***<Study title>***

**Serious Adverse Event Reporting Form**

***EudraCT number:***

*Please email the SAE form to the RGIT CTIMP Inbox at*

*RGIT.ctimp.team@imperial.ac.uk*

*within 24h of notification of event*

Patient Study No:

Treating Clinician:

.……………………………………………………….…

Hospital/Site:

……………………………………………………………..….

**Type of Report**

*Trial Arm*

**Sex**

**Height**

**Weight**

1=First

2=Interim

3=Final

1=

2=

1= Male

2= Female

cm

.

kg

**Date of**

**last trial treatment given prior to SAE**

**Was the trial treatment given at full protocol dose**

**prior to event?**

d d m m m y y

0= No, specify

……………………………………...

1=Yes

**Why was the event serious?**

*(Choose most serious)*

**Where did the SAE take place?**

1= Resulted in death

2= Life

-

threatening

3= Required inpatient hospitalisation or prolongation of

existing

hospitalisation

4= Resulted in persistent or significant disability/incapacity

5= Resulted in congenital anomaly/birth defect

6= Other medically important event

1= Hospital

2= Out

-

patient clinic

3= Home

4= Nursing home

5= Hosp

ice

6= Other, specify……………………………………………..

**Briefly describe SAE**

(

*include relevant symptoms, body site, and relevant lab tests, treatments received)*

continue on a separate sheet if necessary

**Details of SAE**

Serious Adverse Event

Name:

Please code

using the short name of

the adverse event from the

<name of

AE criteria used>

**Duration of SAE**

(dd mmm yy)

**SAE Status**

1= Resolved

2= Resolved with sequelae

3= Persisting

4= Worsened

5= Fatal

6= Not assessable

**Expectedness**

1= Expected\*

2= Unexpected

**Name**

**Grade**

Date of Onset

Date Resolved

or tick box if ongoing

*\* Was the event one of the recognised undesirable effects of the trial medication?*

*RSI versi*

*on used to assess (IB/SmPC)*

*--------------------------*

**Trial Treatment**

**Trial drugs**

**patient was**

**receiving**

**when SAE**

**started**

**Total**

**Daily**

**Dose**

**Start Date of**

**Most Recent Cycle**

(dd mmm yy)

Currently

Ongoing?

0= no

1=Yes

**End Date**

(dd mmm yy)

Causal

relationship to

event

1=Definitely

2= Probably

3= Possibly

4= Unlikely

5= Not related

6=Not assessable

**Action Taken**

0=None

1=Dose reduction

2=Treatment delayed

3=Treatment delayed

and reduced

4=Treatment

permanently stopped

**Other treatments at time of event**

(Please list all relevant concomitant medications, radiotherapy, surgery, etc. (continue on a separate sheet if needed)

Exclude any therapy given for management of the SAE.

**Treatment**

Give

generic name of

drugs/treatment

given in the last

30 days.

**Total**

**Daily**

**Dose**

Route of

Administration

1=Oral

2=Intravenous

3=Subcutaneous

4=Other, specify

**Start Date**

(dd mmm yy)

Currently

Ongoing?

0= no

1=Yes

**End Date**

(dd mmm yy)

**Action Taken**

0=None

1=Dose reduction

2=Treatment delayed

3=Treatment delayed

and reduced

4=Treatment

permanently stopped

**Other relevant information to facilitate assessment**

(Include medical history, drug or alcohol abuse, family history, findings from special investigations)

**Was this event expected in view of the patient’s clinical history?**

0= No

1= Yes

Additional Information:

***Principle Investigator*** *or Authorised Health Professional as Delegated on the Delegation Log*

**Signature**

*Chief Investigator*

…………………………………………………………..

**Print**

**name**

……………………………………………………….…

**Contact**

**telephone**

**no**

………………………………………………………………..

**Date of Review**

d d m m m y y

***SITES TO***

***COMPLETE***

Was SAE drug related?

Yes

No

Event No

Was event unexpected?

Yes

No

***Comments:***

Was the event a SUSAR?

Yes

No

Date site aware

d d m m m y y

Date reported to CI (if

different to the PI above)

d d m m m y y

Date reported to Sponsor

d d m m m y y

Date

d d m m m y y

**Form completed by**

**(Staff Name & Signature)**

……………………………………………

