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## deSCRIBE for DataFax

A Graphical User Interface for  
Planning and Documenting Your  
Study Design

### History

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- The Combined Specification was presented at the 1999 DFUG as a way to
  - describe a DataFax Study set-up in a single document
  - provide version history
  - demonstrate management approval
- DocuPrint was a command line tool designed to quickly produce that spec
- deSCRIBE is the next step in the development of this tool.

## deSCRIBE Goals

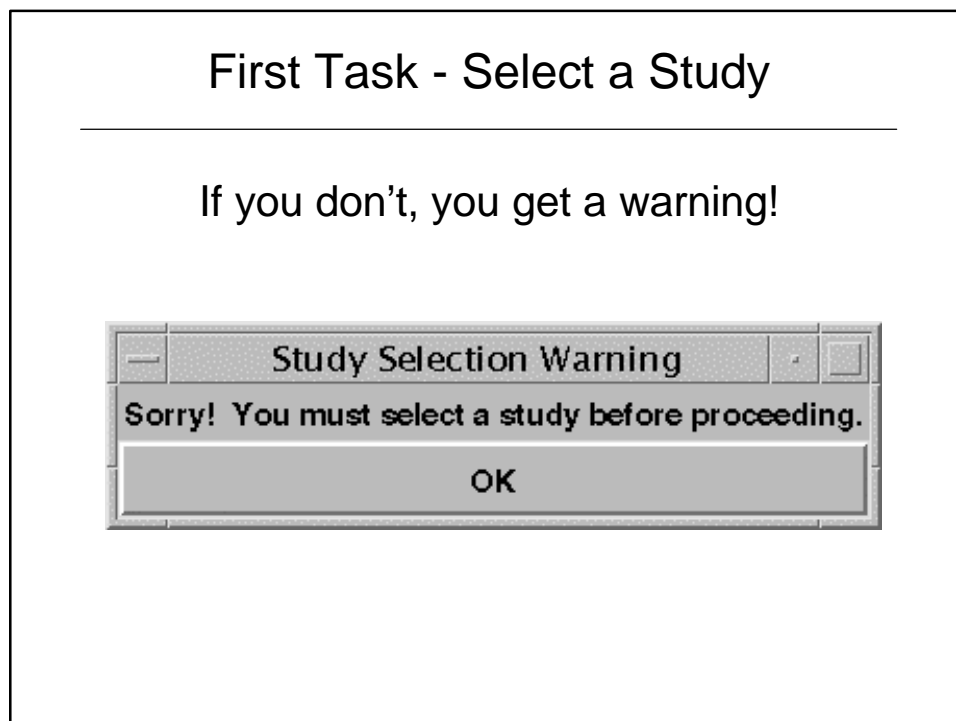
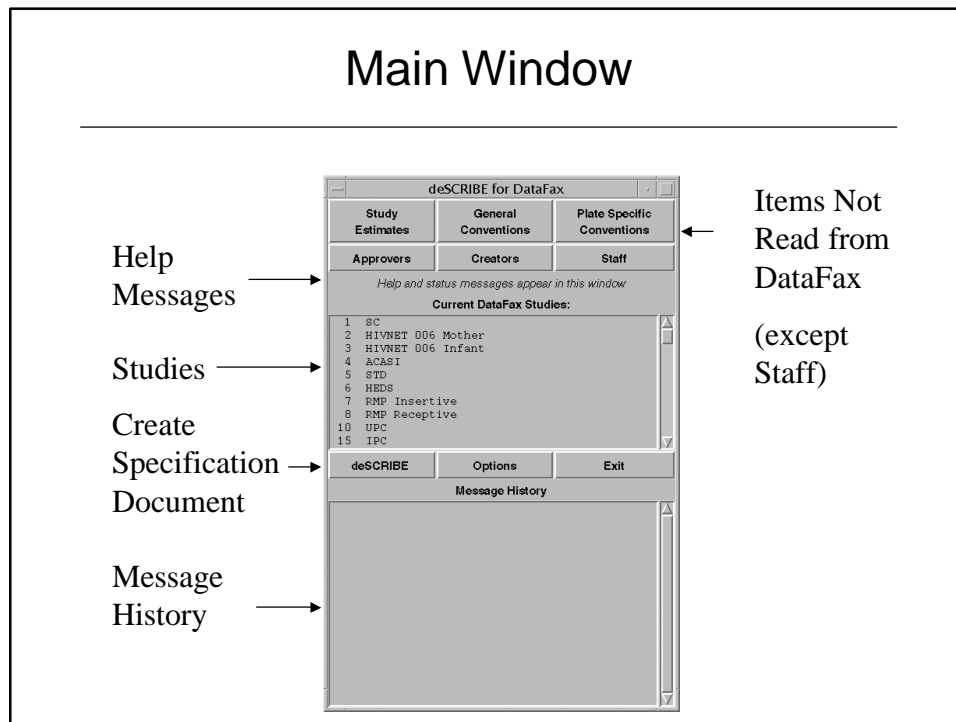
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- Fully explain the set-up of a DataFax Study in a single document with minimal user intervention
- Provide a Graphical User Interface virtually any staff member can use
- Incorporate new elements in DFschema provided in DataFax 3.4
- Perform additional MIF code checks

