
DataFax 3.8+

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Objectives

- Many Paths Paper, Fax, EDC, ASCII import
- One Setup works for both Fax and EDC
- Freedom work from anywhere: LAN or Internet
- Migration X Windows -> QT
- Just 3 Tools DFsystem, iDataFax, DFsetup
- Executables Windows, Mac, Solaris, Linux
- Permissions studies, tools, views, data, metadata
- UNIX Account eventually needed only by user datafax
- UNIX server will continue to provide datafax services

Heads Up

To be discontinued - eventually

- DF lite
- All X Window tools
- Secondary data records
 - but secondary images will remain
- Error status
 - on hold: keys unknown, outside database
 - pending: keys known, inside database

The Transition

DataFax 3.8+ is a transition version

- includes both X window and QT tools
- maintenance only on X window tools
- new development on QT tools

DataFax 3.8-001, -002, etc. will be full software releases.

DataFax 3.8+

3.8 - Aug. 24, 2006

- iDataFax - new EDC tool

3.8-001 - Jan. 24, 2007

- fax processing added to iDataFax

3.8-002 - Spring 2007

- iDataFax supercedes DFvalidate and DFreports

DFsystem 3.8+

System Admin Functions

- register new studies
- name study administrators

Study Admin Functions

- define study roles
- register and manage study users
- assign roles to users
- disable a study to take it offline
- restrict study database access

Study Roles - user permissions

- iDataFax Views
- DataFax Tools
- Reports - DataFax & Study Specific
- Study Database
 - read / modify / write - by work flow levels
 - data: create, modify, delete, register as lost
 - queries: create, modify, delete, reply, approve
 - reasons: create, modify, delete, approve

Study Roles - Limitations

Each user can play different roles

- at different sites, and also for
- different patients at any given site

But a user can only play 1 role at a time for each patient in the study.

Thus, you can not prevent a user from viewing or changing a patient's data under one role while at the same time allowing this under a different role.

Of course any individual could have more than 1 login account with different roles for the same study.

Work Flow - modes & levels

Modes

- View - no changes to record or level
- Edit - level remains unchanged
- Modify - level is changed only if data or metadata are changed
- Validate - level can be changed without any change to data or metadata

Levels

- 0 - new fax queue or pending records
- 1-7 - available for study task tracking

new in 3.8

Work Flow & Permissions

- Role permissions are always applied
 - work flow mode does not grant user any extra permissions
- To update records from refaxed CRFs user requires:
 - view permission to load the existing record
 - modify permission to change it's level
- Delete permission is required to change keys
 - because old version of record must be deleted
- Data and metadata records have separate levels
 - Modify mode:
 - level is changed only if 1+ fields are changed
 - this applies separately to each data and metadata record
 - Validate mode:
 - level is changed on all data and metadata records, even if no changes are made to data or metadata
- iDataFax defaults to: modify - level 1

Select - By Data Fields

Select records by searching data, queries, or reasons for records having any combination of:

- record status
- keys: site, patient, visit, plate
- current work flow levels: 1-7
- creation date
- modification date
- a specified text string

Select - By Data Fields

- **Under Permission Control**
 - primarily for work flow management by central office data management staff, not the clinical sites
- **Users with select permission can select:**
 - records to be reviewed
 - mode: view, edit, modify, validate
 - sign-off level: 1-7 per write user's permissions
- **Users without select permission get:**
 - mode: modify
 - sign-off level: 1

Example Roles

Clinical Sites

- EDC sites
- Fax Sites

Data Management

- Incoming Faxes: router & data entry
- Reviews: e.g. query content review

Clinical Management

- Site Monitors
- Principal Investigators

EDC Sites

iDataFax: modify mode, save to level 1

- new data entry
- minimizing the need for data queries
 - reasons, missing value codes, lost data log
- getting to green:
 - find and finishing incomplete & pending records
 - find and replying to queries

EDC Sites

The top screenshot shows the configuration for 'Clinical Sites - EDC' with the following checked items:

- iDataFAX Views:** Data, Queries, Reasons, Reports
- DataFAX Tools:** Status, Setup, Viewer, Validate, Reports, Ldl, QC, Export, Batch, New Data
- DataFAX Reports:** DF_ATcrfs, DF_ATfaxes, DF_ATmods, DF_CTcrfs, DF_CTpages, DF_CTqcs, DF_CTvisits, DF_ICcenters, DF_ICimages, DF_ICkeys, DF_ICqcs, DF_Icr
- Study Reports:** Patient_Schedule, Study_Status

The bottom screenshot shows a permissions table for the same site:

Get	Show			Show	Modify	Write	Data	Queries				Reasons								
Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels	C	M	D	L	C	M	D	A	R	C	M	D	A	
<input checked="" type="checkbox"/>	ALL	ALL	0-6	<input type="checkbox"/> none <input type="checkbox"/> none	<input type="checkbox"/> none <input type="checkbox"/> none	0-6	0-1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Fax Sites

