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

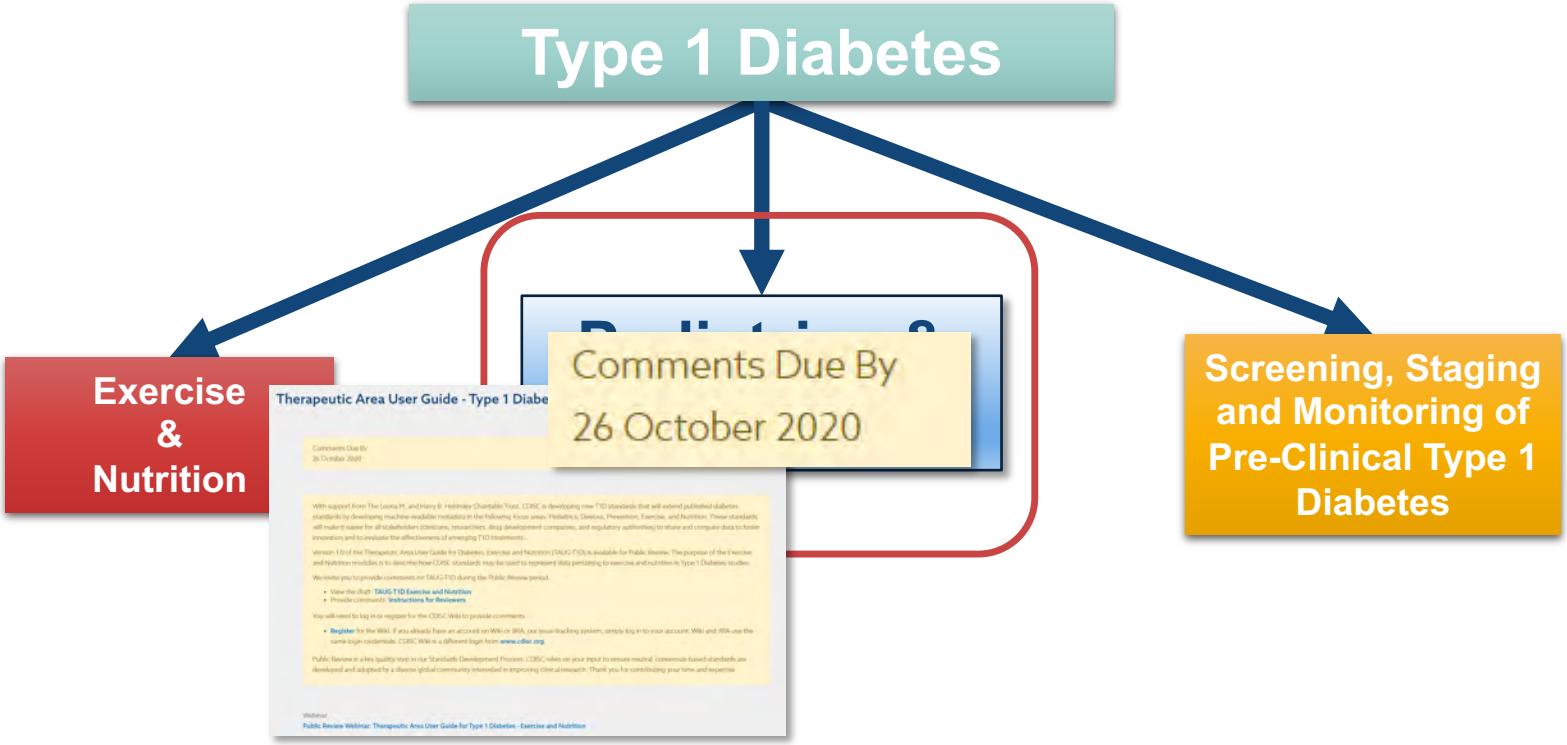
- Rebecca Baker, Standards Developer, CDISC
- Richard Marshall, Consultant Standards Developer, CDISC
- Kathleen Mellars, Consultant Standards Developer, CDISC
- John Owen, Head of Partnerships and Development, CDISC

Type 1 Diabetes TAUG – Pediatrics and Devices

Publication Webinar

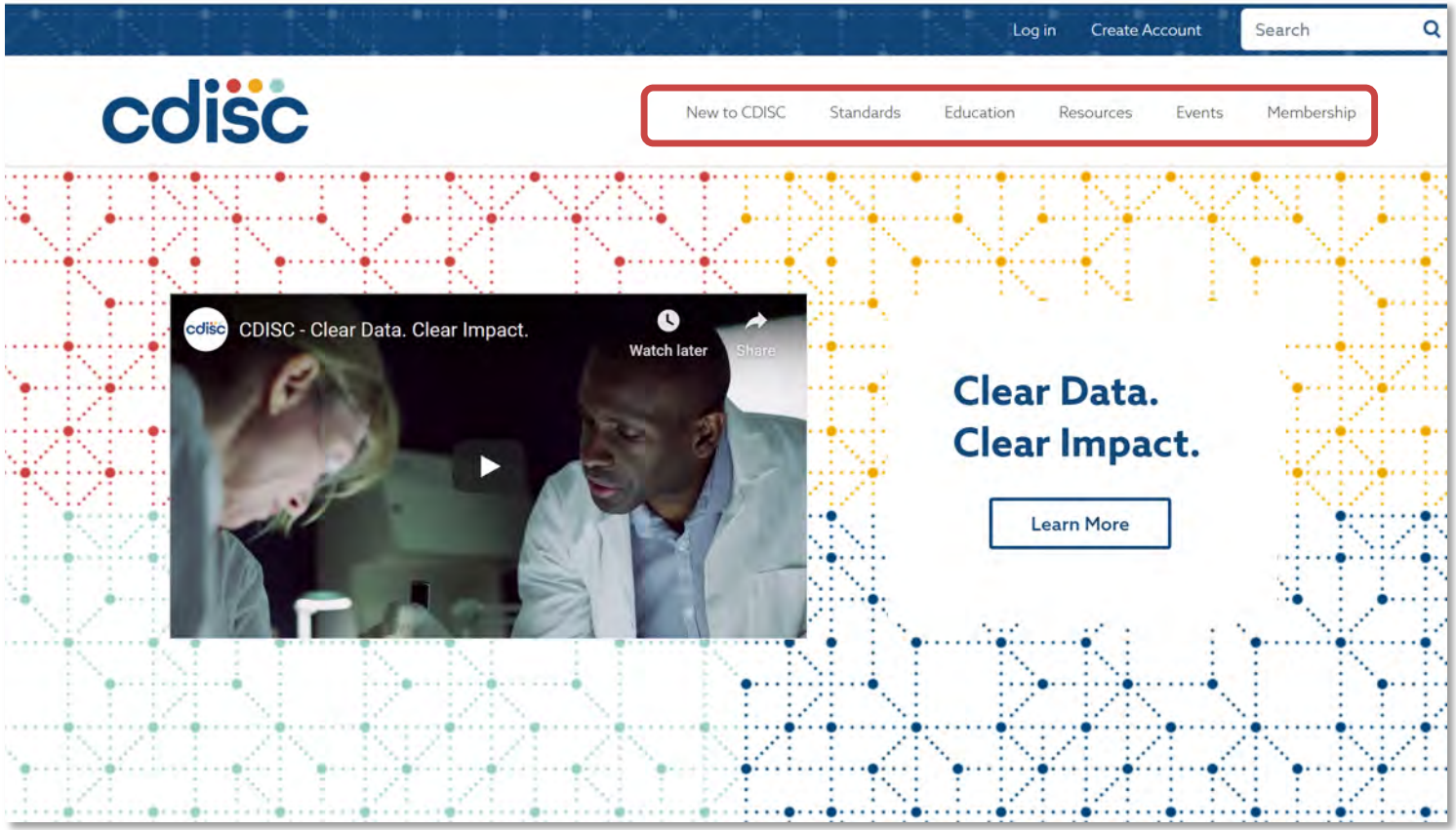
15th October 2020

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

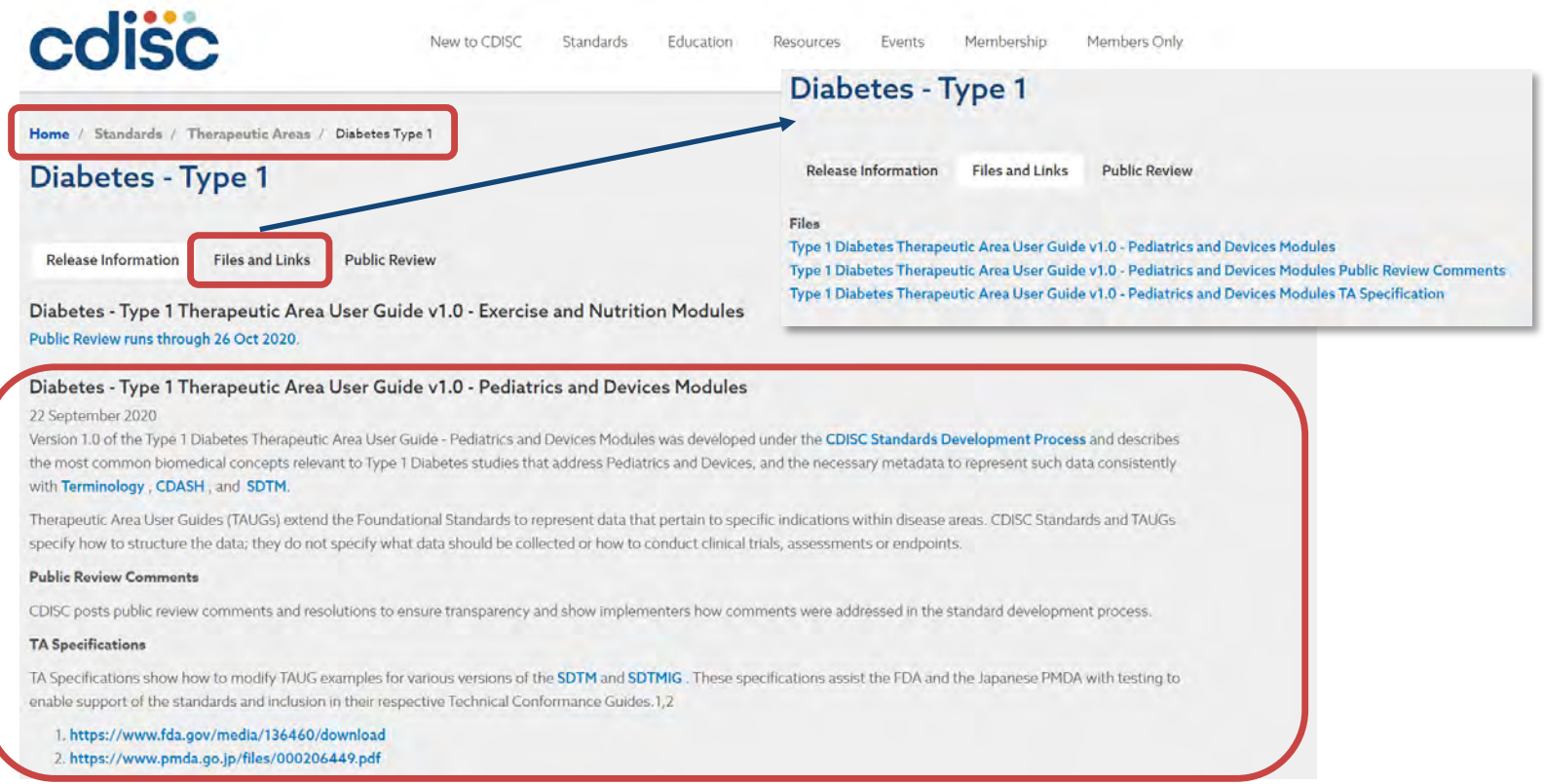


https://www.cdisc.org/public-review/therapeutic-area-user-guide-type-1-diabetes-exercise-and-nutrition

https://www.cdisc.org/



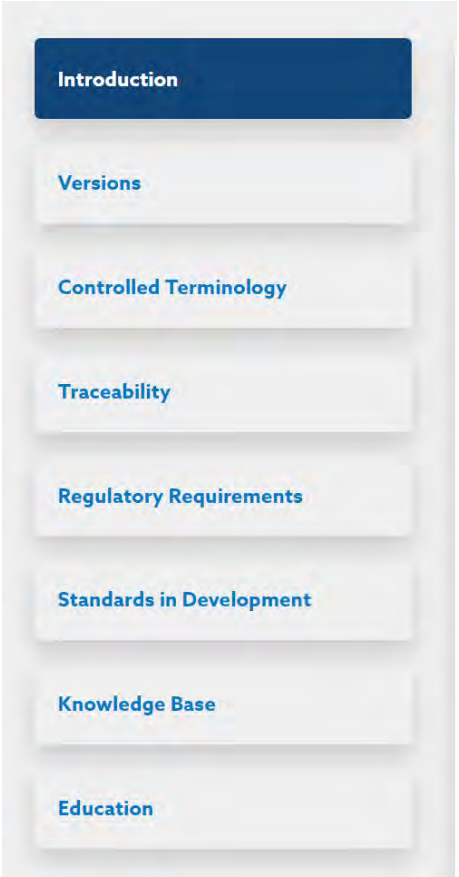
Type 1 Diabetes – Pediatrics and Devices



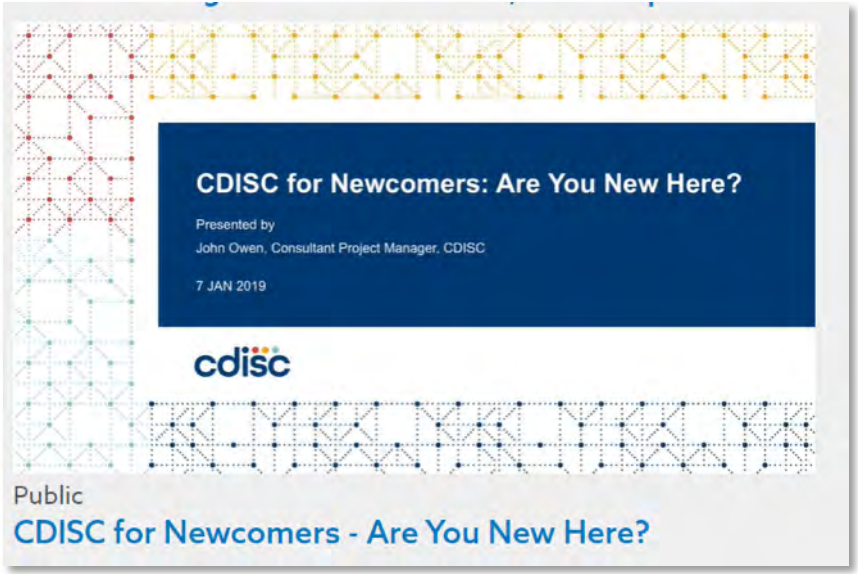
Getting Started with CDISC Standards - Videos

