



TasP

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

20 May 2016

Serious Adverse Event Reporting



00596253

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

i.e. Date of original Initial Notification Form

Complementary Notification Date

1. Patient details

TasP ID

50707

Name

KN

Sex



Male

Female

Date of birth

19880612

Enrolment date

20150514

2. Description of the reported SAE

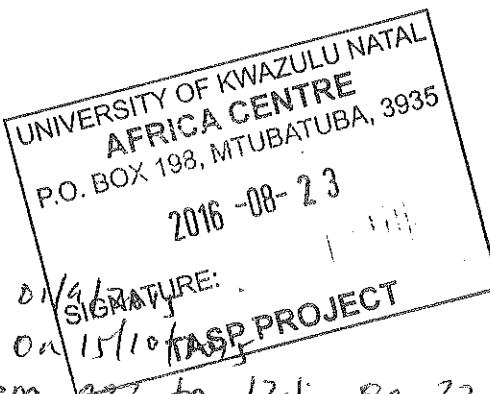
Acute renal failure

Date of SAE onset

20150831

3. Complementary information

Discontinued Atriple on 01/09/2015
Started ABC/3TC/EFV on 15/10/2015
Creatinine improved from 235 to 121 on 27/10/2015
Urea normal



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

8. SAE Outcome

Death → Date of death Probable Diagnosis

Unknown to date

Ongoing

☒ Improved → Another complementary SAE notification form must be submitted.

Worsened

Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name Colin S. Smith

Signature [Signature]

Date form completed 20160531