

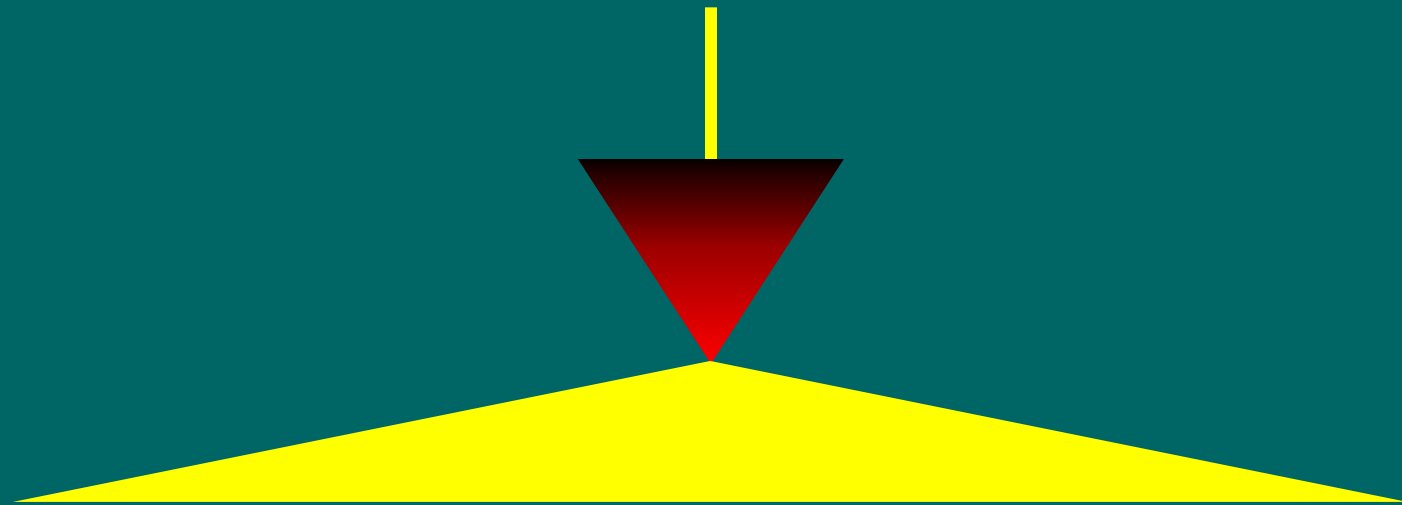
Clinical Data Management Personnel: The Evolution of Roles and Skills in a Small CRO

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**The Evolution of Roles and Skills of
Clinical Data Management Personnel**



**Assembling A Clinical Data Management
Department from Scratch**

From our experiences we should be able to recognize:

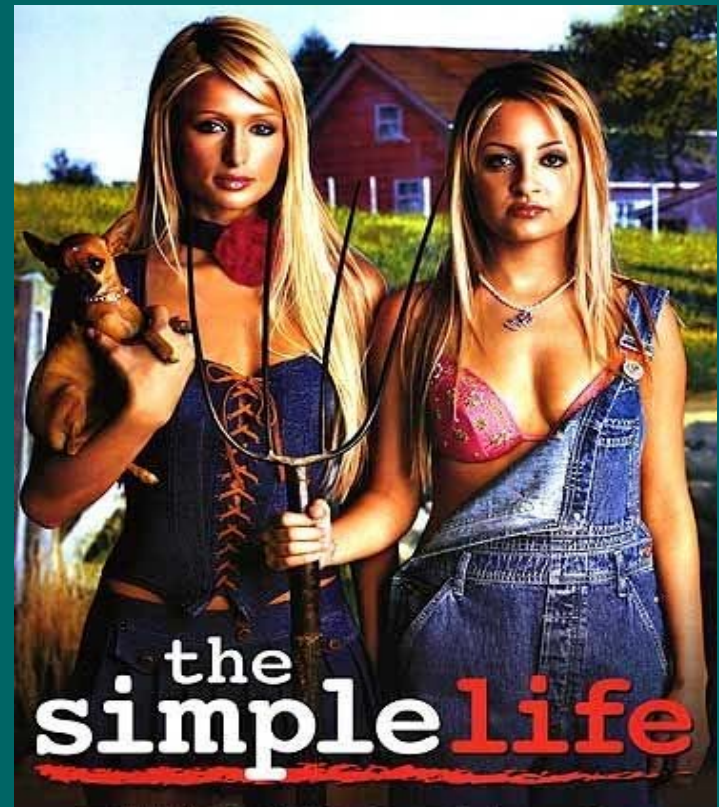
- **A “Subatomic” Structure of a Clinical Data Management Department**
- **Exegeses That Stimulated Staff Expansion**
- **Value (néé *Necessity*) of Cross-training Clinical Data Management Personnel**
- **Potential New Functions for Clinical Data Management and its Personnel**

