



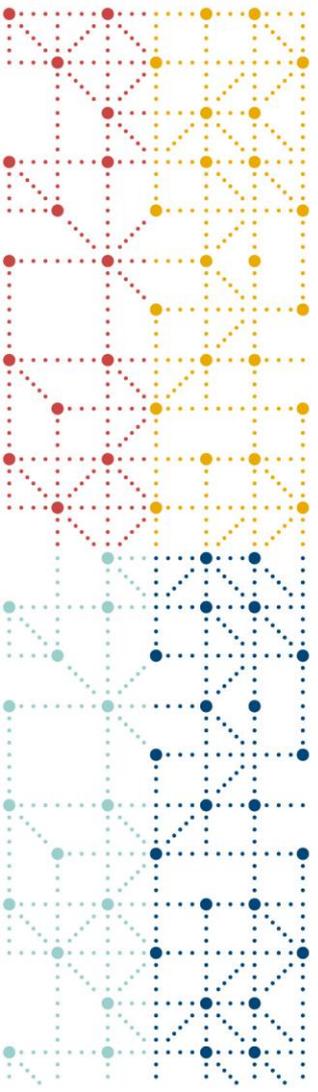
# CDISC Standards Development Project for Type 1 Diabetes

## 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.

# Data Collection



CDASH

# Data Tabulation



SDTM

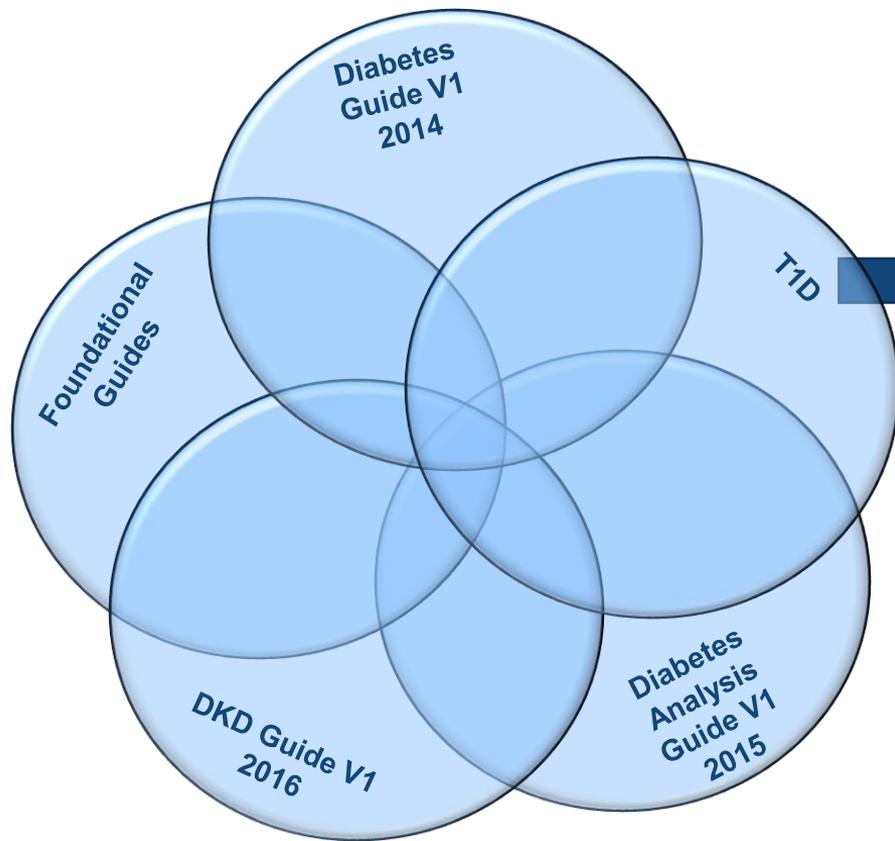
# Data Analysis



ADaM

Controlled Terminology

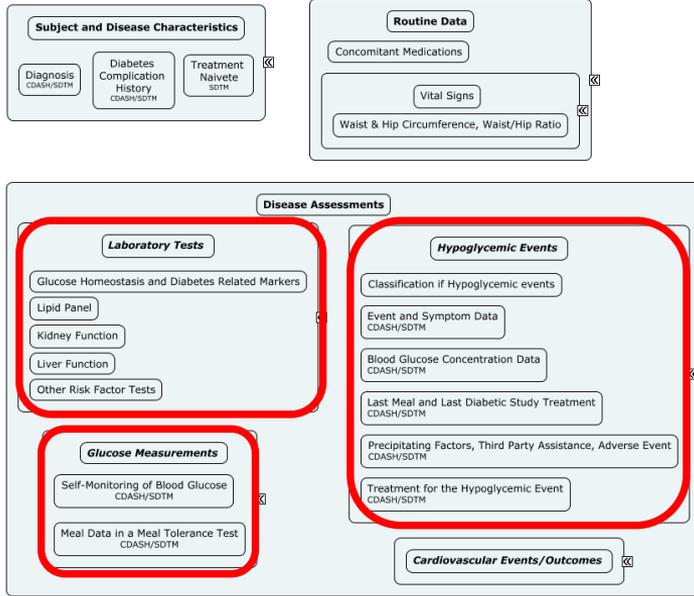
Beginning to End



**SCOPE = New T1D Concepts**  
(not already covered in previous guides)

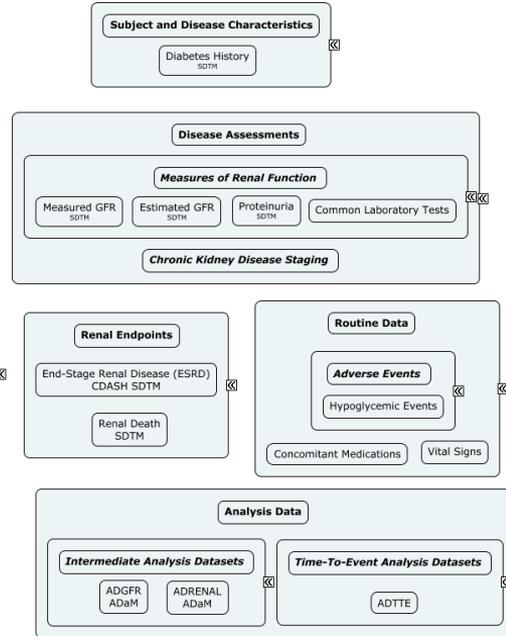
### Diabetes Version 1.0

Released Aug 2014



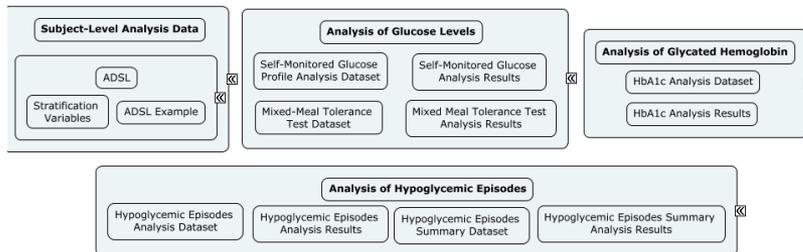
### Diabetic Kidney Disease

Released Dec 2016



### Diabetes ADaM Supplement

Released Dec 2015



# Standards Development Process and timelines

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Standards Update

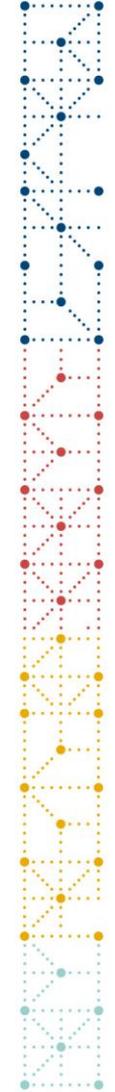
## T1D Pediatrics and Devices



## T1D Exercise and Prevention



Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
