**REDUCe2 SAR Reporting guide**

All Serious Adverse Reactions MUST be **reported** to [bsctusafety@bsms.ac.uk](mailto:bsctusafety@bsms.ac.uk) within **24 hours** of the **research team being aware** of the event.

Once a signed initial report is received a follow up should be submitted as soon as there are any updates to the SAR. If the patient is still an inpatient or there is an unavoidable delay in the provision of further information, inform the BSCTU as soon as possible.

Should there be a requirement for clarification or further information required, an email detailing the request will be sent. Response to the request is required as per the timelines dictated in the email.

The minimum acceptable information for an initial SAR report is**:**

**- Patient Study ID**

**- SAR term-** ideally this should be an overall diagnosis however if not known at the time of reporting, presenting symptoms can be listed instead

**- Intervention details**

**- The seriousness criteria**

Complete **Principal Investigator (PI)** and **site name** in the trial information box

**SECTION.1. PATIENT DETAILS**

* Fill in fields in the box as indicated.

**SECTION.2. TYPE OF REPORT** Ensure you indicate type of report

\*Each new report sent must have a new clear first page\*

**Initial Report**

* First SAR report of the event, it may be where not all details are available, the form is unsigned, or the event is marked as ongoing.
* In the interests of timely reporting, it is acceptable to submit an initial report without full details or a PI/Co-Investigator signature.
* If the initial report is submitted without a PI/ co-investigator signature, it **must be followed up** with a signed copy reporting expectedness and causality **ASAP** within **2 working days of the initial form being submitted**

**Follow up report**

* Additional information to an initial report is being provided in this report. The event may still be marked as ongoing or resolved. If ongoing, further reports must be submitted until the resolution of the event.
* Identify the follow up with the SAR Reference number that was included on the acknowledgement email for the initial report from BSCTU
* If it is the 1st follow up enter 1 after #, 2nd report, put 2 after #, etc.
* **Add date of report**

**SECTION.3. WHY WAS THE EVENT SERIOUS?**

**Seriousness Criteria:** If there is more than one criteria, choose the most significant one.

**SECTION.4. DESCRIPTION OF EVENT**

**SAR term:** Enter keywords that best summarise the event. e.g. chest pain. Referring to **the CTCAE Version 4.03 Grading Scale**

If the event title/diagnosis changes please submit a new form as a follow up form and the PI or Co-Investigator will need to counter-sign the form (next to the causality assessment) to confirm that the causality assessment is still valid (or they will need to change the assessment if necessary).

**Assessment of Intensity**: **As per protocol section 22 - Severity should be recorded and graded according to the CTCAE Version 4.03 Grading Scale**

**Date of Onset:** Please report the date the event met the seriousness criteria. If a full date is not known either on the first or subsequent reports then UNK/ Month /Year should be completed.

**Date Resolved**: Please report the date that the event resolved, or tick ongoing.

**Multiple Serious Adverse Reactions MUST be reported on individual SAR forms.**

**Description of Event:** If the SAR is due to an admission to hospital, provide the admission and discharge dates. The description must have sufficient details for evaluation by the individuals reviewing the SAR. Abbreviations of clinical conditions should not be used. Summarise any relevant laboratory or diagnostic tests or provide **anonymised** lab reports or discharge summary (with patient ID), where applicable and if available. Add further details of action taken with respect to study intervention (IMP) if needed, as indicated in table in Section 6.

**SECTION.5. SAR STATUS**

* **Resolved** - The event has resolved e.g. patient has been hospitalised, received treatment, discharged and the event has resolved. Provide details of the date of resolution of the SAR.
* **Resolved with Sequelae** – The event is resolved but there are still some residual problems as a result of the SAR e.g. the patient hospitalised for DVT and then discharged on warfarin. The patient no longer requires hospital treatment but the pre-existing symptoms persist. Provide details of the date of resolution of the SAR
* **Ongoing** - The event has not resolved at this time. This will require follow up until resolution of event.
* **Worsened** – The event has worsened and is not resolved at this time. This will require follow up until resolution of event
* **Fatal** - Where the event is fatal, details of the date of death and the cause of death MUST be obtained. Supporting **anonymised** documents should be provided with SAR form.

**SECTION.6. CAUSALITY ASSESSMENT**

**Causal relationship must be assessed by PI or a delegated Investigator EXPECTEDNESS ASSESSMENT**

* **Expected-** The event is an expected reaction based on the information contained in the intervention side effects as written in the protocol (Section 22).
* **Unexpected**: The event is unexpected based on the information contained in Summary of Product Characteristics, known treatment/intervention side effects as written in the protocol.

This study involves a cohort with advanced cirrhosis with a high morbidity and mortality. Hence in this patient population worsening of existing conditions, hospitalisations and acute illnesses are to be expected.

**Expected SAR will include the following (only if they result in hospitalisation)**

* LTAD or LVP leakage or blockage
* Cellulitis
* Pain at site of insertion not controlled by analgesia
* Bacterial peritonitis
* Sepsis which in the opinion of the PI is directly related to LTAD or LVP
* Death (only if in the opinion of the researchers directly related to the LTAD or LVP)
* Doubling in serum creatinine from baseline
* Bleeding if directly related to LTAD or LVP
* Bowel perforation if directly related to LTAD and LVP
* Failed drainage and or drain displacement

**If the event is related and unexpected,** it is a **Suspected Unexpected Serious Adverse Reaction** **(SUSAR)** and requires expedited reporting - inform the Sponsor immediately.

* If the causality assessment of an SAR changes, the investigator must submit a new SAR form to confirm this and sign it. The new form has to contain a new first page and the rest of the form can be updated accordingly to the changes made, initialled and dated. A reason for a change in causality should also be provided on the ‘Description of Event’ section of the form

**SAR REPORTED BY**

The report and causality assessment should be signed off by the PI or a delegated Investigator, **wherever possible.**

**ADDITIONAL NOTES**

Please return the completed form and any anonymised copies of supporting documents to the BSCTU office at [bsctusafety@bsms.ac.uk](mailto:bsctusafety@bsms.ac.uk)

All supporting documentation must have all patient identifiable data removed. The documents MUST only be identified with the addition of the patient study ID and initials.

If you have queries regarding your SAR submission, please contact [bsctusafety@bsms.ac.uk](mailto:bsctusafety@bsms.ac.uk) or the REDUCe2 Trial Manager, Alison Porges, on 07721 860469.