These Objectives Will be Framed by Our Experiences Over the Past Ten Years...

- **Beginning**
- **Evolution**
- **Adaptation**

How Does A Pharmaceutical CRO find a Home in Little Rock, Arkansas?

By Importing the Talent, of Course



Company Beginnings

- **Established by a Biochemist / Toxicologist with Pharma Experience**
- **Originally Specialized in Regulatory Documentation**
- **Eventually expanded into Quality Assurance and Clinical Data Management**

Clinical Data Management Department

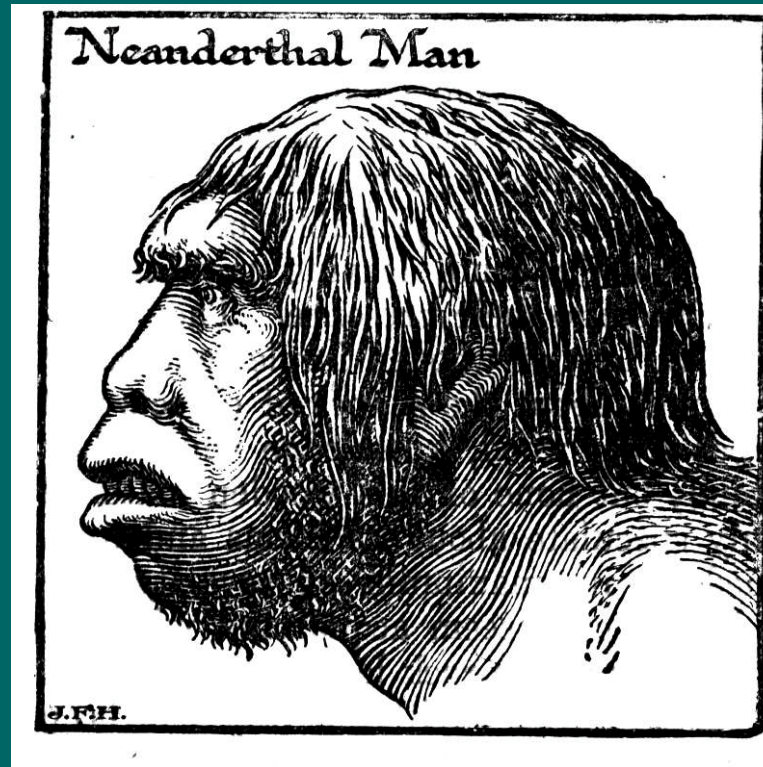
- **Core Personnel Came From Existing Staff**
 - **Biologist / Medical Writer**
 - **Statistician**
- **A Senior Manager was Hired**
- **First Projects were Salvage, Retrospective Efforts...Which led to...**
- **Prospective Studies**

Process...

- **Original Hard Copy and Working Photocopy**
- **Basic Data Review (no specifications)**
- **Manual Data Clarification Forms**
- **Medical & Data Review Performed by Sponsor**
- **Organizational Free-for-All**

Technology...

- **SAS Database Platform**
- **Pre - 21 CFR Part 11 Specifications**
- **Data Entry Through SAS FS Edit**
- **Medical and Therapy Vocabularies in Hard Copy**



It is not necessary to change. Survival is not mandatory...

