

Serious Adverse Event Reporting


00199204

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

2 0 1 4 0 7 1 8

i.e. Date of original Initial Notification Form

Complementary Notification Date

2 0 1 4 0 7 2 5

1. Patient details

TasP ID

1 6 2 0 7

Name

N.D.

Sex

Male

☒ Female

Date of birth

1 9 7 7 0 8 2 8

Enrolment date

2 0 1 2 0 4 2 5

2. Description of the reported SAE

Participant on 3TC, TDF, Atravir with CD4 349. Presents with 1 week history of headache, backache & pain. She is on continuation of PTB treatment. Clinically suspected to have meningitis and referred to hospital.

Date of SAE onset 2 0 1 4 0 7 1 2

3. Complementary information

Participant was admitted to Alcobisa Hospital. Lumbar puncture confirmed mixed meningitis. She was started on IV Rocephin given for 7 days. She was re-started on Intensive phase TB treatment and given IV steroids. She responded well to treatment. was discharged at 24/7/2014.

4. New diagnosis?
☒ Yes → Describe

No

Mixed Meningitis
Disseminated TB

Date of new diagnosis

2 0 1 4 0 7 1 8

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

Generic Name	Dose	Frequency	New judgement of causality
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
↳ Describe

No

Participant with co-morbid HIV & TB. Having recurrent TB due to poor immunity.

8. SAE Outcome

Death → Date of death

Probable Diagnosis _____

Unknown to date

Ongoing

Improved

Worsened

Another complementary SAE notification form must be submitted.

☒ Recovered → Date of recovery

Recovered without sequelae
or

☒ Recovered with sequelae

↳ Describe Pt restarted on TB treatment, will continue treatment as outpatient.

Physician reporting SAE Complementary Notification

Name Gugelinde Mchulisi

Signature

Date form completed 2.01.40725