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

You will remain on mute
Housekeeping

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

Audio issues?
Shut down & restart GoToWebinar
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
Public Review Webinar: Screening, Staging, and Monitoring of Pre-Clinical Type 1 Diabetes

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TUE 22 JUN
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
Diabetes Type 1 - Pediatrics and Devices

Release Information | Files and Links | Partnerships | Archive

Diabetes Type 1 Therapeutic Area User Guide v2.0 - Pediatrics and Devices Modules

26 May 2021

Version 2.0 of the Type 1 Diabetes Therapeutic Area User Guide - Pediatrics and Devices Modules was developed under the CDISC Standards Development Process and describes the most common biomedical concepts relevant to Type 1 Diabetes studies that address Pediatrics and Devices, and the necessary metadata to represent such data consistently with Terminology, CDASH, SDTM and ADaM.

Version 2.0 contains the addition of analysis concepts relevant to Type 1 Diabetes – Pediatrics and Devices as well as corrections to some minor inconsistencies in v1.0.

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

Public Review Comments

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

TA Specifications

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

1. https://www.fda.gov/media/136460/download

Listen to the Webinar Recording.

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

T1D Screening, Staging and Monitoring – Pre-Clinical T1D
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
Diabetes Type 1 - Exercise and Nutrition

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.

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1. https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources

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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<tr>
<td>Therapeutic Area User Guide: Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes</td>
<td>16 July 2021</td>
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<td>ADaM Examples of Traceability</td>
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Diabetes Type 1 - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes

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

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 Marsh 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 T1DSSM, 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 the 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 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


   - 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

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.
# T1D SSM Modules

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

<table>
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<tr>
<th><strong>Title</strong></th>
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<td><strong>Version</strong></td>
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<td><strong>Status</strong></td>
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<td>02 Apr 2021</td>
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<td>This is the draft Version 1.0 of the Therapeutic Area Data Standards Modules for Type 1 Diabetes. This document is based on CDASH 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).</td>
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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

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T1D Screening, Staging and Monitoring – Pre-Clinical T1D
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 ITEST 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 v.3.4. The IS terminology in this section is being reviewed and developed preceding publication of the IS domain updates for SDTMIG v.3.4. The equivalent pre-coordinated autoimmune antibody tests continue to exist in the LB domain for SDTMIG Versions 3.2 and 3.3.
### 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.

| Row | STUDYID | ISUSUBID | ISSPEC | ISTEST | ISSORP | ISSOREU | ISSORRSU | ISSORHRI | ISSORESC | ISTRSPEC | ISTRRENSH | ISTRRENU | ISTMETHOD | VISTNUM | VSTCNC |
|-----|---------|----------|--------|--------|--------|---------|----------|----------|----------|----------|------------|-----------|-----------|-----------|---------|--------|
| 1   | ABC123  | IS       | ABC001 | 1      | 123,456| ATAB    | POSITIVE | POSITIVE | POSITIVE | SERUM    | FLUORESCENT IMMUNOASSAY | 1         | 2018-10-02 |           |         |
| 2   | ABC123  | IS       | ABC001 | 2      | 123,456| ATAB    | POSITIVE | 32       | 10       | 32       | JDF Unit | FLUORESCENT IMMUNOASSAY | 1         | 2018-10-02 |           |         |
| 3   | ABC123  | IS       | ABC001 | 3      | 123,456| ATAB    | POSITIVE | POSITIVE | POSITIVE | SERUM    | ELISA      | 1         | 2018-10-02 |           |         |
| 4   | ABC123  | IS       | ABC001 | 4      | 123,456| ATAB    | POSITIVE | 26       | 15       | 26       | ELISA      | 1         | 2018-10-02 |           |         |
| 5   | ABC123  | IS       | ABC001 | 5      | 123,456| ATAB    | POSITIVE | POSITIVE | POSITIVE | SERUM    | RIA        | 1         | 2018-10-02 |           |         |
| 6   | ABC123  | IS       | ABC001 | 6      | 123,456| ATAB    | POSITIVE | 2.2      | 0.2      | 2.2      | IA/ml     | 1         | 2018-10-02 |           |         |
| 7   | ABC123  | IS       | ABC001 | 7      | 123,456| ATAB    | NEGATIVE | NEGATIVE | NEGATIVE | SERUM    | LPS        | 1         | 2018-10-02 |           |         |
| 8   | ABC123  | IS       | ABC001 | 8      | 123,456| ATAB    | NEGATIVE | NEGATIVE | NEGATIVE | SERUM    | LPS        | 1         | 2018-10-02 |           |         |

**IS NSV Metadata**

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**T1D Screening, Staging and Monitoring – Pre-Clinical T1D**

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".
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.

**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 dates/times of centrifugation of the specimen.

**Row 3:** Shows the start and end dates/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.
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 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.

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<td>Single Nucleotide Variation</td>
<td>GENOTYPE</td>
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<td>T:C</td>
<td>6</td>
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<td>11</td>
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<td>GF</td>
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</tbody>
</table>
### 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 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.

