DataFax 2014.1.0 Upgrade Methodology and Lessons Learned

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Unsuccessful or problematic upgrade to DataFax 2014.1.0 held huge risk for the NIAID DataFax Operations.
Primary Upgrade Reasons

01 Modularization
- Modularization of plates and items (CDISC compliance); better ability to view data across plates

02 Security concerns
- DataFax now uses protocol TLS instead of SSLv3.0 due to security vulnerabilities

03 Batch Tool
- Ability to use the Batch tool operations directly from the Client tool

04 Signatures
- 21 CFR Part 11 compliant e-signature module was added
Primary Upgrade Reasons (continued)

06
CDISC ODM

06
CDISC ODM export has been added further allowing CDISC compliance

07
Multi-media

07
Multimedia files (PDFs, DICOM images, audio, video) to be attached to patient records
Risks Management

- Cost-shifting role of setup primarily to internal team (away from experienced NIH Data Managers)
- Training users: internal team, NIH DMs, international site contacts (iDF + DFSetup aspects)
- Internal learning curve especially with regard to known factors such as: applying modules intelligently, edit check programming syntax changes for module references; using batch from client tool; reconfiguring other tools such as new syntax requirement for DFbatch
- Reconfiguring of time fields
- Storage impact switching to PNG – additional 10-fold growth in ongoing disk usage
Upgrade Methodology – 3 Phase Approach

- **Dev Server** – Functionality testing; functionality orientation/understanding; training development
- **QA Server** – Planning of upgrade methodology; official testing and documentation
- **Prod Server** – Official upgrade, validation and documentation on production server
1. Clone Production server to QA server - using the NetAPP storage & VMWare environments (segregated and controlled testing environment)

2. Upgrade to DataFax 2014.1.0 on QA server

3. Run DFmigrate tool on QA server

4. Review DFmigrate log; documenting issues; development of roadmap

5. Perform mini-ATK testing critical functionalities

6. Perform Full-ATK
Upgrade Methodology – Prod Server

07 Back-up
- Restrict user access; back-up of production server

08 Prod Upgrade
- Upgrade to DataFax 2014.1.0 on production server

09 Run DFMigrate
- Run DFMigrate tool on production server

10 DFMigrate Review
- Review DFMigrate log; documenting any new issues

11 Mini-ATK
- Perform mini-ATK testing critical functionalities

12 Full ATK
- Perform Full-ATK
Upgrade Methodology – Prod Server (continued)

13 Access
Upgrade on Prod server successful; allow user access

14 Migration Roadmap
Review of all studies – ensure that any migration issues are fixed

15 Documentation
Upgrade documentation reviewed / authorized / saved

16 Closure of Upgrade
Successful upgrade and closure of upgrade
Development of the DFmigrate “Road Map”

- Reviewed all studies – Setup State
- Lengthy output to wade through!!!
- Could not fix the Setup State on the QA server – had to be fixed on the production server (during “official” upgrade)
- Limited time during official upgrade, so needed an exact “road map” of where to correct setup issues
Most Common DFmigrate Issues

- Meta-words used on ‘Name’ removed
- Format contains invalid characters for numeric field, e.g. nn:nn for numeric time
- Invalid length for numeric field (Max: 10)
- Other setup warnings/errors that were previously not addressed
Why Do a Mini-ATK?

- Reduced ATK developed specifically to focus on a reduced set of critical DataFax functionalities
- Utilized as a “go/no-go” decision maker for the full-ATK (spot early-on issues)
- It also covers some tests currently not contained in the full-ATK, e.g.
  - DFimport.rpc for electronic mSource data
  - CRF page submissions via email
  - Functionality of Python scripts
Upgrade Timeline

- **Dev Server** – 2 Months
- **QA Server** – 1 Month
- **Prod Server** – 2 Days (Thursday & Friday, with the possibility to extend over weekend if necessary)

Interesting to note was that the DataFax 4.3 upgrade was performed in Oct 2014; DataFax 2014.1.0 upgrade was performed in Jun 2015. Only 8-month period between 2 upgrades.
Upgrade Documentation

- Mini-ATK documentation as performed on QA server as well as production server
- Full ATK documentation as performed on QA server and production server
- DFMigrate log review and corrections as implemented on the production server
Upgrade Challenges

- Development of the DFmigrate log road map (had to be performed across all projects)
- Transform to Time Style for all studies
- What to do about store length warning and format errors for numeric fields?
- Bugs in DFSetup change logs
- Forgot to update DFbatch commands in cron
- Storage: impact of PNG is serious ~ 10-fold
- Licensing challenges (needed 3 server licenses instead of our usual 2)
Summary

- Many advantages to new features available in DataFax 2014.1.0
- Learning curve in stepping into new module framework – best practices in development
- Excellent user support from vendor
- Excellent responsiveness to user requests from vendor
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