



Authorisation of Treatment as Prevention - ANRS 12249  
Ukaphila Kwami, ukaphila kwethu

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Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00004981

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

20121010

i.e. Date of original Initial Notification Form

Complementary Notification Date

20121121

2012-11-26

10:00

1. Patient details

TasP ID

11797

Name

HS

Sex

Male

☒ Female

Date of birth

19731280

Enrolment date

20120322

2. Description of the reported SAE

Shortness of breath

Date of SAE onset

20121010

3. Complementary information

Diagnosed with Asthma whilst in hospital. Prescribed  
Asthavent Spray 2 puffs PRN, prednisolone 20mg bd for 2 weeks  
and Amoxicillin 500mg tabs x 7.

4. New diagnosis?

☒ Yes → Describe

Asthma

No

Date of new diagnosis

20121010

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

As previously indicated.

Generic Name	Dose	Frequency	New judgement of causality
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related 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? ☒ Yes ☐ No

This includes the patient's medical history

Describe

## 8. SAE Outcome

Unknown to date  
Ongoing  
☒ Improved  
Worsened  
Recovered

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

Date of recovery

Recovered without sequelae  
or  
Recovered with sequelae  
Describe

## Physician reporting SAE Complementary Notification

Name Dr. [Signature]

Signature [Signature]

Date form completed 20121121