NCI Protocol #: 10434
Protocol Version Date: March 03, 2025

Protocol Title: Randomized Phase 2 Study of CPX-351 + Pomalidomide versus CPX-351 in Newly Diagnosed AML with MDS-Related Changes

Informed Consent Version Date: March 03, 2025

The summary of changes table below provides a detailed summary and rationale for all changes to the treatment consent form for protocol #10434, from amendment 11 (Version 07/11/2023) to amendment 12 (Version 03/03/2025). The amendment is being submitted to make additional modifications.

SUMMARY OF CHANGES -CONSENT FORM: TREATMENT

I. Changes to the consent per Protocol Amendment 11

Summary of changes for Amendment #12 version 03/03/2025		
#	**Section**	**Comment**
1.	General	The protocol version date was updated to "03/03/2025".
2.	Unknown Future Studies	Updated biobank information to include UNC-Chapel Hill

Research Study Treatment Informed Consent Document

Study Title for Participants: Comparing the Addition of an Anti-Cancer Drug, Pomalidomide, to the Usual Chemotherapy Treatment (daunorubicin and cytarabine liposome) in Newly Diagnosed Acute Myeloid Leukemia with Myelodysplastic Syndrome-Related Changes

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol 10434, Randomized Phase 2 Study of daunorubicin and cytarabine liposome + Pomalidomide versus daunorubicin and cytarabine liposome in Newly Diagnosed AML with MDS-Related Changes, (NCT#TBD)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have acute myeloid leukemia with myelodysplastic syndrome-related changes or acute myeloid leukemia after previous chemotherapy or radiation treatment. Myelodysplastic syndromes occur because the bone marrow cells do not develop into mature blood cells and stay within the bone marrow in an immature state.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

- Can we lower the chances of your acute myeloid leukemia (AML) growing by adding pomalidomide, to daunorubicin and cytarabine liposome therapy which is one of the standard treatment most people get for AML?

- What is the safe, tolerable, and effective schedule of pomalidomide treatment when it is given in combination with daunorubicin and cytarabine liposome, to manage your AML?

Pomalidomide is an investigational drug, because it has been approved by the US Food and Drug Administration (FDA) for the treatment of different cancers but not for AML. Daunorubicin and cytarabine liposome is approved for treatment of AML alone. The combination of daunorubicin and cytarabine liposome and pomalidomide is experimental and has not been approved by the FDA. In a different clinical trial, pomalidomide was given to more than 40 patients with AML at different doses. The maximal pomalidomide dose that was tolerated well among these patients was determined to be 4 mg.

What is the usual approach to my acute myeloid leukemia?

The usual approach for patients who are not in a study is treatment with an FDA approved therapy that involves two drugs: liposomal (a fat droplet) daunorubicin and cytarabine, called daunorubicin and cytarabine liposome. Daunorubicin and cytarabine liposome is given at the beginning of therapy, called induction. Daunorubicin and cytarabine liposome is given by infusion, on Days 1, 3 and 5 of induction. A second round of induction therapy with daunorubicin and cytarabine liposome may be given if you do not respond to the first treatment. The second induction therapy must be started 21 days after your first induction therapy. Daunorubicin and cytarabine liposome infusion will be given on Days 1 and 3 of the second induction therapy.

After you recover from the induction therapy, you would get daunorubicin and cytarabine liposome again for a period called consolidation. Consolidation is a treatment that is given after cancer has disappeared following the initial therapy and is used to kill any cancer cells that may be left in the body. Consolidation therapy would occur about 5 to 8 weeks after you received induction therapy. During consolidation, daunorubicin and cytarabine liposome infusion will happen on Days 1 and 3 of treatment cycle. You may also receive a second consolidation therapy with daunorubicin and cytarabine liposome, if the study doctor believes it will benefit you. The second consolidation therapy will be given to you approximately 5-8 weeks after the start of the first consolidation therapy.

If you qualified for a bone marrow transplant, you would have a bone marrow transplant before or after consolidation therapy. For patients who get the usual approach for this cancer, about 18 of 100 patients are free of cancer after 5 years.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study if one is available.
- You may choose not to be treated for cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

What will happen if I decide to take part in this study?

The first part of this study will attempt to evaluate if pomalidomide effect in reducing AML cancer is better if given for 14 days versus 21 days, when given after induction therapy. We will also evaluate whether pomalidomide administration for 14 or 21 days is better tolerated.

Up to 6 patients will be enrolled in each of one of two groups to evaluate the different periods of pomalidomide therapy. Initially patients will complete daunorubicin and cytarabine liposome induction therapy and then placed in one of two groups to receive 4 mg of pomalidomide:

Group A: will take pomalidomide for **14 days**.

