



TasP

ANRS 12249 Complementary SAE Notification



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Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

Serious Adverse Event Reporting

ANRS 12249 Complementary SAE Notification

SAE-AC

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

SAE No. 1569

Initial Notification Date

20130318

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130412

1. Patient details

TasP ID

15691

Name

ZM

Sex

Male

☒ Female

Date of birth

19771116

Enrolment date

20130128

2. Description of the reported SAE

Abdominal distension, weight loss, chronic diarrhoea & megaloblastic anaemia

Date of SAE onset

20130318

3. Complementary information

Persistent abdominal pain with anaemia. Clinical examination on 09/04/2013 revealed a tender mass in the right iliac fossa & suprapubic region - suggestive of an inflammatory pelvic mass. Referred to local district hospital for ultrasound examination

4. New diagnosis?

☒ Yes → Describe

Pelvic mass, cause not yet ascertained

No

Date of new diagnosis

20130409

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. TENOFUVIR	300mg	oral o.d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. LAMIVUDINE	300mg	oral o.d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3. EFAVIRENZ	600mg	oral o.d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4. FERRUS SULPHATE	200mg tds	oral	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> 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

Pelvic mass, requires further investigation

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 Collins Muthi

Signature

Xinf

Date form completed

2013 04 12