



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukaphila kwami: ukuphila kwethu (my health for our health)

Ukaphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00317350

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

2014 05 29

i.e. Date of original Initial Notification Form

Complementary Notification Date

2015 04 08

1. Patient details

TasP ID

27506

Name

D. A.

Sex

☒ Male

☐ Female

Date of birth

19701124

Enrolment date

20131319

2. Description of the reported SAE

Treated in hospital for probable acute cholecystitis. Had deranged LFTs which were present from baseline but improved whilst followed up in trial.

Date of SAE onset

20140527

3. Complementary information

Started on PTB Rx on 5/6/2014. No details in clinical notes on how this was diagnosed as treatment initiated in government facility. Participant last seen in clinic on 21/10/2014, informed trial nurse has been getting treatment (ART) from government facility.

4. New diagnosis?

☒ Yes → Describe
☐ No

Pulmonary Tuberculosis

Date of new diagnosis

20140605

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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
1. AS IN INITIAL REPORT			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

Abnormal LFTs present at baseline

8. SAE Outcome

Death → Date of death

Probable
Diagnosis _____

☒ 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

Coum. J. Wuji

Signature

XWJ

Date form completed

20150408