

Take care of your health...  
*for yourself and everyone important to you.*



Study Visit Calendar



## **Welcome to the ARIA clinical research study!**

This is your personal study visit calendar for the study. It will help you prepare for your study visits and tell you what procedures will be performed. Please bring this booklet with you to every study visit.

The study will last about 1 year. You will have to visit the study center about once every 3 months for tests and evaluations to check your health and to see if the study treatment you are taking is working to control your HIV. A telephone call (or other type of contact) with the study center will be required every 4-6 weeks in between the visits to the study center.



Inside this booklet there is a space for you to write down information for each of your study visits, including:

- Important questions
- Appointment date and time
- Viral load and CD4+ count

The study visit calendar helps you know:

- What to expect at each visit
- How to prepare so that the visit goes smoothly
- What to bring
- How long the visit will take so that you can plan ahead

*Every study visit is important, so please return for your scheduled appointments. If you have any questions, please ask the study staff at any time.*

**Thank you for your participation in this important research study!**

## My Study Information

<b>Study Subject Number</b>	
<b>Study Doctor Name</b>	
<b>Study Doctor Phone Number</b>	
<b>Study Nurse Name</b>	
<b>Study Nurse Phone Number</b>	

Notes:

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## The ARIA Study: An Overview

The ARIA study is a clinical research study designed for women who have HIV and have not yet received treatment for their HIV disease. The study is comparing two HIV treatments to see if an investigational combination pill (containing three drugs, at least two of which are approved) used for HIV treatment works as well as an approved HIV treatment regimen of multiple pills for women.

The investigational treatment is a combination of three drugs. These drugs are dolutegravir, abacavir (Ziagen also known as ABC), and lamivudine (Epivir also known as 3TC). Abacavir and lamivudine have been approved to treat HIV. Dolutegravir has been submitted for approval. The investigational treatment is taken as a single pill.

In this study, the investigational treatment will be compared to an approved treatment regimen. The approved treatment is taken as three pills. These pills are atazanavir (Reyataz), ritonavir (Norvir), and tenofovir/emtricitabine (Truvada).

## The ARIA study is divided into parts:

**Randomization Phase:** Half of the subjects in the study will be randomly assigned (like flipping a coin) to receive DTG/ABC/3TC for 48 weeks and half to receive ATV+RTV+TDF/FTC for 48 weeks.

**Continuation Phase:** If you are in the group taking DTG/ABC/3TC and stay in the study until Week 48, you may be able to continue in the study and receive study drug at no cost, until:

- It gets approved and is available where you live, or
- It stops working well for you, or
- You leave the study, or
- The pharmaceutical company stops developing the drug.

If you are in the group receiving ATV+RTV+TDF/FTC, you will complete the study at Week 48 and no longer receive your HIV drugs as part of the study.



## Visit 1: (Day 1 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- This is a fasting visit. Please do not eat or drink anything (except water and any other medications you may be prescribed) for at least 6 hours before your visit.
- Please allow \_\_\_ hours for this visit

### Visit Procedures:

- The study staff will answer any questions you have.
- You will receive a limited physical exam in which your weight and vital signs will be checked.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will provide a urine sample for laboratory testing.
- You will have a urine pregnancy test to see if you are pregnant.
- You will have an electrocardiogram (ECG), which measures activity in your heart.
- You will complete a short survey by phone about depression and suicide.
- You will complete a short questionnaire about your quality of life related to your health.
- You will receive study medication if you still qualify for the study.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.

## Visit 2: (Week 4 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- Please bring all bottles of study medications (even if empty) with you to this visit.
- Please allow \_\_\_ hours for this visit

### Visit Procedures:

- The study staff will answer any questions you have.
- You will receive a limited physical exam and your weight will be checked.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will complete a short questionnaire about your satisfaction with your HIV treatment.
- You will return your study medication for counting and receive new study medication.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.



## Visit 3: (Week 8 Visit)

May be conducted as a telephone, clinic, or home visit as agreed with the study staff

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Visit Procedures:

- Someone from the study site will be contacting you to ask if you have questions about the study and to follow up with you regarding your study treatment.
- Please inform the study staff if your medications have changed since your last visit or if you have been ill.



## Visit 4: (Week 12 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- This is a fasting visit. Please do not eat or drink anything (except water) for at least 6 hours before your visit. If you take your study medications (or any other medications) in the morning, it is okay to take them with water.
- Please bring all bottles of study medications (even if empty) with you to this visit.
- Please allow \_\_\_ hours for this visit.

### Visit Procedures:

- The study staff will answer any questions you have.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will receive a limited physical exam and your weight will be checked.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will complete a short questionnaire about your satisfaction with your HIV treatment.
- You will return your study medication for counting and receive new study medication.
- Please inform the study staff if your medications have changed since your last visit or if you have been ill.



## Visit 5: (Week 18 Visit)

May be conducted as a telephone, clinic, or home visit as agreed with the study staff

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Visit Procedures:

- Someone from the study site will be contacting you to ask if you have questions about the study and to follow up with you regarding your study treatment.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.

## HIV Viral Load Testing for ARIA

When we talk about “viral load,” it just means how much HIV is in your blood. HIV is measured in “copies per milliliter (copies/mL)” or how much the HIV in your blood is multiplying. The greater the amount of HIV in your blood, the more serious the disease is likely to be.