Getting Started with CDISC Standards – CDISC Primer

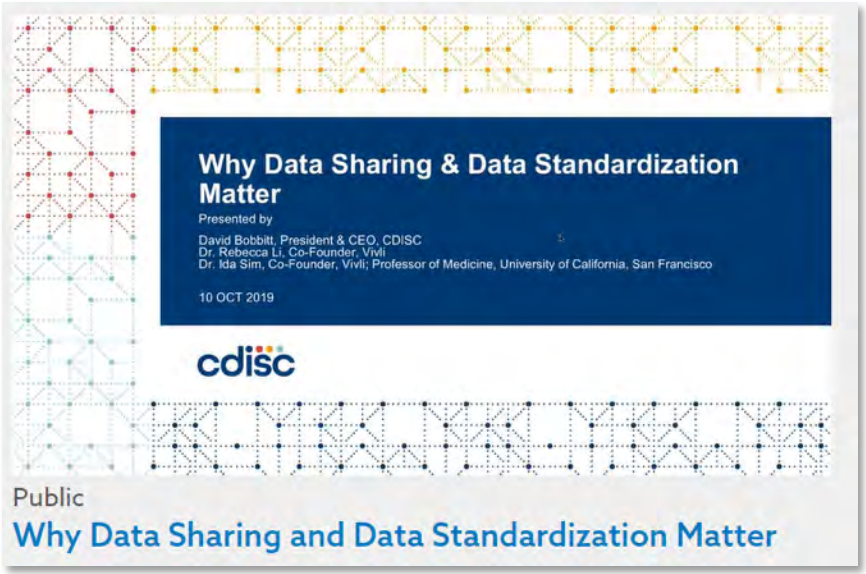
https://www.cdisc.org/primer



Getting Started with CDISC Standards - Webinars

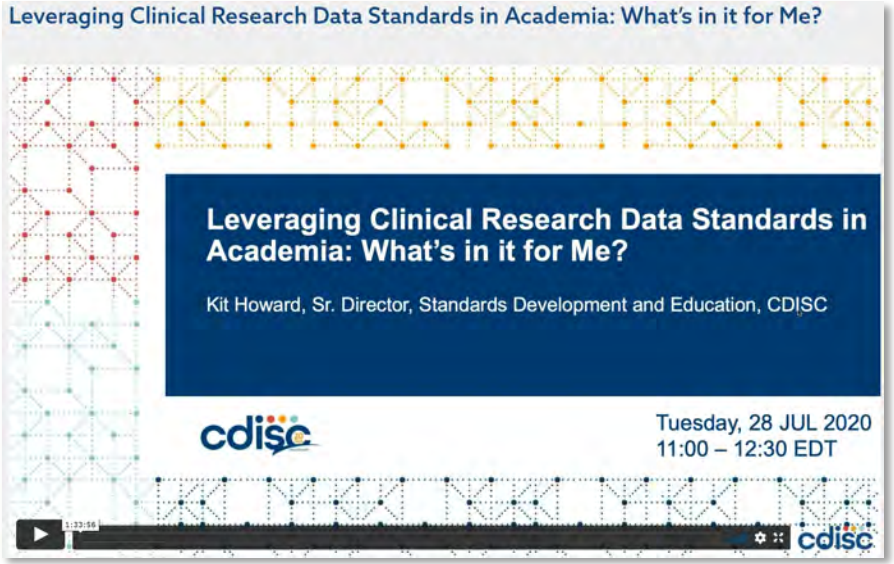


[CDISC for Newcomers]



[Why Standards Matter]

Getting Started with CDISC Standards - Webinars



CDISC for Academics

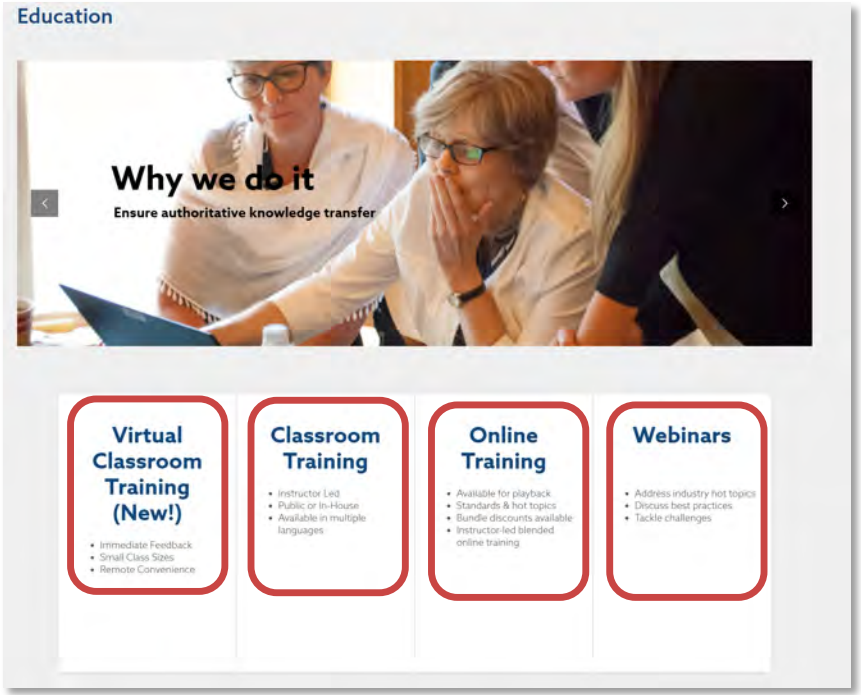
If you've ever asked any of these questions:

- "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?"

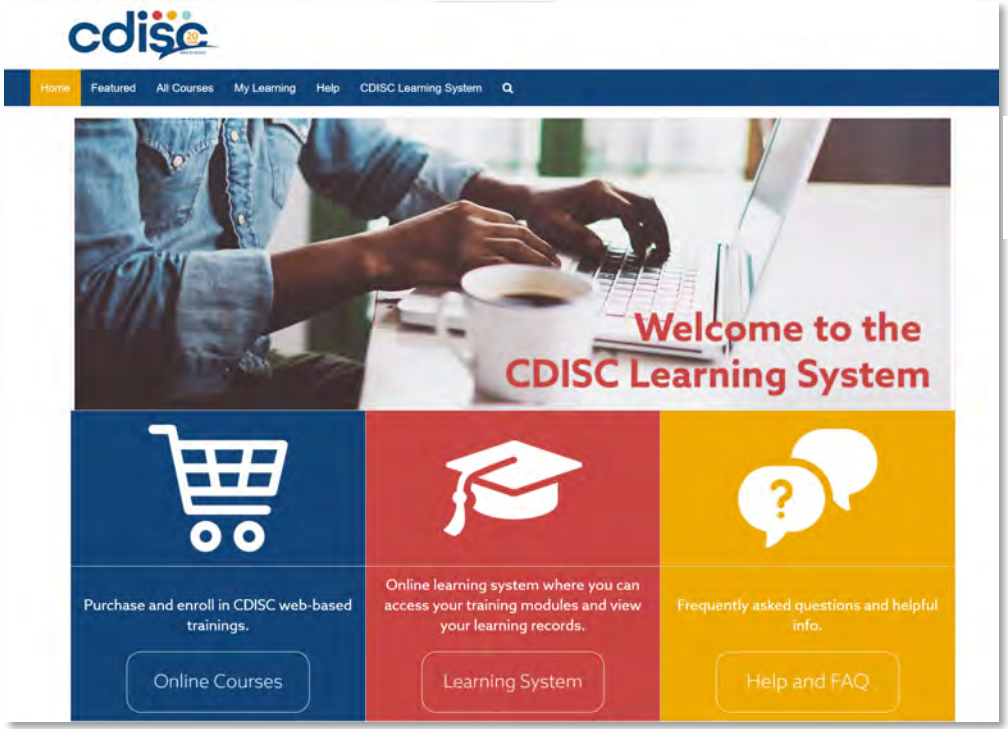
This webinar is for you.

Getting Started with CDISC Standards - Education

https://www.cdisc.org/education



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

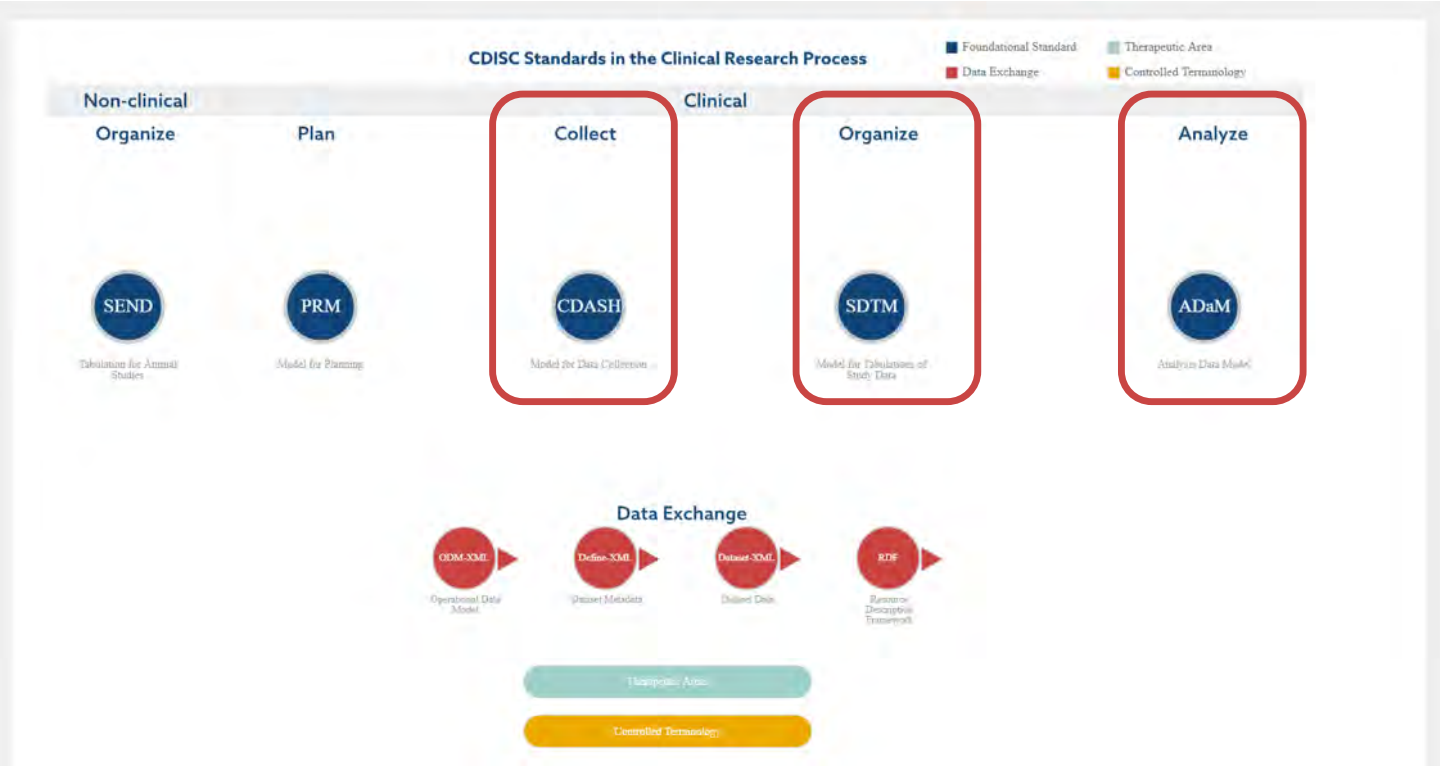
This training outlines how academic and research organizations can implement CDISC standards within their organizations. In this training, learners will understand the benefits of adopting CDISC standards. The training will also provide academics with a useful toolkit and helpful information for collecting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

