

Serious Adverse Event Reporting

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to
ANRS within 8 days.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002



00596254

SAE No.

Initial Notification Date

i.e. Date of original Initial Notification Form

Complementary Notification Date 20160531

1. Patient details

TasP ID

22007

Name

BN

Sex

Male

☒ Female

Date of birth

19610511

Enrolment date

20130417

2. Description of the reported SAE

Renal failure

Admitted to Heleisa hospital with gastroenteritis and creatinine 2.400.

Date of SAE onset

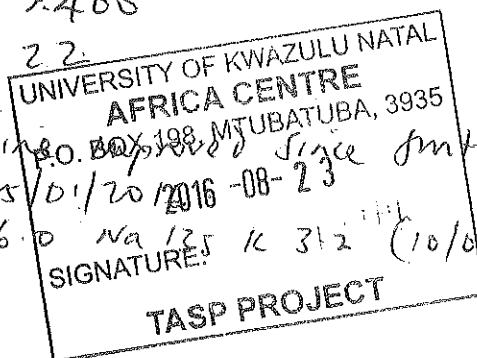
20160122

3. Complementary information

up Creatinine

ABC/3TC/EFV on 25/01/2016

Creat 151 urea 6.0 Na 125 K 3.2



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.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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

Initially on TDF/3TC/EFV from 10/08/2012 before switching to Atripla on 8/5/2013

8. SAE Outcome

Death

→ Date of death

Probable Diagnosis

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

Signature

Date form completed

C. Iwaguchi
Xup
20160531