

DataFAX Software Development Wish List

Study Setup	Score	Rank
1. add a view only mode (in addition to the current view only permission)	2.8	90-98
2. better implementation of styles so that a style can be replaced by another style without needing to manually fix some variable attributes at the field level.	3.2	57-67
3. support data modules, i.e. sets of data fields that are repeated on 1 or more plates	3.3	43-56
4. improve support for CRF modifications (i.e. adding, deleting and re-ordering fields) to studies in progress so that the database and audit trail are not effected	4.6	2-3
5. allow different users to work simultaneously setting up different plates	3.3	43-56
6. support importing a DFsetup file created/modified outside the DataFAX setup tool	2.9	85-89
7. resize field widgets by dragging larger or smaller	2.7	99-109
8. allow more than one skip pattern for each data field	2.6	110-121
9. in edit checks dialog include editing options in a menu at the top of the window	2.6	110-121
10. support for separate IDs for screening and post-screening phases of a study	3.1	68-77
11. add support for landscape CRF pages	3.7	20-26
12. add a clock time data type	3.1	68-77
13. make variable re-order circular so the last field can become the first with a single click	2.2	135-143
14. ability to receive and store digital photos to a specified field on a specified plate	2.0	146
15. CDISC compatibility (including utilities to write ODM and SDM)	3.3	43-56
16. allow edit checks to be specified at the data field level in addition to any edit checks already specified in the style used by the data field	3.5	30-38
17. allow variables to be defined throughout the full length of A4 pages	2.3	130-134
18. option to notify specified users by email when new records arrive in the study new queue	3.2	57-67
Key Field Limits		
1. study IDs: increase from 1-500 to any 5 alpha-numeric characters (5^{34})	3.5	30-38
2. plate num: increase from 1-500 to 1-65535	3.3	43-56
3. visit num: increase from 0-65535 to $0-2^{32}$	3.1	68-77
4. patient IDs: increase from $1-2^{31}$ to $1-2^{32}$	2.9	85-89
5. center IDs: increase from 1-2146 to 1-65535	3.0	78-84

User Permissions

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|---|-----|---------|
| 1. permission to use each GUI tool and shell level program | 2.4 | 123-129 |
| 2. some permissions on what a user can do within each tool
(e.g. validation tool retrieval methods, configuration tool files, setup tool plates) | 3.0 | 78-84 |
| 3. permission to enter, edit, delete, view, import and export data, QCs and images for all or specified fields, plates, visits, patient IDs, and center IDs | 3.0 | 78-84 |
| 4. ability to define user roles (i.e. a specified combination of permissions) | 3.8 | 16-19 |
| 5. support for different study groups so that all users do not share group studies | 3.3 | 43-56 |
| 6. support for an admin group for users granted permissions equivalent to user datafax | 3.4 | 39-42 |

Configuration Tool

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|---|-----|---------|
| 1. allow a common centers database to be used in multiple studies | 2.9 | 85-89 |
| 2. allow importing configuration files created or modified outside the dfconfig tool | 3.1 | 68-77 |
| 3. add a conditional field map to the existing conditional maps for cycles, visits, plates, and terminations (to reduce the need for edit checks) | 3.4 | 39-42 |
| 4. support for "drift visits" in the visit map (i.e. consecutive visits covering follow-up in contiguous, non-overlapping time periods identified by 2 date fields) | 2.2 | 135-143 |
| 5. option to generate a DFqcsort file based on the order of visits defined in the visit map so that QC notes and data records are always sorted in visit map order | 2.6 | 110-121 |

Validation Tool - Build Set Features

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|---|-----|---------|
| 1. enhance retrieval by data fields to include QC note and reason attributes | 3.5 | 30-38 |
| 2. enhance retrieval by variables to work with more than 1 plate at a time | 3.6 | 27-29 |
| 3. in retrieval by variables allow center IDs to be used in the retrieval criteria | 3.2 | 57-67 |
| 4. quick menu option to retrieve secondary CRF pages for the current page (if any) in a separate view-only window | 3.3 | 43-56 |
| 5. quick menu option to retrieve all CRF pages for the current patient in a separate view-only window | 3.8 | 16-19 |
| 6. history feature that allows a user to review and rebuild previous retrieval sets | 2.4 | 123-129 |
| 7. new patient binder dialog showing all visits completed and scheduled, suitable for both patient review and for RDE (raw/remote data entry) | 3.3 | 43-56 |
| 8. when records are locked and can not be retrieved show the users holding the locks | 3.8 | 16-19 |

