

Getting them on your side:

The Care and Feeding of Clinical Coordinators

Part I: The Model

by

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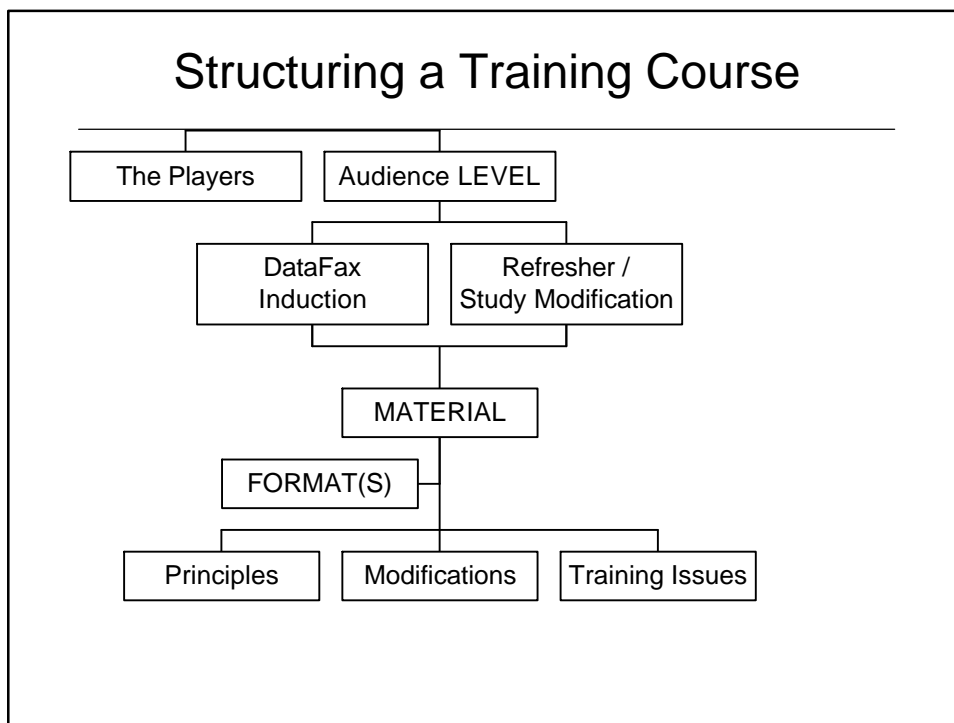
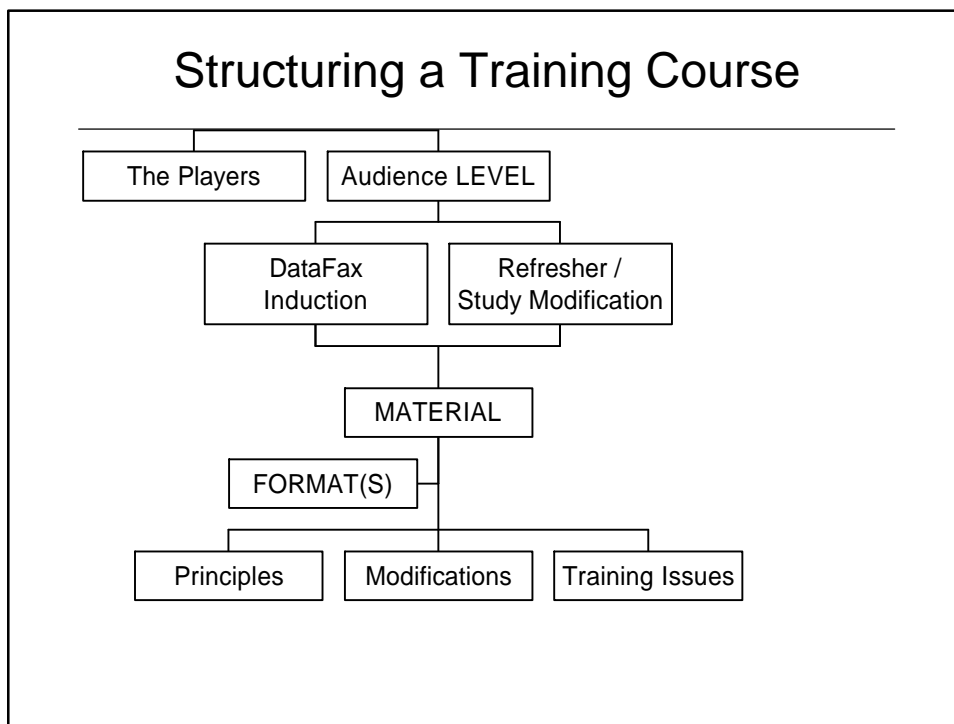
KeraVision, Inc.

