

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



00125366

SAE No.

SAE Visit Date

20140716

Initial Notification Date

20140718

Notification time

1600

1. Patient details

TasP ID

16207

Name

N.D.

Sex

Male

☒ Female

Date of birth

19770828

Enrolment date

20120425

2. Measurements

Height

156 cms

Last known: Weight

66 8

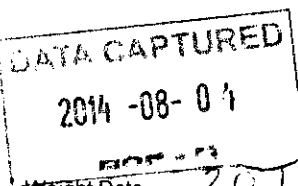
Kgs

CD4 count

349

Viral Load

56660



Weight Date

20140716

CD4 Date

20131024

Viral Load Date

20131028

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. ?Meningitis 20140718 20140712

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.

Participant on 3TC, TDF, Atrivir with CD4 349. Presented with week history of headache, backache & neck pain. Participant is on continuation phase of TB treatment. Clinically suspected to have meningitis and referred to Hlabisa hospital for investigation and treatment. She is currently admitted.

6. Medications

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

Generic Name	Daily dose	Route of adminis- tration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Lop / Ritonavir	800/200mg	oral	HIV	20120618	Unrelated	Yes	None	
					Poss. related	No	Reduce	
					Cannot be assessed		Interrupt Stop	
2. Lamivudine	300mg	oral	HIV	20090513	Unrelated	Yes	None	
					Poss. related	No	Reduce	
					Cannot be assessed		Interrupt Stop	
3. Tenofovir	300mg	oral	HIV	20120618	Unrelated	Yes	None	
					Poss. related	No	Reduce	
					Cannot be assessed		Interrupt Stop	
4. Rifampicin	300mg	oral	PTB	20140206	Unrelated	Yes	None	
					Poss. related	No	Reduce	
					Cannot be assessed		Interrupt Stop	
5. Isoniazid	150mg	oral	PTB	20140206	Unrelated	Yes	None	
					Poss. related	No	Reduce	
					Cannot be assessed		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

Participant with evidence of treatment failure; no clinical improvement. Has co-morbid TB and HIV. Very ill.

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

G. Mkhulisi

Signature



Date form completed

20140718