Type 1 Diabetes Pediatrics & Devices Publication

John Owen, Head of Partnerships and Development, CDISC
Rebecca Baker, Standards Developer, CDISC
Kathleen Mellars, Consultant Standards Developer, CDISC
Richard Marshall, Consultant Standards Developer, CDISC

Thursday, 15 OCT 2020
11:00AM – 12:30PM EDT
Today’s Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources
Housekeeping
Housekeeping

• You will remain on **mute** for the entirety of the webinar
• There will be a Q&A after all of the presentations are finished
• Audio issues? Shut down and restart the GoToWebinar app
• The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  • To access – make sure that you create a login for the CDISC website if you haven’t already
  • If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer’s domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!
Submitting Questions

• To send a question, use the “QUESTIONS” function on your GoToWebinar app. (See red arrow)

• You can submit questions at any time during the presentation, we’ll answer them during the Q&A.

• If you have a question for a specific presenter, please indicate the presenter’s name at the beginning of the question
  • Examples:
    • John: ‘Question’
    • Alana: ‘Question’
Content Disclaimer

• The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.

• This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.
Our Presenters

• Rebecca Baker, Standards Developer, CDISC
• Richard Marshall, Consultant Standards Developer, CDISC
• Kathleen Mellars, Consultant Standards Developer, CDISC
• John Owen, Head of Partnerships and Development, CDISC
Type 1 Diabetes TAUG – Pediatrics and Devices

Publication Webinar

15th October 2020

• John Owen (CDISC)
• Rebecca Baker (CDISC)
• Richard Marshall (CDISC)
• Kathleen Mellars (CDISC)
Type 1 Diabetes

Exercise & Nutrition

Screening, Staging and Monitoring of Pre-Clinical Type 1 Diabetes

Type 1 Diabetes – Pediatrics and Devices

Diabetes - Type 1 Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules

22 September 2020

Version 1.0 of the Type 1 Diabetes Therapeutic Area User Guide - Pediatrics and Devices Modules was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to Type 1 Diabetes studies that address Pediatrics and Devices, and the necessary metadata to represent such data consistently with Terminology, CDASH, and SDTM.

Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertain to specific indications within disease areas. CDISC Standards and TAUGs specify how to structure the data; they do not specify what data should be collected or how to conduct clinical trials, assessments or endpoints.

Public Review Comments

CDISC posts public review comments and resolutions to ensure transparency and show implementers how comments were addressed in the standard development process.

TA Specifications

TA Specifications show how to modify TAUG examples for various versions of the SDTM and SDTMIG. These specifications assist the FDA and the Japanese PMDA with testing to enable support of the standards and inclusion in their respective Technical Conformance Guides 1, 2.

1. https://www.fda.gov/media/134460/download
Getting Started with CDISC Standards - Videos

https://www.cdisc.org/new-to-cdisc
Getting Started with CDISC Standards – CDISC Primer

https://www.cdisc.org/primer
Getting Started with CDISC Standards - Webinars

CDISC for Newcomers

Why Standards Matter
If you’ve ever asked any of these questions:

• “I’m only doing one study. How can you standardize only one study?”

• “Why should I use standards? I’m going to publish, not submit to regulators.”

• “How can I use standards if there aren’t any for the data I’m collecting?”

• “My research is observational. What relevance do standards have for me?”

This webinar is for you.
Getting Started with CDISC Standards - Education

https://www.cdisc.org/education
Getting Started with CDISC Standards - Education

Free Training
Including:

- CDISC for Academic Researchers
  On Demand

- SDTM001: An Introduction to the Study Data Tabulation Model
  On Demand

- TA001: Overview of Therapeutic Area User Guides
  On Demand

- TA010: Diabetes User Guide
  On Demand

- T1D P&D TAUG
  Available Mid-Oct
Getting Started with CDISC Standards - Academics

CDISC for Academic Researchers
On Demand

Course Description
This training outlines how academic and research organizations can implement CDISC standards within their organizations. In this training, learners will understand the benefits of adopting CDISC standards. The training will also provide academics with a useful toolkit and helpful information for collecting and organizing research data using CDISC standards. This training also outlines navigating CDISC resources and how to contribute to clinical research standard development.

Course-Level Learning Outcomes
- Describe the CDISC standards and how they improve the findability, accessibility, interoperability, and reusability of research data in order to recognize their value in academic research.
- Identify individual CDISC standards in order to set the stage for implementation.
- Support the adoption of implementing CDISC standards for data collection and organization in academic research.
CDISC Foundational Standards Documentation

https://www.cdisc.org/standards
SDTM provides a standard for organizing and formatting data to streamline processes in collection, management, analysis and reporting. Implementing SDTM supports data aggregation and warehousing; fosters mining and reuse; facilitates sharing; helps perform due diligence and other important data review activities; and improves the regulatory review and approval process. SDTM is also used in non-clinical data (SEND), medical devices and pharmacogenomics/clininformatics studies.

SDTM is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan).

Details on the requirements for FDA are specified in the FDA's Data Standards Catalog for NDA, ANDA, and certain BLA submissions. For more information, please visit the FDA Guidance on Standardized Data.

Details on the requirements for PMDA can be found on the Advanced Review with Electronic Data Promotion Group page.

Please be aware that the SDTM and SDTMIG have separate web pages. The SDTM supports multiple implementation guides (IG) and a new version of the SDTM will appear to support them.

ADaM defines dataset and metadata standards that support:

- efficient generation, replication, and review of clinical trial statistical analyses, and
- traceability among analysis results, analysis data, and data represented in the Study Data Tabulation Model (SDTM).

ADaM is one of the required standards for data submission to FDA (U.S.) and PMDA (Japan).

Details on the requirements for FDA are specified in the FDA's Data Standards Catalog for NDA, ANDA, and certain BLA submissions. For more information, please visit the FDA Guidance on Standardized Data.

Details on the requirements for PMDA can be found on the Advanced Review with Electronic Data Promotion Group page.
CDISC Therapeutic Area user Guide Documentation

https://www.cdisc.org/standards/therapeutic-areas
Certification

https://www.cdisc.org/education/cdisc-standards-certification

CDISC Standards Certification

Introducing CDISC Standards Certification

To accommodate the high demand for professionals with proven experience implementing CDISC Standards and integrating our standards into an organization’s systems and processes, CDISC is now offering certification to individuals within the standards community with documented experience, a passing grade on the certification exam and annual certification maintenance.

