



TasP

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AI

## Serious Adverse Event Reporting

### ANRS 12249 Initial SAE Notification

Completed forms must be sent to  
ANRS within 48 hrs.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

00317493

SAE No.

SAE Visit Date

Initial Notification Date 20150301

Notification time 0830

#### 1. Patient details

TasP ID

46237

Name

G.Z.

Sex

Male

☒ Female

Date of birth

19621030

Enrolment date

20131013

#### 2. Measurements

Height

Cms

Last known: Weight

92.8

Kgs

Weight Date

20150618

CD4 count

682

CD4 Date

20150421

Viral Load

<40

Viral Load Date

20150115

#### 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

DATA CAPTURED  
2016-02-20  
16:00

#### 4. Details of SAE

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

Event Name

Date investigator  
became aware

Date of onset of SAE

1. Epistaxis 20160229 20160227

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.

This patient is known to have multiple myeloma, not currently on treatment. Her family report that on 27/2/16 she was admitted to Hlabisa hospital with epistaxis. No further information is known at this time. Blood tests taken 28/2/16 at Hlabisa show Hb 7.8 with normal MCV, + platelets in normal range -  $264 \times 10^9/L$ .