***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 Data Query**

**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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| **Version No** | **Date** | **Author(s)** | **Date reissued to previous recipients** |
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**Standard Operating Procedure**

1. **Purpose**

The purpose of this standard operating procedure (SOP) is to ensure that data recorded on the ***insert trial title*** electronic Case Report Forms (eCRFs) are regularly monitored for accuracy, completeness and compliance with the protocol.

1. **Scope**

This SOP describes the process for generating and resolving ***insert trial title*** data queries on ***insert data capture system e.g. MACRO*** database.

1. **Responsibility**

Trial staff are responsible for ensuring the necessary data are complete and accurate on the electronic case record form (eCRF). Trial staff are also responsible for amending any data queries raised by the database or by a Monitor or Data Manager. Details of the monitoring activities are given in a separate document.

1. **Procedure**
   1. **Raising data queries**
      1. Data queries can be:

* Generated automatically by ***insert data capture system e.g. MACRO*** (these are either missing or irregularity data queries); or
* Raised by Data Entry staff during data entry of eCRFs/CRFs or by a Monitor, Data Reviewer or Data Manager whilst reviewing eCRFs e.g. during source data verification (these are manual data queries).
  + 1. To raise a *manual irregularity* data query:

***Add bullet pointed steps on how to raise manual queries along with screenshots.***

* 1. **Resolution of data queries**
     1. A staff member (with ***insert data capture system e.g. MACRO*** data entry role) will need to resolve each query by completing one of the following:
* Amend to the correct value or information.
* Add new or additional information.
* Provide additional clarification. For example, when it is deemed necessary to overrule a database warning, this should be done and the reason should be stated.
* Confirm data are missing/unobtainable. The associated missing eCRF and/or fields should be indicated as such on the database and amended to ‘unobtainable’.

It is important to remember that overriding warnings and setting data to missing or unobtainable may result in a protocol deviation. Please check the protocol and if necessary report findings to the trial co-ordinator.

* + 1. To view and resolve *missing* data queries:

***Insert bullet point steps on how to raise missing data queries along with screenshots.***

* + 1. Process for viewing and resolving *irregularity* data queries:

***Insert bullet point steps on how to view and resolve irregularity data queries along with screenshots.***

* + 1. Process for viewing and resolving *manual irregularity* data queries:

***Insert bullet point steps on how to view and resolve manual data queries along with screenshots.***

* + 1. Process for viewing and resolving *range check* data queries:

***Insert bullet pointed steps on how to view and resolver range check data queries along with screenshots.***

1. **References**
   1. SOPs:
   * ***Insert trial title SOP00 Data Entry V0.0 DDMMYYYY***

**Appendix 1 – *insert data capture system i.e. MACRO* database status icons**

***Insert screenshot***