



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



00057424

SAE No.	SAE Visit Date	20130523
	Initial Notification Date	20130603
	Notification time	1815

1. Patient details

TasP ID: 23204
Name: L.X
Sex: ☐ Male ☒ Female
Date of birth: 19820101
Enrolment date: 20130523

DATA CAPTURED
2013-06-24
DCP-G

2. Measurements

Height: 170 Cms
Last known: Weight: 64.5 Kgs
CD4 count: 360
Viral Load: <50
Weight Date: 20130523
CD4 Date: 20130523
Viral Load Date: 20130523

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 ANAEMIA	20130531	UNKNOWN
2.	Y Y Y Y M M D D	Y Y Y Y M M D D
3.		
4.	Y Y Y Y M M D D	Y Y Y Y M M D D
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.

Routine baseline bloods at study entry showed microcytic hypochromic anaemia - Hb 6.2g/dL, MCV 70fL, MCH 28.9g/dL.

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. TENOFOSVIR	300MG	PO	HIV	20110606		<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. LAMIVUDINE	300MG	PO	HIV	20110606		<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
3. EFVIRENZ	600MG	PO	HIV	20110606		<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
4.						<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interr. <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 checked="" 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 checked="" 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

PROBABLY IRON DEFICIENCY ANAEMIA.

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 COLLINS IWHJ1

Signature

Date form completed 20130603