



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00199217

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20140915

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140926

1. Patient details

TasP ID

42258

Name

N.N.N.

Sex

☒ Male

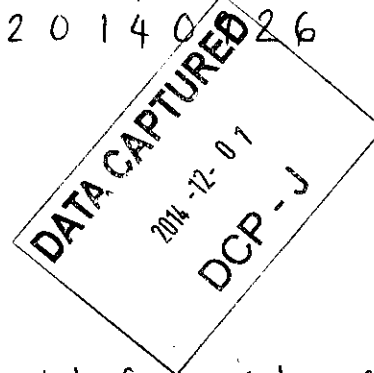
☐ Female

Date of birth

19400120

Enrolment date

20140909



2. Description of the reported SAE

Patient asymptomatic; referred to hospital for raised urea (24.3) and creatinine (525). Known hypertensive and diabetic on treatment. On Abacavir, Lamivudine (renal dose) and Effavirenz. Referred for renal investigation + hyperglycaemia.

Date of SAE onset 20140909

3. Complementary information

Participant admitted to hospital on 12/09/2014. Given Intravenous fluid. Blood sugars monitored. Treatment changed, started on Lasix (furosemide). He was discharged after 10 days, with urea 19 and creat 427. He will be reviewed in hospital 2 weeks post discharge (09/10/2014).

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?

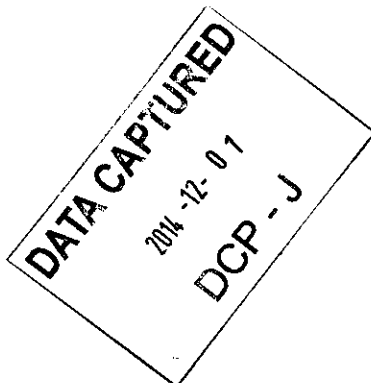
Yes → Section 6

☒ 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 ☐
Describe

Patient has diabetes and hypertension as well as HIV which could all result in Renal failure.

8. SAE Outcome

Death → Date of death

Probable Diagnosis _____

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 Mkhulisi

Signature [Signature]

Date form completed 20140926