
Preparing for Study Setup

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Workshop Objective

- **Focus is on Setup Requirements**
 - What information do you need before beginning setup of a DataFax database?
 - Ideas/suggestions for meeting setup requirements
 - Examples

What is required?

- Barcoded Case Report Forms (CRFs)
- Visit Map
- Centers Database
- Variable Definitions
 - Variable names
 - Variable description
 - Coding
 - Legal Ranges
 - Required vs. Optional

Case Report Forms

CRF Design Objectives

- Collect all pertinent data
- Aid in data management
- Reduce the amount of time needed for CRF creation and database setup

Basic Concepts

- Barcode only those pages to be collected/stored in the database (study #, plate #, visit # (barcode or 1st field))
- 8.5" x 11" or A4 – portrait layout
- Each plate contains a Patient Identifier
- Data fields follow the DataFax format for each of the 6 field types
- VisitDate for scheduled/termination assessments

CRF Issues

1. Re-using plate numbers
2. Creating Validation Tool backgrounds
3. VisitDate date fields
4. Continuation plates and trigger questions
5. Event Reports
6. Sequence Numbers
7. Missed Visit plates
8. Maximizing ICR

1. Can a plate be re-used across different visits?

Yes, but are the following also the same?

1. Page and question numbering
 2. Sequence number type (barcode or first data field)
 3. Page titles
- 1 and 2 must be identical if the same plate number is to be used.

Re-Using a Plate Number

What if the sequence number appears in the barcode and the page title differs across visits, but everything else is the same?

Okay but...

Only the first instance of each unique plate gets imported into DFsetup

2. Creating Validation Tool Backgrounds

The screenshot shows the header of a clinical data form. At the top left, it says 'Clinical Data Fax Systems, Inc. Test Study 254'. In the center, it says 'Example Blood Pressure Trial'. At the top right, it says 'Form 1.1'. Below this is a barcode. Under the barcode, there are three labels: 'Data Fax #254', 'Plate #006', and 'Sequence #001'. Below the barcode are three input fields: 'Patient Number' (four boxes), 'Patient Initials' (three boxes labeled 'F', 'M', 'I'), and 'Visit Date' (three boxes labeled 'day', 'month', 'year'). At the bottom of the form, there is a box containing the text '1 and 6 MONTH FOLLOW-UP (Page 1 of 10)'.

- Create a background version of the CRF
- Specify a range of legal visits within the CRF title

3. Where are VisitDates required?

- On at least one of the required plates for each scheduled visit (P,B,S,T,F) and for each termination visit (T,F,E,A,W)
- On plates that signal termination

Where are VisitDates optional but recommended?

- For optional assessments that have a visit/sequence number that lies between scheduled assessments

Visit Date Rules

- Ascending visit numbers correspond to chronological ordering of VisitDates
e.g. visit 1, VisitDate = 2001/01/01
visit 2, VisitDate = 2001/02/01
etc.
- Multiple VisitDates for the same visit must refer to the same date of the study

4. Continuation Plates

- Are necessary when a single CRF plate does not have an adequate number of fields to capture all potential data
- Often required for
 - Con Meds
 - AEs
 - Medical History

Continuation Plates

Clinical DataFax Systems, Inc.
Test Study 254

Example Blood Pressure Trial

Form 2.3

DataFax#294

Plate#004

Medications PageNumber

Patient Number

Patient Initials

F M L

CURRENT MEDICATIONS

List any medications (prescribed and non-prescribed) which the patient is currently taking.

If None, put an X in this box:

- Define
 - page number field so that sequence # is not between baseline and termination visits
 - e.g. format=1nn, legal range=101-199
 - 'Check if None' question
 - Trigger question needed to check for supplemental pages

Trigger/Link Questions

Have additional medications been recorded on the Current Medications Continuation Form 2.4? Yes No

- Used to track optional/conditional plates and conditional termination
- Simple choice/check questions are best
- Program response to trigger an edit check, DFcplate_map or DFcterm_map
- Automate checking and, if necessary, addition of missing page QC notes

5. Event Reports

Clinical Data Fax Systems, Inc.
Test Study 254

Example Blood Pressure Trial

Form B.1

DataFax #254 Plate #911

Adverse Event Report Number

Patient Number

Patient Initials F M L

ADVERSE EVENT REPORT

- Sequence Numbering:
format = 2nn, range = 201-299
- Use page map to map sequence number to a meaningful QC Report label (i.e. AE Report # `%{S.2}`)

6. Sequence Numbers – barcode or data field?

Barcode

- Range = 0-511
- Pre-printed for each assessment in CRF book
- Generates more paper

First Data Field

- Range = 0-65535
- Investigators complete as required for each assessment
- Field type = number, choice, check
- Generates less paper

Sequence Number as a Data Field

Clinical DataFax Systems, Inc. Form 3.1
Test Study 254

Example Blood Pressure Trial

DataFax #254 Plate #006

Follow-up: 1 Month 2 Month
 3 Month 4 Month

Patient Number Patient Initials F M L
Visit Date day month year

MONTHLY FOLLOW-UP FORM

- Sequence Numbering:
format = choice codes (i.e. 10, 20, 30, 40)
- Use page map to map sequence number to a meaningful QC Report label
(e.g. 10 = 1 Month Follow-up)

