Data recording and internal quality checks v1.0

Procedure

Pharmacology Module

WorldWide Antimalarial Resistance Network (WWARN)

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Pharmacology Module

Version History

Version number	Revision(s) & reason for amendment	Release Date
1.0	Creation of procedure	[DD/MM/YYY]

For more information, contact:
pharmacology@wwarn.org

WorldWide Antimalarial Resistance Network (WWARN)
www.wwarn.org

Contents

1. Purpose

This procedure describes the process and provides instruction for recording and validating data (source and case record form) generated during a clinical trial.

2. Scope

This procedure applies to study team members responsible for recording and validation of data for the duration of the clinical trial.

3. Abbreviations

CD	Compact Disc
CRF	Case Record Form
DCF	Data Clarification Form
ECG	Electrocardiogram
eCRF	Electronic Case Record Form
GCP	Good Clinical Practice
PI	Principle Investigator

4. Duties and Responsibilities

N/A

5. Materials and Equipment

N/A

6. Procedure

6.1 Source data

Source data (reference SA GCP Guidelines 2006) are generated throughout the study by those team members delegated responsibility for performing protocol-specific assessments and/or otherwise eliciting information from subjects.

Each of these team members is responsible for keeping accurate records and should:

- Sign/date the entry at least on a visit by visit basis.

- Clearly show the original entry.
- Delete incorrect entries with a single line and initial/date the correction with a reason given if necessary.

6.2 Validating source data

At specific time-points, as determined by the PI, a member of the study team will oversee a review of all, or a pre-specified selection of, the source data to identify obvious errors and omissions relating to dates, signatures, use of black ink, consistency and possible exclusions/withdrawal criteria. Errors will be discussed with the investigator immediately, and corrective actions documented.

All laboratory results (or other assessments such as ECG traces) will be reviewed by an investigator who documents clinical relevance with his/her signature and date.

If subjects are contacted to clarify issues relating to data, a note of the date and content of the conversation is recorded in the source data**.**

6.3 Storing source data

The source data must be stored in a safe and confidential manner between visits, and be made available to other team members or the monitor as required by the protocol.

6.4 Protocol deviations

A log of protocol deviations should be maintained throughout the study (PHA3_Exh1: protocol deviation log).

6.3 Paper CRF data

CRFs will only, generally, be completed for successfully enrolled study subjects (i.e. received at least one dose of the investigational product).

A designated team member will be responsible for transcribing relevant source data to the CRFs. Original and corrected entries are maintained as above.

Clinical data should not be entered into the CRF before it has been reviewed by the investigator.

Prior to the investigator signing declarations in the CRF, a study team member should conduct a review of all, or a review of pre-specified selection of, CRF data for accurate transcription as detailed above.

Should corrections be made to CRF data after the investigator has signed a declaration, the investigator should counter-sign and date the correction.

Pre-entry checks, data entry and any discrepancies noted will be documented in an eCRF/CRF data entry tracking log (PHA3_Exh2: eCRF/CRf data entry tracking log). Discrepancies will be reported to the investigator for clarification and/or alteration of the source document prior to final data entry as documented on the log.

6.4 Electronic CRF (eCRF) data

Data will only, generally, be entered for successfully enrolled study subjects (i.e. received at least one dose of the investigational product).

A member of the study team designated to perform data entry will ensure that the relevant source data for entry (i.e. batch) have been approved by the investigator.

The data enterer will perform pre-data entry checks that:

- The subject identifiers are recorded correctly
- Visit dates appear to the suitable (i.e. no impossible dates, are sequential)
- There are no relevant missing data

Pre-entry checks, data entry and any discrepancies noted will be documented in an eCRF/CRF data entry tracking log (PHA3_Exh2: eCRF/CRF data entry tracking log). Discrepancies will be reported to the investigator for clarification and/or alteration of the source document prior to final data entry as documented on the log.

The data will be entered into the database strictly according to the source data/CRF.

6.5 Database backup

The data will be backed-up on a day-specific CD after each day spent working on the database:

- A copy of the day's database will be made and written onto the appropriate CD, (this back-up copy will be renamed with the database name, version and current date).

- CDs will be kept in a secure location for the duration of the study as determined by the PI.
- A log of the database backup will be maintained by data entry personnel (PHA3_Exh3: eCRF/CRF database backup log).

6.6 Documentation

All documentation relating to data entry will be filed in the Study Manual.

7. References

Department of Health, 2006. Guidelines for Good Practice
in the Conduct of Clinical Trials with Human Participants in South Africa.
Department of Health: Pretoria, South Africa.
http://www.doh.gov.za/nhrec/norms/gcp.pdf (Accessed 21 November 2010)

ICH Topic E 6 (R1) Guideline for Good Clinical Practice, 2009. Available
from:http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf (Accessed 21 November 2010)