

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification


00093283

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

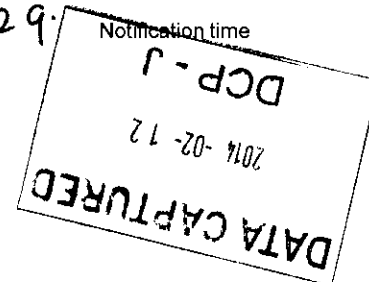
SAE No.

SAE Visit Date

20140123

Initial Notification Date

20140129


1. Patient details

TasP ID

20140

Name

Z. N

Sex

Male

☒ Female

Date of birth

19600831

Enrolment date

20130828

2. Measurements

Height

166 Cms

Last known: Weight

61.2

Kgs

Weight Date

20140123

CD4 count

815

CD4 Date

20130827

Viral Load

379400

Viral Load Date

20130827

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

Date of onset of SAE

1. SEVERE ELEVATION OF GAMMA GLUTAMYL TRANSFERASE 2014 01 27 2013 08 28

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.

Abnormal LFTs. ALT 37 ALP 183 GGT 584
At baseline GGT 204, ALP 131 ALT 45 on 26/08/2013
prior to initiating ART

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

	Generic Name	Daily dose	Route of adminis- tration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	ATRIPLA TDF/FTC/EFV	300/200/600	ORAL	HIV	2013 10 24	Unrelated <input checked="" type="radio"/> Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	None Reduce Interrupt Stop
2.						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

Worsening of LFT on starting ART

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

DR COLLINS Iwaghi

Signature

[Signature]

Date form completed

2014 01 29