

**Serious Adverse Event Reporting**
**ANRS 12249 Initial SAE Notification**

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



00317474

SAE No.

SAE Visit Date

Initial Notification Date 20 15 10 30

Notification time 11 55

**1. Patient details**

TasP ID

52952

Name

Z.A.M

Sex

Male

Female

Date of birth

19880129

Enrolment date

20150415

**2. Measurements**

Height

146 Cms

Last known: Weight

46.8

Kgs

Weight Date

20151012

CD4 count

969

CD4 Date

20150414

Viral Load

52069

Viral Load Date

20150414

**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

2015-11-02

DC CC

**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. MDR-TB 20151026 20151012

2.

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.

New TasP Patient, complained of cough at baseline visit, and on visits in June 2015  
Genexpet showed rifampicin resistant TB. (taken 12/10/15) + Oct 2015.  
Presumed MDR until culture results known.  
Patient was unable to get to Hlabisa until 26/10/15 where she is admitted to  
initiate treatment. She is not yet on ART, as she was lost to follow up between  
July + October 2015.  
This may have been deliberate  
as CD4 was 969 in a control cluster.  
She will have been in wellness programme.

## 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. Amoxycillin	1.5g	PO	Cough	20151012	20151017	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	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
6.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		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?

This includes the patient's medical history

Yes ☐ No ☒

Describe

Patient is immunocompromised.  
At risk of TB.

## 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

20151030