Official Title	Dose-Adjusted Etoposide, Prednisone, Vincristine, Cyclophosphamide,and Doxorubicin (DA-EPOCH) ± Rituximab (R) + Tafasitamab-cxix for the Treatment of Newly-Diagnosed Adults with Philadelphia chromosome-negative (Ph-) B-cell Lymphoblastic Lymphoma/Leukemia (B-ALL)
NCT Number	NCT05453500
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University of Washington (UW)
Fred Hutchinson Cancer Center (FHCC)

Consent to take part in a research study:

Dose-Adjusted Etoposide, Prednisone, Vincristine, Cyclophosphamide, and Doxorubicin (DA-EPOCH) ± Rituximab (R) + Tafasitamab-cxix for the Treatment of Newly-Diagnosed Adults with Philadelphia chromosome-negative (Ph-) B-cell Lymphoblastic Lymphoma/Leukemia (B-ALL)

Principal Investigator: Ryan Cassaday, MD. University of Washington; Fred Hutchinson Cancer Center. (206) 606-1202

Emergency number (24 hours): (206) 598-6190

University of Washington Medical Center Paging Operator: Please ask the operator to page the hematology/oncology fellow on call.

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to look at the effects of a combination treatment regimen called dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin) plus tafasitamab-cxix. This combination will be referred to as DA-EPOCH-Tafa in the remainder of this consent form.

People who agree to join the study will be asked to attend approximately 25 visits over 6 months; participants will also be asked to agree to staying in the hospital for the first 6 days of the study for observation. The study involves physical exams, assessment of your disease and your health, blood draws, and occasional bone marrow biopsies.

We do not know if this drug combination would help treat B-cell acute lymphoblastic leukemia (ALL) and could even make your condition/disease worse. DA-EPOCH-Tafa could cause side effects such as nausea, vomiting, hair loss, abnormal blood cell counts, fever, and abdominal pain as described below in this form.

You do not have to join this study. You can choose to receive standard methods to treat your ALL instead of participating in this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need in order to make an informed decision about joining this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study.

We invite you to join this research study.

We invite you to join this research study because you have B-cell ALL. Up to 30 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say “yes” or “no”, or to drop out after joining. If you say “no,” you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

Etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, and tafasitimab-cxix are anti-cancer drugs already approved by the U.S. Food and Drug Administration (FDA). DA-EPOCH is commonly and effectively used in the treatment of high-grade lymphomas and is generally well-tolerated, even in older adults.

We are doing this study to determine the effects of the combination of dose-adjusted EPOCH plus Tafa in patients with newly diagnosed B-cell acute lymphoblastic leukemia. We want to know:

- How effective DA-EPOCH-Tafa will be in adults with B-cell ALL;
- What side effects occur when DA-EPOCH-Tafa is given and how long they last;
- What overall effects, good or bad, DA-EPOCH-Tafa has on B-cell ALL.

If you join this study, we would give you DA-EPOCH-Tafa and watch carefully for any side effects. Patients who are CD20+ will also receive rituximab, a drug received via an infusion approved by the FDA.

The doctors will watch patients carefully for any side effects.

What research tests, procedures, and treatments are done in this study?

If you decide to participate in this study, and meet the requirements necessary for participation, the following tests, procedures and treatments will be conducted at various time points throughout the study.

1) **Medical History & Physical Exam:** You will be asked questions about your medical history. This includes ongoing conditions you have and medications you are taking. Physical exams and vital sign measurements will assess your overall health status; this includes blood pressure, heart rate, temperature, respiration, height and weight.

2) **Blood Tests:** Blood samples will be taken for routine tests at screening, before each cycle, and for monitoring mid-treatment cycle. Blood samples for research may be collected at screening and at the end of each cycle.

3) **Bone Marrow Aspirate &/or Biopsy:** Multiple bone marrow aspirate/biopsy procedures may be done throughout the study as part of standard care to determine the amount of cancer present in your bone marrow. Some marrow may be used for research purposes, and some will be used for routine tests. For the bone marrow aspirate, a sample of the inner bone marrow cells are taken by a needle inserted into a bone in your body (typically the pelvis or hip bone). In a bone marrow biopsy, a very small piece of the bone will be removed. These procedures are completed using local anesthesia.