## Sources of Information

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- |                 |                         |
|-----------------|-------------------------|
| •DFgetparam.rpc | •DFfile_map             |
| •DFschema       | Sequence Code Location  |
| •DFschema.stl   | Early Termination       |
| •DFvisit_map    | •DFtips                 |
| •DFpage_map     | Field locations         |
| Form Names      | Pre/Post Processes      |
| •DFcplate_map   | •DFuserPerms -l         |
| •DFlut_map      | •specSTOR               |
| •DFmissing_map  | User Defined Variables  |
|                 | Created outside DataFax |



## Study Estimates Window

- Helps plan disk space and personnel requirements
- Short and long term

Edit Estimates of Anticipated Requirements for Study 38				
Save		Close		
Study Start Date	Time to Completion	Forms / Patient	# Patients	Refax Factor
15-Apr-1999	12 Years	10	1500	1.3
During First Year		36	300	1.1

## General Conventions

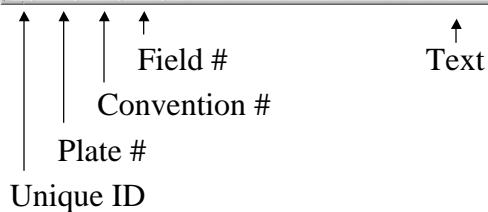
Add / Edit General Conventions / Assumptions	
Add	Delete
Save	
Close	
<i>Click here to edit convention 1. Conventions can be longer than the entry window. Just keep typing.</i>	
#	<b>Data Control Technician Notes which apply to ALL Plates</b>
1	A Y will be entered for any comments text field in which comments are found. The comments themselves will not be entered.
2	All other text fields will be entered completely.
3	If text fields are illegible, enter as much as is readable and indicate the illegible portion with three question marks.
4	Illiterate or poorly worded text fields should be entered exactly as written.
5	If a required field is blank, add a QC note requesting it be completed.
6	All DCTs will enter QC notes as internal. A DC will review all internal QC notes before changing them to external and sending.
7	All fields must be tabbed through.
8	Required fields that are left blank will turn red. A QC note must be added to blank required fields before datafax will allow the
9	All numeric fields must be filled in completely. A QC note must be added if leading zeros are missing.

↑  
Unique ID

↑  
Text

## Plate Specific Conventions

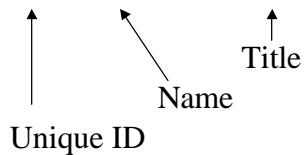
Add / Edit Plate Specific Conventions / Assumptions					
Add		Delete		Save	Close
#	Plate	Convention	Field	Data Control Technician Note	
1	100	1	10	Start date required only at Visit 202 and 302 UNLESS Cycle 3 participant is PreCore.	
2	101	1	79	If additional plates are faxed in, fix the barcode on the subsequent pages so they are sequentially numbered plates 102, 103	
3	101	2	10	Start date required only at Visit 202 and 302 UNLESS Cycle 3 participant is PreCore.	
4	102	1	79	If additional plates are faxed in, fix the barcode on the subsequent pages so they are sequentially numbered plates 103, 104	
5	102	2	10	Start date required only at Visit 202 and 302 UNLESS Cycle 3 participant is PreCore.	
6	103	1	79	If additional plates are faxed in, fix the barcode on the subsequent pages so they are sequentially numbered plates 104, 105	
7	103	2	10	Start date required only at Visit 202 and 302 UNLESS Cycle 3 participant is PreCore.	
8	104	1	79	If additional plates are faxed in, fix the barcode on the subsequent pages so they are sequentially numbered plates 105, 106	



