CDISC Public Webinar – Standards Updates and Additions

26 Feb 2015
Agenda

• SHARE Research Concepts
  ▪ Julie Evans, CDISC
  ▪ Anthony Chow, CDISC
  ▪ Rene Dahlheimer, CDISC
  ▪ Sam Hume, CDISC

• CDISC Education and Events Updates*
  ▪ John Ezzell, CDISC

*After Q&A session & time permitting
Question & Answer

• ‘Presenter’: Question

Examples:

• Julie: What are the characteristics of Research Concepts?
Agenda

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  ▪ Julie Evans, CDISC
  ▪ Anthony Chow, CDISC
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  ▪ Sam Hume, CDISC

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The CDISC Vision is to Inform Patient Care & Safety Through Higher Quality Medical Research
# Agenda

<table>
<thead>
<tr>
<th>Topic</th>
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<th>Speaker</th>
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<td>Julie Evans</td>
</tr>
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<td>Short Theory of RCs in CDISC</td>
<td>10</td>
<td>Julie Evans</td>
</tr>
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<td>RCs in Practice in CDISC</td>
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<td></td>
</tr>
<tr>
<td>Sources of RCs: TAs, CDISC stakeholders</td>
<td>30</td>
<td>Anthony Chow, Rene Dahlheimer</td>
</tr>
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<td>End to End Standards</td>
<td>15</td>
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<td>CDISC RCs and the Broader World</td>
<td>10</td>
<td>Julie Evans</td>
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<tr>
<td>Q &amp; A</td>
<td>20</td>
<td>All</td>
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</table>
Research Concepts

• Key component of the SHARE vision
• New to the CDISC community
• Fresh slate: No standard CDISC Research Concept content yet
• Can be represented independent of any implementation such as SDTM, CDASH, SEND, ADaM
Short Theory of CDISC Research Concepts

• Definition
• SHARE Metamodel / ISO 11179 Concept System
• BRIDG-aligned
• Sources
Research Concepts – What are they?

- A Research Concept is a unit of knowledge created by a unique combination of characteristics. (ISO 11179)
  - In general, for CDISC: Research Concepts are high-level building blocks of clinical research information that encapsulate lower level implementation details like variables and terminologies.
  - For SHARE: A Research Concept is a unique, meaningful combination of SHARE Concepts and Rules that define the independent units of knowledge found within each CDISC class.

- SHARE provides the repository for RCs and Value Level Metadata
  - But, no current RC content means big effort to develop – perhaps more than what CDISC has done to date.
Research Concepts: Why do we need them?

• Provide clinical meanings for our standards
• Communicate with clinical SMEs
• Quicker, more effective way to develop CDISC standards
• More consistent application of standards
• Facilitate interchange between disparate systems and linking to Healthcare standards
SHARE Model Driven Architecture

**OMG MOF**

- **M3** Meta-Meta Model
- **M2** Meta-Model
- **M1** Model
- **M0** Real-world object

**Level Description**

- **Modeling language**: 
  - UML 2.0, MOF
- **Model for expressing other models**: 
  - ISO 11179, SHARE Meta-Model
- **Abstract representation of real-world**: 
  - CDISC Model, BRIDG
- **Data transport file; Repository**: 
  - SDTM, ADaM and CDASH datasets; SHARE Repository

*OMG MOF: Object Management Group Meta Object Facility – a standard for model driven architecture*
New class in metamodel
Research Concepts in Practice in CDISC

Pilots
- Therapeutic Areas
- External Sources of RCs
- End to End Standards

CDISC Standard Research Concepts (in SHARE)
## Pulmonary Function Test

### Forced Vital Capacity

- Was the test performed?
- Reason Test Not Performed
- What was the date of respiratory system testing?
- What was the time of respiratory system testing?
- Forced Vital Capacity
- Percent Predicted Forced Vital Capacity
- What was the location used for measurement?
- What was the method of respiratory system testing?