4) **Computed Tomography (CT) Scan:** A CT is a medical imaging method that takes 3-dimensional pictures of sections of the body. CT scans of the neck, chest, abdomen and pelvis will be done if your doctor believes your cancer is present in more areas than just your bone marrow. If you have certain other imaging tests as part of your medical care, your doctor may also consider the results of those tests.

This may allow you to avoid having extra CT scans. This procedure would be done as part of standard care.

5) **Lumbar Puncture (LP):** Multiple LPs may be done throughout the study to determine the amount of cancer present in your cerebrospinal fluid. The LP procedure will be done as part of standard care. Some cerebrospinal fluid will be used for research purposes, and some will be used for clinical tests. For the LP, a sample of cerebrospinal fluid is taken by a needle inserted into your spine. During this time, chemotherapy is also administered into your cerebrospinal fluid. If you have disease in your cerebrospinal fluid, a plastic device called an Ommaya reservoir may be implanted under your scalp to make this procedure easier.

Treatment Procedures

Each cycle of therapy is given approximately every 21 days.

All participants will receive the following:

1) **Etoposide (E)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

2) **Doxorubicin (H)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

3) **Vincristine (O)** is administered intravenously (through an IV, line or port) on days 1-4 of each cycle.

4) **Cyclophosphamide (C)** is administered intravenously (through an IV, line or port) on day 5 of each cycle.

5) **Prednisone (P)** is administered orally or intravenously (through an IV, line or port) twice a day on days 1-5 of each cycle.

6) **Tafasitamab-cxix (Tafa)** is administered intravenously (through an IV, line, or port) once a day on days 1, 8, and 15 of each cycle.

If you have CD20+ ALL you will receive rituximab which is administered intravenously (through an IV, line or port) on day 1 or 5 of each cycle, in addition to DA-EPOCH.

The dose of etoposide, doxorubicin and cyclophosphamide you will receive will be determined by the side effects and specific blood test results (neutrophil and platelet count). If you tolerate DA-EPOCH relatively well, the dose of etoposide, doxorubicin and cyclophosphamide will increase during the next cycle of treatment. If you experience significant side-effects then the dose will be decreased.

You will receive either filgrastim (Neupogen®) or pegfilgrastim (Neulasta®) in addition to your DA-EPOCH-Tafa therapy. These are synthetic versions of a substance that is naturally produced in your body. When certain medications are used to fight cancer cells they can also negatively affect the white blood cells that help

your body fight off infections. Filgrastim and pegfilgrastim are used to prevent or reduce the risk of infection by helping the white blood cells recover after the study treatment.

Filgrastim is administered by an injection once a day starting on day 6, 7, or 8 during each cycle. It will continue until your white blood cell count has recovered to a level deemed acceptable by your provider.

Pegfilgrastim is administered by a single injection on day 6, 7, or 8 during each cycle.

You may also receive premedications prior to starting tafasitamab to help minimize the risk of infusion-related reactions. These premedications may include acetaminophen, an antihistamine (such as Benadryl), and a glucocorticoid (such as dexamethasone).

Procedures Summary

Procedure	Screening	Within 3 Days Before Each Cycle	Monitoring During Cycles (1 or more times per week)	Interim Response Assessment	Post Therapy	Follow -up
Medical History & Physical Exam	X	X			X	X
Blood Tests	X	X	X		X	X
Bone Marrow Aspirate & Biopsy	X			X	X	
Pregnancy Test	X					
CT Scan	X			X	X	
Lumbar Puncture	X			X		

Long-Term Follow-Up

In the follow-up portion of this study we will be keeping track of your ALL via regular visits with a physician of your choice. In order to do this we will obtain information from you by conducting physical exams (as described earlier). A typical follow-up schedule is every 3 months for 2 years and then every 6 months for 3 years (total follow-up time of 5 years). These visits may be performed by physicians outside of your study team as long as medical records documenting these visits are made available to the study team for review. This information will help us learn the long term effects of the study treatment, DA-EPOCH-Tafa ±rituximab.