## Approvers

### “Responsible Heads”

Add / Edit Specification Approvers				
Add		Delete	Save	Close
#	Name	Title		
1	Al Willians	Database Manager		
2	Renee Holt	Protocol Operations Coordinator		
3	Darryl Pahl	Database Manager		
4	Yijian Haung	Faculty Statistician		
5	Tom Darden	Deputy Director		



## Creators

Add / Edit Specification Creators			
	Add	Delete	Save
#	Name	Title	Function
1	Phil Kirsch	System Administrator	General Study Configuration
2	Stacie Kentop	Desktop Publisher	Plate Backgrounds
3	Janet Quade	Data Coordinator Supervisor	Style / Data Definitions / Standard QC Notes
4	Nena Gannon	Data Coordinator Supervisor	Style / Data Definitions / Standard QC Notes
5	Claire Lyons	Data Coordinator	Style / Data Definitions
6	Scott Horton	Data Operations Manager	DataFax Edit Checks, Conventions and Assmptions
7	Thula Weisel	Project Manager	All
8	Leslie Cottle	Protocol Operations Coordinator	All
9	Lzhi Xie	Programmer	SAS Names, DataFax and SAS Edit Checks

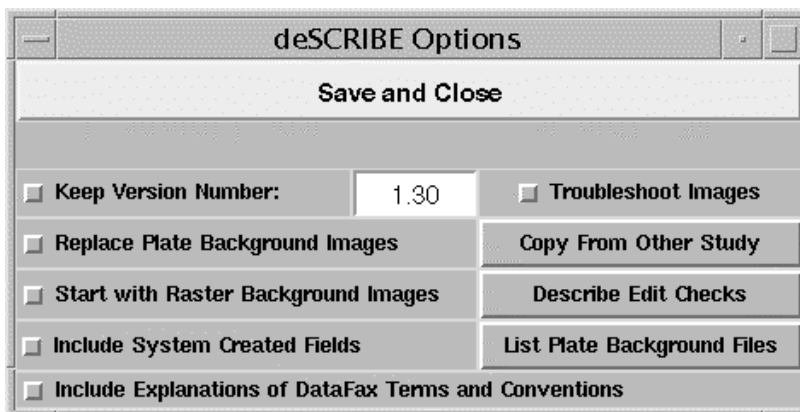
↑      ↑                      ↑                      ↑  
**ID   Name                      Title                      Function**

## Staff

View Staff Permissions Table								
Close								
User	Maximum Level	Status Tool	Set-Up Tool	CRF Viewer	Reports Tool	QC Tool	Validation Tool	Lost Data
alice	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
carrie	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ckwelly	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
darryl	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
datafax	7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
deborah	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
horton	7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
janelq	7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
lernel	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
lynebr	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
mklotz	7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
nenag	7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
peter	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

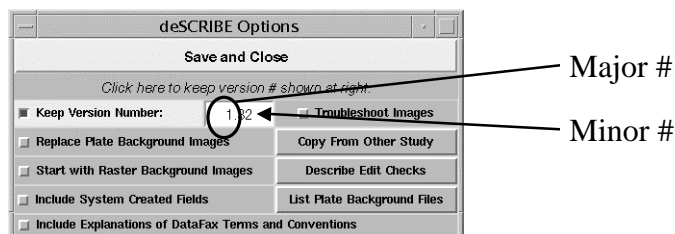
- Possible Future Additions:
- Full Name
  - Title
  - Function
  - Add Button
  - Edit Function

## Options



## Option #1: Version Number

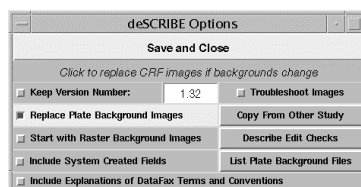
- User-Definable
- Auto-Increments (*decimal portion*)
- Included in the name of the output file
- Keeping a previous version number overwrites a previously created file



