Public Review Webinar: Screening, Staging, and Monitoring of Pre-Clinical Type 1 Diabetes

John Owen, Head of Partnerships & Development, CDISC

Diane Corey, Data Manager Standards Developer, C-Path

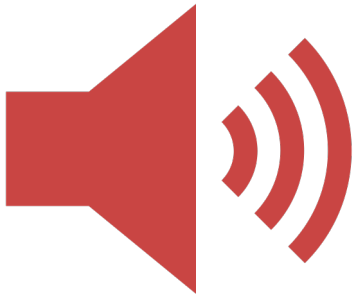
TUE 22 JUN
11:00AM-12:30PM ET

Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Presentation Agenda
4. Feature Presentation
5. Question & Answer Session
6. Upcoming Learning Opportunities & Resources

Housekeeping

Housekeeping

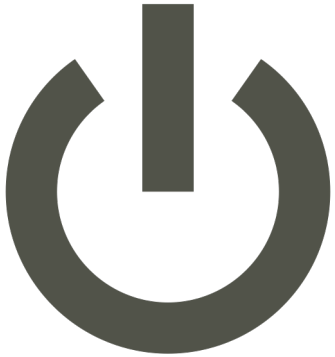


You will remain on **mute**

Housekeeping

There will be a **Q&A** after the presentation

Housekeeping



Audio issues?

Shut down & restart GoToWebinar

Housekeeping

A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website

Our Presenters

- John Owen, Head of Partnerships & Development, CDISC
- Diane Corey, Data Manager Standards Developer, C-Path

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11:00AM-12:30PM ET

T1D Screening, Staging and Monitoring – Pre-Clinical T1D

Public Review Webinar

22nd June 2021

John Owen

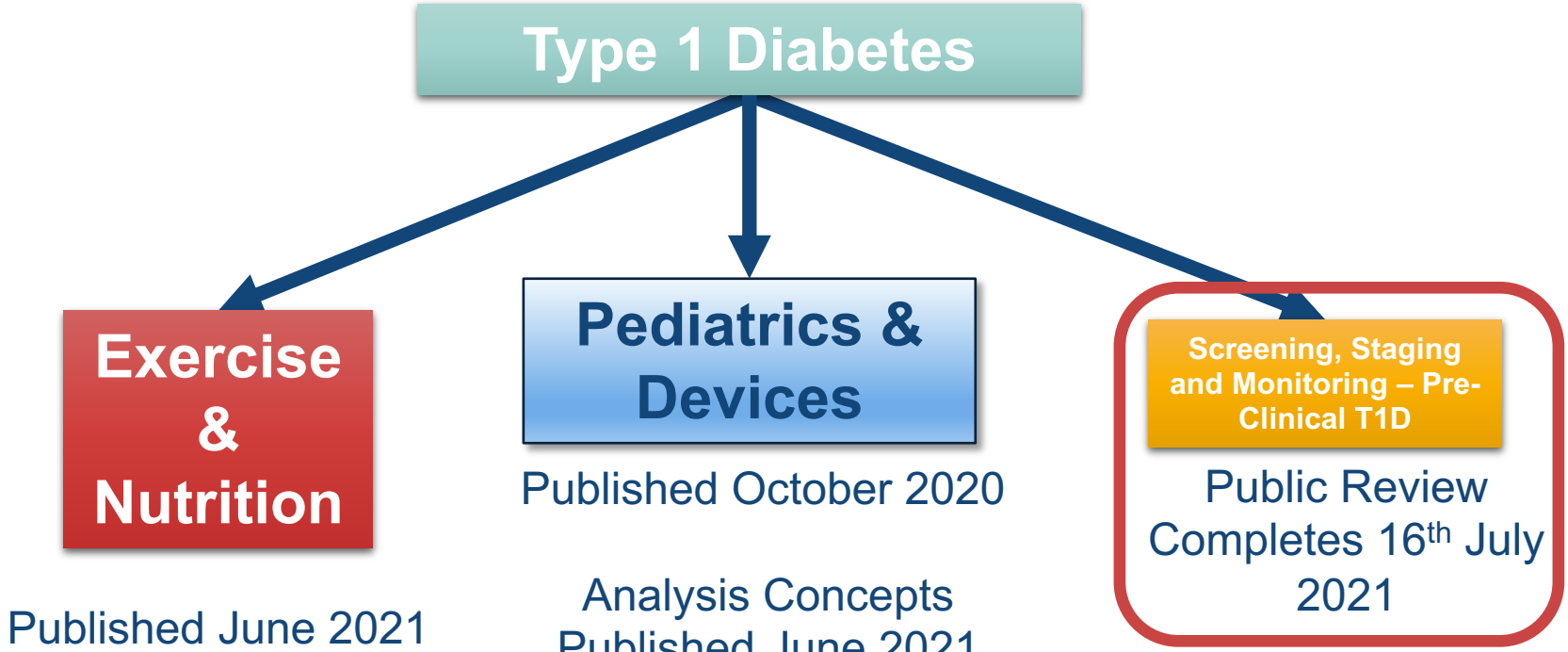
Diane Corey

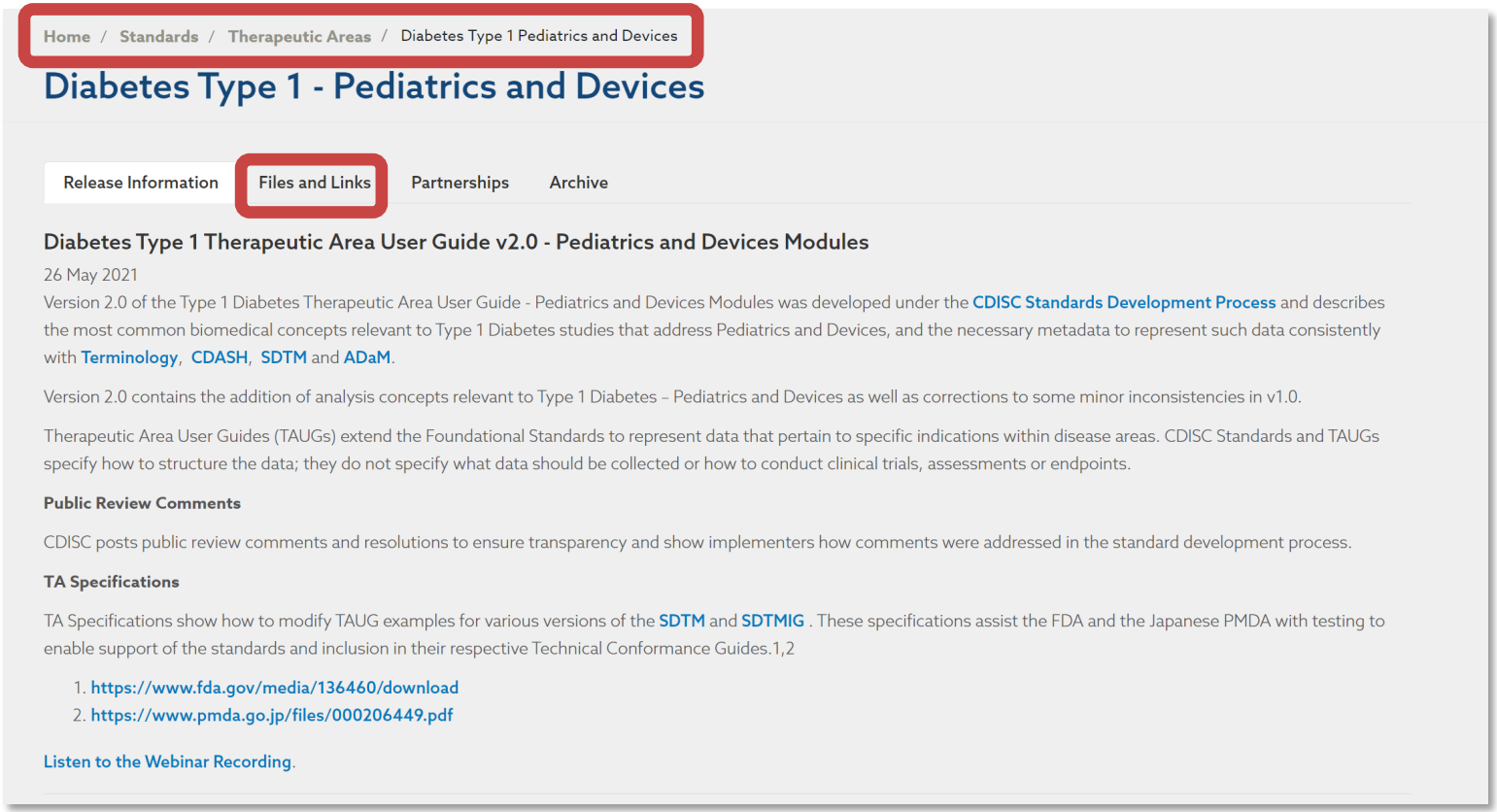
Project Status

John Owen

Name Change

- From
  - T1D Prevention
- To
  - Type 1 Diabetes - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes

