



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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

## Serious Adverse Event Reporting

SAE-AI

v10 Feb 2012



00010037

### 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

SAE No.

SAE Visit Date

20121112

Initial Notification Date

20121119

Notification time

1330

#### 1. Patient details

TasP ID

14345

Name

AS

Sex

☐ Male

☒ Female

Date of birth

19450510

2012-11-21

Enrolment date

20121011

QC QC

#### 2. Measurements

Height

154 Cms

Last known: Weight

33.7 Kgs

Weight Date

20121112

CD4 count

41

CD4 Date

20121011

Viral Load

444700

Viral Load Date

20121011

#### 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.

Diarrhoea

20121112

20121011

2.

Hypotension

20121112

20121112

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.

bloody diarrhoea of approximately 3-4 weeks duration, dehydration, associated hypotension. BP 76/57. started on intravenous fluids in local primary health care clinic, ambulance called for transfer to hospital. Also pyrexial at 38.6°C. Had seen a GP on 8/11/2012 for similar symptoms and prescribed Allergex, Panadol, Ciprofloxacin.

## 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. COTRIMOXAZOLE 960		PO	PROPHYLAXIS	20121011		<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. VIT B COMPLEX T		PO	SUPPLEMENT	20121011		<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.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input 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 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

Possibly related to Advanced HIV infection. Patient also anemic with weight loss

## 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 RICHARD LESSELLS

Signature *Richard Lessells*

Date form completed 20121119