



Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukuphila kwethu (we health for our health)



00423102

Ukaphila 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
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

51019

Name

N M

Sex

Male

☒ Female

Date of birth

1971 03 28

Enrolment date

2015 01 19

2. Measurements

Height

168 Cms

Last known: Weight

60.3

Kgs

Weight Date

2015 04 07

CD4 count

310

CD4 Date

2015 01 29

Viral Load

< 40

Viral Load Date

2015 04 07

DATA CAPTURED

2015-05-06

DC QC

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

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 01 29

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 LFTs present at baseline visit on 29/1/2015; ALT 49
ALP 213 GGT 666. Improving. GGT now 419, ALT 70, ALP
151. Patient is Hepatitis BSAg positive
Patient was on TDF/3TC/EFV when joined trial this was switched
to Atripla on 09/02/2015

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	300/300/600 PO		HIV	20110825	20150209	Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
2. TDF/FTC/EFV	300/200/600 PO		HIV	20150209		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> 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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Abnormal LFTs present at baseline
Patient is also hepatitis B Ag +ve.

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

Signature

Date form completed

C 1 May 1

Kmfg

20150424