**Form 55.005B RSI Summary**

**Text in red to be deleted upon completion of form**

**Note: Multiple IMPs may be collated into the RSI where this occurs the text should be updated accordingly**

|  |  |
| --- | --- |
| **Trial** |  |
| **IMP** |  |
| **Current version of the SmPC/iB for clinical management** |  |
| **Version of IB/SmPC acting as RSI** |  |
| **Marketing authorisation holder** |  |
| **Marketing authorisation number** |  |
| **Sponsor ref.** |  |
| **Other IMPS used in trial** |  |
| **EudraCT** |  |
| **CTA** |  |
| **RSI version no.**  |  |

**For investigators:** The requirement to update the RSI is a Sponsor/Co-Sponsor responsibility. The Sponsor/Co-Sponsor will review and update the RSI as per their Standard Operating Procedures (SOP). The version of the RSI used for assessing expectedness of Serious Adverse Reactions will only be updated via an amendment prior to the start of the new DSUR reporting period. As per the Sponsor/Co-Sponsor SOPs, future amendments to the RSI will be circulated to sites as part of the usual amendment process. However, as Sponsor has responsibility for all SAR expectedness assessments, responsibility for RSI version control is a sponsor responsibility only.

The Sponsor/Co-Sponsor regularly reviews SmPC/IBs for changes that may impact on the clinical management of trial participants. Updates will be circulated to investigators via e-mail as necessary and in accordance with Sponsor SOPs. The update and accompanying e-mail must be filed within the Investigator Site File. For clinical/non-clinical information on the investigational medicinal product(s) the following link should be referred to <insert EMC link>.

**For Sponsor:**

This document in accordance with the attached SmPC/IB forms the reference safety information (RSI) for this trial. The table below should be used to determine the expectedness of any serious adverse reactions that occur within the trial. The RSI has undergone clinical review by the Chief Investigator for the trial and is used by the Sponsor Pharmacovigilance manager or their delegate to assign expectedness.

Where an event is not listed below, or where an event occurs that is of a severity greater than that detailed within the table, that event cannot be classed as an expected adverse event. Synonymous terms are acceptable as listed events e,g hyperkalaemia/elevated serum potassium. Where greater specificity (e.g. acute renal failure is listed, event term is interstitial nephritis) is provided within an SAE term that event cannot be classed as expected unless otherwise stated below within section A with justification for being classified as such within section B.

In general fatal SARs are not considered expected unless specifically detailed as such within the table below. Where fatal SARs are considered expected please see section B for justification of their inclusion.

**Section A: Listings of Adverse Reactions**

| **System organ class**Listed term | **Frequency** | **Severity of adverse reaction** AR: Adverse reactionSAR: Serious adverse reactionLF: Life threateningF: Fatal\* | **Further information related to listed event** |
| --- | --- | --- | --- |
|  |  | **AR** | **SAR** | **LF** | **F** |  |
| **System organ class** |  |  |  |  |  |  |
| Preferred term |  |  |  |  |  | Where further information is contained within section 4.8 this can be listed here for clarification |

**Section B: Further information, comments, and justifications relating to the RSI**

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| The benefit/risk ratio for this trial is not sufficient to consider life threatening or fatal serious adverse reactions expected.Or provide detailed information regarding why life threatening or fatal events may be included. Justification for the inclusion or exclusion of other expected events should also be included within this section, |

**Section C: Approval of the RSI**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sign off** | **Role** | **Signature** | **Date** |
| Preparation of document | Pharmacovigilance manager |  |  |
| Checking of document | Clinical trials pharmacist |  |  |
| As the chief investigator I confirm that I have clinically reviewed this document and confirm that the information is correct | Chief investigator |  |  |