Paper CRFs

- record new patient data
- make corrections in response to queries

Fax Machine

- fax CRFs after each patient assessment
- fax corrected CRFs as needed

Data Management - Fax Entry

iDataFax: validate mode, save to level 2

- review and route unidentified CRFs
- review ICR and complete data entry
- add queries
 - created by edit checks
 - created manually
- enter reasons from CRF margin notes
- enter corrections from refaxed CRFs

Data Management - Fax Entry

Name: Data Management - Fax Entry Status: Active

Description: Enter new data records from faxed CRFs

Tools & Reports **Permissions**

<input type="checkbox"/> iDataFax Views	<input type="checkbox"/> DataFax Tools	<input type="checkbox"/> DataFax Reports	<input type="checkbox"/> Study Reports
<input type="checkbox"/> Data	<input type="checkbox"/> Status	<input type="checkbox"/> DF_ATcrfs	<input type="checkbox"/> Patient_Schedule
<input type="checkbox"/> Queries	<input type="checkbox"/> Setup	<input type="checkbox"/> DF_ATfaxes	<input type="checkbox"/> Study_Status
<input type="checkbox"/> Reasons	<input type="checkbox"/> Viewer	<input type="checkbox"/> DF_ATmods	
<input checked="" type="checkbox"/> Fax	<input type="checkbox"/> Validate	<input type="checkbox"/> DF_CTcrfs	
<input type="checkbox"/> Data - with Select	<input type="checkbox"/> Reports	<input type="checkbox"/> DF_CTpages	
<input type="checkbox"/> Reports	<input type="checkbox"/> Ldl	<input type="checkbox"/> DF_CTqacs	
	<input type="checkbox"/> QC	<input type="checkbox"/> DF_CTvisits	
	<input type="checkbox"/> Export	<input type="checkbox"/> DF_ICcenters	
	<input type="checkbox"/> Batch	<input type="checkbox"/> DF_ICimages	
	<input type="checkbox"/> New Data	<input type="checkbox"/> DF_ICkeys	
		<input type="checkbox"/> DF_ICqacs	
		<input type="checkbox"/> DF_icr	

Name: Data Management - Fax Entry Status: Active

Description: Enter new data records from faxed CRFs

Tools & Reports **Permissions**

Get	Shows	Shows	Modify	Write	Data	Queries	Reasons												
Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels	C	M	D	L	C	M	D	A	B	C	M	D	A
<input checked="" type="checkbox"/>	ALL	ALL	0-6	<input type="checkbox"/> none <input checked="" type="checkbox"/> all	0-6	2	<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"/>	<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 type="checkbox"/>				<input type="checkbox"/> none			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Data Management - Fax Pass 2

iDataFax: validate mode, save to level 3

- retrieve records from level 2
- review data and metadata
- make corrections as needed

Data Management - Fax Pass 2

Name: Data Management - Fax Pass 2 Status: Active

Description:

Tools & Reports **Permissions**

<input type="checkbox"/> iDataFax Views <input checked="" type="checkbox"/> Data <input checked="" type="checkbox"/> Queries <input checked="" type="checkbox"/> Reasons <input type="checkbox"/> Fax <input checked="" type="checkbox"/> Data - with Select <input type="checkbox"/> Reports	<input type="checkbox"/> DataFax Tools <input type="checkbox"/> Status <input type="checkbox"/> Setup <input type="checkbox"/> Viewer <input type="checkbox"/> Validate <input type="checkbox"/> Reports <input type="checkbox"/> Ldl <input type="checkbox"/> QC <input type="checkbox"/> Export <input type="checkbox"/> Batch <input type="checkbox"/> New Data	<input type="checkbox"/> DataFax Reports <input type="checkbox"/> DF_ATcrfs <input type="checkbox"/> DF_ATfaxes <input type="checkbox"/> DF_ATmods <input type="checkbox"/> DF_CTcrfs <input type="checkbox"/> DF_CTpages <input type="checkbox"/> DF_CTqcs <input type="checkbox"/> DF_CTvisits <input type="checkbox"/> DF_ICcenters <input type="checkbox"/> DF_ICimages <input type="checkbox"/> DF_ICkeys <input type="checkbox"/> DF_ICqcs <input type="checkbox"/> DF_icr	<input type="checkbox"/> Study Reports <input type="checkbox"/> Patient_Schedule <input type="checkbox"/> Study_Status
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Name: Data Management - Fax Pass 2 Status: Active

Description:

