



TasP

AnRS 12249 (AnRS 12249 is a Phase III trial of the use of the AnRS 12249 (AnRS 12249) for the treatment of HIV/AIDS)

Shungu
Ukuphila kwami, ukuphila kwethu
Africa Centre TasP Trial

SAE-AC

15 Feb 2012

Serious Adverse Event Reporting



00015603

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 20121119 i.e. Date of original Initial Notification Form
Complementary Notification Date 20121123

1. Patient details

TasP ID 14345
Name A.S
Sex ☐ Male ☒ Female
Date of birth 19450510
Enrolment date 20121011

2. Description of the reported SAE

Weight loss, bloody diarrhoea and hypotension
Reported SAE started after enrolment but exact date not known
as missed an appointment

Date of SAE onset 20121011

3. Complementary information

Telephone discussion on 23/11/2012. Died in hospital on
16/11/2012. Diagnosis was advanced HIV, HIV wasting
syndrome and pulmonary tuberculosis. More information to
follow

4. New diagnosis?

☒ Yes → Describe Pulmonary TB during hospital admission
☐ No Details to follow
Date of new diagnosis 20131116

5. Patient treatment

a) Did the event resolve after discontinuation of treatment? ☐ Yes ☐ No ☒ N/A

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 7

DATA CAPTURE

2013-06-05

DCP - S

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?

This includes the patient's medical history

☒ Yes ☐ No

Describe

Advanced HIV disease

8. SAE Outcome

- ☐ Unknown to date
☐ Ongoing
☐ Improved
☐ Worsened
☐ Recovered



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

Patient died on 16/11/2012.

→ Date of recovery

☐ Recovered without sequelae

or

☐ Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name *DR RICHARD LESSELLS*

Signature *[Signature]*

Date form completed *20121123*