



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Uthupila Kwami, ukuphila kwethu (my health for our 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



00057292

SAE No.

Initial Notification Date

20130912

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130917

1. Patient details

TasP ID

28520

Name

Sex

☒ Male

☐ Female

Date of birth

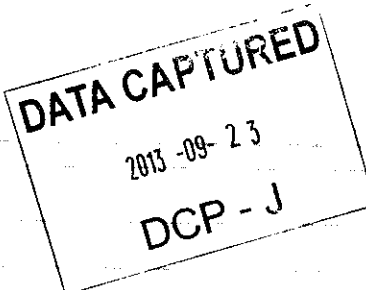
19400303

Enrolment date

20130514

2. Description of the reported SAE

DEATH.



Date of SAE onset

20130907.

3. Complementary information

He was admitted to the hospital on 7/9/2013 with a diagnosis of Congestive Cardiac failure, Renal impairment and lower respiratory tract infection, had chest x-ray done but not sure of report. He died after about one week in admission.

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

10/09/2013

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☐ No

☒ N/A

→ Which treatment?

Date reintroduced

10/09/2013

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
Hydrochlorothiazide	12.5mg	daily
Furosemide	40mg	daily
Spironolactone	25mg	daily
Gabapentin	10mg	as needed
AFRIPAL	245mg 200mg 600mg	daily
ABC 3TC EFV	300mg 150mg 600mg	daily

New judgement of causality

- ☐ Unrelated
☐ Poss. related
☒ Cannot be assessed
☐ Unrelated
☐ Poss. related
☒ Cannot be assessed
☐ Unrelated
☐ Poss. related
☒ Cannot be assessed
☐ 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: Hypertensive / CCF / ? Chronic renal failure

8. SAE Outcome

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

Another complementary SAE notification form must be submitted within 8 days for improved, worsened, or recovered.

Date of recovery: 11/22/13

Recovered without sequelae or Recovered with sequelae

Describe:

DATA CAPTURED
2013-09-23
DCP - J

Physician reporting SAE Complementary Notification

Name

Dr. Oluwuyi A. A. Oluwogbe

Signature

Date form completed

2013 09 18