



00317349

**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

20150213

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150312

**1. Patient details**

TasP ID

30783

Name

P.P.M

Sex

☒

Male

Female

Date of birth

19620213

Enrolment date

20130708

**DATA CAPTURE**

2015-03-23

DCP-Z

**2. Description of the reported SAE**

Patient had weight loss + psychomotor slowing since December 2014. He was referred to hospital on query meningitis or query malnutrition. He was discharged on 2/2/15. <sup>On error</sup> After discharge he had diarrhoea + vomiting. He died at home on 8/2/15.

Date of SAE onset

201412

**3. Complementary information**

Inpatient hospital notes now reviewed. He attended hospital on 23/1/15. His lumbar puncture was clear of cells or yeast or bacteria, but did have low chloride + low protein. He was given IV Ceftriaxone + IV metronidazole. Final diagnosis was severe acute malnutrition. There is no mention in the medical notes of any diarrhoea or vomiting prior to discharge.

**4. New diagnosis?**
☒

Yes → Describe

Confirmed Severe acute Malnutrition.

No

Date of new diagnosis

20150127

**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 was immunocompromised + at risk of opportunistic infection regardless of participation in this trial.

## 8. SAE Outcome

9 Death

→ Date of death

20150208

Probable

Diagnosis

Gastroenteritis

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 20150312