



Ukuphila kwami, ukuphila kwethu

SAE-AC

Africa Centre TasP Trial

Serious Adverse Event Reporting

Antiretroviral Treatment as Prevention - ANRS 12249



00004327

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

20120619

i.e. Date of original Initial Notification Form

Complementary Notification Date

20120706

1. Patient details

TasP ID

15647

Name

M.D

Sex

Male

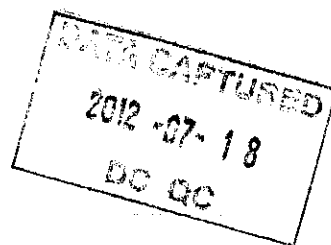
☒ Female

Date of birth

19500412

Enrolment date

20120523



2. Description of the reported SAE

Severe diarrhoea

Acute Renal Failure

Raised Creatinine → Grade 4

Date of SAE onset 20120619 see initial notification

3. Complementary information

Admitted to hospital on 8/6/2012. Discharged on 27/6/2012. Seen in trial clinic on 3/7/2012. Treated with intravenous infusions whilst in hospital. Diarrhoea resolved. Creatinine has improved and now passing adequate amounts of urine. Not restarted ART yet.

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. STAVUDINE	30mg	bd	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. LAMIVUDINE	150mg	bd	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. EFAVIRENZ	600mg	o.d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. TENOFOVIR	300mg	o.d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

(switched to Tenofovir)

2012/07/06
Unrelated

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

see initial SAE notification

8. SAE Outcome

☐ Unknown to date
☐ Ongoing
☒ Improved
☐ Worsened
☐ Recovered

→ Another complementary SAE notification form must be submitted within 8 days from now.
 → Date of recovery
 Recovered without sequelae
 or
 Recovered with sequelae
 → Describe

Physician reporting SAE Complementary Notification

Name RICHARD LESSELLS

Signature *[Signature]*

Date form completed 20120706