

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



00317471

SAE No.

SAE Visit Date

2015 10 07

Initial Notification Date

2015 10 27

Notification time

16 07

1. Patient details

TasP ID

54620

Name

B.G.K

Sex

Male

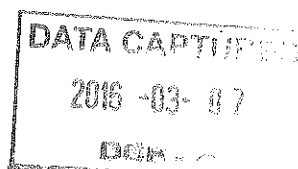
Female

Date of birth

1985 08 08

Enrolment date

2015 10 07


2. Measurements

Height

152 Cms

Last known: Weight

53.5

Kgs

Weight Date

2015 10 19

CD4 count

745

CD4 Date

2015 10 07

Viral Load

<40

Viral Load Date

2015 10 07

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. Deranged LFT 2015 10 09 2015 10 07

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.

Transfer into TasP already on TDF/FTC/EFV. Baseline LFT: ALT 347, ALP 242, GGT 942. Hep B sAg negative. Seen in clinic 19/10/15. Clinically well, denies alcohol or traditional medicine. Repeat LFT 19/10/15: ALP 634, ALP 226, GGT 739. CMP, TAT, Hep A+E/C pending. Referred to Hlabisa for USS liver on 26/10/15.

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?	Action taken
					Date stopped		(BNF/SPC)	
1.	TDF/FTC/EFV (Atrazine)		PO	HIV	20150318	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	Reduce
						Poss. related	No	Interrupt
						Cannot be assessed		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

This patient came into the trial with this problem.

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 MELANIE HILL

Signature [Signature]

Date form completed 20151027