Group B: will take pomalidomide for **21 days**.
Pomalidomide is a capsule taken by mouth daily, starting at Day 21 after induction therapy, or within three days after the second induction has been completed. The study doctor will follow up closely on all patients participating in groups A and B, to determine which group has the best response and tolerability to the pomalidomide therapy. The study doctor will use this pomalidomide treatment schedule for the second part of the study to further collect information about how the combination of pomalidomide and daunorubicin and cytarabine liposome induction therapy may help in controlling AML.

The second part of this study will compare between the effectiveness of receiving induction therapy in combination with pomalidomide, versus receiving induction therapy only. The second part of the study will enroll up to 78 additional patients, who will be placed in one of two groups to receive the following treatment options:

Group 1: Daunorubicin and cytarabine liposome for induction alone, OR

Group 2: Daunorubicin and cytarabine liposome for induction followed by pomalidomide for 14 days. Pomalidomide treatment will start twenty-one days after completing induction therapy.

If you respond to the treatment offered in your assigned group, you will get daunorubicin and cytarabine liposome consolidation therapy alone for up to 2 more cycles. If you have had too much daunorubicin over time or your study doctor thinks daunorubicin and cytarabine liposome is no longer a good chemotherapy for you, you may have consolidation therapy with cytarabine only. If you are not responding to therapy, you will be taken off the study.

After you finish all study related treatments, the study doctor will continue to follow your condition for 5 years from when you started induction therapy. This is called long term follow-up. During long term follow-up, your condition will be monitored, and the study doctor will look for any side effects you may experience. Follow-up will involve you coming in for clinic visits and sometimes having phone calls with the study team.

If you complete consolidation therapy and do not have a bone marrow transplant, you will be monitored every 1 to 2 months for the first year as a part of your usual care. In addition, you will have bone marrow biopsies or aspirates every 3 months for the first year to monitor your disease. When you have completed the study, you will come into the clinic for one last visit. In this last visit, you would have blood drawn, a physical exam and have your medical history taken.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there is a risk that adding pomalidomide during the usual treatment may not be as good as daunorubicin and cytarabine liposome alone at treating your cancer.

There is also a risk that you could have side effects from the addition of pomalidomide. While the drugs are not given together at the same time, some side effects may be worse and may be different than you would get with the usual approach for AML.

Some of the most common side effects that the study doctors know about are:

- Tumor lysis syndrome
- Bleeding which could be severe
- Heart damage
- Severe allergic reactions
- Liver damage
- Death

There may be some risks that the study doctors do not yet know about.

Benefits

There is evidence that adding pomalidomide to similar therapies is effective in improving some treatment outcomes for your type of cancer. It is not possible to know now if daunorubicin and cytarabine liposome with pomalidomide will result in a better response compared to the usual approach. This study will help the study doctors learn things that will help people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. This may mean you will have one last study visit to make sure there are no additional concerns before you stop participating in the study. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (NCI). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

This study is being done to identify if there is a safe, tolerable, and effective schedule of pomalidomide treatment when it is given in combination after induction therapy with daunorubicin and cytarabine liposome. Additionally, the study will evaluate if the combination of pomalidomide and daunorubicin and cytarabine liposome

induction therapy is more effective in controlling AML than induction therapy with daunorubicin and cytarabine liposome alone. The addition of pomalidomide to the usual induction therapy could help treat your AML cancer. However, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better, the same or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the pomalidomide increases the response of patients to therapy compared to the usual approach.

An immunomodulating agent is a substance that stimulates or suppresses the immune system and may help the body fight cancer, infection, or other diseases. This immunomodulator drug, pomalidomide, is already approved by the FDA for use in multiple myeloma, but it has not been approved for your AML cancer. FDA also has not approved pomalidomide use in combination with daunorubicin and cytarabine liposome for treating AML.

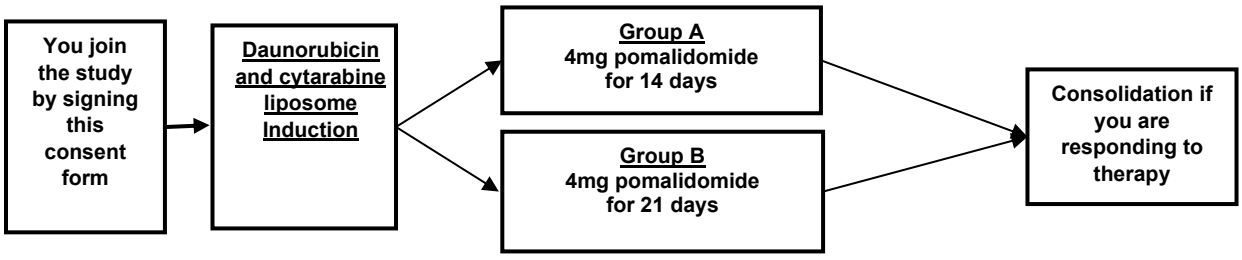
What are the study groups?

