



TasP

Agreement to Participate in ANRS 12249
Ukaphila kwazi, ukaphila kwethu (for use inside)

Ukaphila kwazi, ukaphila kwethu

Africa Centre TasP Trial

SAE-AI

ANRS 12249

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



00015516

SAE No.

SAE Visit Date

20140808

Initial Notification Date

20140811

Notification time

1600

1. Patient details

TasP ID

12229

Name

S.M.

Sex

☐ Male☒ Female

Date of birth

19600204

Enrolment date

20120510

2. Measurements

Height

153 Cms

Last known: Weight

61.7

Kgs

Weight Date

20140626

CD4 count

78

CD4 Date

20140524

Viral Load

440

Viral Load Date

20140528

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

Tick all that apply

☒ Resulted in death → Date of death 20140803☐ 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

DATA CAPTURED
2014-08-14
Probable cause Unknown
DC QC

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 20140808 20140803

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.

Participant last attended clinic on 26/6/2014. She reported flu-like symptoms and was treated symptomatically. Her CD4 count was dropping from 121 to 78, however her viral load is suppressed. She was on Atripla. Latest blood results reveal Potassium 5.8 and a repeat was ordered. She had recently lost a son and had several stressors. She was reported to have died at home.

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	1 tab	orally	HIV	20130702		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Rev
						Cannot be assessed		Interrupt
								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

Pt had falling CD4 count & cough
she may have had TB which was
not investigated. She also had small
streptococci.

8. SAE Outcome

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 GUGLIELMO MARCHIS

Signature

Date form completed 20140811