You do not have to be in long-term follow-up. You could say “yes” or “no”. Either way, you could still join this study. If you choose not to join long-term follow-up, you would not be contacted regularly, and we would not ask your doctor to send medical records, but we might still need to contact you for some other reason.

How long would you stay in this study?

The total time expected on this study may be up to approximately 5.5 years. The total time includes 1 to 8 cycles of actual treatment which will be approximately 1.5 to 6

months if all therapy is given on time. As described above, we may follow your health status for up to 5 years following study treatment.

Doctors could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

What are the side effects (risks)?

In this part of the consent form, we describe the side effects we expect from the tests and treatments in this study. DA-EPOCH-Tafa could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we would tell you if we discover new side effects that could affect you.

This form lists side effects of *individual* drugs. Other side effects could occur when we use these drugs *together*.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. Many side effects go away soon after you stop taking DA-EPOCH-Tafa. In some cases, side effects can last a long time or never go away.

Treatment for your disease may lead to an increased risk of bleeding due to low levels of fibrinogen (blood plasma protein) in your blood. Low levels of fibrinogen can also result in blood clots, which may lead to swelling in the arms and legs. Clots can also travel to the lungs, causing shortness of breath, or to the brain, causing a stroke. This may be serious or life-threatening. If you develop low fibrinogen levels, you may receive a transfusion of a blood product called cryoprecipitate to prevent complications such as bleeding.

There is also a risk of death.

Etoposide

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Hair Loss • Nausea • Vomiting • Loss of Appetite • Diarrhea	• Low Blood Pressure • Swelling of Lips and/or Mouth • Abdominal Pain • Liver Damage	• Absence of Menstruation • Temporary Blindness &/or Eye Pain • Poor Circulation/Low Blood Oxygen Levels (bluish skin discoloration)

• Low White Blood Cell Count • Low Platelet Count • Anemia	• Weakness, Numbness, Tingling, Pain in Hands &/or Feet • Hypersensitivity	• Tongue &/or Facial Swelling • Lung Inflammation &/or Scarring • Laryngospasm • Rash • Metabolic Acidosis • Mucositis • Myocardial Ischemia: *decreased blood flow to the heart due to a blockage of the coronary arteries. Symptoms include chest pain, neck/jaw/shoulder/arm pain, increased heart rate, shortness of breath, nausea &/or vomiting. This can be life-threatening- seek immediate medical attention if you have chest discomfort.* • Itching • Reversible Posterior Leukoencephalopathy Syndrome (RPLS): *condition that may cause seizures, high blood pressure, headache, confusion, blindness and fatigue.* • Seizure • Stevens-Johnson Syndrome: *severe, painful red &/or purple rash that spreads to most of the body also characterized by blisters, tongue swelling &/or shedding of skin. This can be life threatening- seek immediate medical attention.* • Toxic Epidermal Necrolysis (TEN): *similar to Stevens-Johnson Syndrome- painful red rash that spreads quickly, blisters on the skin and mucous membranes, peeling skin &/or fever. This can be life threatening- seek immediate medical attention.* • Toxic Megacolon: *widening of the large intestine characterized by severe abdominal pain, bloating,*

		fever, rapid heart rate, bloody/frequent diarrhea &/or dehydration. This may be life threatening- seek immediate medical attention. • Vasospasm: *sudden restriction in blood flow caused by blood vessels temporarily squeezing*

Prednisone

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• High Blood Pressure • Headache • Difficulty Falling/Staying Asleep • Personality Changes (mood swings, severe depression, euphoria, emotional instability) • Bruising • Thin, Fragile Skin • Impaired Wound Healing • Carbohydrate Intolerance • Diabetes • Edema • Muscle Mass Loss &/or Weakness • Infections	• Congestive Heart Failure: *inability of the heart to pump blood as well as it should- characterized by shortness of breath when exercising or lying down; fatigue, swelling of legs, ankles, feet; irregular heartbeat; persistent cough or sudden shortness of breath with pink/blood tinged mucous; chest pain; fainting. This may be life threatening- seek immediate medical attention.* • Petechiae: *very small broken blood vessels in skin or lining of the mouth which may result in bleeding* • Bloating • Stomach Ulcer • Elevated blood levels of liver enzymes (ALT, AST, Alkaline Phosphatase increased) • Facial Reddening • Weak/Brittle Bones • Cataracts • Sweating	• Increased Intracranial Pressure • Seizure • Vertigo • Hives & Fever • Menstrual Irregularities • Cramping • Pancreatitis • Ulcerative Esophagitis • Bone Decay of Femoral and Humoral Heads • Fracture of Long Bones, Vertebra • Steroid Myopathy • Tendon Rupture (particularly Achilles tendon) • Kaposi's Sarcoma: *a raised red, purple, brown or black tumor caused by a viral infection- often occurring on lower limbs, back, face, mouth, genitalia.* • Bulging of Eye • Glaucoma &/or Increased Intraocular Pressure • Hypersensitivity • Blood Clots

