
Efficient Creation & Distribution of CRFs for DataFax Systems

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Efficient Creation & Distribution of CRFs for DataFax
Systems

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SCHARP Overview

- Public Health Sciences Division,
Fred Hutchinson Cancer Research Center,
Seattle, WA
- Statistical Data Management Center
(SDMC)
 - HIV Prevention Trials Network (HPTN)
 - HIV Vaccine Trials Network (HVTN)
 - Acute HIV Infection Network (AHIN)

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Efficient Creation & Distribution of CRFs for DataFax Systems

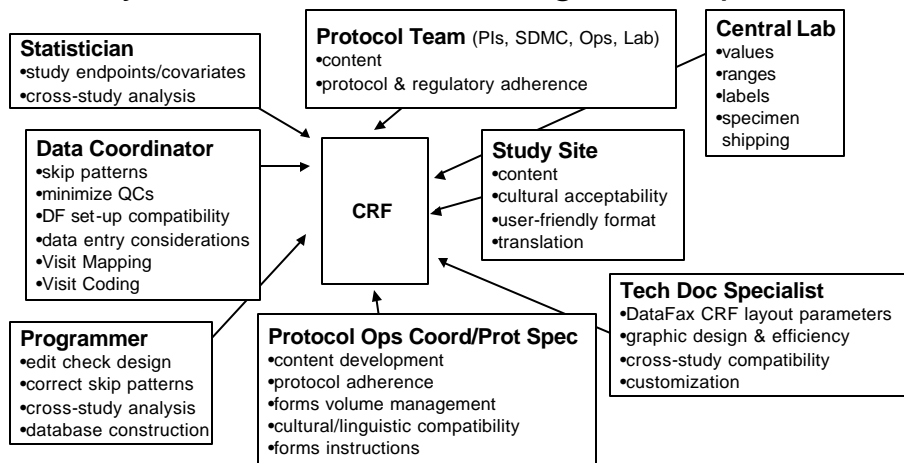
- CRF development process
- Effective CRF design for DataFax
- Using advanced FrameMaker tools to customize CRFs
- Distribution of CRFs

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CRF Development Process

Players/Factors Influencing Development



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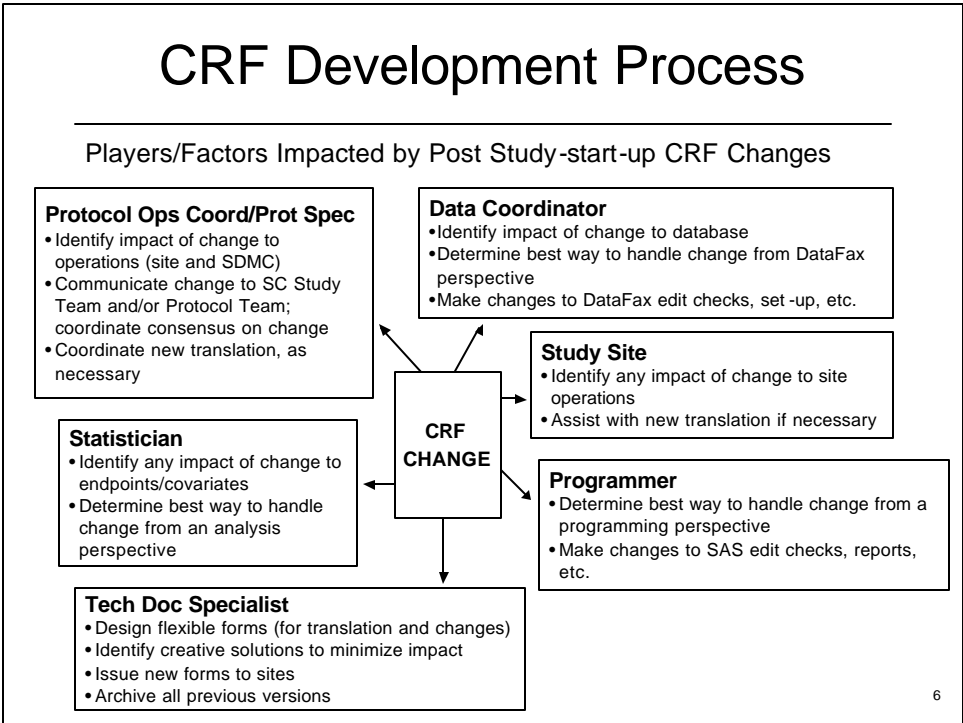
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CRF Development Process