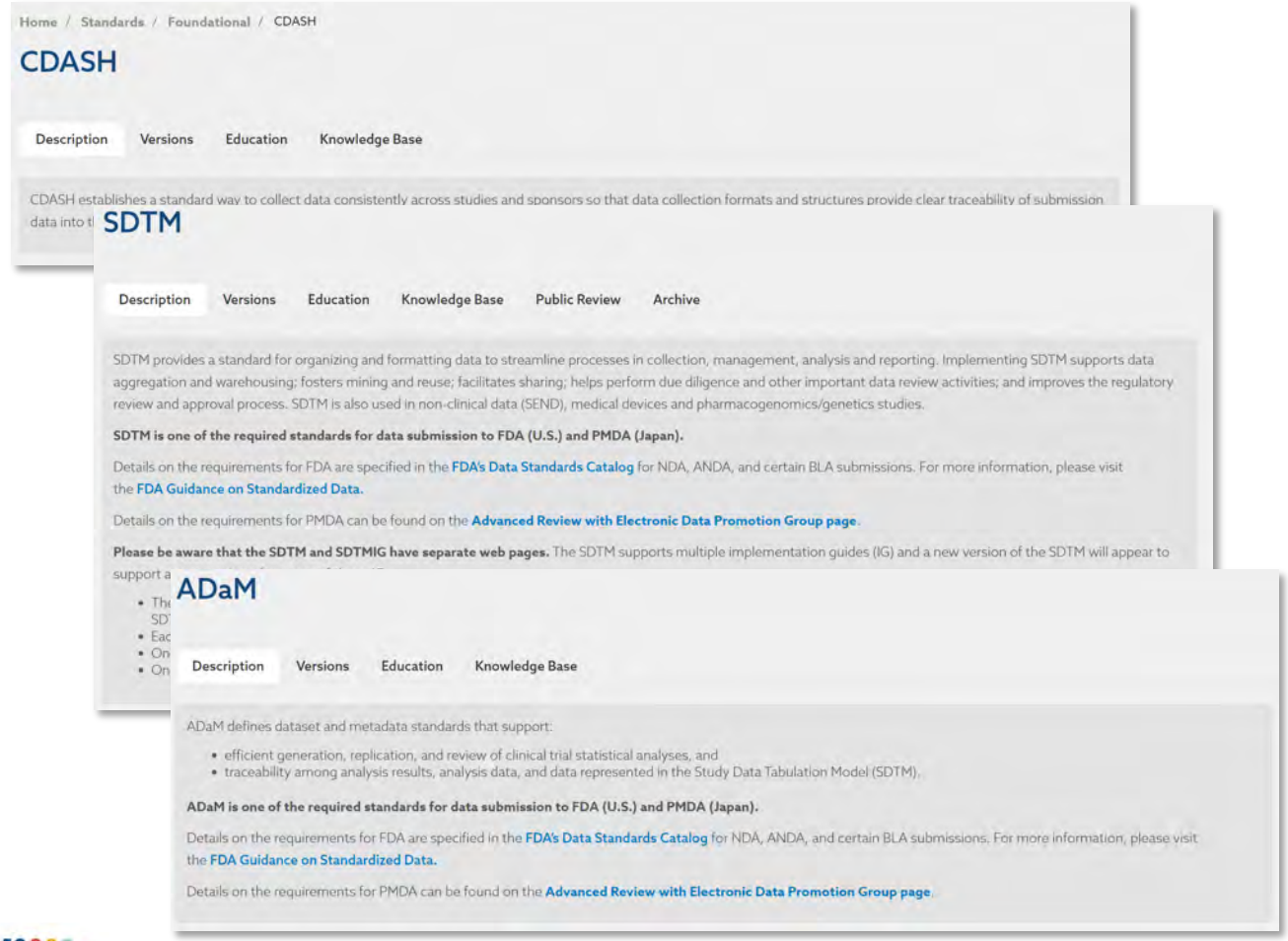
Course-Level Learning Outcomes

- 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

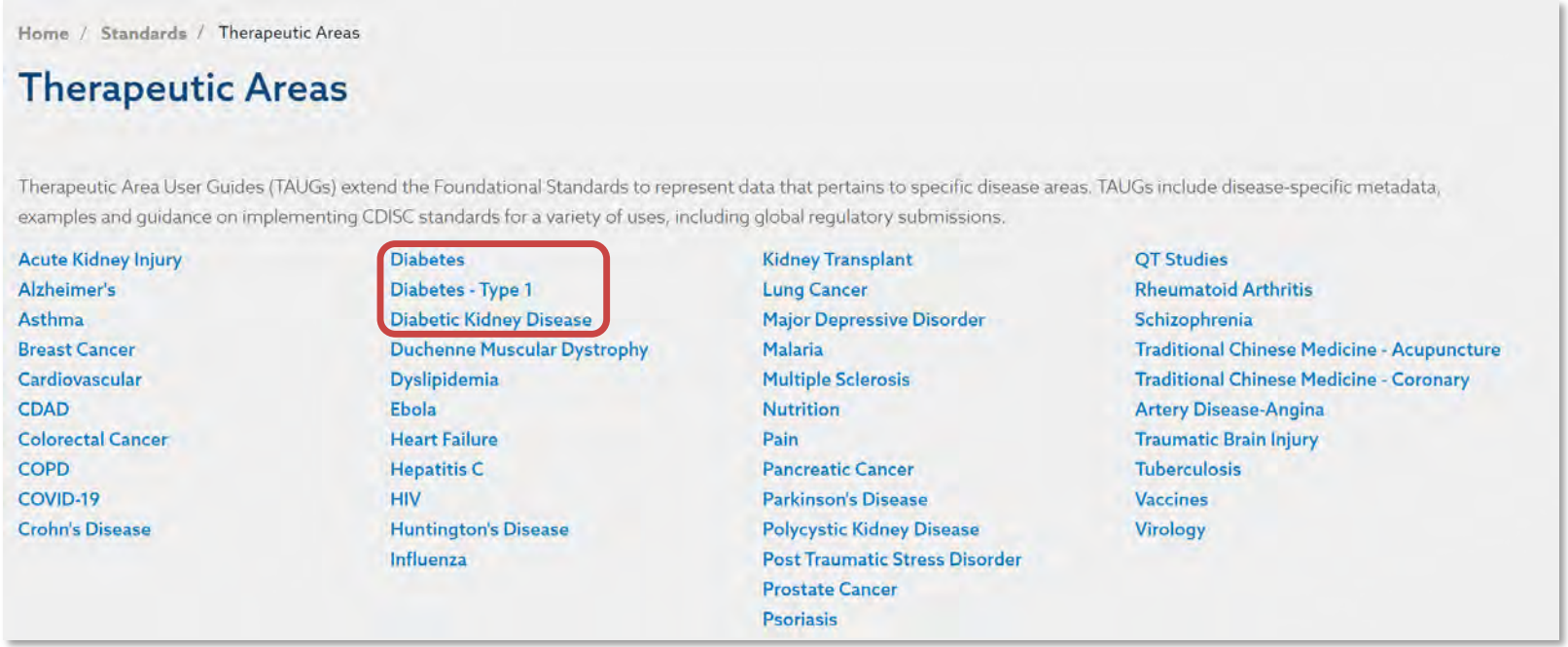
https://www.cdisc.org/standards




Home / Standards / Foundational / CDASH
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
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
ADaM
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.

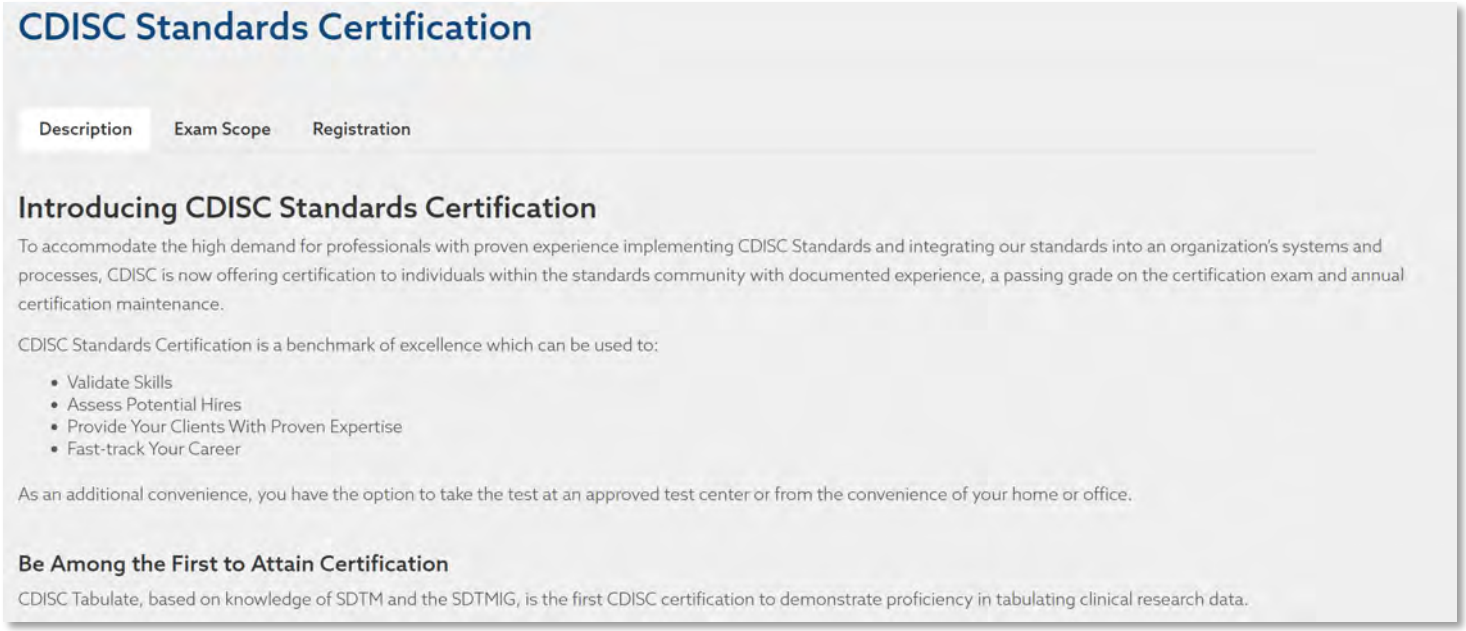
CDISC Therapeutic Area user Guide Documentation

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



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.

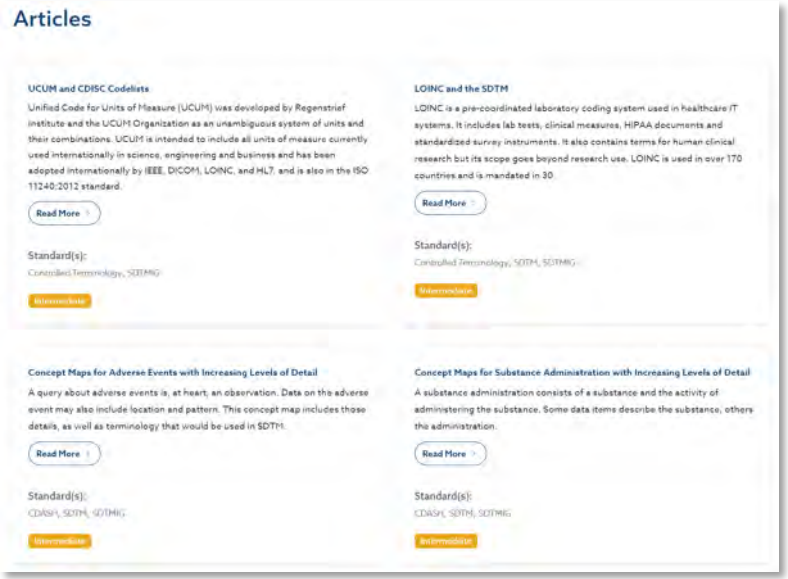
Be Among the First to Attain Certification

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

Knowledgebase

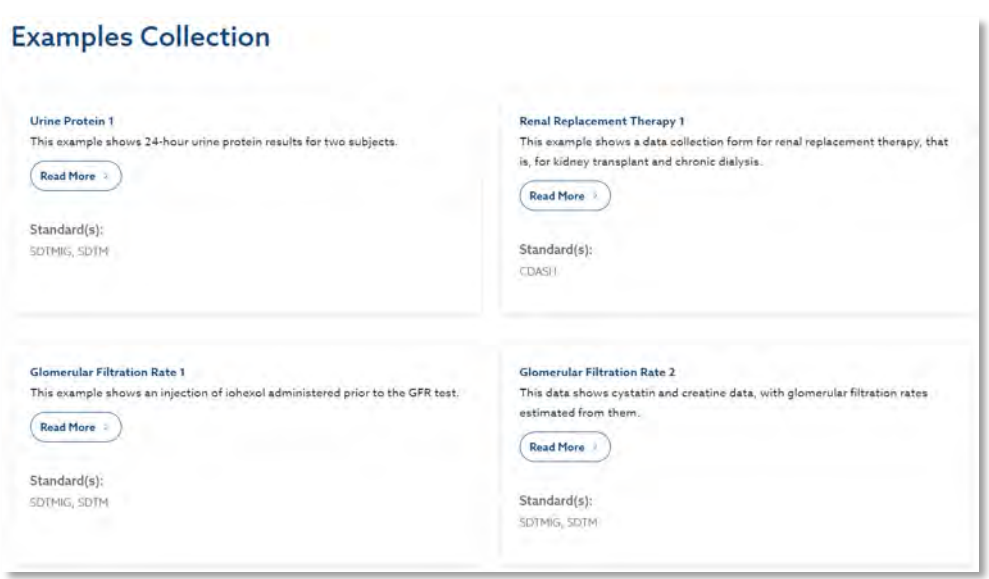
Articles

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



Examples Collection

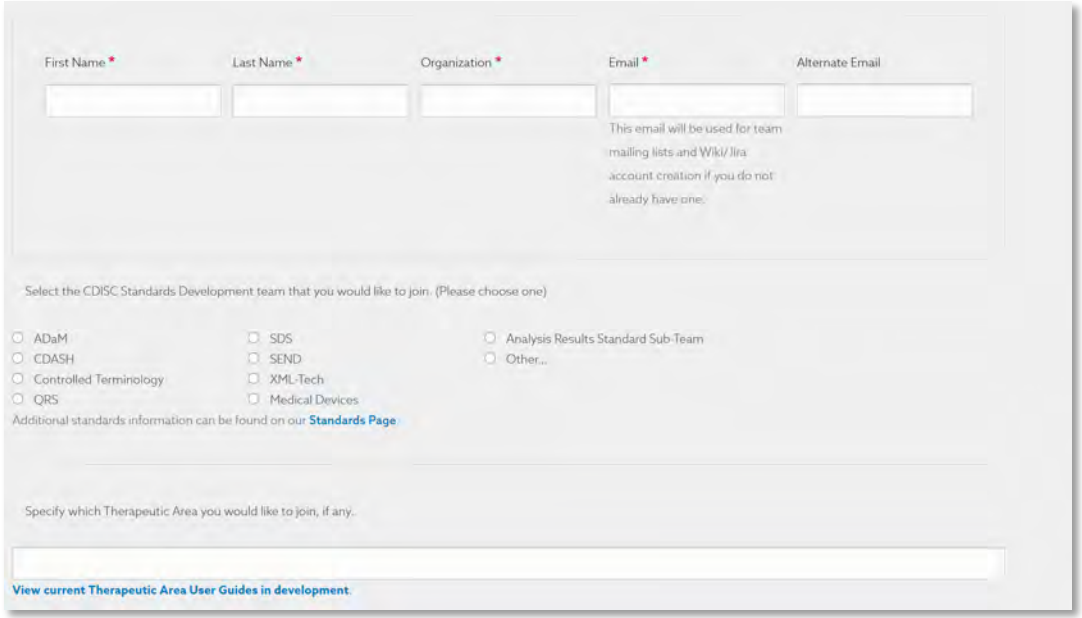
A set of CDISC-curated examples culled from our Foundational Standards and Therapeutic Area User Guide (TAUGs)



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

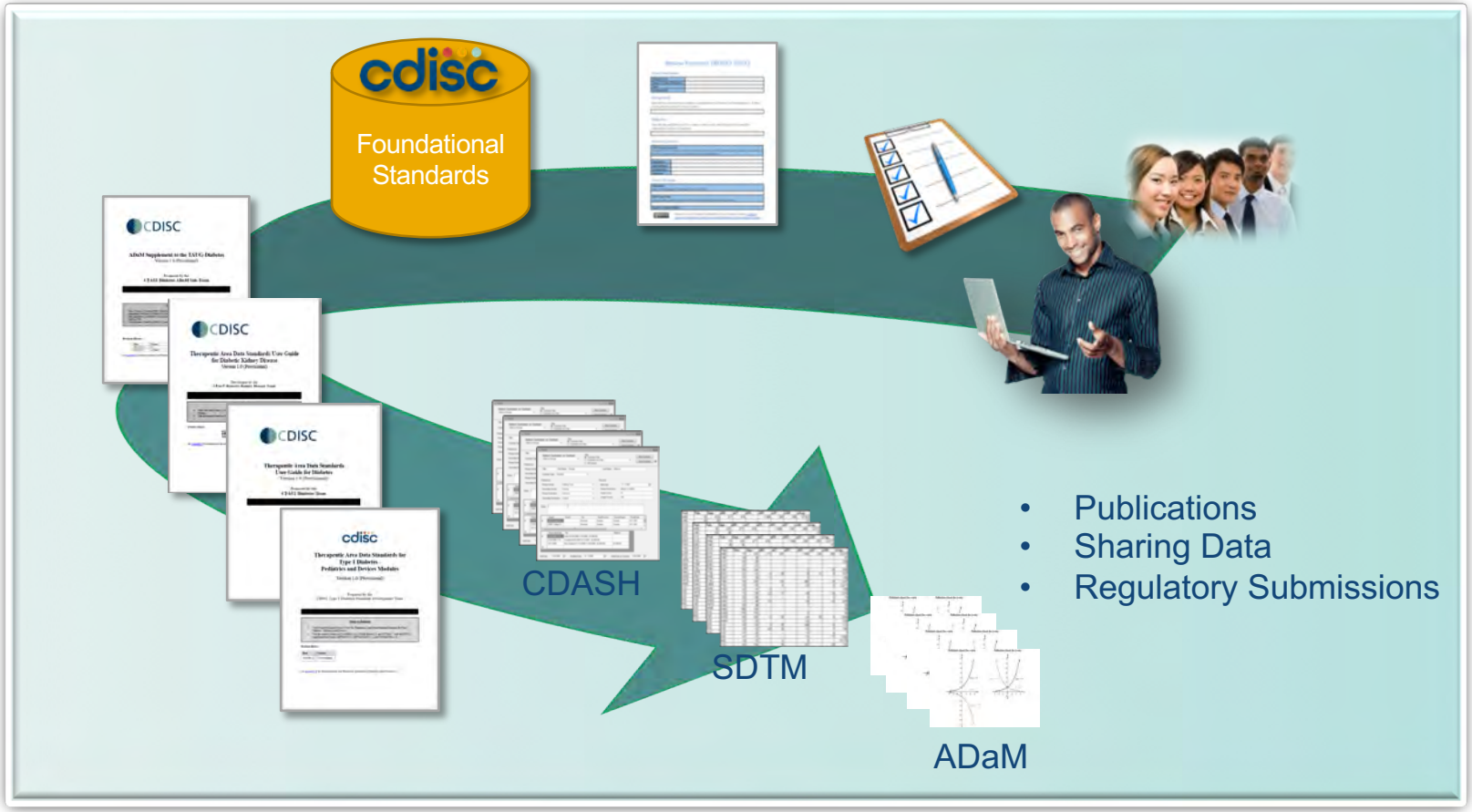
- Knowledgebase Articles
- Public Webinars/Interchanges/User Networks

