27. DATA MANAGEMENT PROCEDURES [DCRI]

27.1 Procedures for Completing the Case Report Forms

The Case Report Forms (CRFs) are required and should be completed for each enrolled participant, including those who are screened but fail to be randomized (only screening CRFs are required for these participants). These forms are used to transmit the information collected in the performance of this study to the DCRI. The investigator must review the case report forms for completeness and accuracy and must sign and date all forms where required.

The CRFs as well as CRF guidelines will be available on the trial website for downloading in .pdf format. Each site will be responsible for downloading the appropriate forms for completion at the individual study sites. When completing the case report form, the site should follow the instructional guidelines appropriate for that page or unit that is to be submitted. During CRF completion:

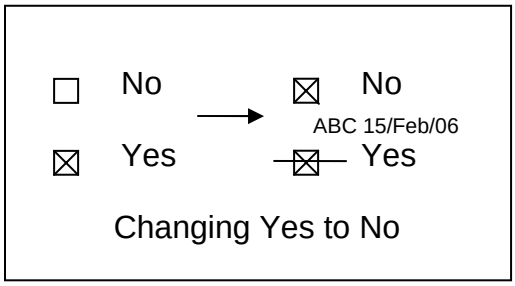
- Use permanent media (blue or black ink only).
- Complete the participant identifiers on every page (center number, participant number as assigned from the CALERIE ID log, and participant's initials).
- Participant initials: Record as first, middle and last. If no middle initial is available, record a (-) in the space provided. For hyphenated last names, record the initial of the first part of the hyphenated name. Record initials consistently throughout the CRF.
- Complete all items on the CRF.
- Do not write outside of the fields provided. Such data will not be collected in the study database.
- Ensure all items captured on the CRF are legible.
- Numbering Multiple Pages: Some CRF pages may require additional repeated pages in order to capture all of the necessary information. These pages have a decimal, followed by a blank line. Please complete the number by putting "1" on the blank line of the first page followed by "2", "3," etc.
- Record dates using a 2 digit number for the day, a three-letter abbreviation as noted below for the month and a 4 digit number for the year. If the date is unknown, record UNK in the space provided.

January=JAN	April=APR	July=JUL	October=OCT
February=FEB	May=MAY	August=AUG	November=NOV
March=MAR	June=JUN	September=SEP	December=DEC

27.2 GCP Procedures for Making Change to Data Forms

When completing the case report form:

- Any changes to the CRF *before it is submitted* should be made by marking a single line through the erroneous data and writing in the corrected data.
- All data changes should be initialed and dated.
- DO NOT use correction fluid or tape.
- Once a CRF page has been submitted to the coordinating center (CC), do not make any changes on the form or resubmit the form with data changes. An exception to this are the log pages, which are added to and resubmitted over the course of the study.
- Data changes to pages which have already been submitted should be made on a Data Clarification form (DCF), indicating the original value along with the corrected entry, the signature of the person changing data and the date. Do not transcribe these changes on to the CRF page itself, since the DCF is considered part of the CRF.



27.3 Missing Value Codes

In cases where a participant has reached a visit, but for some reason has not completed a particular CRF page, the page must still be submitted to the CC with the correct identifying participant information completed. The not done box at the top right of the form should be completed with the appropriate code from the CRF code list. If the entire visit is not completed, but the participant remains enrolled in the study, the CRF pages should be submitted with a single slash through the pages and an initial and date. Each database screen corresponding to a CRF page incorporates an additional No Data field, which allows the CC to record an uncompleted page. Pages that are not submitted to the CC will be considered missing.

Additionally, individual tests collected in the CRF will have separate fields indicating if they were not completed. If part of a page has been completed, it is necessary to mark individual not done items for the remainder of the page.

If a participant does not reach a visit due to withdrawal from the study, do not submit any pages for the remaining visits. However, the CRF Study Completion page must be completed and submitted. No study completion form is required for screening failures.

27.4 Forwarding Data Forms to the Coordinating Center

At study start-up, the CC monitor will mail pre-addressed FedEx labels to sites for the purpose of submitting completed CRF pages. The case report form will be divided into discrete sections or units. Upon completion of all pages from a given unit, a copy of these pages should be made. The copied pages for each unit should be sent by FedEx courier to the CC, and will be entered into the study database. The original CRF forms will remain at the site for reference and monitoring purposes. Copies of all completed DCFs should be made in the same manner, with the originals kept in the same location as the original CRF pages. Unlike CRF pages, it is acceptable to either fax DCFs to the CC at the listed number on the bottom of the DCF form or to submit them by FedEx.

27.5 Data Management Quality Control Procedures

Data Management will implement a multi-tiered approach to quality control, which will include double data entry, data validation checks, monthly standard QC reports and periodic internal auditing. Additionally, all external data transfers will be validated according to standard DCRI practices. Detailed procedures are described in the DCRI's standard SOPs. Any items arising from these checks requiring site input will be sent and tracked using the standard query resolution process as described below.

27.6 Query Resolution Process

The CC will develop a series of data validation checks in collaboration with trial management and the trial statistician. These programmed checks will reference logical inconsistencies or items out of range of expected norms. These checks are run in real time, and will be reviewed daily for data entry errors and obvious corrections as defined in the data management working instructions at the CC. Obvious corrections will be made and tracked through the database. Additionally, other checks may be employed by the statistician requiring verification from the sites.

All of these queries will be distributed to the sites as DCFs (Data Clarification Forms) on a weekly basis via email. The DCF will include trial and participant identification information, a detailed description of the issue, and current data stored in selected relevant fields. The sites will be able to confirm the data (if appropriate) or submit corrected data on the form itself. If the query is not answered appropriately, the query will be reissued with further clarification. The DCF should be signed and dated by the study coordinator or other delegate elected by the site PI, and sent to the CC to update the database. DCFs can be submitted by FedEx along with other submitted forms or can also be faxed in independently. The CC will have a complete record of DCFs distributed to the sites, and periodically will provide the sites with a report detailing any DCFs which remain outstanding.

27.7 Data Management Performance and QC Reports

(TBD at a later date when report shells are available).