Release Highlights

dfdiscoVer 2018
DFdiscover 2018 Highlights

1. **Look & Feel**
2. **eCRFs**
3. **Site Definitions**
4. **Reporting**
5. **Metadata Editor Panel**
6. **Export to Excel**
7. **Batch Edits View**
8. **Edit Coding Dialog**
9. **User Profile / Certificate Info**
10. **Edit Check Functions**
11. **Web Services / Public API**
12. **... and more**
Look & Feel
Visual Interface

- Updated design
- More intuitive user experience
- Optimized for high-resolution screens
LOOK & FEEL

Visual Interface

- Updated icons
- Enhanced coloring
Visual Interface

- Coloring and shading for emphasis and consistency
Date Picker

- Pop-up calendar view for date selection
Formatting

- Auto-alignment of text, date, and number field length
- Formatting guide for number and date fields
Metadata Editor

- Metadata editor panel provides detailed field information & help messages
LOOK & FEEL

Video Help

- Embed videos in help messages
Updated Terminology

- **DataFax Term**
  - Patient / Participant
  - Fax
  - Center
  - QC / Quality Control Note
  - Problem
  - Raw Data Entry
  - Assessment
  - Sign-Off Level

- **DFdiscover Term**
  - Subject
  - Image
  - Site
  - Query
  - Category
  - EDC Data Entry / EDC
  - Visit
  - Save Level
New DFexplore Preferences

- Set any View as the default
- Display date picker
- Auto text alignment and format guides
- Display metadata editor (details)
- Customize eCRF background color (details)
- Open reports in a new tab (details)
eCRFs
Design forms for EDC-only studies from *within* DFsetup

**Easy, Quick Setup**

- Build forms without background images
- Easy to modify, group, or re-order fields

**Flexible**

- Seamless transition between DFexplore, DFcollect, and DFweb with no additional modification
- Forms can be longer than standard paper size
- Easily modified color palette
Design forms for EDC-only studies within DFsetup

**eCRFs in DFsetup**

**eCRFs in DFexplore**
Adding a new eCRF field in DFsetup.
New **Group** Option: Fields may be grouped in DFsetup with a single label displayed in DFexplore

**FIELD DESCRIPTIONS**

<table>
<thead>
<tr>
<th>Field Description</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race (Am. Indian or Alaska Native)</td>
<td>11</td>
</tr>
<tr>
<td>Race (Asian)</td>
<td>12</td>
</tr>
<tr>
<td>Race (Black or African American)</td>
<td>13</td>
</tr>
<tr>
<td>Race (Native Hawaiian or Pacific Is)</td>
<td>14</td>
</tr>
<tr>
<td>Race (White)</td>
<td>15</td>
</tr>
</tbody>
</table>

**FIELDS 12-15 ARE NOW GROUPED WITH FIELD 11**

The **Prompt** assigned to the first field in the Group will display as a single label that applies to all fields in the group.

**Check Box Code Label**
Help Messages: In DFexplore, Help messages appear within the body of the eCRF.

Help message can be defined using HTML (new) or rich text.

Help messages are also displayed at the bottom of the DFexplore window, and in the new Metadata panel.
Site Definitions

New Site Properties

- New properties: enrollment, start date, end date, protocol
- In DFsetup under View > Sites (formerly View > Centers)
- Visualize in new reports
  - Link to more information about new reports
- Export with study data
  - Link to more information about metadata export
- Use in new edit check functions
  - Link to more information about new edit check functions
Mark sites for use in testing only
- Can be referenced via edit check
- Data from test sites can be more easily excluded during data export

Set site-specific enrollment

Set different effective dates for protocol versions
SITE DEFINITIONS

Set site start and end dates

Set site-specific country
Reporting
New Reports

- New reports offer charts and graphs
- Interactive, customizable, and sharable
- Can be saved as PDF, Excel, and HTML
REPORTING

- Enrollment by Site
- Visits by Site
- CRFs by Site
- Queries by Site

- Sites Definition
- Database Definition

- Status and Level Summary
- Plate Status
- Queries by Field
- Inbound Traffic

Same reports as previous versions (DF_PTmissing, DF_PTvisits, DF_QCreports, etc.)
Graphic Visualization

