



TasP

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



00288006

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](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2015 01 13

Initial Notification Date

2015 01 15

Notification time

1630

#### 1. Patient details

TasP ID

16169

Name

M.C.M.

Sex

Male

☒ Female

Date of birth

19770505

Enrolment date

20120903

#### 2. Measurements

Height

156 Cms

Last known: Weight

38.7

Kgs

Weight Date

2015 01 13

CD4 count

633

CD4 Date

2014 11 03

Viral Load

<40

Viral Load Date

2014 11 03

#### 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. Acute Psychosis 2015 01 13 2014 12 09

2.

3.

4.

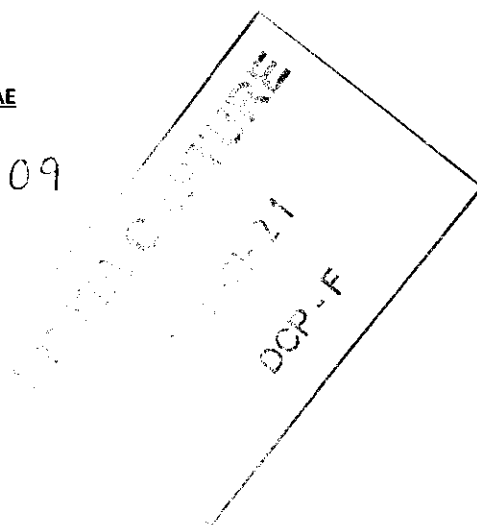
5.

#### 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.

Participant known with Scleroderma. On 3TC/TDF/EFV as Atripla, CD4 633 and viral load suppressed. She came to inform clinic that she had been admitted to hospital during the holidays from 9/12/2014 - 17/12/2014 for acute psychosis. Her family discharged her against medical advice. She is currently apyschotic and not on any treatment for psychosis.



## 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	1 tab	oral	HIV	20121130		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	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? ☒ Yes ☐ No  
This includes the patient's medical history

Describe

Pt with underlying autoimmune disease, she recovered quickly from psychosis despite not being on treatment & is still on Atripla.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20141220

☒ Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name DR GUG'ELIHE MKHULISI

Signature

Date form completed 20150115