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

SAE No.

SAE Visit Date

20150331

Initial Notification Date

20150423

Notification time

**1. Patient details**

TasP ID

49344

Name

ZM

Sex

Male

☒ Female

Date of birth

19880804

Enrolment date

20141023

**2. Measurements**

Height

158 Cms

Last known: Weight

46.9

Kgs

Weight Date

20150421

CD4 count

325

CD4 Date

20150331

Viral Load

286724

Viral Load Date

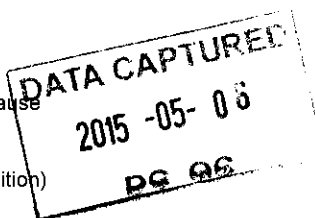
20150331

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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

Probable cause


**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. Severe Anaemia 20150416 20150331

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.

Routine bloods showed severe anaemia with Hb 5.2g/dL  
referred to hospital for investigation and blood transfusion

## 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>Causality assessment</u>	<u>Expected reaction?</u> (BNF/SPC)	<u>Action taken</u>
1.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
2.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt Stop
4.	Unrelated	Yes	None					
	Poss. related	No	Reduce					
	Cannot be assessed		Interrupt Stop					
5.	Unrelated		None					
	Poss. related	Yes	Reduce					
	Cannot be assessed	No	Interrupt Stop					
6.	Unrelated		None					
	Poss. related	Yes	Reduce					
	Cannot be assessed	No	Interrupt 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

Not on ART as in control cluster and not eligible for ART, but retained after 6 months and found eligible under new guidelines. Currently not on ART.

## 8. SAE Outcome

Died

Unknown to date

☒ Ongoing

Improved

Recovered

→ A complementary SAE notification must be submitted within 8 days

→ Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

## Physician reporting SAE

Name

Signature

Date form completed

Colin S. Inyang  
Xup  
20150423