PhUSE 2014

DH03 - SDTM in Business Intelligence

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Agenda

- Data Warehouse Principles
- Domains as Dimensions
- Using SDTM Domains for Data Pooling
- Birth of a Star Schema
- Populating a Fact Table
- Derived Variables and Analyses – Definers
- Dashboards and Delivery – Consumers
- Dashboards and Delivery – Reconciliation
Background: Increasing Demands on Clinical Development

- Growing volumes of data
- More global in scale
- Increasing regulatory scrutiny
Data Warehouse Principles

Large scale, reporting focused applications:

High volumes of aggregated data from multiple upstream transactional systems

Simplified point in time reporting and historical audit capability

Instant analyses without programming

Integration of varied analysis tools

Dashboards of common reports

Self service reporting
Domains as Dimensions

SDTM as a presentation format is familiar, well understood:
- Domains evolve, but are well defined and rarely updated
- Domains are further extendable with SUPP Domains
- Variables do not change
- Consistent timing variables
- Domains are key controlled
Using SDTM Domains for Data Pooling

SDTM keys allow the warehouse to:
1. Load records incrementally
2. Delete studies with incorrect / changed studyid
3. Handle logical deletions
4. Create Therapeutic Area level star schema
5. Create Compound level star schema
6. Track reconciliation records
7. Track reconciliation comments

..and assist us in up-versioning Medical Dictionary Data
Using SDTM Domains for Data Pooling

1. SDTM
2. Coding
3. Study List
4. OBIEE RPD
5. OBIEE RPD
6. OBIEE
7. OBIEE RPD

Global Clinical & Safety Data Warehouse

ORACLE HEALTH SCIENCES
Birth of a Star Schema

Creation and population of the Fact table:
Complete the star schema joins to add the dimensions
Include keys for all of the satellite tables
Create logical tables to include SUPP domains
Limit columns to derived and key variables only
Avoid destructive changes to ensure access to historical point in time data
Dimensions may evolve, but the fact table and joins do not
Populating a Fact Table

Fact table contains SDTM keys
Outer joins on all satellite tables
User can start at any table, and collect data from any combination
Derived Variables and Analyses - Definers

Definers use the BI interface to design and develop reports:
Definers create analysis variables, analyses, reports, compile dashboards and add writeback sections
Definers can select any variable from any table without joins
Expression builder to create measures and derived variables
Measures can be defined as part of the analysis, without changing the underlying data structures
Writeback can be enabled for comment tracking
Dashboards and Delivery - Consumers

Consumers view, report on, comment on, and export data:
Access dashboards containing multiple analyses
Externally accessible, reports and data available anywhere
Access to dashboards and data is limited by data warehouse role
Use selection prompts to retrieve correct analysis set
Easy to export data to excel, csv, ppt, pdf etc.
Dashboards and Delivery - Consumers

Uses of the warehouse include:

- Responding to regulatory queries
- Cross-study analysis
- Data reconciliation
- Ongoing medical review
- Streamlined statistical analysis for submission
- Modeling of protocol design and trial simulation
- Safety monitoring and signal detection
Dashboards and Delivery - Reconciliation

No Match Records highlighted in Red

Click Update to enter comments

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Find out more!

Contact us

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