—W. Edwards Deming

Clinical Data Management Evolution

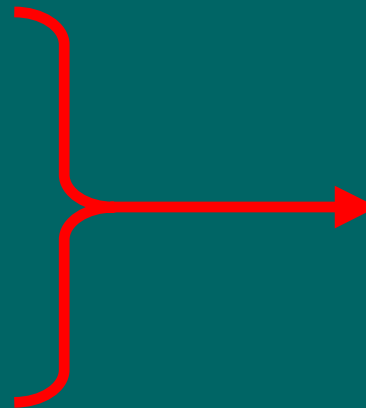
Clinical Data Management Staff Expanded

- Non-Statistician Programmers**
- Medical Personnel**
- Data Personnel**

Clinical Data Management Evolution

Duties Defined and Expanded

- **Project Managers**
- **Data Managers**
- **Medical Managers**
- **Programming**



**Cross
Training**

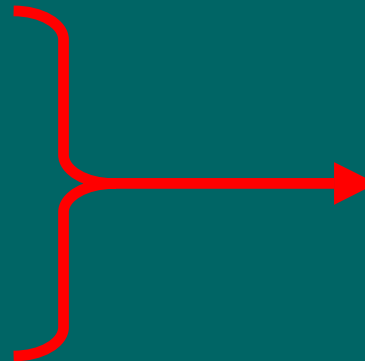
Process ...

- **In-House Medical and Data Review Guidelines Implemented**
- **21 CFR Part 11 Documentation Implemented**
- **Data Edit Catalog Developed**
- **Data Clarification System Implemented**

Technology...

- **Streamlined Programming Processes**

- **CRF Tracking**
- **Entry Screens**
- **DCF System**



Integrated

- **Automated Vocabulary Systems**
- **21 CFR Part 11 / Validation**



Progress has not followed a straight ascending line, but a spiral with rhythms of progress and retrogression, of evolution and dissolution.

—Johannn Wolfgang Von Goethe

Clinical Data Management Adaptation

- **Is Needs-based**
- **Uses Newly Developed Skills Efficiently**
- **Benefits from Cross-Trained Personnel**
- **Provides additional professional opportunities and Department Expansion**

Clinical Data Management Adaptation

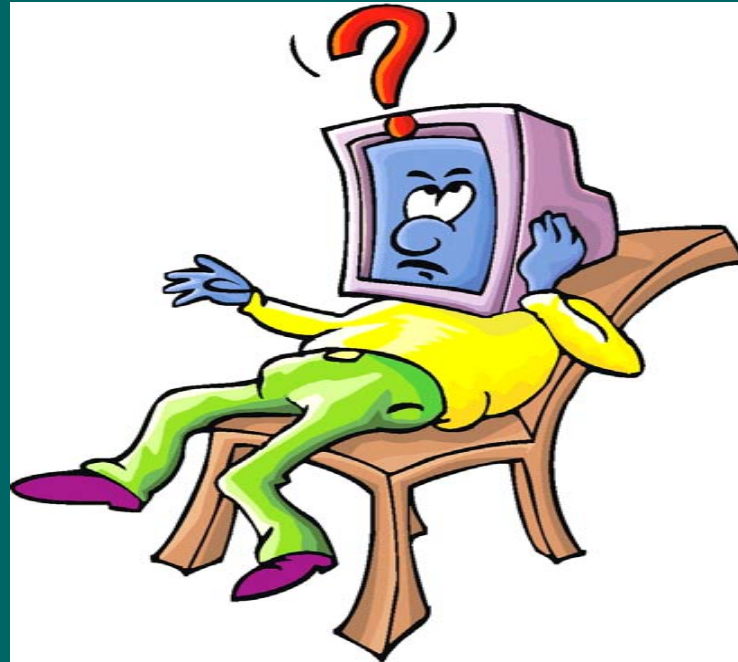
- **QC/QA-related Services**
- **Ancillary Services**

QC/QA Services Derived from Clinical Data Management Include:

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

Ancillary Services Derived from Clinical Data Management Include:

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



Lately it occurs to me what a long, strange trip it's been.

—Jerry Garcia

Final Thoughts...

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