Validation Tool - Other Features

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|---|-----|---------|
| 1. allow a set of records to be deleted with a single reason | 2.7 | 99-109 |
| 2. integrated MEDRA coding | 4.1 | 9-10 |
| 3. support for an exception log, used to register unexpected visits and plates that have been received. (note: this is the flip side of the lost data log which is used to register required visits and plates that will not be received) | 2.6 | 110-121 |
| 4. support for data management SOPs/Guidelines available from the main menu | 2.2 | 135-143 |
| 5. ability to send a CRF directly to another study database (not via the router) | 2.8 | 90-98 |
| 6. ability to re-load look-up tables (as currently implemented for edit checks) | 2.6 | 110-121 |
| 7. ability to record notes, associate them with a data field, plate, visit or patient and categorize them, e.g. CRF margin notes, investigator comments, CRA comments, data management notes, etc. | 3.5 | 30-38 |
| 8. improved clipboard window (with ability to resize, move, save, print) | 2.2 | 135-143 |
| 9. ability to save a layout of validation tool windows as the startup default | 3.0 | 78-84 |
| 10. ability to save validation tool preferences as the startup default | 2.8 | 90-98 |
| 11. field history option (in addition to the current record history option) | 3.2 | 57-67 |
| 12. GUI for creation of DDE sets (i.e. a wizard for shell level program DFdde.set) | 2.2 | 135-143 |
| 13. display DRF info field (if used) when traversing records using a DRF file | 2.3 | 130-134 |
| 14. ability to include records retrieved from the new queue but not yet validated when creating a PDF file. | 2.4 | 123-129 |
| 15. ability to validate investigator signatures using a lookup table of known signatures | 2.4 | 123-129 |
| 16. ability to use bolding, color, and more than 1 line in field level help messages | 2.6 | 110-121 |

QC Notes

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| 1. assign a unique ID to each QC note and use it for QC tracking | 3.3 | 43-56 |
| 2. in patient PDFs, link all QC notes sent to the sites with each CRF page | 3.5 | 30-38 |
| 3. ability to categorize internal QCs to indicate their purpose | 2.8 | 90-98 |
| 4. in the QC dialog show the first and most recent date the QC was sent to the site | 3.5 | 30-38 |
| 5. allow editing, creation and deletion of QC notes in the QC tool | 2.7 | 99-109 |
| 6. move QC report creation, transmission scheduling, tracking, viewing and printing to the QC tool (from their current location in the reports tool) | 2.7 | 99-109 |
| 7. allow QCs to be linked to a: plate, visit, patient or center (in addition to the current ability to link QC notes to a data field) | 4.2 | 5-8 |

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| 8. allow multiple QC notes to be linked to each field, plate, visit, patient or center | 4.6 | 2-3 |
| 9. allow each field level QC note to be linked to more than one data field (including fields on more than 1 plate) so that the QC note can be viewed, edited and resolved from any of the linked fields | 4.4 | 4 |
| 10. allow QCs to be directed to more than one individual at each clinical site | 2.5 | 122 |

Edit Checks

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|---|-----|---------|
| 1. add support for an array data type | 3.2 | 57-67 |
| 2. provide access to visit map info | 3.1 | 68-77 |
| 3. GUI wizard for specifying, scheduling, and reviewing batch edit check runs | 3.4 | 39-42 |
| 4. ability to undo an edit check's effects (on QCs and data changes) | 2.7 | 99-109 |
| 5. ability to test edit checks using a separate data file, i.e. without having to enter test data into the database | 3.7 | 20-26 |
| 6. dfsizedof() function that returns the number of elements in a group | 2.4 | 123-129 |
| 7. dfbackward() and dfforward() boolean functions used to determine the direction of field traversal | 2.6 | 110-121 |
| 8. ability to pass arguments to functions by reference (as well as by value) | 3.1 | 68-77 |

