



TasP

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

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

# Serious Adverse Event Reporting

SAE-AC

v6 Feb 2012



00009905

## ANRS 12249 Complementary SAE Notification

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No. \_\_\_\_\_ Initial Notification Date 20130111 i.e. Date of original Initial Notification Form  
Complementary Notification Date 20130125

### 1. Patient details

TasP ID 12027  
Name S.S  
Sex ☒ Male ☐ Female  
Date of birth 19640929  
Enrolment date 20121210

### 2. Description of the reported SAE

Previous pulmonary TB x 2. Presented with cough, haemoptysis, dyspnea.  
AFB negative, Sputum xpert negative. Admitted to hospital  
on 19/12/2012.

Date of SAE onset 20121213

### 3. Complementary information

Started on Anti-tuberculous chemotherapy whilst in  
hospital on 19/12/2012

### 4. New diagnosis?

☒ Yes → Describe Pulmonary TB → Not culture proven  
☐ No  
Date of new diagnosis 20121218

### 5. Patient treatment

a) Did the event resolve after discontinuation of treatment? ☐ Yes ☐ No ☒ N/A

Which treatment? \_\_\_\_\_

Date discontinued Y Y Y Y M M D D

b) Did the event reappear after reintroduction of treatment? ☐ Yes ☐ No ☒ N/A

Which treatment? \_\_\_\_\_

Date reintroduced Y Y Y Y M M D D

c) Has the complementary information mentioned above  
modified your judgement of causality regarding one or  
more treatments compared to your initial notification?

☐ Yes → Section 6 ☒ No → Section 7

DATA CAPTURE

2013-04-08

DCP - S

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. _____	_____	_____	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

## 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

Probable Pulmonary TB →  
not culture proven

## 8. SAE Outcome

☐ Unknown to date

☐ Ongoing

☒ Improved

☐ Worsened

☐ Recovered

Another complementary SAE notification form must be submitted within 8 days from now.

Date of recovery 2013 01 25

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name

Richard LESSELL

Signature

*[Signature]*

Date form completed

2013 01 25