



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Efficacy, safety, tolerability, and health for our health)



00057410

Mchakwini
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

SAE No.

SAE Visit Date

20130730

Initial Notification Date

20130808

Notification time

1. Patient details

TasP ID

27489

Name

T.D

Sex

Male

☒ Female

Date of birth

19680304

Enrolment date

20130730

2. Measurements

Height

160 Cms

Last known: Weight

53.1

Kgs

Weight Date

20130730

CD4 count

562

CD4 Date

20130730

Viral Load

<50

Viral Load Date

20130730

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. ELEVATED γ-GLUTAMYLTRANSFERASE 20130806 20130730

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 done at the baseline visit showed elevated gamma-glutamyltransferase γ 396 U/L

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. TENOFOVIR	300mg	PO	HIV	20100722	<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. LAMIVUDINE	300mg	PO	HIV	20100722	<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
3. EFAVIRENZ	600mg	PO	HIV	20100722	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" 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

DATA CAPTURED

2013-08-17

RCP-6

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

Abnormality 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

COLLINS JWGJ

Xup

20130808