
DataFax 3.7

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Visit Map

- Removed many of the old restrictions
- Added new scheduling possibilities
- DataFax 3.6 identifies what's missing:
 - overdue visits
 - missing CRF pages
- DataFax 3.7 also identifies the unexpected:
 - visits that should not have occurred
 - CRF pages that should not have been completed
- DFconfig - new appearance

Visit Map - Cycles

Screening Cycle

- visits: X (screening)
- screening visits may be scheduled or unscheduled

In-Study Cycles

- visits: P(pre-baseline), B(baseline), S(scheduled), T(termination), W(window), O(optional), R(on termination), r(on next scheduled visit)
- required, optional or conditional
- scheduled from previous cycle or visit
- may consist of a single visit (type B or F)

End Cycle

- visits: O(optional), A(abort), R(on end of follow-up)
- container for event reports and unscheduled assessments

Visit Map - Visits

Visit Numbers & Visit Order

- chronological order is now inferred from the order in which visits are listed in the visit map
- this can differ from a numerical ordering of visit numbers
e.g. visit 25 can be inserted between visits 1 and 2

Visit List Definitions

- a single visit map entry for a list of unscheduled visits
- using visit number substitutions to create unique visit labels
e.g. 5001-5999 | Adverse Event Report #%{S.2.3}

Conditional Cycle Map

Rules:

If the condition is met, the specified cycles become: Required, Optional, or Unexpected

May be used for screening and in-study cycles

Multiple action lists may follow each condition, i.e. some cycles may become required while others become unexpected or optional

If more than one condition is met for the same cycle, the last condition wins

Conditional Visit Map

Rules:

If the condition is met, the specified visits become: Required, Optional or Unexpected

Multiple action lists may follow each condition, i.e. some visits may become required while others become unexpected or optional

If more than one condition is met for the same visit, the last condition wins

Conditions may be specified for any visit type

Optional visits that become required, are required immediately, and are not subject to cycle termination or abort dates

Visit requirements only kick in if the cycle is required

Conditional Plate Map

Rules:

If the condition is true, then at specified visits, the specified plates become: Required, Optional or Unexpected

Multiple action lists may follow each condition, i.e. some may plates may become required while others become unexpected or optional when the condition is true, or different plates may become required at different visits

If more than one condition is met for the same plates at the same visits, the last condition wins

Plate requirements do not kick in until the visit arrives

Conditional Termination Map

Rules:

If the condition is met, the patient terminates on the VisitDate of the visit on which the condition was met, in one of 2 ways:

A = Abort:

- all follow-up ends for all cycles
- any type R visits in the End cycle become due

E = Early Termination of the current cycle

- the next cycle, if any, begins

DF_QCupdate

~/work/DFX_schedule

Summary data file and a revised report, DF_PTvisits

- Visit need: required, required-next, optional, excluded
- Visit status: not done, overdue, done, early term, abort
- Visit date: scheduled and reported
- Tags conditional visits and conditional terminations
- Contains a record for each cycle with similar info

~/work/DFunexpected.drf

DataFax retrieval file and a new report, DF_PTunexpected

- records each unexpected data record in the database
- identifies why the record is unexpected
 - e.g. visit occurred 15 days after termination.

Page Map

Visit Acronyms -patient status list in QC report

S | 1010-4309 | C%{S.1.1} v%{S.2.2}.%{S.4.1}

Result: C1 v01.0, C1 v01.1, ... C4 v30.9

Page Labels -refax and Q&A lists in QC reports

*| 0-2299 | Plate %P Visit %S.1.2}.%S.3.2}

55 |0-2299 | MEDS Visit %S.1.2}.%S.3.2}

Result for plate 303: Plate 303 Visit 15.01

Result for plate 55: MEDS Visit 15.01

DF_QCreports

Original Format #1

- compact, short variable labels (17 char)
- QC note formatted on a single line (+query text)

Original Format #2

- still compact
- QC notes numbered within each report
- Problem type shown at beginning of each QC

New Format #1 & #2

- Longer variable labels (40 char)
- QC note formatted on 2 lines (+query text)

