



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
(Ukaphila kwami, ukuphila kwethu)

Ukaphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AI
v31 jan 2013

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

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

00057432

SAE No.	SAE Visit Date	20130403	Notification time
	Initial Notification Date	20130408	

1. Patient details

TasP ID: 19849
Name: N.M.
Sex: ☐ Male ☒ Female
Date of birth: 19771225
Enrolment date: 20130219

DATA CAPTURED
2013-04-12
00:00

2. Measurements

Height: 166 Cms
Last known: Weight: 89.0 Kgs Weight Date: 20130403
CD4 count: 206 CD4 Date: 20130222
Viral Load: 234900 Viral Load Date: 20130214

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 Name	Date investigator became aware	Date of onset of SAE
1. RAISED BLOOD PRESSURE.	20130403	20130325
2.	Y Y Y Y M M D D	Y Y Y Y M M D D
3.		
4.	Y Y Y Y M M D D	Y Y Y Y M M D D
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.

26-28wks pregnant LMP ?/09/2012. Admitted to hospital for 5 days due to raised blood pressure. No further information available. Discharge 30/03/2013.
Current BP 137/96 mmHg. She was given treatment whilst in hospital, does not know names of medications

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	PMCT	20130111	20130304	<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. ATRIPLA	300/200/600	ORAL	HIV	20130304		<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.						<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
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? ☒ Yes ☐ No
This includes the patient's medical history

Describe History incomplete

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

☒ Recovered

→ Date of recovery 20130330

☒ Recovered without sequelae

or

Recovered with sequelae

→ Describe

Emt 2013/04/11 was held by Collins do put the date on D/B as 2013/01/01. 2013/04/11

A complementary SAE notification must be submitted within 8 days

Physician reporting SAE

Name

DR COLLINS LWJ

Signature

Xinfeng

Date form completed

20130408