

**Serious Adverse Event Reporting**



00596250

**ANRS 12249 Complementary SAE Notification**

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

SAE No.

Initial Notification Date

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150531

**1. Patient details**

TasP ID

22176

Name

TM

Sex

Male

☒ Female

Date of birth

19561009

Enrolment date

20130520

**2. Description of the reported SAE**

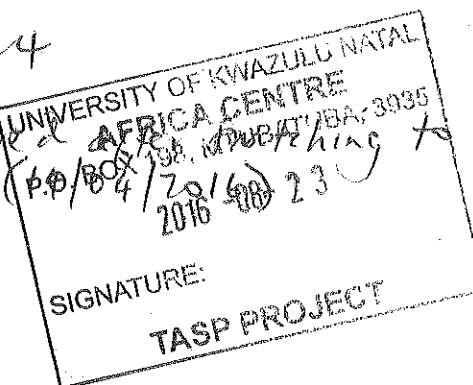
Acute Renal failure

Date of SAE onset

20150324

**3. Complementary information**

Creatinine improved  
Currently 197



ABC/3TC/EFV on 15/5/2015

**4. New diagnosis?**

Yes → Describe

☒ No

Date of new diagnosis

20150514

**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? ☐ Yes ☒ No  
 This includes the patient's medical history ☐ Describe

## 8. SAE Outcome

☐ Death → Date of death \_\_\_\_\_ Probable Diagnosis \_\_\_\_\_  
☐ Unknown to date  
☐ Ongoing  
☒ Improved → Another complementary SAE notification form must be submitted.  
☐ Worsened  
☐ Recovered → Date of recovery \_\_\_\_\_  
     ☐ Recovered without sequelae  
     or  
     ☐ Recovered with sequelae  
     → Describe \_\_\_\_\_

## Physician reporting SAE Complementary Notification

Name

Signature

Date form completed

C. [Signature]  
 2015 05 31