Set options to customize the graph

Different enrollment targets
Customizable Graphs: Same data, different perspective

Total Enrollment By Site

or

Total Enrollment By Site Over Time
Report Output: New Save Options

- Internet connection not needed
- Everything needed to render the report is encapsulated in this output

Saving to Excel provides the source data for additional reporting
Multiple Report Tabs

- Open multiple reports at one time
- Reports run during the same session are available for viewing
REPORTING

View Database and Report Side-By-Side

- Reports can be dragged into a new window for simultaneous data review.
Metadata Editor Panel
Overview

METADATA EDITOR PANEL

The image shows a software interface with a metadata editor panel. The panel includes fields for various data entries, such as Vital Signs, with corresponding options for categories, units, and status. There is also a section for notes and comments. The interface suggests a focus on data entry and management, likely for a clinical or research setting. The text snippet indicates a protocol for an ABCD study, focusing on safety, immunogenicity, and dose-escalation in adults in South Africa. The study aims to evaluate safety and immunogenicity at escalating dose levels compared to a control vaccine.
Overview

- Review and manage queries, reasons, and missing value codes in the same window as the record
- Includes study-, plate-, and field-level help
- Enabled through Preferences
  - Alternative to query, reason, and missing value panels below subject binder
Queries, Reasons, & Missing Values

- Add and review queries, reasons, and missing value codes all in one place
Help Messages

- Appear below queries and reasons to guide user on study-, plate- and field level directions

- Customizable formatting (HTML)
  - Can include CRF completion guidelines, training videos, field-level help messages, etc.
- Original query & reason panel is available when metadata editor panel is disabled
- New buttons for adding, modifying, and deleting queries and reasons (as allowed by user permissions)
Export to Excel

DFsetup User Guide – Section 5.6. Export Setup
DFexplore User Guide – Section 9.8. Exporting Data Records
Setup Definition

- Export any database setup component from DFsetup to Excel
  - Quick output
  - Can be used for specifications, documentation, review, and sharing
  - Include visit maps, conditional visits, edit checks, etc.
- Customize Excel formatting and filter the specific components
  - Filter plates, field properties, etc. from Excel output
Setup Definition

- Filter and select the database configuration components to export
- Filter and select field properties to export
- Select custom style and coloring for Excel spreadsheet
## Database Specifications

### Export to Excel

<table>
<thead>
<tr>
<th>Name</th>
<th>Legal</th>
<th>Need</th>
<th>Format</th>
<th>Units</th>
<th>Plate Enter</th>
<th>Field Enter</th>
<th>Field Exit</th>
<th>Plate Exit</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>VISITNUM</td>
<td>$[ids]</td>
<td>Essential</td>
<td>Essential</td>
<td>aaaa</td>
<td>Hide</td>
<td></td>
<td></td>
<td></td>
<td>Name must be unique</td>
</tr>
<tr>
<td>SUBJID</td>
<td>$[ids]</td>
<td>Essential</td>
<td>Essential</td>
<td>aaaa</td>
<td>Reset,Background</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VISDAT</td>
<td>01/JAN/2016-today</td>
<td>Required</td>
<td>DD/MMM/YYYY</td>
<td>CopyVisDate</td>
<td></td>
<td></td>
<td></td>
<td>Visit Date expected to be within 14-21 days from enrollment</td>
<td></td>
</tr>
<tr>
<td>VRORRES</td>
<td>40.0-275.0</td>
<td>Optional</td>
<td>nnnn</td>
<td>html_legal_range</td>
<td>Email sent to site staff if outside of legal range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Visit Map
Study Data

- Export by plate or module from DFexplore List View
- Excel, csv, or pipe-delimited formats
- New metadata output options
Study Data

- Add metadata output to export
  - Variable metadata (prompt, units)
  - Site definition metadata (site ID, investigator name)
  - Visit map metadata (visit label, visit date)
  - Image metadata (sender, arrival date, format)
Batch Edits View
Batch User Interface
New Features

- Clarified Apply > Which options
- New ‘Site’ criterion
- Select edit checks from a list
New Features

- New site criterion allows user to run batch reports for all subjects within a site without listing a range of subject IDs
  - Useful for sites with transferred subjects
New Features

- Look up and select edit checks by plate and field without opening DFsetup.
Interactive Output

- Double-click the log entry to go to the record and field in Data View
Interactive Output

- Quickly build Data View tasks from batch history
Interactive Output

- Split screen to compare the output from previous run in batch history.

