***Text in blue is for instruction only and should be deleted.***

***Text in black should be included if appropriate for the trial.***

**SOP Ref No *Insert trial title*\_SOP00**

**SOP title SAE Reconciliation**

**Version *Insert number* 0.0**

**Date issued *Insert date* DDMMMYYYY**

**Valid until *Insert date* DDMMMYYYY**

**Author(s) Name:**

**Signature:**

**Date:**

**Approved by Name:**

**Signature**

**Date**

**Modification history**

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1. **Purpose**

The purpose of this standard operating procedure (SOP) is to outline the procedures required to reconcile serious adverse events reported during the trial and recorded on the ***insert trial title*** study database, with the serious adverse events (SAEs) forms recorded on the safety database. Reconciliation is completed in order to ensure accuracy and consistency.

1. **Scope**

This SOP describes the activities which need to be carried out in order to complete reconciliation of all SAEs recorded on the ***insert trial title*** study database and the safety database.

1. **Responsibility**

The ***insert trial title*** Data Manager and the Study Coordinator will be responsible for ensuring SAE reconciliation activities are completed on an on-going basis. All SAE reconciliation must be completed prior to database lock.

1. **Definitions**
* Adverse event: Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.
* SAE: A serious [adverse event](http://en.wikipedia.org/wiki/Adverse_event) (SAE) in clinical trials is a adverse event which can be categorized in one (or more) of the following categories:
	+ - results in death
		- [life-threatening](http://en.wikipedia.org/wiki/Death)
		- requires inpatient [hospitalization](http://en.wikipedia.org/wiki/Inpatient_care) or
		- prolongation of existing hospitalization
		- results in persistent or significant disability/incapacity
		- is a congenital anomaly/birth defect
		- requires intervention to prevent permanent impairment or damage
* Study Database : Database where all data, defined per protocol, are collected during the study.
* Safety Database: An open database, since it continues to receive new SAEs or updates on pre exisiting SAEs related to clinical trials even when the study database has been locked.
1. **Prior to reconciliation**
* Often SAEs continue to be reported after a clincial trial has ended. It is important to agree on a time cut off, after which no new SAEs or any updates will be added to the study database. This is so that the study database can be considered as closed even if the safety database continues to recieve new SAEs or updates regarding the clinical trial.
* Before starting the SAE reconciliation procedure the Data Manager must ensure all data to be included in the reconciliation process is entered on the database and has been coded and cleaned.
1. **Procedure**
	1. **Identify SAEs**
2. Create a list of all of the SAEs that exist in the study database.
3. Create a list of all of the SAE forms reported in parallel (eg paper SAE Reports) to the pharmaceutical companies.
4. Compare both lists and query if:
	* SAE’s which exist in the study database and are not reported in the safety database.
	* SAE’s which exist in the safety database and are not reported in the study database.
5. The total number of SAE’s reported in the safety database must be the same as the total number of SAE’s reported in the study database.
	1. **Validate key variables of the reported SAEs**
6. Based on the SAE report, make a list of all key variables which need to be validated.
7. Define the match criteria for each of these key variables eg.
	* Dates are an exact match.
	* Free text can be consistent.
	* All drugs present on the SAE Report form should be present in the eCRF but not vice versa (because not all drugs given during the study relates to the SAE).
8. Cross check these variables between SAE reports and the study database in a systematic and transparent matter (eg using the SAE Reconciliation Checklist Template).
9. Depending on the nature of any discrepancies produced by SAE reconciliation, it may be necessary to go back to the Site Investigator for further clarification or seek further assistance from the study team before deciding on the best course of action.
10. Resolved queries should be reviewed by the Data Manager and any changes needed should be updated on the study database and/or safety database depending on the query resolution outcome.
11. All SAE related data in the study database should be reflected in the data collected in the safety database.
12. Changes or updates to the study database are the responsibility of the Data Manager.
13. Changes or updates to the safety database are the reponsibility of the Drug Safety Officer.

1. **References to other SOPs**

***Insert trial title Data Entry SOP00 V0.0 DDMMMYYYY***

***Insert trial title Data Query SOP00 V0.0 DDMMMYYYY***

***Insert trial title SAE Reconciliation Checklist Template V0.0 DDMMMYYYY***