

Serious Adverse Event Reporting



00596249

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No. : _____

Initial Notification Date _____

i.e. Date of original Initial Notification Form

Complementary Notification Date 20160531

1. Patient details

TasP ID

16966

Name

TG

Sex

☐ Male

☒ Female

Date of birth

1979 06 21

Enrolment date

2013 01 14

2. Description of the reported SAE

Drug induced liver injury

Date of SAE onset

2013 07 17

3. Complementary information

Participant recovered

LFTs normalised

26/5/2015

30/3/2016

Alt 9

Alt 11

ALT 36

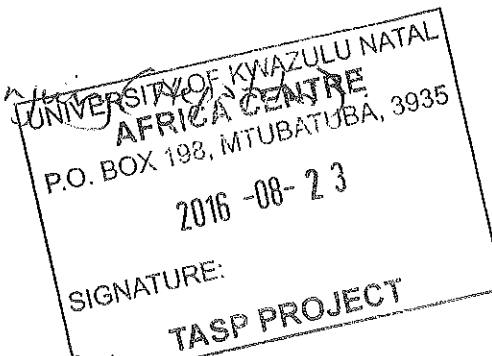
ALT 87

ALP 156

ALP 59

GGT 97

GGT 39



4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

2013 07 22

Xunfeng

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

☐ No

☐ N/A

Which treatment?

TDF/FTC/EFV

Date discontinued

2013 07 22

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☐ No

☐ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

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

8. SAE Outcome

Death → Date of death 10/10/2016 Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

☒ Recovered → Date of recovery 20150526

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name

Signature

Date form completed

C. W. J. J. J.

20160531