
DataFax and the Future

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EDC isn't always paperless

- Many systems depend on source worksheets. (99% of records)
- Some have taken to scanning those sheets and emailing to monitors to reduce travel.

Paperless trials remain elusive, but ...

- HL7, BRIDG, CDSIC and many other initiatives are working on various aspects of the problem
- And—given the potential gains in efficiency and accuracy—innovative people will eventually succeed.
- OnTarget recently claimed to be ready with two trials. *

* http://www.clinpage.com/article/ending_mindless_monitoring/C9

And DataFax already can import machine data

- If you've already exported it to ASCII
 - from Excel spreadsheet
 - SAS datasets
 - or some other application
- Transmitted via email or ftp.
- Imported via DFimport.rpc into pre-defined plates.

You just need a person at either end.

iDataFax 4.1 can

- Submit scanned CRFs
- Import other patient documents

So it's not that hard to imagine complete
automation of such processes

Only minor changes to existing
programs would be required.

Machines Have Identity

Confirm Your Identity

[Help with this page](#)

Identification Identification Code Enter Code

We need to confirm your identity — We apologize for the inconvenience, but we don't recognize the computer you're using. In order to help prevent an unauthorized person from accessing your accounts, we need to verify your identity before you log on.

Confirm Your Identity

Why don't you recognize my computer?

- You may have bought a new computer or are using one you haven't previously used.
- You may have changed the settings on your browser or switched to a new browser.
- You may have deleted your cookies.
- You may have reconfigured your computer, operating system or other software settings.
- Your Internet Service Provider may have changed settings on their system.

What do I need to do?

All you need to do is get an Identification Code. Make sure your phone or your e-mail inbox is close by and click "Next" below to follow the quick and easy process.

[Next](#) [Cancel](#)

Data can is
currently being
submitted via
email

from Nelson Yiga <yiganelson@yahoo.com>
subject **RE:Tororo MEMS DATA.**
to MEMS@dfnetresearch.com, 'Meighan L. Krows'
cc Michael Enyakoit <menyakoit@yahoo.com>

Hi all,

Please receive Tororo MEMS Data.

Thank you.

Nelson.

— Tororo15October2010.txt —

```
Patient;Monitor;Date;Hour;Intervals
283652;283652;05/19/2010;09:32:00 PM;
283652;283652;05/20/2010;09:27:00 PM;23:55
283652;283652;05/21/2010;09:55:00 PM;24:28
283652;283652;05/22/2010;09:35:00 PM;23:40
283652;283652;05/23/2010;10:25:00 PM;24:50
283652;283652;05/24/2010;10:43:00 PM;24:18
283652;283652;05/25/2010;09:41:00 PM;22:58
283652;283652;05/26/2010;09:23:00 PM;23:42
283652;283652;05/27/2010;10:06:00 PM;24:43
283652;283652;05/28/2010;09:45:00 PM;23:39
283652;283652;05/29/2010;11:32:00 PM;25:47
283652;283652;05/30/2010;10:30:00 PM;22:58
283652;283652;05/31/2010;09:19:00 PM;22:49
283652;283652;06/01/2010;10:39:00 PM;25:20
```

Tororo15October2010.txt

An alternative DFincoming process could

- Trigger a DFbatch process which would
- Import attached data into specified fields on designated plates
- Include the source IP or MAC address in the audit trail

Then existing processes take over

- Legal Ranges, edit checks and human review could occur.
- Human operators could verify the source via existing context function or DF_ATmods
- QC notes could be added and
- Validation Levels applied.
- Data could be exported in any format currently supported

It would also be helpful to have

- A function that would split incoming data strings based on any selected delimiter.
- The ability to link a person to a machine by email and phone number.

DFsystem might allow

- Studies defined to “Accept Machine Data”
 - From a list of specific address
 - With a defined delimiter (e.g. “CSV”, “TAB”)
 - Via a specified batch job or jobs
- Permissions for “Machines” limited to specific plates, centers, visits and validation levels.

DFcenters might link “Machines” to

- Batch files (allowing multiple jobs in cases where various machines provide different data)
- Human contacts (phone and email)
- Documentation
 - Batch validation requirements, tests, approvals
 - Machine validation documentation (provided by sites)

Other Possibilities

- Each remote system could trigger different batch jobs based on the ...
 - Email subject
 - Number of data fields in each record
 - Field delimiter used

Advantages

- **Flexibility**
 - The system depends on field order and delimiter.
 - You don't need the whole schema.
 - The source doesn't have to comply with CDISC, HL7 or any other standard.
 - You only need to verify that the remote system is exporting defined elements in an expected fashion.
- **Documentation**
 - DFbatch already produces logs
 - DFincoming already writes addresses to the fax_log along with the date received.
 - File size could replace number of pages
 - Or "number of records"

What about PRO?

- A user or mobile device could be defined as "Patient"?
- Given access to only diary or "PRO" plates.
- Limited to a single participant ID.
- Allowed to create data only, respond to QCs or (in 4.1) import documents.
- Login via iDataFax or other browser.
- Queries for these forms could go straight to a patient's email.
- Each patient could be allowed access from only one or two mac addresses
- Or email from patients could be read straight in to a comments field

But would that meet regulations?

- According to FDA Guidance on ePRO (Dec 2009) *"Use of ePRO instruments may pose a problem if direct control over source data is maintained by the sponsor or the CRO and not by the clinical investigator. We consider the investigator to have met his or her responsibility when the investigator retains the ability to control and provide access to the records that serve as the electronic source documentation for the purpose of an FDA inspection."*

So you might ...

- Forward a de-identified copy of the participant's email to the investigator.
- Or have a post-process that notified the site when a participant entered data.
- Have the investigator's staff validate ePRO records to a specific validation level.
- You could also have a journal of that data emailed or ftp'd to the investigator.
- After which the investigator could "approve" by validating specified keys.

It would require

- Secure email connections or de-identified data.
- Additional informed consent, especially in Europe.
- Visit Maps and/or edit checks to verify receipt of minimal data.

What could you call it?

- DataFlex
- Defined Data
- DataBytes

How do you eat an Elephant?

One *byte* at a time

Databases may never speak the
same language ...

But we can build systems today
that facilitate translation of what's
important.