CDISC Standards Certification is a benchmark of excellence which can be used to:

- Validate Skills
- Assess Potential Hires
- Provide Your Clients With Proven Expertise
- Fast-track Your Career

As an additional convenience, you have the option to take the test at an approved test center or from the convenience of your home or office.

Be Among the First to Attain Certification

CDISC Tabulate, based on knowledge of SDTM and the SDTMIG, is the first CDISC certification to demonstrate proficiency in tabulating clinical research data.
Knowledgebase

**Articles**
Search and find useful information specific to your area of interest.

**Examples Collection**
A set of CDISC-curated examples culled from our Foundational Standards and Therapeutic Area User Guide (TAUGs)

https://www.cdisc.org/kb
Volunteer for a CDISC Team

https://www.cdisc.org/volunteer
Summary

Engagement
- Introduction to CDISC Videos
- Webinars

Education
- CDISC Primer
- Education Courses
- Webinars
- Certification

Implementation
- Models and Implementation Guides
- TAUGs
- Knowledgebase Example Collection

Support
- Knowledgebase Articles
- Public Webinars/Interchanges/User Networks
CDISC Membership

Join the collaborative efforts of over 480 CDISC member organizations

https://www.cdisc.org/membership
• Publications
• Sharing Data
• Regulatory Submissions
Therapeutic Area Data Standards for Type 1 Diabetes - Pediatrics and Devices Modules
Version 1.0 (Provisional)

Prepared by the
CDISC Type 1 Diabetes Standards Development Team

Notes to Readers
- This is the provisional Version 1.0 of the Therapeutic Area Data Standards Modules for Type 1 Diabetes - Pediatrics and Devices.
- This document is based on CDA SHG v2.0, CDASH Model 1.0, and SDTM v1.7 and the SDTM Implementation Guides (SIDM011v3.1, SIDM012v3.1, and SIDM013v1.10).

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023-09-22</td>
<td>1.0 Provisional</td>
</tr>
</tbody>
</table>

See Appendix A1 for Representations and Warranties, Limitations of Liability, and Disclaimers.
Hypoglycemic Episodes Analysis Dataset

Measures of Renal Function
- Proteinuria
- Estimated GFR

Renal Replacement Therapy
- ADGFR: eGFR & Cr Criteria for the Renal Composite Endpoint Evaluation
- ADRENAL: All Qualifying Criteria and Renal Endpoint Evaluation
- ADTTE: Time-to-Event Analysis

DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use
- Devices Used to Manage Diabetes

Blinded CGM Device
- CGM Device Properties and Settings
- DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use

Device History
- Devices Used to Manage Diabetes

Subject-Level Analysis Data Example
- Hypoglycemic Episodes Analysis Dataset
- Hypoglycemic Episodes Summary Analysis Results
- HbA1c Analysis Dataset
- HbA1c Analysis Results
- Self-Monitored Glucose Profile Analysis Datasets
- Self-Monitored Glucose Profile Analysis Results
- Mixed-Meal Tolerance Test Datasets
- Mixed-Meal Tolerance Test Analysis Results

CDASH

Diabetes Complication History
- Self-Monitoring of Blood Glucose
- Meal Tolerance Test
- Hypoglycemic Events

Measures of Renal Function
- Proteinuria
- Estimated GFR

Renal Replacement Therapy
- ADGFR: eGFR & Cr Criteria for the Renal Composite Endpoint Evaluation
- ADRENAL: All Qualifying Criteria and Renal Endpoint Evaluation
- ADTTE: Time-to-Event Analysis

DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use
- Devices Used to Manage Diabetes

Blinded CGM Device
- CGM Device Properties and Settings
- DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use

Device History
- Devices Used to Manage Diabetes

Subject-Level Analysis Data Example
- Hypoglycemic Episodes Analysis Dataset
- Hypoglycemic Episodes Summary Analysis Results
- HbA1c Analysis Dataset
- HbA1c Analysis Results
- Self-Monitored Glucose Profile Analysis Datasets
- Self-Monitored Glucose Profile Analysis Results
- Mixed-Meal Tolerance Test Datasets
- Mixed-Meal Tolerance Test Analysis Results

SDTM

Diabetes Complication History
- Self-Monitoring of Blood Glucose
- Meal Tolerance Test
- Hypoglycemic Events

Last Meal and Last Diabetic Study Treatment
- Precipitating Factors, Third Party Asst, Adverse Event

Mixed-Meal Tolerance Test Analysis Results
- Mixed-Meal Tolerance Test Datasets

CDASH

Diabetes Complication History
- Self-Monitoring of Blood Glucose
- Meal Tolerance Test
- Hypoglycemic Events

Measures of Renal Function
- Proteinuria
- Estimated GFR

Renal Replacement Therapy
- ADGFR: eGFR & Cr Criteria for the Renal Composite Endpoint Evaluation
- ADRENAL: All Qualifying Criteria and Renal Endpoint Evaluation
- ADTTE: Time-to-Event Analysis

DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use
- Devices Used to Manage Diabetes

Blinded CGM Device
- CGM Device Properties and Settings
- DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use

Device History
- Devices Used to Manage Diabetes

Subject-Level Analysis Data Example
- Hypoglycemic Episodes Analysis Dataset
- Hypoglycemic Episodes Summary Analysis Results
- HbA1c Analysis Dataset
- HbA1c Analysis Results
- Self-Monitored Glucose Profile Analysis Datasets
- Self-Monitored Glucose Profile Analysis Results
- Mixed-Meal Tolerance Test Datasets
- Mixed-Meal Tolerance Test Analysis Results

ADaM

Diabetic Kidney Dz v1.0

Renal Replacement Therapy
- ADGFR: eGFR & Cr Criteria for the Renal Composite Endpoint Evaluation
- ADRENAL: All Qualifying Criteria and Renal Endpoint Evaluation
- ADTTE: Time-to-Event Analysis

DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use
- Devices Used to Manage Diabetes

Blinded CGM Device
- CGM Device Properties and Settings
- DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use

Device History
- Devices Used to Manage Diabetes

Subject-Level Analysis Data Example
- Hypoglycemic Episodes Analysis Dataset
- Hypoglycemic Episodes Summary Analysis Results
- HbA1c Analysis Dataset
- HbA1c Analysis Results
- Self-Monitored Glucose Profile Analysis Datasets
- Self-Monitored Glucose Profile Analysis Results
- Mixed-Meal Tolerance Test Datasets
- Mixed-Meal Tolerance Test Analysis Results

