

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
(Ukuphila kwami, ukuphila kwethu (my health for my health))**Ukuphila kwami, ukuphila kwethu****Africa Centre TasP Trial****Serious Adverse Event Reporting****ANRS 12249 Initial SAE Notification****SAE-AI**

00057409

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

SAE No.

SAE Visit Date

2013 06 19

Initial Notification Date

2013 08 05

Notification time

1. Patient details

TasP ID

28995

Name

M.Z

Sex

☒ Male

Female

Date of birth

1975 02 28

Enrolment date

2013 06 13

2. Measurements

Height

176 cms

Last known: Weight

66 2

Kgs

Weight Date

2013 06 13

CD4 count

40

CD4 Date

2013 06 13

Viral Load

1132111

Viral Load Date

2013 06 17

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 NameDate investigator
became awareDate of onset of SAE

1. MULTI-DRUG RESISTANT TB 2013 06 28 2013 06 17

2. _____

3. _____

4. _____

5. _____

DATA CAPTURE

2013-08-12

DCP-S

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.

Patient was admitted to hospital on 17/06/2013 for treatment of MDR-TB which has been on-going since 1/04/2013. He was discharged from hospital on 16/7/2013. Treatment is still on-going.

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	PO	HW	20120927		<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
2. LAMIVUDINE	300mg	PO	HW	20120927		<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	20120927		<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

MULTI-DRUG RESISTANT TREATMENT

8. SAE Outcome

☐ Died

☐ Unknown to date

☐ Ongoing

☒ Improved

☐ Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery 20130805

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

Physician reporting SAE

Name

Signature

Date form completed

COLINS JHUTJ

XMP

20130805