DataFax 2014
What’s Coming?

DataFax Developers
DF/Net Software ULC
Client Tools

Welcome to DataFax 2014
New in DFsetup 2014
Modular and CDISC-Compatible Setups
### MEDICATION CHANGE LOG

Record any change, addition or cessation of medication since the patient's initial assessment.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Type of Change</th>
<th>Date of Change</th>
<th>Current Total Dose</th>
<th>Reason for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New Dose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>New Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stop Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Restart Drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>day</td>
<td>month</td>
<td>year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(mg)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. 

Reason for Change: 

2. 

Reason for Change: 

3. 

Reason for Change: 

4. 

Reason for Change: 

5. 

Reason for Change:
DFsetup – Components

- **STYLES**
  - Field Definitions

- **MODULES**

- **PLATES**
  - Module References
  - Field References
DFsetup – Modules

- New layer between styles and fields
- Allows grouping of fields
- Field definition decoupled from field reference
- Easy to use 21 CFR Part 11-compliant E-signature module
  - Signature name, date, time
- DFmigrate creates plate-based modules
Module Definition
Module Layout

Blood Pressure Screenings Visits

- Age: 16-79 years old
- Male or female, not pregnant and using a reliable contraceptive method
- Taking blood pressure medication
- Major surgery or other medical emergency in the past 6 months
- Patient has signed informed consent and agrees to return for monthly follow-up visits
- Systolic blood pressure 100-200 mmHg or Diastolic blood pressure 95-105 mmHg on Reading 3 at both Screen 1 and Screen 2

Patient is eligible
DFsetup – Fields

- **New field name labels, order**
  - Generic (4.3) = Name
  - Unique (4.3) = Alias

- **New properties**
  - Prompt
  - Constant
  - Use
  - Units
  - Comments
  - Hidden - Masked
DFsetup – Fields (cont’d)

- New property inheritance and locking behavior

- New ‘SimpleTime’ style and data type
  - hh:mm:ss
  - hh:mm

- Patient/Subject IDs increased to 15-digit maximum
Field Definition
Field References
DFsetup

Other Setup Additions
DFsetup – Other Additions

- New Import Definitions functionality
  - From another study (Plates, Styles, Modules)
  - From a file (e.g. CDISC library)

- Interactive setup state/problem window

- Field/module support added to edit check language

- Binary DFsetup file replaced with JSON format file
DFsetup – Other Additions (cont’d)

- Addition of study- and plate-level help
- Customization of plate order within visits (DFvisit_map)
- Addition of ‘Level’ specification to global ‘always’ reason
New in iDataFax 2014
iDataFax

List View
List View – Modules View

- Group and view data according to DFsetup module definitions
- Alphabetical listing of modules
- Display all plate data associated with the selected module
- Define/save module or plate views
- Save data by plate or module
List View – Modules View

Switch to Data View

Missing Value

Reason for Data Value

Save [1]  Final  Incomplete  Pending

Last Save: September 17, 2014 13:04:17
iDataFax

Data View
Data View – Documents/Images/Media

- Import and storage of supporting patient documents/media in different formats
  - PNG, JPG, TIFF
  - PDF
  - DICOM
  - audio
  - video
- Maximum single file size = 25 MB
- Multiple media attachments per record
- Print/Save snapshot of current image to a local file
ADVERSE EVENT REPORT

1. DESCRIPTION OF ADVERSE EVENT

Event Start Date: 19/01/13
Intensity: 1
Relationship to Study Drug: 2
Action(s) Taken: 2 4 5
Outcome: 1

Description: chest pain/discomfort, fatigue, dizziness
iDataFax

Batch Edits View
Batch Edits View

- New client tool batch capabilities
- Interactive batch execution of edit checks
- Access controlled by role permissions
- Record locking enforced
- Optionally build a task set of changed records
- Split-screen control file-output log view
Batch Edits View – Control/Log Files

- Accessed locally or from study server
- Backwards compatible with 4.3 and earlier
- Control files
  - GUI or XML
  - XML editor with syntax highlighter
- Output logs
  - XML or HTML
  - Default stylesheets perform transformation
  - Include information about all records processed
Batch Edits Input/Output
Batch Edits Program – DFbatch

- New command-line DFbatch program
- User password-controlled
- User role permissions enforced
- Local or server-side control file
- Behavior consistent with Batch Edits View
iDataFax

Dashboard View
Dashboard View

- New Dashboard View displays
  - Basic study metrics
  - Menu of commonly performed tasks
- Access controlled by role permissions
- Default view – iDataFax iDataFax user preference
- Double-clicking cell or legend marker opens task set and relevant iDataFax view
- Print/save tables and graphs
Dashboard View

Your Study Sites

New CRF pages (all sites) | 0
Pending CRF pages | 3
Incomplete CRF pages | 11
Outstanding queries | 22
Overdue visits | 0
Missing pages | 0
Pending reasons | 3
Rejected reasons | 0

Double click any cell above or legend marker below to fetch relevant records. Press Cmd-1 or select Dashboard from the View menu to return to this view.

