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# iDataFax

Wayne & Eric  
Clinical DataFax Systems Inc.



## Primary Objective

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### MANY PATHS

- fax
- email attachments
- import ASCII records
- raw data entry
- iDataFax

### ONE GOAL

- same study setup
- same database
- same reports
- same tools:
  - DFsas
  - DFexport
  - etc.



## Benefits

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- Same study setup and central office tools
  - not a lot to learn
  - nothing lost: same reports and other central office tools
- Select best data collection method for the task at hand
  - Sites: some fax, some use iDataFax
  - CRFs: some faxed, some entered using iDataFax
  - Phase: fax patient entry CRFs, switch to iDataFax for follow-up
  - Process: sites use iDataFax, CRAs fax source verified CRFs
- Low Risk: ability to make mid-course corrections
  - switch a site from iDataFax to faxing or vice versa



## This Morning's Agenda

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- New DFsystem tool - Eric
- New iDataFax tool - Wayne
- DataFax 3.8 - Eric
- Looking Ahead - Wayne
- Feedback - Clients



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# The New DFsystem

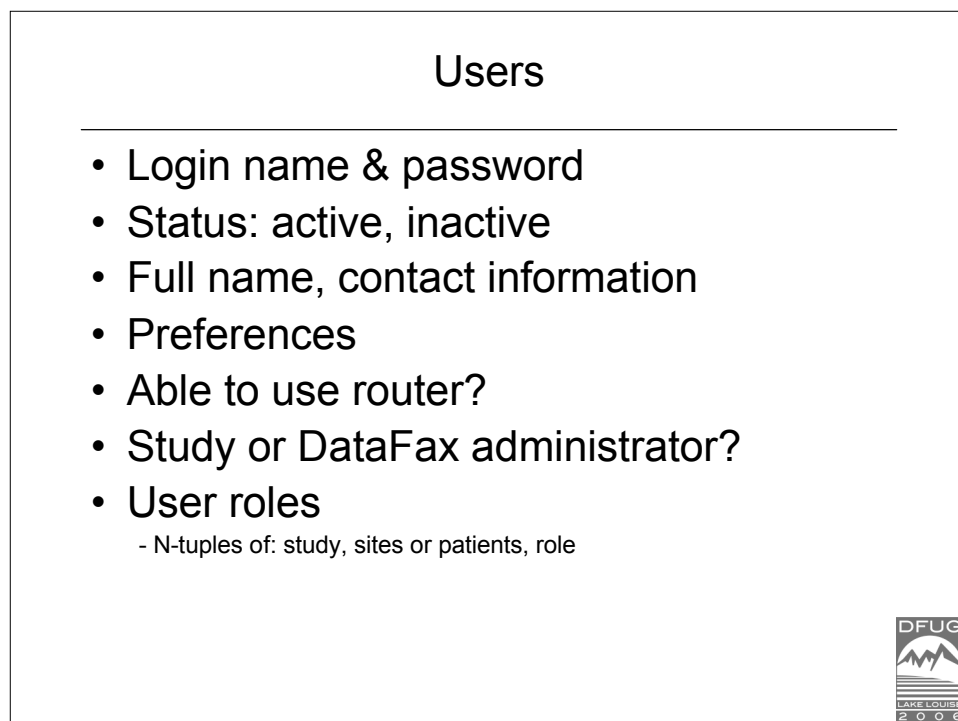
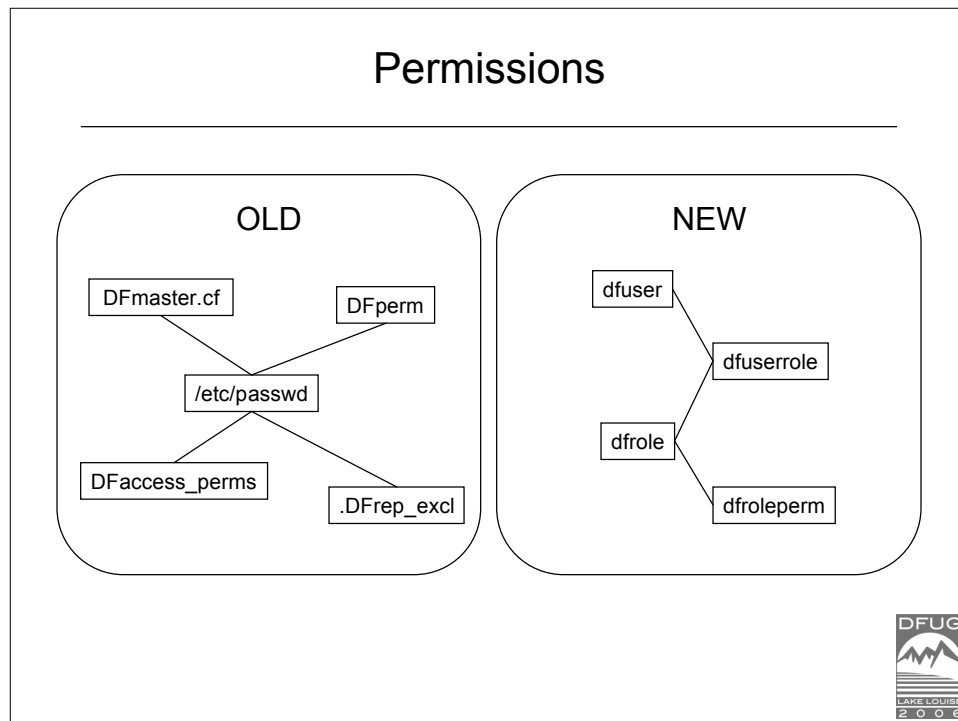


