Case Report Form Design Issues

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Introduction

- Garbage in = Garbage out?
- Using Case Report Form (CRF) design guidelines to provide quality data

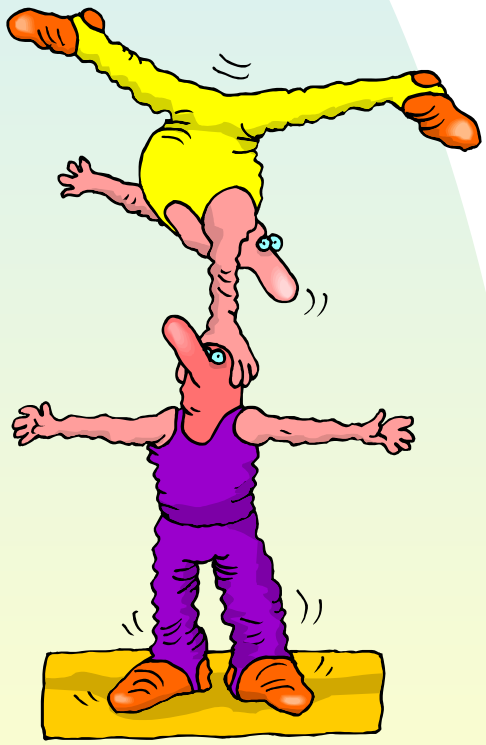
Topics of Discussion

- Timing of the CRF design process
- Participants in CRF design
- Goals of CRF design
- Selected CRF design guidelines
- Examples: good and not so good
- Process improvement
- Resources

Timing of the Design Process

- During protocol development
  - Pro: identification of problems with protocol procedures prior to protocol finalization
  - Con: numerous versions of CRFs may be necessary
- After protocol finalization
  - Pro: fewer versions of CRFs and fewer reviews prior to finalization
  - Con: if issues between CRF/data and protocol arise, protocol amendment may be required

Participants in CRF Design



- CRF Designer
- Statistician
- Medical Director for study
- Database Designer/Programmer
- Clinical Monitor
- Investigator/Site Coordinator
- Data Entry Personnel

Goals of CRF Design

- Check logistics, design, and practicality of the protocol
- Expedite accurate processing, analysis, and interpretation of data
- Check protocol adherence and/or investigator compliance
- Fulfill regulatory requirements

Cato, A., and Cook, L. (1984)

Selected CRF Design Guidelines

Language and Terminology

- Use well-known terminology and abbreviations
- Remember that some terms have different meanings to different people
- Provide definitions when necessary
- When a comparative judgement is required, define the basis for the comparison

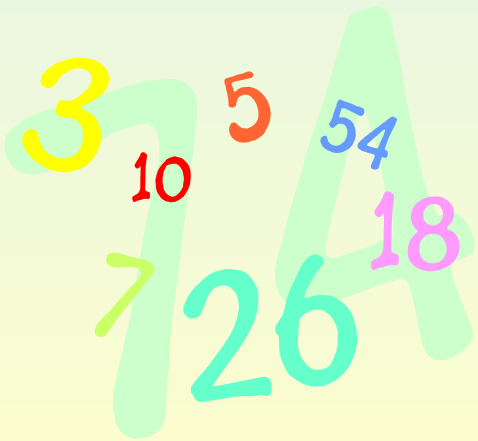
Language and Terminology Example

(If yes, record all information on the **Non-Study Feeding Record** form)		
7. been fed any solid/baby foods? (If yes, record all information on the **Non-Study Feeding Record** form)		
8. How would you describe your baby's overall acceptability and tolerability of this study formula? Satisfactory: Reason:_____ Unsatisfactory: Reason:_____		

Selected CRF Design Guidelines

Measurements/Calculations

- Specify unit of measurement
- Indicate the number of decimal placed to be recorded
- If an average value is to be calculated, create a place on the CRF for the calculation
- Indicate how measurements should be collected (rectal vs. oral temp., sitting vs. supine BP)



Measurements/Calculations Example 1

VITAL SIGNS

Was Exam Performed? ☐ **Yes**, complete below

☐ **No**, specify

reason:_____

Heart Rate: (beats/min)	**Respirations:** (resp/min)	**Temperature:**
☐☐☐/min	☐☐/min	☐☐☐.☐ **Unit:** ☐°F ☐°C **Method:** ☐ Oral ☐ Tympanic ☐ Rectal ☐ Axillary ☐ Other, specify:_____

