



TasP

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

Mathambane

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00059970

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2013 09 19

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 11 05

1. Patient details

TasP ID

30 3 31

Name

Z-M

Sex

Male

☒ Female

Date of birth

1994 01 17

Enrolment date

2013 07 15

DATA CAPTURED

2013 -11- 07

2. Description of the reported SAE

Hospital admission for tuberculosis

Date of SAE onset

2013 07 25

3. Complementary information

Patient died in hospital on 31/10/2013
for tuberculosis of the cervical lymph-nodes

4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above
modified your judgement of causality regarding one or
more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1. As previously discussed.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

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

TB lymph node

8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

Recovered



Another complementary SAE notification form must be submitted within 8 days from now.



Date of recovery

Died

31/10/2013

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name

Dr Collins / Wagh

Signature

Knf

Date form completed

20131105