To: CTEP Protocol and Information Office

From: Alice Chen, MD, DTC, NCI

Date: August 4, 2025

Re: Amendment to Protocol 10490: *Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 2 Talazoparib and Temozolomide.*

We are submitting this amendment to make changes conforming with Revision 4 of the protocol, including new timing of drug administration on the 'gapped schedule,' updated sample collection timing, and administrative changes.

The version date is now 5/21/2025. Thank you for your consideration.

I. Investigator-Initiated Adult Treatment Consent Changes

#	***Section***	***Comments***
1	*Footer*	Updated the version date.
2	*Title*	Added a 'treatment' identifier to avoid confusion with the addition of new screening informed consent documents.
3	*Are there other reasons why I might stop being in the study?* *What exams, tests, and procedures are involved in this study?* *Participant Study Calendar*	Removed the requirement for a second pregnancy test in participants able to become pregnant on cycle 1 day 1 so long as the screening pregnancy test was performed within 8 days of the start of treatment and updated the description.
4	*What is the purpose of this study?*	Updated the number of participants in the trial to match the updated design.

#	***Section***	***Comments***
5	*What are the study groups?* *Participant Study Calendar*	Modified the agent administration schedule to the 'gapped schedule' of temozolomide on days 1 through 5 and talazoparib on days 8 through 26.
6	*What exams, tests, and procedures are involved in this study?* *Participant Study Calendar*	Updated the frequency of the labs performed during the first two cycles of treatment to correspond with the new administration schedule and the new exploratory objective to correlate reticulocyte count decline from C1D1 to C1D15 with grade 3+ anemia at C2D1.
7	*Known future studies*	Simplified the language regarding what participants' blood samples for ctDNA analysis will be used for.
8	*What is involved in this optional sample collection?* *Participant Study Calendar*	Reduced the frequency of the optional blood collections for ctDNA analysis to every restaging (rather than every cycle) to lessen the burden on participating patients.
9	*How will information about me be kept private?* *What if I change my mind about this optional sample collection?*	Removed references to the 'biobank' and added 'laboratory' where appropriate, as this study does not utilize the ETCTN biobank.
10	*Participant Study Calendar*	Removed erroneous references to a baseline blood sample collected for the purposes of germline sequencing. Germline sequencing for any participant who consents to it will be performed on a portion of one of the blood samples collected for ctDNA analysis.

Research Study Informed Consent Document - Treatment

Study Title for Participants: Testing the combination of anti-cancer drugs talazoparib and temozolomide in people ≥18 years old with advanced stage rare cancers

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol 10490, "Rapid Analysis and Response Evaluation of Combination Anti-neoplastic Agents in Rare Tumors (RARE CANCER) Trial: RARE 2 Talazoparib and Temozolomide" (NCT05142241)

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 an advanced cancer that is considered rare and for which there is no standard treatment.

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 the combination of the two study drugs, talazoparib and temozolomide, make your type of rare cancer stop growing or shrink?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your advanced rare cancer. The usual approach is defined as care most people get for the type of rare cancer you have.

What is the usual approach to my advanced rare cancer?

The usual approach for patients who are not in a study is treatment with radiation, kinase inhibitor drugs, immunotherapy drugs, or chemotherapy drugs. There are no treatments that are FDA-approved for your health condition or proven to help patients with your health condition live longer, including radiation and chemotherapy.

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?

If you decide to take part in this study, you will be treated with the study drugs talazoparib and temozolomide. The Study Team will monitor your cancer and your safety. You will continue to get doses of talazoparib and temozolomide for as long as your cancer does not get worse, the side effects are tolerable, you agree to stay on study, and the study doctor agrees it is still in your best interest to take part in the study.

After you stop treatment, your doctor will continue to follow your condition for 30 days from your last treatment date or until you start a new treatment. During those 30 days, your doctor will watch you for side effects. This follow up will be a phone call from your study team. Follow up will consist of a telephone call from the Study Team between Day 27 and Day 30 after the last dose of the study drugs.

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 the talazoparib and temozolomide may not be as good as the usual approach at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drugs. These side effects may be worse and may be different than you would get with the usual approach for your cancer. Some of the most common side effects that the study doctors know about are:

- Tiredness
- Anemia (tiredness from low red blood cell counts)
- Constipation, diarrhea, nausea, vomiting
- Headache, seizure
- Dizziness
- Hair loss

- Bruising, bleeding
- Difficulty sleeping
- Muscle weakness, paralysis, difficulty walking
- Trouble with memory
- Loss of appetite

The combination of talazoparib and temozolomide may have some risks that the study doctors do not yet know about.

Benefits

There is some evidence in people with another cancer that this treatment can shrink or stabilize cancer, but we do not know if this will happen in people with your type of cancer. It is unlikely that this treatment will help you live longer. This study may help the study doctors learn things that may help other 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; your doctor can help you with this. 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.
- 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 (the National Cancer Institute). 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?

