



00317310

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 20160322 i.e. Date of original Initial Notification Form
Complementary Notification Date 20160516

1. Patient details

TasP ID 51041
Name N.Q.M.
Sex ☒ Male ☐ Female
Date of birth 19670721
Enrolment date 20150413

2. Description of the reported SAE

Participant defaulted anti-epileptic treatment due to excessive use of alcohol (as reported by partner). He was admitted to hospital on 5/3/16 with status epilepticus.

Date of SAE onset 20160305

3. Complementary information

Relatives report that participant remained unconscious throughout hospital stay. He died in hospital on 02/04/2016. Multiple attempts to trace hospital records unsuccessful.

4. New diagnosis?

☒ Yes → Describe Death due to status Epilepticus
☐ No

Date of new diagnosis 20160402

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

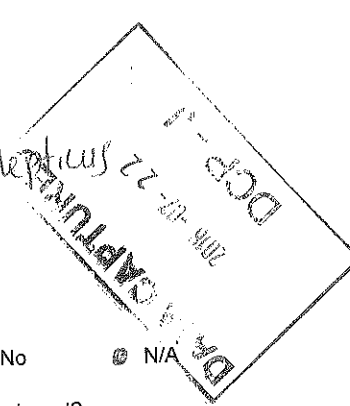
→ Which treatment?

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 ☒

No ☐

Describe

Participant defaulted his anti-convulsants & therefore at risk of seizures.

8. SAE Outcome

☒ Death

→ Date of death

20160402

Probable Diagnosis

status epilepticus

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 GUGIEHUE MKHULU

Signature

Date form completed 20160516