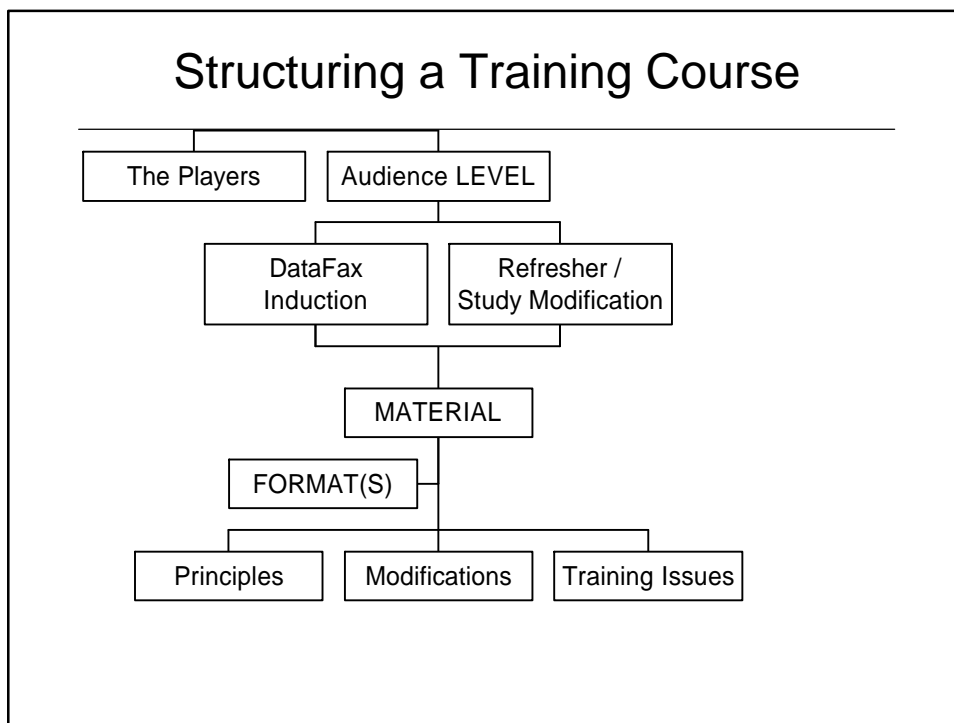
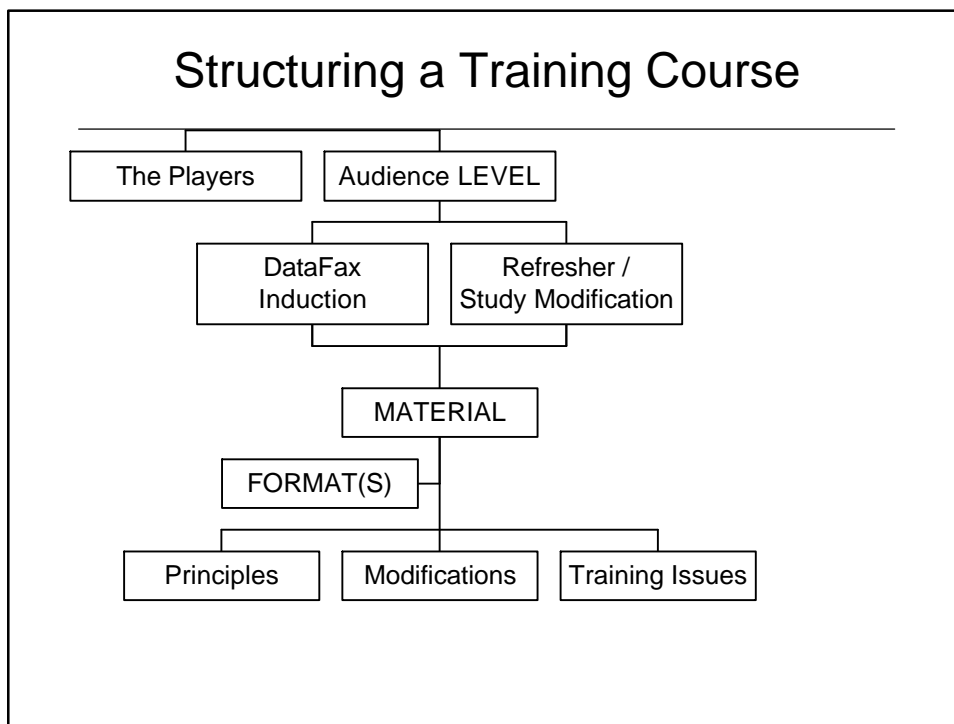
Getting them on your side:

