

Serious Adverse Event Reporting
ANRS 12249 Initial SAE Notification

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



00125387

SAE No.

SAE Visit Date

20141103

Initial Notification Date

20141121

Notification time

09 50

1. Patient details

TasP ID

45243

Name

T.M.

Sex

☒ Male

Female

Date of birth

19820115

Enrolment date

20141015

2. Measurements

Height

175 Cms

Last known: Weight

51.3

Kgs

Weight Date

20141027

CD4 count

24

CD4 Date

20141023

Viral Load

142190

Viral Load Date

20140922

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

☐

Resulted in death → Date of death

Probable cause

☐

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

☐

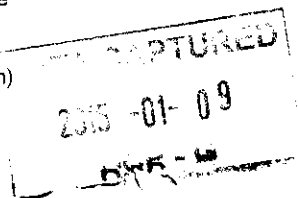
Congenital abnormality / birth defect

☐

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. Pancytopenia 20141029 20140820

2. Vomiting 20141103 20141103

3. Immunosuppression 20141029 20140922

4.

5.

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.

This patient was pancytopenic + severely immunosuppressed (CD4 of 2 on 22/4/14) prior to enrollment into TasP. He was due for a doctor review at TasP clinic because of this; but he started vomiting and was too weak to attend TasP. On 3/11/14 he attended Hlabisi hospital. He was transfused 1 unit of blood; given a short course of steroids and fast-tracked onto ART in hospital. He was discharged on 8/11/14. Vomiting stopped. Hb improved from 7.3 to 9.2.

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. Cotamoxazole	2 tablets	P.O.	Prophylaxis	20141023		<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.						<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
3.						<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
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? ☒ Yes ☐ No
This includes the patient's medical history

Describe

This patient is severely immunosuppressed and prior to hospitalisation was ART naive which put him at risk of these events.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered → Date of recovery 20141108

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name MELANIE HILL

Signature 

Date form completed 20141121