This study has two parts. The first part will investigate the safety and effectiveness of receiving pomalidomide after daunorubicin and cytarabine liposome induction therapy. The study doctors want to test what schedule of pomalidomide can be better in managing AML cancer, specifically, if it is given for 14 days versus 21 days. Once the best pomalidomide treatment schedule is identified, it will be test in the second part to study the effectiveness of using pomalidomide in combination with daunorubicin and cytarabine liposome induction therapy versus daunorubicin and cytarabine liposome induction therapy alone, in controlling AML from getting worse.

Depending on when you enroll on this study, you may participate in one of the study parts only. Initially, you will get to undergo induction therapy with daunorubicin and cytarabine liposome. You will get daunorubicin and cytarabine liposome through a vein in your arm for about 1-1/2 hours on Days 1, 3 and 5 during induction therapy. You may have a second round of induction therapy and receive daunorubicin and cytarabine liposome on Days 1 and 3.

If you are enrolled in part 1 of this study, you will be placed in one of two groups to start pomalidomide treatment (see Figure 1 below).

Figure 1: Part 1, Determination of Pomalidomide Treatment Schedule



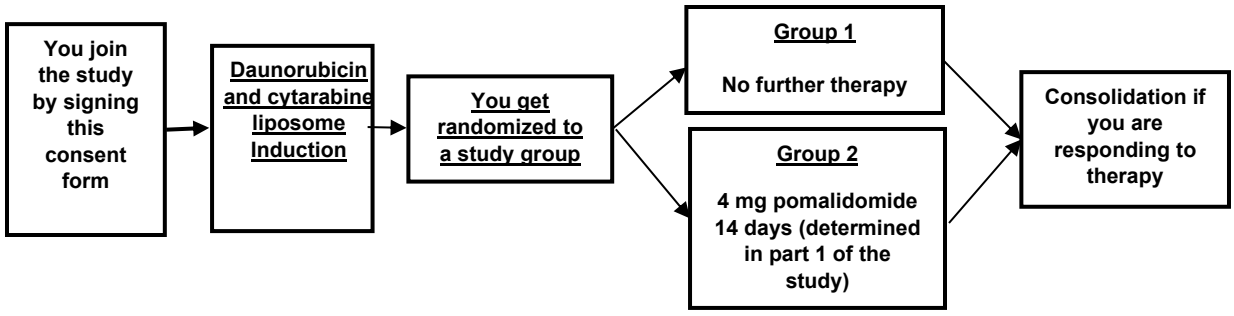
Part 1 study groups:

- **Group A**: will take 4mg of pomalidomide for **14 days**.
- **Group B**: will take 4mg of pomalidomide for **21 days**.

Pomalidomide is a capsule taken by mouth. Pomalidomide capsules should be swallowed whole, and should not be broken, chewed, or opened. If a dose of pomalidomide is missed, it can be taken up to 12 hours after the time it would normally be taken. If it has been more than 12 hours, the dose should be skipped. If you vomit after taking pomalidomide, you should not make it up and you should take your next dose as scheduled. If you are responding to therapy, you will receive daunorubicin and cytarabine liposome(for up to 2 more treatment cycles called consolidation therapy (or cytarabine alone). You will receive daunorubicin and cytarabine liposome on Days 1 and 3 of these cycles. The cycles will be about 5-8 weeks apart. See the study calendars at the end of this document for more information.

The second part of the study will enroll up to 78 new patients as soon as the best pomalidomide treatment scheduled is established by the study doctors. This treatment schedule will be used in the second part of the study. If you enrolled in part 2 of the study, after you finish daunorubicin and cytarabine liposome consolidation therapy, you will be placed in one of two groups (see Figure 2 below).

Figure 2: Part 2, Comparison of Pomalidomide in Combination with Induction, versus Induction Only



We will use a computer to assign you to one of the study groups. This process is called "randomization." It means that your doctor will not choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2.

The groups in the second part of the study are:

- **Group 1:** If you are in this group, you will get daunorubicin and cytarabine liposome only. You will get daunorubicin and cytarabine liposome infusion through a vein in your arm for about 1-1/2 hours on Days 1, 3 and 5 during induction therapy. You may have a second round of induction therapy and receive daunorubicin and cytarabine liposome on Days 1 and 3. About 5 to 8 weeks after you started induction and if you are responding to therapy, you will receive daunorubicin and cytarabine liposome for up to 2 more treatment cycles during consolidation therapy (or cytarabine alone). You will receive daunorubicin and cytarabine liposome on Days 1 and 3 of these cycles. The cycles will be about 5-8 weeks apart. See the study calendars at the end of this document for more information.
- There will be about 39 people in this group.

