



00125362

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

2014 06 27

Initial Notification Date

2014 07 03

Notification time

11 00

**1. Patient details**

TasP ID

29835

Name

S. N.

Sex

Male

☒ Female

Date of birth

19851231

Enrolment date

20130903

**2. Measurements**

Height

152 cms

Last known: Weight

34.0

Kgs

Weight Date

20140627

CD4 count

91

CD4 Date

20140611

Viral Load

150960

Viral Load Date

20140623

**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. severe wasting 20140627 20140611

2. fatigue-grade 4 20140627 20140620

3.

4.

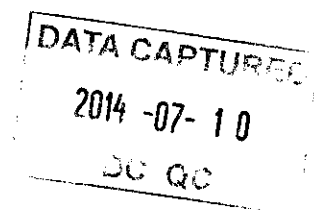
5.

**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 with MDR-TB on treatment. Discharged from hospital after 6 month stay. Presented with progressive fatigue & general weakness and loss of weight. Currently unable to walk. Clinically severely emaciated, weight 34kg. Referred to hospital for admission and nutritional support.



## 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. Tenofovir	300mg	oral	HIV	20131206		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
2. Lamivudine	300mg	oral	HIV	20131206		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
3. Efavirenz	600mg	oral	HIV	20131206		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
4. Kanamycin	500mg	IM	MOR-TB	20131122		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
5. Pyrazinamide	1000mg	oral	MOR-TB	20131122		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
6. Ethionamide	250mg	oral	MOR-TB	20131122		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
7. Tenofovir	250mg	oral	MOR-TB			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce Interrupt Stop
8. Moxifloxacin	400mg	oral	MOR-TB			<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None Reduce 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 severely ill with co-morbid MOR TB and advanced AIDS disease.

## 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 DR G MUKHERJEE

Signature

Date form completed 20140703