Vincristine

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)

• Pain, Tingling &/or Numbness in Hands &/or Feet • Hair Loss • Constipation	• Edema • High/Low Blood Pressure • Loss of Control of Voluntary Movements, Difficulty Walking, Loss of Coordination • Dizziness • Fever • Headache • Rash • Increased Uric Acid Levels • Parotid Pain • Abdominal Cramps and/or Pain • Loss of Appetite • Diarrhea • Nausea • Mouth Sores • Anemia • Low White Blood Cell Count • Low Platelet Count • Bowel Obstruction due to Temporary Paralysis of Intestinal Muscles • Vomiting • Weight Loss • Painful &/or Difficult Urination • Urinary Retention &/or Increase in Urinary Output • Vein Inflammation, Irritation, Necrosis • Back, Jaw, Limb, Muscle &/or Bone Pain • Deep Tendon Reflex Loss • Increased risk of bleeding	• Heart Attack • Coma • Cranial Nerve Dysfunction • Seizure • Vertigo • Death of Intestinal Tissue &/or Holes in Intestine • Decrease in Kidney Function • Hemolytic Uremic Syndrome: *damaged red blood cells clog the kidneys leading to kidney failure- a treatable condition characterized by bloody diarrhea/urine, vomiting, abdominal pain, fatigue, swelling, confusion, bleeding from nose and mouth. This may be life threatening- seek immediate medical attention.* • Blood Clots • Hepatic Sinusoidal Obstructive Syndrome (SOS): *blockage of veins in the liver characterized by swelling in the abdomen, increased bilirubin levels and liver size* • Muscle Wasting • Temporary Blindness • Uncontrolled Eye Movement • Deafness • Difficulty Breathing • Sore Throat • Hypersensitivity

Cyclophosphamide

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)

• Hair Loss • Absence of Menstruation • Hormone Suppression • Impaired Ovulation • Nausea • Vomiting • Swelling of Lips and/or Mouth • Low White Blood Cell, Neutrophil, Platelet and Red Blood Cell Count due to Impaired Bone Marrow Function • Blood in Urine	• Fever • Abdominal Pain • Loss of Appetite • Diarrhea • Mucositis • Low Sperm Count &/or Decreased Sperm Motility • Sterility • Hemorrhagic Cystitis: *sudden blood in urine and bladder pain. This may be life threatening- seek immediate medical attention.* • Blurred Vision • Increased Uric Acid Levels • Tumor Lysis Syndrome: *usually seen within a few days of starting treatment. A large increase in dying cancer cells can result in metabolic complications noted by nausea, vomiting, swelling, shortness of breath, kidney failure. This may be life threatening- seek immediate medical attention.* • Impaired Wound Healing • Liver &/or Heart Damage • Radiation Recall: *a skin rash that looks like a severe sun burn- seen in people who have recently received radiation therapy* • Increased risk of bleeding	• Acute Respiratory Distress Syndrome: *sudden failure of the respiratory system characterized by rapid, difficult breathing and low blood oxygen levels. This may be life threatening- seek immediate medical attention.* • Bladder/Urinary Fibrosis • Confusion • Shortness of Breath • Abnormally Slow Heart Rate • Inflammation &/or Blood Surrounding the Heart • Hemorrhagic Colitis: *sudden, severe abdominal pain and bloody diarrhea &/or vomiting &/or fever. This may be life threatening- seek immediate medical attention.* • Hepatic Sinusoidal Obstruction Syndrome (SOS): *a potentially serious form of liver injury that causes abdominal swelling, jaundice, confusion, and other signs of liver failure. This may be life threatening – seek immediate medical attention.* • Hypersensitivity • Low Potassium &/or Sodium Levels • Lung Inflammation &/or Scarring • Yellow Discoloration of Skin &/or Whites of Eyes • Return of Old Infections • Acute Mesenteric Ischemia: *inadequate blood flow to intestines leading to severely damaged colon- marked by severe abdominal pain and bloody stool. This may be life threatening- seek immediate medical attention.* • Multi-organ Failure • Nerve Damage