CDISC Membership

Join the collaborative efforts of over

[480 CDISC member organizations]

https://www.cdisc.org/membership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Foundational Standards
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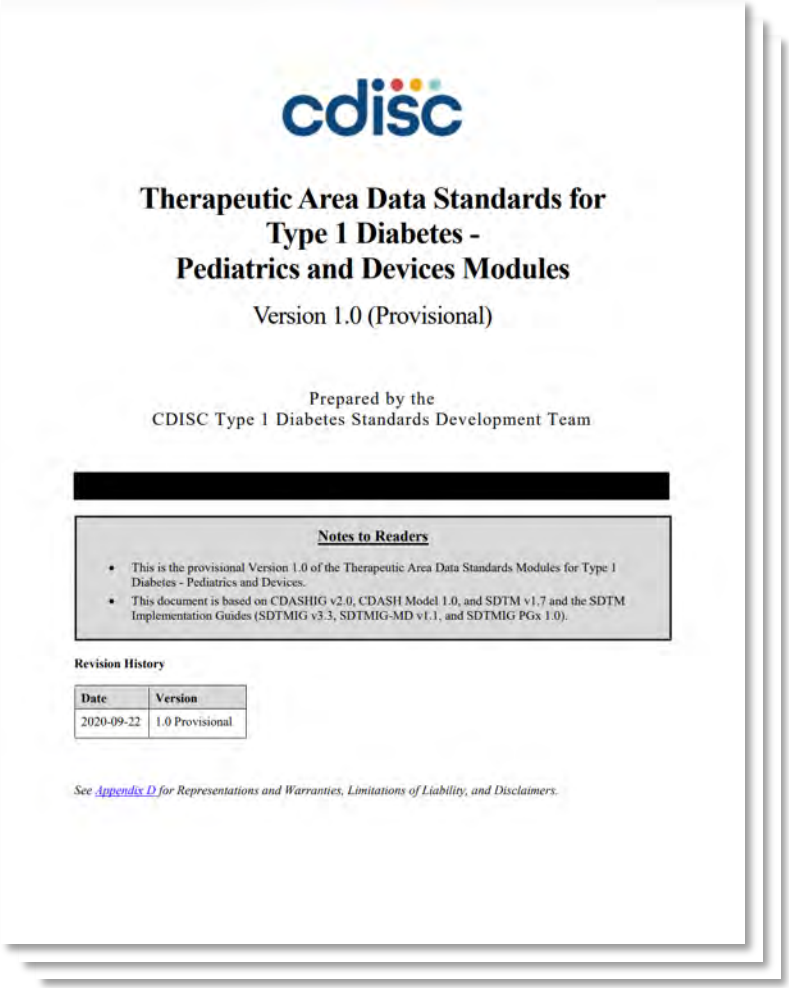
CDASH
SDTM
ADaM
• Publications
• Sharing Data
• Regulatory Submissions



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

[redacted]

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).

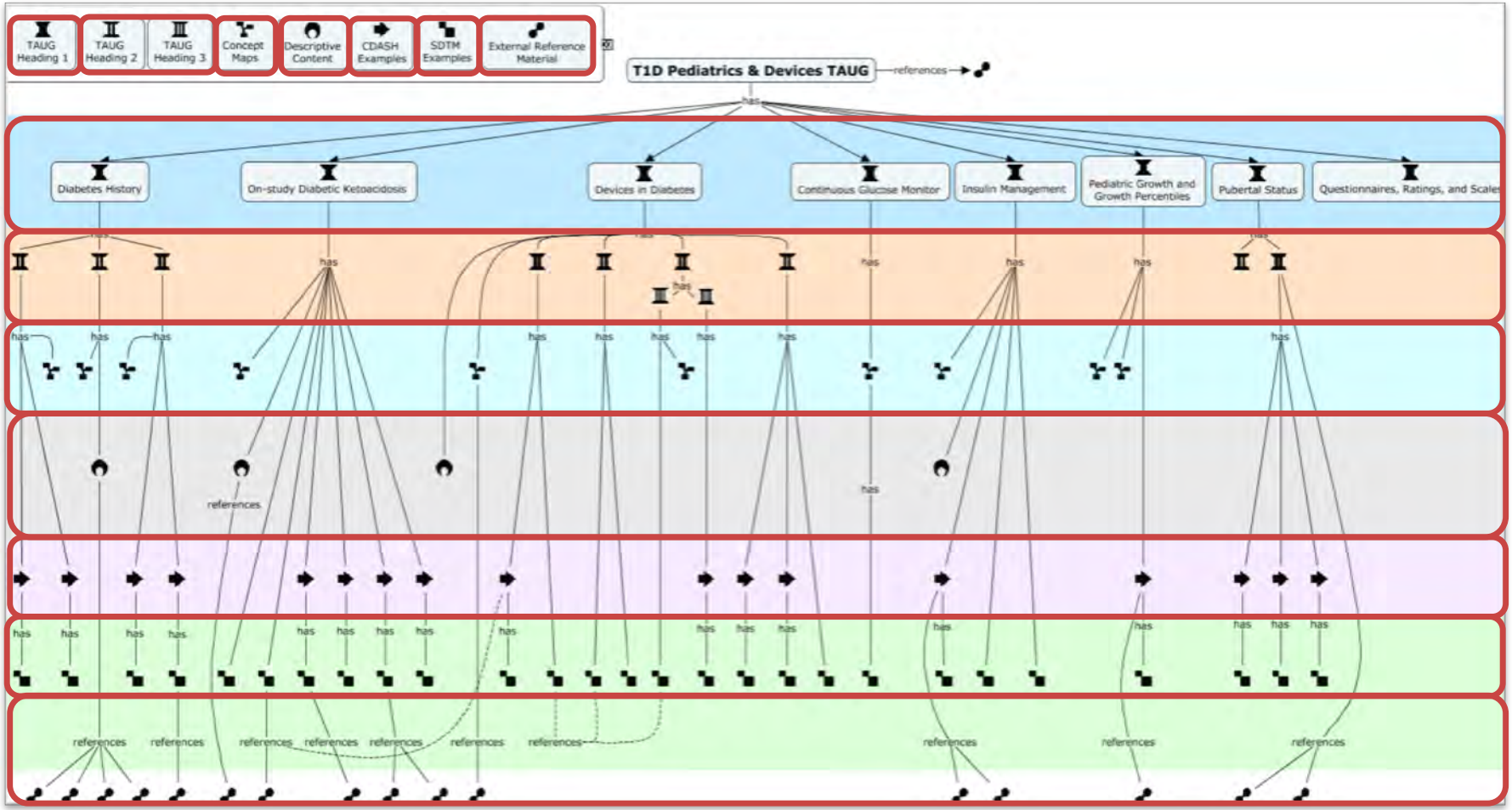
Revision History

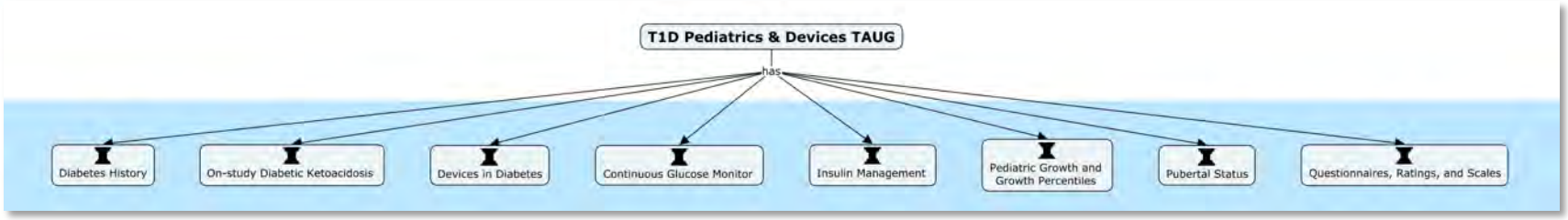
Date	Version
2020-09-22	1.0 Provisional

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 DKA Laboratory DKA Symptoms/Precipitating Factors DKA Event – Device in Use Devices Used to Manage Diabetes Device History & More
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 DKA Laboratory DKA Symptoms/Precipitating Factors DKA Event – Device in Use Device History Devices Used to Manage Diabetes & More
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	

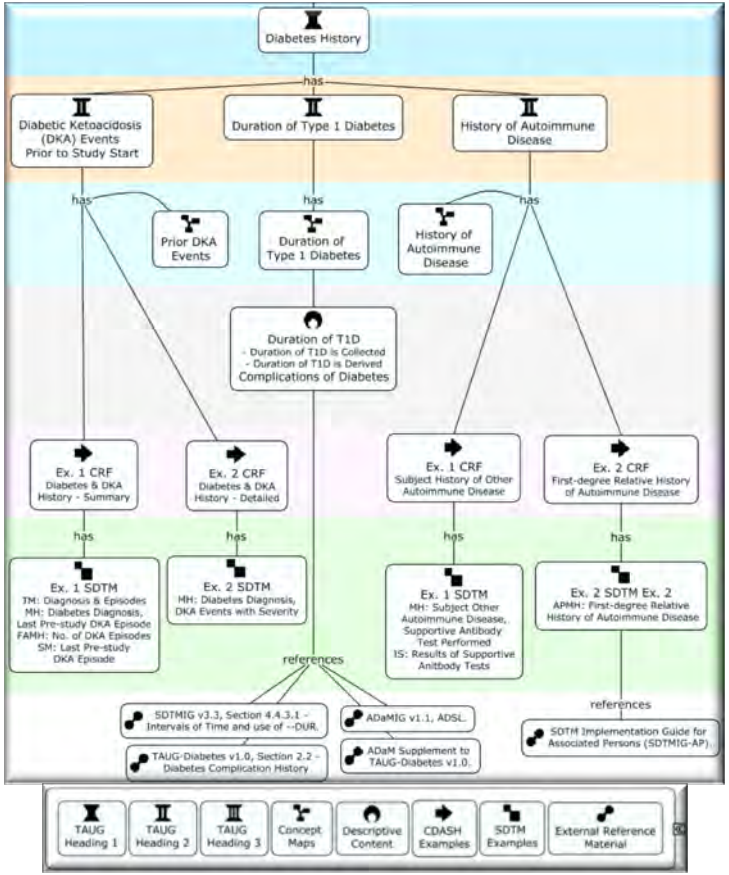

TAUG Heading 1
TAUG Heading 2
TAUG Heading 3
Concept Maps
Descriptive Content
CDASH Examples
SDTM Examples
External Reference Material
T1D Pediatrics & Devices TAUG
references
has
Diabetes History
On-study Diabetic Ketoacidosis
Devices in Diabetes
Continuous Glucose Monitor
Insulin Management
Pediatric Growth and Growth Percentiles
Pubertal Status
Questionnaires, Ratings, and Scales
has
references



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

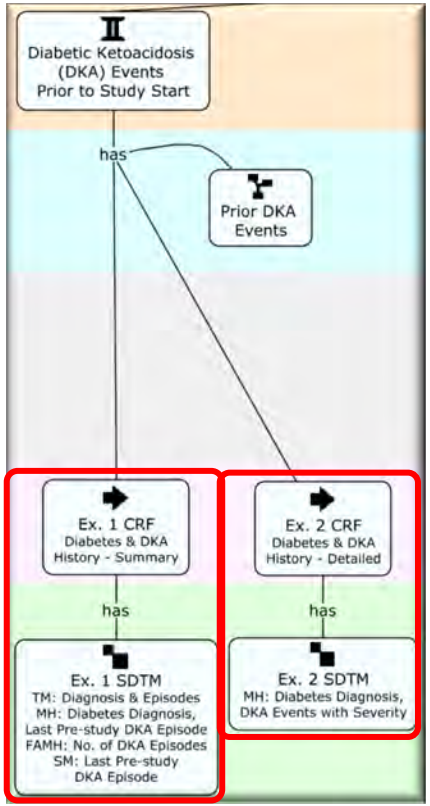

On-study Diabetic Ketoacidosis
Devices in Diabetes
Continuous Glucose Monitor
Diabetes History

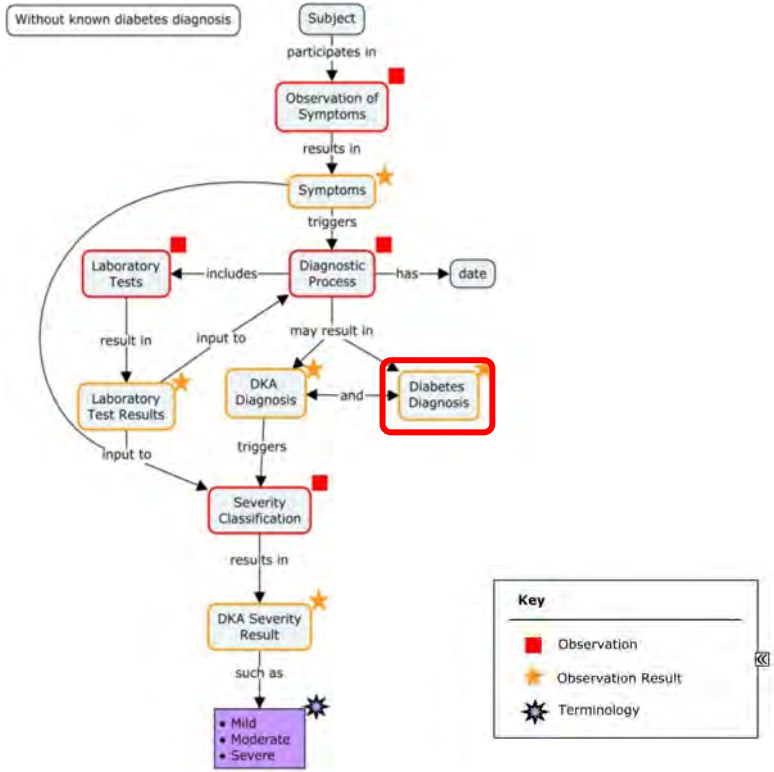
Diabetes History



Diabetes History

Diabetic Ketoacidosis Events Prior to Study Start

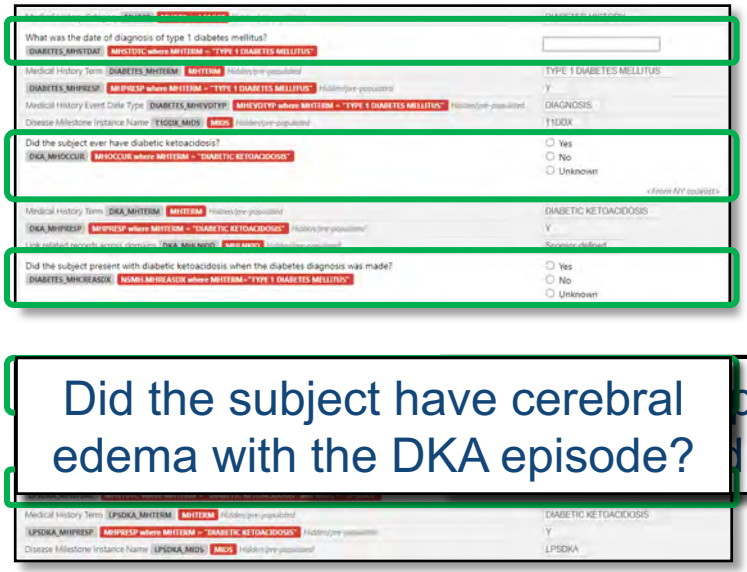




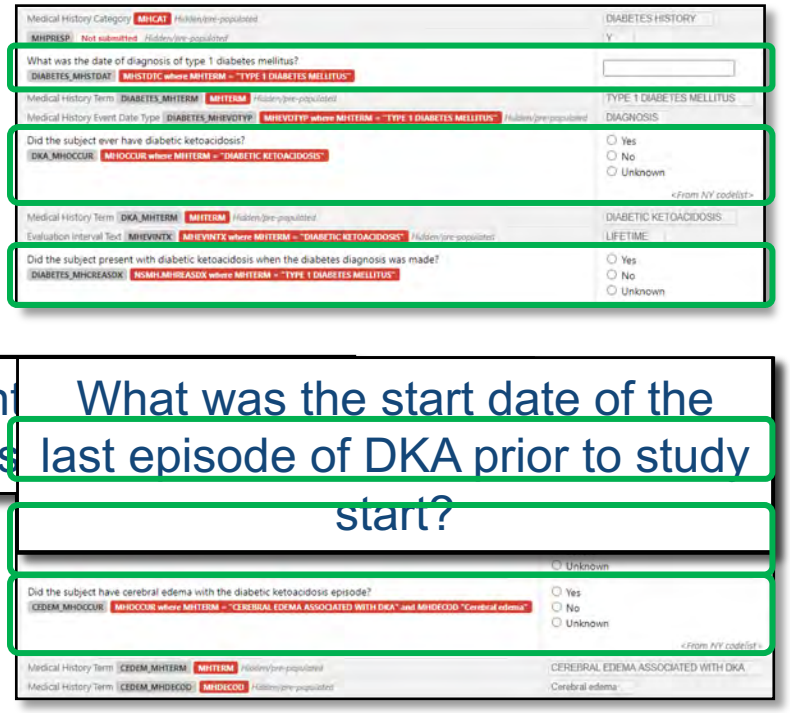
Diabetes History

Diabetic Ketoacidosis Events Prior to Study Start

Example 1



Example 2



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

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHLNKID	MHTERM	MHDECOD	MHEVDTYP	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