DF_PTvisits

Visit Scheduling

- Dates for all scheduled visits, either:
date done, e.g. 25/JAN/04 or date scheduled, e.g. ~25/JAN/04
- number of days overdue

Visit Need tags

o = optional, r = required, n = next visit, x = excluded, ? = unknown

Visit Status tags

D=done, L=lost, T=cycle terminated, A=abort, *=overdue, .=not done

Other tags

CT#=conditional termination
CV#=conditional visit
Etp= early termination plate
mvp= missed visit plate

DF_PTunexpected

Example:

21050 Visit 20 : Week 20 follow-up

Plate(s) : 5-8,15-17,19-23

Problem : unexpected visit: 48 days post termination

32082 Visit 15 : Week 15 follow-up

Plate(s) : 5

Problem : unexpected visit: excluded by visit condition 3

73126 Visit 200 : Cycle 2 baseline

Plate(s) : 5-8

Problem : unexpected visit: aborted in prior cycle

Output matches DataFax retrieval file DFunexpected.drf
created by DF_QCupdate

DFconfig

New look & feel

Appears in the study toolbox

Permissions match DFsetup permissions

Contains:

- Visit Map
- All 4 Conditional Maps
 - Cycles, Visits, Plates, Termination
- Page Map
- Centers database
- Missing value codes
- Lookup table map

Setup Tool

Reorganization of Menus

Preferences

Reason for data change:

- global on, global off, by field

Variable Label size:

- small (17 char) vs large (40 char)

View Only

- allows specified users to see but not change study setup information

Access to DFconfig

Edit Checks

Functions

dfaddreason()

- request a reason for data change

dfeditqc()

- change status, problem, usage, query, note

dfvarinfo()

- can get information about fields from other records

Edit Checks

Parameter Lists

example:

RIP(value)

Checks to see if the current field has been completed, as it should have been, when the previous field equals a specified value, as in:

Treatment given? []no []yes specify_____

If yes is coded 2, the specify field can use RIP(2) to perform the check.

Validation Tool - QC Notes

Auto-Resolve

Separate preference for illegal and missing value QCs

New Dialog

New organization

More space for query and note text

Delete

Immediate, no longer waits for record sign off

QC New Again

Current data value displayed in the QC note is updated when QC status is set back to new

Validation Tool - Reason

When does the reason dialog appear?

New preference: after each data change or on record sign-off

Fix bar code

A reason must be given for any key field change

Record delete

A reason must be given for any record deletion

Validation Tool - DDE

Complements the current DFdde system

DFdde.set is still used to create sets to be double entered
DFdde reports are still available

Real Time Double Entry

First entry hidden during double entry
User doing double entry is notified of discrepancies
Second pass decision wins
Reason dialog used to record reason for changes

Router

New GUI

Truly Multi-User

Record list

- Shows all records in the router by fax# & page#
- Shows status of each page
- Shows locks

Notify User Dialog

- shows name of users known to DataFax (not all on system)

SQL Loader

Oracle, PostgreSQL, MySQL

- Creates database tables from DataFax schema
- Loads current data records into SQL tables

DFlite

DFItserver

now exits after 2 hrs if there is no network communication with DFlite clients

Out of Licenses

if all licenses are in use, clients now see a new dialog which reads "out of licenses", previously the connection failed without explanation

Creating PDF files

Passwords

It is now possible to specify a password that must be used to open the PDF file

Specifying a password also encrypts the file contents

Page Labels

It is now possible to add header and footer labels:

- Custom text

- Patient Keys: ID, Visit, and Plate numbers

- Time stamps: Record creation & modification

- Work flow: validation level and record status

- DataFax Study# and CRF page ID#

ICR

Dates with 3 Character Months

e.g. 15/JAN/2004

use 1/4 inch boxes, as for digits

accuracy should be over 90% in most cases

use simple strokes, avoid loops and flourishes

keep the characters inside the boxes

Other New Features

QC tool

define and save personal retrieval tasks

DFexport.rpc

optional csv format (comma delimiters)

Emailed QC Reports

shows specified sender, not user datafax

sender specified in re-purposed field 10 of DFcenters

Record Context

faster retrieval of information on slow networks

Other

DFcmpSchema

- new option records records with errors in a DRF
- checks for trailing '|' expected on data records