		• Scarring of Ovaries • Pancreatitis • Skin/Fingernail Color Changes • Pneumonia • Pulmonary Hypertension • Kidney Infection/Damage • Reversible Posterior Leukoencephalopathy Syndrome (RPLS) • Rhabdomyolysis: *breakdown of muscle tissue that releases dangerous proteins into the bloodstream. The kidneys have a difficult time removing these proteins, leading to kidney failure. Symptoms include abdominal pain, muscle pain, nausea, vomiting, fever, rapid heart rate, dehydration, dark red/brown urine, reduced or no urine output. This may be life threatening- seek immediate medical attention.* • Secondary Cancer • Sepsis &/or Septic Shock • Stevens-Johnson Syndrome • Testicular Atrophy: *decrease in size of male reproductive organs & possible loss in function.* • Low Platelet Count • Blood Clots • Toxic Epidermal Necrolysis • Toxic Megacolon

Doxorubicin

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• General Feeling of Discomfort, Illness, Uneasiness • Hair Loss • Sensitivity to Sunlight	• Inflammation &/or Damage to Heart • Itching • Radiation Recall • Rash	• Coma • Death of Intestinal Tissue • Conjunctivitis • Darkening of Nails, Skin, Mouth

• Temporary Discoloration of Saliva, Sweat, Tears and/or Urine • Absence of Menstruation • Dehydration • Abdominal Pain • Loss of Appetite • Diarrhea • Mucositis • Nausea • Vomiting • Low White Blood Cell Count • Low Neutrophil Count • Low Platelet Count • Anemia • Weakness	• Infertility (may be temporary) • Increased Uric Acid in Blood • Sores on Lining of Esophagus, Stomach, Small Intestine • Hardening of Veins • Fever • Low Sperm Count &/or Decreased Sperm Motility • Hepatitis/Transaminases Increased • Bilirubin Increased • Fever • Infection	• Inflammation of the Cornea • Increased Tear Production • Secondary Cancers • Seizure • Sepsis &/or Shock • Stevens-Johnson Syndrome • Hypersensitivity • Toxic Epidermal Necrolysis (TEN)

Rituximab

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Swelling • High Blood Pressure • Fever • Fatigue • Chills • Headache • Inability to Fall/Stay Asleep • Pain • Rash • Itching • Nausea • Diarrhea • Abdominal Pain • Weight Gain • Low White Blood Cells, Neutrophils, Platelets • Anemia	• Low Blood Pressure • Dizziness • Anxiety • Increased lactate dehydrogenase (LDH) levels in blood: *can be observed after damage to different healthy tissues (liver, muscle, etc.) as well as cancer cells* • Increased Blood Glucose Levels • Vomiting • Shortness of Breath	• Chest Pain • Acute Respiratory Distress Syndrome • Arrythmia • Bowel Obstruction/Perforation • Heart, Kidney Failure • Swelling of the Brain &/or Spinal Cord • Inflammation of the Liver • Decrease in Blood Oxygen • Lupus-Like Syndrome • Mucositis • Eye Inflammation • Lung Infection, Inflammation • Reversible Posterior Leukoencephalopathy (RPLS)

• Elevated blood levels of liver enzymes (Increased ALT) • Numbness, Weakness, tingling Sensation • Cough • Stuffy &/or Bloody Nose • Night Sweats • Hypersensitivity • Infection		• Progressive Multifocal Leukoencephalopathy (PML): *rare viral disease characterized by clumsiness, progressive weakness and visual, speech and personality changes that develop over several weeks to months. This may be life threatening – seek immediate medical attention.* • Stevens-Johnson Syndrome • Toxic Epidermal Necrolysis (TEN) • Infection Reactivation • Tumor Lysis Syndrome

