Case Report Form Design for Web-based Clinical Trial Data Management Systems

Catherine Dillon
Wenle Zhao, Valerie Durkalski
Department of Medicine
Medical University of South Carolina, Charleston, SC
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Web-based Data Collection Systems

- Allows data to be directly entered at the time of collection
- Allows for real-time (or close to real-time) data reporting
- Creates special opportunities that should be considered during CRF development
Why are CRFs needed?

- Data collection
- Database programming/ User interface
- Reporting of clinical trial data
- To ensure proper conduct of the trial
- To ensure standardization of procedures across sites
CRFs should reflect:

- Study protocol
- Statistical analysis plan
- Site procedures
Functionality of eCRFs

- Real time feedback to sites regarding data errors
- Real time monitoring of study data
- Real time feedback to sites regarding protocol procedures
- Facilitates standardization of data capture across sites
- Facilitates standardization of care across sites
- Facilitates site training
Optimization of functionality

- Requires input from end users during development
- Requires flexibility to allow for modifications based upon end user requirements
- Is moot without timely data entry
CRF Design

- Standard structure
- Should facilitate data entry/ match data entry screen
- Must accommodate the person collecting the data
- All data points on a CRF should be related
- Only data points to be collected at a particular time point should be on one form
CRF Design

- Self explanatory
- Evident units
- Evident skip patterns
- Not visually overwhelming
- Uniquely numbered data points
- Limited text fields
- Finite number of data points
CRF Design

- One question, one time only
- Make sure question cannot be interpreted differently than intended
- Combine questions, when possible
2 Questions:

Do you work? Yes/No

If yes, how many hours per week? __ __ hrs/wk

Should be combined into 1:

How many hours per week do you normally work? (If none, enter 0) __ __ hrs/wk
SECTION I: DEMOGRAPHICS

1. Gender: □ Male □ Female

2. Date of birth _____-____-____ (mm-dd-yyyy)

3. Is the patient Hispanic, Latino, or Latina?
   □ No
   □ Yes

3.1 Specify origin:
   □ 1 Cuban
   □ 2 Mexican
   □ 3 Puerto Rican
   □ 4 Other: ______________________

4. With what race does the patient identify? (check all that apply)
   □ White or Caucasian
   □ American Indian or Alaska Native
   □ Black or African-American
   □ Native Hawaiian or other Pacific Islander
   □ Asian
   □ Other ______________________

5. Years of education completed: ______ □ N/A □ Unknown

6. Number of siblings (full or half brothers/sisters): _____

SECTION II: ADMISSION HISTORY

1. Initial hospital admission _____-____-____ (mm-dd-yyyy)

1a. Hospital transfer □ Yes □ No

   Date of transfer: _____-____-____ (mm-dd-yyyy)

2. Date and time enrolled _____-____-____ (24-hour time)

3. Date of onset of jaundice _____-____-____ (mm-dd-yyyy)
   □ N/A, patient not jaundiced

4. Symptoms that prompted patient or parent to seek medical attention

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unk</th>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea/vomit:</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>Lethargy</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>Malaise</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
## Good Design

### Form 02: Demographics (version 1)

<table>
<thead>
<tr>
<th></th>
<th>Ethnicity:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hispanic or Latino</td>
</tr>
<tr>
<td></td>
<td>Not Hispanic or Latino</td>
</tr>
<tr>
<td></td>
<td>Unknown or not reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Race:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>American Indian / Alaska Native</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
</tr>
<tr>
<td></td>
<td>Black / African American</td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian / Other Pacific Islander</td>
</tr>
<tr>
<td></td>
<td>White / Caucasian</td>
</tr>
<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>

|   | If other, specify: |

|   | Date of traumatic brain injury: |
|   | ___ ___ - ___ ___ - ___ ___ ___ (dd-mm-yyyy) |

|   | Time of traumatic brain injury: |
|   | ___ : ___ (24 hour clock hh:mm) |
Data types

- Defined data types greatly increase the quality of the data (limit text)
- Must set up for so that data is collected properly but that data entry is not blocked
- Data type should be clearly defined on the form
Data validation rules

- Based upon study protocol
- Based upon common logic
- Should ensure that data is properly collected without blocking data entry
- Soft rules and hard rules are needed
Data validation rules

- Warnings - missing data, range checks
- Rejections - logic violations
- Protocol violations - retraining tool
- Alert - communication tool
Reporting Capabilities

- Data quality reports
- Enrollment reports
- Subject Progress Reports
- Protocol adherence reports
- Monitoring reports
Balance between data quality and quantity

- More, more, more data!
- I might want to look at that some day....
- It’s not hard to collect -- it’s right there!
But.....

- Finite resources
- Data quality can suffer
- Is it required for proper management of the protocol?
- Is it included in your statistical analysis plan?
- Sometimes- Less is more.
- Sometimes- Less is too little.
Questions?