

Getting them on your side:

The Care and Feeding of Clinical Coordinators

Part II: The Nitty Gritty

by

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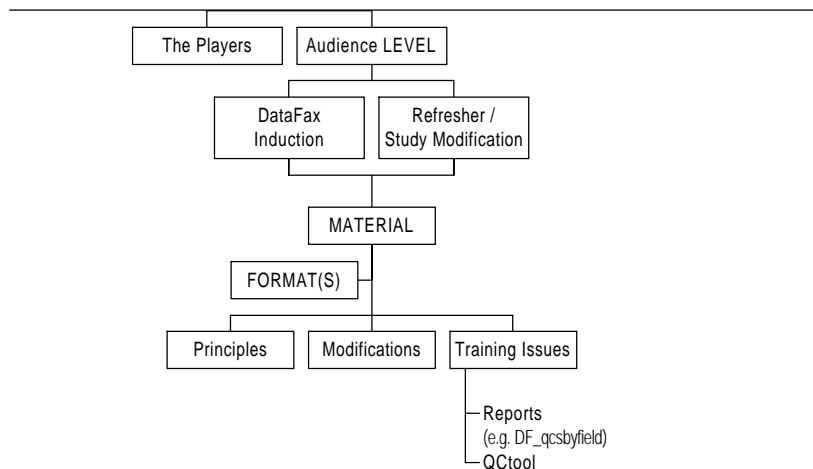
Getting them on your side:

The Care and Feeding of Clinical Coordinators

Part II: The Nitty Gritty

It is standard procedure for centers conducting clinical trials to receive specific data quality feedback from their Clinical Research Assistant (CRA). Overall quality of data collection can be improved by periodic review of the database to identify problem areas that are common to one or more centers. Such a review process has been used to select examples for use in group training sessions at KeraVision, Inc. This presentation will outline how the material may be categorised and demonstrated to clinical staff.

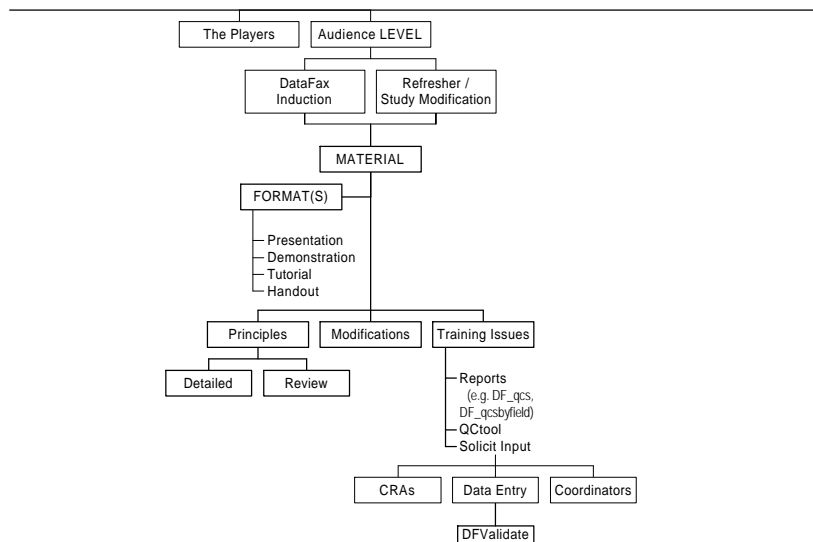
Structuring a Training Course



DataFAX Data Issues

- Training Issues
- Making Corrections
- Inconsistencies
- Incomplete Forms
- Illegible Data
- Miscellaneous

Structuring a Training Course



DataFax Data Issues

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Training Issues

Example: VA Forms

- Recording technique
 - Wrong line recorded (20/16 vs. 20/20)
 - Incomplete testing
 - Some letters were not crossed out or circled.
 - An entire line was not crossed out.
 - Only one line of data was marked - no lines above or below were circled or crossed out
- Messy recording
 - All letters were lined through as well as circled.

Training Issues

Example: Patient Comments

- Use of incorrect form a frequent problem.
 - Explained that this is a “Cost/Benefit” problem with specialised (i.e. visit- and/or eye- specific) CRF design. Makes for a cleaner database but increases the probability that the wrong form would be used.*
 - Obliterate bar code and re-identify form
 - If needed, correct the title of the page

Training Issues

Example: Patient Comments

- Comment section
 - Field size is limited. Solutions:
 - Abbreviations
 - DOP that specifies that the string may be truncated with "...SEE CRF"
 - Better solution: Provide concise information!
- Write legibly.
- Although the comment extending into the margin was captured on this image...

DataFax Data Issues

- Training Issues
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Making Corrections

Example: **LOG Forms**

- On this form, the correction to the date field in the margin was, more typically, cut off in the received fax image.
- When there are multiple corrections, space can be saved by the use of brackets with a single initial/date. This also improves legibility.

Making Corrections

Example: **Field types**

- **CHOICE field:**
 - Line out original response and
 - Circle the correct answer.
 - Poor example: shows both boxes with “X” but unclear what is latest response.

Making Corrections

Example: **Field types**

- **NUMERIC field:**
 - Line out the field and make the correction outside of the field.
 - Corrected example: shows an initial poor correction (inside the box with the original data) as well as a clarification, thus avoiding a query.

DataFax Data Issues

- Training Issues
- Making Corrections
- **Inconsistencies** Examples:
 - Patient ID and Initials
 - Exam Date and Visit number
 - Exam Eye and Operative Eye
- Incomplete Forms
- Illegible Data
- Miscellaneous

DataFax Data Issues

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Incomplete Forms

Example: **Header**

- Sometimes patient IDs are not pre-printed (e.g. forms from supplemental binders).
- A partial or missing patient ID generates a query to confirm the number associated with the initials
 - Note: if initials are missing as well, the data may be invalid and the image must be discarded.

DataFax Data Issues

- Training Issues
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Illegible Data

Example: **Various**

- Taking a little extra time to improve legibility will save time required to respond to a query (pull the binder; correct the data; refax the page; refile).
 - “4” that looks like a “6”
 - Small writing
 - Bunched writing/unclear abbreviations

DataFax Data Issues

- Training Issues
- Making Corrections
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- Miscellaneous
-- and where we would be without this category??!

Miscellaneous Issues

Example: **Faxing**

- Keep fax machines clean to prevent “fax noise” -- as it gets worse, entire batches may be illegible and requiring refaxing.
- Set paper guides to correct width (causes image to shrink which turns off OCR and can be difficult to read).

DataFax Data Issues

- Training Issues
- Making Corrections
- Inconsistencies
- Incomplete Forms
- Illegible Data
- Miscellaneous
- Good Examples..... *Thank-you!*

GOOD Corrections!:

Example: **Various**

- CHOICE field
- Contrast Sensitivity
- LOG form