



TasP

Antiretroviral Treatment as Prevention - ANRS 12249
Ukuphila kwami, ukuphila kwethu

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Africa Centre TasP Trial

Serious Adverse Event Reporting

SAE-AC

Feb 2013



00059963

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20130716

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130724

1. Patient details

TasP ID

28603

Name

NT

Sex

☐

Male

☒

Female

Date of birth

19580612

Enrolment date

20130521

2. Description of the reported SAE

Develop a skin rash and mouth ulcers after switching
from AZT/3TC/EFV to Atripla

Date of SAE onset

20130712

3. Complementary information

Patient was advised to stop taking Atripla and referred to hospital. She was
concerned about stopping her ART, so carried on taking it. She was
diagnosed with Oral herpes. On review on 18/7/2013 there were no lesions
within the buccal cavity but encrusted labial ulcers consistent with Herpes

4. New diagnosis?



Yes

Describe

Orolabial Herpes.

No

Date of new diagnosis

20130717

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?



☒ Yes

☐ No

☒ N/A

Handwritten 'X' mark and '11/8/2013'

Which treatment?

Date discontinued

Y Y Y Y M M D D

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☒ No

☐ N/A

Which treatment?

Date reintroduced

Y Y Y Y M M D D

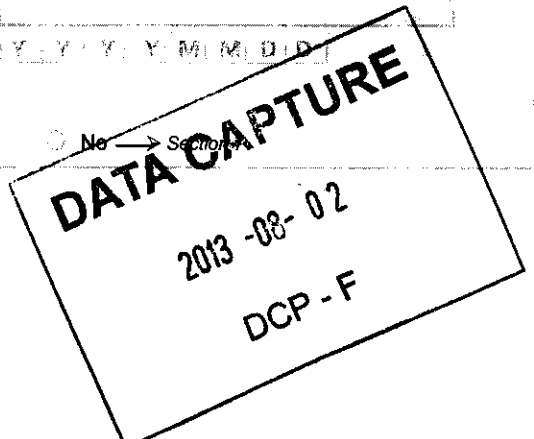
c) Has the complementary information mentioned above
modified your judgement of causality regarding one or
more treatments compared to your initial notification?



Yes → Section 6



No → Section 6



6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. ATRIPLA TDF/FTC/EFV	300/200/600	o-d	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input 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

OROLABIAL HERPES SIMPLEX

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

COLLINS / WUJI

Signature

Xmp

Date form completed

20130724