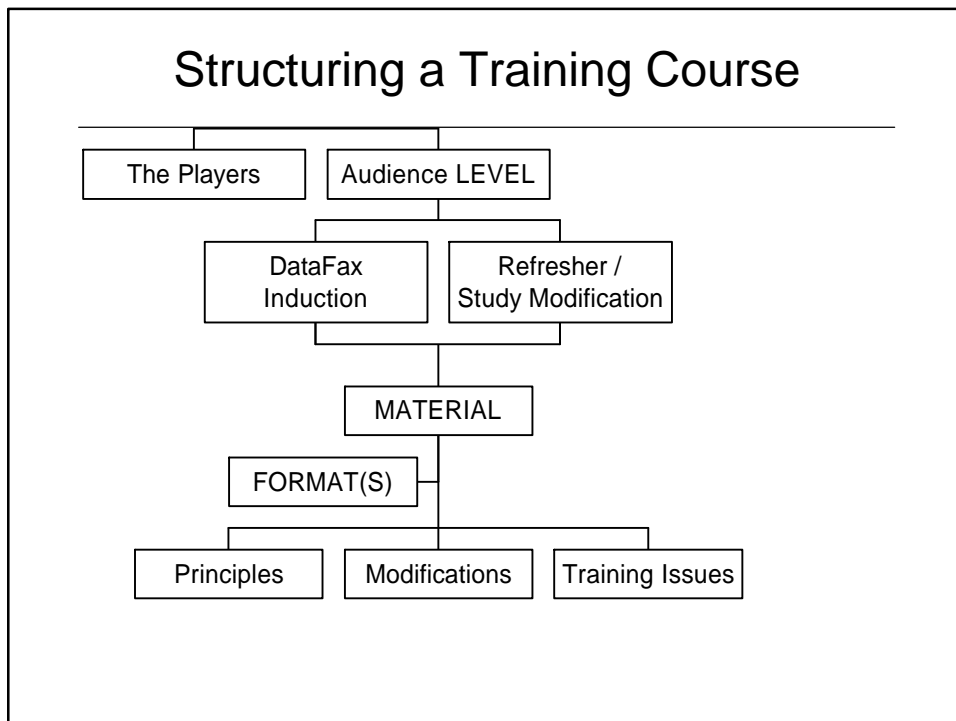
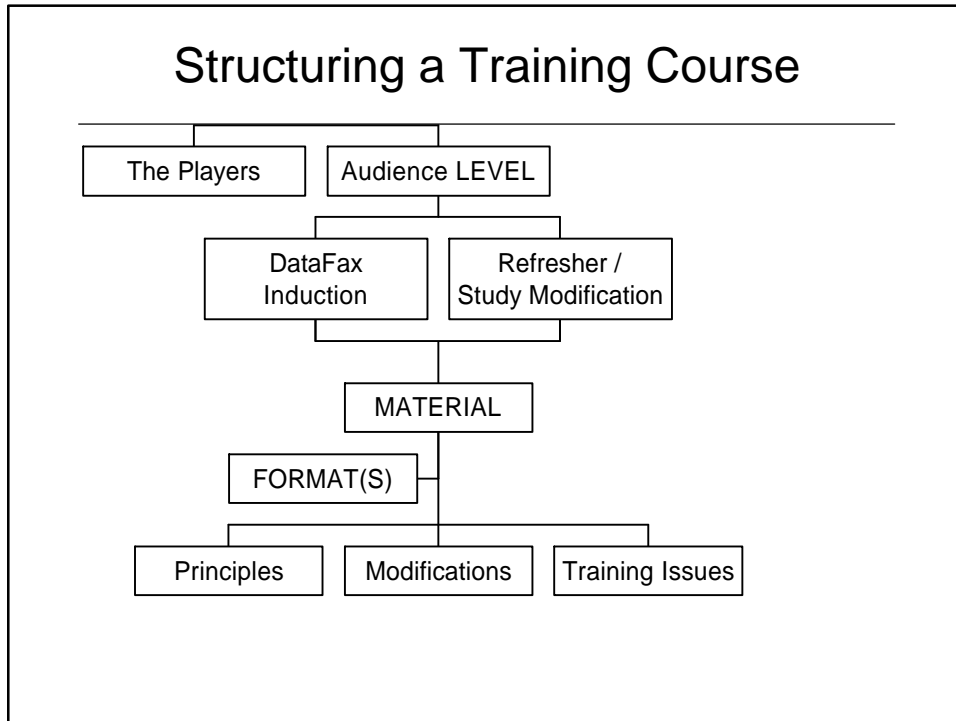
The Care and Feeding of Clinical Coordinators

Part I: The Model

For Phase III clinical trials, KeraVision has invested considerable resources in running training sessions for their coordinators. The planning and preparation of these events has had the beneficial side-effect of internal training of clinical and data staff. The sessions have been received favourably and their efficacy has been demonstrated by relatively clean data collection and quick resolution of data which are "dirty" (in the DataFax sense!). The "state" of the database has, in turn, reflected well on DataFax and has led to its implementation outside of the traditional clinical realm. This presentation will review the structure of these training sessions as well as a brief discussion of departmental accretion via the DataFax medium.





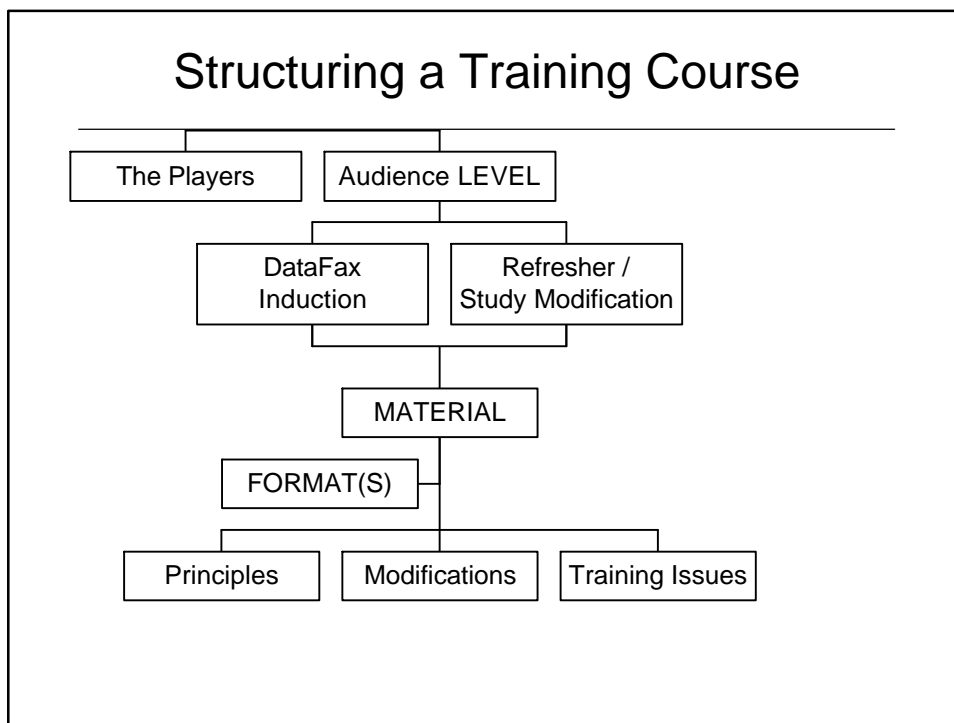
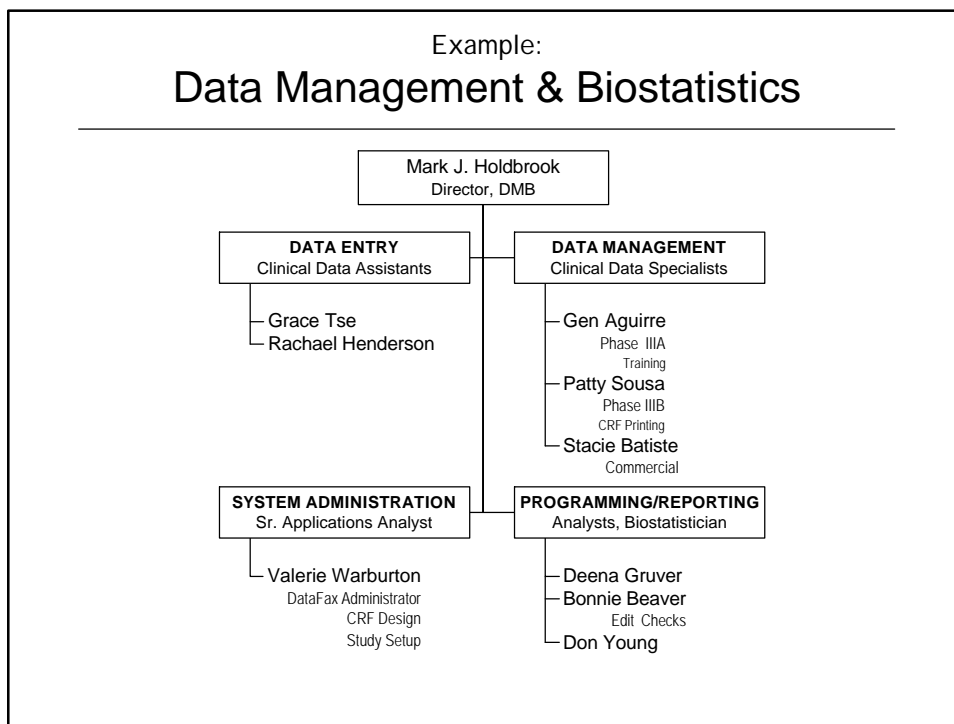


