

**Evolving Roles and Skills in Clinical Data  
Management:**

**Where Did We Come From and  
Where are We Going?**

**C. Michael Bailey**

**Project Manager  
Department of Clinical and Data Management Services  
Biotechnical Services, Inc.**

# **Define Data Management Skill Sets**

**Management**

**Data Support**

**Medical Support**

**Programming Support**

**Validation Support**

**Quality Assurance**

## **Define These Skill Sets...**

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

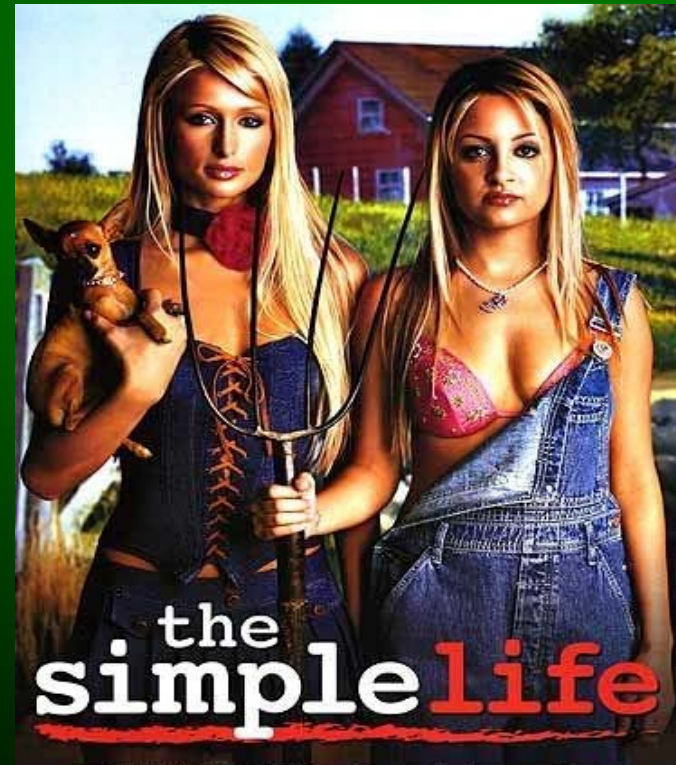
**...using 10 years of clinical data management experience as a case study**