7. Why define a missed visit plate?

- Missed visits are a fact of life
- Easy way for investigators to notify data management office of unavailable data
- Will stop DataFax from complaining that required assessments are overdue
- No Lost Data Log entries are necessary

Missed Visit Plate Example

Clinical Data/Fac Systems, Inc.
Test Study 254
Example Blood Pressure Trial
Form E.1

DISPATCH Plate #000 Follow-up: 1 Month 2 Month
Missed: 3 Month 4 Month

Patient Number:
Patient Initials:
F M L

MISSED VISIT FORM

1. Date of form completion:
day month year

2. Please provide a reason why the visit was missed: _____

Investigator's Signature: _____ Date:
day month year

8. Maximizing ICR with CRF design

- Avoid 3-character month in date fields
- Avoid string type data fields
- Avoid shading/outlining
- Avoid clutter
- Include instructions for CRF completion:
 - use a dark blue or black fine tipped pen
 - keep numbers inside the box
 - print digits in a plain script

Miscellaneous CRF Design Tips

- Position field labels to the right of data fields
- Group sections to improve appearance
- Number questions for use in QC report descriptions
- Place instructions, coding keys, etc. on facing pages
- Use form numbers/labels on all plates (for use in page map)

Issuing CRFs to Investigators

- Paper
 - verify that printed CRFs match originals used in setup, check every plate
- PDF file
 - embed fonts
 - de-select 'Fit to Page' print option

Visit Map Design Issues

Objectives

- Automate Patient Visit Scheduling
- Detect, Flag and Track
 - Overdue Visits
 - Missing CRF pages from completed visits
- Study Monitoring Reports
 - Patient summary reports
 - Center summary reports

Basic Concepts

- Number (0-65535)
- Type
- Label
- Due day and overdue allowance
- VisitDate
- Required and optional plates
- Missed visit plate

Visit Map Issues

1. Is a visit map required?
2. Defining visit numbers
3. Page Maps
4. Automate Overdue Visit Calculations
5. Automate Missing Page Calculations
6. Helping your Visit Map
7. Common Scenarios
8. Changing a visit map

1. Is a Visit Map Required?

- Yes
 - if QC reports are to be generated
 - if DataFax will be used to track overdue visits and missing pages
 - if user-added QC notes are to be collected in QC reports

But what if the study has no scheduling requirements?

Defining a Minimal Visit Map

- A minimal visit map should be defined for single visit studies to allow DataFax to check for missing plates:
 - visit type should be screening
 - Example:
1 | X | Survey | 1 | 9 | 0 | 0 | 1-5 | | |

2. How should visit numbers be defined?

- Integer in the range 0-65535
- Unique for each visit
- Assigned sequentially according to the order in which visits are performed
- Gaps are allowed
- Visit/sequence numbers are still required for assessments that do not correspond to scheduled visits

Visit Numbering for Event Reports

- Event Reports, con meds, etc. should be assigned a range of sequence numbers that place them at the end of the visit map
- Be sure that sequence numbers do not match or fall within the range of numbers assigned to scheduled visits

Visit Date Rules

- Ascending visit numbers correspond to chronological ordering of VisitDates
e.g. visit 1, VisitDate = 2001/01/01
visit 2, VisitDate = 2001/02/01
etc.
- Multiple VisitDates for the same visit must refer to the same date of the study

3. Is a Page Map Necessary?

No, but...

- A page map replaces the plate and sequence numbers on Quality Control Reports with meaningful labels
- This is very helpful to investigators

Page Map Definition Tips

- Make an entry for each occurrence of each unique plate (required and optional)
- Use the visit number + CRF form number (in this order) as the page label - makes Refax List more readable
- Avoid idiosyncratic abbreviations

4. Automate Overdue Visit Calculations

- Visit scheduling is calculated from baseline visit date
- Visits are overdue upon arrival of a visit with a higher visit number or upon expiry of the overdue allowance
- Specify realistic visit windows
- Optional, early termination and abort type visits are never overdue

5. Automate Missing Page Calculations

- Whenever possible, define plates as 'Required' in visit map
- Arrival of any plate signifies that the visit (per visit number on the plate) has occurred
- Use an edit check (dfaddmpqc) when the visit map can not be used

6. "Helping" your Visit Map

Minimize QC Report Errors by using:

- edit checks to minimize data entry errors in keys fields and VisitDates
- DF_ICkeys to detect inconsistencies in patient initials and in ID, plate and visit keys
- DF_ICvisitdates to catch VisitDates that are inconsistent, illegal and out of order
- DF_PTvisits -E and -L options to check for VisitDates far off schedule

7. Some Common Scenarios

7.1 Defining optional/unscheduled visits in a visit map

- Placement within the visit map depends on whether or not a VisitDate date has been defined
- VisitDate present
 - define between scheduled visits
 - visit numbers must follow the sequential ordering of scheduled visits
- VisitDate not present
 - define at the end of the visit map
 - assign visit numbers beyond the termination visit

