INTERPRETING CDISC ADaM IG THROUGH USERS INTERPRETATION

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Interpreting CDISC ADaM IG through Users Interpretation

Disclaimer

The information contained in this presentation is based on personal research of the author and does not necessarily represent Cytel Inc..
Interpreting CDISC ADaM IG through Users Interpretation

Introduction

- **2004** Statistical Analysis Dataset Model
  General Considerations
- **2008** IG Draft for Public Comment
- **2009** December IG Final
- **9 years later** we have an IG (v1.0), a new model (v2.1), two new models, Validation Checks and a new Pilot

<table>
<thead>
<tr>
<th>Document / Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis Data Model (ADaM), Version 2.1</td>
</tr>
<tr>
<td>Analysis Data Model (ADaM), Implementation Guidance, Version 1.0</td>
</tr>
<tr>
<td>CDISC ADaM Validation Checks, Version 1.2</td>
</tr>
<tr>
<td>Analysis Data Model (ADaM), Examples in commonly used Statistical Analysis Methods</td>
</tr>
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<td>Analysis Data Model (ADaM), Data Structure for Adverse Event Analysis (ADAE), Version 1.0</td>
</tr>
<tr>
<td>The ADaM Basic Data Structure for Time-to-Event Analyses (ADTTE), Version 1.0</td>
</tr>
<tr>
<td>IG compliance update of CDISC-FDA Pilot 1</td>
</tr>
</tbody>
</table>
Interpreting CDISC ADaM IG through Users Interpretation

Introduction

- FDA SDTM based submission in 2010 → 23%
- FDA SDTM based submission in 2011 → 39% and 32% ADaM based
- ADaM is also adopted by the sponsors as a standard regardless of submission
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The Question

Are ADaM IG and all developed models enough?

What is the gray area and where IG leaves more space for interpretations?

How different users (sponsor) have interpreted such a gray area?
Conclusions

- There is still space for further development for the CDISC ADaM team.
- Feedback from users experience will inform the CDISC ADaM team on what needs to be clarified and/or added/changed.
- One idea could be to launch a survey among the CDISC users to see what they would like to see in next IG.
  - SAS Institute use the same approach since 1976 with the SASware Ballot for the release of new versions / new functionalities (http://support.sas.com/community/ballot/).
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Conclusions

- It is the opinion of some users that some rules can be challenged
- Having PARCATx classifying PARAM would be useful when same parameters can be «measured» with different approaches or on different locations
- When AVALC contains categorical results (e.g. a scale) and AVAL contains summary patient information (e.g. Average) then the one-to-one relationship rule does not apply
- Same name, same value, same metadata….but it should be meaningful. E.g. information coming from DS
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Conclusions

- Always check the ‘reviewer preferences’
- Each sponsor should have its own Implementation Guidance and Governance Team
  - Further interpretation of the CDISC IG
  - Identify gray area of ADaM and ‘take a position’
  - Policy for non-standard analysis datasets
Conduct a **systematic review** of what has been «published» so far. It is a common approach used in Medicine (see A gentle introduction to Meta-analysis, PhUSE 2007)

Similar previous published work

- SAS Programmer Resources on the web Experiences
  - Acquired Surfing the Net, PhUSE 2006
- A systematic review of PhUSE, PhUSE 2007
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Materials & Methods

- CDISC papers presented at SAS conferences were selected through Lex Jansen website (lexjansen.com):
  - SAS Global Forum
  - PharmaSUG
  - PhUSE including single day events
  - Other local area SAS user groups

<table>
<thead>
<tr>
<th>CDISC</th>
<th>Clinical</th>
<th>SDTM</th>
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**SAS proceedings: CDISC (427 Papers)**