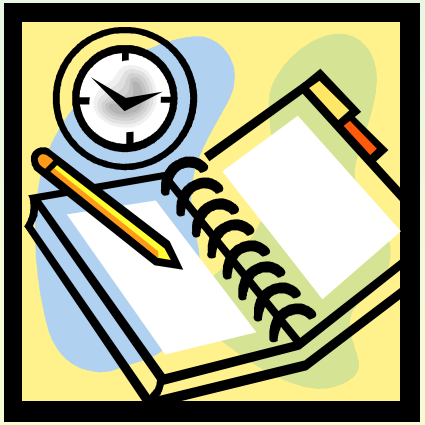
Weight:	**Length/Height:**	**Head Circumference:**
☐☐.☐☐ **Unit:** ☐kg ☐lb Scale ID: _____	☐☐.☐ **Unit:** ☐cm ☐in	☐☐.☐cm

Measurements/Calculations Example 2

Study Visit	1	2	3	
Study Period	Week –4	Week –2	Day 1	We
Exam Performed? Y=Yes N=No	Y N	Y N	Y N	Y
Date of examination (mm/dd/yyyy)	/ /	/ /	/ /	/
Date of last dose of test drug (mm/dd/yyyy)		/ /	/ /	/
Enter exact time (AM/PM) of the last dose of test drug		☐ AM ☐ PM	☐ AM ☐ PM	
Enter exact time (AM/PM) for start of BP measurements	☐ AM ☐ PM	☐ AM ☐ PM	☐ AM ☐ PM	
Body Weight (lbs)				
Circle Arm Used for Measuring Blood Pressure L=Left R=Right	L R	L R	L R	L
Blood Pressure (mmHg) (mean of 3 readings) Sitting Position – 5 min. — Systolic				
Blood Pressure (mmHg) (mean of 3 readings) Sitting Position – 5 min. — Diastolic				
Pulse Rate (beats/min) Sitting Position – 5 min.				

Selected CRF Design Guidelines

Times and Dates



- If using 24-hr clock times, indicate as such on the CRF
- If using 12-hr clock times, include AM and PM check boxes
- Collect dates in the same format (US or European) on all CRFs
- If complete dates are required, clearly indicate this on the CRF

Times and Dates Example

Study Visit	1	2	3	
Study Period	Week –4	Week –2	Day 1	We
Exam Performed? Y=Yes N=No	Y N	Y N	Y N	Y
Date of examination (mm/dd/yyyy)	/ /	/ /	/ /	/
Date of last dose of test drug (mm/dd/yyyy)		/ /	/ /	/
Enter exact time (AM/PM) of the last dose of test drug		☐ AM ☐ PM	☐ AM ☐ PM	
Enter exact time (AM/PM) for start of BP measurements	☐ AM ☐ PM	☐ AM ☐ PM	☐ AM ☐ PM	
Body Weight (lbs)				

Circle Arm Used for Measuring Blood Pressure L=Left R=Right		L R	L R	L R	L
Blood Pressure (mmHg) (mean of 3 readings) Sitting Position – 5 min.	Systolic				
	Diastolic				
Pulse Rate (beats/min) Sitting Position – 5 min.					

Selected CRF Design Guidelines

Miscellaneous

- Use “continuing” boxes for therapy, treatment, or AEs that may continue past study completion
- Capture the reason for each therapy, treatment, procedure, etc.
- Use AE prompts on applicable CRFs (concomitant therapy, procedures, treatments, exams, etc.)
- Avoid capturing the same piece of data in more than one place on the CRFs

Miscellaneous
Example 1

MEDICATION RECORD (ALL VISITS)

