



TasP

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



00442978

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.

SAE Visit Date

20150512

Initial Notification Date

20150618

Notification time

1. Patient details

TasP ID

32524

Name

N.C

Sex

Male

Female

Date of birth

19880423

Enrolment date

20140903

2. Measurements

Height

159 Cms

Last known: Weight

54.3

Kgs

Weight Date

20150617

CD4 count

250

CD4 Date

20150528

Viral Load

<40

Viral Load Date

20150608

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 20150512 20150512

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.

Had mild Anaemia at the baseline clinic visit. Was reviewed by a doctor and started on FeSO₄, Hb has fluctuated since then and is now 5.3g/dL, microcytic, hypochromic. Referred to local hospital for investigation and transfusion, but has not attended.

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		HTV	20141001		<input checked="" type="radio"/> Unrelated	Yes	<input checked="" type="radio"/> None
						<input type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
2.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
3.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
4.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
5.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> Cannot be assessed		Interrupt
								Stop
6.						<input type="radio"/> Unrelated	Yes	None
						<input type="radio"/> Poss. related	No	Reduce
						<input type="radio"/> 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

iron deficiency anaemia, cause not yet identified

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

COLLINS JMWJ

Xinf

20150618