

**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

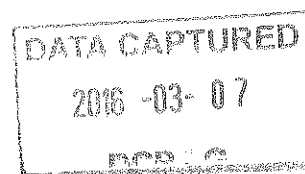


00317425

SAE No. \_\_\_\_\_ SAE Visit Date 20160211  
Initial Notification Date 20160212 Notification time 1500

**1. Patient details**

TasP ID 22007  
Name R.B.N.  
Sex ☐ Male ☒ Female  
Date of birth 29610511  
Enrolment date 20130417



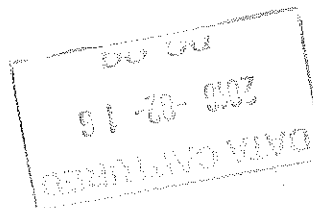
**2. Measurements**

Height 144 Cms  
Last known: Weight 89.9 Kgs Weight Date 20151210  
CD4 count 743 CD4 Date 20151126  
Viral Load <40 Viral Load Date 20150608

**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. Renal failure 20160212 20160122

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 Atripla since May 2013. Has type II diabetes - poorly controlled. Presented to hospital with vomiting. Was admitted on 22/1/2016; urea 22.4 & creatinine 468. She was started on IV fluids. She was started on Actrapid 6 units tds & Protaphane 10 units noct. Metformin was stopped. Her ART was changed to Abacavir, renal dose Lamivudine & Efavirenz. She was discharged on 10/2/16. She will be followed up at trial clinic.

## 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 <del>oral</del>	oral	HIV	20120800	20160122	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
2. Emtricitabine	200mg	oral	HIV	20130503		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20120800		Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
4. Metformin	3g	oral	Diabetes	20070000		Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
5. Protaphane	10units	IM	Diabetes	20151120		Unrelated Poss. related Cannot be assessed	<input type="radio"/> Yes <input checked="" 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

Participant with uncontrolled diabetes; at risk of renal failure.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 20160210

Recovered without sequelae

or

☒ Recovered with sequelae

Describe

A&T regimen changed to ABC/  
3TC/EFV

## Physician reporting SAE

Name GUG'ELIHE MKHULISI

Signature

Date form completed 20160212