CDISC360
Art of the Possible Initial Concepts
San Diego Interchange
Welcome to the Clinical Study Definition System

What is CDISC 360?
CDISC 360 is an ambitious new project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect – substantially improved efficiency, consistency, and re-usability.

We are inviting your organization to join us in this important project by getting involved. CDISC values the input and collaboration of our members; we want to ensure your needs and expectations are taken into account so that the project achieves results that are supported and endorsed by our community.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle.

The Opportunity
The CDISC foundational standards define research data and metadata structures, but writing these standards as documents has yielded more text than metadata. Gaps in standards metadata limit automation opportunities. The inherent flexibility provided by the standards supports a broad range of implementations, but that flexibility also allows for inconsistencies that make scaling automation difficult. The lack of a conceptual foundation for the standards further contributes to these inconsistencies. The relationships that would be expressed by these concepts remain largely implicit in the current versions of the standards.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle. New software tools will consume this new metadata to ease standards implementations while increasing data processing efficiencies.

CDISC 360 will demonstrate the feasibility of standards-based metadata-driven automation as a start towards realizing the primary benefits expected of the CDISC standards: substantially improved efficiency, consistency, and re-usability across the clinical research

Objectives
CDISC 360 will develop proof-of-concept enhancements to the CDISC standards metadata as well as related proof-of-concept software to confirm that the enhanced standards can be used to automate preparation of study specification metadata and end-to-end study data processing.

The focal point of this project is concept-based modeling. CDISC will not deliver software to industry as an outcome of CDISC 360. However, during the project, an enhanced set of API prototypes will be developed to demonstrate that the concept-based metadata can be accessed in order to implement metadata-driven automation.

Scope
CDISC 360 will implement end-to-end standards-based metadata-driven automated processing by conducting three use cases, demonstrated by implementing portions of the CDISC Type 1 Diabetes TUG.

Metadata / Data Processing Use Cases

Use Case 1: Create end-to-start specification - Demonstrate the ability to produce a standards-based, machine-readable specification for the data and analysis artifacts to be created in the study.

Use Case 2: Generate start-to-end metadata - Demonstrate the ability to generate study-specific artifacts given the standards specification from Use Case 1.

Use Case 3: Transform data start-to-end - Demonstrate the ability to process data and execute data transformations given the study specification from Use Case 2.
Welcome to the Clinical Study Definition System

CDISC 360

Log in to your account

Email Address
laurasantos@mdemail.com

Password
******

Login

Forgot Password?

Create an account

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end-to-end clinical research data lifecycle. New software tools will consume this new metadata to ease standards implementations while increasing data processing efficiencies.

The inherent flexibility provided by the standards supports a broad range of implementations, but this flexibility also allows for inconsistencies that can make automation difficult. The lack of a conceptual foundation for the standards further contributes to these inconsistencies. The relationships that would be described by these concepts remain largely implicit in the current versions of the standards.

CDISC 360 seeks to implement standards so linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end-to-end clinical research data lifecycle. New software tools will consume this new metadata to ease standards implementations while increasing data processing efficiencies.

The final goal of this project is concept-based modeling. CDISC will not deliver software to industry as an outcome of CDISC 360. However, during the project, an enhanced set of API prototypes will be developed to demonstrate that the concept-based metadata can be accessed in order to implement metadata-driven automation.

CDISC 360 will demonstrate the feasibility of standards-based metadata-driven automation as a start towards realizing the primary benefits expected of the CDISC standards: substantially improved efficiency, consistency, and reusability across the clinical research data lifecycle.
Laura Santos
Welcome to CDISC360

360 Participation Continues to Grow
Participation has grown through the summer. Currently, 67 individuals from 29 member companies are contributing actively to the project, across six workstreams. With this large number of participants working remotely across the globe, effective online collaboration tools are key to project success. As previously reported, project participant Microsoft, is providing its Azure product as a cloud collaboration platform. At this point, the platform instance has been configured and access has been provided to all project participants. A subset of participants is currently installing the software tools to build and run the scripts to execute the project use cases; these participants have already begun to build and run initial scripts!

360 at the 2019 US Interchange
There will be many opportunities to learn about CDISC 360 at the 2019 US Interchange. The Project will be the focus of the second Opening Plenary and include presentations by CDISC Board Members Dave Evans and Chris Decker, CDISC VP, Data Science Dr. Sam Hume, and me. Sam's presentation will include a demo of the progress made on the 360 Project to date. Next, a breakout session titled “CDISC 360 Use Cases - Industry Perspectives’ will include a presentation on each of the three 360 Project use cases, delivered by the individual workstream leads. Finally, a post-conference CDISC 360 workshop will be held on Friday 18 October.

