

### Serious Adverse Event Reporting



00057335

## 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

20130528

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

Complementary Notification Date

2013.0531

#### 1. Patient details

TasP ID

12216

Name

C.J.

Sex

☐

Male

☒

Female

Date of birth

19660808

Enrolment date

20120614

#### 2. Description of the reported SAE

Re-referred to hospital with Acute Confusion on 27/05/2013

Date of SAE onset

20130518

#### 3. Complementary information

Admitted to hospital on 27/05/2013. Had a lumbar puncture on the same day. This was normal including a negative cryptococcal antigen. Unfortunately she died on 29/05/2013

#### 4. New diagnosis?

☒ Yes → Describe

Probable Pulmonary TB.

☐ No

Date of new diagnosis

20130528

#### 5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☐ Yes

☐ No

☒ N/A

Which treatment?

Date discontinued

Y Y Y Y M M D D

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☐ No

☒ N/A

Which treatment?

Date reintroduced

Y Y Y Y M M D D

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

Probable Pulmonary tuberculosis

## 8. SAE Outcome

Unknown to date

Ongoing

Improved

Worsened

Recovered

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

Date of recovery

☒ Death

Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE Complementary Notification

Name

COLLINS, IWHJ

Signature

Kup

Date form completed

20130531