CDASH

What’s New and What’s Ahead
12 May 2011

Prepared and presented by the CDASH Leadership Team
Agenda

- What’s new in CDASH V1.1
- What’s ahead in 2011
WHAT’S NEW IN CDASH V1.1
## V1.0 Domain Tables

<table>
<thead>
<tr>
<th>Data Collection Field</th>
<th>Variable Name (CDASH variable name shaded)</th>
<th>Definition</th>
<th>Case Report Form Completion Instruction</th>
<th>Additional Information for Sponsors</th>
<th>CRASH Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Age</td>
<td>AGE</td>
<td>Numeric age of subject.</td>
<td>Record age of the subject</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>3 Age Units</td>
<td>AGEU</td>
<td>Those units of time that are routinely used to express the age of a person (QNC) (AGEU) (see Section 2.2)</td>
<td>Record the appropriate age unit (e.g., years, months, weeks, etc.).</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>41 Today’s date</td>
<td>DMDAI</td>
<td>Date of collection.</td>
<td>The date of collection may be derived from the date of visit and if so, a separate date field is not needed.</td>
<td></td>
<td>Recommended: Conditional</td>
</tr>
<tr>
<td>5 Sex</td>
<td>SEX</td>
<td>The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female, the distinguishing peculiarity of male or female (NCI – CDISC Definitions). (SEX) (see Section 2.2)</td>
<td>Record the appropriate sex (e.g., female, male)</td>
<td></td>
<td>Highly Recommended</td>
</tr>
</tbody>
</table>

- Replaced “Data Collection Field” with CRF Labels: Question Text, Prompt
- CRF Labels are now part of conformance
# V1.1 Domain Tables

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question Text</td>
<td>Prompt</td>
<td>SDTM or CDASH Variable Name</td>
<td>BRIDG</td>
<td>Definition</td>
<td>CRF Completion Instructions</td>
<td>Information for Sponsors</td>
<td>Core</td>
</tr>
</tbody>
</table>

- **Question Text**
  - Contains the full question text for the data collection field.
### V1.1 Domain Tables

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<tr>
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</table>

- **Prompt**
  - Contains the short prompt for the data collection field; could be used as the CRF label

Either Question Text or Prompt can be used on the CRFs.
# SDTMIG Variable Name OR CDASH Variable Name

- Lists the SDTMIG variable name defined in the SDTMIG when the data collected can be placed directly into the SDTMIG variable with no transformation.

- Shaded variable names are CDASH fields and are used when the data collected will either not be part of a submission dataset or when the data collected must be transformed or mapped before placing in a SDTMIG variable
## V1.1 Domain Tables

<table>
<thead>
<tr>
<th></th>
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</table>

**BRIDG**

- This column contains the BRIDG Release 3.0.3 classification. This information is included to provide a general idea of how the CDASH variable maps to BRIDG.
Why BRIDG Classifications?

• The Biomedical Research Integrated Domain Group (BRIDG) Model is a domain analysis model representing protocol-driven biomedical/clinical research.

• Provides the basis for harmonization among standards within the clinical research domain and between biomedical/clinical research and healthcare.

• Included in CDASH to show how CDASH variables link to the BRIDG Model

• Refer to http://www.cdisc.org/bridg for more information on the BRIDG model.
**DEFINITION**

- Describes the purpose of the data collection field. The text may or may not mirror the text in the SDTMIG (in the “Variable Label” or “CDISC Notes” columns). Where applicable CRF text examples that might be used for labels containing <prompt> are presented in italics.

- If there is controlled terminology associated with this field, the codelist name will be given in this column (e.g., {NY}).
### V1.1 Domain Tables

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- **CRF Completion Instructions**
  - Contains standard instructions for the clinical site on how to enter collected information on the CRF
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- **Information for Sponsors**
  - Contains further information, such as rationale and implementation instructions, on how to implement the CRF data collection fields
V1.1 Domain Tables

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- **Core**
  
  Contains the CDASH core designations for basic data collection fields (see Section 4.3 for definitions of core designations)
Additional Implementation Help

• Collection of dates
  ▪ Refined recommendation regarding an unambiguous date
  ▪ Added information about collecting dates needed for relative timing variables in SDTM
    • Relative timing variables are derived date/time values that are then used for comparison against CRF collected date/time information for the determination of when an event or intervention occurred in relation to that derived timepoint.
    • Relation to Reference Period: (BEFORE, DURING, AFTER) or
    • Relation to anchor (ONGOING, COINCIDENT)
Relative Timing Variables

