Evolving Roles and Skills in Clinical Data Management:

Where Did We Come From and Where are We Going?

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Define Data Management Skill Sets

Management

Data Support

Medical Support

Programming Support

Validation Support

Quality Assurance
Objectives

**Define These Skill Sets...**

...as a function of building a data management department from the ground up...

...using 10 years of clinical data management experience as a case study
From This Presentation, You Should Learn:

- A Basic Clinical Data Management Department Makeup
- The Needs That Motivate Staff Expansion
- The Value (read—Necessity) of Cross-Training Clinical Data Management Personnel
- Potential New Functions for Clinical Data Management and its Personnel
How Does A Pharmaceutical CRO find a Home in Little Rock, Arkansas?

By Importing Outside Talent
How Does A Pharmaceutical CRO in Little Rock, Arkansas Staff a Data Management Department?

By Recruiting Homegrown Talent
Company Beginnings

- Established by a Biochemist / Toxicologist with East Coast Pharma Experience
- Originally Specialized in Regulatory Documentation
- Eventually expanded into Quality Assurance, Animal Health, and Clinical Data Management
Clinical Data Department Beginnings

Core Personnel Came From Existing Staff

- A Biologist / Medical Writer
  - “Data Management”

- A Statistician
  - All programming

- A Senior Manager
  - Study liaison
  - Management Structure
Early Data Management Work

The First Contracts awarded included:

- Completion efforts for studies started by other vendors, but not completed
- Rescue efforts intended to salvage data and conclusions from failed or ill-executed studies
- The retrospective drawing together of related studies for meta-analyses
Early Data Management Work

These First Contracts eventually lead to...

- Prospective Clinical Trials
- Clinical Trial Extensions
- Ancillary Data Management Services
Origins

Early Data Management Processes

- Original Hard Copies and Working Photocopies
- Basic Data Review (minimal guidelines)
- Manual Data Clarification Forms
- Medical Review Performed by Sponsor
- Organizational Free-for-All
Early Data Management Technology

- Used SAS Database Platform
- Used pre-21 CRF Part 11 specifications
- Data entry performed through SAS FS Edit
- Medical and Therapy Vocabularies existed in Hard Copy Only
- Vocabulary Coding was Performed Manually, recorded directly on the Working CRF Copy
Clinical Data Management Evolution

Evolution + Denial = Extinction

—Anonymous
Clinical Data Management Evolution

Clinical Data Management Staff Expanded—

- Non-Statistician Programmers
- Medical Personnel
- Data Management Personnel
- Quality Assurance Personnel
- Support Personnel
  - Data Entry
  - Administrative
Clinical Data Management Evolution

Duties Defined and Expanded—

- Project Managers
- Data Managers
- Medical Managers
- Programmers
- QA Specialists
- Administrative

Cross Training
Clinical Data Management Evolution

Cross-Training Personnel—

- Supplements Personnel Skill Sets
- Increases Productivity
- Increases Efficiency
- Increases Practical Communication
- Allows for a Smaller Department
- Decreases personnel expense
Process Evolution...

- Medical Review Guidelines Introduced & Implemented
- Data Review Guidelines Expanded & Implemented
- 21 CFR Part 11 Documentation Implemented
- Data Edit Catalog Developed
- Data Clarification System Implemented
- Data Management Plan Takes Shape
Technology Evolution...

- **Streamlined Programming Processes**
  - CRF Tracking
  - Entry Screens
  - DCF System
  - Vocabulary Systems

- **21 CFR Part 11 / Validation**

Programmatically Integrated

System & Documentation were further Integrated by...
...the reasonable man adapts himself to the world. The unreasonable one persists in trying to adapt the world to himself. Therefore, all progress depends upon the unreasonable man...

—George Bernard Shaw
Adaptation & Progress...

...If [anything] wants to go to hell in a basket, technology can help it get there by jet...

—Charles M. Allen
Clinical Data Management Adaptation

- Stimulated by Low Demand of traditional CDM work
- Is Needs-based
- Takes Advantage of Cross-Trained Skills in Department Personnel, Increasing Efficiency
- Provides Additional Professional Opportunities and Department Expansion
Clinical Data Management Adaptation

Areas of Expansion—

• Quality Control /Quality Assurance Services
• Ancillary Services
Potential QC/QA Services Offered Through a Data Management Department include:

- Software and Process Validation
- Quality Assurance Services
- Monitoring
- AE Surveillance Services
Potential Ancillary Services Offered Through a Data Management Department include:

- Medical Vocabulary Application
- Data Screening Paradigms
- Stand Alone Statistical Services
- Clinical Study Report Preparation
When the going gets weird, the weird turn pro.

—Dr. Hunter S. Thompson
Today

What We Learned...

• Cross-train Staff
• Keep Staff Small
• Motivation for Innovation
• Cultivate Alternate Services
• Evolution is Good
• Anticipate More Evolution
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