
Problems & Solutions from the CDSI Support Archives

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Problem Agenda

How can we...

- Route incoming faxes to other locations?
- Add or delete fields from a database into which data has already been received?
- Close-out a DataFax study once it has been completed?

Problem: Supplementary routing of new faxes

- Faxes from certain sites should be forwarded in their entirety to a third site
“All faxes from the German center must be copied to a monitor that performs English translation.”
- Fax pages of a specific type should be forwarded to a third site
“All adverse event CRFs must be forwarded upon arrival to an external event adjudicator.”
- CRFs with specific data should be forwarded to a third site
“All CRFs that indicate screening failure must be brought to the attention of the principal investigator.”

Solution: Routing of complete faxes

- At what step of the processing is the identification of the sender known?
 - Once the transmission has been received by HylaFAX
- At HylaFAX receipt time, fax may contain cover pages, unwanted CRFs, etc.
 - Alternative is to delay routing until later but this then requires dealing with `$DATAFAX_DIR/work/fax_log`, piecing together valid pages from the transmission -> this quickly becomes too complex

Solution: Routing of complete faxes

- At HylaFAX receipt time, `/var/spool/fax/etc/FaxDispatch` is consulted for additional processing instructions
- Fax is still processed within DataFax in normal fashion

Solution: Routing of complete faxes

- Typical `FaxDispatch` file

```
case "$SENDER" in
*905*522*7284*) SENDTO="eric@datafax.com" ;;
*888*555*1212*) SENDTO="gates@hotmail.com" ;;
*) SENDTO=" " ;;
esac
```

- The '*' match anything and allow for non-numeric in sender id
- Sender id must be known in advance

Solution: Routing of complete faxes

- Contents of email are all pages of the fax, in it's original multi-page TIFF format
- Multi-page TIFFs can be viewed with tools like IrfanView32, <http://irfanview.tuwien.ac.at>
- Can be converted to PDF or other formats
 - Requires tinkering with
`/var/spool/fax/bin/faxrcvd`

Solution: Routing of a specific type of CRF

- At what step of the process is the identification of the specific CRF reliable?
 - During incoming processing by DFinbound.rpc the CRF is identified by its plate number -> can be done immediately and automatically
 - Not immediate if study server is down
 - Not automatic if plate number is not read
- Must keep up-to-date with DFrouter
- In what format should the CRF be sent?
- How should the CRF be sent?

Solution: Routing of a specific type of CRF

- DFsetup: use plate procedure to attach a command to the identification of a specific plate



- Fax command:

```
/opt/datafax/bin/DFsendfax $image 18885551212
```

Requires update to /opt/hylafax/lib/fax/typerules described in 3.5-001 notes

Solution: Routing of a specific type of CRF

- Email command (all one line):

```
/opt/datafax/bin/DFpsprint $image > /tmp/$$;  
/opt/datafax/bin/DFsendfax /tmp/$$  
mailto:recipient; /bin/rm -f /tmp/$$
```

where *recipient*, *study*, and /opt/datafax may need to be updated.

Without converting to PostScript format first, DFsendfax will transmit the contents of the email as a Sun rasterfile.

Solution: Routing of a CRF with certain data

- At what step of the process is the data reliable?
 - Not level 0
 - Likely level 1 (or first review)
 - Definitely level 2 (or second review)
- Route each CRF at most once

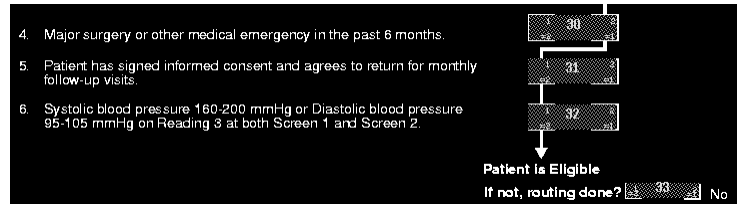
What happens if the CRF data acquires the conditioned value only after first/second level review?
- In what format should the CRF be sent?
- How should the CRF be sent?