- **Study Reference Period**
  - RFSTDTC (first dosing date)
  - RFENDTC (last dosing date)

- **CMPRIOR = "Y"**
  - (to informed consent, no start date captured, no end date captured)

- **VISDAT**
  - ("Screening Visit" date)

- **CMSTDAT**
  - (Commenced start date)

- **CMENDAT**
  - (Commenced end date)

- **CMONGO = "Y"**
  - (as of last patient contact, no end date captured)

- **VISDAT**
  - ("Follow-up Visit" date)

- **LAST PATIENT CONTACT**

End date
Normalized vs. De-normalized

• Section 4.4
  Normalized = “Long and Skinny”: one record per test
  De-normalized = “Wide”: one record per assessment with a 1:1 database question: CRF field ratio

  ▪ CDASH presents FINDINGS class domains typically using a normalized structure similar to SDTM.
  ▪ If you choose to build de-normalized, utilize CDISC controlled terminology and/or SDTMIG for variable naming conventions
    Example included in DA
Conformance to CDASH

- Vendors and other CDASH users wanted to be able to evaluate whether or not they are “conformant”
- No criteria for conformance in V1.0
- Conformance in CDASH described in two levels
  - V1.1 – describes conformance at the CRF level
Conformance Rules

• Conformance is evaluated at the individual CRF level means:
  
  ▪ All Highly Recommended and applicable Recommended/Conditional are present in the CRF.
  ▪ All code lists displayed in the CRF use or map to current published CDISC Controlled Terminology. Subsets of Controlled Terminology can be used. See Appendix A.
  ▪ The implementation follows the Best Practice recommendations in Section 3.4 of CDASH v1.1.
  ▪ CDASH Question Text or Prompt is used as much as reasonably possible. Permissible deviations and exceptions are discussed in Section 1.3. Semantic consistency is key when deviations are necessary.

• Sponsors need to determine what additional data fields to add to address study-specific and therapeutic area requirements, and applicable regulatory and business practices.
New and Updated Fields

- A few new data collection fields
  - SPONSOR – optional common identifier
  - VISENDAT – optional common timing variable
  - AEOCCUR, CMOCCUR – optional domain variable
  - SCYN, EXYN, MHYN – optional domain variables
  - DAPERF – optional domain variable
- A few changes, clarifications and additions:
  - SITENO removed as a result in a change in the definition of this field in the SDTMIG
  - EXVOLT/EXVOLTU deprecated in favor of SDTMIG EXVAMT/EXVAMTU
New Appendices

- Appendix E – variable naming fragments that are unique to CDASH
- Appendix G – changes from V1.0 to V1.1
### Appendix E: CDASH Variable Naming Fragments

This list of naming conventions that are specific to CDASH has been included as an aid to implementers. Refer to the SDTMIG for additional variable naming fragments.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>DAT</em></td>
<td>This is a generic date field that can be implemented in a system that will store partial dates. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>YR</em></td>
<td>This is a year field that can be implemented in a system that will not store partial dates, so that only the portion of the date that is available is recorded in the database. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>MO</em></td>
<td>This is a month field that can be implemented in a system that will not store partial dates, so that only the portion of the date that is available is recorded in the database. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>DY</em></td>
<td>This is a day field that can be implemented in a system that will not store partial dates, so that only the portion of the date that is available is recorded in the database. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>TIM</em></td>
<td>This is a generic time field. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>NY</em></td>
<td>This is a field that can be used in any CRF to indicate whether or not there is data to record. Used primarily as a data cleaning field. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
<tr>
<td><em>PERF</em></td>
<td>This field is used to capture a response to whether or not a planned measurement, test or observation was performed. The -- should be replaced with the domain code for the CRF or data being collected.</td>
</tr>
</tbody>
</table>
## Appendix G

