

**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



00317456

SAE No.

SAE Visit Date

20150308

Initial Notification Date

20150326

Notification time

08 55

**1. Patient details**

TasP ID

14847

Name

E.N.M.

Sex



Male

Female

Date of birth

19721225

Enrolment date

20120818

**2. Measurements**

Height

170 Cms

Last known: Weight

48.6

Kgs

2015-03-27

Weight Date

20150218

CD4 count

938

CD4 Date

20150218

Viral Load

&lt;40

Viral Load Date

20150218

**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
Date of onset of SAE
became aware

1. Renal failure 20150326 20150218

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.

Blood results taken in TasP on 18/2/15 showed a new renal failure (creatinine 290 - whereas in Sept. 2014 Cr=88 and was always normal prior to that). He was on aripin with CD4 938 - undetectable viral load. He attended Hlabisi hospital (date unknown). Nursing Staff inform me that he died at Hlabisi (date unknown). His last blood test was 16/3/15 - Creatinine 340. I will obtain the inpatient notes for more details.

## 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. Atapla	T	PO	HIV	20130405		Unrelated	<input checked="" type="radio"/> Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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

ELACR → Patient was on DRT prior to TAP, but started TDF April 2013 + was stable until this point.  
The patient was on a TDF containing regimen prior to entry into TAP. Further comment at this point not possible until details known.

## 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

MELANIE HILL

Signature

Date form completed

2015 03 26