



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu

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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



00317412

SAE No.

SAE Visit Date

20150731

Initial Notification Date

20150804

Notification time

1200

1. Patient details

TasP ID

24250

Name

S. N. G.

Sex

☒ Male

☐ Female

Date of birth

19560306

Enrolment date

20130405

2. Measurements

Height

Cms

Last known: Weight

58.8

Kgs

Weight Date

20140918

CD4 count

497

CD4 Date

20140918

Viral Load

8161

Viral Load Date

20140918

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. MDR-Tuberculosis 20150731 20150709

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 enrolled in Trial since 2013. is not on ART as he was not yet eligible with CD4 count 497. He was called for routine clinic follow up and he reported that he had recently been diagnosed with MDR-TB on sputum and was admitted to hospital to start treatment since 09/07/2015. More information to follow once he has been discharged.

6. Medications

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

	Generic Name	Daily dose	Route of adminis- tration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.						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	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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

HIV positive patient, not on ART - sus-
ceptible to TB. MDR TB highly
prevalent in subdistrict.

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 GUG'ELUVE MUKHULU

Signature

Date form completed 20150804