
DataFax 4.1

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Recent History

Version	Release	Comment
3.7.004	2005-06	X-Window focus ends
3.8	2006-08	hello QT & iDataFax
3.9	2009-04	adios X-Window Tools
4.0	2009-12	see videos
4.1	2010-12	our focus today

DataFax 4.0 videos
www.datafax.com/Support

- MedDRA coding
- Site Monitoring
- Electronic Data Capture
- Raw Data Entry
- Fax Data Entry
- Unidentified Fax Router
- ICR Merge
- iDataFax User Preferences

**New Features in
iDataFax 4.1**

iDataFax

Capturing Scanned CRFs

Scanned CRFs –1st method

Email CRFs to datafax@server

- Available since DataFax 3.3
- Scan CRFs to create a TIFF or PDF file
- Send to the study server as an email attachment
- Processed just like an incoming fax

New in DataFax 4.1

- More than one TIFF/PDF attachment
- No longer requires an empty subject and body

Scanned CRFs – 2nd method

iDataFax - Submit PDF

iDataFax – Data View – File – Submit PDF...

Select PDF file and click 'Transmit'

Sends PDF to study server – processed like a fax

Benefits:

- secure transmission - SSL encryption
- immediate confirmation that PDF was delivered
- no fax modems, phone lines or phone bills
- sender ID = 'iDataFax Submit PDF:user login'

Note: current desktop scanners are fast and smart
(e.g. Fujitsu desktop S1500 scans 40 pages/min to PDF)

Scanned CRFs – 3rd method

iDataFax – Import Patient Documents

- Attach scanned documents to data records
 - ✓ scan a death certificate and link it to the death record in the patient's binder
 - ✓ scan a batch of consent forms and link to each patient's study baseline record
 - ✓ scan worksheets or CRFs and perform split-screen data entry (like fax view)

Benefits:

- Alternative to Shuttle Forms or Fax Router
- Skips the new queue - no Fax View processing required
- Documents are immediately available in iDataFax
- Delivery is confirmed by immediate visual feedback
- sender ID = 'iDataFax Import PDF:user login'

Import Patient Documents

3 Modes:

1. **attach images to current data record**
note: multiple images can be attached to each record
2. **attach images to specified data records**
note: user identifies destination (keys) for each image
3. **perform split-screen data entry**
 - scan CRFs or work sheets to PDF
 - import PDF and identify each page
 - split-screen data entry, as in Fax View

iDataFax

Importing Data beyond DFimport.rpc

Importing Data Records

Challenges:

- Input records may not have all fields
- Input field order \neq Plate field order
- Input date format \neq study date format
- Input numeric format \neq study format
e.g. input = 7.3415 for a field with format n.nn
- Query management ?
create missing value QCs for missing fields in input?
resolve missing value QCs if input has a legal value?

Importing Data Records

Features:

- map input fields to plate fields
- specify a value for missing fields
- convert dates to study format
- review and correct input values
- resolve & create queries
- create task set for post import review
- save import specifications for reuse

iDataFax

Back to the Future

DATA VIEW

Record Selection & Navigation:

- **Expression Builder**
 - for ad hoc searches and pre-defined tasks
- **Record Navigation**
 - patient binder or
 - record list: id,visit,plate,level,status
- **Sort on site names in search dialog**

DATA VIEW

QC Window – show more details*

- QC Type: clarification vs correction
- QC Use: internal vs external
- QC Report Status: e.g. in sent report
- Internal Notes
- Modification user-date-time stamps

*controlled by a new role permission

DATA VIEW

Review Field Properties

- Field – Show Field Properties
- 3.7 showed 3 field properties:
field name, description and legal range
- 4.1 shows all field properties

FAX VIEW

Record Selection & Navigation:

- Create Tasks
- Show Image Review Dialog before and/or after Duplicate Resolution
- Sender ID is now included in the Image Review Dialog

LOGIN ONCE

File – New Study (Alt-N):

- Current session remains on screen
- Study selection dialog appears
- Launch another iDataFax session
 - for same or different study
- Re-Login is only required if the new study is on a different server

Router

User Aids:

- Study selection drop down list
- Scale image size: 50-200% and 'zoom to fit'.

