



***BIOTECHNICAL SERVICES, INC.***

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**The Lexicon—  
One CRO's Experience Using Medical  
Dictionaries  
in Clinical Trial Data Management**

**C. Michael Bailey  
Project Manager  
Department of Clinical Data Management and Statistical Services  
Biotechnical Services, Inc.**

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**Language is not an abstract construction of the learned, or of dictionary makers, but ... has its bases broad and low, close to the ground.**

**—Noah Webster**

**A synonym is a word you use when you can't spell the word you first thought of.**

**— Burt Bacharach**

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- ◆ **Introduction**
  - ◆ **Clinical Data Management Process**
  - ◆ **Evolution of Medical Dictionary Use**
  - ◆ **Dictionaries and Term Assignment**
  - ◆ **Conclusions**

## **Why use a Medical Dictionary?**

**To organize a large amount of clinical data so that common clinical events are grouped together prior to analysis.**

**Or**

**To increase the signal to noise ratio of statistically detectable clinical events.**

# Why use a Medical Dictionary?

**The ultimate goal:**

**To provide meaningful data and analyses  
from which to draw confident conclusions.**

## Data Management

- ◆ **Data Capture**
- ◆ **Data Cleaning**
- ◆ **Data Analyses and Reporting**

## Data Capture

- ◆ **Data Collection**
- ◆ **Data Receipt**
- ◆ **Data Tracking**

## Data Cleaning

- ◆ **Medical and Data Review**
- ◆ **Double Data Entry with Resolution**
- ◆ **Data Screens**



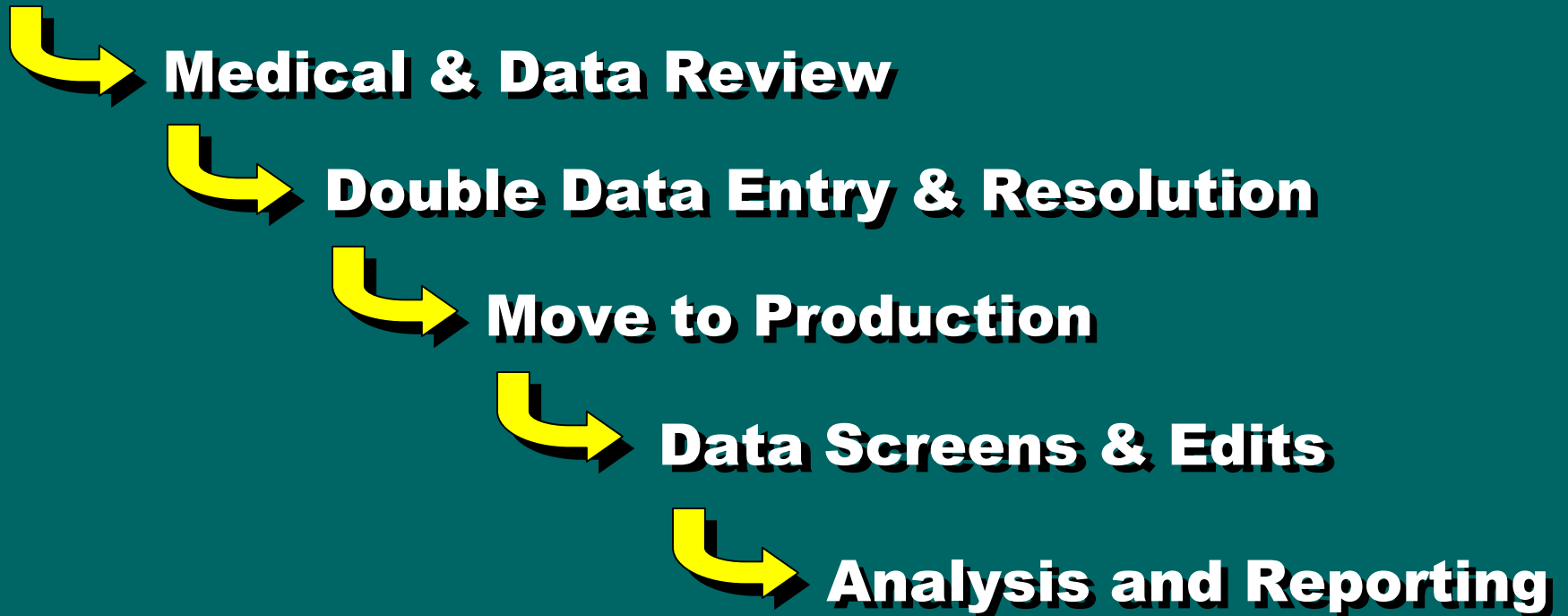
## Data Analysis and Reporting

- ◆ *Ad hoc* Reports
- ◆ Data Listings
- ◆ Summary Tables

# Clinical Data Management Process

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## Receipt & Tracking



# Clinical Data Management Process

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## Data Encoding

Receipt & Tracking

Medical & Data Review

Double Data Entry & Resolution

Move to Production

Data Screens & Edits

Analysis and Reporting

## First Applications

- ◆ **Sponsor specific**
- ◆ **Addressed more than Adverse Experiences**
- ◆ **Hard copy collections**
- ◆ **Terms associated with numeric codes**
- ◆ **Codes manually written on CRFs**

# Evolutionary Exigency I

- ◆ **Hard copy manual searching cumbersome**
- ◆ **Transcribing codes on CRFs error-ridden**



- ◆ **Manual code assignment is time-consuming**

## First Advance

- ◆ **Obtained ASCII files of Dictionaries**
- ◆ **Converted dictionaries to SAS® Datasets**



- ◆ **Providing an interface with existing CDMS**

### **First Advance (continued)**

- ◆ **Built a simple assignment application**
- ◆ **Collapsed identical *verbatim* terms into unique terms**
- ◆ **Compared unique terms to Dictionary LLTs, assigning exact matches**
- ◆ **Automatically wrote code into database file with *verbatim* terms**

## Advantages

- ◆ **Facilitated the coding process by**
  - **Collapsing identical verbatim terms**
  - **Automatically writing to database**
- ◆ **Offered refined term fine-tuning**



## **Evolutionary Exigency II**

- ◆ **Editing codes is labor intensive**
  - **requiring editing each individual record**
  - **time consuming**
  - **error ridden**
  
- ◆ **Using sub-dictionary flags is problematic**

## Second Advance

- ◆ **Remove code fields from datasets**
- ◆ **Program *verbatim*—dictionary term associations into data listing and summary applications**



- ◆ **outputting associated dictionary terms when programs are executed**

## Advantages

- ◆ **Facilitated the coding process by**
  - **editing multiple identical terms once**
  - **producing real-time coding**

## Disadvantage

- ◆ **Loss of term fine tuning**

## Dictionary

- ◆ **Greater Granularity**

**Dictionary with a larger variety of LLTs and Preferred Terms**

- ◆ **Lesser Granularity**

**Dictionary with a restricted variety of LLTs and Preferred Terms**

## Dictionary

### ◆ Greater Granularity

- Provide more LLTs as association choices for *verbatim* terms
- More easily used by non-medical data personnel

## Dictionary

### ◆ Lesser Granularity

- Practically, the Preferred Terms become the LLTs
- Requires medical background or medical terms training (at minimum)

### **Our Experience tells us...**

- ◆ **There exist several adverse experience dictionaries, each with advantages and disadvantages**
- ◆ **All can be assimilated into CDM and problems addressed**
- ◆ **MedDRA is eminent (and that is not a bad thing)**