

Nth Analytics

Clinical Biometrics Services

Capabilities Presentation 2006

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Nth Analytics

Services:

- Statistical Analysis Plans (SAP)
- Statistical Analyses
- PK/PD Analysis
- SAS Programming
- Standard reports

Specialties:

- Registered CDISC Solutions Provider
- SAS BI – Enterprise Guide

Nth Analytics

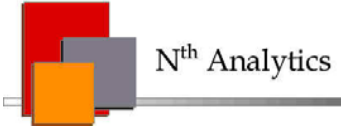
Our expertise:

- We use only senior level personnel
- Average pharmaceutical experience is 10 + years
- State of the art SAS BI Server

Nth Analytics

Recent Projects:

- CDISC SDTM v3.1 analysis files
 - including an automated mapping process and a generic table package
- CDISC v3.1 analysis files (SDTM and ADaM)
 - full table package
- Integrated Legacy database from several studies
 - full table package
- ADDT: automated DEFINE.PDF documentation for eSub SAS transport files



Why CDISC?

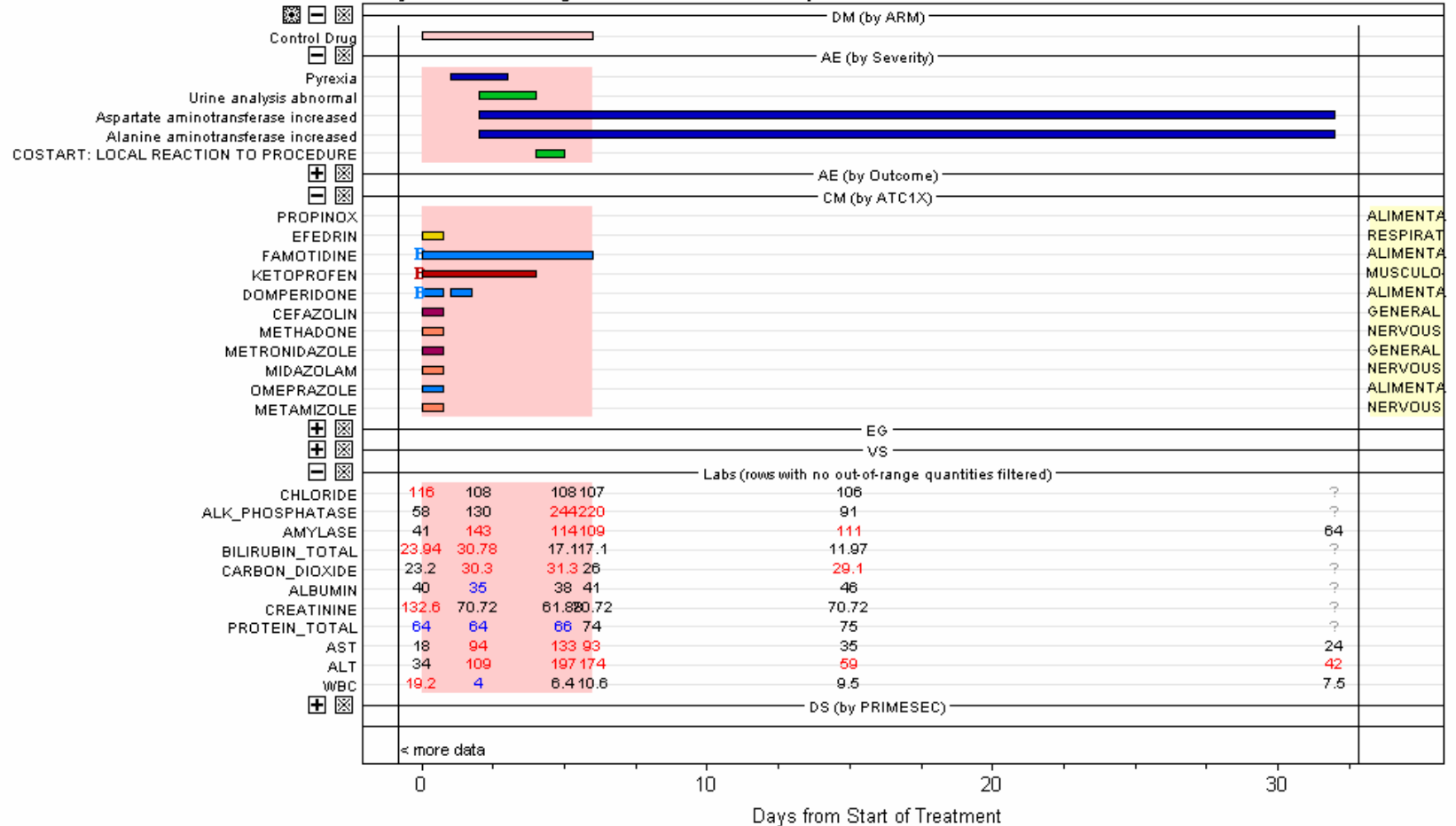
The FDA Without Standards

- Submissions standards vary from sponsor to sponsor and within sponsor
- Interpretations of the guidance vary
- FDA reviewers must use multiple tools
- Lost time spent understanding the format
- Decodes and terminology are not standard
- Some sponsors are still sending hard copies

