



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila kwami, ukuphila kwethu)

Ukaphila 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



00317487

SAE No.

SAE Visit Date

20151126

Initial Notification Date

20151207

Notification time

1030

1. Patient details

TasP ID

20159

Name

S.M.

Sex

Male

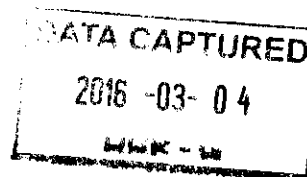
Female

Date of birth

19620114

Enrolment date

20130819



2. Measurements

Height

UUU Cms

Last known: Weight

55.5

Kgs

Weight Date

20151126

CD4 count

374

CD4 Date

20151012

Viral Load

<40

Viral Load Date

20151012

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)

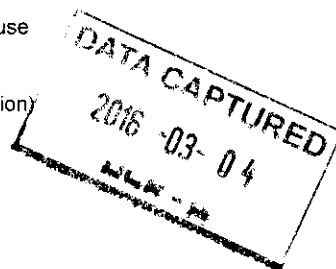
☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)

☐ 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. Epilepsy 20150812 20140812

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 seen in TasP clinic 12/8/15 w/ GTX-type fits for 12 months. No trauma/ head injury. Denied excessive alcohol. Referred for CT head on 29/9/15. Missed appointment. Seen in TasP clinic 26/11/15 + reported that he was admitted at Hlabisa hospital 29/10/15 to 6/11/15 for fits. Was commenced on epilim 300mg nocte by Hlabisa. CT brain re-booked for 1/3/2016.

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/ TDF/FTC/EFV	T	PO	HIV	20131010		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2.	Hydrochlorothiazide 12.5mg	PO		Hypertension	UUUUUUUU		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3.	Enalapril 10mg	PO		Hypertension	20131114		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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
L Describe

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered → Date of recovery 20151106

☒ Recovered without sequelae

or

Recovered with sequelae

L Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20151207