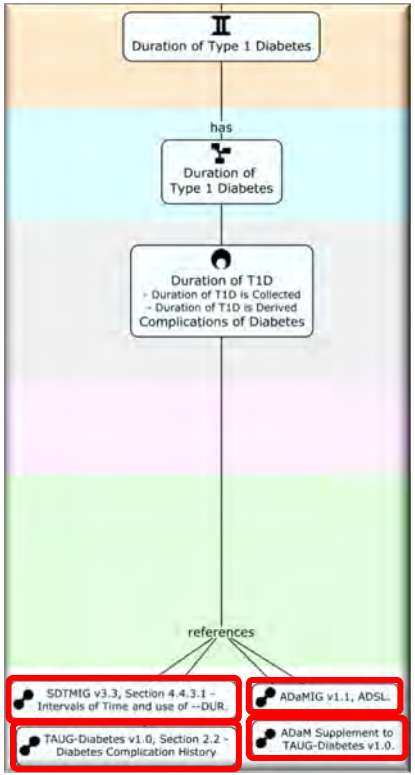
Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHGRPID	MHTERM	MHDECOD	MHEVDTYP	MHCAT	MHPRESP	MHOCCUR	MHSEV	VISIT	VISITNUM	MHDTC	MHSTDTC	MHEVINTX	MHREASDX
1	ABC124	MH	0001	1		TYPE 1 DIABETES MELLITUS	Type 1 diabetes mellitus	DIAGNOSIS	DIABETES HISTORY	Y	Y		1	SCREENING	2017-09-01	2017-02-13		DIABETIC KETOACIDOSIS
2	ABC124	MH	0001	2		DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y		1	SCREENING	2017-09-01		LIFETIME	
3	ABC124	MH	0001	3	1	DIABETIC KETOACIDOSIS	Diabetic ketoacidosis		DIABETES HISTORY	Y	Y	MODERATE	1	SCREENING	2017-09-01	2017-05-18	SINCE TYPE 1 DIABETES DIAGNOSIS	
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	

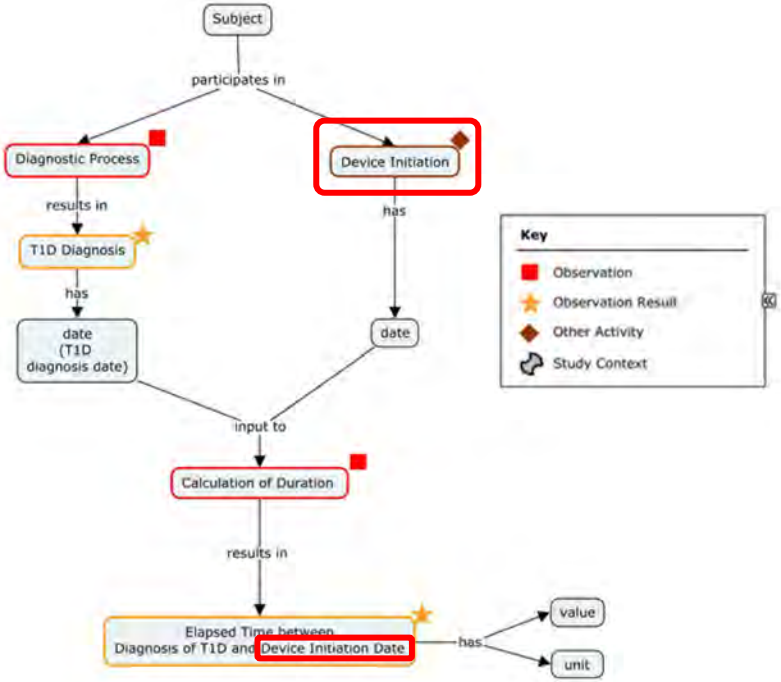
Diabetes History
Diabetic Ketoacidosis Events Prior to Study Start

Modeling Highlights

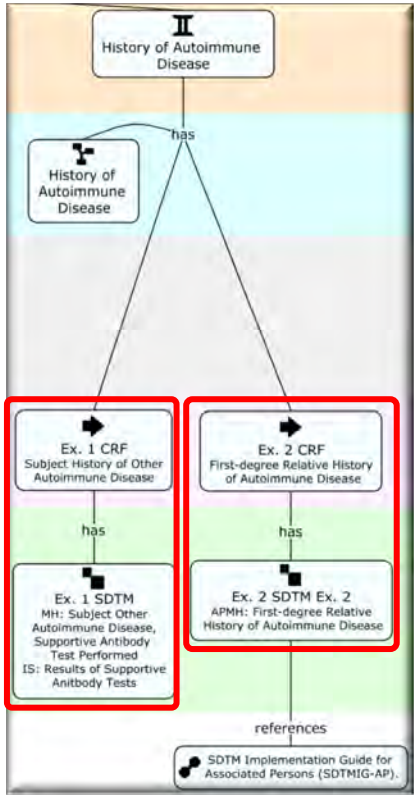
- Use of disease milestones
  - Trial Disease Milestones (TM) domain to define the disease milestones of interest for the study
  - Subject Disease Milestones (SM) domain to record occurrences of each milestone for each subject
- Findings About Medical History (FAMH) domain for number of DKA episodes 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.

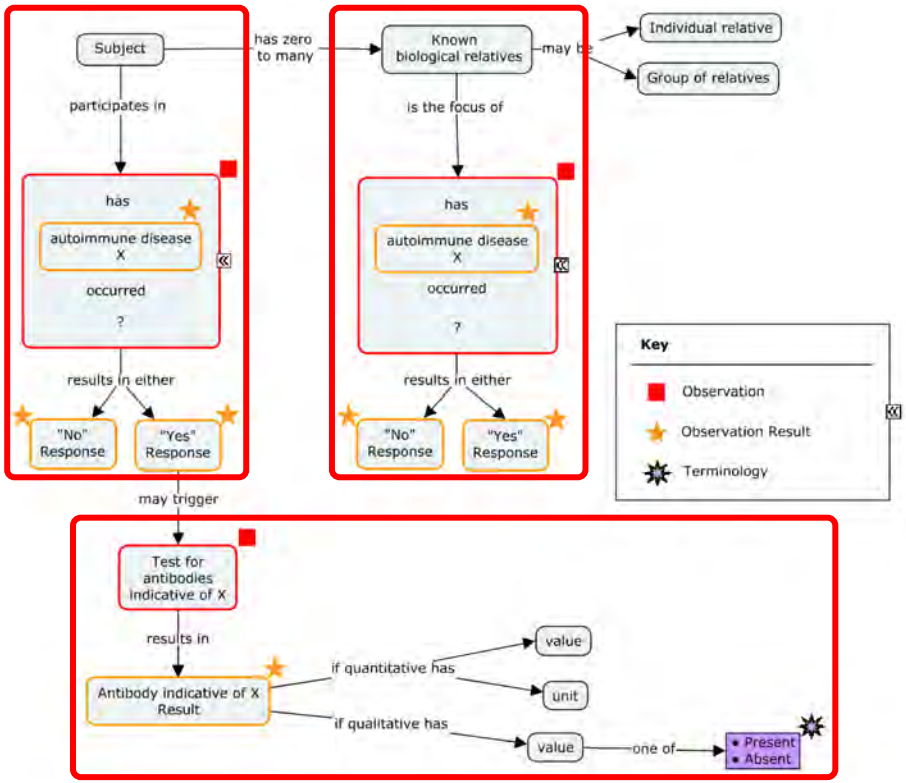
Diabetes History
Duration of Type 1 Diabetes





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	MHEVDTYP	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTC	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	CELIAC 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	2016-10-02	Y

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISGRPID	ISLNKID	ISTESTCD	ISTEST	ISCAT	ISSCAT	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU	ISNAM	ISSPEC	ISMETHOD	VISITNUM	VISIT	ISDTC	ISBDAGNT	ISTSTOPO
1	ABC123	IS	0001	1	1	2	ATIGAAB	Binding IgA Autoantibody	AUTOIMMUNE DISEASE OTHER THAN TYPE 1 DIABETES MELLITUS	SEROLOGY	Present					ABX	SERUM	ELISA	1	SCREENING	2017-09-01	Tissue Transglutaminase	SCREEN

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHEVDTYP	MHCAT	MHSCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHDTC	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	CELIAC 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

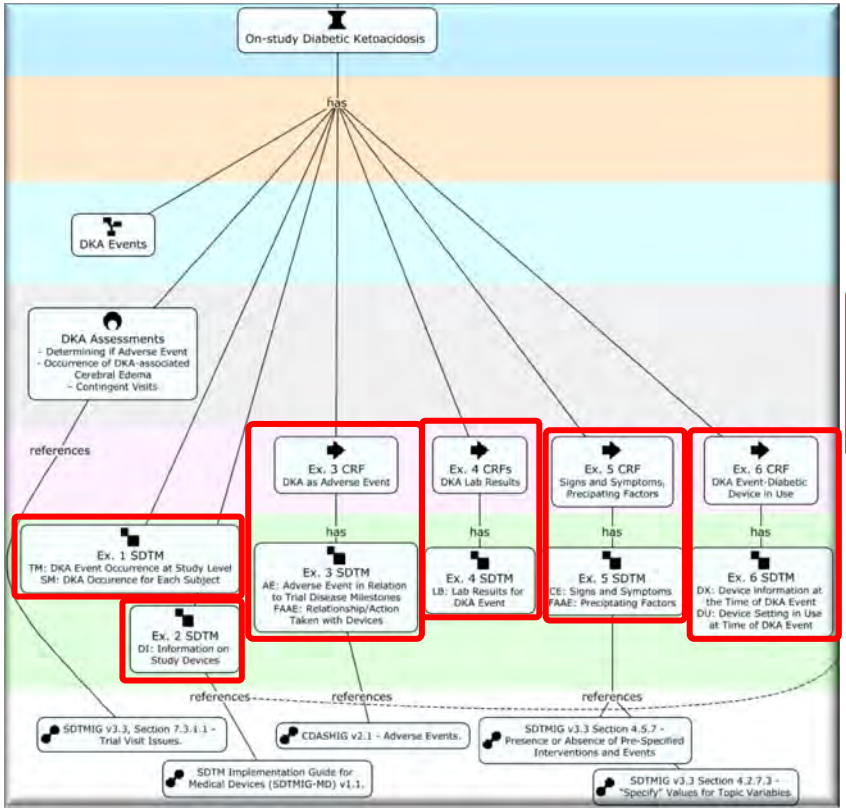
- Convention for representation of occurrence of pre-specified groups of conditions (e.g., occurrence of autoimmune disease other than type 1 diabetes)
  - Same value in MHTERM and either MHCAT or MHSCAT to indicate that the record represents information about a category of events
  - MHPRESP = “Y” to 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 ISTESTCD / ISTEST).
  - ISBDAGNT NSV to indicate the binding agent for the test.

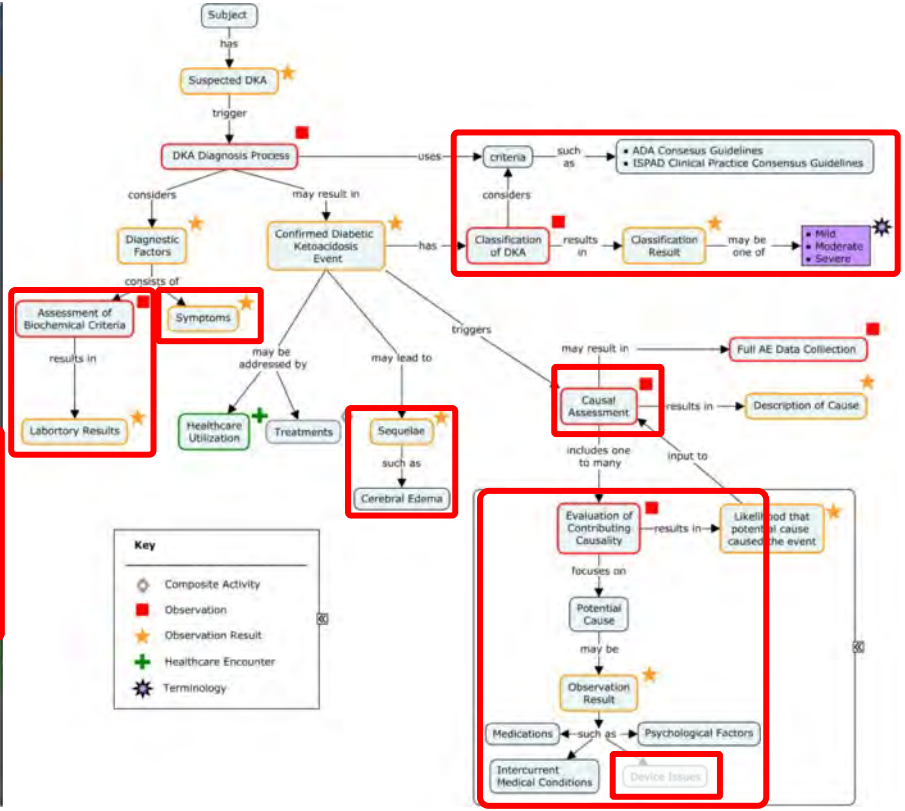
Diabetes History
Known Issues

- 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

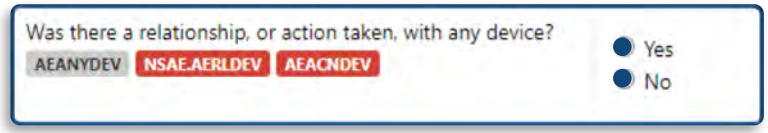
- Adverse Events (AE) domain for details of the DKA episode (e.g., start date, severity, relationship to study treatment, relationship to device(s))
- Findings About Adverse Events (FAAE) dataset for:
  - Recording the occurrence pre-specified adverse events (i.e., cerebral edema)
  - Action Taken / 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



Single device assessed

Multiple devices assessed

ae.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	AESEQ	AESPID	AETERM	AEDECOD	AEPRESP	AESER	AESEV	AEACN	AEACNOTH	AEACNDEV	AEREL	AEOUT	AESHOSP	AECONTRT	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