### Forced Expiratory Volume in 1 Second

- Was the test performed?
- Reason Test Not Performed
- What was the date of respiratory system testing?
- What was the time of respiratory system testing?
- Forced Expiratory Volume in 1 Second
- Percent Predicted FEV1
- FEV1 Reversibility
- What was the location used for measurement?
- What was the method of respiratory system testing?
RCmap

• A methodology to visually define a research concept
  ▪ Gears toward experts in the field (e.g., pulmonologist for COPD therapeutic area)
  ▪ To break down a concept into elements and their relationships
  ▪ Reusable, like a template
  ▪ Allow metadata developer to bind CDISC variables to concept elements
**CDISC variable binding**

**CDISC variable binding with CT**

**Laboratory Procedure**
- SDTM.LB.LBTEST
- SDTM.LB.LBTESTCD

**Completion Status**
- SDTM.LB.LBSTAT
- NOT DONE (C49484)

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**BRIDG Alignment: BRIDG definition and ISO 21090 datatype to support decision making process**

**Laboratory Procedure**
- SDTM.LB.LBTEST
- SDTM.LB.LBTESTCD
  - BRIDG_DEFINEDACTIVITY.nameCode

**Completion Status**
- SDTM.LB.LBSTAT
  - BRIDG_DEFINEDACTIVITY.negationIndicator

---

BRIDG Class: DefinedActivity  
BRIDG Element: nxmCode  
ISO 21090 Data Type: CD  
Example SDTM Mapping: LBLOINC, LBTEST, LBTESTCD, QTEST, QTESTCD, AEENTPT, CEENTPT, CESTTPT, CESTTPT, CMSTTPT, MENTPT, SUENTPT, SUSTTPT  
Definition and Usage: DEFINITION: A coded value specifying the non-unique textual identifier for the activity. EXAMPLE(S): CPT4 or SNOMED term for a surgical procedure. Coded value for a single analytic procedure in a lab test. The code and text of an individual question on the eligibility checklist of a protocol. OTHER NAME(S): NOTE(S): The textual description of the activity is captured in the complex data type CD.
Gap Analysis: Identified a new element, proposing to be added as a CDISC variable (as opposed to a supplemental qualifier)
<table>
<thead>
<tr>
<th>Concept from Rcode</th>
<th>NCI Definition</th>
<th>Domain Prefix</th>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Variable's XML Dtype</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Codelist Name</th>
<th>Possible Value(s) for This Variable for This RC</th>
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<tr>
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<td>Named locations of or within the body.</td>
<td>LB (C49592)</td>
<td>LBLOC (C119849)</td>
<td>Specimen Collection Anatomic Location</td>
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<td>text</td>
<td>LOC (C74456)</td>
<td>Anatomical Location</td>
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<td>text</td>
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<td>LBTST (C117142)</td>
<td>Lab Test or Examination Name</td>
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<td>text</td>
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<td>Laboratory Test Name</td>
<td>Neutrophils (C63321)</td>
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<td>LB (C49592)</td>
<td>LBOINC (C83311)</td>
<td>LOINC Code</td>
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<td>Unit of Measure (C25709)</td>
<td>A named quantity in terms of which other quantities are measured or used, as a standard measurement of like kinds.</td>
<td>LB (C49592)</td>
<td>LBORRESU (C83106)</td>
<td>Original Units</td>
<td>Char</td>
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<td>UNIT (C71620)</td>
<td>Unit</td>
<td>% (C25613); cells/μL (C67242)</td>
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<td>Laboratory Test Result (C36292)</td>
<td>The outcome of a laboratory test.</td>
<td>LB (C49592)</td>
<td>LBORRESU (C83106)</td>
<td>Character Result/Finding in Std Format</td>
<td>Char</td>
<td>text</td>
<td>LBORRESU (C102580)</td>
<td>Laboratory Test Standard Character Result</td>
<td>BORDERLINE (C14157); INDETERMINATE (C48658); INVALID (C59013); NEGATIVE (C38757); POSITIVE (C38758);</td>
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<td>A indication that a result lies within normal parameters.</td>
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<td>LBNRIND (C83094)</td>
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<td>Reference Range Indicator</td>
<td>HIGH (C73800); LOW (C73801); NORMAL (C73727)</td>
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Tabs in Lab RC Spreadsheet

