

00093267

SAE No.

SAE Visit Date

20130821

Initial Notification Date

20130822

Notification time

1. Patient details

TasP ID

23434

Name

S.M

Sex

Male

☒ Female

Date of birth

19731109

Enrolment date

20130821

2. Measurements

Height

167 Cms

Last known: Weight

66

Kgs

Weight Date

20130821

CD4 count

49

CD4 Date

20130821

Viral Load

NOT READY

Viral Load Date

20130821

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 Name

Date investigator

Date of onset of SAE

became aware

1. Sepsis - 20130821 20130720
with cellulitis

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.

Patient was unwell at the baseline clinic visit. Swollen/Painful
Left arm with fever longer than one month. She was
tachycardic and hypotensive. Nurse thought she had cellulitis
of the left arm

6. Medications

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

	<u>Generic Name</u>	<u>Daily dose</u>	<u>Route of administration</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.	NIL	NIL	NIL	NIL		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
2.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce 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

cellulitis present at baseline clinic visit

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

COLLINS J W G I

Signature

Xmp

Date form completed

20 13 08 22