

**Serious Adverse Event Reporting**


00093240

**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

20140509

i.e. Date of original Initial Notification Form

Complementary Notification Date

20140523

**1. Patient details**

TasP ID

25615

Name

TG

Sex

☒ Male

Female

Date of birth

19720902

Enrolment date

20130905

**2. Description of the reported SAE**

Acute gastroenteritis resulting in renal failure exacerbated by Tenofovir in Atripla.

Date of SAE onset

20140429

**3. Complementary information**

Admitted to hospital on 9/05/2014. Creatinine peaked at 970 on 11/05/2014. Following rehydration as inpatient creatinine dropped to 154. Discharged from hospital on 14/5/2014. Repeat U/E on 21/5/2014 showed creatinine of 139. Now prescribed AZT/3TC/EFV.

**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?

ATRIPLA (TENOFIVIR)

Date discontinued

20140508

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

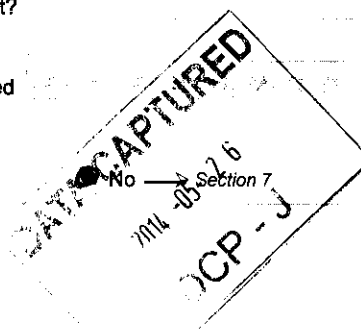
Date reintroduced

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

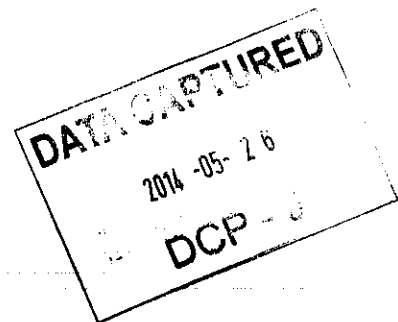
ACUTE GASTROENTERITIS

## 8. SAE Outcome

Unknown to date  
Ongoing  
☒ Improved  
Worsened  
Recovered → Date of recovery

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

Recovered without sequelae  
or  
Recovered with sequelae  
→ Describe



Physician reporting SAE Complementary Notification

Name

COLLINS JWH/1

Signature

Xmp

Date form completed

2014 05 23.