



00317411

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

20150724

Initial Notification Date

20150804

Notification time

1100

**1. Patient details**

TasP ID

41702

Name

S.G.

Sex



Male

Female

Date of birth

19810714

Enrolment date

20141003

**2. Measurements**

Height

168 Cms

Last known: Weight

44.0

Kgs

Weight Date

20150706

CD4 count

381

CD4 Date

20150706

Viral Load

&lt;40

Viral Load Date

20150706

**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  
became aware

Date of onset of SAE

1. Acute renal failure 20150723 20150716

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 TDF/FTC/EFV with CD4 381 and suppressed viral load. Reported chronic diarrhoea and was seen by trial medical officer. On routine checking of blood results, he was found to have Potassium 1.9; urea 12 and creatinine 110. He was referred to hospital and was admitted on 24/7/2015. He was given IV fluid and antibiotics and improved quickly. His urea was 3.1 & creatinine 57 on 27/7/2015 & he was discharged.

## 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. Tenofovir	300mg	oral	HIV	20131209	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
2. Emtricitabine	200mg	oral	HIV	20131209	Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20131209	Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
4.					Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
5.					Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
6.					Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> 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 had diarrhoea for 1 month which could account for his renal impairment.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20150728

☒ Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name DR GUGELIHE MUKHULISI

Signature

Date form completed 20150804