



00317490

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

SAE No.

SAE Visit Date

Initial Notification Date 20151217 Notification time 1435

1. Patient details

TasP ID 20014
Name D.B.
Sex Male ☒ Female
Date of birth 19661124
Enrolment date 20130326

2. Measurements

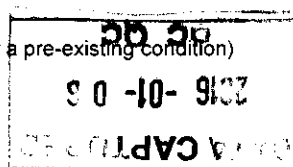
Height 164 Cms
Last known: Weight 81.0 Kgs Weight Date 20151117
CD4 count 481 CD4 Date 20150615
Viral Load 149 Viral Load Date 20150615

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. hospital admission 20151215 20151119

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.

Patient known to the tertiary gynaecology services. Previously had endometrial sampling as endometrial thickening seen on USS.
Was due for a review at NPA (gynae hospital) 19/11/15.
Nursing staff now tell me that she was admitted as inpatient from 19/11/15 to 24/11/15. Was due for r/v in TasP on 7/12/15 but did not attend.
∴ No details of admission known

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

	Generic Name	Daily dose	Route of administration	Indication	Date started	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
					Date stopped			
1.	Atorlip	T	PO	HIV	20150715	<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?

This includes the patient's medical history

Yes ☒ No ☐
Describe

This patient had microscopic anaemia prior to joining TRIP+ was investigated for fibrosis

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

→ A complementary SAE notification must be submitted within 8 days

☒ Recovered

→ Date of recovery 20151202

☒ Recovered without sequelae

or

Recovered with sequelae

→ Describe

Physician reporting SAE

Name

MELANIE HILL

Signature

Date form completed

20151217