7.1 Optional/Unscheduled Visits

Example #1

| | | |
|------|---|-------------|
| 0 | X | Screening |
| 10 | B | Baseline |
| 20 | S | Follow-up 1 |
| 21 | O | Optional 1 |
| 30 | S | Follow-up 2 |
| 31 | O | Optional 2 |
| etc. | | |
| 90 | T | Termination |

Example #2

| | | |
|------|---|-------------|
| 0 | X | Screening |
| 10 | B | Baseline |
| 20 | S | Follow-up 1 |
| 30 | S | Follow-up 2 |
| etc. | | |
| 90 | T | Termination |
| 101 | O | Optional 1 |
| 102 | O | Optional 2 |
| etc. | | |

7.2 Screening vs Pre-Baseline Visits

Screening (X)

- Can only come before P and B visits
- Will not trigger overdue visit notification unless a scheduled visit arrives
- Missing page QC notes will be generated

Pre-Baseline (P)

- Only scheduled visit allowed before B visit
- Will trigger overdue visit notification
- Missing page QC notes will be generated

7.2 Example

```

0 | X | Screen 1 | 0 | 0 | 0 | 0 | 1-2 | | |
1 | X | Screen 2 | 0 | 0 | 0 | 0 | 1-2 | | |
3 | P | Week 1 Tests | 3 | 9 | -14 | 3 | 3-5 | | |
4 | P | Week 2 Tests | 3 | 9 | -7 | 3 | 3-5 | | |
5 | B | Randomization | 6 | 9 | 0 | 0 | 6-10 | | |

```

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- Screening visits are considered optional until arrival of visit 3 (P)
- Due day of P visits must always be specified as a negative number

7.3 Multiple Baseline (B) visits

- If multiple visits are required before baseline can be established, and baseline may occur at any visit, then multiple baselines may be defined
- First B visit is required, all others are optional
- Baseline (Day 0) will be taken from the last type B visit received

7.3 Example

```

0 | X | Screen | 0 | 0 | 0 | 0 | 1-2 | | |
1 | B | Baseline 1 | 3 | 9 | 0 | 0 | 3-6 | | |
3 | B | Baseline 2 | 3 | 9 | 0 | 0 | 3-6 | | |
4 | B | Baseline 3 | 3 | 9 | 0 | 0 | 3-6 | | |
5 | S | Follow-up 1 | 7 | 9 | 30 | 7 | 7-10 | | |

```

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- If visits 3 and 4 ARE required in order to establish randomization, they must instead be defined as Pre-Baseline (P) visits

Conditional plate map vs. edit checks to define conditional plates

DFcplate_map

- Defines conditional plates, not visits
- Will not generate missing page QCs for visits that have not arrived

Edit checks

- Defines conditional plates within visits and across visits
- Can generate missing page QCs for visits that have not arrived

Termination Visits

- Define a termination visit (T or W) for each cycle
- Include abort (A) and early termination (E) visit(s) where appropriate
- Mark termination plates (e.g. death report) as such in the setup tool
- Define a conditional termination using DFcterm_map
- If needed define a final (F) visit after all cycles

8. Can a visit map be changed mid-study?

Yes, but ...

- Overdue visit and missing page QC notes already in the database may no longer be valid
- QC notes added by users and/or edit checks may no longer be valid

What to Do?

Run DF_QCupdate with the -d option

- deletes all overdue and missing page QC notes that were previously added to the database by DataFax
- review any QC notes added by edit checks
- if necessary, change and re-execute edit checks and run DF_QCupdate

Defining a Centers Database

Minimum Requirements

- Define an entry for each participating center (Clinical Monitor)
 - number (0-2146), contact person, primary fax # (20 chars), case IDs
- Define an Error Monitor
 - number, contact person, primary fax #

What if a patient changes centers?

- Update the centers database:
 - Remove patient ID from the old center
 - Add the same patient ID to the new center
- Run DF_QCupdate to correct center ID #s in all existing QC notes for the patient

Variable Definitions

Variable Names

- Define a Unique and Generic name for each variable
- Avoid auto naming unless in a hurry
- Keep Generic names short (≤ 8 chars)
- Include underscore (_) for readability
- Be consistent

Variable Description

- Appears on QC reports to guide investigators to problem data fields
- Include question numbering as on CRF
- Include upper and lower case as used on CRF
- Avoid idiosyncratic abbreviations

Variable Coding

- Applicable to choice and check fields
- Be consistent
 - 1 = Yes
 - 2 = No
- Define a consistent code for 'no choice' or 'not checked'
- Define missing value codes

Legal Ranges

- Recommended but not required
- Edit checks can do this and more
- Can be defined or revised in the database following study start-up

Required vs. Optional

- Determine which data fields should be required vs. optional
- Required fields
 - Are illegal if blank
 - A missing value code satisfies the requirement
- Optional fields
 - Are legal if blank
- Conditionally required fields
 - use an edit check

Finally

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- Simplify CRFs as much as possible
- Simplify visit map as much as possible
- Don't forget your centers database
- Include as much information as possible within variable definitions
- Provide investigators with instructions
- Let DataFax do the work for you