

Serious Adverse Event Reporting


00317348

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

20141211

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150121

1. Patient details

TasP ID

26696

Name

M.C.M.

Sex

☒ Male

Female

Date of birth

19920513

Enrolment date

20130722

2. Description of the reported SAE

This patient was referred to Hlabisa hospital as a possible meningitis. He had a raised protein on lumbar puncture, which was missed. A week later he was admitted to Hlabisa (26/11/14) with severe headache. LP was not repeated. He was referred to a tertiary hospital for CT brain.

Date of SAE onset

20141119

3. Complementary information

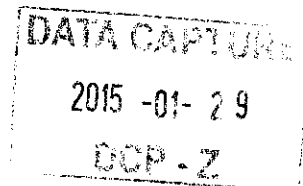
The patient's family informed TasP that he died at the tertiary hospital (Ngwenyane) on 17/01/15. This is the same hospital where he had the CT brain. The details of his transfer to this hospital + his subsequent death are unclear. I am unable to get hold of the Ngwenyane hospital notes. Presumed cause of death: TB meningitis.

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

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 ☐

The patient was at risk of opportunistic infection due to HIV.

8. SAE Outcome

☒ Death

→ Date of death

20150117

Probable
Diagnosis

TB 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 MELANIE HILL

Signature

M Hill

Date form completed 20150121