SUBJECT INFORMATION AND INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor:	**Midland Research Group, Inc.** **1421 East Oakland Park Blvd, Suite # 200** **Oakland Park, FL 33334** **Phone: 954-375-1275 Fax: 954-283-7618**
Study Title:	**Switch to DRV/COB/FTC/TAF from Integrase containing regimens to evaluate changes in Tolerability/Adherence**
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Protocol Number:	**TMC114FD2HTX4005**
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Janssen Scientific Affairs, LLC is providing funding and study drug Symtuza

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KEY INFORMATION

You are invited to take part in a research study. Your doctor recommended you for this study based on his assessment of the Midland ART Adherence Survey (MAAS) that you completed about your adherence to your HIV medication, during your last visit. This research study is studying Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) as a potential treatment for Human Immunodeficiency Virus-1 (HIV) as a replacement regimen for subjects who have difficulty taking their current HIV medications containing an integrase inhibitor, due to side effects and/or tolerability issues. Midland Research Group, Inc. is sponsoring and conducting this research study. As a sponsor of the study, Midland Research Group, Inc. is receiving funds and study drug from Janssen Scientific Affairs, LLC.

First, we want you to know that you can choose not to take part in it. Second, you need to know that there are some big differences between being in a study and the regular care you get from your doctor:

- Outside of a research study, you and your doctor have a great deal of freedom in making decisions about your healthcare.
- When you take part in a research study, the main goal is to learn things to help other people in the future. The study team (your study doctor and the study staff that assist your study doctor) will follow the requirements for the research study.

It's important that you understand the difference between the regular care you get from your doctor and what's involved in this research study.

This Subject Information and Informed Consent (ICF) describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes alternative procedures that are available to you and your right to withdraw from the study at any time. Your study doctor or study staff will go over this consent form with you and answer any questions you may have regarding the study. Ask your study doctor or study staff to explain any words or information in this consent form you do not clearly understand. No guarantees or assurances can be made about the results of the study.

Please read this information carefully before deciding to take part. Research studies are voluntary and include only those who wish to take part. No one can force you to take part in this study and you can stop at any time. If you choose to take part in this research study, you will be asked to read, date and sign this consent form and you will receive a copy of the signed and dated consent form for your records.

Before you decide to take part, please take as much time as you need to ask questions with your study team, with family and friends, or with your personal doctor or other healthcare professional. Feel free to take the time to make an informed decision for yourself and your healthcare.

This study has been approved by Advarra IRB. Advarra is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in

this consent form for yourself. You must then decide if you want to be in the study.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it and you will receive a copy of the signed and dated document for your records.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have Human Immunodeficiency Virus-1 (HIV-1). You are currently taking an integrase inhibitor-based regimen and have self-identified as non-adherent (which means you do not take your HIV medication everyday as prescribed by your Doctor) due to side effects that you experience.

The purpose of this research study is to:

- To see how well subjects are able to take their HIV medications
- To understand reasons why some subjects may not take their HIV medications as prescribed
- To see if switching subjects to Symtuza® changes subjects' side effects and ability to take their HIV medications
- To evaluate the tolerability of switching from integrase containing regimen to Symtuza® with the aid of Patient Reported Outcome Questionnaires
- To evaluate for potential weight loss when switching from integrase containing regimens to Symtuza®

Symtuza® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) is an FDA approved fixed-dose combination tablet complete regimen for the treatment of HIV-1 infection in adults:

- Darunavir is an inhibitor of the HIV-1 protease.
- Cobicistat helps increase the level of darunavir in your body.
- Emtricitabine is another HIV medication and is a HIV NRTI (Nucleoside Reverse Transcriptase Inhibitor).
- Tenofovir is another HIV medication and is a HIV NRTI (Nucleoside Reverse Transcriptase Inhibitor).

This study drug, Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), has been approved by the Food and Drug Administration (FDA) and is available by prescription for the treatment of HIV-1.

