



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila kwazi, ukaphila kwethu emy health for our health)

Ukaphila kwam

Africa Cent

Ukaphila kwethu

Trial

SAE-AC

Serious Adverse Event Reporting



00317357

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

20151022

i.e. Date of original Initial Notification Form

Complementary Notification Date

20151120

1. Patient details

TasP ID

40357

Name

G.S.

Sex



Male

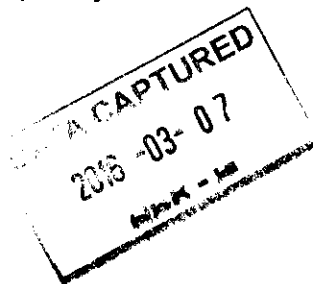
Female

Date of birth

19490423

Enrolment date

20140828



2. Description of the reported SAE

Patient referred to Hlabisa hospital on 21/10/15 with acute on chronic renal failure: Creatinine 1082, Urea 31.1 on blood taken 21/10/15.

Date of SAE onset

20150915

3. Complementary information

Patient did attend Hlabisa hospital and had IV fluid.
Unfortunately he self-discharged (? which date), so doesn't have a discharge letter.
Post self-discharge, on 4/11/15 Creatinine = 710, Urea 21.6 (normal Sodium + urea).
He refuses to re-attend hospital. Is encouraged to increase his water intake.

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	Freq	New judgement of causality
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

Patient entered TAP with renal impairment.

8. SAE Outcome

Death → Date of death
Unknown to date
● Ongoing
Improved
Worsened
Recovered → Date of recovery

Probable Diagnosis _____

Another complementary SAE notification form must be submitted.

Recovered without sequelae
or
Recovered with sequelae
Describe

Ongoing renal failure.
(Another) Complementary SAE will only be submitted if there is any change.

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature 

Date form completed 20 15 11 20