

## DataFax Issues for CRAs

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### Overview

- SOP development
- Training on DataFax
- Study implementation
  - Site training
  - DataFax CRFs as source documentation

## Overview (ctd.)

- Monitoring
- Bioresearch Audit
- Study Expansions
  - International Trials
- Study Closeout
- Market Research/R&D
- Conclusions

## SOP Development

- Golden Rule



Do not be too specific!

- Clinical DataFax SOP should be “like an umbrella”

## SOP Development (ctd.)

- Purpose
  - To track DataFax study data from study subject to the sponsor

## SOP Development (ctd.)

- Procedures
  - Data Collection
    - Define DataFax CRFs as source document
  - Data Transmission and Receipt
  - Data Entry Activities
  - CRA review of primary records
  - CRA turns records clean or dirty

## SOP Development (ctd.)

- QC reports
  - Site refaxes everything which is set for refax
  - Use of Q&A section, site writes letter or responds on QC report
  - Infrequent use of “Note field”, especially for Q&A resolution
  
- Query Resolution

## Training on DataFax

- Training of new CRAs to system
  - Focus directly on training on SOPs and DataFax
  - Training matrix was developed
  - Access without validation privileges is available

## Study Implementation

- Purchase and setup of high quality fax machine
- Training at site
  - Quick learning curve due to
    - Easy to interpret DataFax CRFs
    - “Low tech”

## Study Implementation (ctd.)

- DataFax CRFs as source documentation
  - “Trendsetter”
  - Allowed coordinators to focus on patients and alleviated burden of transcribing data
  - Advantages:
    - Quick turnaround time
    - Less errors
    - Less queries by CR
    - Cost savings

## Monitoring

- DataFax CRFs review by
  - Validate (fast and powerful tool)
  - Variables (easy and consistent tracking of patients with complications)

## Monitoring (ctd.)

- Site Monitoring
  - Monitoring of source documentation (i.e., printout of ophthalmic tests)
  - Use of reports for site visits to review performance (motivational tool)

## Monitoring (ctd.)

- Prior to database freeze
  - Determine significant “dirty” data
- During PMA (Premarket Approval)
  - Use of statistical reports:
    - Patients lost to follow-up
    - Patients with missed visits
    - Patients outside windows, etc.

## Bioresearch Audit



- FDA auditor verified that:
  - Graphic image can not be changed
  - Intentional mistake was made which was caught by Clinical Data Specialist
- GCP audited by CRAs and consultant
  - System proved to be robust

## Study Expansions

- Study Add-Ons (new study arms)
  - Increased flexibility and shortened start-up time

## Study Expansions (ctd.)

- International Trials
  - Advantages:
    - Real time enrollment rates
    - Status reports
  - Challenges:
    - Different clinical trials mentality
    - Language barrier
    - Time difference
    - Script difference

## Study Close-Out

- Learning curve
- Easy to determine outstanding queries and forms for study close-out
  - Developed specific study exit form to turn off cycles

## Market Research/R&D

- Expanding into Marketing and Feasibility Trials
  - Smaller studies
  - Less DataFax CRFs
  - Quick feedback possible to VPs
  - Valuable to company

## Conclusions

- DataFax very well received amongst site personnel and CRAs
- Easy, fast, fun, flexible but robust
- Rest of co. is finding out about its capabilities
  - Branching out to additional studies and feasibility studies
  - Helps CR to maintain value to co. as studies are very expensive

## Questions?