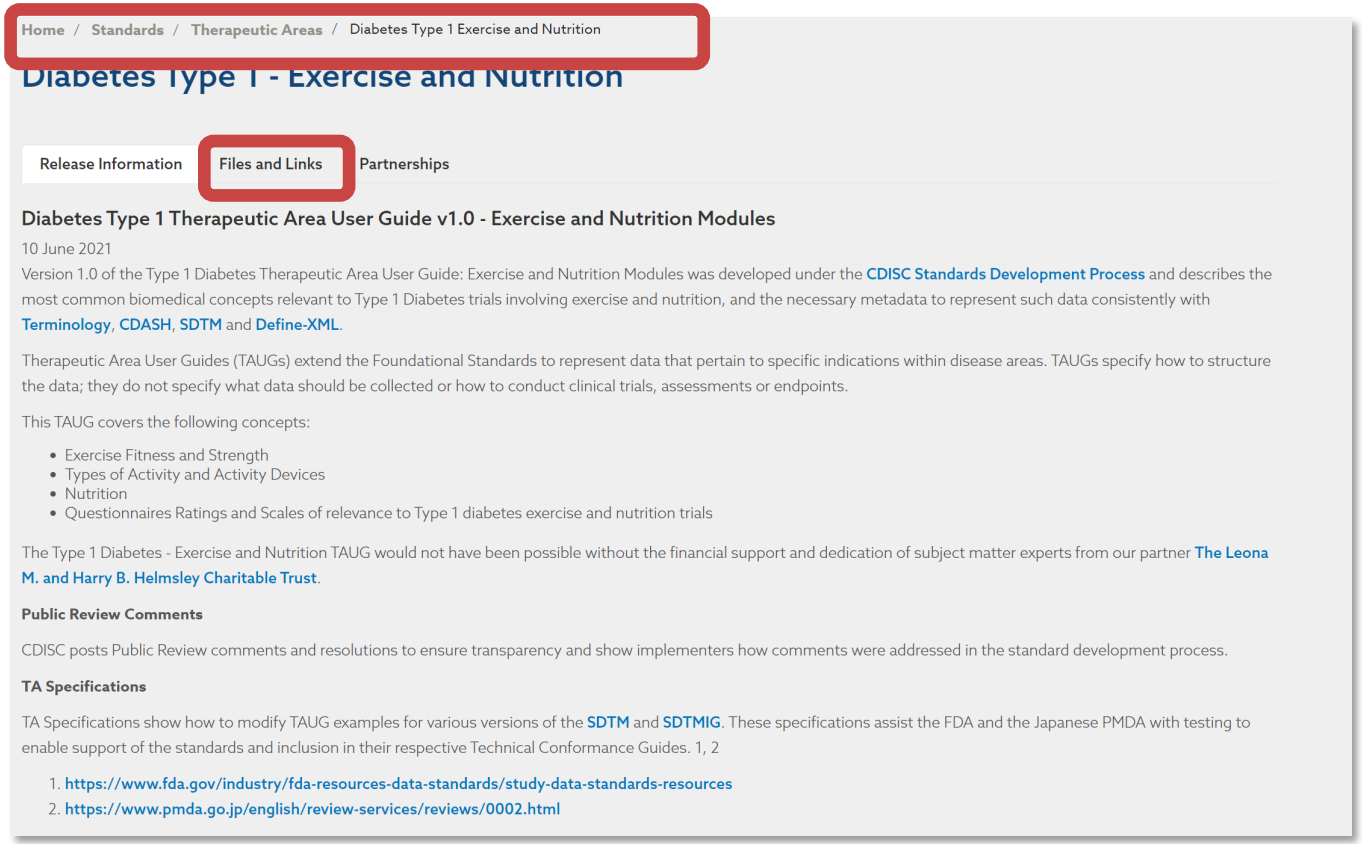

Type 1 Diabetes
Exercise & Nutrition
Published June 2021
Pediatrics & Devices
Published October 2020
Analysis Concepts Published June 2021
Screening, Staging and Monitoring – Pre-Clinical T1D
Public Review Completes 16th July 2021



https://www.cdisc.org/standards/therapeutic-areas/diabetes-type-1-pediatrics-and-devices

T1D Pediatrics and Devices - Summary

- Diabetes History
- On-Study Diabetic Ketoacidosis
- Devices in Diabetes
- CGM
- Insulin Management
- Pediatric Growth and Growth Percentiles
- Pubertal Status
- Analysis
- Questionnaires, Ratings and Scales



Home / Standards / Therapeutic Areas / Diabetes Type 1 Exercise and Nutrition

Diabetes Type 1 - Exercise and Nutrition

Release Information | Files and Links | Partnerships

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

10 June 2021

Version 1.0 of the Type 1 Diabetes Therapeutic Area User Guide: Exercise and Nutrition Modules was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to Type 1 Diabetes trials involving exercise and nutrition, and the necessary metadata to represent such data consistently with Terminology, CDASH, SDTM and Define-XML.

Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertain to specific indications within disease areas. 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.

This TAUG covers the following concepts:

- Exercise Fitness and Strength
- Types of Activity and Activity Devices
- Nutrition
- Questionnaires Ratings and Scales of relevance to Type 1 diabetes exercise and nutrition trials

The Type 1 Diabetes - Exercise and Nutrition TAUG would not have been possible without the financial support and dedication of subject matter experts from our partner The Leona M. and Harry B. Helmsley Charitable Trust.

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

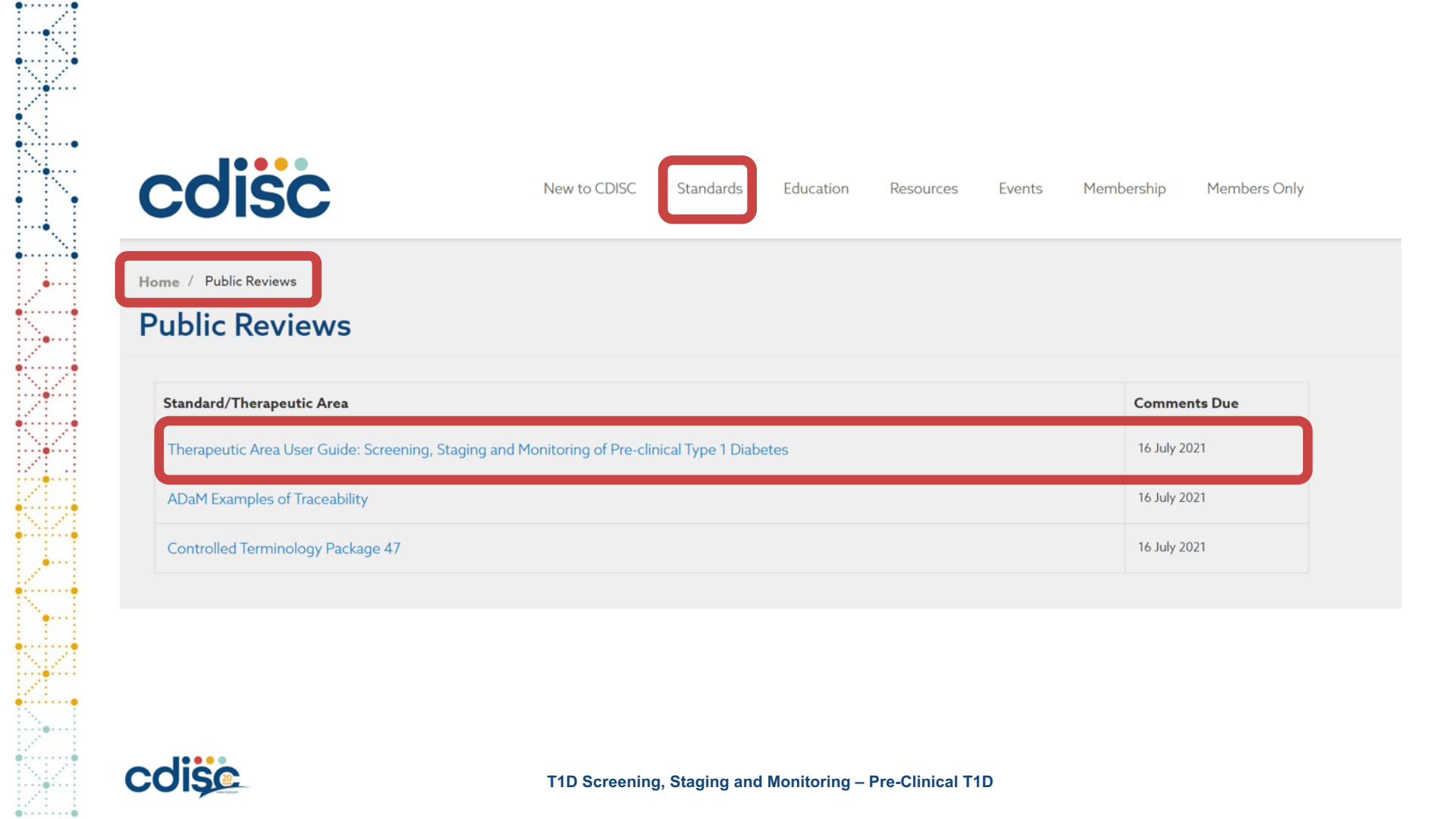
TA Specifications show how to modify TAUG examples for various versions of the SDTM and SDTMIG. These specifications assist the FDA and the Japanese PMDA with testing to enable support of the standards and inclusion in their respective Technical Conformance Guides. 1, 2

1. https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources
2. https://www.pmda.go.jp/english/review-services/reviews/0002.html

https://www.cdisc.org/standards/therapeutic-areas/diabetes-type-1-exercise-and-nutrition