RC Definitions, Template, each RC

New Components identified by TA Project Team

Value Level Metadata
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<tr>
<th></th>
<th>Research Concept</th>
<th>Test Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>NEUTROPHILS</td>
<td>NEUT</td>
<td>A measurement of the neutrophils in a biological specimen.</td>
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<tr>
<td>2</td>
<td>MACROPHAGES</td>
<td>MCPHG</td>
<td>A measurement of the macrophages in a biological specimen.</td>
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<tr>
<td>3</td>
<td>EOSINOPHILS</td>
<td>EOS</td>
<td>A measurement of the eosinophils in a biological specimen.</td>
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<td>4</td>
<td>T-LYMPHOCYTES</td>
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<td></td>
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<tr>
<td>5</td>
<td>MAST CELLS</td>
<td>MASTCE</td>
<td>A measurement of the mast cells in a biological specimen.</td>
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<tr>
<td>6</td>
<td>INF-GAMMA</td>
<td>IFNG</td>
<td>A measurement of the interferon gamma in a biological specimen.</td>
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<td>7</td>
<td>CXCR3</td>
<td>CXCR3</td>
<td>A measurement of the CXCR3, chemokine (C-X-C motif) receptor 3, in a biological specimen.</td>
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<td>8</td>
<td>CCR5</td>
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<tr>
<td>9</td>
<td>RANTES</td>
<td>RANTES</td>
<td>A measurement of the RANTES (regulated on activation, normally, T-cell expressed, and secreted) in a biological specimen.</td>
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<td>10</td>
<td>IL-1beta</td>
<td>INTLK1B</td>
<td>A measurement of interleukin 1 beta in a biological specimen.</td>
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<td>11</td>
<td>IL-6</td>
<td>INTLK6</td>
<td>A measurement of the interleukin 6 in a biological specimen.</td>
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<td>IL-8</td>
<td>INTLK8</td>
<td>A measurement of the interleukin 8 in a biological specimen.</td>
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<td>IL-9</td>
<td>INTLK9</td>
<td>A measurement of the interleukin 9 in a biological specimen.</td>
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<tr>
<td>14</td>
<td>IL-10</td>
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<td>A measurement of the interleukin 10 in a biological specimen.</td>
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<td>IL-17</td>
<td>INTLK17</td>
<td>A measurement of the interleukin 17 in a biological specimen.</td>
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<tr>
<td>16</td>
<td>IL-22</td>
<td>INTLK22</td>
<td>A measurement of the interleukin 22 in a biological specimen.</td>
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<tr>
<td>17</td>
<td>FIBRINOGEN</td>
<td>FIBRINO</td>
<td>A measurement of the fibrinogen in a biological specimen.</td>
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<tr>
<td>18</td>
<td>IP-10</td>
<td>CXCL10</td>
<td>A measurement of the CXCL10, chemokine (C-X-C motif) ligand 10, in a biological specimen.</td>
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<td>19</td>
<td>IgE</td>
<td>IGE</td>
<td>A measurement of the Immunoglobulin E in a biological specimen.</td>
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<td>20</td>
<td>TNF-alpha</td>
<td>TNF</td>
<td>A measurement of the total tumor necrosis factor (cachexin) cytokine in a biological specimen.</td>
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<tr>
<td>21</td>
<td>hsCRP</td>
<td>CRP</td>
<td>A measurement of the C reactive protein in a biological specimen.</td>
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<tr>
<td>22</td>
<td>MMP-8</td>
<td>MMP8</td>
<td>A measurement of the matrix metalloproteinase 8 in a biological specimen.</td>
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<td>23</td>
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<td>A measurement of the matrix metalloproteinase 9 in a biological specimen.</td>
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<td>24</td>
<td>MPO</td>
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<td>A measurement of the myeloperoxidase in a biological specimen.</td>
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<tr>
<td>25</td>
<td>NE</td>
<td>ELA2</td>
<td>A measurement of the neutrophil elastase in a biological specimen.</td>
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<tr>
<td>26</td>
<td>SP-D</td>
<td>SFTPĐ</td>
<td>A measurement of the surfactant protein D in a biological specimen.</td>
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</table>
Identifying and defining new content

<table>
<thead>
<tr>
<th>#</th>
<th>Seq. For Order</th>
<th>Observation Class</th>
<th>Domain Prefix</th>
<th>Variable Name (minus domain prefix)</th>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Variable’s XML Datatype</th>
<th>Controlled Terms, Codelist or Format</th>
<th>Role</th>
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<td>TBD</td>
<td>Findings</td>
<td>LB</td>
<td>CLMETH</td>
<td>LBCLMETH</td>
<td>Sample Collection Method</td>
<td>Char</td>
<td>text</td>
<td>TBD (Talk to Erin at next meeting)</td>
<td>Record Qualifier</td>
<td>The method used to collect a sample</td>
<td>Perm</td>
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</tbody>
</table>

