



BIOTECHNICAL SERVICES, INC.

**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.**

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

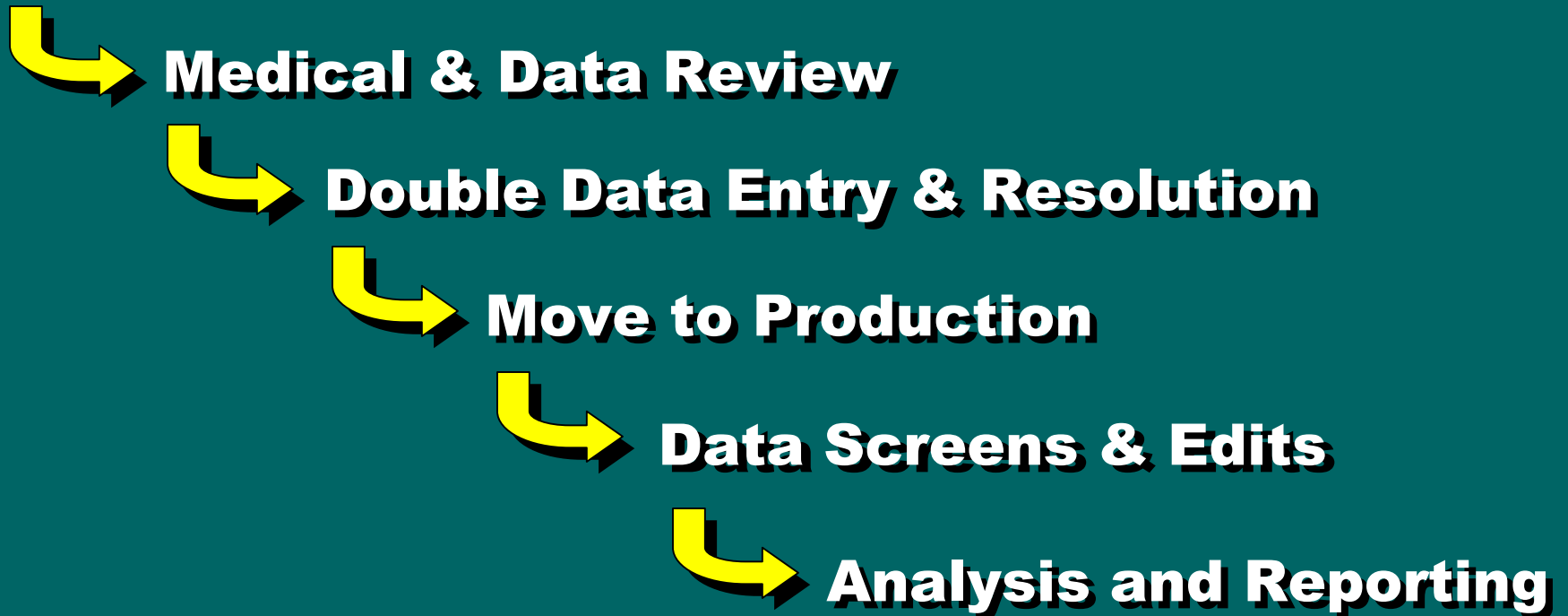
- ◆ **Medical and Data Review**
- ◆ **Double Data Entry with Resolution**
- ◆ **Data Screens**

Data Analysis and Reporting

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

Clinical Data Management Process

Receipt & Tracking



Clinical Data Management Process

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)**