UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit

SERIOUS ADVERSE EVENT FORM

To be completed for any serious adverse events occurring within the protocol-defined reporting period.

PART A - Site Details

Site Name: _____ Name of PI: _____

PART B - Patient Details

Patient Initials: *First, Middle, Last* [F] [M] [L] Patient DOB: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

TRIAL ID: [ ] [ ] [ ] [ ] [ ]

PART C - Report Type

(Use BCTU allocated unique SAE number if this is a follow-up or final report)

Report type: ◯ Initial Report ◯ Follow-up Report ◯ Final Report

If 'Follow-up' or 'Final', please insert unique SAE number: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

PART D - Event Information

Signs and symptoms:

_____

_____

_____

PART E - Event Diagnosis

Diagnosis:

_____

_____

_____

Event Severity:
- ◯ Mild
- ◯ Moderate
- ◯ Severe

PART F - Investigations and Treatment

Investigations, results/ findings and interventions/ treatment:

_____

_____

_____

PART G - Seriousness of Event

Death: *Tick one* ◯ No ◯ Yes

If Yes, date of death: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

If Yes, cause of death: _____

Life Threatening Event *(Please tick one)* ◯ No ◯ Yes

In-patient hospitalisation or prolongation of existing hospitalisation: *(Please tick one)* ◯ No ◯ Yes

If Yes, Initial or Prolonged? *(Please tick one)* ◯ Initial ◯ Prolonged

If Initial, date of admission: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date of discharge: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Persistent or Significant Disability/Incapacity: *(Please tick one)* ◯ No ◯ Yes

Other Medical Reason For Reporting: *(Please tick one)* ◯ No ◯ Yes

If Yes, Please specify:

_____

_____

Part H - Details of Event

Date of onset: D D - M M M - Y Y Y Y | Date became serious: D D - M M M - Y Y Y Y

Date site became aware: D D - M M M - Y Y Y Y

Is event Ongoing: *Tick one* ◯ No ◯ Yes | If 'No', Date Resolved: D D - M M M - Y Y Y Y

PART I - Causality Assessment

Causal relationship of the event to the trial intervention: *(Please select **one** category)*

◯ Unrelated ◯ Unlikely to be related ◯ Possibly related ◯ Probably related ◯ Definately related

As ROSSINI 2 is a non - CTIMP, BCTU will only be collecting Related and Unexpected SAEs.

A Related and Unexpected Serious Adverse Event (RUSAE) means a SAE occurring to a research participant which in the opinion of the Principle Investigator was: - **'Related'** that is, it resulted from the administration of any of the research procedures, and - **'Unexpected'** that is, the type of event is not listed in the protocol as an expected occurrence.

List any underlying comorbidities, concomitant medications or investigations etc. that may be relevant: *(Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only)*

PART J - Details of Person Reporting

Name of Person Reporting:

Signature of Person Reporting: *Must appear on delegation log* | Date of Signature: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Job Title of Person Reporting: | Date Reported: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Name of Principal Investigator or Medically Qualified Delegate:

Signature of Principal Investigator or Medically Qualified Delegate: | Date of PI/Delegate Signature: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Please ***report within 24 hours*** any SERIOUS ADVERSE EVENTS by completing the pages 1 and 2 of this form and faxing or emailing them to the ROSSINI 2 Trial Office: 0121 415 8871 or ROSSINI2@trials.bham.ac.uk Once you have sent the form and the event is resolved, please send the ORIGINALS (with copies of any relevant reports) to **ROSSINI 2 Trial Office, University of Birmingham Clinical Trials Unit, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT**

PART K - To Be Completed By Chief Investigator or Named Delegate

Review of relatedness to the trial intervention by Chief Investigator or delegate: *(Please tick one)*

◯ Unrelated ◯ Unlikely to be related ◯ Possibly related ◯ Probably related ◯ Definately related

Assessment of expectedness with reference to the Protocol by Chief Investigator or delegate: ◯ Expected ◯ Unexpected

PART L - Signatures

In signing this form the Investigator or delegate confirms the **Causality** and **Expectedness** of the event.

Name of CI or Delegate:	Signature of CI or Delegate:

Date of CI or Delegate Signature: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

PART M - Classification of Event

System Organ Classification (SOC) - please indicate the event classification below: (please tick all that apply)

Infections & infestations ☐	Ear & labyrinth disorders ☐	Vascular disorders ☐
Eye disorders ☐	Nervous system disorders ☐	Congenital, familial & genetic disorders ☐
Blood & lymphatic system disorders ☐	Skin & subcutaneous tissue disorders ☐	Social circumstances ☐
Immune system disorders ☐	Renal & urinary disorders ☐	Investigations ☐
Endocrine disorders ☐	Gastrointestinal disorders ☐	Surgical & medical procedures ☐
Metabolism and nutrition disorders ☐	Hepatobiliary disorders ☐	Cardiac disorders ☐
Psychiatric disorders ☐	Reproductive system & breast disorders ☐	Injury, poisoning & procedural complications ☐
Respiratory, thoracic & mediastinal disorders ☐	Pregnancy, puerperium & perinatal conditions ☐	General disorders & administration site conditions ☐
Neoplasms benign, malignant & unspecified (incl. cysts & polyps) ☐	Musculoskeletal & connective tissue disorders ☐	Other ☐

If Other, please specify:

Please provide the sub-classification of System Organ Classification of event (detailed above).

Part N - Clavien - Dindo - Please indicate the classification below:

1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

N/A ☐

Section 1 - Office Use Only

Is the event related and unexpected? *Serious, 'related and unexpected' events require reporting to the REC and sponsor* ◯ Yes ◯ No

SAE Reference Number: ☐☐☐☐☐☐☐☐

Date Reported to REC: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Date Reported to Sponsor: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y