The purpose of this study is to test the good and bad effects of the study drugs called talazoparib and temozolomide. Talazoparib and temozolomide could shrink or stabilize your cancer, but they could also cause side effects, which are described in the risks section below. The study doctors hope to learn if the study drug will shrink or stabilize your type of cancer. We also plan to test the effect of the study drug in the tissue around your tumor, and in your blood.

Talazoparib and temozolomide have already been approved by the FDA to treat other cancers, but the combination has not been approved by FDA.

There will be about 47 people taking part in this study.

What are the study groups?

Each adult taking part in this study will receive the same dose of the study drugs talazoparib and temozolomide. The study drugs are given in cycles, and each cycle is 28 days long. You will get both study drugs as a pill you take by mouth. You will take temozolomide on days 1 through 5 of each cycle and talazoparib on days 8 through 26 of each cycle. See the study calendar for more information.

You also will keep a pill diary. This helps you keep track of when you take your pills. The study doctor will show you how to use this diary. Each time you visit the clinic, you must bring the pill diary, any remaining pills, and the pill bottle.

You will be able to get additional doses of the drugs as long as you stay in the study. These drugs are not approved by the FDA for treatment of your disease.

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:

- An electrocardiogram (EKG) scan before you begin the study and during the study to check your heart
- A pregnancy test in people who are able to become pregnant before you begin the study and possibly during the study
- Blood counts done every week during the first cycle of treatment and three out of four weeks during the second cycle of treatment.

Optional tumor biopsies and blood samples for research purposes may be collected during the study to see how your tumor tissue or blood cells change in response to the study drugs. There is more information about these optional tests in the "Optional studies you may choose to take part in" section near the end of this document.

A patient study calendar is attached at the end of this document. It shows how often these exams, tests and procedures 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 the study drugs talazoparib and temozolomide may not be as good as the usual approach for your cancer at shrinking or stabilizing 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.

Talazoparib and temozolomide 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 7 months after you have completed the study.

Side Effect Risks

The study drugs talazoparib and temozolomide 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 drugs.

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. Some side effects may make it hard for you to have children.
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.

This study is looking at a combination of drugs that are not usually used to treat this type of cancer. This different combination of drugs may increase your side effects or may cause new side effects.

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.

Possible Side Effects of Talazoparib (PF-06944076)

(Table Version Date: September 23, 2024)

COMMON, SOME MAY BE SERIOUS In 100 people receiving talazoparib (PF-06944076), more than 20 and up to 100 may have:
• Anemia which may require blood transfusion • Nausea • Tiredness • Bruising, bleeding • Loss of appetite
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving talazoparib (PF-06944076), from 4 to 20 may have:
• Pain • Constipation, diarrhea, heartburn, vomiting • Sores in the mouth which may cause difficulty swallowing • Fever • Infection, especially when white blood cell count is low • Dizziness, headache • Changes in taste • Hair loss
RARE, AND SERIOUS In 100 people receiving talazoparib (PF-06944076), 3 or fewer may have:
• Cancer of bone marrow caused by chemotherapy • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions • A new cancer resulting from treatment of earlier cancer

Possible Side Effects of Temozolomide

(Table Version Date: September 28, 2018)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, more than 20 and up to 100 may have:
• Headache, seizure • Constipation, nausea, vomiting, diarrhea • Trouble with memory • Difficulty sleeping • Muscle weakness, paralysis, difficulty walking • Dizziness • Tiredness • Hair loss
OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, from 4 to 20 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require transfusions • Severe skin rash with blisters and can involve inside of mouth and other parts of the body • Rash

RARE, AND SERIOUS In 100 people receiving Temozolomide, 3 or fewer may have:
• Cough, damage to the lungs which may cause shortness of breath • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require blood transfusions • Liver damage which may cause yellowing of eyes and skin, swelling • A new cancer including leukemia resulting from treatment of a prior cancer

Additional Drug Risks

The study drug could interact with other drugs. Your study doctor will give you a clinical trial wallet card that lists the study drugs you are taking. Share this information with your family members, caregivers, other health care providers, and pharmacists.

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.

For women: Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 7 months after your last dose of study drugs.

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 rare cancer. 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 costs of getting the talazoparib and temozolomide 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 or your insurance provider will not have to pay for the study drugs talazoparib and temozolomide while you take part in this study.

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 or the study agent 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.

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.

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 Dr. Alice Chen at (240) 781-3320.

For questions about your rights while in this study, call the NIH Office of Human Subjects Research Protections (OHSRP) at (301) 402-3713.

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 these optional studies hope the results will help other people with your condition in the future. Some of these results will be added to your medical records and you or your study doctor will know the results.

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

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

Optional biopsy and blood sample collections for known laboratory 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.

