



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila Kwami, Ukuphila Kwethu (my health for our health)



00423101

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

## Serious Adverse Event Reporting

### ANRS 12249 Initial SAE Notification

SAE-AI

Completed forms must be sent to  
ANRS within 48 hrs.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2015 04 07

Initial Notification Date

2015 04 24

Notification time

#### 1. Patient details

TasP ID

43967

Name

H-Z

Sex

Male

☒ Female

Date of birth

1963 04 03

Enrolment date

2014 09 22

#### 2. Measurements

Height

161 cms

Last known: Weight

59.9

Kgs

Weight Date

2015 04 23

CD4 count

565

CD4 Date

2015 04 07

Viral Load

<40

Viral Load Date

2015 02 03

#### 3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☒ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

DATA CAPTURED  
2015-05-06  
DC QC

#### 4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator  
became aware

Date of onset of SAE

1. Elevated Gamma Glutamyl transaminase 2015 04 15 2015 04 07

2.

3.

4.

5.

#### 5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

Abnormal liver enzymes ALT 76, ALP 155, GGT 488  
GGT 212 at baseline Started on Atripla 13/10/2014.  
Admits to taking herbal remedies and drinking alcohol

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. TDF/FTC/EFV	300/200/600 Po		HIV	20141013		Unrelated	<input checked="" type="radio"/> Yes <input type="radio"/> No	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop

## 7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research? ☒ Yes ☐ No

7b. According to the physician, is this SAE related to any causes other than the research? ☒ Yes ☐ No

This includes the patient's medical history

☒ Describe

CrAT was abnormal at baseline but has gradually gotten worse since starting atypical/Herbal remedies/Alcohol

## 8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name

COLLINS Iwuyi

Signature

Xnf

Date form completed

20150424