- CRF content determined
- On-line CRF development begins
- SC Study Team process begins
- DataFAX visit map and schedule of forms created
- Draft CRF set completed
 - DataFAX set-up begins
- CRF walk-through with Study Team
 - Forms pilot tested at sites
- CRF revisions made
- Draft CRF form set sent to Protocol Team for sign-off
- Internal forms review
 - DataFAX set-up completed, Site Training, CRF translation
- Final CRF revisions made
- CRF and other study materials produced and distributed

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Effective CRF Design for DataFax

- CRF Development Tips
 - Establish and document CRF conventions
 - Establish and document a version control plan for CRF changes
 - Establish a formal CRF review process
 - Standardize forms wherever possible (e.g., create CRF libraries or modules)
 - Provide users with forms instructions that include DataFax-specific information (e.g., how to correctly mark a response box, how to mark changes, etc.)

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Effective CRF Design for DataFax

- CRF Design Tips
 - Follow DataFax specifications
 - Create a CRF template
 - Design template so that it can be used for 8.5 x 11 and A4 page sizes (to support both domestic and international sites without having to make any changes)
 - Include all CRF elements that repeat on every form (e.g., organization name, binary version code, etc.)
 - Create standard character and paragraph styles (to ensure consistency and efficiency)
 - Include CRF “clip-art” (e.g., date boxes, response check boxes, barcodes, arrows, etc.)

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Effective CRF Design for DataFax

- CRF Design Tips cont.
 - Utilize as many of your software's automation tools as possible (e.g., FrameMaker's variables, conditional text, anchored frames, etc.)
 - Include binary version code and version date on every CRF
 - Include file (and pathname) on every CRF
 - Allow for as large a bottom margin as is feasible (to eliminate the possibility of data being lost if a faxed image is skewed)

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Effective CRF Design for DataFax

- CRF Design Tips cont.
 - Use distinctive text styles to distinguish between interviewer instructions and participant questions
 - Recommended response box sizes
 - boxes that will hold numbers (hard coded or handwritten) or date information (including 3-character month), use .25" x .25"
 - response check boxes, use .166" x .166"
 - Recommended choice box positioning
 - If a question is "Mark all that apply," arrange the boxes in the most space-efficient way
 - If the question is "Mark only one," arrange the boxes as to not obscure the labels in DataFax set-up

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Effective CRF Design for DataFax

EXAMPLE: *Mark all that apply.*

9b. Please specify reason the participant was not enrolled. *Mark all that apply.*

<input type="checkbox"/> ineligible	<input type="checkbox"/> medical procedures too intrusive
<input type="checkbox"/> partner was not able/willing to provide informed consent or does not satisfy low risk criteria for HIV infection	<input type="checkbox"/> visit schedule too demanding
<input type="checkbox"/> concerns about possible harm	<input type="checkbox"/> compensation inadequate
	<input type="checkbox"/> other, please specify: _____

EXAMPLE: *Mark only one.*

2c. Early termination. Please indicate primary reason below. *Mark only one.*

<input type="checkbox"/> Participant refused further participation.
<input type="checkbox"/> Participant unable to adhere to visit schedule.
<input type="checkbox"/> Participant relocated, no remote follow-up planned.
<input type="checkbox"/> Investigator decision, please specify: _____

7a. In the last 3 months, how often did you use a female condom (such as Femidon or Reality®) when you had vaginal intercourse? *Mark only one.*

<i>never or rarely</i>	<i>sometimes</i>	<i>about half the time</i>	<i>often</i>	<i>almost always or always</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Effective CRF Design for DataFax

- CRF Design Tips cont.
 - Pre-code as much data as is appropriate (e.g., visit codes, site number, etc.)
 - Whenever possible, “hide” information on the CRF that is only necessary in the DataFax background (e.g., the visit code on a termination form)
 - Use standard form names and acronyms
 - Avoid using underlined text
 - Consistency is key: use the same size boxes, line widths, arrows, fonts, etc. on all CRFs and form sets

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Using Advanced FrameMaker Tools to Customize CRFs

- **Conditional Text**
- **Anchored Frames**
- **Variables**
- **FrameMaker Books**

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Advanced FrameMaker Tools: **Conditional Text**

- Conditional text can be used to create multiple variations of a single document
- Can be used to make text appear or disappear
- Any unit of text can be made conditional, from one character to entire sections