T1D Exercise and Nutrition - Summary

- Exercise Fitness and Strength Status
- Nutrition
- Types of Activity and Activity Devices
- Questionnaires, Ratings and Scales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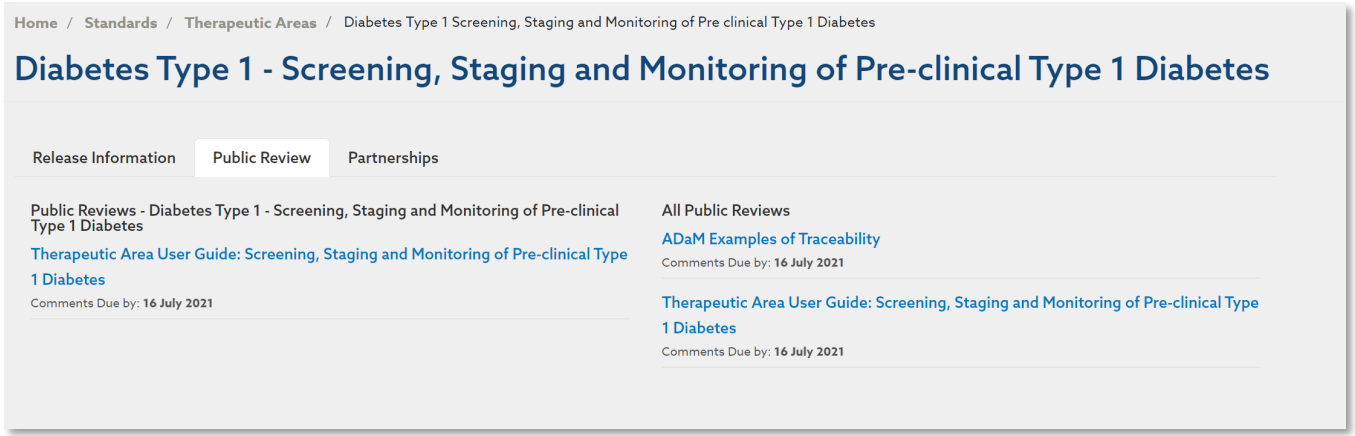


https://www.cdisc.org/standards/therapeutic-areas/diabetes-type-1-screening-staging-and-monitoring-pre-clinical-type-1

Therapeutic Area User Guide: Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes

Comments Due By
16 July 2021

CDISC invites you to submit comments on version 1.0 of the Therapeutic Area User Guide: Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes (TAUG-T1D) during Public Review. The purpose of these TAUG-T1D modules is to describe how CDISC standards may be used to represent data pertaining to Screening, Staging and Monitoring in Pre-clinical Type 1 Diabetes studies.

To Provide Comments

View the draft: **T1D Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes**
Instructions for providing comments: **Instructions for Reviewers**

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

Register for the Wiki. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account; Wiki and JIRA use the same login credentials. CDISC Wiki is a different login from **www.cdisc.org**.

T1D SSM - Instructions for Reviewers

Created by John Owen, last modified by Richard Marshall on May 14, 2021

Reviewers are requested to provide comments via JIRA; wiki and JIRA use the same credentials, so if you can see this page, then you can use JIRA.

The project associated with the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules is **Diabetes (TADIAB)**, located at: https://jira.cdisc.org/projects/TADIAB/

- If you have no edits or comments to a page
- To add comments to JIRA from within the Wiki
- To add comments from within JIRA

If you have no edits or comments to a page

1. Click 'Like' at the bottom of the page. This will help us determine who has read each page.

To add comments to JIRA from within the Wiki

1. Select the text (ideally, a short, unique phrase) to which you wish to attach the comment. After a moment, two icons should appear.
2. Click on the 3 arrow JIRA icon. This will trigger a Create Issue form.
3. Choose the project associated with this document from the **Project** drop-down menu ("Diabetes").
4. Choose "Review Comments" from the **Issue Type** drop-down menu.
5. Fill out the form.
    a. The **Summary** field will be pre-populated with the text that you selected. You can change this or leave it as it is.
    b. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
    c. In the **Components** field, choose the module to which the comment applies.
    d. In case of technical difficulties, please make sure to include a brief description of the context of your comment.
6. Click the "Create" button in the bottom left corner of the form to submit your comment as an issue.

Instructions for creating an issue from within the Wiki can be found here: https://confluence.atlassian.com/doc/use-jira-applications-and-confluence-together-427623543.html.

To add comments from within JIRA

1. Go to the JIRA project associated with this document (https://jira.cdisc.org/projects/TADIAB).

> Keeping JIRA open in a separate window to capture comments is easier than navigating back and forth between the wiki and JIRA.

2. Click on the "Create" button in the top menu to bring up the Create Issue form.
3. Choose the project associated with this document from the **Project** drop-down menu "Diabetes", if it has not already been selected for you.
4. From the **Issue Type** drop-down menu, set the issue type to "Review Comments".
5. Fill out the form.
    a. In the **Summary** field, describe the content to which the comment applies.
    b. In the **Components** field, choose the module to which the comment applies.
    c. Enter your comment, and any additional details, in the **Description** field. Please be thorough, so your comment can be addressed properly.
6. Click the "Create" button in the bottom right corner of the form to submit.

Instructions for creating an issue can be found here: https://confluence.atlassian.com/display/JIRA/Creating+an+Issue.

Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Therapeutic Area User Guide Home

Created by Matthew Warren, last modified by Richard Marshall on May 14, 2021

This is the landing page for the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules.

⚠ The Type 1 Diabetes (T1D) Project Team are piloting the use of *Biomedical Concept Modules* and therefore T1D content is not in the usual TAUG structure.

What would you like to do?

- **Read the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules (T1D SSM)**
  - T1D SSM Modules
  - Draft Standards of Interest to TAUG-Type 1 Diabetes (Screening, Staging and Monitoring for Pre-Clinical T1D)
- **Look at examples**
  - T1D SSM Examples — This is where all examples used in the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules live.

    ⚠ Note: Readers are recommended to use this directory only *after* reading the Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules in their entirety at least once.
- **Provide feedback**
  - T1D SSM - Instructions for Reviewers — This is where to find detailed instructions for how to use JIRA to provide feedback on the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules.

- Other resources you may find helpful:
  - Introduction to Therapeutic Area Standards — This provides an overview of what to expect, and what *not* to expect, from a therapeutic area user guide.
  - TA001 - Overview of Therapeutic Area User Guides — This is a free introductory course on therapeutic area standards on the CDISC training campus.
  - Reading on the Wiki — This page touches on some of the ways the Wiki edition of the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules has been optimized for web use, with which a reader new to the CDISC Wiki may be unfamiliar.

Comments on the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D Modules should be entered into JIRA at: https://jira.cdisc.org/projects/TADIAB/. For more details, see the T1D SSM - Instructions for Reviewers.

Status
This is a DRAFT standard, which means that it is still in development and not yet ready for provisional or general use.

This document is best read online.

Search in this space

Search

T1D SSM Modules

Created by John Owen, last modified by Richard Marshall on May 14, 2021

Title	Therapeutic Area Data Standards Modules for Type 1 Diabetes - Screening, Staging and Monitoring for Pre-clinical Type 1 Diabetes
Team	CDISC Type 1 Diabetes Standards Development Team
Version	1.0 for Internal Review
Status	Draft
Released	02 Apr 2021
Notes	• This is the draft Version 1.0 of the Therapeutic Area Data Standards Modules for Type 1 Diabetes - Screening, Staging and Monitoring for Pre-clinical Type 1 Diabetes. • This document is based on CDASHIG v2.1, CDASH Model v1.1 , SDTM v1.7 and the SDTM Implementation Guides (SDTMIG v3.3 and SDTMIG-MD v1.1), ADaMIG v1.1, and the draft standards of interest for Genomic Findings (GF).

Sections for this document are the child pages listed below.

- T1D SSM Introduction
- T1D SSM Islet Autoantibodies Module
- T1D SSM Polygenic Risk Score Module
- T1D SSM Staging Module
- T1D SSM History of Viral Infections Module
- T1D SSM Microbiome Module
- T1D SSM Questionnaires, Ratings, and Scales (QRS) Module
- Appendices

« T1D SSM - Instructions for Reviewers

T1D SSM Introduction »

Overview of the TAUG-Type 1 Diabetes - Screening, Staging and Monitoring for Pre-Clinical T1D

TAUG Overview

- Islet Autoantibodies Module
  - Identifying the presence of specific islet autoantibodies circulating in a subject's serum can provide evidence of an increased risk of developing type 1 diabetes (T1D). Autoantibodies of interest to T1D trials are represented in the IS domain.
  - SDTM IS, BE
- Polygenic Risk Score Module
  - Genetic variations that are risk factors for type 1 diabetes (T1D) play a role in the prediction of disease. Identifying genetically at-risk pre-symptomatic subjects is a critical component of T1D screening studies.
  - SDTM GF
  - ADaM ADGRS **(NEW)**
- Staging Module
  - American Diabetes Association (ADA) has established a system that uses 3 defined stages of progression from the detection of T1D-specific metabolic markers to symptomatic T1D
  - References QRS

TAUG Overview

- History of Viral Infections Module
  - Viral infections in childhood may be associated with an increased risk of type 1 diabetes (T1D). Knowing the history of viral infections may relate to prevention (e.g., vaccination or treatment of viral infections associated with autoimmunity development).
  - CDASH Subject's Acute Illnesses, SDTM CE, VS
  - CDASH Mother's History of Viral Infection. SDTM APMH, APCM
- Microbiome Module **(NEW)**
  - Samples for microbiome data can come from many sources (e.g., stool samples, nasal/oral/body swabs. Microbiome bacteria and viruses may be associated with an increased risk of type 1 diabetes
  - SDTM BE, RELSPEC, BS, DI, MB, RELDEV
- Questionnaires, Ratings, and Scales (QRS) Module

