



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

# Serious Adverse Event Reporting

## 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



00596263

SAE No.

Initial Notification Date

i.e. Date of original Initial Notification Form

Complementary Notification Date 2016 05 31

### 1. Patient details

TasP ID

54620

Name

BK

Sex

Male

☒ Female

Date of birth

1985 08 07

Enrolment date

2015 10 07

### 2. Description of the reported SAE

Dmg induced liver injury

Date of SAE onset

2015 10 07

### 3. Complementary information

LFTs normalised 13/01/2016

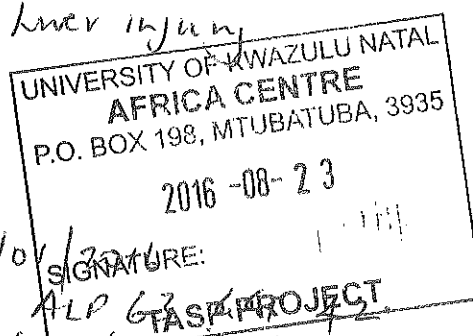
Bil 17

ALT 42

SIGNATURE:

ALP 63 TASP PROJECT

Was admitted to hospital and treated to TDF/3TC/Aluvia.  
Returned to TasP on 23/11/2015.



### 4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

### 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.			<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?

This includes the patient's medical history

Yes ☒ No ☐  
 Describe

Joined the trial already on TDF/FTC/EFV.

## 8. SAE Outcome

Death → Date of death \_\_\_\_\_ Probable Diagnosis \_\_\_\_\_

Unknown to date

Ongoing

Improved

Worsened

Recovered → Date of recovery 2016 01 13.

Recovered without sequelae ☒

or

Recovered with sequelae ☐

Describe

## Physician reporting SAE Complementary Notification

Name

Signature

Date form completed

C. W. M. J.  
 2016 05 31