Router

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| 1. show all users currently working in the router | 3.3 | 43-56 |
| 2. add a view only mode | 2.7 | 99-109 |
| 3. show a thumbnail image of each record in the record list | 2.1 | 144-145 |
| 4. attempt to identify and flag CRF pages (pages with what appear to be bar codes) | 1.8 | 150 |

Audit Trails

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|---|-----|-------|
| 1. new audit trail for key changes associated with a given CRF page. | 3.7 | 20-26 |
| 2. new audit trail of study setup changes including addition and deletion of data fields, and changes to field definitions, configuration files, and user permissions | 4.7 | 1 |
| 3. new audit trail of actions performed in the following tools: | | |
| a. DFrouter (who routed which records) | 3.3 | 43-56 |
| b. DFsystem (changes to studies, users, etc.) | 4.1 | 9-10 |
| c. DFvalidate (retrievals performed, start and release times, etc.) | 3.1 | 68-77 |
| d. DFreports (reports run, datetime and options used) | 3.1 | 68-77 |
| 4. processing history for a specified CRF image or all CRFs in a specified fax | 3.3 | 43-56 |

SQL Loader (supporting ORACLE, PostgreSQL and MySQL)

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| 1. option to create any of the following SQL databases: | | |
| a. all tables contain typed fields (i.e. number, date, etc. as defined in the study schema) for which any invalid values must be translated to null | 2.3 | 130-134 |
| b. all tables contain character fields (i.e. all values are stored as character strings exactly as exported from DataFax) | 2.2 | 135-143 |
| c. an SQL database with both typed and character versions of each table | 2.8 | 90-98 |
| 2. option to output value labels instead of value codes (e.g. yes,no instead of 1,2) | 2.6 | 110-121 |
| 3. option to output 2 fields for each date, one date field (with imputation for partial dates if specified in the study schema) and one character field containing the character string representation of the date as stored in DataFax | 2.6 | 110-121 |
| 4. option to create SQL tables for study configuration files: centers, visit map, etc. | 3.0 | 78-84 |
| 5. option to create SQL tables containing audit trail records | 2.8 | 90-98 |
| 6. option to create SQL tables for DataFax summary files: DFX_schedule,DFX_keys, etc. | 2.2 | 135-143 |
| 7. option to create an SQL table containing all code/label pairs (i.e. an SQL table with records containing: table name, field name, value code, value label) | 2.8 | 90-98 |
| 8. option to merge records from 2 or more studies into a single SQL database | 2.2 | 135-143 |
| 9. ability to map specified fields from one or more DataFax plates to specified fields in the SQL database (when the current default behavior, each DataFax plate = an SQL table, does not provide an adequate solution). | | |
| a. where SQL Loader creates the SQL tables based on the DataFax schema | 1.9 | 147-149 |
| b. where the SQL database has been pre-defined independent of DataFax | 2.2 | 135-143 |

DFsas

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|---|-----|---------|
| 1. allow user specified data set naming conventions | 3.3 | 43-56 |
| 2. create SAS jobs that merge data from different study databases | 2.6 | 110-121 |
| 3. create a format library | 3.9 | 12-15 |

QC Reports

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|---|-----|--------|
| 1. option to include the creation or modification date of each QC note | 2.7 | 99-109 |
| 2. option to show number of times each QC note has appeared in previous reports | 3.5 | 30-38 |
| 3. ability to create and send more than 1 QC report to the same site per day | 3.7 | 20-26 |
| 4. prettier cover sheets | 2.7 | 99-109 |

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| 5. user specified query/instruction to be used for overdue visits and missing plates | 3.1 | 68-77 |
| 6. when sending QC reports as PDF email attachments: | | |
| a. put cover sheet and messages in the body of the email | 3.2 | 57-67 |
| b. show all recipients in the mailto list | 2.9 | 85-89 |
| c. ability to specify a different encryption password for each site | 2.7 | 99-109 |
| 7. notify a specified user (by email) when a QC report can not be faxed and "Failed" is written to the QC fax log | 3.9 | 12-15 |
| 8. remove investigator signature line from refax pages (but keep it on Q&A pages) | 3.1 | 68-77 |