About 30 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY

Your participation in this study will last approximately 16 weeks and will include approximately three to four study visits to the study site.

Your first visit will be for screening to see if you are eligible for the study. If you are eligible for the study and agree to participate, the next visit will be your baseline visit. These two visits can be completed on the same day or you can choose to return within 45 days to initiate the baseline visit. Baseline visit will be the first visit you receive your new study drug. Your next visit will be 4 weeks after baseline and your last visit will be 12 weeks later. The assessments and study procedures for each visit are described in more detail below.

SCREENING

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent form. The following screening tests and study procedures will then be performed to determine if you qualify to take part in this study:

- Study staff will collect your vitals (blood pressure, pulse, temperature, height and weight) along with medical history of HIV-1 disease, current medications and medication history will be documented and a physical exam will be performed.
- Study staff will review any available HIV-1 resistance tests and hepatitis B immunity/viral loads will be documented.
- If you are a woman who can have a child, you may be required to use two forms of contraception. Study staff will discuss this in more detail with you.
- Study staff will also review the inclusion/exclusion criteria (the criteria that will allow you to be included in the study (inclusion), the criteria that would keep you from being in the study (exclusion) and to see whether or not you are able to participate in the study).

This study will use competitive enrollment. This means that when a target number of subjects begins the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of subjects has already begun the study.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

BASELINE VISIT

This visit may occur the same day that you have your screening visit or you have the option of waiting up to 45 days to complete this visit. Study staff will review inclusion/exclusion criteria of the study and confirm whether or not you are able to continue in the study, prior to this visit. Please do not take your HIV medication the day of the visit, because you will be assigned study drug on that day. During this visit you will be asked to have the following test and study procedures:

- You will read the HIV Symptom Index Questionnaires, otherwise referred to as Patient Reported Outcome (PRO) questionnaire and write/mark answers directly onto the questionnaire. (This will take no more than five minutes)

- If you decided to return within 45 days after your screening visit, the following will occur:
    - You will be asked about any medical issues you may have had since your last visit.
    - You will be asked about any medications changes.
    - You will have a physical examination including vital signs (temperature, heart rate, and blood pressure), height and weight.
- You will have blood samples collected for testing which includes a complete blood count (CBC), complete metabolic panel (CMP), Urinalysis (UA), CD4 Lymphocytes, and HIV-1 quantitative viral load.
- If you or the study staff are unsure of your hepatitis B immunity/viral load, a hepatitis B quantitative viral load will be included with your other blood tests.
- If you are female of childbearing potential, a urine pregnancy test will be performed.
- If your HIV-1 viral load was above 200 copies/mL from your last recent labs, an HIV-1 Genotype will be performed to check if you have any resistance to the new study drugs you will be taking.
- You will be given a 30-day supply of the study drug, Symtuza® and take your first dose at the study site.
- The study team will talk to you about the importance of adherence and taking the study drug at the same time each day.
- Your next visit will be four weeks from this visit.

WEEK 4 VISIT

This will be your first return visit after your first month on the study drug. Study staff will ask you questions related to you and being on the study drug.

- You will read the Midland ART Adherence Survey (MAAS) and the HIV Symptom Index questionnaires and write/mark answers directly onto the questionnaires. (This will take no more than five minutes)
- You will be asked about any medications changes.
- You will also be asked if you have had any new medical issues or have been sick since your last visit.
- You will have vital signs (temperature, heart rate, and blood pressure, height and weight) performed.
- You will have blood samples collected for testing which includes a complete blood count (CBC), complete metabolic panel (CMP), Urinalysis (UA), CD4 Lymphocytes, and HIV-1 quantitative viral load.
- If you are female of childbearing potential, a urine pregnancy test will be performed.
- If your HIV-1 viral load was above 200 copies/mL from your baseline labs, an HIV-1 Genotype may be performed to check if you have any resistance to the study drugs you will be taking.
- You will be given a 90-day supply of the study drug, Symtuza® and take your first dose at the study site.
- The study team will talk to you about the importance of adherence and taking the

study drug at the same time each day.
- You will be asked to bring the study drug bottle dispensed at your baseline visit and study staff will make sure you are taking your study drug as directed.
- Your next visit will be 12 weeks from this visit.