## Authentication

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- **UNIX DataFax users continue to use existing UNIX authentication**
  - For now, subject to change in future
- **iDataFax users have a unique electronic signature**
  - Combination of unique login name and password
  - Password expiration built-in
  - Required for every "login" to iDataFax
  - Required for every "login" to DataFax Administration tool





## Roles

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- Defined within context of a study
- Name and descriptive label
- Access to which DataFax tools?
  - All originals, plus
  - DFbatch and DFexport
- Access to which iDataFax views?
- Access to which standard & study reports?
- Role permissions
  - N-tuples of: visits, plates, read/write levels, read-only levels, data permissions, query permissions, reason permissions, view hidden fields, view internal queries
  - Data permissions: create, modify, delete, (un)mark lost
  - Query permissions: create, modify, delete, reply, approve
  - Reason permissions: create, modify, delete, approve



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## iDataFax



## iDataFax - what is it ?

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- separate application (with versions for: Windows, Mac OS X, Linux and Solaris)
- requires an internet connection to access a DataFax study database
- login and password authentication
- SSL encryption
- user roles define permissions
- data entry, update and review
- meta-data management
  - queries from central office
  - reasons for data values
  - missing value types



## iDataFax - login

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### User connects to a DataFax server

- using: server, login name, and password
- password aging

### While connected to a DataFax server

- user selects from list of authorized studies
- able to close a study and select another one
- timeout occurs after specified period of inactivity

### Timeout Recovery

- user must log back in to the DataFax server
- on selecting study, user can return to the previous record with unsaved changes, if any



## iDataFax - Walk Around

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### Navigation

sites-patients-assessments-pages

### Data window

data and image views, like DFvalidate

### Meta-data windows

Queries, Reasons, Missing value codes

### Save

Set status = Final, Incomplete or Pending

### Messages

Field level help

### Menus

File Edit View Show Patient Assessment Page Field Help



## How do sites manage study “CRFs”?






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- Case Record Books (CRB)
- Open a Site
  - shows CRBs ‘on the shelf’, new and in-progress
- Filter CRBs
  - new, on-study, cases with incomplete data, etc.
- Open a CRB
  - locks CRB
  - shows patient assessments from the visit map
- Open Assessments
  - shows CRF pages within each assessment



