

**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



00317407

SAE No.

SAE Visit Date

20150519

Initial Notification Date

20150528

Notification time

1630

**1. Patient details**

TasP ID

21907

Name

E.B.N.

Sex

Male

☒ Female

Date of birth

19450120

Enrolment date

20130308

**2. Measurements**

Height

157 Cms

Last known: Weight

55.0

Kgs

Weight Date

20150512

CD4 count

246

CD4 Date

20140721

Viral Load

&lt;40

Viral Load Date

20150211

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

Tick all that apply

☐ Resulted in death → Date of death

☐ 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

Probable cause

2015-05-12

DATA CAPTION

**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. Severe Anaemia 20150515 20150512

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 AZT/3TC/EFV with CD4 count 246 and suppressed viral load. On review of her blood results; she had haemoglobin 4.3g/dl in the absence of abnormal bleeding. She was referred to hospital where she was admitted and transfused 2 units of blood. Her haemoglobin improved. She will be switched to ABC/3TC/EFV, as AZT was identified as a cause.

## 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. Zidovudine	600mg	oral	HIV	20130726		<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
2. Lamivudine	300mg	oral	HIV	20130726		<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20130726		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	None Reduce Interrupt Stop
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	None Reduce Interrupt Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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? ☐ Yes ☒ No

This includes the patient's medical history

Describe

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

☒ Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery 20150524

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Patient is on haematinics and new ART regimen will be changed.

## Physician reporting SAE

Name DR GUGELIHLE MUKHULISI

Signature

Date form completed 20150528