

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



00125372

SAE No.

SAE Visit Date

20140812

Initial Notification Date

20140828

Notification time

0900

1. Patient details

TasP ID

33311

Name

X.M.

Sex

☒ Male

☐ Female

Date of birth

19940304

Enrolment date

20140729

2. Measurements

Height

Cms

Last known: Weight

410

Kgs

Weight Date

20140812

CD4 count

45

CD4 Date

20140729

Viral Load

<40

Viral Load Date

20140729

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

☐

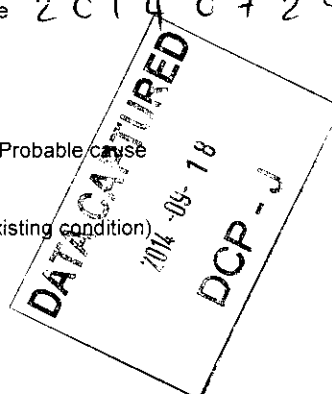
Congenital abnormality / birth defect

☐

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. chronic gastroenteritis 20140826 20140801

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 newly enrolled in trial with CD4 count 45 and suppressed viral load on FDC. He presented to TasP clinic on 12/8/14 reporting passing loose stool. He was given oral rehydration solution and Loperamide. He was reported by his relatives to have been admitted to Hospital on 22/8/2014 as the diarrhoea had not resolved.

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. Atripla	1 tab	oral	HIV	20140731		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
2. Potassium	600mg	oral	hypokalemia	20140731		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
3. Cotrimoxazole	960mg	oral	Prophylaxis	20140729		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
4. Multivitamins	1 tab	oral	Maintenance	20140731		Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No 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 has Malnutrition and severe wasting with low CD4 count. He is highly susceptible to infections.

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 GUGELIHE MICHULISI

Signature

Date form completed 20140828