Data Management Plan

STUDY NAME

Revision History:

Date	Author(s)	Remarks
DD-MON-YYYY	XXXXX	Created Initial DMP

Overview:

Case Report Forms (CRFs) for approximately _____ patients will be forwarded to _____ on an ongoing basis by _____. The database will be built on _____ *(i.e. REDCap, OpenClinica, etc.)* and will [will not] include subject data entry. The CRF data will be entered directly into the database application [electronically tracked prior to double [single] data entry]. After entry [and reconciliation of the two entries], _____ will perform electronic edit checks on all subject records to ensure accuracy and consistency. All queries generated as a result of these edit checks will be forwarded to _____ for resolution. Once all queries have been received and the database updated, a database audit will be performed on all entered data to ensure at least ___% accuracy of the database.

Case Report Form (CRF) Handling and Review:

The CRFs will arrive with a CRF Tracking Receipt Log indicating which pages are enclosed. Upon receipt, the CRF Tracking Receipt Log will be reviewed for accuracy against pages received and any discrepancies will be noted and communicated to _____electronically or in writing.

The CRFs are double data entered according to the process outlined in the Data Entry Guidelines.

Once entry and cleaning are complete, edit checks are run to further ensure accuracy and consistency. See the Data Validation Checklist document for details on the edit checks.

Data Clarification Forms (DCFs) and Data Changes:

Queries are generated using Data Clarification Forms for data discrepancies and sent via _____ (i.e. regular mail, fax etc.) to _____ for resolution. DCFs will be forwarded as received [on completed patients only] [only once].

Data changes are made and documented as follows:

1. Once received, DCFs are processed and the database updated according to the procedures in the Data Entry Guidelines. Original CRFs are not changed/corrected with information from the DCF rather the DCF is stored with the CRF as documentation for the change that will be made to the data in the database. The resolution section of the DCF should be utilized to document that the database modifications resulting from query resolutions were completed and verified. The resolution on the DCF for a query resolution requiring either no change to the existing data or an additional query should be document as “No Change” or “Required” respectively.
2. See the Data Entry Guidelines document for details regarding CRF changes and clarifications Data Entry staff are authorized to make.

3. Obvious data changes that _____ is authorized to make include but are not limited to the following. CRFs are corrected [not changed] for obvious data changes. [Only the data as it is entered into the database will be corrected.]
    a. Times not recorded in military format will be corrected; however, any questionable times will be queried.
    b. Header information (site number, subject number, etc.) which is incomplete or inconsistent will be corrected whenever possible.
    c. When a year recorded is obviously incorrect, it will be corrected; however, Adverse Events and Concomitant Medications will be queried for verification if appropriate.
    d. When specification data is provided, but the accompanying check box has been left blank (i.e. Other, specify is provided for Reason for Discontinuation but the check box is not checked), the accompanying check box will be checked.
    e. If any data is not recorded in the CRF standard format (i.e. DDMMYYYY), the data will be changed to the correct standard format)
    f. If fractions are used when recording height or weight, a change will be made to convert the fraction and round it to the nearest whole number.
4. Site-Generated Changes can be updated on the original by the site only, if the original has not been sent to _____ for processing. These changes are transcribed in black ink. If an existing response is changed, a single line is drawn through the existing response and the correction is recorded as closely as possible to the original location of the response. The original CRF information should not be obliterated by the change. The change is initialed, dated and a brief reason of "Site-Generated Change" or "SGC" is recorded. If the original has already been sent to ____, then a DCF is completed documenting the revision or change with Reason for change indicated as "Site Generated Change" or "SGC".

Coding Process/Dictionaries:

Coding of adverse events and concomitant medications will be performed at _____. Adverse events will be auto-encoded with the _____ (i.e. sponsor) provided MedDRA dictionary Version _____. Medications will be auto-encoded with the _____ (i.e. sponsor) provided WHO Drug dictionary Version _____.

Non-matches will be reviewed by _____. The _____ will determine if the term needs to be corrected or clarified in any way and will route specific recommendations for clarification or correction back to the Data Manager. The Data Manager will take appropriate action (i.e. database correction, DCF) based on the recommendations.

At _____ (i.e. end of study, first of the month, etc) listings of coded variables will be provided to _____ for review and approval.