One of the goals of HIV treatment is to lower the amount of HIV in your blood to less than 50 copies/mL. This is called being “undetectable.”

### Viral Load Testing and Study Participation

At your next (and all subsequent) study visit(s), your viral load will be tested to see if you are eligible to continue participating in the study on the same schedule or if changes are required. Your study nurse will provide specific details if your visit schedule will need to change based on your viral load test. You will need to have more frequent blood tests if your viral load is not “undetectable,” which means below 50 copies/mL.

1. A blood sample will be taken at your next study visit (Visit 6 [Week 24]).
2. The blood sample will be sent to a lab to test the viral load count.
3. Viral test results will be sent to the study doctor and nurse.
4. Your study doctor or nurse will contact you if additional tests are needed.

### Importance of Following Instructions on Study Procedures and Medication Schedules

Missing just one dose of study medication can change the level of HIV in your blood. Missing a day or more of study medication gives HIV a chance to change and find a new way to reproduce. When this happens, the HIV in your blood can become “resistant” to your current or other similar medications, meaning they may no longer work as well or at all.

If you have any questions, talk to the study doctor or staff. They can provide you with more instruction on how to take your study medication the right way and give you some tips on how to remember to take your medication at around the same time each day.





## Visit 6: (Week 24 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- This is a fasting visit. Please do not eat or drink anything (except water) for at least 6 hours before your visit. If you take your study medications (or any other medications) in the morning, it is okay to take them with water.
- Please bring all bottles of study medications (even if empty) with you to this visit.
- Please allow \_\_\_ hours for this visit.

### Visit Procedures:

- The study staff will answer any questions you have.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will receive a limited physical exam and your weight will be checked.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will complete a short questionnaire about your satisfaction with your HIV treatment.
- You will return your study medication for counting and receive new study medication.
- Please inform the study staff if your medications have changed since your last visit or if you have been ill.

## Visit 7: (Week 30 Visit)

*May be conducted as a telephone, clinic, or home visit as agreed with the study staff*

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Visit Procedures:

- Someone from the study site will be contacting you to ask if you have questions about the study and to follow up regarding your study treatment.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.



## Visit 8: (Week 36 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- This is a fasting visit. Please do not eat or drink anything (except water) for at least 6 hours before your visit. If you take your study medications (or any other medications) in the morning, it is okay to take them with water.
- Please bring all bottles of study medications (even if empty) with you to this visit.
- Please allow \_\_\_ hours for this visit.

### Visit Procedures:

- The study staff will answer any questions you have.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will receive a limited physical exam and your weight will be checked.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will return your study medication for counting and receive new study medication.
- Please inform the study staff if your medications have changed since your last visit or if you have been ill.



## Visit 9: (Week 42 Visit)

*May be conducted as a telephone, clinic, or home visit as agreed with the study staff*

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Visit Procedures:

- Someone from the study site will be contacting you to ask if you have questions about the study and to follow up regarding your study treatment.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.



## Visit 10: (Week 48 Visit)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- This is a fasting visit. Please do not eat or drink anything (except water) for at least 6 hours before your visit. If you take your study medications (or any other medications) in the morning, it is okay to take them with water.
- Please bring all bottles of study medications (even if empty) with you to this visit.
- Please allow \_\_\_ hours for this visit.

### Visit Procedures:

- The study staff will answer any questions you have.
- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will provide a urine sample for laboratory testing.
- You will receive a limited physical exam and your weight will be checked.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will complete a short questionnaire about your quality of life related to your health.
- You will complete a short questionnaire about your satisfaction with your HIV treatment.
- You will return your study medication for counting. If you are assigned to DTG/ABC/3TC and are continuing in the study, you will receive new study medication.
- Please inform the study staff if your medications have changed since your last visit or if you have been ill.

**If you are assigned to ATV+RTV+TDF/FTC,  
your participation is complete.**

**Thank you for volunteering!**

## Visit 11+

(Week 60 Visit and Every 12 Weeks After That)

**Refer to the continuation phase on page 7 for more details.**

- Your blood will be taken for laboratory testing and to measure the amount of HIV and your CD4+ cells.
- You will receive a limited physical exam and your weight will be checked.
- You will provide a urine sample for analysis (every 24 weeks).
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide.
- You will return your study medication for counting and receive new study medication.
- Please inform the study staff if your medications or dosages have changed since your last visit or if you have been ill.

**Please use the tracker provided on the next page to track your viral loads, CD4+ cell count, and next visit date.**





## Withdrawal Visit

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Reminders:

- Please bring all bottles of study medication (empty, partially empty, and full) with you to this visit.

### Visit Procedures:

- Your blood will be taken for laboratory testing and to measure the amount of HIV and CD4+ cells.
- You will receive a limited physical exam and your weight will be checked.
- You may need to provide a urine sample for analysis.
- You will have a blood test to see if you are pregnant.
- You will complete a short survey by phone about depression and suicide
- You will complete a short questionnaire about your quality of life related to your health.
- You will complete a short questionnaire about your satisfaction with your HIV treatment.



## Stay Informed

Your study team can help you find the ARIA study results online once they become available.

Doctors conducting the study sometimes present findings at medical conferences. Regulatory agencies use study results to decide if the drug will gain approval and can then be prescribed by doctors.

Ask your study team if you still have questions regarding study results.

**Thank you for your participation  
in the ARIA Study.**