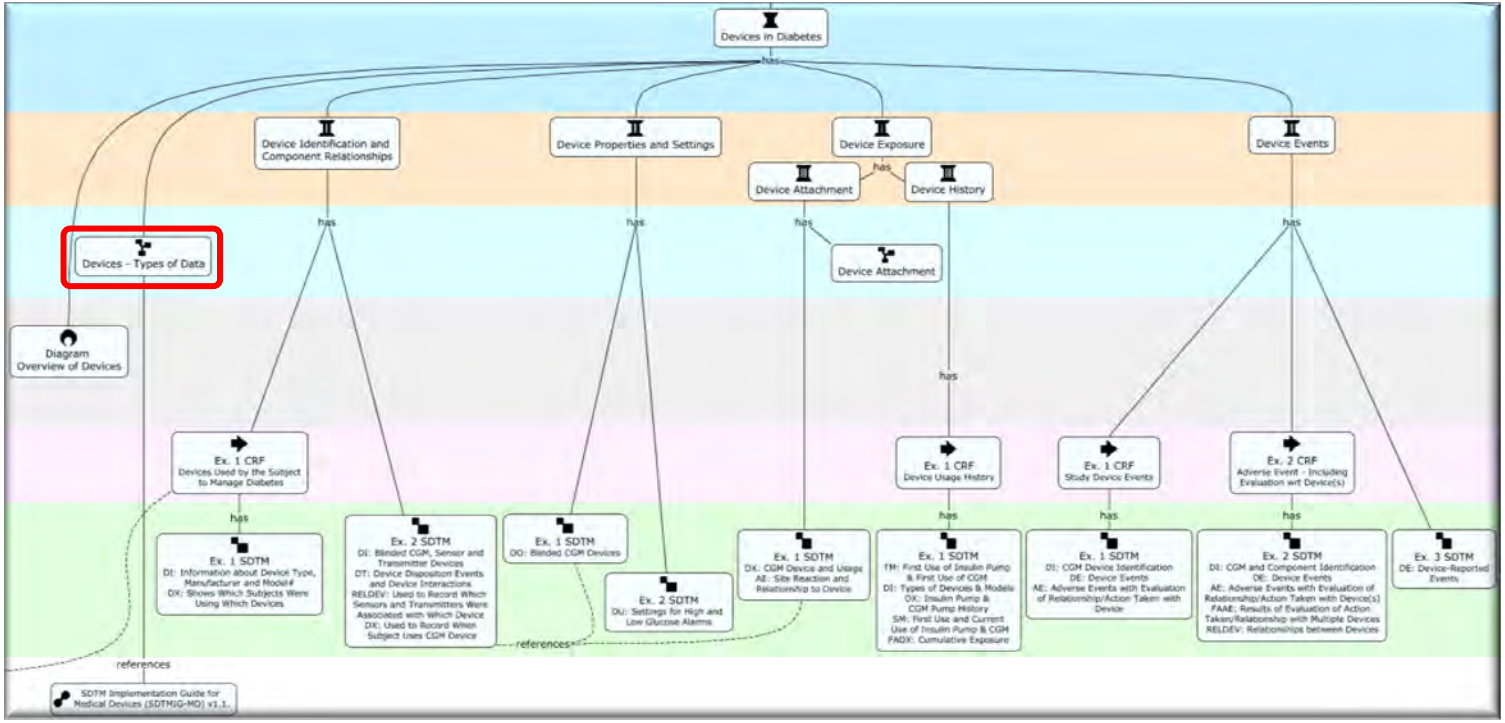
On-study Diabetic Ketoacidosis

Known Issues

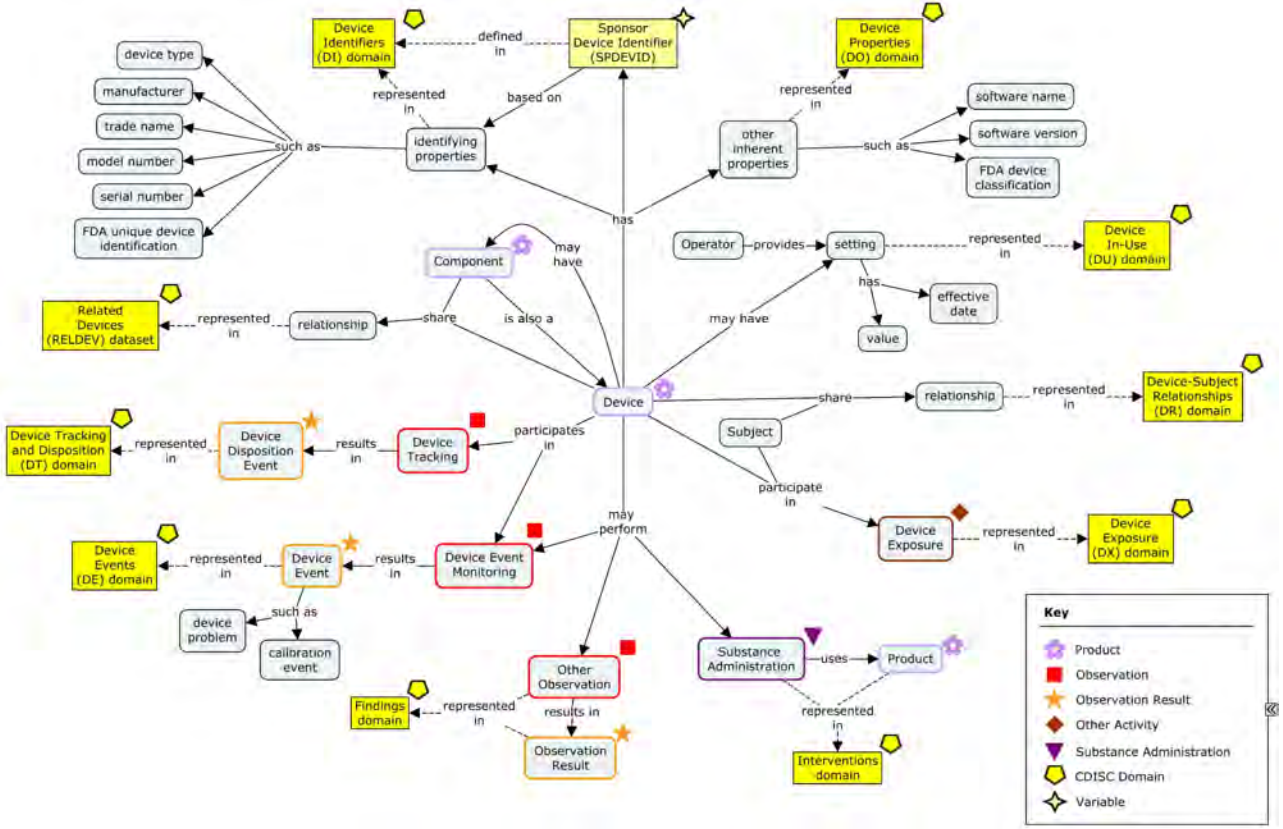
- Populating Variables --ACNDEV and --RLDEV When Multiple Values are Collected
  - Proposed use of “MULTIPLE” keyword with Findings About.
- Use of Adverse Event Severity (AESEV)
  - Proposed use of AESTDSEV and AESSEVCN NSVs for representation of AE severity assigned according to a named set of criteria (e.g., ADA Consensus Guidelines or ISPAD Clinical Practice Consensus Guidelines).


On-study Diabetic Ketoacidosis

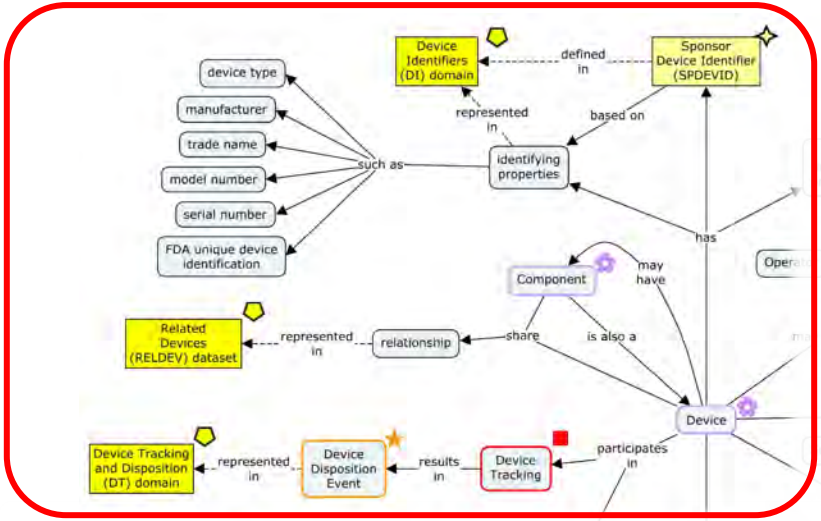
Devices in Diabetes



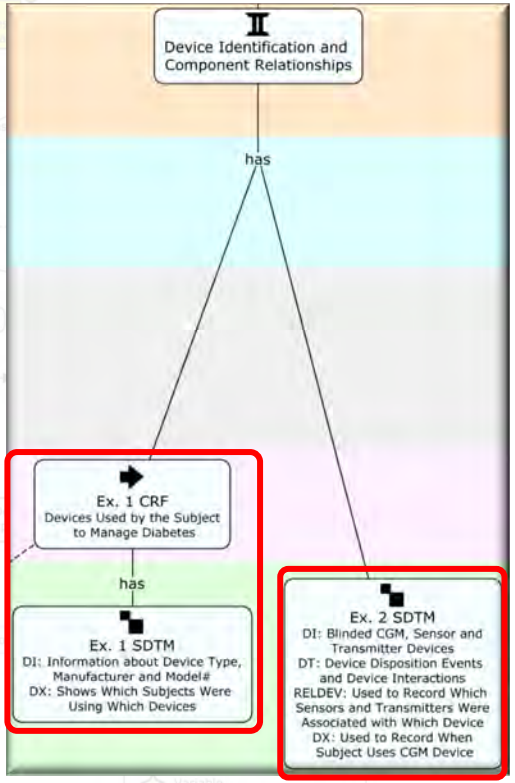
Devices in Diabetes



Devices in Diabetes

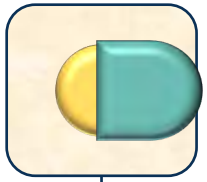


Device Identification and Component Relationships

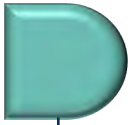


Device Identification and Component Relationships - Example 2

CGM-1



CGM-SNS-1



CGM-TRN-1

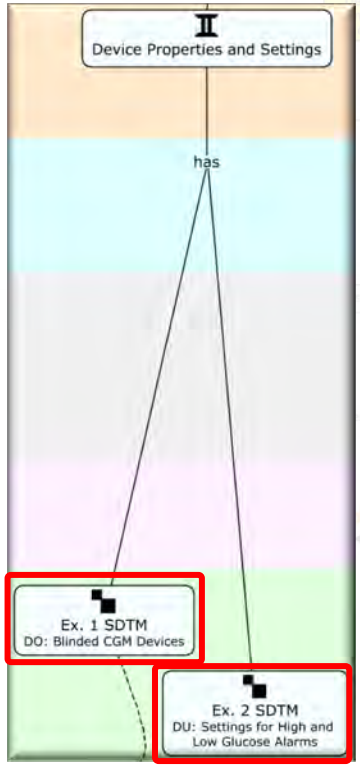
CGM Device Sensor Transmitter

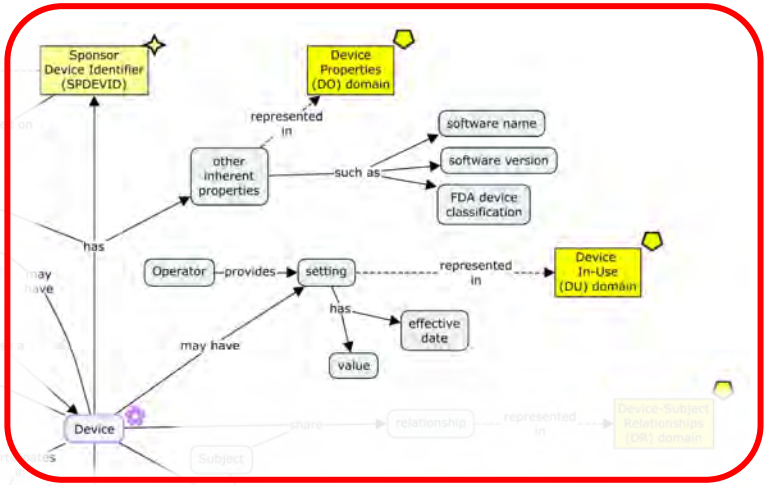
dl.xpt

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
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

Tuesday	Wednesday	Thurs
12	13 Get new CGM!	14
19	20 Replace CGM sensor	21
26	27 Replace CGM sensor	28
5	6 Replace CGM sensor	7
12	13 Replace CGM sensor + transmitter	14

