



TasP

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

Ukaphila 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



00008820

SAE No.

SAE Visit Date

20130613

Initial Notification Date

20130618

Notification time

1100

1. Patient details

TasP ID

19650

Name

Sex



Male



Female

Date of birth

19560712

Enrolment date

20130529

2. Measurements

Height

167 cms

Last known: Weight

47.0

Kgs

Weight Date

20130529

CD4 count

510

CD4 Date

20130522

Viral Load

145

Viral Load Date

20130529

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. PULMONARY TB 20130613 20130611

2.

3.

4.

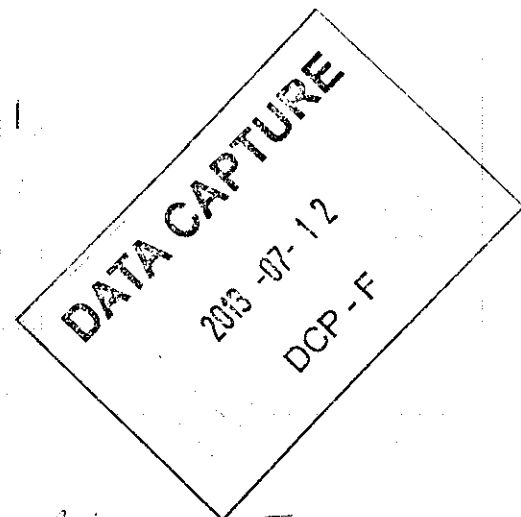
5.

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.

Admitted to hospital on 11/06/2013 for Pulmonary TB
informed research team by phone



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. TEMOVIR	300mg	PO	HIV			<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
Xmp 18/6/2013								
2. LAMIVUDINE	300mg	PO	HIV	20050720		<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. EFVIRAZ	600mg	PO	HIV	20050720		<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. STAVUDINE	60mg	PO	HIV	20050720		<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

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

PULMONARY TB

8. SAE Outcome

☐ Unknown to date
☒ Ongoing
☐ Improved
☐ Recovered

☒ Ongoing → A complementary SAE notification must be submitted within 8 days
☐ Recovered → Date of recovery 12/10/2013

☐ Recovered without sequelae
 or
☐ Recovered with sequelae
 Describe

Physician reporting SAE

Name DR COLLINS MWJ

Signature Xmp

Date form completed 20130618