
The DataFax ATK for 3.8-001

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What has not changed?

Objective and approach. The ATK still:

- Provides clients with an acceptance test plan
- Confirms the core functionality of the DataFax software
- Based on meeting data management objectives
- Consists of a series of tests organized into distinct modules

What is different?

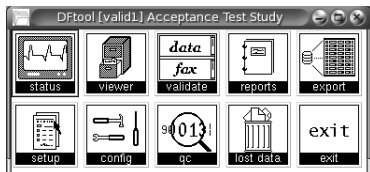
ATK 3.7-004 to ATK 3.8-001:

- General changes
- Changed behavior
- New features

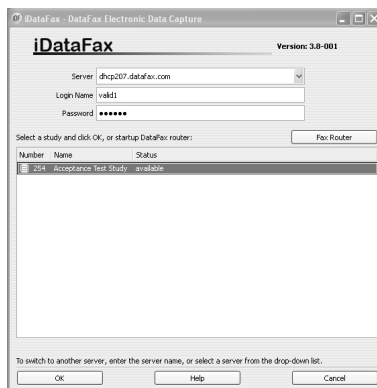
General Changes

Updated Screen Captures

- DataFax = Solaris 10

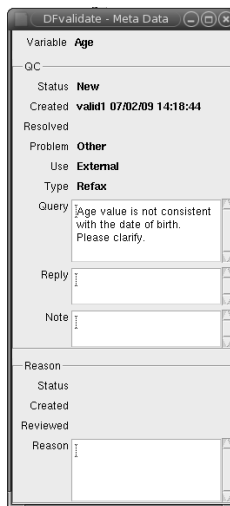


- iDataFax = Windows



Meta Data Window

- Single window
- QCs and reasons



Record Locking

- Status tool
- Does user hold locks on any database records?

The screenshot shows the 'DataFax Status' tool interface. It includes sections for Server Status, User Status, and Database Status. The Database Status section contains a table with the following data:

Level	Clean	Birky	Error	CLEW	BIRY	ERRR	Lost	Total
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	1	1
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	1	1
P Total	0	0	0	S Total	0	0		

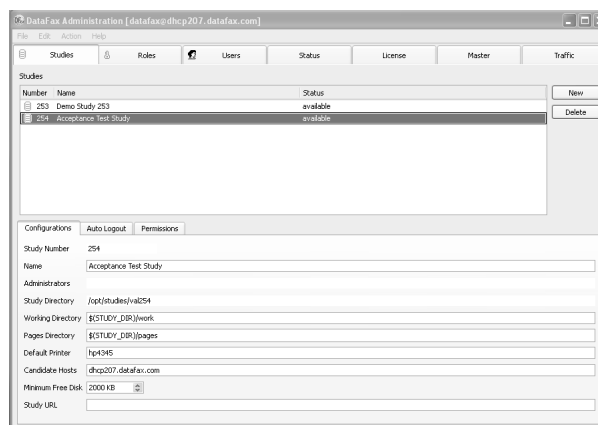
Additional information from the screenshot: Server Status shows DataFax Master and Study Server running on dhcp203.dshbc.com. User Status shows user 'validi' with tool 'DataFax Status Tool' and no locks. Database Status includes fields for Centers, Patient Ids, Visits, and Plates.

Changed Behavior and New Features

ATK Installation

- New ATK installation?
 - directly install 3.8-001 ATK.TAR (Test Step 1.3)
- Existing ATK installation?
 - first remove existing ATK.TAR before installing 3.8-001 ATK.TAR
 - existing ATK.TAR files will not be overwritten

ATK Configuration



ATK Configuration

New DFsystem tool:

- Studies Tab
 - configure study val254 directories and printer
- Users Tab
 - define DataFax/iDataFax account for valid1
 - define DataFax/iDataFax account for datafax
- Roles Tab
 - define role permissions and assign to users
- Create UNIX account for user valid1
- Install iDataFax application

Field Color Coding

	3.7	3.8-001
Resolved QCs	magenta	green
Unresolved QCs	blue	blue
Approved reasons	not applicable	green
Pending reasons/QCs	not applicable	orange
Missing value codes	orange	green