Serious Adverse Events (SAE) Reconciliation:

_____ will perform a reconciliation of Serious Adverse Events (SAEs) as recorded in the AE dataset versus an SAE report provided from _____. The reconciliation will be performed _____ (i.e. once at the end of the data collection phase, monthly etc). It will include reconciliation of the adverse event name, start date, _____, and _____.

[Include here details of how exact the matches need to be etc.]

Lab Data Processing:

Electronic lab data will be provided via _____ from _____ to _____once [twice] [three times] during the study. The first submission will occur approximately _____ and the final submission will occur _____ and contain data for the whole study. The final submission will be cumulative data and will overwrite the previous data transmission(s). The data will contain _____ (i.e. conventional units, standard units, reference ranges, etc). In addition to the 2 submissions of production data, there will be one test file sent to _____ at the beginning of the data collection phase to use to set up the upload program.

Completeness of the lab data will be checked after each production data submission to be sure results are received for all parameters for all patients for all visits (See Data Validation Checklist for details on edit checks which will be performed against the lab data). Electronic lab data will not be checked against hard copy laboratory results.

Reports and Ad-hoc Queries:

Reports will be needed _____ for _____ (i.e. DSMB, data cleaning throughout study, etc).

The following reports will be created for this study (See Report Specifications document for details).

Report Name	Execution	Time point
Patient accrual	Online user report	As needed
Pass 2 Complete	DM team	As needed
DSMB Report	DM team	Monthly

Reports will be generated and validated/QC'd according to the specifications outlined in SOP XX-XXXX

Quality Management Activities:

The study team will ensure quality data by using standard and streamlined processes for data collection and processing, data entry and data cleaning. The data manager will monitor the quality of data throughout the clinical trial and at least one quality inspection will take place to determine the error rate (See Data Audit section below for details)

Data Audit:

_____ [QA Dept.] will perform a final quality audit of a random sample of _____patients *(minimum # of patients = 10 or 10% of total patient; whichever is greater)*. All CRFs from the random sample patients will be 100% checked against the database.

If the error rate is less than or equal to _____% from the random sample patient and the errors encountered are not significant, ____will correct the errors and finalize the database. If the error rate is greater than _____%, or if the errors encountered are significant, a rework of these sections of the database will be performed before transmission of the final database to _____.

Data Lock Procedures:

The database will be locked after completion of the following:

- All active clinical research subjects have completed their final visit and any follow-up visit activities
- All coding of clinical events is complete
- Reconciliation of the SAE system or database is complete
- All external data in support of the clinical trial must be loaded into the clinical database and cleaned
- All outstanding queries must be resolved and the clinical database updated, according to the processes outlined in the SOP XX-XXX and this Data Management Plan

Locking the database restricts access to the clinical data to only those team members who have been granted access.

After the database has been locked, a quality audit will be performed (see section Data Audit above for details). Once an acceptable error rate is reached, the database will be frozen. A frozen database cannot be added to or updated by any team member. If it becomes necessary

to update data on a frozen database, the database must be unfrozen according to the processes outlined in SOP XX-XXX.

Records Retention Procedures:

All documentation relating to the clinical study including the clinical data will be archived and retained for _____years in accordance with the processes outlined in SOP XX-XXX.

Project Team Personnel:

Principal Investigator: XXXXXXX
Project Manager: XXXXXXX
Data Manager: XXXXXXX
Biostatistician: XXXXXXX

Deliverables:

Data Management Deliverables are listed below.

1. Database Specifications
2. CRF Guidelines
3. Data Entry Guidelines
4. Final Data Management Plan
5. Queries
6. Monthly Data Management Reports
7. Coding Listings
8. Final Database

Data Transfers:

One data transfer of the database will be provided to _____ after the final database freeze. Data transfers (databases) to _____ will be handled as follows and in accordance with appropriate SOPs:

1. _____files will be created. Dataset names will retain their original naming conventions and are stored as extract views or tables.
2. A quality checklist to document the creation process will be completed by _____and included in hard copy form along with the database transfer.

Specific format and transfer of data will be dependent upon requirements for those receiving the data. Those details will be included in this document and agreed upon during the development and approval of this plan.