

# Type 1 Diabetes Pediatrics & Devices Publication

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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’

A screenshot of the GoToWebinar app's 'Questions' interface. It features a dark blue header with the word 'Questions' and a downward arrow. Below the header is a large white text area for entering a question. At the bottom of the interface is a grey bar containing a 'Send' button with a paper plane icon.



# 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

15<sup>th</sup> October 2020

- John Owen (CDISC)
- Rebecca Baker (CDISC)
- Richard Marshall (CDISC)
- Kathleen Mellars (CDISC)





# Type 1 Diabetes

Exercise  
&  
Nutrition

Therapeutic Area User Guide - Type 1 Diabe

Comments Due By  
26 October 2020

With support from the Laura M. and Henry B. J. Institute Charitable Trust, CDISC is developing new T1D standards that will extend published diabetes standards by developing machine readable modules in the following focus areas: Pathophysiology, Diagnosis, Prevention, Exercise, and Nutrition. These standards will make it easier for all stakeholders (clinicians, researchers, drug development companies, and regulatory authorities) to share and compare data to foster innovation and to evaluate the effectiveness of emerging T1D treatments.

Version 1.0 of the Therapeutic Area User Guide for Diabetes Exercise and Nutrition (TAUG T1D) is available for Public Review. The purpose of the Exercise and Nutrition modules is to describe how CDISC standards may be used to represent data pertaining to exercise and nutrition in Type 1 Diabetes studies.

We invite you to provide comments on TAUG T1D during the Public Review period.

- View the Draft TAUG T1D Exercise and Nutrition
- Provide comments/ suggestions for feedback.

You will need to log in or register for the CDISC Web to provide comments.

- Register for the Web: If you already have an account on Web or Web, use your tracking system, simply log in to your account. Web and Web use the same login credentials. CDISC Web is a different login from [www.cdisc.org](http://www.cdisc.org).

Public Review is a key quality step in our Standards Development Process. CDISC relies on your input to ensure neutral, consensus-based standards are developed and adopted by a diverse global community interested in improving clinical research. Thank you for contributing your time and expertise.

Webinar  
Public Review Webinar: Therapeutic Area User Guide for Type 1 Diabetes - Exercise and Nutrition

Comments Due By  
26 October 2020

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

<https://www.cdisc.org/public-review/therapeutic-area-user-guide-type-1-diabetes-exercise-and-nutrition>

The screenshot shows the CDISC website homepage. At the top, there is a dark blue navigation bar with 'Log in' and 'Create Account' links, and a search bar on the right. Below this is a white navigation menu with a red border containing the following items: 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', and 'Membership'. The main content area features a large video player on the left with the title 'CDISC - Clear Data. Clear Impact.' and a play button. To the right of the video is a white box with the text 'Clear Data. Clear Impact.' and a 'Learn More' button. The background of the page is decorated with a pattern of colored dots (red, yellow, green, blue) connected by dotted lines, forming a grid-like structure.

# Type 1 Diabetes – Pediatrics and Devices



New to CDISC Standards Education Resources Events Membership Members Only

[Home](#) / [Standards](#) / [Therapeutic Areas](#) / [Diabetes Type 1](#)

## Diabetes - Type 1

[Release Information](#) [Files and Links](#) [Public Review](#)

### Diabetes - Type 1 Therapeutic Area User Guide v1.0 - Exercise and Nutrition Modules

[Public Review runs through 26 Oct 2020.](#)

#### 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/136460/download>
2. <https://www.pmda.go.jp/files/000206449.pdf>

## Diabetes - Type 1

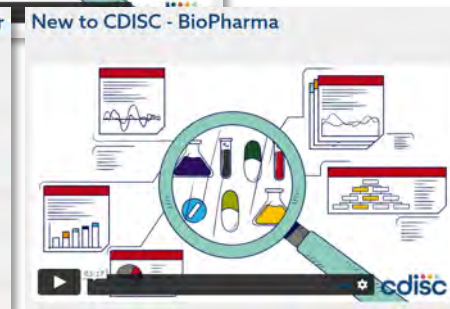
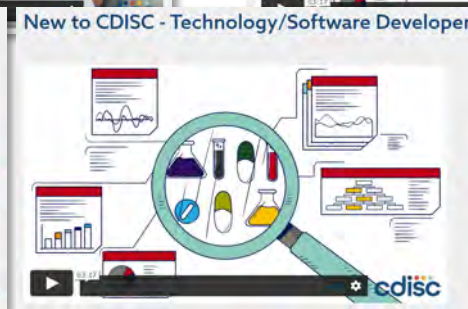
[Release Information](#) [Files and Links](#) [Public Review](#)

#### Files

- [Type 1 Diabetes Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules](#)
- [Type 1 Diabetes Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules Public Review Comments](#)
- [Type 1 Diabetes Therapeutic Area User Guide v1.0 - Pediatrics and Devices Modules TA Specification](#)



# Getting Started with CDISC Standards - Videos





# Getting Started with CDISC Standards – CDISC Primer

<https://www.cdisc.org/primer>

**CDISC Primer**

**cdisc**  
**PRIMER**  
*In collaboration with PHUSE*

Welcome to CDISC Primer!

The CDISC Primer brings together a series of short, animated videos as well as helpful links to introduce newcomers to the suite of CDISC Standards. To explore the Primer, click on one of the CDISC standards below.

**SEND**  
Tabulation for Animal Studies

**CDASH**  
Collection for Clinical Studies

**SDTMIG**  
Tabulation for Clinical Studies

**ADaM**  
Analysis for Clinical Studies

**Introduction**

Versions

Controlled Terminology

Traceability

Regulatory Requirements

Standards in Development

Knowledge Base

Education

# Getting Started with CDISC Standards - Webinars



**CDISC for Newcomers: Are You New Here?**

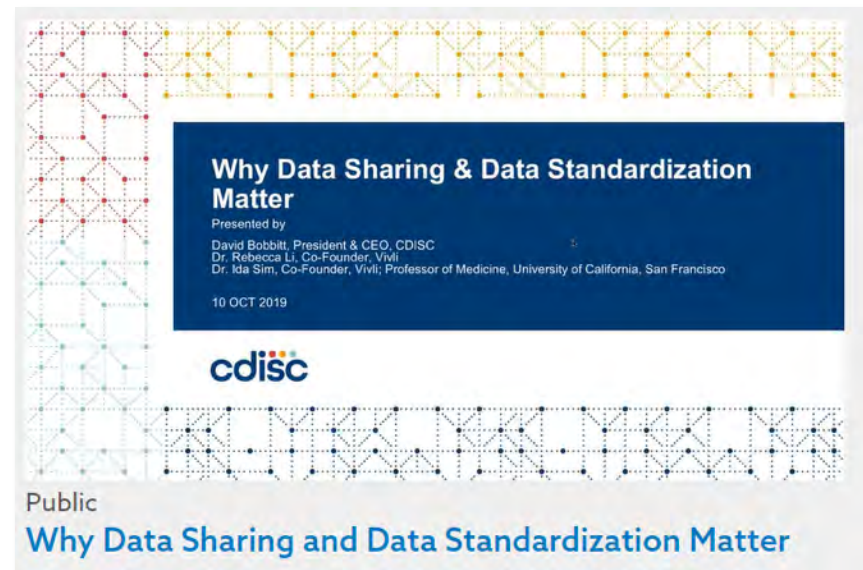
Presented by  
John Owen, Consultant Project Manager, CDISC

7 JAN 2019

**cdisc**

Public  
**CDISC for Newcomers - Are You New Here?**

[CDISC for Newcomers](#)



**Why Data Sharing & Data Standardization Matter**

Presented by  
David Bobbitt, President & CEO, CDISC  
Dr. Rebecca Li, Co-Founder, Vivli  
Dr. Ida Sim, Co-Founder, Vivli; Professor of Medicine, University of California, San Francisco

10 OCT 2019

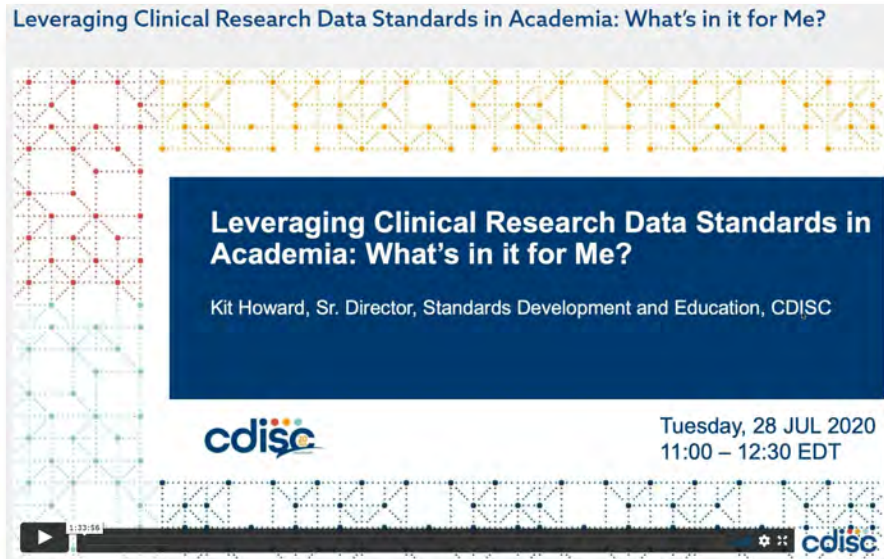
**cdisc**

Public  
**Why Data Sharing and Data Standardization Matter**

[Why Standards Matter](#)



# Getting Started with CDISC Standards - Webinars



[CDISC for Academics](#)

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>

Education



**Why we do it**  
Ensure authoritative knowledge transfer

- Virtual Classroom Training (New!)**
  - Immediate Feedback
  - Small Class Sizes
  - Remote Convenience
- Classroom Training**
  - Instructor Led
  - Public or In-House
  - Available in multiple languages
- Online Training**
  - Available for playback
  - Standards & hot topics
  - Bundle discounts available
  - Instructor-led blended online training
- Webinars**
  - Address industry hot topics
  - Discuss best practices
  - Tackle challenges

# Getting Started with CDISC Standards - Education

cdisc

Home Featured All Courses My Learning Help CDISC Learning System

Welcome to the  
CDISC Learning System

Purchase and enroll in CDISC web-based trainings.  
Online Courses

Online learning system where you can access your training modules and view your learning records.  
Learning System

Frequently asked questions and helpful info.  
Help and FAQ

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 standards development.

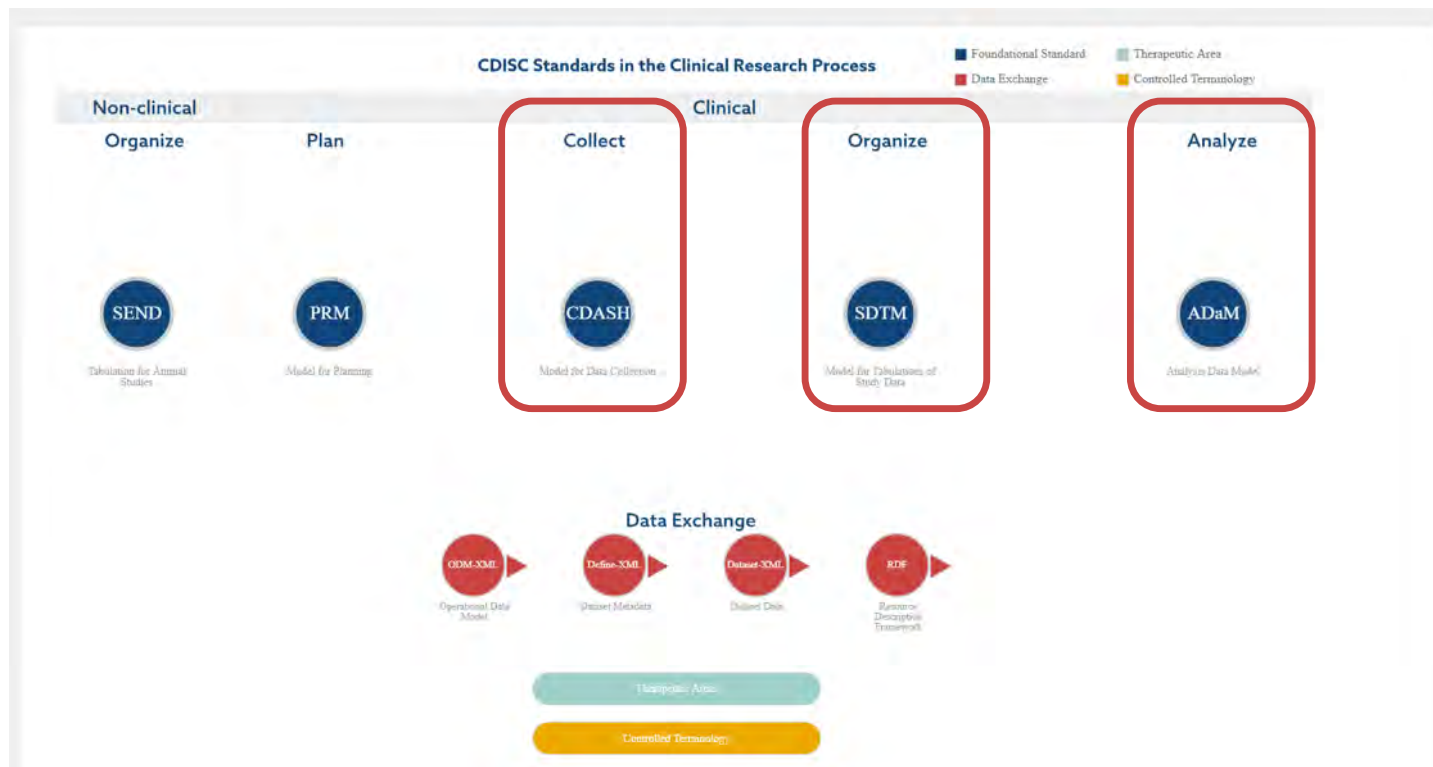
### Course-Level Learning Outcomes

- 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>



## CDASH

Description Versions Education Knowledge Base

CDASH establishes a standard way to collect data consistently across studies and sponsors so that data collection formats and structures provide clear traceability of submission data into the **SDTM**