2 New iDataFax Modules

Module 7 - iDataFax Data Entry

- Enter and save data for new study subjects
- Execute programmed edit checks
- Add reasons to explain entered data
- Confirm database audit trail information

Module 8 - Review of iDataFax Data

- Query previously entered data
- Review existing reasons
- Review pending data

Module 7 - iDataFax Data Entry

- First time login of valid1
 - change password
- Patient binder view
 - different record navigation
- Record sign-off
 - Final vs clean, Incomplete vs dirty
- Pending record status
 - be aware of save status in Test Step 7.4 and 7.5
 - reasons are not required for data changes

Module 7 - iDataFax Data Entry

The screenshot shows the iDataFax data entry interface. On the left is a navigation tree with folders for 'Site 01 - Clinical DataFax Systems Inc. (Oncor Medical)', 'Site 20 - Hospital #1', 'Site 20 - Hospital #2', 'Site 99 - Hospital #99', and 'Patient'. The main area displays two screens of data entry:

Screen 1: Date: 23/04/07. Readings: 107 / 096 mmHg (systolic/diastolic), 172 / 098 mmHg, 172 / 098 mmHg.

Screen 2: Date: 25/04/07. Readings: 171 / 096 mmHg (systolic/diastolic), 169 / 096 mmHg, 170 / 096 mmHg.

Eligibility Criteria:

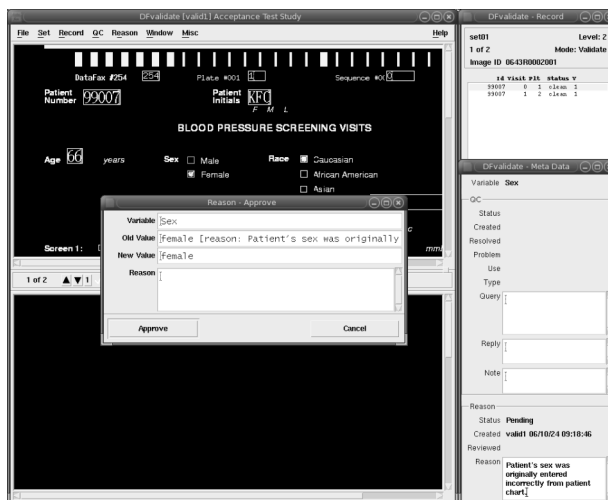
Criteria	Yes	No
1. Age 18-70 years old.	<input checked="" type="radio"/>	<input type="radio"/>
2. Male, or if female, not pregnant and using a reliable contraceptive method.	<input checked="" type="radio"/>	<input type="radio"/>
3. Taking blood pressure medication.	<input type="radio"/>	<input checked="" type="radio"/>
4. Major surgery or other medical emergency in the past 6 months.	<input type="radio"/>	<input checked="" type="radio"/>
5. Patient has signed informed consent and agrees to return for monthly follow-up visits.	<input checked="" type="radio"/>	<input type="radio"/>
6. Systolic blood pressure 160-200 mmHg or Diastolic blood pressure 95-120 mmHg on Reading 3 of both Screen 1 and Screen 2.	<input checked="" type="radio"/>	<input type="radio"/>

At the bottom, it states 'Patient is Eligible' and 'Once Completed, Please Fax This Form to (605) 874-4788.' There are also buttons for 'Save (0-3)', 'Final', 'Incomplete', and 'Pending'.

Module 8 - Review of iDataFax Data

- Performed in the Validation tool
- Pending reasons
 - added during iDataFax data entry only
 - require approval by data management
- Pending records
 - added during iDataFax data entry only
 - retrieval requires specific criteria (Test Step 8.4)
 - cannot be edited

Module 8 - Review of iDataFax Data



Edit Checks

- Modules 6, 7, 9, and 13
- Same behavior in DFvalidate and iDataFax
 - exception = lookup table (Medications Log)
- \$STUDY_DIR/lib/DFedits.bin must exist for iDataFax
- Execute automatically in iDataFax
- Add auto reasons when a field's value is modified
 - e.g. "Set by edit check CalcWeight"
 - reason = approved, field = green

