



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI



00317491

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

SAE No.

SAE Visit Date

Initial Notification Date 2015 12 17

Notification time 16 24

#### 1. Patient details

TasP ID

51960

Name

Z.S.M.

Sex

Male

☒ Female

Date of birth

1980 01 12

Enrolment date

20150218

#### 2. Measurements

Height

164 Cms

Last known: Weight

54.3

Kgs

Weight Date

20150901

CD4 count

499

CD4 Date

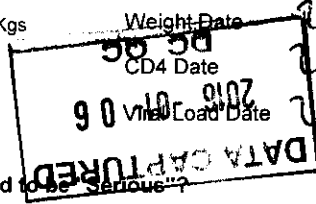
20150901

Viral Load

<40

Viral Load Date

20150901



#### 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. Hospitalisation 20151215 20151204

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.

Details unknown to TasP. Patient apparently admitted in NPA (tertiary gynae hospital) with lower abdominal pain on 4/12/15. Referred by private GP. Will be reviewed in TasP in 2016 for more details of admission.

## J. 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	T	PO	HIV	20150317		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. Salbutamol	PEN	INH	Asthma	20050101		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. Budesonide	II BD	INH	Asthma	20050101		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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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 immunosuppressed and at risk of gynaecological problems

## 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

MELANIE HILL

Signature



Date form completed

20151217