



Antiretroviral Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu (my health, for our health)

**Ukuphila kwami, ukuphila kwethu**

**Africa Centre TasP Trial**

**Serious Adverse Event Reporting**

**SAE-AC**



00057291

**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

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

Complementary Notification Date

**1. Patient details**

TasP ID

Name

Sex

Male

Female

Date of birth

Enrolment date

**2. Description of the reported SAE**

Date of SAE onset

**3. Complementary information**

**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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
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

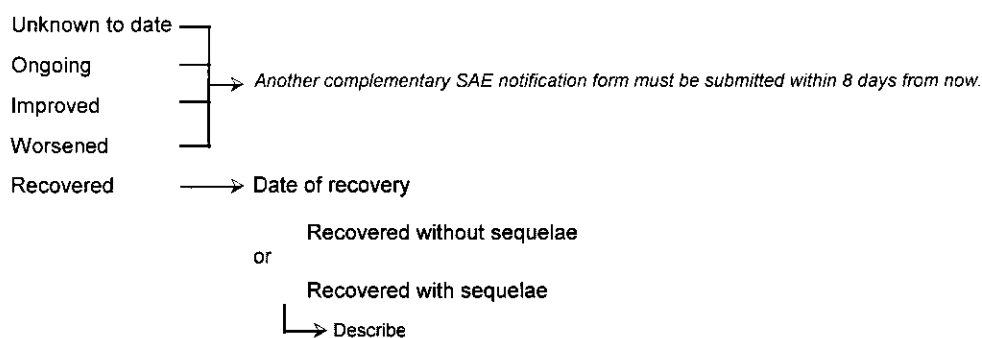
7b. According to the physician, is this SAE related to any causes other than the research?

Yes No

*This includes the patient's medical history*

Describe

## 8. SAE Outcome



## Physician reporting SAE Complementary Notification

Name

Signature

Date form completed