MEDICATIONS ☐ None			
Drug Name)	**Start Date** (MO/DY/YR)	**Stop Date** (MO/DY/YR)	**Continues (X)**
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐
	☐☐/☐☐/☐☐	☐☐/☐☐/☐☐	☐
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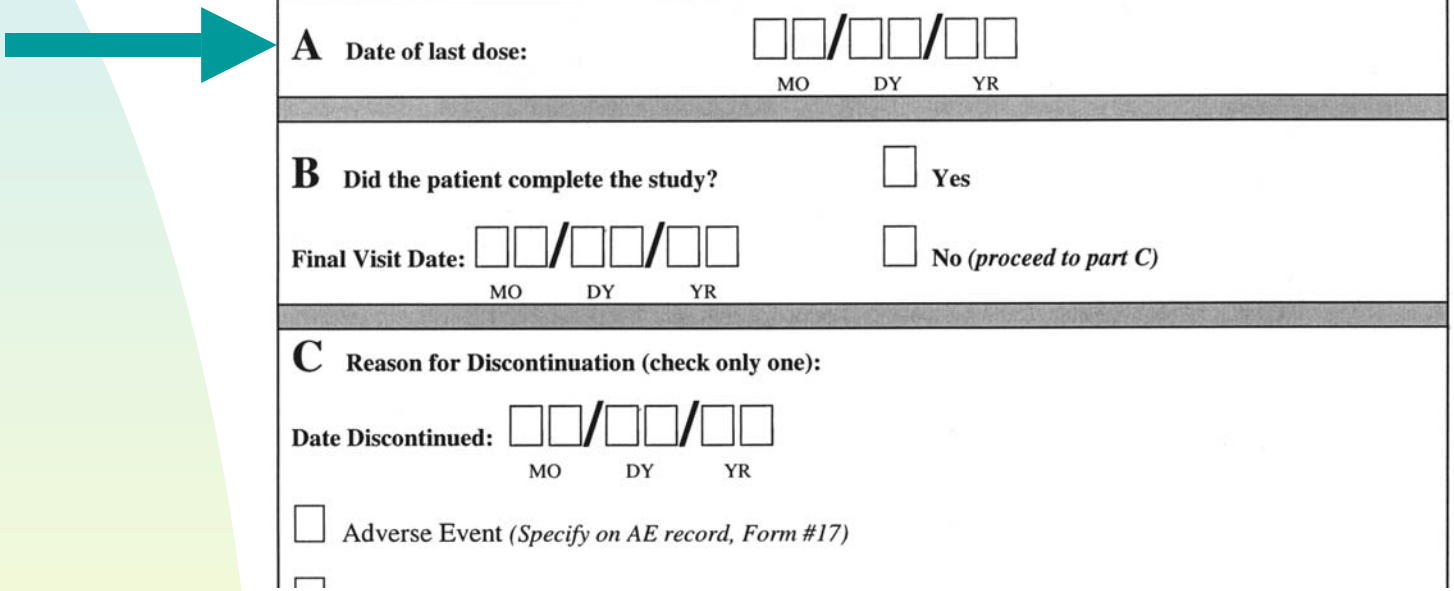
Miscellaneous
Example 2



COMPLETION/TERMINATION RECORD

A **Date of last dose:** ☐☐/☐☐/☐☐
MO DY YR

B **Did the patient complete the study?** ☐ **Yes**

Final Visit Date: ☐☐/☐☐/☐☐ ☐ **No** ***(proceed to part C)***
MO DY YR

C **Reason for Discontinuation (check only one):**

Date Discontinued: ☐☐/☐☐/☐☐
MO DY YR

☐ Adverse Event *(Specify on AE record, Form #17)*

☐

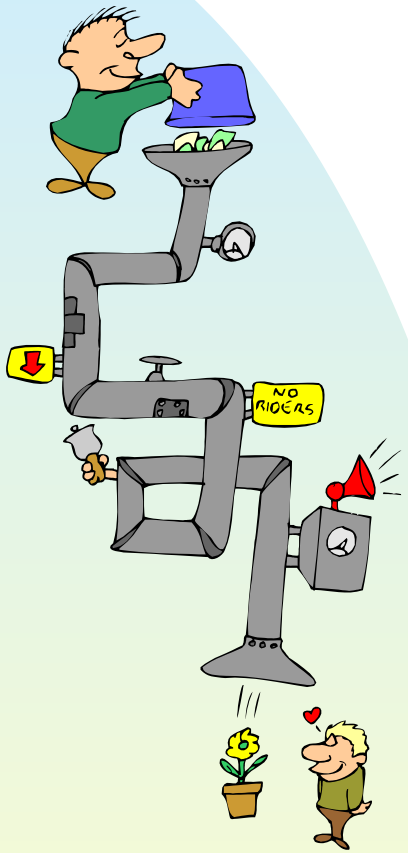
Process Improvement

- Define your organization's process for CRF design
- After study completion evaluate and document which CRFs worked well and which did not
- Get input from others involved in CRF design inside and outside of your organization

Resources

- Spilker, B., and Schoenfelder, J. (1991). *Data Collection Forms for Clinical Trials*. New York, NY, Raven Press.
- Good Clinical Data Management Practices, Version 3, September 2003, Society of Clinical Data Management.
- Drug Information Association (www.diahome.org)
- Society for Clinical Data Management (www.scdm.org)

Summary



To ensure quality data, apply CRF design principles:

- Determine the best time for the CRF design process
- Involve the right people
- Know the goals of CRF design
- Apply CRF design guidelines
- Include process improvement as part of CRF design
- Search out resources