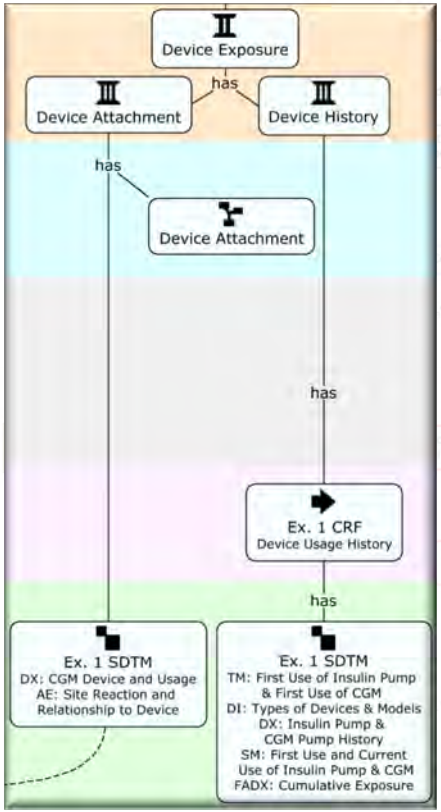
Devices in Diabetes



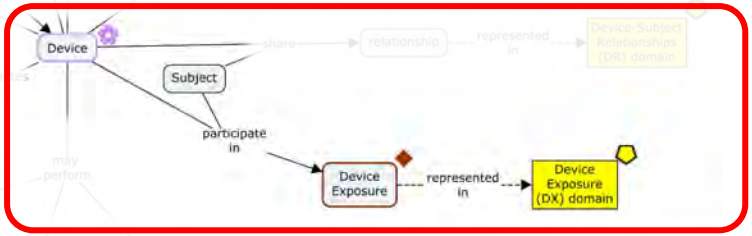


Device Properties and Settings

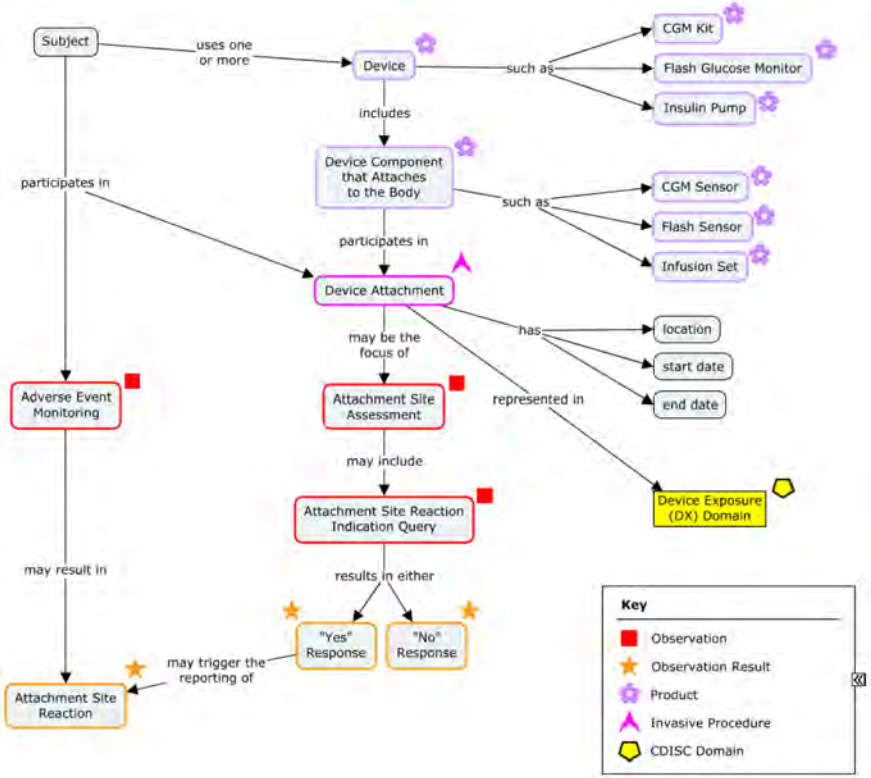
Devices in Diabetes



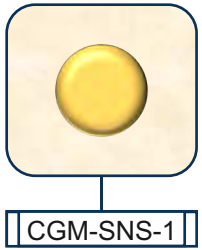
Device Exposure

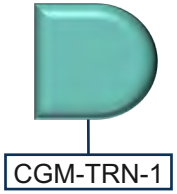


Devices in Diabetes
Device Attachment



Device Exposure / Device Attachment





Tuesday	Wednesday	Thurs
12	13 Get new CGM!	14
19	20 Replace CGM sensor	21
		28

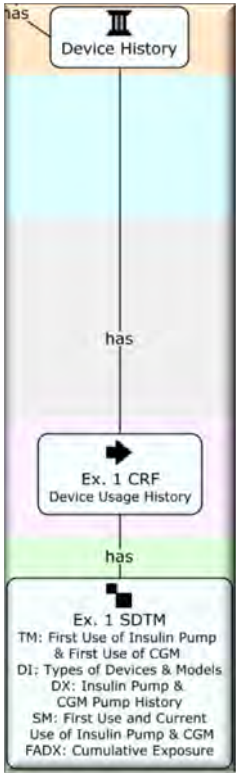
dx.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXCAT	DXROUTE	DXLOC	DXLAT	DXDIR	DXRSDISC	VISITNUM	VISIT	DXSTDTC	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	DXSTDTC	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	ABDOMINAL REGION	RIGHT	ANTERIOR		5	Visit 5	2019-03-15T08:35	2019-03-22T08:45
18	T001	DX	0002	CGM-TRN-14	10	CGM Transmitter	CGM COMPONENT REPLACEMENT						5	Visit 5	2019-03-15T08:35	2019-04-12T09:00
19	T001	DX	0003	CGM-3	1	CGM	SUBJECT DEVICES						1	Visit 1	2019-02-02	2019-02-03
20	T001	DX	0003	CGM-SNS-3	2	CGM Sensor	CGM COMPONENT REPLACEMENT	SUBCUTANEOUS	ABDOMINAL REGION	LEFT	ANTERIOR	PAIN AT SENSOR SITE	1	Visit 1	2019-02-02T14:15	2019-02-03T09:30
21	T001	DX	0003	CGM-TRN-3	3	CGM Transmitter	CGM COMPONENT REPLACEMENT					PAIN AT SENSOR SITE	1	Visit 1	2019-02-02T14:15	2019-02-03T09:30

Devices in Diabetes
Device History

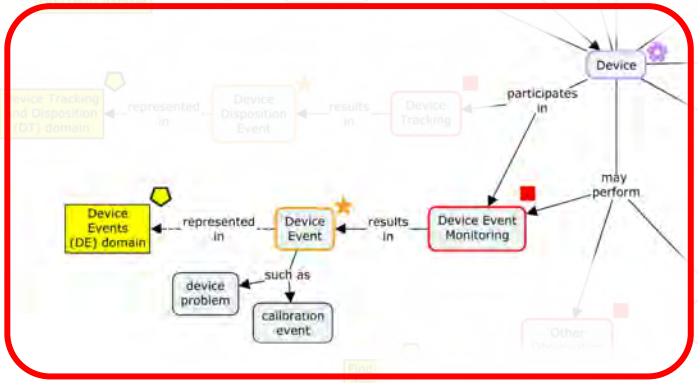


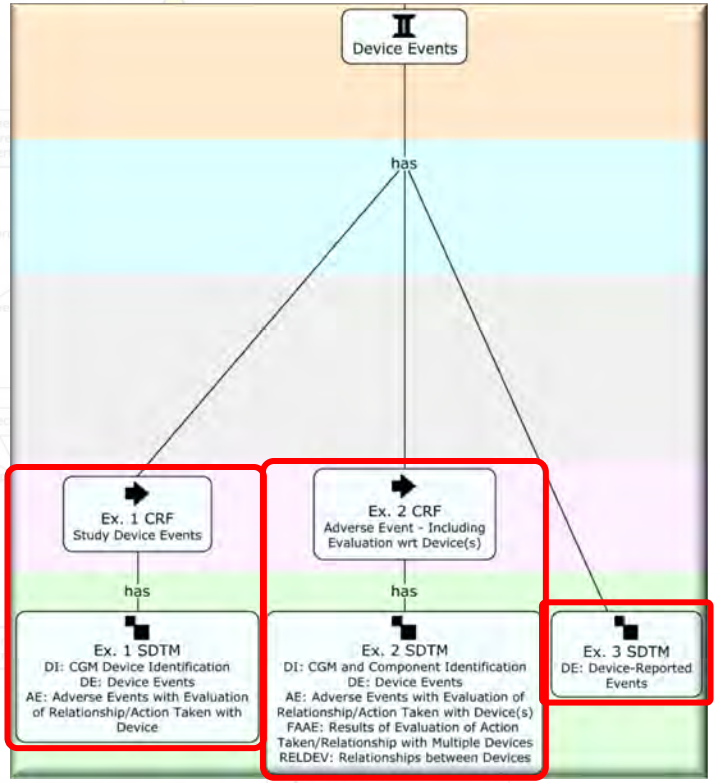
dx.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXCAT	DXSCAT	DXPRESP	DXOCCUR	VISITNUM	VISIT	DXDTC	DXSTDTC	DXENTPT	DXENRTPT	MIDS
1	T1D-01	DX	0001	IP-0	1	Any Insulin Pump Device	INSULIN PUMP HISTORY	GENERAL	Y	Y	1	Visit 1	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	Visit 1	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	Visit 1	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	Visit 1	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	Visit 1	2019-01-21				
6	T1D-01	DX	0002	CGM-0	2	Any Continuous Glucose Monitoring Device	CONTINUOUS GLUCOSE MONITOR HISTORY	GENERAL	Y	Y	1	Visit 1	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	Visit 1	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	Visit 1	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	Visit 1	2019-02-05				

Devices in Diabetes

Device Events

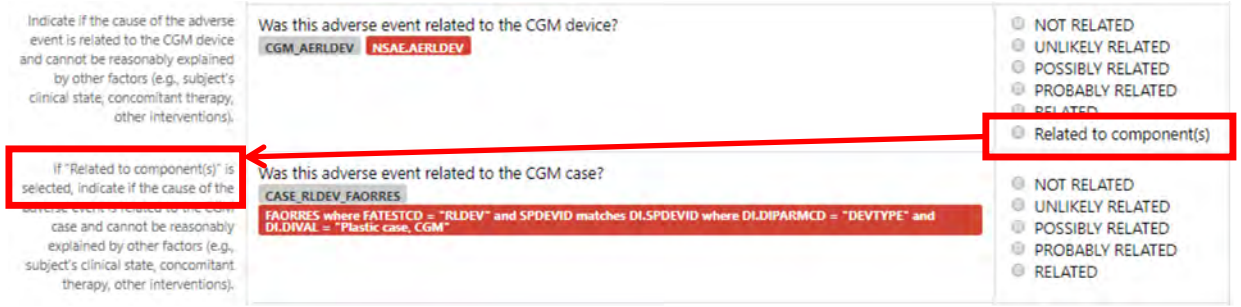




Devices in Diabetes
Device Events

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.



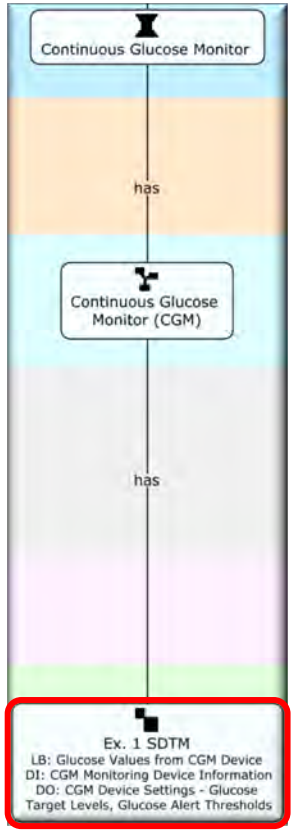
Devices in Diabetes

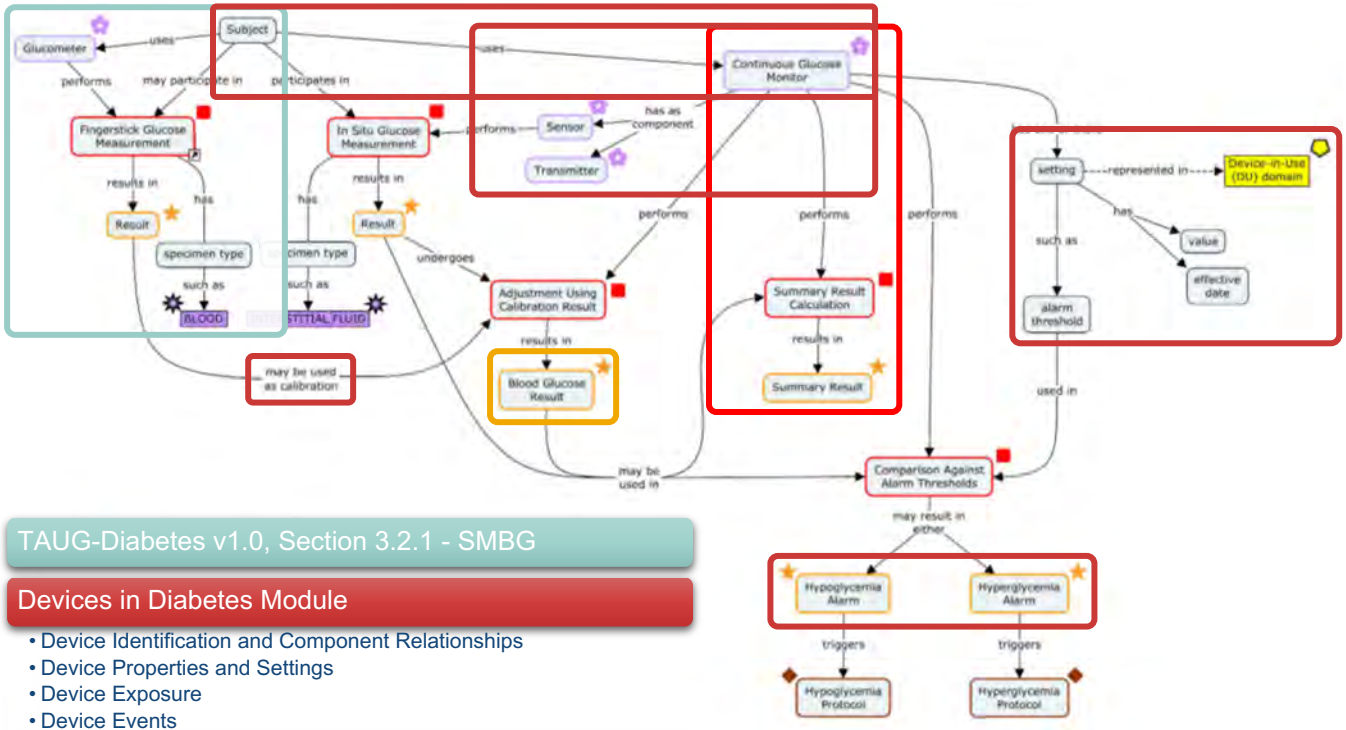
Known Issues

- 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





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

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBMETHOD	LBANMETH	VISITNUM	VISIT	VISITDY	LBDTC	LBENDTC	LBDY	LBENDY
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
2	T005	LB	001	CGM-001	2	GLUCPED	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
3	T005	LB	001	CGM-001	3	GLUCPED	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
4	T005	LB	001	CGM-001	4	GLUCPED	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
5	T005	LB	001	CGM-001	5	GLUCPED	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
6	T005	LB	001	CGM-001	6	GLUCPED	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
7	T005	LB	001	CGM-001	7	GLUCPED	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
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

LBCOLSRT
MEAN
STANDARD DEVIATION
COEFFICIENT OF VARIATION
PROPORTION LOW
PROPORTION HIGH
PROPORTION WITHIN TARGET RANGE
TIME IN CRITICAL LOW RANGE

- 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”)