T1D Peds & Dev v1.0

DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use
- Devices Used to Manage Diabetes

Blinded CGM Device
- CGM Device Properties and Settings
- DKA Events Prior to Study Start
- History of Autoimmune Disease
- DKA Laboratory
- DKA Symptoms/Precipitating Factors
- DKA Event – Device in Use

Device History
- Devices Used to Manage Diabetes

Subject-Level Analysis Data Example
- Hypoglycemic Episodes Analysis Dataset
- Hypoglycemic Episodes Summary Analysis Results
- HbA1c Analysis Dataset
- HbA1c Analysis Results
- Self-Monitored Glucose Profile Analysis Datasets
- Self-Monitored Glucose Profile Analysis Results
- Mixed-Meal Tolerance Test Datasets
- Mixed-Meal Tolerance Test Analysis Results
### Hypoglycemic Episodes Analysis Dataset

**ADGFR:** eGFR & Cr Criteria for the Renal Composite Endpoint Evaluation

**ADRENAL:** All Qualifying Criteria and Renal Endpoint Evaluation

**ADTTE:** Time-to-Event Analysis

---

<table>
<thead>
<tr>
<th>CDASH</th>
<th>ADaM</th>
<th>T1D Peds &amp; Dev v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH</td>
<td>DE</td>
<td>CM</td>
</tr>
<tr>
<td>LB</td>
<td>FAAE</td>
<td>FACM</td>
</tr>
<tr>
<td>AG</td>
<td>AE</td>
<td>DU</td>
</tr>
<tr>
<td>CE</td>
<td>DE</td>
<td>RP</td>
</tr>
<tr>
<td>TS</td>
<td>CM</td>
<td>VS</td>
</tr>
<tr>
<td>MH</td>
<td>DP</td>
<td>RP</td>
</tr>
<tr>
<td>CM</td>
<td>LB</td>
<td>DO</td>
</tr>
<tr>
<td>DI</td>
<td>CM</td>
<td>RP</td>
</tr>
<tr>
<td>EX</td>
<td>FH</td>
<td>CM</td>
</tr>
<tr>
<td>LB</td>
<td>RELDEV</td>
<td></td>
</tr>
<tr>
<td>ML</td>
<td>VS</td>
<td>RP</td>
</tr>
<tr>
<td>FA</td>
<td>DE</td>
<td>RP</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>SDTM</th>
<th>ADaM</th>
<th>Diabetic Kidney Dz v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH</td>
<td>DE</td>
<td>CM</td>
</tr>
<tr>
<td>AG</td>
<td>AE</td>
<td>DU</td>
</tr>
<tr>
<td>CE</td>
<td>DE</td>
<td>RP</td>
</tr>
<tr>
<td>TS</td>
<td>CM</td>
<td>VS</td>
</tr>
<tr>
<td>AG</td>
<td>DP</td>
<td>RP</td>
</tr>
<tr>
<td>DD</td>
<td>CM</td>
<td>VS</td>
</tr>
<tr>
<td>MH</td>
<td>DP</td>
<td>RP</td>
</tr>
<tr>
<td>CE</td>
<td>CM</td>
<td>VS</td>
</tr>
<tr>
<td>LB</td>
<td>RELDEV</td>
<td></td>
</tr>
<tr>
<td>PR</td>
<td>VS</td>
<td>RP</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>ADaM</th>
<th>Diabetic Kidney Dz v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH</td>
<td>DE</td>
</tr>
<tr>
<td>AG</td>
<td>AE</td>
</tr>
<tr>
<td>CE</td>
<td>DE</td>
</tr>
<tr>
<td>TS</td>
<td>CM</td>
</tr>
<tr>
<td>AG</td>
<td>DP</td>
</tr>
<tr>
<td>DD</td>
<td>CM</td>
</tr>
<tr>
<td>MH</td>
<td>DP</td>
</tr>
<tr>
<td>CE</td>
<td>CM</td>
</tr>
<tr>
<td>LB</td>
<td>RELDEV</td>
</tr>
<tr>
<td>PR</td>
<td>VS</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>ADaM</th>
<th>Diabetic Kidney Dz v1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH</td>
<td>DE</td>
</tr>
<tr>
<td>AG</td>
<td>AE</td>
</tr>
<tr>
<td>CE</td>
<td>DE</td>
</tr>
<tr>
<td>TS</td>
<td>CM</td>
</tr>
<tr>
<td>AG</td>
<td>DP</td>
</tr>
<tr>
<td>DD</td>
<td>CM</td>
</tr>
<tr>
<td>MH</td>
<td>DP</td>
</tr>
<tr>
<td>CE</td>
<td>CM</td>
</tr>
<tr>
<td>LB</td>
<td>RELDEV</td>
</tr>
<tr>
<td>PR</td>
<td>VS</td>
</tr>
</tbody>
</table>
• Document Maps
• Modeling Strategy
• Modeling Highlights
• Known Issues
Diabetes History
Diabetes History
Diabetes History
Diabetic Ketoacidosis Events Prior to Study Start

Ex. 1 CRF
Diabetes & DKA History - Summary

Ex. 1 SDTM
- TM: Diagnosis & Episodes
- MH: Diabetes Diagnosis, Last Pre-study DKA Episode
- FAMH: No. of DKA Episodes
- SM: Last Pre-study DKA Episode

Ex. 2 CRF
Diabetes & DKA History - Detailed

Ex. 2 SDTM
- MH: Diabetes Diagnosis, DKA Events with Severity

Key
- Observation
- Observation Result
- Terminology

Without known diabetes diagnosis

Subject participates in

Observation of Symptoms

results in

Symptoms

triggers

Laboratory Tests

includes

Diagnostic Process

has date

may result in

Laboratory Test Results

DKA Diagnosis

results in

Severity Classification

DKA Severity Result

such as

- Mild
- Moderate
- Severe
Diabetes History
Diabetic Ketoacidosis Events Prior to Study Start

**Example 1**

<table>
<thead>
<tr>
<th>Medical History Term</th>
<th>Type 1 Diabetes Mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis</td>
<td></td>
</tr>
<tr>
<td>Did the subject ever have DKA?</td>
<td></td>
</tr>
<tr>
<td>Did the subject present with DKA when the diabetes diagnosis was made?</td>
<td></td>
</tr>
<tr>
<td>How many episodes of DKA has the subject had since diagnosis of type 1 diabetes mellitus?</td>
<td></td>
</tr>
<tr>
<td>Start Date of DKA Episode</td>
<td></td>
</tr>
<tr>
<td>Severity of DKA episode</td>
<td></td>
</tr>
<tr>
<td>Did the subject have cerebral edema with the DKA episode?</td>
<td></td>
</tr>
</tbody>
</table>