## Option #2: Replace Images

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- Plate Images with Field Numbers provide a key to the all plate-specific tables
- These need to be replaced when image background files are updated or additional fields are defined



## Option #3: Start with Raster

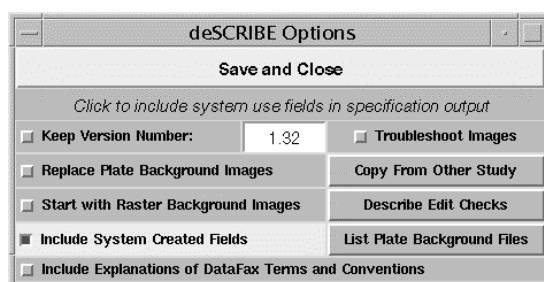
---

- A single postscript prologue is created every time plates are imported
- If you perform another import without re-importing previously defined plates, prologue information may be missing
  - Which may interfere with DFprintdb
  - DocuPrint and deSCRIBE
- Starting with Raster Images solves this problem, but reduces image quality

## Option #4: Include System Fields

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- Fields 1-7, N, N-1 and N-2 are included in Field Definition Tables
- Primarily targeted at individuals with minimal prior DataFax experience



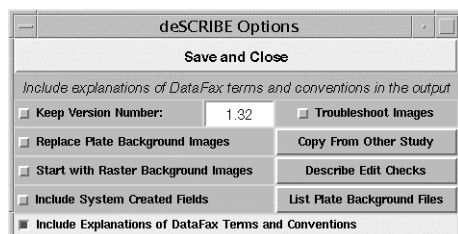
## Option #5: Explanations

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Adds explanations of terms like

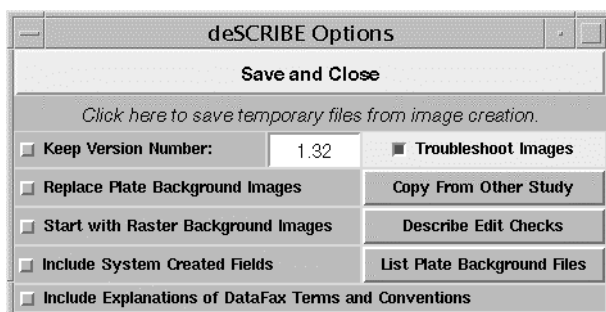
- Plate
- Visit
- Page Map

to the output document



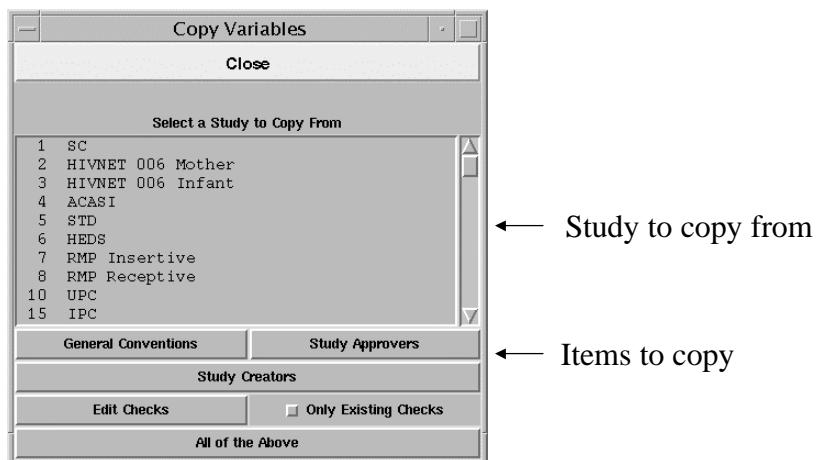
## Option #6: Troubleshoot Images

- Saves temporary files from the image creation process
- Can be used to research problems



