



TasP

Antiretroviral Treatment as Prevention - ANRS 12249

(Ukuphila Kwami) (ukuphila kwethu) (my health for our health)

Maginaleni
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00059965

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

20130729

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130806

1. Patient details

TasP ID

16966

Name

T. G

Sex

Male

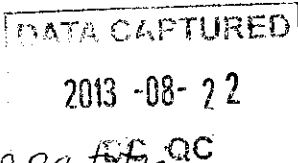
☒ Female

Date of birth

19760671

Enrolment date

20130114



2. Description of the reported SAE

Probable drug induced hepatitis

Date of SAE onset

20130725

3. Complementary information

Admitted to hospital on 5/8/2013. Declined admission on 2/08/2013. Referred to hospital as ALT still rising and INR now abnormal.

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. As previously reported			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? ☐ Yes ☒ No
This includes the patient's medical history
L Describe

8. SAE Outcome

- Unknown to date
☒ Ongoing
 Improved
 Worsened
 Recovered
- Another complementary SAE notification form must be submitted within 8 days from now.
- Date of recovery
- Recovered without sequelae
 or
 Recovered with sequelae
 L Describe

Physician reporting SAE Complementary Notification

Name

COLLINS IWAJI

Signature

Kmp

Date form completed

20130806