Islet Autoantibodies Module

Know Issues

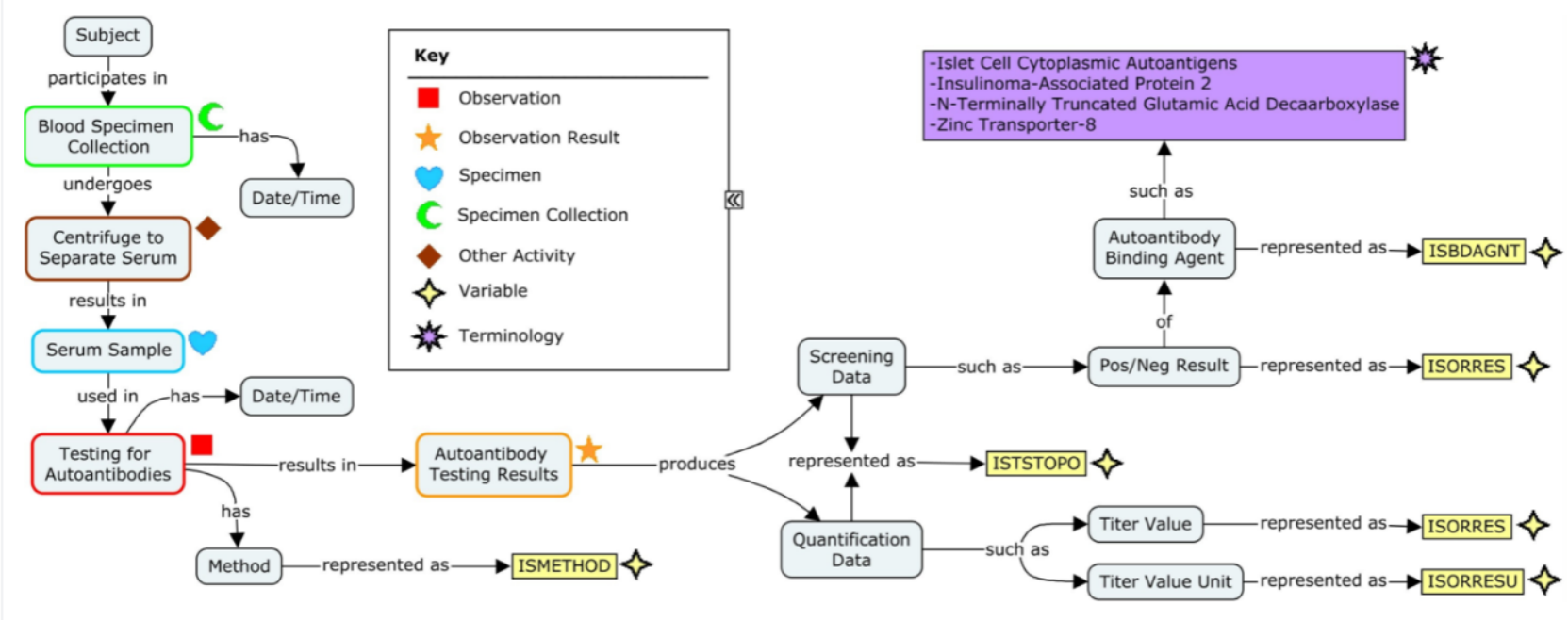
Known Issues for Islet Autoantibodies Module

Assumptions in the IS Domain

The SDTMIG v.3.3 defines the Immunogenicity Specimen Assessments (IS) domain as "A findings domain for assessments that determine whether a therapy induced an immune response." The forthcoming SDTMIG v.3.4 updates the IS domain to include pathological antibodies found in autoimmune disease. The IS domain in this user guide is based on these updated assumptions and includes representation of confirmatory antibody tests for autoimmune diseases.

In this section, confirmatory autoantibody test data are mapped to the IS domain, employing a post-coordinated structure using the ISTEST and ISBDAGNT variables, in contrast to the pre-coordinated structure in the Laboratory Test Results (LB) domain, to which these tests had traditionally been mapped . This modeling approach is novel, and is based on the IS domain structural updates scheduled for internal and public review, as well as inclusion in the upcoming SDTMIG v3.4. The IS terminology in this section is being reviewed and developed preceding publication of the IS domain updates for SDTMIG v3.4. The equivalent pre-coordinated autoimmune antibody tests continue to exist in the LB domain for SDTMIG Versions 3.2 and 3.3.

Concept Map. T1D Autoantibodies



Example 1

This example shows the results of a subject's pediatric islet cell autoantibody panel. The specific autoantibody detected or quantified by ISTEST (Autoantibody) is represented in the ISBDAGNT (Binding Agent) variable. Repeat testing for confirmation of results is represented in the same manner as the example below but is not shown here for brevity.

is.xpt

Rows 1, 3, 5, 7: Show the screening of autoantibodies against various T1D-specific autoantigens in the subject's serum, where ISTSTOPO="SCREEN".
Rows 2, 4, 6, 8: Show the quantification of the detected autoantibodies in the subject's serum, where ISTSTOPO="QUANTIFY".

is.xpt

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISREFID	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU	ISORNRHI	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	VISITNUM	ISDTC	ISBDAGNT	ISTSTOPO
1	ABC123	IS	ABC001	1	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	POSITIVE			POSITIVE			SERUM	FLUORESCENT IMMUNOASSAY	1	2018-10-02	ISLET CELL CYTOPLASMIC AUTOANTIGENS	SCREEN
2	ABC123	IS	ABC001	2	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	32	JDF Unit	10	32	32	JDF Unit	SERUM	FLUORESCENT IMMUNOASSAY	1	2018-10-02	ISLET CELL CYTOPLASMIC AUTOANTIGENS	QUANTIFY
3	ABC123	IS	ABC001	3	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	POSITIVE			POSITIVE			SERUM	ELISA	1	2018-10-02	ZINC TRANSPORTER-8	SCREEN
4	ABC123	IS	ABC001	4	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	26	ELISA unit/mL	15	26	26	ELISA unit/mL	SERUM	ELISA	1	2018-10-02	ZINC TRANSPORTER-8	QUANTIFY
5	ABC123	IS	ABC001	5	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	POSITIVE			POSITIVE			SERUM	RIA	1	2018-10-02	INSULINOMA-ASSOCIATED PROTEIN 2	SCREEN
6	ABC123	IS	ABC001	6	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	2.2	U/mL	0.9	2.2	2.2	U/mL	SERUM	RIA	1	2018-10-02	INSULINOMA-ASSOCIATED PROTEIN 2	QUANTIFY
7	ABC123	IS	ABC001	7	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	NEGATIVE			NEGATIVE			SERUM	LIPS	1	2018-10-02	N-TERMINALLY TRUNCATED GLUTAMIC ACID DECARBOXYLASE	SCREEN
8	ABC123	IS	ABC001	8	123.456	ATAB	Autoantibody	PEDIATRIC ISLET AUTOANTIBODY	2200	LU	5000	2200	2200	LU	SERUM	LIPS	1	2018-10-02	N-TERMINALLY TRUNCATED GLUTAMIC ACID DECARBOXYLASE	QUANTIFY

IS NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
ISBDAGNT	Binding Agent	text	(ISBDAGT)	Non-standard Record Qualifier	eCRF
ISTSTOPO	Test Operational Objective	text	(TSTOPOBJ)	Non-standard Record Qualifier	eCRF

Specific details about the events associated with the specimen used in the panel represented in IS can be represented in the Biospecimen Events (BE) domain and analysis are not shown for brevity.

. Device domain information related to the collectic

be.xpt

Row 1: Shows specimen collection. The value in SPDEVID for this row identifies the vessel into which the specimen is collected.
Row 2: Shows the start and end date/times of centrifugation of the specimen.
Row 3: Shows the start and end date/times of storing the specimen. The value in SPDEVID identifies the freezer in which the specimen is stored.
Row 4: Records the date/time a portion of the specimen was utilized to perform the islet autoantibody assay. The value in SPDEVID for this row identifies the assay serial number.

be.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	BESEQ	BEREFID	BETERM	BEDECOD	BECAT	VISITNUM	BEDTC	BESTDTC	BEENDTC	BESPEC
1	ABC123	BE	ABC001	TS1234	1	123.456	Collecting	COLLECTING	COLLECTION	1	2018-10-02	2018-10-02T15:07	2018-10-02T15:07	BLOOD
2	ABC123	BE	ABC001		2	123.456	Centrifuging	CENTRIFUGING	PREPARATION	1	2018-10-02	2018-10-02T15:07	2018-10-02T15:37	SERUM
3	ABC123	BE	ABC001		3	123.456	Storing	STORING	STORAGE	1	2018-10-02	2018-10-02T15:37	2018-10-03T12:02	SERUM
4	ABC123	BE	ABC001	PIAP0132	4	123.456	Consuming	CONSUMING	CONSUMPTION	1	2018-10-02	2018-10-03T12:02	2018-10-03T13:20	SERUM

BE NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
BESPEC	Specimen Material Type	text	(SPECTYPE)	Non-standard Record Qualifier	eCRF

Polygenic Risk Score

Known Issues

Known Issues for Polygenic Risk Score Module

Modeling of T1D Genetic Risk Score

Currently there is an effort to update the modeling of gene expression and genetic variation information. This new modeling approach includes the draft Genomic Findings (GF) domain. The anticipated date of publication for this effort is late 2021.

