STANDARD OPERATION PROCEDURE

DATA ENTRY

COMPREHENSIVE CANCER TRIAL UNIT

THE CHINESE UNIVERSITY OF HONG KONG

EFFECTIVE DATE: 06 OCT. 2001
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I. Definitions of Data Entry

♣ The term “Data entry” in this section is defined as the process in transferring the data from CRF to the corresponding Data Entry Screen.

A Clarification of some terms used in the section of data-entry

1. Logging Date (patient visit date)
   ➢ In general, it is the date of patient visit

2. Front-page (Appendix I)
   ➢ A front page is attached to the CRF as the first page to document the date the CRF is “ready for input”, the date “Data entry” is first started, “Verification” has been done the first time and the whole CRF has been entered and verified as “Complete”. All of these dates will be entered in database by the data-entry clerk.
   ➢ This front-page is divided in several domains including screening, eligibility, treatment cycles, off treatment, death, progression and SAE.

3. Date of “Ready for input”
   ➢ All the essential fields of the CRF are completed which can be placed in a specific area labelled “IN” in dark room. The term “IN” means that the CRF is ready for data entry. Then, the study nurse needs to note down the date in the box of “ready for input”.
   ➢ Essential field
   - Physical examination, laboratory results (including CBP with differential, liver and renal function tests), treatment information (including dosage and date) and toxicity and other protocol specific information.

4. Date of data entry
   ➢ The date of transferring the data from the CRF to the Data Entry Screen.

5. Date of Verification
   ➢ This date is the first time that the data-entry printout is being verified with the CRF by the study nurse.

6. Date of completeness
   ➢ The date that the study nurse has confirmed that there is no discrepancy between the CRF and the data-entry printout.
II. Training for the data entry clerk(s)

1. Briefing session on protocol and trial by study nurse.
2. Briefing session on the Data Entry Screen including the format, range, field properties (expected value, field type, field length and etc) by the programmer/statistician.
3. Special attention is needed on the primary keys that it is not allowed for any mistake. Some of the primary keys include trial number, patient number and patient initials.
4. Briefing session on the NCI CTC code and toxicity by study nurse.
5. Review the Data Entry Screen and NCI CTC code by the data entry clerk.
6. The data-entry clerk must sign a confidential agreement which mention the obligation to keep confidential of all the information s/he obtained or access during data entry
7. Testing the Data Entry Screen.

III. Steps in testing of the Data Entry Screen

♣ In order to ensure that the Data Entry Screen screens are accurate and that their functions are working correctly, testing the Data Entry Screen is necessary.
1. A test scripts will be written by programmer to test the Data Entry Screen which will include date and time of the testing, the name of the tester, the functionality being tested, the expected data-entry input from the tester and the expected outcome such as blood count, laboratory result, concurrent/concomitant medication.
2. A space also will be provided for the tester to document any difficulties and problems encounter during the testing process.
3. The testers must include the study nurse, the programmer and the data entry clerk.
4. After the testing is done, a meeting will be held by the study nurse, data-entry clerk, programmer and CCTU director to discuss the results of test and suggested revisions.
IV. Procedure in transferring the data from the CRF to the Data Entry Screen

The procedure in transferring the data from the CRF to the Data Entry Screen is divided into nine steps and illustrated in appendix II.

