
Advanced Study Setup

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The Basics

Minimum Setup Requirements

- Register study in the System Tool
- Design CRFs \implies PostScript file
- Register each CRF plate
- Define variables
- Select data schema numbering
- Define the study visit map
- Create a centers database

DataFax Key Fields

Study Number

- Numeric, 1 to 249
- First field in barcode on all plates
- Uniquely identifies a single study/database

DataFax Key Fields (cont'd)

Plate Number

- Numeric, 1 to 500
- Second field in barcode on all plates
- Uniquely identifies a single plate within the study

DataFax Key Fields (cont'd)

Visit/Sequence Number

- Numeric, 0 to 65,535 (0-511 if barcoded)
- Third field in barcode or data field #6 with data schema numbering
- Uniquely identifies each repetition of a plate
- Sequential for all visits defined with a VisitDate date field

DataFax Key Fields (cont'd)

Patient ID Number

- Numeric, 0 to 2,147,483,648
- Always data field #7 with data schema numbering
- Uniquely identifies a single patient/case within the study
- Construct by combining center + patient (e.g. ccppp)

CRF Design Tips

Special “Dummy” Plates

- Allow non-CRF pages to be collected and stored in database
- Defined by key fields only
- Serve as placeholders for images
- Are not part of investigators’ CRFs
- Faxes will arrive in Router Tool

Creating Special “Dummy” Plates

- Design a new CRF plate
- Create and import a PostScript file
- Register plate
- Define key fields
- Include in visit map, if necessary

Validating Special “Dummy” Plates

- Instruct investigators to complete ID, initials when faxing source docs
- Router Tool
 - Locate page
 - Identify Study, Plate and Visit
- Validation Tool
 - Enter key fields, assign record status

Cross-Plate Links

- Allow linkage of optional reports (AEs, meds, procedures) to scheduled follow-ups
- Performed by
 - Edit checks (batch mode)
 - Conditional Plate Map

Creating Cross-Plate Links on CRFs

- On scheduled follow-up CRFs
 - Trigger field (simple Y/N question)
 - Report #, Page # or Date fields
- On optional report CRFs
 - Report # or Page # field defined as the sequence number
 - Date of report or procedure

Defining Cross-Plate Links in Setup

- Edit checks
 - Defined in DFedits file
 - Dependent upon value of trigger field
 - May be run in batch mode
- Conditional Plate Map
 - Defined in DFcplate_map file
 - Dependent upon value of trigger field
 - Executed when running DF_QCupdate

Hidden Data Fields

- Allow data not relevant to investigators, to be entered and stored in database
- Defined in Setup Tool, not on CRFs
- Can be entered via lookup tables

Creating Hidden Data Fields

- Location is critical, allow adequate space
- Draw out variable widget
- Define variable attributes
- Attach an edit check look-up table (if necessary)

Internal Plates

- Used to record internal study information (e.g. protocol problems)
- Not part of the investigators' CRFs
- Entered in Validation Tool using raw data entry

Creating Internal Plates

- Design a new CRF plate(s)
- Create and import a PostScript file
- Register plate
- Define all data fields

DataFax Date Fields

Date Formats

- 2 digit year vs. 4 digit year
- Numeric month (01, 02) vs. character month (JAN, FEB)
- Upper case (explicit) vs. lower case (optional) date components
- Multiple (logical) formats for dates within the same study
- Choice of component delimiters

Dates With 2 Digit Years

- Implied, 100-year range must be defined
- 2-Digit years are interpreted as falling within specified range
- Implied range can be defined at study, style or variable level
- Adjust range for birth date variables

Legal Ranges for Dates

- Same format as the date to which they apply
- Double quotes must be used when specifying legal values that include a blank space(), coma (,), tilde (~) or dash (-) in the format
- Example:
MMM DD, yyyy → “Jan 01, 1999”~today

Partial Dates

- Specify how partial dates are to be treated in legal range tests
- Imputation methods
 - Never
 - First of month/year
 - Middle of month/year
 - Last of month/year

Partial Dates (cont'd)

- Specified using upper vs. lower case components
- Must be logical (i.e. DD/mm/yyyy is illegal)
- Defined at study, style or variable level

