

**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



00317486

SAE No.

SAE Visit Date

20151201

Initial Notification Date

20151202

Notification time

11 00

**1. Patient details**

TasP ID

22017

Name

F.M.

Sex

Male

☒ Female

Date of birth

19740805

Enrolment date

20150308

**2. Measurements**

Height

167

Cms

Last known: Weight

85.1

Kgs

Weight Date

20151026

CD4 count

849

CD4 Date

20151026

Viral Load

&lt;40

Viral Load Date

20151026

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

Tick all that apply

☐ Resulted in death → Date of death

Probable cause

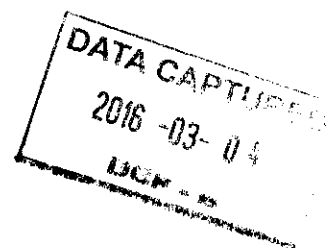
☐ Life threatening (i.e. at risk of death at time of event)

☐ 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

Date of onset of SAE

became aware

1. Grade 4 low Hb. 20151201 20150318

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 transferred into TasP already on TDF/FTC/EFV. TasP baseline Hb March 2015 was 6.1. On 26/10/15 Hb was again 6.1, microcytic hypochromic. She only received Iron supplements on 3/11/15. She was removed from TasP clinic by MoD on 1/12/15. She was not aware she had such severe anaemia. She is well compensated; no symptoms of anaemia. Denies menorrhagia. HR 60, normal heart sounds. She is now under investigation & prescribed Iron supplements for 6 months.

## 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	T	P	HIV	20150429		<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. ferrous Siphate 600mg PO			Anaemia	20151103		<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
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

Patient transferred in at baseline with Hb 6.1.

## 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 20151202