



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

Nov 2011

## Serious Adverse Event Reporting



00317309

### ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20 1 6 03 03

i.e. Date of original Initial Notification Form

Complementary Notification Date

20 1 6 04 26

#### 1. Patient details

TasP ID

5 2 4 3 4

Name

S. T. S.

Sex

Male

☒ Female

Date of birth

1 9 7 4 0 5 0 3

Enrolment date

20 1 5 0 6 3 0

#### 2. Description of the reported SAE

Participant presented with abdominal pain & vomiting of two days duration. She was referred to hospital for investigation and was admitted on 01/03/2016.

Date of SAE onset

20 1 6 03 01

#### 3. Complementary information

Participant reported headache, vomiting & abdominal cramps. Lumbar puncture was normal. FBC, U&E, LFT were unremarkable. C-reactive protein was 258. She was treated as suspected meningitis. She was given Ceftriaxone IV & fluids. She was discharged on 10/03/2016 after symptoms resolved.

#### 4. New diagnosis?

☒ Yes → Describe

No

? Meningitis

Date of new diagnosis

20 1 6 03 03

#### 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

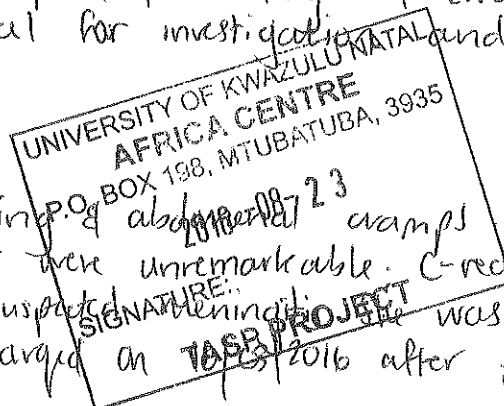
→ Which treatment?

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

Immunosuppressed patient susceptible to meningitis.

## 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 20160310

Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name GUG'ELHE MKHULIS

Signature

Date form completed 20160426