

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



00125367

SAE No.

SAE Visit Date

2014 07 18

Initial Notification Date

2014 07 18

Notification time

15 40

1. Patient details

TasP ID

3 2 8 5 6

Name

N.M.M.

Sex

☒ Male

Female

Date of birth

1 9 7 0 0 1 0 5

Enrolment date

2014 07 08

2. Measurements

Height

Cms

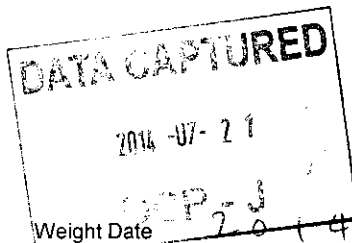
Last known: Weight

65 00 Kgs

CD4 count

543

Viral Load



Weight Date

2014 07 17

CD4 Date

2014 07 16

Viral Load Date

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. Grade 3 Neuropathy 2014 07 18 2014 07 16

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.

fixed dose combination
Patient transferred into TasP from government clinic already on ART (TDF/FTC/3TC).
Presented for his baseline TasP visit on 16/07/2014. He reported weakness and
weight loss to the nursing staff. His routine TasP blood tests taken on that day
showed Creatinine of 580, Urea of 29.6 and Sodium 123. On 18/07/14 he attended
clinic with psychomotor slowness + weakness. He was referred to Hlabisa hospital via ambulance.

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	300mg	PO	HIV	2012	Unrelated	<input checked="" type="radio"/> Yes	None
					20140718	<input checked="" type="radio"/> Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
2.	BTC	800mg	PO	HIV	2012	Unrelated	Yes	None
					20140718	<input checked="" type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> Stop
3.	EFV	600mg	PO	HIV	2012	Unrelated	Yes	None
					20140718	<input checked="" type="radio"/> Poss. related	<input checked="" type="radio"/> No	Reduce
						Cannot be assessed		Interrupt
								<input checked="" type="radio"/> 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

Patient was already on TDF which could be a cause or contributing factor to this renal failure. Fixed dose ARV's stopped.

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 

Date form completed 2014 07 18