WEEK 14 EVENT

Your study doctor will send a prescription of Symtuza® to the pharmacy of your choice in order to make sure you will be available to pick up the study drug from your pharmacy when the study ends. Your insurance may require a prior authorization to approve your study drug and the study staff will handle this for you.

WEEK 16 VISIT

You will return to the study site for a final visit. The following study procedures will be done:

- You will read the Midland ART Adherence Survey (MAAS) and the HIV Symptom Index questionnaires and write/mark answers directly onto the questionnaires. (This will take no more than five minutes)
- You will be asked about any medications changes.
- You will also be asked if you have had any new medical issues or have been sick since your last visit.
- You will have vital signs (temperature, heart rate, and blood pressure, height and weight) performed.
- You will be asked to bring the study drug bottles dispensed at your week 4 visit and study staff will make sure you are taking your medication as directed.
- You will have blood samples collected for testing which includes a complete blood count (CBC), complete metabolic panel (CMP), Urinalysis (UA), CD4 Lymphocytes, and HIV-1 quantitative viral load.
- If you are female of childbearing potential, a urine pregnancy test will be performed.
- If your HIV-1 viral load was above 200 copies/mL from your baseline labs, an HIV-1 Genotype may be performed to check if you have any resistance to the new study drugs you have been taking.
- The study team will ask you if you have been able to pick up Symtuza® from your pharmacy, in order to continue the study therapy since this will be your last study visit.

Schedule of Study Events

Study Procedures	Screening/Baseline combined visit	Screening (if not same day as screen)	Baseline (if not same day as screen)	Week 4	Week 14 Event	Week 16	Early Discontinuation & Post Study Visits (30 Days after last visit)
Vitals	X	X	X	X		X	X
MAAS	X	X		X		X	X
HIV-SI	X		X	X		X	X
History and Physical	X	X					
History and Symptom based physical			X	X		X	X
Complete Blood Count	X		X	X		X	X
CD4 panel	X		X	X		X	X
Complete Metabolic Panel	X		X	X		X	X
HIV-1 Quantitative viral load	X		X	X		X	X
Urinalysis	X		X	X		X	X
Study Drug Dispensation			X	X			
Study Treatment Adherence and Accountability				X		X	
Commercial Script sent to Subject's Pharmacy					X		
HIV Genotype	if viral load >200 copies/mL at last check		if viral load >200 copies/mL at last check	if viral load >200 copies/mL at last check		if viral load >200 copies/mL at last check	if viral load >200 copies/mL at last check
Urine pregnancy	if indicated		if indicated	if indicated		if indicated	if indicated
Hepatitis B viral load	if indicated		if indicated	if indicated		if indicated	if indicated

EXPECTATIONS

If you participate in this study, you will be expected to:

- Take study drug as instructed by study staff once a day, at the same times from day to day.

