



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
 (Avenir: savoir, comprendre, agir pour la santé, la vie et le bien-être)

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



00317478

SAE No.

SAE Visit Date

20151105

Initial Notification Date

20151106

Notification time

1115

1. Patient details

TasP ID

21822

Name

S.N

Sex



Male

Female

Date of birth

19850420

Enrolment date

20130828

2. Measurements

Height

000 Cms

Last known: Weight

61.1

Kgs

Weight Date

20151105

CD4 count

3

CD4 Date

20150803

Viral Load

1375636

Viral Load Date

20150803

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. Gastroenteritis 20151105 20150801

2. Renal impairment 20151105 20150801

3. Pulmonary TB 20151105 20150716

4. 1st line ART failure 20151105 20150716

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.

This patient was seen in TasP clinic on 16/7/15 complaining of night sweats + having high VL. He was referred to Hlabisa hospital for CXR on 2PTB. He attended Hlabisa on 11/8/15 but had developed acute gastroenteritis + was found to have renal impairment secondary to this. He was admitted for the entire month of August. His creatinine peaked at 834umol/l. Whilst an inpatient he was diagnosed with PTB + started TB Rx. (presumably on basis of CXR) He was also changed to 2nd line treatment as an inpatient.

6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	Atripla	T	PO	HIV	20130918	<input checked="" type="radio"/> Unrelated	Yes	None
					20150800	Poss. related	<input checked="" type="radio"/> No	Reduce
					(Stopped for reason of Rx failure)	Cannot be assessed		Interrupt
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?

This includes the patient's medical history

☒ Yes ☐ No

Describe

Patient is immunocompromised + at risk of infection

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery

20150900 Discharged from hospital Sept 2015

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name

MEUNIC HILL

Signature

[Signature]

Date form completed

20151106