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Advanced FrameMaker Tools: Conditional Text

Sample conditional text setting for draft CRFs (disables DataFax signature line and study barcode)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

SAMPLE: DO NOT FAX TO DATAFAX

HIV020 PRO2000 Intl (049) Missed Visit (463)

Participant ID

Conditional text setting for domestic vs. international versions of the same form (switches date labels and DataFax study barcodes)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

HIV020 PRO2000 Domestic (039) Missed Visit (463)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)

HIV020 PRO2000 Intl (049) Missed Visit (463)

Participant ID

Advanced FrameMaker Tools: Conditional Text

Site version (displays hard coded data)

DataFax postscript (hides data)

<p>Statistical Center for HIV/AIDS Research & Prevention (SCHARP)</p> <p>HIV020 (049) ENR1 (024) Enrollment Unit (001) Page 1 of 1</p> <p>Participant ID: 01010102</p> <p>Enrollment Unit: A or B (Domestic) C or D (Intl)</p> <p>1. Participant Category: Mark only one.</p> <p>2. Was a Screening ID other than the assigned protocol-specific? Participant ID used to label specimens sent to an HIV-1 Reference Laboratory? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>2a. Did the Screening ID use the SCHARP format? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p>2a1. Enter the Screening ID: 01010102</p> <p>QUESTIONS FOR PARTICIPANT</p> <p>3. For each of the following reasons, please indicate how much you agree or disagree with each statement.</p> <p>3a. I joined the vaccine trial because... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3b. I receive the HIV tests... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3c. I receive other tests or medical care... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3d. I expect to help fight a vaccine that might... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3e. The vaccine might protect me against HIV... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3f. I will be paid for being in the study... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3g. I will be informed about HIV research... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3h. It might help me to avoid high-risk behavior... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3i. I am helping my community... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>3j. I know someone with HIV infection... <input type="checkbox"/> agree strongly <input type="checkbox"/> agree <input type="checkbox"/> agree not at all <input type="checkbox"/> disagree strongly</p> <p>4. We do not know if the vaccine we are testing will protect against HIV infection, and if it does, how much protection it will provide. How effective do you think the vaccine is likely to be?</p> <p>not effective at all <input type="checkbox"/> not effective <input type="checkbox"/> somewhat effective <input type="checkbox"/> very effective <input type="checkbox"/> don't know</p> <p>October 11, 2000</p>	<p>Statistical Center for HIV/AIDS Research & Prevention (SCHARP)</p> <p>HIV020 (049) ENR1 (024) Enrollment Unit (001) Page 1 of 1</p> <p>Participant ID: []</p> <p>Enrollment Unit: A or B (Domestic) C or D (Intl)</p> <p>1. Participant Category: Mark only one.</p> <p>2. Was a Screening ID other than the assigned protocol-specific? 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How effective do you think the vaccine is likely to be?</p> <p>not effective at all <input type="checkbox"/> not effective <input type="checkbox"/> somewhat effective <input type="checkbox"/> very effective <input type="checkbox"/> don't know</p> <p>October 11, 2000</p>
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Advanced FrameMaker Tools: Anchored Frames

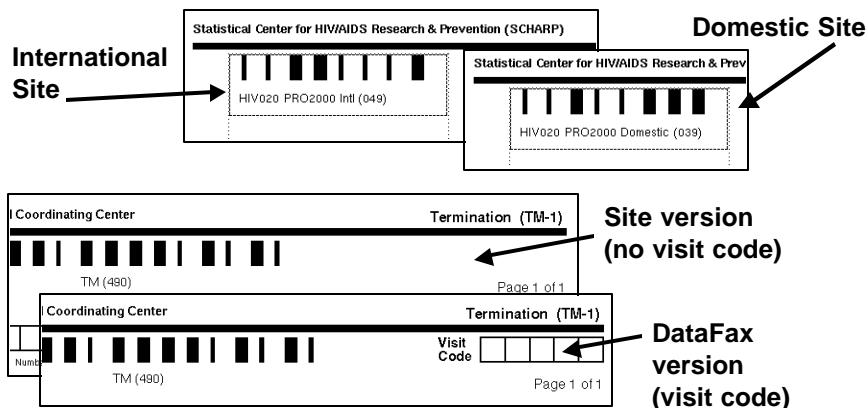
- Anchored frames are used to attach graphic objects to text so that when text is edited, the graphic moves along with it
- Anchored frames can be placed in multiple positions in relation to the text (above, below, inline, sidebar, etc.)
- Conditional text tags can be assigned to anchored frames, allowing you to “hide” or “show” graphics