**Example 2**

<table>
<thead>
<tr>
<th>Medical History Category</th>
<th>DKA History associated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis of type 1 diabetes mellitus</td>
<td></td>
</tr>
<tr>
<td>Did the subject ever have DKA?</td>
<td></td>
</tr>
<tr>
<td>Did the subject present with DKA when the diabetes diagnosis was made?</td>
<td></td>
</tr>
<tr>
<td>How many episodes of DKA has the subject had since diagnosis of type 1 diabetes mellitus?</td>
<td></td>
</tr>
<tr>
<td>Start Date of DKA Episode</td>
<td></td>
</tr>
<tr>
<td>Severity of DKA episode</td>
<td></td>
</tr>
<tr>
<td>Did the subject have cerebral edema with the DKA episode?</td>
<td></td>
</tr>
</tbody>
</table>

Did the subject have cerebral edema with the DKA episode?  
What was the start date of the last episode of DKA prior to study start?
Diabetes History
Diabetic Ketoacidosis Events Prior to Study Start

Modeling Strategy

• Medical History (MH) domain for:
  • Type 1 diabetes
  • Occurrence of any DKA episodes
  • Individual DKA episodes
  • Cerebral edema associated with DKA

Example 1

Example 2
Modeling Highlights

• Use of disease milestones
  • Trial Disease Milestones (TM) domain to define the disease milestones of interest for the study
  • Subject Disease Milestones (SM) domain to record occurrences of each milestone for each subject

• Findings About Medical History (FAMH) domain for number of DKA episodes since T1D diagnosis

• Use of:
  • MHREASDX NSV to represent whether DKA was a presenting sign at diabetes diagnosis. Derivation of reason text from the collected Yes/No/Unknown is specified in Define-XML metadata.
  • MHEVDTYP to indicate that MHSTDTC is date of diagnosis
  • MHEVINTX to indicate “since type 1 diabetes diagnosis” for individual DKA episodes and “lifetime” for any occurrence of DKA.
  • MHGRPID to group occurrence of cerebral edema with the associated DKA episode.
Diabetes History
Duration of Type 1 Diabetes
Diabetes History
History of Autoimmune Disease
Modeling Strategy

• History of autoimmune disease modeled as medical history:
  • Medical History (MH) domain for the subject’s history
  • Associated Persons Medical History (APMH) domain for family history

• Immunogenicity Specimen Assessments (IS) domain for results of supportive antibody tests.
Diabetes History
History of Autoimmune Disease

Modeling Highlights

• Convention for representation of occurrence of pre-specified groups of conditions (e.g., occurrence of autoimmune disease other than type 1 diabetes)
  • Same value in MHTERM and either MHCAT or MHSCAT to indicate that the record represents information about a category of events
  • MHPRESP = “Y” to indicate that the value of MHTERM is pre-specified
  • MHOCCUR is “Y” or “N” to indicate whether or not the group of conditions occurred for the subject (or associated person)

• Use of:
  • MHSUABTS NSV to indicate whether a supporting antibody test was performed for the autoimmune disease shown in MHTERM.
  • ISTSTOPO NSV to indicate the operation objective of the test (i.e., whether the test was screening for or quantifying the antibody specified in ISTESTCD / ISTEST).
  • ISBDAGNT NSV to indicate the binding agent for the test.
Assumptions in the Immunogenicity Specimen Assessments (IS) domain
- Defined in SDTMIG v3.3 as “A findings domain for assessments that determine whether a therapy induced an immune response”
- Expect updates in SDTMIG v3.4 to include pathological antibodies found in autoimmune disease
- Modeling follows SDTMIG v3.4

CRF annotation for Associated Person Domains
- Use APMH annotation to make it clear CRF is for the associated person data

Use of the Non-standard Variable MHREASDX
- In DKA Events Prior to Study Start the NSV MHREASDX was used to represent the CRF question “Was diabetic ketoacidosis the reason for diagnosis of type 1 diabetes mellitus?”

Pre-specified Groups of Medical History Conditions
- Use of MHTERM and MHCAT or MHSCAT for groups/category of medical history conditions
On-study Diabetic Ketoacidosis
On-study Diabetic Ketoacidosis

Modeling Strategy

- Adverse Events (AE) domain for details of the DKA episode (e.g., start date, severity, relationship to study treatment, relationship to device(s))
- Findings About Adverse Events (FAAE) dataset for:
  - Recording the occurrence pre-specified adverse events (i.e., cerebral edema)
  - Action Taken / Relationship with multiple devices
  - Precipitating factors
- Laboratory Test Results (LB) domain for results of lab tests associated with the DKA episode
- Clinical Events (CE) domain for signs and symptoms of DKA
- Device Exposure (DX) domain for details of devices in use at the time of the DKA episode
- Device In-Use (DU) domain for device setting values at the time of the DKA episode
- Use of disease milestones:
  - Trial Disease Milestones (TM) domain to define a DKA episode as an event of interest in the study
  - Subject Disease Milestones (SM) domain to record and identify DKA episodes for each study
  - Use of the MIDS variable in all domains to associate collected data with a particular DKA episode
  - Use of the RELMIDS variable to record the temporal relationship between the collected data and the DKA episode
On-study Diabetic Ketoacidosis

Modeling Highlights

• Use of:
  • AESSEVCN and AESTDSEV NSVs to store, respectively, the name of a standardized set of severity criteria and the severity of the DKA episode according to the named criteria.

