

Serious Adverse Event Reporting


00199222

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

20141103

i.e. Date of original Initial Notification Form

Complementary Notification Date

20141126

1. Patient details

TasP ID

21303

Name

Q.K.K

Sex

Male

☒ Female

Date of birth

19830101

Enrolment date

2. Description of the reported SAE

Acute psychosis whilst on Atriple. Resulted in treatment change to TDF/3TC/NVP by hospital staff.

Date of SAE onset

20141010

3. Complementary information

NVP was discontinued by trial staff as she had a high CS4 count which puts her at risk of severe hypersensitivity. She developed renal impairment and was admitted to hospital. Her renal impairment resolved with treatment. She remains psychotic.

4. New diagnosis?
☒ Yes → Describe

Renal impairment.

☒ No

Xmf

Date of new diagnosis

20141106

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment?

Tenofovir

Date discontinued

20141117

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

she remains acutely psychotic.
Renal impairment has resolved.

DATA CAPTURE

2015-01-09

DCP - S

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1. TDF/Fc/EFV	300/200/600	O.D	Unrelated
			<input checked="" type="radio"/> 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*
- Describe

8. SAE Outcome

Death → Date of death

Unknown to date

☒ Ongoing → Another complementary SAE notification form must be submitted. *Psychosis is ongoing*

Improved

Worsened

Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

Probable Diagnosis _____

Physician reporting SAE Complementary Notification

Name *COLLINS, J. W. J.*

Signature *[Signature]*

Date form completed *20140126*