



TasP

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

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Africa Centre TasP Trial

## Serious Adverse Event Reporting

SAE-AC



00199206

### 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

20140718

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140731

#### 1. Patient details

TasP ID

32856

Name

N.M.M.

Sex

☒ Male

☐ Female

Date of birth

19700105

Enrolment date

20140708

#### 2. Description of the reported SAE

Patient transferred into the trial on TDF/FTC/EFV. His baseline TasP U+e showed grade 3 renal failure, with creatinine of 380. He was referred to hospital.

Date of SAE onset

20140718

DATA CAPTURED

2014-08-18

#### 3. Complementary information

TDF was stopped and the patient switched to AZT/3TC/Aluvia. In hospital he also received IV fluids. He does not have a discharge letter, but the patient states that no other action was taken. By 24/7/14 his renal function had normalised (creatinine = 70!). He was reviewed in TasP Clinic on 31/7/14, and was well. (\*Discharged on 25/7/14.)

#### 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.			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 ☐  
L Describe

Cause of renal failure was the drug TDF, he was on this prior to inclusion in the study.

## 8. SAE Outcome

Death → Date of death

Probable Diagnosis \_\_\_\_\_

Unknown to date

Ongoing

Improved

Worsened

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 20140725

☒ Recovered without sequelae  
or

Recovered with sequelae

L Describe

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 20140801