VisitDate Date Style

- Must appear at least once for each scheduled visit
- Sorting on VisitDate = sorting on sequence number
- Verify use of VisitDates with DF_ICvisitmap
- Use data schema numbering

Setup Tool Tips

Importing Existing Schema Definitions

- Study → Import Def'n feature
- Import styles and plates from other DataFax studies
- Imported styles replace existing styles that match by name
- Imported plates replace existing plate definitions that match by number

Import Tips

- If only style catalog is needed, copy existing DFschema.stl into study /lib directory
- Maintain same plate numbering across studies
- If original and new plate numbers differ, use workaround
- Beware of DFedits file

Import Workaround: Example

- Import plate 10 from existing study to plate 5 of new study
 1. Make plate 5 in new study the current page
 2. Change plate number to plate 10
 3. Perform Import Def'n for plate 10
 4. Change plate number back to plate 5

Setting Variable Options

- Variable → Options feature
- Used to set default specifications on a study-wide basis
- Will apply to all variables unless overridden at style or field level

Variable Options: Dates

- Implicit date range may need to be modified at style/field level for specific dates, e.g. birth date
- If multiple date formats are used throughout the study, date rounding may need to be modified at style/field level

Variable Options: Auto Features

- Speed up study setup process
- Auto variable naming assigns default name in format p\$(rplate)v\$(field)
e.g. p1v15
- Set Auto Generic Name to “Apply to new/all variables” if generic and unique names can be the same
- Auto Help displays legal range messages in Validation Tool

Copying/Pasting Variable Definitions

- Performed for a single variable, group of variables
- Applies within a plate or across plates
- May edit definitions by prepending, appending, substituting
- Variable position is maintained during cross-plate copy/paste

Copy/Paste Tips

- Where possible, perform on groups of fields
- Select “Modify” to avoid duplicating unique variable names
- Can only perform one of prepend, append, substitute at a time
- Only first occurrence of string is modified

Setup and QC Reports

DataFax Page Map

- Replaces plate and sequence numbers with meaningful labels on QC Reports
- Meta characters simplify page label specifications (e.g. *, %P, %S, %{P.n}, %{n.P}, %{S.n}, %{n.S})
- Entry exists for each occurrence of a plate
- Create in DataFax GUI or text editor

Page Map Tips

- Use CRF form # = page label
- Make use of meta characters
- Maximum length of labels = 17 chars
- Use a meaningful label for Fax/Refax title, i.e. CRF Form Number
- Create in text editor

Customizing QC Note Sort Order

- Customize order in which QC notes appear on QC Reports
- Default = patient ID → visit # → plate # → field #
- Create using a text editor
- Define \$STUDY_DIR/lib/DFqcsort

QC Note Sort Order: Example

- Format → Plate # | Visit # | Order #
5 | 1 | 1 1st = notes on plt 5, v 1
1 | 1 | 2 2nd = notes on plt 1, v 1
* | 1 | 3 3rd = notes on all plts, v 1
* | * | 4 4th = all remaining notes
- Notes are always sorted by ascending ID within each center
- No sort control at individual field level

Customizing QC Report Titles

- Customize titles and sub-titles for external/internal QC Reports
- Create using a text editor
- Define \$STUDY_DIR/lib/QCtitles
- Titles are formatted within tagged blocks
- Optional font types may be specified
- “#” indicates a comment line

QC Report Titles: Example

```
# Title at the top of each page of an external QC report
<EXTERNAL font="^P12 fB">
Study Report <NUM> for: <MON> <DAY>, <YEAR> at <TIME>
To: <WHO>, <WHERE>
</EXTERNAL>
```

- Formatting is specific to type of title
- Opening/closing tags must always appear on a new line
- Substitution occurs for variable tags

QC Report Cover Sheets

- Define cover sheets for external QC reports
- Create using a text editor
- Define \$STUDY_DIR/lib/QCcovers
- Created within a <TEXT> block
- Different centers may receive different/no cover sheets

QC Report Cover Sheets: An Example

```
# QC Report cover sheet for centers 1-20, 25, 30-40
<FOR centers="1~20,25,30~40">
<TEXT font="^P12 fB">
```

```
-----
To: <WHO>
    Center # <CENTER>: <WHERE>
    <DATE>
</TEXT>
</FOR>
```