• Use of “contingent visits” for the set of assessments triggered by the occurrence each DKA episode.
  • More information on contingent visits is available in SDTMIG v3.3, Section 7.3.1.1 - Trial Visit Issues

• Representation of Action Taken and Relationship with device(s) with respect to a single AE:
  • Use of CRF question “Was there a relationship, or action taken, with any device?”
## On-study Diabetic Ketoacidosis Modeling Highlights

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>SPOEVID</th>
<th>FASEQ</th>
<th>FALNKID</th>
<th>PATESTDID</th>
<th>PATEST</th>
<th>FAOSEQ</th>
<th>FAOBJ</th>
<th>FAOQRS</th>
<th>FASTREC</th>
<th>VISITNUM</th>
<th>VISIT</th>
<th>MIDS</th>
<th>RELMIDS</th>
<th>MIDSTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>T001</td>
<td>FA</td>
<td>001</td>
<td>E001</td>
<td>R1</td>
<td>R1</td>
<td>R1</td>
<td>R1</td>
<td>991</td>
<td>DKA1</td>
<td>2015-09-01</td>
<td>2015-09-01</td>
<td>DKA1</td>
<td>DKA1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>T001</td>
<td>FA</td>
<td>001</td>
<td>E001</td>
<td>A1</td>
<td>A1</td>
<td>A1</td>
<td>A1</td>
<td>991</td>
<td>DKA1</td>
<td>2015-09-01</td>
<td>2015-09-01</td>
<td>DKA1</td>
<td>DKA1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>T001</td>
<td>FA</td>
<td>001</td>
<td>E001</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>R2</td>
<td>991</td>
<td>DKA1</td>
<td>2015-09-01</td>
<td>2015-09-01</td>
<td>DKA1</td>
<td>DKA1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>T001</td>
<td>FA</td>
<td>001</td>
<td>E001</td>
<td>A2</td>
<td>A2</td>
<td>A2</td>
<td>A2</td>
<td>991</td>
<td>DKA1</td>
<td>2015-09-01</td>
<td>2015-09-01</td>
<td>DKA1</td>
<td>DKA1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Known Issues

• Populating Variables --ACNDEV and --RLDEV When Multiple Values are Collected
  • Proposed use of “MULTIPLE” keyword with Findings About.

• Use of Adverse Event Severity (AESEV)
  • Proposed use of AESTDSEV and AESSEVCN NSVs for representation of AE severity assigned according to a named set of criteria (e.g., ADA Consensus Guidelines or ISPAD Clinical Practice Consensus Guidelines).
On-study Diabetic Ketoacidosis
Devices in Diabetes
Devices in Diabetes
Devices in Diabetes

Device Identification and Component Relationships
Device Identification and Component Relationships - Example 2

- Sensor
- Transmitter

CGM Device

- CGM-1
- Sensor
- Transmitter
- CGM-SNS-1
- CGM-TRN-1

- 12
- 13
- 14
- 19
- 20
- 21
- 26
- 27
- 28
- 6
- 7
- 12
- 13
- 14

- Get new CGM!
- Replace CGM sensor
- Replace CGM sensor
- Replace CGM sensor

T1D - Pediatrics and Devices Publication Webinar
Devices in Diabetes

Device Properties and Settings

Device Properties (DO domain)
- Device Identifier (BDEVID)
  - software name
  - software version
  - FDA device classification

Device (DU domain)
- Device properties
- Device in-use (DU) domain

Ex. 1 SDTM
DO: Blinded CGM Devices

Ex. 2 SDTM
DU: Settings for High and Low Glucose Alarms

Device Properties and Settings
Devices in Diabetes

Device Exposure

Ex. 1 SDTM
DX: CGM Device and Usage
AE: Site Reaction and Relationship to Device

Ex. 1 SDTM
TM: First Use of Insulin Pump & First Use of CGM
D1: Types of Devices & Models
D2: Insulin Pump & CGM Pump History
SM: First Use and Current Use of Insulin Pump & CGM
PADX: Cumulative Exposure

Subject

Device Exposure represented in Device Exposure (DX) domain

T1D - Pediatrics and Devices Publication Webinar
Devices in Diabetes

Device Attachment

Ex. 1 SDTM
DX: CGM Device and Usage
AE: Site Reaction and Relationship to Device
Devices in Diabetes

Device History

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>SUBDOMAIN</th>
<th>SPID</th>
<th>SEQ</th>
<th>DXID</th>
<th>DXSEQ</th>
<th>DXRT</th>
<th>DXCAT</th>
<th>DXCAT</th>
<th>DXRESP</th>
<th>DXCURR</th>
<th>VISITNUM</th>
<th>VISIT</th>
<th>DXDT1</th>
<th>DXDT2</th>
<th>DXEXPPT</th>
<th>DXEXPPT</th>
<th>MRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>T1D-01</td>
<td>DX</td>
<td>0501</td>
<td>IR-0</td>
<td>1</td>
<td>Any Insulin Pump Device</td>
<td>INSULIN PUMP HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-01-15</td>
<td>2018-05-02</td>
<td>STIP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>T1D-01</td>
<td>DX</td>
<td>0501</td>
<td>IP-07-0001</td>
<td>2</td>
<td>Insulin Infusion Pump Device</td>
<td>INSULIN PUMP HISTORY</td>
<td>CURRENT</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-01-15</td>
<td>2018-05-02</td>
<td>STIP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>T1D-01</td>
<td>DX</td>
<td>0301</td>
<td>CGM-0</td>
<td>3</td>
<td>Any Continuous Glucose Monitoring Device</td>
<td>CONTINUOUS GLUCOSE MONITORING HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-01-15</td>
<td>2018-04-02</td>
<td>CSGM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>T1D-01</td>
<td>DX</td>
<td>0301</td>
<td>CGM-2</td>
<td>4</td>
<td>ANOTHER, CGM Plus</td>
<td>CONTINUOUS GLUCOSE MONITORING HISTORY</td>
<td>CURRENT</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-01-15</td>
<td>2018-08-10</td>
<td>CSGM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>T1D-01</td>
<td>DX</td>
<td>0302</td>
<td>IR-0</td>
<td>1</td>
<td>Any Insulin Pump Device</td>
<td>INSULIN PUMP HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>N</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-02-22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>T1D-01</td>
<td>DX</td>
<td>0302</td>
<td>CGM-0</td>
<td>2</td>
<td>Any Continuous Glucose Monitoring Device</td>
<td>CONTINUOUS GLUCOSE MONITORING HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-02-15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>T1D-01</td>
<td>DX</td>
<td>0302</td>
<td>CGM-1</td>
<td>3</td>
<td>Generic Monitor, CGM Standard</td>
<td>CONTINUOUS GLUCOSE MONITORING HISTORY</td>
<td>CURRENT</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-02-13</td>
<td>2018-01-31</td>
<td>CSGM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>T1D-01</td>
<td>DX</td>
<td>0303</td>
<td>IR-0</td>
<td>1</td>
<td>Any Insulin Pump Device</td>
<td>INSULIN PUMP HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-02-05</td>
<td>2017-12-12</td>
<td>BEFORE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>T1D-01</td>
<td>DX</td>
<td>0303</td>
<td>CGM-0</td>
<td>2</td>
<td>Any Continuous Glucose Monitoring Device</td>
<td>CONTINUOUS GLUCOSE MONITORING HISTORY</td>
<td>GENERAL</td>
<td>Y</td>
<td>N</td>
<td>1</td>
<td>Vis1 1</td>
<td>2018-02-05</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

