

**Serious Adverse Event Reporting**


00199251

**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

20140915

*i.e. Date of original Initial Notification Form*

Complementary Notification Date

20140403

**1. Patient details**

TasP ID

42258

Name

N.N.N.

Sex

☒ Male

Female

Date of birth

19400120

Enrolment date

20140909

**2. Description of the reported SAE**

Diabetic and hypertensive on treatment. Transferred in already on ART. Found to raised urea & creatine as well as hyperglycaemia at baseline. He was referred to Hlabisa hospital for investigation & management.

Date of SAE onset 20140909

**3. Complementary information**

He was admitted on 12/9/2014 and discharged 22/9/2014, was given IV fluid. Upon return 09/10/2014 - He was readmitted with creatinine 500. He was given IV fluid and oral furosemide 40mg b.d. He was discharged after 7 days. He is currently stable clinically. Furosemide stopped at Trial clinic.

**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

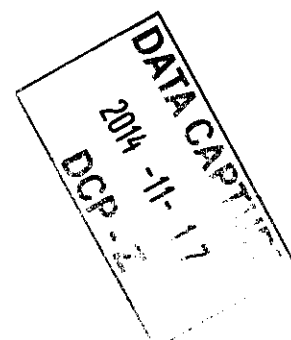
☒ N/A

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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
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?

*This includes the patient's medical history*

☒ Yes ☐ No  
Describe

Patient has Diabetes, hypertension and HIV which all could result in renal failure.

## 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 20141017

Recovered without sequelae

or

☒ Recovered with sequelae

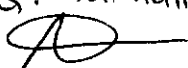
Describe Patient still has raised urea & creatinine.

## Physician reporting SAE Complementary Notification

Name

Dr G. Nkhulisi

Signature



Date form completed

20141103