- Do not take any new medications unless your study doctor has agreed to it. You should speak with your study doctor before taking any new medications.
- You are not allowed to take any of these medications during the study:
    - alfuzosin, carbamazepine, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (such as: dihydroergotamine, ergotamine tartrate, methylergonovine), ivabradine, lomitapide, lovastatin or a product that contains lovastatin, lurasidone, midazolam (when taken by mouth), naloxegol, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort, sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin, or triazolam.
- Do not consume illicit drugs or drugs of abuse during your participation in the study.
- If you are a woman of child bearing potential, you will be required to use effective birth control methods during the study (your study doctor/study staff will discuss birth control options).
- Tell your study staff all the information you know about your health and the medications you may be taking throughout the study period. If you do not tell the study staff everything you may be putting your health at risk.
- Tell your study staff as soon as you can if you are treated by another doctor (for example, in an emergency) and you should inform any treating doctors of your involvement in this study.
- Tell the study doctor/study staff about any changes in your health or problems that you are having (for example, going to the emergency room).
- Tell the study staff about any medications or remedies, including natural or herbal products, which you are taking even if they are obtained without a prescription.
- Do not participate in any other investigational studies (studies of drugs that are not yet approved by the U.S. Food and Drug Administration (FDA).
- Follow all procedures given to you while you are participating in the study. If you do not, you may be discontinued from the study. If you are unsure about what you are supposed to do, ask the study staff.
- Bring your unused study drugs and all empty study drug containers to each of your study visits.
- If you decide to drop out or are not allowed to continue in the study, you may be asked to come in as soon as possible after taking your last dose of study drug. The study staff will ask about any medications you are taking and how you are feeling, obtain laboratory samples (blood), and collect all study drugs provided to you, ask you to complete the PRO questionnaire and return you to your previous HIV medication.
- Complete your subject PRO Questionnaire at every visit after screening.
- It is important that you keep unused study drug out of the reach of children and those who do not have the ability to understand and that the study drug is only taken by you.
- If you forget to follow these instructions in preparation for your study visit, contact

the study staff and let them know. Your visit may need to be rescheduled.

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Symtuza® also referred to as, D/C/F/TAF, is a single tablet containing four medications: darunavir (D), cobicistat (C), emtricitabine (F), and tenofovir alafenamide (TAF). Tenofovir alafenamide (TAF) is a second-generation prodrug of tenofovir (TNF). The first-generation oral prodrug of TNF was tenofovir disoproxil fumarate (TDF). TDF is part of the already approved fixed dose combination FTC/TDF.

This section describes the most severe and/or most frequent possible risks associated with this combination of study drugs. Because you are receiving study treatment for HIV infection with a combination of study drugs at the same time, it is not always possible to tell which study drug caused some of the side effects. This list of side effects is not complete. Please ask your study doctor for more information.

There may be risks with the use of D/C/F/TAF that are not yet known. Sometimes during a study, the sponsor may learn new facts about the study drug. It is possible that this information might make you change your mind about being in the study. If new information is discovered, your study doctor will tell you about it right away.

The most frequently observed side effects (seen in more than 10 percent of research subjects) of D/C/F/TAF were:

- Diarrhea
- Headache
- Skin rash

Other clinically relevant side effects, reported less frequently, include:

- Vomiting
- Inflammation of the pancreas
- Liver disorders
- Increased blood fats (triglycerides and cholesterol) and sugars (glucose)
- Diabetes (new or worsened)
- Changes in body fat (see page 10 for description)
- Lactic acidosis (see page 10 for description)
- Symptoms of infection.

Skin Rash Risks

Skin rash, when it occurs, may be accompanied with fever and/or an increase in liver enzymes (transaminases). It usually develops within the first 4 weeks of study treatment with DRV, is often mild or moderate in severity, often resolves within one week and does not necessarily lead to study treatment interruption.

In some cases, the **rash** has been **severe** or **life-threatening**. Rare cases of Stevens-Johnson syndrome, a serious, potentially life-threatening reaction, and other severe skin reactions have been reported in subjects receiving DRV in combination with other anti-

HIV study drugs, as well as other medications. The signs and symptoms of severe rash may include:

- Mouth and lips sores or ulcers
- Fever
- Itching
- Weakness
- Fatigue
- Malaise
- Muscle or joint pain
- Skin conditions (blisters, hives, boils and peels)
- Swollen eyelids
- Red or inflamed eyes (conjunctivitis)
- Trouble swallowing or breathing
- Inflammation of the liver (hepatitis)
- Increase of white cells in the blood (eosinophilia)

Skin rash usually requires immediate admission to the hospital. This condition usually goes away when all study drugs are stopped. If you develop a rash or any skin abnormality, you should report it the day it appears to your Study Doctor.

