



00317353

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

20150326

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150422

**1. Patient details**

TasP ID

14847

Name

E.M.N

Sex

☒ Male

Female

Date of birth

19721225

Enrolment date

20120818

**2. Description of the reported SAE**

Patient had a new renal failure noted in Feb on 18/2/15. He attended Hlabisa hospital and died in hospital. The hospital notes have now been obtained.

Date of SAE onset

20150218

**3. Complementary information**

The patient attended Hlabisa on 13/3/15, complaining of lower limb weakness, loss of weight + loss of energy. He had a K<sup>+</sup> of 1.8 (low), urea 7.8, (creatinine 379), Hb 6.8 on admission. He was admitted to replace potassium, and started oral Slow-K. He was seen by a doctor on 16/3/15 who requested a blood transfusion. He died on 17/3/15, never receiving a transfusion. Despite renal failure TDF was continued in hospital.

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

No

Hypokalaemia, Anaemia

Date of new diagnosis

20150313

**5. Patient treatment**

a) Did the event resolve after continuation 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

DATA CAPTURED  
2015-04-22  
DC QC

## 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. Cotrimoxazole	TT	P.O.	Prophylaxis	20150204		<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. Amoxycillin	1.5g	P.O.	Cough	20150204	20150209	<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. Paracetamol	1g	P.O.	Cough/pain	20150204	20150214	<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
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input 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

Patient was immunocompromised + sick at entry into the trial.

## 8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 20150526

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

## Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20150528