



TasP

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

Ukaphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AI

v10 Feb 2012

## Serious Adverse Event Reporting

### ANRS 12249 Initial SAE Notification

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



00010036

SAE No.

SAE Visit Date

20120913

Initial Notification Date

20120921

Notification time

1640

#### 1. Patient details

TasP ID

14934

Name

Sex

☒

Male

☐ Female

Date of birth

19840502

Enrolment date

20120821

#### 2. Measurements

Height

1,61 Cms

Last known: Weight

63.4

Kgs

Weight Date

20120821

CD4 count

489

CD4 Date

20120821

Viral Load

2713

Viral Load Date

20120821

#### 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. PHYSICAL ASSAULT 20120913

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

3. Y Y Y Y M M D D Y Y Y Y M M D D

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

5. Y Y Y Y M M D D Y Y Y Y M M D D

#### 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.

Details of assault not known. Mother informed trial  
clinic of assault to participant.

## 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. VITAMIN B6	1	ORAL		20120821		<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. COTRIMOXAZOLE 960mg		ORAL	PCP PROPHYLAXIS	20120821		<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. AMOXYCILLIN 1500mg		ORAL	CHEST INFECTION	20120821	20120825	<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 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



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 LESSEN

Signature

Date form completed 20120921