



Antiretroviral Treatment to Prevent HIV - ANRS 12249
Clinical Event, Adverse Event, or Death (any health for any health)



00125370

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

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

SAE No.

SAE Visit Date

20140814

Initial Notification Date

20140821

Notification time

1600

1. Patient details

TasP ID

21871

Name

S. G.

Sex

☒ Male

☐ Female

Date of birth

19770903

Enrolment date

20140729

2. Measurements

Height

Cms

Last known: Weight

550

Kgs

Weight Date

20140729

CD4 count

192

CD4 Date

20140729

Viral Load

496635

Viral Load Date

20140729

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

Tick all that apply

☐

Resulted in death → Date of death

Probable cause

☐

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

☐

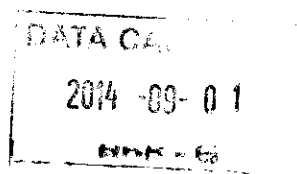
Congenital abnormality / birth defect

☒

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. Pulmonary TB 20140820 20140801

2. Acute Psychosis 20140820 20140815

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 newly enrolled in trial, not yet on ARV's. Presented with TB symptoms and TB diagnosis made on sputum (GeneXpert). Was referred to Nkundusi Clinic (DCH) for initiation of TB Treatment on 14/8/2014 - did not go. Relatives report patient became confused and displayed abnormal behaviour from 15/8/2014 and was referred to hospital and admitted on 18/8/2014 from Nkundusi Clinic.

6. Medications

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

<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>				<u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1. Co-trimoxazole 960mg	oral	Prophylaxis	20140729						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
2. Multivitamins 1 tablet	oral	Supplement	20140729						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.									Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.									Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.									Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.									Unrelated Poss. related Cannot be assessed	Yes 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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Participant newly diagnosed with PTB, may have disseminated TB. Strong history of cannabis use.

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 DR G. MUKHULISI

Signature

Date form completed 20140821