## Patient CRB Icons

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-  Blank CRB
-  CRB with problems:  
illegal values, unresolved queries, etc.
-  CRB with pending pages  
but no other problems
-  CRB with no problems  
no incomplete, missing or overdue pages
-  CRB with lost pages only  
all other pages are blank



## Assessment & Page Icons

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	Required	Optional	Unexpected
Blank	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Pending	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Incomplete	<input checked="" type="checkbox"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
Final	<input checked="" type="checkbox"/>	<input checked="" type="radio"/>	<input checked="" type="checkbox"/>
Lost	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>



## How do sites enter data?

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- Navigate to a CRF page
- If locked by another user
  - warning dialog with 2 options: cancel, view only
  - Save [F..] [I..] [P..]  Patient ID: locked by another user
- Data entry widgets on a CRF background
  - just like DFvalidate
- Keys are predefined & unchangeable
  - maintains CRB integrity
- Standard field navigation using keyboard and mouse



## How do sites save data?

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### Save Buttons - save changes and assign page status

- Pending
  - user is not finished entering data on this page
  - used to indicate that page is not ready for central office review
  - can only be used if current page status = new or pending
- Incomplete
  - page has unresolved QCs (blue) and/or
  - illegal values (red) or blank required/essential fields (red)
- Final
  - page has no blue or red fields; and may include:
    - QCs and/or reasons 'pending resolution' (orange)
    - fields with resolved meta-data (magenta)
    - blank optional fields (yellow)
    - fields with legal values (white)



## Minimizing queries from central office

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During data entry the sites can:

- apply missing value codes
  - allowed on optional and required fields
  - not allowed on essential fields
- add a reason to explain a data value
  - the equivalent of marginal comments
  - makes a problem 'resolved pending review'
- mark an assessment or page as "lost"
  - to do this the user must provide a reason
  - reason status is set to 'resolved pending review'



## Finding queries from central office

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Filter CRBs - select 'patients with problems'

- this includes problems of all types
  - unresolved queries
  - illegal values
  - blank required/essential fields
  - pages missing from partially completed assessments
  - overdue visits
  - pages marked 'incomplete' for other reasons

Use Menu View-Queries

- filter queries by problem type
- jump to CRF & data field with the query



## Responding to queries from central office

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While traversing data fields the sites can:

- identify and read each field level query
  - fields with queries are color coded
  - queries appear in the meta-data query window
- respond to a Q&A query
  - button launches query response dialog
  - query status is set to 'resolved pending review'
- respond to a Correction query
  - correct data field to a legal value
  - use the query response dialog



## How do sites know if a field is OK?

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While focus is on each field:

- message window
  - shows field level help defined in the study setup
- meta-data windows show
  - missing value label
  - query (with status: resolved or unresolved)
  - reason previously entered by the site
- edit checks
  - if(problem) { set field illegal; display message; }
- field color coding
  - standard DataFax colors with one revision



## iDataFax - New Field Colors

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- Blue - unresolved query
- Orange - pending review (query or reason)
- Magenta - resolved (query, reason or missing value)
- Red - illegal, required or essential
- Yellow - blank but optional
- White - legal value

*Note: Blue and/or Red fields prevent users from saving a page with status = 'final'*



## Can central office lock pages, visits and complete CRBs?

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### Specify 'read only' validation levels

- when a record is assigned to these levels data and meta-data can be viewed but not changed in iDataFax
- recommended for patients in progress

### Reserve a 'hidden' validation level

- once assigned to this level records can not be seen in iDataFax
- recommended for completed patients



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# DataFax 3.8(-000)



## Study Definition / Setup

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- Hidden fields
- Essential fields
  - Like required fields, but will not accept a missing value



## Status Changes

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- **Status 3, level 0 data records (pending) can be present in database**
  - Counted by DF\_QCupdate
- **Reason for data change statuses**
  - 0 = pending approved
  - 1 = approved (only status used in 3.7)
  - 2 = rejected
- **Status 0 queries are pending resolved**

