

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

00125378

Ukuphila kwami, ukuphila kwethu**Africa Centre TasP Trial****Serious Adverse Event Reporting****ANRS 12249 Initial SAE Notification****SAE-AI**Completed forms must be sent to
ANRS within 48 hrs
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

20140926

Initial Notification Date

20140929

Notification time

1130

1. Patient details

TasP ID

21541

Name

S. Z.

Sex

Male



Female

Date of birth

19831107

Enrolment date

20140227

2. Measurements

Height

Cms

Last known: Weight

860

Kgs

Weight Date

20140529

CD4 count

1265

CD4 Date

20140529

Viral Load

<40

Viral Load Date

20140314

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply



Resulted in death → Date of death

Probable cause



Life threatening (i.e. at risk of death at time of event)



Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)



Persistent or significant disability / incapacity



Congenital abnormality / birth defect



Grade 4 clinical and biological events



Other serious, medically-important condition → Specify

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event NameDate investigator
became awareDate of onset of SAE

1. Stroke-grade 4 20140926 20140915

2.

3.

4.

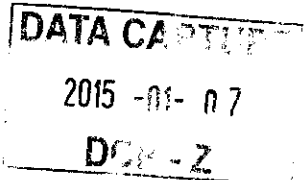
5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

Participant on ART (EFV/3TC/TDF), CD4 1265 & viral load suppressed. Relatives came to inform Trial clinic that she had become weak and unable to walk & talk since 15/9/14. Went to private Dr on 16/9/14 and was referred to hospital. She was admitted for investigation and discharged on 22/9/14 with no definitive diagnosis. She is booked for CT scan on 11/12/2014.



6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of adminis- tration</u>	<u>Indication</u>	<u>Date started</u>	<u>Date stopped</u>	<u>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.	Zenokavir	300mg	oral	HIV	201310		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
2.	Emtracitabine	300mg	oral	HIV	201310		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
3.	Effavirenz	600mg	oral	HIV	201310		<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input checked="" type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
4.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
5.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop
6.							<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> None <input type="radio"/> Reduce <input type="radio"/> Interrupt <input type="radio"/> Stop

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 Participant had stroke at a young age. She is still undergoing investigation. HIV status may be contributing.

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

A complementary SAE notification must be submitted within 8 days

☒ Recovered → Date of recovery 20140922

Recovered without sequelae

or

☒ Recovered with sequelae

Describe Participant has right hemiplegia and is awaiting CT scan in December 2014.

Physician reporting SAE

Name DR GUGIELHLE MKHULISI

Signature

Date form completed 20140929