



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila kwami, ukuphila kwethu)

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



00008815

SAE No.

SAE Visit Date

20121010

Initial Notification Date

20121012

Notification time

1500

1. Patient details

TasP ID

11797

Name

Sex



Male



Female

Date of birth

19731208

Enrolment date

20120322

2. Measurements

Height

166 Cms

Last known: Weight

80.6

Kgs

Weight Date

20120921

CD4 count

384

CD4 Date

20120731

Viral Load

<50

Viral Load Date

20120731

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

Date of onset of SAE

became aware

1. Shortness of breath 20121010 20121010

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.

Informed that patient presented to local hospital with acute shortness of breath. Admitted for further investigations. Currently prescribed Antibiotics

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. ATRILA (TDF/FTC/EFV)	T	PO	HW	20120411		<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 type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. ISONIAZID 300	PO		TS PROPHYLAXIS	20120704		<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 type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. PYRIDOXINE-25mg	PO		NEUROPATHY PREVENTION	20120704		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No 20.1/10/12	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. VITAMIN B6	T	PO	SUPPLEMENT	20120605		<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 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?

☒ Yes ☐ No

This includes the patient's medical history

Describe

Patient complained of weight loss and dry cough recently

8. SAE Outcome

☐ 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 RICHARD LESSELLS

Signature *Richard Lessells*

Date form completed 20121012