
Beyond DataFax 3.7

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Lessons Learned from 4.0

- Developing a completely new product that exceeds a mature and already very good product is hard
- Don't discount what already works, leverage it
- Progress in small, deliverable steps
- Make changes in a backwards-compatible manner

Moving Forward

- Continue to improve existing product
- Continue to deliver new releases in a reasonable timeframe
- Leverage existing database structure

Large Projects - Server

- Firm up the supporting structure – this means updating the server
- Server enforces all database integrity
 - Structural soundness
 - Internal consistency
- Server provides all access to study files
 - Eliminates problems with UNIX filesystem permissions
 - Removes need for NFS, etc.

Large Projects - Keys

- **Higher limits in key fields**
 - Up to 9999 centers, allow dates as visit numbers
 - 3 key fields is enough!
- **3 of 9 barcodes**
 - Optional: existing style and 3 of 9 barcodes can be used
 - More than 255 studies, in fact studies can be numbered or named
 - Study name/number does not appear in records

Large Projects - Filesystem

- **Direct filesystem access to DataFax/study information is not permitted/required**
 - Applies to everything: images, config files, etc.
 - UNIX file permissions are removed from users
 - All access is through study server
 - Client shell scripts will require minor mods
 - "DFgetparam.rpc-like" client access to study info

Large Projects - QCs

- Single QC notes that can be linked to multiple fields
- Multiple QC notes per field
- QC notes on partial keys – patient, visit, or plate-level QC notes
- Direct QCs to individuals
- Comments – like QC notes but do not appear in reports

Large Projects - Schema

- **Modules**
 - Intermediate level between plate and variable
 - Collection of variables appearing in a group
 - Available to DFsas and DFsqlload
- **Database and audit trail updates following field/module/plate changes**
 - Schema version control
- **CDISC**
 - Write ODM and SDS

Large Projects - RDE

- Built on top of strengthened server
- Front-end data arrives via fax, web entry, PDF form data, PDA device, Anoto pen, etc
 - Challenge is to make DataFax independent of the data collection/entry method
 - Back-end and central data/QC management tools remain the same

Smaller Projects

- Patient binder view
 - New front-end to DFvalidate intended primarily for remote users
 - Interface is patient-driven, including a spreadsheet of received, missing, and expected CRFs
 - Users can easily review data and QCs, fix problems, perform raw data entry
 - Requires additional permissions to restrict site access to their patients only
 - With Citrix/VNC, possible RDE solution

Smaller Projects

- Graphical user interfaces for DFsas, DFexport.rpc, and DFimport.rpc
- Retrievals in DFvalidate based on QC note attributes, reason codes, etc
- Field history option, detailing all data changes made to current field

Smaller Projects

- 3.7 fixes?
- Deliver listed smaller projects in a minor release, late fall 2004

Future Projects

- AE/SAE management
- Supplies management
- Site & payment management
- HTML/PDF reporting and publishing
- Workflow & task management

Future Releases

- Approximately one major release per year – preferably in the late fall
- Minor releases as needed during the year
 - released as fixes/enhancements to individual programs as well as patch clusters/"service packs"

Feedback

- What are we missing?
- Is a schedule of one major release per year acceptable?