2018	2019				2020		



# Pediatrics & Devices

On-Study Diabetic Ketoacidosis Events

CGM and Insulin Management

Diabetes History

Lab Tests Related to T1D

Vital Signs Growth Patterns



# Exercise

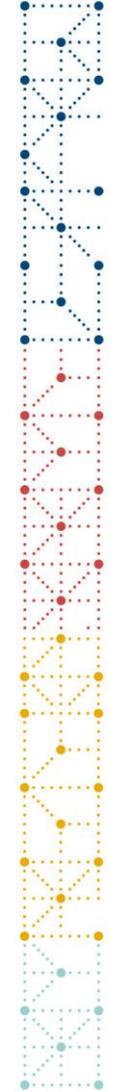
**Exercise: Types of Activity**

**Exercise: Fitness and Strength Status**

**Exercise: Activity Devices** (inc. vitals/lactate measurement)

**Nutrition: Meal Descriptions**

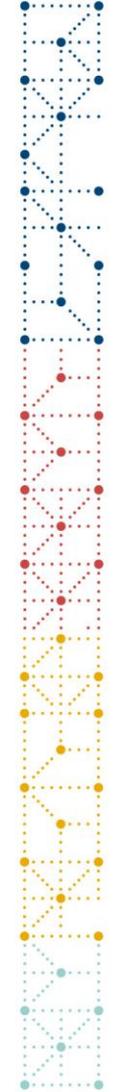
**Nutrition: Meal Nutrient Content**



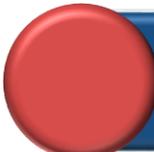
# Exercise

## Exercise: Types of Activity

- Study versus Non-Study Exercise
- Exercise Categories (swimming, running etc)
- Perceived Exercise Intensity

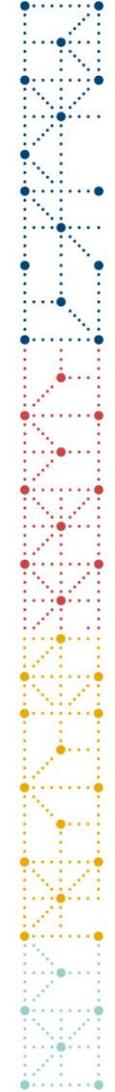


# Exercise



## Exercise: Fitness and Strength Status

- Rockport Walk Test
- Hand Grip Strength

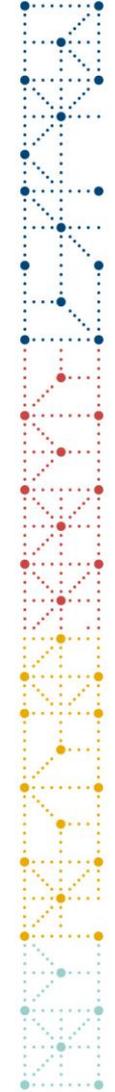


