



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

SAE-AI

31/05/2013

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

00057533

SAE No.

SAE Visit Date

20130426

Initial Notification Date

20130426

Notification time

1630

### 1. Patient details

TasP ID

16118

Name

G. M.

Sex

☐ Male

☒ Female

Date of birth

19760408

Enrolment date

20130416

### 2. Measurements

Height

163 Cms

Last known: Weight

65.90 Kgs

Weight Date

20130416

CD4 count

165

CD4 Date

20130416

Viral Load

Viral Load Date

### 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. ANAEMIA (Hb 5.3) 20130423 20130416

2. ...

3. ...

4. ...

5. ...

DATA CAPTURE

2013-06-03

DGP - S

### 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.

BLOODS FROM ENROLLMENT VISIT (2013/04/16) SHOWED Hb 5.3. REPEATED  
2013/04/19 Hb 5.6. MICROCYTIC HYPOCHROMIC ANAEMIA (MCV 61 MCV 15)  
LIKELY IRON-DEFICIENCY ANAEMIA. FOR FURTHER INVESTIGATION + IRON  
SUPPLEMENTATION. UNLIKELY TO BE RELATED TO MEDICATION (NO MEDICATION  
Prior to ENROLLMENT)

## 6. Medications

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

<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of administration</u>	<u>Indication</u>	<u>Date started</u> <u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
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		Inter. 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

IRON DEFICIENCY ANAEMIA: NEEDS  
FURTHER INVESTIGATION TO ELUCIDATE  
CAUSE

## 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

Richard LESSELL

Signature

*[Signature]*

Date form completed

20130426