



TasP

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

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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002



00057535

SAE No.

SAE Visit Date

20131024

Initial Notification Date

20131030

Notification time

### 1. Patient details

TasP ID

12173

Name

NZ.

Sex

Male

Female

Date of birth

19680330

Enrolment date

20130618

### 2. Measurements

Height

154 Cms

Last known: Weight

40.3

Kgs

Weight Date

20130925

CD4 count

240

CD4 Date

20130925

Viral Load

<50

Viral Load Date

20130925

### 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. LOWER RESPIRATORY TRACT INFECTION 20131024 20131018

2. 20131024 20131018

3. 20131024 20131018

4. 20131024 20131018

5. 20131024 20131018

### 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.

Admitted to Hospital on 18/10/2013 with lower respiratory tract infection. Discharged on 23/10/2013.

## 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. ATRIPLA TDF/FTC/EFV	300/200/600 PO	PO	HIV	20130703		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No <input type="radio"/>	<input checked="" type="radio"/> None Reduce Interrupt Stop
2. ISONIAZID	300MG	PO	TB PROPHYLAXIS	20130425		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No <input type="radio"/>	<input checked="" type="radio"/> None Reduce Interrupt Stop
3. PYRIDOXINE	25mg	PO	PERIPHERAL NEUROPATHY PROPHYLAXIS	20130425		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No <input type="radio"/>	<input checked="" type="radio"/> None Reduce Interrupt Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes No <input type="radio"/>	None Reduce Interrupt Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes No <input type="radio"/>	None Reduce Interrupt Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes No <input type="radio"/>	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 ☐ No

Describe

LOWER RESPIRATORY TRACT  
INFECTION

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery

20131023

☒ Recovered without sequelae  
or

Recovered with sequelae

Describe

## Physician reporting SAE

Name

DR COLLINS J. W. H.

Signature

X. W. H.

Date form completed

20131030