Electronic CRF Design

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Definitions

- eCRFs are the electronic representation of paper data collection forms
- These can be duplicated from paper data collection forms or can themselves be the tool that is used for data collection
  - Data Entry screen
  - Data Fax entry screens (OCR, ICR)
  - EDC - Entry screens
Some general Guidelines

- eCRFs should be very similar to paper CRFs
  - Should mimic the design and flow of paper CRF
- eCRFs should have built-in edit checks tagged to each data field and also tagged to the form as a whole
- If there are no paper CRFs majority of the data cleaning will take place during the completion of the eCRFs.
Things to Consider

- Ease of entry
- Avoid over crowding
- Match electronic form to paper form as much as possible
- Use of pre-coded answer sets
- Avoid excessive use of text fields
- AE designs
Ease of data entry

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the participant met all the criteria for the study?</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of birth:</td>
<td>01/12/1970</td>
</tr>
<tr>
<td>Ethnicity:</td>
<td>Not Hispanic/Latino</td>
</tr>
<tr>
<td>Race:</td>
<td>More than one race</td>
</tr>
<tr>
<td>Education:</td>
<td>13</td>
</tr>
<tr>
<td>LMP:</td>
<td>02/07/2000</td>
</tr>
<tr>
<td>Was participant ever pregnant prior to this visit:</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of last pregnancy outcome:</td>
<td>05/27/1995</td>
</tr>
<tr>
<td>Parity Information:</td>
<td></td>
</tr>
<tr>
<td>Number of vaginal deliveries:</td>
<td>2</td>
</tr>
<tr>
<td>Number of cesarean deliveries:</td>
<td>0</td>
</tr>
<tr>
<td>Number of spontaneous abortions:</td>
<td>0</td>
</tr>
<tr>
<td>Number of induced abortions:</td>
<td>0</td>
</tr>
<tr>
<td>Number of ectopic pregnancies:</td>
<td>0</td>
</tr>
<tr>
<td>Has participant had any reproductive system (not breast) problems in past 12 months?</td>
<td>No</td>
</tr>
<tr>
<td>Does participant have any other significant health problems?</td>
<td>Yes</td>
</tr>
<tr>
<td>If Yes, specify:</td>
<td>HIV/AIDS, ARTHRITIS, AND REFUX (NO MEDICATIONS)</td>
</tr>
</tbody>
</table>

Page 2

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the participant used any of the following contraceptive methods within the 6 months prior to screening?</td>
<td></td>
</tr>
<tr>
<td>12. IUD:</td>
<td>No</td>
</tr>
<tr>
<td>13. Male condom:</td>
<td>No</td>
</tr>
<tr>
<td>14. Female condom:</td>
<td>No</td>
</tr>
<tr>
<td>15. Spermicide:</td>
<td>No</td>
</tr>
<tr>
<td>16. Contraceptive sponge:</td>
<td>No</td>
</tr>
<tr>
<td>17. Diaphragm:</td>
<td>No</td>
</tr>
</tbody>
</table>

FSN: Final Sequence Number (FSN)
Pre-coded Answer Sets

Product Use Questionnaire (Page 1)

12. Which problem did you encounter
   a. Handling before insertion
   b. Orienting device
   c. Inserting device
   d. Pushing into place
   e. Discomfort during insertion
   f. Confirming placement
   g. Other

   Please explain

13. After insertion and before use, did you check to confirm the device was correctly inserted
   1. Yes
   2. No

14. Why did you check
   a. Instructions told me to
   b. Clinician told me
   c. Wanted to confirm it was correctly in place
   d. Was concerned it was not inserted properly
   e. Was not experienced using this kind of device
   f. Felt pain or pressure from device
   g. Other

   Please explain

15. Did you think the device was correctly inserted
   1. Yes
   2. No

Product Use Questionnaire (Page 2)

18. Why did you NOT check
   a. Could not or did not think I could find my cervix
   b. Am not experienced with this device
   c. Felt no pain or pressure from device
   d. Felt confident device was correctly inserted
   e. Felt no pain or pressure from device, so thought it was correctly inserted
   f. Other

   Please explain
### Radio Buttons

#### External Genitalia

Is any part of the finding located on the external genitalia?