DFexport.rpc, DFstatus

- display a meaningful error message if requested centers are not defined for the study

Documentation

- HTML and PDF chapter and section headers have been fixed (no more spurious symbols)
- table overruns in PDF have been fixed

Reports

DF_ICqcs

test for free floating QCs has been moved to DFserver.rpc. DF_ICqcs now runs much faster

DF_XXtime, DF_CTvisits

modified to improve performance when centers have many patient ID ranges

DF_XXkeys

no longer sends records with missing value codes in the VisitDate to VDillegal.drf

DF_SSvisitmap

less cryptic output, shows all conditional maps

Reports

DF_PTcrfs

no longer attempts to disable the study server to generate a warning if the study is in use

DF_SSschema

updated to show "no choice" codes

DF_QCreports

now supports custom titles with more than 4 lines

DF_QCupdate & DF_QCreports

no longer require exclusive access to the database
all QC note changes are journalled

System Admin

System Error Messages

include time and 4 digit years from DFmaster machine
include study number and user name

Disk Full Recovery

faxes received while DFfull existed are now automatically processed on arrival of next fax following removal of DFfull

DFstudyPerms

verifies all permissions listed in the documentation

System Admin

~/studydir/bkgd

for CRF images used by DFsetup & DFvalidate
will be automatically moved from their current
location in the study work directory

~/pages/yyww

only user datafax given write permission

Fax archive directory

all write permissions have been removed

System Admin

DFmaster.rpcd

recognizes localhost as the host it is executing on

DFaccess.rpc

-v option for verbose output
- error messages go to stderr not to system error log

Updated to current public release:

HylaFAX version 4.1.8

DFgs version 7.07

libtiff version 3.6

Bug Fixes - System Admin

uuencoded email attachments

tolerates headers more than 20 lines long

DataFax tool box

fixed re-sizing bug

DFinbound.rpc

now tolerates files with size zero, caused by TIFF library bug

DFrouter

\$(ids) no longer causes ICR to fail

Bug Fixes - Edit Checks

Infinite loop

When edit check name = field name

Infinite loop when \n was missing from last line in DFedits

DFbatch

- dfanympqc()
- recoding choice fields
- warning re unexpected attributes
- logs whether actions were applied

Bug Fixes - Reports

DF_QCreports

- fixed '-s no' option which excludes patients with screening only and no next scheduled visit

DF_ICkeys

- patient IDs are now correctly checked in QC notes
- QC note problems are now described in the DRF

DF_QCupdate

- now correctly ignores records with status error

DF_PTmissing

- corrected %S and %P page map label substitutions

Bug Fixes - Other

DFimport.rpc - to new data queue

- ID & Visit fields are now allowed to be empty
- plate procedures are now triggered

DFsas - proc format

- a proc format is no longer created when text labels are exported instead of code values
- default export type for Check fields has been changed to codes instead of labels, thus:
 - codes are exported to the SAS data files
 - proc formats are created for the labels

Bug Fixes - Setup Tool

Study file map

- fixed failure to always update this file when saving study setup changes

Exit during start-up

- fixed bug related to missing backgrounds

Importing PDF or PS files

- fixed problem with file names containing spaces

Bug Fixes - Validation Tool

Missing Values

The rule that key fields can not have missing value codes is now properly enforced

Display Size

The validation tool can now be re-sized to full US letter / A4 height for large displays

User Preference

Confirmation to switch records without saving changes:
This preference now works when releasing the set or exiting the validation tool

Bug Fixes - Validation Tool

View Mode

When working in view mode it is now possible to retrieve all records when using DF retrieval file and by program retrieval methods.

Level 7

When forcing 'record clean' at level 7 the confirmation dialog appears only once, not for each illegal field and unresolved QC.

Reason for data change

Reason dialog now works on coded check & choice fields.

Obsolete

HP-UX

- no longer supported

Programs no longer supported

- DFicheck.dbx
- DFicheck.shx
- DFreindex

DataFax 3.5

- official support for 3.5 ends March 4, 2004 (1 year after the release of DataFax 3.6)