360 Looking Ahead
Following the US Interchange, CDISC 360 will enter its second six-month phase with several agile sprints planned until the 2020 Europe Interchange in Berlin. The workstream teams expect to build upon their knowledge gained in the early sprints, identify reasonable targets for the second six-month phase, and work down their respective agile sprint backlogs defined for those targets, all toward a more mature development of standard concepts and of execution of the three use cases. A more feature-rich demo will be planned for the 2020 Europe Interchange. A CDISC 360 web page on the CDISC web site is also planned for this period. If you are an employee of a CDISC Member organization and interested in participating in CDISC 360, please send a message to info@cdisc.org.
Select a disease area category

Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

- Autoimmune
- Cardiovascular
- Endocrine
- Gastrointestinal
- Infectious
- Mental Health
- Neurology
- Oncology
- Rare Diseases
- Respiratory
- Treatments
- Other

Back  Continue
Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

Select a disease area

- Acute Kidney Injury
- Diabetes - Type 1
- Diabetes - Type 2
- Diabetic Kidney Disease
- Dyslipidemia
- Kidney Transplant
- Polycystic Kidney Disease

Back
Continue
Select a study focus

- Safety
- Efficacy

Disease Category
- Endocrine

Disease Area
- Diabetes - Type 2

Study Focus

Domains

Concepts

Data Collection

Confirmation

Continue
<table>
<thead>
<tr>
<th><strong>Domains</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Accountability</strong></td>
</tr>
<tr>
<td>A findings domain that contains the accountability of study drug, such</td>
</tr>
<tr>
<td>as information on the receipt, dispensing, return, and packaging.</td>
</tr>
<tr>
<td><strong>Inclusion/Exclusion</strong></td>
</tr>
<tr>
<td>A findings domain that contains those criteria that cause the subject</td>
</tr>
<tr>
<td>to be in violation of the inclusion/exclusion criteria.</td>
</tr>
<tr>
<td><strong>Morphology</strong></td>
</tr>
<tr>
<td>A findings domain relevant to the science of the form and structure of</td>
</tr>
<tr>
<td>an organism or its parts.</td>
</tr>
<tr>
<td><strong>Subject Characteristics</strong></td>
</tr>
<tr>
<td>A findings domain that contains subject-related data not collected in</td>
</tr>
<tr>
<td>other domains.</td>
</tr>
<tr>
<td><strong>ECG Results</strong></td>
</tr>
<tr>
<td>A findings domain that contains ECG data, including position of the</td>
</tr>
<tr>
<td>subject, method of evaluation, all cycle measurements and all findings.</td>
</tr>
<tr>
<td><strong>LabTest Results</strong></td>
</tr>
<tr>
<td>A findings domain that contains laboratory test data such as hematology,</td>
</tr>
<tr>
<td>clinical chemistry and urinalysis. This domain does not include...</td>
</tr>
<tr>
<td><strong>Physical Examination</strong></td>
</tr>
<tr>
<td>A findings domain that contains findings observed during a physical</td>
</tr>
<tr>
<td>examination where the body is evaluated by inspection, palpation,</td>
</tr>
<tr>
<td>percussion, and...</td>
</tr>
<tr>
<td><strong>Vital Signs</strong></td>
</tr>
<tr>
<td>A findings domain that contains measurements including but not limited</td>
</tr>
<tr>
<td>to blood pressure, temperature, respiration, body surface area, body</td>
</tr>
<tr>
<td>mass index...</td>
</tr>
<tr>
<td><strong>Exposure</strong></td>
</tr>
<tr>
<td>An interventions domain that contains the details of a subject’s exposure</td>
</tr>
<tr>
<td>to protocol-specified study treatment. Study treatment may be any...</td>
</tr>
<tr>
<td><strong>Microscopic Findings</strong></td>
</tr>
<tr>
<td>A findings domain that contains histopathology findings and microscopic</td>
</tr>
<tr>
<td>evaluations.</td>
</tr>
<tr>
<td><strong>Questionnaires</strong></td>
</tr>
<tr>
<td>A findings domain that contains data for named, stand-alone instruments</td>
</tr>
<tr>
<td>designed to provide an assessment of a concept. Questionnaires have a...</td>
</tr>
<tr>
<td><strong>Subject Characteristics</strong></td>
</tr>
<tr>
<td>A findings domain that contains subject-related data not collected in</td>
</tr>
<tr>
<td>other domains.</td>
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<td><strong>Vital Signs</strong></td>
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</tr>
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<td>to blood pressure, temperature, respiration, body surface area, body</td>
</tr>
<tr>
<td>mass index...</td>
</tr>
<tr>
<td>Concepts</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Height</td>
</tr>
<tr>
<td>Oxygen Saturation</td>
</tr>
<tr>
<td>Body Frame Size</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>Blood Pressure</td>
</tr>
<tr>
<td>Hip Circumference</td>
</tr>
<tr>
<td>Body Fat Measurement</td>
</tr>
<tr>
<td>Temperature</td>
</tr>
<tr>
<td>Respiratory Rate</td>
</tr>
</tbody>
</table>
The property of a body or region of space that determines whether or not there will be a net flow of heat into it or out of it from a neighboring body or region and...