Description Versions Education Knowledge Base Public Review Archive

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/genetics 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 a

## ADaM

- The SD
- Eac
- On
- On

Description Versions Education Knowledge Base

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>

Home / Standards / Therapeutic Areas

## Therapeutic Areas

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

Acute Kidney Injury

Alzheimer's

Asthma

Breast Cancer

Cardiovascular

CDAD

Colorectal Cancer

COPD

COVID-19

Crohn's Disease

Diabetes

Diabetes - Type 1

Diabetic Kidney Disease

Duchenne Muscular Dystrophy

Dyslipidemia

Ebola

Heart Failure

Hepatitis C

HIV

Huntington's Disease

Influenza

Kidney Transplant

Lung Cancer

Major Depressive Disorder

Malaria

Multiple Sclerosis

Nutrition

Pain

Pancreatic Cancer

Parkinson's Disease

Polycystic Kidney Disease

Post Traumatic Stress Disorder

Prostate Cancer

Psoriasis

QT Studies

Rheumatoid Arthritis

Schizophrenia

Traditional Chinese Medicine - Acupuncture

Traditional Chinese Medicine - Coronary

Artery Disease-Angina

Traumatic Brain Injury

Tuberculosis

Vaccines

Virology

# Certification

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

## CDISC Standards Certification

Description

Exam Scope

Registration

### 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.

### Articles

#### UCUM and CDISC Codelists

Unified Code for Units of Measure (UCUM) was developed by Regenstrief Institute and the UCUM Organization as an unambiguous system of units and their combinations. UCUM is intended to include all units of measure currently used internationally in science, engineering and business and has been adopted internationally by IEEE, DICOM, LOINC, and HL7 and is also in the ISO 11240:2012 standard.

[Read More](#)

#### Standard(s):

CDISC/REG Terminology, SXTMIG

[Intermediate](#)

#### LOINC and the SDTM

LOINC is a pre-coordinated laboratory coding system used in healthcare IT systems. It includes lab tests, clinical measures, HIPAA documents and standardized survey instruments. It also contains terms for human clinical research but its scope goes beyond research use. LOINC is used in over 170 countries and is mandated in 30

[Read More](#)

#### Standard(s):

Controlled Terminology, SDTM, SOTMIG

[Intermediate](#)

#### Concept Maps for Adverse Events with Increasing Levels of Detail

A query about adverse events is, at heart, an observation. Data on the adverse event may also include location and pattern. This concept map includes those details, as well as terminology that would be used in SDTM.

[Read More](#)

#### Standard(s):

CDISC/REG Terminology, SDTM, SOTMIG

[Intermediate](#)

#### Concept Maps for Substance Administration with Increasing Levels of Detail

A substance administration consists of a substance and the activity of administering the substance. Some data items describe the substance, others the administration.

[Read More](#)

#### Standard(s):

CDISC/REG Terminology, SDTM, SOTMIG

[Intermediate](#)

## Examples Collection

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

### Examples Collection

#### Urine Protein 1

This example shows 24-hour urine protein results for two subjects.

[Read More](#)

#### Standard(s):

SDTMIG, SDTM

#### Renal Replacement Therapy 1

This example shows a data collection form for renal replacement therapy, that is, for kidney transplant and chronic dialysis.

[Read More](#)

#### Standard(s):

CDASH

#### Glomerular Filtration Rate 1

This example shows an injection of iohexol administered prior to the GFR test.

[Read More](#)

#### Standard(s):

SDTMIG, SDTM

#### Glomerular Filtration Rate 2

This data shows cystatin and creatine data, with glomerular filtration rates estimated from them.

[Read More](#)

#### Standard(s):

SDTMIG, SDTM

<https://www.cdisc.org/kb>

# Volunteer for a CDISC Team

<https://www.cdisc.org/volunteer>

First Name \*      Last Name \*      Organization \*      Email \*      Alternate Email

This email will be used for team mailing lists and Wiki/Jira account creation if you do not already have one.

Select the CDISC Standards Development team that you would like to join. (Please choose one)

ADaM       SDS       Analysis Results Standard Sub-Team  
 CDASH       SEND       Other...  
 Controlled Terminology       XML-Tech  
 QRS       Medical Devices

Additional standards information can be found on our [Standards Page](#)

Specify which Therapeutic Area you would like to join, if any.

[View current Therapeutic Area User Guides in development.](#)

# 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

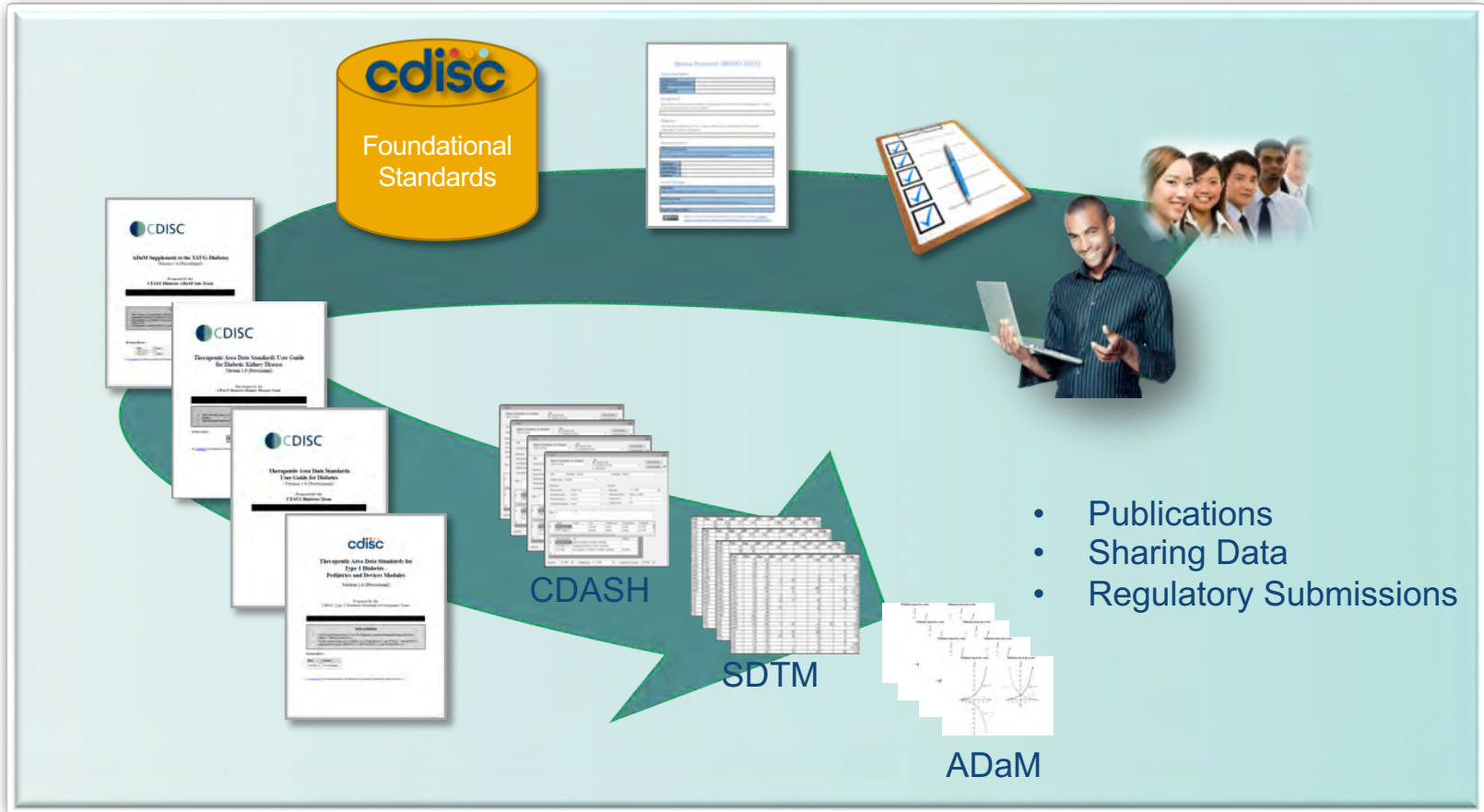
# CDISC Membership

Join the collaborative efforts of over  
480 CDISC member organizations



<https://www.cdisc.org/membership>







# 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 CDASHIG v2.0, CDASH Model 1.0, and SDTM v1.7 and the SDTM Implementation Guides (SDTMIG v3.3, SDTMIG-MD v1.1, and SDTMIG PGx 1.0).

## Revision History

Date	Version
2020-09-22	1.0 Provisional

See [Appendix D](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

Diabetes v1.0

ADaM  
Diabetes v1.0

Diabetic  
Kidney Dz v1.0

T1D Peds & Dev v1.0

CDASH

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

Renal Replacement Therapy

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

SDTM

Diabetes Complication History  
Self-Monitoring of Blood Glucose  
Meal Tolerance Test  
Treatment Naivete  
Hypoglycemic Events  
Last Meal and Last Diabetic Study Treatment  
Precipitating Factors, Third Party Asst, Adverse Event

Measures of Renal Function  
Proteinuria  
Estimated GFR  
Renal Replacement Therapy  
Renal Death

Blinded CGM Device  
CGM Device Properties and Settings  
DKA Events Prior to Study Start  
History of Autoimmune Disease  
DKA Adverse Event & More  
DKA Laboratory  
DKA Symptoms/Precipitating Factors  
DKA Event – Device in Use  
Device History  
Devices Used to Manage Diabetes