The FDA With Standards

Wonderdrug NDA - ISS Data

Subject: XXXXXX - Age: 23 - Sex: M - Race: Hispanic

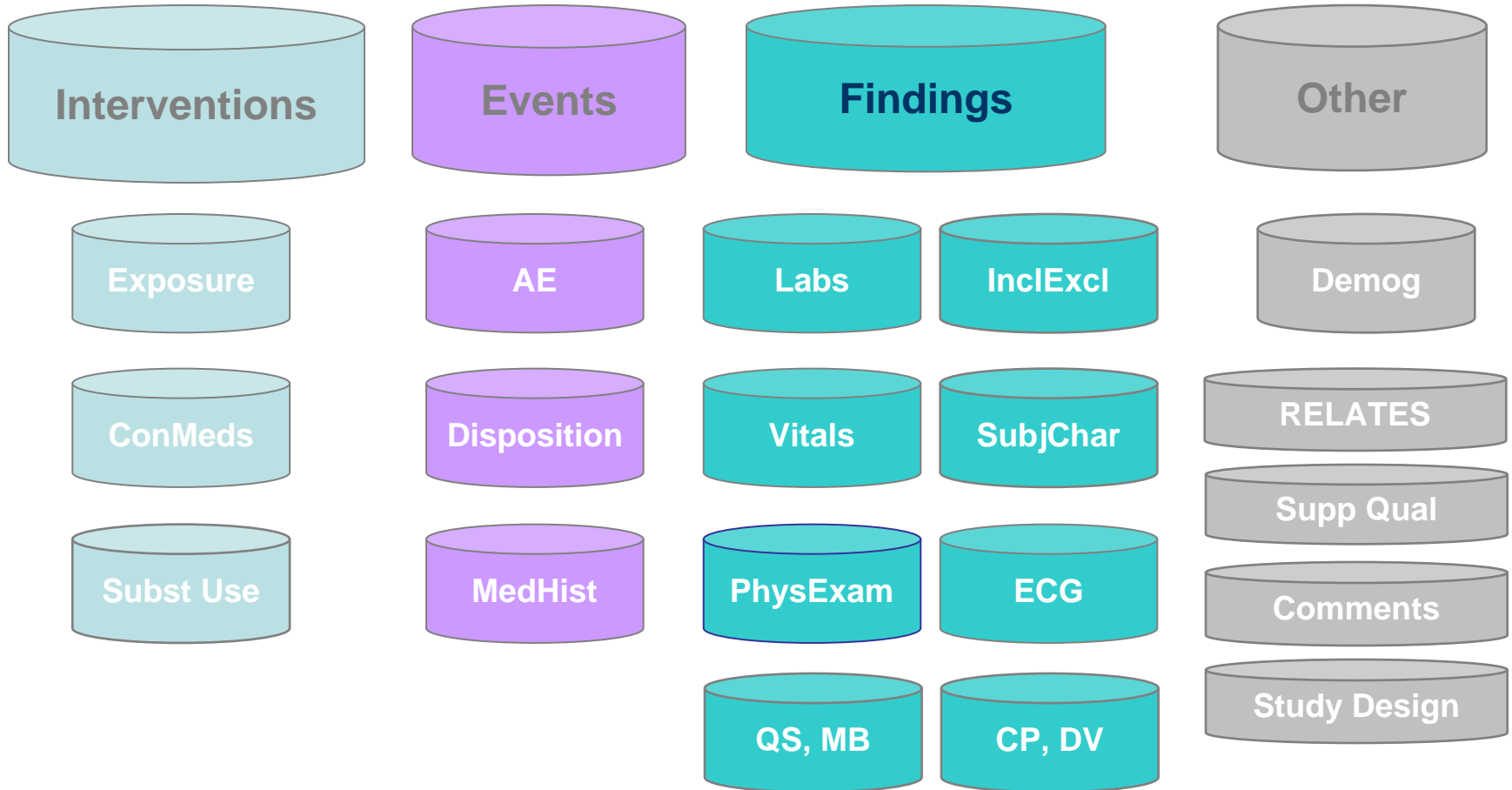


CDISC Background

- Mission: develop and support global platform-independent data standards
- The FDA endorses the CDISC standards
- Goal: A single CDISC standard for the full life-cycle of a clinical trial.
 - Use of the models across the full life-cycle of a clinical trial
 - The CDISC standard will be globally adopted



CDISC SDTM Structure



CDISC Back-end Solution

- Doesn't disturb the design or process of your current studies
- Can be used successfully for a variety of studies designs and formats
- A good solution for legacy data
- No programming added to existing or legacy systems

CDISC Back-end Solution

- Convert the current analysis files to the standard CDISC SDTM format
- Applied to files from any system
- Minimal programming support required for maintenance
- Reasonable cost
- Can be easily outsourced

Our Solution

- Create an ETL Process (extract, transform, load)
 - Define how data fits into the CDISC domains
 - Match data to required, and permitted and expected CDISC data when possible
 - Provide an automated mechanism for specifying the data sources and algorithms
 - Basis for the FDA-mandated “DEFINE.PDF” documentation

Why it Works

- Does not disrupt existing clinical trial systems
- It works for legacy data
- Cost each time is minimized since only the metadata needs to change for each new study
- Table driven metadata provides automatic documentation
- Delay producing subsequent SDTM files is minimized since only new study specific situations cause additional coding

Implementing CDISC Competitive Advantages

- Complies with FDA guidance and standardization goals
- Greatly simplifies Integrated Summary Reports
- One set of Metadata = reduced documentation and maintenance
- Standard macros are developed once and reused

Implementing CDISC Competitive Advantages

- Standard data structure = standard reports
- ADaM files can be generated from SDTM files
- Require CROs to provide data in CDISC format
- Can be used to get your Legacy data into a standard format for cross study analysis and queries.