Introduce the Players

- Explain the functions of your department(s) relative to the study/site.
- **Introduce the staff** (see conference notes pp. 3-5)
 - Preferably on an individual basis (especially those with whom the Coordinators will interact directly)

Introduce the Players

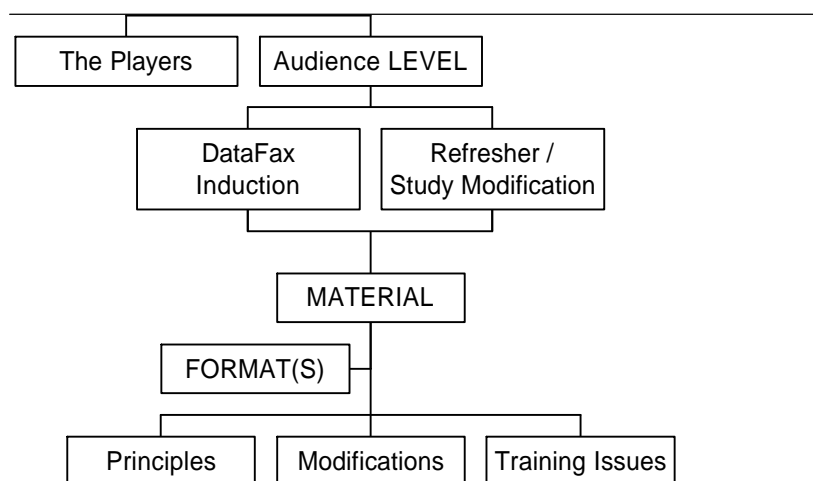
- Explain the functions of your department(s) relative to the study/site.
- **Introduce the staff**
 - Preferably on an individual basis (especially those with whom the Coordinators will interact directly)
 - If time is restricted or individuals are not available, use an Org. Chart



LEVEL: Induction or Refresher?

- Induction
 - New DataFax Installation
 - Protocol initiation
 - 50% or more of audience are neophytes
- Refresher
 - New study
 - Major revisions/protocol amendments
 - 50% or more of attendees have DataFax experience (some reliance on training at the clinical site for new employees by experienced employees/CRA in charge)

