

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

00317304

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

20150807

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150825

1. Patient details

TasP ID

48299

Name

N. Z. N.

Sex

Male

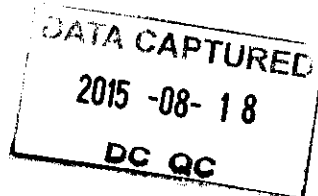
☒ Female

Date of birth

19830707

Enrolment date

20141110

**2. Description of the reported SAE**

Participant on ART with CD4 74 and unsuppressed viral load. Previous ART defaulter. Had raised ALP 927 and GG7 1068 at baseline. Problem worsening since October 2014. Ultrasound liver & X-rays normal. Monitored at trial clinic.

Date of SAE onset 20150622

3. Complementary information

She became unwell at home & on 12/8/2015, relatives called ambulance & she was taken to hospital. She was admitted and bloods showed ALP 1647 & GG7 2390. She was put on IV fluids and supplements (Multivitamins & folic acid) and continued ART + Bactrim. She was discharged on 21/8/15 with ultrasound booking for October 2015 at Referral hospital.

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

<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

No

→ Describe

Participant most likely has obstructive pathology causing her liver enzymes to be elevated.

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 DR GUG'ELIHE MKHULISI

Signature [Signature]

Date form completed 2015 08 25