- **Columns (above) for New Variables**
  - Sequence for order
  - Observation Class
  - Domain Prefix
  - Variable Name minus domain prefix
  - Variable Name with domain prefix
  - Variable Label
  - Type
  - Variable’s XML datatype
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  - Description
  - Core

- **Types of New Content**
  - New Variables
  - New Domains
  - New Codelists
  - New Codelist Values
  - New Codelist Subsets
  - New Suppquals
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</table>
CDISC Clinical Research Data Lifecycle

Trial Design and Setup
- PRM: Author Protocol
- SDM: Design Trial
- CDASH: Design CRFs
- SDTM: Annotate CRFs
- Define: Setup EDC Trial

Trial Execution
- SDM: Trial Registry
- Lab: Capture Lab Data
- SDTM: Capture CRF Data

Analysis and Reporting
- ADaM: Generate CSR
- SDTM: Generate TLF
- ADaM: Generate Tabulations and Listings
- ADaM: Generate Analysis Datasets
- SDTM: Generate Tabulations and Listings

Submission and Archival
- Define: Generate Submission Metadata
- ODM: Generate SR-CRFs
- SDTM: Create Submission
- Define: Data Archive
- ODM: Data Archive
Current End-to-End Standards Activities

• End-to-End Metadata Pilot

• End-to-End Standards in SHARE R3

• Define-XML v2.1 Traceability
End-to-End Metadata Pilot

- **Mission**: Identify metadata needed to improve traceability, to enable the specification of study mapping and transformations, and to enable the automatic generation of clinical study artifacts.

- **Deliverables**: Include generating mapping documents from SHARE, and a gap analysis highlighting missing metadata.
Capture metadata needed to describe both traceability and mapping from CDASH to SDTM, including derivations, in SHARE.
SHARE Relationships Identify Mapping

- CDASH variable
- NCIt Concept (Variable)
- Part of DM domain
- Part of CDASH Standard
- BRIDG & ISO 21090 Mapping
- Maps to SDTM
- NCI EVS codelist and codes
- NCIt Concept (CT code)
- NCIt Concept (CT codelist code)
## End-to-End Map: CDASH to SDTM

<table>
<thead>
<tr>
<th>CDASH Domain</th>
<th>CDASH Variable</th>
<th>SDTM Domain</th>
<th>SDTM Variable</th>
<th>Mapping Instructions</th>
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<td>AESTDAT</td>
<td>AE</td>
<td>AESTDTC</td>
<td>For the SDTM dataset, the SDTM variable --STDT is in 8601 format.</td>
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<td>AESTDTC</td>
<td>For the SDTM dataset, the SDTM variable --STDT is in 8601 format.</td>
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<td>For the SDTM dataset, the SDTM variable --STDT is in 8601 format.</td>
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<td>AEENRF</td>
<td>May be used to derive a value into an SDTM relative to 'Y', the value of 'DURING', 'AFTER' or 'DURING/AFTER' may be derived. Note: AEENRTPT must refer to a 'time' variable.</td>
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<td>Maps directly to SDTM. The sponsor is expected to provide code list attributes.</td>
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<td>Maps directly to SDTM. The sponsor is expected to provide code list attributes.</td>
</tr>
</tbody>
</table>

Programmatically extracted from SHARE using existing standards content.
End-to-End Data Flow Types

• Data flow is comprised of mapping, transformation and derivation
  ▪ Mapping – move a variable unchanged from source to target
  ▪ Transformation – restructures, reformats, changes data type, and integrates
  ▪ Derivation – creates new values in a target database that do not exist in the source (e.g. calculations)
Metadata Needed for Full Description of Data Transformations

source

- Tables
- Columns
- Columns Param
- Values
- Descriptions*

source and target keys

- Tables Map
- Columns Map
- Columns Param Map
- Values Map
- Descriptions Map
- Include Map

target

- Tables
- Columns
- Columns Param
- Values
- Descriptions*
SHARE content is limited by the current standards content (gap analysis is a work in progress).
SHARE R3: End-to-End Standards

- Make use of existing SHARE maps-to relationships and add new ones as the standards content is developed
- Export mapping metadata from SHARE and post to eSHARE
- Protocol-XML
- Traceability enhancements for the XML Technologies
- Provide mapping improvement input to the standards teams
Define-XML v2.1

