

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila kwami, ukuphila kwethu / my health for our health)**Ukaphila kwami, ukuphila kwethu****Africa Centre TasP Trial****Serious Adverse Event Reporting****SAE-AC**

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ANRS 12249 Complementary SAE NotificationCompleted forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20140826

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140802

1. Patient details

TasP ID

32824

Name

J.K.M.

Sex

Male

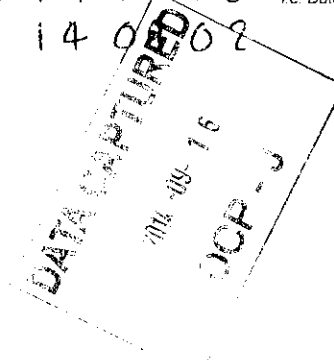
☒ Female

Date of birth

19750215

Enrolment date

20140818

**2. Description of the reported SAE**

The patient was found to have a creatinine of 341 on her baseline TasP blood tests = grade 3 renal failure. Tenofovir was stopped (as a potential cause of the renal failure) + she was referred to Hlabisa hospital.

Date of SAE onset 20140819

3. Complementary information

She attended Hlabisa hospital on 26/8/14, and discharged on 29/8/14. She was diagnosed with a lower respiratory tract infection as an inpatient and given IV antibiotics. She was given IV fluids. Her U+E was repeated on 2/9/14 as an outpatient at Hlabisa Hospital, however creatinine is 306 and urea 15.1.

4. New diagnosis?☒ Yes → Describe

No

Lower Respiratory Tract Infection
(in addition to renal failure)

Date of new diagnosis 20140826

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

☒ No

N/A

Which treatment?

Tenofovir

Date discontinued

20140826

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? ☒ Yes ☐ No
This includes the patient's medical history

Describe

The patient has renal failure at baseline entry into the trial. The cause of renal failure needs to be investigated further.

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 20140829

Recovered without sequelae

or

Recovered with sequelae

Describe

Patient was well enough to be discharged, but renal function still markedly deranged

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

Date form completed 20140902