



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ampikva kwami, ukuphila kwethu)

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
Fax: +33 153 946 002



00093270

SAE No.

SAE Visit Date

2013/03/0

Initial Notification Date

2013/01/01

Notification time

1. Patient details

TasP ID

14847

Name

EM

Sex

☒ Male

☐ Female

Date of birth

19721225

Enrolment date

20130312

2. Measurements

Height

170 Cms

Last known: Weight

56.7

Kgs

Weight Date

2013-10-06

CD4 count

689

CD4 Date

2013-10-06

Viral Load

<50

Viral Load Date

2013-10-06

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

Date of onset of SAE

became aware

1. ELEVATED GAMMA GLUTAMYL TRANSFERASE 20131101 20131030

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.

Gamma glutamyl transferase has been elevated 3-4x ULN when on D4T/3TC/EFV prior to switching to Atripla in April 2013. MCV and MCH have been normal. Routine bloods on 30/10/2013 showed GGT 620, ALT 29 ALP 157.

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>	<u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.	ATRIPLA TDF/FTC/EFV	300/200/600 PO		HRV	20130410		Unrelated <input checked="" type="radio"/> Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.							Unrelated Poss. related Cannot be assessed	Yes No	None Reduce 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
Describe

No

Pre-existing abnormality in JGT, whilst on TDF/FTC/EFV. Need to obtain alcohol history

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

DR COLLINS /WUJ/

Signature

Xnf

Date form completed

20131101