

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



00317420

SAE No.

SAE Visit Date

20150908

Initial Notification Date

20150910

Notification time

1630

1. Patient details

TasP ID

50707

Name

K.B.N.

Sex



Male

Female

Date of birth

19880612

Enrolment date

20141122

2. Measurements

Height

172 Cms

Last known: Weight

64.1

Kgs

Weight Date

20150707

CD4 count

106

CD4 Date

20150514

Viral Load

2239695

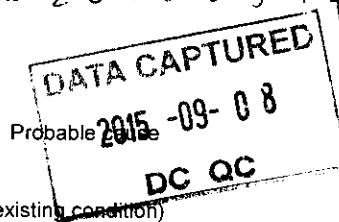
Viral Load Date

20150514

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. Anemia 20150901 20150831

2. Acute renal impairment 20150901 20150831

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 in control arm. He is on Atripla since 25/06/2015. He was diagnosed with pulmonary TB and is on treatment since 09/06/2015. He complained of loin pain & fatigability for weeks duration & was seen by trial clinician on 1/9/15. Bloods taken showed urea 8.5, creatinine 233 and Hb 6.6g/dl. He had abdominal pain and decreased air entry clinically. *He was referred to hospital. He reports he has been admitted to Maseru hospital since 08/09/2015. More information to follow upon discharge. *He was switched to ABC/3TC/EFV (brand disc).

6. Medications

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

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Tenofovir	300mg	oral	HIV	20150625	20150901	Unrelated ● Poss. related ● Cannot be assessed	● Yes No	None Reduce Interrupt ● Stop
2. Emtricitabine	200mg	oral	HIV	20150625	20150901	Unrelated ● Poss. related ● Cannot be assessed	● Yes No	None Reduce Interrupt ● Stop
3. Efavirenz	600mg	oral	HIV	20150625		● Unrelated Poss. related ● Cannot be assessed	Yes ● No	● None Reduce Interrupt Stop
4. Rifampicin	300mg	oral	TB	20150609		Unrelated Poss. related ● Cannot be assessed	Yes No	None Reduce Interrupt Stop
5. Isoniazid	150mg	oral	TB	20150609		Unrelated Poss. related ● Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related ● Cannot be assessed	Yes No	None Reduce 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 advanced HIV and TB. Needs to be investigated to exclude disseminated or resistant TB.

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 DR GUGLIELMO MARCHISI

Signature

Date form completed 20150910