



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Ukaphila kwami, ukaphila kwethu)

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

SAE-AI

## 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

00317431

SAE No.

SAE Visit Date

20160315

Initial Notification Date

20160318

Notification time

1115

#### 1. Patient details

TasP ID

33893

Name

T.N.M.

Sex

Male

☒ Female

Date of birth

19660421

Enrolment date

20160203

#### 2. Measurements

Height

165 Cms

Last known: Weight

48.0

Kgs

Weight Date

20160203

CD4 count

93

CD4 Date

20160203

Viral Load

875436

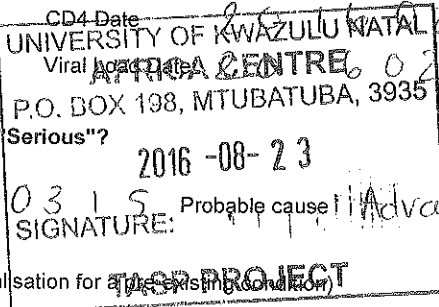
Viral Load Date

20160203

#### 3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☒ Resulted in death → Date of death 20160315
- ☐ 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



Probable cause: Advanced Retroviral Disease

#### 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

20160317 20160315

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 enrolled in control arm of trial on 03/02/2016. She had CD4 93 & VL 875436. She was to be fast-tracked onto ART & due for Doctor's review for ALP 189 & haemoglobin 8.9g/dl blood results. She missed appointments. Upon tracking, relatives reported she had been admitted to Ngweni hospital since 19/2/2016 & died there on 15/03/2016. Details unknown.

## 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.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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

Advanced rebronchial disease at baseline clinic visit.

## 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 GUG'EUHUE MKHULISI

Signature

Date form completed 20160318