This example shows the results for 3 single nucleotide polymorphisms (SNPs) used to derive human leukocyte antigen (HLA) type in 3 subjects. The SNP results are displayed as a colon-delimited pair of the nucleotides found (1 for each allele) at the target locus. The interpretation record results are displayed as the derived HLA types delimited by a forward slash. Both colon and forward slash delimiters are commonly used in genotype notations. It can be assumed that the different delimiter conventions in this example represent how the data were received from the lab.

gf.xpt

Rows 1-3, 5-7, 9-11: Show each subject's genotype for the SNPs identified by the rs numbers (reference SNP cluster ID) shown in GFPVRID (Published Variant Identifier). GFSYM indicates the gene symbol for the genes associated with these SNPs. GFSYMTYP shows that the gene in GFSYM is a protein-coding gene, and the value is taken from the HUGO Gene Nomenclature Committee (HGNC) list of published locus types. GFGENLOC shows the location within each chromosome (GFCHROM) where the SNPs occur.

Rows 4, 8, 12: Show the derived HLA type for subjects based on their 3 SNP genotypes.

gf.xpt

Row	STUDYID	DOMAIN	USUBJID	GFSEQ	GFREFID	GFTESTCD	GFTEST	GFTSTDTL	GFORRES	GFSTRESC	GFCHROM	GFSYM	GFSYMTYP	GFGENLOC	GFPVRID	GFSPEC	GFMETHOD	VISITNUM	VISIT	GFDTC
1	T1D-01	GF	T1D-01-001	1	s00101	SNV	Single Nucleotide Variation	GENOTYPE	C:C	C:C	6	HLA-DQA1	GENE WITH PROTEIN PRODUCT	32640300	rs17426593	DNA	NEXT GENERATION SEQUENCING	1	SCREENING	2020-04-01
2	T1D-01	GF	T1D-01-001	2	s00101	SNV	Single Nucleotide Variation	GENOTYPE	C:C	C:C	6	HLA-DQA1	GENE WITH PROTEIN PRODUCT	32638107	rs2187668	DNA	NEXT GENERATION SEQUENCING	1	SCREENING	2020-04-01
3	T1D-01	GF	T1D-01-001	3	s00101	SNV	Single Nucleotide Variation	GENOTYPE	T:T	T:T	6	HLA-DQA2	GENE WITH PROTEIN PRODUCT	32713706	rs7454108	DNA	NEXT GENERATION SEQUENCING	1	SCREENING	2020-04-01
4	T1D-01	GF	T1D-01-001	4	s00101	INTP	Interpretation	HLA TYPE	DR4-DQ7/DR4-DQ7	DR4-DQ7/DR4-DQ7								1	SCREENING	2020-04-01
5	T1D-01	GF	T1D-01-002	1	s00201	SNV	Single Nucleotide Variation	GENOTYPE	T:C	T:C	6	HLA-DQA1	GENE WITH PROTEIN PRODUCT	32640300	rs17426593	DNA	NEXT GENERATION SEQUENCING	1	SCREENING	2020-04-01
6	T1D-01	GF	T1D-01-002	2	s00201	SNV	Single Nucleotide Variation	GENOTYPE	T:C	T:C	6	HLA-DQA1	GENE WITH PROTEIN PRODUCT	32638107	rs2187668	DNA	NEXT GENERATION SEQUENCING	1	SCREENING	2020-04-01
7	T1D-01	GF	T1D-01-002	3	s00201	SNV	Single Nucleotide Variation	GENOTYPE	T:C	T:C	6	HLA-DQA2	GENE WITH PROTEIN PRODUCT	32713706	rs7454108					
8	T1D-01	GF	T1D-01-002	4	s00201	INTP	Interpretation	HLA TYPE	DR3/DR4-DQ8	DR3/DR4-DQ8										
9	T1D-01	GF	T1D-01-003	1	s00301	SNV	Single Nucleotide Variation	GENOTYPE	T:T	T:T	1	HLA-DQA1	GENE WITH PROTEIN PRODUCT	192567683	rs2816316					
10	T1D-01	GF	T1D-01-003	2	s00301	SNV	Single Nucleotide Variation	GENOTYPE	T:C	T:C	6	HLA-DQA1	GENE WITH PROTEIN PRODUCT	31464003	rs2395029					
11	T1D-01	GF	T1D-01-003	3	s00301	SNV	Single Nucleotide Variation	GENOTYPE	C:C	C:C	6	HLA-DQA2	GENE WITH PROTEIN PRODUCT	29972123	rs1264813					
12	T1D-01	GF	T1D-01-003	4	s00301	INTP	Interpretation	HLA TYPE	DR4-DQ8/DR4-DQ8	DR4-DQ8/DR4-DQ8										

GFCHROM	Chromosome Identifier
GFSYM	Genomic Symbol
GFSYMTYP	Genomic Symbol Type
GFGENLOC	Genetic Location
GFPVRID	Published Variant Identifier

ADaM

ADGRS Dataset Metadata

The following is an example of the ADGRS metadata for the analysis of the Genetic Risk Score as defined in the study protocol. A BDS structure was used. The BDS dataset contains one or more records per subject, per analy analysis timepoint. The dataset includes the supportive rows that are used to calculate the Genetic Risk Score in addition to the parameter that captures the calculated score.

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
ADGRS	Analysis of Genetic Risk Score	BASIC DATA STRUCTURE	One record per subject per parameter per visit.	Analysis	STUDYID, USUBJID, PARAMCD, AVISITN	ADGRS.xpt	ADGRS.SAS/SAP

In this example, the number of risk-increasing alleles of each SNP is based on the information in GFORRES/GFSTRESC while the SNP-based and HLA-based weights are referenced from the study protocol. The genetic risk score is calculated for each subject by combining the HLA-based risk constant with weighted occurrences of risk-increasing alleles.
For example, subject T1D-01-003 is a child with HLA DR4-DQ8/DR4-DQ8 (referenced constant of 3.40), is homozygous for the risk allele of rs1264813 (referenced weight of 0.31), heterozygous for the risk allele of rs2395029 (weight 0.77), homozygous for the non-risk allele of rs2816316 (weight 0.12). A zero is included for all other non-risk increasing SNPs in the risk score. The example score is calculated by the summation of the HLA-based constant and the allele*weight product for each SNP: risk score = 3.40 + (2 * 0.31) + (1 * 0.77) + (0 * 0.12) + 0 = 4.79. [1]

adgrs.xpt

adgrs.xpt

Row	STUDYID	USUBJID	TRT01P	PARAMN	PARAMCD	PARAM	AVISITN	AVISIT	AVAL	APFL	RISKFL	MCRIT1	MCRIT1ML	MCRIT1MN	GFPVRID	GFSTRESC
1	T1D-01	T1D-01-003	DRUG A	1	RFW	Risk Factor Weight	0	Screening	0.12	Y	N	Allele Classification	HOMOZYGOUS NON-RISK ALLELE	0	rs2816316	T:T
2	T1D-01	T1D-01-003	DRUG A	1	RFW	Risk Factor Weight	0	Screening	0.77	N	Y	Allele Classification	HETEROZYGOUS RISK ALLELE	1	rs2395029	T:C
3	T1D-01	T1D-01-003	DRUG A	1	RFW	Risk Factor Weight	0	Screening	0.31	Y	Y	Allele Classification	HOMOZYGOUS RISK ALLELE	2	rs1264813	C:C
4	T1D-01	T1D-01-003	DRUG A	2	RFC	Risk Factor Constant	0	Screening	3.40							
5	T1D-01	T1D-01-003	DRUG A	3	GRS	Genetic Risk Score	0	Screening	4.79							

APFL	Allele Pair Flag	text	Y,N
RISKFL	Risk Flag	text	Y,N
MCRIT1	Analysis Multi-Response Criterion 1	text	Allele Classification
MCRIT1ML	Multi-Response Criterion 1 Evaluation	text	HOMOZYGOUS RISK ALLELE HETEROZYGOUS RISK ALLELE HOMOZYGOUS NON-RISK ALLELE
MCRIT1MN	Multi-Response Criterion 1 Eval (N)	integer	2 (=HOMOZYGOUS RISK ALLELE) 1 (=HETEROZYGOUS RISK ALLELE) 0 (=HOMOZYGOUS NON-RISK ALLELE)

T1D Staging

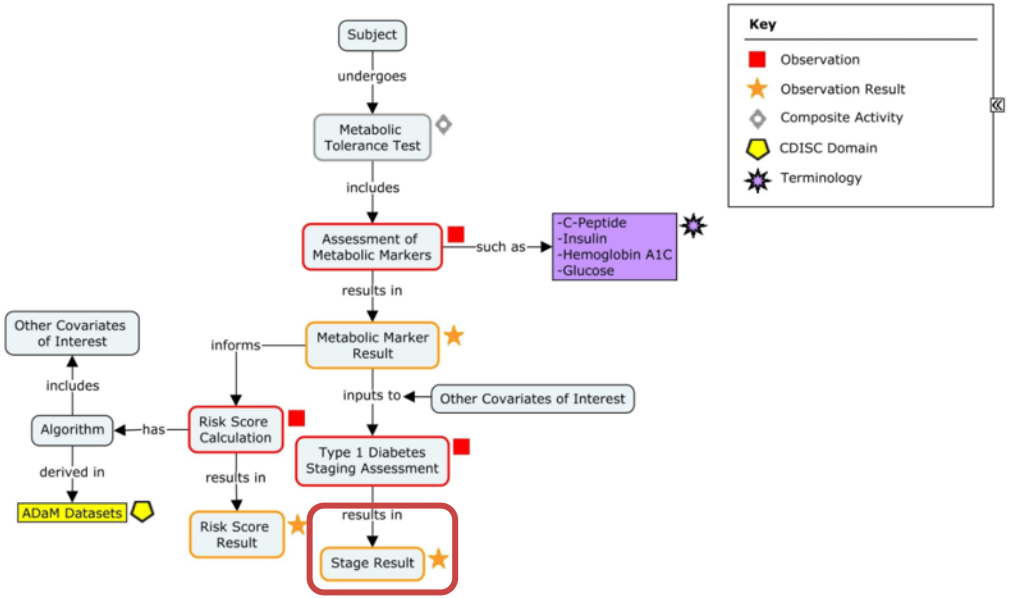
The assessment of autoantibodies and metabolic markers for screening type 1 diabetes (T1D) prior to symptoms provides an opportunity to delay or prevent the onset of severe clinical disease. The American Diabetes Association (ADA) has established a system that uses 3 defined stages of progression from the detection of T1D-specific metabolic markers to symptomatic T1D[1]:

Stage 1: Subjects who have developed two or more T1D–associated islet autoantibodies (e.g., ICA, IA-2A, IAA, ZnT8, GADA) but are normoglycemic.

