



TasP

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

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

00199209

SAE No.

Initial Notification Date

20140814

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140901

1. Patient details

TasP ID

20192

Name

G.M

Sex

Male

☒ Female

Date of birth

19411223

Enrolment date

20120304

2. Description of the reported SAE

The patient was referred to Hlabisa hospital on 14/8/14 with a grade 3 renal failure, following one week of diarrhoea.

Date of SAE onset

20140811

3. Complementary information

The patient did attend hospital on 15/08/2014. She received IV fluids and her renal function improved. Her antihypertensive HCTZ was withheld during the admission but she continued her antiretroviral treatment. The diarrhoea resolved during the admission. She was discharged with a mildly deranged creatinine although it was much improved.

4. New diagnosis?

☒ Yes → Describe

GASTROENTERITIS causing the renal failure
(this was not clear on the initial SAE form)

No

Date of new diagnosis

20140901

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment? HCTZ stopped as it was exacerbating the renal failure

Date discontinued

20140815

b) Did the event reappear after reintroduction of treatment?

☐ Yes

No

☒ N/A

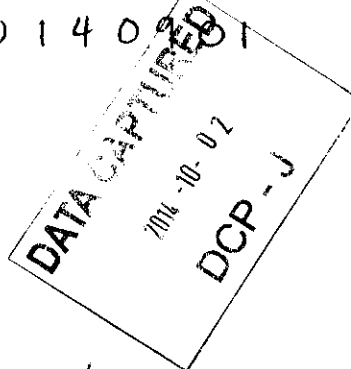
Which treatment?

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

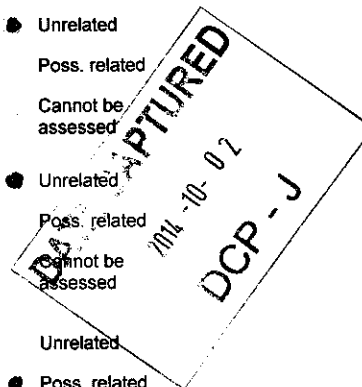
No → Section 7



6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. Abirater	600mg	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. Lamivudine	300mg	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. Efavirenz	600mg	OD	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. HCTZ	12.5mg	OD	<input type="radio"/> Unrelated <input checked="" 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
L Describe

The patient suffered gastroenteritis, which caused renal failure. After rehydration she now has grade 2 hypercreatinemia.

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 20140821

Recovered without sequelae

or

☒ Recovered with sequelae

L Describe

Discharged with a high creatinine (although much improved). For monitoring at TasR Clinic.

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

Date form completed

20140901