A measurement of the oxygen-hemoglobin saturation of a volume of blood.

The categorization of a person's body frame into small, medium and large based on the measurement of wrist circumference or the breadth of the elbow.

The rate of breathing (inhalation and exhalation) measured within in a unit time, usually expressed as breaths per minute.

A measurement of the total fat mass within the subject's body.
Would you like to measure Blood Pressure and Heart Rate at multiple time points?

Yes
No

Back
Continue
Would you like to measure Blood Pressure and Heart Rate at multiple time points?

- Yes
- No

Select time points:
- 5 minutes pre-dose
- 30 minutes post-dose
- 1 hour post-dose
- 2 hour post-dose
- 4 hour post-dose
- 8 hour post-dose
Would you like to collect Vital Signs body position(s)?

Yes
No

Back
Continue
Would you like to collect Vital Signs body position(s)?

- Yes
- No

Select body positions
- Sitting
- Sitting, Standing, Supine

Back
Continue
Let's recap your study definition selections and prepare to assign

Standard Disease Area
- Diabetes - Type 2

Study Focus
- Safety

Domains
- Vital Signs

Concepts
- Height
- Weight
- Heart Rate
- Temperature
- Blood Pressure

Data Collection Options
- 5 minutes pre-dose
- 30 minutes post-dose

Back | Prepare
Study definition was prepared successfully

**Study definition information**

**Study definition name**

**Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements**

**Assign Data Manager**

Rebecca Kim

[Submit]

[Cancel]
Welcome to the Clinical Study Build System

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**Metadata / Data Processing Use Cases**

Use Case 1: Create end-to-start specification – Artifacts to be created in the study. Use Case 2: Generate start-to-end metadata – Demonstrate the ability to generate study-specific artifacts given the standards specific from Use Case 1.

Use Case 3: Transform data start-to-end – Demonstrate the ability to process data and extract data transformations given the study specification from Use Case 2.
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<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Disease Area</th>
<th>Creator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements</td>
<td>Diabetes - Type 2</td>
<td>Santos, Laura</td>
</tr>
<tr>
<td>Serum creatinine, change from baseline</td>
<td>Acute Kidney Injury</td>
<td>Garcia, Mary</td>
</tr>
<tr>
<td>Frequency Listing of Treatment Emergent Adverse Events</td>
<td>Acute Kidney Injury</td>
<td>Dominguez, Teri</td>
</tr>
<tr>
<td>Number of and Reasons for Early Discontinuations from Study</td>
<td>Dyslipidemia</td>
<td>Robinson, Linda</td>
</tr>
<tr>
<td>Demographics</td>
<td>Polycystic Kidney Disease</td>
<td>Santos, Laura</td>
</tr>
</tbody>
</table>
Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

Let's recap your study definition selections

Standard Disease Area
- Diabetes - Type 2

Study Focus
- Safety

Domains
- Vital Signs

Concepts
- Height
- Weight
- Heart Rate
- Temperature
- Blood Pressure

Data Collection Options
- 5 minutes pre-dose
- 30 minutes post-dose
Which CDASH version is needed?

- Version 1.1
- Version 2.0

Which Terminology version is needed?

- 2019-09-03
- 2019-06-06
- 2019-03-01
- 2018-11-20

Which ODM version is needed?

