



Antiretroviral treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for our health)

Ukuphila 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



00008819

SAE No. _____ SAE Visit Date 20130409
Initial Notification Date 20130409 Notification time 1630

1. Patient details

TasP ID 16372
Name PHILANGENKOSI MGENCE
Sex ☒ Male ☐ Female
Date of birth 19611125
Enrolment date 20120926

2. Measurements

Height 176 Cms
Last known: Weight 62.6 Kgs Weight Date 20130327
CD4 count 415 CD4 Date 20130327
Viral Load <50 Viral Load Date 20130327

3. By which criteria is this adverse event considered to be "Serious"?

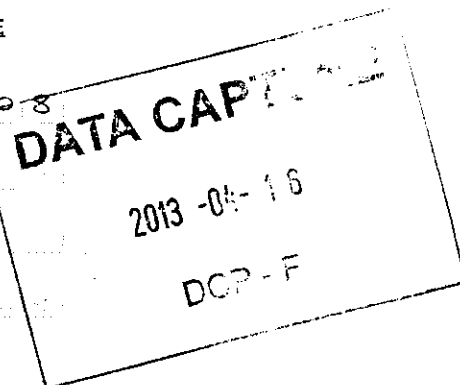
Tick all that apply

- ☐ 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 MULTIDRUG-RESISTANT TB

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. <u>MDR - TB</u>	<u>20130409</u>	<u>20130408</u>
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.

DIAGNOSED = SKEAN POSITIVE PULMONARY TB JAN 2013 - TREATED = STANDARD RIFAMPIN /
ISONIAZID / PYRAZINAMIDE / ETHAMBUTOL. NOW CULTURE + DRUG SUSCEPTIBILITY TEST RESULT
(FROM SPERM COLLECTED 28 JAN 2013) SHOWS MDR-TB. ADMITTED HIASISA HOSPITAL
05/04/2013 + INITIATED MDR-TB TREATMENT 09/04/2013

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 EMTRICITABINE EFAMENZ	300mg 200mg 600mg	oral	HIV			<input checked="" type="checkbox"/> Unrelated <input type="checkbox"/> Poss. related <input type="checkbox"/> Cannot be assessed	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> None <input type="checkbox"/> Reduce <input type="checkbox"/> Interrupt <input type="checkbox"/> Stop
2.	RIFAMPICIN ISONIAZID ETHAMBUTOL PIRAZINAMIDE	4 tabs	oral	TB	11/11/12	20130409	<input checked="" type="checkbox"/> Unrelated <input type="checkbox"/> Poss. related <input type="checkbox"/> Cannot be assessed	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> None <input type="checkbox"/> Reduce <input type="checkbox"/> Interrupt <input type="checkbox"/> Stop
3.	CO-TRIMOXAZOLE 800/160mg		oral	OR Prophylaxis			<input type="checkbox"/> Unrelated <input type="checkbox"/> Poss. related <input type="checkbox"/> Cannot be assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> None <input type="checkbox"/> Reduce <input type="checkbox"/> Interrupt <input type="checkbox"/> Stop
4.							<input type="checkbox"/> Unrelated <input type="checkbox"/> Poss. related <input type="checkbox"/> Cannot be assessed	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> None <input type="checkbox"/> Reduce <input type="checkbox"/> Interrupt <input type="checkbox"/> 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

PREVIOUS TB EPISODES (2007, 2008)

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 20130409