Structuring a Training Course

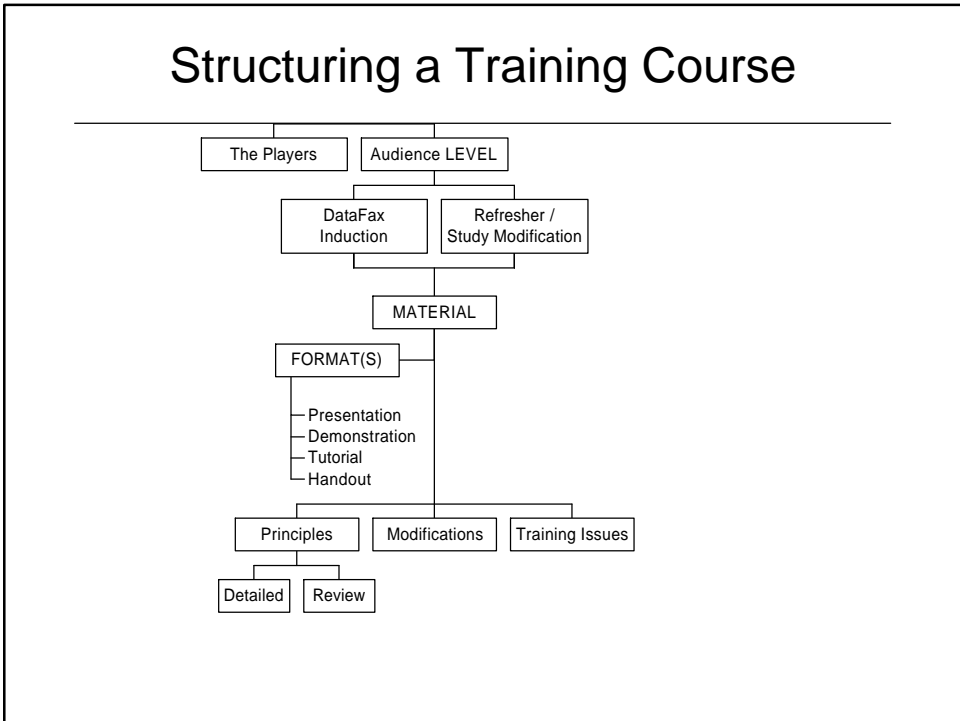
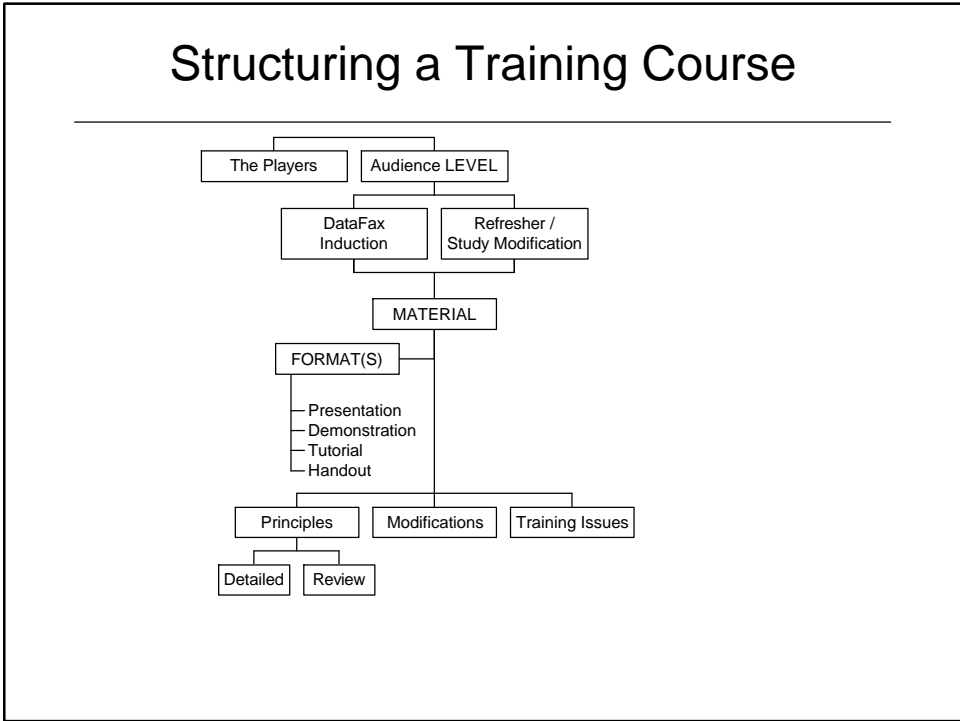


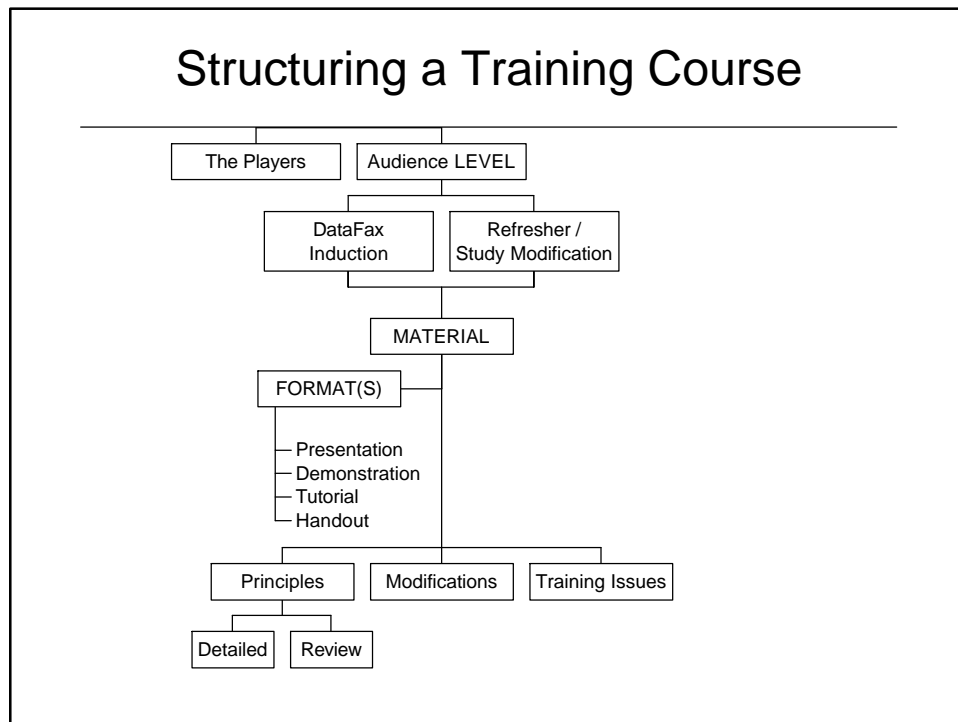
LEVEL: Induction

- DataFax Overview
 - What does DataFax mean to me?
 - <http://www.datafax.com/Products/WhyDataFax.html>
 - <http://www.datafax.com/Products/Overview.html>
- Design rationale
 - Study structure
 - CRF Design (DataFax/OCR compliance)
- Forms Flow
- Study specifics