<table>
<thead>
<tr>
<th>Environment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td></td>
</tr>
<tr>
<td>Started on</td>
<td>2018-03-27 12:49:22 (current)</td>
</tr>
<tr>
<td>Performed by</td>
<td>demouser1</td>
</tr>
<tr>
<td>Working Directory</td>
<td>/opt/studies/demo_prod/batch/</td>
</tr>
<tr>
<td>Control Log</td>
<td>Batch_All</td>
</tr>
<tr>
<td>Log File</td>
<td>Run_All_Edits</td>
</tr>
</tbody>
</table>

### Summary (batch: batch_40)

<table>
<thead>
<tr>
<th>Field</th>
<th>Total</th>
<th>Success</th>
<th>Failure</th>
<th>Truncated</th>
<th>Apply?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records meeting criteria</td>
<td>76</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records logged</td>
<td>27</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elapsed time (seconds)</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>System messages</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data changes</td>
<td>72</td>
<td>72</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Messages</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Queries added</td>
<td>12</td>
<td>12</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Query edits</td>
<td>8</td>
<td>8</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing page queries</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing page queries deleted</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

### Execution History (sorted by reverse chronological order)

<table>
<thead>
<tr>
<th>Date</th>
<th># of Log Entries</th>
<th>Date</th>
<th># of Log Entries</th>
<th>Date</th>
<th># of Log Entries</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018-03-27 12:47:42</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Export Batch Output to Excel

Separate columns for each component to allow for efficient sorting

If batch history is turned on, all output history is automatically saved in individual tabs
**BATCH EDITS VIEW**

Export Batch Output to HTML

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### Batch Edit checks Log for Batch: All, grouped by edit check name

<table>
<thead>
<tr>
<th>Environment</th>
<th>Name</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment</td>
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</tr>
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<td>Name</td>
<td>Value</td>
</tr>
<tr>
<td>Environment</td>
<td>Name</td>
<td>Value</td>
</tr>
</tbody>
</table>

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**Sort by Edit Check**

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**Stylesheet**

**batchlog**

**byeditchek**

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**CalCOBE**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
</tbody>
</table>

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**Partial**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
</tr>
</tbody>
</table>

---

**Execution History (sorted by reverse chronological order)**

<table>
<thead>
<tr>
<th>Date</th>
<th># of Log Entries</th>
<th>Date</th>
<th># of Log Entries</th>
</tr>
</thead>
</table>

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Edit Coding Dialog

DFsetup User Guide – Section 7.3.3. Edit Coding Table
Enhanced Coding Features

- Copy and paste from external sources (e.g. Excel)
- Add, move, and delete rows
- Available for choice, check, and numeric fields
User Profile and Certificate Info
User Profile

Users can:

- Change password
- Confirm full name and email address
- Update contact details
Certificate Info

- Now supports certificates from commercial Certificate Authorities
Edit Check Functions
New Metadata Edit Check Functions

- Site, visit, and image metadata available via new edit check functions:
  - dfsiteinfo()  
  - dfprotocolinfo()  
  - dfvisitinfo()  
  - dfimageinfo()  

- Metadata also available in DFexport (details)
**dfsiteinfo():** Site Metadata Functions and Parameters

- **DFSITE_ID, DFSITE_NAME, DFSITE_INVESTIGATOR, DFSITE_COUNTRY**
  - Useful for subject transfers and auto-filling site-level details on subject CRFs

- **DFSITE_TEST**
  - Program edit checks to perform differently for test sites, e.g. sending emails, running scripts

- **DFSITE_BEGINDATE, DFSITE_ENDDATE**
  - Compare the site's study start and end date against subject visits and procedures

- And more
dfprotocolinfo(): Site Protocol Metadata Functions and Parameters

- DFSITE_PROTOCOL1, DFSITE_PROTOCOLDATE1
- DFSITE_PROTOCOL2, DFSITE_PROTOCOLDATE2
- Protocol amendments and CRF revisions implemented at sites on different dates
  - Add protocol versions and implementation dates in Sites definition
  - Use edit checks to show or hide new fields, CRF backgrounds, plates, or visits associated with a protocol amendment
dfvisitinfo(): Visit Metadata Functions and Parameters

