

## **Notes for the DAIDS Medical Officers and Investigators:**

**This document provides a template for developing the Drug Risk Lists (i.e. side effects of study drugs). Drug Risk Lists should be included in the section of the DAIDS Sample Informed Consent (SIC) Form that addresses possible drug-associated risks to study participants.**

**The Risk Lists shows a list of side effects already known to the Medical Officers. The list draws on relevant sources of risk information. Drug Risk Lists are usually reviewed by the protocol team with guidance from the appropriate DAIDS Medical Officer(s) before it is included in the DAIDS SIC Form.**

**The following are not typically addressed in the DAIDS Risk List, but should be included in the DAIDS SIC Form as per the applicable DAIDS SOPs, and if applicable to the specific study: virologic failure, development of resistance, pregnancy risks related to antiretroviral (ARV) agents, and study product interactions with other agents.**

**Use this template as a tool while developing your protocol. Do not use the bolded information above in your specific protocol SIC Form.**

### **Drug Risks:**

#### **General Disclaimer**

The drug(s) used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known or possible relationship to the drug(s) used in this study. It is very important that you tell your study doctor of any changes in your medical condition while taking part in the study. At any time during the study, if you believe you are experiencing any of these side effects, you have the right to ask questions on possible and /or known risks.

There might be a risk of serious and/or life threatening side effects when non-study medications are taken with the study drugs. For your safety, you must tell the study doctor or nurse about all medications you are taking before you start the study, and you must request approval for taking any new medication(s) while you are in the study.

#### **Use of Combination Antiretroviral Drugs**

The use of combination antiretroviral drugs may cause a change in your immune system. This change is called immune reconstitution inflammatory syndrome.

In some people with advanced HIV infection, symptoms from other diseases may occur soon after starting combination antiretroviral therapy. However, symptoms from other diseases can also occur later. Some of these symptoms may be life-threatening. If you start experiencing new symptoms or notice that existing symptoms are getting worse after starting your antiretroviral therapy, tell your healthcare provider right away.

The use of antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

- Increase in fat around the waist and stomach area
- Increase in fat on the back of the neck
- Thinning of the face, legs, and arms
- Breast enlargement

### **Risk of Rilpivirine (RPV)**

The following serious and life-threatening side effects have been associated with the use of RPV:

- Severe skin rash and allergic reactions. If you get a rash with any of the following symptoms, stop taking RPV and call the study doctor or your healthcare provider right away:
  - Fever
  - Blistering on the skin or ulcers/sores in the mouth
  - Eye redness or
  - Swelling of the face, mouth, tongue, throat or other parts of the body
  - Trouble breathing or swallowing
- Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:
  - Feeling sad or hopeless
  - Feeling anxious or restless
  - Have thoughts of hurting yourself (suicide) or have tried to hurt yourself.
- Liver problems:
  - Yellowing of your skin or the whites of your eyes
  - Dark urine (looks like tea))
  - Light-colored bowel movements
  - Loss of appetite
  - Nausea/vomiting
  - Pain, aching, or tenderness in the right side of your stomach (abdominal) area
  - Your healthcare provider may inform you that you have an elevated liver-related function test. People with a history of liver disease may have an increased risk of liver problems.

Additional side effects may include:

- Headache
- Trouble sleeping
- Feeling tired