Stage 2: Subjects with two or more islet autoantibodies but whose disease has now progressed to the development of dysglycemia from loss of functional β-cell mass.

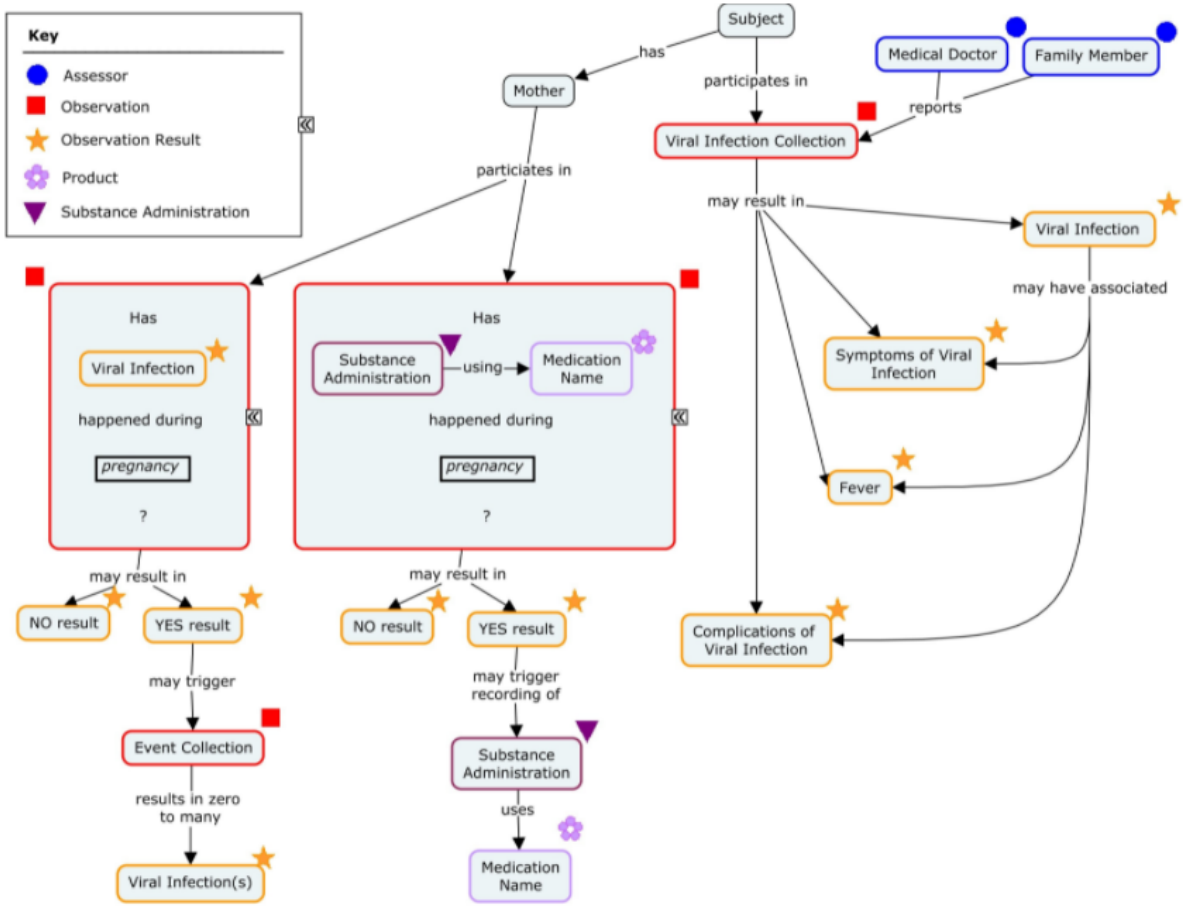
Stage 3: Subjects who have progressed to symptomatic T1D. [2]

Concept Map. Diabetes Staging



For an example and further explanation of the stages modeled as a QRS measure please visit the CDISC website at https://www.cdisc.org/foundational/qrs where QRS supplements are maintained as standalone guides.

History of Viral Infections


Key
Assessor
Observation
Observation Result
Product
Substance Administration
Subject
has
participates in
Mother
particiates in
Medical Doctor
Family Member
reports
Viral Infection Collection
may result in
Viral Infection
may have associated
Symptoms of Viral Infection
Fever
Complications of Viral Infection
Has
Viral Infection
happened during
pregnancy
?
Has
Substance Administration
using
Medication Name
happened during
pregnancy
?
may result in
NO result
YES result
may trigger
Event Collection
results in zero to many
Viral Infection(s)
may result in
NO result
YES result
may trigger recording of
Substance Administration
uses
Medication Name

SUBJECT

Diagnosed Acute Illness

	CESCAT *Hidden/pre-populated*	DIAGNOSIS
	Acute Illness Group Identifier CEGRPID *Pre-populated*	Sponsor-defined
Indicate whether the subject had any diagnosed acute illnesses.	Did the subject have any diagnosed acute illness? CEYN Not submitted	○ Yes ○ No <*From NY codelist*>
Record the name of the acute illness.	What was the diagnosed acute illness name? CETERM	
Indicate who diagnosed the acute illness.	Who diagnosed the acute illness? CEEVAL	○ Health Care Professional ○ Non-Health Care Professional <*From EVAL codelist*>
Record the start date of the acute illness using this format (DD/MON/YYYY).	What was the start date of the diagnosed acute illness? CESTDAT CESTDTC	
Record the end date of the acute illness using this format (DD/MON/YYYY).	What was the end (or resolution) date of the diagnosed acute illness? CEENDAT CEENDTC	

Title : Symptoms Associated with Acute Illness

Example CRF Instructions

Record all symptoms experienced by the subject during any acute illness (whether that acute illness was diagnosed or not). Record each symptom on a separate line. If the subject had a fever, the fever must be entered as a symptom. When a symptom is associated with a diagnosed acute illness, the "Acute Illness Group Identifier" value from the CRF above (e.g., "ILL1") should be entered in the CEGRPID variable below to link the symptom to the diagnosis.

	CECAT *Hidden/pre-populated*	ACUTE ILLNESS
	CESCAT *Hidden/pre-populated*	SYMPTOM
	Symptom identifier CESPID VSLNKID *Hidden/pre-populated*	Sponsor-defined
	Was this symptom considered to be associated with a diagnosed acute illness? CEYN Not submitted	○ Yes ○ No
If the symptom is associated with a diagnosed acute illness, record the Acute Illness Group Identifier of the associated diagnosed acute illness.	If yes, what was the associated diagnosed acute illness group identifier? CEGRPID	
Record all symptoms that occurred. The symptom of fever must be listed when the subject had a fever.	What was the symptom? CETERM	
Record the date the symptom first started using this format (DD/MON/YYYY).	What was the start date of the symptom? CESTDAT CESTDTC	
Record the date the symptom ended using this format (DD/MON/YYYY).	What was the end date of the symptom? CEENDAT CEENDTC	
If the symptom reported is fever, record the temperature measured at the time of the fever.	If the symptom was a fever, was temperature measured? CETPMEAS NSCE.CETPMEAS	○ Yes ○ No <From NY codelist>
If the symptom reported is fever, record the maximum temperature measured at the time of the acute illness.	What was the maximum measured temperature? VSORRES VSORRES where VSTESTCD = "TEMP" and NSVS.VSCOLSRT = "MAXIMUM"	
If the maximum temperature was measured at the time of the acute illness, record the unit.	What was the temperature unit? VSORRESU VSORRESU where VSTESTCD="TEMP" and NSVS.VSCOLSRT = "MAXIMUM"	○ Fahrenheit ○ Celcius

ce.xpt

Row	STUDYID	DOMAIN	USUBJID	CESEQ	CEGRPID	CESPID	CETERM	CECAT	CESCAT	VISITNUM	VISIT	CEDTC	CESTDTC	CEENDTC	CETPMEAS	CEEVAL
1	201-01	CE	201-01-154	1	ILL2		COMMON COLD	ACUTE ILLNESS	DIAGNOSIS	2	MONTH 1	2012-04-14	2012-03-17	2012-03-29		NON-HEALTH CARE PROFESSIONAL
2	201-01	CE	201-01-154	2	ILL2	1	RUNNING NOSE	ACUTE ILLNESS	SYMPTOM	2	MONTH 1	2012-04-14	2012-03-17	2012-03-29		
3	201-01	CE	201-01-154	3	ILL2	2	COUGH	ACUTE ILLNESS	SYMPTOM	2	MONTH 1	2012-04-14	2012-03-21	2012-03-24		
4	201-01	CE	201-01-154	4	ILL2	3	FEVER	ACUTE ILLNESS	SYMPTOM	2	MONTH 1	2012-04-14	2012-03-22	2012-03-23	Y	
5	201-01	CE	201-01-240	1		1	RUNNING NOSE	ACUTE ILLNESS	SYMPTOM	2	MONTH 1	2012-04-30	2007-02-02	2007-02-08		
6	201-01	CE	201-01-240	2		2	SORE THROAT	ACUTE ILLNESS	SYMPTOM	2	MONTH 1	2012-04-30	2007-02-03	2007-02-05		