- Enhance End-to-End traceability support:
  - Trace from ADaM back to SDTM
  - Trace from SDTM back to CDASH
  - Explicitly reference the source variable(s) for a variable in Define-XML
  - Populate Define-XML source variables in SHARE exports
- Work-in-progress
End-to-End Next Steps

- Map spreadsheet SHARE extract for SDTM to ADaM
- Complete the gap analysis to find missing metadata
- State diagram for the CDISC standards
- Define-XML v2.1 traceability improvements
- At the March Intrachange
  - Define-XML v2.1 working sessions
  - Realizing CDISC Standards End-to-End Session
  - Protocol-XML planning
  - CDISC Standards in RDF
CDISC RCs in the Broader World:
Similar efforts that have a lot in common with RCs

Differences in:
- Reference Models
- Context
- Scope
Much higher volume of metadata needs to be identified, developed, curated, governed.
Q AND A
CDISC Education & Events Announcements

John Ezzell, CDISC, Manager of Education Products
Standards currently out for review

• TA CFAST TAUG for Schizophrenia
  ▪ Visit http://www.cdisc.org/standards/dataexchange for more information.
  ▪ Deadline for Comments: 27 Mar 2015

Click here to submit your comments.
# Upcoming USA Public Course Events

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicago, IL</td>
<td>24-27 Mar 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>Expired</td>
<td>Expired</td>
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<tr>
<td>Palo Alto, CA</td>
<td>14-17 Apr 2015</td>
<td>SEND, ODM, Dataset-XML, Define-XML</td>
<td>14 Mar 2015</td>
<td>Expired</td>
<td>Jazz Pharmaceuticals</td>
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<td>Audubon, PA</td>
<td>18-22 May 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>18 Apr 2015</td>
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<td>BIOCLINICA</td>
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</table>

Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](http://cdisc.org/public-courses). Additional 2015 public training events can be found @ [http://cdisc.org/public-courses](http://cdisc.org/public-courses).
# Upcoming Europe Public Course Events

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
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</thead>
<tbody>
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<td>Eschborn (Frankfurt), Germany</td>
<td>14-17 Jul 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>14 June 2015</td>
<td>28 Feb 2015</td>
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</table>

*Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](http://cdisc.org/public-courses). Additional 2015 public training events can be found at [http://cdisc.org/public-courses](http://cdisc.org/public-courses).*
## Upcoming Asia Public Course Events

<table>
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<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
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</thead>
<tbody>
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<td>Tokyo, Japan</td>
<td>9-11 Mar 2015</td>
<td>CDASH, SDTM</td>
<td>Expired</td>
<td>CDISC Member; Government, Hospital, and Academic Staff and Student</td>
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</table>

*Registration deadline indicates online deadline. Offline registration deadlines for each event can be found [here](http://cdisc.org/public-courses).*
CDISC In-House Education

- Below courses readily available for ‘in-house’ training:
  - ADaM
  - BRIDG Deep Dive
  - CDASH
  - SDTM
  - SDTM for Medical Devices
  - SEND
  - Others pending availability

- For more information visit our website or submit request here.
Online Training

- SDTM, CDASH, BRIDG, ADaM, and Therapeutic Area modules available on CDISC Training Campus (http://CDISC.trainingcampus.net)

- Bundle packages available for SDTM, CDASH, and BRIDG modules

- All members should contact training@cdisc.org to retrieve company-specific discount code.

www.cdisc.org/online-courses

Online Courses

Access CDISC online courses here!
Next Public Webinar

• **Agenda:**
  - Dyslipidemia

• **Date:** Mon, Mar 9, 2015 12:00 PM - 1:30 PM CDT

• **Speakers:**
  - John Glover, TransCelerate BioPharma

• Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Next Members-Only Mini Training

• **Topic:** Domain Cross-Reference Document

• **Date/Time:** 11 Mar 2015, 11:00-12:30 PM CST

• **Speakers:**
  - Julie Chason, CDISC
  - Anthony Chow, CDISC
  - Rene Dahlheimer, CDISC
  - Amy Palmer, CDISC

• Register [here](#).
CDISC Members Drive Global Standards

Thank you for your support!
Any more questions?

Thank you for attending this webinar.

CDISC’s vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research