



TasP

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



00060056

Ukaphila kwami, ukaphila 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
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2013 10 24

Initial Notification Date

2013 10 30

Notification time

1. Patient details

TasP ID

20433

Name

T.V.

Sex

Male

Female

Date of birth

1971 11 02

Enrolment date

2013 04 08

DATA CAPTURED
2013-10-05
DC QC

2. Measurements

Height

174 cms

Last known: Weight

63.4

Kgs

Weight Date

2013 10 24

CD4 count

266

CD4 Date

2013 10 24

Viral Load

< 50

Viral Load Date

2013 07 18

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 2013 10 28 2013 UUUU

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 full blood count showed severe anaemia with a normocytic and a slight hypochromic picture; Hb 5.2 MCV 90.7 MCH 26.8 Haemoglobin was 10.2g/dL in April 2013; so Hb must have dropped after that. Patient has been contacted to attend for further investigation.

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</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.	ATRIPLA TDF/FTC/EFV	300/200/600	PO	HIV	20130522	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <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

NORMOCYTIC ANAEMIA,
REQUIRES FURTHER INVESTIGATION

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

DR COLLINS MWJ

Signature

[Signature]

Date form completed

20131030