

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



00057394

SAE No.		SAE Visit Date	20140424
		Initial Notification Date	20140425
		Notification time	

1. Patient details

TasP ID: 19882

Name: M-ENI DAVID

Sex: ☒ Male ☐ Female

Date of birth: 19480626

Enrolment date: 20130204

2. Measurements

Height: 157 Cms

Last known: Weight: 46.7 Kgs Weight Date: 20140415

CD4 count: 885 CD4 Date: 20140319

Viral Load: 250 Viral Load Date: 20130903

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. TUBERCULOSIS	20140414	20140423
2.		
3.		
4.		
5.		

2014-05-27
DC CC

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.

Started on Tuberculosis treatment on 19/11/2013 after a CXR although Sputum GXP on 26/8/2013 was negative.
Developed acute shortness of breath on 23/4/2014 and was transferred to hospital by ambulance.

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. ATRIPLA TDF/FTC/EFV	300/200/600	PO	HTV	20130521		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2.				Y Y Y Y M M D D		<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.				Y Y Y Y M M D D		<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.				Y Y Y Y M M D D		<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.				Y Y Y Y M M D D		<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.				Y Y Y Y M M D D		<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

PROBABLE PULMONARY TB

8. SAE Outcome

☐ Died

☐ Unknown to date

☒ Ongoing

☐ Improved

☐ Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery Y Y Y Y M M D D

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

Physician reporting SAE

Name

COLINS HWJ

Signature

[Signature]

Date form completed

20140425