ADaM

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

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

ADRENAL: All Qualifying Criteria and Renal  
Endpoint Evaluation

ADTTE: Time-to-Event Analysis

Diabetes v1.0

ADaM  
Diabetes v1.0

Diabetic  
Kidney Dz v1.0

T1D Peds & Dev v1.0

CDASH

MH  
LB

PR

MH DE CM  
FAMH FAAE FACM  
TM LB VS  
SM CE RP  
IS DX  
APMH DI

SDTM

AG CE TS  
CM MH DI  
EX LB  
ML FA

MH CE  
AG DD  
LB  
PR

MH DI RELDEV VS  
FAMH AE DU RP  
TM FAAE DE  
SM LB DO  
IS CE CM  
APMH DX FACM  
DI EC  
DT EX

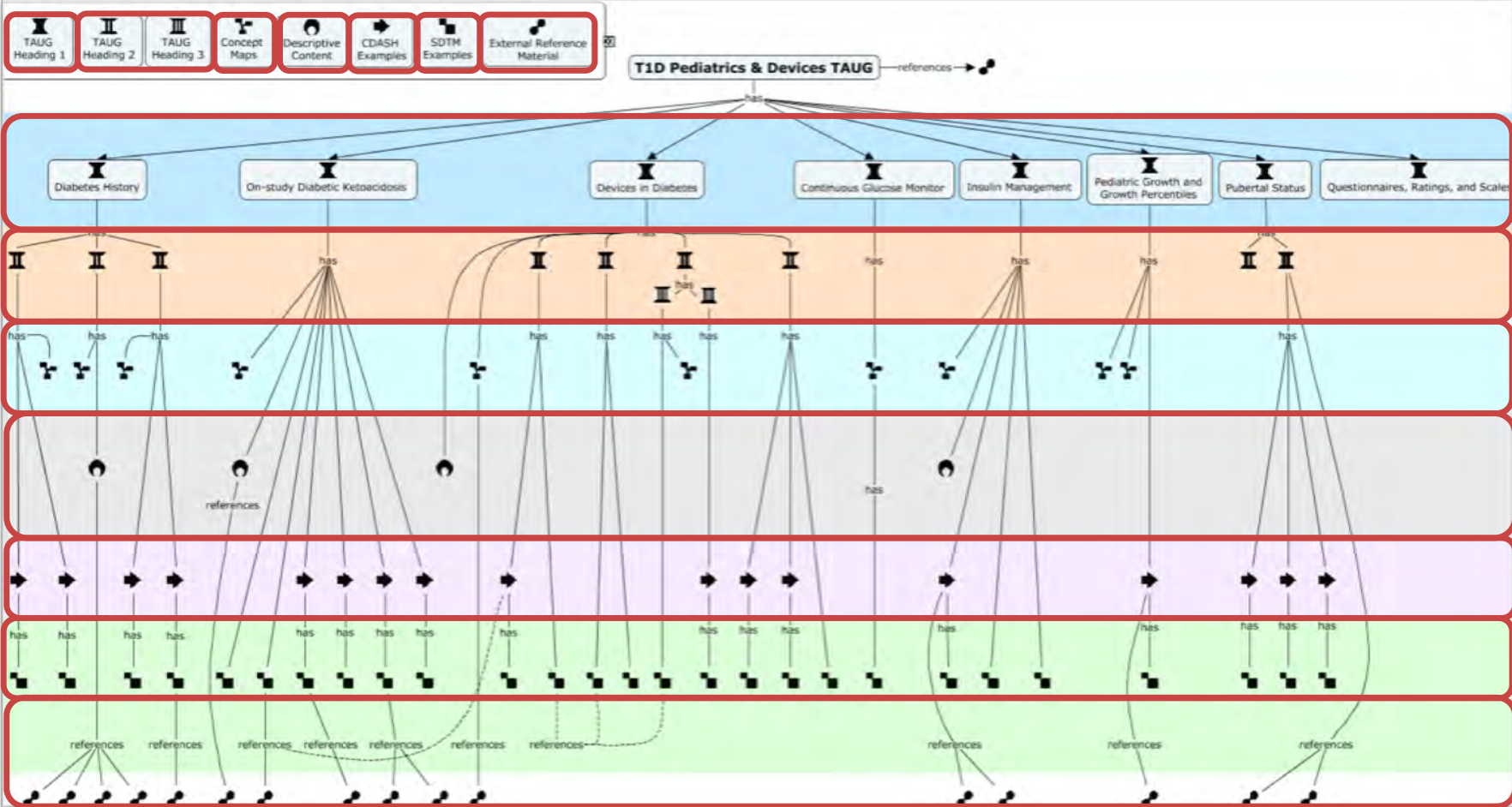
ADaM

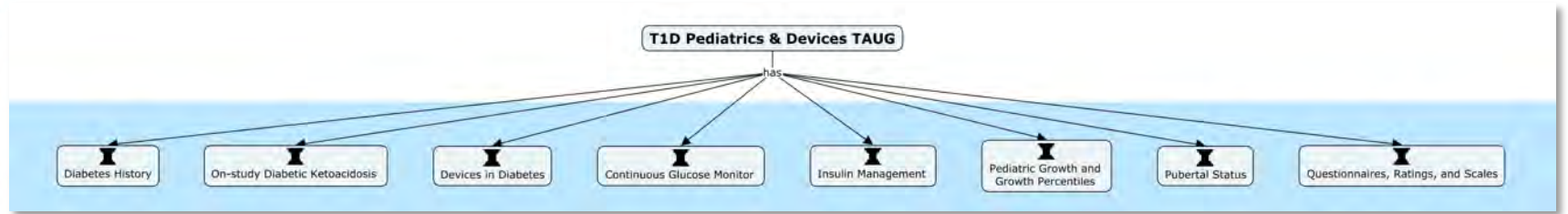
Hypoglycemic Episodes Analysis Dataset

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

ADRENAL: All Qualifying Criteria and Renal  
Endpoint Evaluation

ADTTE: Time-to-Event Analysis





- Document Maps
- Modeling Strategy
- Modeling Highlights
- Known Issues



  
On-study Diabetic Ketoacidosis

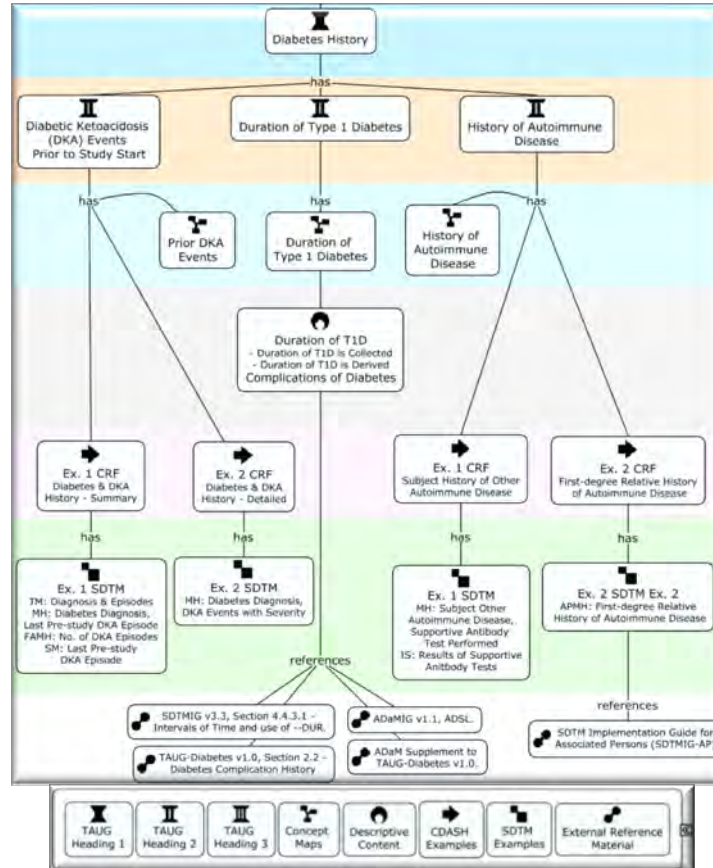
  
Devices in Diabetes

  
Continuous Glucose Monitor

  
Insulin

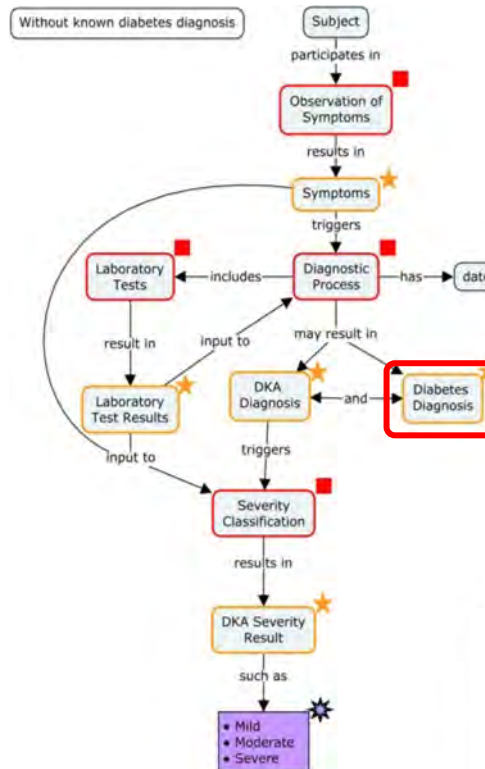
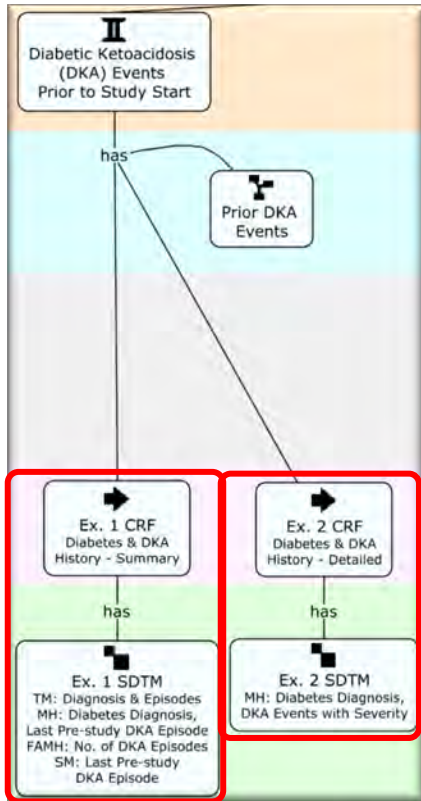
  
Diabetes History

# Diabetes History



# Diabetes History

## Diabetic Ketoacidosis Events Prior to Study Start



# Diabetes History

## Diabetic Ketoacidosis Events Prior to Study Start

### Example 1

What was the date of diagnosis of type 1 diabetes mellitus? <b>DIABETES_MHDIAG</b> <b>DIABETES_MHDIAG</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS"	<input type="text"/>
Medical History Term <b>DIABETES_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i> <b>DIABETES_MHDIAG</b> <b>MHDIAG</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS" <i>History/pre-populated</i>	TYPE 1 DIABETES MELLITUS
Medical History Event Date Type <b>DIABETES_MHIEVTYP</b> <b>MHIEVTYP</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS" <i>History/pre-populated</i> Disease Milestone Instance Name <b>T1DXD_MIDS</b> <b>MIDS</b> <i>History/pre-populated</i>	Y DIAGNOSIS T1DXD
Did the subject ever have diabetic ketoacidosis? <b>DKA_MHOCURR</b> <b>MHOCURR</b> where <b>MHITERM</b> = "DIABETIC KETOACIDOSIS"	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>&lt;From RV code list&gt;</small>
Medical History Term <b>DKA_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i> <b>DKA_MHDIAG</b> <b>MHDIAG</b> where <b>MHITERM</b> = "DIABETIC KETOACIDOSIS" <i>History/pre-populated</i>	DIABETIC KETOACIDOSIS
Did the subject present with diabetic ketoacidosis when the diabetes diagnosis was made? <b>DIABETES_MHCREASD</b> <b>MHCREASD</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS"	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

### Example 2

Medical History Category <b>MHCAT</b> <i>History/pre-populated</i>	DIABETES HISTORY
<b>MHDIAG</b> <i>Not submitted</i> <i>History/pre-populated</i>	Y
What was the date of diagnosis of type 1 diabetes mellitus? <b>DIABETES_MHDIAG</b> <b>MHDIAG</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS"	<input type="text"/>
Medical History Term <b>DIABETES_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i>	TYPE 1 DIABETES MELLITUS
Medical History Event Date Type <b>DIABETES_MHIEVTYP</b> <b>MHIEVTYP</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS" <i>History/pre-populated</i>	DIAGNOSIS
Did the subject ever have diabetic ketoacidosis? <b>DKA_MHOCURR</b> <b>MHOCURR</b> where <b>MHITERM</b> = "DIABETIC KETOACIDOSIS"	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>&lt;From RV code list&gt;</small>
Medical History Term <b>DKA_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i> Evaluation Interval Text <b>MHIEVINTX</b> <b>MHIEVINTX</b> where <b>MHITERM</b> = "DIABETIC KETOACIDOSIS" <i>History/pre-populated</i>	DIABETIC KETOACIDOSIS LIFETIME
Did the subject present with diabetic ketoacidosis when the diabetes diagnosis was made? <b>DIABETES_MHCREASD</b> <b>MHCREASD</b> where <b>MHITERM</b> = "TYPE 1 DIABETES MELLITUS"	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown

Did the subject have cerebral edema present with the DKA diagnosis?

Medical History Term <b>LPSDKA_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i> <b>LPSDKA_MHDIAG</b> <b>MHDIAG</b> where <b>MHITERM</b> = "DIABETIC KETOACIDOSIS" <i>History/pre-populated</i>	DIABETIC KETOACIDOSIS
Disease Milestone Instance Name <b>LPSDKA_MIDS</b> <b>MIDS</b> <i>History/pre-populated</i>	LPSDKA

What was the start date of the last episode of DKA prior to study start?

Did the subject have cerebral edema with the diabetic ketoacidosis episode? <b>CEDM_MHOCURR</b> <b>MHOCURR</b> where <b>MHITERM</b> = "CEREBRAL EDEMA ASSOCIATED WITH DKA" and <b>MHIECOD</b> "Cerebral edema"	<input type="radio"/> Unknown <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <small>&lt;From RV code list&gt;</small>
Medical History Term <b>CEDM_MHITERM</b> <b>MHITERM</b> <i>History/pre-populated</i>	CEREBRAL EDEMA ASSOCIATED WITH DKA
Medical History Term <b>CEDM_MHIECOD</b> <b>MHIECOD</b> <i>History/pre-populated</i>	Cerebral edema

# 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

*mh\_xpt*

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHLNKID	MHTERM	MHDECOD	MHEVDYTP	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTC	MHSTDTC	MIDS	MHREASDX
3	ABC123	MH	0002	1		TYPE 1 DIABETES MELLITUS	Type 1 diabetes mellitus	DIAGNOSIS	DIABETES HISTORY	Y	Y	1	SCREENING	2017-09-10	2015	T1DDX	NOT DIABETIC KETOACIDOSIS
4	ABC123	MH	0002	2	2	DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y	1	SCREENING	2017-09-10			
5	ABC123	MH	0002	3		DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y	1	SCREENING	2017-09-10	2017-07-07	LPSDKA	

#### Example 2

*mh\_xpt*

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHTERM	MHDECOD	MHEVDYTP	MHCAT	MHPRESP	MHOCCUR	MHSEV	VISIT	VISITNUM	MHDTC	MHSTDTC	MHEVINTX	MHREASDX
1	ABC124	MH	0001	1		TYPE 1 DIABETES MELLITUS	Type 1 diabetes mellitus	DIAGNOSIS	DIABETES HISTORY	Y	Y	1	SCREENING	2017-09-01	2017-02-13			DIABETIC KETOACIDOSIS
2	ABC124	MH	0001	2		DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y	1	SCREENING	2017-09-01				DIABETIC KETOACIDOSIS
3	ABC124	MH	0001	3	1	DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y	IMMEDIATE	1	SCREENING	2017-09-01	2017-08-18	SINCE TYPE 1 DIABETES DIAGNOSIS	DIABETIC KETOACIDOSIS
4	ABC124	MH	0001	4	1	CEREBRAL EDEMA ASSOCIATED WITH DKA	Cerebral edema		DIABETES HISTORY	Y	N	1	SCREENING	2017-09-01			SINCE TYPE 1 DIABETES DIAGNOSIS	





