

### Serious Adverse Event Reporting



00057241

## 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

20130822

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

Complementary Notification Date

20130828

**1. Patient details**

TasP ID

24642

Name

d G

Sex

Male

☒ Female

Date of birth

19590602

Enrolment date

20130430

**2. Description of the reported SAE**

Sied in hospital on 30/07/2013.

Date of SAE onset

20130704

**3. Complementary information**

Admitted to hospital on 19/7/2013 with gastroenteritis and dehydration. Information on treatment received whilst in hospital not yet available.

**4. New diagnosis?**
☒ Yes → Describe

No

Acute gastroenteritis resulting in Acute renal failure

Date of new diagnosis

20130719

**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. ATRIPLA TDF/FTC/EFV	300/200/600	0-2	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. HYDROCHLORID THIAZIDE	12.5 MG	0-2	<input type="radio"/> Unrelated <input checked="" type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. ISONIAZID	300 MG	0-5	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. VITAMIN B6 T		0-2	<input checked="" 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

Pre-renal failure from Acute gastroenteritis may have been exacerbated by tenofovir + Hydrochlorothiazide

## 8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

Recovered

Dead

Another complementary SAE notification form must be submitted within 8 days from now.

Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name

COLLINS JIMMY

Signature

Date form completed

20130828