



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Ukuphila kwami, ukuphila kwethu)

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00199218

## 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

20140828

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140926

### 1. Patient details

TasP ID

33311

Name

X.M.

Sex

☒ Male

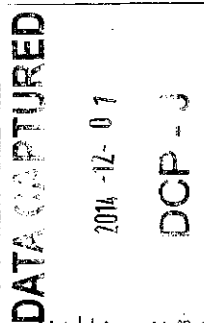
☐ Female

Date of birth

19940304

Enrolment date

20140729



### 2. Description of the reported SAE

Participant referred to hospital with weakness, cough, oedema and diarrhoea. He is on Abipla (TDF/FTC/EFV) with viral load of 45. He was reported by relatives to have died in hospital on 15/9/2014.

Date of SAE onset 20140812

### 3. Complementary information

Hospital notes reviewed. Patient diagnosed with TB Abdomen and chronic gastroenteritis with underlying malnutrition. Co-managed with dietician. Started on TB treatment and nutritional supplements on 12/9/14. Patient died in hospital on 15/9/2014.

### 4. New diagnosis?

☒ Yes → Describe

TB Abdomen

No

Malnutrition

Date of new diagnosis 20140912

### 5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date reintroduced

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

## 6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related 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?

*This includes the patient's medical history*

Yes ☒ No ☐  
Describe

Participant clinically very ill; with low CD4 and malnutrition - highly susceptible to Tuberculosis.

## 8. SAE Outcome

☒ Death

→ Date of death

20140915

Probable

Diagnosis TB Abdomen.

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE Complementary Notification

Name

Dr G. Aluhulisi

Signature

Date form completed

20140926