# Diabetes History

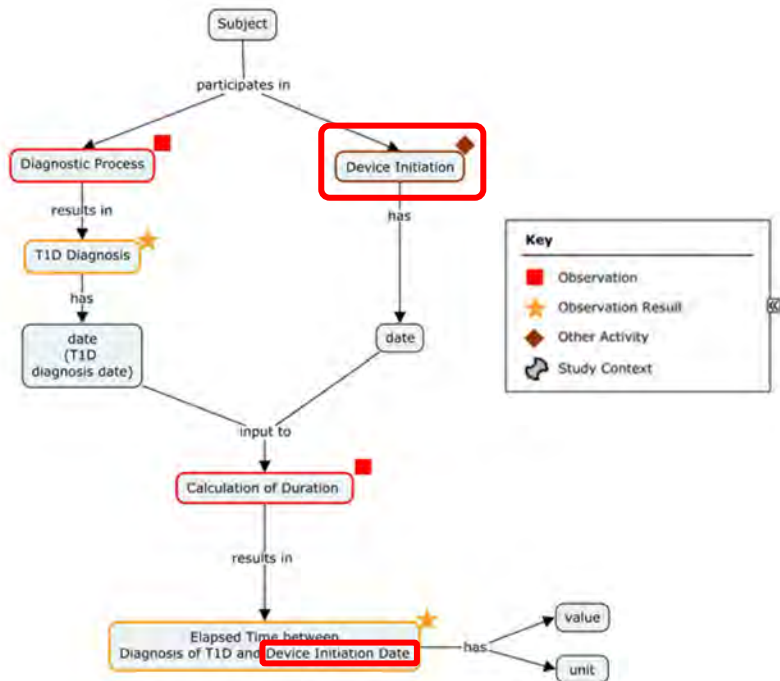
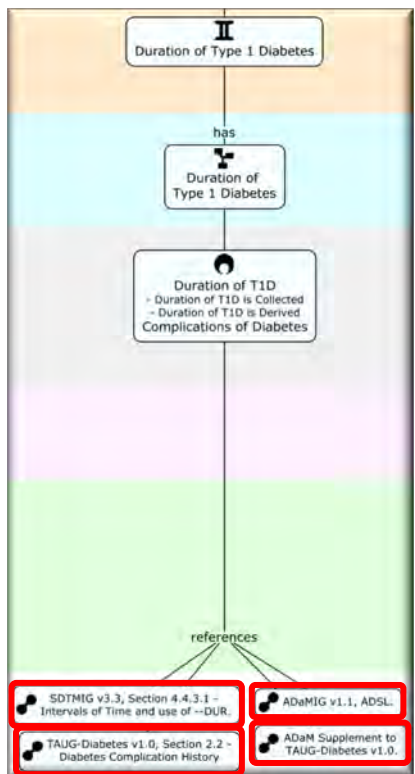
## Diabetic Ketoacidosis Events Prior to Study Start

### 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.

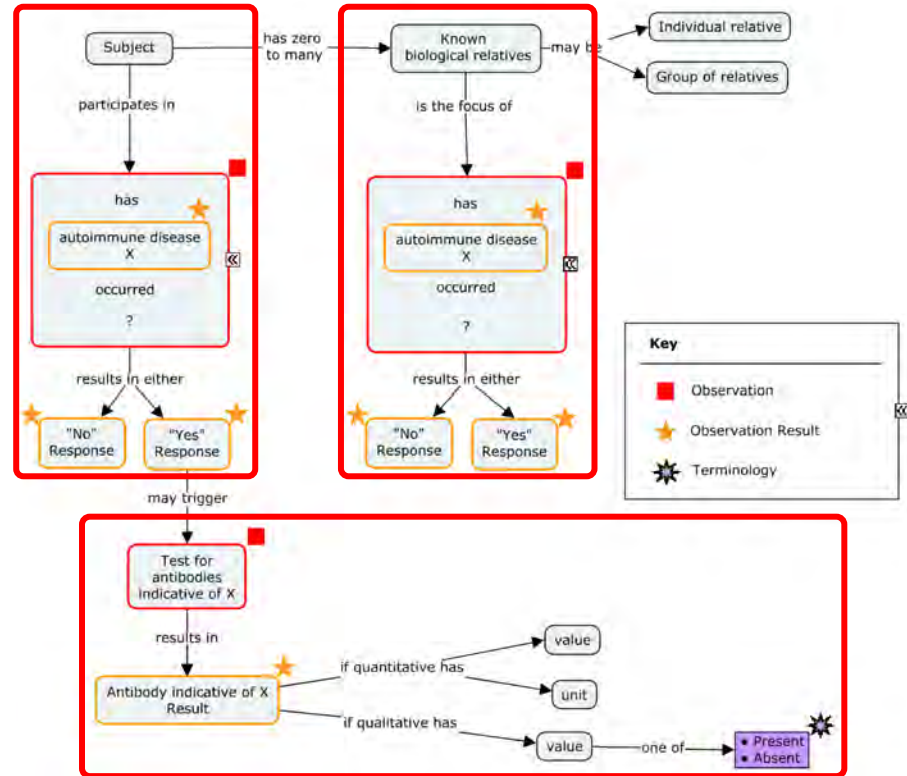
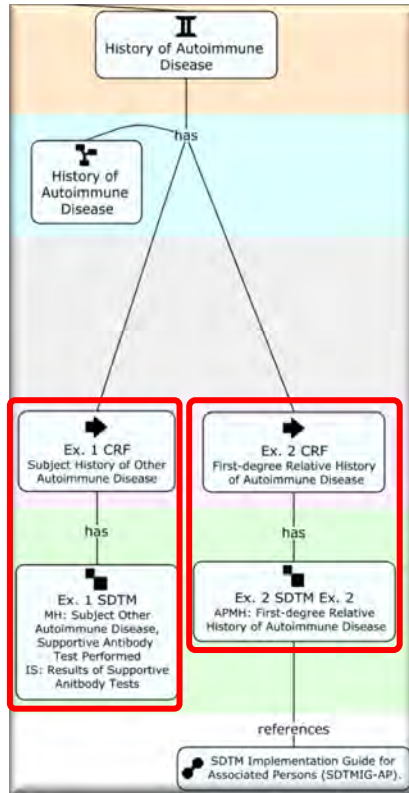
# Diabetes History

## Duration of Type 1 Diabetes



# Diabetes History

## History of Autoimmune Disease



# 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.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHLNKID	MHTERM	MHEVDTP	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTCT	MHSTDTC	MHSUABTS
1	ABC123	MH	0001	1	1		AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	Y	Y	1	SCREENING	2017-09-01		
2	ABC123	MH	0001	2	1	2	CELIAK DISEASE	DIAGNOSIS	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS			1	SCREENING	2017-09-01	2017-02-05	Y
3	ABC123	MH	0001	3	1	3	CROHN'S DISEASE	DIAGNOSIS	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS			1	SCREENING	2017-09-01	2016-10-03	Y

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHEVDTP	MHCAT	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTCT	MHSTDTC
1	ABC123	APMH	0001RFD	1	0001	RELATIVE, FIRST DEGREE	TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE HISTORY	TYPE 1 DIABETES MELLITUS	Y	Y	1	SCREENING	2017-09-05	
2	ABC123	APMH	0001RFD	2	0001	RELATIVE, FIRST DEGREE	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE HISTORY	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	Y	Y	1	SCREENING	2017-09-05	
3	ABC123	APMH	0001M	1	0001	MOTHER, BIOLOGICAL	TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE HISTORY	TYPE 1 DIABETES MELLITUS	Y	N	1	SCREENING	2017-09-05	
4	ABC123	APMH	0001M	2	0001	MOTHER, BIOLOGICAL	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE HISTORY	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	Y	Y	1	SCREENING	2017-09-05	
5	ABC123	APMH	0001M	3	0001	MOTHER, BIOLOGICAL	CELIAK DISEASE	DIAGNOSIS	AUTOIMMUNE DISEASE HISTORY	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS			1	SCREENING	2017-09-05	2017-02-15
6	ABC123	APMH	0001B1	1	0001	BROTHER, BIOLOGICAL	TYPE 1 DIABETES MELLITUS	DIAGNOSIS	AUTOIMMUNE DISEASE HISTORY	TYPE 1 DIABETES MELLITUS	Y	Y	1	SCREENING	2017-09-05	2016
7	ABC123	APMH	0001B1	2	0001	BROTHER, BIOLOGICAL	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS		AUTOIMMUNE DISEASE HISTORY	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	Y	N	1	SCREENING	2017-09-05	



# 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 ISTECD / ISTECD).
  - ISBDAGNT NSV to indicate the binding agent for the test.





# Diabetes History

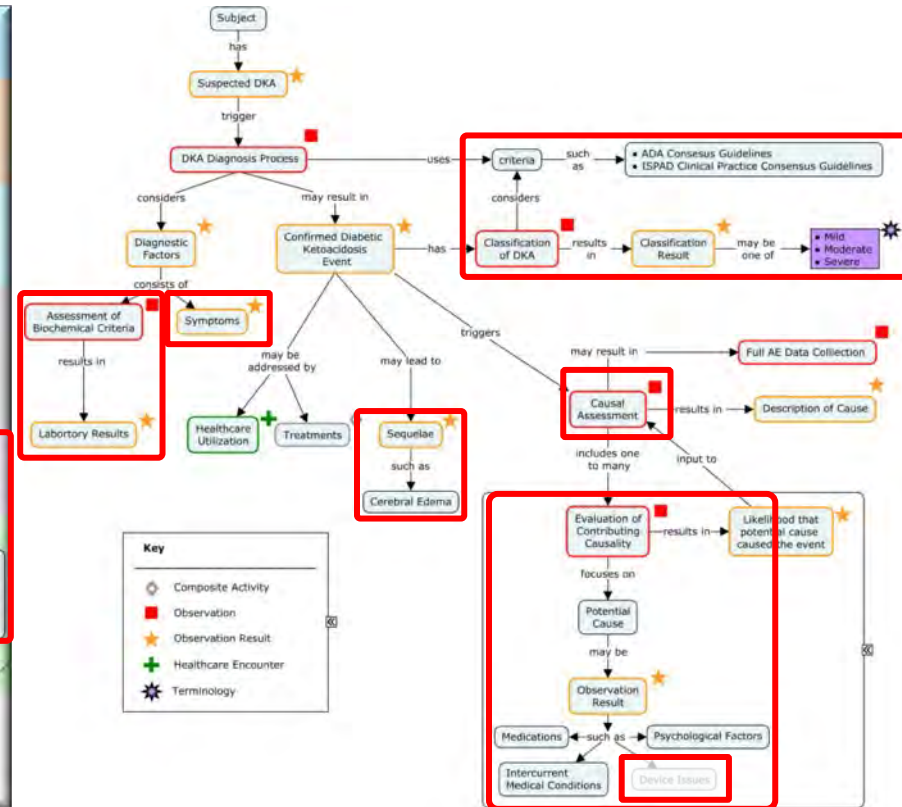
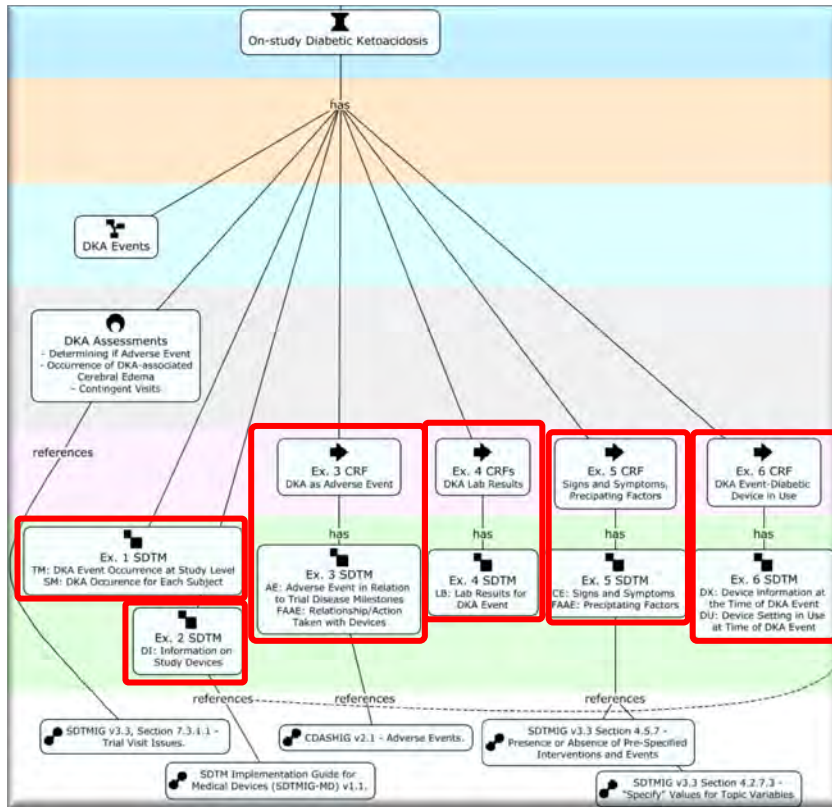
## Known Issues

- 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



Diabetes History

# 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

Was there a relationship, or action taken, with any device?

