



Ukuphila kwami, ukuphila kwethu

SAE-AI

Africa Centre TasP Trial

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



00648509

SAE No.

SAE Visit Date

20160622

Initial Notification Date

20160624

Notification time

1030

1. Patient details

TasP ID

33812

Name

B.M.7.

Sex



Male

Female

Date of birth

19740409

Enrolment date

20160516

2. Measurements

Height

162 Cms

Last known: Weight

55.0

Kgs

Weight Date

20160516

CD4 count

59

CD4 Date

20160516

Viral Load

352802

Viral Load Date

20160516

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

Tick all that apply

☒ Resulted in death → Date of death 20160618 Probable cause Suspected TB IRIS

☐ Life threatening (i.e. at risk of death at time of event)

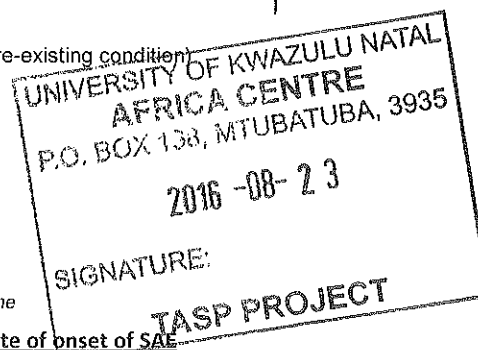
☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)

☐ 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 ? TB IRIS 20160623 20160618

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 in Control Cluster. He was recently initiated on Atripla. His baseline CD4 count was 59. TB screen (Symptoms & sputum for Genexpert) was negative. He was fasttracked onto ART. TB IRIS symptoms were explained to him. On routine checking of his results; his TB culture (sputum) was positive for TB. He was reached and relative reported he had died in hospital on 18/6/2016. More info to follow if available.

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. Tenofovir	300mg	oral	HIV	20160523		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
2. Emtricitabine	200mg	oral	HIV	20160523		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20160523		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce 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?

Yes ☒ No ☐

This includes the patient's medical history

Describe participant severely immunocompromised upon enrolment. Suspected TB IRIS.

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

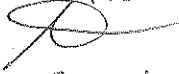
→ Describe

Physician reporting SAE

Name

GUGIEUTHE MKHULISI

Signature



Date form completed

20160624