<table>
<thead>
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<th>SAS Global Forum 2013</th>
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<tbody>
<tr>
<td>The Hash of Hashtags as a &quot;Russian Doll&quot; Structure; An Example with XML Creation</td>
</tr>
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<td>Joseph Hinson</td>
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<td>Keywords: xml</td>
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<td>Pages: 23 Size: 303 KB</td>
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<td>Adding New Rows in the ADaM Basic Data Structure: When and How</td>
</tr>
<tr>
<td>Mario Widel, Sandra Manjoe</td>
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<tr>
<td>Pages: 12 Size: 603 KB</td>
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<tr>
<td>Using the ADaM ADAF Structure for Non-AE Data</td>
</tr>
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<td>Mario Widel, Sandra Manjoe</td>
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<td>Pages: 32 Size: 780 KB</td>
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<tr>
<td>Developing Your SDTM Programming Toolkit</td>
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<td>David Bocca</td>
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<td>Keywords: SDTM, macro, CDISC</td>
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<tr>
<td>Pages: 10 Size: 65 KB</td>
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<td>From SDTM to ADaM</td>
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<td>Bob Lan, Regen Li, Sai Ma, Suwen Li</td>
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<tr>
<td>Pages: 7 Size: 605 KB Download the poster (204 KB)</td>
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<td>A Practical Approach to Creating Define.XML by Using SDTM Specifications and Excel Functions</td>
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<td>Amos Shi</td>
</tr>
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<td>Keywords: xml</td>
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</table>
Interpreting CDISC ADaM IG through Users Interpretation

Materials & Methods

- Additional information from the CDISC interchange conferences (Worldwide, Europe, Regional), discussions/blogs (http://www.cdisc.org/public-discussion-forum)
Interpreting CDISC ADaM IG through Users Interpretation

Materials & Methods

- Linkedin CDISC Groups (CDISC, CDISC ADaM, CDISC Advocates).

- CDISC
  - 4561 members

- CDISC SDTM Experts
  - 1667 members

- CDISC ADaM
  - 507 members

- CDISC Advocates
  - 2119 members

- CDISC Analyst (SDTM)
  - 950 members
# Interpreting CDISC ADaM IG through Users Interpretation

## Materials & Methods

- An excel file tracking all CDISC presentations

<table>
<thead>
<tr>
<th>Title, Author, Company, Conference, Year</th>
<th>My Comment/Notes</th>
<th>Keywords identifying contents</th>
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<tr>
<td>Building Flexible ADaM Analysis Variable Metadata</td>
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<td></td>
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<td>Kin &amp; L Consulting Services, Celgene</td>
<td>Yes</td>
<td>CRO, PHAR, MA</td>
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<td>Traceability</td>
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<td>ADaM Implications from the “CDER Data Standards Common Issues” and SDTM Amendment 1 Documents</td>
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<td>2012 PharmaSUG</td>
<td>CRO, SDSIm pact, SDSIm pact</td>
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<td>CDISC ADaM Application: Does All One-Records-per-Subject Data Belong in ADaM?</td>
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<td></td>
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<td>Octagon</td>
<td>2012 PharmaSUG</td>
<td>CRO, ADaM, BDC, Traceability</td>
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<td>2012 PharmaSUG</td>
<td>CRO, Yes, Macro, YeaL label</td>
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<td>SDTM and ADaM Metadata Playing Together Nicely</td>
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<td>2012 PnUSE CDISC UG</td>
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Quantitative Results

- 482 papers discussing CDISC topics were found
- 102 were focusing on the implementation of ADaM
- ADaM was most discussed at PharmaSUG and PhUSE (with respectively 50% and 28%)
- Authors were prevalent from CROs with 58% of the presentations (Pharma: 32%).

BDS Define.xml Pooling

Governance Validation

Traceability Derived Observations Analysis

Terminate Controlled Terminology

Flags PARAM OpenCDISC SAS Macro Metadata

Applications

ADTTE ADAE ADSL ADLB
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Qualitative Results

- **Generic** topics
  - The obvious rules
  - Traceability
  - non-ADaM Analysis Datasets
  - Analysis-Ready
  - ADaM does not support listings
  - CDER SDS impact
  - Validation

- **ADSL** topics
  - One or several subject-level datasets
  - Use of TRTxxSDT/TRTxxEDT in oncology studies

- **BDS** topics
  - Misuse of Indicator Variables
  - Deriving rows or adding columns
  - PARCATy cannot split PARAM
  - How to populate TRTP/TRTA in BDS
  - ADLB and how to represent / classify AVAL

- **Other** topics
  - Use of ADAE and ADTTE
  - Pooling (ISS/ISE strategy)
  - Governance
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Qualitative Results

The obvious rules

- ADXXX Naming conventions
- SAS XPT v5 rules
- AD split
  - E.g. ADLBH, ADLBC, ADLBU
- Meaningfull AD Label
  - E.g. Efficacy AD containing primary endpoint should be clearly identifiable
- SDTM fragment can be used to create new variable when ADaM rules do not apply
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Qualitative Results

Traceability

Traceability makes possible to understand the full data flow from data collection to reporting

