
DataFax at Inovio: A small pharma experience

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DataFax at Inovio: A small pharma experience

- Inovio Pharmaceuticals, Inc. is a small pharmaceutical company focused on the discovery, development, and delivery of DNA vaccines for infectious diseases and cancers
- Our Clinical Scientists wear many hats:
 - Study Manager
 - Monitor/CRA
 - Medical Writer
 - Study Supply Management
 - System/Study Validation
 - Database Set-up
 - Database Administrator
 - CRF Designer
 - Data Entry
 - Data Manager
 - Data Export
 - Database Audit
 - Database Lock

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- Today's focus:
 - System/Study Validation
 - Database Set-up
 - CRF Design
 - Data Management
 - Database Audit
 - Database Lock

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- System/Study Validation:
 - Inovio purchased DataFax v 3.8 in Oct 2010
 - One study
 - Database set up by CDSI
 - CRFs were outsourced
 - Staff training provided by DF/Net and VLW
 - Steep learning curve
 - Documentation and validation required
 - More in-depth training required

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- System/Study Validation (cont):
 - Once DF 4.0 became available, Inovio decided to upgrade
 - Series of SOPs implemented with the help of DF/Net
 - Migration performed by DF/Net
 - ATK performed in-house
 - » Long and complicated process
 - » Steep learning curve for new users

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- System/Study Validation Lessons Learned:
 - ATK is an excellent way to familiarize one's self with DataFax
 - Team approach: Clinical, IT, QA, Consultants
 - Documentation is key

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- Database set-up (post 4.02):
 - Training provided by DF/Net at Inovio
 - One new study set up in-house
 - » Long and complicated process
 - Several new studies set up by VLW
 - » One study was 10 arms, 4 different schedules
 - Database validation/UAT performed in-house for both new studies
 - DFUG 2011 provided an opportunity to learn edit checks in-depth
 - We were able to apply this training toward current and future studies.

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- Database Set-up Lessons Learned:
 - Training, preparation, and planning are very important
 - Good database set-up can help avoid extra work later
 - DFSEQ is a very useful field
 - Consultants are invaluable to small pharma!

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- CRF Design:
 - Inovio scientists know how to design CRFs, but not how to create them
 - DataFax has unique requirements
 - Very few of our clinical sites have used DataFax
 - Training and guidance required
 - Many resources available for ideas for CRFs (HVTN, HPTN, SCHARP)
 - Inovio was able to reach out to consultants to design our CRFs to fit our protocols

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- CRF Design Lessons Learned:
 - Framemaker can be difficult for a new user
 - Proper planning and good CRF design up front create much less work later
 - CRF instructions and training for sites
 - CRF libraries cut down on work required for new studies
 - DFSEQ can be pre-printed for complicated studies

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- Data Management:
 - DataFax allows many different ways of reviewing data
 - Export to Excel, Review on screen, Tasks
 - Changing levels as a way to communicate to other reviewers
 - Easy query system to use
 - Reasons can be used to add information or clarifications (we monitor our own studies)
 - Reports to monitor data entry and fax volume, audit trail, etc.
 - DFSAS to export data for tables and listings

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- Data Management Lessons Learned:
 - We realized we needed many more SOPs and plans for Data Management
 - Data Management is a continual process, from database build to CSR
 - DFSAS is a very valuable tool for us
 - Continual learning as we use the system

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- Database Audit:
 - Close-out of our first in-house study
 - Unfamiliar with how to perform an audit with DataFax
 - Team approach: Clinical, Programmer, Consultants (DF/Net)
 - CRF and Image can be printed side-by-side for easy review
 - New SOPs and forms created for the process

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- Database Audit Lessons Learned:
 - Per previous slides, data management is a continual process
 - Good learning experience for all involved
 - Processes in place for future studies
 - Helps to ensure clean database prior to lock

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- Database Closure and Lock:
 - Once again, Inovio reached out to our Consultants (DF/Net) for assistance
 - New SOPs and forms for the process
 - Team approach: Clinical and IT
 - Milestone for Inovio Clinical Development

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- Database Closure and Lock Lessons Learned:
 - May need to keep read-only access during the CSR process
 - Processes and documentation required in case database needs to be reopened
 - Helps to have a different set of eyes review everything prior to lock
 - Be sure to run all tables and datasets
 - Checklists to assist in steps

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- DataFax's capabilities has allowed Inovio to maintain our smaller studies in-house
- It is a convenient and valuable tool
- Many lessons learned as our company and the number of studies grew
- Future directions
 - More utilization of look-up tables
 - Running scripts
 - Integrated data review
 - CDISC/SDTM

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Obrigado!

