

**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



00010039

SAE No.	SAE Visit Date	2 0 1 3 0 3 1 8
Initial Notification Date	2 0 1 3 0 3 1 9	Notification time 0 9 3 0

**1. Patient details**

TasP ID 1 5 6 9 1  
Name ZODWA MKHAWAZI  
Sex ☐ Male ☒ Female  
Date of birth 1 9 7 7 1 1 1 6  
Enrolment date 2 0 1 3 0 1 2 8

**2. Measurements**

Height 1 6 2 Cms  
Last known: Weight 4 2 0 0 Kgs Weight Date 2 0 1 3 0 3 1 8  
CD4 count 8 5 3 CD4 Date 2 0 1 3 0 1 2 8  
Viral Load < 5 0 Viral Load Date 2 0 1 3 0 2 0 5

**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. ABDOMINAL DISTENSION	2 0 1 3 0 3 1 8	2 0 1 3 0 3 1 8
2. ...	...	...
3. ...	...	...
4. ...	...	...
5. ...	...	...

**DATA CAPTURE**

2013 -04- 0 5

**DCP - S**
**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.

RECENT INVESTIGATIONS FOR WEIGHT LOSS, CHRONIC DIARRHOEA + MICROCYTIC ANAEMIA.  
PRESENTED WITH ABDOMINAL DISTENSION, ON EXAMINATION HAD GENERALISED TENDERNESS  
ADMITTED TO HILBISA HOSPITAL 2013/03/18 - SEEN IN OUTPATIENT DEPARTMENT BLOODS  
SHOWED PERSISTENT ANAEMIA (HB 7.0) + THROMBOCYTOSIS (PLT 682) BUT OTHERWISE NORMAL  
DISCHARGED WITH NO SPECIFIC TREATMENT

## 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. TENOFVIR	300mg	oral	HIV	20120822		<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	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. LAMIVUDINE	300mg	oral	HIV	20080807		<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	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. EFAVIRENZ	600mg	oral	HIV	20120822		<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	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. FERROUS SULPHATE 200mg tds		oral	ANAEMIA	20130128		<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	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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

CHRONIC GI PROBLEM - NEEDS FURTHER INVESTIGATION (DIFFERENTIAL DIAGNOSIS BOWEL TB, PARASITIC INFECTION, MALIGNANCY)

## 8. SAE Outcome

☐ 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

RICHARD LESSELLS

Signature

*[Signature]*

Date form completed 20130319