Liver Disorder Risks
Uncommon cases of **liver disorders** (including inflammation of the liver that can cause fatigue, loss of appetite, nausea, vomiting, jaundice, dark urine, pale colored stools, liver tenderness) have been reported in subjects receiving DRV and other ARV study drugs. Subjects with liver diseases such as hepatitis B and/or hepatitis C may have worsening of their condition. Some of the liver disorders, which occur or worsen when taking DRV, can be severe and might be sometimes life threatening. The function of the liver and other organs will be monitored throughout the study.

Antiretroviral Drug Risks
Different antiretroviral (ARV) study drugs, including DRV, may affect **fat and sugar metabolism** and may cause **diabetes**. The most frequently observed laboratory abnormalities with DRV are increases in blood fats (triglycerides and cholesterol) and sugars (glucose). Rare cases of pancreatitis (inflammation of the pancreas that can cause abdominal pain and vomiting, and which can be sometimes life threatening) have been reported in subjects receiving DRV and other ARV study drugs. Pancreatic function will be monitored throughout the study.

Changes in Body Fat Risks
Changes in body fat can happen in some people who take antiviral study drugs. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known.

Lactic acidosis Risks
A serious condition called **lactic acidosis** (high levels of lactic acid in the blood), and liver problems with enlargement of the liver and fat in the liver, including deaths, were reported in HIV-infected subjects who received anti-HIV study medications similar to emtricitabine. Symptoms of liver problems include:

- Yellowing of the skin or whites of the eyes
- Dark urine
- Light-colored bowel movements
- Loss of appetite
- Nausea
- Lower stomach pain

If you notice any of these symptoms, you must immediately report them to the study doctor or study staff.

Kidney Problem Risks
New or worse kidney problems, including kidney failure, can happen in some people who take TAF or TDF. Renal function will be monitored throughout the study.

Bone problem Risks
Bone problems can happen in some people who take TAF or TDF. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your study doctor may need to do additional tests to check your bones.

Hepatitis B Infection Risks
Other serious side effects include **worsening of your Hepatitis B infection**. Your hepatitis B Virus (HBV) infection may become worse (flare-up) if you take Emtricitabine and/or TDF and then stop it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

Bleeding Risks
There have been reports of increased risk of **bleeding in subjects with hemophilia** and receiving a protease inhibitor. Report all bleeding episodes to your Study Doctor.

Muscle Pain Risks
Muscle pain, tenderness, weakness and swelling of the muscle can develop, particularly when also taking medicinal products to lower cholesterol. On rare occasions these muscle disorders have been serious with a rapid breakdown of skeletal muscle tissue ("rhabdomyolysis"). This condition can also cause acute kidney failure if not treated properly.

Additional side effects reported for all classes of antiretrovirals, including D/C/F/TAF

Development of study drug resistance

The use of antiretrovirals can result in HIV becoming resistant (the study drugs become less effective in suppressing the virus). That is the reason why it is very important you take your study drugs very strictly as prescribed by your study doctor.

Immune Reconstitution Inflammatory Syndrome
A condition called immune reconstitution inflammatory syndrome can happen in some subjects with advanced HIV infection (AIDS) when combination anti-HIV study treatment is started. Signs and symptoms of inflammation from opportunistic infection that a person has or had may occur as the study drugs work to control the HIV infection and strengthen the immune system.

Autoimmune Disorder Risks
Autoimmune disorders (a situation in which your immune system attacks healthy cells in your body by mistake) such as Graves' disease (a disease in which the thyroid produces excessive thyroid hormones), polymyositis (a disease caused by inflammation leading to weakness of the muscles), and Guillain-Barre syndrome (a disease that occurs when the body's immune system attacks part of the nervous system, leading to nerve inflammation that causes muscle weakness), have also been reported to occur in the setting of immune reconstitution. However, the time to onset is variable and the disorder can occur many months after starting study treatment. Call your study doctor right away if you notice any signs or symptoms of an infection after starting study drugs.

