

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



00317408

SAE No.

SAE Visit Date

20150601

Initial Notification Date

20150604

Notification time

1530

1. Patient details

TasP ID

21906

Name

N.T.D.

Sex

Male

☒ Female

Date of birth

19931222

Enrolment date

20130308

2. Measurements

Height

Cms

Last known: Weight

450

Kgs

Weight Date

20150513

CD4 count

166

CD4 Date

20150513

Viral Load

743902

Viral Load Date

20150513

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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

Probable cause

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. Pneumonia 20150602 20150613

2. Anaemia 20150602 20150618

3.

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.

Participant came for first clinic visit, was found to have CD4 166 and Viral load 743902; she is not on ART. She tested positive for pregnancy. She presented with TB symptoms and was referred to hospital. At hospital, she was admitted & diagnosed with pneumonia and anaemia on 18/05/2015. She was transfused 2 units blood and given iv antibiotics and discharged on 24/05/2015. She has been reviewed and started on ART.

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.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								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

Participant with low CD4 + pregnant is highly susceptible to pneumonia.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered

Date of recovery 20150524

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Patient still anaemic; she is on haematinics.

Physician reporting SAE

Name DR GUGIE LILIE MKHULISI

Signature

Date form completed 20150604