## Option #7: Copy From Other Study

- Quickly import User Defined variables



## Option #8: Describe Edit Checks

- Summarize purpose or function

Check Name	Description
Hastr_date	Checks to see if the start date is given when visit code is 101 or 201 and the event code is filled.
LNon_adp	Alert DCTs that this is not an AIEDRP visit and they need to find the correct visit code.
LRespec_method	Checks to make sure that the method is specified if the "Other-Specify" method field is marked.
TR_med_consistent	Erases 99 from the medication code field if the current field and the four fields in between are blank or adds QC n
TR_stop_ongoing	Confirm that "stop-date" OR "ongoing" is completed, BUT NOT BOTH.
add_9000	Adds 9000 to the page number.
chk_PHAill	Checks to make sure that if field #6 is marked as yes, then at least one event code must be provided.
chk_TT1B	Checks to make sure that if field is marked, then no other fields above are marked. Also checks to make sure if
chk_age	Checks that the participant is 18 years of age or greater.
chk_both	Checks that the test date field must be completed if this field is marked, or both must be blank.
chk_cycle	Determine the cycle number 1, 2, or 3.
chk_date	Checks that either a code exists and a start date is completed or neither are completed.
chk_ether	Checks that either this field or the previous field must be completed, but not both.

↑  
Name

↑  
Description

## Option #9: CRF File Locations

- Can be used to find CRF files when plates need updating

Plate #	Plate Label	File Location
010	Enrollment Demographics	
020	Enrollment Serococonversion Symptoms	
030	Enrollment Timing and Route of Transmission	
040	Enrollment Test Results	
045	Cycle Determination	
060	Enrollment Treatment Regimen	
100	HIV/AIDS Associated Events	/aiedrp/aiedrp_core/forms/HIV/AIDS_events.fm
101	HIV/AIDS Associated Events Information Continuation	/aiedrp/aiedrp_core/forms/HIV/AIDS_events_continued.fm
102	HIV/AIDS Associated Events	/aiedrp/aiedrp_core/forms/
103	HIV/AIDS Associated Events	/aiedrp/aiedrp_core/forms/
104	HIV/AIDS Associated Events	/aiedrp/aiedrp_core/forms/
105	HIV/AIDS Associated Events	/aiedrp/aiedrp_core/forms/
120	Lab Results	/aiedrp/aiedrp_core/forms/lab_results.fm

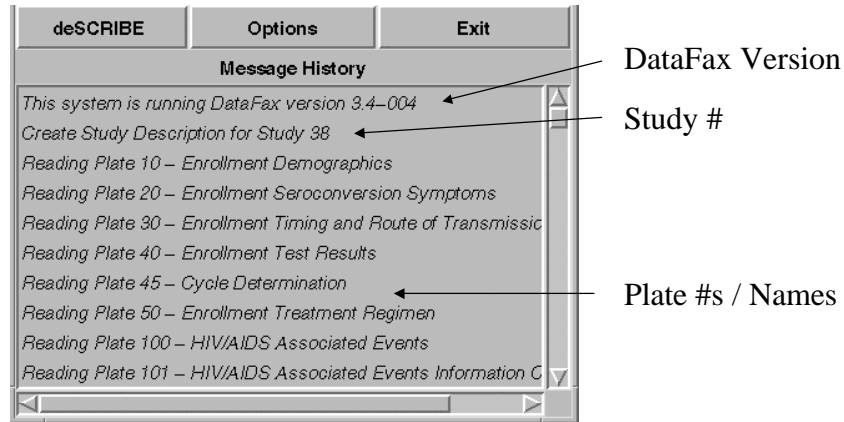
↑  
Plate #

↑  
Label

↑  
Location (User Supplied)

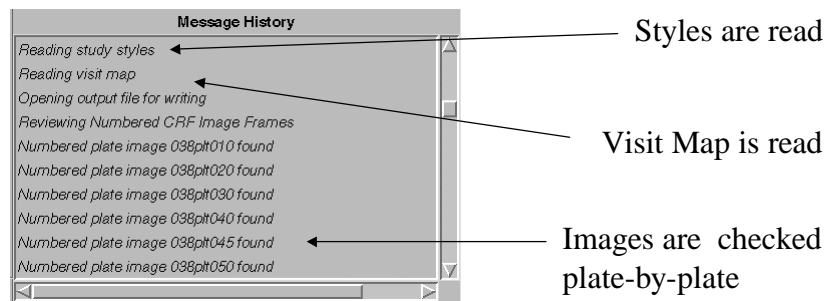
## When you press deSCRIBE

- Information updates track the process



## deSCRIBE Process (Continued)

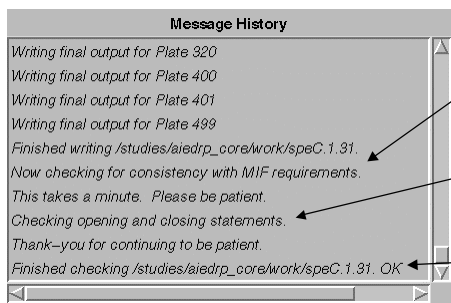
- After plates are read



## deSCRIBE Process (*Completion*)

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- MIF code checks  
to find errors that will make FrameMaker fail



