

Serious Adverse Event Reporting


00199211

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

20140714

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140903

1. Patient details

TasP ID

31565

Name

O.B.M.

Sex

☒ Male

Female

Date of birth

19591225

Enrolment date

20140627

2. Description of the reported SAE

Initial SAE reported this patient is a known hypertensive with renal failure - of unknown cause. He was referred to Hlabisa hospital. The 1st Complementary SAE reported that he attended hospital and only received IV fluids. He was discharged with a high creatinine still.

Date of SAE onset 20140703

3. Complementary information

The patient was re-admitted to hospital on 11/8/14 with confusion and renal failure. He had a lumbar puncture which was normal. He also had IV fluids. He was discharged on 14/8/14. His creatinine on 13/8/14 was 224. We reviewed him at TasP clinic, and his wife confirmed he has been confused for 8 months. He does not have capacity to consent so is exited for TasP.

4. New diagnosis?
☒ Yes → Describe

No

Confusion - cause unknown.

In addition to renal failure.

Date of new diagnosis

20140902

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

DATA COMPLETED
2014-10-07
DCP

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?

☒ Yes ☐ No

This includes the patient's medical history

Describe

This appears to be a long-standing confusion prior to entry to Task. He has now been transferred back to government healthcare.

8. SAE Outcome

Death → Date of death

Unknown to date

Ongoing

Improved

Worsened

Probable Diagnosis _____

→ Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery 2014 08 14

Recovered without sequelae

or

☒ Recovered with sequelae

Describe

Discharged from hospital on 14/8/14 but still has renal failure and confusion.

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature *MH*

Date form completed 2014 09 03