DataFax	Clean	Dirty	Error	S3, L0
iDataFax	Final	Incomplete		Pending



## Validation

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- Goodbye set locking, except for new queue
- Hello record locking
  - 'In Use' count in DFstatus replaced by 'Locks'
- New retrieval methods for locating pending queries and reasons for data value
- Pending records visible in view-only mode
- Allow illegal/missing data values with a reason for data value on clean records
- "Once a reason, always a reason"



## Validation

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- Revised field color coding:

OLD		NEW	
Unresolved query	Blue	Unresolved query	Blue
Resolved query	Magenta	Query or reason pending approval	Orange
Missing value code	Orange	Resolved / approved query or reason, missing value code	Magenta
Illegal or missing, required value	Red	Illegal or missing, required value	Red
Blank	Yellow	Blank	Yellow
"Otherwise"	White	"Otherwise"	White



## Edit Check Behavior in iDataFax

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- UNIX system functions are no-ops
  - dfun(), dfsystem(), dlopen(), dload(), dftread(), dfwrite(), dfrewind()
- dflookup() returns exact match or default value
  - Facilities for partial/full table display will come later
- New dfperm( ID, Visit, Plate) function
  - Returns TRUE if user has permission to read the record
  - References to data fields on non-permitted records return "missing value"
- New TRUE/FALSE function to determine if user is in iDataFax
- Simplified dfaddqc() behavior
  - Displays: problem type, query text, and 2 buttons
    - "Add" - add query with status "new, unresolved"
    - "Cancel" - do not add query



## Queries

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- Validation Tool: Add -> Refax/Q&A -> Resolve/Approve
- iDataFax: Read -> Reply
  
- Re-purposed field (12, item within report page) contains reply to query
- Status 0 = pending resolved
- Validation level tracks query, not data record
  - Can ask for either or both during export
- Several reports have been updated
- DF\_QCupdate
  - Recommend running it nightly in a cron job



## System Administration

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- Authentication required
- Two-levels of administrator: system and study
- Multi-user administration tool
- Fewer & revised study server parameters
- 1 incoming and 1 outgoing daemon
- No more slaves dialog
- New system identification and license codes



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# Looking Ahead



## Timeline

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### iDataFax demo

available now running on a CDSI server

### DataFax 3.8

June 1, 2006 target

### Minor Releases

about every 6 months



## The View Menu

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### Study Info

study documents, messages, newsletters, etc.

### Patients

patient scheduling and status information

### Data

data entry window

### Queries

query management window

### History

user session history: who, what, when



## Tasks in iDataFax - Examples

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### Data Entry

– performed by the participating clinical sites

### Data Review

– targeted checks, add QCs, approve replies and reasons

### SAE Review

– immediate review of all reported serious adverse events

### Endpoint Adjudication

– consultants review specified data and classify outcomes

### Source Verification

– performed by CRAs visiting the clinical sites

### Final Review and Lock

– visit by visit or case by case



## Tasks in iDataFax - Implementation

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How are tasks defined ?

- task name, label, instructions
- relevant data records: task and non-task
- record locking method: patient, visit, page
- meta-data permissions: add, modify, etc.
- data entry mode & work flow level

How are tasks used ?

- tasks belong to roles
- users select tasks from an iDataFax menu



## Offline Functionality

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### Check Out

- allow users to lock and load whole patient CRBs
- or whole patient assessments / visits

### Check In

- happens automatically on next login
- modified records are submitted to the database
- all locks are released
- local record storage is cleared



## 21 CFR PART 11

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### Electronic Signatures

user login name and password

### Electronic Records

digital signatures: public / private key technology



## iDataFax Demo Study

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- Register by sending an email to [support@datafax.com](mailto:support@datafax.com)
- We will enter you as a user assigned to your company's 'site' and send you a login name and password
- Download iDataFax from the support section of the web site
- Connect to [idemo.datafax.com](http://idemo.datafax.com)
- We hope you will try it out and provide us with feedback and suggestions



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Questions  
Comments  
Suggestions