T1D - Pediatrics and Devices Publication Webinar

59
Devices in Diabetes

Device Events

Ex. 1 CRF
Study Device Events

Ex. 2 CRF
Adverse Event - Including Evaluation wrt Device(s)

Ex. 1 SDTM
DI: CGM Device Identification
DE: Device Events
AE: Adverse Events with Evaluation of Relationship/Action Taken with Device

Ex. 2 SDTM
DI: CGM and Component Identification
DE: Device Events
AE: Adverse Events with Evaluation of Relationship/Action Taken with Device(s)

Ex. 3 SDTM
DE: Device-Reported Events

Relationships between Devices
Devices in Diabetes
Device Events

Modeling Highlights

• Collection and representation of relationship and action taken with a specified device or its individual components
  • CGM devices modeled as individual devices (identified by serial number) and components modeled as types of device (identified by manufacturer and catalog number).
  • AE CRF shows collection of information about device as a whole vs components.
Known Issues

• Device Components
  • Alignment with GMDN: acknowledgement of issues with use of GMDN terminology, especially when modeling device components
  • Exposure to devices: proposed modeling for use of “any device” vs specific devices of a particular type.
  • Component replacement: proposed use of Device Tracking and Disposition (DT) domain to represent component replacement.

• Use of the Non-standard Variable (NSV) AERLDEV
  • New variable for “Relationship To Device” being proposed for addition to standard.
  • Variable name still under discussion

• Populating Variables --ACNDEV and --RLDEV When Multiple Values are Collected
  • Proposed use of “MULTIPLE” keyword with Findings About.

• Population of --OCCUR
  • Assign value of “Y” for pre-specified terms selected from a list (e.g. a drop-down with no accompanying Yes/No question) when --OCCUR is present in dataset.
Devices in Diabetes
Continuous Glucose Monitor

TAUG-Diabetes v1.0, Section 3.2.1 - SMBG

Devices in Diabetes Module
- Device Identification and Component Relationships
- Device Properties and Settings
- Device Exposure
- Device Events

SDTMIG v3.3, Section 6.3.6 - Laboratory Test Results
Continuous Glucose Monitor

Modeling Strategy

- Laboratory Test Results (LB) domain for device-produced, summary results

- Device Properties (DO) domain for settings that are modifiable but are defined in the protocol as static during the study.
Continuous Glucose Monitor

Modeling Highlights

- LBTESTCD / LBTEST used to indicate the test performed by the device:
  - May indicate the tested substance (e.g., glucose, plasma equivalent glucose)
  - May indicate a test describing the distribution of results (e.g., plasma equivalent glucose distribution)
  - May identify standalone summary measures like Glucose Management Indicator (GMI)

- LBCOLSRT NSV may be used to indicate the summary statistic used to produce the result (e.g., mean, standard deviation, etc.)

- LBANMETH indicates the analysis method applied to obtain a summarized result (e.g., “GMI % FORMULA” or “GMI MMOL/MOL FORMULA”)

- LBDTC and LBENDTC define the start and end of the period over which results have been summarized

- DOTSTDTL may be used to further describe the property (e.g., “HIGH” or “LOW” for “Glucose Target Level” or “Glucose Alert Threshold”)
Continuous Glucose Monitor

Known Issues

• Large Volume of Raw Data
  • Representation of summary data in SDTM
Continuous Glucose Monitor
Insulin Management
Insulin Management

Modeling Strategy

- The domain(s) used for representation of insulin administration depend on whether insulin is the protocol-specified study treatment:
  - Exposure domains are used when insulin is the protocol-specified study treatment (Example 3):
    - The Exposure (EX) domain used to represent administration of study treatment in the protocol-specified unit (EXDOSU)
    - The Exposure as Collected (EC) domain may be used to represent study treatment administration as collected
  - The Concomitant and Prior Medications (CM) domain is used when insulin is not the protocol-specified study treatment (Examples 1 and 2)

- Information about insulin administration may be represented the Findings About (FA) domain when the timing of the assessment is not the same as the timing of the administration
  - Findings About Concomitant and Prior Medications (FACM) dataset used to represent mean total daily dose over the last 7 days in Example 1.

- Device In-Use (DU) domain for device settings that are modifiable during the study
  - Insulin pump settings in Example 2
Insulin Management

Modeling Highlights

• Representation of administration of pre-mixed insulin as:
  • A single record in EC for blinded administration (as collected)
  • Two records in EX for unblinded administration, with dose derived according to the mixture ratio

• Use of:
  • FACOLSRT to indicate the type of collected summary result:
    • Example 1: FACOLSRT = “MEAN” for “mean total daily dose over the last 7 days”, where FATEST = “Total Daily Dose” and FAEVLINT = “-P7D” to define the evaluation interval as the 7 days before the date in FADTC
  • CMCOLSDT to indicate the type of collected summary dose:
    • Example 2: CMCOLSDT = “MEAN” to indicate that CMDOSTOT contains the mean total daily dose for the dosing period starting on the date in CMSTDTC and ending on the date in CMENDTC
  • DUTPT to indicate the timepoint for which the setting value applies:
    • Example 2: DUTPT is “MORNING”, “LUNCH”, “DINNER” or “NIGHT” to indicate the timepoint for which the “Carbohydrate to Insulin Ratio Setting” value applies when the device allows different setting values for different timepoints.
  • --PSTRG and --PSTRGU variables to store the “pharmaceutical strength”, or concentration, of insulin (e.g., ECPSTRG = 100 and ECPSTRGU = “IU/mL” for U-100 insulin)
Insulin Management

Known Issues

• Use of UNIT Code, “U”
  • At the time of publication, the definition of the code “U” ("A single undivided thing occurring in the composition of something else") suggested that it was not an appropriate unit for the quantification of insulin products.
  • A terminology change request had been submitted
  • An updated definition for “U” was released with Terminology Package 44 on 25-Sep-2020: "A single undivided thing occurring in the composition of something else; a unit representing equivalence with a reference measurement."