CDISC – The Fine Points

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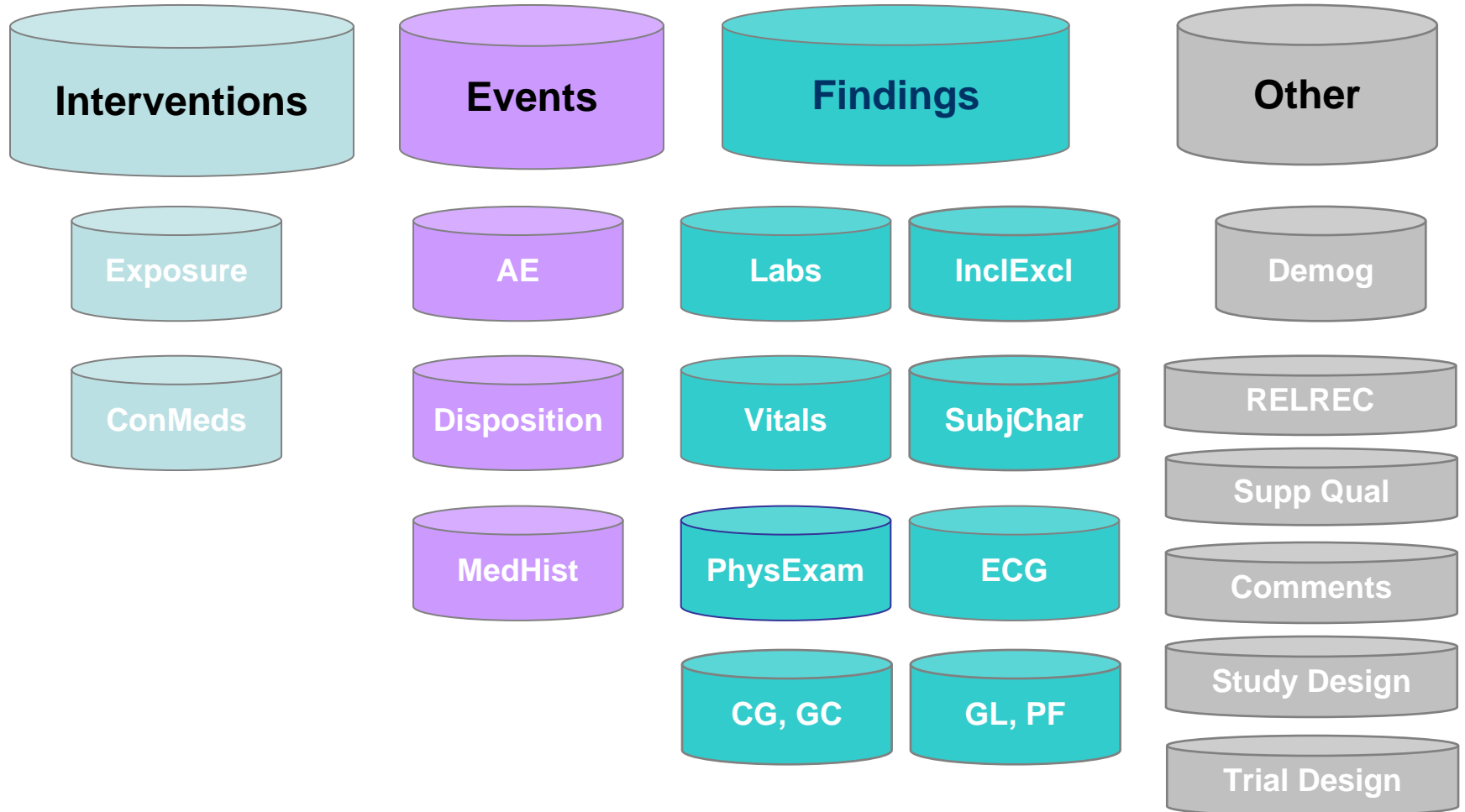
- Some specifics about CDISC formats
- What you really need to know about domains
- What to do with nonstandard data
- **Case Study**

CDISC Solution- Case Study

- We provided standard SDTM and ADaM analysis files in version 3.1
- Created new domains for glucose data
- What you need to know.
 - Understand what goes into the standard domains as well as what does not
 - How to create domains for new data
 - Where to put data that doesn't fit



Sample Study: CDISC Domains



Sample Study-SDTM Data

- Standard Data
- Subject Characteristic Data
- Related Data
- Non-standard variables
- Non-standard domains
- Trial and Study Design Data

Standard Domains

- **AE, DM, EX, CM, MH, LB** etc.
- Map study data to CDISC variables
- CDISC specific data
 - Standard variable names, labels and type
 - Required variables
 - Controlled terms
 - Date formats

Subject Characteristic Data

- SC domain
- Data collected once per subject that does not change during the trial
- Examples:
 - **Pregnancy**
 - **Height**
 - **Weight**
 - **BMI**

Related Data Across Domains

- RELREC domain
- Provides a link between data in two domains
- Example:
 - **CG – Blood Glucose**
 - **AE event**
- 2 records per event in RELREC
 - One links to the AE domain
 - One links to the CG domain

Non-standard Variables

- SUPPQUAL domain
- Captures non-standard data not presently included in the general observation class domains.
- Associates this data with the parent records
- Examples:
 - **Subject flags (ITT, Primary, Treated, Randomized)**
 - Data that doesn't fit into a domain
 - **LB - Clinically significant lab flag**
 - **AE - Treatment emergent AE**
 - **CG - Hypoglycemic event**

Non-standard Domains

- Study specific domains
- Examples:
 - **Blood glucose**
 - **Pulmonary Function tests**
- Identify the classification of the data
- Create new domain code from reserved code list
- Create new domain using appropriate class format
- Use standard variables with new domain code

Trial and Study Design Data

- TA domain – Trial Arms
- TE domain – Trial Elements (Screen, Run-In etc.)
- TV domain – Trial Visits
- SE domain – Subject Elements
- SV domain – Subject Visits

In Summary

- CDISC complies with FDA Guidance
- Can be implemented on the back-end of any system
- Does not disrupt or add code to a current system
- Works well for Legacy data
- Saves analysis time when using a standard set of files
- Mapping from a standard database to CDISC needs to be done once
- **Easily Outsourced**