



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



00057414

*Embangdelweni*  
**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

2013 05 21

Initial Notification Date

2013 05 27

Notification time

1730

**1. Patient details**

TasP ID

13172

Name

SX

Sex

Male

☒ Female

Date of birth

19 8 1 08 13

Enrolment date

2012 09 21

**2. Measurements**

Height

161 cms

Last known: Weight

65.7

Kgs

Weight Date

2013 05 21

CD4 count

665

CD4 Date

2013 05 21

Viral Load

<50

Viral Load Date

2013 05 21

**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 2013 05 23 2013 05 21

2.

3.

4.

5.

DATA CAPTURE

2013-05-30

DCP - 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.

Microcytic hypochromic Anaemia, Hb 6.4, MCV 75.9  
MCH 15.3

## 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. TENOFOVIR                | 300MG       | PO                      | HW         |              |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>Stop |
| 2. ATRIPLA<br>(TDF/FTC/EFV) | 300/200/600 | PO                      | HW         | 20121010     |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>Stop |
| 3.                          |             |                         |            |              |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>Stop |
| 4.                          |             |                         |            |              |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>Stop |
| 5.                          |             |                         |            |              |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>Stop |
| 6.                          |             |                         |            |              |              | Unrelated            | Yes                          | None              |
|                             |             |                         |            |              |              | Poss. related        | No                           | Reduce            |
|                             |             |                         |            |              |              | Cannot be assessed   |                              | Interrupt<br>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

Iron deficiency anaemia

## 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

COLLINS IHWJI

Signature

Xmp

Date form completed

2013 0527