

**Serious Adverse Event Reporting**


00199225

**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

2014 11 28

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

Complementary Notification Date

2014 12 11

**1. Patient details**

TasP ID

346 39

Name

E.S.

Sex

Male

☒ Female

Date of birth

1959 05 08

Enrolment date

2014 08 05

**2. Description of the reported SAE**

This type 2 diabetic patient was admitted to Hlabisa hospital on 2014/11/13 with diarrhoea and vomiting. This caused acute renal impairment. Creatinine peaked at 1214  $\mu\text{mol/L}$ . Her medications were renal-adjusted - including changing TDF to AZT and she had IV fluid.

Date of SAE onset

2014 11 11

**3. Complementary information**

This patient was discharged on 2014/12/04. Her renal function improved dramatically. On 2014/12/02 Creatinine = 312. On 2014/12/04 Creatinine = 195. Her blood sugar improved to  $<10$  on average. She was discharged on: AZT/3TC/EFV; amlodipine; glimepiride; furosemide. She will be followed up in TasP to ensure renal function normalises.

**4. New diagnosis?**

Yes  $\longrightarrow$  Describe

☒ No

Date of new diagnosis

DATA CAPTURE

2015 -01- 29

DCP - Z

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment?

☒ Yes

No

N/A

Which treatment?

HCTZ/Metoprolol/TDF all stopped  
due to renal failure

Date discontinued

2014 11 13

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  $\longrightarrow$  Section 6

☒ No  $\longrightarrow$  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

Describe

The patient is immunocompromised and at risk of gastroenteritis (which caused dehydration & subsequent renal impairment)

## 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 20141204

Recovered without sequelae

or

Recovered with sequelae

Describe

Renal function improved but not entirely normalised. I anticipate it will normalise as an outpatient.

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

Date form completed 20141211