• Representation of Insulin Parameters (e.g., carbohydrate ratio, insulin sensitivity)
  • Examples show use of device domains when set on insulin pump
  • Alternative representation (e.g., FACM) may be needed when not set on a device

• Populating the DUDTC Variable for Devices in Continuous Use
  • SDTMIG-MD will be updated to allow for setting change date/time in DUDTC when device in continuous use and device determines timing of operation affected by the setting.
Insulin Management
Pediatric Growth and Growth Percentiles
Pediatric Growth and Growth Percentiles

Modeling Strategy

• Vital Signs (VS) domain for all vital signs measurements and percentiles

Modeling Highlights

• Use of:
  • VSANMETH to indicate the criteria for calculating percentiles
  • VSRESCAT to represent the categorization of BMI percentile results (e.g., normal, overweight, obese)
  • VSGRPID to group the percentile with the underlying vital signs measurement
Pediatric Growth and Growth Percentiles
Pubertal Status
Pubertal Status
Reproductive Status

Modeling Strategy
• Reproductive System Findings (RP) domain for testicular volume measurements

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>RPSEQ</th>
<th>RPTESTCD</th>
<th>RPTEST</th>
<th>RPCAT</th>
<th>RPSCAT</th>
<th>RPORRES</th>
<th>RPORRESU</th>
<th>RPSTRES</th>
<th>RPSTRESU</th>
<th>RPLAT</th>
<th>RPMETHOD</th>
<th>VISITNUM</th>
<th>VISIT</th>
<th>IPDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ABC123</td>
<td>RP</td>
<td>0001</td>
<td>1</td>
<td>VOLUME</td>
<td>Volume</td>
<td>PUBLERTAL STATUS</td>
<td>MALE</td>
<td>6</td>
<td>mL</td>
<td>8</td>
<td>8</td>
<td>mL</td>
<td>TESTIS</td>
<td>RIGHT</td>
<td>ORCHIDOMETRY</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>ABC123</td>
<td>RP</td>
<td>0001</td>
<td>2</td>
<td>VOLUME</td>
<td>Volume</td>
<td>PUBLERTAL STATUS</td>
<td>MALE</td>
<td>9</td>
<td>mL</td>
<td>9</td>
<td>9</td>
<td>mL</td>
<td>TESTIS</td>
<td>LEFT</td>
<td>ORCHIDOMETRY</td>
<td>1</td>
</tr>
</tbody>
</table>

• Medical History (MH) domain for historical date of first menstruation (menarche)

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MHSEQ</th>
<th>MHTERM</th>
<th>MHCAT</th>
<th>MHSCAT</th>
<th>MHOCUR</th>
<th>VISITNUM</th>
<th>VISIT</th>
<th>MHDT</th>
<th>MHSTDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ABC123</td>
<td>MH</td>
<td>0001</td>
<td>1</td>
<td>MENARCHE</td>
<td>PUBLERTAL STATUS</td>
<td>FEMALE</td>
<td>Y</td>
<td>Y</td>
<td>1</td>
<td>SCREENING</td>
<td>2017-05-05</td>
</tr>
<tr>
<td>2</td>
<td>ABC123</td>
<td>MH</td>
<td>0002</td>
<td>1</td>
<td>MENARCHE</td>
<td>PUBLERTAL STATUS</td>
<td>FEMALE</td>
<td>Y</td>
<td>N</td>
<td>1</td>
<td>SCREENING</td>
<td>2017-05-05</td>
</tr>
</tbody>
</table>

• Clinical Events (CE) domain for on-study date of first menstruation (menarche)
Pubertal Status

Known Issues

• Modeling of Date of Menarche (MH)
  • SDTMIG v3.3 provides examples of other data related to menarche (e.g., Age at menarche) which have been represented in the Reproductive System Findings (RP) domain
  • Date of first menstruation has been modeled as the (start) date of menarche in Events domains because menarche was considered an event
    • Medical History (MH) used for historical menarche
    • Clinical Events (CE) for on-study menarche
  • The data was collected as a date and dates for medically significant events should not be represented as test results in the Findings --ORRES variable
Pubertal Status
<table>
<thead>
<tr>
<th>Full Name and Abbreviation</th>
<th>Subtitle (Where Applicable)</th>
<th>Copyright Permission Status</th>
<th>Supplement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Distress Scale (DDS)</td>
<td>DDS for Adults with Type 1 Diabetes (T1-DDS)</td>
<td>Granted</td>
<td>Supplement in progress</td>
</tr>
<tr>
<td></td>
<td>DDS for Parents of Teens with Type 1 Diabetes (Parent-DDS)</td>
<td>Granted</td>
<td>Supplement in progress</td>
</tr>
<tr>
<td></td>
<td>DDS for Partners of Adults with Type 1 Diabetes (Partner-DDS)</td>
<td>Granted</td>
<td>Supplement in progress</td>
</tr>
<tr>
<td>Diabetes Treatment Satisfaction Questionnaire (DTSQ)</td>
<td>DTSQ - Status</td>
<td>Denied</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DTSQ - Change</td>
<td>Denied</td>
<td></td>
</tr>
<tr>
<td>Glucose Monitoring System Satisfaction Survey (GMSS-T1D)</td>
<td>Version: Type 1 Diabetes (GMSS-T1D)</td>
<td>Granted</td>
<td>Supplement in progress</td>
</tr>
<tr>
<td>Hypoglycemic Confidence Scale (HCS)</td>
<td>Hypoglycemia Fear Survey</td>
<td>Requested</td>
<td>Supplement in progress</td>
</tr>
<tr>
<td></td>
<td>HFS - Parent (HFS-P)</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFS - Parent of Young Children (HFS-P-YC)</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td>Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE)</td>
<td>INSPIRE Survey - Child</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INSPIRE Survey - Teen</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INSPIRE Survey - Adult</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INSPIRE Survey - Parent</td>
<td>Requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>INSPIRE Survey - Partner</td>
<td>Requested</td>
<td></td>
</tr>
</tbody>
</table>

| Pediatric Quality of Life Inventory: 3.2 (PedQL) Diabetes Module | PEDSQL Acute Version: Toddlers (0-4 years) | Requested |
| PEDSQL Acute Version: Young Child (5-7 years) | Requested |
| PEDSQL Standard Version: Young Child (5-7 years) | Requested |
| PEDSQL Acute Version: Child (8-12 years) | Requested |
| PEDSQL Standard Version: Child (8-12 years) | Requested |
| PEDSQL Acute Version: Adolescent (13-18 years) | Requested |
| PEDSQL Standard Version: Adolescent (13-18 years) | Requested |
| PEDSQL Acute Version: Young Adult (18-25 years) | Requested |
| PEDSQL Standard Version: Young Adult (18-25 years) | Requested |
| PEDSQL Acute Version: Adult (>25 years) | Requested |
| PEDSQL Standard Version: Adult (>25 years) | Requested |
| Problem Areas in Diabetes (PAID) | PAID - Pediatric | Requested |
| PAID - Child | Requested |
| PAID - Parent of Child | Requested |
| PAID - Teen | Requested |
| PAID - Parent of Teens | Requested |
| PAID - Parent | Requested |

