
DataFax 2004 Wish List

Top 10

Wayne & Eric
CDSI



2004 DataFax Wish List

- Initiated at DFUG 2004
- Additions accepted up to June 1st
- Five point rating scale
"Please indicate how important each of the following modifications is to your company or organization"
Not at all Somewhat Very
[] 1 [] 2 [] 3 [] 4 [] 5
- Each client (company or organization) was allowed to contribute a single response to each item on the list
- if more than one response was received they were averaged
- For each of the items on the wish list, the DataFax client responses were averaged and ranked.



Response Rate

“We will not pester anyone to submit a reply. We'll assume that those who do not respond are ecstatic with DataFax just as it is, and can't imagine that it could be improved in any way.”

Replies were received from ~ 33% of all DataFax clients.



The Challenge

1. Identify widely perceived needs
2. Get the priorities right
3. Find a good general solution
4. Select the least complicated solution
5. Don't break existing user behavior
6. Maintain backward database compatibility
7. Deliver in a timely fashion
8. Don't increase the cost



10. Built in Support for MedDRA Coding

Why:

MedDRA is the standard for AE coding

Solutions:

- dflookup - works for single level coding
- a third-party solution currently exists
(see user talk on Wed.)



9. Create a log for DFsystem

Why:

- want ability to track DataFax system changes

Problem:

- many of the configuration files maintained by DFsystem can also be modified using an editor

Solution #1:

- give DF control over all configuration files (no more external editing)

Solution #2:

- cvs



8. Allow Higher Level QCs

- **Specifics:**
 - currently all QCs must be linked to a data field
 - but some QCs are related to the: Patient, Visit, or CRF page
- **Solution:**
 - new DFqctype_map for QC problem types
 - code | level | problem label
 - 51 | patient | “not eligible”
 - Access to these QCs in DFvalidate:
 - patient QCs - all patient ID fields
 - visit QCs - the visit field of all plates for the visit
 - page QCs - the plate field under the bar code



7. Support for XML/HTML Reporting and Publishing

Why:

- desire to put standard DataFax reports and other information on a study web site

Solution #1:

- new report that runs DF reports, and
- creates reportname.html output

Solution #2:

- tagged content & default style sheets
- way of posting it to the web server



6. Create a User Training Kit

Why:

- we need to standardize user training and keep training logs

Solutions:

- use the existing ATK
- modify the ATK to create a UTK



5. Allow QCs linked to 2+ Fields

Why is it needed:

- clinical sites might correct a different field, perhaps on a different CRF page, thus the page the QC is on might not be refaxed, and so resolving the QC becomes a problem

Solution #1:

- use a Q&A QC (instead of a refax QC) so the site can explain how they fixed the problem

Solution #2:

- DFqclinks.dat: link keys point to QC keys
- new edit check function: dflinkqc



4. Allow CRF Modifications to a study in progress

- **Problem:**
 - can not add, delete or reorder fields because this renders the audit trail useless for any existing data records
 - requires programming to re-structure existing data and meta-data records (QCs and reasons)
- **Solution:**

Redesign CRF plate as desired, but:

 - do not delete fields from the data screens, instead use edit checks to skip/auto-fill obsolete fields during new data entry
 - do not change the current field numbering, instead order any new fields at the end of the current field list
 - use dfmoveto to achieve desired field traversal
 - we will add dfdirection which will give you perfect control over field traversal in both forward and backward directions



Example

Task:

- In study 75, the old version of plate 101 has 44 user data fields
(note: all records have 3 system fields past the last user data field for: record status, creation and modification)
- We want to add field a new field between fields 8 and 9

Solution:

- Redesign the CRF placing the new field between fields 8 & 9
- In DFsetup:
 - Import the new CRF page
 - Define the new field.
Since it is the next field it will appear as field 45 - leave it this way!
- Write edit checks to manage field traversal
- Restructure the existing data records putting something into this new field



Example

Fix Field Traversal

- edit check on exit from field 8
`if(dfdirection() > 0) dfmoveto(@[45]);`
- edit check on exit from field 45
`if(dfdirection() > 0) dfmoveto(@[9]);`
`if(dfdirection() < 0) dfmoveto(@[8]);`



Example

Re-structure the existing data records

- step 1: export and reformat current data records
`DFexport.rpc -f "1-44, '*', 45-47" -s "primary,secondary"`
`-p 75 101 plt101.new`
- step 2: import the reformatted data records
`DFimport.rpc -r 75 plt101.new`
- step 3: verify that everything is OK
`DF_ICrecords 75 -p 101`



3. Allow Multiple QCs per Field

- **Solution:**
 - user defined QC problem types: lib/DFqctype_map
 - allow only one QC for each problem type
- **Required software changes:**
 - DFconfig: DFqctype_map
 - DFvalidate: QC dialog and data structures
 - DFviewer & DF lite: static QC dialog
 - DFqc: stats for new QC problem types
 - Edit Checks: QC functions
 - Reports: DF_CTqcs, etc.
 - DFimport.rpc: problem type becomes a key field



2. Track Study Setup Changes

- **Specifics:**
 - data fields (addition, deletion, re-ordering)
 - field definitions (description, legal values, etc.)
 - study configuration files (all DFconfig files)
 - user permissions
- **Problem:**
 - DF tools do not have control over all changes
- **Solution:**
 - we can only track what DF controls (DFsetup)
 - use CVS for all ASCII files



1. Don't change a thing !

“We're ecstatic with DataFax just as it is,
and can't imagine that it could be
improved in any way.”

- 66% of DataFax clients

