

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

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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

Poor Design

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

Black or African-American

Asian

American Indian or Alaska Native

Native Hawaiian or other Pacific Islander

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-yy)

1a. Hospital transfer Yes

No

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

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

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

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

	Yes	No	Unk		Yes	No	Unk
Nausea/vomit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lethargy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abdominal pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Malaise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Good Design

Form 02: Demographics (version 1)

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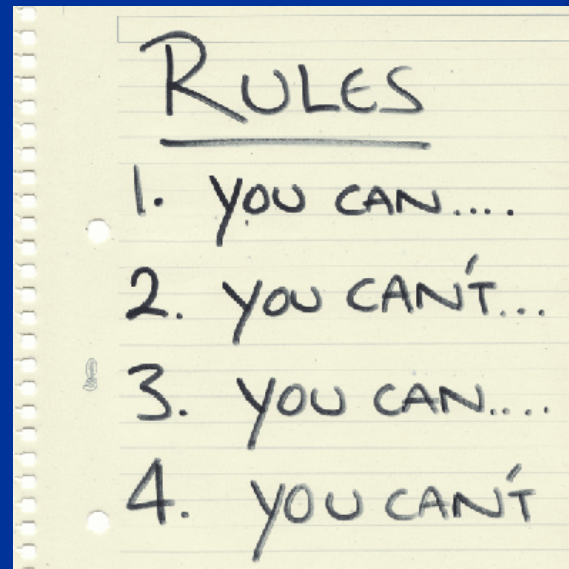
1	Ethnicity:	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Unknown or not reported
2	Race:	<input type="radio"/> American Indian / Alaska Native <input type="radio"/> Asian <input type="radio"/> Black / African American <input type="radio"/> Native Hawaiian / Other Pacific Islander <input type="radio"/> White / Caucasian <input type="radio"/> Other
3	If other, specify:	
4	Date of traumatic brain injury:	_____ (dd-mm-yyyy)
5	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?