- **Group 2:** If you are in this group, you will get daunorubicin and cytarabine liposome plus pomalidomide. You will get daunorubicin and cytarabine liposome infusion through a vein in your arm for about 1-1/2 hours on Days 1, 3 and 5 during induction therapy. You may have a second round of induction therapy and receive daunorubicin and cytarabine liposome on Days 1 and 3. After completing induction therapy, you will take pomalidomide for 14 days. Pomalidomide is a capsule taken by mouth. Pomalidomide capsules should be swallowed whole, and should not be broken, chewed, or opened. The study doctor will tell you how long you will have to take it. If a dose of pomalidomide is missed, it can be taken up to 12 hours after the time it would normally be taken. If it has been more than 12 hours, the dose should be skipped. If you are responding to therapy, you will receive daunorubicin and cytarabine liposome(for up to 2 more treatment cycles called consolidation therapy (or cytarabine alone). You will receive daunorubicin and cytarabine liposome on Days 1 and 3 of these cycles. The cycles will be about 5-8 weeks apart. See the study calendars at the end of this document for more information.

  There will be about 39 people enrolled in this group.

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- A pregnancy test before you start pomalidomide, every week you are taking pomalidomide, and about 1 month after you finish taking pomalidomide.
- Blood tests to monitor your health and response to treatment.

This study will use genetic tests that may identify changes in the genes in your bone marrow. Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these changes would not affect your treatment in this study, however, they could affect your health in other ways. If there are changes found that could cause health problems, then your study doctor will discuss your options with you.

Listed below are procedures that will be done for research purposes only.

You will need to have mandatory bone marrow biopsies and blood samples taken. Before you start study treatment, you will have a bone marrow biopsy and blood samples (about 8 teaspoons each) taken. About 14 days after you started treatment if you are enrolled at University of North

Carolina (UNC) or John Hopkins University (JHU), you will have another bone marrow biopsy (8 teaspoons) collected. On about Day 21, you will have a blood sample taken (about 8 teaspoons). If you are in Group 1, the Day 21 blood sample will be collected before you start taking pomalidomide. On Day 28, if you are enrolled at UNC or JHU, you will give another blood sample and bone marrow biopsy taken (about 8 teaspoons each). Between Days 42 and 64, you will have another bone marrow biopsy and you will give more blood samples (about 8 teaspoons each of blood and about 9 teaspoons of bone marrow). The study biopsy takes small amounts of bone marrow and bone from your body. This is like the biopsy you had that helped diagnose your cancer.

Your blood and bone marrow will be used to look at your genetic material, to look at the types of immune cells in your blood, and to see what types of proteins (called receptors) are on your immune cells. This information will help us understand what type of cells, genes and proteins are involved when people respond to therapy. Your study doctor will get the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.

A patient study calendar is attached at the end of this document. It shows how often these blood and bone marrow collections will be done.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that pomalidomide with daunorubicin and cytarabine liposome may not be as good as daunorubicin and cytarabine liposome alone at treating your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The pomalidomide (CC-4047) and (Daunorubicin and Cytarabine) Liposome (CPX-351; Vyxeos) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

The pomalidomide used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 28 days after you have completed the study.

Pomalidomide is in the same drug class as lenalidomide and thalidomide. While not seen in people, these other drugs are known to cause the following side effects: birth defects; damage to the brain which may cause tiredness, changes in thinking; swelling and pain in the abdomen.

Women are advised to not get pregnant while taking pomalidomide. You have been informed that the risk of birth defects is unknown. If you are a woman, you agree not to become pregnant while taking pomalidomide. If you are a man, you agree to use a latex condom during sexual contact with females of childbearing potential while participating in the study, during dose interruptions, and for at least 28 days following discontinuation from the study even if you have undergone a successful vasectomy.

Daunorubicin and cytarabine liposome requires contraception for at least 6 months after the last dose for both females of childbearing potential and for males.

Genetic Testing Risks

The genetic test used in this study will test your tumor for genetic changes in your bone marrow. This change also may be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Since this study is only testing tumor tissue, we will not know if a genetic change in your tumor is also in your normal tissue. If you want to find out if the change is in your normal tissue, then you will need to get other tests done outside of this study.

Genetic tests of normal tissue can reveal information about you and about your relatives. The study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

Biopsy Risks

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for the study biopsy that describes the risks in more detail.