# of Opening and Closing Brackets

A close statement exists for every open statement

New output file name

## Requirements

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- Solaris  
(Only tested in a SUN environment to-date)
- Perl, Tk
- ras2ps, pstopnm and pnmtorast
- DataFax  
3.4 for Staff Permission functions
- A Defined Study with some set-up completed

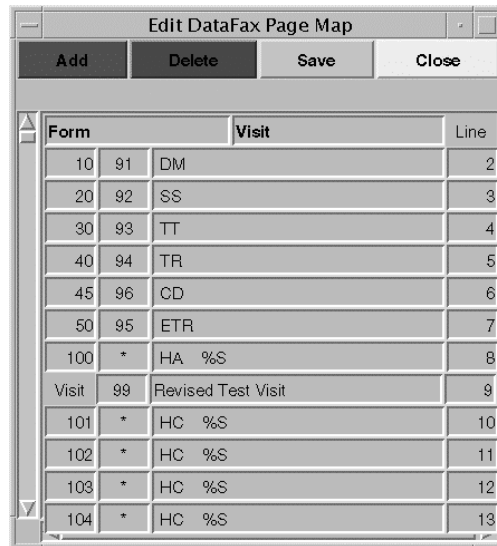
## Possible Future Directions

- Other operating systems
- Include Centers Database
- Interoperability with DataFax for
  - Permissions (through DFuserPerms)
  - Visit Map (create or modify the DFvisit\_map file)
  - Page Map (create or modify the DFpage\_map file)

## Possible Visit Map Interface

View / Edit Visit Map for Study 38 – AIEDRP Core																			
Add			Delete			Save			Close										
#	Type	Visit Label	Visit Date Plate	Field	Due After Baseline	Allow	Required Dates			Optional Dates		Missed Visit Plate							
91	B	Demographics	0	0	0	0	10						---						
92	S	Seroconversion Symptoms	0	0	0	0	20						---						
93	S	Transmission	0	0	0	0	30						---						
94	S	Test Results	0	0	0	0	40						---						
95	S	Enrollment TXR	0	0	0	0	50						---						
96	T	Cycle Determination	0	0	0	0	45						---						
<b>Cycle</b>	<b>I</b>	<b>Pre-Core</b>	<b>C</b>	<b>Due</b>	<b>0</b>	<b>Days after</b>	<b>Visit</b>	<b>96</b>	<b>if Field</b>	<b>13</b>	<b>on Plate</b>	<b>45</b>	<b>at Visit</b>	<b>96</b>	<b>=</b>	<b>1</b>	<b>Allow</b>	<b>2</b>	<b>Days</b>
101	B	Day Zero	120	9	0	14	120						---						
106	S	Week 8	120	9	56	28	100 120 130				101 102 103 104 105 131 132 133 134 135		200						
108	S	Week 16	120	9	112	28	100 120 130				101 102 103 104 105 131 132 133 134 135		200						
110	S	Week 24	120	9	168	28	100 120 130				101 102 103 104 105 131 132 133 134 135		200						
111	S	Week 32	120	9	224	28	100 120 130				101 102 103 104 105 131 132 133 134 135		200						
112	S	Week 40	120	9	280	28	100 120 130				101 102 103 104 105 131 132 133 134 135		200						

## Possible Page Map Interface



The screenshot shows a window titled "Edit DataFax Page Map" with four buttons: "Add", "Delete", "Save", and "Close". Below the buttons is a table with columns for "Form", "Visit", and "Line". The table contains the following data:

Form	Visit	Line
10 91	DM	2
20 92	SS	3
30 93	TT	4
40 94	TR	5
45 96	CD	6
50 95	ETR	7
100 *	HA %S	8
Visit 99	Revised Test Visit	9
101 *	HC %S	10
102 *	HC %S	11
103 *	HC %S	12
104 *	HC %S	13