- Traceability in the ADaM Standard; PharmaSUG 2013
- Derivations and traceability in ADaM: examples; CDSIC UG Washington DC; 2012
- Examples of Building Traceability in CDISC ADaM Datasets for FDA Submission; PharmaSUG 2012

- When to use xxSEQ vs SRCDOM/SRCVAR/SRCSEQ

- Keeping SDTM variables

- PARAMTYP and DTYPE in BDS Structure

- Use of ANLxxFL and CRITx

- Metadata, especially when traceability is complex (e.g. complex algorithm)

- Use of Intermediate Analysis Datasets
Qualitative Results

Non-ADaM Analysis Datasets

Not all Analysis Datasets are ADaM

- Common Misunderstanding about ADaM Implementation; PharmaSUG 2010
- Class should be ‘Other’
- Keep SDTM structure
- Key variables from ADSL
- Use ADaM principles when creating new variables
- Use ADaM principles when creating new observations
- Use BDS variables if applicable (e.g. TRTx, CRITx)
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Qualitative Results

Analysis Ready

"Analysis ready" - Considerations, Implementations, and Real World Applications; PharmaSUG 2012
Laboratory Analysis Dataset (ADLB): a real-life experience; CDISC Europe Interchange 2013
Linkedin ADaM Group Discussion http://www.linkedin.com/groupItem?view=&gid=3092582&type=member&item=245409684&qid=379c7b1b-df19-4772-acf1-3d279ef5b245&trk=group_most_popular-0-b-ttl&goback=%2Egmp_3092582&_mSplash=1

As per ADaM IG

Analysis datasets have a structure and content that allows statistical analysis to be performed with minimal programming

→ one-proc-away

- Output programs should only focus on selecting (and extracting) the statistical models and «eventually» improving the standard statistical outputs template
- It is preferable to have complex derivation in the derived (and fully validated) analysis datasets
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Qualitative Results

Analysis Ready (cont.)

- Complex derivations for exposure

ADEXSUM derived from ADEX

<table>
<thead>
<tr>
<th>SITEID</th>
<th>SUBJID</th>
<th>PARAMCD</th>
<th>PARAM</th>
<th>AVAL</th>
<th>AVALCAT1</th>
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<td>0004</td>
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<td>Nr. of Administrations</td>
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<tr>
<td>0102</td>
<td>0004</td>
<td>OVERD</td>
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<tr>
<td>0102</td>
<td>0004</td>
<td>RDI</td>
<td>Relative Dose Intensity (%)</td>
<td>123.52941176</td>
<td>&gt;110%</td>
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<tr>
<td>0102</td>
<td>0004</td>
<td>TDUR</td>
<td>Treatment Duration (months)</td>
<td>1.6755646817</td>
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</table>

Table 15.3.15.1 Treatment Exposure - Safety Analysis Set

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Placebo (N=50)</th>
<th>75 mg q3w + SoC (N=58)</th>
<th>150 mg q3w + SoC (N=50)</th>
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<tbody>
<tr>
<td>Last initiated administration (Number of adm.)</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Min</td>
<td>4.0</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Median</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Q3</td>
<td>9.0</td>
<td>8.0</td>
<td>10.0</td>
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<tr>
<td>Max</td>
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<td>Relative Dose Intensity (%)</td>
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<td>&lt;=75%</td>
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<tr>
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<tr>
<td>&gt;90%&lt;=110%</td>
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<td></td>
</tr>
</tbody>
</table>

Look-up Dataset supporting Outputs Production
Interpreting CDISC ADaM IG through Users Interpretation

Qualitative Results

Validation

- SDTM, ADaM and define.xml with OpenCDISC; PharmaSUG 2013
- Interpreting ADaM standards with OpenCDISC; PhUSE 2012

- OpenCDISC is commonly accepted
- Opportunity for Improvement is on the tool outputs
  - That’s why some companies have also developed their own internal tool
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Qualitative Results

In some instancies when validation rules fail IG might require revisions

Character Tests with AVAL/AVALC and deriving rows

Common Misunderstanding about ADaM Implementation; PharmaSUG 2010

<table>
<thead>
<tr>
<th>AVISIT</th>
<th>PARAMCD</th>
<th>QSORRES</th>
<th>QSSTRESP</th>
<th>QSSTRESPN</th>
<th>AVAL</th>
<th>AVALC</th>
<th>DTYPE</th>
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<tbody>
<tr>
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<td>QS1</td>
<td>VERY BAD</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>VERY BAD</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>QS1</td>
<td>BAD</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>BAD</td>
<td></td>
</tr>
<tr>
<td>Week 12</td>
<td>QS1</td>
<td>GOOD</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<td></td>
<td>2.333</td>
<td></td>
<td>AVERAGE</td>
<td></td>
</tr>
</tbody>
</table>