CE NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
CETPMEAS	Temperature Measured	text		Non-standard Record Qualifier	CRF
CEEVAL	Evaluator	text	(EVAL)	Non-standard Record Qualifier	CRF

This example shows the maximum measured temperature that corresponds to the fever symptom recorded in the preceding CE example.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSLNKID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VISIT	VSDTC	VSENDTC	VSCOLSRT
1	201-01	VS	201-01-154	1	3	TEMP	Temperature	102.5	F	102.5	102.5	F	2	MONTH 1	2012-03-22	2012-03-23	MAXIMUM

VS NSV Metadata

Variable	Label	Type	Codelist	Role	Origin
VSCOLSRT	Collected Summary Result Type	text	(COLSTYP)	Non-standard Record Qualifier	CRF

MOTHER

Title: Biological Mother's Viral Infection History while Pregnant

	MHPRESP *Hidden/pre-populated*	Y *<From NY codelist>*
	Domain DOMAIN *Hidden/pre-populated*	APMH *<From DOMAIN codelist>*
	Relationship to Subject SREL *Hidden/pre-populated*	MOTHER, BIOLOGICAL *<From RELSUB codelist>*
	MHCAT *Hidden/pre-populated*	VIRAL INFECTION
Indicate if the biological mother experienced any viral illnesses during pregnancy. If Yes, include the appropriate details where indicated on the CRF.	Did the subject's mother have any viral illnesses during pregnancy? MHOCCUR	○ Yes ○ No *<From NY codelist>*
Record all relevant viral illnesses, as defined in the protocol. Record only one viral illness per line.	What was the medical condition or event term? MHTERM	
	Evaluation Interval Text MHEVINTX *Hidden/pre-populated*	DURING PREGNANCY

› View CRF Metadata

Title: Biological Mother's Medications during Pregnancy

	CMPRESP *Hidden/pre-populated*	Y *<From NY codelist>*
	Domain DOMAIN *Hidden/pre-populated*	APCM *<From DOMAIN codelist>*
	Relationship to Subject SREL *Hidden/pre-populated*	MOTHER, BIOLOGICAL *<From RELSUB codelist>*
Indicate if the biological mother took any medications/treatments while pregnant. If Yes, include the appropriate details where indicated on the CRF.	Did the subject's mother take any medications during pregnancy? CMOCCUR	○ Yes ○ No *<From NY codelist>*
Provide the full trade or proprietary name of the medication/treatment; otherwise, record the generic name. Record only one treatment per line.	What was the medication? CMTRT	
	Evaluation Interval Text CMEVINTX *Hidden/pre-populated*	DURING PREGNANCY

apmh.xpt

Row 1: Shows the mother's free-text answers to the question regarding what type of infections she had while pregnant
Row 2: Shows that the mother did not have any infections during pregnancy.

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHEVINTX
1	201-01	APMH	201-01-M231	1	201-01-154	MOTHER, BIOLOGICAL	INFLUENZA	VIRAL INFECTION	Y	Y	1	BASELINE	DURING PREGNANCY
2	201-01	APMH	201-01-M425	1	201-01-178	MOTHER, BIOLOGICAL	ANY INFECTIONS	VIRAL INFECTION	Y	N	1	BASELINE	DURING PREGNANCY

apcm.xpt

Row 1: Shows the mother's free-text answers to the question regarding what type of medications she used while pregnant.
Row 2: Shows that the mother did not take any medications during pregnancy.

apcm.xpt

Row	STUDYID	DOMAIN	APID	CMSEQ	RSUBJID	SREL	CMTRT	CMPRESP	CMOCCUR	VISITNUM	VISIT	CMEVINTX
1	201-01	APCM	201-01-M231	1	201-01-154	MOTHER, BIOLOGICAL	PENICILLIN	Y	Y	1	BASELINE	DURING PREGNANCY
1	201-01	APCM	201-01-M425	1	201-01-178	MOTHER, BIOLOGICAL	ANY MEDICATIONS	Y	N	1	BASELINE	DURING PREGNANCY

Title: Biological Mother Viral History

	MHPRESP CMPRESP *Hidden/pre-populated*	Y *<From NY codelist>*
	Relationship to Subject SREL *Hidden/pre-populated*	MOTHER, BIOLOGICAL *<From RELSUB codelist>*
	Evaluation Interval Text MHEVINTX CMEVINTX *Hidden/pre-populated*	DURING PREGNANCY
	DOMAIN MH_DOMAIN DOMAIN *Hidden/pre-populated*	APMH *<From DOMAIN codelist>*
	MHCAT *Hidden/pre-populated*	VIRAL INFECTION
Indicate if the biological mother had influenza while pregnant.	Did the subject's mother have influenza during pregnancy? INFLUENZA_MHOCCUR MHOCCUR where MHTERM="Influenza"	○ Yes ○ No *<From NY codelist>*
Indicate if the biological mother had a sore throat while pregnant.	Did the subject's mother have a sore throat during pregnancy? SORETHROAT_MHOCCUR MHOCCUR where MHTERM="Sore Throat"	○ Yes ○ No *<From NY codelist>*
Indicate if the biological mother had a strep throat while pregnant.	Did the subject's mother have strep throat during pregnancy? STREPTHROAT_MHOCCUR MHOCCUR where MHTERM="Strep Throat"	○ Yes ○ No *<From NY codelist>*
	CM_DOMAIN DOMAIN *Hidden/pre-populated*	APCM *<From DOMAIN codelist>*
Indicate if the biological mother took antibiotics while pregnant.	Did the subject's mother take antibiotics during pregnancy? ANTIBIOTICS_CMOCCUR CMOCCUR where CMTRT="Antibiotics"	○ Yes ○ No *<From NY codelist>*
Indicate if the biological mother took anti-inflammatory steriods while pregnant.	Did the subject's mother take anti-inflammatory steroids during pregnancy? STERIODS_CMOCCUR CMOCCUR where CMTRT="Anti-inflammatory steriods"	○ Yes ○ No *<From NY codelist>*
Indicate if the biological mother took any diabetic medication while pregnant.	Did the subject's mother take diabetes medication during pregnancy? DIABETES_CMOCCUR CMOCCUR where CMTRT="Diabetes Medication"	○ Yes ○ No *<From NY codelist>*

apmh.xpt

Row 1: Shows the mother had an influenza infection while pregnant.
Rows 2-3: Show that the mother did not have any sore or strep throat infections during pregnancy.

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHCAT	MHPRESP	MHOCCUR	VISITNUM	VISIT	MHEVINTX
1	201-01	APMH	201-01-M450	1	201-01-160	MOTHER, BIOLOGICAL	INFLUENZA	VIRAL INFECTION	Y	Y	1	BASELINE	DURING PREGNANCY
2	201-01	APMH	201-01-M450	2	201-01-160	MOTHER, BIOLOGICAL	SORE THROAT	VIRAL INFECTION	Y	N	1	BASELINE	DURING PREGNANCY
3	201-01	APMH	201-01-M450	3	201-01-160	MOTHER, BIOLOGICAL	STREP THROAT	VIRAL INFECTION	Y	N	1	BASELINE	DURING PREGNANCY

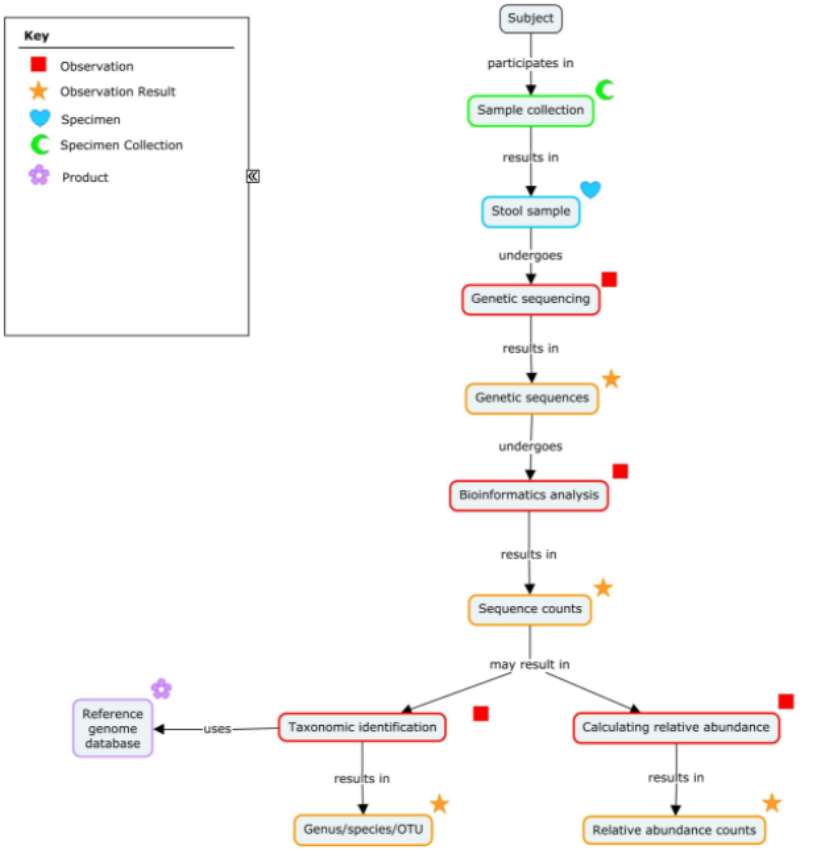
apcm.xpt

Row 1: Shows the mother had taken antibiotics while pregnant.
Rows 2-3: Show that the mother did not take any anti-inflammatory or diabetes medication during pregnancy.

