



TasP

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
Fax: +33 153 946 002



00596251

SAE No.

Initial Notification Date

i.e. Date of original Initial Notification Form

Complementary Notification Date 20150531

1. Patient details

TasP ID

42735

Name

MM

Sex



Male

Female

Date of birth

19550119

Enrolment date

20140929

2. Description of the reported SAE

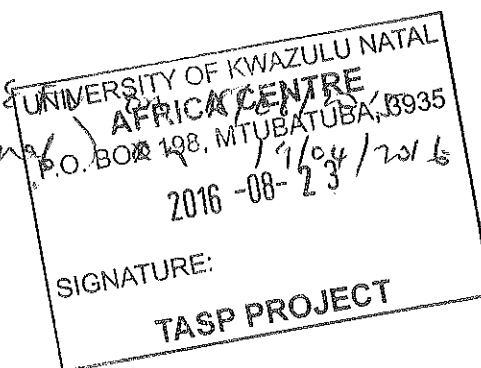
Renal failure

Date of SAE onset

20150219

3. Complementary information

Switched to AZT/3TC/
Creatinine 104 (normal)
Atripla stopped 17/6/2015



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?

☐ Yes ☒ No

This includes the patient's medical history

Describe

8. SAE Outcome

☐ Death → Date of death 15 JUL 2012 Probable Diagnosis _____
☐ Unknown to date
☐ Ongoing
☐ Improved
☐ Worsened
☒ Recovered → Date of recovery 20151012
☒ Recovered without sequelae
 or
☐ Recovered with sequelae
 Describe

Physician reporting SAE Complementary Notification

Name C. Iwuji
 Signature [Signature]
 Date form completed 20160531