AEANYDEV NSAE.AERLDEV AEACNDEV

- Yes
- No

Single device assessed

Multiple devices assessed

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	AESQ	AESPID	AETERM	AEDECOD	AEPRESP	AESER	AESEV	AEACN	AEACNOTH	AEACNDEV	AEREL	AEOUT	AESHOSP	AECONTR	AESTDTC	AEENDTC	AESTDY	MIDS	AERLDEV	AESTDSEV	AESVCRTN
1	T001	AE	001		1	AE0007	Diabetic ketoacidosis	Diabetic ketoacidosis	Y	Y		DOSE NOT CHANGED		MULTIPLE	NOT RELATED	RECOVERED/RESOLVED	Y	Y	2013-09-01	2013-09-07	27	DKA1	MULTIPLE	MILD	ADA Version x
2	T001	AE	001		2	AE0049	Diabetic ketoacidosis	Diabetic ketoacidosis	Y	Y		DOSE INCREASED	RE-EDUCATION ON DEVICE USE	MULTIPLE	NOT RELATED	RECOVERED/RESOLVED WITH SEQUELAE	Y	Y	2014-10-24	2014-11-03	445	DKA2	MULTIPLE	SEVERE	ADA Version x
3	T001	AE	012		1	AE0034	Diabetic ketoacidosis	Diabetic ketoacidosis	Y	Y		DOSE NOT CHANGED		NONE	NOT RELATED	RECOVERED/RESOLVED	Y	Y	2015-05-09	2015-05-11	26	DKA1	NOT RELATED	MODERATE	ISPD Version x
4	T001	AE	012	Automated Insulin Delivery System	2	AE0042	Diabetic ketoacidosis	Diabetic ketoacidosis	Y	Y		DOSE INCREASED		CHANGED TO AUTOMATIC INSULIN DELIVERY MODE	NOT RELATED	RECOVERED/RESOLVED	Y	Y	2016-03-19	2016-03-21	341	DKA2	POSSIBLY RELATED	MILD	ISPD Version x
5	T001	AE	014		1	AE0067	Diabetic ketoacidosis	Diabetic ketoacidosis	Y	Y		DOSE NOT CHANGED		NONE	NOT RELATED	RECOVERED/RESOLVED	Y	Y	2015-08-14	2015-08-19	39	DKA1	NOT RELATED	SEVERE	ISPD Version x

faae.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	FASEQ	FALNKID	FATESTCD	FATEST	FAOBJ	FAORRES	FASTRESC	VISITNUM	VISIT	MIDS	RELMIDS	MIDSDTC
1	T001	FA	001	Electronic Insulin Pump	1	AE0007	RLDEV	Relationship to Device	Diabetic ketoacidosis	NOT RELATED	NOT RELATED	99.1	DKA CONTINGENT VISIT 1	DKA1	ENTIRE EVENT	2013-09-01
2	T001	FA	001	Electronic Insulin Pump	2	AE0007	ACNDEV	Actions Taken with Device	Diabetic ketoacidosis	NONE	NONE	99.1	DKA CONTINGENT VISIT 1	DKA1	ENTIRE EVENT	2013-09-01
3	T001	FA	001	Real-Time Continuous Glucose Monitor	3	AE0007	RLDEV	Relationship to Device	Diabetic ketoacidosis	NOT RELATED	NOT RELATED	99.1	DKA CONTINGENT VISIT 1	DKA1	ENTIRE EVENT	2013-09-01
4	T001	FA	001	Real-Time Continuous Glucose Monitor	4	AE0007	ACNDEV	Actions Taken with Device	Diabetic ketoacidosis	NONE	NONE	99.1	DKA CONTINGENT VISIT 1	DKA1	ENTIRE EVENT	2013-09-01

# On-study Diabetic Ketoacidosis

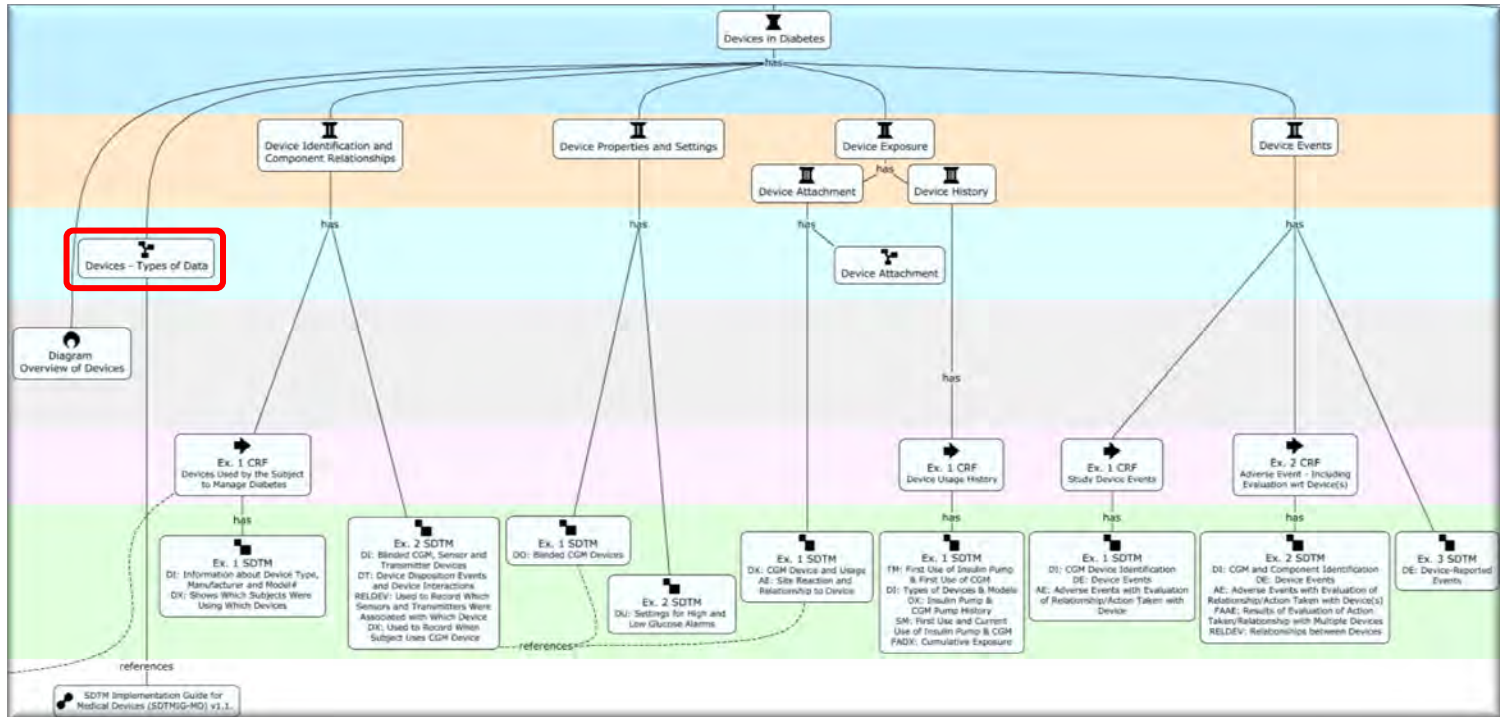
## Known Issues

- 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).



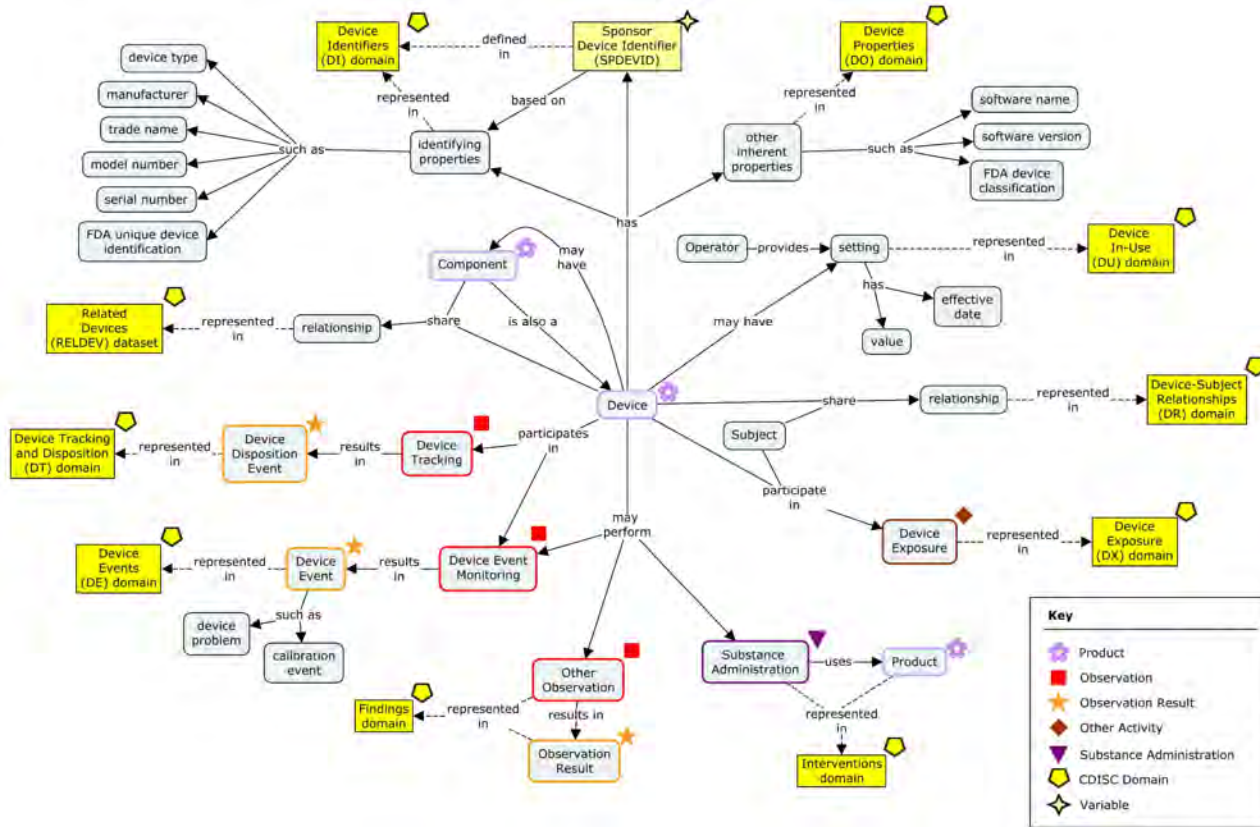
On-study Diabetic Ketoacidosis

# Devices in Diabetes



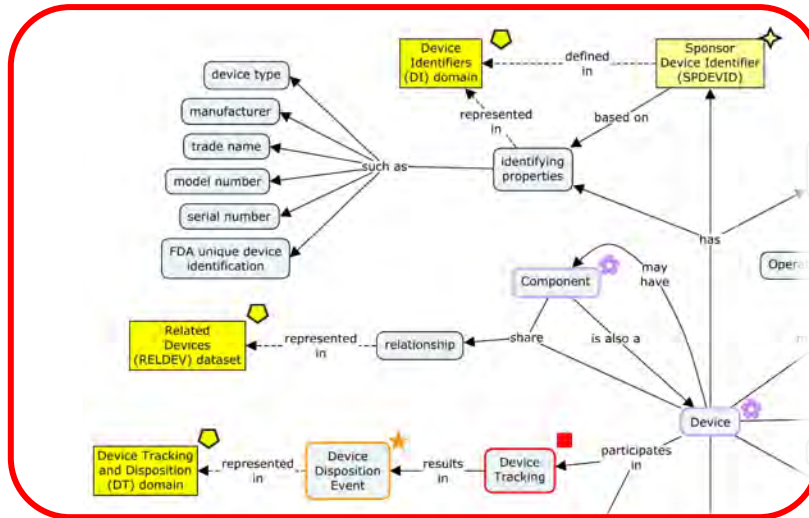
TAUG Heading 1	TAUG Heading 2	TAUG Heading 3	Concept Maps	Descriptive Content	CDASH Examples	SDTM Examples	External Reference Material
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# Devices in Diabetes