apcm.xpt

Row	STUDYID	DOMAIN	APID	CMSEQ	RSUBJID	SREL	CMTRT	CMPRESP	CMOCCUR	VISITNUM	VISIT	CMEVINTX
1	201-01	APCM	201-01-M450	1	201-01-160	MOTHER, BIOLOGICAL	ANTIBIOTICS	Y	Y	1	BASELINE	DURING PREGNANCY
2	201-01	APCM	201-01-M450	2	201-01-160	MOTHER, BIOLOGICAL	ANTI-INFLAMMATORY STEROIDS	Y	N	1	BASELINE	DURING PREGNANCY
3	201-01	APCM	201-01-M450	3	201-01-160	MOTHER, BIOLOGICAL	DIABETES MEDICATION	Y	N	1	BASELINE	DURING PREGNANCY

Microbiome


Key
Observation
Observation Result
Specimen
Specimen Collection
Product
Subject
participates in
Sample collection
results in
Stool sample
undergoes
Genetic sequencing
results in
Genetic sequences
undergoes
Bioinformatics analysis
results in
Sequence counts
may result in
Reference genome database
uses
Taxonomic identification
Calculating relative abundance
results in
Genus/species/OTU
results in
Relative abundance counts

Stool samples may be collected periodically to assess whether any bacteria/viruses of interest are present, or to quantify the bacteria or virus present. These samples are usually collected at home according to a schedule and then sent to the center for storage and further processing. The samples are then analyzed using 16S or shotgun sequencing techniques to see what bacteria or viruses are in each sample. Counts and relative abundance of the sequence reads are calculated with the help of bioinformatics analysis and can be represented in the Microbiology Specimen (MB) domain.

mb.xpt

Rows 1-2: Show the raw counts and relative abundance of Cyanobacteria in a stool sample.
Rows 3-4: Show the raw counts and relative abundance of Firmicutes in a stool sample.
Rows 5-6: Show the raw counts and relative abundance of Bacteroidetes in a stool sample.
Rows 7-9: Show the identification of bacteria found in a stool sample by next-generation sequencing.

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSTRESN	MBSPEC	MBMETHOD	VISITNUM	MBDTC
1	201-01	MB	201-01-154	1	H123456.1	CYANBACT	Cyanobacteria	COUNTS	322	322	322	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
2	201-01	MB	201-01-154	2	H123456.1	CYANBACT	Cyanobacteria	RELATIVE ABUNDANCE	0.0012416076	0.0012416076	0.0012416076	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
3	201-01	MB	201-01-154	3	H123456.1	FIRMICUT	Firmicutes	COUNTS	3145	3145	3145	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
4	201-01	MB	201-01-154	4	H123456.1	FIRMICUT	Firmicutes	RELATIVE ABUNDANCE	0.692495171	0.692495171	0.692495171	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
5	201-01	MB	201-01-154	5	H123456.1	BACTOID	Bacteroidetes	COUNTS	2904	2904	2904	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
6	201-01	MB	201-01-154	6	H123456.1	BACTOID	Bacteroidetes	RELATIVE ABUNDANCE	0.580547686	0.580547686	0.580547686	STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
7	201-01	MB	201-01-154	7	H123456.1	MCORGIDN	Microbial Organism Identification		Cyanobacteria	Cyanobacteria		STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
8	201-01	MB	201-01-154	8	H123456.1	MCORGIDN	Microbial Organism Identification		Firmicutes	Firmicutes		STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11
9	201-01	MB	201-01-154	9	H123456.1	MCORGIDN	Microbial Organism Identification		Bacteroidetes	Bacteroidetes		STOOL	NEXT GENERATION SEQUENCING	1	2012-04-11

Information about specimen collection and storage may be represented in the Biospecimen Events (BE) domain. Because stool samples are usually collected at home, the dates of collection will not correspond with study visits. Some forms of testing (microbiome identification, for example) may require more or less detail in the collection/shipping/handling of specimens. It is up to the trial protocol to determine what level of detail is appropriate .

be.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	BESEQ	BEREFID	BETERM	BEDECOD	BEPARTY	BEPRTYID	VISITNUM	BEDTC	BESTDTC	BEENDTC	BESPEC
1	201-01	BE	201-01-154	SC001	1	H123456	Collecting	COLLECTING	HOME		1	2012-03-01	2012-03-01T11:05		STOOL
2	201-01	BE	201-01-154		2	H123456.1	Aliquoting	ALIQUOTING	LAB	1	1	2012-03-02	2012-03-02T09:40		STOOL
3	201-01	BE	201-01-154		3	H123456.2	Aliquoting	ALIQUOTING	LAB	1	1	2012-03-02	2012-03-02T09:50		STOOL
4	201-01	BE	201-01-154		4	H123456	Freezing	FREEZING	LAB	1	1	2012-03-02	2012-03-02T10:05		STOOL
5	201-01	BE	201-01-154		5	H123456	Storing	STORING	LAB	1	1	2012-03-02	2012-03-02T10:05	2012-04-11T15:37	STOOL
6	201-01	BE	201-01-154		6	H123456	Thawing	THAWING	LAB	1	1	2012-04-11	2012-04-11T15:37		STOOL

bs.xpt

Row	STUDYID	DOMAIN	USUBJID	BSSEQ	BSREFID	BSTESTCD	BSTEST	BSCAT	BSORRES	BSORRESU	BSSTRESC	BSSTRESN	BSSTRESU	BSSPEC	VISITNUM	BSDTC
1	201-01	BS	201-01-154	1	H123456	VOLUME	Volume	SPECIMEN MEASUREMENT	45	mL	45	45	mL	STOOL	1	2012-03-01
2	201-01	BS	201-01-160	1	H987456	VOLUME	Volume	SPECIMEN MEASUREMENT	55	mL	55	55	mL	STOOL	1	2012-10-02

Questionnaires, Ratings and Scales

Table 1. Identified QRS Measures of Interest to Type 1 Diabetes - Screening, Staging and Monitoring for Pre-clinical Type 1 Diabetes

Full Name and Abbreviation	Copyright Permission Status	Supplement Status
Patient Health Questionnaire-9 (PHQ-9)	Granted	Done
Patient Health Questionnaire-15 (PHQ-15)	Granted	Done
Type 1 Diabetes Staging	Public domain	Terminology in progress

- Note that additional QRS instruments were identified for development of supplements in
  - T1D – Pediatrics and Devices
  - T1D – Exercise and Nutrition
- Refer the QRS sections of these guides for more information

Thank You!

Questions & Answers

Audience Questions

Related to the polygenic risk score section: Is this a standard method to calculate the risk score?

Audience Questions

You mentioned that the new GF domain will be published later in 2021. Is the domain specification available to review?

Audience Questions

In some of the examples, there are domains such as BE (Biospecimen Events) , BS (biospecimen findings) and some device domains (such as DI (Device Identification)). Is it mandatory to use these domains when dealing with Type 1 Diabetes data?

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- Register at: https://learnstore.cdisc.org/
- Contact us at: training@cdisc.org

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Upcoming CDISC Events

2021 Webinars

Date	Webinar Title
1 JUL	Controlled Terminology Updates for Q2 2021
6 JUL	CDASH Office Hours + eCRF Portal Update
30 SEP	Controlled Terminology Updates for Q3 2021

Visit https://www.cdisc.org/education/webinars for information on additional Public Training events.

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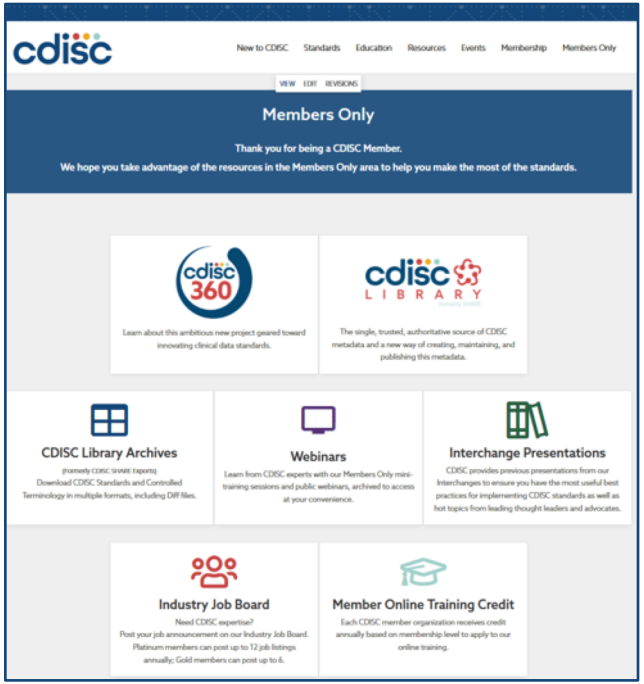

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