

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu (my health for my health)**Ukuphila kwami, ukuphila kwethu****Africa Centre TasP Trial****SAE-AI****Serious Adverse Event Reporting****ANRS 12249 Initial SAE Notification**

00125369

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20140814

Initial Notification Date

20140814

Notification time

1540

1. Patient details

TasP ID

20192

Name

G.M.

Sex

Male

☒ Female

Date of birth

19411223

Enrolment date

20120304

2. Measurements

Height

Cms

Last known: Weight

40.5

Kgs

Weight Date

20140814

CD4 count

204

CD4 Date

20140324

Viral Load

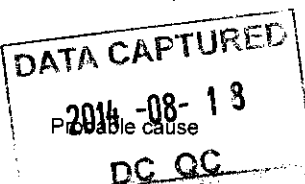
<40

Viral Load Date

20140402

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

☐ Resulted in death → Date of death☐ Life threatening (i.e. at risk of death at time of event)☒ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)☐ Persistent or significant disability / incapacity☐ Congenital abnormality / birth defect☐ Grade 4 clinical and biological events☐ Other serious, medically-important condition → Specify**4. Details of SAE**

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event NameDate investigator
became awareDate of onset of SAE

1. Grade 3 renal failure 20140813 20140811

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

Patient attended TasP clinic on 11/08/14 complaining of diarrhoea that had lasted one week. She was given oral rehydration solution and her U+E checked. Her creatinine was 304. She was recalled to clinic on 14/8/14, and referred to Alabisa hospital for further management. as an urgent case as she was hypotensive + tachycardic.

6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Abacavir	600mg	P.O.	HIV	2013 09 11		Unrelated Poss. related ● Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
2. Lamivudine	300mg	P.O.	HIV	2013 09 11		Unrelated Poss. related ● Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
3. Efavirenz	600mg	P.O.	HIV	2013 09 11		Unrelated Poss. related ● Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
4. HCTZ	12.5mg	P.O.	hypertension			Unrelated Poss. related ● Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
5. Amlodipine	5mg	P.O.	hypertension			Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6. Oral rehydration solution	PRN	P.O.	Diarrhoea	2014 08 11		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop

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 ☐ Describe

8. SAE Outcome

- Died
- Unknown to date
- Ongoing ☐ A complementary SAE notification must be submitted within 8 days
- Improved ☐
- Recovered ☐ Date of recovery
- Recovered without sequelae
- or
- Recovered with sequelae ☐ Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 2014 08 14