

**Serious Adverse Event Reporting**


00199226

**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

20141212

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

Complementary Notification Date

20150126

**1. Patient details**

TasP ID

43517

Name

M.M.M.

Sex

☒ Male

☐ Female

Date of birth

19631018

Enrolment date

20140930

**2. Description of the reported SAE**

Participant newly enrolled in trial; CD4 count 16, viral load 64228 on Atripla. He had become unwell at home with diarrhoea, vomiting and loss of strength. He had been taken to hospital by relatives.

Date of SAE onset 20141127

**3. Complementary information**

He was admitted on 01/12/14. Started on IV fluid. Reviewed by trial clinician on 10/12/14. Pt unwell with altered mental state. Lumbar Puncture was done. Results showed cryptococcal meningitis and was started on treatment. He continued to deteriorate and eventually died on 27/12/2014.

**4. New diagnosis?**
☒ Yes → Describe  
☐ No

Cryptococcal Meningitis

Date of new diagnosis

20141211

**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

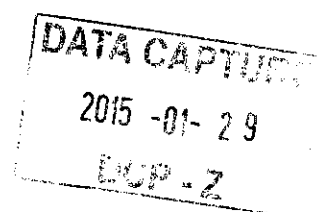
☒ N/A

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

Patient with very low CD4 count, susceptible to opportunistic infection.

## 8. SAE Outcome

☒ Death

→ Date of death

20141227

Probable  
Diagnosis

Cryptococcal meningitis

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 NICOTULISI

Signature

Date form completed 20150126