Same name, Same Value, Same Metadata.....but it should be meaningful

→ «End of Study Reason» in ADSL, ESREAS or DSDECOD?
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Qualitative Results

ADaM does not support listings

- An Evaluation of the ADaM Implementation Guide v1.0 and the Analysis Data Model v2.1; PhUSE 2009
- Considerations for CSR Output Production from ADaM Datasets; PhUSE 2012

- The focus of CDISC as well as ADaM is submission
- A lot of derivations are also required for listings production …… indicating that such derivations should be done by using ADs
- «Derivations» can then be removed if ADs are part of submission
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Qualitative Results

CDER Common SDS Issues Document

- ADaM Implications from the “CDER Data Standards Common Issues” and SDTM Amendment 1 Documents; PharmaSUG 2012

- USUBJID consistency

- Linear CDISC Implementation is suggested

- ADaM should not rely on SDTM derived variables (e.g. flags)

- Do not forget SUPPQUALs

- When submitted to FDA ADaM should at the minimum support key analysis
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Qualitative Results

ADSL - One or several subject-level datasets

- CDISC ADaM Application: Does All One-Record-per-Subject Data Belong in ADSL?; PharmaSUG 2012
- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- ADaM on a Diet: Preventing Wide and Heavy Analysis Datasets; PhUSE 2011

- ADSL core information driven by the SAP
- Other ADSL-like can be added e.g. ADBASE
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Qualitative Results

TRTxxSDT/TRTxxEDT vs TRT01P: The Oncology fight for mapping cycles date information

- [Linkedin ADaM Group Discussion http://www.linkedin.com/groupItem?view=&gid=3092582&type=member&item=228552283&qid=2742e47ed7cd-44a5-9fc6-083901aa2f76&trk=group_items_see_more-0-b-ttl&_mSplash=1]

- Cycle ≠ Period
- Use exposure analysis dataset
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Qualitative Results

BDS - PARCATy cannot split PARAM

- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- ADaM Implementation Guide Status Update; CDISC UG Atlantic 2013

PARCATy can be not used as a qualifier of PARAM

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>PARCAT1</th>
<th>PARAMN</th>
<th>PARAM</th>
<th>AVALC</th>
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<tbody>
<tr>
<td>01010001</td>
<td>Investigator</td>
<td>1</td>
<td>Best Overall Response</td>
<td>SD</td>
</tr>
<tr>
<td>01010001</td>
<td>Reviewer</td>
<td>1</td>
<td>Best Overall Response</td>
<td>PR</td>
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</table>

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>PARAMN</th>
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<th>AVALC</th>
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<tbody>
<tr>
<td>01010001</td>
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<td>Best Overall Response (Investigator)</td>
<td>SD</td>
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<tr>
<td>01010001</td>
<td>2</td>
<td>Best Overall Response (Reviewer)</td>
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</table>

?????? Can the CDISC ADaM team change this rule ?????
Qualitative Results

BDS - Misuse of Indicator Variables and Criteria Variables

- Common Misunderstanding about ADaM Implementation; PharmaSUG 2012
- Flags for Facilitating Statistical Analysis Using CDISC Analysis Data Model; PharmaSUG 2013

A significant lab value

- SIGF = Y

A baseline observation

- CRITFL = Y
- PREFL = Y

SIGF = Y

AVALCAT1N = Significant

PREFL = Y
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Qualitative Results

BDS - Deriving Rows or Adding Columns?

- Designing and Tuning ADaM Datasets; PharmaSUG 2013
- Common Misunderstanding about ADaM Implementation; PharmaSUG 2012
- Adding new Rows in the ADaM Basic Data Structure. When and How; SAS Global Forum 2013
- Derived observations and associated variables in ADaM datasets; PharmaSUG 2013
- Section 4.2 of IG illustrates the 6 rules for the creation of rows vs columns
- All rules except one, require the creation of a new records
  - «A parameter invariant function of AVAL and BASE on the same row that does not involve a transformation of BASE should be added as a new column»
  - Adding a new column is restricted to available BDS variables
    - a.g. CHG=AVAL-BASE
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Qualitative Results

BDS - Deriving Rows or Adding Columns? (cont.)

