



00125386

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20141117

Initial Notification Date

20141118

Notification time

1630

1. Patient details

TasP ID

28932

Name

N.N.M.

Sex

Male

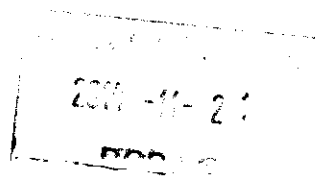
● Female

Date of birth

19801225

Enrolment date

20140217


2. Measurements

Height

161 Cms

Last known: Weight

70.0

Kgs

Weight Date

20140922

CD4 count

228

CD4 Date

20140707

Viral Load

<40

Viral Load Date

20140707

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

Tick all that apply

- ☒ Resulted in death → Date of death 20141115 Probable cause Cervical Cancer
- ☐ 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° to Ca Cervix 20141117 20141029

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; CD4 228 & suppressed viral load. Was clinically suspected to have cervical carcinoma, was awaiting histological confirmation & was attending Gynaecological Hospital. She was reported to be severely ill as of 29/10/14 thus missed appointment for Dr review at clinic. She was advised to use Ambulance service & go to hospital. She was reported to have died at home on 15/11/2014.

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	400mg	oral	HIV	20140221		<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	20140221		<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	20140221		<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? ☒ Yes ☐ No

This includes the patient's medical history

Describe Patient most likely had cervical cancer

8. SAE Outcome

☒ Died

Unknown to date
Ongoing
Improved
Recovered



→ Date of recovery

Recovered without sequelae
or

Recovered with sequelae
→ Describe

Physician reporting SAE

Name DR GUIG'ELIHLE MKHULISI

Signature

Date form completed 20141118