



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



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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
Fax: +33 153 946 002

SAE No.

291

SAE Visit Date

20150413

Initial Notification Date

20150423

Notification time

1. Patient details

TasP ID

29103

Name

FM

Sex

Male

☒ Female

Date of birth

19680121

Enrolment date

20130528

2. Measurements

Height

155 Cms

Last known: Weight

49.3

Kgs

Weight Date

20150413

CD4 count

246

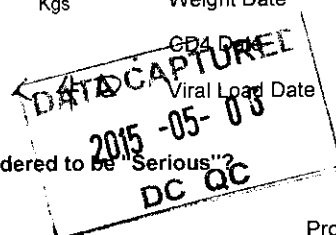
CD4 Date

20150413

Viral Load

Viral Load Date

20150413



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 20150416 20150413

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.

Severe anaemia picked up on routine safety bloods. Patient has been referred to hospital for blood transfusion as Hb is 4.9g/dL. Was started on AZT/3TC/EFV due to mild renal impairment. At baseline Hb was 9.7g/dL in June 2014. AZT will be discontinued. Patient is also on TB treatment.

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. AZT/3TC (LAMZUS)	1 b.i.d	PO	HIV	20140611		Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. EFAVIRENZ 600mg	PO		HIV	20140611		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						Poss. related	<input checked="" type="radio"/> 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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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

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 (Hunji)

Signature

Xup

Date form completed

20150423