- Version 1.3.1
- Version 1.3.2

Back
Continue
ODM successfully created
Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

Let's recap your study definition selections

Standard Disease Area

- Diabetes - Type 2

Study Focus

- Safety

Domains

- Vital Signs

Concepts

- Height
- Weight
- Heart Rate
- Temperature
- Blood Pressure

Data Collection Options

- 5 minutes pre-dose
- 30 minutes post-dose
Define.xml was successfully generated
Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements

Let's recap your study definition selections

**Standard Disease Area**
- Diabetes - Type 2

**Study Focus**
- Safety

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**Concepts**
- Height
- Weight
- Heart Rate
- Temperature
- Blood Pressure

**Data Collection Options**
- 5 minutes pre-dose
- 30 minutes post-dose
### Vital Signs (Timepoint)

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was the date of the vital signs measurement? (DD-MMM-YYYY)</td>
<td></td>
</tr>
<tr>
<td>What was the time of the vital signs measurement? (24 hour clock)</td>
<td></td>
</tr>
<tr>
<td>Were vital signs performed?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Reason Not Performed</td>
<td></td>
</tr>
<tr>
<td>What was the result of the weight measurement?</td>
<td>kg/LB</td>
</tr>
<tr>
<td>What was the result of the height measurement?</td>
<td>cm/in</td>
</tr>
<tr>
<td>What was the result of the temperature measurement?</td>
<td>°C/°F</td>
</tr>
</tbody>
</table>

### Vital Signs (Timepoint)

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Position</th>
<th>Systolic Blood Pressure</th>
<th>Diastolic Blood Pressure</th>
<th>Heart Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 min pre-dose</td>
<td>Sitting/Standing/Supine</td>
<td>mmHg/inHg</td>
<td>mmHg/inHg</td>
<td>beats/min</td>
</tr>
<tr>
<td>30 min post-dose</td>
<td>Sitting/Standing/Supine</td>
<td>mmHg/inHg</td>
<td>mmHg/inHg</td>
<td>beats/min</td>
</tr>
</tbody>
</table>
### VS (Vital Signs) - [SDTMIG 3.2]

<table>
<thead>
<tr>
<th>Variable</th>
<th>Where Condition</th>
<th>Label / Description</th>
<th>Type</th>
<th>Length or Display Format</th>
<th>Controlled Terms or Format</th>
<th>Origin / Source / Method / Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDID</td>
<td></td>
<td>Unique identifier for a study.</td>
<td>text</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOPNAME</td>
<td></td>
<td>Five-character abbreviation for the domain.</td>
<td>text</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSID</td>
<td></td>
<td>Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.</td>
<td>text</td>
<td>40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSSEQ</td>
<td></td>
<td>Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.</td>
<td>integer</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSTESTCD</td>
<td></td>
<td>Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., &quot;1TEST&quot;). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: SBP, Diastolic, BMI.</td>
<td>text</td>
<td>8</td>
<td>Vital Signs Test Code</td>
<td>(6 Terms)</td>
</tr>
<tr>
<td>VSTEST</td>
<td></td>
<td>Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 48 characters. Examples: Systolic Blood Pressure, Diastolic Blood Pressure, Body Mass Index.</td>
<td>text</td>
<td>40</td>
<td>Vital Signs Test Name</td>
<td>(6 Terms)</td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>Result of the vital signs measurement as originally received or collected.</td>
<td>text</td>
<td>30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Temperature</td>
<td>float</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Insulin</td>
<td>float</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Diastolic Blood Pressure</td>
<td>float</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Systolic Blood Pressure</td>
<td>float</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Weight</td>
<td>float</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUES</td>
<td></td>
<td>VSVALUES for Heart Rate</td>
<td>float</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUESU</td>
<td></td>
<td>Original units in which the data were collected. The unit for VSVALUESU: examples: IN, L, BLAST/MIN.</td>
<td>text</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VSVALUESU</td>
<td></td>
<td>VSVALUESU for Temperature</td>
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**Study Definitions**

**BY CREATOR**

<table>
<thead>
<tr>
<th>Name</th>
<th>Standard Disease Area</th>
<th>Creator</th>
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<tbody>
<tr>
<td>Height, weight, heart rate, temperature, and pre- and post-dose blood pressure measurements</td>
<td>Diabetes - Type 2</td>
<td>Santos, Laura</td>
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<td>Serum creatinine, change from baseline</td>
<td>Acute Kidney Injury</td>
<td>Garcia, Mary</td>
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<td>Frequency Listing of Treatment Emergent Adverse Events</td>
<td>Acute Kidney Injury</td>
<td>Dominguez, Teri</td>
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<td>Number of and Reasons for Early Discontinuations from Study</td>
<td>Dyslipidemia</td>
<td>Robinson, Linda</td>
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<td>Demographics</td>
<td>Polycystic Kidney Disease</td>
<td>Santos, Laura</td>
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