### 7.7 Appendix G: Changes from V1.0 to V1.1

The following table lists the major changes from CDASH V1.0 to v1.1.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Type</th>
<th>Section</th>
<th>Domain</th>
<th>Variable</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor</td>
<td>Consistency</td>
<td>All</td>
<td>All</td>
<td>NA</td>
<td>“Start” date used instead of “onset” date for consistency throughout CDASH v1.1.</td>
</tr>
<tr>
<td>Minor</td>
<td>Consistency</td>
<td>All</td>
<td>All</td>
<td>NA</td>
<td>“Study” used in place of “trial” in most places for consistency. Where “trial” is used in a quote or reference to a published title, it was not changed.</td>
</tr>
<tr>
<td>Major</td>
<td>Addition</td>
<td>All</td>
<td>All</td>
<td>NA</td>
<td>Question Text and Prompt text replaced Data Collection Field in all domain tables.</td>
</tr>
<tr>
<td>Minor</td>
<td>Clarification</td>
<td>All</td>
<td>All</td>
<td>NA</td>
<td>Column heading changed to SDIM or CDASH Variable Name</td>
</tr>
<tr>
<td>Major</td>
<td>Addition</td>
<td>All</td>
<td>All</td>
<td>NA</td>
<td>BRIDG Classifications added to all domain tables.</td>
</tr>
<tr>
<td>Minor</td>
<td>Clarification</td>
<td>1.3</td>
<td>All</td>
<td>NA</td>
<td>The term “Sample” has been replaced with “specimen” to be consistent with the SDIM and the LAB standard.</td>
</tr>
<tr>
<td>Minor</td>
<td>Clarification</td>
<td>3.3</td>
<td>Best Practices</td>
<td>NA</td>
<td>Replaced CRF workflow diagram with a simplified version.</td>
</tr>
<tr>
<td>Minor</td>
<td>Deletion</td>
<td>3.4</td>
<td>Best Practices</td>
<td>CRF Type</td>
<td>Removed this column because all the recommendations refer to both paper and electronic CRFs.</td>
</tr>
<tr>
<td>Major</td>
<td>Clarification</td>
<td>New section</td>
<td>NA</td>
<td>NA</td>
<td>Added a new section 5.1 De-normalized vs. Normalized data structures. Added to provide more information for implementers.</td>
</tr>
<tr>
<td>Major</td>
<td>Addition</td>
<td>6.1</td>
<td>Common Identifiers</td>
<td>SPONSOR</td>
<td>An optional sponsor identifier variable used with external data warehouses (e.g. Janus), electronic medical records and/or other partnerships for sharing data.</td>
</tr>
<tr>
<td>Major</td>
<td>Deprecation</td>
<td>6.1</td>
<td>Common Identifiers</td>
<td>SITENO</td>
<td>SITENO has been deprecated in CDASH v1.1 and should no longer be used, because SDIM IG V3.1.2 has</td>
</tr>
</tbody>
</table>
WHAT’S AHEAD IN 2011
CDASH Project Plan 2011

Q1 2011

- CDASH ODM & CRFs
- E2B Metadata Tables & DILI
- DEVICES - 5 Domains
- Alzheimer's CDASH UG
- PK CRFs
- QS & UG
- CDASH UG

Q2 2011

- ICV
- ????
- ICV
- ICV

Q3 2011

- ICV
- Publish

Q4 2011

- CDASH ODM & CRFs
- E2B Metadata Tables & DILI
- DEVICES - 5 Domains
- Alzheimer's CDASH UG
- PK CRFs
- QS & UG
- CDASH UG
**CDASH project Plan 2011**

- **CDASH ODM & CRFs**
  - Sub-team reinstated in February 2010
  - Incorporate the changes made in CDASH v1.1
  - Ongoing

- **E2B Metadata tables and DILI**
  - CDASH E2B tables almost ready for team review
  - Potential new domains: PARENT, FAMILY, DEATH
    - PARENT & FAMILY are non-subject data domains
  - Team has Drug Safety input from EU members
  - DILI implementation guide to be developed
    - Sub-team has begun work
    - Call for CRFs issued, to be followed by CRF analysis
CDASH project Plan 2011

• Devices
  ▪ Five draft SDTMIG domains to be reviewed by the CDASH team
    • DEVICE PROPERTIES, DEVICE ID, DEVICE TRACKING, DEVICE MALFUNCTIONS, DEVICE linking
    • Public review July 2011

• Alzheimer’s CDASH User Guide
  ▪ Alzheimer’s SDTMIG published for review
    • Review period ended February 2011
  ▪ Terminology sub-team is working on controlled terminology
  ▪ CDASH activity is ongoing, and will await completion of Terminology development
CDASH project Plan 2011