Standard Reports

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|--|-----|---------|
| 1. DF_CTqcs: as well as total QCs and number of QCs resolved (shown now) also show number of QCs not resolved (we don't like having to subtract) | 3.2 | 57-67 |
| 2. DF_WF reports: option to create a report for a list of users, or all users | 3.0 | 78-84 |
| 3. DF_WFcrfs: option to create a DRF for records validated in < 5 seconds | 2.8 | 90-98 |
| 4. DF_SScenters: change column ordering to match column ordering in the dfconfig centers dialog | 2.6 | 110-121 |
| 5. incorporate PDFWriter as a printer available in DataFax | 4.0 | 11 |
| 6. add a -p printer_name option to all reports, to direct output to a specified printer, including ability to write directly to a PDF file | 3.9 | 12-15 |
| 7. support for XML/HTML reporting and publishing | 4.2 | 5-8 |
| 8. ability to run all of the reports in a history list (in order) | 3.0 | 78-84 |
| 9. option to dump report contents to a data file without formatting, titles etc. | 3.7 | 20-26 |

New Reports

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| 1. list dirty records with no unresolved QCs or illegal fields (and create a DRF) | 3.7 | 20-26 |
| 2. count reasons for data change used (optionally by field, plate, visit, patient, site) | 2.7 | 99-109 |
| 3. count missing value codes used (optionally by field, plate, visit, patient, site) | 2.6 | 110-121 |
| 4. progress report showing number of QCs resolved over time (optionally by site, visit, plate) | 3.7 | 20-26 |
| 5. progress report showing number of new records and refaxes received over time (optionally by site, visit, plate) | 3.8 | 16-19 |

Study/Site Management Modules for:

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| 1. study drugs | 2.1 | 144-145 |
| 2. CRFs, patient and physician pamphlets, other supplies | 2.3 | 130-134 |
| 3. IRB approvals | 2.4 | 123-129 |
| 4. site payments | 2.8 | 90-98 |

System Level

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|--|-----|---------|
| 1. support for LINUX | 2.3 | 130-134 |
| 2. support for free BSD | 1.4 | 151 |
| 3. support for MAC OS X | 1.9 | 147-149 |
| 4. support for GNOME and KDE desktops | 1.9 | 147-149 |
| 5. installation script with option to check all study databases for incompatibilities | 3.5 | 30-38 |
| 6. user authentication and password expiration (replaces current UNIX authentication). This plus the planned move to have the study server look after all file management will remove the need for users to have a UNIX login account. | 3.3 | 43-56 |
| 7. ability to export all DataFax files (configuration, journals, fax log, etc.) | 3.6 | 27-29 |
| 8. show full user name not just login name in DFsystem-Users dialog | 3.2 | 57-67 |
| 9. version control on all study setup/configuration files | 4.2 | 5-8 |
| 10. improved ICR | 3.4 | 39-42 |
| 11. ability to receive and process encrypted email attachments containing CRFs | 2.9 | 85-89 |
| 12. GUI wizard to generate FDA compliant PDF and SAS submission files | 3.2 | 57-67 |
| 13. enhance DFsystem-Users-Status to include the following study access modes: | 3.9 | 12-15 |
| a. disable : study is active but temporarily disabled, faxes can still be routed to the study but will not be processed until the study is enabled | | |
| b. read-only : study data and configuration files can be viewed but not changed, no faxes can be routed to the study | | |
| c. locked : study is no longer available, no access is granted to anyone for any purpose, no faxes can be routed to the study | | |

User Support

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| 1. index all manuals | 3.3 | 43-56 |
| 2. add a frequently asked question section to the support section of the web site | 3.5 | 30-38 |
| 3. new training courses: | | |
| a. overview and recommended practices for data managers | 3.2 | 57-67 |
| b. design and use of visit maps and conditional maps for patient and CRF tracking | 3.6 | 27-29 |
| c. UNIX scripting for DataFax programmers | 3.2 | 57-67 |

Other

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| 1. a user training kit (UTK) similar to the ATK but used to standardize training and keep training records | 4.2 | 5-8 |
| 2. a dialog showing records in the new queue for each study, updated at specified intervals, with a new data alarm for each study that can be toggled on/off | 2.7 | 99-109 |
| 3. pre-filled (default) server name and user name in DFlite login dialog | 2.4 | 123-129 |