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Advanced FrameMaker Tools: Anchored Frames

CRF graphics, such as study barcodes and visit codes, can be placed in an anchored frame with a conditional tag allowing creation of different “versions” of a single form from one file



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Advanced FrameMaker Tools: Anchored Frames

As a result of your participation in a vaccine study, have you had any social impacts you have not previously told us about? Have you...

	yes	no		<i>if yes...</i>	What impact has this had on your quality of life?		
	<input type="checkbox"/>	<input type="checkbox"/>	▶		<i>minimal</i> disturbance	<i>moderate</i> disturbance	<i>major</i> disturbance
1. been turned down for a new job, lost a job, or experienced other problems at work?.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. had trouble getting or keeping housing, or had other problems related to housing?.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. had any other problems? Please specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

As a result of your participation in a vaccine study, have you had any social impacts you have not previously told us about? Have you...

	yes	no		<i>if yes...</i>	What impact has this had on your quality of life?		
	<input type="checkbox"/>	<input type="checkbox"/>	▶		<i>minimal</i> disturbance	<i>moderate</i> disturbance	<i>major</i> disturbance
1. been turned down for a new job, lost a job, or experienced other problems at work?.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. been turned down by an educational program, told to leave an educational program, or experienced other problems at school?.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. had trouble getting or keeping housing, or had other problems related to housing?.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. had any other problems? Please specify:.....	<input type="checkbox"/>	<input type="checkbox"/>	▶		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In anchored frames, response boxes automatically moved with each question when another question was added

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Advanced FrameMaker Tools: Variables

- Variables are used where text is repeated in more than one place
- Variables can be used to insert information on a CRF that can be changed for each “customized” version of the form
- Variables can be system generated (e.g., date, page number, file name, etc.) or user defined

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Advanced FrameMaker Tools: Variables

Variables, such as site number, cohort, and visit code variables can be changed to create customized versions for each site or situation

CRF name and acronym in two locations remain consistent as one variable

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Advanced FrameMaker Tools: FrameMaker Book Files

- FrameMaker books tie several files together so you can work with them as one unit
- Many components of the files can be changed and managed on a book level
- The same file can be included in multiple books

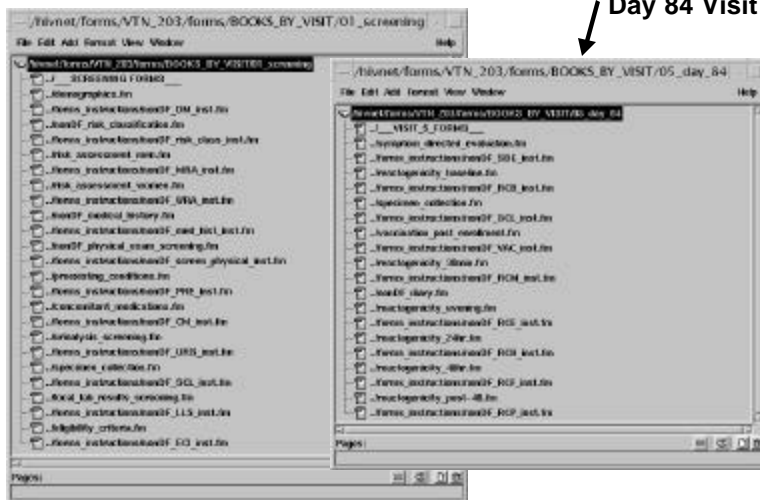
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Advanced FrameMaker Tools: FrameMaker Book Files

Books can be created using the same files for specific purposes

Screening Visit

Day 84 Visit

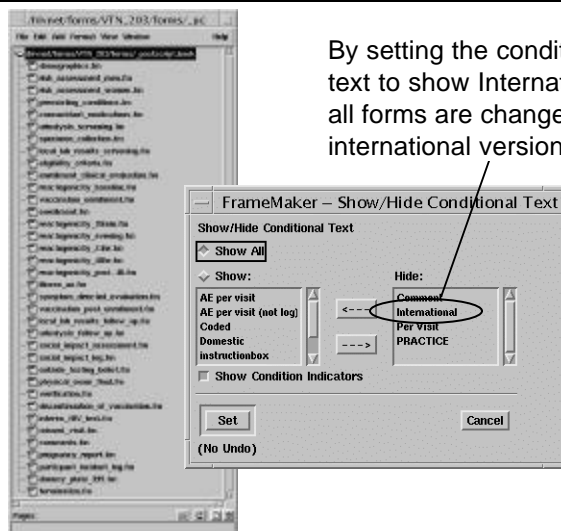


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Advanced FrameMaker Tools: FrameMaker Book Files

