



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ungulate Status: ukuphila kwethu, ukuphila kwethu)



00060013

Mchakwini
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AI

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20130604

Initial Notification Date

20130605

Notification time

1730

1. Patient details

TasP ID

21595

Name

N.N.

Sex



Male

Female

Date of birth

19440963

Enrolment date

20130423

2. Measurements

Height

Cms

Last known: Weight

58.5

Kgs

Weight Date

20130521

CD4 count

344

CD4 Date

20130423

Viral Load

1979000

Viral Load Date

20130423

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

- ☒ Resulted in death → Date of death 20130601 Probable cause UNKNOWN.
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name

Date investigator
became aware

Date of onset of SAE

1. DEATH? CAUSE: 20130604 UNKNOWN.

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.
Attach copies of any relevant hospital records, laboratory test results etc.

Patient was first seen in clinic on 23/4/2013. He was started on Atripla on 21/05/2013. Relatives reported he was feeling weak but refused to go to the hospital. He died on 1/6/2013. Cause of death is unknown.

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. ATRIPLA TDF/FTC/EFV	T 300/200/600	PO	HIV	20130521		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. B-COMPLEX	T	PO	SUPPLEMENT	20130521		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. CO-TRIMOXAZOLE	960mg	PO	PROPHYLAXIS	20130521		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. HYDROCHLOROTHIAZIDE	12.5mg	PO	HYPERTENSION	20130521		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

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

Not clear as information supplied by relatives

8. SAE Outcome

☒ Died

Unknown to date

Ongoing

Improved

Recovered



A complementary SAE notification must be submitted within 8 days



Date of recovery

Recovered without sequelae
or

Recovered with sequelae
Describe

Physician reporting SAE

Name

Signature

Date form completed

COLLINS Mwji
Xmp
20130605