



TasP

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

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



00057411

SAE No.

SAE Visit Date

20130812

Initial Notification Date

20130814

Notification time

1. Patient details

TasP ID

19455

Name

ZG

Sex

Male

Female

Date of birth

19820602

Enrolment date

20130208

DATA CAPTURED

2013-08-20

DC QC

2. Measurements

Height

159 Cms

Last known: Weight

59.0

Kgs

Weight Date

20130812

CD4 count

80

CD4 Date

20130812

Viral Load

< 50

Viral Load Date

20130612

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. SEVERE ANAEMIA 20130814 20130812

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.

Routine bloods showed severe microcytic hypochromic anaemia with Hb 6.3g/dL; mcv 85.2 mch 26.6 pg.

# 6. Medications

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

| Generic Name              | Daily dose     | Route of administration | Indication | Date started<br>Date stopped       | Causality assessment  | Expected reaction?<br>(BNF/SPC)                                  | Action taken   |
|---------------------------|----------------|-------------------------|------------|------------------------------------|---|--|--|
| 1. ATRIPLA<br>TDF/FTC/EFV | 300/200/600 PO |                         | HIV        | 20130221                           | <input checked="" type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed | <input type="radio"/> Yes<br><input checked="" type="radio"/> No | <input checked="" type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><input type="radio"/> Stop |
| 2.                        |                |                         |            | Y Y Y Y M M D D<br>Y Y Y Y M M D D | <input type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed            | <input type="radio"/> Yes<br><input type="radio"/> No            | <input type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><input type="radio"/> Stop            |
| 3.                        |                |                         |            |                                    | <input type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed            | <input type="radio"/> Yes<br><input type="radio"/> No            | <input type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><input type="radio"/> Stop            |
| 4.                        |                |                         |            | Y Y Y Y M M D D<br>Y Y Y Y M M D D | <input type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed            | <input type="radio"/> Yes<br><input type="radio"/> No            | <input type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><input type="radio"/> Stop            |
| 5.                        |                |                         |            | Y Y Y Y M M D D<br>Y Y Y Y M M D D | <input type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed            | <input type="radio"/> Yes<br><input type="radio"/> No            | <input type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><input type="radio"/> Stop            |
| 6.                        |                |                         |            | Y Y Y Y M M D D<br>Y Y Y Y M M D D | <input type="radio"/> Unrelated<br><input type="radio"/> Poss. related<br><input type="radio"/> Cannot be assessed            | <input type="radio"/> Yes<br><input type="radio"/> No            | <input type="radio"/> None<br><input type="radio"/> Reduce<br><input type="radio"/> Interrupt<br><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?  
This includes the patient's medical history

☒ Yes ☐ No

Describe

Severe <sup>inf</sup> myelofibrotic hypochromic anemia

# 8. SAE Outcome

☐ Died

☐ Unknown to date

☒ Ongoing

☐ Improved

☐ Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery Y Y Y Y M M D D

☐ Recovered without sequelae

or

☐ Recovered with sequelae

→ Describe

DATA CAPTURED  
2013-08-20  
DC QC

# Physician reporting SAE

Name

Signature

Date form completed

COLLINS Iwgh  
Ximfuz  
20130814