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

SAE No.

SAE Visit Date

20151015

Initial Notification Date

20151019

Notification time

**1. Patient details**

TasP ID

24377

Name

T. T.

Sex

☒ Male

☐ Female

Date of birth

19611020

Enrolment date

20131114

**2. Measurements**

Height

157 Cms

Last known: Weight

42.5

Kgs

Weight Date

20151015

CD4 count

303

CD4 Date

20150226

Viral Load

<40

Viral Load Date

20150226

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

Tick all that apply

☐ Resulted in death → Date of death

☐ Life threatening (i.e. at risk of death at time of event)

☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)

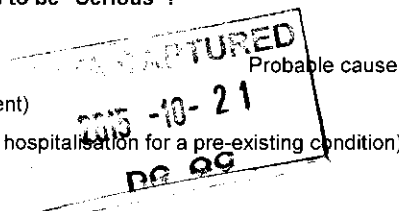
☐ Persistent or significant disability / incapacity

☐ Congenital abnormality / birth defect

☒ Grade 4 clinical and biological events

☒ Other serious, medically-important condition → Specify

Suspected tuberculosis (Pulmonary)



**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. Grade 4 ↑ GGT 20151015 20150919

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.

ART name at enrolment on 14/11/2013 Baseline LFTs ALT 67, ALP 159  
GGT 416 (Grade 3). Known history of alcohol abuse. Current LFTs  
ALT 41, ALP 229 GGT 620. Also complaining of symptoms  
suggestive of pulmonary TB. Referred to hospital

## 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. TDF/FTC/EFV 300/200/600 PO			HN	20131204		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
						<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	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

LFTs including GGT with grade 3 abnormality at baseline due to Alcohol abuse.

## 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

Colin C. Wuji

Xinf

20151020