

**Serious Adverse Event Reporting**

**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



00317303

SAE No.

Initial Notification Date

20150615

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150824

**1. Patient details**

TasP ID

25333

Name

S.S.M.

Sex

Male

☒ Female

Date of birth

19601016

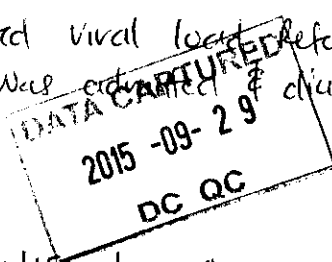
Enrolment date

20130716

**2. Description of the reported SAE**

Participant on Atripla; CD4 185 and suppressed viral load. Referred to hospital by private Dr with abdominal pain and vomiting. Was examined & diagnosed with acute pancreatitis with amylase 2383.

Date of SAE onset 20150609



**3. Complementary information**

She was transferred to regional hospital on 12/6/15 when she was admitted & diagnosed with gallstone pancreatitis. She was operated on 13/6/2015 and discharged on 26/6/2015. She is currently well & being followed up as an outpatient.

**4. New diagnosis?**

☒ Yes → Describe  
No

Gallstone Pancreatitis

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

Gallstones were found to be the cause of the patient's condition. She is well post-operation.

## 8. SAE Outcome

Death → Date of death \_\_\_\_\_ Probable Diagnosis \_\_\_\_\_

Unknown to date

Ongoing

Improved

Worsened

Recovered → Date of recovery 20150626

Recovered without sequelae ☒

or

Recovered with sequelae

Describe

Another complementary SAE notification form must be submitted.

## Physician reporting SAE Complementary Notification

Name DR GUG'ELITE MKHULISI

Signature

Date form completed 20150824