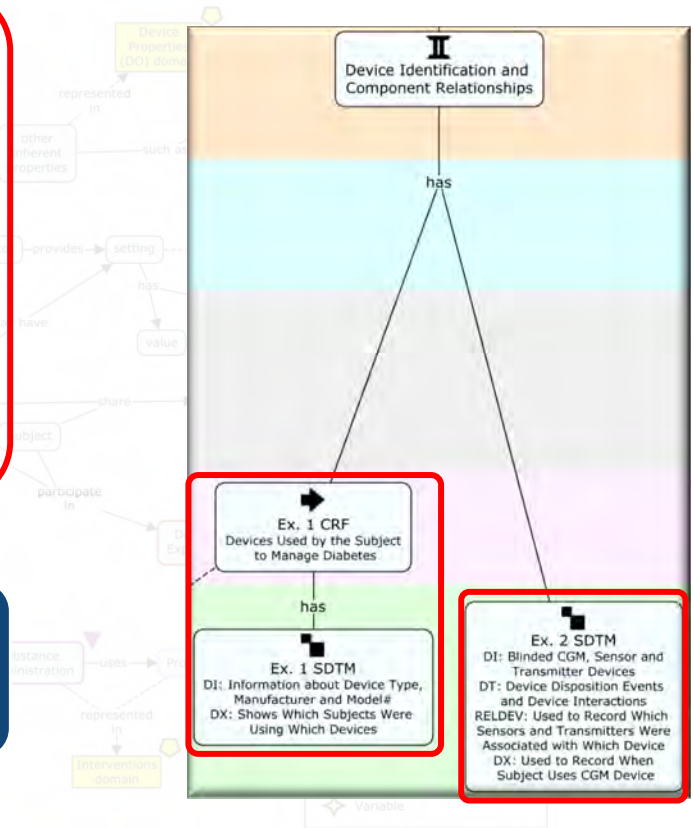




# Devices in Diabetes



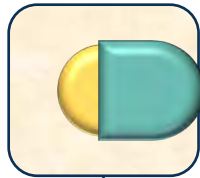
## Device Identification and Component Relationships



# Device Identification and Component Relationships - Example 2



CGM-1



CGM-SNS-1



CGM-TRN-1

di.xpt

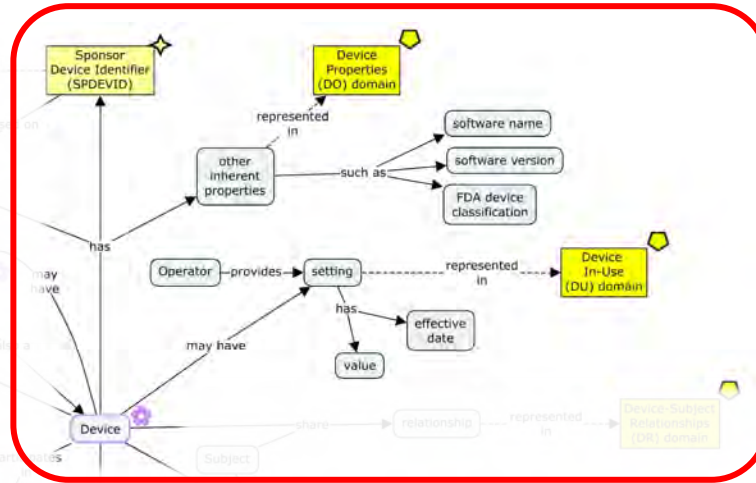
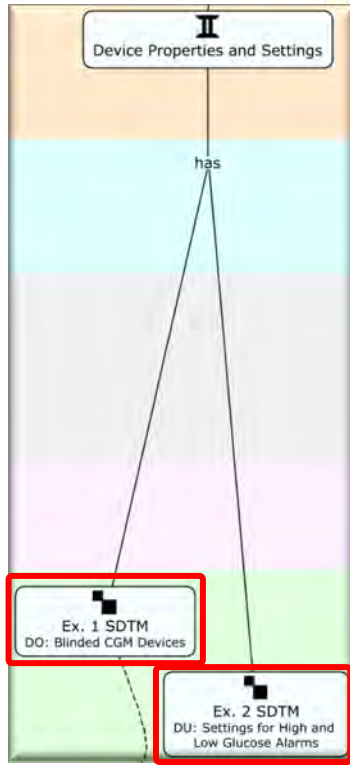
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1	T001	DI	CGM-1	1	DEVTYPE	Device Type	Invasive Continuous Glucose Monitors (CGMs)
2	T001	DI	CGM-1	1	MANUF	Manufacturer	CGM Devices, Inc.
3	T001	DI	CGM-1	1	SERIAL	Serial Number	59466N-1
4	T001	DI	CGM-2	1	DEVTYPE	Device Type	Invasive Continuous Glucose Monitors (CGMs)
5	T001	DI	CGM-2	1	MANUF	Manufacturer	CGM Devices, Inc.
6	T001	DI	CGM-2	1	SERIAL	Serial Number	59466N-2
7	T001	DI	CGM-3	1	DEVTYPE	Device Type	Invasive Continuous Glucose Monitors (CGMs)
8	T001	DI	CGM-3	1	MANUF	Manufacturer	CGM Devices, Inc.
9	T001	DI	CGM-3	1	SERIAL	Serial Number	59466N-3
10	T001	DI	CGM-SNS-1	1	DEVTYPE	Device Type	implantable glucose monitoring system sensor
11	T001	DI	CGM-SNS-1	1	MANUF	Manufacturer	CGM Devices, Inc.
12	T001	DI	CGM-SNS-1	1	SERIAL	Serial Number	S89533-B5
13	T001	DI	CGM-SNS-2	1	DEVTYPE	Device Type	implantable glucose monitoring system sensor
14	T001	DI	CGM-SNS-2	1	MANUF	Manufacturer	CGM Devices, Inc.
15	T001	DI	CGM-SNS-2	1	SERIAL	Serial Number	S89533-B6
16	T001	DI	CGM-SNS-3	1	DEVTYPE	Device Type	implantable glucose monitoring system sensor
17	T001	DI	CGM-SNS-3	1	MANUF	Manufacturer	CGM Devices, Inc.
18	T001	DI	CGM-SNS-3	1	SERIAL	Serial Number	S89533-B7
19	T001	DI	CGM-TRN-1	1	DEVTYPE	Device Type	Implantable glucose monitoring system transmitter
20	T001	DI	CGM-TRN-1	1	MANUF	Manufacturer	CGM Devices, Inc.
21	T001	DI	CGM-TRN-1	1	SERIAL	Serial Number	TX12466
22	T001	DI	CGM-TRN-2	1	DEVTYPE	Device Type	Implantable glucose monitoring system transmitter
23	T001	DI	CGM-TRN-2	1	MANUF	Manufacturer	CGM Devices, Inc.
24	T001	DI	CGM-TRN-2	1	SERIAL	Serial Number	TX12467
25	T001	DI	CGM-TRN-3	1	DEVTYPE	Device Type	Implantable glucose monitoring system transmitter
26	T001	DI	CGM-TRN-3	1	MANUF	Manufacturer	CGM Devices, Inc.
27	T001	DI	CGM-TRN-3	1	SERIAL	Serial Number	TX12468

Sensor

Transmitter

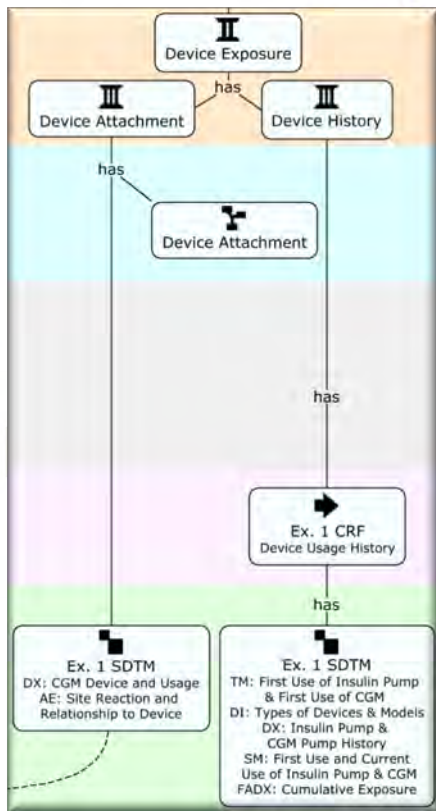
	Tuesday	Wednesday	Thursday
12		13 <i>Get new CGM!</i>	14
19		20 <i>Replace CGM sensor</i>	21
26		27 <i>Replace CGM sensor</i>	28
5		6 <i>Replace CGM sensor</i>	7
12		13 <i>Replace CGM sensor + transmitter</i>	14

# Devices in Diabetes

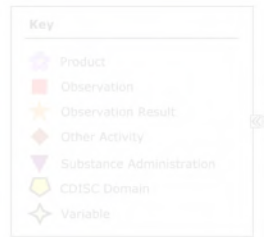
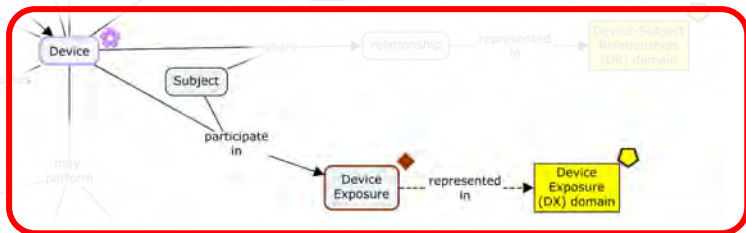


**Device Properties and Settings**

# Devices in Diabetes



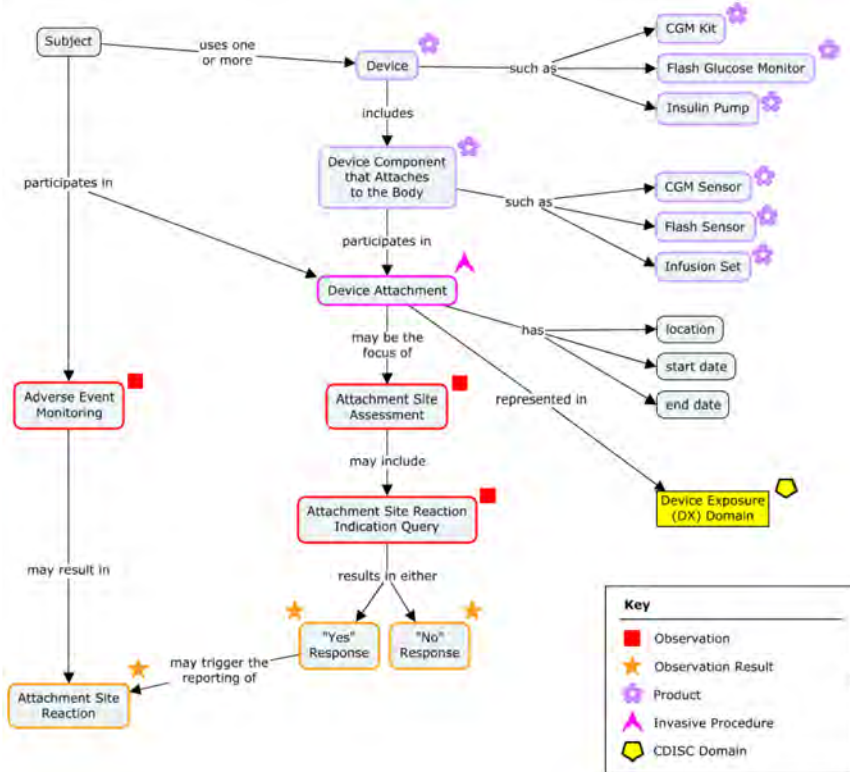
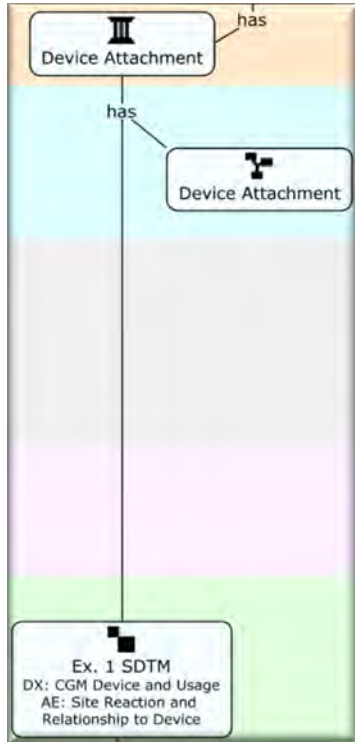
Device Exposure





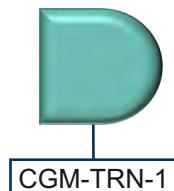
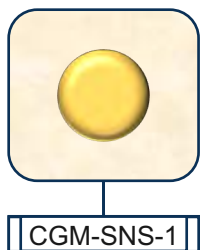
# Devices in Diabetes

