



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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AI

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

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



00547576

SAE No.

220

SAE Visit Date

20150318

Initial Notification Date

20151104

Notification time

1. Patient details

TasP ID

22017

Name

FM

Sex

Male

☒ Female

Date of birth

19740805

Enrolment date

20150318

2. Measurements

Height

167 Cms

Last known: Weight

85.1

Kgs

Weight Date

20151026

CD4 count

849

CD4 Date

20151026

Viral Load

<40

Viral Load Date

20150722

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 20150320 20150318

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 had severe anaemia at baseline (Hb 6.1g/dL, MCV 70, MCH 18)
follow up FBC on 27/10/2015 showed Hb 6.1g/dL, MCV 72, MCH 19
The anaemia is currently being investigated. Currently on
Ferrous sulphate.

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. TDF/FTC/EFV	300/200/600 po		HIV	20150318		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
Transfer-in on regimen						Poss. related	<input checked="" type="radio"/> No	Reduce
Actual initiation date unknown						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		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?

This includes the patient's medical history

☒ Yes ☐ No
Describe

Probable iron deficiency anaemia present at baseline

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

Signature

Date form completed

Colin 11/11/15
XUP

2015 11 04