Side Effect Risks

The pomalidomide and daunorubicin and cytarabine liposome used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drug.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Pomalidomide can cause birth defects and you should not become pregnant if you are taking pomalidomide as a part of the study.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

You should notify your doctor immediately at the first sign of poorly formed or loose stools or an increased frequency of bowel movements. Loperamide (Imodium) should be kept on hand and should be taken as recommended by your doctor.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

All Study Groups: Possible side effects of daunorubicin and cytarabine liposome are listed in the tables below. This drug is part of the usual approach for treating this type of cancer:

Possible Side Effects of daunorubicin and cytarabine liposome
(Table Version Date: August 18, 2022)

COMMON, SOME MAY BE SERIOUS
In 100 people receiving (Daunorubicin and Cytarabine) Liposome (CPX-351; Vyxeos), more than 20 and up to 100 may have:

- Infection, especially when white blood cell count is low
- Constipation, diarrhea, nausea, vomiting
- Chills, tiredness, fever
- Swelling of the body
- Loss of appetite
- Headache
- Difficulty sleeping
- Cough, shortness of breath
- Nose bleed
- Bruising, bleeding, rash
- Low blood pressure which may cause feeling faint

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving (Daunorubicin and Cytarabine) Liposome (CPX-351; Vyxeos), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Abnormal heartbeat
- Bloating, heartburn
- Pain
- Sores in the mouth which may cause difficulty swallowing
- Swelling and redness of the gums
- Reaction during or following a drug infusion
- Kidney damage which may require dialysis
- Dizziness
- Changes in taste
- Worry, confusion
- Blood in urine
- Fluid around lungs
- Damage to the lungs which may cause shortness of breath
- Hair loss, itching
- Increased sweating
- High blood pressure which may cause headaches, dizziness, blurred vision

RARE, AND SERIOUS

In 100 people receiving (Daunorubicin and Cytarabine) Liposome (CPX-351; Vyxeos), 3 or fewer may have:

- Heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness

Precautions and Warnings:

- Hemorrhage (bleeding) including serious or fatal events have occurred
- Daunorubicin, a drug in daunorubicin and cytarabine liposome has a known risk of heart damage.
- Allergic reactions including severe reactions have occurred.
- Tissue Necrosis: Daunorubicin has been associated with severe tissue death.

Precautions and Warnings:
• Embryo-fetal toxicity: Daunorubicin and cytarabine can cause birth defects in animals. You should avoid getting pregnant while on daunorubicin and cytarabine liposome

In addition to side effects listed above, patients who receive pomalidomide in combination with daunorubicin and cytarabine liposome (Groups A, B and 1) may experience side effects related to pomalidomide itself. These side effects are listed below.

Possible Side Effects of Pomalidomide
(Table Version Date: May 22, 2022)

COMMON, SOME MAY BE SERIOUS In 100 people receiving pomalidomide (CC-4047), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving pomalidomide (CC-4047), from 4 to 20 may have:
• Constipation, diarrhea • Swelling of arms, legs • Tiredness, fever • Infection • Bruising, bleeding • Pain • Numbness, tingling or pain of the arms and legs • Confusion • Kidney damage which may require dialysis • Difficulty emptying the bladder
RARE, AND SERIOUS In 100 people receiving pomalidomide (CC-4047), 3 or fewer may have:

- Heart attack
- Nausea
- Death
- Liver damage which may cause yellowing of eyes and skin, swelling
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Loss of appetite
- Second primary malignancies
- A new cancer resulting from treatment of earlier cancer
- Dizziness
- Abnormal unpleasant sensation
- Feeling of "pins and needles" in arms and legs
- Damage to the brain which may cause changes in thinking and may be life-threatening
- Stroke which may cause paralysis, weakness, headache
- Sensing things that are not there
- Cough, shortness of breath
- Damage to the lungs which may cause shortness of breath
- Skin rash developing 1-8 weeks after a drug is given which may be accompanied by fever, lymph node swelling and organ failure
- Rash
- Severe skin rash with blisters and peeling which can involve mouth and other parts of the body
- Blood clot which may cause swelling, pain, shortness of breath

Pomalidomide is in the same drug class as lenalidomide and thalidomide. While not seen in people, these other drugs are known to cause the following side effects: birth defects; damage to the brain which may cause tiredness, changes in thinking; swelling and pain in the abdomen.

Consolidation with cytarabine only: for those who receive cytarabine only during consolidation therapy. This may happen if you have had too much daunorubicin over time, or if your heart function does not qualify you for daunorubicin and cytarabine liposome.

Possible Side Effects of Cytarabine
(Table Version Date: August 30, 2019)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, more than 20 and up to 100 may have:
• Blood clot • Swelling in the rectum which may cause rectal pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth and GI tract which may cause difficulty swallowing or pain • Rash • Fever

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Cytarabine, from 4 to 20 may have:
• Heart failure which may cause shortness of breath, swelling of ankles, cough or tiredness • Chest pain • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Damage to the lungs which may cause shortness of breath • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Severe blood infection • Liver damage which may cause yellowing of skin or eyes • Kidney damage which may cause swelling, may require dialysis • Numbness and tingling of the arms and legs • Muscle pain • Dizziness • Headache • Flu-like syndrome with fever, bone pain, rash, redness of eyes, or chest pain • Swelling and redness of the eye • Hair loss

RARE, AND SERIOUS In 100 people receiving Cytarabine, 3 or fewer may have:
• Brain damage, Posterior Reversible Encephalopathy syndrome, which may cause headache, seizure, blindness • Difficulty speaking, trouble standing or walking

