



TasP

Antiretroviral Treatment as Prevention - ANRS 12249  
(Efficacy events, safety events, virology events, pregnancy events)

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

## Serious Adverse Event Reporting

## ANRS 12249 Initial SAE Notification

SAE-AI

v31 jan 2013



00057403

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

SAE No.

SAE Visit Date

20130715

Initial Notification Date

20130717

Notification time

## 1. Patient details

TasP ID

28086

Name

N.M

Sex

☐ Male☒ Female

Date of birth

19770112

Enrolment date

20130513

## 2. Measurements

Height

166 Cms

Last known: Weight

65.0

Kgs

Weight Date

20130524

CD4 count

142

CD4 Date

20130513

Viral Load

337

Viral Load Date

20130513

## 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

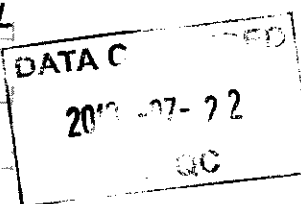
1. PELVIC INFLAMMATORY DISEASE 20130715 20130714

2. Y Y Y Y M M D D Y Y Y Y M M D D

3. \_\_\_\_\_

4. Y Y Y Y M M D D Y Y Y Y M M D D

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.

Admitted to hospital with lower abdominal pain.  
Being treated for Pelvic Inflammatory disease. Awaiting  
a pelvic ultrasound scan.

## 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. STAVUDINE	60mg	PO	HW	20080423		<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	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	PO	HW	20080423		<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. EFVIRENZ	600mg	PO	HW	20080423		<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
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

## 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

PELVIC INFLAMMATORY DISEASE

## 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 IWUJI

Signature

*[Signature]*

Date form completed

20130717