



00423104

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

SAE No.

SAE Visit Date

20150519

Initial Notification Date

20150609

Notification time

1. Patient details

TasP ID

35021

Name

N.N

Sex

Male

Female

Date of birth

19640101

Enrolment date

20150511

2. Measurements

Height

Cms

Last known: Weight

60.5

Kgs

Weight Date

20150511

CD4 count

473

CD4 Date

20150511

Viral Load

287789

Viral Load Date

20150521

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

Tick all that apply

- ☒ Resulted in death → Date of death 20150601 Probable cause Decompensated Liver Cirrhosis
- ☐ 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. LIVER CIRRHOSIS 20150603 20150411

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.

Known alcoholic liver disease with cirrhosis. Recently discharged from hospital prior to baseline visit. Had ascites which was drained. Presented again on 19/5/2015, with massive ascites with no encephalopathy. Was not taking Spironolactone & furosemide which was discharged on. Referred back to hospital on 19/5/2015 but did not attend. Died at home on 1/6/2015.

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>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.					Unrelated	Yes	None
					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

Decompensated Alcoholic liver disease with cirrhosis

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 JMMJ1

Signature

Amf

Date form completed

20150609