- Pharmacokinetic CRFs
  - CDASH work will begin later in 2011

- Questionnaires and User Guide
  - CDASH sub-team proposed to investigate the potential scope of standardization
  - Terminology sub-team is working on controlled terminology
  - CDASH activity will await completion of Terminology development
3.2 Adverse Events (AE)

These recommendations are for non-solicited or pre-specified adverse events. As with all the data collection variables recommended in CDASH Standard Version 1.0, it is assumed that sponsors will add other data variables as needed to meet protocol-specific and other data collection requirements (e.g., TA-specific data elements and others as required per protocol, business practice and operating procedures). Sponsors should define the appropriate collection period for adverse events. All CDASH variables and all Required and Expected SDTMIG variables are included in the mapping table except the common identifier variables. See section 3.1 for details on common identifier variables.

3.2.1 CDASH to SDTM Mapping—AE

<table>
<thead>
<tr>
<th>Question Text</th>
<th>CDASH Field</th>
<th>CDASH Core</th>
<th>SDTM Variable Name</th>
<th>SDTM Core</th>
<th>Implementation Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were any adverse events experienced?</td>
<td>AEYN</td>
<td>O</td>
<td>NS</td>
<td>NS</td>
<td>Can be represented as a question with possible responses of Y or N. The purpose for collection of this field is purely administrative in nature. Thus, it is recommended that the information not be submitted as part of a SDTM submission. Only AEs that have actually occurred appear in the AE SDTM domain.</td>
</tr>
<tr>
<td>AE Number</td>
<td>AESPID</td>
<td>O</td>
<td>AESPID</td>
<td>Perm</td>
<td>Can be represented as open entry field designed to capture either numeric or alphanumerical responses based on sponsor convention. The purpose of this field is administrative in nature and can be used to link intervention related records to a specific event across domains (e.g., link AE domain records to CM domain records). In these cases, a RELREC record using AESPID may be created to communicate this relationship to a review agency.</td>
</tr>
</tbody>
</table>

- Text and Implementation Notes include more explanatory mapping information and examples.
- Tables include all CDASH fields PLUS all Required and Expected SDTMIG variables and how to get to them from CDASH data collection.
Tier 1 Conformance - as described in V1.1 standard.

Tier 2 Conformance is evaluated at the operational level and means that:

- All Tier 1 conformances are met.
- All data collection fields are defined using CDASH naming conventions in the operational database unless an equivalent SDTMIG variable can be used for data collection in a user-friendly manner (e.g., using recommended input format for data collection).
- All non-CDASH fields in CRF follow CDASH recommendations for Creating Fields That Do Not Exist in CDASH (Section 2.4.3).
- All Best Practice recommendations in Section 3 of CDASH V1.1 are followed.
### General

- **Any AEs?**
  - [ ] NO [N]  [ ] YES [Y]

### Details

#### Verbatim Term


#### Start Date

- [OID=AE_5_2010-03-10] | CDM:AE:DATE

#### Ongoing?

- [ ] NO [N]  [ ] YES [Y]

#### End Date

- [OID=AE_9_2010-03-10] | CDM:AE:DATE

#### Severity

- [ ] MILD [MILD]
- [ ] MODERATE [MODERATE]
- [ ] SEVERE [SEVERE]

#### Seriousness

- [ ] NO [N]  [ ] YES [Y]

#### Congenital Anomaly or Birth Defect

- [ ] NO [N]  [ ] YES [Y]

