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## Using FrameMaker's Advanced Features to Create Customized Case Report Forms

Martha Thompson  
Statistical Center for HIV/AIDS Research and Prevention  
(SCHARP)

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### Preview

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- SCHARP Overview
- What is a customized CRF?
- Why Customize CRFs?
- FrameMaker Basics
- Solutions Lead to Innovations
- What We Learned

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## SCHARP Overview

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- SCHARP (formerly HIVNET) is the statistical coordinating center for an NIH-funded network of HIV prevention trials conducted at both domestic and international sites
- SCHARP functions



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## SCHARP Overview, continued

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- Studies
  - Numerous (26+)
  - Varied science (Behavioral, Epidemiological, Clinical, etc)
  - Need for cross-study analysis
  - Often very long studies (2-5 years)
- Sites
  - Numerous
  - Some site staff are new to research/clinical trials
  - Usually running many studies at once, not just ours
  - Can have high turnover of staff

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## What is a customized CRF?

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- A customized CRF is an electronic file which behaves like a template for a multitude of products
- In a few keystrokes, this file (or an entire form set) can be altered for output as
  - a DataFax disabled draft or pilot CRF
  - a site- or cohort-specific final CRF
  - a DataFax background screen with custom coding that is not printed on the site's CRF
  - a blank CRF background screen for annotated SAS data sets

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## Why customize CRFs? The life of a single CRF at SCHARP

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### Draft Version of CRF

- Draft CRF
- Reviewed by Protocol Team
- Reviewed by internal SCHARP Study Team
- May be sent to sites for pilot testing

### Final Version of CRF

- Issued to sites as final CRF (could be hard copy or PDF)
- Postscript version, used for DataFax screen backgrounds
- Same postscript file gets used for background CRF image for annotated SAS data sets

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## Why Customize CRFs?

### Some problems we encountered

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|---------------------|--|
| Draft CRF           | <ul style="list-style-type: none"><li>• Identify as Sample or Draft</li><li>• Disable Signature Line and Study Barcode</li></ul> |
| Final CRF for Sites | <ul style="list-style-type: none"><li>• Customize with Site ID and Site Name</li></ul>   |
| Postscript CRF      | <ul style="list-style-type: none"><li>• Didn't want Site ID and Site Name customization to appear</li></ul>                      |

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## FrameMaker tools: a brief introduction

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- Text Lines v.s. Text Frames
- Variables
- Conditional Text
- Anchored Frames
- FrameMaker Book files
- Importing Formats

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## FrameMaker basics: text lines v.s. text frames

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### Text Lines

- are a single graphic element
- can't use any of Frame's advanced text features
- can only be formatted with character tags/designer

### Text Frames

- contain a text flow
- can use any of Frame's advanced text features, including
  - text wraparound
  - paragraph tags/designer
  - conditional text
  - variables
  - cross-referencing
  - autonumbering
  - anchored frames

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## FrameMaker basics : variables

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- Variables
  - must be inside a text frame
  - can be alpha or numeric
  - can be a pre-defined system variable, or a user-defined variable
- We use user-defined variables for Site ID and Site Name

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## FrameMaker basics : anchored frames

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- Anchored Frames:
  - must be inside a text frame
  - can be used to attach objects to a text flow
  - user can assign conditional text tags to anchored frames

Relationship to Study Drug Treatment

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## FrameMaker basics: books

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- What is a FrameMaker book?
  - a set of files that the user assembles
- What do books do?
  - arrange files in specific order
  - user can open, save, print, or import formats for any subset or all of the files in the book

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## FrameMaker basics : importing formats

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- Can be implemented at the file or book level
- The user tells Frame to import formats from another file, making sure only Variable Definitions and Conditional Text Settings are selected

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## Import Format files

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Case	Conditional Text Setting	Variable Definition
Sample	Show sample, show coded	000, Site Name
Site #1	hide sample, show coded	010, Boston
Site #2		020, New York
Site #3		030, Chicago
Postscript	hide sample, hide coded	Hidden

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## Solutions Lead to Innovations

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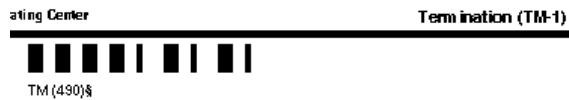
- Visit Coding that is invisible to sites

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## Example: Visit Coding, Termination form

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Show coded for sites: visit boxes are invisible



Hide coded for postscript: visit boxes visible



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## Solutions Lead to Innovations


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- Visit Coding that is invisible to sites
- Visit Coding that is partially invisible to sites


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## Example: Visit Coding, Concomitant Meds log

Show coded for sites: some visit boxes are invisible

Study Center	Concomitant Medications Log (CM-1)
	Page <input type="text"/> <input type="text"/>
CM (423)	<i>Note: Number</i>

Hide coded for postscript: all visit boxes visible

Study Center	Concomitant Medications Log (CM-1)
	Visit Code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CM (423)	Page <input type="text"/> <input type="text"/> <i>Note: Number</i>

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## Solutions Lead to Innovations

- Visit Coding that is invisible to sites
- Visit Coding that is partially invisible to sites
- Demographics question important for cross-study analysis that is invisible to sites

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**Example:**  
**Extra question, Demographics form**

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Show coded for sites: extra question is invisible

*Fax first page (SE-1) only to HIVNET Datafax*

1a. Birthdate, if available:      *da*      *mm*      *yy*  
         

2. What is your current marital status?

never married

married (monogamy)

Hide coded for postscript: extra question is visible

*Fax first page (SE-1) only to HIVNET Datafax*

1a. Birthdate, if available:      *da*      *mm*      *yy*  
         

2. What is your current marital status?

never married

married (monogamy)

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**Solutions Lead to Innovations**

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- Visit Coding that is invisible to sites
- Visit Coding that is partially invisible to sites
- Demographics question important for cross-study analysis that is invisible to sites
- Cohort-specific question that is invisible to all other cohorts

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## Example: Cohort-specific question

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Show "cohort 1" for that cohort and postscript

8. Have you ever had an adverse reaction to products containing latex or nonoxynol-9 (such as condoms, rubber gloves, diaphragm jelly)? .....

➔ *if yes to any of*

Hide "cohort 1" for all other cohorts

8. Have you ever had an adverse reaction to products containing latex or nonoxynol-9 (such as condoms, rubber gloves, diaphragm jelly)? .....

➔ *if yes to any of*

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## What we learned

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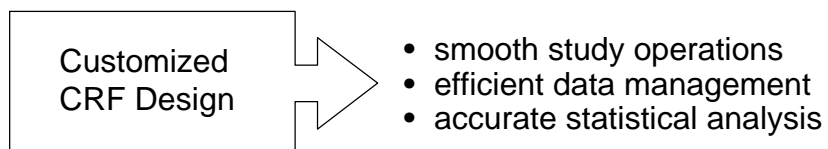
- Don't make it more complicated than it needs to be
- Have as few tags as possible
- Make the tag name generic, so can be used in other studies

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## Summary

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- Frame's advanced text features allow us to streamline design and production of CRFs



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