



00125365

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

20140718

Initial Notification Date

20140718

Notification time

1623

**1. Patient details**

TasP ID

21308

Name

K.N.

Sex

Male

● Female

Date of birth

19781103

Enrolment date

20130219

**2. Measurements**

Height

154 Cms

Last known: Weight

490

Kgs

CD4 count

128

Viral Load

3051758

Weight Date

2014-08-14 0526

CD4 Date

20140313

Viral Load Date

20140526

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

Tick all that apply

- ☒ Resulted in death → Date of death 20140717 Probable cause TB Abdomen
- ☐ 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. Death

20140718 20140717

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.

Participant on Aluvia, 3TC and Didanosine with comorbid abdominal TB. Participant with longstanding history of being severely ill. Was referred to hospital on 11/6/14 but did not go. Was followed up by Tracking Team on 4/7/14 and had not gone to hospital. Was reported to have died at home 17/7/14.

## 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. Atuvici (lopi/rif) 300/200mg	oral	HIV	20040707			Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. Lamivudine 300mg	oral	HIV	20040707			Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3. Didanosine 250mg	oral	HIV	20040707			Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4. Rifampicin 300mg	oral	TB Abdomen	20130918			Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5. Isoniazid 150mg	oral	TB abdomen	20130918			Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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

Participant will longstanding history of severe illness, failed to go to hospital with community HIV and extrapulmonary TB.

## 8. SAE Outcome

☒ Died

Unknown to date

Ongoing

Improved

Recovered



→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name Dr. G. Nkikulisi

Signature

Date form completed 20140718