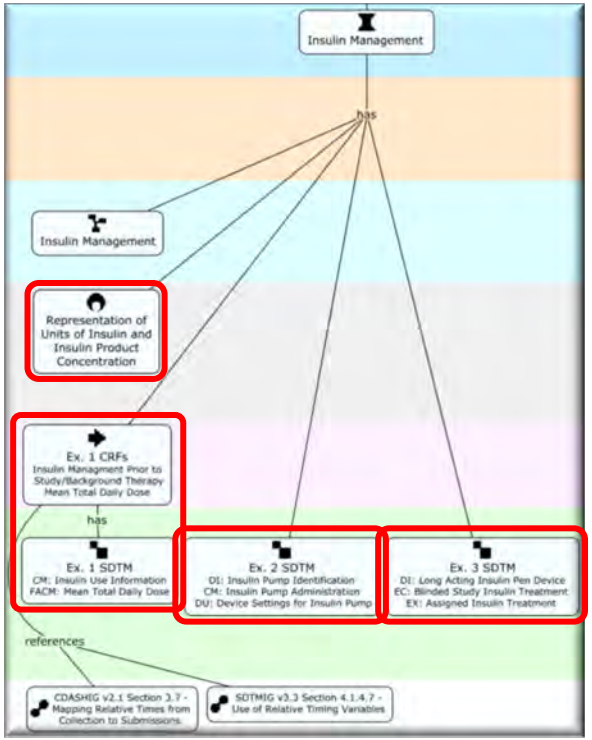
Continuous Glucose Monitor

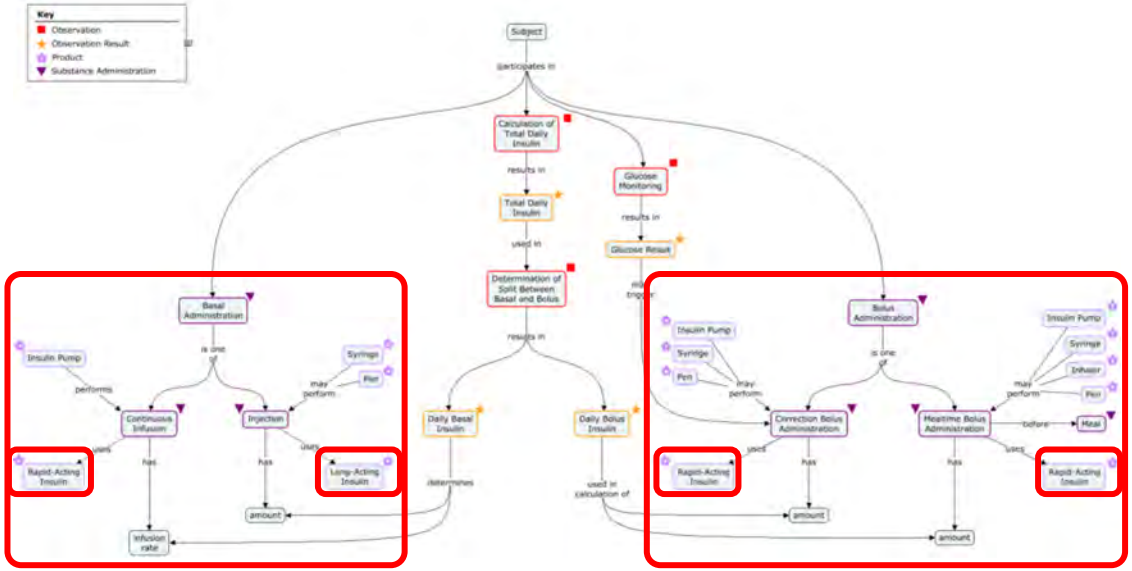
Known Issues

- Large Volume of Raw Data
  - Representation of summary data in SDTM


Continuous Glucose Monitor

Insulin Management





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

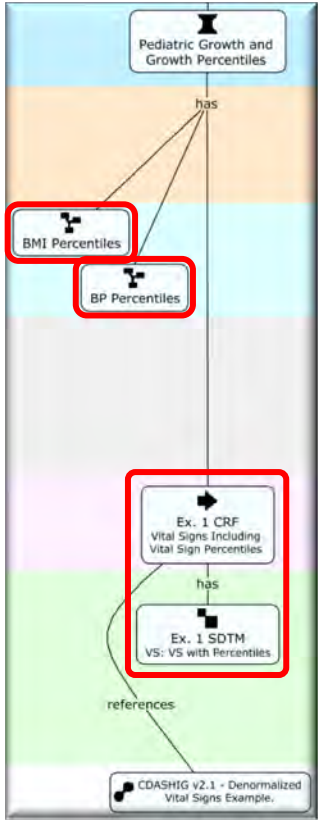
Known Issues

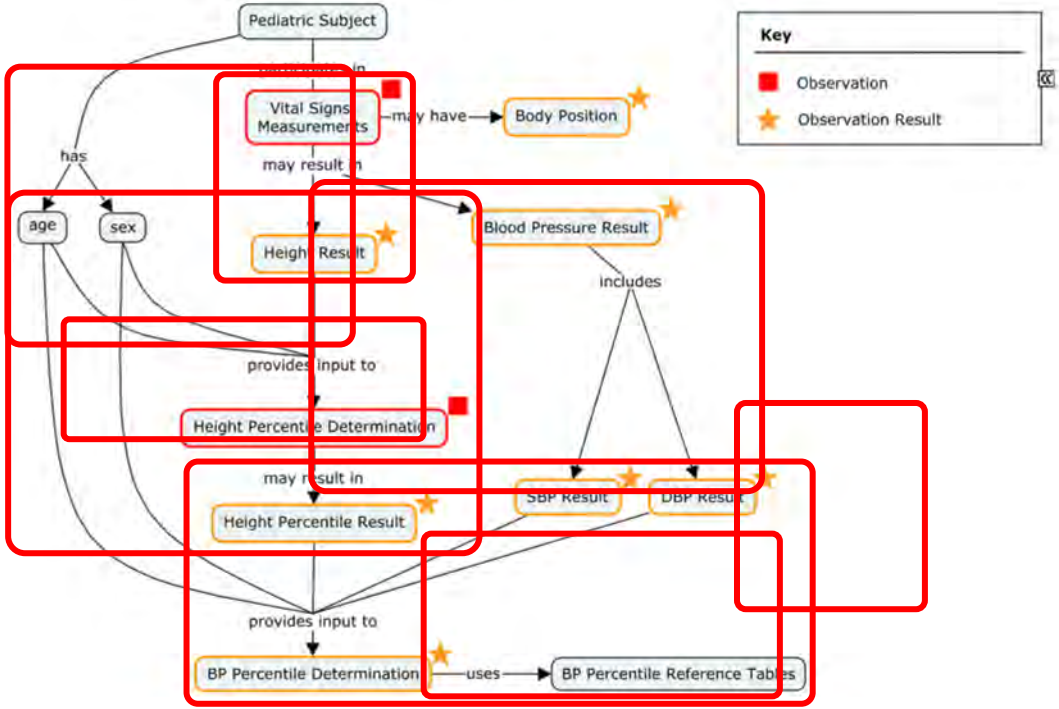
- Use of UNIT Code, “U”
  - At the time of publication, the definition of the code “U” (“A single undivided thing occurring in the composition of something else”) suggested that “U” was not an appropriate unit for the quantification of insulin products.
  - A terminology change request had been submitted
  - 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

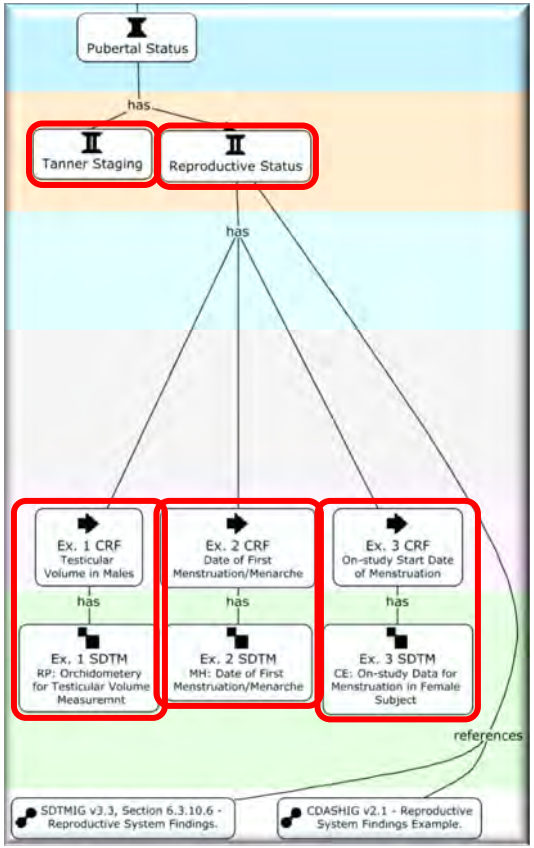
- Use of:
  - VSANMETH to indicate the criteria for calculating percentiles
  - VSRESCAT to represent the categorization of BMI percentile results (e.g., normal, overweight, obese)
  - VSGRPID to group the percentile with the underlying vital signs measurement

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	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	RPTESTCD	RPTEST	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	ORCHIDOMETERY	1	SCREENING	2017-09-15
2	ABC123	RP	0001	2	VOLUME	Volume	PUBERTAL STATUS	MALE	9	mL	9	9	mL	TESTIS	LEFT	ORCHIDOMETERY	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	CEPRESP	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

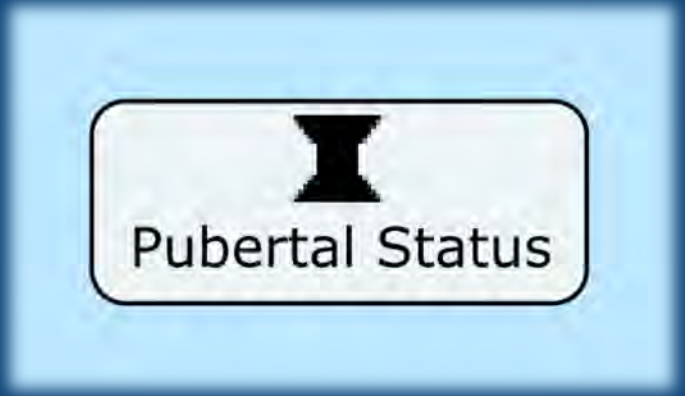
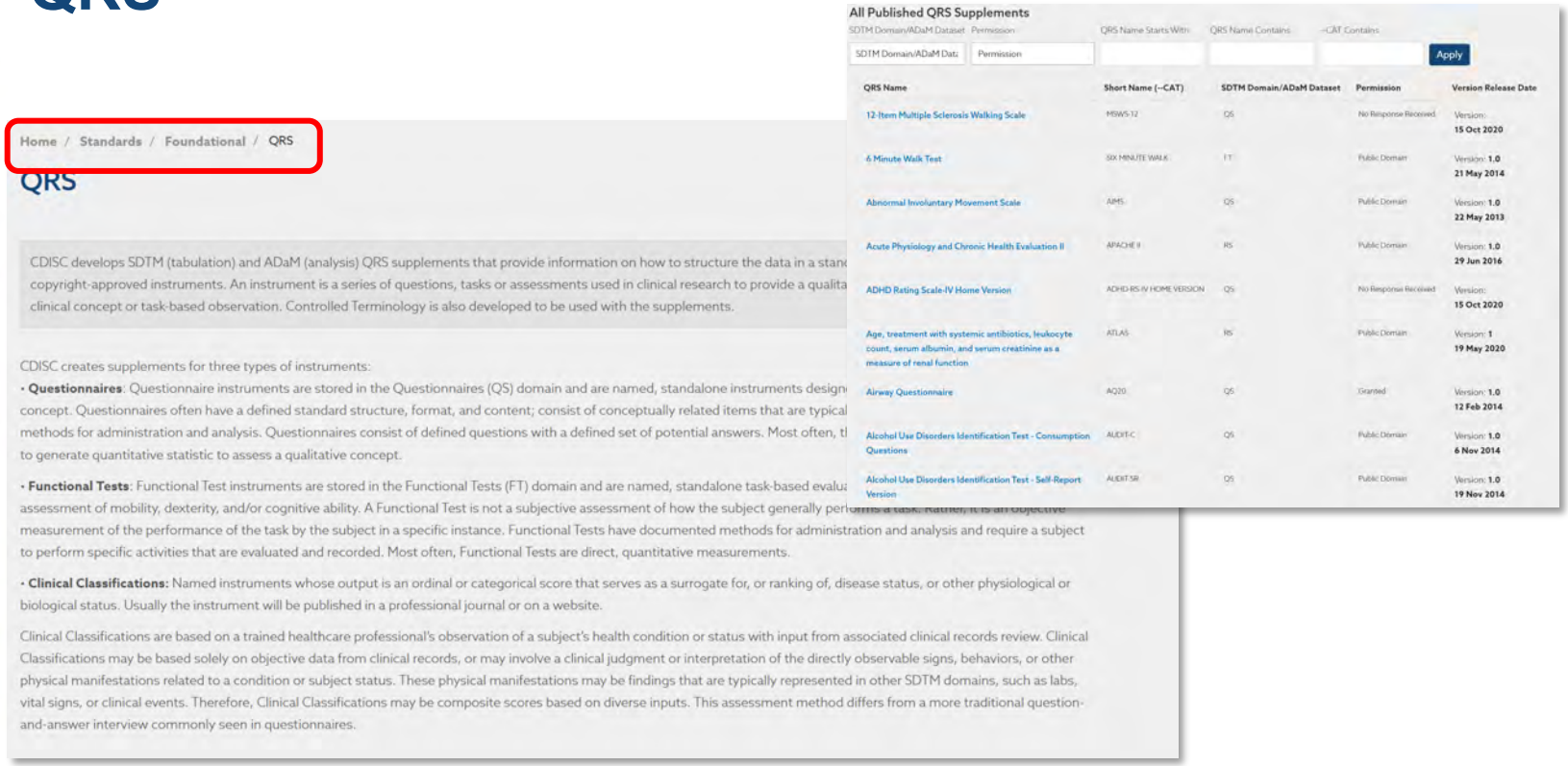

Pubertal Status

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
	DDS for Parents of Teens with Type 1 Diabetes (Parent-DDS)	Granted	Supplement in progress
	DDS for Partners of Adults with Type 1 Diabetes (Partner-DDS)	Granted	Supplement in progress
Diabetes Treatment Satisfaction Questionnaire (DTSQ)	DTSQ - Status	Denied	
	DTSQ - Change	Denied	
Glucose Monitoring System Satisfaction Survey (GMSS)	Version: Type 1 Diabetes (GMSS-T1D)	Granted	Supplement in progress
Hypoglycemic Confidence Scale (HCS)		Granted	Supplement in progress
Hypoglycemia Fear Survey		Requested	
	HFS - Parent (HFS-P)	Requested	
	HFS - Parent of Young Children (HFS-P-YC)	Requested	
Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE)	INSPIRE Survey - Child	Requested	
	INSPIRE Survey - Teen	Requested	
	INSPIRE Survey - Adult	Requested	
	INSPIRE Survey - Parent	Requested	
	INSPIRE Survey - Partner	Requested	
Pediatric Quality of Life Inventory 3.2 (PedsQL) Diabetes Module	PEDSQL Acute Version: Toddlers (2-4 years)	Requested	
	PEDSQL Standard Version: Toddlers (2-4 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 (>26 years)	Requested	
	PEDSQL Standard Version: Adult (>26 years)	Requested	
Problem Areas in Diabetes (PAID)	PAID - Pediatrics	Requested	
	PAID - Child	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 stan
copyright-approved instruments. An instrument is a series of questions, tasks or assessments used in clinical research to provide a qualita
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 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, t
to generate quantitative statistic to assess a qualitative concept.

- **Functional Tests**: Functional Test instruments are stored in the Functional Tests (FT) domain and are named, standalone task-based evalu
assessment of mobility, dexterity, and/or cognitive ability. A Functional Test is not a subjective assessment of how the subject generally per
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.

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?

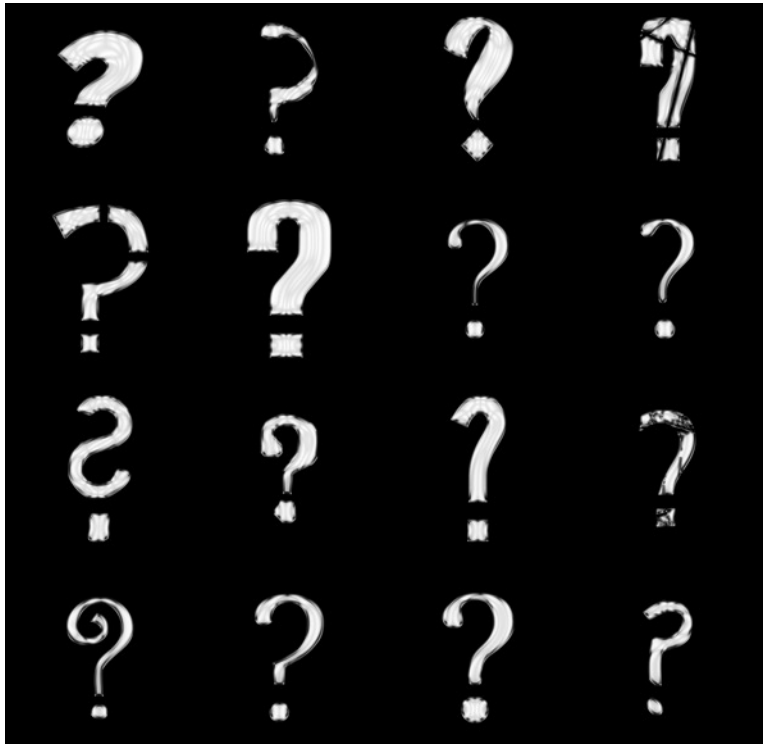
Audience Questions

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!

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

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!