
Transitioning the Site and the Project Office to Internet-Based Data Management

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Overview

- Data management at the Population Health Research Institute (PHRI)
- DataFax study setup worksheets
- Training
- Feedback from clinical sites
- Tips and tricks

Population Health Research Institute (PHRI)

- Previous studies used fax -based collection
- New studies will use a combination of Internet and fax -based
- February 2008
 - 79 countries
 - 56 active studies use fax-based data collection
 - 3 studies use iDataFax
 - 1 study uses Internet-based data collection software developed by PHRI

Current Experience with Internet-based Data Collection

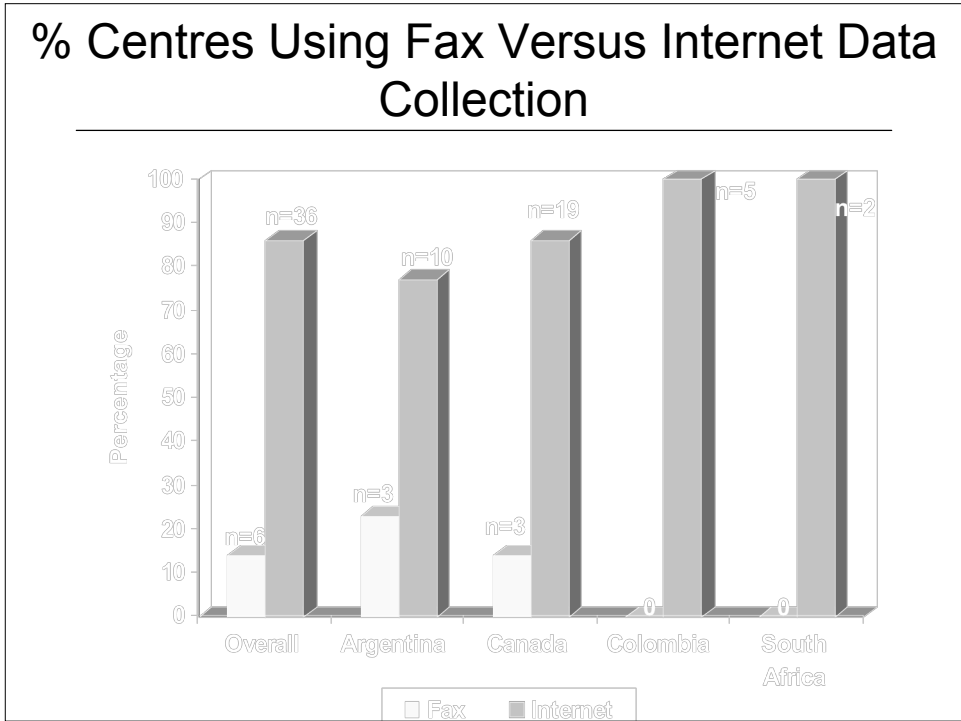
- Using iDataFax as well as fax-based data collection in a multi-centre, international, randomized controlled trial

Overall

- 15 countries, 170 centres, 10,000 pts

Currently

- 4 countries active (42 centres)
- 85% centres iDataFax (n=36)
- 15% centres only faxed- based (n=6)



Fax Versus Internet (during recruitment)

	HOPE-3 36 sites (Internet)	HOPE-3 6 sites (Fax)	Other Study 540 sites (Fax)
Time from clinic visit to data entry (days)	9	6	9
Time to clean data ¹ (days)	15	10	24
% clean on arrival	74	81	68
% clean data	95	98	97

¹QC reports sent weekly

DataFax Study Setup Worksheets

1. Study configuration and user permissions
2. Case report form review
3. Patient scheduling
4. Plate definitions and actions
5. Missing value codes
6. Variable definition conventions, style and index
7. Lookup tables
8. Edit checks
9. Page map (patient status and refax/Q&A)
10. Centres database
11. Roles – validation levels and standard tasks
12. Testing – plate, edit checks, visit map

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Study Configurations and User Permissions

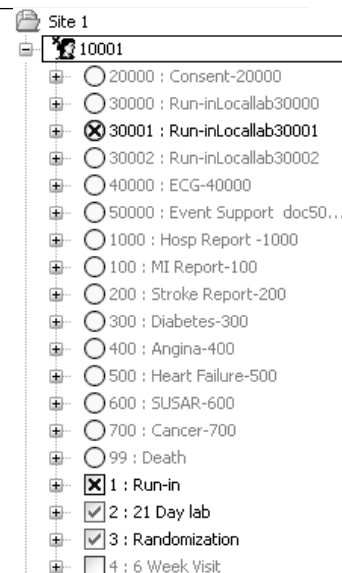
- **All users required to have their own unique electronic signature – 21CFR11**
 - Electronic signature certification
 - ~ 6 staff members per site require iDataFax access
 - Automated user account process
 - Create, modify, disable accounts
 - Reset passwords
- **99 license limit**
 - HOPE-3 centres - 473 accounts
 - Internal accounts

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Patient Scheduling

1. **Unscheduled visits must be defined in the visit map in order to be seen in the participant binders**
2. **Use arbitrary sequence numbers**
3. **Enter unscheduled visits first in the visit map (before scheduled visits)**



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Lookup Tables

1. QC LUT
2. Data Field LUT
3. Reasons LUT
 - Request reason for change on all variables
 - Inconsistencies in the use of reasons on data fields

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Roles – Validation Levels and Standard Tasks

- Standard roles for Project Office
- Site roles – dependent upon site delegated tasks
 - Restrict access to plates or participants
 - View only permission on specific plates
 - Access to queries
 - Ability to respond to queries

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Testing

- Plate testing
 - Fax form
 - iDataFax entry (including participant binders)
- Edit check testing
- Visit map testing
- User role testing
 - Hidden fields

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Site Personnel Training

1. Read data collection manual - contents include:
 - Fax and computer requirements
 - User names and passwords
 - Downloading and installing the software
 - Starting the iDataFax program and logging in
 - Data entry (including reasons)
 - Queries and quality control reports
 - Faxed-based data management
 - Using both Internet and fax-based data management
 - Training module
 - Frequently asked questions

Site Personnel Training continued

2. Complete the training module

- Downloading and installing iDataFax
- Data entry
- Data inconsistency warnings
- Adding reasons to data fields
- Finding and responding to queries
- Fax in test form

3. Site initiation call

- Review data entry procedures
- Review completed training module

Site Personnel Training continued

Common training module problems:

- Site cannot download the program due to blocked security ports and firewalls or blocked network access (to download programs)
- Adding reason to incorrect data field
- Respond to query but do not correct data on screen

Project Office Personnel Training

- Use of new interface
- Review, interpretation and approval - reasons and queries
- Site support
 - IT support
 - Software or connection problems
 - User name and passwords
 - Project Office
 - How to use iDataFax

Feedback from Clinical Sites

OVERALL IMPRESSION

- Very user friendly
- Available data clean when submitted to the Project Office

SITE CONCERNS

- Time to enter data
- Providing reasons for data change

Tips and Tricks

1. Automate user account creation process
2. Enter unscheduled visits in the visit map
3. Add DFWarning to edit checks

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1. Automate user account creation process
2. Enter unscheduled visits in the visit map
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4. QC report generation
5. Preparation for system downtime
6. Financial considerations
7. CRF sign-off

Summary and Conclusion

Using Internet-based data management is a different approach data management and involves a mind-shift in previous procedures

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Using Internet-based data management is a different approach data management and involves a mind-shift in previous procedures

Challenges of Internet-based data collection are different than in previous procedures but are surmountable