## Device Attachment





# Device Exposure / Device Attachment



	Tuesday	Wednesday	Thursday
12		13 <i>Get new CGM!</i>	14
19		20 <i>Replace CGM sensor</i>	21
			28

dx.xpt

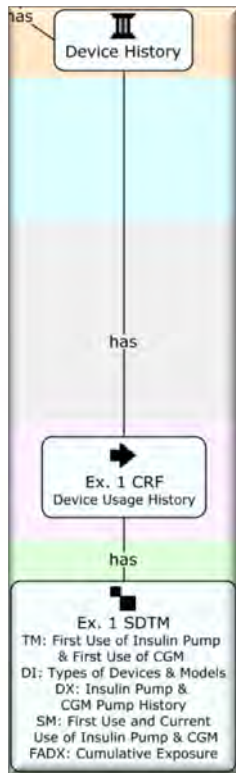
Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXCAT	DXROUTE	DXLOC	DXLAT	DXDIR	DXRSDISC	VISITNUM	VISIT	DXSTDTDC	DXENDTC
1	T001	DX	0001	CGM-1	1	CGM	SUBJECT DEVICES						1	Visit 1	2019-02-13	2019-04-10
2	T001	DX	0001	CGM-SNS-1	2	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	ABDOMINAL REGION	LEFT	ANTERIOR		1	Visit 1	2019-02-13T10:35	2019-02-20T10:00
3	T001	DX	0001	CGM-TRN-1	3	CGM Transmitter	CGM COMPONENT REPLACEMENT						1	Visit 1	2019-02-13T10:35	2019-03-13T09:30

dx.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXCAT	DXROUTE	DXSTDTDC	DXENDTC
1	T001	DX	0001	CGM-1	1	CGM	SUBJECT DEVICES		2019-02-13	2019-04-10
2	T001	DX	0001	CGM-SNS-1	2	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-02-13T10:35	2019-02-20T10:00
3	T001	DX	0001	CGM-TRN-1	3	CGM Transmitter	CGM COMPONENT REPLACEMENT		2019-02-13T10:35	2019-03-13T09:30
4	T001	DX	0001	CGM-SNS-11	4	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-02-20T10:05	2019-02-27T10:45
5	T001	DX	0001	CGM-SNS-33	5	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-02-27T10:55	2019-03-06T09:30
6	T001	DX	0001	CGM-SNS-46	6	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-03-06T09:35	2019-03-13T09:30
17	T001	DX	0002	CGM-SNS-63	9	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-03-15T08:35	2019-03-22T08:45
18	T001	DX	0002	CGM-TRN-14	10	CGM Transmitter	CGM COMPONENT REPLACEMENT		2019-03-15T08:35	2019-04-12T09:00
19	T001	DX	0003	CGM-3	1	CGM	SUBJECT DEVICES		2019-02-02	2019-02-03
20	T001	DX	0003	CGM-SNS-3	2	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	2019-02-02T14:15	2019-02-03T09:30
21	T001	DX	0003	CGM-TRN-3	3	CGM Transmitter	CGM COMPONENT REPLACEMENT		2019-02-02T14:15	2019-02-03T09:30

# Devices in Diabetes

## Device History



*dx.xpt*

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXCAT	DXSCAT	DXPRESP	DXOCCUR	VISITNUM	VISIT	DXDTC	DXSTDTC	DXENTPT	DXENRPT	MIDS
1	T1D-01	DX	0001	IP-0	1	Any Insulin Pump Device	INSULIN PUMP HISTORY	GENERAL	Y	Y	1	Visit1	2019-01-15	2018-05-02			STIP
2	T1D-01	DX	0001	IP-OT-0001	2	Infusions Inc. Pump Standard	INSULIN PUMP HISTORY	CURRENT			1	Visit1	2019-01-15	2018-05-02	2019-01-15	ONGOING	CURIP
3	T1D-01	DX	0001	CGM-0	3	Any Continuous Glucose Monitoring Device	CONTINUOUS GLUCOSE MONITOR HISTORY	GENERAL	Y	Y	1	Visit1	2019-01-15	2018-04-02			STCGM
4	T1D-01	DX	0001	CGM-2	4	ANOther, CGMPlus	CONTINUOUS GLUCOSE MONITOR HISTORY	CURRENT	Y	Y	1	Visit1	2019-01-15	2018-08-10	2019-01-15	ONGOING	CURCGM
5	T1D-01	DX	0002	IP-0	1	Any Insulin Pump Device	INSULIN PUMP HISTORY	GENERAL	Y	N	1	Visit1	2019-01-21				
6	T1D-01	DX	0002	CGM-0	2	Any Continuous Glucose Monitoring Device	CONTINUOUS GLUCOSE MONITOR HISTORY	GENERAL	Y	Y	1	Visit1	2019-01-21	2018-02-15			STCGM
7	T1D-01	DX	0002	CGM-1	3	Generic Monitors, CGM Standard	CONTINUOUS GLUCOSE MONITOR HISTORY	CURRENT	Y	Y	1	Visit1	2019-01-21	2018-02-15	2019-01-21	ONGOING	CURCGM
8	T1D-01	DX	0003	IP-0	1	Any Insulin Pump Device	INSULIN PUMP HISTORY	GENERAL	Y	Y	1	Visit1	2019-02-05	2017-12-12	2019-02-05	BEFORE	STIP
9	T1D-01	DX	0003	CGM-0	2	Any Continuous Glucose Monitoring Device	CONTINUOUS GLUCOSE MONITOR HISTORY	GENERAL	Y	N	1	Visit1	2019-02-05				



# 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.

Indicate if the cause of the adverse event is related to the CGM device and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).

Was this adverse event related to the CGM device?  
`CGM_AERLDEV` `NSAE_AERLDEV`

NOT RELATED  
 UNLIKELY RELATED  
 POSSIBLY RELATED  
 PROBABLY RELATED  
 RELATED  
 Related to component(s)

If "Related to component(s)" is selected, indicate if the cause of the adverse event is related to the CGM case and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).

Was this adverse event related to the CGM case?  
`CASE_RLDEV_FAORRES`  
`FAORRES` where `FATESTCD = "RLDEV"` and `SPDEVID` matches `DI.SPDEVID` where `DI.DIPARMCD = "DEVTYPE"` and `DI.DIVAL = "Plastic case, CGM"`

NOT RELATED  
 UNLIKELY RELATED  
 POSSIBLY RELATED  
 PROBABLY RELATED  
 RELATED



# Devices in Diabetes

## 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**

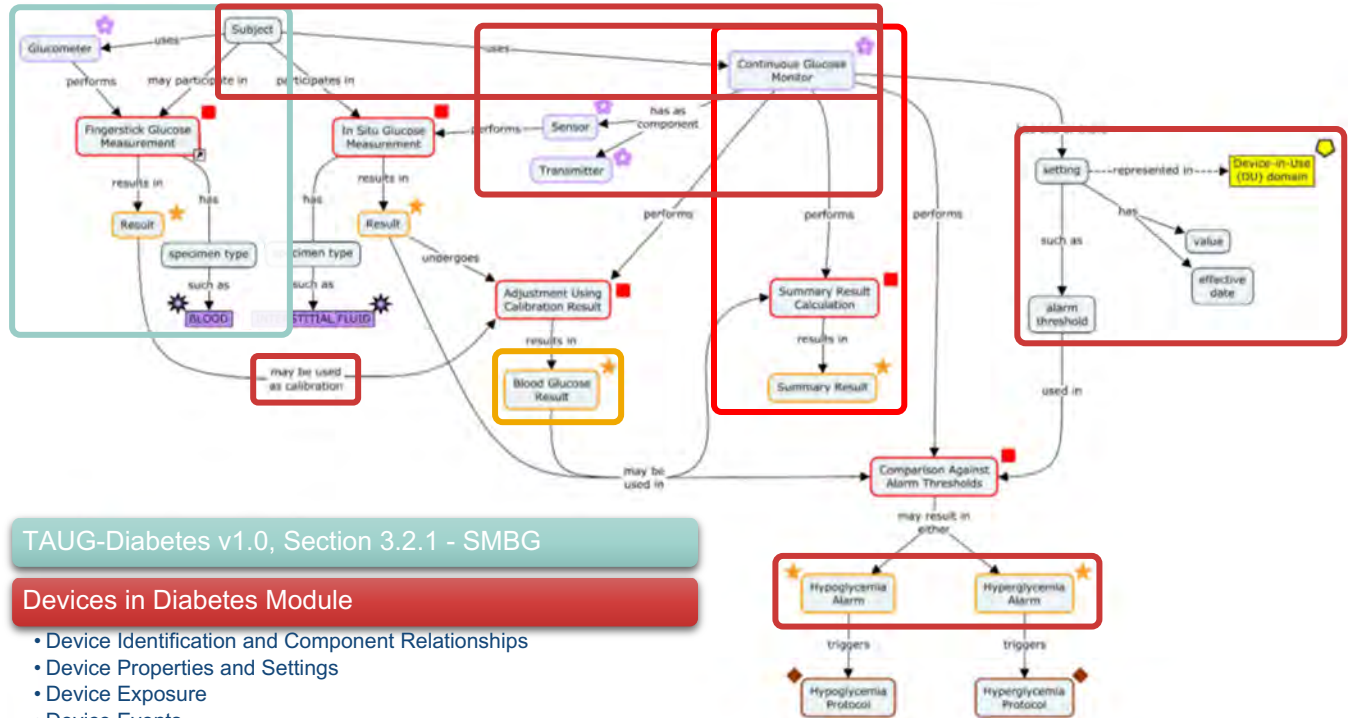
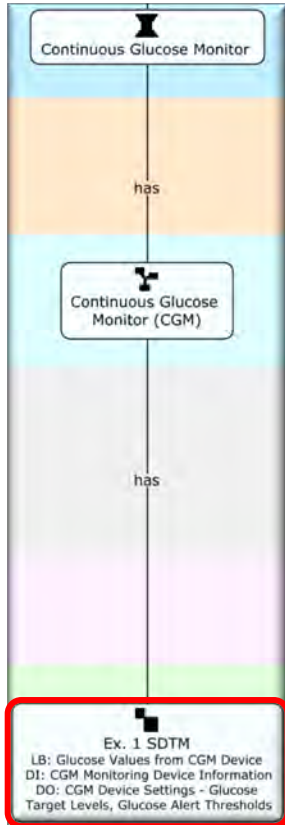
- Assign value of “Y” for pre-specified terms selected from a list (e.g. a drop-down with no accompanying Yes/No question) when --OCCUR is present in dataset.





Devices in Diabetes

# Continuous Glucose Monitor



# Continuous Glucose Monitor

## Modeling Strategy

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

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRES	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBANMETH	VISITNUM	VISIT	VISITDY	LBOTC	LBENDC	LBDY	LBENDY	LBCLSRT
1	T005	LB	001	CGM-001	1	GLUCPE	Plasma Equivalent Glucose	113.7	mg/dL	113.7	113.7	mg/dL	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	MEAN
2	T005	LB	001	CGM-001	2	GLUCPD	Plasma Equivalent Glucose Distribution	15		15	15		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	STANDARD DEVIATION
3	T005	LB	001	CGM-001	3	GLUCPD	Plasma Equivalent Glucose Distribution	13.7		13.7	13.7		INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	COEFFICIENT OF VARIATION
4	T005	LB	001	CGM-001	4	GLUCPD	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTION LOW
5	T005	LB	001	CGM-001	5	GLUCPD	Plasma Equivalent Glucose Distribution	0	%	0	0	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTION HIGH
6	T005	LB	001	CGM-001	6	GLUCPD	Plasma Equivalent Glucose Distribution	100	%	100	100	%	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	PROPORTION WITHIN TARGET RANGE
7	T005	LB	001	CGM-001	7	GLUCPD	Plasma Equivalent Glucose Distribution	0	min	0	0	min	INTERSTITIAL FLUID	CALCULATION	DEVICE ALGORITHM	2	WEEK 2	15	2016-09-28T08:00	2016-09-29T08:00	14	15	TIME IN CRITICAL LOW RANGE
8	T005	LB	001	CGM-001	8	GMI	Glucose Management Indicator	6.04	%	6.04	6.04	%	INTERSTITIAL FLUID	CALCULATION	GMI % FORMULA	2	WEEK 2	15	2016-09-15T08:00	2016-09-29T08:00	1	15	

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

do.xpt

Row	STUDYID	DOMAIN	SPDEVID	DOSEQ	DOTESTCD	DOTEST	DOTSTDTL	DOORRES	DOORRESU
1	T005	DO	CGM-001	1	GLUCTGLV	Glucose Target Level	LOW	80	mg/dL
2	T005	DO	CGM-001	2	GLUCTGLV	Glucose Target Level	HIGH	130	mg/dL
3	T005	DO	CGM-001	3	GLUCALTH	Glucose Alert Threshold	CRITICAL LOW	<50	mg/dL
4	T005	DO	CGM-001	4	GLUCALTH	Glucose Alert Threshold	LOW	<69	mg/dL
5	T005	DO	CGM-001	5	GLUCALTH	Glucose Alert Threshold	HIGH	>180	mg/dL
6	T005	DO	CGM-001	6	GLUCALTH	Glucose Alert Threshold	CRITICAL HIGH	>250	mg/dL

