



00079217

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

SAE No.

SAE Visit Date

2013 11 18

Initial Notification Date

2013 11 21

Notification time

1. Patient details

TasP ID

23474

Name

B.N.

Sex

☒ Male

☐ Female

Date of birth

19610204

Enrolment date

20130429

2. Measurements

Height

169 cms

Last known: Weight

63.0

Kgs

Weight Date

20131001

CD4 count

204

CD4 Date

20130904

Viral Load

<50

Viral Load Date

20130904

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

Tick all that apply



Resulted in death → Date of death

20131110

Probable cause

UNKNOWN



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

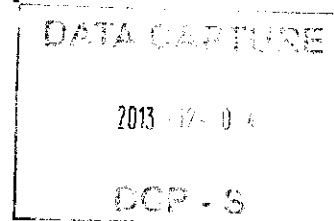
20131118 20131001

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.

Patient missed clinic appointment on 6/11/2013. Relative was phoned. Relative informed trial staff participant died in hospital on 10/11/2013. We have visited the hospital to review hospital records, but hospital has no record of patient having been an inpatient.

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. ATRIPLA TDF/FTC/EFV	T	PO	HW	20130605		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
2. VITAMIN B6	T	PO		20130605		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes 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?

This includes the patient's medical history

Yes No
Describe

Adequate information on circumstances of death not available.

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

COLLINS I WUJI

Signature

Kinf

Date form completed

20131121