Conditional text settings can be set on a book level

By setting the conditional text to show International, all forms are changed to the international version

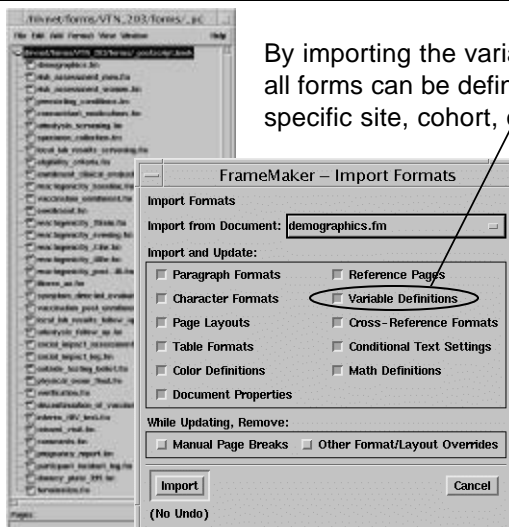


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Advanced FrameMaker Tools: FrameMaker Book Files

Multiple elements can be imported from one file into a book

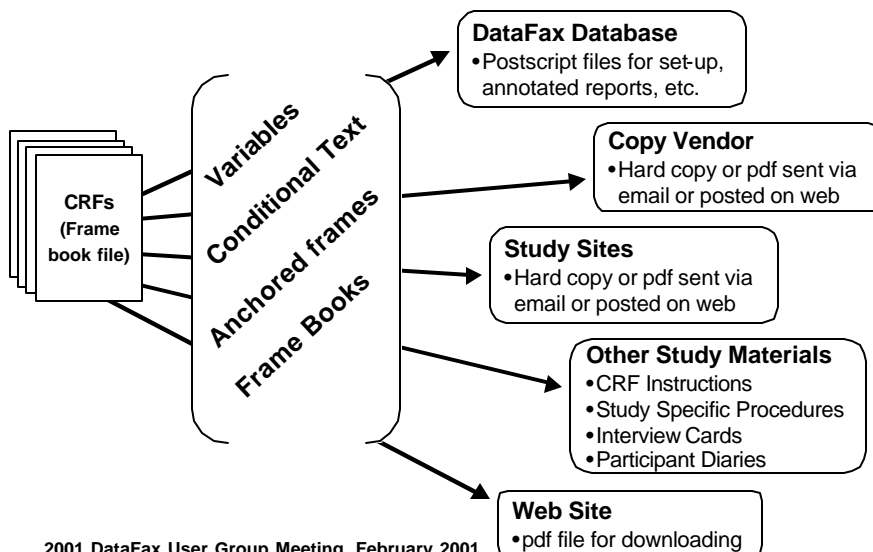


By importing the variable definitions, all forms can be defined for a specific site, cohort, or visit

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Distribution of CRFs



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Efficient Creation & Distribution of CRFs for DataFax Systems

- Create a CRF development process
- In addition to following DataFax's CRF design guidelines, create other time-saving CRF conventions
- Use a powerful software application for creating and customizing CRFs (such as Adobe FrameMaker)
- Regardless of what software you use, ensure that it includes flexibility for different output and distribution options

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On-line Resources

- **Statistical Center for HIV/AIDS Research & Prevention (SCHARP):** www.scharp.org
HIV/AIDS Research organization within the Public Health Sciences Division of the Fred Hutchinson Cancer Research Center in Seattle, WA.
- **Adobe FrameMaker:** www.Adobe.com
A great solution for designing and publishing Case Report Forms and other study materials in multiple formats and across computer platforms.
- **FrameMaker User Reference site:** www.FrameUsers.com
A comprehensive FrameMaker® Reference Site and largest FrameMaker User Network (FUN) available to anyone around the world. Their email list is the most useful Frame resource we've found.
- **DataFax:** www.datafax.com
DataFax is the premier fax-based data management system for clinical trials.

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