Tafasitamab-cxix (Tafa)

Likely (>10% of patients)	Less Likely (1-10%)	Rare but Serious (<1%)
• Infusion-related reactions • Low neutrophil count (neutropenia) • Low red blood cell count (anemia): *may cause tiredness or require a transfusion* • Low platelet count (thrombocytopenia) • Low white blood cell count (leukopenia) • Diarrhea • Nausea • Constipation • Vomiting • Peripheral Neuropathy: *nerve damage causing weakness, pain, numbness and tingling in the hands and/or feet* • Fatigue • Low potassium levels (hypokalemia) • Fever with low neutrophils (febrile neutropenia)	• Syncope: *brief loss of consciousness (a.k.a. fainting)* • Pulmonary embolism: *blood clot in the lungs* • Acute kidney injury: *decreased ability of kidneys to filter the blood* • Infection • Abnormal liver function tests • Chills • Bronchitis • Dizziness • Shortness of breath • Facial flushing • Itching • Chest tightness • Feeling warm • Decreased platelet count • Pneumonia (lung infection) • Decreased platelet count • Tumor lysis syndrome: *usually seen within a few*	• Progressive Multifocal Leukoencephalopathy (PML): *rare viral disease characterized by clumsiness, progressive weakness and visual, speech, and personality changes that develop over several weeks to months. This may be life threatening – seek immediate medical attention*.

• Low lymphocyte count (Lymphopenia) • Urinary tract infection • Weakness (asthenia) • Back pain • Inflamed and sore mouth (stomatitis) • Insomnia • Abdominal Pain • Fever (pyrexia) • Decreased white blood cell count • Distorted taste (dysgeusia) • Hypertension • Headache • Rash • Alopecia • Hypotension • Bone pain • Muscle spasms • Decreased neutrophil count • Oropharyngeal pain • Pain in extremities • Upper respiratory tract infection	*days of starting treatment. A large increase in dying cancer cells can result in metabolic complications noted by nausea, vomiting, swelling, shortness of breath, kidney failure. This may be life threatening – seek immediate medical attention.*	
Risks for Tafasitamab-cxix noted in this section come from experience with similar treatment approaches. It is expected that risks from Tafasitamab-cxix with this investigational combination are likely to be similar.		

Filgrastim/pegfilgrastim

Likely (>20% of patients)	Less Likely (4-20%)	Rare but Serious (<4%)
• Nausea, Vomiting • Pain in Bone	• Anemia- *may cause tiredness or require a transfusion* • Damage to the lungs- *may cause shortness of breath* • Internal bleeding- *may cause coughing up of blood* • Swelling or tenderness of vessels	• Rupture of spleen leading to bleeding in the belly- *characterized by sudden or severe pain in the left side of the abdomen spreading up to your shoulder. This may be life threatening- seek immediate medical attention.*

	• Allergic Reaction- *characterized by rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat. This may be life threatening- seek immediate medical attention.*	

Reproductive risks

Chemotherapy and radiation treatments could cause sterility (unable to have children).

Taking DA-EPOCH-Tafa may involve unknown risks to an embryo fetus (unborn baby) or nursing infant. Therefore, you could not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study and are a female of childbearing potential, you would have to agree to use an effective method of birth control. If you are already using a method of birth control, you would have to check with the study doctor or a member of the study staff to make sure it is acceptable.

The effects of fathering a child are also unknown. Men of childbearing potential who join this study must also agree to use one or more forms of effective and acceptable birth control.

Other possible side effects

For most people, needle punctures for blood draws do not cause any serious problems. However, drawing blood from your arm may cause pain. You might get a bruise. Some people feel lightheaded after a blood draw. Very rarely, you could get an infection where the needle entered the vein. If you have a central venous catheter, we will use this to draw the blood, which may lessen the discomfort, but the small risk of infection remains.

What are the benefits?

We do not know if this study would help you. We are testing DA-EPOCH-Tafa to see its effects on people with B-cell ALL. You might get better if you receive DA-EPOCH-Tafa, but your condition could stay the same or even get worse. We hope the information from this study will help other people with B-cell ALL in the future.

