

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



00093294

SAE No.

SAE Visit Date

20140527

Initial Notification Date

20140529

Notification time

1. Patient details

TasP ID

27506

Name

D.D

Sex

☒ Male

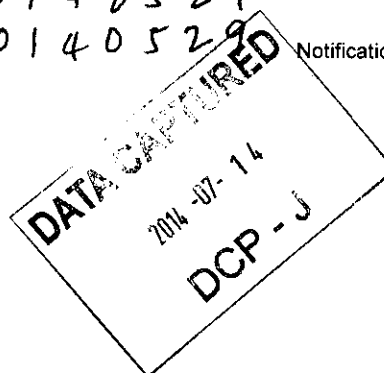
☐ Female

Date of birth

19701124

Enrolment date

20130319


2. Measurements

Height

175 Cms

Last known: Weight

53

Kgs

Weight Date

20140513

CD4 count

205

CD4 Date

20131029

Viral Load

<50

Viral Load Date

20131029

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
became aware
Date of onset of SAE

1. PROBABLE ACUTE CHOLECYSTITIS 20140527 20140527

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.

Presented to hospital on 27/05/2014 with abdominal pain, fever and deranged LFTs → mainly obstructive picture but with normal bilirubin. USS - liver was reported to be normal. He was started on i.v Ceftriaxone + metronidazole.

GGT 433, ALP 341 AST 60 ALT 44 Total Bil 3,

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>	<u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.	TDF/FTC/EFV (Atrivir®)	300/200/600	IV	HIV	20130417		Unrelated ● Poss. related Cannot be assessed	● 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

DATA CAPTURED
2014-07-14
DCP - J

DATA CAPTURED
2014-07-14
DCP - J

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

Acute cholecystitis, abnormal liver function test was present prior to enrolment

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 Iwan J

Signature

Date form completed

20140529