



00648503

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

20160413

Initial Notification Date

20160415

Notification time

1100

**1. Patient details**

TasP ID

27506

Name

D.M.D.

Sex

☒ Male

Female

Date of birth

19701124

Enrolment date

20130319

**2. Measurements**

Height

175 Cms

Last known: Weight

52.9

Kgs

Weight Date

2016

CD4 count

283

CD4 Date

2016

Viral Load

&lt;40

Viral Load Date

2016

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

Tick all that apply



Resulted in death → Date of death

20160413



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. Death 2° Assault 20160414 20160404

2.

3.

4.

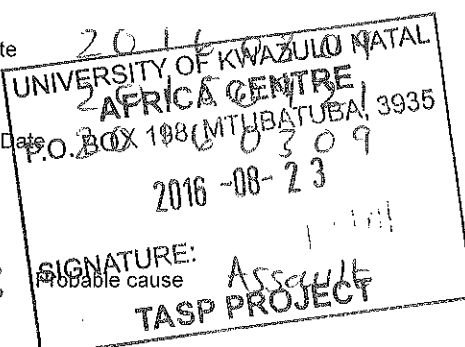
5.

**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 in control cluster. He was on Atripla, with CD4 count 283 & suppressed viral load. Relatives reported that he had been assaulted and admitted to hospital on 04/04/2016. He was unconscious throughout the admission. He died in hospital on 13/04/2016. He had no visible injuries. Details of his admission are unknown currently.



## 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	2013	uu uu	<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. Emtricitabine	300mg	oral	HIV	2013	uu uu	<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	2013	uu uu	<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.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> 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	<input 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

Participant was assaulted.

## 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

GUGLIEUVE MIKHAILIS

Signature



Date form completed

2016 04 15