



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



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**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

SAE No.

SAE Visit Date

20130705

Initial Notification Date

20130709

Notification time

**1. Patient details**

TasP ID

16267

Name

Embonongwele B. Z

Sex

☒ Male

☐ Female

Date of birth

19810412

Enrolment date

20130612

**2. Measurements**

Height

174 Cms

Last known: Weight

58.00 Kgs

Weight Date

20130612

CD4 count

255

CD4 Date

20130612

Viral Load

427000

Viral Load Date

20130627

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

Tick all that apply



Resulted in death → Date of death

20130703

Probable cause

RENAL FAILURE



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 Name

Date investigator  
became aware

Date of onset of SAE

1. RENAL FAILURE 20130705 20130625

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.

Telephone message from a relative: Admitted to a hospital outside the district on 25/6/2013 and died on 03/07/2013. Blood results from hospital seen on the Online result system showed worsening renal failure. No further diagnosis could be ascertained

## 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. ZIDOVUDINE 600mg	Oral	HN		20120105		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE 300mg	Oral	HN		20120105		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. EFFAVIREN2 600mg	Oral	HN		20120105		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input 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 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 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 Renal failure

## 8. SAE Outcome

☒ Died

☐ Unknown to date

☐ Ongoing

☐ Improved

☐ Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE

Name

Signature

Date form completed

COLLINS Iwan

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20130709