

**Serious Adverse Event Reporting**
Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu (my health for our health)


00057203

**ANRS 12249 Complementary SAE Notification**

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No. \_\_\_\_\_ Initial Notification Date 2013 10 17 i.e. Date of original Initial Notification Form  
Complementary Notification Date 2013 01 01

**1. Patient details**

TasP ID 26739  
Name \_\_\_\_\_  
Sex ☐ Male ☒ Female  
Date of birth 1985 11 16  
Enrolment date 2013 07 22

**DATA CAPTURED**
**2013 -10- 06**
**DC QC**
**2. Description of the reported SAE**

Admitted to hospital 10/10/2013 with pleural TB.

Date of SAE onset 2013 09 02

**3. Complementary information**

Discharged from hospital 15/10/2013.  
Continuing with TB treatment.

**4. New diagnosis?**

☐ Yes → Describe \_\_\_\_\_  
☒ No

Date of new diagnosis Y Y Y Y M M D D

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment? ☐ Yes ☐ No ☒ N/A

→ Which treatment? \_\_\_\_\_

Date discontinued Y Y Y Y M M D D

b) Did the event reappear after reintroduction of treatment? ☐ Yes ☐ No ☒ N/A

→ Which treatment? \_\_\_\_\_

Date reintroduced Y Y Y Y M M D D

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

☐ Yes → Section 6 ☒ No → Section 7

## 6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. ATRIPLA TDF/FTC/EFV	300/200/600	O.D	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

## 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

☐ Unknown to date  
☒ Ongoing  
☐ Improved  
☐ Worsened  
☐ Recovered

☐ Another complementary SAE notification form must be submitted within 8 days from now.  
☐ Date of recovery

Recovered without sequelae  
 or  
 Recovered with sequelae  
☐ Describe

## Physician reporting SAE Complementary Notification

Name DR COLLINS / WUJI

Signature Knp

Date form completed 20130111