Osteonecrosis Risks
Some subjects receiving anti-HIV study drugs may develop a bone disease called osteonecrosis (bone damage caused by loss of blood supply to the bone). This may be more likely with long-term HIV treatment, more severe damage to the immune system, being overweight, or with the use of alcohol or medicines called corticosteroids. Signs of osteonecrosis are:

- Joint stiffness
- Aches and pains (especially of the hip, knee and shoulder)
- Difficulty in movement

If you notice any of these symptoms tell your study doctor.

Allergic Reaction Risks
As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Difficulty breathing
- Wheezing
- Sudden drop in blood pressure
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment and alert the study doctor and study staff immediately if you have any of these symptoms during the study.

Side effects due to the combination of study drug with other drugs

Use of study drug with other drugs could result in either drugs working less effectively or could result in side effects which could be serious. It is important that you inform your study doctor of any other medications (including over the counter medications) that you are considering taking.

Reproductive Risk

If you are a woman:

- Taking part in the study might harm your unborn child or breastfed baby. You cannot take part in this study if you are pregnant or breastfeeding a child.
- You must agree not to become pregnant while you are in this study.
- Women who are able to get pregnant must agree to practice sexual abstinence or use adequate reliable birth control methods from screening until 90 days (or longer based on local regulations) after stopping study treatment.

If you are not heterosexually active you are asked to provide periodic confirmation of continued abstinence from heterosexual intercourse. You will have regular pregnancy testing while taking study drugs. The study doctor will counsel you on adequate, reliable birth control methods if you choose not to continue abstinence.

Otherwise, the type of birth control you use must be discussed with the study doctor before you begin the study. The study doctor must approve the method you use before you can enter the study.

If you use a hormonal birth control method (for example, the pill, injection, patch, vaginal ring, etc.) you should consider other methods of birth control. This is because the hormonal ingredients may increase or decrease when taken with the study drugs.

The use of birth control methods does not apply if the male partner has been vasectomized at least 2 months prior to screening.

- If you get pregnant during the study, you must tell the study doctor immediately. You will have to stop taking the study drug. The study doctor will advise you about your medical care and will ask you to allow him/her to collect information about your pregnancy and the health of your baby.

If you are a man:

- The effect of the study drug on your sperm is unknown.
- Men with a female partner of childbearing potential must agree to use adequate reliable contraceptive methods (as explained above) during the study until 90 days after last study treatment dose (or longer, if dictated by local regulations).

Men who have had a vasectomy without a reversal operation are not required to use birth control methods.

- You must agree not to donate sperm during the study until 90 days after end of study treatment (or longer, if dictated by local regulations).
- It is your responsibility to ensure that your partner(s) is (are) not pregnant prior to entry into the study or become(s) pregnant during study treatment and for up to 90 days after end of study treatment (or longer, if dictated by local regulations).
- If your partner becomes pregnant while you are in this study, the sponsor may ask you and your partner to allow them to collect information about her pregnancy and the health of the baby.

RISKS OF STUDY PROCEDURES

- Blood samples: Possible side effects from blood drawing include:
    - Faintness
    - Inflammation of the vein
    - Pain
    - Bruising
    - Bleeding
    - Infection
- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

UNFORESEEN RISKS

There are adverse events that are not known or happen rarely when subjects take these study drugs. You will be told of any new information that might cause you to change your mind about continuing to take part in this study as soon as the information is available.

As with any new drug, extra care has to be taken to monitor the side effects that are not always obvious. If you feel any side effects or unusual symptoms, please notify your study doctor as soon as possible at the phone number listed on page one of this consent form.

BIRTH CONTROL RESTRICTIONS

Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

It is not known whether the study drug(s) may affect an unborn baby and their effects **may be hazardous**. It is important that women must not become pregnant during this study. Taking Symtuza® may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study. Effective birth control must be used by women who are still able to

become pregnant from the screening visit until the end of the study (Screening Visit to Visit Week 16).