Tools & Reports **Permissions**

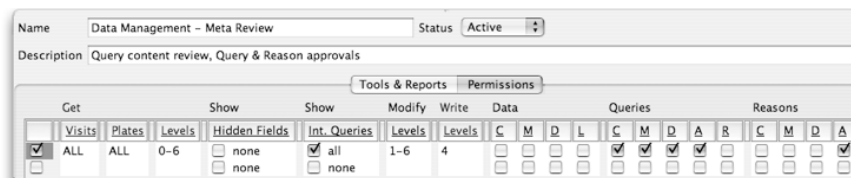
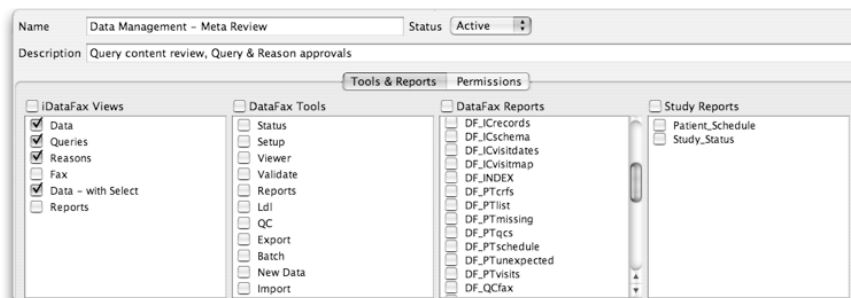
Get	Shows	Show	Modify	Write	Data	Queries	Reasons												
Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	C	M	D	L	C	M	D	A	B	C	M	D	A	
<input checked="" type="checkbox"/> ALL	<input checked="" type="checkbox"/> ALL	0-7	<input type="checkbox"/> none <input type="checkbox"/> none	<input checked="" type="checkbox"/> all <input type="checkbox"/> none	0-7	3	<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 type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Data Management - Metadata Review

iDataFax: validate mode, save to level 4

- Select - By Data Fields
 - queries and reasons at levels 2-3
 - outstanding queries for content review
 - pending queries & reasons for approval
- Field - Review Queries & Reasons
 - modify / add / delete queries & reasons
 - update status of each query & reason
 - save: Final or Incomplete

Data Management - Metadata Review



Site Monitor

iDataFax: validate mode, save to level 5

- Select - By Data Fields
 - data records with status Final
 - at levels 1,3-4
- Compare data with medical records
 - skip any records with pending metadata
 - add QCs to flag any discrepancies
 - save to level 5

Site Monitor

Name: Site Monitor Status: Active

Description: Confirm that patient study data matches medical records

Tools & Reports **Permissions**

<input type="checkbox"/> iDataFax Views <input checked="" type="checkbox"/> Data <input checked="" type="checkbox"/> Queries <input checked="" type="checkbox"/> Reasons <input type="checkbox"/> Fax <input checked="" type="checkbox"/> Data - with Select <input checked="" type="checkbox"/> Reports	<input type="checkbox"/> DataFax Tools <input type="checkbox"/> Status <input type="checkbox"/> Setup <input type="checkbox"/> Viewer <input type="checkbox"/> Validate <input type="checkbox"/> Reports <input type="checkbox"/> Ldl <input type="checkbox"/> QC <input type="checkbox"/> Export <input type="checkbox"/> Batch <input type="checkbox"/> New Data <input type="checkbox"/> Import	<input type="checkbox"/> DataFax Reports <input type="checkbox"/> DF_ICrecords <input type="checkbox"/> DF_ICschema <input type="checkbox"/> DF_ICvisdates <input type="checkbox"/> DF_ICvismap <input type="checkbox"/> DF_INDEX <input checked="" type="checkbox"/> DF_PTcrfs <input checked="" type="checkbox"/> DF_PTlist <input checked="" type="checkbox"/> DF_PTmissing <input checked="" type="checkbox"/> DF_PTqcs <input checked="" type="checkbox"/> DF_PTschedule <input checked="" type="checkbox"/> DF_PTunexpected <input checked="" type="checkbox"/> DF_PTvisits <input type="checkbox"/> DF_QCfax	<input checked="" type="checkbox"/> Study Reports <input type="checkbox"/> Patient_Schedule <input type="checkbox"/> Study_Status
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Name: Site Monitor Status: Active

Description: Confirm that patient study data matches medical records

Tools & Reports **Permissions**

Get	Shows	Shows	Modify	Write	Data	Queries				Reasons					
Visits	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels	C	M	D	A	R	C	M	D	A
<input checked="" type="checkbox"/> ALL	ALL	0-7	<input type="checkbox"/> none <input type="checkbox"/> none	<input checked="" type="checkbox"/> all <input type="checkbox"/> none	1,3-4	5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DFsystem 3.8-002

- copy & paste: roles + users
- filter user list by studies and roles

iDataFax 3.8-002

- reports view
- dfexecute(), dflookup(), dfwhoami()
- visit map ranges #-# vs #~#
- record history
- create PDF for selected records

iDataFax 3.8-002

Page - Review Images

- select a different primary image
- correct keys on a secondary image
- delete a secondary image

No secondary records in iDataFax

All Images Belong to the Primary Record

- deleting a record effects all images
- changing keys effects all images