- **DFVISIT_DATE**
  - Compare study procedure dates to visit dates
- **DFVISIT_TYPE, DFVISIT_ACRONYM, DFVISIT_LABEL, DFVISIT_DUE**
### dfimageinfo(): Image Metadata Functions and Parameters

- **DFIMAGE_FORMAT, DFIMAGE_SENDER, DFIMAGE_PAGES**
  - Identify document format, sender, and how many pages are included

- **DFIMAGE_ARRIVAL, DFIMAGE_FIRSTARRIVAL, DFIMAGE_LASTARRIVAL**
  - Compare study visit and procedure dates to document submission dates
Edit Check Improvements

- Edit checks referencing multiple data records within subject binder use cache for increased speed
- `dfmail()` allows email messages to be formatted in HTML
- `dfeditqc()` has been updated
  - to allow the query category to be changed in studies where multiple queries are not enabled, restoring pre-DataFax 2016 behavior
  - to include an optional parameter to silently edit the query without opening the query dialog
- Maximum password attempts via edit check (including eSignature module) now generates email notification
Web Services / Public API
<table>
<thead>
<tr>
<th><strong>What is it?</strong></th>
<th><strong>What does it do?</strong></th>
</tr>
</thead>
</table>
| ▪ RESTful web API using full features of HTTP  
  ▪ Data interchange in JSON format  
  ▪ Accessible by authorized and registered systems  
  ▪ Session-based | ▪ Provides interface to access resources (studies, records, keys, users)  
  ▪ Supports development of mobile apps and integration with other systems  
  ▪ Overcomes network disruptions (session maintained if disconnected)  
  ▪ Allows simple API requests that do not require backend knowledge |
Web API Architecture

WEB SERVICES / PUBLIC API

Web Clients

DF Client Applications

DFws API

DFdiscover Server

HTTPS

HTTPS

HTTPS
Web API Server

- Server-side RESTful Web Listener application
- Fully configurable (ports, connections, database, sessions)
- Multi-threaded sessions handler
- Interact with multiple API-enabled DFdiscover servers
Web API Security

- HTTPS (SSL encrypted)
- API Token (Authentication to Access API)
- JWT as API request token
- URI, Session token, Expiry & Request verification
- Session Expiration handler
- Independent threads per user per session
DFws Usage Examples

- DFcollect – Mobile application for data entry (coming soon)
- DFweb – Web application for data entry (coming soon)
- Other examples:
  - PHP-based web portal for cross-study reports
  - Curl-based calls from scripts
  - PHP scripts for web apps or web CMS (e.g. WordPress)
  - Cloud applications: AWS, Azure, Google apps
  - Desktop applications
Web API Licensing

- New 'Features' property in DFdiscover license
- To enable the API, add DFws feature to DFdiscover license
- Number of API seats can be limited
More Features and Improvements
Notable Features

- Increased maximum number of studies from 255 to 999 (licensed feature)
- Increased maximum number of user seats to 500
- DFexplore can be accessed via web browser (DFnavigator)
- New DFattach command-line utility to efficiently include external subject documents
- New DFreport command-line utility to run all new HTML and legacy reports
Notable Improvements

- "Don't show this again" option in warning dialogs
- DFsas now exports format statements based on either style or field attributes
- Up to 98 response options can now be defined for choice type fields
- Query category can be changed when editing a query in studies without multiple queries, mimicking pre-DataFax 2016 behavior
- DFsetup linking development to production study separates setup configuration from other configuration items
- Site, visit, protocol, and image metadata also available for export
- Significant updates to the documentation and Acceptance Test Kit (ATK)
Notable System Changes

- Solaris no longer supported
- 64-bit on Linux and OS X; Windows client continues to be 32-bit
- DATAFAX_DIR environment variable is no longer used
- New terminology and application names are used throughout the software, in arguments, parameters, etc.
Learn More About DFdiscover 2018

- DFdiscover 2018 Release and Installation Notes
- DFexplore User Guide
- DFsetup Study Setup User Guide
- DFadmin System Administrator Guide
- Programmer Guide
- Standard Reports Guide
Thank you for deploying