



00125384

Completed forms must be sent to  
ANRS within 48 hrs.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

SAE Visit Date

Initial Notification Date **2014 11 05** Notification time **09 45**
**1. Patient details**

TasP ID

**29 224**

Name

**T.M.M.**

Sex

☒ Male

Female

Date of birth

**1954 01 28**

Enrolment date

**2013 05 22**
**2. Measurements**

Height

**160** Cms

Last known: Weight

**64.0**

Kgs

Weight Date

**2014 09 25**

CD4 count

**654**

CD4 Date

**2014 07 01**

Viral Load

**<50**

Viral Load Date

**2014 02 05**
**3. By which criteria is this adverse event considered to be "Serious"?**

Tick all that apply

- ☒ Resulted in death → Date of death **2014 10 20** Probable cause **Pneumonia**
- ☐ Life threatening (i.e. at risk of death at time of event)
- ☐ Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital abnormality / birth defect
- ☐ Grade 4 clinical and biological events
- ☐ Other serious, medically-important condition → Specify

**4. Details of SAE**

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name	Date investigator became aware	Date of onset of SAE
1. Vomiting	2014 11 04	2014 10 12
2. Renal impairment	2014 11 04	2014 10 12
3. Pneumonia	2014 11 04	2014 10 12
4. Death	2014 11 04	2014 10 20
5.		

**DATA CAPTURE**  
2015 -01- 07  
DCP - Z

**5. Description of SAE**

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

The family of this patient informed TasP of his death. He was last seen at TasP clinic 25/9/14. No problems were reported. It is unclear when he became unwell, but on 12/10/14 he attended Hlabisi hospital with persistent vomiting. I have reviewed the hospital notes. On admission his creatinine was 256. He was prescribed IV fluids; and antibiotics for a pneumonia. Sadly he did not respond to this treatment and died in hospital on 20/10/14.

## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. Atripla	One tablet	PO	HIV	20130615		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2. Hydrochlorothiazide 12.5mg		PO	Hypertension	UNKNOWN	20141012	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3. Enalapril	10mg	PO	Hypertension	UNKNOWN	20141012	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4. Ampicillin	600mg 2g 4g	IV	Pneumonia		20141012	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5. Metronidazole	1.5g	IV	?Pneumonia		20141012	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6. 0.9% Saline	3 litres	IV	Dehydration		20141012	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

## 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 immunosuppressed and at risk of infection.

## 8. SAE Outcome

☒ Died

Unknown to date

Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name MELANIE HILL

Signature

Date form completed 20141105