

**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



00099541

SAE No.

SAE Visit Date

20130919

Initial Notification Date

20130919

Notification time

1500

**1. Patient details**

TasP ID

20798

Name

M P

Sex

Male

Female

Date of birth

19740912

Enrolment date

20130327

**2. Measurements**

Height

162 Cms

Last known: Weight

49.30 Kgs

Weight Date

20130919

CD4 count

632

CD4 Date

20130910

Viral Load

AWAITING  
250

Viral Load Date

20130910

**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. ANAEMIA 20130917 UNKNOWN

2.

3.

4.

5.

**DATA CAPTURED**

2013-10-02

DCP-J

**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.

Patient noticed to have low HB → 5,7g/dl, MCV-63,3fl.  
mch-16,5pg. She was called and reviewed on 19/9/2013  
Report history of heavy bleeding with clots during last menstrual  
period (26/8/2013). No dizziness nor other symptoms reported.  
Rale+. She was started on Fesoy, Vit. C and referred to hospital  
for further work up esp rule out cause of Menorrhagia.

## 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. <del>Atipiz</del>	300mg	oral	HIV	20111010		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> Cannot be assessed		Interrupt
								Stop
2. Isomlegid	300mg	oral	TB prophylaxis	20130910		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> Cannot be assessed		Interrupt
								Stop
3. Pyridoxine	25mg	oral	Neuropathy prophylaxis	20130910		<input checked="" type="radio"/> Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> Cannot be assessed		Interrupt
								Stop
4. Tenofovir	300mg	oral	HIV	20111010		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> Cannot be assessed		Interrupt
								Stop
5. Zidovudine	300mg	oral	HIV	20111010		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> Cannot be assessed		Interrupt
								Stop
6. Efavirenz	600mg	oral	HIV	20111010		Unrelated	Yes	None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						<input checked="" type="radio"/> 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

Had Menorrhagia during the last menstrual period.

## 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. Oluwayinka A. Chene

Signature

*[Signature]*

Date form completed

20130919