# Exercise



## Exercise: Activity Devices

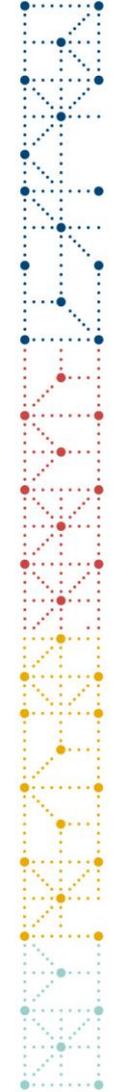
- Activity Wearables
  - Chest Straps
  - Watches
- Vital Signs Data
- Sleep Data
- Devices for Measuring Lactate



# Exercise

## 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

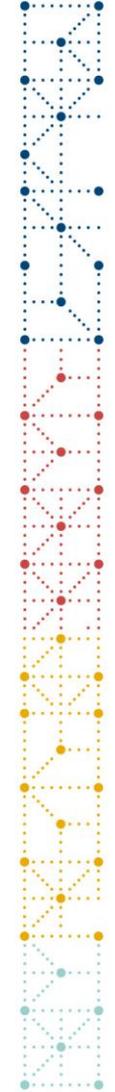


**Exercise**



## Nutrition: Meal Nutrient Content

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



# Prevention

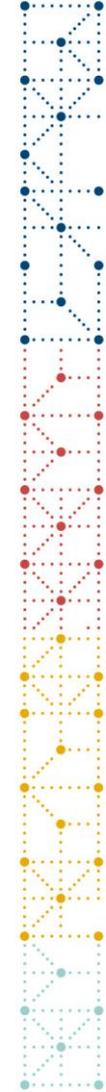
**Metabolic Markers**

**History of Viral Infections**

**Family History of T1D**

**Islet Auto-Antibodies**

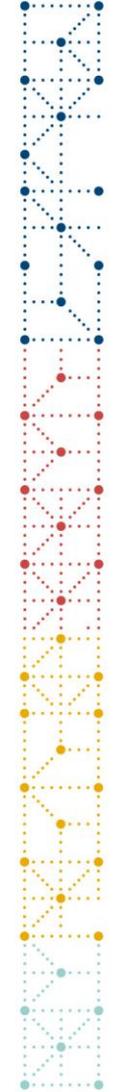
**Genetic Risk**



# Prevention

## Metabolic Markers

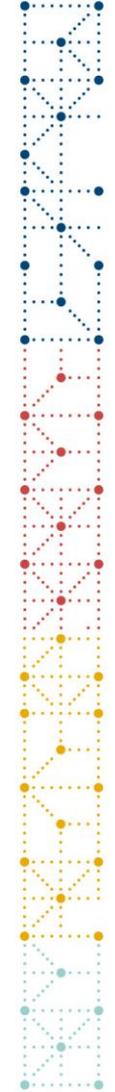
- OGTT/MMTT
  - Insulin/C-Peptide/Glucose
- HbA1C
- CGM Glucose Measurements
- Indices & Risk Scores derived from
  - Glucose
  - C-Peptide
  - Age
  - BMI
- Staging of Diabetes (ADA)
  - Stage1, 2, 3



