1.0 Scope

This Standard Operating Procedure (SOP) has been written in order to conduct clinical studies according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (ICH-GCP) guidelines.

This SOP describes in particular the procedure of entering the data on a Case Report Form (CRF) in the database. This procedure applies to data on all CRFs of the trials of the European Group for Blood and Marrow Transplantation (EBMT).

2.0 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CRF</td>
<td>Case Report Form</td>
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<tr>
<td>CT</td>
<td>Clinical Trial</td>
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<tr>
<td>CTO</td>
<td>Clinical Trials Office</td>
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<tr>
<td>EBMT</td>
<td>European Group for Blood and Marrow Transplantation</td>
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<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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3.0 Responsibilities

CT Coordinator Is responsible for the entry of data in the database. If necessary he produces a manual to facilitate data entry by other personnel.

CTO Personnel Can enter study data (possibly with help of manual).
4.0 Introduction

An essential element of conducting a clinical trial is efficient data entry and management. Only that data that is essential for the purposes of the study must be collected. This SOP describes the full data entry management process including: data entry; data protection during the study; and data backup systems during the study.

ICH GCP Guidelines specify that appropriately qualified individuals must supervise the trial data entry and management (ICH 5.5).

5.0 Procedure

5.1 Data entry

Data entry must be done by trained data entry staff. For multicentre studies where the CRFs are being sent to a coordinating centre for data entry, a copy of the CRF must be retained by the Investigator, with the originals going to the coordinating centre. The coordinating centre must keep a log of all CRFs received, maintained by the CT personnel for the study.

5.2 Data Corrections by CTO Staff

Some studies may have a Work Instruction (WI) that defines allowable corrections that may be carried out by CTO staff. In addition other allowable corrections may be defined in a pan study work instruction. Such corrections must be made using green ballpoint pen and must be initialled and dated.
5.3 **Storage of CRFs**

All stored CRFs must be kept in a secure environment such as a locked filing cabinet in a locked room only accessible by authorised personnel in accordance with the terms of the Data Protection Act 1998.

5.4 **Data Protection during the study**

Participant confidentiality must be maintained at all times and all study records must be kept anonymous; identifying participants by their study number and initials rather than their name or hospital number. They may also be identified by date of birth if allowed by national applicable laws. The participating hospital must keep a list of patient details.

5.5 **Data Transfer**

After CRFs are completed original pages must be sent to the relevant EBMT CTO (unless stated otherwise in the protocol). Copies must be kept on site and filed as stated in the protocol. If paper CRFs must be transferred for data entry, they must be sent by post. A log must always be maintained of documents sent and received at each centre involved. If electronic data transfer is used, this must be via a secure system, password protected and encrypted where possible.

5.6 **Database Security**

The database itself must be password protected, with each data entry staff member having their own password. If data entry is performed at the investigator site it is essential that the investigator does not have access to the whole database, to protect against biases occurring due to investigators making decisions based on interim data.
5.7 Database Backup Systems during the study

Whatever the format of the database software used to manage the study data, there must always be a back-up system in place to guard against loss of data due to software or environmental disasters. All trial data is held on departmental and research groups file servers for which there is a data backup service that provides a reliable means of protection.

6.0 References

- ICH Harmonised Tripartite Guideline for Good Clinical Practice 1996
- EU Clinical Trials Directives 2001/20/EC and 2004/28/EC
- Data Protection Act 1998

7.0 Appendices

Not applicable.