



TasP

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



00317400

Ukaphila 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

SAE No.

SAE Visit Date

20150309

Initial Notification Date

20150311

Notification time

1600

#### 1. Patient details

TasP ID

44446

Name

M.D.S.

Sex



Male

Female

Date of birth

19481024

Enrolment date

20140910

DATA CAPTURE

2015-03-26

DCP-2

#### 2. Measurements

Height

167 Cms

Last known: Weight

60.1

Kgs

Weight Date

20150211

CD4 count

377

CD4 Date

20141102

Viral Load

14557

Viral Load Date

20141102

#### 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. Death - due to congestive cardiac failure 20150309 20150317

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.

Participant had presented with oedema + cough in November 2014. Was referred to hospital for chest xray + ECG. He only went to hospital in February 2015. Sputum and chest xray were negative for TB. He was reviewed on 11/2/2015. He had improved and was started on Atridol and Potassium replacement. He was admitted to hospital on 17/2/2015 with signs of cardiac failure and he deteriorated and died on 02/03/2015. Hospital records show he was known with cardiac failure and had defaulted treatment. He also had renal impairment with urea 30 and creat 176.

## 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	20150211		Unrelated <input checked="" type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2. Emtricitabine	200mg	oral	HIV	20150211		Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20150211		Unrelated Poss. related Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> 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

Patient was known with congestive cardiac failure. He had defaulted treatment & not disclosed to trial clinic.

## 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 GUGIELHLE MKHULISI

Signature

Date form completed

20150311