

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami, ukaphila kwethu (my health for our health)**Ukaphila kwami, ukaphila kwethu****Africa Centre TasP Trial****SAE-AC****Serious Adverse Event Reporting**

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ANRS 12249 Complementary SAE NotificationCompleted forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20140821

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140912

1. Patient details

TasP ID

21871

Name

S. G.

Sex

☒ Male

Female

Date of birth

19770903

Enrolment date

20140729

2. Description of the reported SAE

Participant newly enrolled in trial, not on ART. Diagnosed TB positive of genexpert. Presented to hospital with acute confusion and was admitted for investigation.

Date of SAE onset

20140814

3. Complementary information

Participant admitted on 19/8/14. Started on TB treatment. Lumbar puncture negative for meningitis. Started on Haloperidol 2.5mg nocte, slowly improved. Following a 3 week hospital stay, he was discharged on 4/9/14 on TB treatment & haloperidol.

4. New diagnosis?☒ Yes → Describe

? Substance Induced Psychosis

No

? Psychosis secondary to Tuberculosis

Date of new diagnosis

20140820

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**DATA CAPTURE**

2015-01-07

DCP-2

6. Medications

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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
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
Describe

No

Psychosis may be due to disseminated Tuberculosis.

8. SAE Outcome

Death → Date of death

Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 20140904

☒ Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name Dr GUG'ELITHE MKHULISI

Signature

Date form completed 20140912