



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

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Serious Adverse Event Reporting

SAE-AC



00199221

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

20140718

i.e. Date of original Initial Notification Form

Complementary Notification Date

20141107

1. Patient details

TasP ID

16207

Name

N.D.

Sex

Male

☒ Female

Date of birth

19770828

Enrolment date

20120425

2. Description of the reported SAE

Participant on 3TC/TOF/Atova; CD4 349. Was admitted to hospital & diagnosed with mixed (TB & bacterial) meningitis following 1 week of symptoms. She was treated with 10 antibiotics & started on TB treatment. She was discharged 24/7/14.

Date of SAE onset 20140712

3. Complementary information

Relatives reported that patient died in hospital on 24/10/2014 following admission on 15/11/2014 as self referral. She had recurrent meningitis diagnosed on Lumbar puncture. She complicated with a stroke (Right hemiplegia). Her condition deteriorated despite TB treatment. She demised during admission.

4. New diagnosis?

☒ Yes → Describe

No

Death due to mixed meningitis
(Disseminated TB)

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

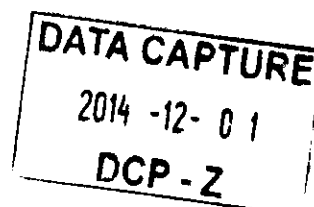
→ Which treatment?

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.			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

Patient with co-morbid HIV & TB, not improving with treatment. Suspected resistant TB.

8. SAE Outcome

☒ Death

→ Date of death

20 14 10 24

Probable
Diagnosis

Mixed meningitis
Disseminated TB

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name DR GUG'ELHLE MKHALISI

Signature

Date form completed 20 14 11 07