<table>
<thead>
<tr>
<th>Tanner Staging</th>
<th>Public Domain</th>
<th>Supplement in progress</th>
</tr>
</thead>
</table>

| Type 1 Diabetes and Life Measures (TIDAL) | Requested |
| Treatment Related Impact Measure for Diabetes (TRIM-D) | To be requested |
CDISC develops SDTM (tabulation) and ADaM (analysis) QRS supplements that provide information on how to structure the data in a standard format, validated by copyright-approved instruments. An instrument is a series of questions, tasks, or assessments used in clinical research to provide a qualitative or quantitative assessment of a clinical concept or task-based observation. Controlled Terminology is also developed to be used with the supplements.

CDISC creates supplements for three types of instruments:

- **Questionnaires**: Questionnaire instruments are stored in the Questionnaires (QS) domain and are named, standalone instruments design concept. Questionnaires often have a defined structure, format, and content, consist of conceptually related items that are typical methods for administration and analysis. Questionnaires consist of defined questions with a defined set of potential answers. Most often, they are used to generate quantitative statistics from a qualitative concept.

- **Functional Tests**: Functional Test instruments are stored in the Functional Tests (FT) domain and are named, standalone task-based evaluative assessment instruments. Functional Test is not a subjective assessment of how the subject generally performs. It is a performance measurement of the performance of the task by the subject in a specific instance. Functional Tests have documented methods for administration and analysis and require a subject to perform specific activities that are evaluated and recorded. Most often, Functional Tests are direct, quantitative measurements.

- **Clinical Classifications**: Named instruments whose output is an ordinal or categorical score that serves as a surrogate for, or ranking of, disease status, or other physiological or biological status. Usually, the instrument will be published in a professional journal or on a website.

Clinical Classifications are based on a trained healthcare professional’s observation of a subject’s health condition or status with input from associated clinical records review. Clinical Classifications may be based solely on objective data from clinical records, or may involve a clinical judgment or interpretation of the directly observable signs, behaviors, or other physical manifestations related to a condition or subject status. These physical manifestations may be findings that are typically represented in other SDTM domains, such as labs, vital signs, or clinical events. Therefore, Clinical Classifications may be composite scores based on diverse inputs. This assessment method differs from a more traditional question-and-answer interview commonly seen in questionnaires.
Thank you to the T1D Team
Thank You!
John, Rebecca, Richard and Kathy
Type 1 Diabetes Pediatrics & Devices Publication

John Owen, Head of Partnerships and Development, CDISC
Rebecca Baker, Standards Developer, CDISC
Kathleen Mellars, Consultant Standards Developer, CDISC
Richard Marshall, Consultant Standards Developer, CDISC

Thursday, 15 OCT 2020
11:00AM – 12:30PM EDT
Audience Questions

Will the TAUG also mention the SNOMED-CT code for Diabetes Type 1, LOINC codes for suggested tests, and UMDNS codes for classes of devices? We need these for retrieval from EHRs into SDTM.
If the device settings are not being used in analysis, no need to include DO even though specified in protocol. Is that correct?
Audience Questions

For the large amount of raw CGM data, has it been discussed as being separated out as a split domain based on LBTESTCD?
Rebecca: What is the reason for calculating vital signs percentiles in SDTM, instead of handling in ADaM?
Audience Questions

Can you clarify which data from devices are represented in SDTM or ADaM?
Audience Questions

Are there special rules for handling devices in SDTM?
Audience Questions

Does data have to be in SDTM format for submission to regulatory authorities for device approval?
Audience Questions

How do leave comments for the public review?
Audience Questions

Are the eCRFs available for download in machine readable format?
Audience Questions
Audience Questions
Audience Questions
Audience Questions
Audience Questions
Audience Questions
Audience Questions
Upcoming Learning Opportunities
2021 CDISC Upcoming Events

February 2021 – TechniCon Virtual Events

Submit Abstracts Now. Registration Open Soon!

April 2021 – Europe Virtual Event

2021 Europe Interchange
28-29 April

February 2021 – Abstract Submissions and Registration Coming Soon.
Free Upcoming Webinar Lineup – Registration Open!

Linking Data in SDTM
20 OCT 2020, 11:00 AM - 12:30 PM EDT
• Data collected together, or otherwise related to each other, may appear in different records or datasets when represented in SDTM-based datasets. All SDTM Identifier variables can be used for linking. Do you understand how each one can be used?

Introducing the Next Generation CDISC Library
22 OCT 2020, 11:00 AM - 12:30 PM EDT
• Join CDISC to learn about the new and exciting next generation CDISC Library and how we are managing the crossroads of standards and technology to shape the future by leveraging a more flexible, scalable, agile, and modernized suite of technology solutions.

Introducing the Analysis Results Standard: Project Start Up and Call for Volunteers
27 OCT 2020, 11:00 AM - 12:30 PM EDT
• Join us as we kick off the development of CDISC’s newest standard – Analysis Results Standard.

Introducing the Analysis Results Standard: Project Start Up and Call for Volunteers
10 NOV 2020, 11:00 AM - 12:30 PM EDT
• CDISC, with support from our partner TransCelerate Biopharma, is developing version 2.0 of the CDASH SAE Supplement, which will capture how to structure serious adverse events (SAE) concepts for regulated clinical trials.
Special Announcement

WEBINAR
INTRODUCING THE NEXT GENERATION CDISC LIBRARY

Date: 22 OCTOBER 2020  |  Time: 11:00 AM - 12:30 PM EDT

Learn about the new and exciting next generation CDISC Library and how CDISC is managing the crossroads of standards and technology.
New Virtual Training Methods

• CDISC Provides Many Ways to Begin or Continue Growing Your Standards Knowledge.
  • Popular self-paced training plus new Blended Learning and Virtual Classroom settings.
Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!