

Instructions: Complete this form when documenting data entry errors in CBR BRIMS and/or the CDR Data Services databases. Please contact the Study Management Group with all questions.

BSS:

Case ID:

Where can the data entry error be found? (Mark all that apply)

- | | | |
|---|---|--|
| <input type="checkbox"/> CBR, GTEx Green Kit | <input type="checkbox"/> CDR, GTEx Green Kit | <input type="checkbox"/> CDR, GTEx Pink Kit |
| <input type="checkbox"/> CBR, GTEx Yellow Kit | <input type="checkbox"/> CDR, GTEx Yellow Kit | <input type="checkbox"/> Tissue Data Collection Form |
| <input type="checkbox"/> CBR, GTEx Aqua Kit | <input type="checkbox"/> CDR, GTEx Aqua Kit | |
| <input type="checkbox"/> CBR, GTEx Pink Kit | <input type="checkbox"/> | |
| <input type="checkbox"/> Other, specify | | |

Please specify:

To be completed by the site identifying the error.

Site identifying error:

Brief description of data error identified:

Date Study Management Group first notified:

Description of Error (questions 1a, 1b, 1c and 1d) to be completed by Error Source.

1. Error Description, Error Source

a. Provide a detailed description of the data entry error identified.

b. What is the appropriate data correction?

c. Name of person requesting data correction:

d. Date requested:

Submit this form to the Study Management Group after completion of Questions 1a, 1b, 1c and 1d (if applicable, submit updated forms to the CBR)

Corrective Action to be completed by CBR (questions 2a, 2b and 2c) and, if applicable, the Study Management Group.

2. Corrective Action, CBR

a. Provide a detailed description of the steps taken to correct the data entry error.

b. Name of the person authorizing corrective action:

c. Date authorized:

2. Corrective Action, CDR (If applicable)

d. Provide a detailed description of the steps taken to correct the data entry error.

e. Name of the person authorizing corrective action:

f. Date authorized:

Correction Verification to be completed by Error Source (questions 3a, 3b, 3c and 3d) and, if applicable, CBR or the Study Management Group (questions 3e, 3f, 3g and 3h).

3. Correction Verification, Error Source

a. Were the steps detailed in 2a/2d completed?

Yes No

i. If No, explain.

b. Did the steps taken in 2a/2d resolve the data entry error detailed in 1a?

Yes No

i. If No, explain.

c. Name of person verifying completion of data correction:

d. Date verified:

Correction Verification to be completed by the CBR or Study Management Group, if applicable (questions 3e, 3f, 3g and 3h).

3. Correction Verification, CBR/Study Management Group (If applicable)

Yes No

e. Were the steps detailed in 2a/2d completed?

i. If No, explain.

f. Did the steps taken in 2a/2d resolve the data entry error detailed in 1a?

Yes No

i. If No, explain.

g. Name of person verifying completion of data correction:

h. Date verified:

Comments

If the error noted in this DCF is deemed significant by the Study Management Group or BSS, a Nonconformance Report (NCR), including a Root Cause Analysis and Corrective/Preventive Actions (CAPA) plan will be required from the originating entity.

Submit completed form to the Study Management Group.