

**TasP**Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu (my health for our health)**Ukuphila kwami, ukuphila kwethu****Africa Centre TasP Trial****Serious Adverse Event Reporting****ANRS 12249 Initial SAE Notification****SAE-AI**Completed forms must be sent to  
ANRS within 48 hrs.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

00317463

SAE No.

SAE Visit Date

20151005

Initial Notification Date

20151006

Notification time

1300

**1. Patient details**

TasP ID

34634

Name

S.E

Sex

Male

● Female

Date of birth

19590508

Enrolment date

00000000

**2. Measurements**

Height

000 Cms

Last known: Weight

73.0

Kgs

Weight Date

2015-10-07 05

CD4 count

516

CD4 Date

20150811

Viral Load

&lt;40

Viral Load Date

20150811

DATA CAPTURED

2015-10-07 05

20150811

20150811

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

Tick all that apply

- ☐ Resulted in death → Date of death Probable cause
- ☐ 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. ?Upper GI bleed 20151006 20150913
2. Uncontrolled diabetes 20151006 20150913  
Mellitus type 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 reporting that she had been admitted to Alabisi hospital from 13/09/15 to 16/09/15. She complained of haematemesis (not witnessed during the admission). The doctor also recognised poor blood sugar control. She was treated with H. pylori eradication regimen and discharged on a PPI metformin + glibenclamide.

## 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. Metformin	500mg	PO	D.M. type II	2014 01 01		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. HCTZ	12.5mg	PO	Hypertension	2014 01 01		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Aspirin	150mg	PO	Unclear ?hypertension	2004 05 28 2015 09 13		<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input checked="" type="radio"/> Stop
4. AZT/3TC/EFV	600/300/600mg	PO	<del>600/300/600mg</del> Ganciclovir HIV	2015 02 17		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Patient was on long-term aspirin prior to TMP Strept

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 2015 09 19

☒ Recovered without sequelae

or

Recovered with sequelae

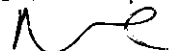
Describe

## Physician reporting SAE

Name

MELANIE HILL

Signature



Date form completed

2015 10 06