



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Rapidly learn, rapidly live! (my health for my health))

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



00059974

SAE No.

Initial Notification Date

20130911

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130918

1. Patient details

TasP ID

23157

Name

SIBIYA BHAKIFA

Sex

☒ Male

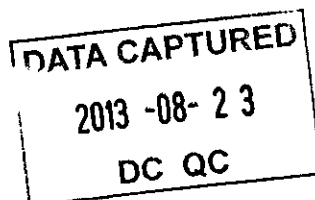
☐ Female

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 on 24-07-2013 but never seen at hospital. He was seen on 5-9-2013 when he was referred for physiotherapy but yet to go due to finance. BP today - 142/93 mmHg, GCS 15/15, CV - Normal, Power normal in all muscle group but still with hemiparetic gait.

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	$\frac{1}{1}$	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 ☒ Describe

No

STROKE due to poorly controlled BP → Poor compliance.

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 OHUMUYINWA A. OHOWE

Signature

Date form completed

20130918.