The purpose of MM1OA-EA02 is to compare the usual treatment of the drugs azacitidine and venetoclax to the combination treatment of azacitidine, venetoclax, and gilteritinib.
  - Researchers are trying to find out if adding the drug gilteritinib can lower the amount of leukemia in your body.

WHAT does this study involve?

- This study is a part of the myeloMATCH Precision Medicine Trial, which you have previously agreed to participate in.
- If you are matched to the MM1OA-EA02 treatment study and choose to participate, you will be assigned by chance (randomized) to one of three study groups. Each study group will consist of approximately 49 participants.
  - **Group 1:** You will receive azacitidine (by injection into a vein in your arm or just beneath the skin) and venetoclax (a tablet you will take daily by mouth).
  - **Group 2:** You will receive azacitidine (via injection), venetoclax (via daily tablet), and gilteritinib (also a daily tablet you will take by mouth).
  - **Group 3:** You will receive azacitidine (via injection), venetoclax (via tablet), and the gilteritinib tablet, but starting on day 8 of the treatment cycle.



- Each cycle lasts 28 days and there will be a maximum of 24 cycles.
- After you finish MM1OA-EA02 study treatment, your doctor will monitor your condition for 10 years (every 3 months for the first 2 years, then every 6 months thereafter).

WHO will take part in this study?

- Approximately 147 people diagnosed with AML will take part in MM1OA-EA02. You must be at least 60 years of age; however, individuals younger than 60 are eligible if your treating physician decides you would be better served by a treatment that includes azacitidine chemotherapy (instead of the more intensive cytarabine-based chemotherapy).
- You must also have a FLT3-ITD or D835 mutation, as required by the myeloMATCH Precision Medicine Trial.
- 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?

- Just as if you were getting the usual care for your cancer, 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.
  - You/your insurance plan will **not** have to pay for venetoclax and gilteritinib while you take part in MM1OA-EA02.
  - Check with your insurance company for find out what they will pay for.
- Taking part in the study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer.
- You will not be paid for taking part in MM1OA-EA02.

IF you would like to know more

- About the MM1OA-EA02 study, talk with your doctor, or:
  - Visit www.ecog-acrin.org and search MM1OA-EA02, then select the link to MM1OA-EA02.
    - » For information about medical facilities where the study is available, scroll down the page to Locations and Contacts.
    - » For more information on myeloMATCH, including a list of the myeloMATCH treatment trials, visit www.swog.org/myelomatch-overview.
  - 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
  - Insurance coverage: visit www.cancer.gov/clinicaltrials/learningabout/payingfor
- About ECOG-ACRIN:
  - Visit www.ecog-acrin.org
  - For a list of patient resources and links to patient advocacy groups, visit https://ecog-acrin.org/patients/resources

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ECOG-ACRIN cancer research group