- E.g. how to identify the worst post baseline observation (minimum)

<table>
<thead>
<tr>
<th>USUBJID</th>
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<th>WORST</th>
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<td>80</td>
<td>75</td>
</tr>
<tr>
<td>01010001</td>
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<td>XXXXX</td>
<td>78</td>
<td>75</td>
</tr>
<tr>
<td>01010001</td>
<td>Week 3</td>
<td>XXXXX</td>
<td>75</td>
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- IG section 4.5.3 Identification of Post-Baseline Conceptual Timepoint Rows

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<th>AVISIT</th>
<th>PARAM</th>
<th>AVAL</th>
<th>DTYPE</th>
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<td>Week 1</td>
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<td>80</td>
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</tr>
<tr>
<td>01010001</td>
<td>Week 2</td>
<td>Week 2</td>
<td>XXXXX</td>
<td>78</td>
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</tr>
<tr>
<td>01010001</td>
<td>Week 3</td>
<td>Week 3</td>
<td>XXXXX</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>01010001</td>
<td>Post-Baseline Minimum</td>
<td>XXXXX</td>
<td>75</td>
<td>MINIMUM</td>
<td></td>
</tr>
</tbody>
</table>

→ Or flag worst post-baseline record (ANL01FL=Y)
BDS – Mixed Questions

How to populate TRTP and TRTA in BDS

TRTA is a record-level identifier that represents the actual treatment attributed to a record for analysis purposes. TRTA indicates how treatment varies by record within a subject and enables analysis of crossover and other multi-period designs. TRTxxA (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context. TRTA is required when there is an analysis of data as treated and at least one subject has any data associated with a treatment other than the planned treatment.

ADLB and Outputs Production

- Producing Clinical Laboratory Shift Tables From ADaM Data; PharmaSUG 2011
- Using the ADaM ADAE Structure for Non-AE Data; SAS Global Forum 2013
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Qualitative Results

Pooling: ISS/ISE Strategy

- Approaches to Creating ADaM Subject-Level Analysis Datasets (ADSL) for Integrated Analyses; PhUSE 2012
- ADaM or SDTM? A Comparison of Pooling Strategies for Integrated Analyses in the Age of CDISC; PhUSE 2012
- ADaM in a Pool! A Concept on how to Create Integrated ADaM Datasets; PhUSE 2012
- ADaM Implications from the “CDER Data Standards Common Issues” and SDTM Amendment 1 Documents; PharmaSUG 2012
- Strategies for Implementing SDTM and ADaM Standards; PharmaSUG 2005

- An hot topic fearly supported by the IG
- Pooling in SDTM or in ADaM?
- An ADaM sub-team is working on developping a process
Interpreting CDISC ADaM IG through Users Interpretation

Qualitative Results

Implementing ADaM in your Organization, Governance and CRO Surveillance

- Defining the Governance and Process of Implementing ADaM across an Organization; PhUSE 2011
- The 5 Biggest Challenges of ADaM; NESUG 2010

- «Start small and build iteratively different levels of standards and refining the standards and process along the way»
  - Make your own interpretation and standardise it (Sponsor IG)
  - Develop and manage your standards (governance)
  - Support your team

- Having in place the sponsor’s IG and standards will set clear expectations on what and how CRO will deliver
Interpreting CDISC ADaM IG through Users Interpretation

Conclusions

- There is still space for further development for the CDISC ADaM team.
- Feedback from users experience will inform the CDISC ADaM team on what needs to be clarified and/or added/changed.
- One idea could be to launch a survey among the CDISC users to see what they would like to see in next IG.
  - SAS Institute use the same approach since 1976 with the SASware Ballot for the release of new versions / new functionalities (http://support.sas.com/community/ballot/).
Interpreting CDISC ADaM IG through Users Interpretation

Conclusions

- It is the opinion of some users that some rules can be challenged
  - Having PARCATx classifying PARAM would be useful when same parameters can be «measured» with different approaches or on different locations
  - When AVALC contains categorical results (e.g. a scale) and AVAL contains summary patient information (e.g. Average) then the one-to-one relationship rule does not apply
  - Same name, same value, same metadata….but it should be meaningful. E.g. information coming from DS
Conclusions

- Always check the ‘reviewer preferences’
- Each sponsor should have its own Implementation Guidance and Governance Team
  - Further interpretation of the CDISC IG
  - Identify gray area of ADaM and ‘take a position’
  - Policy for non-standard analysis datasets
Questions

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