DataFax at Inovio: A small pharma experience

Sandra Oyola, Clinical Scientist
Inovio Pharmaceuticals, Inc.
Blue Bell, PA

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

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

• 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

- **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

• 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!

Thank You!

Merci

Gracias