Solution: Routing of a CRF with certain data

- Requires an edit check and diligence by staff to stay current with data reviews
 - Keep up-to-date with the contents of the new queue
 - Also need to keep up-to-date with the contents of DFrouter
 - Edit check is straight-forward to create
 - Execute edit check at plate exit time
- Need historical information to remember that a CRF was previously routed
 - Add a hidden field that records if the CRF is routed

Solution: Routing of a CRF with certain data

- Plate 1, Study 254 (ATK)



- Attach `do_route()` edit check to plate exit of new ROUTED variable

Solution: Routing of a CRF with certain data

```
edit do_route() {
  number eligible, status, yes=2, no=1;
  string drf_input, command, k1, k2, k3;
  string email="mailto:adjudicator@yahoo.com";

  if (dflevel()<2 || ROUTED==yes) return;

  eligible = (ELIG1==yes && ELIG2==yes &&
  ELIG3==no && ELIG4==no && ELIG5==yes &&
  ELIG6==yes);

  if (!eligible && ROUTED!=yes) {
    k1=ID; k2=DFSEQ; k3=DFPLATE;
    drf_input=k1+"|"+k2+"|"+k3+"|"+DFRASTER;
  }
}
```

Solution: Routing of a CRF with certain data

```
# all one input line
command="echo '"+drf_input+"' |
/opt/datafax/bin/DFpdf -d -o /tmp/$$ 254;
/opt/datafax/bin/DFsendfax /tmp/$$ "+email+"
1>/dev/null; /bin/rm -f /tmp/$$";

status=dfsystem(command);
if (status==0)
    ROUTED=yes;
}
}
```

- Test with faxed-in sample CRFs

Problem: Adding/removing fields from a plate

- Fields are stored based upon their position
- Special steps are needed to add, remove, or re-order one or more fields on a plate
 - not needed when only changing the attributes (e.g., size or screen position) of a field
- Easy to do before study data has been validated for the plate
- Harder to do after study data has been validated for the plate
- Integrity of audit trail data

Solution: Re-validate CRFs

- If there is a small number of records of the specific plate type, re-validating the CRFs is the least problematic solution
 - Use Set->Validate menu item to demote all records to level 1 before commencing
- For a larger number of records, a programmatic solution is recommended

Solution: Minimize the disruption

- If new fields are added, add them at the end of the record if at all possible
- When existing fields are deleted, leave the fields in the database and use an edit check to fill deleted fields with a missing code
- If existing fields are re-ordered, use `dfmoveto()` in edit checks to change the screen traversal order instead of changing the database order

Solution: Adding fields

- Add fields at the end of the record and, if necessary, use `dfmoveto()` to modify the traversal order for a more pleasing screen result
- Adding fields before the end of the record will link QC notes to the wrong field because they are also position based
- Requires careful documentation of changed field positions
- Use `DFexport.rpc` and `DFimport.rpc`

Solution: Adding fields

1. Document where new field numbers are added
 - *Original plate 001 has 35 fields, user data up to field 32, followed by status, creation, and modification*
 - *Add new fields 33 and 34*
2. Get current plate data, excluding lost records, out of database, inserting missing values into new fields

```
DFexport.rpc -p -f "1-32,'*','*',33-35" -s  
"primary,secondary" 254 1 plt001.new
```

Solution: Adding fields

3. Add fields to setup
4. Replace existing records with records from step 2
`DFimport.rpc -r 254 plt001.new`
5. Confirm new database structure with `DF_ICrecords`
`DF_ICrecords 254 -p 1`
6. Optionally add edit checks to change screen traversal order

Solution: Deleting fields

- Never delete fields from plate definition
- Create an edit check that fills the "deleted fields" with missing value codes for new records
- Optionally also skip over "deleted fields" during data entry
- How does one automatically ascertain which records have the "deleted fields"?

Reasonable solution is to use a cut-over date: any records entered after this date have the "deleted fields"

Solution: Deleting fields

- At plate exit, for new records entered after cut-over date:

```
edit handle_deleted_fields()
{
  date cutover="02/02/06";

  if (today() > cutover && DFVALID == 0) {
    if (dfblank(n1) && !dfmissing(n1)) n1="ND";
    if (dfblank(n2) && !dfmissing(n2)) n2="ND";
  }
}
```

Solution: Re-ordering fields

- Never re-order fields in plate definition
- Use `dfmoveto()` in edit checks to change the screen traversal order
- Will generally require more than one edit check at different field exits
- Not foolproof during backwards traversal of fields

Solution: Re-ordering fields

- Existing traversal order is f1, f2, f3, f4, f5
- Desire is to re-order as f1, f4, f2, f3, f5
- Do not modify plate definition
- Needed field exit edit checks

```
edit leave_f1() { dfmoveto(f4); }  
edit leave_f4() { dfmoveto(f2); }  
edit leave_f3() { dfmoveto(f5); }
```