If you are female and wish to participate in this study, you must:

- Be of non-child bearing potential [for example, physiologically incapable of becoming pregnant, including any female who is 2 years post-menopausal, or surgically sterile (defined as having a bi-lateral oophorectomy, hysterectomy or tubal ligation)]
- Be of child bearing potential, have a negative serum pregnancy test (blood test) or urine at Screening Visit to Visit Week 16, and agree to one of the following acceptable birth control methods used consistently and correctly as stated below for the duration of the study – from Visit 1 (Screening) until 14 days after Visit Week 16
- Not have sex while in the study; or
- Use hormonal contraceptive such as
    - Oral contraceptive
    - Contraceptive implant
    - Injectable hormonal contraceptive
- Use a double barrier method such as
    - Condom plus intrauterine device (IUD)
    - Diaphragm plus spermicide
- Maintain a sexual relationship with the same male partner (a monogamous relationship) throughout the study who has had a vasectomy (surgically sterilized)

If you think that you have become pregnant during the study, it is important that you inform the study staff immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study staff will refer you to seek the appropriate care, the cost of which will be your responsibility. The study staff may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your HIV-1. Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
There is no compensation for participating in this study.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. You will not lose any of your legal rights or release the sponsor, the study doctor, the study staff, or study site from liability for mistakes by signing and dating this consent document.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS
There will be no charge to you or your insurance company for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. You or your usual health care payer will be responsible for any other health care costs, not related to the study.

FUTURE RESEARCH STUDIES
Your private information or biospecimens collected during this study **will not be used or distributed for future research studies,** even if identifiers are removed.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00040527.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check YES, NO or N/A).

❒ **YES** - If yes, please complete the information below

❒ **NO**

❒ **N/A** – My primary care provider is also my study doctor

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

1. Your name.
2. Address.
3. Phone number.
4. Date of birth.
5. Medical history.
6. Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

1. Representatives of Janssen Scientific Affairs, LLC., who is funding this study
2. Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
3. The Food and Drug Administration (FDA) and other US federal and state agencies.
4. Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
5. Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.

During this study your Study Doctor, study nurses and other study staff will record information about you, your health and your participation in the study on forms provided by Sponsor. These forms are known as case report forms. You will not be able to participate in this study if you do not consent to the collection of this information about you.

The information collected about you will be held by the study site, Sponsor and Sponsor’s authorized representatives. To ensure that your personal information is kept confidential, your name and any other information that allows you to be identified directly will not be entered on the case report forms or included in any records or samples your study doctor provides to

the Sponsor or Sponsor's authorized representatives. Instead, you will only be identified by a code. The code is used so that your study doctor can identify you if necessary.

The Sponsor and its authorized representatives will analyze and use the coded information they receive for the purposes of this study. Such purposes include:

1. Checking your suitability to take part in the study,
2. Monitoring your study treatment with the study drug,
3. Comparing and pooling your study treatment results with those of other subjects in clinical studies,
4. Establishing whether the study drug meets the appropriate standards of safety set by the authorities,
5. Establishing whether the study drug is effective,
6. Supporting the development of the study drug,
7. Supporting the licensing application for regulatory approval of the study drug anywhere in the world,
8. Supporting the marketing, distribution, sale and use of the study drug anywhere in the world, and/or
9. As otherwise required or authorized by law.

Your coded study information may also be used for additional unanticipated medical and/or scientific research projects in the future relating to your disease or similar diseases and development of the study drug (but at all times in compliance with applicable law and regulation).

If necessary for these purposes, the Sponsor may share your information with its affiliates, people and companies with whom the Sponsor works, Advarra IRB and regulatory or other governmental agencies, such as the FDA. Although efforts will be made to protect your privacy, absolute confidentiality of your records cannot be guaranteed. Your medical information and records may be re-disclosed and no longer protected by federal privacy law.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this consent form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this consent form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of the Person Obtaining the Authorization

_____ _____

Signature of the Person Obtaining the Authorization Date