

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



00423095

SAE No.

SAE Visit Date

20150416

Initial Notification Date

20150420

Notification time

1. Patient details

TasP ID

40923

Name

H.N

Sex

Male

Female

Date of birth

19790612

Enrolment date

20140922

Intervention

2. Measurements

Height

Cms

Last known: Weight

69.5

Kgs

Weight Date

20150304

CD4 count

591

CD4 Date

20150128

Viral Load

<40

Viral Load Date

20150128

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

Tick all that apply

☐ Resulted in death → Date of death

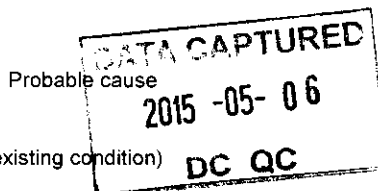
☐ Life threatening (i.e. at risk of death at time of event)

☒ 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

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. Gastroenteritis 20150416 20150405

2. Delirium 20150416 20150405

3. Acute renal failure 20150416 20150409

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.

Developed diarrhoea/vomiting of 4 days duration. associated with confusion and weakness. Presented to hospital on 9/4/2015 and was admitted. Admission bloods showed Creatinine of 298, urea 22.6. She was started on IV fluids + 1.V Rocephin. She self-discharged from hospital on 15/4/2015 before further inrx could be done. U/E were not repeated during hospital stay. Creatinine 56, urea 5.1 on 28/1/2015 prior to diarrhoea/admission

6. Medications

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

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	TDF/FTC/EFV	245/200/600	PO	HIV	20141007	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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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

Acute gastroenteritis causing pre-renal failure, exacerbated by tenofovir

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

COUNDS IUNG1

Signature

Kup

Date form completed

20150420