<table>
<thead>
<tr>
<th>Option</th>
<th>Selection Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right labia majora</td>
<td>Blank</td>
</tr>
<tr>
<td>Left labia majora</td>
<td>Blank</td>
</tr>
<tr>
<td>Right labia minora</td>
<td>Blank</td>
</tr>
<tr>
<td>Left labia minora</td>
<td>Blank</td>
</tr>
<tr>
<td>Clitoris / prepuce</td>
<td>Blank</td>
</tr>
<tr>
<td>Introtitus</td>
<td>Blank</td>
</tr>
<tr>
<td>Perineum / Anus</td>
<td>Blank</td>
</tr>
<tr>
<td>Urethra</td>
<td>Blank</td>
</tr>
<tr>
<td>Other</td>
<td>Blank</td>
</tr>
</tbody>
</table>

Specify:

#### Cervix

Is there any part of the finding located in the cervix?

<table>
<thead>
<tr>
<th>Option</th>
<th>Selection Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior cervical trunk</td>
<td>Blank</td>
</tr>
<tr>
<td>Posterior cervical trunk</td>
<td>Blank</td>
</tr>
<tr>
<td>Right cervical trunk</td>
<td>Blank</td>
</tr>
</tbody>
</table>
Check Boxes

1. ¿Fecha de nacimiento?
2. Edad:
3. Residente de Lote:
4. Sexualidad:
5. Raza/Tipo Étnico:
   a) Hispánico/Latino:
   b) No Hispánico ni Latino:
   c) Americano/Americano:
   d) No de Hawai o otro isla del pacífico:
6. ¿Obtuvo el consentimiento informado?
7. Antibióticos en los últimos 7 días?:
8. ¿Allergia a la Penicilina?:
9. Faringitis:
10. Toque de Muestra/Fecha:
11. Antibiótico indicado hoy:
12. ¿Se indicó antibiótico?:
Dates

- Dates can be designed to be entered as a single item; however, you may have problems with incomplete dates.
- FHI uses separate items for each part of the date and a derivation to get the date.
- We also need to keep in mind the format that the dates will be collected (e.g., dd/ mm/ yyyy, mm/ dd/ yyyy, dd/ mon/ yyyy) and set up the screens appropriately.
Repeating Records
Instructions: Use this form to record additional information about a specific participant or to clarify data recorded on another form. For Visit Code, enter the visit code of the form or visit on which you are commenting. Please print information legibly.

Record the acronym(s) of the form(s) to which the comments apply: GSAE FSN 200138. or □ not applicable

See upper right hand corner of form for acronym. For example, this form’s acronym is GCOM-1.

Comments:

Paracetamol 2 tablets TDS every 6 hours. Spectrum for ATV-143. she was referred for further TB investigations. ART to be commenced once diagnosis was finalised. On 04-01-07 participant went for TB investigations at Chiwangiza General Hospital, an examination. Temp 37°C BP 120/80. ill looking with shortness of breath. Plan: Cef, ATV-143 and 2 tablets TDS and Vitamin B complex tablets TDS.

05-01-07 Admission participant was seen by doctor Cef revealed bilateral infiltration, it sided prevalence
**Text Fields (2)**

**COMMENTS FORM**

**visit date (text):** 11/05/2006

**Clinic Record Number:** 000964/99

**Record acronyms of forms to which these comments apply:** GTRT, GIV

**Comments:**

- This client was due for her 24.0 ART regular visit yesterday (10/05/06)
- But did not return. Today being Thursday and tomorrow being a public holiday, she has been provided with 29 (6) more pills of both Combivir and Nevirapine to take her through the weekend. She will therefore return to the clinic on Monday 15/05 for her regular visit. This therefore explains why an interim visit has been done and yet she's due for her regular visit.

**Staff ID:** 78
Testing of eCRFs

- eCRFs should be tested for ease of entry and data cleaning programs
- Electronic check
- Tab order
- Order of items on the form
- Answer sets (code lists)
Tools for testing

- Test data - to test error specifications and train data entry staff
- Data base specifications
- List of tables
- Error specification document
- Variables and formats in each table
- List of pre-coded answer sets (codelists)
- Expected error matrix
Conclusions

- Design eCRFs as you would paper CRFs
- Error checks should be tested for each eCRF and tested with test data
- eCRF should be reviewed not only by study team but also by data entry staff
- Store documentation of for the design of the eCRFs