# 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

## 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 “U” 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.

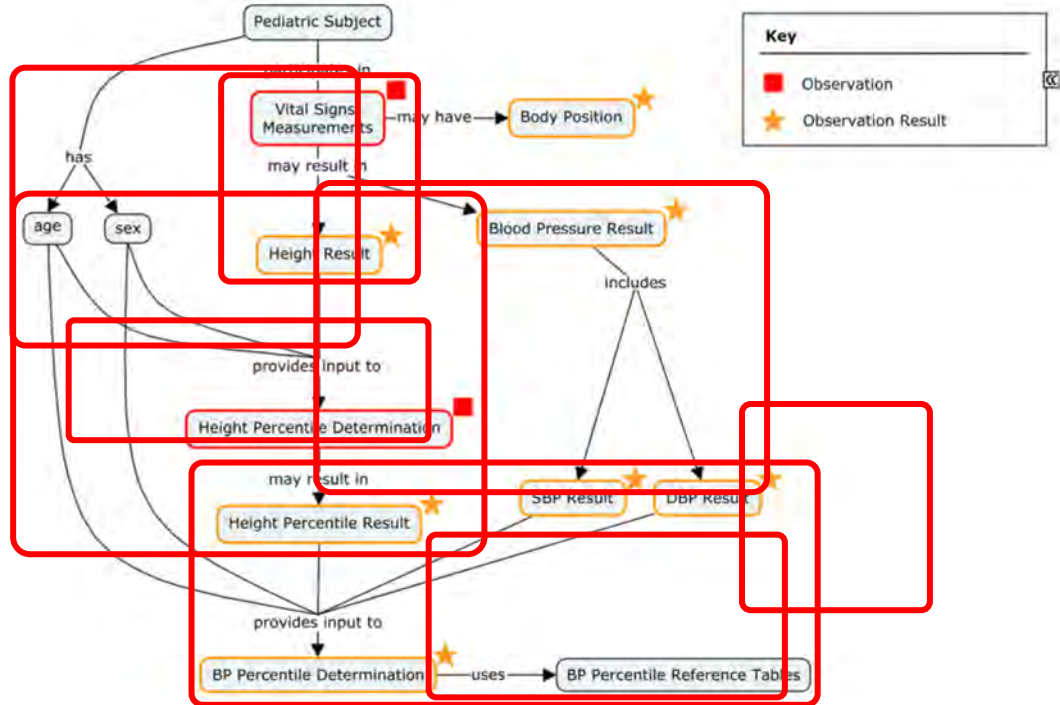
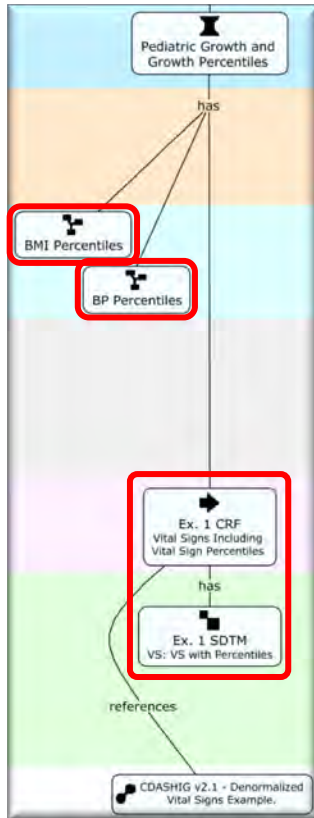
RESOLVED





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

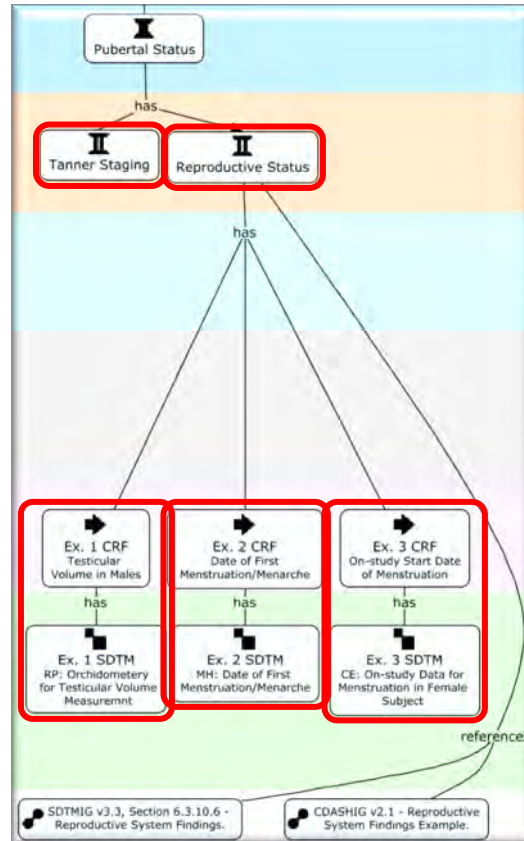
vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEC	VSGRPID	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSRESCAT	VSANMETH	VSLOBXFL	VISITNUM	VSDTC
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		



Pediatric Growth and  
Growth Percentiles

# Pubertal Status



# Pubertal Status

## Reproductive Status

### Modeling Strategy

- Reproductive System Findings (RP) domain for testicular volume measurements

*rp.xpt*

Row	STUDYID	DOMAIN	USUBJID	RPSEQ	RPTSTCD	RPTST	RPCAT	RPSCAT	RPORRES	RPORRESU	RPSTRESC	RPSTRESN	RPSTRESU	RPLOC	RPLAT	RPMETHOD	VISITNUM	VISIT	RPDTC
1	ABC123	RP	0001	1	VOLUME	Volume	PUBERTAL STATUS	MALE	8	mL	8	8	mL	TESTIS	RIGHT	ORCHIDOMETRY	1	SCREENING	2017-09-15
2	ABC123	RP	0001	2	VOLUME	Volume	PUBERTAL STATUS	MALE	9	mL	9	9	mL	TESTIS	LEFT	ORCHIDOMETRY	1	SCREENING	2017-09-15

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

*mh.xpt*

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHCAT	MHSCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTC	MHSTDTC
1	ABC123	MH	0001	1	MENARCHE	PUBERTAL STATUS	FEMALE	Y	Y	1	SCREENING	2017-05-05	2014-08-01
2	ABC123	MH	0002	1	MENARCHE	PUBERTAL STATUS	FEMALE	Y	N	1	SCREENING	2017-05-05	

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

*ce.xpt*

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CECAT	CESCAT	CEPRES	CEOCCUR	VISITNUM	VISIT	CEDTC	CESTDTC	CEEVINTX
1	ABC123	CE	0002	1	MENARCHE	PUBERTAL STATUS	FEMALE	Y	N	2	VISIT 2	2017-07-05		SINCE THE LAST VISIT
2	ABC123	CE	0002	2	MENARCHE	PUBERTAL STATUS	FEMALE	Y	Y	3	VISIT 3	2017-10-15	2017-08-01	SINCE THE LAST VISIT



# 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 1. Identified QRS Measures of Interest to Type 1 Diabetes - Pediatrics and Devices**

Full Name and Abbreviation	Subtitle (Where Applicable)	Copyright Permission Status	Supplement Status				
Diabetes Distress Scale (DDS)	DDS for Adults with Type 1 Diabetes (T1-DDS)	Granted	Supplement in progress	Pediatric Quality of Life Inventory 3.2 (PedsQL) Diabetes Module	PEDSQL Acute Version: Toddlers (2-4 years)	Requested	
	DDS for Parents of Teens with Type 1 Diabetes (Parent-DDS)	Granted	Supplement in progress		PEDSQL Standard Version: Toddlers (2-4 years)	Requested	
	DDS for Partners of Adults with Type 1 Diabetes (Partner-DDS)	Granted	Supplement in progress		PEDSQL Acute Version: Young Child (5-7 years)	Requested	
Diabetes Treatment Satisfaction Questionnaire (DTSQ)	DTSQ - Status	Denied			PEDSQL Standard Version: Young Child (5-7 years)	Requested	
	DTSQ - Change	Denied			PEDSQL Acute Version: Child (8-12 years)	Requested	
Glucose Monitoring System Satisfaction Survey (GMSS)	Version: Type 1 Diabetes (GMSS-T1D)	Granted	Supplement in progress		PEDSQL Standard Version: Child (8-12 years)	Requested	
Hypoglycemic Confidence Scale (HCS)		Granted	Supplement in progress		PEDSQL Acute Version: Adolescent (13-18 years)	Requested	
Hypoglycemia Fear Survey		Requested			PEDSQL Standard Version: Adolescent (13-18 years)	Requested	
	HFS - Parent (HFS-P)	Requested			PEDSQL Acute Version: Young Adult (18-25 years)	Requested	
	HFS - Parent of Young Children (HFS-P-YC)	Requested			PEDSQL Standard Version: Young Adult (18-25 years)	Requested	
Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE)	INSPIRE Survey - Child	Requested		Problem Areas in Diabetes (PAID)	PEDSQL Acute Version: Adult (>26 years)	Requested	
	INSPIRE Survey - Teen	Requested			PEDSQL Standard Version: Adult (>26 years)	Requested	
	INSPIRE Survey - Adult	Requested			PAID - Pediatrics	Requested	
	INSPIRE Survey - Parent	Requested			PAID - Child	Requested	
	INSPIRE Survey - Partner	Requested			PAID - Parent of Child	Requested	
					PAID - Teen	Requested	
					PAID - Parent of Teens	Requested	
					PAID - Parent	Requested	
				Tanner Staging		Public Domain	Supplement in progress
				Type 1 Diabetes and Life Measures (T1DAL)		Requested	
				Treatment Related Impact Measure for Diabetes (TRIM-D)		To be requested	

# QRS

Home / Standards / Foundational / QRS

## QRS

CDISC develops SDTM (tabulation) and ADaM (analysis) QRS supplements that provide information on how to structure the data in a standard copyright-approved instruments. An instrument is a series of questions, tasks or assessments used in clinical research to provide a qualitative 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 designed for administration and analysis. Questionnaires often have a defined standard 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 to assess a qualitative concept.
- **Functional Tests:** Functional Test instruments are stored in the Functional Tests (FT) domain and are named, standalone task-based evaluations of assessment of mobility, dexterity, and/or cognitive ability. A Functional Test is not a subjective assessment of how the subject generally performs a task; rather, it is an objective 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.

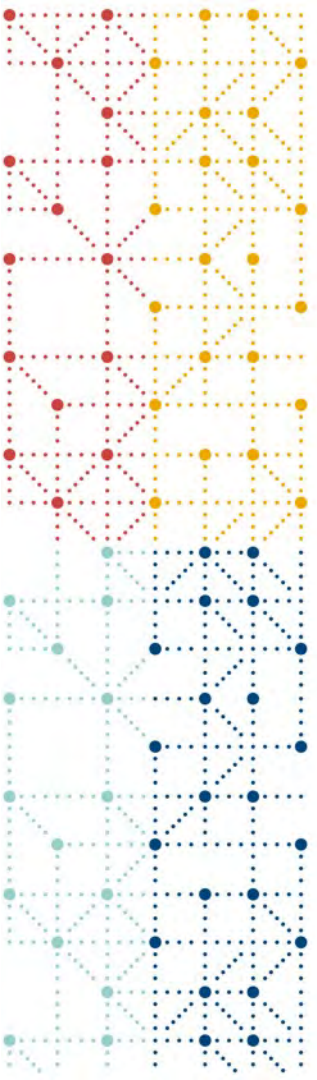
Clinical Classifications are based on a trained healthcare professional's observation of a subject's health condition or status with input from associated clinical records review. Clinical Classifications may be based solely on objective data from clinical records, or may involve a clinical judgment 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.

### All Published QRS Supplements

SDTM Domain/ADaM Dataset	Permission	QRS Name Starts With	QRS Name Contains	--CAT Contains	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Apply"/>
QRS Name	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version Release Date	
<a href="#">12-Item Multiple Sclerosis Walking Scale</a>	MSWS-12	QS	No Response Received	Version: 15 Oct 2020	
<a href="#">6 Minute Walk Test</a>	SIX MINUTE WALK	FT	Public Domain	Version: 1.0 21 May 2014	
<a href="#">Abnormal Involuntary Movement Scale</a>	AIMS-	QS	Public Domain	Version: 1.0 22 May 2013	
<a href="#">Acute Physiology and Chronic Health Evaluation II</a>	APACHE II	RS	Public Domain	Version: 1.0 29 Jun 2016	
<a href="#">ADHD Rating Scale-IV Home Version</a>	ADHD-RS-IV HOME VERSION	QS	No Response Received	Version: 15 Oct 2020	
<a href="#">Age, treatment with systemic antibiotics, leukocyte count, serum albumin, and serum creatinine as a measure of renal function</a>	ATLAS	RS	Public Domain	Version: 1 19 May 2020	
<a href="#">Airway Questionnaire</a>	AQ20	QS	Granted	Version: 1.0 12 Feb 2014	
<a href="#">Alcohol Use Disorders Identification Test - Consumption Questions</a>	ALEXTC	QS	Public Domain	Version: 1.0 6 Nov 2014	
<a href="#">Alcohol Use Disorders Identification Test - Self Report Version</a>	ALEXSR	QS	Public Domain	Version: 1.0 19 Nov 2014	

# 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.



# Audience Questions



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?





# Audience Questions



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



### TechniCon

- Tuesday, 2 February: Asia-Pacific Rim
- Wednesday, 3 February: EMEA
- Friday, 5 February: India
- Monday, 8 February: Americas

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!

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## 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.



**Blended Learning  
from CDISC**

Online Resources  
+ In-Person Instruction  
More Personalized Learning

Classes Starting Soon!

The graphic features a central laptop screen with a person's head inside, surrounded by icons for a lightbulb, a camera, a magnifying glass, a speech bubble, a calendar, and a person icon. The background is blue with white and yellow dotted lines.



**CDISC Redefines Data Standards Training  
NEW VIRTUAL CLASSROOM!**

- 100% Instructor Led
- Immediate Feedback
- Small Class Sizes
- Remote Convenience

cdisc

The graphic shows a large smartphone in the center with a person standing on it, pointing at a screen. Surrounding the phone are several people in various work settings, connected by a network of lines. The background is a light green color.



# Thank You!

Questions, comments, concerns? Email [bklinke@cdisc.org](mailto:bklinke@cdisc.org)

Don't forget to fill out the feedback survey!