Additional Drug Risks
Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study
- Write down in your medication diary when you take the study drug at home

<u>For patients taking pomalidomide:</u>

Pregnancy:
All patients taking pomalidomide must follow guidelines for prevention of pregnancy. This is because there is a risk of harm to a fetus if pregnancy occurs while taking pomalidomide. These guidelines are outlined below:

Women:
If you are a woman, you must not be pregnant.
You will be considered not of childbearing potential if you meet the following criteria:

- absence of menstrual periods (natural menopause) for the past 24 consecutive months **or**
- have had a hysterectomy (the surgical removal of the uterus) or both ovaries surgically removed

If you do not meet these criteria, you will be considered a female of childbearing potential. If there is ANY chance that you can become pregnant, you must follow the guidelines below. If you ARE a female of childbearing potential, you will not be able to participate in this research study unless you have had two negative pregnancy tests, one within 10-14 days and one within 24 hours of starting pomalidomide.

In addition, with your doctor's knowledge and approval, you agree to use TWO reliable forms of birth control or practice complete abstinence from heterosexual intercourse during the following time periods related to this study:

- for at least 28 days before starting pomalidomide
- while participating in this study
- during dose interruptions
- and for at least 28 days after discontinuation from the study

You agree to inform the investigator immediately if:

- you have any reason to suspect you are pregnant
- you find that circumstances have changed and that there is a risk of becoming pregnant
- you have stopped using the approved forms of TWO reliable birth control methods
- you must talk to your doctor before changing any birth control methods

The following methods of birth control are considered acceptable birth control methods:

Highly Effective Methods	Additional Effective Methods
Intrauterine device (IUD)	Latex condom
Hormonal (birth control pills, injections, implants, levonorgestrel-releasing intrauterine system [IUS], medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills [*e.g*. desogestrel])	Diaphragm
Tubal ligation	Cervical Cap
Partner's vasectomy	

Special Note: Certain HIV-protease inhibitors, griseofulvin, modafinil, penicillin, rifampin, rifabutin, phenytoin, carbamazepine, or certain herbal supplements such as St. John's Wort may

reduce the effectiveness of hormonal contraceptives during and up to one month after discontinuation of these concomitant therapies.

Therefore, females of childbearing potential requiring treatment with one or more of these drugs must choose ONE non-hormonal method as the highly effective method of birth control (IUD, tubal ligation, partner's vasectomy) along with ONE of the additional effective methods (latex condom, diaphragm, cervical cap) or abstain from heterosexual contact while taking pomalidomide.

You must use at least one highly effective method and one additional effective method of birth control AT THE SAME TIME. However, your doctor may recommend that you use two barrier methods for medical reasons.

If you have sex without using TWO reliable methods of birth control, or if for any reason you think you may be pregnant, you must IMMEDIATELY stop taking pomalidomide and tell your doctor.

You will have pregnancy tests before and during treatment, even if you agree not to have reproductive heterosexual intercourse. You will have a pregnancy test done by the doctor every week during the first 28 days of this study. You will then have a pregnancy test every 28 days during your participation in this study if your menstrual cycles are regular or every 14 days if your cycles are irregular. You will also have a pregnancy test if you miss your period or have unusual menstrual bleeding. In addition, you will have pregnancy tests when you are discontinued from the study and at Day 28 after discontinuation from the study if your menstrual cycles are regular. If your menstrual cycles are irregular, you will have pregnancy tests when you are discontinued from the study and at Days 14 and 28 after discontinuation from the study.

You must not breastfeed a baby while you are participating in this study and for at least 28 days after you have been discontinued from the study.

You must NEVER share pomalidomide (or other study drugs) with someone else. You must NEVER donate blood while you are participating in this study and for at least 28 days after you have been discontinued from the study. You will be counseled at least every 28 days and at discontinuation from the trial about not sharing pomalidomide (and other study drugs), the potential risks of fetal exposure, and abstaining from blood and donations.

If you have any reason to suspect you are pregnant, you must IMMEDIATELY stop taking pomalidomide and tell your doctor. If you have a positive pregnancy test while participating in this study, you must IMMEDIATELY stop taking pomalidomide and tell your study doctor. If you have a positive pregnancy test within 28 days after you have been discontinued from this study, you must IMMEDIATELY tell your doctor.

Study subjects who become pregnant will be monitored throughout the pregnancy and will continue to be monitored for 30 days after delivery (premature delivery, aborted fetus, full-term pregnancy, or no longer pregnant).

<u>Men:</u>
You have been informed about the risk of birth defects and you agree to use a latex condom every time you have sex with a female of childbearing potential while you are participating in this study and for at least 28 days after you have been discontinued from the study, even if you have had a successful vasectomy. You must tell your doctor if you have sex with a female of childbearing potential without using a latex condom or if you think for any reason your partner

may be pregnant. Do not father a baby or donate sperm while taking part in this study; abstinence is not an effective method of birth control.