## History of Viral Infections

# Prevention

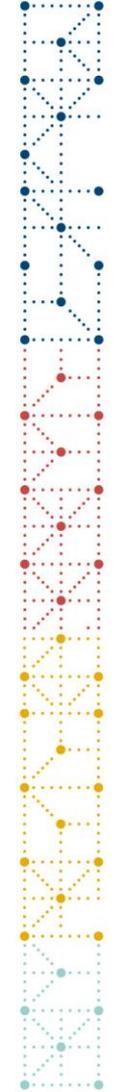
- Subject Viral Infections
  - Confirmatory Tests
- Pregnant Mother Viral Infections
  - Confirmatory Tests



# Prevention

## Family History of T1D

- First Degree Relatives T1D History

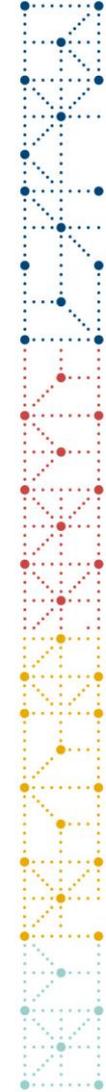


**Prevention**



## 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**

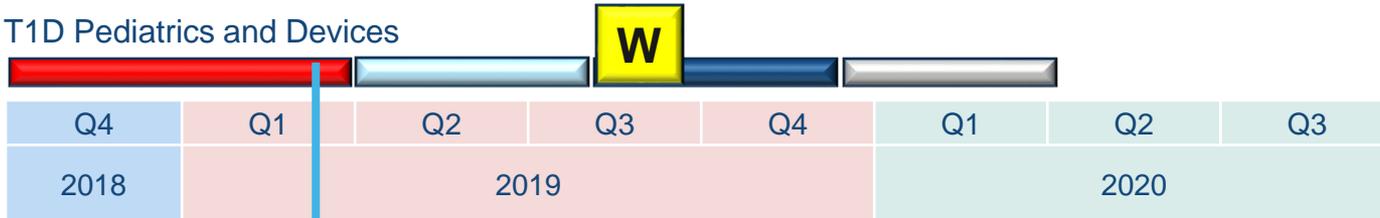
## • Prevention

- **Patient Health Questionnaire 9 (PHQ9)**
- **Patient Health Questionnaire 15 (PHQ15)**

# Next Steps – Pediatrics and Devices

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Standards Update

## T1D Pediatrics and Devices



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

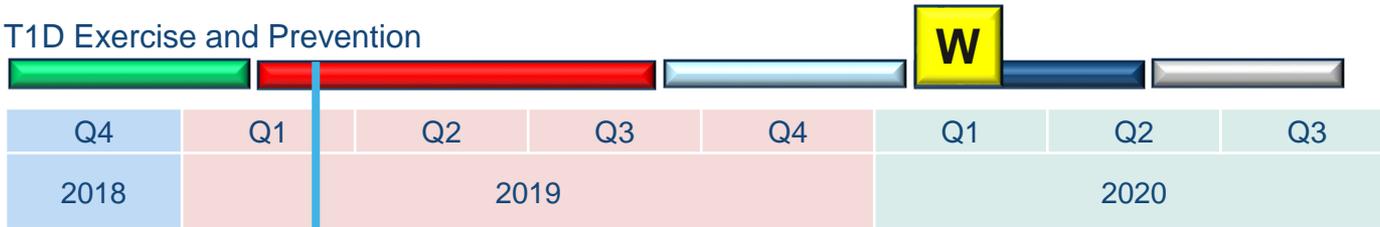
**Public Review** – August to December 2019 (Next Public Webinar August 2019)



# Next Steps – Exercise and Prevention

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Standards Update

## 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!

John Owen  
jowen.external@cdisc.org



**cdisc**