Record Status (88)
- Pending (3)
- Lost (2)
- Incomplete (11)
- Final (72)

Query Status (43)
- Pending (3)
- Outstanding (22)
- Resolved (18)

Reason Status (113)
- Pending (3)
- Rejected (0)
- Approved (110)
Other iDataFax Additions
Bookmarked Patient/Site PDFs
Creation of multiple, patient-specific bookmarked PDF files in a single operation
- Specify patients or sites
- Optionally include audit trail information
- Also available from command line – DFpdfpkg

Available in Data and List Views
iDataFax

CDSIC ODM Export
iDataFax – CDISC ODM Export

- Export of study data in CDISC ODM format
  - Conforms to ODM standard 1.3.2
  - Meta data only OR meta data + user data
  - Automatic mapping of DataFax data types

- Available in Data and List Views
ODM Export Interface

- Main interface:
  - Study: 154 - Demo Study 154
  - Description: Screening Data - Site 1
  - Output File: /Users/jeanine/Desktop/ODM/screen_site1.xml
  - Stylesheet:
    - Include DataFax system fields (1-7, NF-1, NF)
  - Meta Data: type study event numbers or right-click cell to select from popup list

- Details:
  - Forms:
    - Blood Pressure Screening Visits: 0
    - Patient Entry Form: 1
    - Medical History: 1
    - Current Medications: 1
    - Monthly Follow-up Form: 1
    - Patient Evaluation Report: 30
    - Study Termination: 30
    - Medication Log: 1
    - Adverse Event Report: 1
    - Death Report: 40
    - Weekly Patient Diary: 1
    - Date Log: 30

- Options:
  - OK to start ODM export?

- Confirmation:
  - File OID: Study154_20140919_120530241
    - Number of events: 1
    - Number of forms: 1
    - Number of subjects: 8
  - ODM export completed!
Other iDataFax Additions
iDataFax – Other Additions

- **Reports View**
  - DF_QCreports - new ‘-R’ option to include Refax QCs only, with page breaks between patients
  - Improved HTML rendering for custom reports

- **Fax View**
  - Enforces user role plate permissions
Review Images dialog now includes image type

Record deletion now requires a password

New lookup table search option – ANY, ALL, ONLY

Export/import user tasks, views, history lists between studies
New in DFsystem 2014
DFsystem

CRF Watermarks
DFsystem – CRF Watermarks

- Defined in DFsystem Studies tab
- Stored in $STUDY_DIR/lib/DFwatermark

Watermark definition
- Watermark text = 100 characters maximum
- May contain meta words (user login name, date, time)
- Select font size, color, and position
- Multiple watermarks per study
- Assigned to study roles

- Copy/paste watermarks from study to study
DFsystem – Watermark Definition
iDataFax – CRF Watermarks

- Available by user login role
  - If multiple watermarks assigned, first one is used

- Watermarks
  - Displayed when printing/saving existing data
  - Printed on all data records and corresponding images
  - Not displayed when printing/saving blank CRFs
  - Not visible on data entry screens

- Can be published between development/production studies (DFsetup)
**ADVERSE EVENT REPORT**

1. **DESCRIPTION OF ADVERSE EVENT**

   - **Event Start Date**: 9/1/13
   - **Intensity**: 1
   - **Relationship to Study Drug**: 2
   - **Action(s) Taken**: 2, 4, 5
   - **Outcome**: 1
   - **Is This A Serious Event?**: Yes

   **Description**: Chest pain/discomfort, fatigue, dizziness

2. **CHANGES**

   During the study, use this form to record all changes in this Adverse Event until it is resolved or the study ends. Fax all additions to this form immediately, and if the adverse event is serious, call the Clinical Safety Monitor immediately.

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Intensity</th>
<th>Relationship to Study Drug</th>
<th>Action(s) Taken</th>
<th>Outcome</th>
<th>Is This A Serious Event?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<tr>
<td>3</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

3. **RESOLUTION OR STUDY TERMINATION**

   Complete the following and fax this page when the event is resolved or when the patient has completed the study.

   **Does the description of this event continue on subsequent page(s)?**: No

   **Has this adverse event been resolved?**: Yes

   **Date of resolution**: 2/5/13

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**Investigator’s Signature**: Dr. J. Lewis

**Date**: 2/5/13

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**Printed on**: 2014/09/19 14:50:17 by jeanine
General DataFax Changes
General DataFax Changes

- **DFsas** (command-line program)
  - New ‘-a’ option to create DFsas job files using field Alias
  - Default uses field Name

- **Legacy Sun Raster image format replaced with PNG**
  - Updated image processing
  - Improved image quality

- **New command-line program DFRas2png**
  - Converts Sun Raster images to PNG
  - Smaller image file size (~50%) with same image quality
Thank you, eh

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