



TasP

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting

Authorised Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (with my health for my health)



00317358

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

20151027

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151124

1. Patient details

TasP ID

54620

Name

B.G.K

Sex

Male

☒ Female

Date of birth

19850808

Enrolment date

20151007

2. Description of the reported SAE

Baseline LFT's in TasP showed grade 4 event. Was already on ART before transfer in to TasP. Was clinically well despite LFT's. At baseline ALT 344, ALP 242, GGT 942. Referred to Hlabisa hospital for USS.

Date of SAE onset 20151007

3. Complementary information

Patient was admitted at Hlabisa hospital. Her liver USS was normal, and hepatitis screen normal (Hepatitis A, B+C negative). She remained clinically well during admission. Her ART was changed to TDF/FTC/zidovudine (from atazanavir). The LFT's improved on 23/11/15 ALT 208, ALP 93, GGT 386.

4. New diagnosis?

☒ Yes → Describe

No

Dry Induced Liver Injury

Date of new diagnosis 20151110

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment? ~~EFVIRAZONE~~ EFAVIRENZ

Date discontinued

20151110

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

2016-07-21

DCP-S

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. EFVIRENZ	600mg	ON	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. TDF	300mg	ON	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. 8 FTC	200mg	ON	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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 was already on ART prior to joining Tasp.

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 2015 11 23

☒ Recovered without sequelae
or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 2015 11 24