DFsetup

Global Edit Checks & Lookup Tables

DataFax Folders – available to all studies

~/ecsrc - edit check source files

~/lut - lookup table files

- Study administrators
 - can now edit these global files in DFsetup
- Other DFsetup users
 - can now view these global files in DFsetup

Publishing Setup Changes

4.1 Adds:

- Study tasks (for data and fax view)
- DFsas job files
- Study specific reports

4.1 Fixes:

- Publishing new screen backgrounds now removes any old backgrounds that are not longer used

Other Setup Changes

4.1 Adds:

- Case mapping for dates
e.g. enter jan -> JAN

4.1 Fixes:

- Users can no longer import setup specifications from a study they don't have permission to view
- A4 background scaling corrected

DFsystem

Electronic Signatures

Enter Password to Sign Data Records

- specified in study role definitions
- using new data permission option 'P'
- use for all or only some data records
- use for all or only some study roles

see 21 CFR Part 11 – section 11.200

User Passwords

New Security Settings:

- Minimum length
- Complexity rules
- Expiry interval
- Reuse rules
- Failure lockout and notification

see 21 CFR Part 11 – section 11.300

Study Management 1 of 4

Creating New Studies

1) Select a Study Space

parent directories set by UNIX system admin

2) Name a Study Folder

study directory = SpaceName/FolderName

Why?

- 1) allow UNIX administrators to manage the file system
- 2) avoids common errors
 - naming a study space (e.g. /opt/studies) as the study dir.
 - creating a new study directory inside another study dir.

Study Management 2 of 4

Study Status Options

- Enable - available to all
- Disable - available to no one
- Restrict - available to admins
- Read Only - view but not change
- Read/Write - normal access

To change study status select DFsystem:Status-Action

Study Management 3 of 4

Delete Study Options:

- 1) **Remove Study from DataFax**
 - study directory remains on the server, but
 - study does not appear in study selection list
- 2) **Delete Study Data**
 - to remove test data and work files
- 3) **Delete Study Data and Setup**
 - to restart study setup from scratch

Study Management 4 of 4

Restore Study Options

- 1) **Restore Previous Study**
- 2) **Restore & Renumber Previous Study**
 - study directory must exist on the server
 - renumber when restoring a completed study if the study number has been reused

Edit Checks

New Functions 1 of 3

`dfcenter(Patient#)`

- returns center ID for specified patient

New Functions 2 of 3

dfprefinfo(PreferenceName)

- returns current preference setting
- can also be used to return user's:
 - ★ mode:
view, edit, modify, validate, dde
 - ★ work flow level:
0-7

New Functions 3 of 3

dfpassword(message,# of tries)

- launches new password request dialog
- displays message
- asks user to enter their password
- returns TRUE if correct password is entered
- returns FALSE after specified # of tries or if user selects the 'Cancel' button

Enhanced Functions 1 of 2

dfhelp(message)

- supports multiline messages
- supports HTML formatting
- adds new Help button:
 - launches help dialog
 - displays the message
 - includes a print option

Enhanced Functions 2 of 2

dftrigger(id,vis,plt,status,level,ECs,action)

- new action = 5:
 - allows edit checks to open a blank record without first creating it (status pending).
- if id,visit,plate = the current record:
 - focus returns to the current record after it is saved to the study database.

New Edit Check

DFopen_study()

- Runs when user selects the study
- Possible uses:
 - display messages
 - set and lock user preferences
 - control visits shown in the patient binder

UNIX Command Line

DFaccess.rpc

Command line equivalent to DFsystem

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DFprintdb

Book Marked PDFs

Can now be created in 2 ways:

- from iDataFax
- from the command line using DFprintdb

DFstatus

2 New Options for DataFax Server Status

`%DFstatus -l` ... current logins

User	Host
------	------

dwt	localhost
jack	ham-gateway.datafax.com

`%DFstatus -m` ... current seat usage

Seats in Use:

Admin	1 of 4
General	15 of 26
Total	16 of 30

DFsqlloader

Creates Snapshots of a DataFax Study DB

Supported SQL databases:

- ORACLE
- PostgreSQL
- MySQL
- MS SQL Server (new)