

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification

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



00547578

SAE No.

SAE Visit Date

2015 03 23

Initial Notification Date

2015 11 04

Notification time

1. Patient details

TasP ID

23382

Name

NG

Sex

Male

☒ Female

Date of birth

1985 02 18

Enrolment date

2015 03 23

2. Measurements

Height

Cms

Last known: Weight

65

Kgs

Weight Date

2015 10 27

CD4 count

275

CD4 Date

2015 10 27

Viral Load

<40

Viral Load Date

2015 03 23

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
became aware

1. Grade 4 increase in GGT 2015 03 27 2015 03 23

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 presented to trial clinic on 23/3/2015, the same day completed treatment for pulmonary TB. At baseline, ALT 45, ALP 572, GGT 927, Bil 8. Was also on TDF/FTC/EFV at baseline. LFTs have improved with time ALT 46, ALP 195, GGT 442 on 27/10/2015. Was first reviewed by trial clinician in 04/2015, due another review.

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. RIFAFOUR then RIF/INH (Completed on day presented to clinic)		PO	Pulmonary TB	20150922	20150323	Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> Yes No	None Reduce Interrupt Stop
2. TDF/FTC/EFV (generic)		PO	HW	20150323		Unrelated Poss. related Cannot be assessed	<input checked="" type="radio"/> 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

Elevation of GGT/LFTs was already present at baseline.

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

Signature

Date form completed

COLLINS, Iwanj

[Signature]

20151104