



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

## Serious Adverse Event Reporting

SAE-AI

v10 Feb 2012



00026560

## ANRS 12249 Initial SAE Notification

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

SAE No. \_\_\_\_\_

SAE Visit Date

2012-11-26 16

Phone call

Initial Notification Date

2012-11-26 16

Notification time

## 1. Patient details

TasP ID

1 2 3 5 7

Name

P. N

Sex

☐

Male

☒

Female

Date of birth

1 9 8 7 0 9 2 8

Enrolment date

2 0 1 2 0 9 2 6

## 2. Measurements

Height

1 6 1 Cms

Last known: Weight

6 1 0 0 Kgs

Weight Date

2 0 1 2 1 1 0 8

CD4 count

9 5

CD4 Date

2 0 1 2 0 9 2 1

Viral Load

1 5 1 1 0

Viral Load Date

2 0 1 2 0 9 2 1

## 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. Severe headache 20121121 20121108

2. Y Y Y Y M M D D Y Y Y Y M M D D

3. \_\_\_\_\_

4. Y Y Y Y M M D D Y Y Y Y M M D D

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.

Developed severe headache on 8/11/2012. Admitted to hospital for 2 days. Investigated with a chest-x-ray and a lumbar puncture. Both normal. Discharged on 11/11/2012. Re-admitted on 14/11/2012 for the lumbar puncture as was not done in first admission. Discharged 15/11/2012.

## 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. ISONIAZID	300mg	ORAL	TB PROPHYLAXIS	20120921		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. PYRIDOXINE	25mg	ORAL	PROPHYLAXIS PERIPHERAL NEUROPATHY	20120921		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. CO-TRIMOXAZOLE	960mg	ORAL	PROPHYLAXIS BACTERIAL	20121017		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. VITAMIN BCO T		ORAL		20120921		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

## 8. SAE Outcome

☒ 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. RICHARD LESSELLS

Signature

Date form completed 20121121

## 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. TENOFOVIR	300mg	ORAL	HIV	20120401		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	ORAL	HIV	20070827		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. EFAVIRENZ	600mg	ORAL	HIV	20121017		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

## 8. SAE Outcome

☐ Unknown to date☐ Ongoing☐ Improved☐ Recovered

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Date of recovery

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

## Physician reporting SAE

Name

DR Richard LESSELLS

Signature

Date form completed

20121121

