

**Serious Adverse Event Reporting**


00059973

**ANRS 12249 Complementary SAE Notification**

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

20130919

*i.e. Date of original Initial Notification Form*

Complementary Notification Date

20130927

**1. Patient details**

TasP ID

20798

Name

MP

Sex

Male

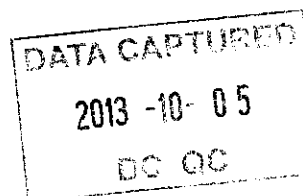
☒ Female

Date of birth

19740912

Enrolment date

20130327


**2. Description of the reported SAE**

ANAGMIA

Date of SAE onset

UNKNOWN

**3. Complementary information**

Patient with low HB-5.7g/dl, referred to hospital on 19/9/2013 for work up of her asymptomatic anaemia. Difficult to follow up patient as phone is on voicemail. Progress report will follow.

**4. New diagnosis?**

Yes → Describe

☒ No

Date of new diagnosis

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

→ Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

## 6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. <del>ARIPRAZOLE</del>	<del>50/200/600</del>	<del>daily</del>	Unrelated
2. <del>Bonazone</del>	<del>300mg</del>	<del>daily</del>	Poss. related
3. Pyridoxine	25mg	daily	Cannot be assessed
Tenofovir	300mg	daily	Unrelated
Lamivudine	150mg	bid.	Poss. related
4. Emtriva	600mg	daily	Cannot be assessed

## 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

Menorrhagia during her last menstrual period.

## 8. SAE Outcome

Unknown to date ☐

☒ Ongoing ☐ Improved ☐ Worsened ☐

Recovered ☐ → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

Another complementary SAE notification form must be submitted within 8 days from now.

## Physician reporting SAE Complementary Notification

Name

DR ALUMINIA A. OLIVEIRA

Signature

2013 09 27.

Date form completed