

**Serious Adverse Event Reporting**


00199212

**ANRS 12249 Complementary SAE Notification**

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2014 08 28

*i.e. Date of original Initial Notification Form*

Complementary Notification Date

2014 09 12

**1. Patient details**

TasP ID

333 11

Name

X.M.

Sex

☒ Male

Female

Date of birth

1994 03 04

Enrolment date

2014 07 29

**2. Description of the reported SAE**

Participant with CD4 45 and viral load suppressed on Atripla. Presented with 2 weeks of diarrhoea. He was given treatment at TasP Clinic and then referred to hospital by relatives as he was not improving. He was admitted.

Date of SAE onset 2014 08 12

**3. Complementary information**

Participant admitted on 23/8/14 for chronic gastroenteritis and anaemia. Haemoglobin was 4.7 and he was transfused unit of blood and it improved to 10.7 g/dl. He was given 10 antibiotics and 10 fluid, as well as oral Potassium replacement for Potassium of 2.3. He improved and was discharged on 30/8/14.

**4. New diagnosis?**

Yes → Describe

☒ No

Date of new diagnosis

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

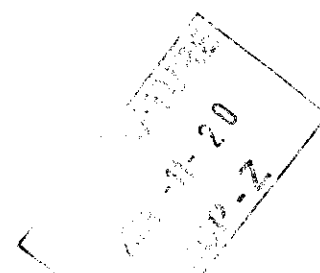
☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7


## 6. Medications

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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

## 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 stage IV HIV, also has underlying malnutrition, he is highly susceptible to opportunistic infections.

## 8. SAE Outcome

Death → Date of death

Probable Diagnosis \_\_\_\_\_

Unknown to date

☒ Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE Complementary Notification

Name DR GUGLIELMO MICHULISI

Signature

Date form completed 2014 09 12