You must NEVER share pomalidomide (or other study drugs) with someone else. You must NEVER donate blood, sperm, or semen while you are participating in this study and for at least 28 days after you have been discontinued from the study. You will be counseled at least every 28 days regarding abstaining from donating blood, sperm, or semen; birth control requirements; not sharing pomalidomide (and other study drugs); and the potential risks of fetal exposure. Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your acute myeloid leukemia. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety and prevent and treat side effects
- the biopsies done before you begin study treatment, at Day 14, Day 21, at the end of induction therapy, and between days 42-64.
- the cost of daunorubicin and cytarabine liposome
- the cost of getting daunorubicin and cytarabine liposome and pomalidomide (if applicable) ready and giving it to you
- your insurance co-pays and deductibles

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- the biopsy completed at Day 28
- processing and shipping your specimens (from research blood draws and biopsies) for research studies

You or your insurance provider will not have to pay for the pomalidomide while you take part in this study. However, you or your insurance company will have to pay for costs of preparing and administering pomalidomide.

Taking part in this 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 may:

- Have more travel costs
- Need to take more time off work
- Have other additional personal costs

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study treatment now or in the future. This would include any organization helping the company with the study.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The University of North Carolina at Chapel Hill and Johns Hopkins University.

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading this optional study hope the results will help other people with your condition in the future. The results will not be added to your medical records and your study doctor will know the results.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to this study. There is no penalty for saying "no". You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for the following study.

Optional sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, some of your bone marrow and/or blood will be collected and stored. Storing samples for future studies is called "biobanking." The biobank is being run by Johns Hopkins University and The University of North Carolina at Chapel Hill and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your blood and/or bone marrow samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code.

Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes. If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

What is involved in this optional sample collection?
If you agree to take part, here is what will happen next:

1. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
2. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
3. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance.

How will information about me be kept private?
Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.

3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?
You will not benefit from taking part. The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?
There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?
If you decide you no longer want your samples to be used, you can call the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I need my tissue or blood samples to be returned?
Tumor tissue or blood samples that remain in the biobank can be returned if needed for medically necessary events or procedures to assure appropriate medical care, such as for DNA or RNA analysis. Specimens may also be returned if tissue is needed to determine eligibility for enrollment in a research protocol or clinical trial. Every effort will be made to facilitate medically necessary events or procedures to assure appropriate medical care for a patient with a serious or life-threatening illness.

Tumor tissue or blood samples and genetic material (DNA and RNA) that is no longer in the biobank or that has already been given to or used by researchers cannot be returned. No samples will be returned for matters related to patients needing or wanting genetic testing to determine medically important risks.

What if I have questions about this optional sample collection?
If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*).

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for known future studies:
I agree that my samples and related health information may be used for the laboratory study described above.

YES NO

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

This is the end of the section about optional studies.

Conflicts of Interest

Joshua Zeidner, the Principal Investigator on this study, receives money from Bristol Myers Squibb for work that is not part of this study. These activities may include consulting or serving on advisory boards. If you would like more information, please ask the researchers listed on the first page of this form.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature

Patient-friendly calendar – Arm A

	Before you begin study treatment	First Part of the Study "Induction"								Pomalidomide cycle				Once blood tests are normal or by Day 64	Second Part of the Study "Consolidation"[d] (5-8 weeks after starting study treatment)						After Study Treatment
		Day 1	Day 2	Day 3	Day 4	Day 5	Days 6-13	Day 14	Days 15-20[c]	Day 21	Days 22-27	Day 28	Days 29-42		Before consolidation therapy begins	1st day	3rd day	4th day to 20th day	21st day	35 days after end of consolidation therapy	
Daunorubicin and cytarabine liposome[a]		X		X		X			X							X	X				
Pomalidomide[b]										X	X	X	X								
Pre study (before you begin study treatment) procedures including informed consent, demographics, medical history and height	X																				
Check of all medications you are taking during the study	X	X----------																			----------X
Physical exam, vital signs, and weight	X	X	X	X	X	X		X	X	X				X		X			X	X	X
An assessment of how you perform everyday activities and tasks	X	X								X				X		X			X		X
Side effects evaluation		X----------																			----------X
Blood draws for complete blood count and general health	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X
Echocardiogram (will also be taken as your doctor indicates it is necessary)	X														X						
Urine or Serum Pregnancy test[e]	X						X		X	X	X	X	X								