Edit Checks

Weight . kg or . lbs

Reason	
Status	Approved
Created	valid1 07/02/12 09:27:19
Reviewed	valid1 07/02/12 09:27:19
Reason	Set by edit check WeightEquiv

Double Data Entry (DDE)

- Module 9
- Appearance of records in record list
 - “new, level 0” until selected for entry
 - selecting record displays existing status and level
 - user applies or changes status/level at sign-off
- Existing QCs are preserved/transferred to DDE record
 - e.g. Test 9.3, DOB contains QC but no value
 - QCs may be edited

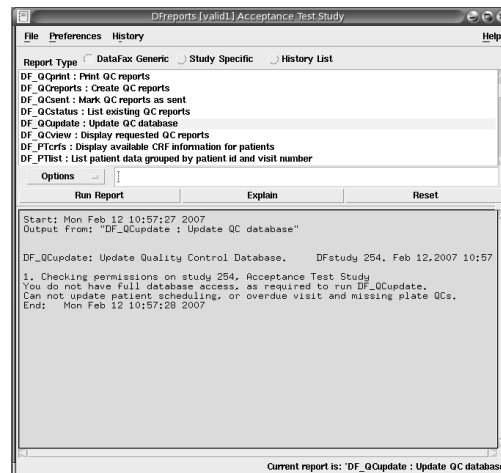
Lost Data Log

- Module 10
- Creating lost records
 - now required to set level of lost record
 - level was automatically assigned by DataFax in 3.7-004

QC Report Generation

- Module 11
- .drf files created by reports (e.g. VDIllegal.drf) now stored in a new \$STUDY_DIR/drf directory (Test 11.2)
- DF_QCupdate requires unrestricted permissions
 - valid1 Write/Modify perms = level 0-3 (Module 1)
 - must use DFsystem to increase levels to 0-7
 - issue for QC report generation in all studies

QC Report Generation



QC Review and Resolution

- Modules 12 and 13
- iDataFax
 - locate and reply to QCs using Query View tool
- DFvalidate
 - approve query replies/resolve QCs

QC Review and Resolution

Site / Patient	Assessment : Page	Field : Problem	Status & Replies
Site 0 - Clinical DataFax Systems Inc. (Error Monitor)			
Site 10 - Hospital #1			
Site 20 - Hospital #2			
Site 99 - Hospital #99			
X 99001	Baseline : Form 2	Smoking Status : (Missing)	Outstanding - valid! 3/14/1998 1:50:22 PM
X 99002	Baseline : Form 2	Date of Birth := 05/12/30 (Inconsistent)	Outstanding - valid! 10/23/2006 10:27:20 AM
X 99002	2 Month Follow-up : Form 5, 2 Month	Birth date does not match age on Form 1 New Bottle Med. Code # := 1324 (Other) This value does not match medication code at entry (see Form 2)	Outstanding - valid! 3/14/1998 1:42:29 PM
X 99004	Baseline : Form 2	Pulse beats/minute : (Missing)	Outstanding - valid! 3/14/1998 2:00:23 PM
X 99004	Baseline : Form 4, Pg 1	Missing Page	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99005	Screening Visits	Overdue visit	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99005	Baseline : Form 2	Missing Page	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99005	Baseline : Form 4, Pg 1	Missing Page	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99007	Screening Visits : Form 1	Screen 1, Read 1 systolic := 107 (Inconsistent) This value is inconsistent with all other BP readings. Please explain.	Outstanding - valid! 10/23/2006 2:51:05 PM
X 99007	Baseline : Form 4, Pg 1	Missing Page	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99007	1 Month Follow-up	Overdue visit	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99007	2 Month Follow-up	Overdue visit	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99007	3 Month Follow-up	Overdue visit	Outstanding - valid! 10/24/2006 2:01:46 PM
X 99007	Study Termination	Overdue visit	Outstanding - valid! 10/24/2006 2:01:46 PM

Future Plans

Control Panel

- replace X windows interface with Qt
- create more user-friendly log reports

Questions?