LEVEL: Induction

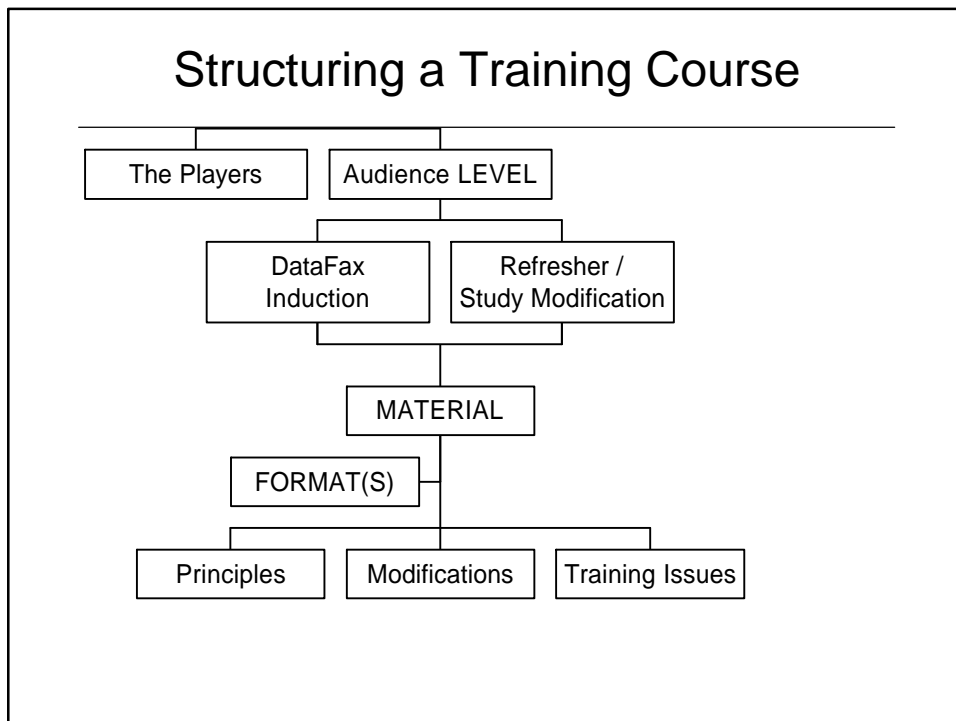
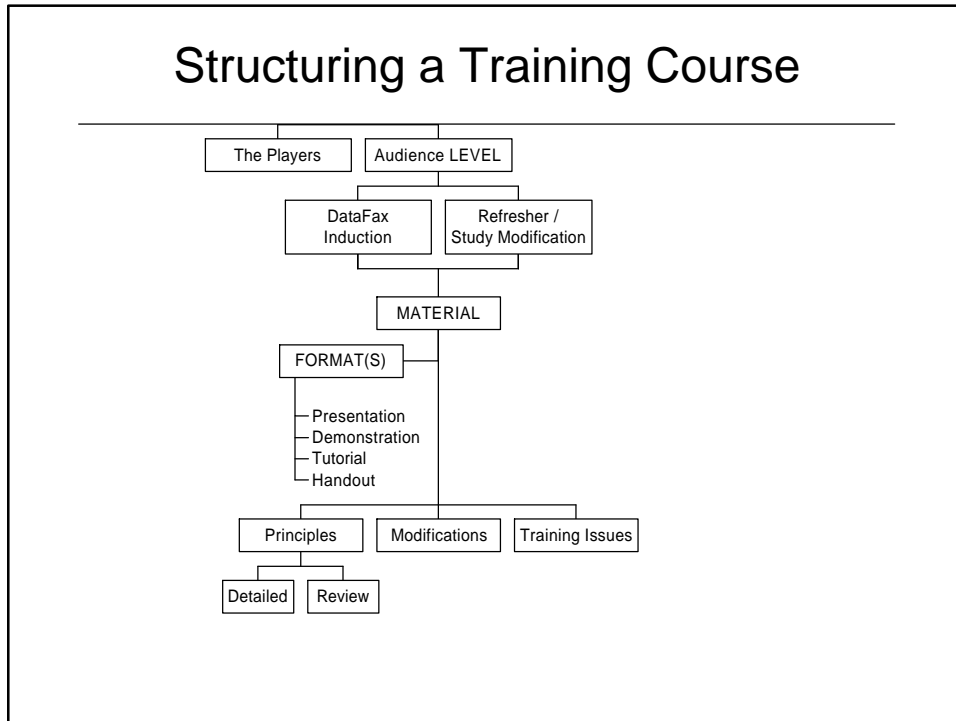
- Visual Props
 - Sample binders Examples:
 - Individual Patient Binder
 - Binders for occasional use
 - Flipchart for collecting feedback during session.
 - Visual cues will trigger other ideas.





