

**Serious Adverse Event Reporting**


00199214

**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

20 14 08 28

i.e. Date of original Initial Notification Form

Complementary Notification Date

20 14 09 15

**1. Patient details**

TasP ID

33311

Name

X.M.

Sex

☒ Male

Female

Date of birth

19 94 03 04

Enrolment date

20 14 07 29

**2. Description of the reported SAE**

Patient on atypa with suppressed viral load, but CD4=45. Had 2 weeks of diarrhoea. He was admitted on 28/8/14 (CENSA MA) 23/8/14 for gastroenteritis and anaemia. He was transfused one unit of blood, rehydrated + given potassium replacement. He was discharged 31/8/14.

Date of SAE onset

20 14 08 12

**3. Complementary information**

The patient was reviewed at TasP clinic following discharge. Unfortunately he has deteriorated further, with widespread oedema, ascites, cough, further weight loss and weakness. He has been referred back to Alibis hospital with a provisional diagnosis of pulmonary and extrapulmonary TB.

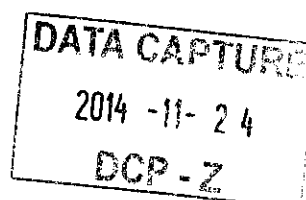
**4. New diagnosis?**
☒ Yes → Describe

Tuberculosis: Pulmonary and Extra Pulmonary

No

Date of new diagnosis

20 14 09 11


**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.			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

The patient is very immunocompromised and at risk of opportunistic infections.

## 8. SAE Outcome

Death → Date of death

Probable Diagnosis \_\_\_\_\_

Unknown to date

☒ Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature



Date form completed 2014 09 15