You have other choices besides this study.

You do not have to join this study. You are free to say “yes” or “no”. Your regular medical care would not change if you decide to say “no”.

You have other choices for treatment. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Other choices may include:

1) Standard Treatment

2) Another Research Study

3) No Treatment

4) Comfort Care

Enrollment in this study may exclude you from other research studies.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Incyte (the supplier of tafasitamab) and their agents.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center, University of Washington
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other regulatory agencies as required.
- Adaptive Biotechnologies and their agents.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, we are required to report certain sexually transmitted diseases and HIV infection. We also have to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If

an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Would we pay you if you join this study?

You will not be paid to participate in this study.

Would you have extra costs if you join this study?

If you join this study, you or your insurance company would have to pay for the costs of standard treatment in this study. You may have some extra costs. Your insurance company might pay these costs, but some insurance policies do not cover these costs. We could help find out whether your insurance company would cover these costs.

The extra costs are:

- Costs of tests that are given more often than usual.
- Cost of DA-EPOCH.
- Paying the people who give DA-EPOCH-Tafa and the cost of the equipment they use.
- Cost of standard doctor visits and lab tests.
- Cost of any other medical care needed because of this study.

You would **not** be billed for:

- The study drug (Tafasitamab-cxix)
- Cost of blood draws for research and any additional tests done purely for research purposes.
- Cost of pregnancy test, if necessary.

What if you get sick or hurt after you join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact your study doctor. You can call Dr. Cassaday at (206) 606-1202. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information and/or tissue samples be used for?

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

Will my information and/or tissue samples ever be use for future research?

After we do tests on tissue in this study, some tissue may be leftover. We invite you to donate this leftover tissue for future research. This may include genetic research.

If you join this study, you would not have to donate tissue or information for future research. You would be free to say “yes or “no”. Regular medical care would not change if you say “no”.

If you say “no,” your tissue and information (even if made anonymous) will not be used for future research.

If you donate tissue and information, it would be stored in a secure location. If we want to use your tissue for other research or share it with other scientists for research, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask your permission to do the research.

Your donated tissue and information would be used only for research. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The research results would not be included in medical records. The results would not affect your medical care.

Research with tissue and information might help develop new products. If these products make money, there is no plan to share the money with the participants who donate the tissue.

If you donate tissue and information, you could withdraw the donation at any time by calling Dr. Cassaday at 206-606-1202. You would have no penalty for withdrawing the donation, and regular medical care would not change. We could not return donated tissue to you or your doctor, but we might be able to destroy the donated tissue. We could not destroy tissue if it is stored or shared without any label saying who donated it. In this case, it could still be used for research.

Please indicate your choice by initialing next to one of the options below:

_____ **Yes**, I agree my samples can be used for optional future research.

_____ **No**, I do not want my samples used for optional future research.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we would want you to tell the study doctor. The doctor could tell you about the effects of stopping DA-EPOCH-Tafa. You and the doctor could talk about the follow-up care and testing that would help the most.
- Before you leave the study, the doctor might ask you to continue in the follow-up part of the study.

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.

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-606-1202 (Dr. Ryan Cassaday, Sponsor-Investigator) 206-606-8311 (Research Manager)
If you get sick or hurt in this study	(206) 606-1202: Dr. Ryan Cassaday, Sponsor-Investigator
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center) 206-543-0098 (Human Subjects Division, University of Washington)
Your bills and health insurance coverage	(206) 606-1377: Patient Financial Services, Fred Hutchinson Cancer Center

Emergency number (24 hours): (206) 598-6190

University of Washington Medical Center paging operator- please ask the operator to page the hematology-oncology fellow on call.

Consent to Participate

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant

Printed Name	Signature	Date

(Complete only if applicable) If you were a witness for a participant who was not able to read this written consent form, sign below to indicate (1) you were present at the consent discussion in person, (2) you witnessed the verbal presentation of the written consent form, and (3) the participant had the opportunity to ask questions and agreed to take part in the study.

Impartial Witness:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol:
Current consent version date: 02/13/2026
Previous consent version date: 11/06/2024
Copies to: Participant, Medical Records, Research File