LEVEL: Induction: Tutorials

- **Form completion:**
 - Prepare material for transcription (descriptive case studies or data tables) on to DataFax CRFs.
 - Examples:
 - Patient approval
 - Header (Patient ID; Product Status; Cycles/Visits)
 - Use of LOG forms (Medication/Treatment)
 - Ocular Complications/Adverse Events
 - Testing (Corneal Sensation; Contrast Sensitivity)
- **Interpreting QC Reports**

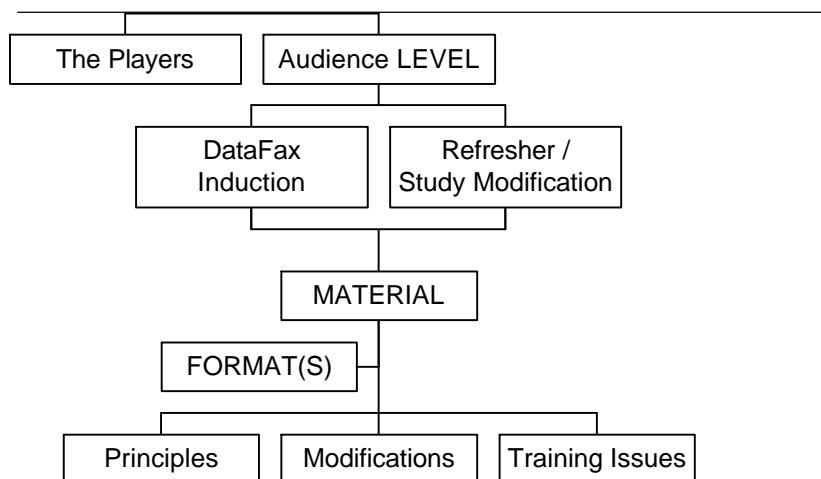


Example:

LEVEL: Refresher

- As preparation for enrolling for a study amendment, most recent training comprised:
 - The DMB Players (See above)
 - Review of DataFax Principles (Follows)
 - DataFax Data Issues (Part II of this presentation)

Structuring a Training Course



MATERIAL: Principles

Review DataFax Principles

- **Forms Flow**
 - Example: allowed time between screening and surgery (Handout: Flow Diagrams)
- **CRF conventions**
 - Example: Origin of form numbering/naming logic
 - Example: Pre-printing of patient IDs

MATERIAL: Principles

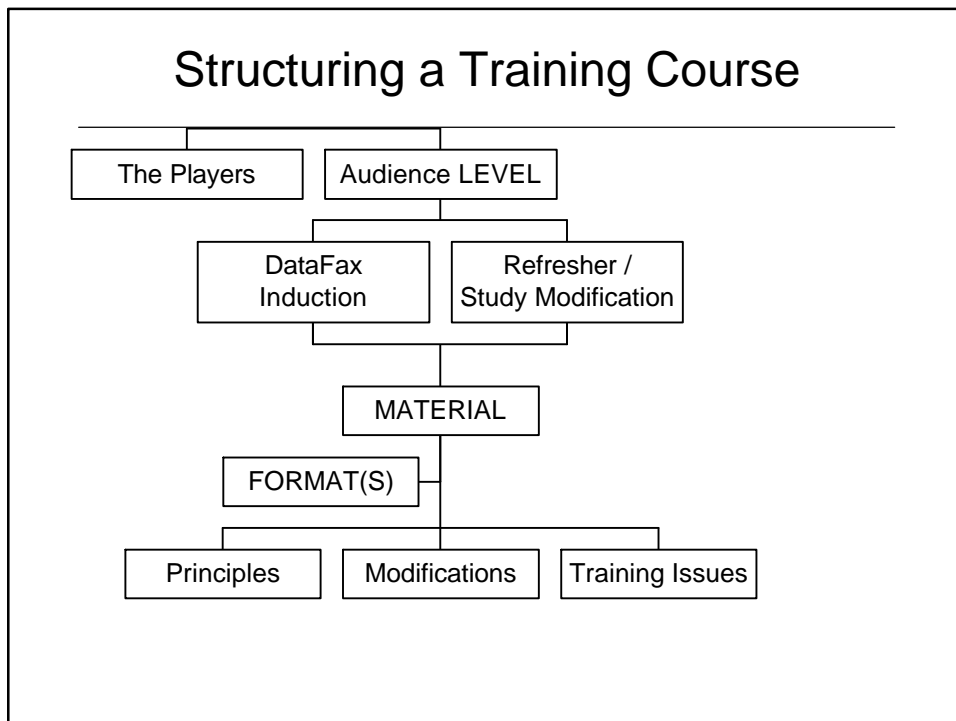
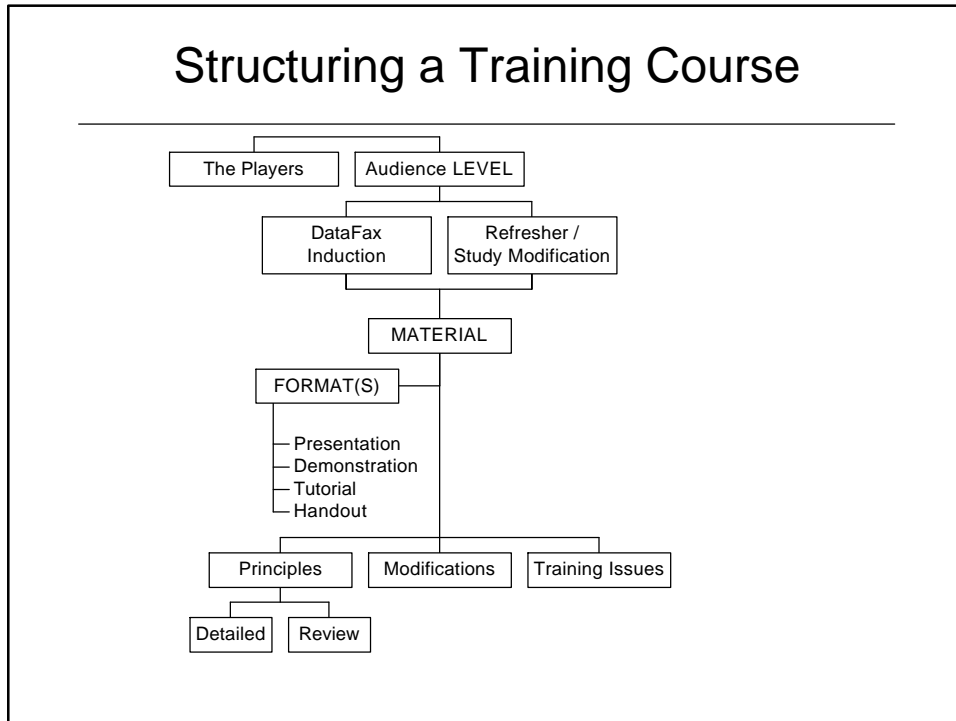
Review DataFax Principles