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

In this example, the number of risk-increasing alleles of each SNP is based on the information in GFORRES/GFRSTREC, 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 1ID-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]
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]

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/qrstwhere QRS supplements are maintained as standalone guides.
History of Viral Infections
T1D Screening, Staging and Monitoring – Pre-Clinical T1D
### Diagnosed Acute Illness

<table>
<thead>
<tr>
<th>CESCAT</th>
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</thead>
<tbody>
<tr>
<td>CEGPID</td>
<td>Pre-populated</td>
</tr>
</tbody>
</table>

**Did the subject have any diagnosed acute illness?**
- Yes
- No

*<From NY codelist>*

**What was the diagnosed acute illness name?**

**Who diagnosed the acute illness?**
- Health Care Professional
- Non-Health Care Professional

*<From EVAL codelist>*

**What was the start date of the diagnosed acute illness?**

**What was the end (or resolution) date of the diagnosed acute illness?**
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 CEGRID variable below to link the symptom to the diagnosis.

- CEGID: Acute Illness Group Identifier
- CEGID: Symptom
- CEGID: Sponsor-defined

Was this symptom considered to be associated with a diagnosed acute illness?
- Yes
- No

If yes, what was the associated diagnosed acute illness group identifier?

What was the symptom?

What was the start date of the symptom?

What was the end date of the symptom?

If the symptom was a fever, was temperature measured?
- Yes
- No

What was the maximum measured temperature?

What was the temperature unit?
- Fahrenheit
- Celsius
### CET NSV Metadata

<table>
<thead>
<tr>
<th>Variable</th>
<th>Label</th>
<th>Type</th>
<th>Codelist</th>
<th>Role</th>
<th>Origin</th>
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</thead>
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<td>Non-standard Record Qualifier</td>
<td>CRF</td>
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<tr>
<td>CEEVAL</td>
<td>Evaluator</td>
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<td>(EVAL)</td>
<td>Non-standard Record Qualifier</td>
<td>CRF</td>
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</table>

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

### VS NSV Metadata

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<th>Origin</th>
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MOTHER
### Title: Biological Mother's Viral Infection History while Pregnant

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<th>From NY code list</th>
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<tbody>
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<td>Domain</td>
<td>DOMAIN</td>
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<td>APMH</td>
</tr>
<tr>
<td>Relationship to Subject</td>
<td>SREL</td>
<td>Hidden/pre-populated</td>
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</tr>
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<td>MHCAT</td>
<td>Hidden/pre-populated</td>
<td>VIRAL INFECTION</td>
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</tr>
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</table>

**Indicate if the biological mother experienced any viral illnesses during pregnancy. If Yes, include the appropriate details where indicated on the CRF.**

**Record all relevant viral illnesses, as defined in the protocol. Record only one viral illness per line.**

**Did the subject's mother have any viral illnesses during pregnancy?**
- Yes
- No

**What was the medical condition or event term?**

**Evaluation Interval Test** | MHREVNTX | Hidden/pre-populated | DURING PREGNANCY |

> View CRF Metadata

### Title: Biological Mother's Medications during Pregnancy

<table>
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<tr>
<th>CMREP</th>
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<th>From NY code list</th>
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<td>APCM</td>
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<tr>
<td>Relationship to Subject</td>
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</tr>
<tr>
<td>CMCAT</td>
<td>Hidden/pre-populated</td>
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<td></td>
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</tbody>
</table>

**Indicate if the biological mother took any medications/treatments while pregnant. If Yes, include the appropriate details where indicated on the CRF.**

**Provide the full trade or proprietary name of the medication/treatment; otherwise, record the generic name. Record only one treatment per line.**

**Did the subject’s mother take any medications during pregnancy?**
- Yes
- No

**What was the medication?**

**Evaluation Interval Test** | CMREVNTX | Hidden/pre-populated | DURING PREGNANCY |

T1D Screening, Staging and Monitoring – Pre-Clinical T1D
### T1D Screening, Staging and Monitoring – Pre-Clinical T1D

#### 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.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
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<th>MSEQ</th>
<th>RSUBJID</th>
<th>SREL</th>
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</tr>
</tbody>
</table>

#### 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.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>APID</th>
<th>CMSEQ</th>
<th>RSUBJID</th>
<th>SREL</th>
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<td>APMC</td>
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<tr>
<td>Did the subject's mother have influenza during pregnancy?</td>
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<tr>
<td>Did the subject's mother have a sore throat during pregnancy?</td>
<td>Yes, No</td>
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<td>Yes, No</td>
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<tr>
<td>Did the subject's mother take antibiotics during pregnancy?</td>
<td>Yes, No</td>
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<tr>
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<tr>
<td>Did the subject's mother take diabetes medication during pregnancy?</td>
<td>Yes, No</td>
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</table>
### apmh.xpt

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

<table>
<thead>
<tr>
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<th>MHSEQ</th>
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<td>201-01-160</td>
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<td>N</td>
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<tr>
<td>3</td>
<td>201-01</td>
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<td>DURING PREGNANCY</td>
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</tbody>
</table>

### apcm.xpt

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

<table>
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<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>APIID</th>
<th>MHSEQ</th>
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</table>
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
                          - Taxonomic identification
                            - Results in
                              - Genus/species/OTU
                                - Results in
                                  - Relative abundance counts
                        - Results in
                          - Calculating relative abundance
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.

<table>
<thead>
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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.

### Table 1: BE.XPT

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Questionnaires, Ratings and Scales
• 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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With Standards – Science Will Prevail!
Washington, DC, or Virtually | 18-22 October
Conference & Trade Show
## 2021 Webinars

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<td>Controlled Terminology Updates for Q2 2021</td>
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<tr>
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