	Before you begin study treatment	First Part of the Study "Induction"								Pomalidomide cycle				Once blood tests are normal or by Day 64	Second Part of the Study "Consolidation"[d] (5-8 weeks after starting study treatment)						After Study Treatment
		Day 1	Day 2	Day 3	Day 4	Day 5	Days 6-13	Day 14	Days 15-20[c]	Day 21	Days 22-27	Day 28	Days 29-42		Before consolidation therapy begins	1st day	3rd day	4th day to 20th day	21st day	35 days after end of consolidation therapy	
Bone marrow biopsy for research purposes (mandatory)	X							X[g]				X[g]		X							
Blood collection for research purposes (mandatory)	X									X[f]		X[g]		X							

a. You will receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) through a vein in your arm on Days 1, 3, and 5 during the induction cycle. If you need a second induction cycle (re-induction), you will also receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) through a vein in your arm on the first and third days of the second cycle before starting pomalidomide treatment. If you get consolidation treatment, you will also receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) on the first and third days of each consolidation cycle.

b. You will receive pomalidomide as capsules that you take by mouth once a day on Days 21 through 42. If you are in group 2 in Part 2 of the study you will take pomalidomide on Days 21-35.

c. Depending on the results of your bone marrow biopsy on Day 14, you may get a second cycle of induction therapy (re-induction), with additional clinic visits and blood draws for general health, beginning between Days 15 and 18 and ending at least 2 days before you start taking pomalidomide. The timing of your other treatment cycles and assessments may be delayed.

d. Depending on the results of your bone marrow biopsy performed once your blood counts are normal or by Day 64, you may get up to 2 cycles of consolidation therapy. The first consolidation cycle will begin 5-8 weeks after you began study treatment. The second consolidation cycle, if you receive it, will begin 5-8 weeks after the beginning of the first consolidation cycle.

e. For women of child-bearing potential. Pregnancy tests must be performed weekly for the first 4 weeks, including a test within 24 hours before starting pomalidomide, as well as after finishing pomalidomide and 28 days after finishing pomalidomide. Women with irregular menstruation must also have pregnancy tests every 14 days during study treatment after the first 4 weeks, as well as 14 days after finishing pomalidomide.

f. Blood collection will be done before you start taking pomalidomide.

g. Only applies if you are enrolled at UNC or JHU.

Patient-friendly calendar – Arm B

	Before you begin study treatment	First Part of the Study "Induction"									Once blood tests are normal or by Day 64	Second Part of the Study "Consolidation"[c] (5-8 weeks after starting study treatment)						After Study Treatment
		Day 1	Day 2	Day 3	Day 4	Day 5	Days 6-13	Day 14	Days 15-27[b]	Day 28		Before consolidation therapy begins	1st day	3rd day	4th day to 20th day	21st day	35 days after end of consolidation therapy	
Daunorubicin and cytarabine liposome[a]		X		X		X			X				X	X				
Pre study (before you begin study treatment) procedures including informed consent, demographics, medical history, and height	X																	
Check of all medications you are taking during the study	X	X----------X																
Physical exam, vital signs, and weight	X	X	X	X	X	X			X		X		X			X	X	X
An assessment of how you perform everyday activities and tasks	X	X							X		X		X			X		X
Side effects evaluation		X----------X																
Blood draws for complete blood count and general health	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X

	Before you begin study treatment	First Part of the Study "Induction"									Once blood tests are normal or by Day 64	Second Part of the Study "Consolidation"[c] (5-8 weeks after starting study treatment)						After Study Treatment
		Day 1	Day 2	Day 3	Day 4	Day 5	Days 6-13	Day 14	Days 15-27[b]	Day 28		Before consolidation therapy begins	1st day	3rd day	4th day to 20th day	21st day	35 days after end of consolidation therapy	
Echocardiogram (will also be taken as your doctor indicates it is necessary)	X											X						
Urine or Serum Pregnancy test[d]	X								X									
Bone marrow biopsy for research purposes (mandatory)	X							X		X	X							
Blood collection for research purposes (mandatory)	X								X[e]	X	X							

a. You will receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) through a vein in your arm on Days 1, 3, and 5 during the induction cycle. If you need a second induction cycle (re-induction), you will also receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) through a vein in your arm on the first and third days of the second cycle before starting pomalidomide treatment. If you get consolidation treatment, you will also receive daunorubicin and cytarabine liposome(liposomal daunorubicin and cytarabine) on the first and third days of each consolidation cycle.

b. Depending on the results of your bone marrow biopsy on Day 14, you may get a second cycle of induction therapy (re-induction), with additional clinic visits and blood draws for general health, beginning between Days 15 and 18. The timing of your other treatment cycles and assessments may be delayed.

c. Depending on the results of your bone marrow biopsy performed once your blood counts are normal or by Day 64, you may get up to 2 cycles of consolidation therapy. The first consolidation cycle will begin 5-8 weeks after you began study treatment. The second consolidation cycle, if you receive it, will begin 5-8 weeks after the beginning of the first consolidation cycle.

d. For women of child-bearing potential.

e. Blood collection on Day 21 only.