- **Design conventions**

(see conference notes p. 9)
- **QC Reports**

(see conference notes p. 10)
- **Faxing**

(see conference notes p. 11)



Modifications

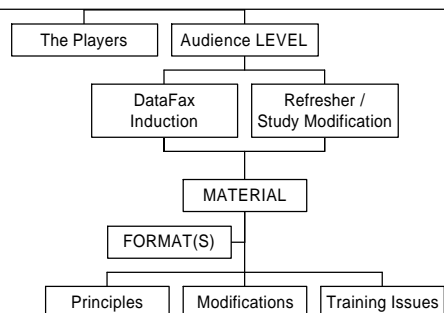
- Present rationale for any changes

Example:

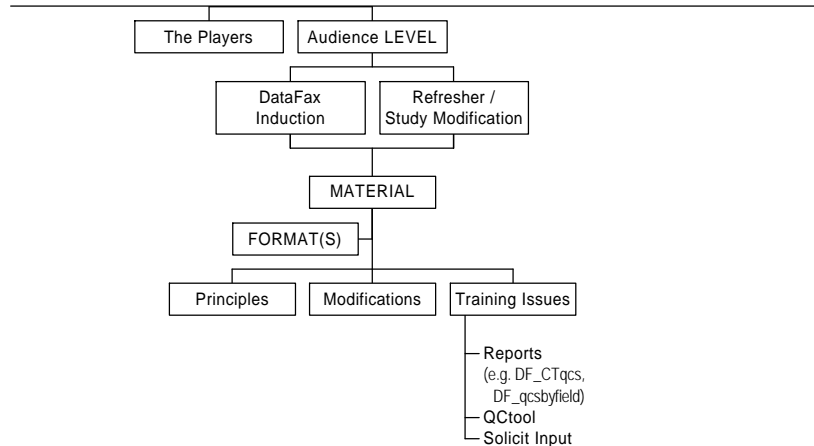
Changes resulting from Amendment

- Test schedule and follow-up for all new Contralateral Eyes and Exchanges from Group A (s12) and B (s212) has been reduced.
- In order for forms tracking to work, these will be segregated into a new DataFax study (s213) (see handout)

Structuring a Training Course



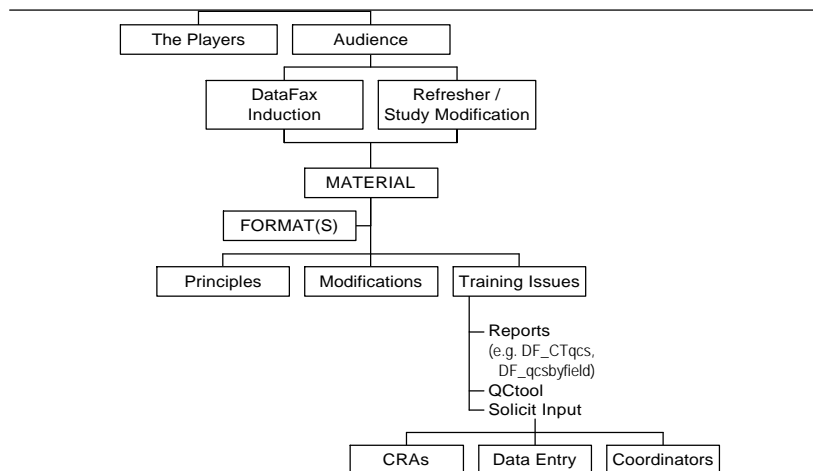
Structuring a Training Course



Concluding the Training Course

- **POSITIVE** wrap up.
 - Close with GOOD examples.
 - Invite discussion (positive and negative).

Structuring a Training Course



COURSES: Beneficial Side Effects

- Soliciting internal input has added benefits:
 - It promotes self-training: preparing material for a training course forces staff to organise their thoughts, categorise problems, and think of possible solutions:
 - CRF design
 - Internal procedures (and documentation!)
 - Improve communication with clinical sites.

COURSES: Beneficial Side Effects

- Soliciting internal input has added benefits:
 - Although these “players” are not the target “audience,” staff attending the Training Course will receive training.
- Concentrated training not only produces better data but it also promotes group cohesion.
- Enhanced internal presence and inter-departmental cooperation.

Departmental accretion via the DataFax medium

Accretion

The growing together or adherence of parts that are normally separate.

Media

A surrounding environment in which something functions and thrives.

Departmental accretion via the DataFax medium

- Phase IV / Commercial Data
 - One-center study comparing Intacs with another method for correcting myopia
 - Large, bonus-based project to collect data from initial procedures
 - Will require importing FileMaker data from first 500 surgeons.
 - Two other studies in preparation...more are anticipated.
- Patient Surveys

Structuring a Training Course

