



TasP

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

Ukaphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AI
v10 Feb 2012

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



00008814

SAE No. _____ SAE Visit Date 20121213
Initial Notification Date 20130111 Notification time 1530

1. Patient details

TasP ID 12027
Name SIPHO SITHOLE
Sex ☒ Male ☐ Female
Date of birth 19640929
Enrolment date 20121210

DATA CAPTURED

2013-01-29

DC QC

2. Measurements

Height 163 Cms
Last known: Weight 58.9 Kgs Weight Date 20121213
CD4 count 145 CD4 Date 20121210
Viral Load 156 Viral Load Date 20121211

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. EXACERBATION OF BRONCHIECTASIS	20121213	20121213
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.

PREVIOUS PULMONARY TB x 2. PRESENTED WITH COUGH, HAEMOPTYSIS, DYSPNOEA.
SPERM X-RAY NEGATIVE. SIGNS OF CHRONIC LUNG DISEASE (BRONCHIECTASIS). ADMITTED
TO HOSPITAL FIRST ON 2012/12/14 THEN AGAIN 2012/12/19. CXR DEMONSTRATED
BRONCHIECTASIS, RESIDUAL LARGE CAVITY + FIBROSIS LEFT UPPER LOBE. TREATED WITH
INTRAVENOUS 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. TENOFOVIR	300mg	oat	HIV	20110811		<input checked="" 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
2. AZIDOTHYDINE	300mg	oat	HIV	20110811		<input checked="" 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
3. EFAMVIRAZ	600mg	oat	HIV	20110811		<input checked="" 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
4. CO-TRIMOXAZOLE	960mg	oat	HIV	20110811		<input checked="" 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

CHRONIC LUNG DISEASE - SEQUELA OF PREVIOUS TB DISEASE

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

[Signature]

Date form completed

20130111