CDISC Standards Development Project for Type 1 Diabetes

T1D Exercise and Prevention Scoping Summary

Presented by John Owen
T1D Senior Project Manager, Standards Development, CDISC
12 Mar 2019
Agenda

1. Project update (Pediatrics, Devices, Exercise and Prevention)
2. Pediatrics and Devices scope recap
3. Overview of the Exercise concepts identified during scoping
4. Overview of the Prevention concepts identified during scoping
5. Questionnaires, Ratings and Scales (QRS) instruments
6. Information on next steps
7. Q&A
T1D - Goals, Strategy, and Outcome

Goal
- To develop and implement a global, non-proprietary clinical data standard for type 1 diabetes
- Identify commonly collected data as well as outcome measures for regulated clinical trials in three therapeutic areas:
  - 1) Pediatrics and Devices
  - 2) Exercise
  - 3) Prevention.

Strategy
- To follow the established CDISC standards development consensus process
- Involve clinical and statistical subject matter experts, CDISC content developers, and volunteers

Outcome
- To enable data sharing, cross-study comparisons, and meta-analyses by standardizing clinical data
- Accelerating and increasing efficiency in T1D research and discovery leading to potential new treatments.

12 March 2019
Data Collection

- CDASH

Data Tabulation

- SDTM

Data Analysis

- ADaM

Controlled Terminology

Beginning to End
SCOPE = New TID Concepts
(not already covered in previous guides)
Standards Development Process and timelines

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T1D Pediatrics and Devices

T1D Exercise and Prevention

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12 March 2019
T1D Prevention and Exercise Scoping Summary
Pediatrics & Devices

- On-Study Diabetic Ketoacidosis Events
- CGM and Insulin Management
- Diabetes History
- Lab Tests Related to T1D
- Vital Signs Growth Patterns
Exercise

- Exercise: Types of Activity
- Exercise: Fitness and Strength Status
- Exercise: Activity Devices (inc. vitals/lactate measurement)
- Nutrition: Meal Descriptions
- Nutrition: Meal Nutrient Content
Exercise: Types of Activity

- Study versus Non-Study Exercise
- Exercise Categories (swimming, running etc)
- Perceived Exercise Intensity
Exercise: Fitness and Strength Status

- Rockport Walk Test
- Hand Grip Strength
Exercise: Activity Devices

- Activity Wearables
  - Chest Straps
  - Watches
- Vital Signs Data
- Sleep Data
- Devices for Measuring Lactate
Nutrition: Meal Descriptions

- Meal Type
  - e.g., Breakfast, Lunch, Dinner, Snack

- Purpose of Meal
  - Regular Meal/Snack
  - Treatment For or Prevention of Hypoglycemic events

- Timing of Meal

- Constituents of Meal
Nutrition: Meal Nutrient Content

- Calorific Content
- Macro-Nutrient Content
- Micro-Nutrient Content
Prevention

- Metabolic Markers
- History of Viral Infections
- Family History of T1D
- Islet Auto-Antibodies
- Genetic Risk
Metabolic Markers

- OGTT/MMTT
  - Insulin/C-Peptide/Glucose
- HbA1C
- CGM Glucose Measurements
- Indices & Risk Scores derived from
  - Glucose
  - C-Peptide
  - Age
  - BMI
- Staging of Diabetes (ADA)
  - Stage 1, 2, 3
History of Viral Infections

- Subject Viral Infections
  - Confirmatory Tests

- Pregnant Mother Viral Infections
  - Confirmatory Tests
Family History of T1D

- First Degree Relatives T1D History
Islet Autoantibodies

- Multiplex Assays
- Individual Autoantibody Assays

Prevention
Genetic Risk

- Representing Genetic Testing Results
  - First Degree Relatives
  - Subject

- HLA/non-HLA SNPs

- Next Generation Sequencing

- Genetic Risk Scores
Questionnaires, Ratings, and Scales (QRS)

• Pediatrics and Devices
  • Diabetes Distress Scale (DDS)
    • Adult/Partner/Parent
  • Diabetes Treatment Satisfaction Questionnaire (DTSQ)
    • Status/Change
  • Glucose Monitoring Satisfaction Survey (GMSS)
  • Hypoglycemia Confidence Scale (HCS)
  • Hypoglycemia Fear Survey (HFS)
    • Worry (Adult/Youth/Parent)
  • Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE)
    • Child/Teen/Adult/Parent/Partner
  • Pediatric Quality of Life Inventory (PedsQL) Diabetes Module
    • Acute/Standard (various ages)
  • Problem Areas in Diabetes (PAID)
    • Pediatrics/Child/Teen/Parent(child&teen)/Parent
  • Quality of Life for Diabetes

• Exercise
  • Clarke Hypoglycemia Awareness Questionnaire
  • International Physical Activity Questionnaire (IPAQ)
    • Admin (short/long) – Telephone (short/long)
  • Physical Activity Readiness Questionnaire for Everyone

• Prevention
  • Patient Health Questionnaire 9 (PHQ9)
  • Patient Health Questionnaire 15 (PHQ15)
## Next Steps – Pediatrics and Devices

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### T1D Pediatrics and Devices

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### Internal Review
- April to July 2019 – CDISC teams plus targeted reviewers

### Public Review
- August to December 2019 (Next Public Webinar August 2019)
Next Steps – Exercise and Prevention

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T1D Exercise and Prevention

- **Concept Modeling and Standards Development** – February to August 2019
- **Internal Review** – September 2019 to January 2020 – CDISC teams plus targeted reviewers
- **Public Review Webinar** – January to May 2020 (Public Review Webinar January/February 2020)
THANK YOU!

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