



TasP

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



00093272

Mchakwini  
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

20131017

Initial Notification Date

20131106

Notification time

#### 1. Patient details

TasP ID

32218

Name

B.T

Sex

☒ Male

☐ Female

Date of birth

19630110

Enrolment date

20131017

#### 2. Measurements

Height

180 Cms

Last known: Weight

63.1

Kgs

Weight Date

20131017

CD4 count

156

CD4 Date

20131017

Viral Load

Viral Load Date

#### 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

MULTI-DRUG RESISTANT TUBERCULOSIS

#### 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. MULTI-DRUG  
RESISTANT TB

20131105 20131017

2.

3.

4.

5.

DATA CAPTURE

2013-11-07

DCP - S

#### 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.

Patient complained of cough, haemoptysis and weight loss at baseline. Investigations for TB with Genexpert showed MDR-TB. Culture awaited. Patient has been admitted to hospital for treatment.

## 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.	AMOXICILLIN	/	/	/	/	/	<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
2.	/	/	/	/	/	/	<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
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
5.	/	/	/	/	/	/	<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
6.	/	/	/	/	/	/	<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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Advanced HIV  
Multi-drug resistant TB.

## 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

Signature

Date form completed

Dr Collins Iwusi  
Xmp

20131106