Problem: Study close-out

- Two phase approach
- First phase is to allow ongoing review of received CRFs but prevent any changes to the database
- Second phase is to shutdown study and remove it to secondary storage

Solution: Phase 1

- **Confirm:**
 1. 0 records awaiting validation
 2. All required pages have been received – no missing pages or overdue visits
 3. All QC notes have been resolved
 4. All required data is clean and has been reviewed according to study SOPs
 5. No primary records with `error` status
 6. No errors are reported by the DataFax consistency (DF_IC) reports

Solution: Phase 1

- Define a database lock date
- Agree upon a policy for handling new faxes that arrive after lock date
 1. No changes -> all new faxes should be printed and removed from the new queue, or
 2. Allow new faxes -> at least one user needs ongoing validation privileges

Solution: Phase 1

1. Perform database compaction

```
DFsortplate.rpc -f -s 254
```

2. Print a listing of current study permissions

```
DFuserPerms -l :254
```

3. Remove validation and setup tool permissions from all permitted users

```
set users=`DFuserPerms -l :254|cut -d' ' -f1`
foreach u ($users)
? DFuserPerms -m ${u}:254:-S0
? end
```

Solution: Phase 1

4. Remove access to DF_QCupdate and DF_QCreports via reports tool

Add the following to \$STUDY_DIR/lib/.DFrep_excl:

```
BEGIN DataFaxGeneric
DF_QCupdate
DF_QCreports
END DataFaxGeneric
```

5. Remove write permissions (except for user datafax) from lib directory and contents

6. Monitor new record queue

Solution: Phase 2

- Create DataFax independent representations of data
 - SAS data sets
 - Journal files
 - PDFs, one per center, of CRF images
 - What else?
- Shutdown study and remove it from DataFax

Solution: Phase 2

- SAS data sets
 1. Better to err on the side of safety and include everything

```
DFsas final -C 254 -p all
```
 2. Edit `final` and add `SETNAME byplate` to global specifications
 3. Create data sets and SAS job

```
DFsas final
```

Solution: Phase 2

- **Audit trail**

Already in a DataFax independent representation: plain ASCII.

1. **Create a tar or zip file of the audit files**

```
cd `DFgetparam.rpc -s 254 DATABASE_DIR`
zip audit.zip *.jnl
```

Solution: Phase 2

- **PDFs, one per center**

```
set f=`DFgetparam.rpc -s 254 CENTERS`
set c=`awk -F\| '$11!~/ERROR/{print $1}' $f`
set p=`DFlistplates.rpc -s 254`
set o=/tmp/$$
foreach ctr ($c)
? foreach plt ($p)
? DFexport.rpc -a -n$ctr -sprimary 254 $plt $o
? end
? DFpdf -i $o -o $ctr.pdf 254
? rm -f $o
? end
```

Solution: Phase 2

- Other files to consider for archiving

- Edit checks source file, `lib/DFedits`, plus any files that it includes
- Plain text output of each plate, possibly with headers, for use in programs like Excel

```
foreach p (`DFlistplates.rpc -s 254`)  
? DFexport.rpc -s all -h 254 $p plt$p.txt  
? End
```

- Sent QC reports, from `reports/QC/sent`, possibly organized into one PDF file per center

Solution: Phase 2

- Listings to consider for archiving

- Database definition: `DF_SSvisitmap`, `DF_SSschema`, `DF_SScenters`
- Database definition: PDF of output from `DFsetup -> Print`
- Center and patient tracking: `DF_CTCrfs`, `DF_PTCrfs`
- Descriptive statistics by plate from `DF_stats`

Solution: Phase 2

- Record all SAS files, audit trail zip file, and center PDFs to durable storage
- Hard to predict what will be durable in 10 years – CD is more favorable, tape is less favorable

Solution: Phase 2

- Use DFsystem studies tool to delete study from DataFax
 - This breaks the association between the study number and the study directory – it does not delete the study directory or any of its contents
 - Revokes permissions for all users of the study
 - This is a better solution than permanently disabling study

Summary

- Faxes can be forwarded in several formats to additional locations using attributes of the fax.
- Data fields can be added, deleted, or re-ordered after a study has been started, but care must be taken in the planning and execution of the process.
- A study close-out procedure that includes the creation of SAS data sets and PDFs is easy to create and follow.