#### Significant Disability

- [ ] NO [N]  [ ] YES [Y]
## User Guide – Fields Not Collected

<table>
<thead>
<tr>
<th>Variable Label</th>
<th>Definition</th>
<th>Reason Excluded From CDASH Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Dispensed</td>
<td>An indicator that the drug name provided is a generic name.</td>
<td>The CDASH standard recommends that the full trade name or proprietary name be recorded if there is a choice. Dictionaries can be used to identify the equivalent generic. In this scenario this fields is not needed on the CRF. If the dictionary does not have this functionality then sites can be instructed to record generic names.</td>
</tr>
<tr>
<td>Response</td>
<td>Did the condition for which the medication was taken respond to treatment?</td>
<td>Applies to medications of interest which are study specific and not generally applicable to general medication CRFs.</td>
</tr>
<tr>
<td>Prescription or OTC</td>
<td>Indicate whether the drug required a prescription or if the subject obtained it OTC.</td>
<td>This level of detail is not required for general medication CRFs.</td>
</tr>
<tr>
<td>Device used to admin drug</td>
<td>For some drugs, such as asthma medications, the delivery device can affect the response</td>
<td>This field applies to medications of interest and devices which are study specific and not generally applicable to general medication CRFs.</td>
</tr>
<tr>
<td>Was drug admin for exacerbation</td>
<td>Used to identify medications taken for a specific indication which has worsened</td>
<td>Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs.</td>
</tr>
<tr>
<td>Was drug admin as a rescue Medication</td>
<td>Used to identify medications taken for a specific indication which has worsened</td>
<td>Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs.</td>
</tr>
<tr>
<td>Cumulative dose used</td>
<td>Calculated total exposure over a specified duration</td>
<td>This can be calculated from other variables on the CRF (dose and frequency or total daily dose and the start and stop dates [optional]).</td>
</tr>
<tr>
<td>Was drug ever used?</td>
<td>Asking if a specific medication was used (e.g., Was aspirin ever used?).</td>
<td>Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs.</td>
</tr>
<tr>
<td>Total duration</td>
<td>Length of time subject was exposed to a drug</td>
<td>Can be calculated from Start Date/Time and Stop Date/Time.</td>
</tr>
<tr>
<td>Total duration unit</td>
<td>Unit of time for subject exposure (e.g., minutes, hours, days, etc.).</td>
<td>Dependent on how the duration algorithm is written.</td>
</tr>
<tr>
<td>Was Medication stopped due to toxicity?</td>
<td>Did the medication reach toxic levels, requiring it to be discontinued?</td>
<td>Applies to medications of interest which are study specific and not generally applicable to all general medication CRFs.</td>
</tr>
<tr>
<td>General Comments</td>
<td>-</td>
<td>CDASH does not recommend the capture of general comments. See the CDASH comments domain for a detailed explanation.</td>
</tr>
<tr>
<td>None Taken</td>
<td>A single box that can be marked to indicate that no concomitant medications were taken</td>
<td>Instead of this question, a Y/N question “Were any drugs taken?” is recommended to avoid ambiguity if this box is not marked, but no medication details are present. This recommended option is listed on Table 3. This approach is consistent with other CDASH domains.</td>
</tr>
<tr>
<td>Category of Medication</td>
<td>-</td>
<td>Applies to medications of interest that are study specific and not generally applicable to all general medication CRFs. These can generally be derived from a medication dictionary.</td>
</tr>
<tr>
<td>Type of Medication</td>
<td>-</td>
<td>Applies to medications of interest that are study specific and not generally applicable to all general medication CRFs. These can generally be derived from a medication dictionary.</td>
</tr>
</tbody>
</table>
User Guide – Role Specific End User Information

Section 1.4

• The user guide has been developed to serve 3 distinct user groups in the execution of a clinical trial as it relates to the collection and the compilation of the study data. Appendix A lists the different target audiences followed by the sections of the user guide that will be most beneficial to that group.

• Some of the sections, such as the conformance rules, pertain to all 3 user groups.

• The 3 user groups targeted by this guide are:
  ▪ CRF Designers
  ▪ Database Builders or Administrators
  ▪ SDTM Programmers

See Appendix A for hyperlinks to the relevant sections for each End User.
User Guide – Role Specific End User Information

CRF Designers (or Developers)
• Use the CDASH data collection fields as “building blocks” in order to design a case report form that meets the objectives of the protocol and that facilitates proper and correct data entry
• When writing CRF completion instructions, utilize the section of the user guide that provides the detail for each of the covered domains
• Create CRF fields that do not currently exist in CDASH but are needed to address the objectives of the protocol.

Database Builders or Administrators
• Build the study’s underlying database
• Ensure that the CRF is in tune with the CDASH core designations and that any variable that is “Highly Recommended” is included on the CRF
• Create variables that do not currently exist in CDASH but are needed to address the objectives of the protocol.
User Guide – Role Specific End User Information

SDTM Programmers

• Utilize those sections of the user guide that address CRF and database “structure”
• Concerned with the mapping of CDASH variables to SDTM compliant datasets.
Questions