1. The data entry clerk requires logging the date of each patient visit in the database within 24 hours of patient’s visit.
2. Study nurse / research assistant must transfer the data from the RT folder to the CRF within 4-weeks time after the end of that cycle.
3. The study nurse / research assistant must ensure all the essential fields of the CRF are completed before putting her signature and date on the column of “ready for input”.
4. After signing the “ready for input”, the study nurse should put the CRF to the specific areas labelled “IN” in dark room.
5. The data must be entered into the Data Entry Screen database within 2 weeks by the data-entry clerk
6. After data-entry by the clerks, a printout with all the inputted data will be printed and attached in the CRF folder. And the CRF will be placed to a specific location labelled “OUT” in dark room to notify the study nurse that the data in the CRF have been transferred to the Data Entry Screen database.
7. The study nurse needs to verify the data between the CRF and the printout within 2-weeks time.
8. If there is no queries, the study nurse need to sign and date the box of “Completeness” in the front-page to notify the completeness in transferring the data in the CRF to the Data Entry Screen. However, if there is any queries or discrepancies between the CRF and the printout, the study nurse need to write down the correct answer(s) in the printout and write down the queries in the query form. Furthermore, the nurse needs to put the date and sign on the box of “Verification” in the front-page to notify the clerks for correction(s).
9. Step 7 to 8 will be preceded until there is no discrepant between the CRF and the Data Entry Screen and the study nurse signed the box of “Completeness” in the front-page. The CRF will go back to the data entry clerk to enter the “Complete” date.
V. Queries From
1. If there is any queries or discrepancies between the CRF and the printout, the study nurse need to write down the correct answer(s) in the printout and write down the queries in the query form (appendix III).
2. In the query form, the study nurse needs to write down the date, the query, number of cycle/treatment, page number in that cycle/treatment as well as the nature of query.
3. The nature of query is divided into 5 different types including “check source of document”, “waiting for result”, “discrepancy with the CRF”, “not yet entered by the data-entry clerk into the data entry screen” and others.

VI. Reminder system to make sure the process of data entry within specific time frame
A. Generic reminder to all trials
1. A reminder will be sent to the study nurse biweekly to remind the study nurse:
   - To complete all the essential fields of the CRF and placed the CRF to the “IN” box within the time-frame (i.e.: 4 weeks after the end of cycle).
   - To complete any missing data in the database
2. Meanwhile, the issue of delay in completing the essential fields of the CRF for data entry must be discussed and addressed in CCTU meeting when it was delayed more than 8 weeks after the end of cycle.

B. Trial specific
1. For trail specific information, additional items will be added to the reminder system. This trial specific section of the reminder system will be tailor-made to each protocol by the study nurse and the programmer. For example, the time required in obtaining the laboratory test for EBVDNA and HBV is much longer than routine laboratory tests, then a separated reminder will be generated to remind the study nurse to complete this information accordingly to the different time-frame.
VII. Missing Data Code on CRF:

♣ Missing data can be divided into three types as described as follow:

NK: Not Known
The data cannot be captured or obtained although all the preparation tasks are performed and ensured

ND: Not Done
The information does not captured because of
1. Forgotten
2. Unavailability of the test in our local Laboratory

NA: Not Applicable
The information is not applicable.

VIII. Missing data code for database:

Generic missing code:
♣ The numeric code for NK is “9”, ND is “8” and NA is “7” when the range of that field can be defined.

Special event:
♣ For some test/examination that the range of the field cannot be defined or unknown, one more question will be added to indicate the nature of missing data of that field.
♣ For example, for the test of HBVDNA, the range of the result is unknown. Then, a question must be added to indicate whether the result is “not known”, “not available” or “not done” when the result did not write on the CRF.
Appendix I

**FrontPage**

<table>
<thead>
<tr>
<th>CRF</th>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Baseline</td>
<td>Ready to input</td>
<td>Date entry</td>
<td>Verified</td>
<td>Completed</td>
</tr>
<tr>
<td>2 Cycle 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Cycle 2</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4 Cycle 3</td>
<td></td>
<td></td>
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<tr>
<td>5 Cycle 4</td>
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<td></td>
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<tr>
<td>7 Cycle 5</td>
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<tr>
<td>8 Cycle 6</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>10 Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Off treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 Progression</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 SAE</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Appendix II

Data-entry flow diagram

- Logging in computer by clerk (within 24 hours of patient visit)

- Transfer the data from RT folders to CRF

- Input data by Clerks (first-in-first-out)

- Printout the inputted data by clerks

- Verification by the study nurse

- Queries:
  - Yes: For correction by the clerk
  - No: Completed

- 2 weeks

- 4 weeks after the end of cycle/treatment

- Within 2 weeks

Within 2 weeks