# 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**

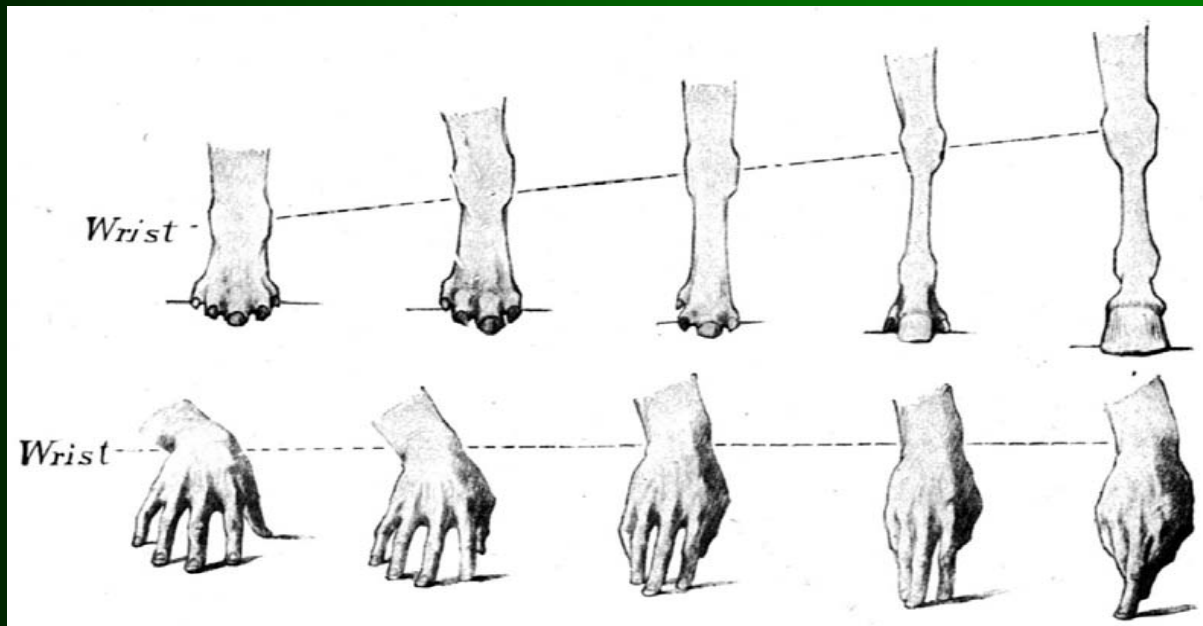
# Early Data Management Processes

- **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 CFR 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**

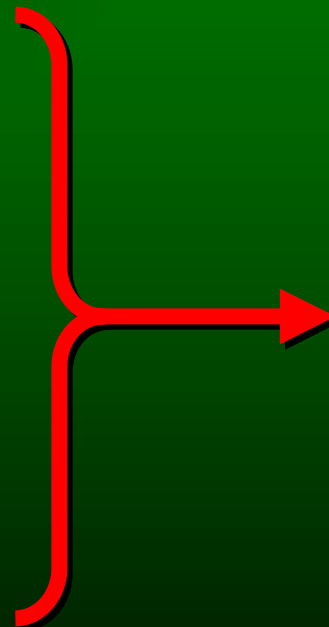
### **Clinical Data Management Staff Expanded—**

- **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**

**Programmatically  
Integrated**

- **21 CFR Part 11 / Validation**

**System &  
Documentation  
were further  
Integrated by...**

## Adaptation & Progress...

***...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:**

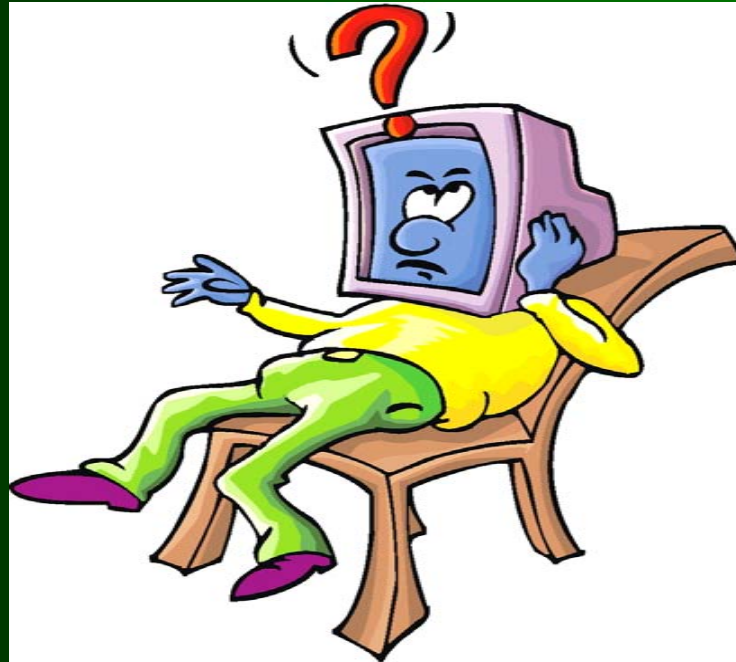
- **Software and Process Validation**
- **Quality Assurance Services**
- **Monitoring**
- **AE Surveillance Services**

**Potential Ancillary Services Offered Through a Data Management Department include:**

- **Medical Vocabulary Application**
- **Data Screening Paradigms**
- **Stand Alone Statistical Services**
- **Clinical Study Report Preparation**



**Today** \_\_\_\_\_



***When the going gets weird, the weird  
turn pro.***

**—Dr. Hunter S. Thompson**

## What We Learned...

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

# **Contact Information**

**C. Michael Bailey**

**Project Manager**

**Clinical and Data Management Services**

**Biotechnical Services, Inc.**

**4610 West Commercial Drive**

**North Little Rock, AR 72116**

**Phone: (501) 758-6290 extension 125**

**FAX: (501) 753-5963**

**Email: [mbaile@biotechnicalservices.com](mailto:mbaile@biotechnicalservices.com)**