Known future studies

If you choose to take part in these optional studies, researchers will collect blood and tissue biopsy specimens for research throughout the study. The researchers will use the blood and the tissue from the biopsy to:

1. Collect blood specimens for research to see if we can find mutations in your circulating tumor DNA (ctDNA) that may be related to how your respond to the drug combination.
2. Measure changes in circulating tumor cells in your blood to explore tumor adaptation to drugs over time.

3. Perform a specific, targeted sequencing test on your tumor tissue in a clinically approved laboratory.
    - **You and your doctor will receive the results of this test**. The results will be added to your electronic medical record and may be used to guide your medical care.
    - Your doctor will discuss these results with you and tell you about any gene variations that might make you able to take part in targeted therapy clinical trials in the future.
4. Measure effects of your cancer or talazoparib and temozolomide treatment on your tumor's genes.
    - This test is done for research only. **We will not give you any individual results from this test or add this information to your medical record.**
    - Your tumor contains genes, which serve as the "instruction book" for the cells that make up our bodies. Determining whether different tumor gene variations affect how the study drugs works against tumors will help scientists understand which patients might respond best to these drugs.

What is involved in this optional sample collection?

If you agree to take part in these studies, here is what will happen next:

1. Blood samples (about 1.5 tablespoons each) will be collected from a vein in your arm or from an existing central venous catheter on day 1 of the first treatment cycle; on day 1 of subsequent cycles when you have a scan for measuring your tumors; at time of the optional disease progression/restaging follow-up biopsy; and at time of disease progression. Additionally, maximum of 3 tissue biopsies will be collected at baseline; on cycle 3 day 1; and at the time of disease progression/restaging to measure effects of the study treatment on your tumor, including genomic sequencing studies.
2. 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.
- Typical risks of biopsy collection include, but are not limited to, bleeding, infection, pain and scarring. There is also some risk associated with radiation exposure if a CT scan is involved in the biopsy procedure.
- 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. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers. 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.

However, if you choose to have the optional tumor biopsy before leaving the study, we will perform a specific, targeted sequencing test on this tumor tissue in a clinically approved laboratory, and you and your doctor will receive the results of this test. These results will also be added to your electronic medical record. Your doctor will discuss these results with you and tell you about any gene variations that might make you able to take part in targeted therapy clinical trials in the future.

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, Dr. Alice Chen, at (240) 781-3320, who will let the laboratoryknow. Then, any sample that remains in the laboratorywill 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 have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, Dr. Alice Chen, at (240) 781-3320.

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 studies described above.

YES NO

This is the end of the section about optional studies.

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

Participant Study Calendar

Day	Participant Activity
Before starting study drug	• Check in at the Outpatient Clinic • Medical history and physical exam, including ECOG Performance Status (an assessment of how you are doing with your daily living activities) • Echocardiogram to test your heart • Tumor measurements by CT/MRI or PET • Routine blood tests • Pregnancy test for people who are able to become pregnant • Optional blood samples for research may be collected • Optional tumor biopsy for research may be obtained
Cycle 1 Day 1	• Check in at the Outpatient Clinic • Physical exam • Routine blood tests • Optional blood samples for research may be collected before taking study drugs • Begin taking temozolomide daily by mouth*
Cycle 1 Day 2	• Check in at the Outpatient Clinic • Optional blood samples for research may be collected before taking study drugs • Continue taking temozolomide daily by mouth*
Cycle 1 Day 8	• Check in at the Outpatient Clinic • Routine blood tests • Physical exam • Begin taking talazoparib by mouth once a day*
Cycle 1 Day 15	• Check in at the Outpatient Clinic • Routine blood tests • Physical exam • Optional blood samples for research may be collected before taking study drugs • Continue taking talazoparib by mouth once a day*
Cycle 1 Day 22	• Check in at the Outpatient Clinic • Routine blood tests • Continue taking talazoparib by mouth once a day*

Cycle 2 Day 1	• Check in at the Outpatient Clinic • Physical exam • Routine blood tests • • Begin taking temozolomide daily by mouth*
Cycle 2 Day 8	• Check in at the Outpatient Clinic • Routine blood tests • Begin taking talazoparib by mouth once a day*
Cycle 2 Day 22	• Check in at the Outpatient Clinic • Routine blood tests • Continue taking talazoparib by mouth once a day*
Cycle 3 and onwards, Day 1	• Check in at the Outpatient Clinic • Physical exam • Routine blood tests • Optional tumor biopsy for research may be collected before taking study drugs on Cycle 3 Day 1 only • Tumor measurement by CT/MRI or PET to measure any changes in the size of your tumors will be performed at the end of Cycle 2 (before cycle 3), and at the end of every 2 cycles after that (less often once you have been on study for >1 year) • Optional blood samples for research may be collected before taking study drugs at every tumor measurement cycle • Begin taking temozolomide daily by mouth*
After Cycle 3	• Optional tumor biopsy and blood collections for research may be obtained if your disease comes back or shows signs of coming back

* Temozolomide is taken on days 1-5 of each cycle; talazoparib is taken on days 8-26 of each cycle.