Data Integration: SDTM, ADaM and more, approaches to using electronic data at every stage of the drug life-cycle

CDISC DC Implementation Network User Group
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agenda

- CCDA overview
- CCDA concepts and navigation
- data analysis in the drug life-cycle
  - monitoring and reviewing SDTM lab data
  - patient profiles and specific adverse events
  - reviewing ADaM and SDTM consistency
  - looking at adverse events in FAERS data
Commonwealth Clinical Data Analytics (CCDA) overview

Data can be obtained from a range of sources and loaded into CCDA

Data can be manipulated, merged and analyzed through a repeatable and traceable process

Data analyses can be represented in graphs and reports and downloaded for further use
CCDA concept

- “zero footprint” web-based implementation – needs only a standard browser on the user’s computer
- supports rapid incremental development of analyses with high data visibility to help catch errors early
- data in CCDA is accessed and manipulated within an analysis, a series of connected and fully customizable steps
  - each step performs a single action, such as joining two tables, according to specifications that you provide via a user-friendly “step configuration” interface
    - steps are translated into SQL supported by a relational database (Postgres, Oracle)
diagram view of an analysis with a graph
ANALYSIS tab allows you to create new analyses and access existing ones

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Project Name</th>
<th>Create Timestamp</th>
<th>Update Timestamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA and FAERS, CDC/BIRX comparison and reports only</td>
<td>NDA and FAERS for CDC/BIRX comparison and reports only.</td>
<td>DCDBIS Demo</td>
<td>14-Sep-2016 21:38 EDT</td>
<td>14-Sep-2016 21:38 EDT</td>
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<td>NDA and FAERS, CDC/BIRX comparison and reports with multiple drugs</td>
<td>NDA and FAERS for CDC/BIRX comparison and reports with multiple drugs.</td>
<td>DCDBIS Demo</td>
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<td>14-Sep-2016 21:37 EDT</td>
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<tr>
<td>Map of Market</td>
<td>compute map-of-market tables for Signal (created by gordon on 2010-07-09 11:54:20)</td>
<td>Signal Contract</td>
<td>14-Sep-2016 11:56 EDT</td>
<td>14-Sep-2016 11:56 EDT</td>
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<tr>
<td>Demo - Serotonin Syndrome in FAERS</td>
<td>Incidence of Treatment Emergent AEs, linking SDTM AADM V2.</td>
<td>FDA Demo</td>
<td>19-Aug-2016 12:13 EDT</td>
<td>19-Aug-2016 12:13 EDT</td>
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<td>Incidence of Treatment Emergent AEs, linking SDTM AADM V2</td>
<td>Incidence of Treatment Emergent Adverse Events by Treatment Group by Patient for Cardiac Disorder SOC, beta SDTM and AADM V2</td>
<td>FDA Demo</td>
<td>19-Aug-2016 12:13 EDT</td>
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</tr>
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<td>LB analysis from SDTM Setup, er</td>
<td>Copy of LB analysis from SDTM Setup, shows lab results in Multi Time Series Graph for each patient SDTM Setup contains pre-set joins of SDTM tables so all have arm and converts iso dates to a usable format extraneous tables removed from analysis</td>
<td>FDA Clinical, Demo 3</td>
<td>14-Sep-2016 10:26 EDT</td>
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<tr>
<td>LOAD and Transform NEISS dataset</td>
<td>Initial ETL (converting to a similar structure as FAERS)</td>
<td>NEISS-CADES</td>
<td>15-Jul-2016 12:36 EDT</td>
<td>07-Sep-2016 11:49 EDT</td>
</tr>
<tr>
<td>Explore NEISS dataset at 2010-07-14 11:30-43</td>
<td>Compare NEISS reported terms to FAERS</td>
<td>NEISS-CADES</td>
<td>15-Jul-2016 12:36 EDT</td>
<td>07-Sep-2016 11:49 EDT</td>
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DATA EXPLORER tab provides a view of all tables within a folder.
DATA EXPLORER provides statistics for variables including row Count, missing variables, and number of unique values.
DATA EXPLORER allows a quick view into the frequency distribution of variables by table.
and by graph
CCDA login page
ANALYSIS tab allows you to create new analyses
create, name, and describe the analysis
access the new analysis by selecting “Manage Diagram” or “Manage Steps”
choose actions from the palette to begin the analysis
use the access step provides access to the selected LB table
use the subset to select unique values and eliminate duplicates, if desired
import outside data sources, join a custom list of lab tests of interest with clinical data
use the list to monitor lab values for lab tests of interest
export results as database table or as a csv or text delimited file
analyses can be configured to display both multi-patient and single-patient profiles
compare treatment emergent AEs in ADAM and SDTM data for a clinical trial
discrepancy due to treatment emergent AEs being defined by any AE occurring after 1st exposure to drug, irrespective of end of exposure
aggregate AEs based on body system of interest
compare data to clinical study report
step view of analysis with a bar graph
CCDA provides the ability to use outside data sources.
find FAERS reports for drugs of interest
compare FAERS reports for BUPRENORPHINE/NALOXONE and CLONIDINE
questions and discussion