- Substitution occurs for variable tags
- Blank lines are preserved

Cover Sheet Messages

- Send messages to selected centers
- Create using a text editor
- Define \$STUDY_DIR/lib/QCmessages
- File may contain 1+ messages
- Centers may receive none, 1 or more of the messages
- Not necessary to define a cover sheet in order to use QCmessages

Cover Sheet Messages: An Example

All centers (1-50) receive meeting announcement. Centers 3, 10, 47 receive message regarding missing baseline assessments

```
<FOR centers="1-50">  
<TEXT font="^P10 fCW">
```

PLEASE NOTE:

There will be a study coordinators' meeting held on October 15, 1999 in Toronto, Canada. Details to follow at a later date.

```
</TEXT>  
</FOR>
```

```
<FOR centers="3,10,47">  
<TEXT font="^P10 fB">
```

We have not yet received the baseline assessment for your first patient. As this data must be reviewed by us within 3 days of patient randomization, please fax this information to us as soon as possible. If you are having problems, please contact us.

```
</TEXT>  
</FOR>
```

Designing Study SOPs

Workflow Management - Tasks

- Clearing Unidentified Fax Router
- CRF review and validation tasks
- Data management roles
- Study management roles
- Data export and analysis
- System administration roles

Work Flow Management - SOPs

- Who performs task
- What does task involve
- When must task be performed
- How task is to be performed (i.e. DataFax tools, reports, validation levels used)

Optional Setup Features for Data Validation

Defining a Validation Task List

- Set retrieval criteria for common Validation Tool tasks
- Create using a text editor
- \$STUDY_DIR/lib/.DFtasks.username
- One file per username
- Multiple tasks per file identified by a label/name

.DFtasks.username: An Example

```
BEGIN Level 1 Entry of New Records
Mode=Validate
Level=1
Type=New Records
END
BEGIN Level 3 Entry
Mode=Validate
Level=3
Type=By Data Fields
validation=2
status=error dirty
END
```

Defining a Raw Data Entry Map

- Controls order in which plates are presented during raw data entry
- Create using a text editor
- \$STUDY_DIR/lib/DFraw_map
- Each record represents one ordering
- If no DFraw_map, plates are ordered numerically

DFraw_map: An Example

Label | Visit | List of Plates

Screening | 0 | 4 1 2 3

Baseline | 1 | 10 11 5 6 7 8 9

Month 1 Follow-up | 2 | 15 14 13 12

DataFax Report Permissions

Creating a Reports Exclusion File

- Restricts access to DataFax reports
- Restricted reports will not appear in the Reports Tool
- Create using a text editor
- \$STUDY_DIR/lib/.DFrep_excl
- .DFrep_excl has 2 parts → Generic and Study Specific

Creating a Reports Exclusion File (cont'd)

- Exclusion criteria specification:
 1. Report name without any usernames
→ all users denied access
 2. Report name followed by -* +username
→ all users denied access except those following the “+”
 3. Report name followed by +* -username
→ all users granted access except those following the “-”

.DFrep_excl: An Example

```
BEGIN DataFaxGeneric  
DF_QCupdate -* +dick +jane  
DF_QCreports -* +dick +jane  
DF_QCfax +* -spot  
END
```

```
BEGIN StudySpecific  
randexclusion -* +jane  
aecheck  
END
```

Testing Plate and Variable Definitions

Testing Objectives

- Fax processing (barcode, ICR)
- Data field attributes (format, legal values, description)
- Height and length of data fields
- Data field traversal (includes skip patterns)
- Page/plate labels

Test Steps

1. Fax a completed copy of each plate into study database
2. Retrieve records in the Validation Tool
3. De-select "Edit Checks" in the Validation Tool's file preferences
4. Traverse each field, enter test data
5. Use checklist in Setup Worksheets

Testing Variables Definitions Using DF_SSvars

- List of variables that includes selected information from the study schema
- Output organized by plate → variables
- Some useful options:
 - S → select definition and output format
 - P → select plates
 - F → select variables by field #
 - M → match on specified string

Testing Study Schema Using DF_ICschema (Early Access Program)

- Checks schema for common errors and inconsistencies
- Output = Errors and/or Warnings
- Some useful options:
 - P #~# → check only specified plates
 - e → report only Errors
 - w → report only Warnings
 - pg # # → set page size for output