



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ungulate Event, ungulate Event, ungulate Event for our health)

~~Ukuphila kwami, ukuphila kwethu~~

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00059976

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

20130911

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130925

1. Patient details

TasP ID

23157

Name

S.B.

Sex

☒ Male

☐ Female

Date of birth

19531027

Enrolment date

20130517

2. Description of the reported SAE

STROKE.

Date of SAE onset

20130724

3. Complementary information

Patient with history of stroke onset on 24-7-2013
yet to go to hospital for physiotherapy.
BP done at clinic today 128/91 mmHg.

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.	ATRIPLA	T	daily	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.	Hydrochlorothiazide	12.5mg	daily	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed
3.	Enalapril	10mg	bid	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" type="radio"/> Cannot be assessed
4.	Amlodipine	10mg	daily	<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input checked="" 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?
This includes the patient's medical history

☒ Yes
☐ No
 Describe

Poorly Controlled BP leading to stroke.

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

DR OUMUYINA A. OLOWE.

Signature

Date form completed

2013 0925.