

Serious Adverse Event Reporting


00199250

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

2014105

i.e. Date of original Initial Notification Form

Complementary Notification Date

2018127

1. Patient details

TasP ID

21303

Name

Q.K.K.

Sex

Male

☒ Female

Date of birth

19830101

Enrolment date

20130219

2. Description of the reported SAE

Patient with psychotic features and renal impairment was admitted to hospital. Renal impairment improved after treatment. NVP was stopped due to risk of hypersensitivity. She remained psychotic.

Date of SAE onset

20141010

3. Complementary information

Patient's family discharged her from hospital against medical advice. She was reviewed at trial clinic. She is much improved; is a psychotic and functional. She is not on antipsychotics. She no longer has renal impairment. Was given TDF/3TC/EFV at hospital; review of her meds will be done by clinician.

4. New diagnosis?
☒ Yes → Describe
No

Brief psychotic disorder

Date of new diagnosis

20141010

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?

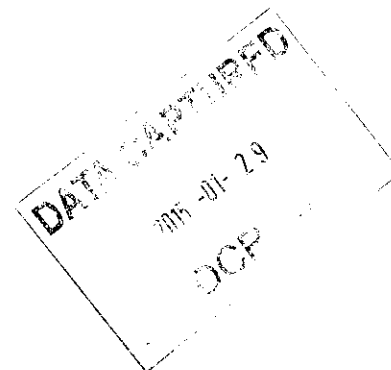
Yes → Section 6

☒ 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? Yes No

This includes the patient's medical history

☒ Yes
L Describe

Short duration of psychosis supports brief psychotic disorder. Patient now on TDF/3TC/EFV - no recurrence of symptoms.

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

L Describe

Patient treatment to be reviewed; currently undergoing close observation.

Physician reporting SAE Complementary Notification

Name GUG'ELHIE NIKHULISI

Signature

Date form completed 20150127