CDISC Standards Development Project for Type 1 Diabetes

Pediatrics and Devices Scoping Summary Webinar

Thursday 4th October 2018
11:30-12:00 (CDT)
CDISC – What we do

• CDISC is a global, non-profit charitable organization
• Develop data standards to streamline clinical research
• Enable connections to healthcare
• Empowering the valuable information offered by patients participating in research studies around the world.

https://www.cdisc.org/about/what-we-do
Diabetes work done so far

- Diabetes V1
  Released Aug 2014

- Diabetes ADaM Supplement V1
  Released Dec 2015

- Diabetic Kidney Disease V1
  Released Dec 2016
Concepts already developed in Diabetes V1
Summary of the T1D Project

- Collaborative project between CDISC and The Leona M. and Harry B. Helmsley Charitable Trust
- Development of new T1D CDISC data standards
- Extending the published diabetes standards by developing metadata in the following focus areas:
  - Pediatrics
  - Devices
  - Prevention
  - Exercise
## Summary of the Project

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
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<tbody>
<tr>
<td>Pediatrics and Devices</td>
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<td></td>
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<td>Exercise</td>
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<td>Prevention</td>
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### CDISC Standards Development Process

<table>
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<tr>
<th>Stage 0</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3a</th>
<th>Stage 3b</th>
<th>Stage 3c</th>
<th>Stage 4</th>
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Scoping Process

Prior research into the proposed standard

Research into scientific/medical literature

Public Database Searches

Regulatory Requirements

Implementation Issues with V1.0 from user community

Updates to standards since release of V1.0

Deferred concepts From V1.0

Evaluation against existing content (gap analysis)

Identify new concepts for development

Narrow scope to a smaller, meaningful, set of concepts

T1D P&D Project Charter Package

Scoping Evaluation

Other global requirements/Initiatives
T1D Standards Development

SCAPE = New T1D Concepts for Pediatrics & Devices
(not already covered in previous guides)
Summary of the T1D Scope

T1D Project
Pediatrics and Devices

- Diabetic Ketoacidosis
- CGM and Insulin Management
- Diabetes History
- Lab tests related to T1D
- Vital signs growth patterns
- Questionnaires, Ratings, and Scales
Diabetic Ketoacidosis (DKA)

- Signs and symptoms leading up to a DKA event
- Device information during the event
- Treatments
- Outcome
CGM and Insulin Management

- Continuous Glucose Monitors
  - Representing devices and device properties
  - Data from glucose measurements
  - Raw data versus summary data
  - Data transfers from CGM devices
  - Calibration
- Insulin Management
  - Type of insulin delivery
  - Type of insulin
  - Basal/Bolus dosing and total daily dose
  - Management of dose changes
  - Correction factors
  - Algorithms for frequency/size of meals
  - Events related to infusion set/injection site
Diabetic History

- Antibodies for diagnosis of T1D
- Severe DKA at diagnosis
- Duration of diabetes
- History of other auto-immune diseases
- Pubertal status
- Family history of T1D
- Family history of autoimmune disease
- History of exposure to viral diseases
- Diabetes treatment history (including diet and exercise)
- Hypoglycemic unawareness
Lab tests related to T1D

- HLA typing (pharmacogenomics)
- Sexual development hormones (Testosterone, LH)
- T1D Antibodies
- Lab related data from CGM devices (raw versus summary)
Vital signs growth patterns

- Height/Weight BMI for abnormal growth patterns
- Analysis: percentiles of BMI and blood pressure specific for pediatrics (for example US CDC percentile)
Final scoping for Pediatrics & Devices will be combined with the scoping of Exercise to provide a final list of QRS instruments to develop CDISC data standards supplements for.

Scoping for the exercise component of the project will start at the end of October 2018.
**Next steps**

### Modeling of Biomedical Concepts
- Develop an approach for meeting the initial requirements
- Define in more detail the information that will comprise the proposed new or enhanced standard, including comparisons to existing standards.
- Developing concept maps to facilitate semantic understanding of new information requirements where appropriate.
Please direct any off-line questions or comments to John Owen (jowen.external@cdisc.org)
Back-up slides
## Annotated CRF: Diabetes History

### Enter the date of diagnosis of diabetes.

<table>
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<tr>
<th>CRASH Variable Name</th>
<th>CRASH Core</th>
<th>SOTM Variable Name</th>
<th>SOTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
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<td>MHESTDT</td>
<td>HR</td>
<td>MHSTOTC</td>
<td>Perm</td>
<td>Enter the date of diagnosis of diabetes.</td>
<td>Map directly to SOTM with QNAM=MDXTDC and QLABEL=Date of Diagnosis.</td>
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### Select the specific type of diabetes.

<table>
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<tr>
<th>CRASH Variable Name</th>
<th>CRASH Core</th>
<th>SOTM Variable Name</th>
<th>SOTM Core</th>
<th>Case Report Form completion instructions</th>
<th>Mapping Instructions</th>
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<td>O</td>
<td>MHVENT</td>
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# SDTM Example – Diabetes Diagnosis History

## mh.xpt

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<th>STUDYID</th>
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<th>MHTERM</th>
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# ADaM Example – Hypoglycemic events

## Table 3.1: ADHYPO Analysis Dataset

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<th>ASEXGR</th>
<th>TLX</th>
<th>TLXGR</th>
<th>TSEX</th>
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## Table 3.2: ADHYPO Analysis Dataset

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<th>Row</th>
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</tbody>
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The Global Team

**Doers**
- Forms the core standards development Team
- CDISC standards development experts
- Diabetes SMEs from external organizations

**Reviewers**
- Provide concepts from Real World Data
- Forms the global standards review community
- Leads to consensus based standards