



TasP

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

Mchakwini

Ukaphila kwami, ukaphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AI

v31 jan 2013



00093274

ANRS 12249 Initial SAE Notification

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

SAE No.	SAE Visit Date	20131104
	Initial Notification Date	20131106
	Notification time	

1. Patient details	
TasP ID	24444
Name	P. M.
Sex	<input type="radio"/> Male <input checked="" type="radio"/> Female
Date of birth	19600807
Enrolment date	20131021

2. Measurements	
Height	162 Cms
Last known: Weight	60.0 Kgs
CD4 count	105
Viral Load	217800
Weight Date	20131021
CD4 Date	20131021
Viral Load Date	20131021

3. By which criteria is this adverse event considered to be "Serious"?	
Tick all that apply	
<input type="checkbox"/> Resulted in death → Date of death	Probable cause
<input type="checkbox"/> Life threatening (i.e. at risk of death at time of event)	
<input checked="" type="checkbox"/> Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)	
<input type="checkbox"/> Persistent or significant disability / incapacity	
<input type="checkbox"/> Congenital abnormality / birth defect	
<input type="checkbox"/> Grade 4 clinical and biological events	
<input type="checkbox"/> 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. SUSPECTED PULMONARY TB	20131104	20131028
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.		

DATA CAPTURE

2013 -11- 07

DCP - S

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 presented to trial clinic on 4/11/2013 complaining of weakness of 1 week duration, cough productive of yellowish sputum, weight loss and loss of appetite. She had a temperature of 39.5, tachycardic with BP 93/62. She was ill-looking & also had oral/oropharyngeal candida.

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. CO-TRIMOXAZOLE	960mg PO		PCP & BACTERIAL PROPHYLAXIS	20131021		<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.						<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
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?

This includes the patient's medical history

Yes ☒ No ☐

Describe

Advanced HIV disease with suspected Pulmonary TB.

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

DR COLLINS (WUJ)

Signature

Xm fmgj

Date form completed

20131006