



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ungulate Kwana, ukuphila Kwethu (my health, for our health))

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC



00059968

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

2013 03 28 ^{inf}

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 11 04

1. Patient details

TasP ID

27506

Name

D.D

Sex

☒ Male

Female

Date of birth

19701124

Enrolment date

20130319

2. Description of the reported SAE

Abnormal hepatic enzymes, mainly grade 4 elevation
of gamma glutamyl transferase.

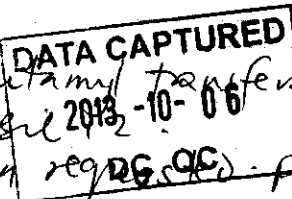
Date of SAE onset

UNKNOWN

3. Complementary information

Worsening of elevation of gamma glutamyl transferase
GGT 1547 ALP 427 ALT 50 Tbil 2013-10-06

An ultrasound of the liver has been requested - patient
denies alcohol ingestion.



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

Generic Name	Dose	Frequency	New judgement of causality
1. ATRIPLA (TDF/FTC/EFV)	300/200/600	T OD	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. DOXYCYCLINE	100mg	bd	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input 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

Abnormality present at baseline but has gotten worse.

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
 → Describe

Physician reporting SAE Complementary Notification

Name

DR COLINS MWJ

Signature

[Signature]

Date form completed

20131028