

**Serious Adverse Event Reporting**
**ANRS 12249 Initial SAE Notification**

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



00317399

SAE No.

SAE Visit Date

20150212

Initial Notification Date

20150213

Notification time

1500

**1. Patient details**

TasP ID

41644

Name

T. G.

Sex

Male

☒ Female

Date of birth

19760906

Enrolment date

20140905

**2. Measurements**

Height

159 Cms

Last known: Weight

47.0

Kgs

Weight Date

20141125

CD4 count

29

CD4 Date

20141002

Viral Load

97459

Viral Load Date

20141030

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

Tick all that apply



Resulted in death → Date of death

20150210

Probable cause

Suspected TB.  
Treatment 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
Date of onset of SAE
became aware

1. Death 2°? PTB; 20150212 20141023

2. Treatment failure 20150202 20141110

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.

Participant on Atripla; Mtn low CD4 and unsuppressed viral load. Was unwell, reviewed by trial clinician and referred to hospital for suspected TB but never went. Relatives were unwilling to call ambulance for pt to go to hospital. Resistance test confirmed treatment failure but patient died before second line could be initiated.

## 6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	TDF	300mg	oral	HIV	2013 UU UU	Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2.	ZTC	300mg	oral	HIV	2013 UU UU	Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
3.	Effavirenz	600mg	oral	HIV	2013 UU UU	Unrelated Poss. related <input checked="" type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt 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 did not go to hospital when referred. She most likely had 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 GUGUYHBE MUKHULISI

Signature

Date form completed 2015 0213